Long-term Follow-up in 1,528 Left Main PCI Patients from a Large Single Center Experience
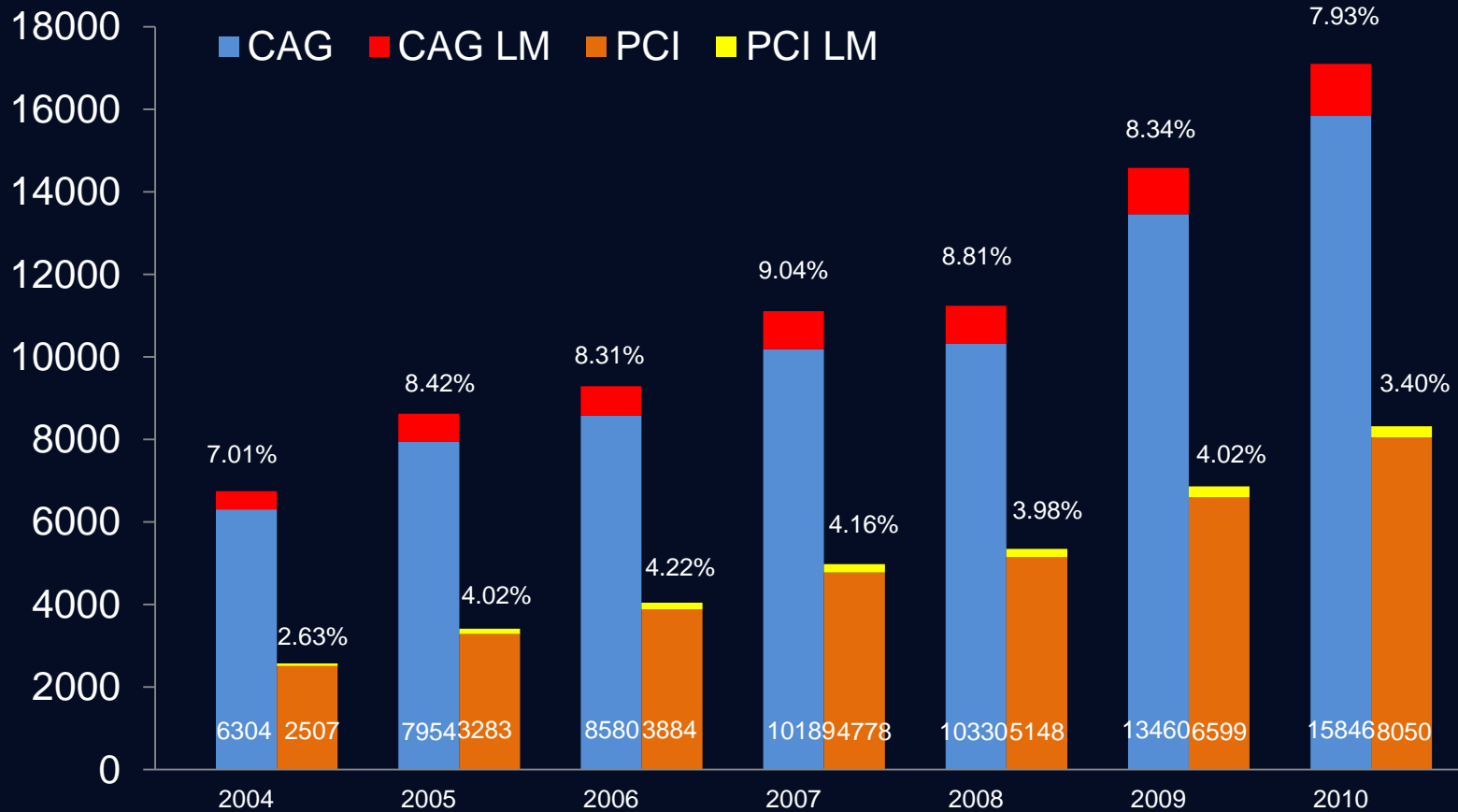
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Background

- PCI with DES implantation has been considered an alternative therapy to CABG for left main (LM) patients with low to moderate risk according to previous randomized trials and registries

- We prospectively collected the PCI data and long-term clinical follow-up results (up to 8 years) in 1,528 consecutive patients undergoing LM PCI from Jan. 2004 to Dec. 2010 at Fu Wai Hospital

Wijns. W., et al. Eur Heart J. 2010
Kushner. FG., et al. J Am Coll Cardiol. 2009
Serruys, PW., et al. N Engl J Med. 2009
Mohr, FW., et al. Lancet. 2013

Proportion of LM Patients at Fu Wai

CAG: Patients undergoing coronary angiography only
CAG-LM: LM patients in CAG population
PCI: Patients undergoing percutaneous coronary intervention
PCI-LM: LM patients in PCI population

Baseline Characteristics

34,249 patients underwent PCI from Jan 2004 to Dec 2010 at Fu Wai Hospital

↓

LM PCI Patients n=1,528

↓

Clinical follow-up after PCI at 30 days, 6 months, 1 year, and annually up to 8 years

	Results
Age (years)	59.98 ± 10.67
Female	324 (21.2%)
Prior MI	387 (25.3%)
Prior PCI	343 (22.4%)
Diabetes	369 (24.1%)
Hypertension	824 (53.9%)
Hyperlipidemia	766 (50.1%)
Family History of CAD	183 (12.0%)
Prior Stroke	100 (6.5%)
Peripheral Vascular Disease	80 (5.2%)
COPD	12 (0.8%)
Current Smoker	433 (28.3%)
LVEF (%)	62.81 ± 7.55
Angina	
Stable	464 (30.4%)
Unstable	1017 (66.6%)
Silent Ischemia	47 (3.1%)

* All data represented as n (%) or mean $\pm$ SD
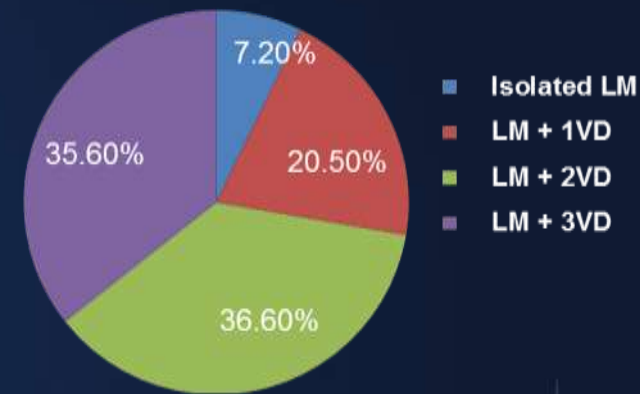
Angiographic Characteristics &Different Scores

	Results
PCI Access	
Radial Approach	861 (56.3%)
Femoral Approach	667 (43.7%)
LM Lesion Type	
De Novo	1482 (97.0%)
Restenotic	46 (3.0%)
Number of Target Lesions	1.69 ± 0.80
Number of Stents per Patient	2.16 ± 1.15
IVUS Usage	575 (37.6%)
Complications During Procedure	61 (4.0%)
PCI Procedural Success	1507 (98.6%)
Baseline SYNTAX Score	23.95 ± 7.06
Residual SYNTAX Score	4.42 ± 5.87
Modified ACEF Score	1.21 ± 0.75
Clinical SYNTAX Score	29.74 ± 22.16
Logistic Clinical SYNTAX Score	8.34 ± 3.00
SYNTAX Score II – PCI	25.60 ± 7.83
SYNTAX Score II – CABG	26.72 ± 9.62

