Trends, Risk Factors, and Comparison with Surgery for Early Stroke after TAVR – Reports from PARTNER and TVT Registry (in High- & Intermediate-Risk pts)

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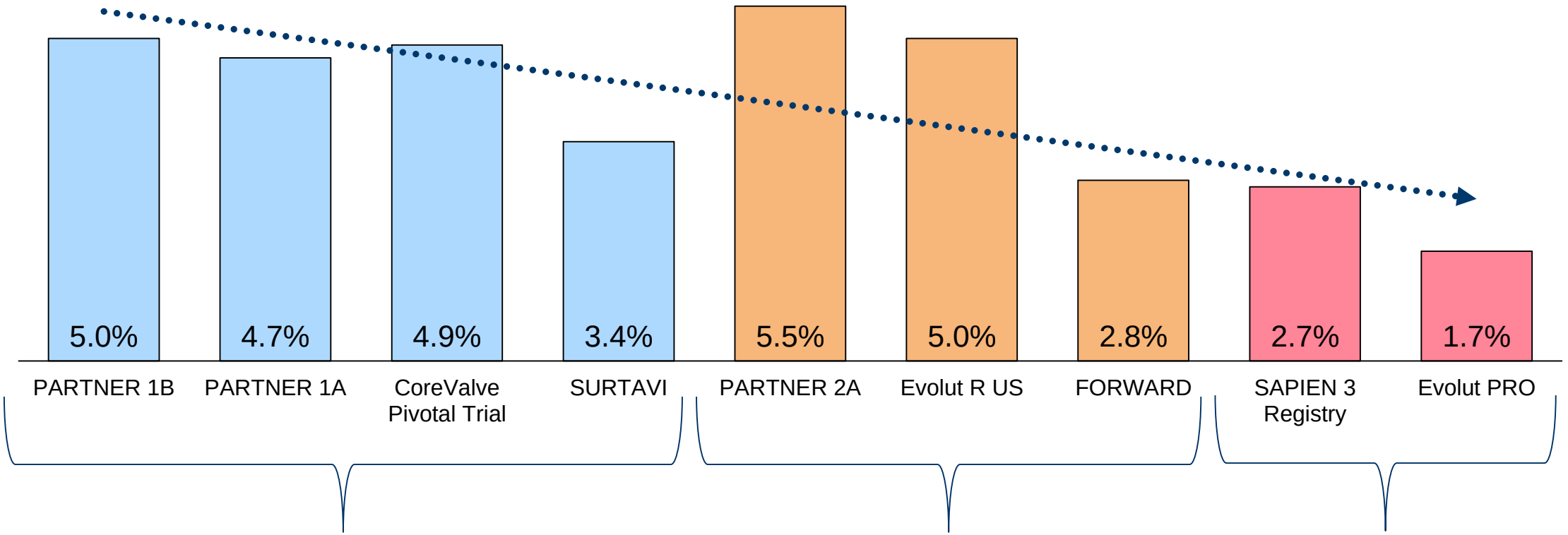
Disclosures

- **No financial disclosure**
- **National Co-PI for the Sentinel trial**

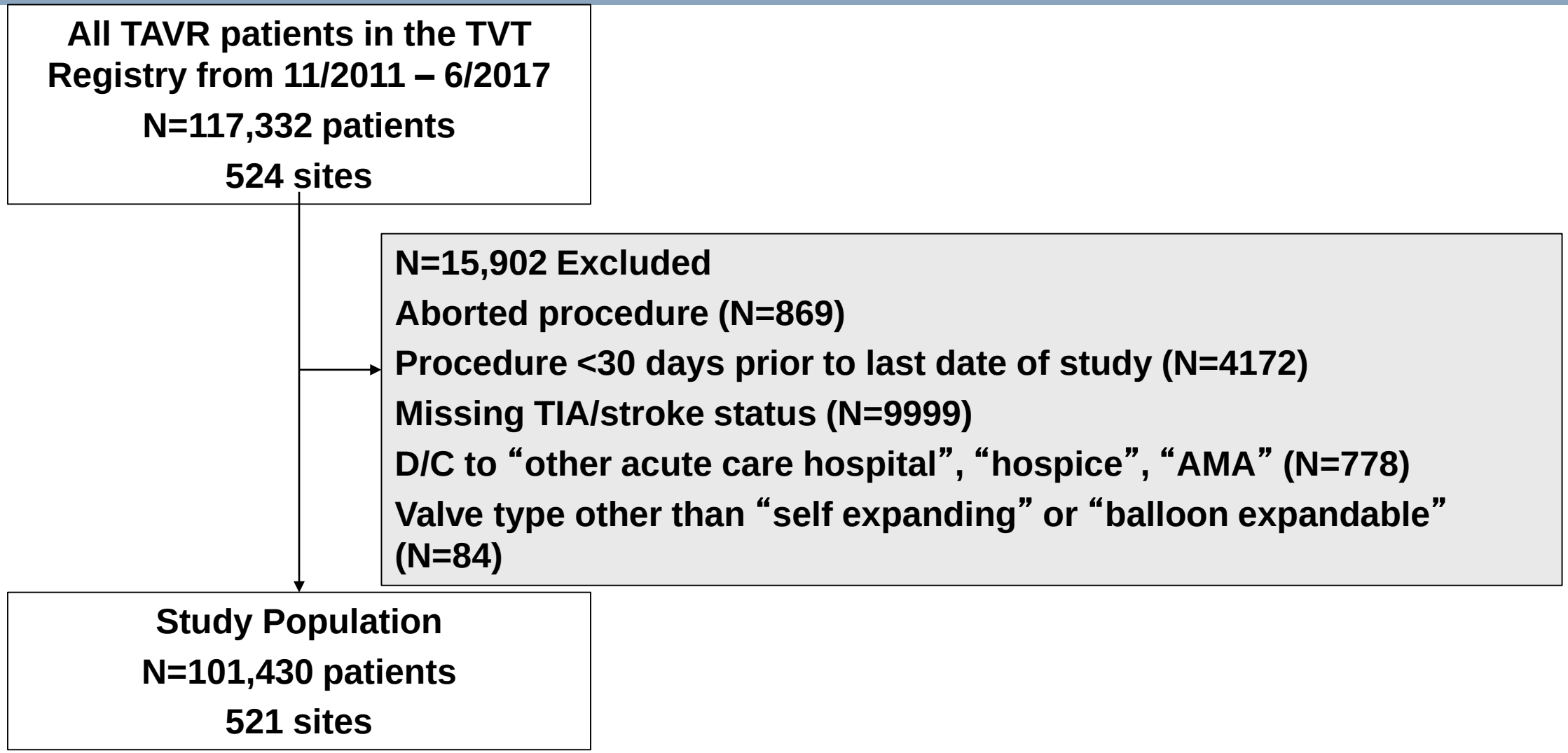
Topics

- **Trends (TVT Registry)**
- **Risk Factors**
- **Comparison With SAVR**

Post-TAVR 30-Day Stroke Rates Declining Major Clinical Trials



TVT data Analysis

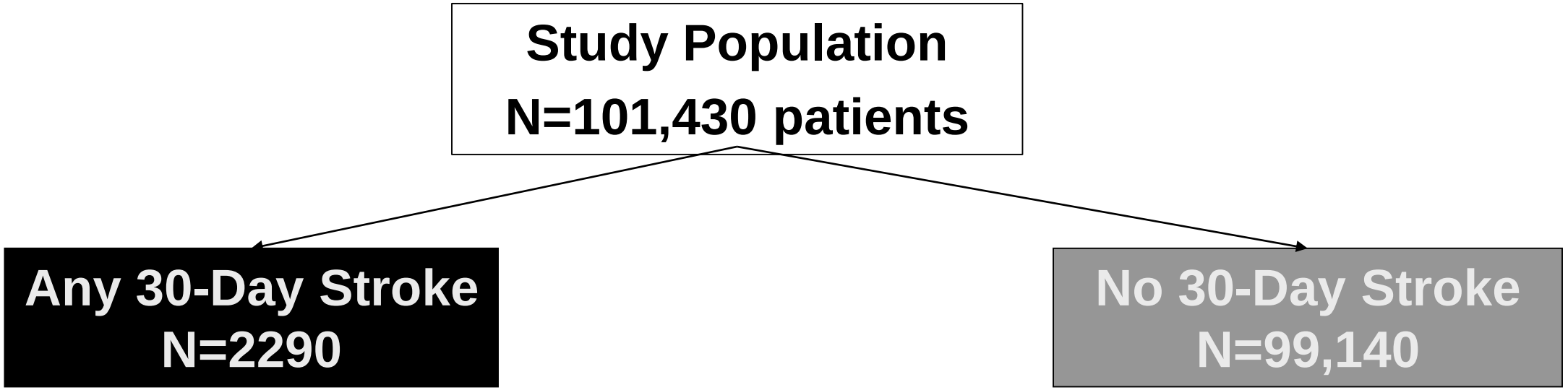


Huded et al, JAMA 2019 in press

Stroke Events Adjudication

Characteristic	% of Stroke Events
Neuroimaging performed	98.7%
Neurologist / neurosurgeon confirmation of diagnosis	93.8%
Symptom duration >24 hours	82.3%
Social activities impaired	48.6%
Neurocognitive function impaired	34.5%
New aid or assistance required	41.2%
Death as a result of stroke/TIA	11.3%

