Outpatient Clinic:
Tal 21

**Prof. Dr. Sigmund Silber**
**FACC, FESC**
**Cardiology Practice and Hospital**
**Munich, Germany**

CathLab:
Hospital Dr. Müller

# Stable Angina Pectoris:

- When to Revascularize ?
- Or have the COURAGE to defer angio ?
- Are the USA Appropriateness Criteria applicable to Europe ?

# Stable Angina Pectoris:

1. What is the difference between Guidelines and Appropriateness Criteria ?
2. Did COURAGE change the ESC Guidelines for the indication to coronary angiography ?
3. Do we need the USA Appropriateness Criteria for the Decision whether to Revascularize or not ?

# Stable Angina Pectoris:

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# Guidelines...

- ...are not a text book.
- ...are the result of the scientific analysis of the available data.
- ...refer only to a part of the patients - due to the usually strict inclusion / exclusion criteria of the randomized trials.
- ...therefore do not replace medical experience.

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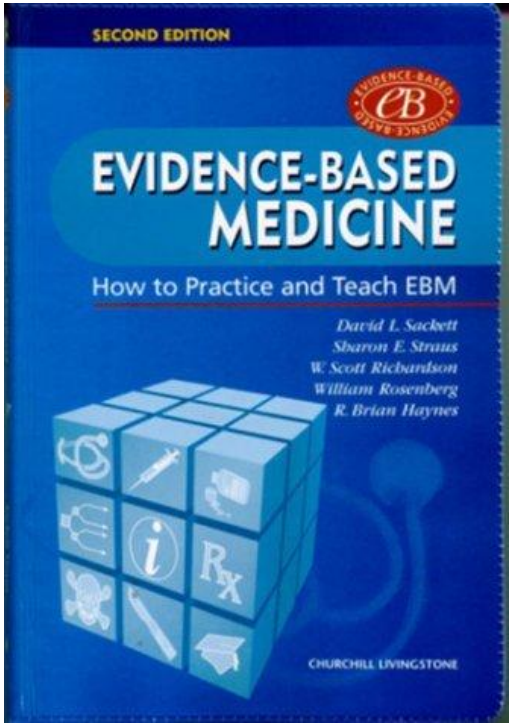
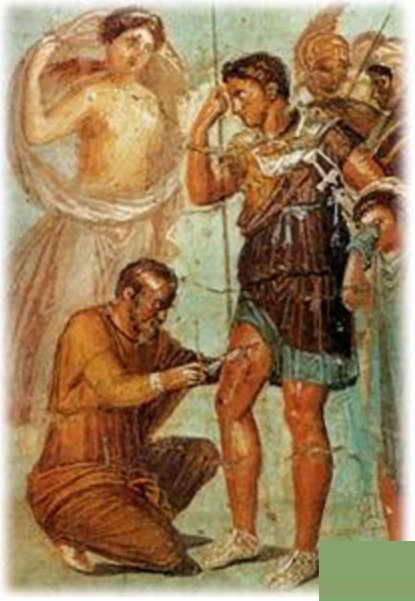
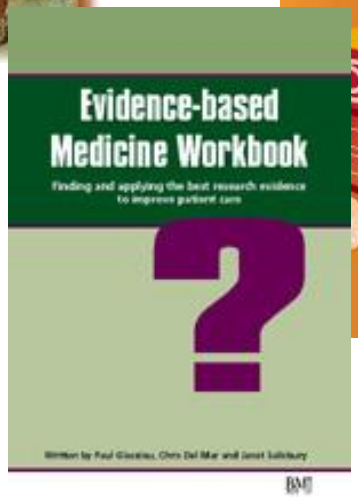
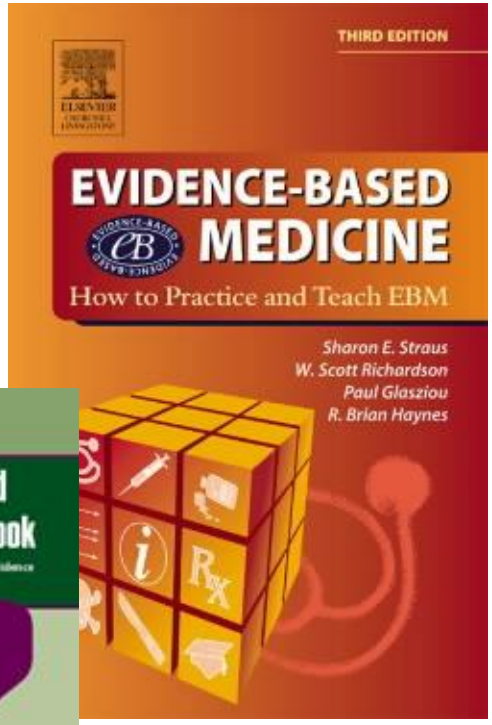
- ...are the result of the scientific analysis of the available data.
- ...refer only to a part of the patients - due to the usually strict inclusion / exclusion criteria of the randomized trials.
- ...therefore do not replace medical experience.
- **...are recommendations what you should do or could do - but not what you must do.**
- **...are not legally binding.**
- **but they are more and more read and applied by health care providers and patients / relatives.**
- **and - if you do not follow the guidelines and complications occur, you may justify, why you did not follow the guidelines !**

# Guidelines are based on Evidence: What is Evidence ?





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

# If you don‘t know...
# Randomize !


# The Power for the Clinical Outcome must also be considered !

# Levels of Evidence from Randomized Studies:



# Levels of Evidence from Randomized Studies:

- The evidence derived from randomized studies is uniformly assessed in the USA (AHA/ACC) and in Europe (ESC):

| | |
|---|---|
| Level of evidence A | *ACC/AHA/ESC:*<br>Data derived from multiple randomized clinical trials or meta-analyses. |
| Level of evidence B | *ACC/AHA:*<br>Data derived from a single randomized trial or nonrandomized studies.<br>*ESC:*<br>Data derived from a single randomized clinical trial or large nonrandomized studies. |

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- **These definitions, however, do not account for the differences of qualities between the randomized studies, because important parameters, like the choice of the primary endpoint - clinical or surrogate - are not considered.**

# The Problem with Level of Evidence C

- The level of evidence C represents „expert opinion“

| | |
|---|---|
| Level of evidence C | *ACC/AHA:*<br>Only consensus opinion of experts, case studies, or standard-of-care.<br>*ESC:*<br>Consensus of opinion of the experts and/or small studies, retrospective studies, registries. |

# The Problem with a Class III Recommendation:

- A Class III „recommendation“ is confusing:
  - may be ineffective = does not harm
  - may be harmful = **contraindication**

Class III *ACC/AHA:*

Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

*ESC:*

Evidence or general agreement that the treatment or procedure is not useful or effective and in some cases may be harmful.

Committee for Practice Guidelines
To improve the quality of clinical practice and patient care in Europe

# PCI

## GUIDELINES FOR PERCUTANEOUS CORONARY INTERVENTIONS

These guidelines represent the views of the ESC Committee for Practice Guidelines Task Force for the Percutaneous Coronary Interventions (PCI), and were arrived at after careful consideration of the available evidence. Health professionals are expected to take them fully into account when exercising their clinical judgement. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with that patient, and where appropriate and necessary the patient's guardian or carer.

**For more information**
**www.escardio.org**

# Stable Angina Pectoris:

1. What is the difference between Guidelines and **Appropriateness Criteria** ?
2. Did COURAGE and DEFER change the ESC PCI Guidelines ?
3. Do we need the USA Appropriateness Criteria ?

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doi:10.1016/j.jacc.2008.10.005


APPROPRIATENESS CRITERIA

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

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

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

## Appropriateness Criteria

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CORONARY REVASCULARIZATION WRITING GROUP

Manesh R. Patel, MD, Chair; Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA*; John W. Hirshfeld, MD†; Peter K. Smith, MD, FACC‡; John A. Spertus, MD, MPH, FACC†

TECHNICAL PANEL

Frederick A. Masoudi, MD, MSPH, FACC, Moderator; Ralph G. Brindis, MD, MSH, FACC, FSCAI, Methodology Liaison; Gregory J. Dehmer, MD, FACC, FACP, FSCAI, FAHA, Writing Group Liaison*; Manesh R. Patel, MD, Writing Group Liaison; Peter K. Smith, MD, FACC, Writing Group Liaison‡; Karen J. Beckman, MD, FACC§; Charles E. Chambers, MD, FACC, FSCAI, FAHA*; T. Bruce Ferguson, Jr, MD, FACC, FAHA‖; Mario J. Garcia, MD, FACC¶; Frederick L. Grover, MD, FACC‖; David R. Holmes, Jr, MD, FACC, FSCAI*; Lloyd W. Klein, MD, FACC, FSCAI, FAHA†; Marian Limacher, MD, FACC†; Michael J. Mack, MD‖; David J. Malenka, MD, FACC††; Myung H. Park, MD, FACC#; Michael Ragosta III, MD, FACC, FSCAI*; James L. Ritchie, MD, FACC, FAHA†; Geoffrey A. Rose, MD, FACC, FASE**; Alan B. Rosenberg, MD††; Richard J. Shemin, MD, FACC, FAHA‖; William S. Weintraub, MD, FACC, FAHA††

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

The American College of Cardiology Foundation (ACCF), Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, and the American Association for Thoracic Surgery, along with key specialty and subspecialty societies, conducted an appropriateness review of common clinical scenarios in which coronary revascularization is frequently considered. The clinical scenarios were developed to mimic common situations encountered in everyday practice and included information on symptom status, extent of medical therapy, risk level as assessed by noninvasive testing, and coronary anatomy. Approximately 180 clinical scenarios were developed by a writing committee

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

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

The technical panel scored each indication on a
from 1 to 9 as follows:

Appropriate: Score 7 to 9

Appropriate for the indicati
nary revascularization **is**
sonable approach f
prove
the patients'

provided, meaning coronary
acceptable and **may** be a reasonable
ndication but with uncertainty implying
esearch and/or patient information is needed to
er classify the indication.

Inappropriate: Score 1 to 3

Inappropriate for the indication provided, meaning coronary revascularization is **not** generally acceptable and is **not** a reasonable approach for the indication and is **unlikely** to improve the patients' health outcomes or survival.

**Table 2. Patients Without Prior Bypass Surgery**

| Indication | | Appropriateness Score (1–9) | | |
|---|---|---|---|---|
| | | CCS Angina Class | | |
| | | Asymptomatic | I or II | III or IV |
| 12. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• Low-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | I (1)* | I (2) | U (5) |
| 13. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• Low-risk findings on noninvasive testing<br>• Receiving a course of maximal anti-ischemic medical therapy | I (2) | U (5) | A (7) |
| 14. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• Intermediate-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | I (3) | U (5) | U (6) |
| 15. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• Intermediate-risk findings on noninvasive testing<br>• Receiving a course of maximal anti-ischemic medical therapy | U (4) | A (7) | A (8) |
| 16. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• High-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | U (6) | A (7) | A (8) |
| 17. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• High-risk findings on noninvasive testing<br>• Receiving a course of maximal anti-ischemic medical therapy | A (7) | A (8) | A (9) |
| 18. | • One- or 2-vessel CAD without involvement of proximal LAD<br>• No noninvasive testing performed | † | U (5) | A (7) |
| 19. | • One- or 2-vessel CAD with borderline stenosis "50% to 60%"<br>• No noninvasive testing performed<br>• No further invasive evaluation performed (i.e., FFR, IVUS) | † | I (2) | I (3) |
| 20. | • One- or 2-vessel CAD with borderline stenosis "50% to 60%"<br>• No noninvasive testing performed or equivocal test results present<br>• FFR less than 0.75 and/or IVUS with significant reduction in cross-sectional area | I (3) | U (6) | A (7) |
| 21. | • One- or 2-vessel CAD with borderline stenosis "50% to 60%"<br>• No noninvasive testing performed or equivocal test results present<br>• FFR or IVUS findings do not meet criteria for significant stenosis | I (1) | I (2) | I (2) |
| 22. | • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses<br>• Low-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | I (1) | I (2) | I (3) |
| 23. | • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses<br>• Low-risk findings on noninvasive testing<br>• Receiving a course of maximal anti-ischemic medical therapy | I (1) | U (4) | U (6) |
| 24. | • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses<br>• Intermediate-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | I (3) | U (4) | U (6) |
| 25. | • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses<br>• Intermediate-risk criteria on noninvasive testing<br>• Receiving a course of maximal anti-ischemic medical therapy | U (4) | U (5) | A (7) |
| 26. | • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses<br>• High-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | U (4) | U (5) | A (7) |
| 27. | • Chronic total occlusion of 1 major epicardial coronary artery, without other coronary stenoses<br>• High-risk criteria on noninvasive testing<br>• Receiving a course of maximal anti-ischemic medical therapy | U (5) | A (7) | A (8) |
| 28. | • One-vessel CAD involving the proximal LAD<br>• Low-risk findings on noninvasive testing<br>• Receiving no or minimal anti-ischemic medical therapy | U (4) | U (5) | A (7) |
| 29. | • One-vessel CAD involving the proximal LAD<br>• Low-risk findings on noninvasive testing<br>• Receiving maximal anti-ischemic medical therapy | U (4) | A (7) | A (8) |

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

Appropriateness criteria are developed to serve as a supplement to ACC/AHA guideline documents. Appropriateness criteria are designed to examine the use of diagnostic and therapeutic procedures to support efficient use of medical resources during the pursuit of quality medical care. The process of appropriateness criteria development has been defined previously (1). Briefly, the appropriateness criteria writing group combines specific clinical characteristics to create prototypical patient scenarios. These scenarios are then provided to a separate technical panel for appropriateness rating. The technical panel is created from nominations given by multiple relevant professional societies and provider-led organizations as well as from health policy and payer communities. To preserve objectivity, the technical panels are created so as to not include a majority of individuals whose livelihood is tied to the technology under study.

