Complications After TAVR: Frequency and Clinical Importance

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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 Complications - 2012

VARC Results

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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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

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

CARDIOVASCULAR RESEARCH FOUNDATION
A Passion for Innovation

COLUMBIA UNIVERSITY MEDICAL CENTER
NewYork-Presbyterian

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

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
STS score	8.7	[7.0, 10.3]
Log Euroscore	22.8	[20.3, 25.3]
Age (years)	81.5	[80.8, 82.2]
Female	52.0	[46.3, 57.6]
NYHA 3 or 4	82.0	[77.5, 86.5]
AVA (cm^2)	0.61	[0.53, 0.68]
Mean gradient (mmHg)	47.6	[45.7, 49.5]

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Unpublished data/Submitted JACC

TAVR Outcomes - VARC Meta-Analysis
(16 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

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NewYork-Presbyterian

TAVR Outcomes - VARC Meta-Analysis
(16 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

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TAVR Outcomes - VARC Meta-Analysis
(16 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

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

Endpoint	*Pooled Estimate (%)*	*[95% CI]*
Endocarditis	0.6	[0.2, 1.4]
Coronary obstruction	0.7	[0.4, 1.1]
Tamponade	2.7	[1.7, 4.2]
LV perforation	0.4	[0.1, 1.5]
Conversion to surgery	1.3	[0.0, 2.6]
Unplanned CPB	1.3	[0.3, 2.2]
Annulus rupture	0.5	[0.2, 1.7]
Aortic rupture	0.9	[0.4, 2.2]
Aortic dissection	1.1	[0.4, 2.5]

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Unpublished data/Submitted JACC

TAVR Complications

- *Strokes*
- *Vascular/Bleeding Events*
- *Para-Valvular Regurgitation*
- *New Pacemakers*
- *Valve Durability*

TAVR Complications - 2012

Strokes and TAVR

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

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

1. Cardioangiological Center Bethanien (CCB), Frankfurt, Germany; 2 Department of Cardiology, West-German Heart Center Essen, University Duisburg-Essen, Essen, Germany; 2. 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 ± 1.8 yrs and mean logES 24.8 ± 5.6%

RESULTS:

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

Eggebrecht et al. EuroUntervention 2012; On-line (March 20, 2012)

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

Editorial Response

EDITORIALS

Transcatheter Aortic-Valve Implantation — At What Price?

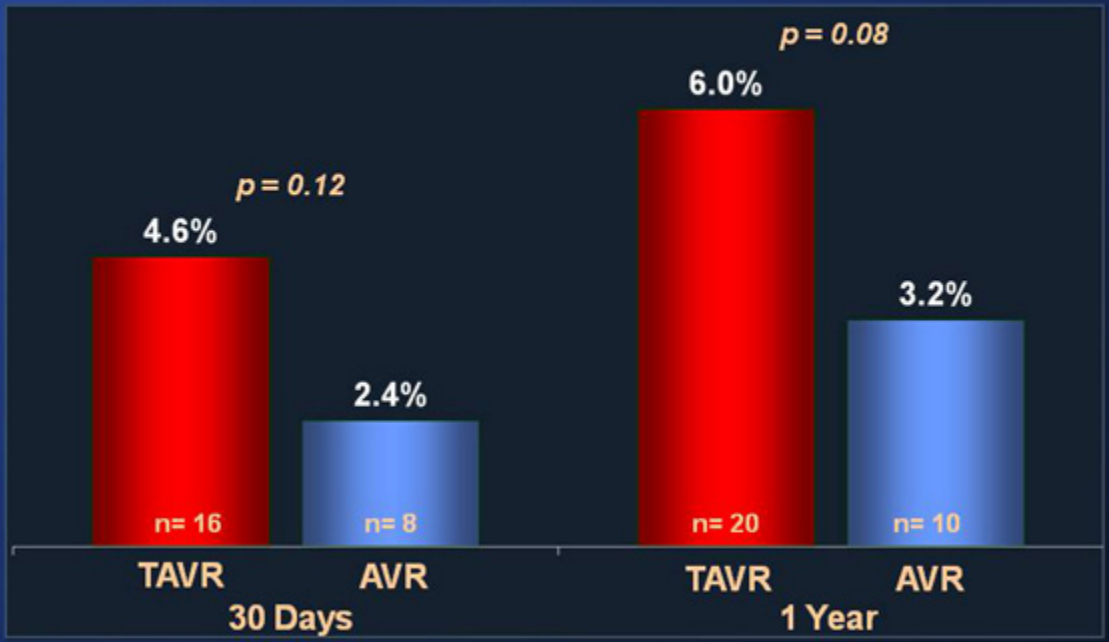
Hartzell V. Schaff, M.D.

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

Strokes in PARTER
High-risk cohort

THE PARTNER TRIAL

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

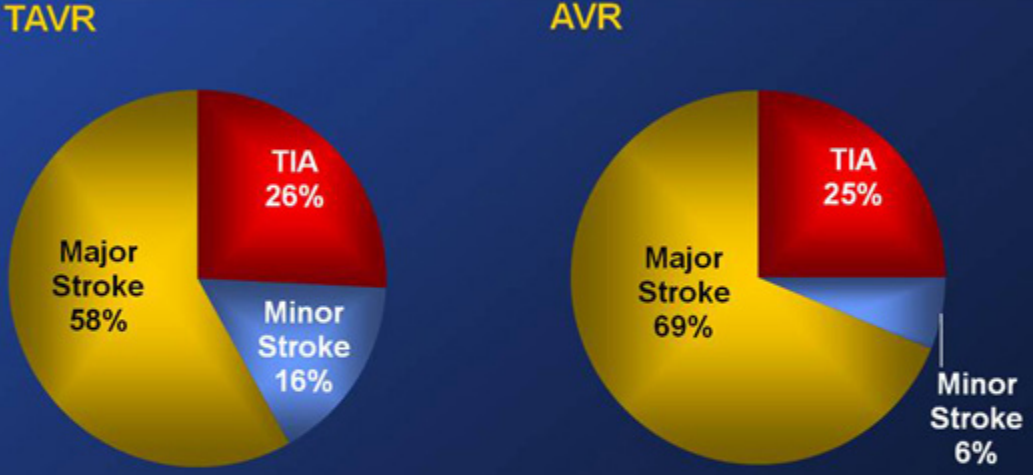
D. Craig Miller, MD,[a] Eugene H. Blackstone, MD,[b] Michael J. Mack, MD,[c] Lars G. Svensson, MD, PhD,[b] Susheel K. Kodali, MD,[d] Samir Kapadia, MD,[b] Jeevanantham Rajeswaran, MSc,[b] William N. Anderson, PhD,[e] Jeffrey W. Moses, MD,[d] E. Murat Tuzcu, MD,[b] John G. Webb, MD,[f] Martin B. Leon,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

