A Critical Analysis of the Outcomes of Cohorts A and B of the PARTNER trial

Josep Rodés-Cabau, MD

Quebec Heart & Lung Institute, Laval University, Quebec city, Quebec, Canada

INSTITUT UNIVERSITAIRE DE CARDIOLOGIE ET DE PNEUMOLOGIE DE QUÉBEC

AFFILIÉ À UNIVERSITÉ LAVAL

SOLACI

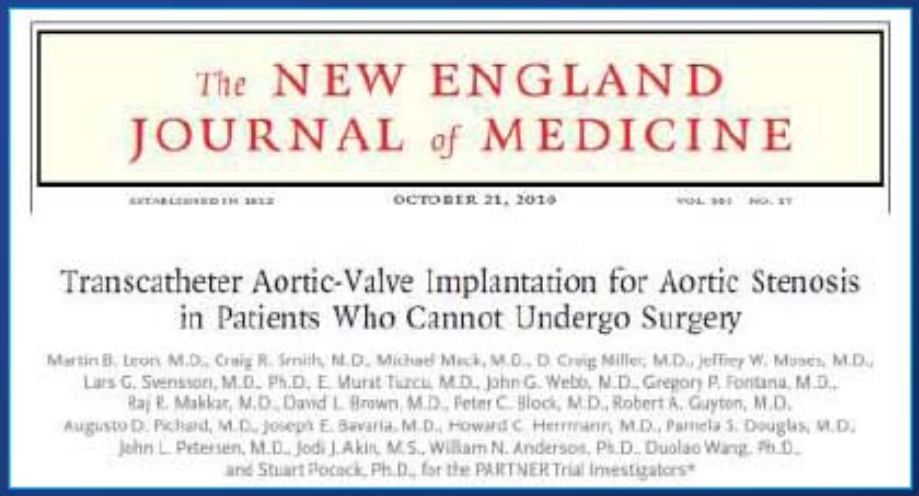
Mejico DF, August 2012

Conflict of Interest Disclosure

- **Consultant for Edwards Lifesciences and St. Jude Medical**

PARTNER Manuscripts in NEJM (October, 2010 – May, 2012)

THE PARTNER TRIAL



The NEW ENGLAND JOURNAL of MEDICINE

OCTOBER 21, 2010

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 S. 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*

The NEW ENGLAND JOURNAL of MEDICINE

JUNE 9, 2011

Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. 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., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

Raj R. Makkar, M.D., Gregory P. Fontana, M.D., Hasan Jilaihawi, M.D., Samir Kapadia, M.D., Augusto D. Pichard, M.D., Pamela S. Douglas, M.D., Vinod H. Thourani, M.D., Vasilis C. Babaliaros, M.D., John G. Webb, M.D., Howard C. Herrmann, M.D., Joseph E. Bavaria, M.D., Susheel Kodali, M.D., David L. Brown, M.D., Bruce Bowers, M.D., Todd M. Dewey, M.D., Lars G. Svensson, M.D., Ph.D., Murat Tuzcu, M.D., Jeffrey W. Moses, M.D., Matthew R. Williams, M.D., Robert J. Siegel, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Stuart Pocock, Ph.D., Craig R. Smith, M.D., and Martin B. Leon, M.D., for the PARTNER Trial Investigators*

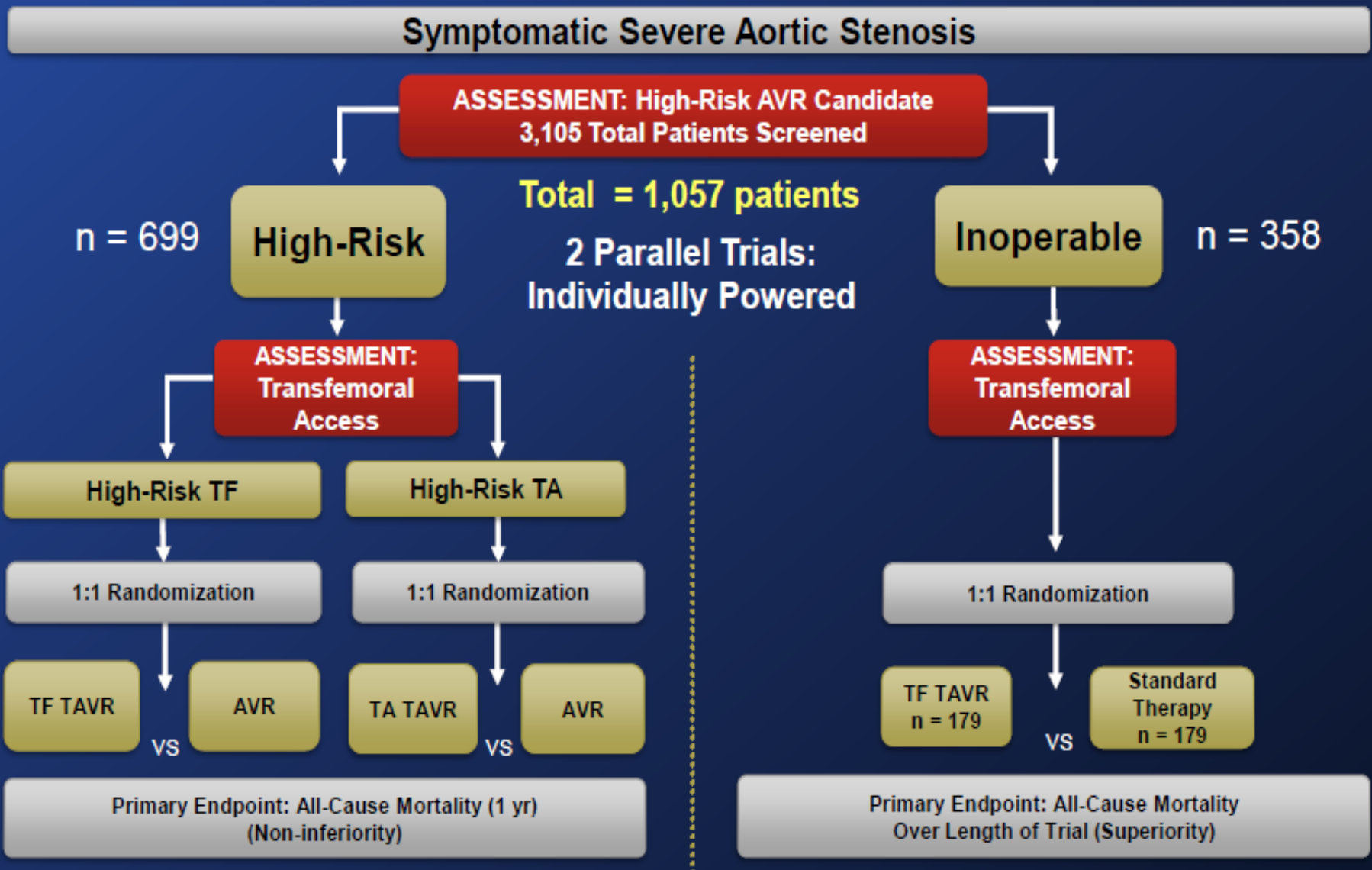
The NEW ENGLAND JOURNAL of MEDICINE

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*

PARTNER Study Design



Patient Characteristics (1)

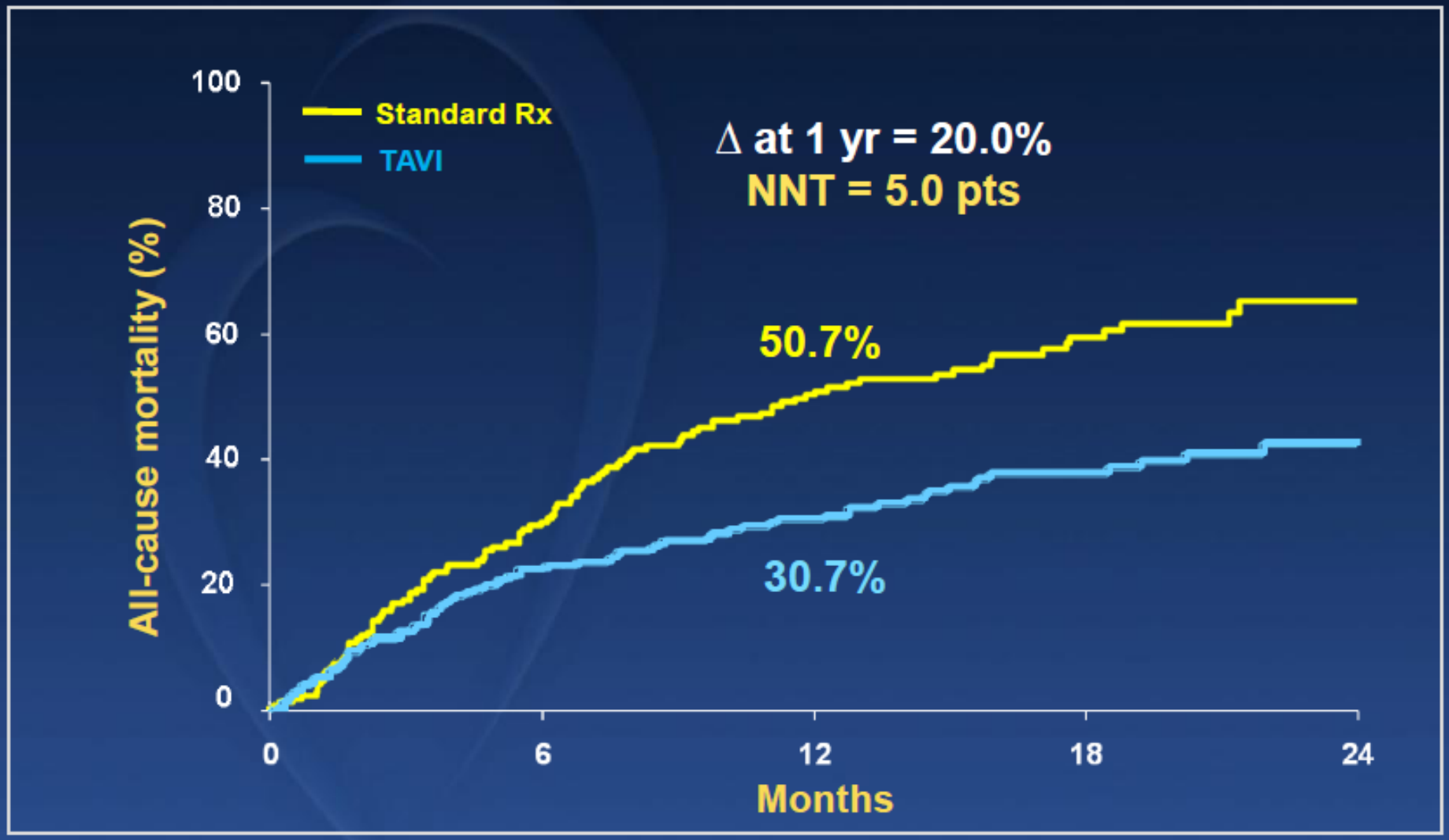
THE PARTNER TRIAL

Characteristic	*TAVR* *n = 179*	*Standard Rx* *n = 179*	*p value*
Age – yr	83.1 ± 8.6	83.2 ± 8.3	0.95
Male sex (%)	45.8	46.9	0.92
STS Score	11.2 ± 5.8	12.1 ± 6.1	0.14
NYHA			
I or II (%)	7.8	6.1	0.68
III or IV (%)	92.2	93.9	0.68
CAD (%)	67.6	74.3	0.20
Prior MI (%)	18.6	26.4	0.10
Prior CABG (%)	37.4	45.6	0.17
Prior PCI (%)	30.5	24.8	0.31
Prior BAV (%)	16.2	24.4	0.09
CVD (%)	27.4	27.5	1.00

Patient Characteristics (2)

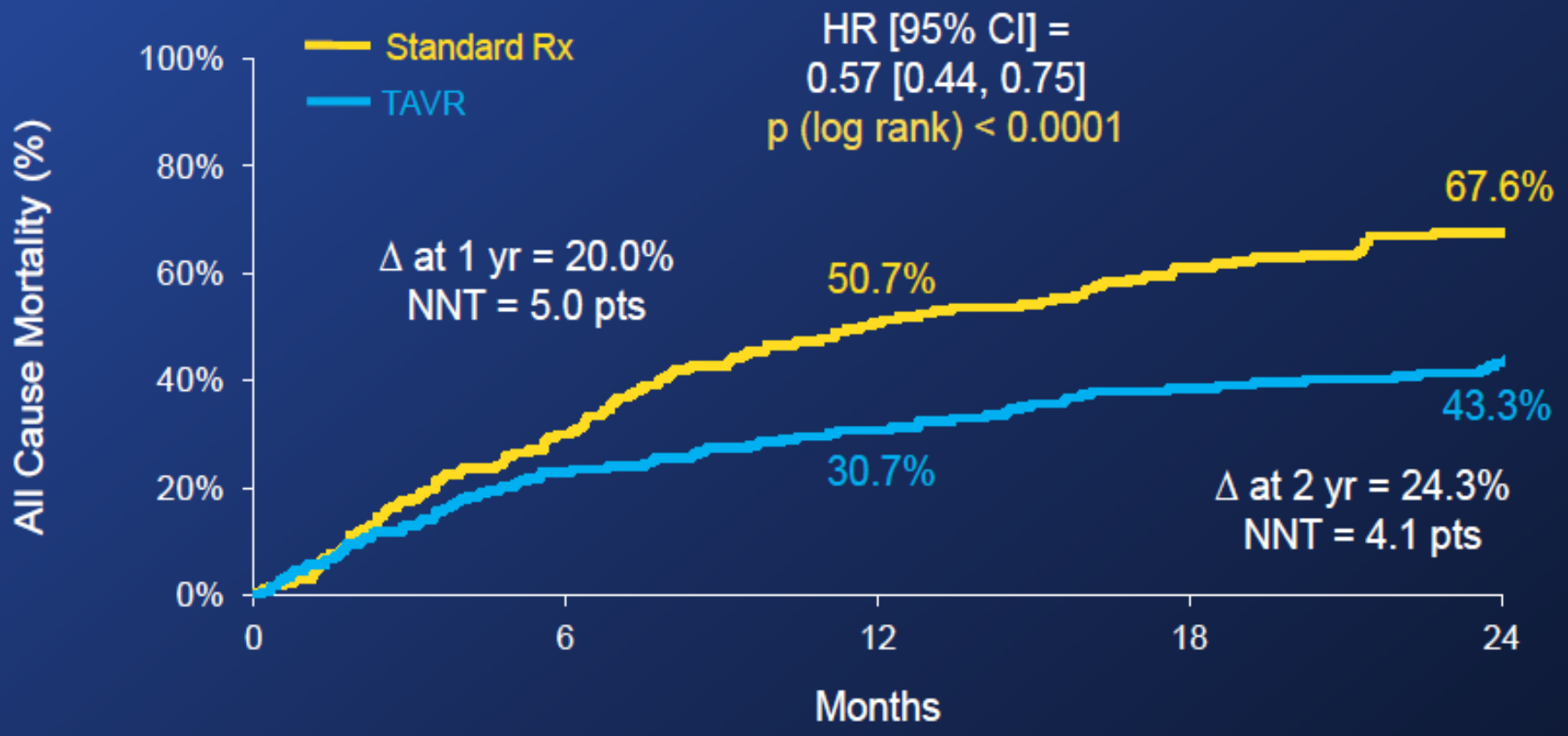
Characteristic	*TAVR* *n = 179*	*Standard Rx* *n = 179*	*p value*
PVD (%)	30.3	25.1	0.29
COPD			
Any (%)	41.3	52.5	0.04
O_2 dependent (%)	21.2	25.7	0.38
Creatinine > 2 mg/dL (%)	5.6	9.6	0.23
Atrial fibrillation (%)	32.9	48.8	0.04
Perm. pacemaker (%)	22.9	19.5	0.49
Pulmonary HTN (%)	42.4	43.8	0.90
Frailty (%)	18.1	28.0	0.09
Porcelain aorta (%)	19.0	11.2	0.05
Chest wall radiation (%)	8.9	8.4	1.00
Chest wall deformity (%)	8.4	5.0	0.29
Liver disease (%)	3.4	3.4	1.00

All Cause Mortality



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

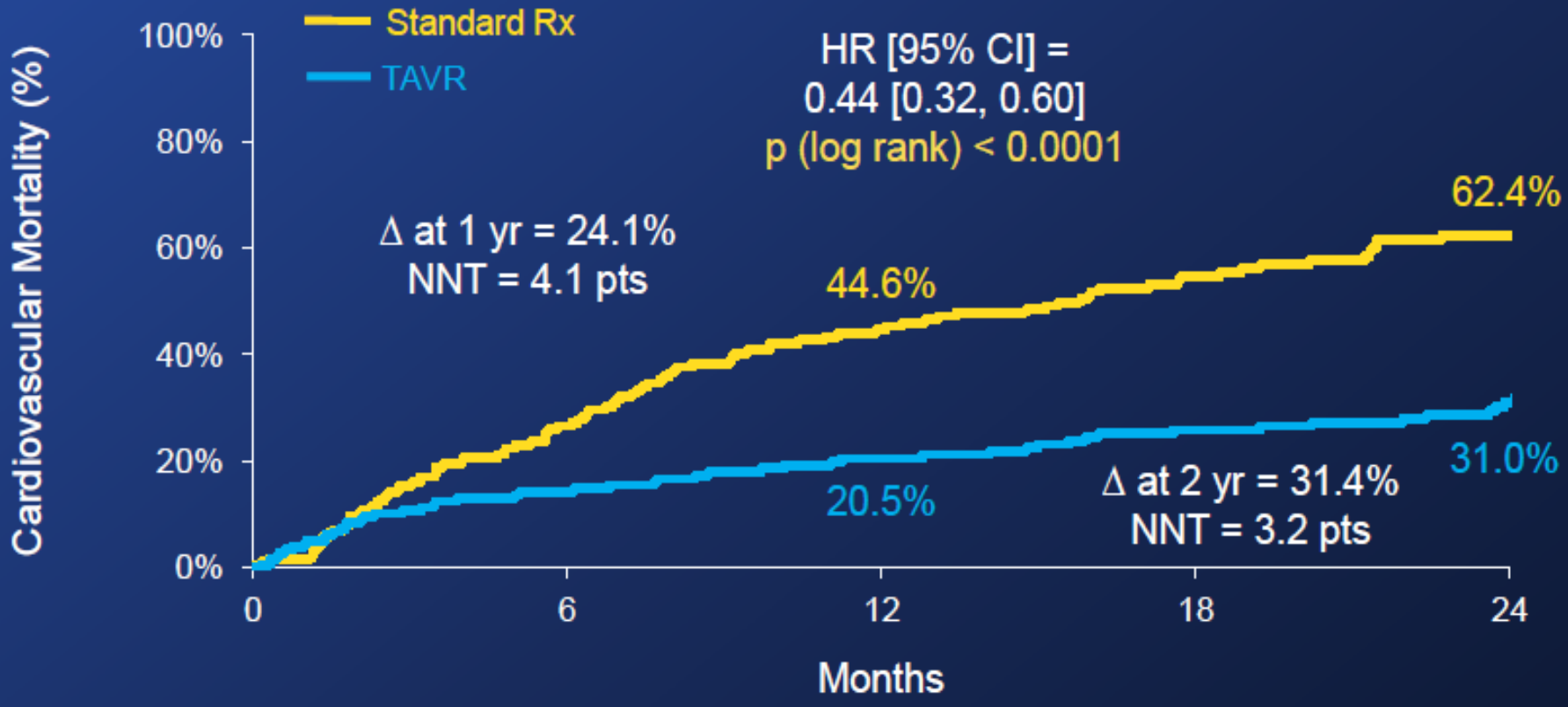
All Cause Mortality (ITT)
Crossover Patients Followed



Numbers at Risk

TAVR	179	138	124	110	83
Standard Rx	179	121	85	67	51

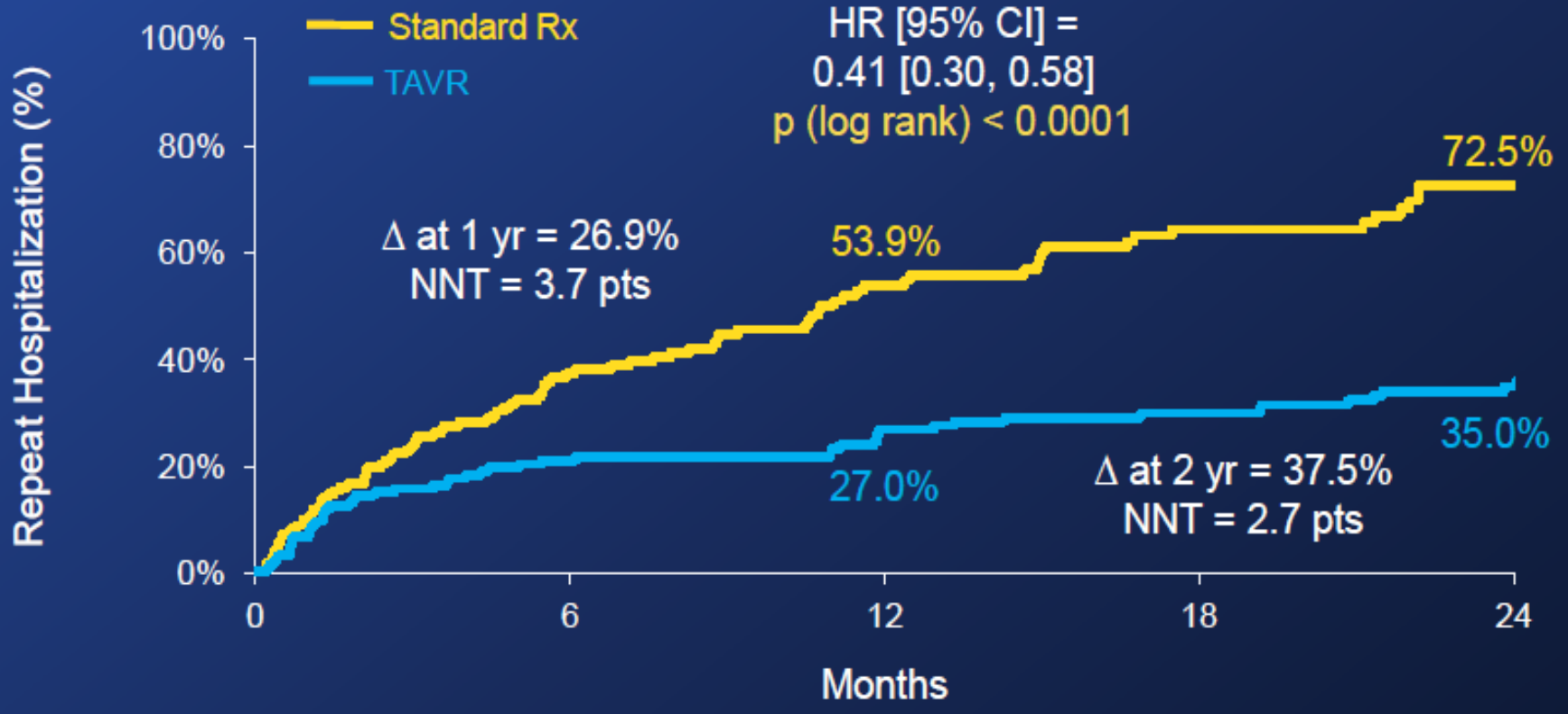
Cardiovascular Mortality (ITT)
Crossover Patients Censored



