

Strokes After TAVR: Perspectives from the US CoreValve Trials

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Conflict of Interest Statement

Over the past year, I have received the following:

Research Grants: Medtronic, Boston Scientific, Abbott
Vascular, Covidien, Cook

Medical Advisory Board: Boston Scientific, Abbott Vascular,
GE Healthcare, Covidien

Stroke After TAVR

- Neurologic Definitions
- Neurologic Assessment
- Extreme Risk Findings
- High Risk Findings
- Predictors of Stroke

Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation Clinical Trials

A Consensus Report From the Valve Academic Research Consortium

Martin B. Leon, Nicolo Piazza, Eugenia Nikolsky, Eugene H. Blackstone, Donald E. Cutlip, Arie Pieter Kappetein, Mitchell W. Krucoff, Michael Mack, Roxana Mehran, Craig Miller, Marie-angéle Morel, John Petersen, Jeffrey J. Popma, Johanna J. M. Takkenberg, Alec Vahanian, Gerrit-Anne van Es, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys

Table 4 Stroke and TIA

Diagnostic criteria

Acute episode of a focal or global neurological deficit with at least one of the following: change in the level of consciousness, hemiplegia, hemiparesis, numbness, or sensory loss affecting one side of the body, dysphasia or aphasia, homianopia, amaurosis fugax, or other neurological signs or symptoms consistent with stroke

Stroke: duration of a focal or global neurological deficit >24 h; OR <24 h if available neuroimaging documents a new haemorrhage or infarct; OR the neurological deficit results in death

TIA: duration of a focal or global neurological deficit <24 h, any variable neuroimaging does not demonstrate a new hemorrhage or infarct

No other readily identifiable non-stroke cause for the clinical presentation (e.g. brain tumour, trauma, infection, hypoglycemia, peripheral lesion, pharmacological influences), to be determined by or in conjunction with the designated neurologist*

Confirmation of the diagnosis by at least one of the following:

Neurologist or neurosurgical specialist

Neuroimaging procedure (CT scan or brain MRI), but stroke may be diagnosed on clinical grounds alone

Stroke classification

Ischemic: an acute episode of focal cerebral, spinal, or retinal dysfunction caused by infarction of the central nervous system tissue

Hemorrhagic: an acute episode of focal or global cerebral or spinal dysfunction caused by intraparenchymal, intraventricular, or subarachnoid hemorrhage

A stroke may be classified as undetermined if there is insufficient information to allow categorization as ischemic or haemorrhagic

Stroke definitions¹

Disabling stroke: an mRS score of 2 or more at 90 days and an increase in at least one mRS category from an individual's pre-stroke baseline

Non-disabling stroke: an mRS score of <2 at 90 days or one that does not result in an increase in at least one mRS category from an individual's pre-stroke baseline

Rankin	Modified Scale
0	No symptoms at all
1	No significant disability despite symptoms; able to carry out all duties and activities
2	Slight disability; unable to carry out all previous activities but able to look after own activities without assistance
3	Moderate disability; requiring some help but able to walk without assistance
4	Moderately severe disability; unable to walk without assistance and unable to attend to own bodily needs without assistance
5	Severe disability; bedridden, incontinent, and requires constant nursing care and attention
6	Death

Stroke After TAVR

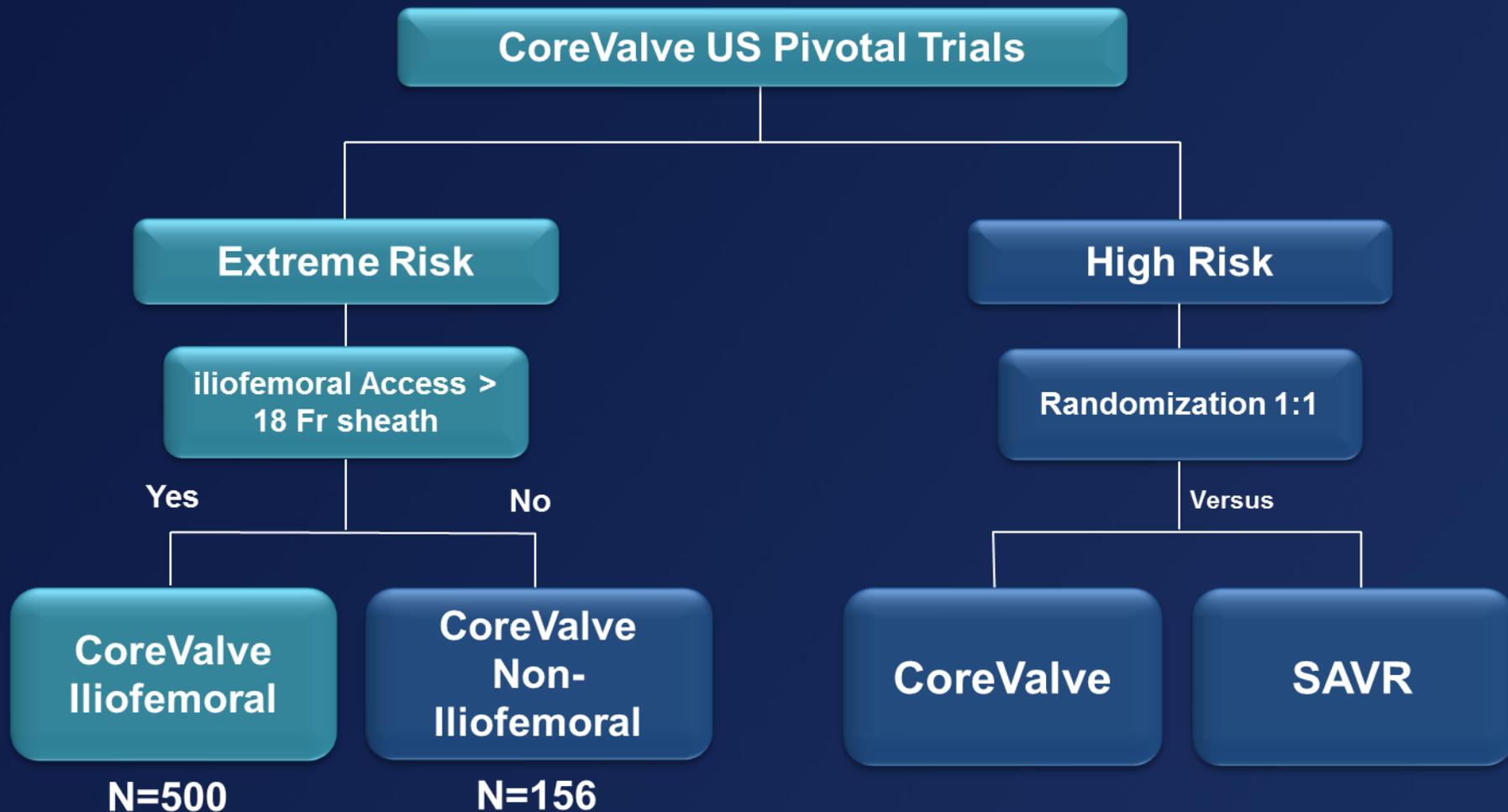
- Neurologic Definitions
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Before and Immediately Post-Procedure

