Clinical Outcomes of TAVR in Asian Pacific

The Asian TAVR Registry

Sung-Han Yoon, MD

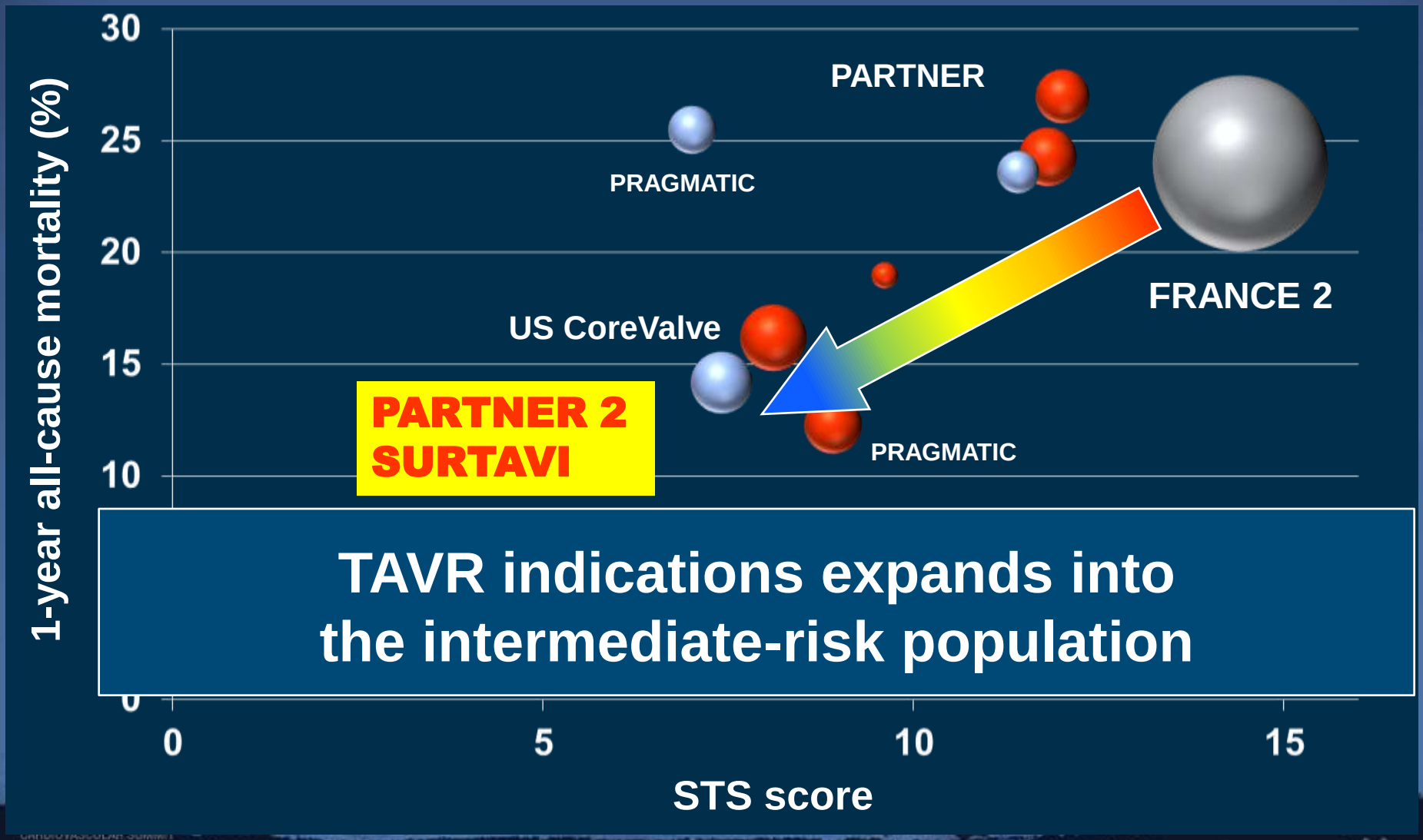
On Behalf of Asian TAVR Registry Investigators

Background

TAVR has been established as treatment option for high-risk and inoperable patients with severe AS. Recent studies showed expanding indication of TAVR toward lower risk populations as well as other group of patients such as bicuspid aortic valve.

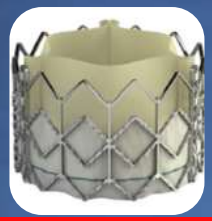
Despite a large body of evidence, data regarding clinical outcomes of TAVR in Asian Pacific is still limited.