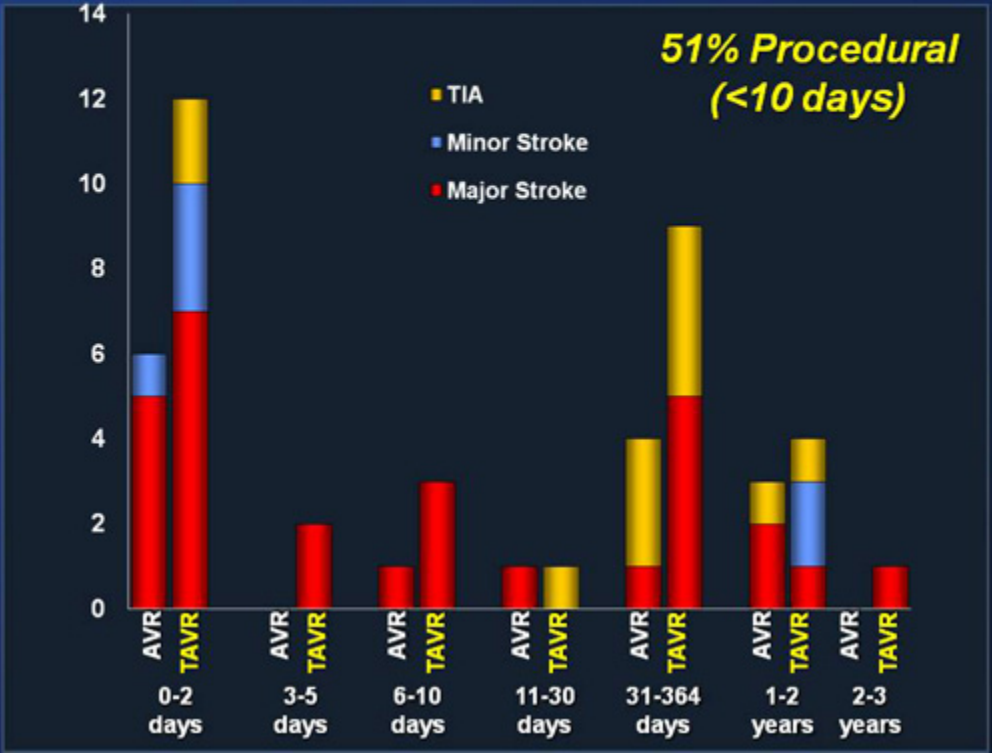
THE PARTNER TRIAL



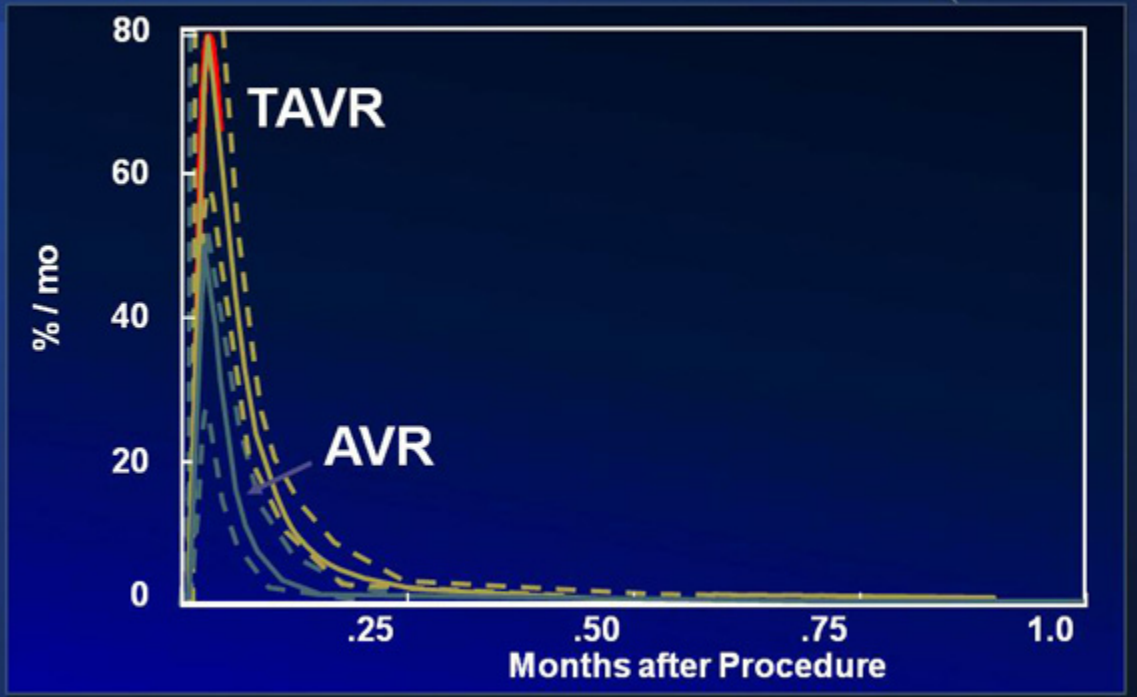
47 patients, 49 neuro events

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

THE PARTNER TRIAL

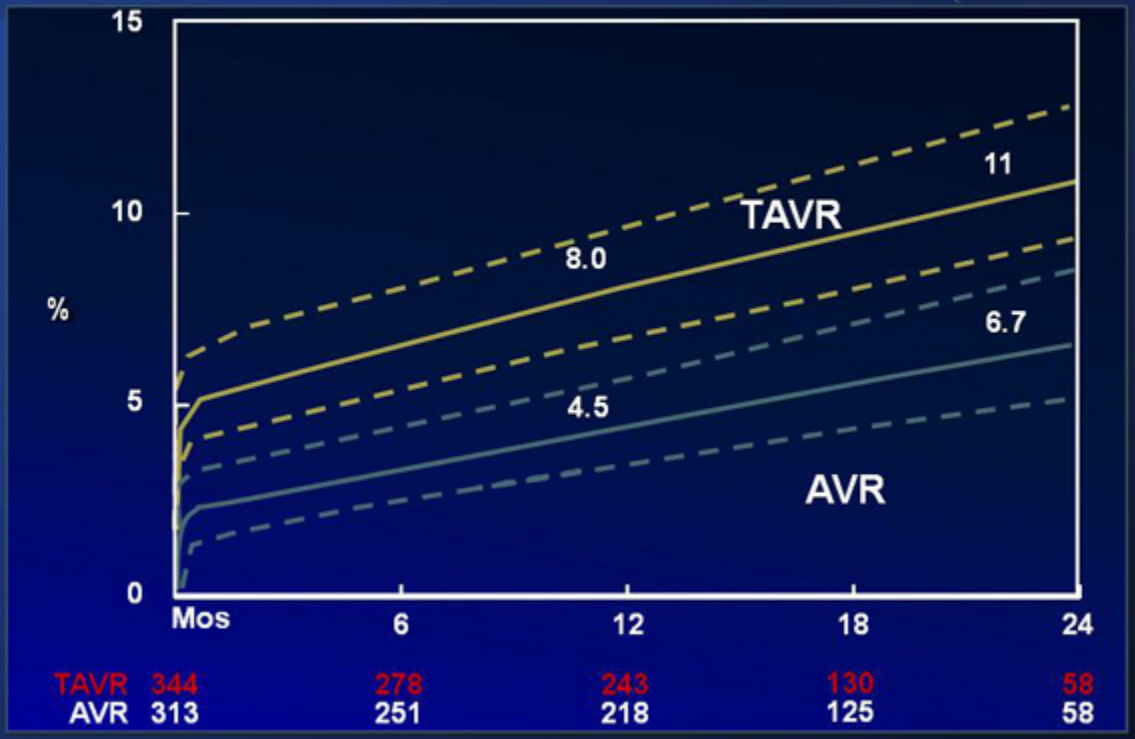
Early high peaking hazard phase

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

THE PARTNER TRIAL

Late constant hazard phase

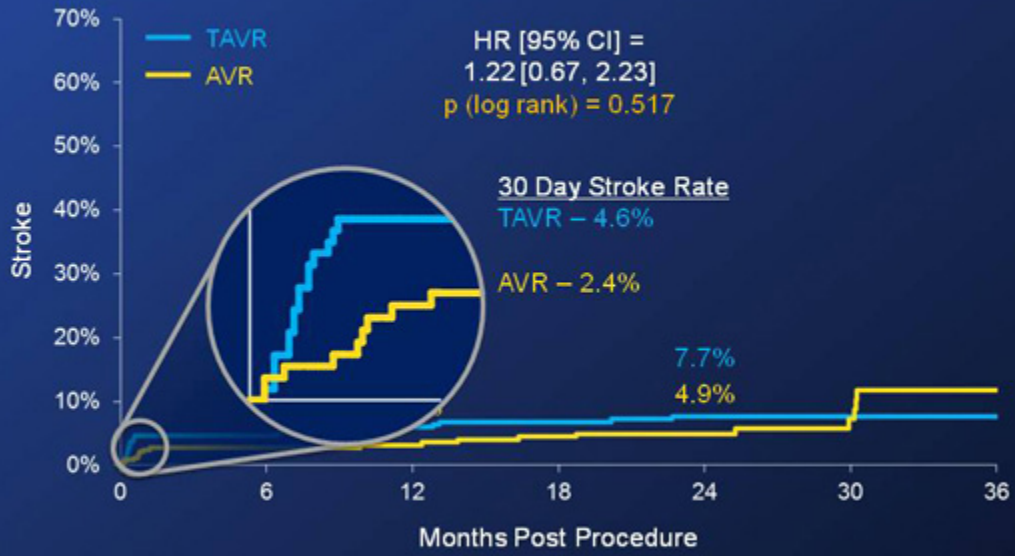
Risk Factor	*Coefficient ± SD*	*P*	*R (%)*
Constant hazard phase			
TAVR	0.40±0.43	0.4	22
(Higher) NYHA	0.95±0.40	.02	75
Stroke or TIA within 6-12 mo	1.93±0.64	.002	60
Non-TF TAVR candidate*	2.3±0.45	<.0001	96
History of PCI (less risk)	-1.60±0.63	.01	77
COPD (less risk)	-1.06±0.47	.03	79

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

R(%) = bagging reliability

Strokes (ITT)

