TAVR: Year in Review in 12 minutes

Raj R. Makkar, MD
Director, Interventional Cardiology & Cardiac Catheterization Laboratories
Associate Director, Cedars-Sinai Heart Institute
Professor of Medicine, University of California, Los Angeles
Stephen Corday Chair in Interventional Cardiology

Excellent Review in 20 pages, 111 references, 5 tables

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YEAR IN REVIEW

Transcatheter Aortic Valve Replacement: 2015 in Review

KISHORE J. HARJAI, M.D.,[1] CINDY L. GRINES, M.D.,[2] and MARTIN B. LEON, M.D.[3]

From the [1]Geisinger Clinic, Pearsall Heart Hospital, Wilkes-Barre, Pennsylvania; [2]Detroit Medical Center Heart Hospital, Detroit, Michigan; and [3]Columbia University Medical Center, New York, New York

Transcatheter aortic valve replacement (TAVR) has emerged as an attractive option for patients with severe symptomatic aortic stenosis (AS) who are either at high risk or extreme risk for surgical aortic valve replacement (SAVR). This article summarizes the major advances in TAVR that were published or reported in 2015. (J Interven Cardiol 2016;29:27–46)

J Interventional Cardiology 2016

Most Influential or Promising TAVR Studies in 2015

Table 1. The Most Influential or Promising TAVR Studies Published in 2015

Author/Study	Major Findings
Mack/PARTNER 1A[1]	In high-risk patients randomized to TAVR (using the first generation ESV) versus SAVR, the risk of 5-year death was similar, with no structural valve deterioration in either group.
Reardon/core valve high risk study[2]	In high-risk patients randomized to TAVR (using the MCV) versus SAVR), all-cause mortality as well as death or major stroke were significantly lower with TAVR at 2 years.
Kapadia[3]/ PARTNER IB	In extreme risk patients, TAVR showed a persistent reduction in mortality at 5 years compared to medical therapy.
Thyregod/NOTION[94]	In low risk patients randomized to TAVR versus SAVR, 1-year and 2-year outcomes were equivalent between the groups.
Hermann/PARTNER II (TCT 2015).	Favorable results of S3 Valve in 583 high risk or inoperable patients.
Manoharan[80]	Favorable rates with the Evolut R system in 60 patients. (The S3 and Evolut R valves were both approved by the FDA in 2015).
Dvir/PARTNER II registries (TCT 2015)	Excellent outcomes with the XT valve implantation in patients with failed surgical bioprostheses. The FDA approved the XT valve for this indication.
Gooley[88]	Mechanically expanded Lotus THV beats the self-expanding MCV in a small non-randomized study. Better anatomic positioning and lower rate of moderate PVL with Lotus THV.
Several[107,108]	'Minimalist' TAVR, performed with moderate sedation and local anesthesia, without TEE monitoring, continues to show excellent outcomes.
Makkar[32]	Reduced motion of transcatheter and surgical valves is commoner than previously thought. Appears to resolve with therapeutic anticoagulation.
Chieffo[23]	Cardiac CTA could replace routine coronary angiography in a large majority of patients undergoing TAVR.

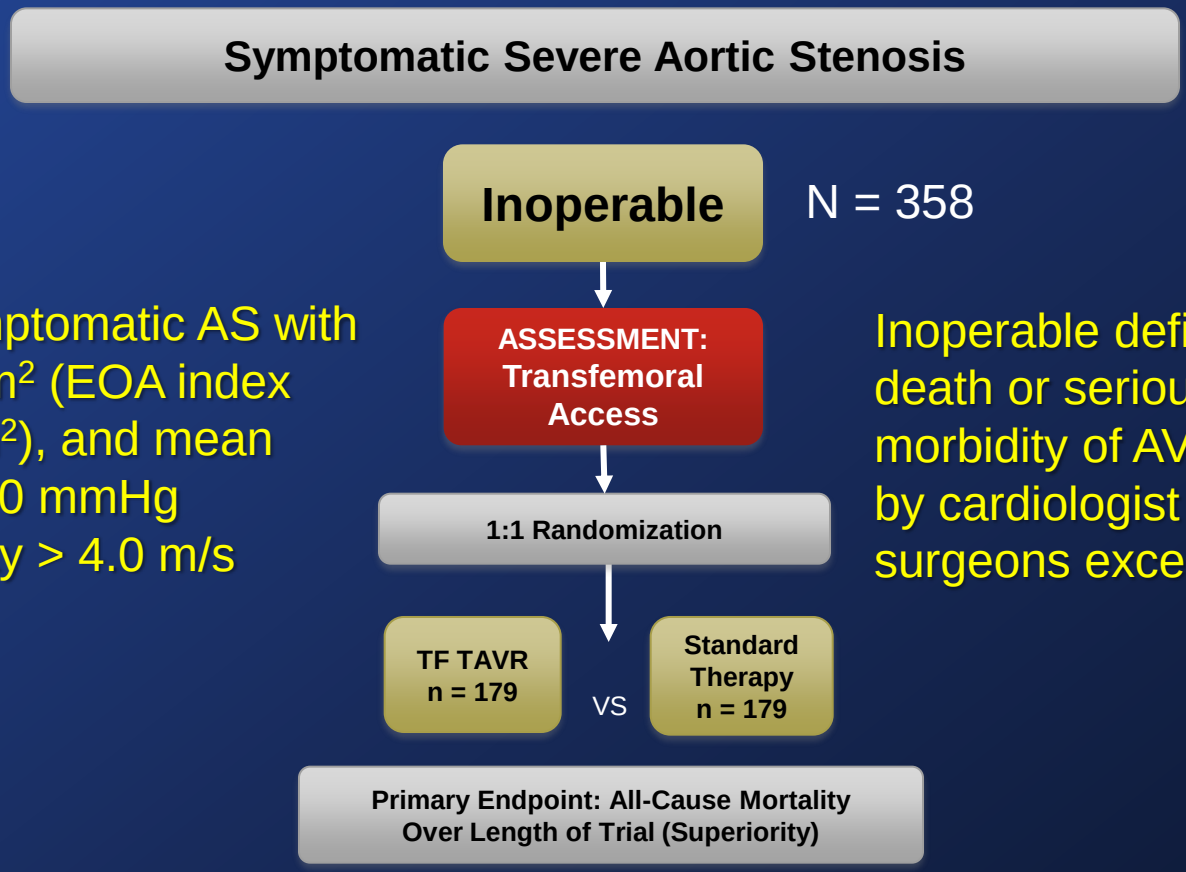
THE PARTNER TRIAL

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators*

Lancet 2015

PARTNER Study Design

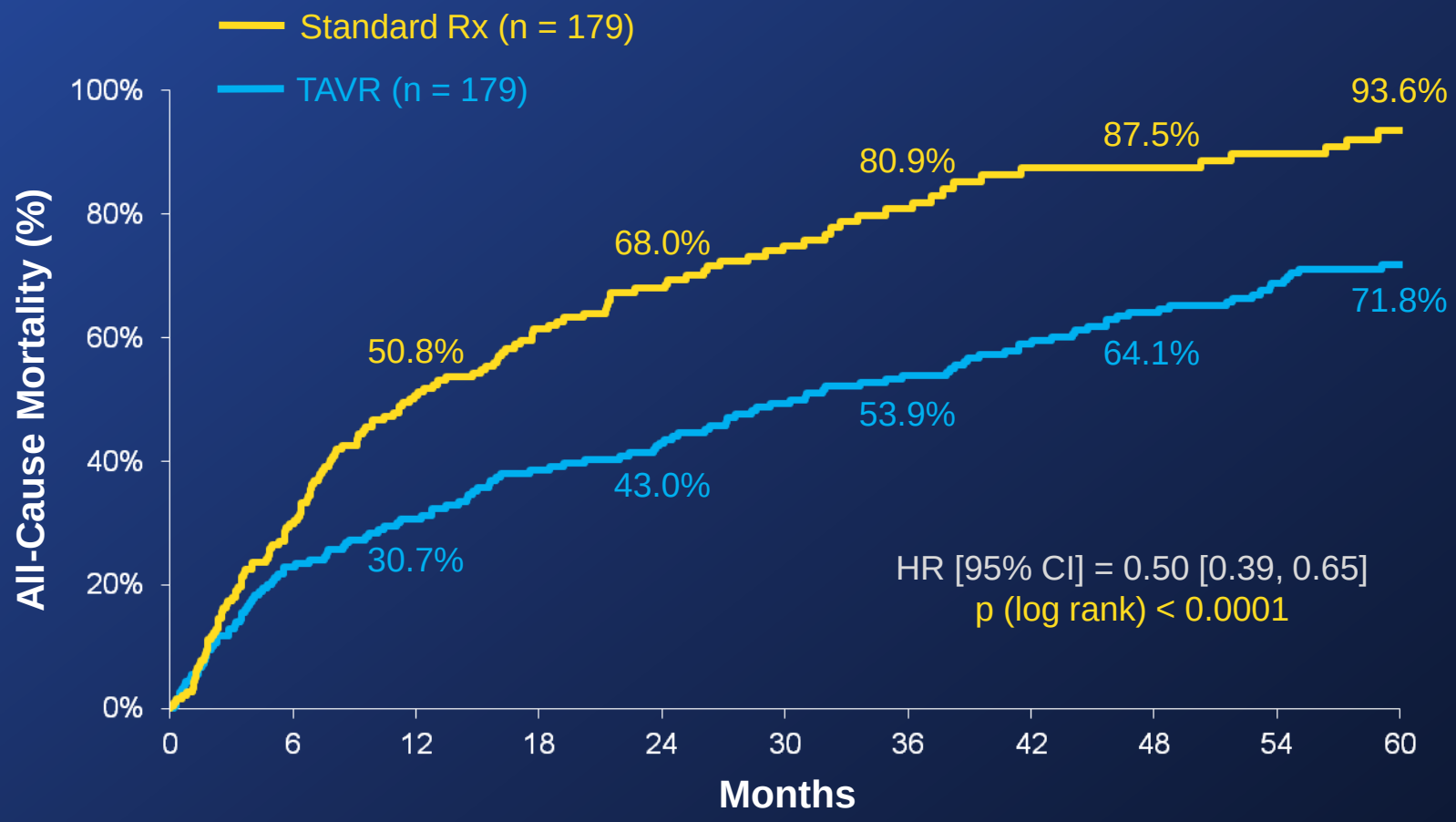


Severe Symptomatic AS with AVA< 0.8 cm^2 (EOA index < 0.5 cm^2/m^2), and mean gradient > 40 mmHg or jet velocity > 4.0 m/s

Inoperable defined as risk of death or serious irreversible morbidity of AVR as assessed by cardiologist and two surgeons exceeding 50%.

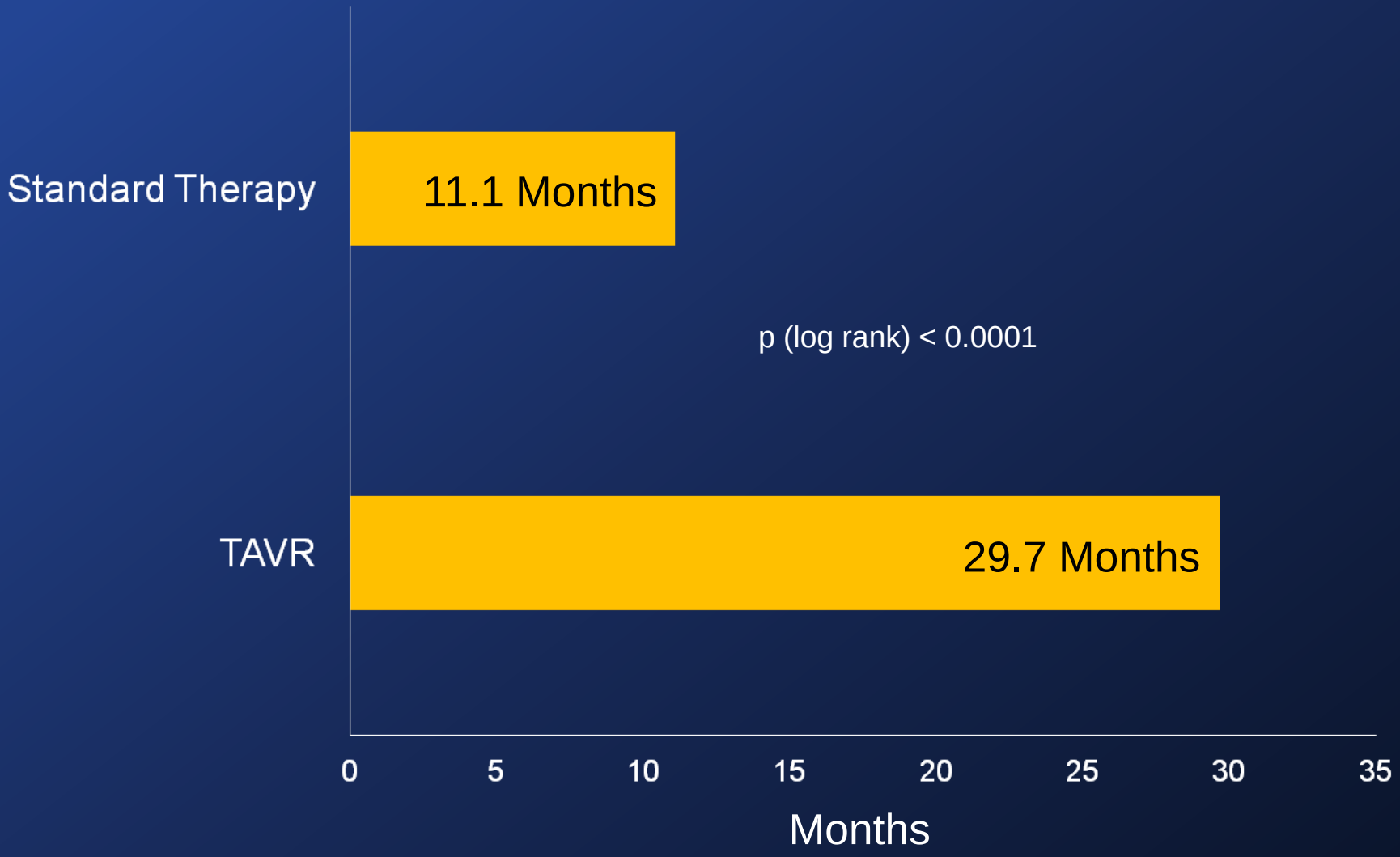
- *Primary endpoint evaluated when all patients reached one year follow-up.*
- *After primary endpoint analysis reached, patients were allowed to cross-over to TAVR.*

