

# Stroke after Surgical vs. Transfemoral Transcatheter Aortic Valve Replacement: In Depth Analysis from the PARTNER Trial

**Chetan P. Huded, MD MSc**

On behalf of S. Kapadia, S. Kodali, L. Svensson, E. Tuzcu, S. Baron, S. Arnold, D. Cohen, D. Miller, V. Thourani, H. Herrmann, M. Mack, M. Szerlip, R. Makkar, J. Webb, C. Smith, J. Rajeswaran, E. Blackstone, & M. Leon.

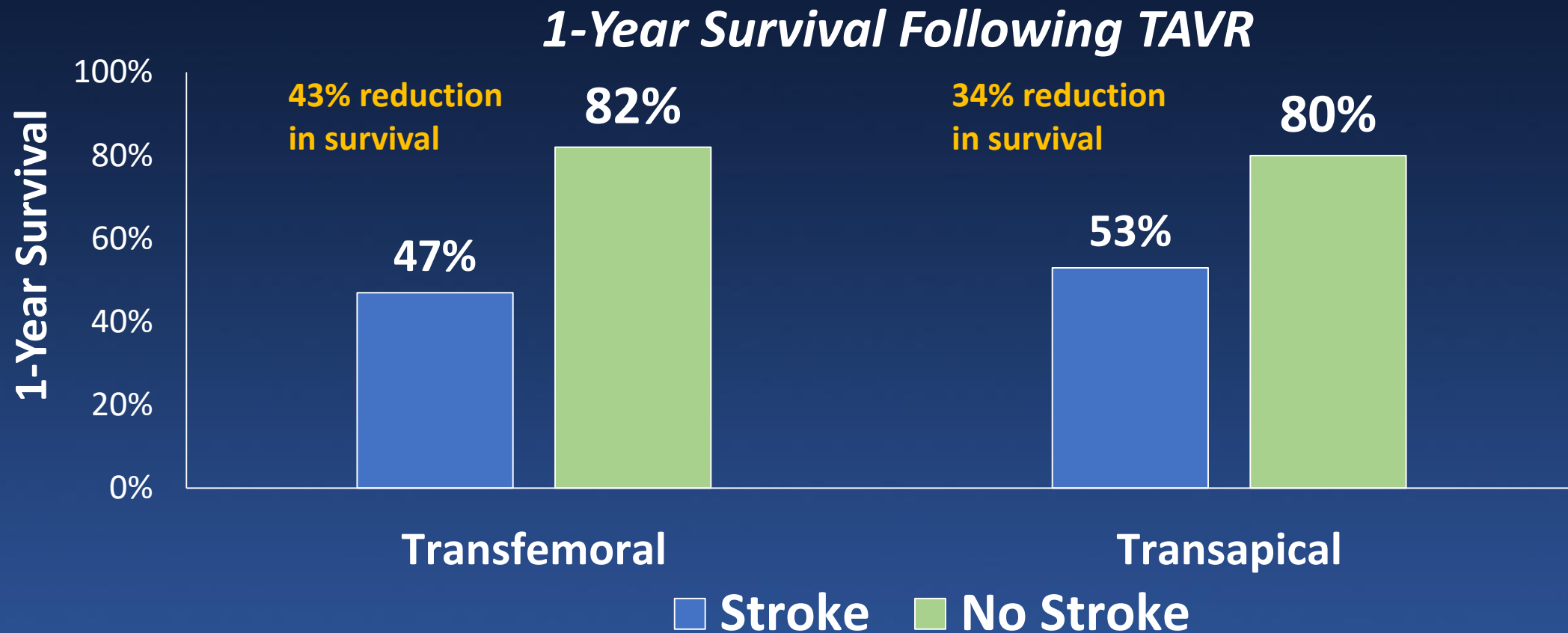
# Disclosure Statement of Financial Interest

I, Chetan Huded, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

# Background

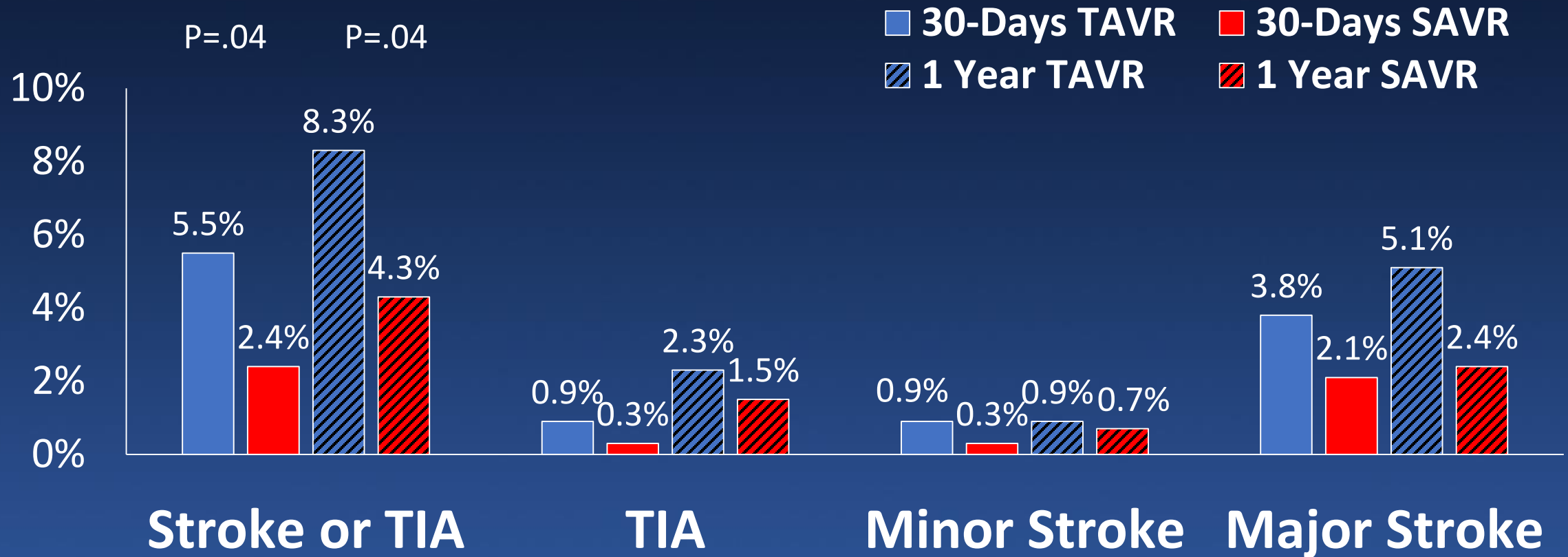
- Stroke is an important complication of aortic valve replacement procedures.
- In contemporary practice, >90% of TAVR is performed from a transfemoral (TF) approach.
- The risk of stroke in TF-TAVR vs. SAVR is unknown.

