SAPIEN 3 Transcatheter Aortic Valve Replacement Compared with Surgery in Intermediate-Risk Patients:
A Propensity Score Analysis

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on behalf of The PARTNER Trial Investigators

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THE PARTNER II TRIAL

Disclosure Statement of Financial Interest

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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	• Boston Scientific, Claret Medical, Edwards Lifesciences, Medtronic, St. Jude Medical
• Consulting Fees/Honoraria	• Abbott Vascular, Edwards Lifesciences, St. Jude Medical
• Major Stock Shareholder/Equity	• None

The PARTNER 2A and S3i Trials
Study Design

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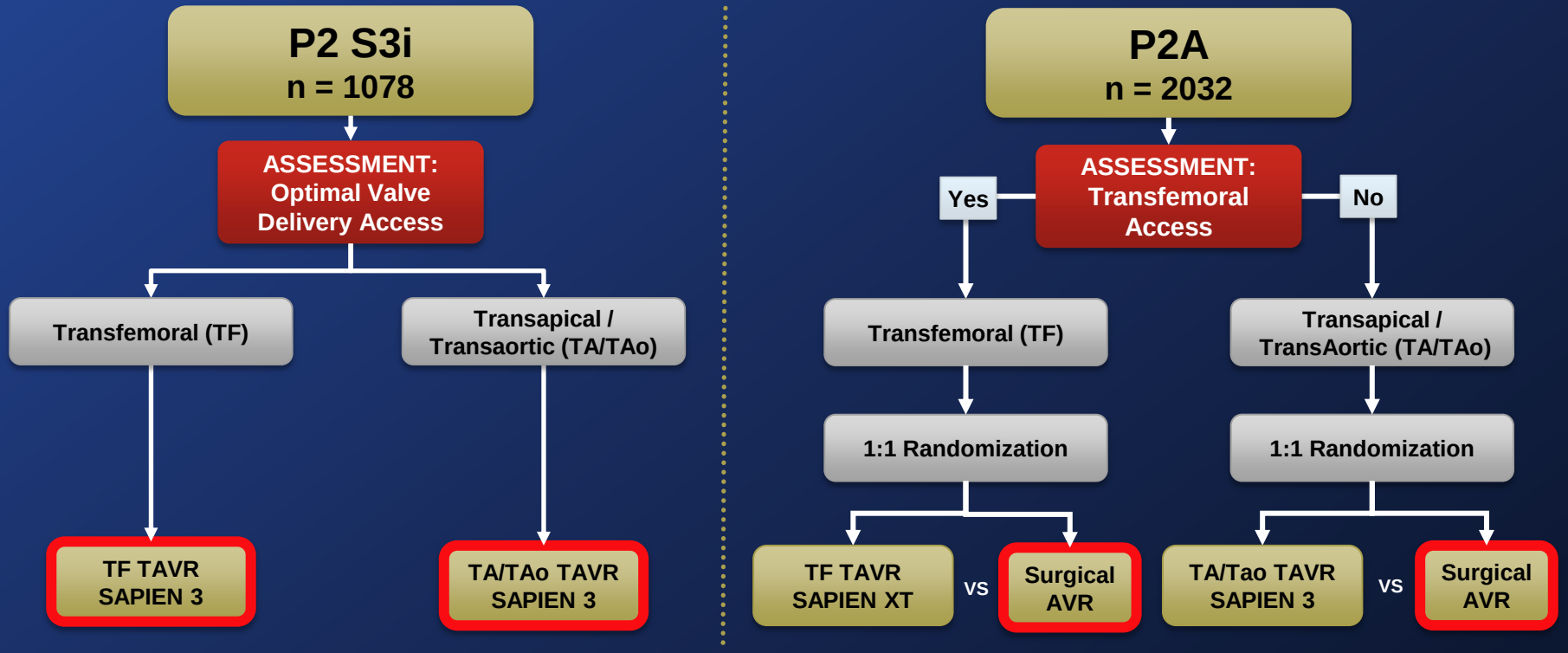
Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team



