

***Long-term Outcomes of PCI versus CABG
in Patients with Multi-vessel CAD:
Observations from CREDO-Kyoto PCI/CABG Registry***

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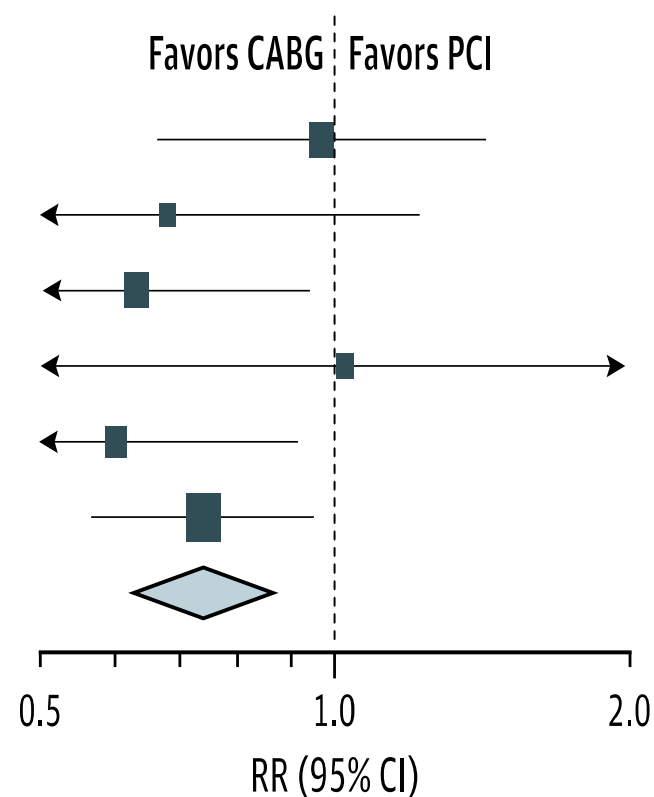


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Meta-analysis of RCTs comparing PCI versus CABG in Multivessel CAD: BMS/DES Era

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



Previous randomized trials in the DES era reported survival benefit with CABG over PCI.

Thoughts on the RCTs and Registries Comparing PCI/CABG

Gold standard

- RCT might be the gold standard to compare the clinical outcomes after PCI and CABG.

Importance of technical expertise

- However, the findings from RCTs may not be universally applicable when evaluating the interventions such as PCI and CABG, in which technical expertise is playing the integral role.

External validity

- Furthermore, external validity of the findings from RCTs might be severely hampered by their exclusion criteria; The conclusions from RCTs could not be applicable to those elderly patients with serious co-morbidities, who are often excluded from RCTs, but often encountered in the real clinical practice, particularly in Japan.

Thoughts on the RCTs and Registries Comparing PCI/CABG

Geographic and ethnic differences

- The clinical relevance of the possible difference between PCI and CABG for ischemic protection might depend on the absolute rates of ischemic events and relative distributions of cardiac/non-cardiac mortality, that could be varied according to the geography and ethnicity.

Feasibility of RCTs

- RCTs comparing PCI with CABG are not feasible in Japan, where PCI is commonly performed in patients with complex left main and/or triple vessel coronary artery disease in daily clinical practice.

Role of registries

- What we should do in this Japanese situation is to demonstrate that the long-term mortality after PCI is not so much different from that after CABG in meticulously conducted observational studies.

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, 10-year FU completed)

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, 5-year FU completed)

Including presenting with acute myocardial infarction

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

Cohort 3: 2011-2013 G-2 DES Era (Now collecting data)

