THE PARTNER 3 TRIAL

Five-year Clinical And Echocardiographic Outcomes From The PARTNER 3 Low-risk Randomized Trial

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Disclosures

Institutional Research Support

- Edwards Lifesciences - Abbott Vascular
- Boston Scientific - Medtronic
- Corvia - CathWorks
- Phillips - Zoll/Therox
- I-Rhythm - JC Medical
- JenaValve

Consulting/Advisory Boards

- Medtronic - Edwards Lifesciences
- Boston Scientific - Abbott Vascular
- HeartBeam

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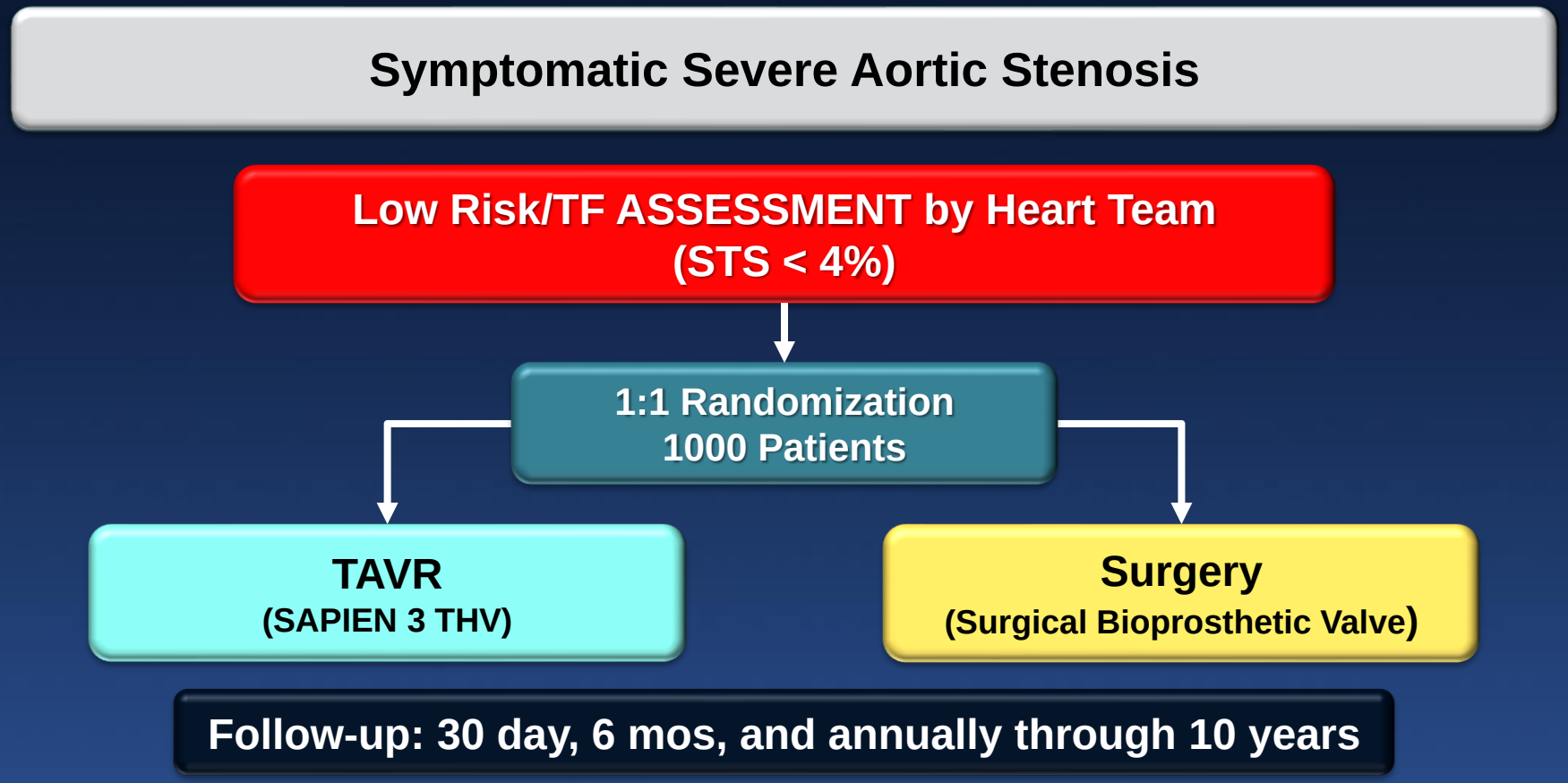
Background

- The PARTNER 3 trial, comparing TAVR vs. Surgery in low-risk patients with severe symptomatic AS, showed superior or similar primary endpoint clinical outcomes (death, stroke, and rehospitalization) at 1 and 2 years.
- Since the majority of AS patients treated with surgery have low surgical risk profiles and are younger, the 5-year outcomes from PARTNER 3 are essential to inform patient-centered therapy for initial and subsequent aortic valve procedures.

