Asian TAVI Registry

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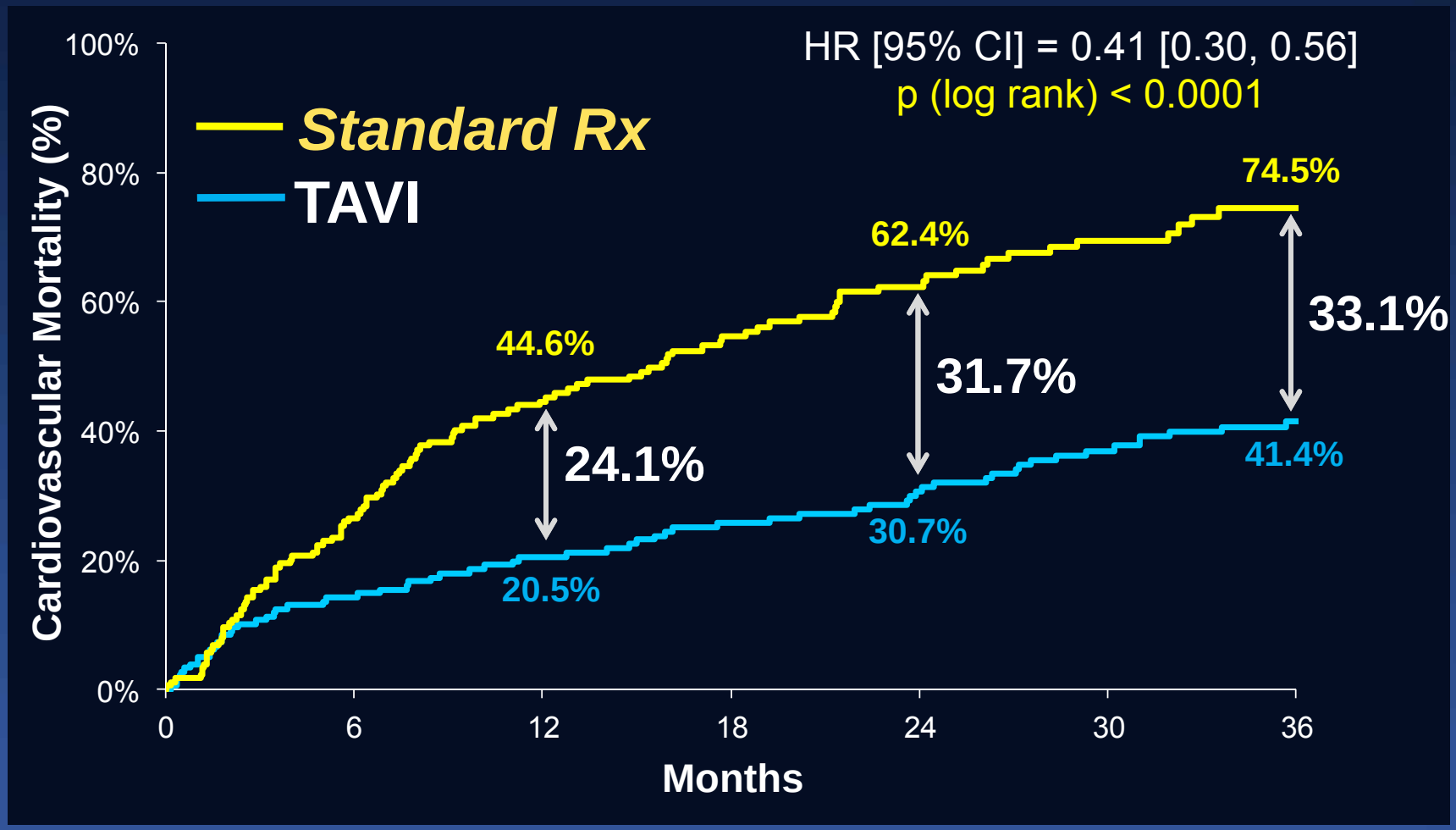
Current TAVI

For Symptomatic Severe AS

- *Inoperable,*
- *High Risk Group of Patients*

TAVI for Inoperable Patients

3-Year Mortality of SAPIEN

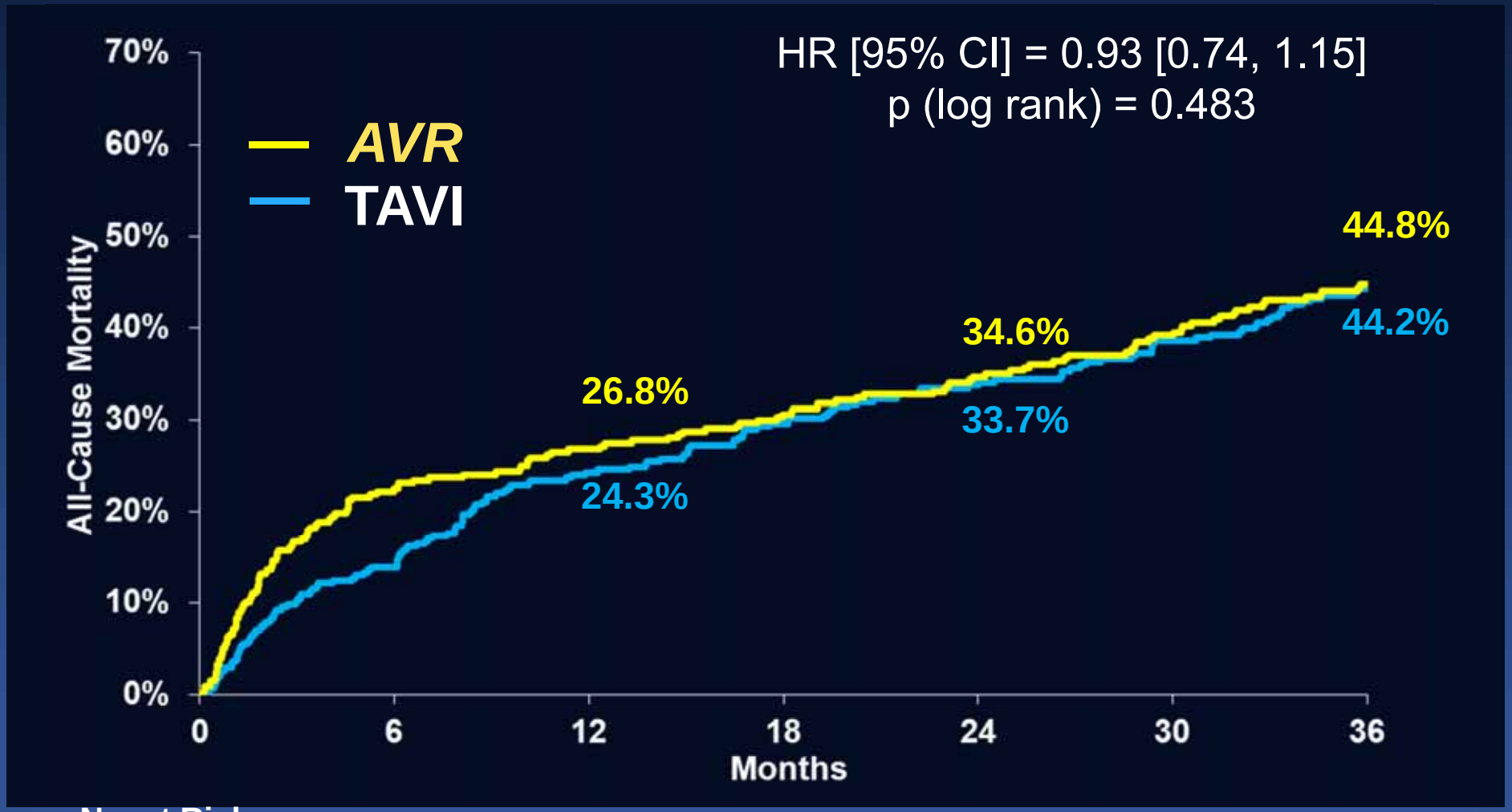


No. at risk

Standard Rx	179	121	85	62	46	27	17
TAVR	179	138	124	110	101	88	70

TAVI for High Risk Patients

3-Year Mortality of SAPIEN



No. at Risk							
TAVI	348	298	261	239	222	187	149
AVR	351	252	236	223	202	174	142

TAVI for High Risk Patients

2-Year Mortality of CoreValve

TAVI Is *Even* Better !
in High Risk Group of Patients.