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

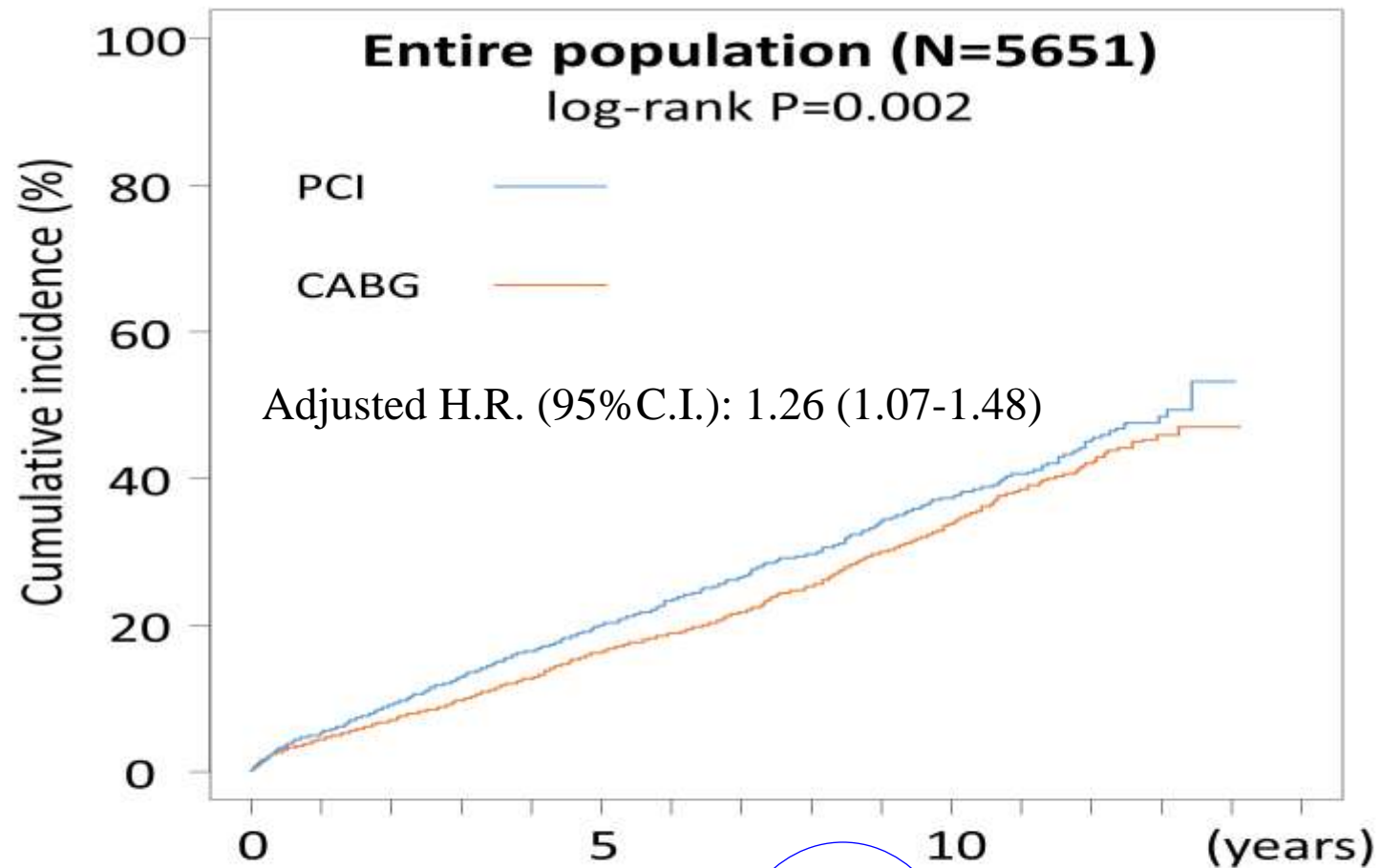
PCI versus CABG in Triple Vessel CAD

Baseline Characteristics

	PCI (N=3165)	CABG (N=2486)	P value
Age, years	69.4±10.0	67.5±9.00	<0.001
Male	70%	72%	0.054
Diabetes mellitus			
Not on insulin therapy	36%	36%	0.96
On insulin therapy	13%	17%	<0.001
Previous MI	23%	32%	<0.001
eGER <30, not on HD	5%	7%	0.02
Dialysis	156(4.9)	143(5.8)	0.19
Malignancy	10%	8%	0.007
Anemia	15%	19%	<0.001
Proximal LAD disease	86%	96%	<0.001
Chronic total occlusion	41%	56%	<0.001
SYNTAX score	23.2±9.68	26.5±13.8	<0.001

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

Mortality risk of PCI relative to CABG in TVD

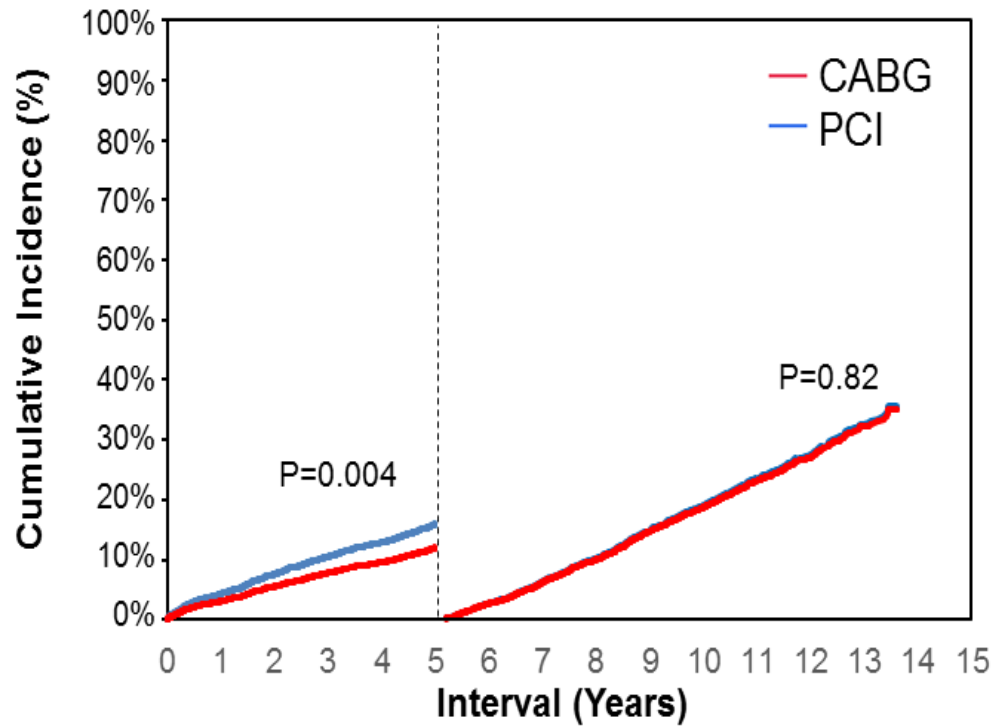


		5 years	10 years	
PCI	N of death	600 (20%)	839 (37%)	
	N of patients at risk	1908	692	
CABG	N of death	383 (16%)	606 (34%)	
	N of patients at risk	1670	732	