Primary Endpoint: All-Cause Mortality, All Stroke, or Mod/Sev AR at One Year
(Non-inferiority Propensity Score Analysis)

Quintile Propensity Score Analysis:
Primary Endpoint

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Surgery		TAVR			
# Patients	Mortality, Stroke, AR ≥ Mod	# Patients	Mortality, Stroke, AR ≥ Mod	Proportional Difference	Weighting
191	28.3%	138	13.8%	-14.5%	0.14
175	22.9%	171	9.9%	-12.9%	0.18
147	**19.7%**	**197**	**10.7%**	**-9.1%**	**0.20**
126	23.0%	219	14.6%	-8.4%	0.23
108	19.4%	238	15.1%	-4.3%	0.25

Overall weighted difference of proportions
- 9.2%
[-12.4%,-6.0%] two-sided 90% CI

Primary Endpoint - Non-inferiority

Death, Stroke, or AR ≥ Mod at 1 Year (VI)

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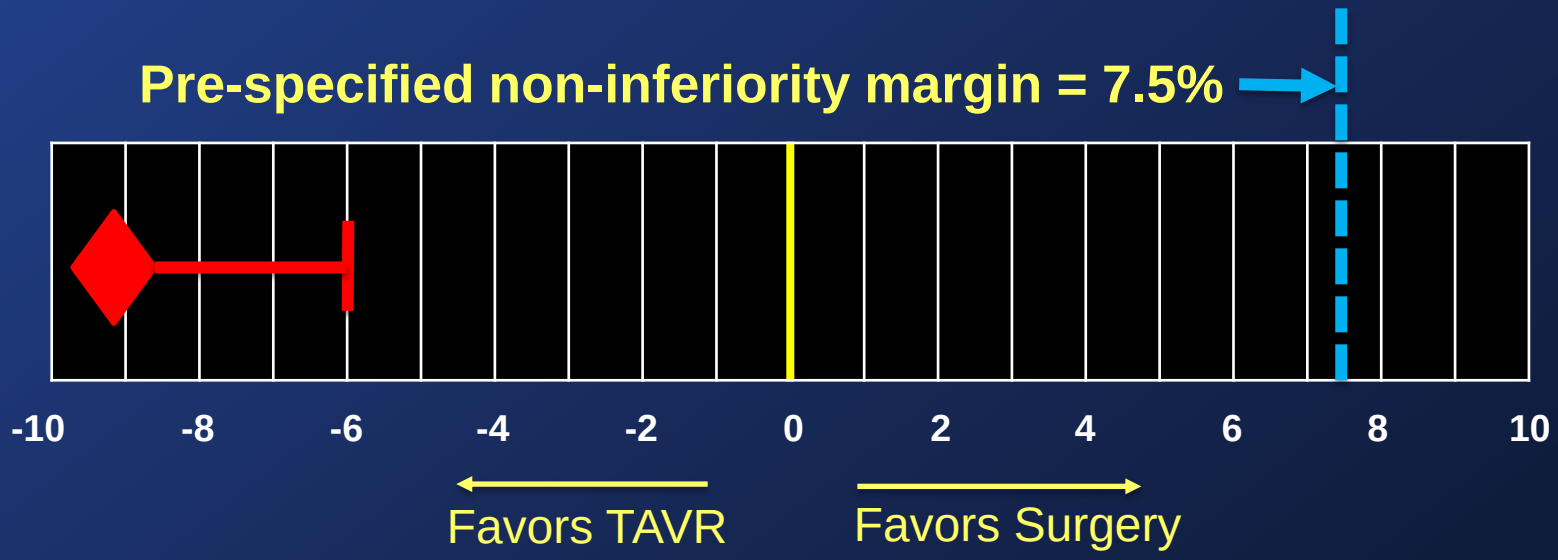
Weighted Difference **-9.2%**
Upper 1-sided 95% CI **-6.0%**