Numbers at Risk

TAVR	179	138	124	110	83
Standard Rx	179	121	85	62	42

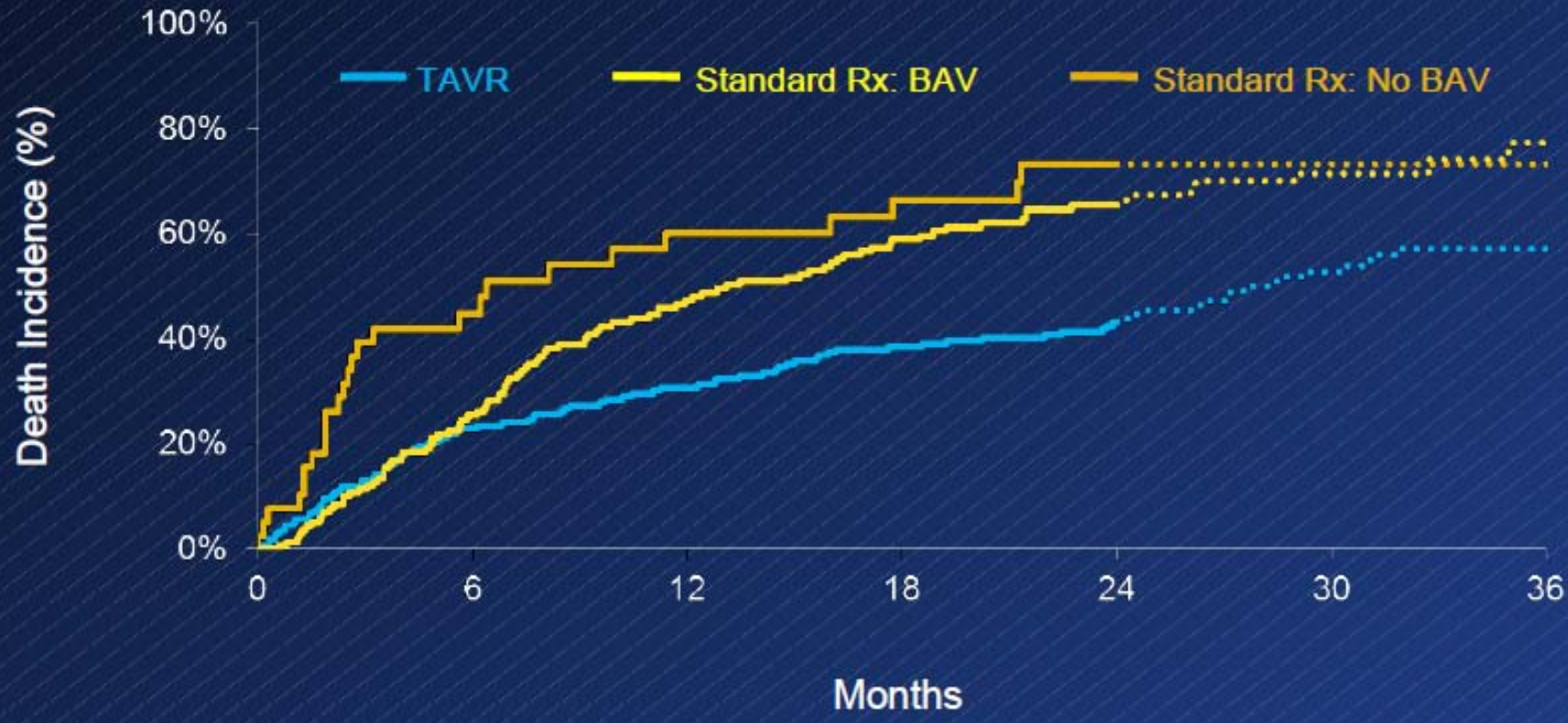
Repeat Hospitalization (ITT)



Numbers at Risk

TAVR	179	115	100	89	64
Standard Rx	179	86	49	30	17

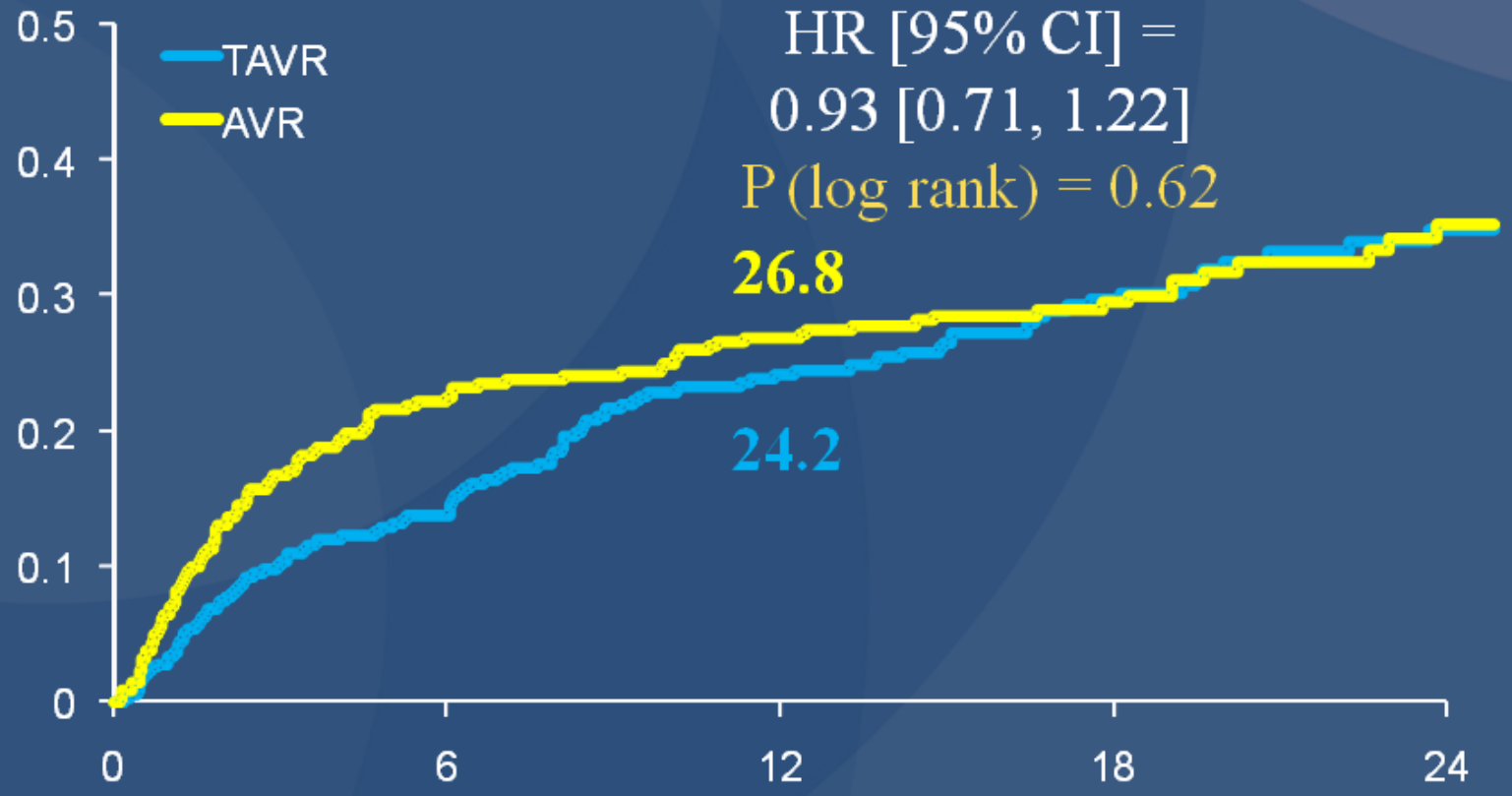
All Cause Mortality vs BAV



Numbers at Risk

TAVR	179	138	124	110	83	47	14
Standard Rx: BAV	142	105	74	54	37	18	5
Standard RX: No BAV	39	18	13	10	7	2	1

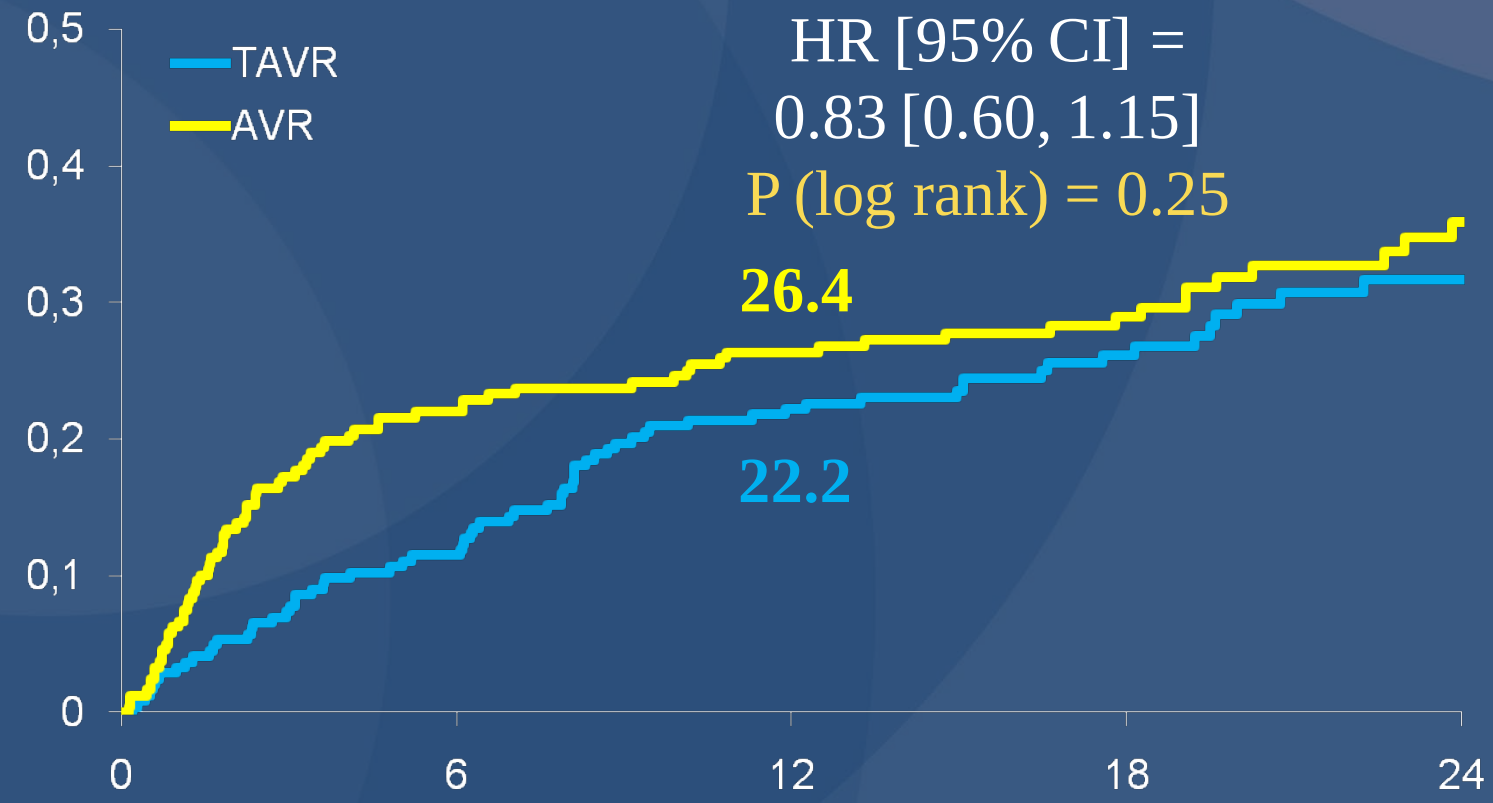
Primary Endpoint:
All-Cause Mortality at 1 Year



No. at Risk

348	TAVR	298	260	147	67
351	AVR	252	236	139	65

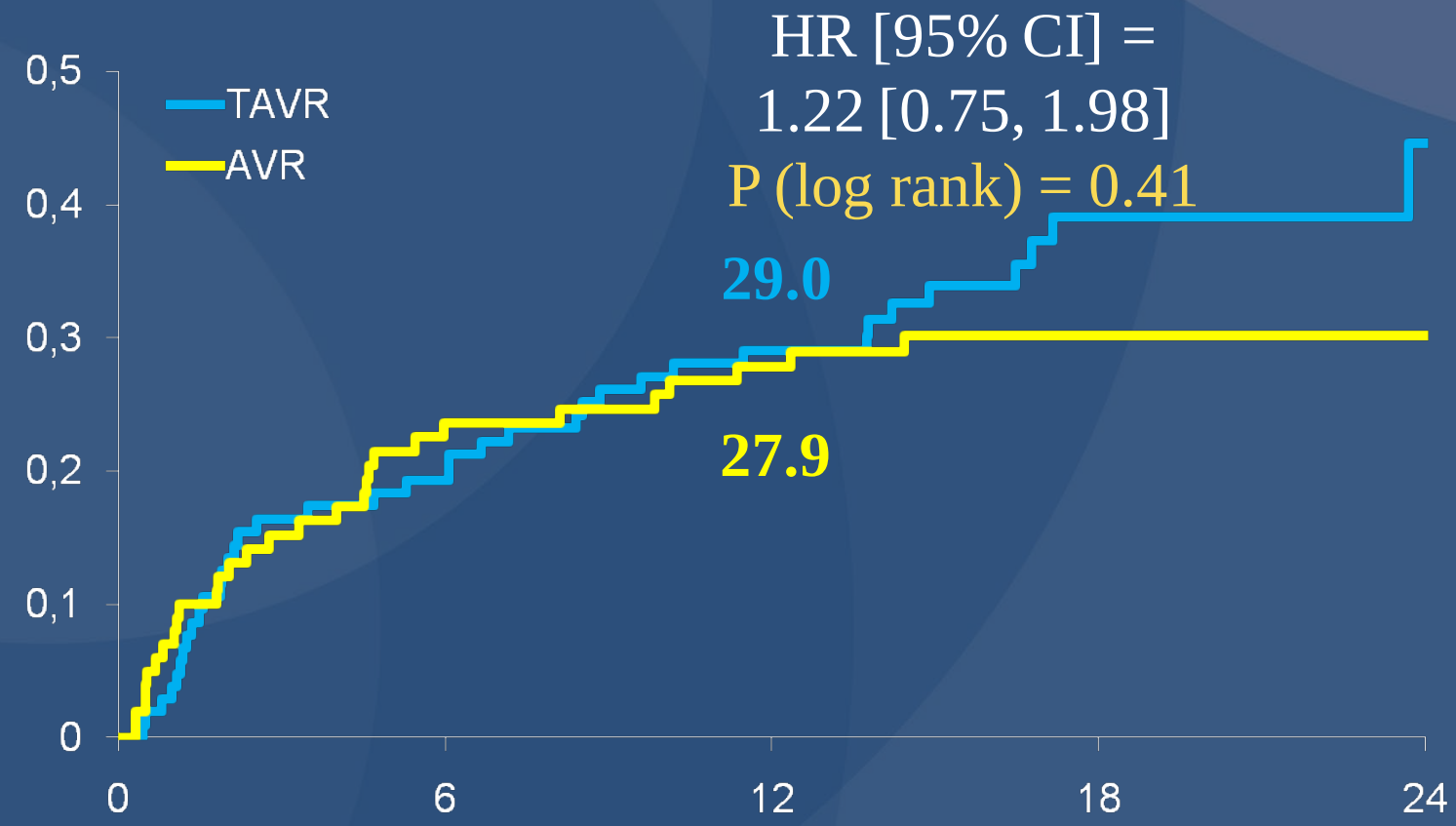
All-Cause Mortality
Transfemoral (N=492)



No. at Risk

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

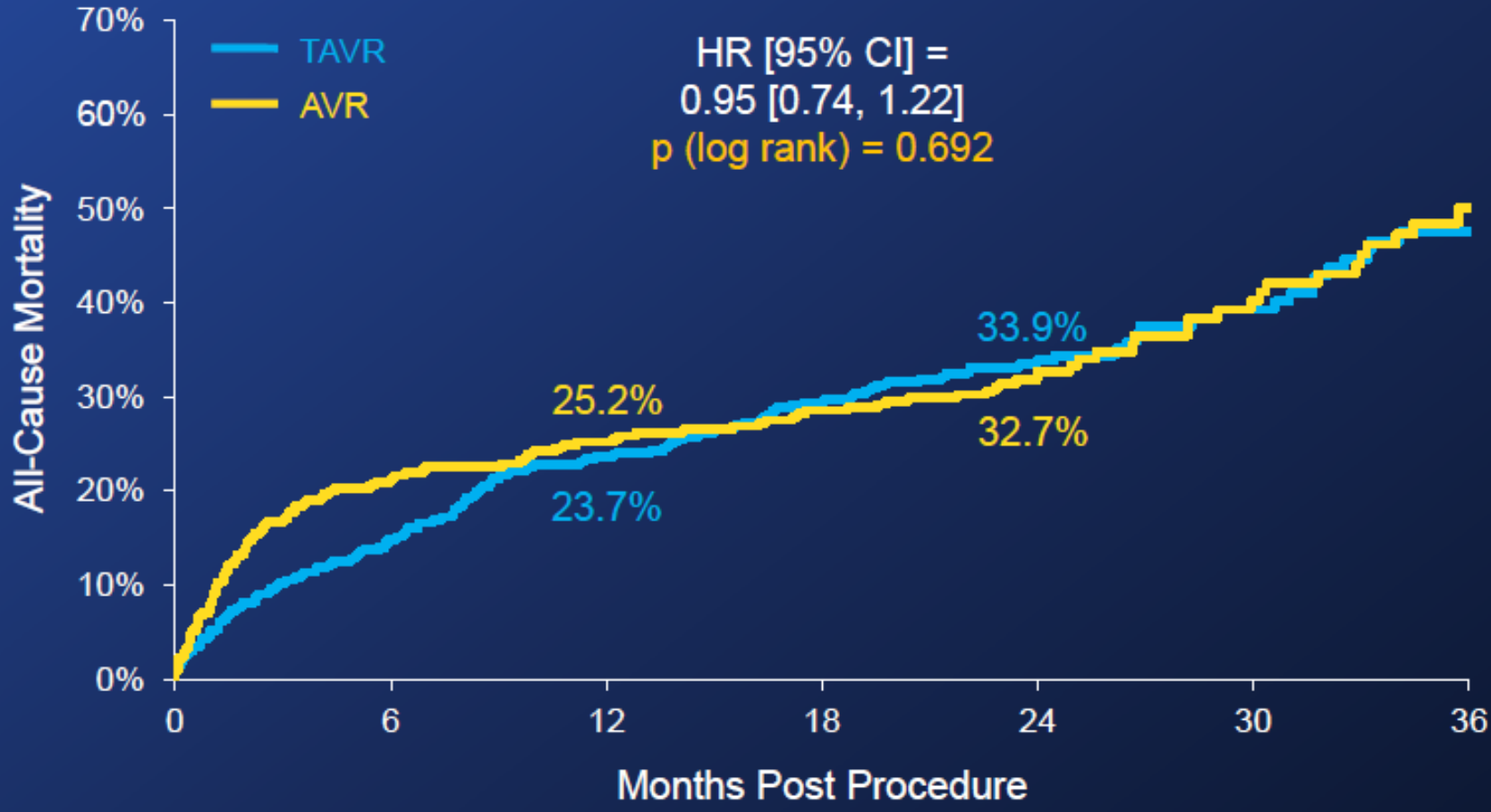
All-Cause Mortality
Transapical (N=207)



No. at Risk

104	TAVR	83	72	28	8
103	AVR	72	68	30	9

All-Cause Mortality (AT)

