“Is Stroke Risk with TAVR Exaggerated?”

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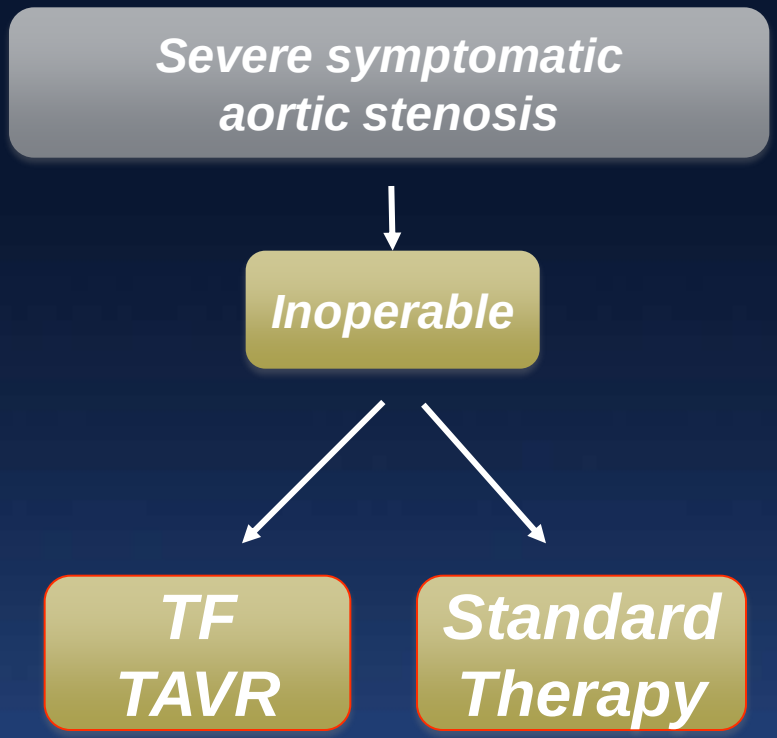
Disclosure Statement of Financial Interest

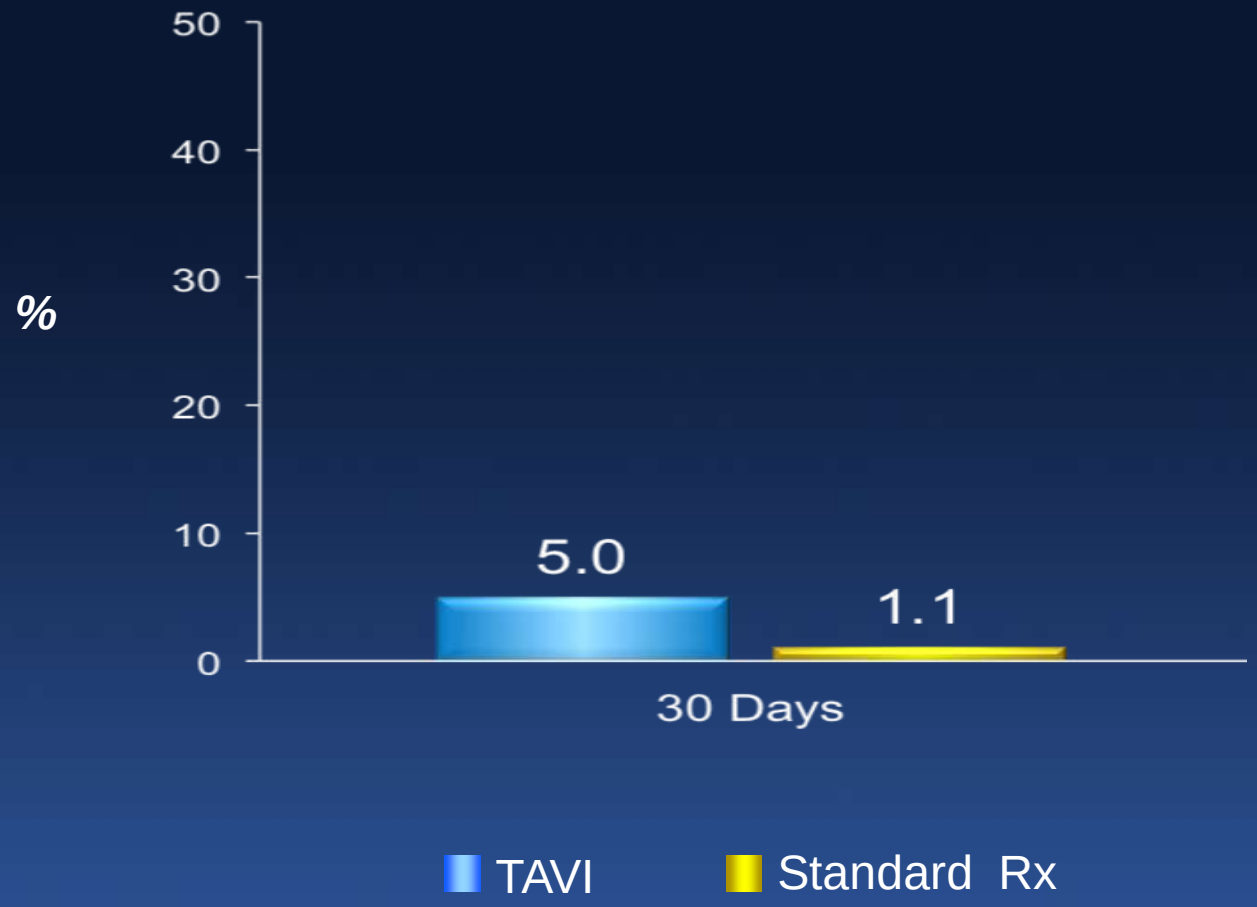
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Edwards Lifesciences
• Grant/Research Support	• Siemens
• Grant/Research Support	• Phillips
• Grant/Research Support	• Paieon Medical
• Grant/Research Support	• Valtech Cardio
• Grant/Research Support	• Guided Delivery Systems
• Grant/Research Support	• Cardiapex
• Grant/Research Support	• Entourage Medical
• Grant/Research Support	• St Jude Medical
• Grant/Research Support	• Endoluminal Solutions

