

11:20 V207 **Evidence – based indications for PCI vs. Bypass Surgery following recent trials in patients with stable CAD**
S. Silber (München)

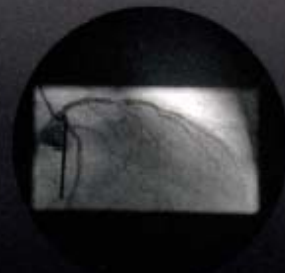
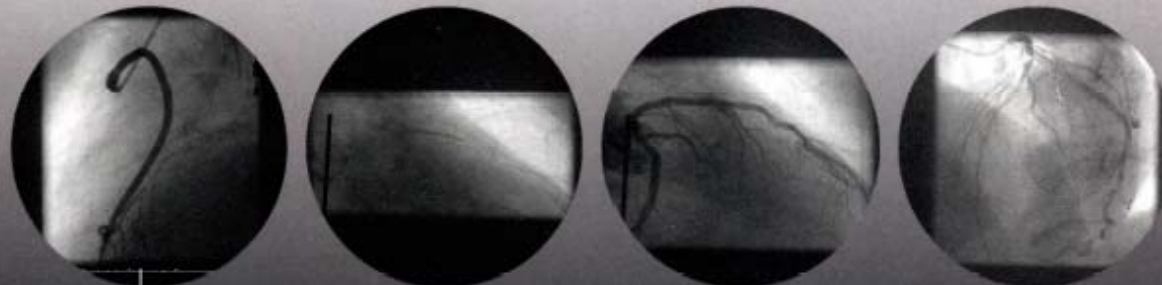


Praxis:
Tal 21

Prof. Dr. med. Sigmund Silber
Kardiologische Praxis und Praxisklinik
München

Herzzentrum München
an der Isar
Am Isarkanal 36

Entscheidung bei chronischer KHK

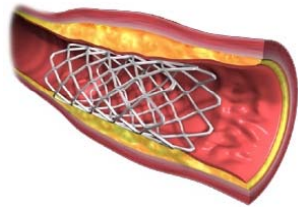


Stent oder Bypass?

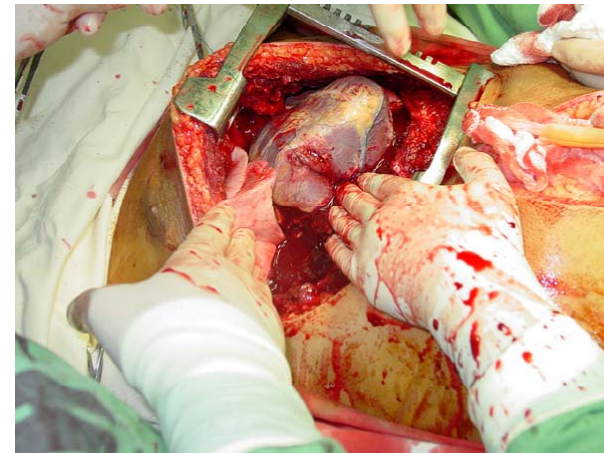
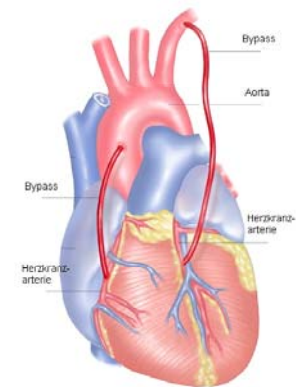
Eine interdisziplinäre Empfehlung

Stent oder Skalpell (SOS) ?

Koronarintervention (PCI)

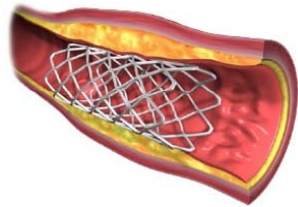


Bypass-OP

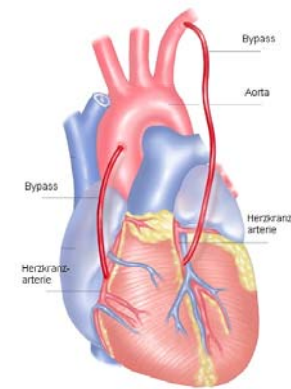


Stent oder Skalpell (SOS) ?

Koronarintervention (PCI)

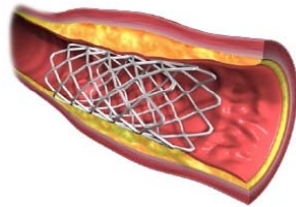


Bypass-OP

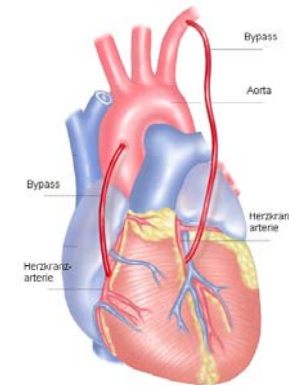


Stent oder Skalpell (SOS) ?

Koronarintervention (PCI)



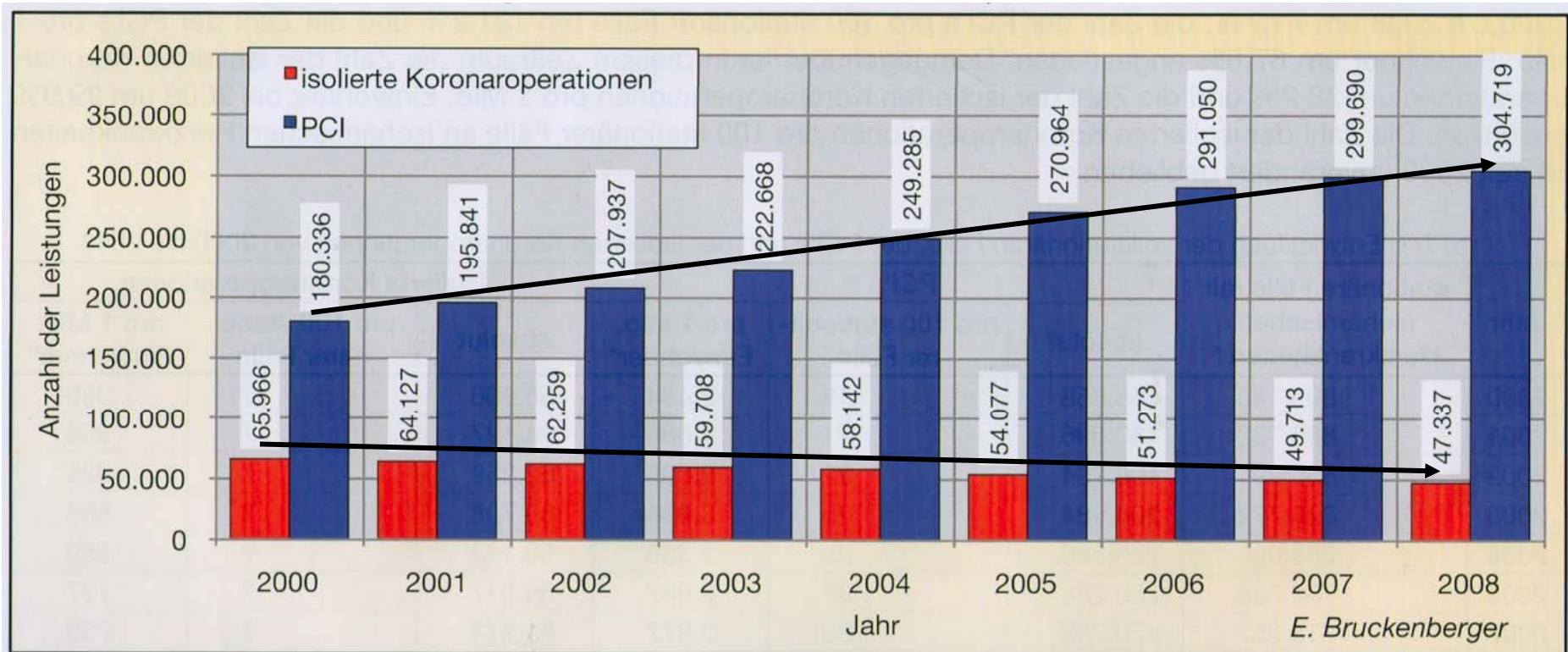
Bypass-OP



Herzoperation...

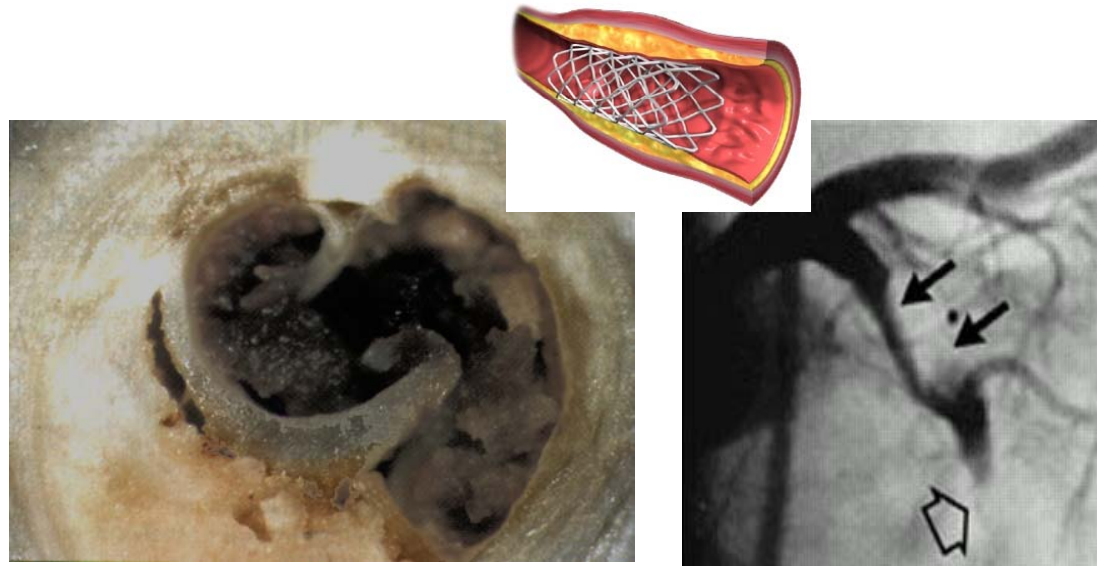


PCI vs. isolierte Bypass-OP in Deutschland

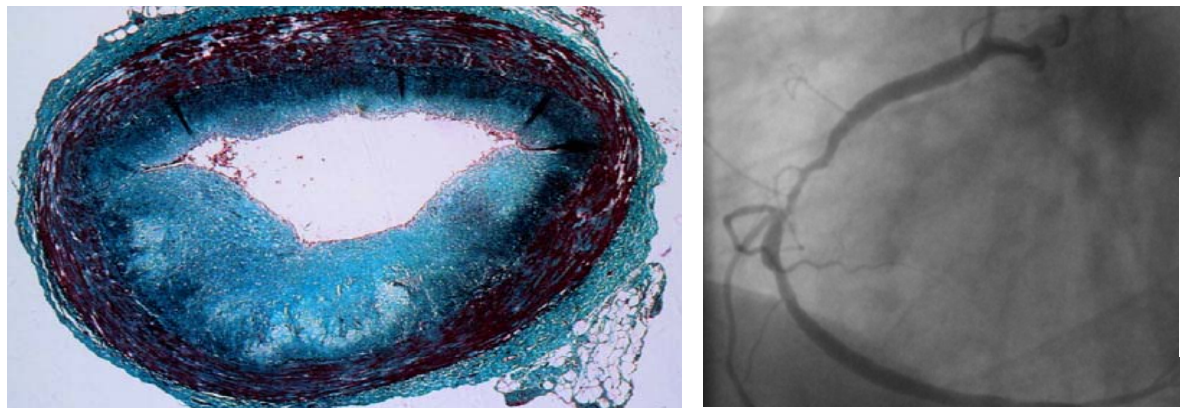


Entscheidungen bei stenosierender KHK:

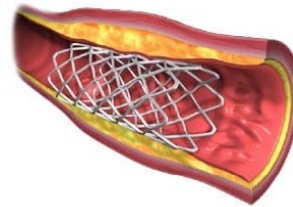
Akutes Koronarsyndrom



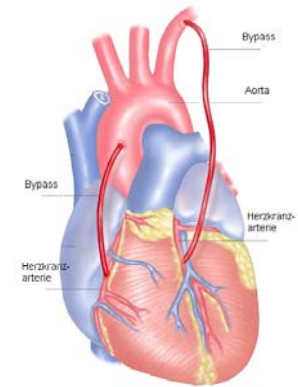
Stabile KHK



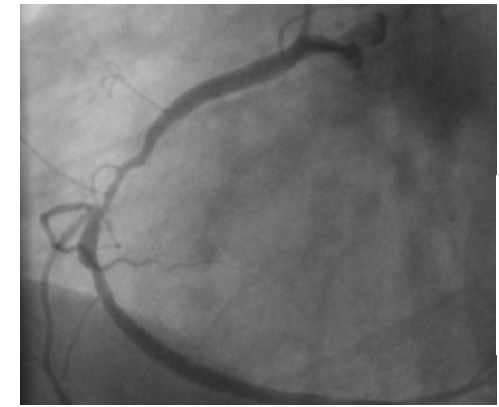
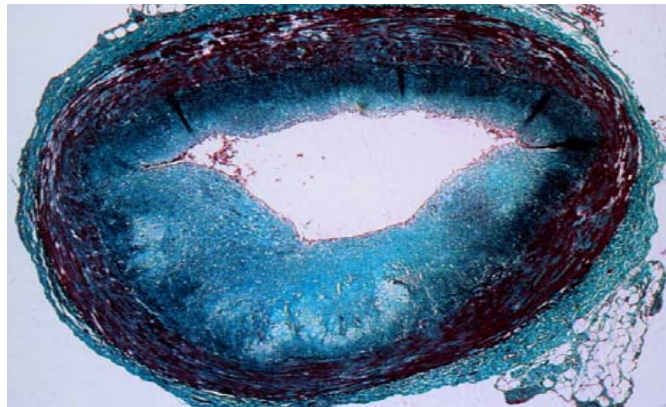
Entscheidungen bei stenosierender KHK:



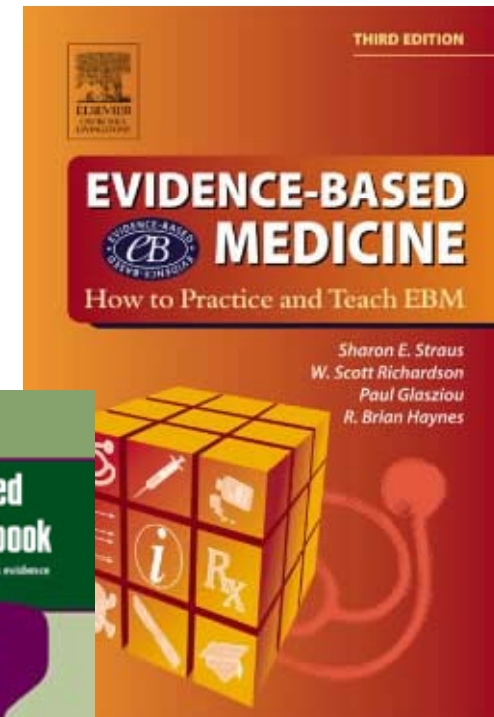
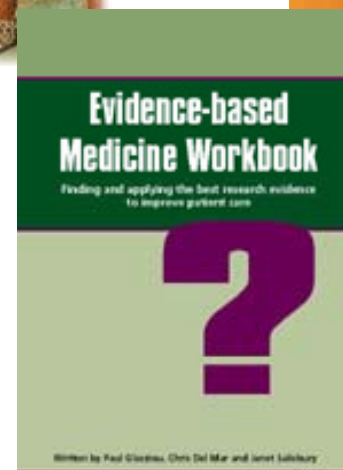
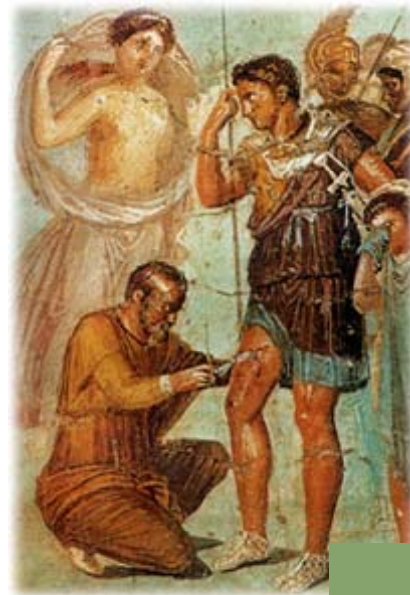
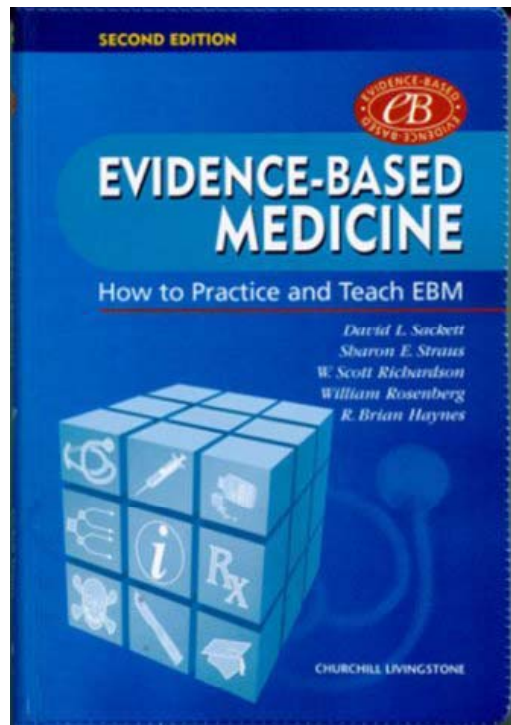
oder



Stabile KHK



EBM: Evidenz-basierte Medizin (nicht „Eminenz-basierte“ Medizin)



EBM: Evidenz-basierte Medizin

1. **Register:** prospektiv oder retrospektiv
2. **Randomisierte Studien:** immer prospektiv

EBM: Evidenz-basierte Medizin

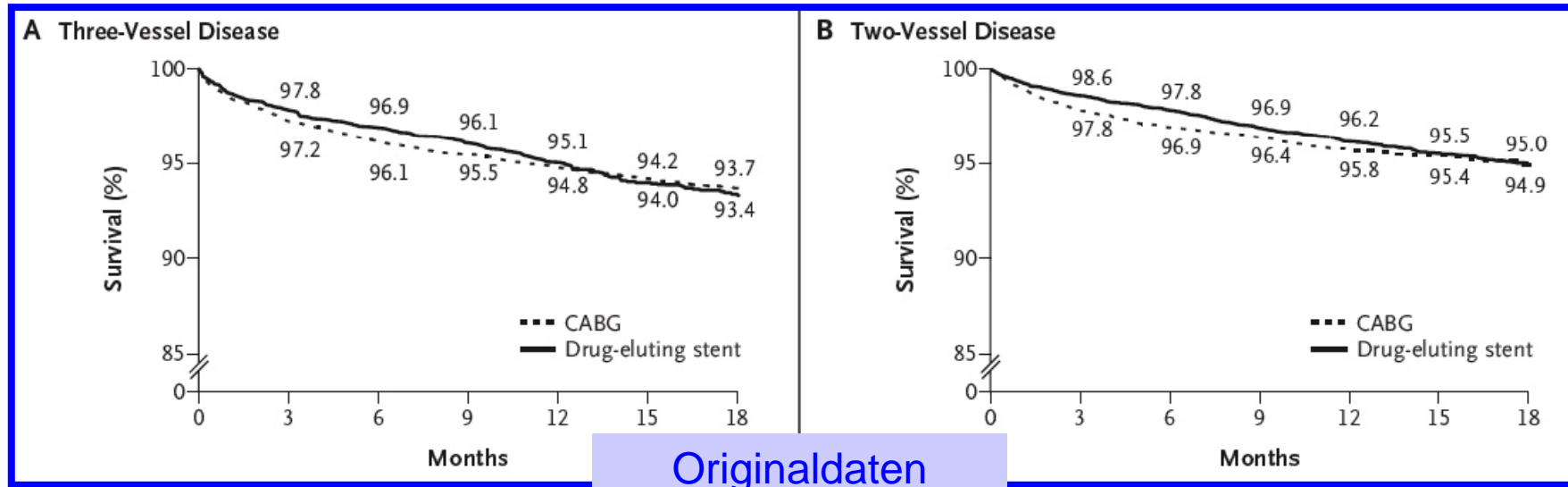
1. **Register:** prospektiv oder retrospektiv
2. **Randomisierte Studien:** immer prospektiv

Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease

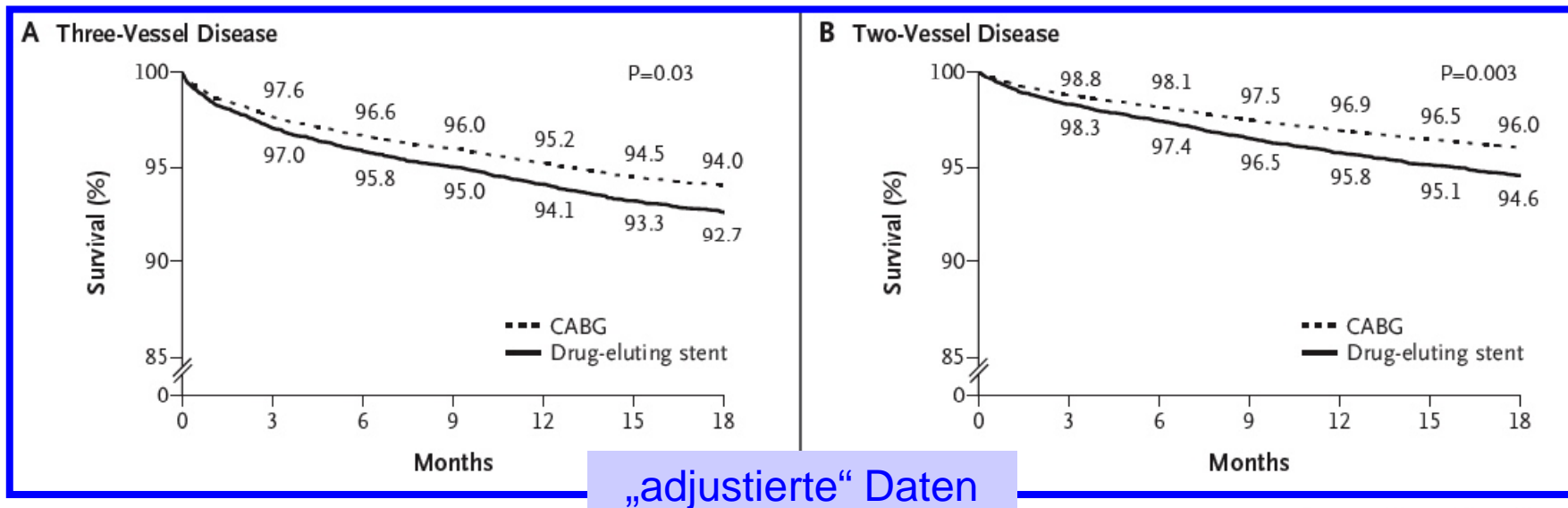
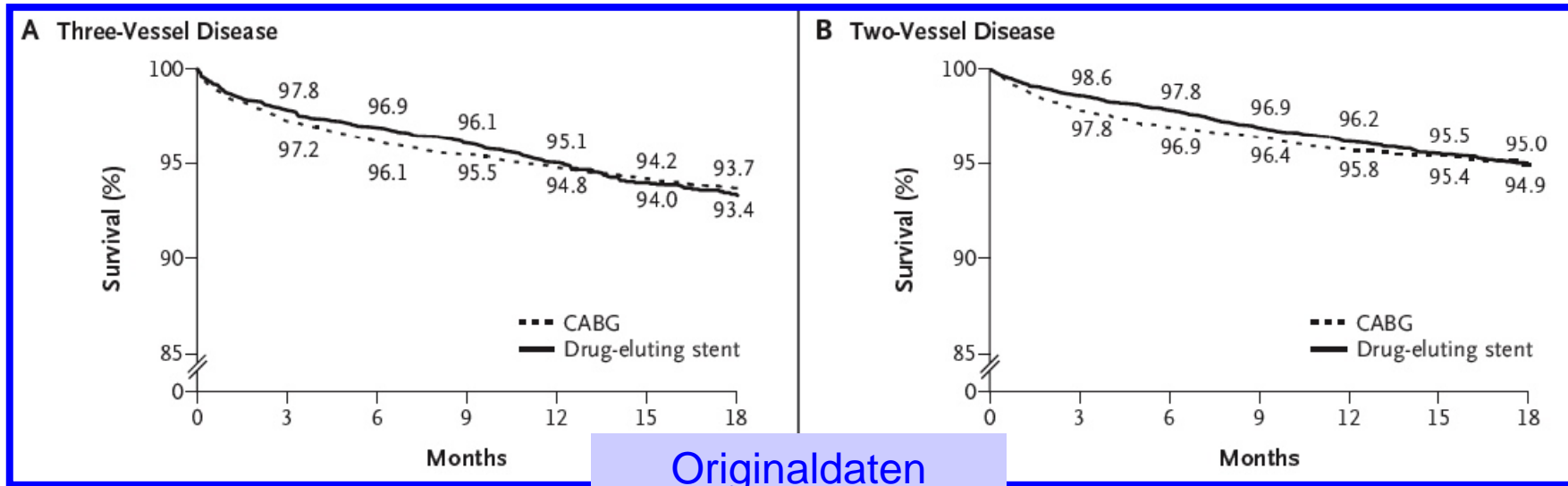
Risk Factor	CABG (N=7437)	Stent (N= 9963)	P Value
Cerebrovascular disease (%)	7.7	7.7	<0.001
Peripheral arterial disease (%)	10.7	7.0	<0.001
Hemodynamic instability or Congestive heart failure (%)	1.8	0.2	<0.001
None	84.3	89.9	<0.001
At current admission	12.6	7.4	
Before current admission	3.1	2.7	
Malignant ventricular arrhythmia (%)	0.7	0.4	0.03
Chronic obstructive pulmonary disease (%)	17.4	6.6	<0.001
Diabetes (%)	38.2	32.7	<0.001
Renal failure (%)			0.01
Requiring dialysis	2.2	2.4	
Creatinine >2.5 mg/dl (220 μmol/liter)	2.0	1.4	
No renal failure	95.8	96.3	
No. of diseased vessels (%)‡			<0.001
3, with proximal LAD artery	51.5	11.8	
3, without proximal LAD artery	18.4	13.1	
2, with proximal LAD artery	20.0	26.1	
2, without proximal LAD artery	10.1	49.0	

Wie soll man diese Ungleichheiten in den Ausgangswerten des Registers zuverlässig „adjustieren“ ?

Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease



Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease



Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease

Edward L. Hannan, Ph.D., Chuntao Wu, M.D., Ph.D., Gary Walford, M.D., Alfred T. Culliford, M.D., Jeffrey P. Gold, M.D.,
Craig R. Smith, M.D., Robert S.D. Higgins, M.D., Russell E. Carlson, M.D., and Robert H. Jones, M.D.

CONCLUSIONS

For patients with multivessel disease, CABG continues to be associated with lower mortality rates than does treatment with drug-eluting stents and is also associated with lower rates of death or myocardial infarction and repeat revascularization.

Drug-Eluting Stents vs. Coronary-Artery Bypass Grafting in Multivessel Coronary Disease

Edward L. Hannan, Ph.D., Chuntao Wu, M.D., Ph.D., Gary Walford, M.D., Alfred T. Culliford, M.D., Jeffrey P. Gold, M.D.,
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CONCLUSIONS

For patients with multivessel disease, CABG is associated with lower mortality rates than does treatment with DES. CABG is also associated with lower rates of death from revascularization.

nicht randomisiert!
Gruppen nicht vergleichbar!
künstliche „Adjustierung“ erforderlich

Wenn Du's nicht weisst...
randomisiere !



EBM: Evidenz-basierte Medizin

1. **Register:** prospektiv oder retrospektiv

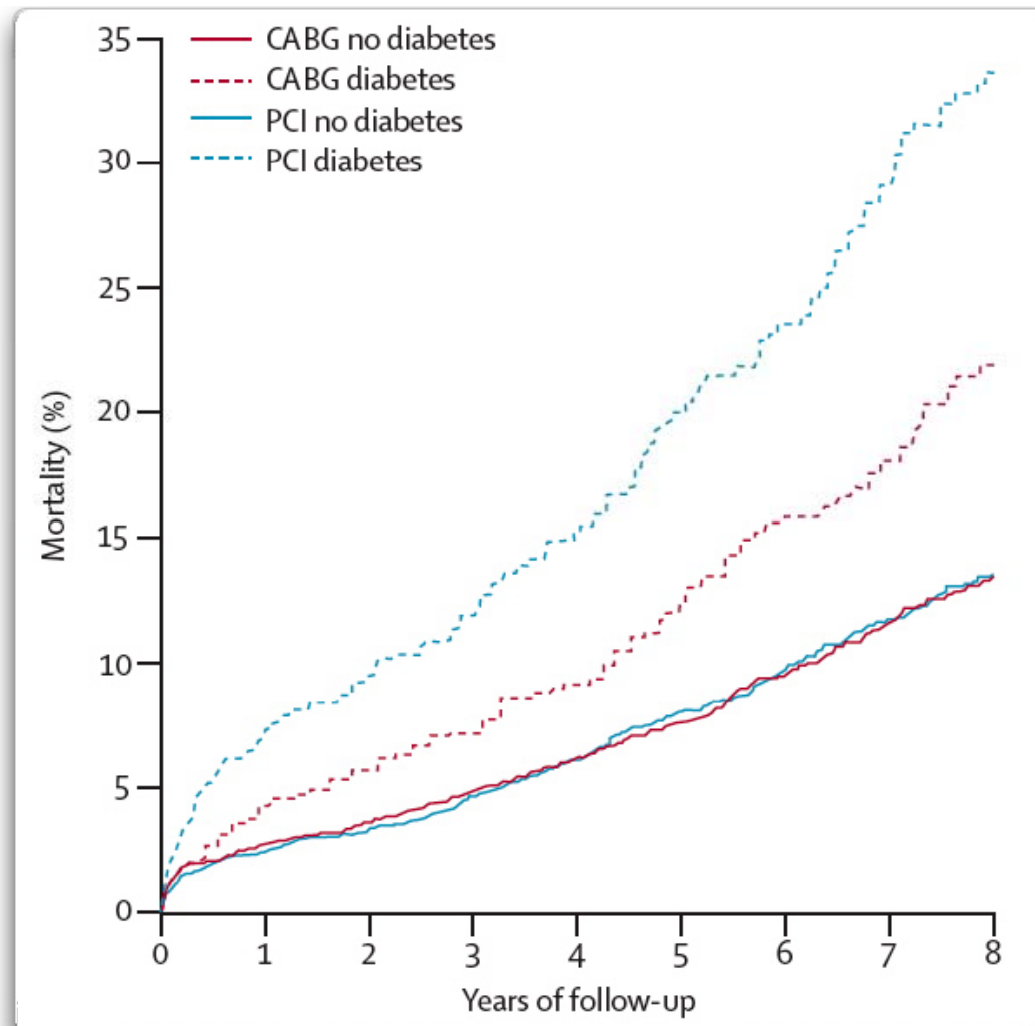
2. **Randomisierte Studien:** immer prospektiv

- Vorteil: keine Adjustierung erforderlich
- aber unbekannte „Störgrößen“ werden trotzdem nicht erfasst

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

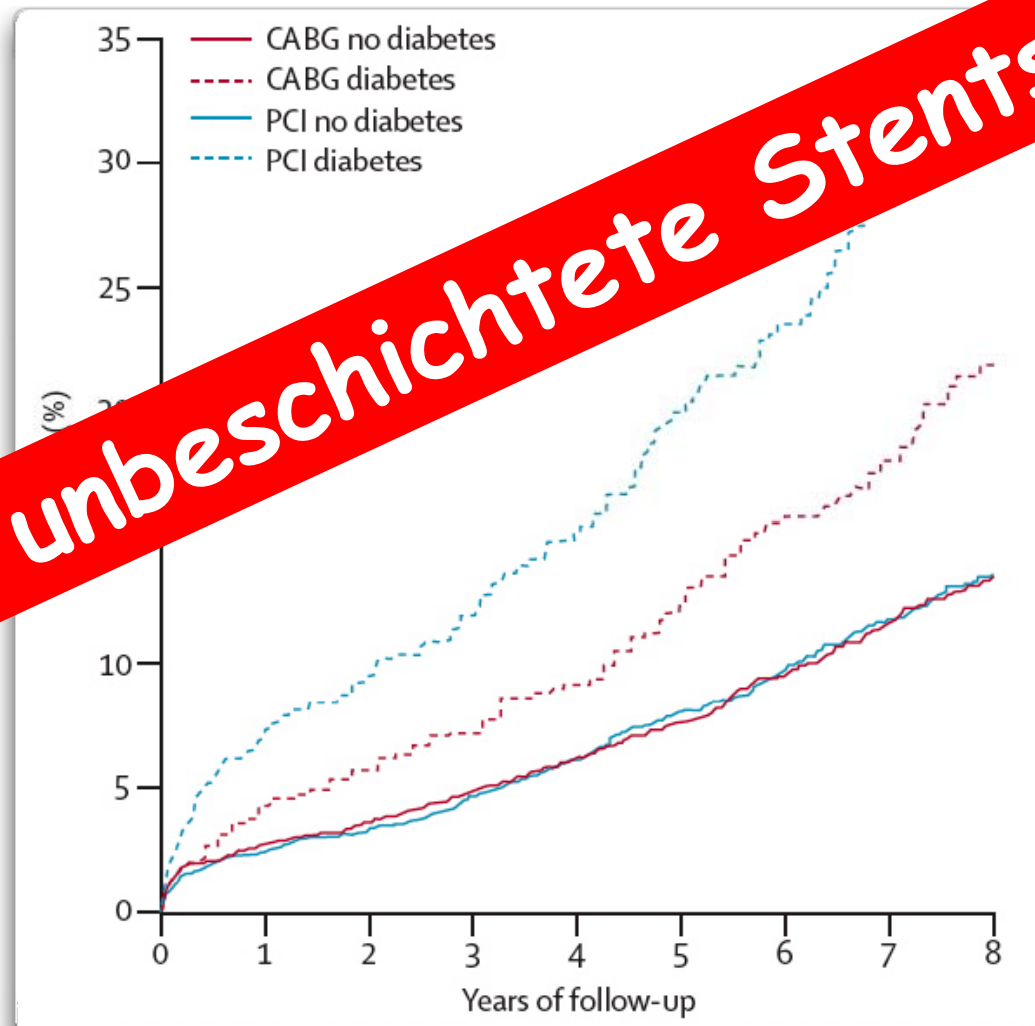
Mark A Hlatky, Derek B Boothroyd, Dena M Bravata, Eric Boersma, Jean Booth, Maria M Brooks, Didier Carrié, Tim C Clayton, Nicolas Danchin, Marcus Flather, Christian W Hamm, Whady A Hueb, Jan Kähler, Sheryl F Kelsey, Spencer B King, Andrzej S Kosinski, Neuza Lopes, Kathryn M McDonald, Alfredo Rodriguez,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