* All data represented as n (%) or mean ± SD

LM Lesion Location

- Ostium: 11.50%
- Shaft: 6.50%
- Distal Bifurcation: 82.00%

LM Lesion Type

- Isolated LM: 7.20%
- LM + 1VD: 20.50%
- LM + 2VD: 36.60%
- LM + 3VD: 35.60%
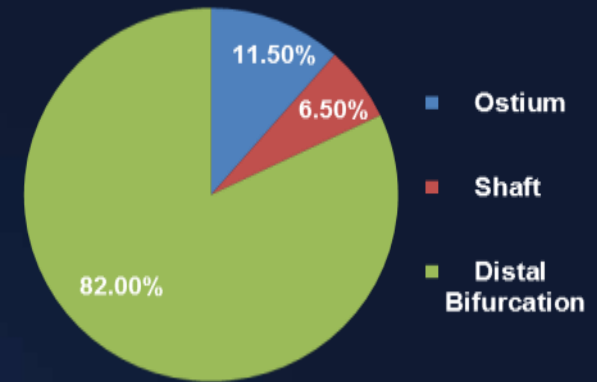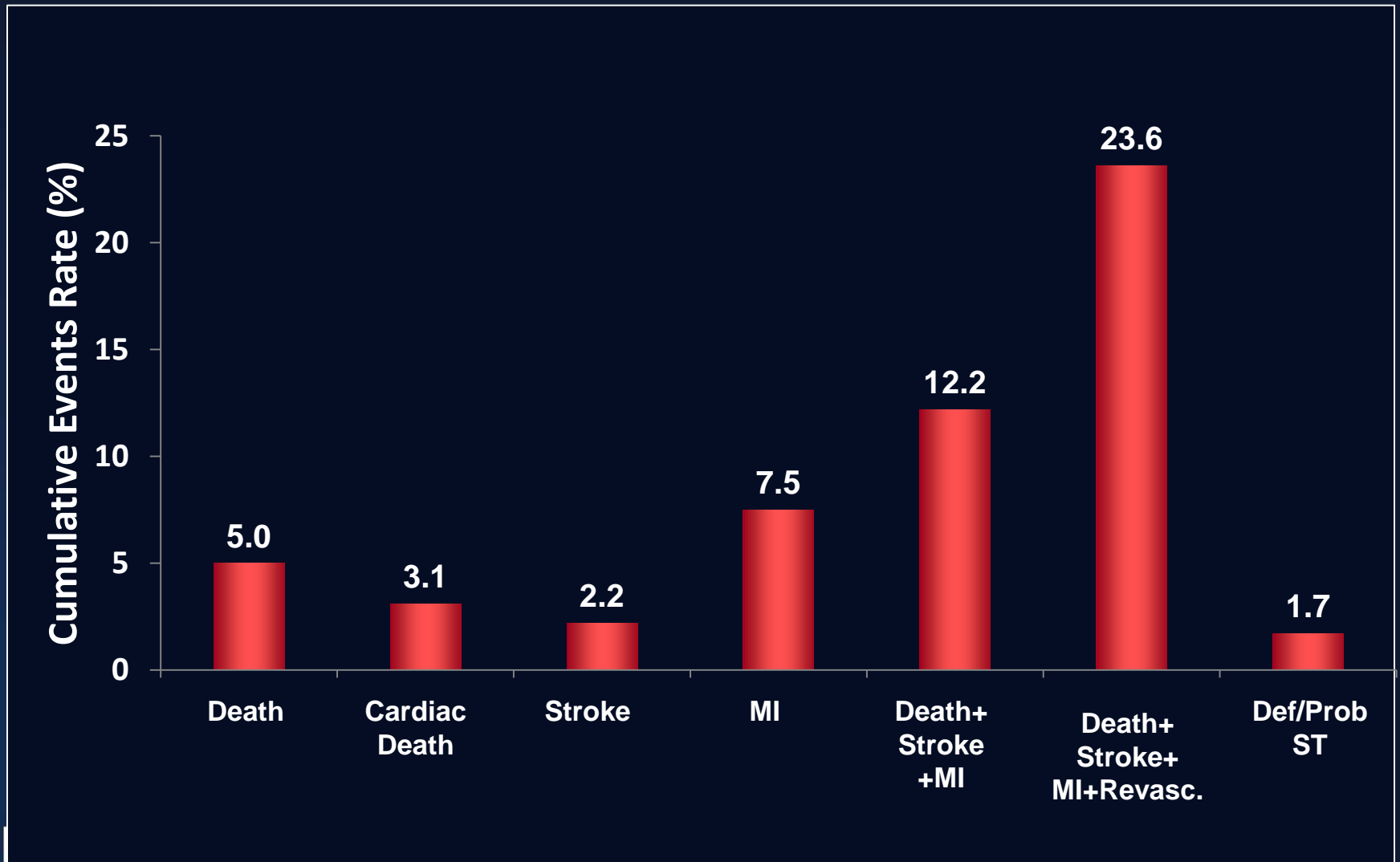
Clinical Outcomes at 30 Days
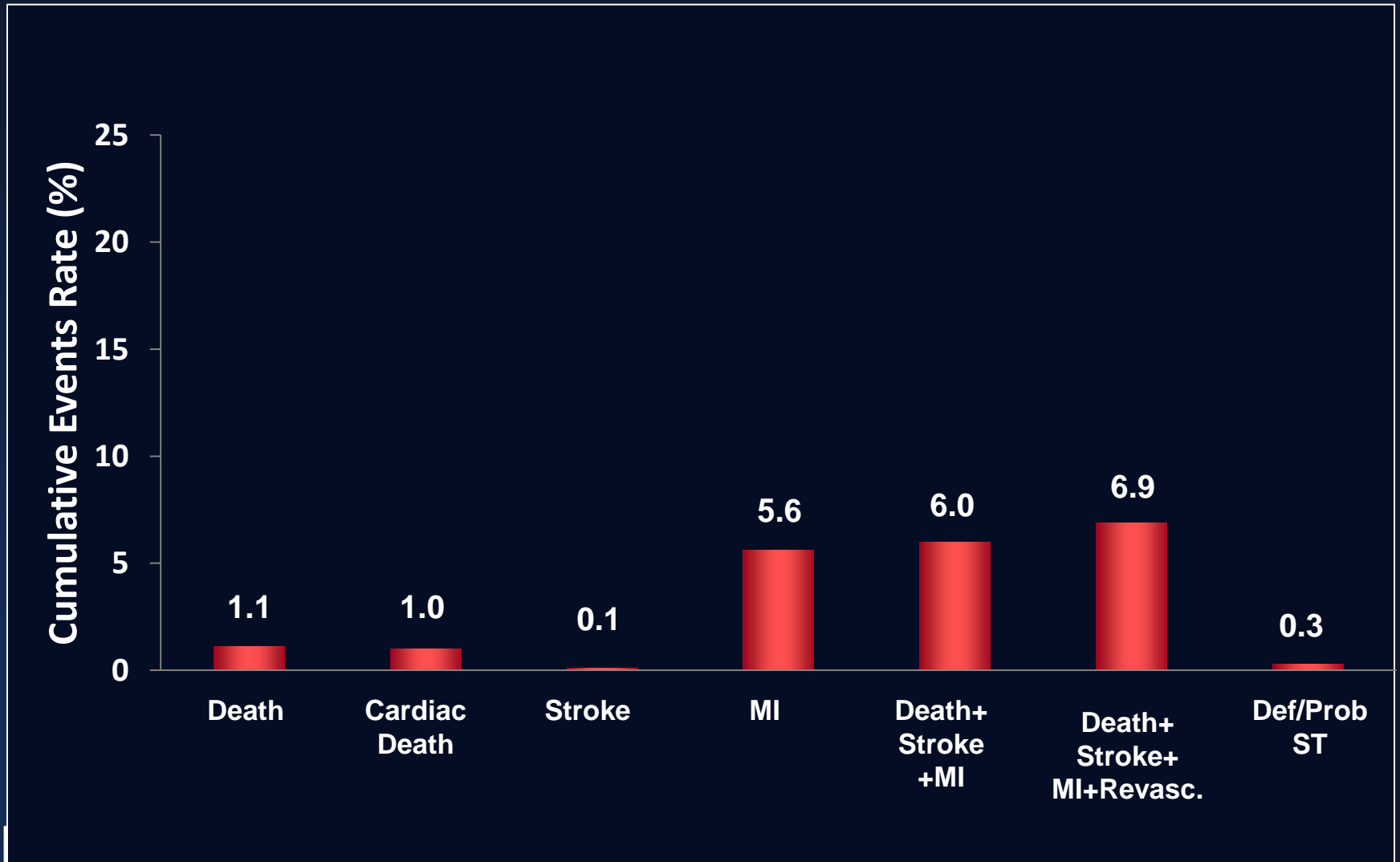
Long-Term Clinical Outcomes
(Mean Follow-up of 4.4 Years)

