

A Stroke after TAVR “Primer” Time Course, Changing Incidence, Ascertainment Challenges, and Comparison vs. Surgery

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Disclosures

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

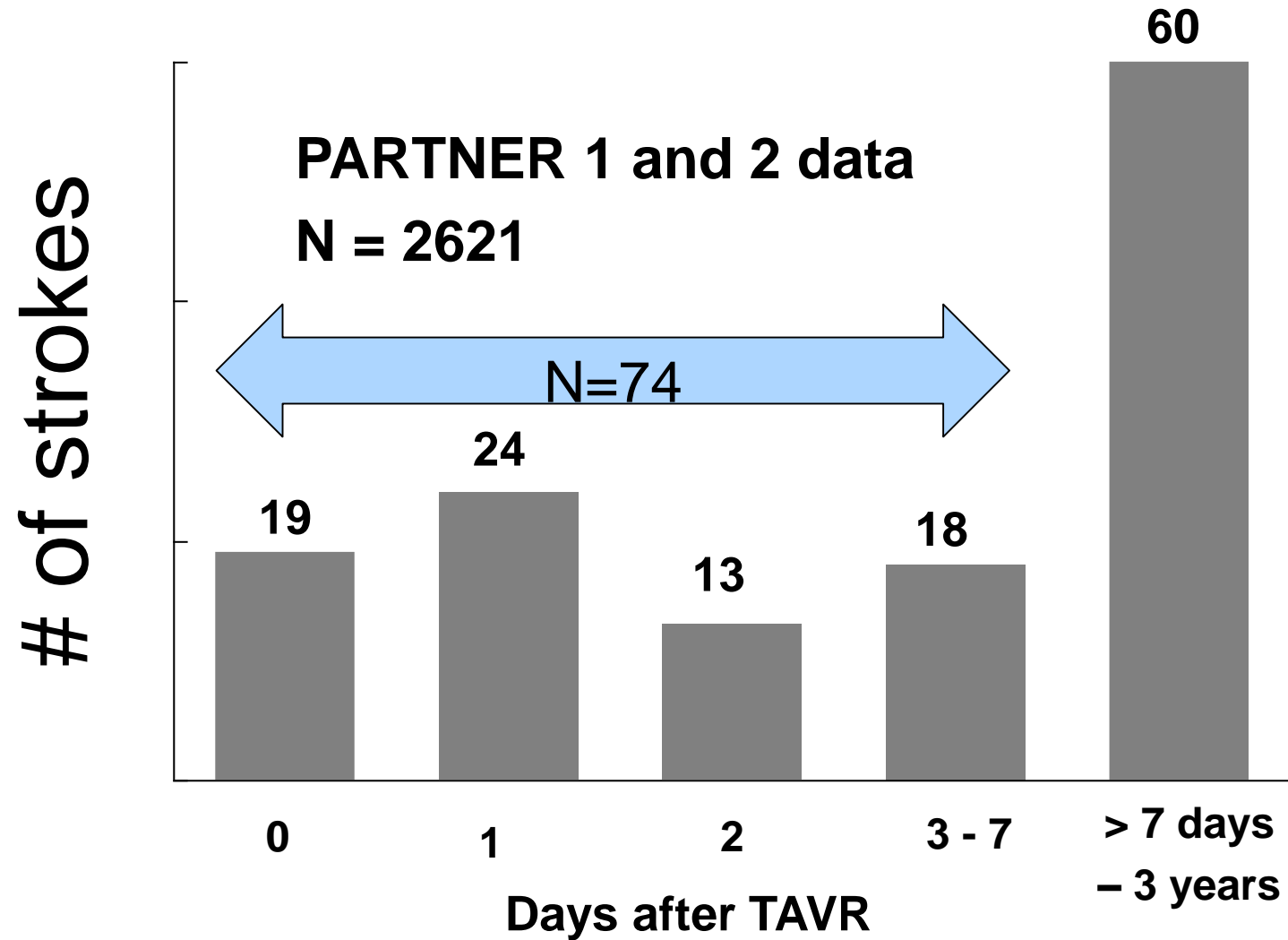
Topics

- **Time Course**
- **Changing Incidence**
- **Ascertainment Challenges**
- **Comparison With SAVR**

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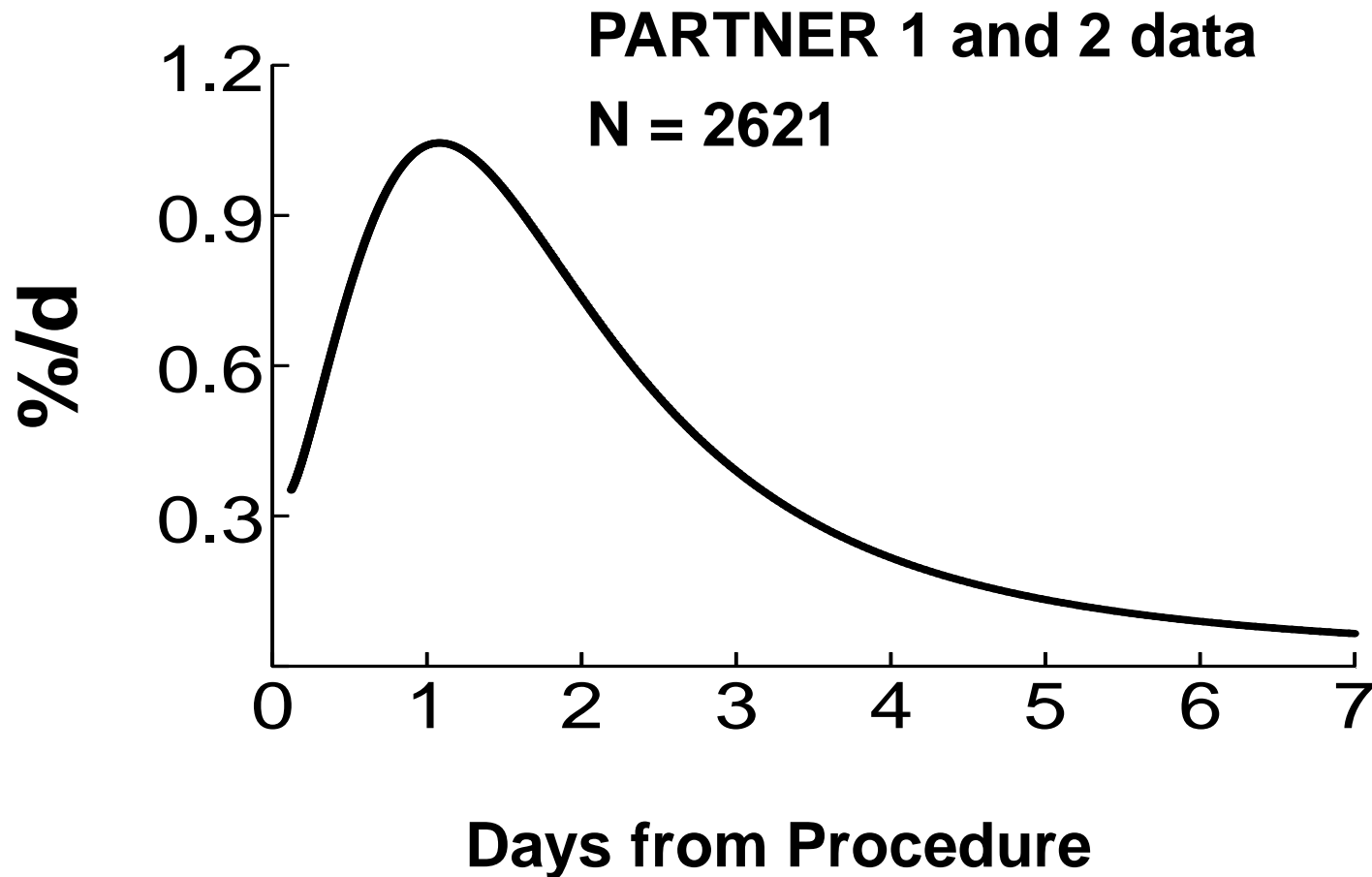
Number of Strokes



