

# TAVR Update 2012: The Year in Review

*Martin B. Leon, MD*

*Columbia University Medical Center  
New York Presbyterian Hospital  
New York City*



# Disclosure Statement of Financial Interest

## Martin B. Leon, MD

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

### Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity

### Company

- Abbott, Boston Scientific, Edwards Lifesciences, Medtronic
- Meril Lifescience, Angioscore, Micell
- Sadra, Claret, Coherex, Medinol, Valve Medical

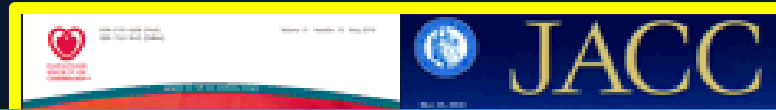
# TAVR in Review (2011-12)

- **Clinical Outcomes**
- **Complications**
- **Adjunctive Imaging**
- **New Technology**

# TAVR in Review (2011-12)

## Clinical Outcomes

# VARC MANUSCRIPT



European Heart Journal (2011) 32, 205–217  
doi:10.1093/eurheartj/ehq406

**CLINICAL RESEARCH**  
*Valvular medicine*

## Standardized endpoint definitions for

tra  
tria  
Ac

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doi:10.1016/j.jacc.2010.12.005

**CLINICAL RESEARCH**

**Valvular Medicine**

Mart  
Don  
Roxa  
Johan  
John

## Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation Clinical Trials

A Consensus Report From the Valve Academic Research Consortium

Martin B. Leon, Nicolo Piazza, Eugenia Nikolsky, Eugene H. Blackstone, Donald E. Cutlip, Arie Pieter Kappetein, Mitchell W. Krucoff, Michael Mack, Roxana Mehran, Craig Miller, Marie-angéle Morel, John Petersen, Jeffrey J. Popma, Johanna J. M. Takkenberg, Alec Vahanian, Gerrit-Anne van Es, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys  
*New York, New York*

# Outcomes after TAVR using VARC criteria: Review of the literature and a study-level meta-analysis of 3,519 patients from 16 studies

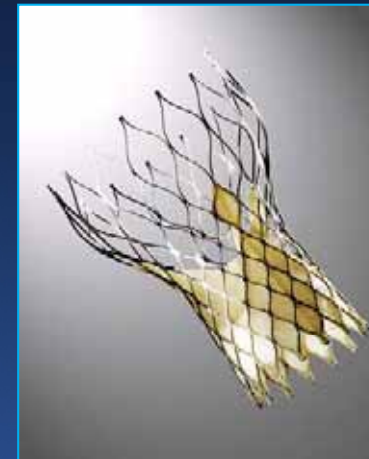
***Philippe Généreux, MD***

***Columbia University Medical Center  
Cardiovascular Research Center***



***Stuart Head***

***Erasmus University Medical  
Center***



***JACC 2012; In Press***

# New PARTNER NEJM Publications

The NEW ENGLAND JOURNAL of MEDICINE

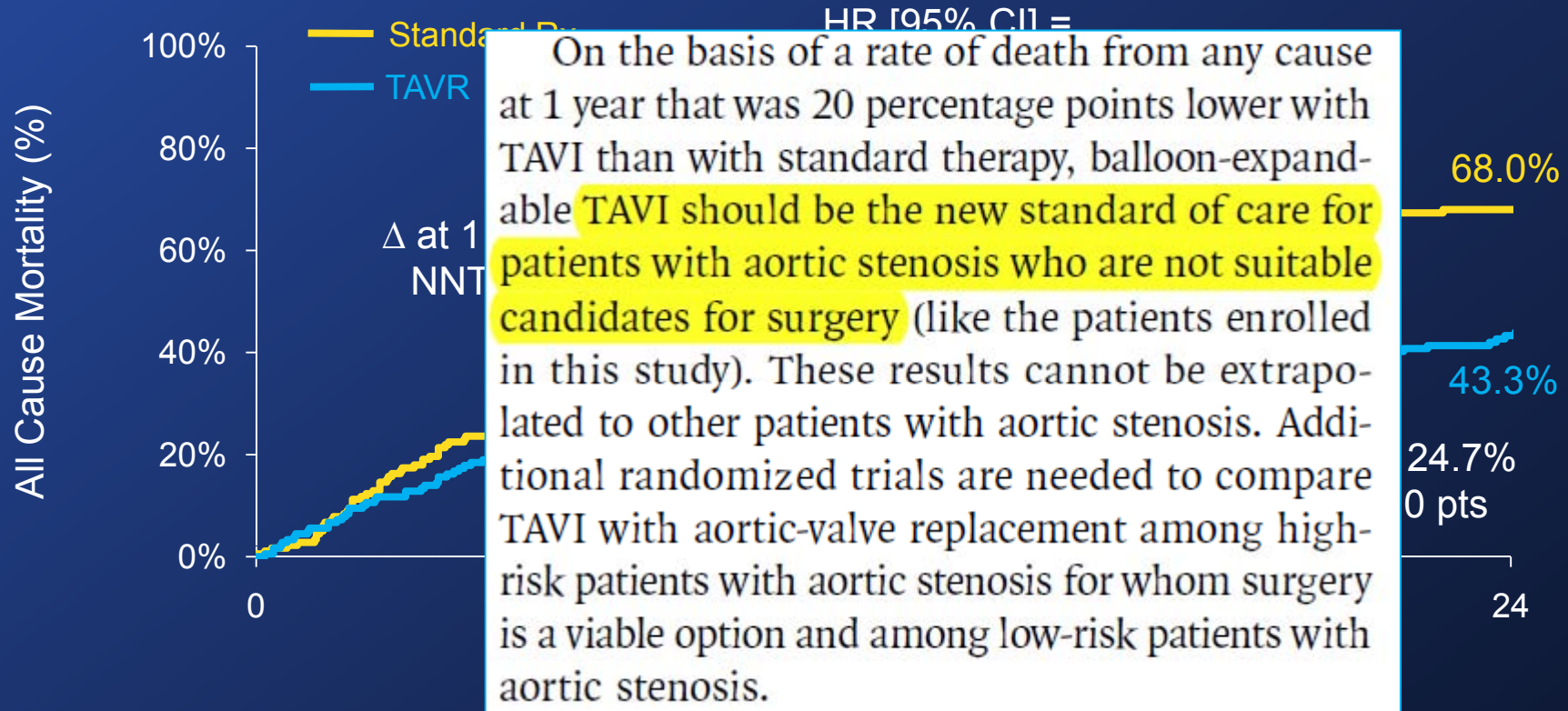
ORIGINAL ARTICLE

## 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 (ITT)

## Crossover Patients Censored



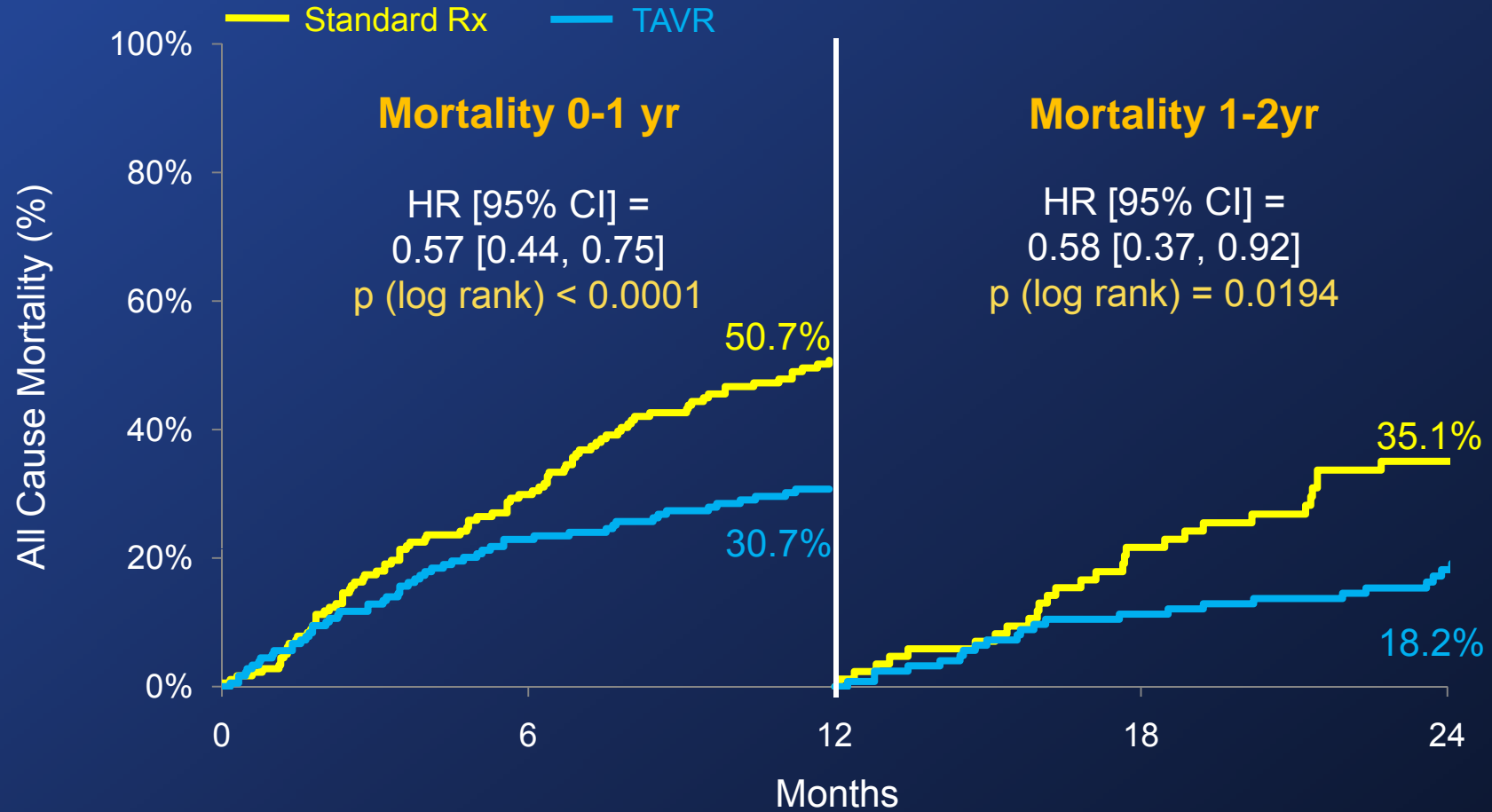
### Numbers at Risk

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



# All Cause Mortality (ITT)

## Landmark Analysis



### Numbers at Risk

	0	6	12	18	24
TAVR	179	138	124	110	83
Standard Rx	179	121	85	62	42

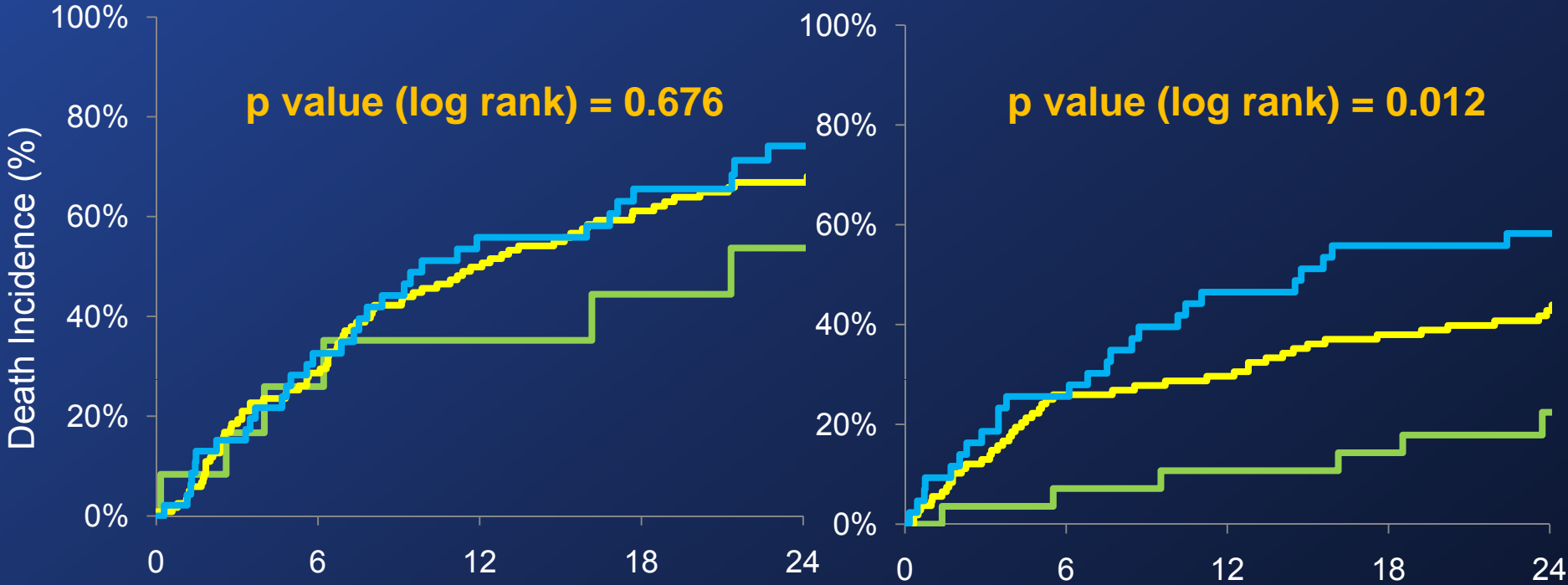
# Mortality Stratified by STS Score (ITT)



— STS <5      — STS 5-14.9      — STS ≥15

## Standard Rx

## TAVR



**Numbers at Risk**

**Months**

**Months**

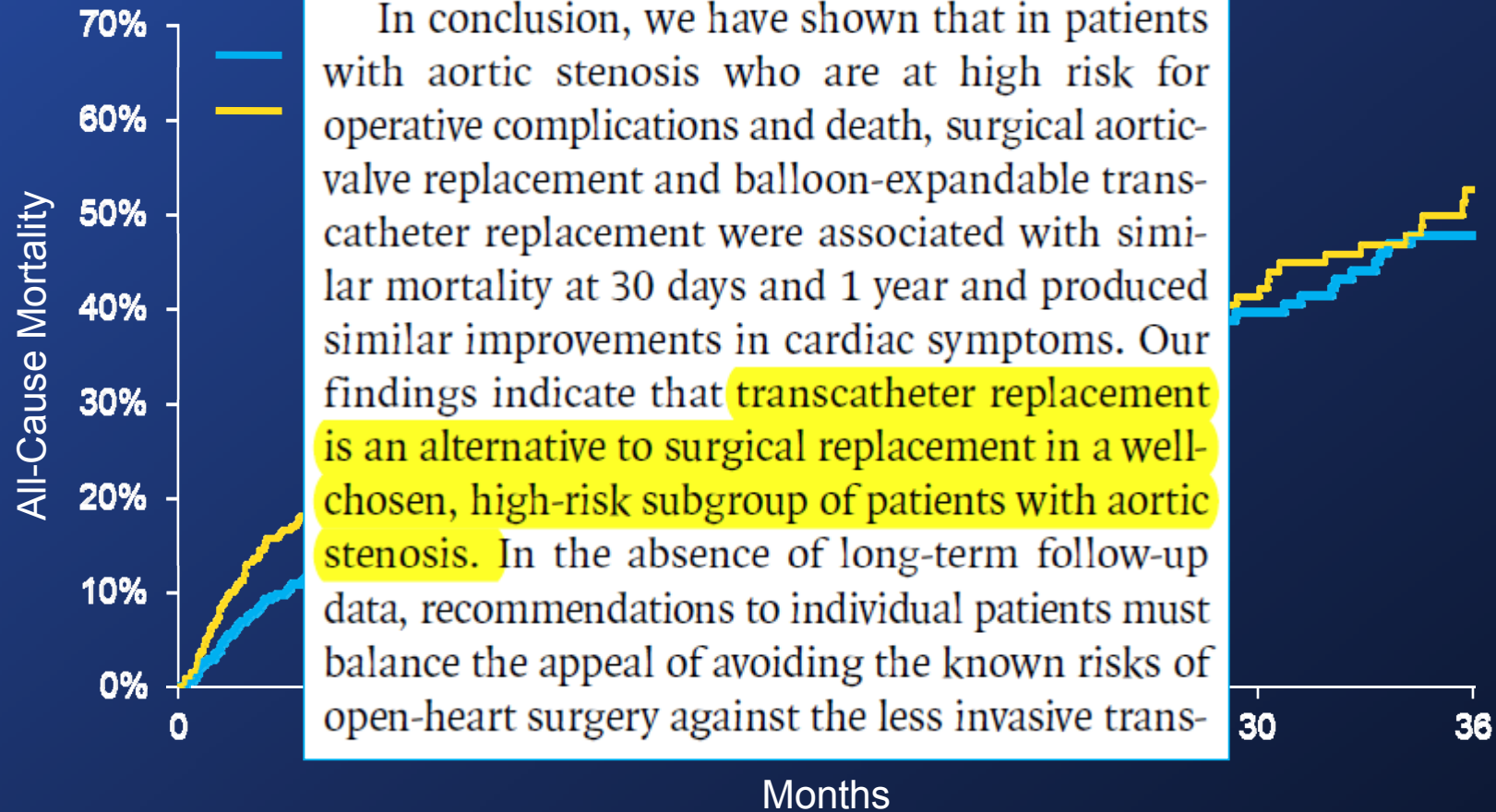
12	8	7	6	5	28	26	25	24	16
119	84	59	42	29	108	80	76	67	52
47	29	19	14	8	43	32	23	19	15

# Hospitalization Through 2 Years



	<i>TAVR</i>	<i>Standard Tx</i>	<i>p value</i>
Repeat Hospitalizations (No.)	78	151	<.0001
Repeat Hospitalizations (%)	35.0%	72.5%	<.0001
Days Alive Out of Hospital Median [IQR]	699 [201-720]	355 [116-712]	.0003

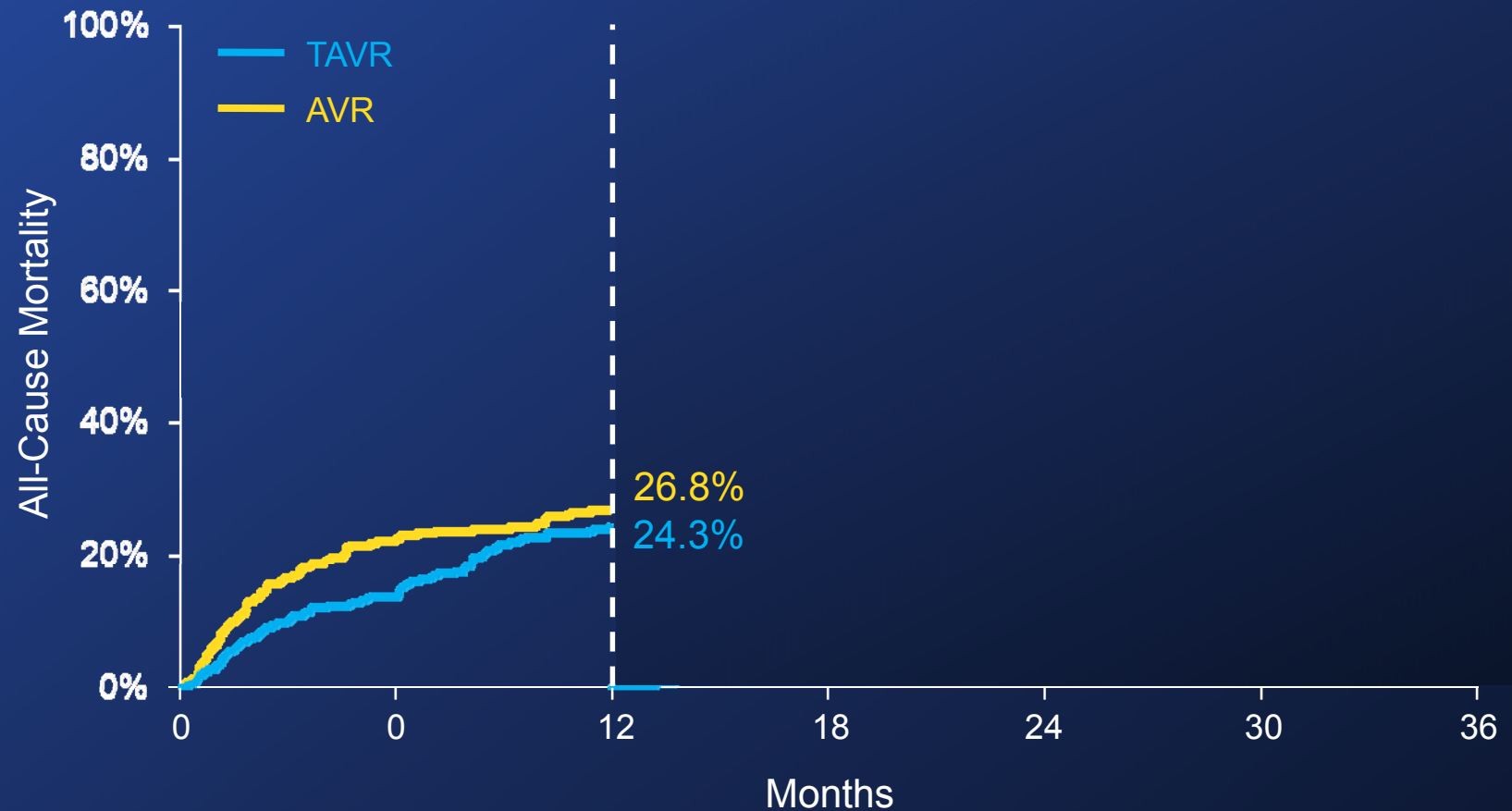
# All-Cause Mortality (ITT)



## Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

# All-Cause Mortality (ITT) Landmark Analysis

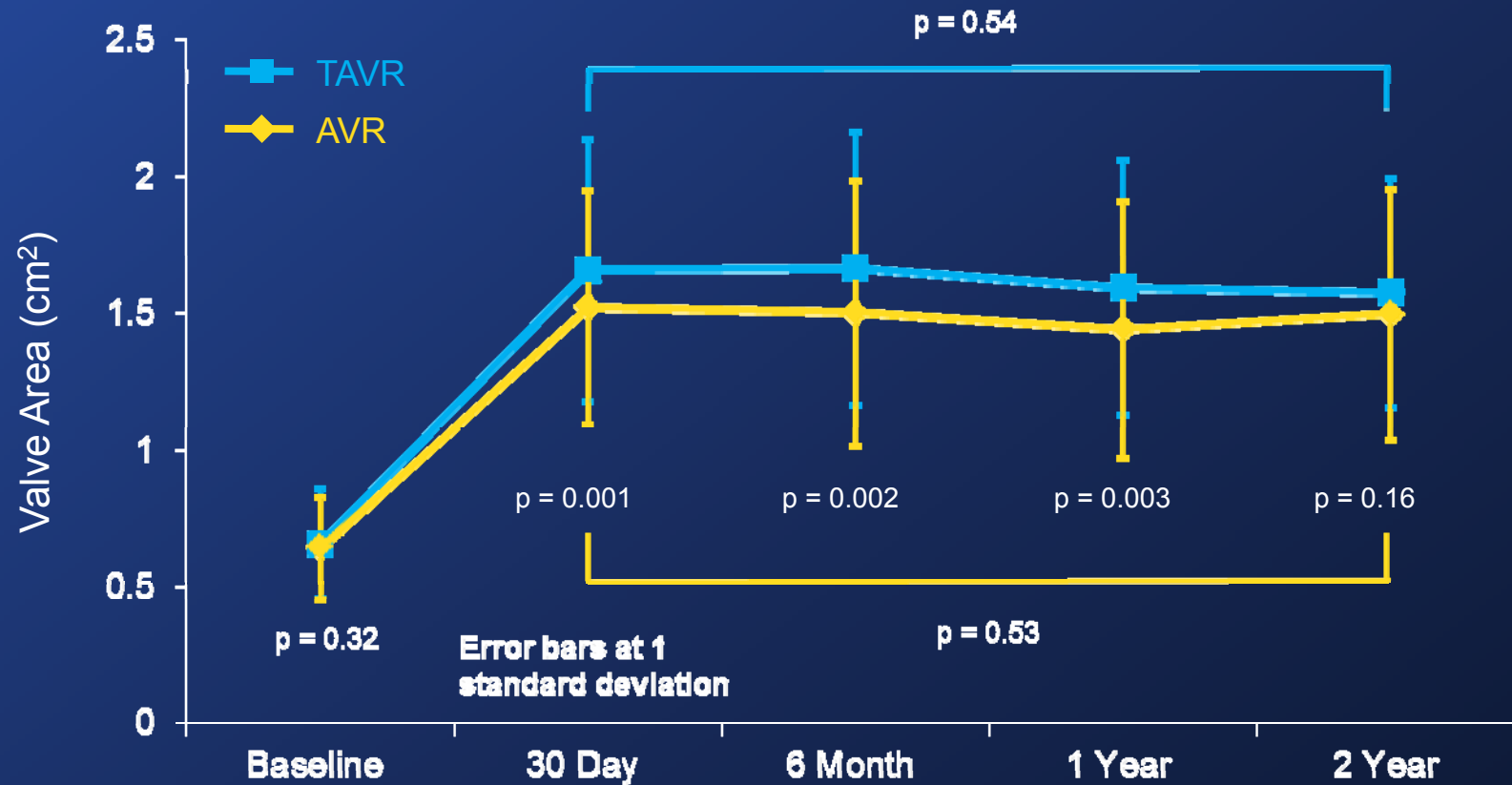


## Numbers at Risk

TAVR	348	298	260	234	172	70	31
AVR	351	252	236	217	165	65	32

# Echocardiographic Findings

## AVA (AT)

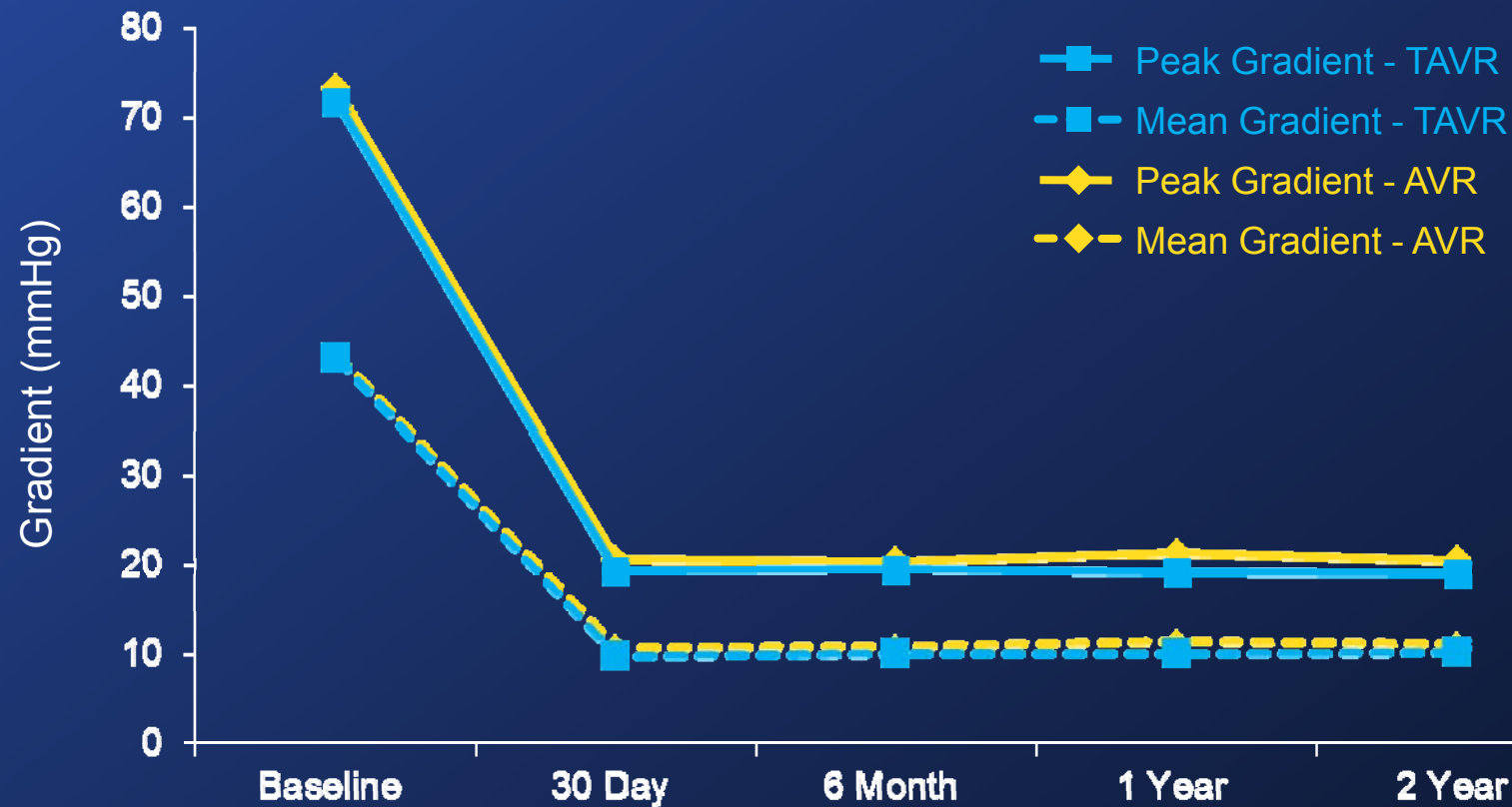


### Numbers at Risk

TAVR	301	269	223	210	139
AVR	290	224	162	151	110

# Echocardiographic Findings

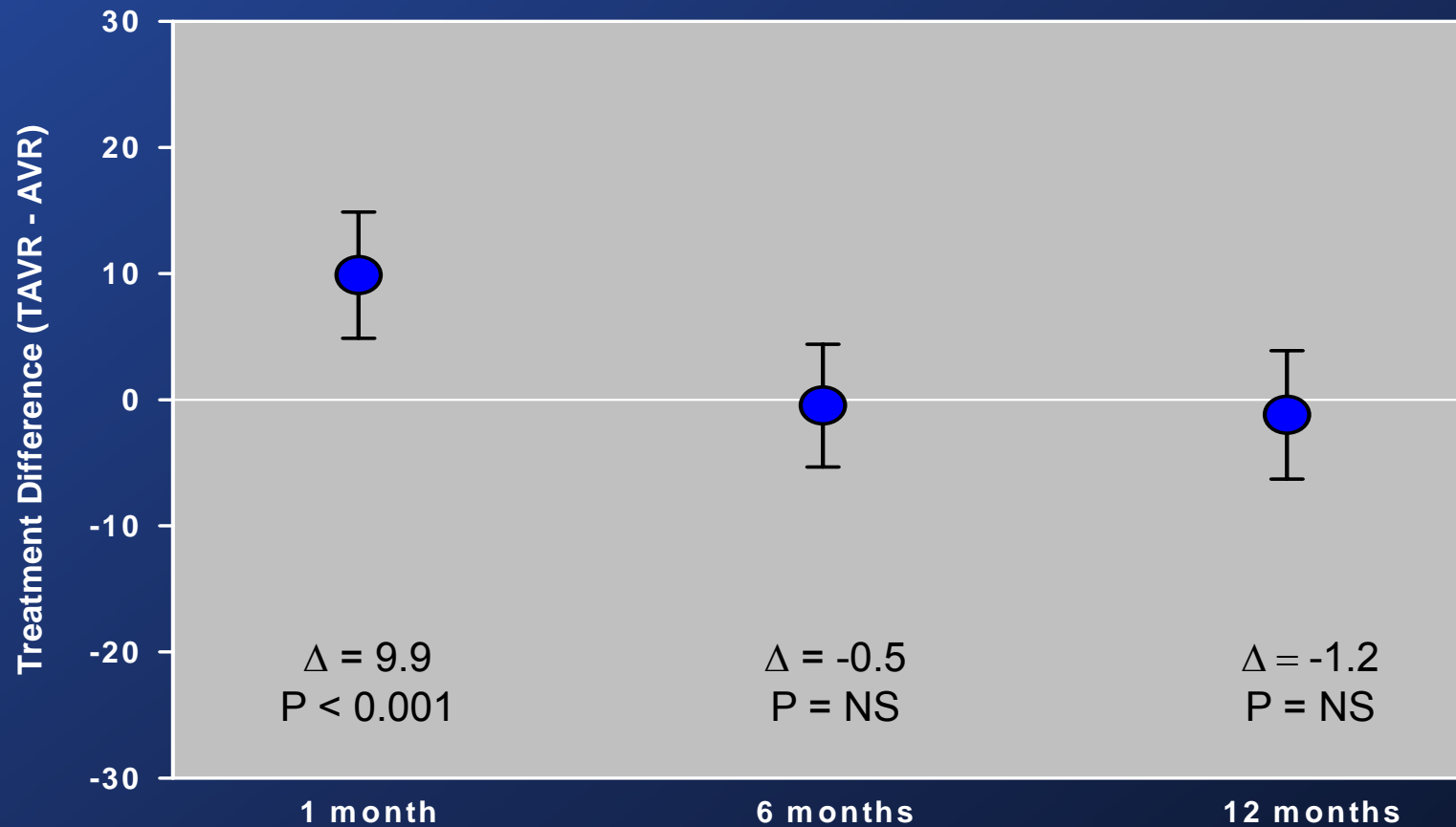
## Mean and Peak Gradients (AT)



