

The Asian TAVR Registry

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The Asian TAVR Registry

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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

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Baseline Characteristics

	Overall (N = 998)	Balloon Expandable (N = 654)	Self Expandable (N = 344)	p value
Age	81.8 ± 6.6	82.7 ± 6.5	80.1 ± 6.5	< 0.001
Female	53.3%	58.1%	44.5%	< 0.001
BMI, kg/m ²	23.0 ± 3.8	22.8 ± 3.9	23.4 ± 3.6	0.03
Diabetes mellitus	30.1%	30.1%	30.1%	0.99
NYHA class III/IV	63.0%	59.7%	68.9%	0.008
CAD	44.7%	40.6%	52.2%	0.001
Previous stroke	10.5%	9.1%	13.0%	0.07
Peripheral vascular disease	15.4%	16.2%	14.0%	0.41
COPD	11.7%	12.2%	10.7%	0.52

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Baseline Characteristics

	Overall (N = 998)	Balloon Expandable (N = 654)	Self Expandable (N = 344)	p value
Logistic EuroSCORE	16.5 ± 12.0	16.4 ± 11.2	16.6 ± 13.2	0.86
STS score	5.2 ± 3.8	5.4 ± 3.8	5.0 ± 3.8	0.13
LVEF, %	59.2 ± 12.3	59.9 ± 11.9	58.0 ± 12.8	0.03
Mitral regurgitation ≥ moderate	13.9%	9.5%	22.1%	< 0.001
Pulmonary hypertension	12.7%	6.0%	25.1%	< 0.001
Bicuspid aortic valve	5.8%	1.5%	13.7%	< 0.001

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Procedural Outcomes

	Overall (N = 998)	Balloon Expandable (N = 654)	Self Expandable (N = 344)	p value
Procedural success	97.5%	97.3%	98.0%	0.52
Conversion to surgery	1.8%	1.8%	1.7%	0.88
Coronary obstruction	1.3%	1.5%	1.0%	0.76
Implantation of two valves	4.5%	0.7%	11.4%	< 0.001
New permanent pacemaker	9.5%	4.0%	19.4%	< 0.001
Paravalvular leakage ≥ moderate	9.8%	7.3%	14.4%	0.001
Device success	85.5%	91.1%	75.3%	< 0.001

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30-Day Outcomes

	Overall (N = 998)	Balloon Expandable (N = 654)	Self Expandable (N = 344)	p value
Stroke				
All	3.8%	4.4%	2.7%	0.22
Disabling	2.2%	2.6%	1.7%	0.56
Non disabling	1.5%	1.8%	1.0%	0.41
Bleeding				
Life-threatening	6.4%	6.7%	5.7%	0.55
Major	4.5%	4.0%	5.4%	0.37

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30-day Outcomes

	Overall (N = 998)	Balloon Expandable (N = 654)	Self Expandable (N = 344)	p value
Vascular complications				
Major	5.0%	6.0%	3.0%	0.05
Minor	4.7%	5.6%	3.0%	0.08
Acute kidney injury	3.3%	2.6%	4.7%	0.10
Early safety endpoints	14.6%	15.5%	13.0%	0.34

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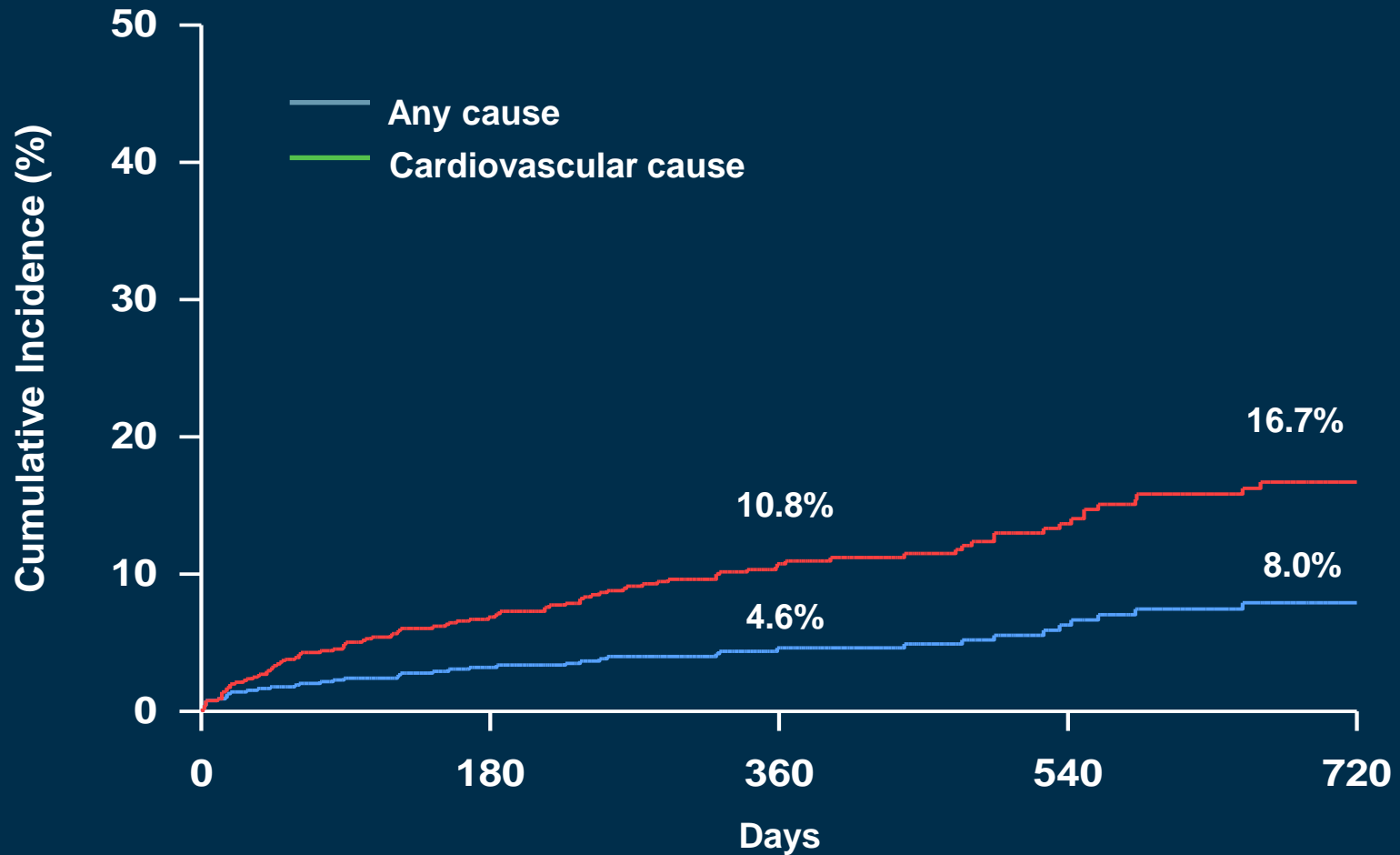
Mortality

