Debate: SAVR for Low-Risk Patients in 2017 is Obsolete

AVR vs TAVI

Joseph E. Bavaria, MD
Roberts-Measey Professor of Surgery
Vice Chair, Division of Cardiovascular Surgery
University of Pennsylvania
Immediate Past President-Society of Thoracic Surgeons (STS)

STS/EACTS LatAm, Cartagena, Sept 2017

Disclosures

Penn Primary Investigator: Medtronic Surtavi Trial; Edwards Partner Trial(s); St. Jude/Abbott Portico Trial

Chairman: STS/ACC TVT Steering Committee (2017-2020)

Co-Chairman: Institutional and Operator Requirements Writing Committee for STS/ACC (NCD)

Previous Holder of Founders Equity in CardiAQ TMVI (Now Edwards)

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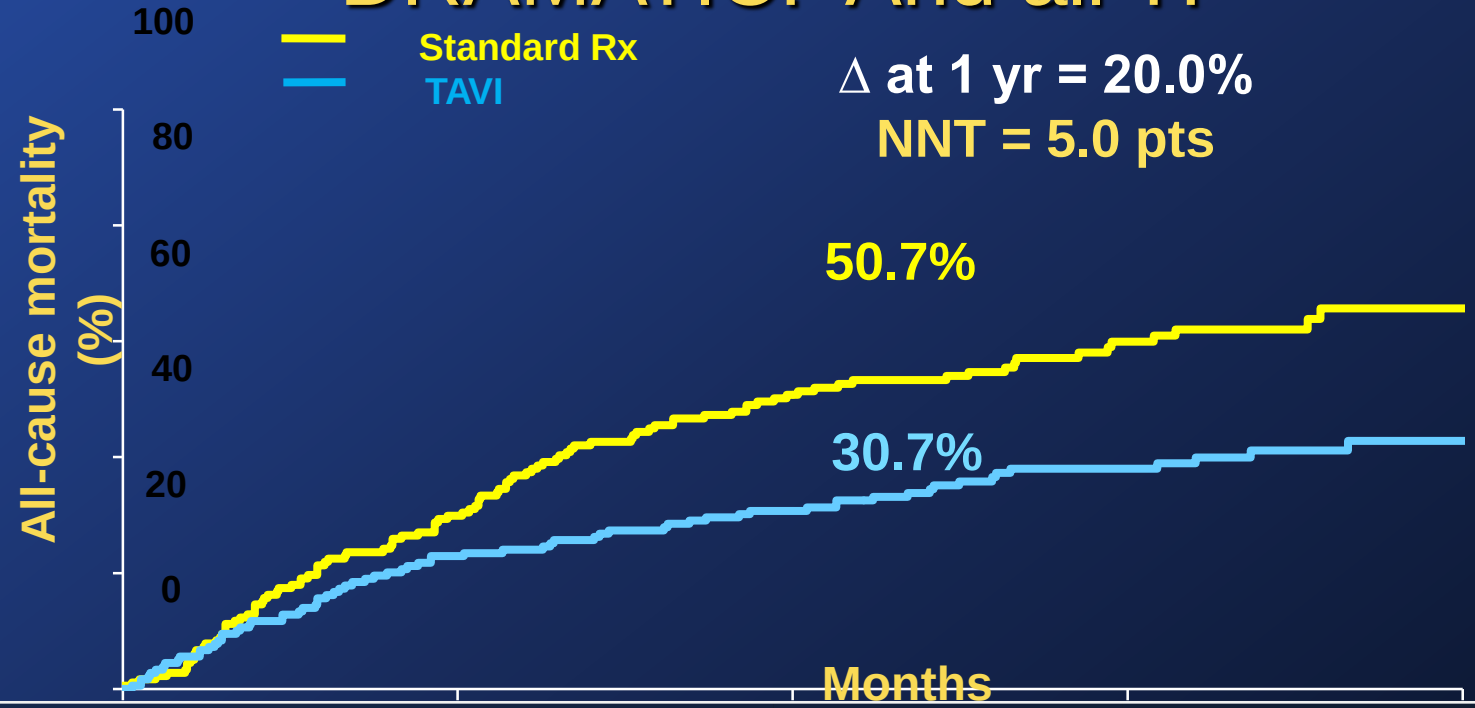
I do BOTH AVR and TAVI

Theme of this talk:

Data Driven and …. The Data just keeps on Coming in!!!

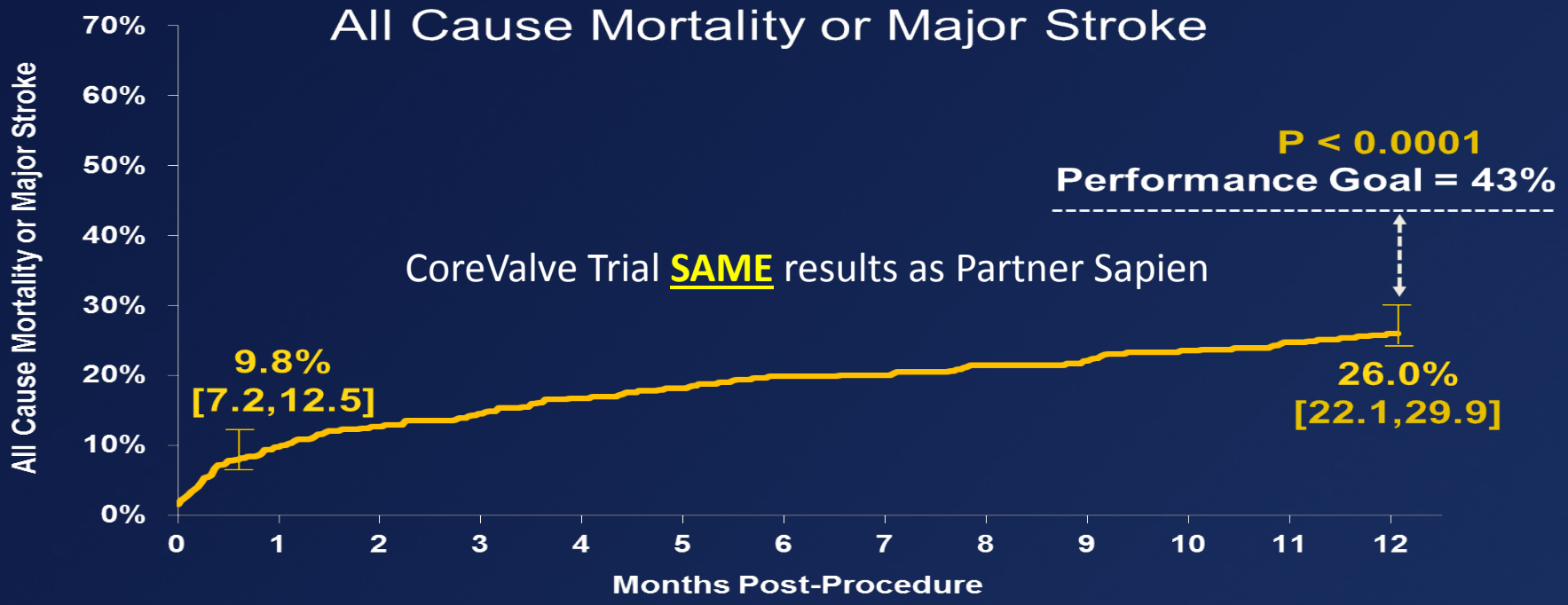
Non-op (Extreme Risk)
Patients
STS score > 10 (mean 12)

All Cause Mortality …… EASY! DRAMATIC! And all TF



Numbers at Risk	0	6	12	18	24
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

Primary Endpoint: Iliofemoral



So ….. Easy Decision!
All Extreme Risk (STS > 10)
Receive a TAVI

High Risk for Surgical AVR Patients
STS score > 8

PARTNER Cohort A

1-Year outcomes published on-line June 5, 2011 @ NEJM.org and in print June 9, 2011

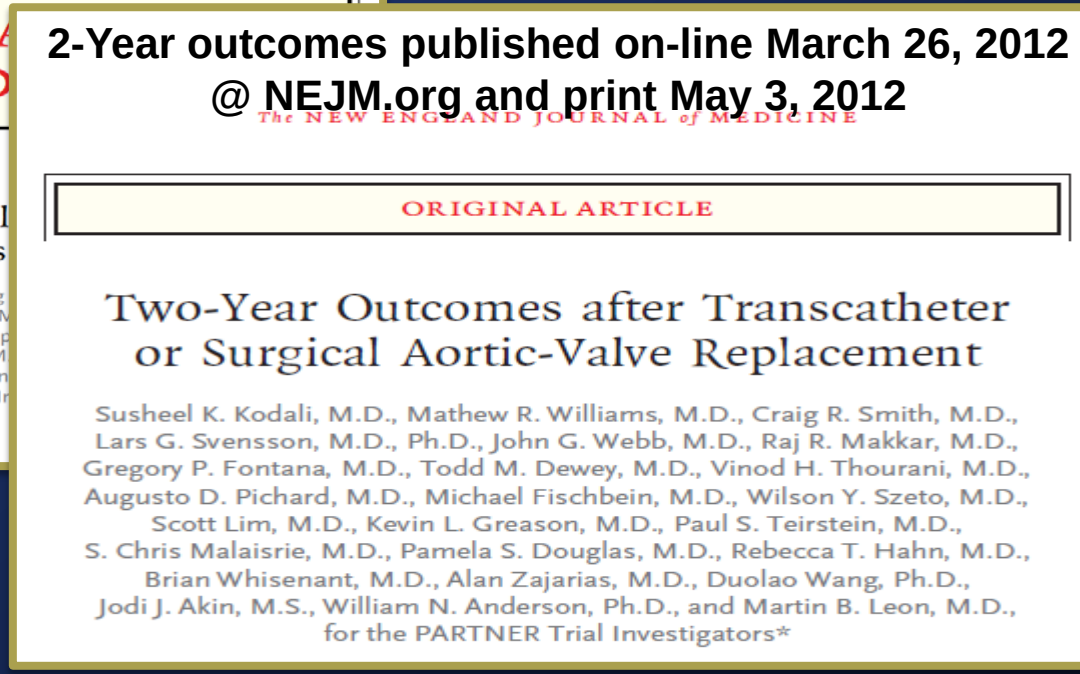
The NEW ENGLA
JOURNAL of MED

ESTABLISHED IN 1812 JUNE 9, 2011

Transcatheter and Surgical Aortic-Val
in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M
Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kap
Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M
Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson
and Stuart J. Pocock, Ph.D., for the PARTNER Trial In