### Numbers at Risk

TAVR	307	275	233	218	144
AVR	295	228	168	155	112

# KCCQ Overall Summary (Primary Endpoint) TF Subgroup





# Index Procedure/Admission

## Resource use (per-protocol population)



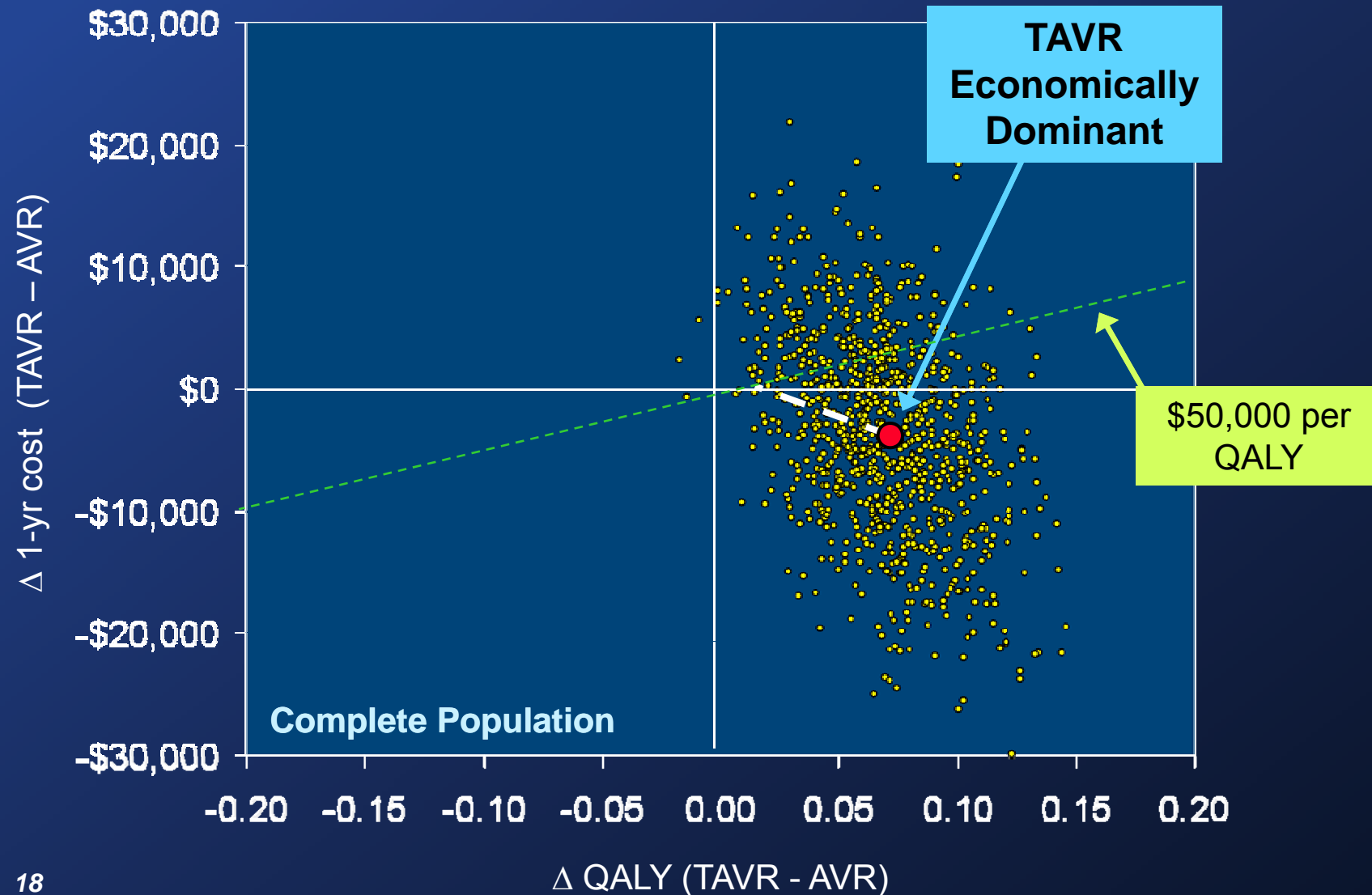
<i>Resource Category</i>	<i>TF-TAVR</i> (N = 234)	<i>AVR</i> (N= 221)	<i>Difference</i> (95% CI)*	<i>P-value</i>
Procedure duration (min)	244 ± 78	330 ± 102	87 (69 – 104)	<0.001
Total hospital LOS, days	10.2 (7)	16.4 (12)	6.2 (3.8 – 8.2)	<0.001
ICU	3.3 (2)	5.6 (3)	2.3 (0.9 – 3.3)	<0.001
Non-ICU	6.9 (4)	10.8 (8)	4.0 (2.2 – 5.5)	<0.001
Post procedure	7.4 (5)	13.5 (10)	6.1 (3.7 – 8.0)	<0.001
Major vasc. complication	13.2%	3.2%	10.1% (5.1 – 15.1)	<0.001
Major bleeding	9.4%	22.6%	13.2% (-6.6 to -19.9)	<0.001
New pacemaker, n (%)	16 (6.8%)	13 (6.0%)	0.8% (-3.7 – 5.3)	0.73

LOS data are shown as mean (median).

\*95% CIs from 1,000 bootstrap replications of study data.

# TAVR vs. AVR: Transfemoral

## Cost per QALY gained



# Current TAVR Eligibility According to Operative Risk



# SOURCE Family of Registries

## 1-Year Results from Combined Cohort I and Cohort II of The SOURCE Registry

The European Registry of Transcatheter Aortic Valve Replacement using the Edwards SAPIEN™ Valve

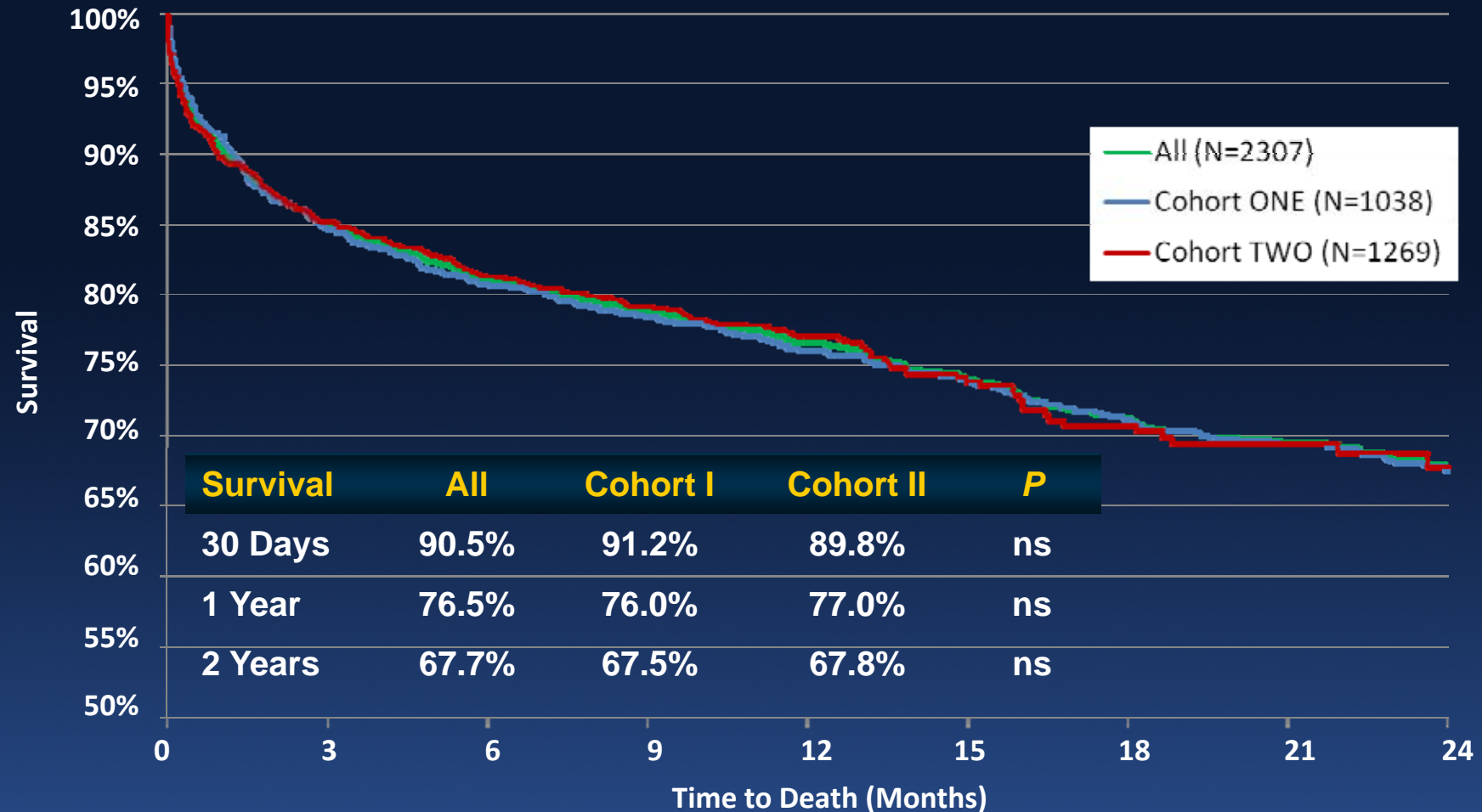
**M Thomas, G Schymik, T Walther, D Himbert, T Levefre, H Treede, E Eggebrecht, P Rubino, A Colombo, R Lange, O Wendler**

on behalf of **The SOURCE Registry Investigators**

# Baseline Characteristics

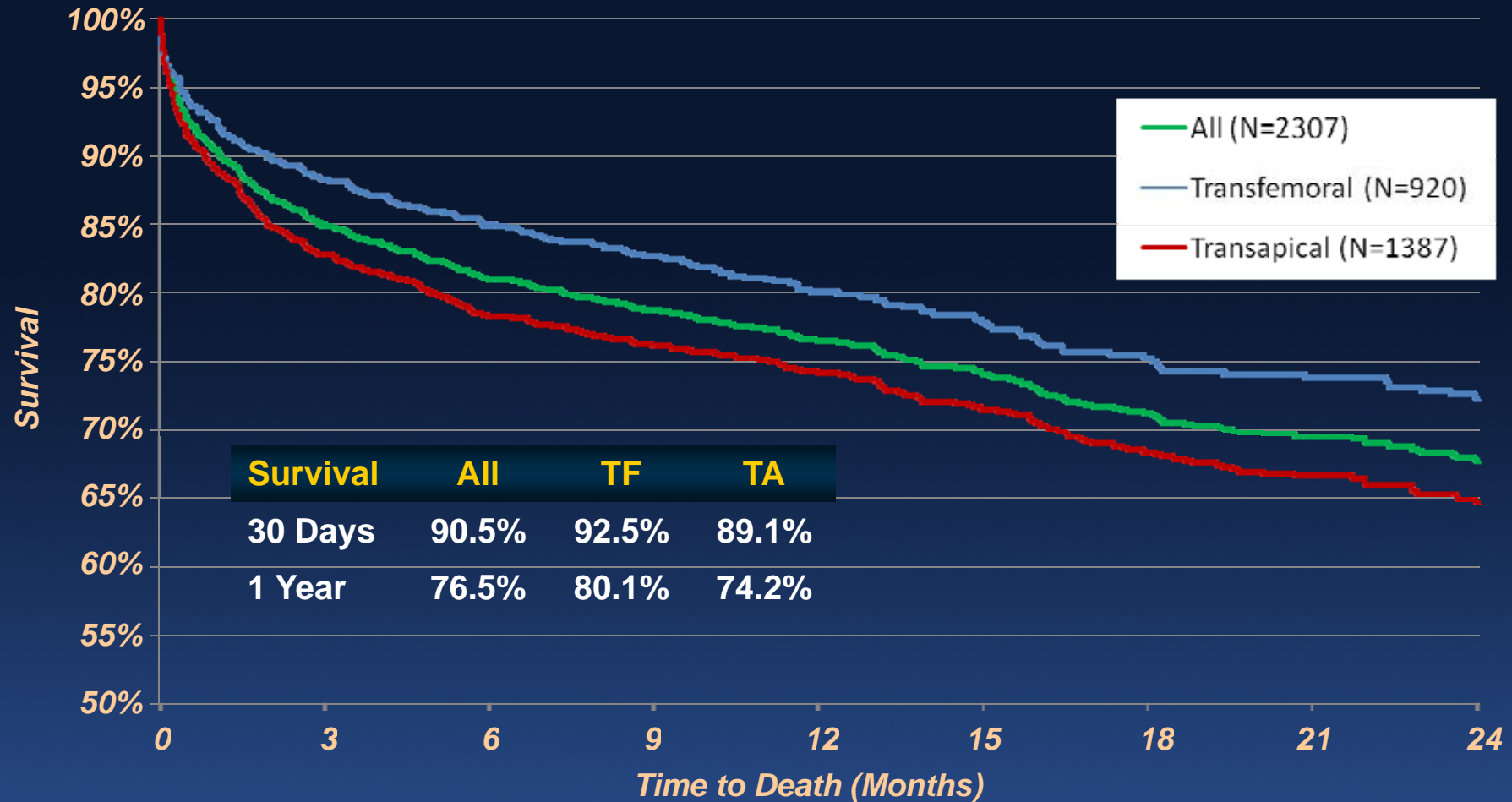
	<b>Cohort I (n=1038)</b>	<b>Cohort II (n=1269)</b>	<b>p</b>
Age (yrs)	81.2±6.9	81.1±6.9	0.77
Female (n/%)	576 (55.5%)	745 (58.7%)	0.06
BMI (kg/m <sup>2</sup> )	26.1±4.5	26.6±5.0	0.1
Diabetes (n/%)	281 (27.1%)	347 (27.3%)	0.89
Respiratory	<b>Cohort I</b>	<b>Cohort II</b>	0.23
Renal insufficiency <20 (n/%)	345 (33.2%)	560 (44.1%)	0.49
Peripheral vascular disease 20-40 (n/%)	507 (48.8%)	525 (41.4%)	0.76
Porcelain aorta >40 (n/%)	186 (17.9%)	184 (14.5%)	0.39
Cerebral artery stenosis >50% (n/%)	132 (12.7%)	140 (11.0%)	0.53
Carotid artery stenosis >50% (n/%)	132 (12.7%)	140 (11.0%)	0.22
<b>Logistic EuroSCORE</b>	<b>27.6±15.5</b>	<b>25.0±15.3</b>	<b>&lt;0.001</b>

# KM 1-year Survival – Cohort 1 vs. 2



N @ Risk	30 Days	1 Year	2 Years
All (N=2307)	2080	1506	487

# KM 1-year Survival – TF vs. TA



N @ Risk	30 Days	1 Year	2 Years
All (N=2307)	2080	1506	487



## FRANCE 2:

# FRench Aortic National Corevalve and Edwards Registry



**Martine Gilard, MD**  
**University of Brest, France**



**On behalf of the scientific committee and the investigators**  
**M Laskar, P Donzeau-Gouge, K Chevreul, H Eltchaninoff, J Fajadet, B Lung,**  
**P Leprince, A Leguerrier, M Lievre, A Prat, E Teiger**

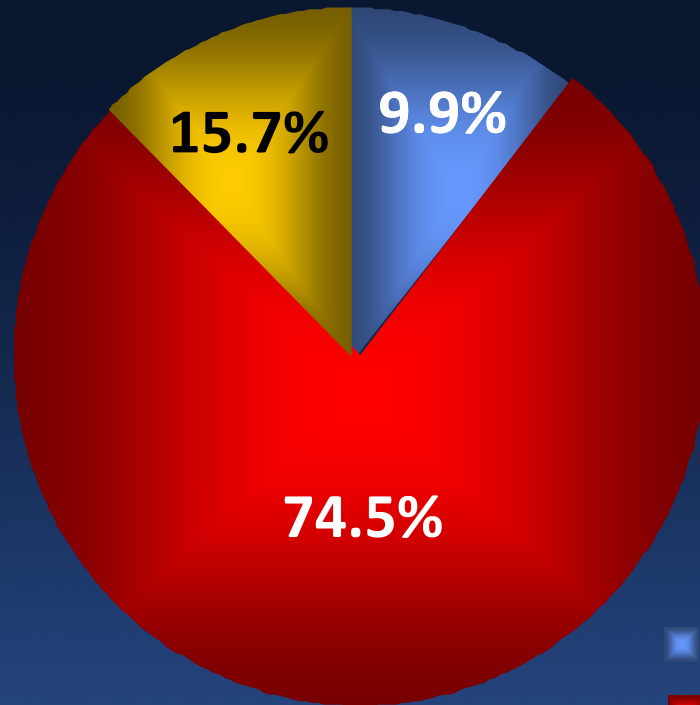


## *Interim analysis*

**1688 consecutive patients  
from 33 centers**

**January 1, 2010 to March 1, 2011**

## Procedural Characteristics



General anesthesia, %      71.6 %  
Peri-procedure TEE, %      65.9 %

- Operative room
- Cath-lab
- Hybrid room

# Belgian TAVR Registry

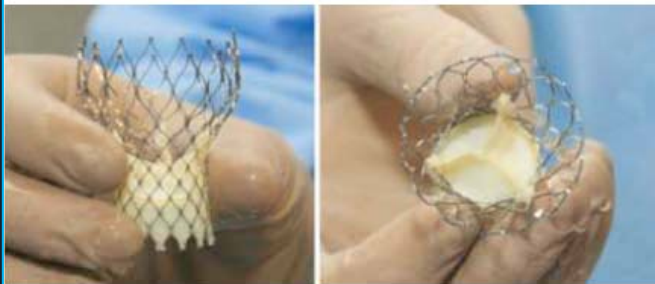
*Procedural, 30-day, 1 year, 2 year, and 3 year  
outcomes following Corvalve or Edwards TAVI:  
Results of the Belgian TAVI Registry*

**Johans Bosmans**  
**University Hospital; Antwerp, Belgium**

*On behalf of the Belgian TAVR registry participants*

# Belgian TAVR Registry

*Prospective, non-randomized multicenter registry*



No « mixed » centers



## CoreValve (n=297)

University Hospital Antwerp (n=95)  
Sart-Tilman (n=63)  
VUB-Bonheiden-sted.ZH Aalst (n=45)  
Middelheim (n=30)  
Namur (n=15)  
Virga Jesse Hasselt (n=14)  
St.Jan Brugge (n=13)  
Roeselaere (n=14)  
St Jean Brussels (n=8)

## Edwards Sapien (n=303)

UCL (n=109)  
OLV-Aalst (n=61)  
KU Leuven (n=44)  
Gilly-Jolimont (n=21)  
Citadelle (n=19)  
Erasme (n=15)  
Bouge (n=13)  
Genk (n=12)  
Mont Godinne (n=9)

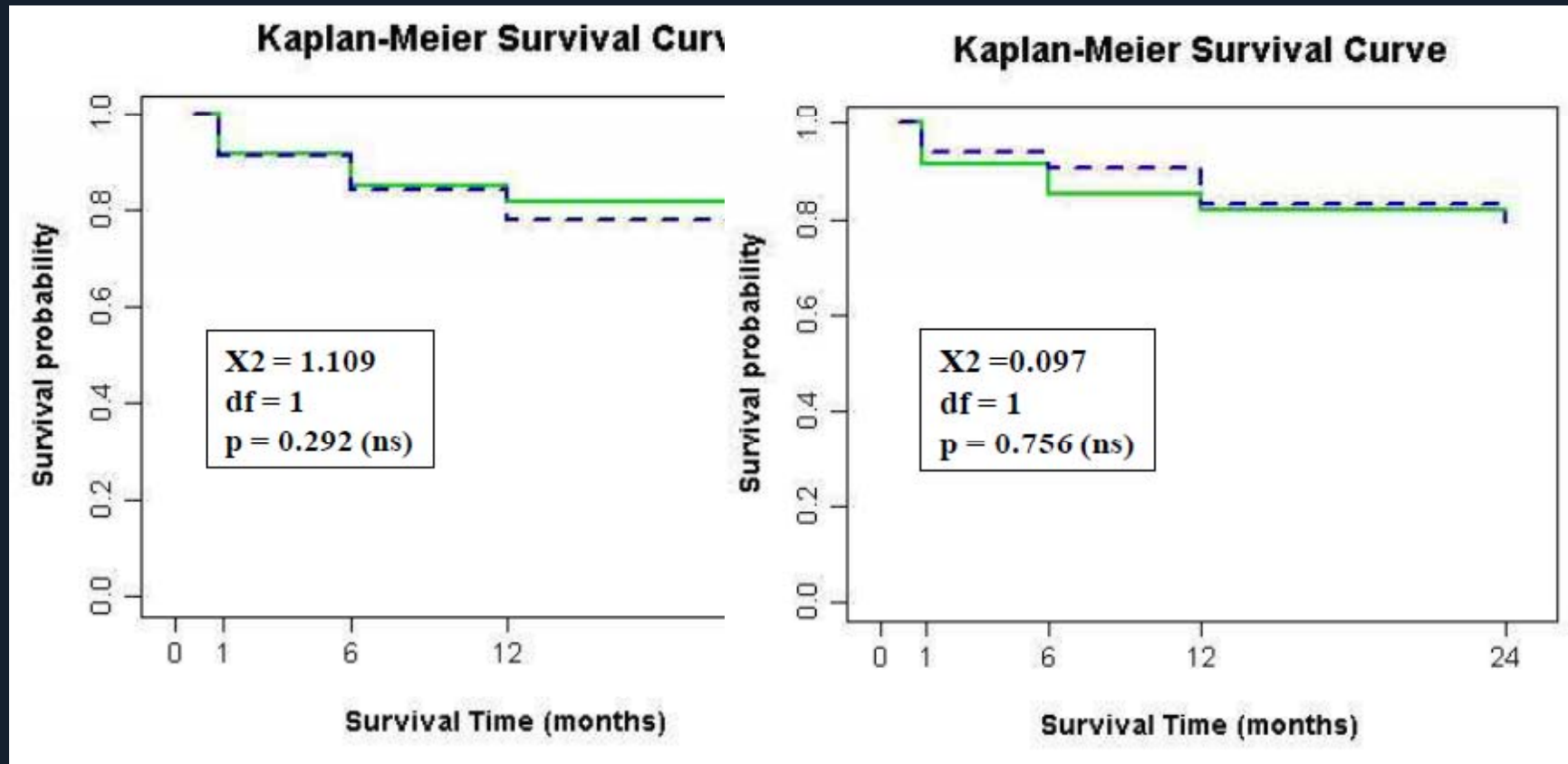
- 600 high-risk AS pts
- 18 centers
- no core labs
- enrollment till 04/11
- serial clinical and echo assessments thru 3 years

# Belgian TAVR Registry

## *mid-term survival*

*Edwards (TA+TF) - CoreValve (TF+SC)*

*Edwards (TF) - CoreValve (TF)*



# UK TAVR Registry

## Long-Term Outcomes After Transcatheter Aortic Valve Implantation in High-Risk Patients With Severe Aortic Stenosis

The U.K. TAVI (United Kingdom  
Transcatheter Aortic Valve Implantation) Registry

Neil E. Moat, MBBS, MS,\* Peter Ludman, MA, MD,† Mark A. de Belder, MA, MD,‡  
Ben Bridgewater, PhD,§ Andrew D. Cunningham, PhD,|| Christopher P. Young, MD,¶  
Martyn Thomas, MD,¶ Jan Kovac, MD,# Tom Spyt, MD,# Philip A. MacCarthy, BS, PhD,\*\*  
Olaf Wendler, MD, PhD,\*\* David Hildick-Smith, MD,†† Simon W. Davies, MBBS, MD,\*  
Uday Trivedi, MBBS,†† Daniel J. Blackman, MD,‡‡ Richard D. Levy, MD,§  
Stephen J. D. Brecker, MD,§§ Andreas Baumbach, MD,|| Tim Daniel, MB, CHB,¶¶  
Huon Gray, MD,## Michael J. Mullen, MBBS, MD\*\*\*

*London, Birmingham, Bristol, Middlesbrough, Manchester, Leicester, Brighton, Leeds,  
and Southampton, United Kingdom*

### METHODS:

- 870 consecutive TAVR pts (age 81.9 yrs, logES 18.5) from 25 UK centers;  
FU from 11 to 46 months; 53% CV and 47% Sapien; 69% trans-femoral;  
median # implants per center = 24

# UK TAVR Registry

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Huon Gray, MD,## Michael J. Mullen, MBBS, MD\*\*\*

*London, Birmingham, Bristol, Middlesbrough, Manchester, Leicester, Brighton, Leeds,  
and Southampton, United Kingdom*

### RESULTS:

- Mortality at 30 days, 1 yr, and 2 yrs was 7.1%, 21.4%, and 26.3%;  
no significant differences in survival CV vs. Edwards
- Mortality predictors @ 1 year: UNIVARIATE = renal dysfunction, CAD  
non-TF approach; MULTIVARIATE = LVEF < 30%, mod/severe AR,  
and COPD

# Treatment of High Risk Aortic Stenosis Patients with Transcatheter Medtronic CoreValve Implantation

Axel Linke **University of Leipzig Heart Center, Leipzig, Germany**

Ulrich Gerckens **Gemeinschaftskrankenhaus Bonn, Bonn, Germany**

Peter Wenaweser **University Hospital Bern, Bern, Switzerland**

Corrado Tamburino **Ferrarotto Hospital, University of Catania, Catania, Italy**

Johan Bosmans **University Hospital Antwerp, Antwerp Belgium**

Stephen Brecker **St. George's Hospital, London, United Kingdom**

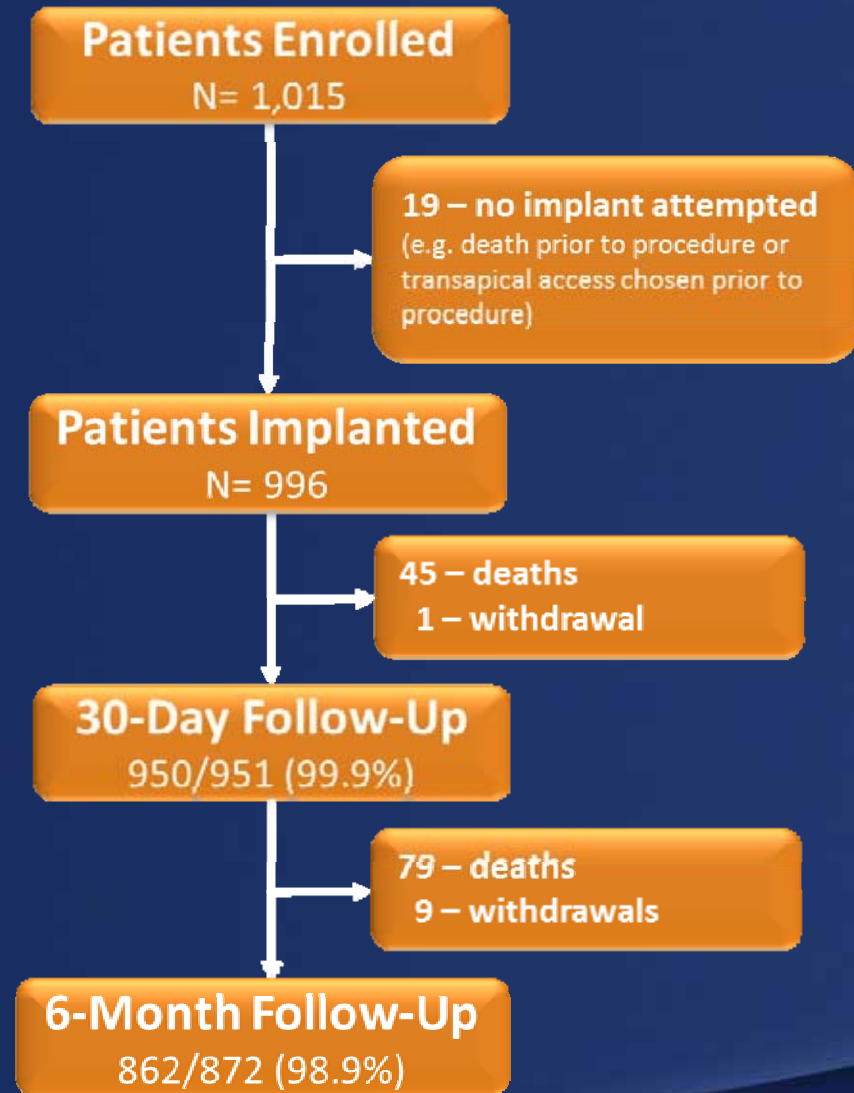
Robert Bauernschmitt **ISAR Heart Center, Munich, Germany**