# Stroke is Associated with a Major Reduction in 1-Year Survival after TAVR



Kapadia et al. Circ Cardiovasc Interv. 2016

# PARTNER 1A Raised Concern of Increased Neurologic Risk of TAVR



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

# Objective

To study the risk of neurologic events and relationship to quality of life in a large prospective cohort of SAVR vs. TF-TAVR in a pooled analysis of the PARTNER Trials.

# Methods

April 2007 – October 2015

**PARTNER 1 (N=3159)**

1A (High Risk)  
TAVR vs SAVR

1B (Inoperable)  
TAVR vs. Medical Tx

**PARTNER 2 (N=2805)**

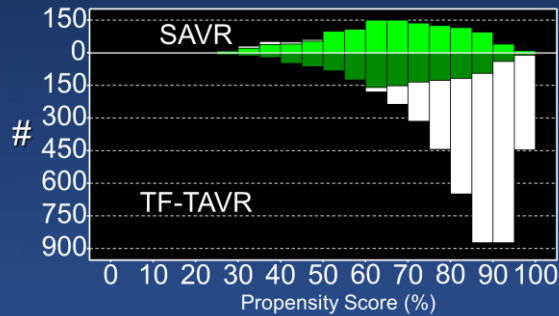
2A (Intermediate Risk)  
TAVR vs SAVR

2B (Inoperable)  
Sapien vs. Sapien XT

**PARTNER 2 S3 (N=1661)**

≥ Intermediate Risk TAVR  
Registry  
Sapien 3

TF-TAVR: 4389  
SAVR: 1248



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

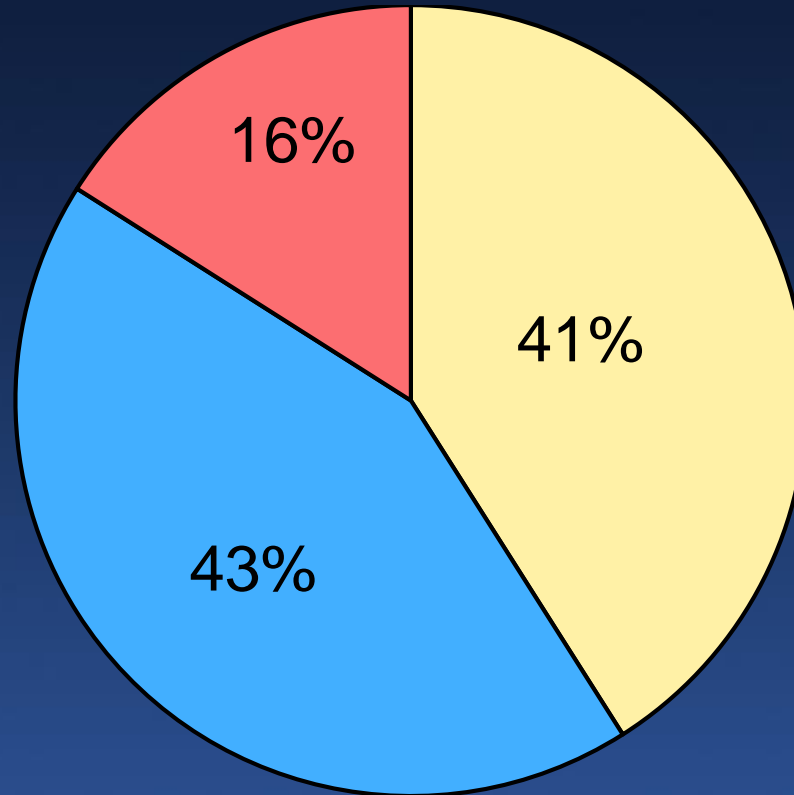
- Excluded 1988 (26%)
1. Medical therapy arm
  2. Non-femoral TAVR
  3. Cross-over between TAVR/SAVR
  4. Died prior to AVR

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

# TF-TAVR Devices in the Propensity Matched Study Population



■ SAPIEN ■ SAPIEN XT ■ SAPIEN 3



# Study Outcomes

## Outcome

## Analysis

1. 30-Day Neurologic Events

Chi square test

2. Early and Late-Phase Neurologic Risk

Multiphase non-proportional hazards model

Competing risk methodology

3. Relationship of Post-op AV Gradients and Stroke

Time-related hazard model of stroke with post-procedure AV gradient

4. Relationship of Stroke with 1 Year Quality of Life

1 Year KCCQ overall summary score  
Linear regression

# Stroke Event Adjudication

Score	Symptoms / Disability
0	No symptoms
1	Symptoms with no significant disability
2	Slight disability
3	Moderate disability
4	Moderately severe disability
5	Severe disability / bedridden
6	Death

