Selection for Revascularization in Stable Ischemic Heart Disease

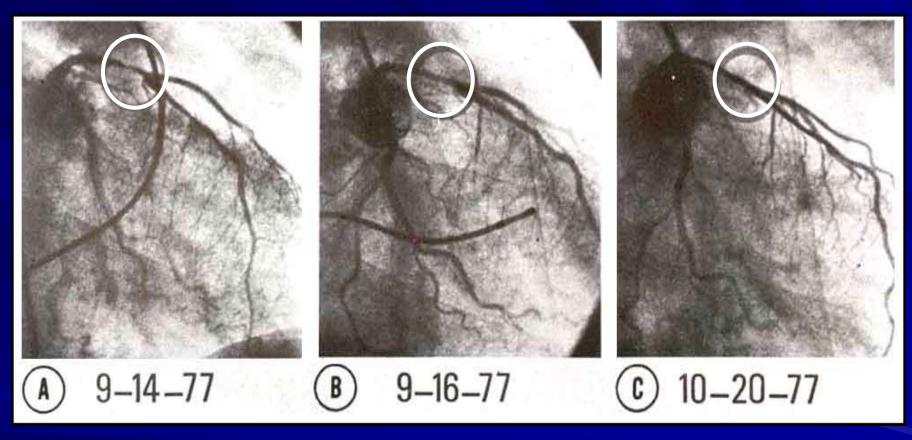
Spencer King MD MACC FESC

Professor of Medicine, Emeritus Emory University School of Medicine Editor, JACC: Cardiovascular Interventions

(No COI)

Does PCI relieve angina?

The First Coronary Angioplasty for Stable CAD; 1977



First coronary angioplasty lesion (circles) two days before (A),

immediately after (B), and one month after (C) balloon dilation



Spencer B. King III, MD (left) and Bernhard Meier, MD; (right) shared their memories of Andreas Gruentzig, MD, who performed the first angioplasty on Dolf Bachmann (center).

Meta-Analysis of Randomized Trials of PTCA versus Medical Therapy in SIHD

End point	Risk ratio (95% CI)
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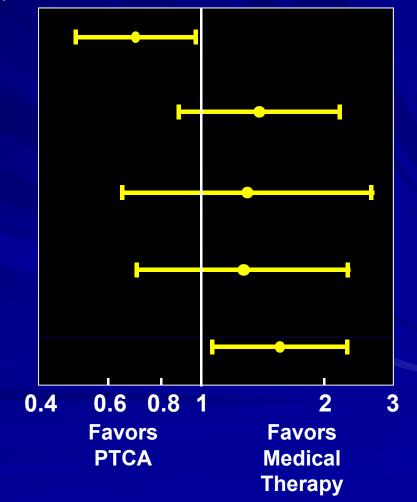
Angina* 0.70 (0.50 – 0.98)

MI 1.42 (0.90 - 2.25)

Death 1.32 (0.65 - 2.70)

PTCA* 1.29 (0.71 – 3.36)

CABG 1.59 (1.09 – 2.32)



*Test of heterogeneity P<0.001

Bucher HC et al. BMJ 2000; 321:73-77

Revascularization to Improve Symptoms



CABG or PCI to improve symptoms is beneficial in patients with 1 or more significant (≥70% diameter) coronary artery stenoses amenable to revascularization and unacceptable angina despite GDMT.



CABG or PCI to improve symptoms is reasonable in patients with 1 or more significant (≥70% diameter) coronary artery stenoses and unacceptable angina for whom GDMT cannot be implemented because of medication contraindications, adverse effects, or patient preferences.

