TAVR in Year Review 2015

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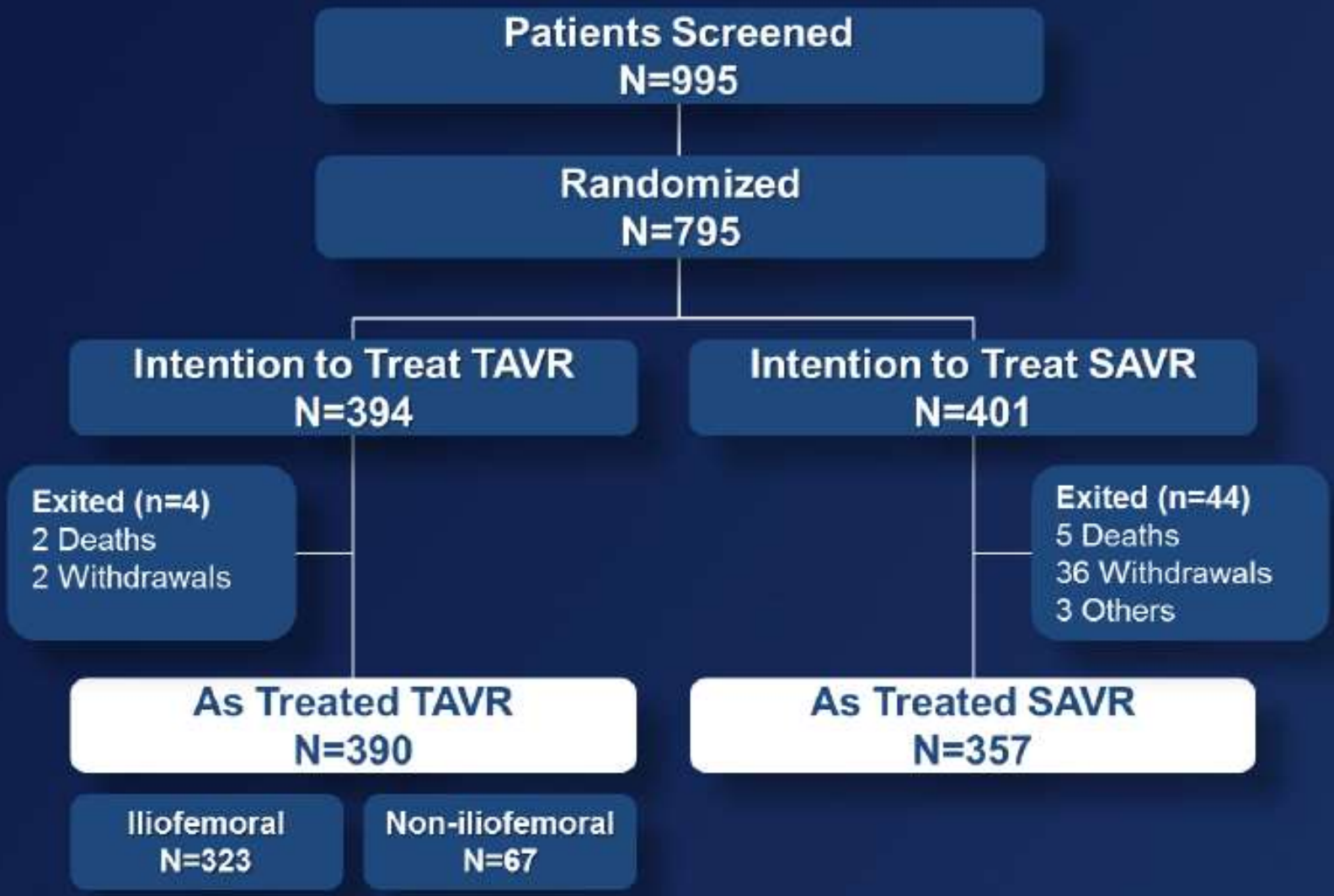
Financial disclosure: None

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

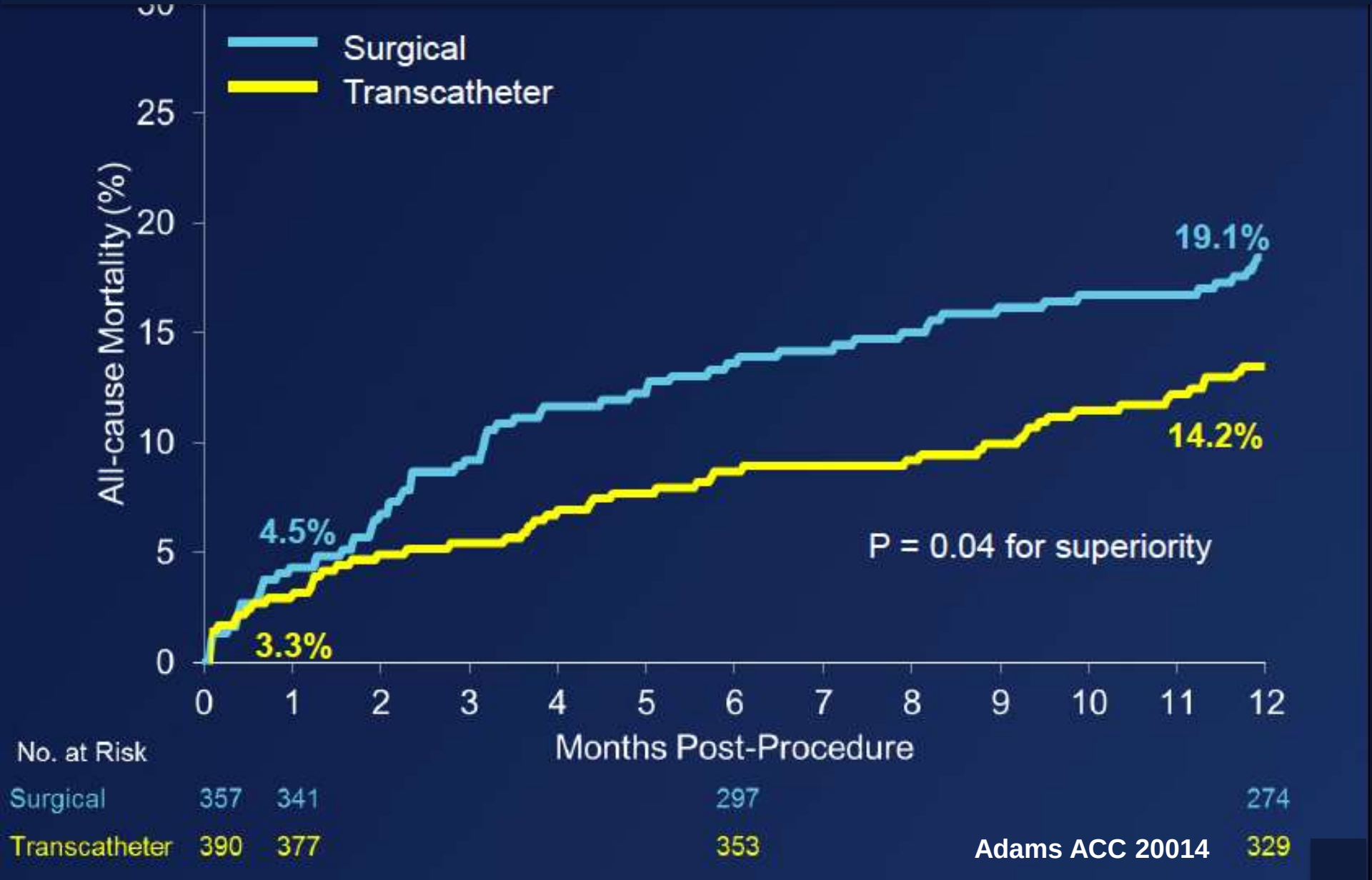
David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