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

THE NATION'S NEWSPAPER

USA TODAY

NO. 1 IN THE USA

# Medicine enough for pain in chest?

## Study sees way to avoid angioplasty

By Steve Sternberg
USA TODAY


The NEW ENGLAND JOURNAL of MEDICINE

# Optimal Medical Therapy with or without PCI for Stable Coronary Disease

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

**CONCLUSIONS**

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

N Engl J Med 2007;356:1503-16

# Guidelines for Percutaneous Coronary Interventions

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

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


European Heart Journal (2005) 26, 804–847

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## 2. Indications for PCI

### 2.1. Indications for PCI in stable coronary artery disease

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

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

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# 2. Indications for PCI

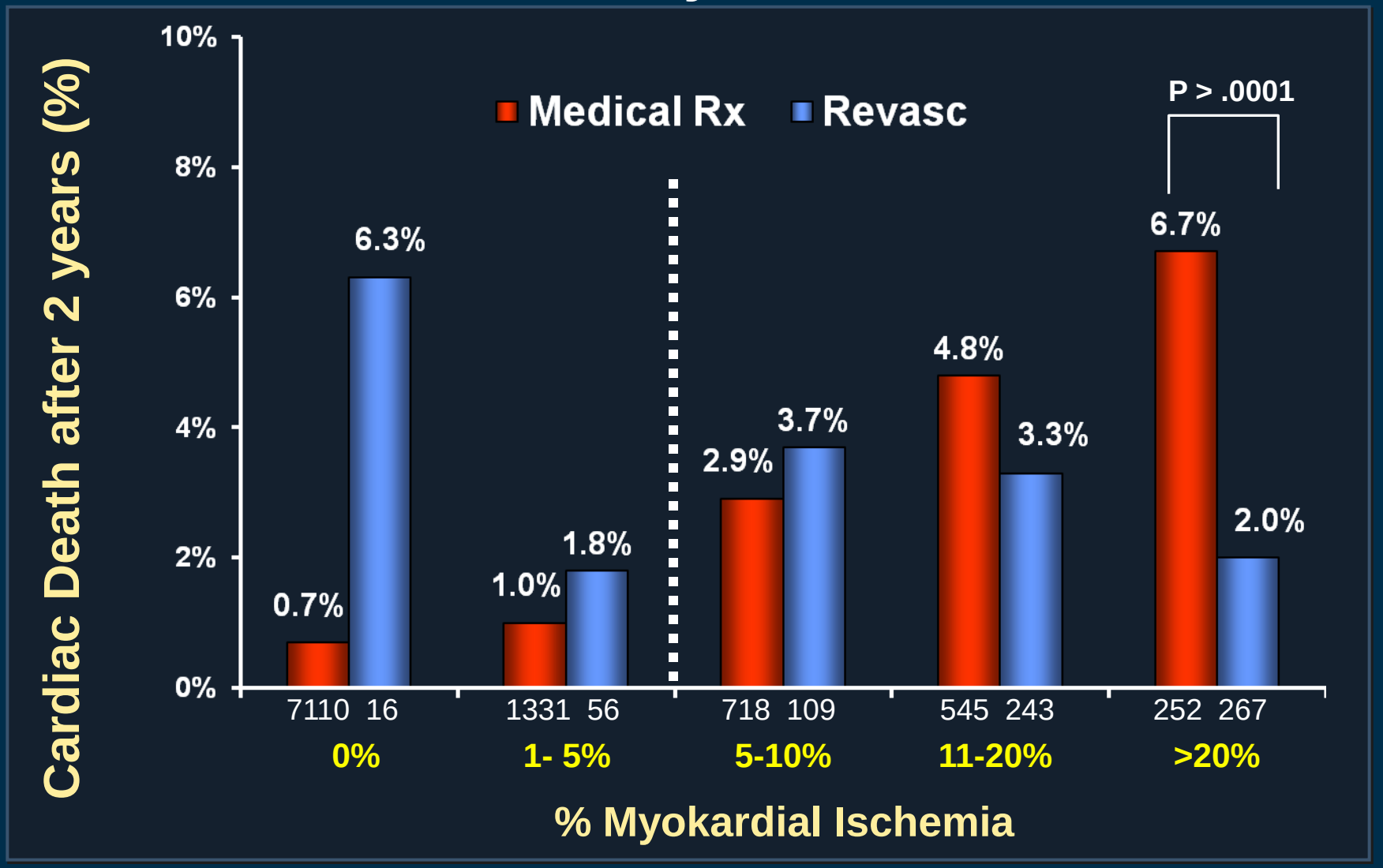
## 2.1. Indications for PCI in stable coronary artery disease

**Table 1** Recommendations of PCI indications in stable CAD

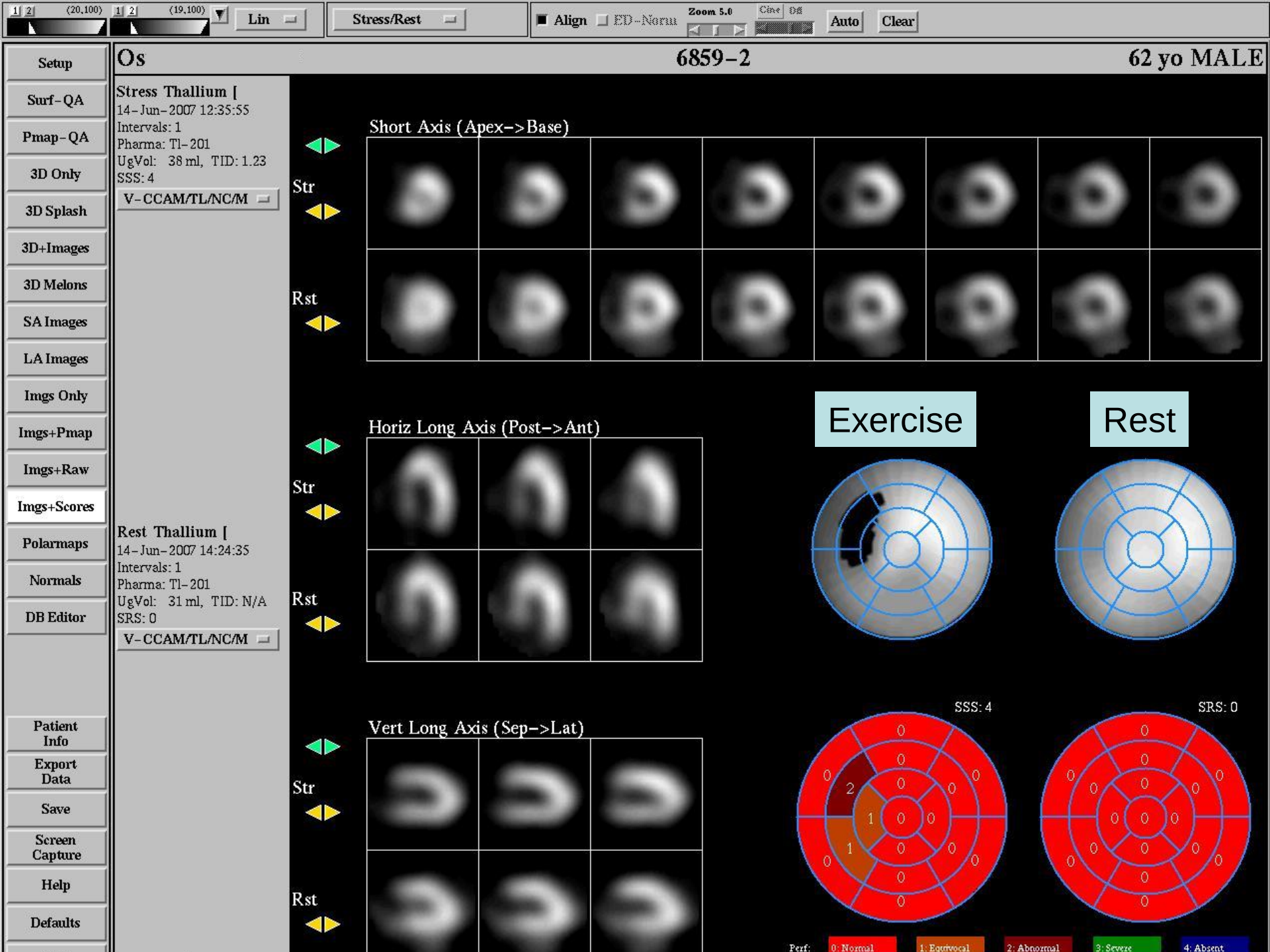
| Indication | Classes of recommendations and levels of evidence | Randomized studies for levels A or B |
|---|---|---|
| Objective large ischaemia | I A | ACME[a]<br>ACIP[b] |

