

Current Status of TAVR: High/Intermediate and Lower Risk

Jung-Min Ahn, MD

Asan Medical Center, University of Ulsan College of Medicine,
Seoul, Korea

The Chain of Clinical Trials

Trial Name	STS Score	Age
Inoperable Population		
PARTNER IB Trial	11.6	83
High Risk Population		
PARTNER IA Trial	11.8	84
CoreValve US Pivotal Trial	7.4	83
Intermediate Risk Population		
PARTNER II Trial	5.8	82
Low Risk Population		
NOTION Trial	3.0	79

PARTNER I Trial

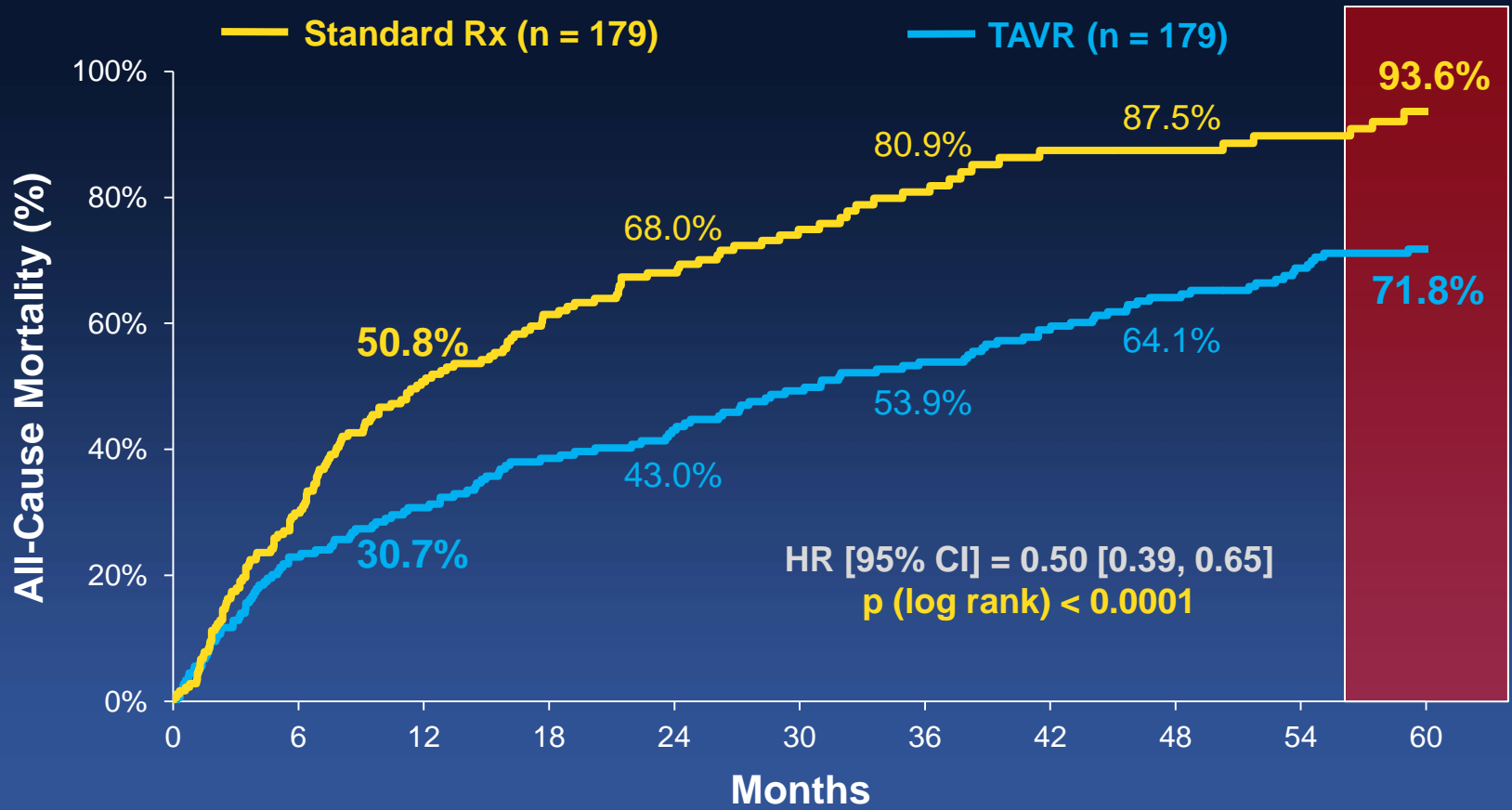


Edwards SAPIEN™ THV
23 mm and 26 mm

Inoperable Patients (PARTNER IB)

STS; 11.6, Age; 83 years-old

All Cause Mortality

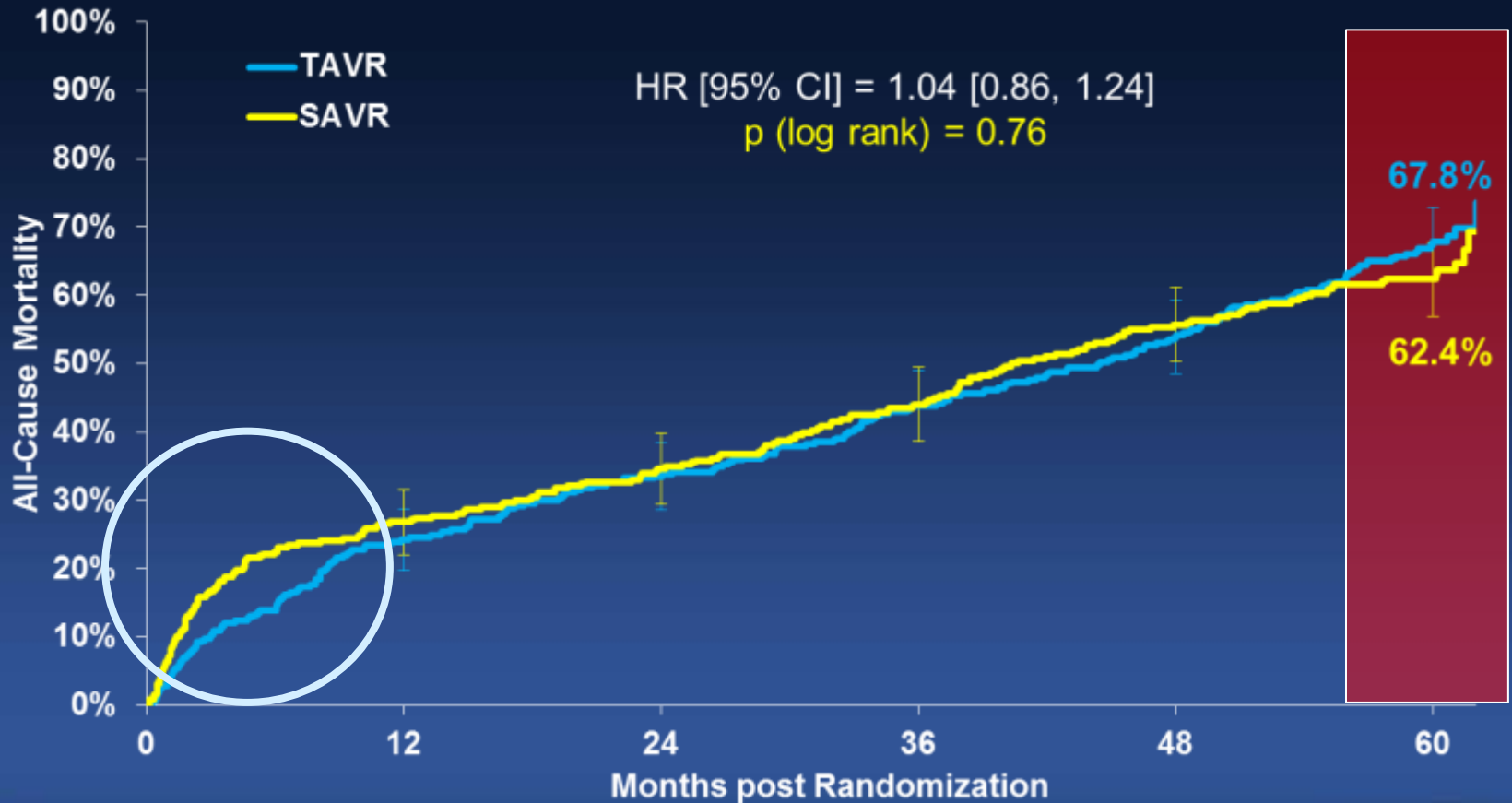


Kapadia SR et al, Lancet. 2015 Jun 20;385(9986):2485-91

High Risk Population (PARTNER IA)

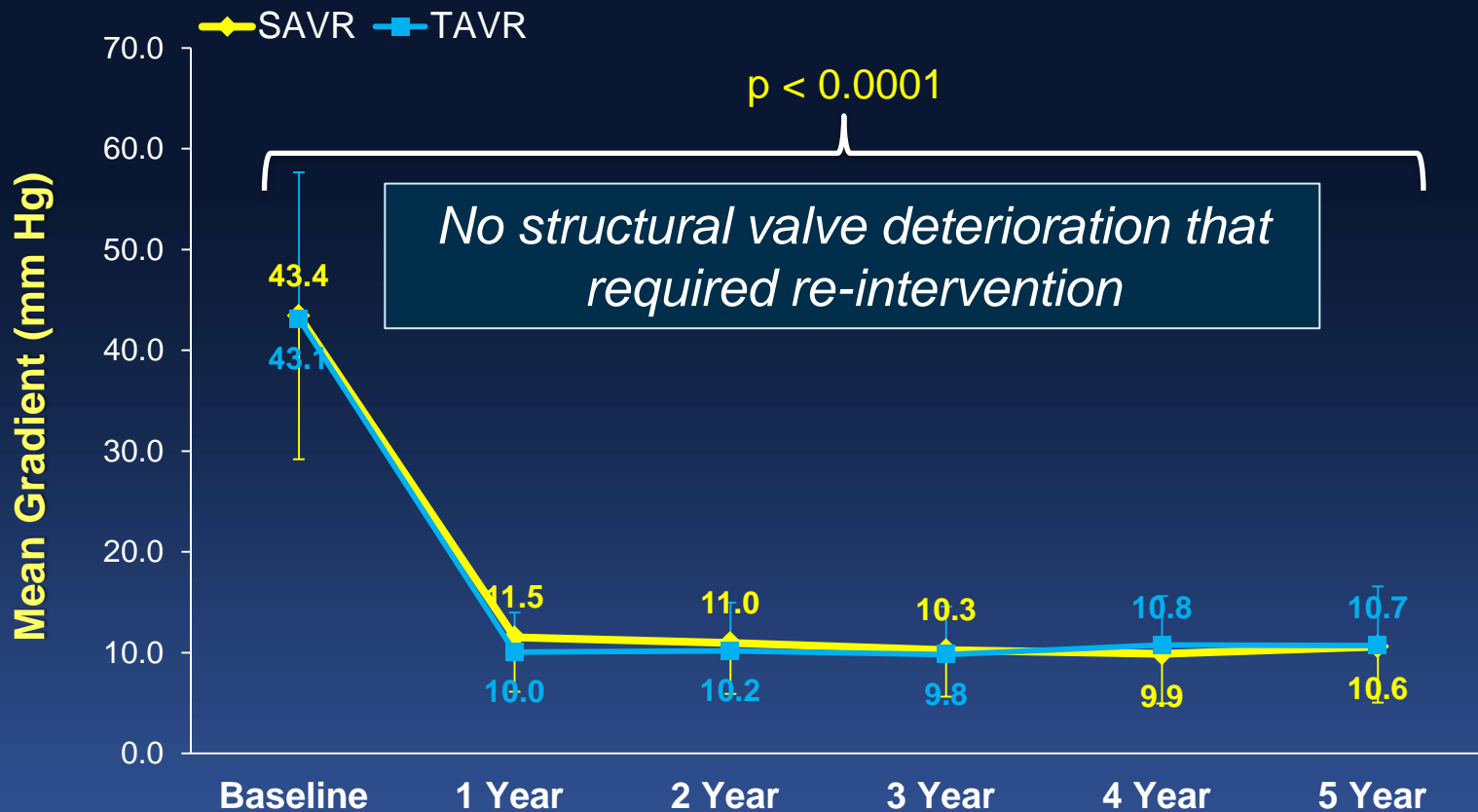
STS; 11.8, Age; 84 years-old

All Cause Mortality



Mack MJ et al, 2015 Jun 20;385(9986):2485-91

Mean Aortic Valve Area



	Baseline	1 Year	2 Year	3 Year	4 Year	5 Year
TAVR	310	219	156	106	79	56
SAVR	299	158	123	86	61	48

