

Contemporary Left Main PCI:

What Do RCTs Tell Us?

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Disclosure

- Potential conflicts of interest
- Unrestricted institutional grant for fellowship from Boston Scientific
- Speaker fees
 - Boston, Medtronic, Abbott Vascular, Miracor

The PCI vs CABG data for left main

- History
- Syntax
 - Multivessel and left main
- The left main trials
 - Excel, Precombat, Noble (compare and contrast)
 - Meta analysis
- Conclusions

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	Clinical Parameters				
<i>No stents used</i>		Angina Relief	Repeat Revascularization	Angio Endpoints	Cost Assessment
<i>Stents used</i>	Mortality & MI		Repeat Revascularization		
GABI	PCI	PCI	Repeat Revascularization	No difference	n/a
EAST	No difference	CABG	Significant decrease of revascularization expected with DES	CABG	PCI
RITA	No difference	CABG		n/a	n/a
ERACI	No difference	CABG		n/a	PCI
CABRI	No difference	CABG		n/a	n/a
BARI	No difference	n/a		n/a	n/a
MASS-2	CABG (MI)	n/a		n/a	No difference
AWESOME	No difference	No difference		n/a	n/a
ERACI-2	PCI	n/a		CABG	No difference
SoS	CABG (Mortality)	CABG		n/a	n/a
ARTS	No difference	n/a		CABG	n/a

SYNTAX Trial Design



62 EU Sites

+



23 US Sites

Heart Team (surgeon & interventionalist)