	Overall (N = 998)	Balloon Expanda ble (N = 654)	Self Expandable (N = 344)	p value
At 30 days				
From any cause	2.5%	3.1%	1.3%	0.12
From cardiovascular cause	1.7%	1.8%	1.3%	0.78
At 1 year *				
From any cause	10.8%	9.4%	12.2%	0.40
From Cardiovascular cause	4.6%	4.3%	5.4%	0.48

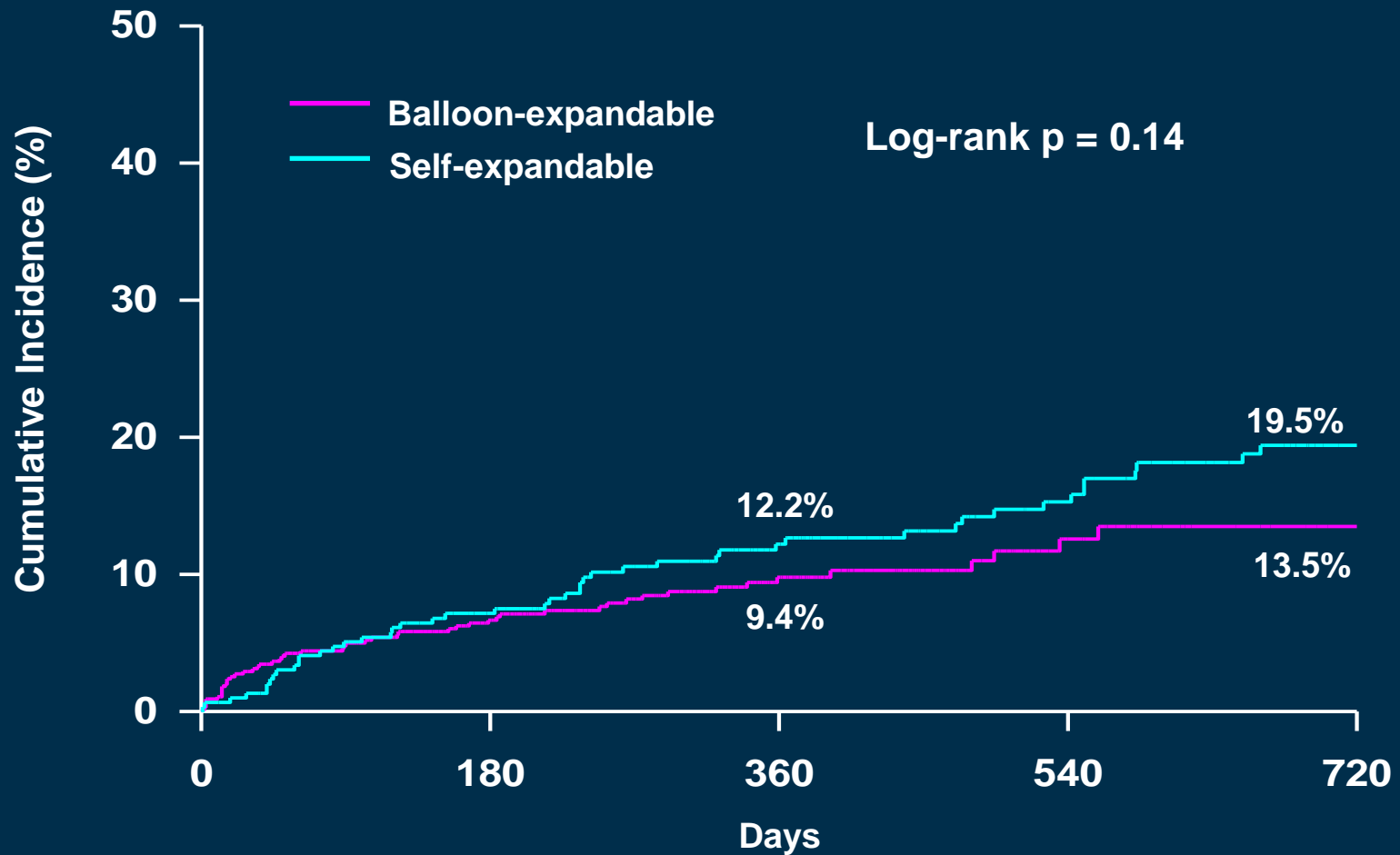
* Estimated as Kaplan-Meier method

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2-Year Mortality



All-cause Mortality



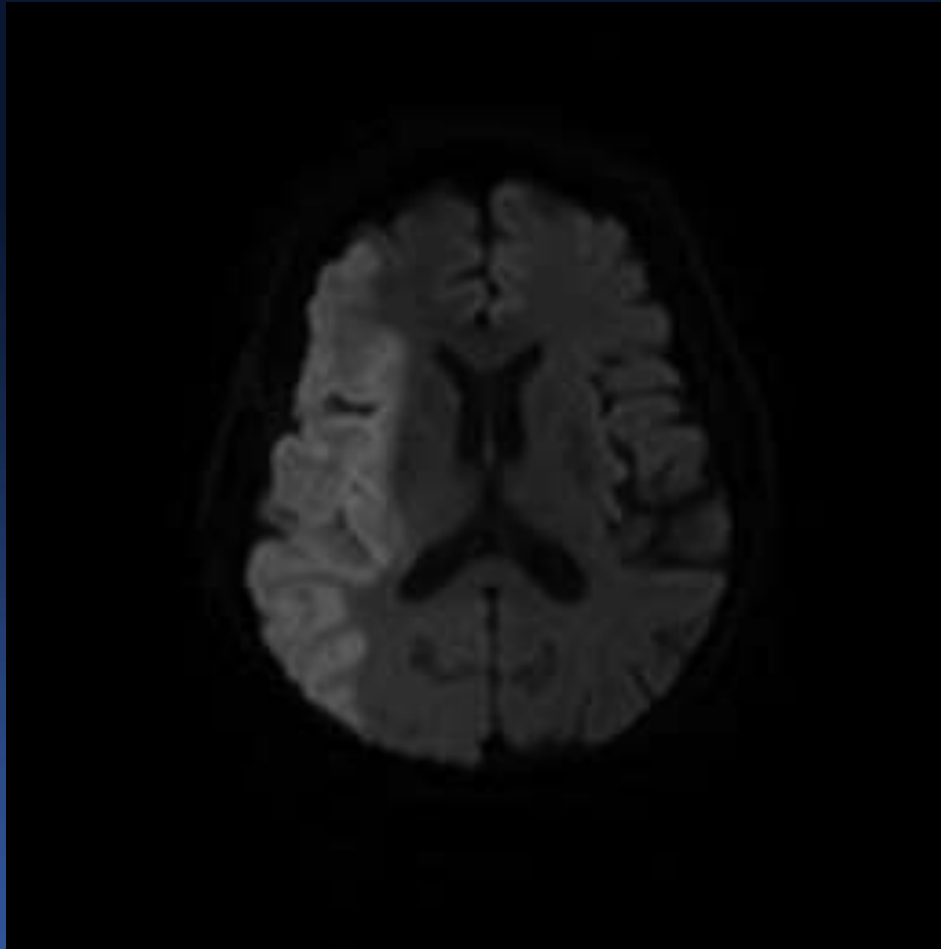
