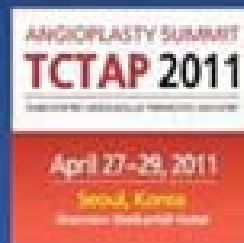


Life after PARTNER (Inoperable and “High Risk” Cohorts): Will TAVR Therapy Change Guidelines for AS Patients

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***Columbia University Medical Center
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Presenter Disclosure Information for
TCTAP 2011; April 27-29, 2011

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NON-PAID Consultant:
Edwards Lifesciences, Medtronic

Consultant:
Symetis

Equity Relationship:
Claret, Sadra

TAVR 2011

Background

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION

American Heart
Association 
Learn and Live™

2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease)

Robert O. Bonow, Blase A. Carabello, Kanu Chatterjee, Antonio C. de Leon, Jr, David P. Faxon, Michael D. Freed, William H. Gaasch, Bruce W. Lytle, Rick A. Nishimura, Patrick T. O'Gara, Robert A. O'Rourke, Catherine M. Otto, Pravin M. Shah and Jack S. Shanewise

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Aortic Stenosis

Indications for AVR - Class I

- Symptomatic patients with severe AS (Class I - B)
- Patients with severe AS undergoing CABG (Class I - C)
- Patients with severe AS undergoing Ao or other heart valve surgery (Class I - C)
- Patients with severe AS and LV systolic dysfunction – EF < 50% (Class I - C)

Aortic Stenosis

Indications for AVR - Class II

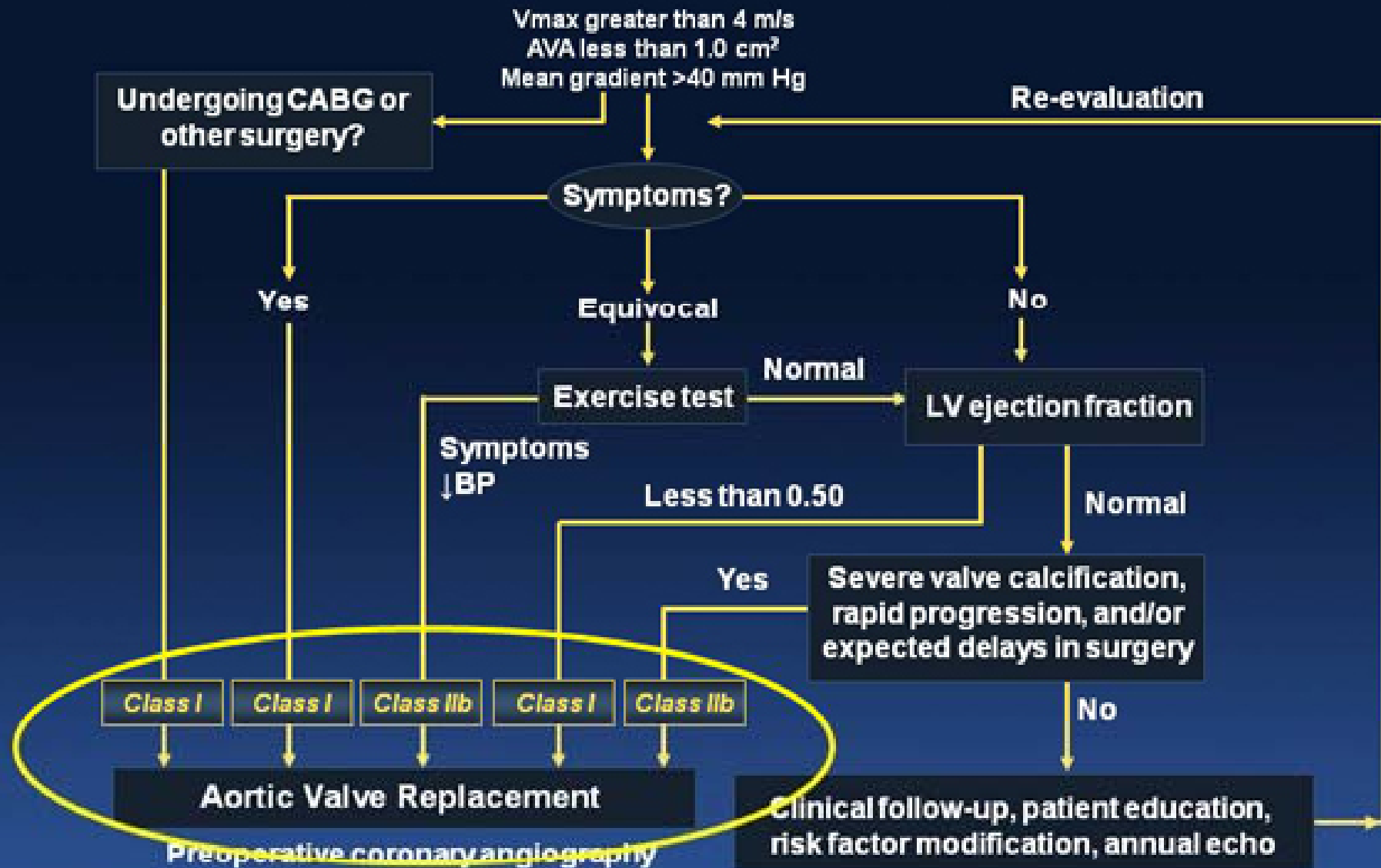
- Patients with moderate AS undergoing CABG, or Ao, or other heart valve surgery (Class IIa - B)
- Asymptomatic patients with severe AS and abnormal response to exercise (Class IIb - C)
- Asymptomatic patients with severe AS and high likelihood of rapid progression or if surgery might be delayed (Class IIb - C)

Aortic Stenosis

Indications for AVR - Class II

- Patients with mild AS undergoing CABG with evidence that progression may be rapid (e.g. moderate or severe valve calcification) (Class IIb - C)
- Asymptomatic patients with extremely severe AS (AVA $< 0.6 \text{ cm}^2$, mean gradient $> 60 \text{ mmHg}$, and jet velocity $> 5 \text{ m/sec}$) when the patient's expected operative mortality is 1% or less (Class IIb - C)

Severe Aortic Stenosis



Aortic Stenosis

Indications for Surgical AVR

Why is surgical AVR so great?

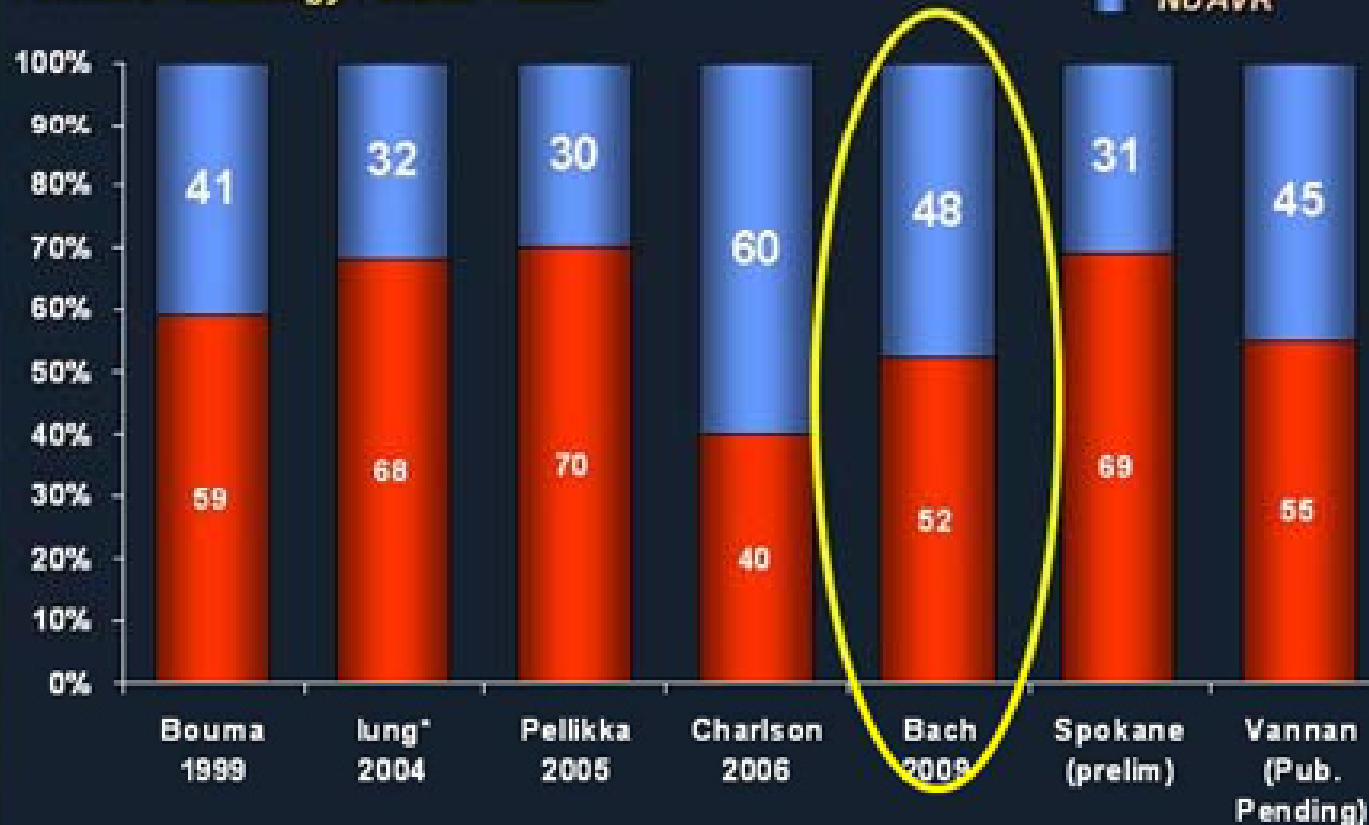
Because our patients...

- 1. Live longer***
- 2. Feel better (marked Sx benefit)***
- 3. Have improved LV function***

At Least 30% of Patients with Severe Symptomatic AS are “Untreated”!

Severe Symptomatic Aortic Stenosis

Percent of Cardiology Patients Treated

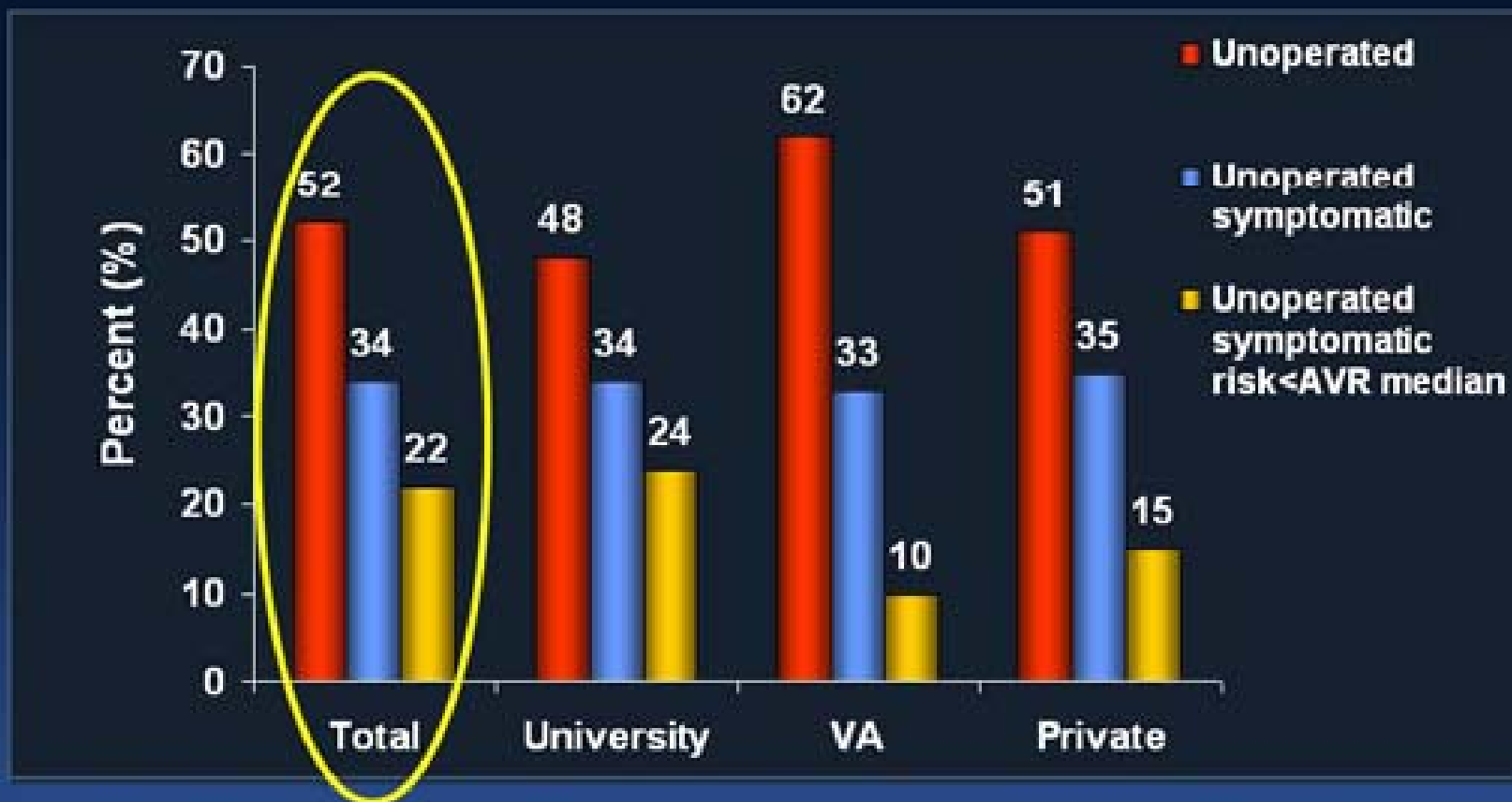


Under-treatment especially prevalent among patients managed by Primary Care physicians

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. *Heart* 1999; 82: 143-148
2. lung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *European Heart Journal* 2003; 24: 1231-1243 (includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pelikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. *Circulation* 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. *J Heart Valve Dis* 2006; 15: 312-321

Severe AS without AVR

Non-operative Patients with Severe AS



Bach DS, et al. *Circ Cardiovasc Qual Outcomes*. 2009;2:533-539

Severe AS without AVR

Rationale for Decisions to Not Perform AVR in Symptomatic Patients with Severe AS

	All Sites (n=126)	University (n=53)	VA (n=20)	Private (n=53)
Comorbidities/ operative risk	61 (48%)	30 (57%)	8 (40%)	23 (43%)
Patient declined	24 (19%)	2 (4%)	5 (25%)	17 (32%)
Symptoms not from AS	24 (19%)	11 (21%)	5 (25%)	8 (15%)
Subvalvular stenosis	3 (2%)	3 (6%)	0	0
Died before surgery	4 (3%)	4 (8%)	0	0
AS not recognized	10 (8%)	3 (6%)	2 (10%)	5 (9%)

Bach DS, et al. Circ Cardiovasc Qual Outcomes. 2009;2:533-539

NOONE Likes Surgery (of any kind)!



Dr. Alain Cribier

First-in-Man PIONEER



Circulation American Heart Association
Learn and Live.

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derameaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Conclusions— Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement.

April 16, 2002

TAVR Technologies

Current Generation Devices

*~ 25,000 patients treated thru 2010
in > 425 interventional centers
around the world!*

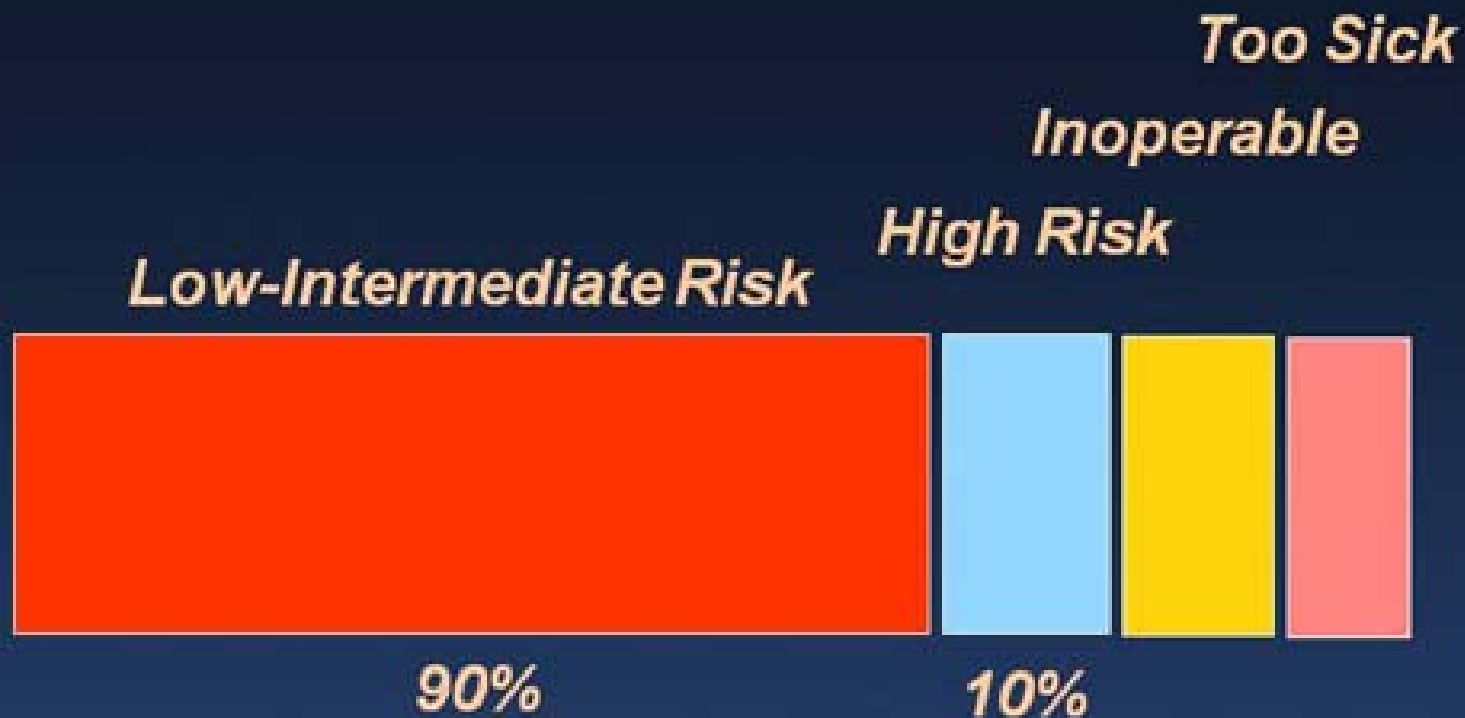
Edwards Lifesciences

Medtronic

TAVR Categories

(risk is a continuum)