Mortality and Risk Across Studies



Adoption of TAVR in Asian Pacific

2009 2011 2013 2015



SAPIEN

Australia →

Korea →

Japan →

Singapore →

CoreValve

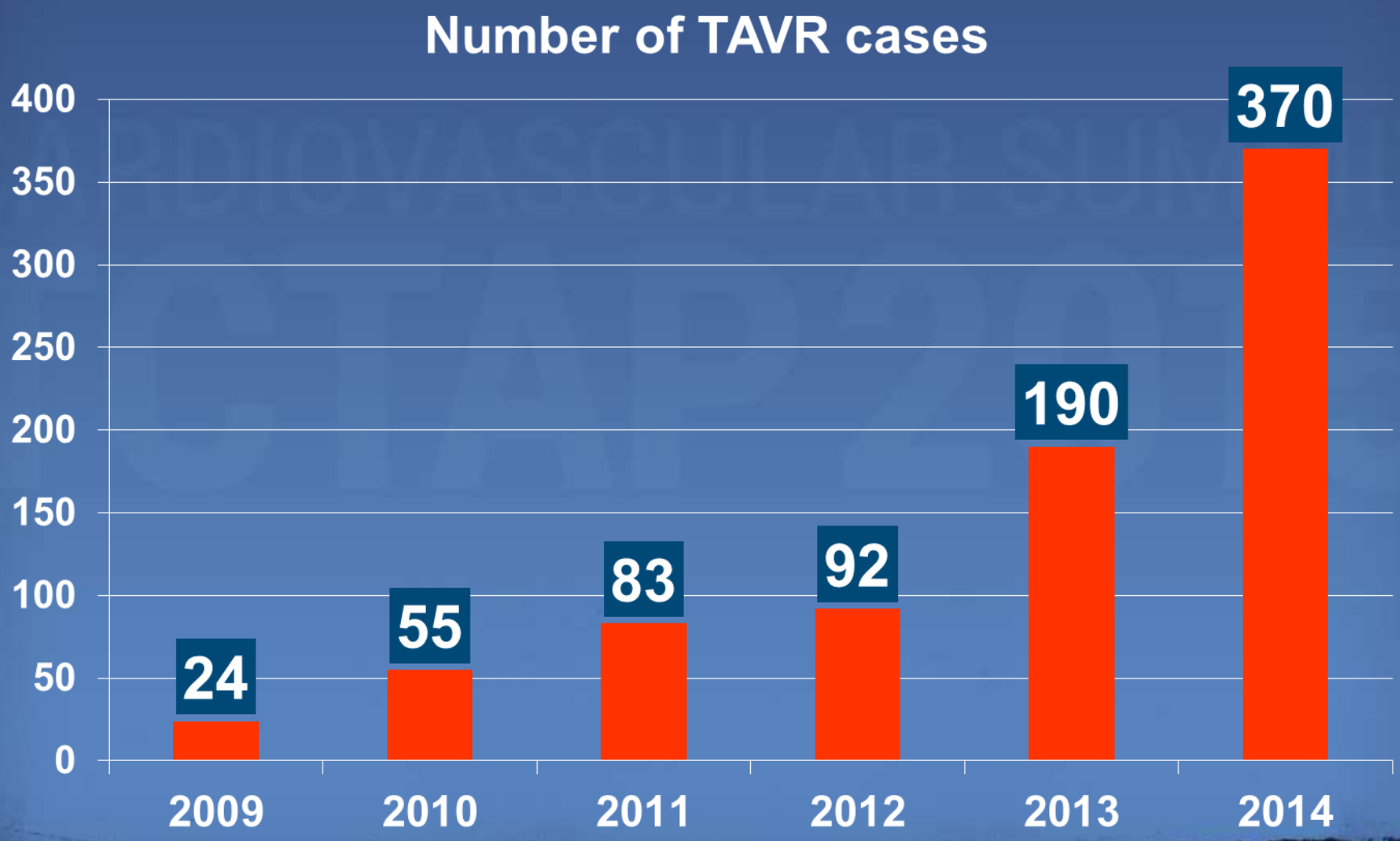
Australia →

Korea →

Taiwan →

Hong Kong →

Annual Case Numbers



The Asian TAVR Registry
12 centers, 6 Countries

Sponsored by CVRF

ClinicalTrials.gov:
NCT02308150

HongKong	Queen Elizabeth Hospital
Singapore	National University Heart Centre
Taiwan	National Taiwan University
	Cheng-Hsin Hospital
Korea	Seoul National University Hospital
	Asan Medical Center
Japan	Shonan Kamakura General Hospital
	Keio University Hospital
	Teikyo University Hospital
	Saiseikai Yokohama Eastern Hospital
	Kokura Memorial Hospital
Australia	Royal Perth Hospital

The Asian TAVR Registry
12 centers, 6 Countries

ClinicalTrials.gov:
NCT02308150

Principal Investigator

Seung-Jung Park, MD, Korea

Co-Principal Investigators

Shigeru Saito, MD, Japan

Paul Kao, MD, Taiwan

Hyo-Soo Kim, MD, Korea

Wei-Hsian Yin, MD, Taiwan

Motoharu Araki, MD, Japan

Edgar Tay, MD, Singapore

Kentaro Hayashida, MD, Japan

Gerald Yong, MD, Australia

Shinichi Shirai, MD, Japan

Yusuke Watanabe, MD, Japan

Michael Lee, MD, Hong Kong

The Asian TAVR Registry

Since February 2009 to April 2015

Total	SAPIEN / XT	CoreValve
940	615	325

The Asian TAVR Registry
Baseline Characteristics

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Age	82.1± 6.5	82.8±6.4	80.8±6.5	< 0.001
Female	52.9%	58.3%	42.5%	< 0.001
BMI, kg/m^2	23.0±3.8	22.8±3.8	23.3±3.6	0.34
Diabetes mellitus	28.3%	29.0%	27.1%	0.48
NYHA class III/IV	74.1%	74.9%	72.9%	0.52
CAD	50.9%	48.2%	56.0%	0.02
Previous stroke	14.4%	13.8%	16.9%	0.01
Peripheral vascular disease	17.0%	17.8%	15.7%	0.42
COPD	1.9%	0.7%	4.0%	0.001

The Asian TAVR Registry
Baseline Characteristics

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Previous PCI	33.5%	33.2%	34.2%	0.77
Previous CABG	12.6%	14.3%	9.2%	0.03
Previous Valve surgery	3.0%	2.2%	4.3%	0.10
eGFR, ml/min/1.73m^2	54.8±20.5	52.4±20.0	59.9±21.9	< 0.001
eGFR ≤ 60 ml/min/1.73m^2	61.1%	69.1%	48.1%	< 0.001
LVEF, %	58.7±12.6	59.2±12.6	57.8±12.5	0.12
Mean gradient, mmHg	51.8±18.8	51.5±18.9	52.3±18.6	0.54
Aortic valve area, cm^2	0.64±0.18	0.63±0.17	0.65±0.18	0.35