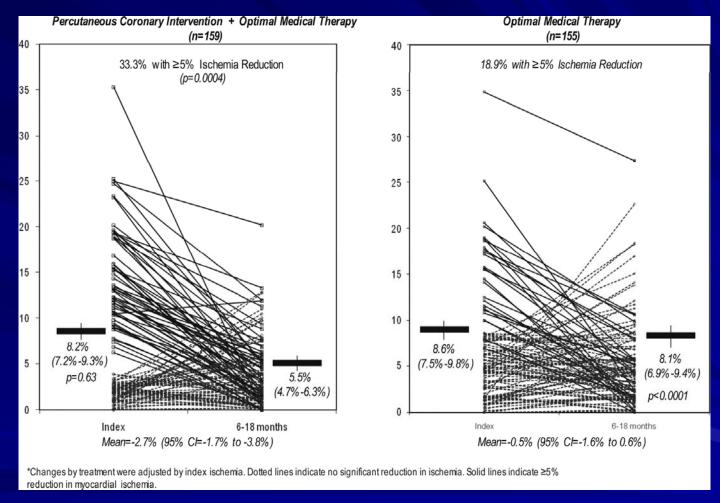
But, is an intervention needed to improve survival?

What is COURAGE?

It is not a comparison of PCI and medical therapy.

Instead, within a setting of good medical care, it compared routine PCI with deferred selective PCI for patients with progression of symptoms or ischemia

Comparison of inducible ischemia with MPS pretreatment and after 6 to 18 months of OMT with or without PCI

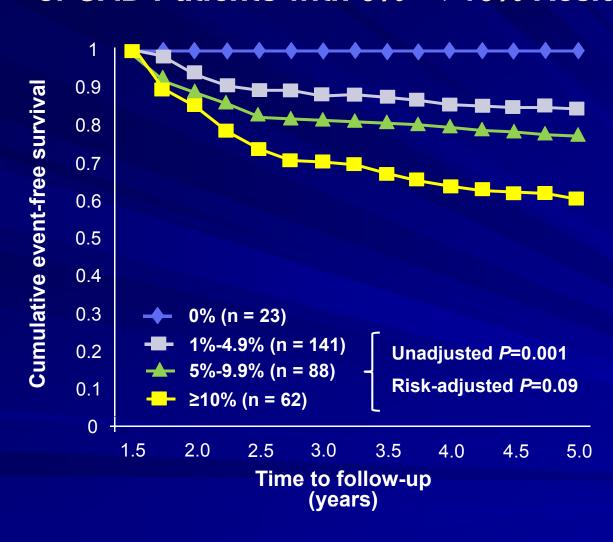


Shaw, L. J. et al. Circulation 2008;117:1283-1291





COURAGE Trial Nuclear Substudy: 5-year Survival of CAD Patients with 0% ->10% Residual Ischemia



Shaw LJ et al. Circulation. 2008;117:1283-1291.

Comparative Outcomes for Patients Who Do and Do Not Undergo Percutaneous Coronary Intervention for Stable Coronary Artery Disease in New York.

Hannan EL, Samadashvili Z, Cozzens K, Walford G, Jacobs AK, Holmes DR Jr, Stamato NJ, Gold JP, Sharma S, Venditti FJ, Powell T, King SB 3rd.

Circ: March 22, 2012 (ahead of print)

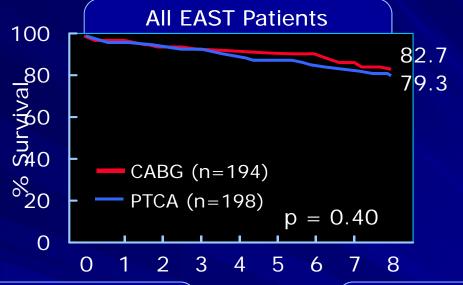
CONCLUSIONS: Most patients with stable CAD in New York undergoing catheterization between 2003 and 2008 received PCI. Patients who received PCI experienced lower mortality, mortality/MI, and revascularization rates.