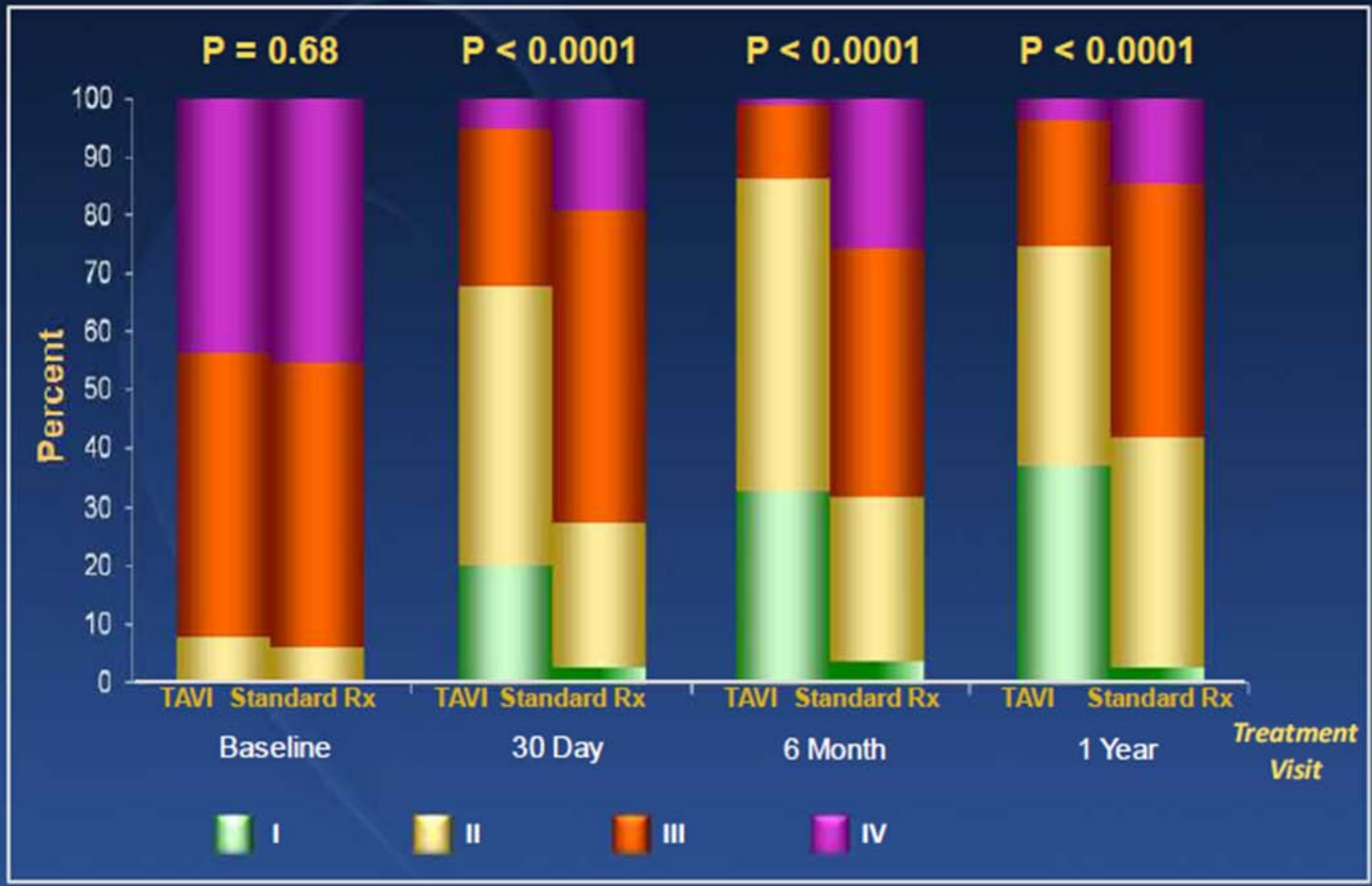


Numbers at Risk

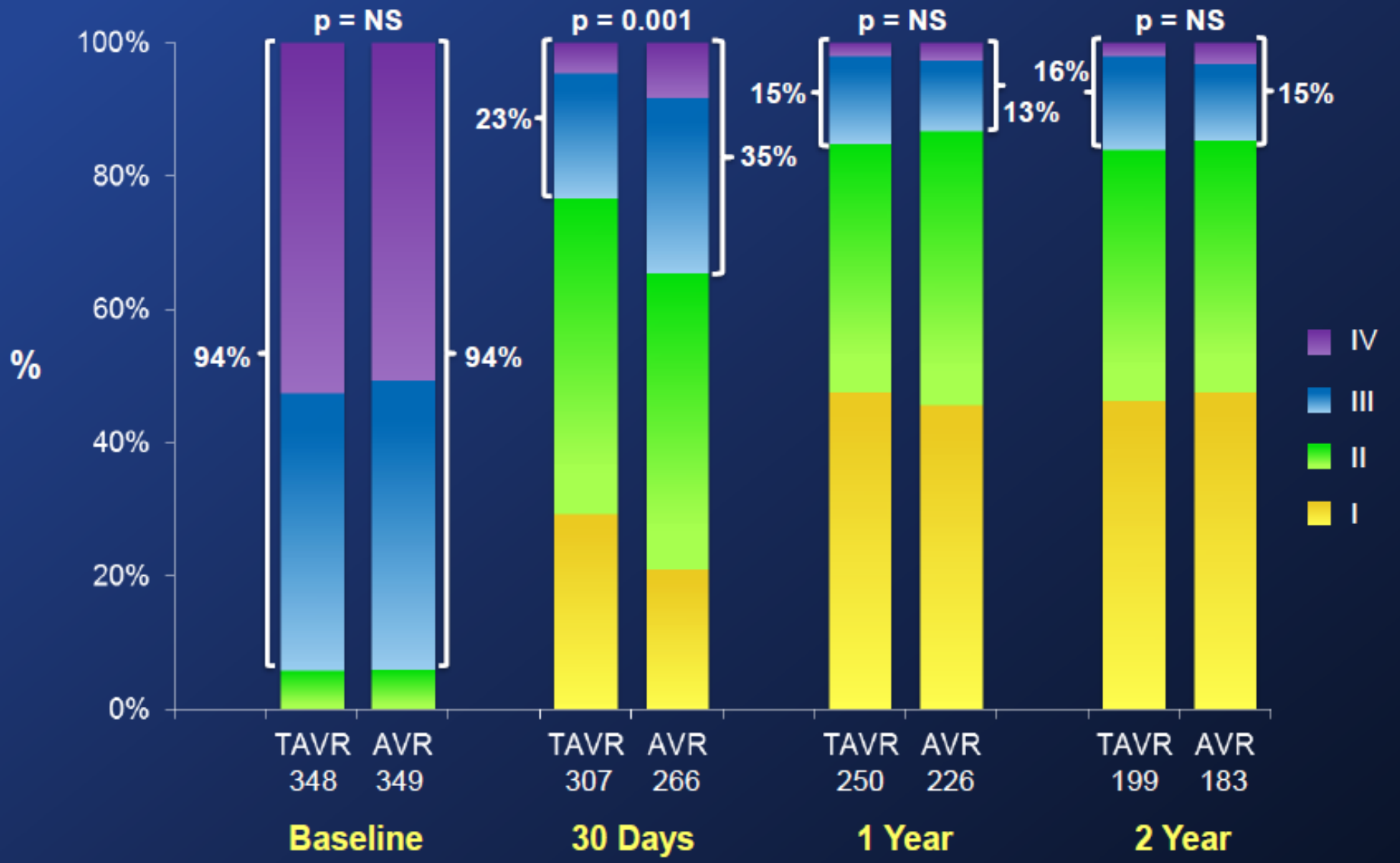
TAVR	344	291	259	232	155	70	29
AVR	313	243	229	211	143	63	28

NYHA Class Over Time

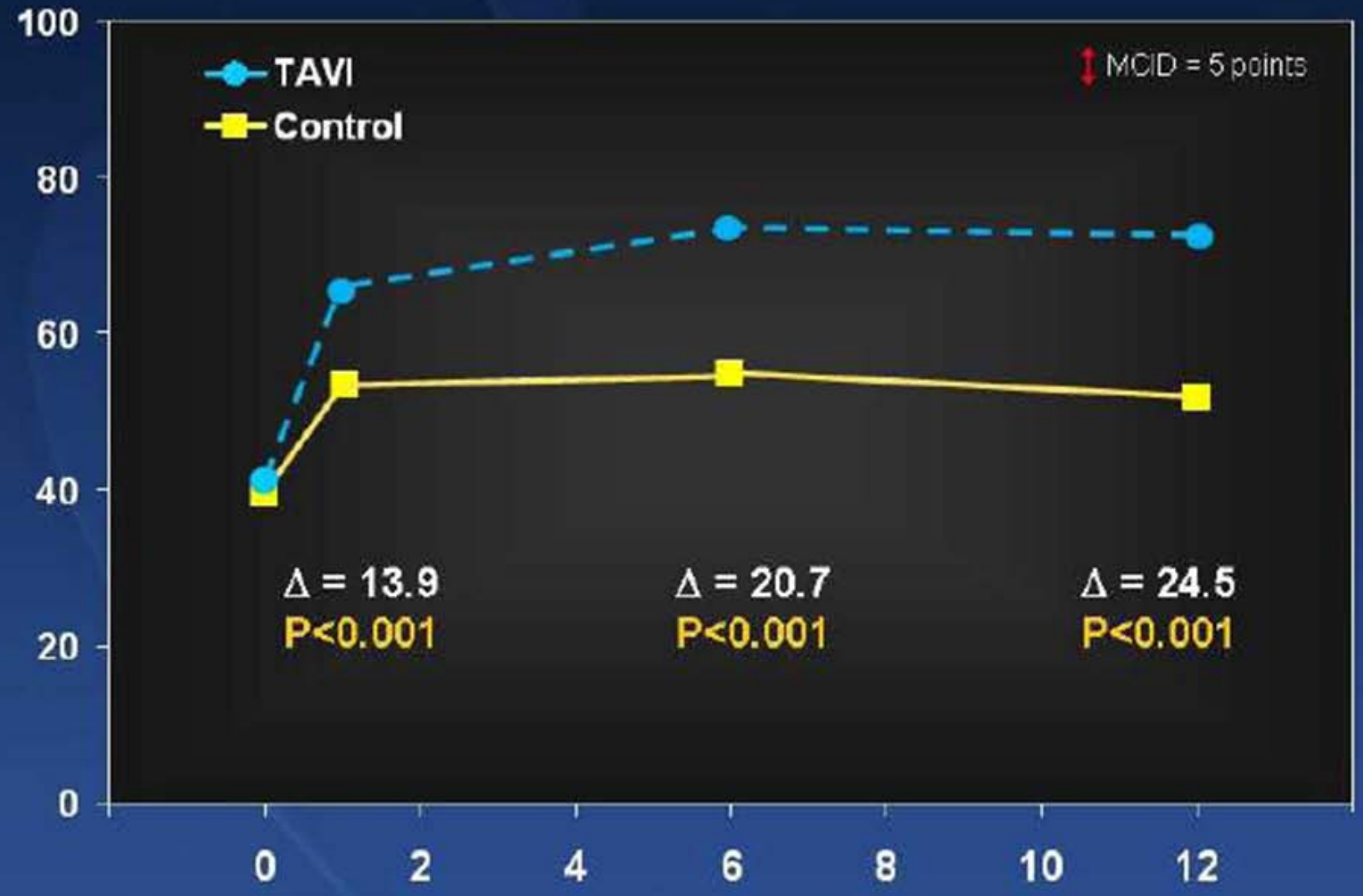
Survivors



NYHA Class Survivors (ITT)



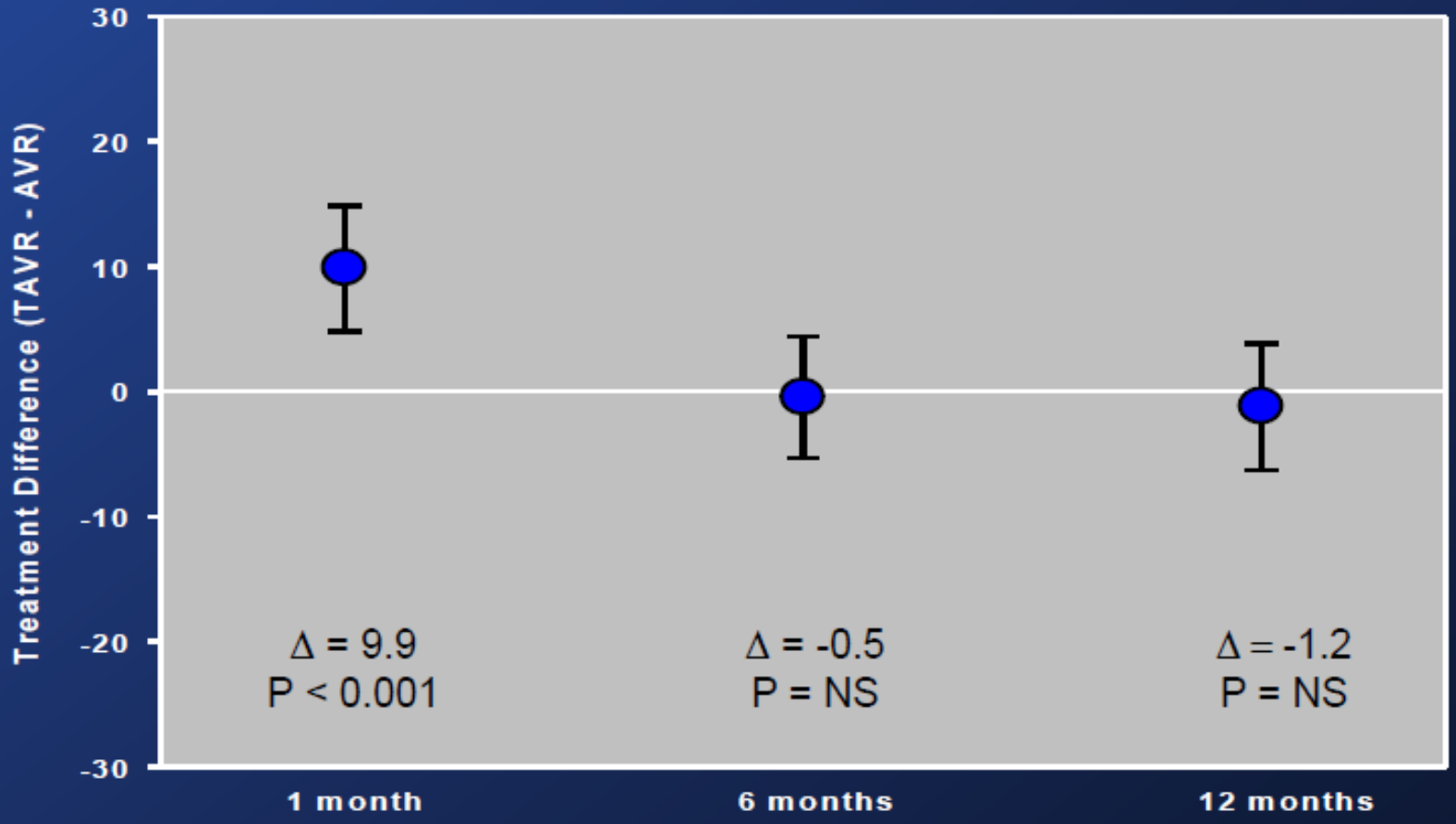
Primary Endpoint: KCCQ Overall Summary



KCCQ Overall Summary (Primary Endpoint)
TF Subgroup

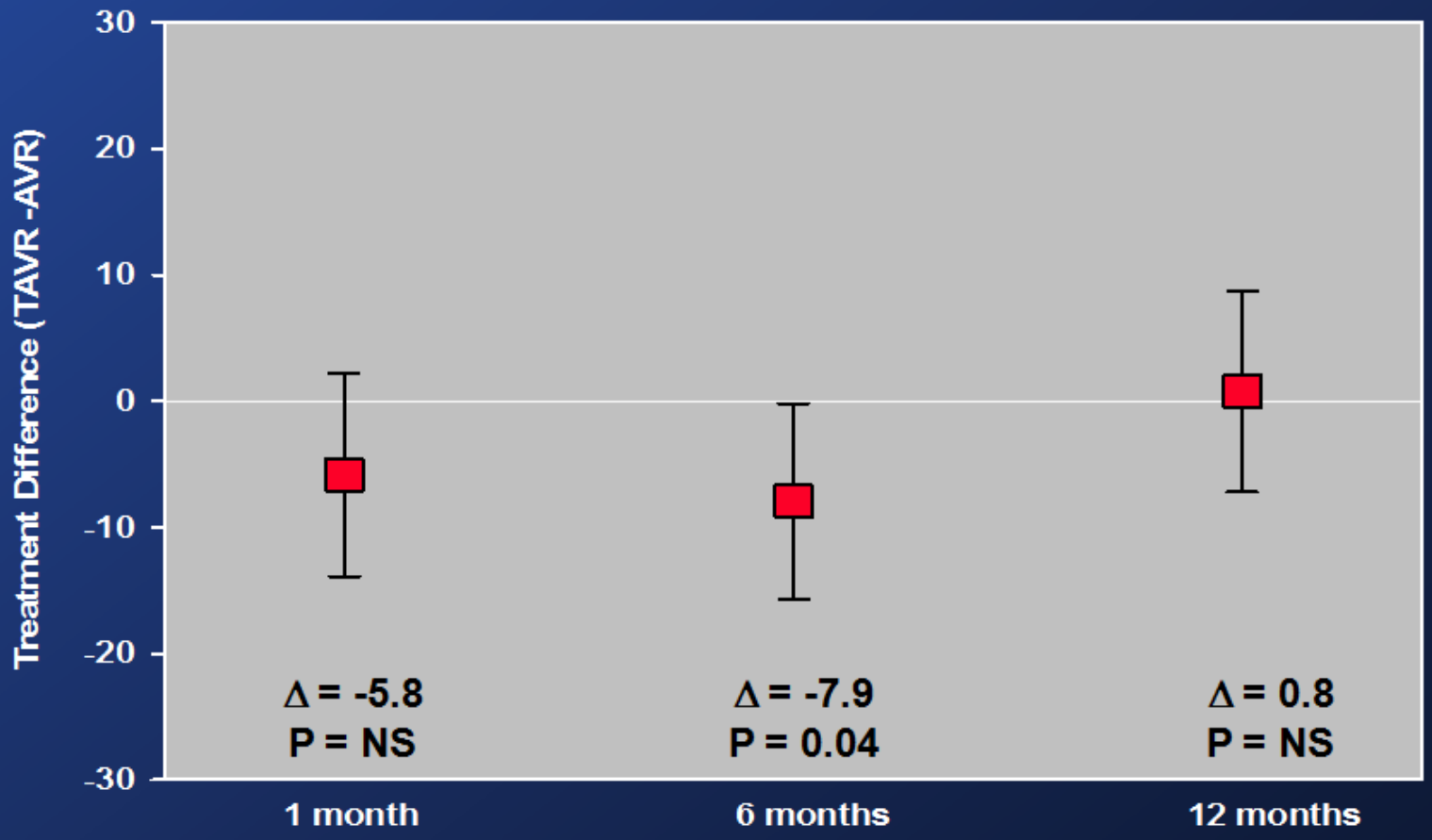
THE PARTNER TRIAL

Reynolds et al. JACC 2012



P-values are for mean treatment effect of TAVR vs. AVR

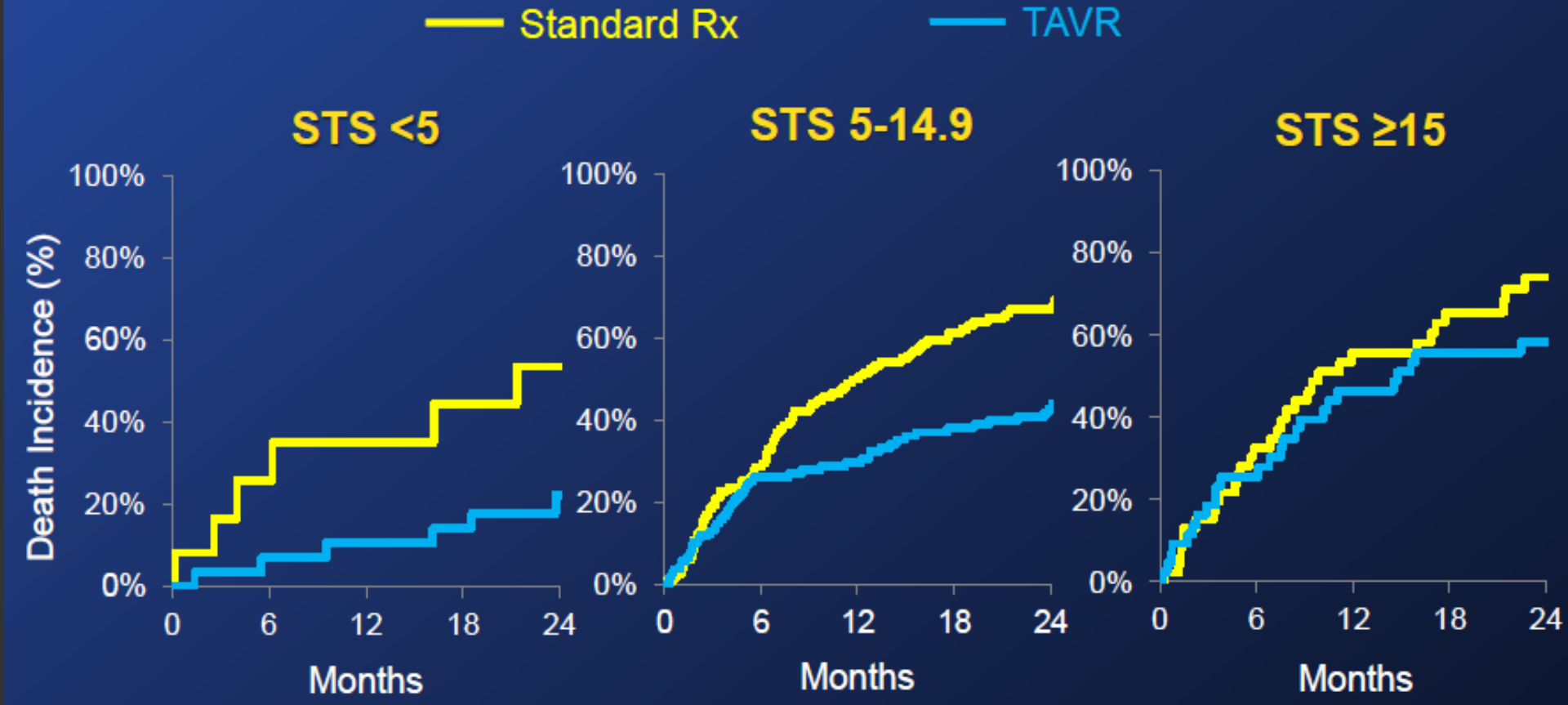
KCCQ Overall Summary (Primary Endpoint)
TA Subgroup