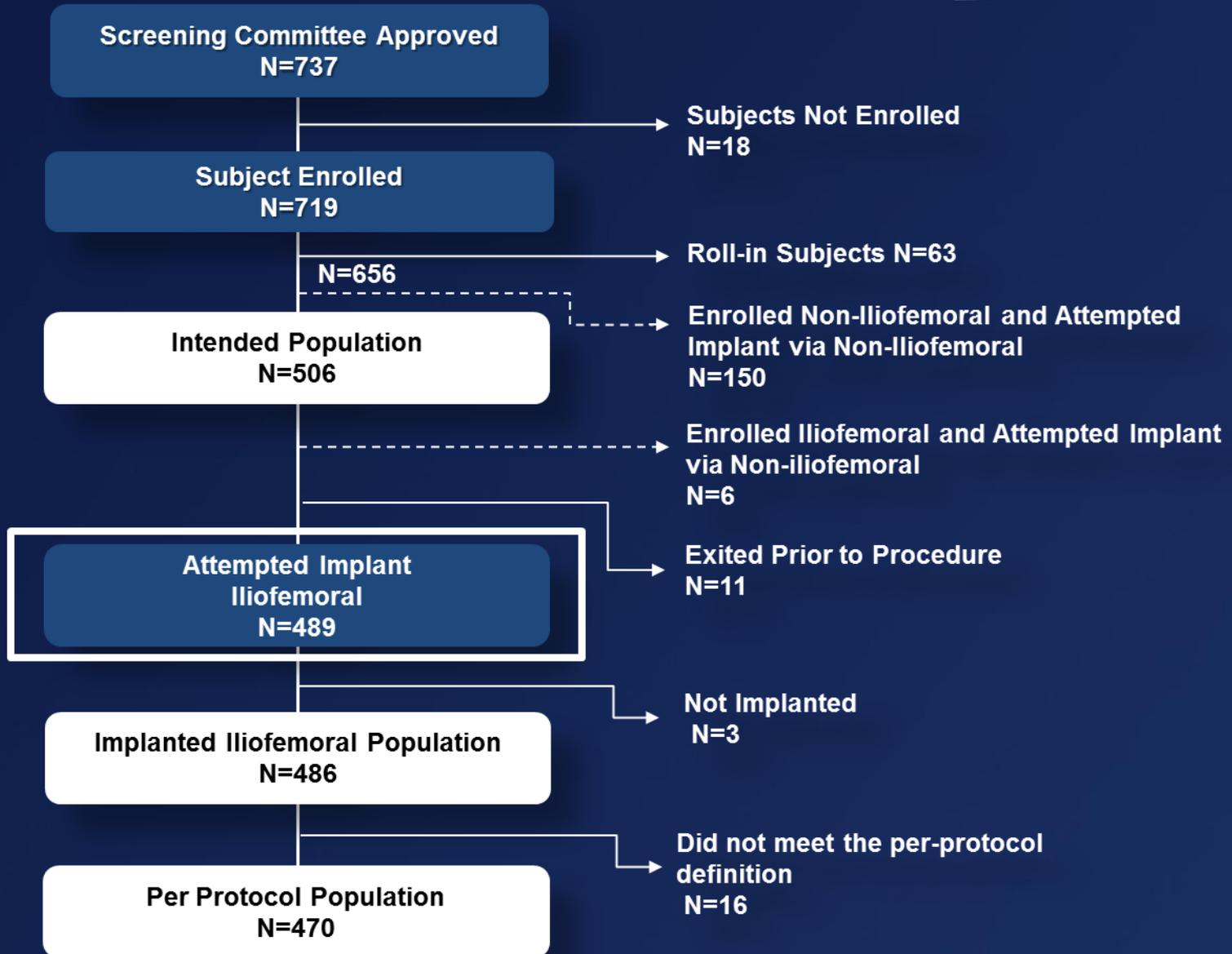
- **NIHSS should be administered within 24 hours post-procedure**
- **Modified Rankin Scale (for patients with a suspected or new neurological event only)**
 - **For subjects with a stroke, assessment to be performed at 7 days or discharge (whichever occurs first), 30 days and 3 months post-stroke.**
- **NIH Stroke Scale**
 - **Any patient with evidence of a neurological event should have a neurology consult and an imaging study if deemed necessary.**
- **Modified Rankin Scale (for subjects with a suspected or new neurological event only)**
 - **Assessment must be performed at 7 days or discharge (whichever occurs first), 30 days and 3 months post-stroke.**