(on behalf of the ADVANCE Investigators)



# CoreValve ADVANCE | Methods

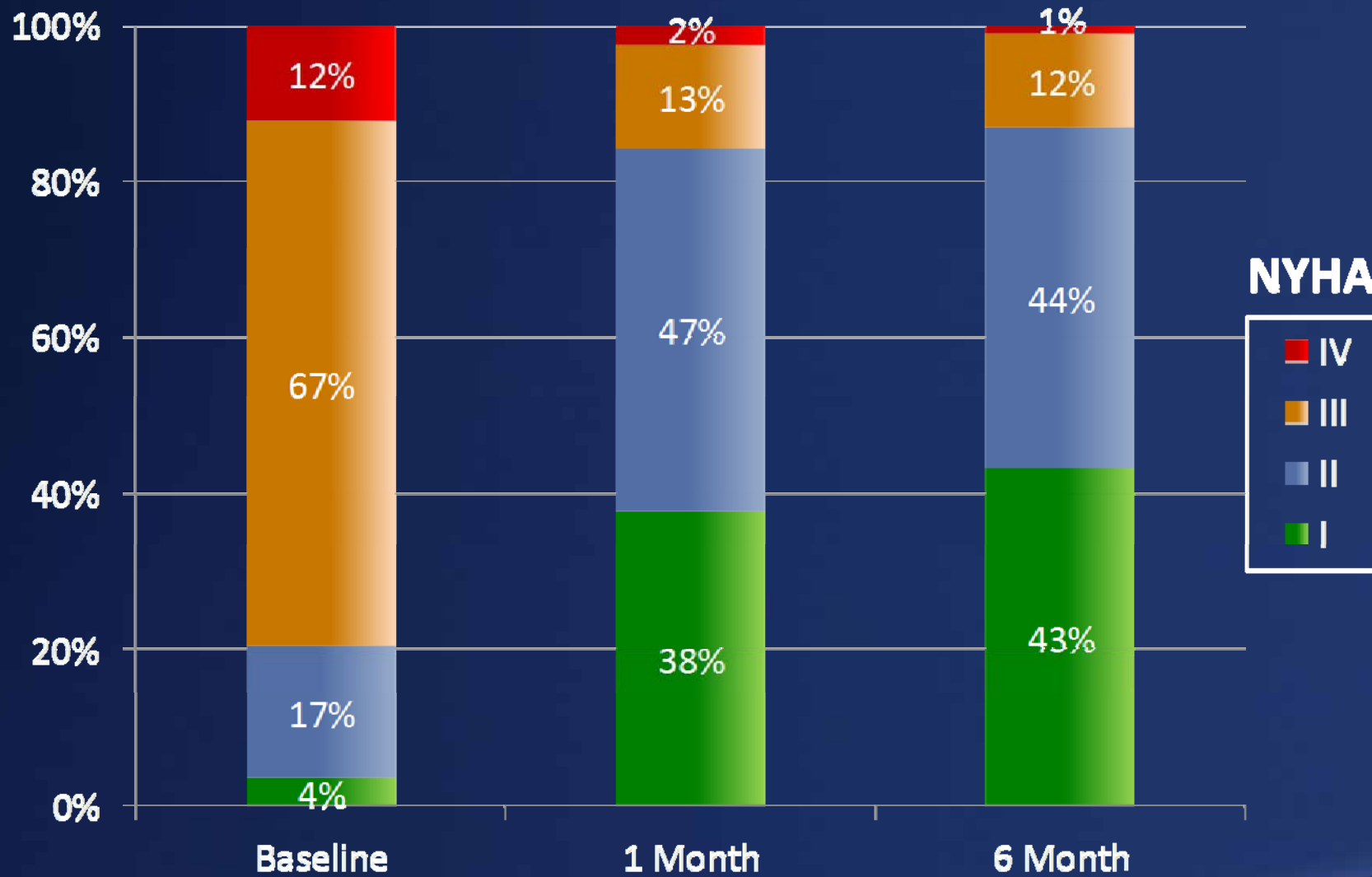
- 1,015 patients enrolled from March 2010 to July 2011
  - 5 year follow-up
- 44 centers - 12 countries in Western Europe, Asia and South America
- All centers had conducted at least 40 TAVI procedures prior to the study and had Heart Team in place
- Clinical endpoints reported according to Valve Academic Research Consortium (VARC)



# CoreValve ADVANCE | Baseline Characteristics

Characteristics	N=1015	%		%
Age (yrs.)	81 ± 6		Prior MI	16.0
Male	49.4		Prior PCI	31.1
Logistic EuroSCORE	19.2 ± 12.4		Permanent Pacemaker	12.8
NYHA			<b>EuroSCORE Relevant Factors</b>	
I or II	20.4		Prior CABG	21.4
III or IV	79.6		Cerebrovascular Disease	12.9
Diabetes	30.9		COPD	22.6
CAD	57.6		Pulmonary Hypertension	12.6
PVD	19.5		Prior median sternotomy	17.3
Atrial Fibrillation	32.8		Renal Failure	14.6

# CoreValve ADVANCE | Symptom Status



# CoreValve ADVANCE | 30-day Outcomes

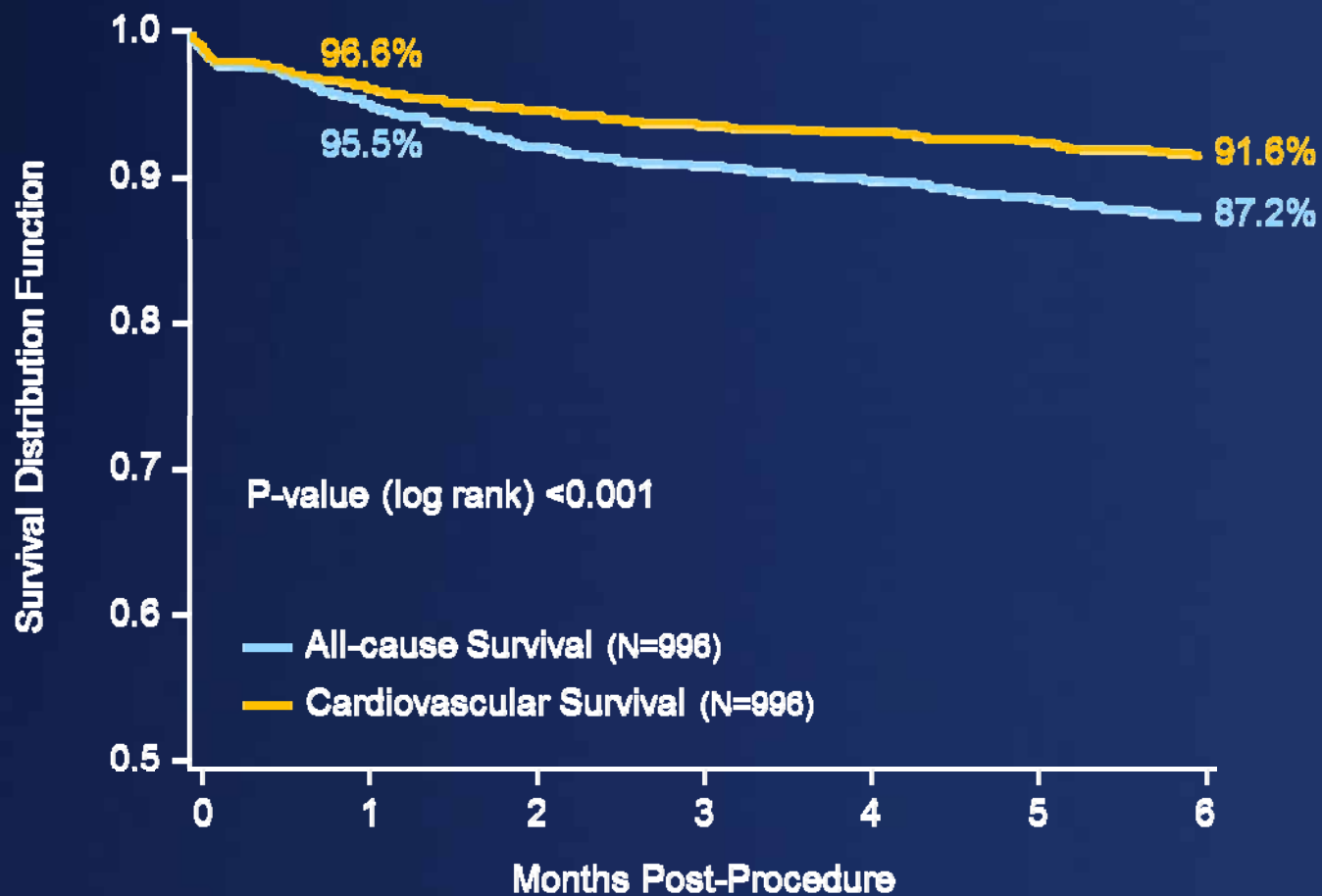
Primary Endpoint N=996	Kaplan-Meier Estimates, %
MACCE	8.3
All-cause Mortality	4.5
Myocardial Infarctions	0.2
Emergent cardiac surgery or percutaneous re-intervention	1.7
Stroke	2.9

Additional VARC Endpoints N=996	Kaplan-Meier Estimates, %
Cardiovascular Mortality	3.4
Major Bleeding	9.7
Life Threatening Bleeding	4.0
Major Vascular Complications	10.7
Acute Kidney Injury - Stage III	0.4

Additional Endpoint N=996	Kaplan-Meier Estimates, %
New Pacemaker Implantation	26.3

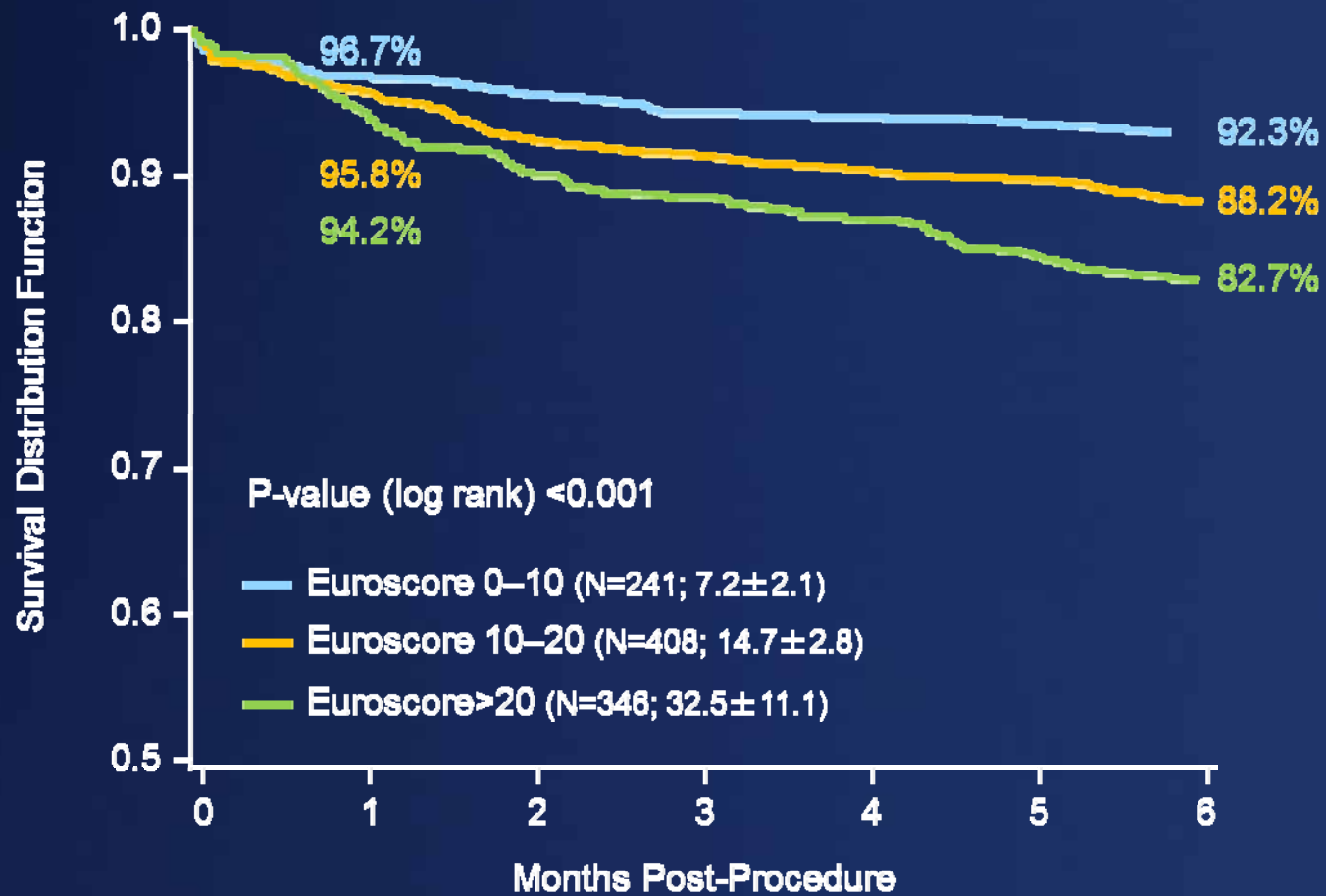
# CoreValve ADVANCE | 6-month Survival

Kaplan-Meier Estimates of Freedom from All-cause Mortality (VARC) and Cardiovascular Mortality (VARC)



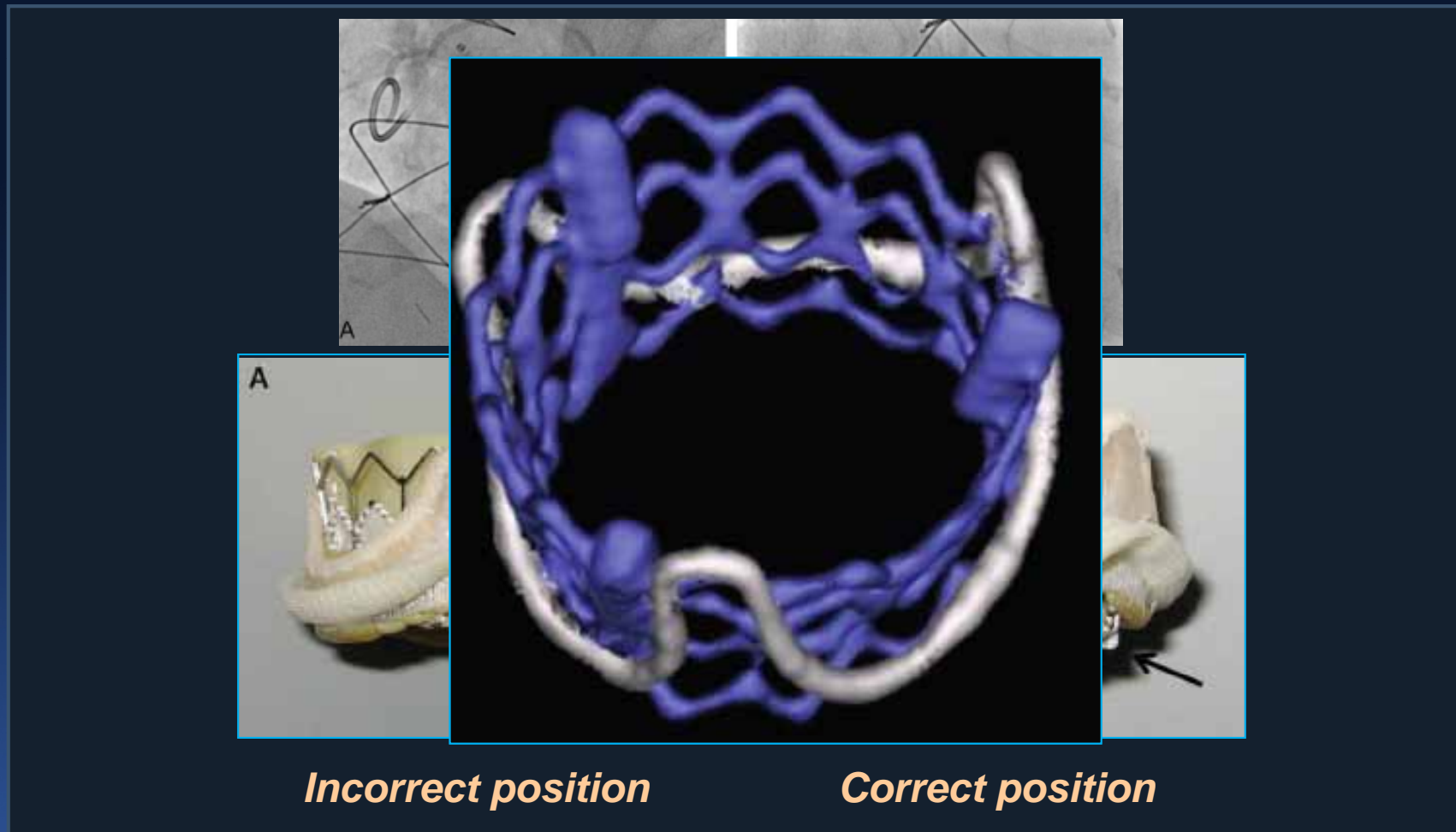
# CoreValve ADVANCE | 6-month Survival

Kaplan-Meier Estimates of Freedom from All-cause Mortality by EuroSCORE group



# New TAVR Clinical Indications

## *Valve - in - Valve*



# New TAVR Clinical Indications

## *Valve - in - Valve*

**Transcatheter Valve-in-Valve Implantation  
for Failed Surgical Bioprosthetic Valves**

## **Transcatheter Aortic Valve Implantation for Failing Surgical Aortic Bioprosthetic Valve**

**From Concept to Clinical Application and Evaluation (Part 2)**

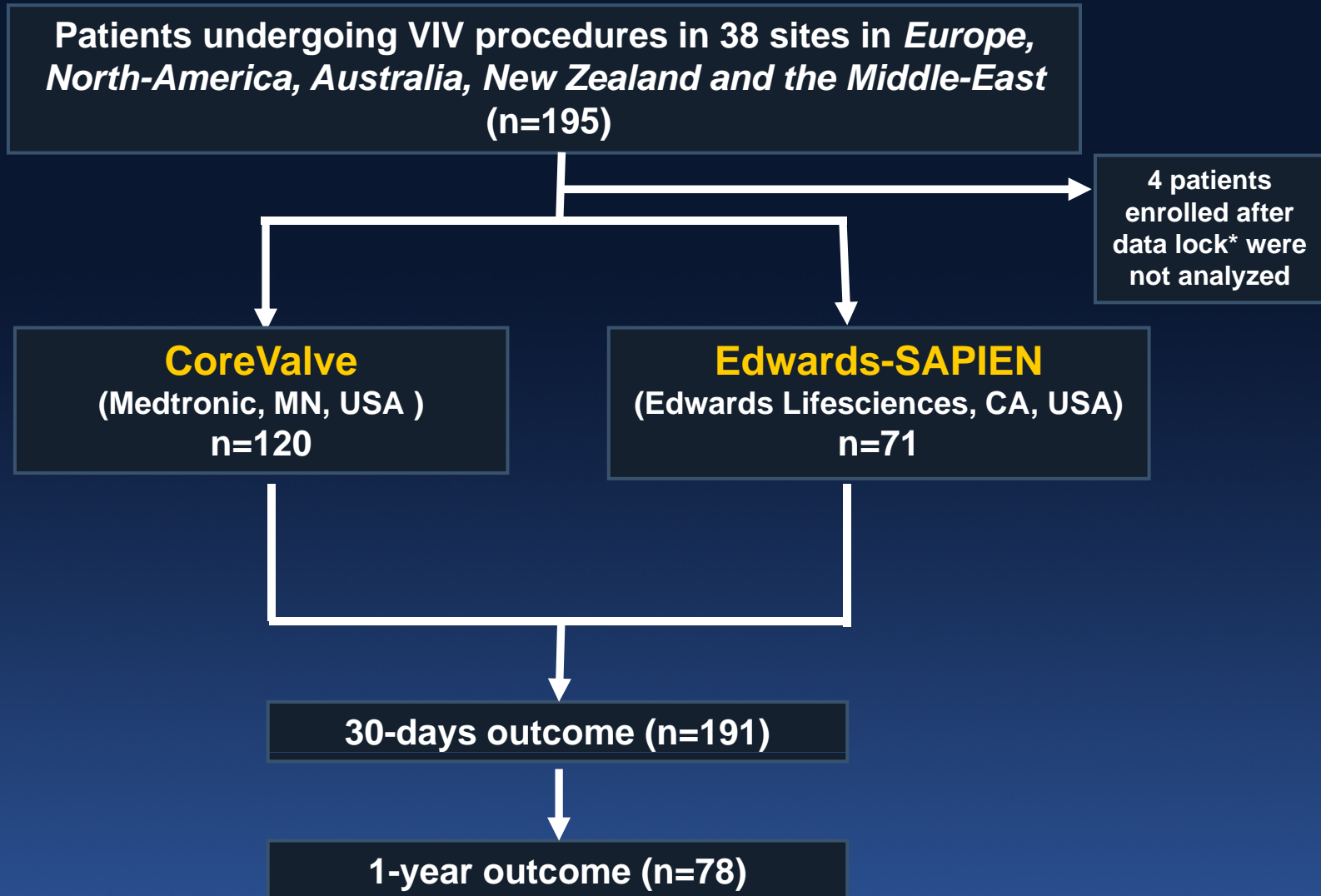
Nicolo Piazza, MD,\* Sabine Bleiziffer, MD,\* Gernot Brockmann, MD,\*  
Ruge Hendrick, MD,\* Marcus-André Deutsch, MD,\* Anke Opitz, MD,\*  
Domenico Mazzitelli, MD,\* Peter Tassani-Prell, MD, PhD,† Christian Schreiber, MD,\*  
Rüdiger Lange, MD, PhD\*

*Munich, Germany*

**J Am Coll Cardiol Intv 2011;4:733-42**



# Global Valve in Valve Registry

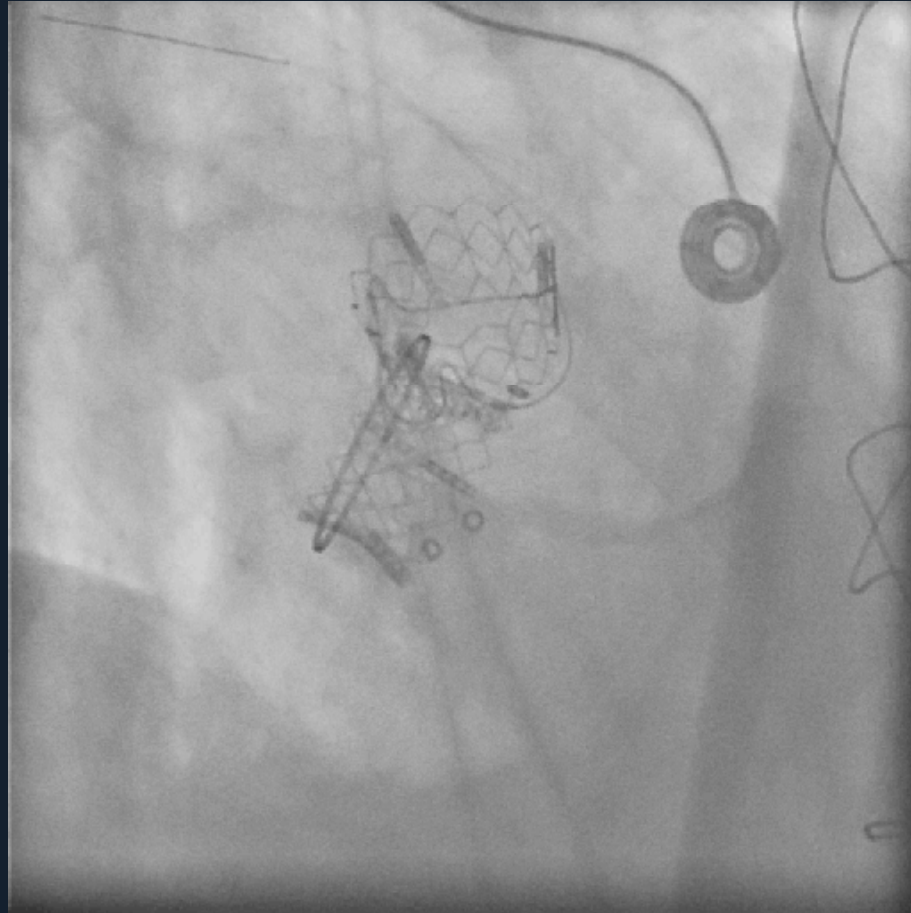


# TAVR 2012

## *Endless Possibilities!*

***Trans-apical  
AVR  
(valve-in-valve)***

***Trans-apical  
MVR  
(valve-in-valve)***



# TAVR in Review (2011-12)

## Complications

# Outcomes after TAVR using VARC criteria: Review of the literature and a study-level meta-analysis of 3,519 patients from 16 studies

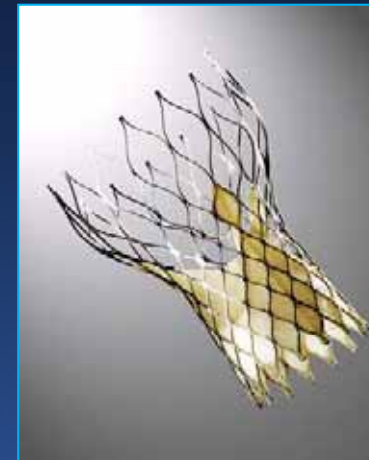
***Philippe Généreux, MD***

***Columbia University Medical Center  
Cardiovascular Research Center***



***Stuart Head***

***Erasmus University Medical  
Center***



***JACC 2012; In Press***

# TAVR Outcomes - VARC Meta-Analysis

## (17 studies; 3,519 patients)

<i>Endpoint</i>	<i>Pooled Estimate (%)</i>	<i>[95% CI]</i>
-----------------	----------------------------	-----------------

### Mortality

All @ 30 days	7.8	[5.5, 11.1]
CV @ 30 days	5.6	[3.7, 8.3]
All @ 1 year	22.1	[17.9, 26.9]
CV @ 1 year	14.4	10.6, 19.5

### Strokes @ 30 days

Major	3.2	[2.1, 4.8]
Major + minor	4.0	[2.4, 6.3]
TIA	1.2	[0.0, 2.3]
All	5.7	[3.7, 8.9]

# TAVR Outcomes - VARC Meta-Analysis

## (17 studies; 3,519 patients)

<i>Endpoint</i>	<i>Pooled Estimate (%)</i>	<i>[95% CI]</i>
<b>Vascular events @ 30 days</b>		
Major	11.9	[8.6, 16.4]
Minor	9.7	[6.7, 14.0]
All	18.8	[14.5, 24.3]
<b>Bleeding @ 30 days</b>		
Life threatening	15.6	[11.7, 20.7]
Major	22.3	[17.8, 28.3]
Minor	9.9	[6.9, 14.3]
All	41.4	[35.5, 47.6]
Transfusion $\geq$ 1 unit	42.6	[19.8, 62.4]

# TAVR Outcomes - VARC Meta-Analysis

## (17 studies; 3,519 patients)

<i>Endpoint</i>	<i>Pooled Estimate (%)</i>	<i>[95% CI]</i>
<b>MI (peri-procedural)</b>	1.1	[0.2, 2.0]
<b>Valve performance @ 30 days</b>		
AVA $\leq$ 1.2 cm <sup>2</sup>	4.8	[3.0, 6.6]
Mean gradient $\geq$ 20 mmHg	1.0	[0.0, 2.1]
AR $\geq$ moderate (PVL)	7.4	[4.6, 10.2]
Valve-in-valve	2.3	[1.3, 4.5]
Valve embolization	1.7	[0.2, 3.3]
<b>Perm Pacemaker @ 30 days</b>		
Edwards	4.9	[3.9, 6.2]
MDT-Corevalve	28.9	[23.0, 36.0]

# Strokes and TAVR

## Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients

Holger Eggebrecht<sup>1</sup>, MD, FESC; Axel Schmermund<sup>1</sup>, MD, FESC; Thomas Voigtländer<sup>1</sup>, MD, FESC; Philipp Kahlert<sup>2</sup>, MD; Raimund Erbel<sup>2</sup>, MD, FESC, FACC, FAHA; Rajendra H. Mehta<sup>3</sup>, MD, MS

*1. Cardioangiological Center Bethanien (CCB), Frankfurt, Germany; 2 Department of Cardiology, West-German Heart Center Essen, University Duisburg-Essen, Essen, Germany; 3. Duke Clinical Research Institute, Durham, NC, USA*

### METHODS:

- Meta-analysis from 53 studies in 10,037 pts treated with TAVI (TA, TF, or TS) published from Jan, 2004 to Nov, 2011
- Mean age  $81.5 \pm 1.8$  yrs and mean logES  $24.8 \pm 5.6\%$

### RESULTS:

- Procedural stroke (< 24 hrs)  $1.5 \pm 1.4\%$ ; 30-day stroke/TIA  $3.3 \pm 1.8\%$ , most major strokes  $2.9 \pm 1.8\%$ ; 1-year stroke/TIA increased to  $5.2 \pm 3.4\%$
- Different stroke rates with different approaches and valve prostheses; lowest with TA-TAVI  $2.7 \pm 1.4\%$  (30-day stroke/TIA)
- Mortality at 30 days + stroke = 25.5% vs. - stroke = 6.9% (> 3.5X)



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## *Editorial Response*

EDITORIALS



### **Transcatheter Aortic-Valve Implantation — At What Price?**

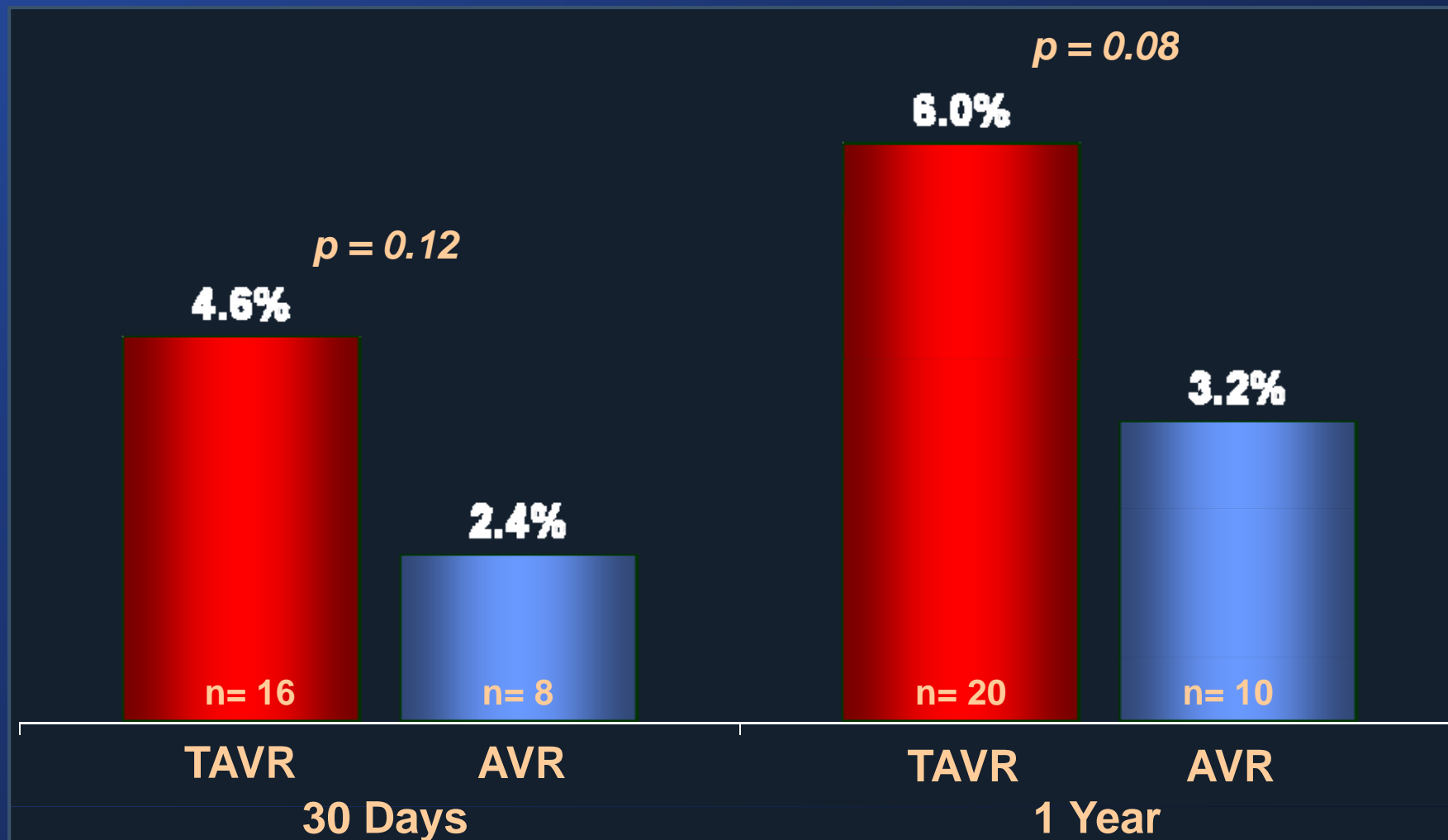
Hartzell V. Schaff, M.D.