PARTNER 3 Study Design



PRIMARY ENDPOINT AT 1 YEAR:
Non-hierarchical composite of all-cause death, all stroke, or rehospitalization (valve-, procedure-, or HF-related)

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Baseline Characteristics

Demographics & Vascular Disease	TAVR (N=496)	Surgery (N=454)	Other Comorbidities	TAVR (N=496)	Surgery (N=454)
Age (years)	73.3 ± 5.8	73.6 ± 6.1	Diabetes	31.3%	30.2%
Male	67.5%	71.1%	COPD (any)	5.1%	6.2%
BMI (kg/m^2)	30.7 ± 5.5	30.3 ± 5.1	Pulmonary Hypertension	4.6%	5.3%
STS Score	1.9 ± 0.7	1.9 ± 0.6	Creatinine > 2mg/dL	0.2%	0.2%
NYHA Class III or IV*	31.3%	23.8%	Frailty (overall; > 2/4+)	0	0
Coronary Disease	27.7%	28.0%	Atrial Fibrillation (h/o)	15.7%	18.8%
Prior CABG	3.0%	1.8%	Permanent Pacemaker	2.4%	2.9%
Prior CVA	3.4%	5.1%	Left Bundle Branch Block	3.0%	3.3%
Peripheral Vascular Disease	6.9%	7.3%	Right Bundle Branch Block	10.3%	13.7%

*$P = 0.01$

Primary Endpoint: Death, Stroke, or Rehosp

Number at risk:

TAVR	496	453	434	415	391	353
Surgery	454	372	349	328	309	276

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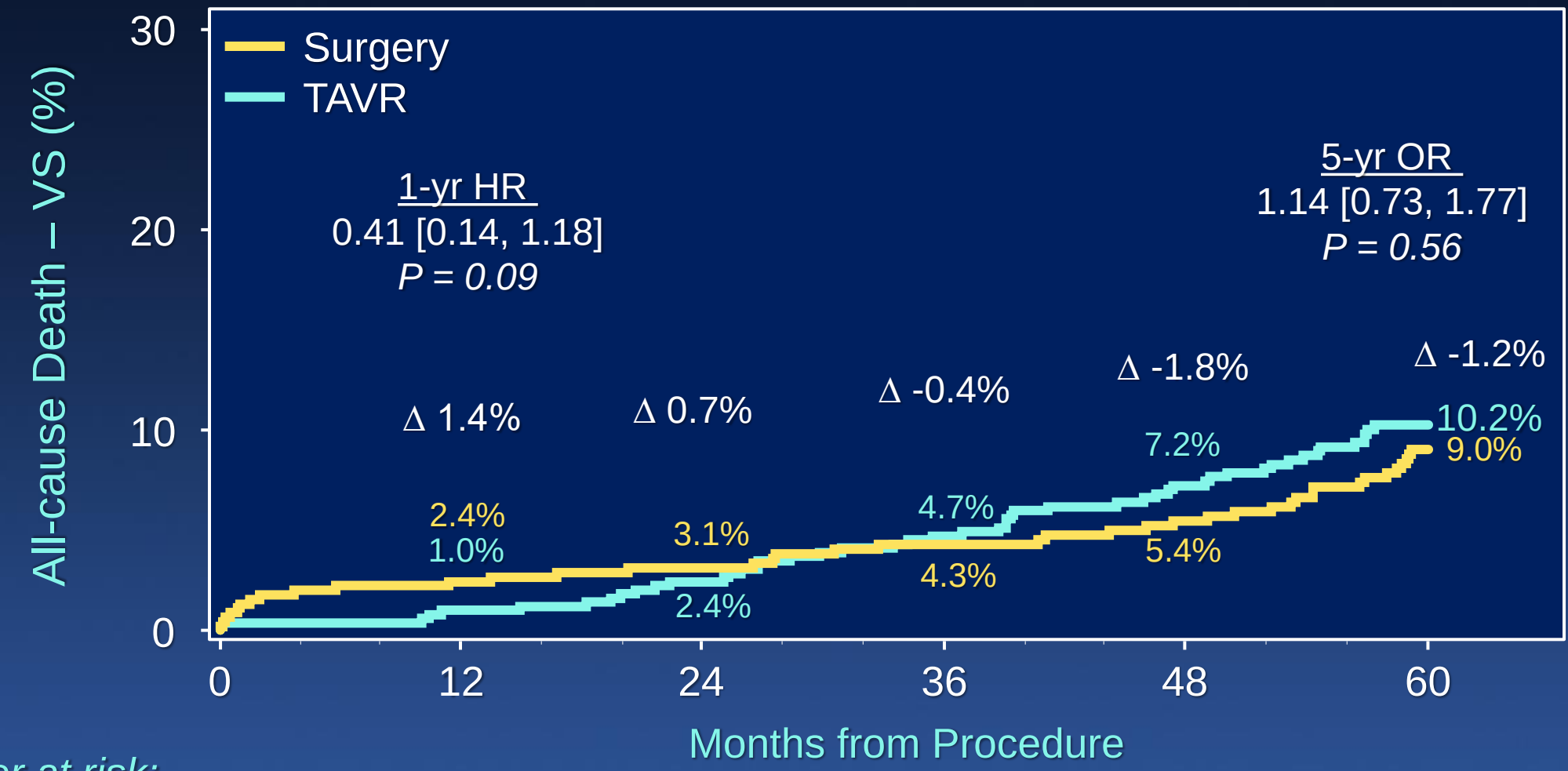
All-Cause Death: Vital Status Sweep



