Comparison of Three-year Outcome after PCI and CABG in Triple Vessel Coronary Artery Disease

Stratified analysis by the SYNTAX Score

CREDO-Kyoto PCI/CABG Registry Cohort-2

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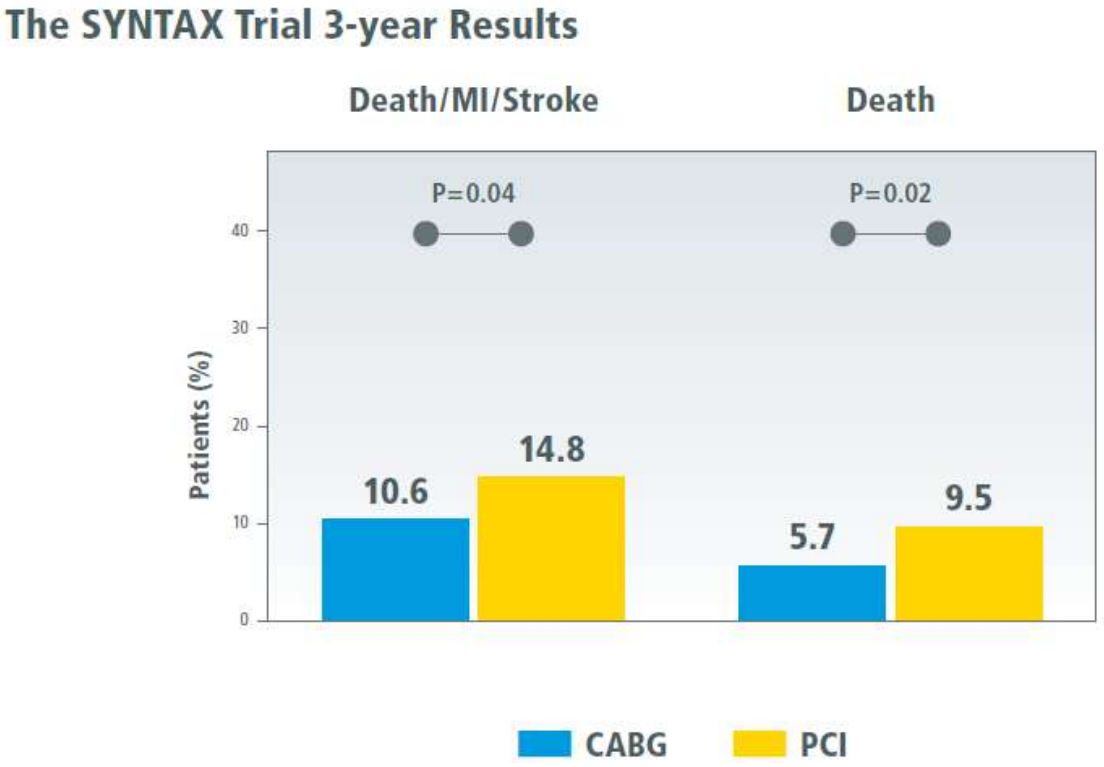
Pharmaceuticals and Medical Devices Agency in Japan

Disclosures

Hiroki Shiomi: Nothing to disclose

Background

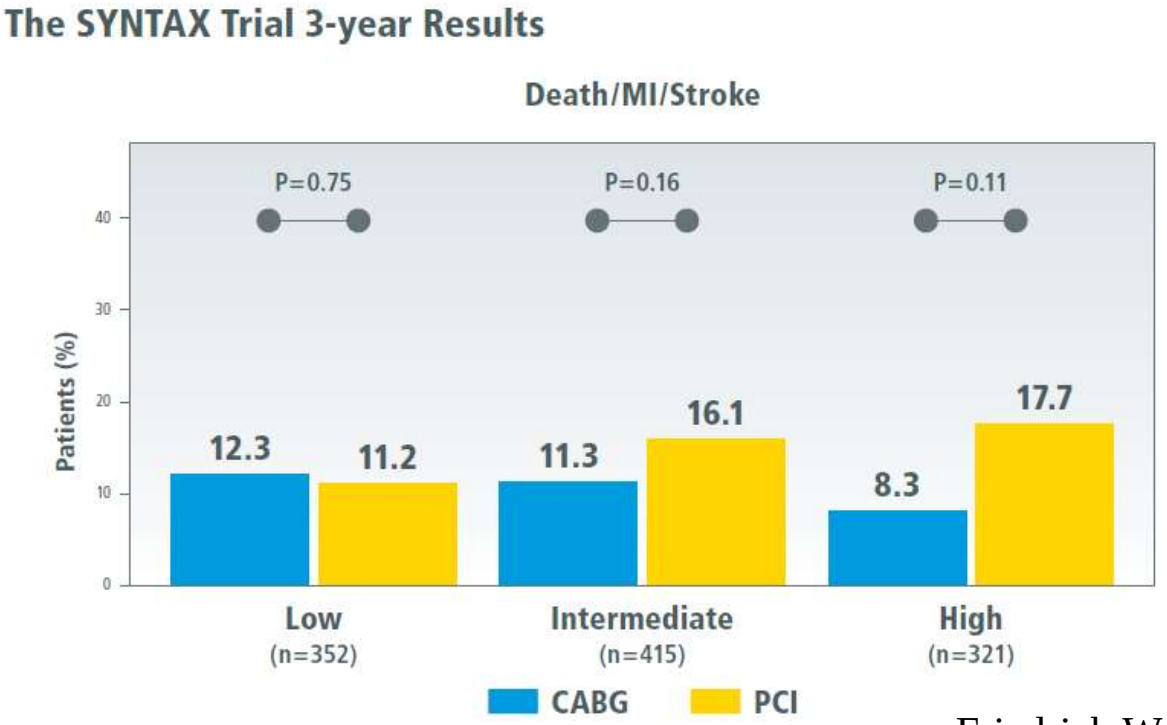
- Three-year results from the SYNTAX trial showed that excess risk of PCI relative to CABG was significant in terms of all-cause death and a composite of Death/MI/Stroke in the triple vessel disease subset.



A.P.Kappetein et al. Eur Heart J. 2011

Background

- The SYNTAX trial also suggested that PCI was associated with higher risk for Death/MI/Stroke in patients with intermediate or high SYNTAX Score, but not in those with low SYNTAX Score.
- However, the limitation of this observation in the SYNTAX trial was apparent lack of statistical power in evaluating this endpoint.