No. at Risk				
Surgical	357	341	274	28
Transcatheter	390	377	329	38

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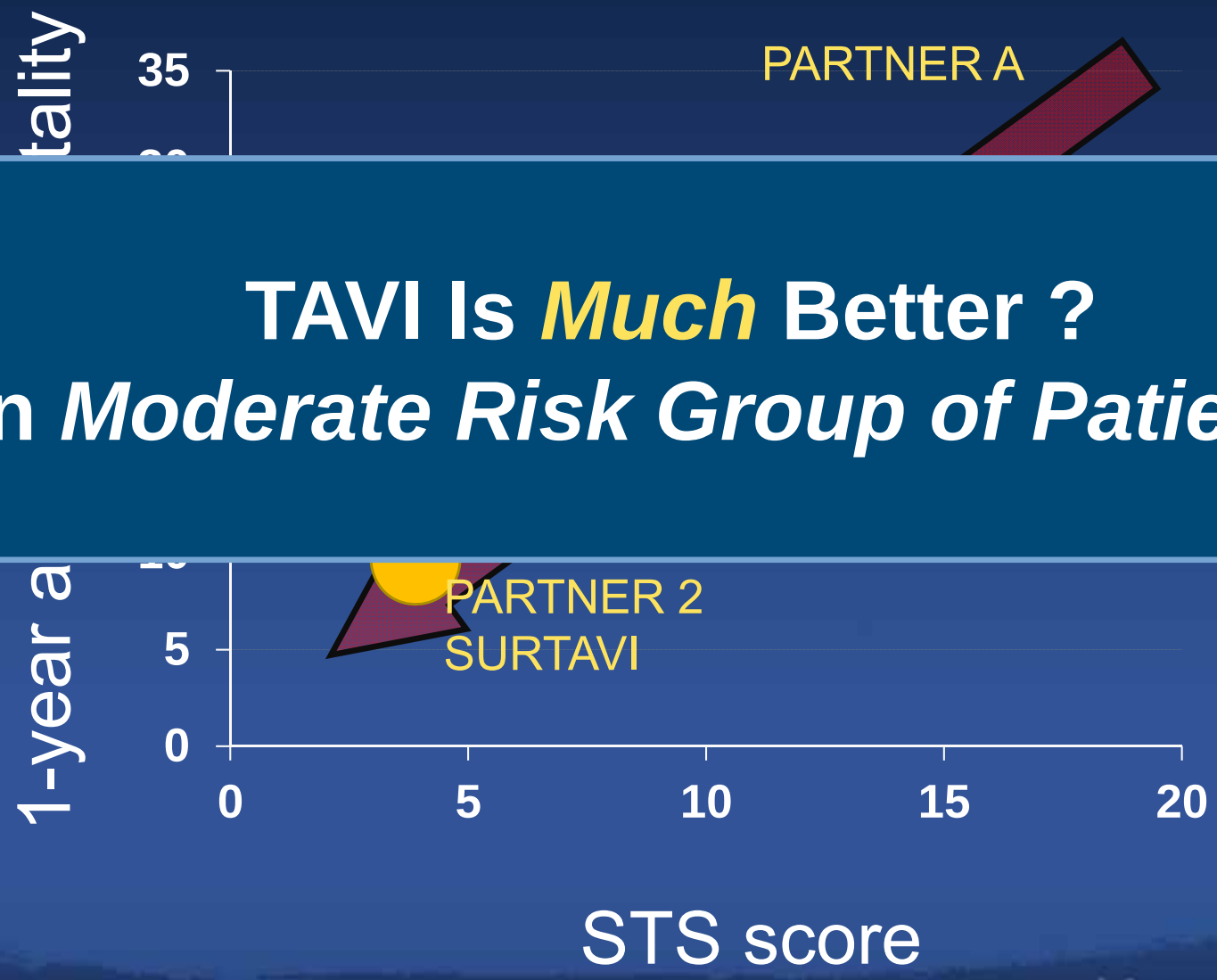
1-year Mortality according to STS Score



TAVI Is *Much* Better ?
in *Moderate Risk Group of Patients.*

Asian TAVI Registry

ClinicalTrials.gov: NCV02195102

Principal Investigators

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Wacin Buddhari, MD, Thailand

Asian TAVI Registry

10 centers, 8 countries

Sponsored by APSIC

Queen Elizabeth Hospital, *HongKong, China*

Nanjing 1st Hospital, *Nanjing, China*

Shonan Kamakura General Hospital, *Kamakura, Japan*

Asan Medical Center, *Seoul, Korea*

Institut Jantung Negara, *Kuala Lumpur, Malaysia*

St. Luke's Medical Center, *Bonifacio, Philippines*

National University Heart Centre, *Singapore*

National Heart Centre of Singapore, *Singapore*

National Taiwan University, *Taipei, Taiwan*

King Chulalongkorn Memorial Hospital, *Bangkok, Thailand*

Current Status of TAVI in Asia

	Edward	CoreValve	Total
Japan	277[B]	81[A]	358
Korea	89	136	225
Singapore	100	41	141
Taiwan	16	86	102
China	5	60	65
Hong Kong	3	58	61
Malaysia	8	32	40
Philippines	0	37	37
Thailand	8	16	24
India	0	24	24
Vietnam	0	2	2
TOTAL	506	573	1079

Updated Feb 20th, 2014

A Include CoreValve Japan Trial and Private Import Cases
B Include Sapien AMT Trial, Sapein XT Japan Trial and commercial launch since Oct 2013

Asian TAVI Registry

Just Started at July 2014,

Feb 2010 to Apr 2014

	Edwards	CoreValve	Total
Asan Medical Center, Korea	61	70	131
National University, Singapore	35		35
Queen Elizabeth Hospital, Hong Kong		36	36
	96	106	202

Baseline Characters

	ASIA			FRENCH 2			PARTNER		SOURCE		ADVANCE
Design	Registry			Registry			RCT		Registry		Registry
Treament	Total	Edw	Core	Total	Edw	Core	Edw(B)	Edw(A)	Edw (I)	Edw (II)	Core
No.	202	96	106	3195	2107	1043	179	348	1038	1269	162
Age, yr	78.4	78.1	78.7	82.7	82.3	82.5	83.1	83.6	81.2	81.1	81
Male, %	54.1	52.1	56.0	51	46.6	48.5	45.8	57.8	44.5	41.3	49.4
STS score	4.4	4.7	4.3	6.4	5.8	-	11.2	11.8	-	-	-
EuroSCORE,%	19.2	19.4	19.0	21.9	22.2	24.7	26.4	29.3	27.6	25	19.2
NYHA, III,IV,%	72.2	79.7	67.6	75.9	75.5	76.1	92.2	94.3	-	-	79.6
CAD, %	50.9	63.5	48.6	47.9	48.7	46.9	67.6	74.9	-	-	57.6
Prior MI, %	-	-	-	16.4	17	15.0	18.6	26.8	-	-	16
Prior CABG, %	7.3	9.3	1.5	18.2	18.2	18.1	37.4	42.6	-	-	21.4
Prior Stroke, %		10.4	4.8	10	10	10	27.4	29.3	5.5	6.1	-
Prior PCI, %	34.5	41.7	24.6	-	-	-	30.5	34	-	-	31.1
Prior BAV, %	-	-	-	-	-	-	16.2	13.4	-	-	-

1. N Engl J Med. 2010;363:538 2. N Engl J Med. 2011;364:1781 3. N Engl J Med. 2012;366:1705
4. TCT 2010 5. J Am Coll Cardiol . 2010;55:1080