Multivariate Predictors of Mortality

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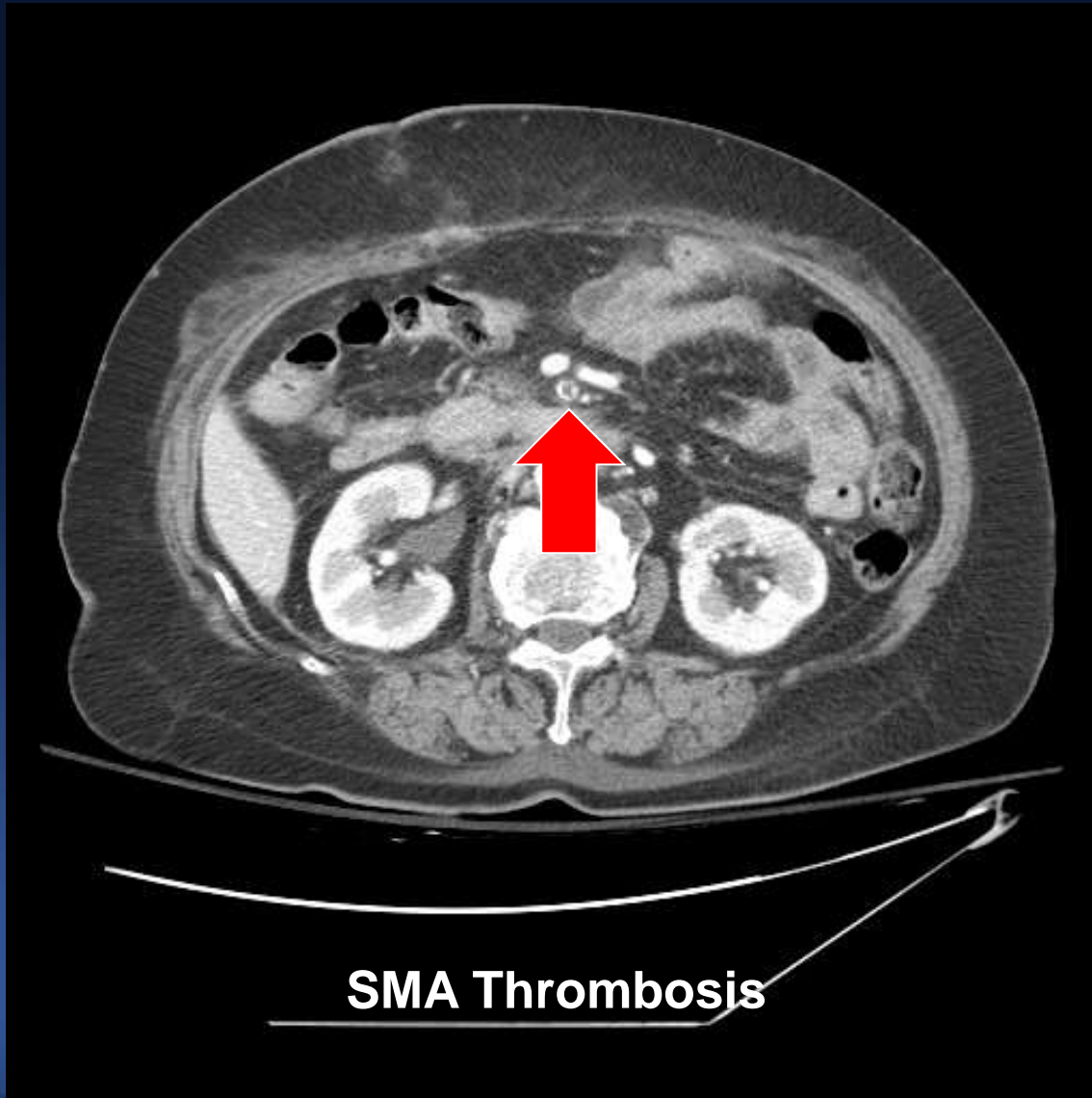
	Multivariate analysis HR (95% CI)	p value
Body mass index, m ² /kg	0.92 (0.87 – 0.97)	0.002
NYHA functional class III or IV	2.15 (1.33 – 3.48)	0.002
STS score	1.07 (1.04 – 1.09)	< 0.001
Diabetes mellitus	1.55 (1.04 – 2.31)	0.03
Prior cerebrovascular accident	1.88 (1.16 – 3.04)	0.011
Mean pressure gradient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