2-Year outcomes published on-line March 26, 2012 @ NEJM.org and print May 3, 2012



The NEW ENGLAND JOURNAL of MEDICINE

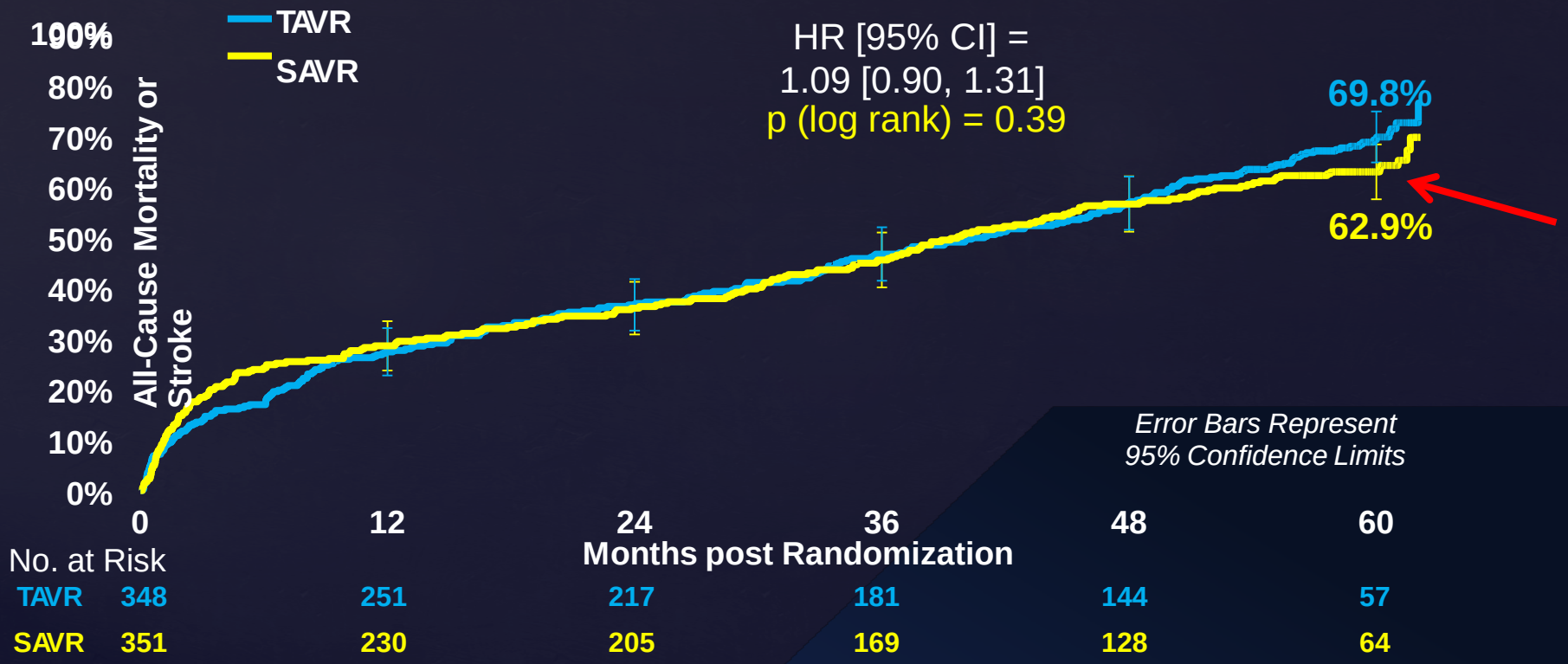
ORIGINAL ARTICLE

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D., Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D., Augusto D. Pichard, M.D., Michael Fischbein, M.D., Wilson Y. Szeto, M.D., Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D., S. Chris Malaisrie, M.D., Pamela S. Douglas, M.D., Rebecca T. Hahn, M.D., Brian Whisenant, M.D., Alan Zajarias, M.D., Duolao Wang, Ph.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

All-Cause Mortality or Stroke (ITT)

