Very Long-term (>10 Years) Follow-up After PCI and CABG:

Observations from CREDO-Kyoto PCI/CABG Registry Cohort-1 and -2

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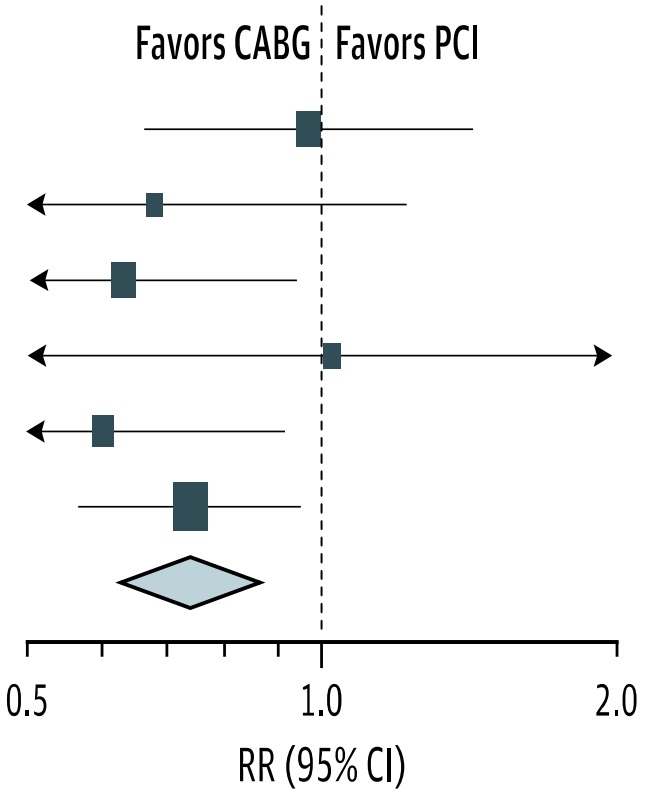
Nothing to disclose.

Meta-analysis of RCTs comparing PCI versus CABG in Multivessel CAD: BMS/DES Era

Mortality

Source	Statistics for Each Study				Death/Total	
	RR (95% CI)		*Z* Value	*P* Value	CABG	PCI
ARTS[10,11]	0.97	(0.66-1.43)	-0.16	.87	46/584	48/590
MASS II[6]	0.67	(0.37-1.23)	-1.29	.20	16/203	24/205
SoS[2,15]	0.63	(0.41-0.95)	-2.23	.03	34/500	53/488
CARDia[7]	1.02	(0.39-2.69)	0.05	.96	8/242	8/248
SYNTAX multivessel[9,12]	0.60	(0.39-0.92)	-2.36	.02	31/547	52/548
FREEDOM[16]	0.73	(0.56-0.95)	-2.31	.02	86/947	118/953
Meta-analysis	**0.73**	**(0.62-0.86)**	**-3.69**	**<.001**	**221/3023**	**303/3032**



Sipahi I, et al. JAMA Intern Med. 2014.

RCT and Registry in Comparing PCI versus CABG

・RCT is the gold standard to compare the clinical outcomes after PCI and CABG.

・However, external validity of the findings from RCTs might be severely hampered by their exclusion criteria and the variations in ethnic, demographic, and procedural characteristics in the real clinical practice.

・Registry would be complementary to RCT in comparing PCI and CABG in the real world clinical practice.

CREDO-KYOTO PCI / CABG Registry

(Coronary REvascularization Demonstrating Outcome Study in Kyoto)

Multicenter registry enrolling consecutive patients with first coronary revascularization

Cohort 1: 2000-2002 BMS Era (N=9877, 30 centers)

Excluding patients presenting with acute myocardial infarction

Isolated Coronary Revascularization	9393 patients
PCI	6878 patients
Stent Use	82%
Isolated CABG	2515 patients
IMA Use	94 %

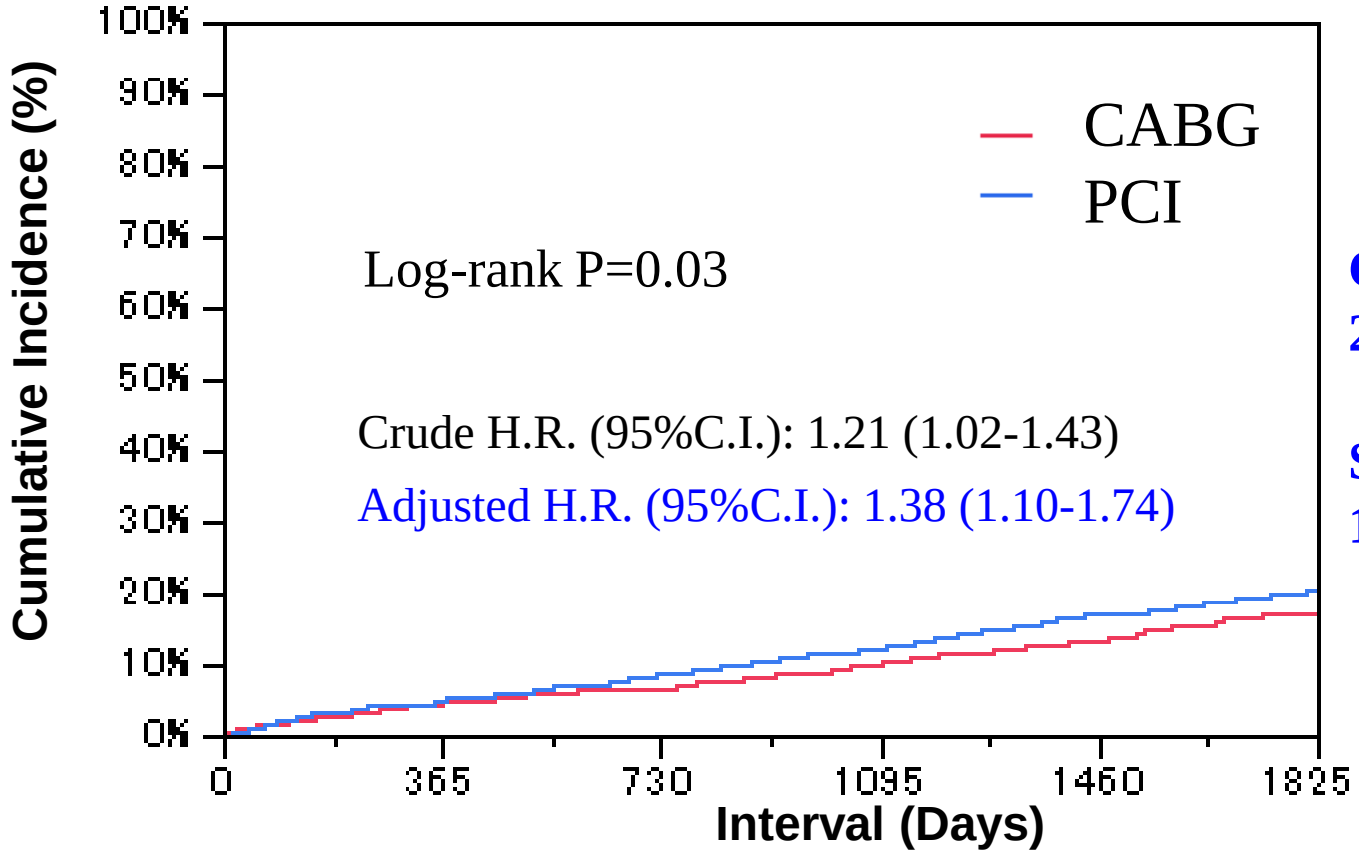
Cohort 2: 2005-2007 G-1 DES Era (N=15939, 26 centers)

Including presenting withacute myocardial infarction

Isolated Coronary Revascularization	15331 patients
PCI	13058 patients
Stent Use	93%
DES Use	53%
Isolated CABG	2173 patients
IMA Use	97 %