THE PARTNER TRIAL

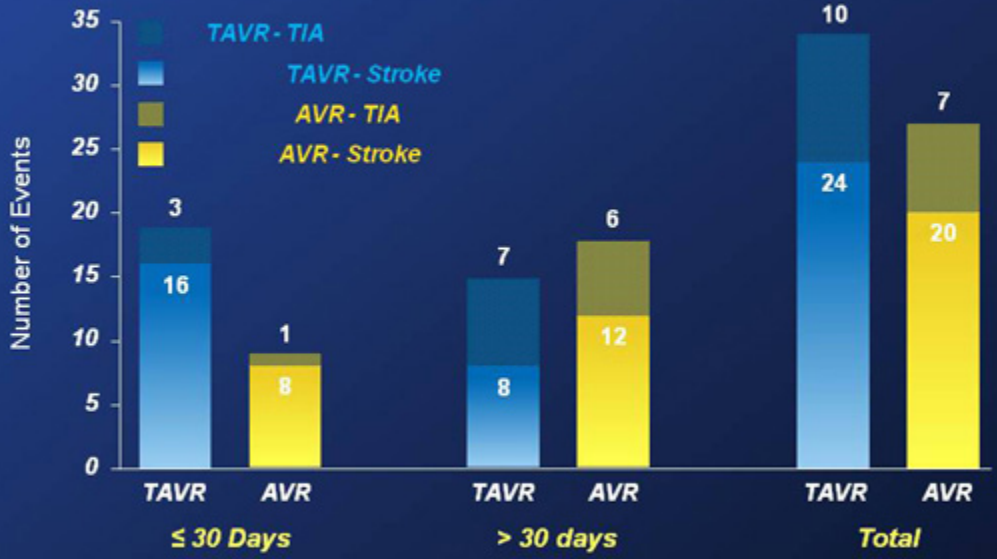


Numbers at Risk

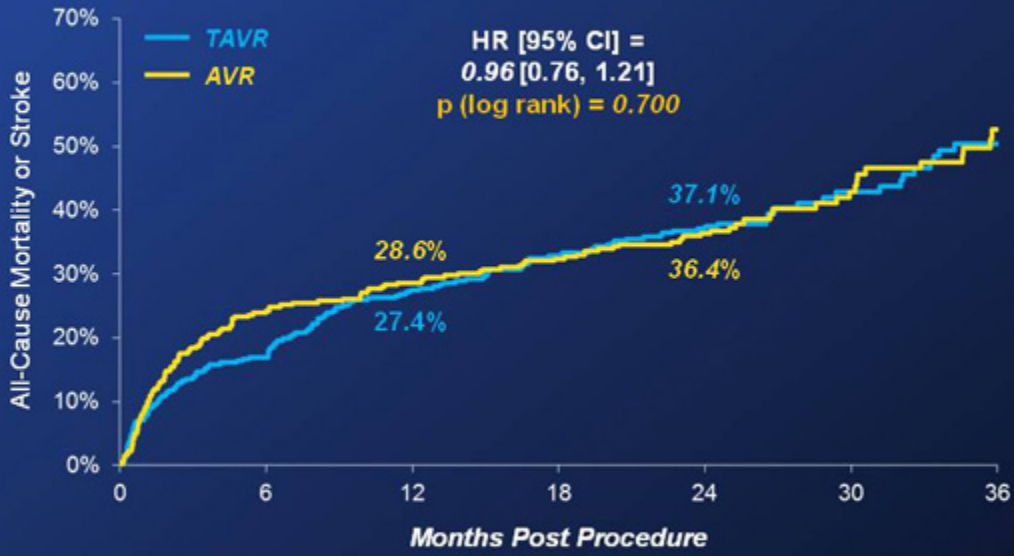
TAVR	348	287	249	224	162	65	28
AVR	351	246	230	211	160	62	31

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

Procedural Predictors of Mortality

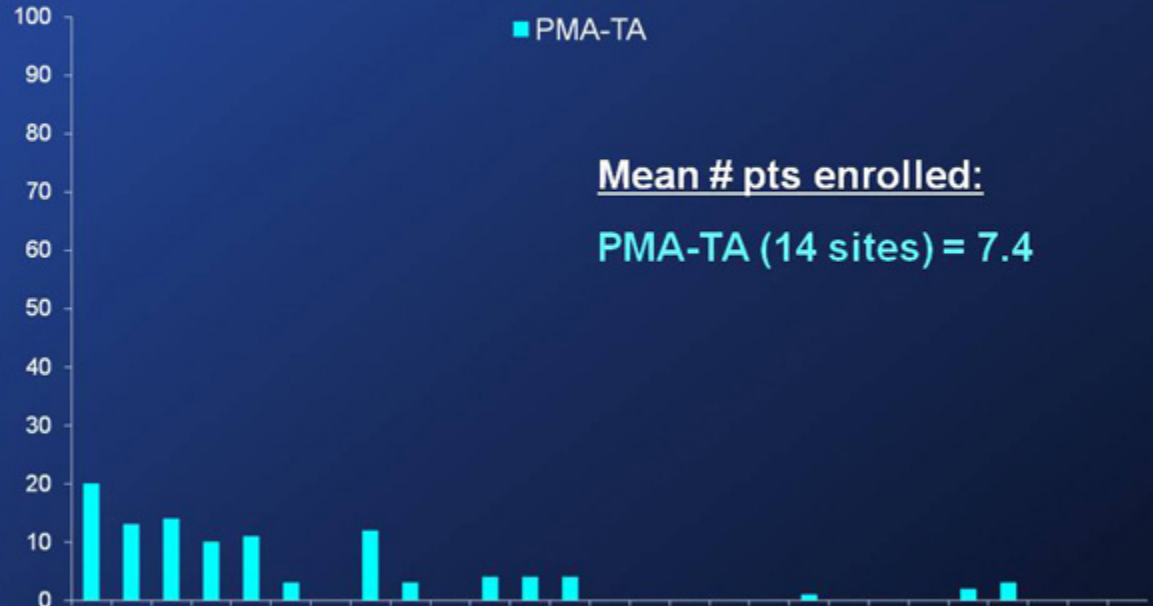
Transapical Aortic Valve Replacement For Critical Aortic Stenosis: Results From the Non-Randomized Continued Access Cohort of The PARTNER Trial

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

STS 2012 | Fort Lauderdale | Jan 30, 2012

THE PARTNER TRIAL

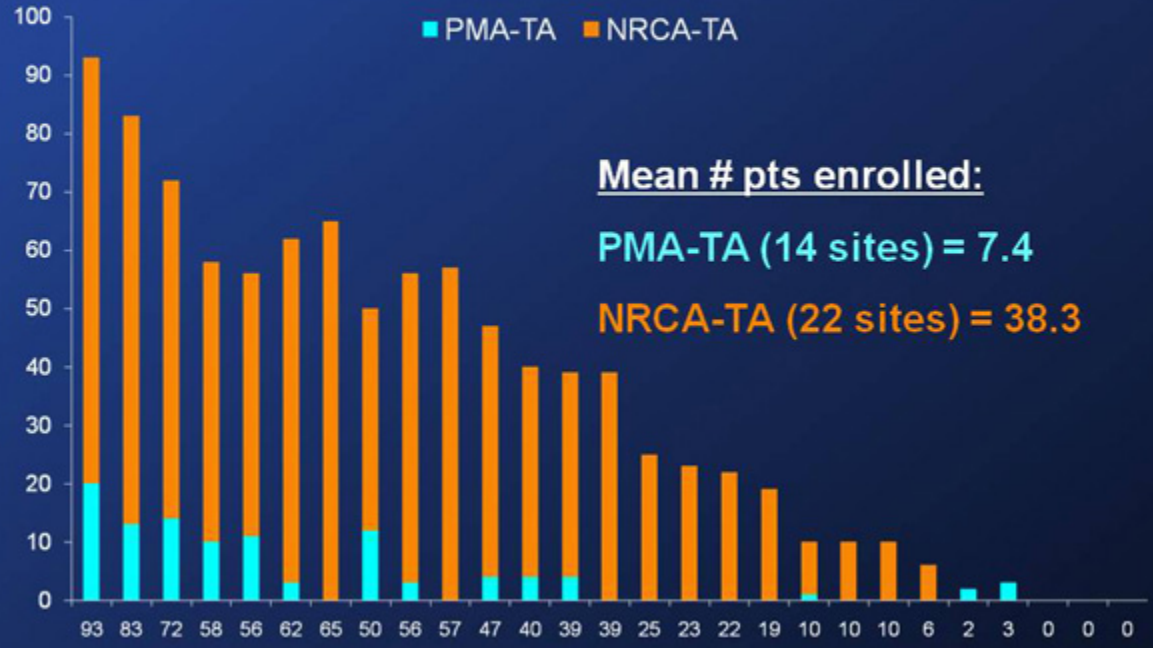
Transapical Enrollment per Site



Mean # pts enrolled:

PMA-TA (14 sites) = 7.4

Transapical Enrollment per Site



Clinical Outcomes at 30 Days and 1 Year (AT)

