

# **The Asian TAVR Registry**

## **What is the Difference?**

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# Worldwide Generalization of TAVR



***>250,000 patients treated with TAVR in >750 centers  
(>65 countries) around the world thru 2015 !***

# Anatomical Concerns

## TAVR in Asian

***Small aortic annulus*** – Device size eligibility, vital complications (Annulus rupture, coronary obstruction, etc).

***Small vascular access*** – Bleeding and Vascular complications, more frequent transapical approach

***Prevalence of Bicuspid Aortic Valve*** – Unfavorable anatomy (heavily calcified aortic valve, calcified raphe, dilated/horizontal aorta)

# The Asian TAVR Registry

Sponsored Investigator; Park Seung-Jung, MD

Collaboration with CVRF, ClinicalTrials.gov: NCT02308150



## 5 Countries,

HongKong  
Singapore  
Taiwan

Korea

Japan

## 11 centers

Queen Elizabeth Hospital

National University Heart Centre

National Taiwan University

Cheng-Hsin Hospital

Seoul National University Hospital

Asan Medical Center

Shonan Kamakura General Hospital

Keio University Hospital

Teikyo University Hospital

Saiseikai Yokohama Eastern Hospital

Kokura Memorial Hospital

# The Asian TAVR Registry

## Baseline Characteristics

	<b>Overall ( N = 848)</b>	<b>SAPIEN (N = 549)</b>	<b>CoreValve (N = 299)</b>	<b>p value</b>
<b>Age</b>	<b>81.8 ± 6.6</b>	<b>82.7 ± 6.5</b>	<b>80.1 ± 6.5</b>	<b>&lt; 0.001</b>
<b>Female</b>	<b>53.3%</b>	<b>58.1%</b>	<b>44.5%</b>	<b>&lt; 0.001</b>
<b>BMI, kg/m<sup>2</sup></b>	<b>23.0 ± 3.8</b>	<b>22.8 ± 3.9</b>	<b>23.4 ± 3.6</b>	<b>0.03</b>
<b>Diabetes mellitus</b>	<b>30.1%</b>	<b>30.1%</b>	<b>30.1%</b>	<b>0.99</b>
<b>NYHA class III/IV</b>	<b>63.0%</b>	<b>59.7%</b>	<b>68.9%</b>	<b>0.008</b>
<b>CAD</b>	<b>44.7%</b>	<b>40.6%</b>	<b>52.2%</b>	<b>0.001</b>
<b>Previous stroke</b>	<b>10.5%</b>	<b>9.1%</b>	<b>13.0%</b>	<b>0.07</b>
<b>Peripheral vascular disease</b>	<b>15.4%</b>	<b>16.2%</b>	<b>14.0%</b>	<b>0.41</b>
<b>COPD</b>	<b>11.7%</b>	<b>12.2%</b>	<b>10.7%</b>	<b>0.52</b>

# The Asian TAVR Registry

## Baseline Characteristics

	<b>Overall ( N = 848)</b>	<b>SAPIEN (N = 549)</b>	<b>CoreValve (N = 299)</b>	<b>p value</b>
<b>Logistic EuroSCORE</b>	<b>16.5 ± 12.0</b>	16.4 ± 11.2	16.6 ± 13.2	0.86
<b>STS score</b>	<b>5.2 ± 3.8</b>	5.4 ± 3.8	5.0 ± 3.8	0.13
<b>LVEF, %</b>	<b>59.2 ± 12.3</b>	59.9 ± 11.9	58.0 ± 12.8	0.03
<b>Mitral regurgitation ≥ moderate</b>	<b>13.9%</b>	9.5%	22.1%	< 0.001
<b>Pulmonary hypertension</b>	<b>12.7%</b>	6.0%	25.1%	< 0.001
<b>Bicuspid aortic valve</b>	<b>5.8%</b>	1.5%	13.7%	< 0.001

# The Asian TAVR Registry

## CT Data

	<b>Overall ( N = 848)</b>	<b>SAPIEN (N = 549)</b>	<b>CoreValve (N = 299)</b>	<b>p value</b>
<b>Annulus area, mm<sup>2</sup></b>	<b>405 ± 75</b>	<b>391 ± 70</b>	<b>431 ± 79</b>	<b>&lt; 0.001</b>
<b>Perimeter, mm</b>	<b>73 ± 7</b>	<b>72 ± 6</b>	<b>75 ± 7</b>	<b>&lt; 0.001</b>
<b>Femoral artery, mm</b>				
<b>Right</b>	<b>6.5 ± 1.3</b>	<b>6.3 ± 1.3</b>	<b>7.2 ± 1.1</b>	<b>&lt; 0.001</b>
<b>Left</b>	<b>6.3 ± 1.5</b>	<b>6.2 ± 1.5</b>	<b>7.0 ± 1.0</b>	<b>&lt; 0.001</b>
<b>Coronary height, mm</b>				
<b>Right</b>	<b>16.6 ± 2.8</b>	<b>16.2 ± 2.9</b>	<b>17.3 ± 2.6</b>	<b>&lt; 0.001</b>
<b>Left</b>	<b>12.8 ± 2.6</b>	<b>12.8 ± 2.4</b>	<b>12.9 ± 3.0</b>	<b>0.88</b>

# The Asian TAVR Registry

## Procedural Data

	Overall ( N = 848)	SAPIEN (N = 549)	CoreValve (N = 299)	p value
<b>Access site</b>				
Transfemoral	86.2%	80.3%	97.0%	< 0.001
Transapical	12.6%	19.5%	-	
Transsubclavian	0.4%	-	1.0%	
Transaortic	0.8%	0.2%	0.2%	
<b>Device size</b>				
23 mm	41.2%	62.1%	2.7%	< 0.001
26 mm	37.7%	33.7%	45.2%	
29 mm	17.2%	4.2%	41.1%	
31 mm	3.9%	-	11.0%	