Friedrich W. Mohr et al. TCT 2010

CREDO-KYOTO PCI / CABG Registry Cohort-2

PCI arm ***total 13087 patients***

CABG arm ***total 2176 patients***

- ***Consecutive Patients Undergoing First Coronary Revascularization***
- ***During January, 2005 and December, 2007***
  after approval of DES in Japan
- ***Multi-center Registry among 26 centers in Japan***

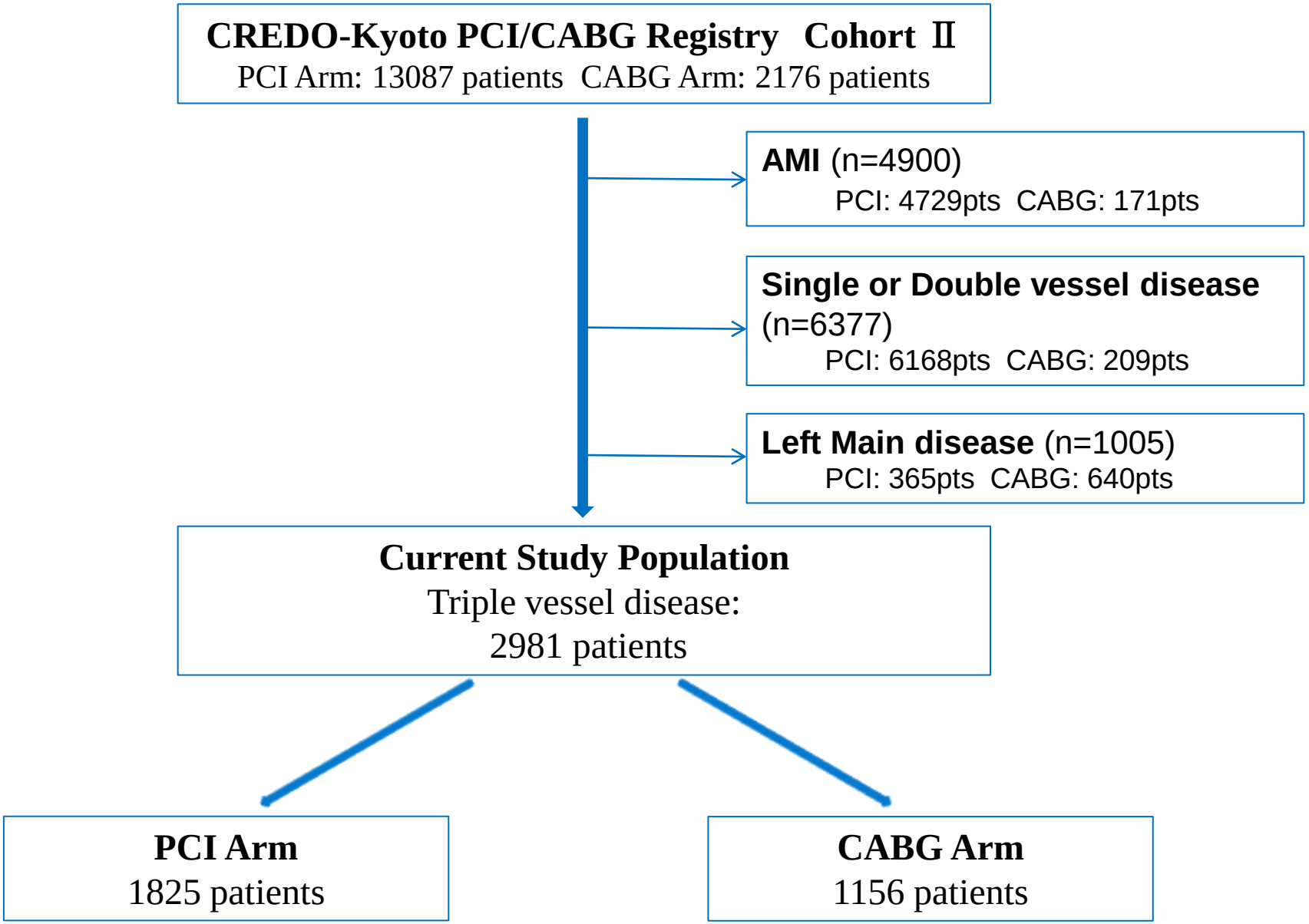
CREDO-Kyoto PCI/CABG Registry Cohort-2
Participating 26 centers and Investigators:

Centers	Investigators		
Kansai Denryoku Hospital	Katsuhisa Ishii		
Kishiwada City Hospital	Mitsuo Matsuda	Masahiko Onoe	Hirokazu Mitsuoka
Kyoto University Hospital	Takeshi Kimura	Ryuzo Sakata	Akira Marui
Nara Hospital, Kinki University School of Medicine	Manabu Shirotani	Noboru Nishiwaki	
Kumamoto University Hospital	Hisao Ogawa	Michio Kawasuji	Seigo Sugiyama
Koto Memorial Hospital	Tomoyuki Murakami	Teruki Takeda	
Mitsubishi Kyoto Hospital	Shinji Miki	Hiroyuki Nakajima	
Shimada Municipal Hospital	Takeshi Aoyama	Makoto Araki	
Shiga University of Medical Science Hospital	Minoru Horie	Hiroyuki Takashima	
Kagoshima University Medical and Dental Hospital	Chuwa Tei	Hiroyuki Yamamoto	
Juntendo University Shizuoka Hospital	Satoru Suwa		
Kokura Memorial Hospital	Masakiyo Nobuyoshi	Hitoshi Okabayashi	Michiya Hanyu
Kobe City Medical Center General Hospital	Toru Kita	Yutaka Furukawa	Yukikatsu Okada
Nishi-Kobe Medical Center	Hiroshi Kato	Hiroshi Eizawa	

CREDO-Kyoto PCI/CABG Registry Cohort-2
Participating 26 centers and Investigators:

Centers	Investigators		
Shizuoka General Hospital	Osamu Doi	Hirofumi Kambara	Katsuhiko Matsuda
Shizuoka City Shizuoka Hospital	Akinori Takizawa	Mitsuomi Shimamoto	Fumio Yamazaki
Kurashiki Central Hospital	Kazuaki Mitsudo	Tatsuhiko Komiya	Kazushige Kadota
Osaka Red Cross Hospital	Masaru Tanaka		
Tenri Hospital	Yoshihisa Nakagawa	Ichiro Yamanaka	
Shimabara Hospital	Mamoru Takahashi		
Japanese Red Cross Society Wakayama Medical Center	Takashi Tamura	Masaki Aota	
Hamamatsu Rosai Hospital	Masaaki Takahashi	Junichiro Nishizawa	Hiroshi Kanda
Maizuru Kyosai Hospital	Ryozo Tatami	Masayuki Kato	
Fukui University Hospital	Jong-Dae Lee	Takaaki Koshiji	Akira nakano
Hyogo Prefectural Amagasaki Hospital	Yoshiki Takatsu	Nobuhisa Ohno	Ryoji Taniguchi
Kitano Hospital	Ryuji Nohara	Kunihiko Nagai	

