TAVR Update 2012: The Year in Review

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NewYork-Presbyterian

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	Company
• Grant/Research Support	• Abbott, Boston Scientific, Edwards Lifesciences, Medtronic
• Consulting Fees/Honoraria	• Meril Lifescience, Angioscore, Micell
• Major Stock Shareholder/Equity	• Sadra, Claret, Coherex, Medinol, Valve Medical

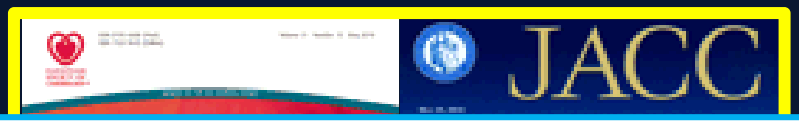
TAVR in Review (2011-12)

- 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

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John

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doi:10.1016/j.jacc.2010.12.005

CLINICAL RESEARCH **Valvular Medicine**

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

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New PARTNER NEJM Publications

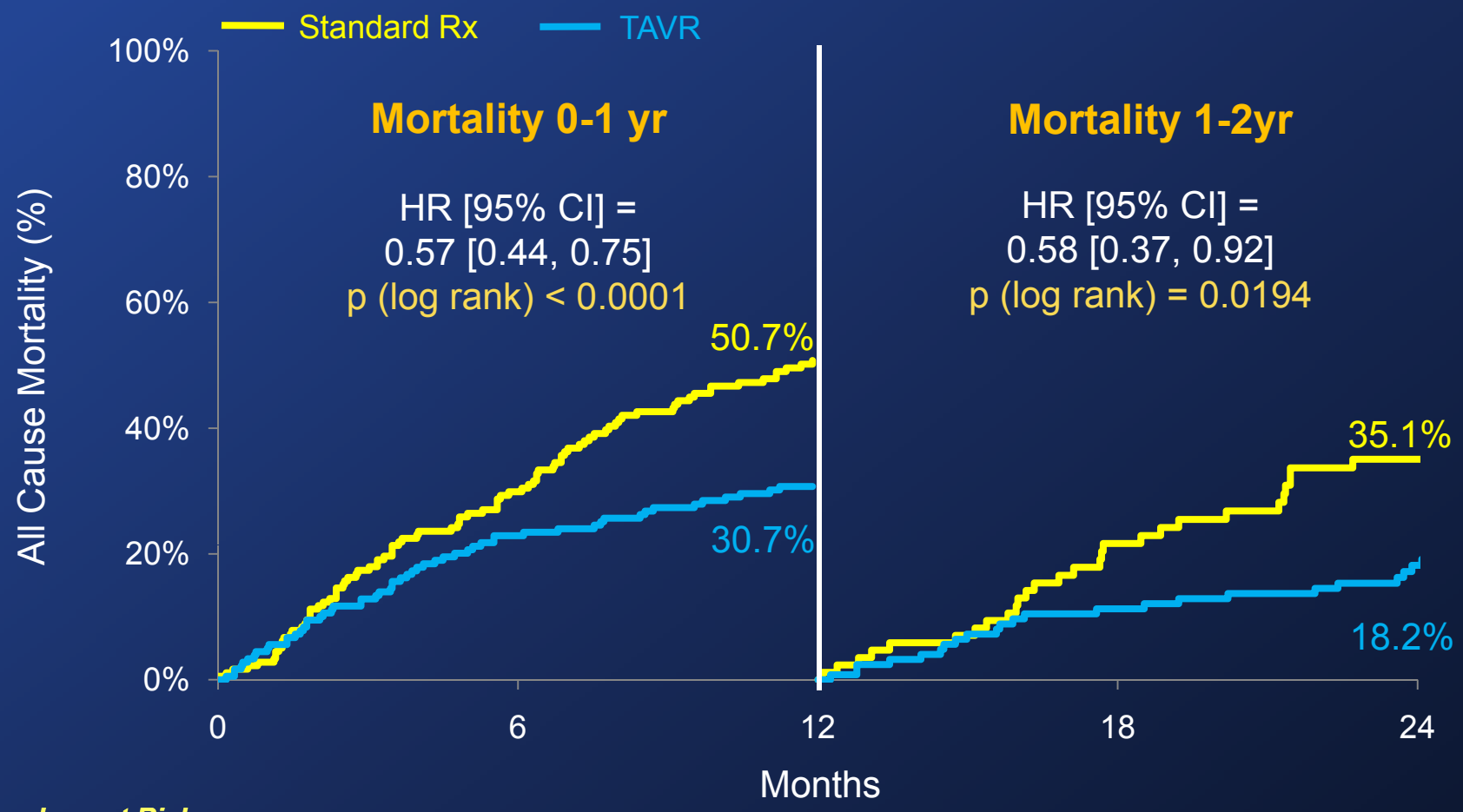
The NEW ENGLAND JOURNAL of MEDICINE

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*

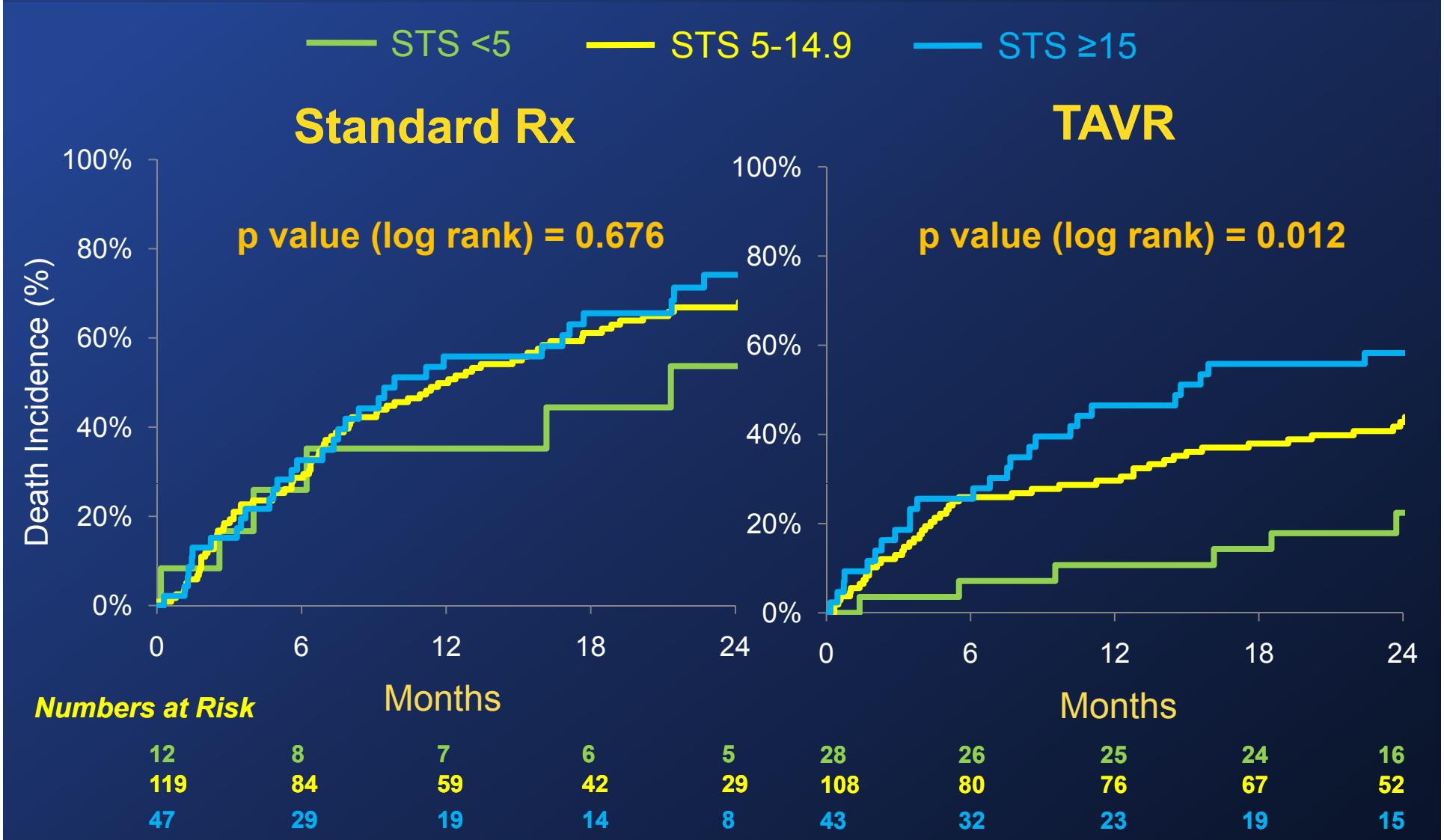
All Cause Mortality (ITT)
Landmark Analysis



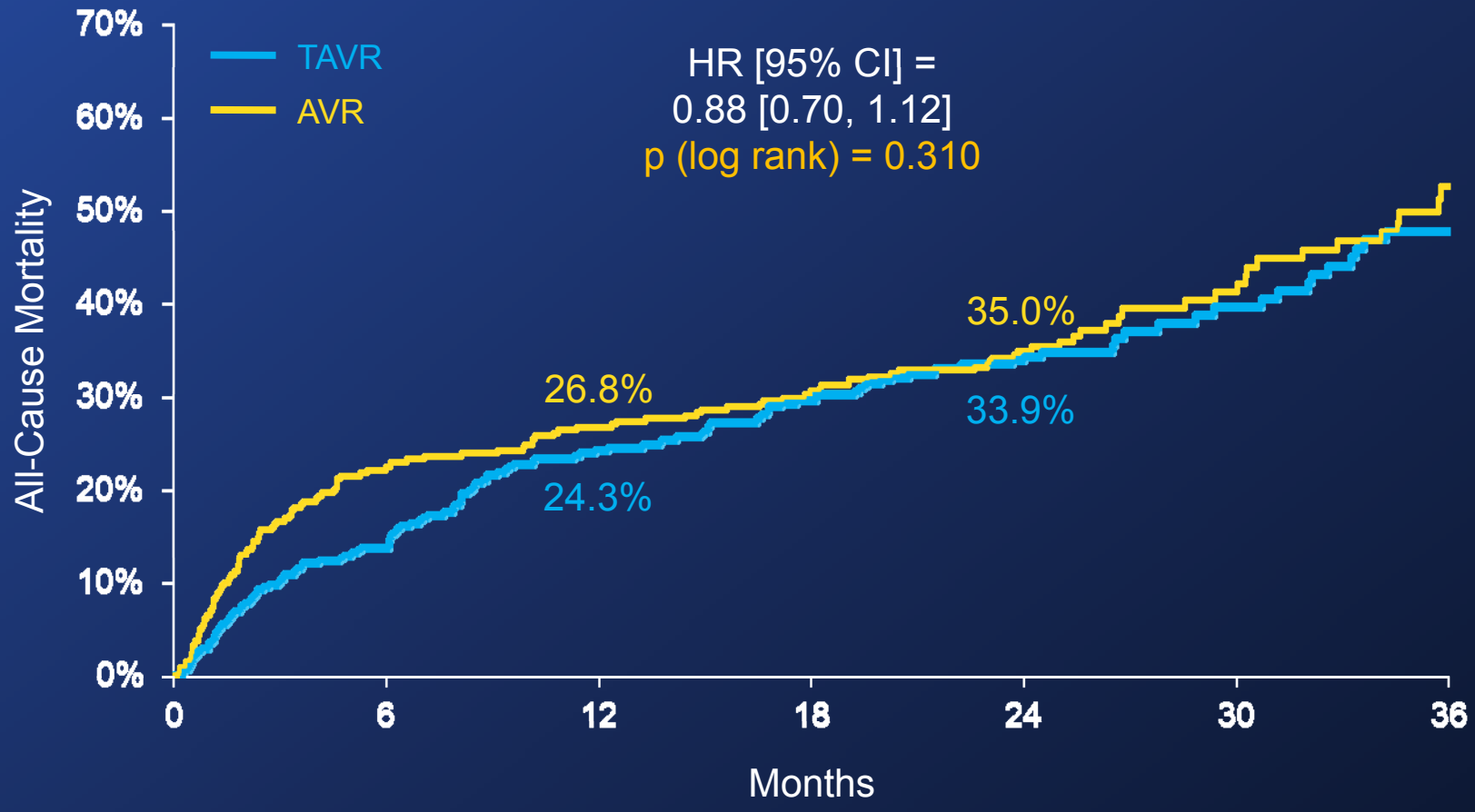
Numbers at Risk

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

Mortality Stratified by STS Score (ITT)



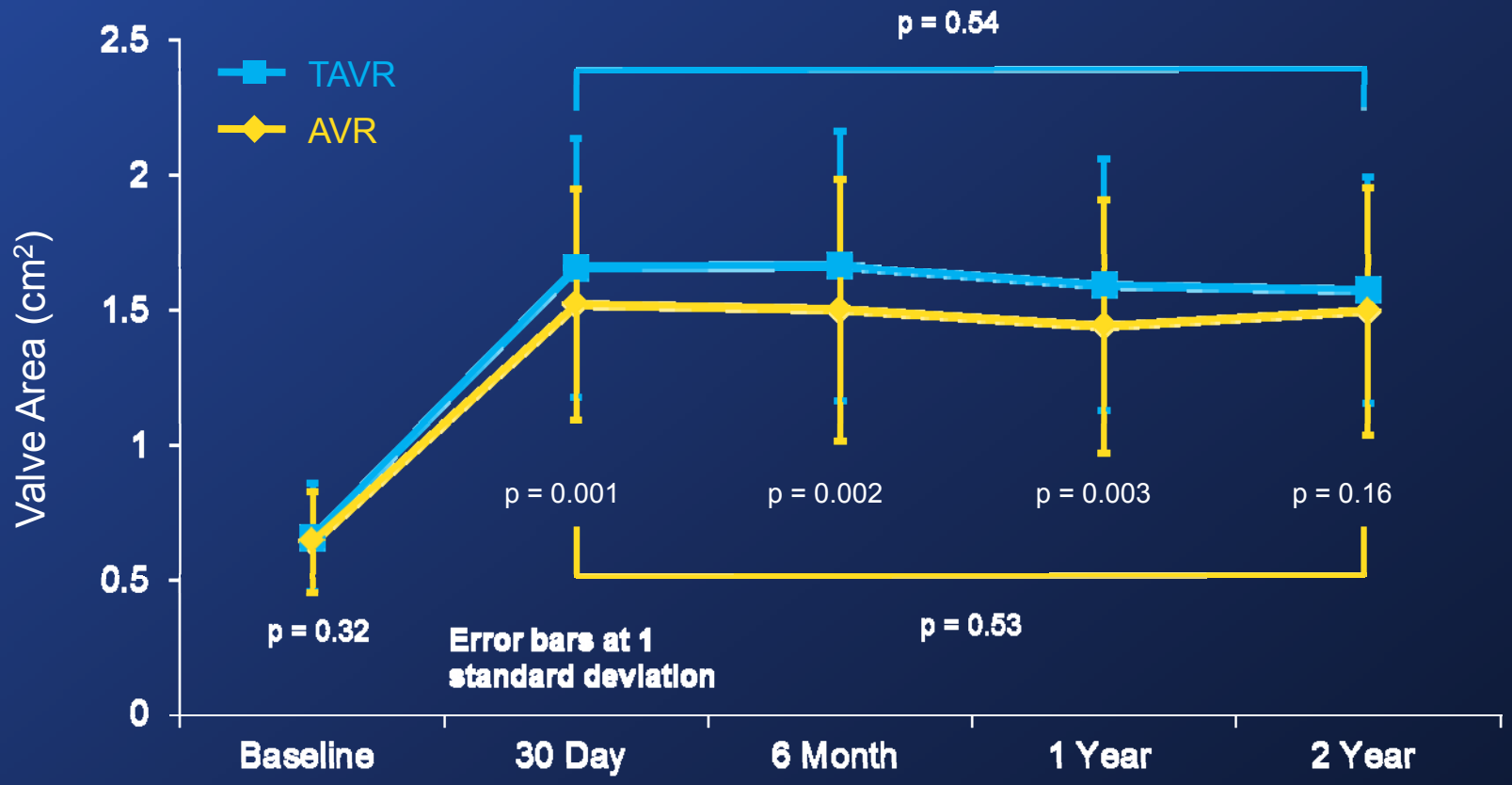
All-Cause Mortality (ITT)



Numbers at Risk

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

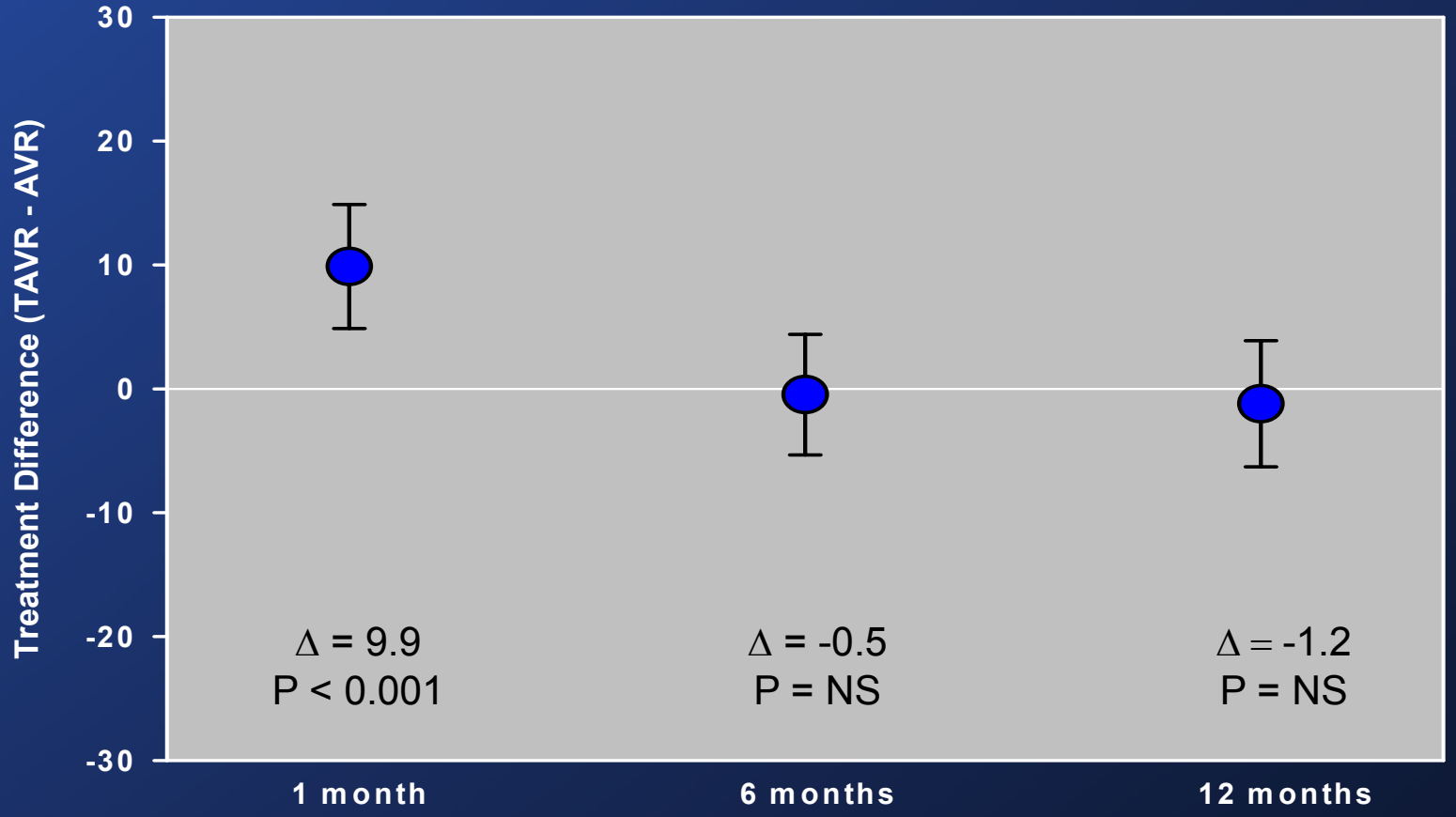
Echocardiographic Findings
AVA (AT)



Numbers at Risk

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

KCCQ Overall Summary (Primary Endpoint)
TF Subgroup



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

DJC8

Index Procedure/Admission

Resource use (per-protocol population)

THE PARTNER TRIAL

Resource Category	*TF-TAVR (N = 234)*	*AVR (N= 221)*	*Difference (95% CI)**	*P-value*
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

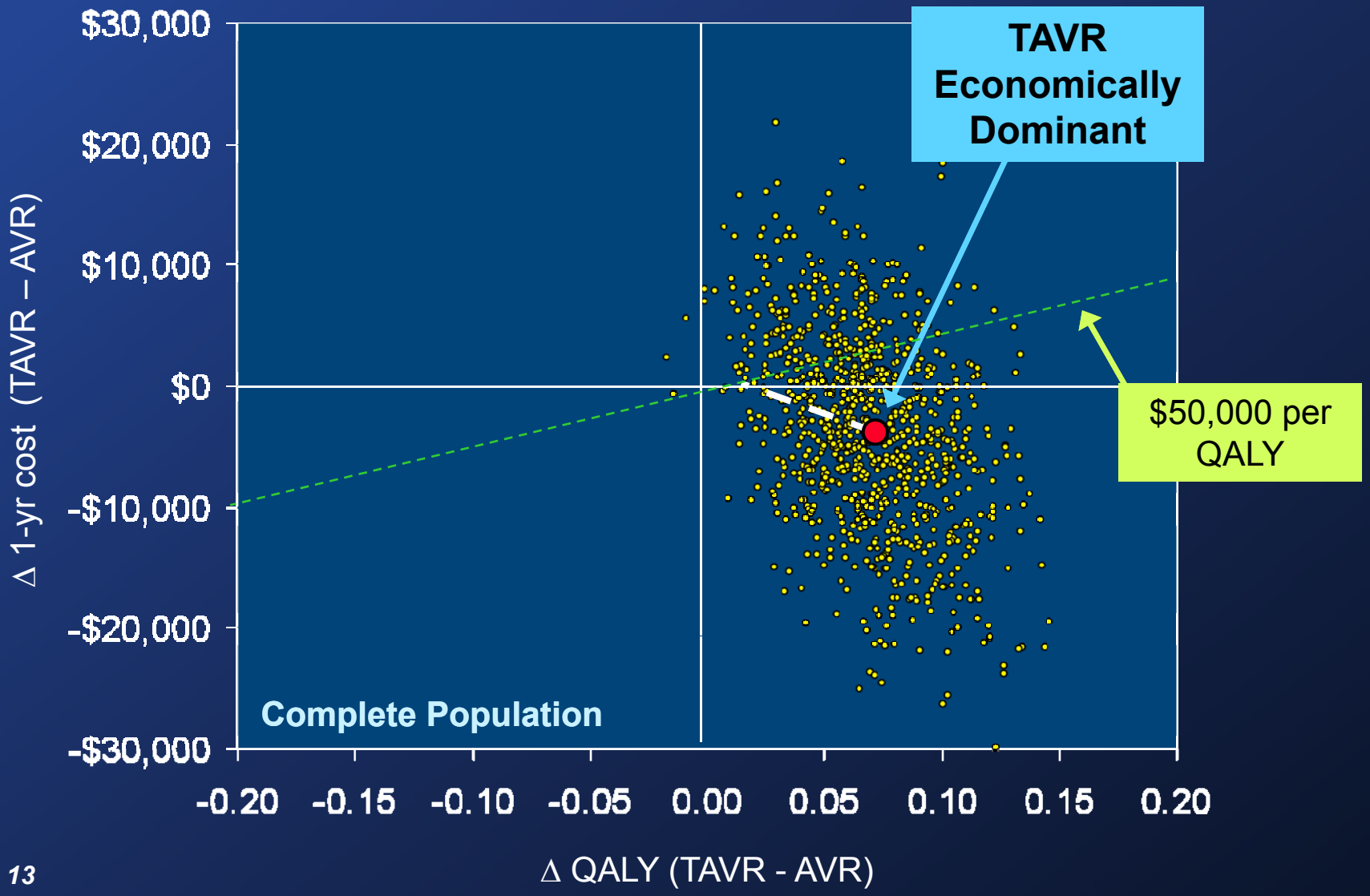
LOS data are shown as mean (median).
*95% CIs from 1,000 bootstrap replications of study data.