# The Asian TAVR Registry

## Procedural Outcomes

	<b>Overall ( N = 848)</b>	<b>SAPIEN (N = 549)</b>	<b>CoreValve (N = 299)</b>	<b>p value</b>
<b>Procedural success</b>	<b>97.5%</b>	<b>97.3%</b>	<b>98.0%</b>	<b>0.52</b>
<b>Conversion to surgery</b>	<b>1.8%</b>	<b>1.8%</b>	<b>1.7%</b>	<b>0.88</b>
<b>Coronary obstruction</b>	<b>1.3%</b>	<b>1.5%</b>	<b>1.0%</b>	<b>0.76</b>
<b>Implantation of two valves</b>	<b>4.5%</b>	<b>0.7%</b>	<b>11.4%</b>	<b>&lt; 0.001</b>
<b>New permanent pacemaker</b>	<b>9.5%</b>	<b>4.0%</b>	<b>19.4%</b>	<b>&lt; 0.001</b>
<b>Paravalvular leakage ≥ moderate</b>	<b>9.8%</b>	<b>7.3%</b>	<b>14.4%</b>	<b>0.001</b>
<b>Device success</b>	<b>85.5%</b>	<b>91.1%</b>	<b>75.3%</b>	<b>&lt; 0.001</b>

# The Asian TAVR Registry

## 30-day Outcomes

	<b>Overall ( N = 848)</b>	<b>SAPIEN (N = 549)</b>	<b>CoreValve (N = 299)</b>	<b>p value</b>
<b>Stroke</b>				
All	<b>3.8%</b>	<b>4.4%</b>	<b>2.7%</b>	<b>0.22</b>
Disabling	<b>2.2%</b>	<b>2.6%</b>	<b>1.7%</b>	<b>0.56</b>
Non disabling	<b>1.5%</b>	<b>1.8%</b>	<b>1.0%</b>	<b>0.41</b>
<b>Bleeding</b>				
Life-threatening	<b>6.4%</b>	<b>6.7%</b>	<b>5.7%</b>	<b>0.55</b>
Major	<b>4.5%</b>	<b>4.0%</b>	<b>5.4%</b>	<b>0.37</b>

# The Asian TAVR Registry

## 30-day Outcomes

	<b>Overall ( N = 848)</b>	<b>SAPIEN (N = 549)</b>	<b>CoreValve (N = 299)</b>	<b>p value</b>
<b>Vascular complications</b>				
<b>Major</b>	<b>5.0%</b>	<b>6.0%</b>	<b>3.0%</b>	<b>0.05</b>
<b>Minor</b>	<b>4.7%</b>	<b>5.6%</b>	<b>3.0%</b>	<b>0.08</b>
<b>Acute kidney injury</b>	<b>3.3%</b>	<b>2.6%</b>	<b>4.7%</b>	<b>0.10</b>
<b>Early safety endpoints</b>	<b>14.6%</b>	<b>15.5%</b>	<b>13.0%</b>	<b>0.34</b>