30-Day Neurologic Events



Any stroke 2.3%
Ischemic stroke 2.1%
Hemorrhagic stroke 0.1%
Undetermined stroke 0.1%
TIA 0.4%

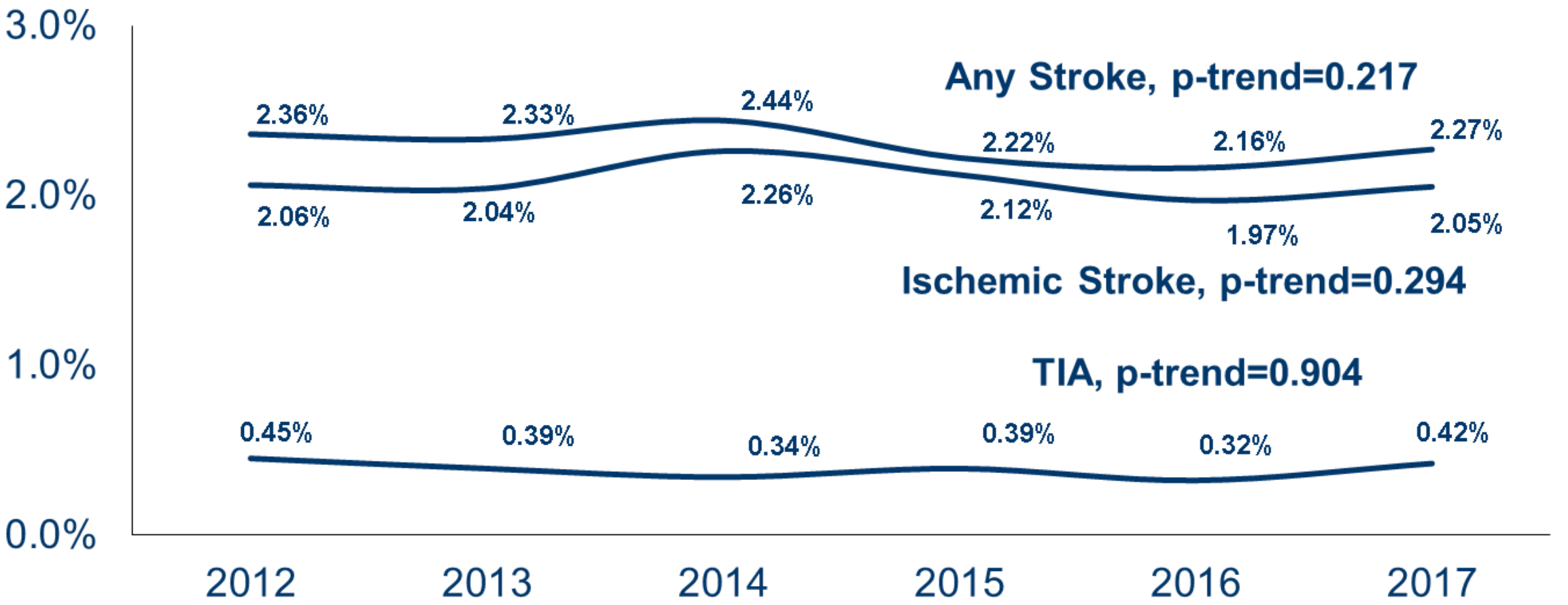
Baseline Characteristics

Characteristic	Overall N=101,430	30-Day Stroke N=2290	No 30-Day Stroke N=99,140	P
Age (years)	83 (76, 87)	84 (78, 88)	82 (76, 87)	<.001
Female	47%	55%	47%	<.001
Prior Stroke	12%	17%	12%	<.001
Prior TIA	9%	14%	9%	<.001
Porcelain Aorta	5%	6%	5%	.008
PAD	30%	35%	30%	<.001
Atrial Fib/Flutter	40%	41%	40%	.493
Carotid Stenosis	20%	24%	20%	<.001

Procedural Characteristics

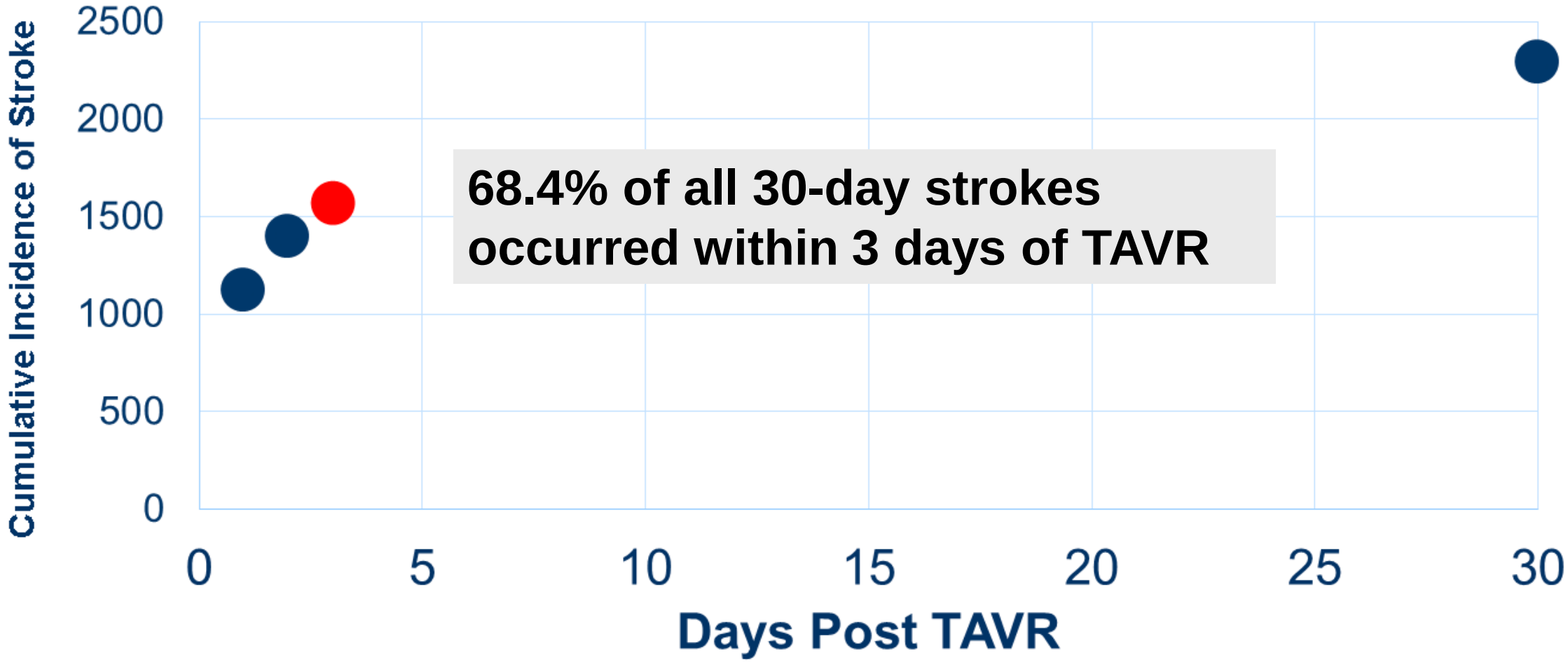
Characteristic	Overall N=101,430	30-Day Stroke N=2290	No 30-Day Stroke N=99,140	P
Valve type - Self Expanding - Balloon Expandable	 26% 74%	 33% 67%	 26% 74%	<.001
Access type - Femoral - Apical/aortic - Other	 84% 13% 3%	 77% 17% 6%	 84% 13% 3%	<.001
General Anesthesia	76%	79%	76%	<.001
In-Hospital AF	4%	8%	4%	<.001