Amenable for both
treatment options

Amenable for only one
treatment approach

Stratification:
LM and Diabetes

Randomized Arms

N=1800

CABG
n=897

vs

TAXUS*
n=903

3VD
66.3%

LM
33.7%

3VD
65.4%

LM
34.6%

Two Registry Arms

N=1275

CABG
n=1077

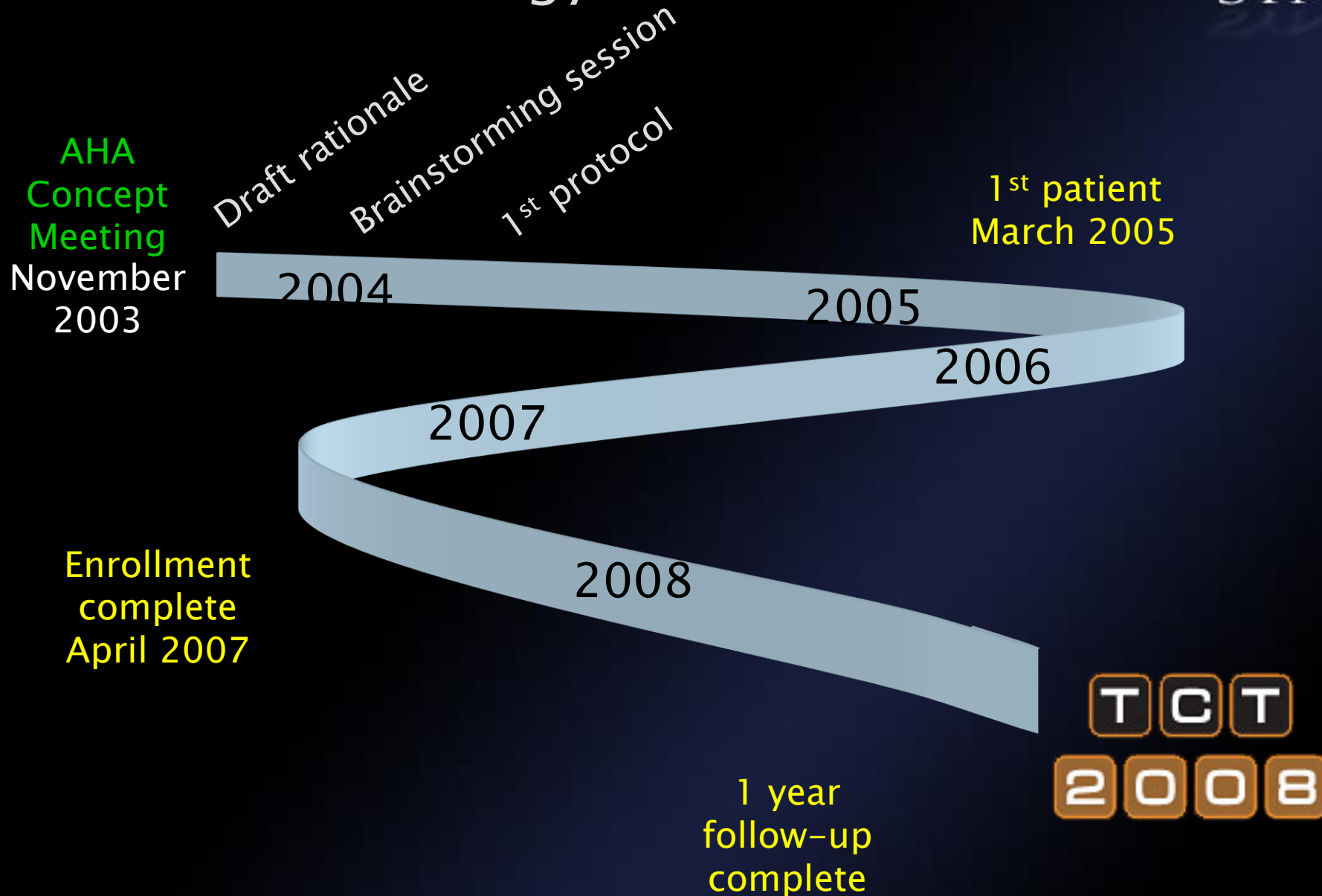
PCI
n=198

5yr f/u
n=649

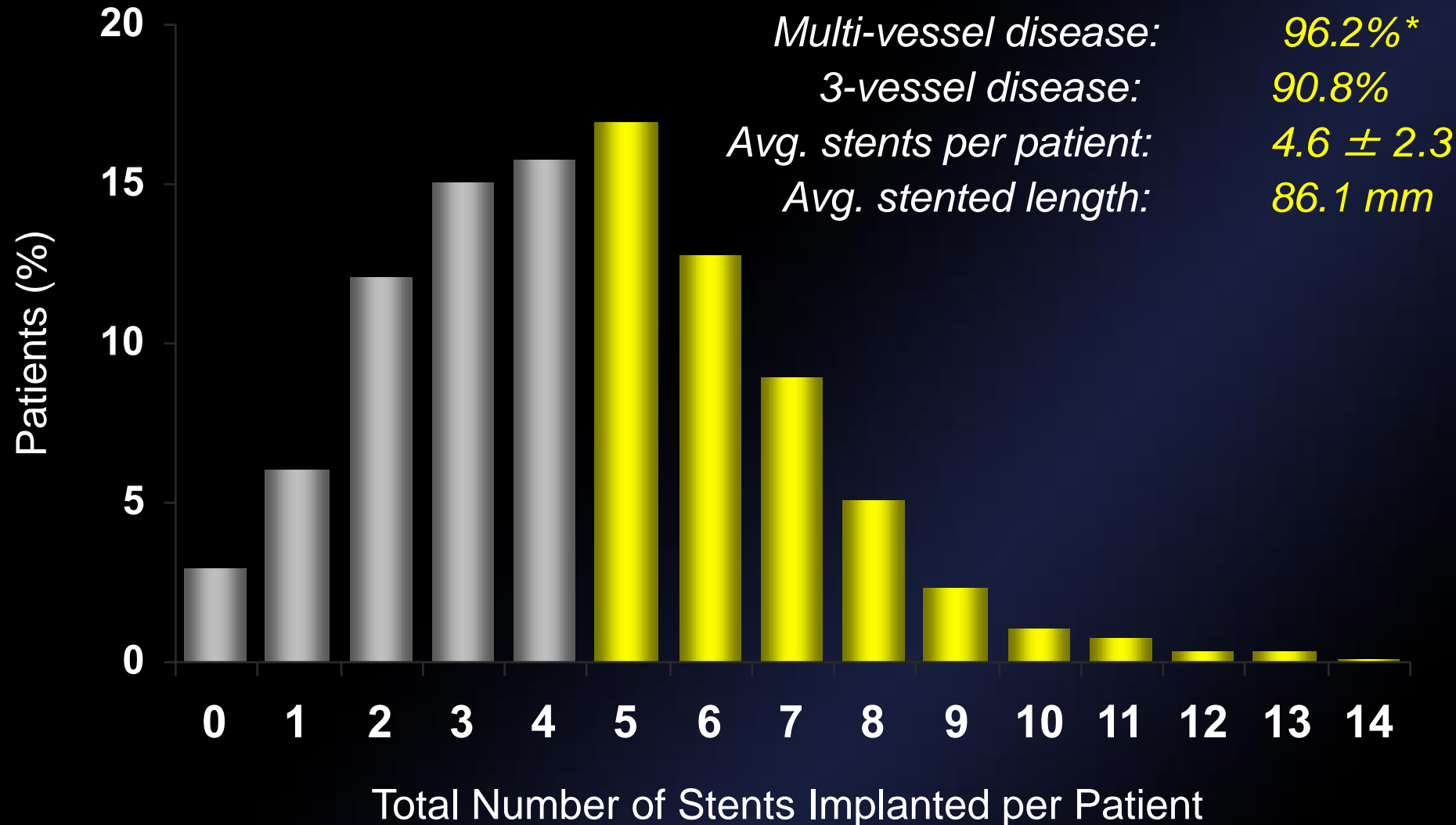
no f/u
n=428

*TAXUS Express

SYNTAX Chronology



Stent Number and Length Higher in the SYNTAX Trial



*3VD+LM/3VD+LM/2VD+LM/1VD

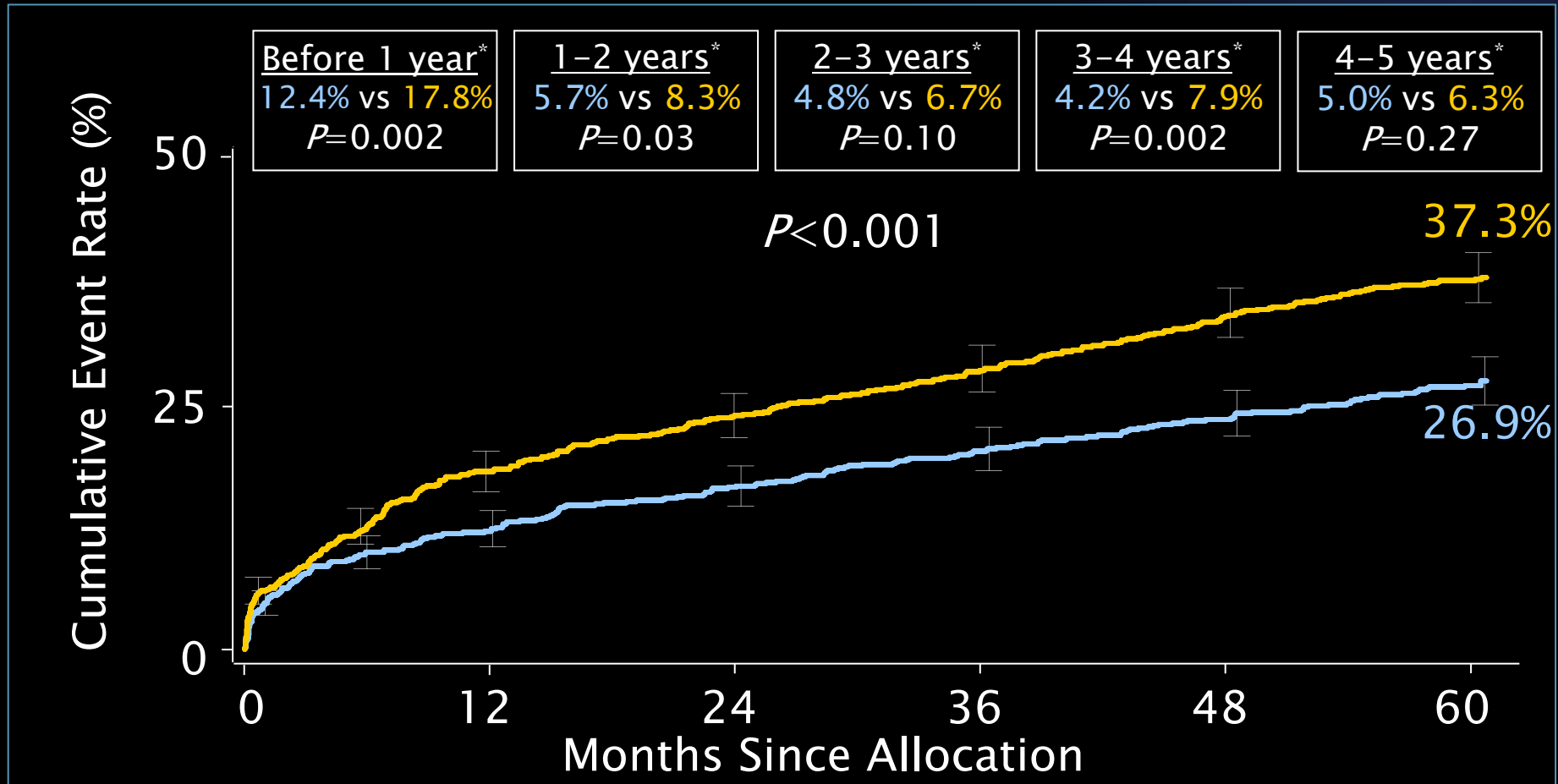
Source: See Glossary

MACCE to 5 Years



■ CABG (N=897)