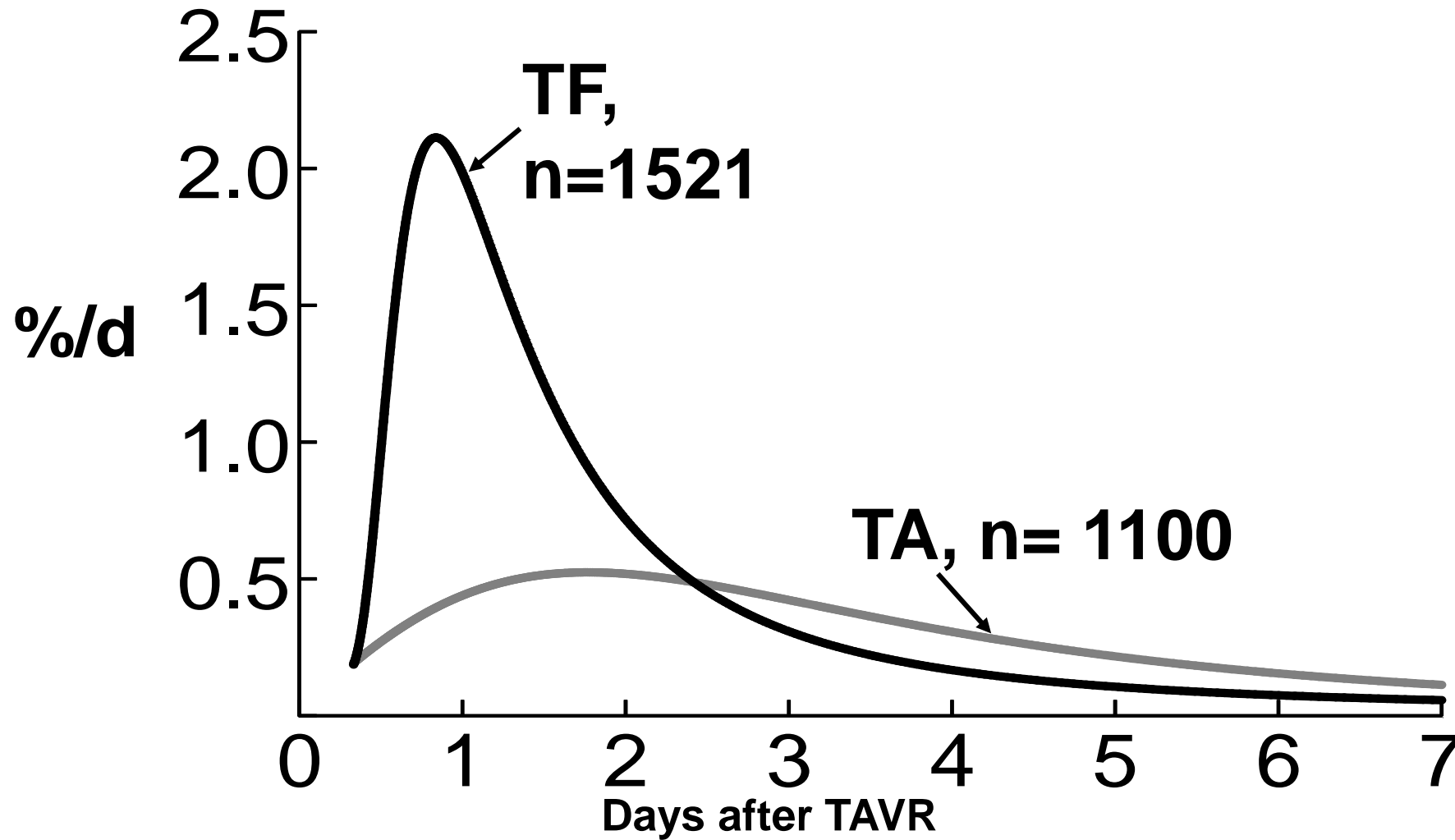
Stroke: 30 days – 1 year

Trial	30 day stroke (%)	1 year stroke (%)	30 days to 1 year stroke (%)
P1A	5.5	8.3	2.8
CoreValve	6.2	12.6	6.4
P2A	5.5	8.0	2.5
P2B	4.8	7.8	3.0