# The Asian TAVR Registry

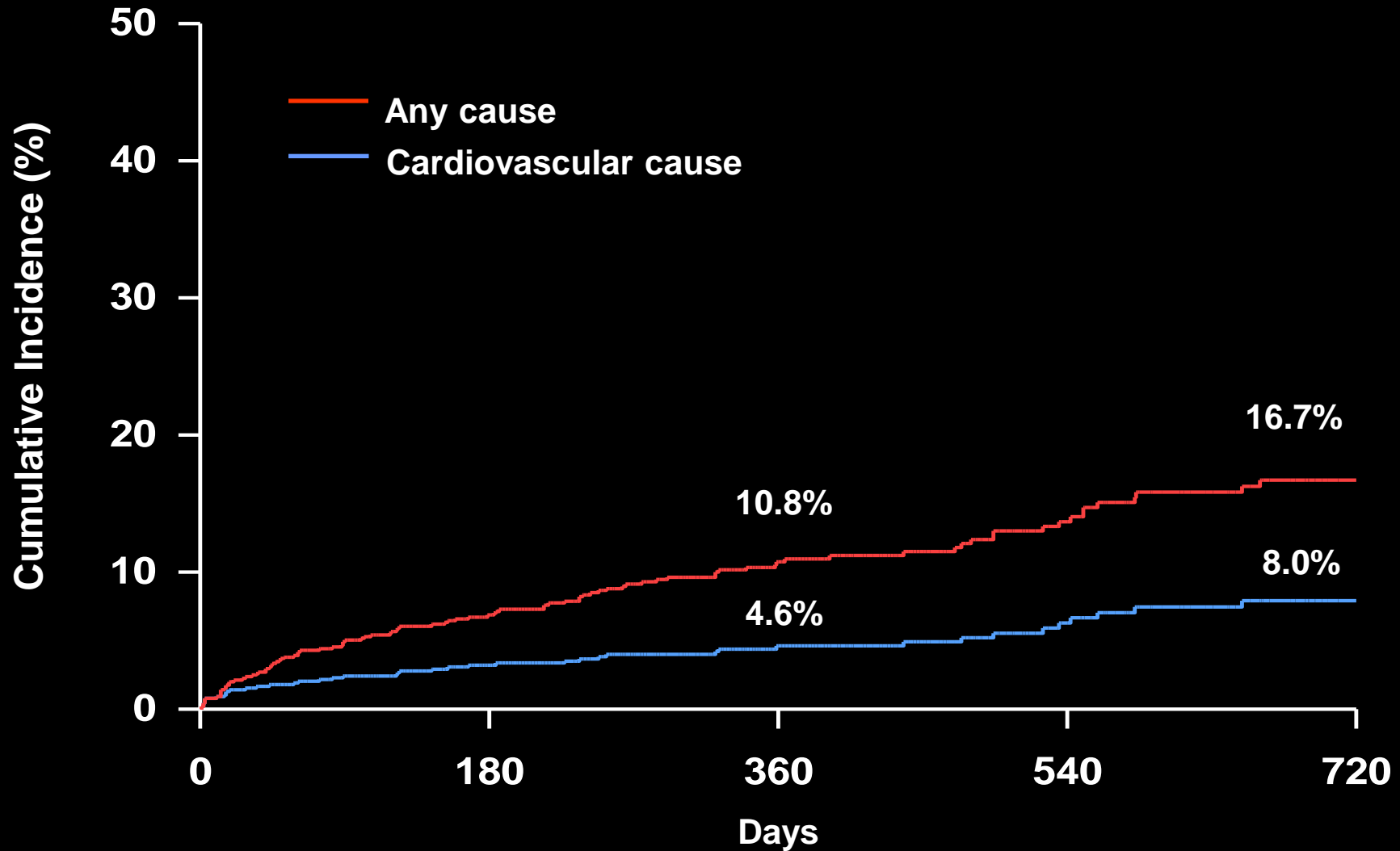
## Mortality

	Overall ( N = 848)	SAPIEN (N = 549)	CoreValve (N = 299)	p value
<b>At 30 days</b>				
From any cause	2.5%	3.1%	1.3%	0.12
From cardiovascular cause	1.7%	1.8%	1.3%	0.78
<b>At 1 year *</b>				
From any cause	10.8%	9.4%	12.2%	0.40
From Cardiovascular cause	4.6%	4.3%	5.4%	0.48

\* Estimated as Kaplan-Meier method

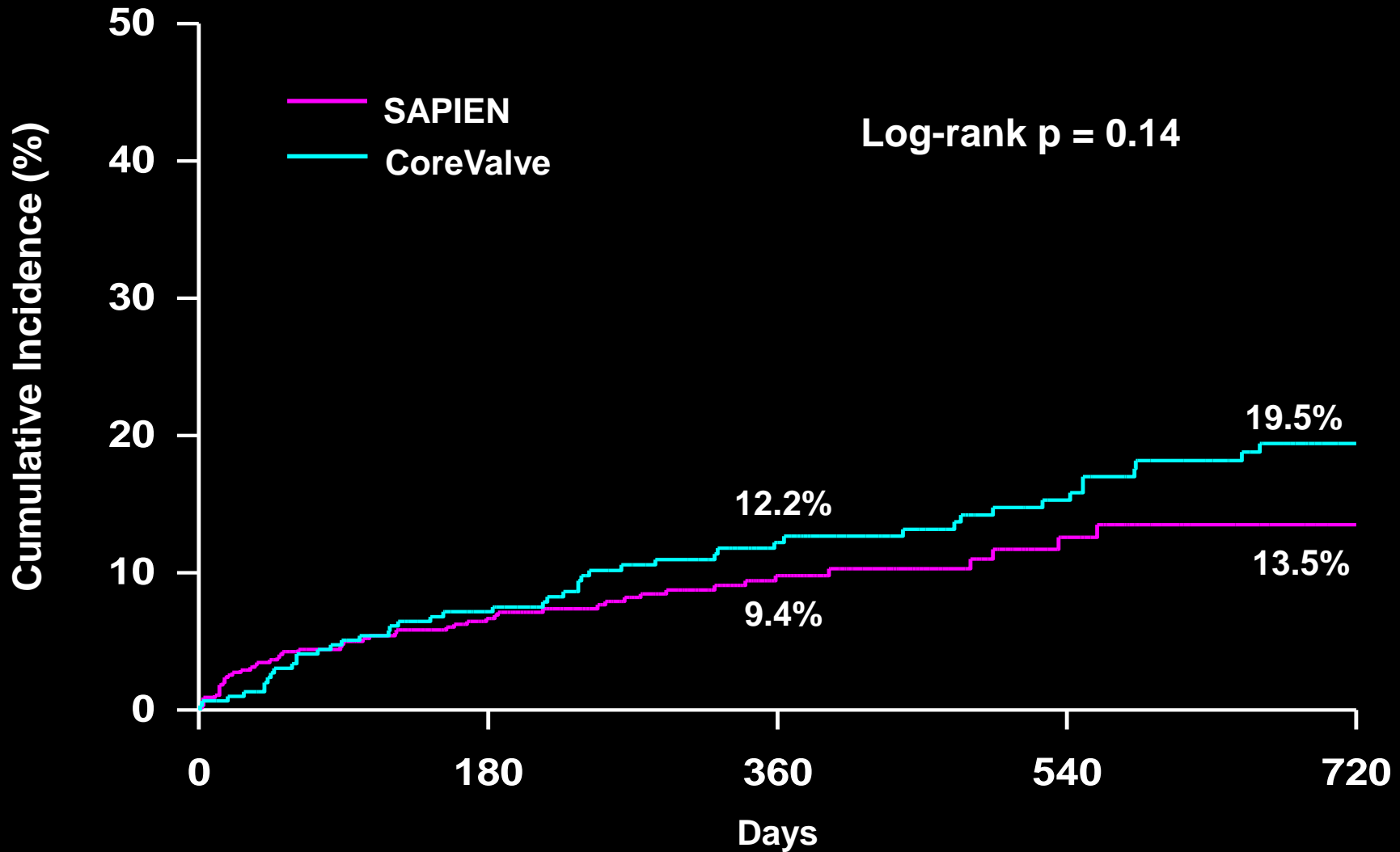
# The Asian TAVR Registry

## 2-Year Mortality



# All-cause Mortality

## SAPIEN vs CoreValve



# Multivariate Predictors of Mortality

## The Asian TAVR Registry

	Multivariate analysis HR (95% CI)	p value
Body mass index, m <sup>2</sup> /kg	0.92 (0.87 – 0.97)	0.002
NYHA functional class III or IV	2.15 (1.33 – 3.48)	0.002
STS score	1.07 (1.04 – 1.09)	< 0.001
Diabetes mellitus	1.55 (1.04 – 2.31)	0.03
Prior cerebrovascular accident	1.88 (1.16 – 3.04)	0.011
Mean pressure gradient <sub>10mmHg</sub>	0.86 (0.77 – 0.96)	0.006
Paravalvular leakage ≥ moderate	2.24 (1.34 – 3.74)	0.002

