Predicted and observed mortality at 10-year in patients with bifurcation lesion in the SYNTAX trial

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Disclosure

Dr. Serruys reports institutional grants from Sinomedical Sciences Technology, SMT (Sahajanand Medical technological), Philips/Volcano, Xeltis, and HeartFlow, outside the submitted work.

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Dr. Morice is a CEO and shareholder of CERC, a CRO based in Paris, having no role in this trial.

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All other authors have no conflict of interest to declare.

Objective and Method

Objective

To investigate the impact of bifurcation lesions on individual predicted and observed all-cause 10-year mortality in the SYNTAX trial.

Methods

1. **The present study is a post-hoc subgroup analysis of the SYNTAXES study, which was an investigator-driven extended 10-year follow-up of the SYNTAX trial.**
2. **For the purpose of the present analysis, patients were categorized in four groups:**

(A) Patients with the presence* of at least one bifurcation lesion in PCI group
(B) Patients without any bifurcation lesion in PCI group
(C) Patients with the presence of at least one bifurcation lesion in CABG group
(D) Patients without any bifurcation lesion in CABG group.

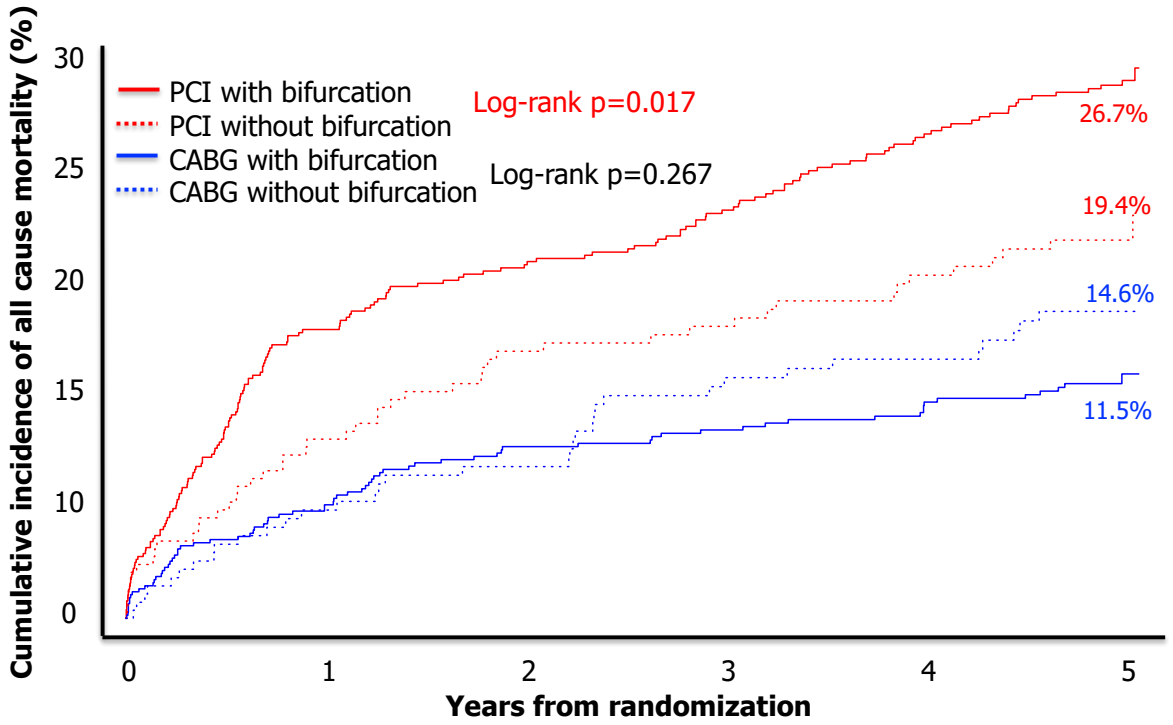
*** On diagnostic angiogram**

Baseline characteristics

	PCI			CABG		
	Patients without Bifurcation (N=248)	Patients with Bifurcation (N=649)	p Value	Patients without Bifurcation (N=239)	Patients with Bifurcation (N=651)	p Value
Age, yrs	63.5 ± 10.0	65.9 ± 9.5	< 0.001	63.7 ± 9.8	65.3 ± 9.8	0.030
Male	71.4 (177/248)	78.4 (509/649)	0.028	74.5 (178/239)	80.6 (525/651)	0.051
Body mass index, kg/m2	28.1 ± 4.8	28.1 ± 4.8	0.961	28.1 ± 4.9	27.9 ± 4.4	0.606
Diabetes	23.4 (58/248)	26.3 (171/649)	0.392	25.5 (61/239)	24.4 (159/651)	0.727
Hypertension	66.1 (164/248)	69.8 (453/649)	0.296	66.9 (160/239)	63.1 (411/651)	0.306
Dyslipidemia	77.6 (191/246)	79.0 (509/644)	0.648	74.0 (174/235)	78.7 (509/647)	0.146
Current smoking	20.6 (51/248)	17.6 (114/649)	0.335	23.6 (56/237)	21.5 (139/647)	0.522
Creatinine clearance, ml/min	89.1 ± 37.9	85.1 ± 34.0	0.132	86.9 ± 31.2	84.6 ± 28.5	0.304
LVEF, %	59.2 ± 12.4	58.5 ± 13.2	0.447	59.1 ± 12.5	57.7 ± 13.1	0.164
Clinical presentation			0.688			0.873
Silent ischemia	14.1 (35/248)	14.2 (92/649)		13.8 (33/239)	15.2 (99/651)	
Stable angina	54.8 (136/248)	57.6 (374/649)		57.7 (138/239)	56.8 (370/651)	
Unstable angina	31.0 (77/248)	28.2 (183/649)		28.5 (68/239)	28.0 (182/651)	
EuroSCORE	3.4 ± 2.5	3.9 ± 2.6	0.018	3.5 ± 2.5	3.9 ± 2.8	0.060
Disease type			0.093			0.162
3VD	56.0 (139/248)	62.2 (404/649)		57.3 (137/239)	62.7 (408/651)	
LMCAD	44.0 (109/248)	37.8 (245/649)		42.7 (102/239)	37.3 (243/651)	
SYNTAX score	21.7 ± 9.0	31.1 ± 11.1	< 0.001	21.3 ± 9.6	32.0 ± 10.6	< 0.001