All-Cause Mortality (ITT)
Crossover Patients Censored at Crossover

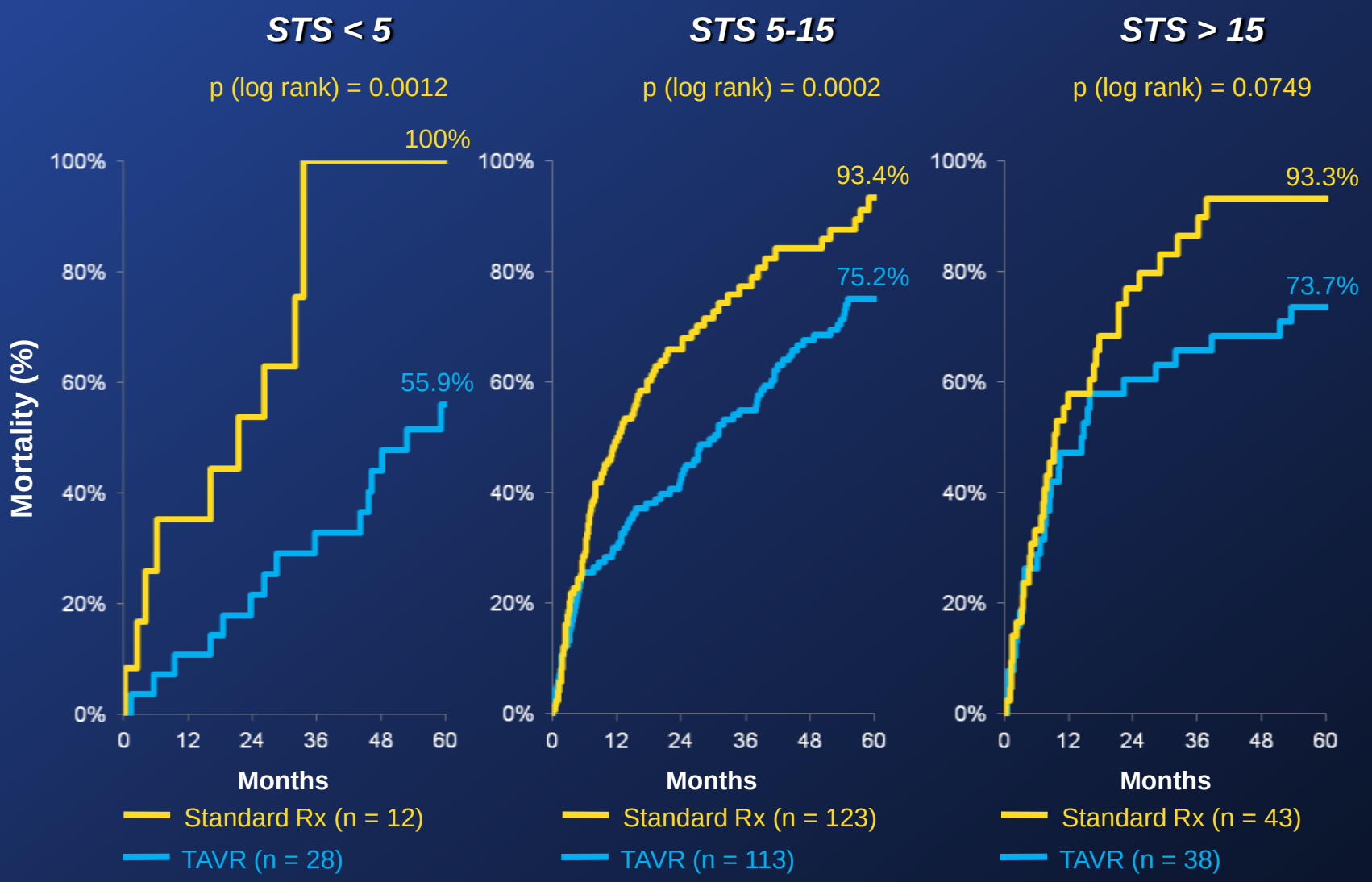


** In an age and gender matched US population without comorbidities, the mortality at 5 years is 40.5%.*

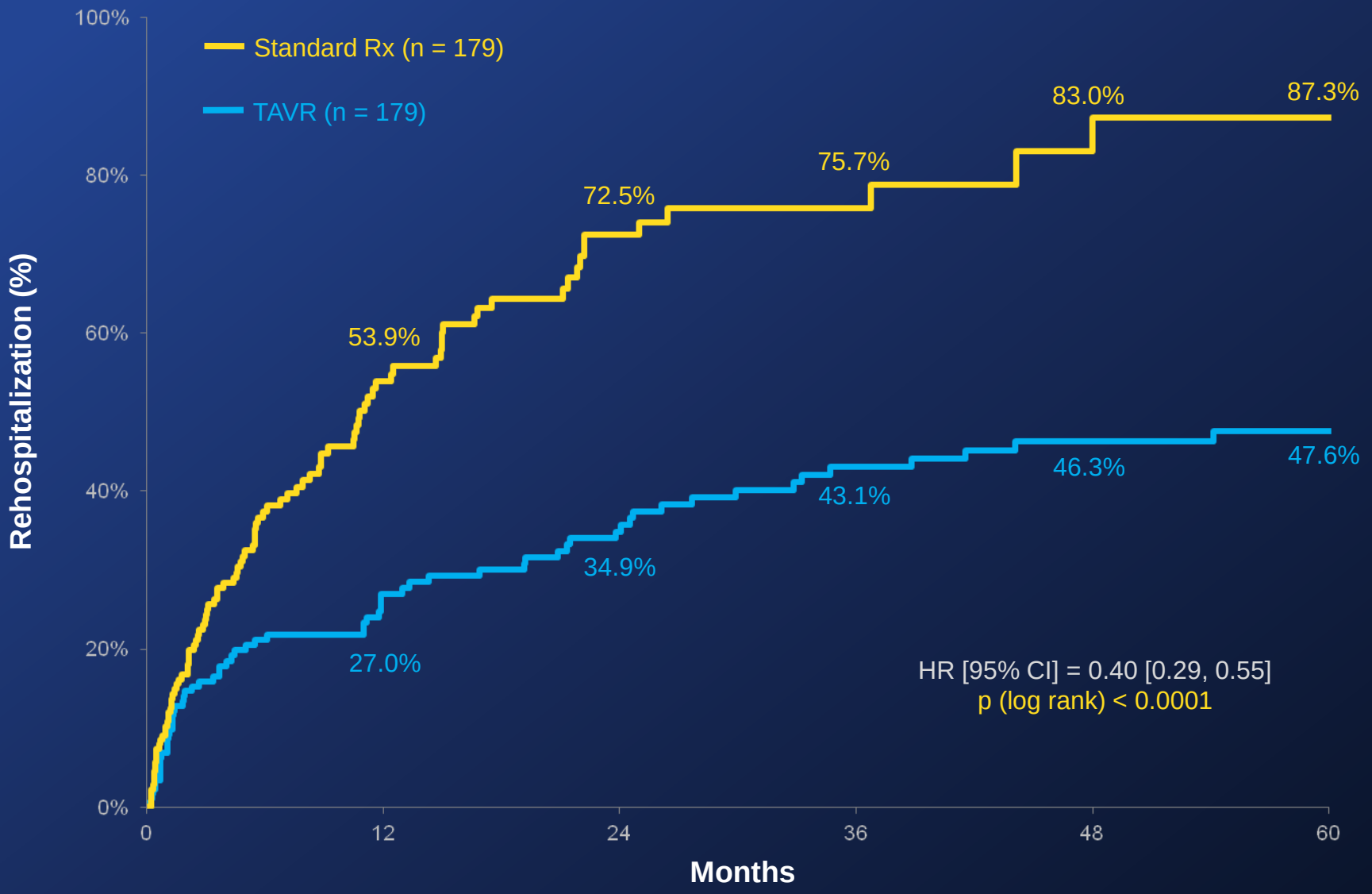
Median Survival



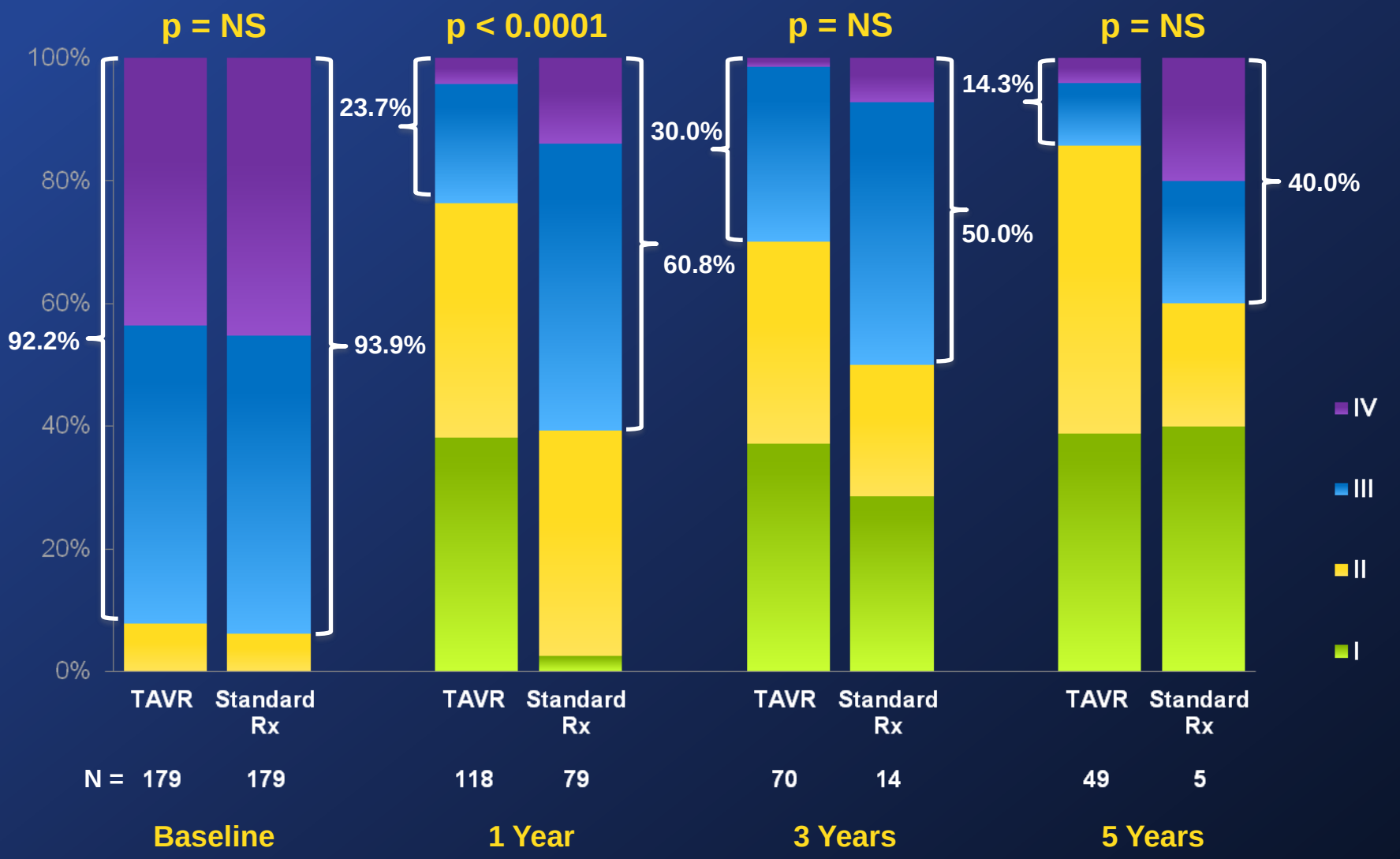
All-Cause Mortality Stratified by STS Score (ITT)



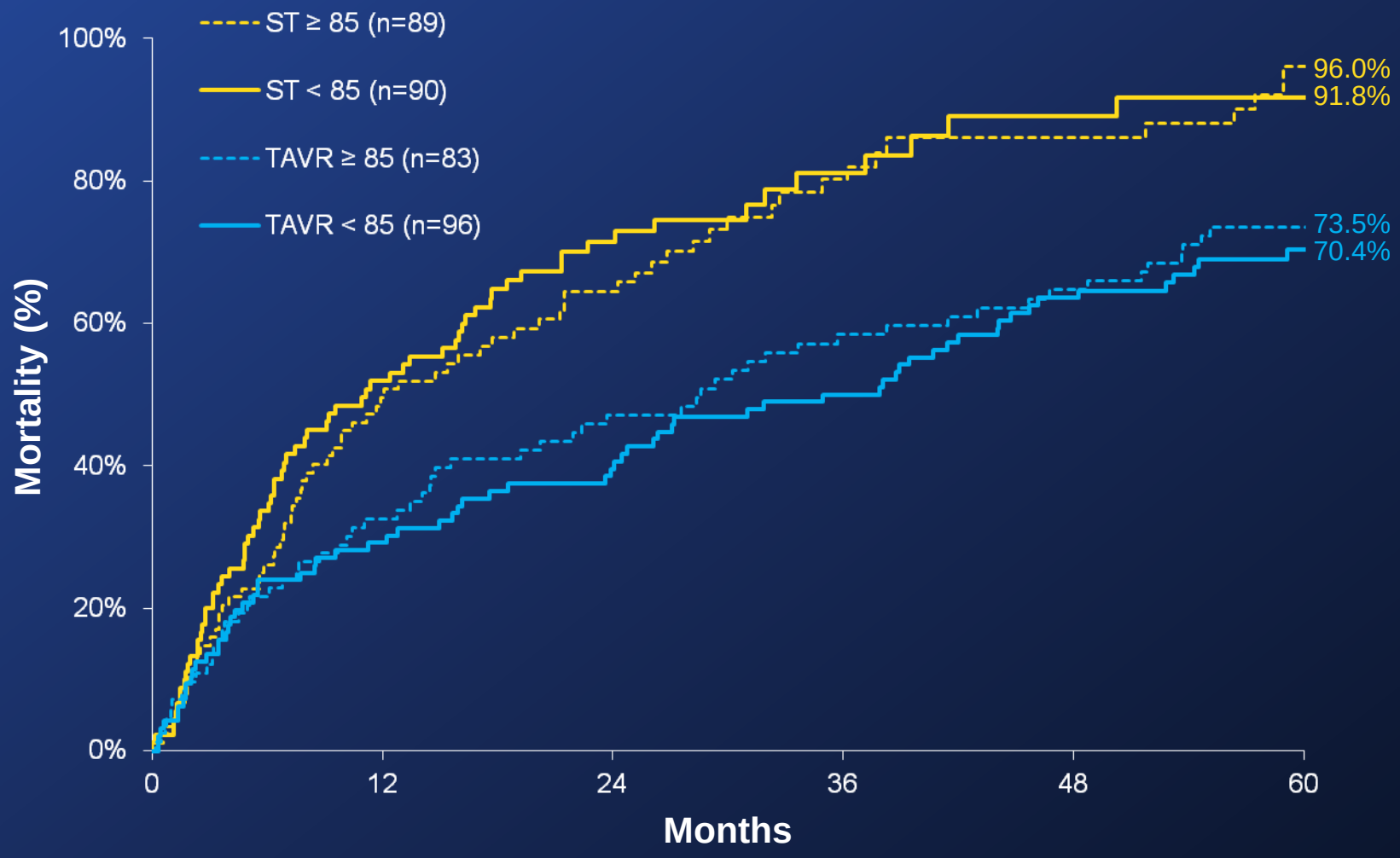
Repeat Hospitalization (ITT)



NYHA Class Over Time (ITT)
Survivors



TAVR Mortality Stratified by Age (ITT)



THELANCET-D-15-00795

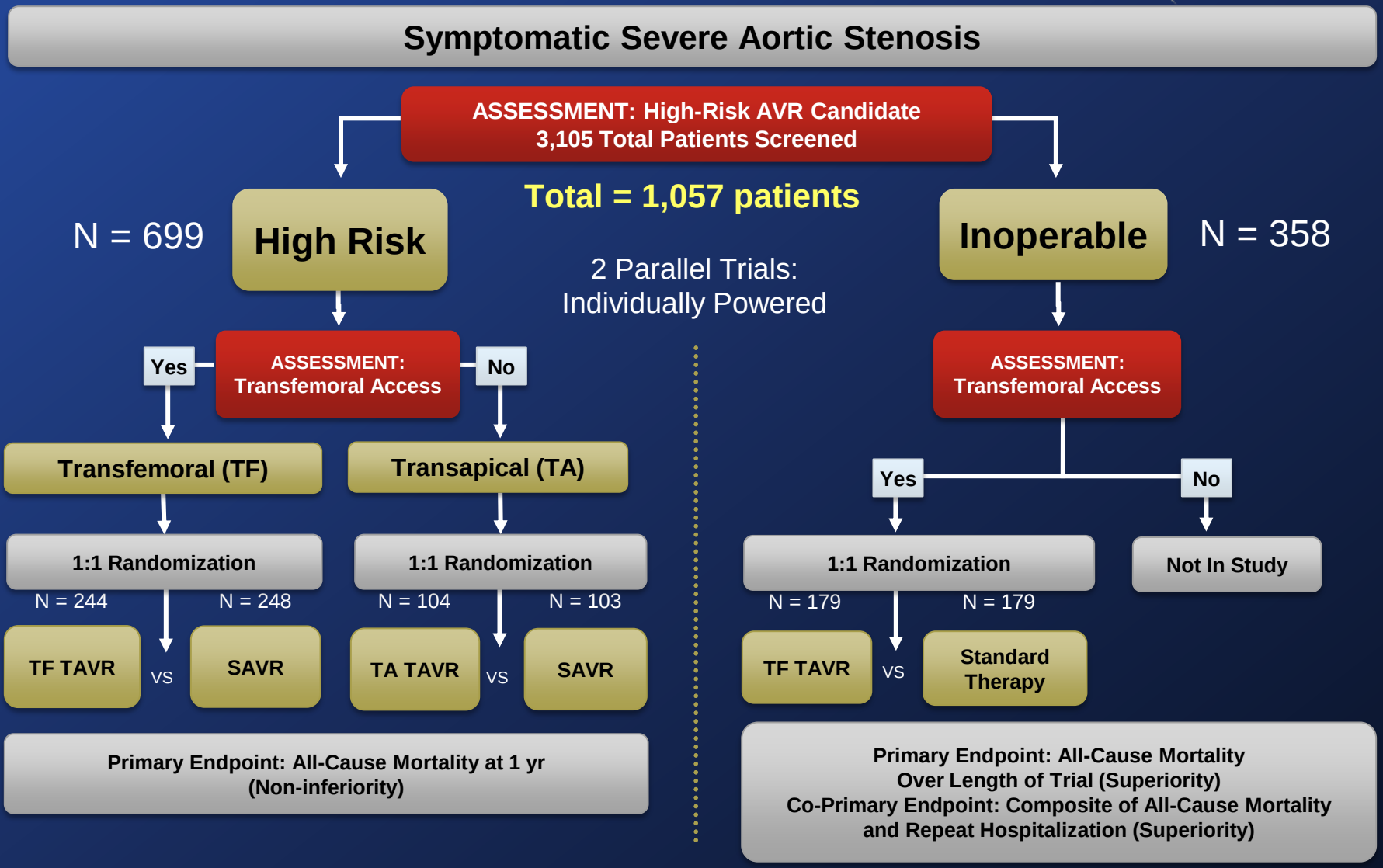
S0140-6736(15)60308-7

Embargo: [add date when known]

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

Michael J Mack, Martin B Leon, Craig R Smith, D Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin*, Michael J Davidson†, Lars G Svensson, for the PARTNER 1 trial investigators*

PARTNER Study Design

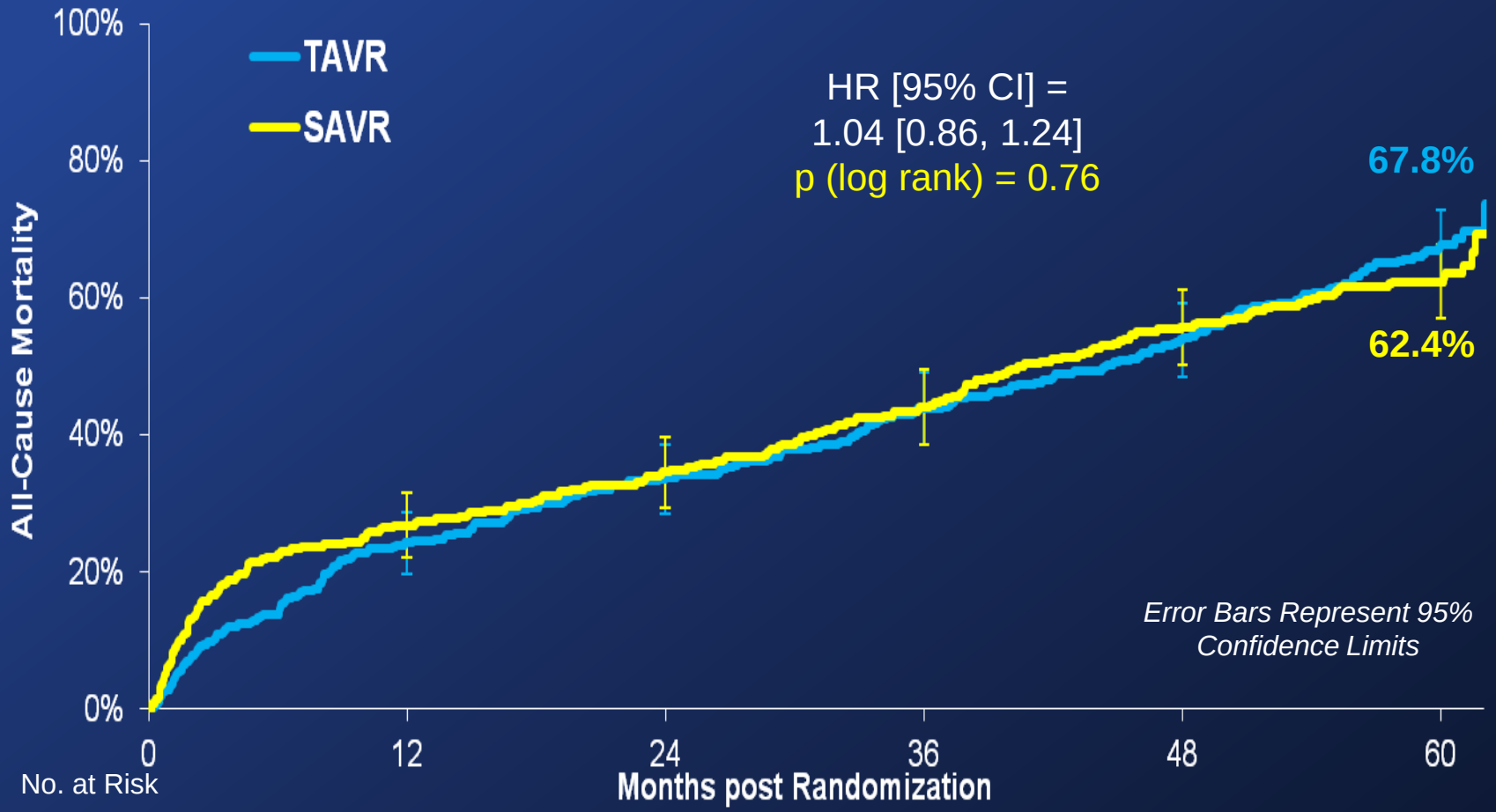


Baseline Patient Characteristics
Demographics

Characteristic	TAVR (n=348) n		SAVR (n=351) n	
Age – years (Mean ± SD)	348	83.6 ± 6.8	349	84.5 ± 6.4
Male	201	57.8%	198	56.7%
NYHA Class III or IV	328	94.3%	328	94.0%
Previous CABG	148	42.5%	152	43.6%
Cerebrovascular disease	96	29.4%	87	26.8%
Peripheral vascular disease	149	43.2%	142	41.6%
STS Score (Mean ± SD)	347	11.8 ± 3.3	349	11.7 ± 3.5