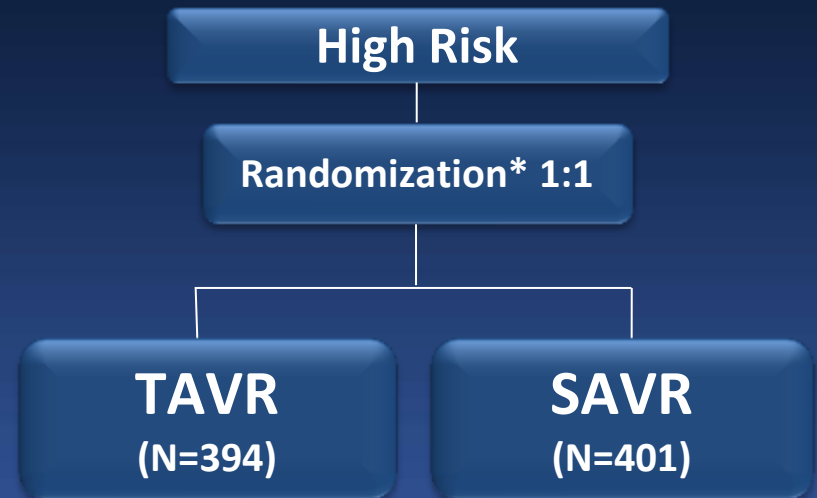
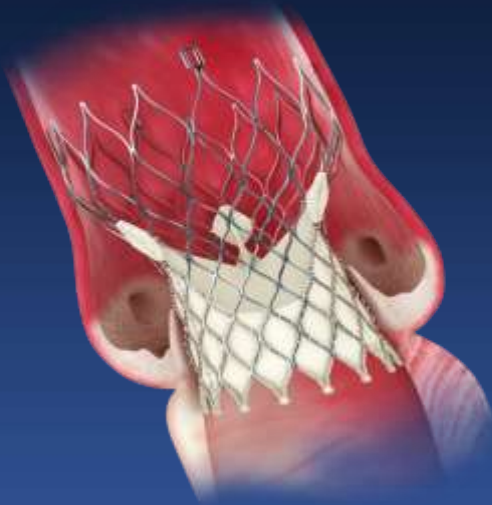
Mack MJ et al, 2015 Jun 20;385(9986):2485-91

ESC (2012) and AHA/ACC (2014) Guideline

COR	LOE	
I	B	For Inoperable Patients
Ila	B	For High Risk Patients

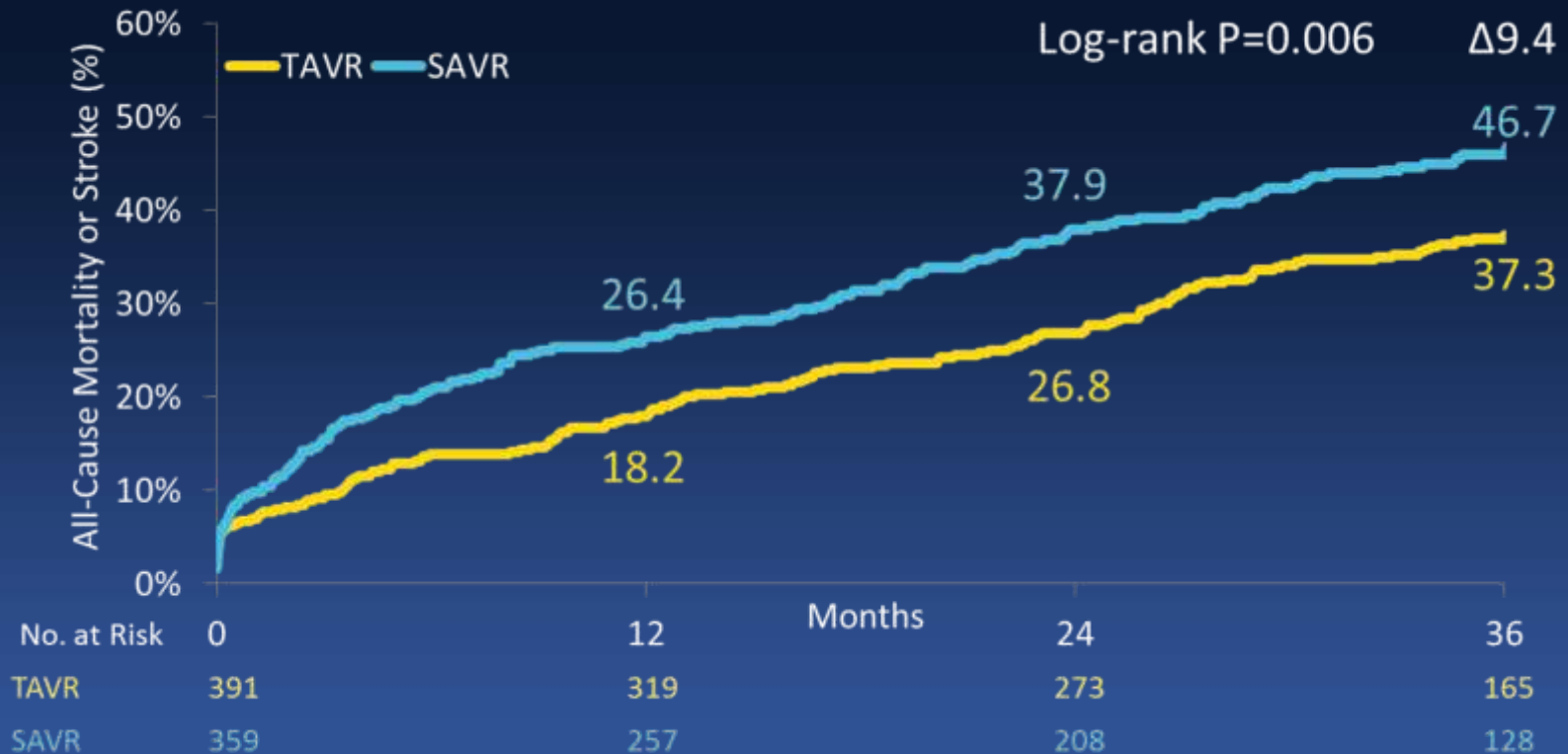
CoreValve US Pivotal Trial

STS; 7.4, Age; 83 years-old



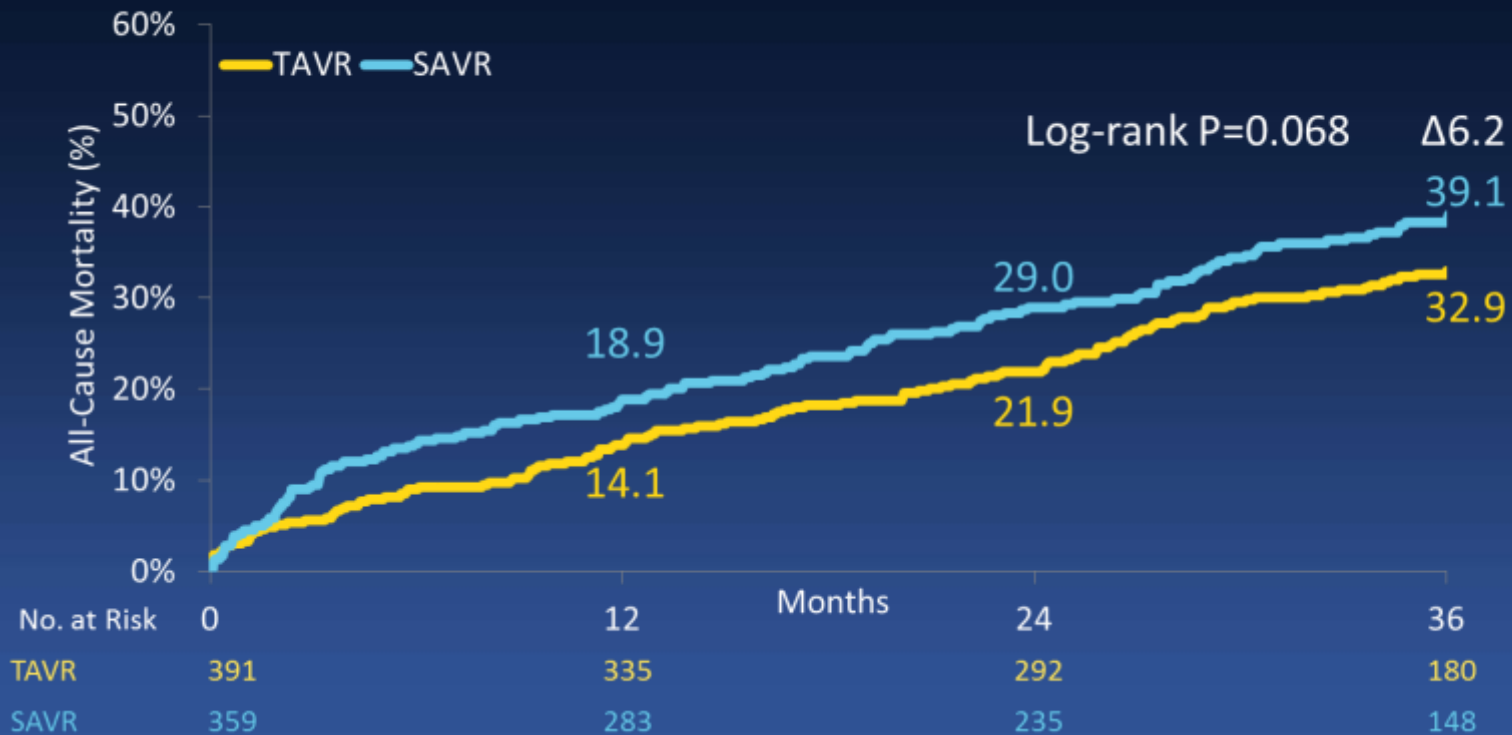
4 Valve Sizes (23, 26, 29, 31 mm)
18F Delivery System