Stroke After TAVR

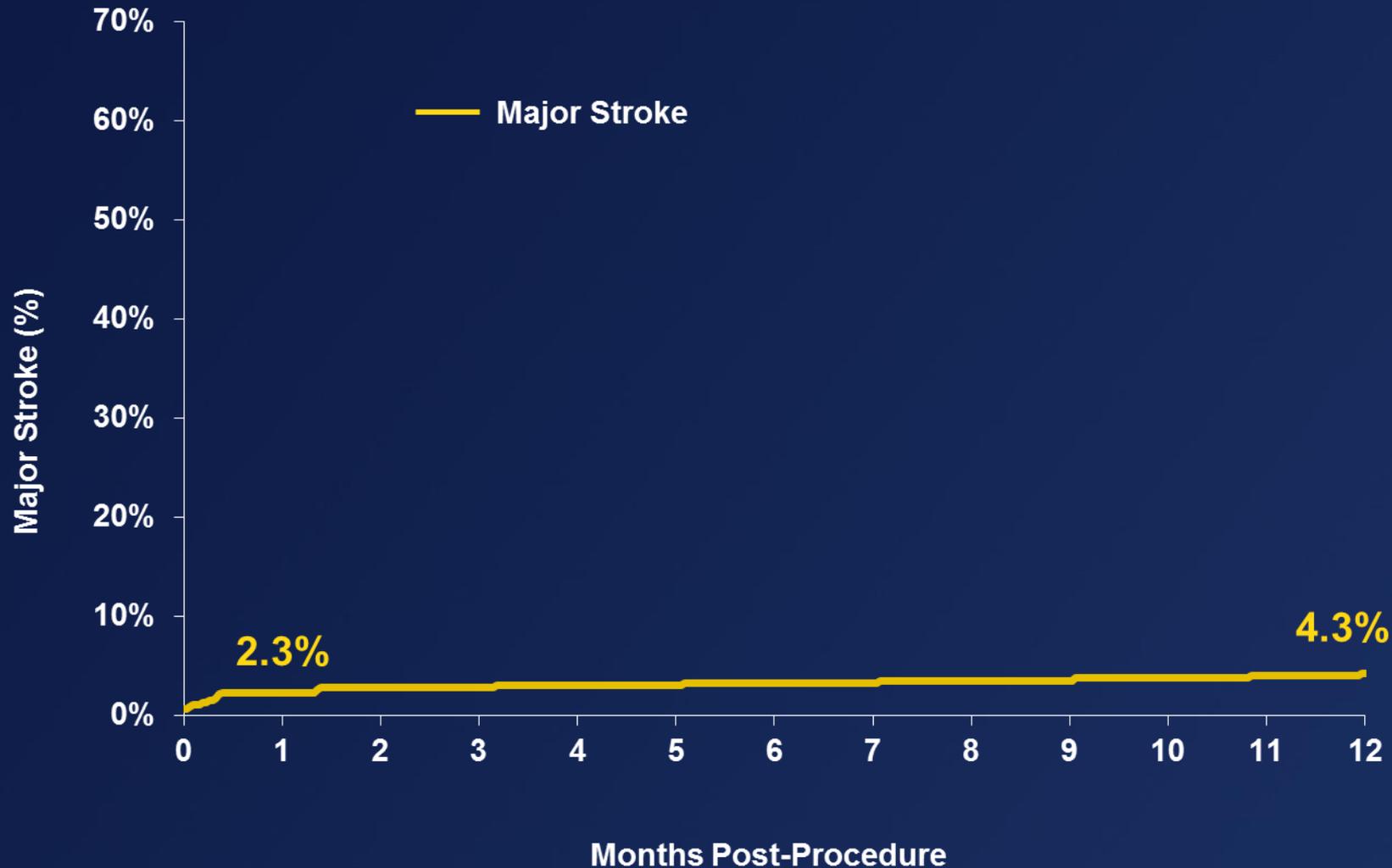
- Neurologic Definitions
- Neurologic Assessment
- **Extreme Risk Findings**
- High Risk Findings
- Predictors of Stroke