CREDO-Kyoto Registry Cohort-2

All-cause Death: 3VD Stratum



CREDO
20.5% vs. 17.5%

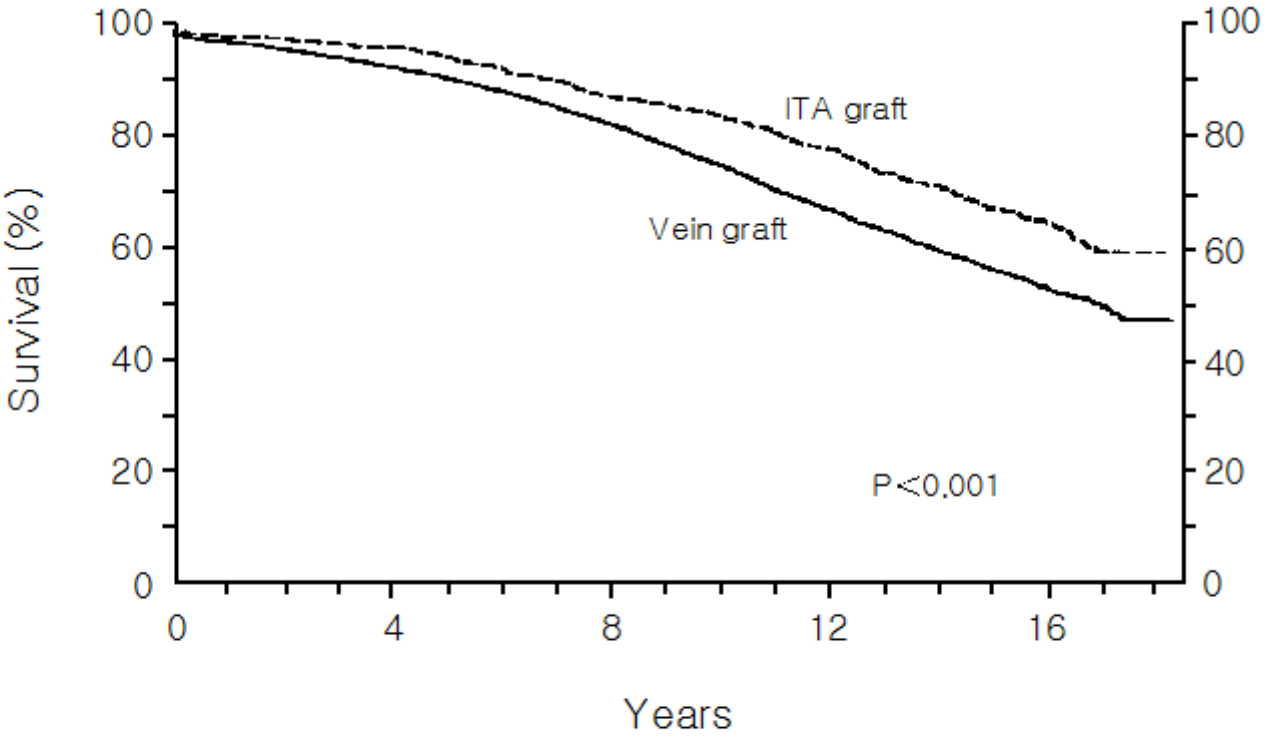
SYNTAX
14.6% vs. 9.2%

Interval	0 day	30 days	1 year	2 years	3 years	4 years	5 years
CABG group							
N of events		12	54	78	114	149	189
N of patients at risk	1154	1132	1064	1027	981	934	653
Incidence		1.0%	4.8%	6.9%	10.2%	13.4%	17.5%
PCI group							
N of events		13	94	156	222	302	353
N of patients at risk	1824	1804	1701	1623	1536	1435	932
Incidence		0.7%	5.2%	8.7%	12.4%	17.0%	20.5%

Shiomi H, et al. Am J Cardiol 2015.

Fifteen Years Follow-up after CABG from the CASS Registry

Internal Thoracic Artery Graft versus Saphenous Vein Grafts Only



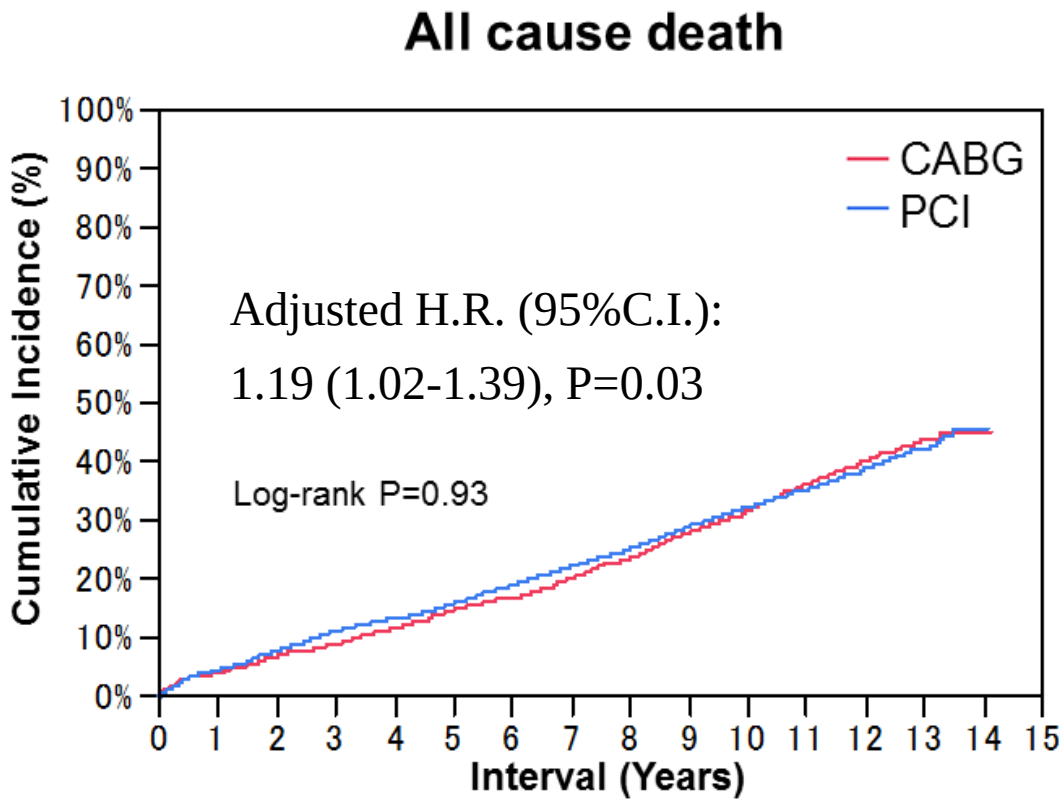
	No. (%) Surviving				
Vein graft	4888 (100)	4495 (92)	3996 (82)	3199 (67)	1008 (53)
ITA graft	749 (100)	715 (95)	649 (87)	576 (77)	288 (64)

Survival benefit of ITA grafts relative to SVG grafts become apparent beyond several years after CABG. Therefore, 5 years may be too short to demonstrate the true survival benefit of CABG over PCI. However, there is a paucity of data on very long-term follow-up beyond 5-year after PCI and CABG.

Cameron A, et al. NEJM 1996.