DJC8 Consider simplifying this table a bit-- new pacemaker doesn't differ and that was reported previously, so perhaps you can get rid of that

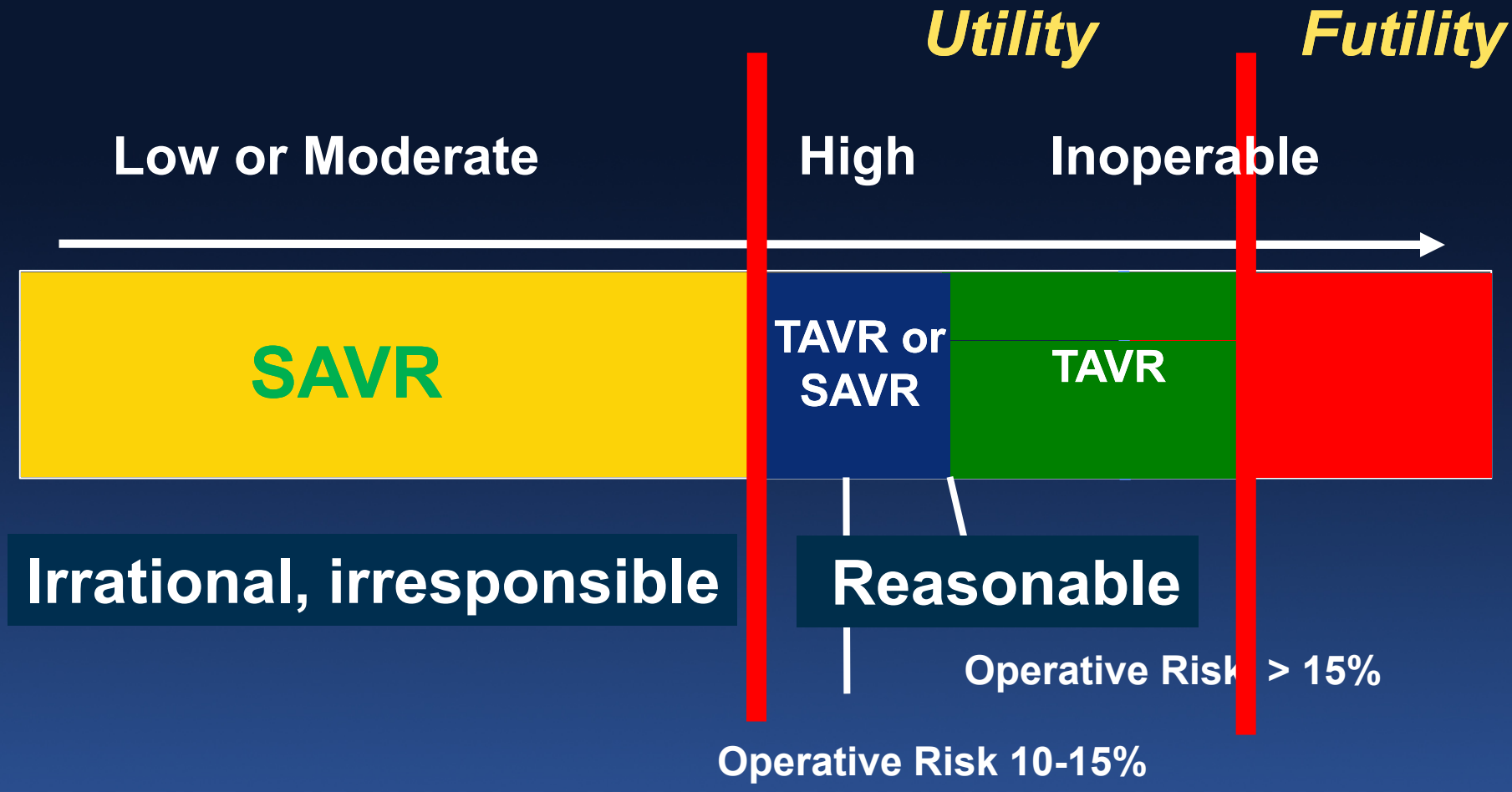
Note that some of your confidence intervals have a dash and others have "to"
David Cohen, 2011-10-19

TAVR vs. AVR: Transfemoral

Cost per QALY gained



Current TAVR Eligibility According to Operative Risk



Adapted from S. Kodali

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**

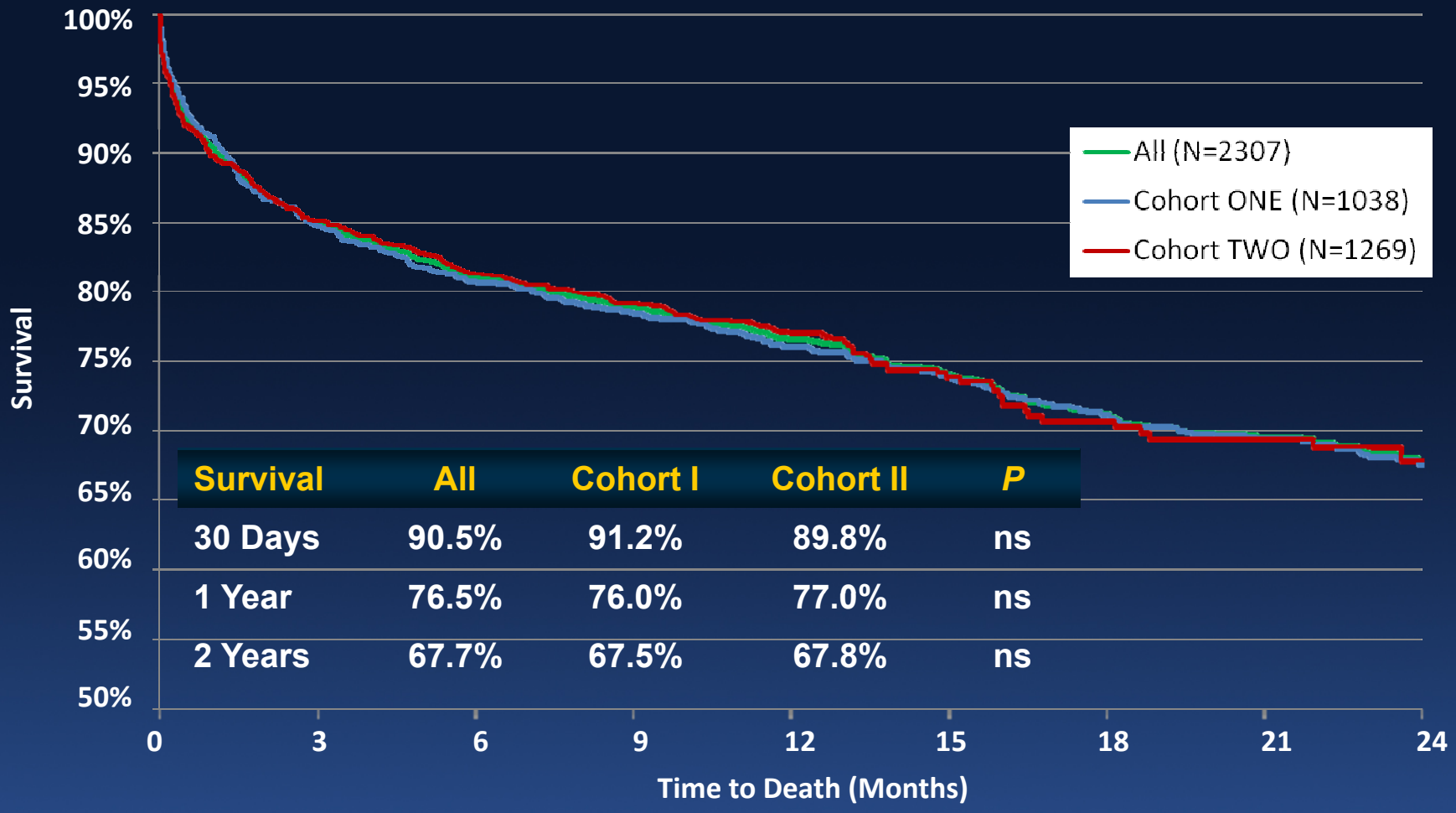
on behalf of **The SOURCE Registry Investigators**

Baseline Characteristics

	Cohort I (n=1038)	Cohort II (n=1269)	p
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^2)	26.1±4.5	26.6±5.0	0.1
Diabetes (n/%)	281 (27.1%)	347 (27.3%)	0.89
Respirat			0.23
Renal ins			0.49
Peripher			0.76
Porcelai			0.39
Cerebral			0.53
Carotid artery stenosis >50% (n/%)	132 (12.7%)	140 (11.0%)	0.22
Logistic EuroSCORE	**27.6±15.5**	**25.0±15.3**	**<0.001**

	Cohort I	Cohort II
<20 (n/%)	345 (33.2%)	560 (44.1%)
20-40 (n/%)	507 (48.8%)	525 (41.4%)
>40 (n/%)	186 (17.9%)	184 (14.5%)

KM 1-year Survival – Cohort 1 vs. 2



Survival	All	Cohort I	Cohort II	*P*
30 Days	90.5%	91.2%	89.8%	ns
1 Year	76.5%	76.0%	77.0%	ns
2 Years	67.7%	67.5%	67.8%	ns

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

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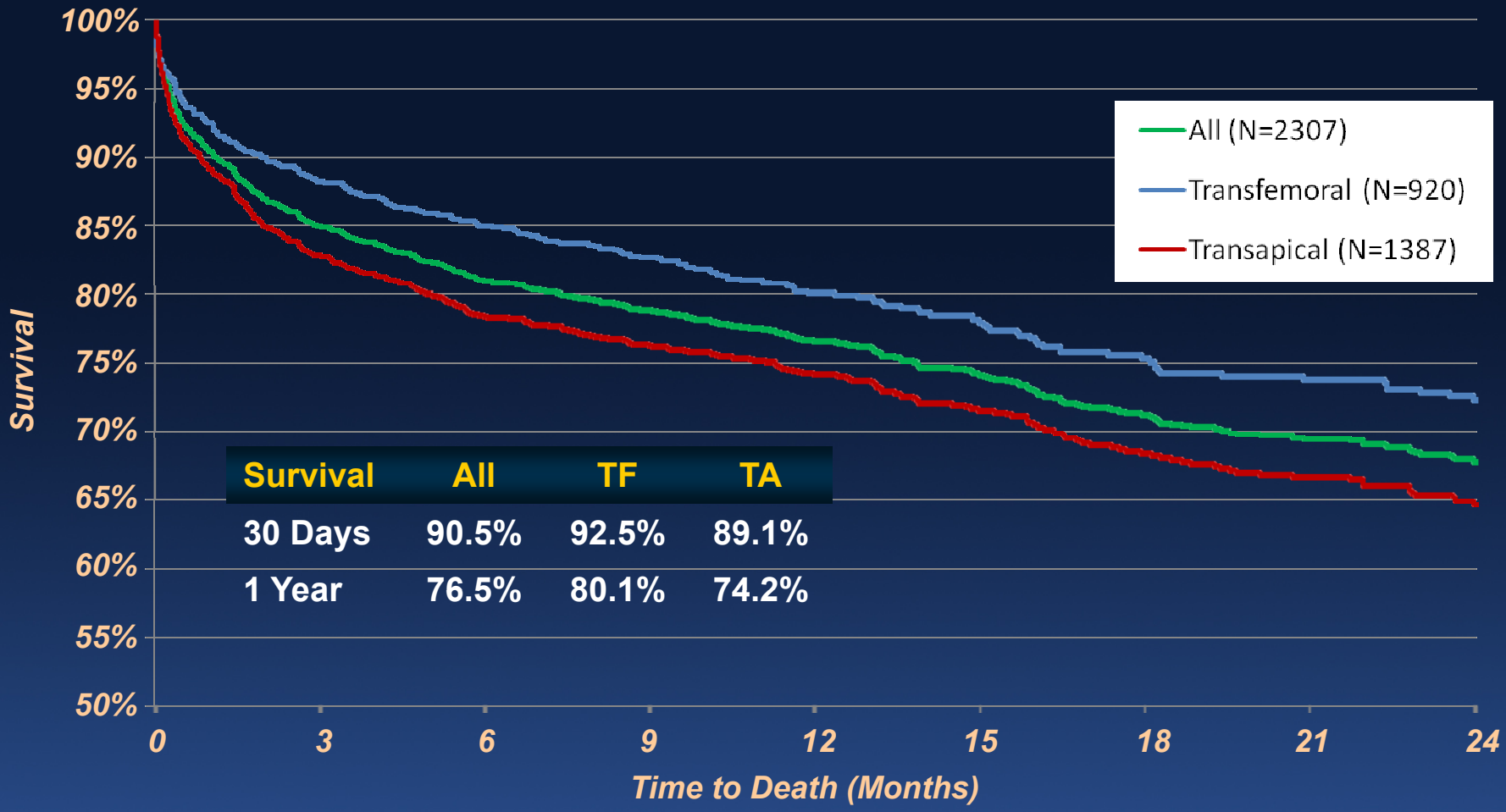
KM 1-year Survival – TF vs. TA



Survival	All	TF	TA
30 Days	90.5%	92.5%	89.1%
1 Year	76.5%	80.1%	74.2%

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

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FRANCE 2:

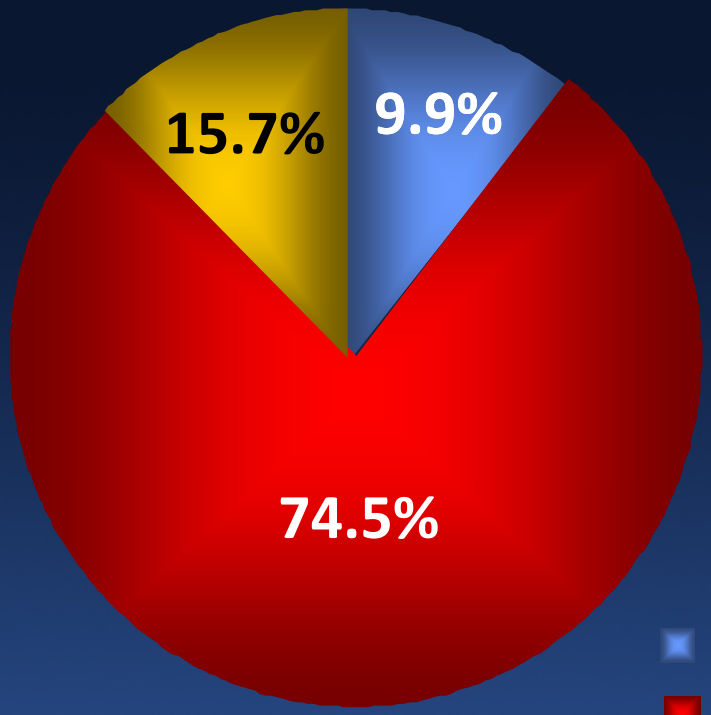
FRench Aortic National Corevalve and Edwards Registry

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 Iung, P Leprince, A Leguerrier, M Lievre, A Prat, E Teiger

FRANCE 2

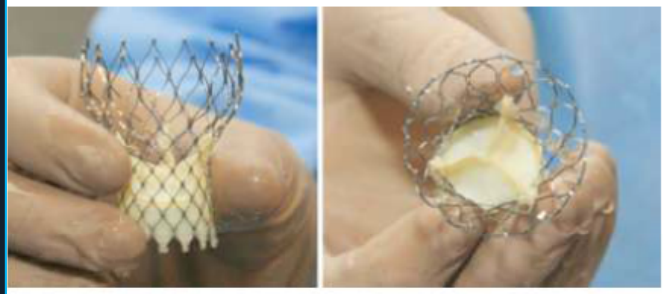
Procedural Characteristics



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

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)

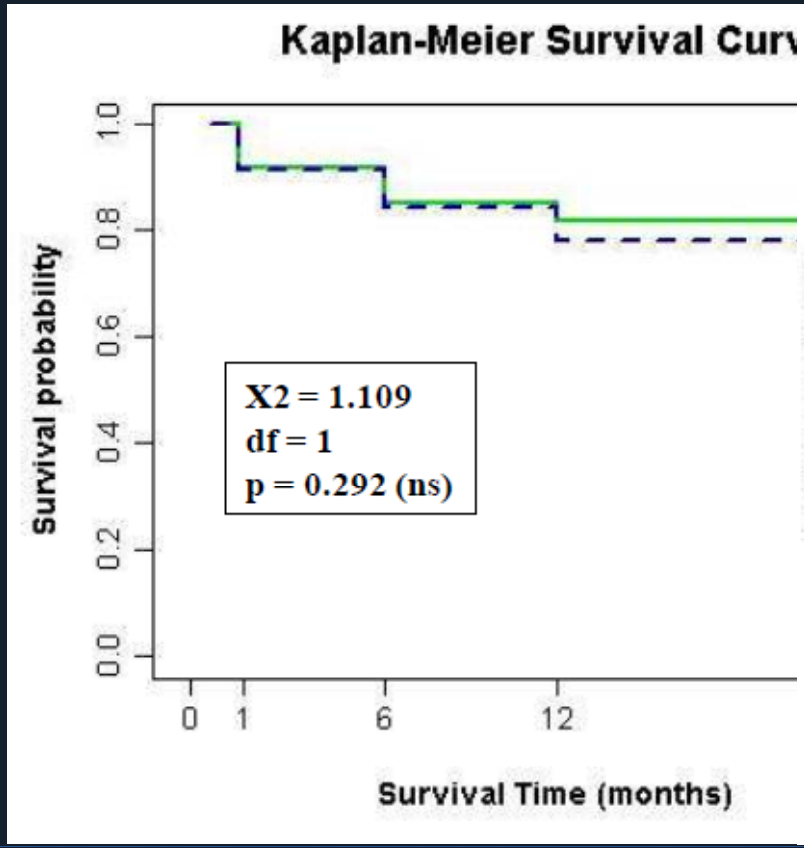
Edwards Sapien (n=303)

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)

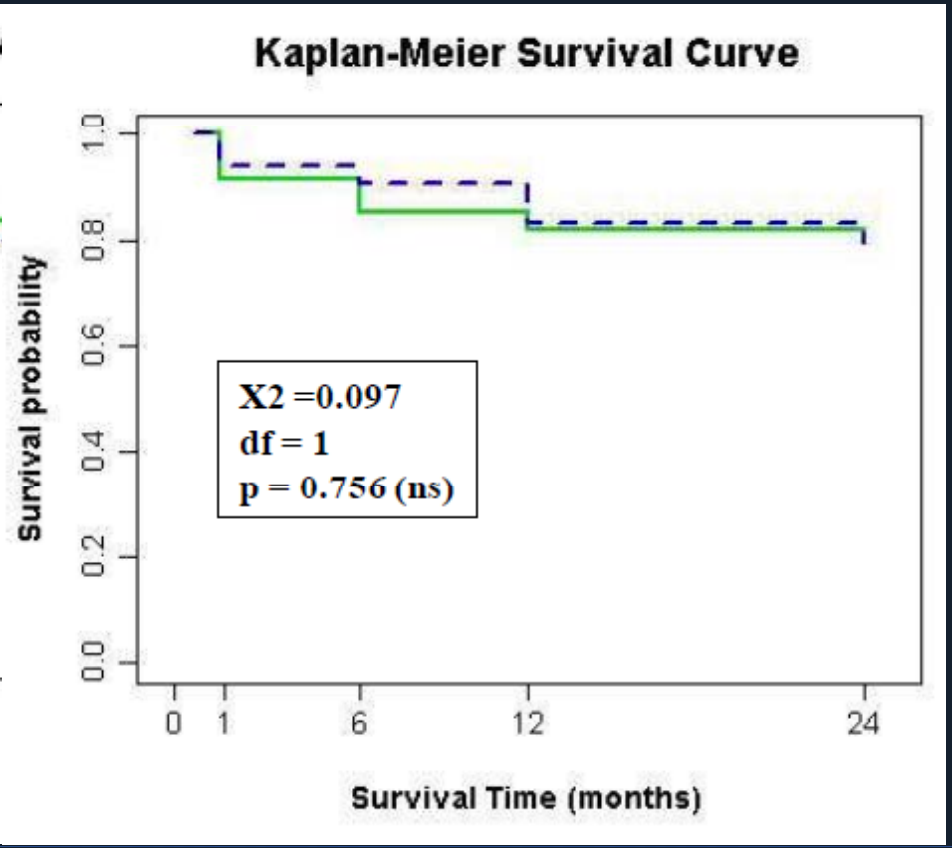
- 600 high-risk AS pts
- 18 centers
- no core labs
- enrollment till 04/11
- serial clinical and echo assessments thru 3 years

Belgian TAVR Registry
mid-term survival

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



Edwards (TF) - CoreValve (TF)



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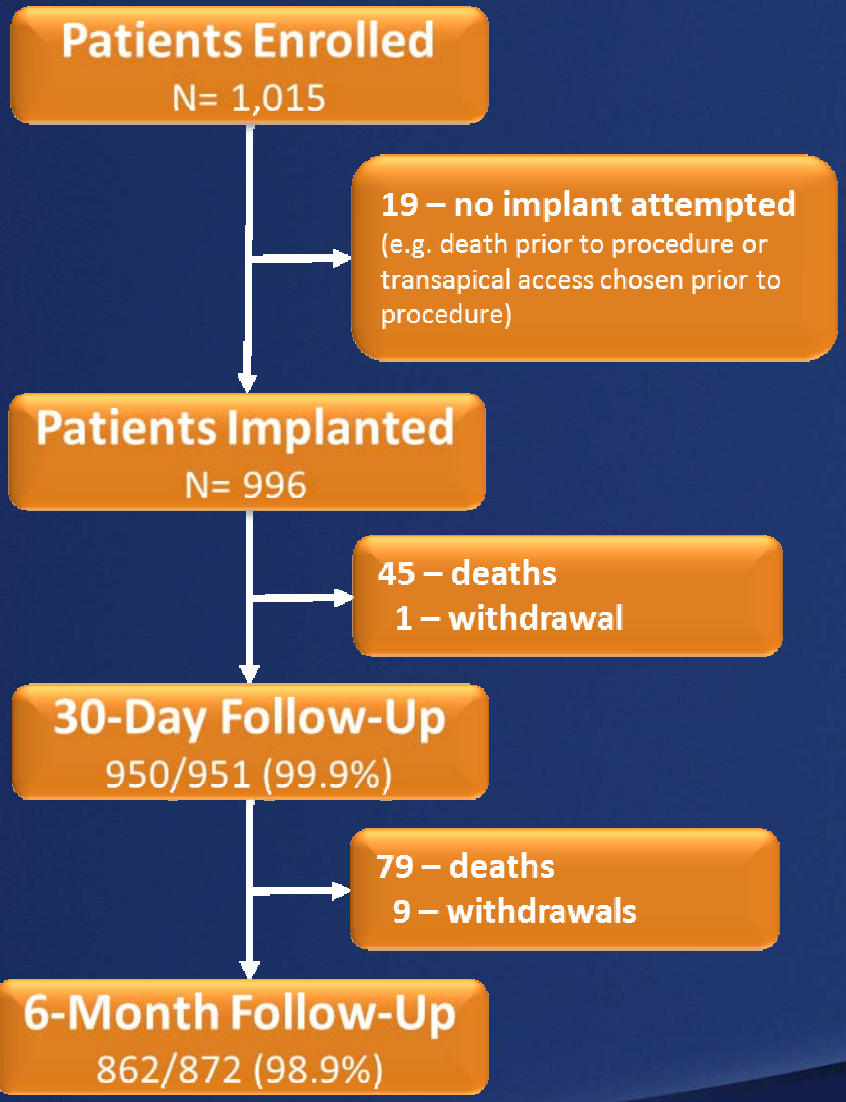
Treatment of High Risk Aortic Stenosis Patients with Transcatheter Medtronic CoreValve Implantation