Number at risk:

TAVR	496	490	479	463	445	415
Surgery	454	435	424	413	404	378

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Causes of Death 0-5 Years

CV Causes

Cause, No. of pts	TAVR	Surgery
Cardiac	**8**	**9**
Acute MI	0	2
Cardiac Arrest	2	1
Cardiogenic Shock	0	1
CHF	2	3
Endocarditis	0	1
Sudden Cardiac Death	4	1
Non-Coronary Vascular Conditions	**11**	**6**
Procedure-related	2	2
Stroke	3	4
Head Injury 2° Fall	6	0
Unknown	**7**	**6**
Totals	**26**	**21**

Non-CV Causes

Cause, No. of pts	TAVR	Surgery
Cancer	9	5
COVID-19	3	1
Cirrhosis	1	0
MVA	1	1
Parkinson's Disease	0	1
Respiratory Failure*	3	4
Sepsis	4	1
Suicide	1	0
Totals	**22**	**13**

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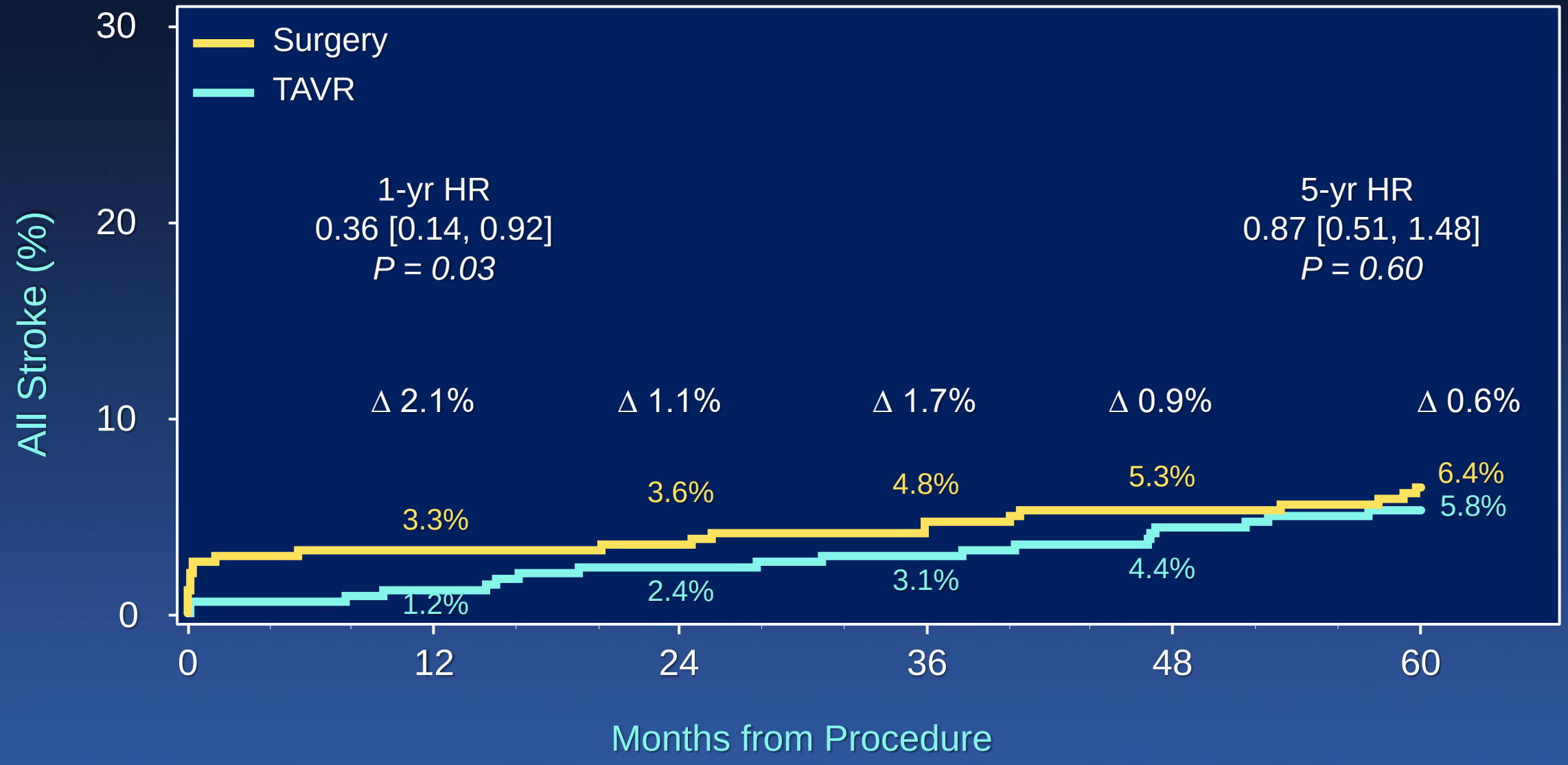
All Stroke