Study Disposition



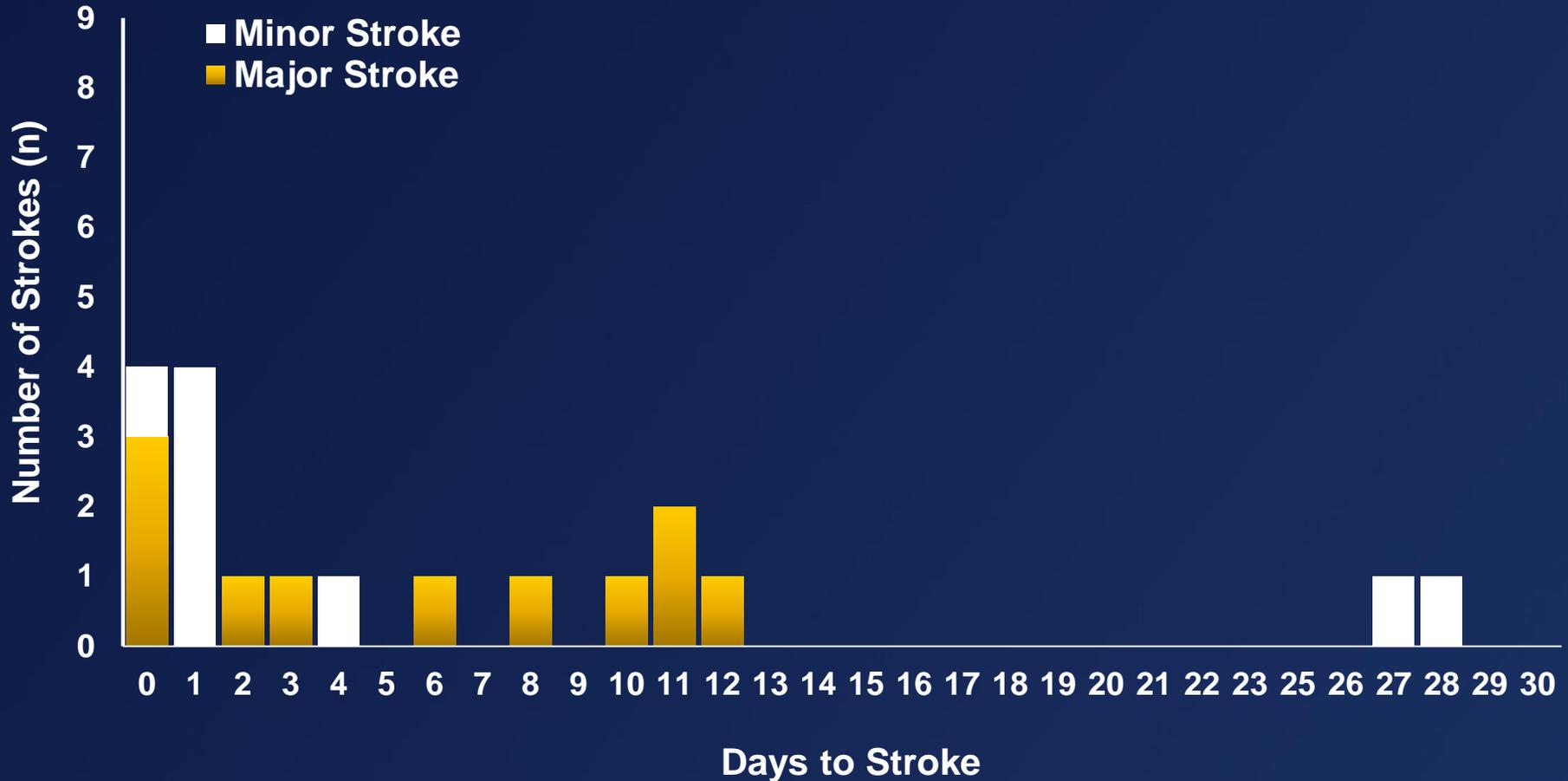
Major Stroke



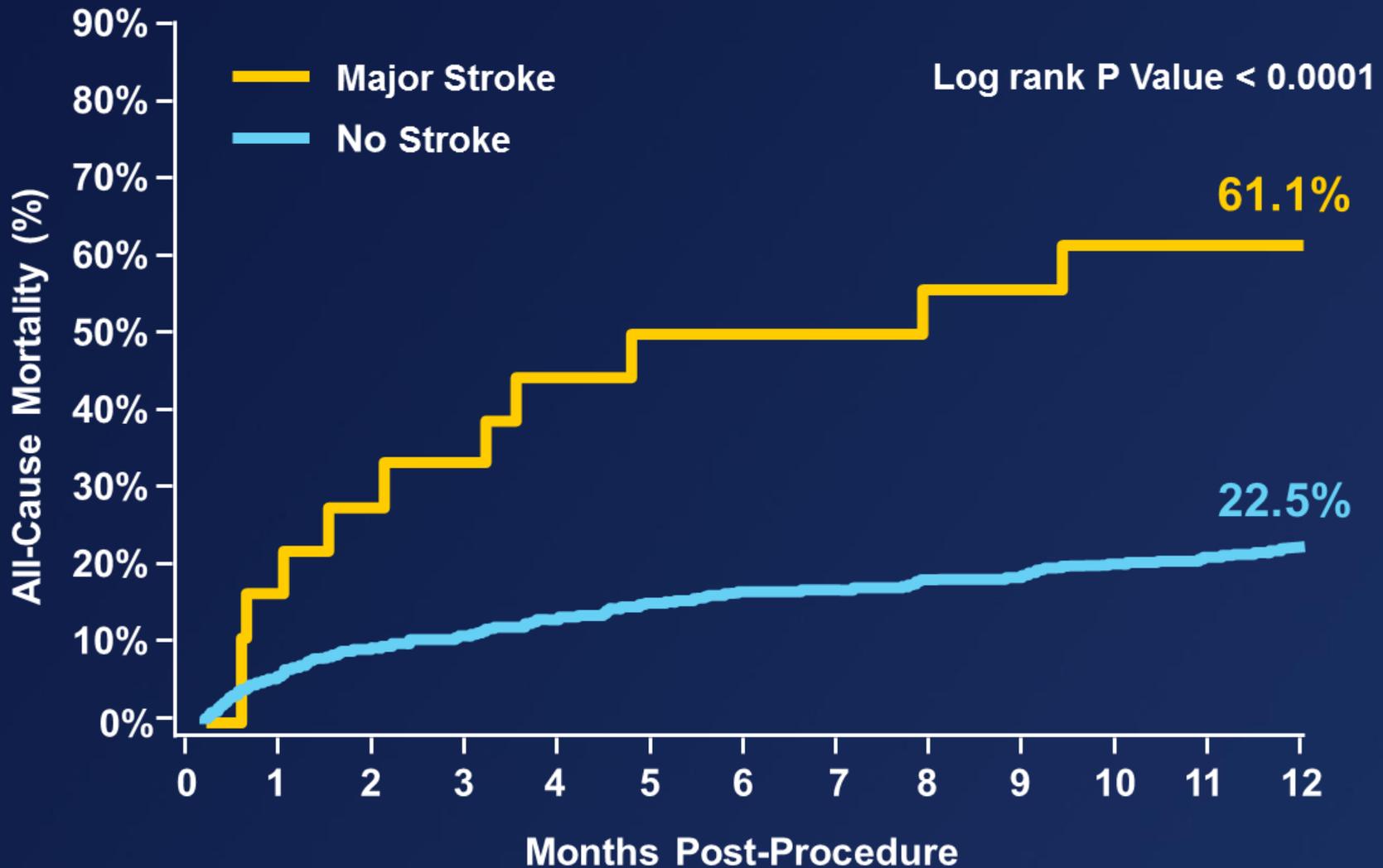
Neurologic Events

Event	1 Month N=471	1 Year N=471
Any Stroke, %	4.0	7.0
Major Stroke, %	2.3	4.3
Minor Stroke, %	1.9	3.2
TIA, %	0.6	1.1

Major and Minor Stroke (1 Month)