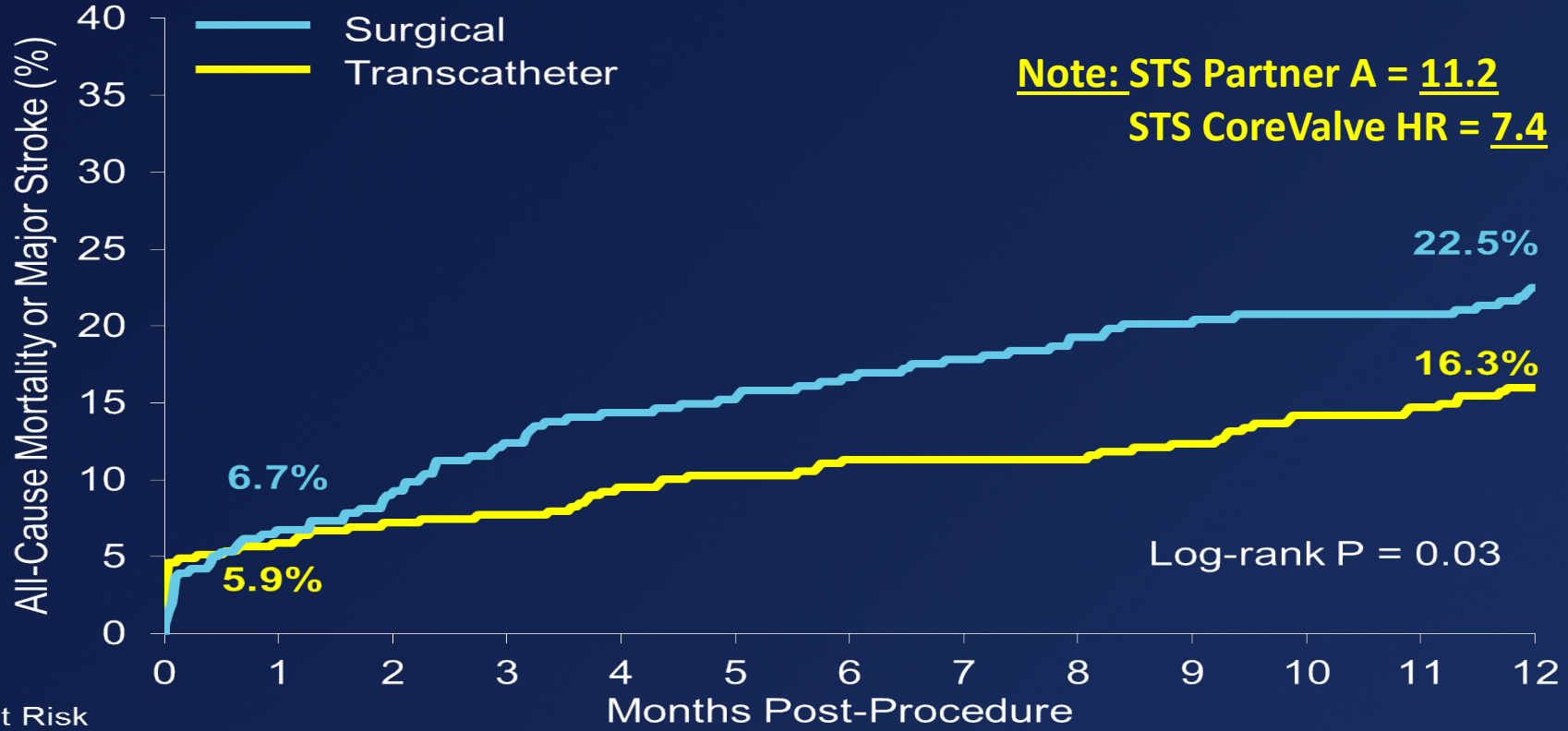
All Patients 5-yr



No. at Risk

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

All-Cause Mortality or Major Stroke

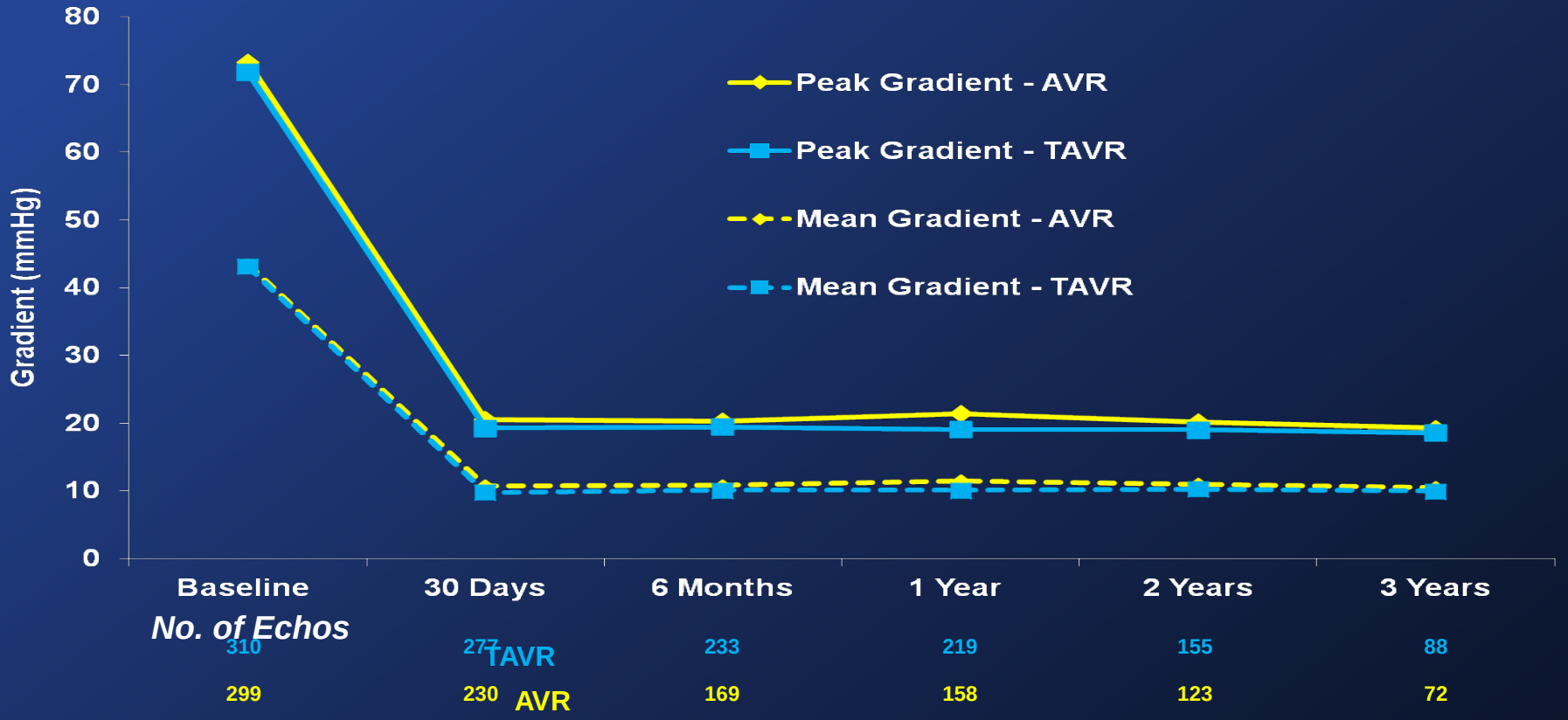


Note: STS Partner A = 11.2
STS CoreValve HR = 7.4

No. at Risk					
Surgical	357	333	289	263
Transcatheter	390	367	344	322

Echocardiographic Findings (AT)

Mean & Peak Gradients



Concepts and Nuance from the Data

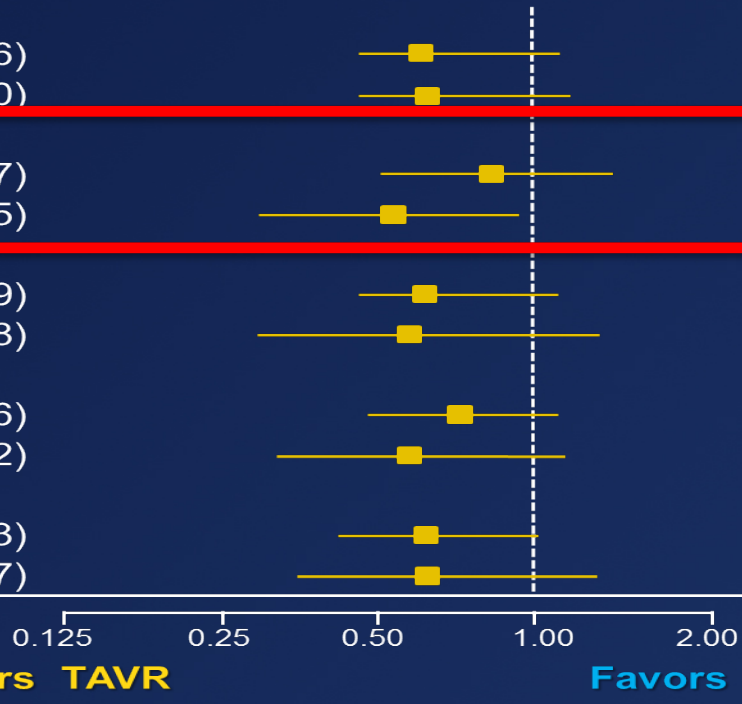
Subgroup Analyses of Treatment Effect
All-Cause Mortality at 1 Year

THE PARTNER TRIAL

Subgroup	TAVR (%) n=348	AVR (%) n=351	RR (95% CI)	P-value for interaction
Overall	24.1	25.4	0.95(0.73-1.23)	
Age				
<85	21.6	24.9	0.87(0.60-1.27)	0.52
>85	27.0	26.1	1.03(0.72-1.47)	
Sex				
Male	28.4	24.2	1.17(0.84-1.63)	0.045
Female	18.4	27.2	1.17(0.84-1.63)	
BMI				
<26	27.3	27.4	0.68(0.44-1.04)	0.66
>26	21.0	23.8	0.99(0.71-1.40)	
STS score				
<11	19.9	21.7	0.88(0.59-1.31)	0.87
>11	28.1	29.3	0.92(0.61-1.38)	
LV ejection fraction				
<55	26.2	27.7	0.96(0.69-1.34)	0.80
>55	22.4	22.1	1.01(0.68-1.50)	

Subgroup Analysis for 1 Year Mortality

Subgroup	All-cause Death at 1 Year K-M Rates TAVR	SAVR	Hazard Ratios (95% CI)	P Value
Age				0.97
>85	15.7	21.4	0.71 (0.43, 1.16)	
≤85	12.9	17.2	0.72 (0.43, 1.20)	
Gender				0.21
Male	15.5	16.7	0.89 (0.55, 1.47)	
Female	12.7	21.8	0.56 (0.33, 0.95)	
BMI				0.79
≤30	15.7	20.6	0.73 (0.48, 1.09)	
>30	10.3	15.8	0.64 (0.30, 1.38)	
LVEF				0.68
≤60	15.8	19.9	0.76 (0.49, 1.16)	
>60	11.6	17.8	0.64 (0.34, 1.22)	
Diabetes				0.86
No	15.8	22.3	0.67 (0.44, 1.03)	
Yes	11.3	15.3	0.72 (0.38, 1.37)	



Women do ESPECIALLY well with TAVI

So ……. Why TAVI trials into **INTERMEDIATE RISK** patients??

THE PARTNER TRIAL

For all the Reasons explained …. The High Risk trials all showed equivalence to AVR. It is the next logical step

So the Real Question is ……. Why **NOT** a New TAVI trial into **INTERMEDIATE RISK** patients??

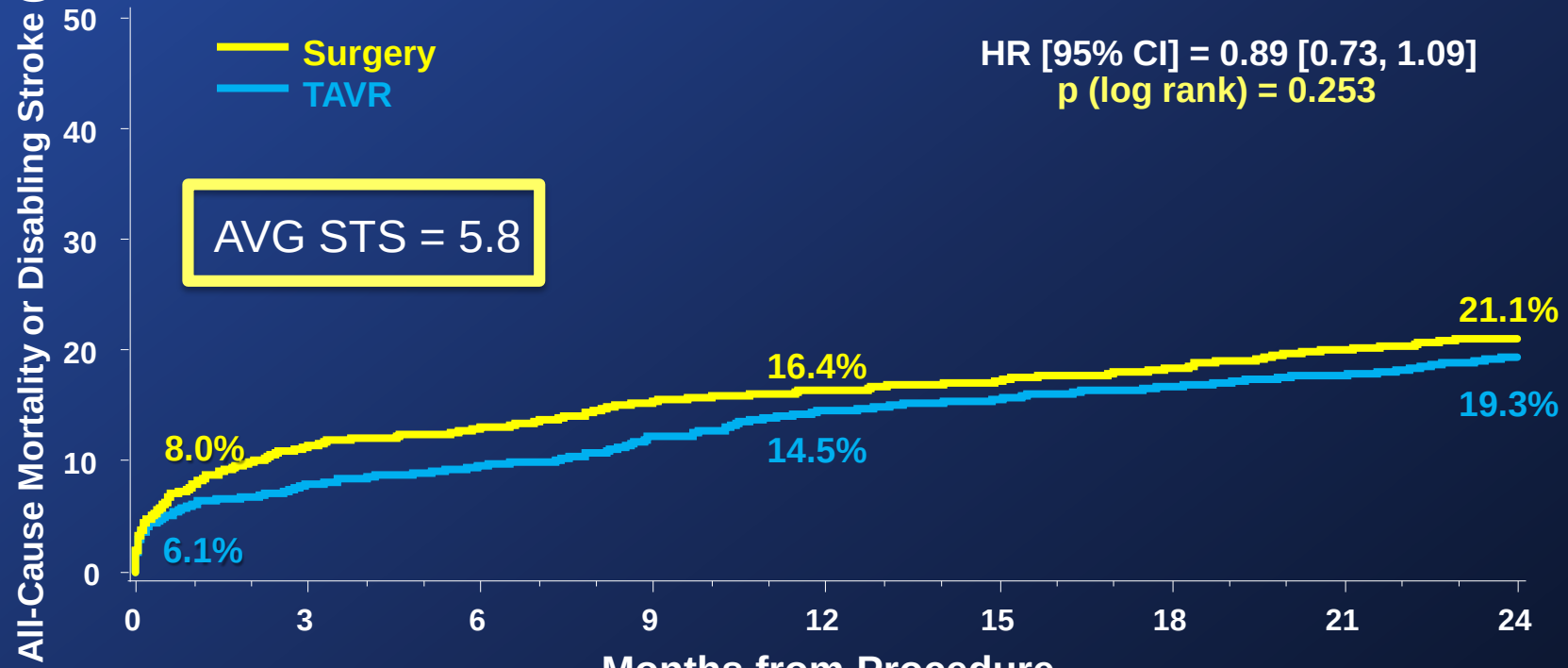
THE PARTNER TRIAL

Intermediate Risk Patients
STS score > 3-4 to 8

P2 RCT Primary Endpoint (ITT)