CREDO-Kyoto Cohort-1 Extended 10- to 14-Year FU

PCI versus CABG for MVD excluding LMCA disease

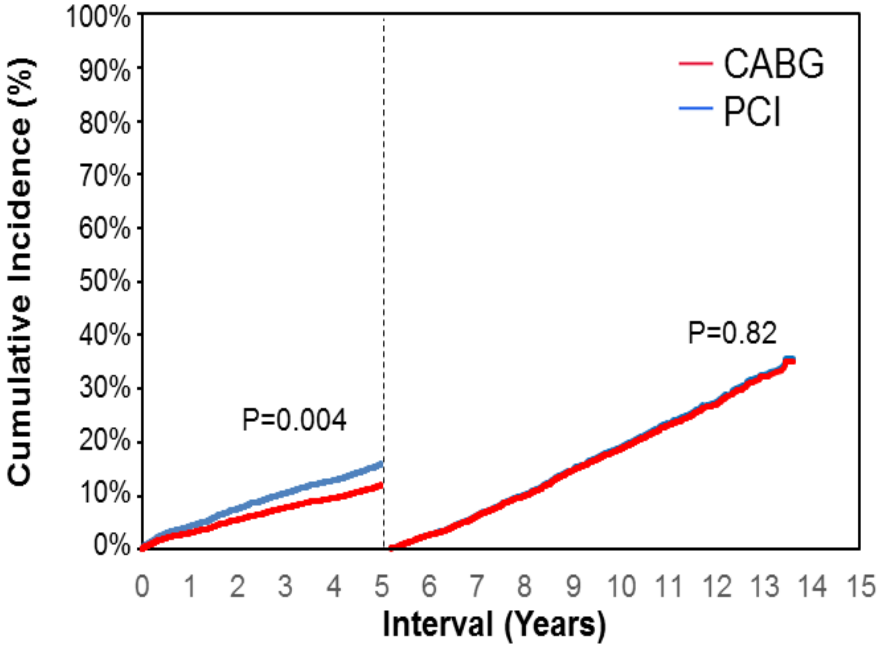


Interval	0 day	30 days	1 year	3 years	5 years	7 years	10 years	12 years	14 years
PCI									
N of patients with at least 1 event		26	157	383	536	726	1019	1156	1189
N of patients at risk	3490	3455	3288	2952	2656	2324	1925	717	4
Cumulative incidence		0.8%	4.5%	11.2%	15.9%	22.1%	32.2%	38.7%	45.5%
CABG									
N of patients with at least 1 event		18	66	147	234	314	475	562	578
N of patients at risk	1662	1639	1578	1443	1271	1138	933	351	1
Cumulative incidence		1.1%	4.0%	9.0%	14.6%	20.2%	31.7%	39.9%	44.9%

CREDO-Kyoto Cohort-1 Extended 10- to 14-Year FU

PCI versus CABG for MVD excluding LMCA disease

Adjusted risk for death: Within 5-year and Beyond 5-Year

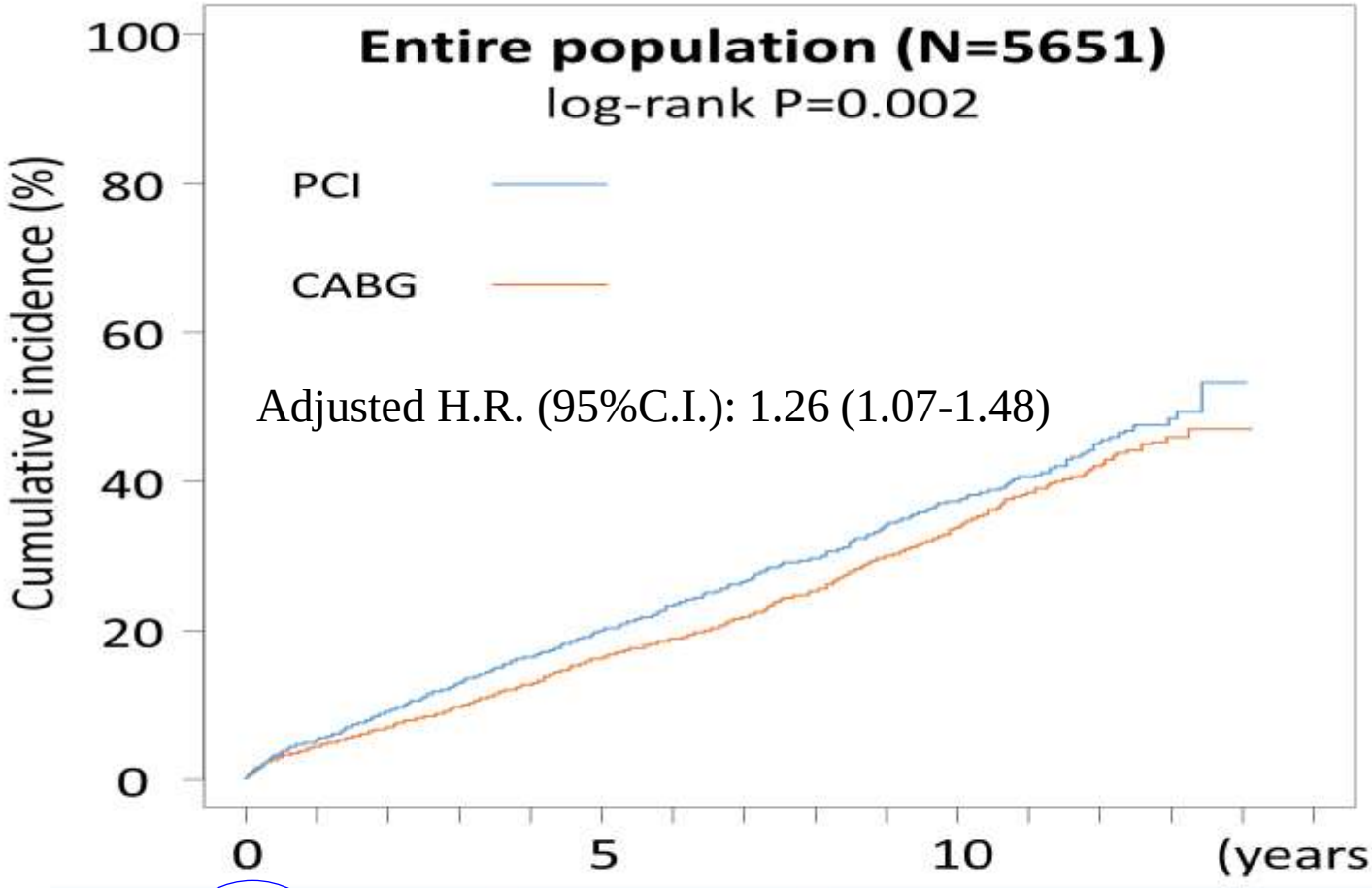


Interval	0 day	30 days	1 year	5 years	6 years	8 years	10 years	12 years
PCI								
Cumulative incidence		0.9%	4.3%	16.0%	3.1%	10.8%	19.6%	28.4%
CABG								
Cumulative incidence		0.6%	3.1%	12.0%	3.0%	10.5%	19.3%	27.9%

We did not see any late survival benefit of CABG over PCI with extended follow-up beyond 5-year. Therefore, selection of revascularization strategies based on the 5-year clinical trial results may be appropriate even considering the longer-term outcomes.