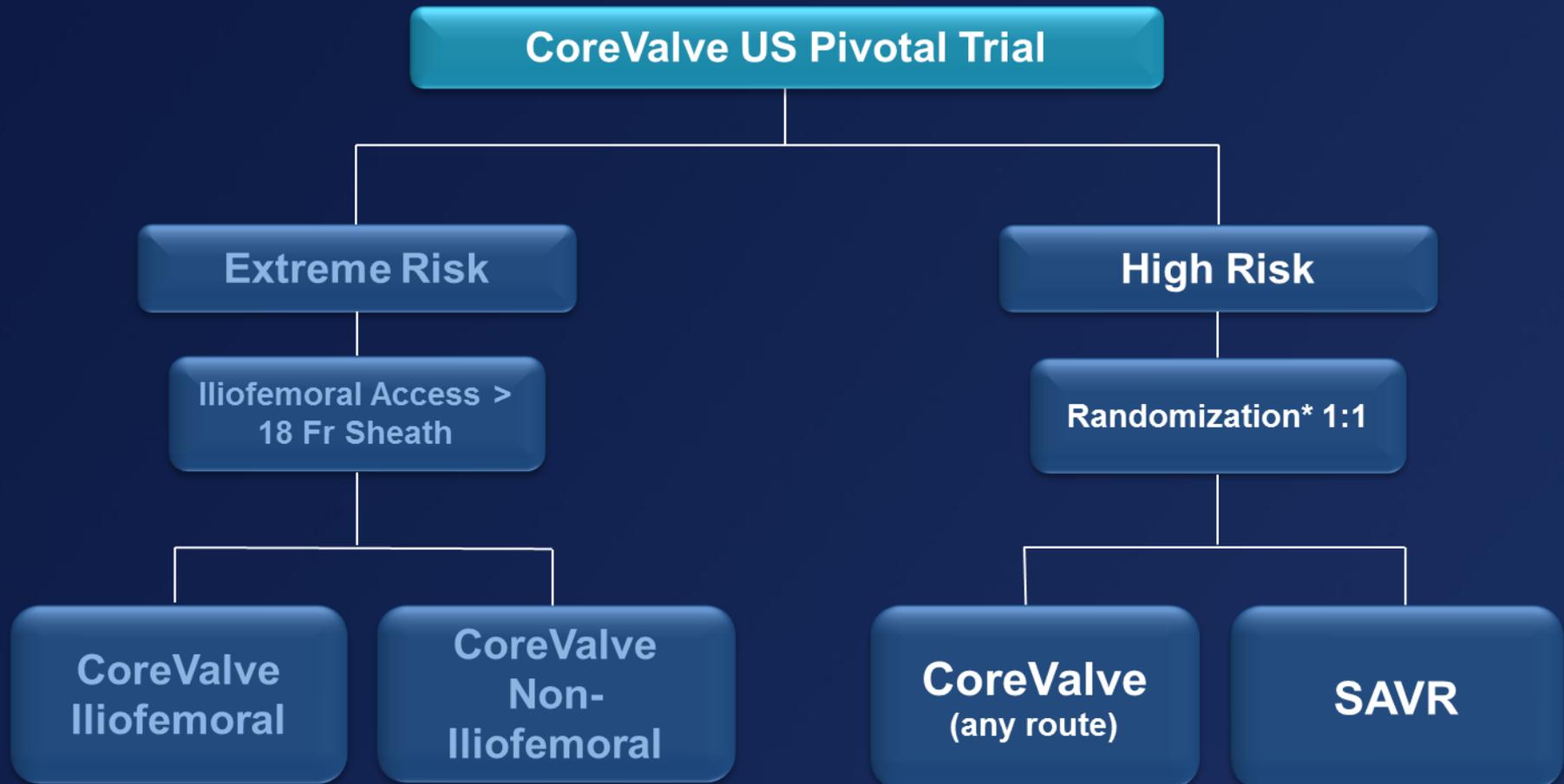


All-Cause Mortality By Major Stroke



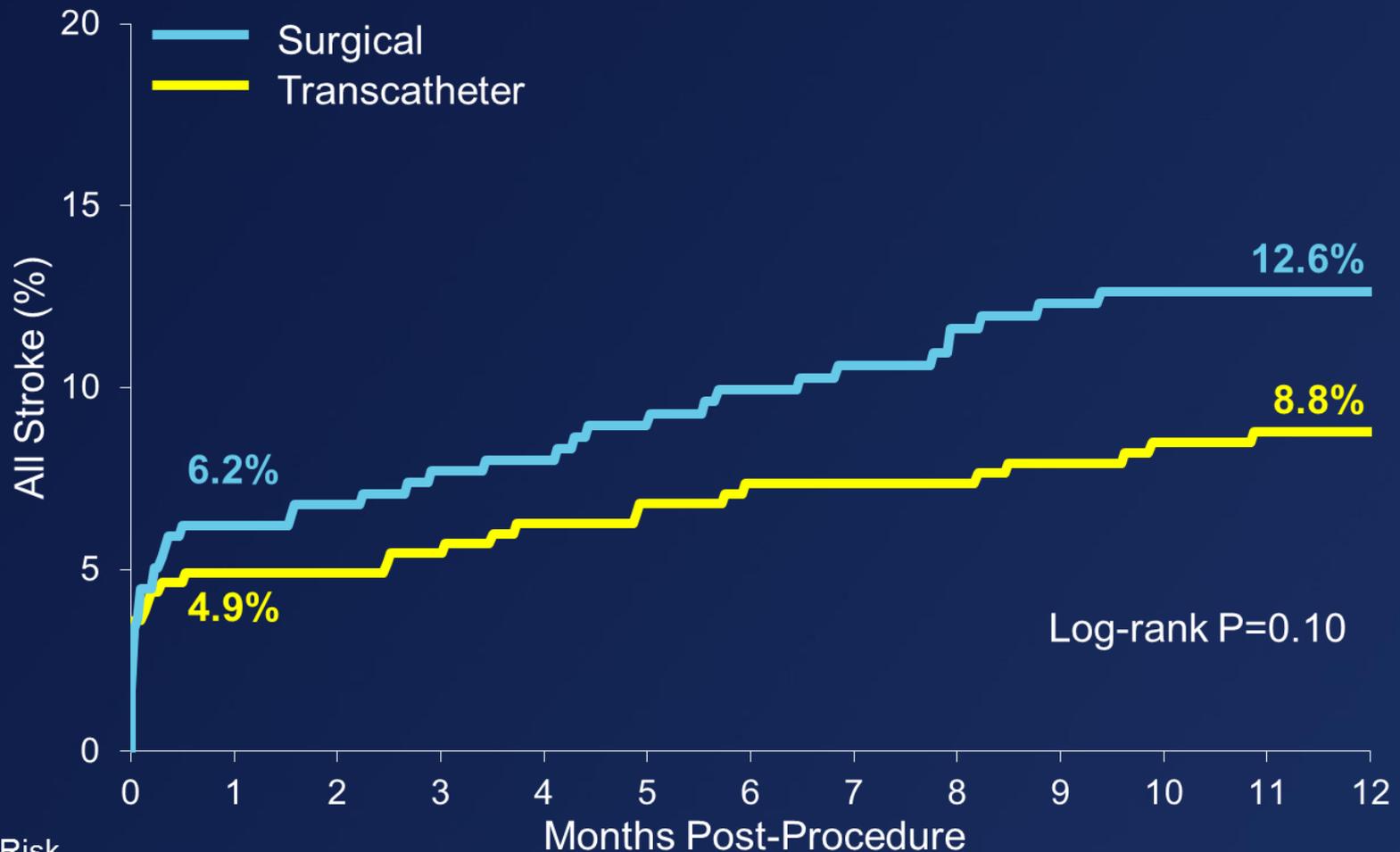
Stroke After TAVR

- Neurologic Definitions
- Neurologic Assessment
- Extreme Risk Findings
- High Risk Findings
- Predictors of Stroke