All-Cause Mortality or Disabling Stroke

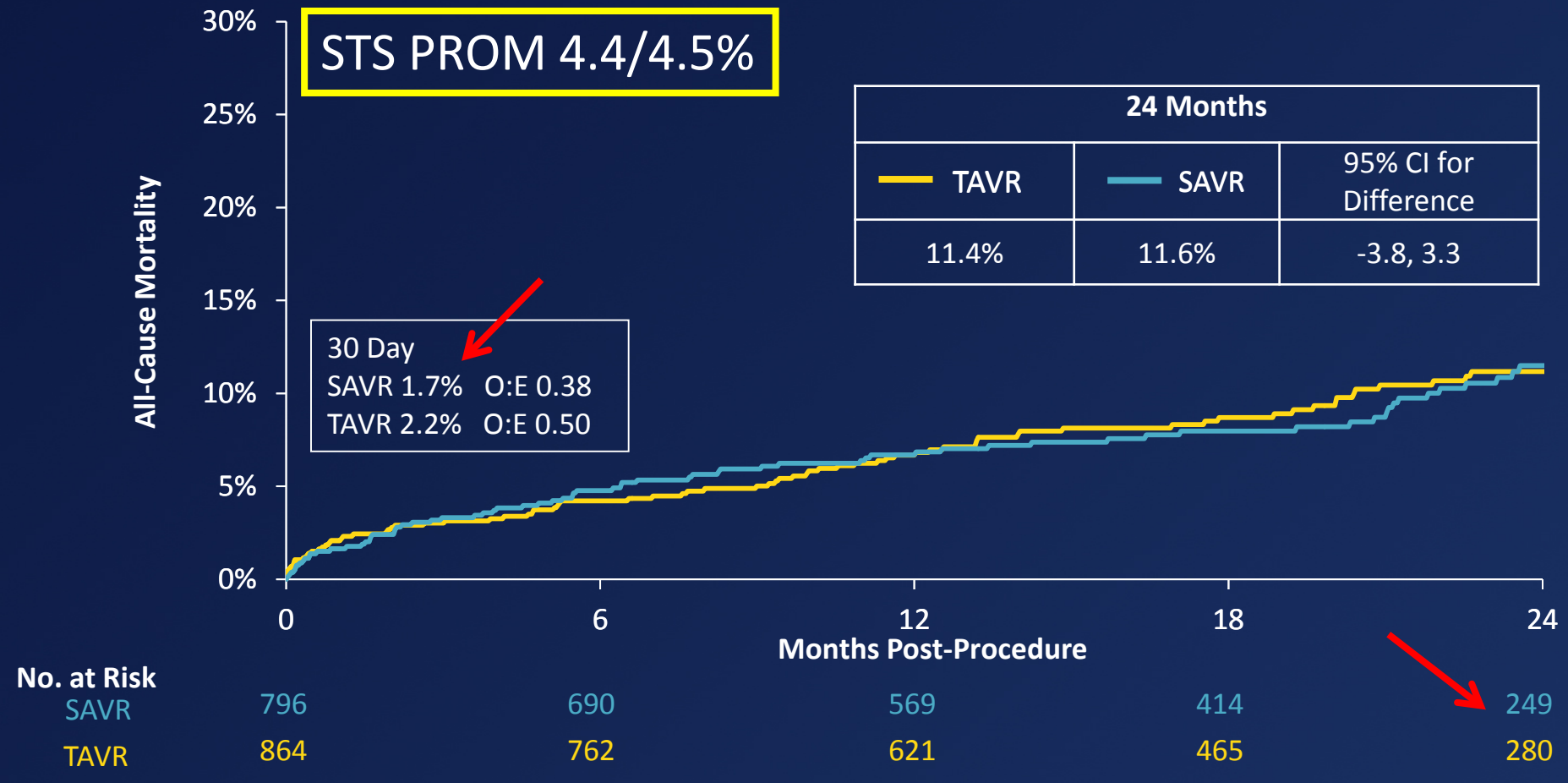
THE PARTNER II TRIAL



Number at risk:

Surgery	1021	838	812	783	770	747	735	717	695
TAVR	1011	918	901	870	842	825	811	801	774

All-Cause Mortality (ACC 4/2017)



- Surgical AVR vs TAVI

Results of Partner/CoreValve Randomized Clinical Trial in Intermediate Risk patients (STS = 4-8)

No Difference!!

- Presented at ACC April 2016 and 2017

Now Newer 3rd Generation Valves??

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

THE PARTNER II TRIAL

Baseline Patient Characteristics

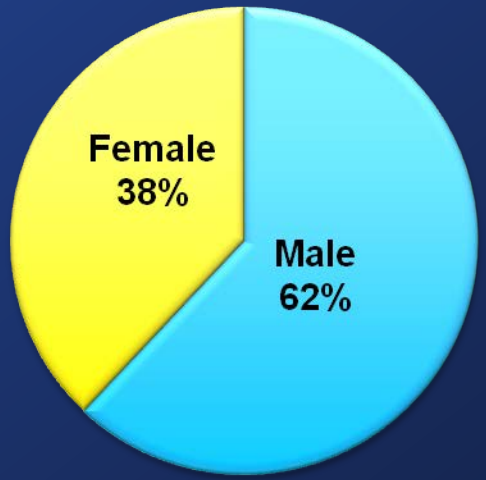
S3i Patients (Intermediate Risk STS 4-8)

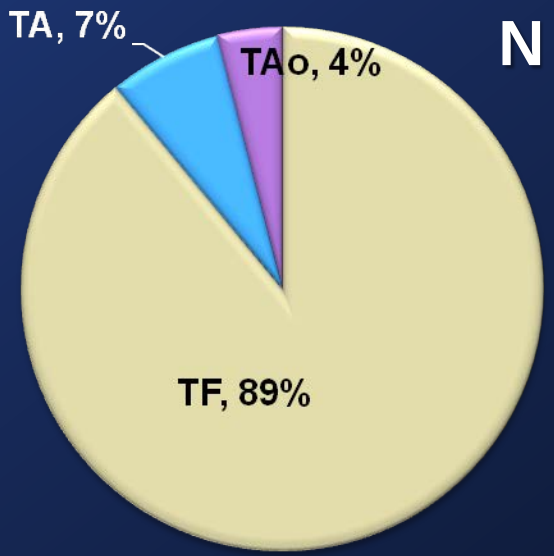
THE PARTNER II TRIAL

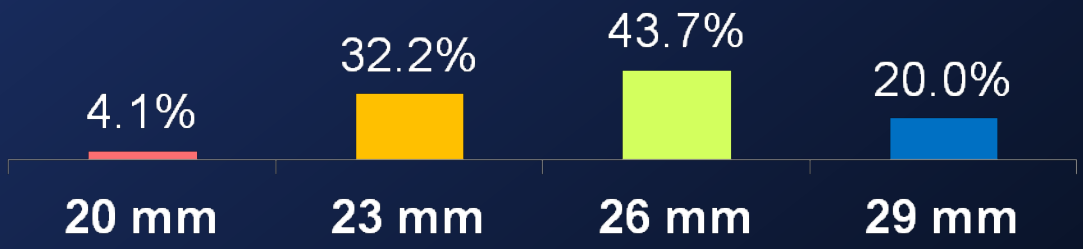
Average STS = **5.3%** (Median 5.2%)

Average Age = **81.9yrs**

N = 1076

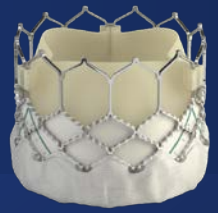






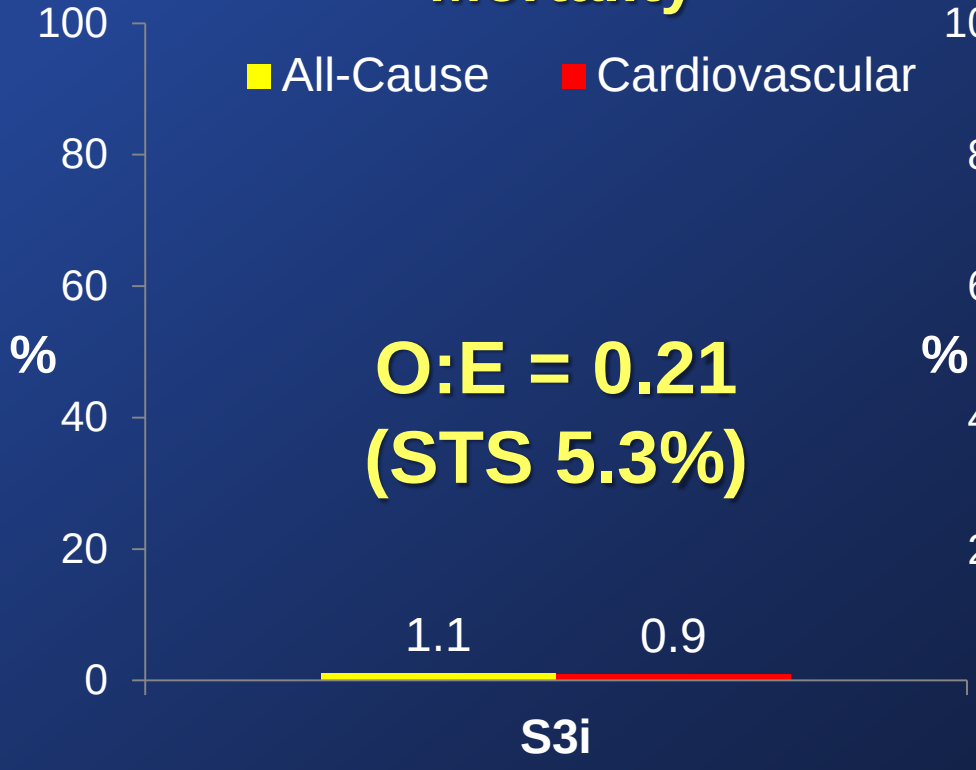
Mortality and Stroke: S3i

At 30 Days (As Treated Patients)