Operable AS patients



Too “SICK” for TAVR

(risk is a continuum)

- The most difficult decision, as it “dooms” a patient to non-definitive standard therapy
- Requires a collaboration among physicians (cardiologist and surgeon), the patient, and the family
- Rationale: pt unlikely to experience symptom benefit from TAVR, unlikely that pt will live 1 year due to co-morbid conditions
- Most common reasons: extreme frailty, end-stage COPD, dementia, malignancy, severe liver disease, too many co-morbidities

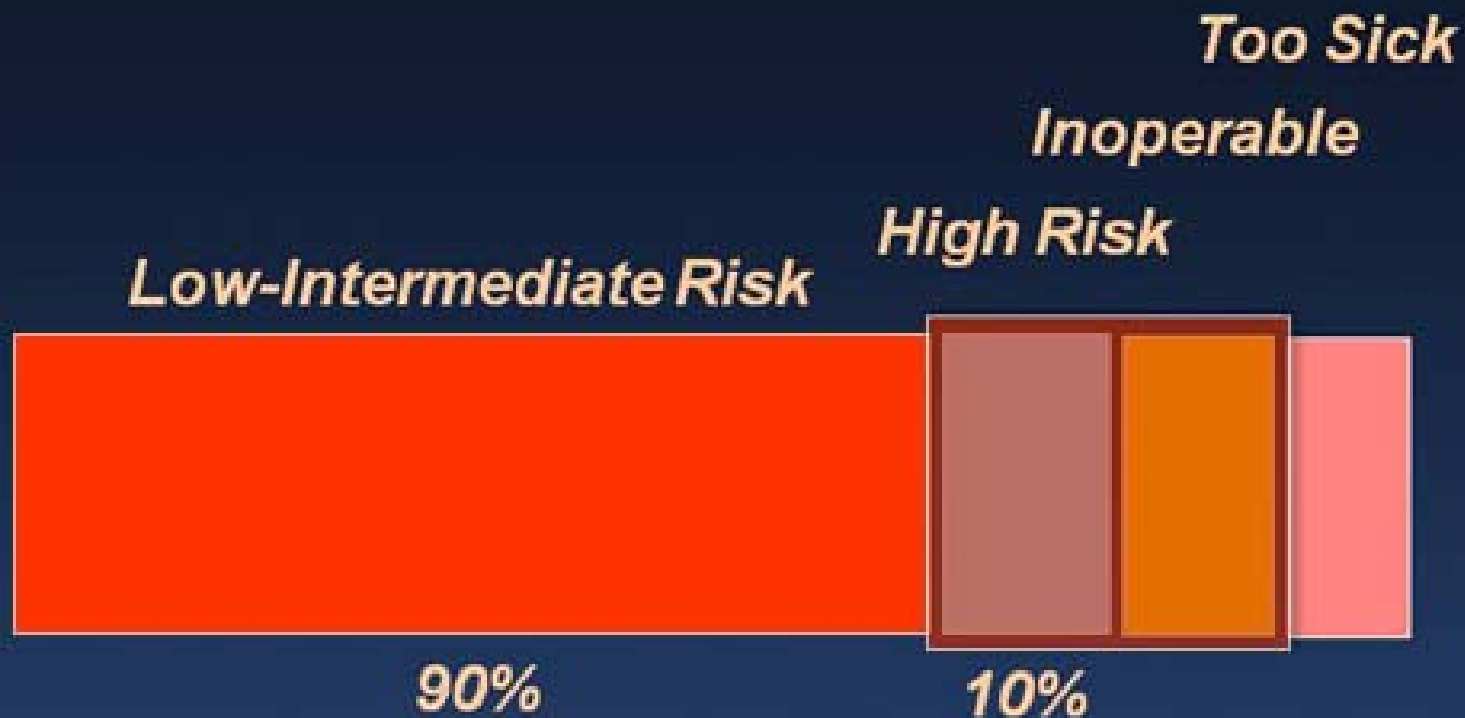
TAVR 2011

The PARTNER Trial

TAVR Categories

(risk is a continuum)

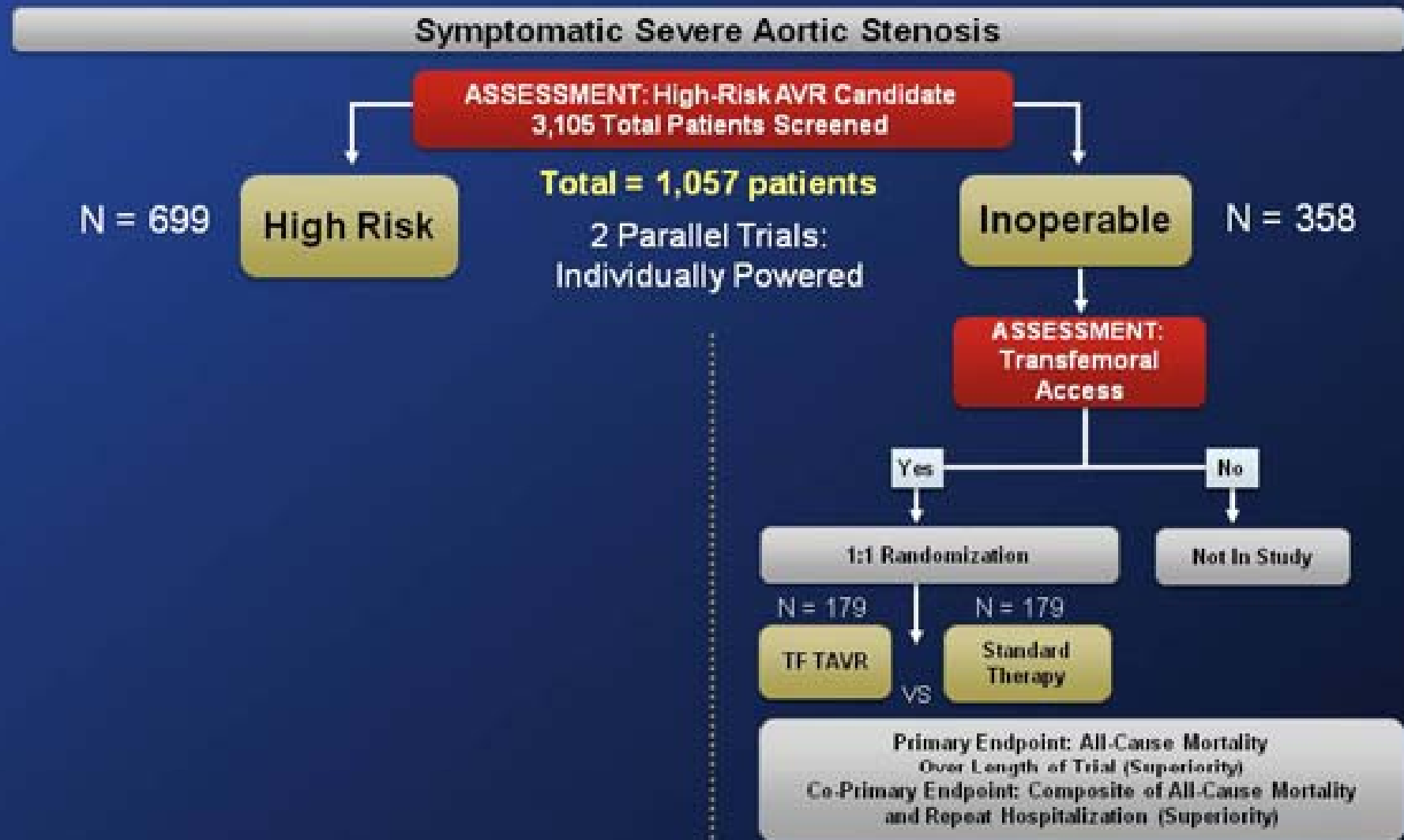
Operable AS patients



TAVR 2011

Study Design

PARTNER Study Design



**Published on-line September 22, 2010
@ NEJM.org and print October 21, 2010**



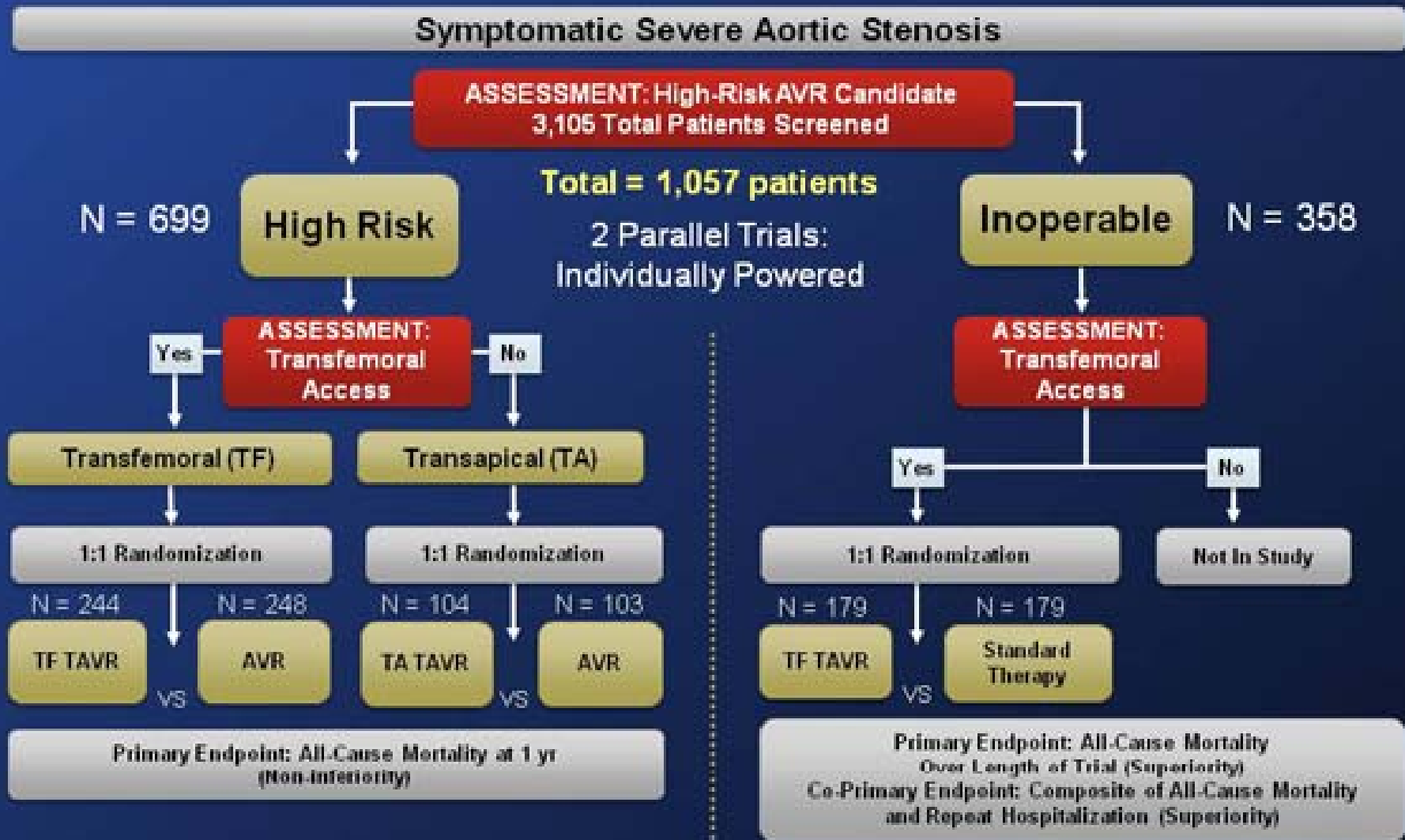
The **NEW ENGLAND**
JOURNAL *of* **MEDICINE**

**Transcatheter Aortic-Valve Implantation for Aortic Stenosis
in Patients Who Cannot Undergo Surgery**

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D.,
Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D.,
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

***On behalf of the Executive Committee, the Investigator Sites,
and the courageous patients who participated in the PARTNER trial!***

PARTNER Study Design



Executive Committee



Lars Svensson

Craig Miller Murat Tuzcu

Craig Smith

Jeff Moses

Marty Leon

John Webb

Michael Mack

Transcatheter AVR

Hybrid OR-Cath Lab



A unique collaborative experience!

Study Devices



Edwards SAPIEN THV
23 and 26 mm valves



RetroFlex
22 and 24 F sheaths



Ascendra
24 and 26 F sheaths

Other Important Endpoints (1)



Safety:

- Neurologic events
 - Prospective: Stroke and stroke plus TIA (all neuro events)
 - Retrospective: Major stroke (modified Rankin Score ≥ 2 @ ≥ 30 days)
- Major vascular complications (VARC definition)
- Major bleeding (modified VARC definition)
- Repeat hospitalization
- New pacemakers and new-onset atrial fibrillation (ECG core lab)
- Procedural events (assigned therapy aborted or converted to AVR, multiple valves, etc.)
- Surgical complications (re-op for bleeding, sternal infection, etc.)

Other Important Endpoints (1)



Safety:

- Neurologic events
 - Prospective: Stroke and stroke plus TIA (all neuro events)
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- Major vascular complications (VARC definition)
- Major bleeding (modified VARC definition)
- Repeat hospitalization
- New pacemakers and new-onset atrial fibrillation (ECG core lab)
- Procedural events (assigned therapy aborted or converted to AVR, multiple valves, etc.)
- Surgical complications (re-op for bleeding, sternal infection, etc.)

Other Important Endpoints (2)



Clinical Effectiveness and Valve Performance:

- NYHA symptoms
- Six-minute walk tests
- Quality-of-life measures and cost-effectiveness (core lab)
- Echocardiography assessment of valve performance (core lab)
 - Peak and mean gradients
 - Effective orifice area
 - Bioprosthetic valve regurgitation (esp. para-valvular)
 - Other: LV ejection fraction, MR, LV mass, evidence of structural valve deterioration

Inclusion Criteria

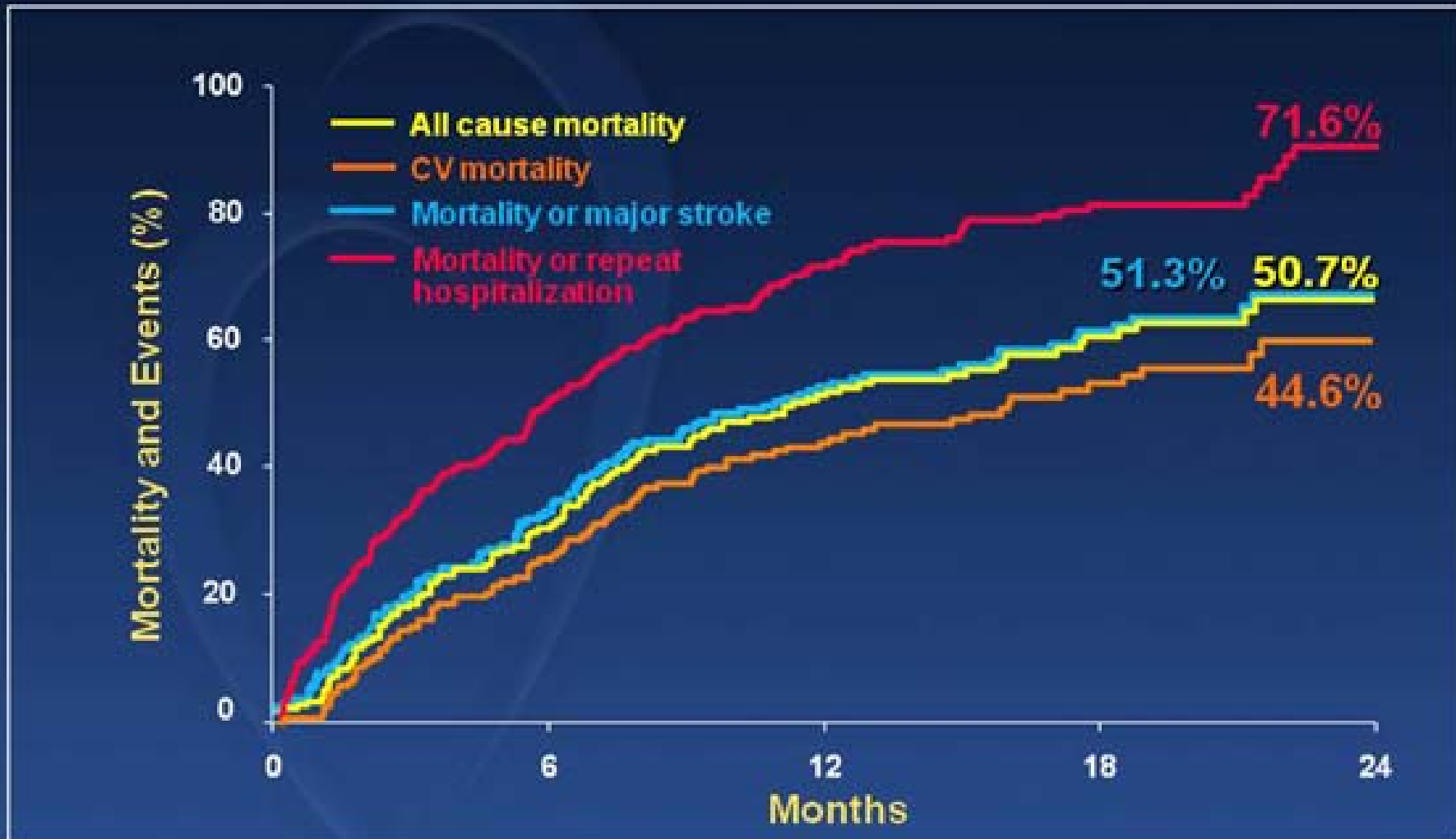


- **Severe AS:** Echo-derived AVA $< 0.8 \text{ cm}^2$ (or AVA index $< 0.5 \text{ cm}^2/\text{m}^2$) and mean AVG $> 40 \text{ mm Hg}$ or peak jet velocity $> 4.0 \text{ m/s}$
- **Cardiac Symptoms:** NYHA Functional Class $\geq \text{II}$
- **Inoperable Cohort:** Risk of death or serious irreversible morbidity as assessed by cardiologist and two surgeons must exceed 50%
- **High Surgical Risk Cohort:** Predicted risk of operative mortality $\geq 15\%$ (determined by site surgeon and cardiologist); guideline = STS score ≥ 10