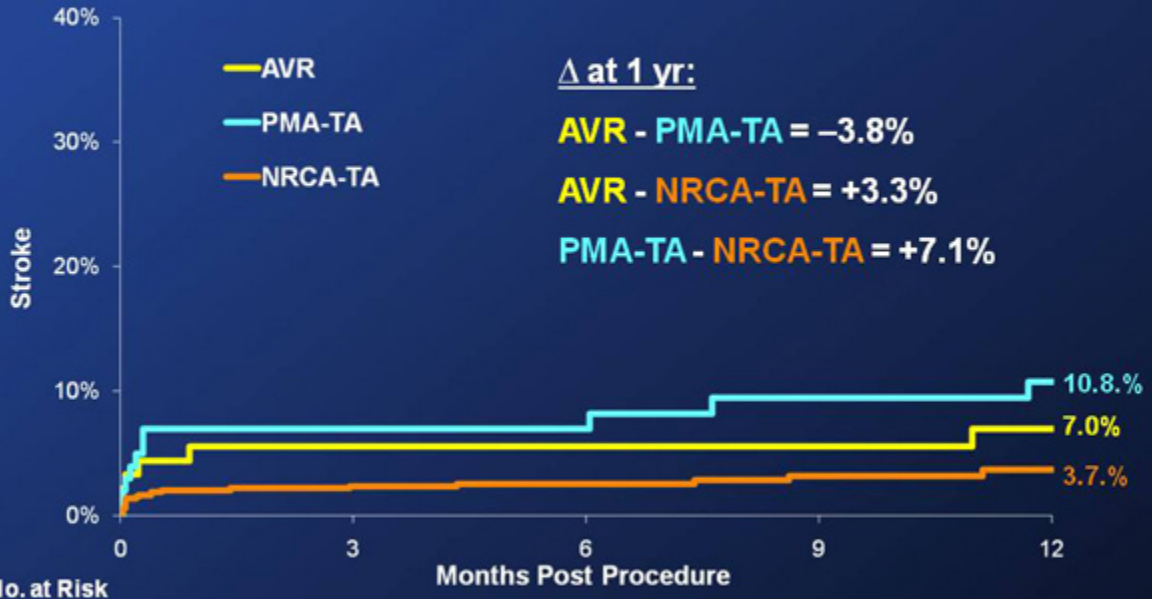
THE PARTNER TRIAL

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.

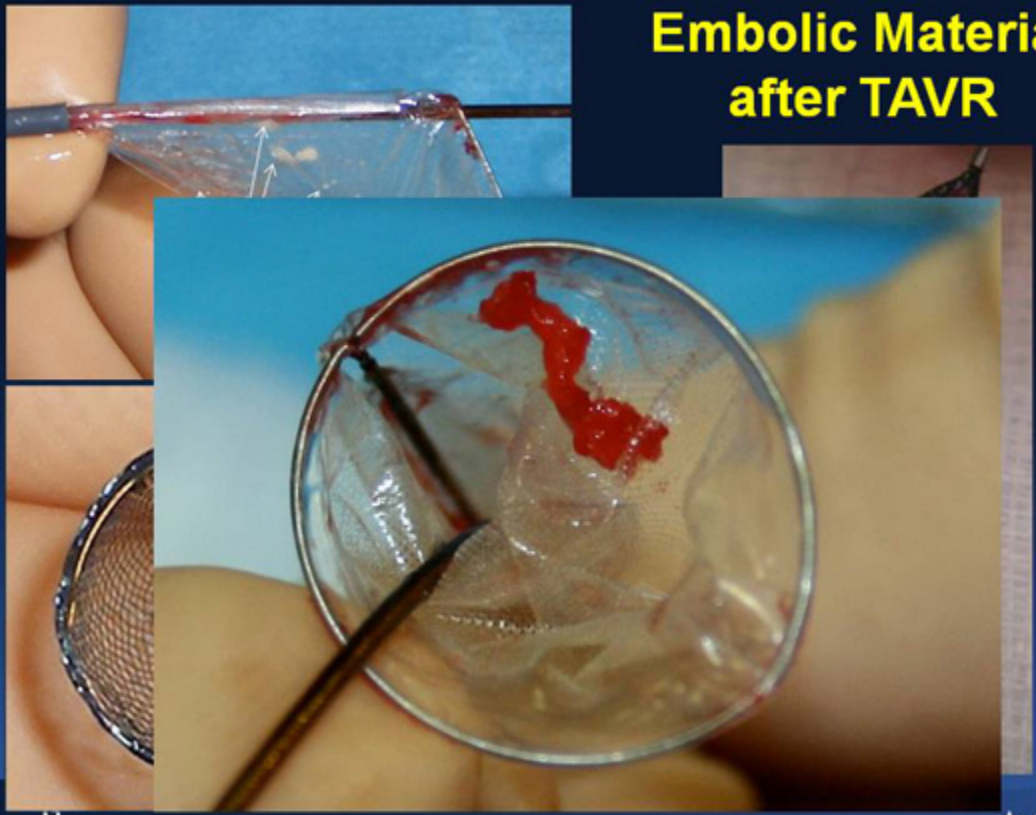
Stroke (AT)



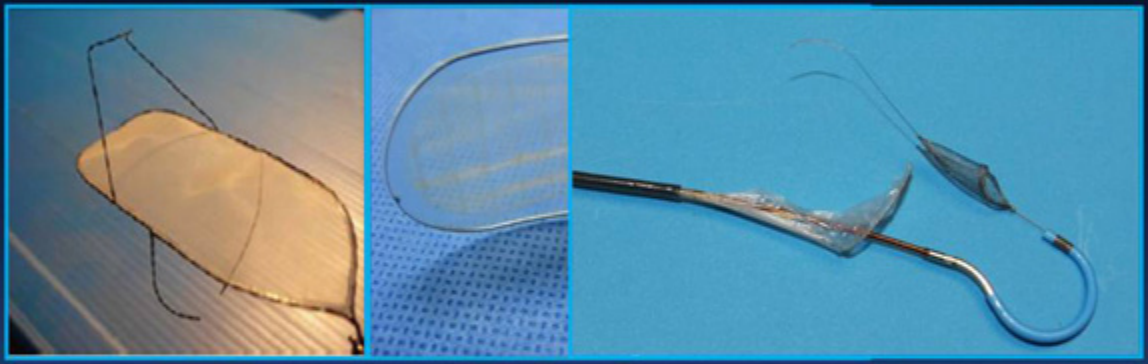
No. at Risk

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

Embolic Material after TAVR



Cerebral Embolic Protection Devices
Deflectors and Filters



SMT (15 pts)

Embrella (20 pts)

Claret (40 pts)

PROTAVI - C

Severe AS + Symptoms
Case selection: Heart Team (high-risk)

↓ Randomization 1:1

Standard TAVR	Standard TAVR + Deflection

Primary Endpoint: Volume of DW-MRI brain lesions @ 1 wk

↓ Re-Randomization 1:1

ASA alone for 3 months	ASA + clopidogrel for 3 months

2nd Primary Endpoint: composite stroke/TIA + bleeding @ 1 year

Co-PIs: Profs Vahanian and Beversdorf

TAVR and Strokes

Summary

- Increased acutely after TAVR (compared with surgery) and mainly embolic in nature – important predictor of subsequent mortality
- After 30 days, no constant hazard associated with TAVR
- Improvements expected (and/or already seen) with...
  - increased operator experience
  - lower profile devices
  - improved pharmacotherapy
  - embolic protection systems

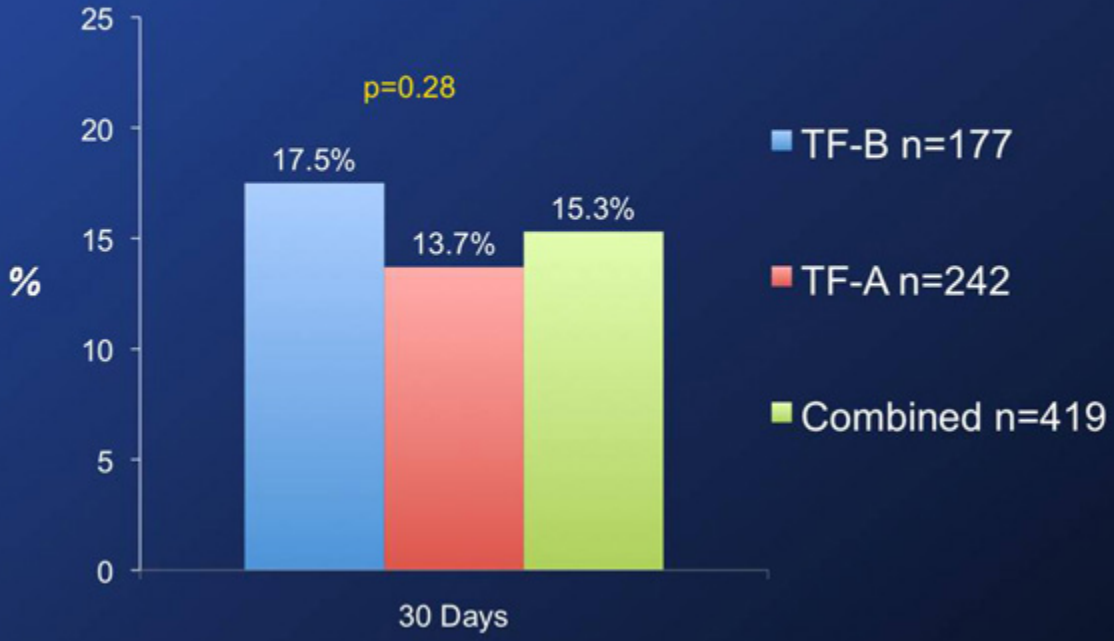
TAVR Complications - 2012

Vascular/Bleeding Events

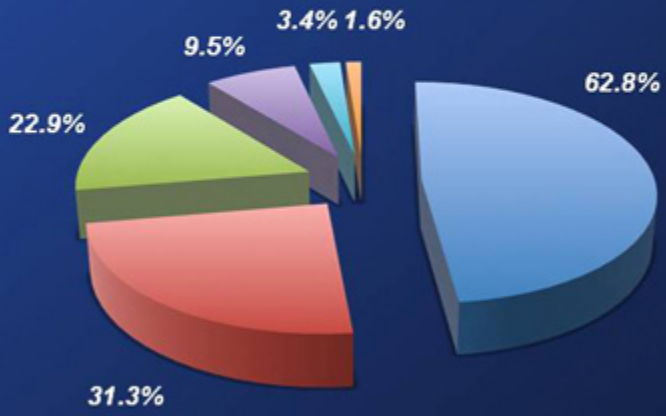
Incidence of Major Vascular Complications After TAVR*