Subgroup

DM vs. Non-DM

Background

- Scant data exist regarding the impact of diabetes mellitus status on PCI for LM coronary artery disease.

- We sought to compare the impact of the presence of DM at baseline among patients undergoing LM PCI on long-term ischemic outcomes.

Baseline Characteristics

	Diabetics N=369	Non-Diabetics N=1,159	P
Age (years)	60.8±9.7	59.7±11.0	0.059
Female	80 (21.7%)	244 (21.1%)	0.8
LVEF (%)	62.63±7.60	62.87±7.54	0.59
Prior MI	110 (29.8%)	277 (23.9%)	*0.02*
Prior PCI	90 (24.4%)	253 (21.8%)	0.31
Hypertension	263 (71.3%)	561 (48.4%)	*<0.0001*
Hyperlipidemia	236 (64.0%)	530 (45.7%)	*<0.0001*
Prior Stroke	38 (10.3%)	62 (5.3%)	*0.001*
Peripheral Vascular Disease	23 (6.2%)	57 (4.9%)	0.33
COPD	5 (1.4%)	7 (0.6%)	0.18
Unstable Angina	236 (64.0%)	781 (67.4%)	0.31

Note: Data represented as n (%) or mean ± SD

Angiographic Characteristics & Procedural Outcomes

	Diabetics N=369	Non-Diabetics N=1,159	P
Angiographic Findings			*0.0006*
Isolated LM	21 (5.7%)	89 (7.7%)	
LM + 1VD	53 (14.4%)	261 (22.5%)	
LM + 2VD	139 (37.7%)	421 (36.3%)	
LM + 3VD	156 (42.3%)	388 (33.5%)	
LM Lesion Location			0.42
Ostium	49 (13.3%)	126 (10.9%)	
Shaft	22 (6.0%)	78 (6.7%)	
Distal Bifurcation	298 (80.8%)	955 (82.4%)	
Number of Target Lesions	1.80 ± 0.87	1.66 ± 0.77	*0.006*
Number of Stents per Patient	2.31 ± 1.23	2.11 ± 1.12	*0.006*
PCI Procedural Success	367 (99.5%)	1140 (98.4%)	0.08
DAPT > 1 year	355 (96.2%)	1101 (95.0%)	0.33
Follow-up Duration (days)	1678 ± 720	1564 ± 739	*0.009*
Baseline SYNTAX Score	25.05 ± 7.19	23.59 ± 6.98	*0.0005*
Residual SYNTAX Score	5.09 ± 6.11	4.20 ± 5.78	*0.01*
Clinical SYNTAX Score	30.30 ± 20.33	29.56 ± 22.76	0.56
Logistic Clinical SYNTAX Score	8.55 ± 2.76	8.27 ± 3.07	0.10
SYNTAX Score II - PCI	26.08 ± 7.78	25.44 ± 7.84	0.17
SYNTAX Score II - CABG	27.38 ± 8.77	26.51 ± 9.87	0.11

Note: Data represented as n (%) or mean $\pm$ SD

Cox Regression Results without and with Multivariate Adjustment in Diabetics vs. Non-Diabetics

Variables	β Value	P	Hazard Ratio [95%CI]
All Cause Death*	0.1693	0.5024	1.184 [0.722,1.943]
All Cause Death* *	0.2683	0.3262	1.308 [0.765,2.234]
Cardiac Death*	-0.0828	0.8102	0.921 [0.468,1.809]
Cardiac Death* *	-0.0466	0.9025	0.955 [0.453,2.010]
Stroke*	1.2442	0.0004	3.470 [1.748,6.888]
Stroke* *	1.1282	0.0019	3.090 [1.518,6.289]
MI*	0.0803	0.7053	1.084 [0.715,1.643]
MI* *	0.0452	0.8403	1.046 [0.674,1.623]
Target Lesion Revascularization*	0.6107	0.0074	1.842 [1.178,2.879]
Target Lesion Revascularization* *	0.7406	0.0024	2.097 [1.300,3.383]
Any Revascularization*	0.2812	0.0620	1.325 [0.986,1.780]
Any Revascularization* *	0.2528	0.1109	1.288 [0.944,1.757]
All Cause Death + Stroke + MI*	0.2896	0.0688	1.336 [0.978,1.825]
All Cause Death + Stroke + MI* *	0.2550	0.1285	1.290 [0.929,1.793]
All Cause Death + Stroke + MI + Any Revascularization*	0.2355	0.0422	1.266 [1.008,1.589]
All Cause Death + Stroke + MI + Any Revascularization* *	0.1987	0.1029	1.220 [0.961,1.549]
Definite or Probable Stent Thrombosis*	-0.1170	0.8016	0.890 [0.357,2.216]
Definite or Probable Stent Thrombosis* *	-0.3195	0.5124	0.727 [0.279,1.889]