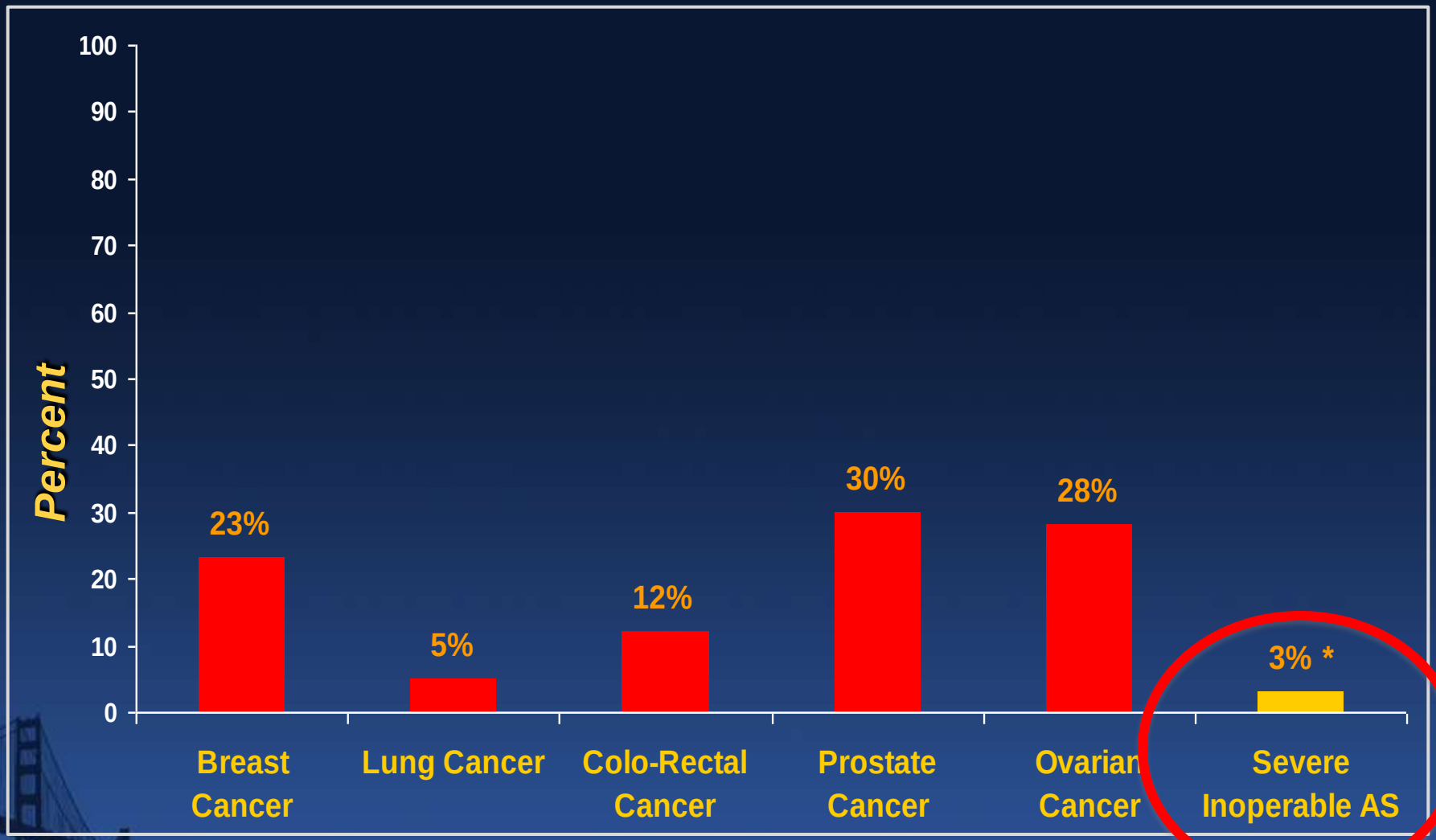
PARTNER 1B


Severe symptomatic aortic stenosis
Inoperable
TF TAVR
Standard Therapy

PARTNER 1B: Major stroke at 30 days

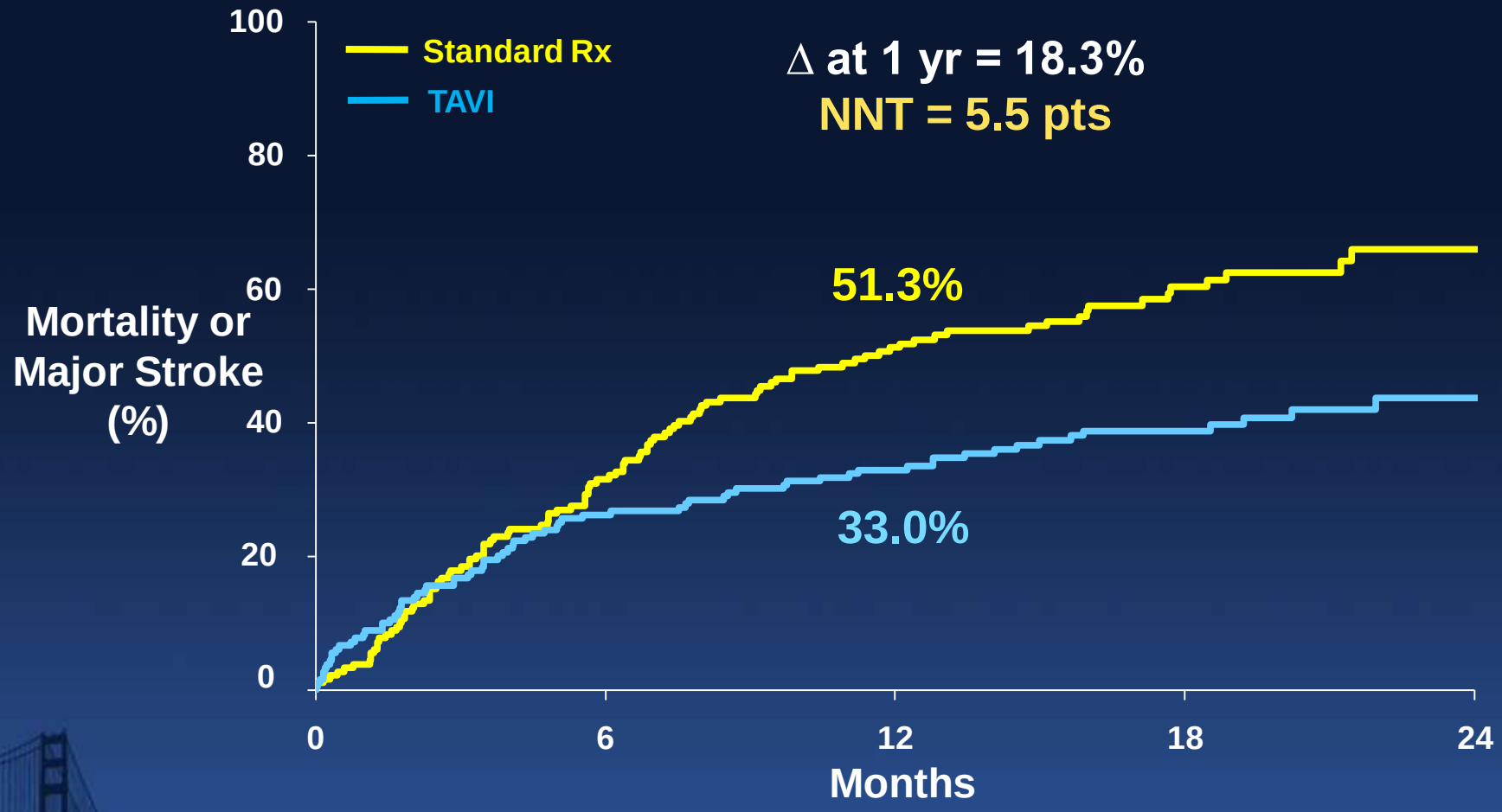


5 Year Survival: Metastic Cancer