Trends in Post-TAVR Neurologic Event Rates

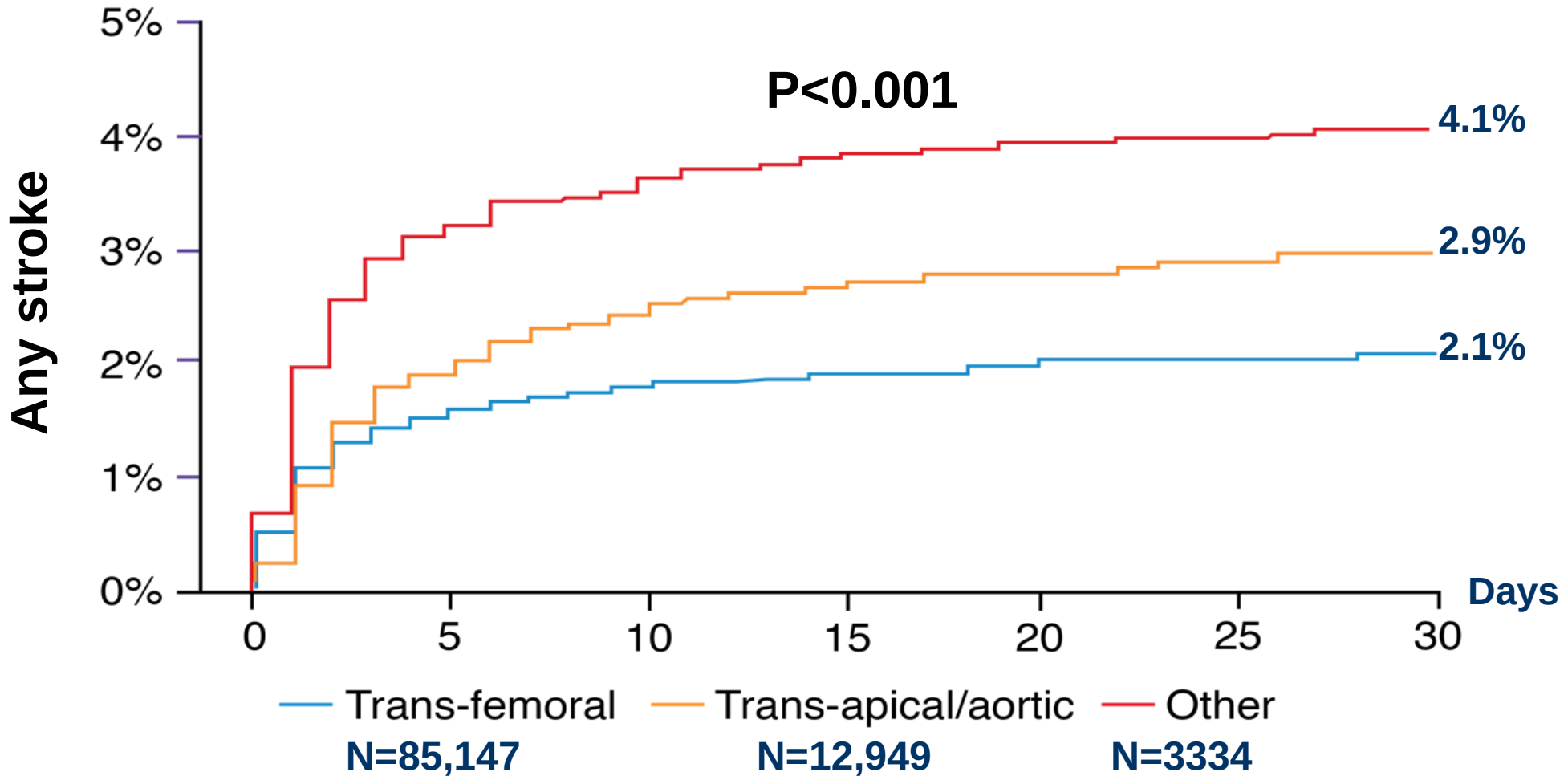


*2017 data through May

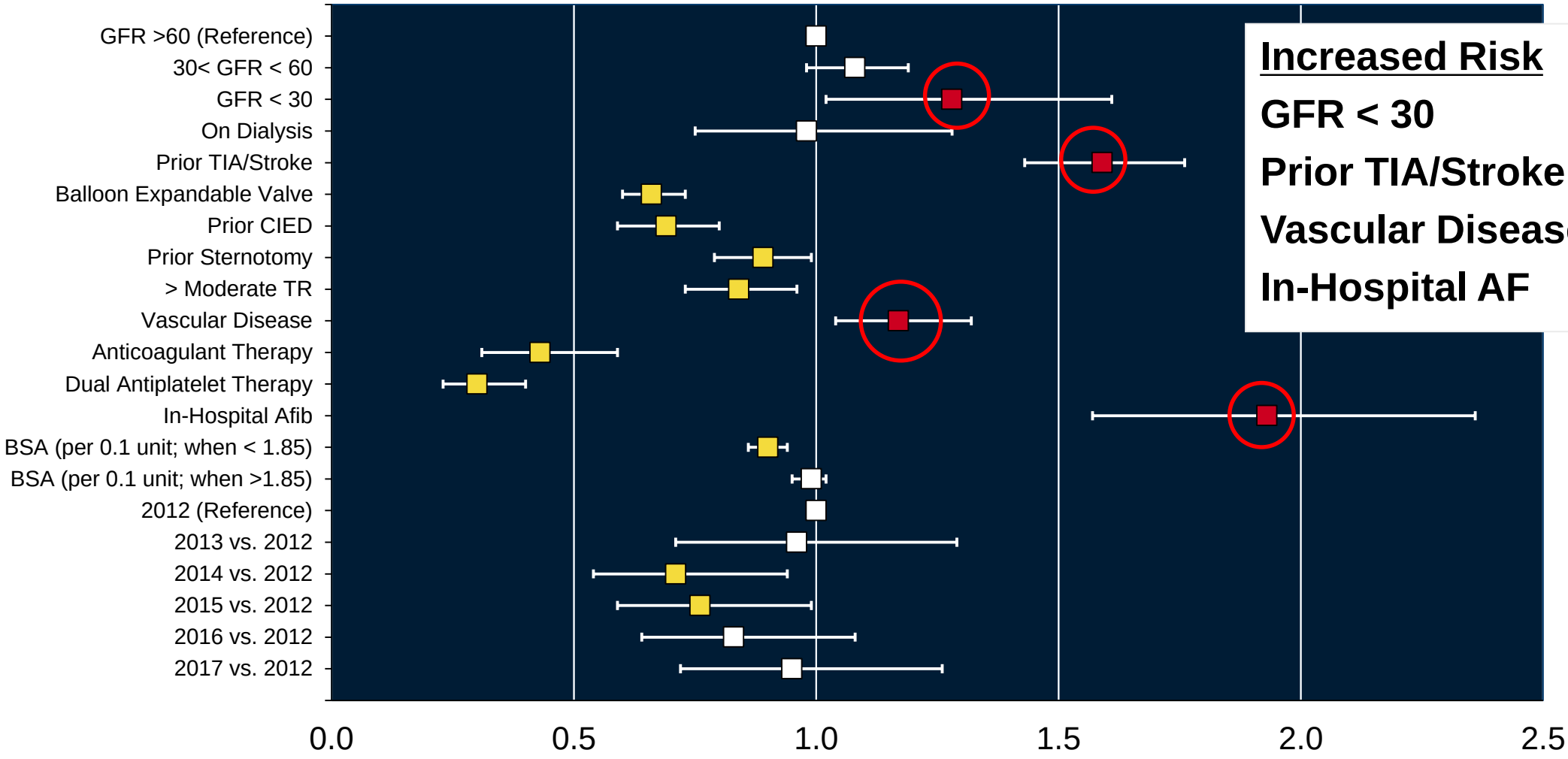
Timing of 30-Day Stroke



Stroke by Access Type