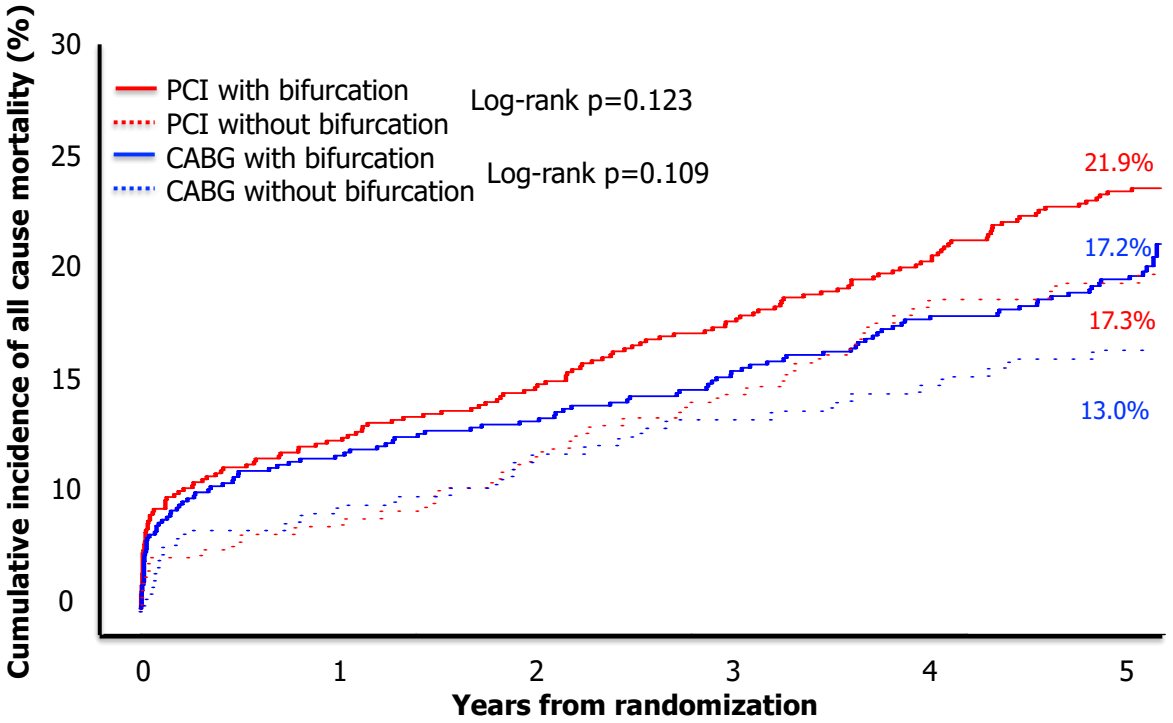
Outcomes at 5-year
Bifurcation vs non-bifurcation

Revascularization at 5-year



Number at risk					
649	526	494	459	418	251
248	218	200	192	180	127
651	560	527	506	476	295
239	208	198	183	176	121

Death or stroke or MI at 5-year



Number at risk					
649	584	564	538	512	319
248	235	224	216	200	138
651	567	546	523	494	310
239	212	205	199	194	135