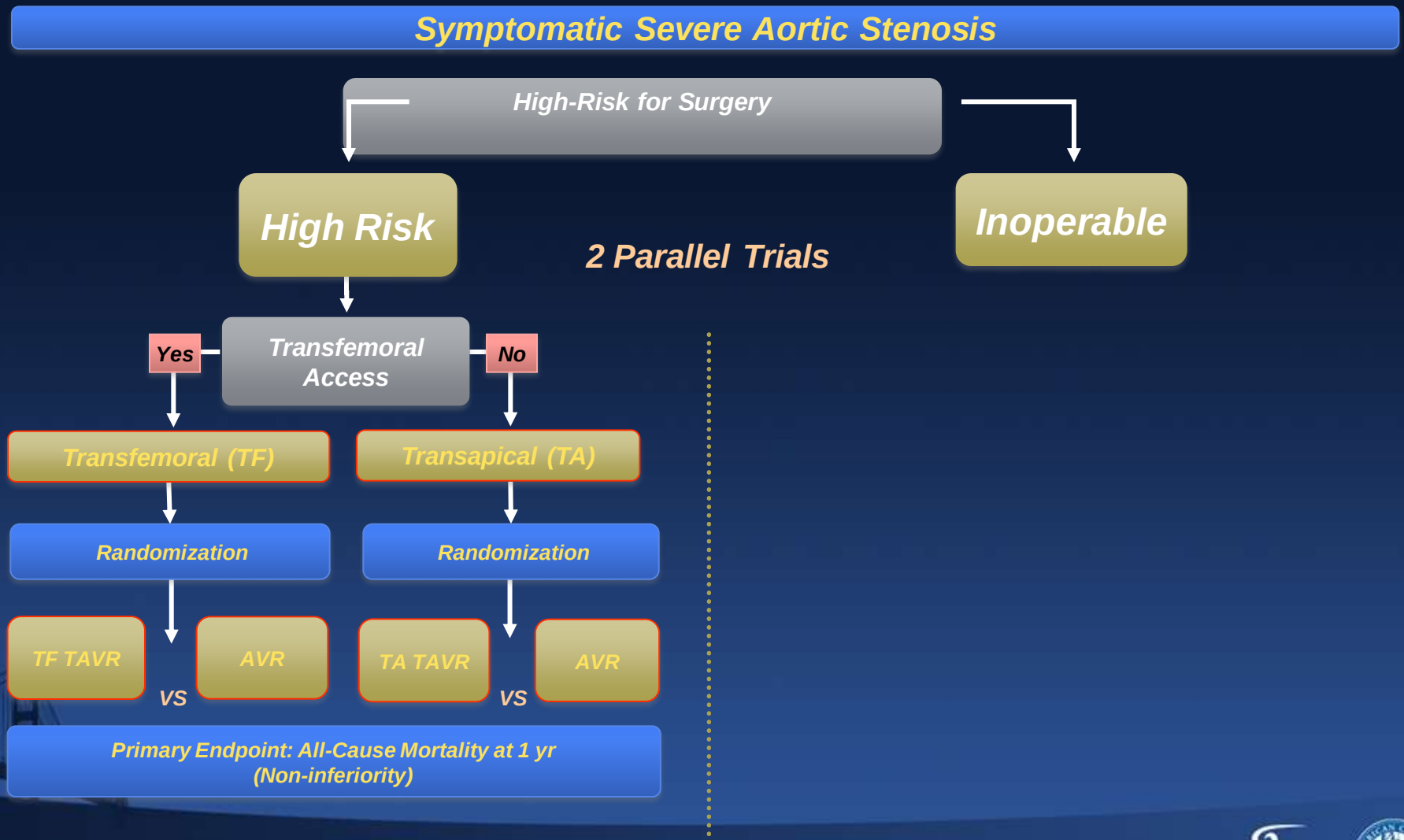


* Constant Hazard Model

PARTNER 1B: Mortality or Major Stroke



PARTNER Study Design



STROKE: The Modified Rankin Scale

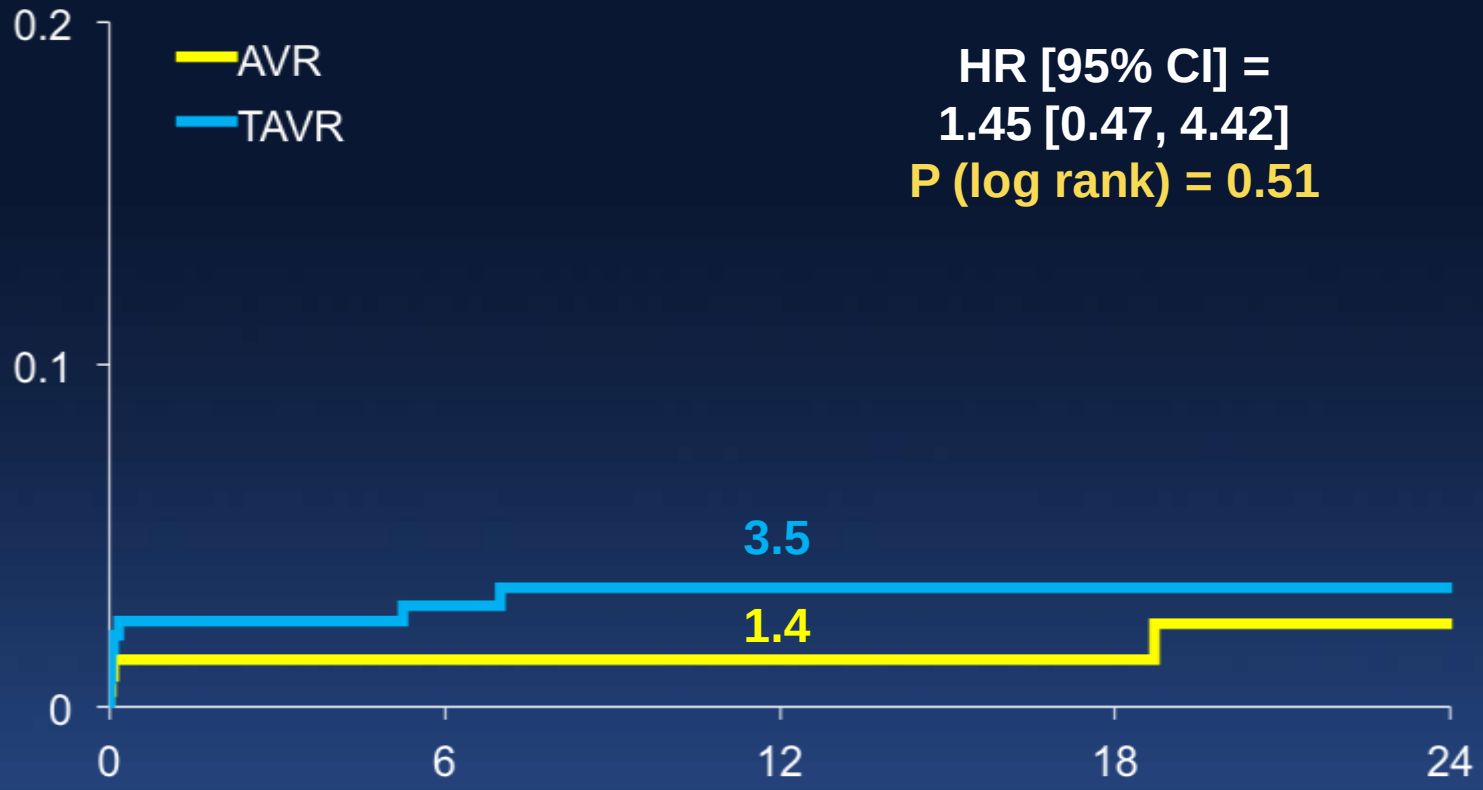
Minor stroke

0 - No symptoms.
1 - No significant disability.