Study Flow Chart



Primary Outcome Measure

- ***Composite of Death, MI and Stroke***

Secondary Outcome Measures

- ***Death***
- ***Cardiac Death***
- ***MI***
- ***Stroke***
- ***Any Coronary Revascularization***

Baseline Characteristics

	PCI	CABG	p value
Number of patients	1825	1156	
Age (years)	69.7±10.0	68.0±8.9	< .001
Age >= 75 years	642 (35%)	305 (26%)	< .001
Male	1295 (71%)	846 (73%)	.19
BMI	23.8±3.6	23.5±3.3	.005
Acute coronary syndrome	182 (10%)	96 (8.3%)	.12
Hypertension	1594 (87%)	972 (84%)	.01
Diabetes mellitus	911 (50%)	644 (56%)	.002
on insulin therapy	252 (14%)	216 (19%)	< .001
Current smoking	462 (25%)	280 (24%)	.50
Heart failure	378 (21%)	256 (22%)	.35

CREDO-KYOTO PCI/CABG Registry Cohort-2

Baseline Characteristics

	PCI	CABG	p value
Number of patients	1825	1156	
Ejection fraction <= 40%	198 (12%)	162 (15%)	.07
Prior myocardial infarction	345 (19%)	291 (25%)	< .001
Prior stroke (symptomatic)	292 (16%)	173 (15%)	.45
Peripheral vascular disease	211 (12%)	151 (13%)	.22
eGFR <30,without hemodialysis	103 (5.6%)	101 (8.7%)	.001
Hemodialysis	98 (5.4%)	75 (6.5%)	.21
Anemia (Hb <11.0g/dl)	284 (16%)	219 (19%)	.02
COPD	60 (3.3%)	25 (2.2%)	.07
Malignancy	192 (11%)	119 (10%)	.84

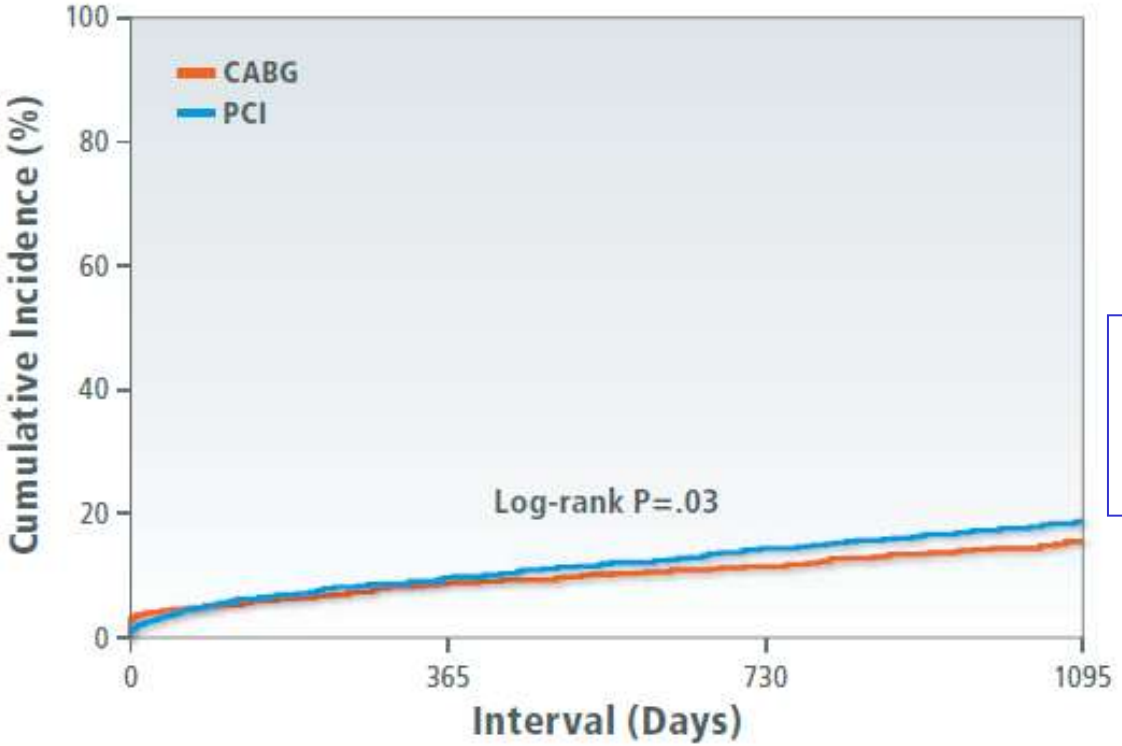
CREDO-KYOTO PCI/CABG Registry Cohort-2

Procedural Characteristics

	PCI	CABG	p value
Number of target lesions or anastomoses	2.05±0.99	3.44±1.05	< .001
Target of proximal LAD	1173 (64%)	1120 (97%)	< .001
Target of CTO	416 (23%)	594 (51%)	< .001
Target of bifurcation	701 (38%)	—	—
Emergency procedure	104 (5.7%)	37 (3.2%)	.002
Total number of stents	2.81±1.66	—	—
Total stent length (mm)	62.0±40.0	—	—
Stent use	1725 (95%)	—	—
DES use	1326 (77%)	—	—
ITA use	—	1133 (98%)	—
Off pump	—	727 (63%)	—