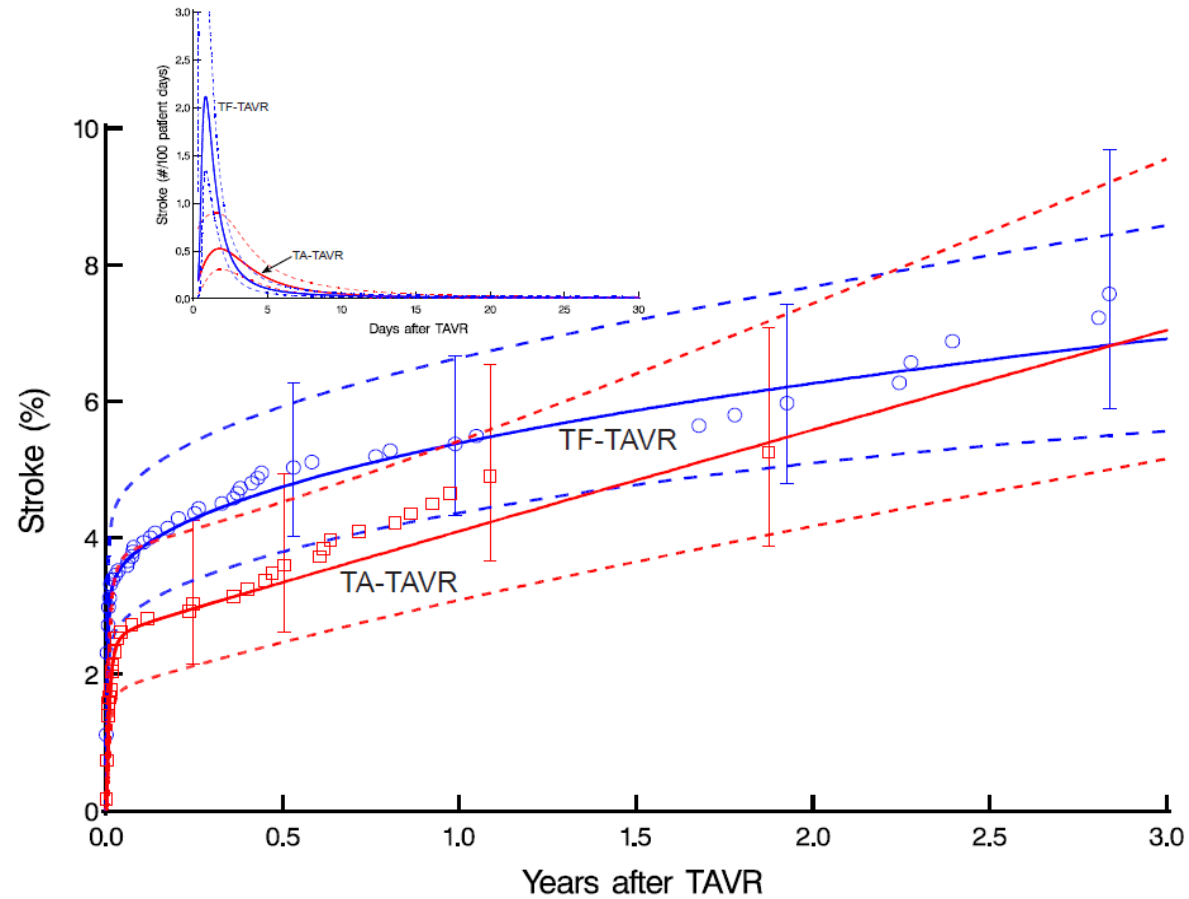
Instantaneous Stroke Risk



Instantaneous Risk of Stroke



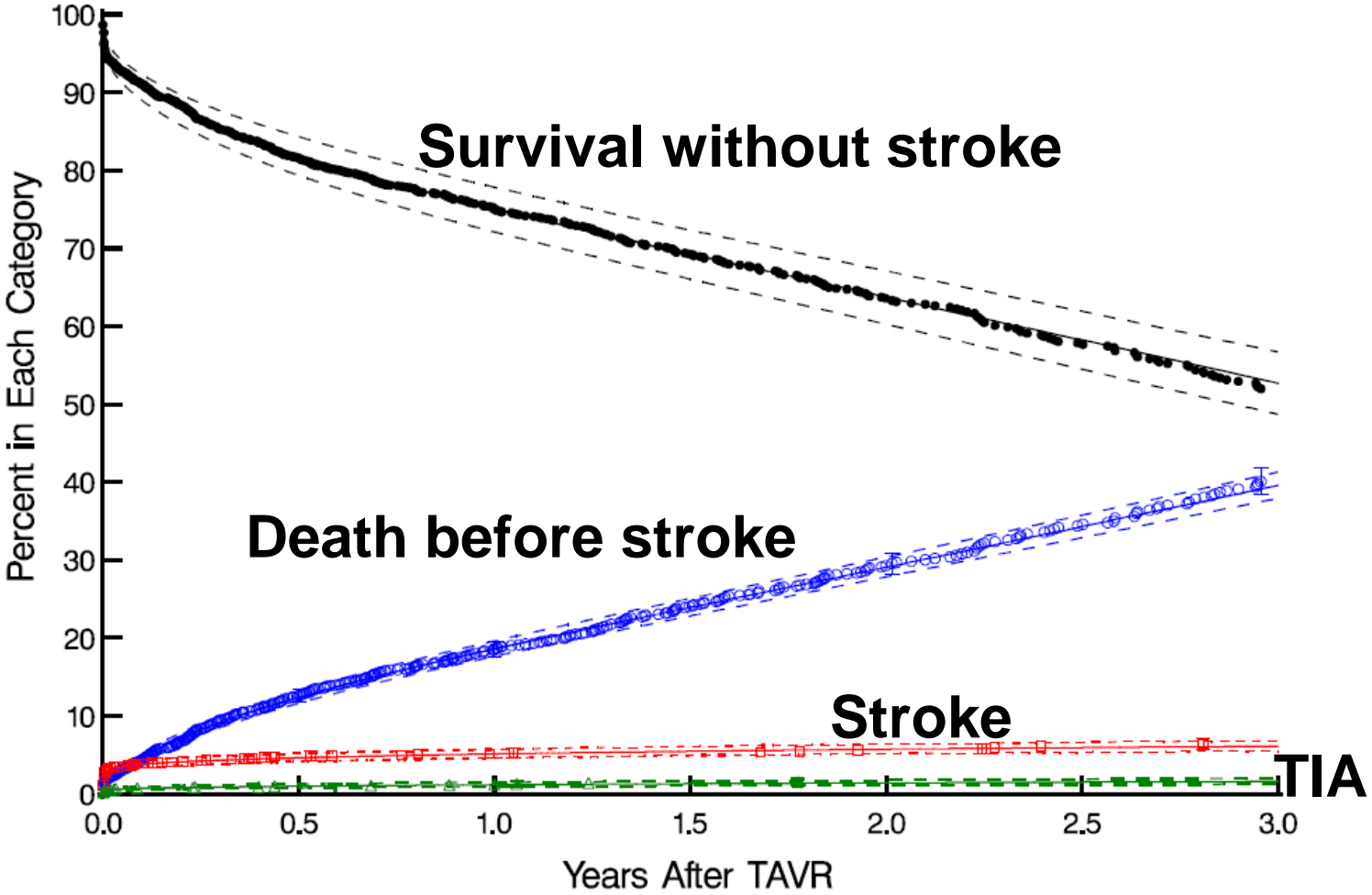
Time after TAVR and Risk of Stroke



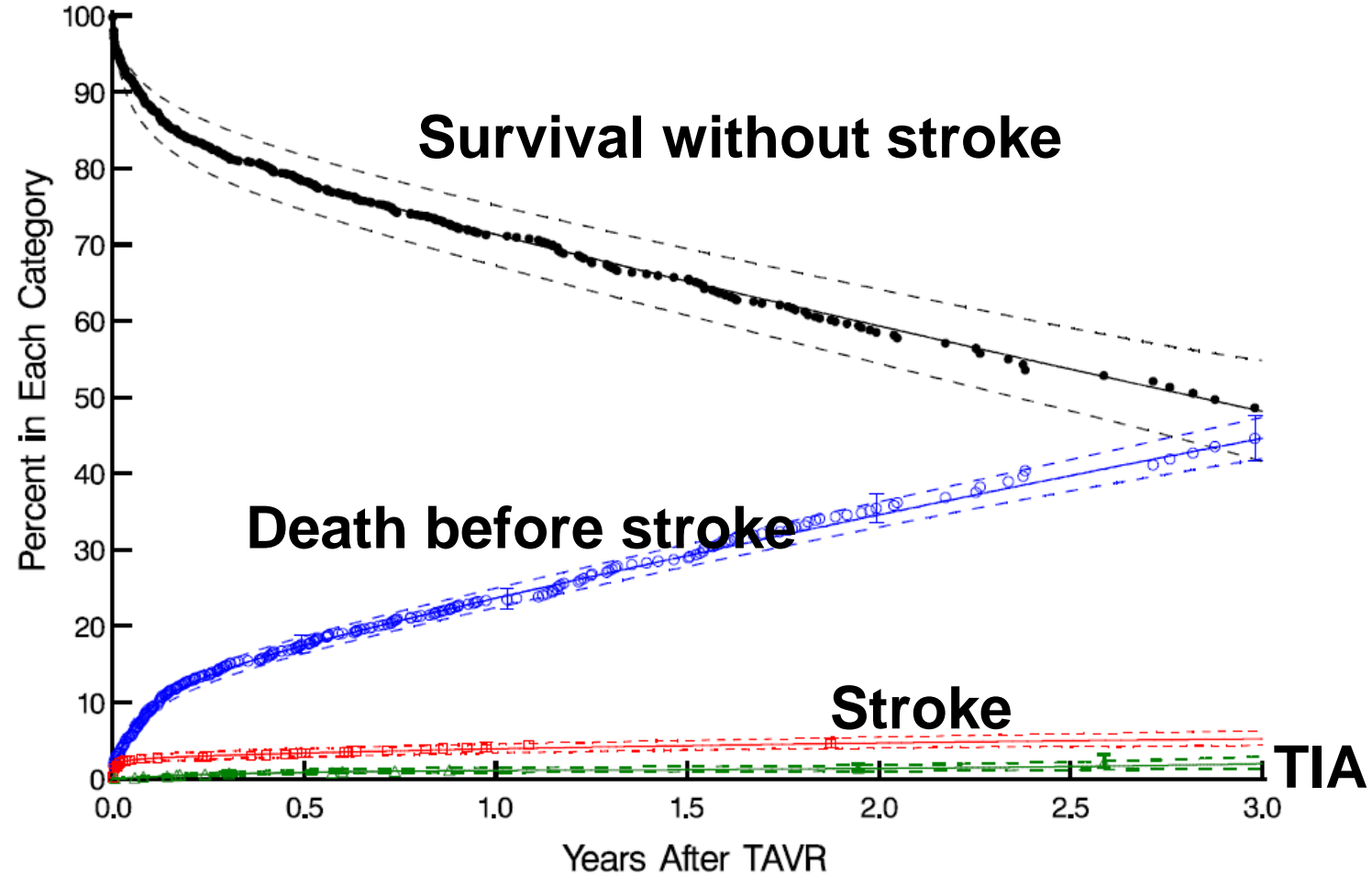
Patients at Risk

TF-TAVR	1521	1231	929	648	468	295	201
TA-TAVR	1100	830	554	316	191	75	45

Competing Risk Analysis for TF TAVR n=1521, 3 year data



Competing Risk Analysis for TA TAVR n=1100, 3 year data



Summary

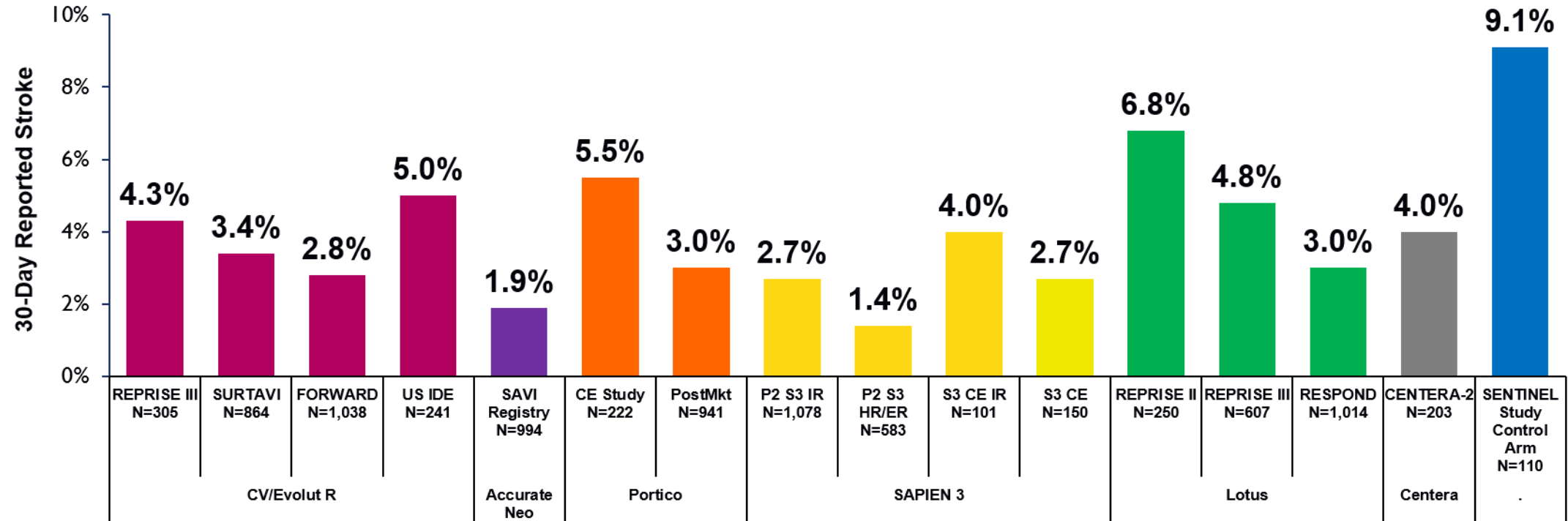
- Majority of risk for stroke after TAVR is immediately after TAVR.
- Continued risk of stroke is constant and low after TAVR

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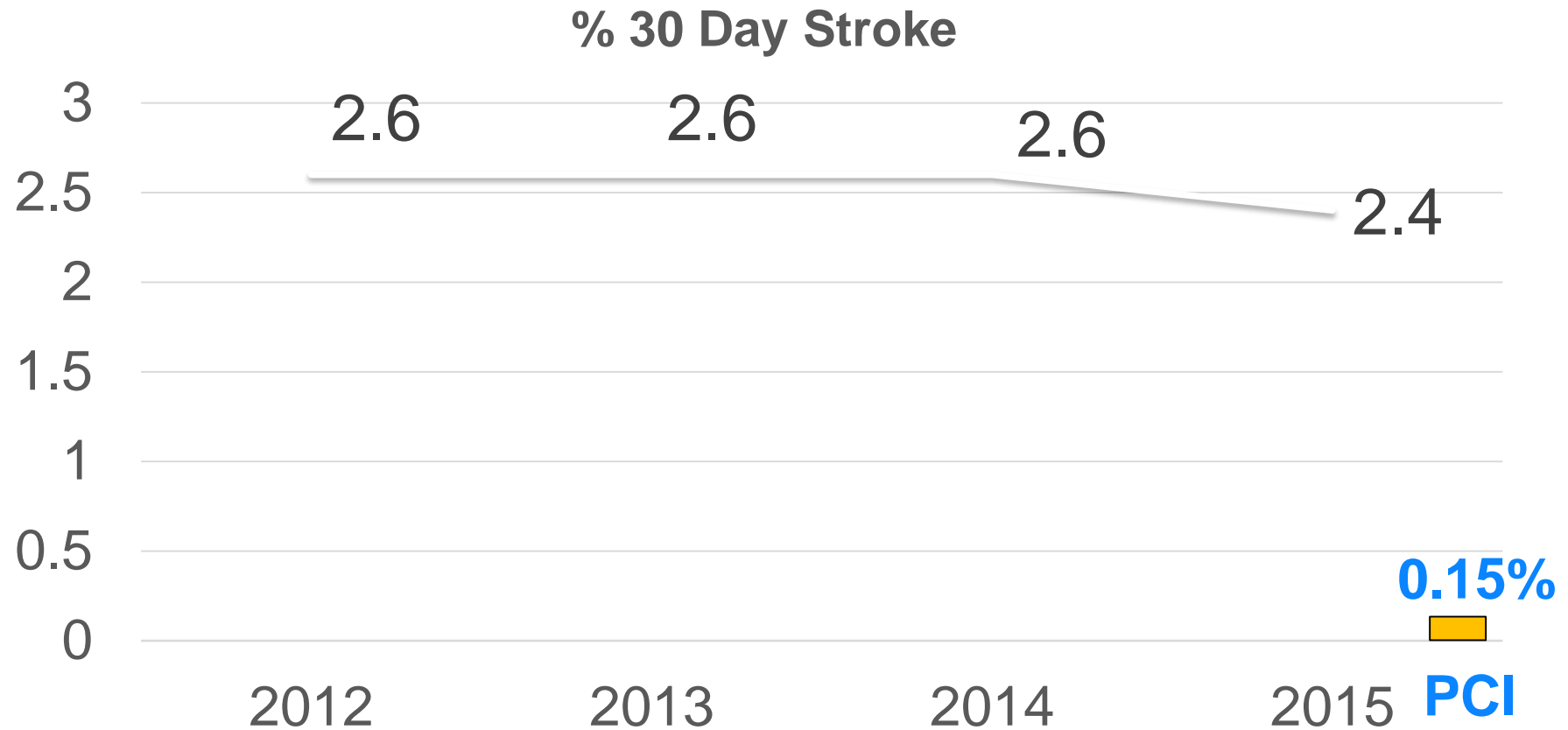
30 Day Clinical Stroke Rates Contemporary TAVR Devices

○ Stroke remains an issue (4% average rate) in contemporary TAVR studies



Valves 2015; Falk, et al. Eur Heart J 2017; Kodali, TCT 2016; Reardon, M NEJM 2017; Reichenspurner H, et al., JACC 2017; Popma et al, JACC:CVInt 2017;10(3):268-75; Maisano F presented at TVT 2018

TVT Stroke Rate



Stroke Risk Summary