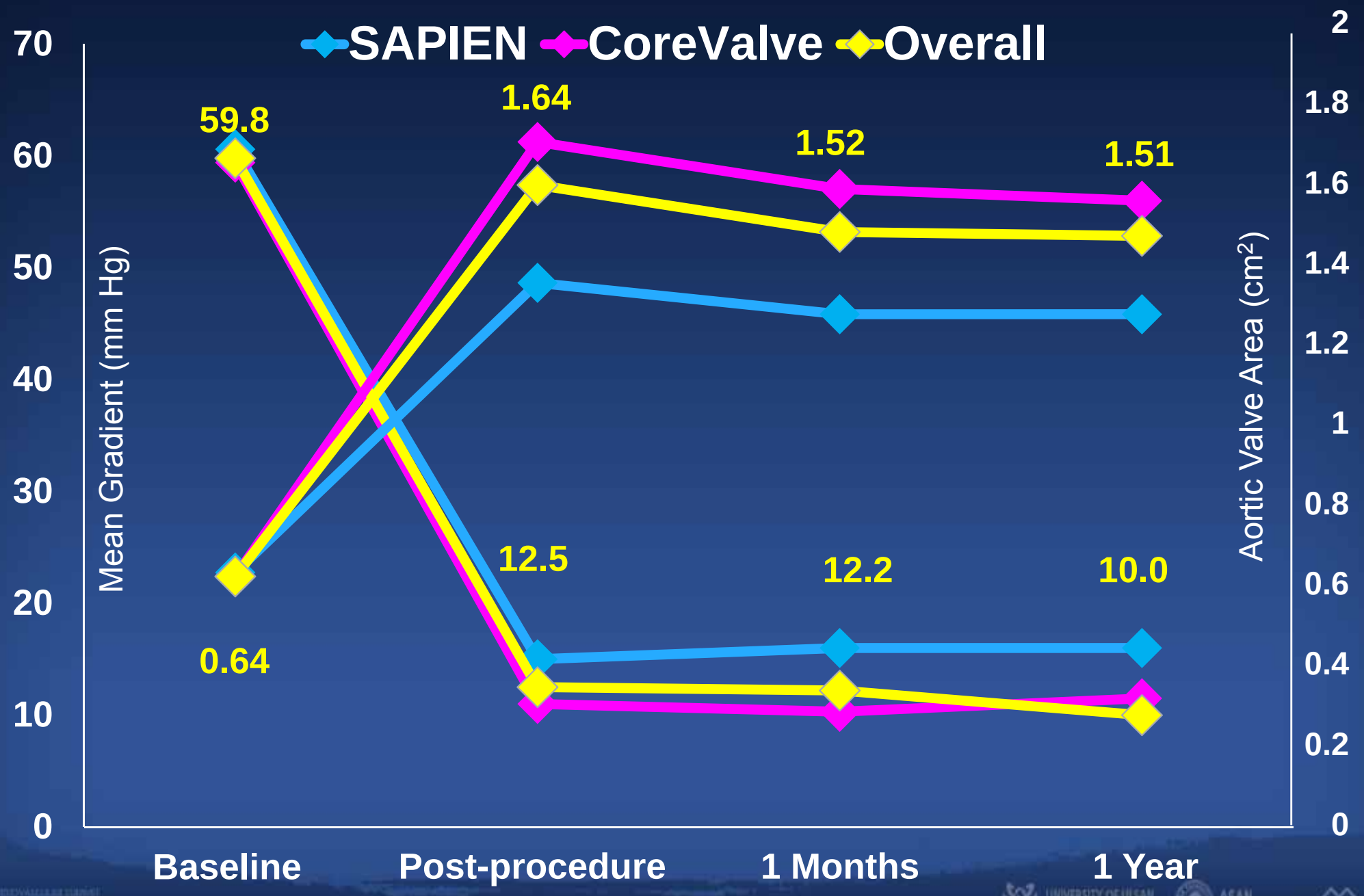
Baseline MDCT Characteristics

	Asian Registry (n = 202)	CHOICE trial (n = 241)
Aortic Annulus Measurement		
Area, mm^2	444.7 ± 83.5	444.5 ± 73.5
Perimeter, mm	76.7 ± 7.1	76.7 ± 6.4
Maximal Diameter, mm	26.5 ± 2.8	26.3 ± 2.2
Minimal Diameter, mm	20.9 ± 2.2	21.5 ± 2.0
Eccentricity index	0.21 ± 0.07	0.18 ± 0.07
Femoral artery diameter, mm		
Right	7.0 ± 1.2	7.8 ± 1.4
Left	7.0 ± 1.1	7.8 ± 1.5
Coronary artery height, mm		
Right	15.2 ± 3.1	13.3 ± 2.8
Left	13.6 ± 2.6	13.5 ± 2.1

Results
Echocardiographic Findings

	Baseline (N=196)	Immediate (N=166)	1 month (N=117) *	1-2 year (N=80) *
LVEF, %	58.7 ± 10.1	59.8 ± 9.3	60.6 ± 7.7	59.7 ± 7.6
AV area, cm^2	0.64 ± 0.17	1.64 ± 1.07	1.52 ± 0.40	1.61 ± 0.43
Mean PG, mmHg	59.8 ± 19.1	12.5 ± 5.8	12.2 ± 5.3	10.0 ± 4.2
Mod-sev AR	32/193 (16.5%)	21/193 (10.9%)	8/117 (9.4%)	9/67 (13.4%)
Mod-sev MR	28/196 (14.2%)	12 (7.9%)	5/69 (7.2%)	3/37 (8.1%)
Pulmonary Hypertension	30/200 (15.0%)	19/101 (18.9%)	10/80 (12.5%)	10/80 (12.5%)
RV-RA PG, mmHg	30.8 ± 12.3	31.0 ± 10.6	30.2 ± 7.7	30.7 ± 13.0

Mean Gradients and AV Area Over Time



30-day Outcomes

	Total (n=194)
All-cause mortality	6 (3.0%)
Major Stoke	2 (1.0%)
Major Vascular Complication	6 (3.1%)
Acute Kidney Injury ≥ Stage 2	2 (1.0%)
Post AR ≥ Moderate	22 (11.8%)
Implant of ≥ 2 valves	12 (6.2%)
Device success according to VARC criteria	158 (91.4%)
Permanent Pacemaker	23 (11.9%)
Coronary obstruction	4 (2.1%)

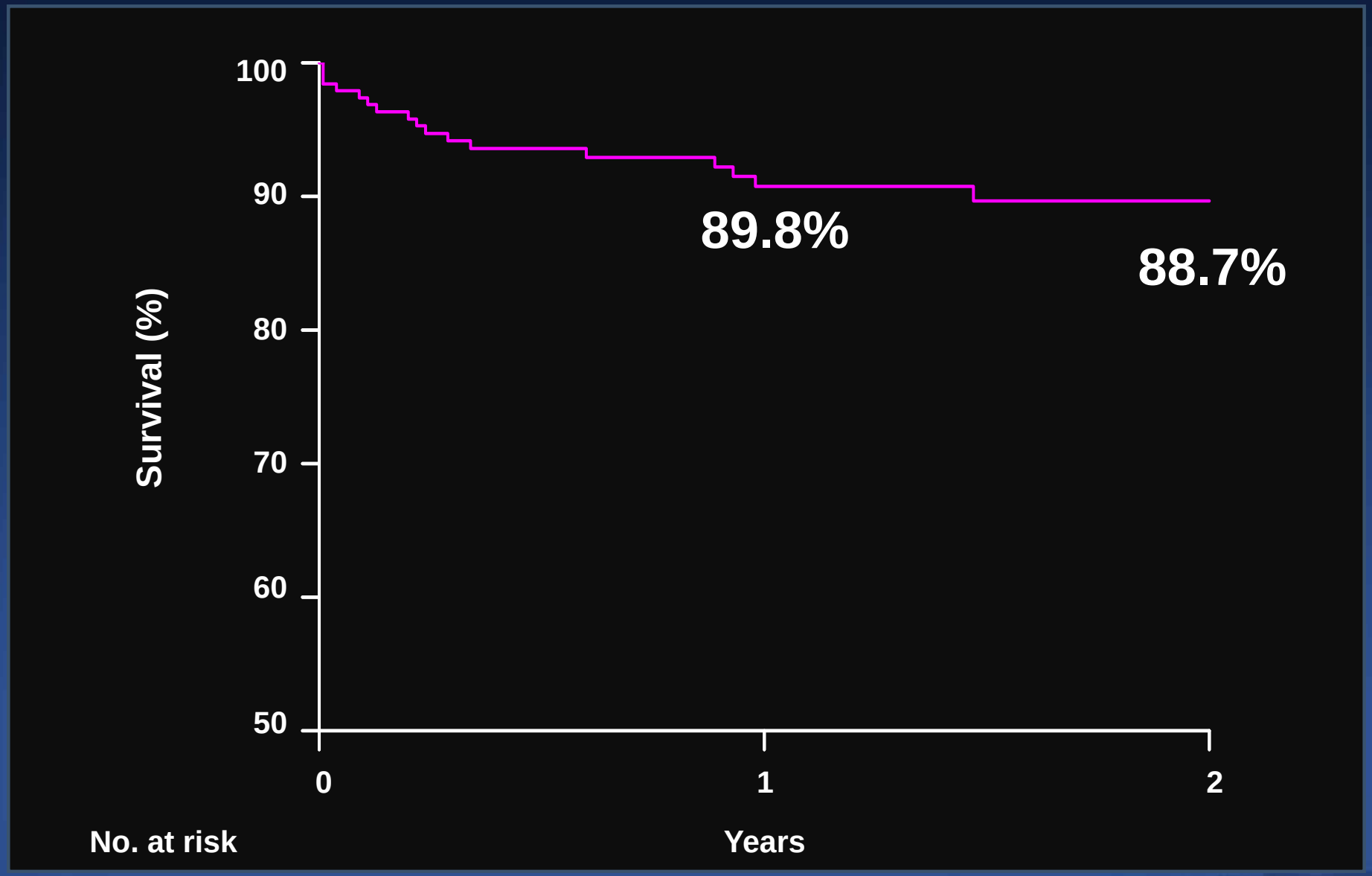
1-year Outcomes

Median Follow-up duration: 1.3 year

	Total (n=206)
Mortality	
All-cause	19 (10.5%)
Cardiovascular	15 (8.2%)
Rehospitalization	9 (6.9%)
Heart failure exacerbation	8
Mitral valve endocarditis	1