CoreValve Randomized Trial



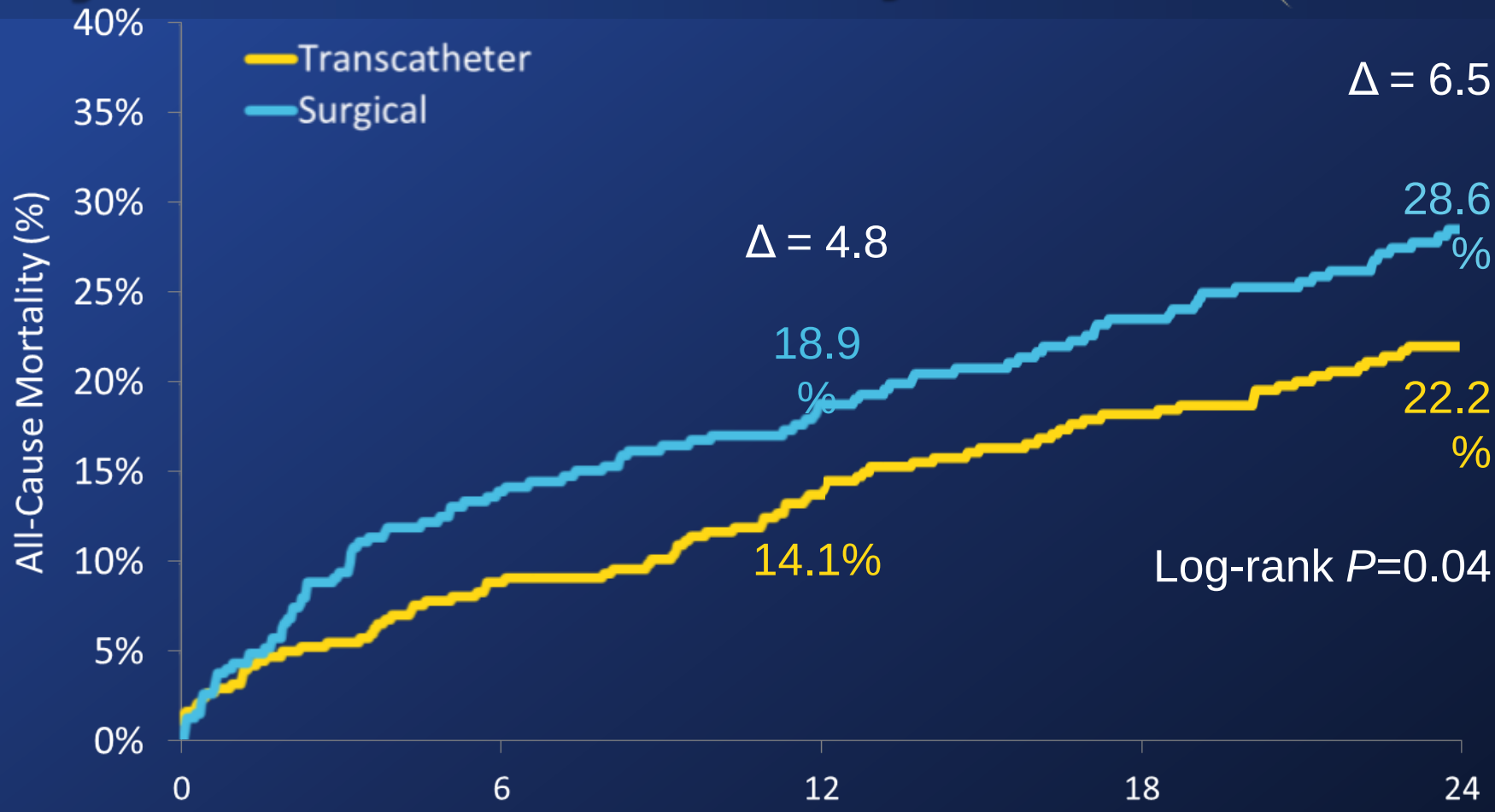
Adams ACC 20014

CoreValve RCT: 1 Year Mortality



Adams ACC 20014

CoreValve RCT
2 year All-Cause Mortality

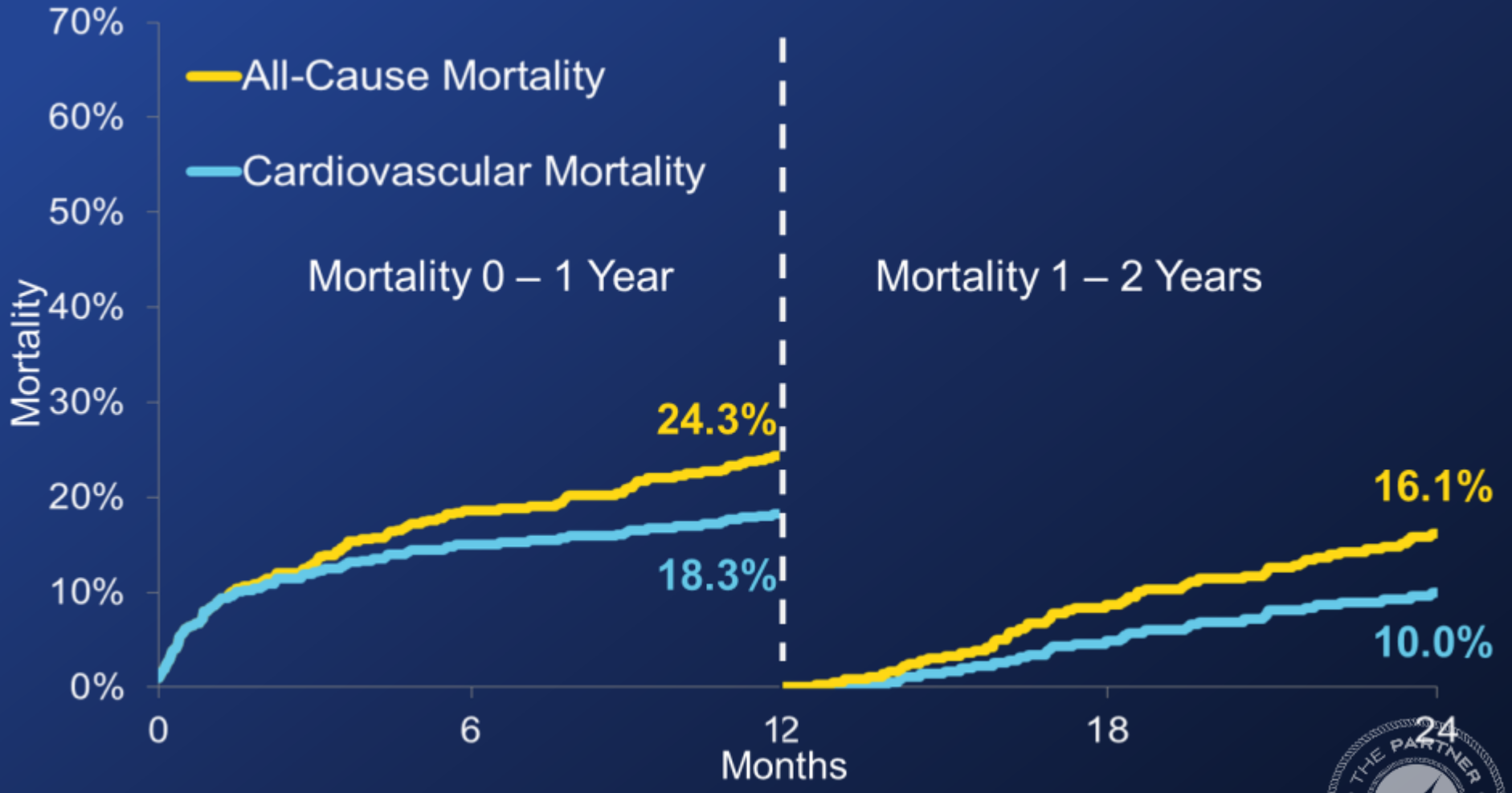


No. at Risk					
Transcatheter	391	378	354	334	219
Surgical	359	343	304	282	191

Reardon ACC 2015

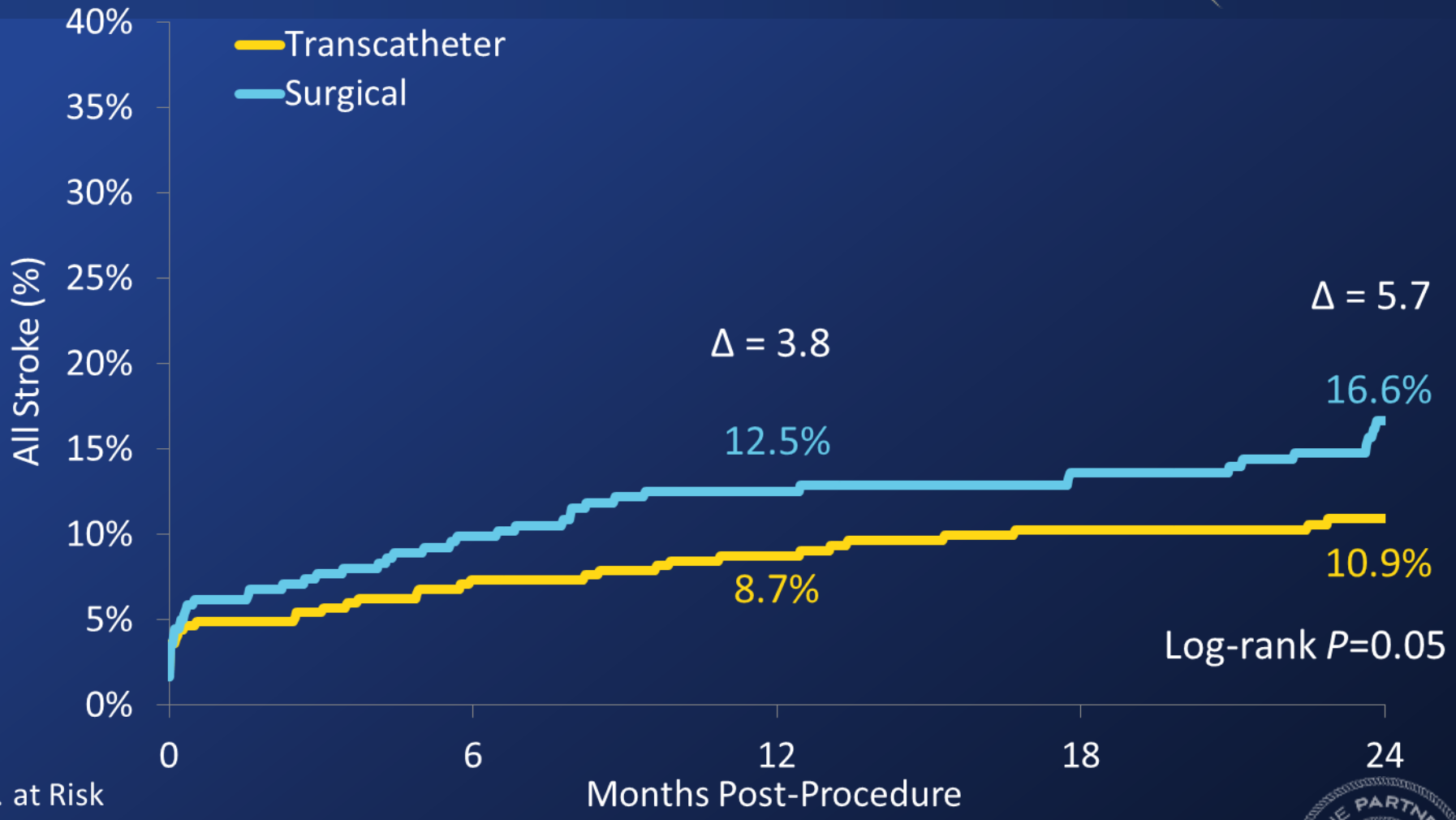
CoreValve RCT

2-Year Mortality - Landmark Analysis



Reardon ACC 2015

CoreValve RCT
All Stroke

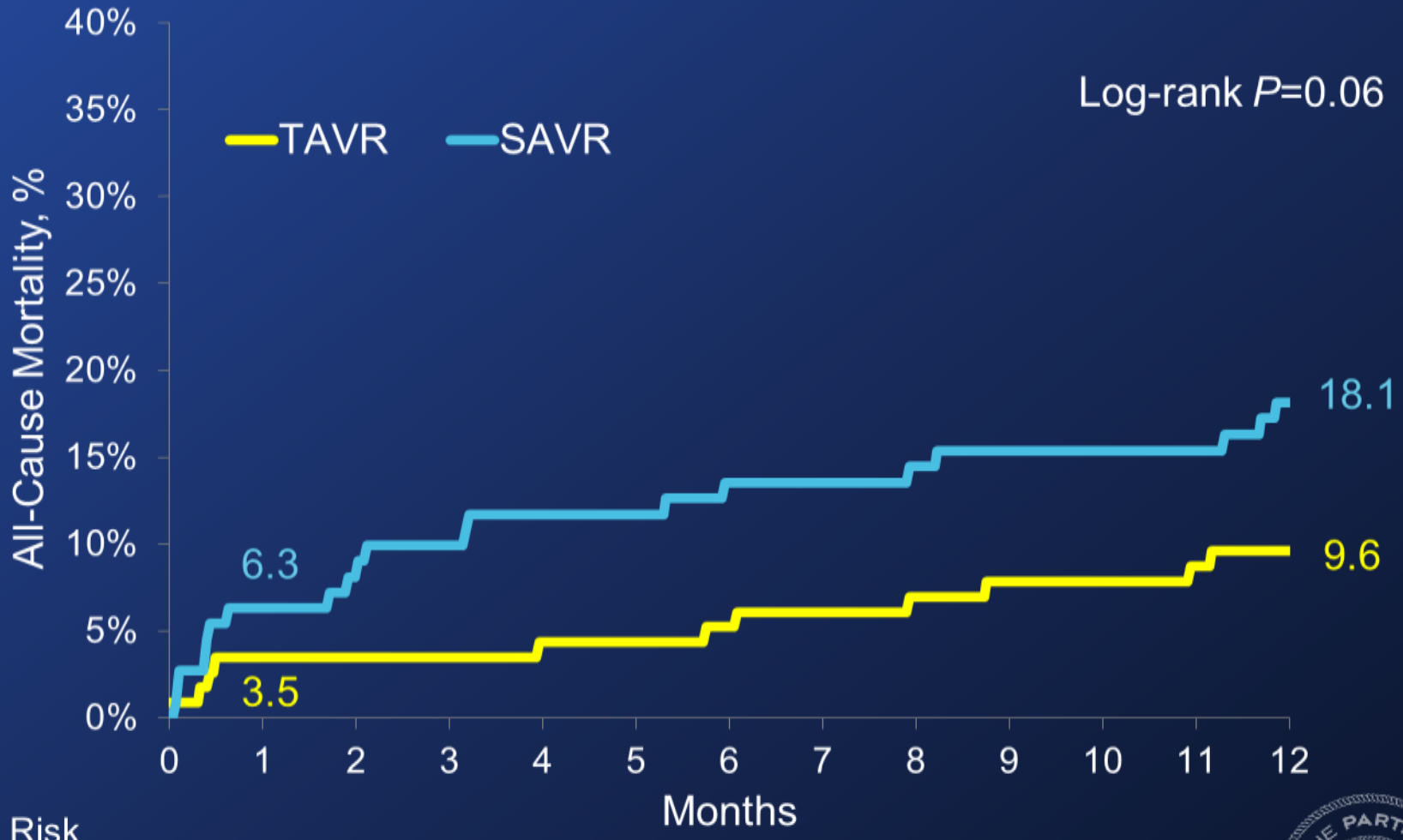


No. at Risk				
Transcatheter	391	364	335	318	205
Surgical	359	324	281	256	169

Reardon ACC 2015

1-Year All-Cause Mortality

Patients with Prior CABG



No. at Risk			
TAVR	115	109	102
SAVR	111	94	89

Conte STS 2015

CoreValve Pivotal TrialAll
Mortality or Major Stroke

** Calculated rate for 117 events in 179 patients (65.4%, lower confidence bound of 57.9% by Exact method) (Makkar RR, et al, New Engl J Med, 2012)*

Yakubov TCT 2014