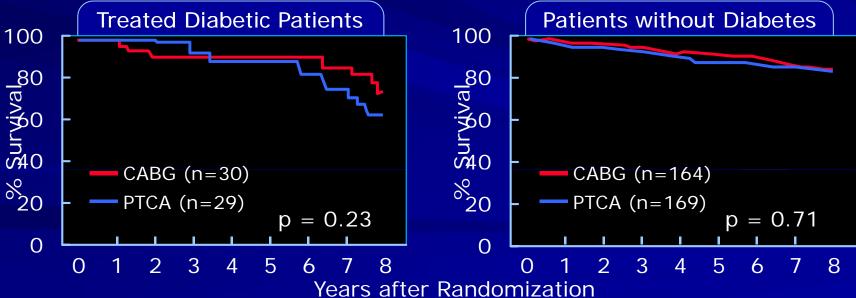
FAME II Trial

- FFR-Guided PCI Plus OMT versus OMT Alone
- Primary Outcome: Death, MI, unplanned urgent revascularization
- Plan for 1800 patients
- Enrollment stopped for safety with 1219 patients enrolled because of a clear benefit of the PCI arm
- A statistically significant reduction in hospital admission and urgent revascularization was seen in the PCI group

If an intervention, which one?

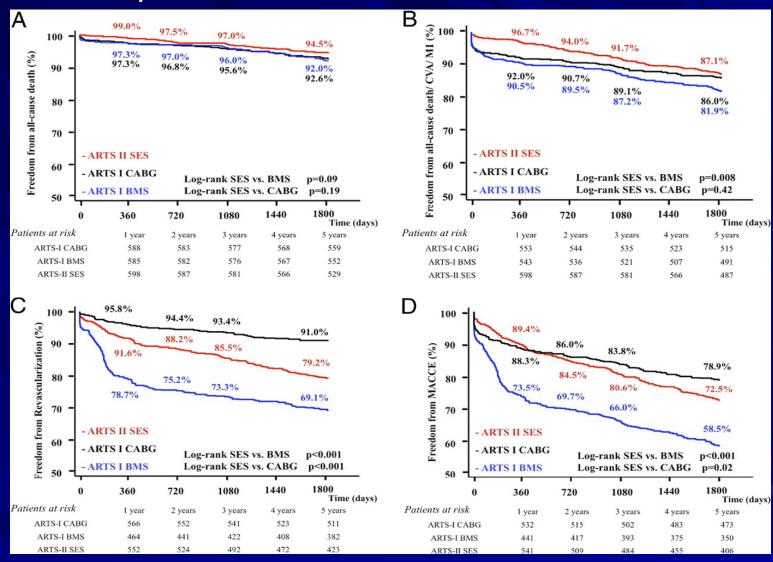






King SB III et al. *J Am Coll Cardiol* 2000; 35: 1116-1121.

Kaplan-Meier Curves of Freedom From Clinical Events

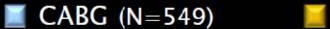


Serruys, P. W. et al. J Am Coll Cardiol 2010;55:1093-1101

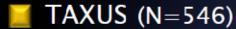


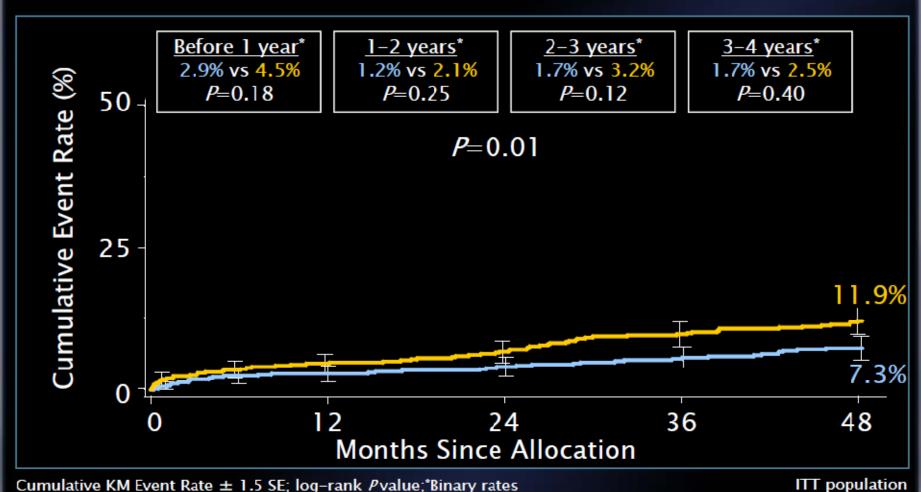
All-Cause Death to 4 Years 3VD Subset





SYNTAX 4-year Outcomes in the 3VD Subgroup • TCT 2011 • November, 2011 • Mohr • Slide 9