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

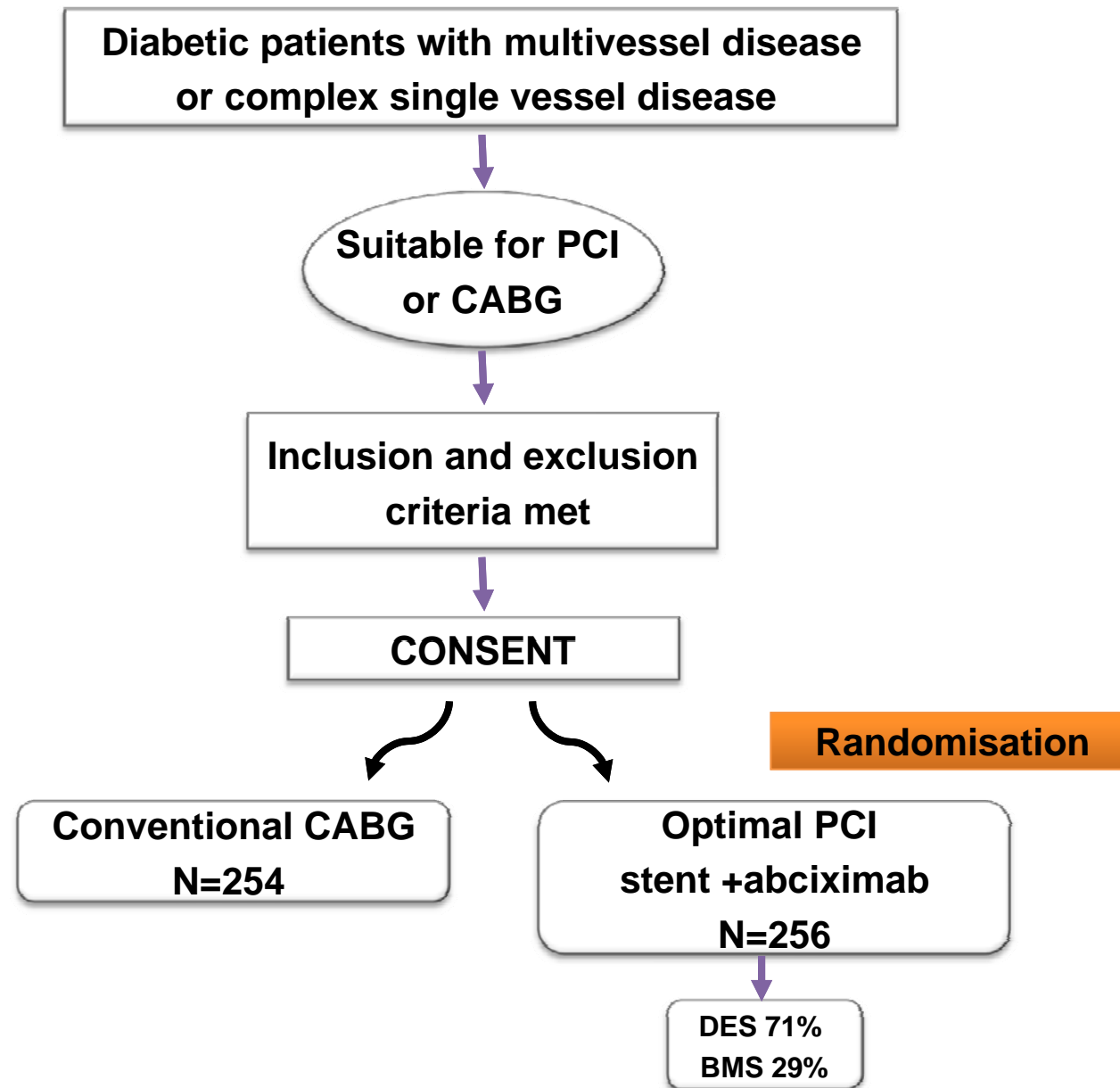
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nur unbeschichtete Stents !

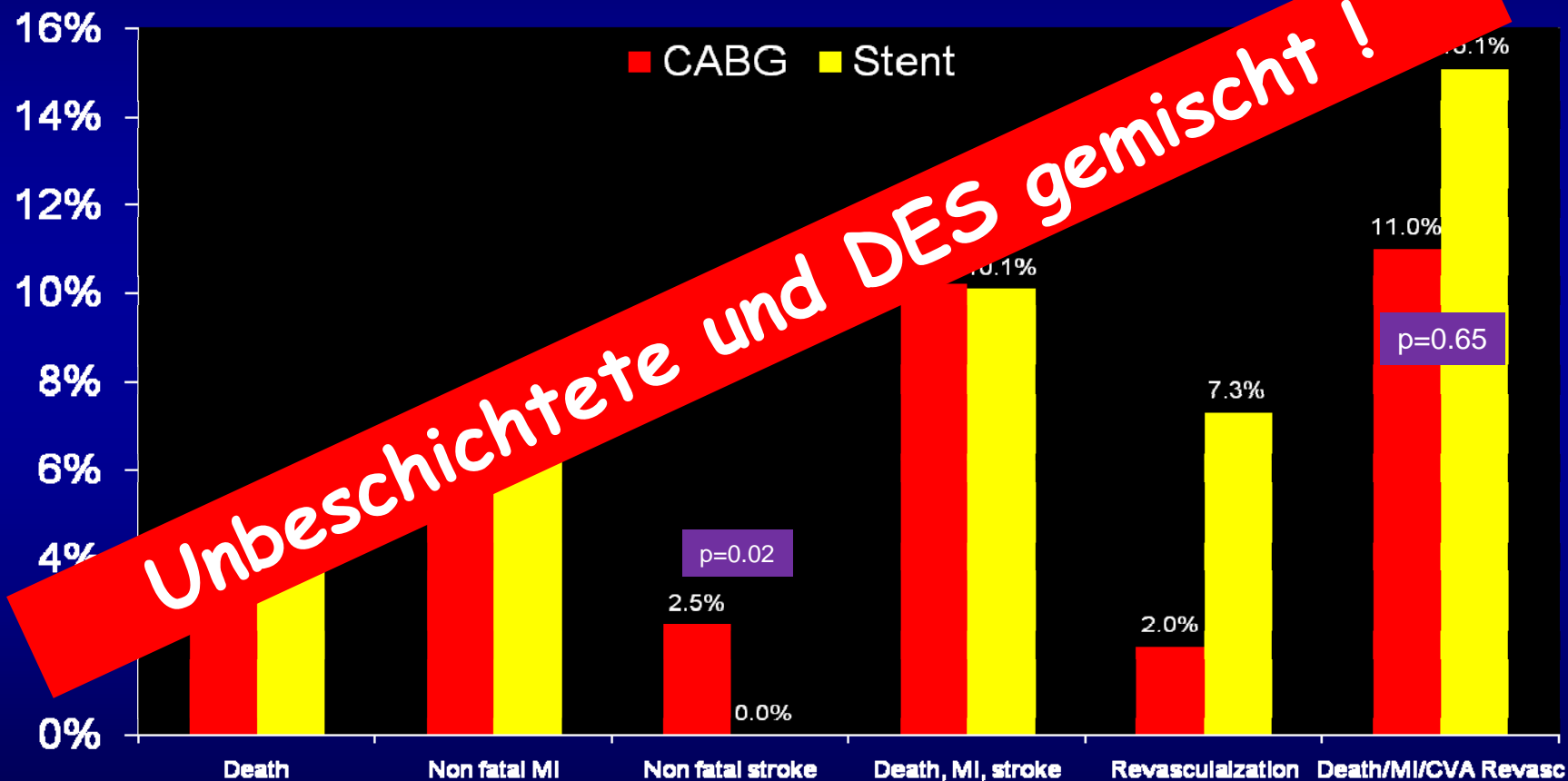
CARDIA – randomisierte Studie



CARDIA

(Coronary Artery Revascularization Diabetes Trial)

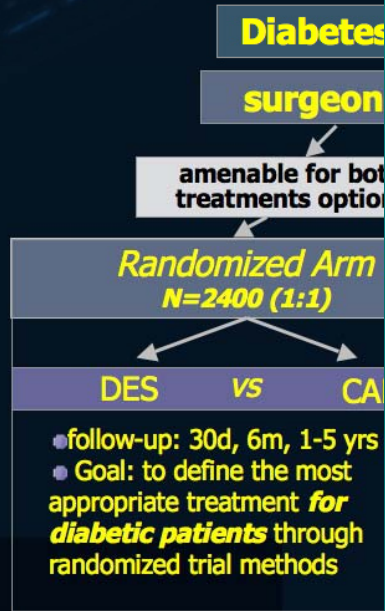
- 510 diabetic pts randomized to CABG vs PCI (71% DES)



DES oder Bypassoperation ?

insbes. bei Diabetes mellitus,
Mehrfässerkrankung / ungeschützter Hauptstammstenose

FREEDOM: Study Design



COMBAT Randomized Trial

COMparison of Bypass surgery and Angioplasty Using Sirolimus Eluting Stent in Patients with Left Main Coronary Disease

Left Main disease

Randomize 1

PCI with Cypher

PRIMARY Endpoint
SECONDARY Endpoints:

PI: Seung
75 centers from

SYNTAX Randomized Trial



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



www.escardio.org

MUNICH ESC Congress 2008

30 August
3 September



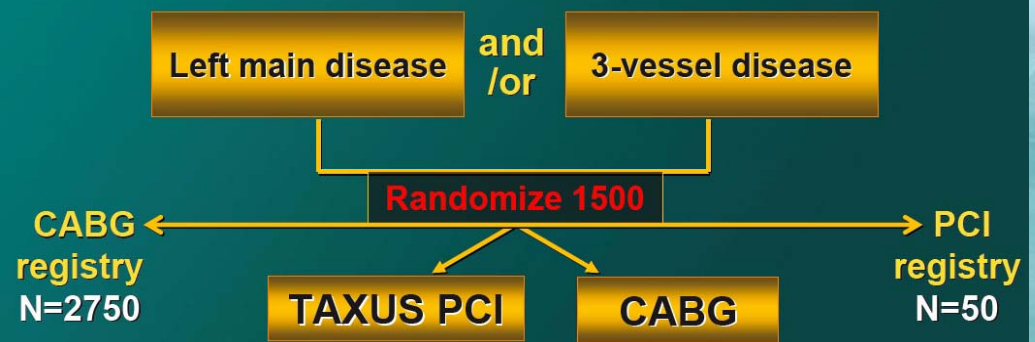
www.escardio.org

IMPORTANT DATES
Abstract submission
deadline - 14 February 2008
Early fee registration
deadline - 31 May 2008

SYNTAX Randomized Trial



De novo disease acceptable for revascularization
N=3300



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



De novo disease

Limited Exclusion Criteria

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

Left Main Disease

(isolated, +1, +2 or +3 vessels)

3 Vessel Disease

(revasc all 3 vascular territories)