In 2000, Bonhoeffer et al. described transvenous placement of a pulmonary-valve prosthesis and speculated that similar technology might be used in other cardiac valves, including the aortic position.<sup>1</sup> Two years later, the first transcatheter in-

patients who are eligible for transfemoral insertion and may decrease vascular injury.

But the increased risk of stroke associated with transcatheter replacement, as compared with surgical replacement, is a special concern. Smith

# All Strokes (major and minor) at 30 Days & 1 Year



ITT Population

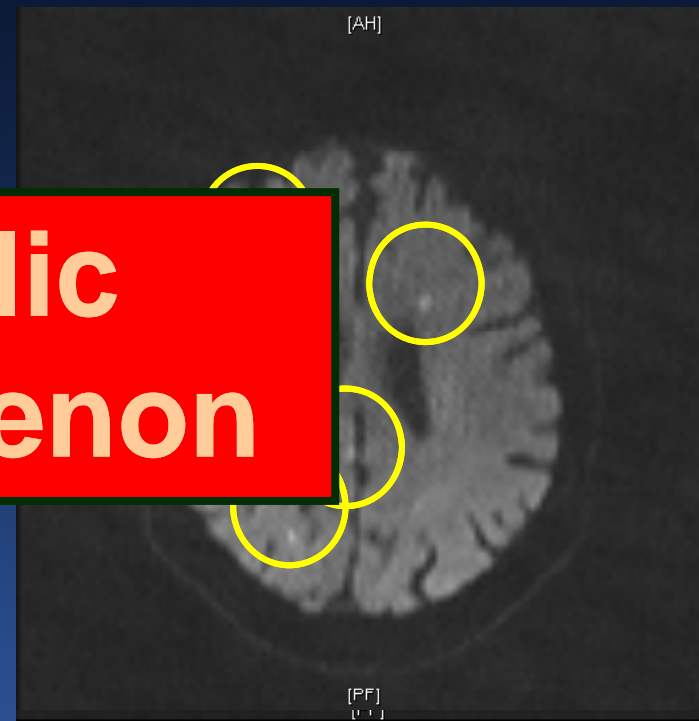
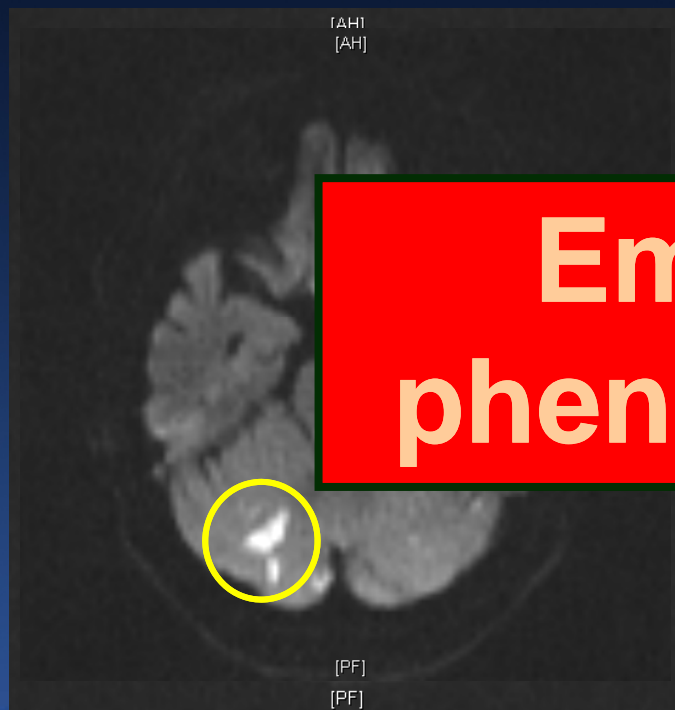
# Diffusion-Weighted MRI Study

Philipp Kahlert, MD  
West German Heart Center Essen

Pre-TAVI

Post-TAVI

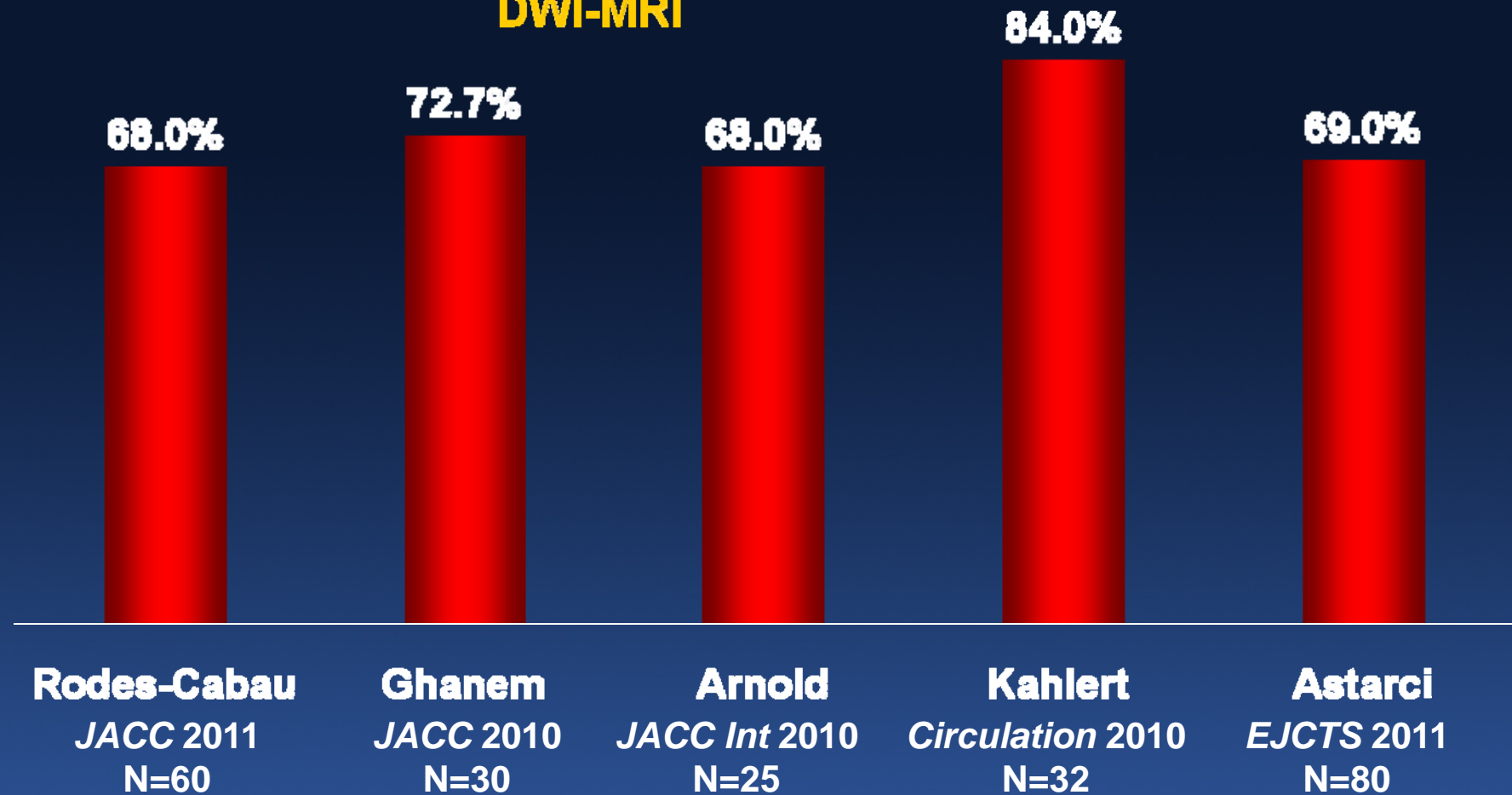
Example of an 82-year-old patient two days after successful TAVI



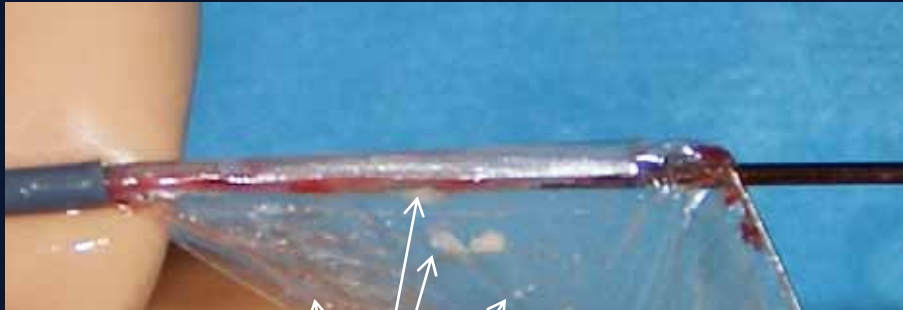
**Embolic  
phenomenon**

# Neuro-imaging with TAVR

**% of patient with new ischemic lesions on  
DWI-MRI**



# Embololic Material after TAVR



# Strokes in PARTNER High-risk cohort



## **Transcatheter (TAVR) versus surgical (AVR) aortic valve replacement: Occurrence, hazard, risk factors, and consequences of neurologic events in the PARTNER trial**

D. Craig Miller, MD,<sup>a</sup> Eugene H. Blackstone, MD,<sup>b</sup> Michael J. Mack, MD,<sup>c</sup> Lars G. Svensson, MD, PhD,<sup>b</sup> Susheel K. Kodali, MD,<sup>d</sup> Samir Kapadia, MD,<sup>b</sup> Jeevanantham Rajeswaran, MSc,<sup>b</sup> William N. Anderson, PhD,<sup>c</sup> Jeffrey W. Moses, MD,<sup>d</sup> E. Murat Tuzcu, MD,<sup>b</sup> John G. Webb, MD,<sup>f</sup> Martin B. Leon, MD,<sup>d</sup> and Craig R. Smith, MD,<sup>d</sup> on behalf of The PARTNER Trial Investigators and Patients, The PARTNER Stroke Substudy Writing Group and Executive Committee

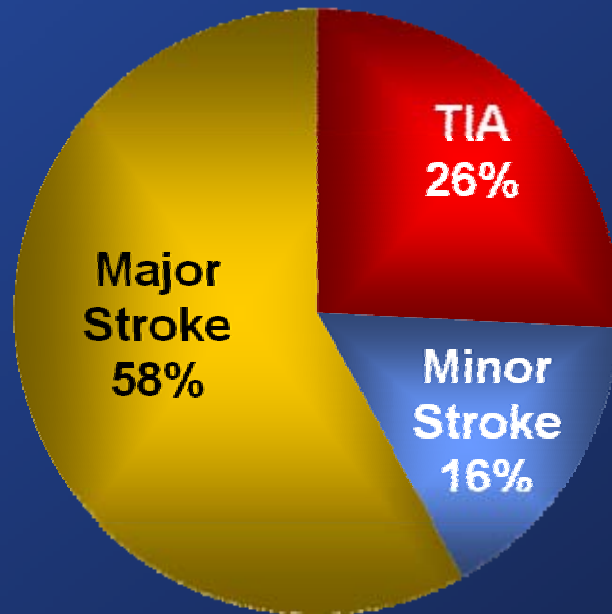
**Conclusions:** After either treatment, there were 2 distinct hazard phases for neurologic events that were driven by different risk factors. Neurologic complications occurred more frequently after TAVR than AVR early, but thereafter the risk was influenced by patient- and disease-related factors. (*J Thorac Cardiovasc Surg* 2012;143:832-43)

***D. Craig Miller et al; J Thorac Cardiovasc Surg 2012;143:832-43***

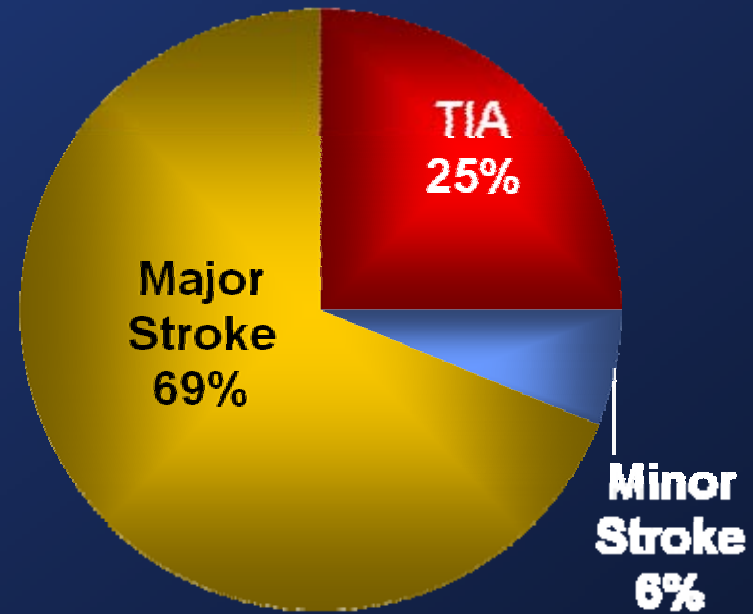
# Distribution of Types of Neurological Events



## TAVR



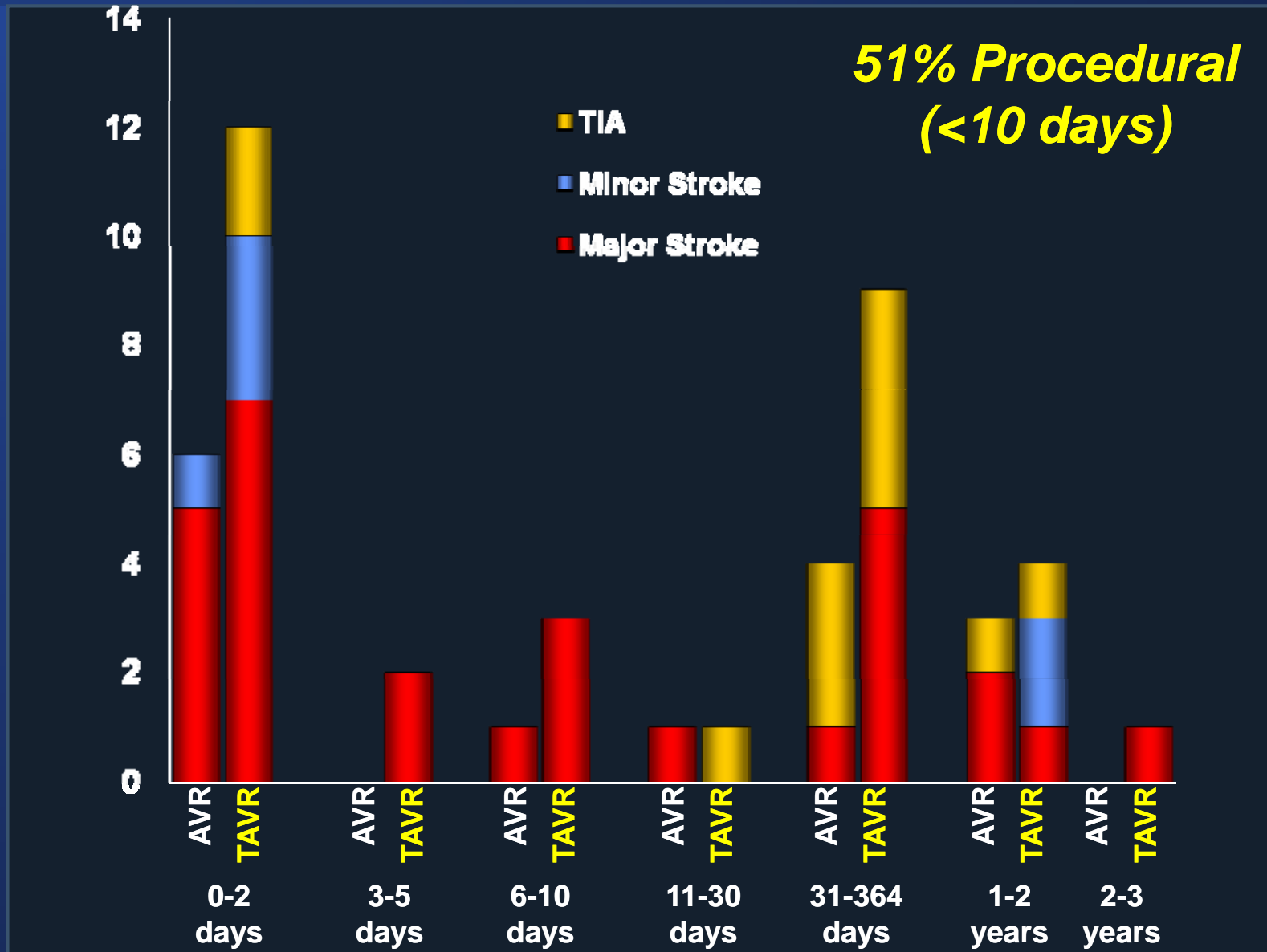
## AVR



***47 patients, 49 neuro events***

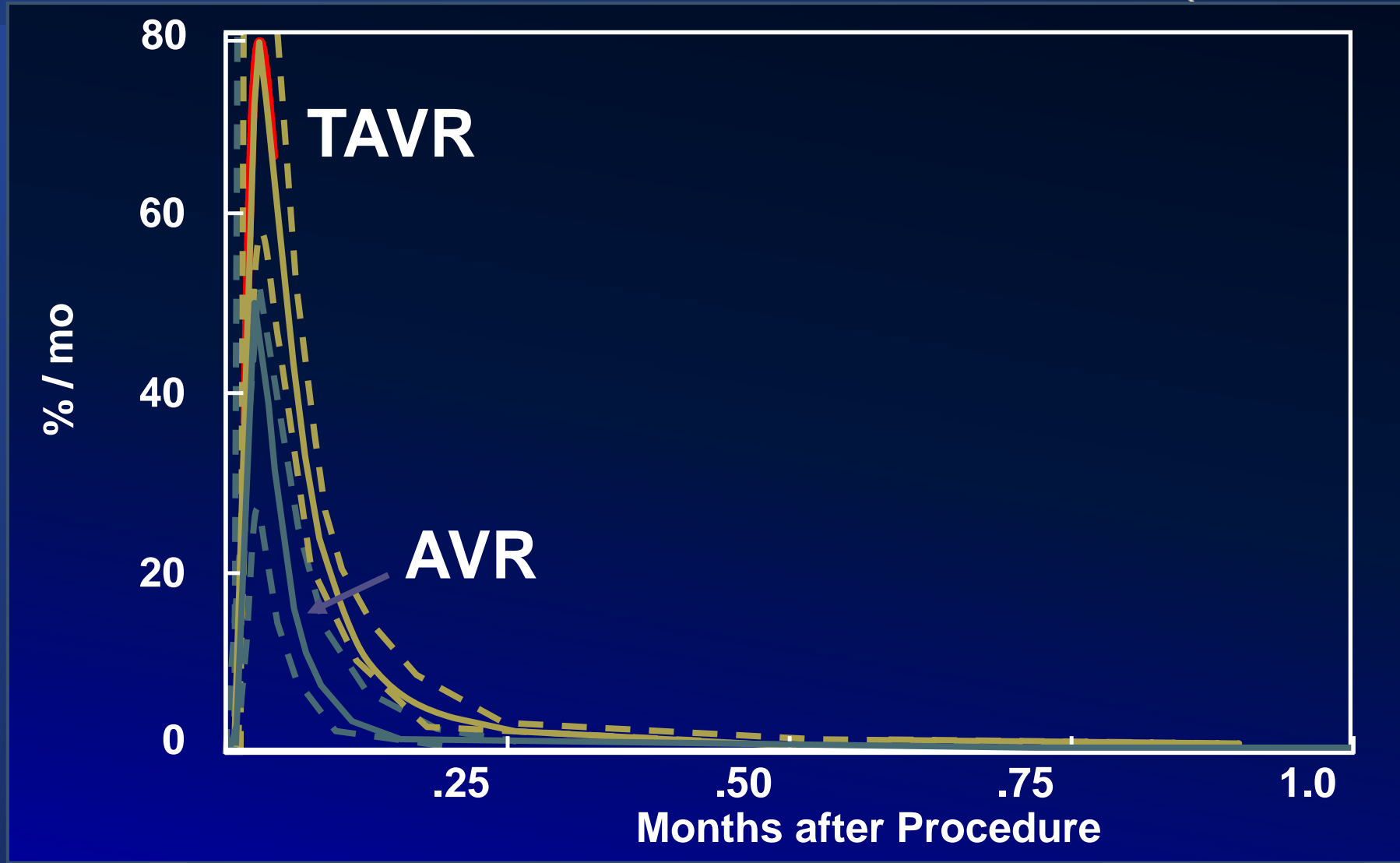
Ischemic - 72%, hemorrhagic - 0%,  
ischemic evolving to hemorrhagic - 4%, unknown - 24%

# Timing and Types of Neurologic Events (strokes and TIAs)





# Early Hazard of Neurologic Event



# Incremental risk factors for neurologic events



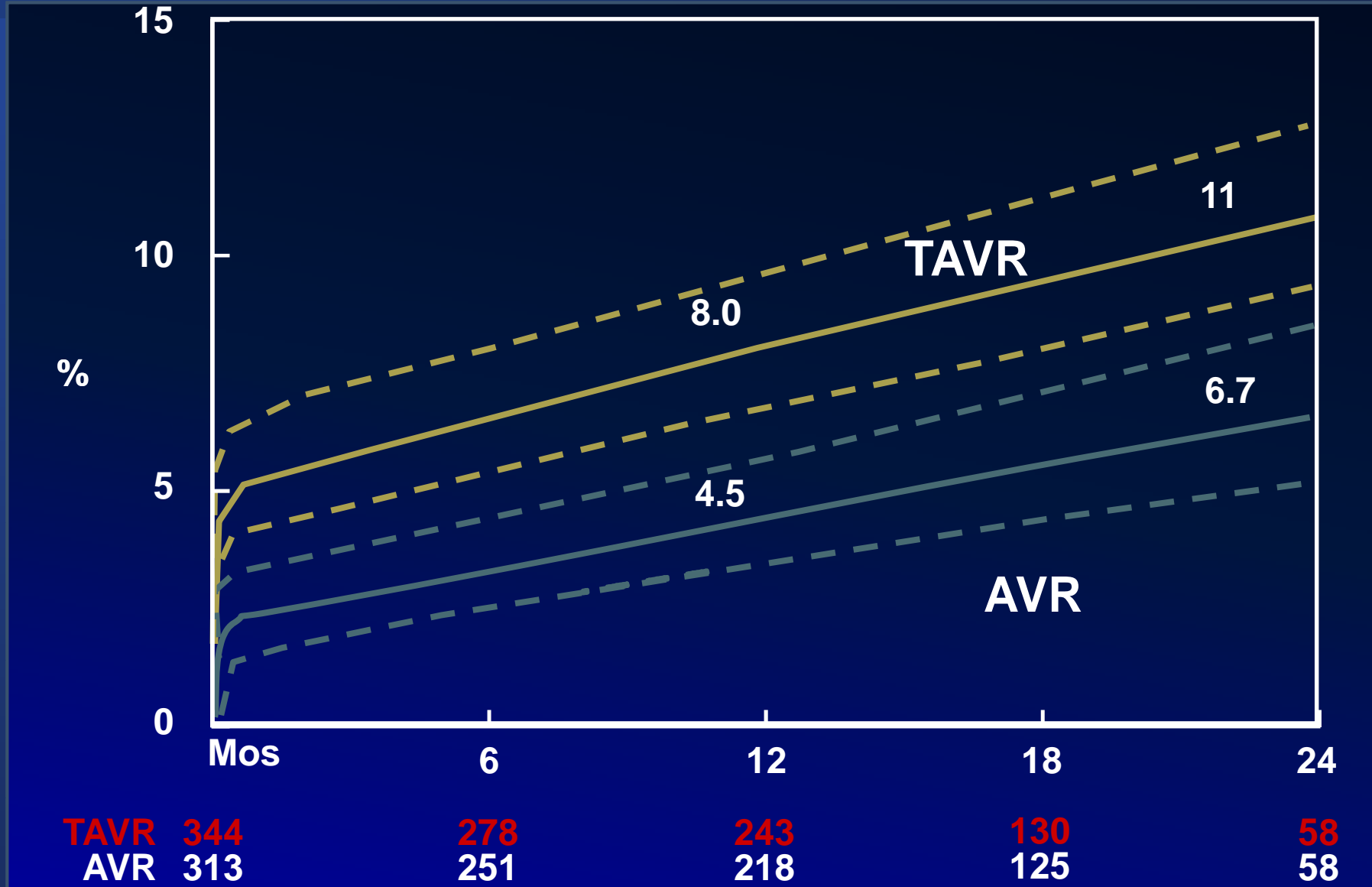
## *Early high peaking hazard phase*

<u>Risk Factor</u>	<u>Coefficient <math>\pm</math> SD</u>	<u>P</u>	<u>R (%)</u>
<i>Early hazard phase</i>			
TAVR	2.21 $\pm$ 0.68	.001	59
Smaller AVA index in TAVR group	-11.8 $\pm$ 5.1	.02	57