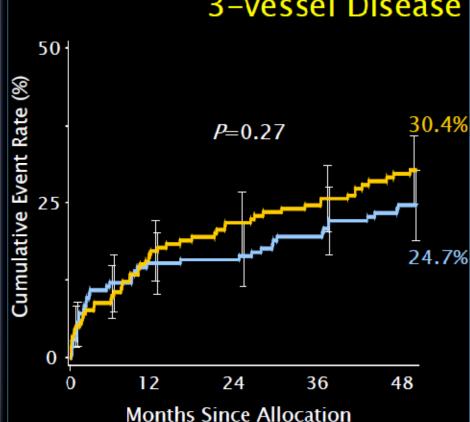
MACCE to 4 Years by SYNTAX Score Tercile Low Scores (0-22)





TAXUS (N=181)

3-vessel Disease



	CABG	PCI	<i>P</i> value
Death	8.7%	9.0%	0.92
CVA	3.9%	1.2%	0.12
МІ	4.9%	8.2%	0.27
Death, CVA or MI	14.8%	15.8%	0.84
Revasc.	11.6%	21.2%	0.02

Cumulative KM Event Rate \pm 1.5 SE; log-rank Pvalue

Site-reported Data; ITT population

SYNTAX 4-year Outcomes in the 3VD Subgroup • TCT 2011 • November, 2011 • Mohr • Slide 17

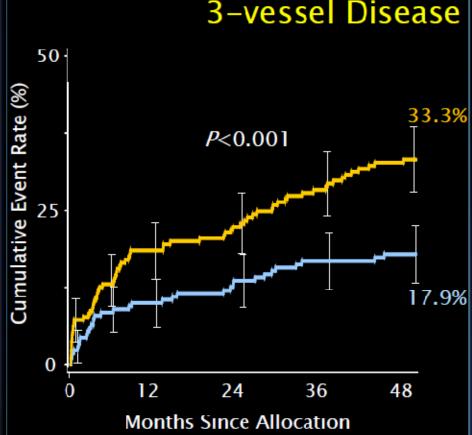
MACCE to 4 Years by SYNTAX Score Tercile Intermediate Scores (23-32)





TAXUS (N=207)

3-vessel Disease



	CABG	PCI	<i>P</i> value
Death	6.8%	12.7%	0.048
CVA	3.6%	2.5%	0.53
МІ	3.1%	10.5%	0.004
Death, CVA or MI	12.4%	18.6%	0.09
Revasc.	8.3%	21.0%	<0.001

Cumulative KM Event Rate \pm 1.5 SE; log-rank Pvalue

Site-reported Data; ITT population

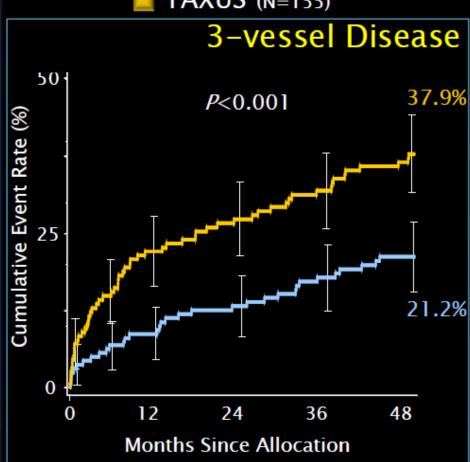
SYNTAX 4 year Outcomes in the 3VD Subgroup - TCT 2011 - November, 2011 - Mohr - Slide 18

MACCE to 4 Years by SYNTAX Score Tercile *High Scores* (233)





■ TAXUS (N=155)



	CABG	PCI	<i>P</i> value
Death	6.5%	14.5%	0.02
CVA	2.6%	5.1%	0.31
MI	1.9%	7.9%	0.01
Death, CVA or MI	11.0%	22.3%	0.008
Revasc.	11.2%	26.7%	<0.001

Cumulative KM Event Rate \pm 1.5 SE; log-rank *P* value

Site-reported Data; ITT population

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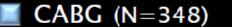
Revascularization to Improve Survival: Non-Left Main CAD Revascularization (cont.)