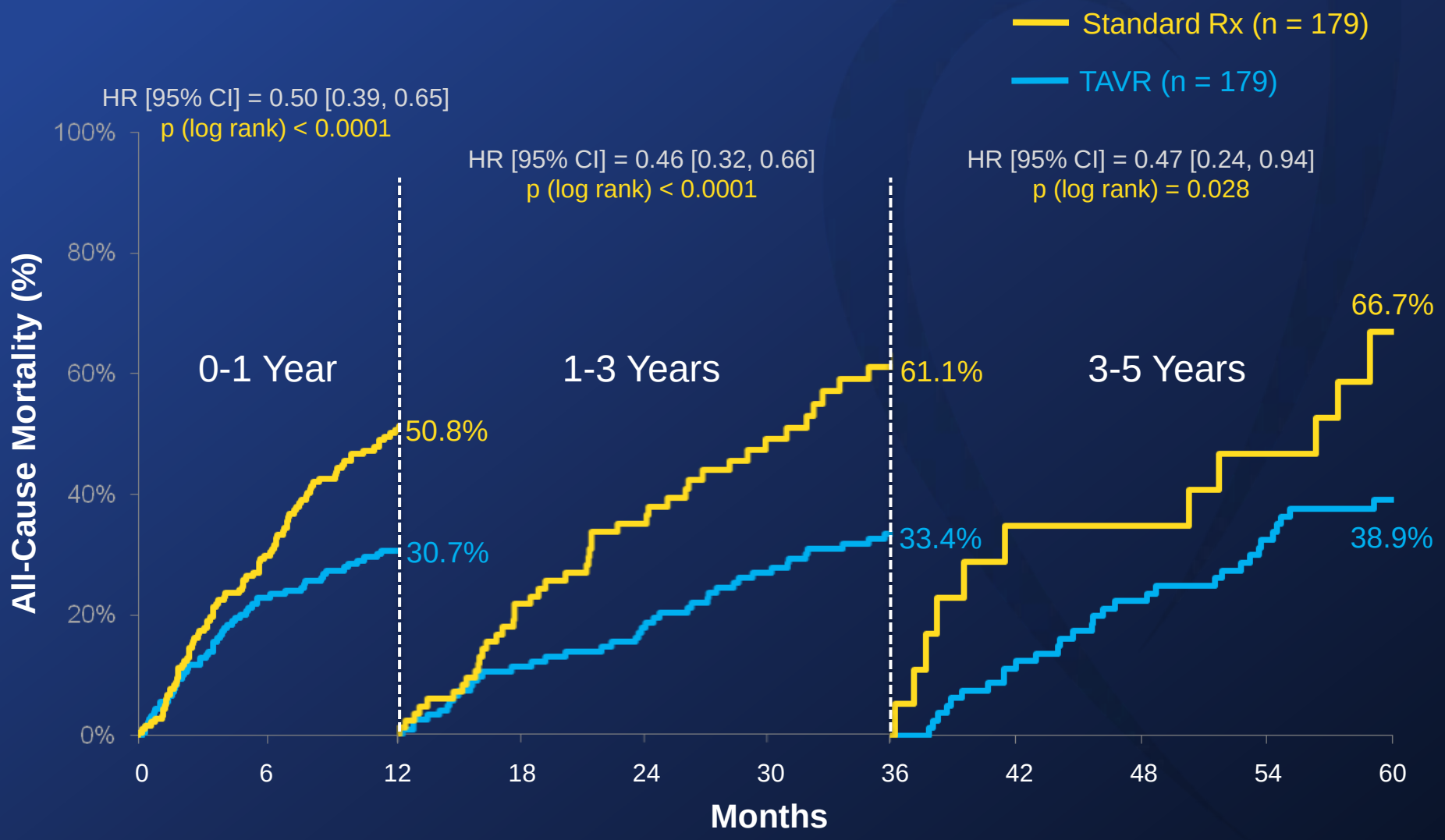
thelancet.
Published Online
March 15, 2015
http://dx.doi.org/10.1016/
S0140-6736(15)60290-2

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial

Samir R Kapadia, Martin B Leon, Raj R Makkar, E Murat Tuzcu, Lars G Svensson, Susheel Kodali, John G Webb, Michael J Mack, Pamela S Douglas, Vinod H Thourani, Vasilis C Babaliaros, Howard C Herrmann, Wilson Y Szeto, Augusto D Pichard, Mathew R Williams, Gregory P Fontana, D Craig Miller, William N Anderson, Jodi J Akin*, Michael J Davidson†, Craig R Smith, for the PARTNER trial investigators

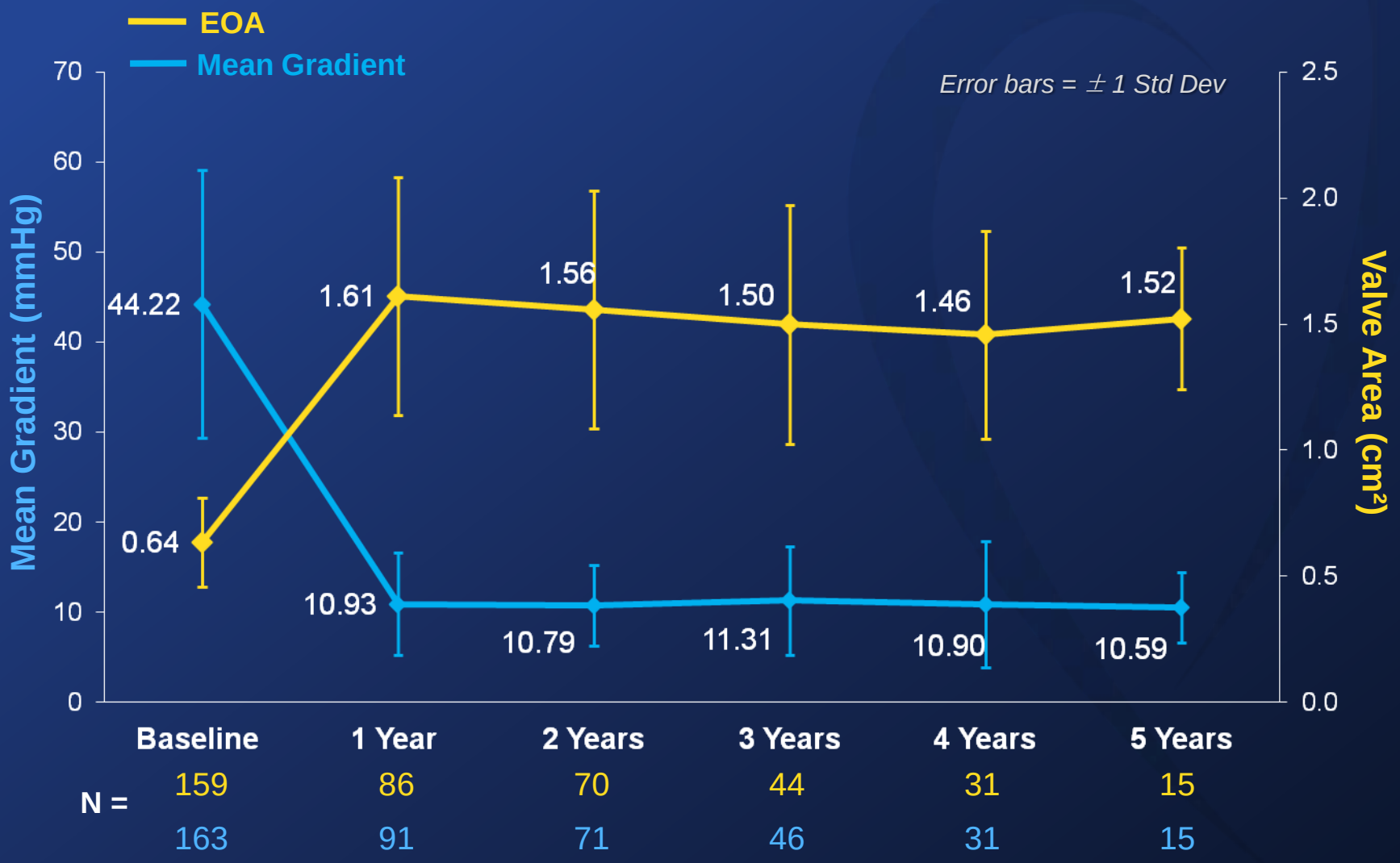
PARTNER – B Trial

All-Cause Mortality (ITT) - Landmark Analysis



Kapadia ACC 2015

PARTNER – B Trial - Durability
Mean Gradient & Valve Area (AT)