1. Leon MB et al. *N Engl J Med.* Oct 21;363(17):1597-607.
2. Thomas M et al. *Circulation.* 2010 Jul 6;122(1):62-9.
3. Rodes-Cabau J et al. *J Am Coll Cardiol.* 2010 Mar 16;55(11):1080-90.
4. Lefevre T et al. *Eur Heart J.* Nov 12
5. Eltchaninoff H et al. *Eur Heart J.* Sep 15.
6. Medtronic. Data on file. COR 2006-02: 18 Fr Safety & Efficacy Study Re-Analysis, August 14, 2009.
7. Zahn. German Registry EuroPCR 2010, Paris, France.
8. Ludman. UK Registry. EuroPCR 2010, Paris, France.
9. Petronio. Italian Registry. EuroPCR 2010, Paris, France.

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



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



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

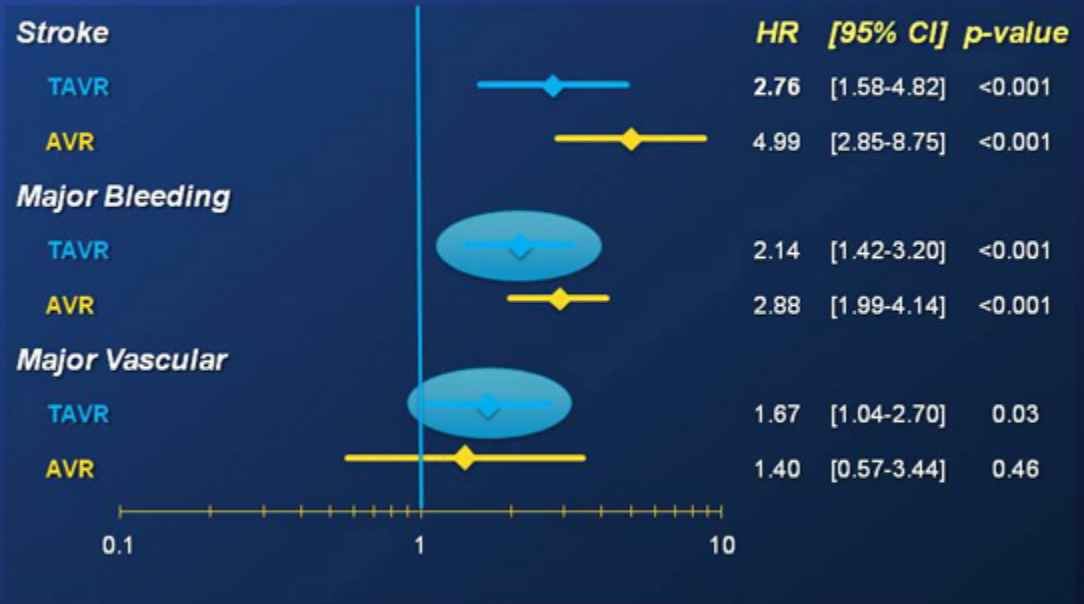
Association between Major VC, Bleeding and Renal Failure

THE PARTNER TRIAL

	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



PARTNER TF AT Population
TF-Cohort A and B: n=419

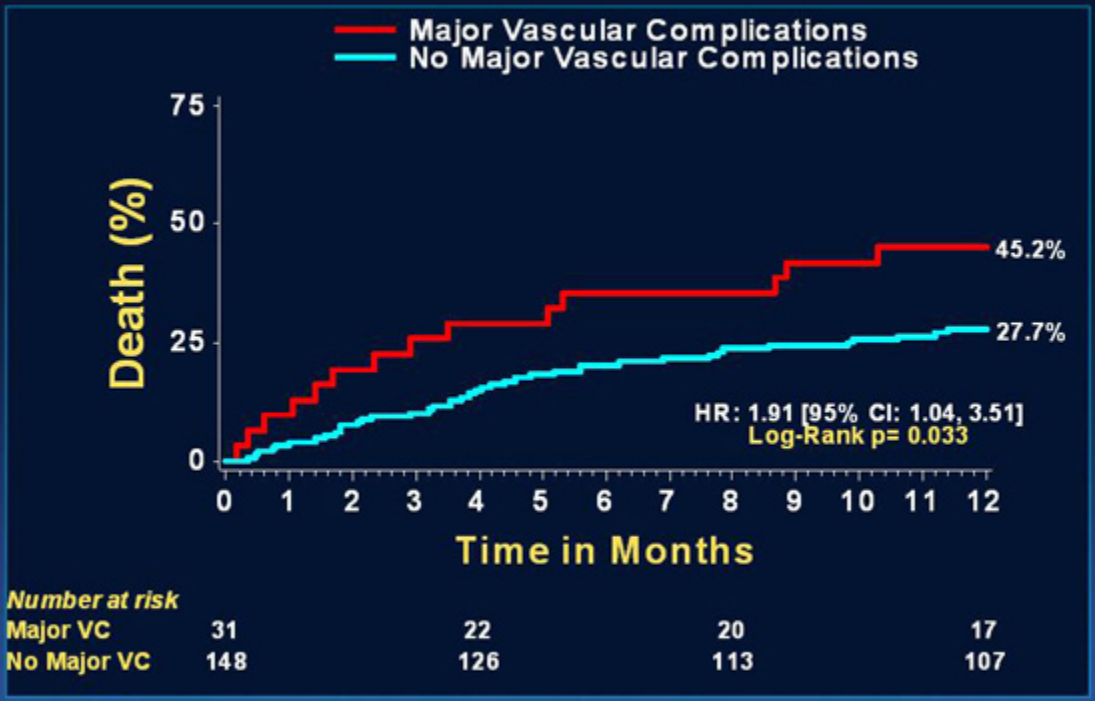
Predictors of 1 Year Major Vascular Complications in Multivariate COX Proportional Hazards Model

Predictor	*Estimate*	*Hazard Ratio*	*p value*
Age	0.0024	1.00	0.93
Peripheral Disease	-0.0172	0.98	0.97
Renal Disease at Baseline	0.6684	1.95	0.16

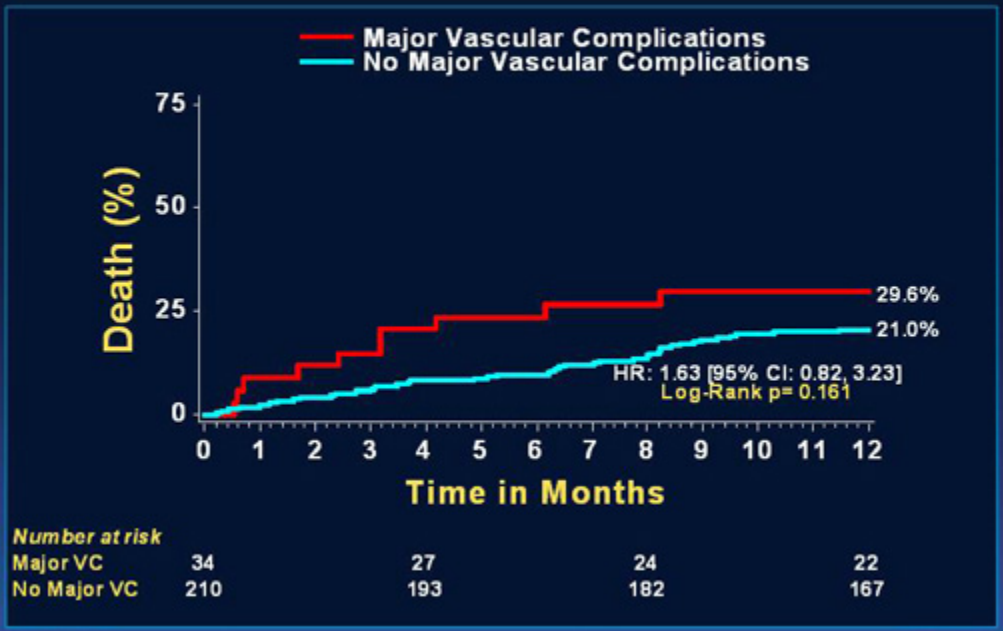
Adding Cohort (B vs. A) and STS score to the model doesn't affect the stability of the model and ***Female Gender*** still remains the only predictor of Major Vascular Complications