Stroke and Systemic Embolization

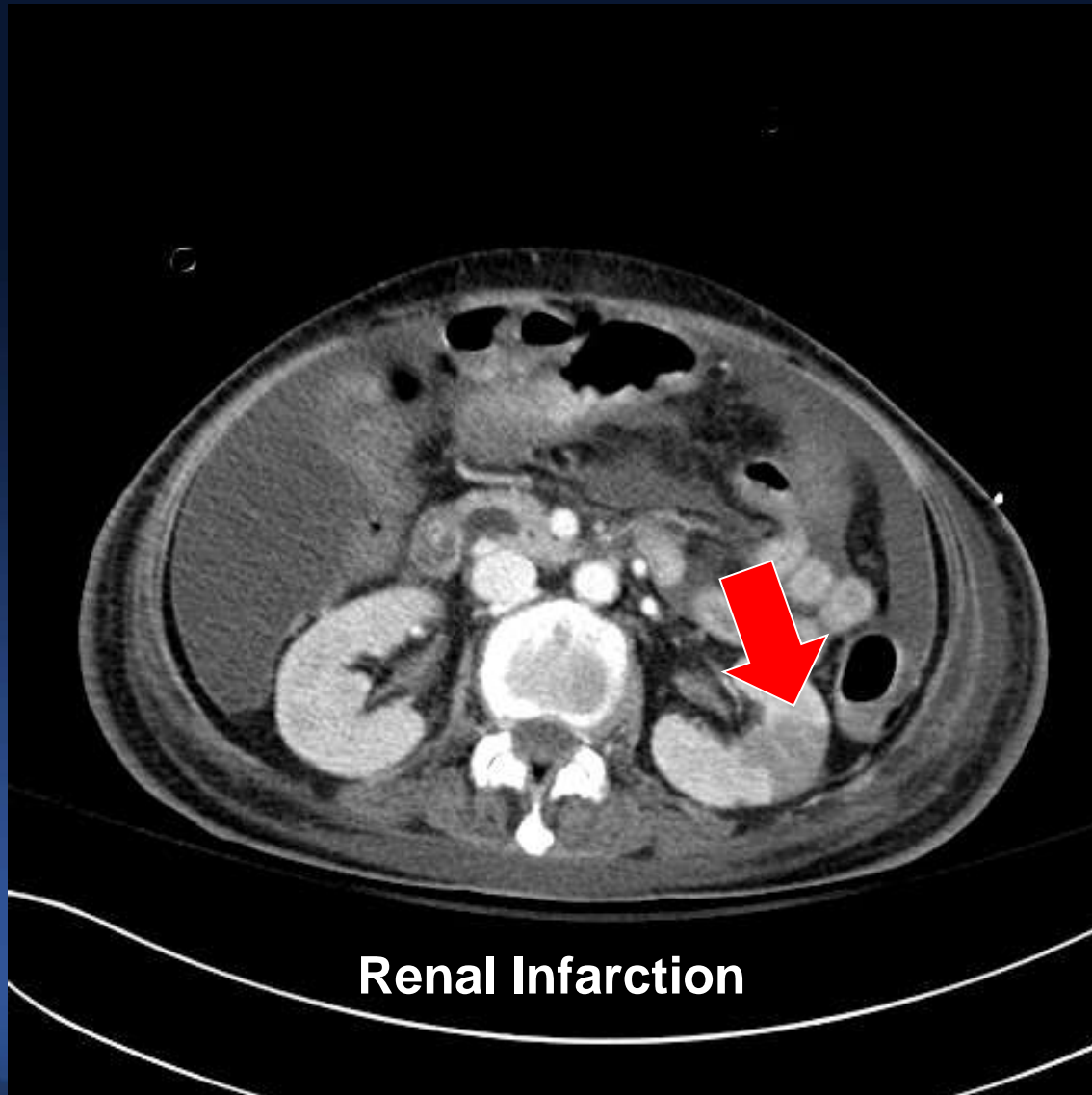
Stroke



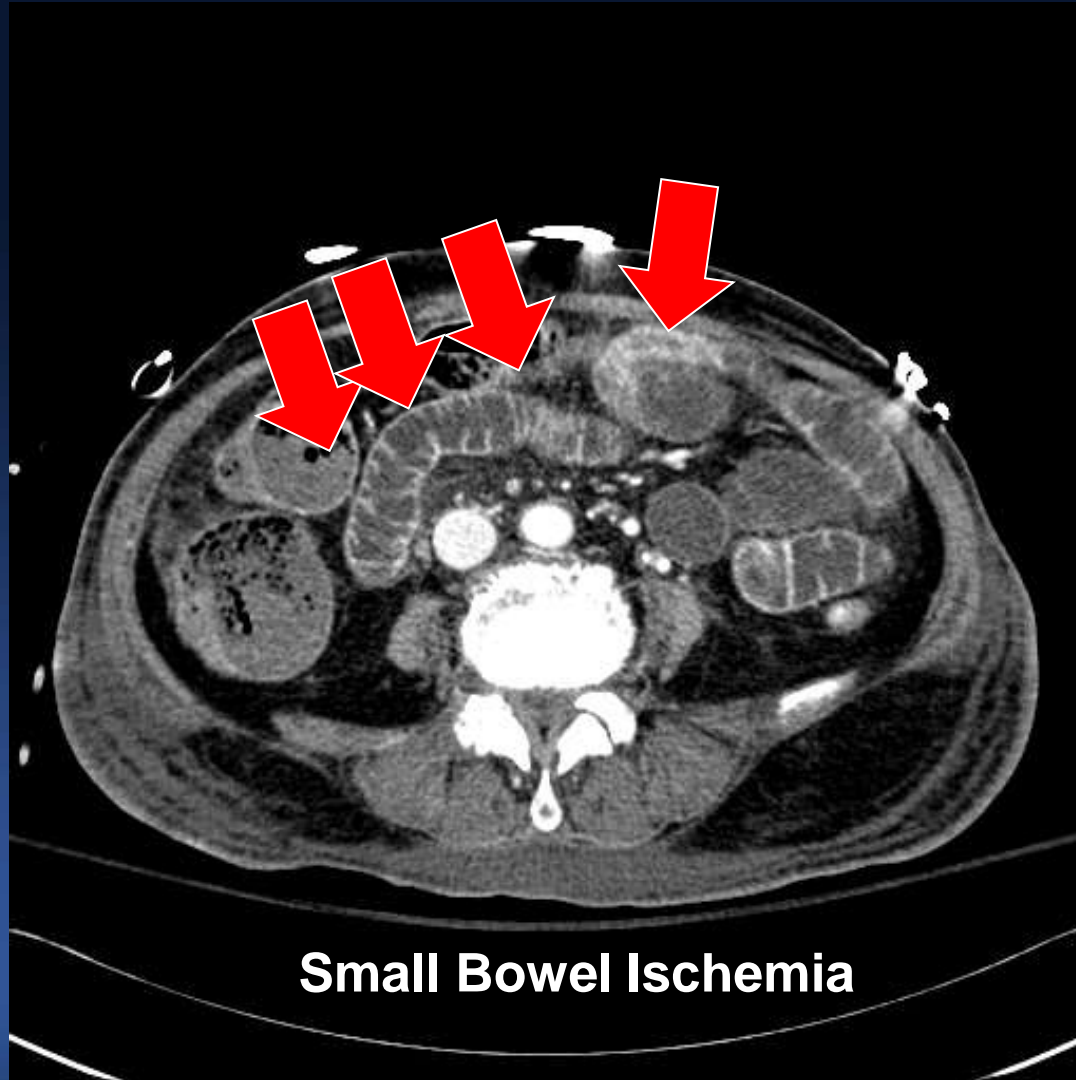
Systemic Embolization



Systemic Embolization



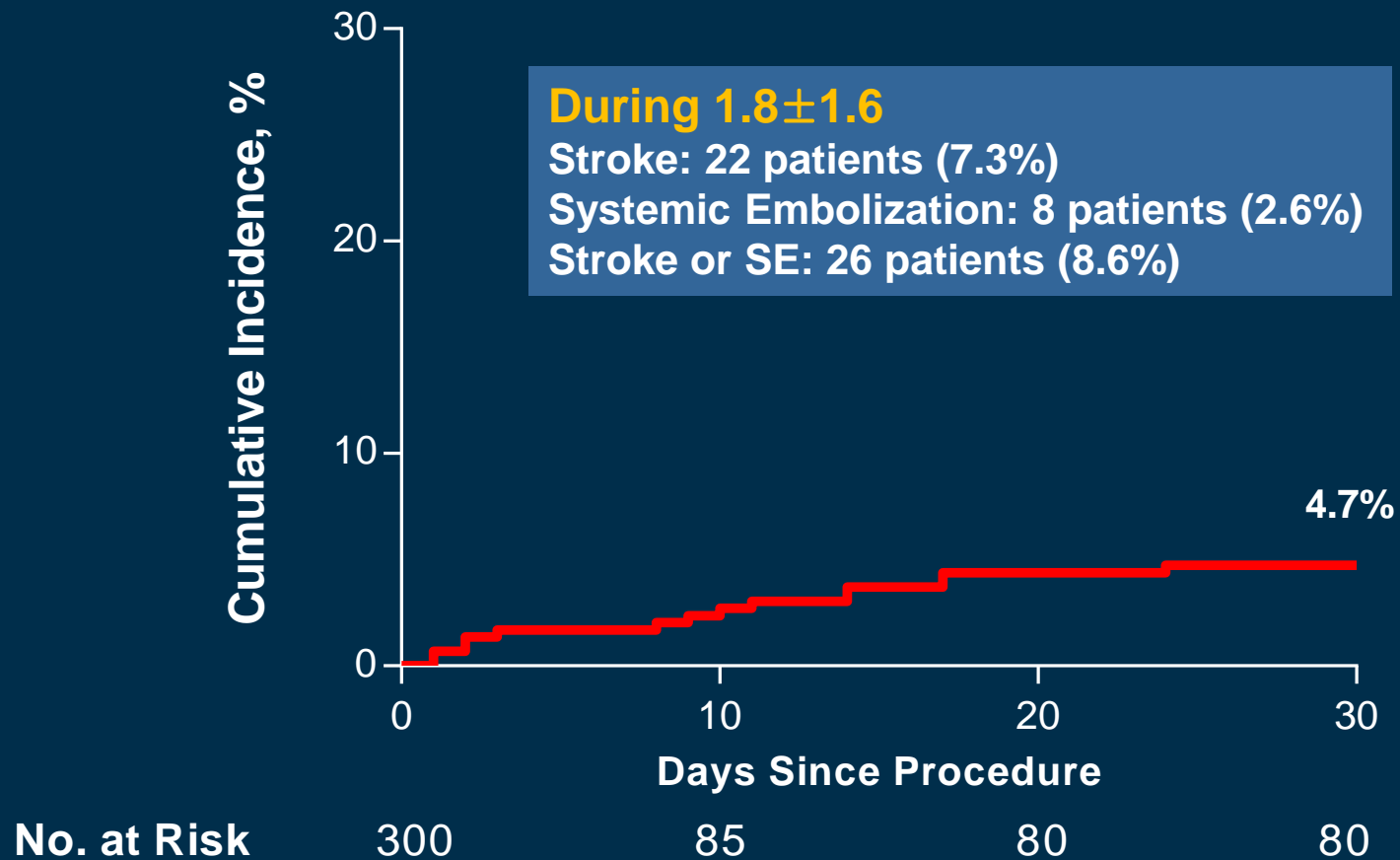
Systemic Embolization



Systemic Embolization

	Location of Systemic Emblization
Case 1	SMA thrombosis without bowel ischemia
Case 2	Renal infarction, small bowel ischemia