**Minor stroke** = 90 day modified Rankin score < 2

**Major stroke** = 90 day modified Rankin score  $\geq$  2

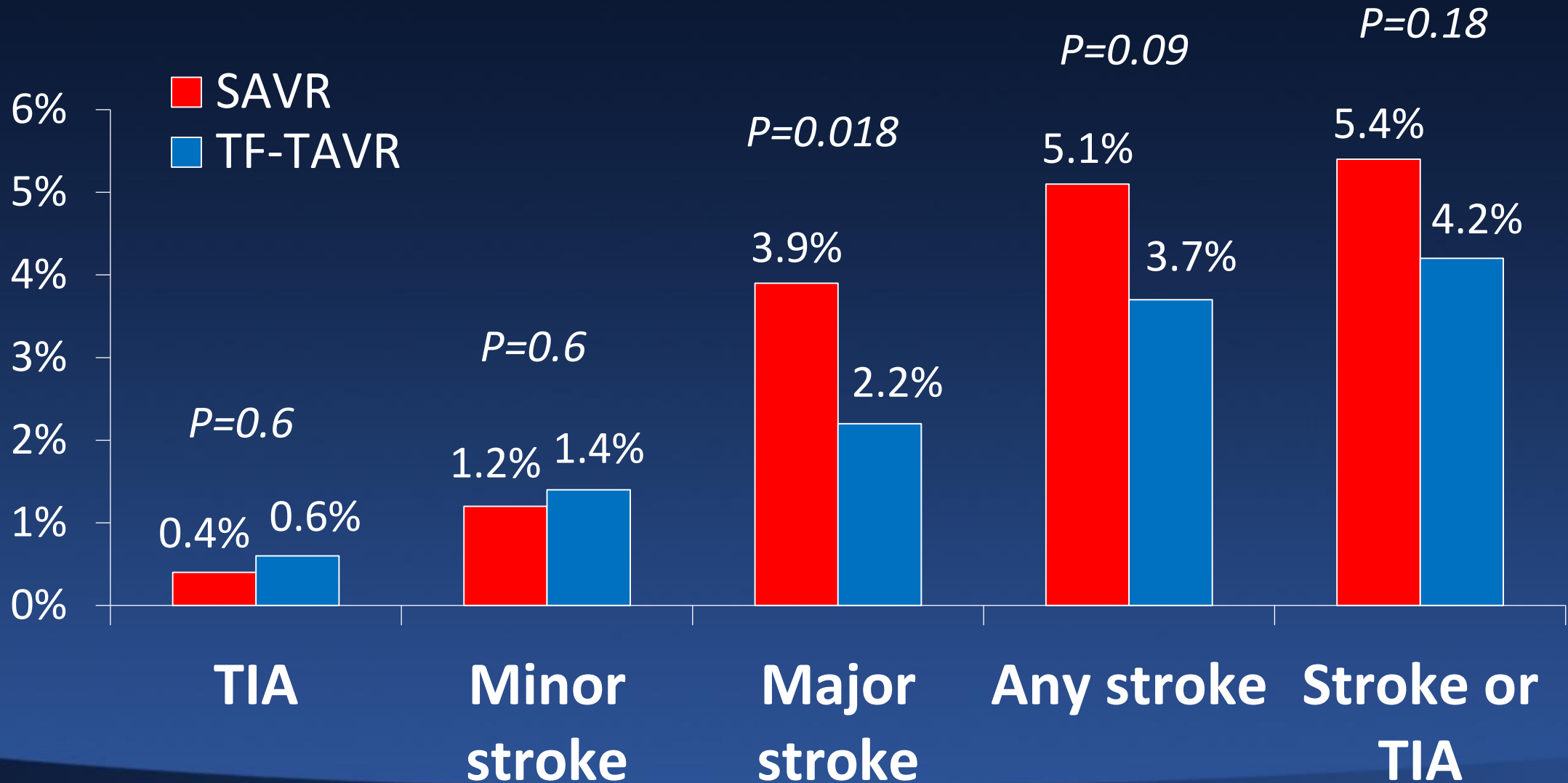
- Independent clinical events committee reviewed all neurologic events.
- Mandated postoperative neurologic assessment in PARTNER 2 and PARTNER S3 (70% of study population)

# Results

# Baseline Characteristics

<i>Characteristic</i>	<i>SAVR (n = 1204)</i>	<i>TF-TAVR (n=1204)</i>	<i>p-value</i>
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