*Atrial fibrillation not significant in multivariable analysis*

*R(%) = bagging reliability*

# Later Hazard of Neurologic Event



# Incremental risk factors for neurologic events



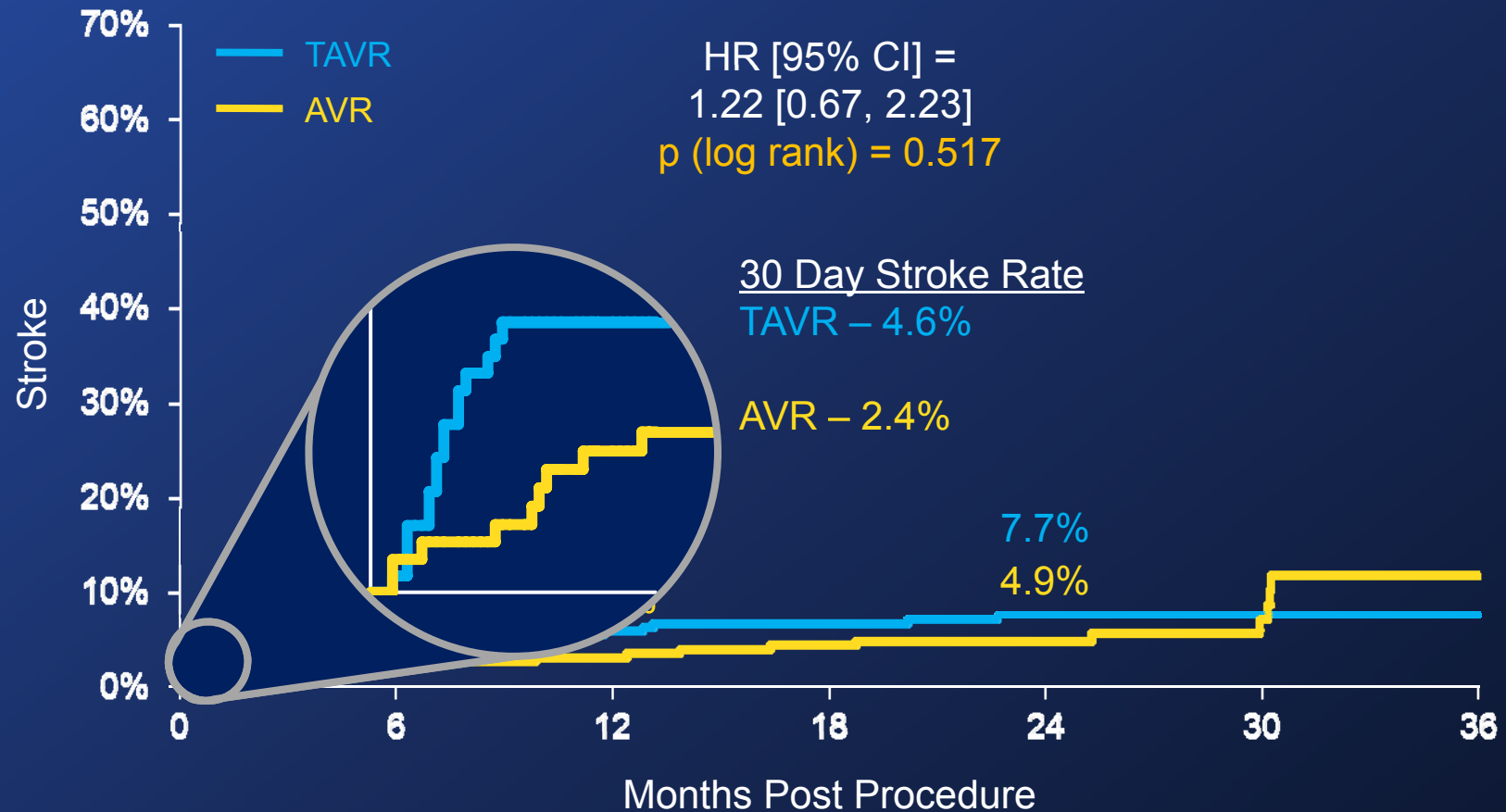
## *Late constant hazard phase*

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

*\*Increased h/o prior CABG, cerebrovascular disease, periperal vascular disease (= increased vasculopathy)*

*R(%) = bagging reliability*

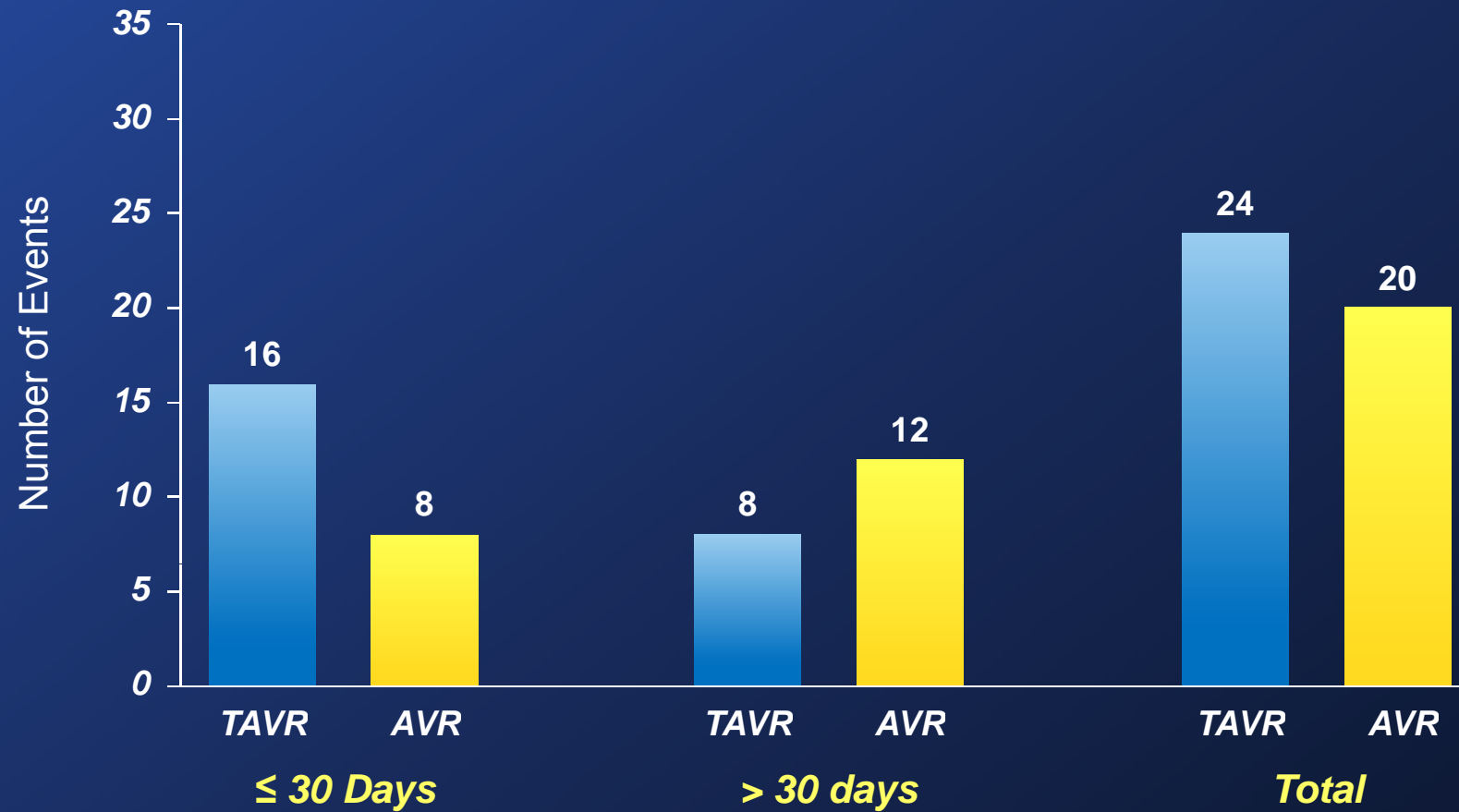
# Strokes (ITT)



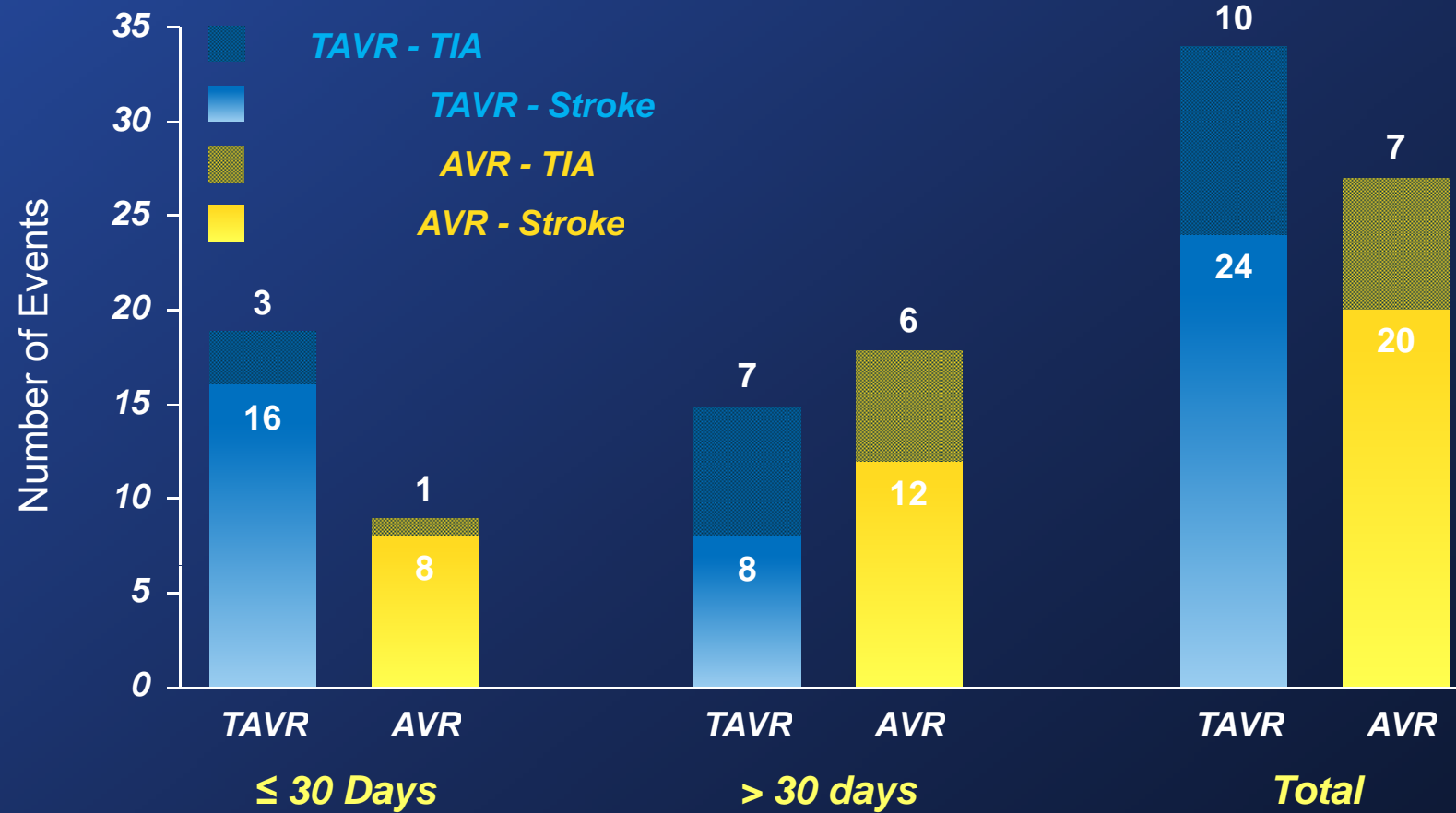
## Numbers at Risk

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

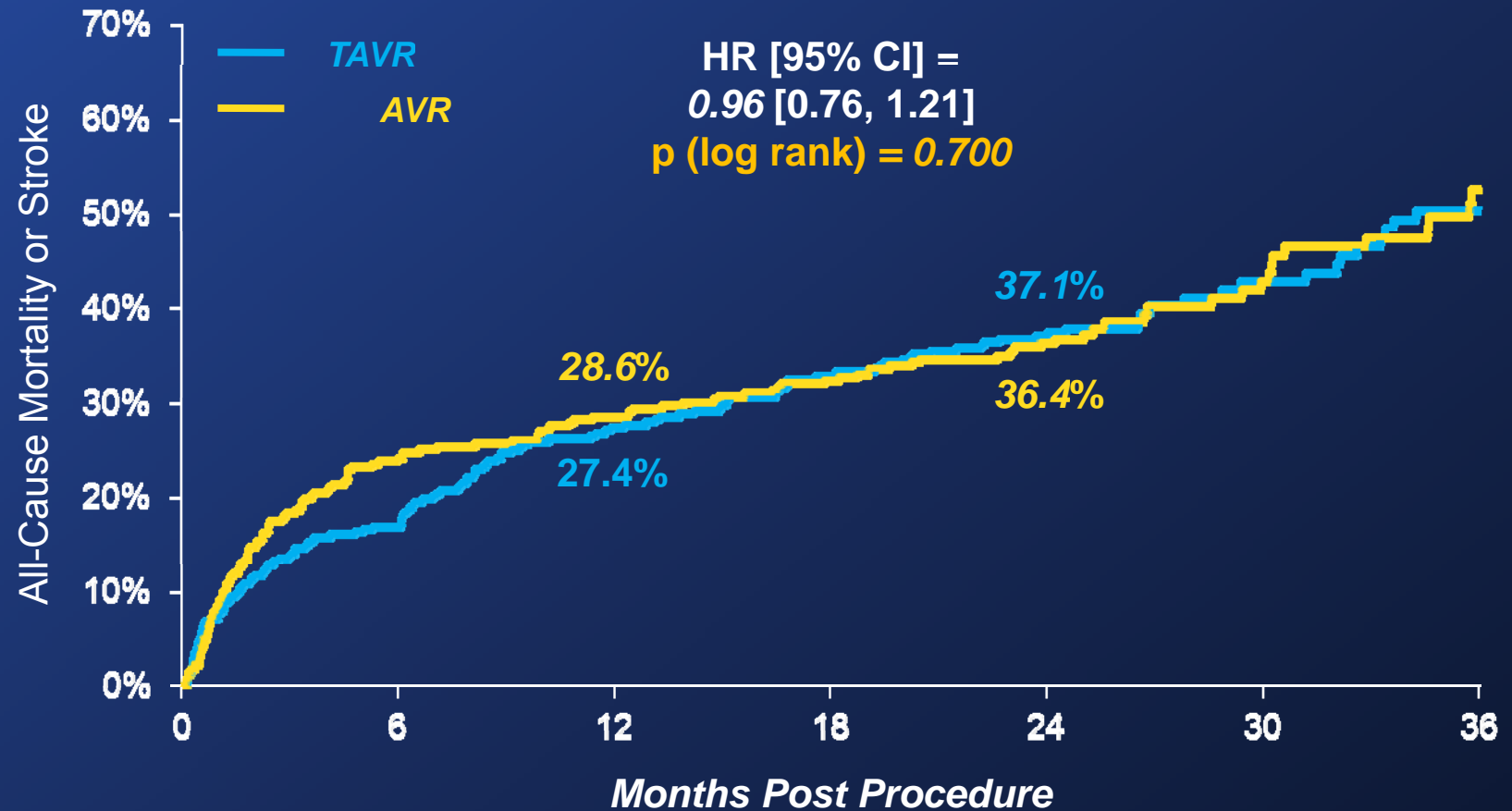
# Strokes (ITT Population)



# All Neurologic Events (ITT)



# All-Cause Mortality or Strokes (ITT)



## Numbers at Risk

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



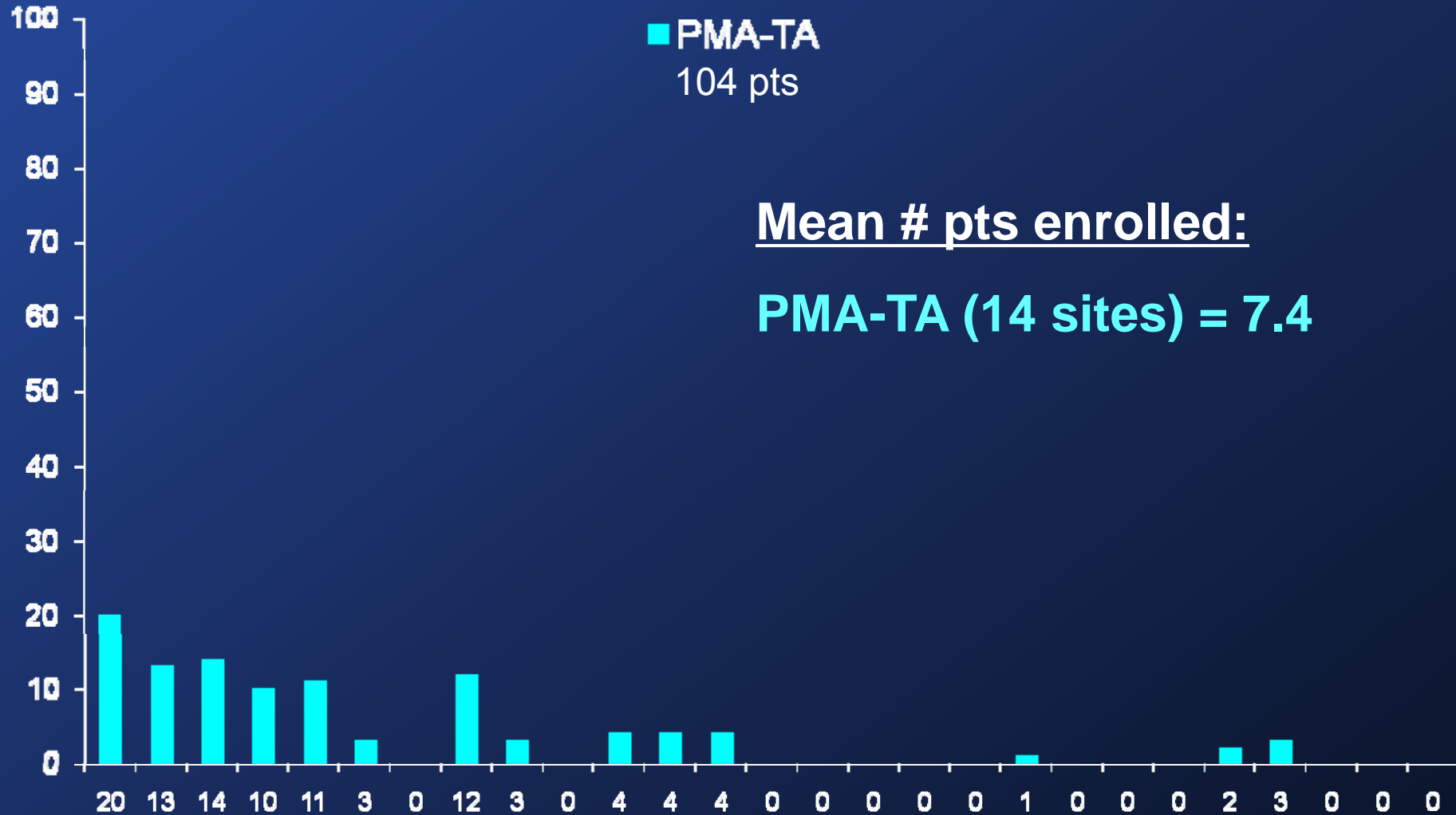
# Transapical Aortic Valve Replacement For Critical Aortic Stenosis: Results From the Non-Randomized Continued Access Cohort of The PARTNER Trial

Todd M. Dewey, MD  
on behalf of The PARTNER Trial Investigators

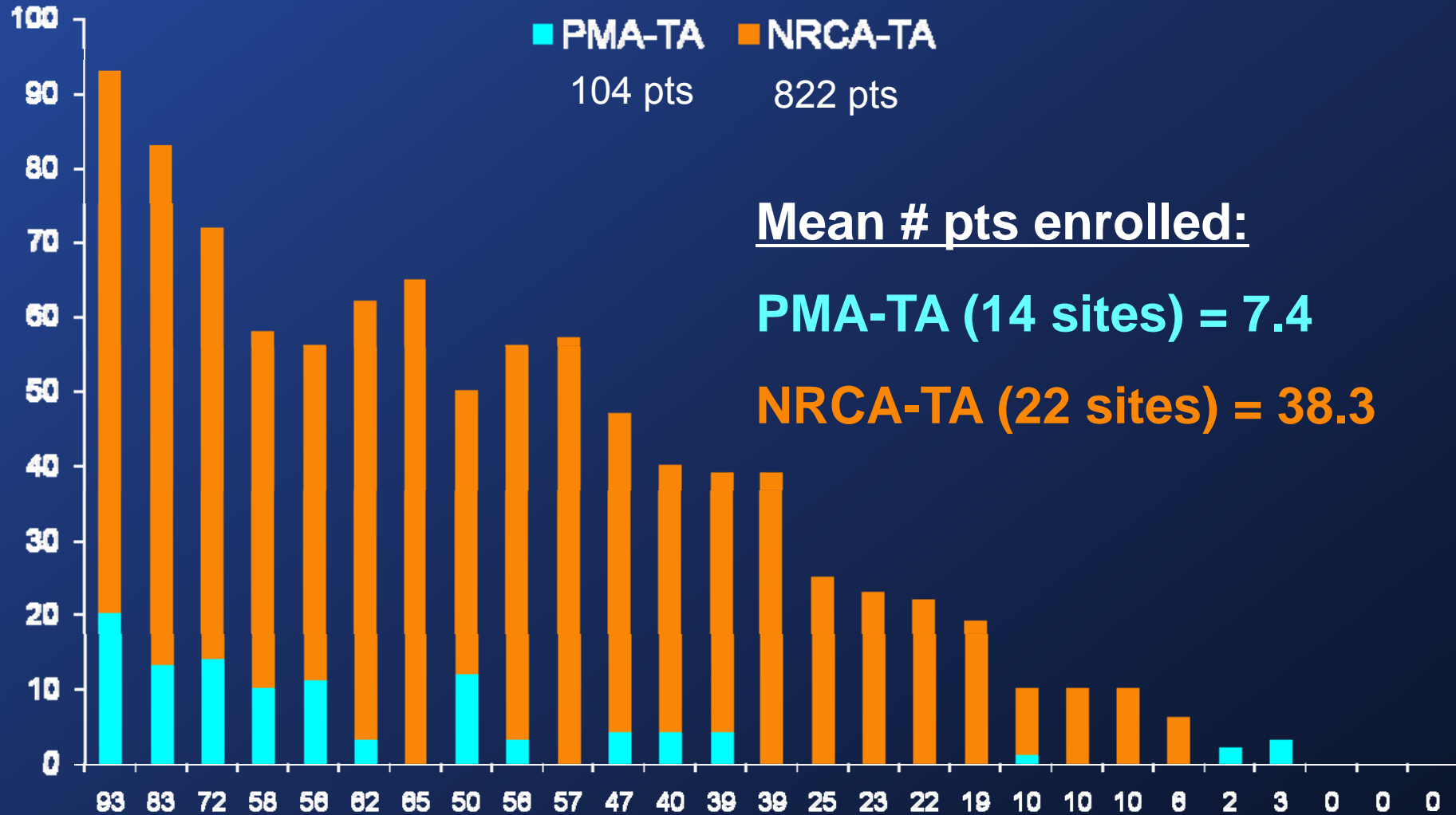
STS 2012 | Fort Lauderdale | Jan 30, 2012



# Transapical Enrollment per Site



# Transapical Enrollment per Site



# Clinical Outcomes at 30 Days and 1 Year (AT)

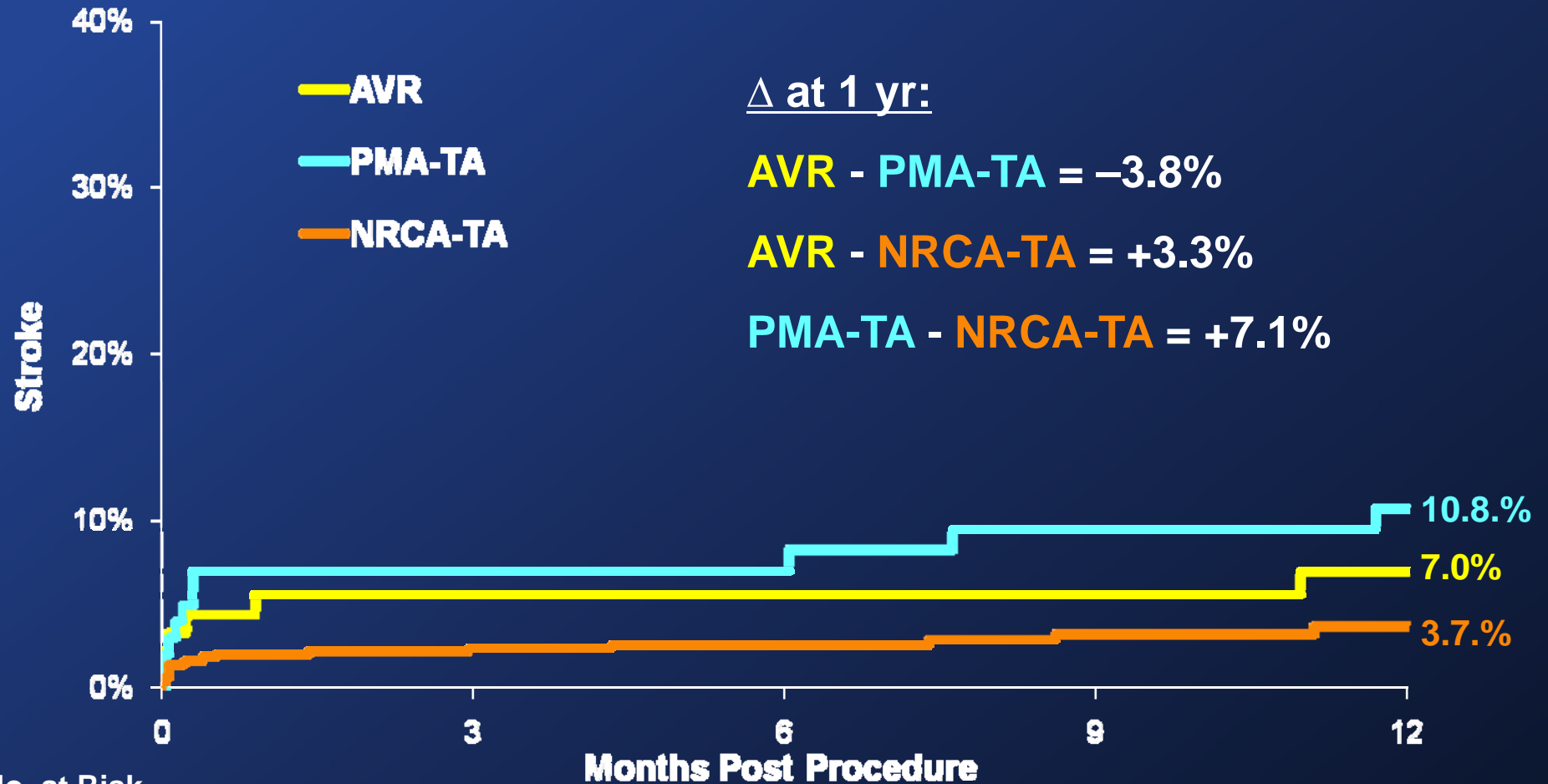


All percents are KM estimates.

Outcome	30 Days			1 Year		
	PMA-TA (n = 104)	AVR (n = 92)	NRCA-TA (n = 822)	PMA-TA (n = 104)	AVR (n = 92)	NRCA-TA (n = 822)
All-Cause Mortality – pts. (%)	9 (8.7%)	7 (7.6%)	66 (8.2%)	30 (29.1%)	23 (25.3%)	148 (23.6%)
Stroke – pts. (%)	7 (7.0%)	5 (5.5%)	16 (2.0%)	10 (10.8%)	6 (7.0%)	22 (3.7%)
Death or Stroke – pts. (%)	16 (15.4%)	11 (12.0%)	80 (9.9%)	36 (34.8%)	27 (29.7%)	163 (25.7%)

Note: p-values between NRCA-TA vs PMA-TA and NRCA-TA vs AVR are all not significant.