TAVR 2011

**Main
Outcomes:
Inoperable**

Standard Therapy Outcomes



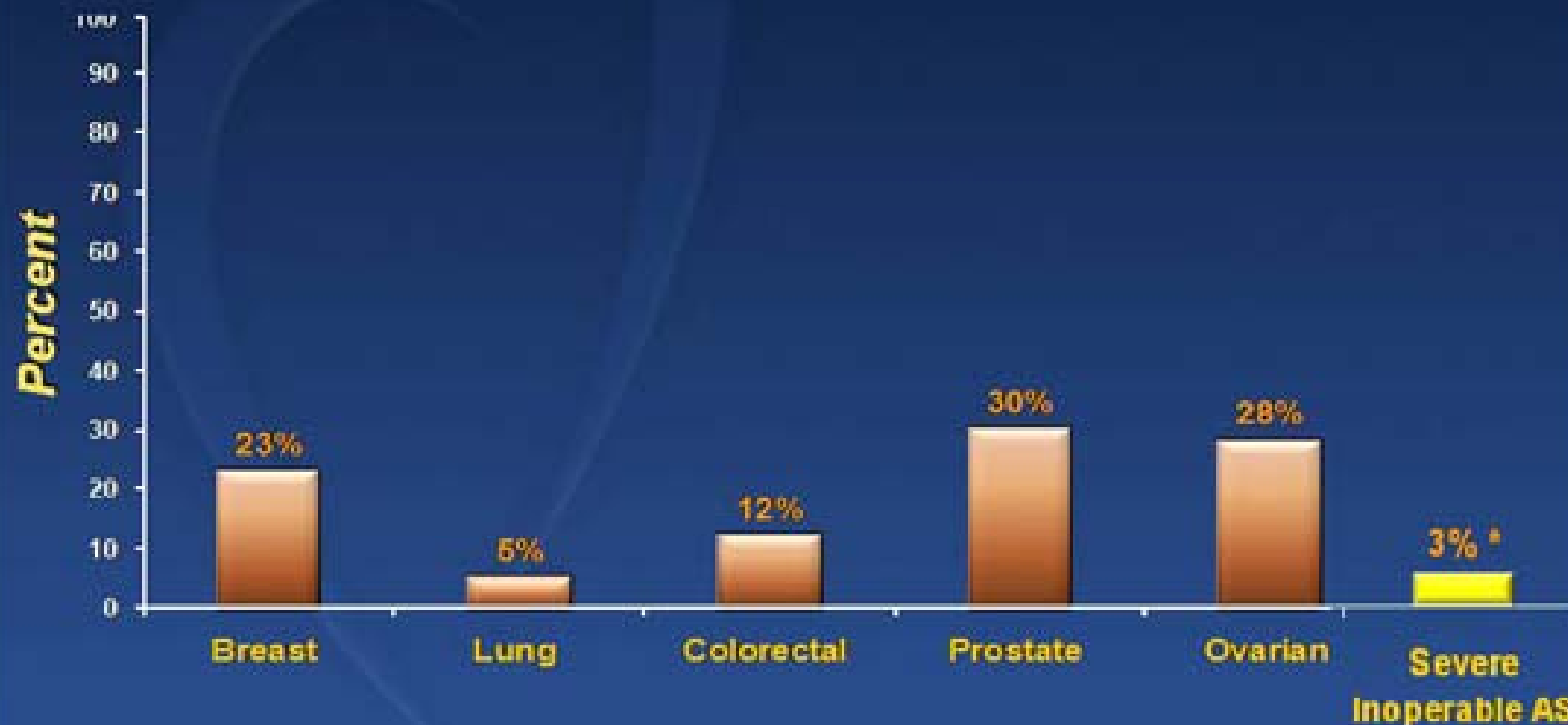
Standard Rx	179	121	83	41	12
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Mortality in Standard Rx

Perspectives



5 Year Survival: Metastatic Cancer



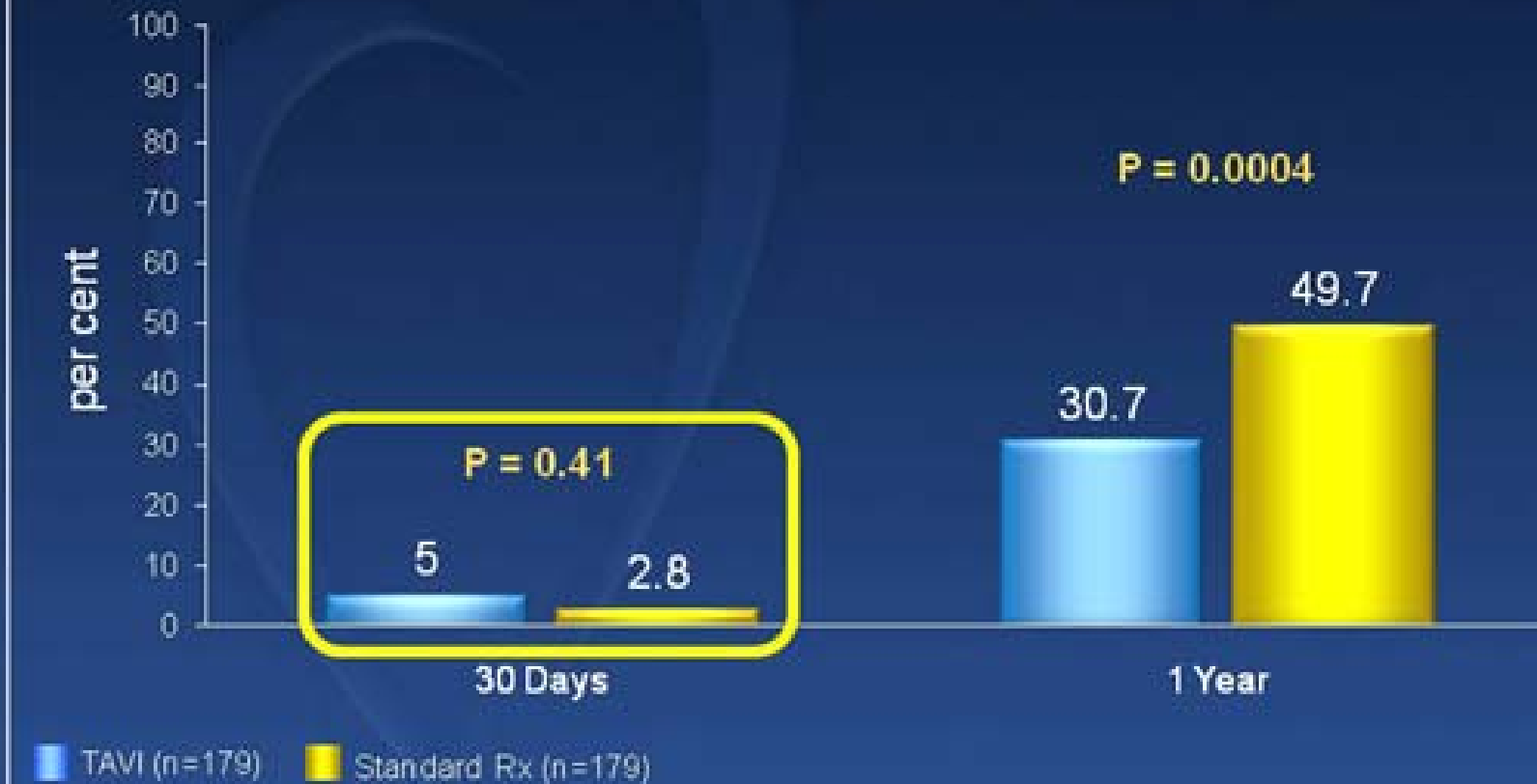
Courtesy of Murat Tuzcu, Interventional PI, CCF

* Constant Hazard Model

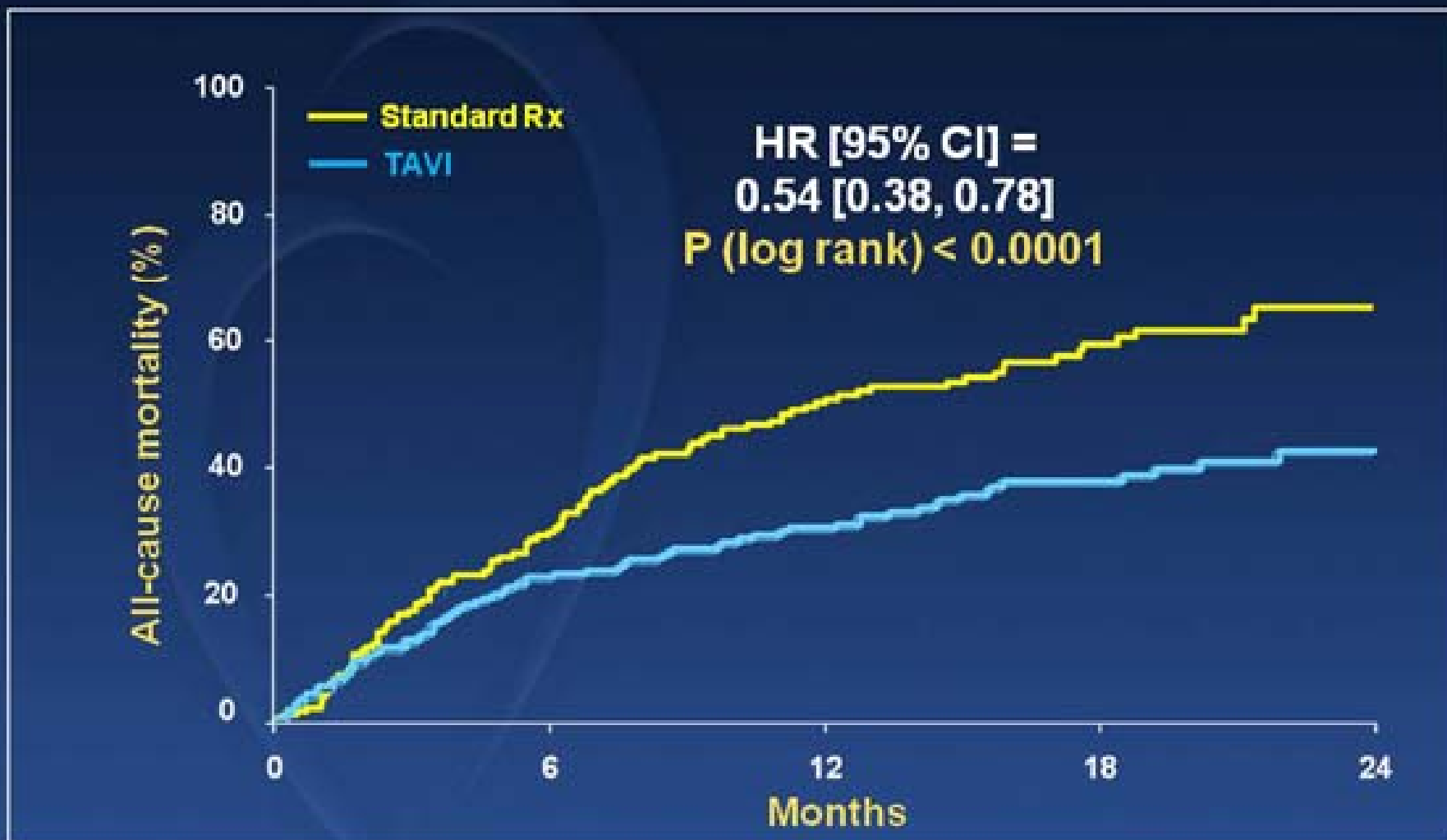
Clinical Outcomes at 30 Days and 1 Year



Death - All Cause

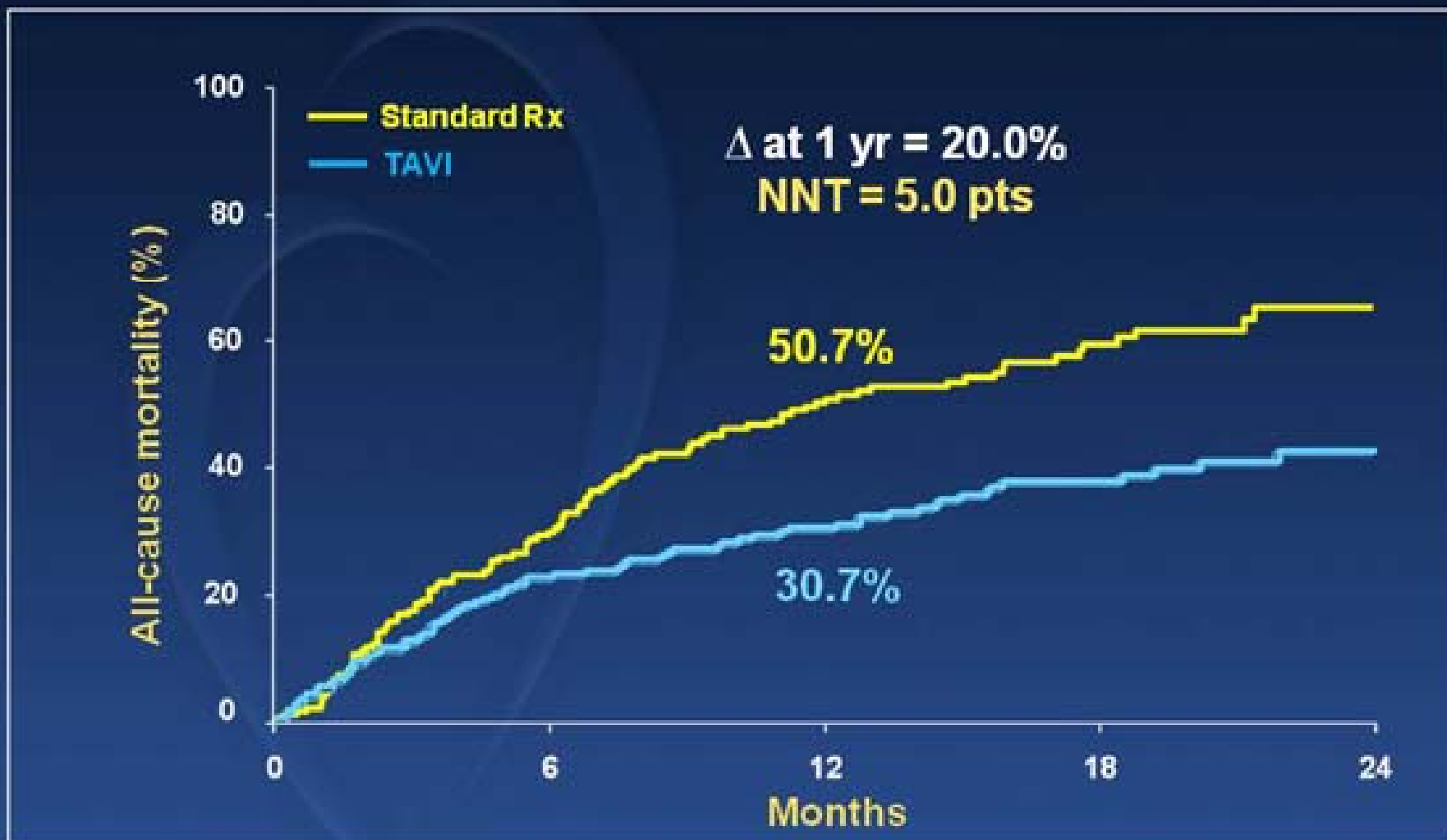


1st Endpt - All Cause Mortality



Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

1st Endpt - All Cause Mortality



Numbers at Risk

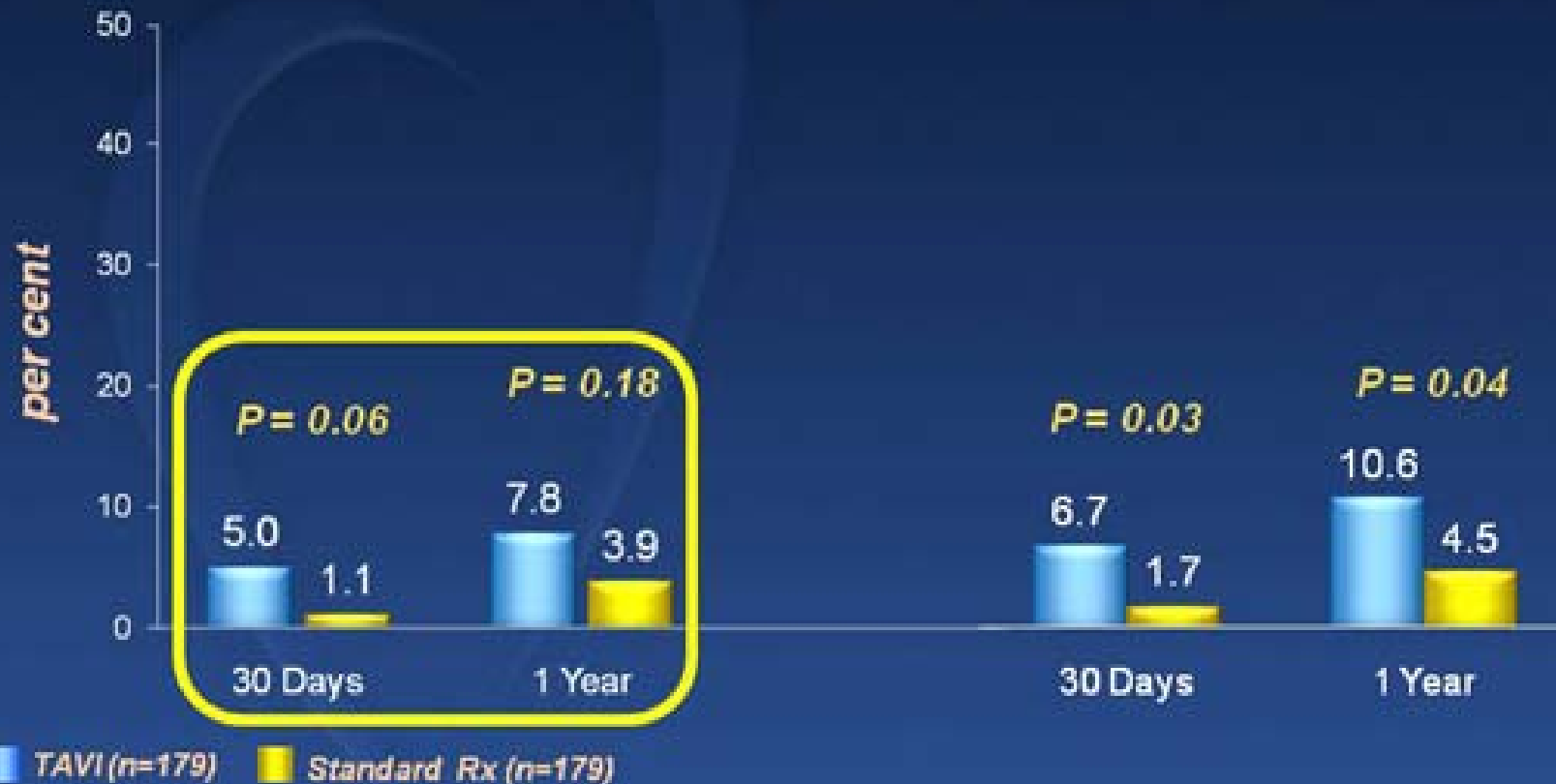
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