European Heart Journal (2005) 26, 804–847

# Improvement of Prognosis depends on the Extent of Myocardial Ischemia




*Hachamovitch et al Circulation.* 2003;107:2900-07.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1 2 (19,100)
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Stress/Rest
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Cine
Dir
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Clear
Setup
Surf-QA
Pmap-QA
3D Only
3D Splash
3D+Images
3D Melons
SA Images
LA Images
Imgs Only
Imgs+Pmap
Imgs+Raw
Imgs+Scores
Polarmaps
Normals
DB Editor
Patient Info
Export Data
Save
Screen Capture
Help
Defaults
Os
6859-2
62 yo MALE
Stress Thallium [
14-Jun-2007 12:35:55
Intervals: 1
Pharma: Tl-201
UgVol: 38 ml, TID: 1.23
SSS: 4
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Intervals: 1
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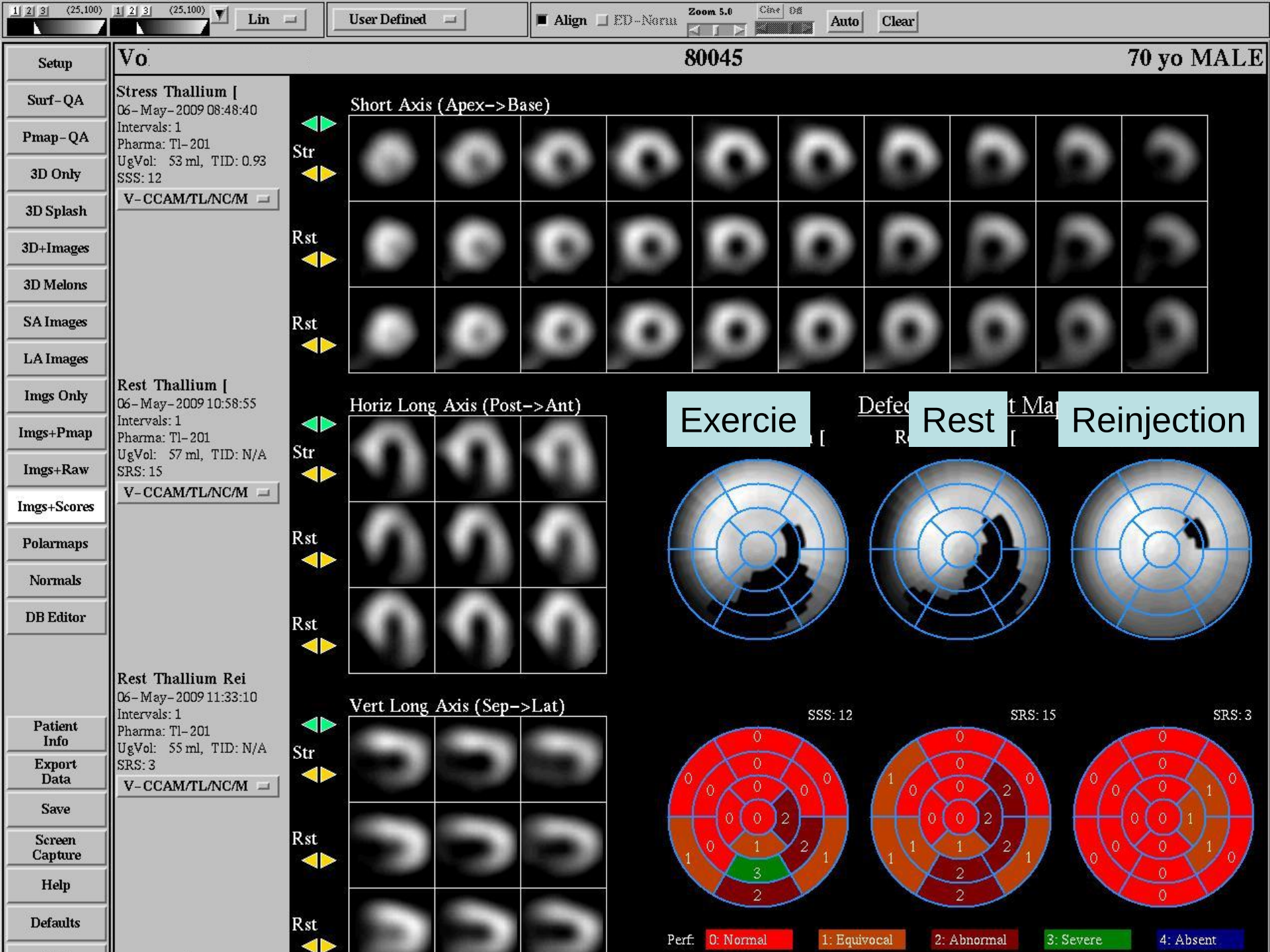
Str
Rst
Horiz Long Axis (Post->Ant)
Str
Rst
Vert Long Axis (Sep->Lat)
Str
Rst
Exercise
Rest
SSS: 4
SRS: 0
Perf:
0: Normal
1: Equivocal
2: Abnormal
3: Severe
4: Absent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3D Splash
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3D Melons
SA Images
LA Images
Imgs Only
Imgs+Pmap
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Imgs+Scores
Polarmaps
Normals
DB Editor
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Save
Screen Capture
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Defaults
80045
70 yo MALE
Stress Thallium [
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Intervals: 1
Pharma: Tl-201
UgVol: 53 ml, TID: 0.93
SSS: 12
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UgVol: 57 ml, TID: N/A
SRS: 15
V-CCAM/TL/NC/M
Rest Thallium Rei
06-May-2009 11:33:10
Intervals: 1
Pharma: Tl-201
UgVol: 55 ml, TID: N/A
SRS: 3
V-CCAM/TL/NC/M
Short Axis (Apex->Base)
Horiz Long Axis (Post->Ant)
Vert Long Axis (Sep->Lat)
Str
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Rst
Exercie
Rest
Reinjection
SSS: 12
SRS: 15
SRS: 3
Perf:
0: Normal
1: Equivocal
2: Abnormal
3: Severe
4: Absent


Stable Angina
2006

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

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

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

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

# PCI for stable CAD

ESC GUIDELINES

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

**Table 6** Summary of recommendations for revascularization in stable angina

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

# PCI for stable CAD

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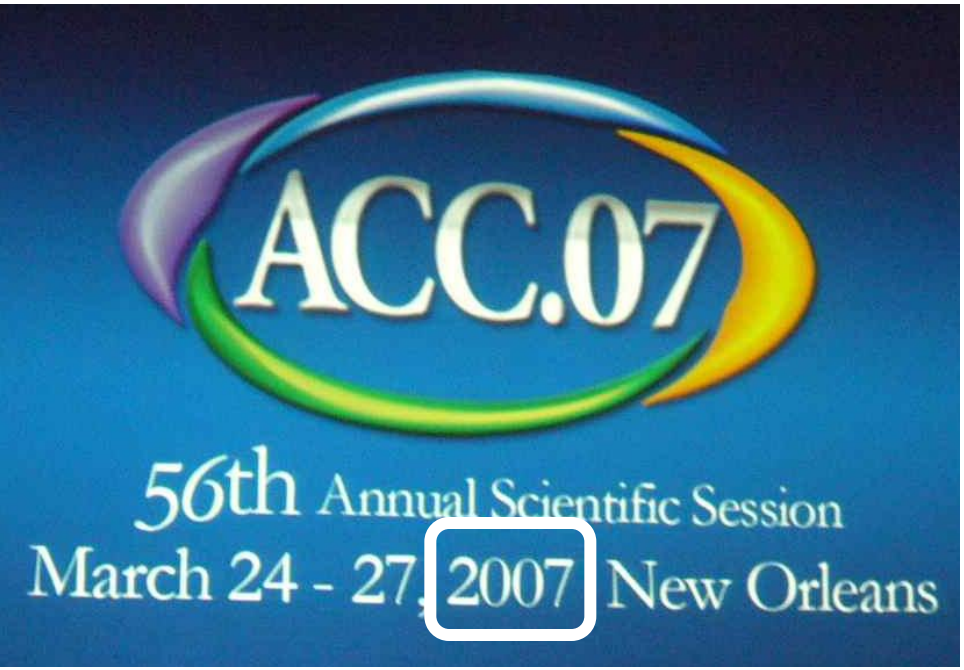


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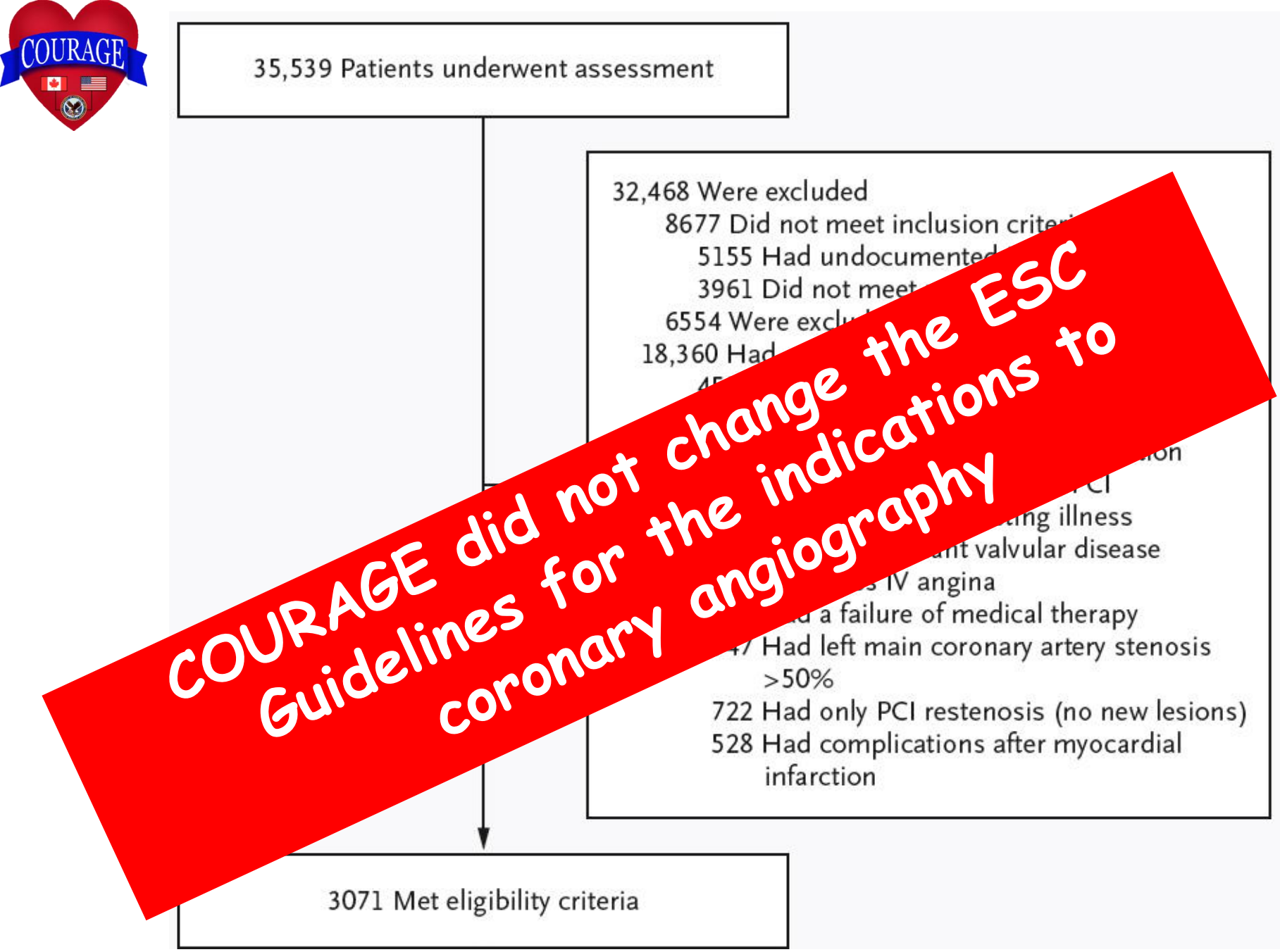
## Study sees way to avoid angioplasty

By Steve Sternberg
USA TODAY




COURAGE did not change the ESC Guidelines for the indications to coronary angiography

N Engl J Med 2007;356:1503-16

# Stable Angina Pectoris:

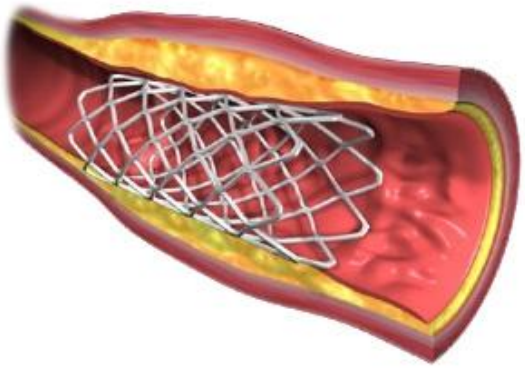
1. What is the difference between Guidelines and Appropriateness Criteria ?
2. Did COURAGE change the ESC Guidelines for the indication to coronary angiography ?
3. Do we need the USA Appropriateness Criteria for the Decision whether to Revascularize or not ?