Pooled Analysis of CREDO-Kyoto Cohort-1 and -2

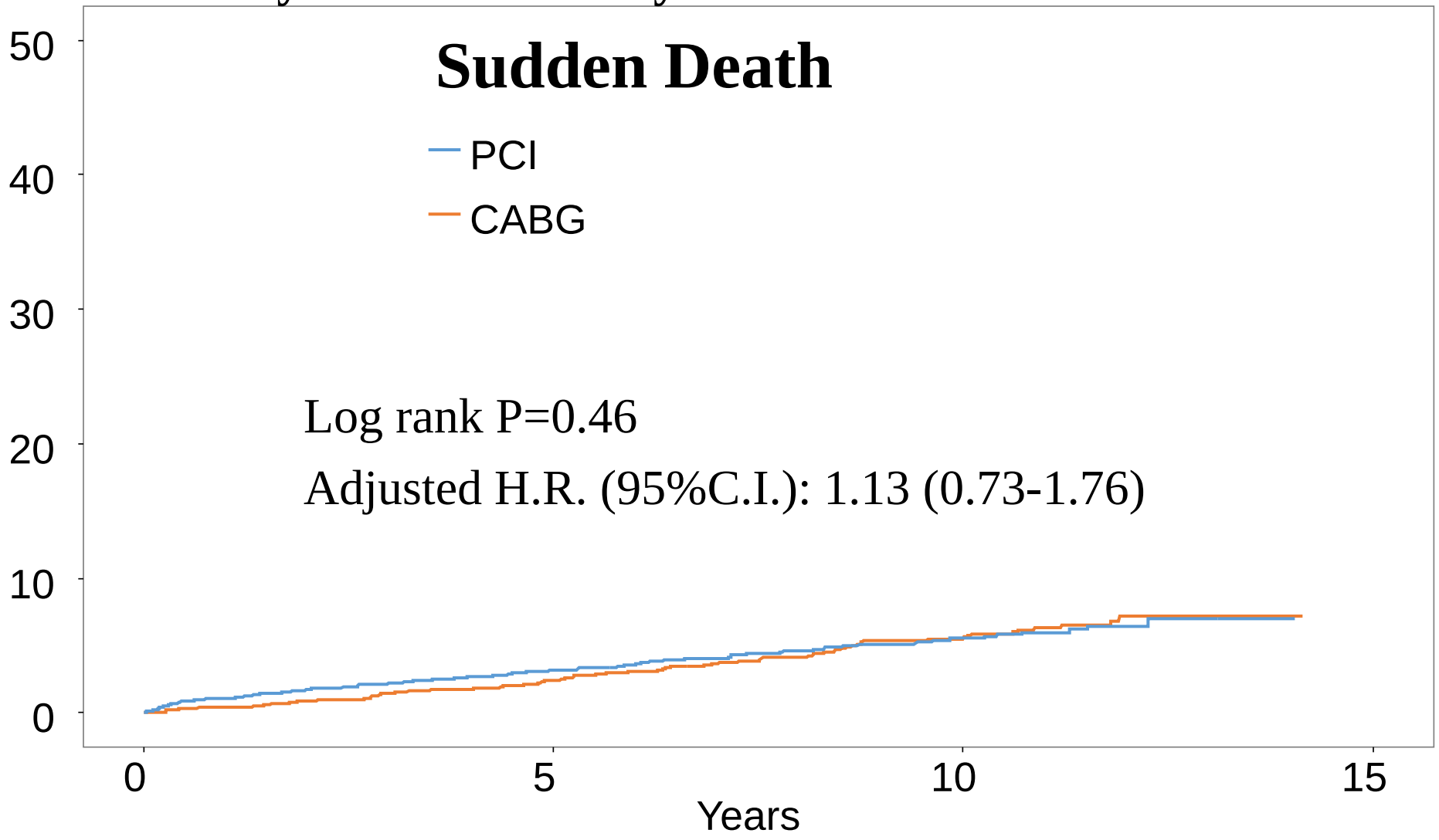
Mortality risk of PCI relative to CABG in TVD



		5 years	10 years	
PCI	0 (0.0%)	600 (20%)	839 (37%)	N of death
	3165	1908	692	N of patients at risk
CABG	0 (0.0%)	383 (16%)	606 (34%)	N of death
	2486	1670	732	N of patients at risk

Yamaji K, et al. Circulation. 2016.

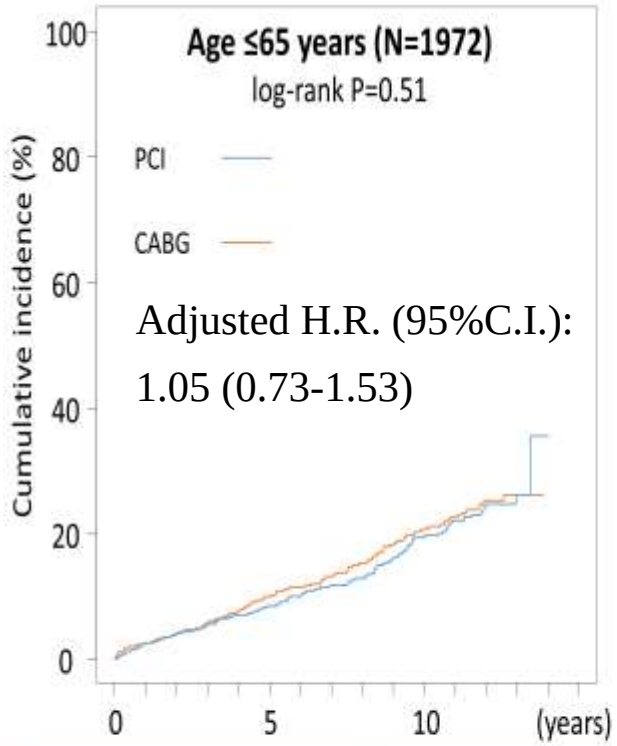
Pooled Analysis of CREDO-Kyoto Cohort-1 and -2



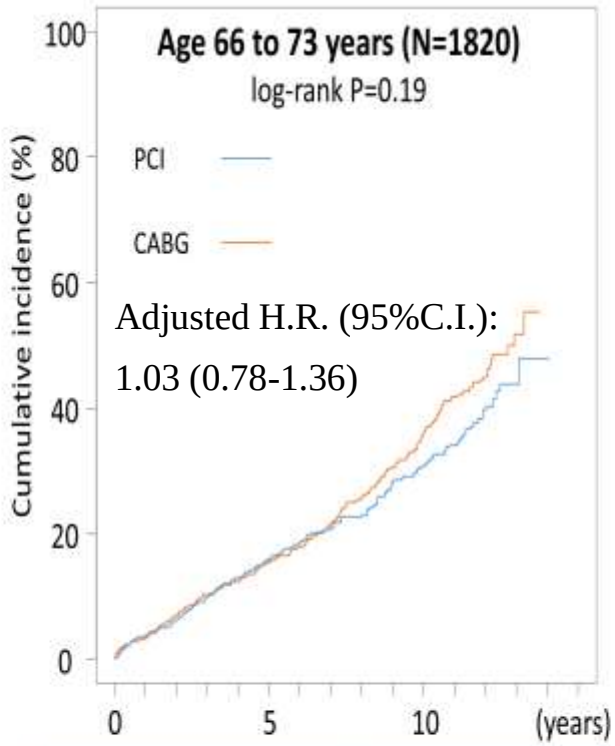
Years	0	5	10	
PCI	0 (0.0%)	89 (3.2%)	114 (5.5%)	N of events
	3165	1908	692	N at risk
CABG	0 (0.0%)	52 (2.4%)	85 (5.5%)	N of events
	2486	1670	732	N at risk

Pooled Analysis of CREDO-Kyoto Cohort-1 and -2

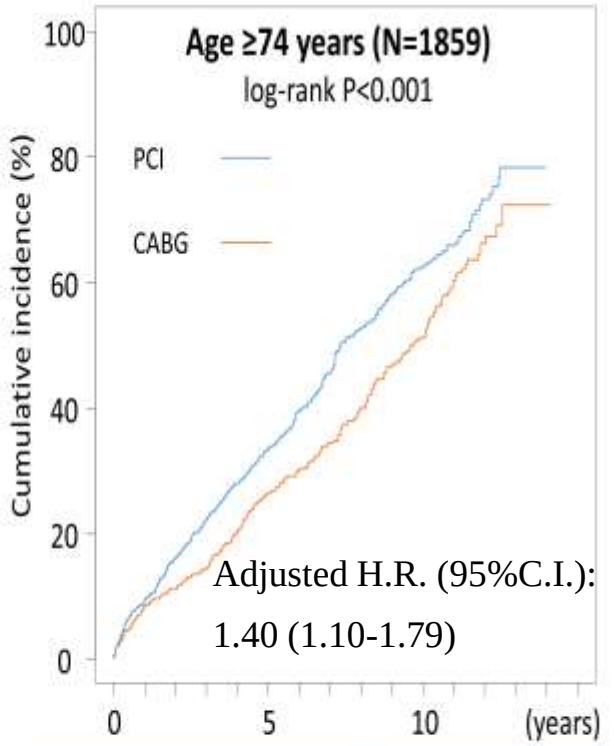
Mortality risk of PCI relative to CABG in TVD According to Age Categories