P-values are for mean treatment effect of TAVR vs. AVR

- **Mortality rate at 1- and 2-year follow-up**
- **Cerebrovascular events**
- **Aortic regurgitation**

Mortality Stratified by STS Score (ITT)



Numbers at Risk

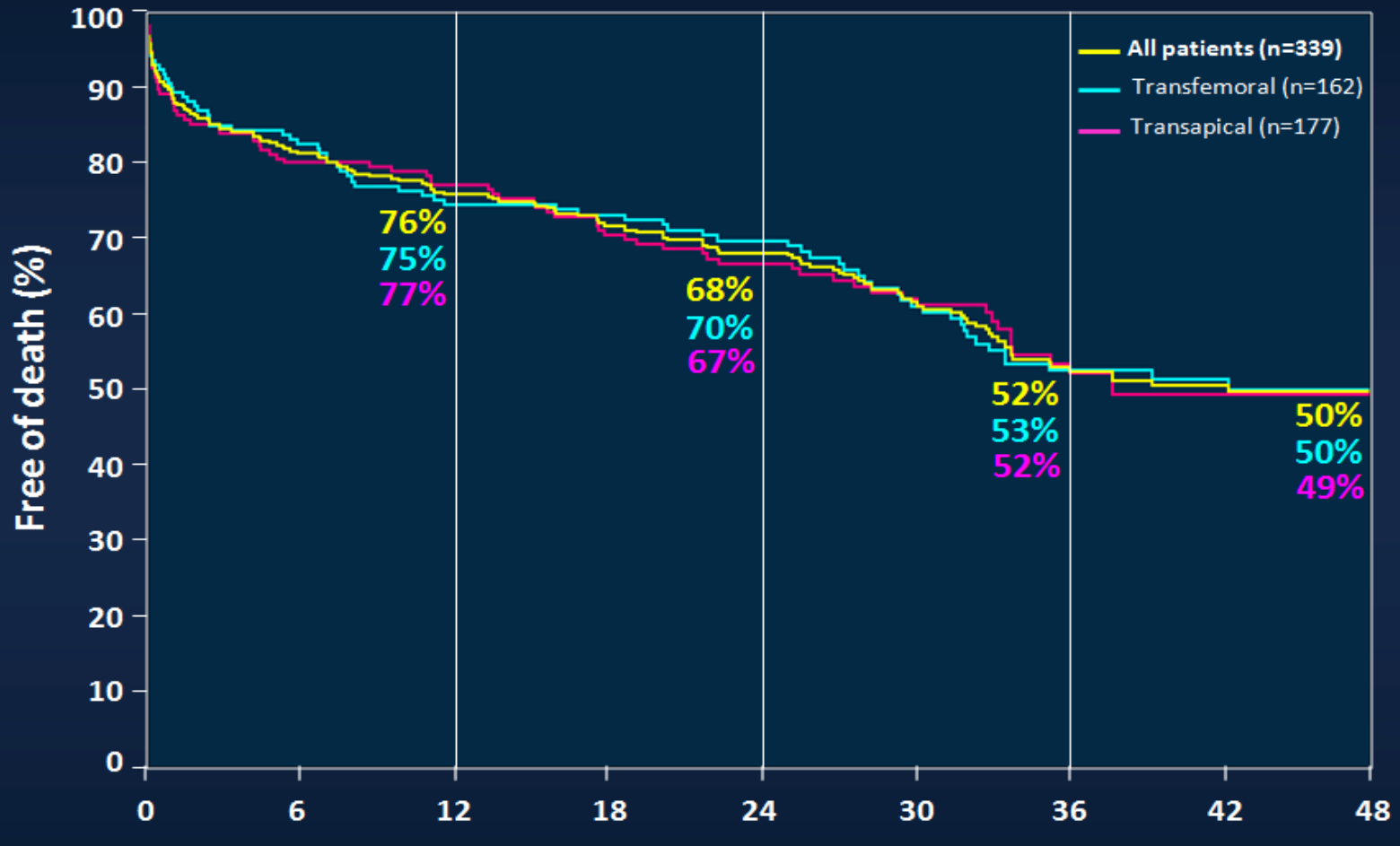
35	28	26	25	24	16	108	80	76	67	52	43	32	23	19	15
	12	8	7	6	5	119	84	59	42	29	47	29	19	14	8

Multivariate Baseline Predictors of Mortality - By Treatment Arm

TAVR	*Hazard Ratio [95% CI]*	*p-value*
Body Mass Index (kg/m^2)	0.93 [0.90-0.97]	<0.001
Mean Gradient (mmHg/10)	0.82 [0.72-0.94]	0.003
Baseline Creatinine	1.06 [1.00-1.13]	0.044
Prior Vascular Surgery or Stent	1.85 [1.01-3.39]	0.045
AVR		
Prior CABG	0.57 [0.40-0.82]	0.002
STS Risk Score	1.07 [1.02-1.12]	0.004
Liver Disease	2.59 [1.16-5.43]	0.020
Moderate/Severe MR	1.77 [1.17-2.68]	0.006

Procedural Predictors of Mortality

48-month Follow-Up Survival Curves
Canadian Multicenter Experience

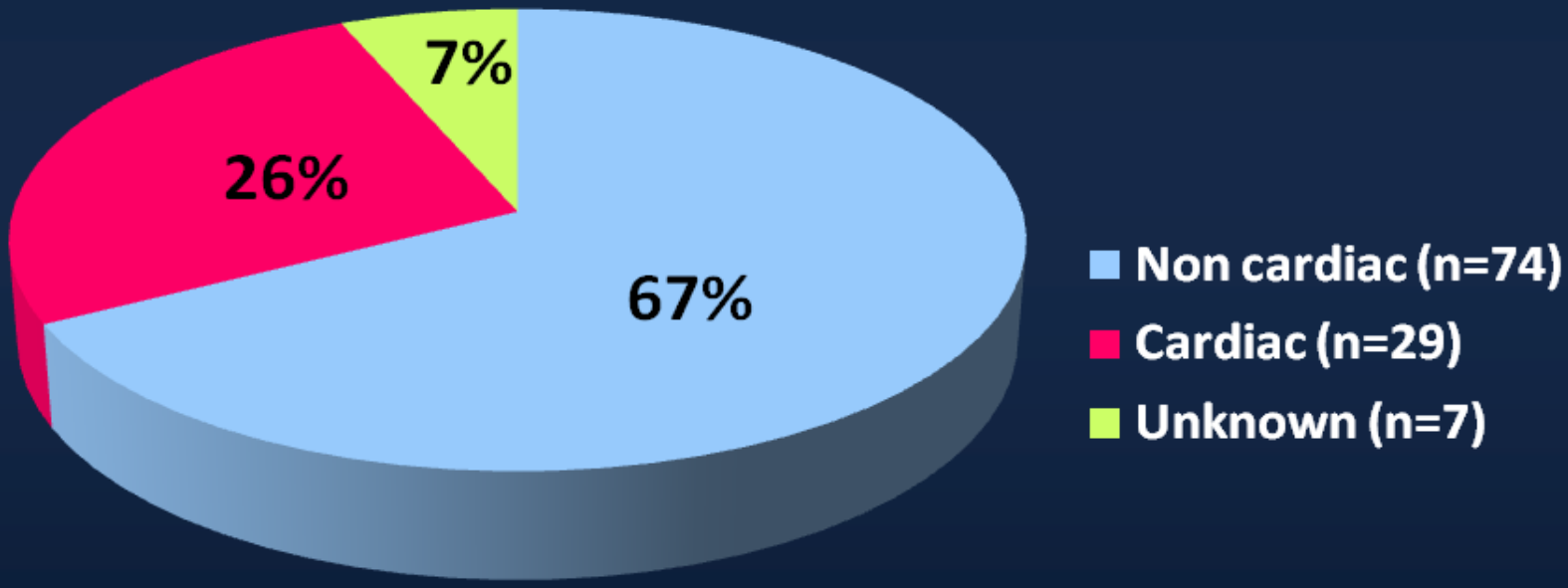


Patients at risk:

All patients	339	271	248	221	190	141	92	59	31
Transfemoral	162	132	117	107	96	72	50	33	16
Transapical	177	139	131	114	94	69	42	26	14

Rodés-Cabau et al. ACC Scientific Sessions 2012

CAUSES OF DEATH AT FOLLOW-UP
Multicenter Canadian Experience



Rodés-Cabau et al. ACC 2012

Predictive Factors of 30-Day Mortality After TAVI

Baseline noncardiac variables

Chronic kidney disease
Diabetes mellitus
BMI<20kg/m^2
Prior stroke

Baseline cardiac variables

Low left ventricular ejection fraction (<40%)
Pulmonary hypertension
Coronary artery disease
Prior balloon aortic valvuloplasty
Moderate or severe mitral regurgitation
Prior acute pulmonary edema

Periprocedural complications

Acute kidney injury
Need for hemodynamic support
Conversion to open heart surgery
Cardiac tamponade
Major vascular complications
Moderate or severe aortic regurgitation (≥2+)

Predictive Factors of 1-Year Mortality After TAVI

Baseline noncardiac variables

- Chronic obstructive pulmonary disease
- Chronic kidney disease
- Diabetes mellitus
- Prior stroke
- Carotid artery stenosis >50%
- Liver disease
- No dyslipidemia
- Systemic hypertension
- Smoking
- Coagulopathy

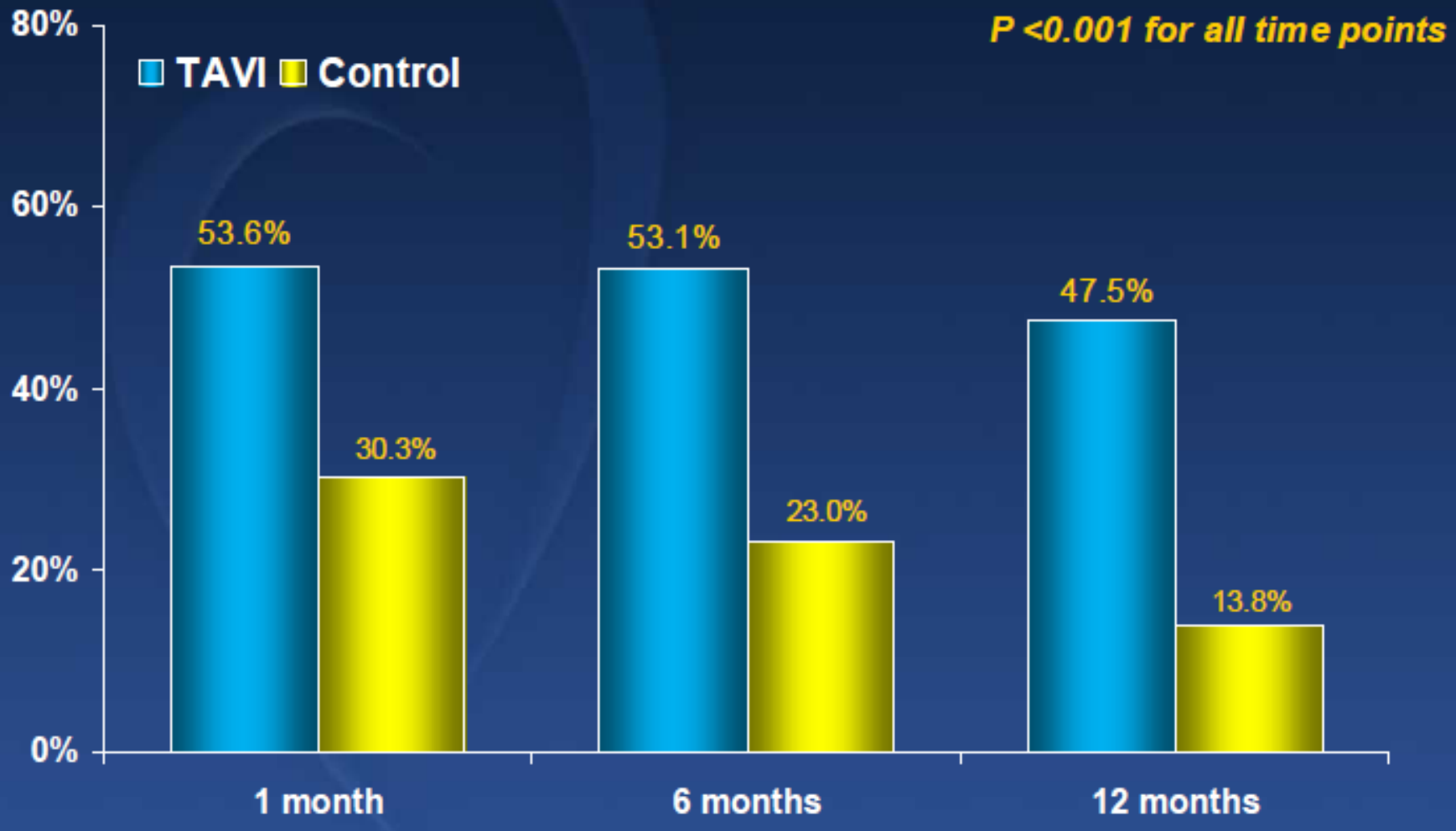
Baseline cardiac variables

- Low left ventricular ejection fraction (<50%)
- Pulmonary hypertension
- Coronary artery disease
- Moderate or severe mitral regurgitation
- Prior acute pulmonary edema

Periprocedural complications

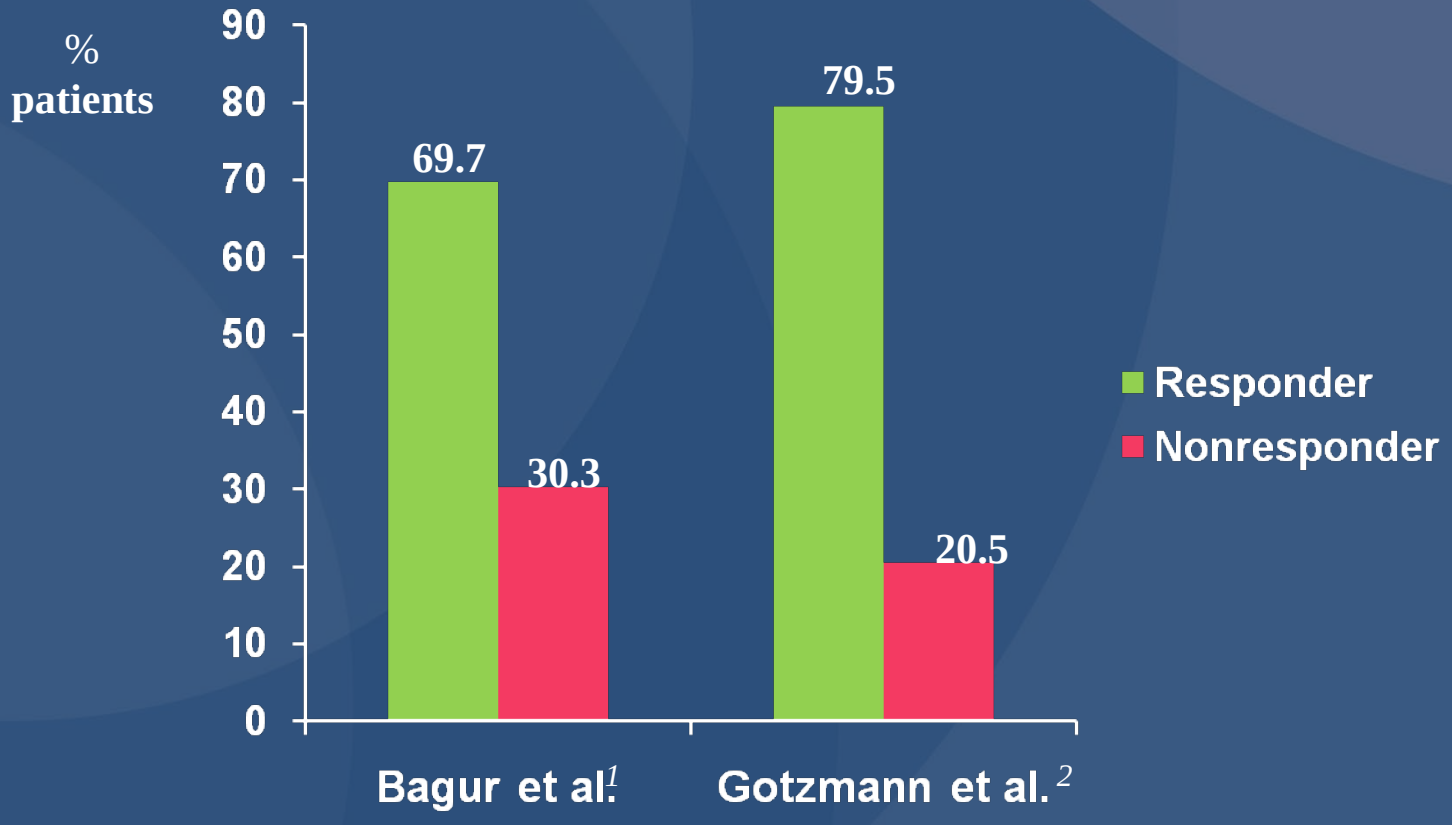
- Acute kidney injury
- Need for hemodynamic support
- Procedural stroke
- Moderate or severe aortic regurgitation (≥2+)

KCCQ-Summary: Favorable Outcome *



*Favorable Outcome = Alive and KCCQ-Summary Score improved = 10 points vs. baseline

Functional Response Following TAVI
"Survival without improvement"



	Bagur et al.[1]	Gotzmann et al.[2]
Functional status assessment	**n=76** Duke Activity Status Index (DASI)	**n=122** NHYA class

1-Bagur et al. Am Heart J 2011; 161:726-34
2-Gotzmann et al. Am Heart J 2011; 0: 1-8e1.

“In judging futility, physicians must distinguish between an effect, which is limited to some part of the patient's body, and a benefit, which appreciably improves the person as a whole. Treatment that fails to provide the latter, whether or not it achieves the former, is "futile".”

Schneiderman, LJ et al. Ann Intern Med 1990

Predictors of poor response to TAVI

	Odds ratio	95%CI	*P* value
***Bagur et al.*[1]**			
Estimated glomerural filtration rate (eGFR)	1.7*	1.3-2.3	0.005
	*for each decrease in eGFR of 10mL/min/m^2		
***Gotzmann et al.*[2]**			
Mitral valve regurgitation (severe)	7.4	2.5-21.81	<0.001
Postprocedural aortic valve regurgitation (moderate and severe)	10.1	3.2-31.9	<0.001

1-Bagur et al. Am Heart J 2011; 161:726-34
2-Gotzmann et al. Am Heart J 2011, in press.

JACC: CARDIOVASCULAR INTERVENTIONS

PUBLISHED BY ELSEVIER INC.