# **What's the difference between Asian and Western Countries?**



# Global TAVR Registry

<b>Total (n=2757)</b>	
<b>Asian (n=923)</b>	<b>European (n=1834)</b>

14 centers from 8 countries  
in Europe and Asia

# TAVR in Asian vs Western Countries

## Baseline Characteristics

	Asian (N = 923)	European (N = 1834)	p value
Age	81.7 ± 6.5	81.8 ± 6.6	0.72
Female	56.2%	48.5%	< 0.001
BMI, kg/m <sup>2</sup>	22.9 ± 3.9	26.6 ± 13.9	< 0.001
NYHA class III/IV	62.9%	82.9%	< 0.001
Diabetes mellitus	28.9%	24.3%	0.09
Hypertension	75.6%	70.8%	0.008
Creatinine, mg/dl	1.2 ± 1.0	1.2 ± 0.8	0.23
COPD	12.1%	22.4%	< 0.001

# TAVR in Asian vs Western Countries

## Baseline Characteristics

	<b>Asian (N = 923)</b>	<b>European (N = 1834)</b>	<b>p value</b>
<b>Peripheral vascular disease</b>	<b>15.0%</b>	<b>16.8%</b>	<b>0.22</b>
<b>Prior CVA</b>	<b>10.2%</b>	<b>11.4%</b>	<b>0.34</b>
<b>Prior PCI</b>	<b>31.5%</b>	<b>24.7%</b>	<b>&lt; 0.001</b>
<b>Prior CABG</b>	<b>8.0%</b>	<b>16.0%</b>	<b>&lt; 0.001</b>
<b>LVEF, %</b>	<b>59.9 ± 11.9</b>	<b>58.0 ± 12.8</b>	<b>0.03</b>
<b>Logistic EuroSCORE</b>	<b>16.3 ± 11.9</b>	<b>16.7 ± 11.6</b>	<b>0.39</b>
<b>STS score</b>	<b>5.2 ± 3.7</b>	<b>5.2 ± 5.1</b>	<b>0.80</b>

# TAVR in Asian vs Western Countries

## Procedural Data

	Asian (N = 923)	European (N = 1834)	p value
<b>Access site</b>			
Transfemoral	85.7%	80.4%	0.001
Non-transfemoral	14.3%	19.6%	
Transapical	92.4%	20.3%	< 0.001
Transsubclavian	2.3%	13.1%	
Transaortic	5.3%	66.7%	
<b>Device type</b>			
SAPIEN XT	66.3%	40.3%	< 0.001
CoreValve	33.7%	59.7%	
<b>CT assessment</b>	97.5%	50.9%	< 0.001

# TAVR in Asian vs Western Countries

## Procedural Outcomes

	<b>Asian (N = 923)</b>	<b>European (N = 1834)</b>	<b>p value</b>
<b>Conversion to surgery</b>	<b>1.6%</b>	<b>0.8%</b>	<b>0.05</b>
<b>Coronary obstruction</b>	<b>1.3%</b>	<b>0.8%</b>	<b>0.23</b>
<b>Annulus rupture</b>	<b>0.3%</b>	<b>0.7%</b>	<b>0.27</b>
<b>Implantation of two valves</b>	<b>4.4%</b>	<b>2.3%</b>	<b>0.002</b>
<b>New permanent pacemaker</b>	<b>9.3%</b>	<b>16.1%</b>	<b>&lt; 0.001</b>
<b>Paravalvular leakage &gt; mild</b>	<b>9.9%</b>	<b>11.7%</b>	<b>0.15</b>
<b>Device success</b>	<b>82.9%</b>	<b>83.0%</b>	<b>0.92</b>