		5 years	10 years	
PCI	0 (0.0%)	84 (8.6%)	133 (19%)	N of death
	1033	715	312	N of patients at risk
CABG	0 (0.0%)	89 (10.0%)	143 (21%)	N of death
	939	686	358	N of patients at risk



		5 years	10 years	
PCI	0 (0.0%)	147 (16%)	214 (31%)	N of death
	964	637	266	N of patients at risk
CABG	0 (0.0%)	126 (15%)	220 (36%)	N of death
	856	593	258	N of patients at risk

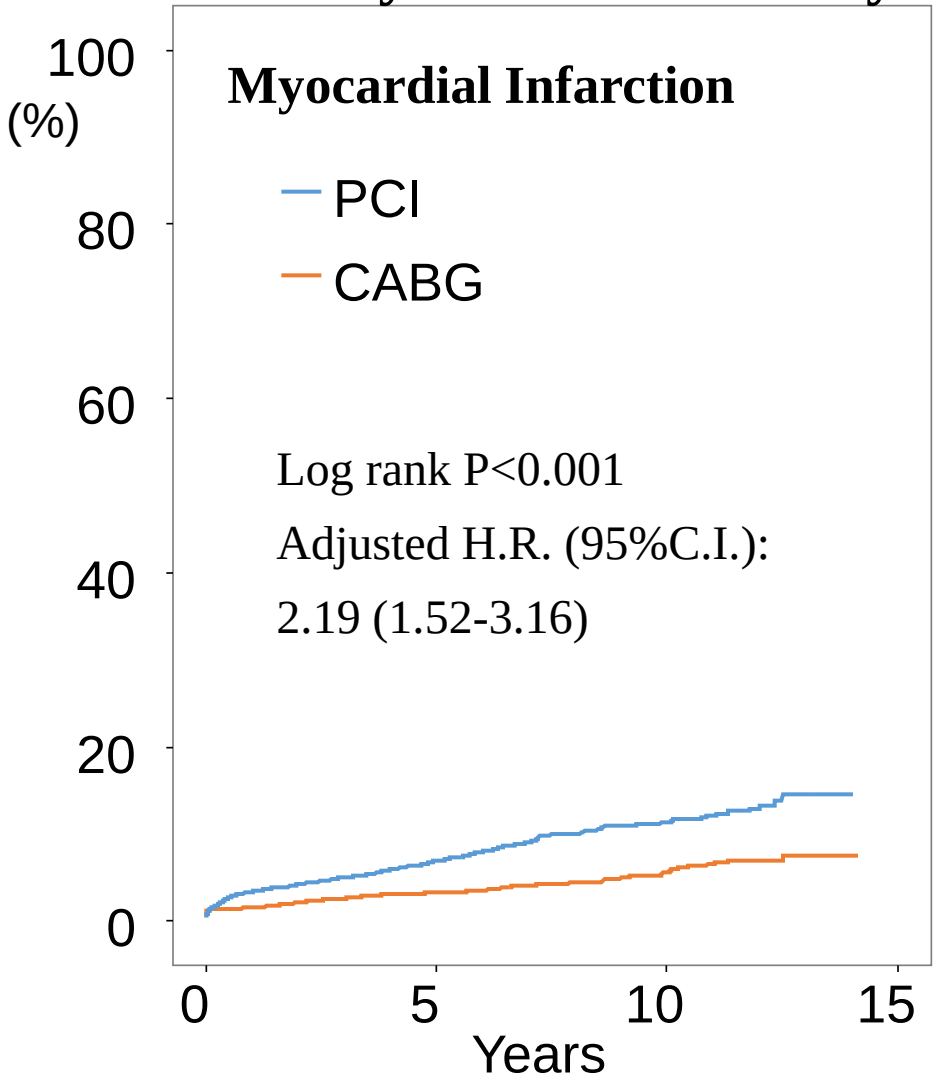


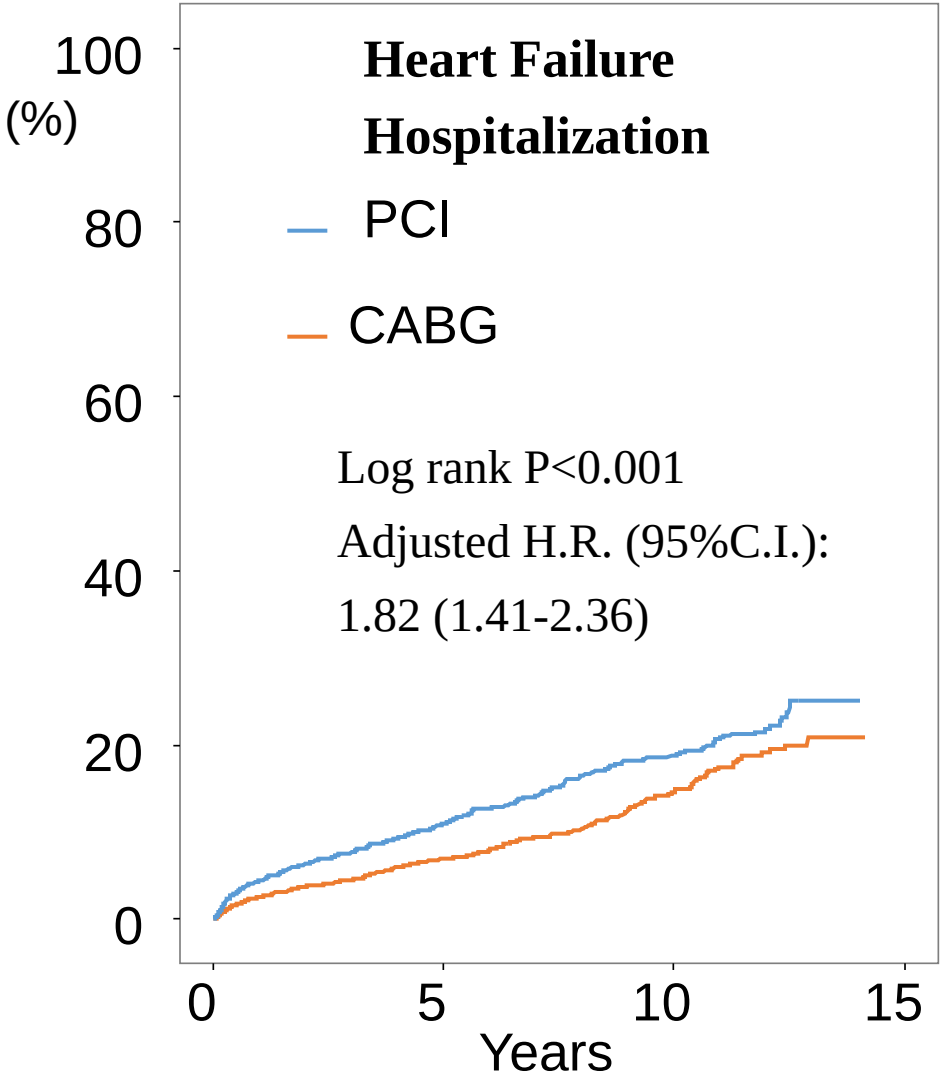
		5 years	10 years	
PCI	0 (0.0%)	369 (34%)	492 (62%)	N of death
	1168	556	114	N of patients at risk
CABG	0 (0.0%)	168 (26%)	243 (51%)	N of death
	691	391	116	N of patients at risk

The excess mortality risk of PCI relative to CABG was seen in patients aged >=74 years, while the risk was neutral in patients aged <74 years.