Major stroke

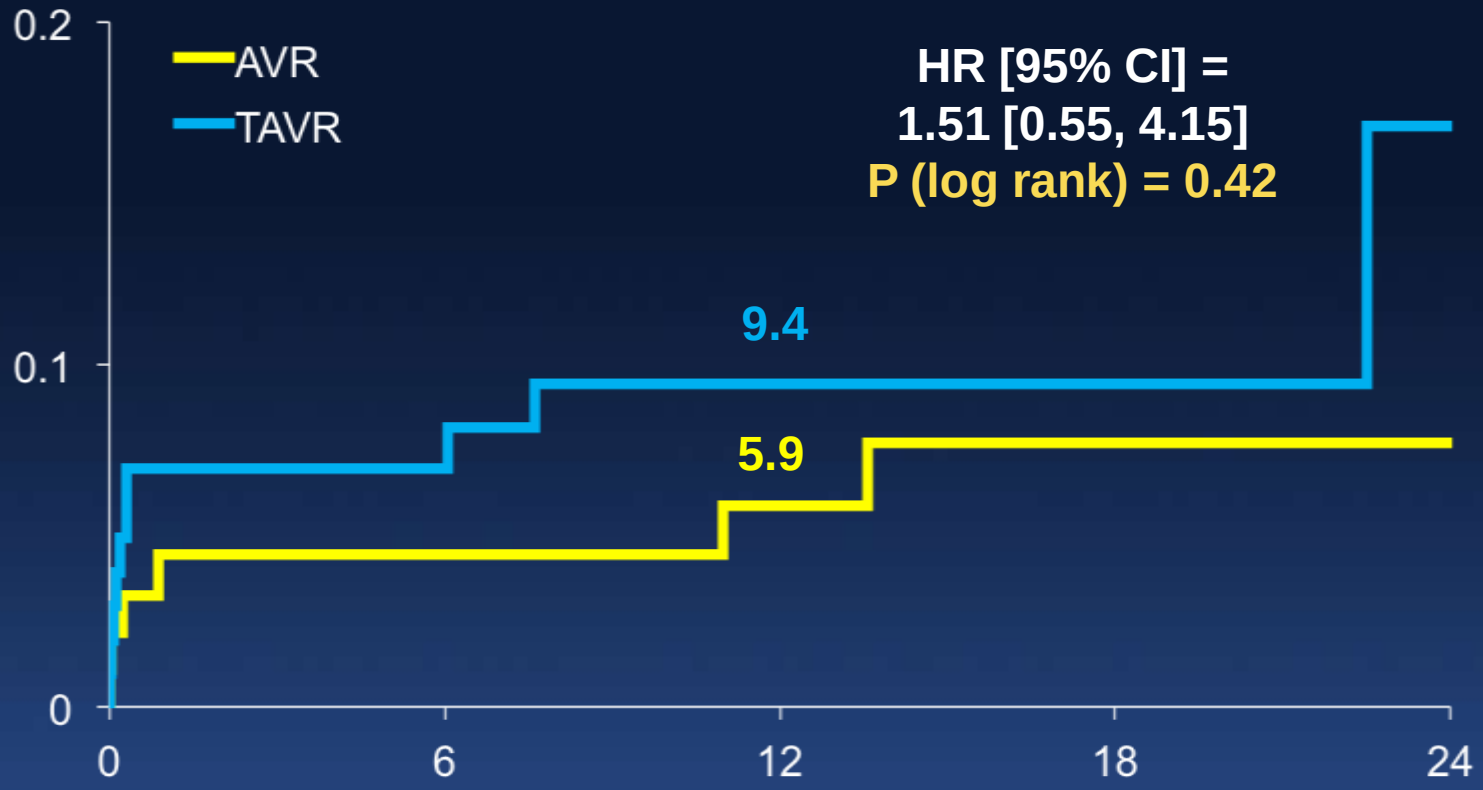
2 - Slight disability. Able to look after own affairs without assistance, but unable to carry out all previous activities.
3 - Moderate disability.
4 - Moderately severe disability.
5 - Severe disability.
6 - Dead.

Major Stroke (As Treated)
Transfemoral (N=461)



No. at Risk		Months		
240	TAVR	183	109	57
221	AVR	159	99	51

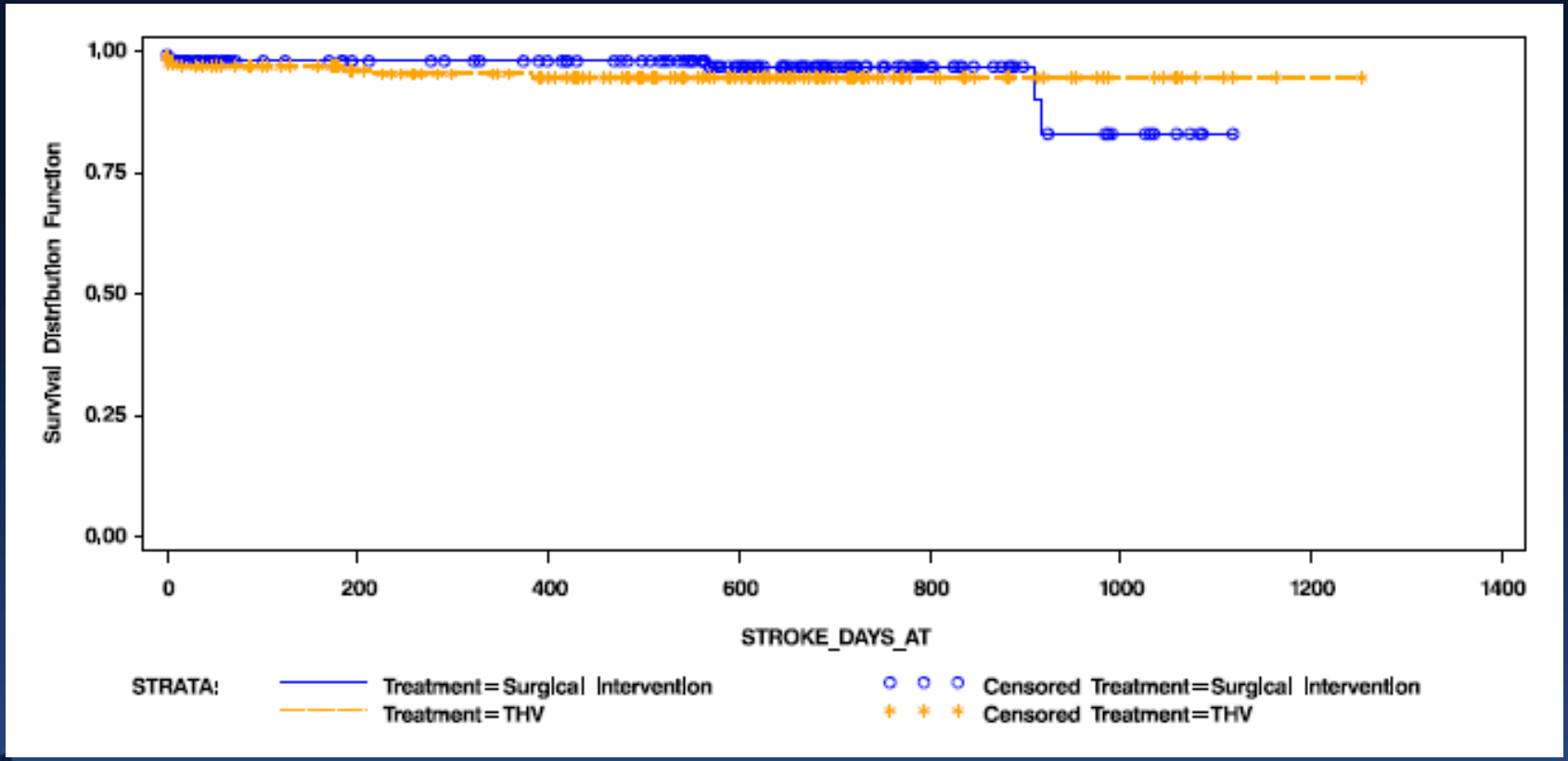
Major Stroke (As Treated)
Transapical (N=196)