The Asian TAVR Registry
Baseline Characteristics

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Logistic EuroSCORE	21.6±15.5	19.0±12.2	26.6±19.5	< 0.001
STS score	7.0±5.6	6.9±4.7	7.1±6.7	0.69
STS < 3	27.6%	28.6%	25.9%	0.62
STS 3 – 8	43.7%	43.5%	43.9%	
STS > 8	28.7%	27.9%	30.2%	

The Asian TAVR Registry
Procedural Data

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Device size, mm				
23 mm	37.4%	56.2%	1.8%	< 0.001
26 mm	39.9%	39.2%	41.2%	
29 mm	18.7%	4.4%	45.5%	
31 mm	4.0%	-	11.4%	
Access site				
Transfemoral	85.8%	80.0%	96.9%	< 0.001
Transapical	12.0%	18.2%	0.0%	
Subclavian	0.4%	0.0%	1.2%	
Transaortic	1.6%	1.5%	1.9%	

The Asian TAVR Registry
Echocardiographic Outcomes

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
LVEF, %	59.7±10.5	59.9±10.4	59.5±10.6	0.66
Mean gradient, mmHg	10.7±4.8	11.4±4.9	9.5±4.4	< 0.001
Aortic valve area, cm^2	1.60±0.41	1.54±0.38	1.69±0.43	< 0.001
Paravalvular Regurgitation				
None-trace	10.5%	10.4%	10.7%	0.27
Mild	35.0%	35.6%	33.9%	
Moderate	9.2%	7.9%	11.7%	
Severe	0.3%	0.2%	0.7%	
≥ Mild	54.4%	53.9%	55.4%	0.68
≥ Moderate	9.5%	8.0%	12.4%	0.037

The Asian TAVR Registry
Procedural Outcomes

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Need for 2nd device	4.3%	1.2%	10.2%	< 0.001
Coronary obstruction	1.3%	1.5%	0.9%	0.56
Aortic root rupture	0.5%	0.8%	0.0%	0.17
Conversion to SAVR	1.6%	1.6%	1.5%	0.99
Permanent pacemaker	10.2%	4.1%	21.8%	< 0.001

The Asian TAVR Registry
Clinical Outcomes

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Mortality				
At procedure	1.2%	1.3%	0.9%	0.61
At 30 days	3.4%	4.0%	2.5%	0.23
At 6 months	7.1%	6.6%	8.0%	0.42
At 1 year *	10.6%	7.6%	14.5%	0.02

* Estimated as Kaplan-Meier method

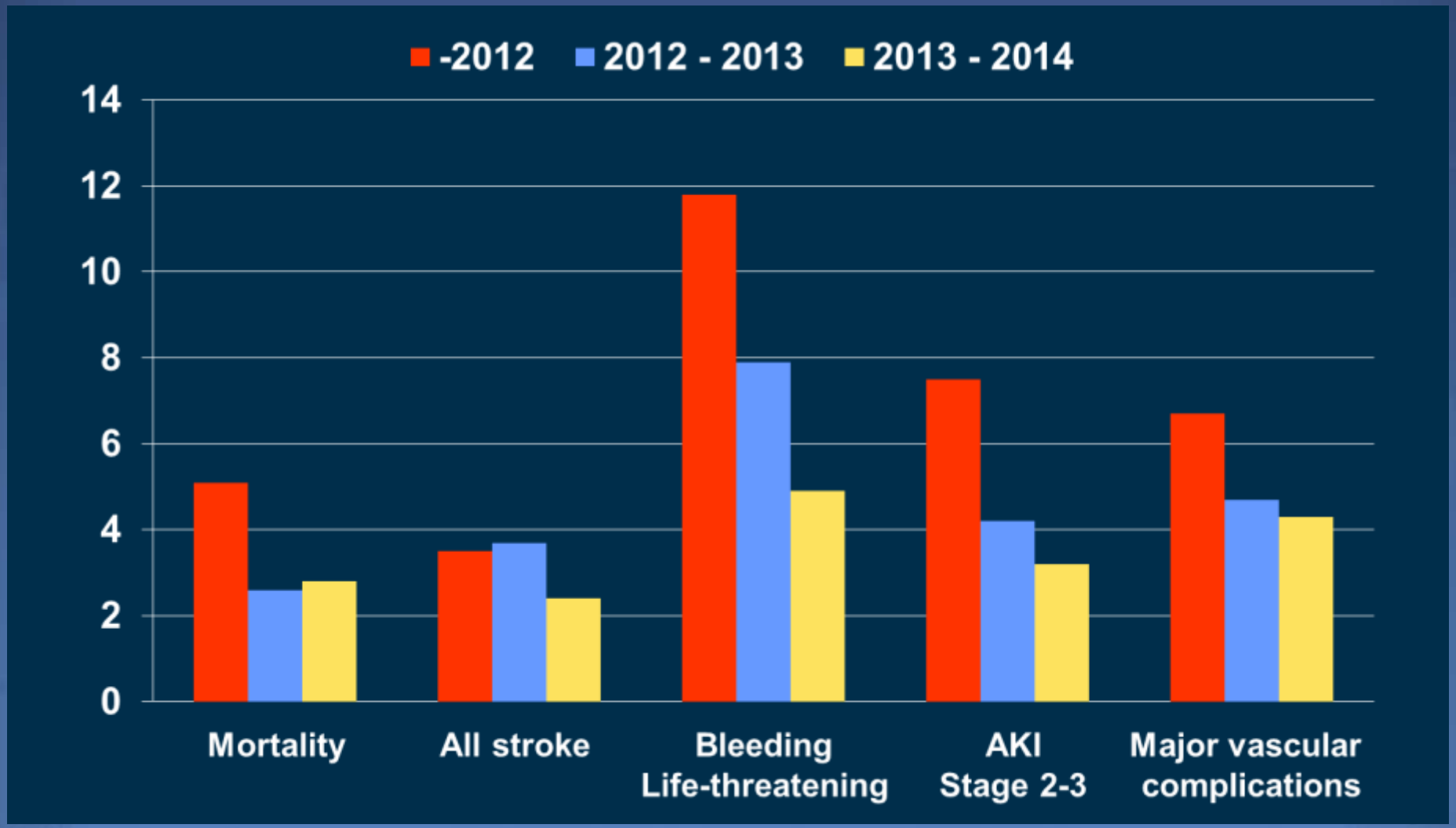
The Asian TAVR Registry
Clinical Outcomes