All Cause Mortality or Stroke



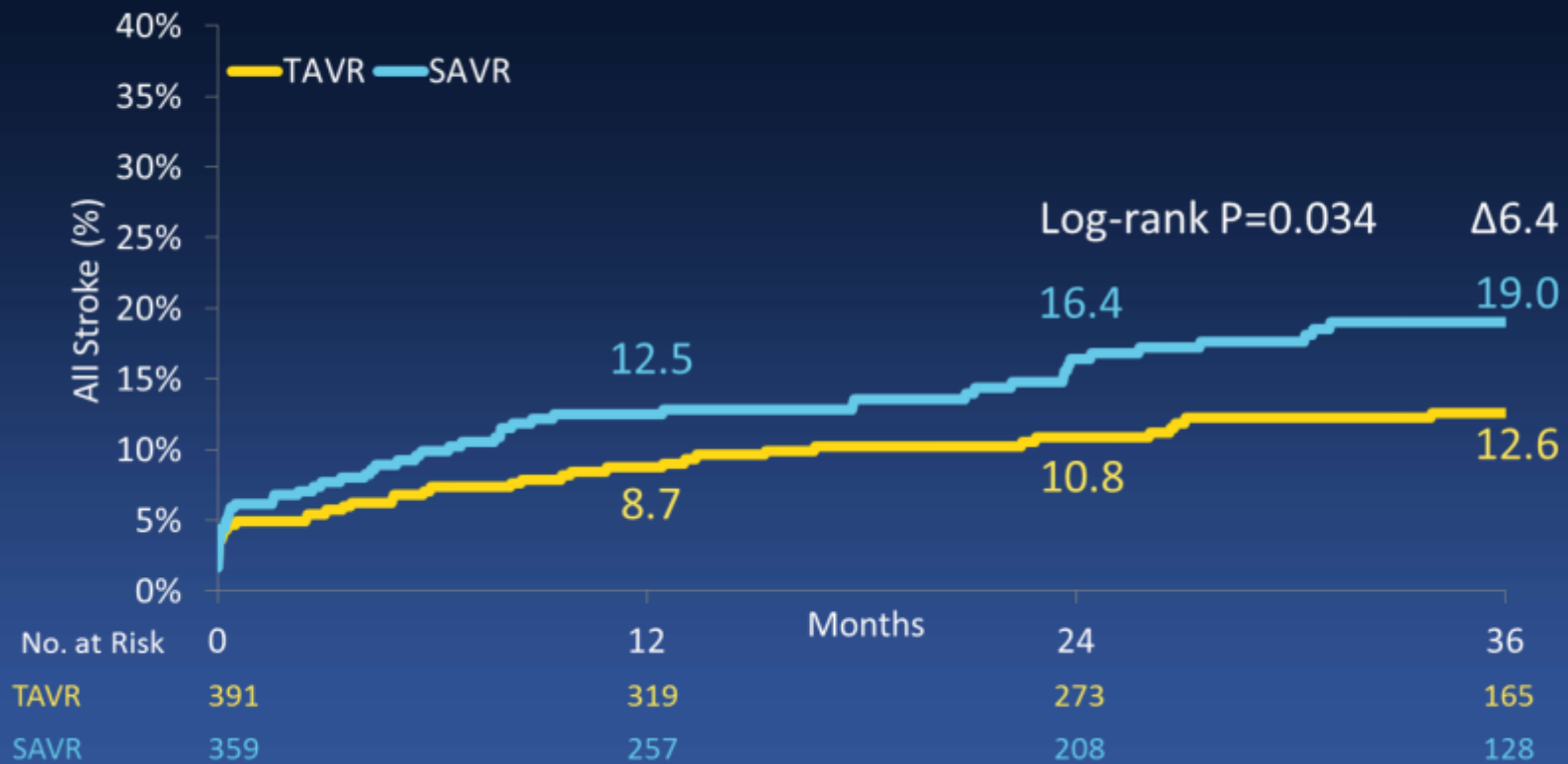
Deeb GM et al. J Am Coll Cardiol. 2016 Jun 7;67(22):2565-74

All Cause Mortality

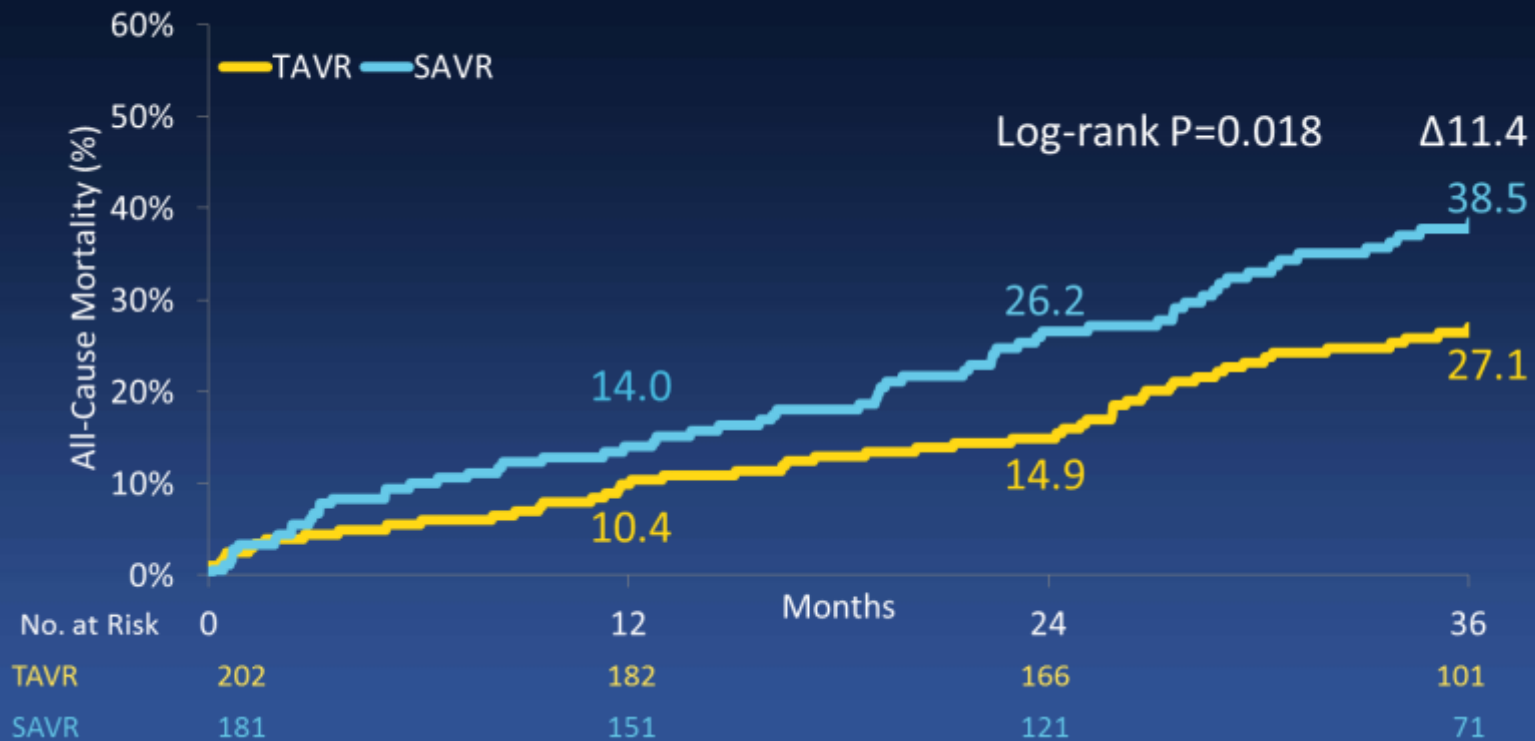


Deeb GM et al. J Am Coll Cardiol. 2016 Jun 7;67(22):2565-74

All Stroke



All Cause Mortality: STS $\leq 7\%$



NEXT Guideline

COR

LOE

I

B

For Inoperable Patients

I

A

For High Risk Patients

PARTNER II Trial

STS; 5.8, Age; 82 years-old



PII - 2010

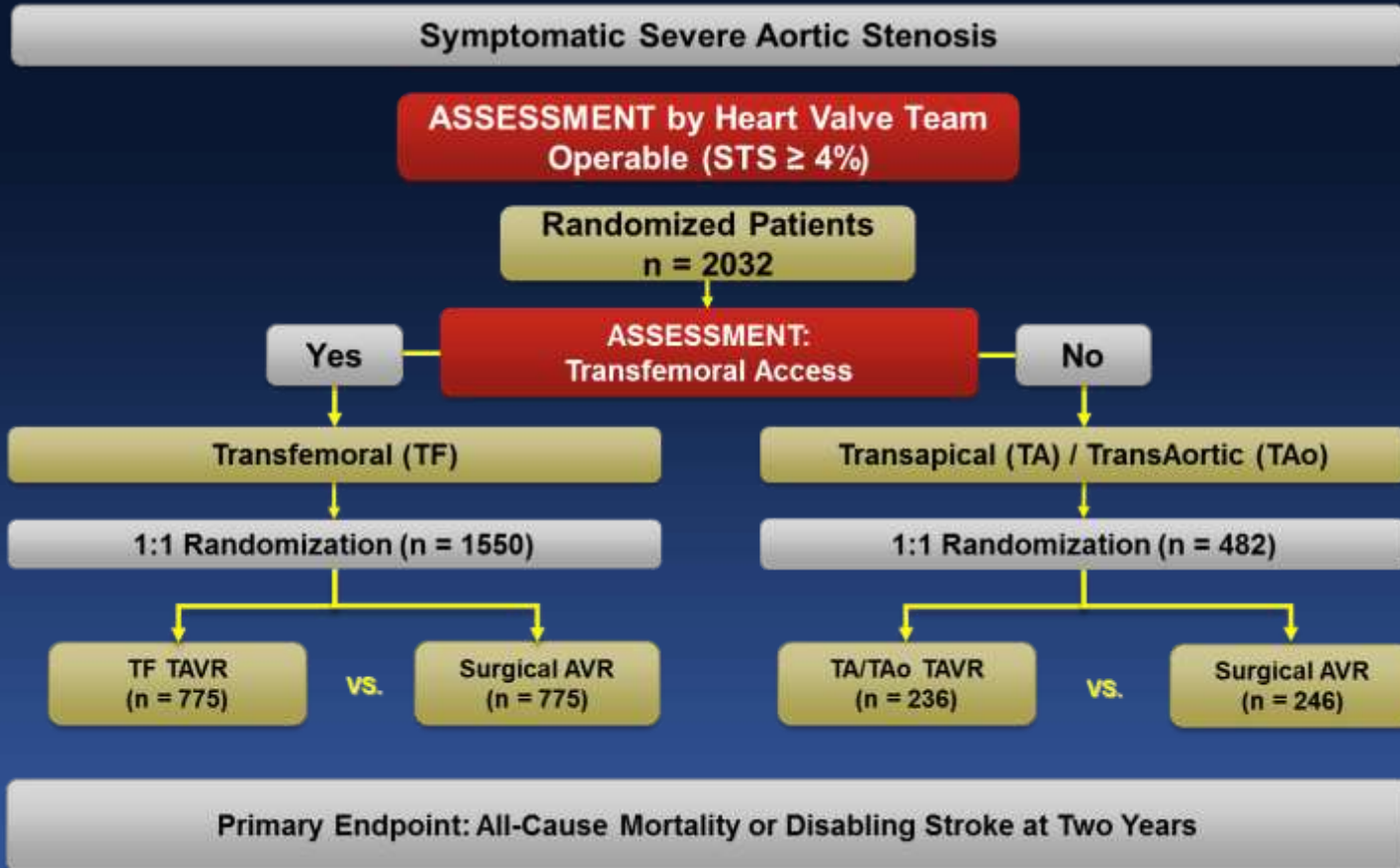
Edwards SAPIEN XT™ THV
23 mm, 26 mm, and 29mm