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 STUDY

CoreValve ADVANCE | Methods

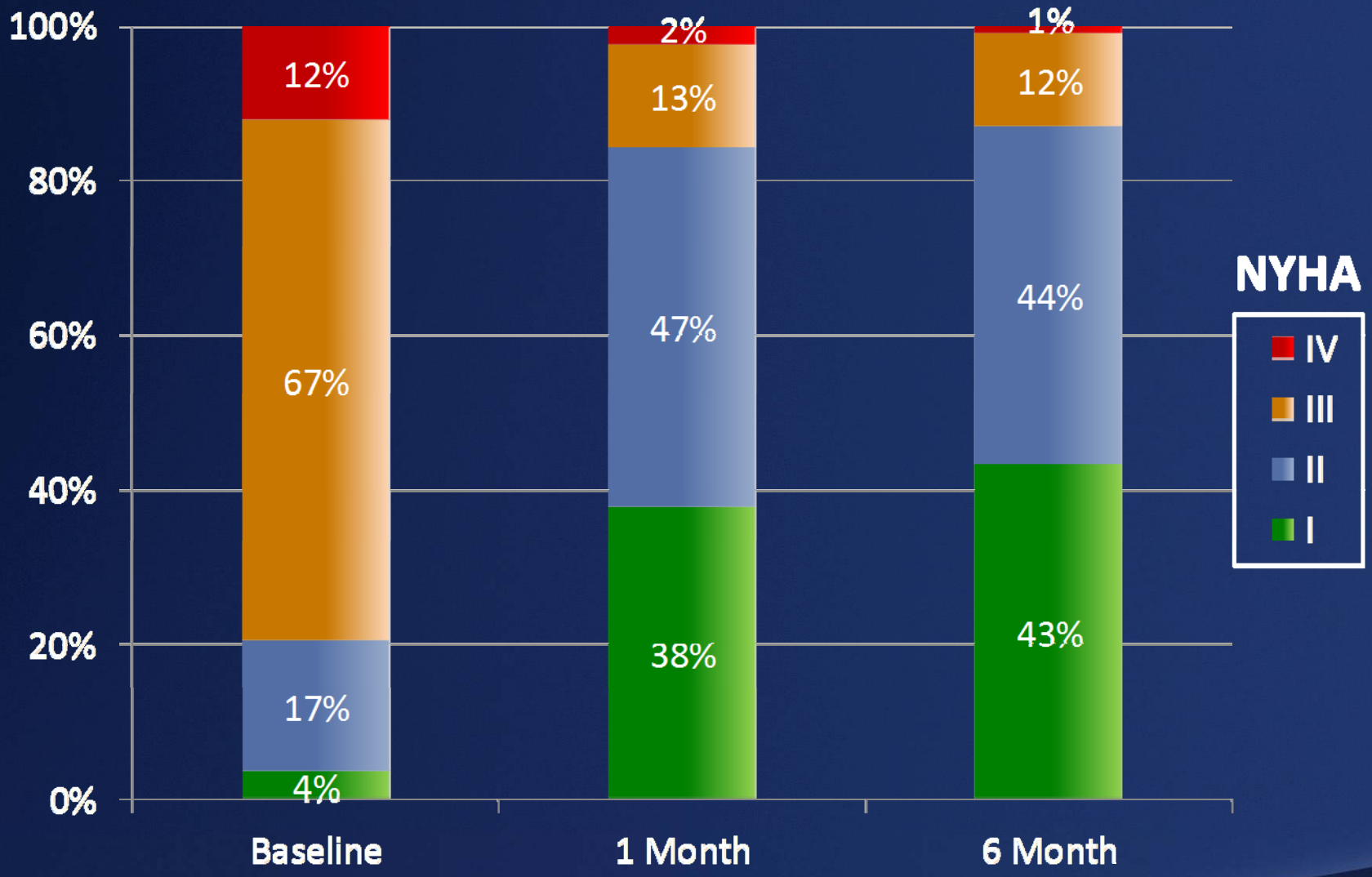
- 1,015 patients enrolled from March 2010 to July 2011
  - 5 year follow-up
- 44 centers - 12 countries in Western Europe, Asia and South America
- All centers had conducted at least 40 TAVI procedures prior to the study and had Heart Team in place
- Clinical endpoints reported according to Valve Academic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

CoreValve ADVANCE | 30-day Outcomes

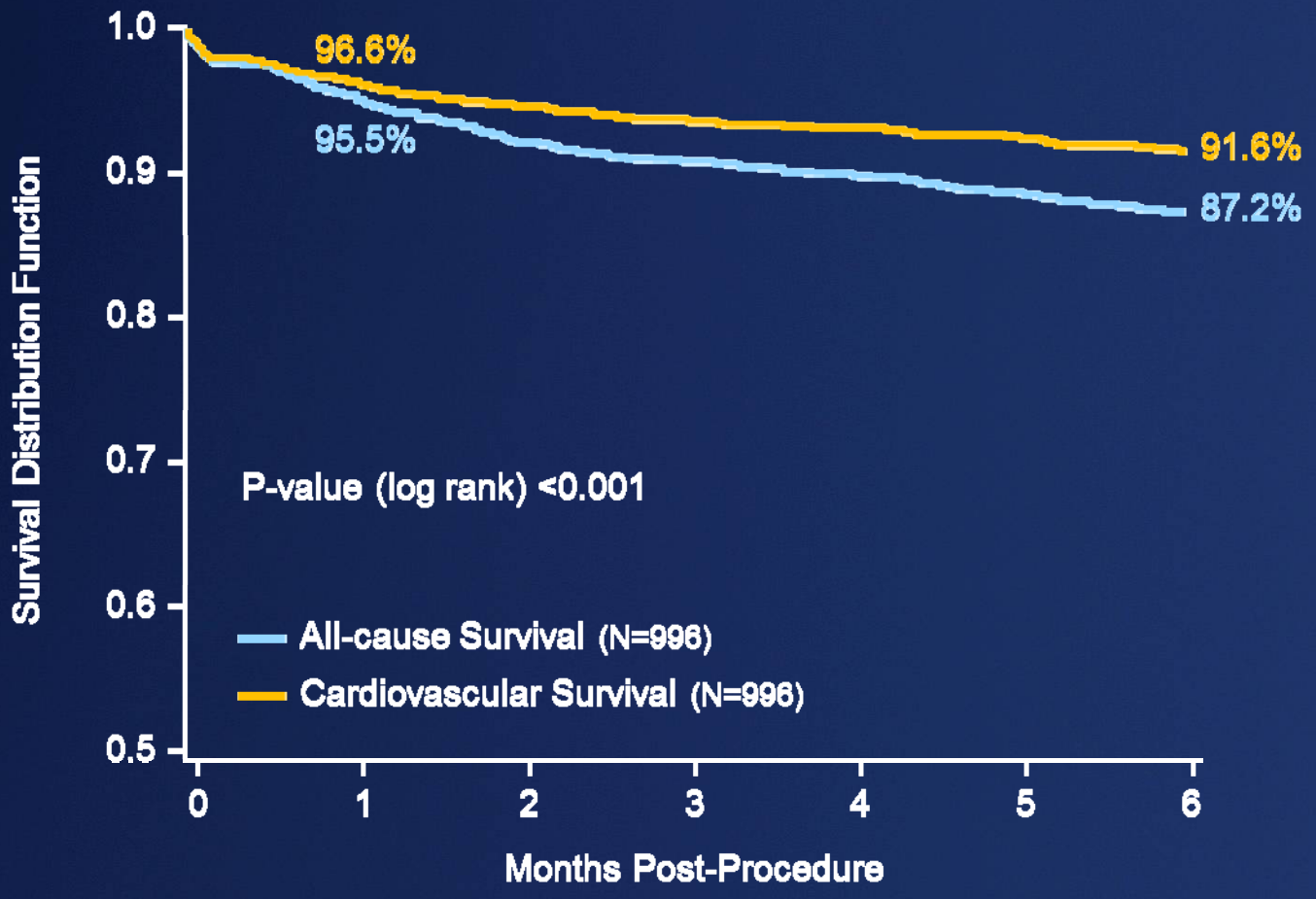
Primary Endpoint N=996	Kaplan-Meier Estimates, %
MACCE	8.3
All-cause Mortality	4.5
Myocardial Infarctions	0.2
Emergent cardiac surgery or percutaneous re-intervention	1.7
Stroke	2.9

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

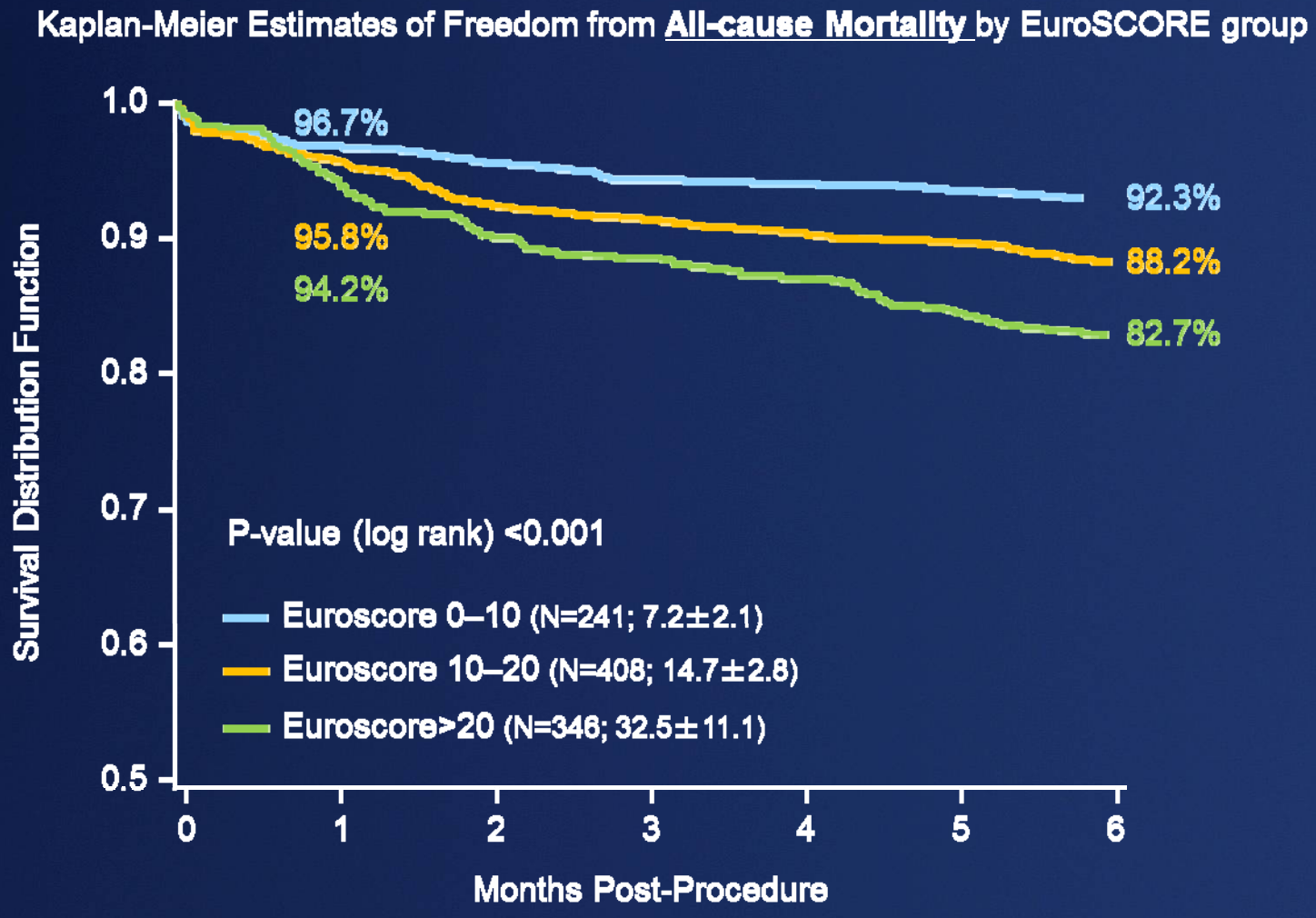
CoreValve ADVANCE | 6-month Survival

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



COREVALVE
ADVANCE STUDY

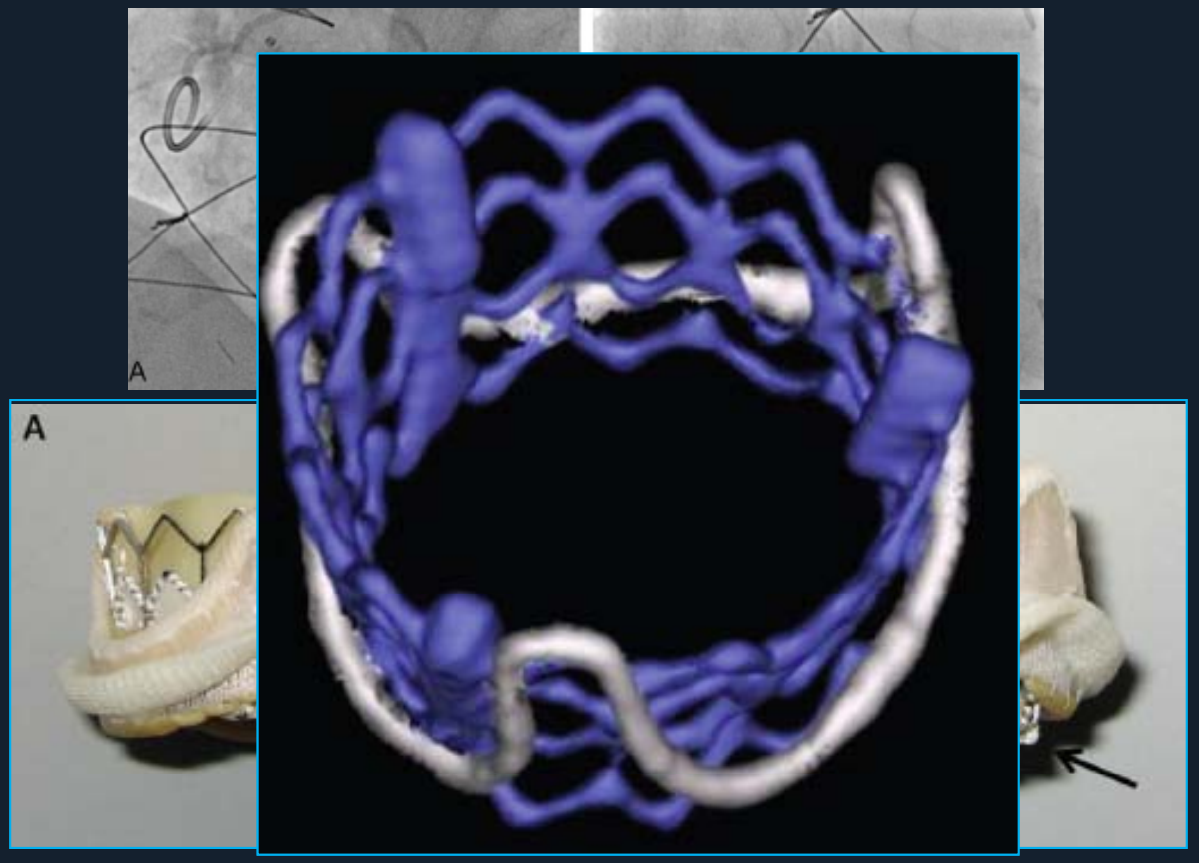
CoreValve ADVANCE | 6-month Survival



COREVALVE
ADVANCE STUDY

New TAVR Clinical Indications

Valve - in - Valve



Incorrect position *Correct position*

Webb JG, Wood DA, Ye J, et al. Circulation 2010;121:1848-57

New TAVR Clinical Indications

Valve - in - Valve

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

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Transcatheter Aortic Valve Implantation for Failing Surgical Aortic Bioprosthetic Valve

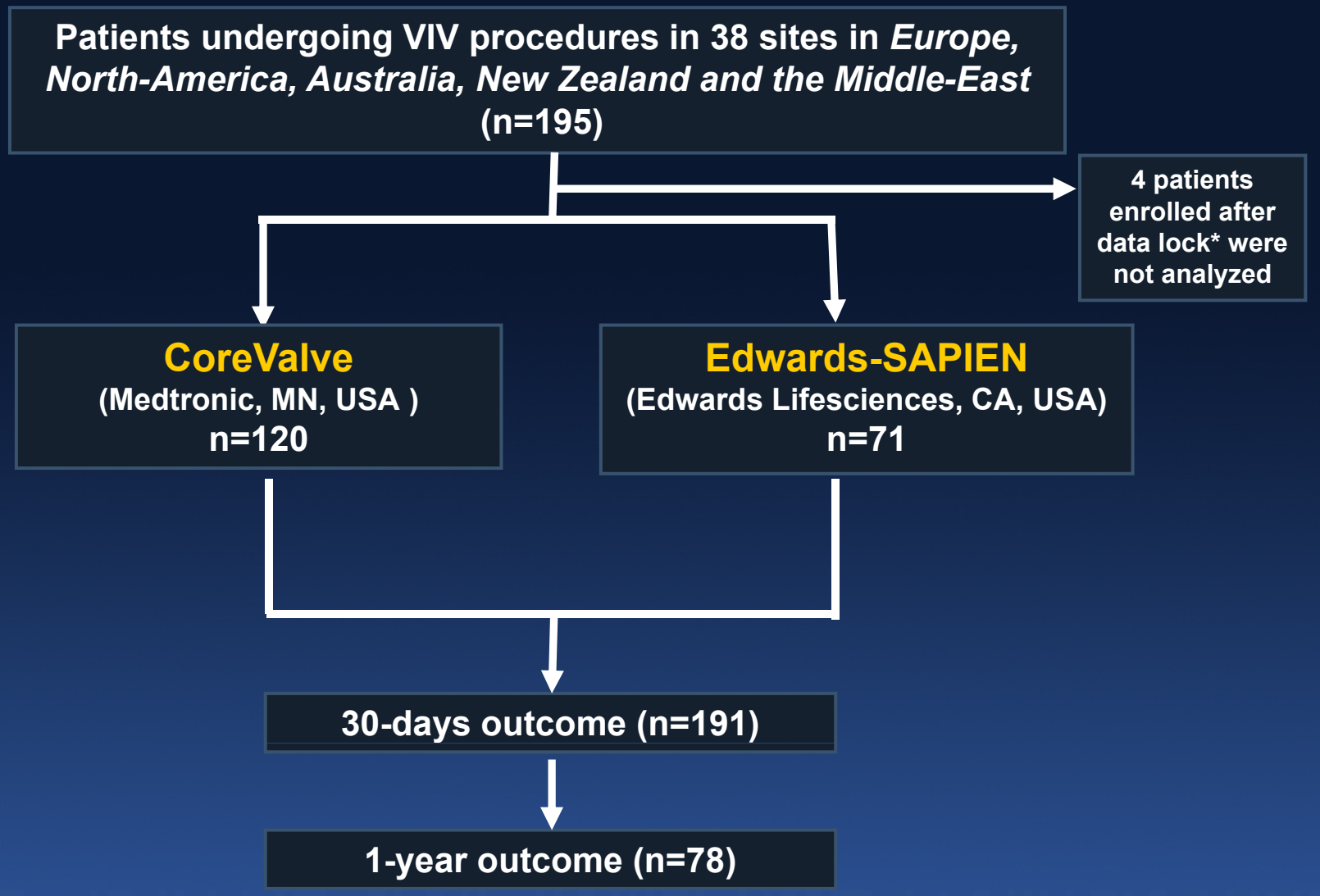
From Concept to Clinical Application and Evaluation (Part 2)

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



*Data lock- Oct 10 2011

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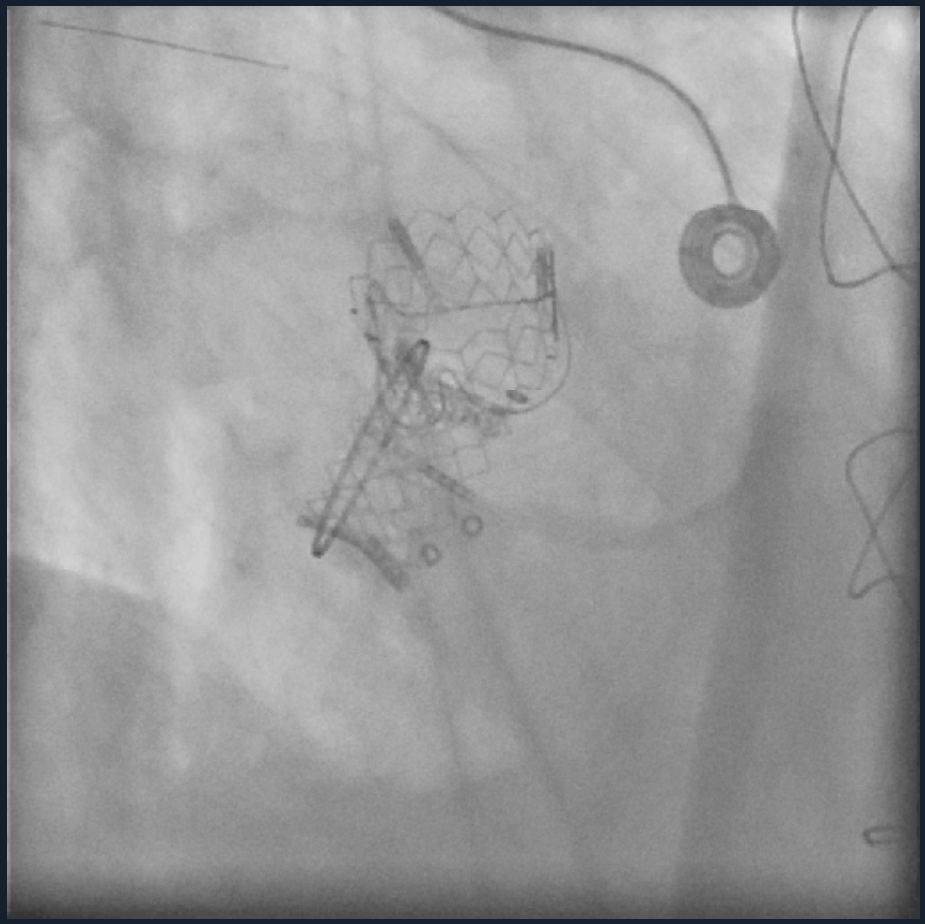
TAVR 2012
Endless Possibilities!

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

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TAVR Outcomes - VARC Meta-Analysis
(17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
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]

P Généreux and S.J.Head
Unpublished data/Submitted JACC

TAVR Outcomes - VARC Meta-Analysis
(17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Vascular events @ 30 days		
Major	11.9	[8.6, 16.4]
Minor	9.7	[6.7, 14.0]
All	18.8	[14.5, 24.3]
Bleeding @ 30 days		
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 ≥ 1 unit	42.6	[19.8, 62.4]

P Généreux and S.J.Head
Unpublished data/Submitted JACC

TAVR Outcomes - VARC Meta-Analysis
(17 studies; 3,519 patients)

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
MI (peri-procedural)	1.1	[0.2, 2.0]
Valve performance @ 30 days		
AVA ≤ 1.2 cm^2	4.8	[3.0, 6.6]
Mean gradient ≥ 20 mmHg	1.0	[0.0, 2.1]
AR ≥ 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]
Perm Pacemaker @ 30 days		
Edwards	4.9	[3.9, 6.2]
MDT-Corevalve	28.9	[23.0, 36.0]

P Généreux and S.J.Head
Unpublished data/Submitted JACC

Published on-line June 5, 2011 @ NEJM.org and print June 9, 2011

Editorial Response

EDITORIALS

Transcatheter Aortic-Valve Implantation — At What Price?

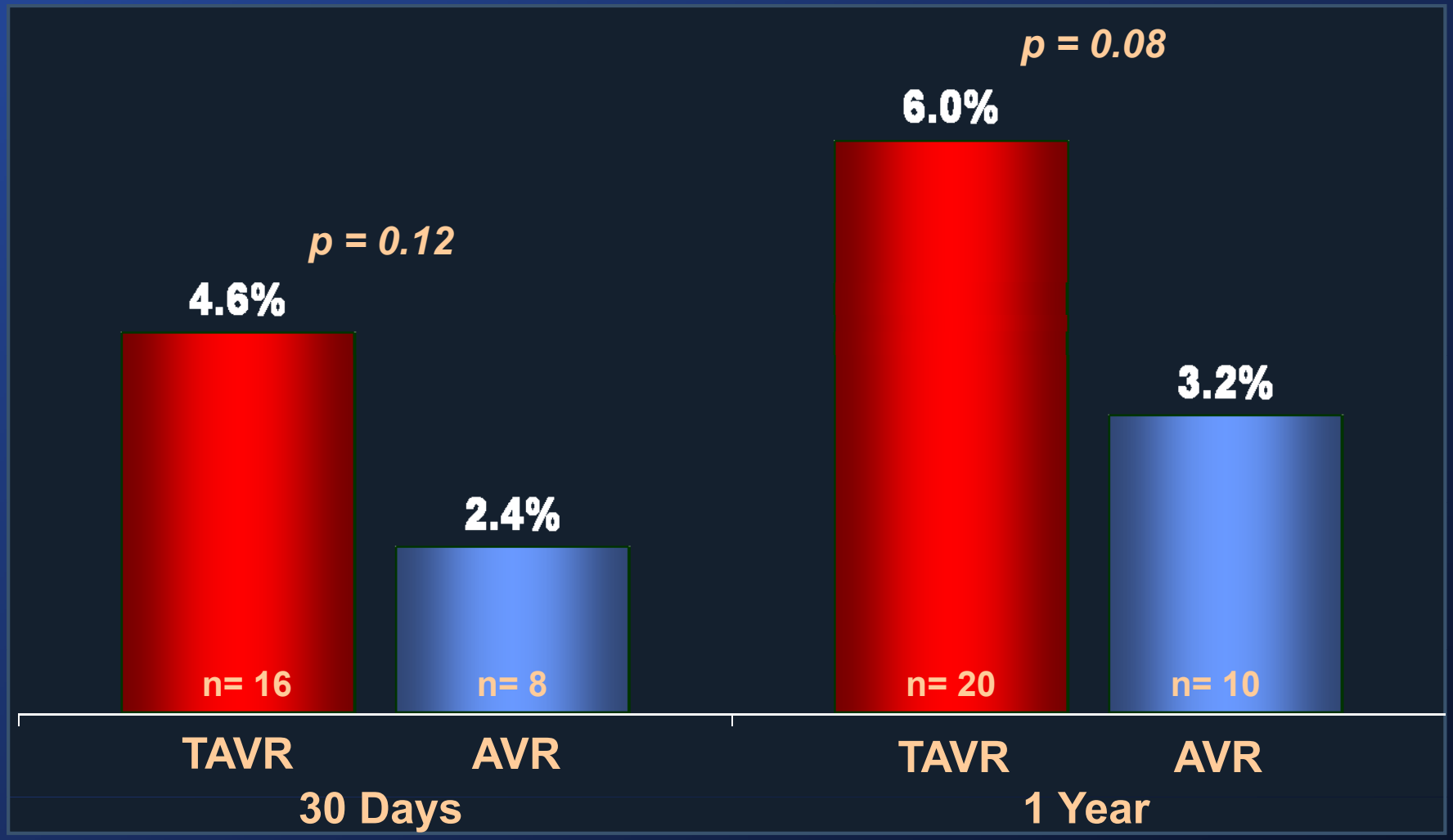
Hartzell V. Schaff, M.D.