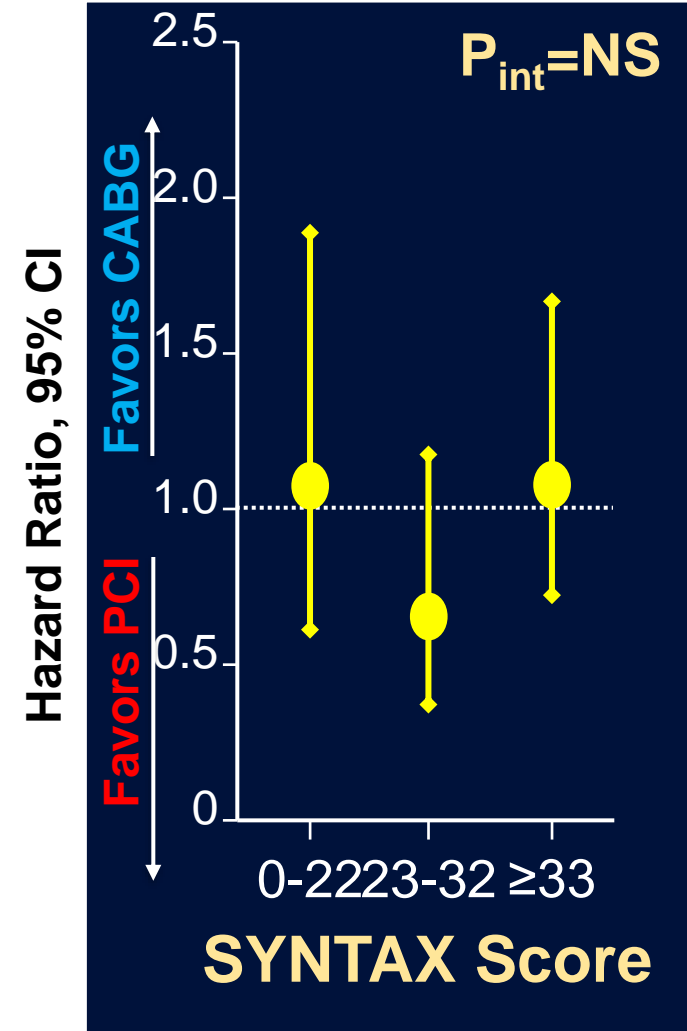
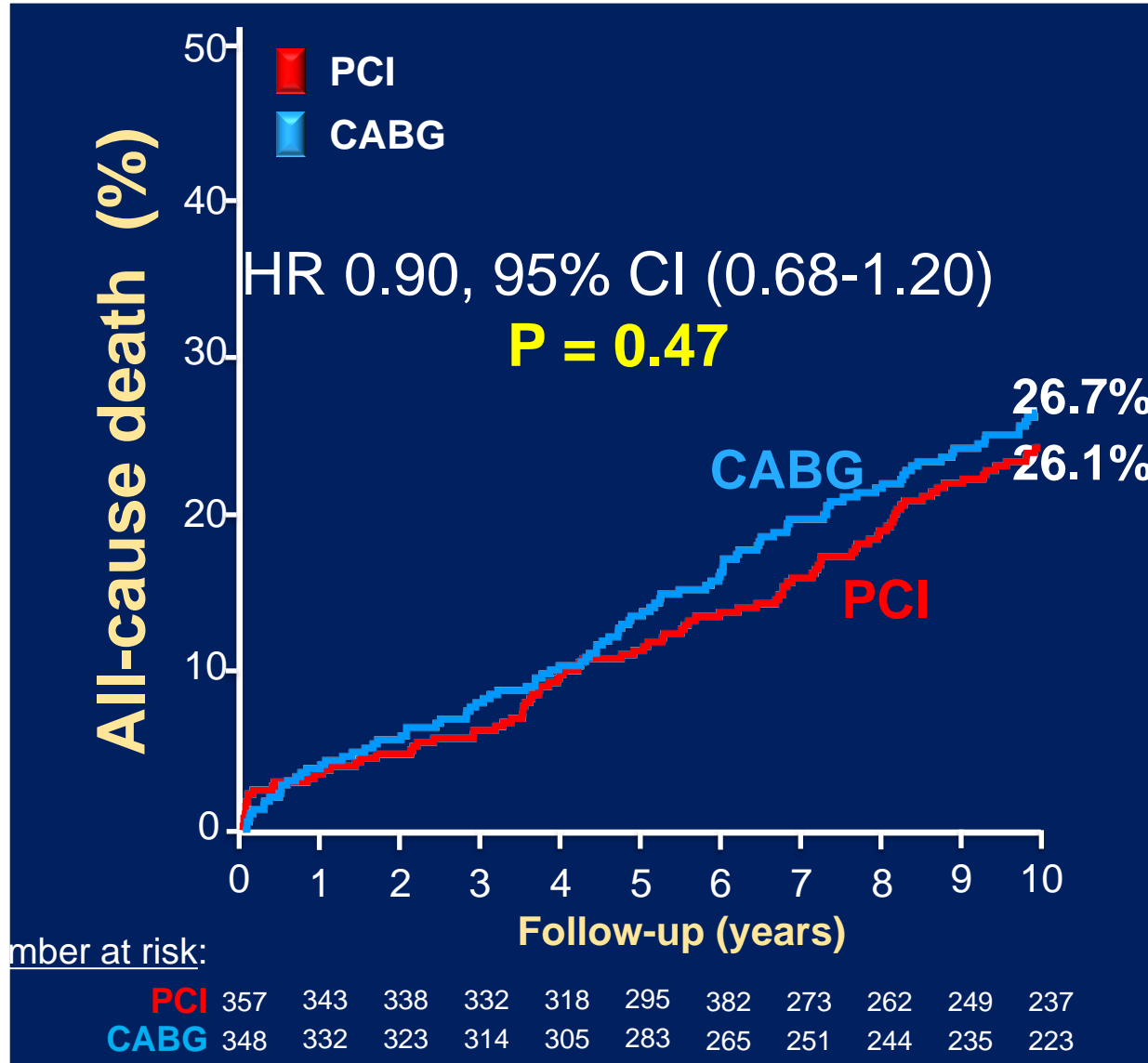
■ TAXUS (N=903)



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

ITT population

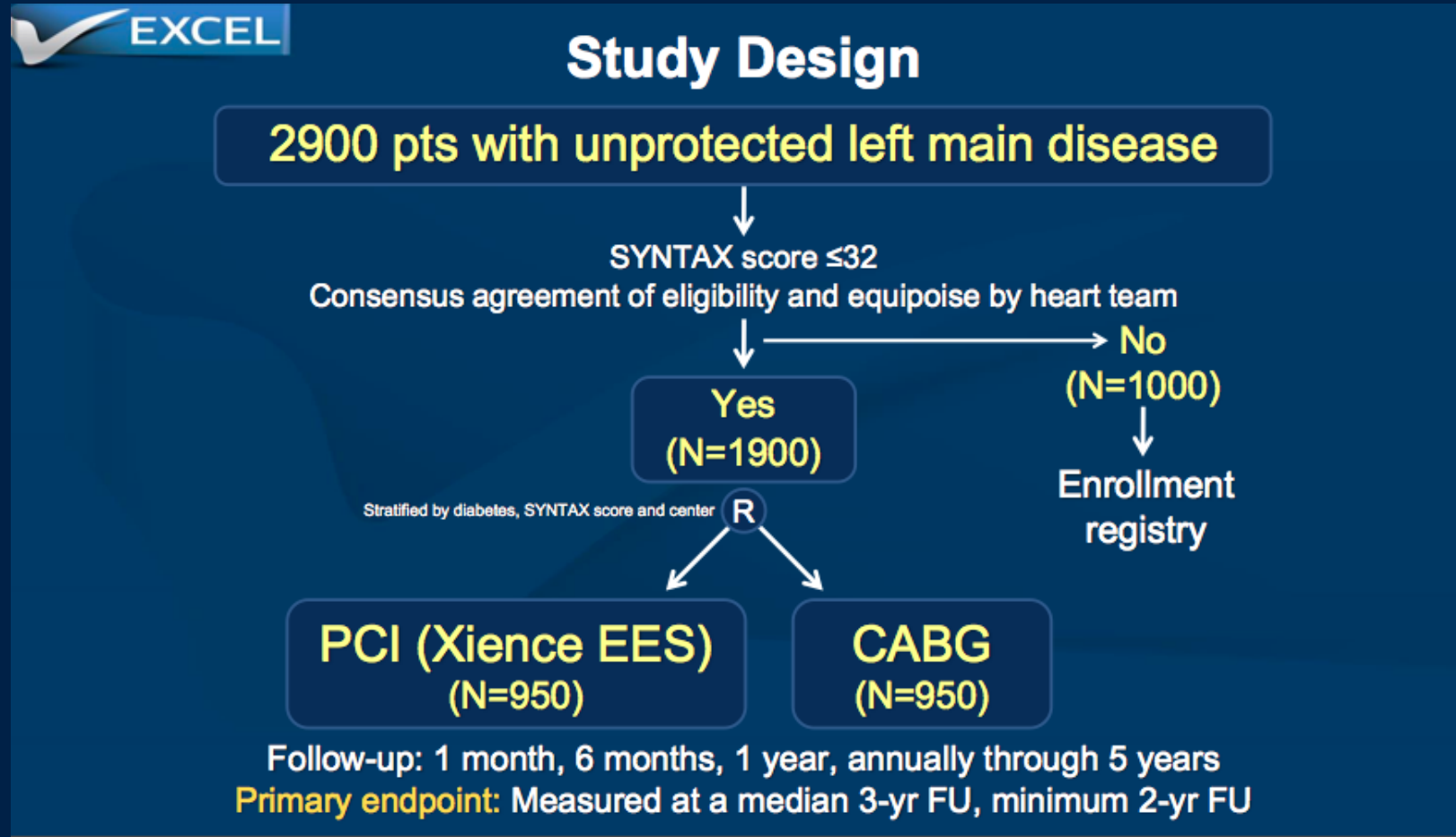
SYNTAX Left Main at 10 Years: Mortality



	SYNTAX	EXCEL	NOBLE
All-comers	Yes	No	No
Patient population	LM/3VD	LM	LM
SYNTAX score	Any	≤ 32	Low
Primary endpoint*	Death/MI/CVA/TVR	Death/MI/CVA	Death/MI/CVA/TVR
Follow up	1 year	3 year (median)	3 year (median)
IVUS	Infrequent	Recommended	Recommended
FFR guidance	Infrequent	Recommended	Recommended
Stent	PES	EES	BES recommended
Angio FU	At discretion	Not recommended	Not recommended