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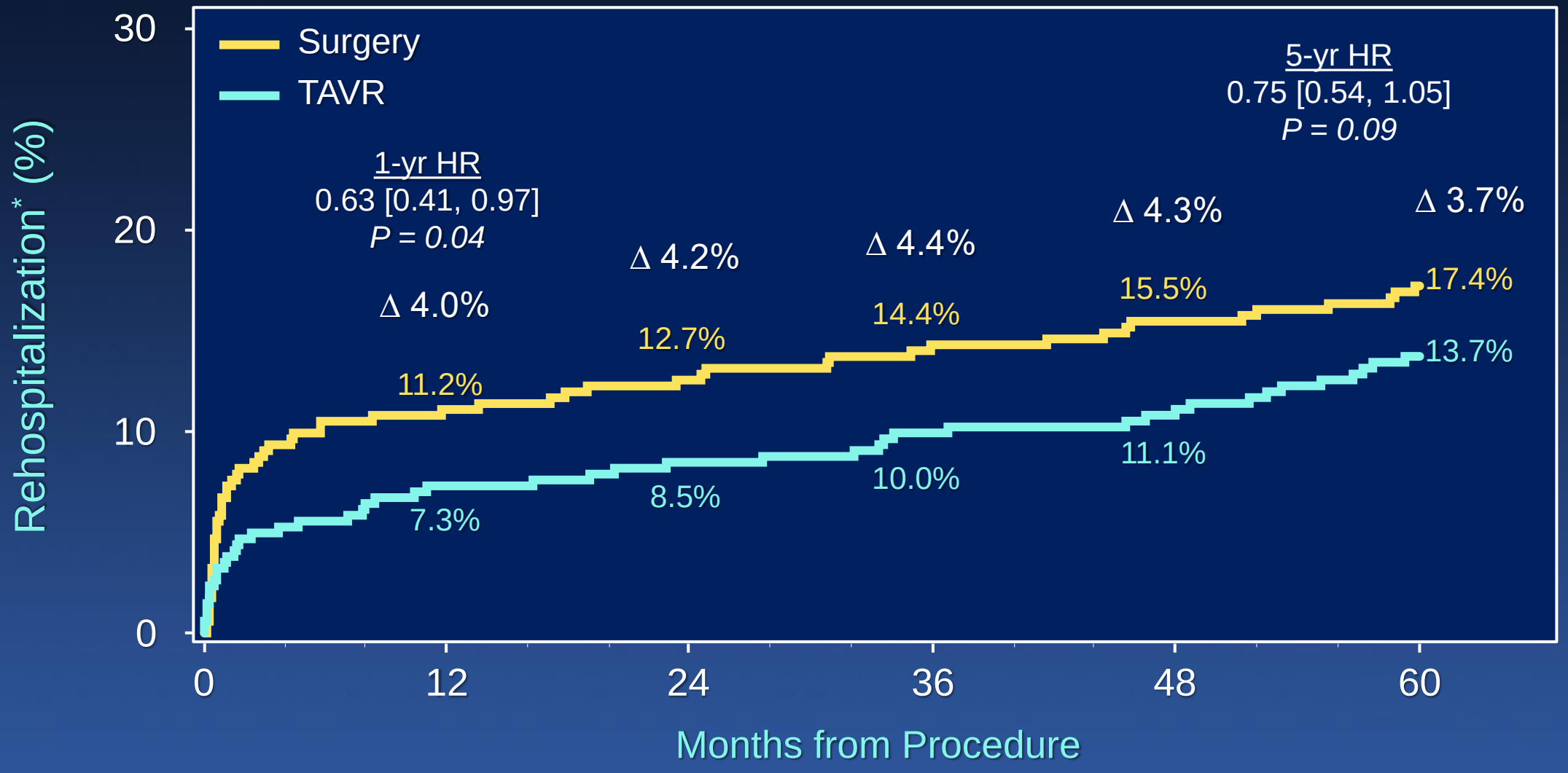
Rehospitalization*