SYNTAX Primary Endpoint

Randomized trial



*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

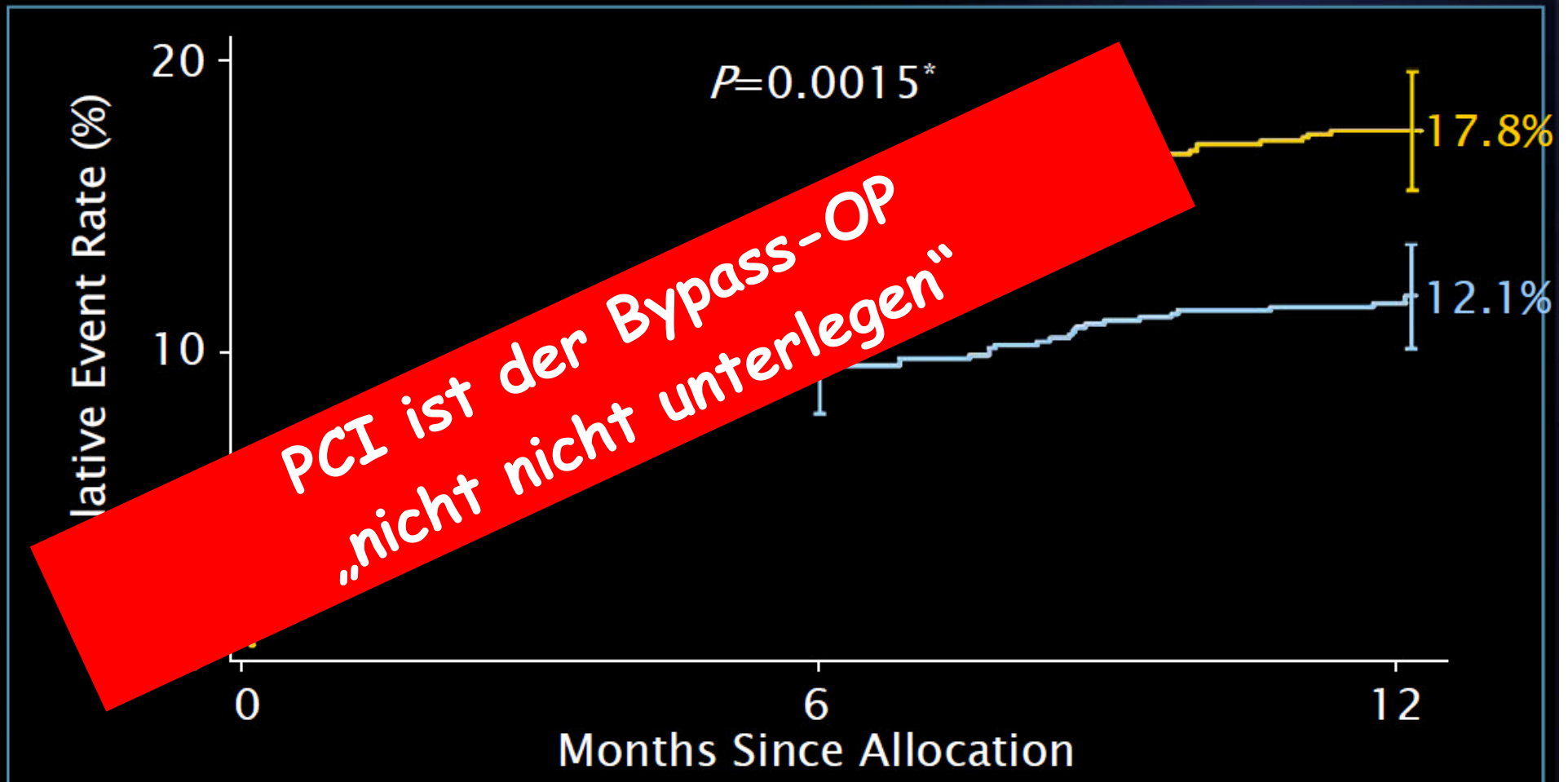
*ARC MACCE definition Circ 2007; 115:2344-2351

MACCE to 12 Months



■ CABG (N=897)

■ TAXUS (N=903)



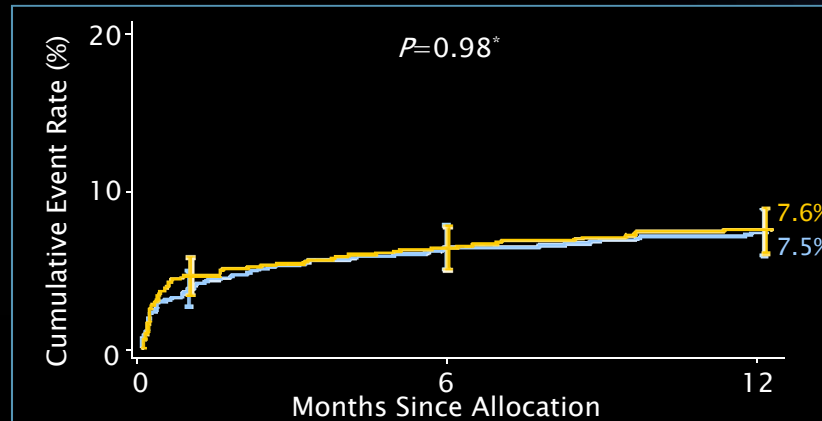
Event Rate \pm 1.5 SE. *Fisher's Exact Test

ITT population

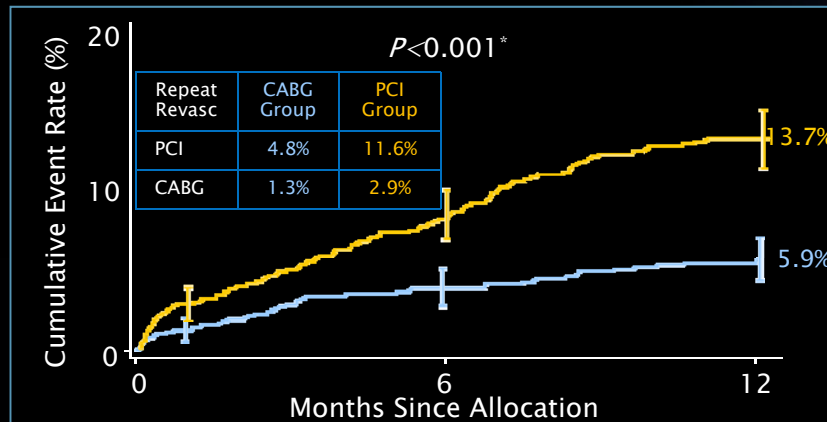
Summary of 1-Year Results



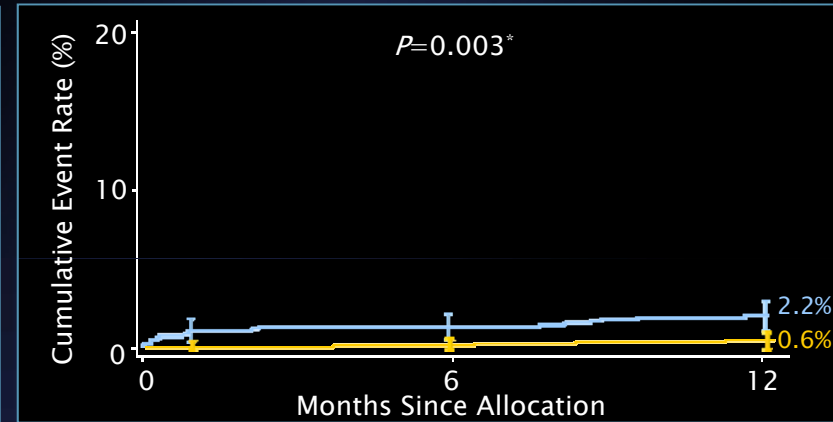
Death/Stroke/MI



Repeat Revasc.



Stroke



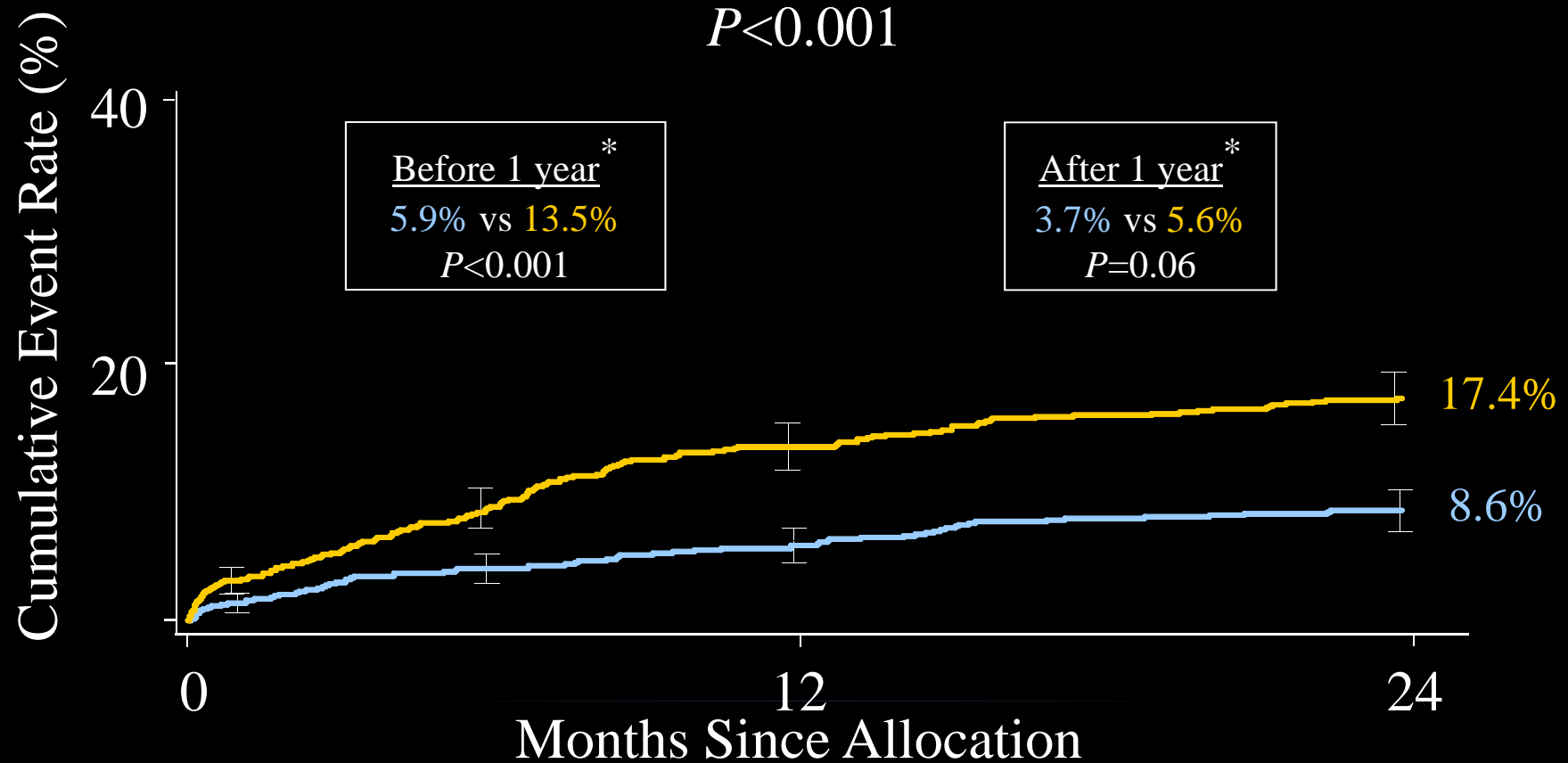
■ CABG (N=897) ■ PCI (N=903)

Repeat Revascularization to 2 Years



■ CABG (N=897)

■ TAXUS (N=903)