Controled for Age, BSA, Gender, Peripheral vascular disease, and Renal disease at baseline (creat>=2)

PARTNER Cohort B TF



PARTNER Cohort A-TF



Bleeding Following TAVR

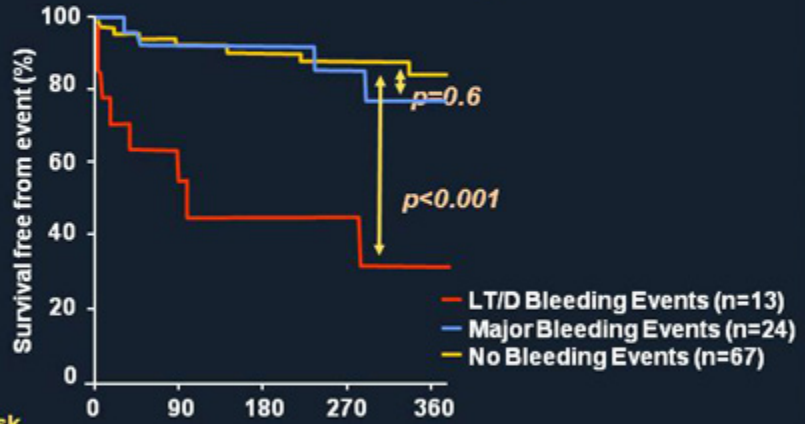
Incidence, predictors and prognostic value of major hemorrhagic complications following TAVI procedure

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

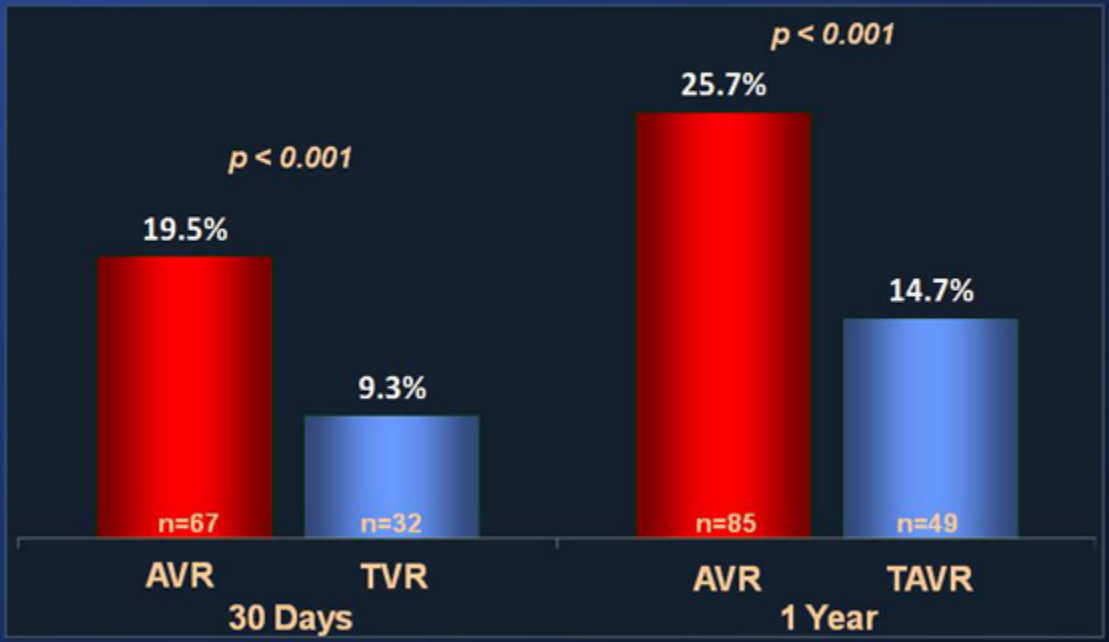
Bleeding Following TAVR

Survival after Bleeding Event



# at risk					
VARC LT/D	13	6	4	3	1
VARC Major	24	17	14	11	7
No Bleeding	64	50	36	24	22

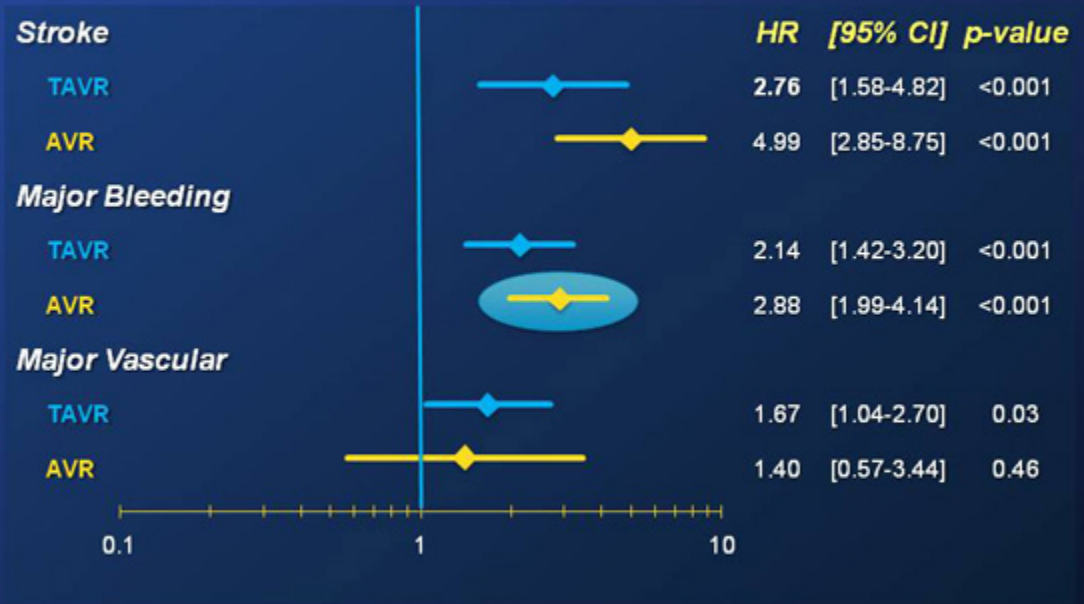
Major Bleeding Events at 30 Days & 1 Year