Note: * Cox regression result without adjustment

** Cox regression result with multivariate adjustment

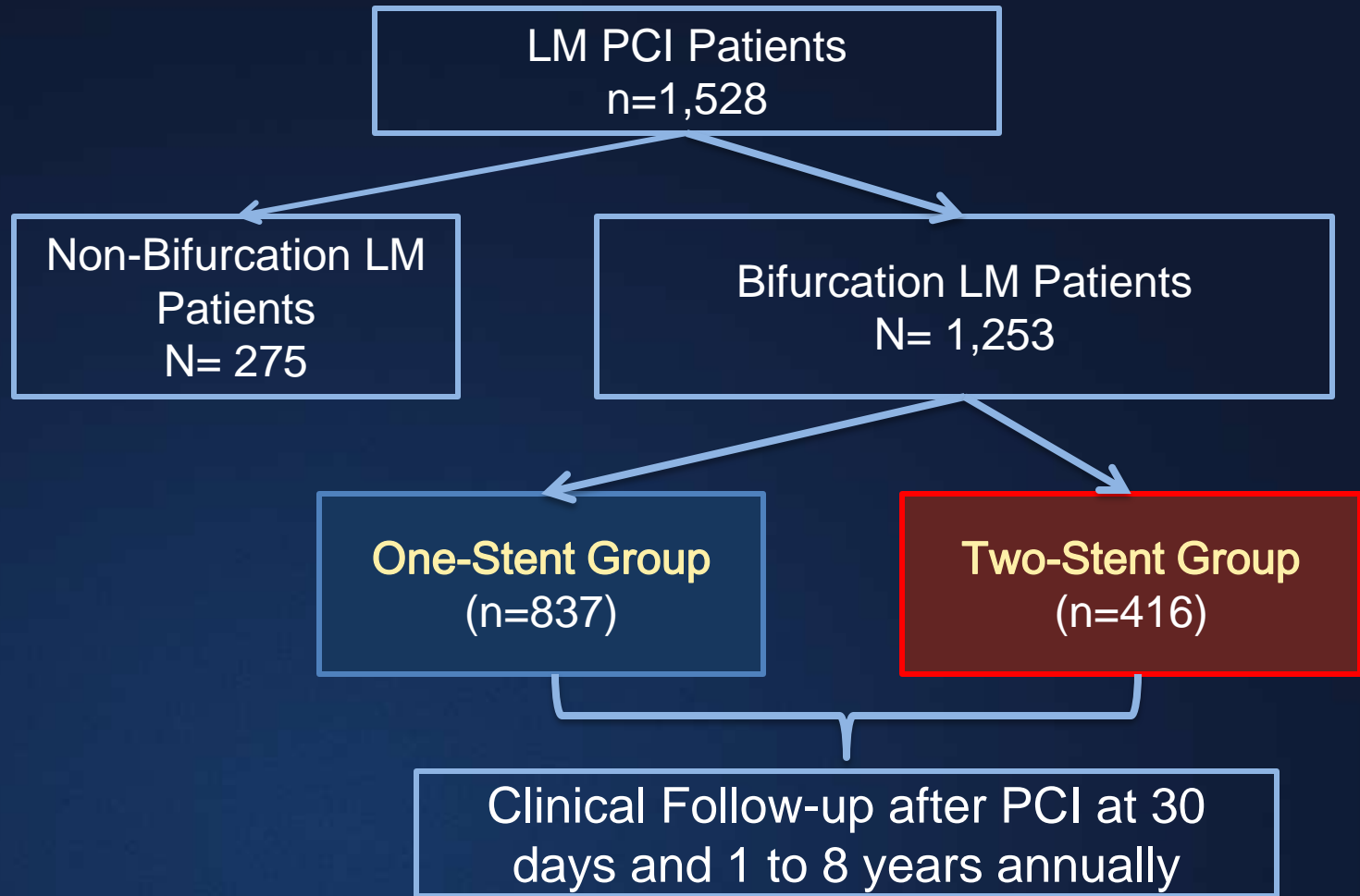# Conclusion

Among this large series of consecutives patients undergoing LM PCI, DM was not associated with an increase in death or ST, but was independently predictive of stroke, and TLR at 6-year follow-up.

Subgroup

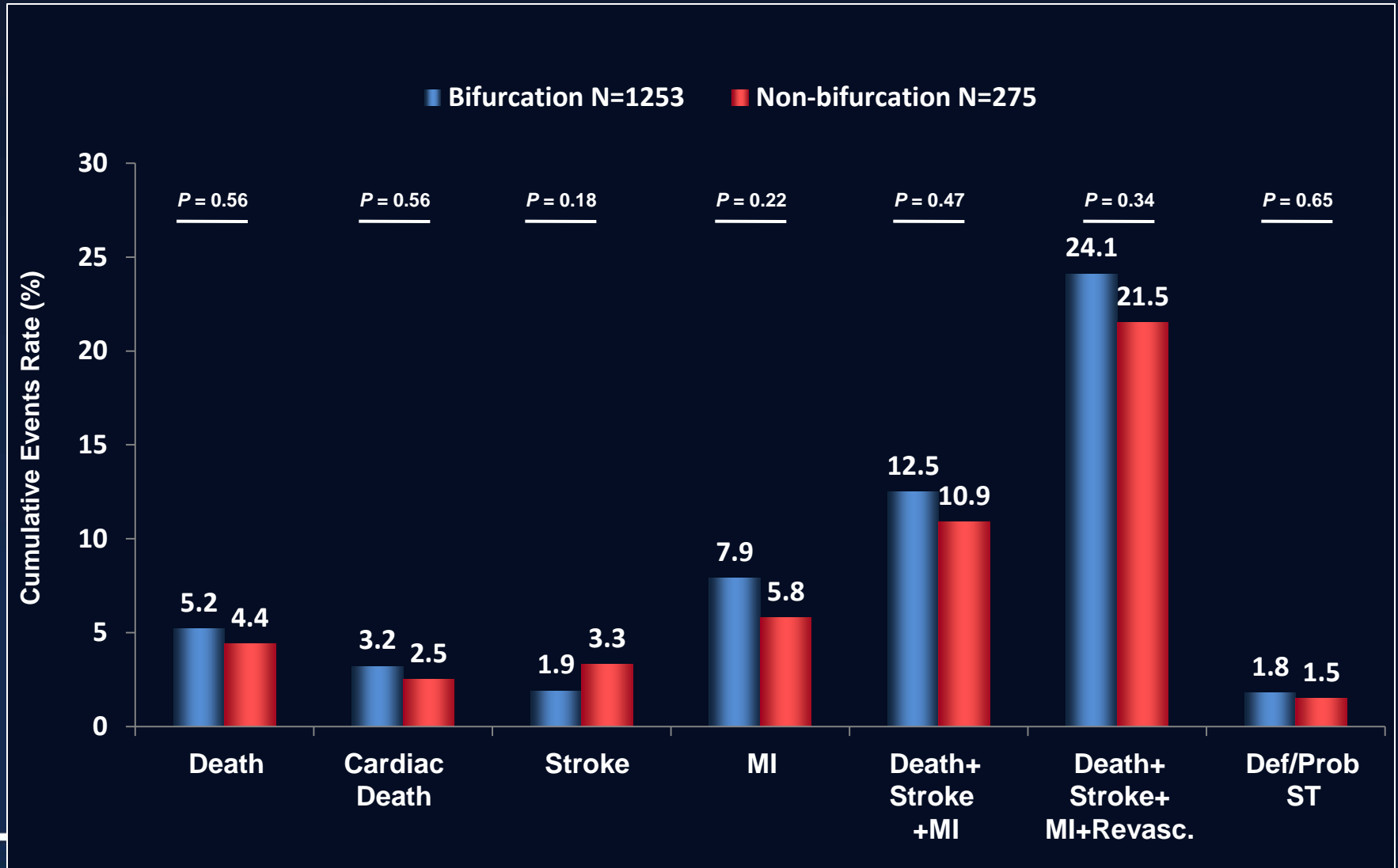## Bifurcation vs. Non-Bifurcation One-Stent vs. Two-Stent

LM Bifurcation and PCI Strategy

Long-Term Clinical Outcomes
(Mean Follow-up of 4.4 Years)