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Stroke				
All	3.0%	2.8%	3.4%	0.69
Disabling	1.2%	1.0%	1.5%	0.75
Non disabling	1.8%	1.8%	1.8%	
Vascular complications				
Major	5.2%	6.0%	3.7%	0.08
Minor	4.6%	5.4%	3.1%	
Acute kidney injury				
Stage 1	5.6%	6.0%	4.9%	0.36
Stage 2	2.4%	2.3%	2.8%	
Stage 3	1.8%	1.3%	2.8%	

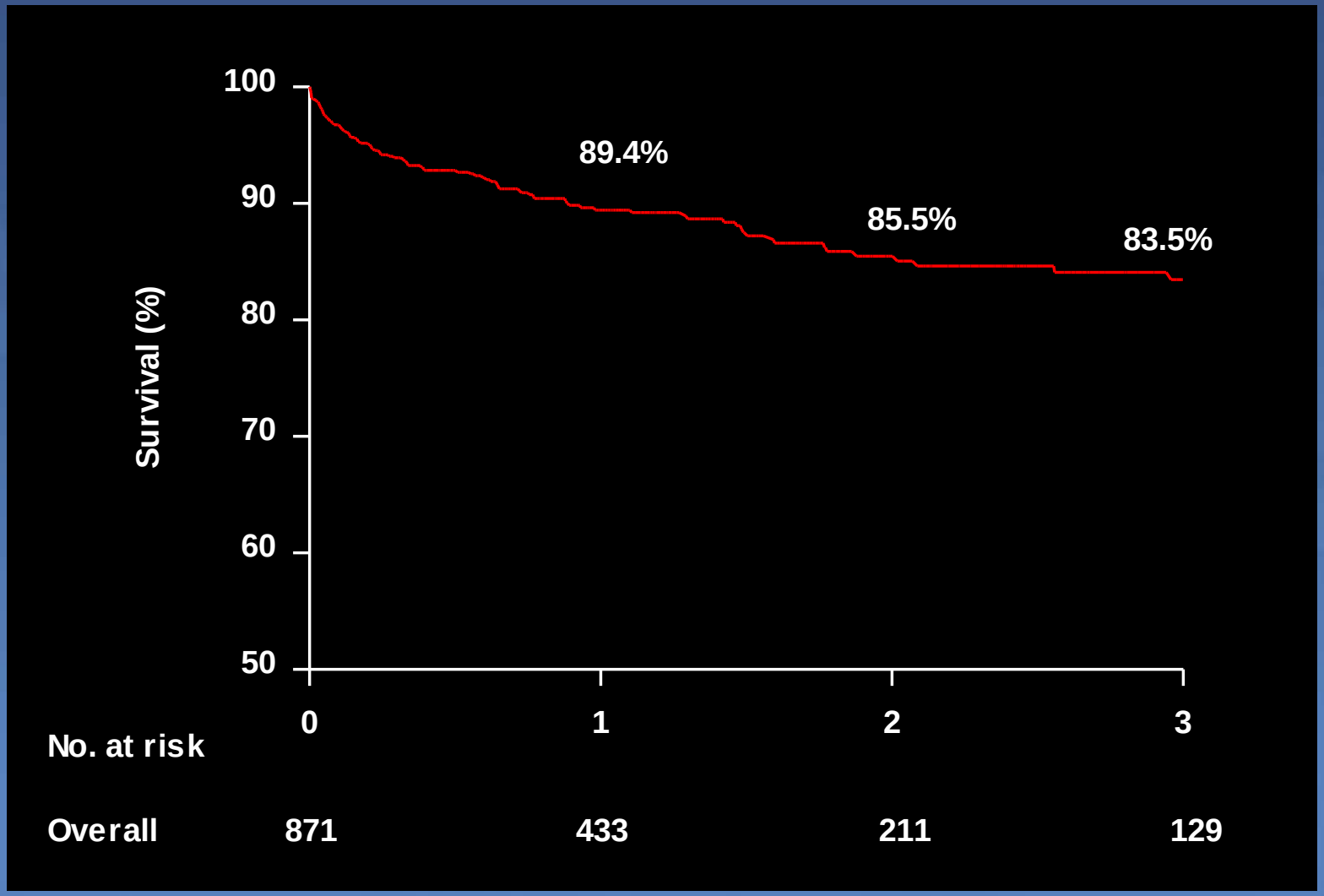
The Asian TAVR Registry
Clinical Outcomes