No. at Risk		Months		
104	TAVR	67	26	5
92	AVR	65	28	7

PARTNER 1A: Late Hazard same as AVR

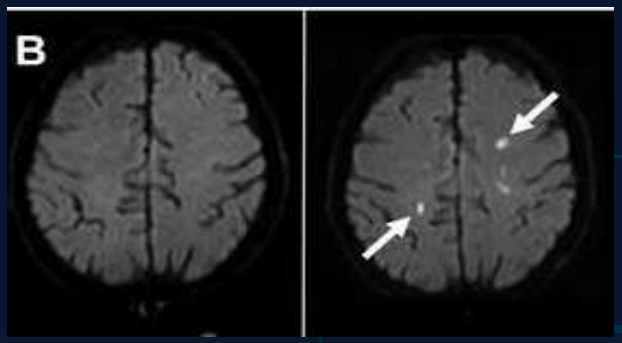
No difference in late stroke out to 2.5 years



PARTNER 1B: Neurological Events at 30 Days

Outcome	30 Days TAVR (N = 348)	30 Days AVR (N = 351)	p-value
All Stroke or TIA – no. (%)	5.5	2.4	0.04
TIA – (%)	0.9	0.3	0.33
All Stroke – (%)	4.6	2.4	0.12
Major Stroke – (%)	3.8	2.1	0.20
Minor Stroke – (%)	0.9	0.3	0.34
Death/maj stroke – (%)	6.9	8.2	0.52

DW-MRI after TAVI



	New lesions	Strokes
Ghanem	73%	10%
Knipp	58%	4%
Kahlert	84%	0%
Astarci	91%	0%
Rodes	68%	3%

Impact of Cerebral Embolism on Neurocognitive Function after Transfemoral Aortic Valve Implantation

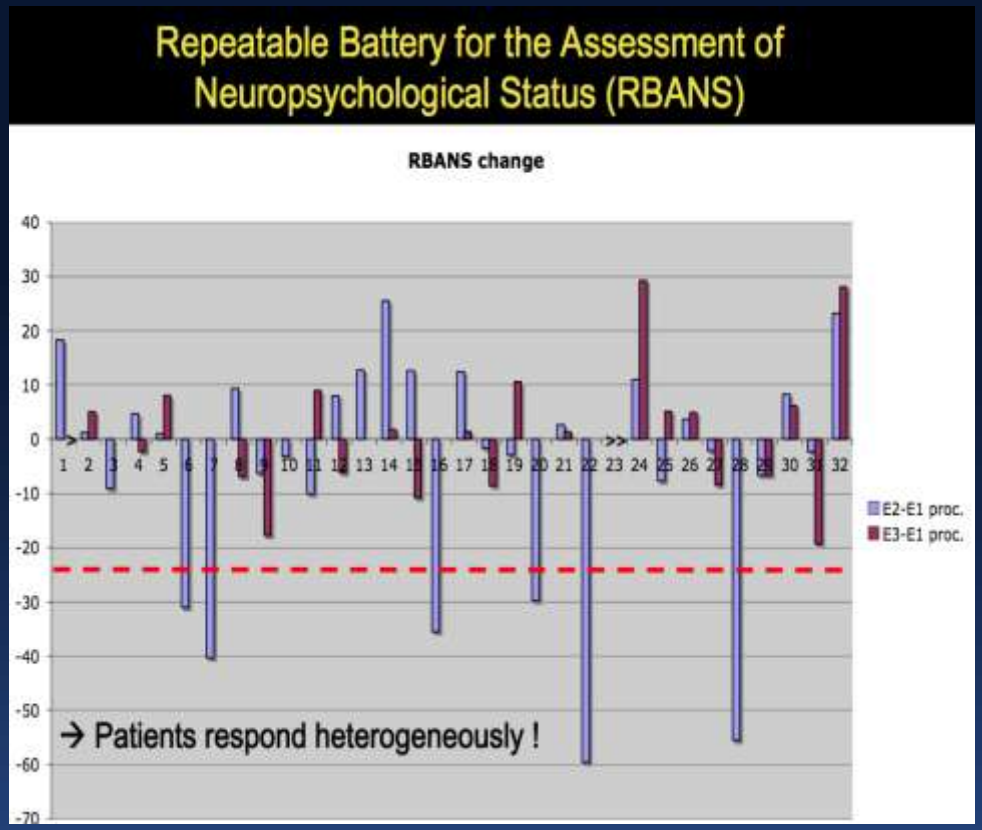
A Prospective Study with Diffusion-Weighted Magnetic Resonance Imaging

Ghanem A, et al. Bonn

8 Domains:

- Attention and concentration (brain stem)
- Visuo-spatial and constructional skills
- Sensory perceptual function
- Language
- Memory (temporal)
- Executive function
- Intellectual function
- Mood, thought content, personality and behavior