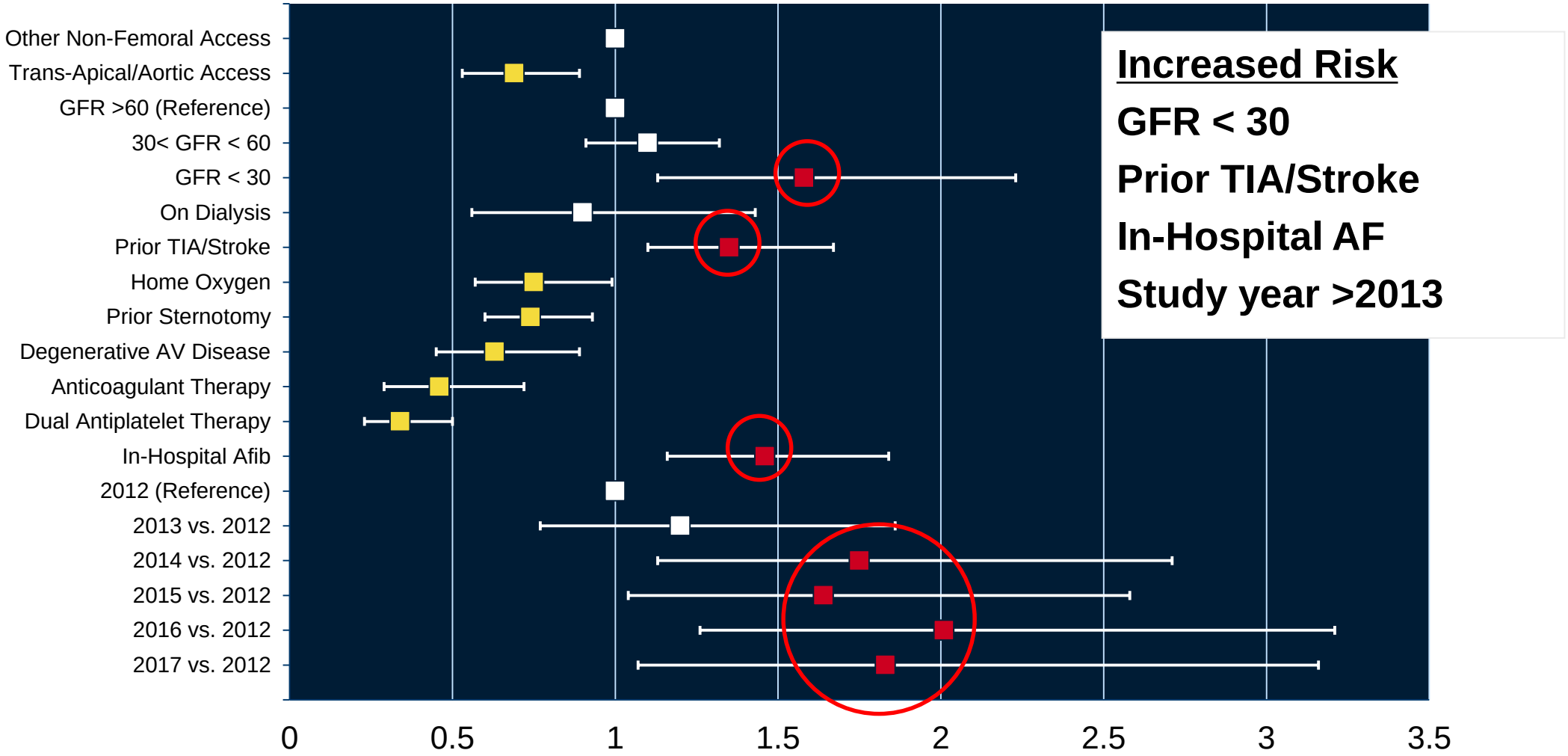


Risk Factors for Stroke (Femoral Cohort)



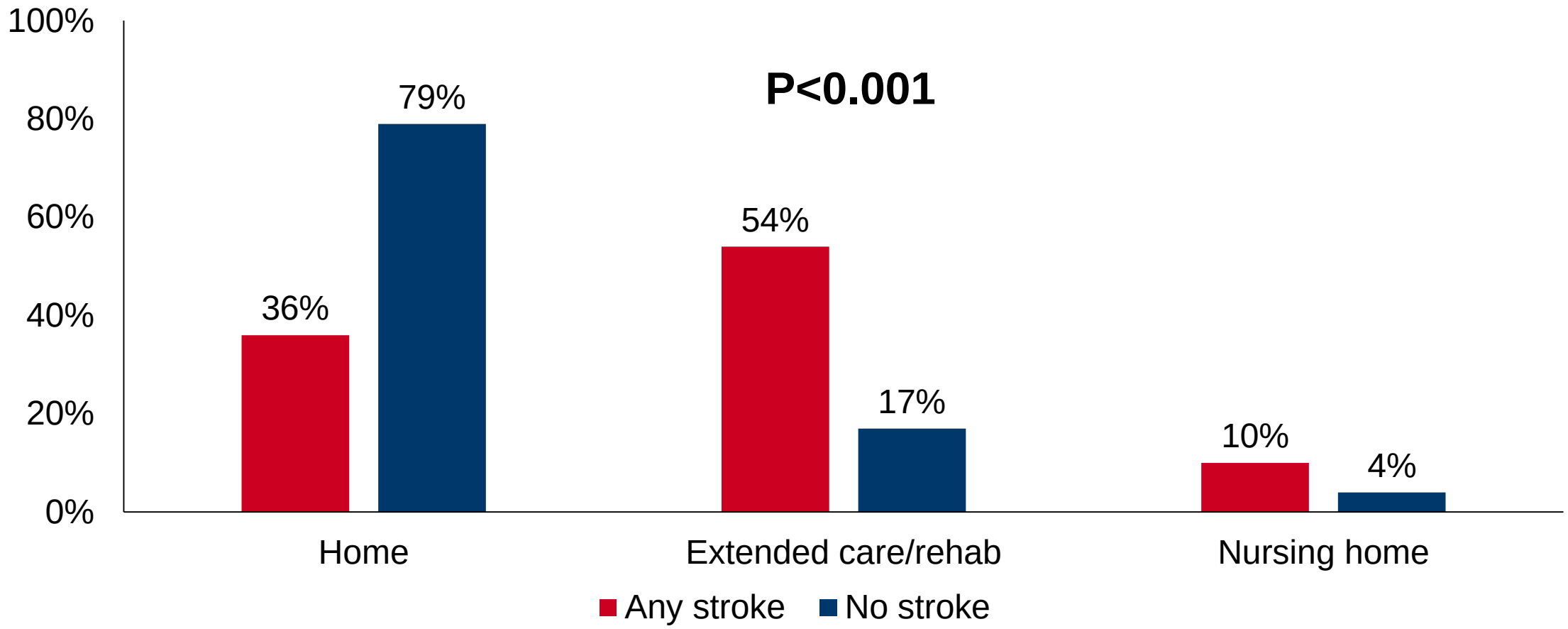
Hazard Ratio for Early Stroke

Risk Factors for Stroke (Non-Femoral Cohort)