	Overall (N = 940)	SAPIEN (N = 615)	CoreValve (N = 325)	p value
Bleeding				
Life-threatening	7.6%	8.1%	6.3%	0.07
Major	6.2%	5.2%	8.0%	
Minor	2.6%	3.3%	1.5%	
Device success	86.2%	90.6%	78.1%	< 0.001
Combined safety Endpoint (30 days)	81.0%	80.3%	82.2%	0.51

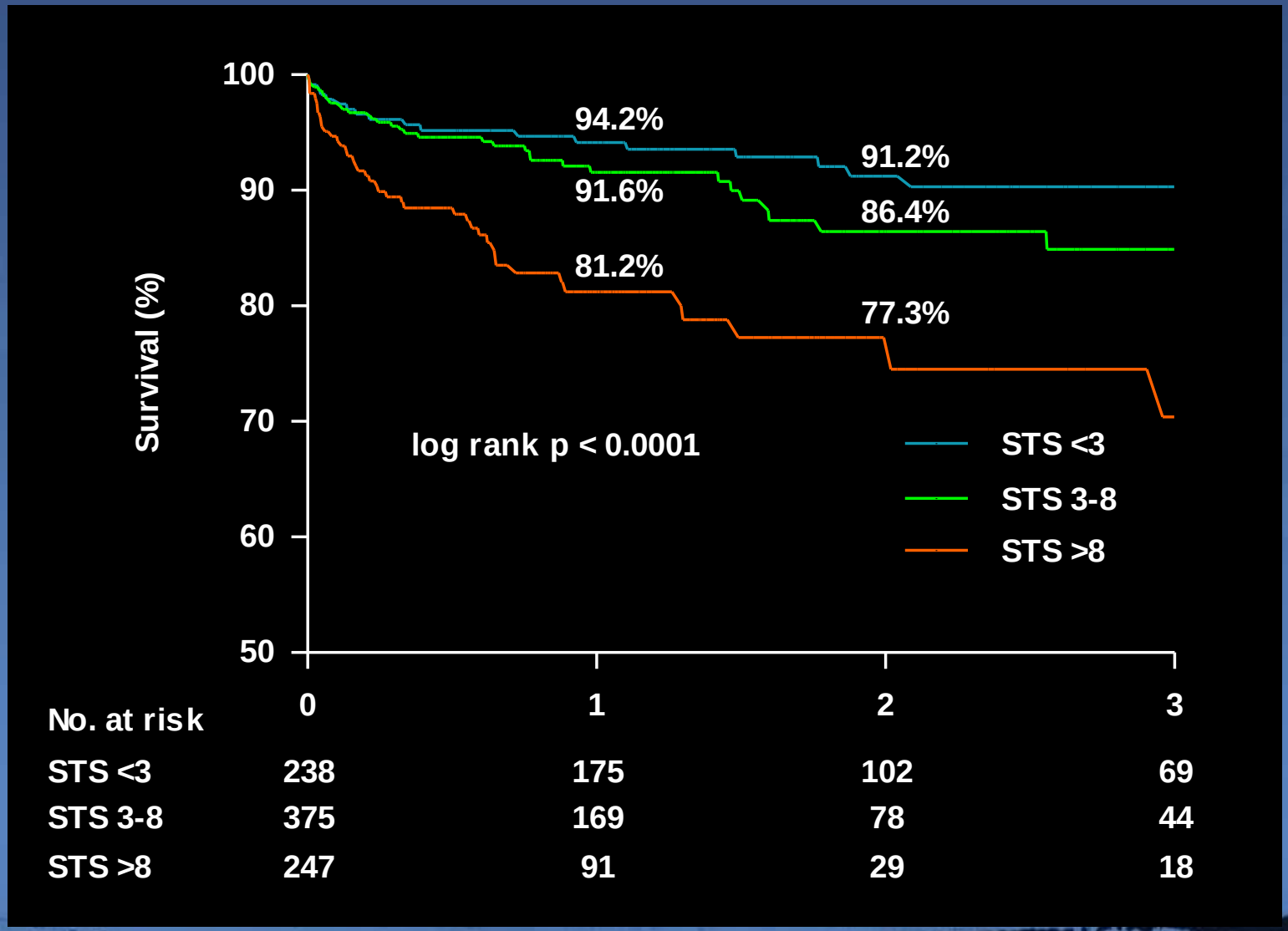
The Asian TAVR Registry
Clinical Outcome and Experience