PII S3 - 2013

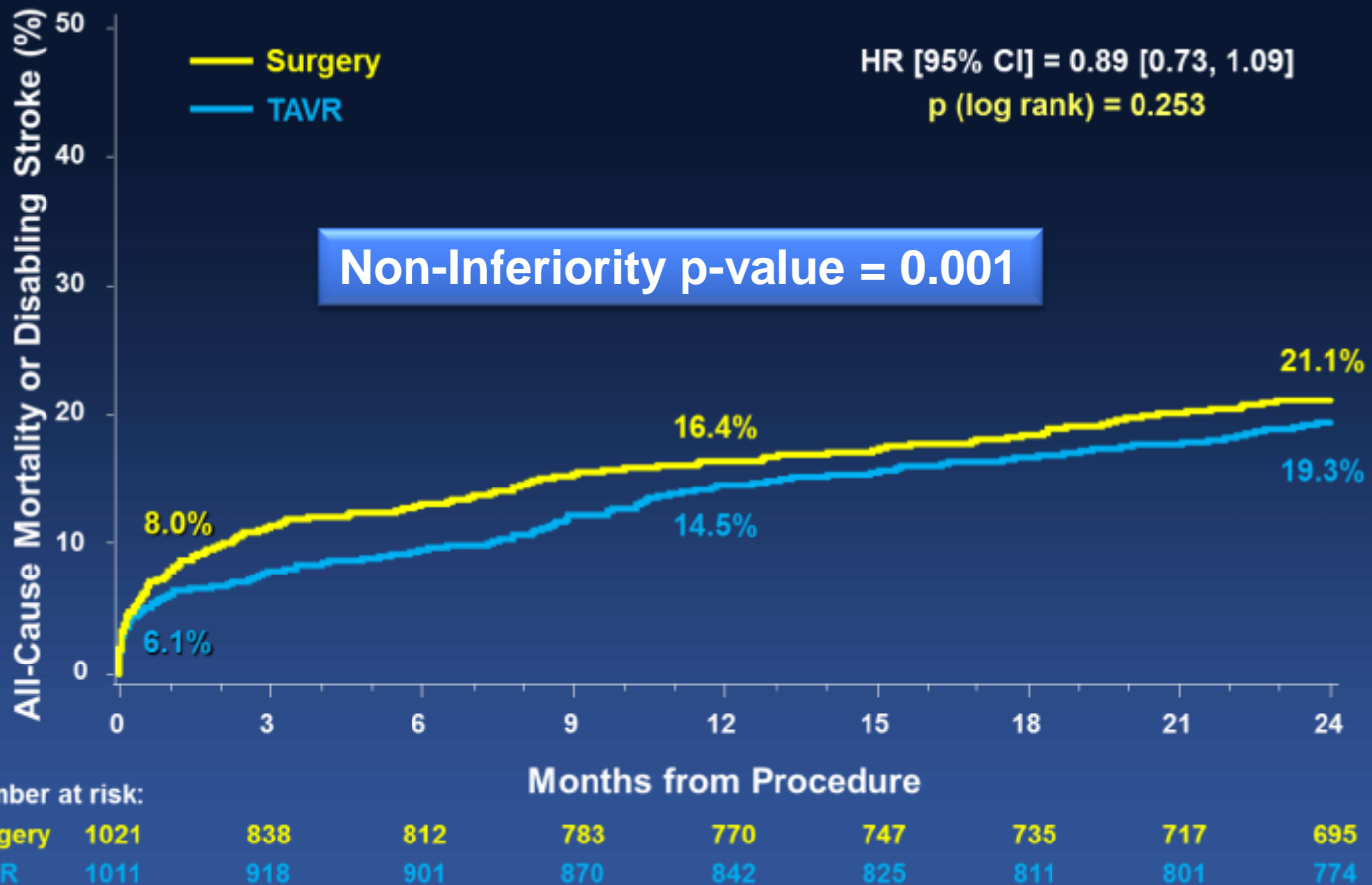
Edwards SAPIEN 3™ THV
20 mm, 23 mm, 26 mm, and 29mm

PARTNER IIA



Primary Endpoint (ITT)

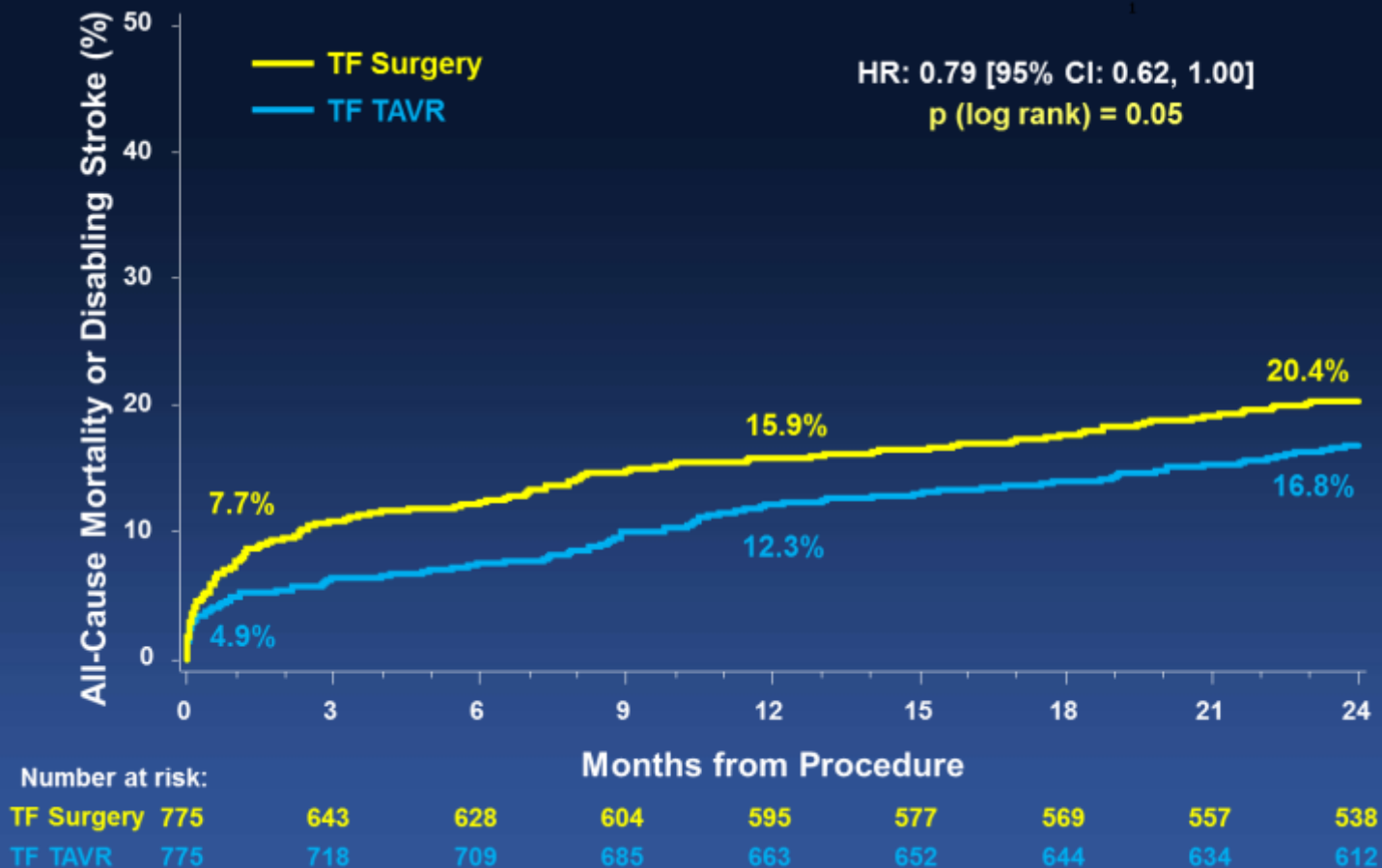
All Death or Disabling Stroke @ 2 Years



Leon MB et al. N Engl J Med. 2016 Apr 28;374(17):1609-20

Transfemoral Cohort (ITT)

All Death or Disabling Stroke @ 2 Years



Leon MB et al. N Engl J Med. 2016 Apr 28;374(17):1609-20

SAPIEN 3 in Intermediate Risk

A Propensity Score Comparison of SAPIEN 3 (S3i Registry) vs SAVR (PARTNER 2A Trial)



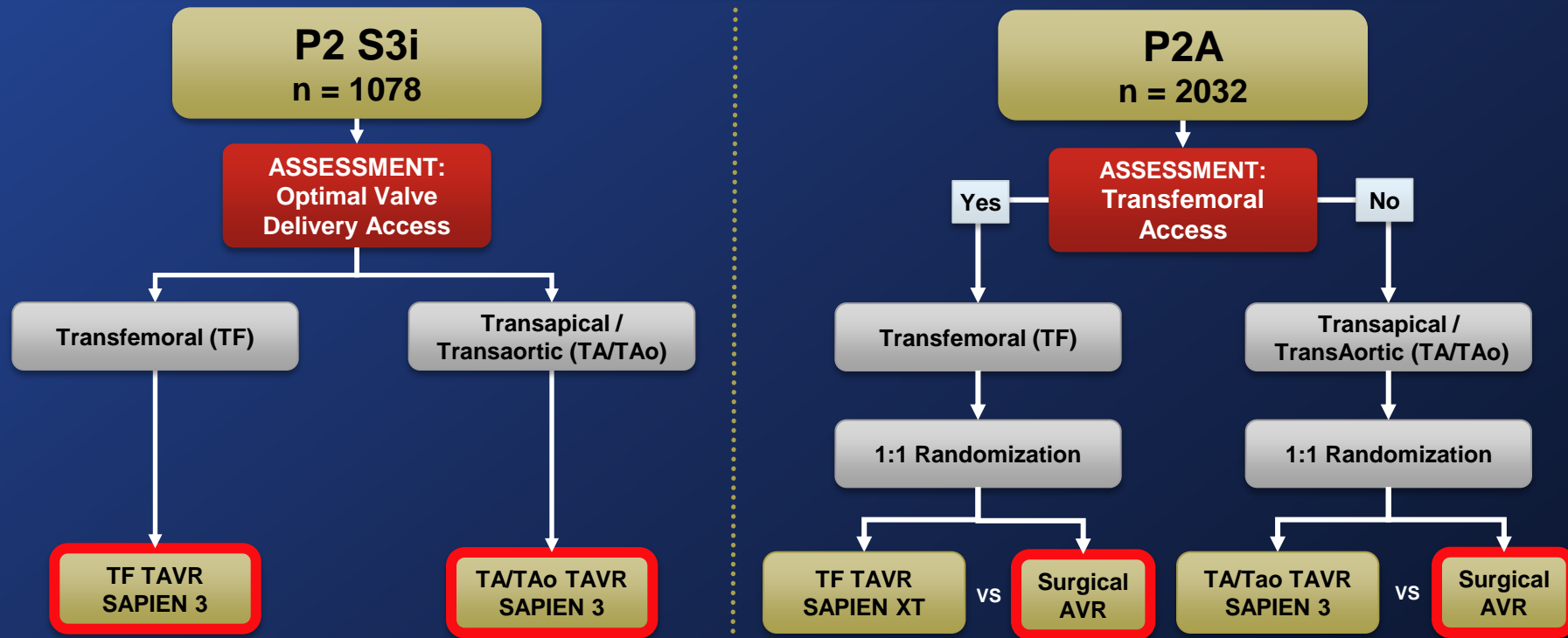
- The 30-day outcomes in *intermediate-risk* patients treated with SAPIEN 3 in PARTNER 2 were...
 - All-cause Mortality: 1.1%
 - Disabling Stroke: 1.0%
 - PVL \geq Moderate: 3.8%

The PARTNER 2A and S3i Trials Study Design



Intermediate Risk Symptomatic Severe Aortic Stenosis

Intermediate Risk ASSESSMENT by Heart Valve Team



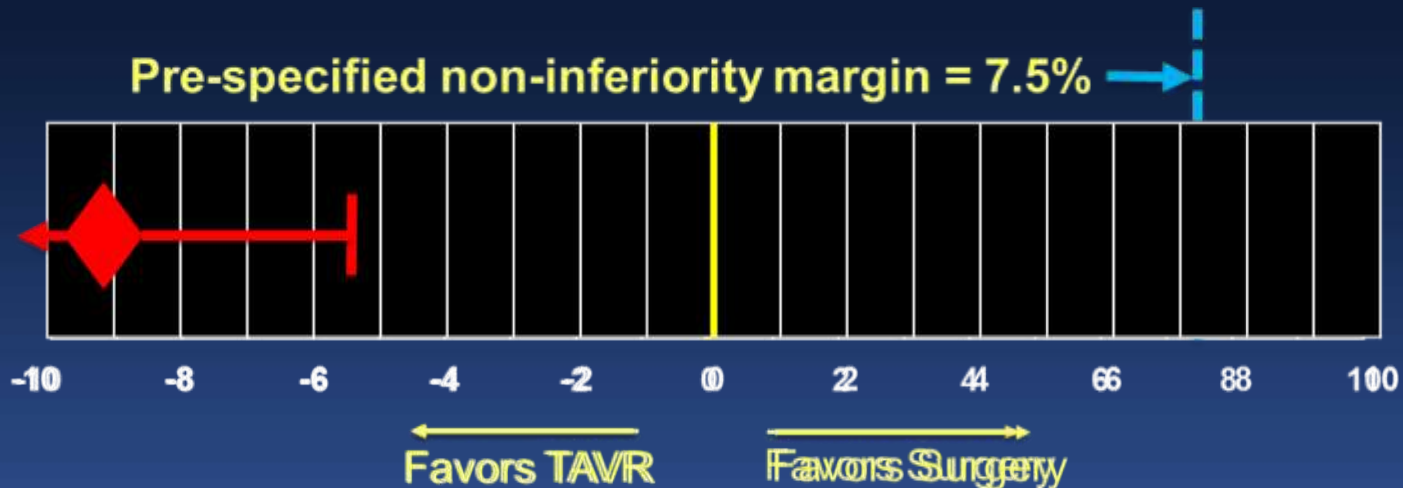
Primary Endpoint: All-Cause Mortality, All Stroke, or Mod/Sev AR at One Year
(Non-inferiority Propensity Score Analysis)