CREDO-KYOTO PCI/CABG Registry Cohort-2

Primary Outcome Measure: Death/MI/Stroke

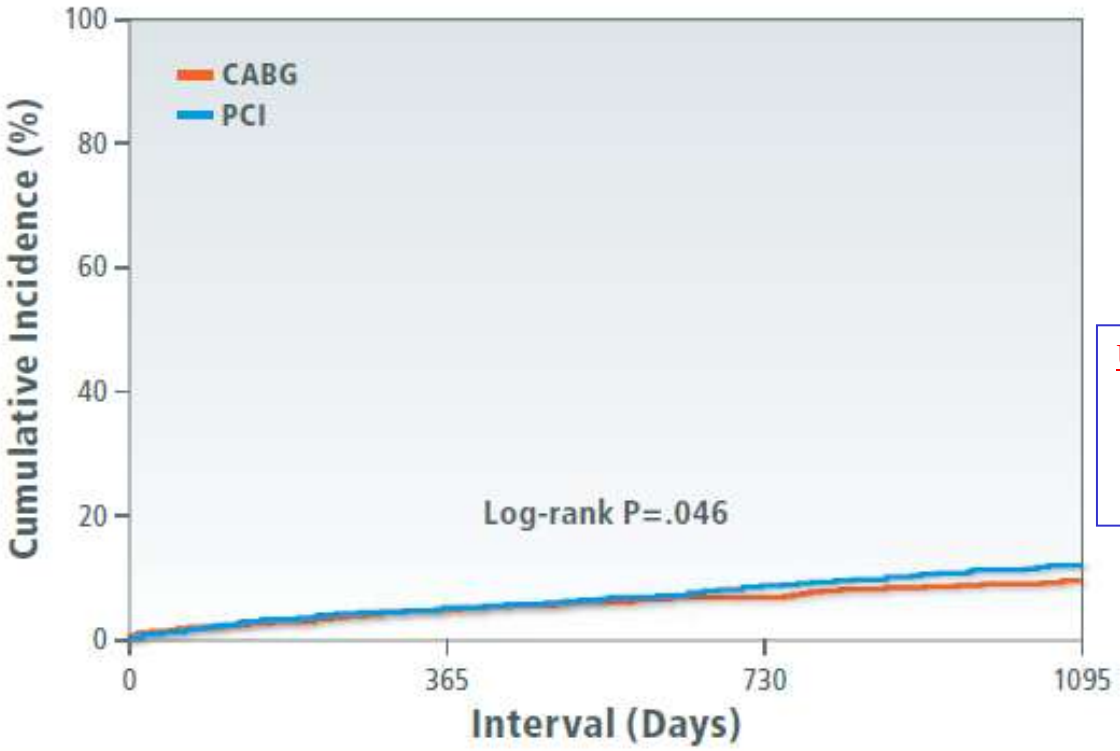


Unadjusted H.R. (95%C.I.)
1.23 (1.02-1.49)
Adjusted H.R. (95%C.I.)
1.47 (1.13-1.92)

Interval	0 Day	30 Days	1 Year	2 Years	3 Years
CABG group					
N of events		44	95	123	153
N of patientus at risk	1156	1095	999	823	470
Incidence		3.8%	8.4%	11.1%	15.2%
PCI group					
N of events		46	167	244	289
N of pts at risk	1825	1757	1596	1217	629
Incidence		2.5%	9.3%	14.0%	18.3%

CREDO-KYOTO PCI/CABG Registry Cohort-2

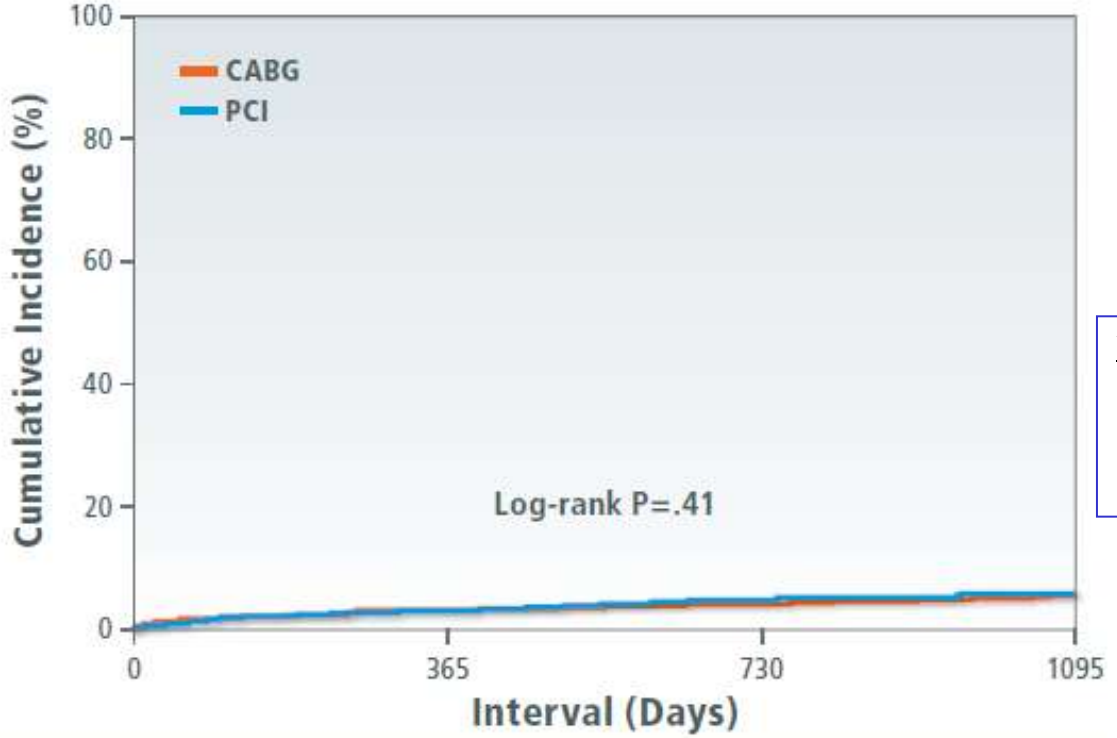
All-cause Death



Unadjusted H.R. (95%C.I.)
1.27 (1.007-1.62)
Adjusted H.R. (95%C.I.)
1.62 (1.16-2.27)

Interval	0 Day	30 Days	1 Year	2 Years	3 Years
CABG group					
N of events		12	52	73	93
N of patientus at risk	1156	1126	1038	864	500
Incidence		1.0%	4.7%	6.6%	9.3%
PCI group					
N of events		11	86	143	179
N of pts at risk	1825	1792	1670	1285	673
Incidence		0.6%	4.8%	8.4%	11.7%