Neurocognitive decline



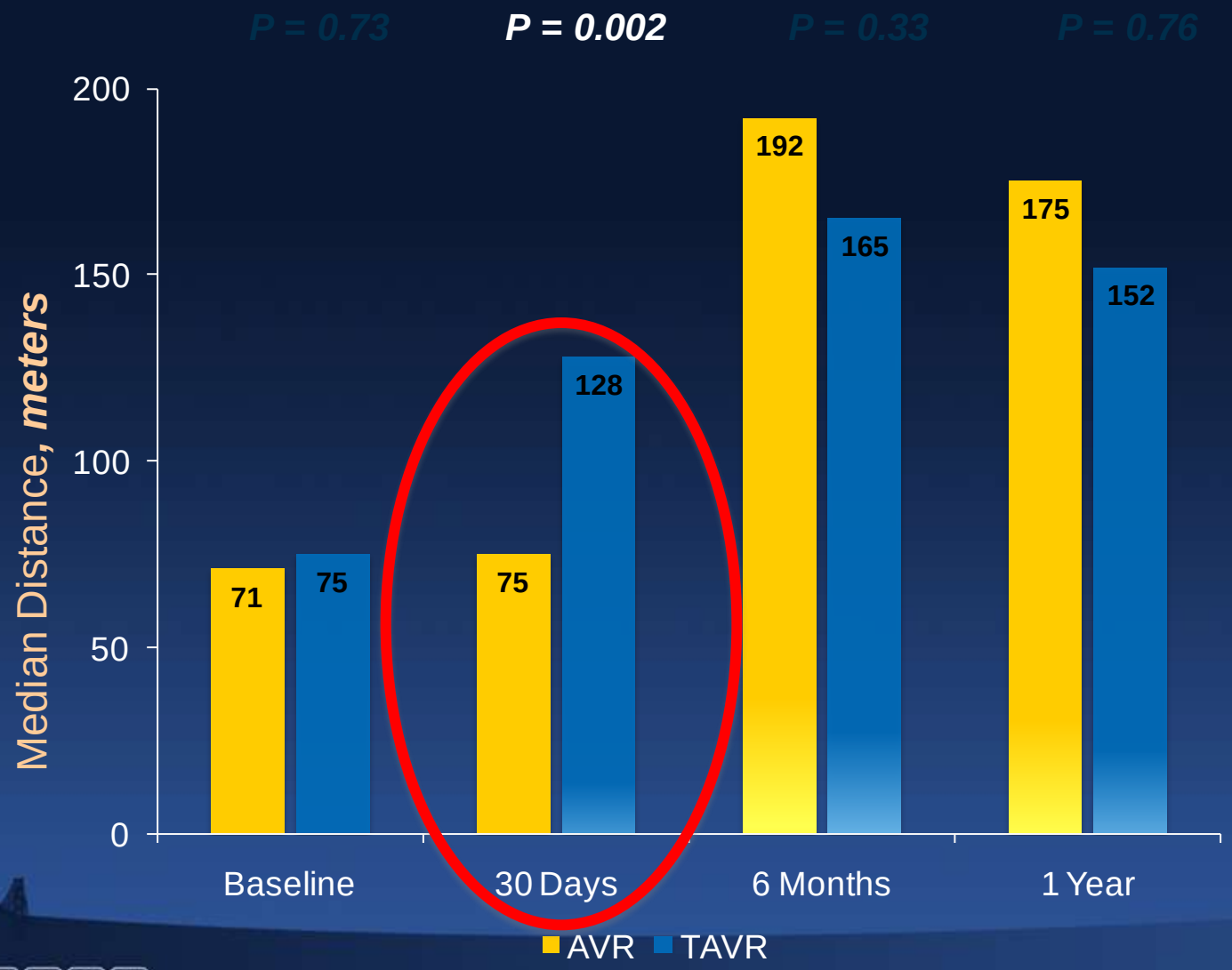
- 82% did not have a neurocognitive decline at any time
- 18% did
- Poor correlation with new DW-MRI lesions
- Correlated with multiple morbidities

PARTNER 1A: Mortality at 30 days after procedure (as-treated)

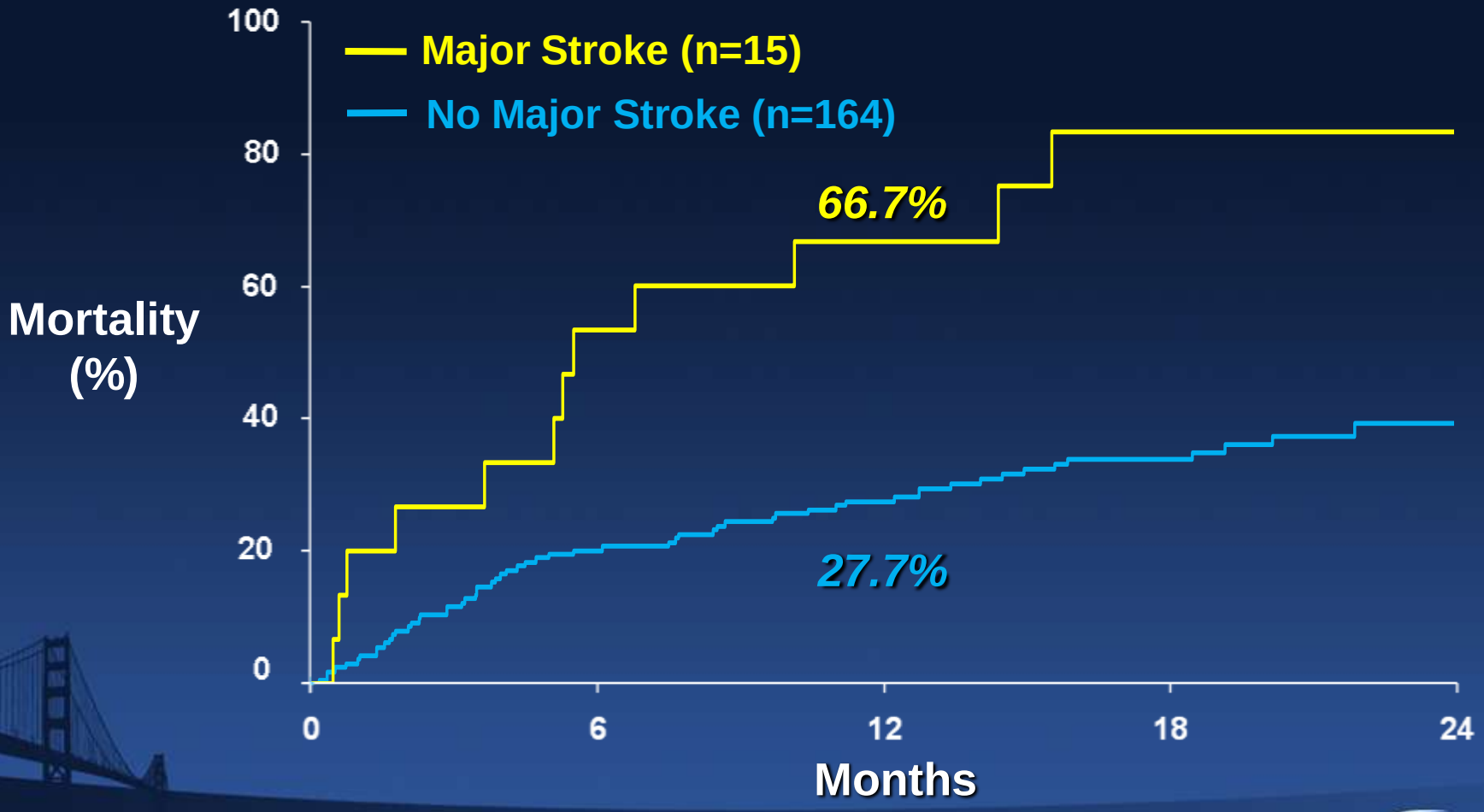
	TAVR	AVR	*p*
Intention to Treat	3.3	6.2	0.13
As Treated	3.7	8.2	<0.046