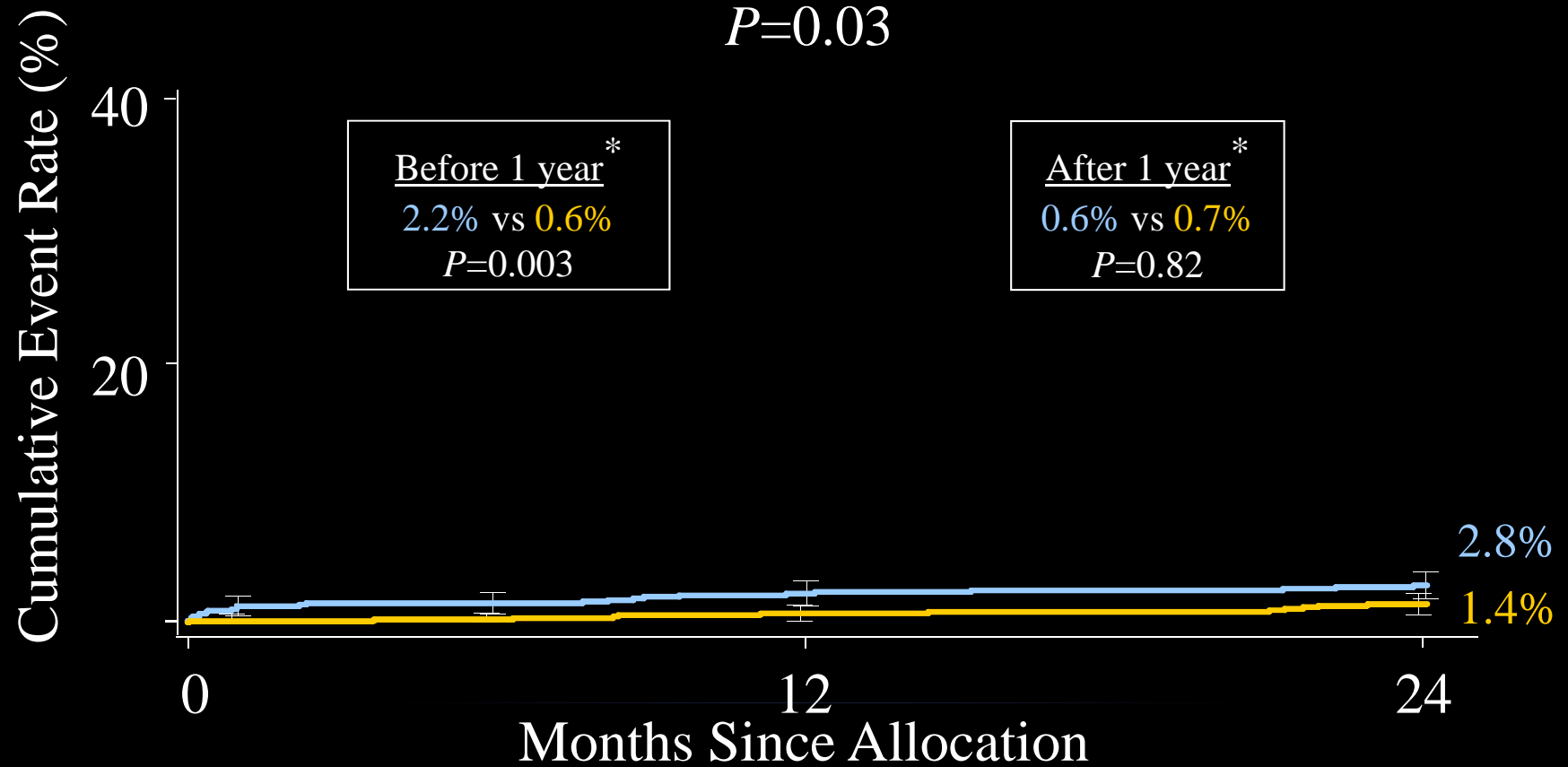


Stroke to 2 Years



■ CABG (N=897)

■ TAXUS (N=903)

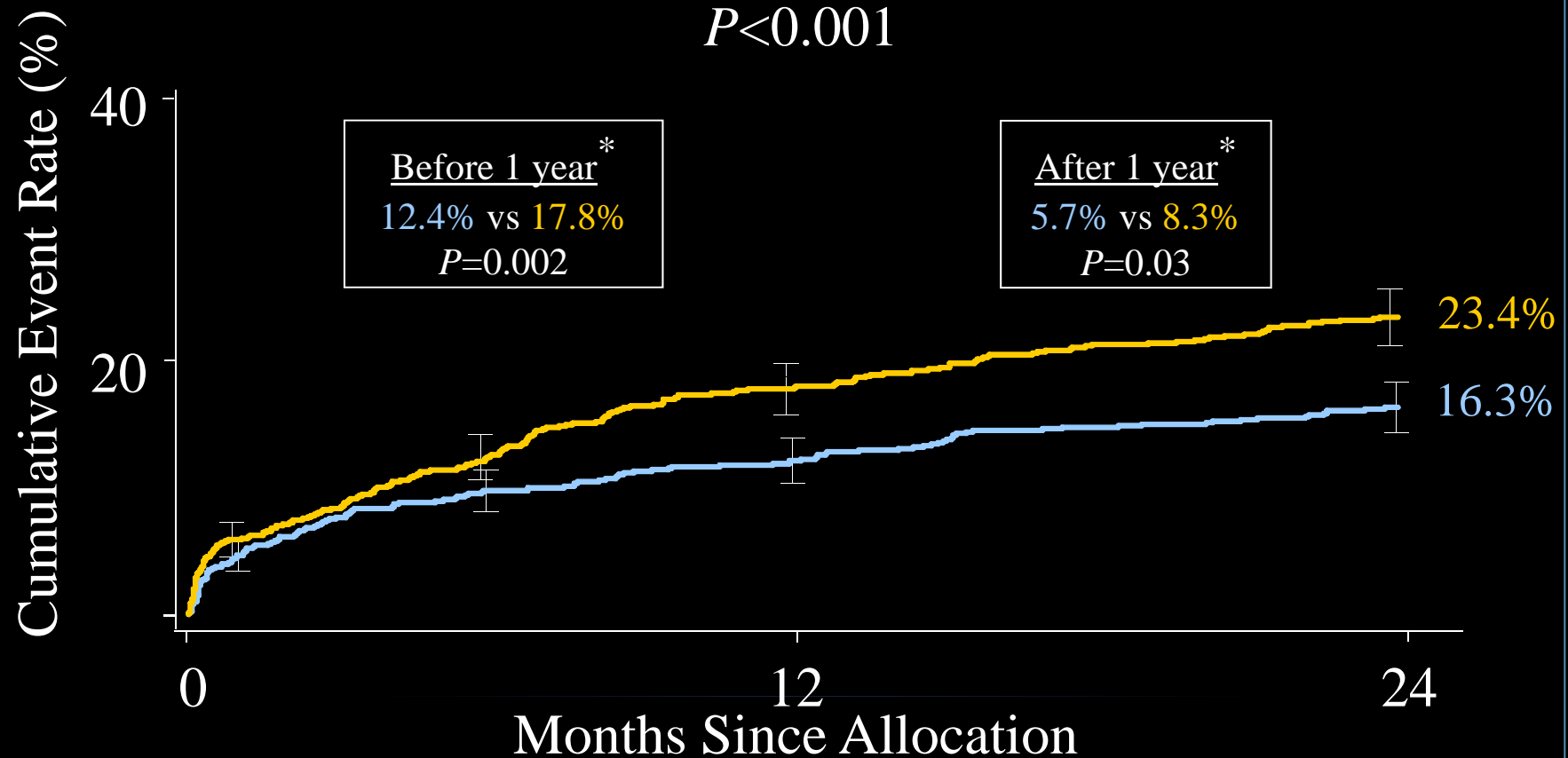


MACCE to 2 Years (primary endpoint)



■ CABG (N=897)

■ TAXUS (N=903)

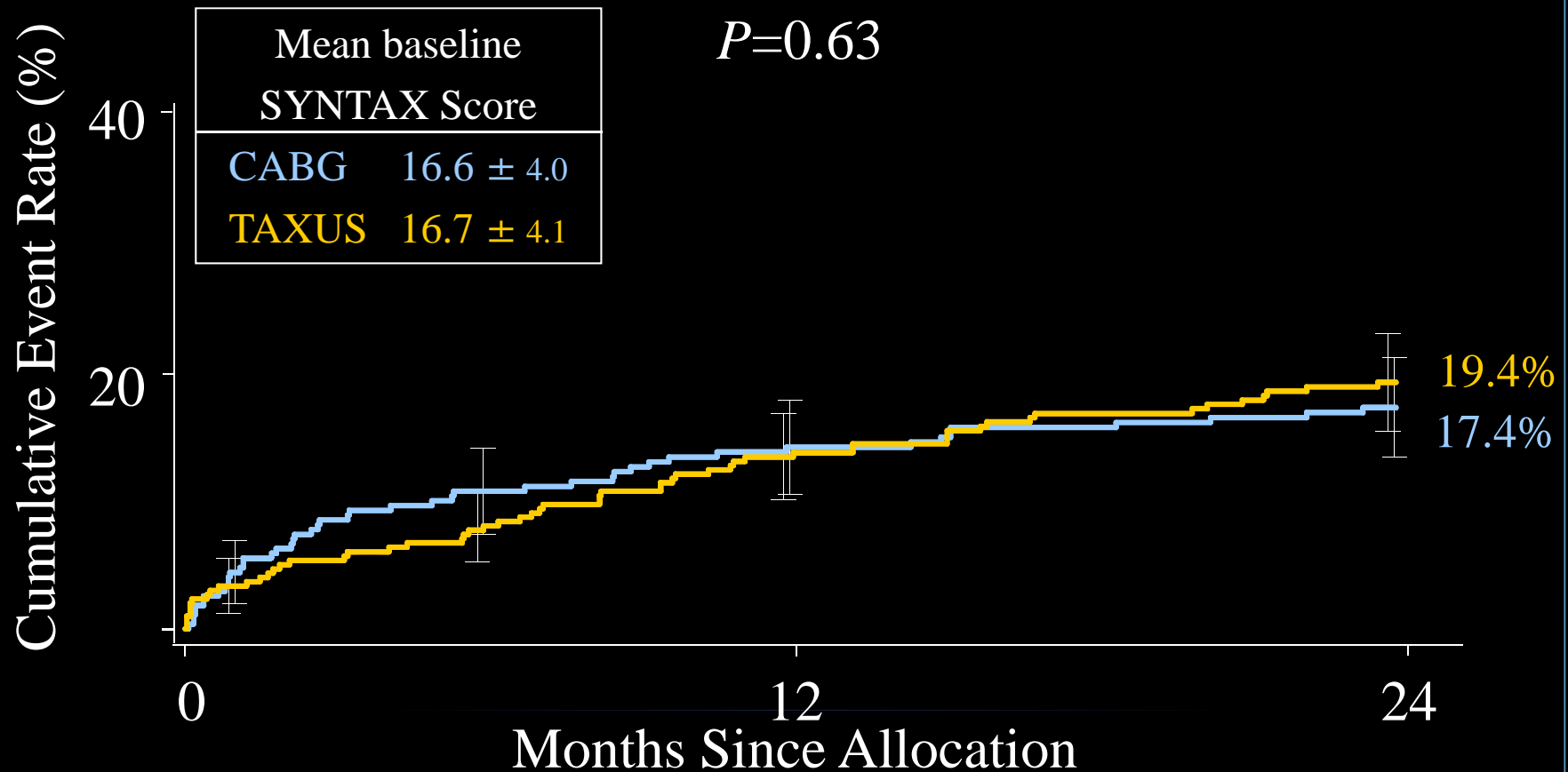


MACCE to 2 Years by SYNTAX Score Tercile Low Scores (0-22)



■ CABG (N=275)

■ TAXUS (N=299)