Cardiac Death

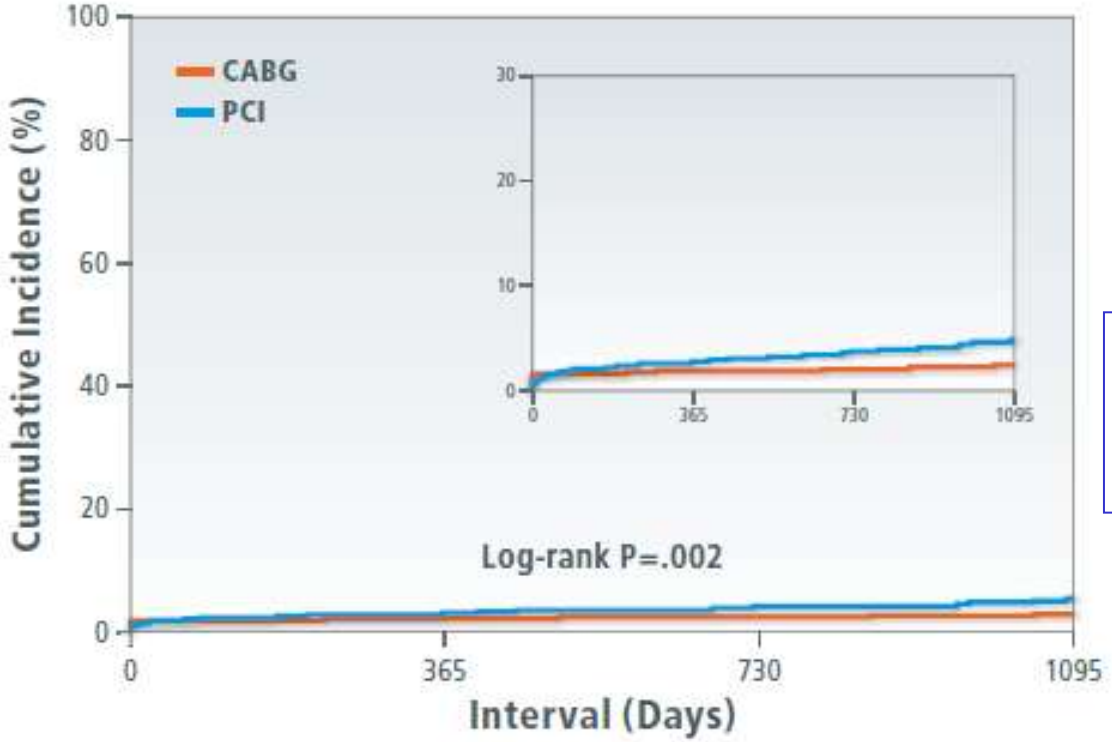


Unadjusted H.R. (95%C.I.)
1.15 (0.87-1.60)
Adjusted H.R. (95%C.I.)
1.30 (0.81-2.07)

Interval	0 Day	30 Days	1 Year	2 Years	3 Years
CABG group					
N of events		12	33	43	53
N of patientus at risk	1156	1126	1038	864	500
Incidence		1.0%	3.0%	3.9%	5.4%
PCI group					
N of events		9	51	83	90
N of pts at risk	1825	1792	1670	1285	673
Incidence		0.5%	2.9%	4.9%	5.6%

CREDO-KYOTO PCI/CABG Registry Cohort-2

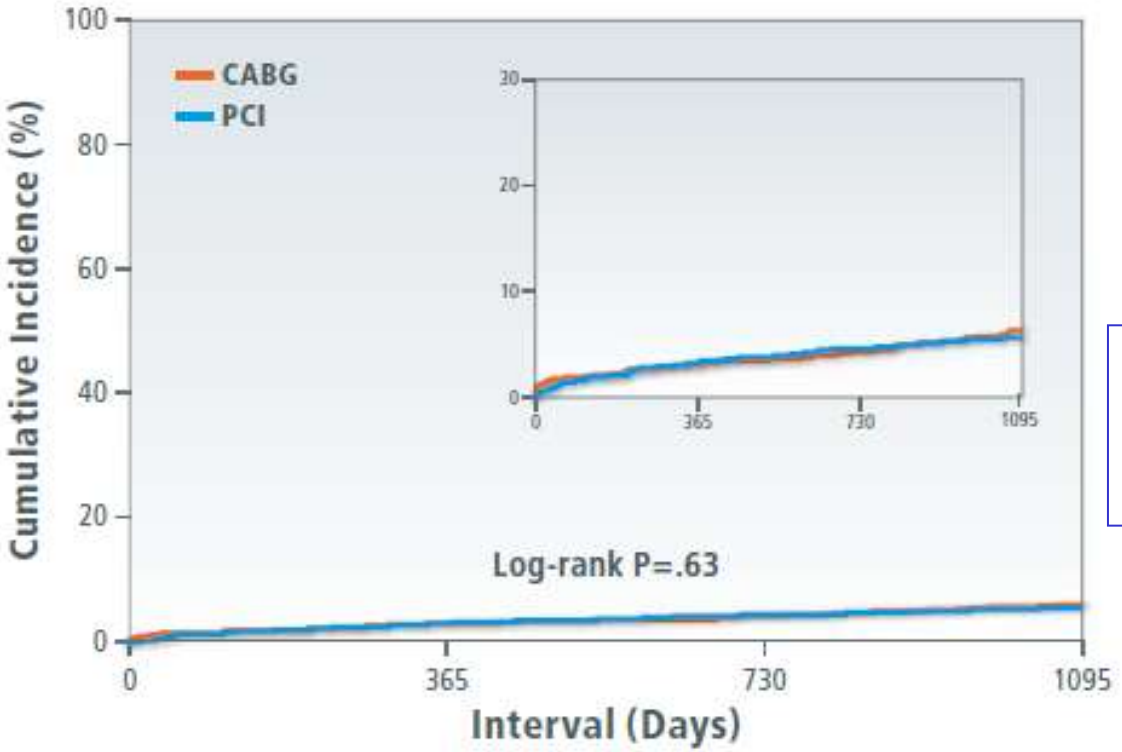
Myocardial Infarction



Unadjusted H.R. (95%C.I.)
1.96 (1.29-3.09)
Adjusted H.R. (95%C.I.)
2.39 (1.31-4.36)

Interval	0 Day	30 Days	1 Year	2 Years	3 Years
CABG group					
N of events		19	22	24	26
N of patients at risk	1156	1110	1023	851	490
Incidence		1.6%	1.9%	2.1%	2.5%
PCI group					
N of events		25	50	66	76
N of patients at risk	1825	1766	1631	1252	653
Incidence		1.4%	2.8%	3.9%	5.0%

Stroke



Unadjusted H.R. (95%C.I.)
0.93 (0.67-1.28)
Adjusted H.R. (95%C.I.)
1.01 (0.64-1.60)

Interval	0 Day	30 Days	1 Year	2 Years	3 Years
CABG group					
N of events		18	36	47	60
N of patients at risk	1156	1110	1013	834	480
Incidence		1.6%	3.2%	4.4%	6.3%
PCI group					
N of events		13	60	80	90
N of patients at risk	1825	1778	1633	1249	648
Incidence		0.7%	3.4%	4.7%	5.7%