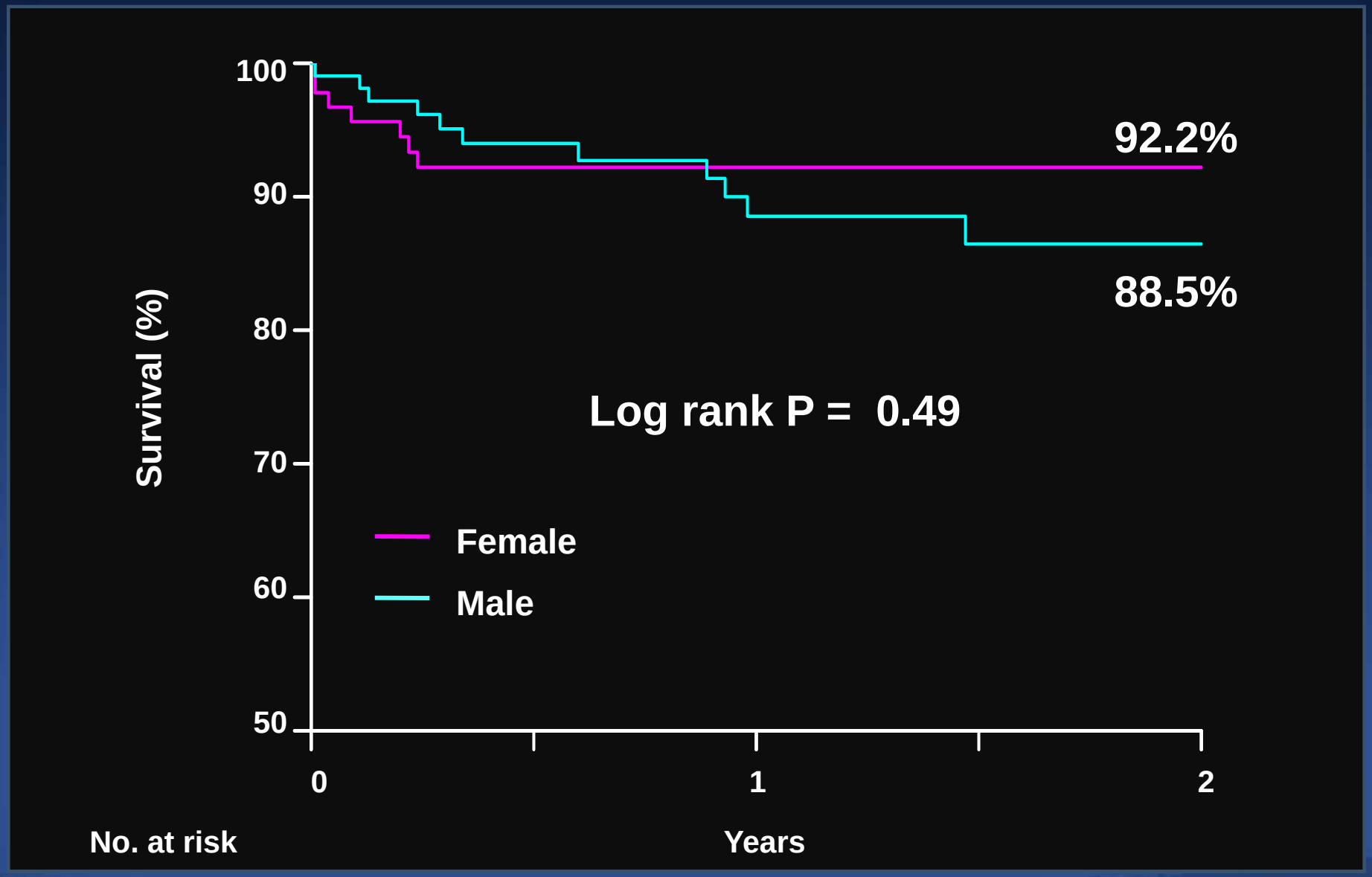
All-cause Mortality

Overall, n=202



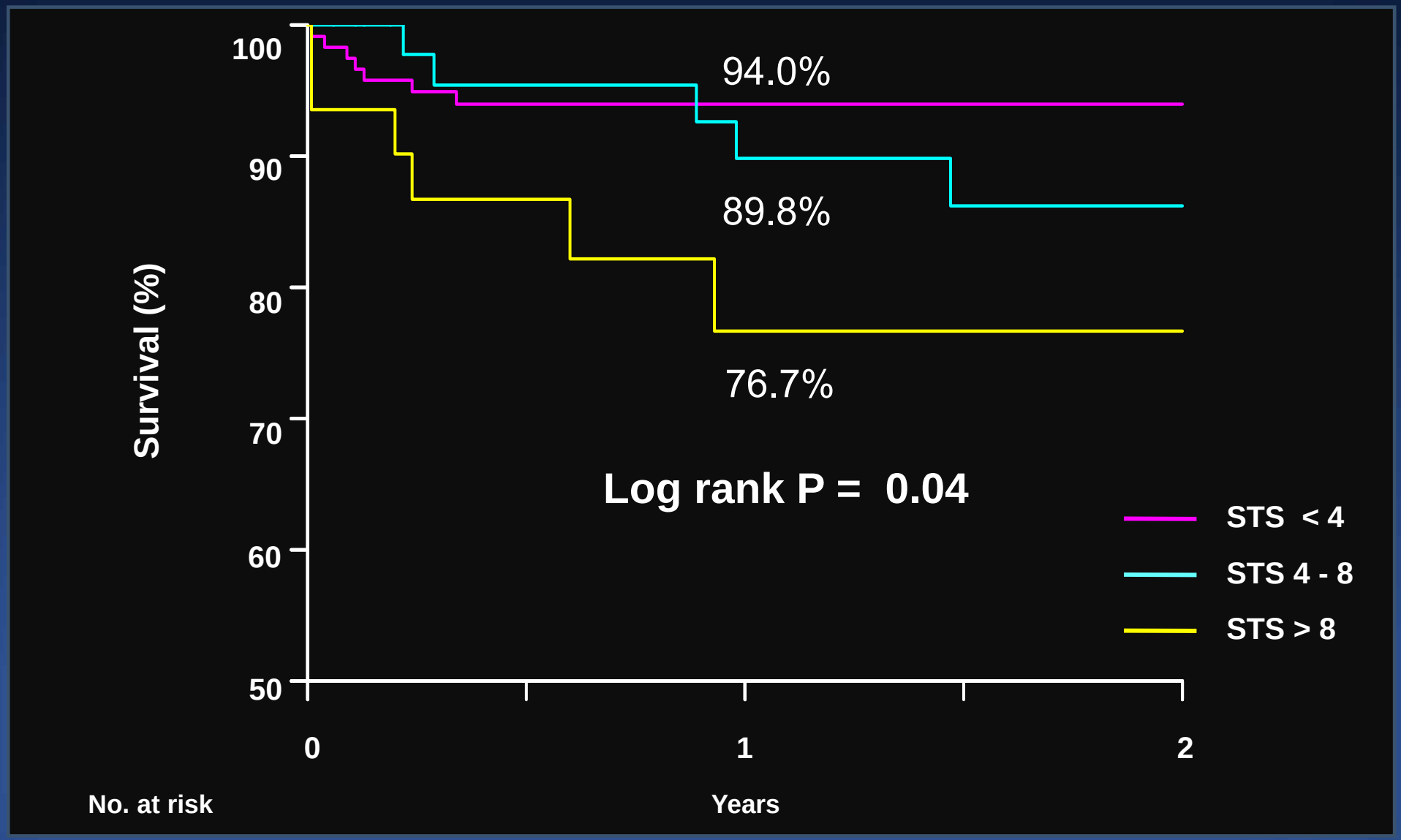
No. at risk			
Overall	196	119	67

All-cause Mortality
Sex Difference



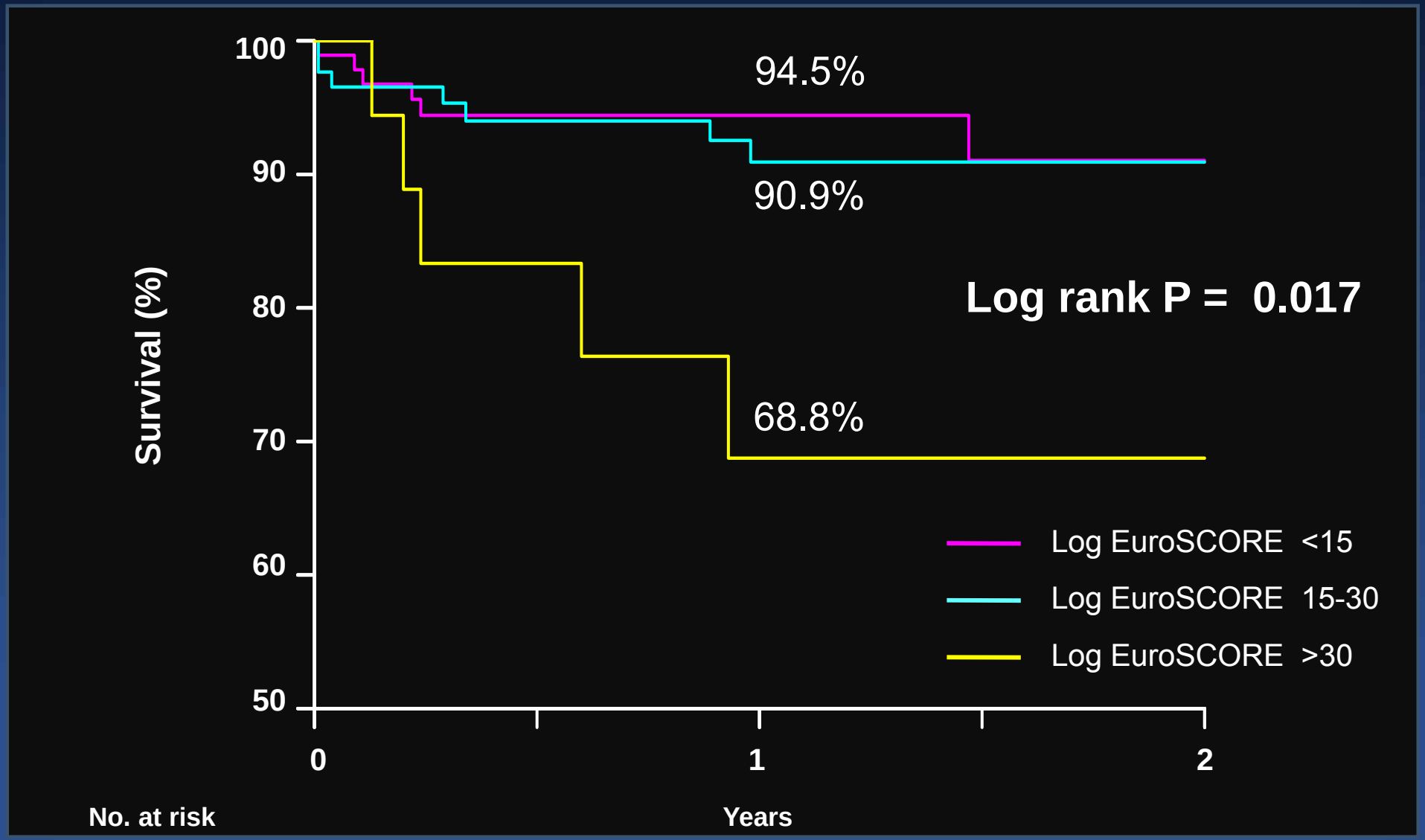
No. at risk			
Male	108	62	32
FeMale	92	59	41