Long-Term Clinical Outcomes (1- vs. 2-Stent) (Mean Follow-up of 4.4 Years)
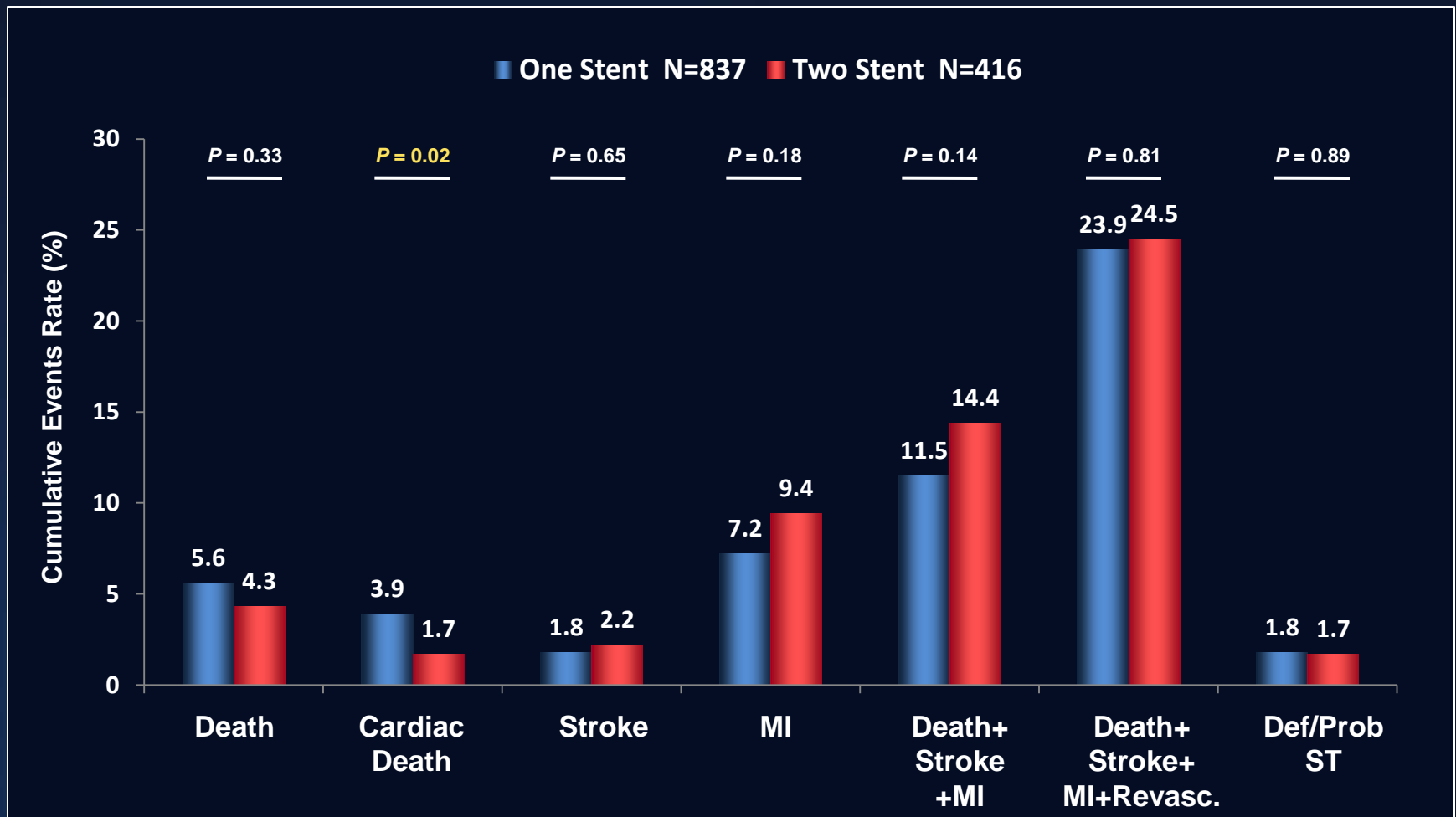
Validation and Comparison of the Long-Term Prognostic Capability of the SYNTAX Score-II Among 1,528 Consecutives Patients Who Underwent Left Main PCI

Submitted to JACC

Background

- Recently, the SYNTAX Score II (SS-II) was developed in an attempt to individualize and help the decision-making process between PCI and CABG.

- However, there is a paucity of data regarding the utility of SS-II in patients undergoing LM-PCI.

- We sought to evaluate, confirm, and compare the long-term prognostic capacity of the SYNTAX score-II (SS-II) and other risk scores among patients undergoing left main percutaneous coronary intervention (LM-PCI).
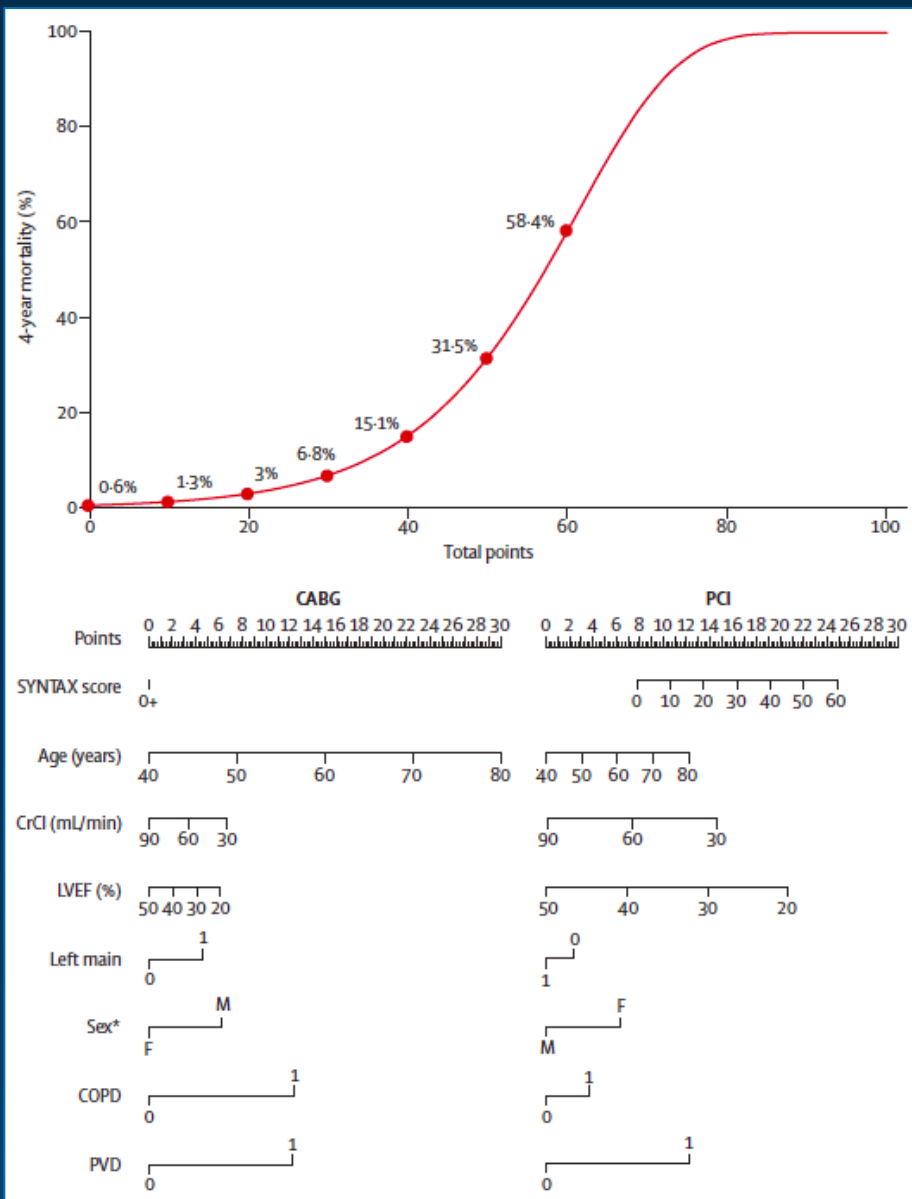
Personalizing Risk Assessment for PCI or CABG
The SYNTAX Score 2
(From the SYNTAX trial)

Rationale: Low, intermediate, and high categories of anatomical complexity in the SYNTAX score hide lower risk patients in the higher SYNTAX score groups, and viceversa