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

PCI versus CABG for MVD excluding LMCA disease

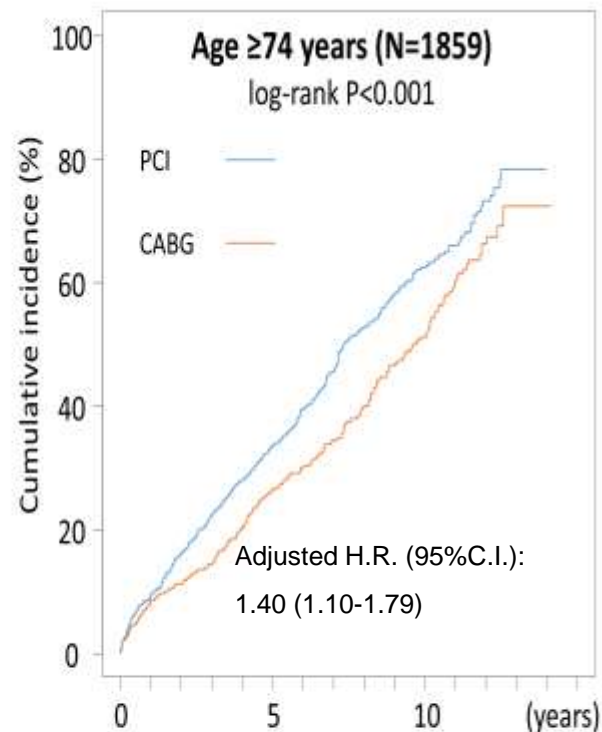
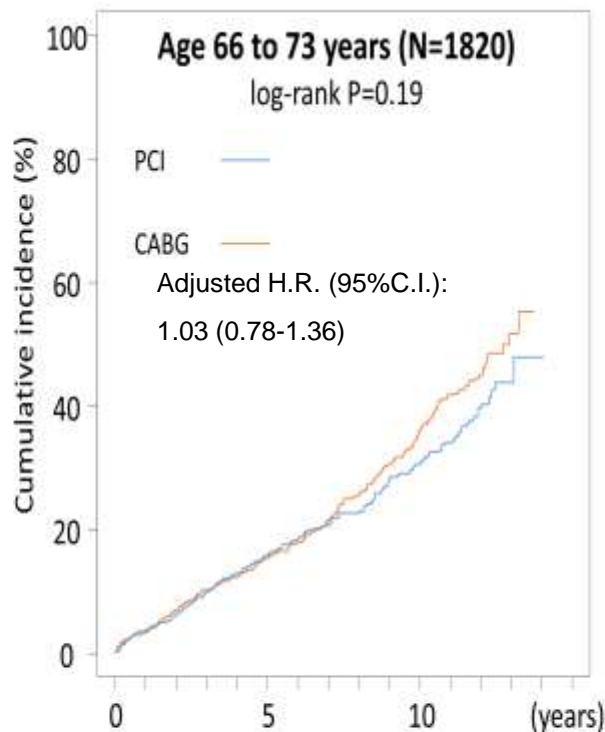
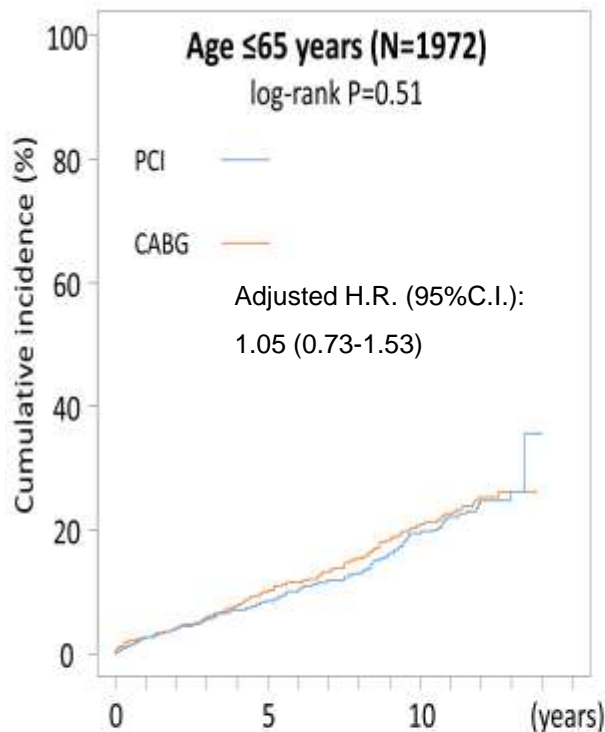
Adjusted risk for death: Within 5-year and Beyond 5-Year