All-cause Mortality
Stratified by STS score



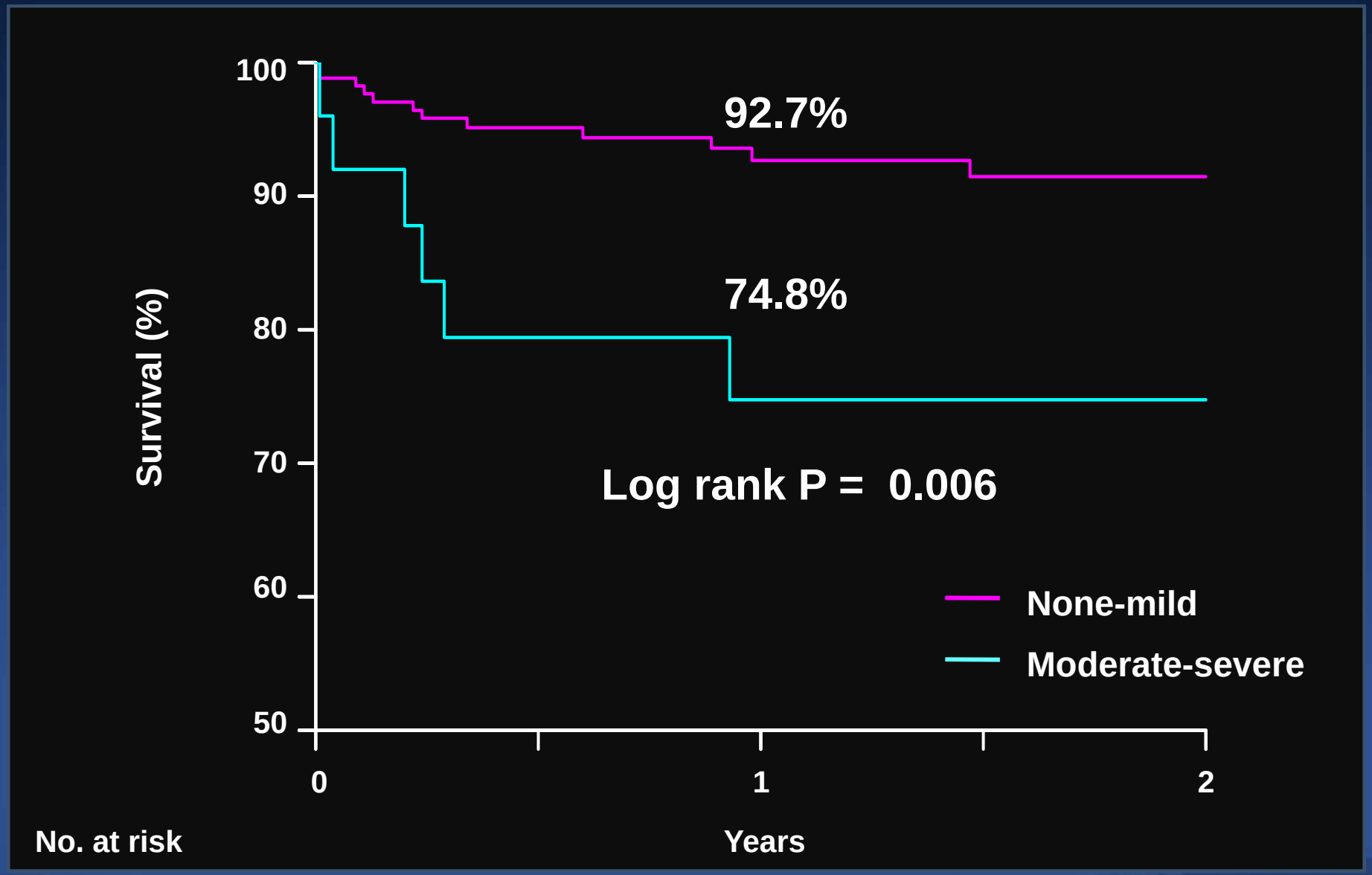
No. at risk			
STS < 4	120	81	46
STS 4 - 8	49	32	19
STS > 8	31	15	8

All-cause Mortality
Stratified by EuroScore



No. at risk			
LES <15	58	58	19
LES 15-30	56	56	48
LES >30	10	10	6

All-cause Mortality
Mitral Regurgitation



No. at risk			
None-mild	172	104	60
Moderate-severe	25	16	12

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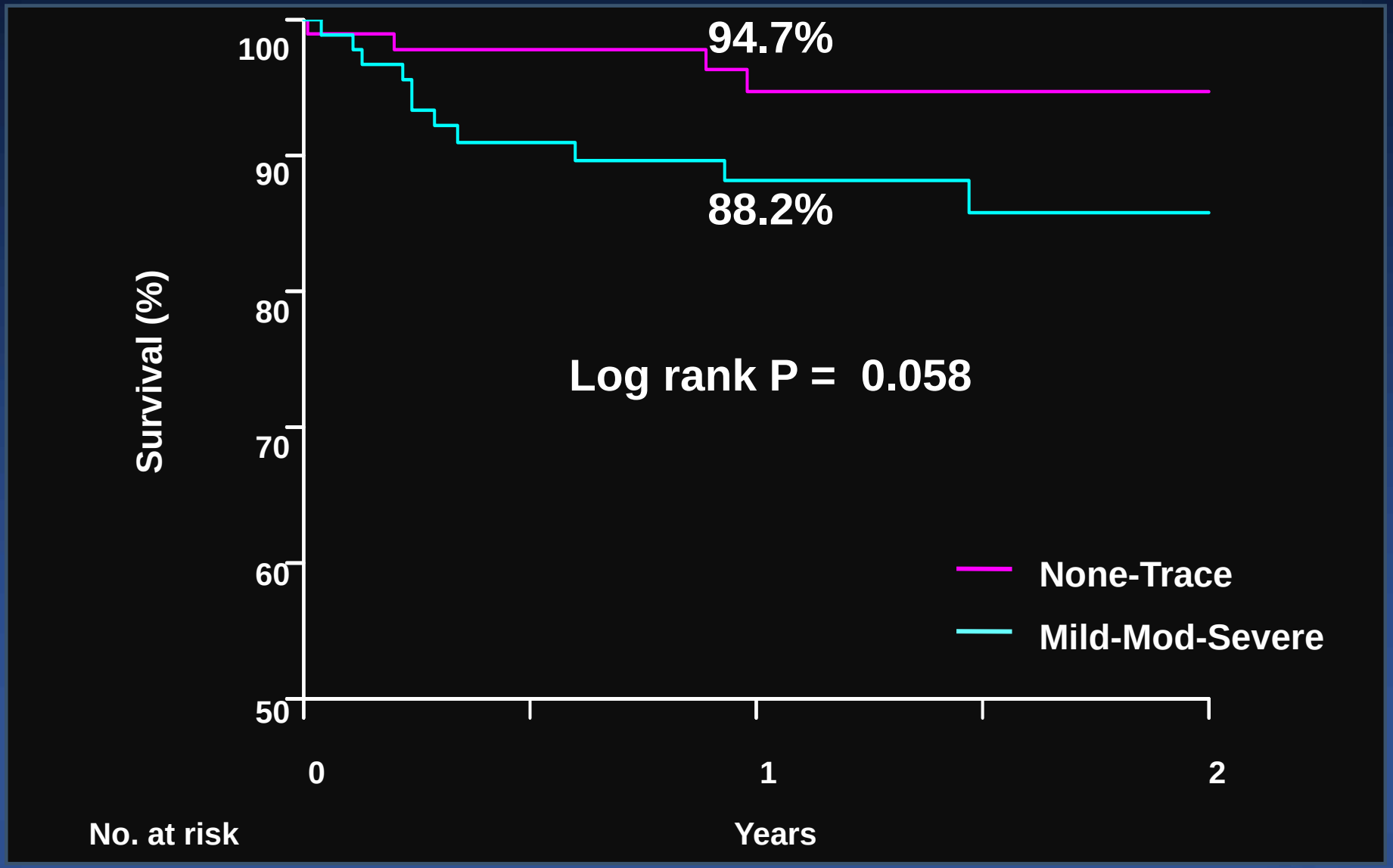
All-cause Mortality