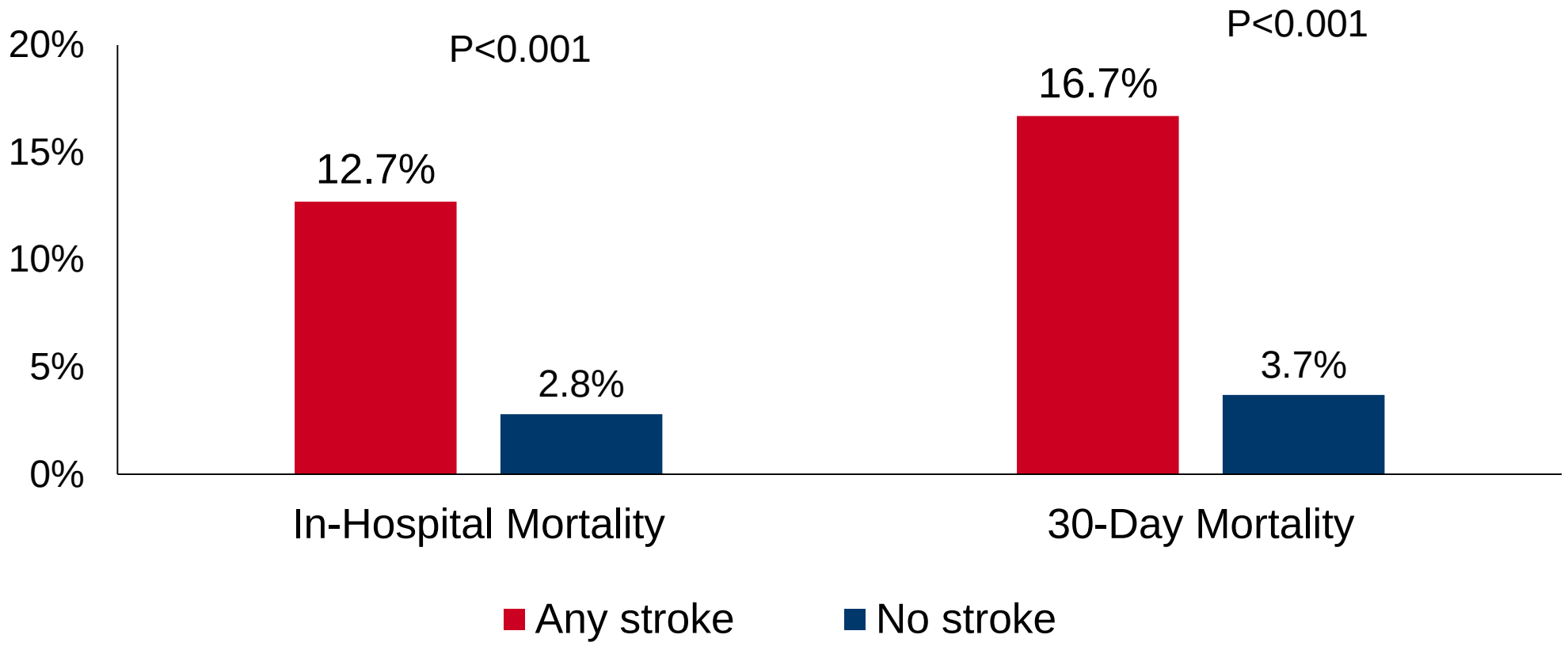


Hazard Ratio for Early Stroke

Association of Post TAVR Stroke with Discharge Destination



Association of Post TAVR Stroke with Mortality



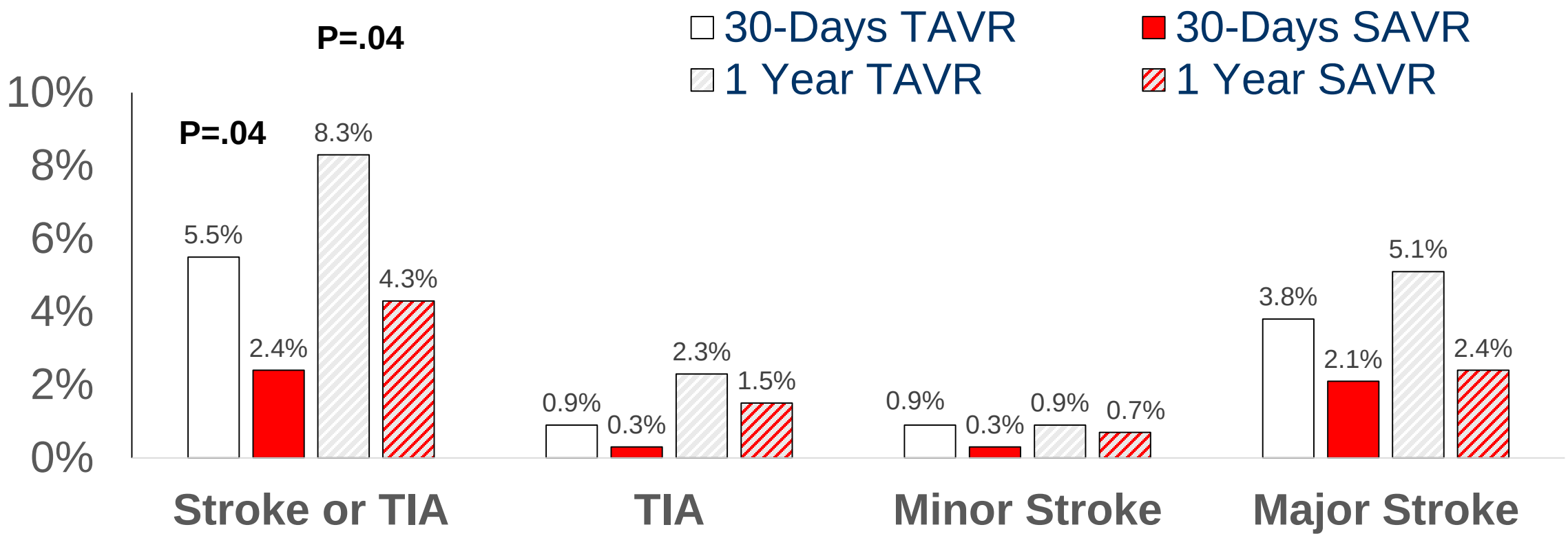
Summary of Observations

- The rate of 30-day stroke has not declined in the first 5 years of TAVR in US practice
- Stroke is associated with increased morbidity and mortality
- Procedural stroke (within 3 days) accounts for 68% of 30 day strokes
- Early stroke is lower in TF vs. alternative access TAVR

Topics

- Trends (TVT Registry)
- Risk Factors
- Comparison With SAVR

PARTNER 1A
Raised Concern of Increased Neurologic Risk of TAVR



Smith et al. N Engl J Med. 2011; 364:2187-98

PARTNER Trial Analysis

April 2007 – October 2015

PARTNER 1 (N=3159)
1A (High Risk)
TAVR vs SAVR

1B (Inoperable)
TAVR vs. Medical Tx

PARTNER 2 (N=2805)
2A (Intermediate Risk)
TAVR vs SAVR

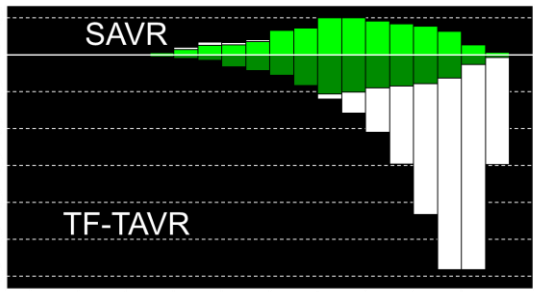
2B (Inoperable)
Sapien vs. Sapien XT

PARTNER 2 S3 (N=1661)
≥ Intermediate Risk TAVR Registry
Sapien 3

TF-TAVR: 4389
SAVR: 1248

Excluded 1988 (26%)
1. Medical therapy arm
2. Non-femoral TAVR
3. Cross-over between TAVR/SAVR
4. Died prior to AVR

1:1 Propensity Matching
TF-TAVR vs. SAVR
Matching caliper ≤ 0.1
96% SAVR cases matched



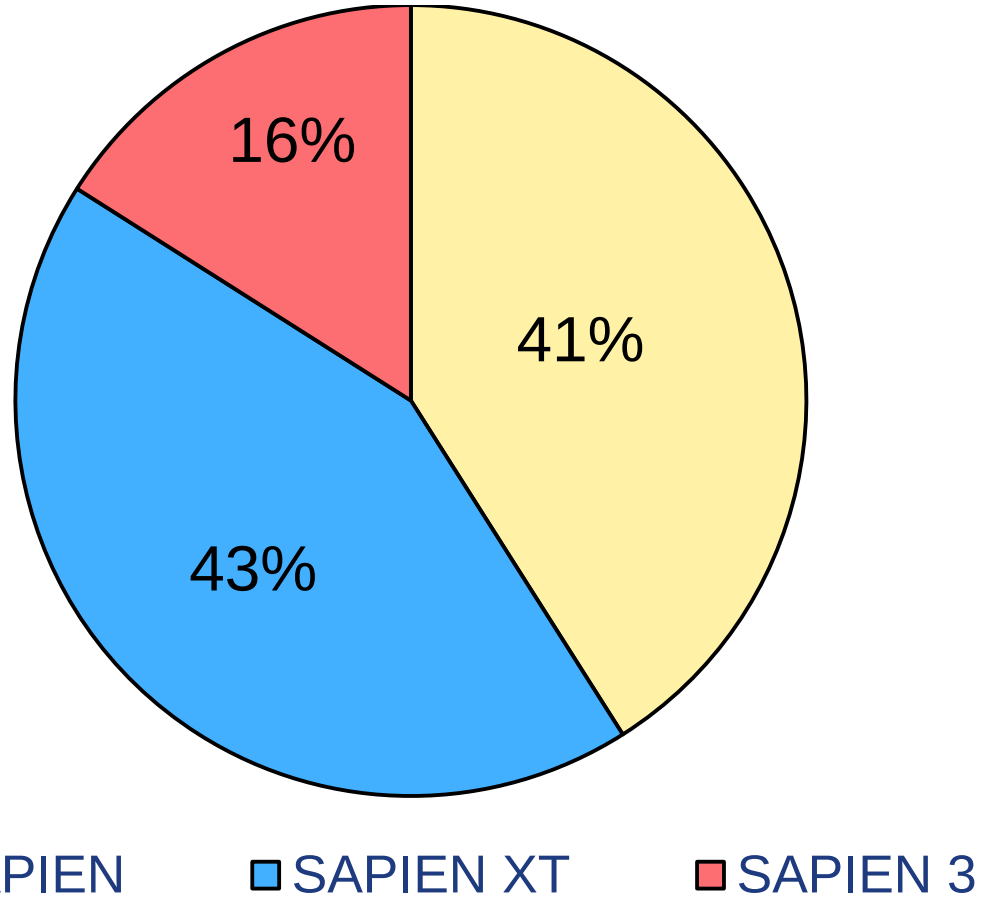
Final Propensity Matched Study Population

As Treated	PARTNER 1	PARTNER 2	S3	Total
TF-TAVR	406	602	196	1204
SAVR	306	898	0	1204