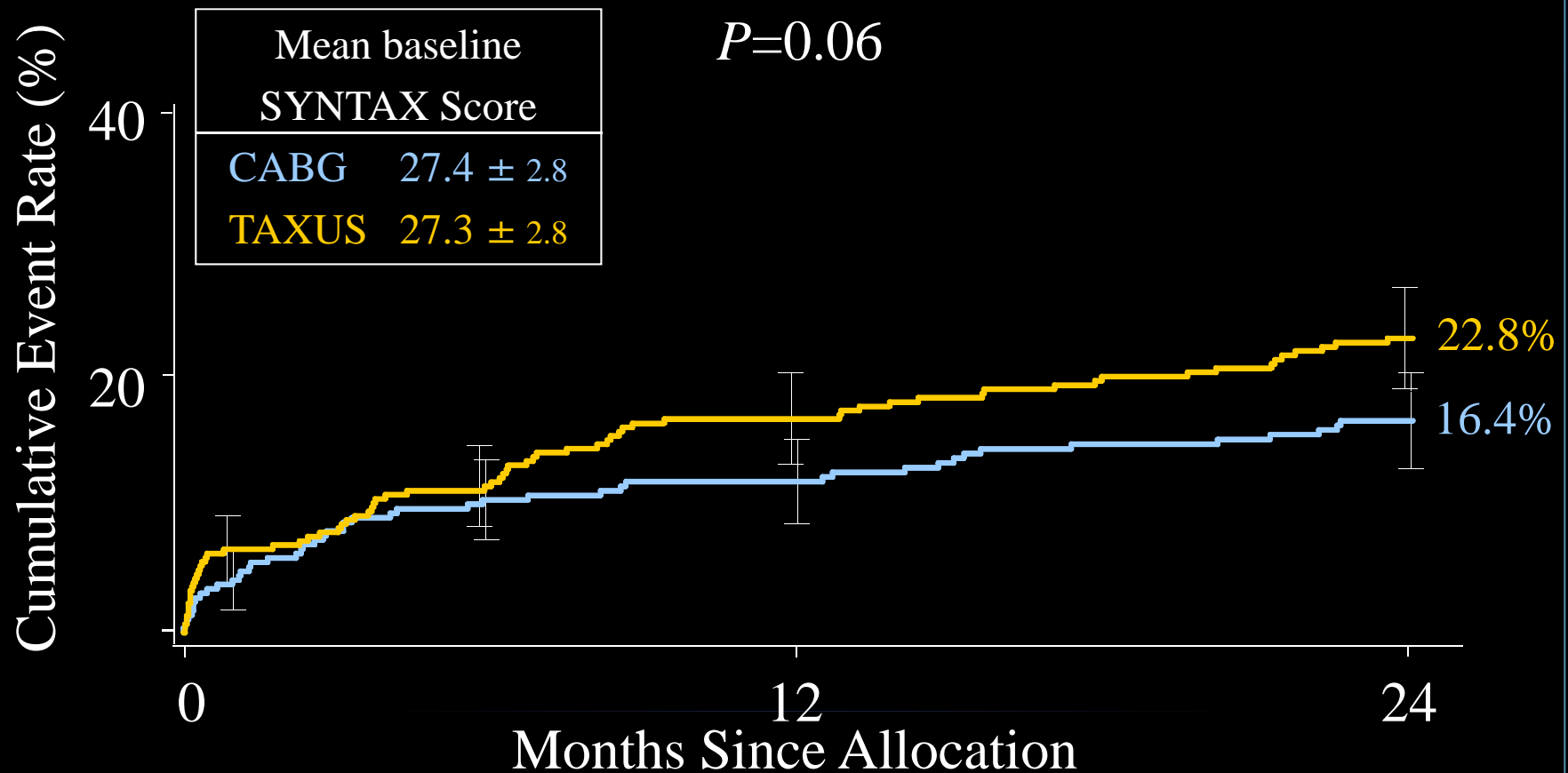


MACCE to 2 Years by SYNTAX Score Tercile *Intermediate Scores (23–32)*



■ CABG (N=300)

■ TAXUS (N=310)

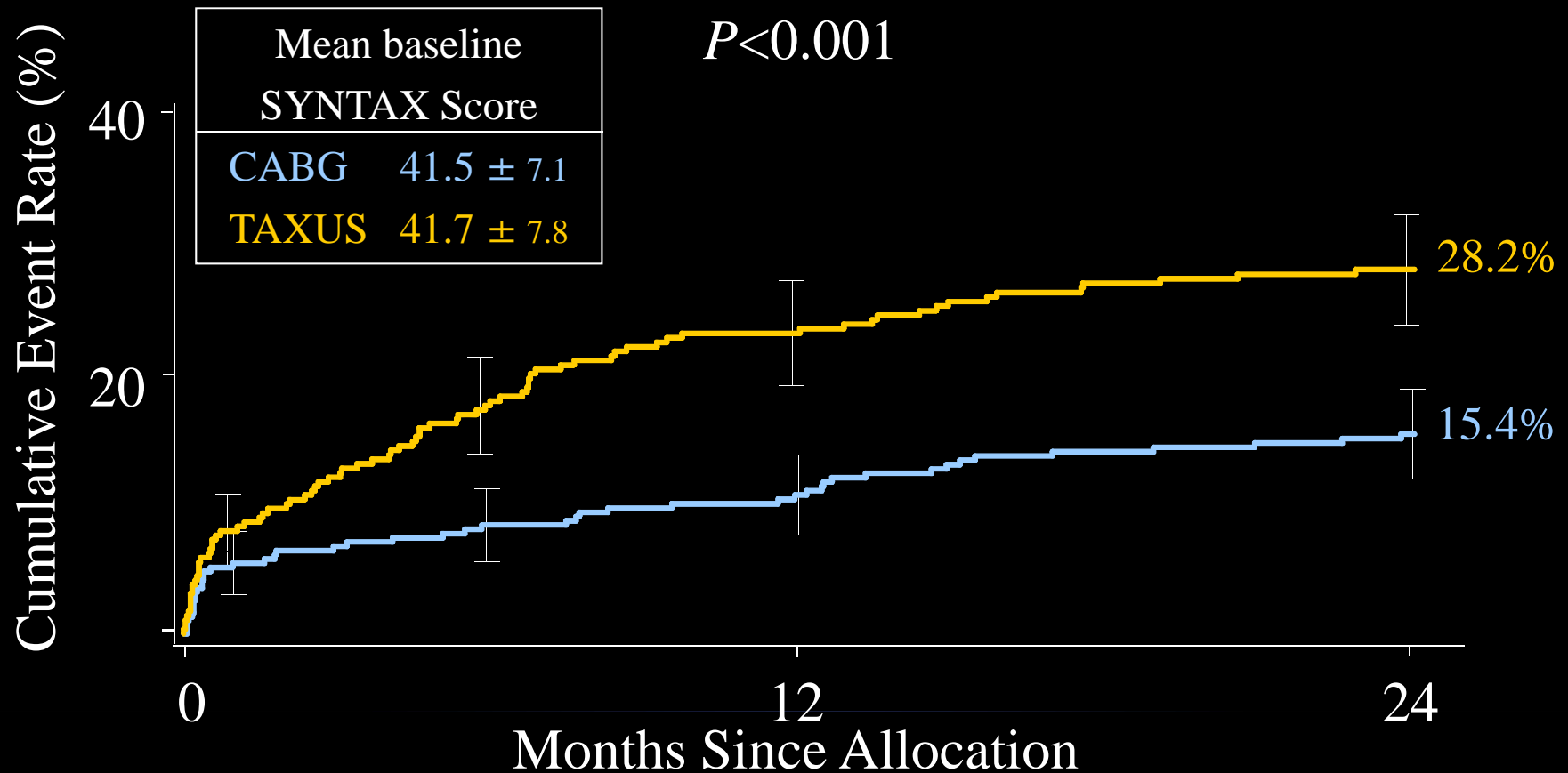


MACCE to 2 Years by SYNTAX Score Tercile *High Scores (≥ 33)*



■ CABG (N=315)

■ TAXUS (N=290)



Diabetes

*Non
Diabetic*

*Oral
Meds*

Insulin

Syntax Score

33-

Bypass

Bypass

Bypass

23-32

DES
oder
Bypass

DES
oder
Bypass

Bypass

0-22

DES
oder
Bypass

DES
oder
Bypass

Bypass

www.syntaxscore.com

Home Tutorial Calculator References Contact

SYNTAX SCORE

Search...



9 **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.

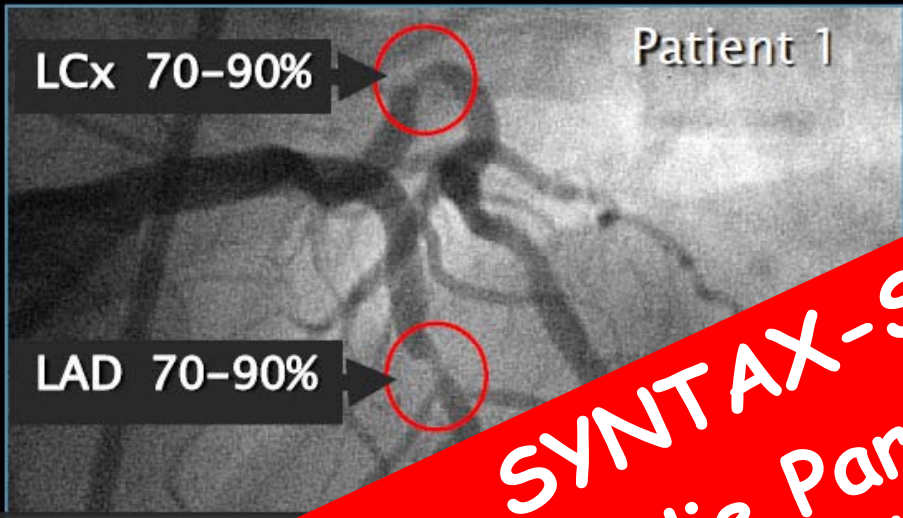


[Start calculator...](#)

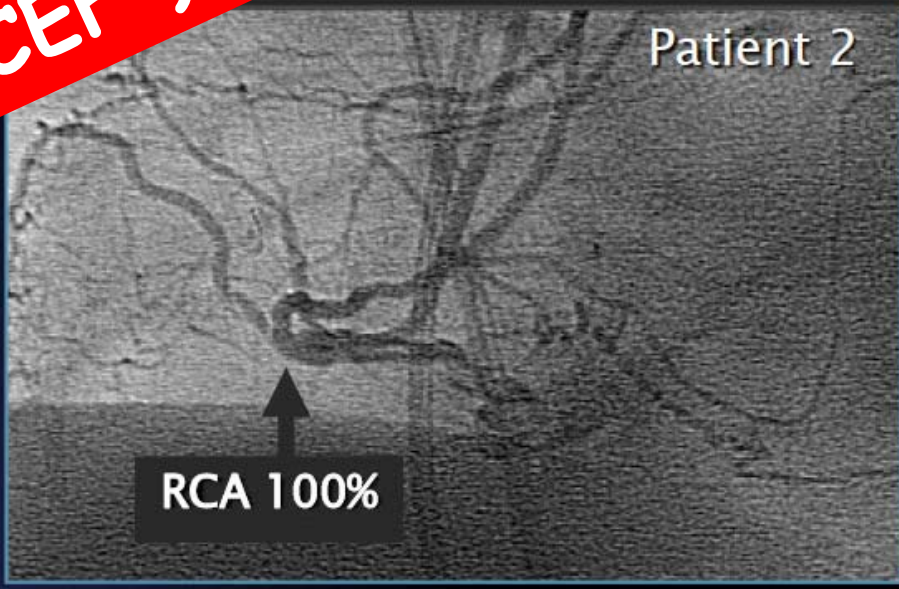
Introducing the SYNTAX Score at EuroPCR 2009