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.[1] 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

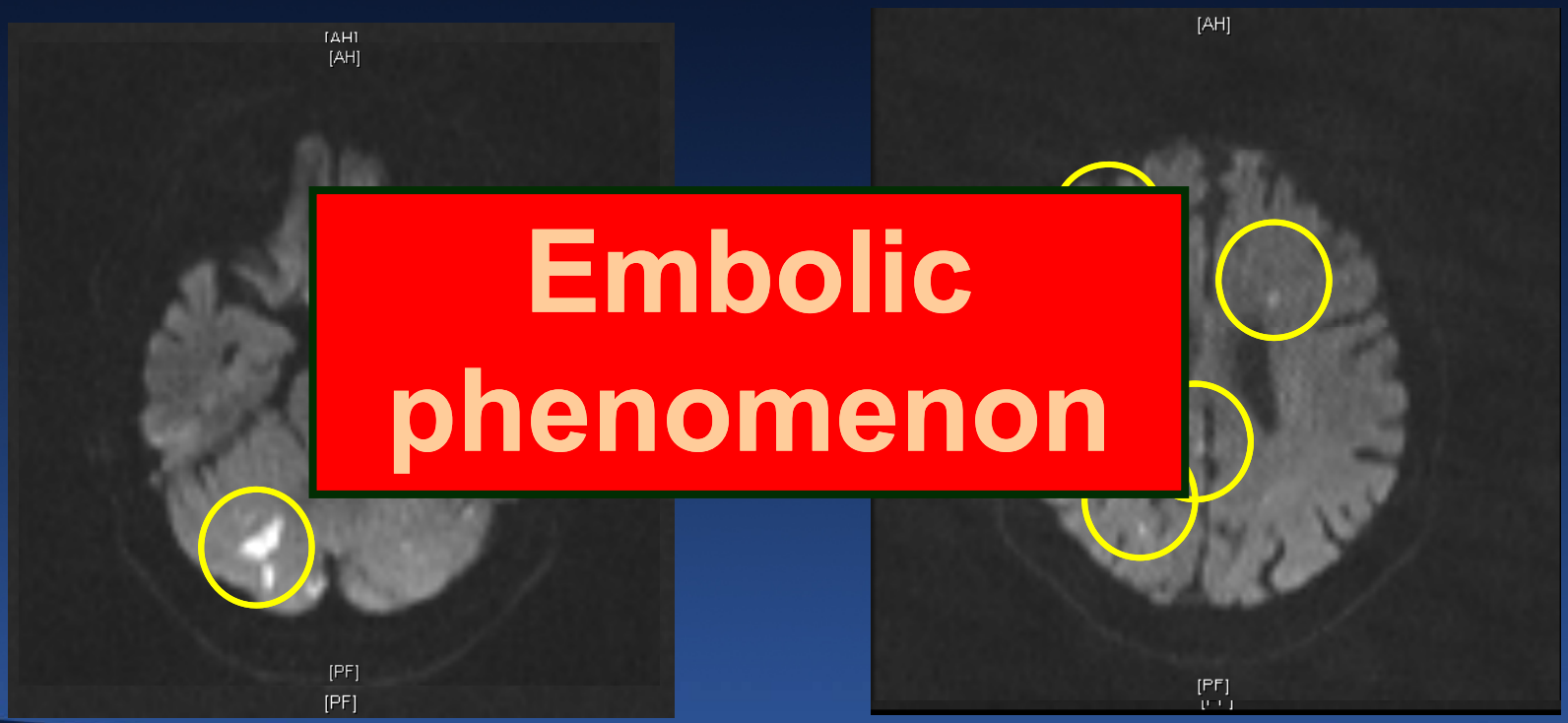
Diffusion-Weighted MRI Study

Philipp Kahlert, MD
West German Heart Center Essen

Pre-TAVI

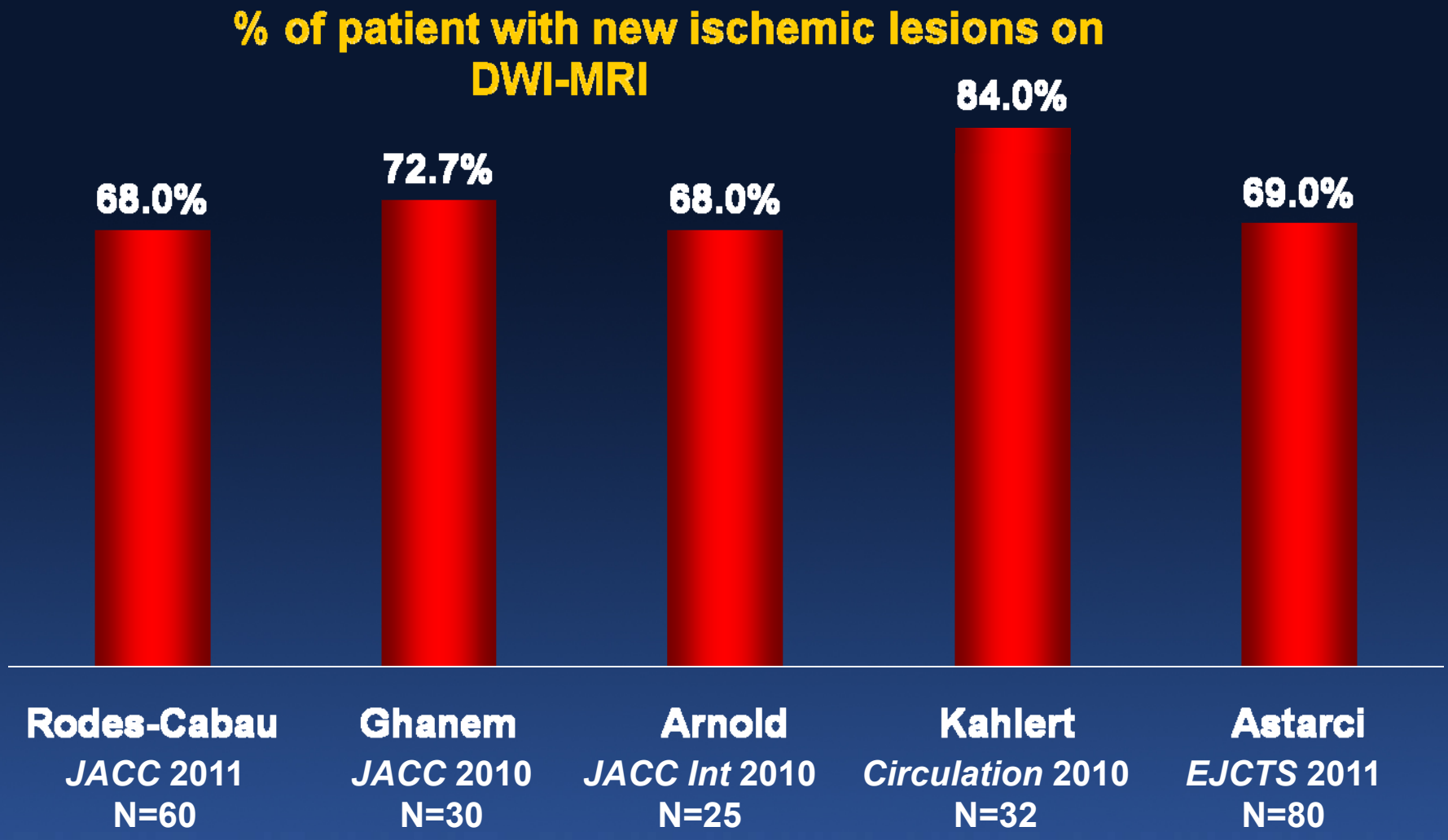
Post-TAVI

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



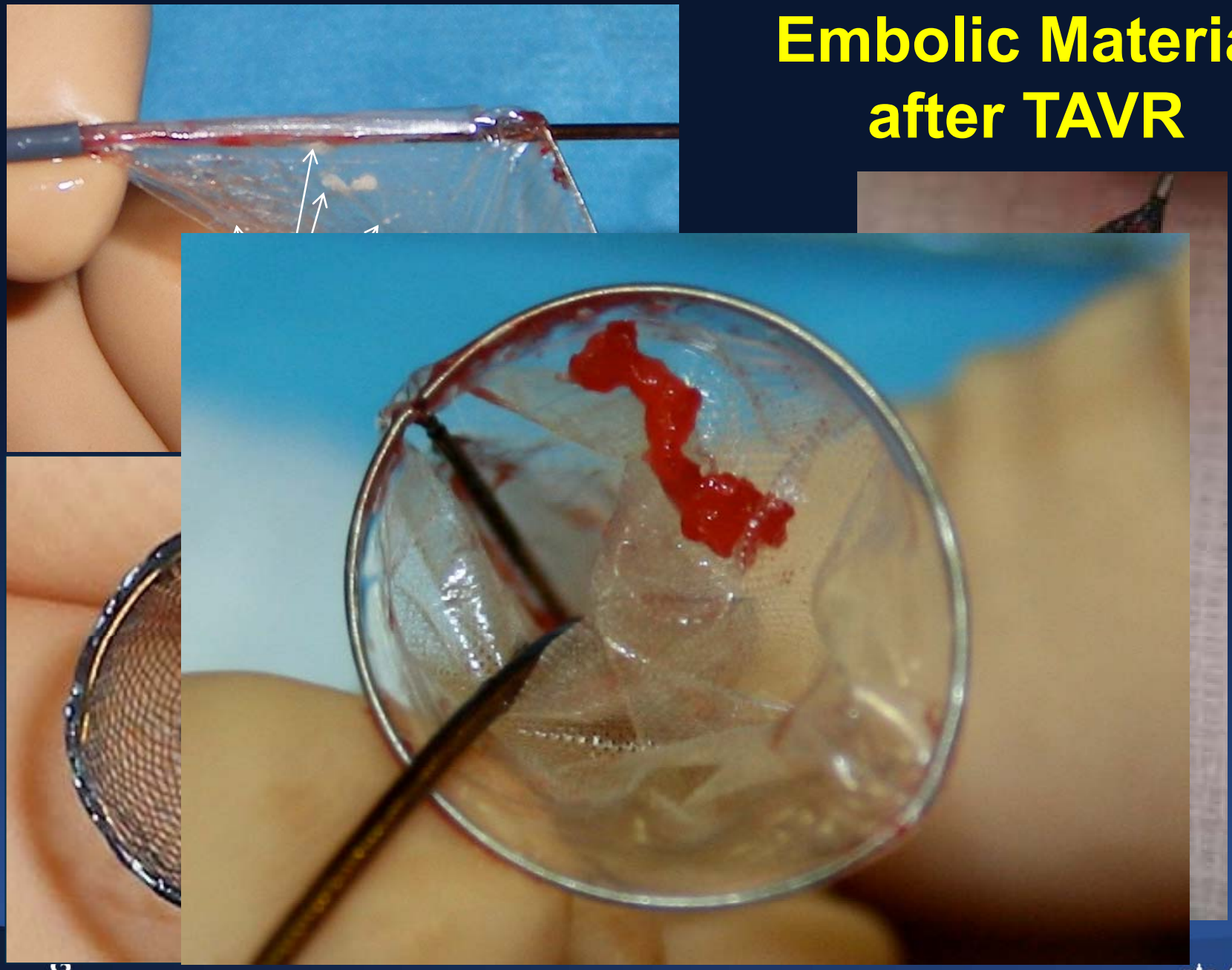
Embolic phenomenon

Neuro-imaging with TAVR



Daneault et al., *JACC* 2011;58: 2143-50

Embolic Material after TAVR



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Strokes in PARTER
High-risk cohort

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

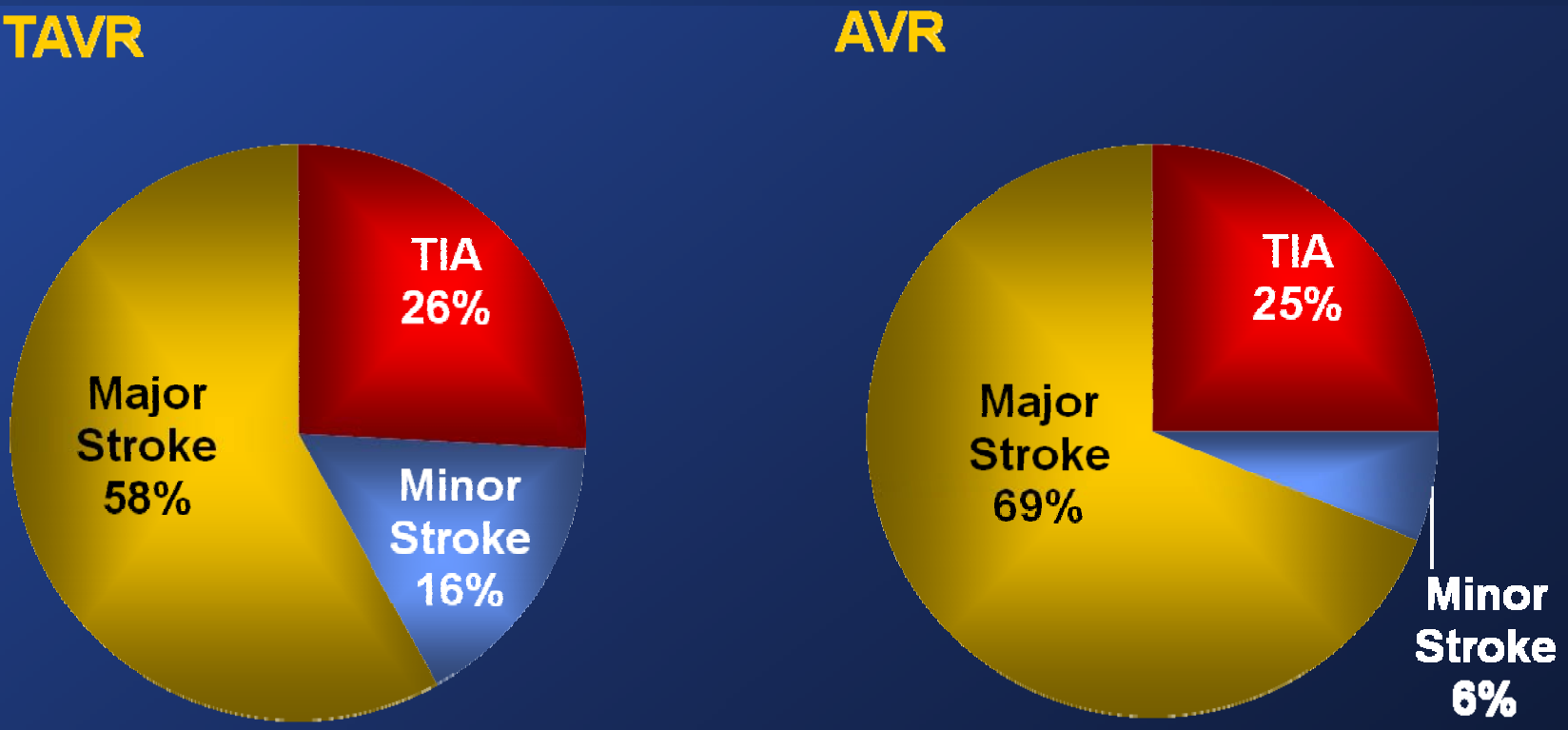
D. Craig Miller, MD,[a] Eugene H. Blackstone, MD,[b] Michael J. Mack, MD,[c] Lars G. Svensson, MD, PhD,[b] Susheel K. Kodali, MD,[d] Samir Kapadia, MD,[b] Jeevanantham Rajeswaran, MSc,[b] William N. Anderson, PhD,[e] Jeffrey W. Moses, MD,[d] E. Murat Tuzcu, MD,[b] John G. Webb, MD,[f] Martin B. Leon, MD,[d] and Craig R. Smith, MD,[d] 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