Kapadia ACC 2015

THELANCET-D-15-00795

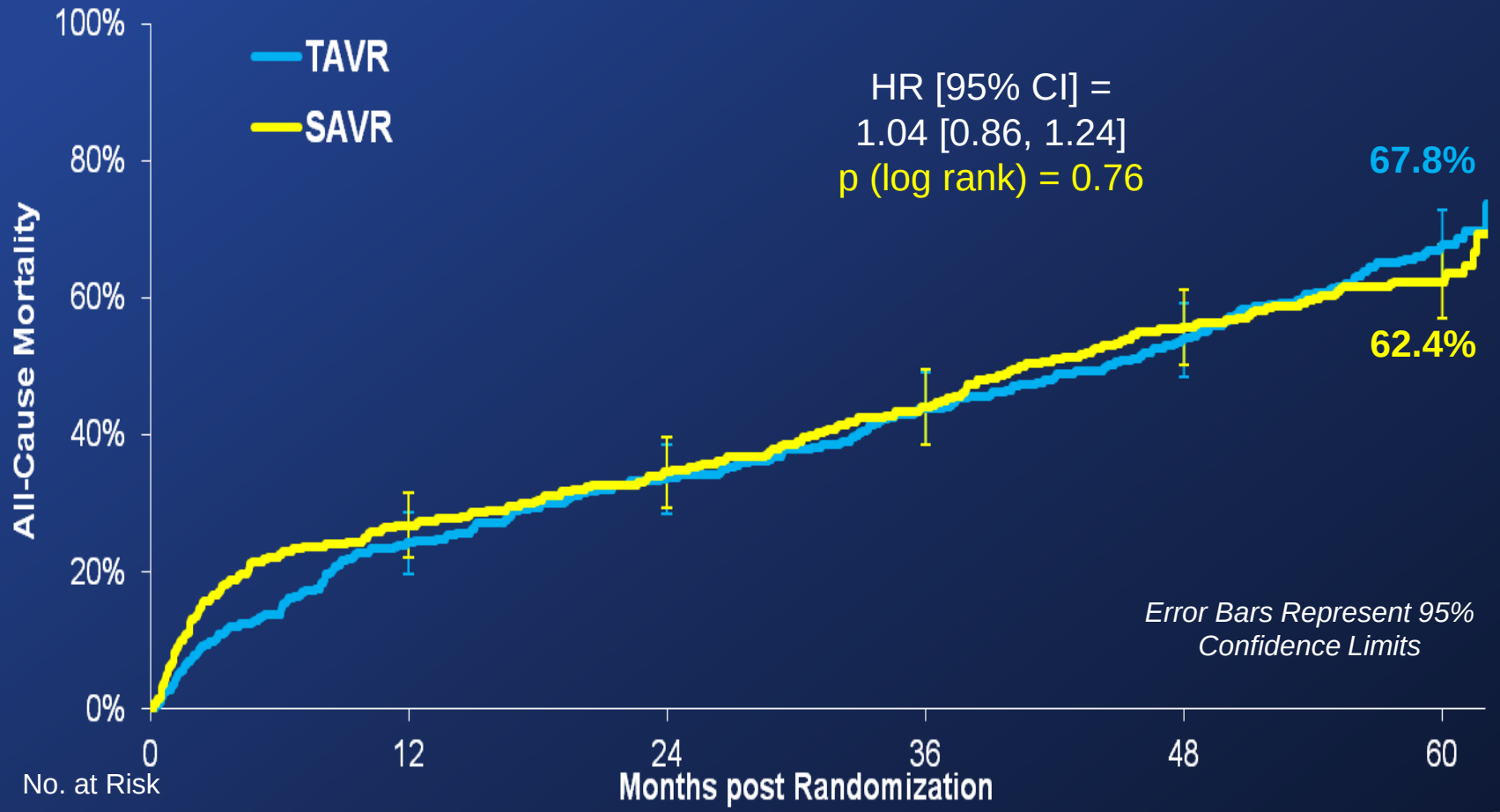
S0140-6736(15)60308-7

Embargo: [add date when known]

5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

Michael J Mack, Martin B Leon, Craig R Smith, D Craig Miller, Jeffrey W Moses, E Murat Tuzcu, John G Webb, Pamela S Douglas, William N Anderson, Eugene H Blackstone, Susheel K Kodali, Raj R Makkar, Gregory P Fontana, Samir Kapadia, Joseph Bavaria, Rebecca T Hahn, Vinod H Thourani, Vasilis Babaliaros, Augusto Pichard, Howard C Herrmann, David L Brown, Mathew Williams, Jodi Akin*, Michael J Davidson†, Lars G Svensson, for the PARTNER 1 trial investigators*

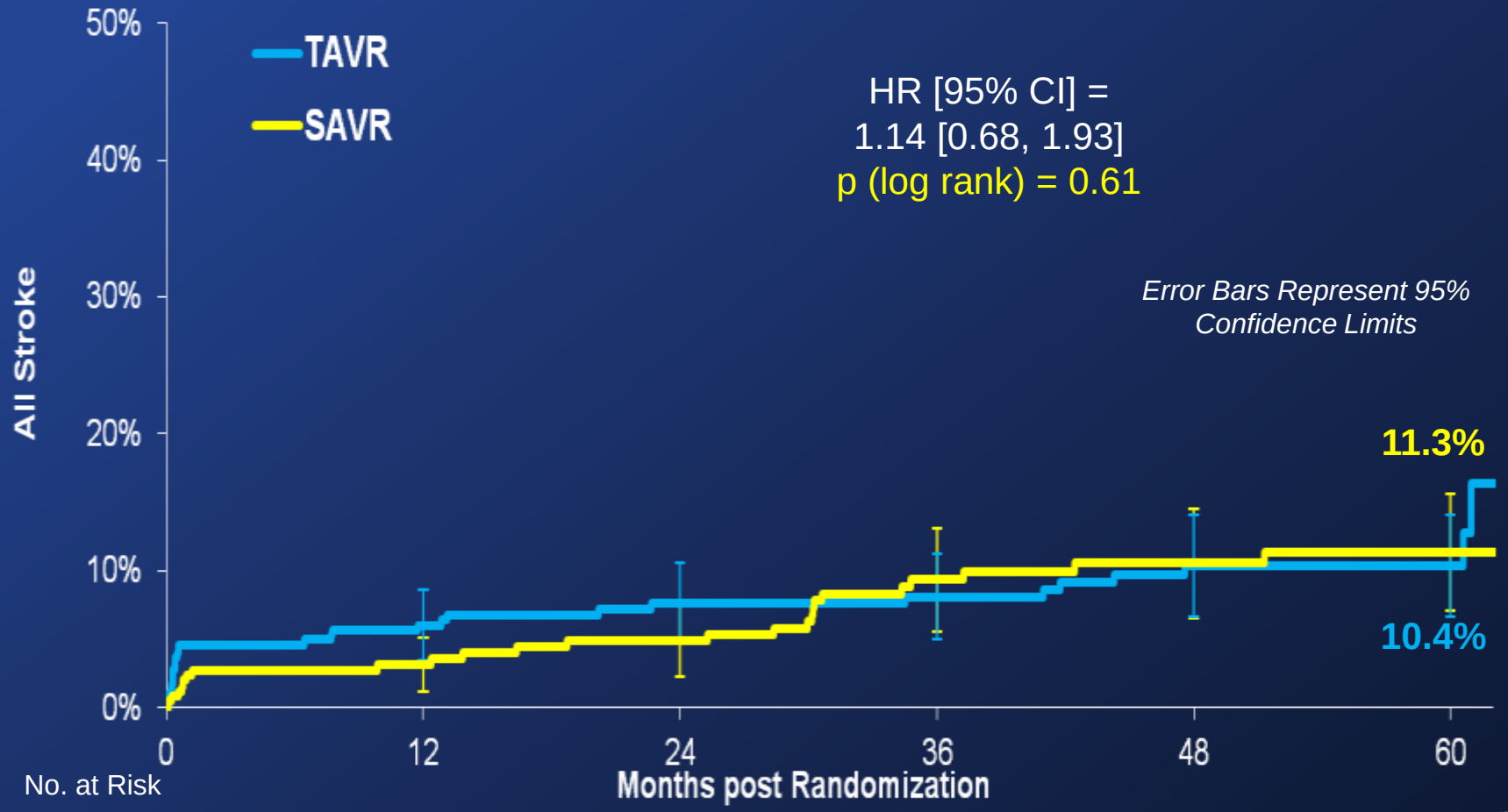
All-Cause Mortality (ITT)
All Patients



No. at Risk

TAVR	348	262	228	191	154	61
SAVR	351	236	210	174	131	64

All Stroke (ITT)
All Patients



No. at Risk

TAVR	348	251	217	181	144	57
SAVR	*351*	*230*	*205*	*169*	*128*	*64*

Choice Study

Original Investigation

Comparison of Balloon-Expandable vs Self-expandable Valves in Patients Undergoing Transcatheter Aortic Valve Replacement
The CHOICE Randomized Clinical Trial

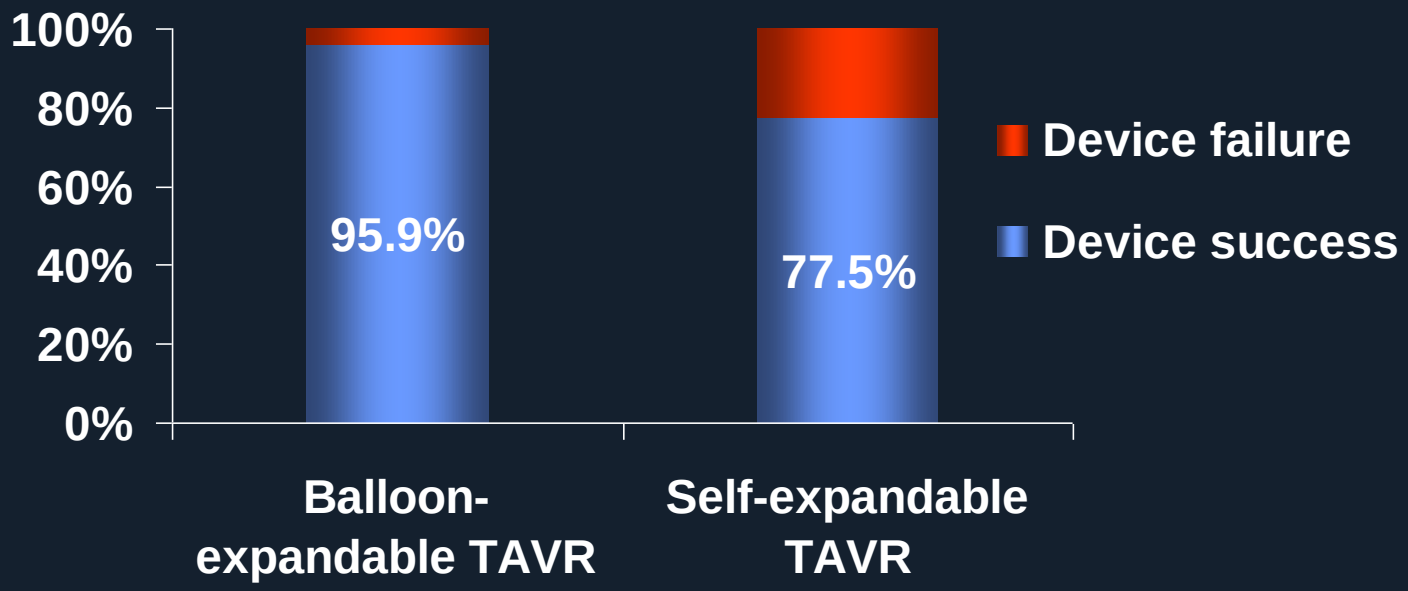
Mohamed Abdel-Wahab, MD; Julinda Mehilli, MD; Christian Frerker, MD; Franz-Josef Neumann, MD; Thomas Kurz, MD; Ralph Tölg, MD; Dirk Zachow, MD; Elena Guerra, MD; Steffen Massberg, MD; Ulrich Schäfer, MD; Mohamed El-Mawardy, MD; Gert Richardt, MD; for the CHOICE investigators