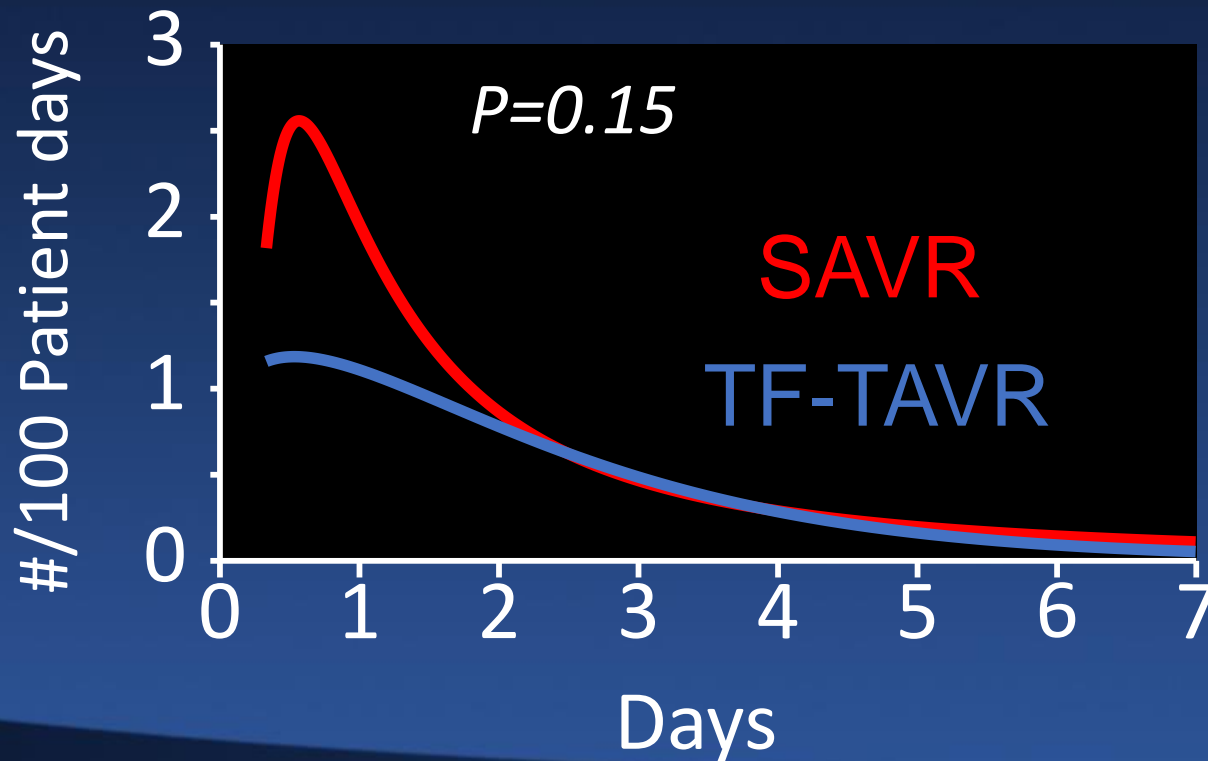
# 30-Day Neurologic Events



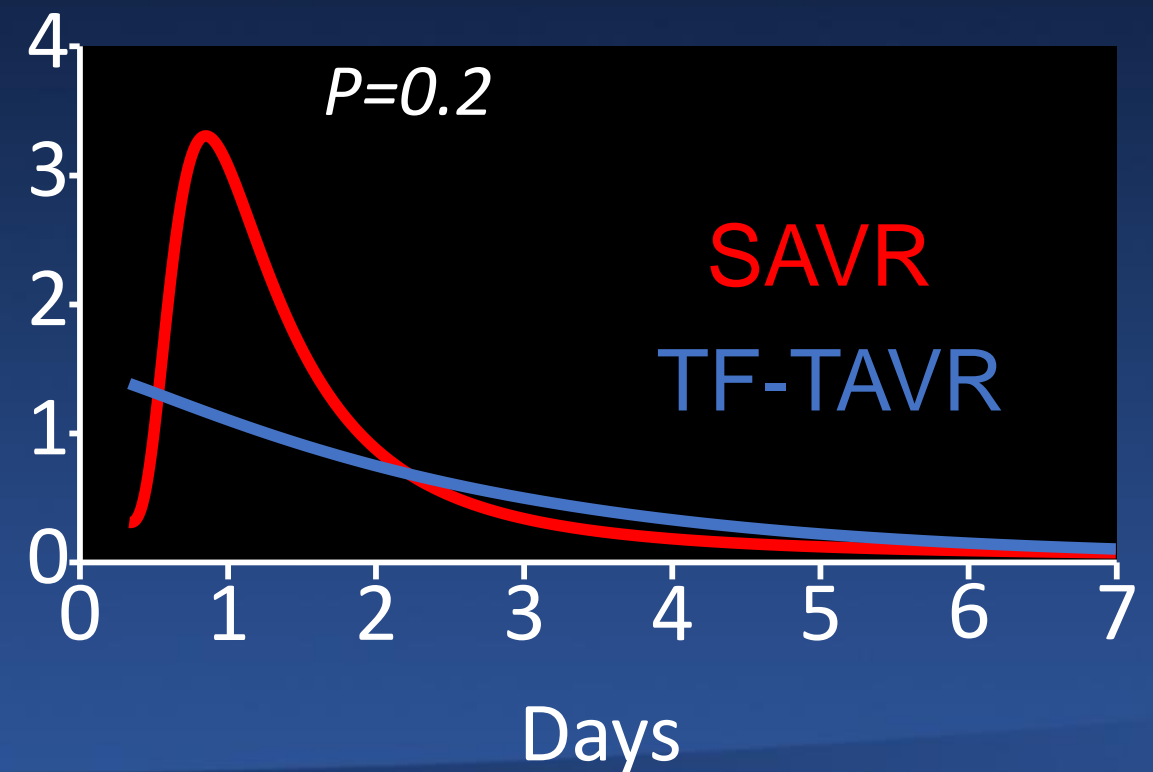
# Early Phase Risk (<7 Days)