Strength: Enables direct, personalized comparisons of long-term estimates of mortality for individual patients with LM or 3VD disease referred to PCI or CABG

Online version under development

Patient Flow

LM PCI Patients
n=1,528

↓

Calculate SYNTAX
Score II for PCI

Low Tertile
SS-II 0-21 (n=508)

Intermediate Tertile
$21 < SS\text{-}II <= 28$
(n=480)

High Tertile
SS-II >28 (n=540)

Clinical Follow-up after PCI at 30 days
and 1 to 8 years annually
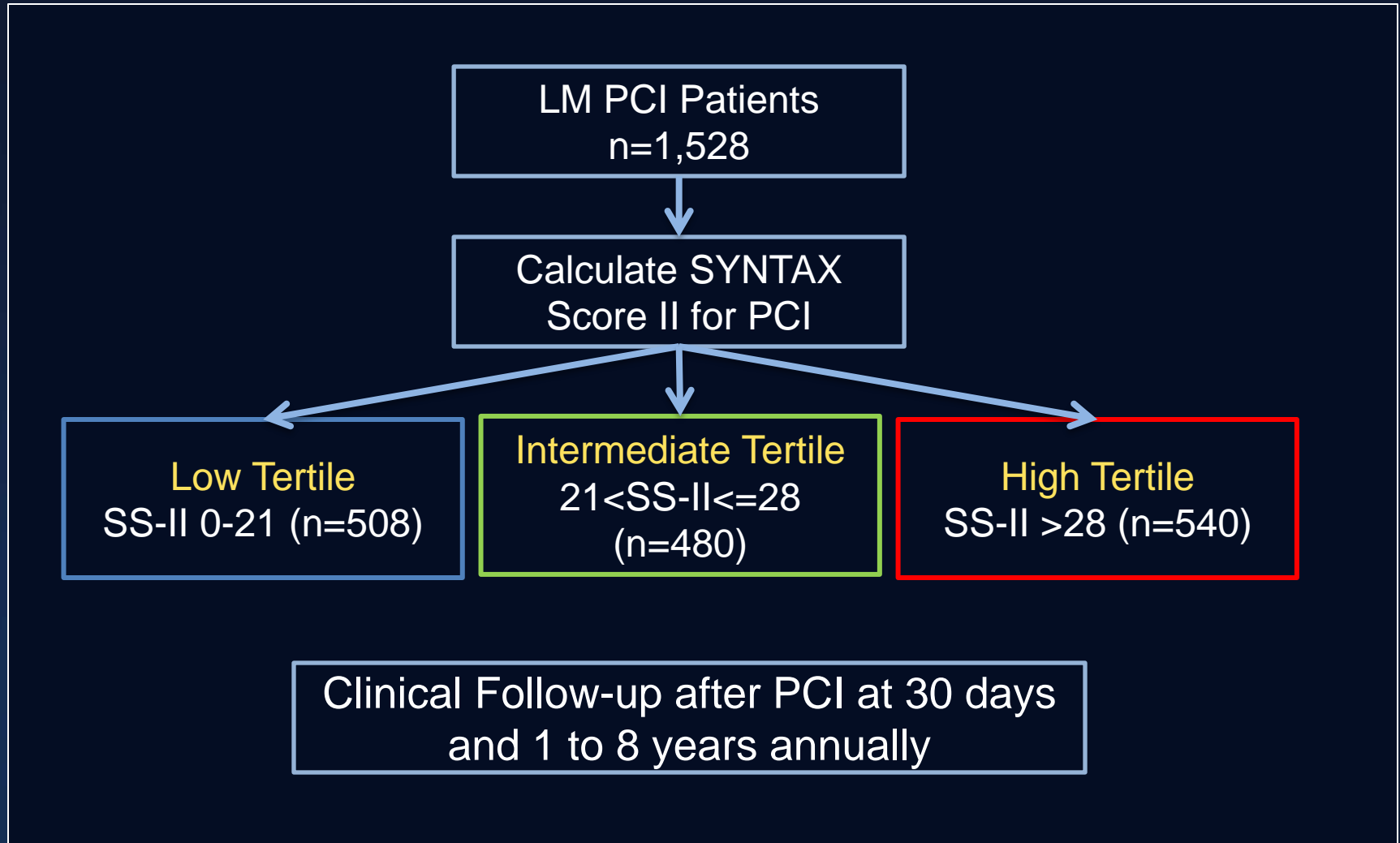
Baseline Clinical Characteristics-1

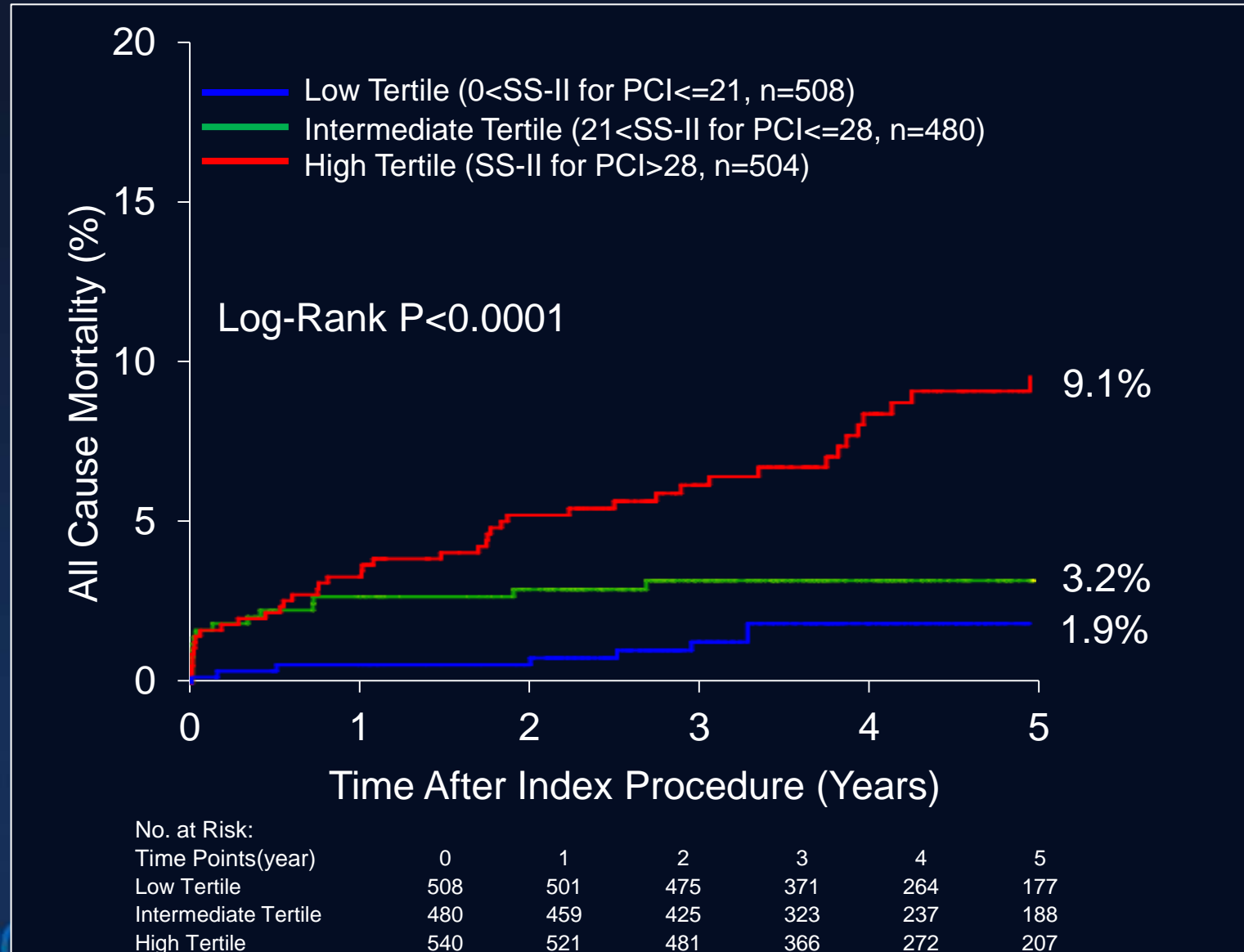|	Low Tertile SS-II ≤21 (n=508)	Intermediate Tertile SS-II >21 and ≤28 (n=480)	High Tertile SS-II >28 (n=540)	p Value
Age (years)	50.3±7.3	60.3±7.8	68.8±7.3	<0.0001
Female	22/508 (4.3)	108/480 (22.5)	194/540 (35.9)	<0.0001
Weight (kg)	76.6±9.8	72.4±10.0	67.9±9.9	<0.0001
Height (cm)	170.5±5.8	167.5±6.8	164.8±8.0	<0.0001
Diabetes mellitus	*115/508 (22.6)*	*118/480 (24.6)*	*136/540 (25.2)*	*0.60*
Hypertension	237/508 (46.7)	272/480 (56.7)	315/540 (58.3)	0.0003
Hyperlipidemia	276/508 (54.3)	236/480 (49.2)	254/540 (47.0)	0.05
Family history of CAD	77/508 (15.2)	51/480 (10.6)	55/540 (10.2)	0.03
Prior myocardial infarction	110/508 (21.7)	115/480 (24.0)	162/540 (30.0)	0.006
Prior PCI	115/508 (22.6)	106/480 (22.1)	122/540 (22.6)	0.97
Prior stroke	18/508 (3.5)	33/480 (6.9)	49/540 (9.1)	0.0009
Peripheral vascular disease	0/508 (0.0)	5/480 (1.0)	75/540 (13.9)	<0.0001
COPD	2/508 (0.4)	3/480 (0.6)	7/540 (1.3)	0.23
LVEF (%)	63.6±6.3	63.2±7.0	61.7±8.9	<0.0001
Creatinine clearance (mL/min)	110.3±24.3	94.1±26.0	68.4±19.1	<0.0001