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

SYNTAX



SYNTAX SCORE 52



SYNTAX-Score:
Wird um die Parameter Alter,
Nierenfunktion und LV-EF erweitert.
(„ACEF“)

EXCEL Clinical Trial:

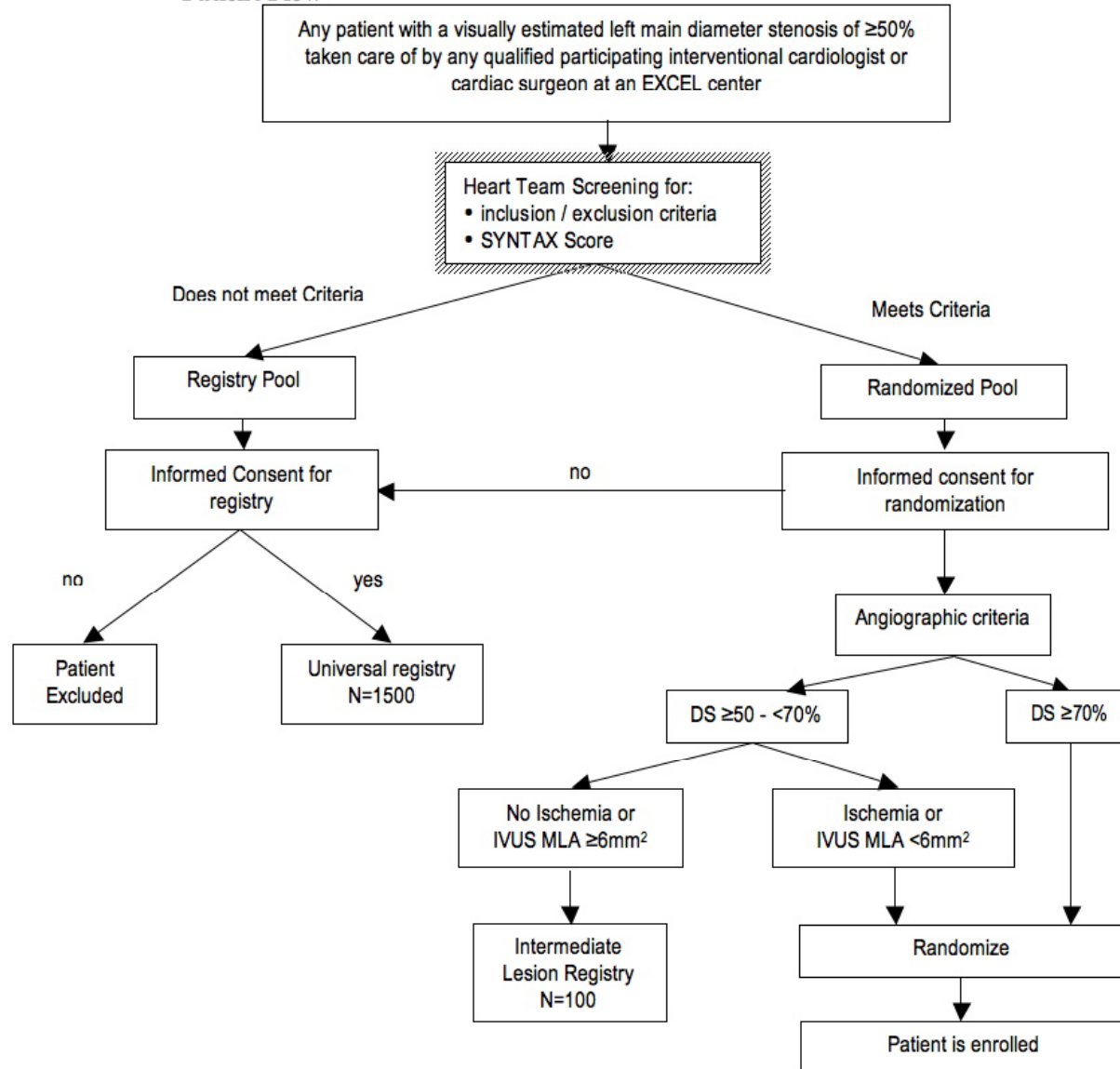
Evaluation of XIENCE PRIME™ versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization

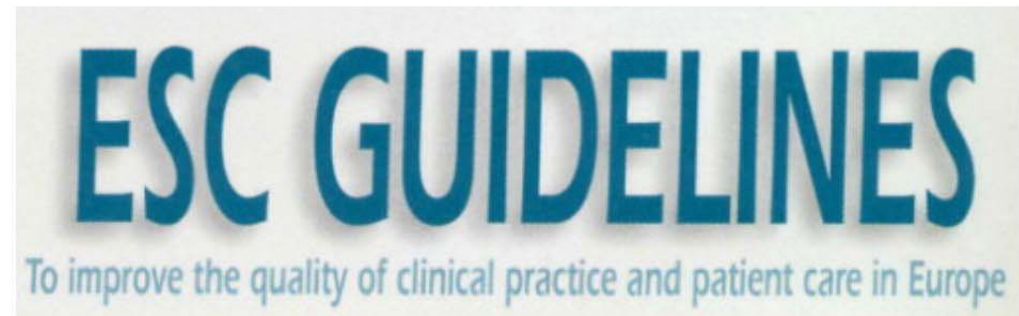
Principal Investigators	<p>Gregg W. Stone, MD Columbia University Medical Center New York, NY, USA</p> <p>Patrick W. Serruys, MD Erasmus Medical Center Rotterdam, The Netherlands</p> <p>Joseph Sabik, MD Cleveland Clinic Main Campus Cleveland, OH, USA</p> <p>A. Pieter Kappetein, MD Erasmus Medical Center Rotterdam, The Netherlands</p>
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EXCEL Clinical Trial:

Evaluation of XIENCE PRIME™ versus Coronary Artery Bypass Surgery for Effectiveness of Left Main Revascularization

Patient Flow





Guidelines for Percutaneous Coronary Interventions

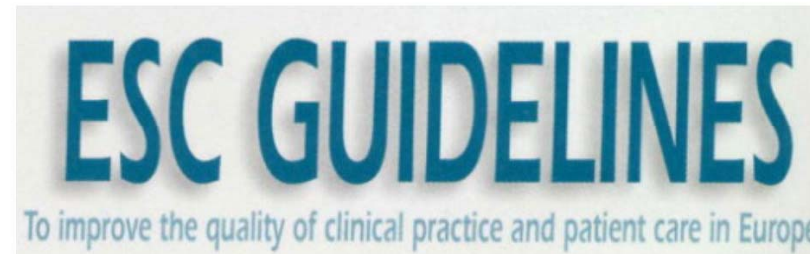
The Task Force for Percutaneous Coronary Interventions
of the European Society of Cardiology

Author and Task Force Members: Sigmund Silber, Chairperson* (Germany),
Anders Ahren (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)

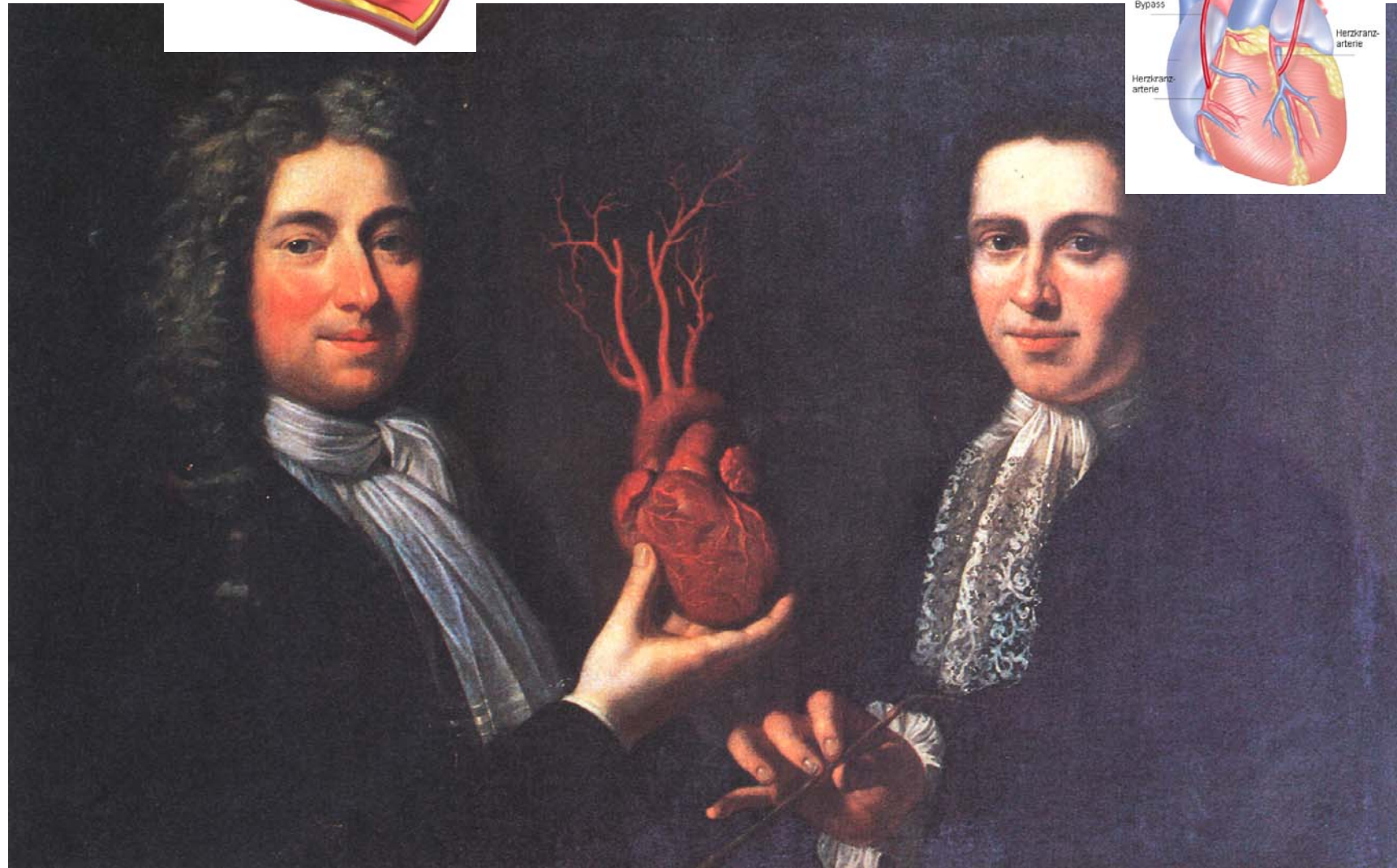
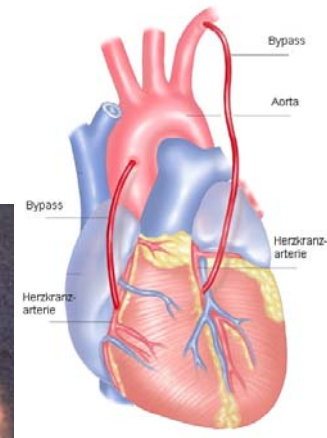
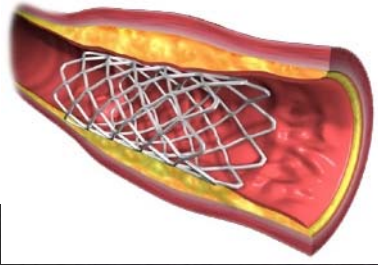
Wann kommt das Update ?



Neue Leitlinien zur koronaren Revaskularisation



ESC Stockholm
Ende August - 2010



Jurr Pool: Die Anatomieprofessoren C. Boekelmann und Jan Six, 1699