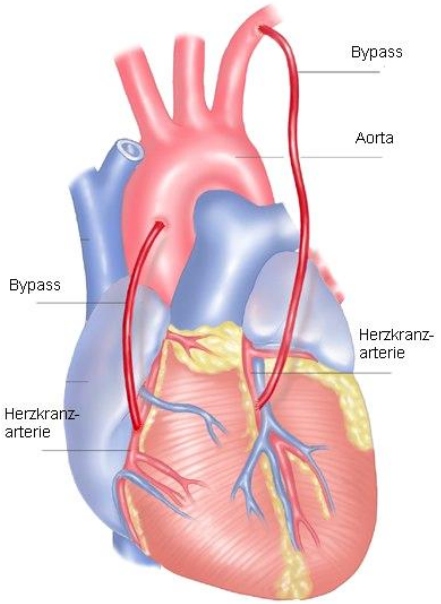
## ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization

| | | | |
|---|---|---|---|
| | | | 9) |
| | | | r IV |
| • One- or 2-vessel CAD without involvement of proximal LAD | | | U (5) |
| • Low-risk findings on noninvasive testing | | | |
| • Receiving no or minimal anti-ischemic medical therapy | | | |
| • One- or 2-vessel CAD without involvement of pr | I (2) | U (5) | A (7) |
| • Low-risk findings on noninvasive testing | | | |
| • Receiving a course of maximal | | | |
| • One- or 2-vessel CAD wi | I (3) | U (5) | U (6) |
| • Intermediate-ri | | | |
| • Recei | | | |

We knew this already from the ESC PCI and Angina Guidelines

# Stent or Bypass ?





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

| | PCI Appropriateness Rating | CABG Appropriateness Rating |
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| • Two-vessel CAD with proximal LAD stenosis<br>• Diabetes | A (7) | A (8) |
| • Two-vessel CAD with proximal LAD stenosis<br>• Depressed LVEF | A (7) | A (8) |
| • Three-vessel CAD<br>• No diabetes and normal LVEF | U (6) | A (8) |
| • Three-vessel CAD<br>• Diabetes | U (5) | A (9) |
| • Three-vessel CAD<br>• Depressed LVEF | U (4) | A (9) |
| • Isolated left main stenosis<br>• No diabetes and normal LVEF | I (3) | A (9) |
| • Isolated left main stenosis<br>• Diabetes | I (3) | A (9) |
| • Isolated left main stenosis<br>• Depressed LVEF | I (3) | A (9) |
| • Left main stenosis and additional CAD<br>• No diabetes and normal LVEF | I (3) | A (9) |
| • Left main stenosis and additional CAD<br>• Diabetes | I (2) | A (9) |
| • Left main stenosis and additional CAD<br>• Depressed LVEF | I (2) | A (9) |

March 2009


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

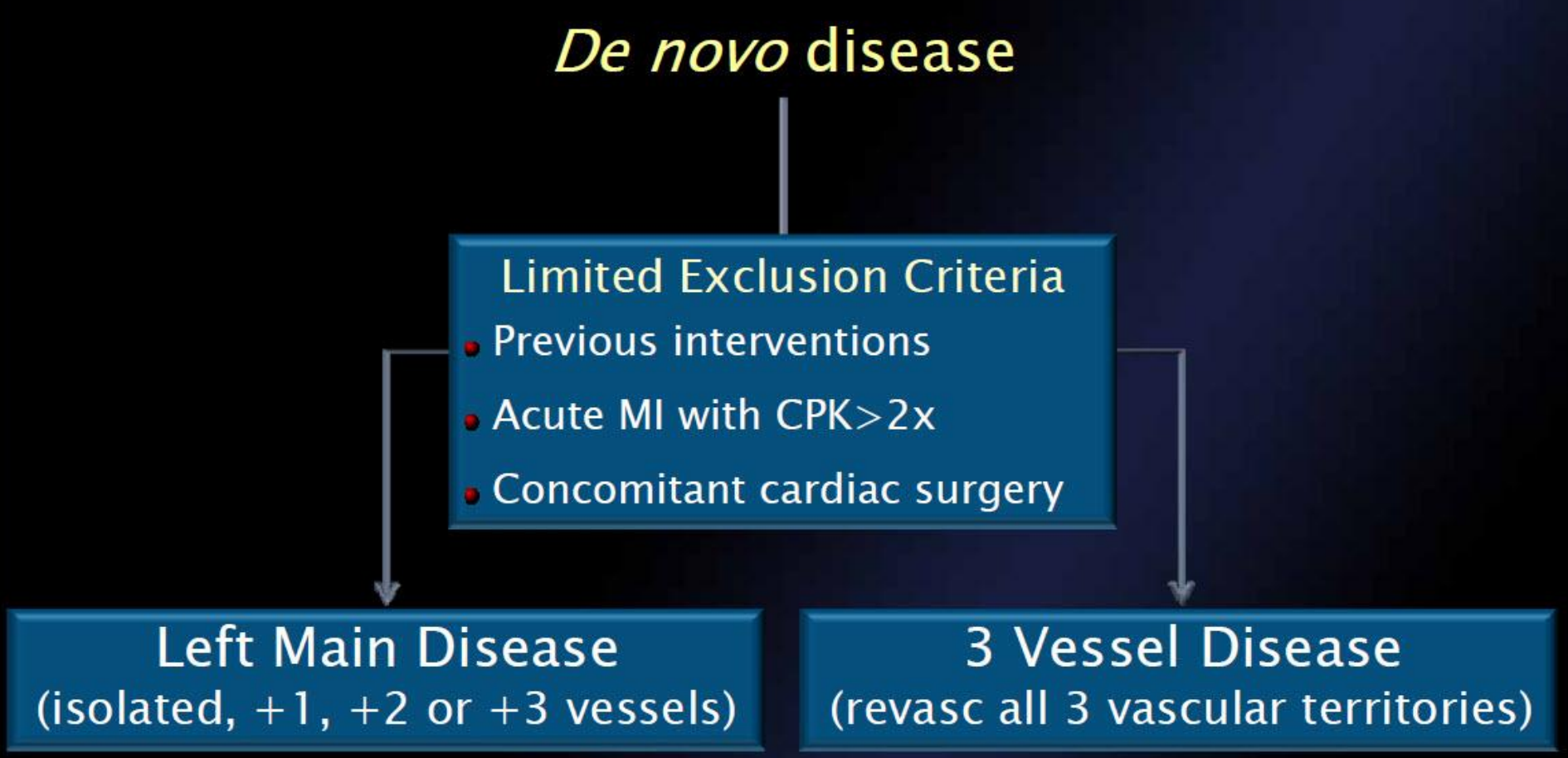
# The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

## *Primary Endpoint Results at One Year in the Randomized Cohort*

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

Conflicts of Interest: None

# SYNTAX Eligible Patients



# SYNTAX Primary Endpoint
## *Randomized trial*

SYNTAX

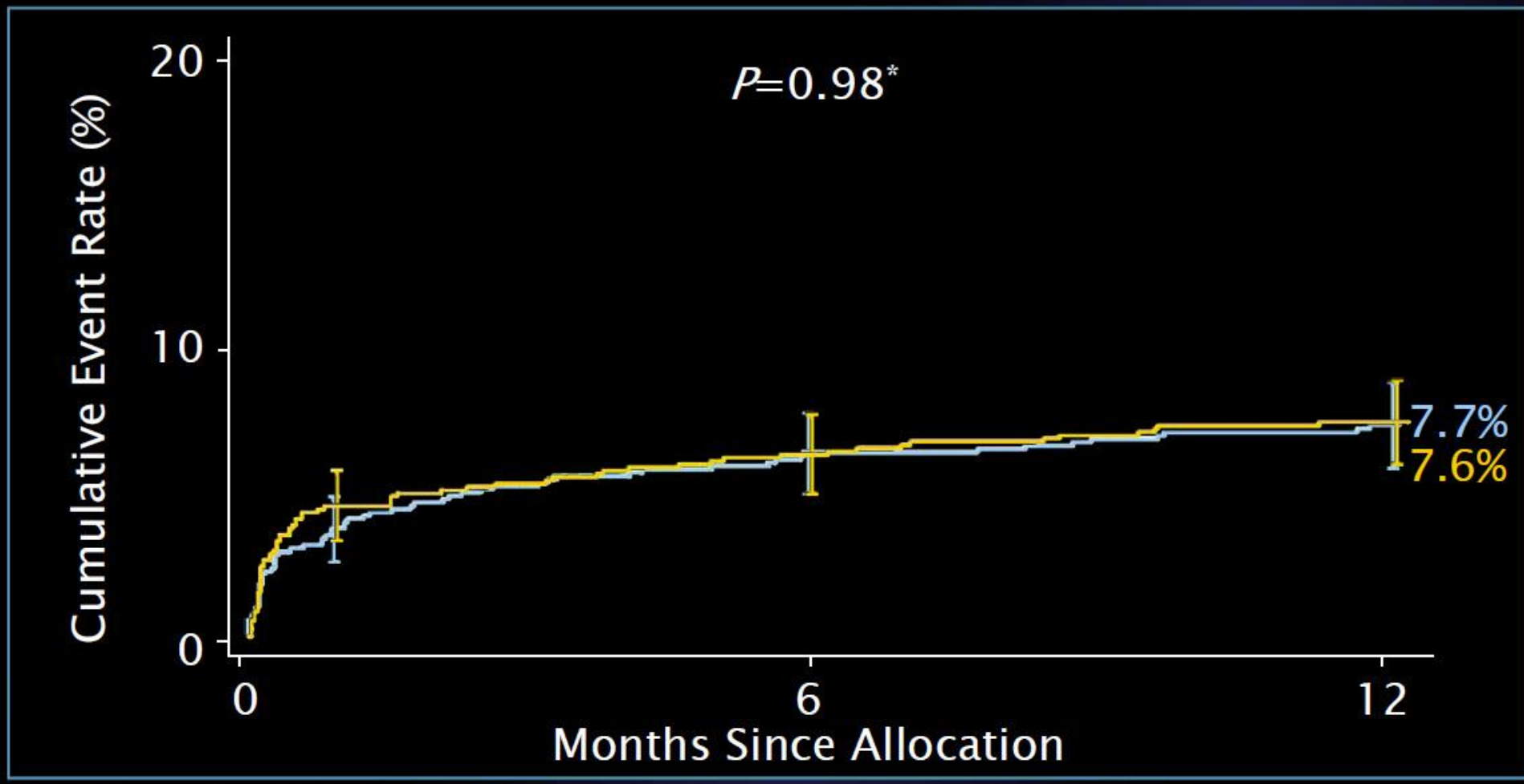
*The primary clinical endpoint is the 12 Month major Cardiovascular or Cerebrovascular event rate (MACCE *)*