*Rehosp defined as valve-, procedure-, or HF-related

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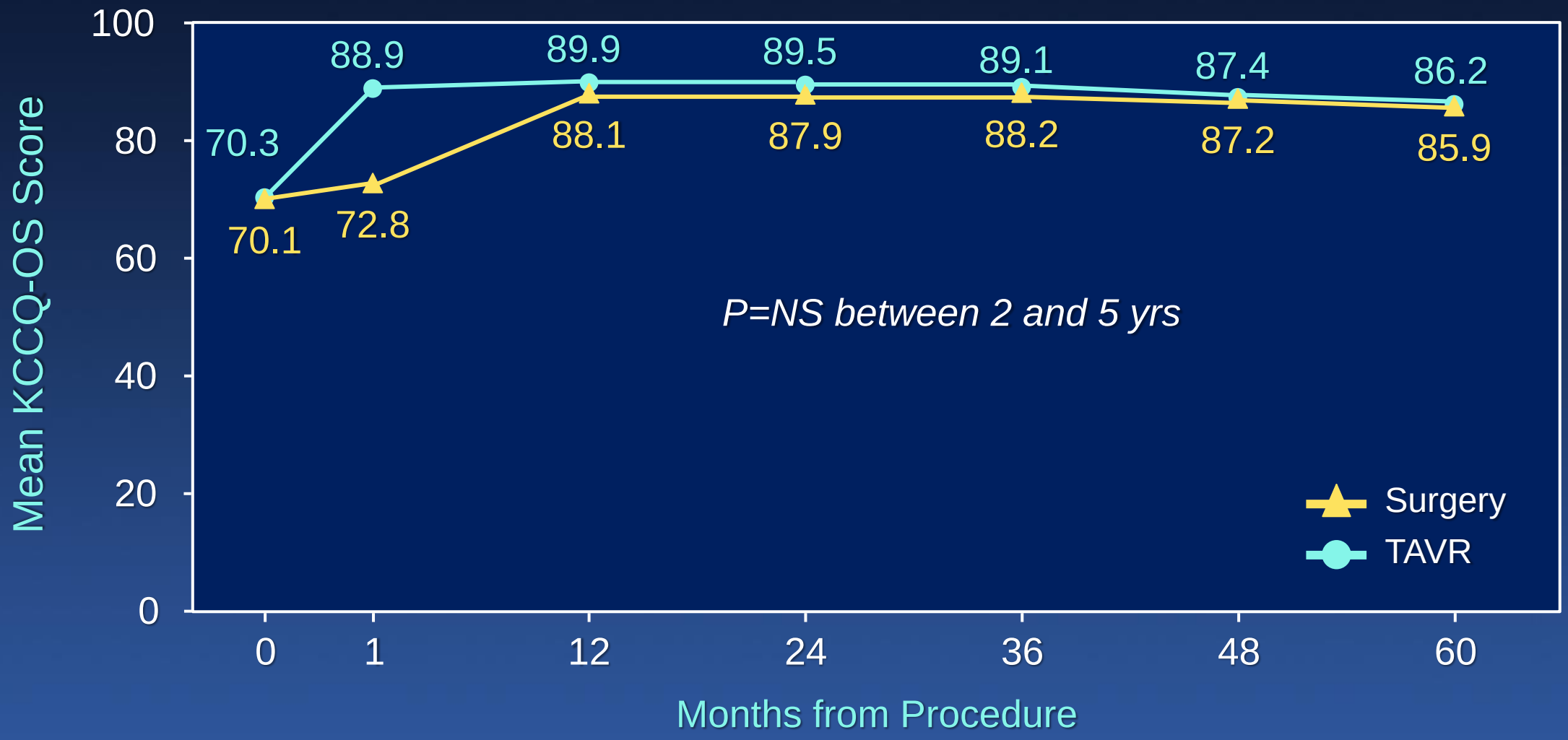
Quality of Life: KCCQ Overall Summary



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Valve Thrombosis

No. of patients

Clinically Significant Valve Thrombosis	0 – 5 Years	
	TAVR	Surgery
Valve Thrombosis Events*	**13 events in 12 pts†**	**1 event in 1 pt**
Clinical Sequelae Related to Thrombosis		
Death	0	0
Stroke (all ischemic)	3	0
Disabling	1	0
Non-disabling	2	0
Stage 2 or 3 HVD	8	0
Resolved with Anticoagulation	7	0

*All patients had confirmatory imaging; 2/14 total events occurred during the COVID-19 pandemic

†1 patient had 2 events (both Stage 1 HVD)