* Randomization stratified by intended access site

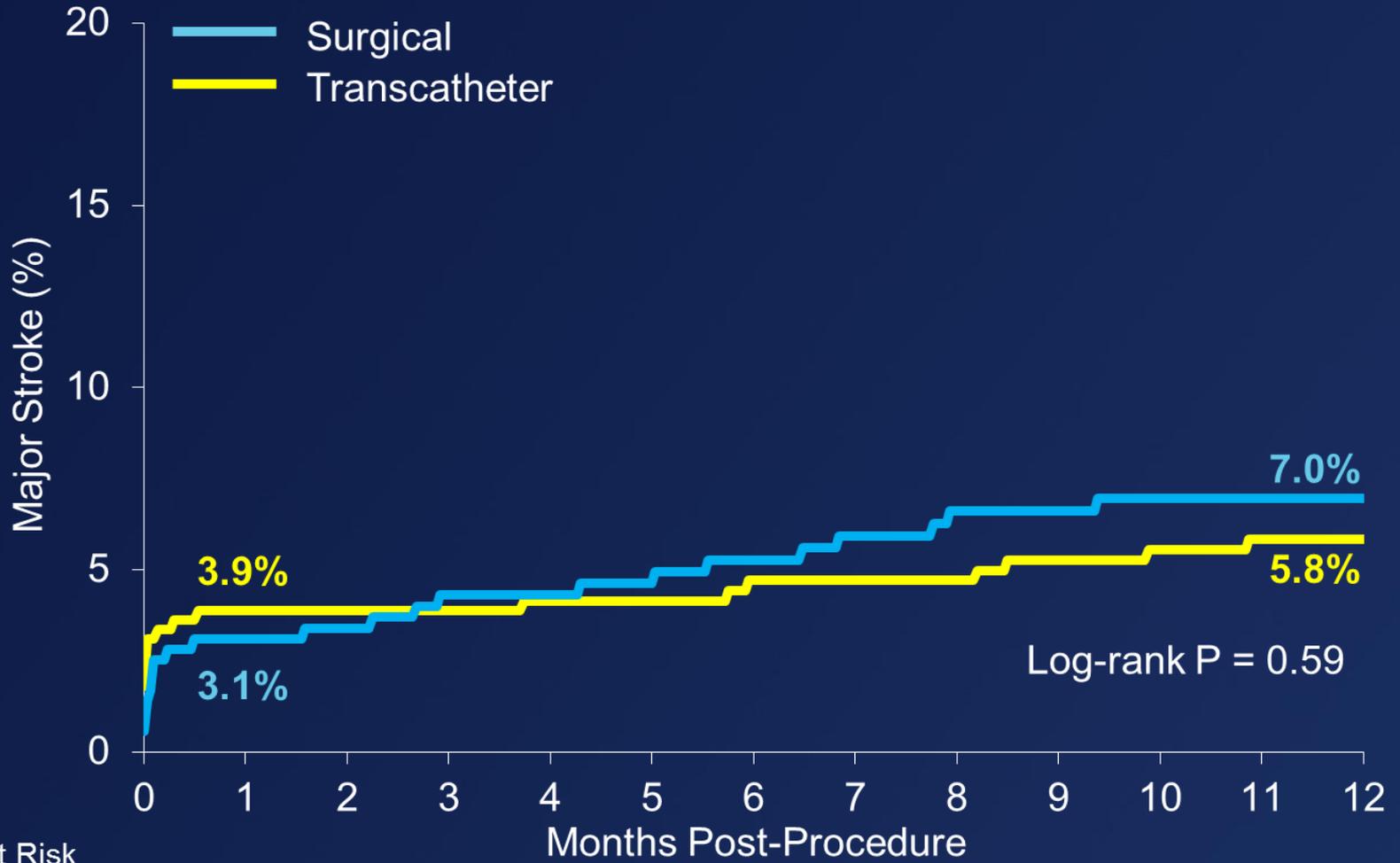
All Stroke



No. at Risk

Surgical	357	322	274	249	
Transcatheter	390	363	334	314	27

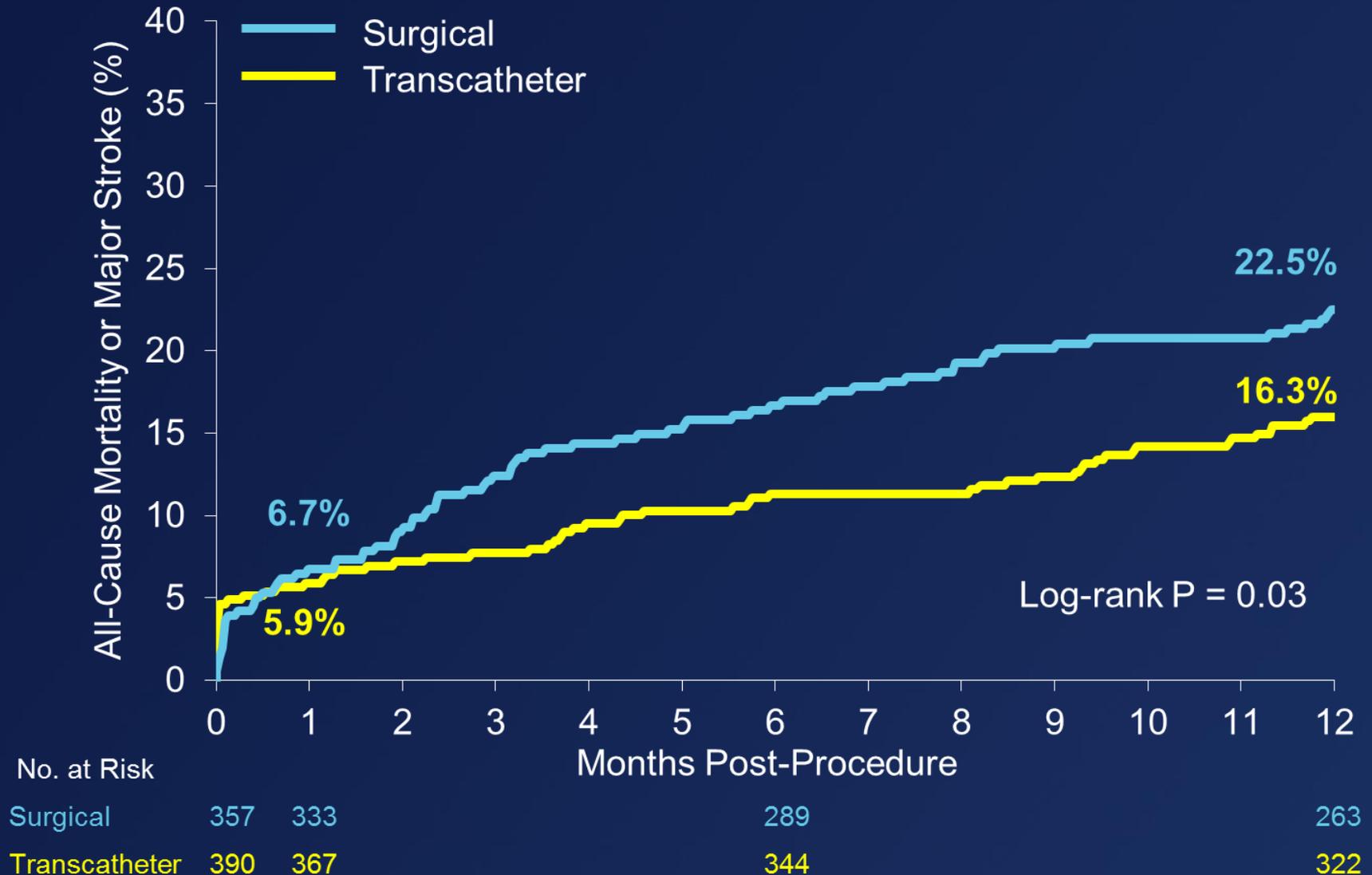
Major Stroke



No. at Risk

Surgical	357	333	289	263
Transcatheter	390	367	344	322

All-Cause Mortality or Major Stroke



Stroke After TAVR

- Neurologic Definitions
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- High Risk Findings
- Predictors of Stroke

Predictors of Stroke-I

Variable	Patients	KM (%) 1-Yr (95% CI)	Rate of All-Stroke (6.7%)	P Value
Age				
≤85	222	5.4 (2.9, 10.0)		0.268
>85	249	7.8 (4.8, 12.7)		
Logistic EuroSCORE				
<22	291	6.6 (4.1, 10.7)		0.897
≥22	180	6.8 (3.5, 12.8)		
STS Score				
<10	263	7.8 (4.9, 12.4)		0.552
10-15 (vs. <10)	125	6.1 (2.8, 12.9)		
>15 (vs. <10)	83	4.2 (1.1, 14.5)		
Diabetes	200	4.4 (2.0, 9.4)		0.110
Hypertension	424	7.4 (5.1, 10.9)		0.071
PVD	165	9.2 (5.2, 16.0)		0.116

Predictors of Stroke-II

Variable	Patients	KM (%) 1-Yr (95% CI)	Rate of All Stroke (6.7%)	P Value
Prior Stroke	65	4.7 (1.3, 16.9)		0.627
Prior TIA	44	7.3 (2.1, 23.3)		0.844
History of A-fib / A-flutter	222	5.6 (3.0, 10.5)		0.344
Post-TAVR Valvuloplasty Performed	99	5.7 (2.2, 14.5)		0.689
More than 1 Valve Implanted	17	5.9 (0.9, 35.0)		0.909

Conclusions

- The US CoreValve Screening Committee used conventional and non-conventional risk factors to determine extreme surgical risk
- The High Risk showed a numeric reduction in the rate of all stroke at 30 days and one year compared with surgery
- The majority of strokes occurred within the 1st 72 hours, but the risk persisted to 14 days
- No predictors of strokes were identified
- Post-TAVR balloon post-dilation did not increase the stroke risk