- High risk/inoperable AS patients evaluated by a heart team
- 5 German centers experienced with both BE (Sapien XT) and SE (CoreValve)
- 121 patients with BE and 120 with SE TAVR (3.12 – 12.13)
- Primary endpoint = 'device success' (successful delivery/deployment of single valve and intended performance [EOA/PVR])

JAMA on-line March 30, 2014

Primary Endpoint – Device Success

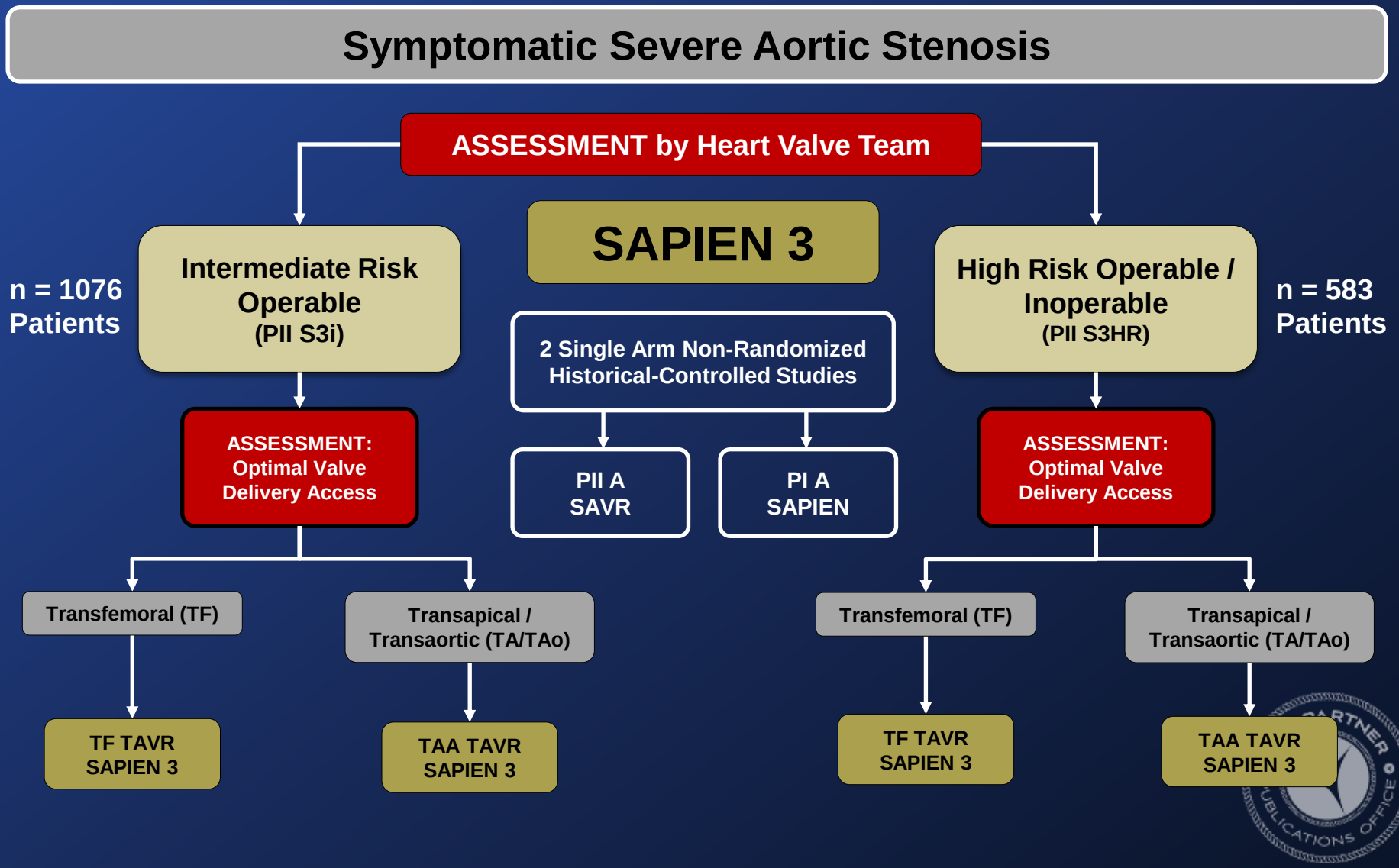
Relative risk 1.24, 95%CI 1.12-1.37, p<0.001



Causes of device failure	BE (n=121)	SE (n=120)
Unsuccessful vascular access, delivery and deployment	0/121 (0)	0/120 (0)
Incorrect position with implantation of more than one valve	1/121 (0.8)	7/120 (5.8)
Inadequate performance of the prosthetic heart valve		
AV area <1.2cm^2 or mean AV valve gradient >20mmHg	0/121 (0)	0/120 (0)
Moderate or severe prosthetic valve regurgitation	5/121 (4.1)	22/120 (18.3)
Total (hierarchical)	5/121 (4.1)	27/120 (22.5)

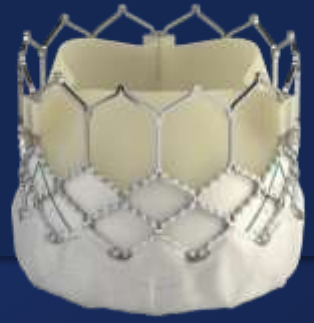
The PARTNER II S3 Trial

Study Design

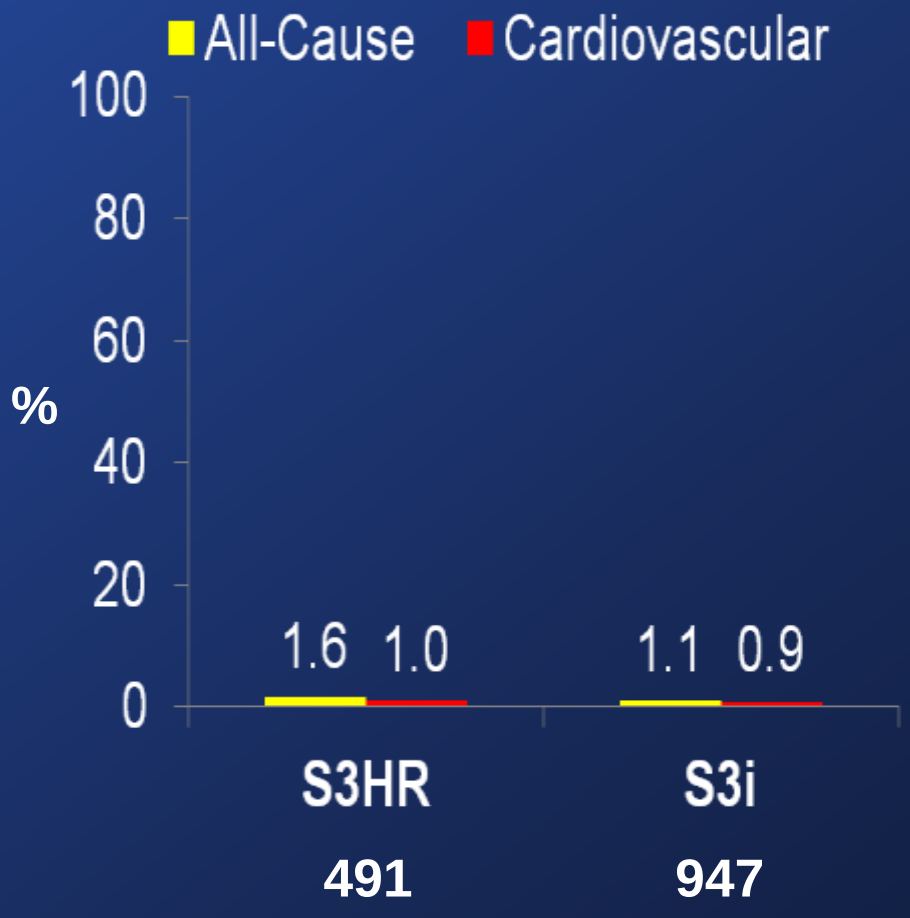


Mortality: S3HR & S3i

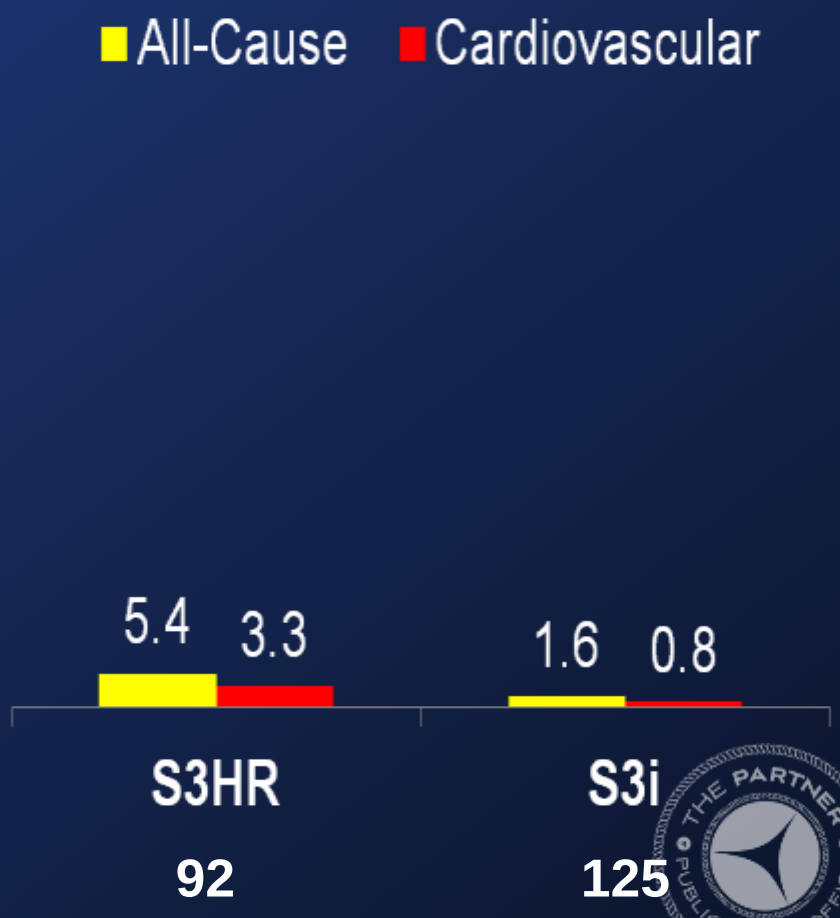
At 30 Days (As Treated Patients)