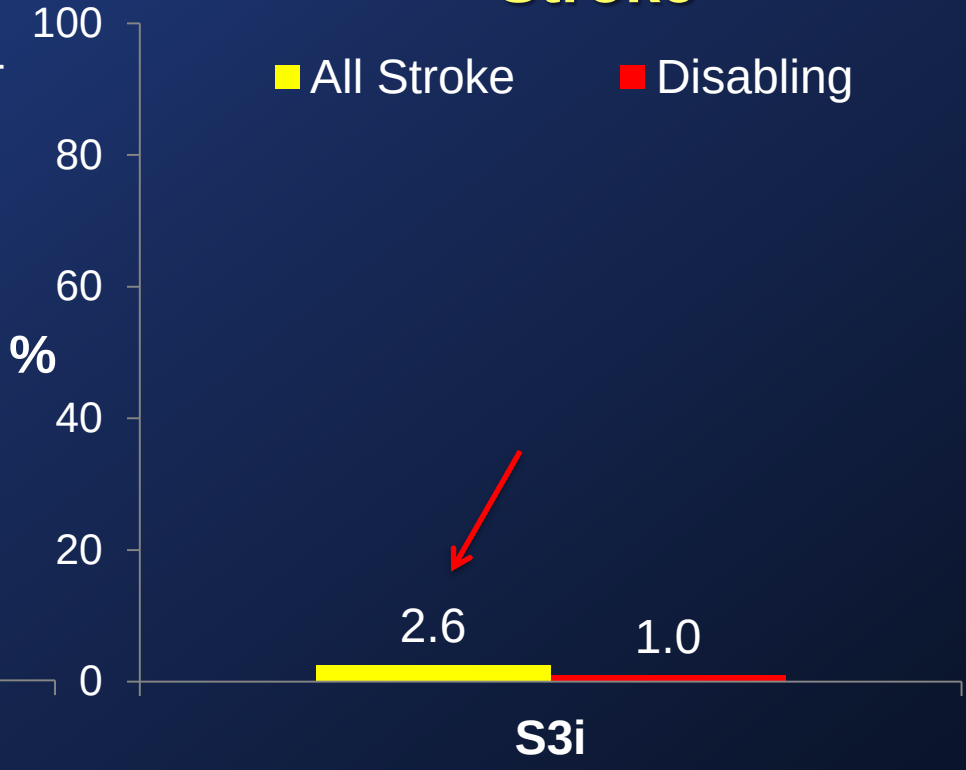
THE PARTNER II TRIAL

Mortality



O:E = 0.21
(STS 5.3%)

Stroke



ACC 2017 – Evolute Pro

Medtronic Receives FDA Approval for CoreValve(TM) Evolut(TM) Pro Transcatheter Valve with Advanced Sealing

March 22, 2017 8:00 AM CT

Medtronic

First-Ever Data at ACC.17 Confirms Safety and Efficacy of New Self-Expanding, Recapturable Heart Valve at 30-Days with High Survival, Low Stroke and Minimal Paravalvular Leak

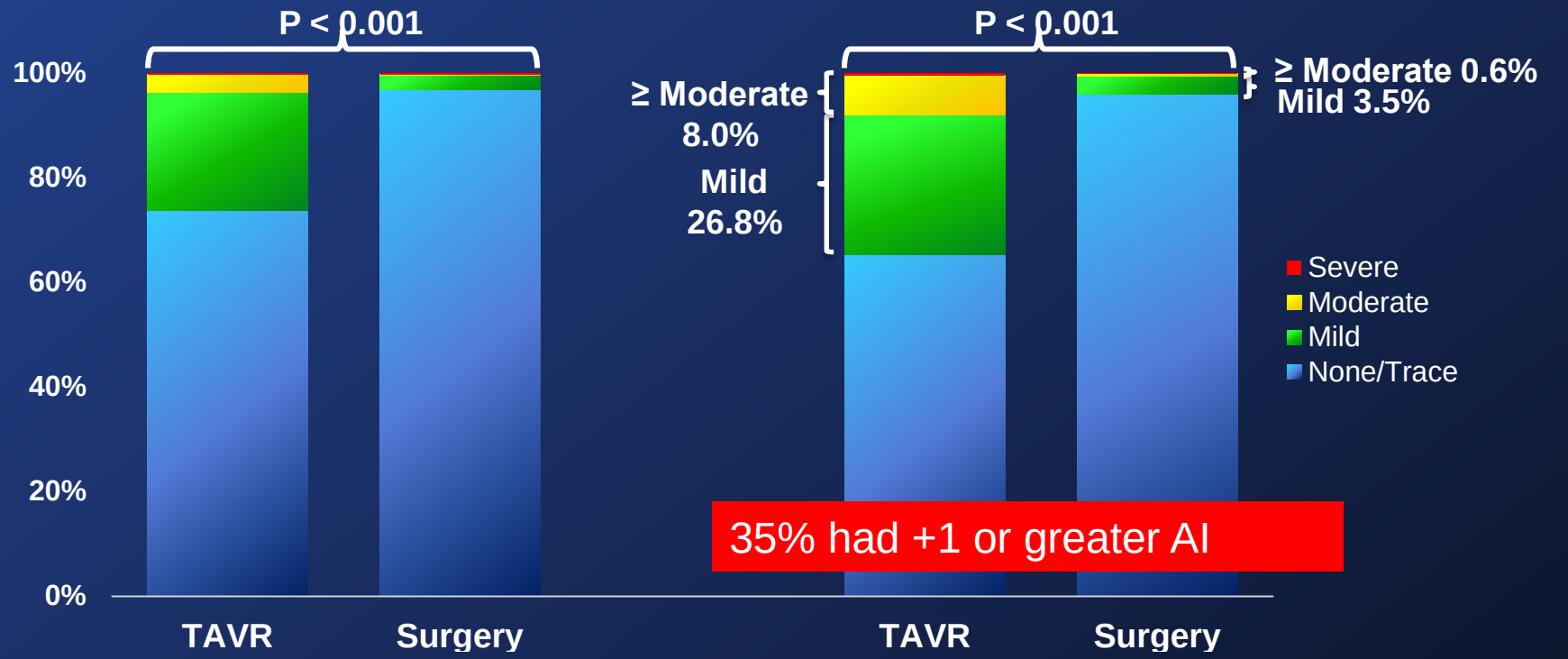
The Evolut PRO Clinical Study (N=60) met its primary endpoint at 30 days with high rates of survival (98.3 percent) and low rates of disabling stroke (1.7 percent). The Evolut PRO valve also showed strong hemodynamic performance with large aortic valve areas (2.0 ± 0.5 cm^2) and mean gradients in the single digits (6.4 ± 2.1 mm Hg) at 30 days. The majority of study subjects (72.4 percent) experienced no/trace PVL and no incidents of moderate or severe PVL were observed at 30 days. Additionally, improving on the already low rates seen in Evolut R clinical studies and real-world TVT and FORWARD registries, the rate of new pacemaker implantation was 10 percent.

A few problems must be solved with TAVI, especially for application into LOW RISK Patients

But I think they will be solved!