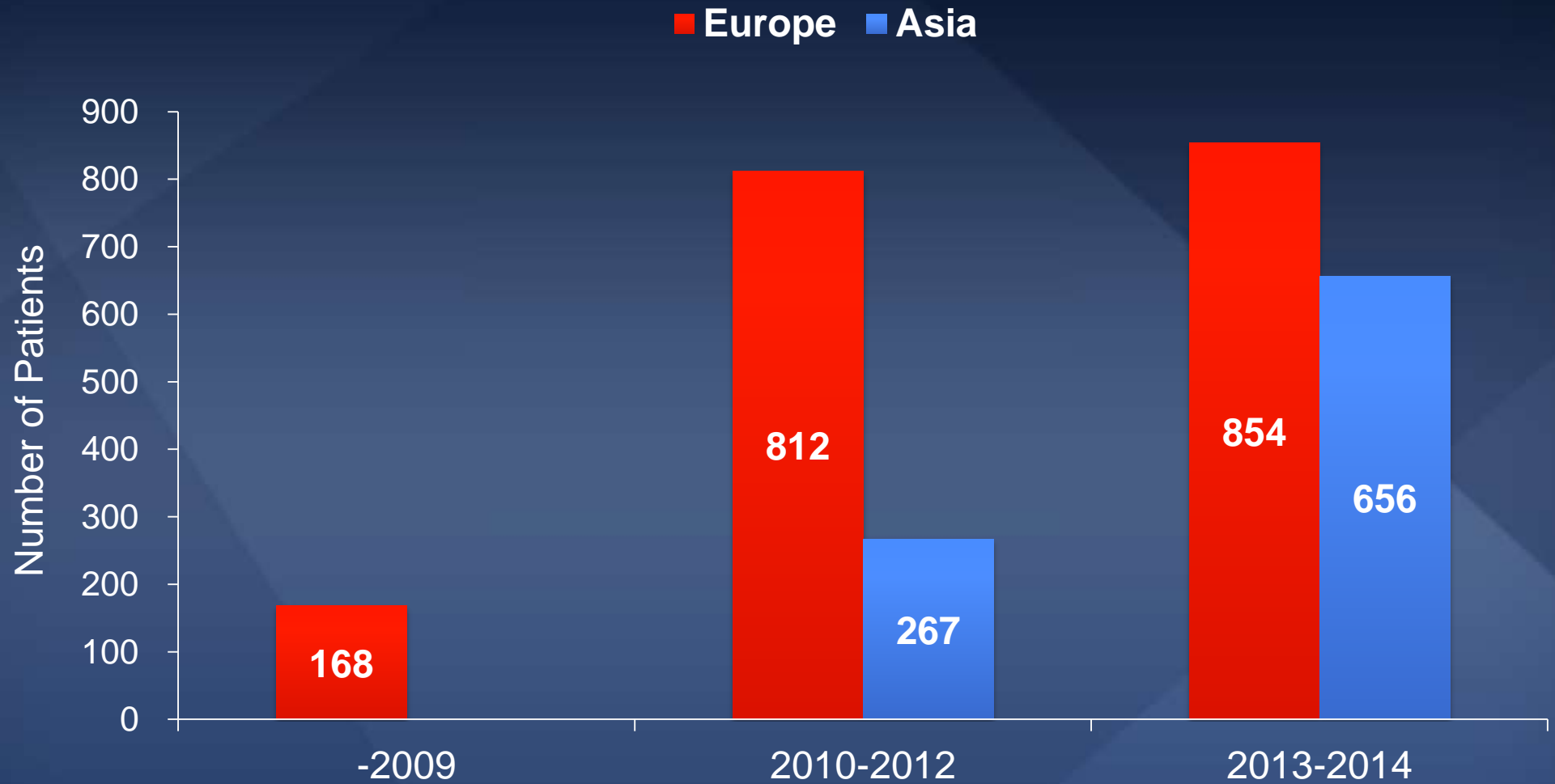
# TAVR in Asian vs Western Countries

## 30-day Outcomes

	<b>Asian (N = 923)</b>	<b>European (N = 1834)</b>	<b>p value</b>
<b>Disabling stroke</b>	<b>1.4%</b>	<b>0.8%</b>	<b>0.14</b>
<b>Life-threatening or major bleeding</b>	<b>11.2%</b>	<b>10.8%</b>	<b>0.77</b>
<b>Major vascular complication</b>	<b>4.7%</b>	<b>7.5%</b>	<b>0.004</b>
<b>Acute kidney injury (stage 2-3)</b>	<b>2.9%</b>	<b>3.0%</b>	<b>0.91</b>