PARTNER 1B: NYHA functional class improved earlier with TAVR than SAVR

PARTNER1A: Six-Minute Walk Test Improved Earlier with TAVR

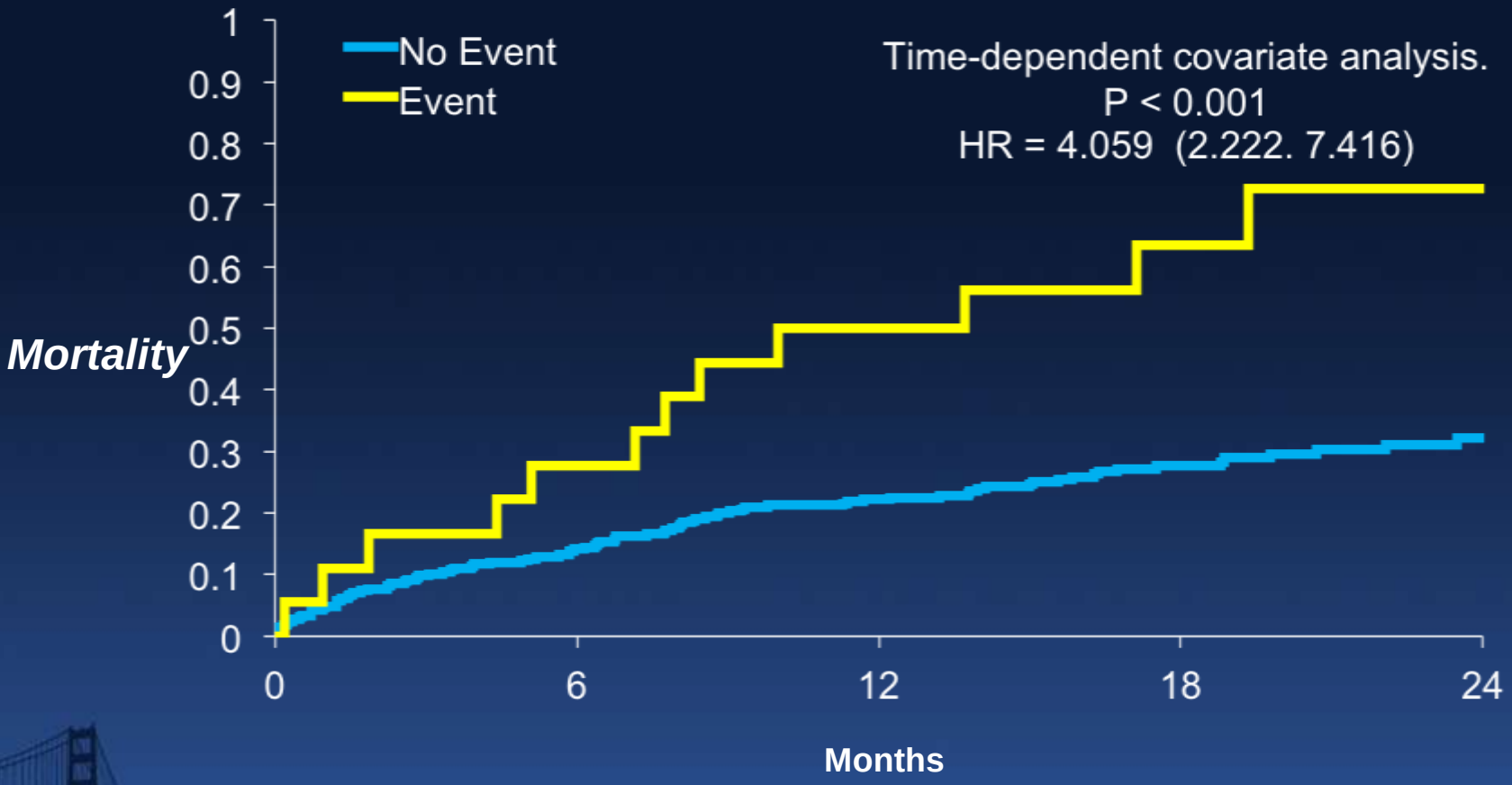


PARTNER 1B: most pts with major strokes do not survive with disability



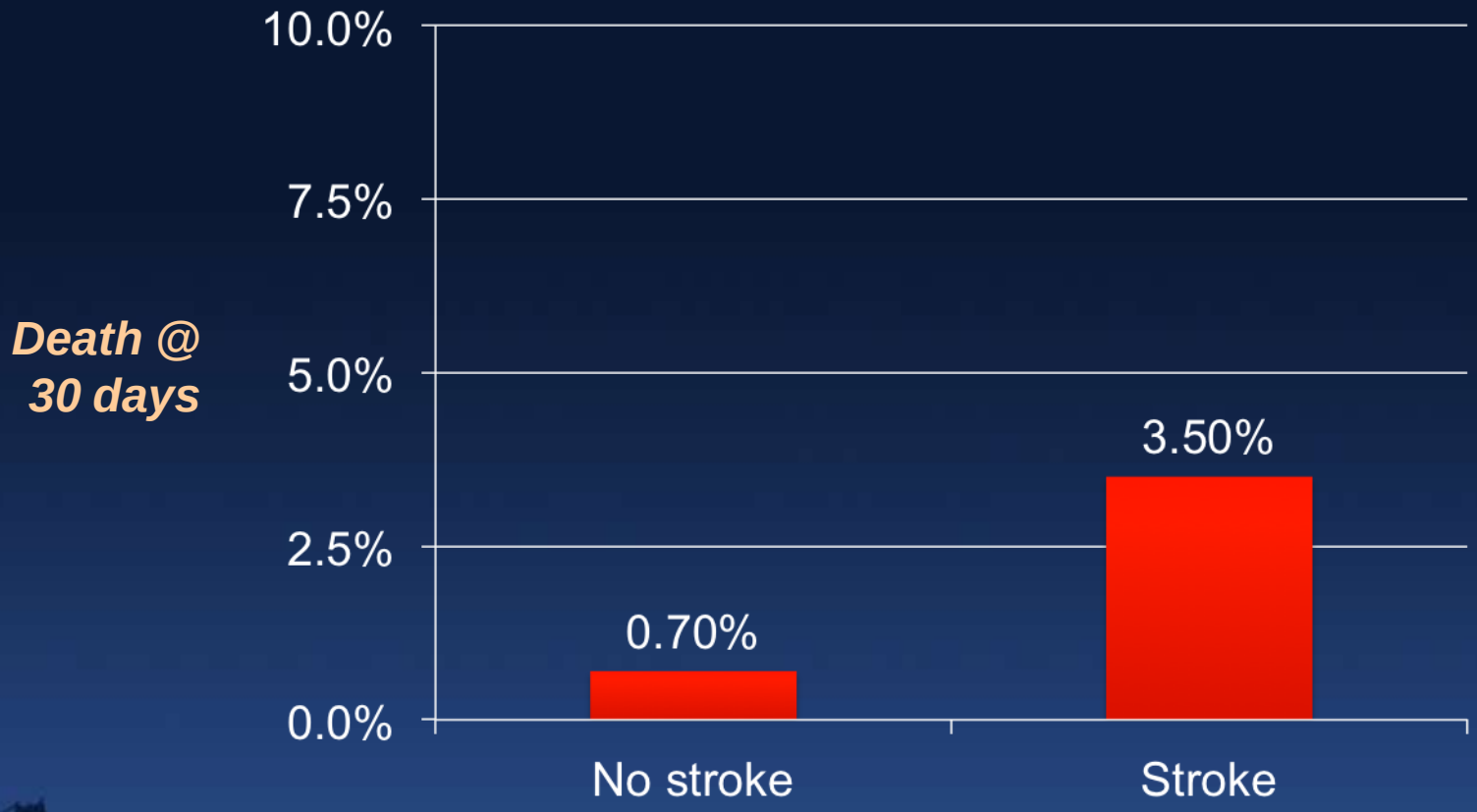
PARTNER 1A: Mortality Stratified by Major Stroke