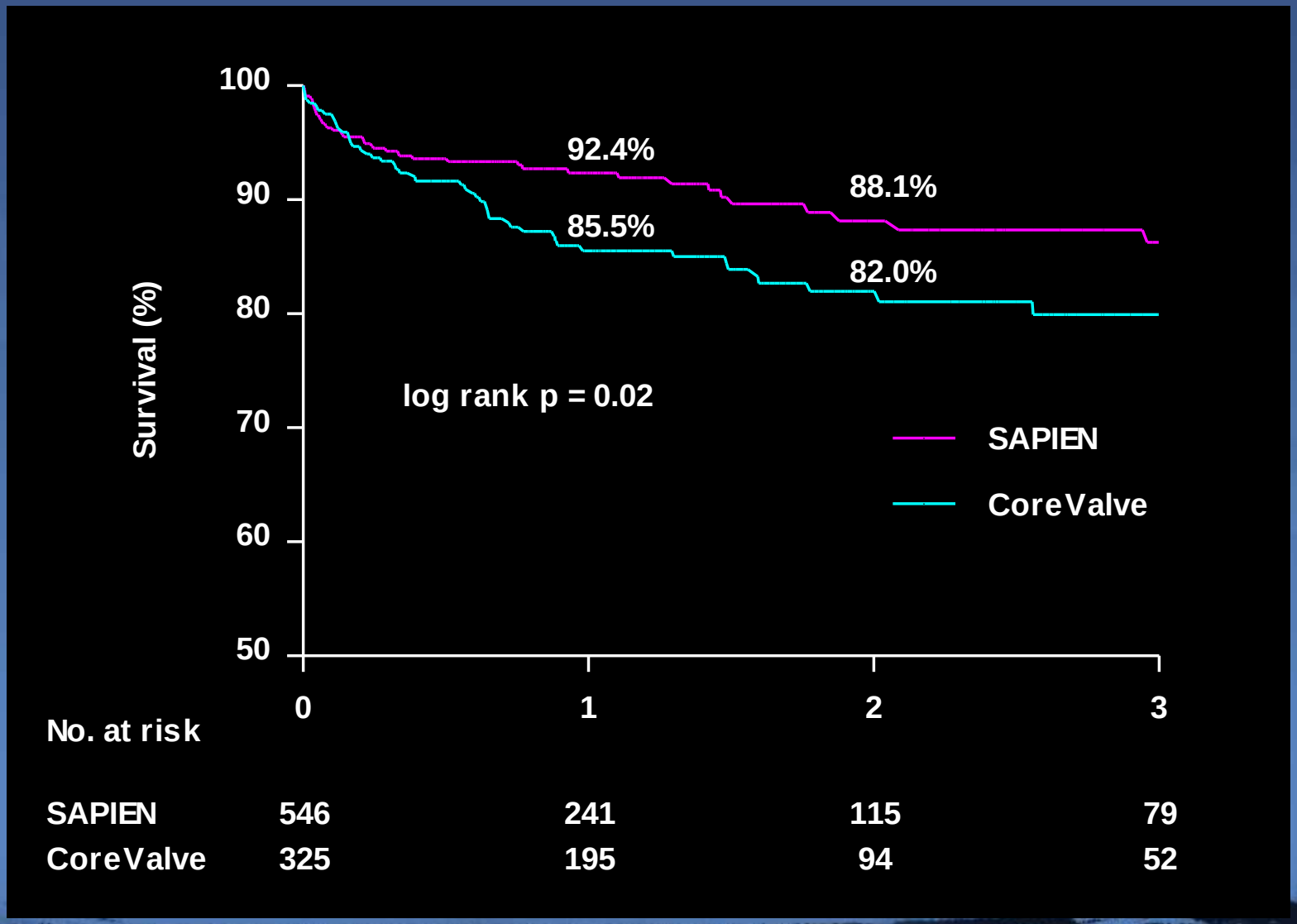
All-cause Mortality
Overall



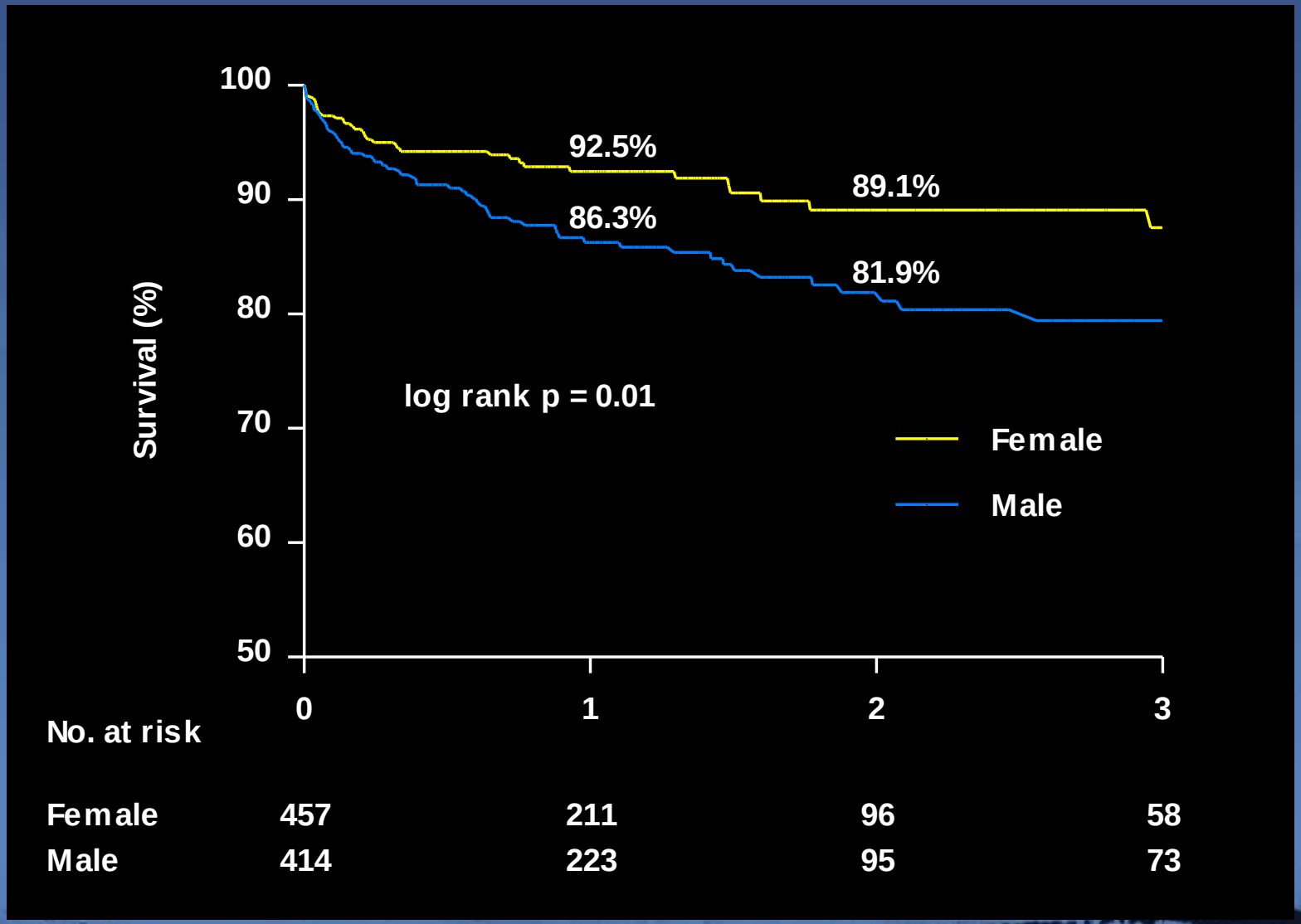
All-cause Mortality
Risk Stratification



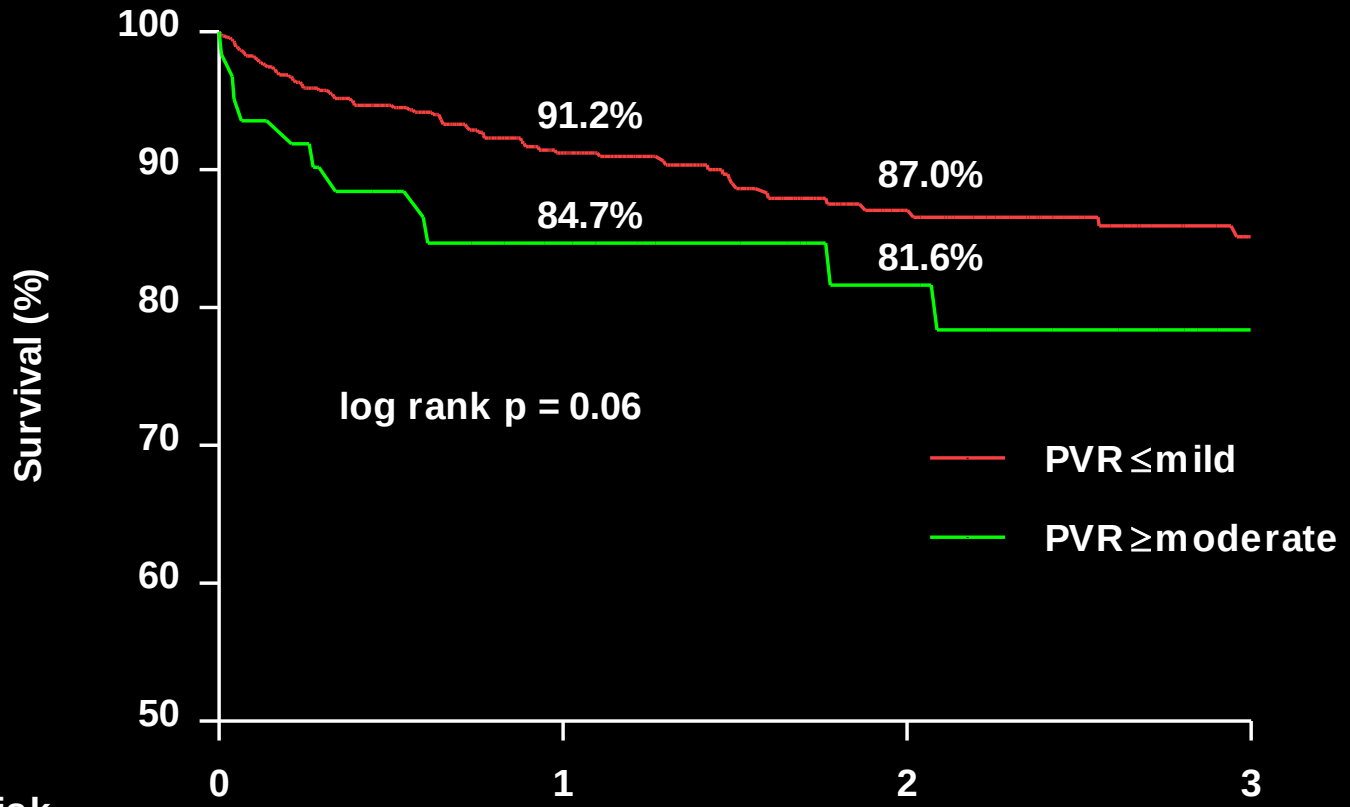
All-cause Mortality
SAPIEN vs CoreValve



All-cause Mortality
Sex Difference



All-cause Mortality
Paravalvular Regurgitation



No. at risk

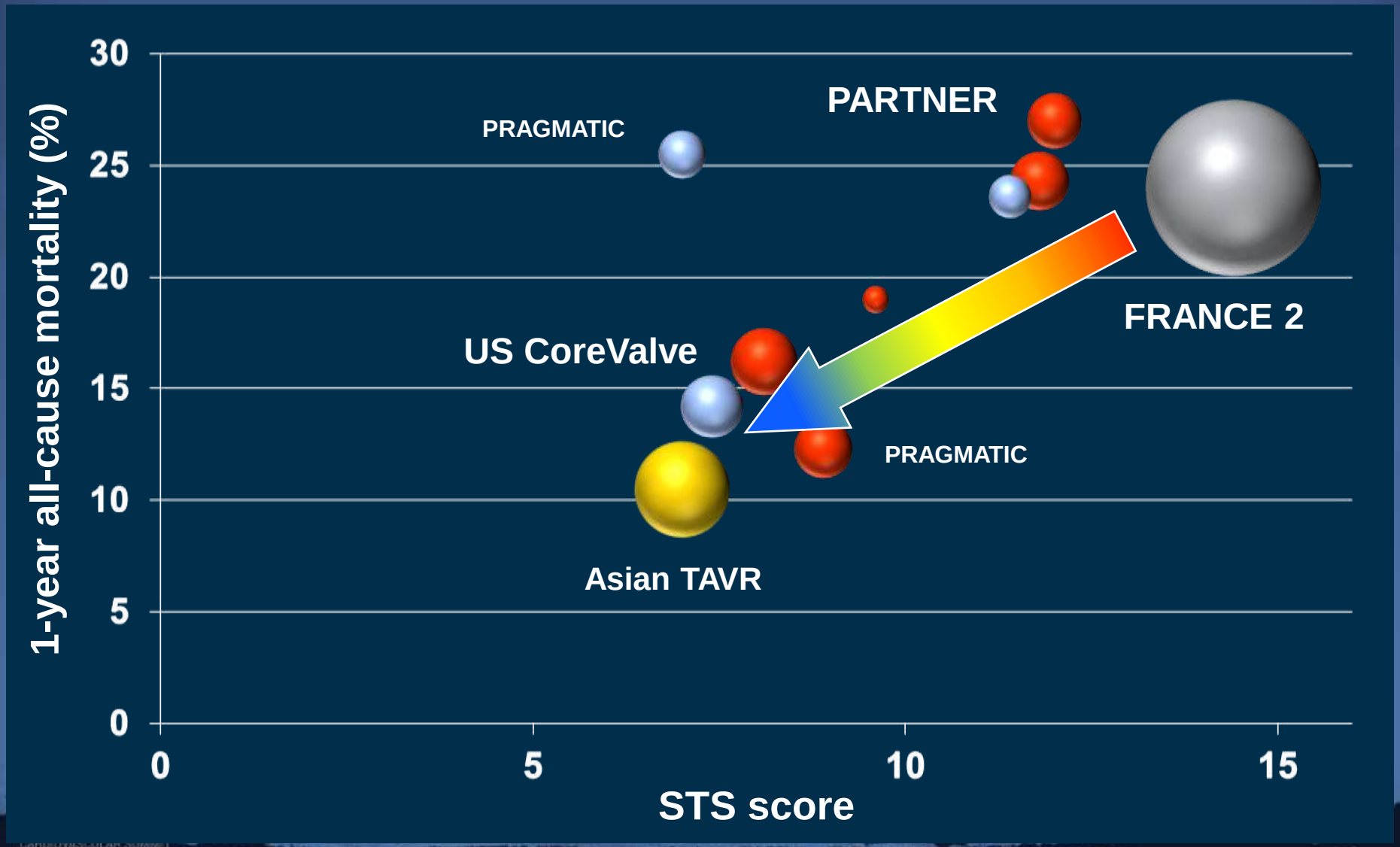
PVR ≤mild	763	389	178	111
PVR ≥moderate	62	42	28	16

The Asian TAVR Registry

Multivariate Predictors of Mortality

	Univariate HR (95% CI)	p value	Multivariate HR (95% CI)	p value
Female	0.57 (0.38 – 0.84)	0.004		
CKD	1.68 (1.11 – 2.54)	0.014	1.86 (1.21 – 2.85)	0.004
DM	1.66 (1.13 – 2.42)	0.01		
COPD	2.32 (0.95 – 5.69)	0.066		
Previous stroke	1.63 (1.10 – 2.43)	0.016	1.58 (1.01 – 2.46)	0.046