Primary Endpoint

Death, Stroke, or AR \geq Mod @ 1 Year

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

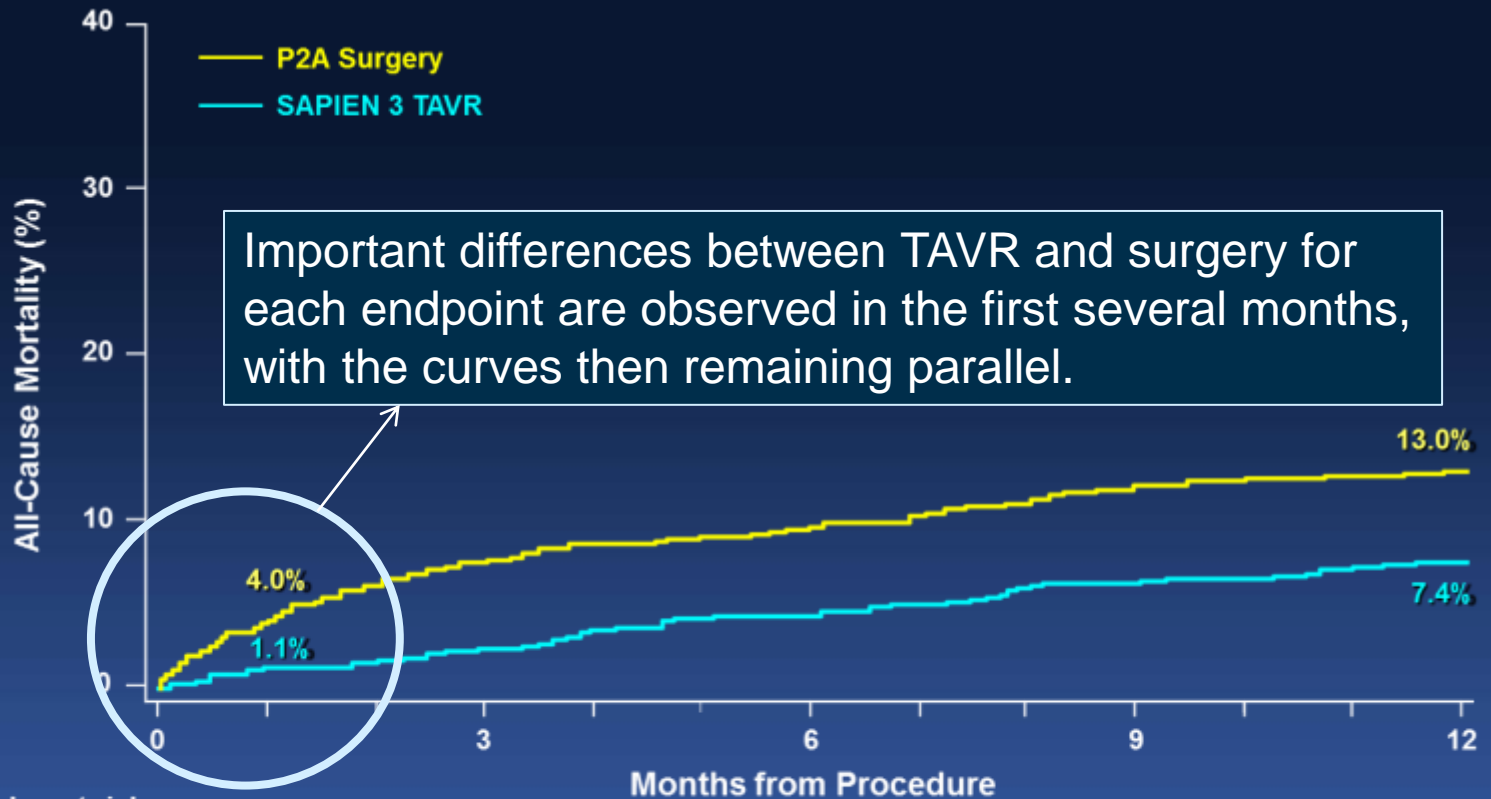
Superiority Testing
p-value < 0.001



Superiority Achieved

Thourani VH et al. Lancet. 2016 May 28;387(10034):2218-25

All Cause Mortality



Number at risk:

P2A Surgery 944
S3 TAVR 1077

859
1043

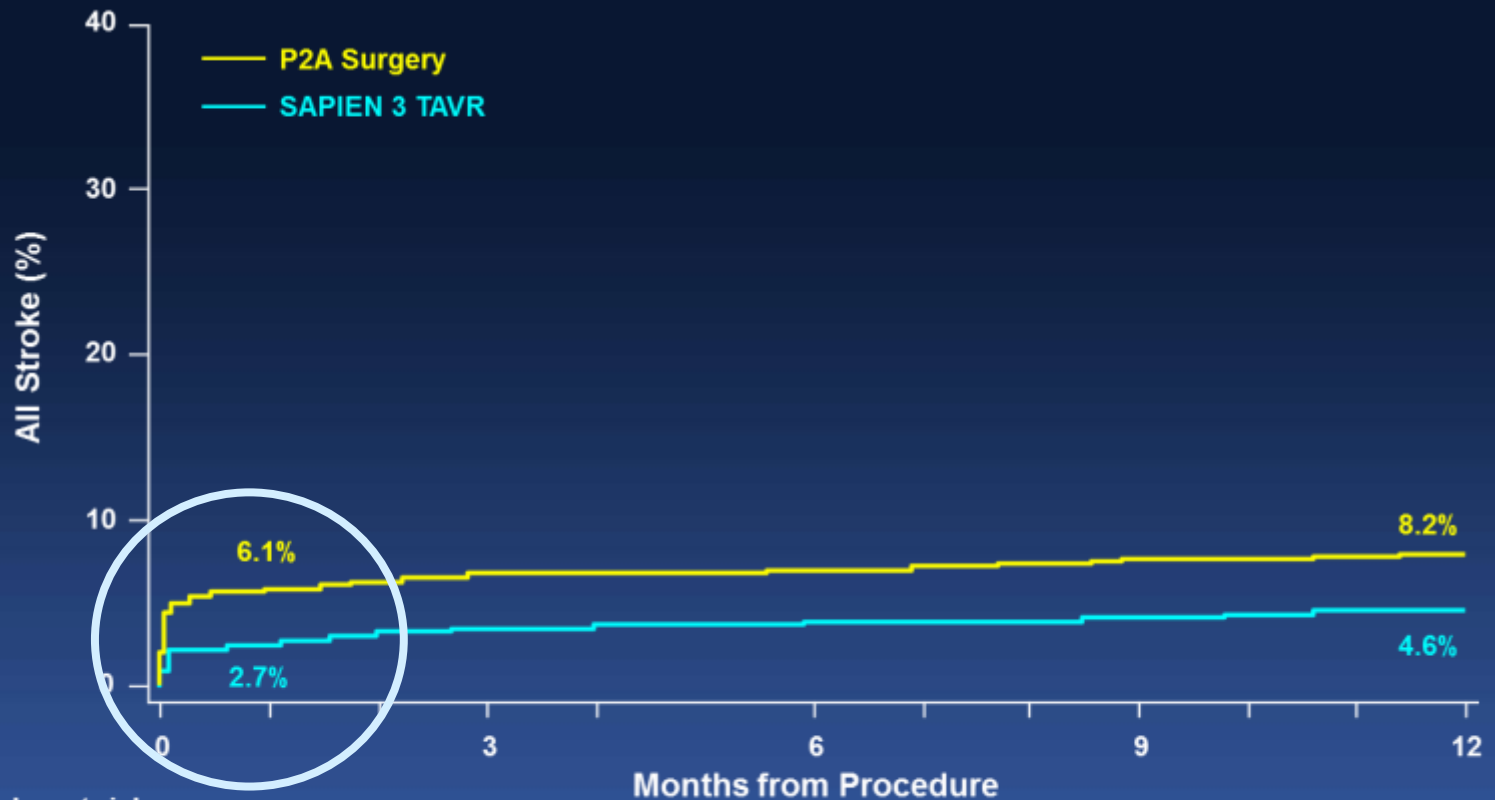
836
1017

808
991

795
963

Thourani VH et al. Lancet. 2016 May 28;387(10034):2218-25

All Stroke

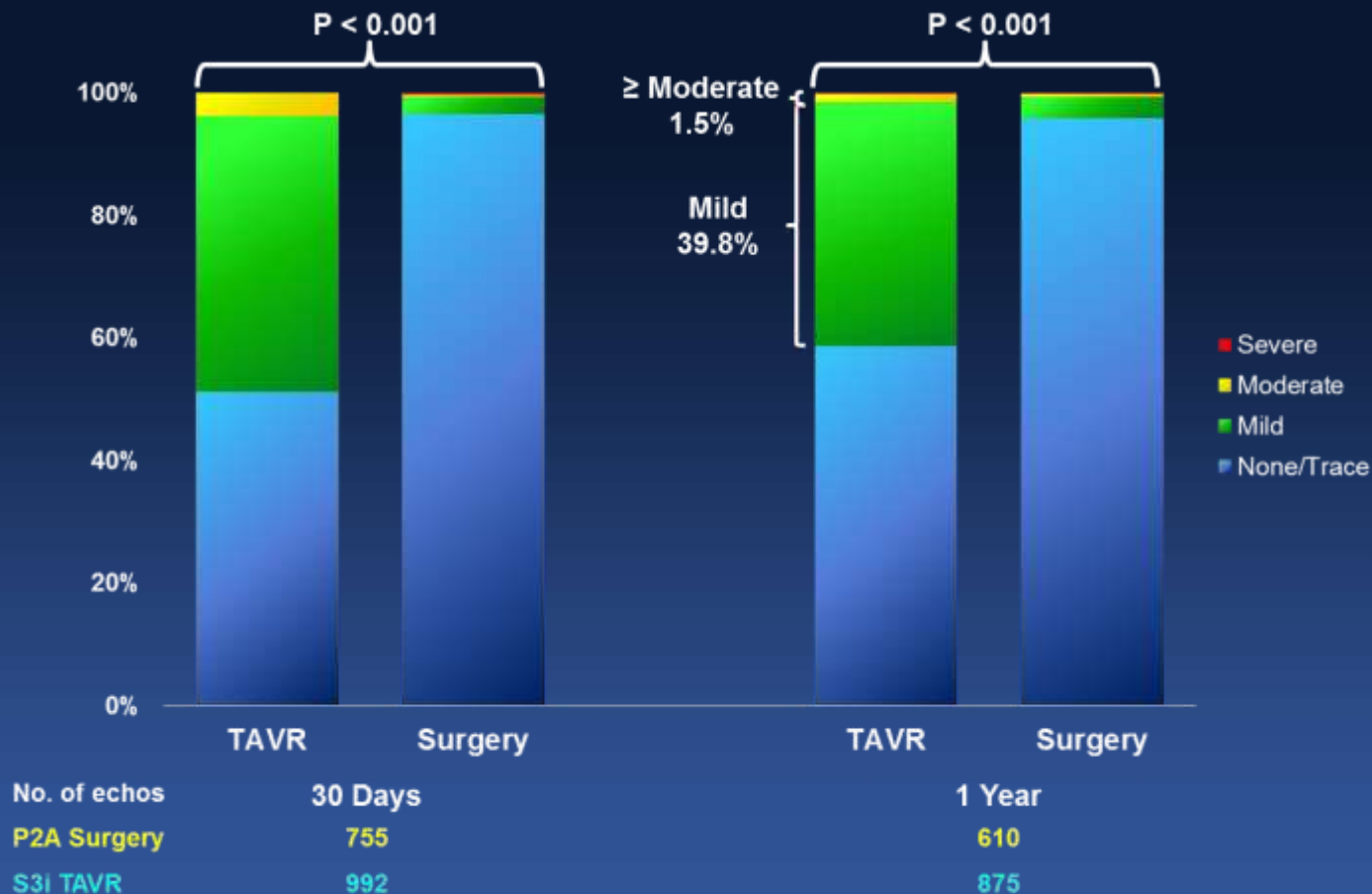


Number at risk:

	0	3	6	9	12
P2A Surgery	944	805	786	757	743
S3 TAVR	1077	1012	987	962	930

Thourani VH et al. Lancet. 2016 May 28;387(10034):2218-25

Paravavular Regurgitation

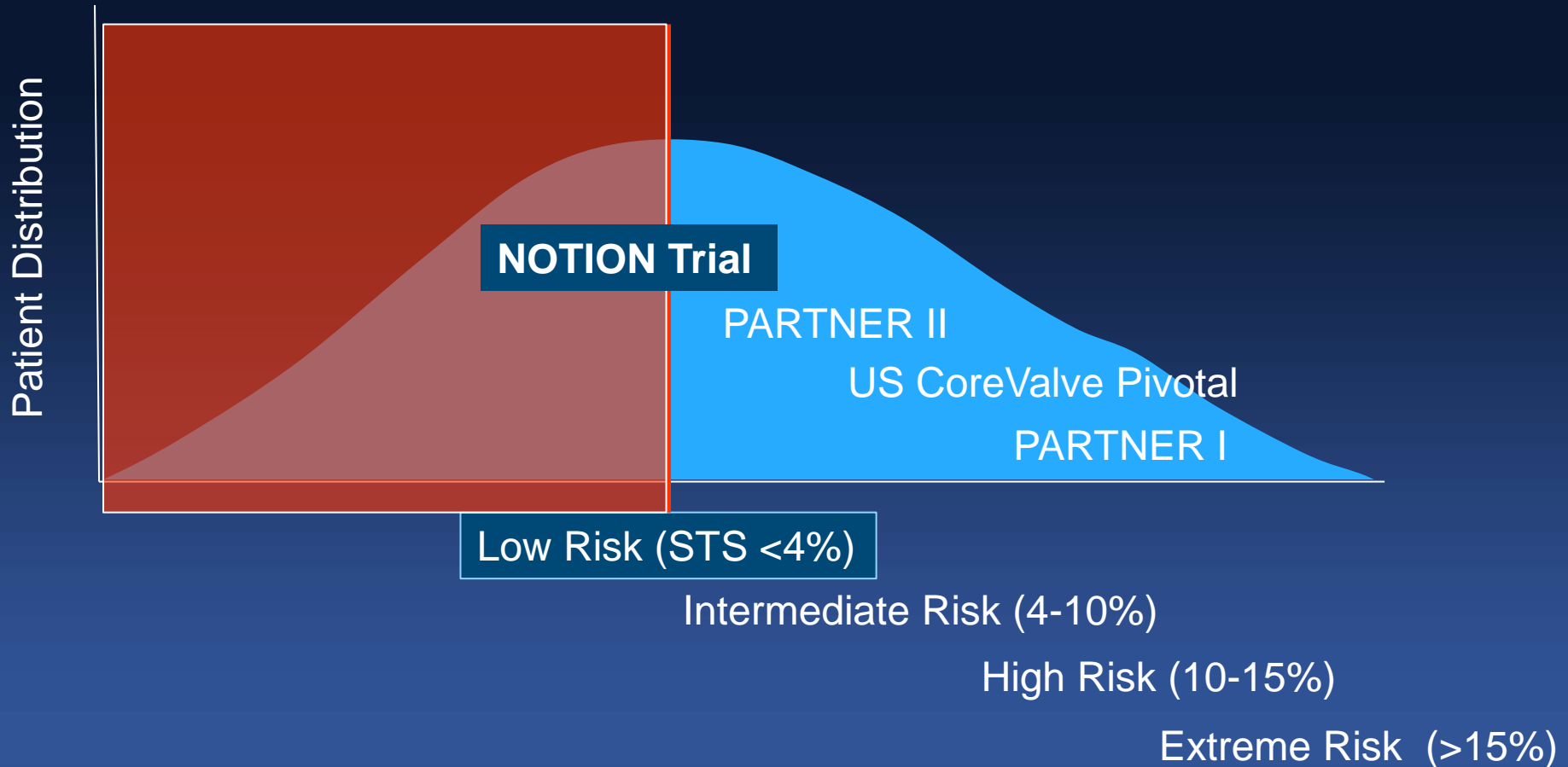


Thourani VH et al. Lancet. 2016 May 28;387(10034):2218-25

NEXT Guideline For TAVR

COR	LOE	
I	B	For Inoperable Patients
I	A	For High Risk Patients
Ila	B	For Intermediate Risk Patients

Operative Risk and Trials



NOTION Trial

- First All Comer Trial to Compare TAVR vs. SAVR
- Age ≥ 70 years
- Self-expanding Bioprosthesis
- Transfemoral or Subclavian Access
- Major Exclusion Criteria
 - Severe CAD
 - Severe other valve disease
 - Prior heart surgery
 - Recent stroke or MI
 - Severe lung or renal disease

Thyregod HG et al, J Am Coll Cardiol. 2015 May 26;65(20):2184-94

Lars Søndergaard et al, Circ Cardiovasc Interv. 2016;9:e003665

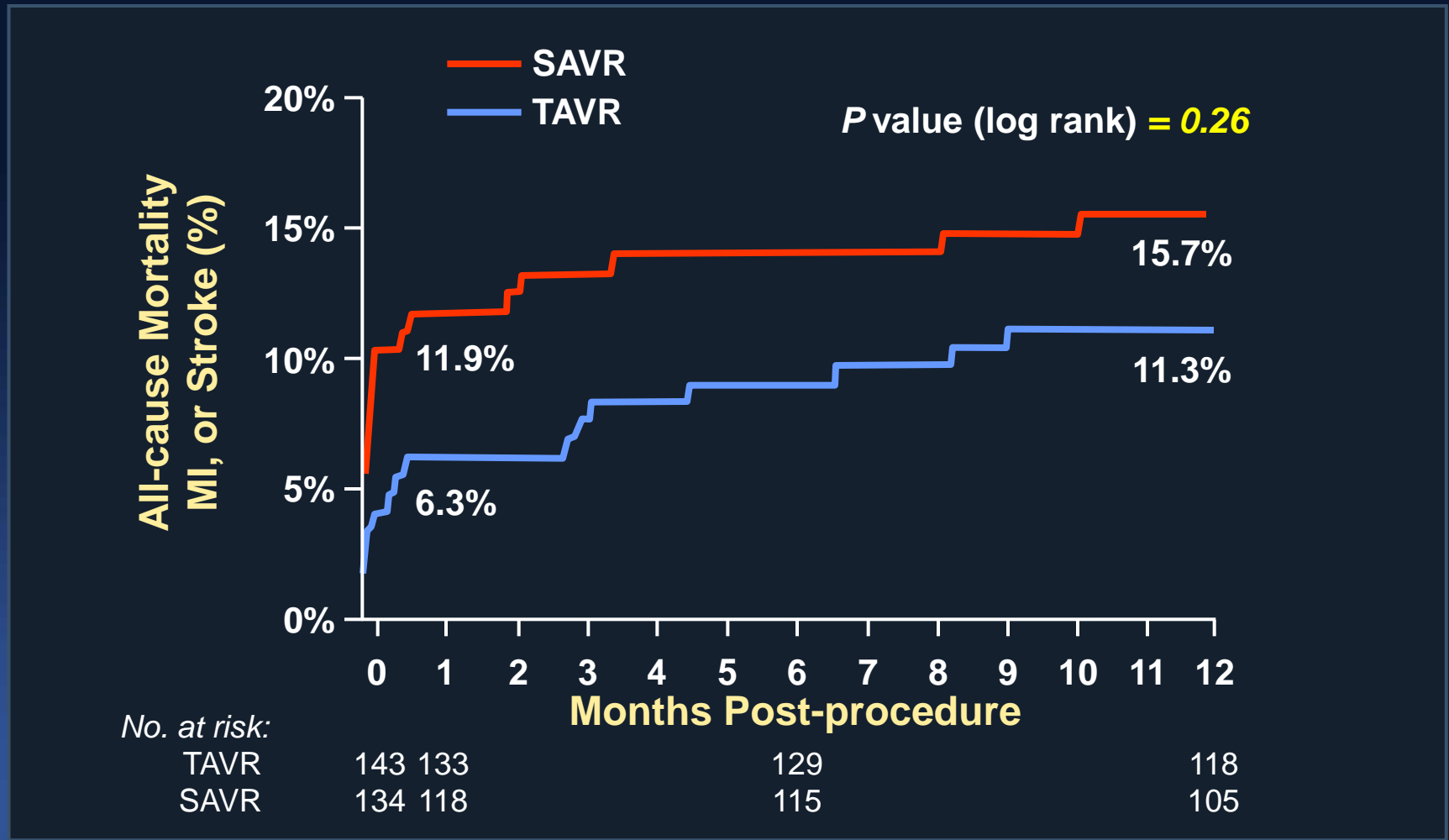
NOTION: Baseline Characteristics

Characteristic, % or mean \pm SD	TAVR n=145	SAVR n=135	P value
Age (yrs)	79.2 \pm 4.9	79.0 \pm 4.7	0.71
Male	53.8	52.6	0.84
Society of Thoracic Surgeons (STS) Score	2.9 \pm 1.6	3.1 \pm 1.7	0.30
STS Score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 \pm 4.0	8.9 \pm 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61