(As Treated TAVR Trial Arm)



Italian Registry (n=663)

Most patients with significant strokes did not live with disability

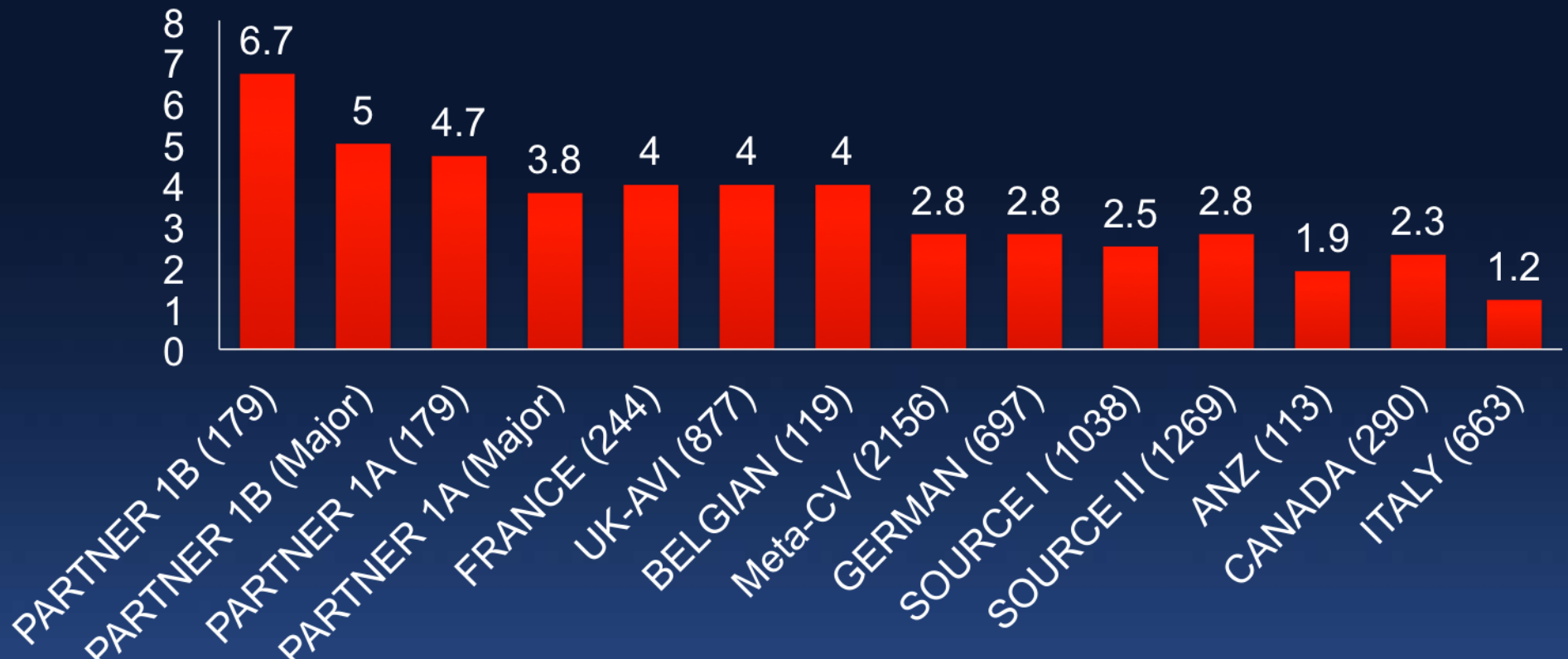


Tamborino et al. EuroPCR

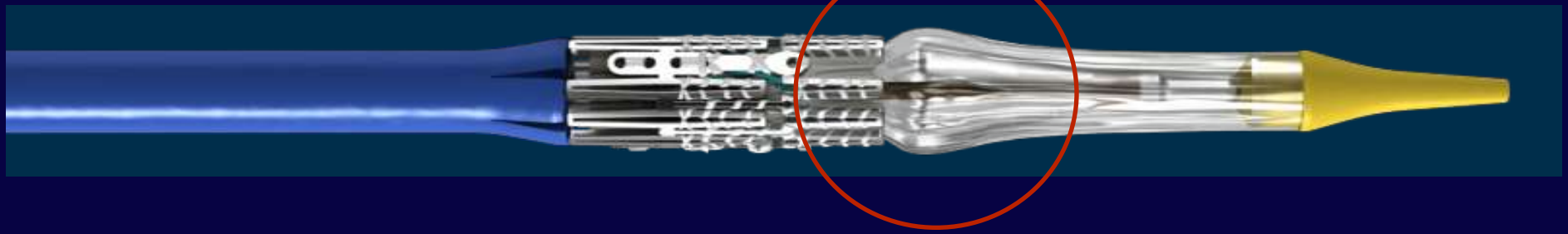
PARTNER 1A: Impact of Stroke on Mortality (as treated)

Complication	*# events (1 yr)*	*# deaths (1 yr)*
TAVR – Major Stroke	18	9
TAVR – Major Vascular	38	14
AVR – Major Bleed	88	36

Stroke Rates at 30 days

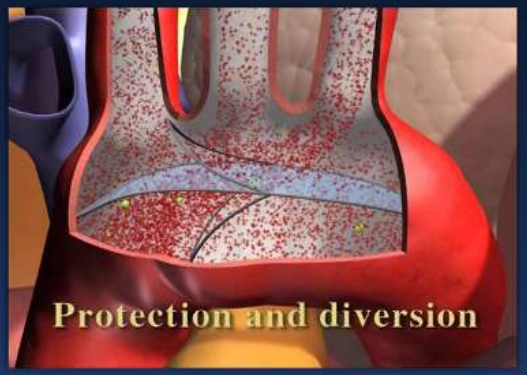


Delivery Systems Are Becoming Less Traumatic



Embrella

- Deflector
- Radial access
- Canadian/German feasibility study



Escort

- Deflector
- Femoral access
- German feasibility study

Claret

- Dual carotid filter
- German feasibility study

Summary

- There is a stroke risk
- Very few patients live with neurological disability
- For most high risk patients benefits outweigh risks
- Stroke risk will fall