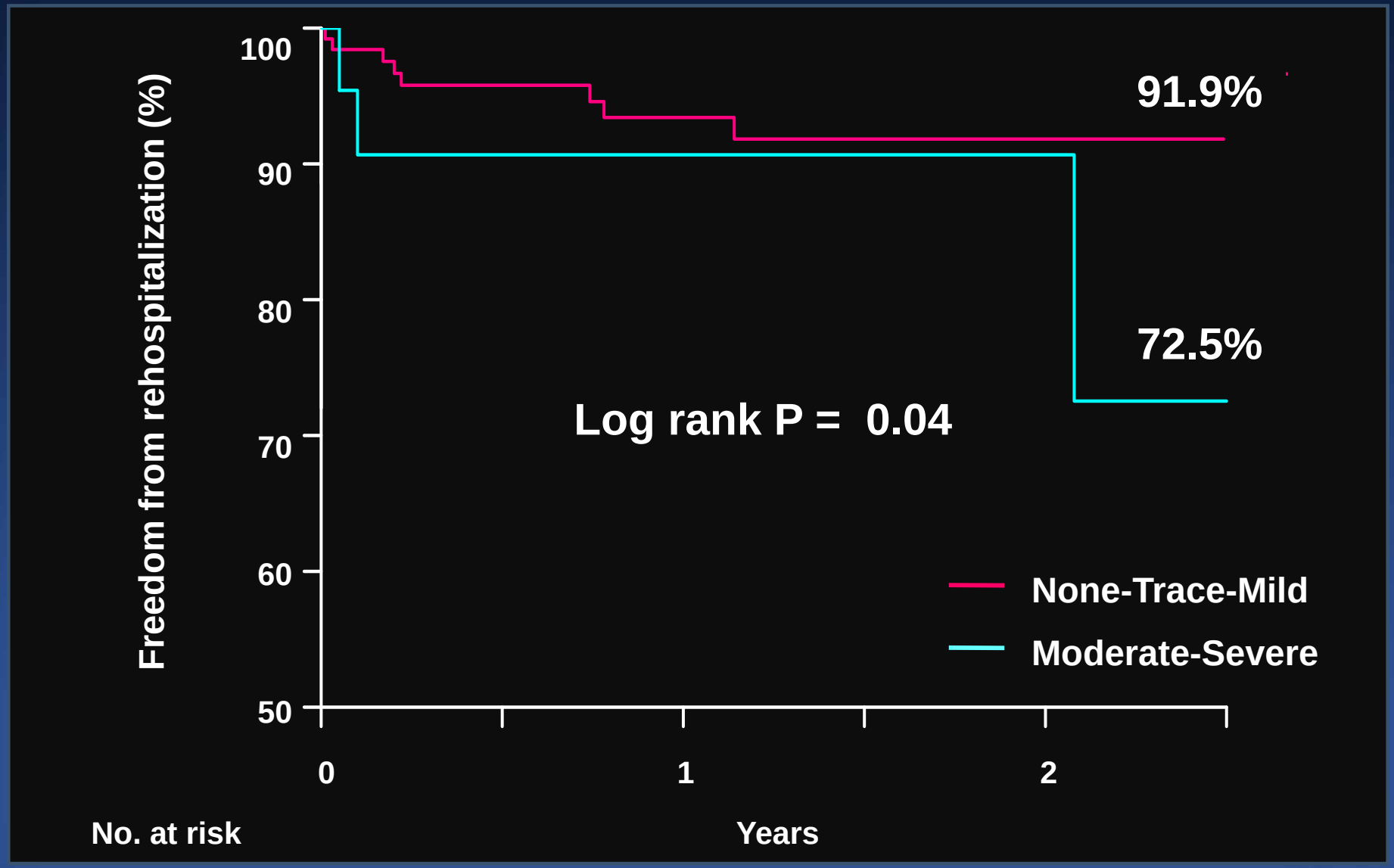
Post-procedural Aortic Regurgitation



No. at risk			
None-Trace	97	59	40
Mild-Mod-Sev	92	57	28

Freedom From ReHospitalization

Post-procedural Aortic Regurgitation



No. at risk			
None-Tr-Mild	129	71	37
Mod-Sev	22	8	6

Comparison of Demographics

Endpoints	Pooled Estimates (%)	ASIA
Log EuroSCORE	22.8	19.2
Age, yrs	81.5	78.4
STS Score	6~11	4.4
Female	52.0	46.5
NYHA III / IV	82.0	71.8
AVA, cm2	0.61	0.64
Mean gradient, mmHg	47.6	59.8

*VARC Meta-Analysis, (16 studies; 3,519 patients)

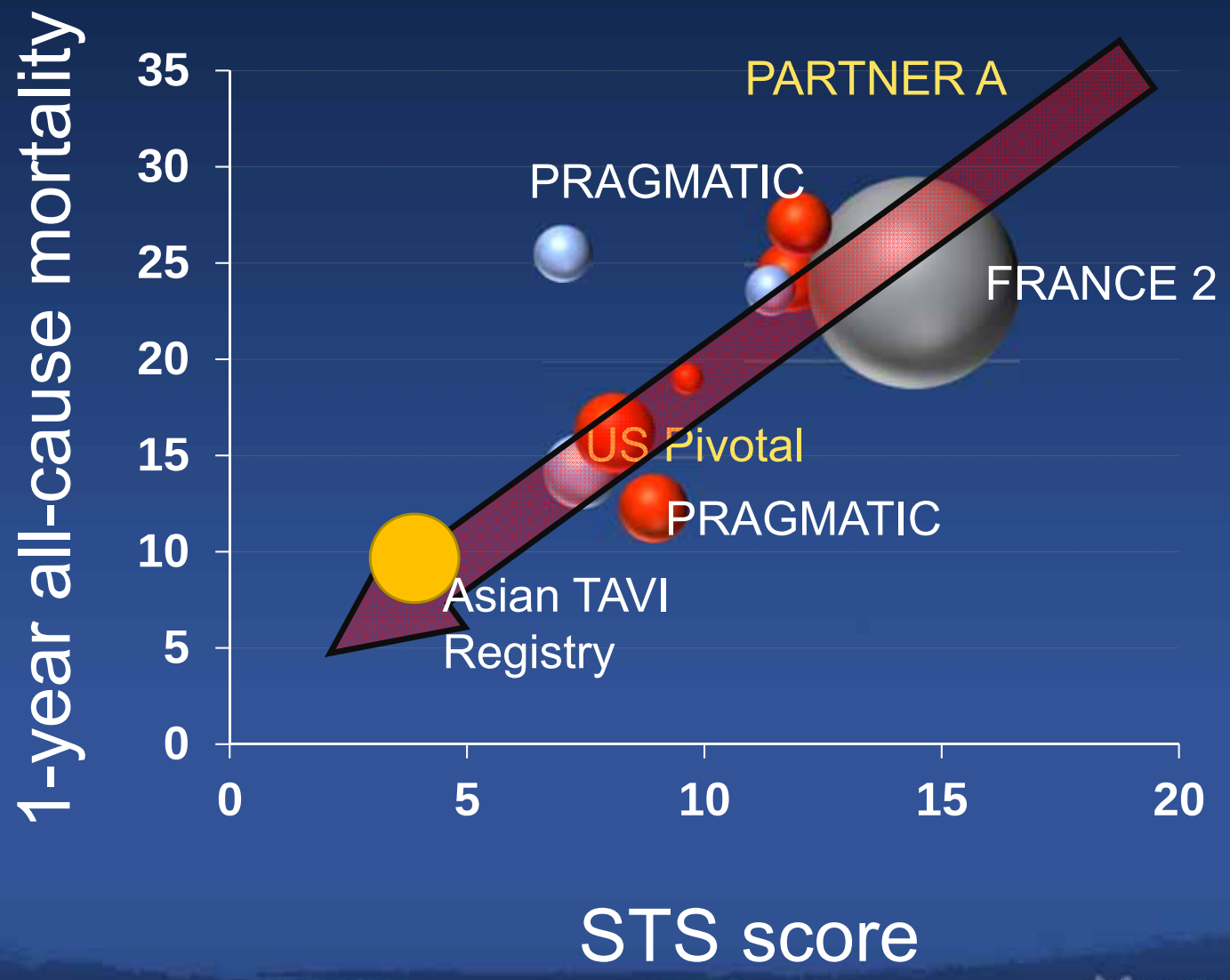
J Am Coll Cardiol 2012;59:2297-306

Comparison of Outcomes

Endpoints (%)	Pooled Estimates	ASIA
Mortality		
All at 30 days	7.8	3.0
All at 1 year	22.1	10.5
Stroke		
Major at 30 days	3.2	1.0
Vascular Cx at 30 days	18.8	3.1
Perm. Pacemaker at 30 days		
CoreValve	28.9	22.9

J Am Coll Cardiol 2012;59:2297-306

1-year Mortality according to STS Score



Asian TAVI Registry

Sapien vs. CoreValve

Baseline Echo Characteristics

	Edward (n=86)	CoreValve (n=99)	P value
LVEF, %	60.4±7.6	58.5±11.3	0.31
AVA, cm^2	0.65±0.17	0.63±0.17	0.48
Mean PG, mmHg	60.1±20.4	64.0±20.8	0.30
LVEF < 40%	1 (2.0%)	8 (11.9%)	0.08
Aortic Regurgitation Mod-Sev	12 (14.1%)	20 (20.6%)	0.26
Mitral Regurgitation Mod-Sev	11 (13.4%)	5 (7.5%)	0.24
Pulmonary HTN	4 (4.7%)	8 (12.5%)	0.10