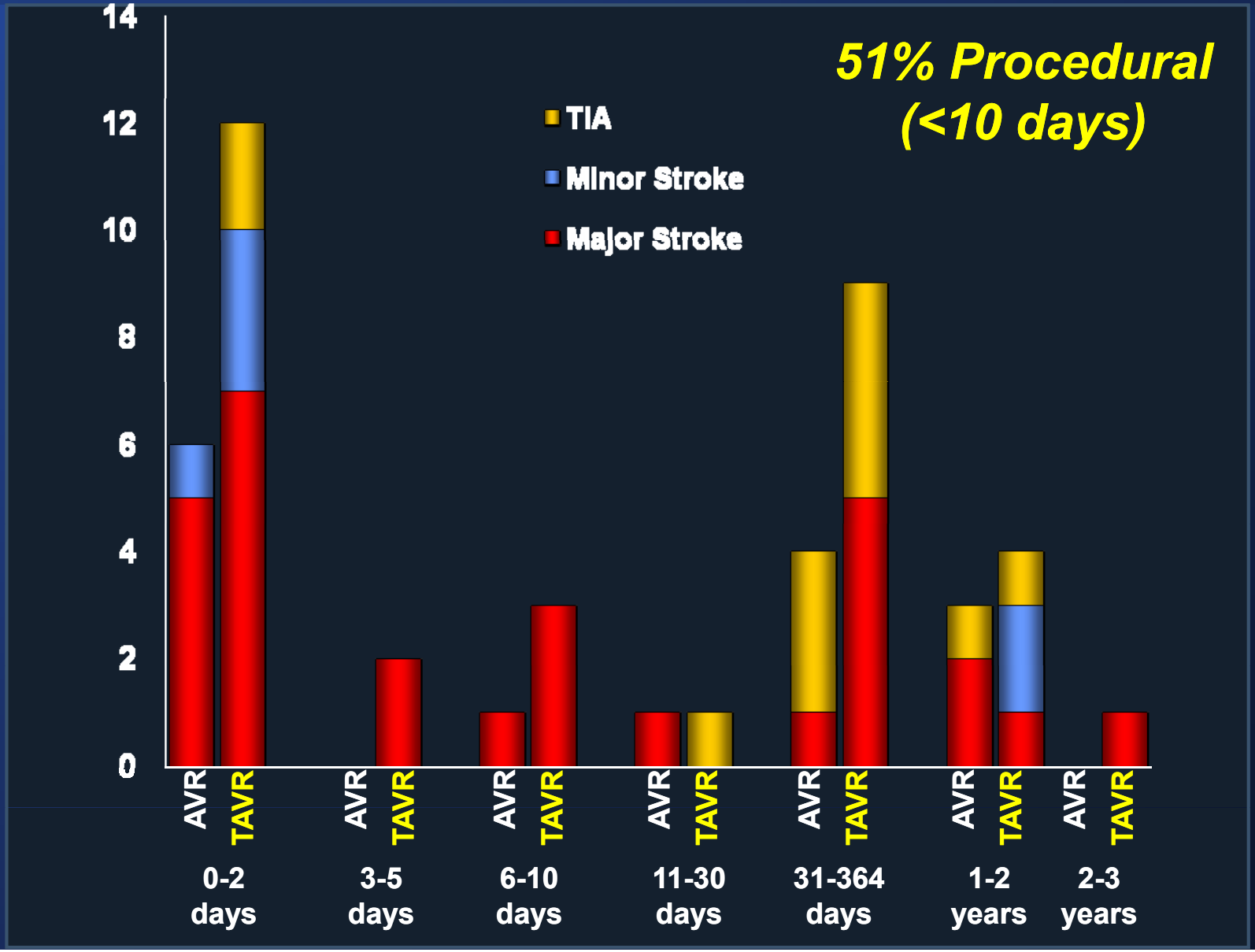
THE PARTNER TRIAL



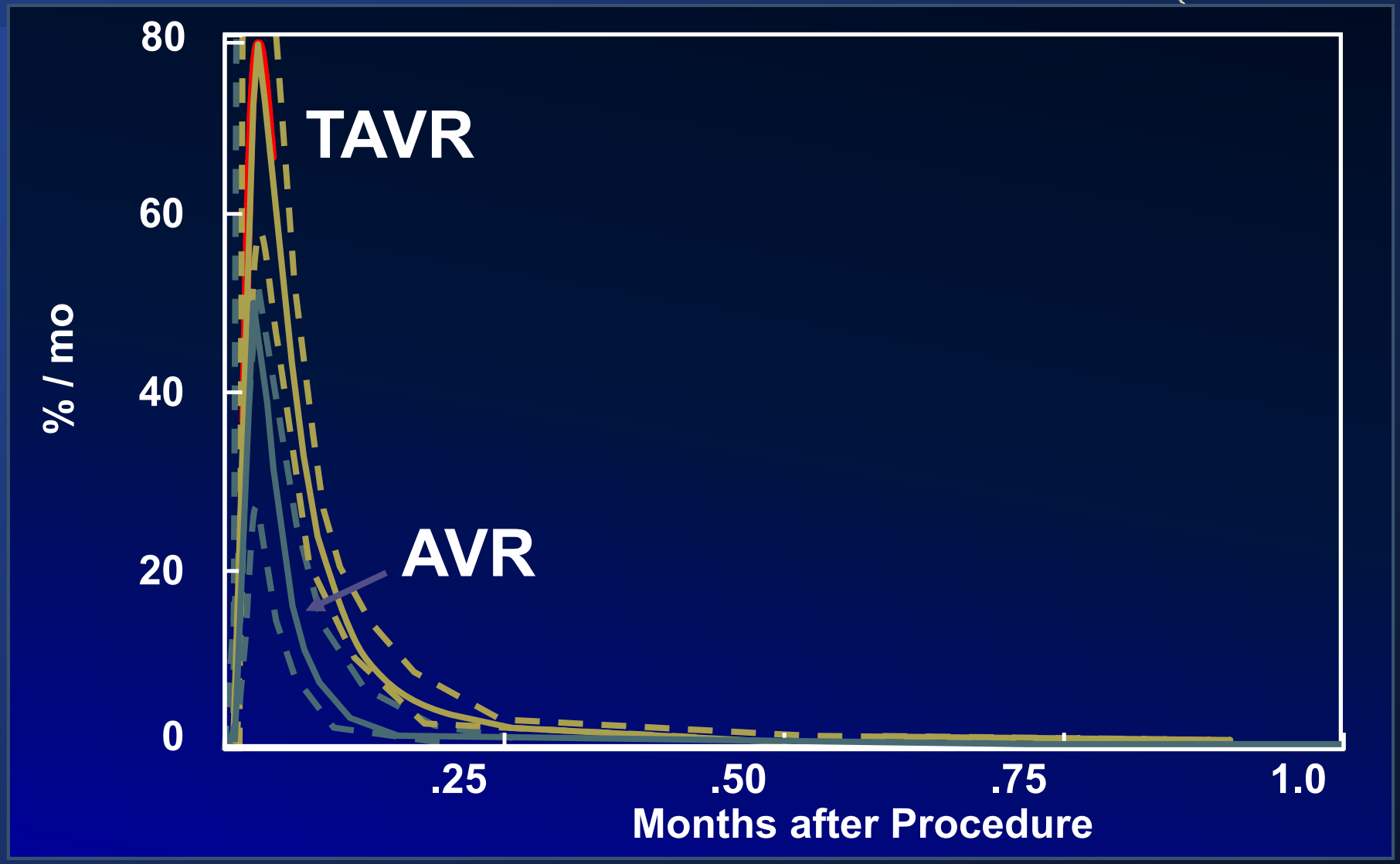
47 patients, 49 neuro events

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

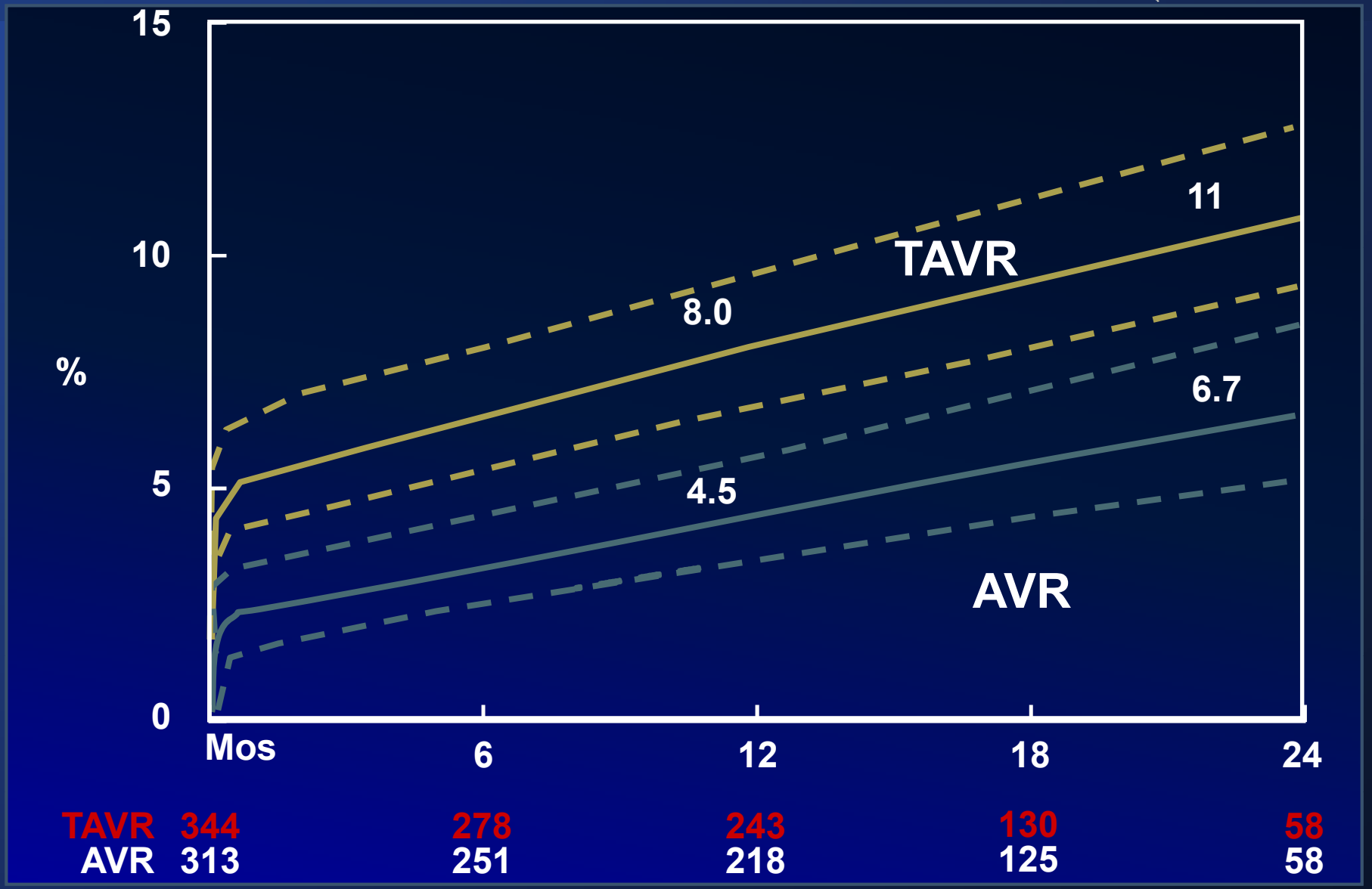
Early high peaking hazard phase

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

Atrial fibrillation not significant in multivariable analysis

R(%) = bagging reliability

Later Hazard of Neurologic Event



Incremental risk factors for neurologic events

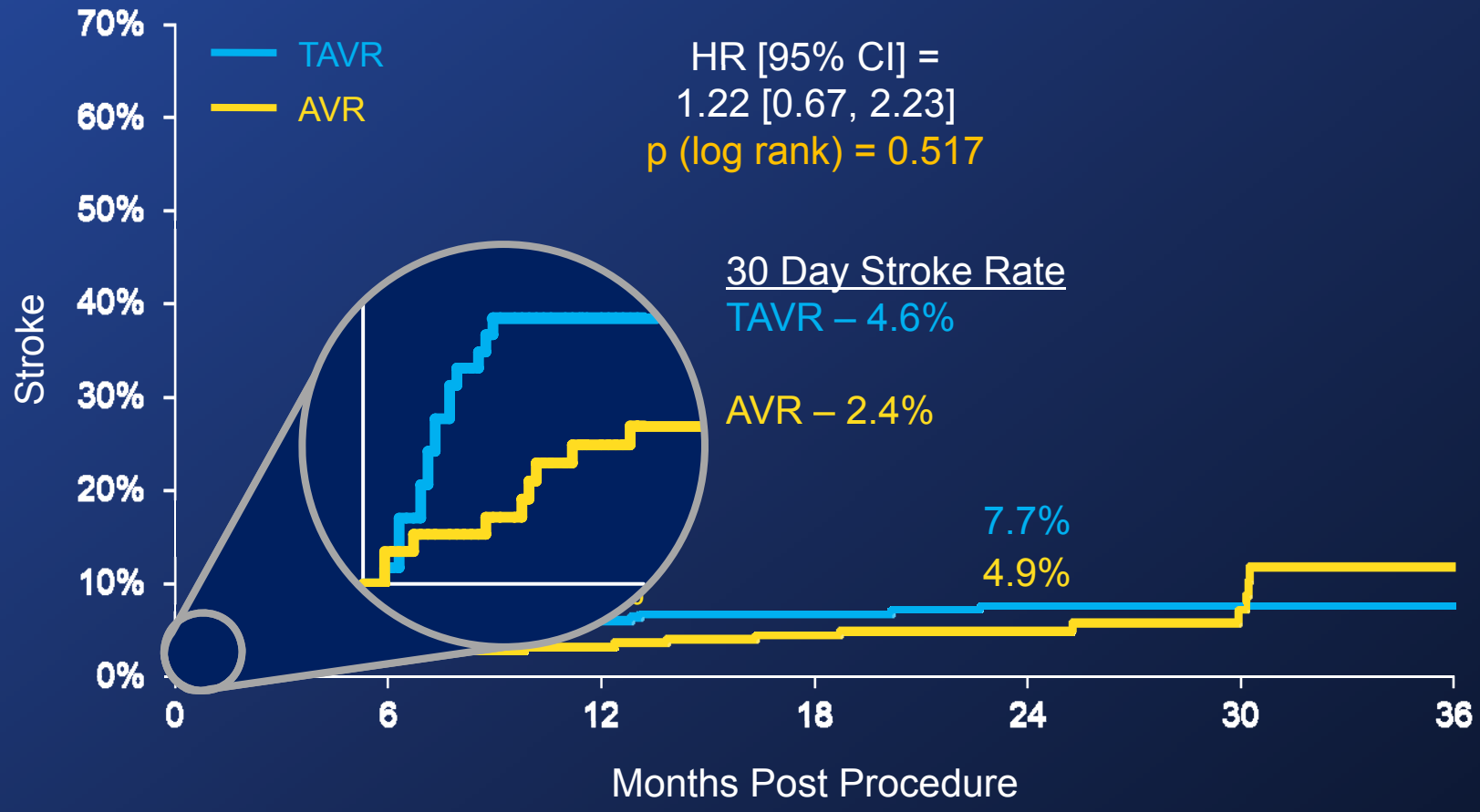
Late constant hazard phase

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

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

R(%) = bagging reliability

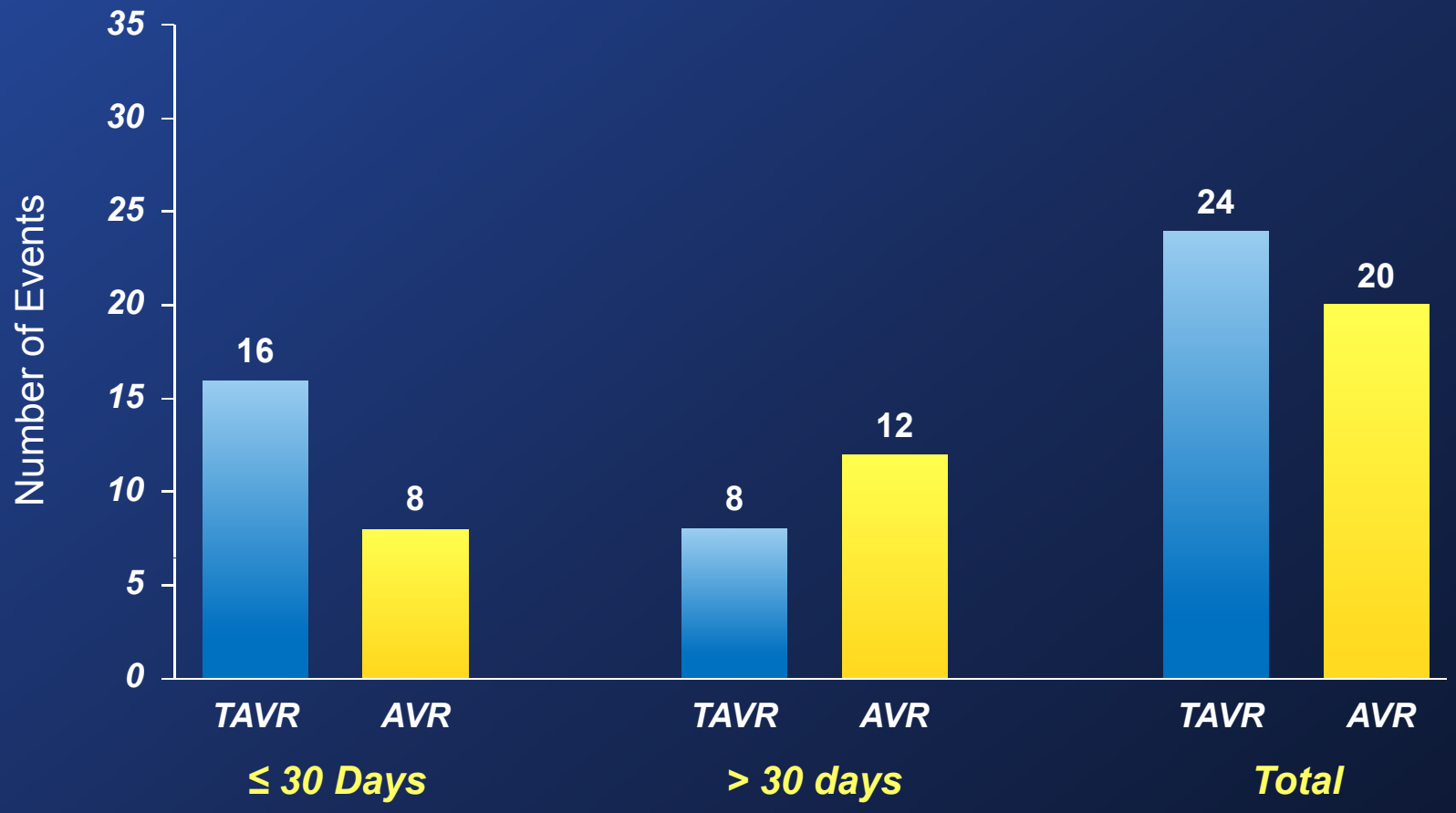
Strokes (ITT)



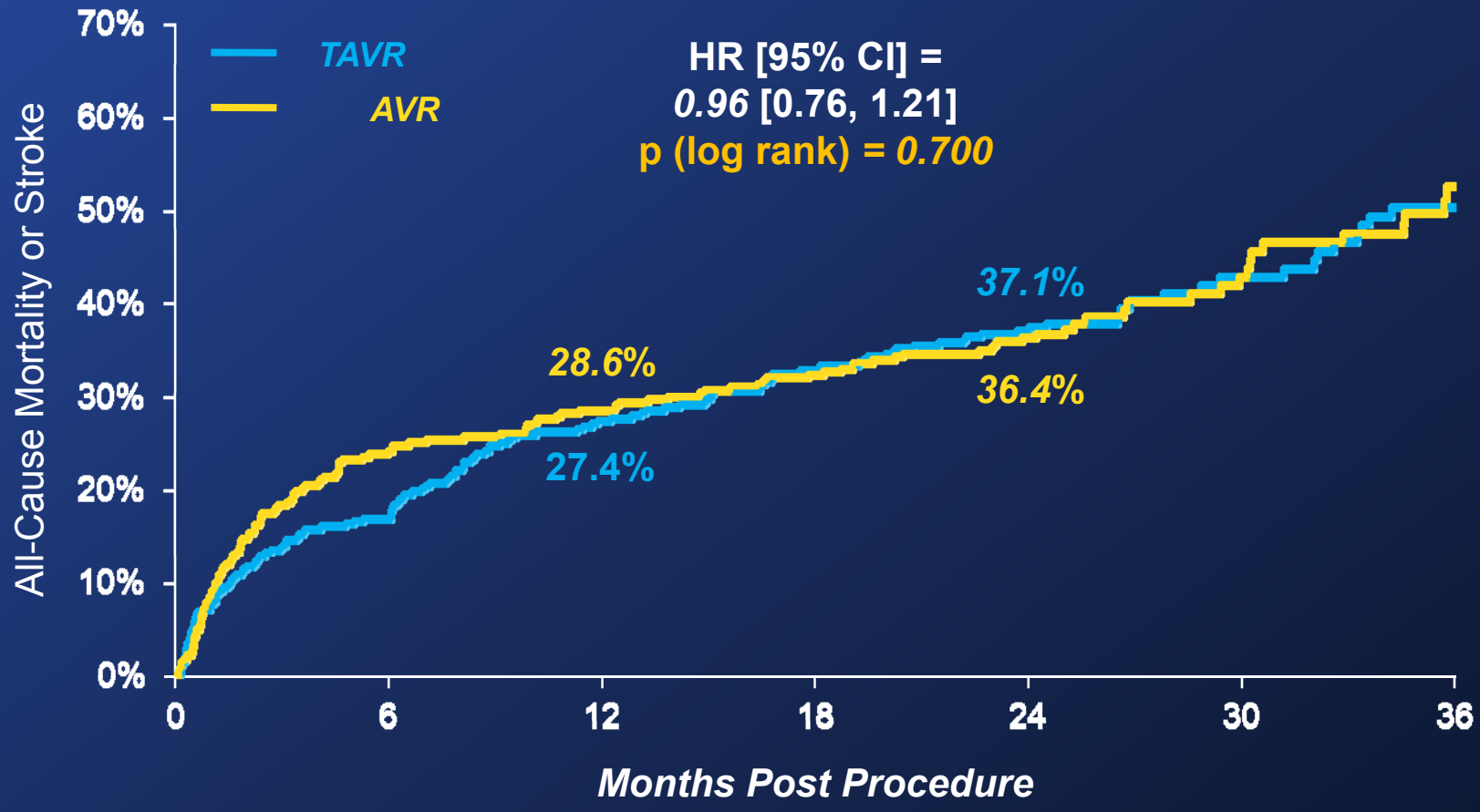
Numbers at Risk

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

Strokes (ITT Population)



All-Cause Mortality or Strokes (ITT)



Numbers at Risk

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

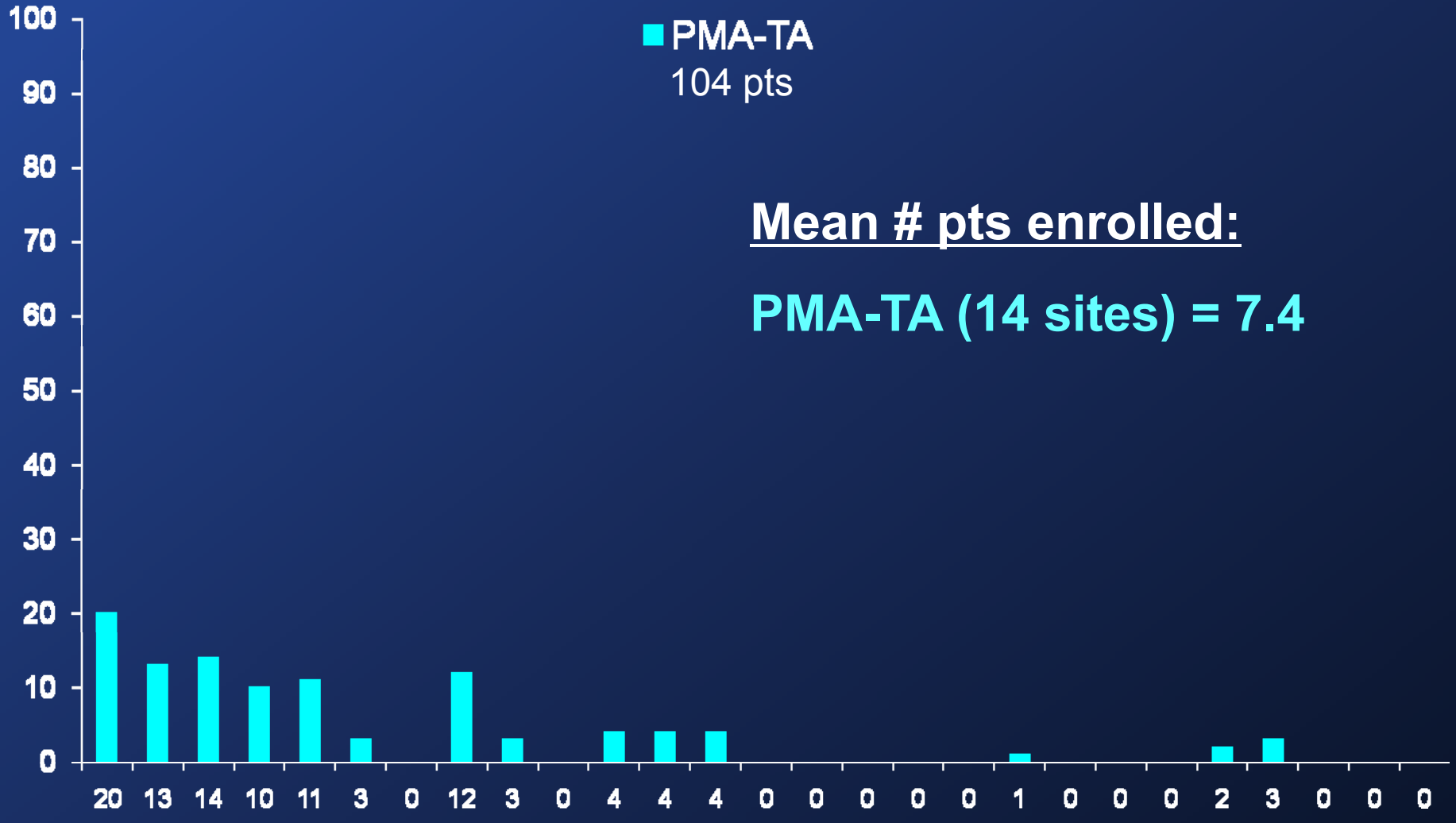
Transapical Aortic Valve Replacement For Critical Aortic Stenosis: Results From the Non-Randomized Continued Access Cohort of The PARTNER Trial

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

STS 2012 | Fort Lauderdale | Jan 30, 2012

THE PARTNER TRIAL

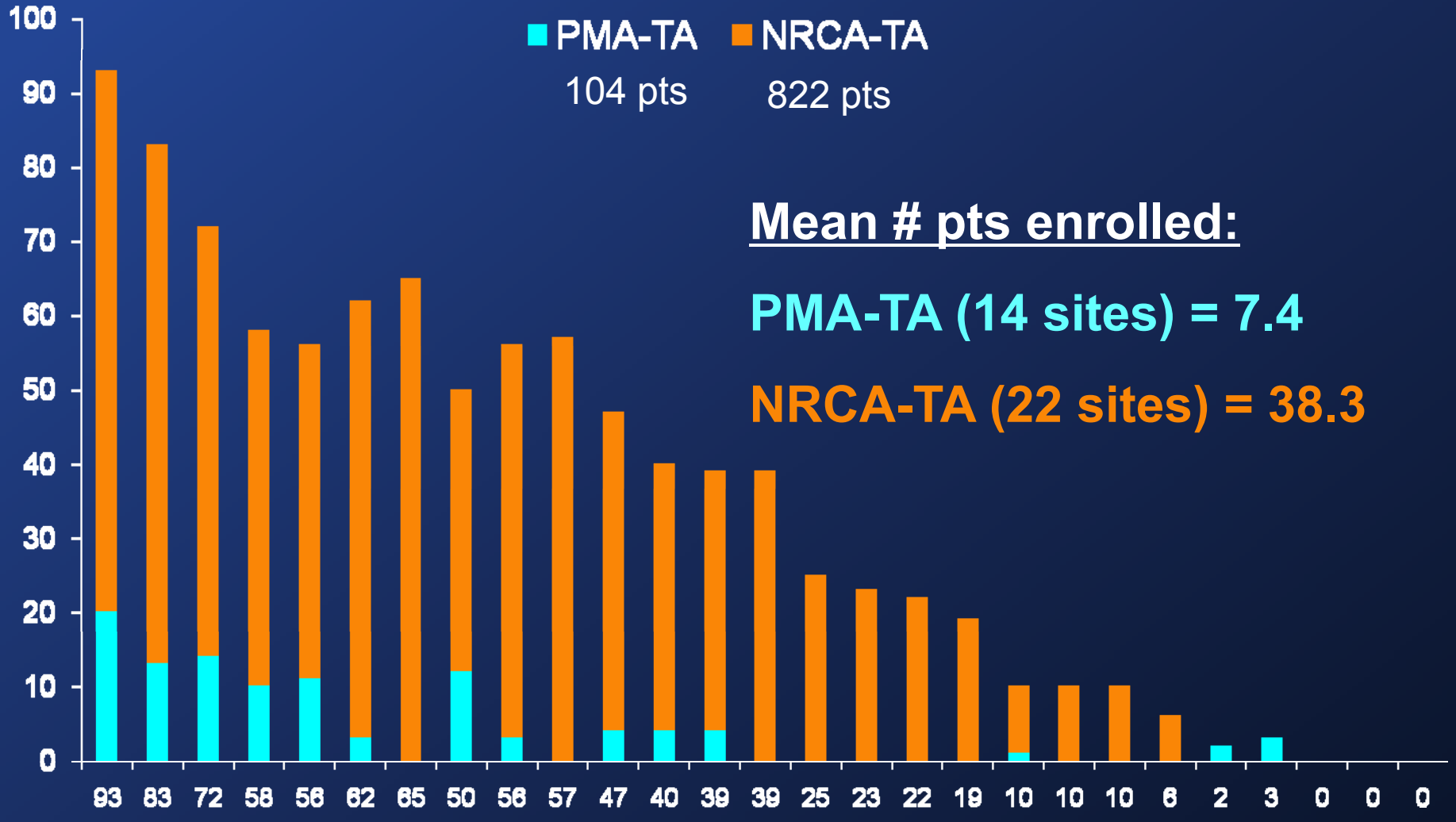
Transapical Enrollment per Site



Mean # pts enrolled:

PMA-TA (14 sites) = 7.4

Transapical Enrollment per Site



Mean # pts enrolled:

PMA-TA (14 sites) = 7.4

NRCA-TA (22 sites) = 38.3

Clinical Outcomes at 30 Days and 1 Year (AT)

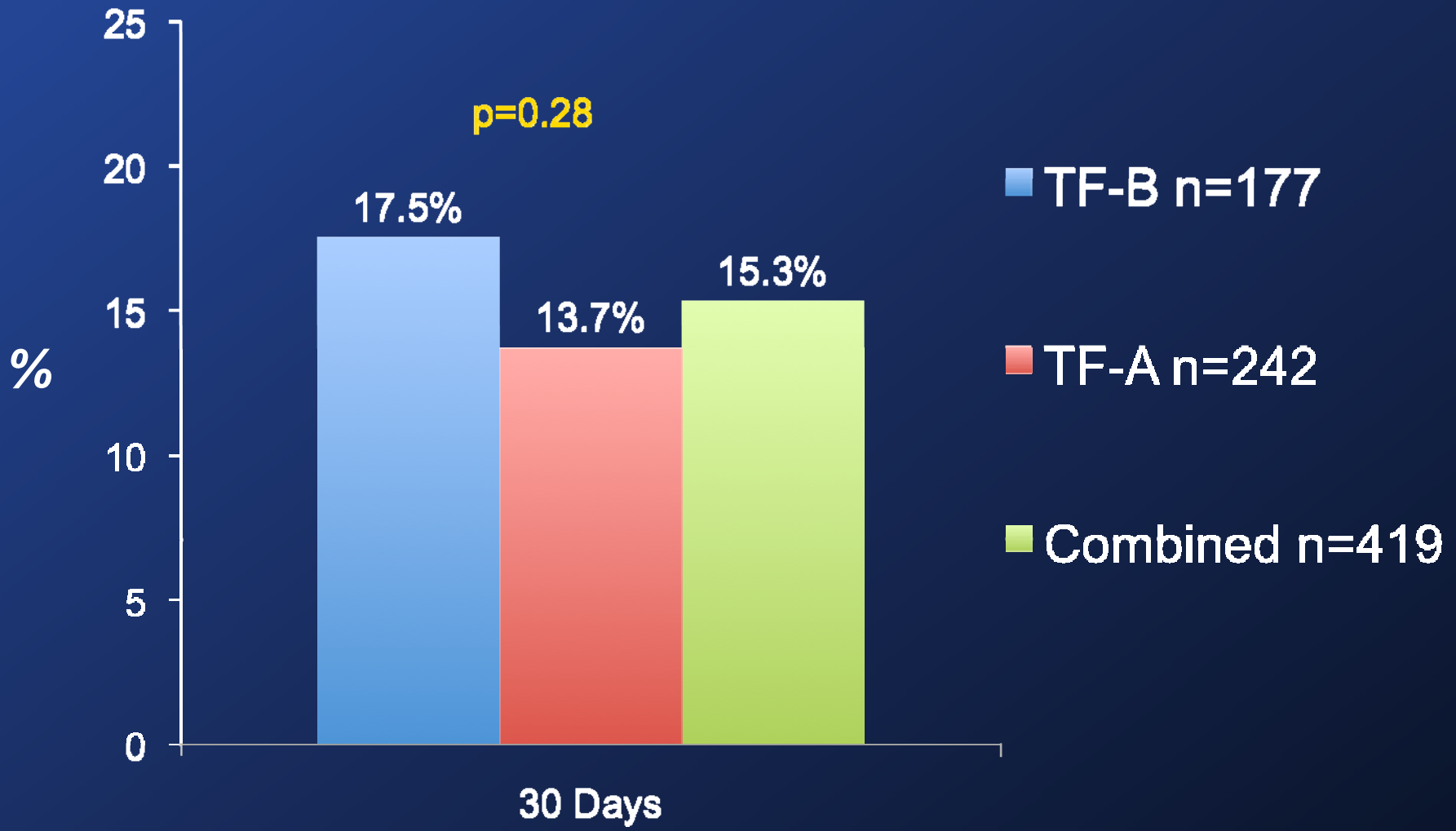
THE PARTNER TRIAL

All percents are KM estimates.