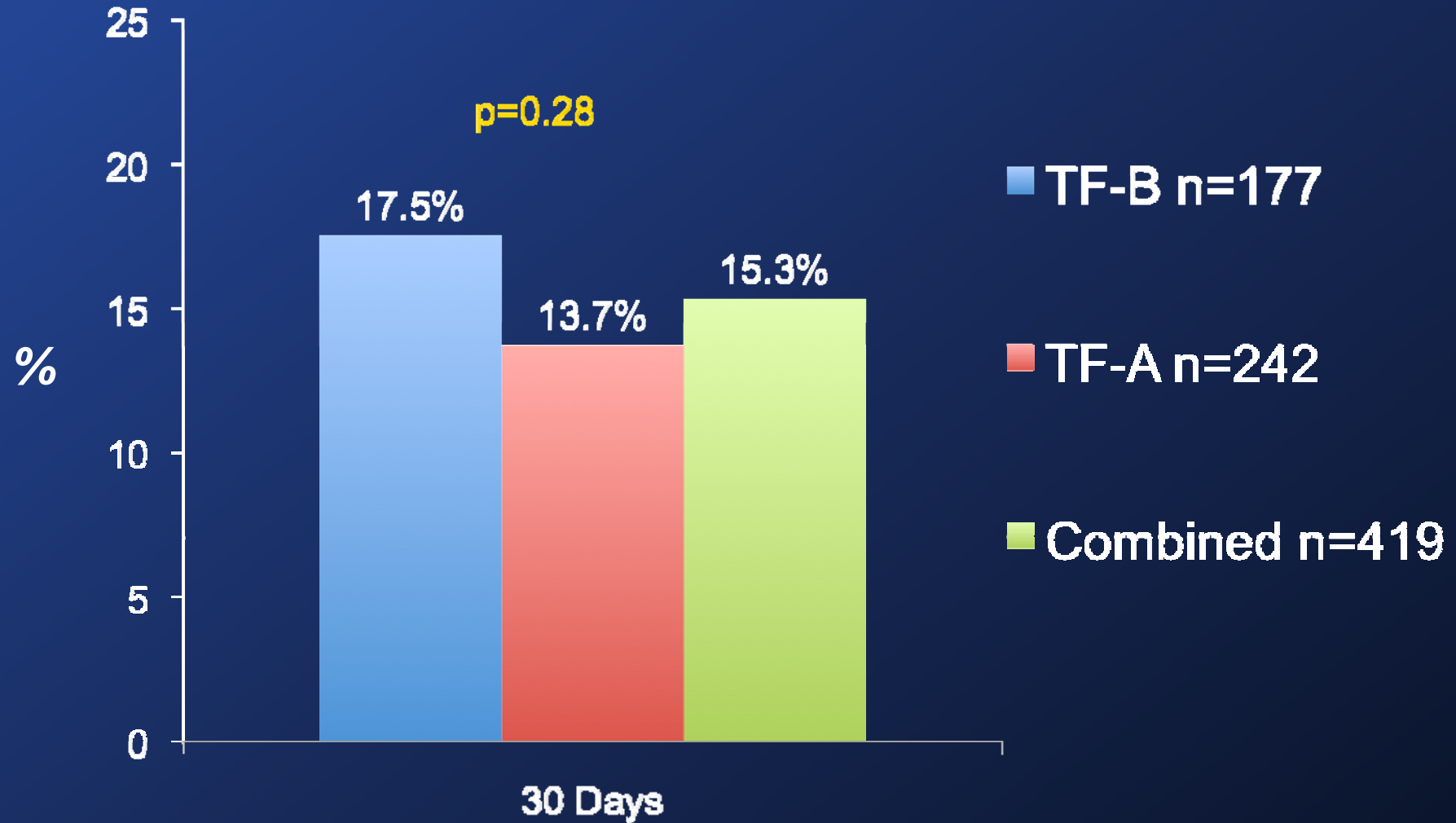
# Stroke (AT)



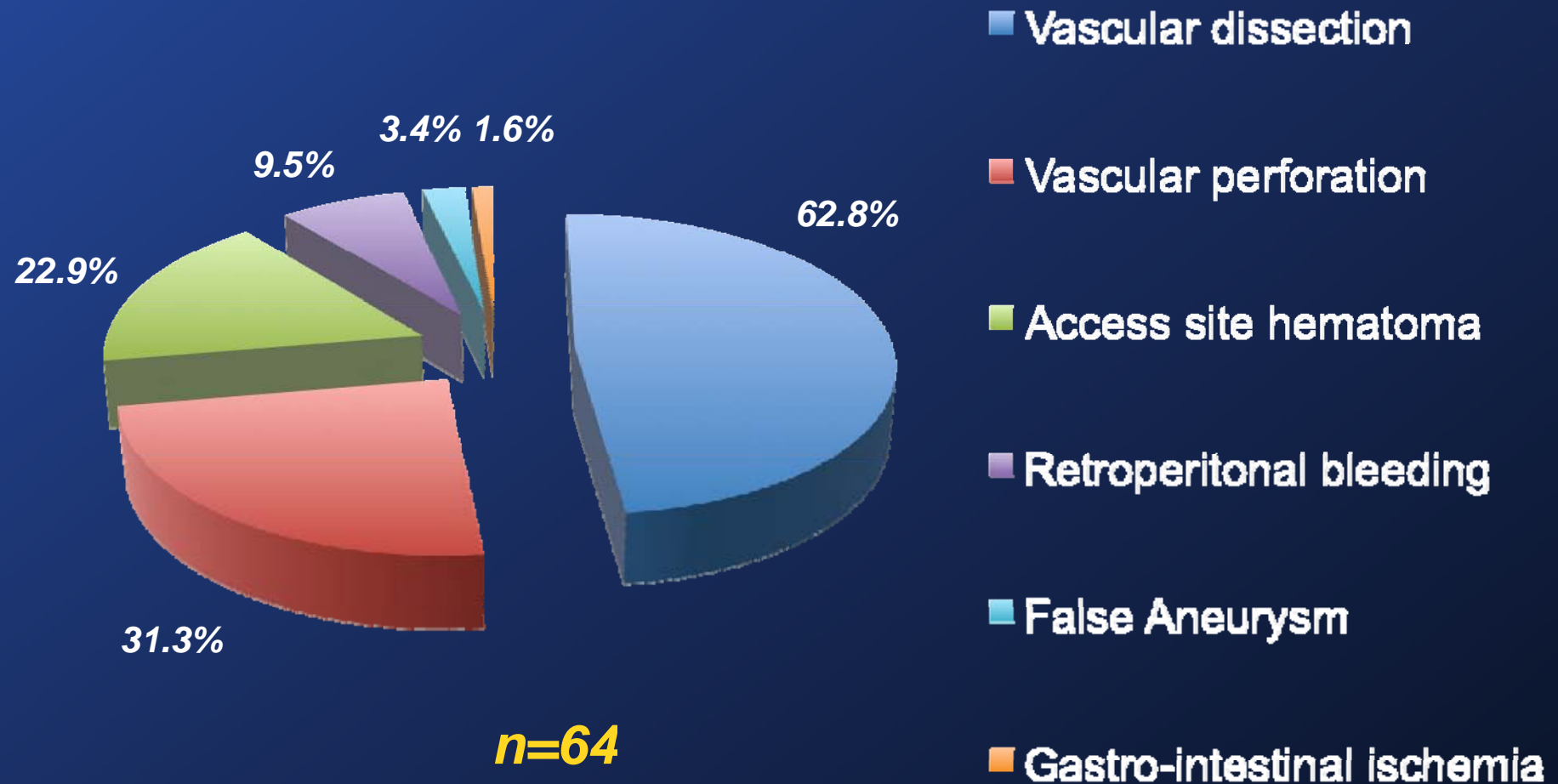
No. at Risk

AVR	92	72	67	66	63
PMA-TA	104	81	77	70	67
NRCA-TA	822	563	365	291	123

# Major Vascular Complications PARTNER TF-Cohort A and B (AT)



# Major Vascular Complications PARTNER TF-Cohort A and B (AT)



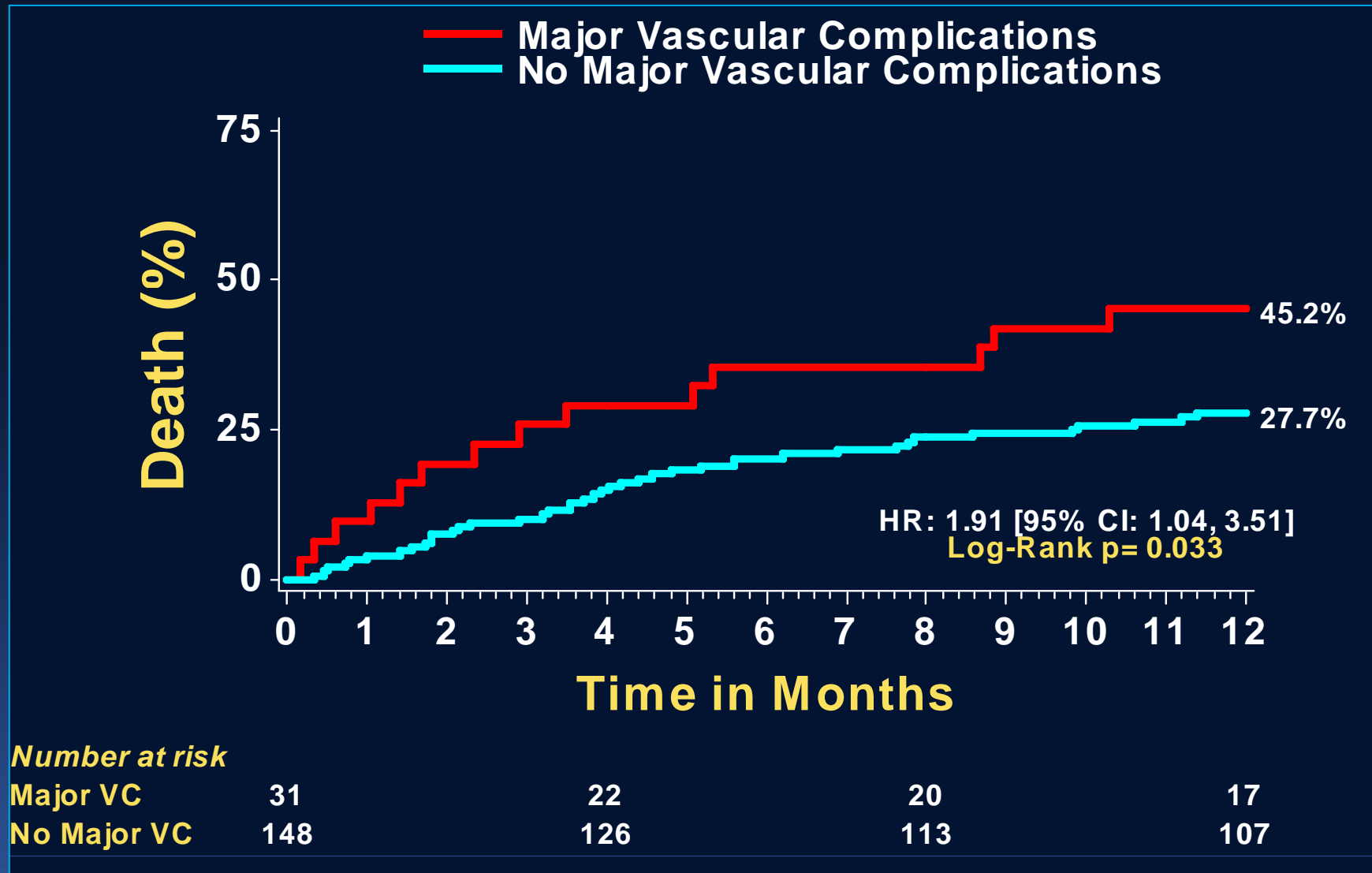
# Association between Major VC, Bleeding and Renal Failure



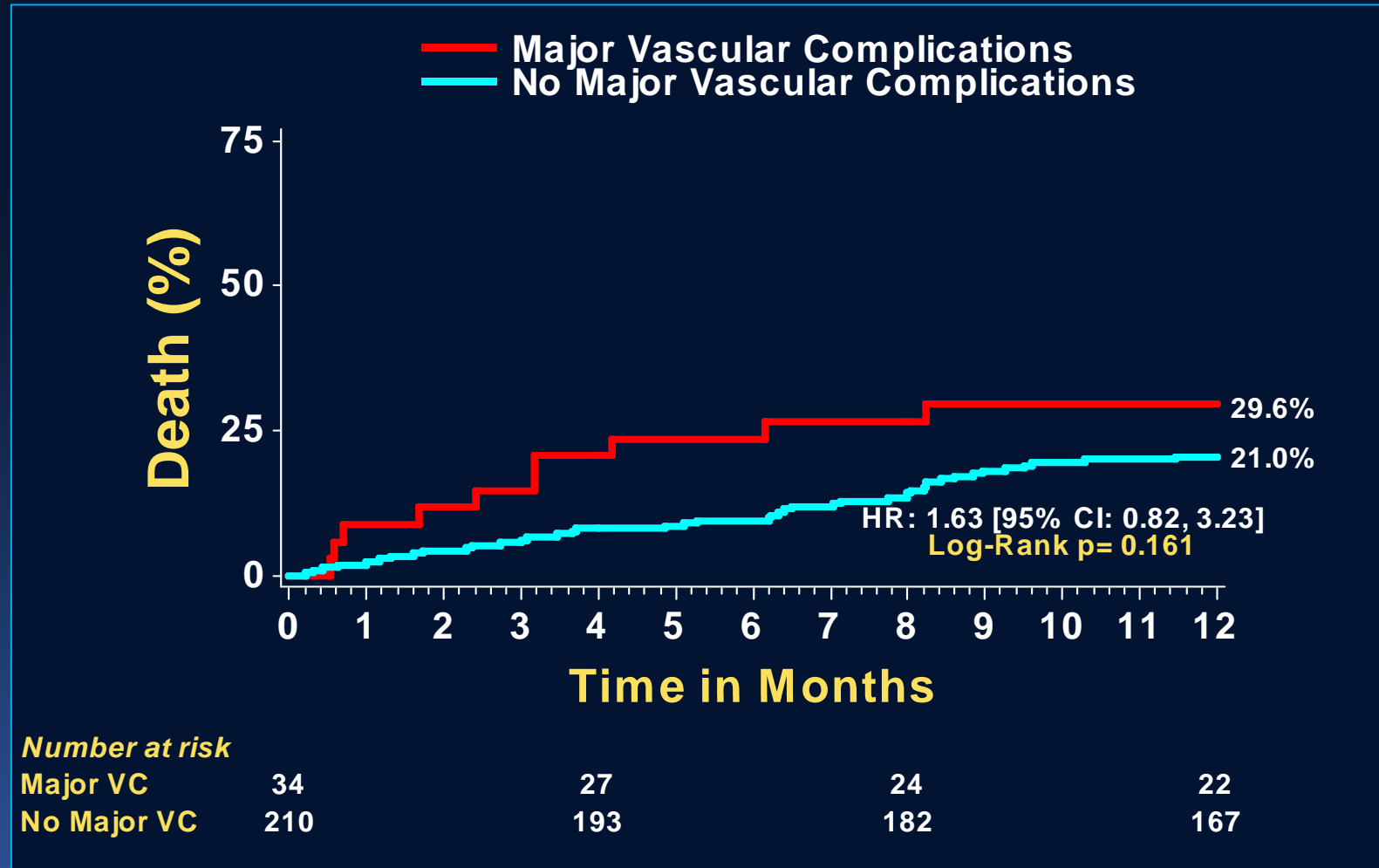
	Major VC n=64	No Major VC n=355	Combined n=419	Hazard Ratio [95% C.I.]	
<i>Hemorrhagic Event</i>	71.9% (46)	13.6% (48)	22.5% (94)	7.60 [5.01,11.52]	<0.0001
Major bleeding	60.9% (39)	6.8% (24)	15.1% (63)	12.73 [7.57,21.42]	<0.0001
Minor bleeding	11.0% (7)	7.1% (25)	7.7% (32)	1.60 [0.69,3.69]	0.26
Bleeding event that requires transfusion	40.7% (26)	5.4% (19)	10.8% (45)	9.23 [5.09,16.76]	<0.0001
<i>Renal Failure (Dialysis required)</i>	8.1% (5)	1.7% (6)	2.7% (11)	4.96 [1.51,16.27]	0.003
Dialysis lasting > 30 days	1.6% (1)	0.6% (2)	0.7% (3)	2.91 [0.26,32.08]	0.36



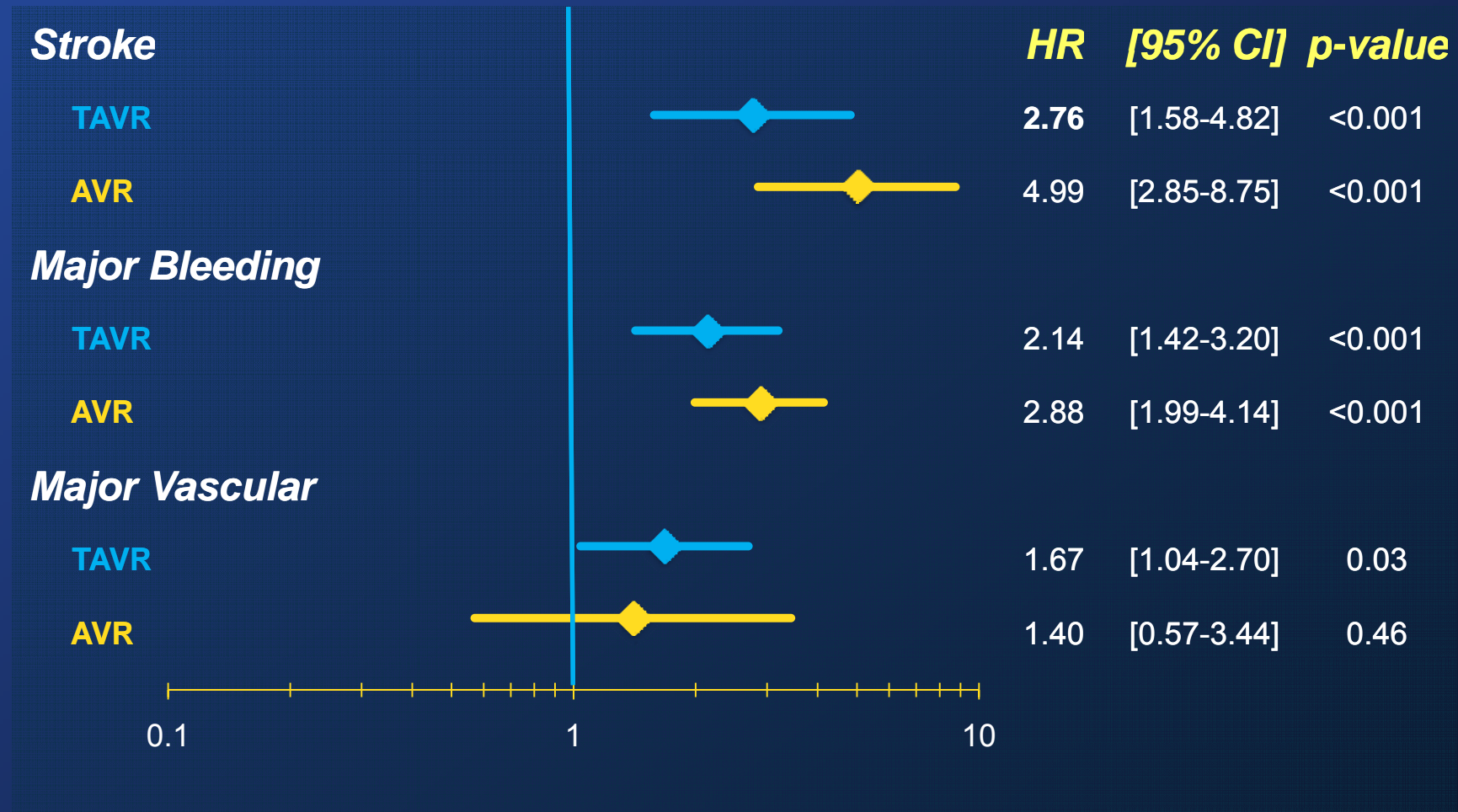
# PARTNER Cohort B TF



# PARTNER Cohort A-TF



# Procedural Predictors of Mortality



# Bleeding Following TAVR

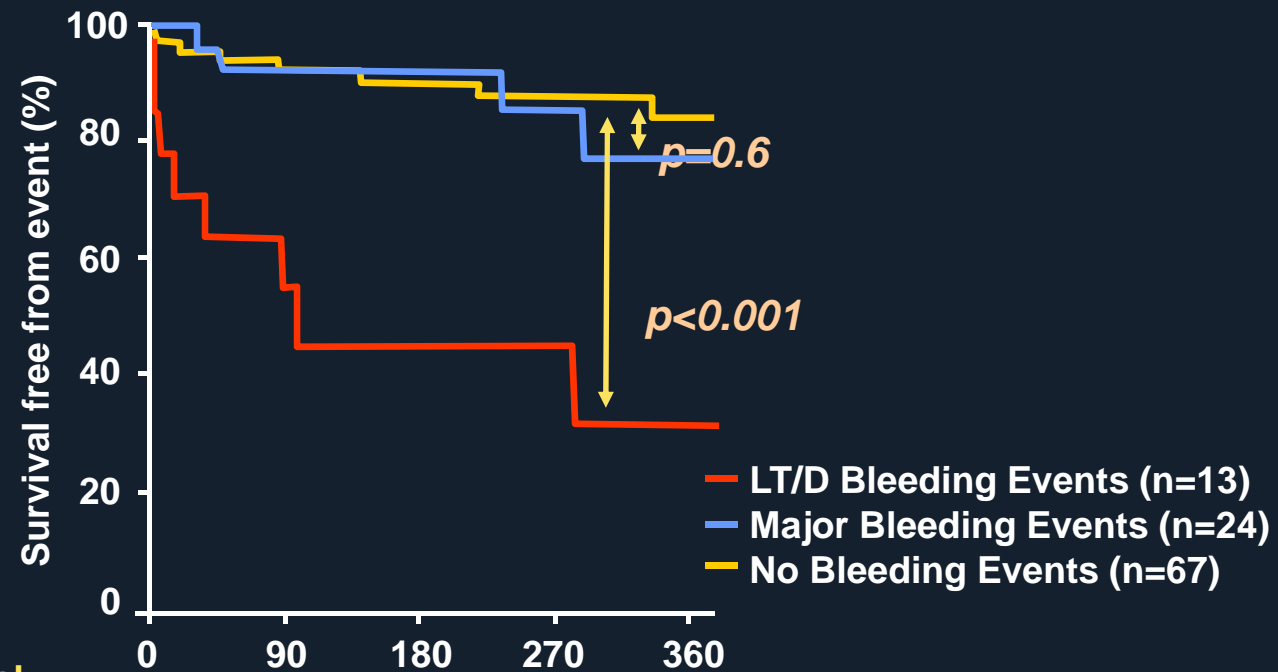
## *Incidence, predictors and prognostic value of major hemorrhagic complications following TAVI procedure*

N. Amabile, A. Azmoun, S. Ghostine, R. Ramadan, Y. Haddouche,  
F. Raoux, NT. To, X. Troussier, R. Nottin, C. Caussin

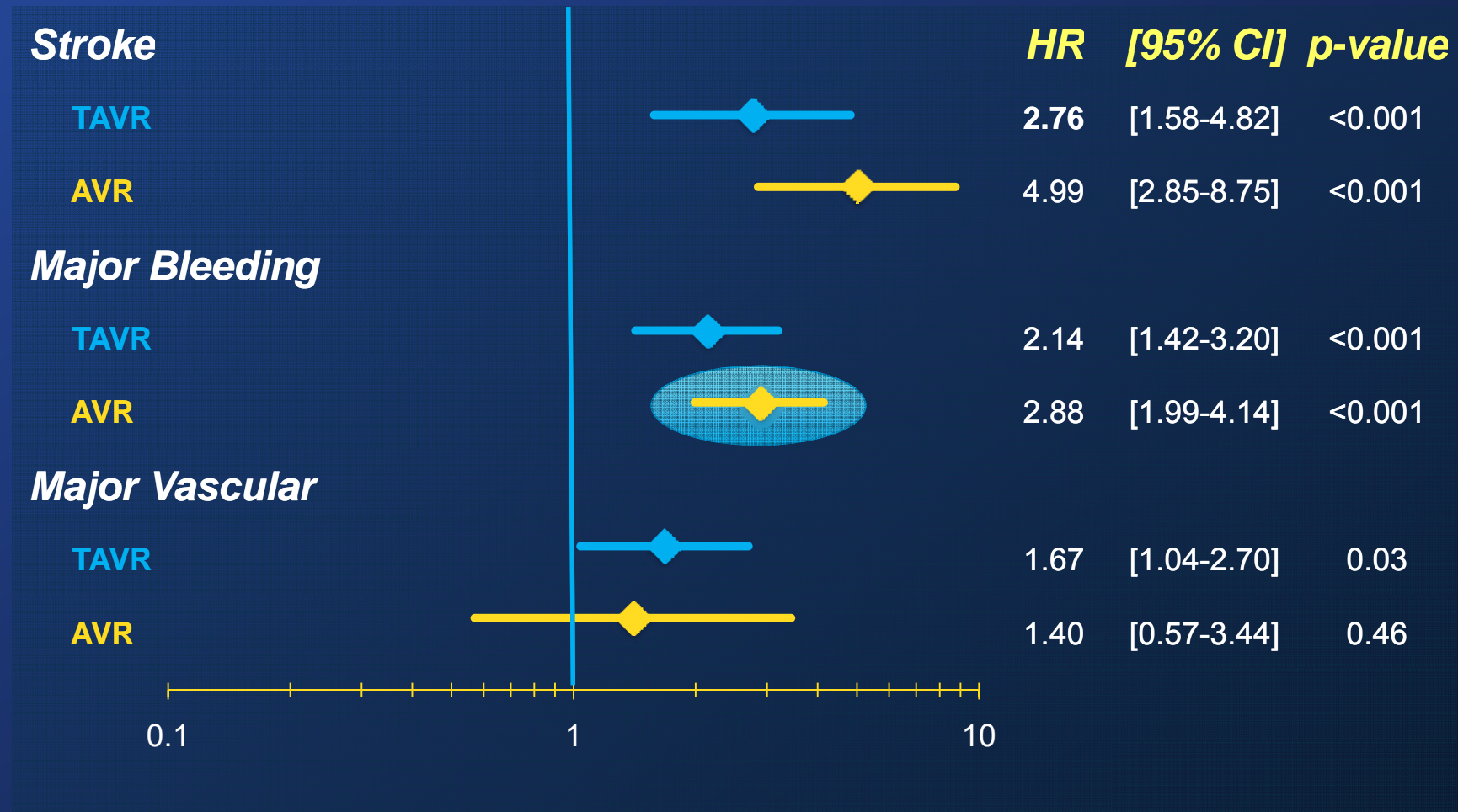
*Department of Cardiology, Centre Marie Lannelongue  
Le Plessis Robinson, France*

# Bleeding Following TAVR

## Survival after Bleeding Event

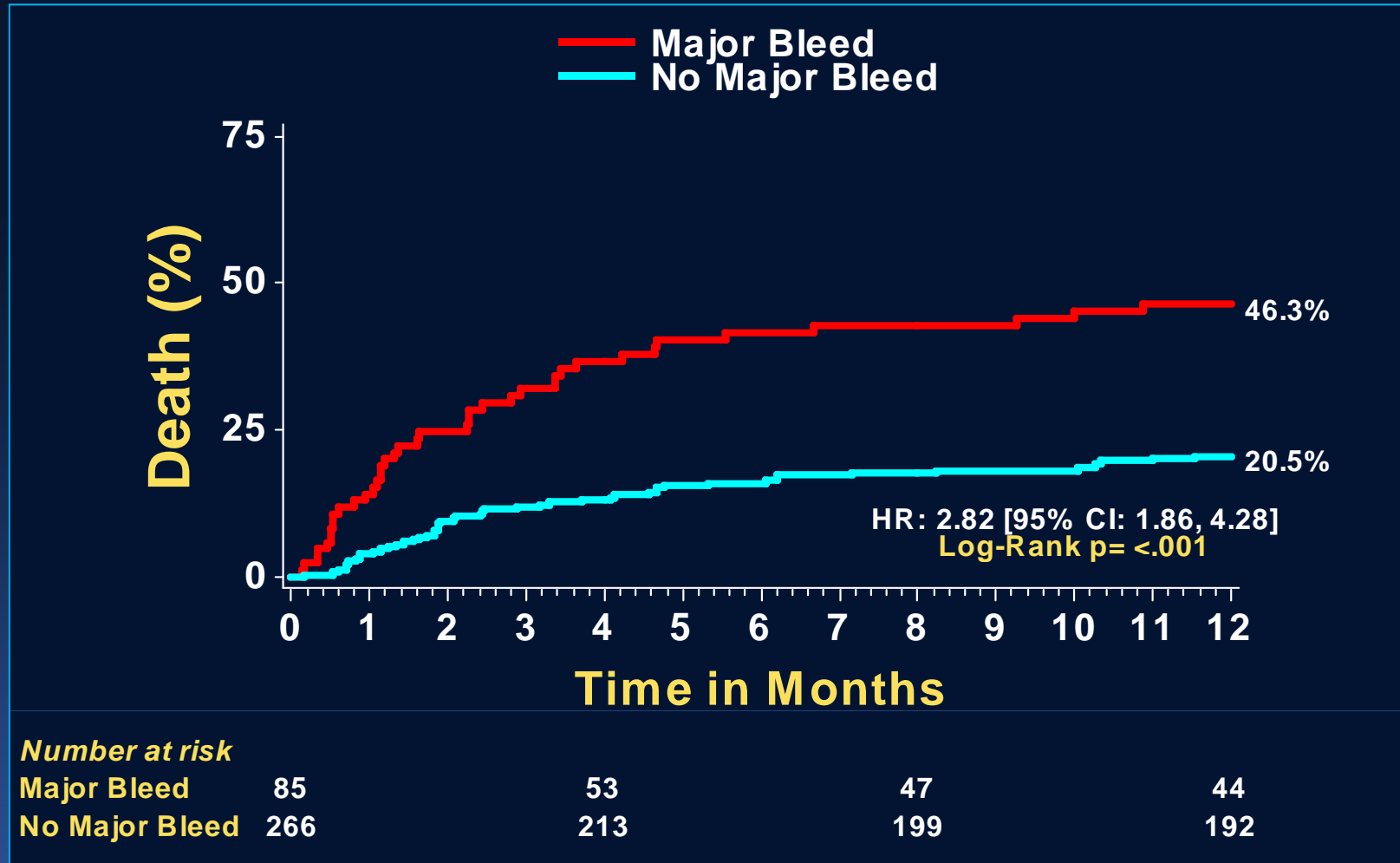


# Procedural Predictors of Mortality



# Bleeding Complications – PARTNER

## Cohort A - Surgery ITT



# TAVR & Conduction Abnormalities

**Sinhal et al. JACC Interv 2008  
(n=123)**

**Piazza et al. JACC Interv 2008  
(n=40)**

**Calvi et al. PACE 2009  
(n=30)**

**Jilaihawi et al. Am Heart J 2009  
(n=34)**

**Gutterez et al. Am Heart J 2009  
(n=33)**

**Erkapic et al. Europace 2010  
(n=50)**

**Haworth et al. CCI 2010  
(n=50)**

**Ferreira et al. Pacing Clin EP 2010  
(n=32)**

**Baan et al. Am Heart J 2010  
(n=34)**

**Latsios et al. Cath Card Interv 2010  
(n=81)**

**Bleiziffer et al. JACC Interv 2010  
(n=123)**

**Godin et al. Am J Cardiol 2010  
(n=67)**

**Piazza et al. EuroIntervention 2010  
(n=91)**

**Roten et al. Am J Cardiol 2010  
(n=67)**

**Fraccaro et al. Am J Cardiol 2011  
(n=70)**

**Guetta et al. Am J Cardiol 2011  
(n=70)**

**Rubin et al. Circ Cardiovasc Interv 2011  
(n=18)**

**Nuis et al. EHJ 2011  
(n=64)**

**Koos et al. J Heart Valve Dis 2011  
(n=80)**

**Aktug et al. Int J Cardiol 2011  
(n=80)**



# Predictors for PPM Medtronic CoreValve

**Pre-existing RBBB**



**Depth of implantation**



**Small LVOT/annulus**



**Septal wall thickness**



**Calcification**



# Pacemakers after TAVR

## Risk for Permanent Pacemaker After Transcatheter Aortic Valve Implantation: A Comprehensive Analysis of the Literature

DAMIR ERKAPIC, M.D.,\* SALVATORE DE ROSA, M.D., PH.D.,† AUGUSTIN KELAVA, PH.D.,‡  
RALF LEHMANN, M.D.,† STEPHAN FICHTLSCHERER, M.D.,†  
and STEFAN H. HOHNLOSER, M.D., F.A.C.C., F.E.S.C., F.H.R.S.\*

From the \*Division of Clinical Electrophysiology, Department of Cardiology; †Department of Cardiology, J.W. Goethe University, Frankfurt, Germany; and ‡Faculty of Human Sciences, Institute of Psychology, Technical University of Darmstadt, Darmstadt, Germany

### Methods:

- **MEDLINE search – meta-analysis from 32 manuscripts and 5,258 patients after TAVR (without baseline pacemaker); Edwards-Sapien = 2,887 pts and Corevalve = 2,371 pts**

### RESULTS:

- **PM after TAVR: ES = 6.5% and CV = 25.8%; odds ratio [OR] 4.91 [95% conf interv [CI] 4.12-5.86],  $p < 0.001$ ; > 90% immediately or within 7 days**
- **Predictors: baseline RBBB (for post-TAVR complete AVB and PM), OR 1.36, 95% CI 1.00-1.84,  $p = 0.02$**

# AKI Following TAVR



European Heart Journal (2010) 31, 865–874  
doi:10.1093/eurheartj/ehp552

CLINICAL RESEARCH  
Valvular heart disease

## Acute kidney injury following transcatheter aortic valve implantation: predictive factors, prognostic value, and comparison with surgical aortic valve replacement

Rodrigo Bagur<sup>1</sup>, John G. Webb<sup>2</sup>, Fabian Nietlispach<sup>2</sup>, Éric Dumont<sup>1</sup>, Robert De Larochelière<sup>1</sup>, Daniel Doyle<sup>1</sup>, Jean-Bernard Masson<sup>2</sup>, Marcos J. Gutiérrez<sup>1</sup>, Marie-Annick Clavel<sup>1</sup>, Olivier F. Bertrand<sup>1</sup>, Philippe Pibarot<sup>1</sup>, and Josep Rodés-Cabau<sup>1\*</sup>

### Methods:

- 213 pts (82 ± 8 yrs) with TAVR (Edwards, TF/TA 52/48%) at 2 Canadian centers.
- AKI = >25% decrease eGFR @ 48 hrs or HD during hosp.
- 119 CKD pts (eGFR < 60) cw 104 surgical AVR pts.