Stroke risk is decreased compared to early feasibility trials (but not much) and is still a significant clinical problem

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Cardiovascular Surgery

Stroke After Aortic Valve Surgery Results From a Prospective Cohort

Steven R. Messé, MD; Michael A. Acker, MD; Scott E. Kasner, MD; Molly Fanning, BS;
Tania Giovannetti, PhD; Sarah J. Ratcliffe, PhD; Michel Bilello, MD, PhD;
Wilson Y. Szeto, MD; Joseph E. Bavaria, MD; W. Clark Hargrove, III, MD;
Emile R. Mohler III, MD; Thomas F. Floyd, MD;
for the Determining Neurologic Outcomes from Valve Operations (DeNOVO) Investigators

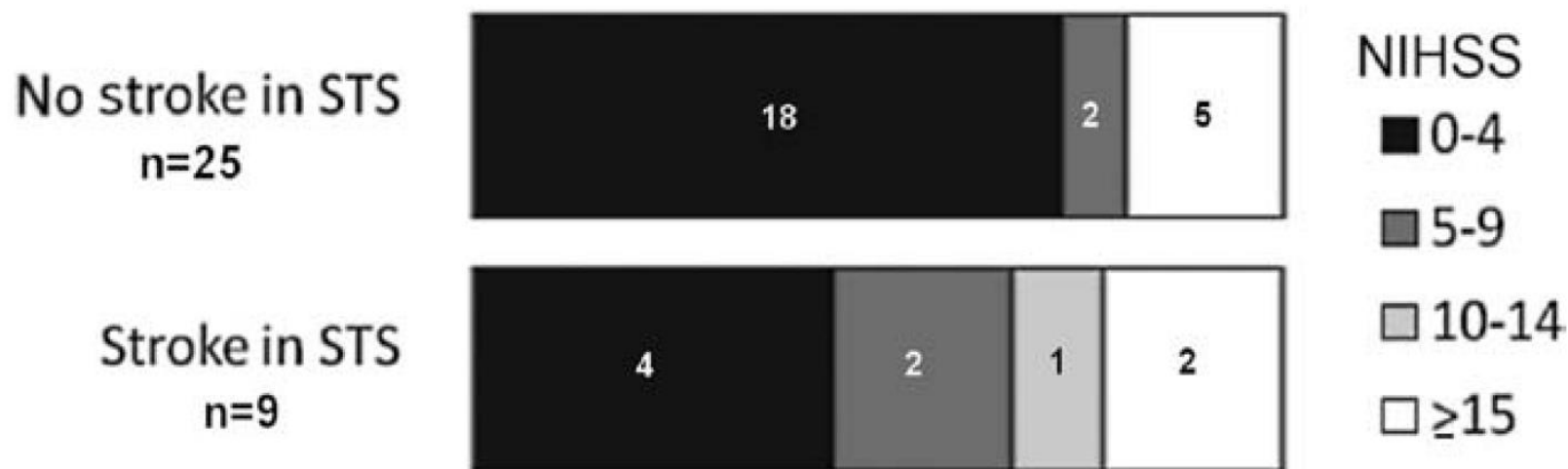
Conclusions—Clinical stroke after AVR was more common than reported previously, more than double for this same cohort in the Society for Thoracic Surgery database, and silent cerebral infarctions were detected in more than half of the patients undergoing AVR. Clinical stroke complicating AVR is associated with increased length of stay and mortality. (*Circulation*. 2014;129:2253-2261.)