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

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

# All-Cause Death/CVA/MI to 12 Months

SYNTAX

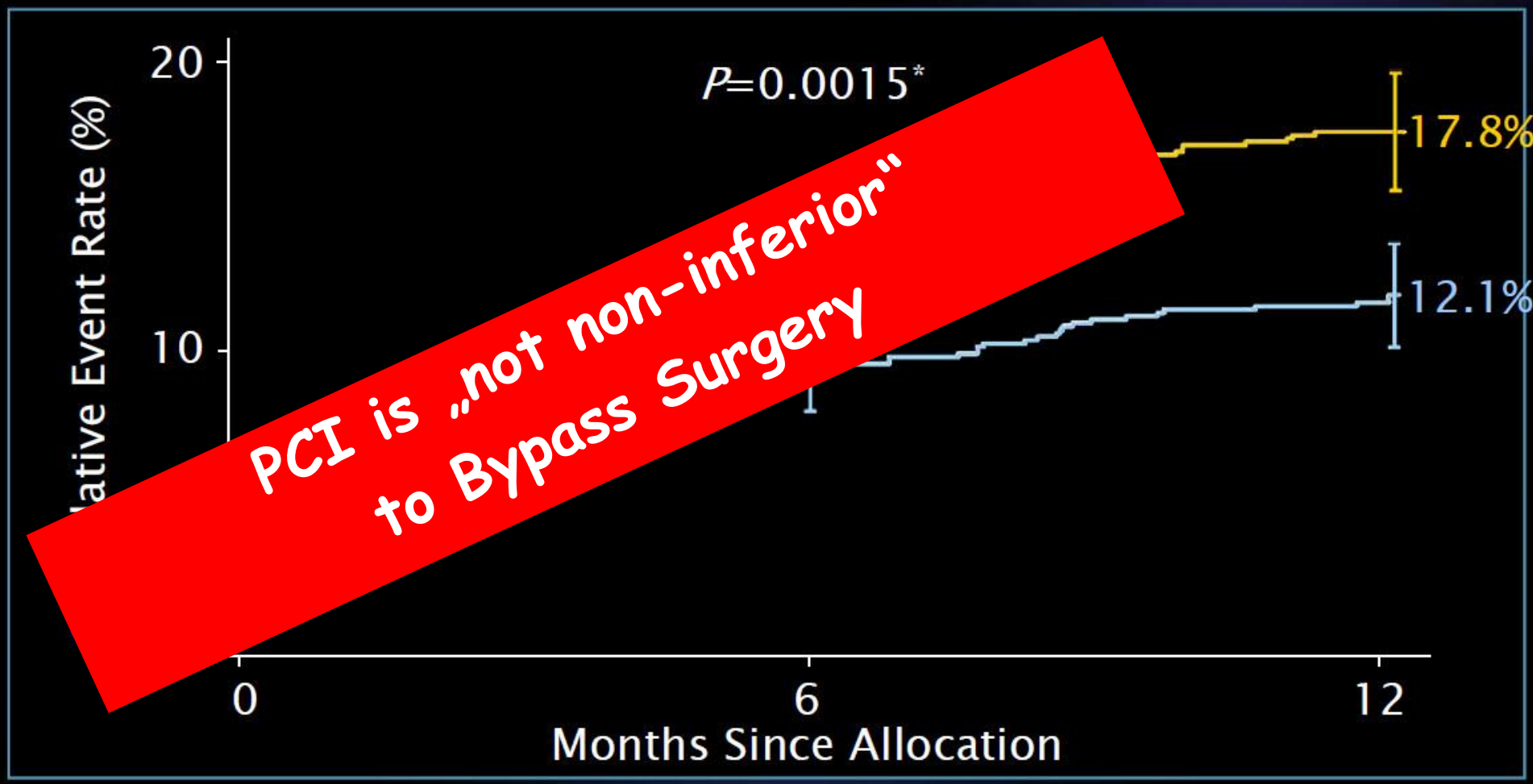



Event Rate ± 1.5 SE. *Fisher's Exact Test

ITT population

# MACCE to 12 Months

SYNTAX

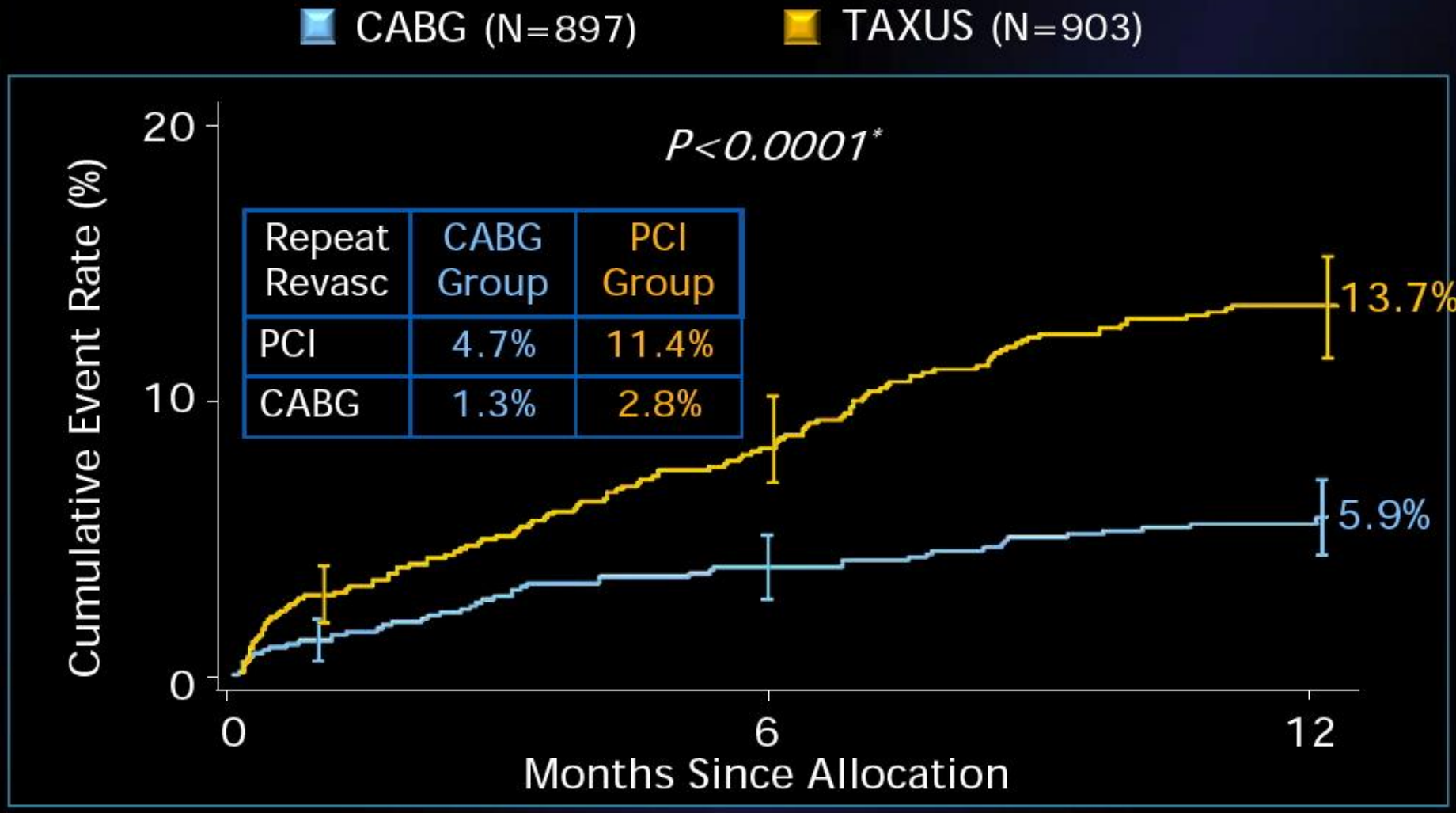



PCI is „not non-inferior" to Bypass Surgery

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

ITT population

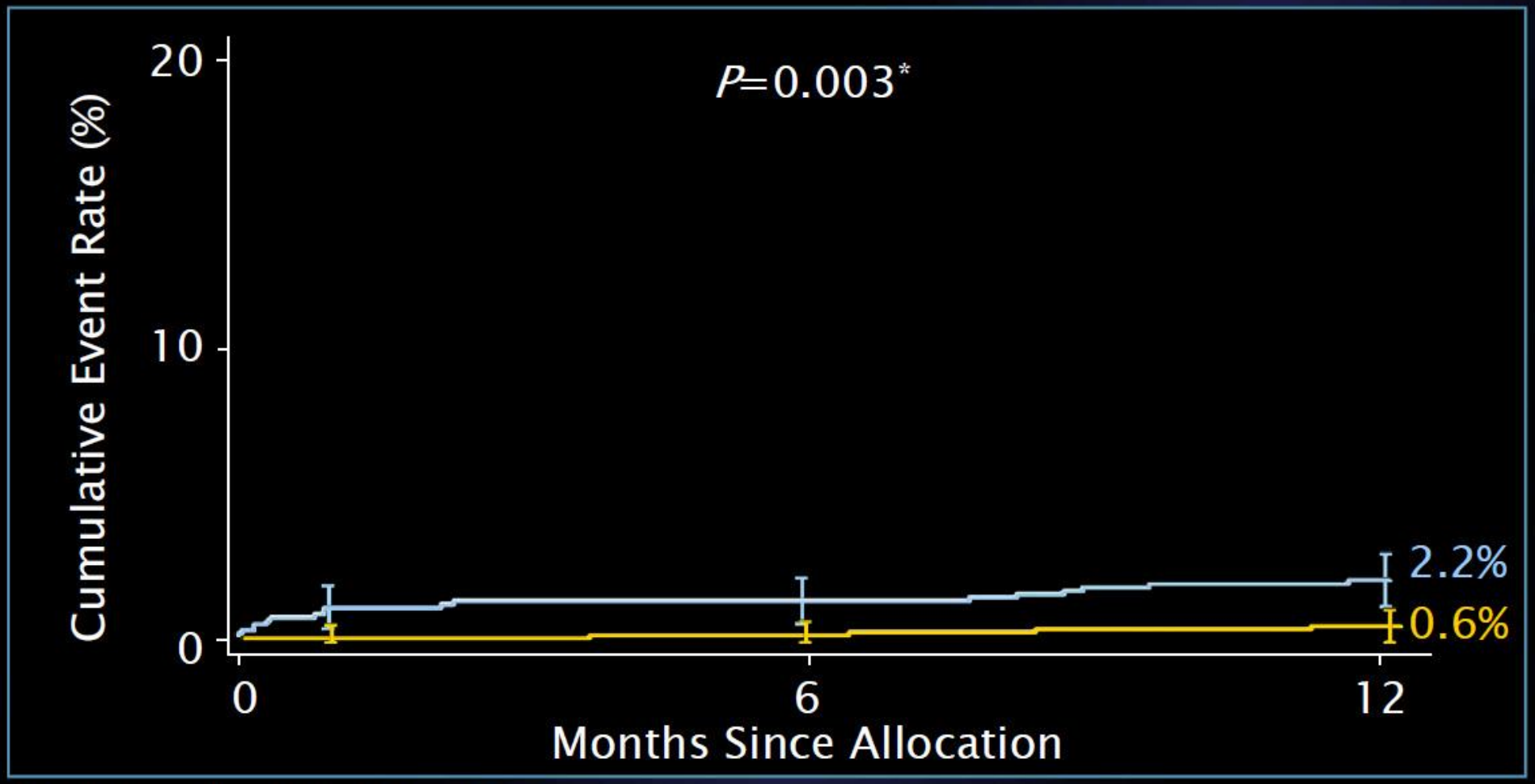
# Repeat Revascularization to 12 Months SYNTAX




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

ITT population

# CVA to 12 Months

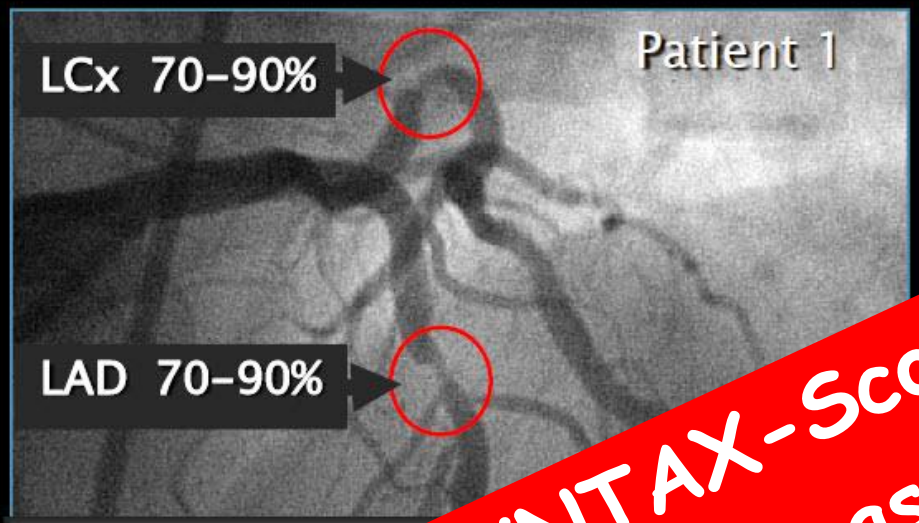



Event Rate ± 1.5 SE. *Fisher's Exact Test

ITT population

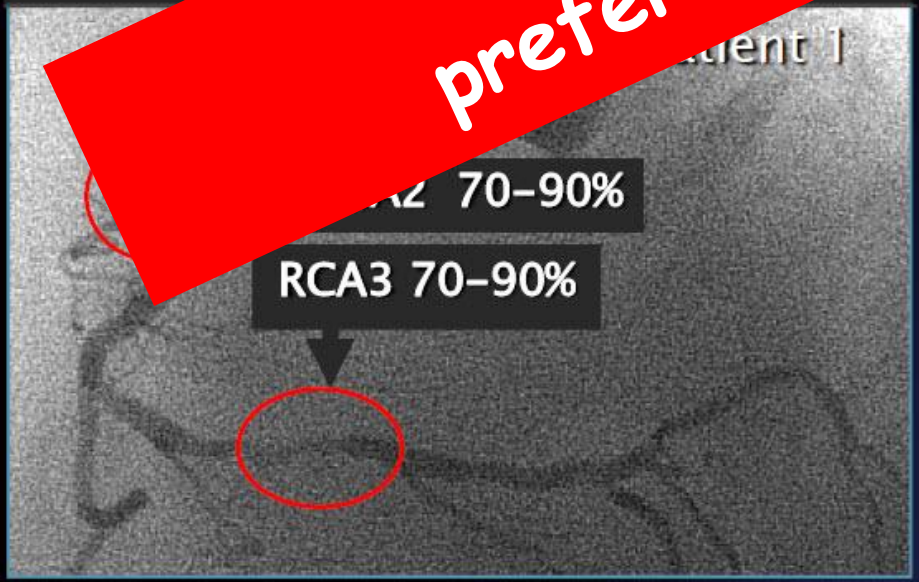
# There is '3-vessel disease' and '3-vessel disease'