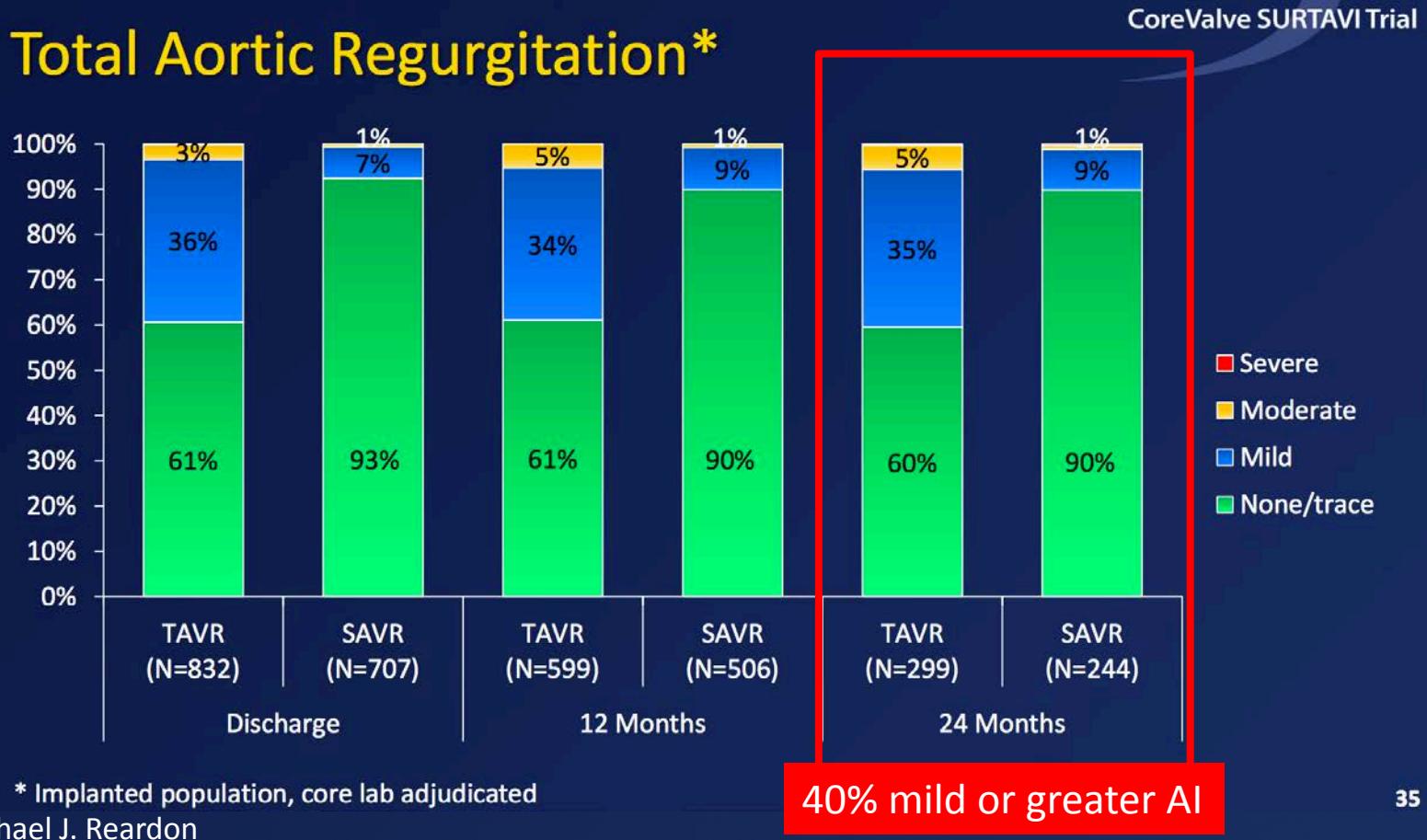
Aortic Valve Insufficiency

Paravalvular Regurgitation (VI)
3-Class Grading Scheme



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

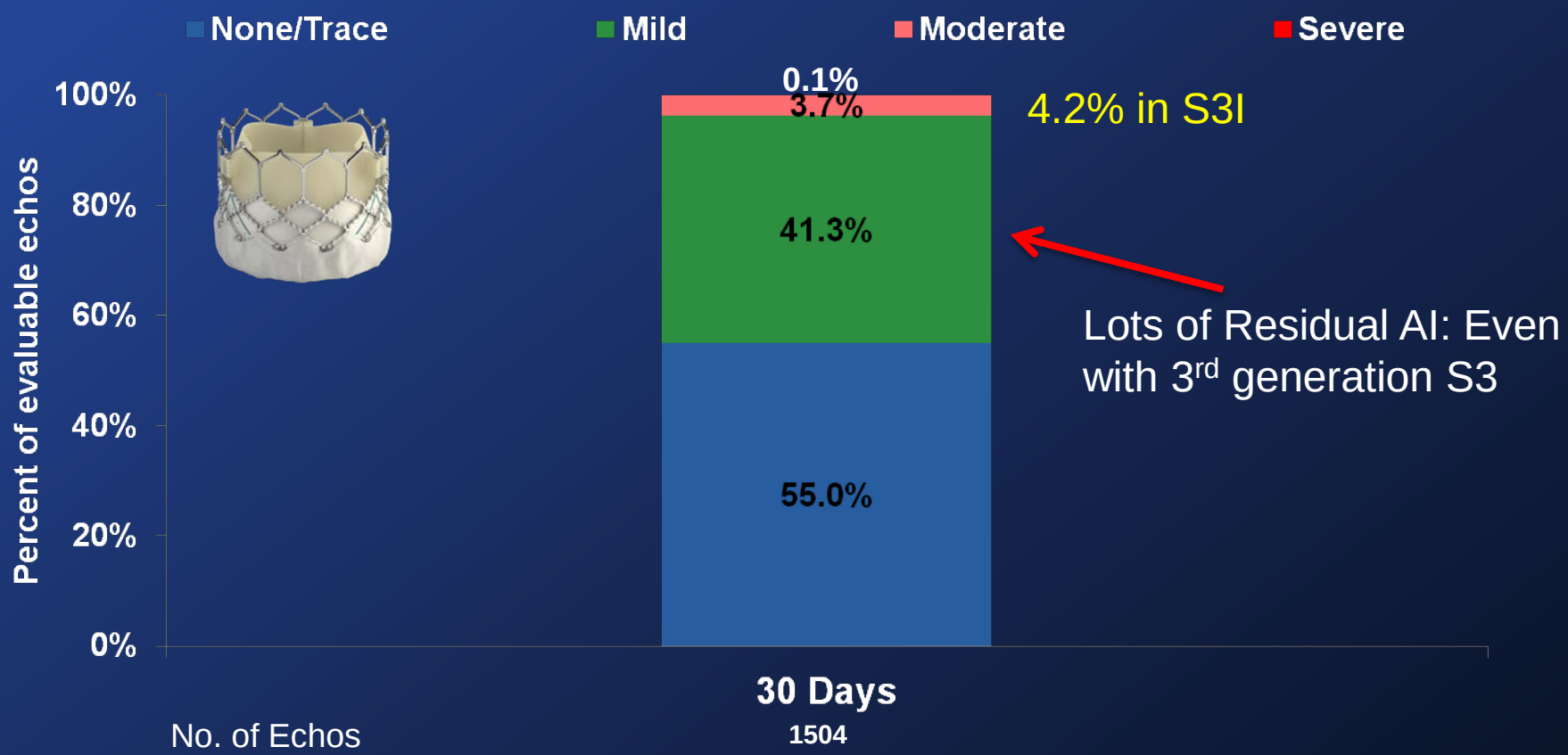
ACC 2017 – CoreValve/Evolute



ACC 2017, Michael J. Reardon

Paravalvular Leak: S3HR & S3i
(Valve Implant Patients)

THE PARTNER II TRIAL



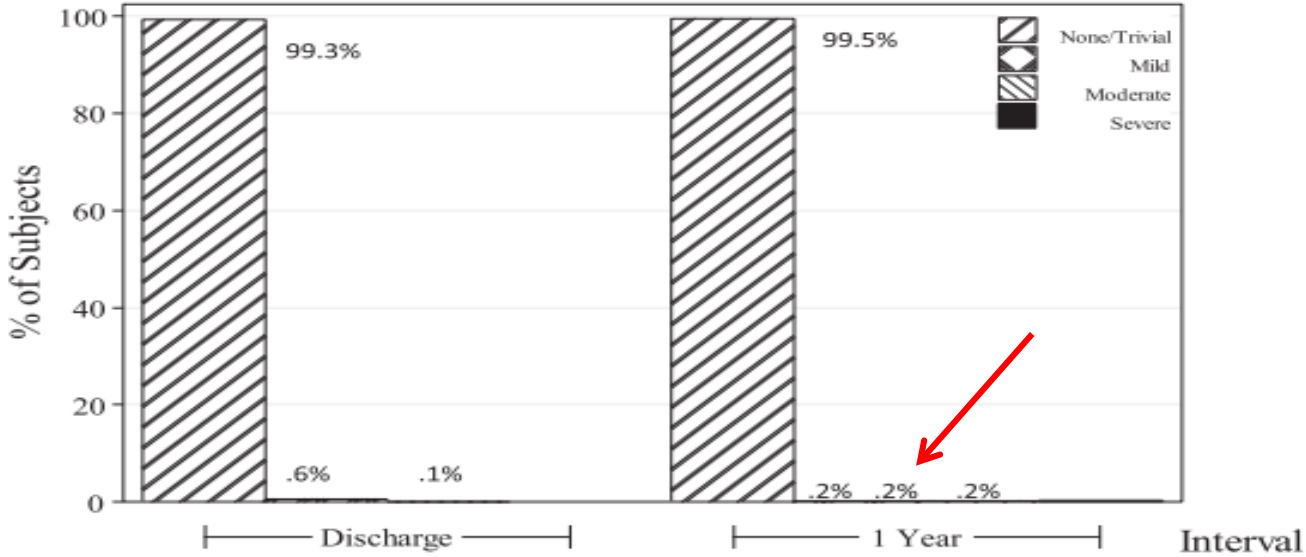
The St Jude Medical Trifecta aortic pericardial valve: Results from a global, multicenter, prospective clinical study

Joseph E. Bavaria, MD,[a] Nimesh D. Desai, MD, PhD,[a] Anson Cheung, MD,[b] Michael R. Petracek, MD,[c] Mark A. Groh, MD,[d] Michael A. Borger, MD,[e] and Hartzell V. Schaff, MD[f]

FIGURE 12. Paravalvular leak over time.