*Instantaneous Risk Modeling*

## Stroke



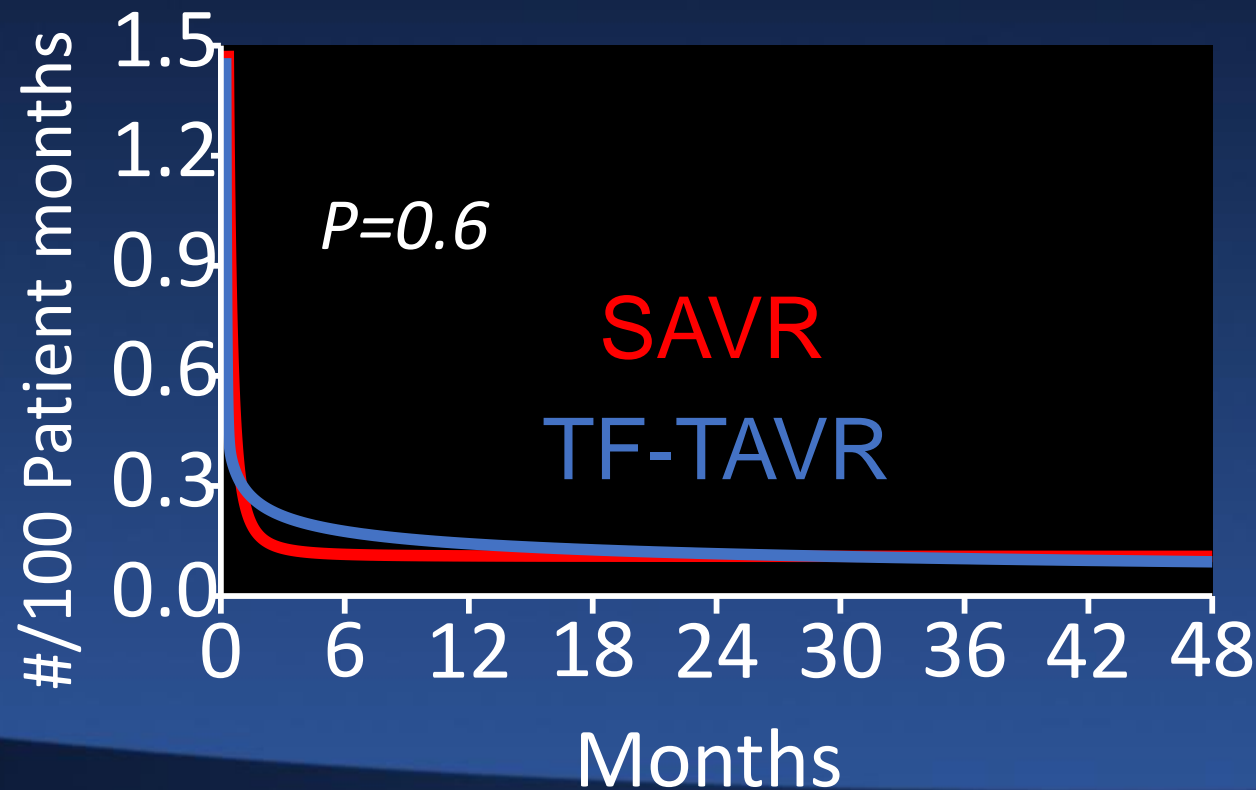
## Stroke or TIA



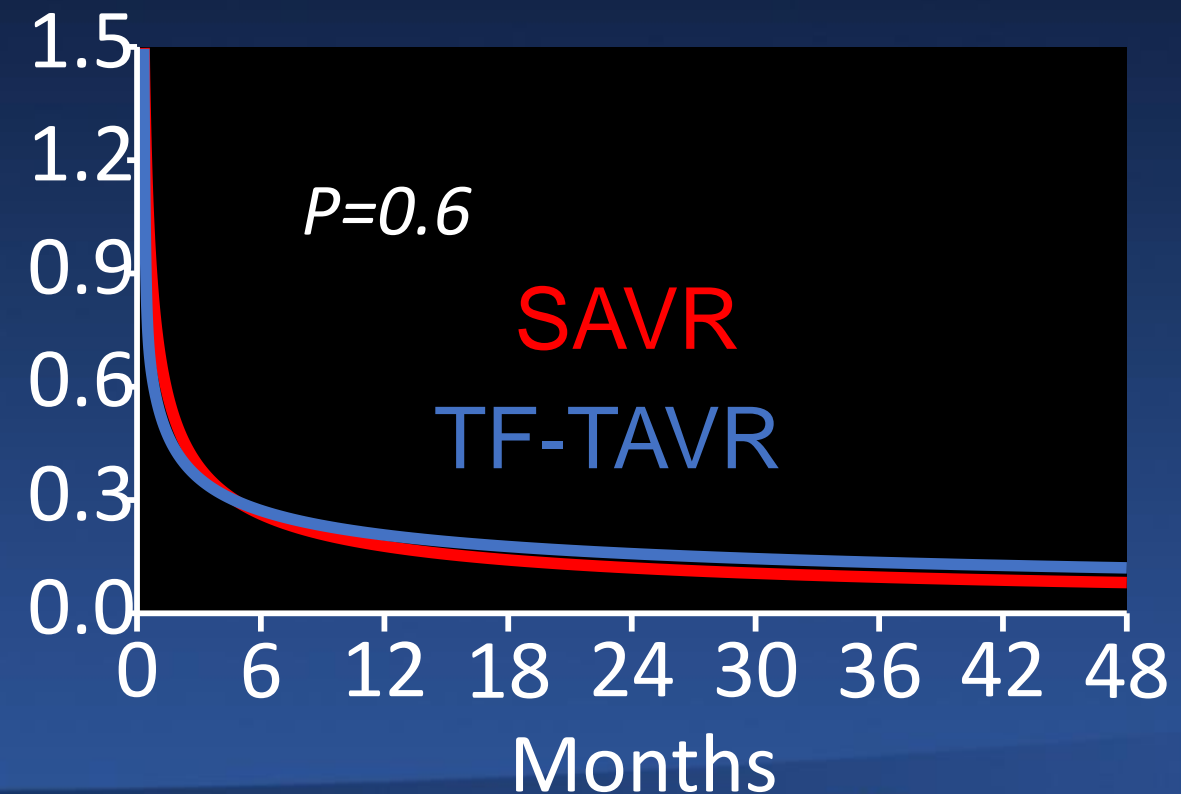
# Late Phase Risk (4 Years)