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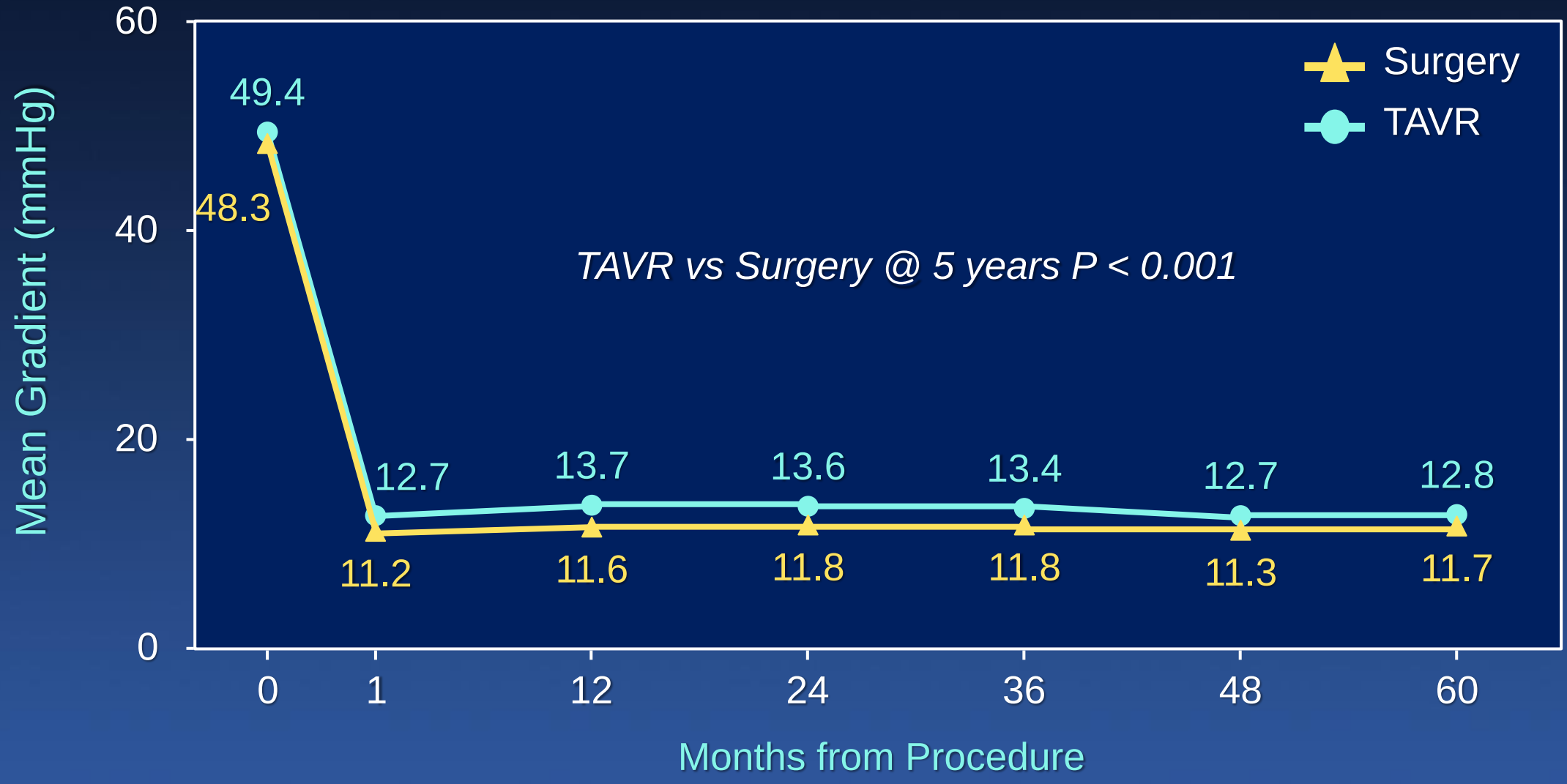
Valve Hemodynamics