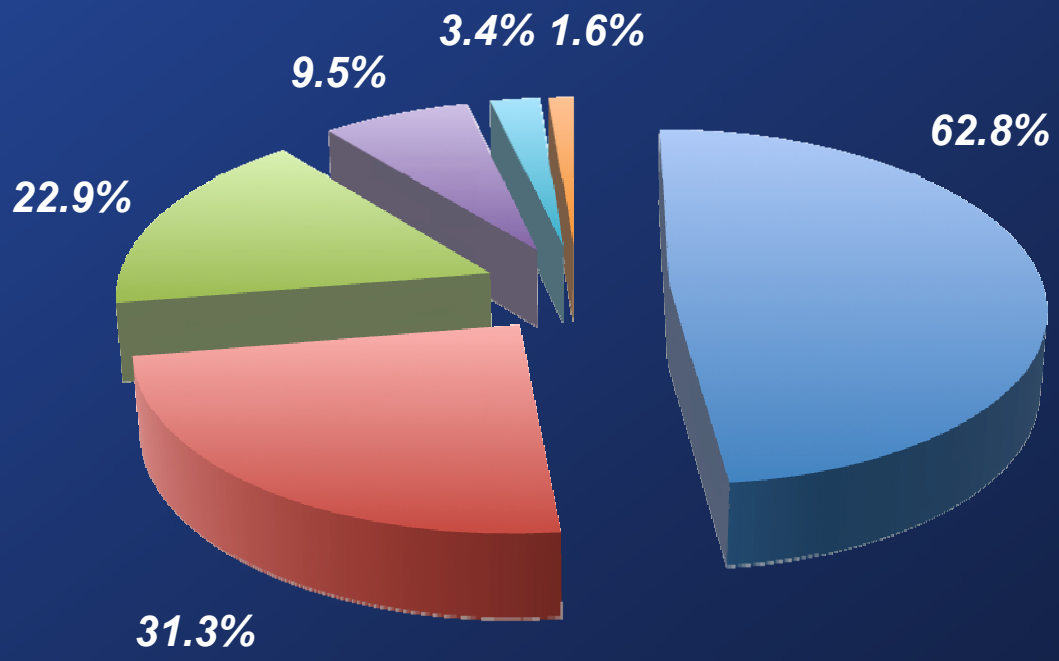
Outcome	30 Days			1 Year		
	PMA-TA (n = 104)	AVR (n = 92)	NRCA-TA (n = 822)	PMA-TA (n = 104)	AVR (n = 92)	NRCA-TA (n = 822)
All-Cause Mortality – pts. (%)	9 (8.7%)	7 (7.6%)	66 (8.2%)	30 (29.1%)	23 (25.3%)	148 (23.6%)
Stroke – pts. (%)	7 (7.0%)	5 (5.5%)	16 (2.0%)	10 (10.8%)	6 (7.0%)	22 (3.7%)
Death or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

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



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



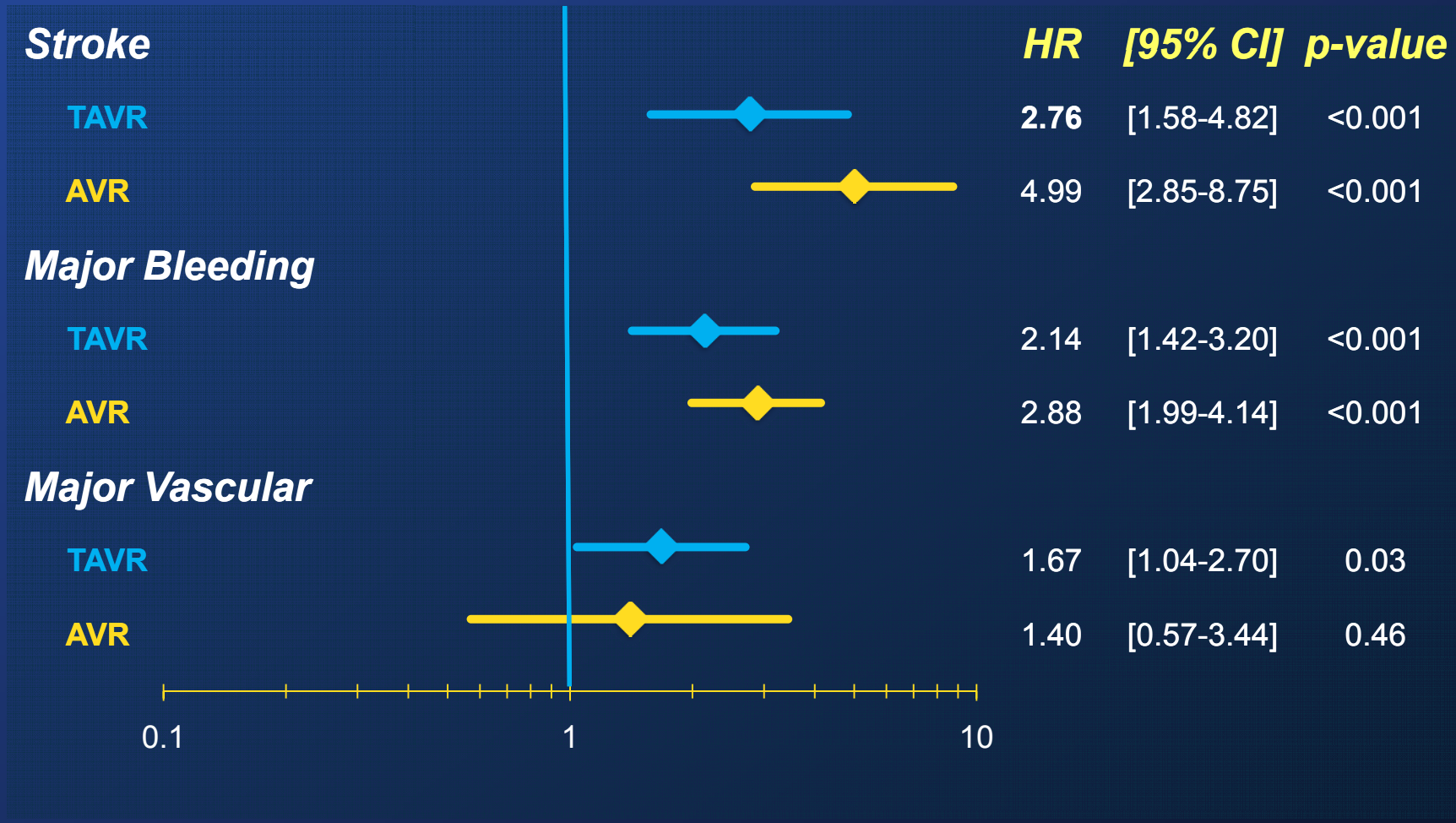
n=64

- Vascular dissection
- Vascular perforation
- Access site hematoma
- Retroperitonal bleeding
- False Aneurysm
- Gastro-intestinal ischemia

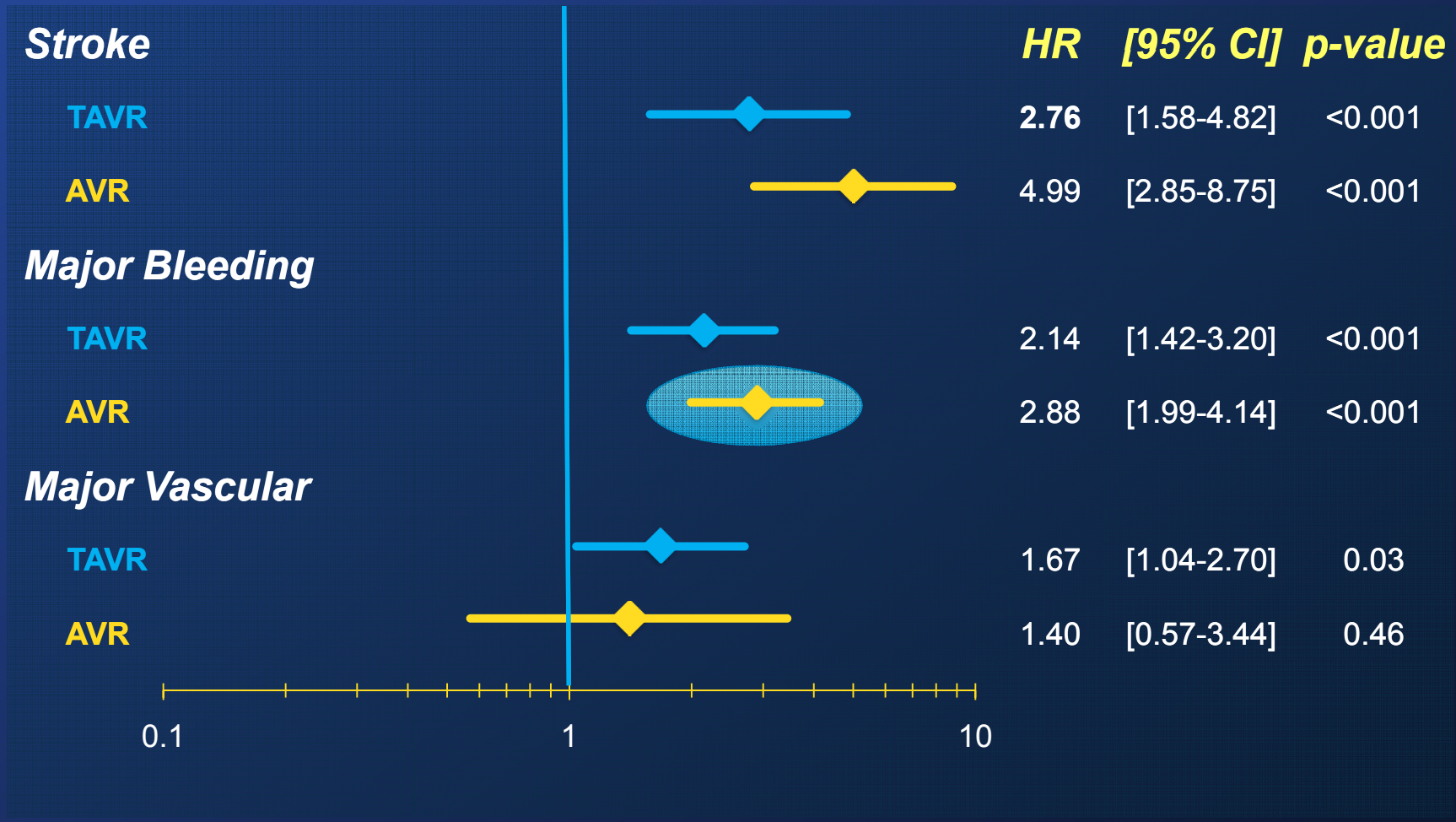
Association between Major VC, Bleeding and Renal Failure

	Major VC n=64	No Major VC n=355	Combined n=419	Hazard Ratio [95% C.I.]	
Hemorrhagic Event	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
Renal Failure (Dialysis required)	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

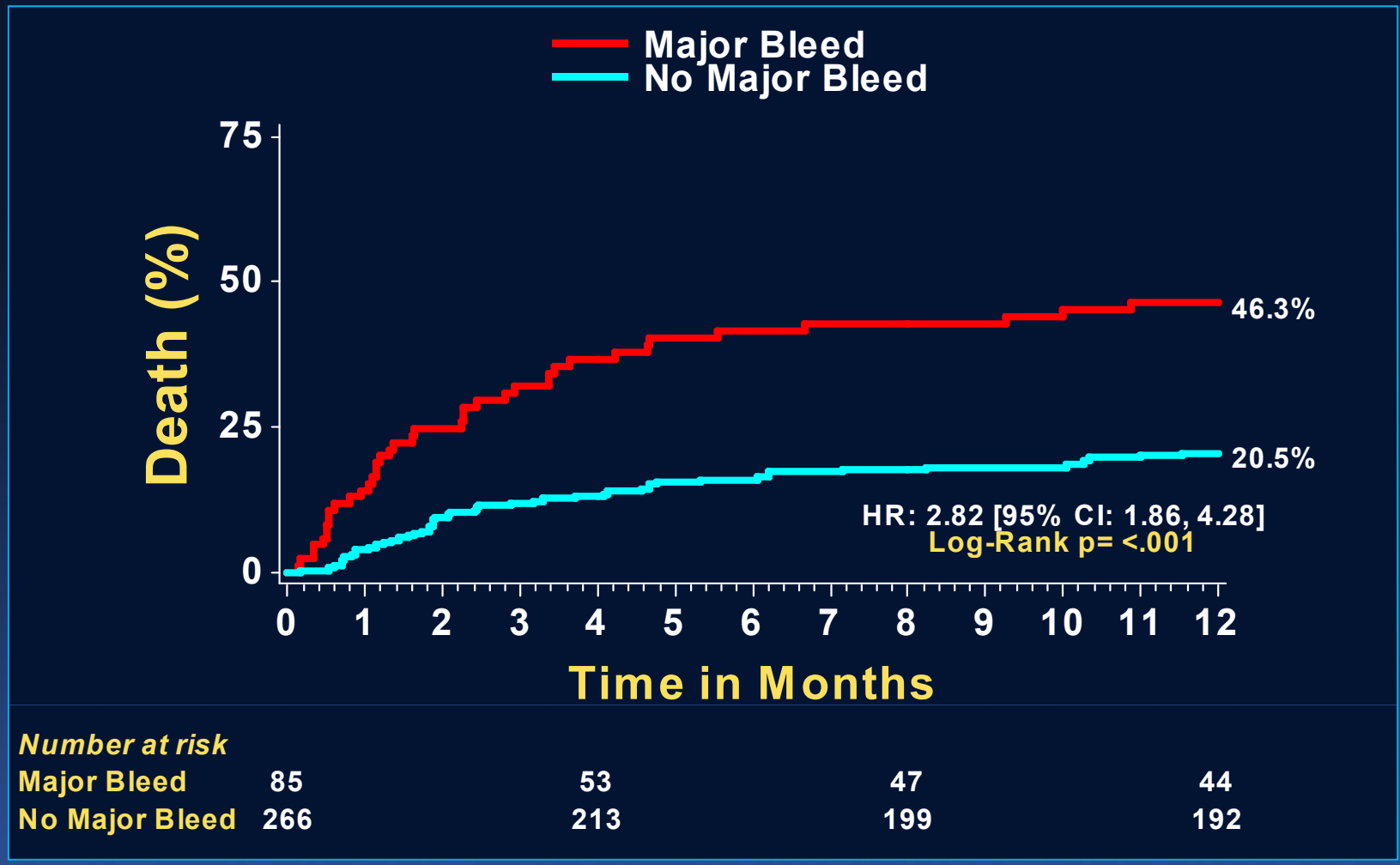
Procedural Predictors of Mortality



Procedural Predictors of Mortality



Bleeding Complications – PARTNER
Cohort A - Surgery ITT



Number at risk				
Major Bleed	85	53	47	44
No Major Bleed	266	213	199	192

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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)

Guitterez 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	✔

adapted from Piazza, N

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**

Erkapic D, de Rosa S, Kelava A, et al;
J Cardiovasc Electrophysiol 2011

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[1], John G. Webb[2], Fabian Nietlispach[2], Éric Dumont[1], Robert De Larochellière[1], Daniel Doyle[1], Jean-Bernard Masson[2], Marcos J. Gutiérrez[1], Marie-Annick Clavel[1], Olivier F. Bertrand[1], Philippe Pibarot[1], and Josep Rodés-Cabau[1]*

Methods:

- *213 pts (82±8 yrs) with TAVR (Edwards,TF/TA 5248%) 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)**

Bagur R, Webb, JG, Nietlispach F, et al; EHJ 2010; 31:865-74

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)**

Elhmidi Y, Bleiziffer S, Piazza N, et al; AHJ 2011; 161:735-9

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 Larochellière, 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)**

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Rodes-Cabau J, Gutierrez M, Bagur R, et al; JACC 2011;57:1988-99

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian

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 Larochellière, 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)***

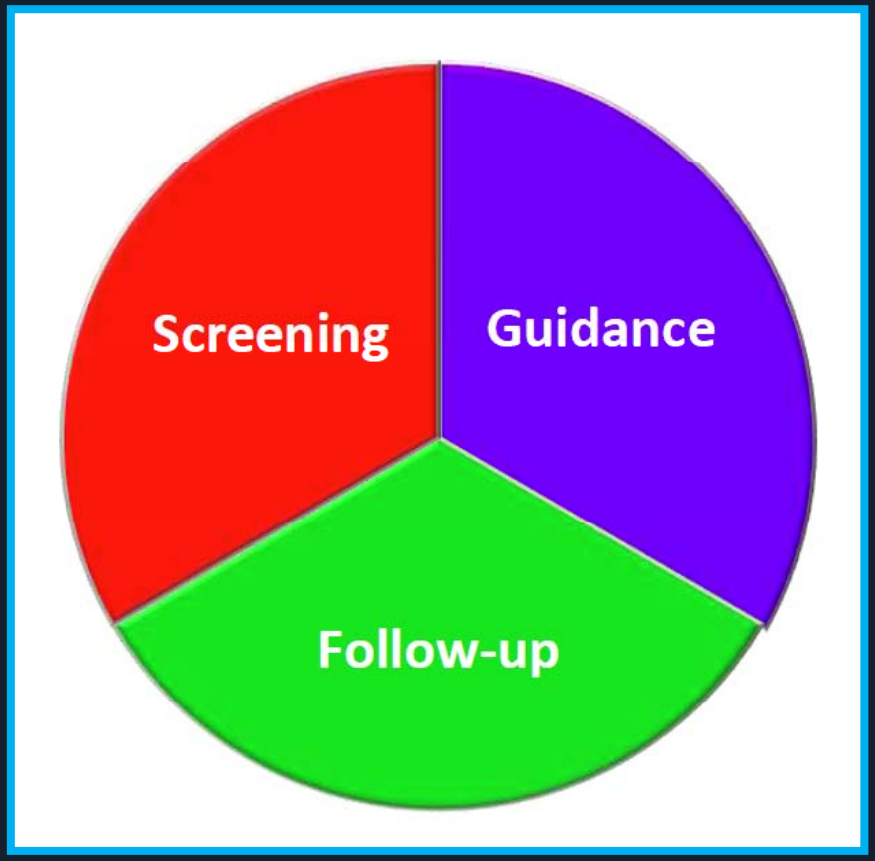
Rodes-Cabau J, Gutierrez M, Bagur R, et al; JACC 2011;57:1988-99

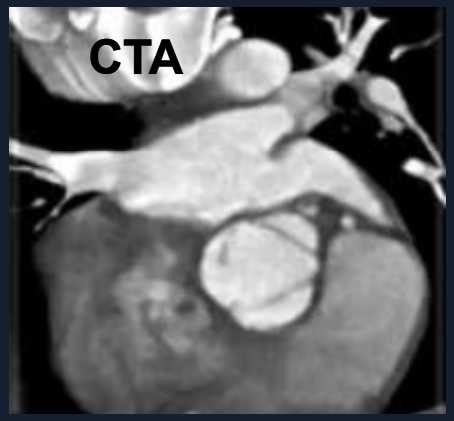
TAVR in Review (2011-12)