Median Follow-up
SAVR: 2 years
TF-TAVR: 1.5 years

Kapadia et al, J Am Coll Cardiol. 2018 Nov 13;72(20):2415-2426

TF-TAVR Devices
Propensity Matched Study Population

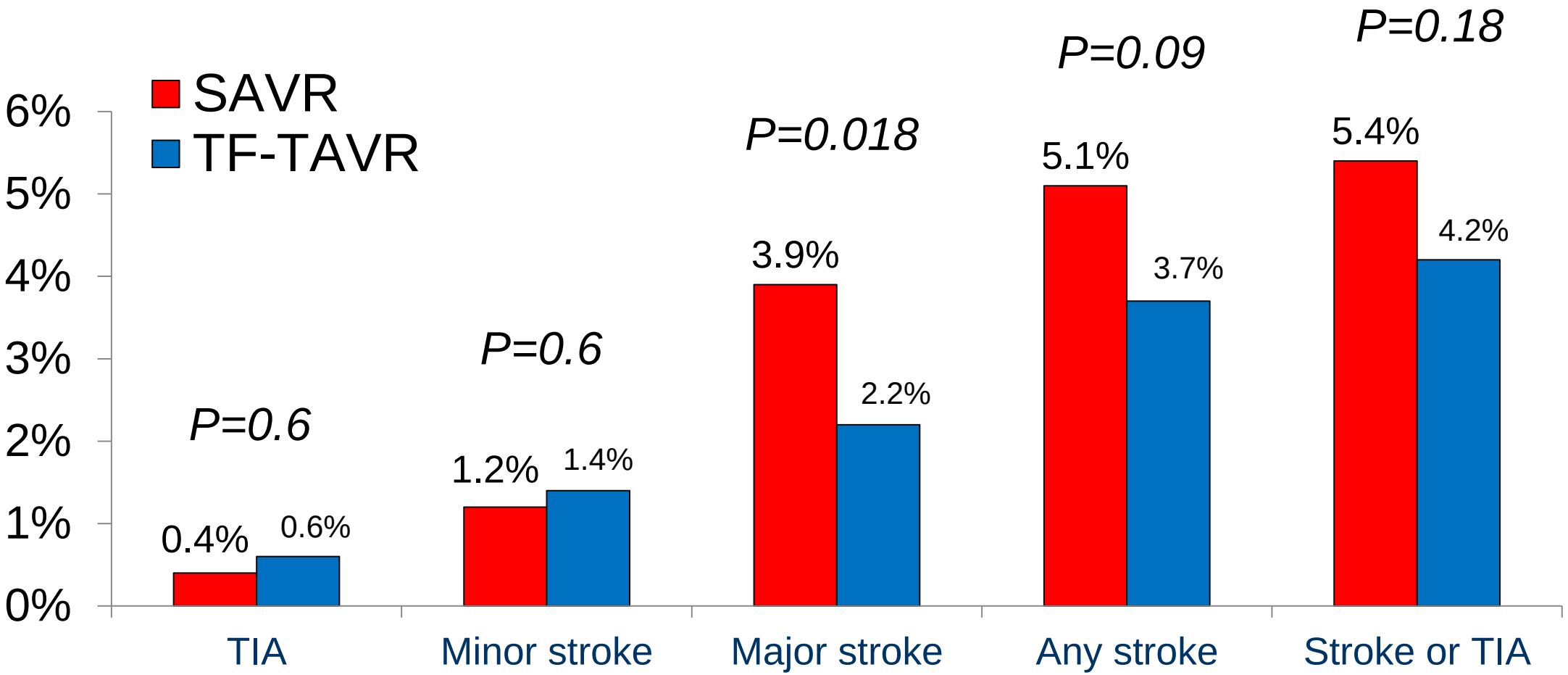


Kapadia et al, J Am Coll Cardiol. 2018 Nov 13;72(20):2415-2426

Baseline Characteristics

Characteristic	SAVR (n = 1204)	TF-TAVR (n=1204)	p-value
Age - yrs	82 ± 6.7	82 ± 7.9	0.10
Female	45%	44%	0.9
CAD - %	69%	70%	0.6
Previous MI - %	20%	20%	0.8
Prior PCI - %	28%	28%	>0.9
Prior CABG - %	30%	31%	0.6
Prior BAV - %	6.4%	3.6%	0.003
Cerebrovascular Disease - %	31%	33%	0.4
Prior Stroke - %	12%	12%	0.8
Peripheral Vascular Disease - %	43%	45%	0.4

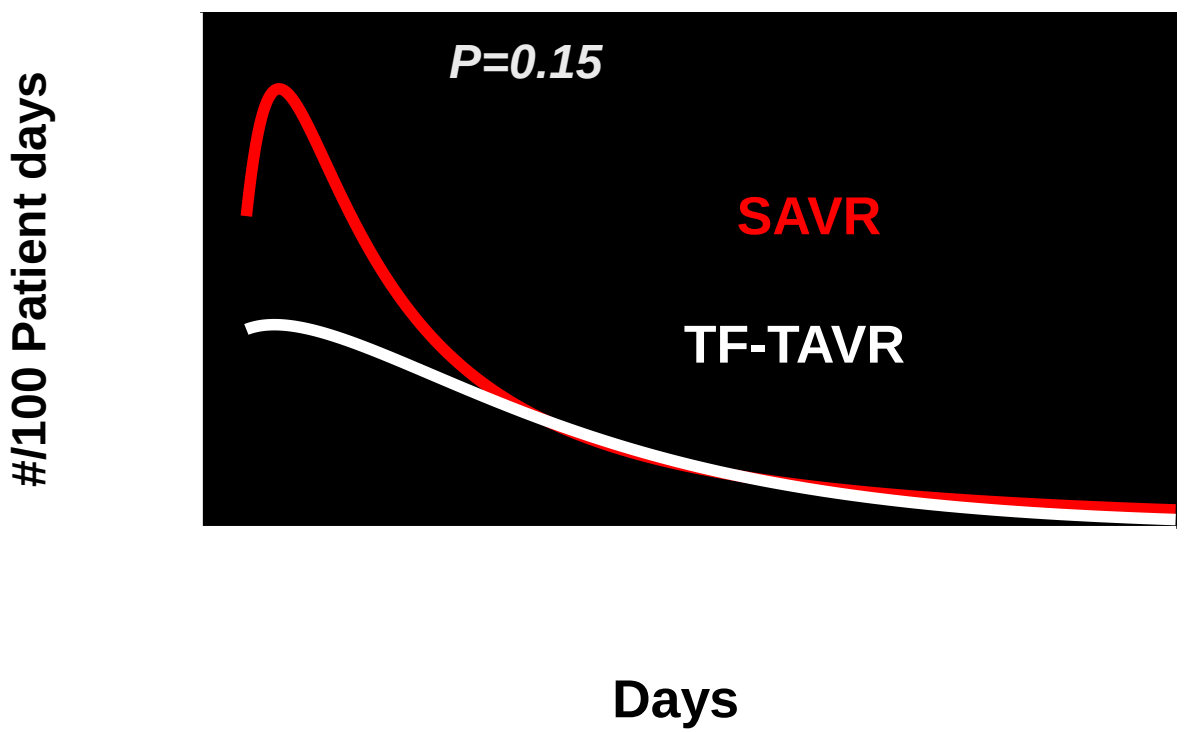
30-Day Neurologic Events



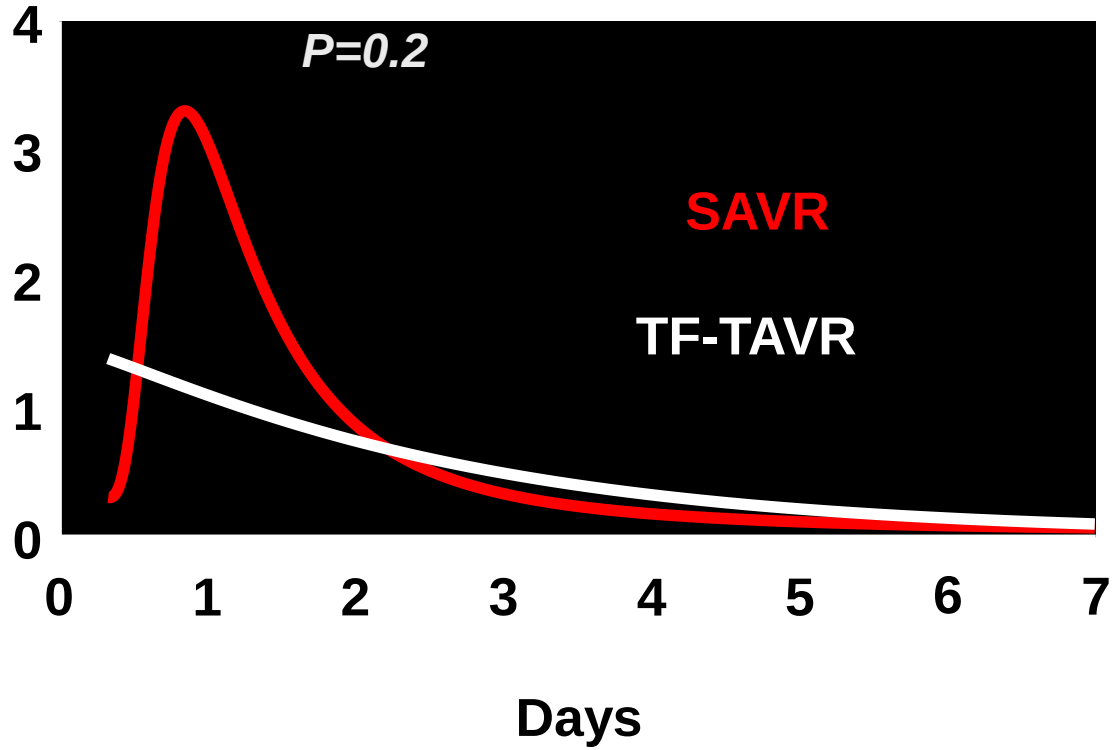
Early Phase Risk (<7 Days)