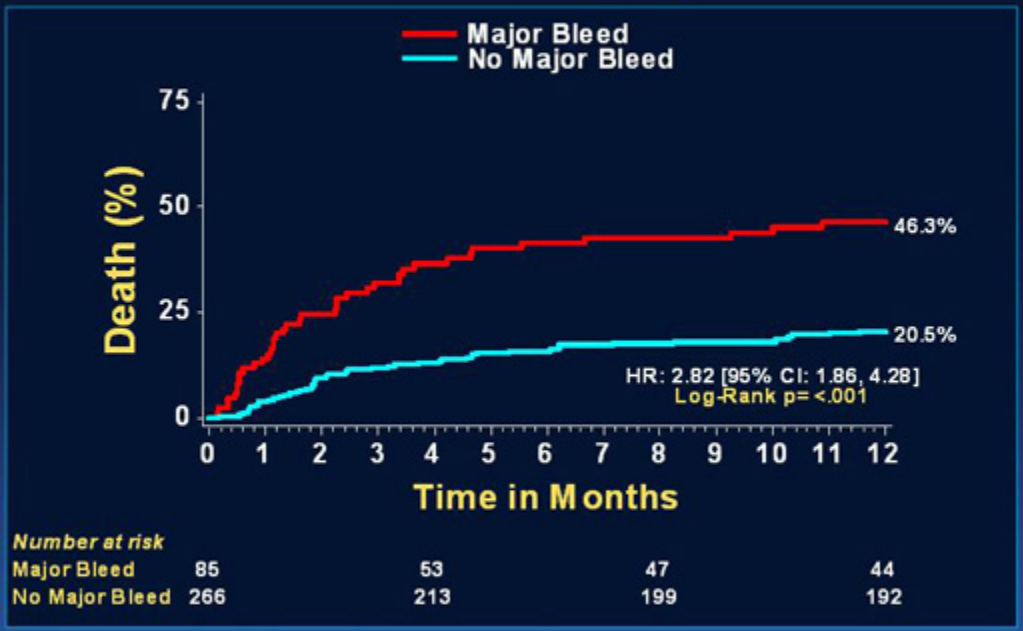
ITT Population

Procedural Predictors of Mortality

Procedural Predictors of Mortality



Bleeding Complications – PARTNER
Cohort A - Surgery ITT



TAVR and Vascular Events

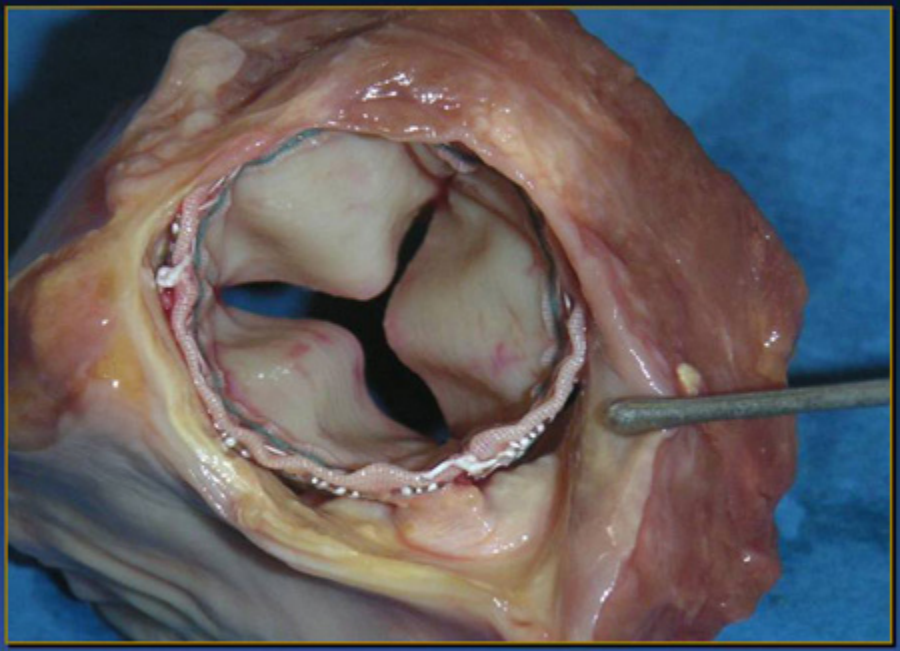
Summary

- Vascular complications after TAVR are frequent and have been associated with increased mortality
- Important predictors are vessel:sheath size ratio, calcification and female gender
- Improvements expected (and/or already seen) with...
  - meticulous CTA screening
  - increased operator experience
  - lower profile devices
  - dedicated access site closure systems
  - alternative access sites (e.g. TA, TS, TAo)

TAVR Complications - 2012

Para-valvular Regurgitation

Para-valvular Regurgitation



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:

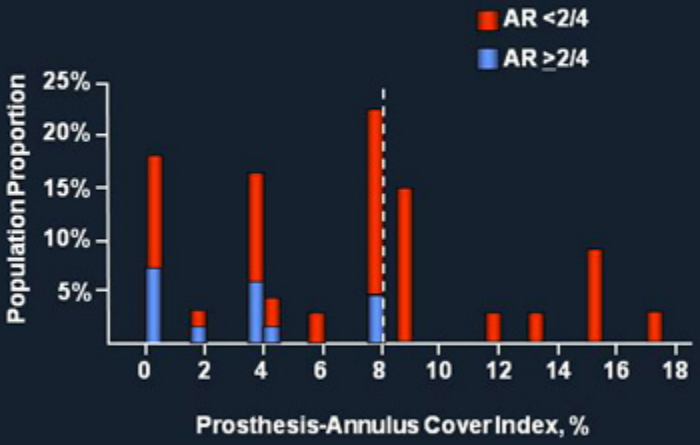
- **After TAVR, PVL absent 7%, 1/4 in 72%, 2/4 in 16%, 3/4 in 5%**
- **Predictors of PVL ≥ 2/4 were increased pt height, larger annulus, and a cover index < 8%**
- **PVL ≥ 2/4 was never seen if annulus was < 22mm or the cover index was > 8%**

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

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

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:

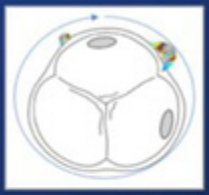
- 100 pts with CoreValve TAVR
- MSCT with and without contrast to assess calcium load in valve and adjacent LVOT estimated by Agaston Score (AgS) and the amount and distribution of calcium at the device landing zone (DLZ-CS) by semi-quantitative scoring (grade 1-4)
- *Calcium levels correlated with PVL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

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

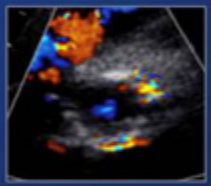
PVL after TAVR Predicts Increased Mortality

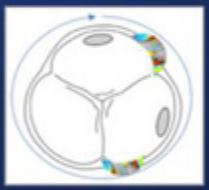
Author (journal)	# patients	TAVR Type	Predicts mortality
Abdel-Wahab (Heart 2011)	690	MCV 84% ES 16%	≥ 2/4 - mortality in-hospital
Tamburino (Circulation 2011)	603	MCV 100%	≥ 2/4 - mortality 30 days – 1 year
Gotzman (AHJ 2011)	145	MCV 100%	≥ Mod - mortality @ 6 mos
Moat (JACC 2011)	870	MCV 52% ES 48%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

PARTNER Grading Criteria for Paravalvular AR

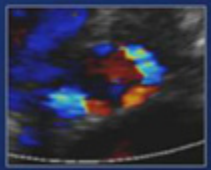


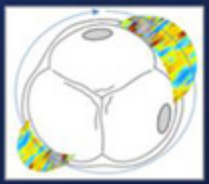
Circumference = 6″
AR = 0.1+0.35 = 0.45″
Ratio = 8%
Severity = Mild