Yamaji K, et al. Circulation. 2016.

Pooled Analysis of CREDO-Kyoto Cohort-1 and -2

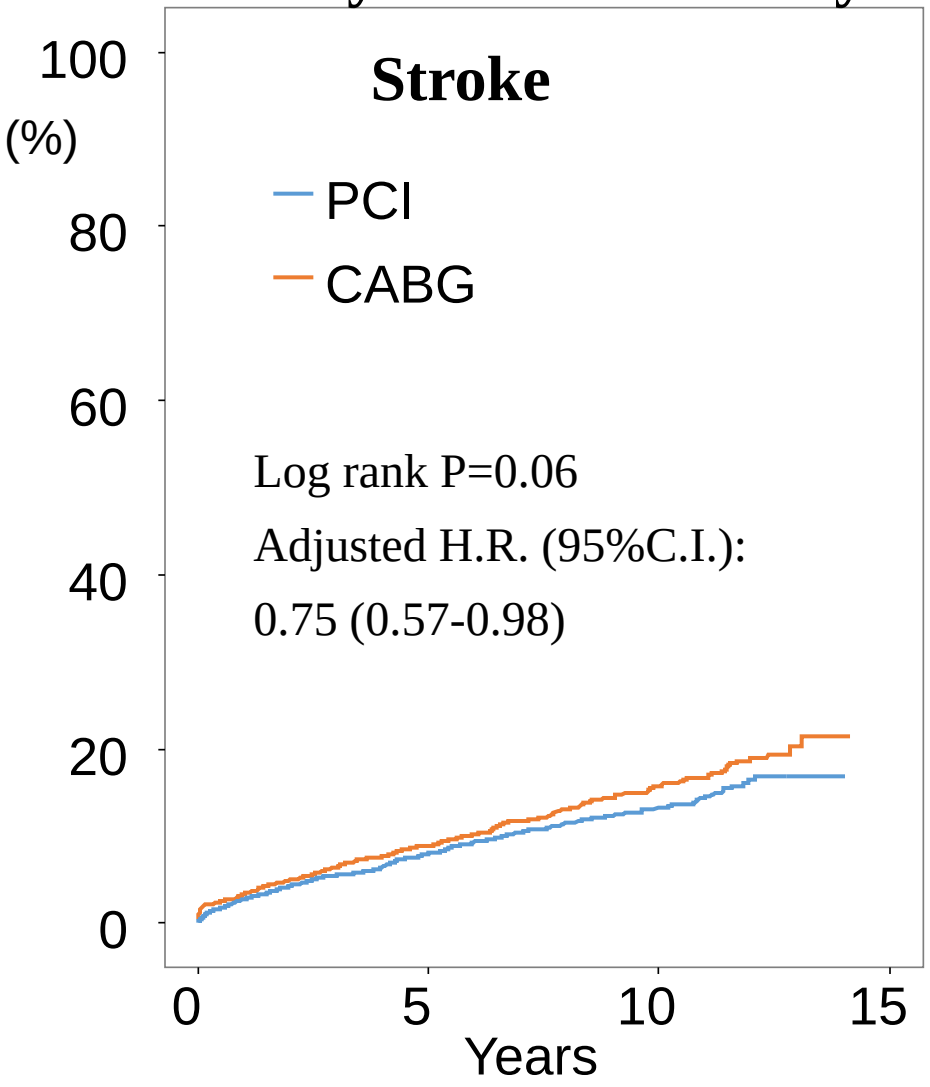


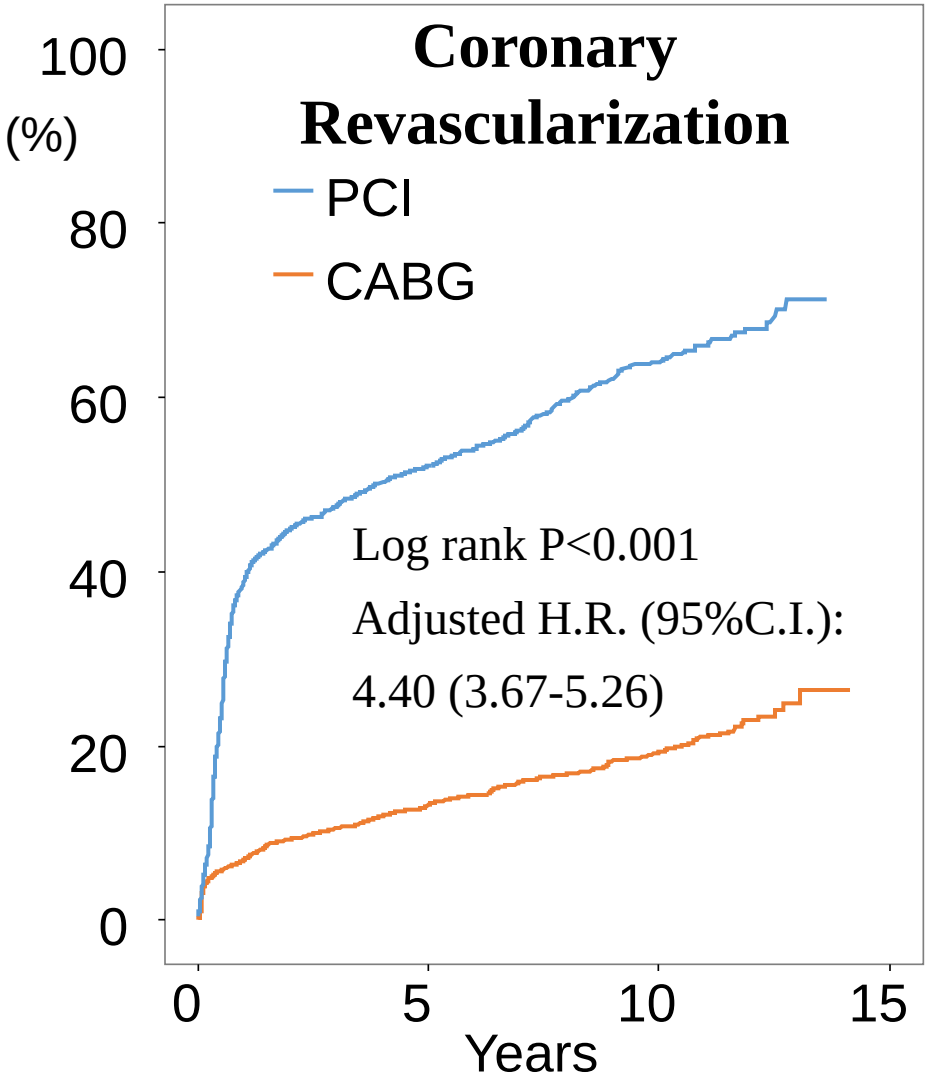


Years	0	5	10	
PCI	0 (0.0%)	197 (7.0%)	245 (11.3%)	N of events
	3165	1808	638	N at risk
CABG	0 (0.0%)	76 (3.3%)	98 (5.6%)	N of events
	2486	1635	706	N at risk

Years	0	5	10	
PCI	0 (0.0%)	309 (10.9%)	398 (18.8%)	N of events
	3165	1780	642	N at risk
CABG	0 (0.0%)	154 (6.9%)	230 (14.5%)	N of events
	2486	1587	676	N at risk

Pooled Analysis of CREDO-Kyoto Cohort-1 and -2





Years	0	5	10	
PCI	0 (0.0%)	223 (8.0%)	280 (13.1%)	N of events
	3165	1811	640	N at risk
CABG	0 (0.0%)	201 (8.8%)	275 (15.8%)	N of events
	2486	1573	673	N at risk

Years	0	5	10	
PCI	0 (0.0%)	1541 (52.1%)	1641 (64.1%)	N of events
	3165	871	198	N at risk
CABG	0 (0.0%)	303 (13.2%)	363 (19.2%)	N of events
	2486	1445	593	N at risk