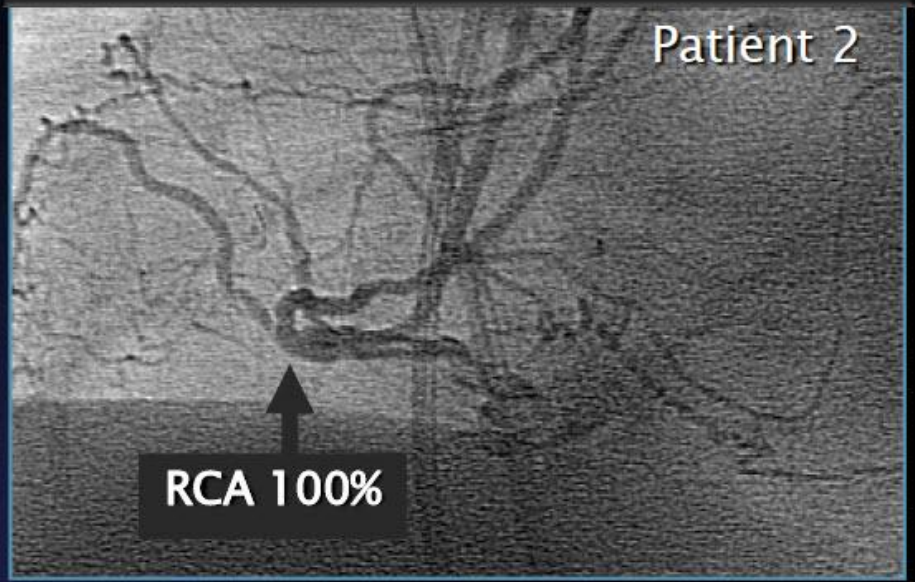
SYNTAX





SYNTAX SCORE 52



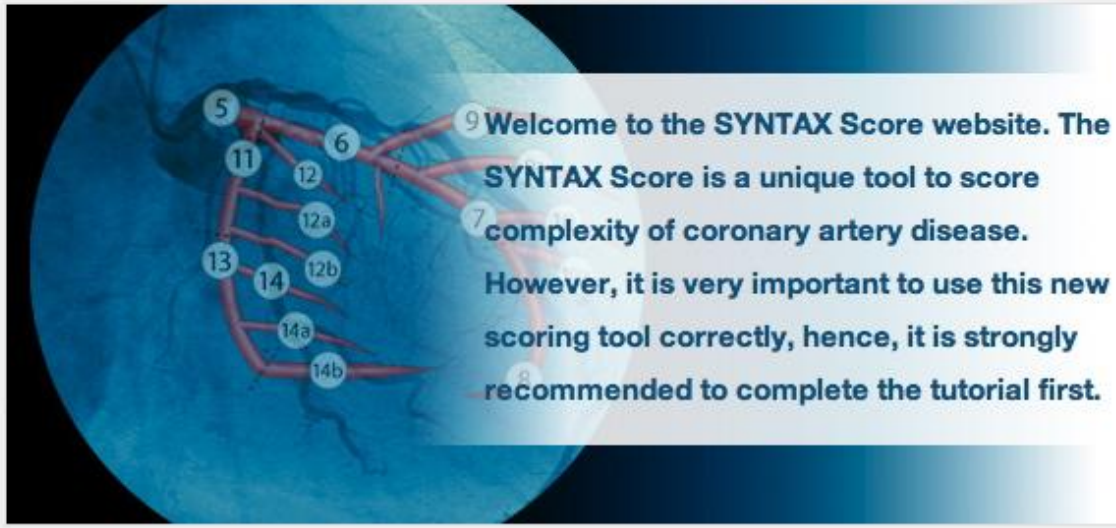

SYNTAX-Score > 33:
prefer Bypass Surgery !

# www.syntaxscore.com

Home Tutorial Calculator References Contact

SYNTAX SCORE

Search...




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

**TUTORIAL**

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

Start tutorial...

**CALCULATOR**

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

Start calculator...

Introducing the SYNTAX Score at EuroPCR 2009

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

| | PCI Appropriateness Rating | CABG Appropriateness Rating |
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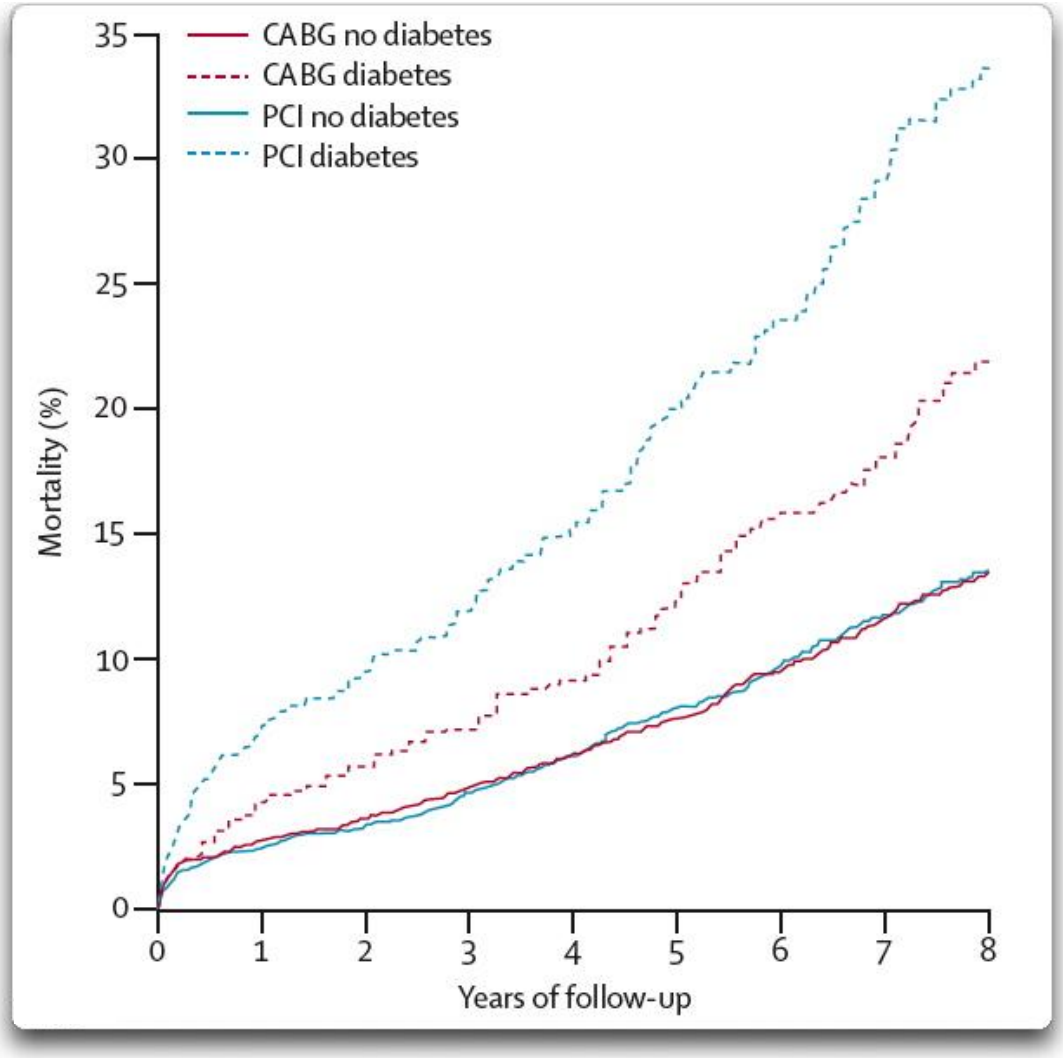
| • Two-vessel CAD with proximal LAD stenosis<br>• Depressed LVEF | A (7) | A (8) |
| • Three-vessel CAD<br>• No diabetes and normal LVEF | U (6) | A (8) |
| • Three-vessel CAD<br>• Diabetes | U (5) | A (9) |
| • Three-vessel CAD<br>• Depressed LVEF | U (4) | A (9) |
| • Isolated left main stenosis<br>• No diabetes and normal LVEF | I (3) | A (9) |
| • Isolated left main stenosis<br>• Diabetes | I (3) | A (9) |
| • Isolated left main stenosis<br>• Depressed LVEF | I (3) | A (9) |
| • Left main stenosis and additional CAD<br>• No diabetes and normal LVEF | I (3) | A (9) |
| • Left main stenosis and additional CAD<br>• Diabetes | I (2) | A (9) |
| • Left main stenosis and additional CAD<br>• Depressed LVEF | I (2) | A (9) |

# Coronary artery bypass surgery compared with percutaneous coronary interventions for multivessel disease: a collaborative analysis of individual patient data from ten randomised trials

*Lancet* 2009; 373: 1190–97

*Mark A Hlatky, Derek B Boothroyd, Dena M Bravata, Eric Boersma, Jean Booth, Maria M Brooks, Didier Carrié, Tim C Clayton, Nicolas Danchin, Marcus Flather, Christian W Hamm, Whady A Hueb, Jan Kähler, Sheryl F Kelsey, Spencer B King, Andrzej S Kosinski, Neuza Lopes, Kathryn M McDonald, Alfredo Rodriguez, Patrick Serruys, Ulrich Sigwart, Rodney H Stables, Douglas K Owens, Stuart J Pocock*