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%

Mortality risk of PCI relative to CABG in TVD

According to Age Categories



	0	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

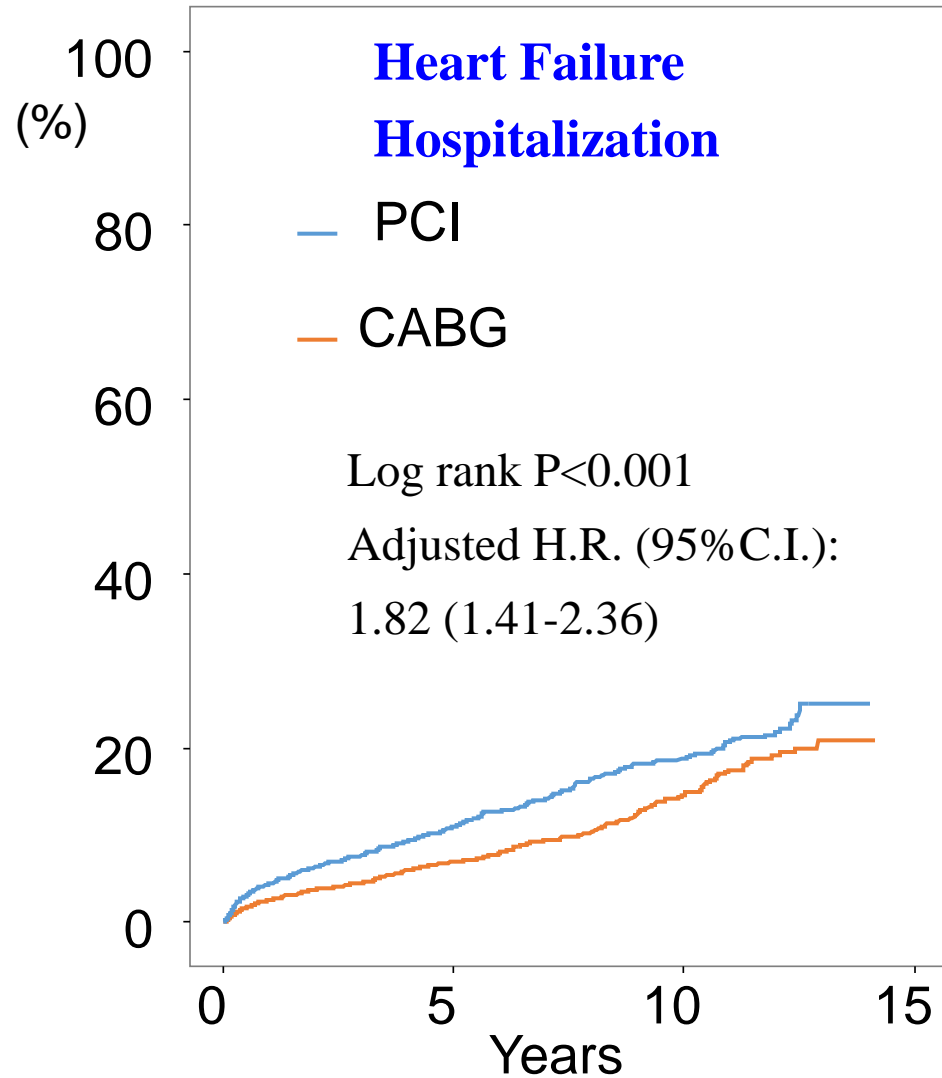
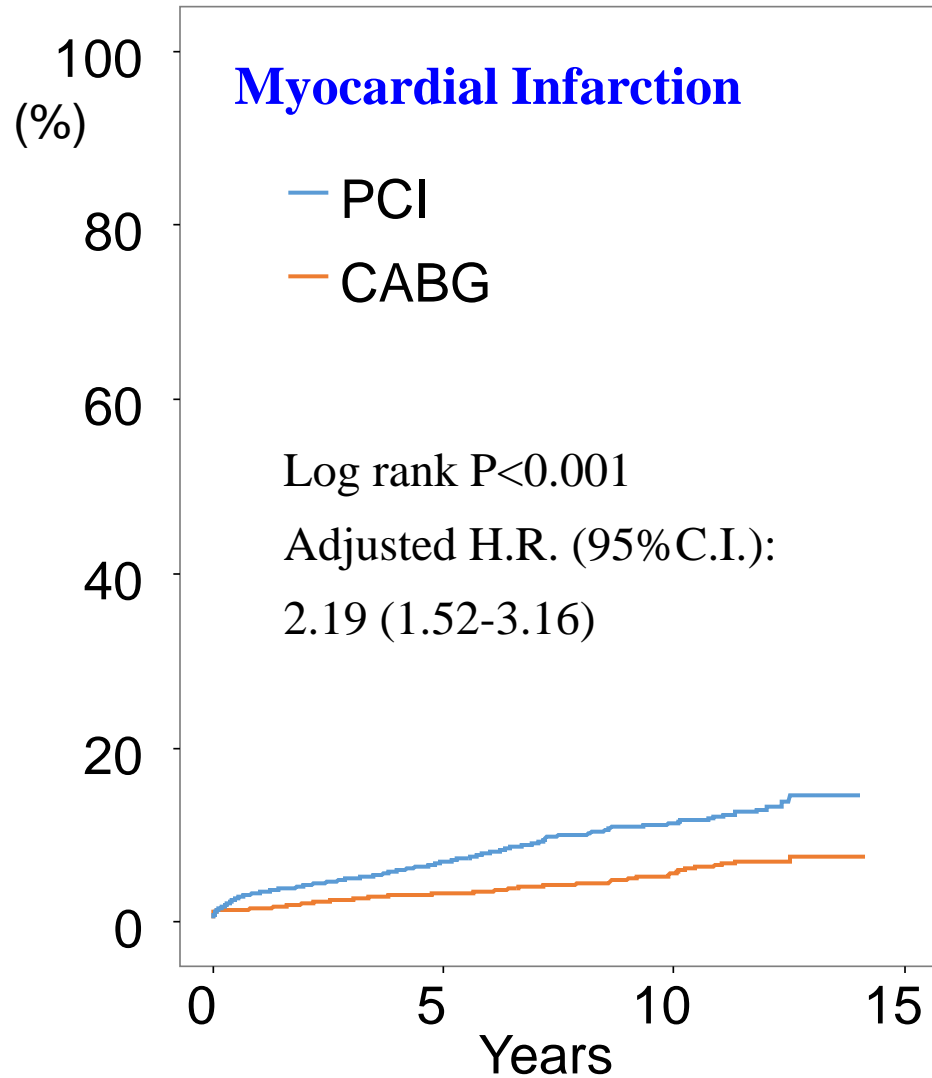
	0	5 years	10 years	
PCI	0 (0.0%)	147 (16%)	214 (31%)	N of death
	964	637	266	N of patients at risk
CABG	0 (0.0%)	126 (15%)	220 (36%)	N of death
	856	593	258	N of patients at risk

	0	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. This result might be due to more complex disease or selection bias in ultra-elderly patients.

Anyway, selection of PCI in relatively young 3VD patients might be appropriate.