Non-Inferiority
p-value < 0.001



Primary Non-Inferiority Endpoint Met

Primary Endpoint - Superiority

Death, Stroke, or AR ≥ Mod at 1 Year (VI)

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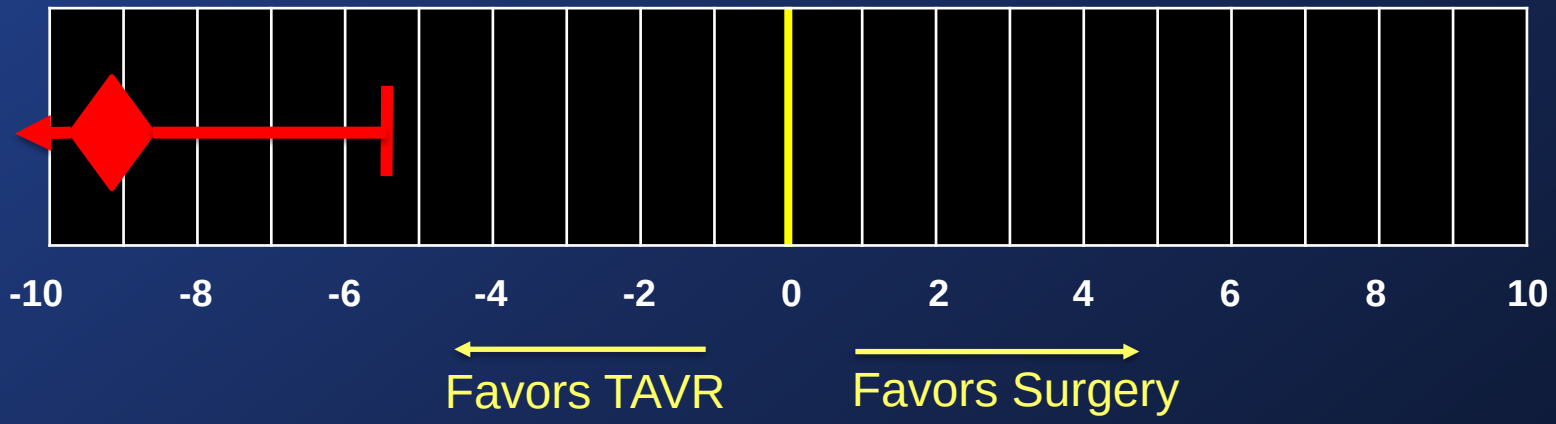
Weighted Difference	**-9.2%**
Upper 2-sided 95.0% CI	**-5.4%**

Superiority Testing
p-value < 0.001



Superiority Achieved

Superiority Analysis
Components of Primary Endpoint (VI)