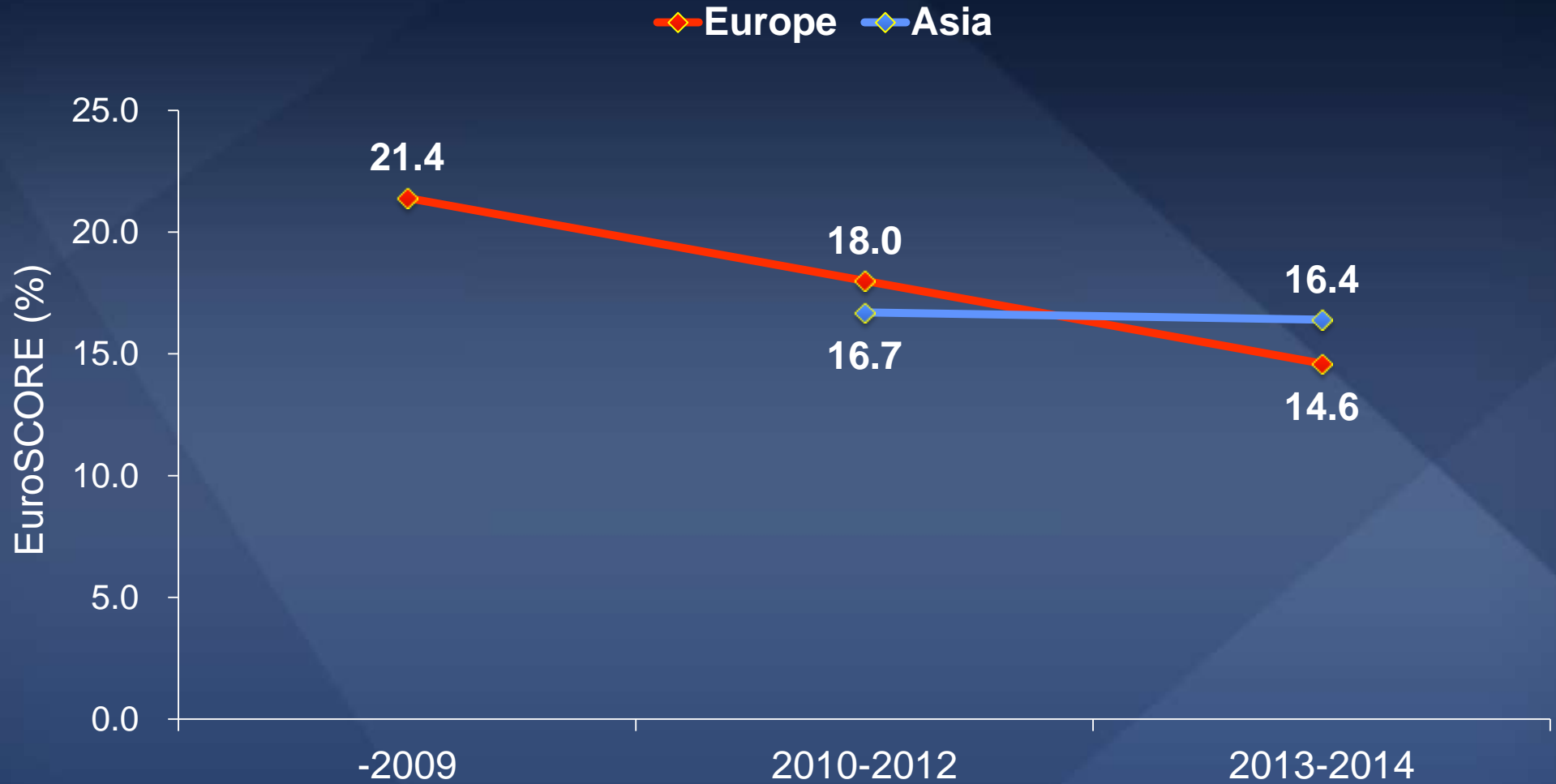
# TAVR in Asian vs Western Countries

## Temporal Trend of TAVR Cases



# TAVR in Asian vs Western Countries

## Temporal Trend of EuroSCORE



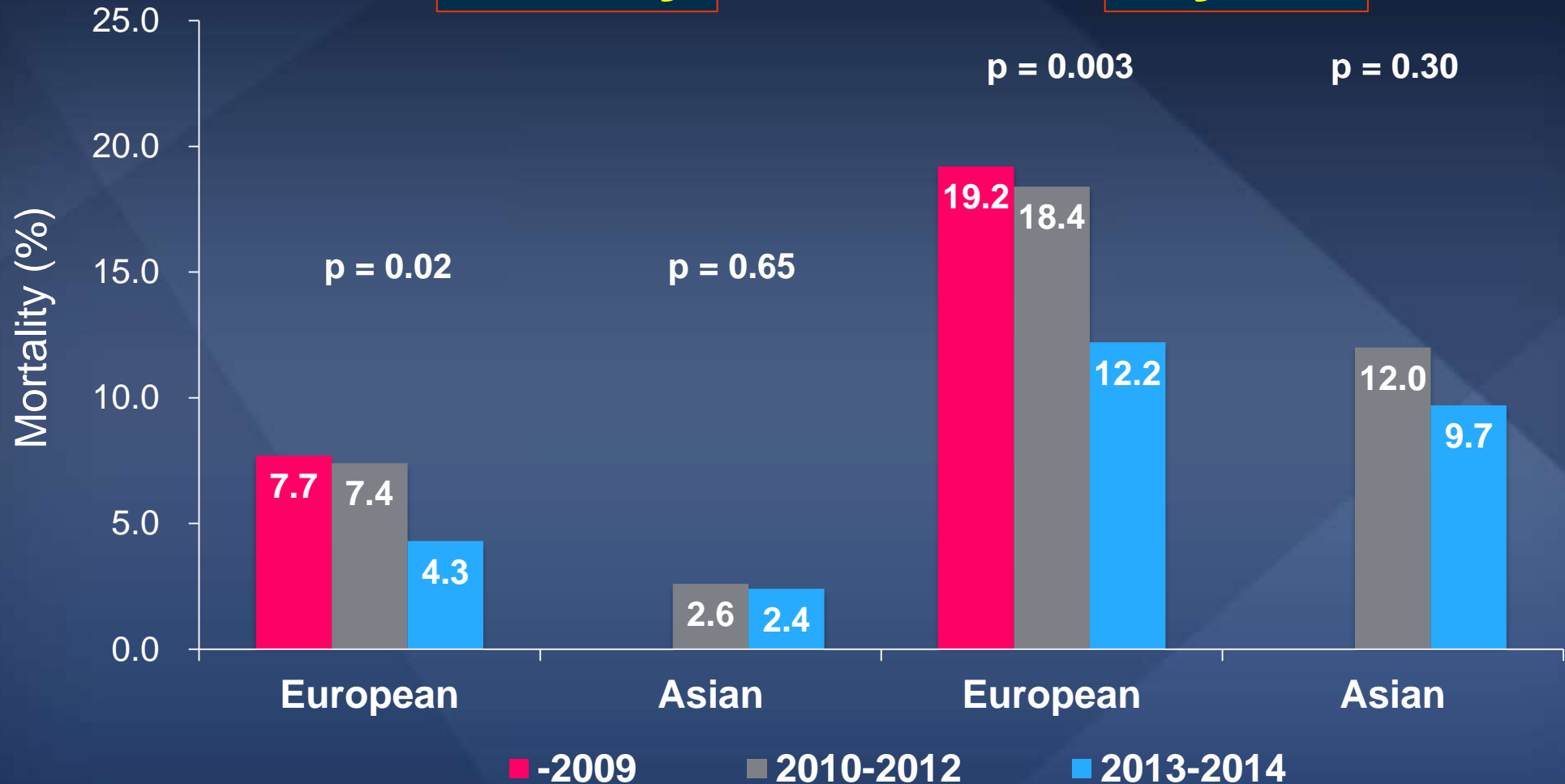


# TAVR in Asian vs Western Countries

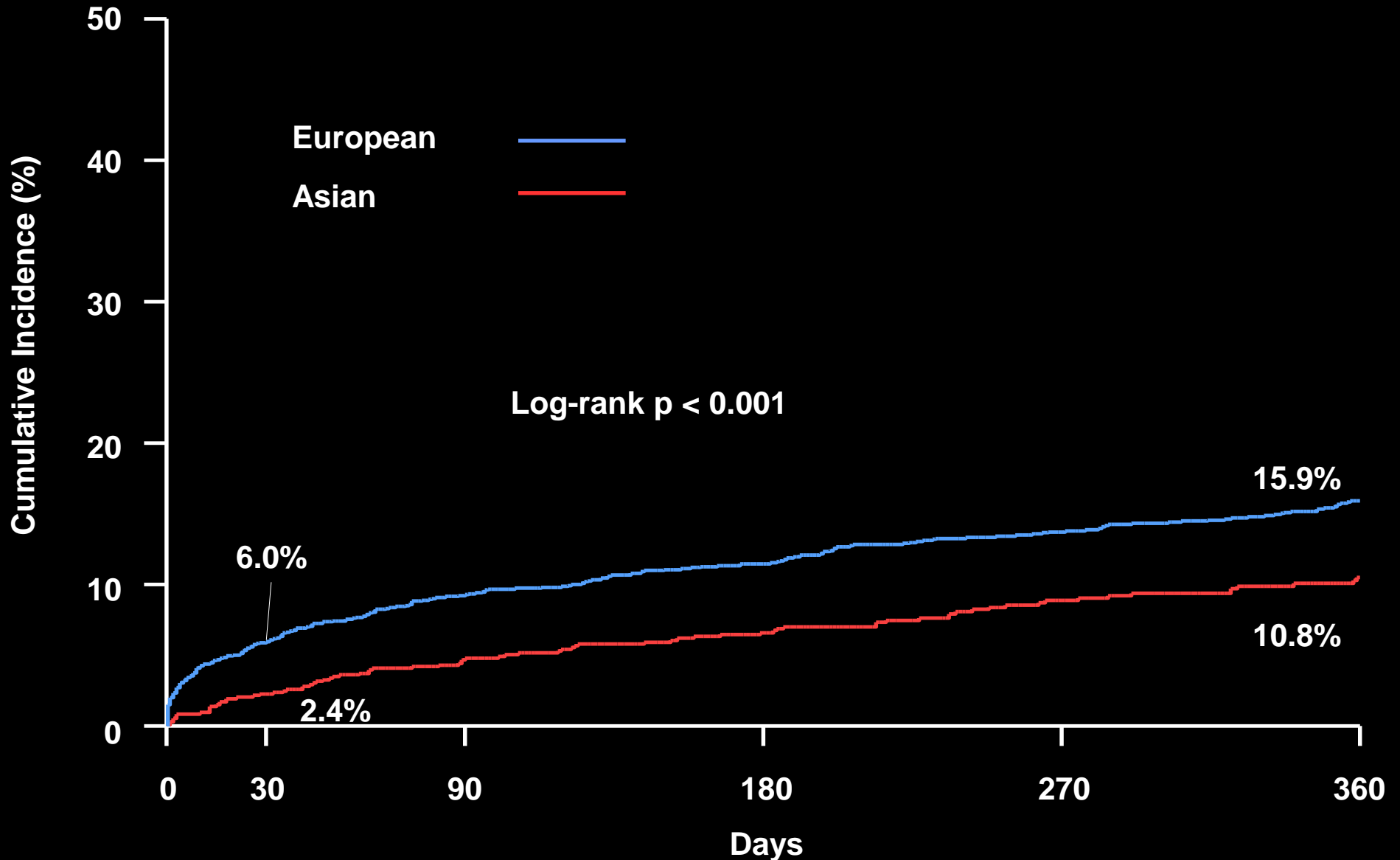
## Temporal Trend of Mortality

**30-day**

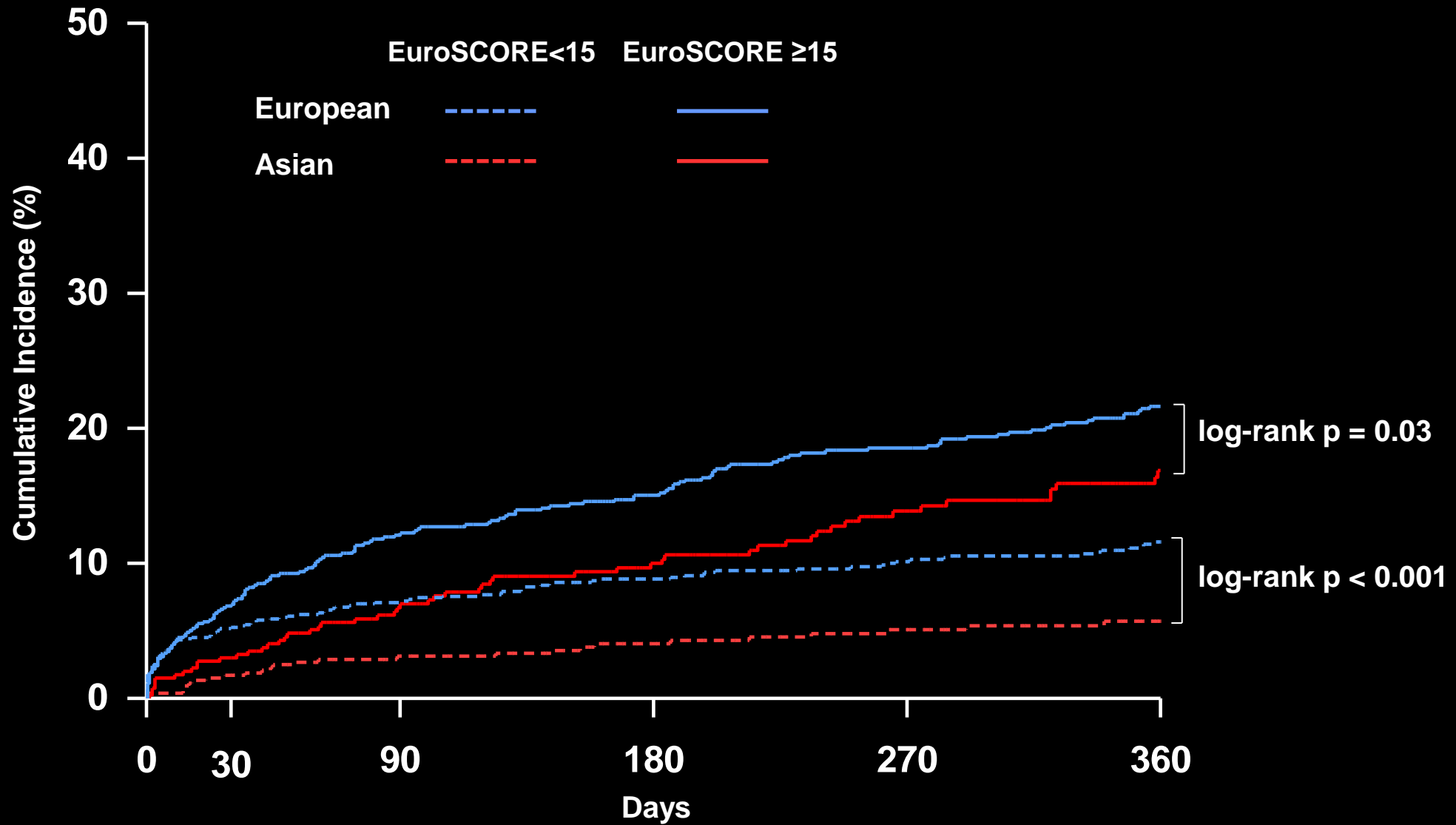
**1-year**



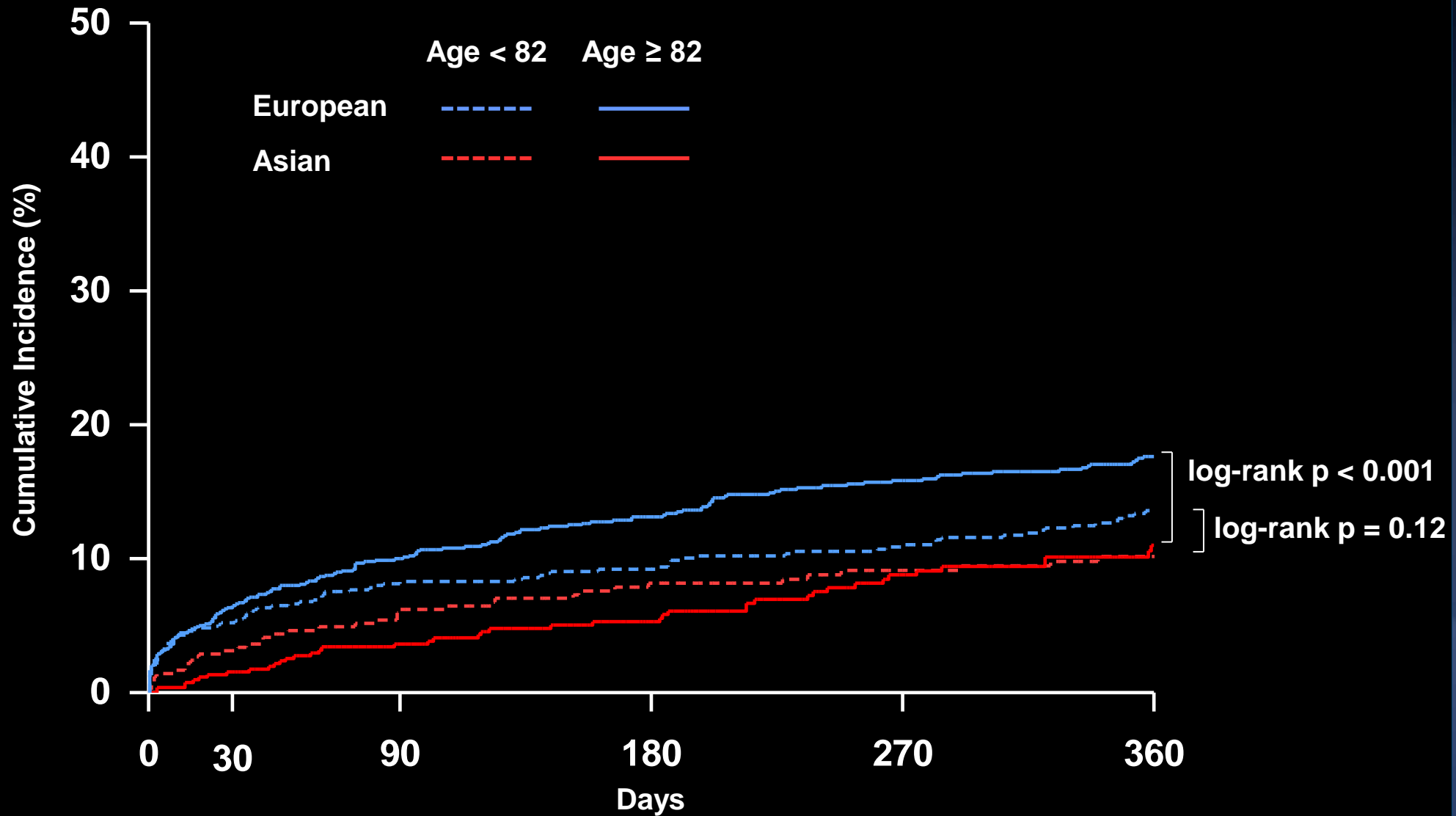
# Asian vs. European 1-Year Mortality



# TAVR in Asian vs. European Stratified According to EuroSCORE



# TAVR in Asian vs. European Stratified