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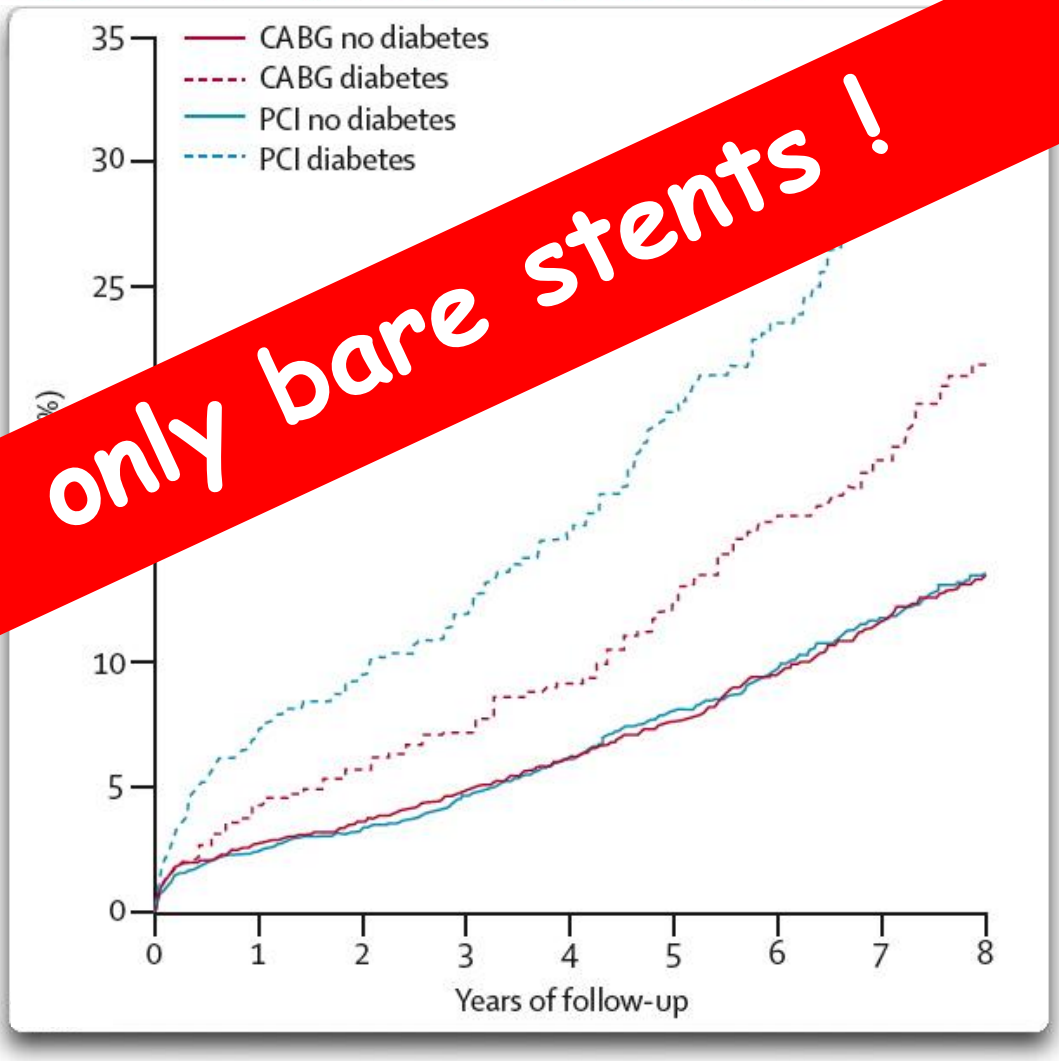
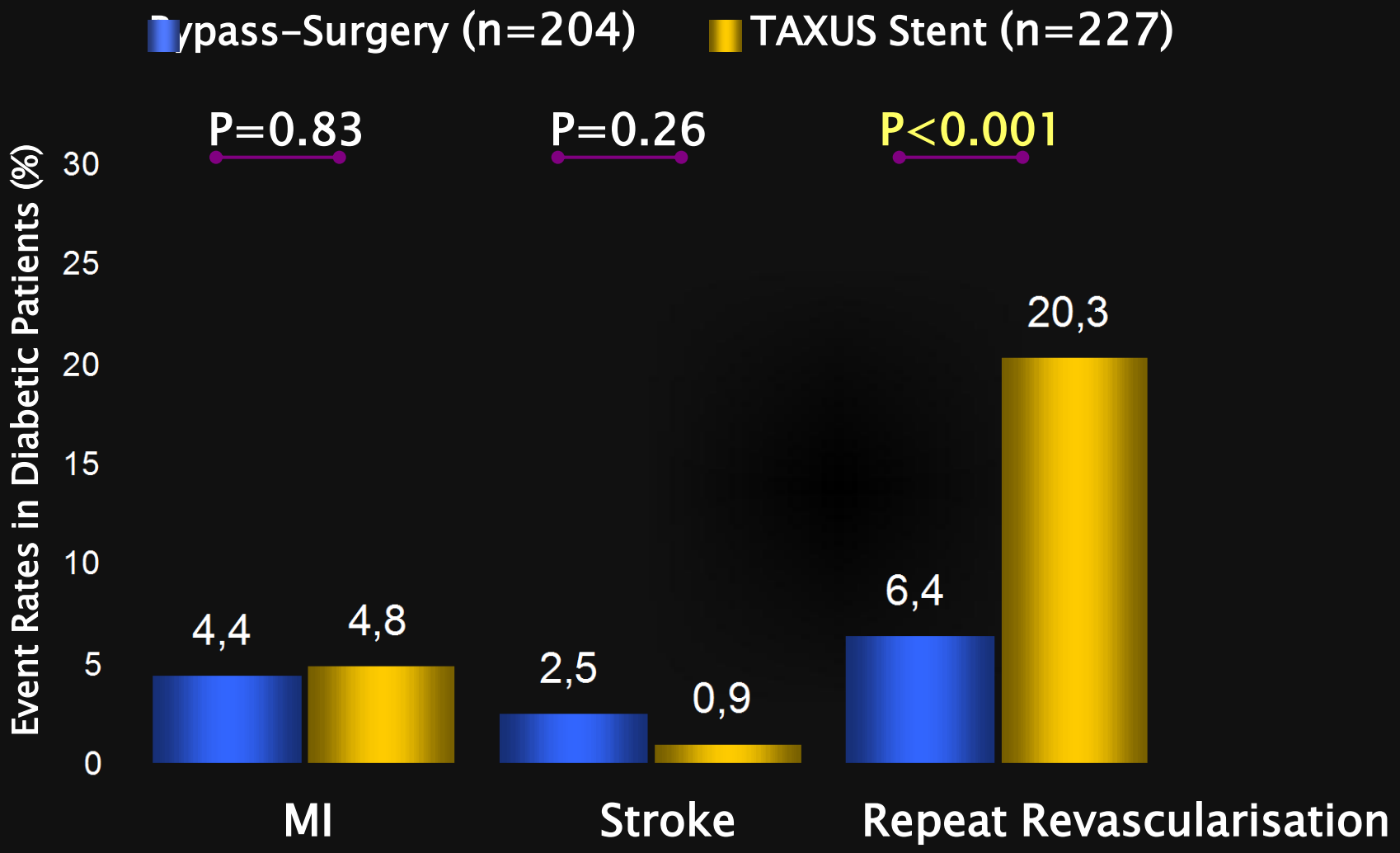
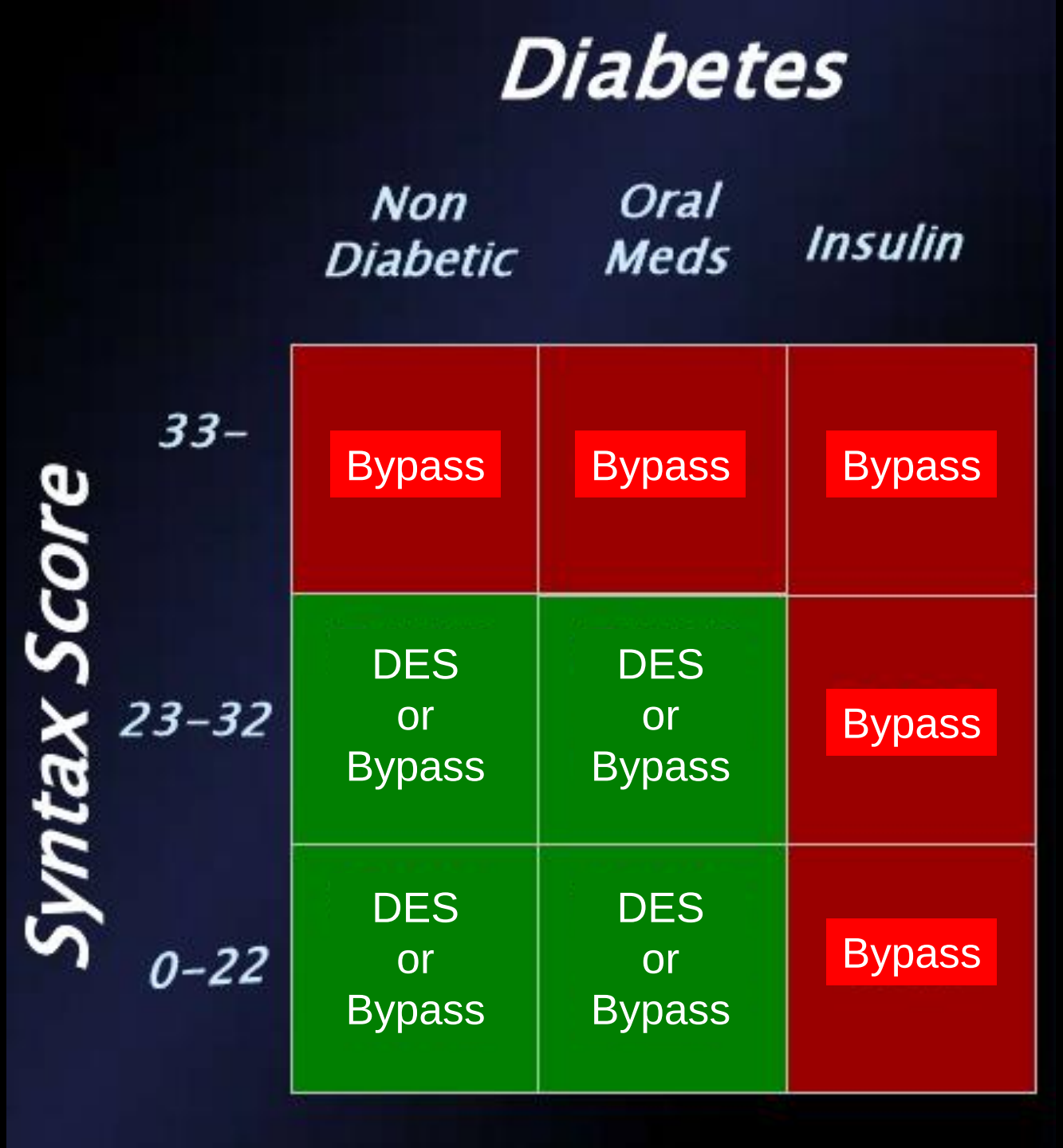


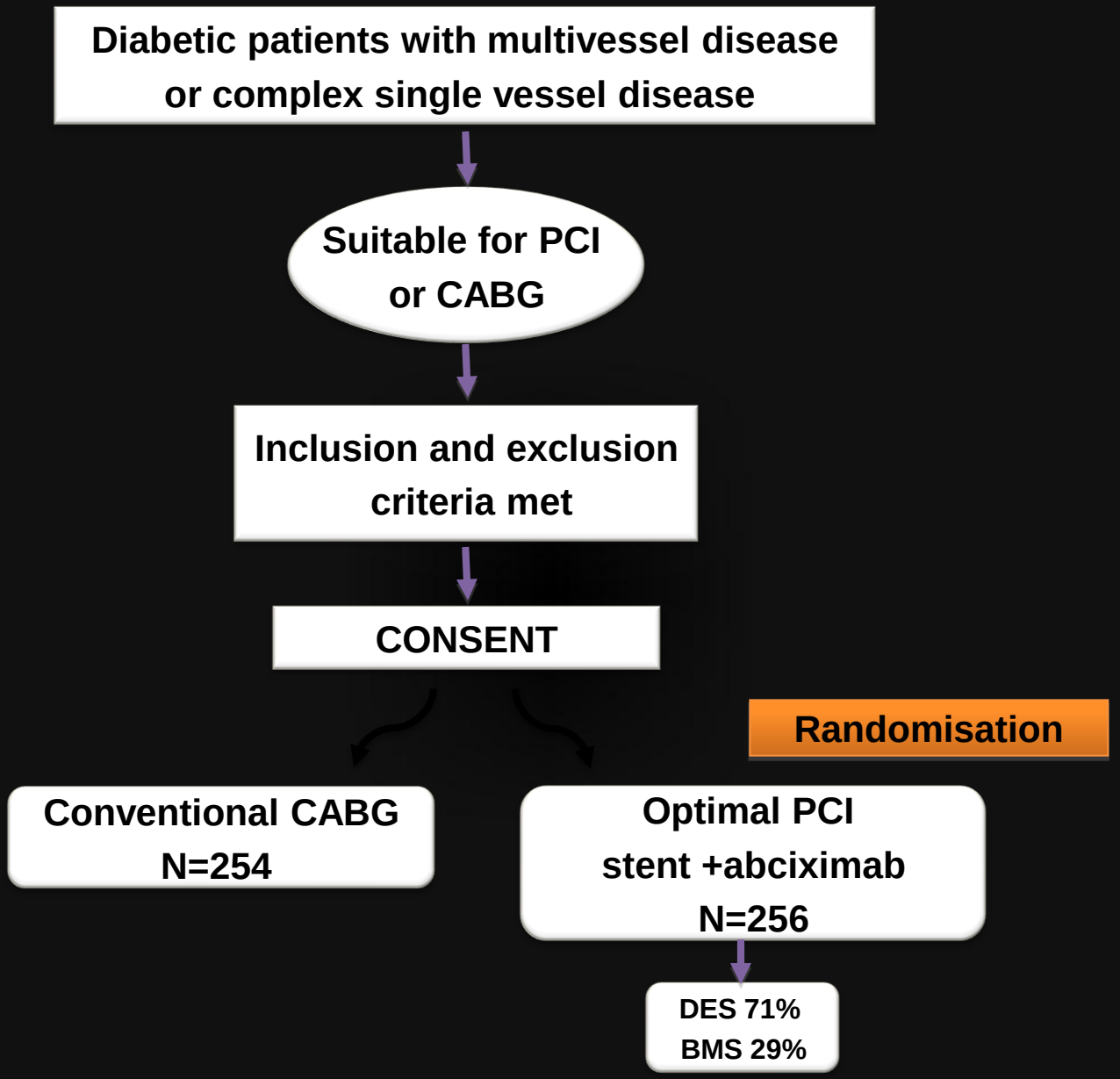

only bare stents !