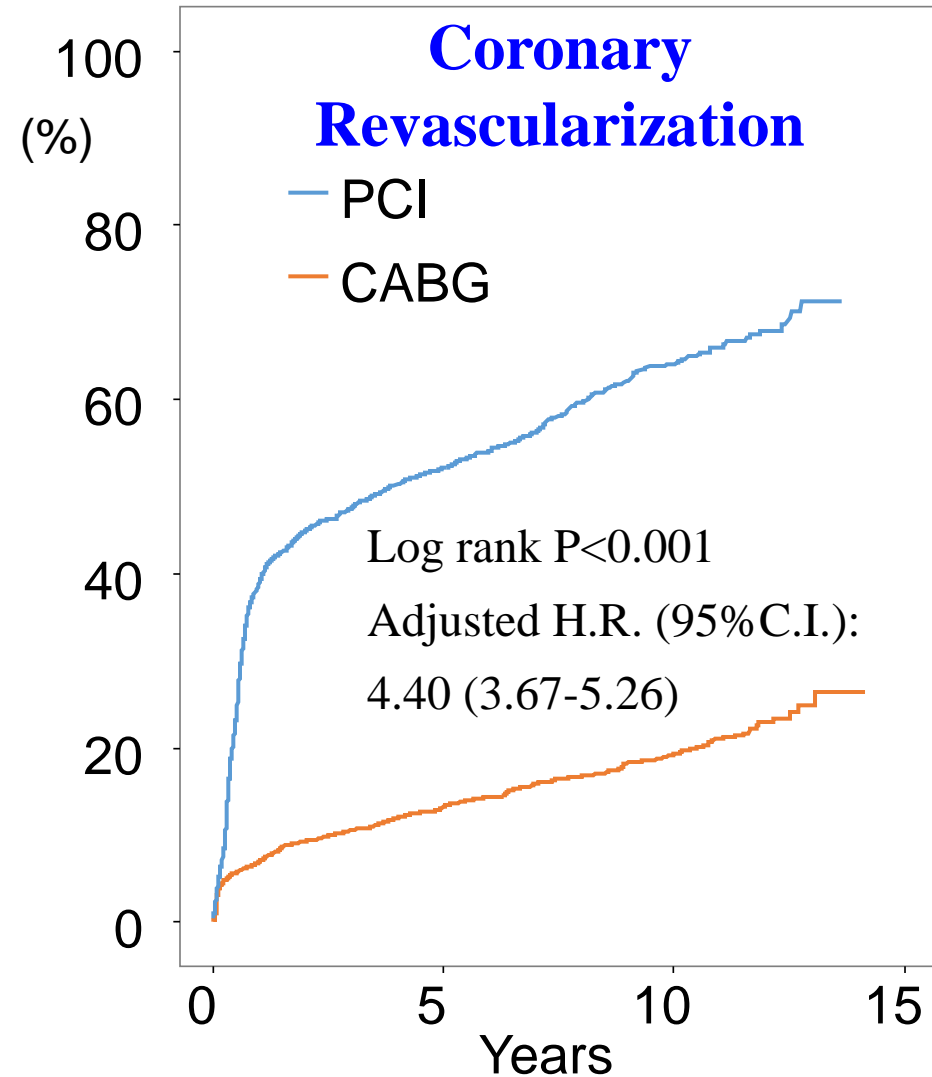
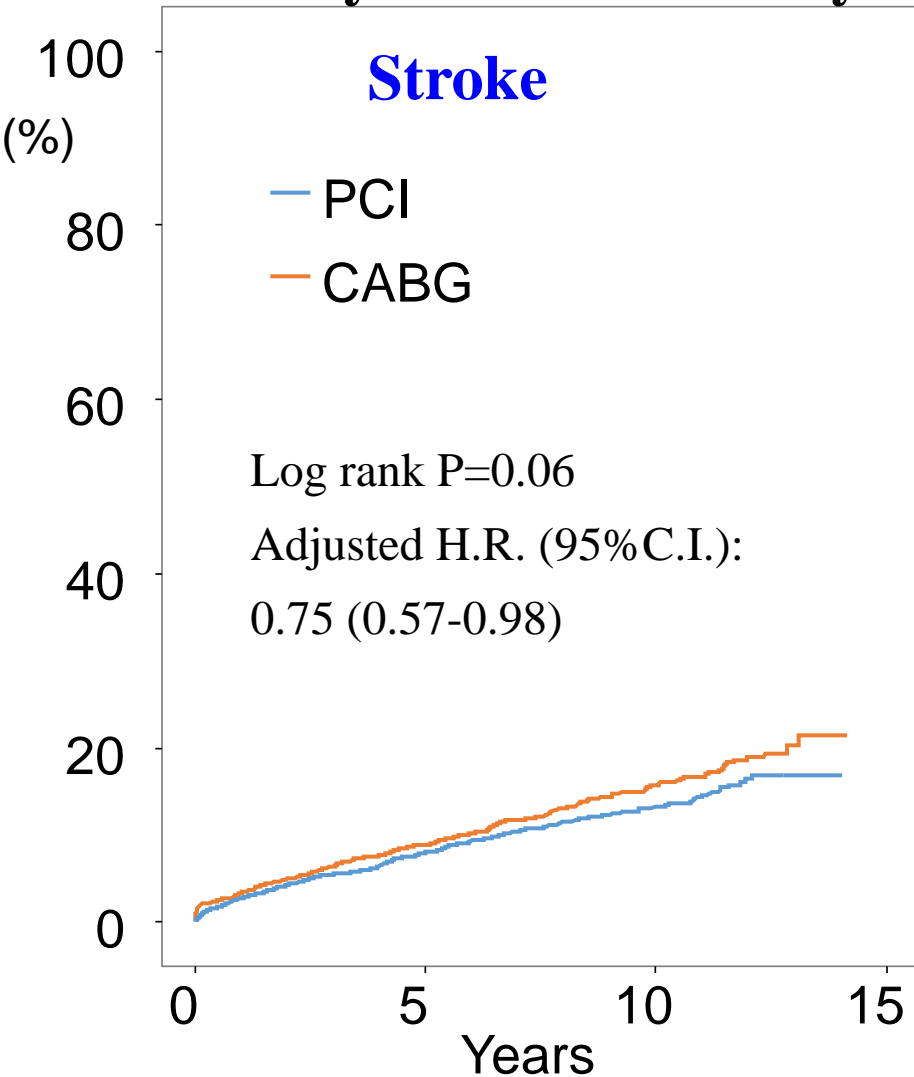
Pooled Analysis of CREDO-Kyoto Cohort-1 and -2



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

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

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

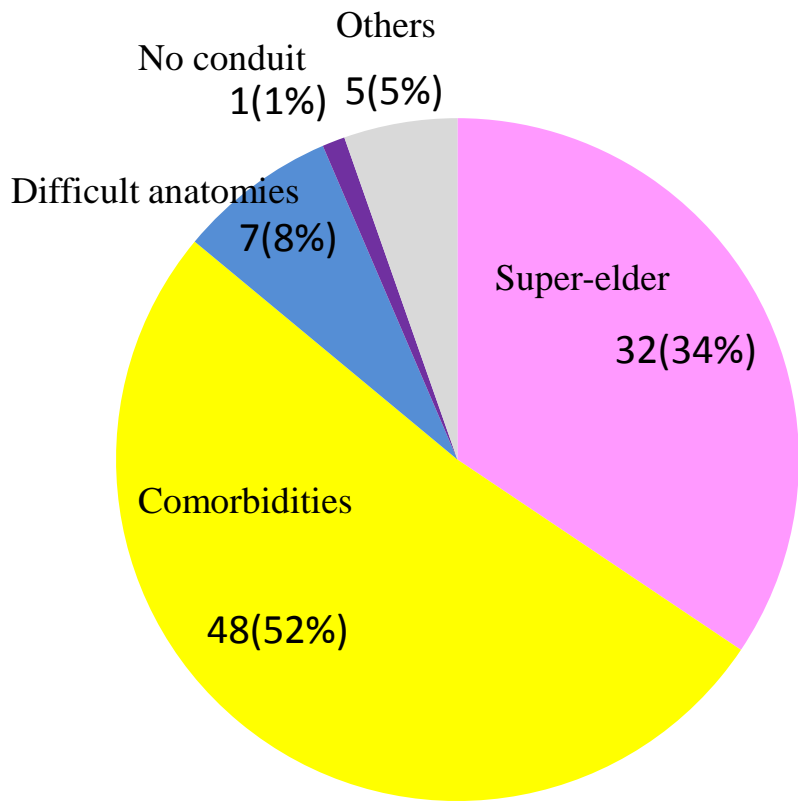


Years	0	5	10	
PCI	0 (0.0%) 3165	223 (8.0%) 1811	280 (13.1%) 640	N of events N at risk
CABG	0 (0.0%) 2486	201 (8.8%) 1573	275 (15.8%) 673	N of events N at risk