All-Cause Mortality (ITT)

All Patients

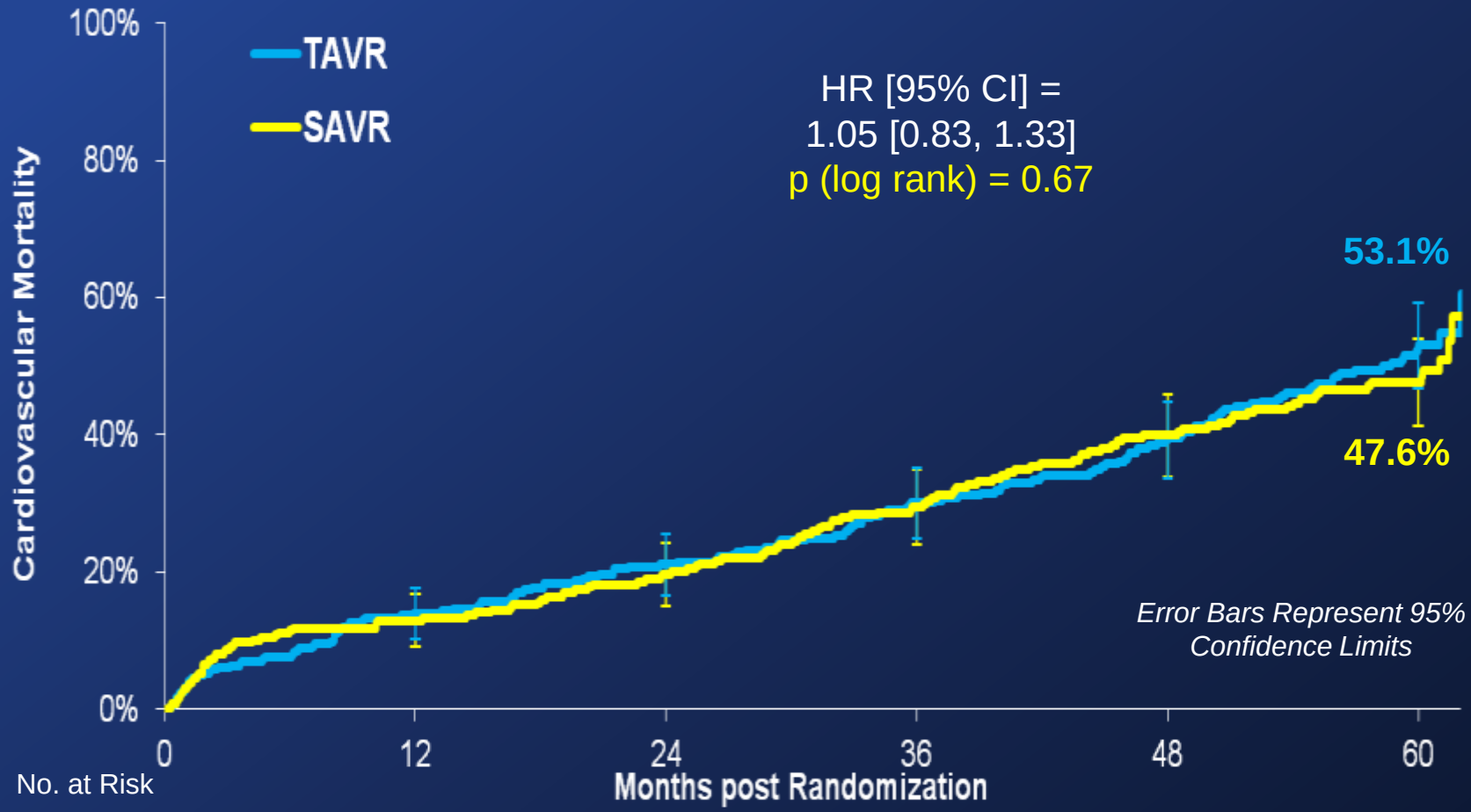


No. at Risk

TAVR	348	262	228	191	154	61
SAVR	*351*	*236*	*210*	*174*	*131*	*64*

Cardiovascular Mortality (ITT)

All Patients

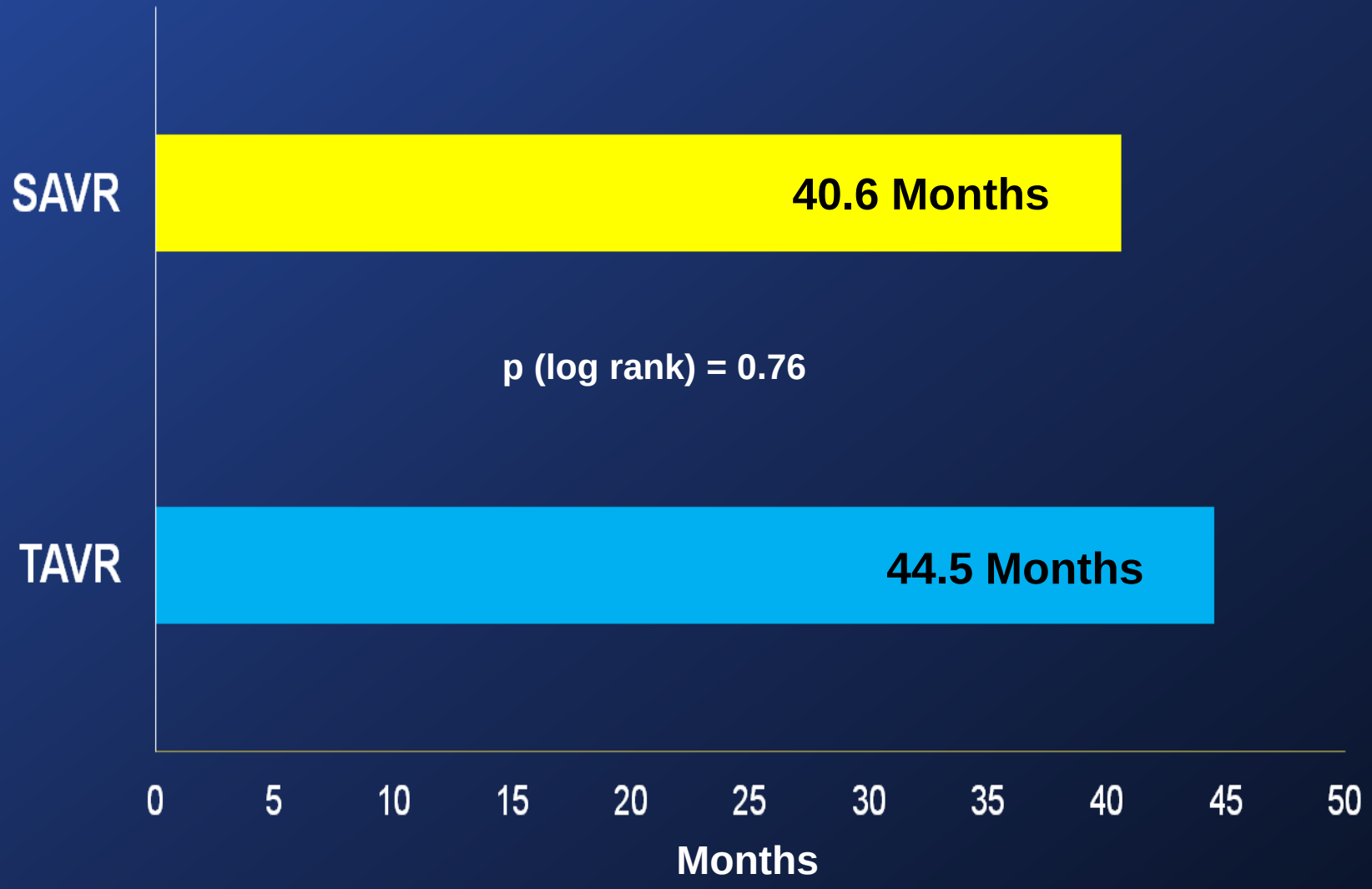


No. at Risk

TAVR 348	262	228	191	154	61
SAVR 351	*236*	*210*	*174*	*131*	*64*

Median Survival

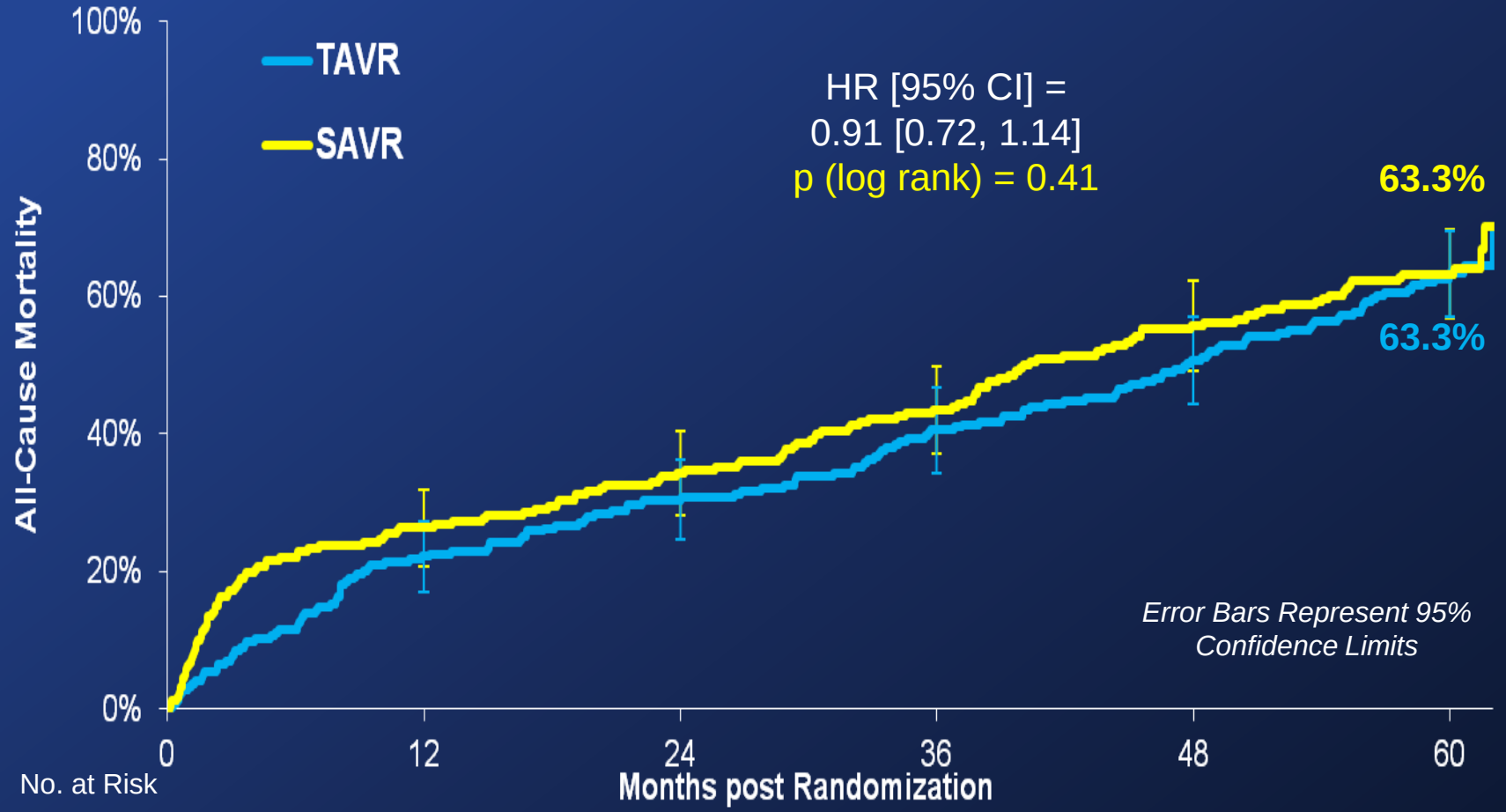
All Patients



All-Cause Mortality (ITT)

Transfemoral Patients

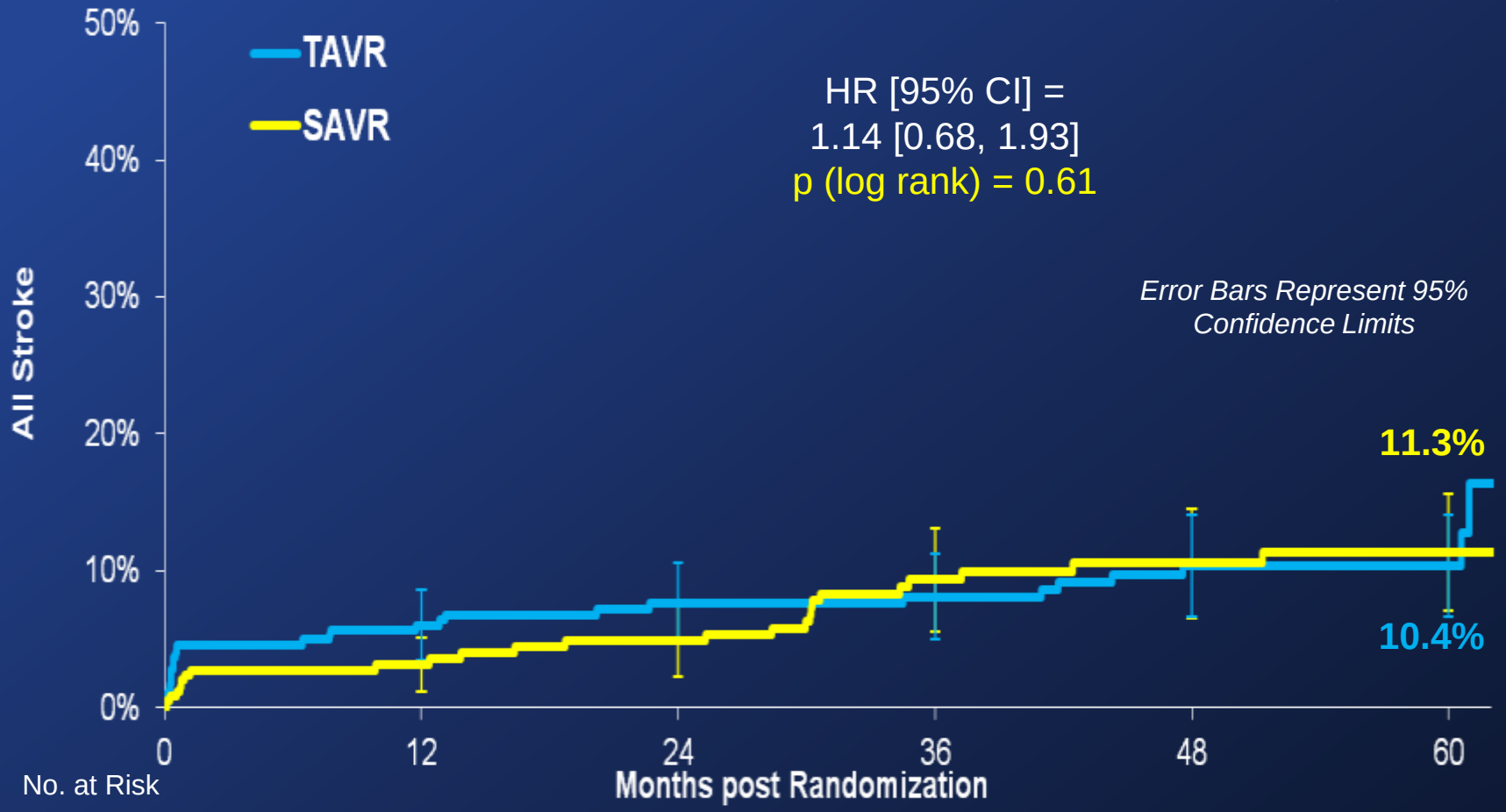
THE PARTNER TRIAL



No. at Risk					
TAVR 244	189	167	141	115	50
SAVR 248	*168*	*150*	*125*	*93*	*46*

All Stroke (ITT)