Mean Gradient



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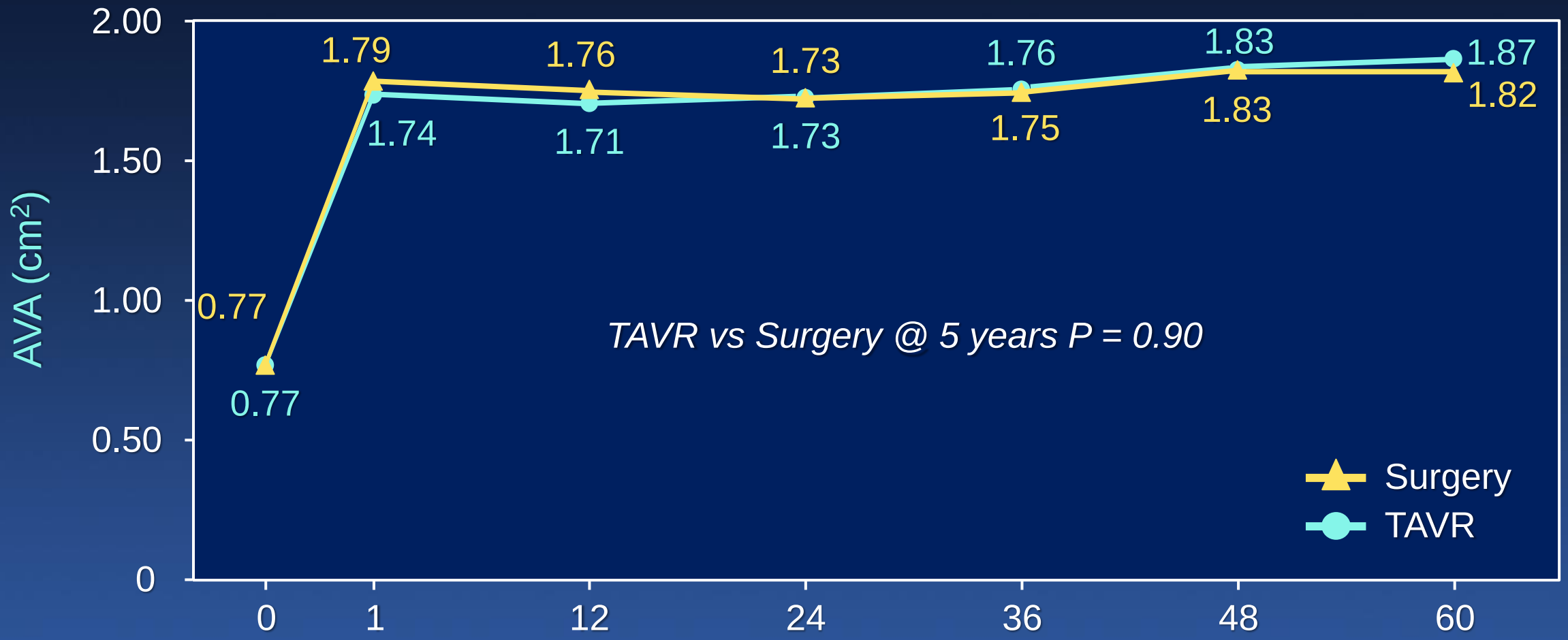
Valve Hemodynamics

Aortic Valve Area



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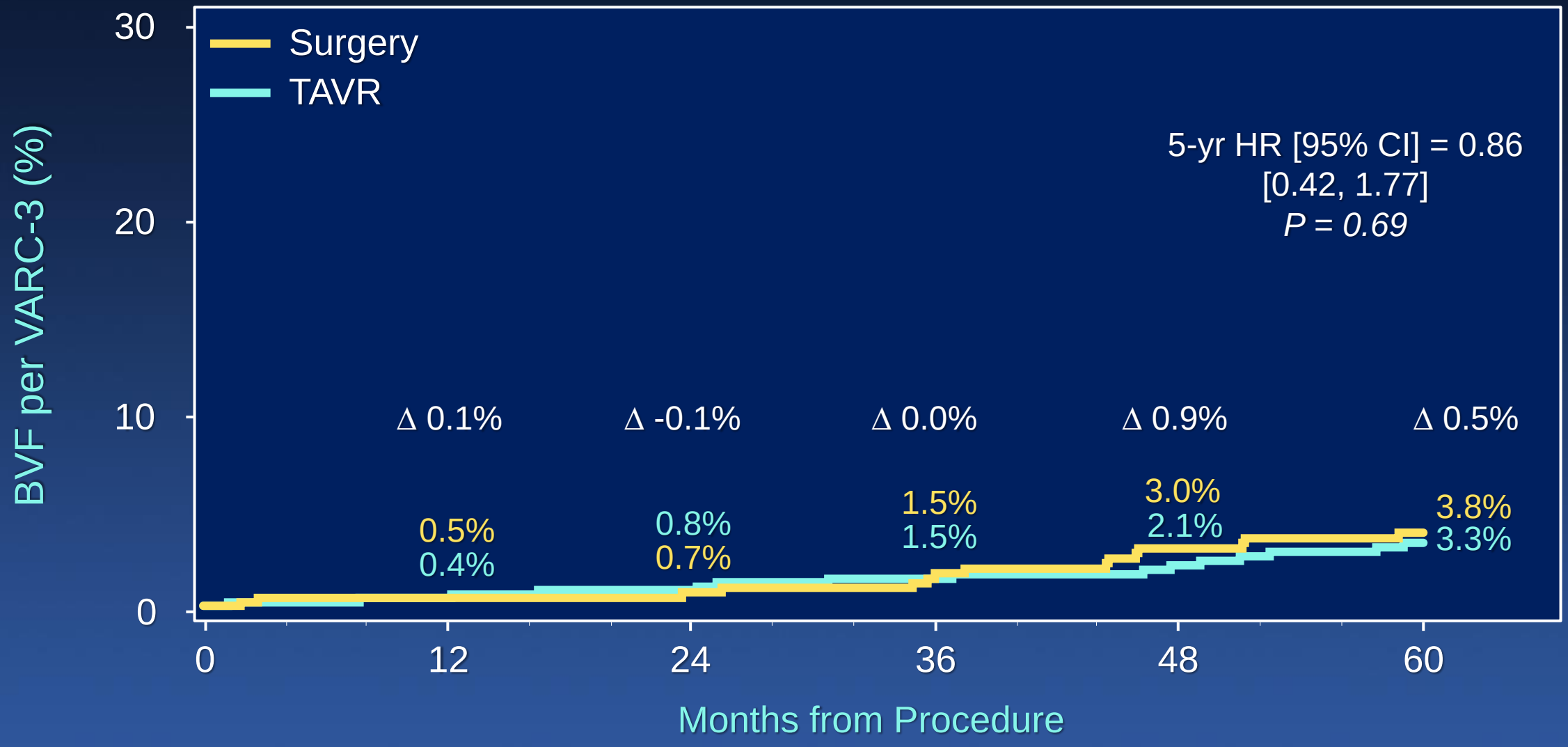
BVF to 5 Years (VARC-3)