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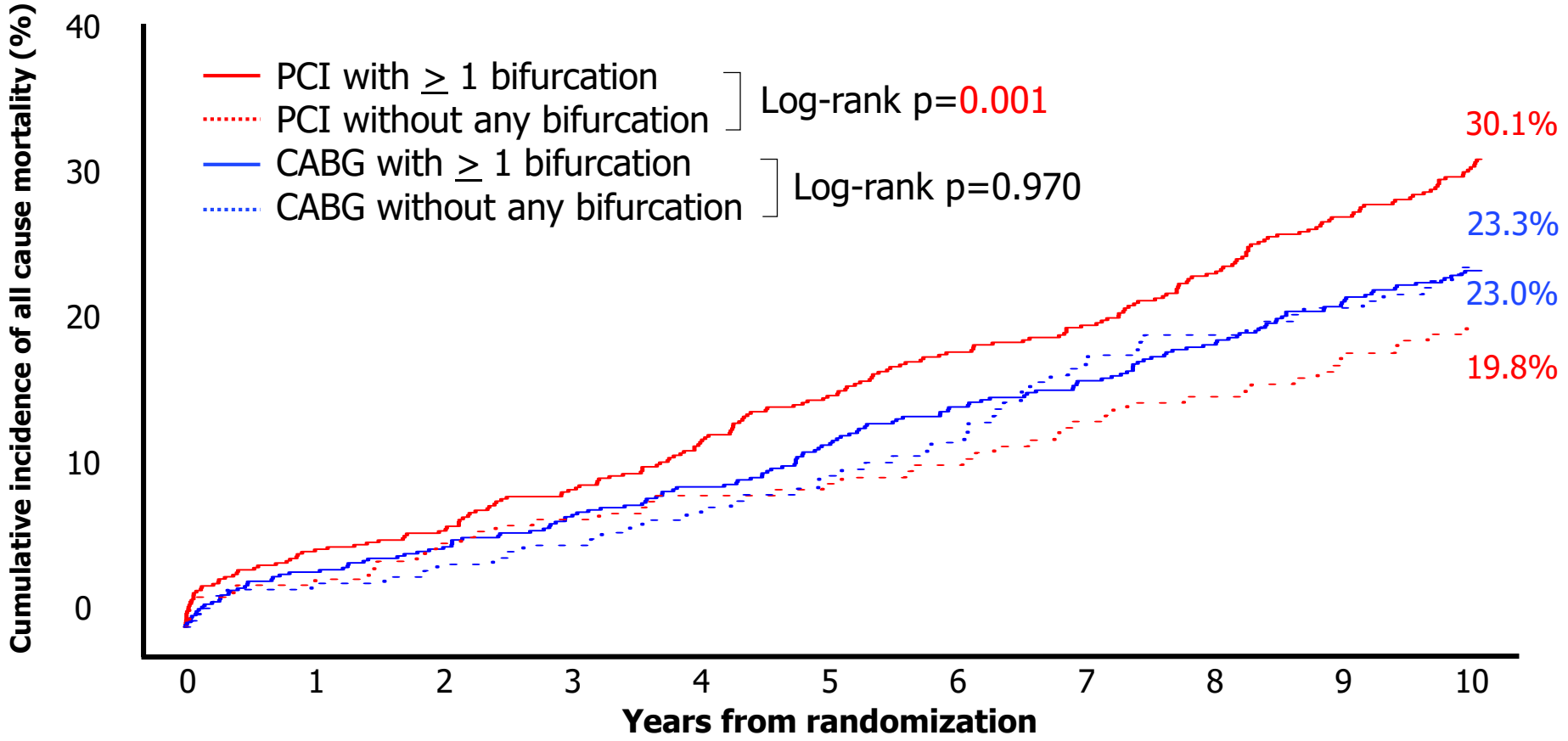
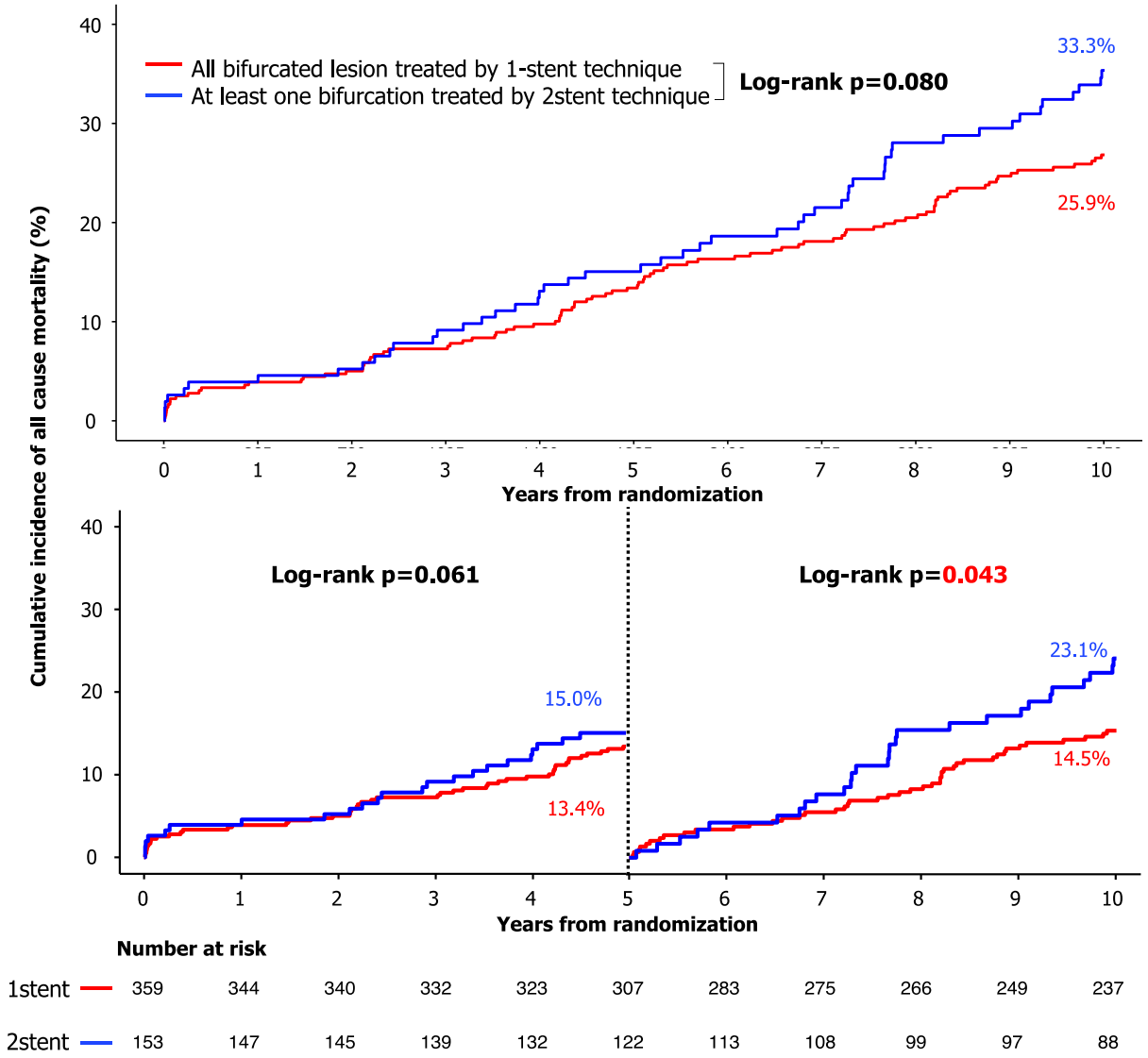