Clinical Outcomes at 30 Days and 1 Year

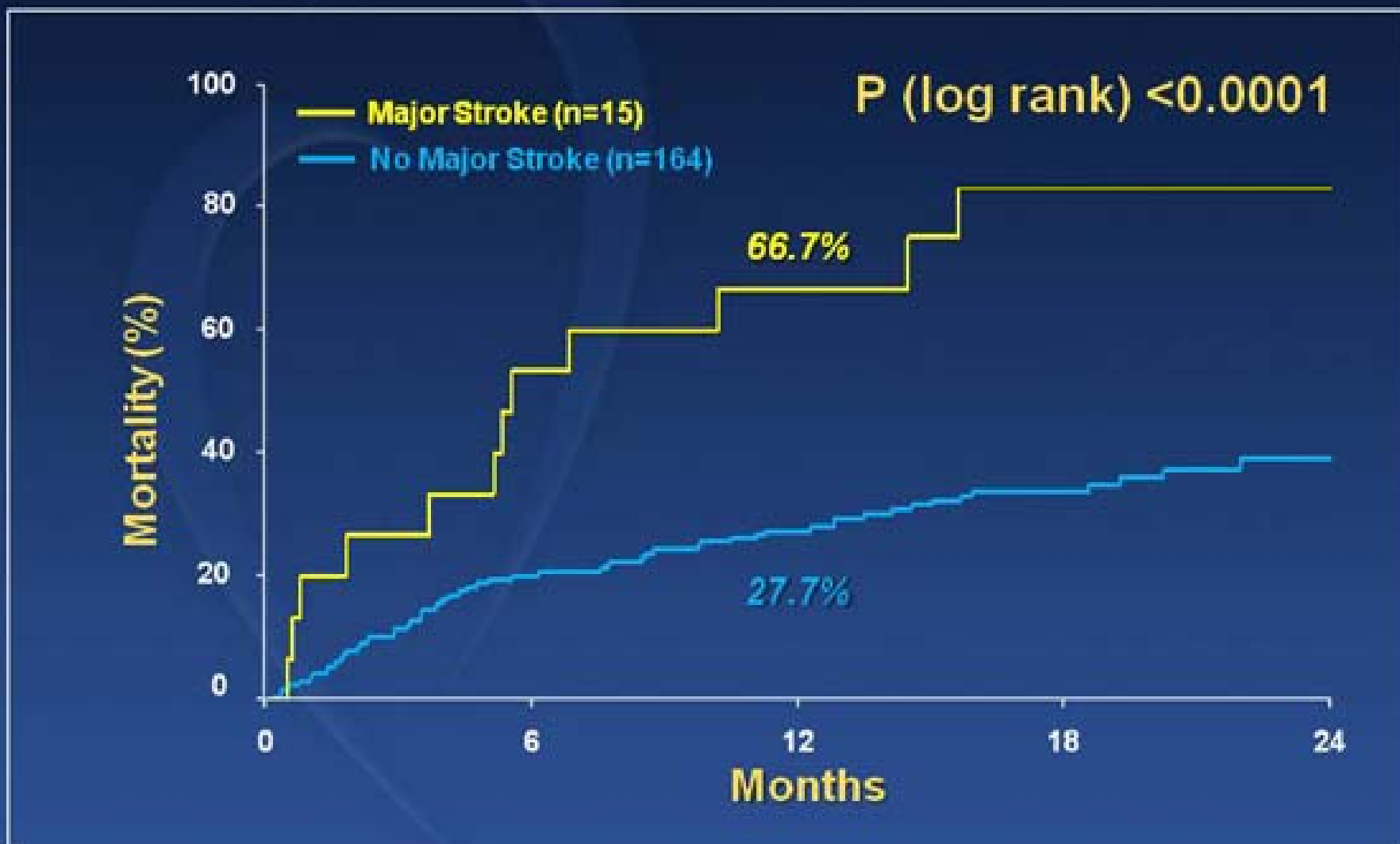


Major Stroke

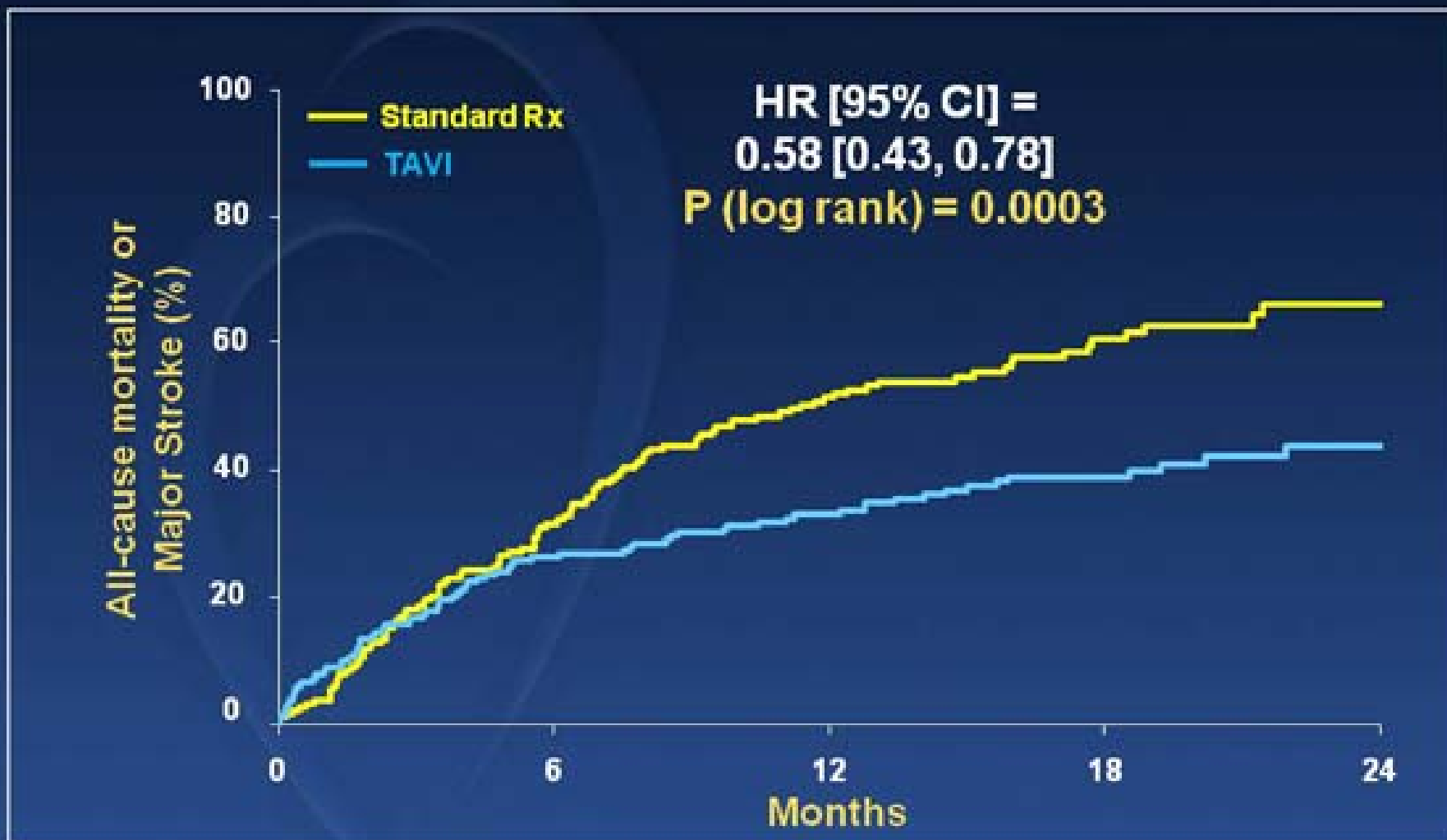
All Stroke or TIA



Mortality vs. Major Stroke TAVI patients

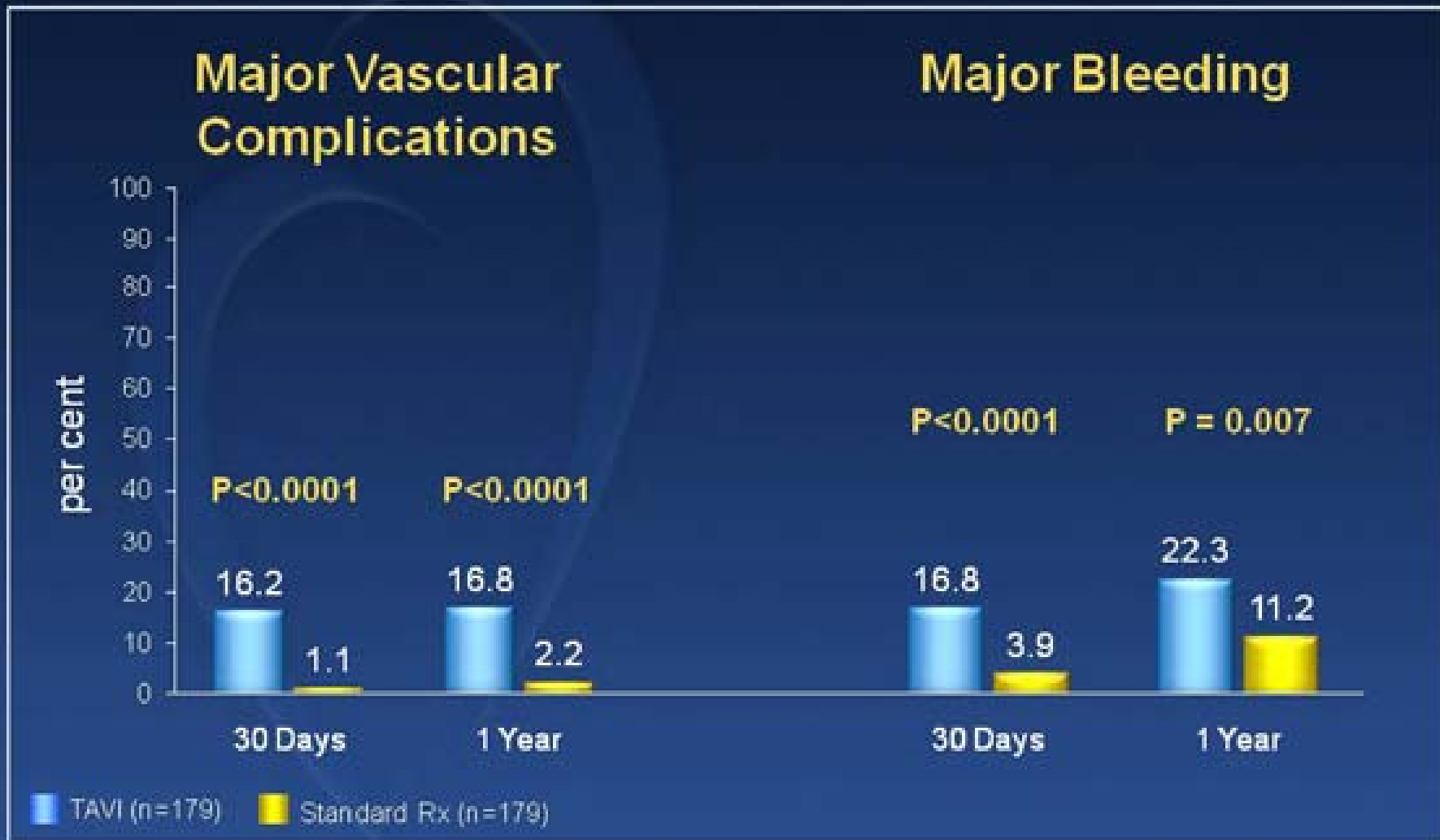


Mortality or Major Stroke



Numbers at Risk					
TAVI	179	132	118	56	25
Standard Rx	179	118	83	41	12

Clinical Outcomes at 30 Days and 1 Year



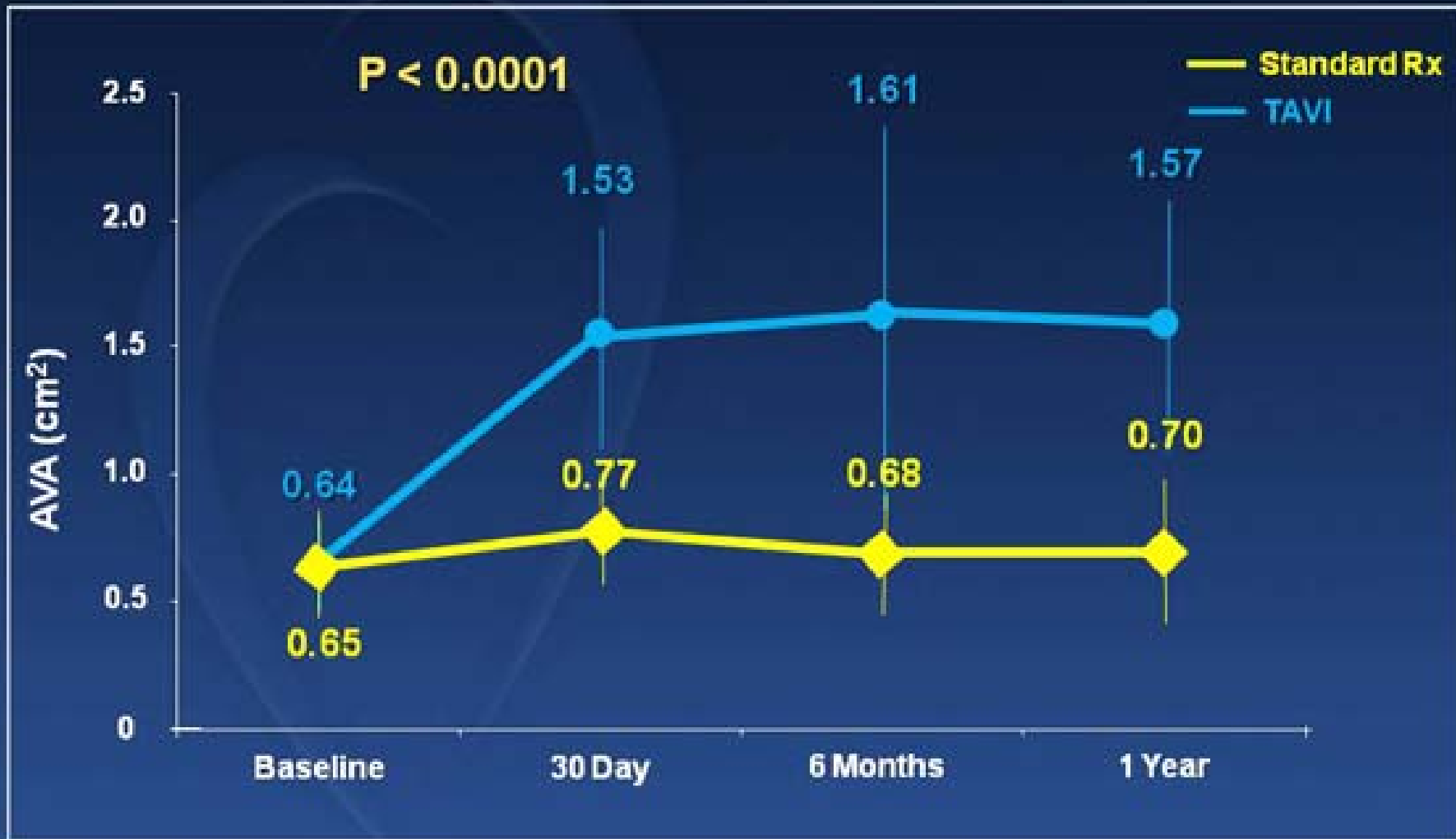
Clinical Outcomes at 30 Days and 1 Year



New Pacemaker