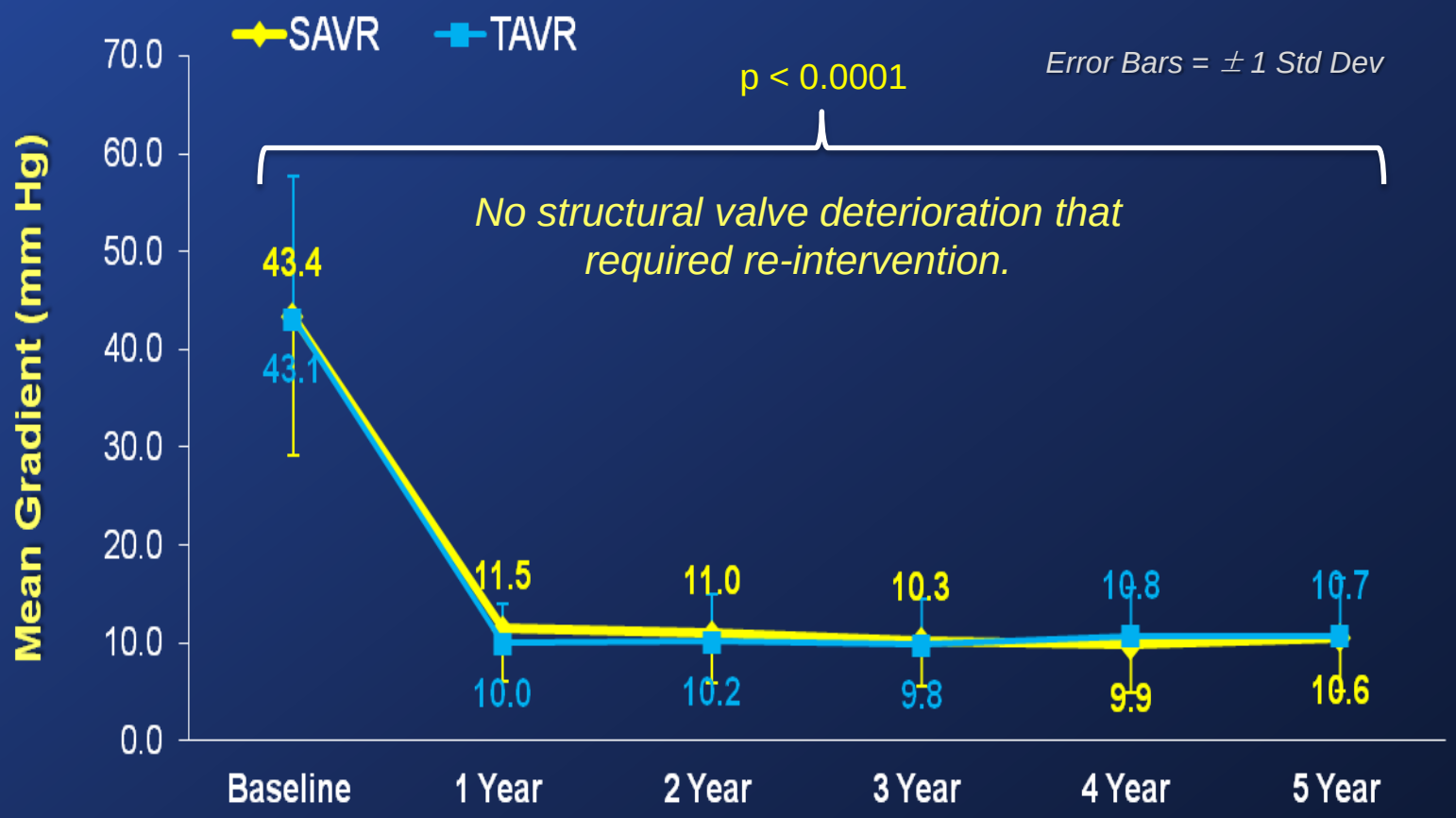
All Patients



No. at Risk

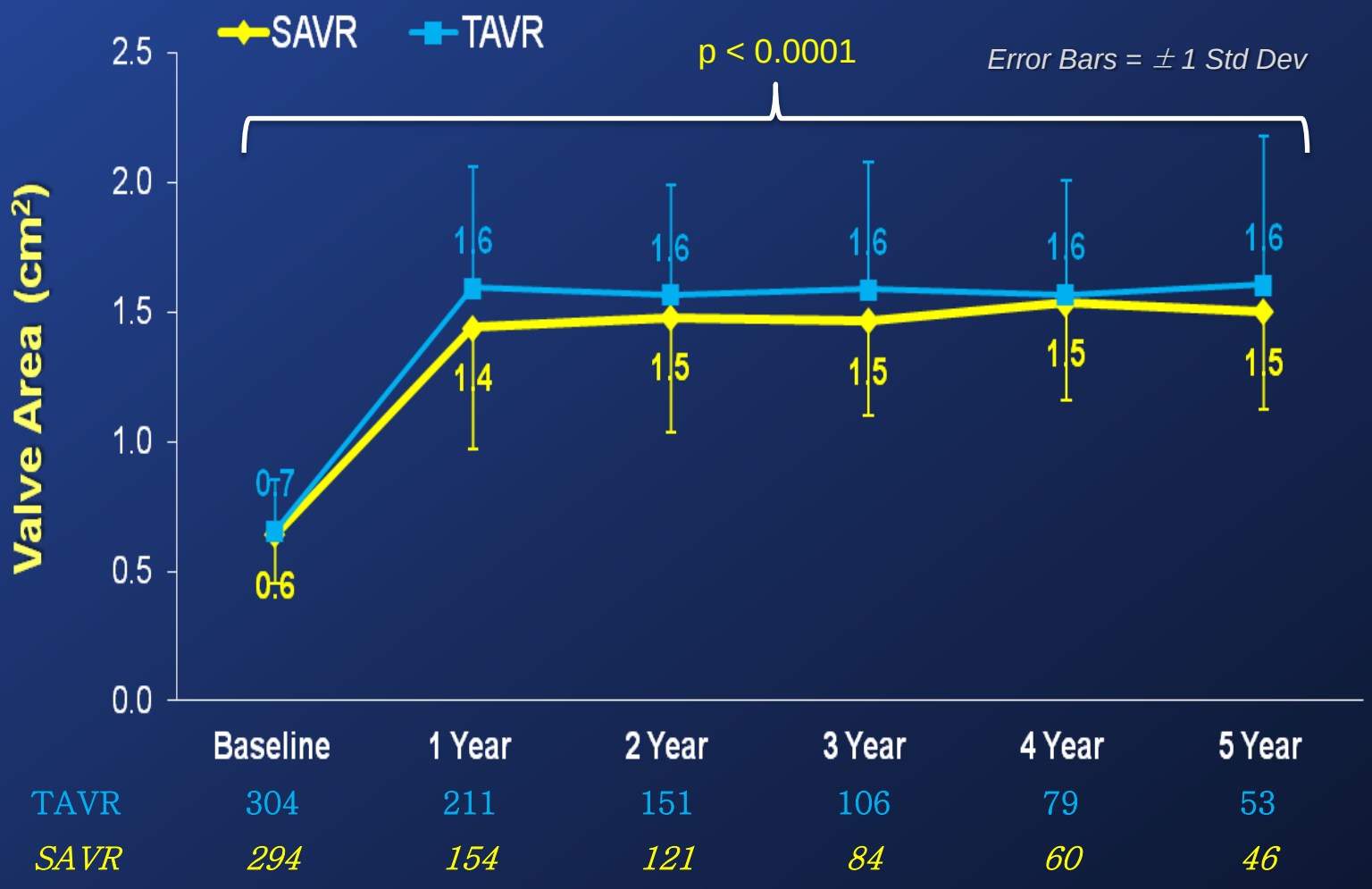
TAVR	348	251	217	181	144	57
SAVR	*351*	*230*	*205*	*169*	*128*	*64*

Aortic Valve Mean Gradient



	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*

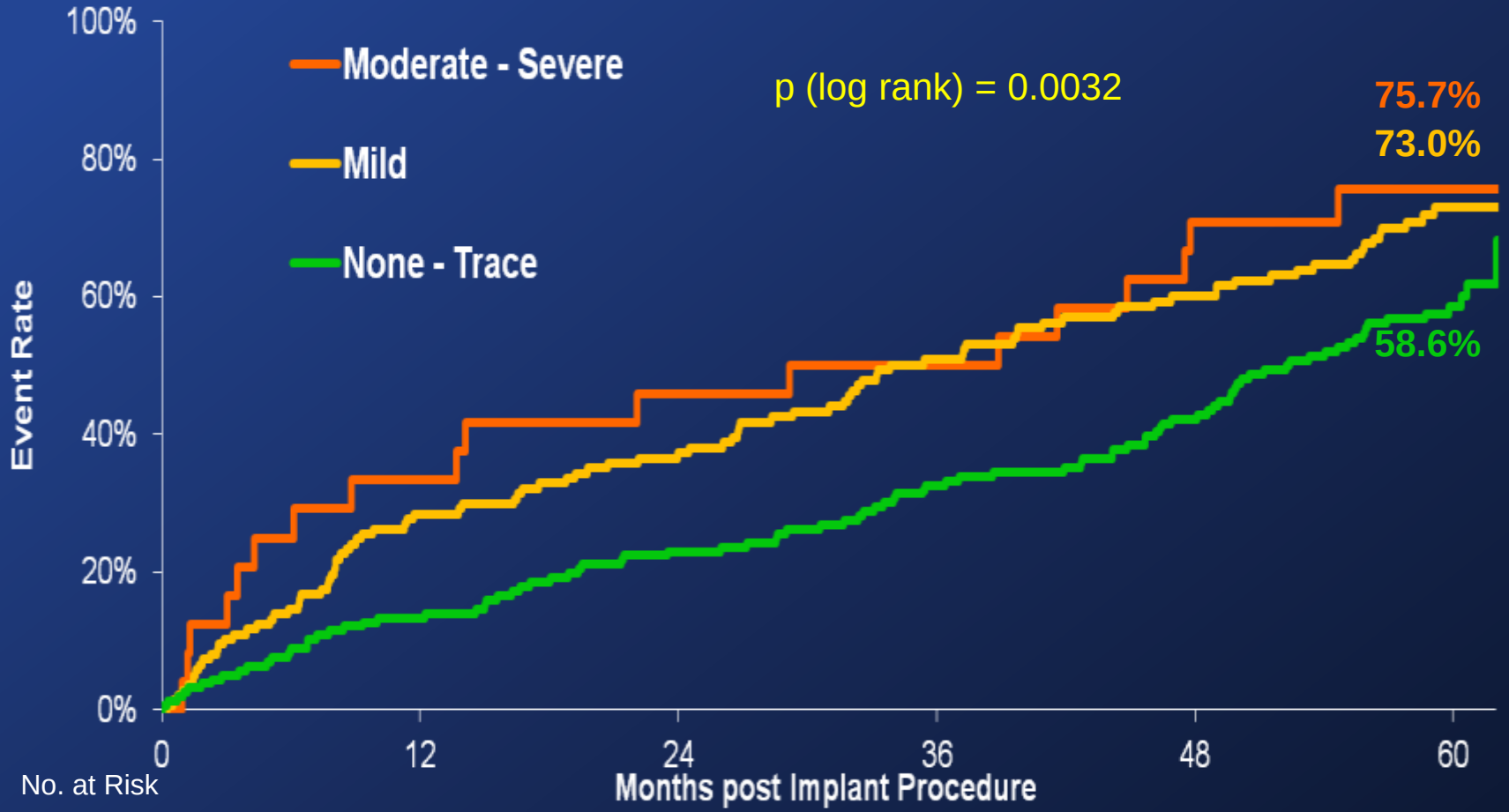
Aortic Valve Area



	Baseline	1 Year	2 Year	3 Year	4 Year	5 Year
TAVR	304	211	151	106	79	53
SAVR	*294*	*154*	*121*	*84*	*60*	*46*

Mortality and Post Procedural PVL

TAVR Patients



No. at Risk

M-S 24	16	13	12	7	2
Mild 137	*98*	*84*	*65*	*52*	*11*
N-T 158	*135*	*120*	*105*	*88*	*34*

Conclusions

- Five year follow-up of patients in The PARTNER Trial supports TAVR as an alternative to surgery in high surgical risk patients with similar mortality and other major clinical outcomes including stroke.
- Improvements in valve function were maintained for five years in both groups.

CoreValve US Pivotal Trial

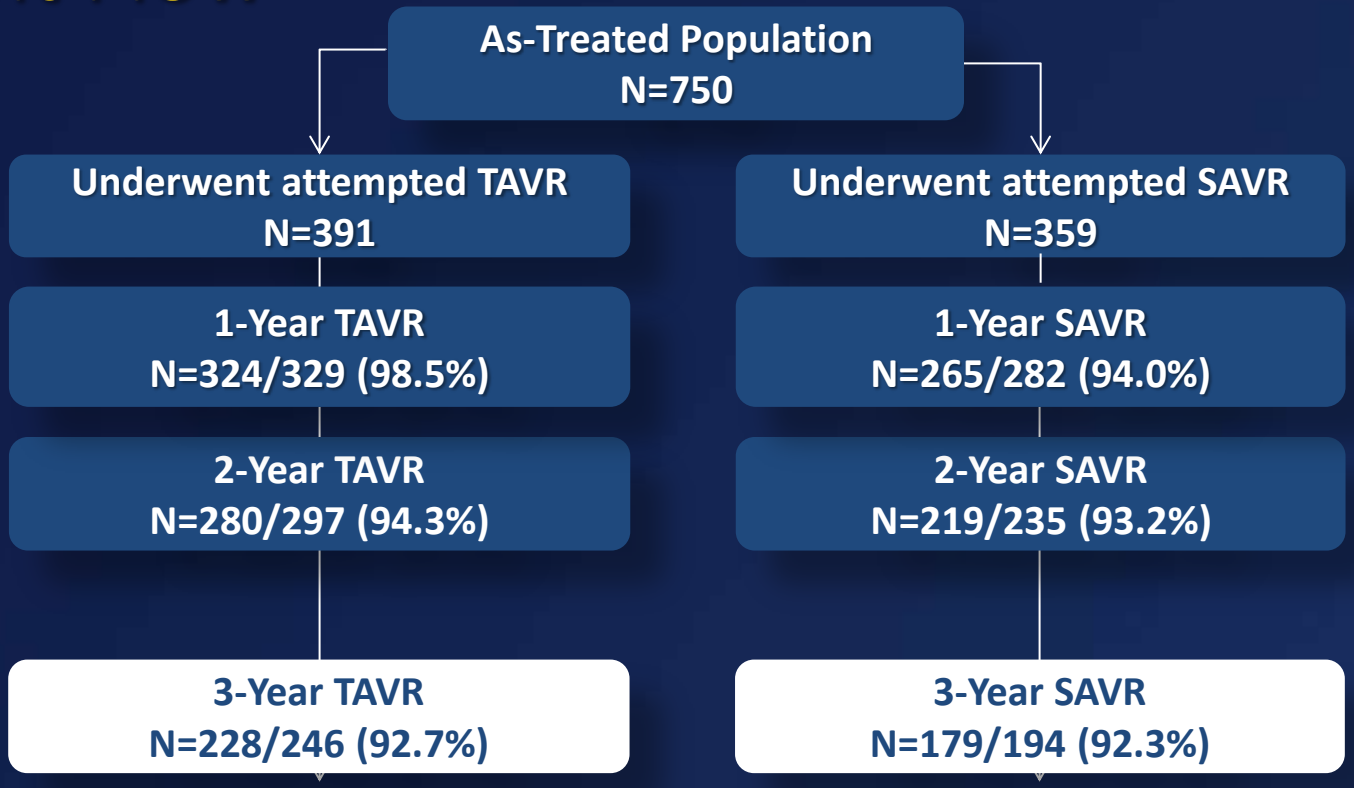
3-Year Results From the US Pivotal High Risk Randomized Trial Comparing Self-Expanding Transcatheter and Surgical Aortic Valves

G. Michael Deeb, MD

On Behalf of the US Pivotal Trial Investigators

Patient Flow

ACC2016



Baseline Demographics

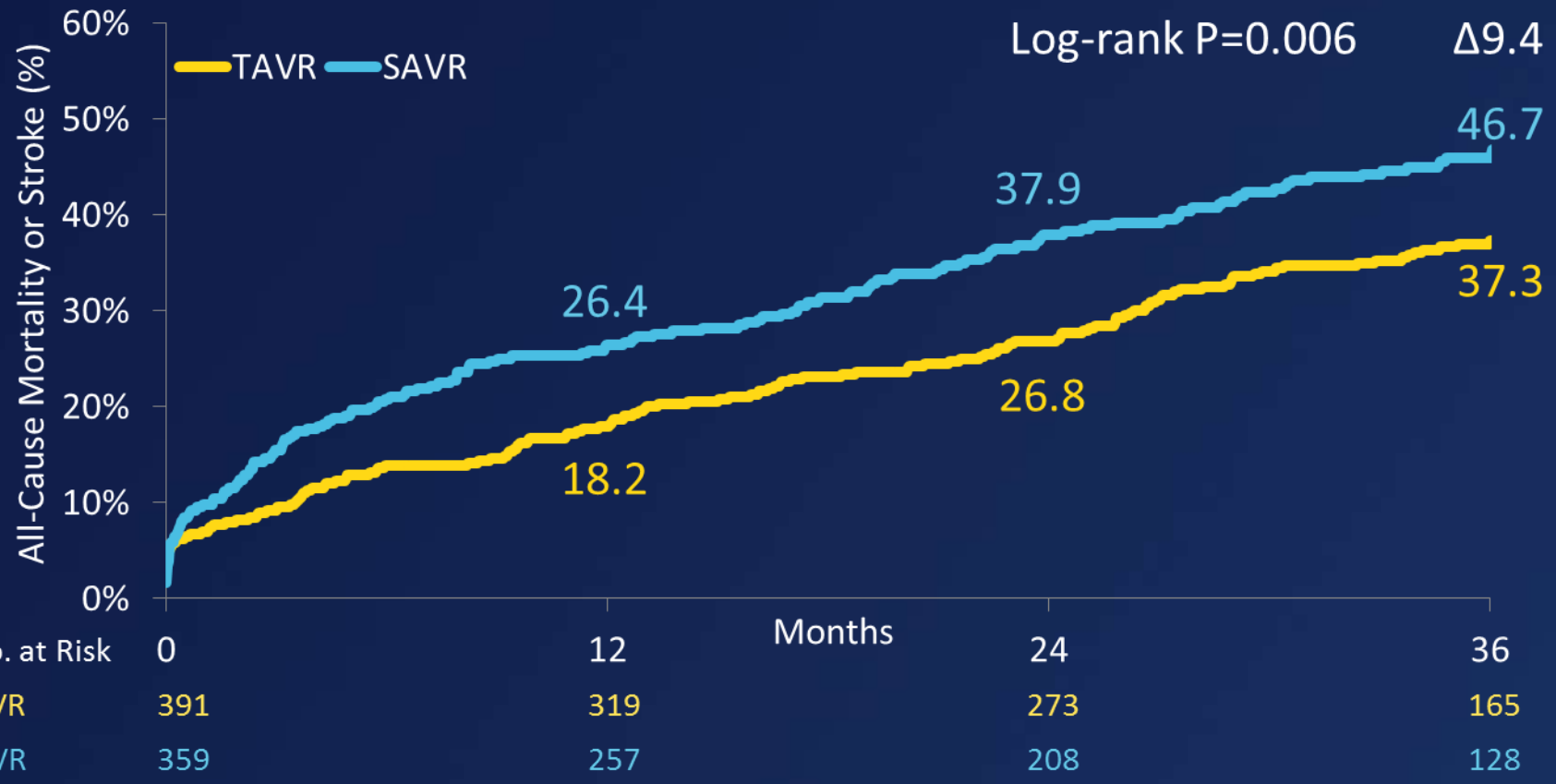
ACC2016

Characteristic, mean ± SD or %	TAVR N=391	SAVR N=359
Age (years)	83.2 ± 7.1	83.3 ± 6.4
Men	52.9	52.4
Society of Thoracic Surgeons (STS) Predicted Risk of Mortality (%)	7.3 ± 3.0	7.5 ± 3.3
New York Heart Association (NYHA) class III/IV	85.4	86.9
Prior coronary artery bypass surgery	29.4	31.5
Diabetes mellitus	34.8*	45.1*
Insulin requiring	11.0	13.1
Prior stroke	12.5	14.0
Modified Rankin 0 or 1	74.5	87.2
Modified Rankin >1	25.5	12.8
STS severe chronic lung disease	13.6	8.9