Transfemoral

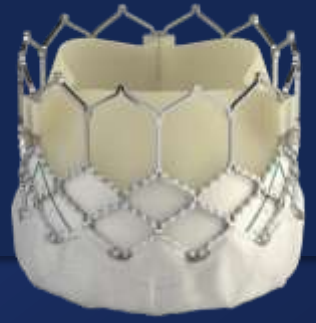


Transapical / Transaortic



Strokes

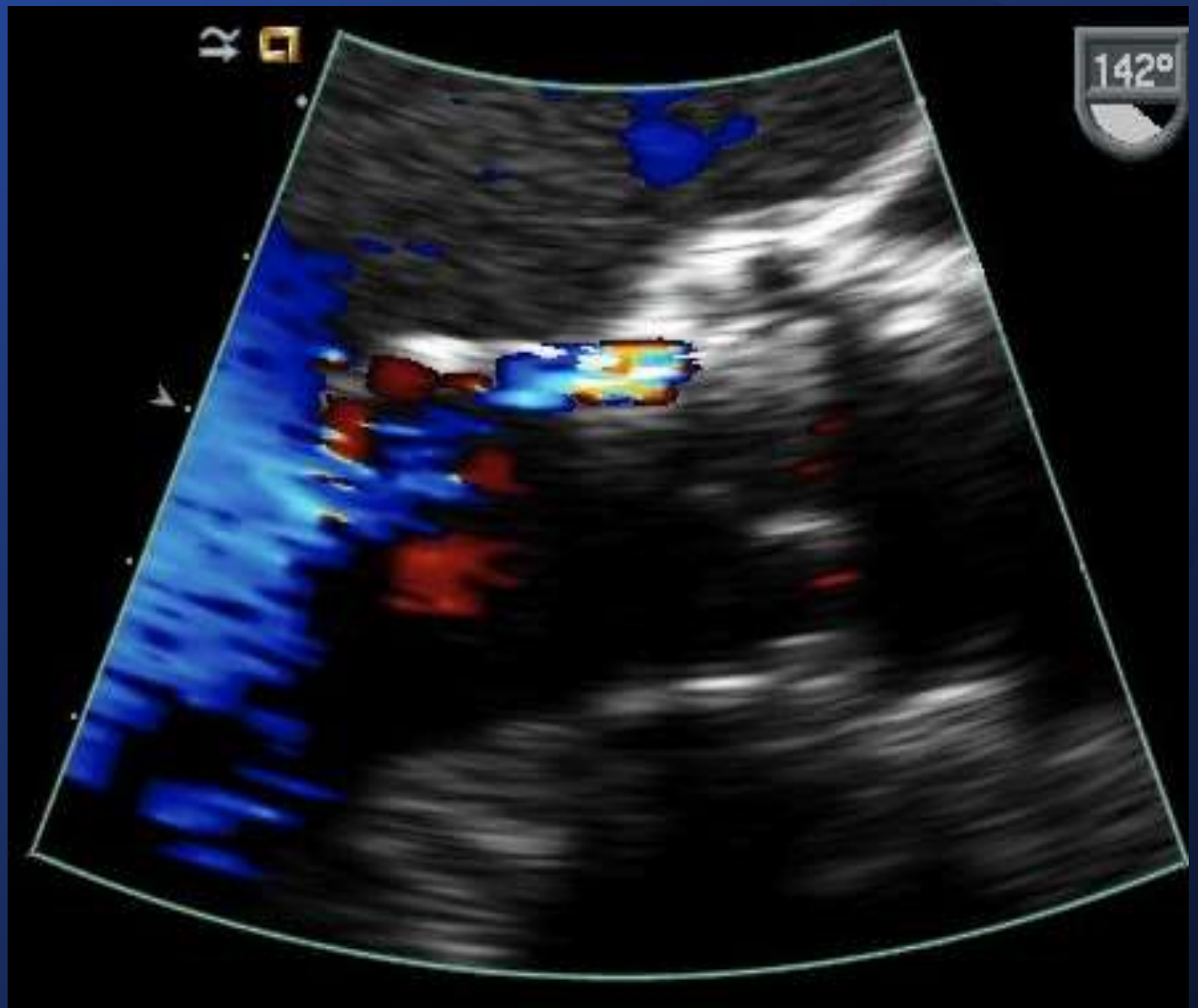
At 30 Days (As Treated Patients)



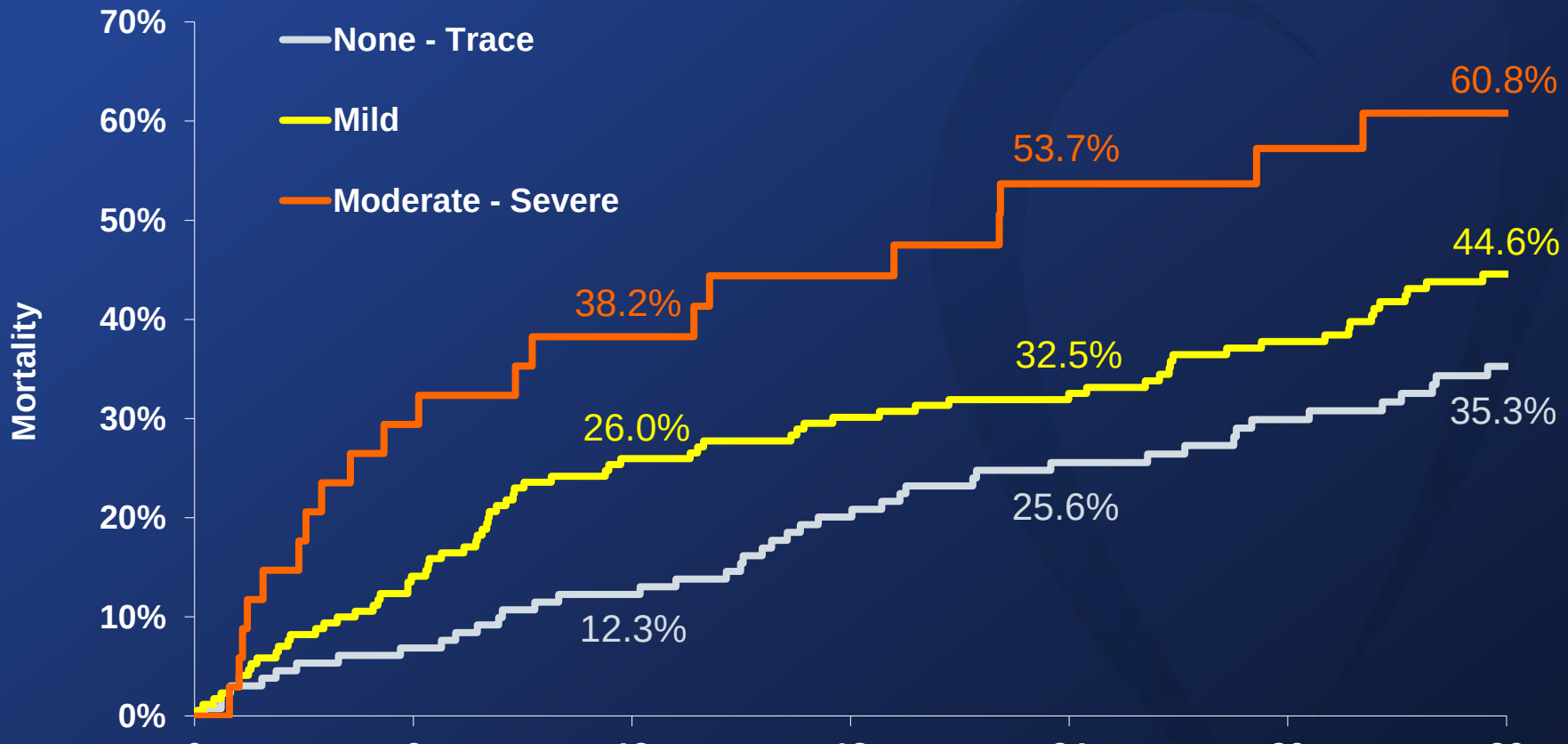
Events (%)	S3HR Overall (n=583)	S3HR TF (n=491)	S3HR TA/TAo (n=92)	S3i Overall (n=1076)	S3i TF (n=951)	S3i TA/TAo (n=125)
All	1.54	1.63	1.09	2.60	2.42	4.00
Disabling*	0.86	0.81	1.09	1.02	0.95	1.60
Non-Disabling	0.69	0.81	0	1.58	1.47	2.40
TIA	0.69	0.61	1.09	0.37	0.42	0