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

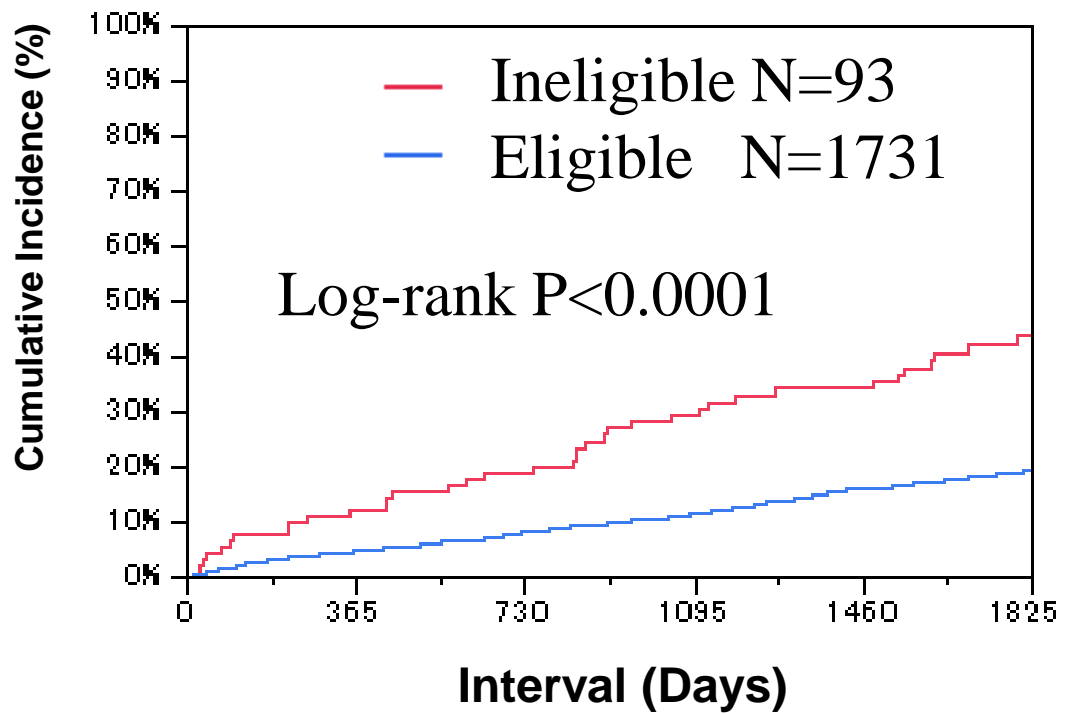
Patients ineligible for CABG

Documentation in the chart as “ineligible for CABG” was found
In 93 (5.4%) out of 1824 PCI patients



PCI Patients: Eligible versus Ineligible for CABG

All-cause Death



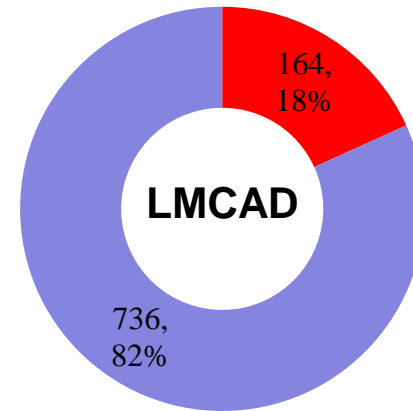
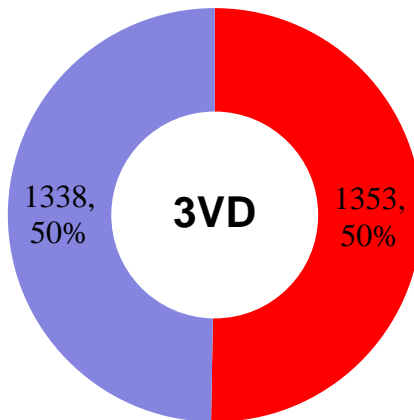
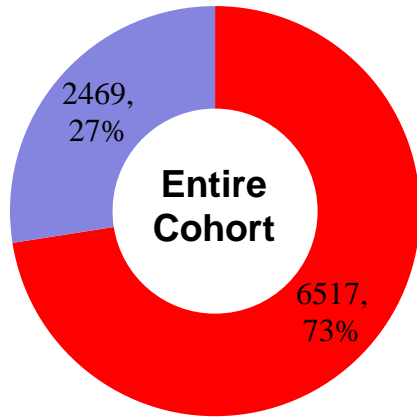
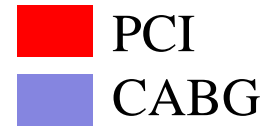
The prevalence of 5.4% patients ineligible for CABG seems to be too low in my own clinical experience.

Future registry comparing PCI with CABG should have a design feature, prospectively excluding those patients ineligible for CABG.