Stroke Detection and Reporting

Strokes = 34 patients (17%; 95% CI, 12-23%)

TIA = 4 patients (2%; 95% CI, 0 -4%)

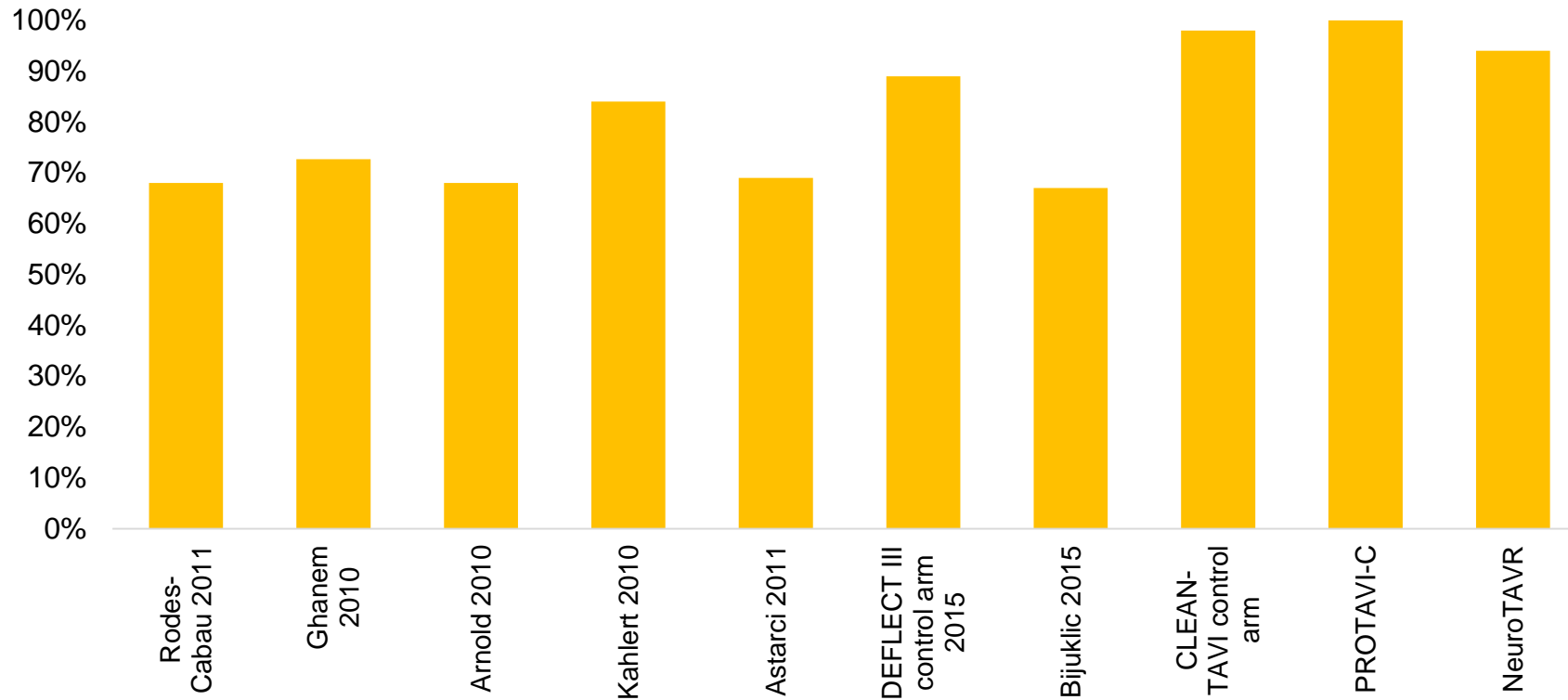
25 “strokes” were not included in STS database



STS database reported 13 patients (6.6%) with stroke but 4 did not have stroke by DeNOVO (alcohol withdrawal, no deficit by day 7)

MRI Lesions After TAVR

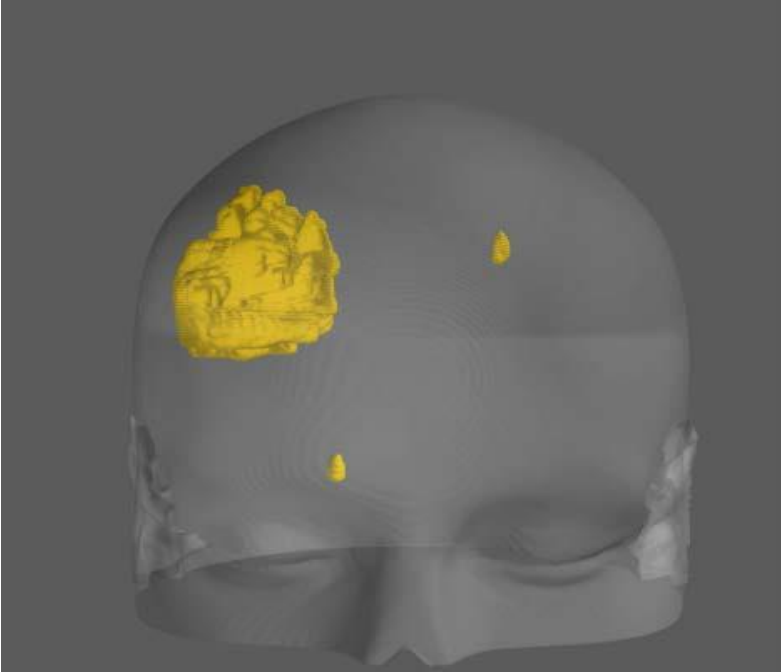
% of TAVI patients with new cerebral lesions on DW-MRI



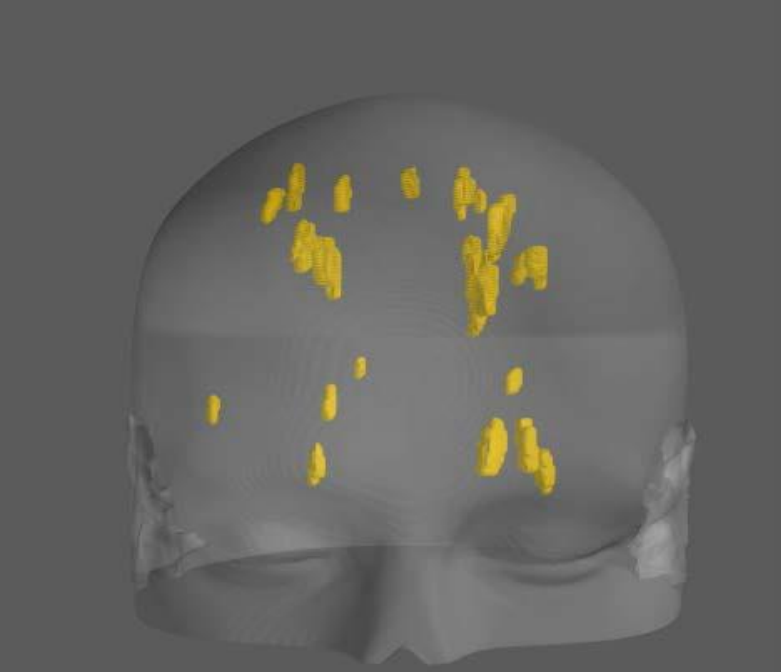
- .1. Rodes-Cabau, et al., JACC 2011; 57(1):18-28
- .2. Ghanem, et al., JACC 2010; 55(14):1427-32
- .3. Arnold, et al., JACC:CVI 2010; 3(11):1126-32
- .4. Kahlert, et al., Circulation. 2010;121:870-878
- .5. Astarci, et al., EJCTS 2011; 40:475-9
- .6. Lansky, et al., EHJ 2015; May 19
- .7. Bijuklic, et al., JACC: CVI 2015
- .8. Linke, et al., TCT 2014
- .9. Vahanian, TCT 2014
- .10. Lansky, et al. London Valves 2015
- .11. Sacco et al., Stroke 2013
- .12. Vermeer et al., Stroke 2003
- .13. Vermeer et al., New Engl J Med 2009