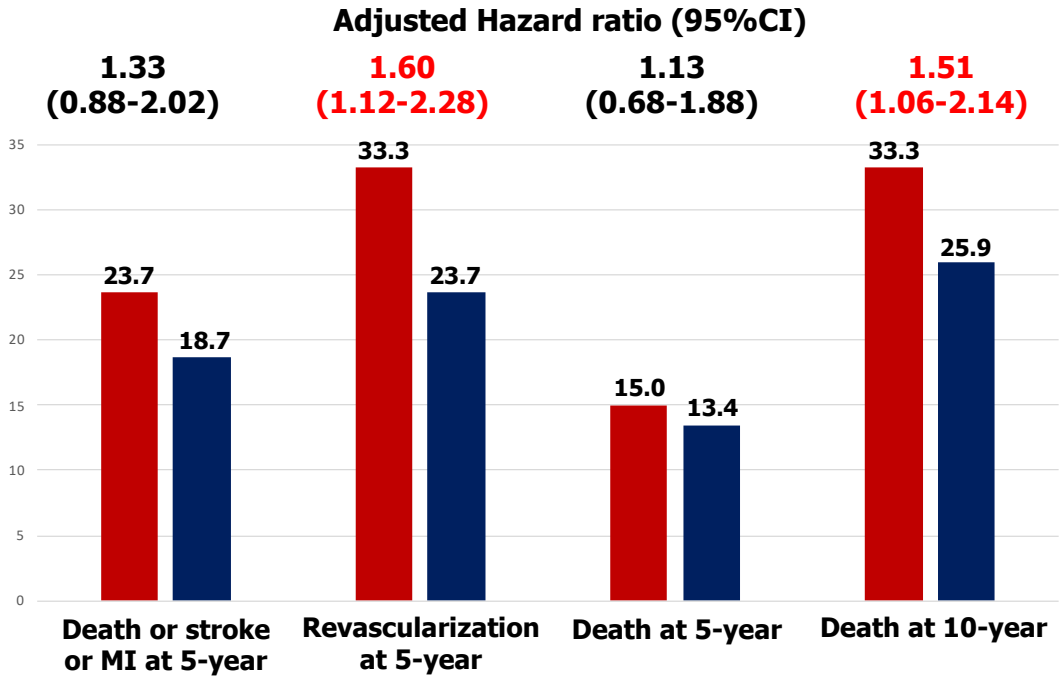
All cause death at 10-year Bifurcation vs non-bifurcation