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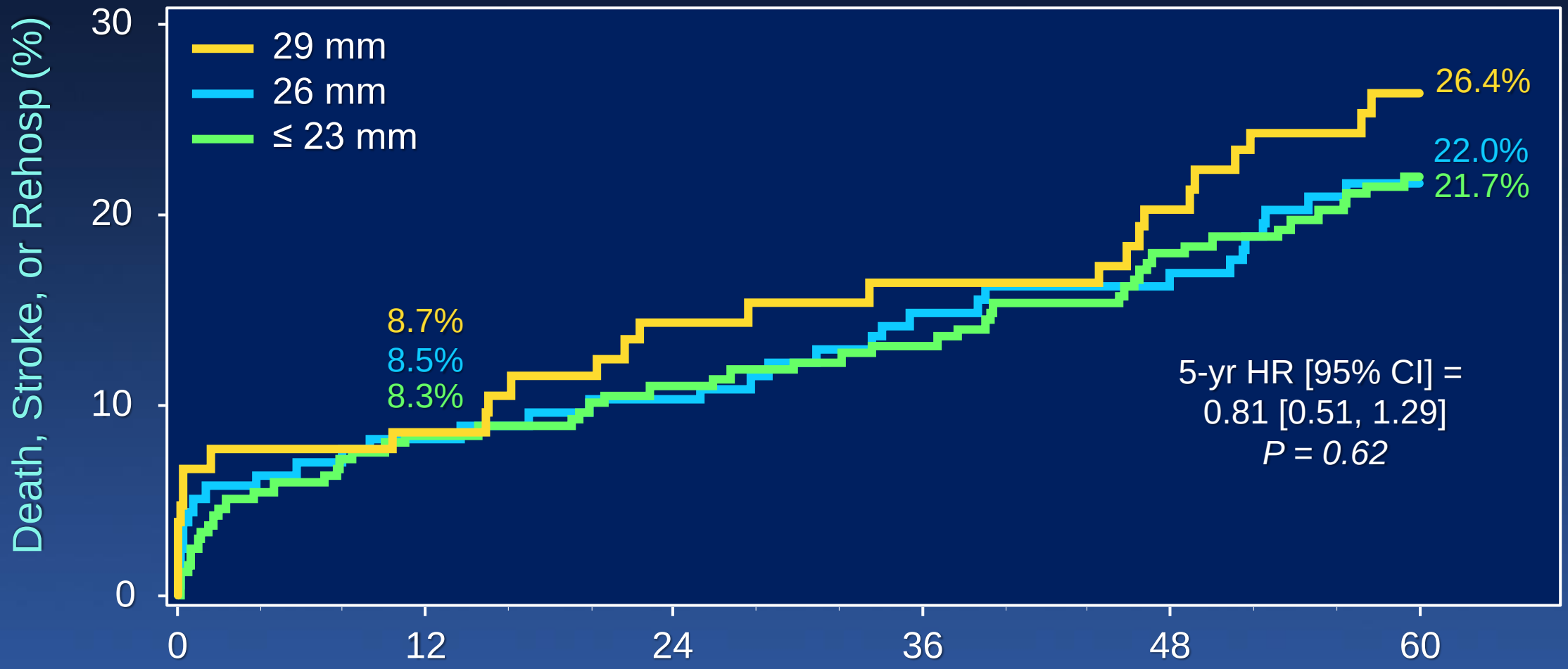
Death, Stroke, or Rehospitalizaiton

By Valve Size – TAVR



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Summary

- Differences in primary endpoint and all-cause mortality seen at 1 year no longer apparent at 5-years
- “Catch-up” driven mainly by differences in late mortality (~0.6%/year), which was not explained by differences in valve failure or cardiac causes→ ? Fluke, COVID-19, valve thrombosis
- Other key endpoints including QOL and rehospitalization are comparable or continue to favor TAVR
- Both TAVR and SAVR demonstrated excellent valve durability

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Clinical Implications

The 5-year follow-up findings from the PARTNER 3 trial reaffirm the clinical and echocardiographic benefits of SAPIEN 3 TAVR as a meaningful alternative to surgical therapy for low-risk severe, symptomatic AS patients