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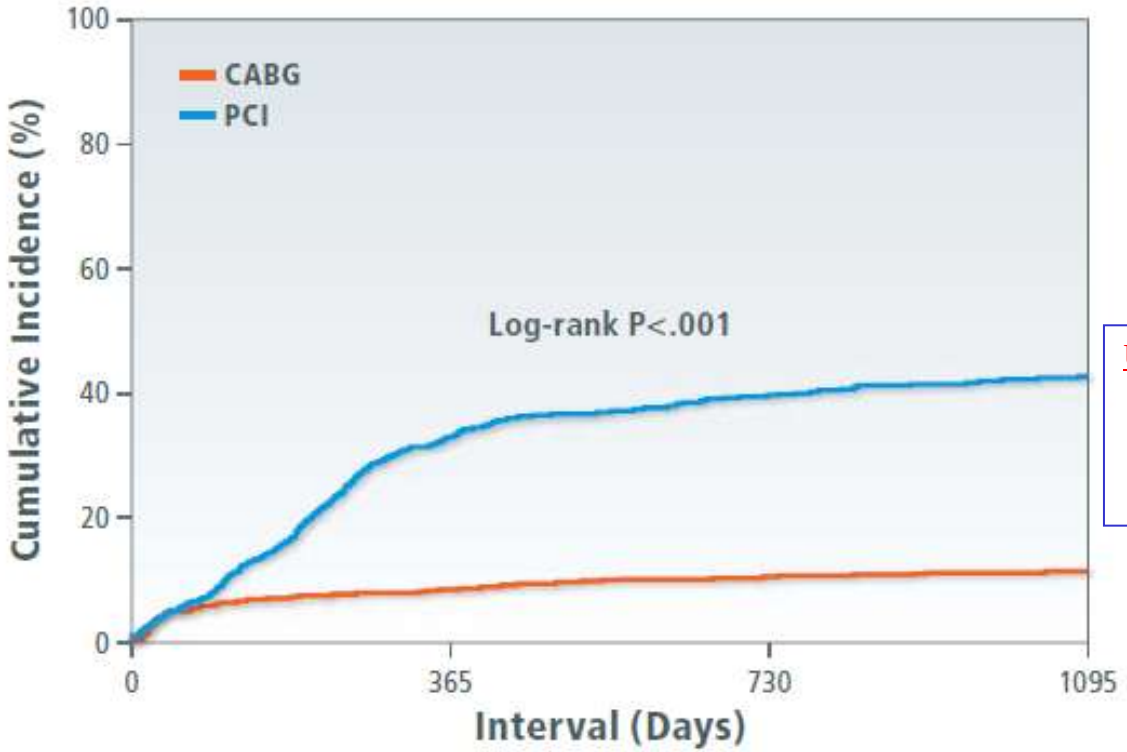
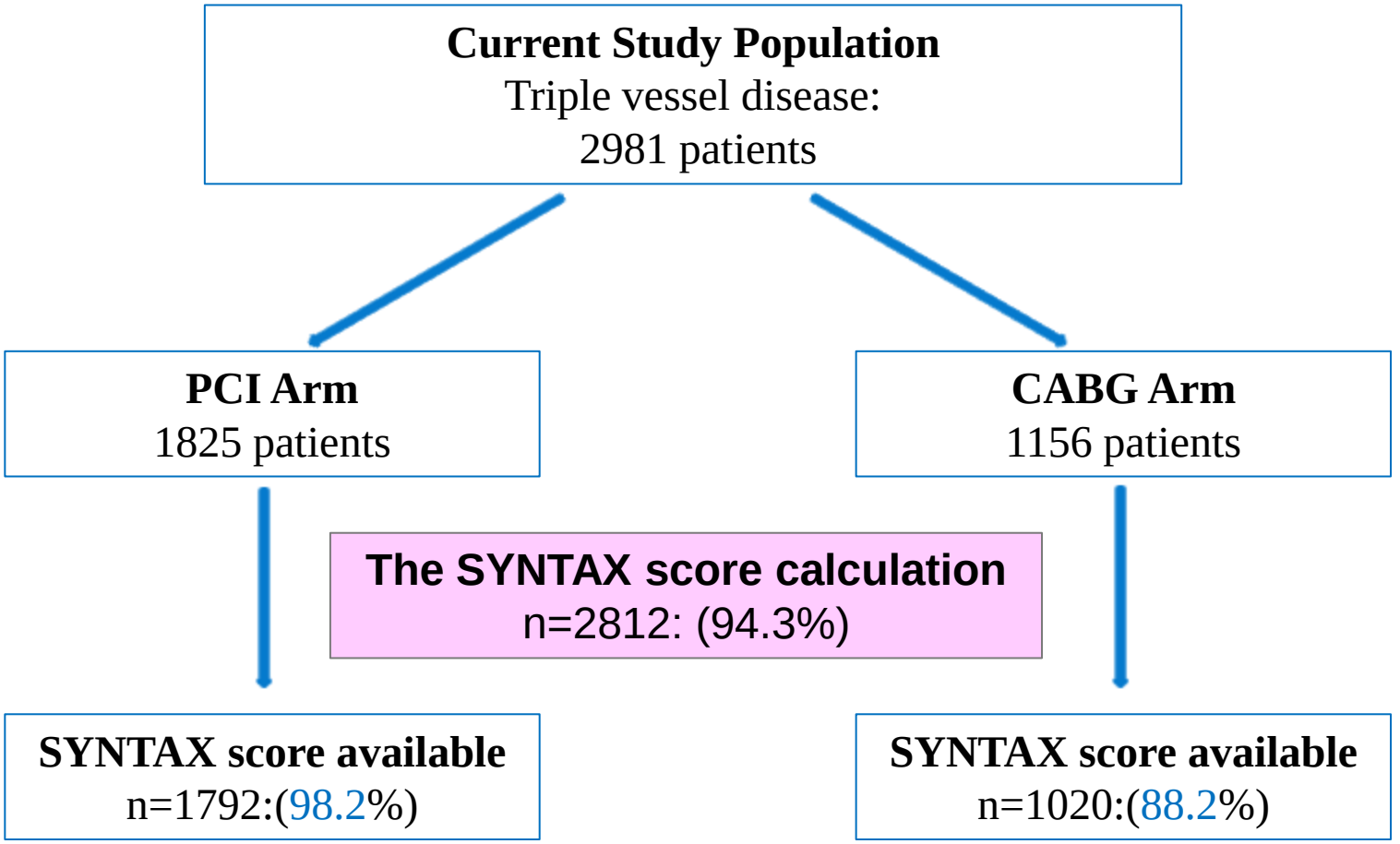
Any Revascularization



Unadjusted H.R. (95%C.I.)
4.43 (3.67-5.39)
Adjusted H.R. (95%C.I.)
4.47 (3.53-5.65)

Interval	0 Day	30 Days	1 Year	2 Years	3 Years
CABG group					
N of events		38	92	112	118
N of patientus at risk	1156	1088	956	778	441
Incidence		3.3%	8.3%	10.3%	11.2%
PCI group					
N of events		62	567	672	703
N of pts at risk	1825	1732	1123	778	367
Incidence		3.4%	32.7%	39.4%	42.5%

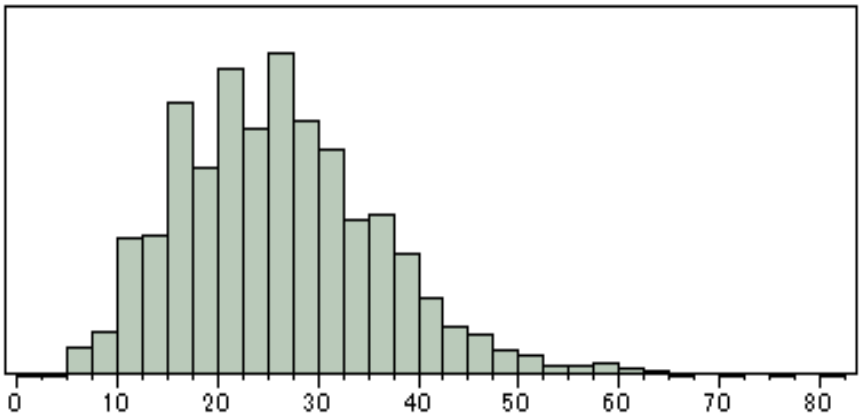
Stratified Analysis by the SYNTAX Score



- The SYNTAX score was calculated by the dedicated SYNTAX score committee.
- All analysis were conducted in a blinded fashion to the clinical data.