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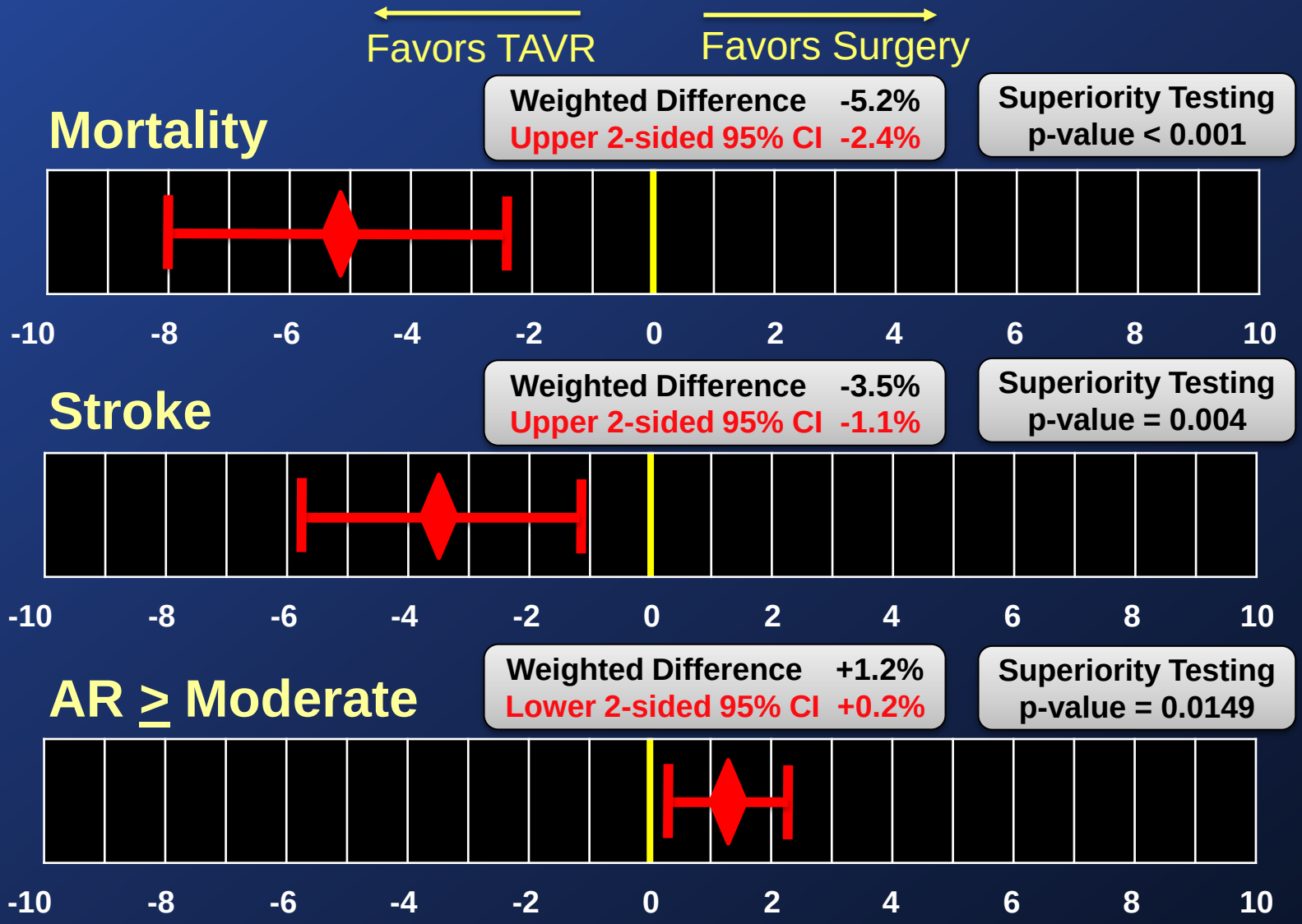

Unadjusted Time-to-Event Analysis
All-Cause Mortality and All Stroke (AT)