Adjunctive Imaging

Adjunctive Imaging during TAVR

Multi-modality Imaging is the RULE

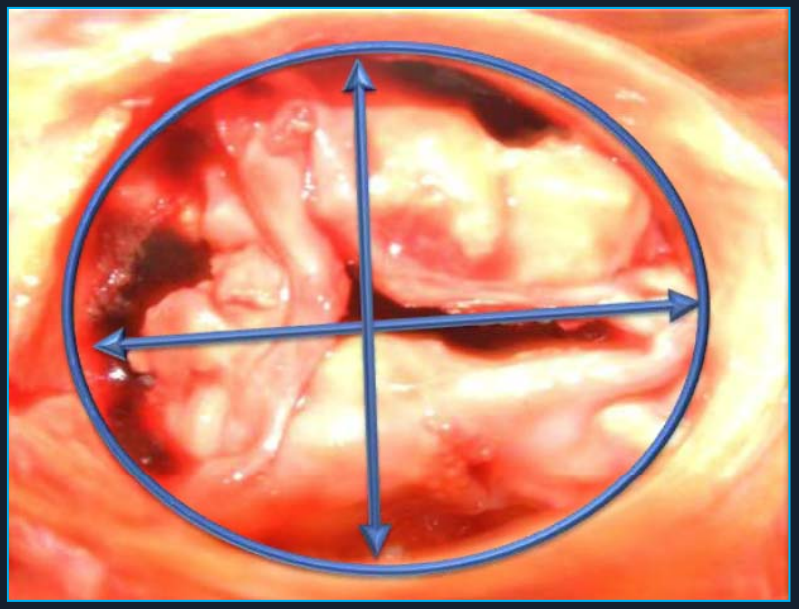




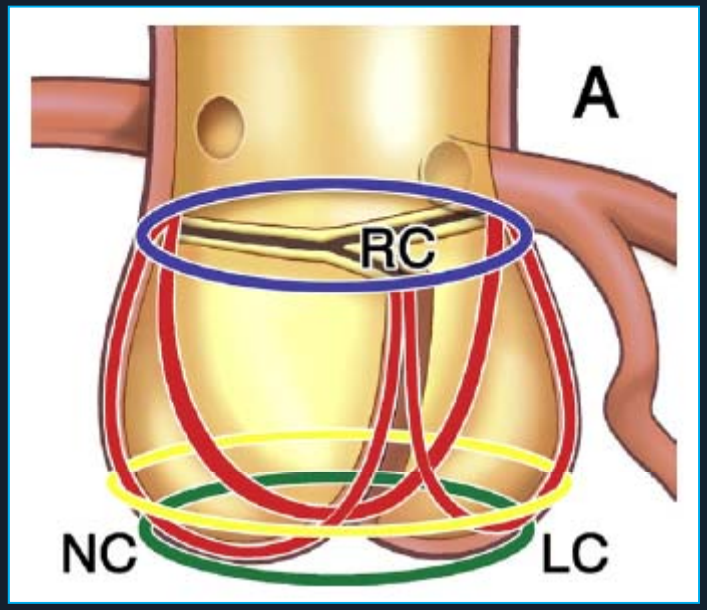
Adapted from: Lutz Buellesfeld

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

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

by **Pre-Procedural Imaging of Aortic Root Orientation and Dimensions**

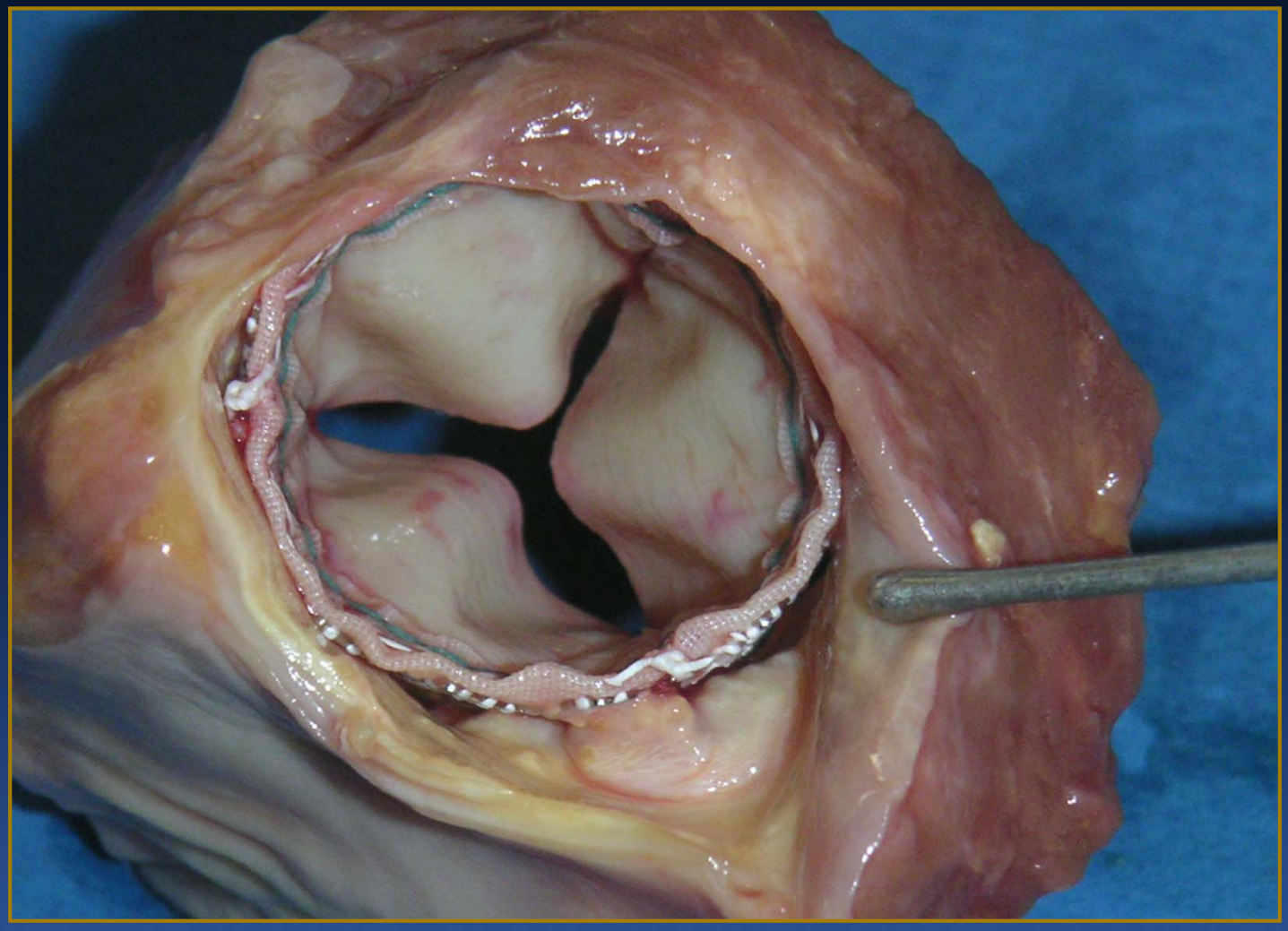
Measurement of Aortic Valve Annulus Using Different Cardiac Imaging Techniques in Transcatheter Aortic

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‡

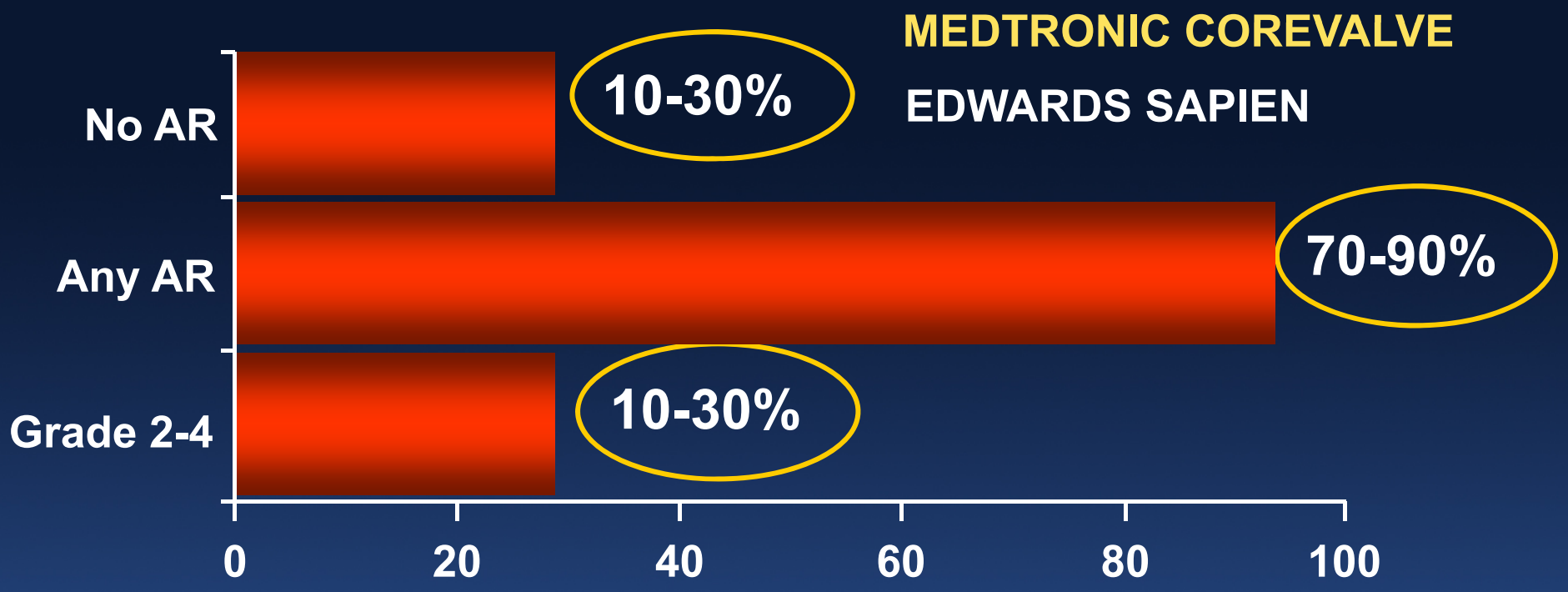
JACC CV Imaging 2011;4:416-29

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 prosthesis (D) – TEE annulus D/prosthesis D***

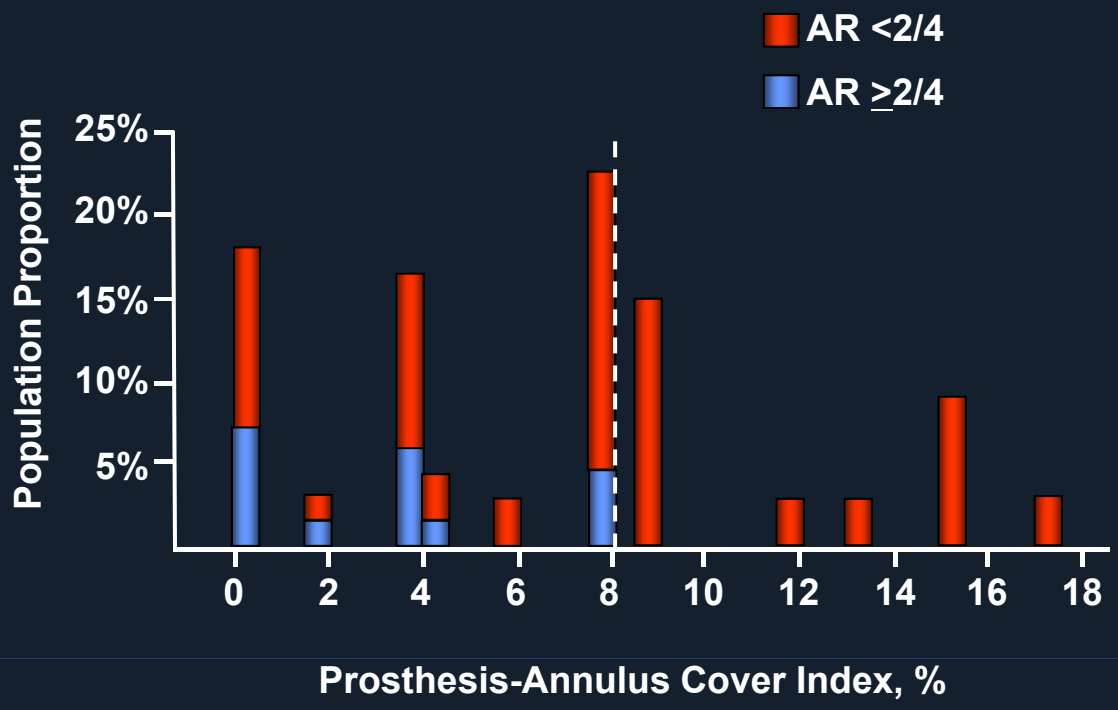
RESULTS:

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

CONCLUSION: Prosthesis/annulus "discongruence" is a strong predictor of post-TAVR ≥ 2/4 PVL

Para-valvular Regurgitation after TAVR

Relationship of Cover Index to PVL



Detaint, D, Lepage L, Himbert D, et al;
JACC Intv 2009;2:821-7

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 Yuecel, 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)***

CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

John D, Buellesfeld L, Yuecel S, et al;
JACC Intv 2010;3:23-43

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian

PVL after TAVR Predicts Increased Mortality

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

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

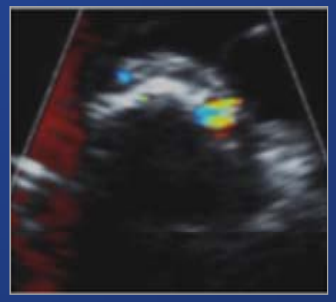
The U.K. TAVI (United Kingdom Transcatheter Aortic Valve Implantation) Registry

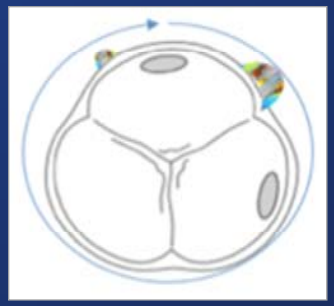
Neil E. Moat, MBBS, MS,* Peter Ludman, MA, MD,† Mark A. de Belder, MA, MD,‡ Ben Bridgewater, PHD,§ Andrew D. Cunningham, PHD,‖ Christopher P. Young, MD,¶ Martyn Thomas, MD,¶ Jan Kovac, MD,# Tom Spyt, MD,# Philip A. MacCarthy, BS, PHD,** Olaf Wendler, MD, PHD,** David Hildick-Smith, MD,†† Simon W. Davies, 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***

PVL after TAVR Predicts Increased Mortality

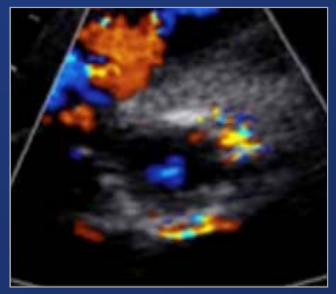
Author (journal)	# patients	TAVR Type	Predicts mortality
Abdel-Wahab (Heart 2011)	690	MCV 84% ES 16%	≥ 2/4 - mortality in-hospital
Tamburino (Circulation 2011)	603	MCV 100%	≥ 2/4 - mortality 30 days – 1 year
Gotzman (AHJ 2011)	145	MCV 100%	≥ Mod - mortality @ 6 mos
Moat (JACC 2011)	870	MCV 52% ES 48%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

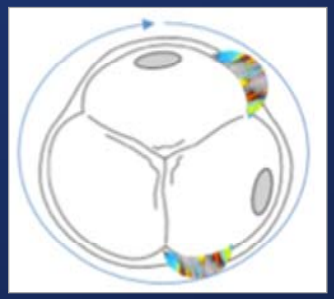
PARTNER Grading Criteria for Paravalvular AR



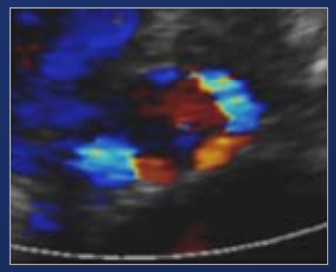


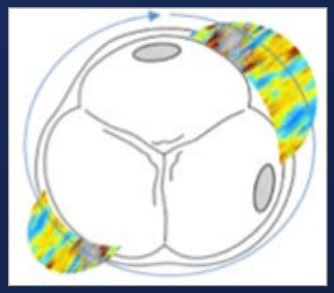
Circumference = 6″
AR = 0.1+0.35 = 0.45″
Ratio = 8%
Severity = Mild





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

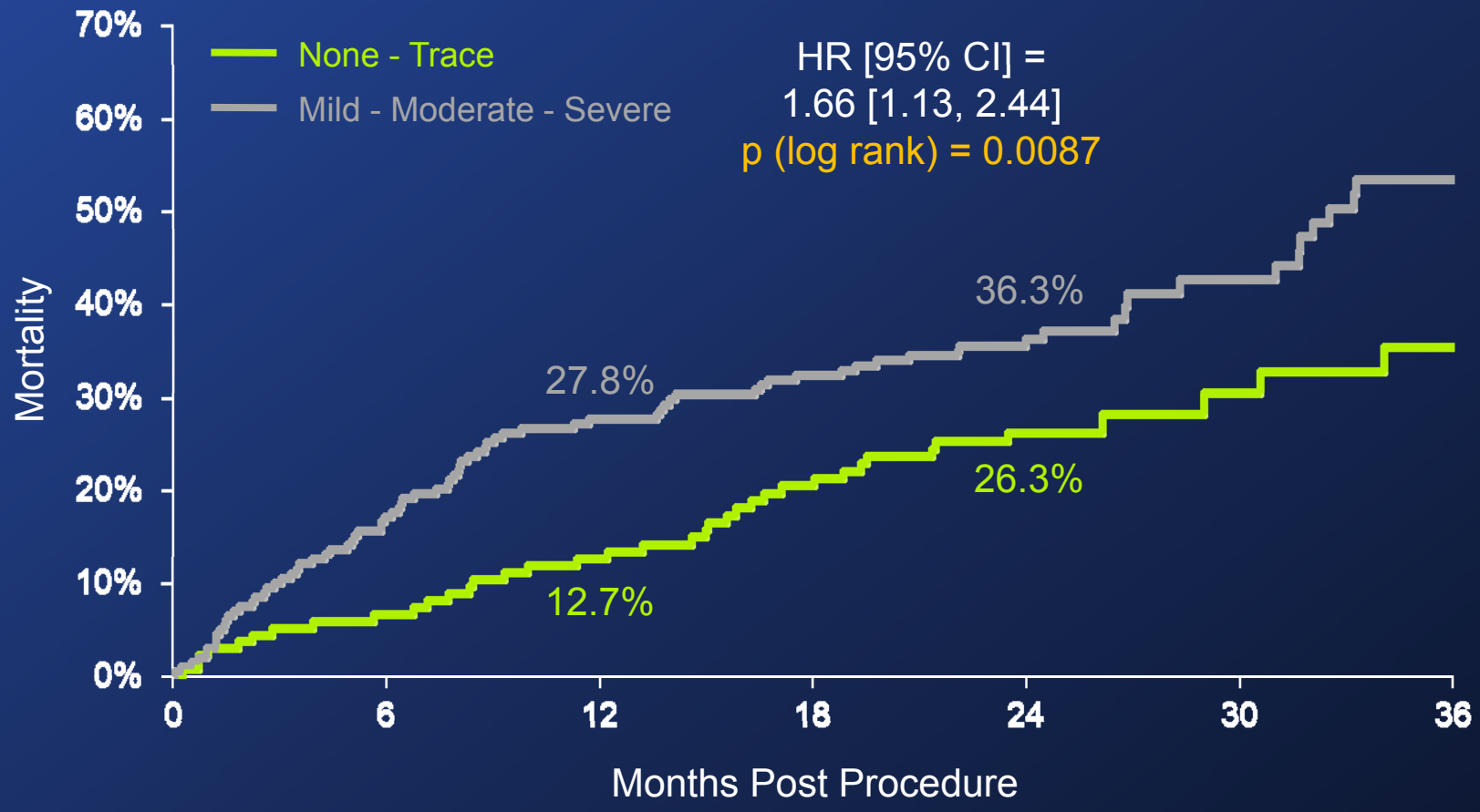




Circumference = 6″
AR = 0.6+1.1 = 1.7″
Ratio = 28%
Severity = Severe

Images courtesy of Pamela Douglas, MD, FASE

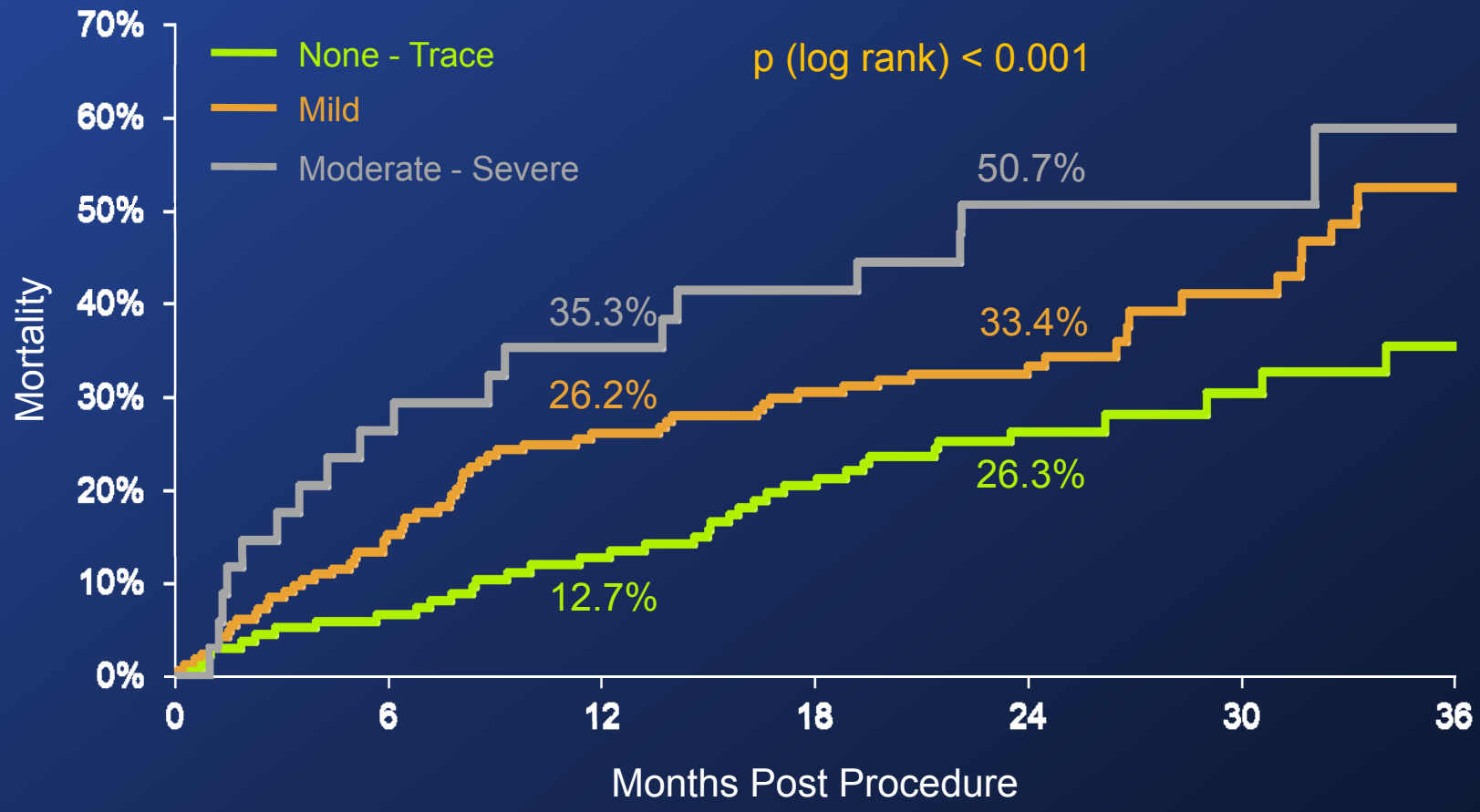
Total AR and Mortality
TAVR Patients (AT)



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**

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

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)

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

Columbia University Medical Center
NewYork-Presbyterian

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] X 100 used to determine the significance of PVL in 146 TAVR pts**

RESULTS:

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

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Sinning et al. J Am Coll Cardiol 2012; 59: 1134-41

COLUMBIA UNIVERSITY MEDICAL CENTER
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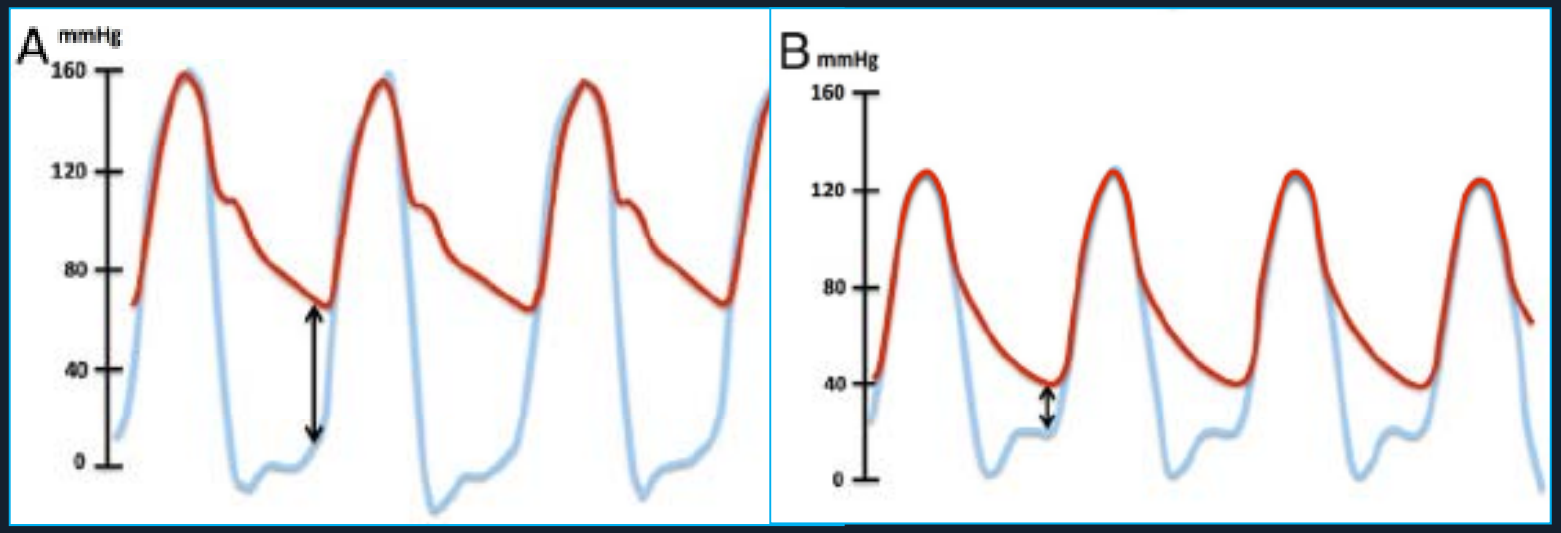
AR Index Predicts PVL



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Sinning et al. J Am Coll Cardiol 2012; 59: 1134-41

TAVR in Review (2011-12)