According to Age



# Multivariate Predictors of Mortality TAVR in Asian vs Western Countries

	Multivariate analysis HR (95% CI)	p value
<b>Race</b>	<b>0.97 (0.71 – 1.34)</b>	<b>0.85</b>
<b>Age, years</b>	<b>1.02(1.00 – 1.04)</b>	<b>0.036</b>
<b>Creatinine, mg/dl</b>	<b>1.10 (1.01 – 1.21)</b>	<b>0.032</b>
<b>NYHA class III/IV</b>	<b>1.66 (1.21 – 2.28)</b>	<b>0.002</b>
<b>STS score</b>	<b>1.14 (1.07 – 1.21)</b>	<b>&lt; 0.001</b>
<b>LVEF, %</b>	<b>0.99 (0.98 – 0.99)</b>	<b>0.01</b>
<b>Transfemoral access</b>	<b>0.62 (0.47 – 0.82)</b>	<b>0.001</b>
<b>Time procedure performed, year</b>	<b>0.89 (0.83 – 0.96)</b>	<b>0.002</b>

# TAVR in Asian Countries

**Clinical outcomes** – Expansion of TAVR including moderate and low-risk patients, demonstrating excellent outcomes with 1-year mortality of 10%

**Anatomical concerns** – Small annulus, vascular access, more frequent bicuspid AS BUT 3-dimensional assessments outweigh the potential risk of complications.

**Difference between Asia and Europe** – Favorable outcomes of TAVR in Asian countries despite limited experiences.

**Evolving TAVR** - Would be mainstream therapy for almost all aortic stenosis patients in All over the world.