**CEC adjudicated or Modified Rankin Score ≥ 2 at 30 days*

Aortic Regurgitation After TAVR



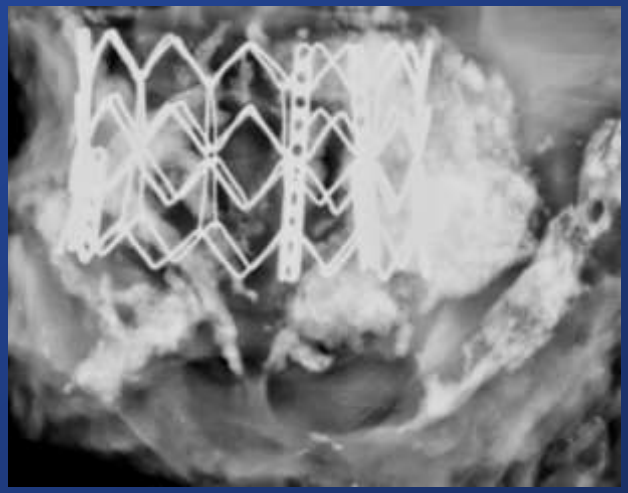
Impact of AR on Mortality after TAVR

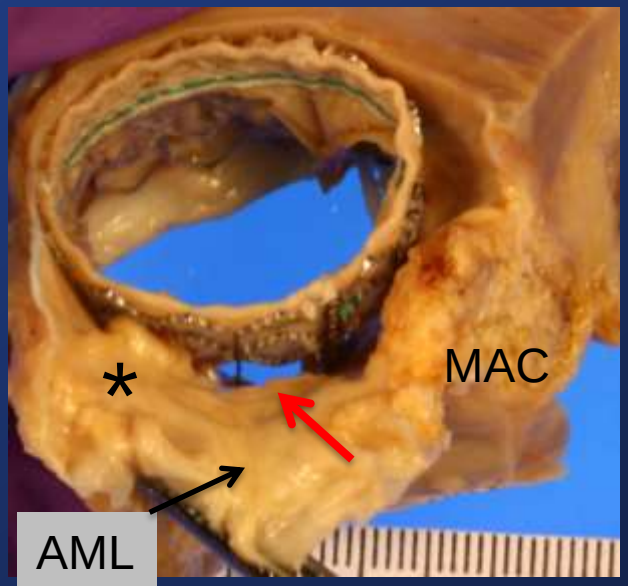


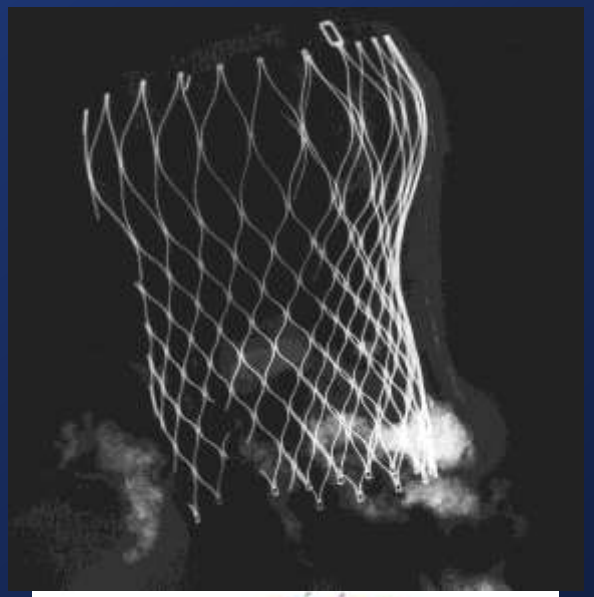
No. at Risk							
None-Tr	131	121	114	102	93	80	63
Mild	171	146	125	117	110	94	62
Mod-Sev	34	24	21	18	15	12	9