1-stent versus 2-stent technique





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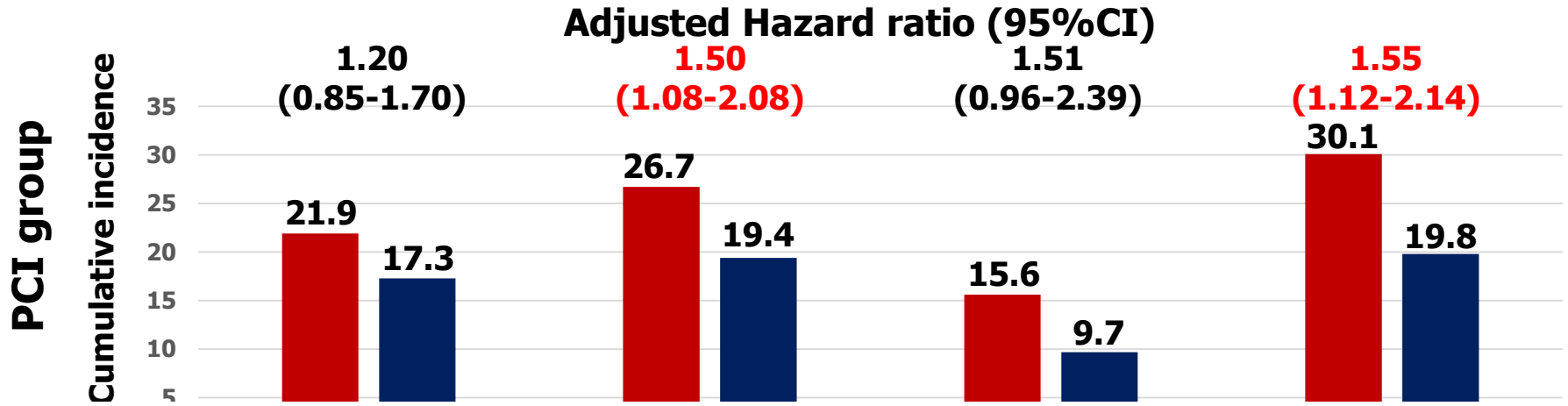
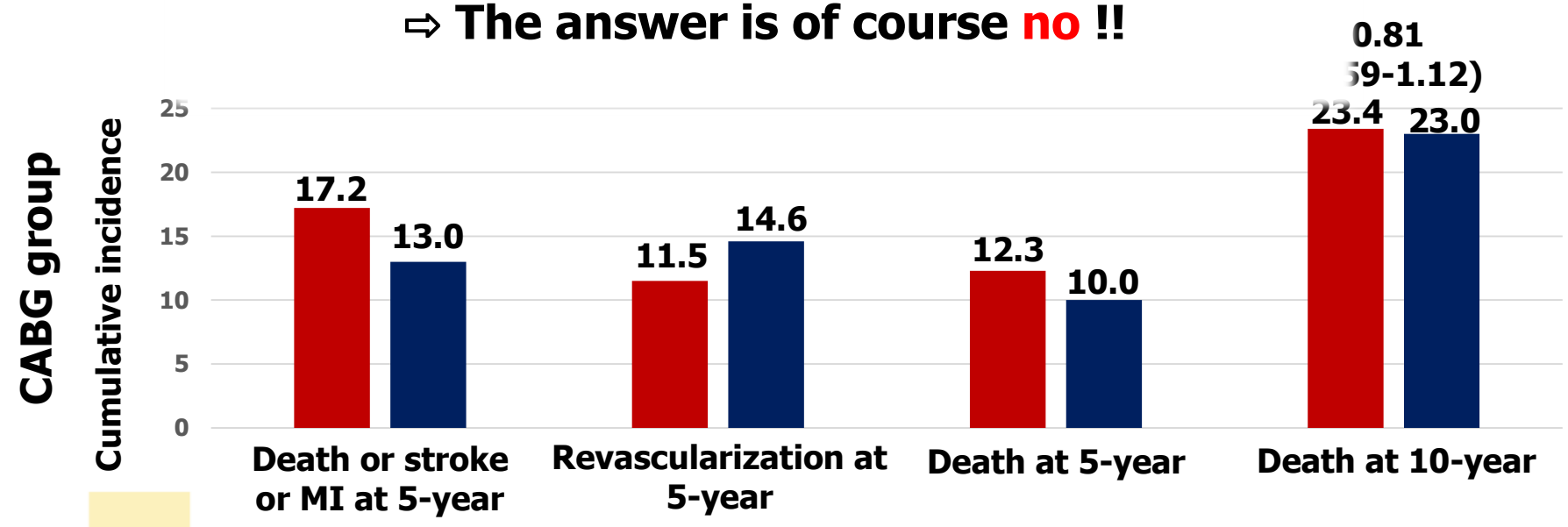
Clinical Outcomes



Based on average treatment effect, should you send all your patients with bifurcation to Surgery?

Bifurcation Non-bifurcation

⇨ **The answer is of course no !!**



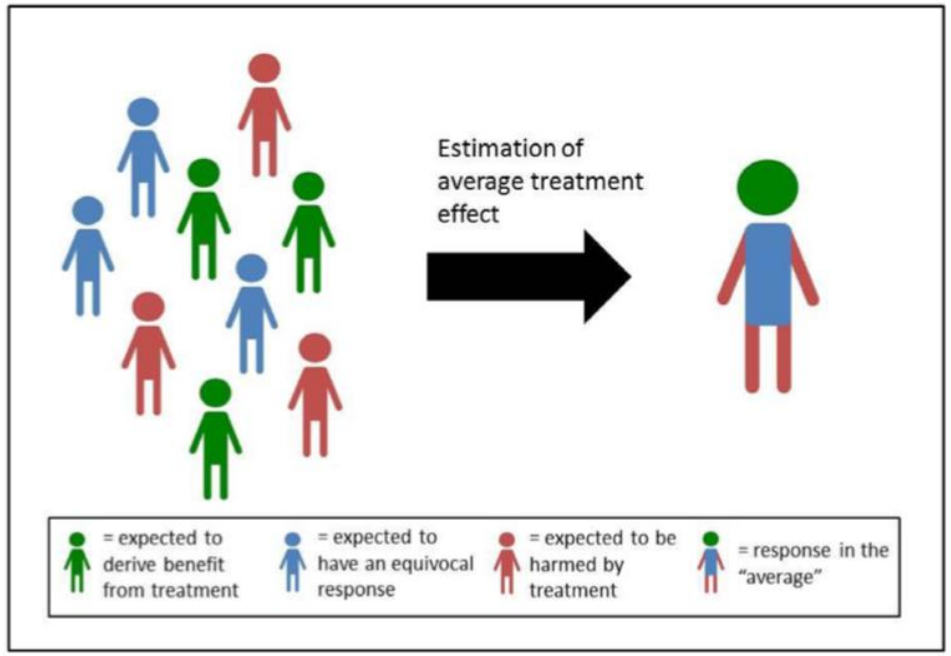
From average treatment effect to individualized prognosis