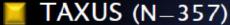
It is reasonable to choose CABG over PCI to improve survival in patients with complex 3-vessel CAD (e.g., SYNTAX score >22) with or without involvement of the proximal LAD artery who are good candidates for CABG.

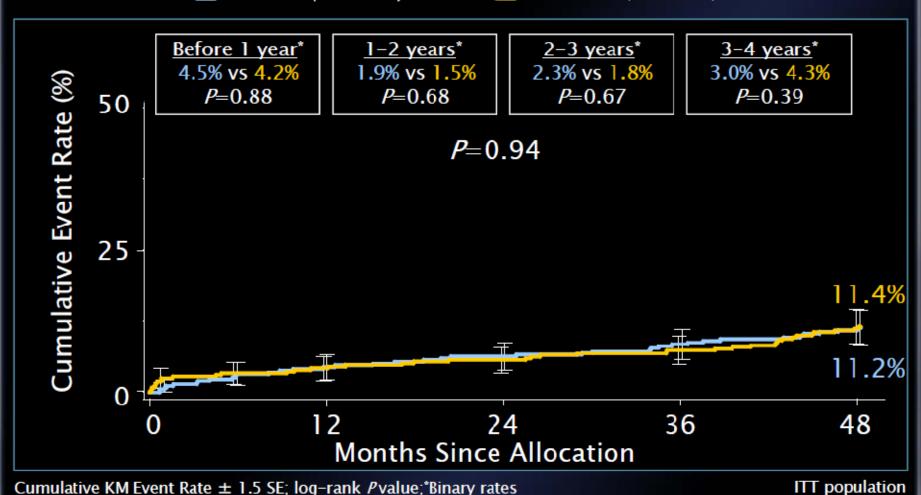
All-Cause Death to 4 Years *Left Main Subset*





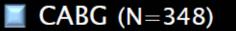
SYNTAX 4-year Outcomes in the LM Subgroup • TCT 2011 • November 2011 • Serruys • Slide 10