Peripheral vascular disease	2.38 (1.60 – 3.55)	< 0.001	1.77 (1.10 – 2.85)	0.019
Mean pressure gradient 10mmHg	0.87 (0.78 – 0.98)	0.017		
LVEF	0.97 (0.96 – 0.98)	< 0.001	0.98 (0.96 – 0.99)	0.011
Transfemoral access	0.57 (0.36 – 0.89)	0.014		
Device (CoreValve)	1.51 (1.03 – 2.20)	0.03	1.73 (1.13 – 2.65)	0.012
Paravalvular leak ≥ moderate	1.74 (0.97 – 3.14)	0.06	1.93 (1.05 – 3.54)	0.033

Mortality and Risk Across Studies



Conclusions

1. In Asian Pacific countries, TAVR has been utilized in intermediate risk patients with severe AS
2. Accumulated experience decreased the short-term mortality and other complications
3. Overall clinical outcomes is comparable to reported studies and will support the trend of expanding indications
4. Further studies will have to clarify the most suitable population with intermediate-risk for TAVR

Acknowledgement

National Taiwan University Hospital, Taiwan

Paul Kao, MD

Mao-Shin, MD

Seoul National University Hospital, Korea

Hyo-Soo Kim, MD

Jun-Bean Park, MD

Shonan Kamakua Hospital, Japan

Shigeru Saito, MD

Futoshi Yamanaka, MD

National University Heart Centre, Singapore

Edgar Tay, MD

Royal Perth Hospital, Australia

Gerald Yong, MD

Saiseikai Yokohama-city Eastern Hospital, Japan

Motoharu Araki, MD

Keio University Hospital, Japan

Kentaro Hayashida, MD

Taku Inohara, MD

Ryo Yanagisawa, MD

Kokura Memorial Hospital, Japan

Shinichi Shirai, MD

Teikyo University Hospital, Japan

Yusuke Watanabe, MD

Chen Hsin General Hospital, Taiwan

Wei-Hsian Yin, MD

Yung Tsai Lee, MD

Queen Elizabeth Hospital, Hong Kong

Michael Lee, MD

Jason Chan, MD