*Instantaneous Risk Modeling*

## Stroke



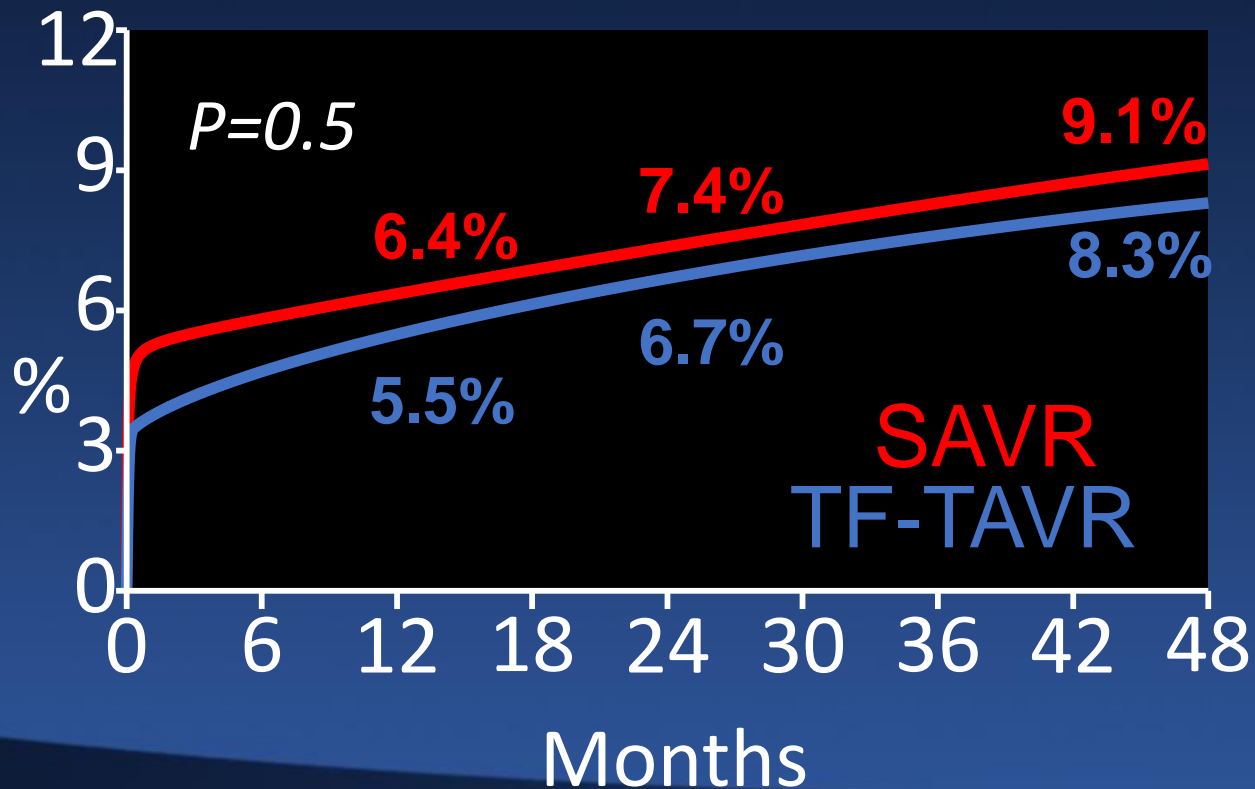
## Stroke or TIA



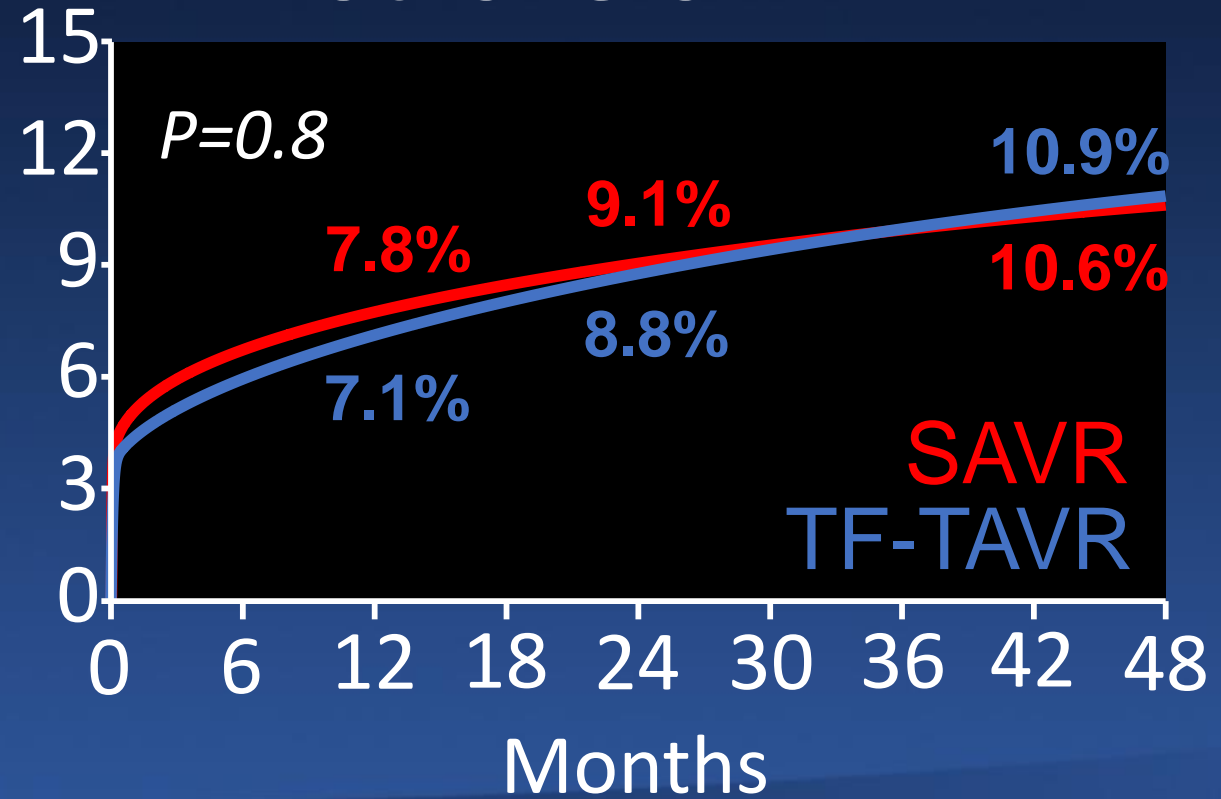
# Cumulative Incidence of Events

*Adjusted for Competing Risk of Mortality*

## Stroke



## Stroke or TIA





# Association of Postoperative AV Gradients and Late Stroke Risk

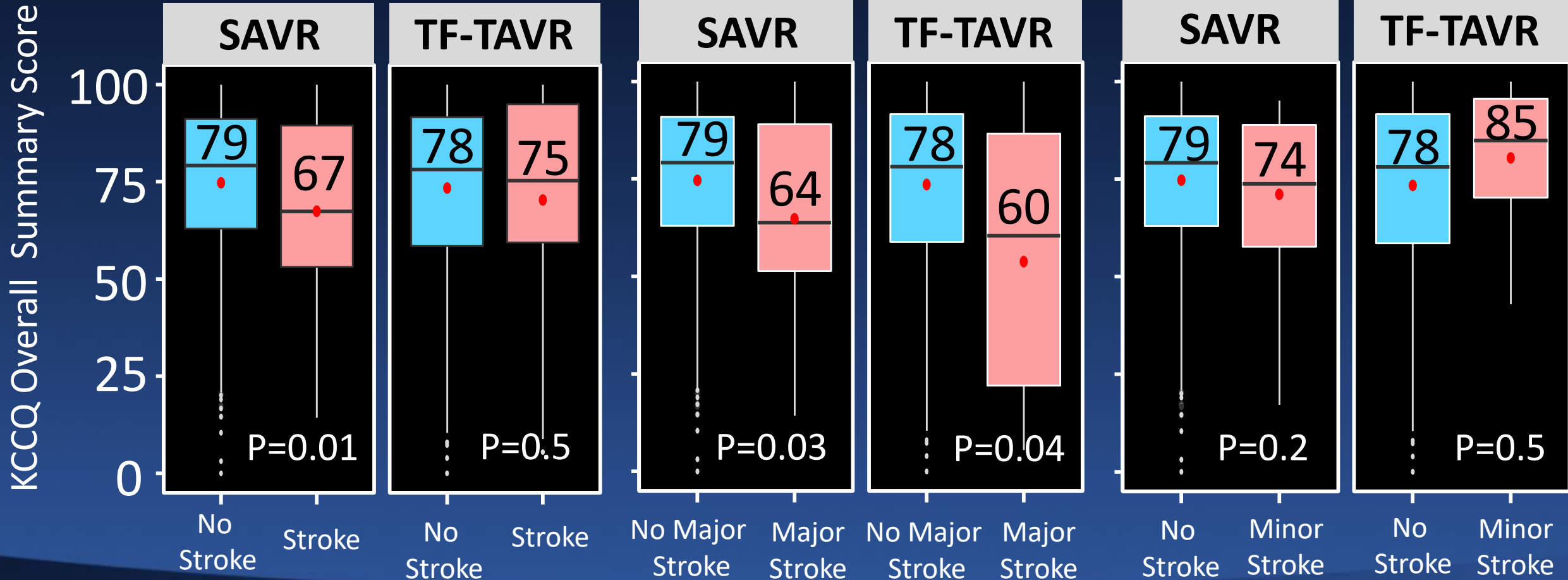
- Increasing post-procedure mean trans-AV gradient was not associated with risk of stroke ( $P > 0.7$ ).
- No interaction of AV gradient and procedure type with risk of stroke ( $P$  interaction  $> 0.2$ ).