EDITORIAL COMMENT

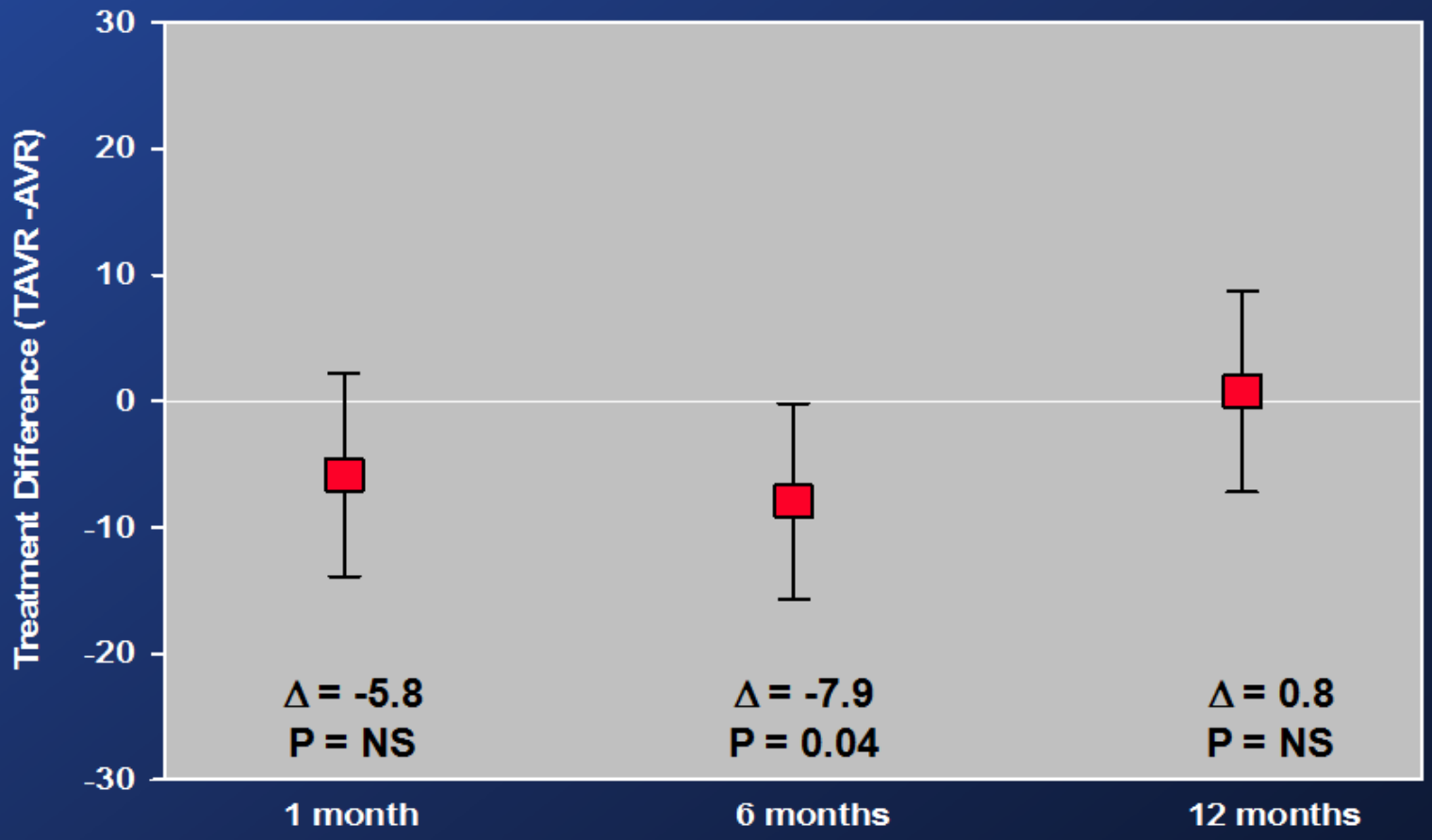
Working Toward a Frailty Index in Transcatheter Aortic Valve Replacement

A Major Move Away From the "Eyeball Test"*

Josep Rodés-Cabau, MD, Michael Mok, MBBS

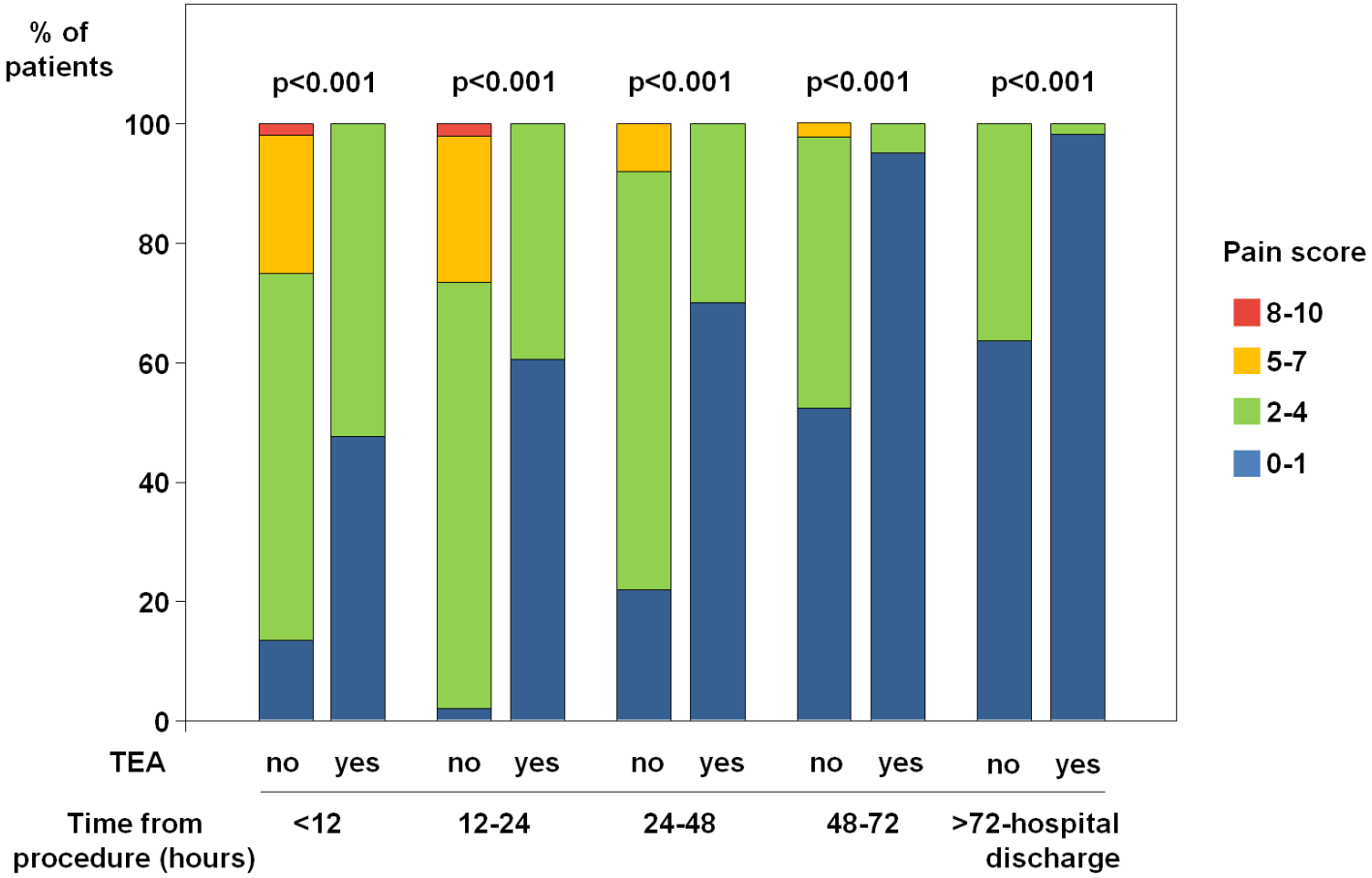
Quebec City, Quebec, Canada

KCCQ Overall Summary (Primary Endpoint)
TA Subgroup



P-values are for mean treatment effect of TAVR vs. AVR

Postoperative pain score at different period times, according to the use of thoracic epidural analgesia (TEA)



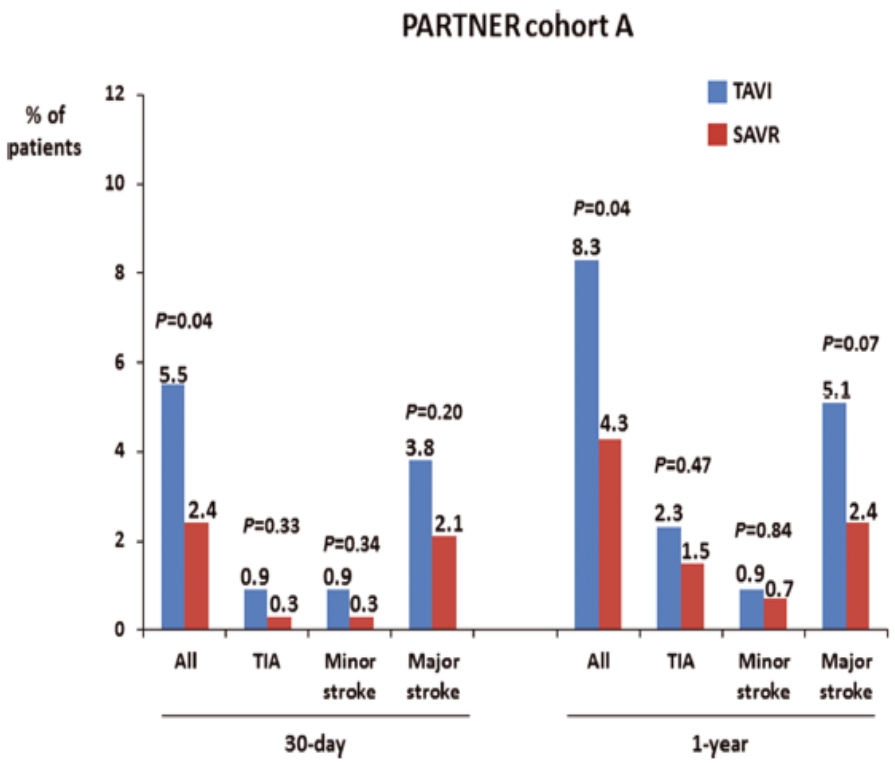
Amat-Santos et al. Heart 2012

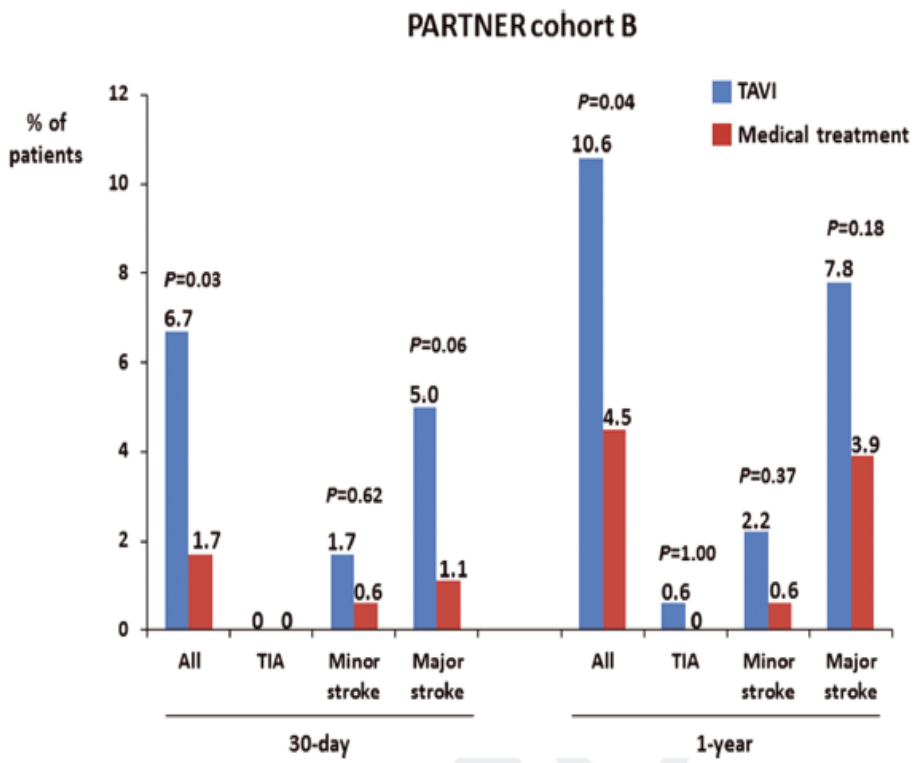
Acute and Late Outcomes of the Propensity Score-Matched Cohort (n=100), according to the use of TEA

Variables	Thoracic Epidural Analgesia NO n=50	Thoracic Epidural Analgesia YES n=50	*p-value*
30-day/in-hospital oucomes			
Orotracheal re-intubation	10 (20.0)	1 (2.0)	0.004
Tracheostomy	5 (10.0)	0	0.056
Pneumonia	8 (16.0)	2 (4.0)	0.046
Sepsis	9 (18.0)	2 (4.0)	0.046
Stroke	3 (6.0)	3 (6.0)	1.00
Myocardial infarction	1 (2.0)	0	0.315
New-onset AF	26 (52.0)	8 (16.0)	<0.001
Hospital Length (days, IQR)	10 (7-16)	8 (7-10)	0.058
30-day death	10 (20.0)	2 (4.0)	0.014
Late (1-year) cumulative outcomes			
Stroke	3 (6.0)	4 (6.0)	1.00
Myocardial infarction	1 (2.0)	0	0.315
Death	15 (30.0)	6 (12.0)	0.026

- Mortality rate at 1- and 2-year follow-up
- Cerebrovascular events
- Aortic regurgitation

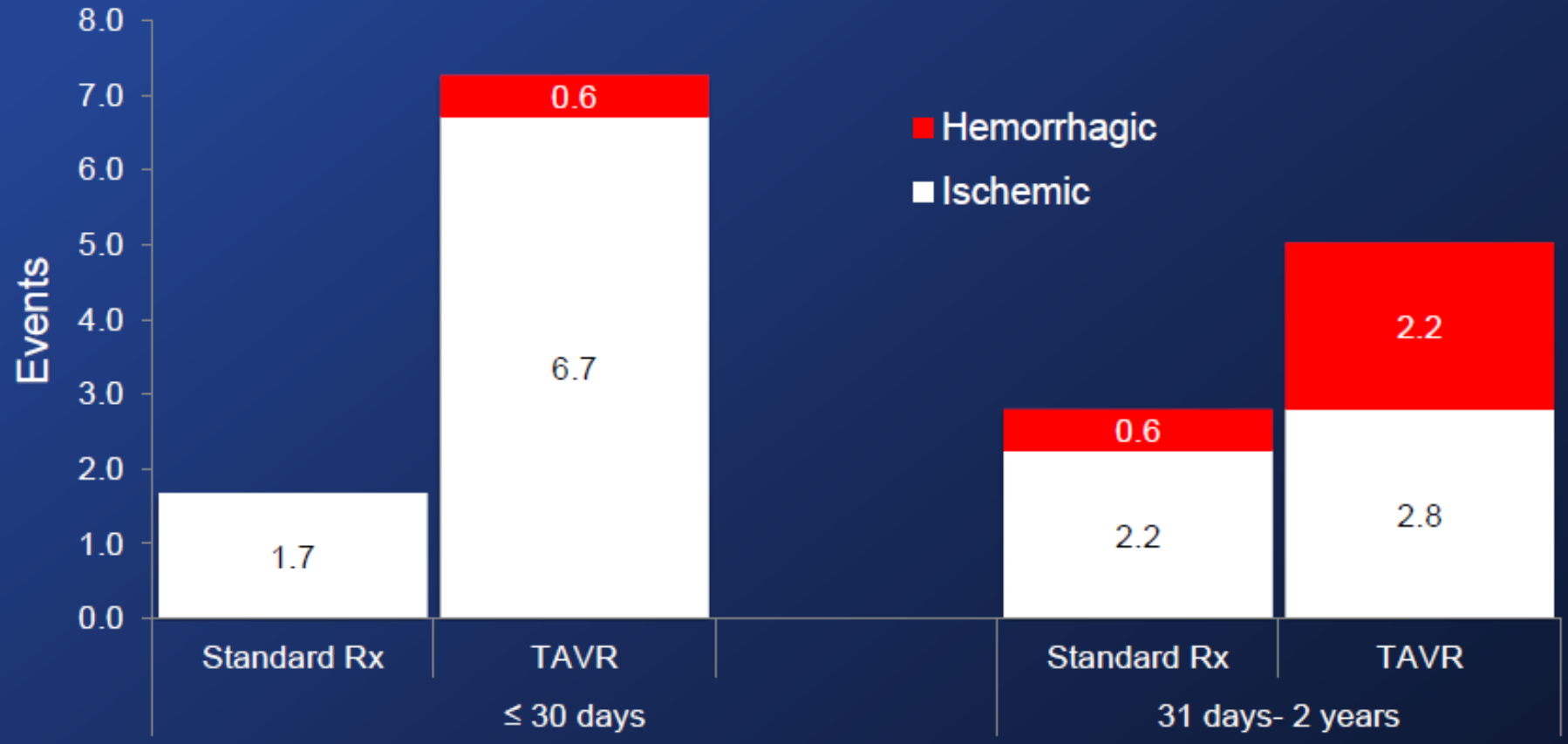
PARTNER trial / Cerebrovascular Events





Leon et al. N Engl J Med 2010
Smith et al. N Engl J Med 2011

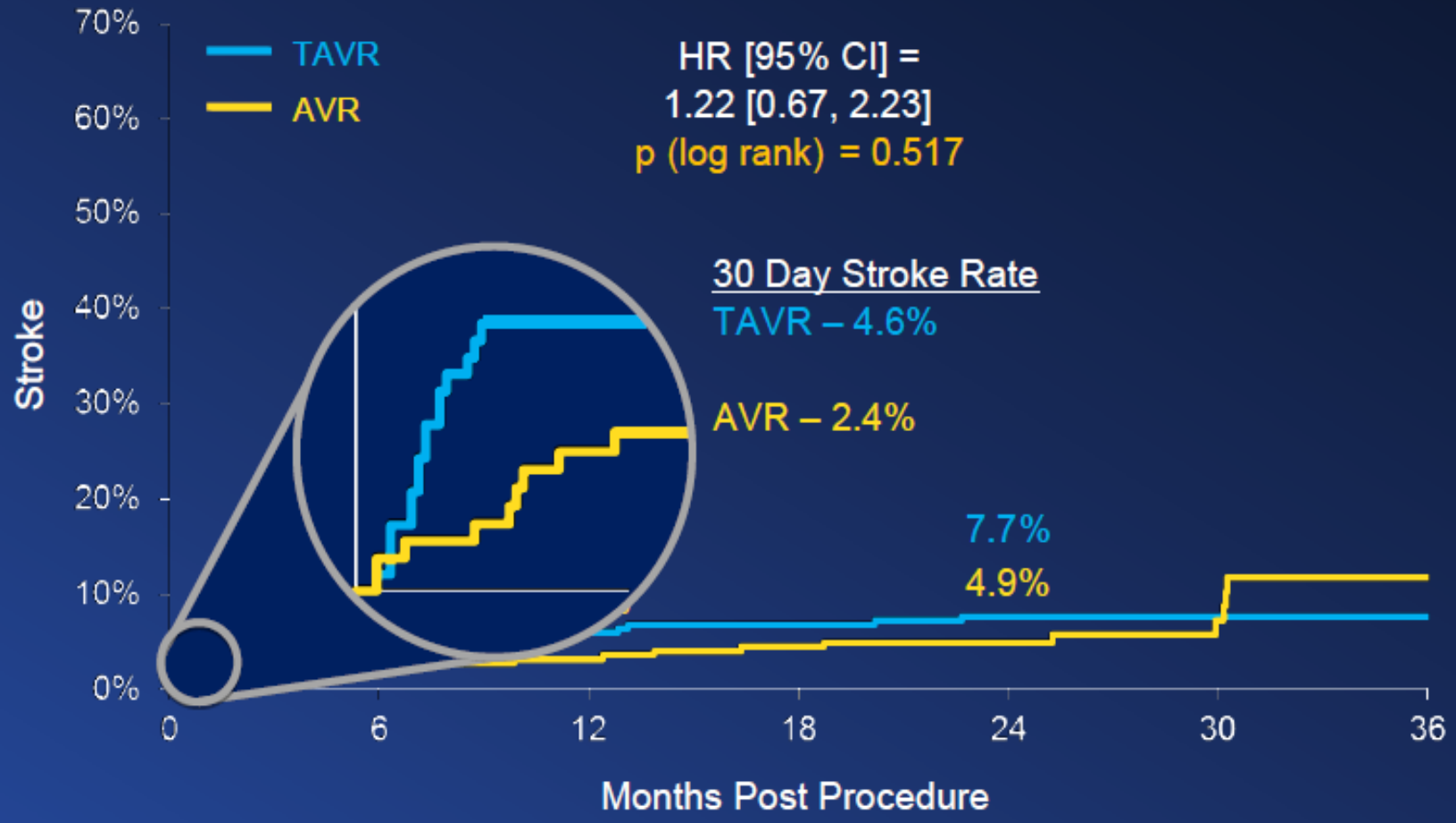
All Strokes (%)



Note: Percents are of patients in the trial (n/179).

	≤ 30 Days	*31 Days – 2 Years*
All Stroke	**p=0.010**	**P=0.319**
Ischemic Stroke	p = 0.017	p = 0.437
Hemorrhagic Stroke	p = 0.316	p = 0.160

Strokes (ITT)



Numbers at Risk

TAVR	348	287	249	224	162	65	28
AVR	351	246	230	211	160	62	31

Incremental risk factors for neurologic events

THE PARTNER TRIAL

Late constant hazard phase

Risk Factor	*Coefficient ± SD*	*P*	*R (%)*
Constant hazard phase			
TAVR	0.40±0.43	0.4	22
(Higher) NYHA	0.95±0.40	.02	75
Stroke or TIA within 6-12 mo	1.93±0.64	.002	60
Non-TF TAVR candidate	2.3±0.45	<.0001	96
History of PCI (less risk)	-1.60±0.63	.01	77
COPD (less risk)	-1.06±0.47	.03	79

Miller C. JTCS 2011

R(%) = bagging reliability

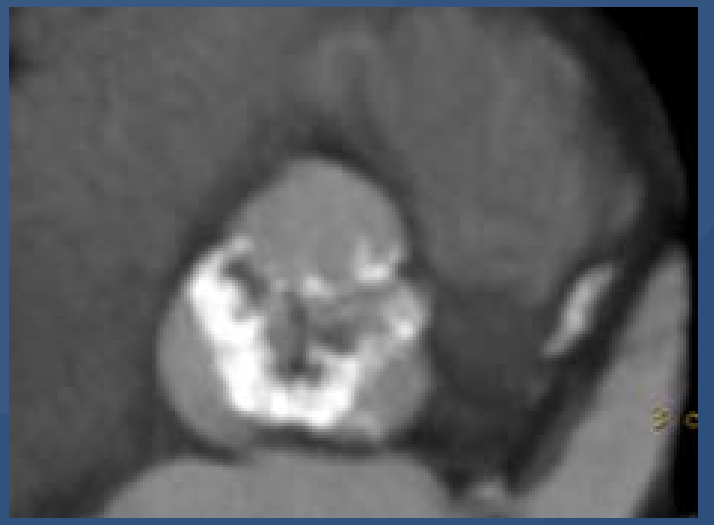
Incremental risk factors for neurologic events