Case 3	Right kidney infarction
Case 4	Kidney and spleen infarction
Case 5	Spleen and right kidney infarction
Case 6	Extensive small bowerl infarction
Case 7	Multiple spleen infarction
Case 8	Spleen, small bowel and large bowel ischemia

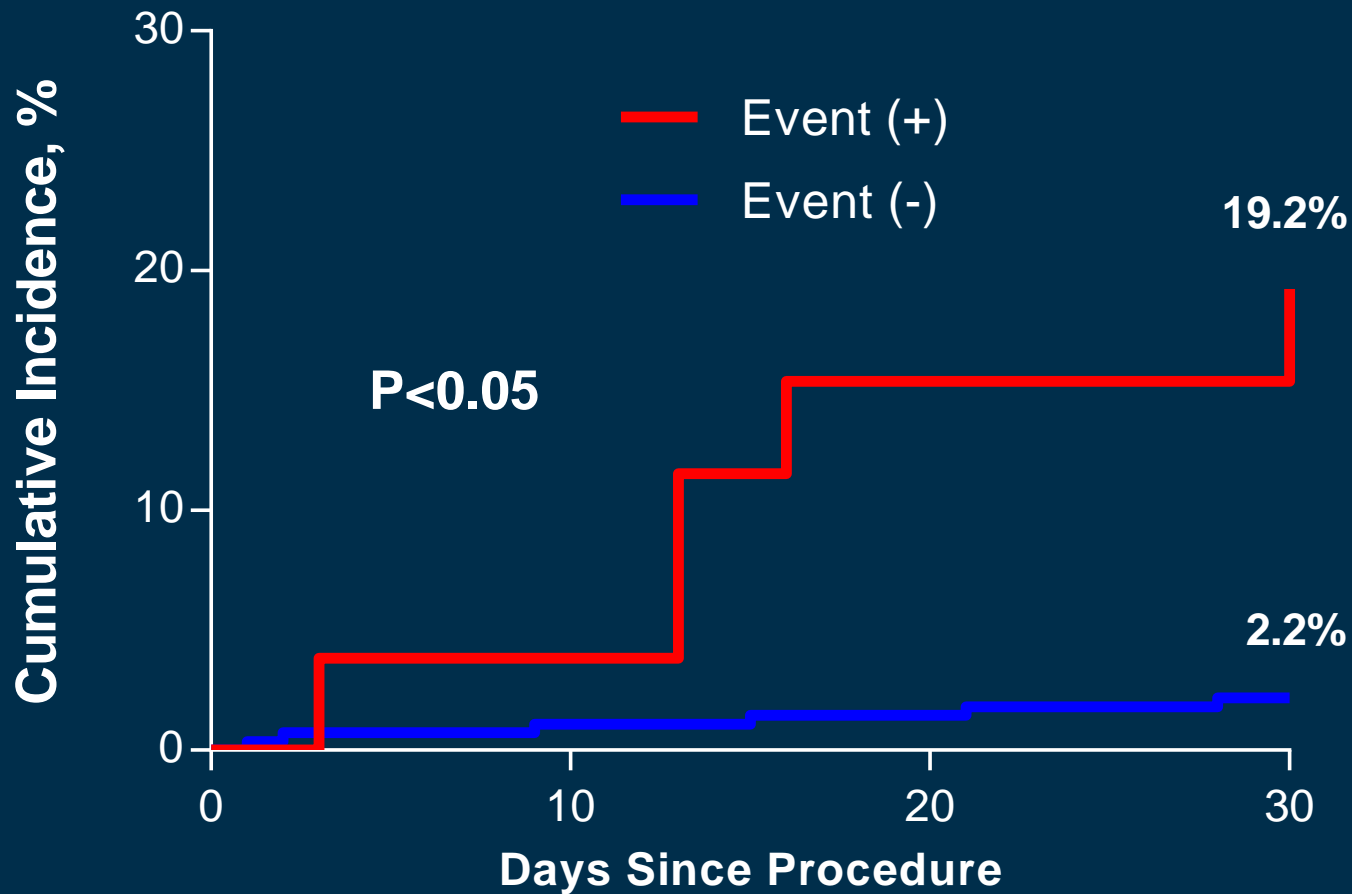
Incidence



*Stroke (22) = Disabling stroke (7) + Non-disabling stroke (11) + TIA (4)