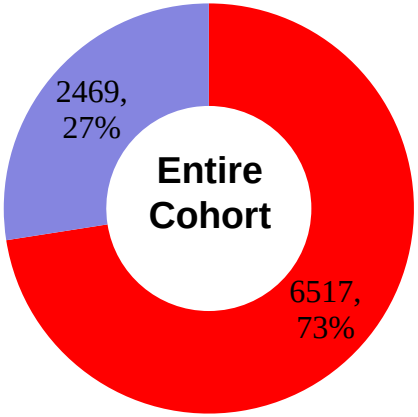
Changes in Coronary Revascularization Strategies

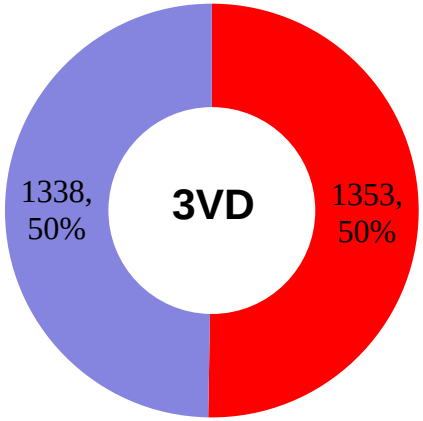
Exclusion of patients with acute myocardial infarction.

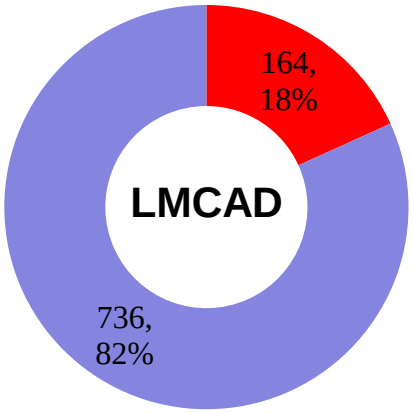
Inclusion of patients from 26 centers that participated in both cohort-1 and -2.

PCI
CABG

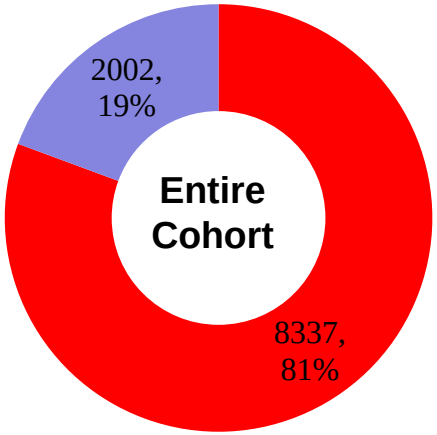
CREDO-Kyoto Cohort 1: 2000-2002 BMS Era (N=8986)

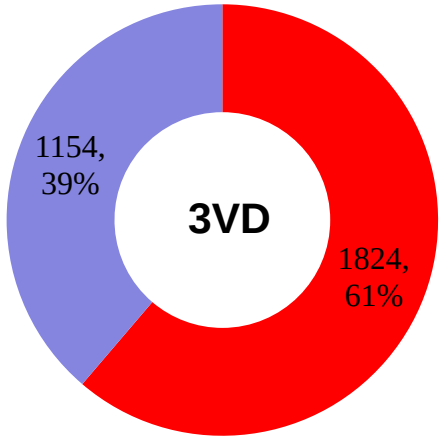


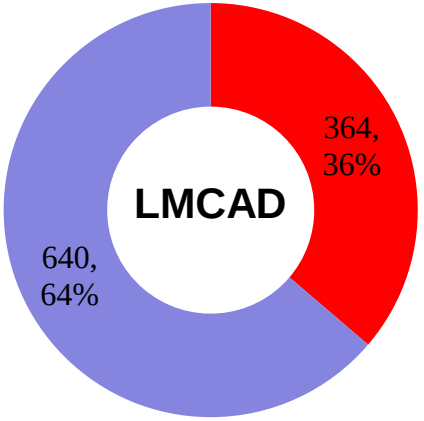




CREDO-Kyoto Cohort 2: 2005-2007 G-1 DES Era (N=10339)





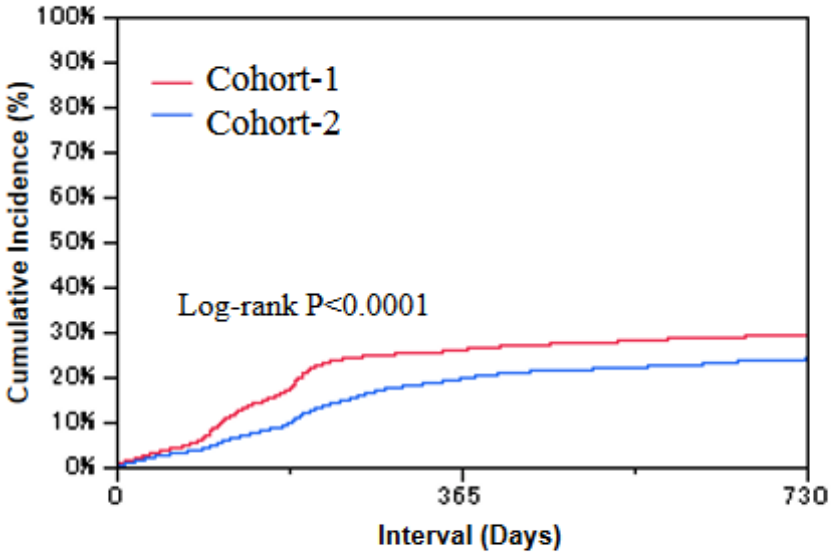


Shiomi H, et al. Am J Cardiol 2014.

Changes in Clinical Outcomes

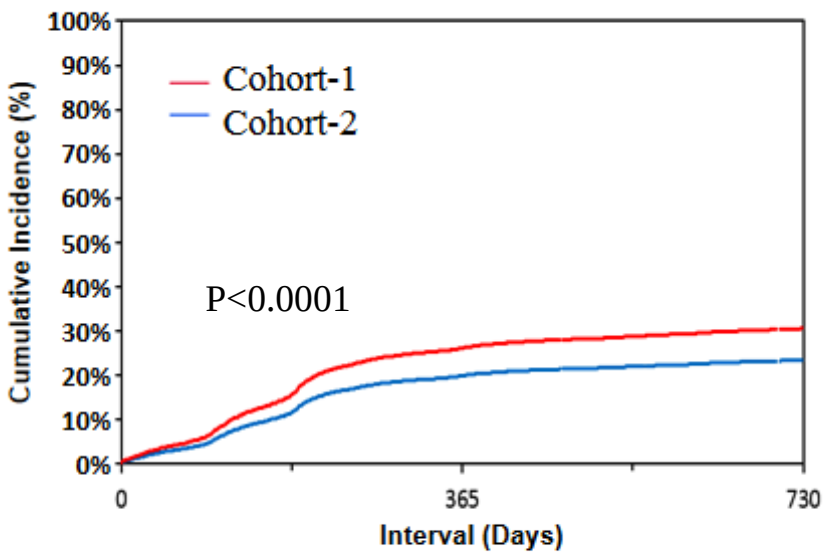
Repeated coronary revascularization

Crude



Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
N of events		263	2290	2572
N of patients at risk	8986	8593	6265	5682
Incidence		3.0%	26.3%	29.7%
Cohort-2 group				
N of events		212	1991	2413
N of patients at risk	10339	10032	7865	7152
Incidence		2.1%	19.8%	24.2%