Instantaneous Risk Modeling

Stroke



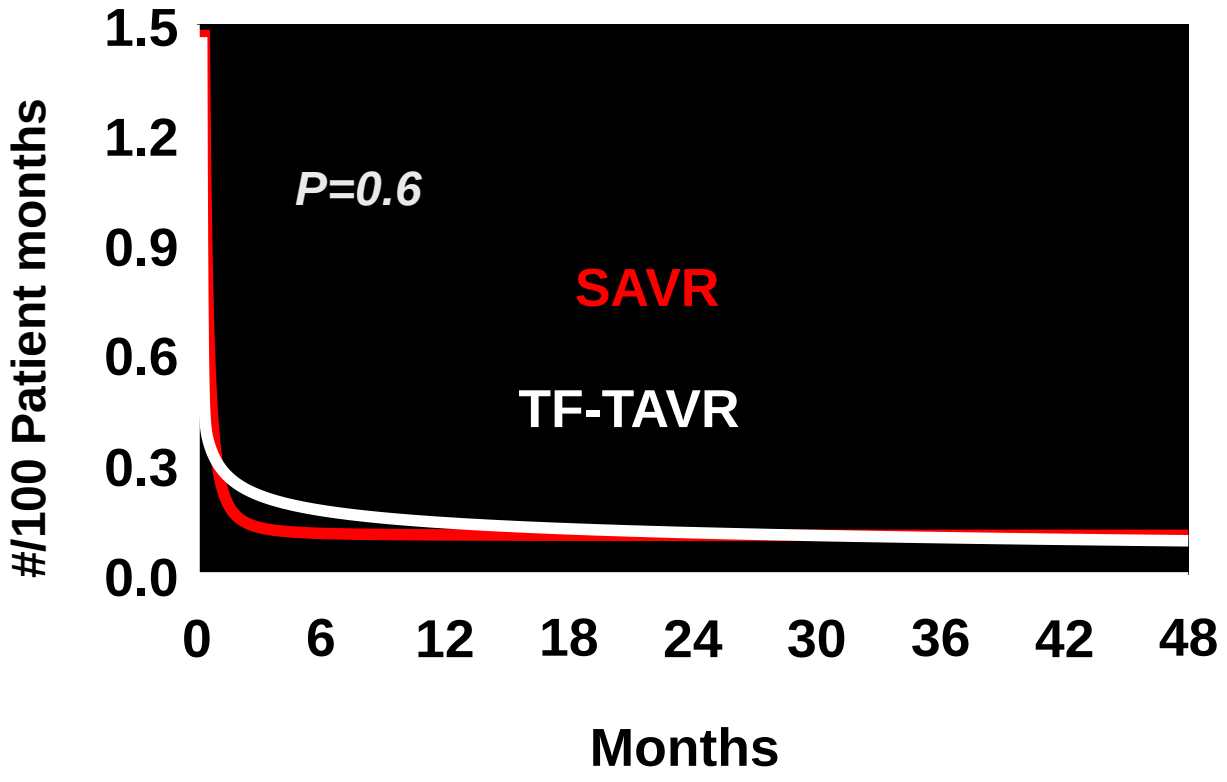
Stroke or TIA



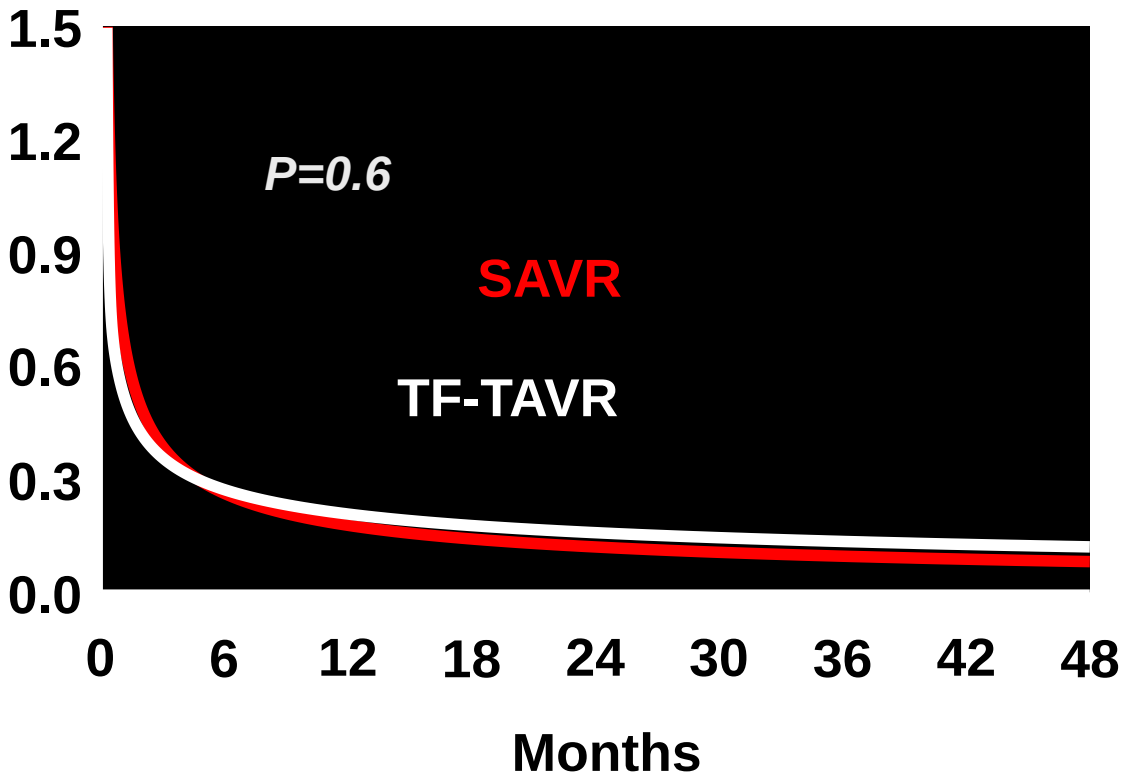
Late Phase Risk (4 Years)