*P <0.01

All-Cause Mortality or Stroke

ACC2016



Other Endpoints at 3 Years

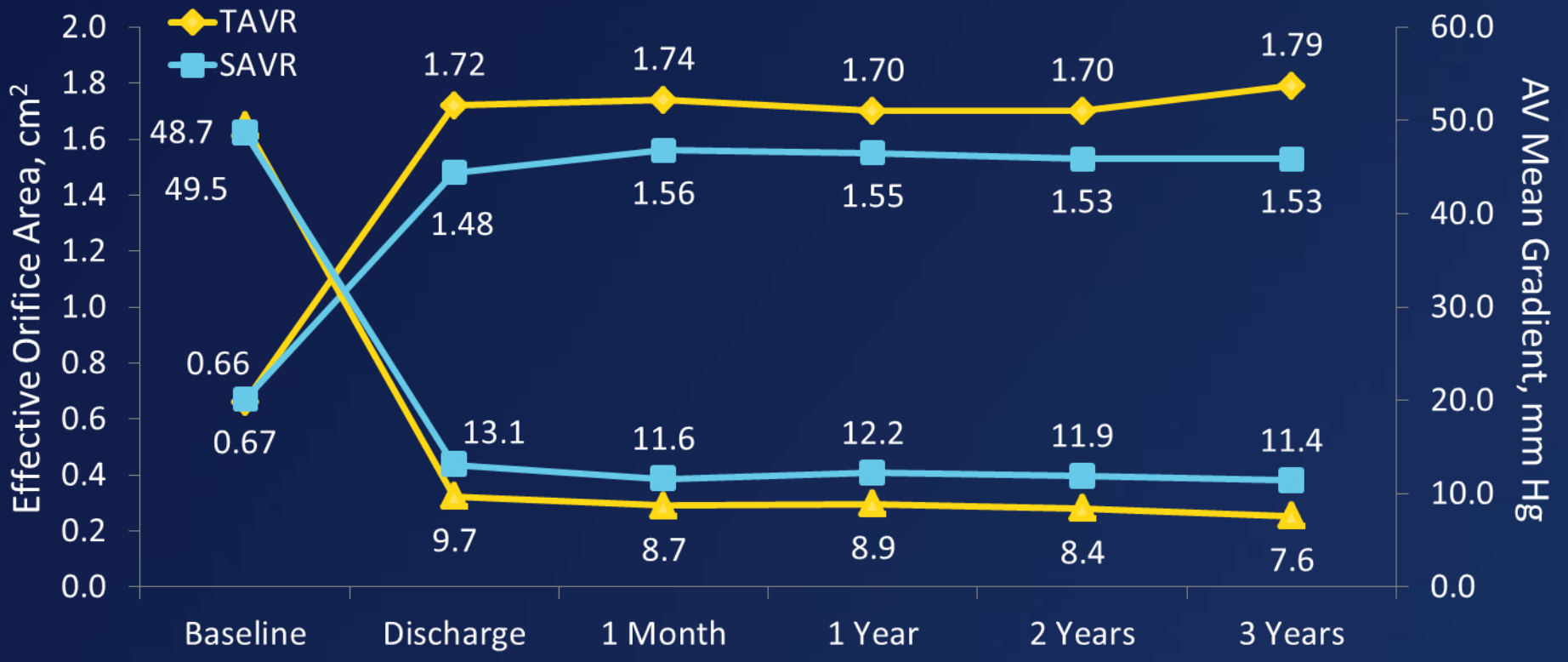
ACC2016

Events	TAVR	SAVR	Log-Rank P Value
Life threatening or disabling bleeding	19.1	41.3	<0.001
Atrial fibrillation	19.8	36.3	<0.001
Reintervention	2.5	0.4	0.020
Pacemaker implant	28.0	14.5	<0.001
Aortic valve hospitalization	27.6	21.9	0.087
Endocarditis	0.9	1.7	0.346

Valve Hemodynamics*

ACC2016

TAVR had significantly better valve performance vs SAVR at all follow-ups (P<0.001)

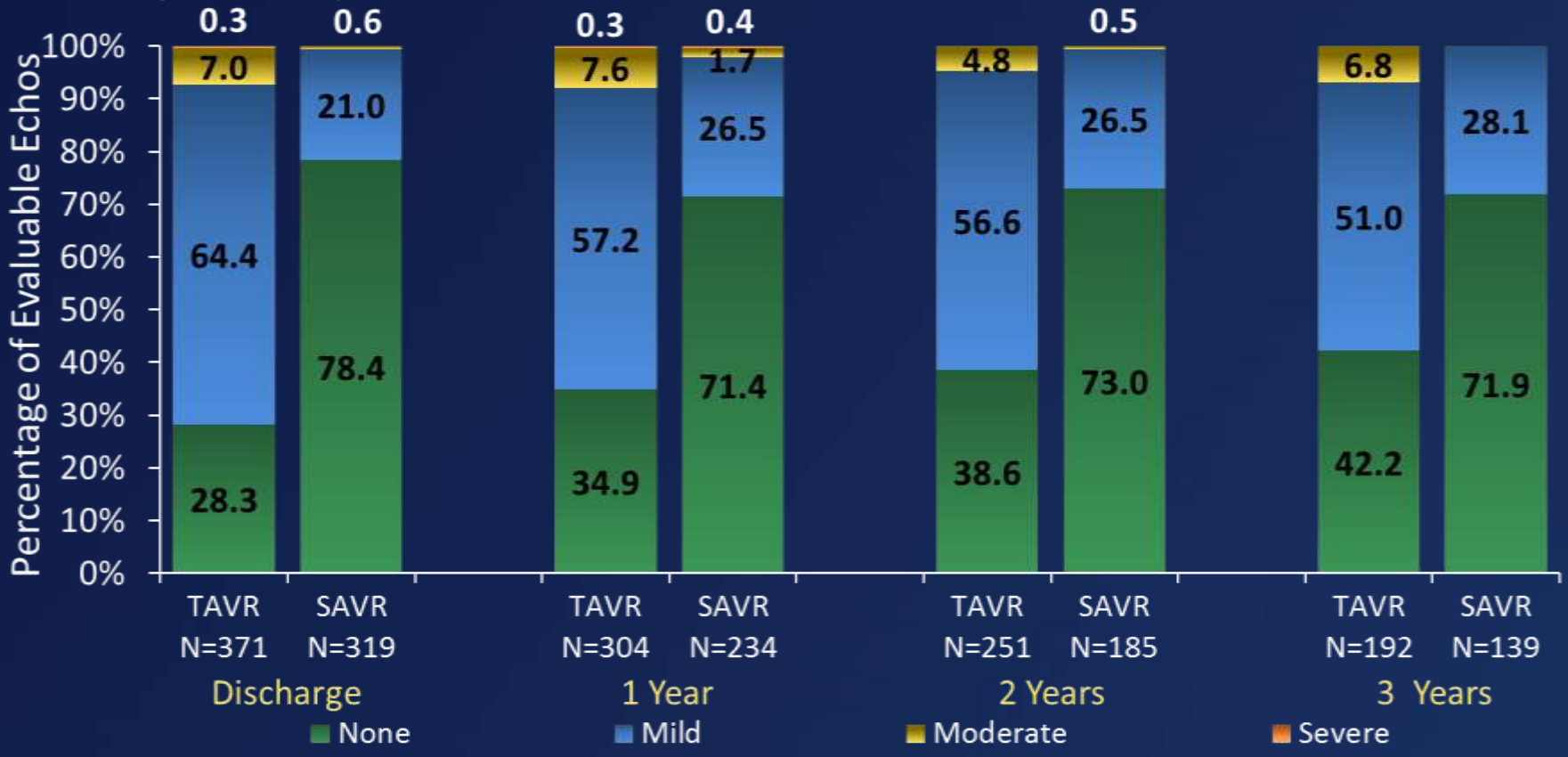


*Site-reported

Total Aortic Regurgitation*

ACC2016

Significantly less AR with SAVR vs. TAVR at Each Time Point (P<0.001)



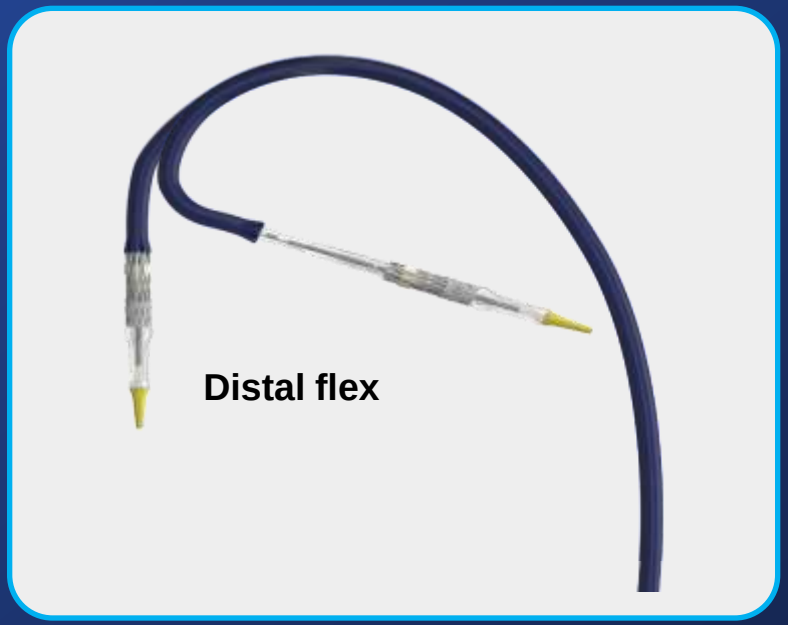
Clinical and Echocardiographic Outcomes at 30 Days with the SAPIEN 3 TAVR System in Inoperable, High-Risk and Intermediate-Risk AS Patients

Susheel Kodali, MD
on behalf of The PARTNER Trial Investigators

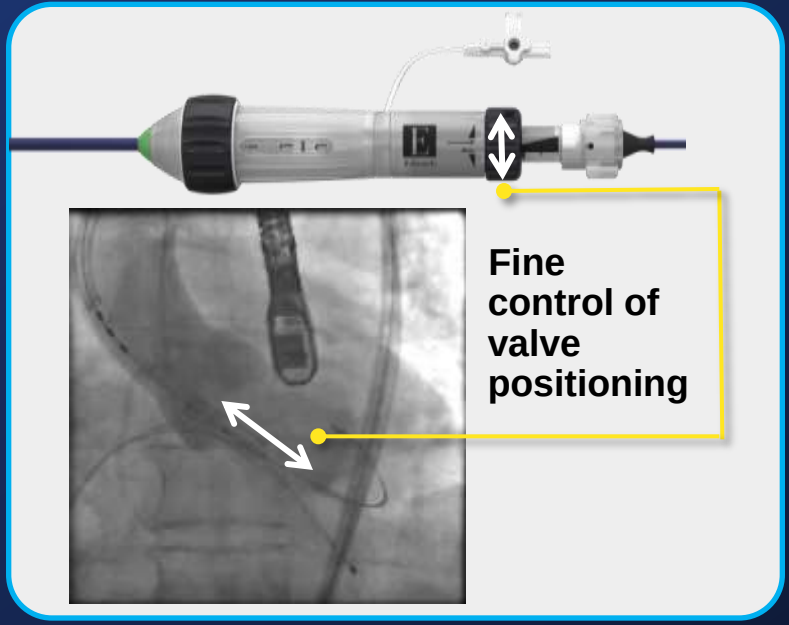
ACC 2015 | San Diego | March 15, 2015

SAPIEN 3 Commander Delivery System
Distinguishing Features

- Improved coaxial alignment



- Accurate positioning

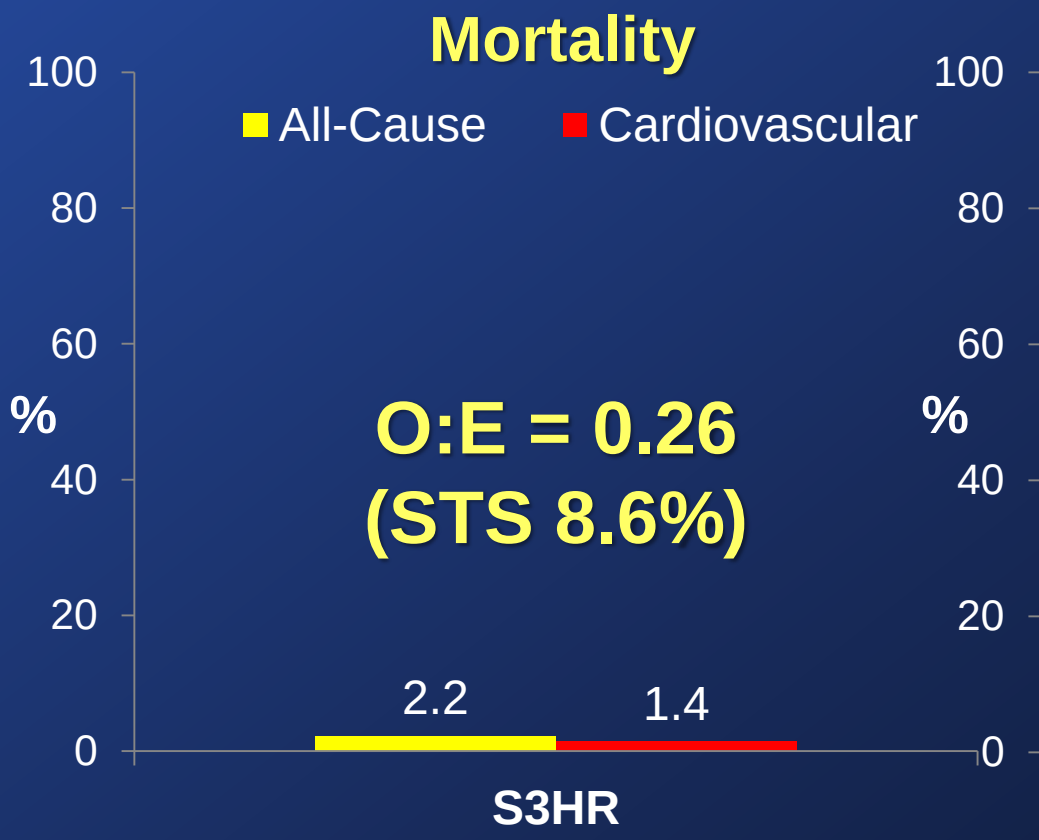


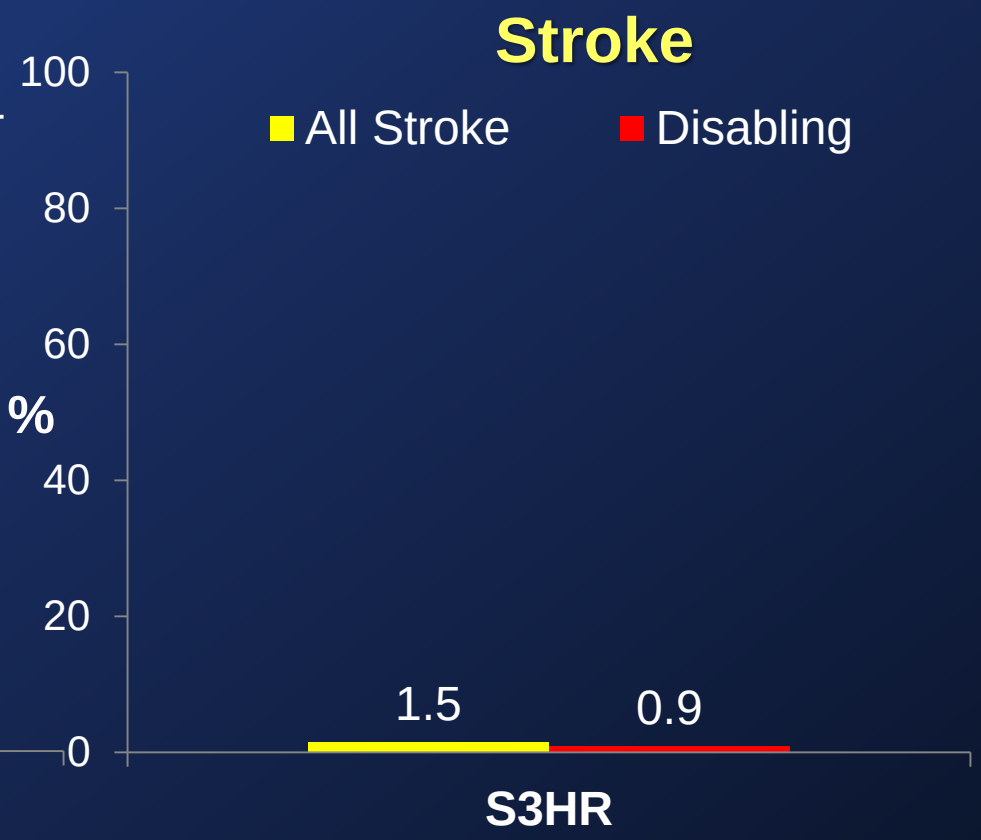
SAPIEN 3 Valve Size	20 mm	23 mm	26 mm	29 mm
Expandable Sheath	14F	14F	14F	16F
Minimum Access Vessel Diameter	5.5 mm	5.5 mm	5.5 mm	6.0 mm

Mortality and Stroke: S3HR

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL





Transcatheter or Surgical Aortic Valve Replacement in Intermediate Risk Patients with Aortic Stenosis:
Final Results from the PARTNER 2A Trial