Adjusted



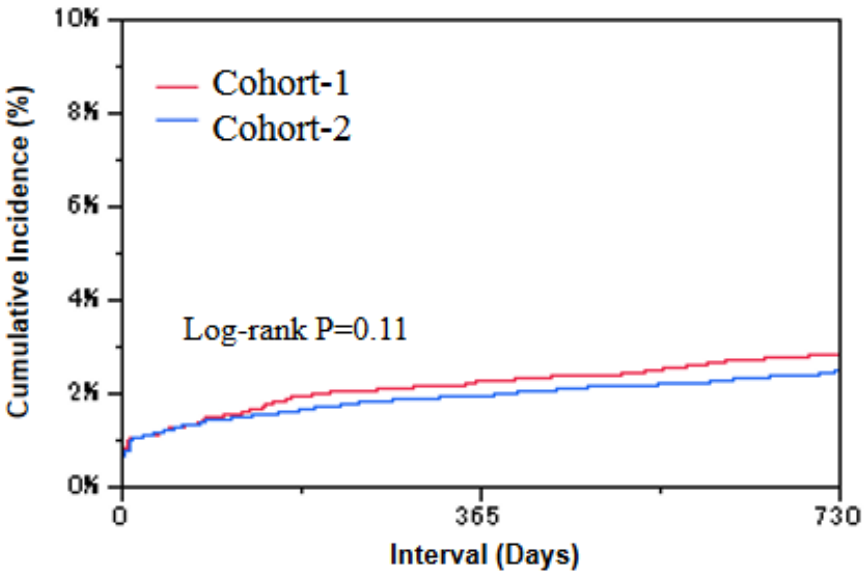
Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
Incidence		2.9%	26.2%	30.6%
Cohort-2 group				
Incidence		2.1%	20.9%	23.5%

Shiomi H, et al. Am J Cardiol 2014.

Changes in Clinical Outcomes

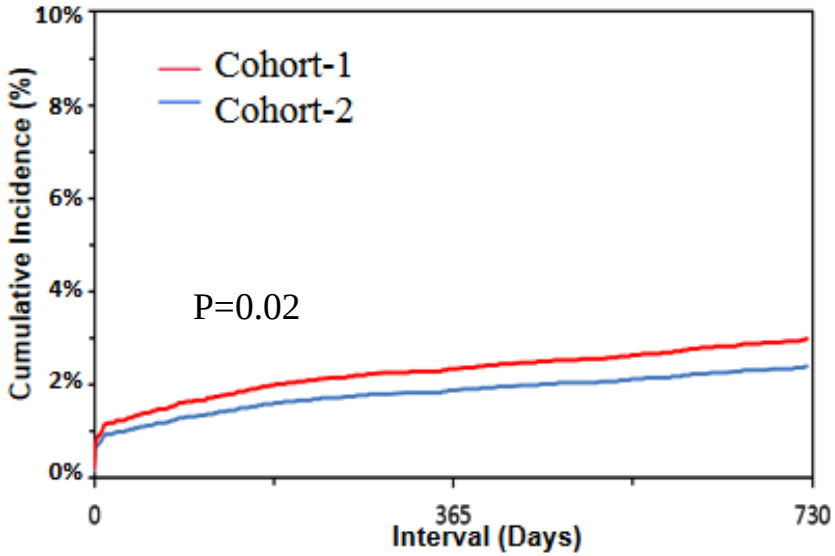
Myocardial infarction

Crude



Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
N of events		101	200	249
N of patients at risk	8986	8757	8327	7882
Incidence		1.1%	2.3%	2.9%
Cohort-2 group				
N of events		115	200	250
N of patients at risk	10339	10129	9639	9242
Incidence		1.1%	2.0%	2.5%

Adjusted



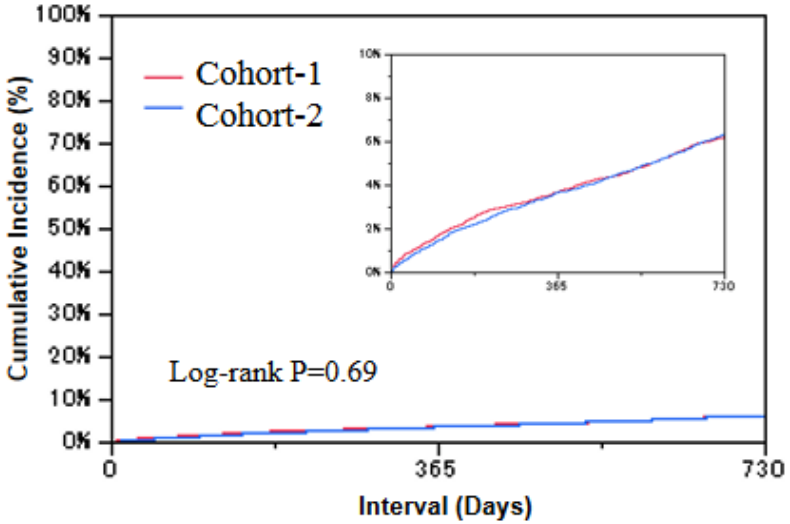
Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
Incidence		1.2%	2.3%	3.0%
Cohort-2 group				
Incidence		1.0%	1.9%	2.4%

Shiomi H, et al. Am J Cardiol 2014.

Changes in Clinical Outcomes

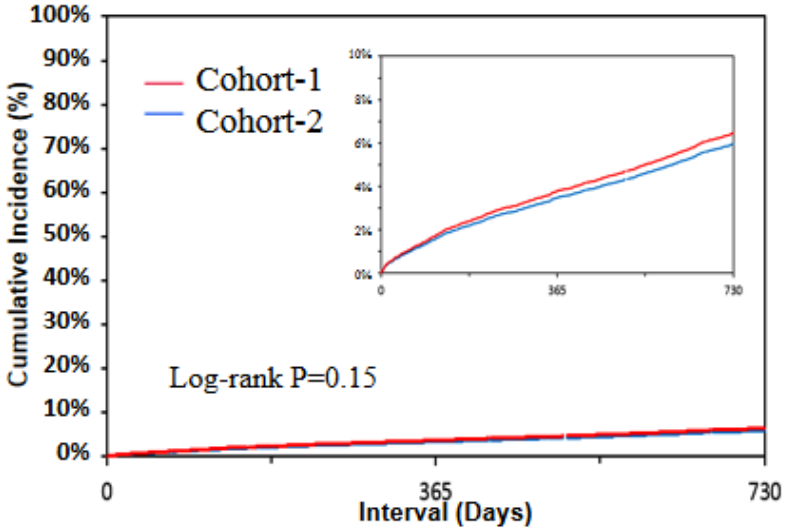
All-cause death

Crude



Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
N of events		75	329	547
N of patients at risk	8986	8841	8480	8064
Incidence		0.8%	3.7%	6.2%
Cohort-2 group				
N of events		60	378	650
N of patients at risk	10339	10240	9810	9449
Incidence		0.6%	3.7%	6.4%

Adjusted



Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
Incidence		0.7%	3.8%	6.5%
Cohort-2 group				
Incidence		0.7%	3.5%	6.0%

Despite the larger proportion of patients treated with PCI in the cohort-2 than in the cohort-1, there was no increased 2-year mortality risk in the entire cohort of first coronary revascularization.

Shiomi H, et al. Am J Cardiol 2014.

Very Long-term (>10 Years) Follow-up After PCI and CABG:

Observations from CREDO-Kyoto PCI/CABG Registry Cohort-1 and -2

Summary

・During very long-term follow-up, CABG was associated with significantly lower mortality risk than PCI in the real clinical practice in Japan. However, the magnitude of survival benefit might be smaller than that reported in the meta-analysis of RCTs.

・We did not see any late survival benefit of CABG over PCI with extended follow-up beyond 5-year.

・The excess mortality risk of PCI relative to CABG was seen in patients aged >=74 years, while the risk was neutral in patients aged <74 years.

・PCI was associated with higher risk for myocardial infarction, heart failure hospitalization, and any coronary revascularization, but lower risk for stroke.

・Despite the larger proportion of patients treated with PCI in the cohort-2 than in the cohort-1, there was no increased 2-year mortality risk in the entire cohort of first coronary revascularization.