Aortic Valve Areas Over Time

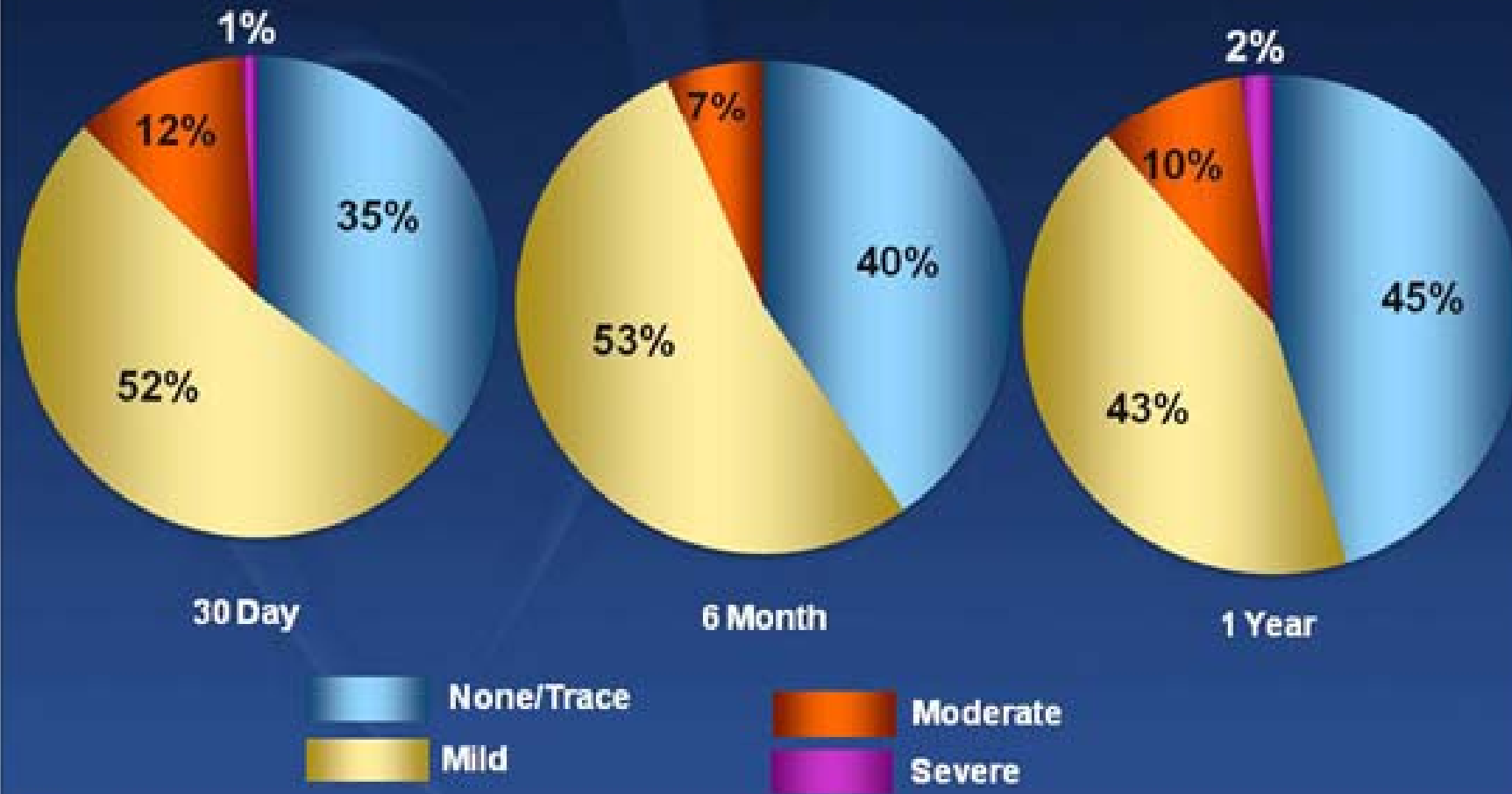


Error bars = ± 1 Std Dev

Paravalvular Regurgitation: TAVI



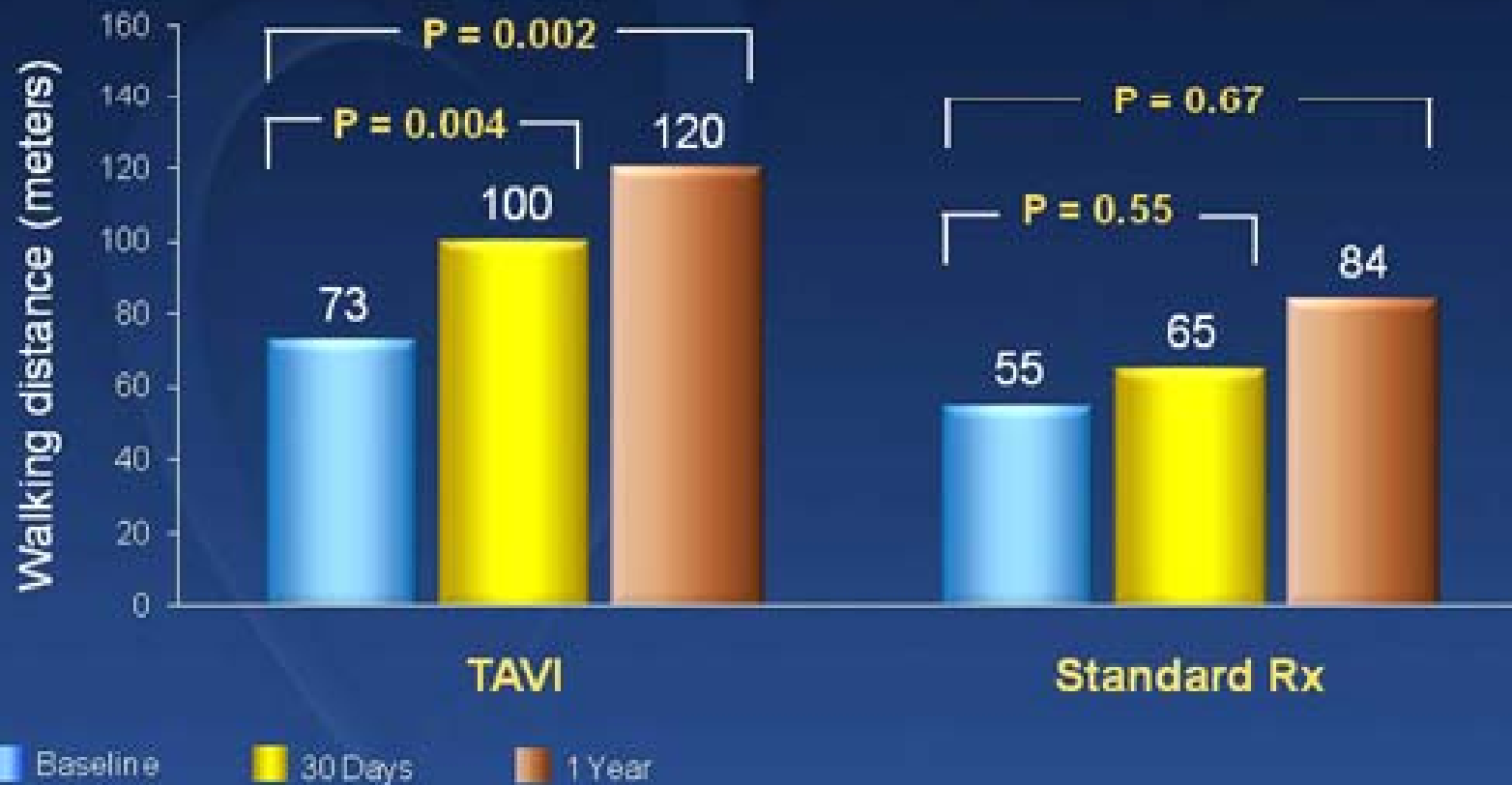
No changes over time



Six-Minute Walk Tests

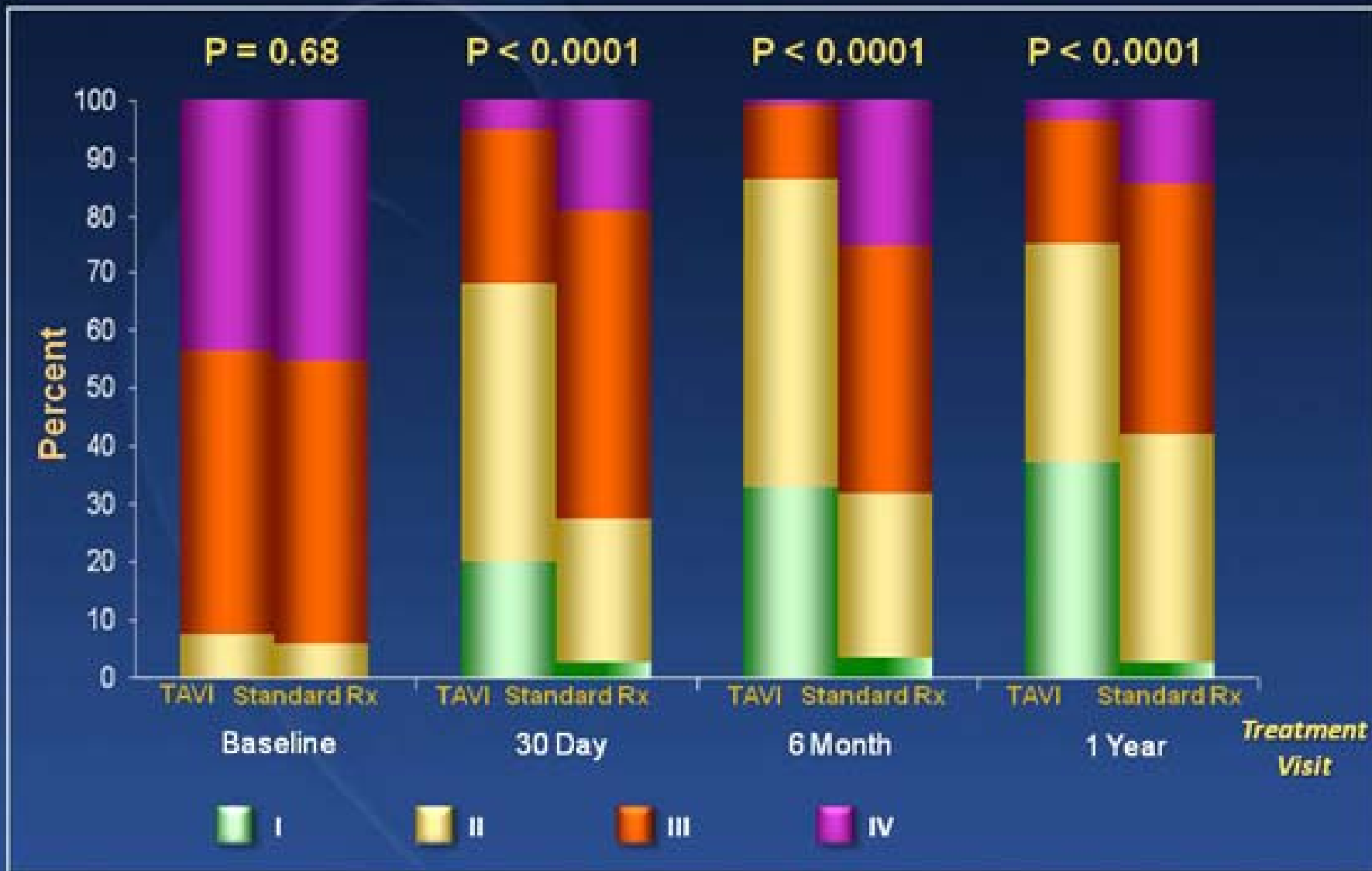


Walking Distance

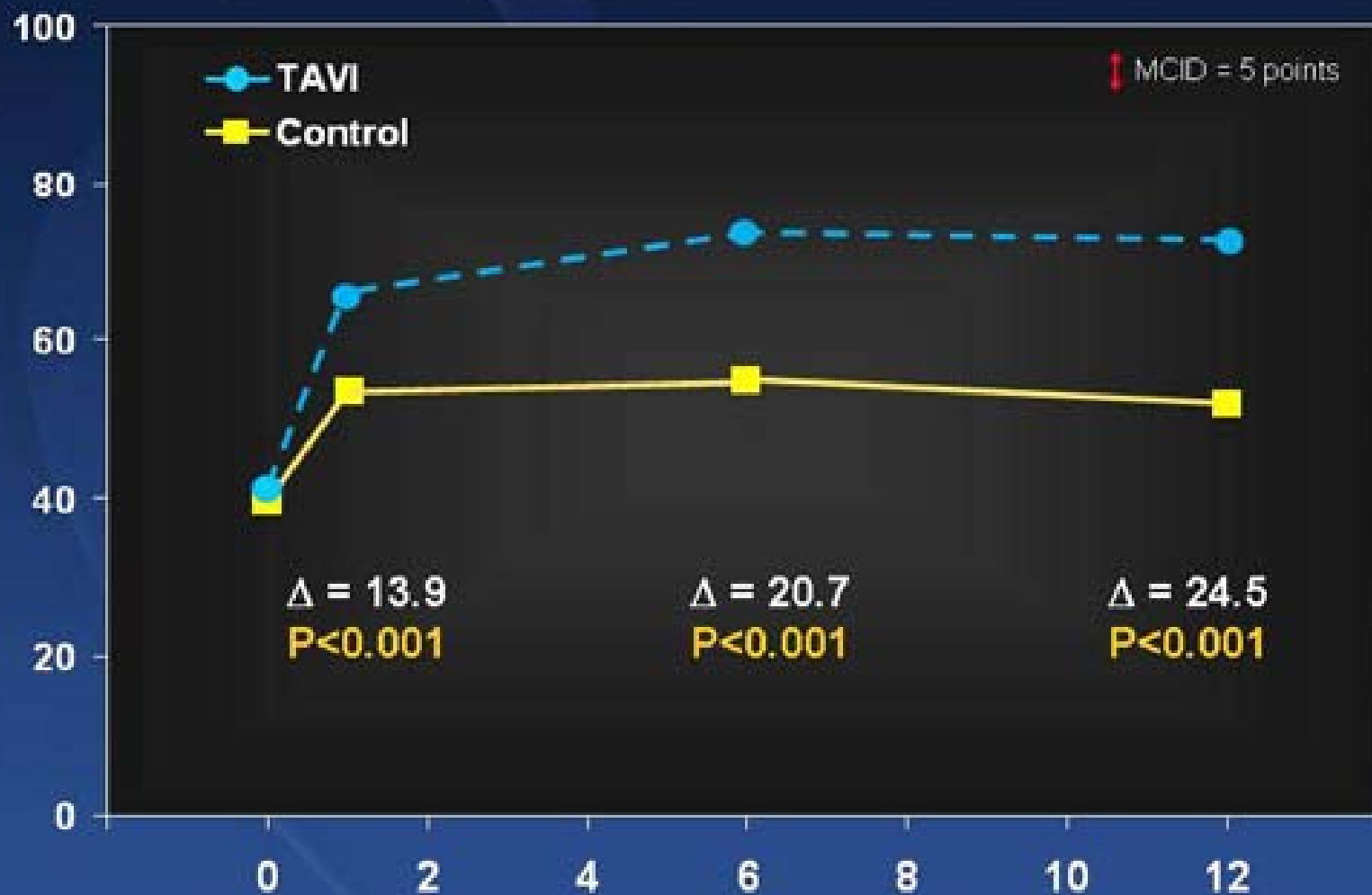


NYHA Class Over Time

Survivors



Primary Endpoint: KCCQ Overall Summary



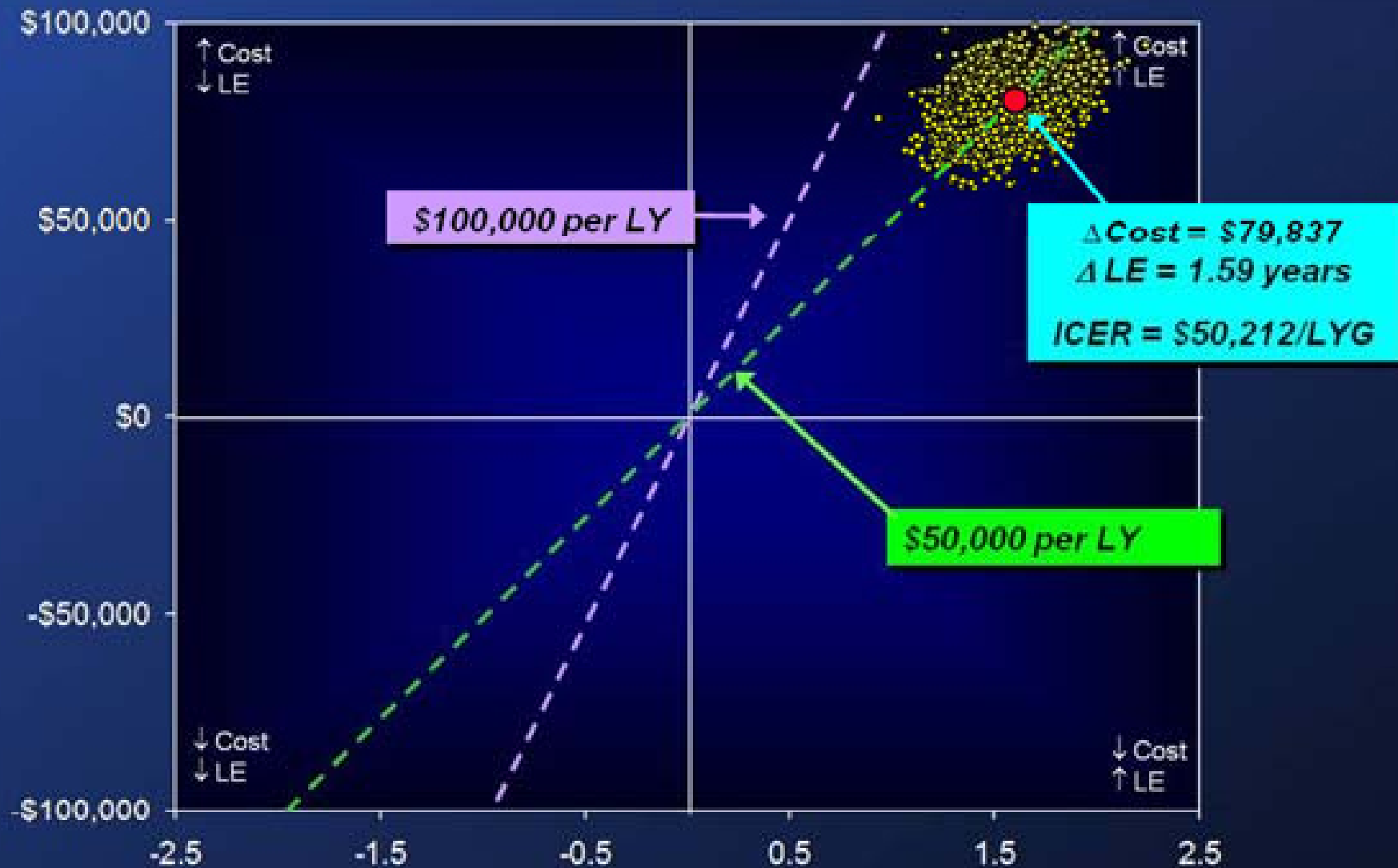
MCID = minimum clinically important difference