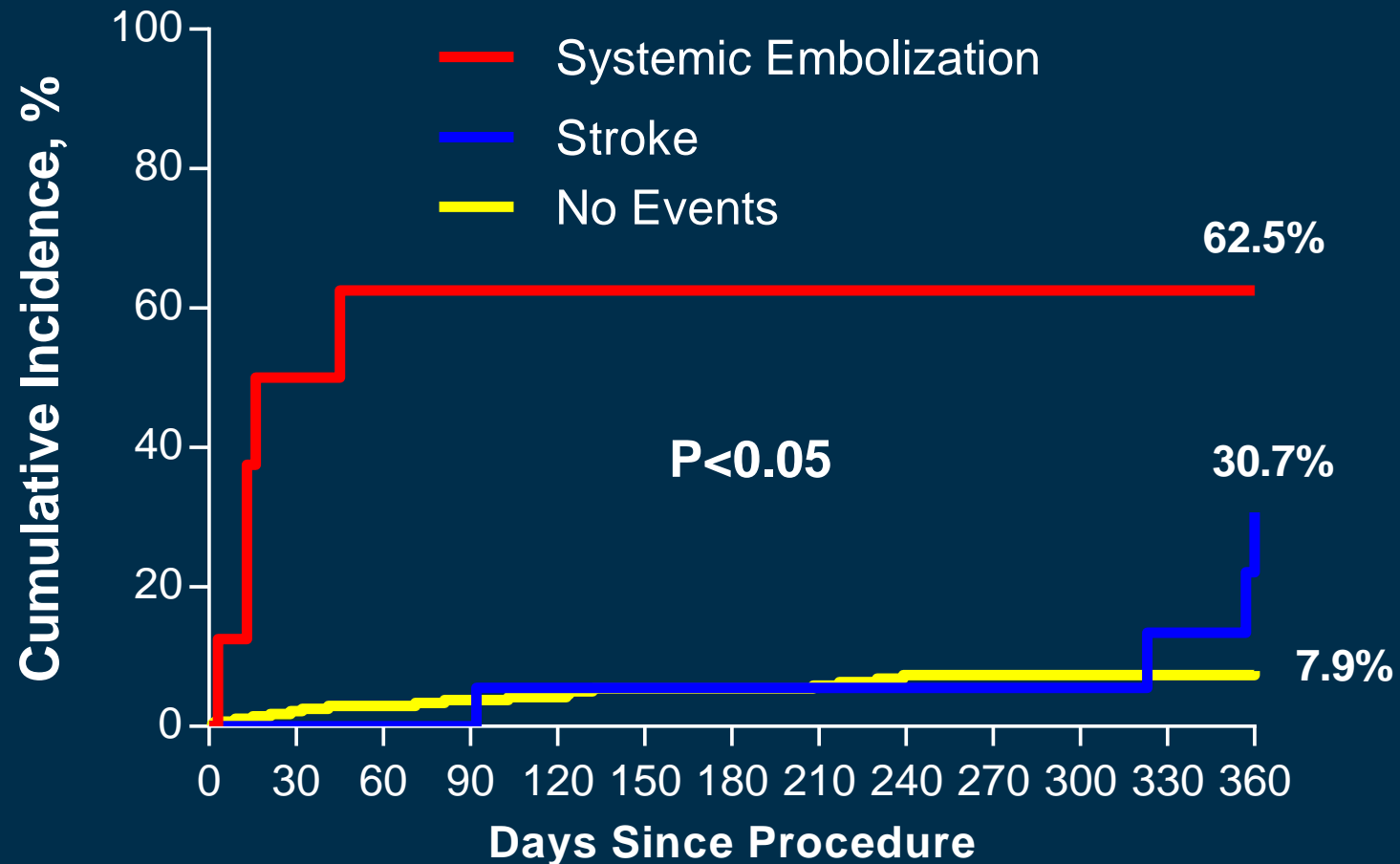
Impact on Mortality

Stroke or Systemic Embolization



Impact on Mortality

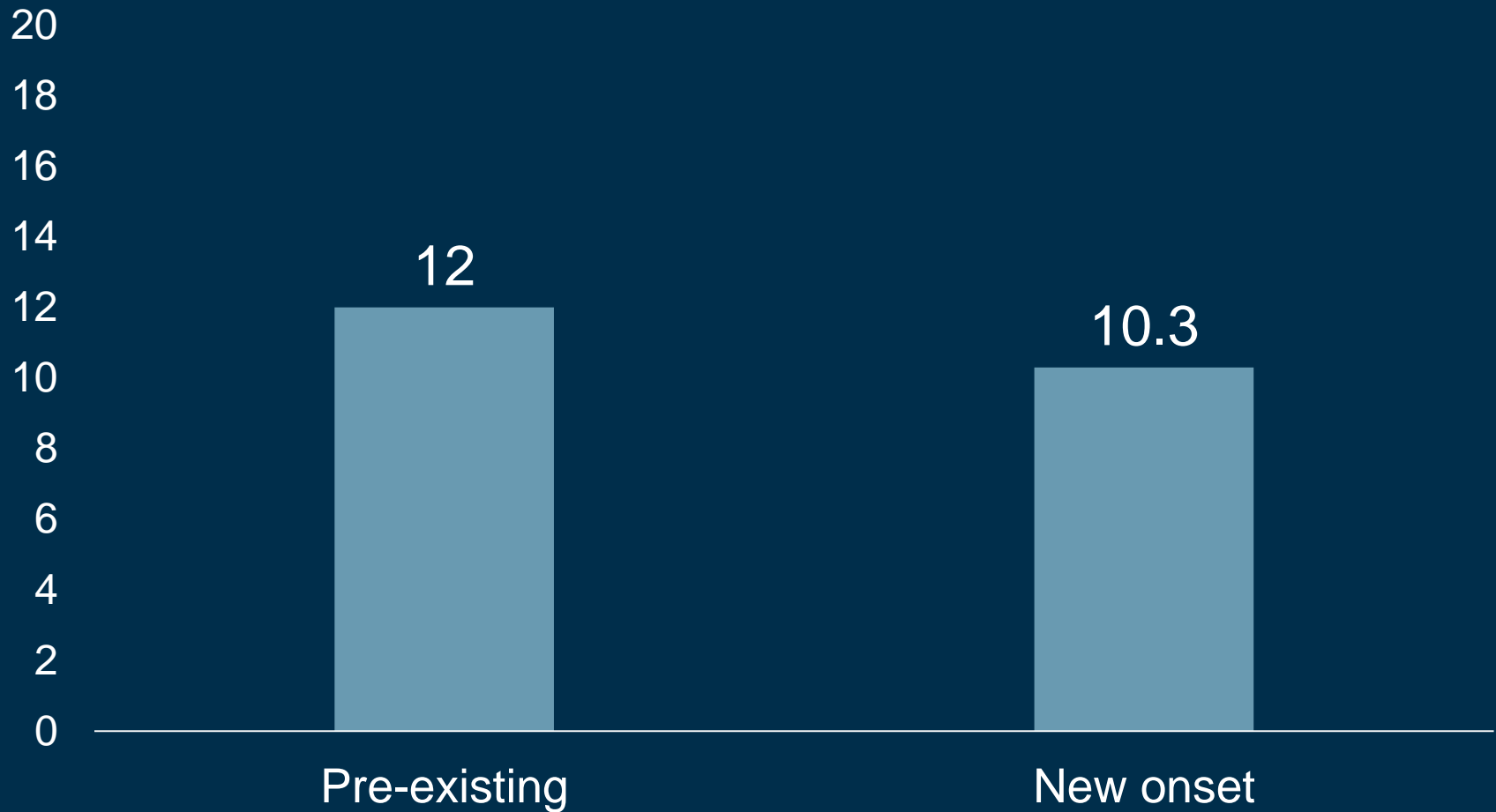
Stroke or Systemic Embolization



Independent Predictors at 30 Days

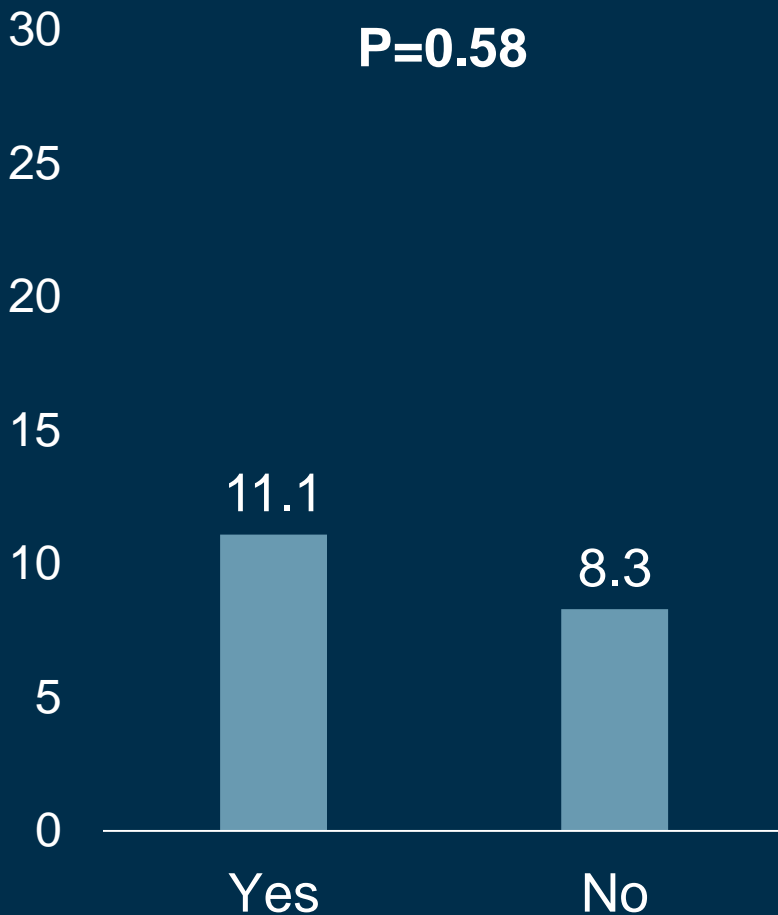
	Multivariate Analysis HR (95% CI)	P Value
Previous CVA	4.40 (1.50-12.9)	0.007
Impaired Renal Function	4.18 (1.30-13.4)	0.02
Post-TAVR New Onset A.Fib	3.49 (1.20-10.1)	0.02
Moderate to Severe Calcification in Ascending Aorta and Aortic Arch	2.70 (0.93-7.87)	0.074