# SYNTAX: Diabetic Patients



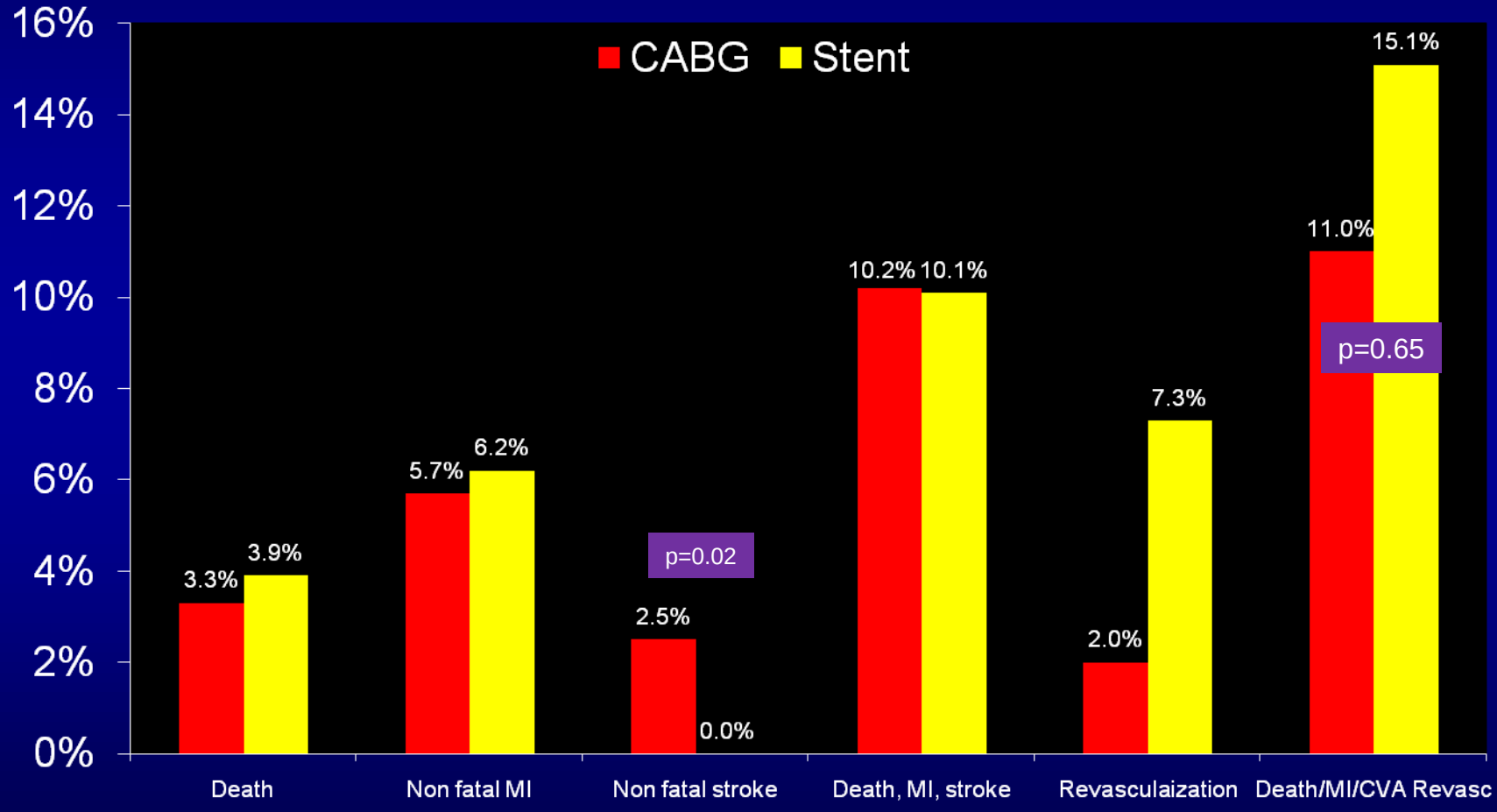

Diabetes
Non Diabetic
Oral Meds
Insulin
Syntax Score
33–
23–32
0–22
Bypass
Bypass
Bypass
DES or Bypass
DES or Bypass
Bypass
DES or Bypass
DES or Bypass
Bypass

# CARDia Trial Design



# CARDIA
## (Coronary Artery Revascularization Diabetes Trial)

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




*ESC, 2008*

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not helpful any more

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| • Isolated left main<br>• Diabetes | I (3) | A (9) |
| • | I (3) | A (9) |
| | I (3) | A (9) |
| al CAD | I (2) | A (9) |
| • sis and additional CAD<br>• De sed LVEF | I (2) | A (9) |

Where is 1-vessel disease with proximal LAD stenosis ?

INTERVENTIONAL/SURGERY

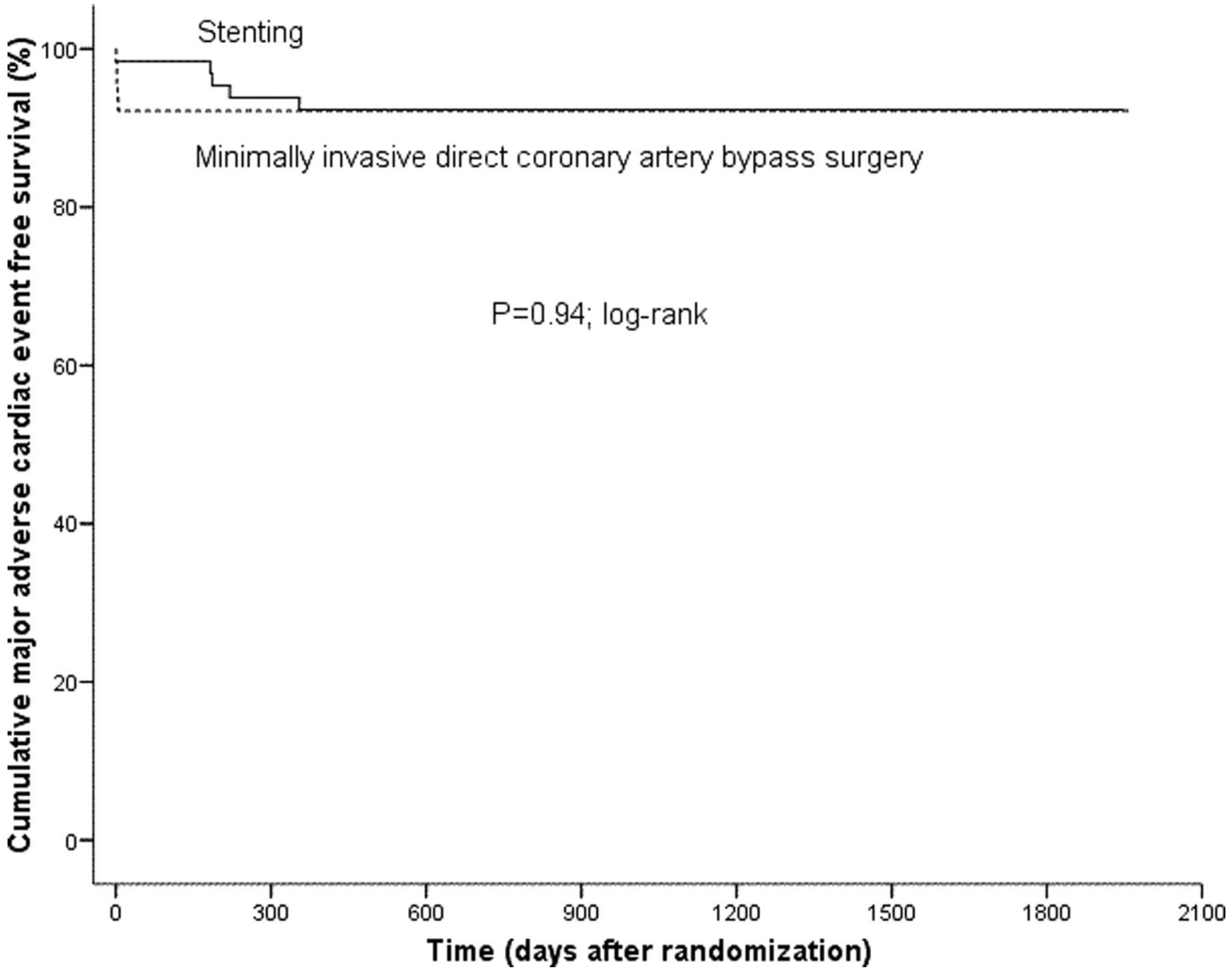
# DES "noninferior" to MIDCAB for isolated LAD disease, small study suggests

JUNE 15, 2009 | Shelley Wood

**Leipzig, Germany** – A small randomized study comparing minimally invasive coronary artery bypass surgery (MIDCAB) with PCI using sirolimus-eluting stents suggests that both approaches are reasonable options in patients with isolated proximal left anterior descending (LAD) coronary artery disease [1]. While repeat procedures were more common for PCI, periprocedural events were more common in the MIDCAB group.

The results appear in the June 23, 2009 issue of the *Journal of the American College of Cardiology*.

# MACE at Mid-Term Follow-Up




**J Am Coll Cardiol 2009;53:2324-2331**

# Summary-1:
# Guidelines vs. Appropriateness Scoring

- **<u>Guidelines</u> are based on scientific evidence from existing clinical trials.**

  **Guidelines make recommendations in classes (I, II, III)**

  **at certain levels of evidence A, B (from randomized trials) and level C, with C representing the „expert opinion“, when strong scientific evidence is missing.**

  **Guidelines in general do not include cost-effectiveness analyses.**

- **<u>Appropriateness Criteria</u> are creating a huge set of various clinical settings not necessarily investigated in clinical trials.**

  **Appropriateness Criteria are classified as Appropriate, Inappropriate or Uncertain, based on „expert opinions“ including also non-medical and health care related people.**

  **Appropriateness Criteria do not refer to contraindications.**

  **Appropriateness Criteria are especially useful for diagnostic methods, where usually no randomized trials exist.**

- **However, the application of Appropriateness Criteria might be a problem for therapeutic decisions, since „Inappropriate“ might sound much stronger than e.g. „IIb C“**

- **For therapuetic decisions, guidelines leave more room for the individual decisions made by the responsible physicians.**

# Summary-2:

- *Question:* **did COURAGE (2007) change the ESC PCI Guidelines for PCI (2005) and stable Angina (2006) ?**

  *Answer:* **no - don‘t defer diagnostic angiography, if in doubt**

- *Question:* **did the USA Appropriateness Criteria change our clinical practice, whom to revascularize ?**

  *Answer:* **no - the importance of demonstrating myocardial ischemia as pointed out in the previous ESC Guidelines is confirmed.**

- *Question:* **are the USA Appropriateness Criteria for Coronary Revascularization applicable to Europe ?**

  *Answer:* **no, because cost-effectiveness was also included in the USA Appropriateness Criteria and the health care systems are very different. What may be inappropriate in the USA might be appropriate in Europe.**

- **<u>Problem:</u> Neither the ESC Guidelines nor the USA Appropriateness Criteria have already implemented the results of the recent randomized Drug-eluting Stents vs. Bypass-Surgery trials.**

# ESC GUIDELINES

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

## Guidelines for Percutaneous Coronary Interventions

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

Authors/Task Force Members: Sigmund Silber, Chairperson* (Germ
Per Albertsson (Sweden), Francisco F. Avilés (Spain), Paolo G
Antonio Colombo (Italy), Christian Hamm (Germany), Eri
(Denmark), Jean Marco (France), Jan-Erik Nordreh
Witold Ruzyllo (Poland), Philip Urban (Switze
Stone (USA),
William Wijns (Belgium)

**When will it be updated ?**

# ESC GUIDELINES

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

EUROPEAN SOCIETY OF CARDIOLOGY

EUROPEAN ASSOCIATION FOR CARDIO-THORACIC SURGERY

12 September 2008

Dear **Additional Contributor**,

I am pleased to officially invite you to serve as an Additional Contributor of the **ESC/EACTS Task Force** to develop the **Guidelines on Coronary Revascularization**. The ESC and the EACTS will jointly sponsor these guidelines.

# ESC GUIDELINES

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

EUROPEAN SOCIETY OF CARDIOLOGY

EUROPEAN ASSOCIATION FOR CARDIO-THORACIC SURGERY

## ESC Stockholm 2010