Instantaneous Risk Modeling

Stroke



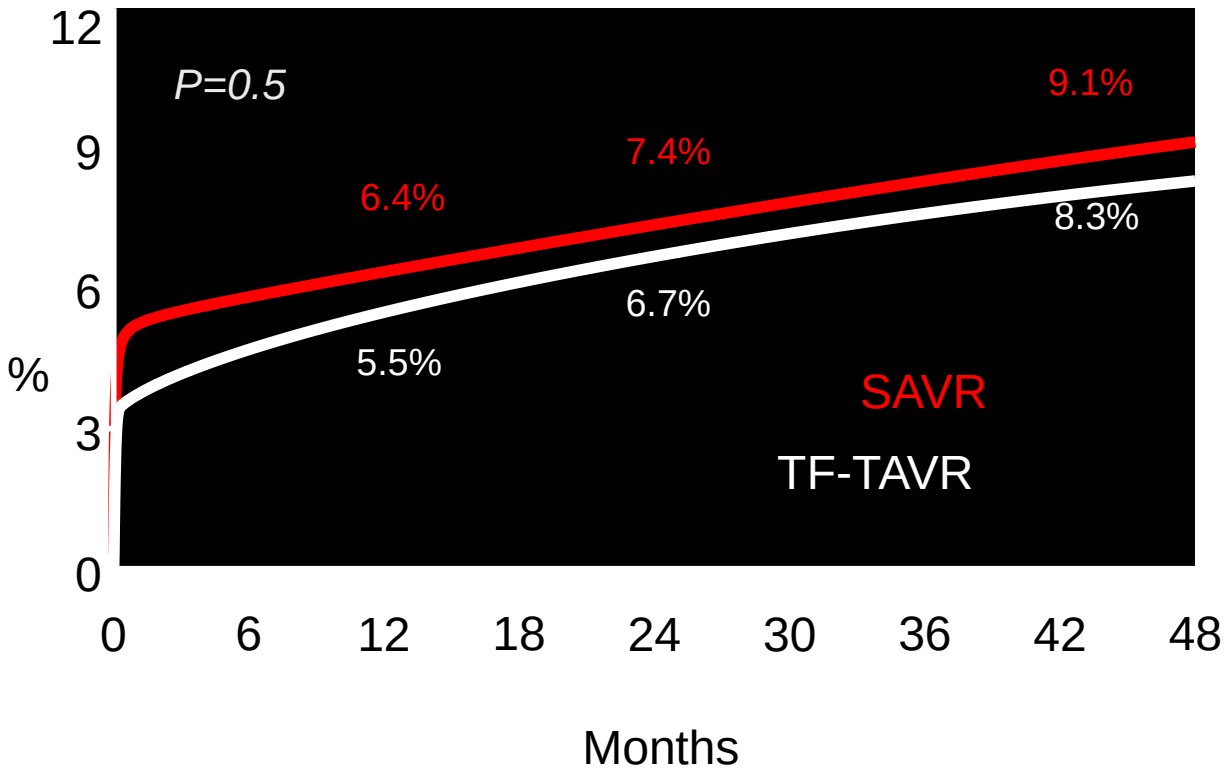
Stroke or TIA



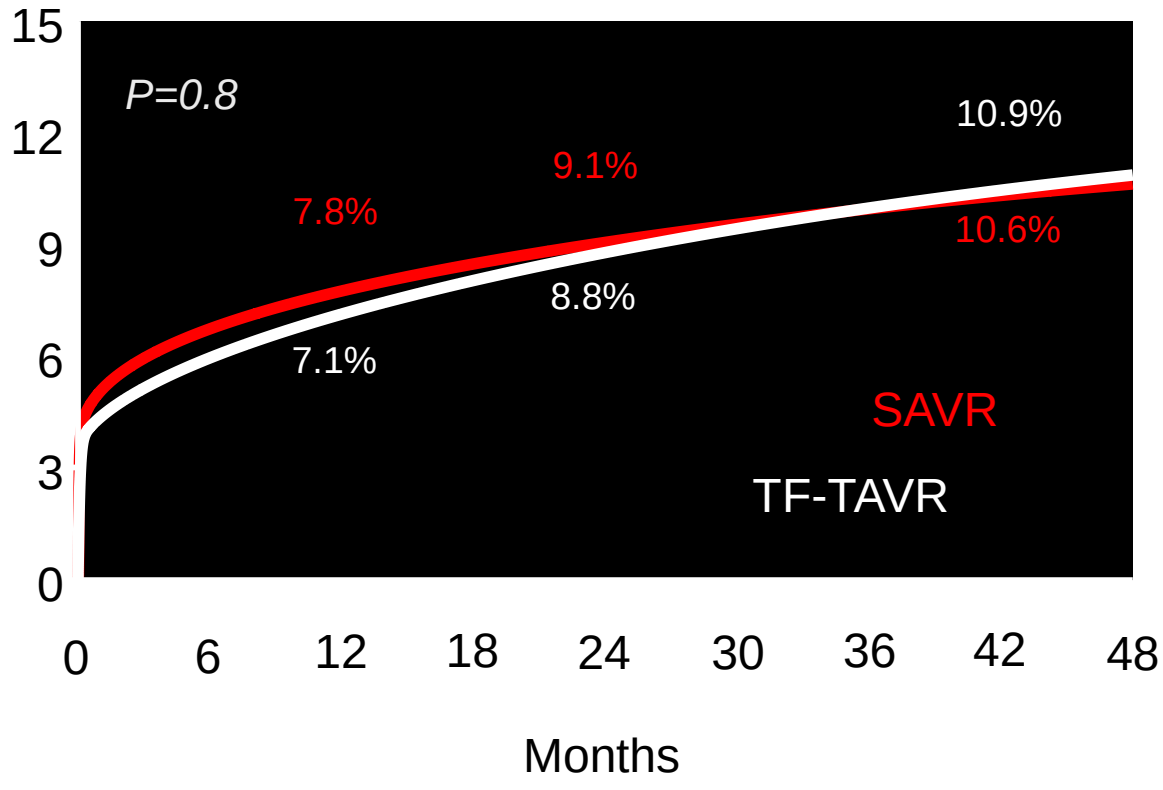
Cumulative Incidence of Events

Adjusted for Competing Risk of Mortality

Stroke



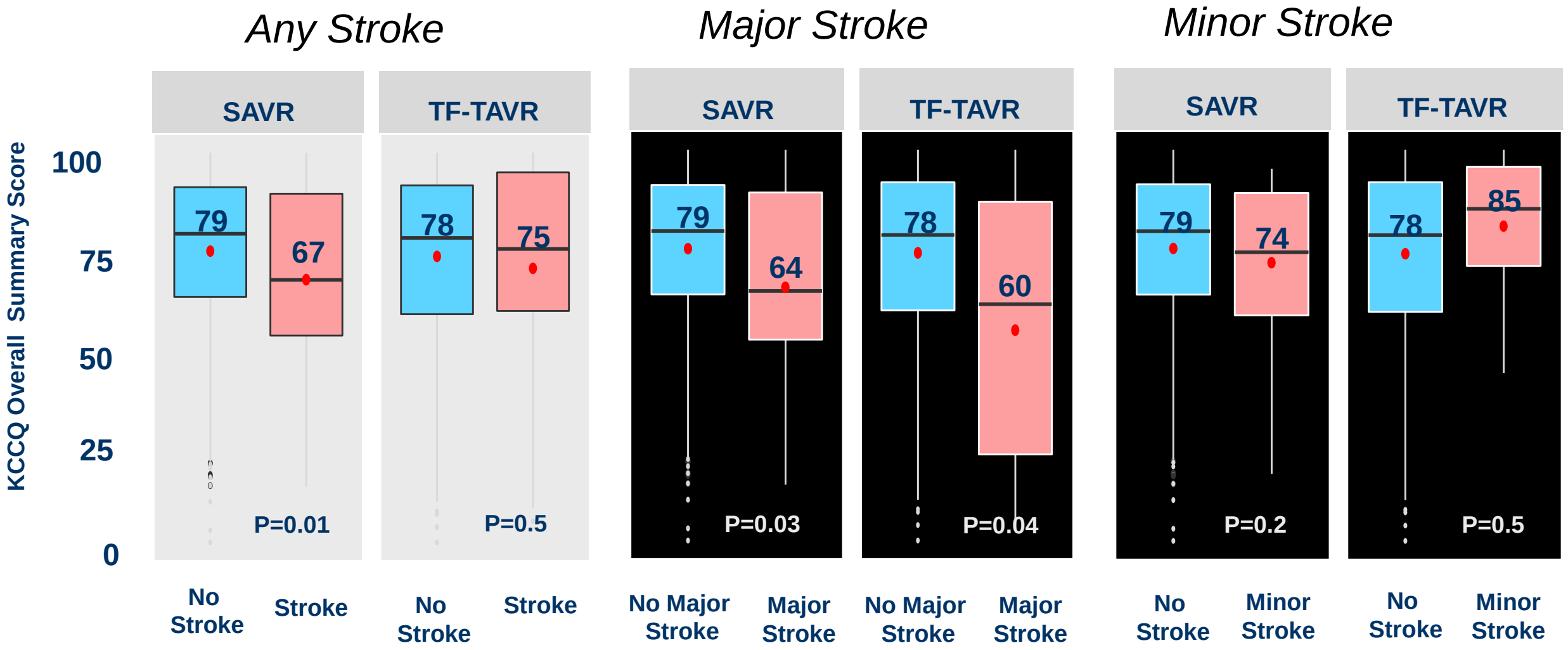
Stroke or TIA



Association of Postoperative AV Gradients and Late Stroke Risk

- Increasing post-procedure mean trans-AV gradient was not associated with risk of stroke (P>0.7).
- No interaction of AV gradient and procedure type with risk of stroke (P interaction >0.2).

Association of Stroke and 1 Year Quality of Life



Principal Findings

1. 30-day major stroke risk lower in TF-TAVR compared to SAVR.
2. Similar pattern of early-peaking (<24 hours) and nearly constant late neurologic risk between SAVR and TF-TAVR.
3. No association with increasing valve gradients and late-phase stroke risk.
4. Major, but not minor, strokes are associated with lower QOL at 1-year.

Kapadia et al, J Am Coll Cardiol. 2018 Nov 13;72(20):2415-2426