Excel 5yrs

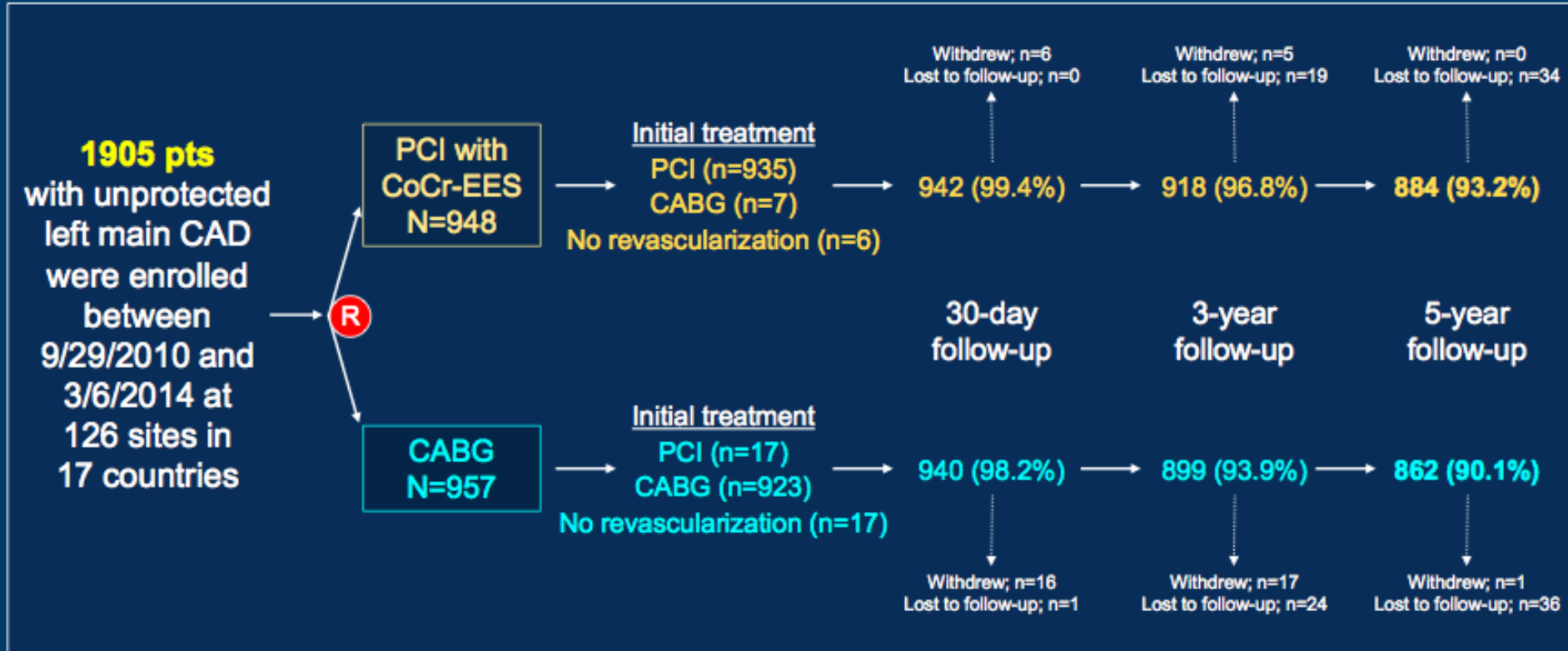
– sample size / endpoint 3 yrs



Excel 5yrs- good follow up



Randomization and Follow-up

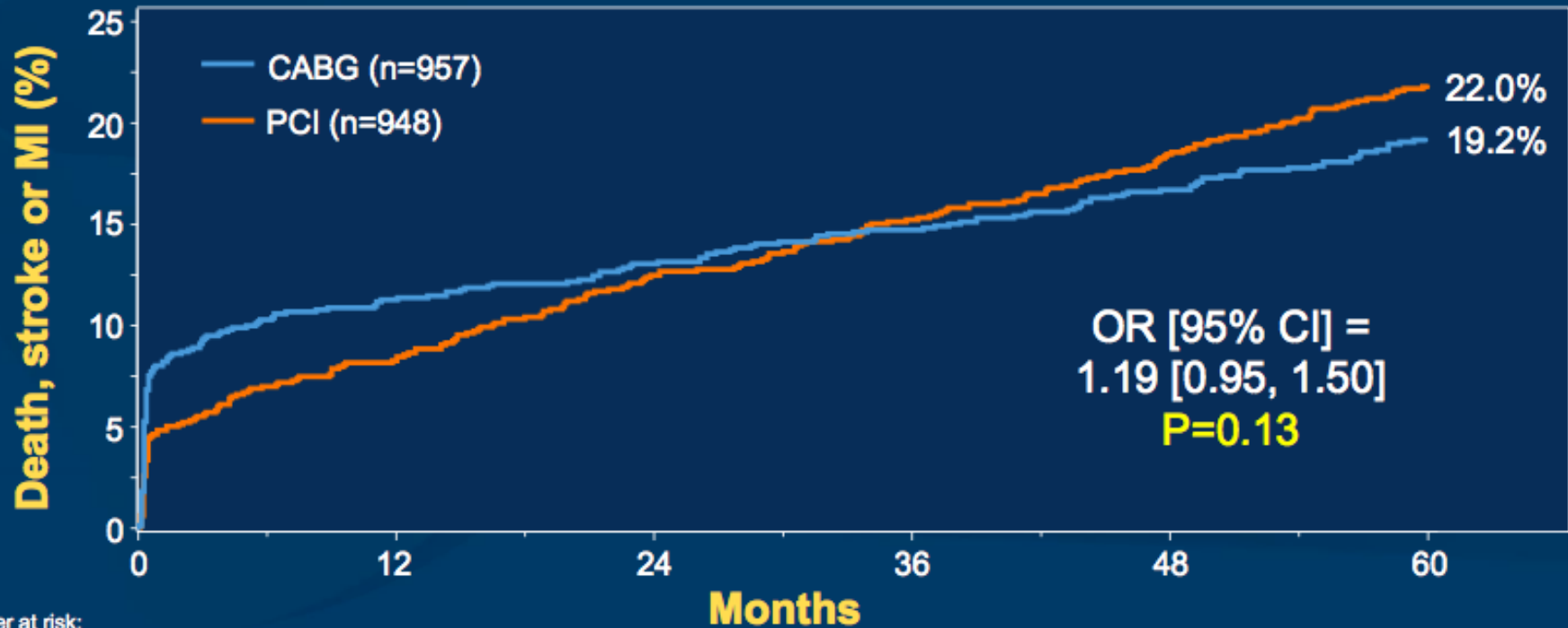


Excel 5yrs- no statistical difference



Primary Endpoint

All-cause Death, Stroke or MI at 5 Years



Number at risk:

PCI	948	854	809	778	738	486
CABG	957	818	789	763	734	532

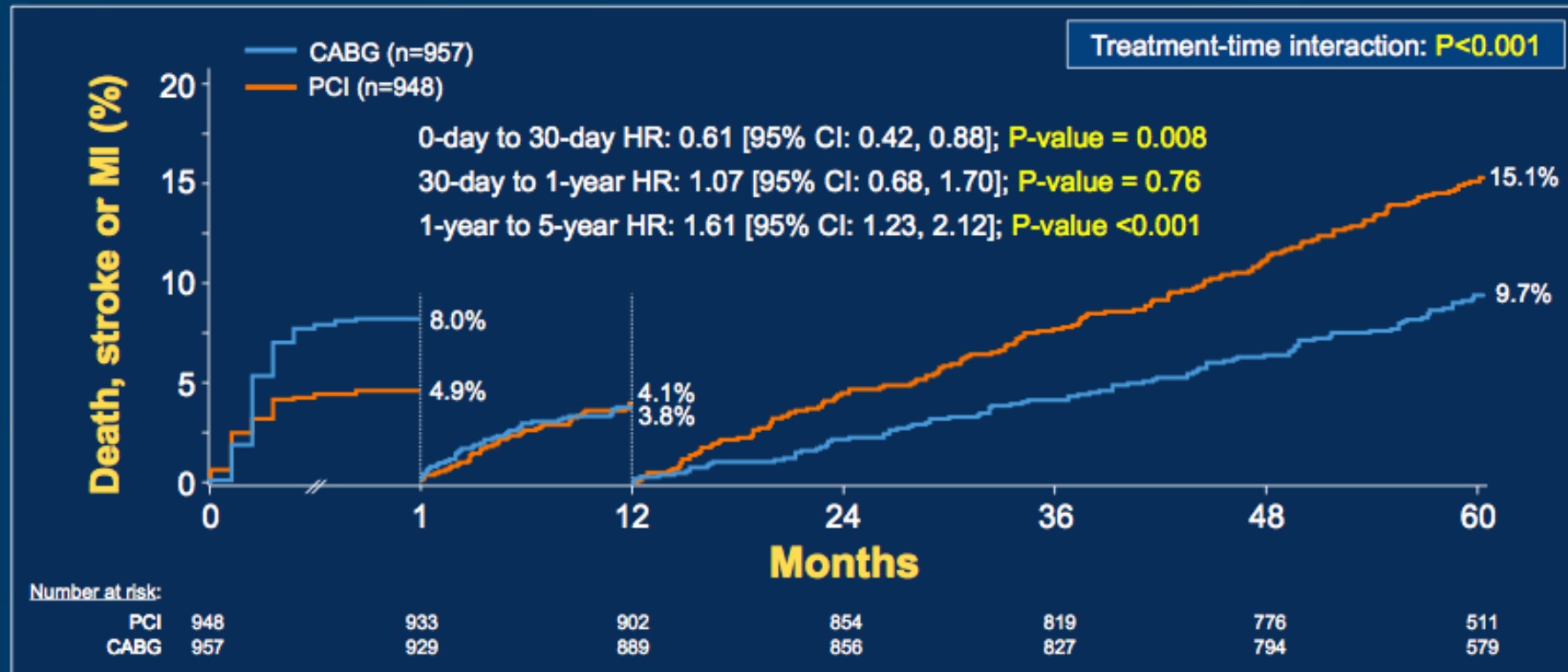
Excel 5yrs- 3 phases



Piecewise Hazards

All-cause Death, Stroke or MI

Three distinct periods of varying relative risk



Excel 5yrs- death and MI rates



Primary Endpoint at 5 Years

All-cause Death, Stroke or MI after Multiple Imputation to Account for Missing Follow-up Data

Population	Kaplan-Meier rate (n events)		Odds ratio [95% CI]
	PCI	CABG	
All-cause death, stroke or MI	21.8%	19.5%	1.15 [0.92, 1.45]
- All-cause death	13.0%	10.1%	1.32 [0.99, 1.77]
- Stroke	3.1%	3.7%	0.83 [0.48, 1.44]
- Myocardial infarction	10.2%	9.6%	1.08 [0.79, 1.46]



Event rates are binary proportions. Odds ratios and 95% confidence intervals were estimated from time offset logistic regression.

Excel 5yrs-



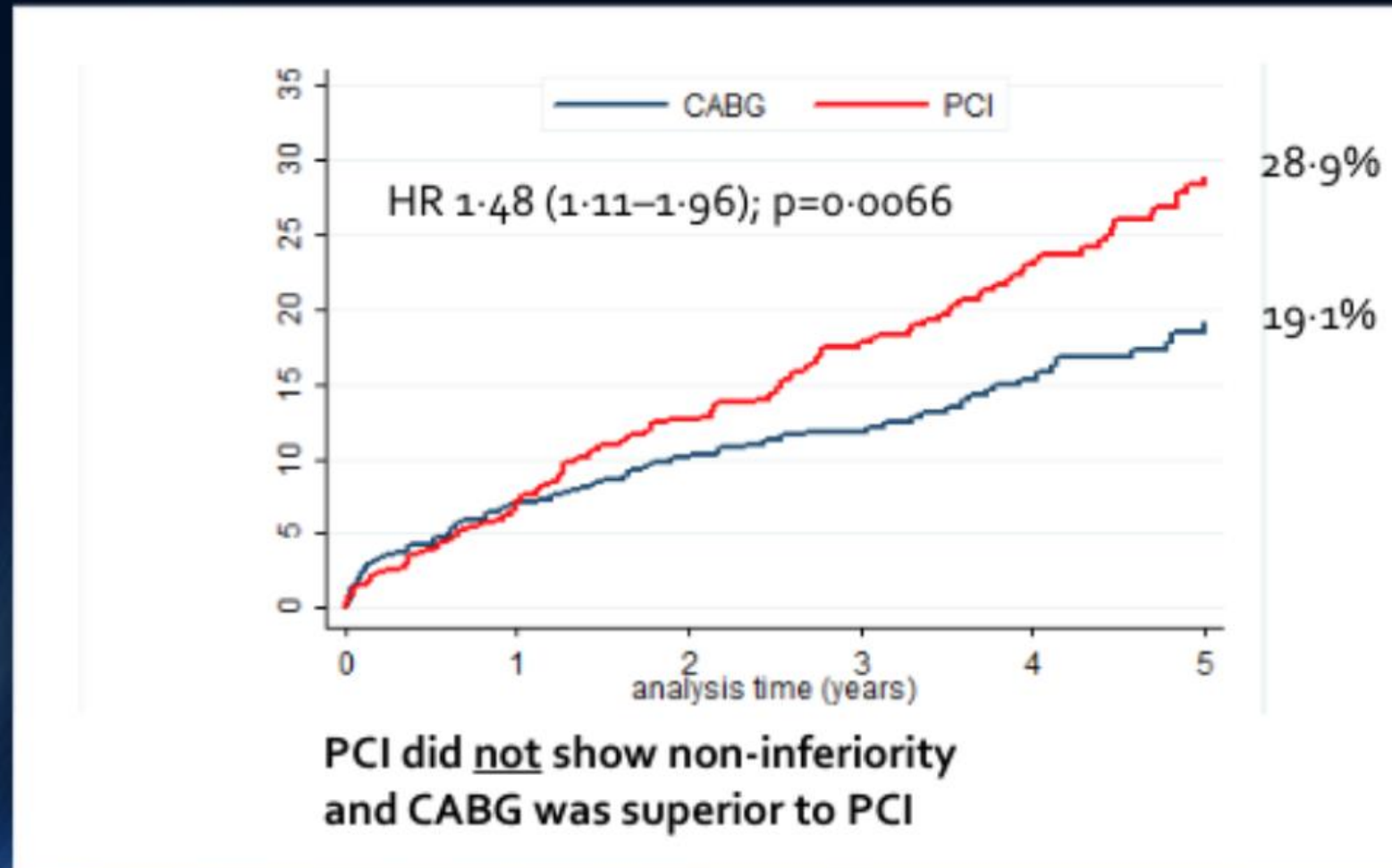
Conclusions

- In the EXCEL trial, treatment of patients with LMCAD and visually-assessed low or intermediate SYNTAX scores with CoCr-EES resulted in similar rates of the clinically meaningful composite outcome of death, stroke or MI at 5 years
- The early benefits of PCI due to reduced peri-procedural risk were attenuated by the greater number of events occurring during follow-up with CABG, such that at 5 years the cumulative mean time free from adverse events was similar with both treatments