### RESULTS:

- AKI after TAVR 11.7%, HD 1.4% and predictive factors for AKI were HBP, COPD and peri-op blood Tx
- AKI was an independent predictor of peri-operative mortality
- In CKD pts (propensity adjusted), AKI less frequent with TAVR (9.2%, HD 2.5%) vs. surgical AVR (25.9%, HD 8.7%; p=0.001)

# AKI Following TAVR

## Incidence and predictors of acute kidney injury in patients undergoing transcatheter aortic valve implantation

Yacine Elhmidi, MD, Sabine Bleiziffer, MD, Nicolo Piazza, MD, PhD, FRCPC, FESC, Andrea Hutter, MD, Anke Opitz, MD, Ina Hettich, MD, Matthias Kornek, MD, Hendrik Ruge, MD, Gernot Brockmann, MD, Domenico Mazzitelli, MD, and Rüdiger Lange, MD, PhD *Munich, Germany*

### **Methods:**

- 236 pts with TAVR (CoreValve 73.5%, Edwards 26.5%) in 1 German center.
- AKI = RIFLE criteria (risk, injury, failure) + RRT based on eGFR changes in the first 7 post-operative days

### **RESULTS:**

- AKI after TAVR, 19.6% and RRT 10.3%; predictive factors for AKI were preop creatinine, PVD, and blood Tx
- Hospital mortality was 15.2% if AKI+ and 7.7% for AKI- (P=0.015) and at 6 mos mortality was 35.6% for AKI+ and 14.3% fo AKI- (P<0.001)

# Myocardial Injury after TAVR

## Incidence, Predictive Factors, and Prognostic Value of Myocardial Injury Following Uncomplicated Transcatheter Aortic Valve Implantation

Josep Rodés-Cabau, MD, Marcos Gutiérrez, MD, Rodrigo Bagur, MD, Robert De Laroche, MD, Daniel Doyle, MD, Mélanie Côté, MSc, Jacques Villeneuve, MD, Olivier F. Bertrand, MD, PhD, Eric Larose, MD, Juan Manazzoni, MD, Philippe Pibarot, PhD, Eric Dumont, MD

*Quebec City, Quebec, Canada*

### **Methods:**

- 101 pts with successful TAVR (Edwards); TF = 38 and TA = 63
- Biomarkers measured at baseline, 6, 12, 24, 48 and 72 hrs after TAVR; CK-MB (ULN = 10 ug/l and cTnT (ULN = 0.03 ug/l)

### **RESULTS:**

- TAVR assoc with some myocardial injury in 99% of pts (TF 97% and TA 100%) as determined by cTnT rise (max value av 0.48 ug/l) and in 77% of pts (TF 47% and TA 95%) by CK-MB rise (max value av 18.6 ug/l)

# Myocardial Injury after TAVR

## Incidence, Predictive Factors, and Prognostic Value of Myocardial Injury Following Uncomplicated Transcatheter Aortic Valve Implantation

Josep Rodés-Cabau, MD, Marcos Gutiérrez, MD, Rodrigo Bagur, MD, Robert De Laroche, MD, Daniel Doyle, MD, Mélanie Côté, MSc, Jacques Villeneuve, MD, Olivier F. Bertrand, MD, PhD, Eric Larose, MD, Juan Manazzoni, MD, Philippe Pibarot, PhD, Eric Dumont, MD

*Quebec City, Quebec, Canada*

### RESULTS (con't):

- TA approach and baseline renal dysfunction was assoc with greater biomarker rise ( $P < 0.01$  for both)
- A larger myocardial injury was assoc with a smaller improvement in LVEF after TAVR ( $P < 0.01$ )
- ***The degree of rise in cTnT was an independent predictor of mortality at 9 mos FU (HR 1.14 for each increase of 0.1 ug/l rise,  $P < 0.028$ )***

# TAVR in Review (2011-12)

## Adjunctive Imaging

# Adjunctive Imaging during TAVR

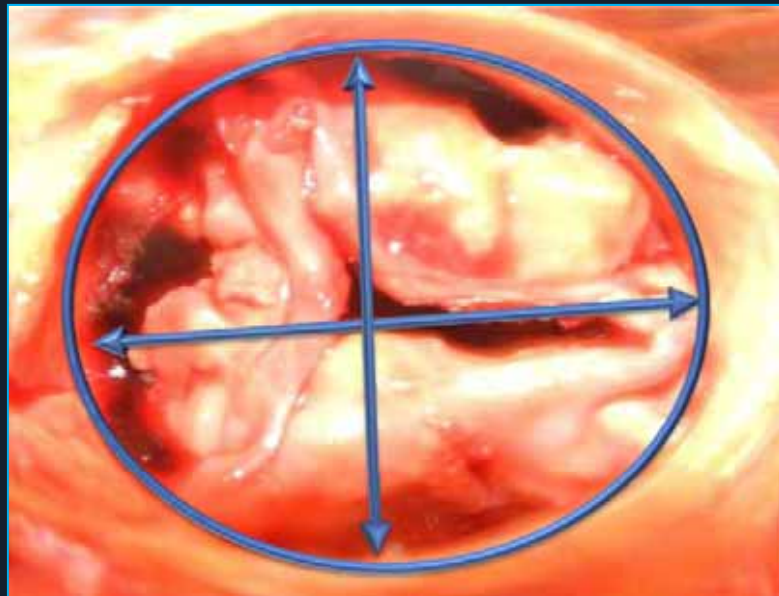
*Multi-modality Imaging is the RULE*



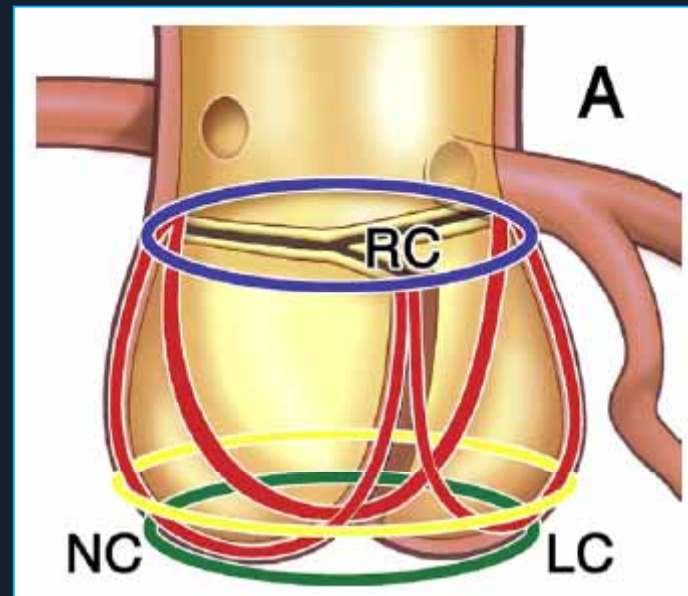


# Adjunctive Imaging during TAVR

## *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)*

# Adjunctive Imaging during TAVR

## *Measurement of Annulus Dimensions*

Preoperative Assessment of Aortic Annulus

**I** Comparison of Aortic Root Dimensions and Geometries  
**I** Before and After Transcatheter Aortic Valve Implantation

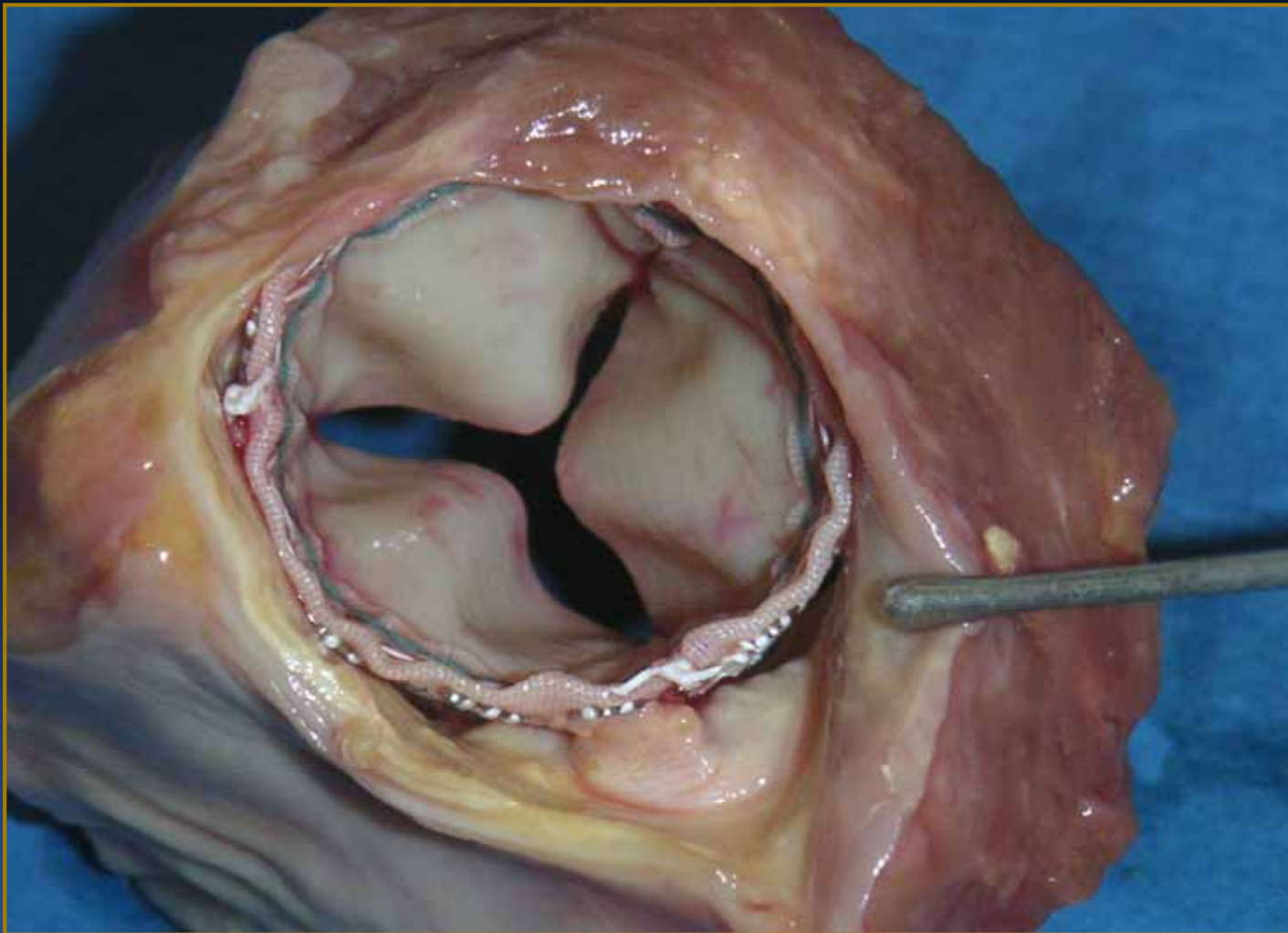
**A** by **Pre-Procedural Imaging of Aortic Root** **phy**  
**G**  
**E** **Orientation and Dimensions**  
**R**

**Mu** Measurement of Aortic Valve Annulus Using Different  
**of** Cardiac Imaging Techniques in Transcatheter Aortic

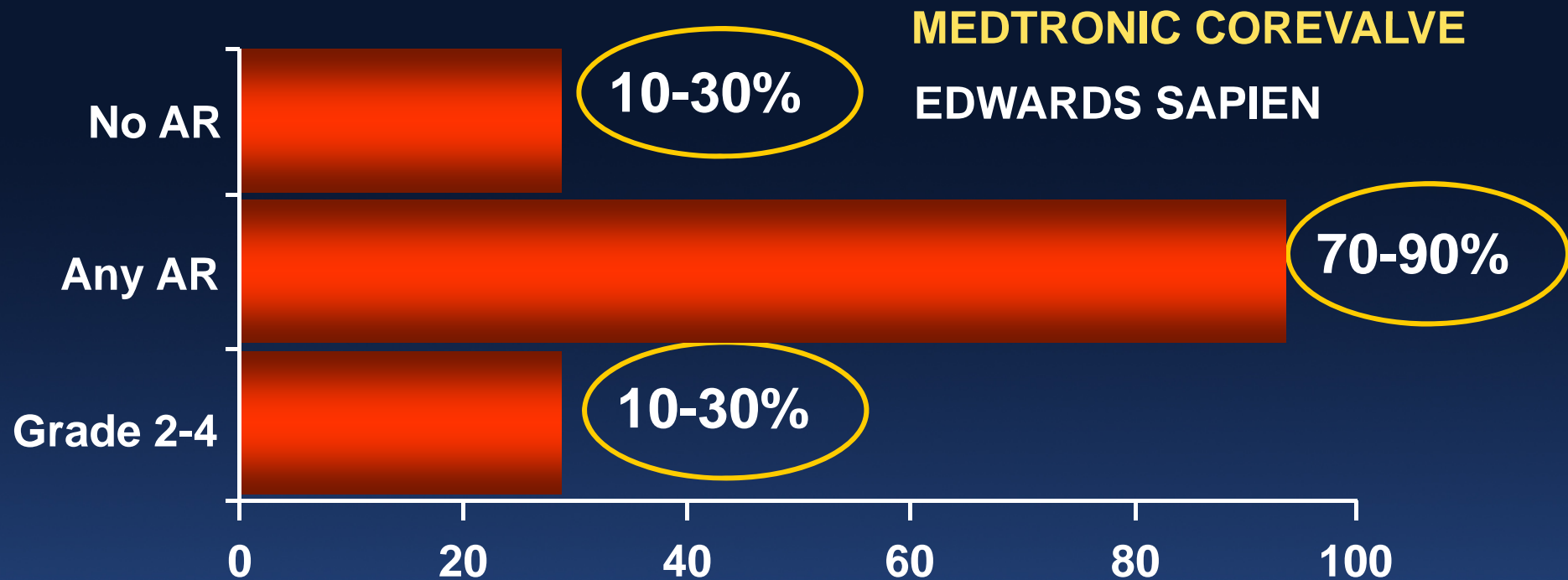
Multidetector Computed Tomography in  
Transcatheter Aortic Valve Implantation

Jonathon Leipsic, MD,\* Ronen Gurvitch, MD,‡ Troy M. LaBounty, MD,§  
James K. Min, MD,§|| David Wood, MD,‡ Mark Johnson, MD,† Amr M. Ajlan, MD,†  
Namal Wijesinghe, MD,‡ John G. Webb, MD‡ **JACC CV Imaging 2011;4:416-29**

# Para-valvular Regurgitation



# Frequency of TAVR Para-Valvular AR (Peer-reviewed)



Rajan et al. *Catheter Cardiovasc Interv* 2009

Jilaihawi et al. *Eur Heart J* 2009

Moss et al. *JACC Cardiovasc Imag* 2008

Clavel et al. *J Am Coll Cardiol* 2009

Himbert et al. *J Am Coll Cardiol* 2008

Detaint et al. *JACC Cardiovasc Interv* 2009

# Para-valvular Regurgitation after TAVR

## CLINICAL RESEARCH

### Determinants of Significant Paravalvular Regurgitation After Transcatheter Aortic Valve Implantation

Impact of Device and Annulus Discongruence

Delphine Détaint, MD, Laurent Lepage, MD, Dominique Himbert, MD, Eric Brochet, MD, David Messika-Zeitoun, MD, Bernard Iung, MD, Alec Vahanian, MD

### Methods:

- 70 pts with TAVR (Edwards).
- Assess congruence betw annulus and device size by analyzing the COVER INDEX:  $100X \text{ prosthesis } (D) - \text{TEE annulus } D / \text{prosthesis } D$

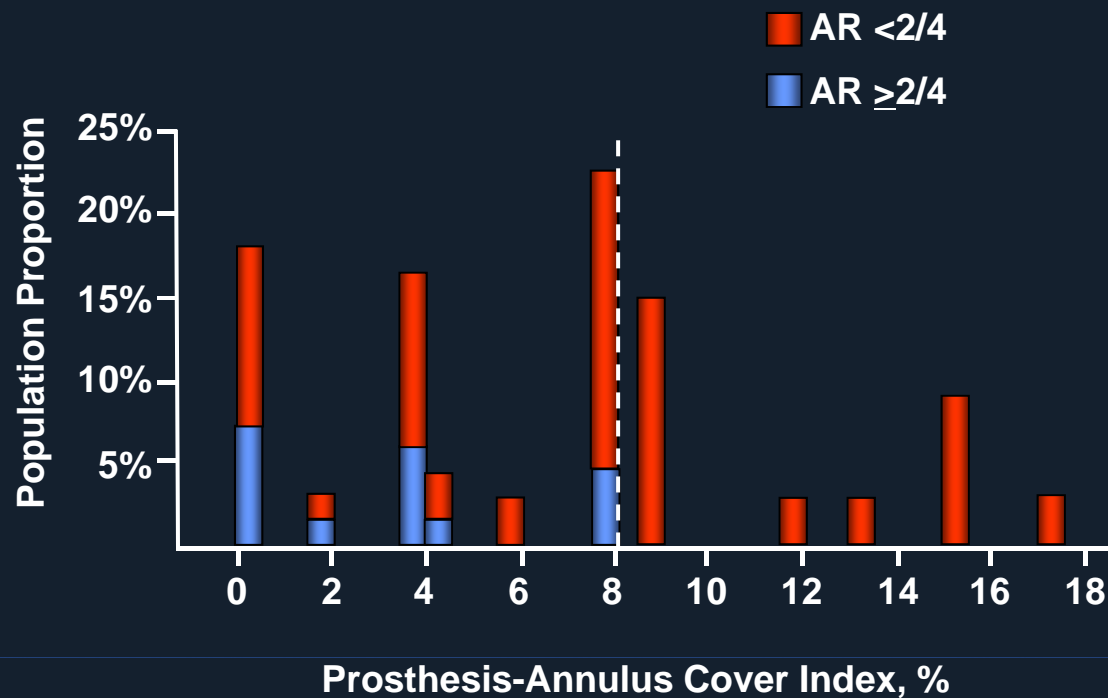
### RESULTS:

- After TAVR, PVL absent 7%, 1/4 in 72%, 2/4 in 16%, 3/4 in 5%
- Predictors of PVL  $\geq 2/4$  were increased pt height, larger annulus, and a cover index  $< 8\%$
- PVL  $\geq 2/4$  was never seen if annulus was  $< 22\text{mm}$  or the cover index was  $> 8\%$

**CONCLUSION:** Prosthesis/annulus “discongruence” is a strong predictor of post-TAVR  $\geq 2/4$  PVL

# Para-valvular Regurgitation after TAVR

## Relationship of Cover Index to PVL



# Para-valvular Regurgitation after TAVR

## Correlation of Device Landing Zone Calcification and Acute Procedural Success in Patients Undergoing Transcatheter Aortic Valve Implantations With the Self-Expanding CoreValve Prosthesis

Daniel John, MD, Lutz Buellesfeld, MD, Seyrani Yucel, MD, Ralf Mueller, MD, Georg Latsios, MD, Harald Beucher, MD, Ulrich Gerckens, MD, Eberhard Grube, MD

*Siegburg, Germany*

### **METHODS:**

- 100 pts with CoreValve TAVR
- MSCT with and without contrast to assess calcium load in valve and adjacent LVOT estimated by Agaston Score (AgS) and the amount and distribution of calcium at the device landing zone (DLZ-CS) by semi-quantitative scoring (grade 1-4)
- **Calcium levels correlated with PVL by angio and TTE (2 weeks later)**

# PVL after TAVR Predicts Increased Mortality

Aortic regurgitation after transcatheter aortic valve implantation: incidence and early outcome. Results from the German transcatheter aortic valve

inter

Mohar

Tran

sev

mo

Michae

Alfried

## Long-Term Outcomes After Transcatheter Aortic Valve Implantation in High-Risk Patients With Severe Aortic Stenosis

The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry

Neil E. Moat, MBBS, MS,\* Peter Ludman, MA, MD,† Mark A. de Belder, MA, MD,‡ Ben Bridgewater, PhD,§ Andrew D. Cunningham, PhD,|| Christopher P. Young, MD,¶ Martyn Thomas, MD,¶ Jan Kovac, MD,# Tom Spyt, MD,# Philip A. MacCarthy, BS, PhD,\*\* Olaf Wendler, MD, PhD,\*\* David Hildick-Smith, MD,†† Simon W. Davies, MBBS, MD,\* Uday Trivedi, MBBS,†† Daniel J. Blackman, MD,‡‡ Richard D. Levy, MD,§ Stephen J. D. Brecker, MD,§§ Andreas Baumbach, MD,|| Tim Daniel, MB, ChB,¶¶ Huon Gray, MD,## Michael J. Mullen, MBBS, MD\*\*\*

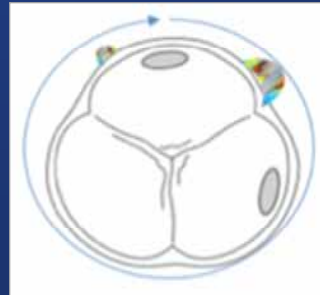
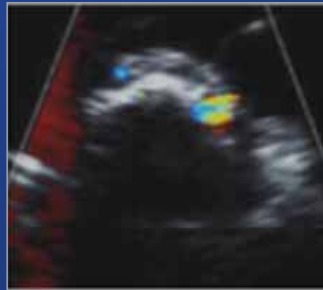
with  
of



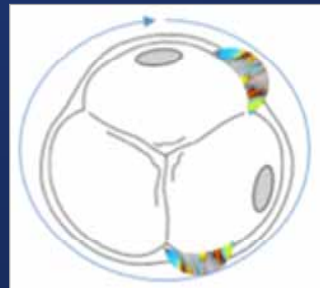
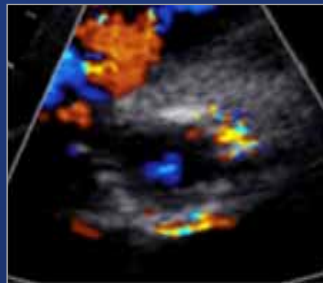
# PVL after TAVR Predicts Increased Mortality

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

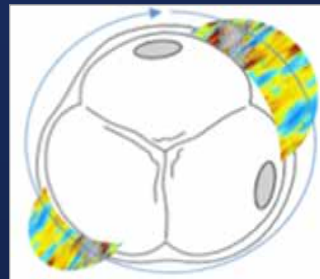
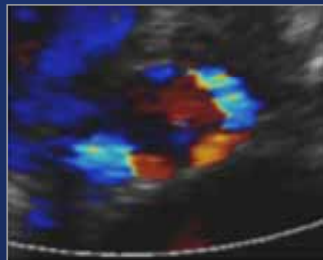
# PARTNER Grading Criteria for Paravalvular AR



Circumference = 6"  
AR = 0.1+0.35 = 0.45"  
Ratio = 8%  
Severity = Mild



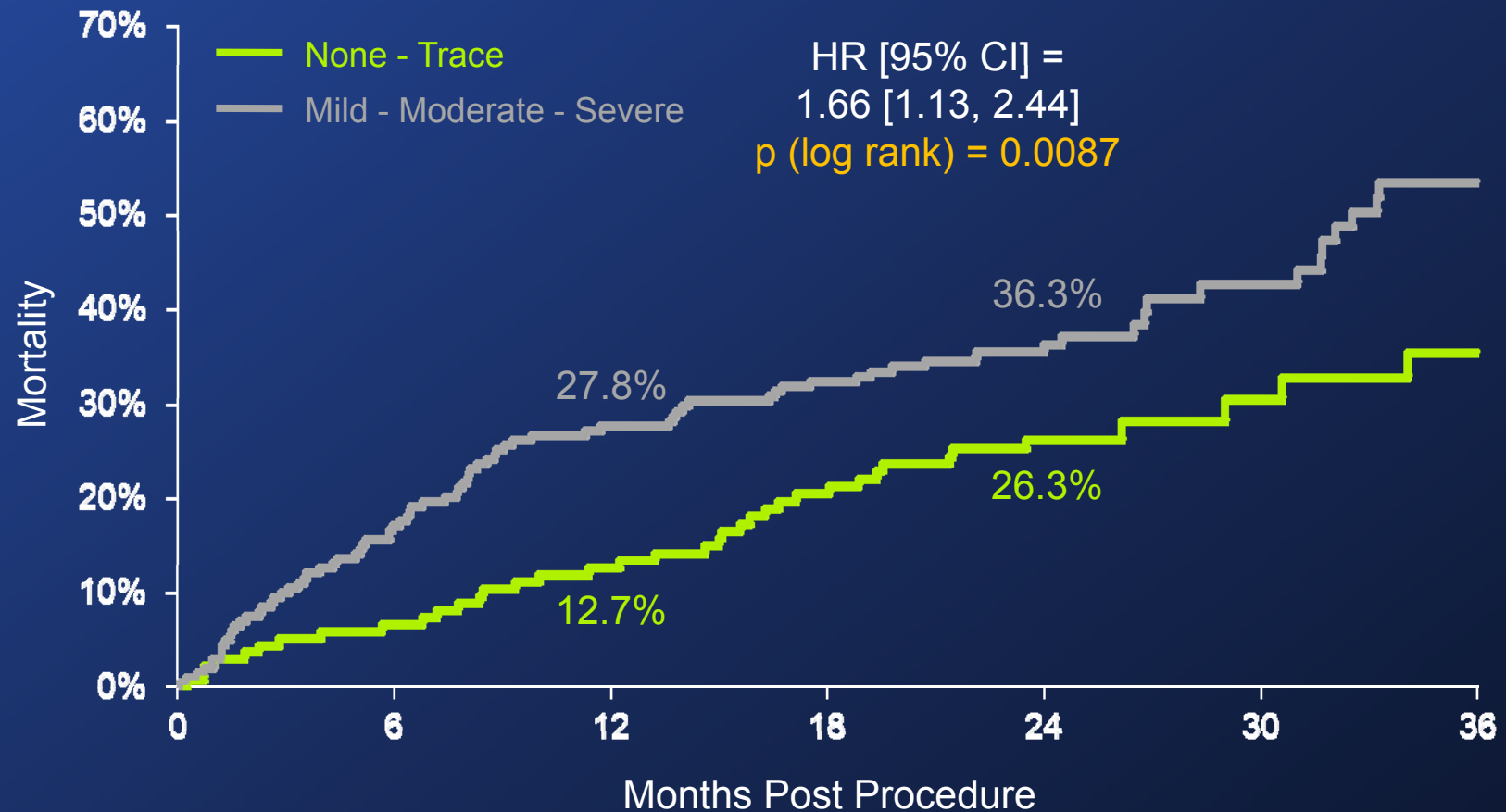
Circumference = 6"  
AR = 0.5+0.5 = 1.0"  
Ratio = 17%  
Severity = Moderate  
(Trans AR also present)



Circumference = 6"  
AR = 0.6+1.1 = 1.7"  
Ratio = 28%  
Severity = Severe

Images courtesy of Pamela Douglas, MD, FASE

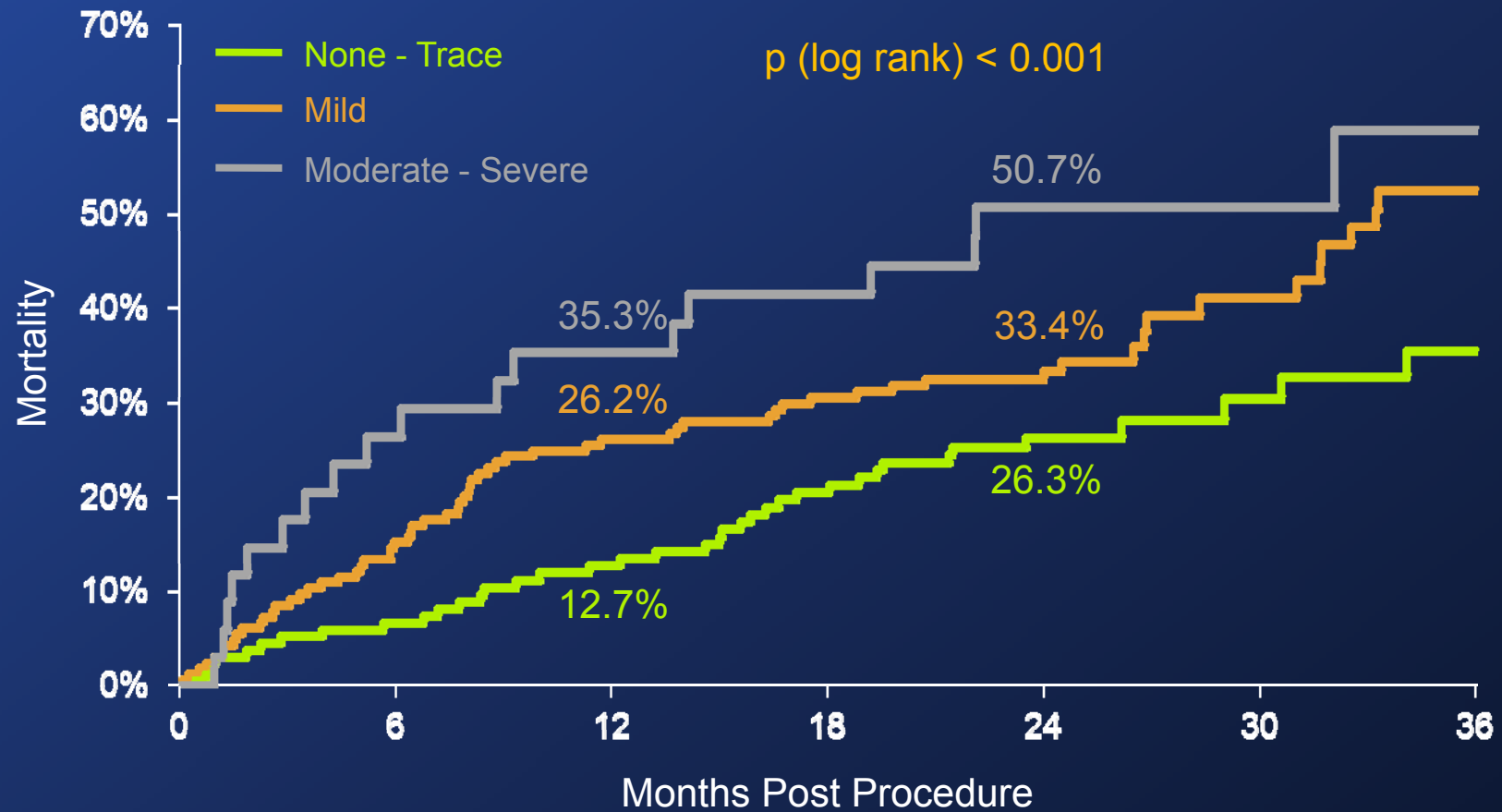
# Total AR and Mortality TAVR Patients (AT)