N=1,016 patients

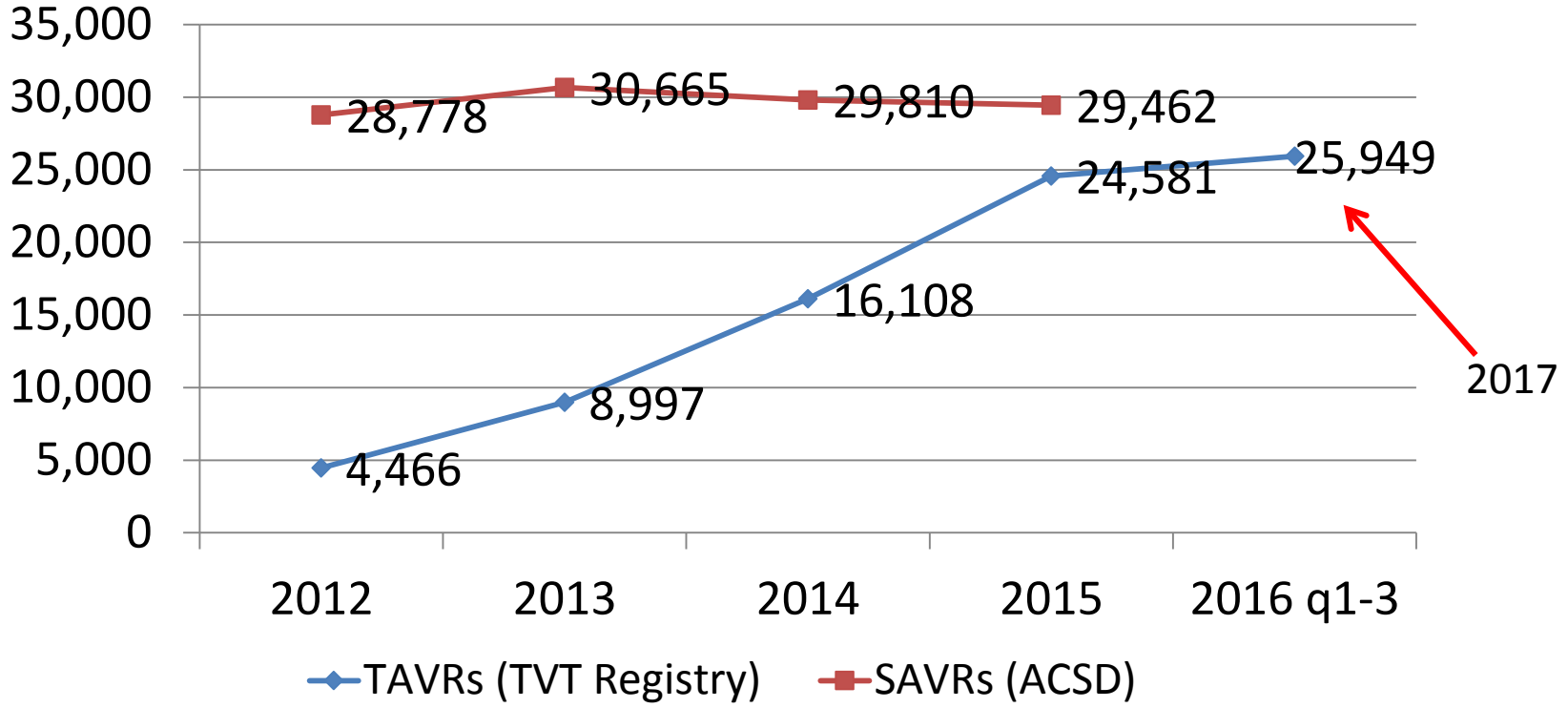
STS = 4.02



Peri-Procedural TAVI AI still exists but is improving steadily

Real World Data

TAVR and SAVR* Procedures In the TVT Registry and STS ACSD*



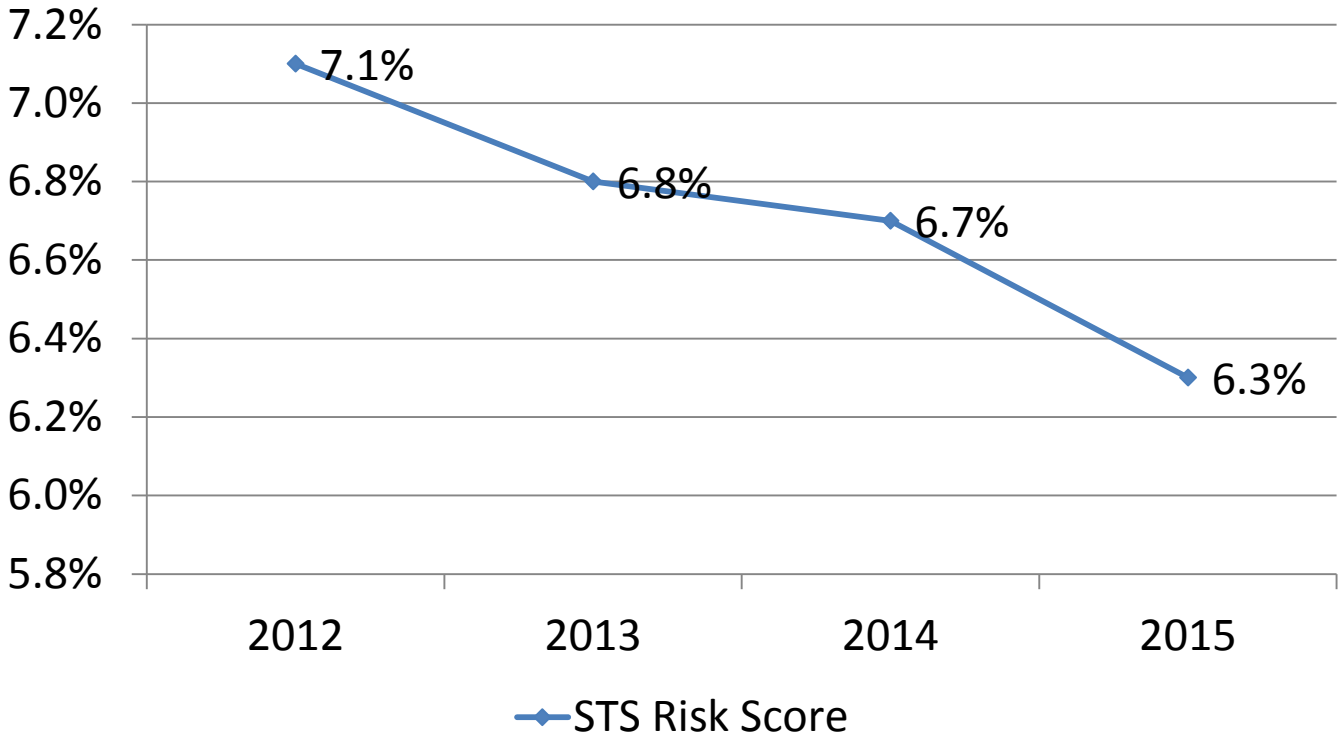
STS National Database
Using data to drive quality

* SAVR= isolated surgical aortic valve replacement; ACSD=Adult Cardiac Surgery Database

Source: STS/ACC TVT Registry Database as of Jan 18, 2017; STS ACSD 2015 Annual Report

NCDR® NATIONAL CARDIOVASCULAR DATA REGISTRY

Median STS Risk Score for all TAVR Procedures



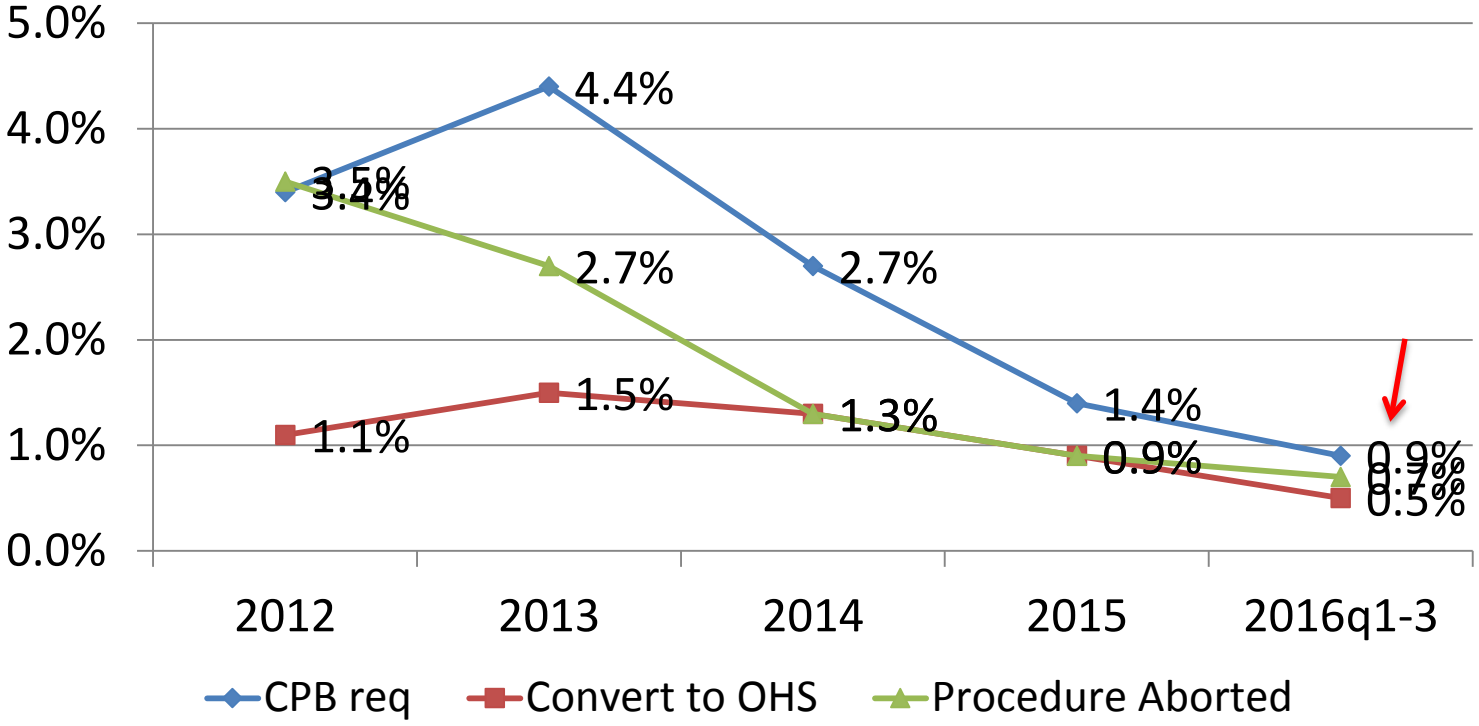
Note: vertical scale accentuates trend.

Why?

Risk creep versus expanded indications versus identification of patients with other factors not included in STS score (frailty, etc)?