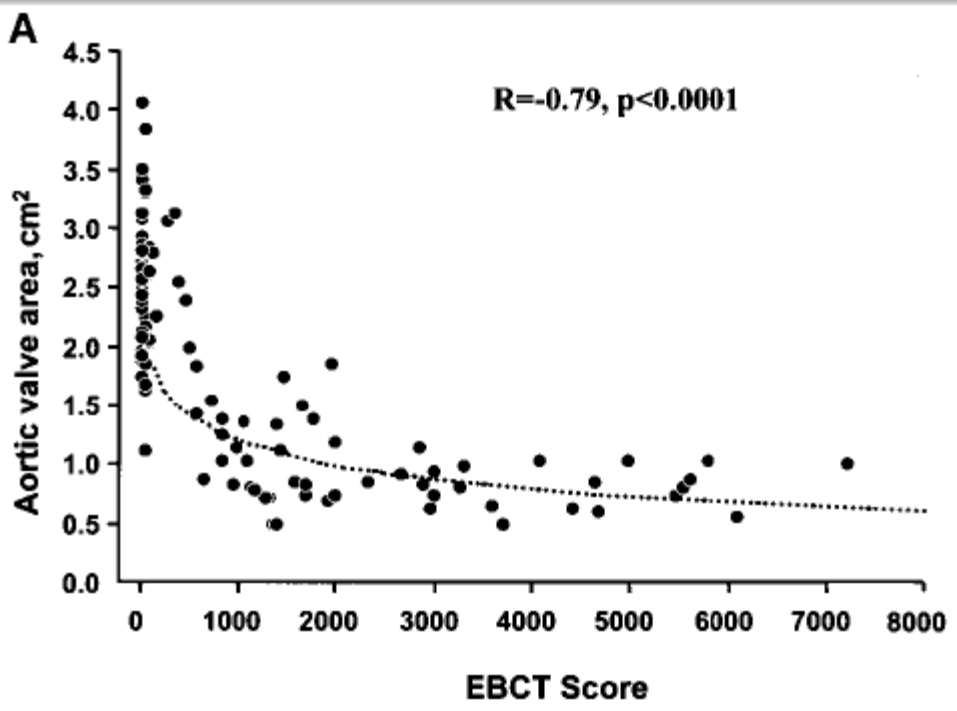
Early high peaking hazard phase

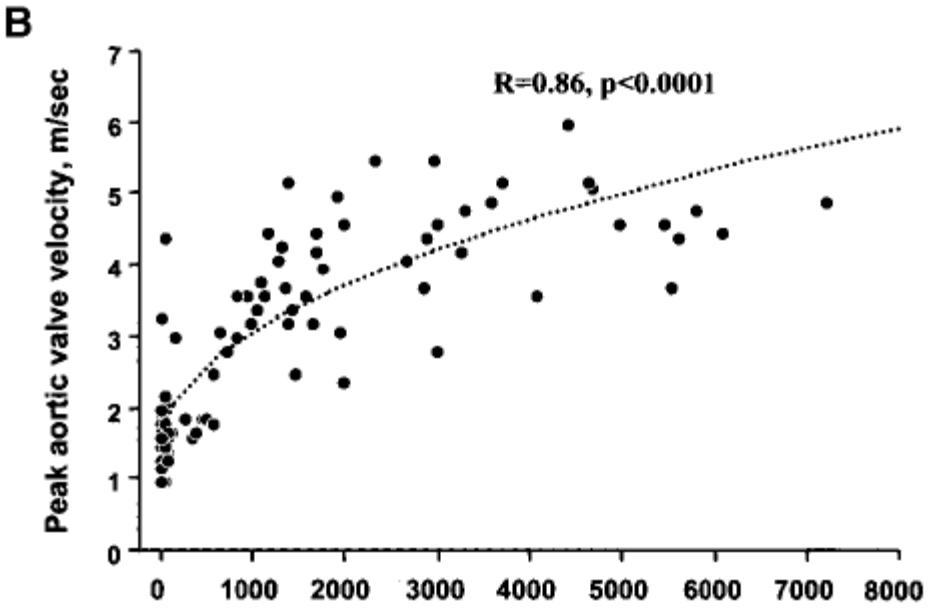
Risk Factor	Coefficient ± SD	P	R (%)
Early hazard phase			
TAVR	2.21±0.68	.001	59
Smaller AVA index in TAVR group	-11.8±5.1	.02	57

Miller C. JTCS 2012

R(%) = bagging reliability

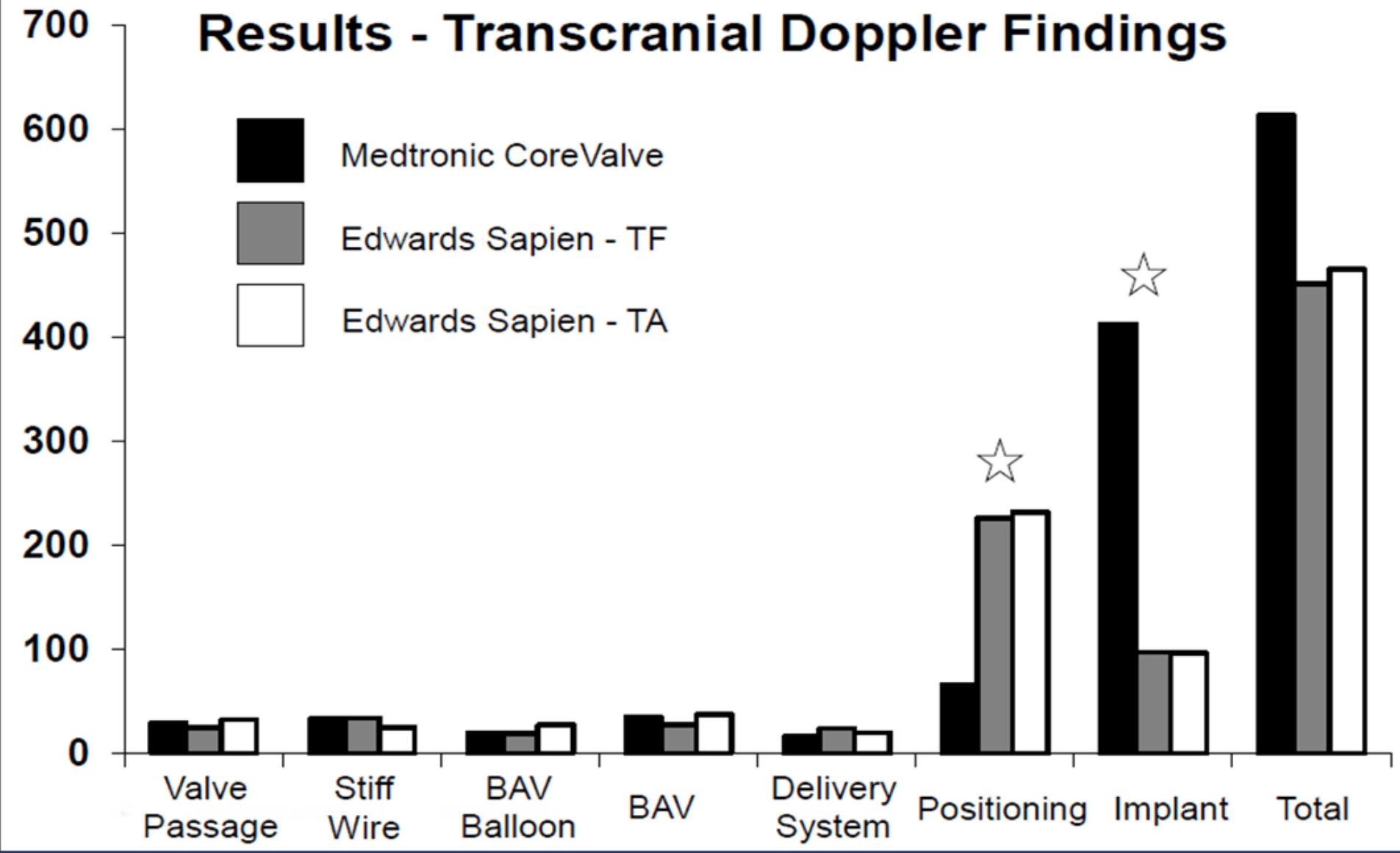






Messika-Zeitoun et al. Circulation 2004

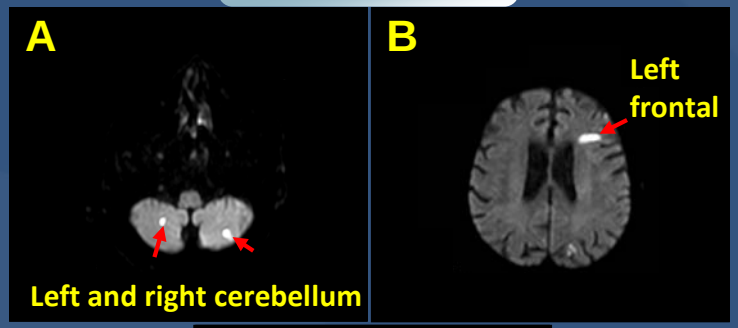
Results - Transcranial Doppler Findings

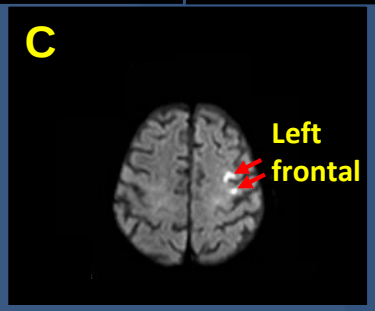


Kahlert et al. AHA Scientific Sessions 2010

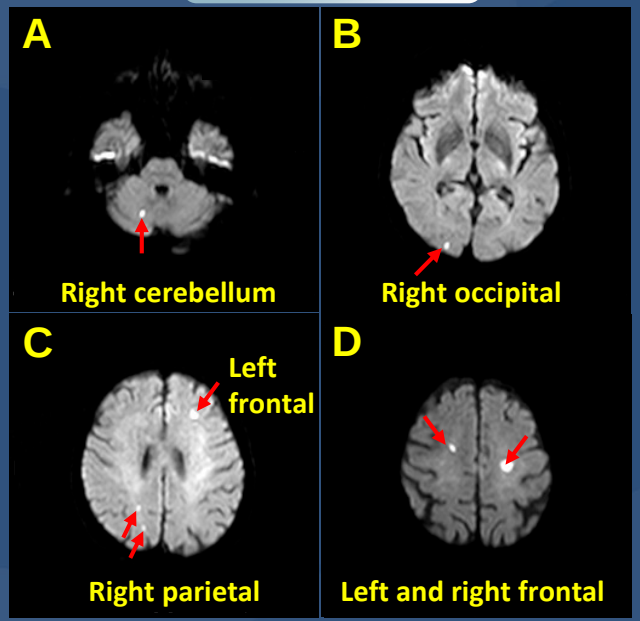
DW-MRI Results Post-TAVI

TA-TAVI

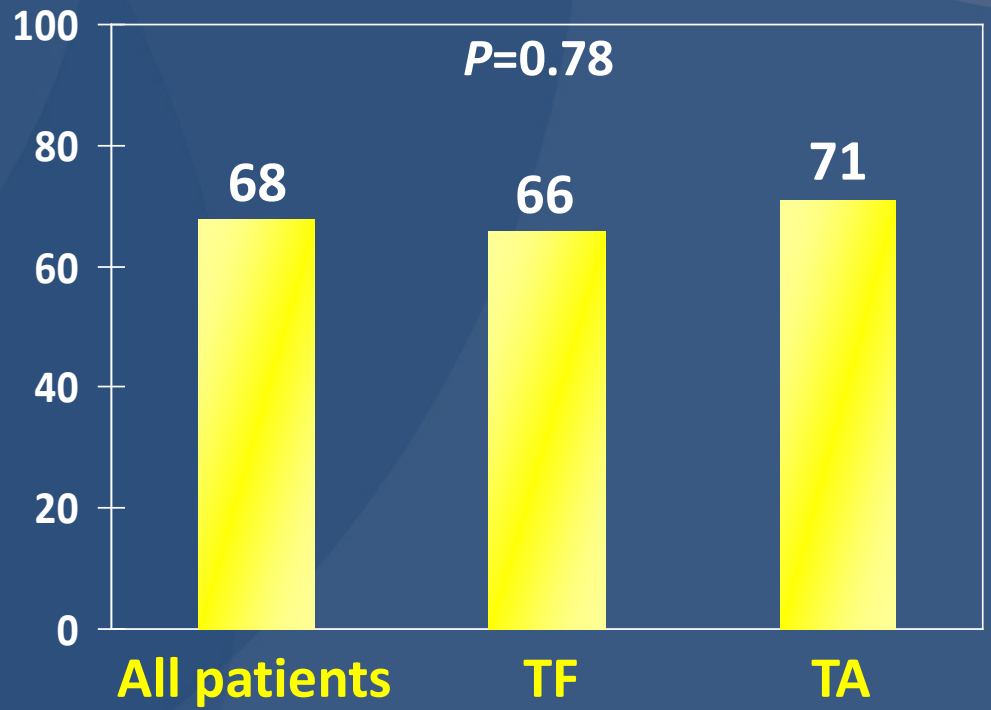




TF-TAVI

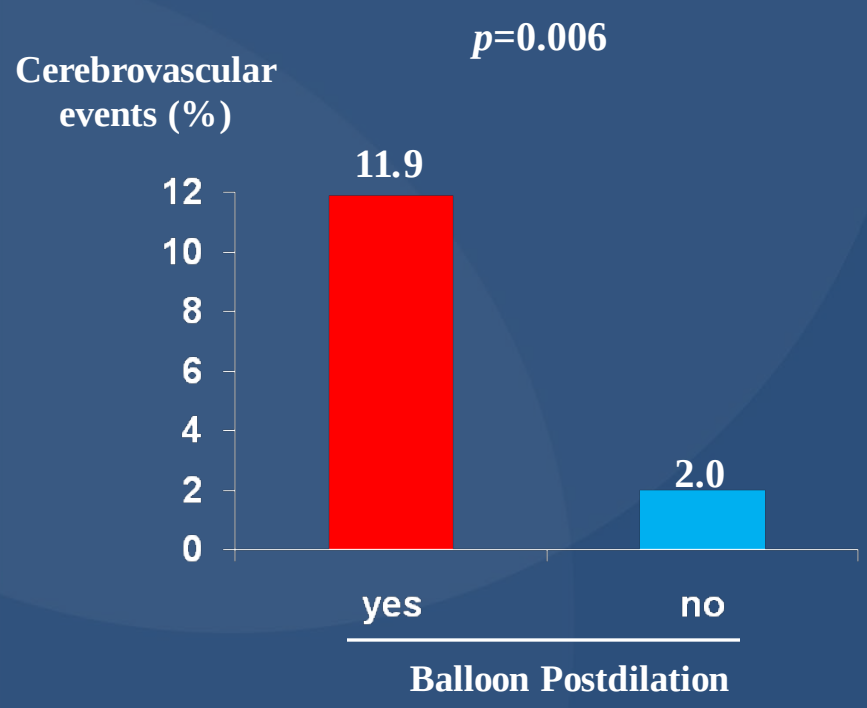


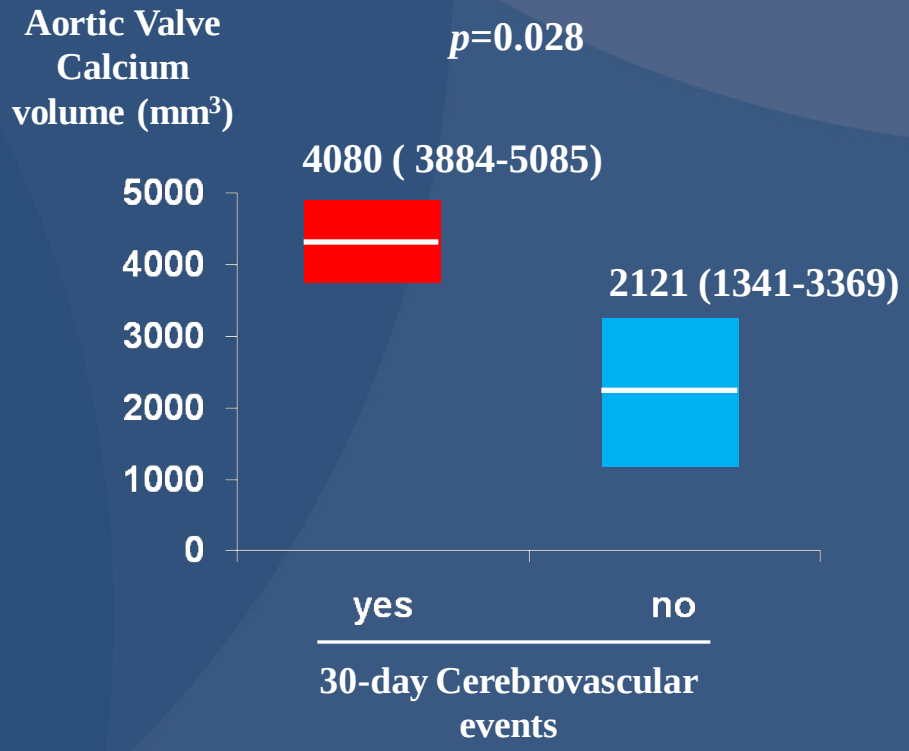
Patients with new lesions (%)



Rodés-Cabau et al. JACC 2011

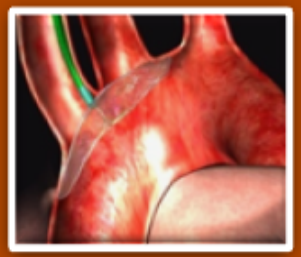
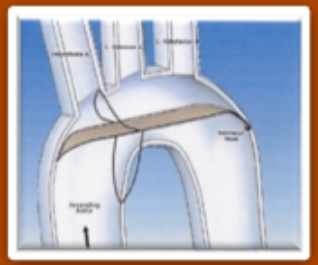
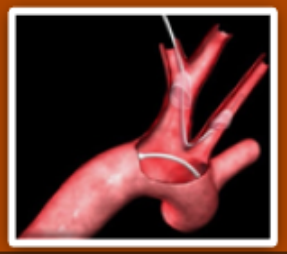
TAVI (n=209) / 30-Day Cerebrovascular Events





Nombela-Franco et al. JACC Intv 2012

EMBOLIC PROTECTION DEVICES

Feature	Embrella	SMT	Claret Medical
			
Access	Radial	Femoral	Radial
Position	Aorta	Aorta	Brachiocephalic Left Common Carotid
Coverage Area	Brachiocephalic & LCC	Brachiocephalic & LCC & LSC	Brachiocephalic & LCC
Mechanism	Deflection	Deflection	Capture
Size	6F	9F	6F
Pore Size	100 microns	~200 microns	140 microns

First-in-man use of a novel embolic protection device for patients undergoing transcatheter aortic valve implantation

Christoph K. Naber[1]*, MD; Alexander Ghanem[2], MD; Alexander A. Abizaid[3], MD; Alexander Wolf[4], MD; Jan-Malte Sinning[2], MD; Nikos Werner[2], MD; Georg Nickenig[2], MD, PhD; Thomas Schmitz[1], MD; Eberhard Grube[2], MD

1. Contilia Heart- and Vascular Center, Elisabeth Krankenhaus Essen, Essen, Germany; 2. Department of Medicine / Cardiology, University of Bonn, Bonn, Germany; 3. Institute Dante Pazzanese of Cardiology São Paulo, São Paulo, Brazil

C.K. Naber and A. Ghanem contributed equally to this work.

KEYWORDS

- TAVI
- aortic stenosis
- aortic valve disease
- embolic protection device

Abstract

Aims: We describe the first-in-human experience with a novel cerebral embolic protection device used during transcatheter aortic valve implantation (TAVI). One current challenge of TAVI is the reduction of procedural stroke. Procedural mobilisation of debris is a known source of cerebral embolisation. Mechanical protection by transient filtration of cerebral blood flow might reduce the embolic burden during TAVI. We aimed to evaluate the feasibility and safety of the Claret CE Pro™ cerebral protection device in patients undergoing TAVI.

Methods and results: Patients scheduled for TAVI were prospectively enrolled at three centres. The Claret CE Pro™ (Claret Medical, Inc. Santa Rosa, CA, USA) cerebral protection device was placed via the right radial/brachial artery prior to TAVI and was removed after the procedure. The primary endpoint was technical success rate. Secondary endpoints encompassed procedural and 30-day stroke rates, as well as device-related complications. Deployment of the Claret CE Pro™ cerebral protection device was intended for use in 40 patients, 35 devices were implanted into the aortic arch. Technical success rate with delivery of the proximal and distal filter was 60% for the first generation device and 87% for the second-generation device. Delivery times for the first-generation device were 12.4±12.1 minutes and 4.4±2.5 minutes for the second-generation device ($p<0.05$). The quantity of contrast used related to the Claret CE Pro System was 19.6±3.8 ml. Captured debris was documented in at least 19 of 35 implanted devices (54.3%). No procedural transient ischaemic attacks, minor strokes or major strokes occurred. Thirty-day follow-up showed one minor stroke occurring 30 days after the procedure, and two major strokes both occurring well after the patient had completed TAVI.

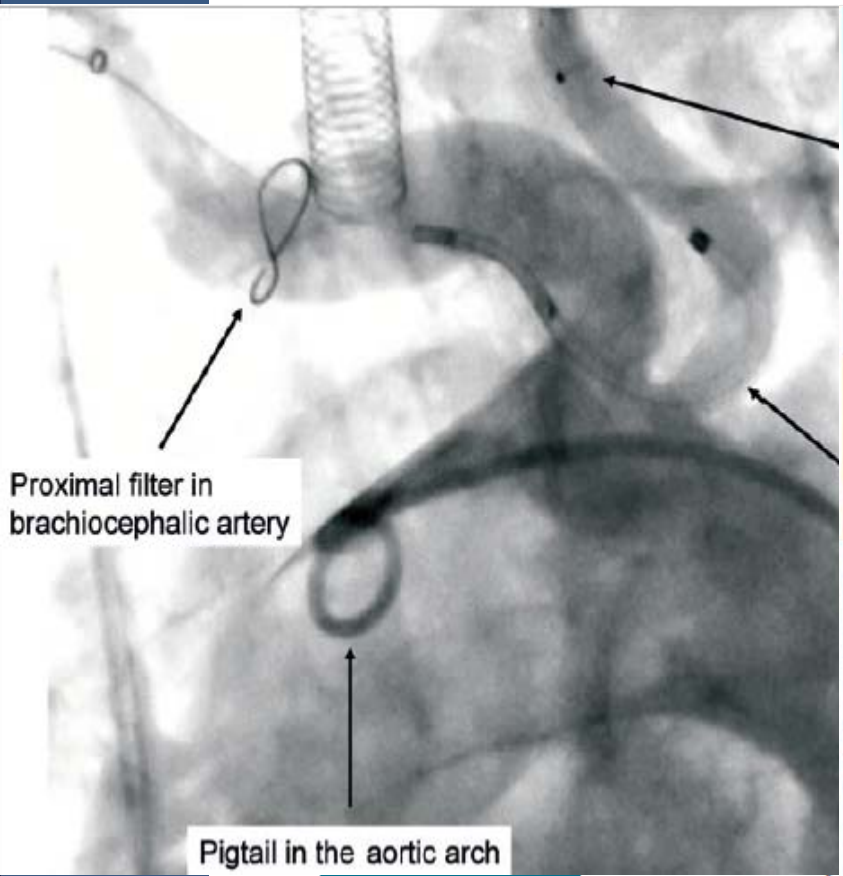
Conclusions: The use of the Claret CE Pro™ system is feasible and safe. Capture of debris in more than half of the patients provides evidence for the potential to reduce the procedural cerebral embolic burden utilising this dedicated filter system during TAVI.