Craig R. Smith, MD
on behalf of the PARTNER Trial Investigators

ACC 2016 | Chicago | April 2, 2016

THE PARTNER II TRIAL

The PARTNER 2A Trial
NEJM On-line

THE PARTNER II TRIAL

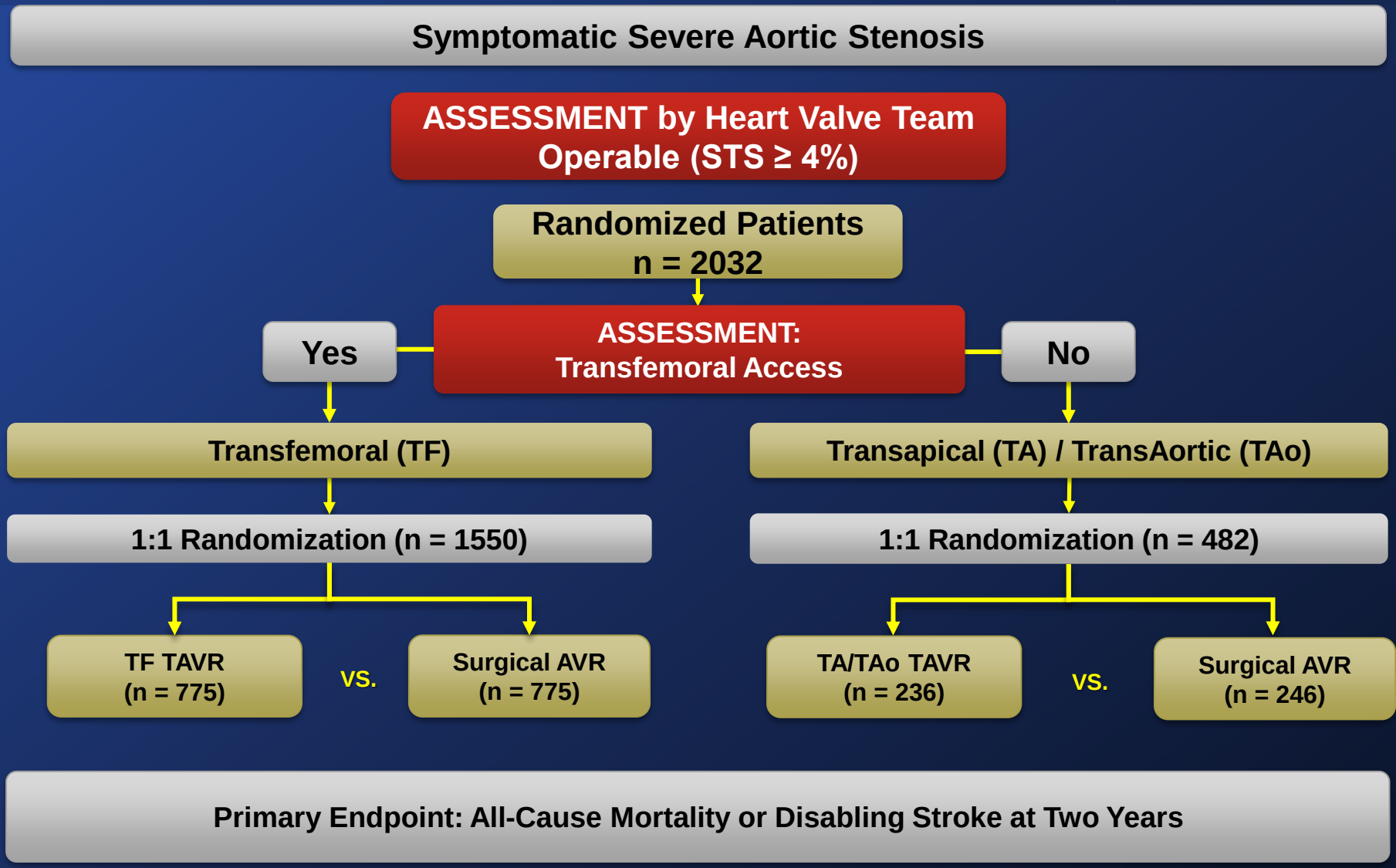
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

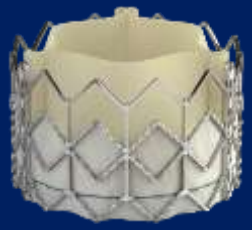
Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

The PARTNER 2A Trial
Study Design



PARTNER SAPIEN Platforms
Device Evolution

THE PARTNER II TRIAL

	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility			
Available Valve Sizes	 23 mm 26 mm	 23mm 26mm 29mm*	 20 mm 23 mm 26 mm 29 mm

*First Implant Oct 30, 2012

Baseline Patient Characteristics
Demographics and Vascular Disease

THE PARTNER II TRIAL

Characteristic	TAVR (n = 1011)	Surgery (n = 1021)	p-value
Age - yrs	81.5 ± 6.7	81.7 ± 6.7	0.63
Male - %	54.2	54.8	0.79
STS Score - %	5.8 ± 2.1	5.8 ± 1.9	0.29
NYHA Class III or IV - %	77.3	76.1	0.53
CAD - %	69.2	66.5	0.20
Prior CABG - %	23.6	25.6	0.33
Cerebrovascular Disease - %	32.1	31.0	0.60
PVD - %	27.9	32.9	0.02

Procedural Complications (AT)

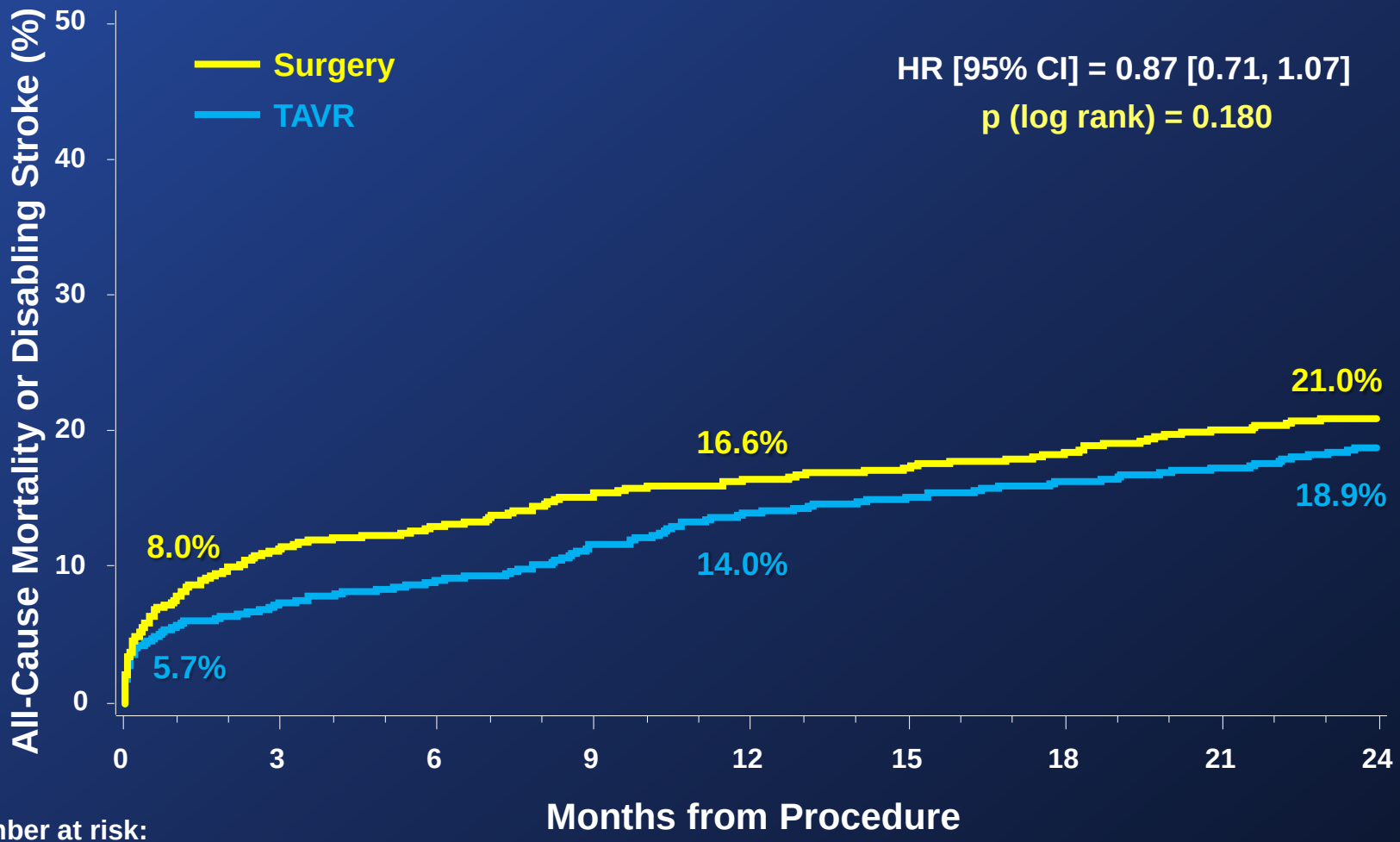
THE PARTNER II TRIAL

Complication	TAVR (n = 994)	Surgery (n = 944)
Procedural deaths (0-3 days)	12 (1.2%)	10 (1.1%)
≥ 2 transcatheter valves*	26 (2.6%)	NA
Valve embolization	10 (1.0%)	NA
Annular rupture	3 (0.3%)	NA
Coronary obstruction	4 (0.4%)	6 (0.6%)
Access site infections	15 (1.2%)	12 (1.3%)

* Valve-in-valve (22) or with valve embolization (4)

Primary Endpoint (AT)
All-Cause Mortality or Disabling Stroke

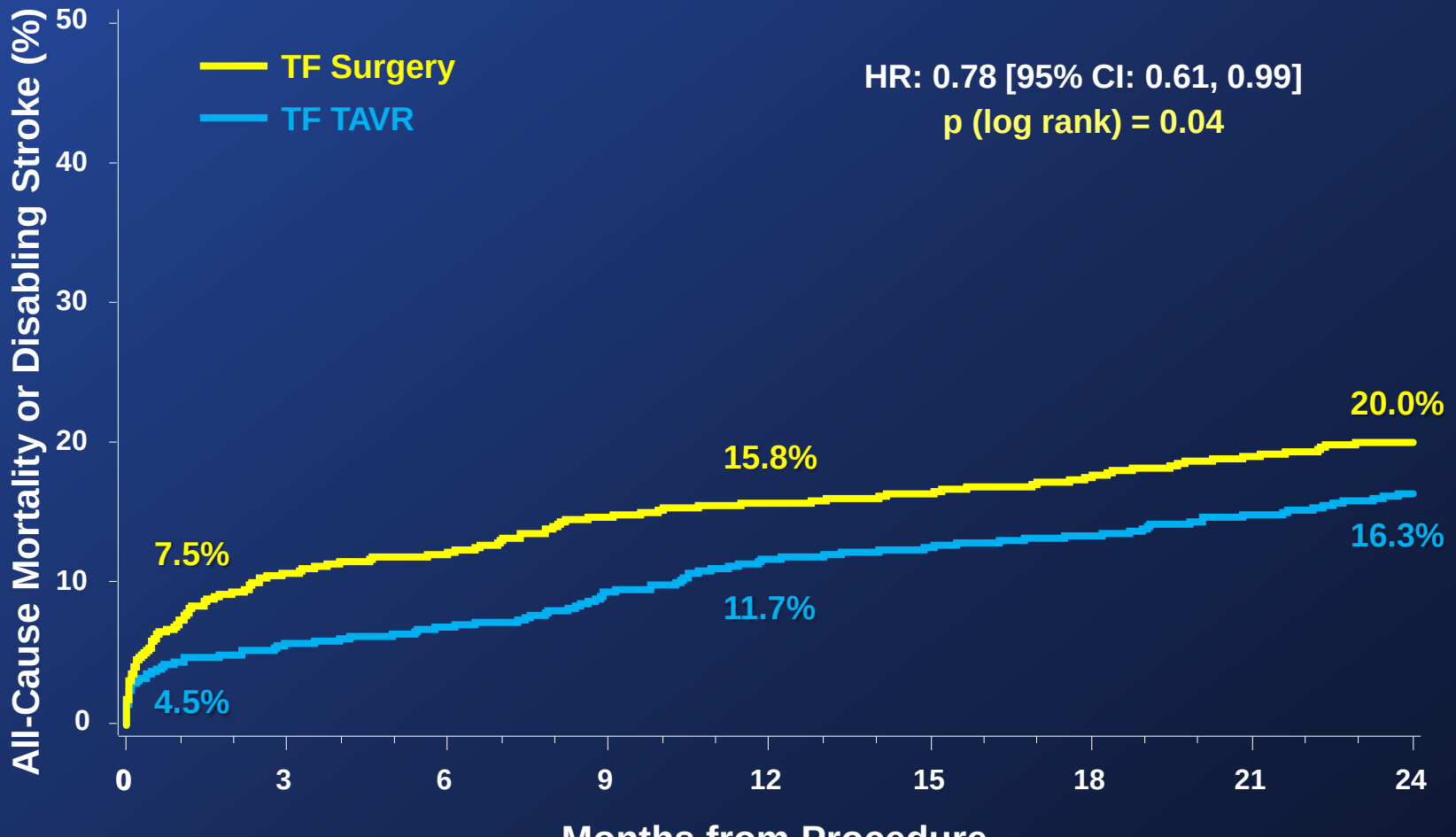
THE PARTNER II TRIAL



Number at risk:									
Surgery	944	826	807	779	766	743	731	715	694
TAVR	994	917	900	870	842	825	811	801	774

TF Primary Endpoint (AT)
All-Cause Mortality or Disabling Stroke

THE PARTNER II TRIAL



Number at risk:									
TF Surgery	722	636	624	600	591	573	565	555	537
TF TAVR	762	717	708	685	663	652	644	634	612

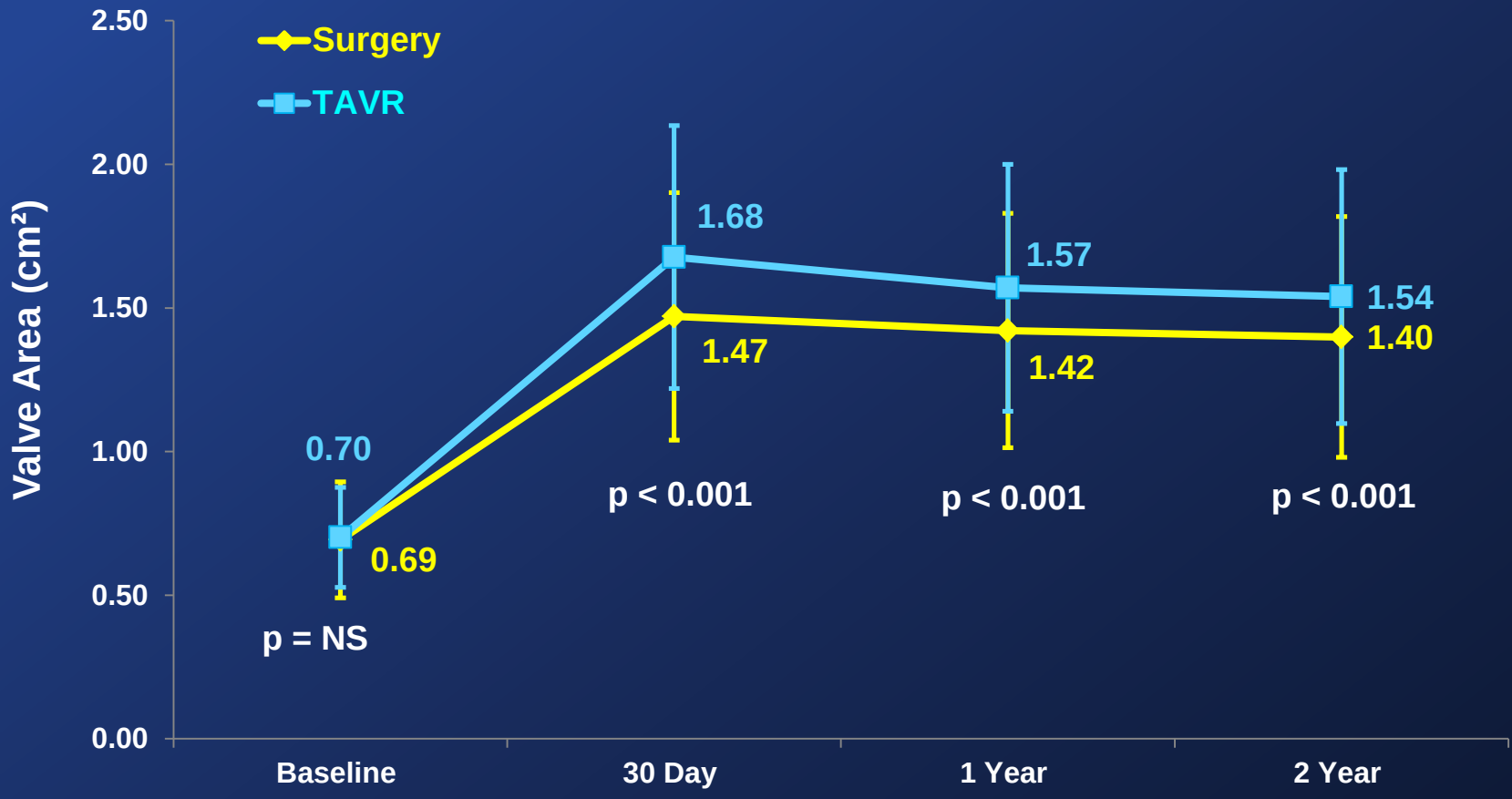
Other Clinical Endpoints (ITT)
At 30 Days and 2 Years

THE PARTNER II TRIAL

Events (%)	30 Days			2 Years		
	TAVR (n = 1011)	Surgery (n = 1021)	p-value*	TAVR (n = 1011)	Surgery (n = 1021)	p-value*
Rehospitalization	6.5	6.5	0.99	19.6	17.3	0.22
MI	1.2	1.9	0.22	3.6	4.1	0.56
Major Vascular Complications	7.9	5.0	0.008	8.6	5.5	0.006
Life-Threatening / Disabling Bleeding	10.4	43.4	<0.001	17.3	47.0	<0.001
AKI (Stage III)	1.3	3.1	0.006	3.8	6.2	0.02
New Atrial Fibrillation	9.1	26.4	<0.001	11.3	27.3	<0.001
New Permanent Pacemaker	8.5	6.9	0.17	11.8	10.3	0.29
Re-intervention	0.4	0.0	0.05	1.4	0.6	0.09
Endocarditis	0.0	0.0	NA	1.2	0.7	0.22