PERSPECTIVE

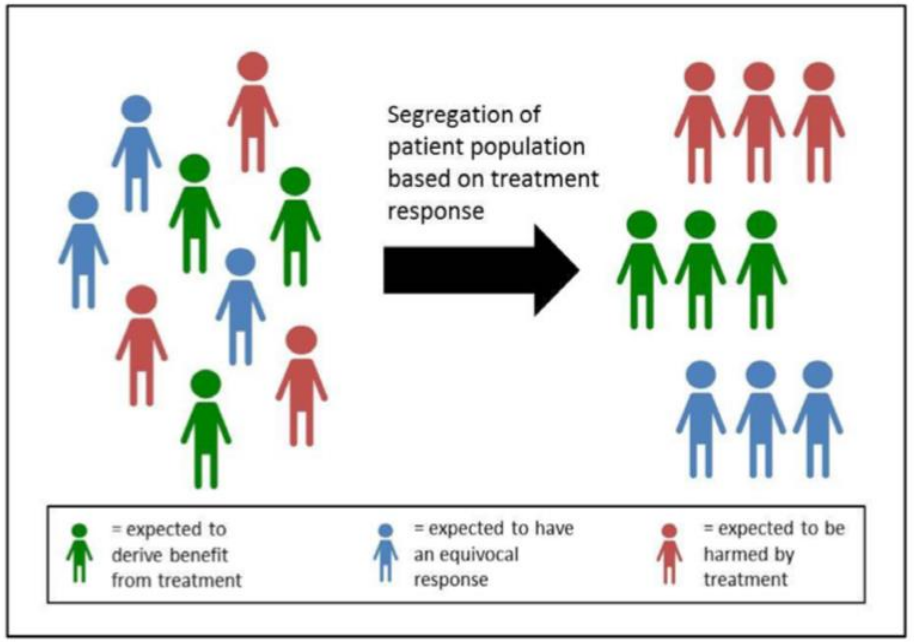
Decision Tools to Improve Personalized Care in Cardiovascular Disease

Moving the Art of Medicine Toward Science

Average treatment effect assessed in clinical trials



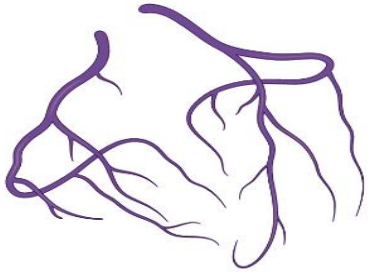
Identification of heterogeneous responses to treatment



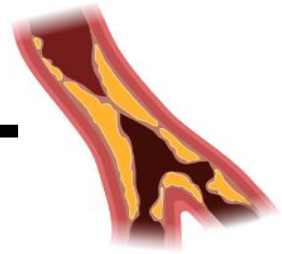
Yeh et al. Circulation 2017;135:1097-1100

Individualized Predicted versus observed treatment benefit for 10-year mortality in bifurcation group