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

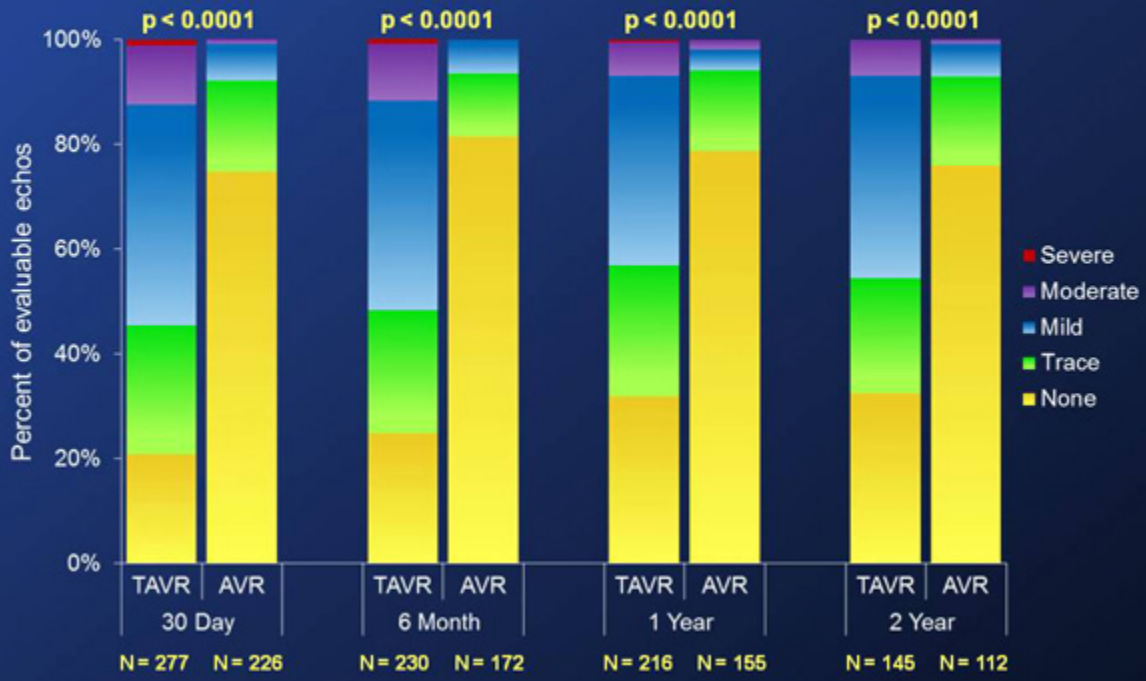




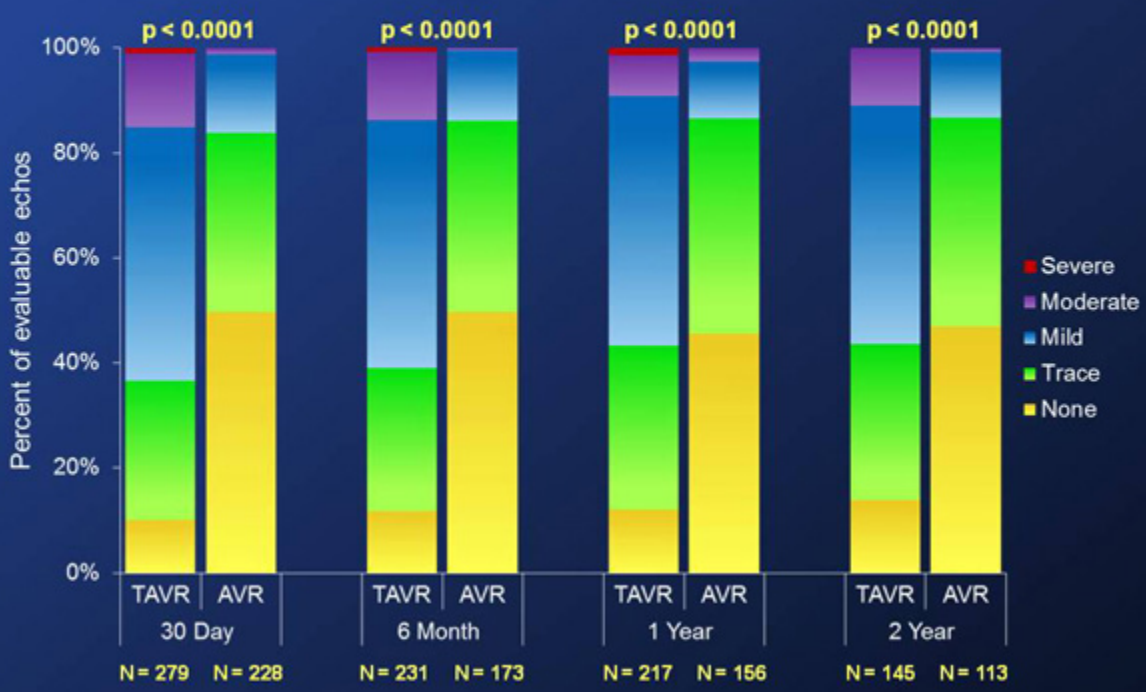
Circumference = 6″
AR = 0.6+1.1 = 1.7″
Ratio = 28%
Severity = Severe

Images courtesy of Pamela Douglas, MD, FASE

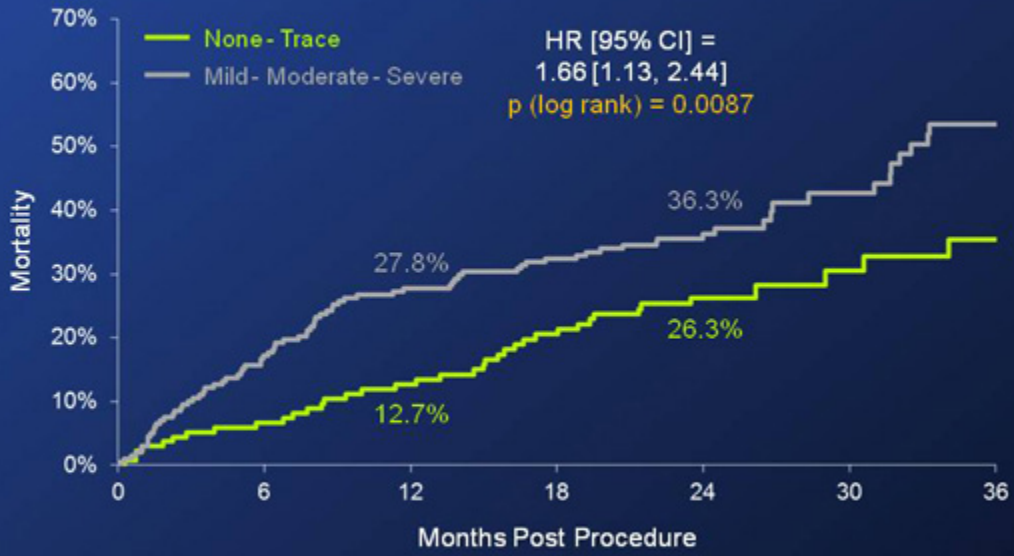
Paravalvular Aortic Regurgitation (AT)



Aortic Regurgitation (AT)



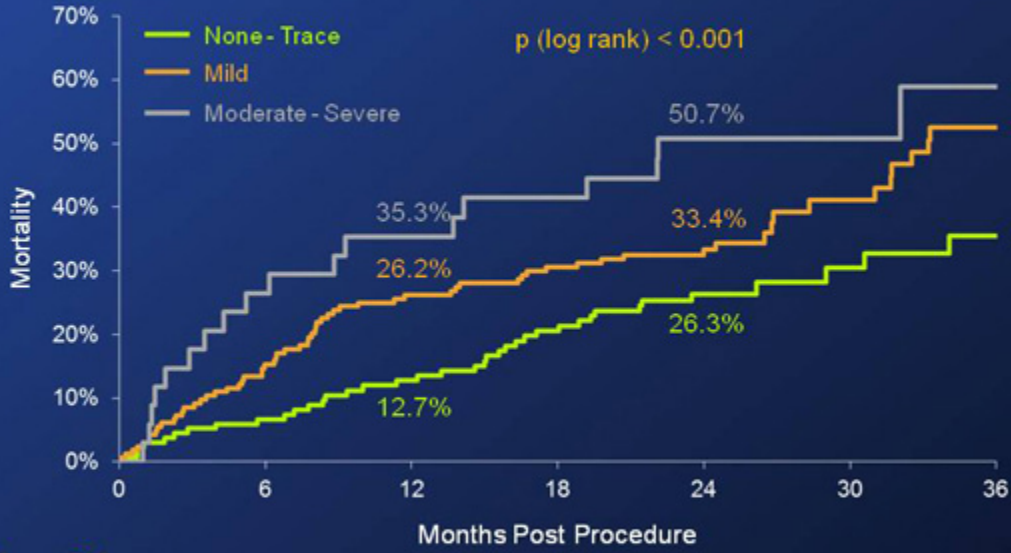
Total AR and Mortality
TAVR Patients (AT)



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)

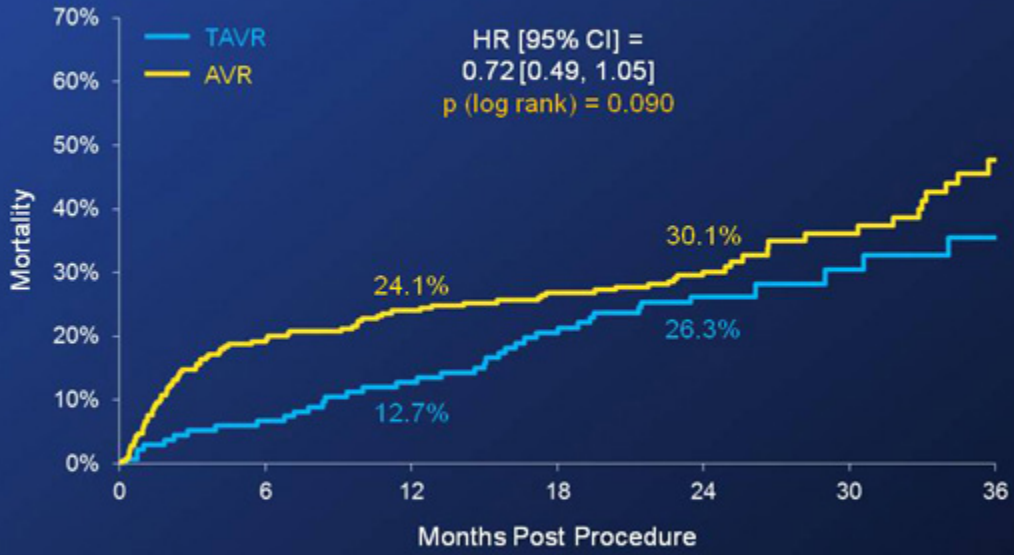


Numbers at Risk

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

Mortality in Patients with None-Trace AR
TAVR vs AVR

THE PARTNER TRIAL



Numbers at Risk

TAVR	135	125	115	101	68	31	11
AVR	252	201	189	176	118	52	22

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)

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

TAVR and Paravalvular AR

Summary

- Paravalvular AR occurs frequently after TAVR (both BE and SE expanding platforms)
- Paravalvular (and toal) AR after TAVR, even mild, is associated with increased subsequent mortality
- Important predictors are valve undersizing, suboptimal valve positioning and severe landing zone calcification
- Improvements expected (and/or already seen) with...
  - careful 3D-CTA and TEE sizing
  - improved valve positioning
  - judicious post-dilatation
  - new THV devices with better subannular fixation and/or space filling materials

TAVR Complications - 2012
Final Thoughts

- The best way to "deal" with serious TAVR complications is to AVOID THEM, by careful case planning, an integrated team approach, early recognition, and definitive management strategies
- Vascular/bleeding major events can be reduced to < 5% with new technology and advanced operator skills
- Strokes (early = < 10 days) can be ~2% with cerebral protection devices and attention to procedural and post-procedural factors (including better pharmacotherapy)

TAVR Complications - 2012

Final Thoughts

- Para-valvular regurgitation can be minimized with better valve sizing and positioning, judicious use of post-dilatation, and device enhancements
- Rare but potentially catastrophic complications (e.g. CA occlusion, Ao rupture) can usually be avoided with meticulous case planning, but when they occur, must be rapidly diagnosed and managed aggressively by the HEART VALVE team