*Event rates are KM estimates, p-values are point in time

Echocardiography Findings (VI)
Aortic Valve Area

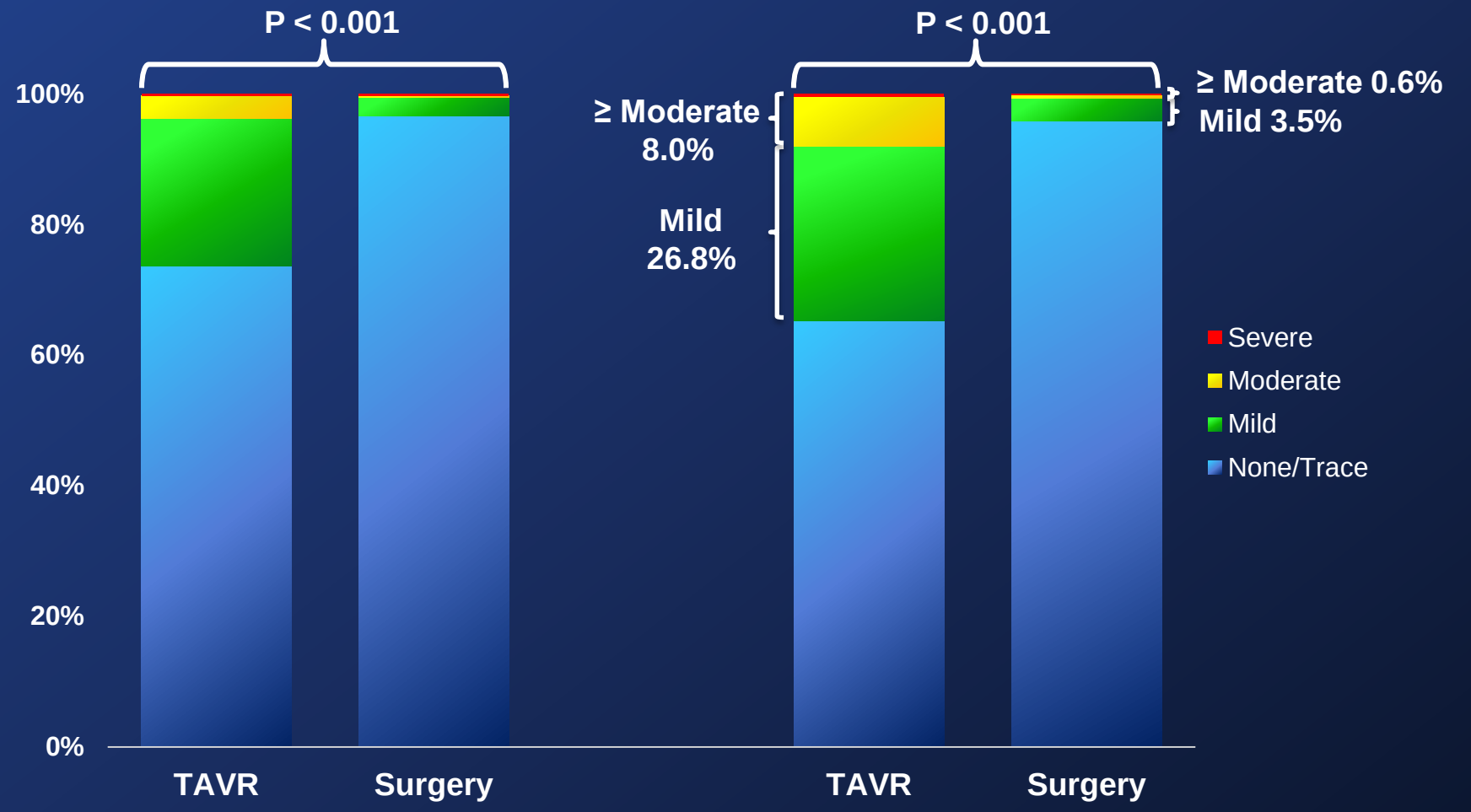


No. of Echos				
Surgery	861	727	590	488
TAVR	899	829	695	567

Error bars represent ± Standard Deviation

Paravalvular Regurgitation (VI)
3-Class Grading Scheme

THE PARTNER II TRIAL



No. of echos	30 Days	2 Years
TAVR	872	600
Surgery	757	514

The PARTNER 2A Trial
Conclusions (1)

THE PARTNER II TRIAL

In intermediate-risk patients with symptomatic severe aortic stenosis, results from the PARTNER 2A trial demonstrated that...

- TAVR using SAPIEN XT and surgery were similar (non-inferior) for the primary endpoint (all-cause mortality or disabling stroke) at 2 years.
- In the transfemoral subgroup (76% of patients), TAVR using SAPIEN XT significantly reduced all-cause mortality or disabling stroke vs. surgery (ITT: $p = 0.05$, AT: $p = 0.04$).

The PARTNER 2A Trial
Conclusions (2)

- Other clinical outcomes:
  - TAVR reduced AKI, severe bleeding, new AF, and LOS
  - Surgery reduced vascular complications and PVR
- The SAPIEN XT valve significantly increased echo AVA compared to surgery.
- In the SAPIEN XT TAVR cohort, moderate or severe PVR, but not mild PVR, was associated with increased mortality at 2 years.

The PARTNER 2A Trial
Clinical Implications

- *The results from PARTNER 2A support the use of TAVR as an alternative to surgery in intermediate risk patients, similar to those included in this trial.*
- In patients who are candidates for transfemoral access, TAVR may result in additional clinical advantages.
- Long-term durability assessments of transcatheter bioprosthetic valves are still lacking and extrapolation of these findings to low-risk patients requires further clinical trial validation.

THE PARTNER II TRIAL

The PARTNER 2A and S3i Trial

Lancet On-line

Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis

Vinod H Thourani, Susheel Kodali, Raj R Makkar, Howard C Herrmann, Mathew Williams, Vasilis Babaliaros, Richard Smalling, Scott Lim, S Chris Malaisrie, Samir Kapadia, Wilson Y Szeto, Kevin L Greason, Dean Kereiakes, Gorav Ailawadi, Brian K Whisenant, Chandan Devireddy, Jonathon Leipsic, Rebecca T Hahn, Philippe Pibarot, Neil J Weissman, Wael A Jaber, David J Cohen, Rakesh Suri, E Murat Tuzcu, Lars G Svensson, John G Webb, Jeffrey W Moses, Michael J Mack, D Craig Miller, Craig R Smith, Maria C Alu, Rupa Parvataneni, Ralph B D'Agostino Jr, Martin B Leon

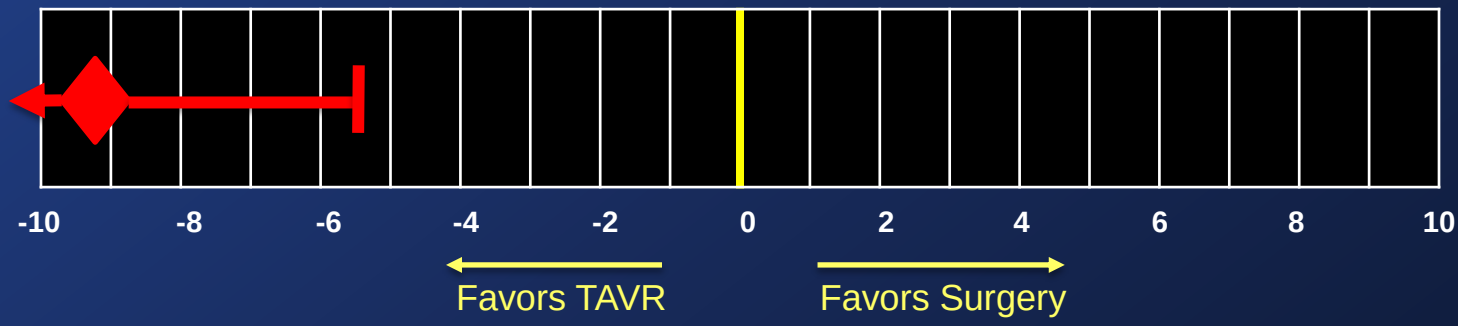
THE PARTNER II TRIAL

Primary Endpoint - Superiority

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

Weighted Difference	**-9.2%**
Upper 2-sided 95% CI	**-5.4%**

Superiority Testing p-value < 0.001

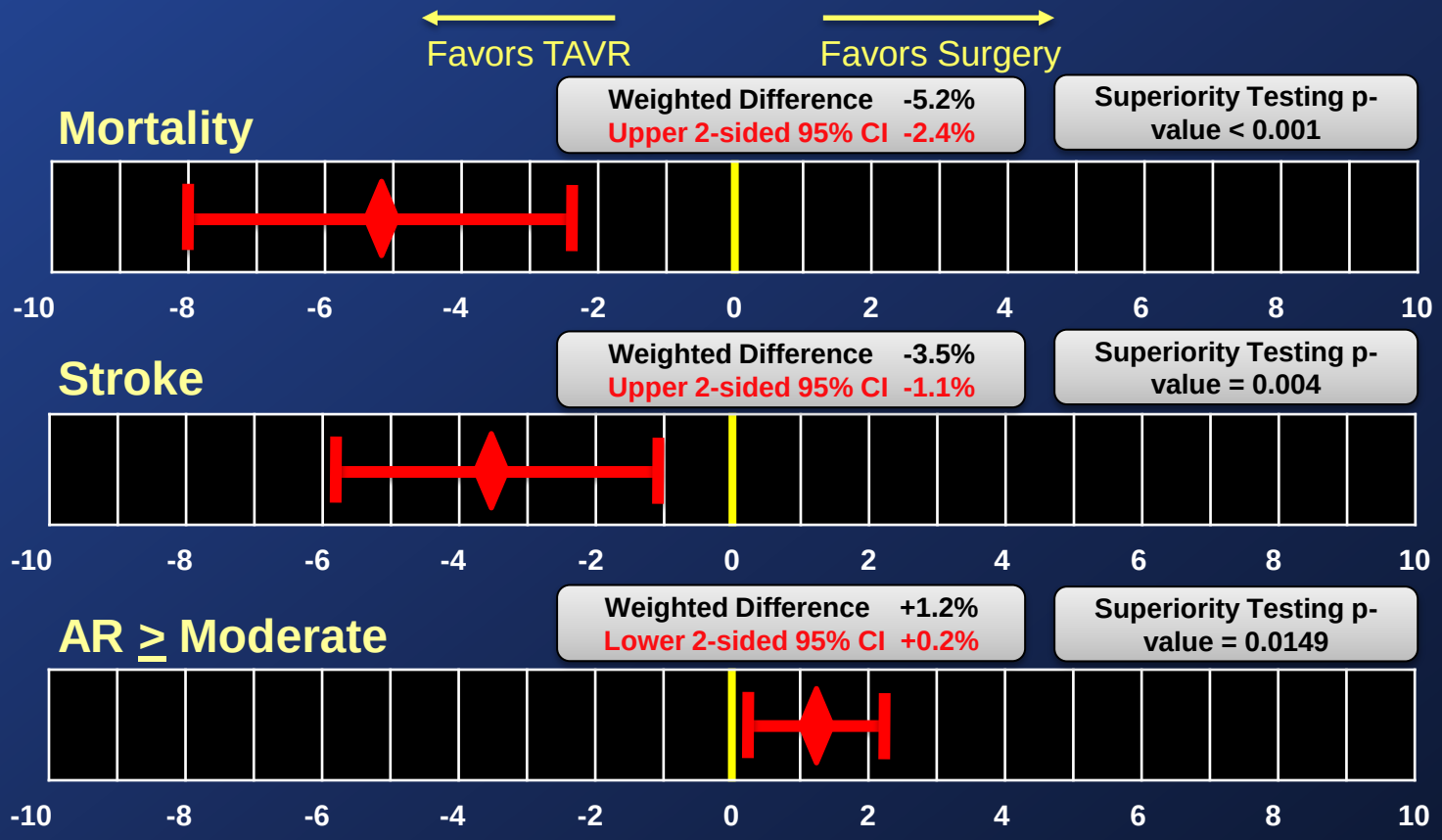


Superiority Achieved

THE PARTNER II TRIAL

Superiority Analysis

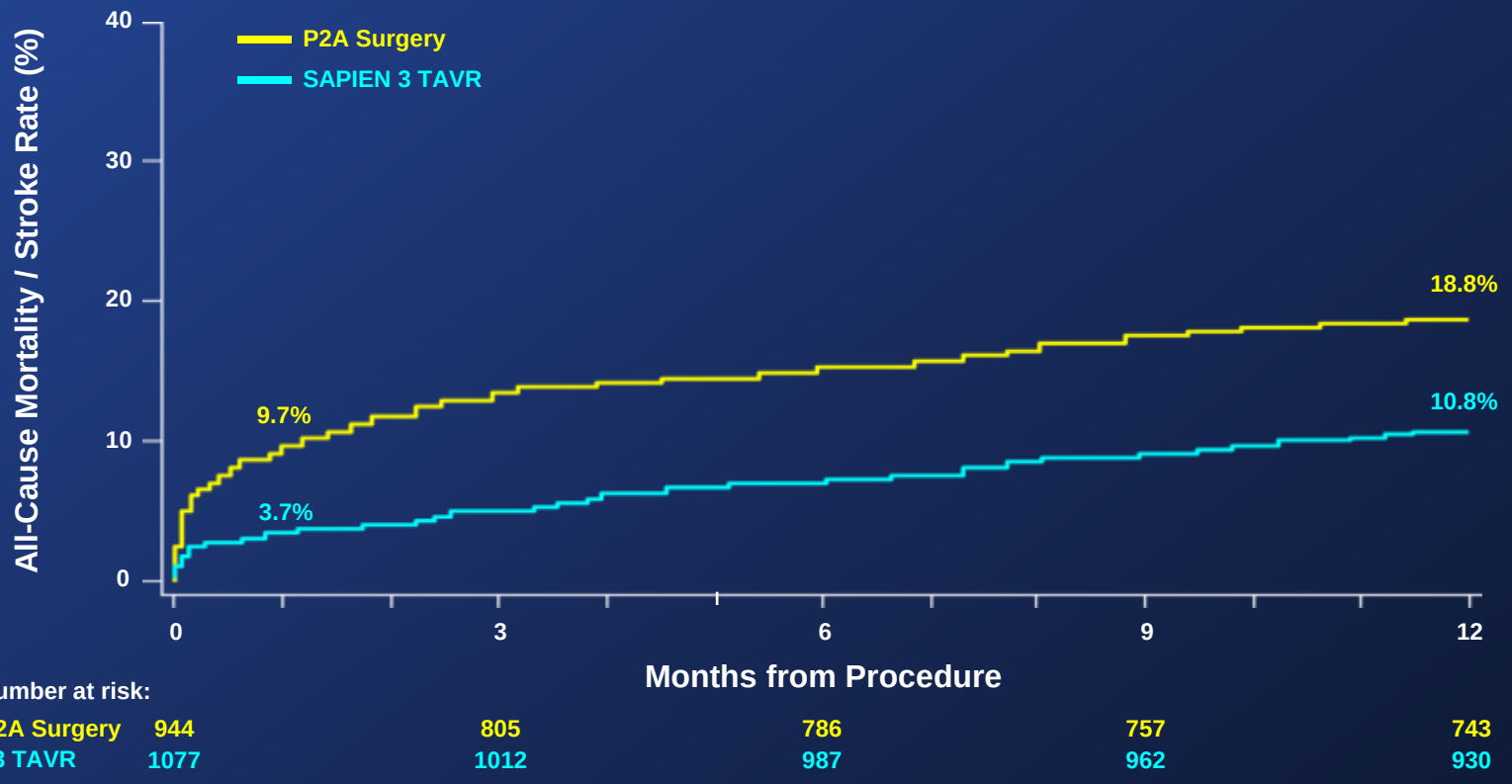
Components of Primary Endpoint (VI)



THE PARTNER II TRIAL

Unadjusted Time-to-Event Analysis

All-Cause Mortality and All Stroke (AT)



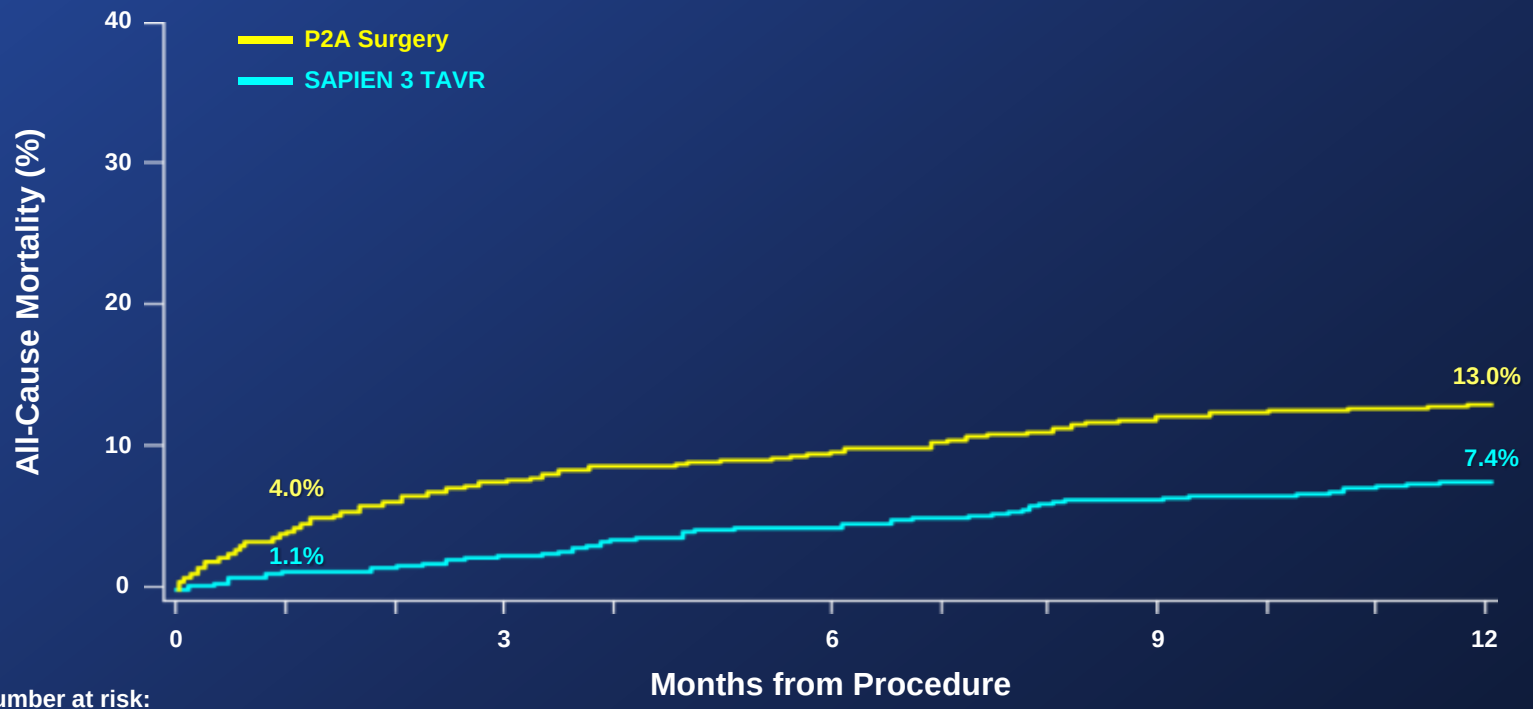
Number at risk:

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

THE PARTNER II TRIAL

Unadjusted Time-to-Event Analysis

All-Cause Mortality (AT)