Post-TAVR New Onset A.Fib

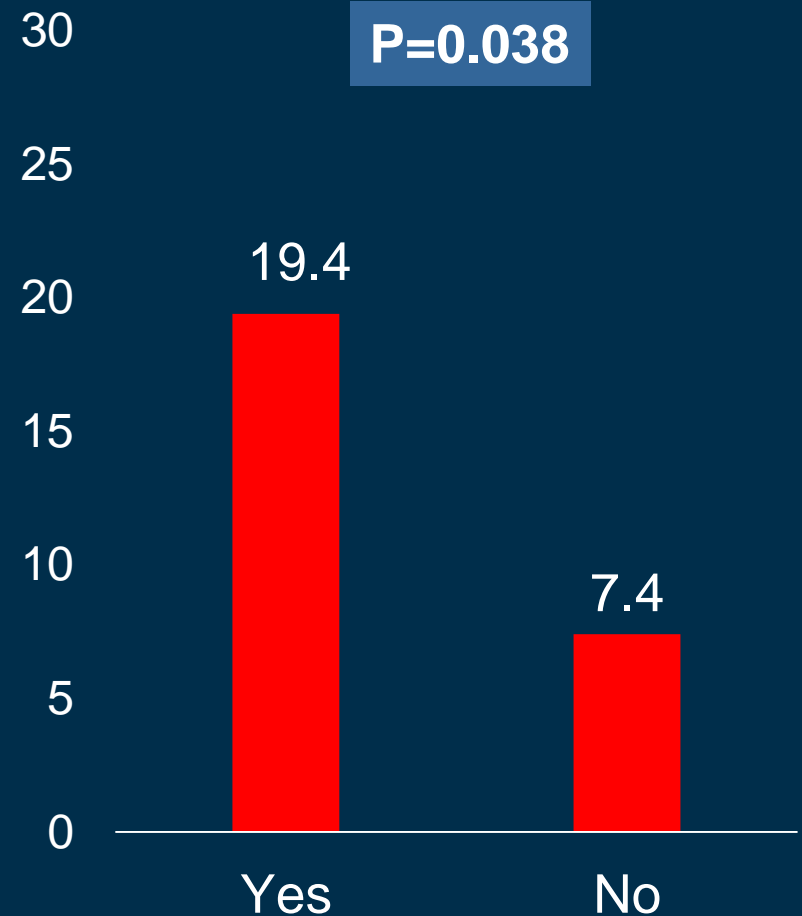


Stroke or Systemic Embolization

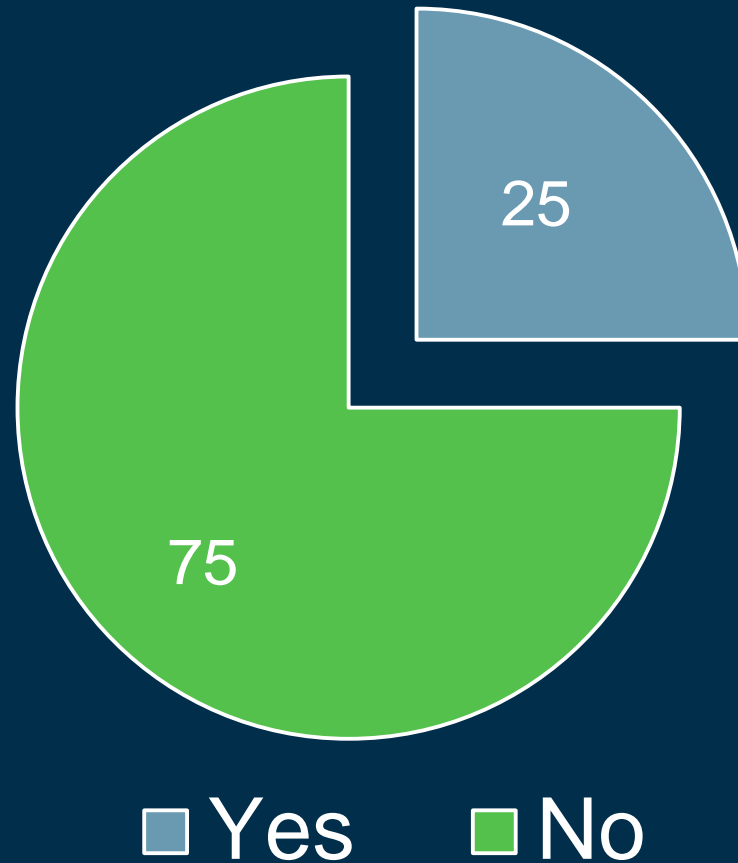
Pre-Existing A.Fib



New Onset A.Fib



Anticoagulation on New Onset A.Fib

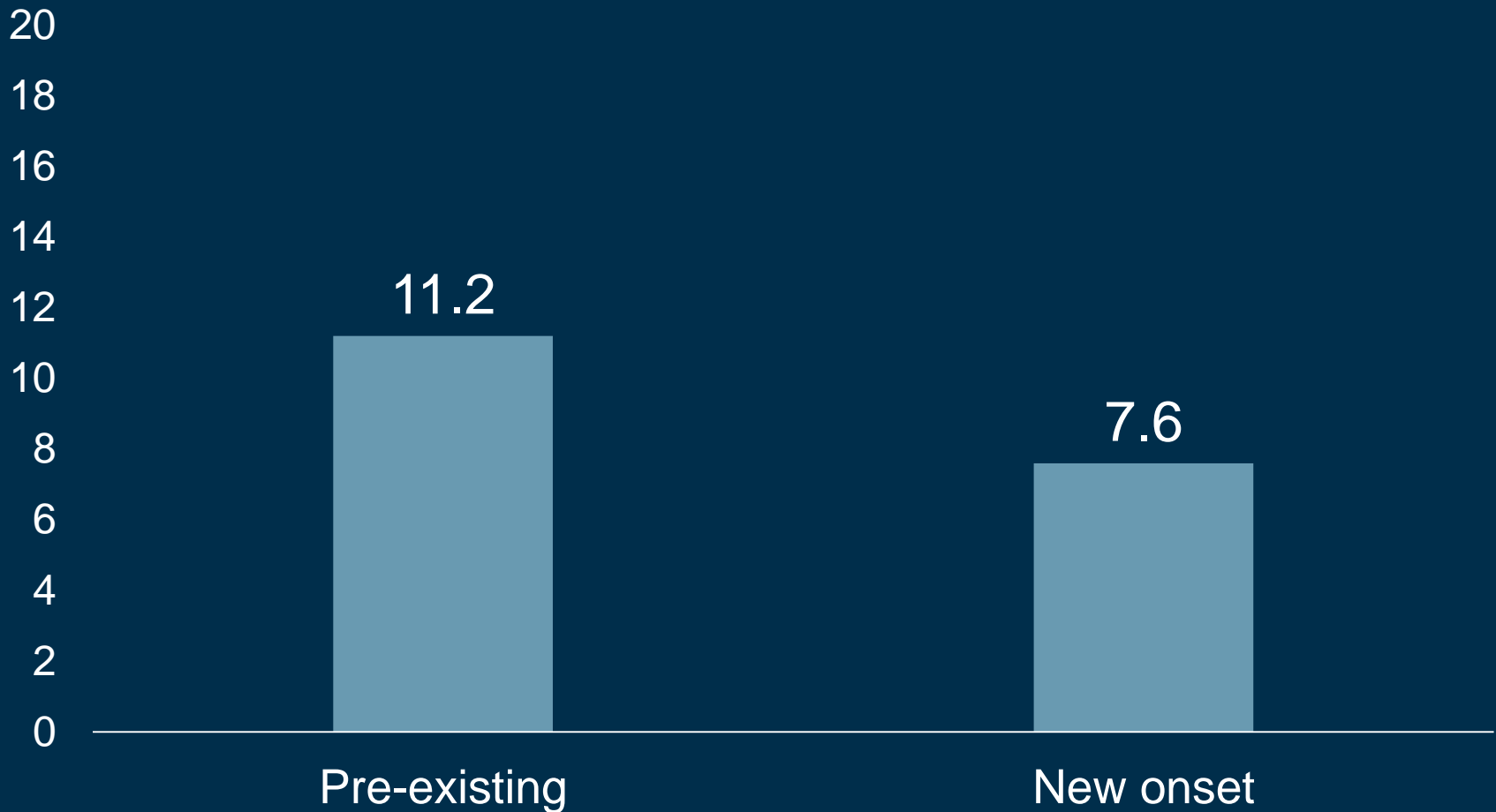


Ascend Aorta and Arch Calcification

Moderate to Severe Calcification



Mod to Severe Asc. Ao Calcification on Stroke or Systemic Embolization



Conclusion

- Despite anatomical concerns including small AV complex and high frequency of BAV disease, outcomes of TAVR in Asian population was excellent.
- Systemic embolic event was associated with higher mortality in recent our experience.
- Early detection of new onset A.fib and more aggressive anticoagulation treatment may prevent this catastrophic complication.
- Aortic calcification may guide the use of embolic protection device, but more study is necessary.