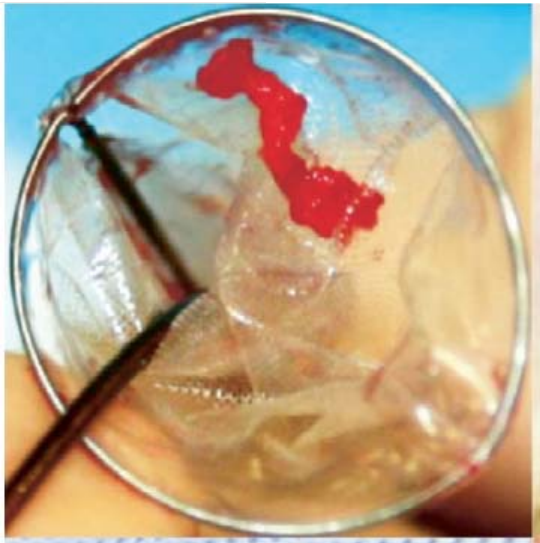
First-in-man use of a novel embolic protection device for patients undergoing transcatheter aortic valve implantation

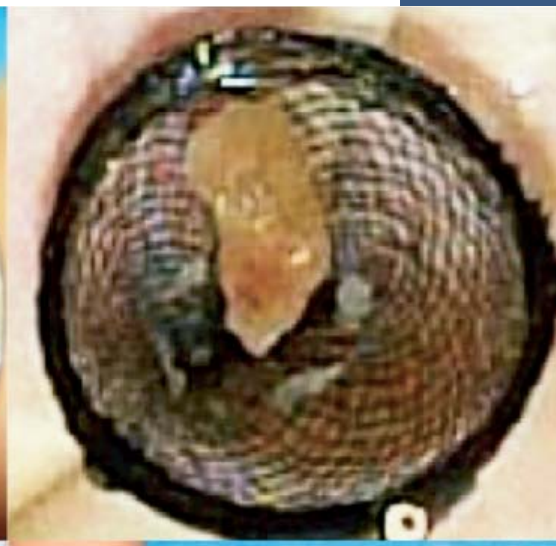
Christoph K. Naber[1]*, MD; Alexander Ghanem[2], MD; Alexander A. Abizaid[3], MD; Alexander Wolf[1], MD; Jan-Malte Sinning[2], MD; Nikos Werner[2], MD; Georg Nickenig[2], MD, PhD; Thomas Schmitz[1], MD; Eberhard Grube[2], MD

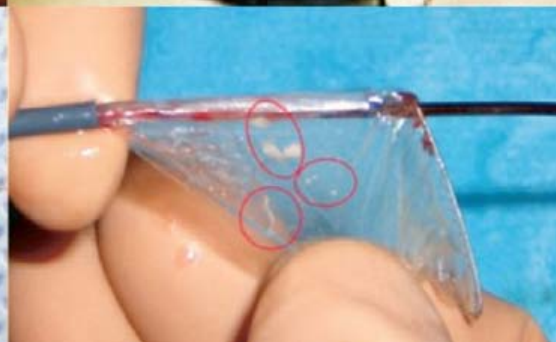
1. Contilia Heart- and Vascular Center, Elisabeth Krankenhaus Essen, Essen, Germany; 2. Department of Medicine / Cardiology, University of Bonn, Bonn, Germany; 3. Institute Dante Pazzanese of Cardiology São Paulo, São Paulo, Brazil

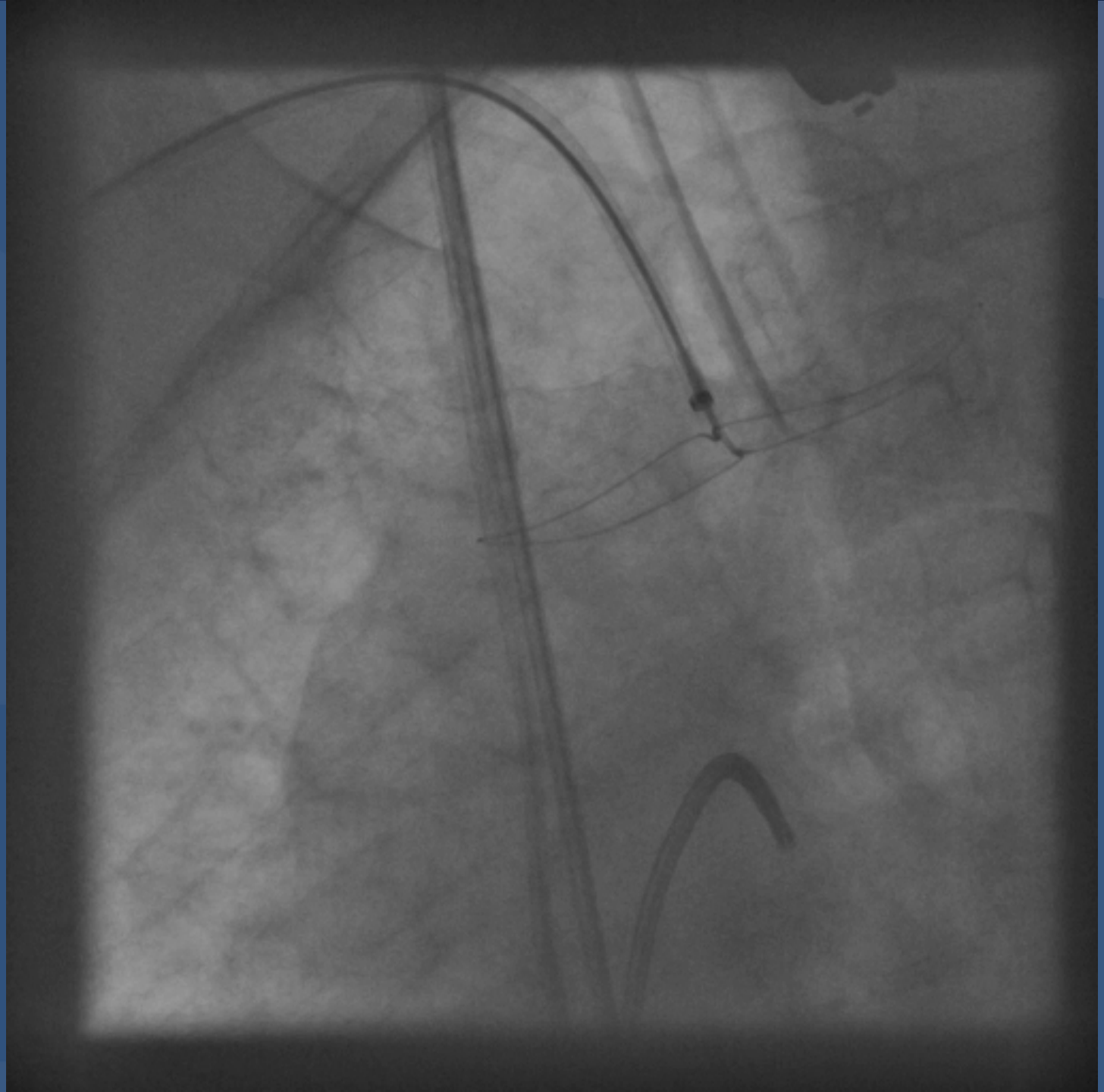
C.K. Naber and A. Ghanem contributed equally to this work.





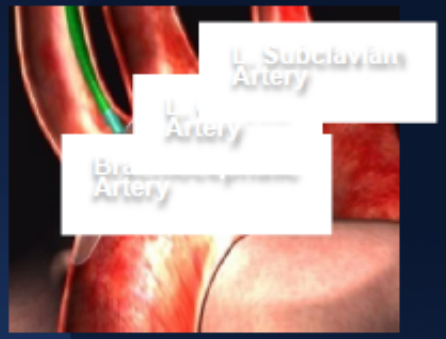






PROTAVI

Prospective Randomized Outcome study in patients undergoing TAVR to Examine Cerebral Ischemia and Bleeding Complications



Symptomatic AS eligible TAVR per label

First Randomization

Procedural Phase

Standard TAVI

Standard TAVI + Deflection

Primary Endpoint: Rate of new DW-MRI brain lesions at 7 days

Second Randomization

Atrial fibrillation requiring Anticoag?

Dual antiplatelet

Single antiplatelet

Post-procedural Phase

Secondary Endpoint: Composite all neuro events + bleeding at 1 year

Afib Registry

Transcatheter Valve Therapies (TVT)
With LAA Occlusion Therapies

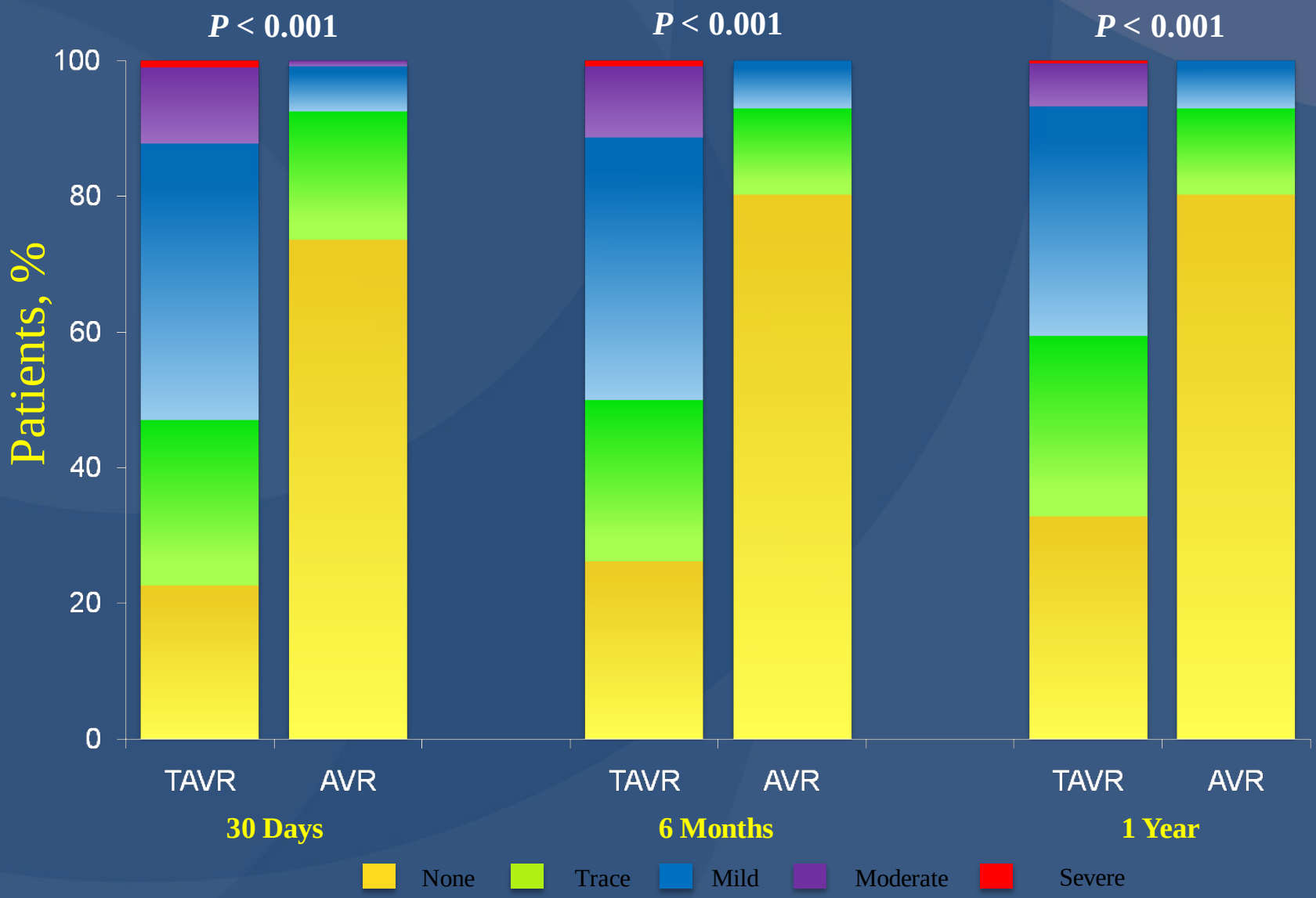
- Mortality rate at 1- and 2-year follow-up
- Cerebrovascular events
- Aortic regurgitation

Echo Findings
Hemodynamic Assessments

	30 Days			1 Year		
Finding	*TAVR*	*AVR*	*p-value*	*TAVR*	*AVR*	*p-value*
AVG – 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
LVEF - %	55.5 ± 11.4	56.0 ± 11.4	0.63	56.6 ± 10.5	57.1 ± 10.3	0.64

Smith et al. N Engl J Med 2011

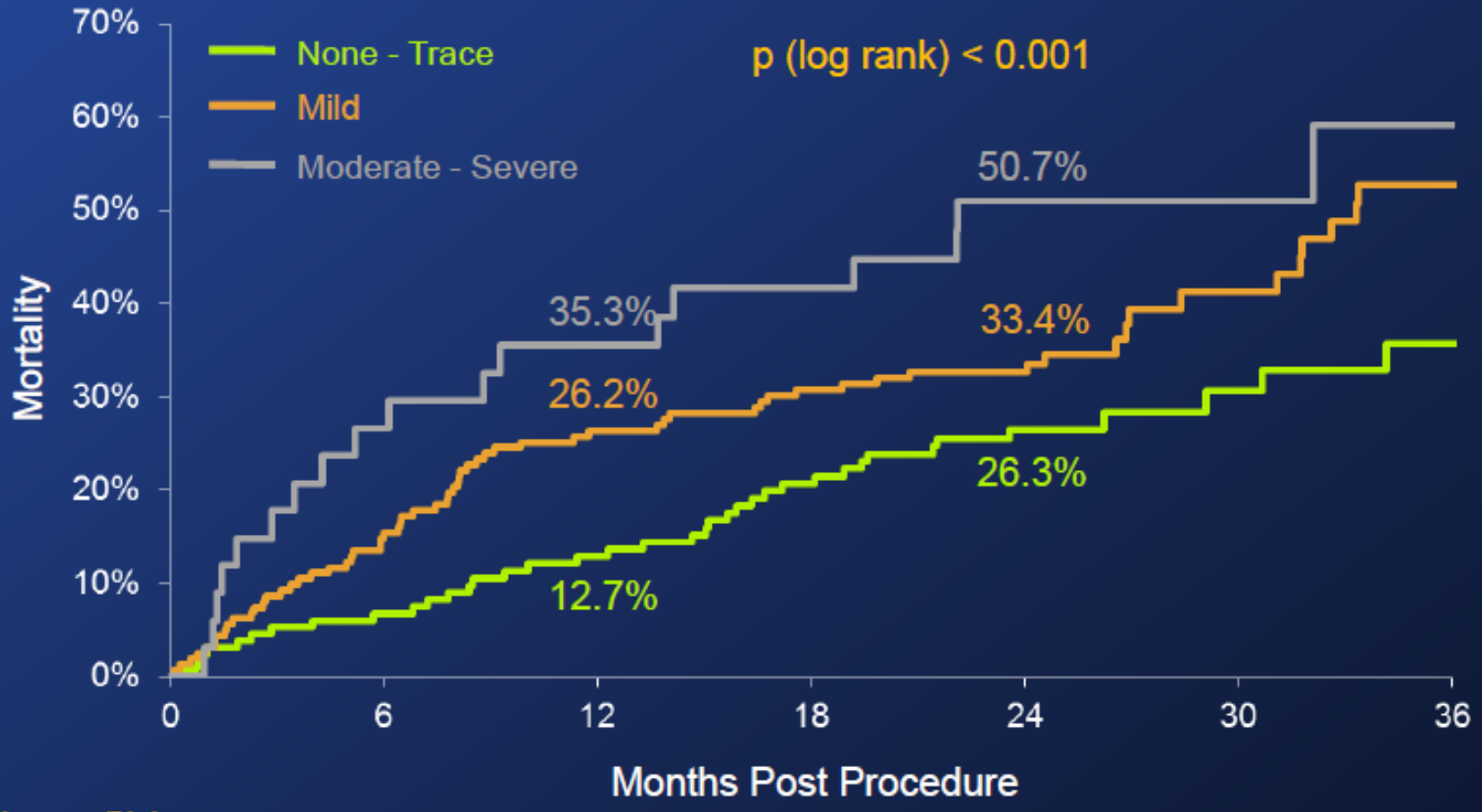
Paravalvular Aortic Regurgitation



PVL after TAVR Predicts Increased Mortality

Author (journal)	# patients	TAVR Type	Predicts mortality
Abdel-Wahab (Heart 2011)	690	MCV 84% ES 16%	≥ 2/4 - mortality in-hospital
Tamburino (Circulation 2011)	603	MCV 100%	≥ 2/4 - mortality 30 days – 1 year
Gotzman (AHJ 2011)	145	MCV 100%	≥ Mod - mortality @ 6 mos
Moat (JACC 2011)	870	MCV 52% ES 48%	≥ Mod - mortality @ 1 year

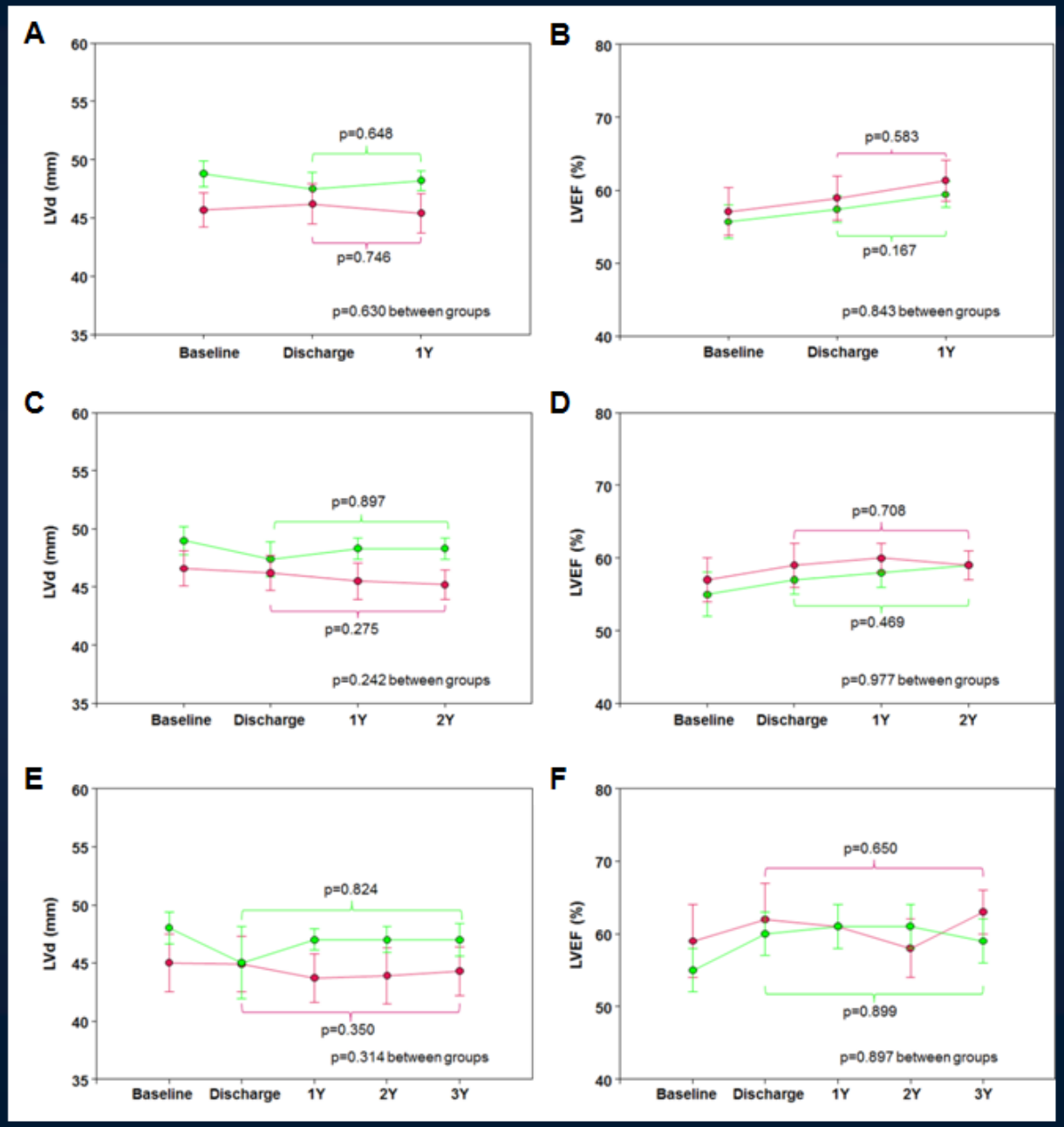
Total AR and Mortality
TAVR Patients (AT)