*Remember it's a different endpoint
to Excel*

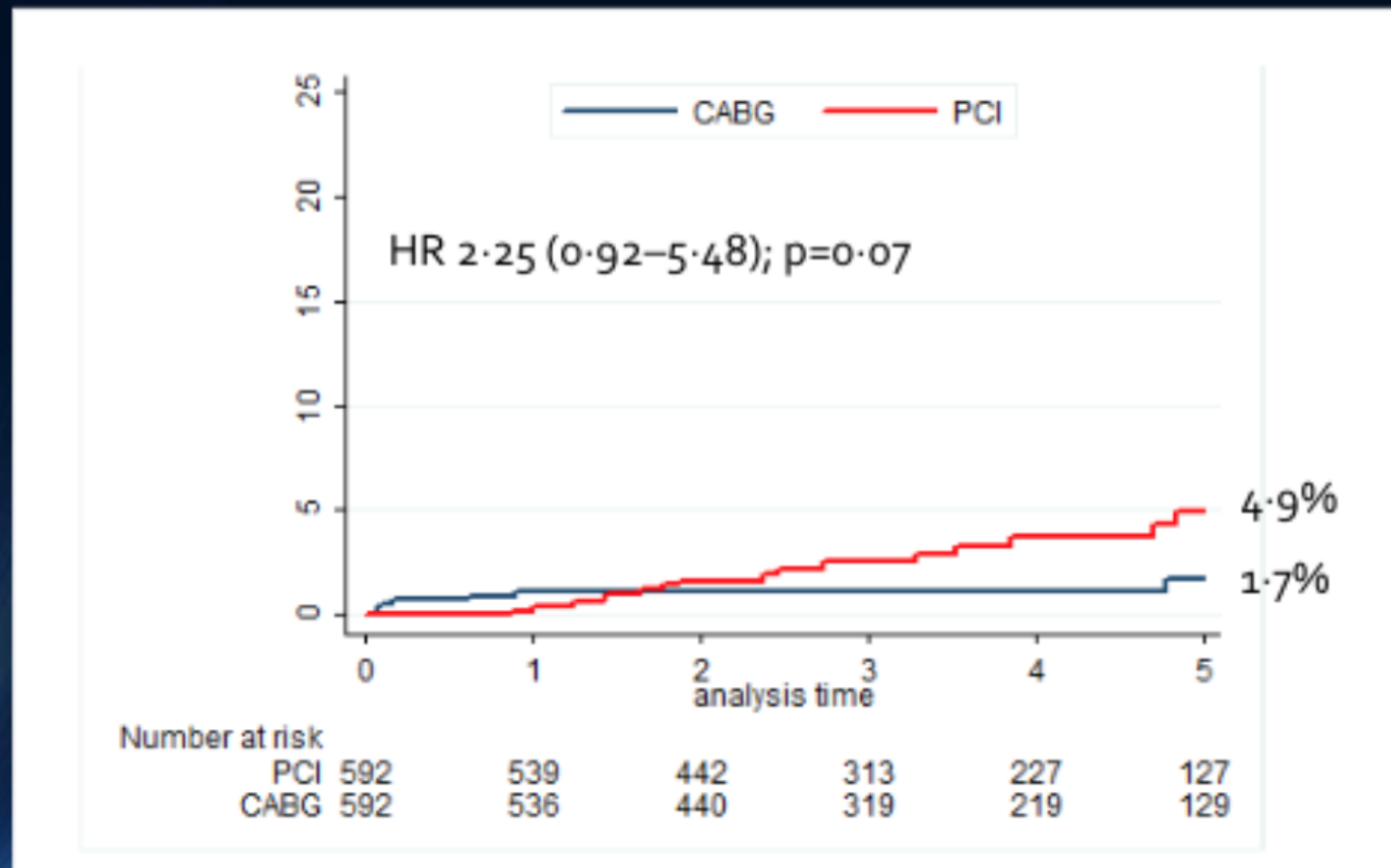
Results

Primary endpoint: MACCE



Results Stroke

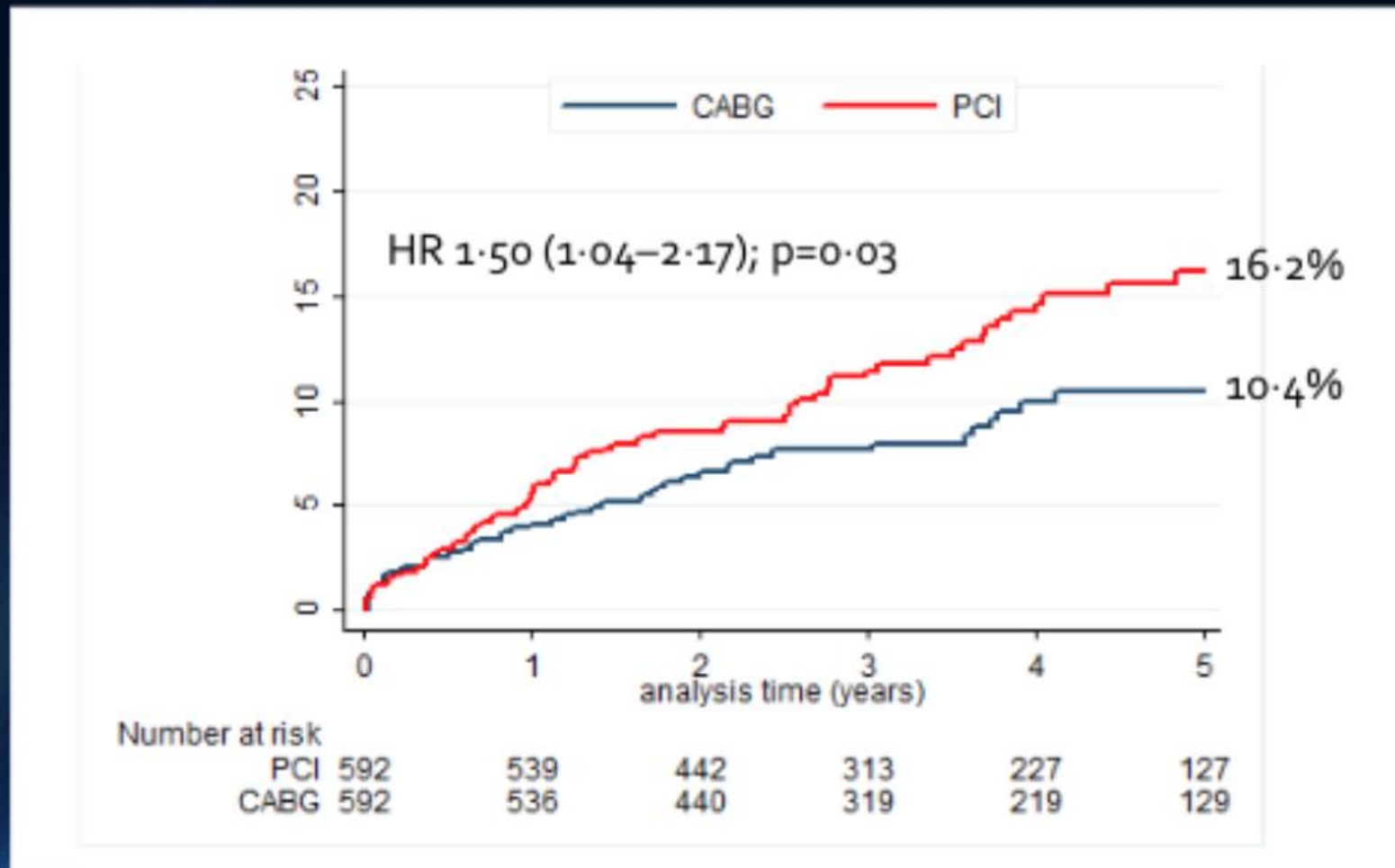
Mmmmm don't understand that !