PARTNER QOL Analyses

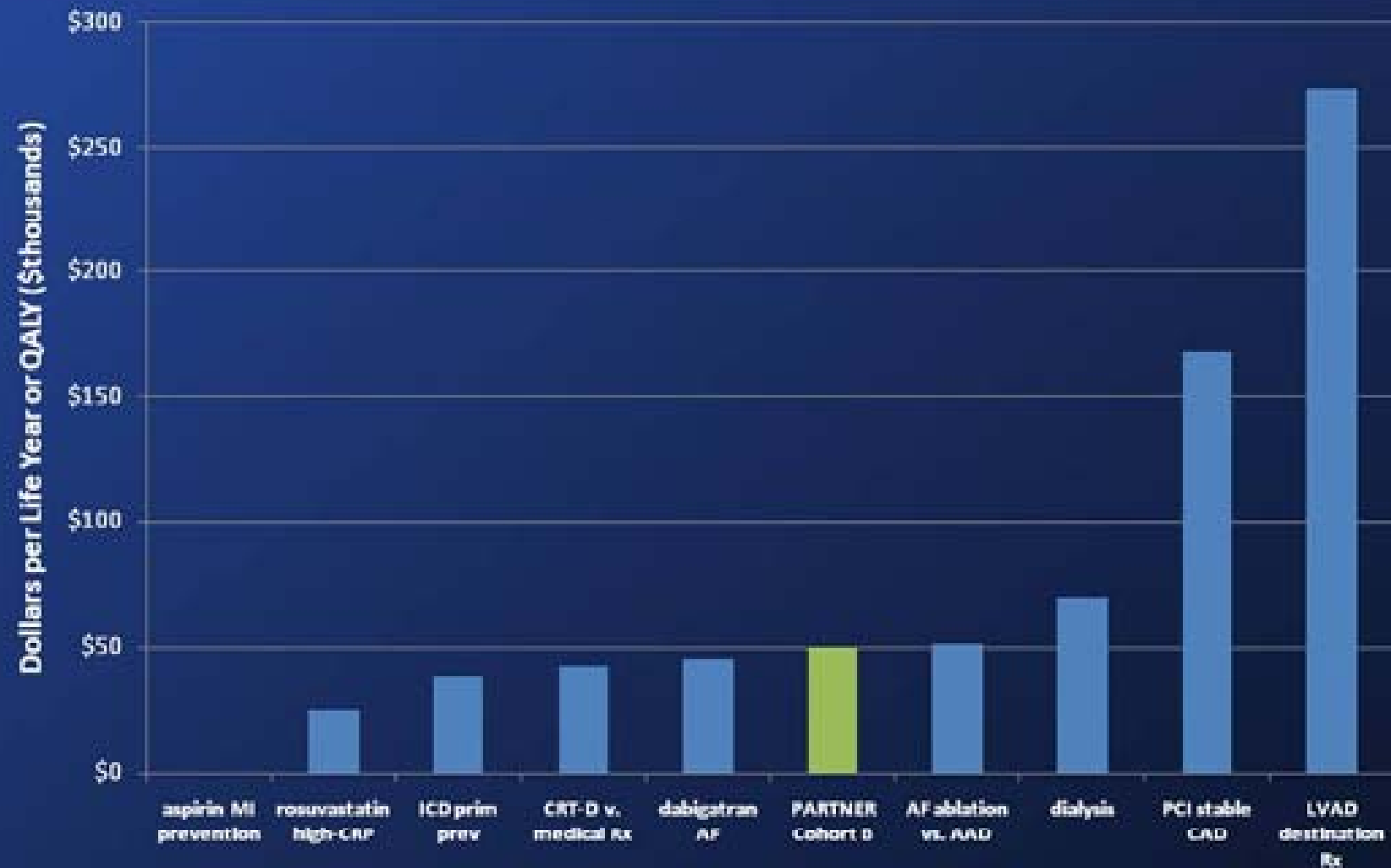


***TAVR not only
adds years to life,
but also,
adds life to years!***

Cost-Effectiveness of TAVR vs. Control Lifetime Results



Published Cost Effectiveness Estimates



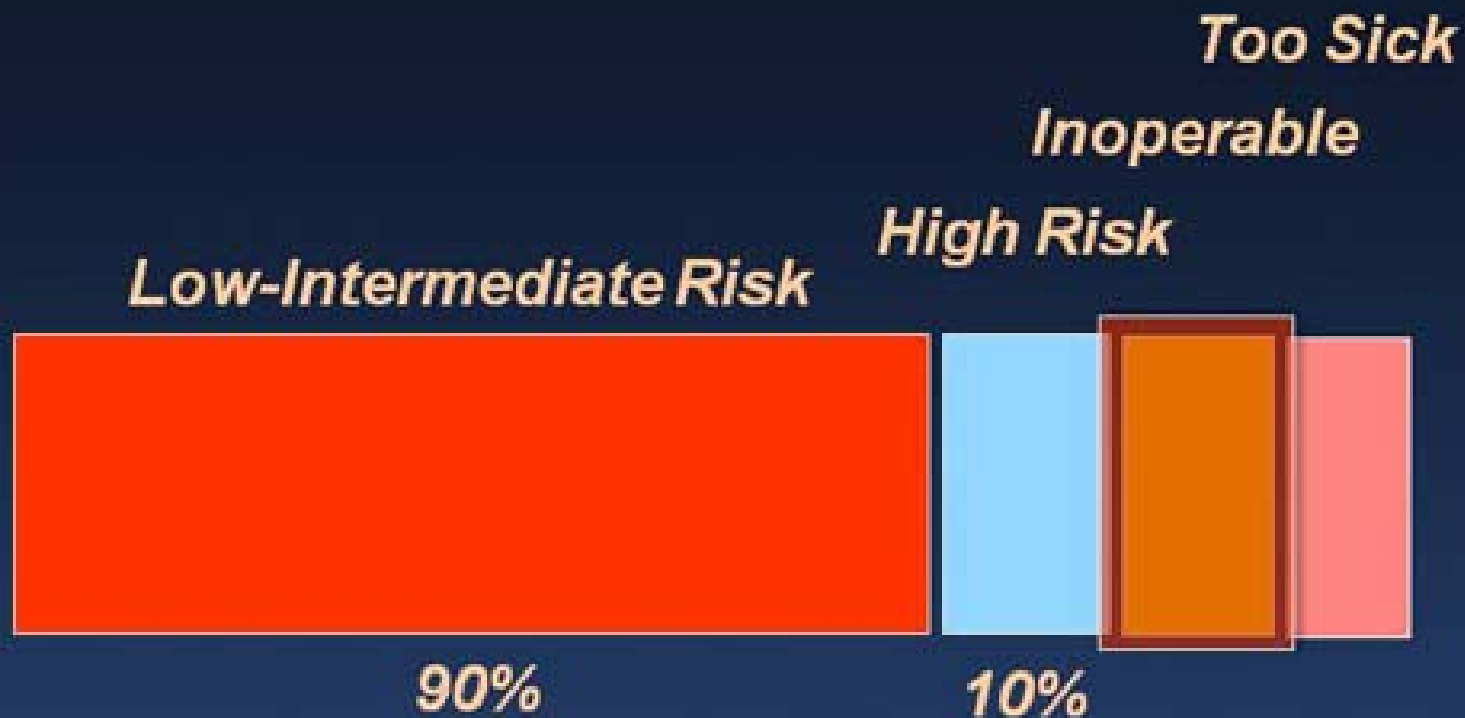
PARTNER - “Inoperable”

- The HEART VALVE TEAM approach is now the preferred model for optimal TAVR success
- Standard therapy is associated with a prohibitive 1-year mortality
- TAVR resulted in...
 - Low (~5%) 30-day mortality
 - Historic reduction in 1-year mortality
 - Improved symptoms in survivors
 - New complications (e.g. strokes, vascular, PVL)
- ***Balloon-expandable TAVR is the new standard-of-care for inoperable patients with severe AS!***

TAVR Categories

(risk is a continuum)

Operable AS patients



TAVR 2011

**Main
Outcomes:
High Risk**

High Risk: Patient Characteristics -1



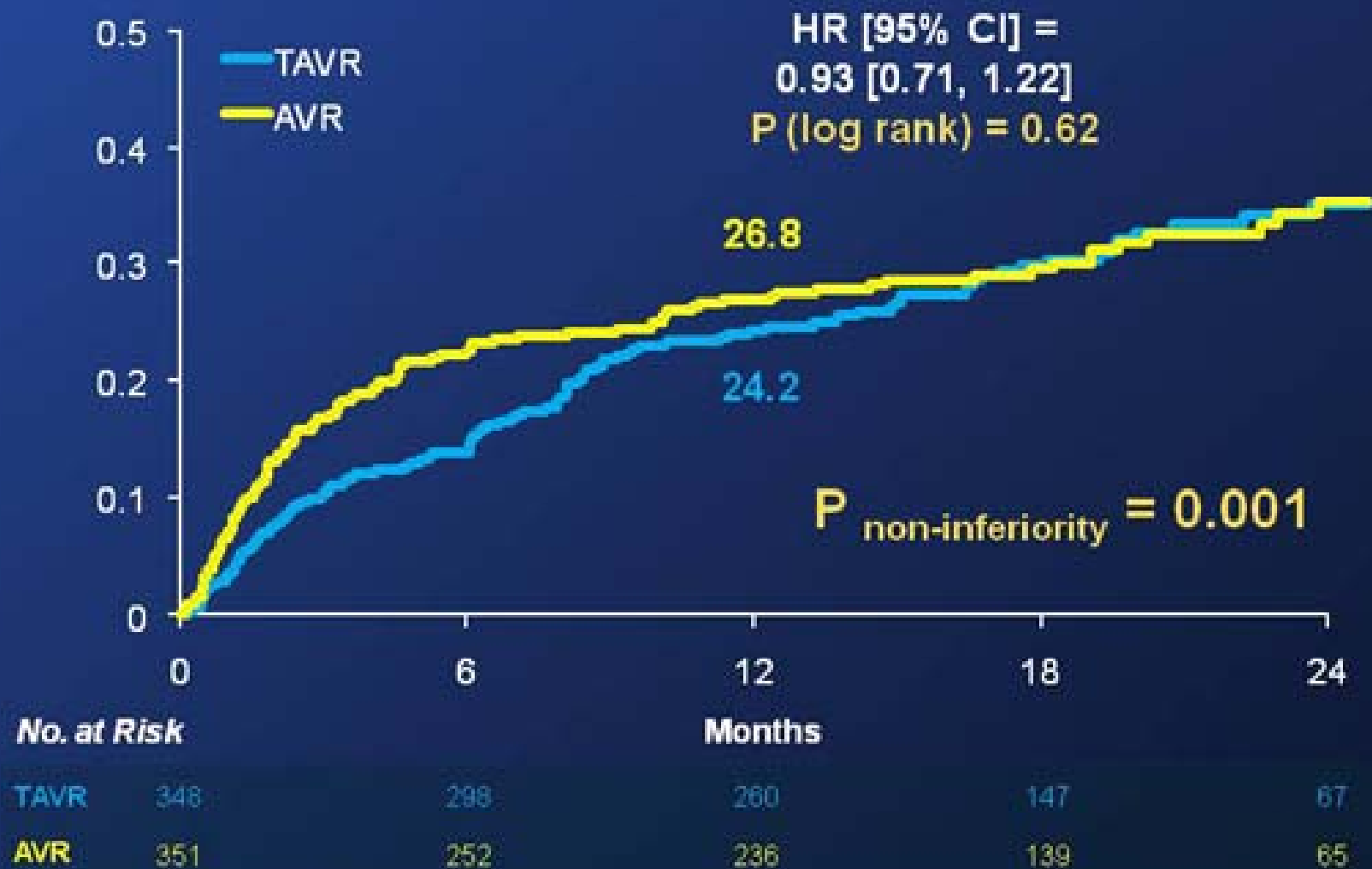
<i>Characteristic</i>	<i>TAVR (N = 348)</i>	<i>AVR (N = 351)</i>	<i>p-value</i>
Age (yr)	83.6 ± 6.8	84.5 ± 6.4	0.07
Male sex - %	57.8	56.7	0.82
STS Score	11.8 ± 3.3	11.7 ± 3.5	0.61
Logistic EuroSCORE	29.3 ± 16.5	29.2 ± 15.6	0.93
NYHA			0.79
II - %	5.7	6.0	
III or IV - %	94.3	94.0	
CAD - %	74.9	76.9	0.59
Previous MI - %	26.8	30.0	0.40
Prior CV Intervention - %	72.1	71.6	0.93
Prior CABG - %	42.6	44.2	0.70
Prior PCI - %	34.0	32.5	0.68
Prior BAV - %	13.4	10.2	0.24
Cerebrovascular disease - %	29.3	27.4	0.60

High Risk: Patient Characteristics -2



<i>Characteristic</i>	<i>TAVR (N = 348)</i>	<i>AVR (N = 351)</i>	<i>p-value</i>
Peripheral vascular disease - %	43.0	41.6	0.76
COPD			
Any	43.4	43.0	0.94
Oxygen dependent	9.2	7.1	0.34
Creatinine > 2mg/dL - %	11.1	7.0	0.06
Atrial fibrillation - %	40.8	42.7	0.75
Permanent pacemaker - %	20.0	21.9	0.58
Pulmonary hypertension - %	42.4	36.4	0.15
Frailty - %	15.6	17.6	0.58
Porcelain aorta - %	0.6	1.1	0.69
Chest wall radiation - %	0.9	0.9	1.00
Liver disease - %	2.0	2.6	0.80

Primary Endpoint: All-Cause Mortality at 1 Year



All-Cause Mortality Transfemoral (N=492)



No. at Risk

Months

TAVR	244	215	188	119	59
AVR	248	180	168	109	56

All-Cause Mortality at 30 Days and 1 Year Patient Subgroups



All-Cause Mortality at 30 Days

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
ITT	12 (3.4)	22 (6.5)	0.07	8 (3.3)	15 (6.2)	0.13	4 (3.8)	7 (7.0)	0.32
AT	18 (5.2)	25 (8.0)	0.15	9 (3.7)	18 (8.2)	0.05	9 (8.7)	7 (7.6)	0.79

All-Cause Mortality at 1 Year

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
ITT	84 (24.2)	89 (26.8)	0.44	54 (22.2)	62 (26.4)	0.29	30 (29.0)	27 (27.9)	0.85
AT	81 (23.7)	78 (25.2)	0.64	51 (21.3)	55 (25.2)	0.33	30 (29.1)	23 (25.3)	0.55

All-Cause Mortality at 30 Days and 1 Year Patient Subgroups



All-Cause Mortality at 30 Days

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
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AT	18 (5.2)	25 (8.0)	0.15	9 (3.7)	18 (8.2)	0.05	9 (8.7)	7 (7.6)	0.79

All-Cause Mortality at 1 Year

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
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AT	81 (23.7)	78 (25.2)	0.64	51 (21.3)	55 (25.2)	0.33	30 (29.1)	23 (25.3)	0.55

Clinical Outcomes at 30 Days and 1 Year

All Patients (N=699)



Outcome	30 Days			1 Year		
	TAVR (N = 348)	AVR (N = 351)	p-value	TAVR (N = 348)	AVR (N = 351)	p-value
All mortality – no. (%)	12 (3.4)	22 (6.5)	0.07	84 (24.2)	89 (26.8)	0.44
Cardiac mortality – no. (%)	11 (3.2)	10 (3.0)	0.90	47 (14.3)	40 (13.0)	0.63
Rehospitalization – no. (%)	15 (4.4)	12 (3.7)	0.64	58 (18.2)	45 (15.5)	0.38
Death or rehosp – no. (%)	25 (7.2)	33 (9.7)	0.24	120 (34.6)	119 (35.9)	0.73
MI – no. (%)	0	2 (0.6)	0.16	1 (0.4)	2 (0.6)	0.69
Acute kidney inj* – no. (%)	10 (2.9)	10 (3.0)	0.95	18 (5.4)	20 (6.5)	0.56

* Renal replacement therapy

Clinical Outcomes at 30 Days and 1 Year

All Patients (N=699)



Outcome	30 Days			1 Year		
	TAVR (N = 348)	AVR (N = 351)	p-value	TAVR (N = 348)	AVR (N = 351)	p-value
Vascular complications						
All – no. (%)	59 (17.0)	13 (3.8)	<0.01	62 (18.0)	16 (4.8)	<0.01
Major – no. (%)	38 (11.0)	11 (3.2)	<0.01	39 (11.3)	12 (3.5)	<0.01
Major bleeding – no. (%)	32 (9.3)	67 (19.5)	<0.01	49 (14.7)	85 (25.7)	<0.01
Endocarditis – no. (%)	0 (0.0)	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New AF – no. (%)	30 (8.6)	56 (16.0)	< 0.01	42 (12.1)	60 (17.1)	0.07
New PM – no. (%)	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