Overt Stroke – Size, Number, LOCATION

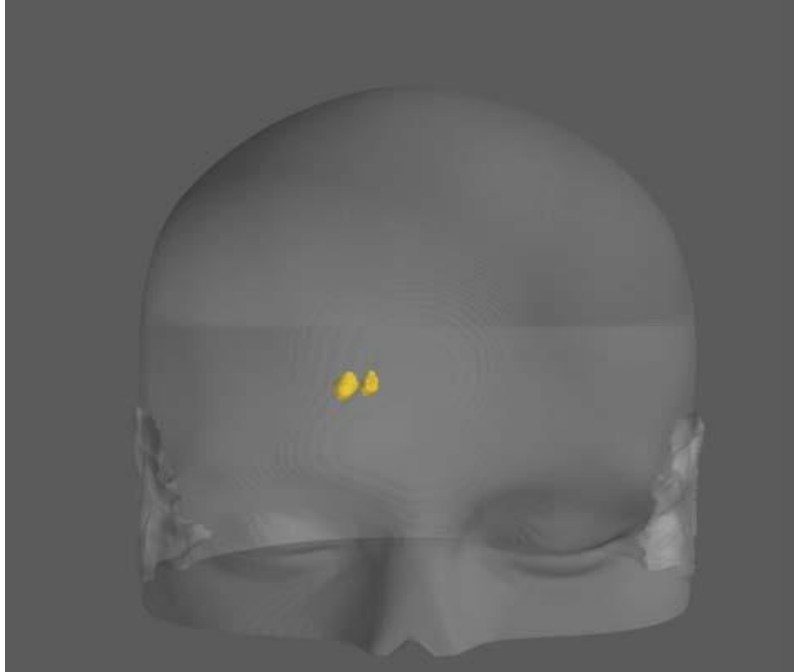
Number



Location



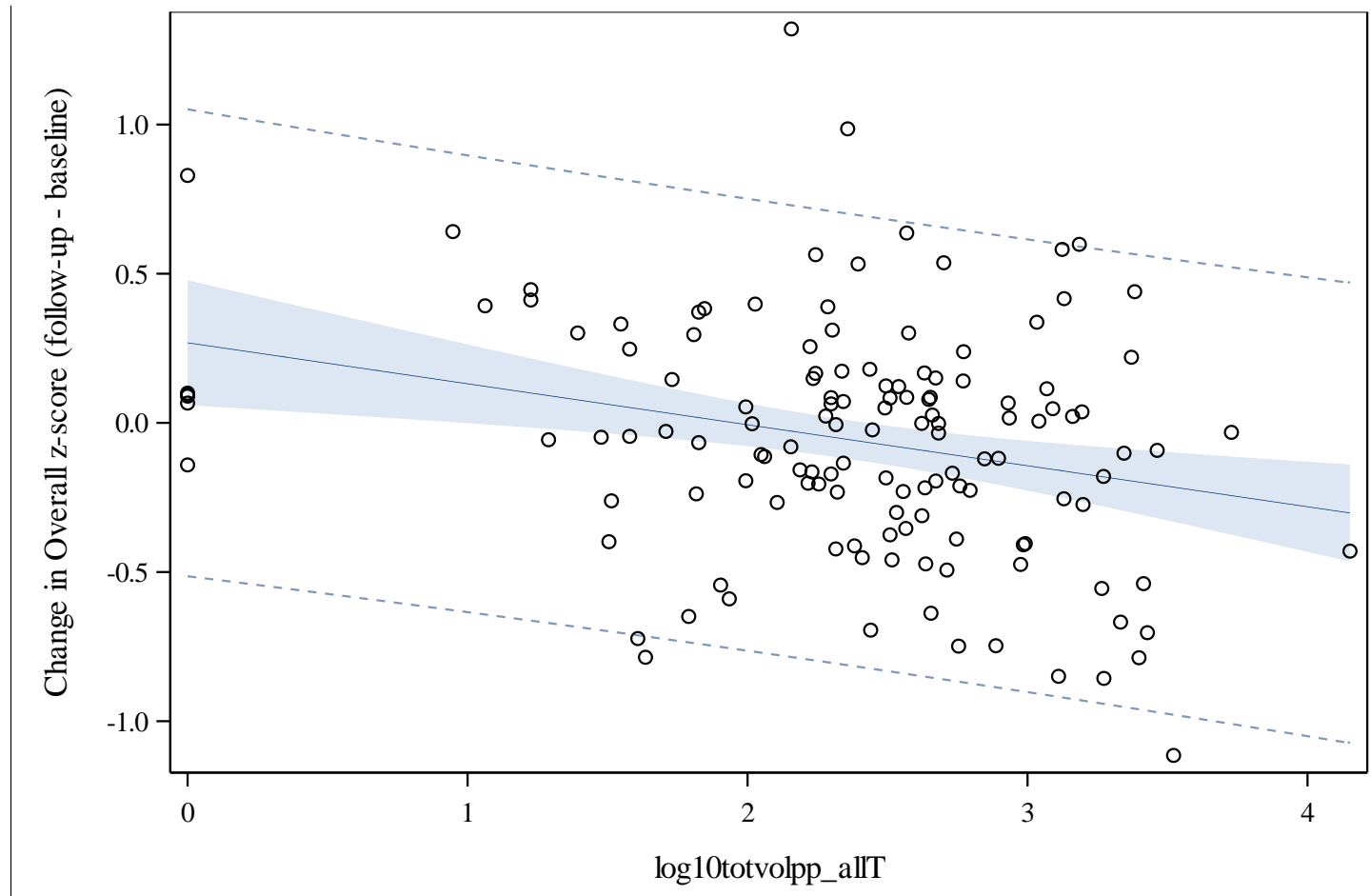
Size

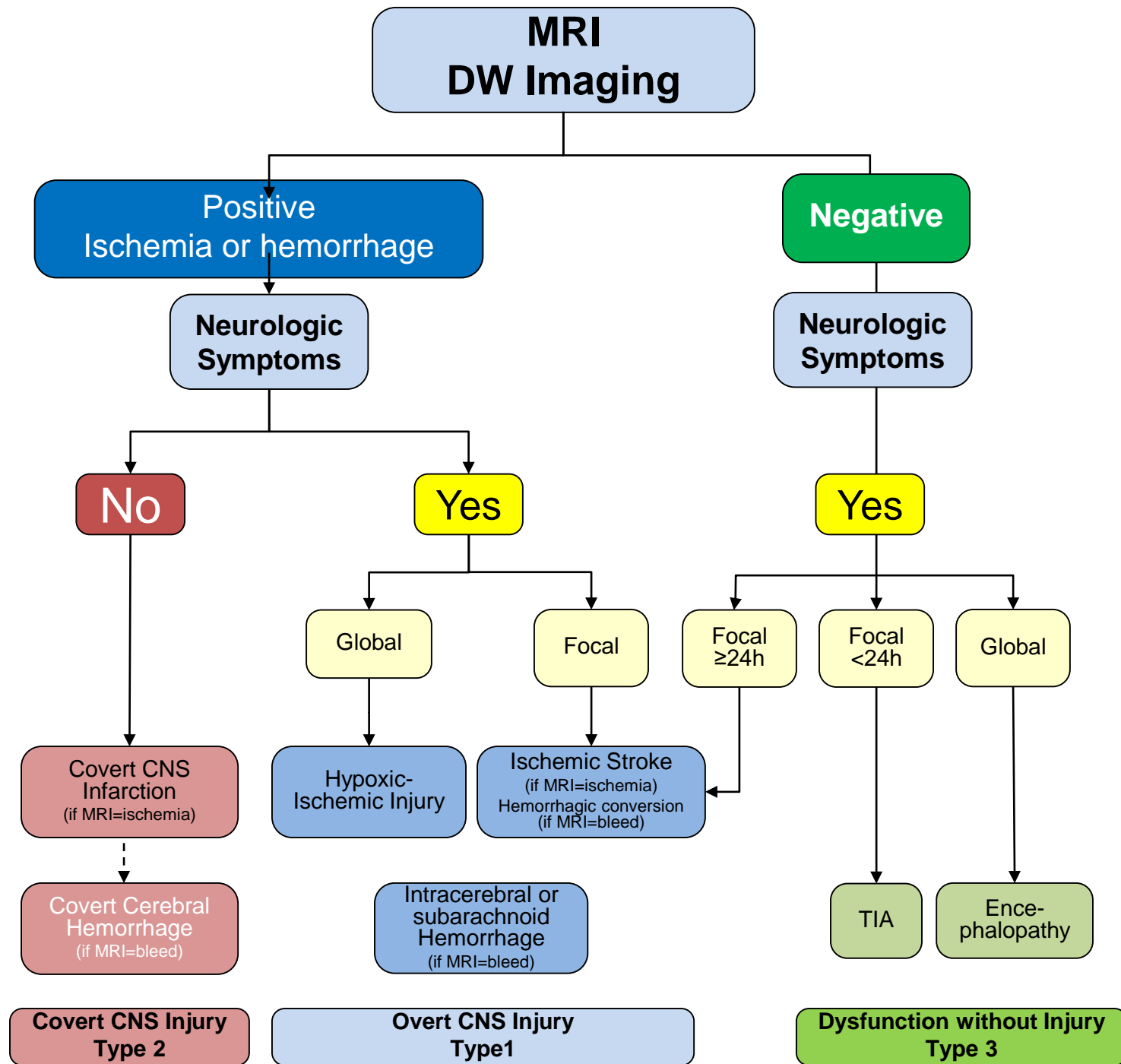


All patients with clinical stroke in control arm of Sentinel Trial

Neurocognitive Changes and Lesions

Lesion Volume, All Territories, $P=0.0015$