Results

Favours surgery – a bit

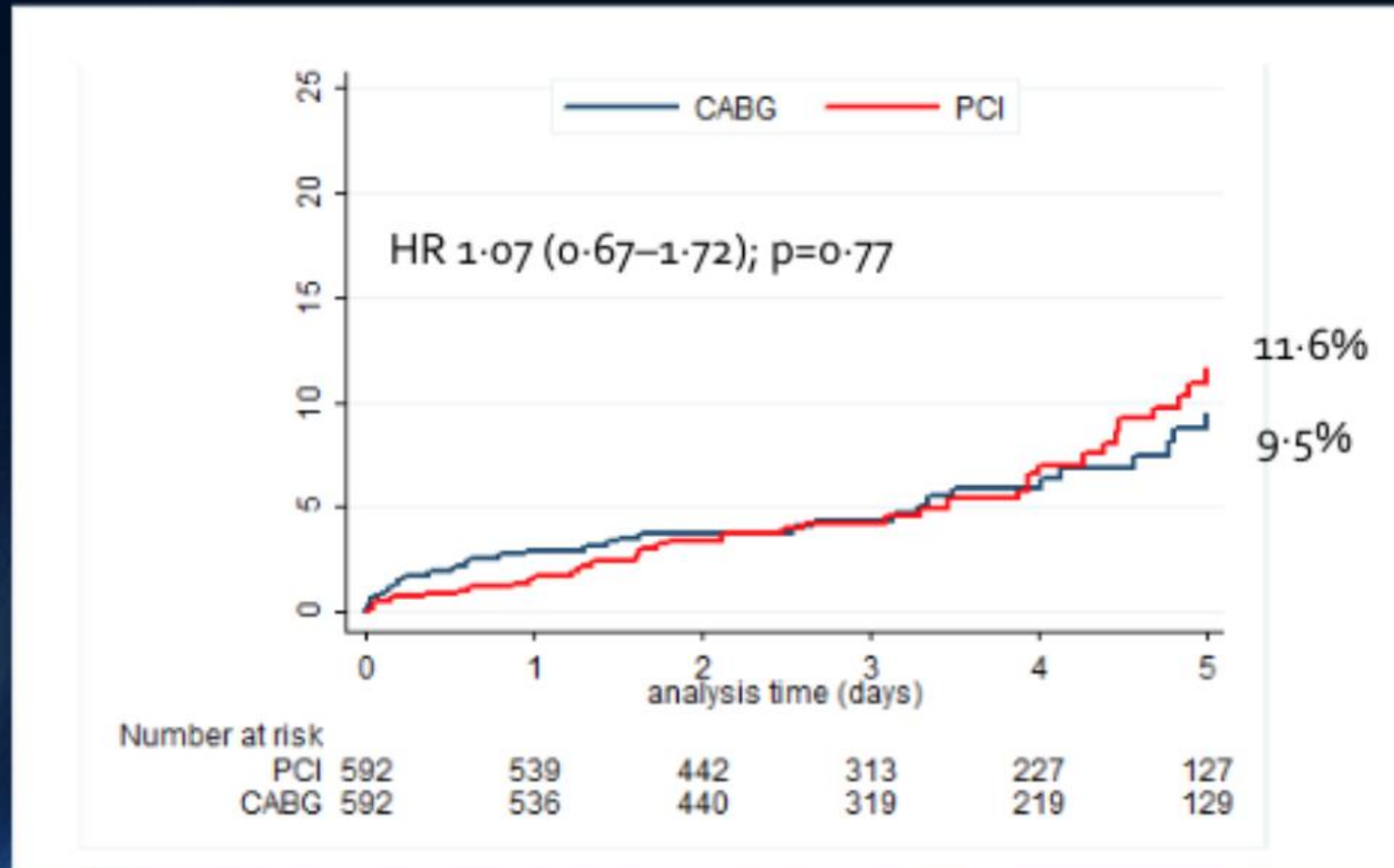
Total repeat revascularization



Results

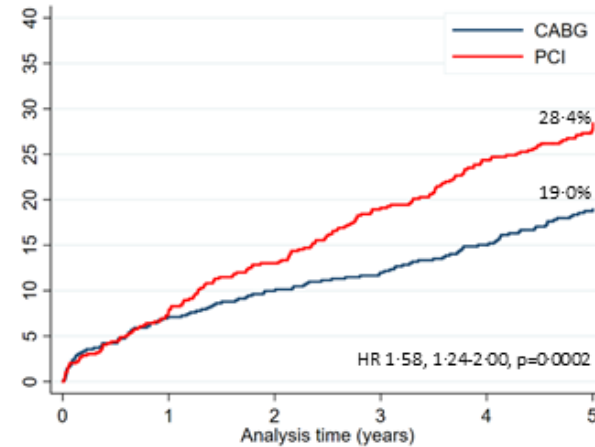
All-cause mortality

It's the same



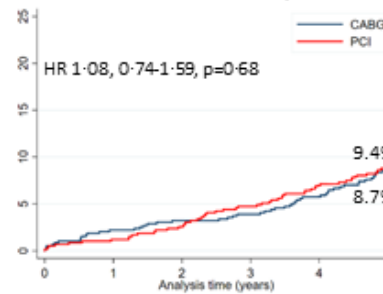
Noble 5 yr

Major adverse cardiac and cerebrovascular events (%)



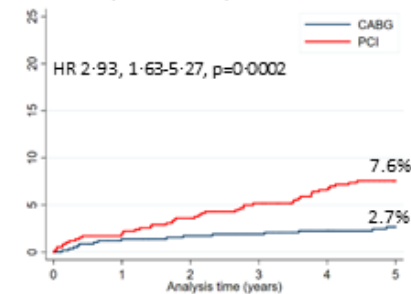
Number at risk		0	1	2	3	4	5
PCI	592	592	546	515	478	439	327
CABG	592	592	550	533	521	493	380

All-cause mortality



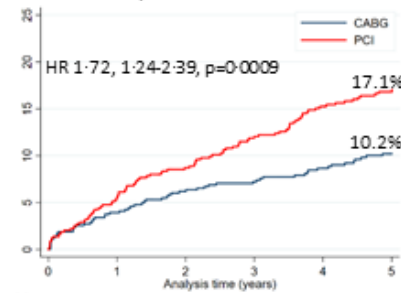
Number at risk		0	1	2	3	4	5
PCI	592	592	585	577	563	541	409
CABG	592	592	579	573	569	547	432

Non-procedural myocardial infarction



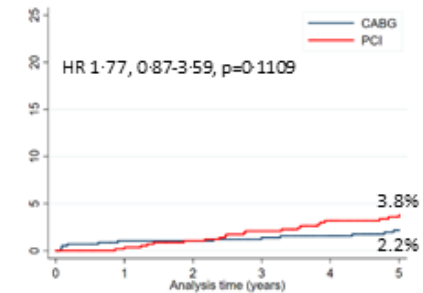
Number at risk		0	1	2	3	4	5
PCI	592	592	575	558	535	509	385
CABG	592	592	572	564	559	538	422

Repeat revascularisation



Number at risk		0	1	2	3	4	5
PCI	592	592	553	528	499	483	348
CABG	592	592	558	540	530	502	387

Stroke



Number at risk		0	1	2	3	4	5
PCI	592	592	583	572	552	525	392
CABG	592	592	573	568	563	540	426

Percutaneous coronary intervention with drug-eluting stents versus coronary artery bypass grafting in left main coronary artery disease: an individual patient data meta-analysis

Marc S Sabatine, Brian A Bergmark*, Sabina A Murphy, Patrick T O'Gara, Peter K Smith, Patrick W Serruys, A Pieter Kappetein, Seung-Jung Park, Duk-Woo Park, Evald H Christiansen, Niels R Holm, Per H Nielsen, Gregg W Stone, Joseph F Sabik, Eugene Braunwald*

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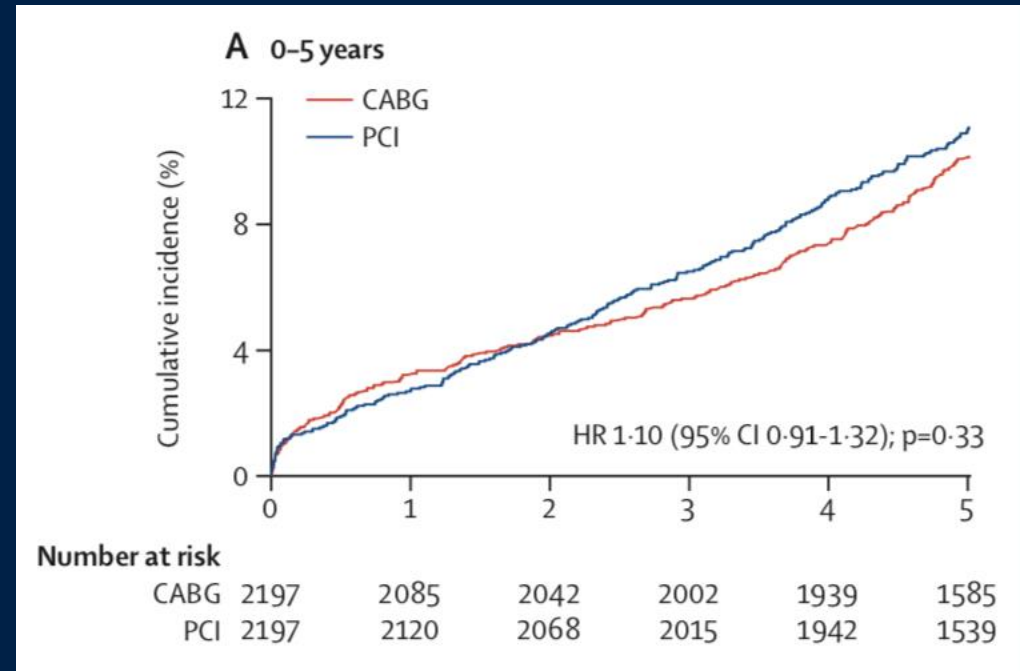
[https://doi.org/10.1016/S0140-6736\(21\)02334-5](https://doi.org/10.1016/S0140-6736(21)02334-5)

Patient level: Syntax Noble Precombat and Excel

	Pooled (n=4394)	PCI (n=2197)	CABG (n=2197)
Demographics			
Age, years	66 (59-73)	66 (59-73)	66 (59-72)
Age ≥65 years	2496 (56.8%)	1223 (55.7%)	1273 (57.9%)
Sex			
Female	1023 (23.3%)	514 (23.4%)	509 (23.2%)
Male	3371 (76.7%)	1683 (76.6%)	1688 (76.8%)

SYNTAX score†	25.0 (18.0-31.0); n=4358	25.0 (19.0-31.0); n=2187	24.0 (18.0-31.0); n=2171
SYNTAX score group			
≤22	1778/4358 (40.8%)	864/2187 (39.5%)	914/2171 (42.1%)
23-32	1627/4358 (37.3%)	858/2187 (39.2%)	769/2171 (35.4%)
≥33	953/4358 (21.9%)	465/2187 (21.3%)	488/2171 (22.5%)