Neurological Events at 30 Days and 1 Year

All Patients (N=699)



Outcome	30 Days			1 Year		
	TAVR (N = 348)	AVR (N = 351)	p-value	TAVR (N = 348)	AVR (N = 351)	p-value
All Stroke or TIA – no. (%)	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
TIA – no. (%)	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
All Stroke – no. (%)	16 (4.6)	8 (2.4)	0.12	20 (6.0)	10 (3.2)	0.08
Major Stroke – no. (%)	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Minor Stroke – no. (%)	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Death/maj stroke – no. (%)	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (26.0)	0.68

All-Cause Mortality or Stroke All Patients (N=699)

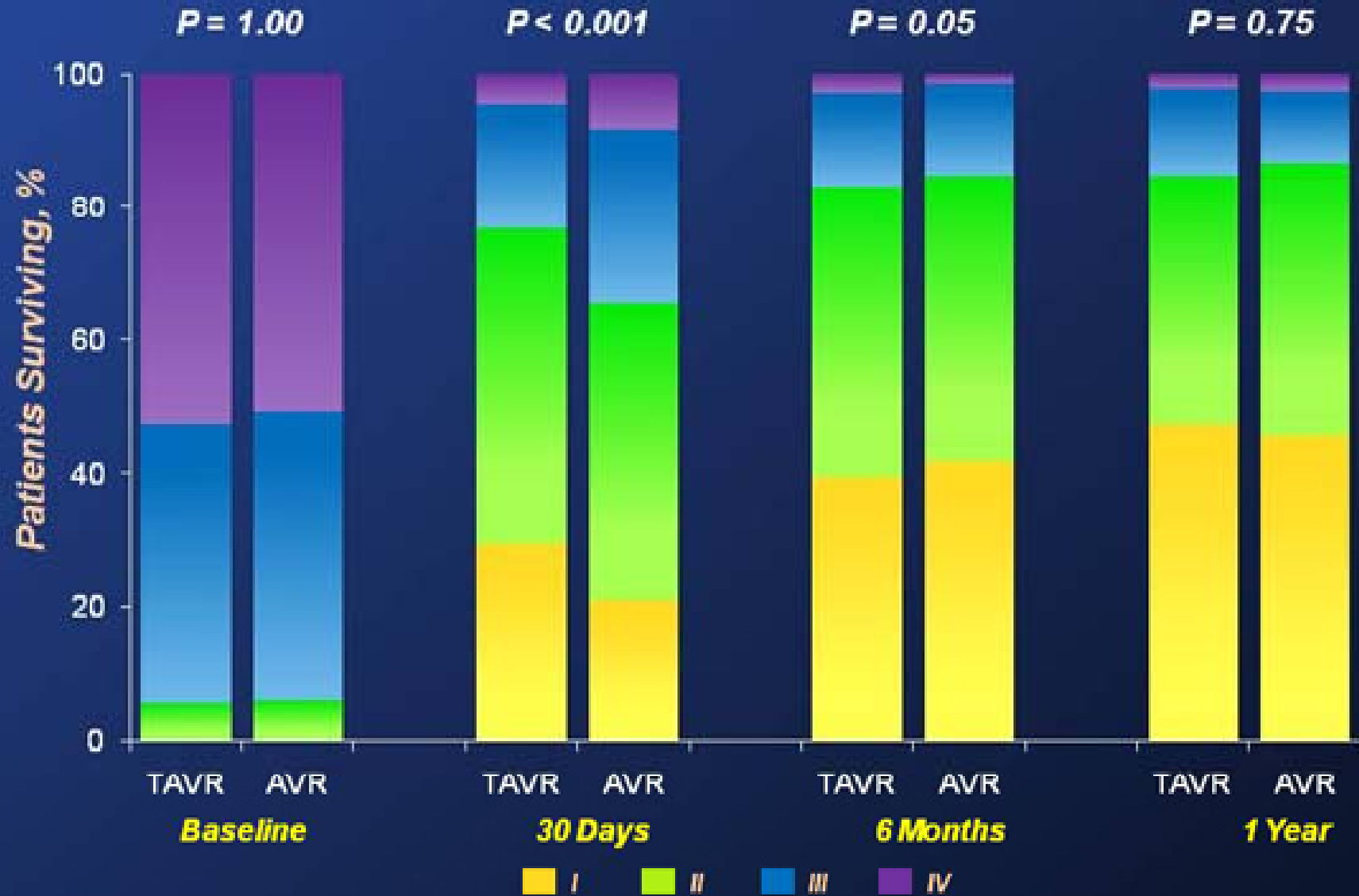


No. at Risk

Months

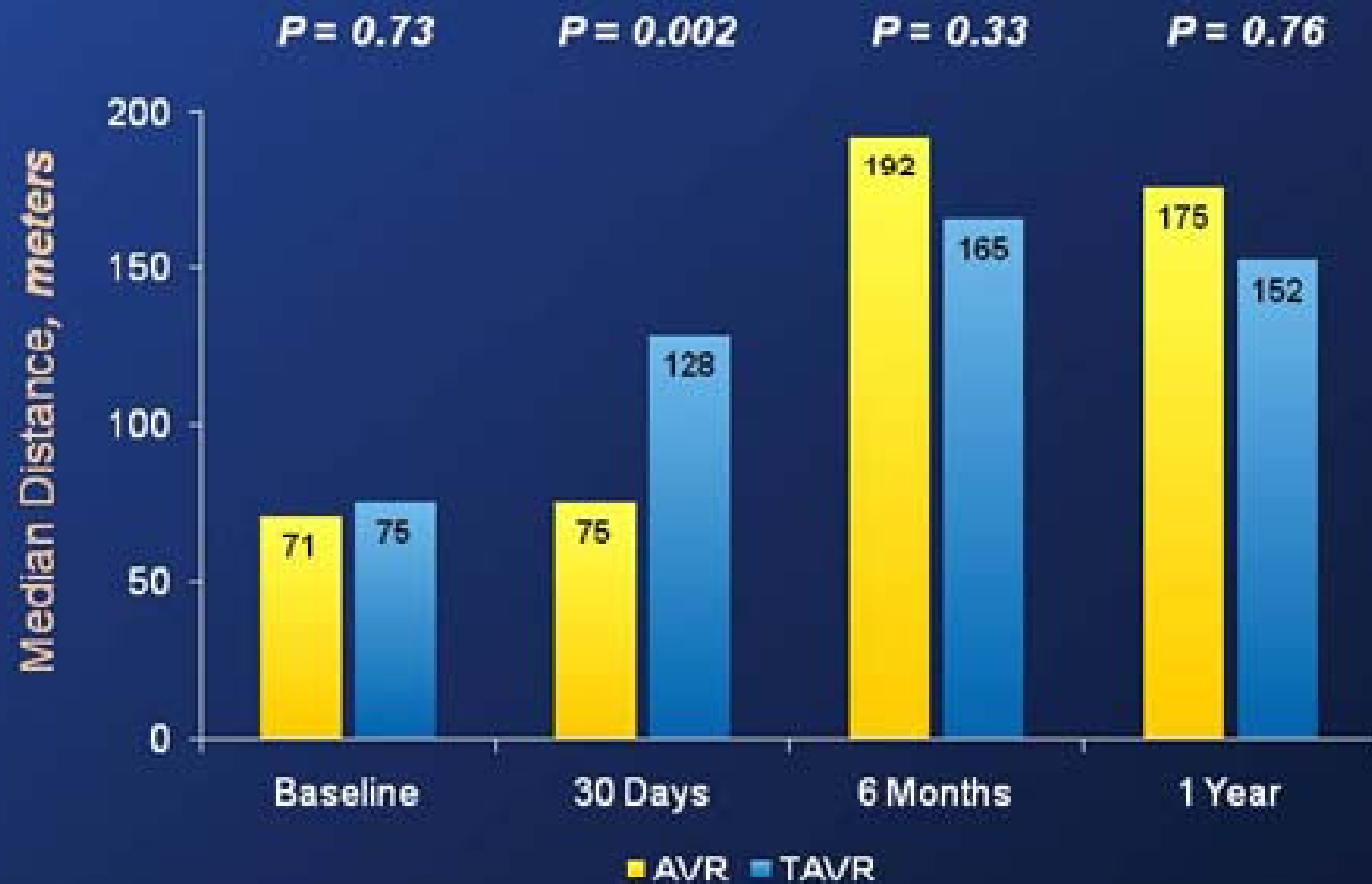
TAVR	348	289	252	143	65
AVR	351	247	232	138	63

NYHA Functional Class



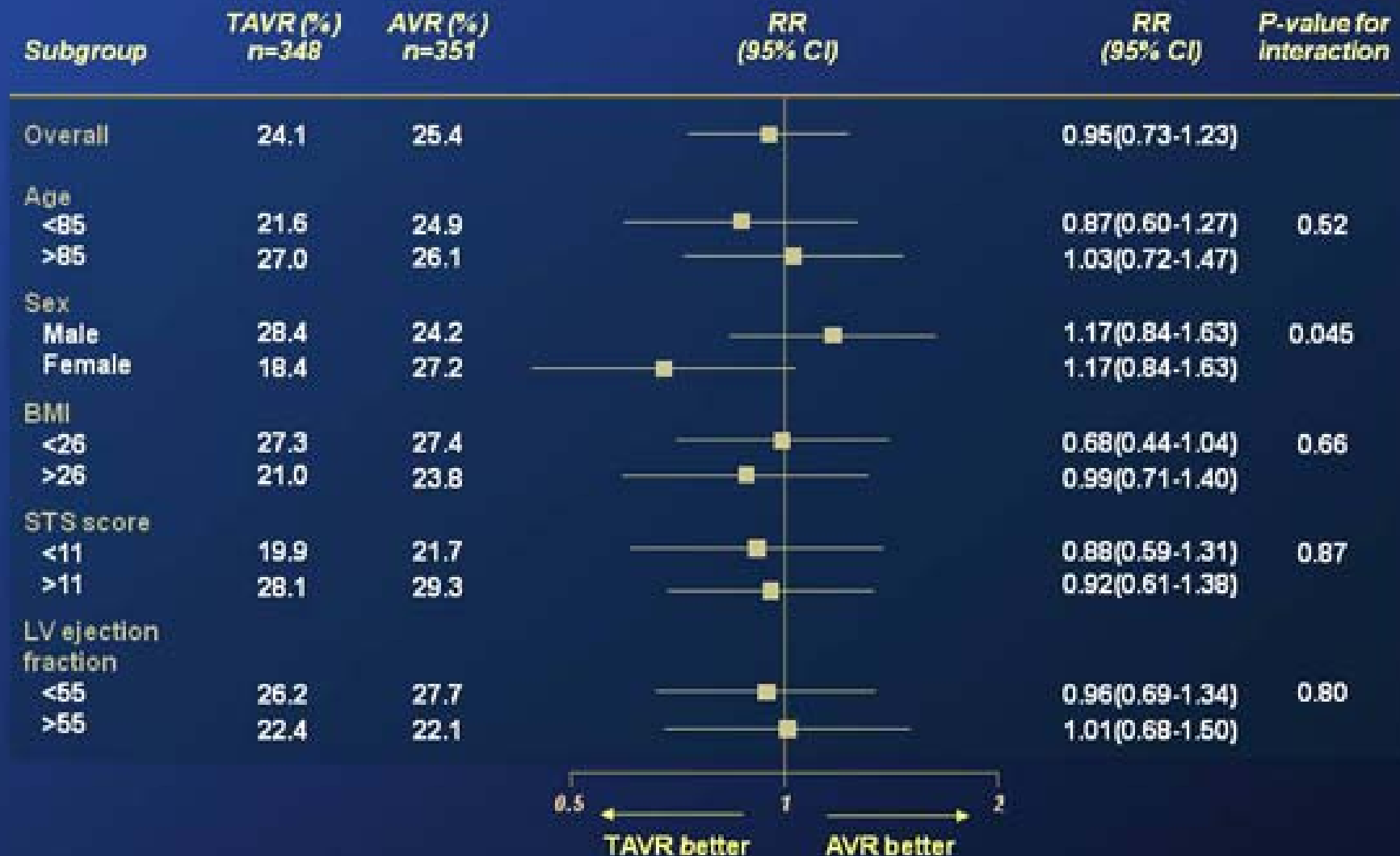
Six-Minute Walk Test

All Patients (N=699)