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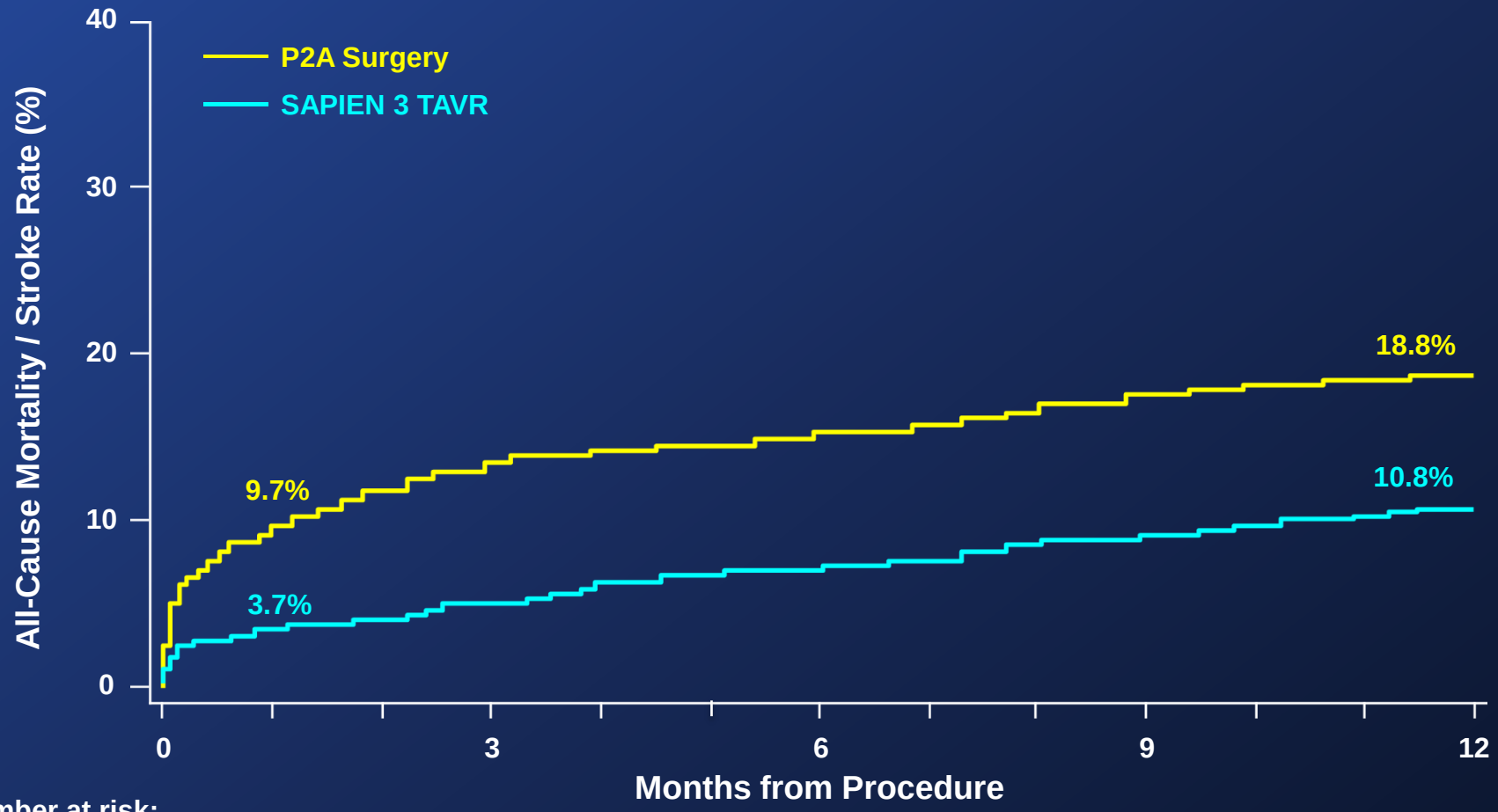

Number at risk:

P2A Surgery	944	805	786	757	743
S3 TAVR	1077	1012	987	962	930

The PARTNER 2A and S3i Trials
Conclusions

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- In intermediate-risk patients, SAPIEN 3 TAVR resulted in low 1-year rates of all-cause mortality (7.4%), all stroke (4.6%), and moderate or severe aortic regurgitation (1.5%)
- A rigorous propensity score analysis comparing SAPIEN 3 TAVR with surgery from PARTNER 2A in intermediate-risk patients at 1 year demonstrated:
  - Non-inferiority for the primary endpoint (composite of all-cause mortality, all stroke, or AR ≥ moderate)
  - Superiority of SAPIEN 3 TAVR for the primary endpoint, all-cause mortality, and all stroke
  - Superiority of surgery for AR ≥ moderate
- Time-to-event analyses indicated that the benefits of SAPIEN 3 TAVR occurred in the first few months, suggesting procedure-related effects

The PARTNER 2A and S3i Trial
Clinical Implications

- *The conclusions from the PARTNER 2A randomized trial and this propensity score analysis provide strong evidence that in intermediate-risk patients with severe aortic stenosis, SAPIEN 3 TAVR compared with surgery improves clinical outcomes and is the preferred therapy.*