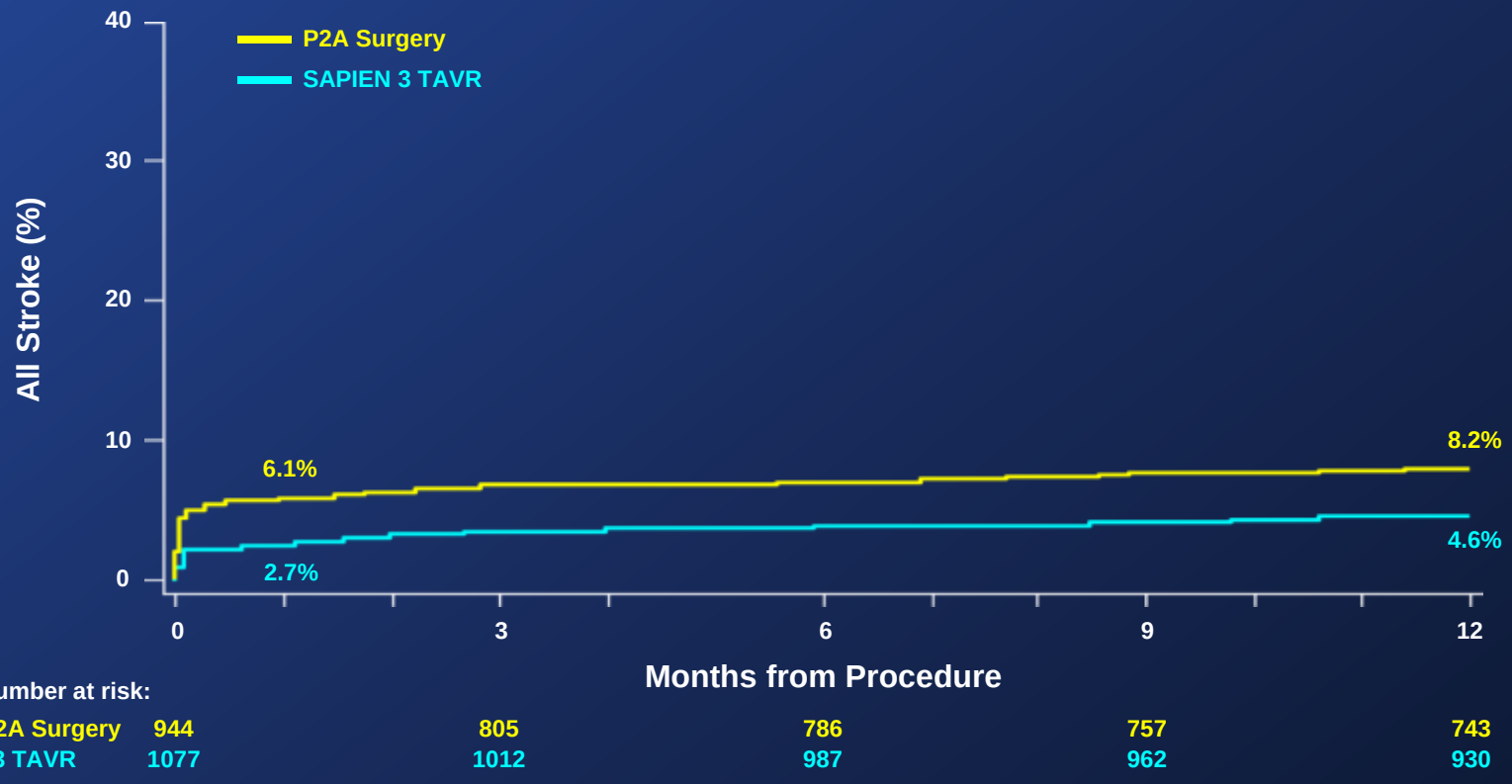
Number at risk:

P2A Surgery	944	859	836	808	795
S3 TAVR	1077	1043	1017	991	963

THE PARTNER II TRIAL

Unadjusted Time-to-Event Analysis

All Stroke (AT)

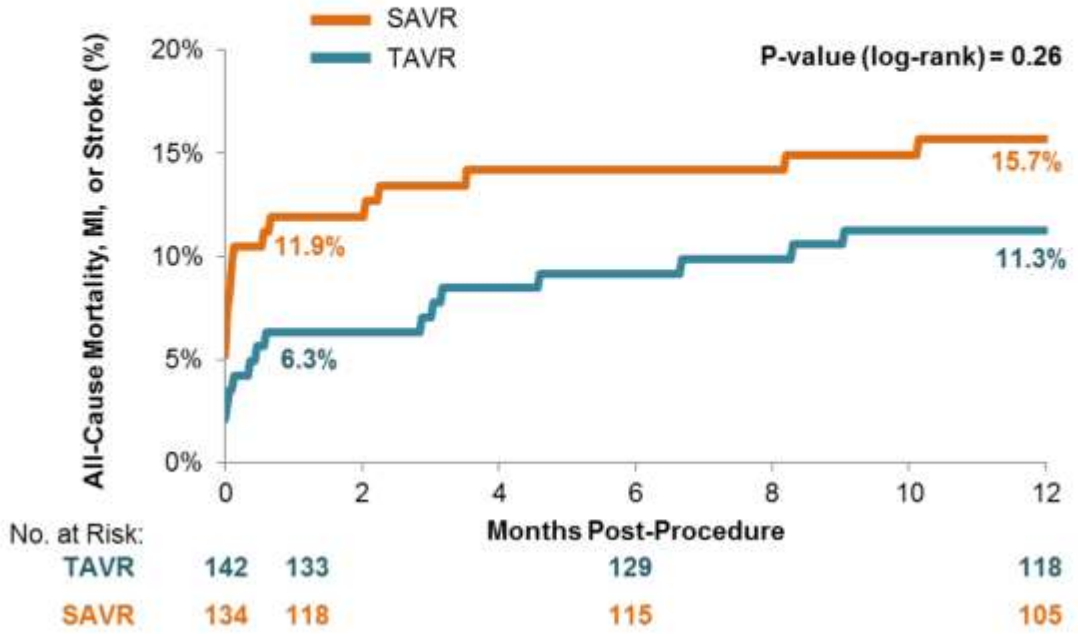


Number at risk:

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

NOTION trial: Low-risk (STS 3.0) trial in 280 patients with 1:1 randomization TAVR vs. SAVR

Death from Any Cause, Stroke or Myocardial Infarction at 1 Year in As-Treated Population



Thyregod H et al; JACC 2015

TAVR registries-2015

Author/Study	Study Type and Purpose	Results
Eggebrecht[7]	German Registry of SAVR (n = 71,927) and TAVR (48,353) since 2008.	20-fold increase in TAVR volumes since 2008, surpassing the annual numbers of isolated SAVR in 2013.
	Assess trends in TAVR volumes and outcomes.	Recent trend towards lower-risk/intermediate-risk patients.
		Complications of TAVR have declined considerably along with the need for emergency cardiac surgery
		at trial versus non-trial hospitals.
		for TAVR at trial versus non-trial hospitals.

- Increase in TAVR volumes
- Decrease in mortality, complications and length of stay
- Alternate access, COPD, CKD associated with increased mortalility
- “generalizability” of outcomes to non-trial hospitals

TAVR registries-2015

O'Connor {OConnor:2015tu}	Meta-analysis, N = 11,310.	Women: higher rates of major vascular complications (6.3% vs 3.4%), major bleeding events (10.5% vs 8.5%), and stroke (4.4% vs 3.6%) but lower rate of significant aortic incompetence (grade ≥2; 19.4% vs 24.5%) (P < 0.05 for all).
	Assess impact of sex on outcomes	No differences in procedural and 30-day mortality
		was associated with higher rates of death at 1 year (20% vs 11%, P < 0.01).
	Assess relation between BNP and outcome.	Additional multivariate predictors of 1-year mortality: moderate/severe PVR, STS PROM.

- Women have better survival at 1 year, similar mortality at 30 days (higher vascular complications but lower AR)
- High BNP levels at 30 days double the 1 year mortality
- CKD-lower procedural success and increased 1 year mortality

Pacemaker after TAVR

Table 4. Recent Studies on Rates of Permanent Pacemaker Implantation After TAVR

Author	Study, THV	Findings
Dizon[46]	PARTNER Substudy, N = 2531 ESV	New PPM required in 6.8%. Patients with prior PPM, new PPM after TAVR, and chronic LBBB, all had worse outcomes relative to no PPM/no LBBB patients.
		repeat hospitalization (42% vs 33%) at 1 year, but no impact on LVEF.
	ESV	
Petronio[50]	ADVANCE-II, N = 194 MCV	New PPM required in 18%. Optimal depth of valve implantation (≤6 mm) reached in 43%, and led to a non-significantly lower incidence of PPM compared with deeper implantation (13% vs 21%; P = 0.14).

- Partner substudy: New PPI 8.8%. Associated with higher death and rehospitalization (42% vs.33%).
- PPI not related with mortality in French TAVR registry
- Length of the membranous septum may be a predictor of PPI

Cerebral Protection in TAVR

Author	System/ Study	Findings
Baumbach[41]	TriGuard, N = 37	Successful cerebral coverage in 80%. New cerebral ischemic lesions similar to historical controls (82% vs 76%). Per-patient total lesion volume 34% lower than reported historical data (0.2 vs 0.3 cm^3), and 89% lower in patients with complete (n = 17) versus
		myocardium) in 63%. Tissue fragments more common with balloon-expandable THV (79% vs 56%; P = 0.05).
Ye[45]	EMBOL-X, first in human, N = 5 (CABG in 3; TAo TAVR in 2)	Multiple microemboli in filters from all cases. Histology revealed various kinds of tissue and thrombus.

- Feasibility of cerebral protection with 5 different devices
- Debris/tissue/thrombus captured with the Montage device
- Reduction in MRI findings, new neurologic deficits and better memory and cognitive function in limited patients

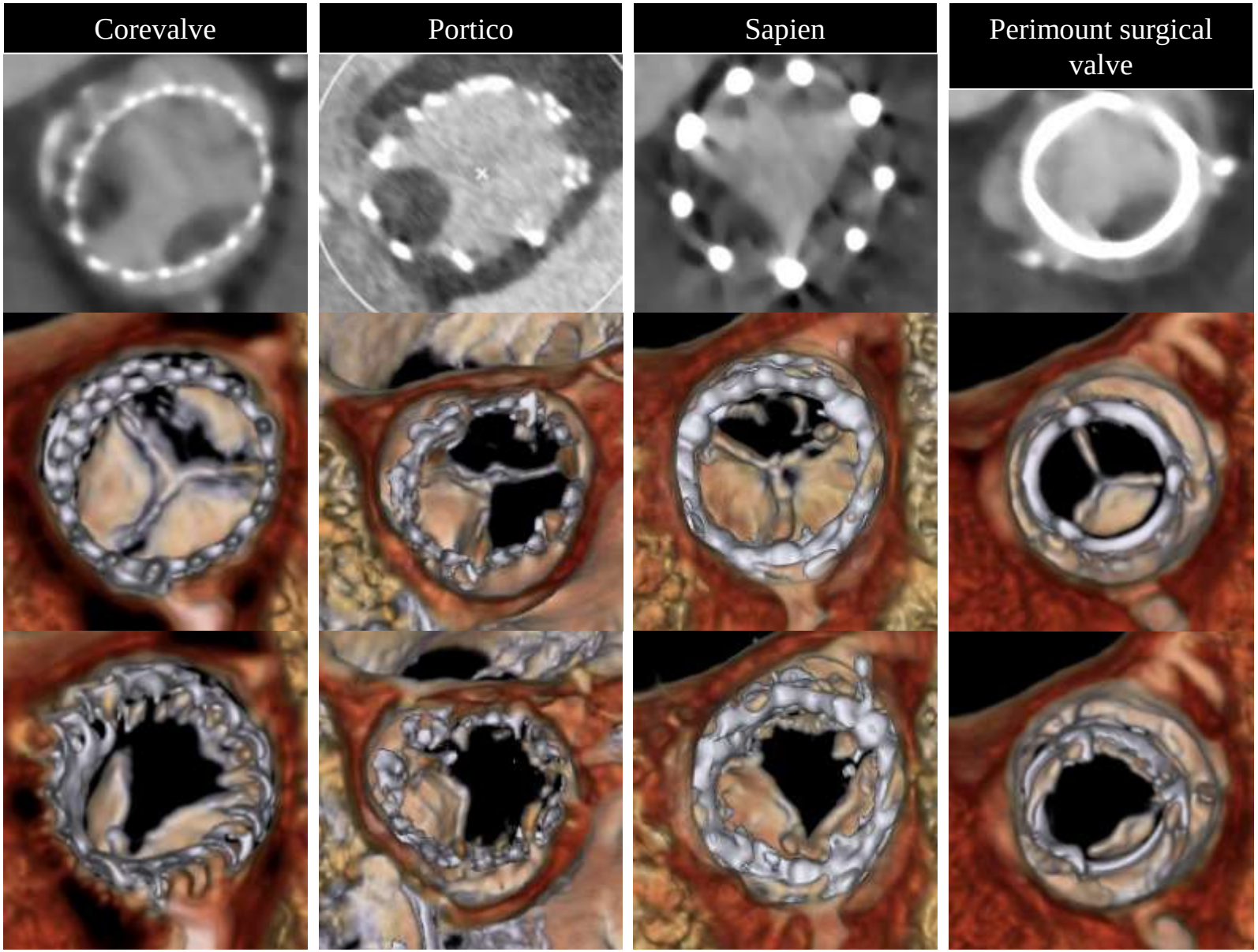
ORIGINAL ARTICLE

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. de Backer, F.M. Asch, C.E. Ruiz, N.T. Olsen, A. Trento, J. Friedman, D. Berman, W. Cheng, M. Kashif, V. Jelnin, C.A. Kliger, H. Guo, A.D. Pichard, N.J. Weissman, S. Kapadia, E. Manasse, D.L. Bhatt, M.B. Leon, and L. Søndergaard

NEJM; Oct 2015

Reduced leaflet motion was observed in all valve types including surgical bioprostheses



Uncertainty and Possible Subclinical Valve Leaflet Thrombosis

David R. Holmes, M.D., and Michael J. Mack, M.D.

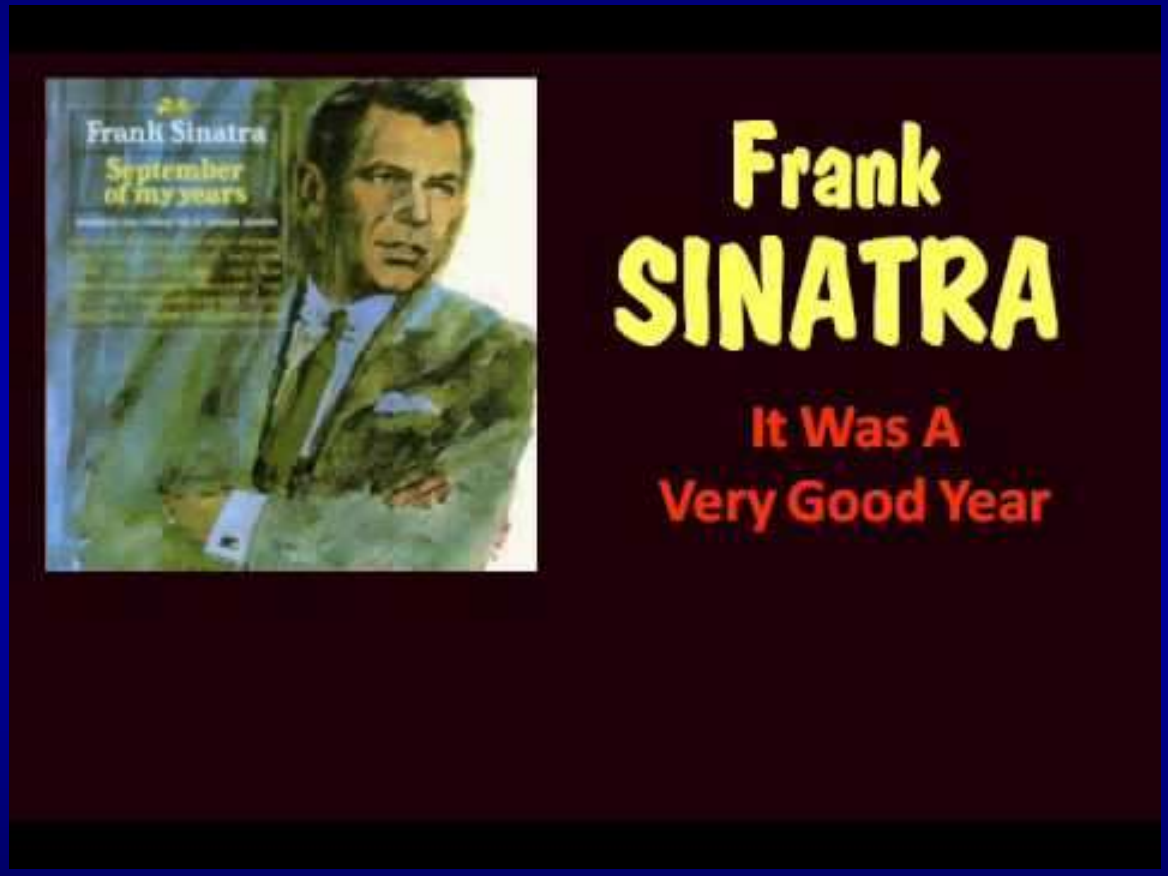
Table 1. Questions Raised by the Study by Makkar et al.

What is the true incidence of reduced aortic-valve leaflet motion? Is it device-specific, is it specific to transcatheter aortic-valve replacement (TAVR), or does it occur as frequently with surgical aortic-valve replacement?
Is reduced leaflet motion caused by thrombus formation on the leaflets? If so, is subclinical leaflet thrombosis related to the stent structure or to deployment strategies (e.g., undersizing or oversizing or other patient-specific factors)?
What does this abnormality mean clinically? How frequent are strokes or transient ischemic attacks in patients with this finding? Should the list of clinical events of potential concern be broadened to include valve durability, central aortic regurgitation, sudden death, or recurrent or unrelenting heart failure?
What is the natural history of the abnormality? When (and at what intervals) should it be evaluated, and does it play a role in premature structural valve deterioration?
What treatment strategy should be studied? If anticoagulation is presumed to be the most effective strategy, will adverse outcomes associated with bleeding result in more complications than this abnormality?
What is the most effect imaging approach for monitoring this abnormality? Is monitoring needed in all patients, and if so, when?
Does this issue need to be fully resolved before the expansion of Food and Drug Administration approval of TAVR for lower-risk patients?

Year-in-Review

- The role of Trans-femoral TAVR was solidified in the treatment of AS in high and intermediate risk patients as a preferred therapy over surgery
- Continued improvement in mortality and complications rates in multiple registries reflect advances in device development, technique refinement, better imaging and patient selection. TAVR in inoperable/high risk with 1-2% mortality at 30 days became a reality!
- The five year data on valve durability are reassuring and comparable to surgery but limited by about 60% mortality in both surgery and TAVR at 5 years. Hemodynamics of TAVR appears better than SAVR
- Field is poised for further research in cerebral protection and adjunctive antithrombotic strategies

For TAVR…


Frank Sinatra
September of my years
Frank
SINATRA
It Was A
Very Good Year