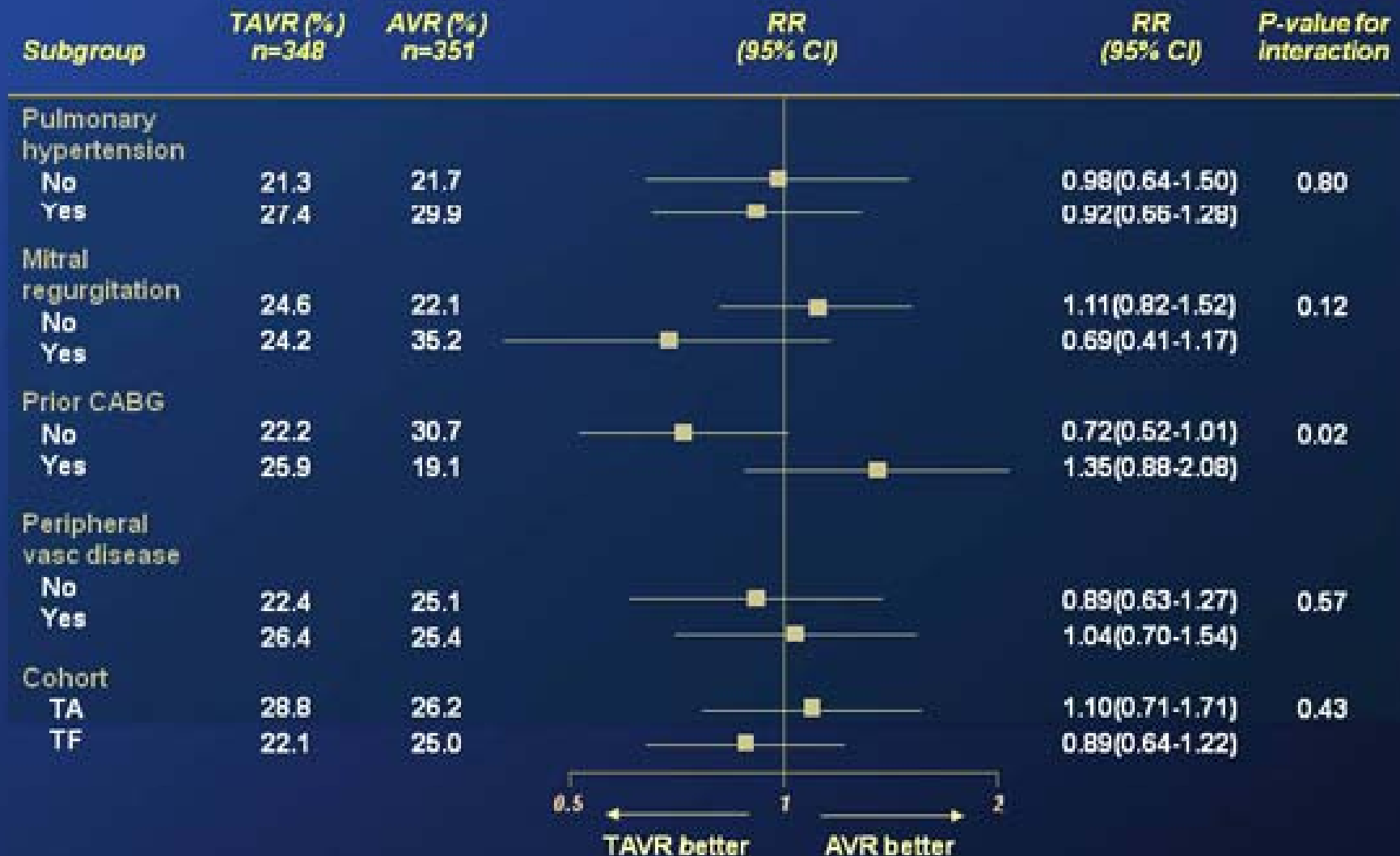
Subgroup Analyses of Treatment Effect

All-Cause Mortality at 1 Year

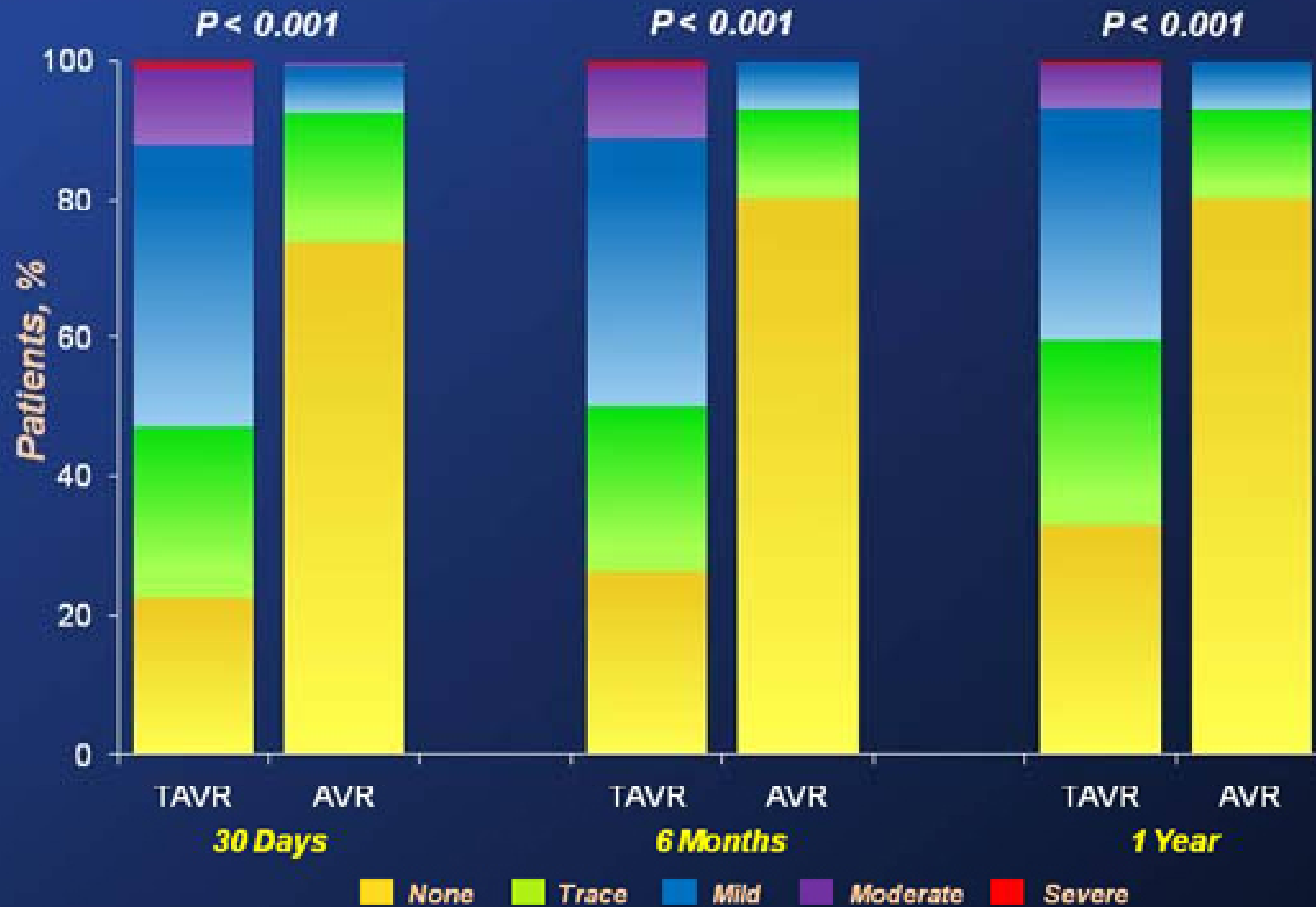


Subgroup Analyses of Treatment Effect

All-Cause Mortality at 1 Year



Paravalvular Aortic Regurgitation



Echo Findings

Hemodynamic Assessments



<i>Finding</i>	30 Days			1 Year		
	<i>TAVR</i>	<i>AVR</i>	<i>p-value</i>	<i>TAVR</i>	<i>AVR</i>	<i>p-value</i>
Mean grad - mmHg	9.9 ± 4.8	10.8 ± 5.0	0.04	10.2 ± 4.3	11.5 ± 5.4	0.008
AVA - cm ²	1.7 ± 0.5	1.5 ± 0.4	0.001	1.6 ± 0.5	1.4 ± 0.5	0.002
LV EF - %	55.5 ± 11.4	56.0 ± 11.4	0.63	56.6 ± 10.5	57.1 ± 10.3	0.64

PARTNER - “High Risk”

- TAVR and AVR procedural mortality were similar and better than anticipated (30 days: TAVR 3.4%, AVR 6.5%, $P=0.07$)
- Mortality at 1-year was also similar for TAVR and AVR (1st endpoint); $P_{\text{non-inferiority}} = 0.001$
- TAVR resulted in...
 - Earlier improvement in symptoms (= at 1-year)
 - Improved echo AV gradients-areas (small Δ not clinically significant)
 - Different peri-procedural hazards - TAVR increased strokes, vascular complics, PVL and AVR increased bleeding and new onset AF

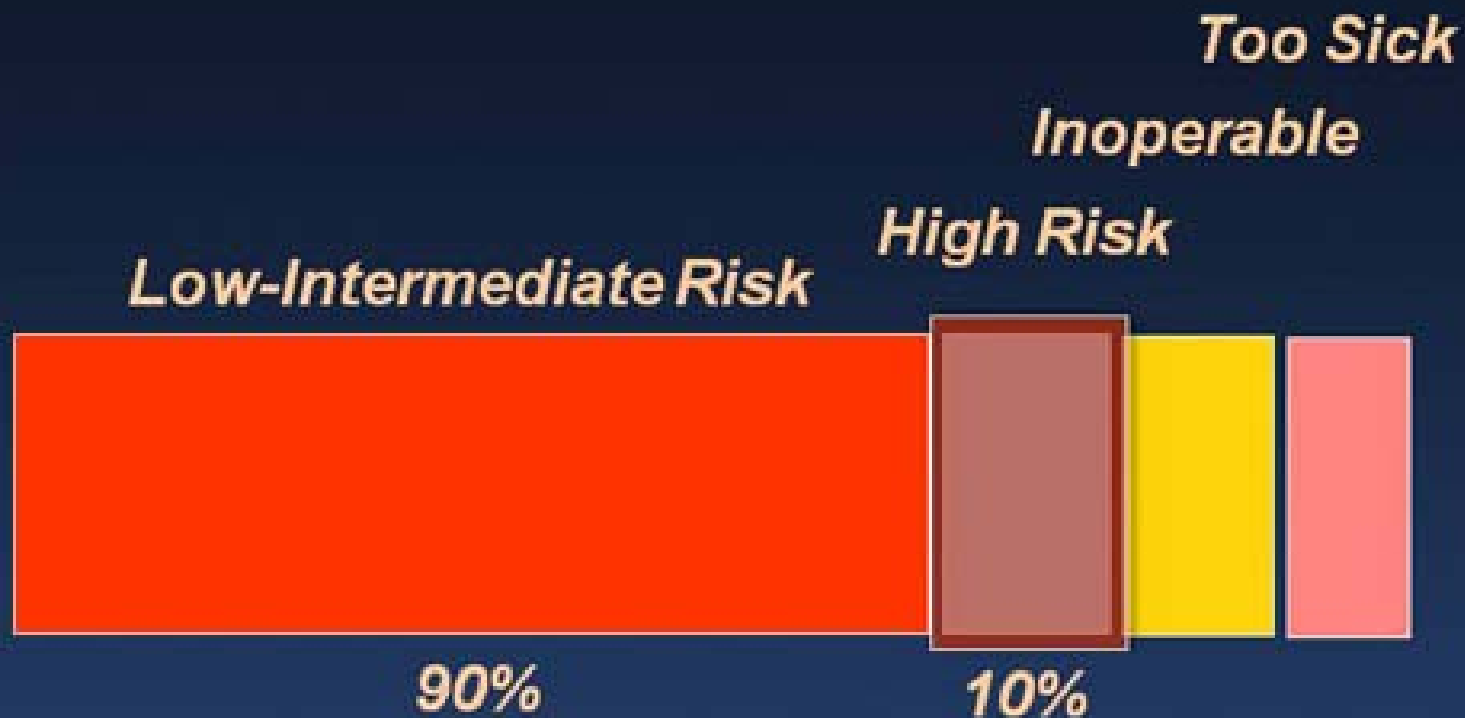
PARTNER - “High Risk”

- *Balloon-expandable TAVR is an exciting new alternative therapy to surgical AVR in selected high-risk patients with severe AS!*
- *The positive momentum from the PARTNER RCT will stimulate an explosion of new TAVR trials designed to improve outcomes and expand clinical indications!!!*

TAVR Categories

(risk is a continuum)

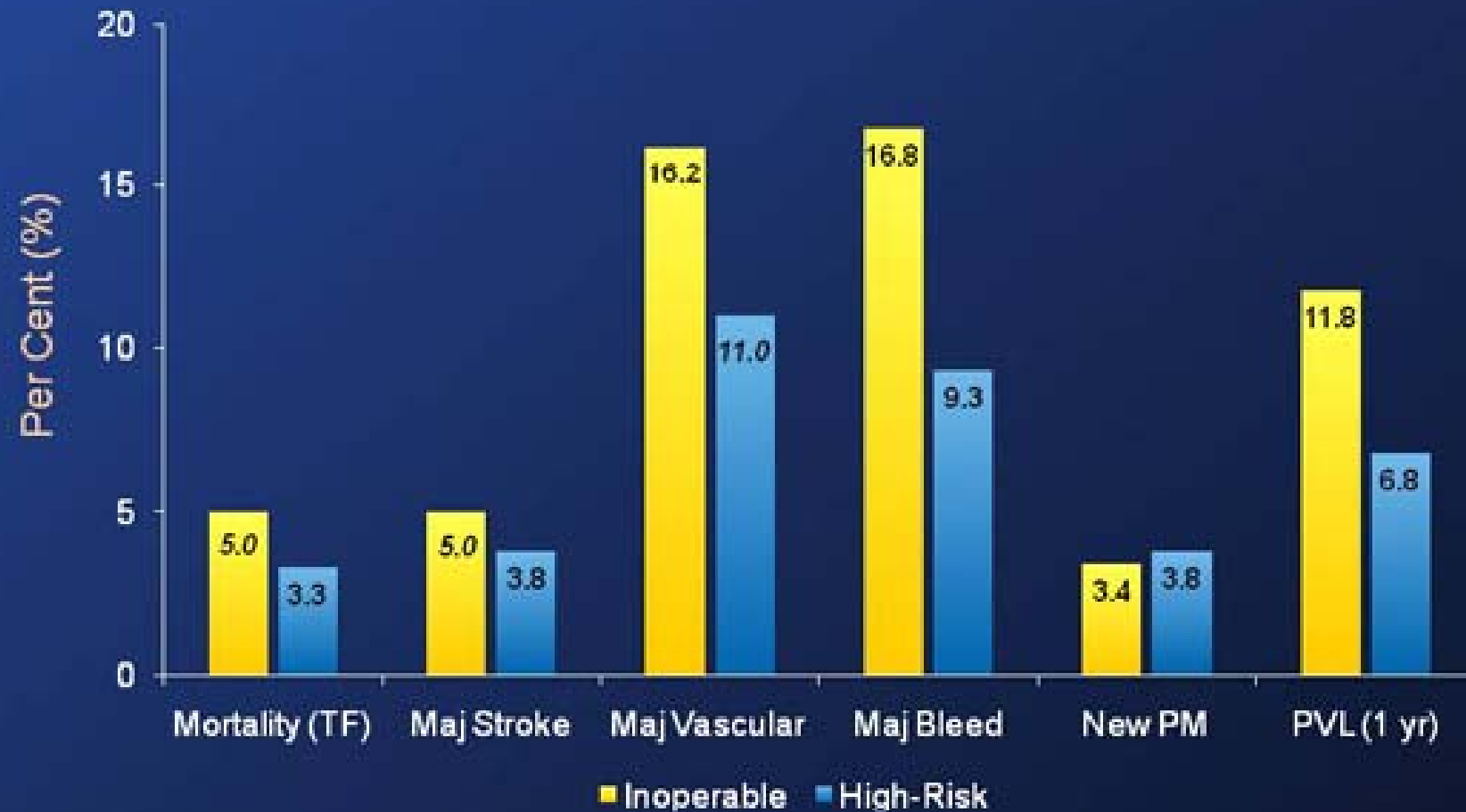
Operable AS patients



TAVR 2011

Life After PARTNER

PARTNER Comparison of Outcomes High-Risk vs. Inoperable Patients - ITT



TAVR 2011

Next Clinical Targets

- Valve-in-valve for bio-prosthetic aortic and mitral valve failure
- Lower risk AS patients (? intermediate risk)
- Mixed AS and CAD patients
- Asymptomatic severe AS
- Low flow - low gradient AS (impedance mismatch)
- Aortic regurgitation

STS Score Breakdown of AVR Pts

STS Database (2006-10)

STS Adult Cardiac Surgery Database
Isolated AV Replacement¹, January 2006 – September 2010

Surgery Year	Number of Records	% of Patients with Predicted Mortality ²									
		≤ 0.01	> 0.01	> 0.02	> 0.03	> 0.04	> 0.05	> 0.06	> 0.07	> 0.08	> 0.09
2006	16953	24.20	75.80	46.79	29.55	20.29	14.36	10.41	7.95	6.21	4.91
2007	18720	22.94	77.06	48.14	31.47	21.61	15.50	11.44	8.64	6.72	5.33
2008	21285	21.67	78.33	49.84	33.05	22.84	16.29	12.23	9.38	7.33	5.91
2009	24428	21.00	79.00	50.45	33.32	22.86	16.31	12.20	9.40	7.34	5.81
2010 ³	18645	22.90	77.10	48.10	31.47	21.61	15.50	11.44	8.64	6.72	5.33
Overall	100031	22.90	77.10	48.10	31.47	21.61	15.50	11.44	8.64	6.72	5.33

STS 3 46%
STS 4 33%
STS 5 25%

Surgery Year	Number of Records	% of Patients with Predicted Mortality ²									
		≤ 0.01	> 0.01	> 0.02	> 0.03	> 0.04	> 0.05	> 0.06	> 0.07	> 0.08	> 0.09
2006	15539	1.30	98.70	80.12	59.17	43.39	32.13	24.74	19.06	15.10	12.07
2007	15878	1.24	98.76	80.99	60.76	44.89	33.37	25.75	20.06	15.73	12.56
2008	17437	1.27	98.73	81.92	61.19	45.29	33.84	25.80	20.06	15.79	12.81
2009	18645	0.90	99.10	81.23	60.79	45.12	33.46	25.62	19.62	15.32	12.27
2010 ³	13270	1.30	98.70	80.12	59.17	43.39	32.13	24.74	19.06	15.10	12.07
Overall	80769	1.21	98.79	81.02	60.40	44.55	33.02	25.25	19.49	15.34	12.29

TAVR - “Lower” Risk Patients

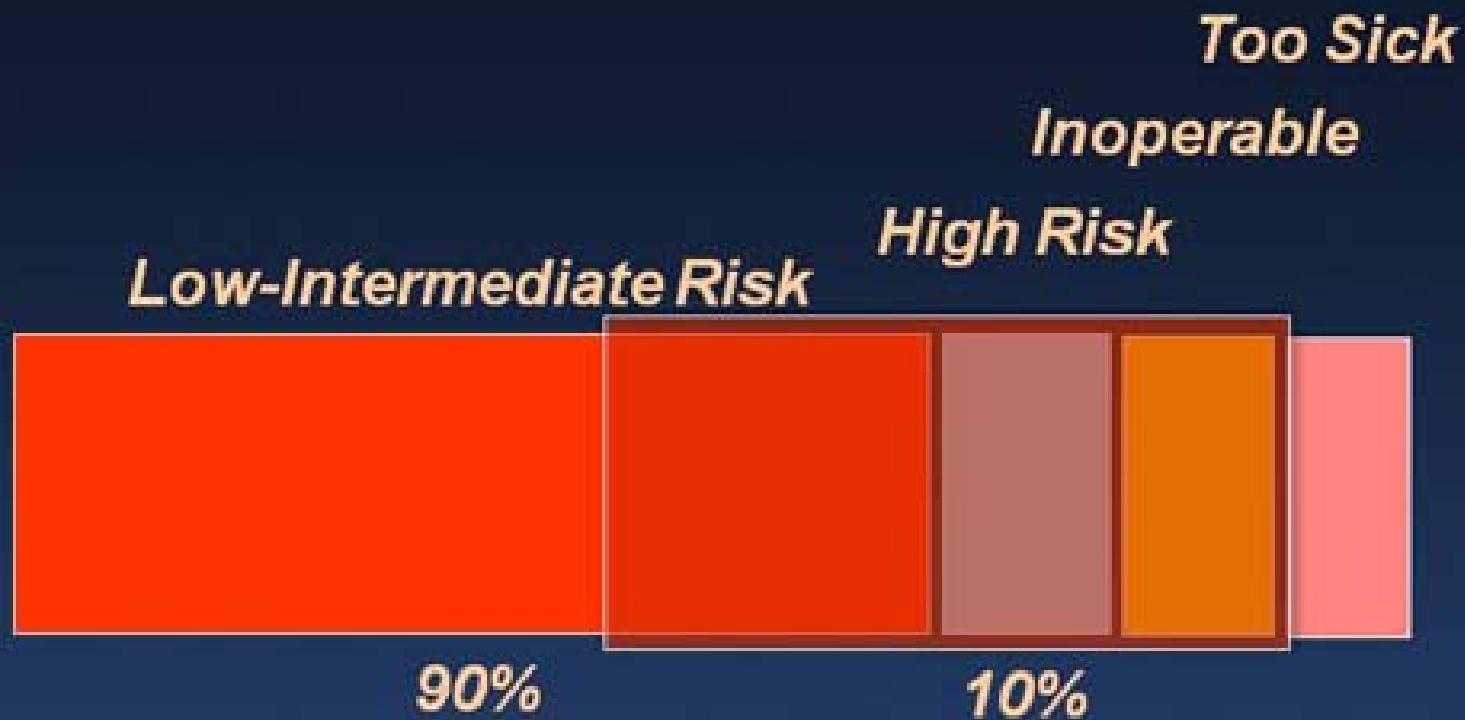
- ***“INTERMEDIATE” RISK CATEGORY***
 - ❖ > 70 yo
 - ❖ STS score > 4 (upper tercile of risk strata)
 - ❖ CAD treatment sub-stratified to AVR + CABG vs. TAVR + PCI (exclude upper tercile SYNTAX score)
 - ❖ Petition exclusion for unusual risk scenarios

Template for PARTNER 2!

TAVR Categories

(risk is a continuum)

Operable AS patients



TAVR 2011

Accessory Devices

- Cerebral embolic protection
- New balloon and “other” valvuloplasty catheter systems
- Access site management (esp. closure and including trans-apical)
- Adjunctive imaging, positioning and telemanipulation systems (e.g. 3D echo, CT, 3D angio, electro-mechanical)

TAVR - The Future

My Rosey Prophecy

Surgery – The “PAST”

***In 5-10 years, most patients
with severe AS requiring AVR
will be treated using TAVR!***

TAVR – The “Future”