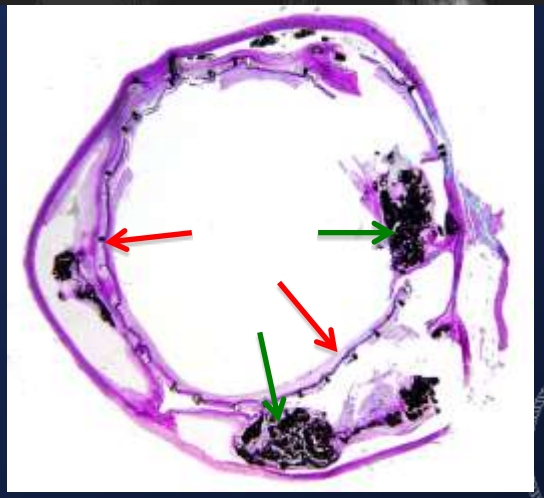
Kodali et al EHJ 2014

Determinants of PVR after TAVR
Underexpantion due to Calcification

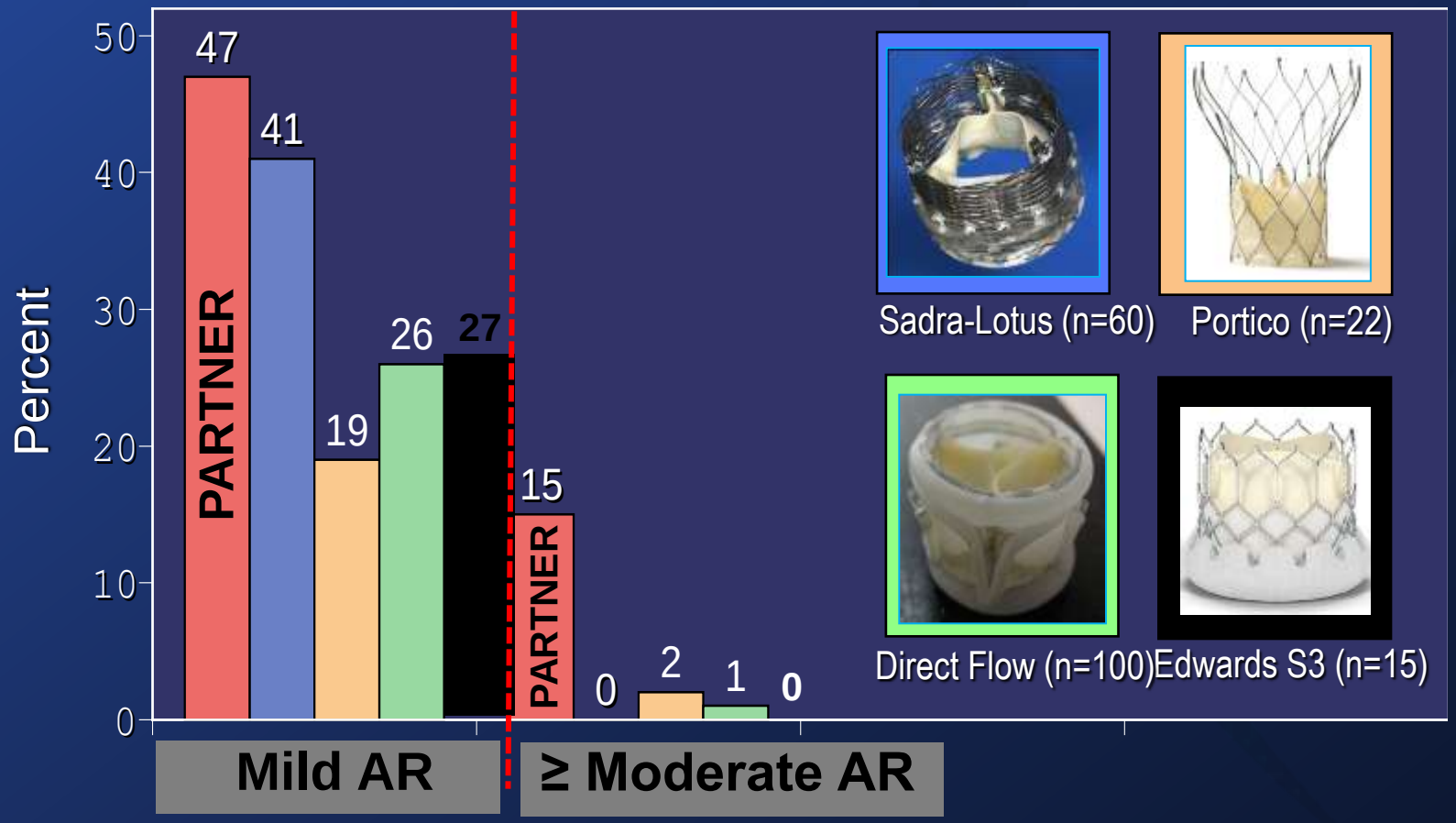




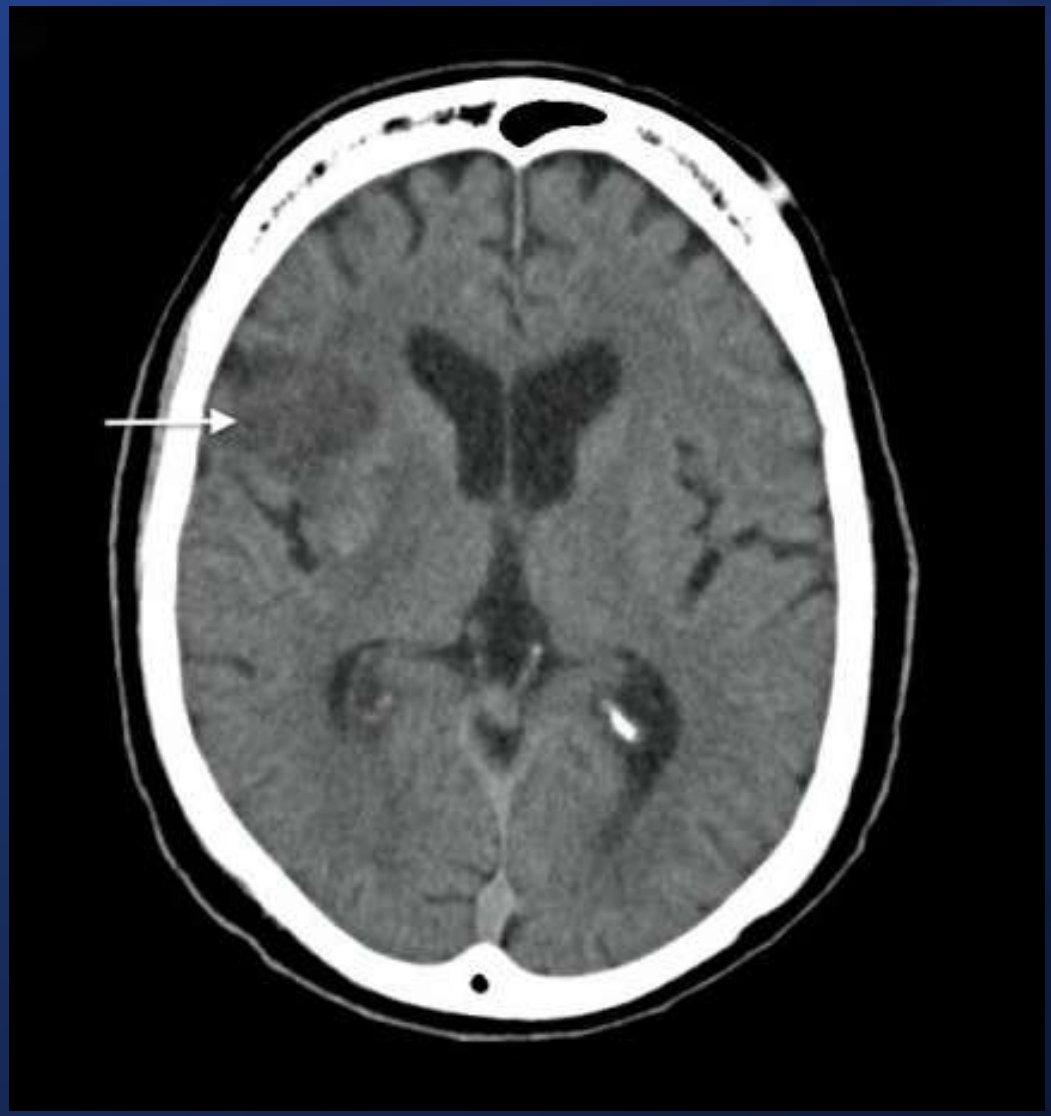




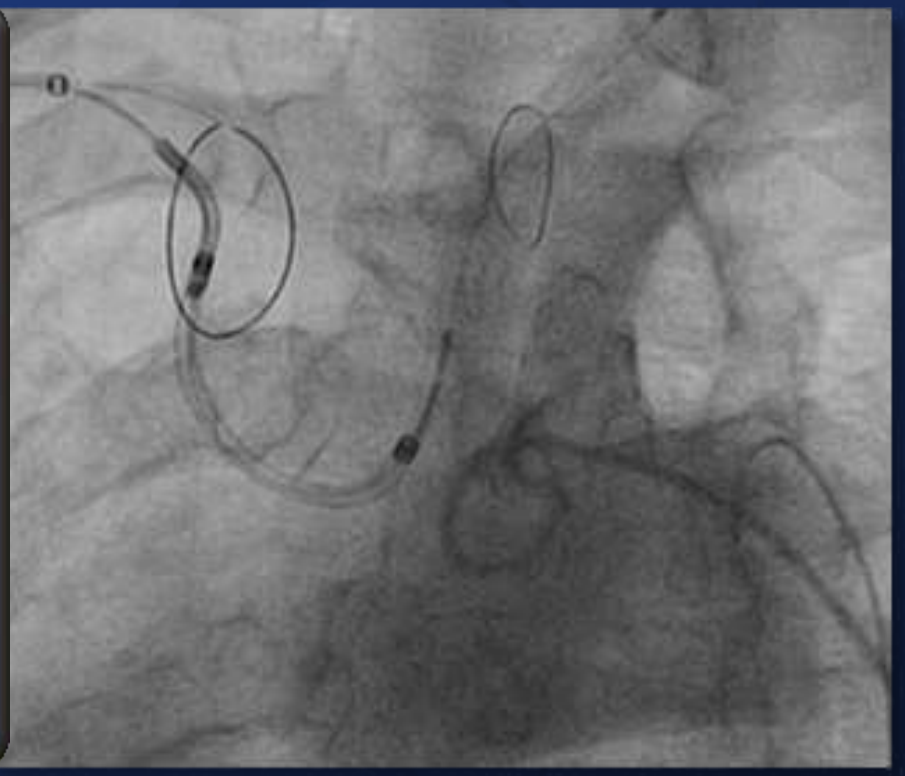
PVR after TAVR
New Transcatheter Valves



Stroke after TAVR



Claret Montage
Cerebral Protection System (CPS)

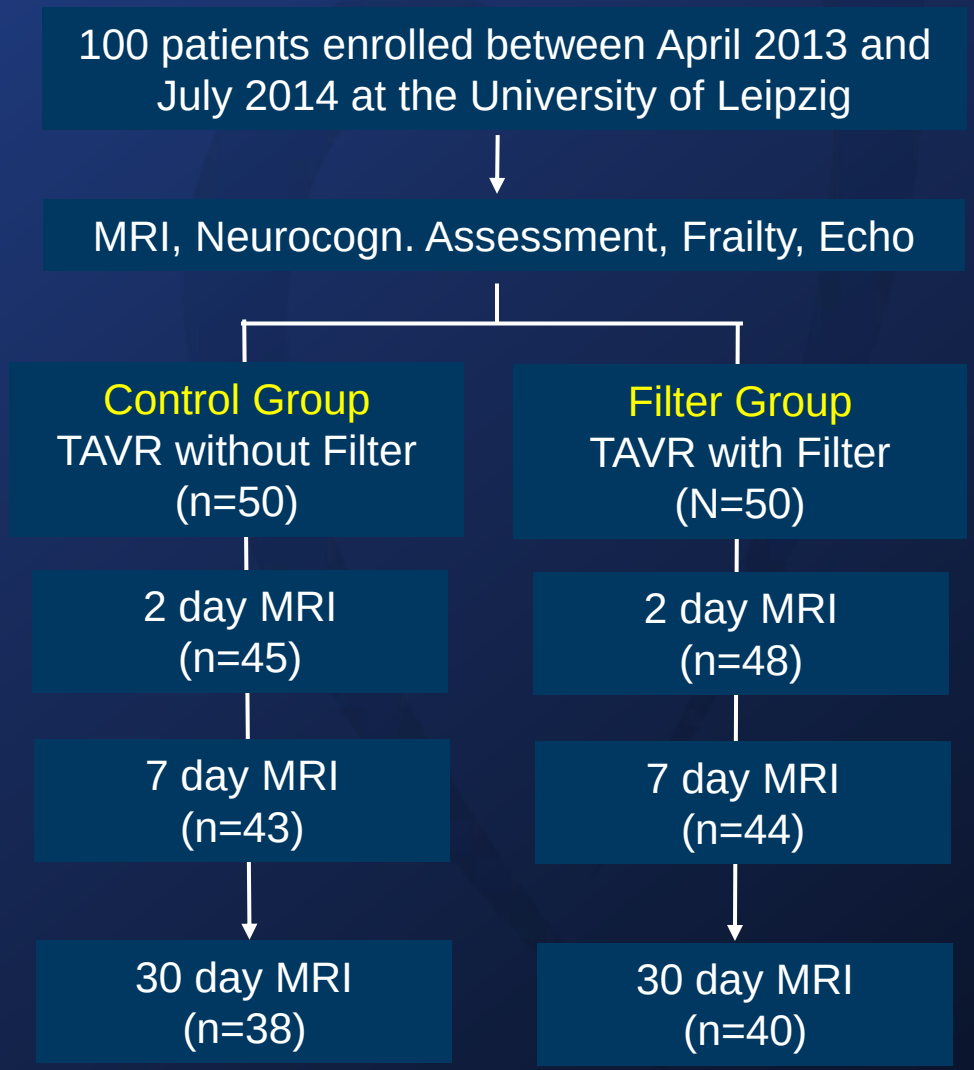


Minimal device “footprint” in the ascending aorta to avoid interaction with TAVR equipment

CLEAN - TAVI

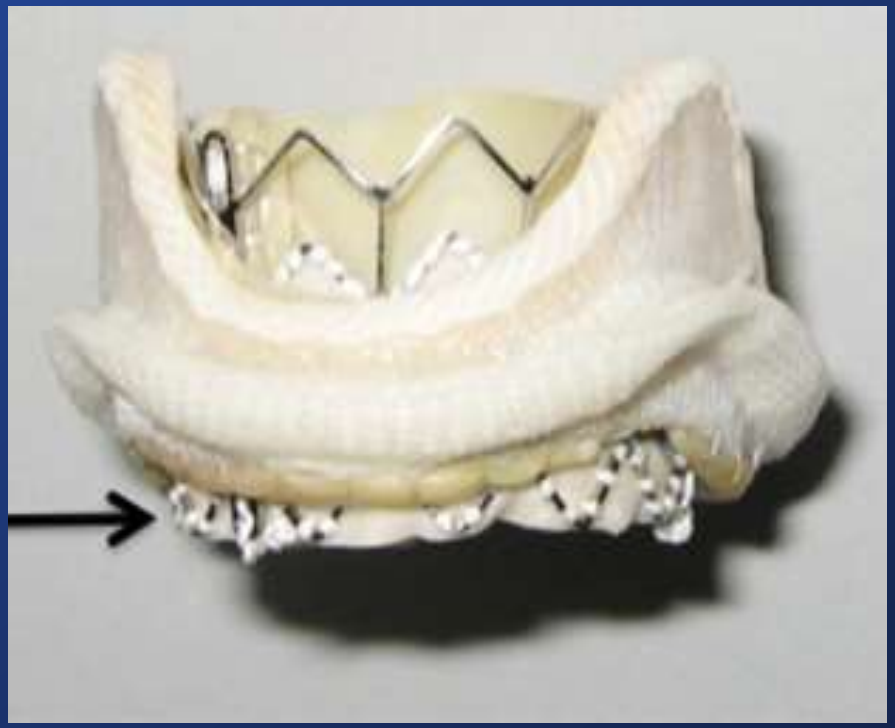
Design

- DESIGN: Prospective, randomized, double-blind single center study
- OBJECTIVE: To evaluate the impact of the Claret Montage™ on number of cerebral lesions in higher-risk patients with aortic stenosis udergoing TAVR with the MCV
- PRINCIPAL INVESTIGATOR
  Axel Linke, MD
  University of Leipzig,
  Heart Center, Germany



Linke et al., TCT 2014

TAVR
Valve in Valve



Original Investigation

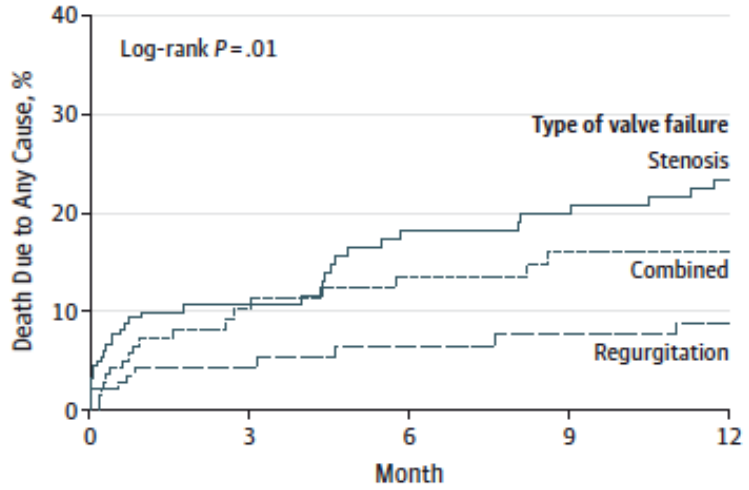
JAMA 2014;312:162-70

Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

Danny Dvir, MD; John G. Webb, MD; Sabine Bleiziffer, MD; Miralem Pasic, MD, PhD; Ron Waksman, MD;

2007 – 5/2013, 55 centers, 496 pts (77 yrs., 56% men, STS-S 9.8%, 30 day mortality 7.6%, stroke 1.7%

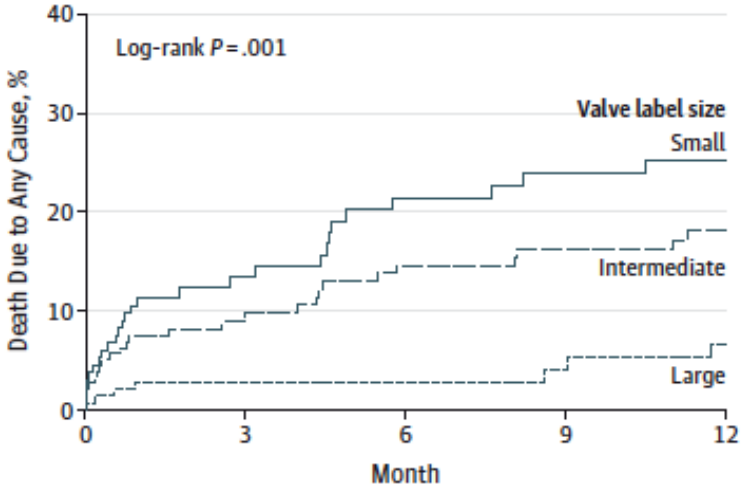
A Mechanism of surgical valve failure



No. at risk by type of valve failure

Stenosis	181	112	98	91	86
Regurgitation	139	92	84	78	76
Combined	139	85	76	68	66

B Surgical valve label size[a]



No. at risk by valve label size

Small	133	81	68	61	57
Intermediate	176	116	103	95	92
Large	139	89	82	76	73

TAVR – 2015

Access Alternatives