Thyregod HG et al, J Am Coll Cardiol. 2015 May 26;65(20):2184-94

Lars Søndergaard et al, Circ Cardiovasc Interv. 2016;9:e003665

NOTION Trial: Death, Stroke, or MI



Thyregod HG et al, J Am Coll Cardiol. 2015 May 26;65(20):2184-94

Lars Søndergaard et al, Circ Cardiovasc Interv. 2016;9:e003665

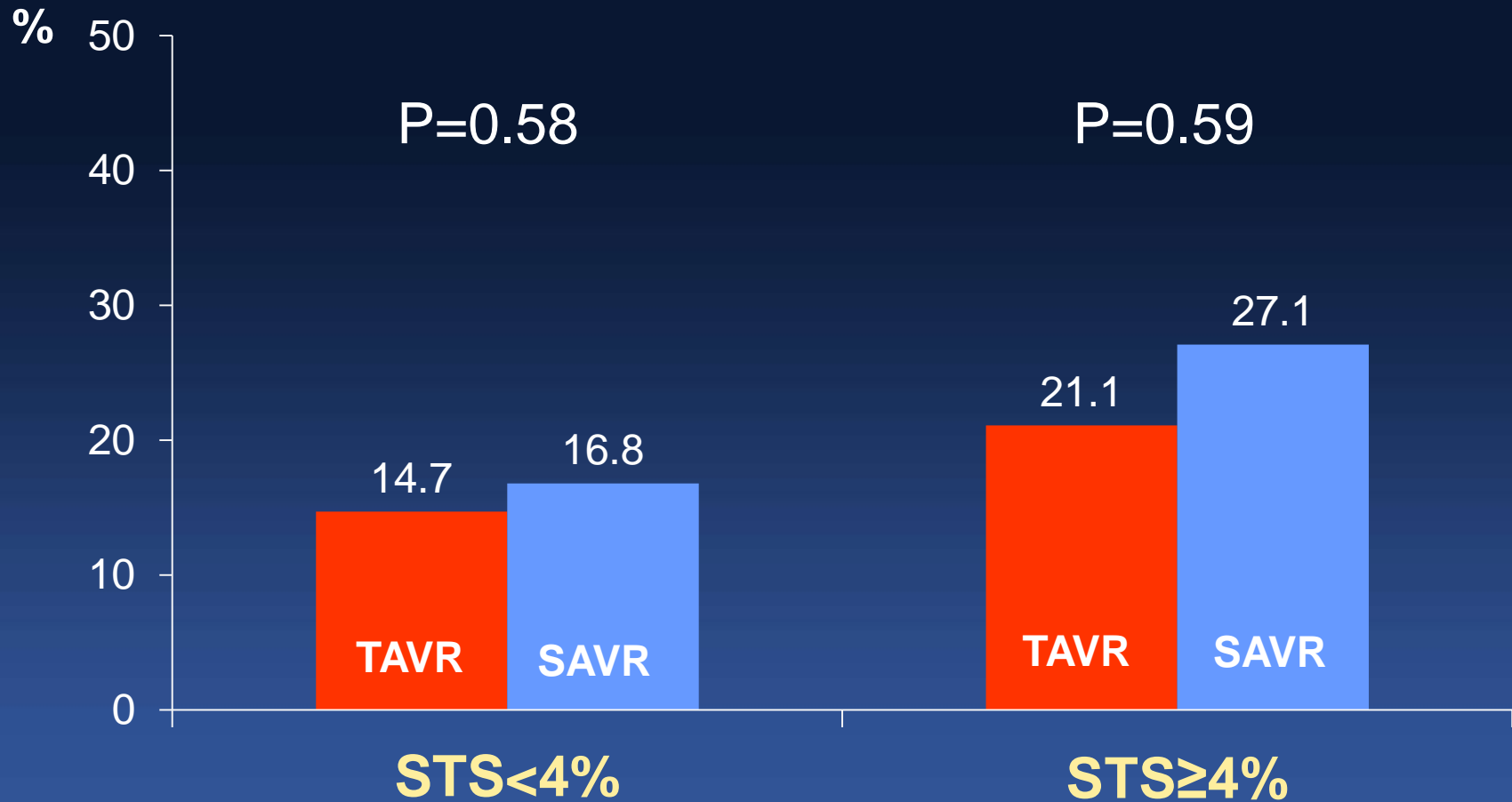
NOTION Trial @ 2 Years

Events (%)	No of Pts With Events (%)		
	TAVR	SAVR	P Value
All-Cause Death	11 (8.0)	13 (9.8)	0.54
Cardiovascular Death	9 (6.5)	12 (9.1)	0.40
Neurologic Events	13 (9.7)	10 (7.8)	0.67
Stroke	5 (3.6)	7 (5.4)	0.46
TIA	8 (6.0)	4 (3.3)	0.30
Myocardial Infarction	7 (5.1)	8 (6.0)	0.69
New-Onset of Worsening A.fib	32 (22.7)	80 (60.2)	<0.001
PPM Implantation	55 (41.3)	5 (4.2)	<0.001
PVL ≥ Moderate	19 (15.4)	1 (0.9)	<0.001

Thyregod HG et al, J Am Coll Cardiol. 2015 May 26;65(20):2184-94

Lars Søndergaard et al, Circ Cardiovasc Interv. 2016;9:e003665

Death, MI, or Stroke @ 2 Years



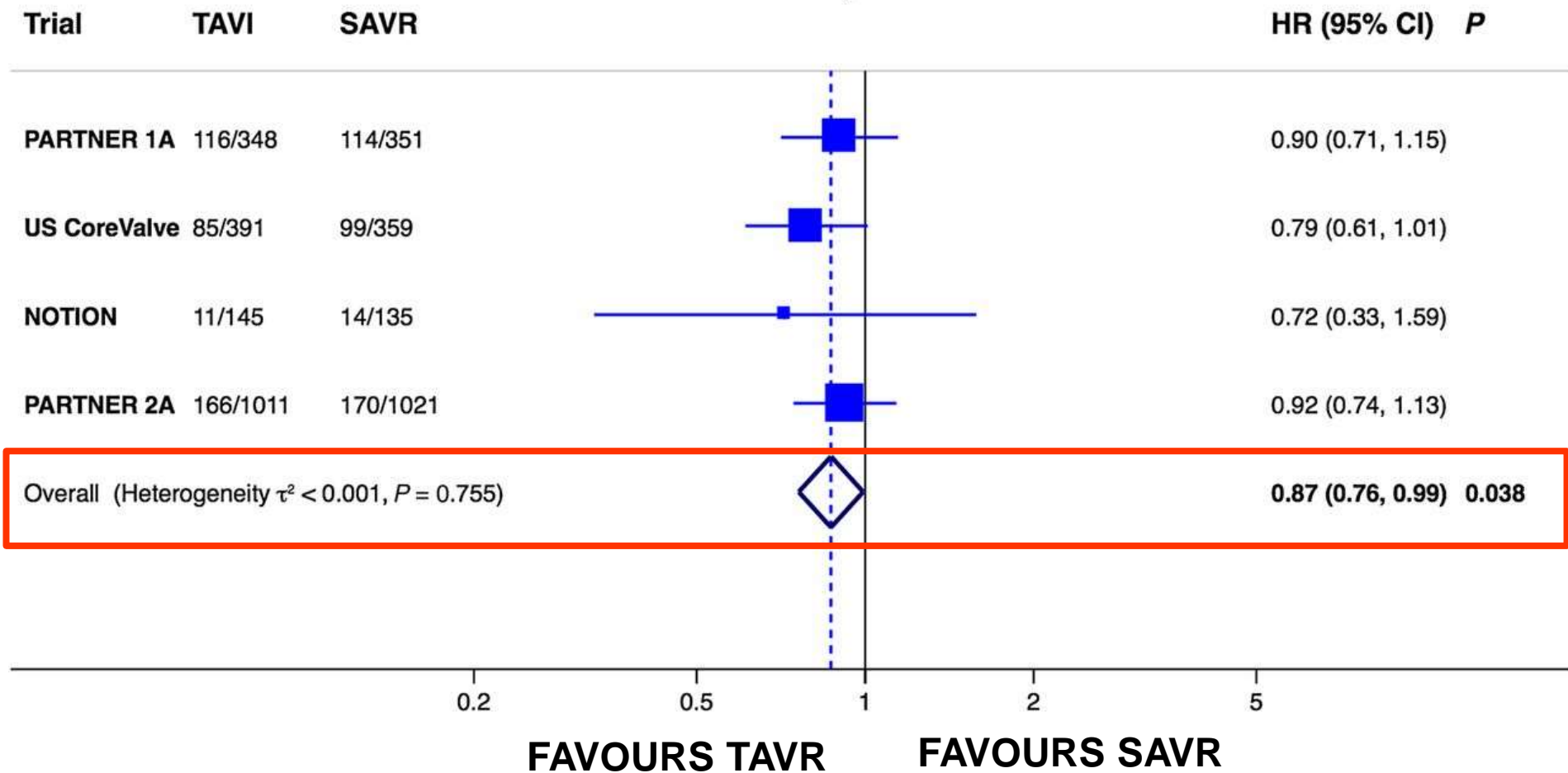
Thyregod HG et al, J Am Coll Cardiol. 2015 May 26;65(20):2184-94

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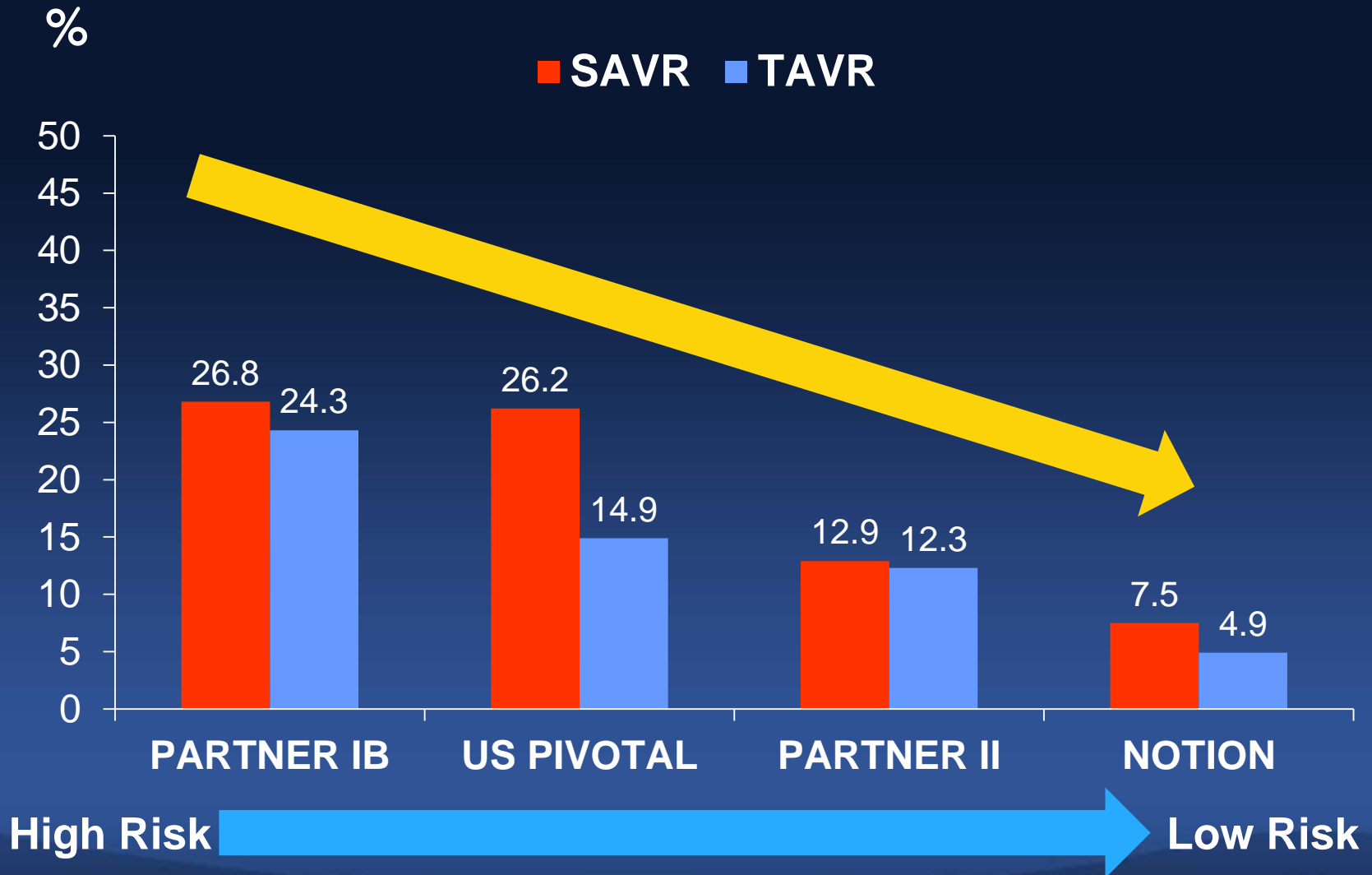
Metaanalysis From 4 Randomized Trials