### Numbers at Risk

None-Tr	135	125	115	101	68	31	11
Mild-Mod-Sev	199	164	143	130	86	39	18

# Mild 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

# 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

# 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)

# AR Index Predicts PVL

## Aortic Regurgitation Index Defines Severity of Peri-Prosthetic Regurgitation and Predicts Outcome in Patients After Transcatheter Aortic Valve Implantation

Jan-Malte Sinning, MD, Christoph Hammerstingl, MD, Mariuca Vasa-Nicotera, MD, Viktoria Adenauer, MD, Sisa Josefina Lema Cachiguango, MD, Anne-Cathérine Scheer, MD, Sven Hausen, MD, Alexander Sedaghat, MD, Alexander Ghanem, MD, Cornelius Müller, MD, Eberhard Grube, MD, Georg Nickenig, MD, Nikos Werner, MD

*Bonn, Germany*

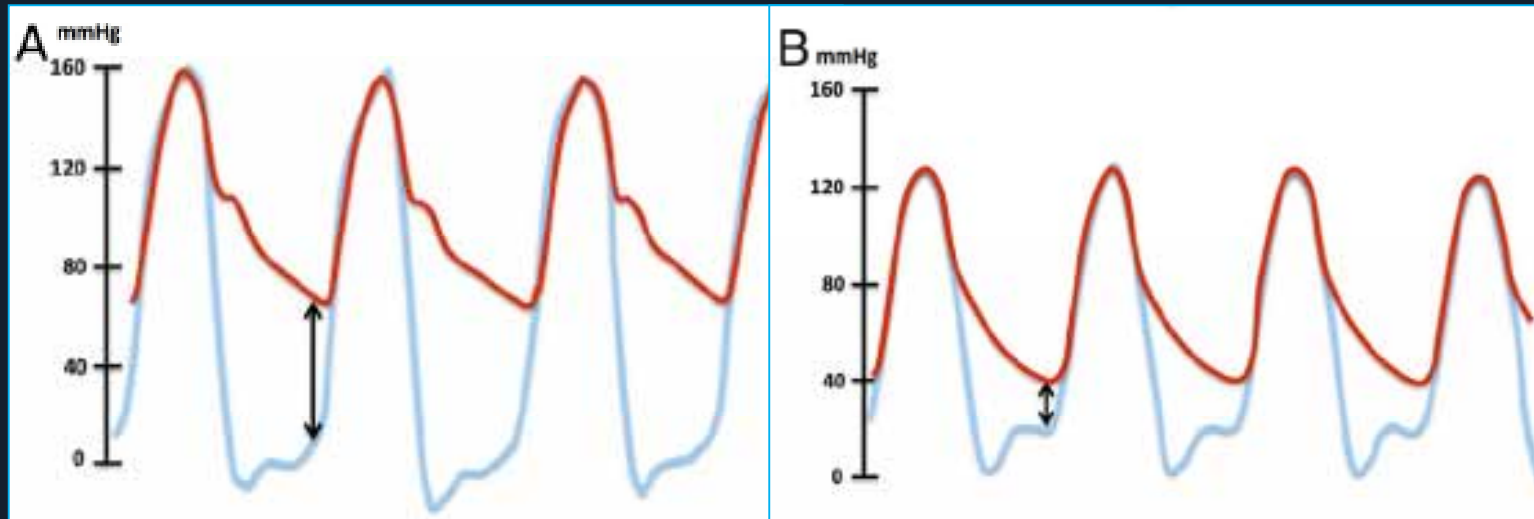
### **METHODS:**

- Dimensionless AR index  $[(DBP-LVEDP)/SBP] \times 100$  used to determine the significance of PVL in 146 TAVR pts

### **RESULTS:**

- AR index  $<25$  predicts  $\uparrow$  1-yr mortality (46.0% vs. 16.7%,  $p<0.001$ ); ind pred of 1-yr mortality beyond TEE measures of PVL severity

# AR Index Predicts PVL



## METHODS:

- Dimensionless AR index  $[(\text{DBP}-\text{LVEDP})/\text{SBP}] \times 100$  used to determine the significance of PVL in 146 TAVR pts

## RESULTS:

- AR index  $<25$  predicts  $\uparrow$  1-yr mortality (46.0% vs. 16.7%,  $p<0.001$ ); ind pred of 1-yr mortality beyond TEE measures of PVL severity



# TAVR in Review (2011-12)

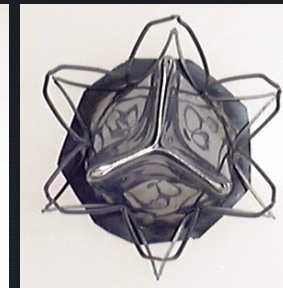
**New  
Technology**

# New TAVR (and “Related”) Technologies

- **New TAVR Systems**
- **Access and Closure Strategies**
- **Cerebral Embolic Protection Devices**
- **Advanced Imaging Modalities**

# New TAVI Systems - *Transfemoral*

- Direct Flow
- Sadra
- St. Jude
- AorTx
- HLT
- EndoTech
- ABPS PercValve



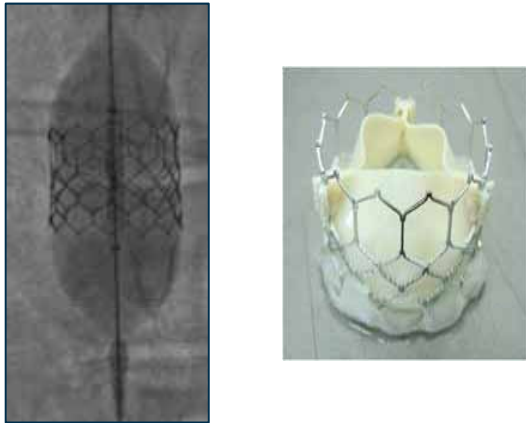
# New TAVI Systems - *Transapical*

- **Jena Valve**  
*(73 pts, + CE approval)*
- **MDT (Engager)**  
*(40 pts)*
- **Symetis**  
*(90 pts, + CE approval)*



# Two New Edwards Valve Platforms

## Edwards **SAPIEN 3** Valve



**Balloon Expandable**

Commercial Device\*

**SAPIEN THV**



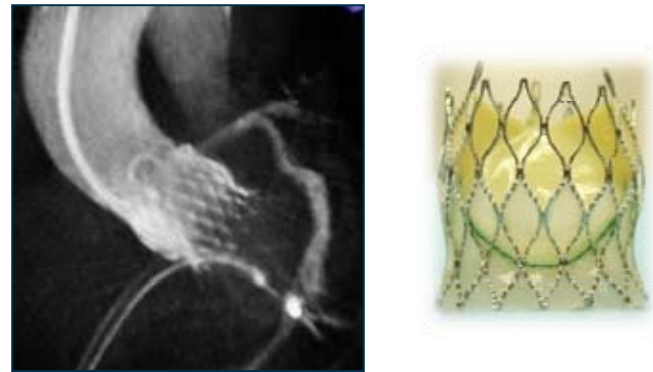
**U.S. Offering**

IDE Trial Enrolling

**SAPIEN XT THV**



## Edwards **CENTERA** Valve



**Self Expanding**

O.U.S. Commercial Offering

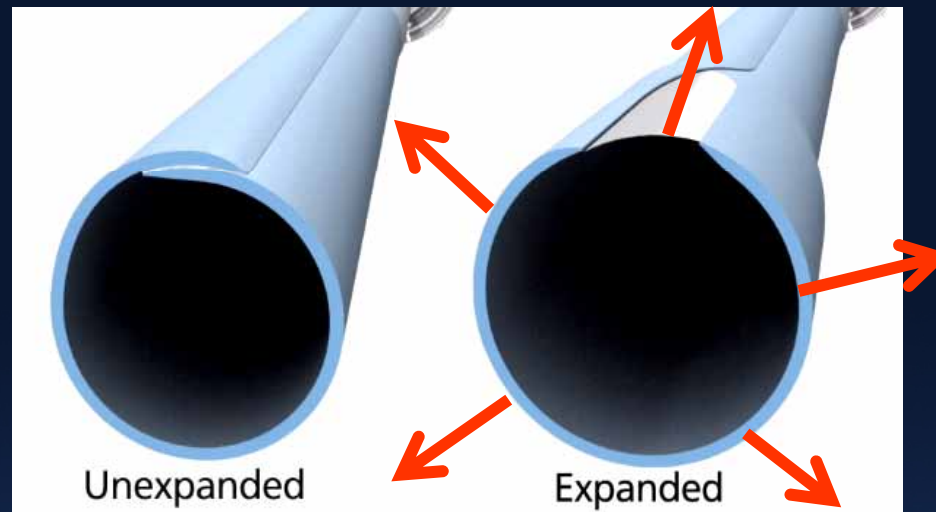
**SAPIEN XT THV**



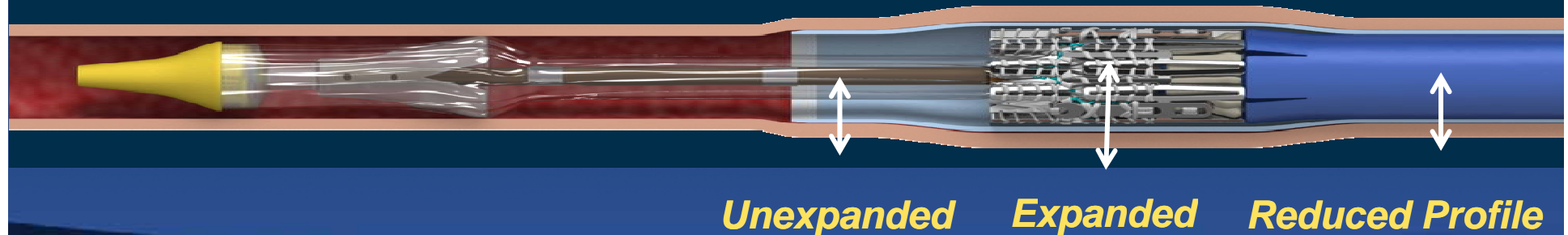
**OUS Offering**



# The New Edwards eSheath

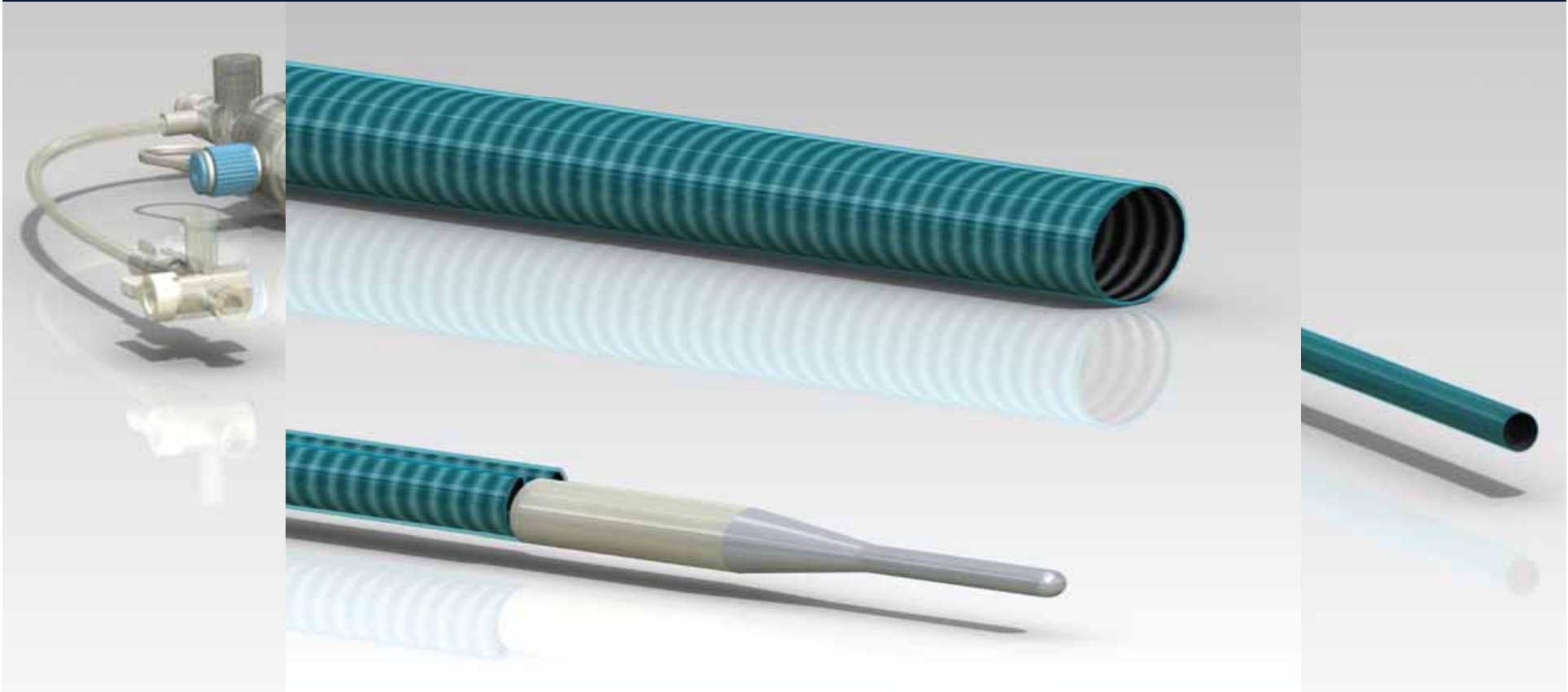


The eSheath expands from 16F to 18F which facilitates smooth delivery system passage, then returns to a reduced profile once the valve has passed through the sheath



# The New Onset Medical SOLOPATH *Balloon Expandable Sheath*

14 F → 18 F

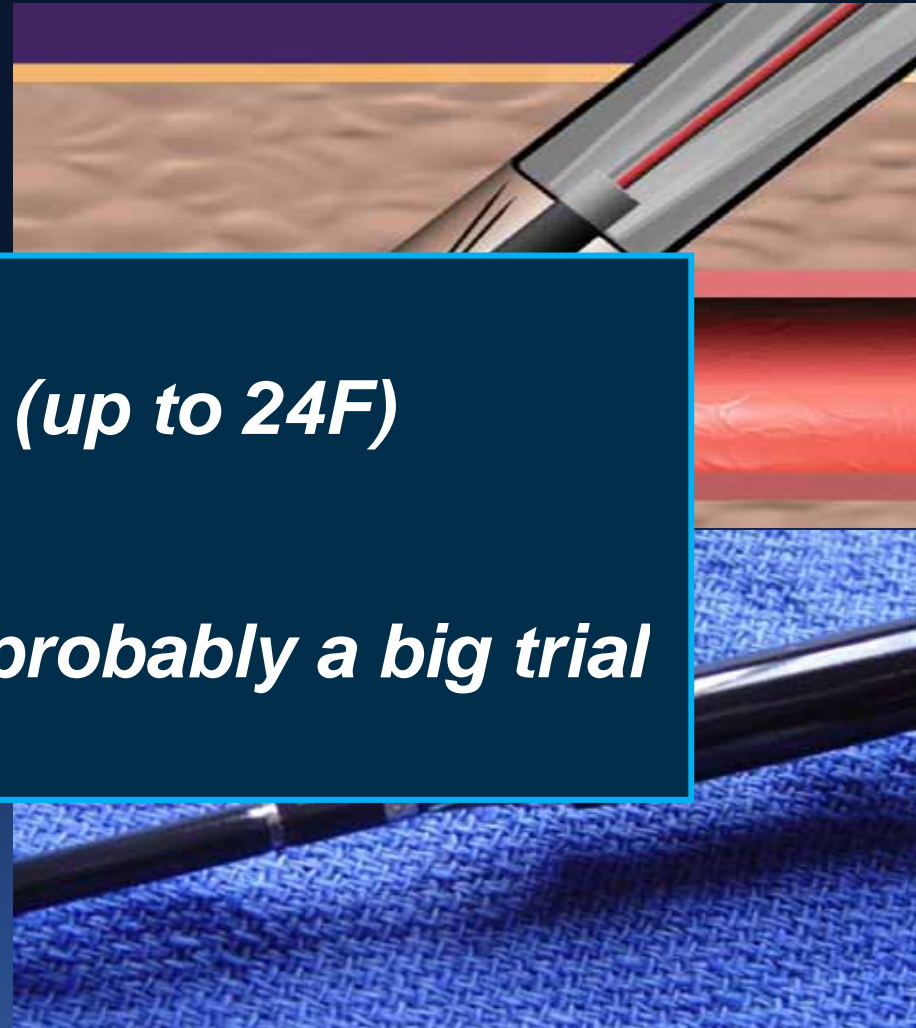


# Vascular Closure - Prostar<sup>®</sup> XL

- 10F Hydrophilic Sheath (J-tip)
- Two sutures (USP 3-0 braided)
- Four titanium
- Monoc
- .038" comp
- Integrated pre-dilator
- Knot Pusher

*CE mark (up to 24F)*

*US approval ~ probably a big trial*





# Large Vessel Closure Landscape

## Category

## Company

## Technology

Emerging Suture  
Based Technologies

Interventional  
Therapies

MediGlobe

SpiRx

Vivasure

ePacing

Sealing Solutions

Vascular Closure  
Systems

Apica Cardiovascular

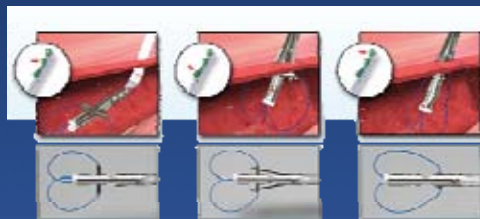
Emerging  
Patch or Plug  
Technologies

*Medtronic, Inc.*

*Abbott Vascular St. Jude Medical*

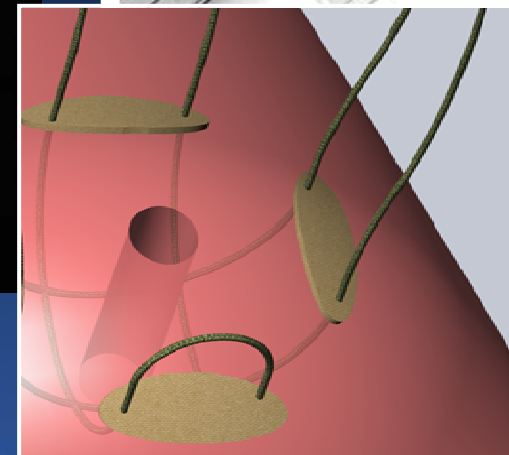
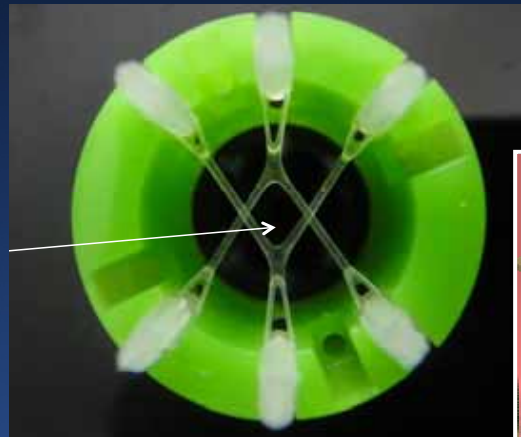
*Cook/Cardica*

Strategic  
Players



# Transcutaneous Ventricular Access and Closure (TVAC)

- *Apica*
- *Entourage CardioClose*
- *MID Permaseal*
- *Novogate*
- *SpiRx*
- *Cardiapex*



# Cerebral Embolic Protection Devices

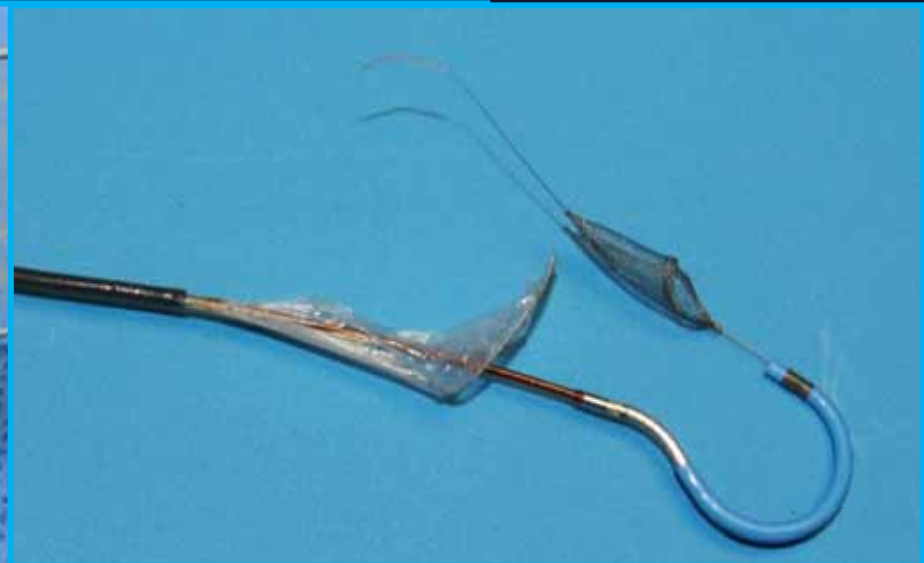
## *Deflectors and Filters*



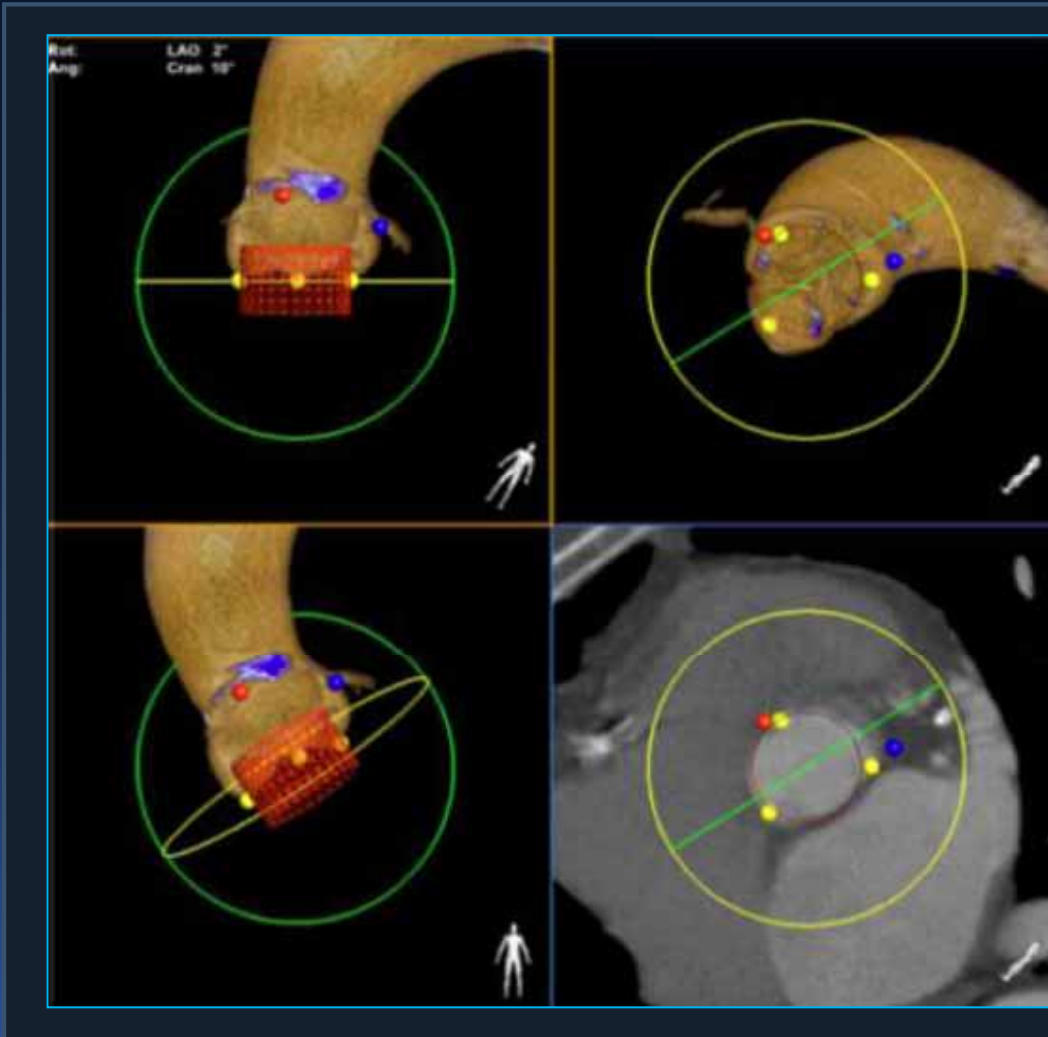
***SMT***  
***(15 pts)***



***Embrella***  
***(20 pts)***



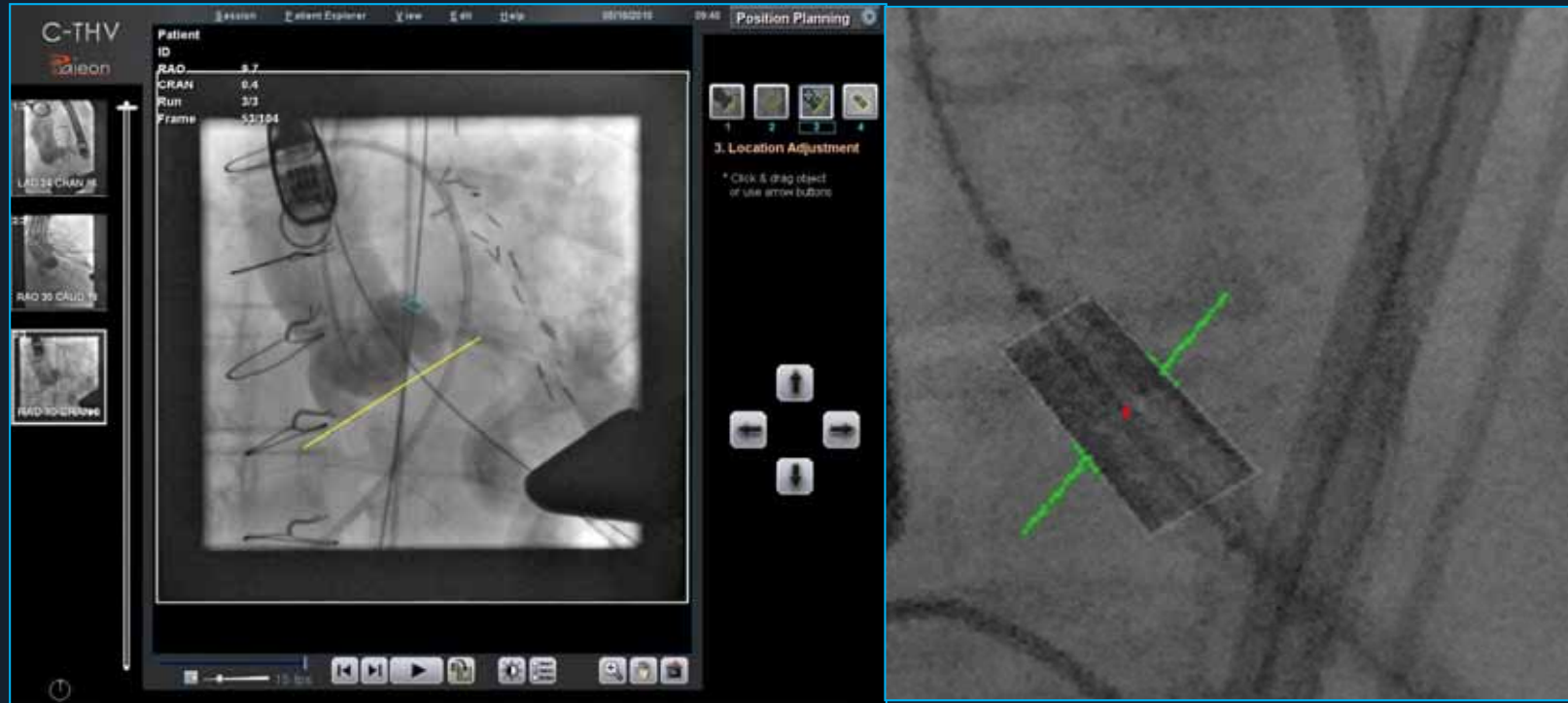
***Claret***  
***(40 pts)***



## CTA

- **Philips**  
3D Navigator
- **Siemens**  
Dyna CT
- **GE**  
Innova Vision

# Advanced Imaging Modalities



*Angio*

Paieon  
cTHV

# TAVR in Review (2011-12)

## Final Thoughts

# TAVR in Review (2010-11)

## *Final thoughts...*

- Dramatic continued growth in TAVR (# cases and clinical research); major indication is high-risk AS (“risk creep” is only moderate in most centers).
- The Heart Valve Team culture remains a dominant theme in clinical practice.
- TAVR is a somewhat less predictable procedure than open AVR and is associated with several complications (strokes, vascular events, perm PPM, and paravalvular AR) - ***All efforts should be directed at reducing these complications.***

# TAVR in Review (2011-12)

## *Final thoughts...*

- **Still unresolved...**
  - “Futility” patients (optimal case selection)
  - Preferred access (e.g. TF vs. TA, vs. TAO)
  - Edwards vs. CoreValve
  - *New clinical indications (All require careful clinical evaluations - usually RCTs)*
- **In the U.S., important new reimbursement and training considerations**
- **New technology advances promise to simplify and improve outcomes after TAVR in the future!**



# Current TAVR Eligibility According to Operative Risk