Numbers at Risk

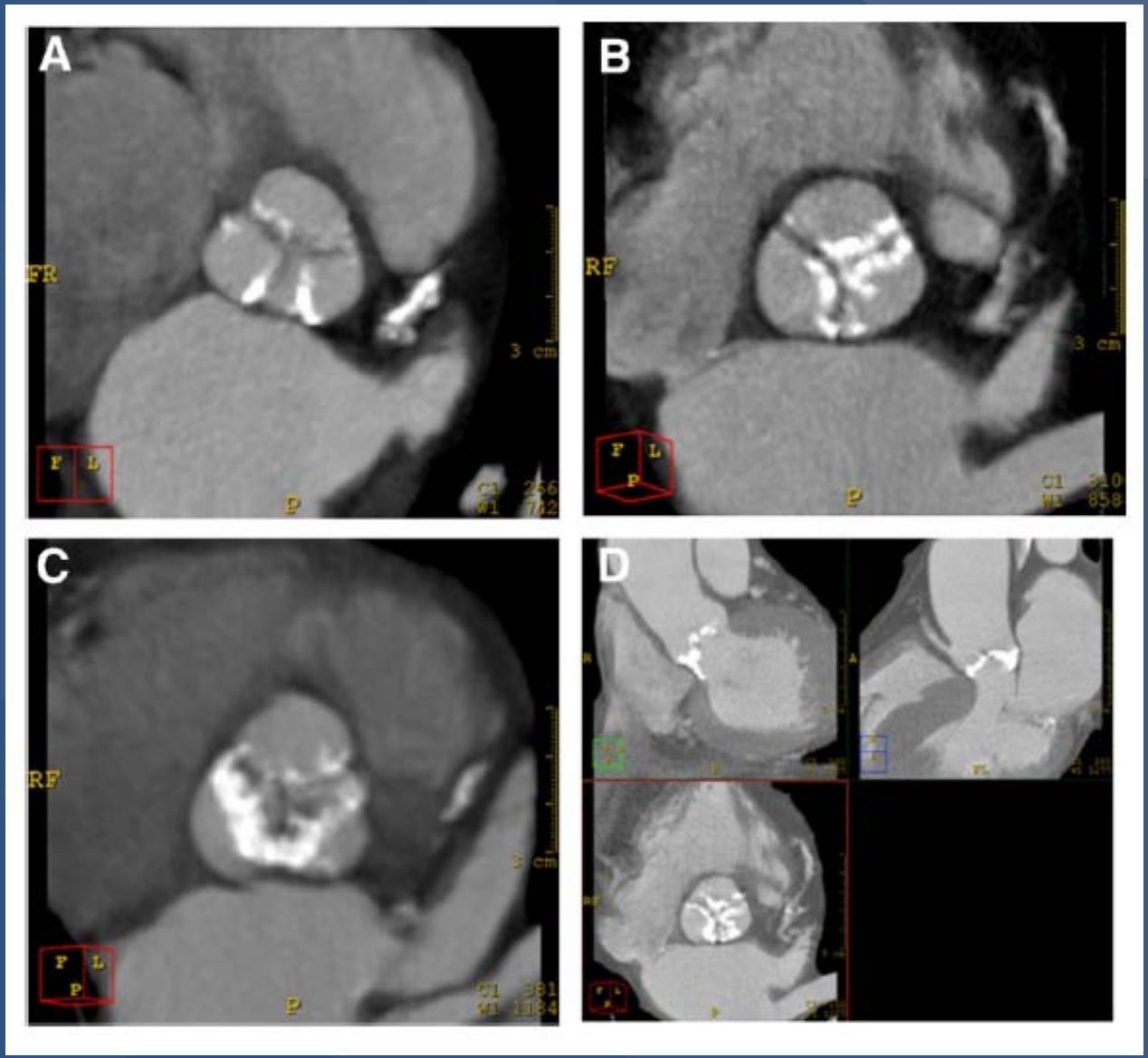
None-Tr	135	125	115	101	68	31	11
Mild	165	139	121	111	71	33	16
Mod-Sev	34	25	22	19	15	6	2

Mild Aortic Regurgitation and LV Changes Over Time



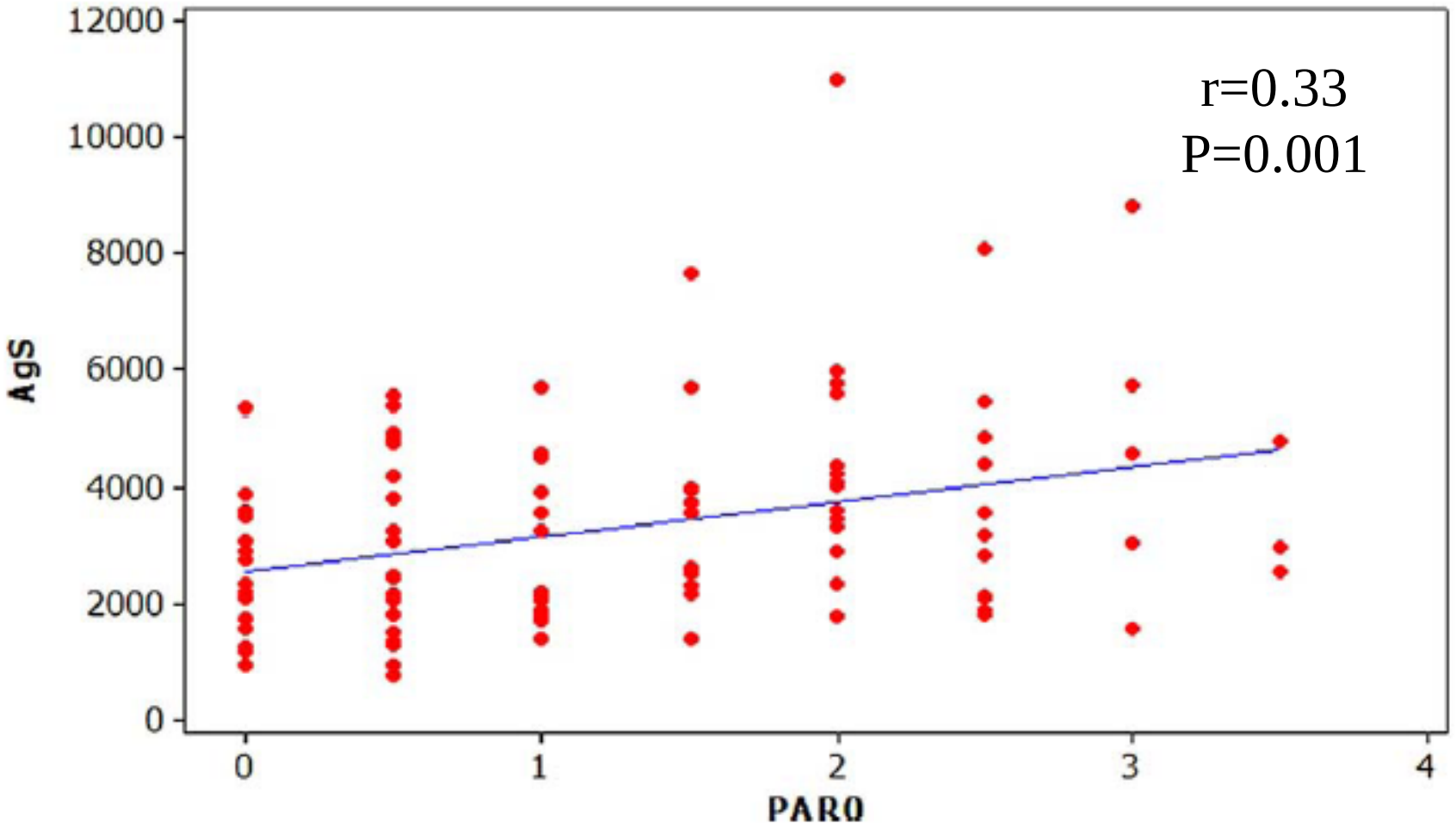
Rodés-Cabau et al.
ACC 2012

The DLZ calcification score



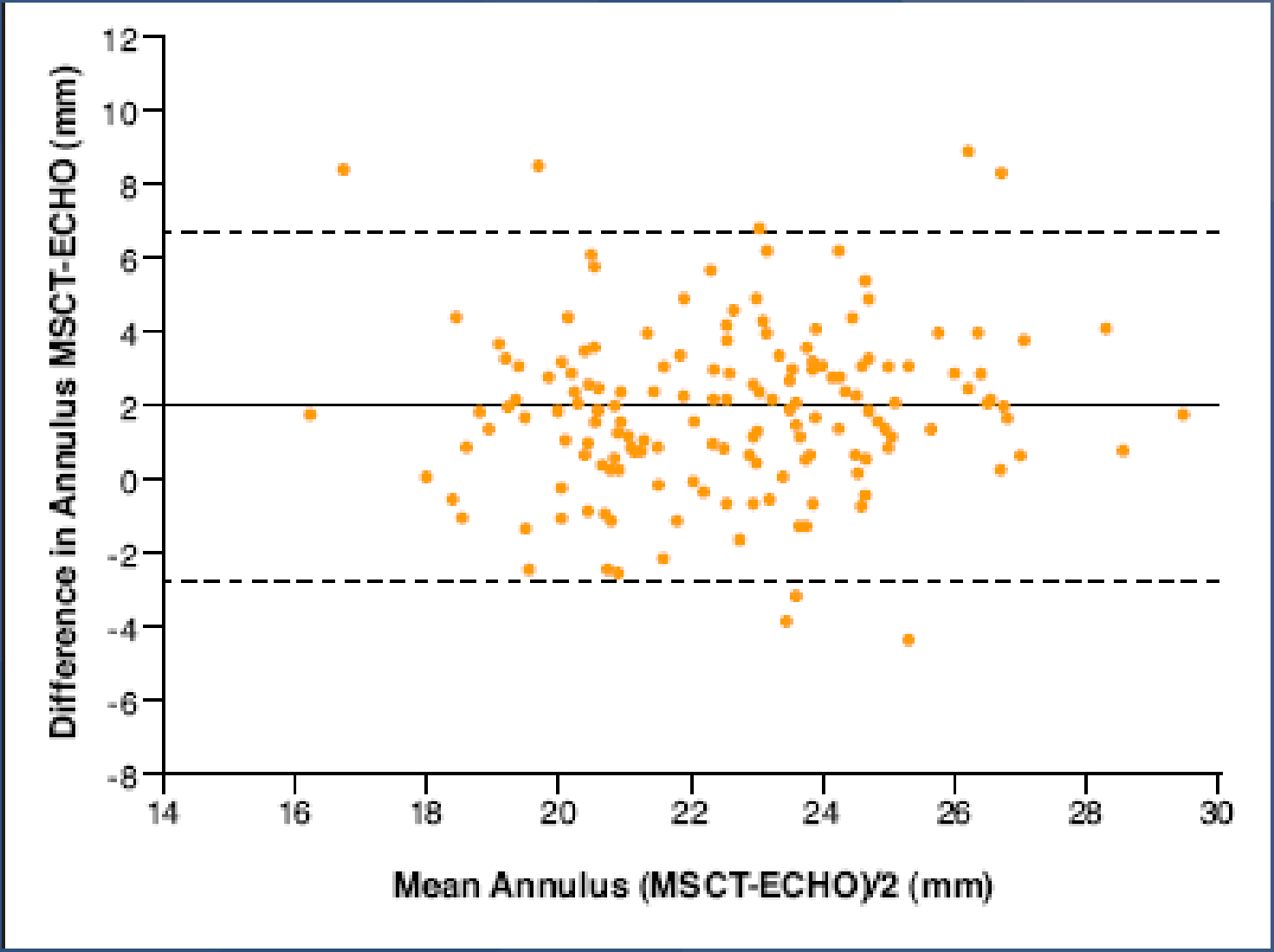
John et al, J Am Coll Cardiol Intv, 2010

Relationship between AgS and PAR after device release



John et al, J Am Coll Cardiol Intv, 2010

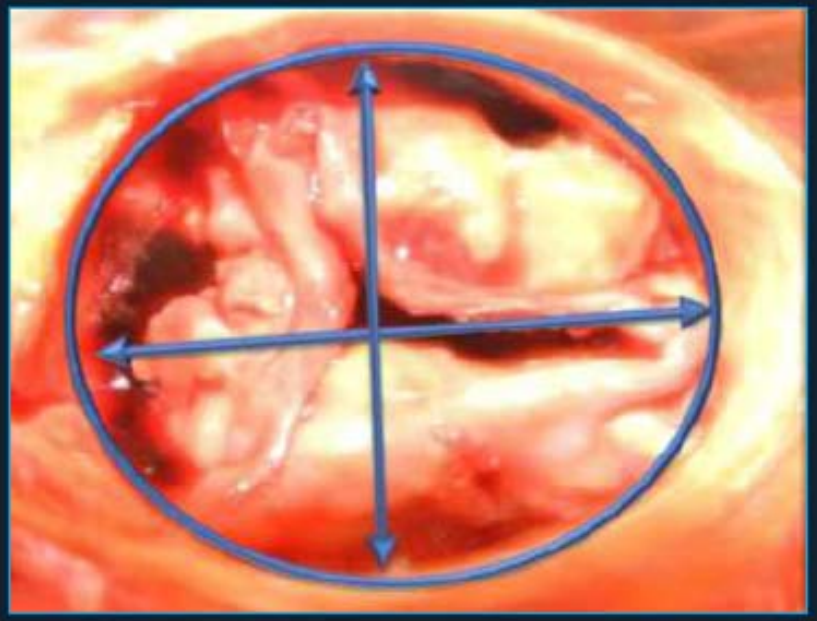
Agreement between MSCT and echocardiography



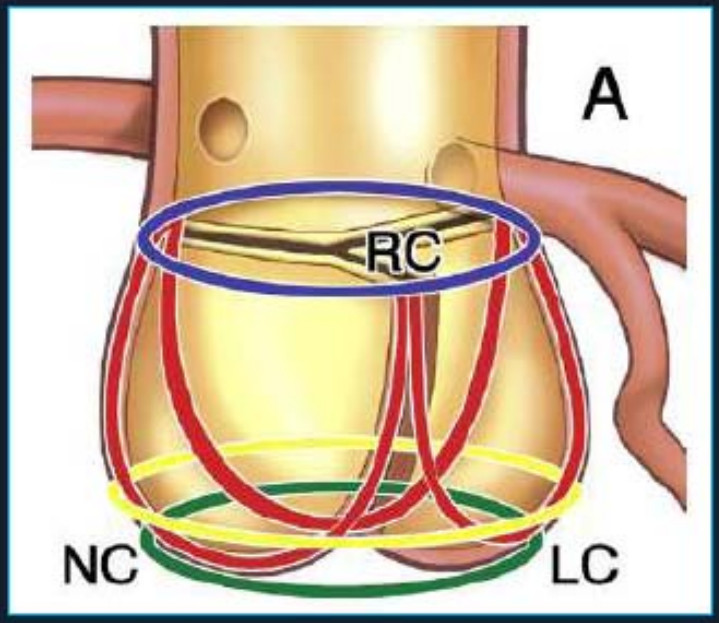
Tops et al, J Am Coll Cardiol Img, 2008

Adjunctive Imaging during TAVR

Measurement of Annulus Dimensions



The native annulus is oval-shaped, 2D measurements assuming a circular shape are problematic



Measurements should be taken at the "hinge-point" of the valve (below the true annulus)

CTA Imaging and PVL

Cross-Sectional Computed Tomographic Assessment Improves Accuracy of Aortic Annular Sizing for Transcatheter Aortic Valve Replacement and Reduces the Incidence of Paravalvular Aortic Regurgitation

Hasan Jilaihawi, BSc (Hons), MBChB,* Mohammad Kashif, MD,* Gregory Fontana, MD,† Azusa Furugen, MD, PhD,* Takahiro Shiota, MD,* Gerald Friede, BS, MS,* Rakhee Makhija, MD,* Niraj Doctor, MBBS,* Martin B. Leon, MD,‡ Raj R. Makkar, MD*

Los Angeles, California; and New York, New York

METHODS:

- Comparison of cross-sectional 3D-MSCT vs. 2D-TEE to measure aortic annular for THV sizing

RESULTS:

- 3D-MSCT highest discriminatory value for predicting PVL
- Prospective 3D-MSCT (cw 2D-TEE) valve sizing reduced post-TAVR mod-severe PVL (7.5% vs. 21.9%, p=0.045)

Jilaihawi et al. J Am Coll Cardiol 2012; 59: on-line

CTA Imaging and PVL

3-Dimensional Aortic Annular Assessment by Multidetector Computed Tomography Predicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

A Multicenter Retrospective Analysis

Alexander B. Willson, MBBS, MPH,* John G. Webb, MD,* Troy M. LaBounty, MD,† Stephan Achenbach, MD,‡ Robert Moss, MBBS,* Miriam Wheeler, MBBS,* Christopher Thompson, MD,* James K. Min, MD,† Ronen Gurvitch, MBBS,* Bjarne L. Norgaard, MD,§ Cameron J. Hague, MD,* Stefan Toggweiler, MD,* Ronald Binder, MD,* Melanie Freeman, MBBS,* Rohan Poulter, MBBS,* Steen Poulsen, MD,§ David A. Wood, MD,* Jonathon Leipsic, MD*

Vancouver, Canada; Los Angeles, California; Giessen, Germany; and Aarhus, Denmark

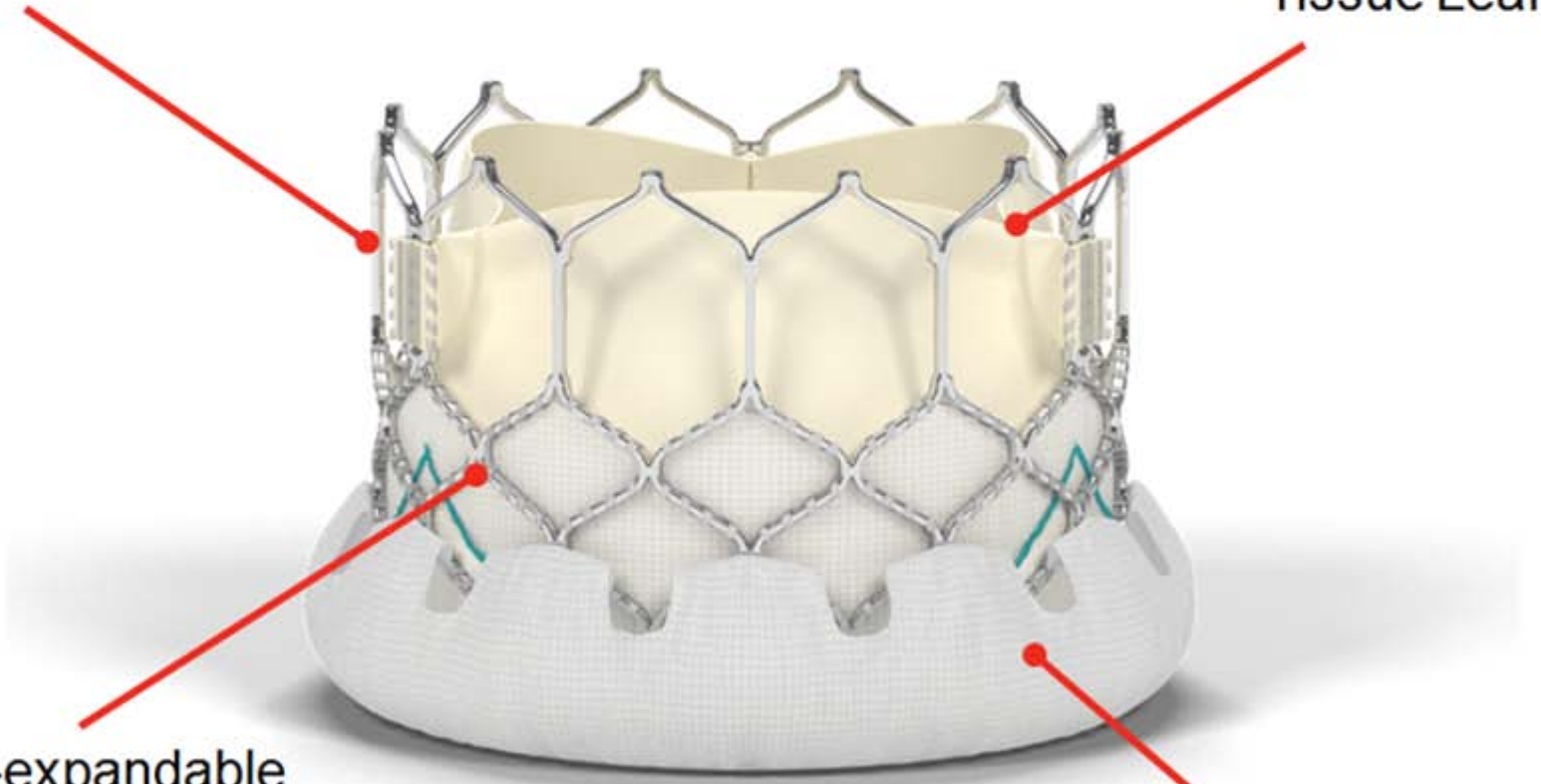
CONCLUSIONS:

- **MSCT derived 3D-annular measurements predicts mod-severe PVL after TAVR; 35.3% cases undersized valve based on MSCT**
- **Oversizing THV size using 3D-MSCT will reduce mod-severe PVL**

SAPIEN 3 Transcatheter Heart Valve

20, 23, 26, and 29 mm sizes

Bovine Thermaf
Tissue Leaflets



Balloon-expandable
Cobalt Chromium Frame
with larger landing zone

External Sealir

Hemodynamics variables after implantation SAPIEN 3 valve

Patient	Age	Aortic Regurgitation Baseline		Aortic Regurgitation 30-day	
		Paravalvular	Transvalvular	Paravalvular	Transvalvular
1	89	Trace	No	Trace	No
2	81	Trace	Trace	Trace	No
3	77	Mild	Trace	Trace	No
4	84	Trace	No	Trace	No
5	78	No	No	No	No
Mean		X	X	X	X

CONCLUSIONS

- TAVI represents a less invasive strategy than SAVR for the treatment of symptomatic severe aortic stenosis

- TAVI is currently the treatment of choice for those patients considered non-candidates for SAVR and a very good alternative for those considered to be at high surgical risk

- Despite the good acute and midterm clinical results obtained in recent large multicenter registries and the PARTNER trial, efforts should be made to improve patient selection and reduce periprocedural complications such as stroke and residual aortic regurgitation