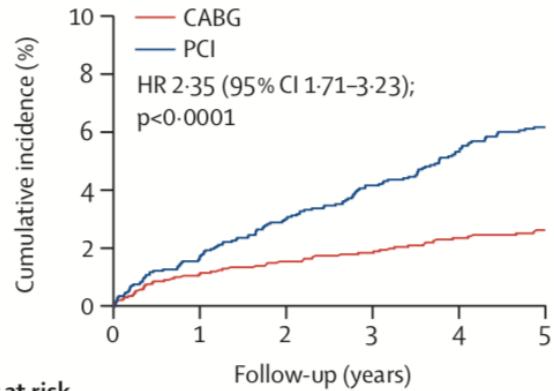
Patient level: Syntax Noble Precombat and Excel



All cause Death at 5yrs p 0.33

Patient level: Syntax Noble Precombat and Excel

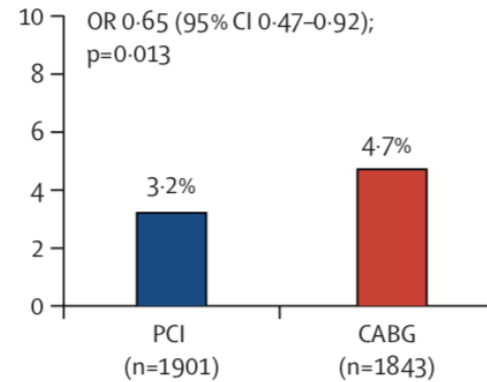
A Spontaneous myocardial infarction



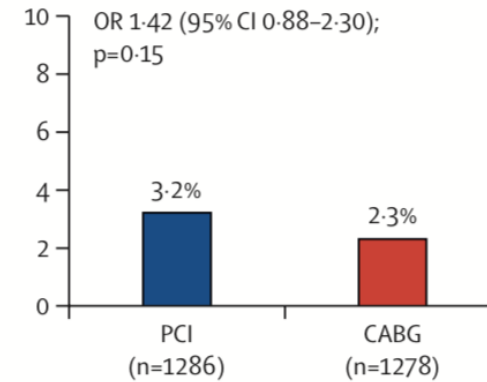
Number at risk

CABG	2197	2054	2000	1954	1884	1450
PCI	2197	2090	2012	1939	1848	1364

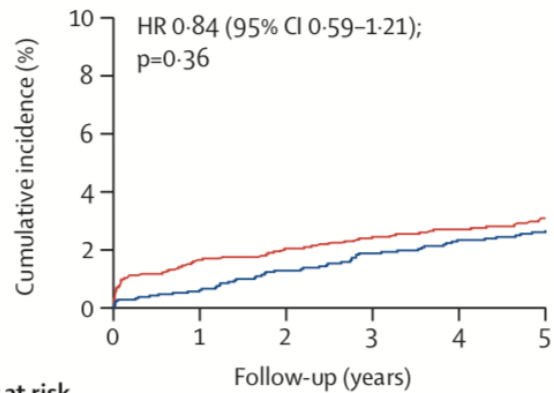
B Procedural myocardial infarction (protocol definition)



C Procedural myocardial infarction (universal definition)



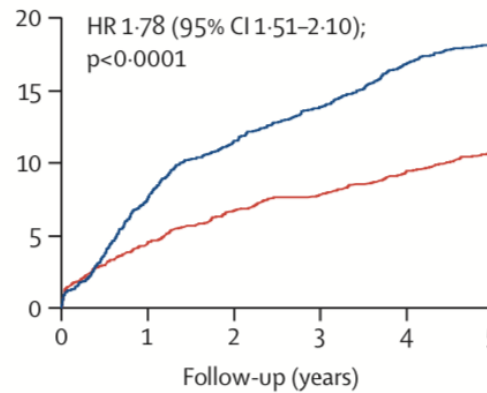
D Stroke



Number at risk

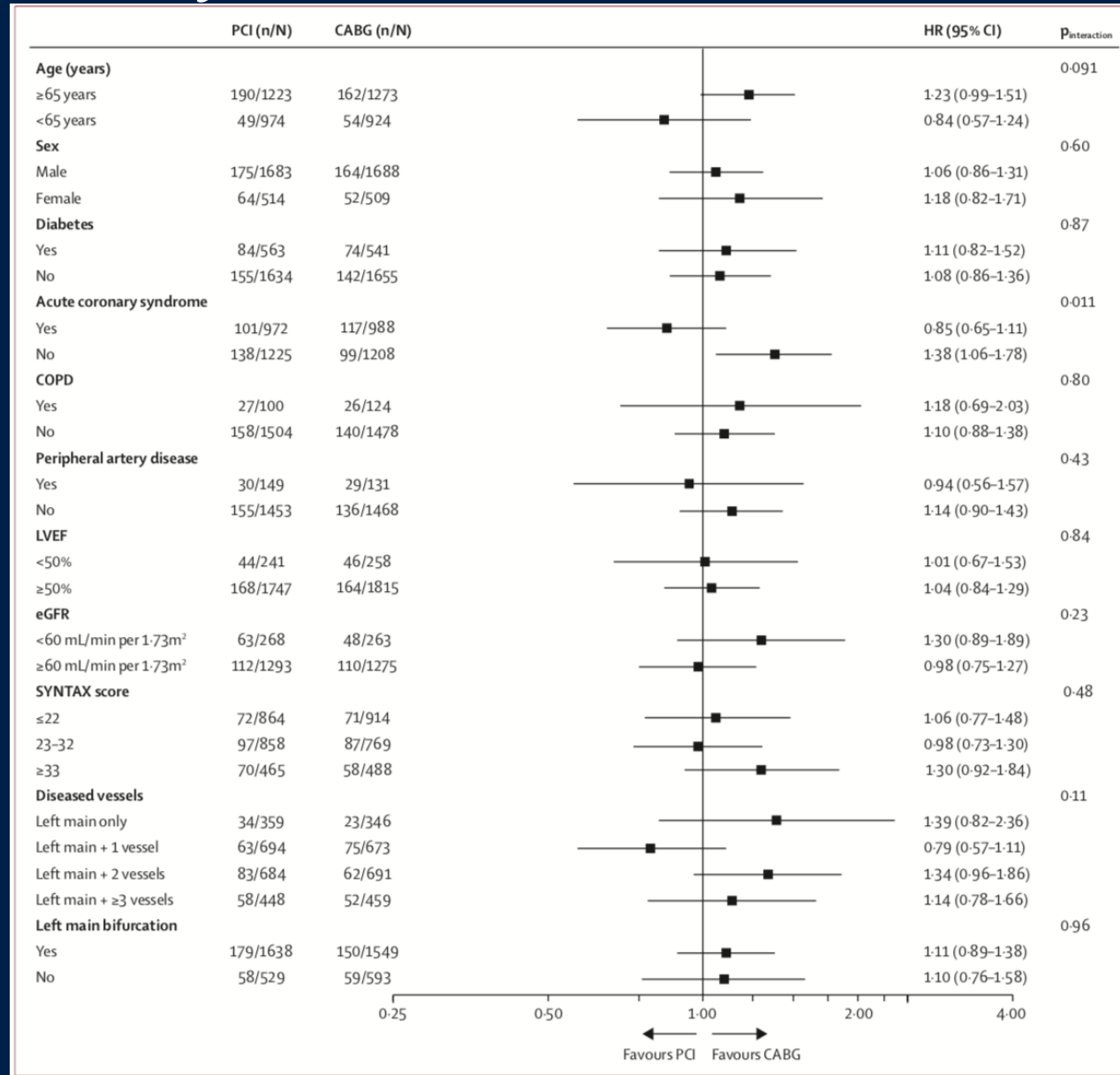
CABG	2197	2049	1998	1953	1885	1451
PCI	2197	2109	2045	1984	1902	1405

E Repeat revascularisation



2197	1988	1900	1842	1749	1336
2197	1972	1838	1745	1624	1196

Patient level: Syntax Noble Precombat and Excel



Conclusions PCI vs CABG

“Debate” about merits of PCI vs CABG may be unhelpful

Very very few patients are really in *equipoise*

Local expertise and patient opinion are relevant and important

Review the patient clinically

Review the angiogram carefully

Asses the ischaemic potential and the expectation of complete revascularization

.... And make the decision together with the patient and the surgeon