Survival Benefit In TAVR

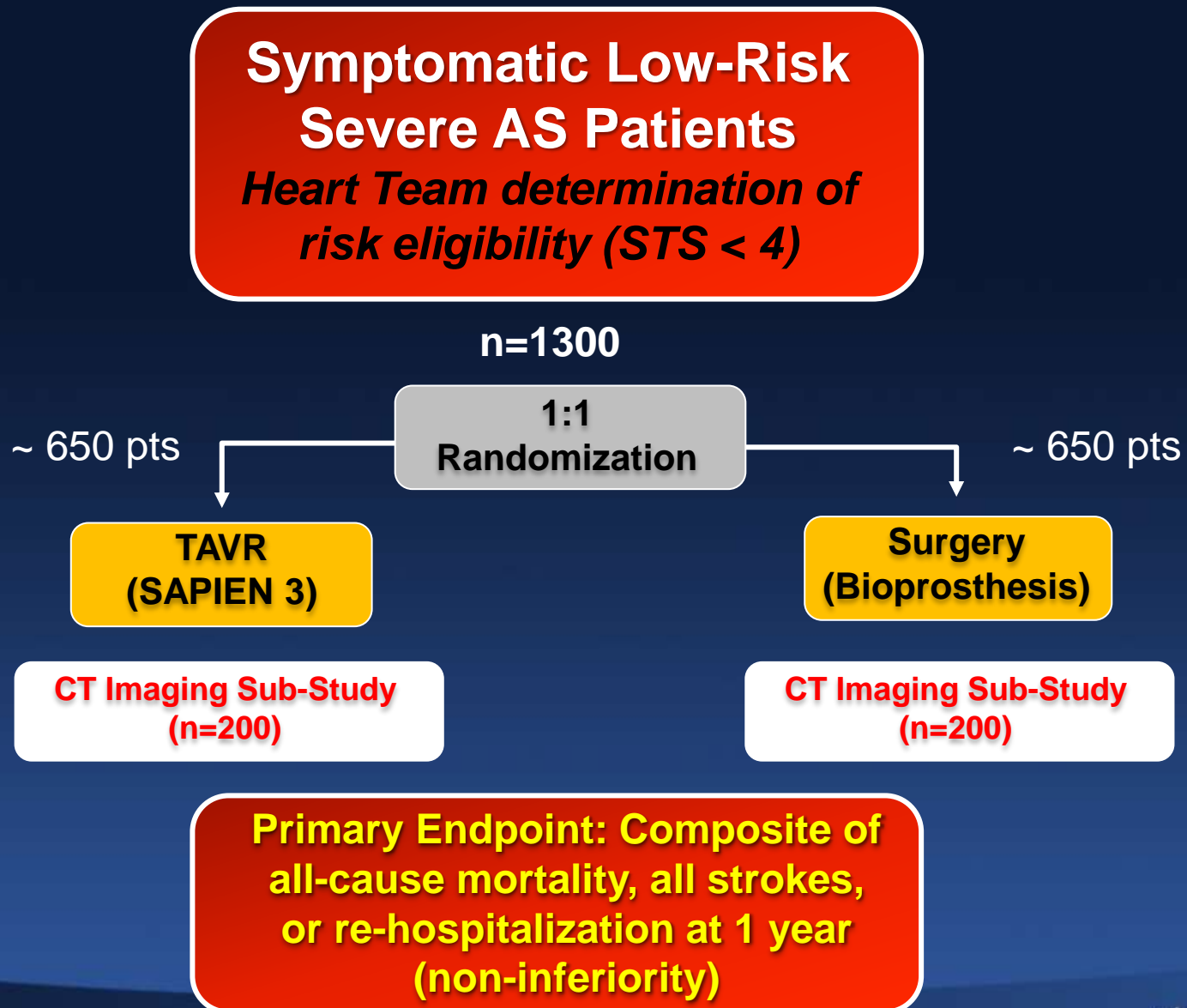
Death from any cause



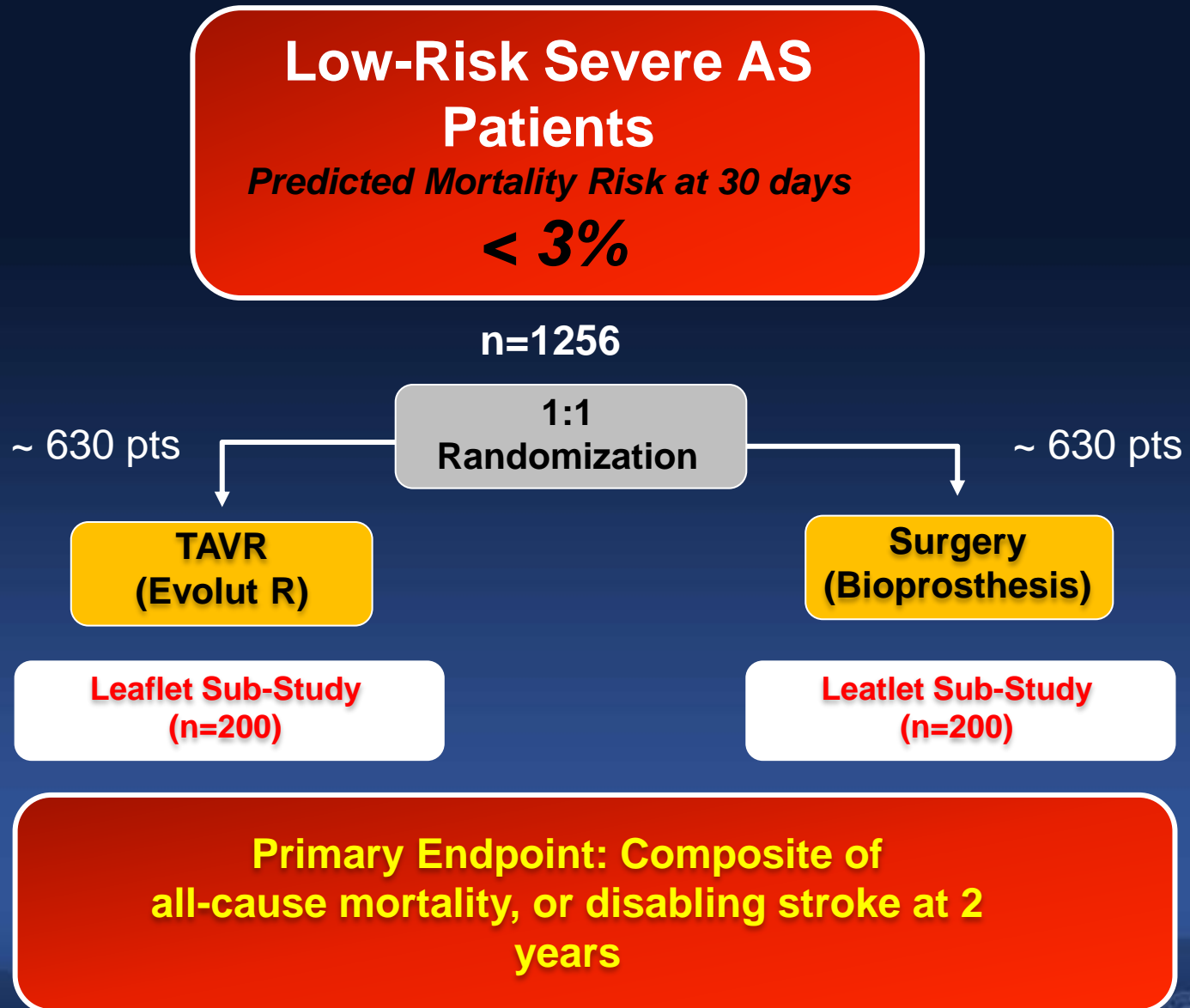
All Cause Mortality @ 1 Year



PARTNER 3 Low Risk Trial



MEDTRONIC TAVR IN LOW RISK PATIENTS



NEXT Guideline For TAVR

COR

LOE

I

B

For Inoperable Patients

I

A

For High Risk Patients

Ila

B

For Intermediate Risk Patients

??

??

For Low Risk Patients

Dr. Alain Cribier at TCTAP 2016



April 16, 2002

My prediction on the future of TAVR

2016 TAVI is indicated in patients who are not optimal candidates to surgery



2020 SAVR is indicated in patients who are not optimal candidates to TAVR !

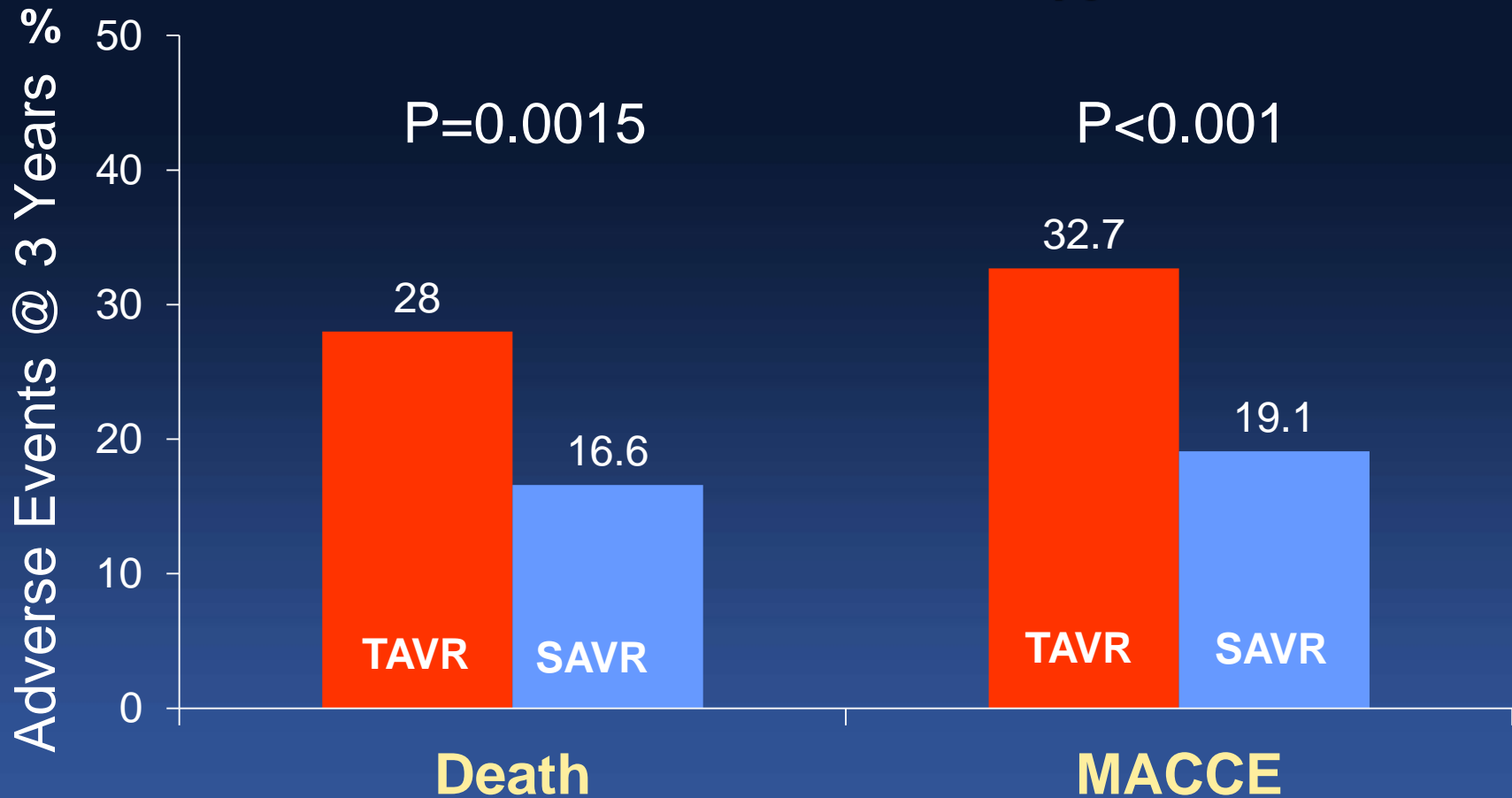
Hope Healthy Centenarian



Thank You for Your Attention

OBSERVANT Study

355 Propensity Score Matched Pairs With EuroScore II < 4%



Stefano Rosato et al, Circ Cardiovasc Interv. 2016;9:e003326