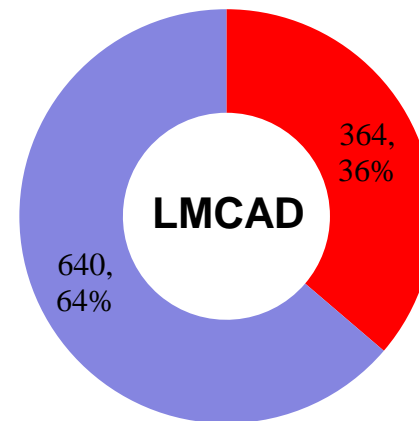
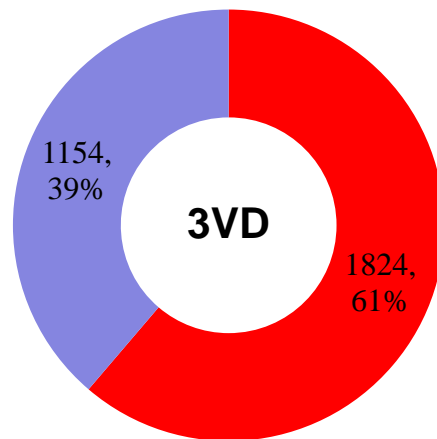
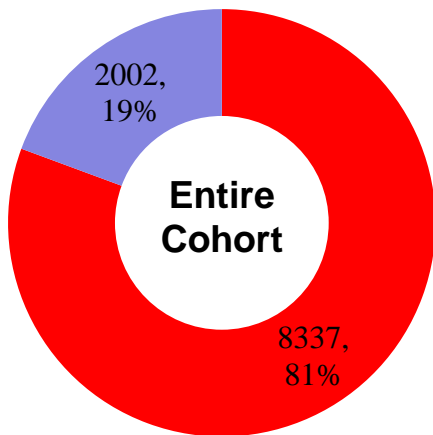
Changes in Coronary Revascularization Strategies

CREDO-Kyoto Cohort-1 versus Cohort-2

CREDO-Kyoto Cohort 1: 2000-2002



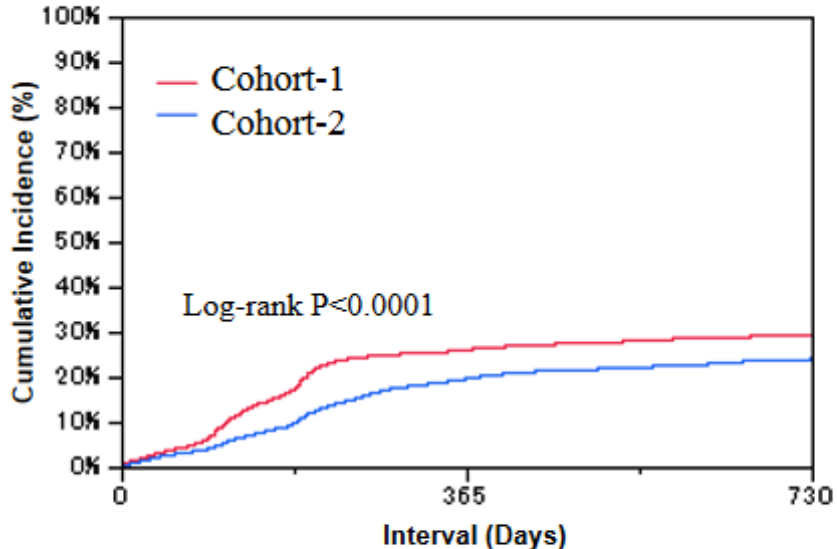
CREDO-Kyoto Cohort 2: 2005-2007



Changes in Clinical Outcomes Between Cohort-1 and -2

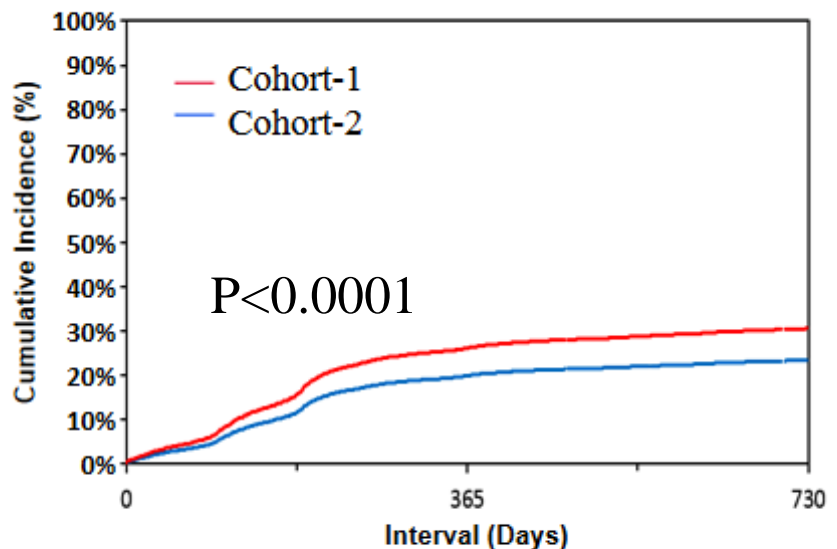
Repeated coronary revascularization

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

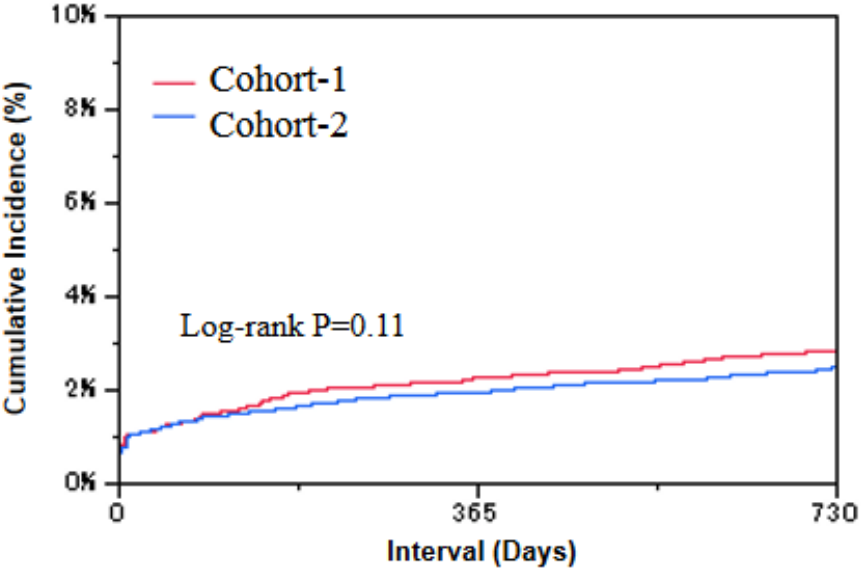


Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
Incidence		2.9%	26.2%	30.6%
Cohort-2 group				
Incidence		2.1%	20.9%	23.5%