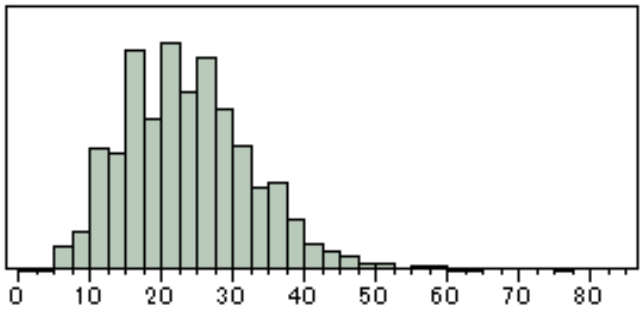
SYNTAX Score Distribution

Entire Cohort (n=2812:94.3%)



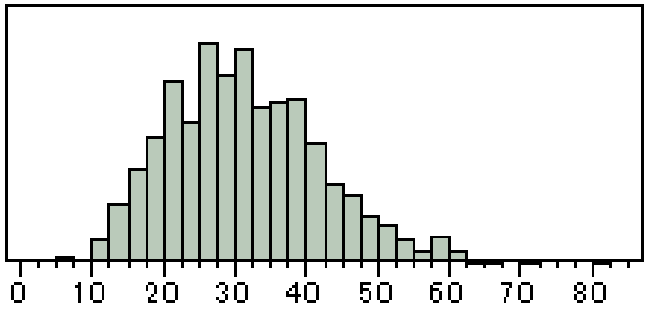
Mean score: 25.9 ± 10.2

PCI arm (n=1792:98.2%)



Mean score: 23.6 ± 9.2

CABG arm (n=1020:88.2%)



Mean score: 30.0 ± 10.5

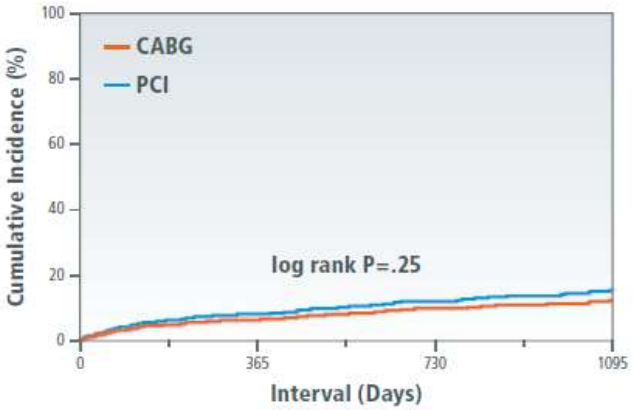
CREDO-KYOTO PCI/CABG Registry Cohort-2

Crude analysis

Death/MI/Stroke

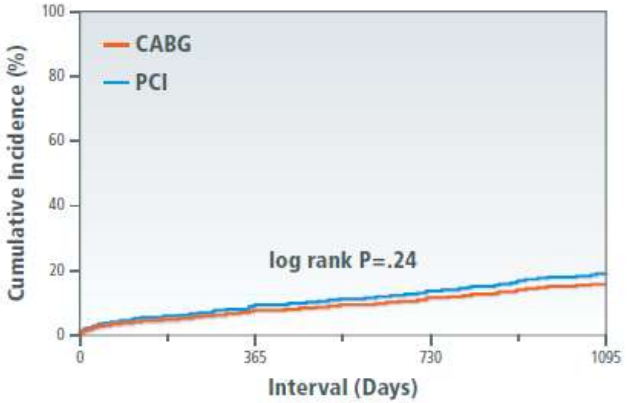
Low SYNTAX Score (<23)

Unadjusted H.R. (95%C.I.): 1.26 (0.86-1.92)



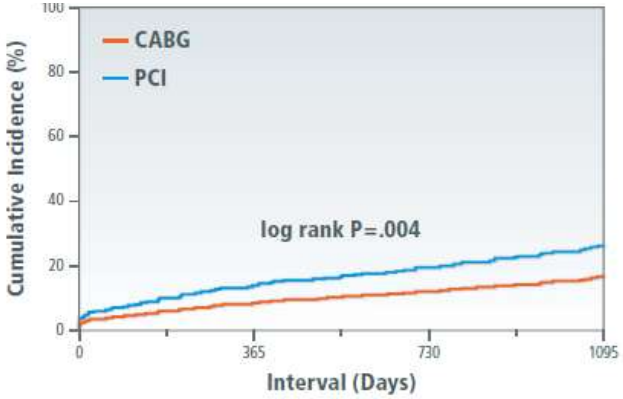
Intermediate SYNTAX Score (23≤ - <33)

Unadjusted H.R. (95%C.I.): 1.21 (0.88-1.66)



High SYNTAX Score (≥33)

Unadjusted H.R. (95%C.I.): 1.68 (1.18-2.39)



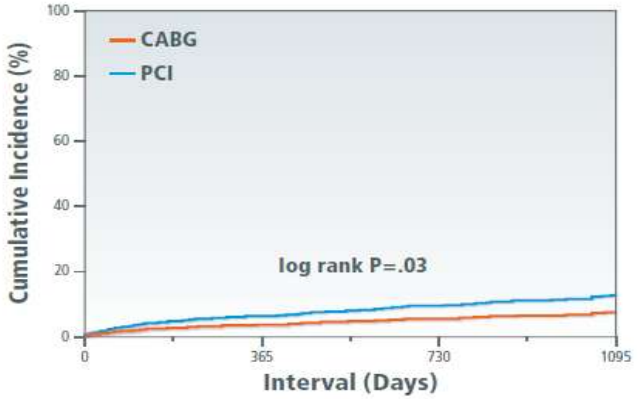
CREDO-KYOTO PCI/CABG Registry Cohort-2

Adjusted analysis

Death/MI/Stroke

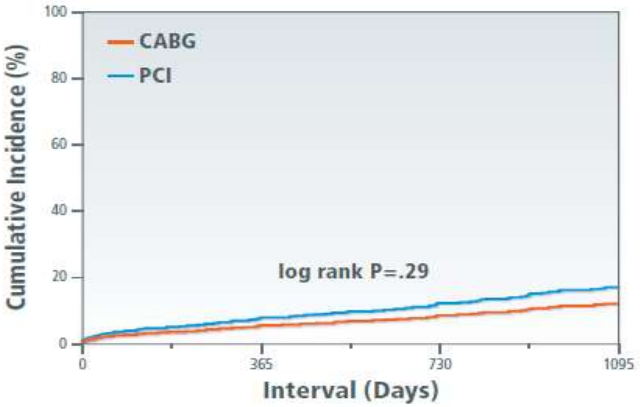
Low SYNTAX Score (<23)