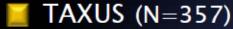


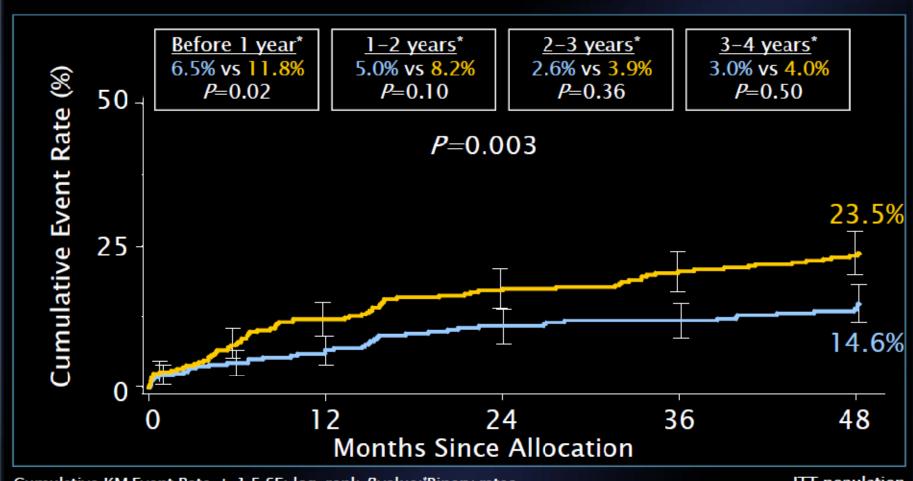


Repeat Revascularization to 4 Years Left Main Subset









Cumulative KM Event Rate ± 1.5 SE; log-rank Pvalue; Binary rates

ITT population

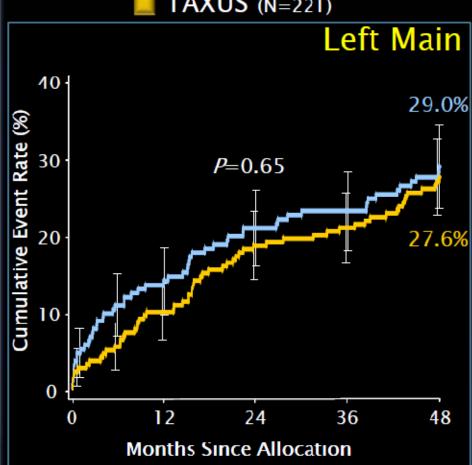
SYNTAX 4-year Outcomes In the LM Subgroup • TCT 2011 • November 2011 • Serruys • Slide 15

MACCE to 4 Years by SYNTAX Score SYNTAX Tercile Low to Intermediate Scores (0-32)









	CABG	PCI	<i>P</i> value
Death	11.8% >	> 7.5%	0.12
CVA	3.9%	> 1.4%	0.11
МІ	3.8%	< 5.1%	0.55
Death, CVA or MI	17.1%	> 13.5%	0.25
Revasc.	16.9%	< 19.1%	0.57

Cumulative KM Event Rate \pm 1.5 SE; log-rank Pvalue

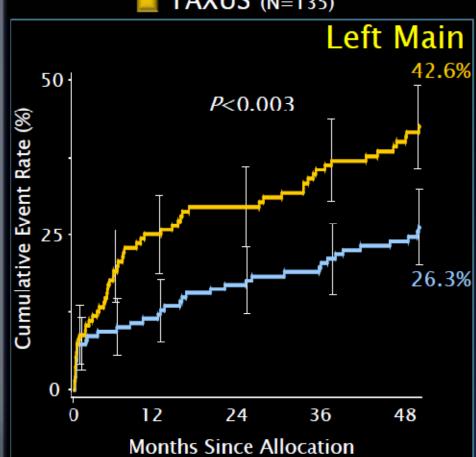
Site-reported Data; ITT population

MACCE to 4 Years by SYNTAX Score SYNTAX Tercile *High Scores* (≥33)









	CABG	PCI	<i>P</i> value
Death	10.5%	17.9%	0.06
CVA	4.9%	1.6%	0.14
МІ	6.1%	10.9%	0.18
Death, CVA or MI	18.5%	23.1%	0.33
Revasc.	11.8%	31.3%	<0.001

Cumulative KM Event Rate ± 1.5 SE; log-rank Pvalue

Site-reported Data; ITT population

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Revascularization to Improve Survival: Left Main CAD Revascularization



CABG to improve survival is recommended for patients with significant (≥50% diameter stenosis) left main CAD.



PCI to improve survival is reasonable as an alternative to CABG in selected stable patients with significant (≥50% diameter stenosis) unprotected left main CAD with: 1) anatomic conditions associated with a low risk of PCI procedural complications and a high likelihood of a good long-term outcome (e.g., a low SYNTAX score [≤22], ostial or trunk left main CAD); and 2) clinical characteristics that predict a significantly increased risk of adverse surgical outcomes (e.g., STS-predicted risk of operative mortality ≥5%).

New information concerning selection of DES or CABG in diabetic patients will be forthcoming from the FREEDOM Trial soon.

ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches)

A randomized controlled trial assessing comparative effectiveness of two initial management strategies for stable patients with moderate-to-severe ischemia on nuclear or echo stress testing: catheterization with revascularization if feasible (PCI or CABG) plus optimal medical therapy (OMT) versus OMT alone.

Patients will be randomized following a stress test but before cardiac catheterization.

Conclusions

- PCI relieves angina
- PCI is the interventional choice for one and most two vessel disease patients
- More extensive disease should be managed surgically
- Many patients with left main disease can be managed with PCI
- Aggressive antiatherosclerotic therapy has improved survival for all CAD patients.