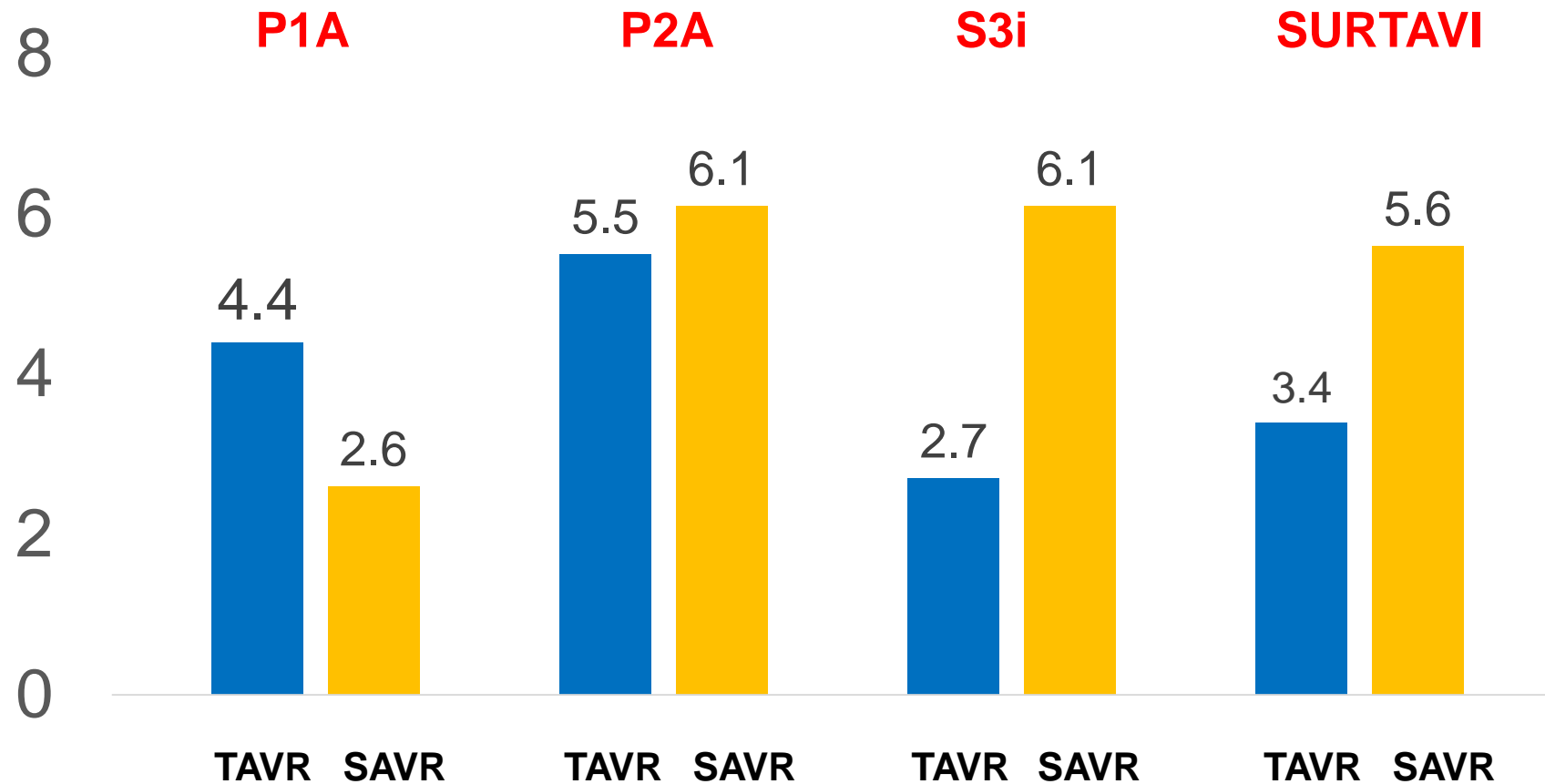
Summary - Ascertainment

- **Definitions of Stroke – NeuroARC Document**
- **Serious underestimation of risk without proper neurologic evaluation**
- **Large number of “covert strokes”**

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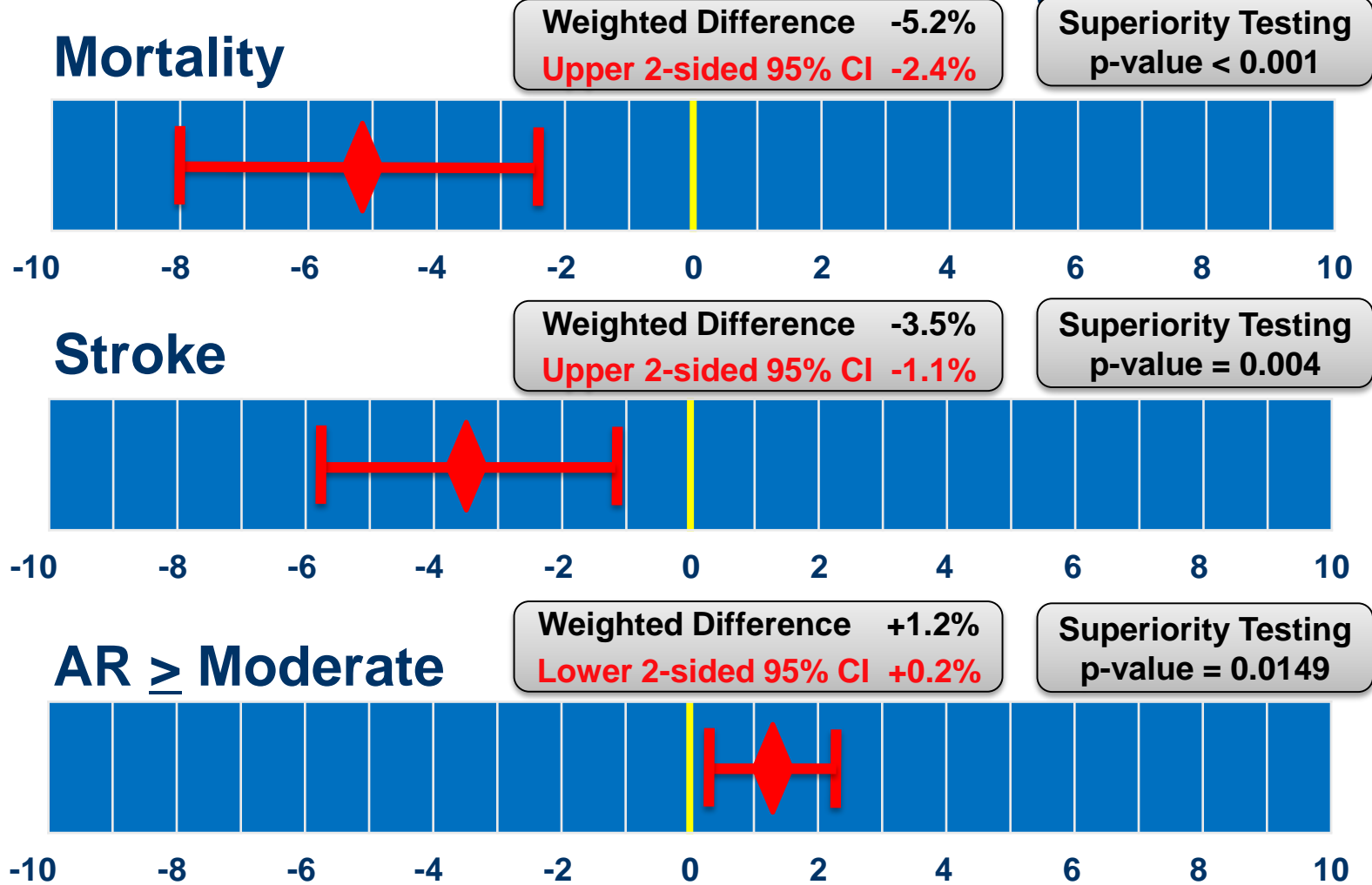
Clinical Stroke : TAVR versus SAVR