LMCAD or 3VD



At least one bifurcation

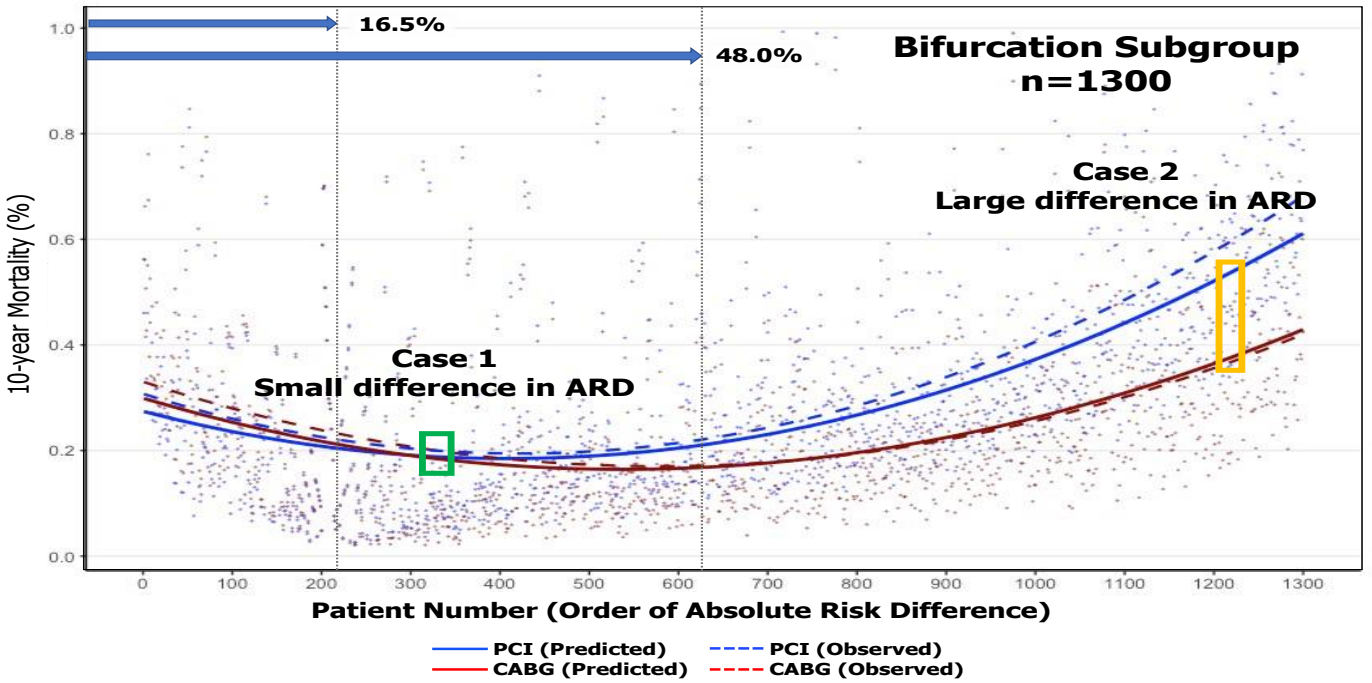


Case1		Case2
58	**Age**	66
Yes	**Diabetes**	Yes
No	**On Insulin**	Yes
No	**PVD**	No
No	**COPD**	No
97	**Creatinine clearance**	41
57	**LVEF**	36
No	**Current smokers**	No
No	**LMCAD**	No
19	**SYNTAX score**	35

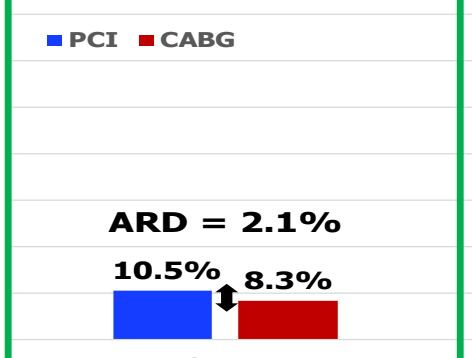
***ARD= (10 year mortality of PCI) – (10 year mortality of CABG)**