Adjusted H.R. (95%C.I.): 1.66 (1.04-2.65)



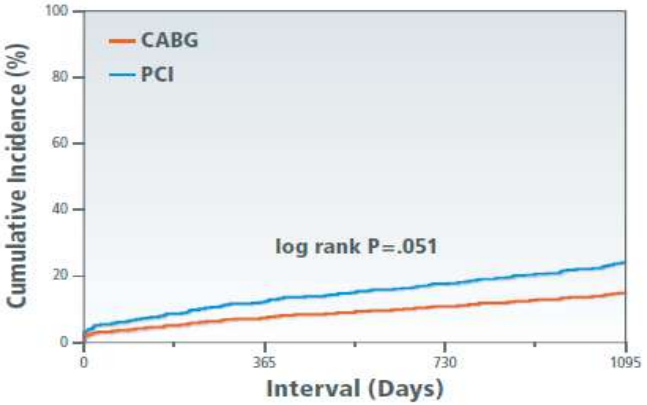
Intermediate SYNTAX Score (23≤ - <33)

Adjusted H.R. (95%C.I.): 1.24 (0.83-1.85)



High SYNTAX Score (≥33)

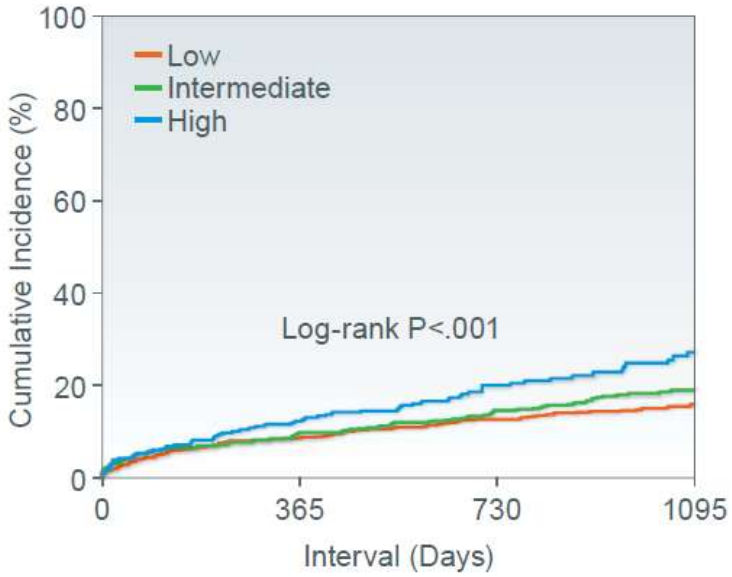
Adjusted H.R. (95%C.I.): 1.59 (0.998-2.54)



CREDO-KYOTO PCI/CABG Registry Cohort-2

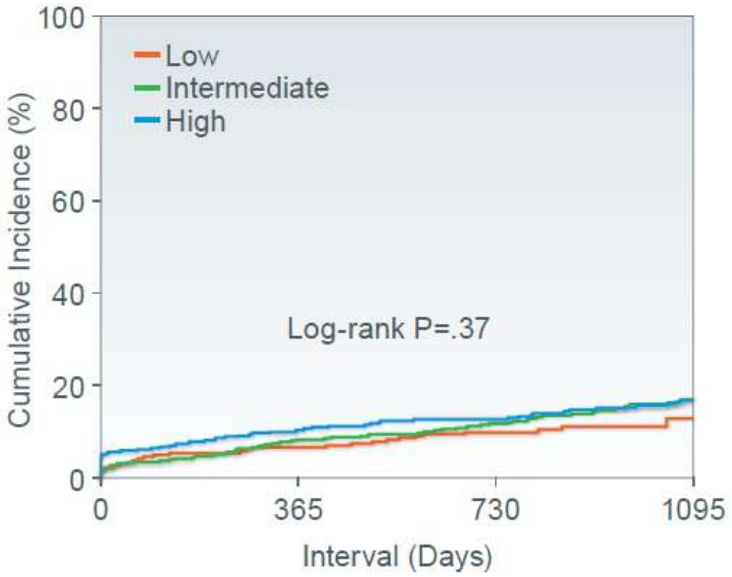
Death/MI/Stroke

PCI Arm



Interval	0 Day	30 Days	1 Year	2 Years	3 Years
Low					
N of events		17	73	105	122
N of patients at risk	874	847	779	607	306
Incidence		2.0%	8.5%	12.5%	15.8%
Intermediate					
N of events		19	60	86	103
N of patients at risk	638	613	554	412	216
Incidence		3.0%	9.6%	14.3%	18.8%
High					
N of events		10	33	52	63
N of patients at risk	280	265	233	170	91
Incidence		3.6%	12.1%	19.8%	27.0%

CABG Arm



Interval	0 Day	30 Days	1 Year	2 Years	3 Years
Low					
N of events		6	16	24	28
N of patients at risk	257	250	230	184	98
Incidence		2.3%	6.3%	9.7%	12.5%
Intermediate					
N of events		10	30	42	55
N of patients at risk	388	373	335	280	152
Incidence		2.6%	8.0%	11.5%	16.7%
High					
N of events		20	37	45	55
N of patients at risk	375	348	320	265	153
Incidence		5.3%	10.1%	12.4%	16.4%

CREDO-KYOTO PCI/CABG Registry Cohort-2

Summary

- Consistent with the observation in the SYNTAX randomized trial, PCI as compared with CABG was associated with significantly higher risk for serious adverse events in patients with TVD.

- The excessive mortality in the PCI group was mostly driven by the excess of non-cardiac death, while the risk for cardiac death was similar between PCI and CABG.

- Protective effect of CABG for myocardial infarction was particularly remarkable.

Summary

- Clinical outcome after PCI was adversely influenced by the increasing SYNTAX scores, while outcome after CABG was not affected by complexity of coronary anatomy.

- Unadjusted risk for serious adverse events was not significantly different between PCI and CABG in the SYNTAX score low and intermediate tertiles.

- However, adjusted analysis suggested that PCI as compared with CABG was associated with significantly higher risk for serious adverse events even in patients with low SYNTAX score tertile.

Conclusions

- CABG would still remain the standard treatment option in patients with TVD, particularly when their SYNTAX scores are high.

- Use of PCI in patients with high SYNTAX score should be seriously discouraged unless the operative risk is prohibitively high.

- Selection of revascularization strategies in TVD patients with less complex coronary anatomy deserves further consideration.