Changes in Clinical Outcomes Between Cohort-1 and -2

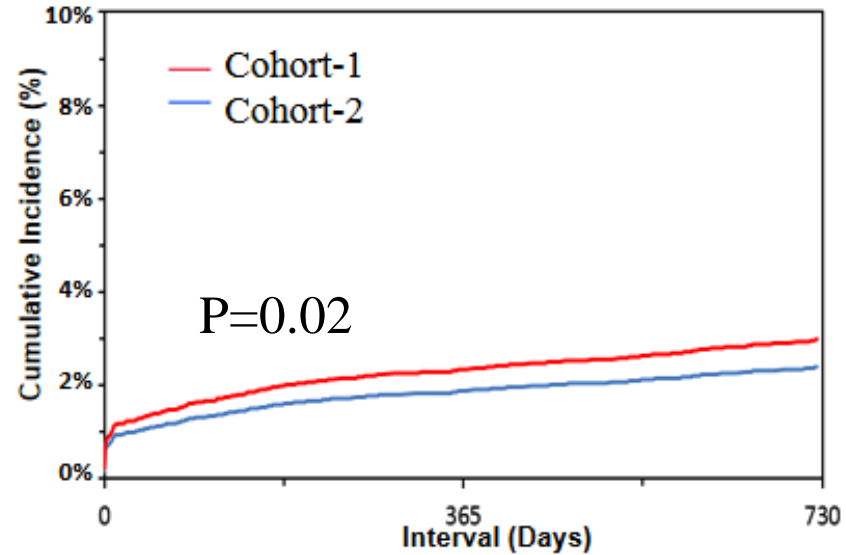
Myocardial infarction

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

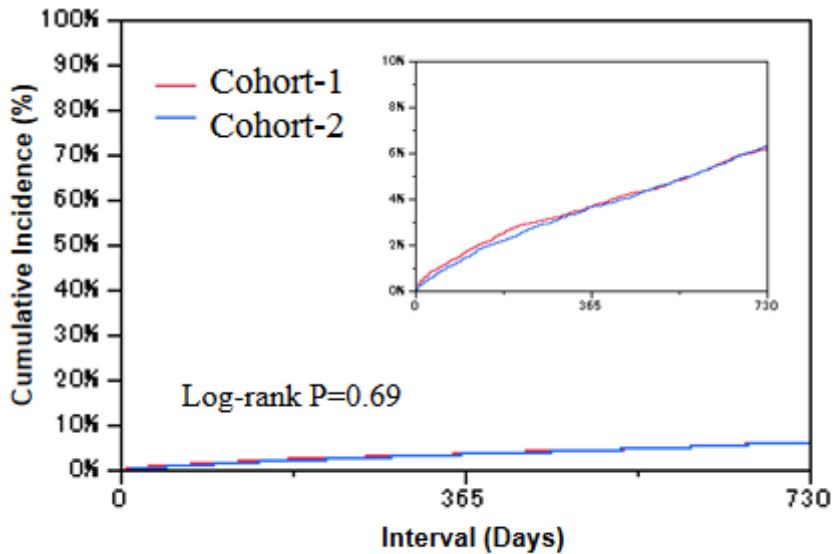


Interval	0 day	30 days	1 year	2 year
Cohort-1 group				
Incidence		1.2%	2.3%	3.0%
Cohort-2 group				
Incidence		1.0%	1.9%	2.4%

Changes in Clinical Outcomes Between Cohort-1 and -2

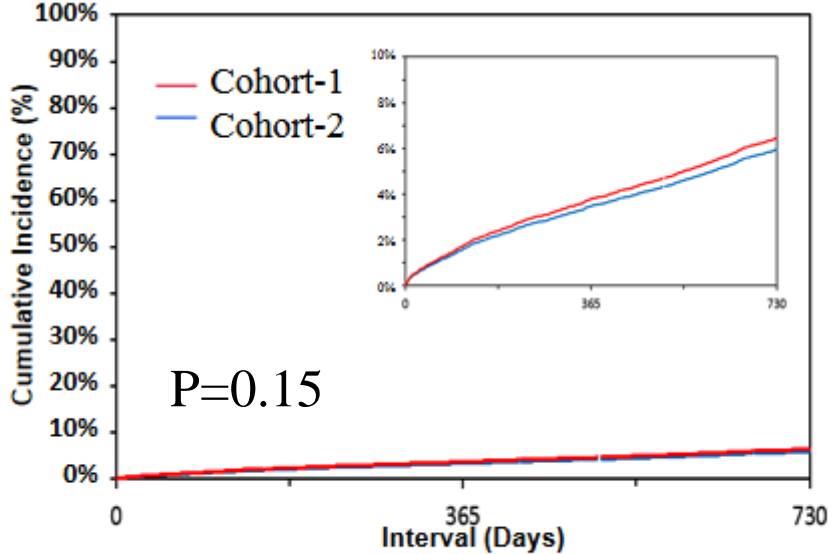
All-cause death

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 more prevalent choice of PCI in LMCA/TVD patients, mortality trended to be lower in the cohort-2 than in the cohort-1, suggesting that we are moving in the right direction.

Long-term Outcomes of PCI versus CABG in Patients with Multi-vessel CAD:

Observations from CREDO-Kyoto PCI/CABG Registry

Conclusions

- Current complex PCI outcomes based on the CREDO-Kyoto registries are reasonably good and almost comparable to CABG outcomes in Japan, where the majority of patients with triple vessel CAD are revascularized with PCI.
- We should continue to pursue the ultimate goal of complex PCI to provide less invasive treatment option alternative to CABG in many of the patients with advanced CAD by verifying the comparable long-term mortality in the timely conducted observational studies.