Superiority Analysis

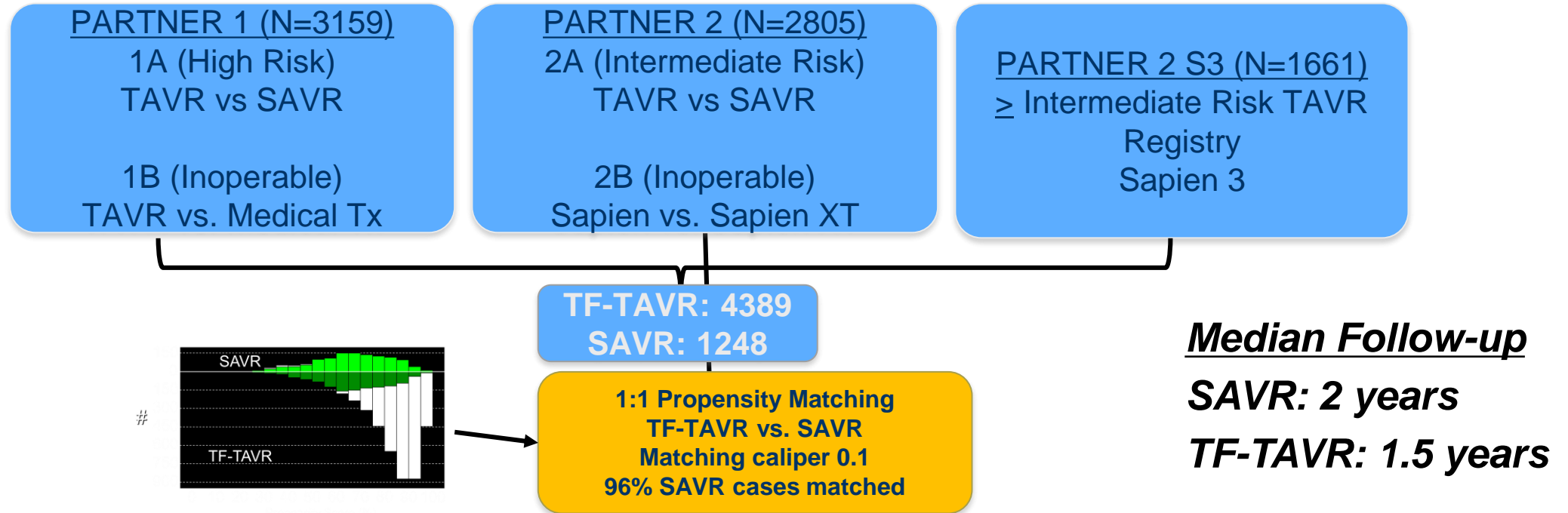
Components of Primary Endpoint (VI)

← Favours TAVR Favours Surgery →



Comprehensive Analysis - PARTNER

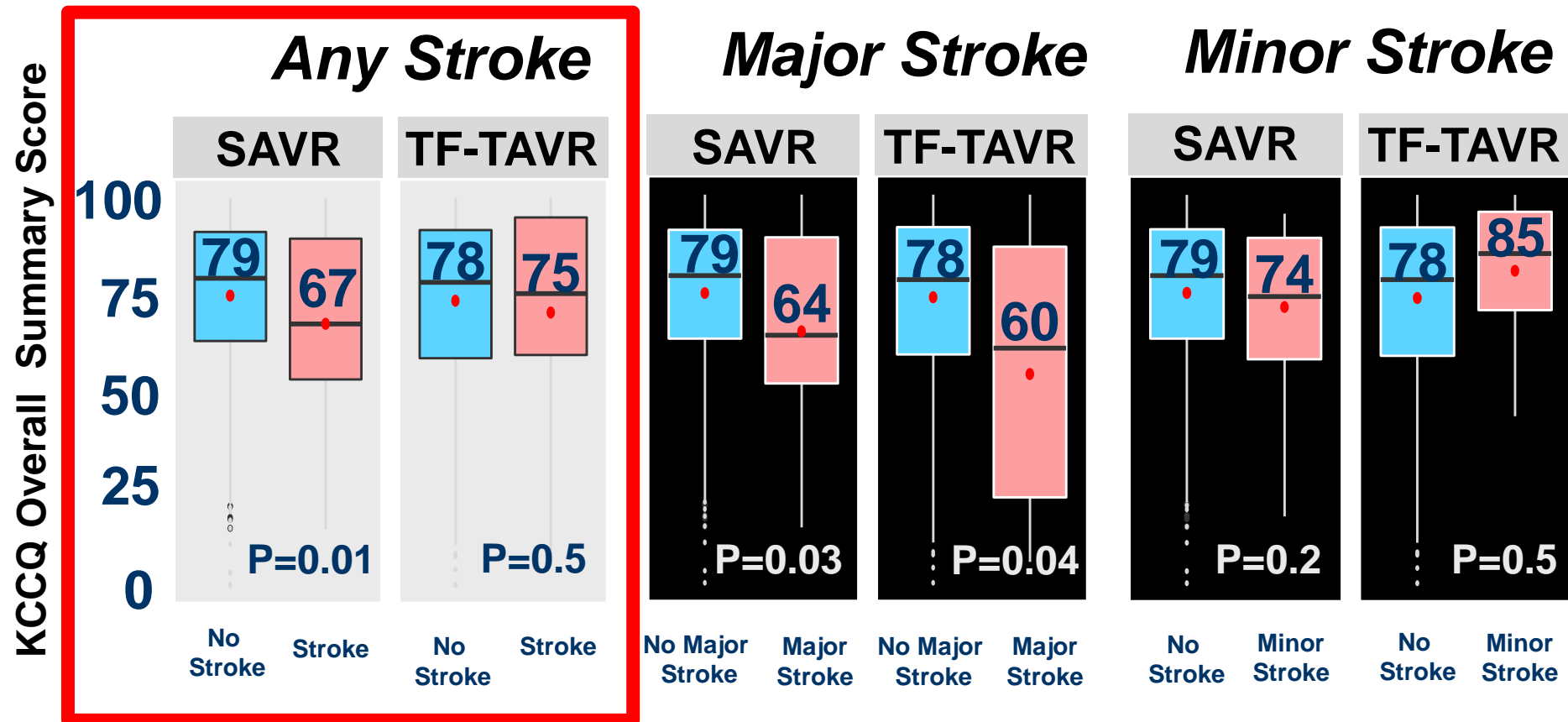
April 2007 – October 2015



Final Propensity Matched Study Population

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

Association of Stroke and 1 Year Quality of Life



Summary

1. 30-day major stroke risk lower in TF-TAVR.
2. Similar pattern of early-peaking (<24 hours) and nearly constant late neurologic risk between SAVR and TF-TAVR.
3. Major, but not minor, strokes are associated with lower QOL at 1-year.