Source: DCRI analysis, Sept 12, 2016

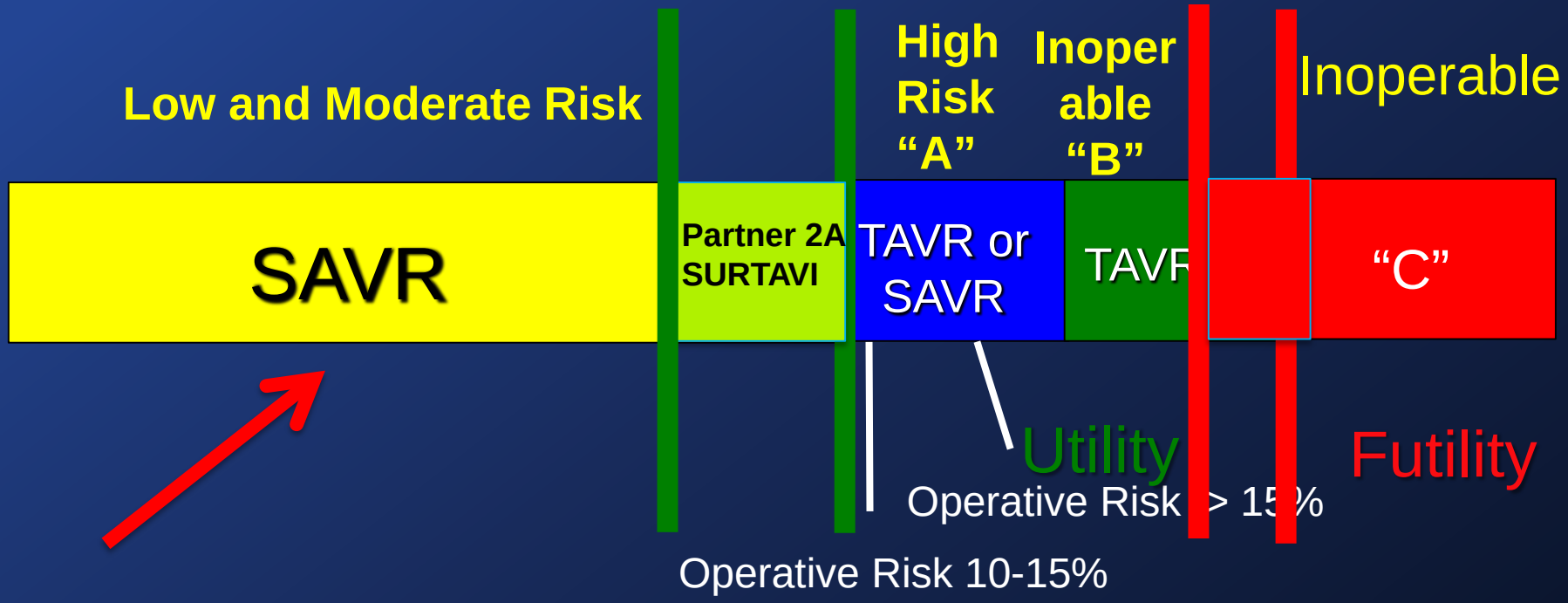
TAVR: Catastrophic Procedure Details



Source: STS/ACC TVT Registry Database.
80,130 records as of Jan 18, 2017

The Near Future??: Treatment of Aortic Stenosis

THE PARTNER II TRIAL



Adapted from S. Kodali and M. Leon

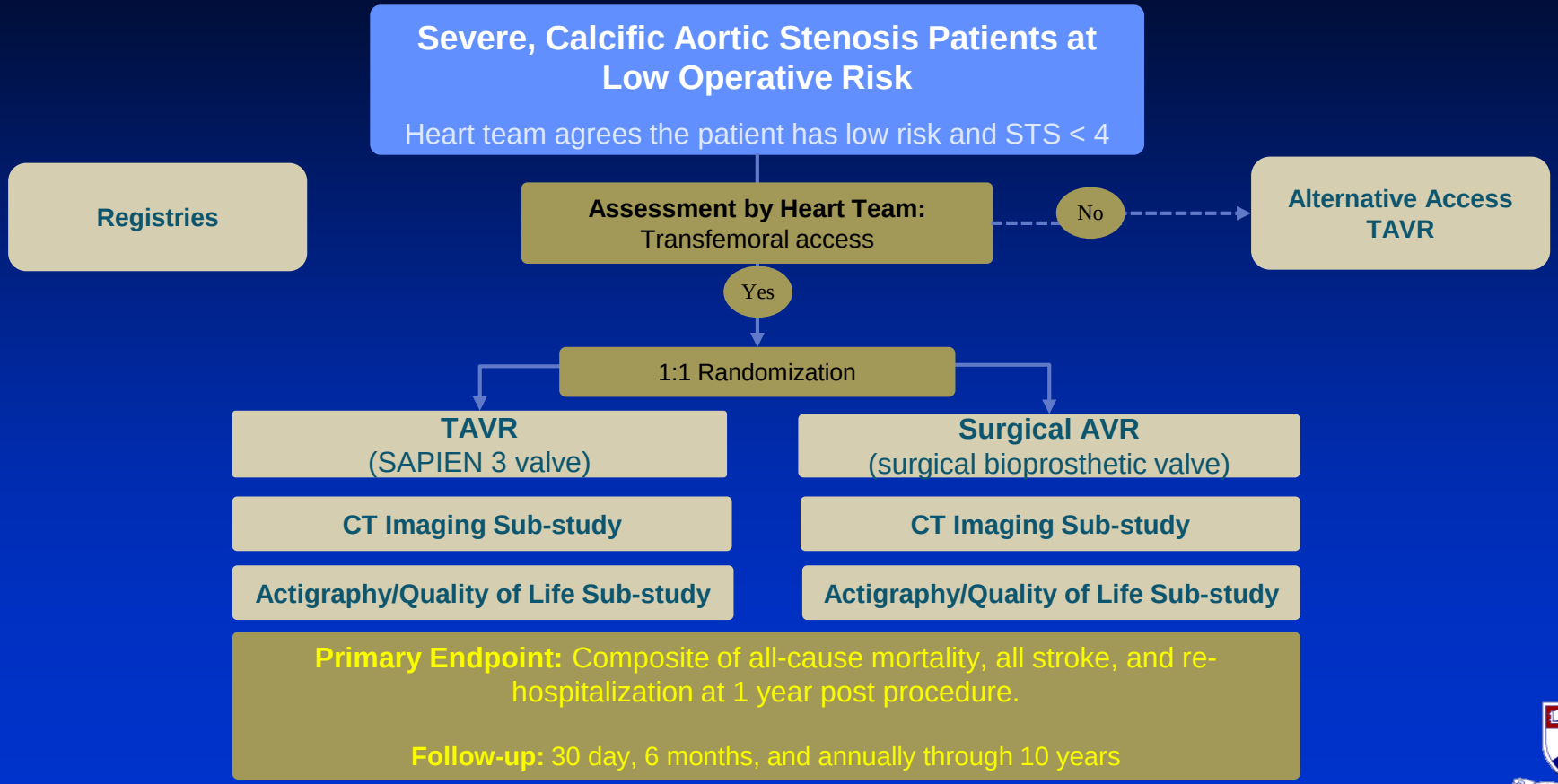
So, Develop the Robust Heart Team and be Prepared …. It will be best for Surgeons, Cardiologists, and Patients

- TAVR vs SAVR vs Cohort C?? Mitral, TV, and CAD??

So NOW the Real Question is ……. Why **NOT** a New TAVI trial into **LOW RISK** patients??

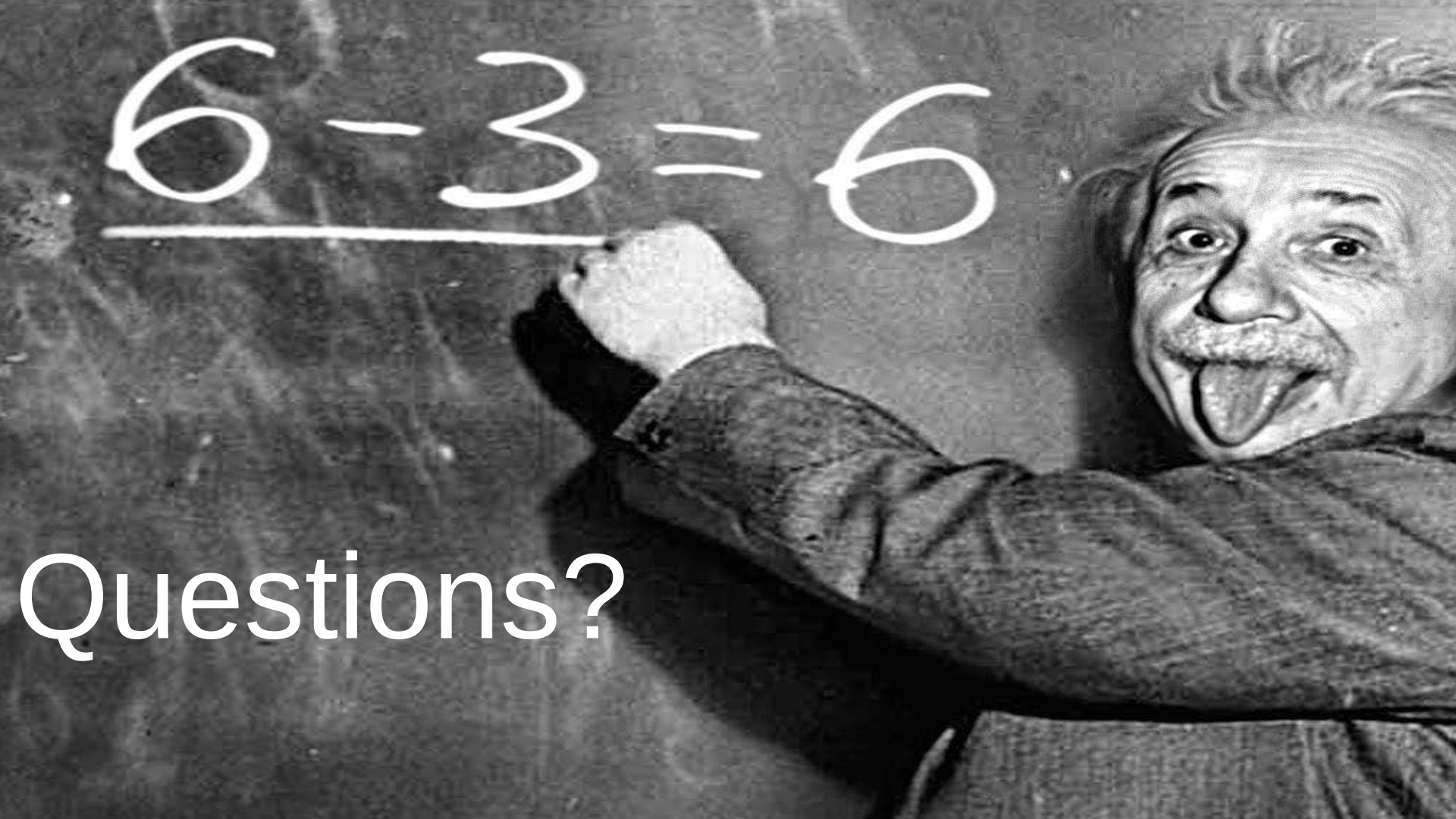
THE PARTNER TRIAL

The PARTNER 3 Low Risk Trial Study Design



The Reality

I don’t expect the results will be any different than in the past 10 years??



Questions?