Predicted ARD

Equipoise of PCI and CABG ← 0% — 4.5% → **CABG Better**

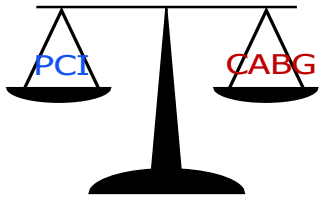


Bifurcation lesion but ARD<4.5%



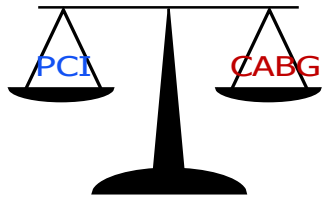
Case1

Predicted Mortality



Equipoise of PCI and CABG

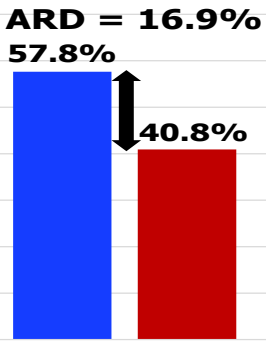
Observed Mortality



Equipoise of PCI and CABG

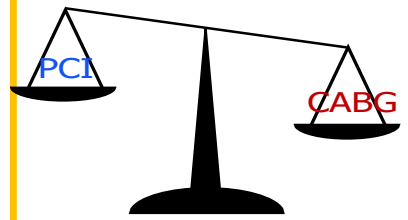
Can be referred for either PCI or CABG

Bifurcation lesion and ARD≥4.5%



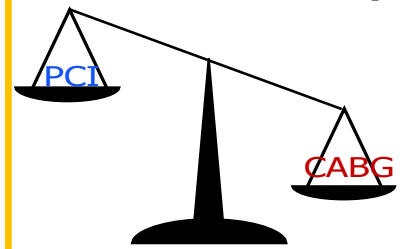
Case2

Predicted Mortality



CABG Better

Observed Mortality



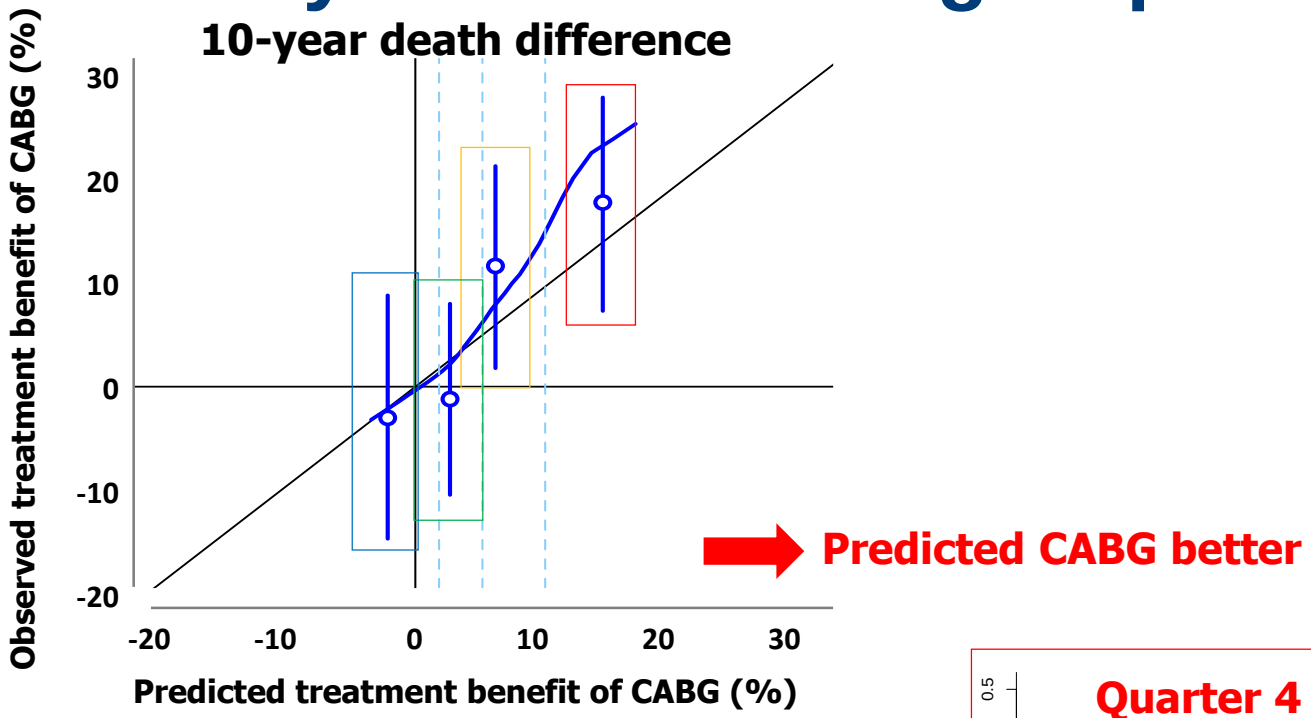
CABG Better

CABG should be recommended

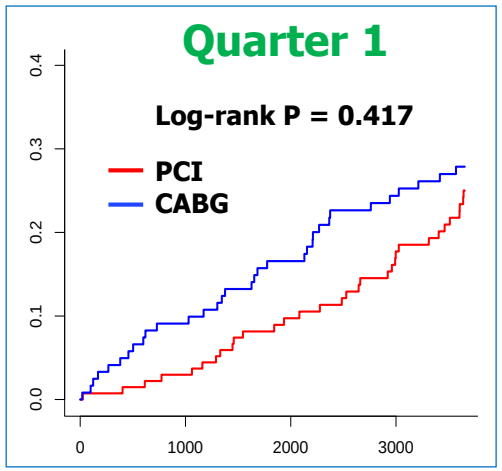
Individualized Predicted versus observed treatment benefit for 10-year mortality in bifurcation group

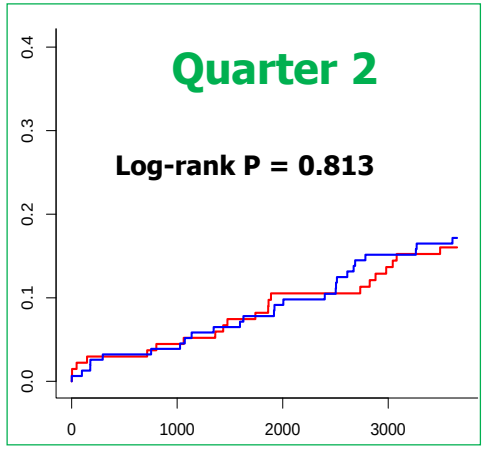
Observed CABG better

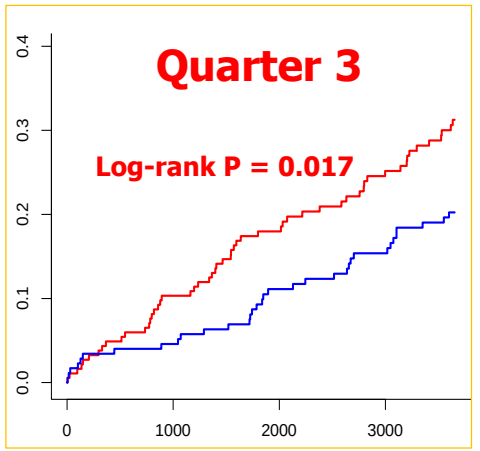
Observed PCI better

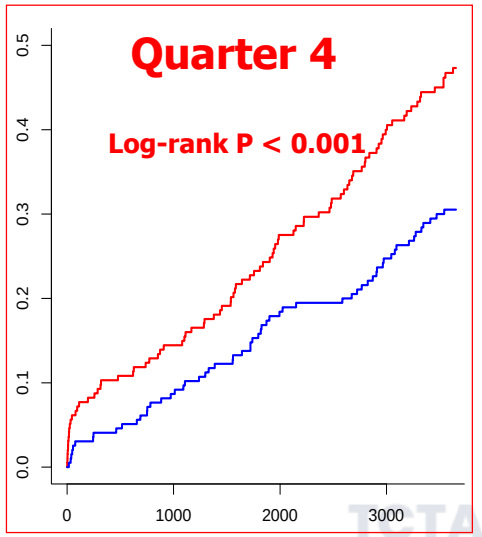


Predicted CABG better









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Conclusion / Take-home Message

- Bifurcation lesion(s) require specific attention from the heart team when deciding between PCI and CABG, considering the overall higher all-cause mortality associated with PCI at long-term.

- Careful evaluation of the bifurcation PCI complexity (anticipated need for 2-stent) and evaluation of individualized10-year vital prognosis using the SS-2020 might be helpful in the decision-making process.