Baseline MDCT Characteristics

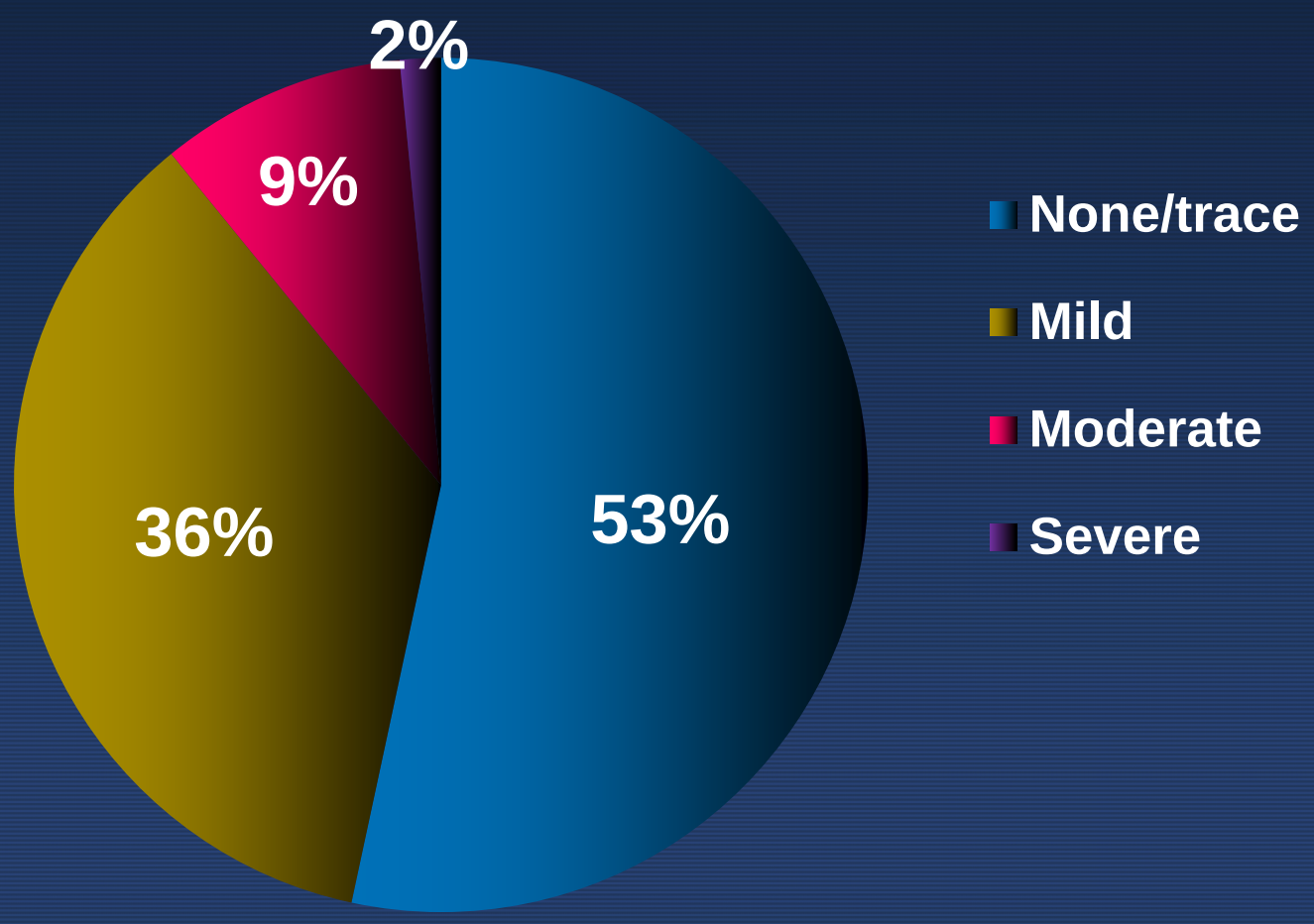
	Edward (n=55)	CoreValve (n=103)	P value
Aortic Annulus Measurement			
Area, mm^2	422.4 ± 70.4	464.1 ± 88.8	0.008
Perimeter, mm	74.9 ± 6.1	77.8 ± 7.4	0.015
Maximal Diameter, mm	25.9 ± 2.5	26.8 ± 3.0	0.057
Minimal Diameter, mm	20.5 ± 2.0	21.2 ± 2.3	0.04
Eccentricity	0.21 ± 0.07	0.21 ± 0.07	0.54
Oversizing, %			
Area	14.0 ± 12.7	37.9 ± 17.2	< 0.001
Perimeter	3.4 ± 6.1	13.9 ± 7.0	< 0.001
Calcification Grade			
Moderate	8 (17.8%)	10 (14.7%)	0.66
Severe	21 (46.7%)	29 (42.6%)	0.67

Procedural Results

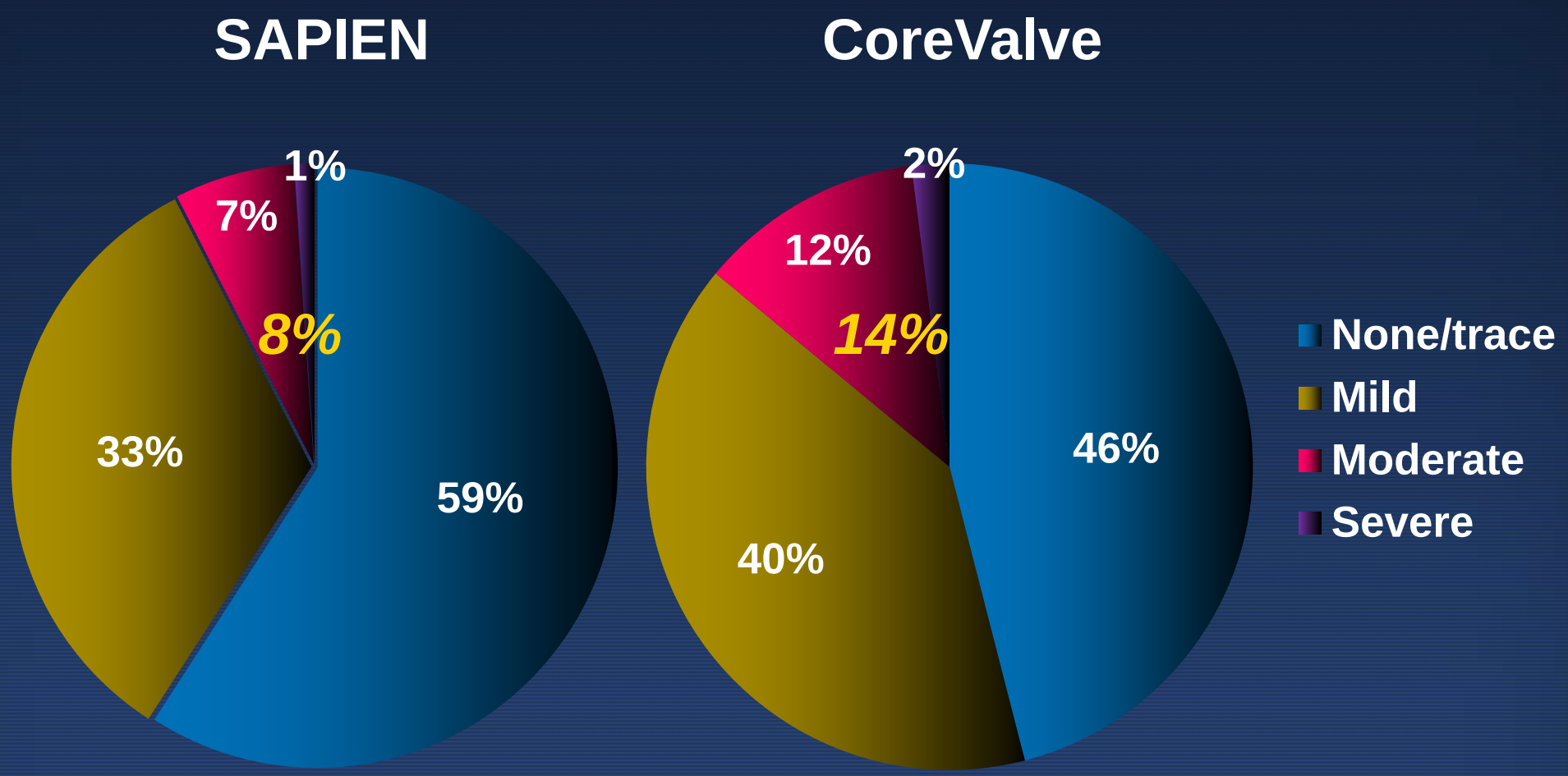
	Total (n=199)	Edward (n=96)	CoreValve (n=104)	P value
Valve Size, mm				
23	45 (22.6%)	45 (47.4%)		
26	90 (45.2%)	47 (49.5%)	43 (41.3%)	
29	51 (25.6%)	3 (3.2%)	48 (46.2%)	
31	13 (6.5%)		13 (12.5%)	
Transfemoral	186 (92.1%)	83 (86.5%)	103 (97.2%)	
Transapical	13 (6.4%)	13 (13.5%)	0	
Direct Aortic	2 (1.0%)	0	2 (1.9%)	
Subclavian	1 (0.5%)	0	1 (0.9%)	
Procedure time, min	99.3 ± 38.1	85.2 ± 26.2	107.4 ± 41.5	< 0.001
Fluoroscopy time, min	26.7 ± 14.7	21.3 ± 10.2	29.9 ± 15.9	< 0.001
Contrast volume, ml	319 ± 114	333 ± 115	310 ± 113	0.90