New Technology

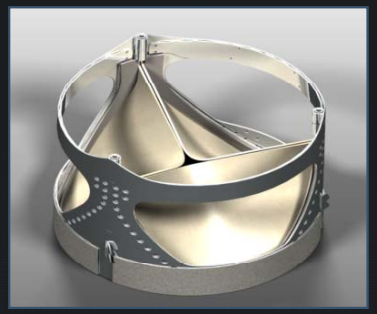
New TAVR (and "Related") Technologies

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

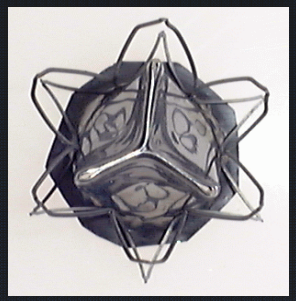
New TAVI Systems - *Transfemoral*

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





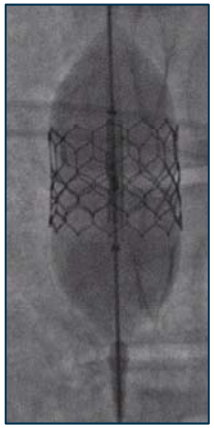


New TAVI Systems - *Transapical*

- **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*

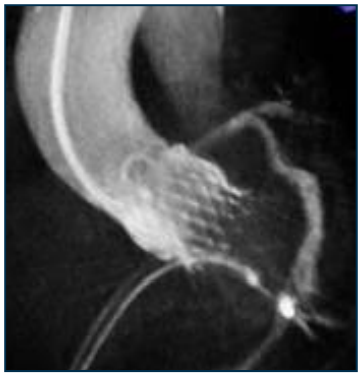
SAPIEN THV

IDE Trial Enrolling

SAPIEN XT THV

U.S. Offering

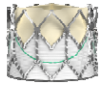
Edwards CENTERA Valve

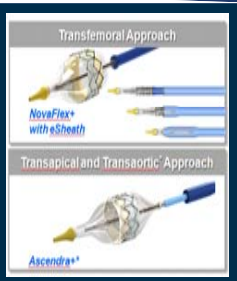


Self Expanding

O.U.S. Commercial Offering

SAPIEN XT THV





OUS Offering

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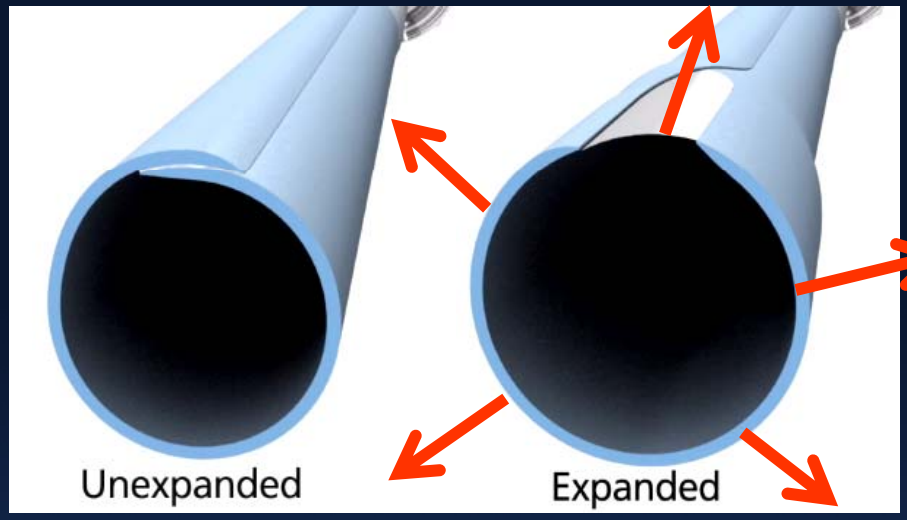
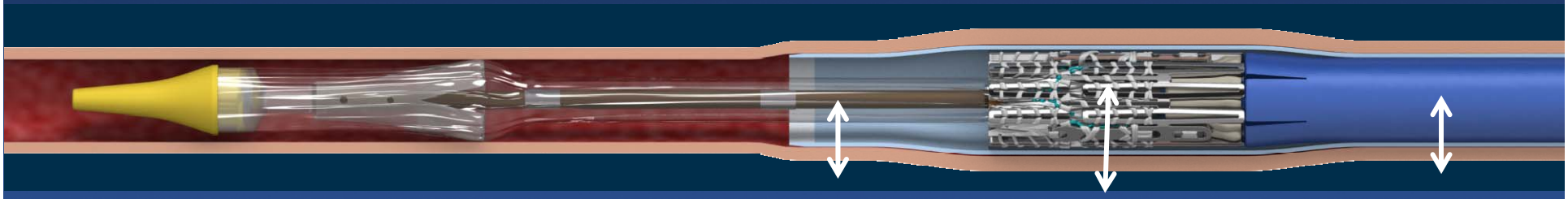
The New Edwards eSheath



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



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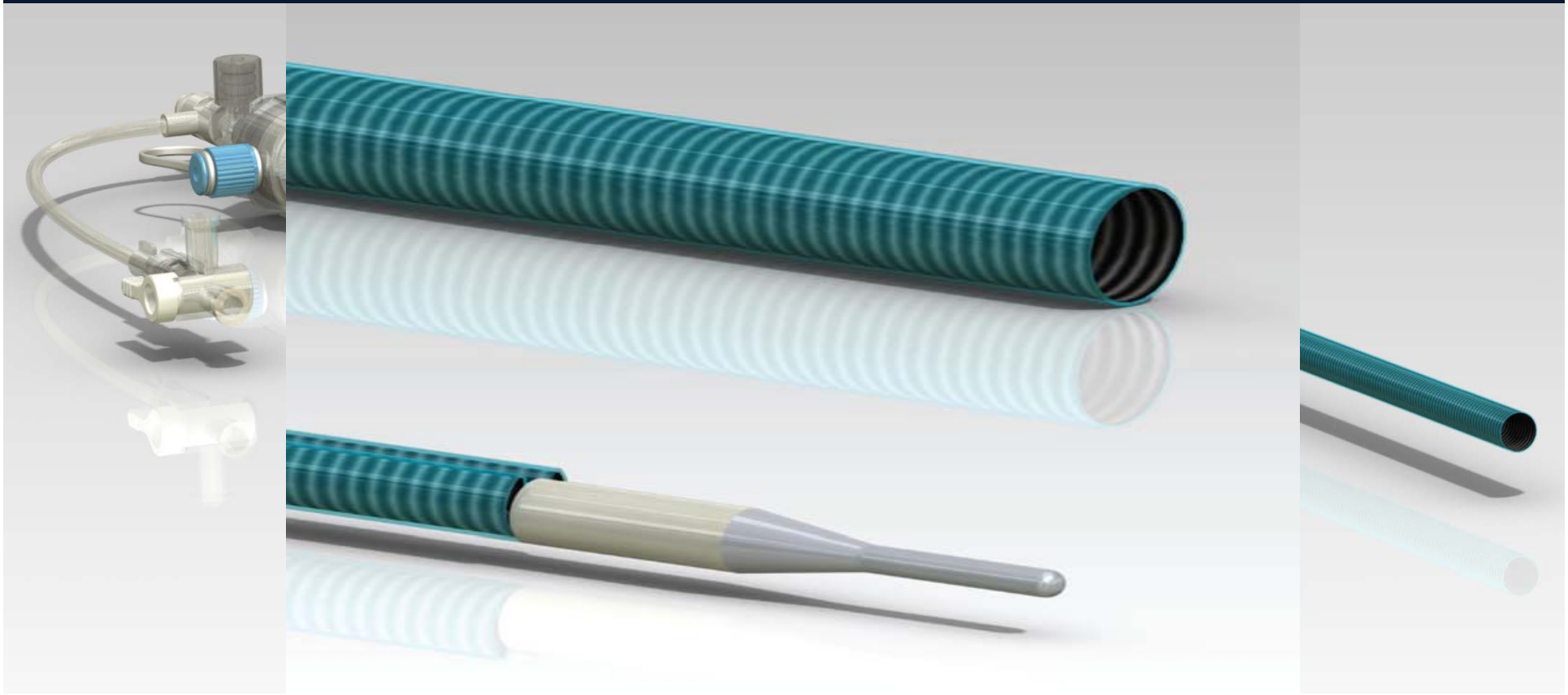
NewYork-Presbyterian

The New Onset Medical SOLOPATH

Balloon Expandable Sheath

14 F ⟶ 18 F



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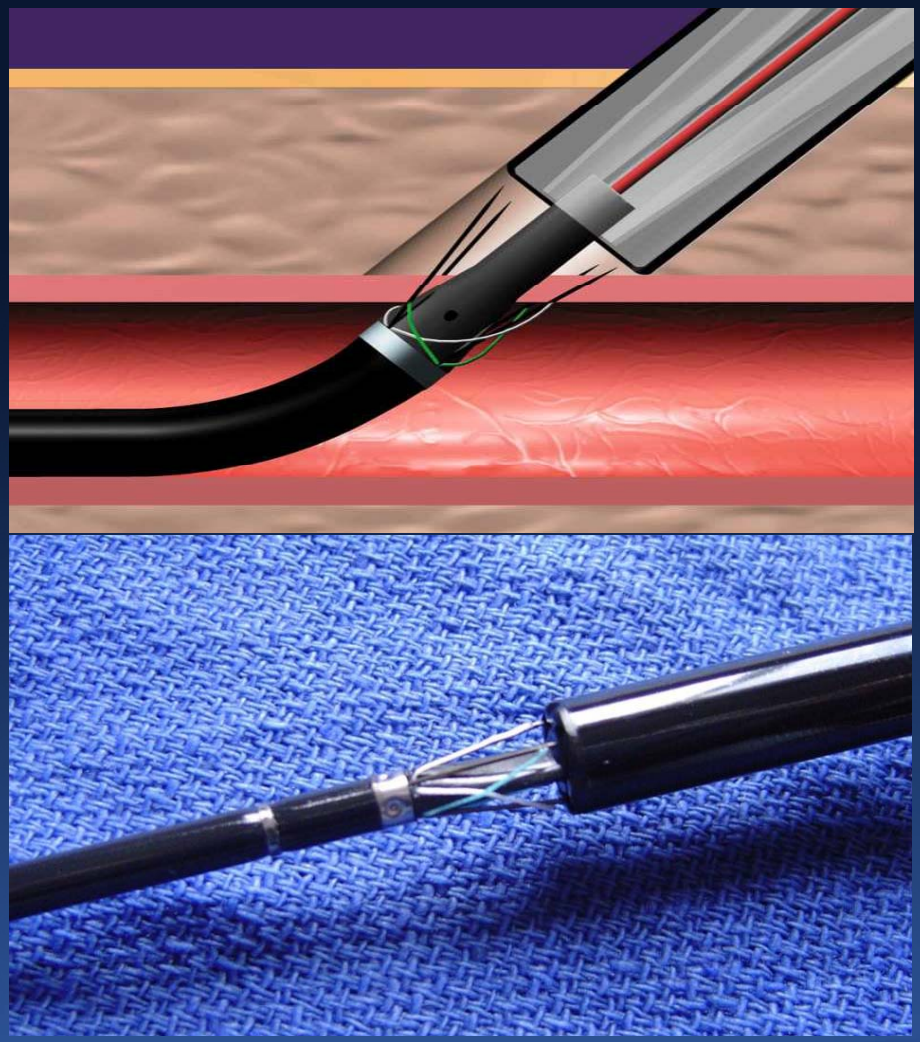
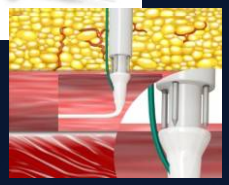
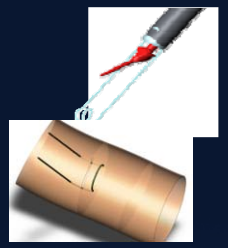
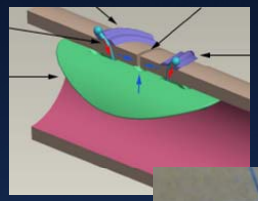
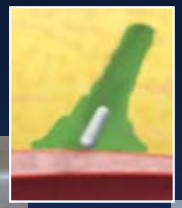
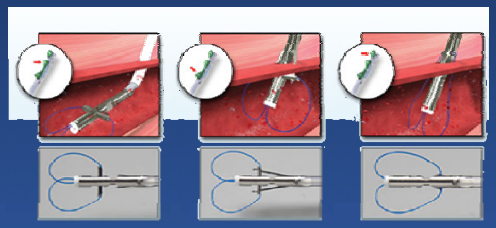
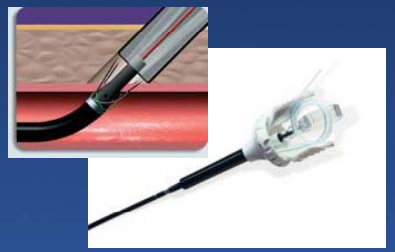
Vascular Closure - Prostar® XL

- 10F Hydrophilic Sheath (J-tip)
- Two sutures (USP 3-0 braided polyester)
- Four needles (nickel titanium)
- Monorail design
- .038” guidewire compatible
- Integrated pre-dilator
- Knot Pusher

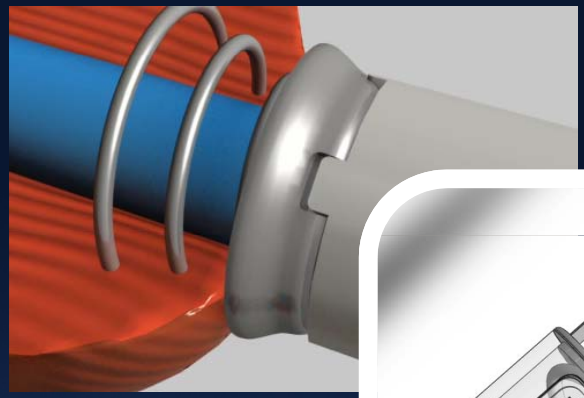


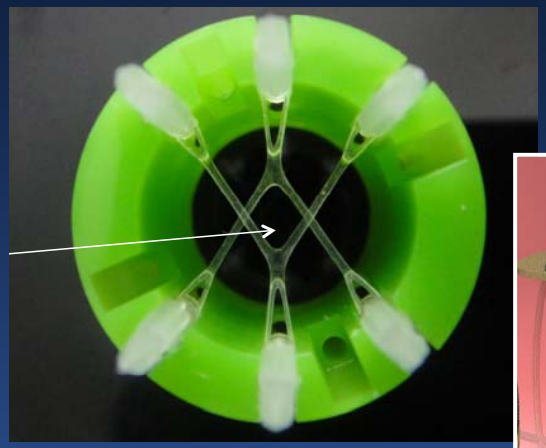
Large Vessel Closure Landscape

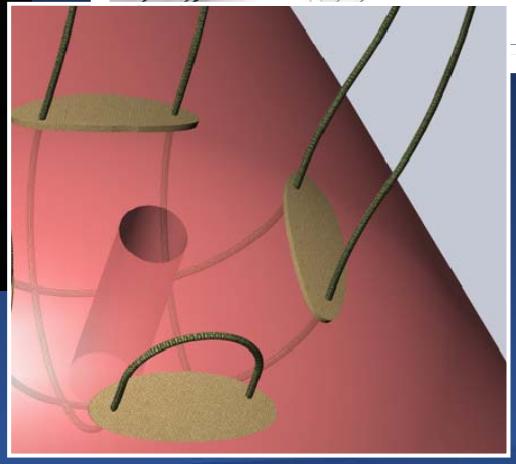
Category	Company	Technology
Emerging Suture Based Technologies	Interventional Therapies	   
	MediGlobe	
	SpiRx	
	Vivasure	
Emerging Patch or Plug Technologies	ePacing	   
	Sealing Solutions	
	Vascular Closure Systems	
	Apica Cardiovascular	
Strategic Players	*Medtronic, Inc.*	
	Abbott Vascular	
	St. Jude Medical	
	Cook/Cardica	COOK MEDICAL cardica

Transcutaneous Ventricular Access and Closure (TVAC)

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

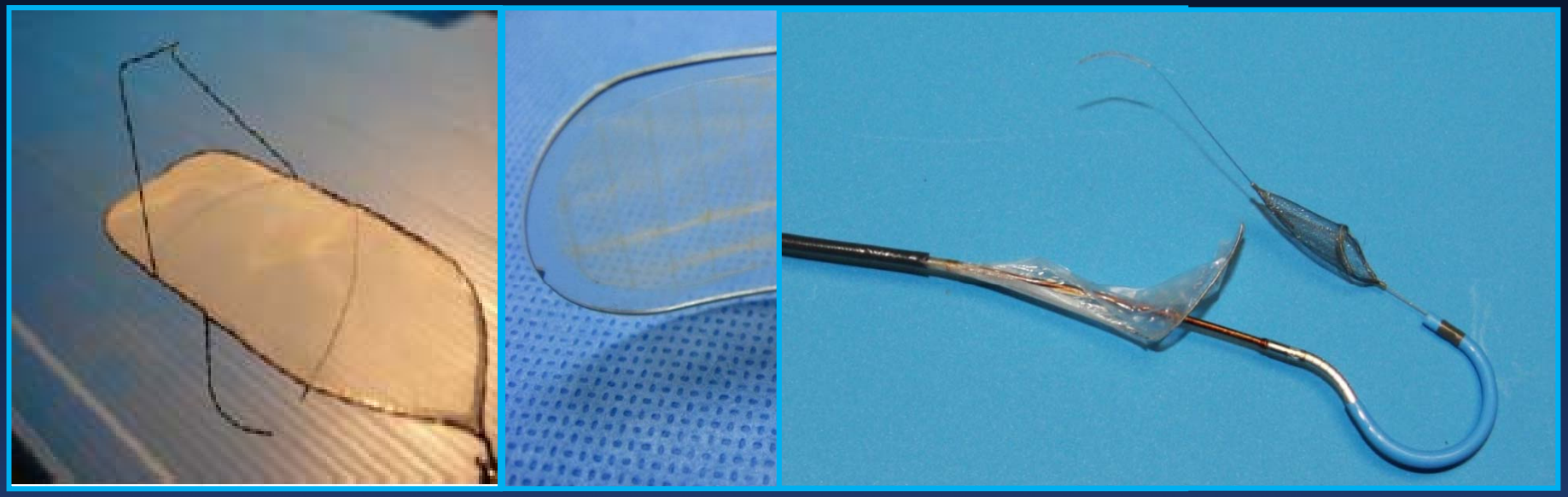






Cerebral Embolic Protection Devices

Deflectors and Filters

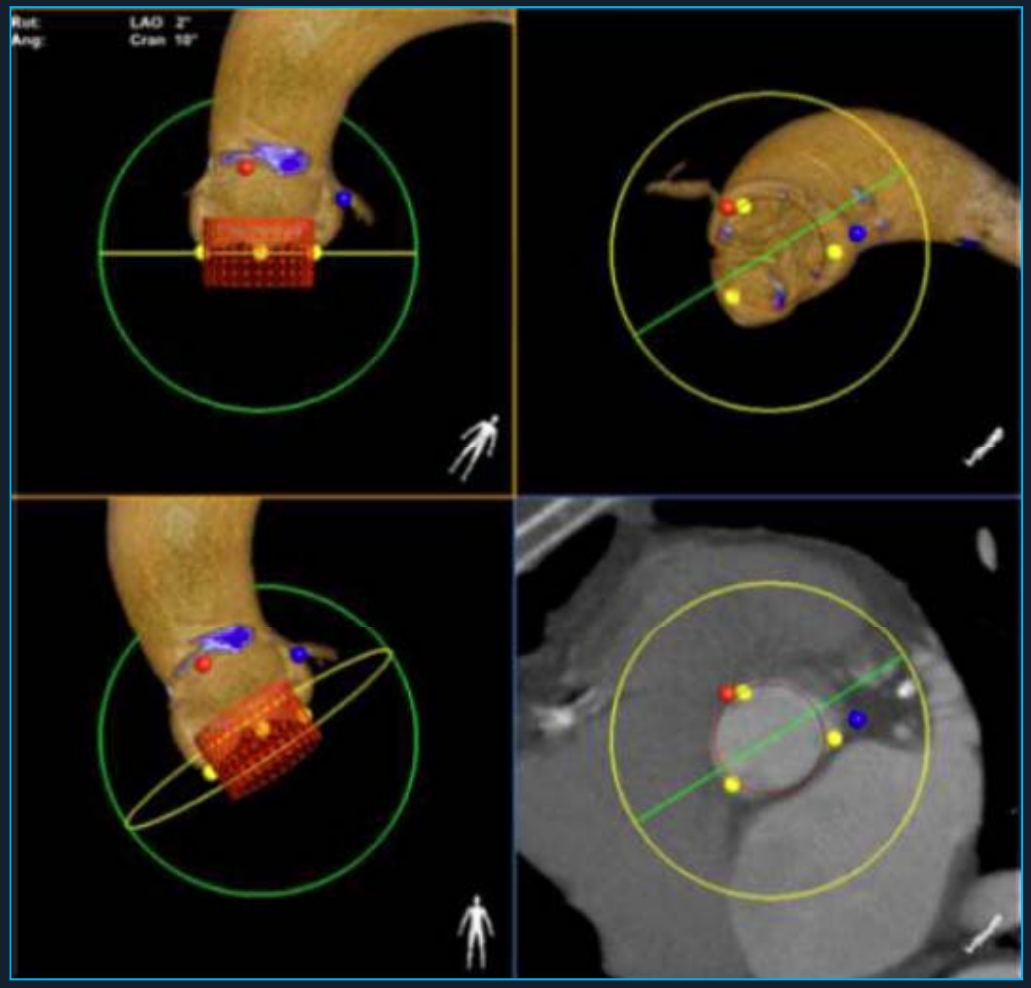


SMT (15 pts)

Embrella (20 pts)

Claret (40 pts)

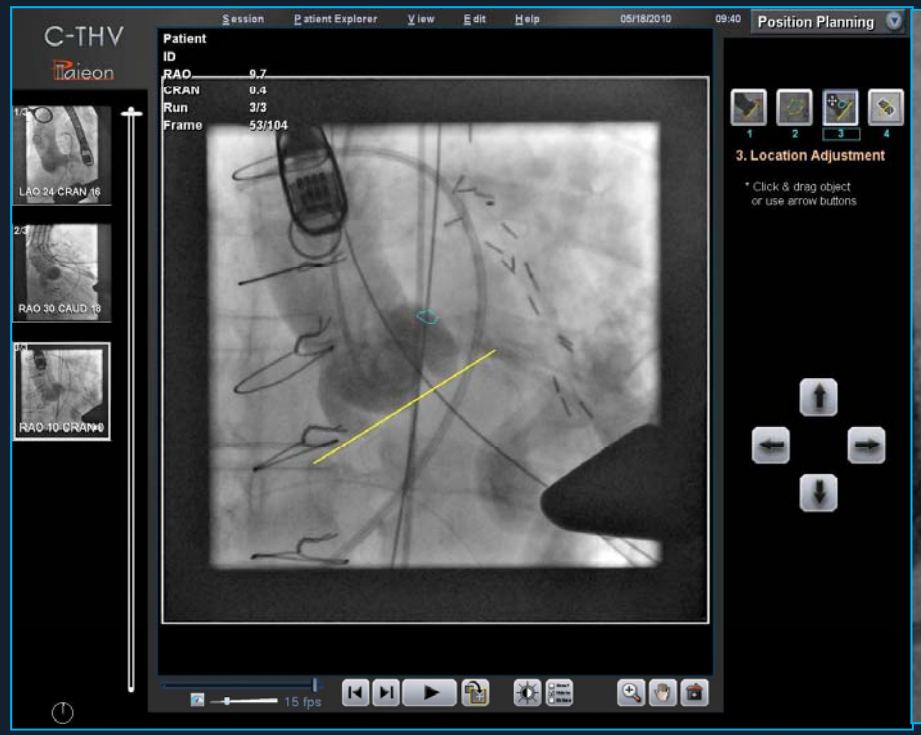
Advanced Imaging Modalities

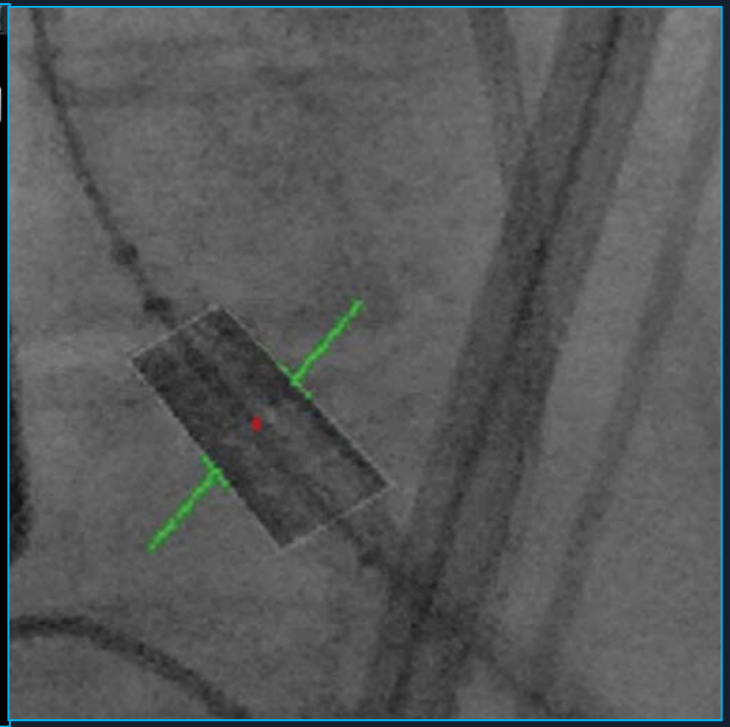


CTA

- ***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 (esp. intermediate risk patients… 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!**