# Association of Stroke and 1 Year Quality of Life

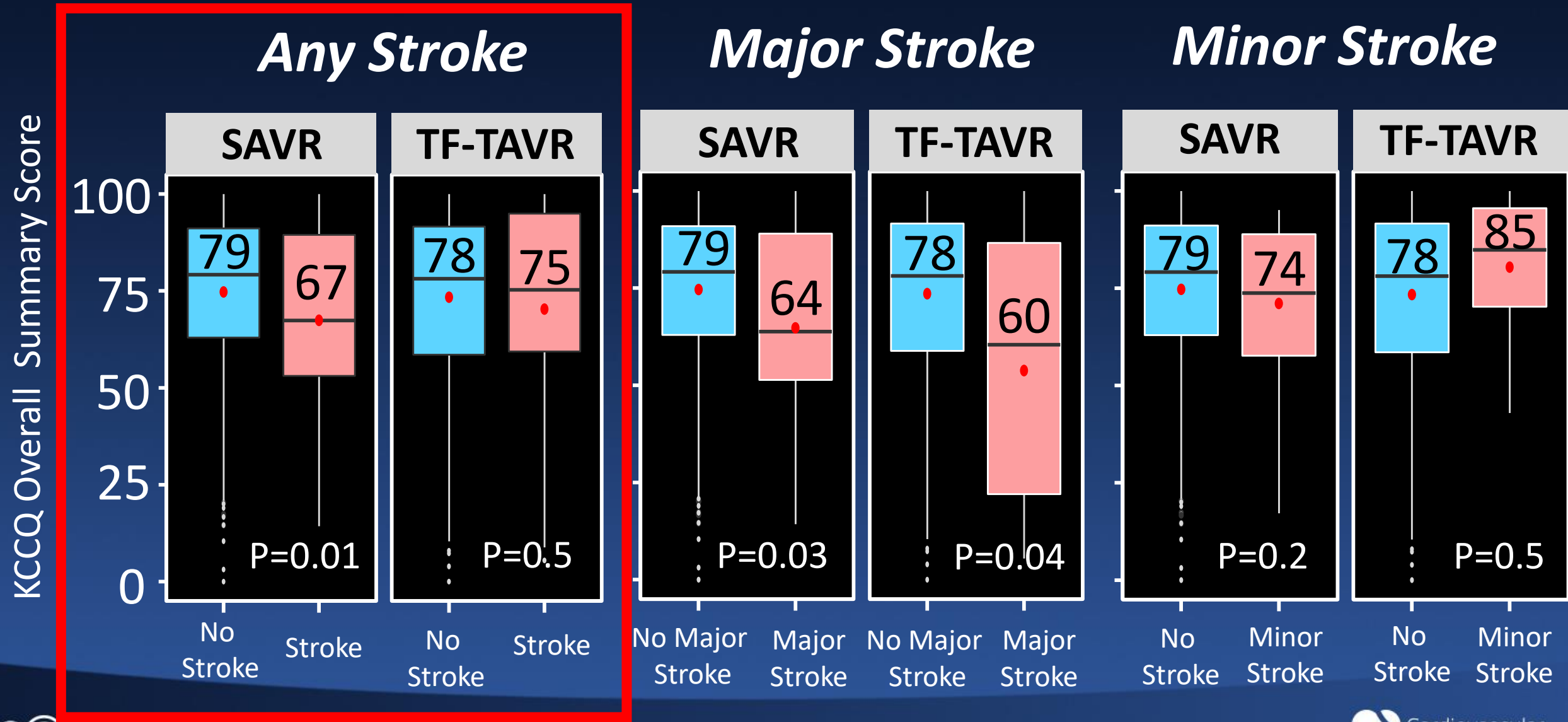
## Any Stroke

## Major Stroke

## Minor Stroke

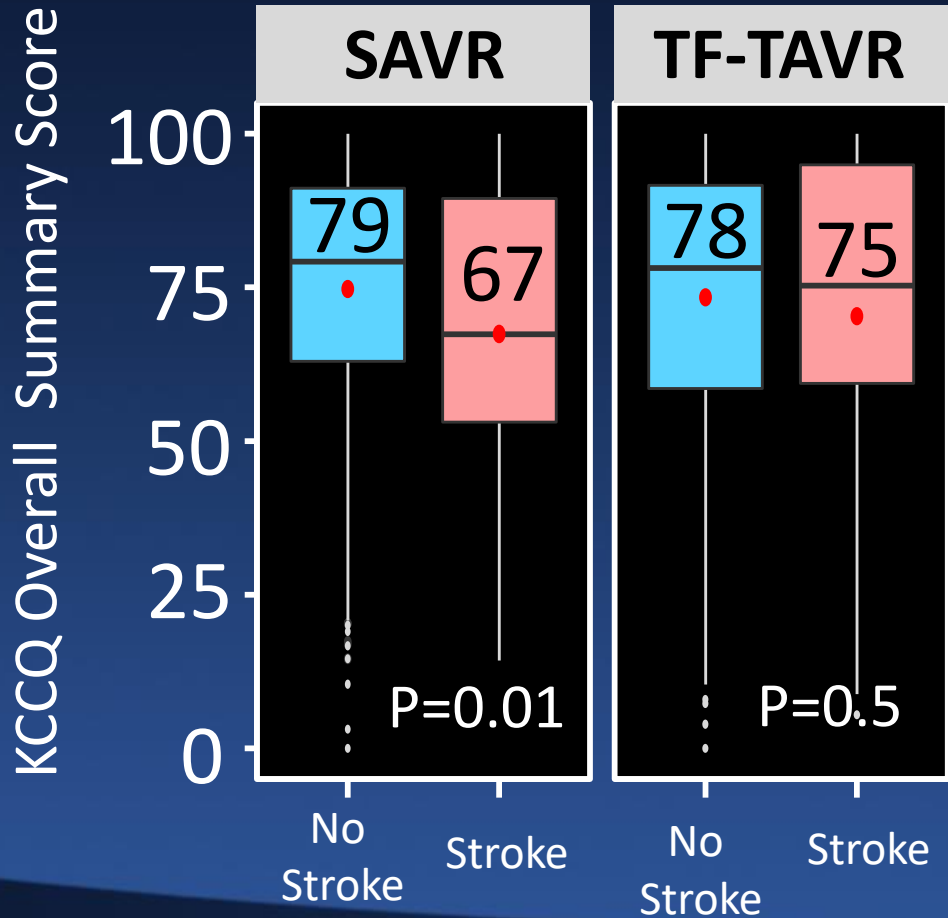


# Association of Stroke and 1 Year Quality of Life

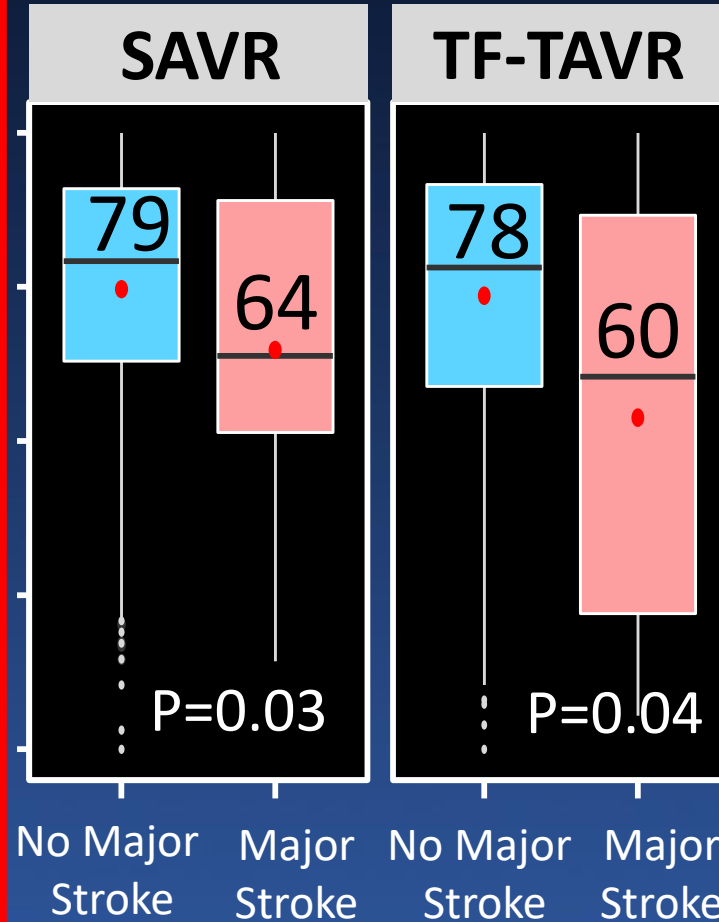


# Association of Stroke and 1 Year Quality of Life

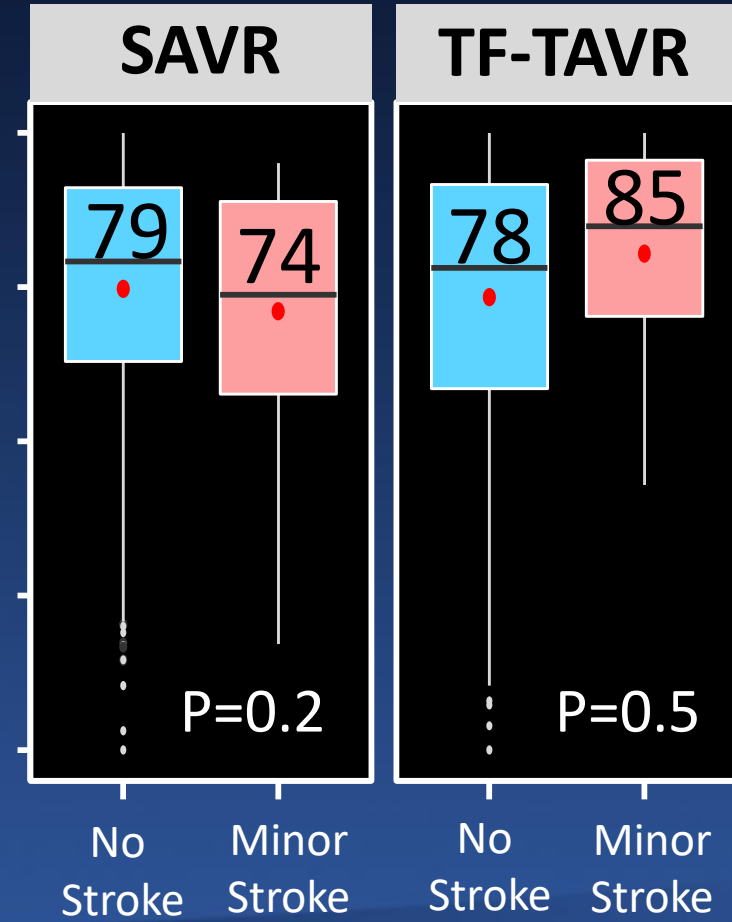
## Any Stroke



## Major Stroke



## Minor Stroke



# Principal Findings

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. 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.

# Limitations

- Non-randomized trial of SAVR vs. TF-TAVR.
- PARTNER 1 no mandated neurologic assessment.
- Changes in TF-TAVR devices over time.
- Hospital and operator-level characteristics not assessed.

# Conclusions

- The risk of early major stroke is significantly higher after SAVR vs. TF-TAVR in similar-risk patients.
- Major stroke is associated with a significantly lower quality of life at 1 year post-AVR.
- Peri-procedural strategies to mitigate stroke risk offer the potential to improve the safety of aortic valve procedures in the coming years.