Aortic Regurgitation

Asian TAVI Registry



Incidence of AR
Asian TAVI Registry



30-day Outcomes

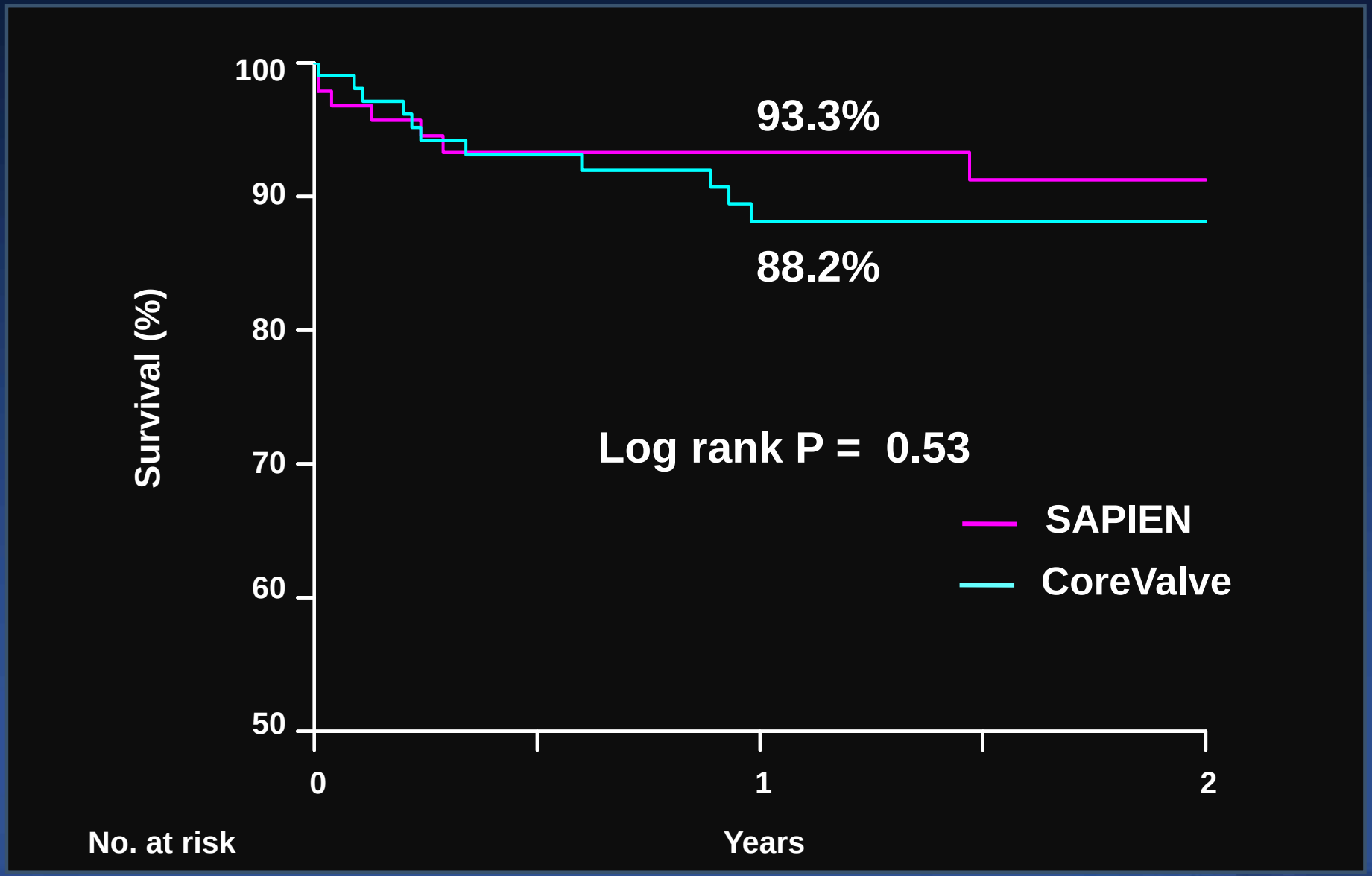
	Total (n=193)	Edward (n=93)	CoreValve (n=100)	P value
Mortality	8 (4.1%)	5 (5.2%)	3 (3.1%)	>0.50
Major Stoke	2 (1.0%)	1 (1.0%)	1 (1.0%)	>0.99
Vascular Complication	6 (3.1%)	3 (3.1%)	3 (3.1%)	>0.99
AKI ≥ St2	2 (1.0%)	1 (1.1%)	1 (1.0%)	> 0.99
Post AR ≥ Mod	22 (11.8%)	7/92 (7.5%)	14/95 (14.0%)	0.15
Implant of ≥ 2 valves	12 (6.2%)	0	12 (12.2%)	< 0.001
Device success	158 (91.4%)	86 (89.6%)	72 (73.5%)	0.004
Permanent Pacemaker	23 (11.9%)	1 (1.2%)	22 (22.2%)	< 0.001
Coronary obstruction	4 (2.1%)	1 (1.2%)	3 (3.1%)	0.62

1-year Outcomes

	Total (n=185)	Edward (n=86)	CoreValve (n=99)	P value
All-cause mortality	15 (8.5%)	8 (9.5%)	7 (7.6%)	0.62
Cardiovascular	11 (6.6%)	7 (8.4%)	4 (4.8%)	0.41
Non-cardiovascular	4 (4.2%)	1 (1.2%)	3 (2.8%)	0.65
Rehospitalization	12 (8.2%)	8 (6.9%)	4 (8.9%)	0.72
Heart failure exacerbation	11	8	3	
Mitral valve endocarditis	1	0	1	

All-cause Mortality

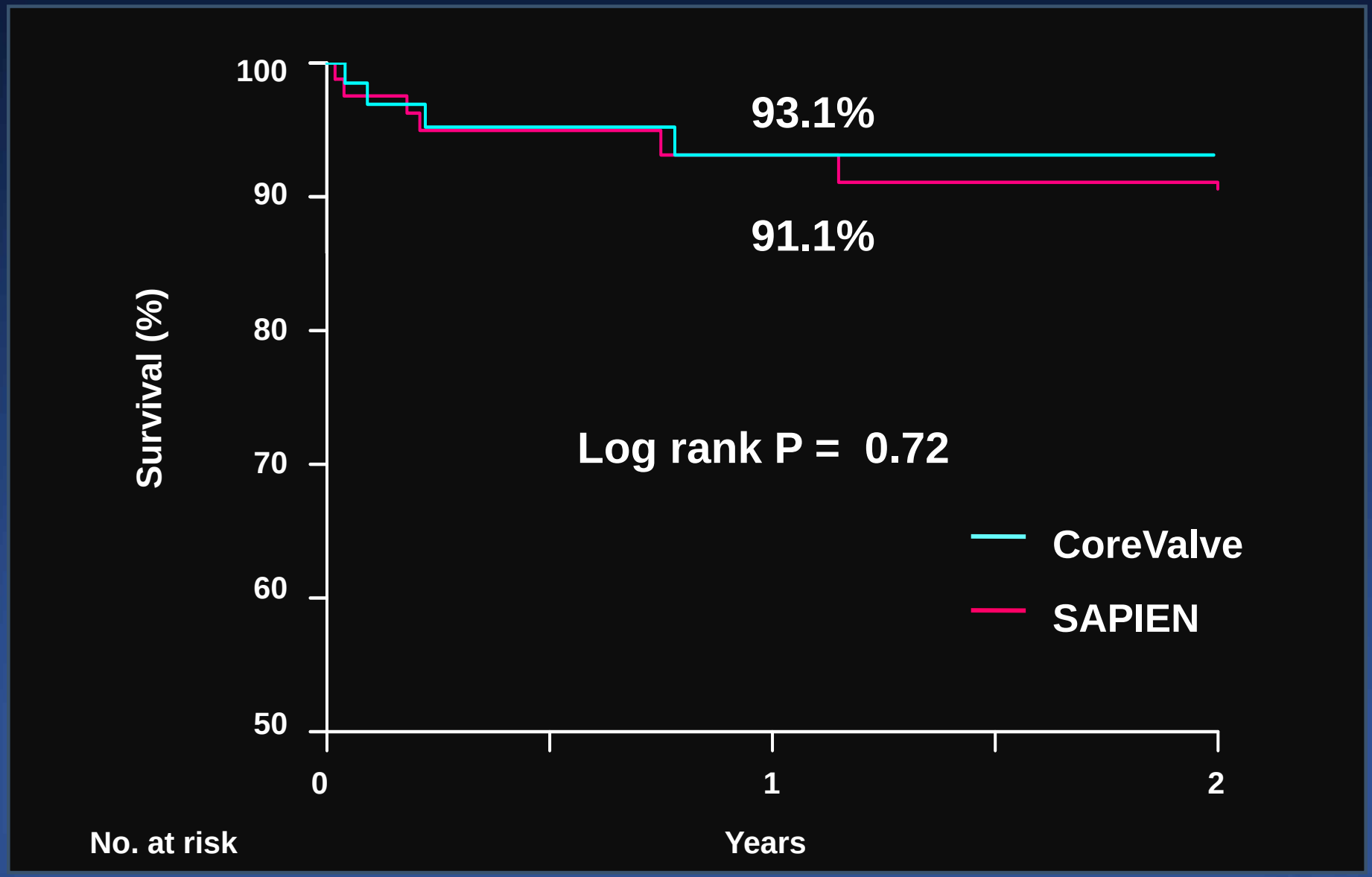
SAPIEN vs. CoreValve



No. at risk			
SAPIEN	95	57	40
CoreValve	105	67	33

Freedom From Rehospitalization

SAPIEN vs. CoreValve



No. at risk			
SAPIEN	85	50	35
CoreValve	69	33	9

Asian TAVI Registry, Outcomes

1. TAVI provides favorable short and 1-year clinical outcomes from Asian Multicenter Registry.
2. There are no difference between SAPIEN and CoreValve in 1-year outcomes and complications such as stroke and vascular complication.
3. Use of CoreValve resulted in the greater chance of aortic regurgitation and need for permanent pacemaker insertion.
4. Asian TAVI Registry data will give us a different insight about Asian patients.