Baseline Clinical Characteristics-2

	Low Tertile SS-II ≤21 (n=508)	Intermediate Tertile SS-II >21 and ≤28 (n=480)	High Tertile SS-II >28 (n=540)	p Value
Angiographic findings				<0.0001
Isolated LM	67/508 (13.2)	22/480 (4.6)	21/540 (3.9)	
LM + 1 vessel	154/508 (30.3)	97/480 (20.2)	63/540 (11.7)	
LM + 2 vessels	173/508 (34.1)	172/480 (35.8)	215/540 (39.8)	
LM + 3 vessels	114/508 (22.4)	189/480 (39.4)	241/540 (44.6)	
LM lesion location				0.004
Ostium	66/508 (13.0)	51/480 (10.6)	58/540 (10.7)	
Shaft	50/508 (9.8)	24/480 (5.0)	26/540 (4.8)	
Distal bifurcation	392/508 (77.2)	405/480 (84.4)	456/540 (84.4)	
LM with final kissing	198/392 (50.5)	203/405 (50.1)	208/456 (45.6)	0.28
LM bifurcation with 2-stent	128/392 (32.7)	137/405 (33.8)	148/456 (32.5)	0.87

All Cause Mortality

Log-Rank P<0.0001

Low Tertile (0<SS-II for PCI<=21, n=508)
Intermediate Tertile (21<SS-II for PCI<=28, n=480)
High Tertile (SS-II for PCI>28, n=504)

9.1%
3.2%
1.9%

All Cause Mortality (%)

Time After Index Procedure (Years)

No. at Risk:

Time Points(year)	0	1	2	3	4	5
Low Tertile	508	501	475	371	264	177
Intermediate Tertile	480	459	425	323	237	188
High Tertile	540	521	481	366	272	207

Cardiac Mortality

Log-Rank P=0.0009

Low Tertile (SS-II for PCI ≤21, n=508)
Intermediate Tertile (SS-II for PCI >21 and ≤28, n=480)
High Tertile (SS-II for PCI >28, n=540)

5.5%
2.1%
1.4%

Cardiac Death (%)

Time After Index Procedure (Years)

No. at Risk:	0	1	2	3	4	5
Low Tertile	508	501	475	371	265	178
Intermediate Tertile	480	460	426	325	239	190
High Tertile	540	523	484	369	277	213

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Myocardial Infarction

Log-Rank P=0.0004

Low Tertile (SS-II for PCI ≤21, n=508)
Intermediate Tertile (SS-II for PCI >21 and ≤28, n=480)
High Tertile (SS-II for PCI >28, n=540)

10.7%
7.0%
4.1%

Time After Index Procedure (Years)

No. at Risk:	0	1	2	3	4	5
Low Tertile	508	487	461	361	257	171
Intermediate Tertile	480	437	403	306	221	175
High Tertile	540	493	457	351	263	201

Ischemic-Driven TVR

Log-Rank P=1.00

Legend:
- Low Tertile (SS-II for PCI ≤21, n=508) — blue
- Intermediate Tertile (SS-II for PCI >21 and ≤28, n=480) — green
- High Tertile (SS-II for PCI >28, n=540) — red

End values: 9.7%, 9.7%, 9.6%

Y-axis: Ischemic-Driven TVR (%)
X-axis: Time After Index Procedure (Years)

No. at Risk:

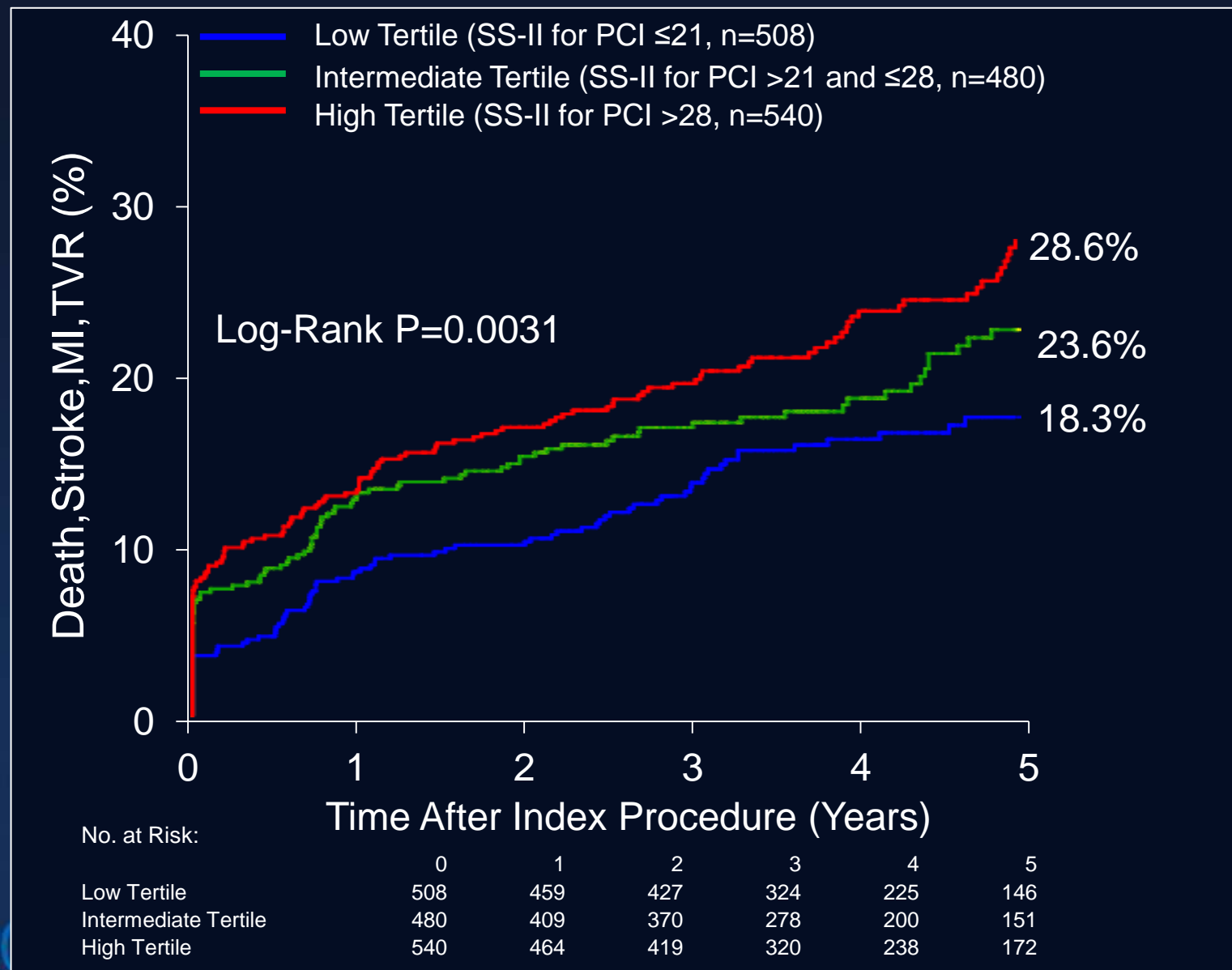|	0	1	2	3	4	5
Low Tertile	508	481	449	345	244	160
Intermediate Tertile	480	443	401	303	225	175
High Tertile	540	505	465	351	267	202

Death/Stroke/MI

Death/Stroke/MI/Revasc.

Independent Predictors of Mortality
n=1,528 LM-PCI

Variable	Adjusted HR [95% CI]	P value
Age (per 10 years increase)	1.30 [0.92, 1.83]	0.14
Male gender	1.79 [0.92, 3.49]	0.08
LVEF (per 10% increase)	*0.65 [0.49, 0.86]*	*0.003*
COPD	*3.28 [1.00, 10.75]*	*0.05*
Creatinine clearance (per 10 cc increase)	1.06 [0.95, 1.17]	0.32
Prior MI	*1.69 [1.03, 2.78]*	*0.04*
History of Stroke	1.60 [0.82, 3.15]	0.17
SS II for PCI (per 10 points increase)	*1.76 [1.10, 2.82]*	*0.02*

Discrimination and Calibration of SYNTAX and Derived Scores for All-Cause Mortality

	AUC [95% CI]	HL (p value)
Anatomical SYNTAX score	0.591[0.526,0.656]	3.453(0.90)
Residual SYNTAX score	0.552[0.488,0.617]	5.015(0.76)
Clinical SYNTAX score	0.729[0.669,0.790]	10.76(0.22)
Logistic Clinical SYNTAX score	0.728[0.664,0.792]	9.468(0.30)
SYNTAX score-II	0.694[0.634,0.754]	6.581(0.58)

AUC=Area under the curve; CI=confidence interval;
HL=Hosmer-Lemeshow

	AUC (95%CI)	P
Baseline Syntax Score	0.591[0.526,0.656]	-
Residual Syntax Sore	0.552[0.488,0.617]	0.11
Clinical Syntax Score	0.729[0.669,0.790]	<0.0001
Logistic Clinical Syntax Score	0.728[0.664,0.792]	<0.0001
Syntax Score II For PCI	0.694[0.634,0.754]	<0.0001
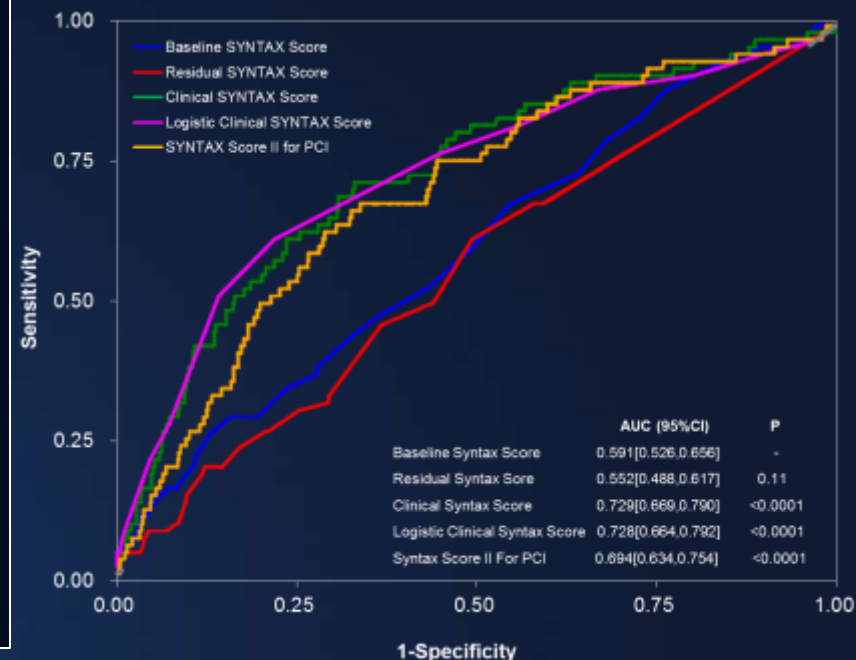
All Cause Death

Reclassification of Adverse Ischemic Events
SYNTAX Score-II vs. Anatomical SYNTAX Score

	NRI or IDI	p Value
All-cause mortality		
NRI	*0.25*	*0.002*
IDI	*0.015*	*0.003*
Cardiac mortality		
NRI	0.05	0.60
IDI	0.001	0.83
Non-Cardiac mortality		
NRI	0.50	0.0003
IDI	0.007	0.002
Definite/probable stent thrombosis		
NRI	0.06	0.69
IDI	-0.005	0.11
All-cause mortality/stroke/MI		
NRI	0.09	0.15
IDI	0.018	<0.0001
All-cause mortality/stroke/MI/ischemia driven revascularization		
NRI	0.02	0.66
IDI	0.00	0.96

Summary

1) Results from this large contemporary cohort of 1,528 consecutives patients undergoing LM-PCI demonstrated favorable short- and long-term outcomes, with low rate of stent thrombosis, revascularization and death.

2) Diabetic patients undergoing LM-PCI had a significant higher rates of stroke (mainly late after PCI) and revascularization after PCI.

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Summary

3) PCI of LM-bifurcation were frequent among our cohort and showed similar favorable results compared to non bifurcation-LM lesions (isolated ostial or mid shaft)

4) The use of a 2 stents strategy for LM-PCI in our cohort appeared safe and associated with low rate of adverse events

Summary

5) Results from this larges series of consecutive patients who underwent LM PCI validated the prognostic capability of the SS-II for long-term mortality among patients with complex coronary artery disease, and confirmed its incremental value in risk prognostication compared to the baseline anatomical SS.

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