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DEBAKEY HEART & VASCULAR CENTER

TAVR-2015: What to Expect

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Houston, Texas

TAVR 2014

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- Mortality reduction to 5 years for “inoperable” patients
- Mortality is equivalent to SAVR at 3 years for “high risk” patients (PARTNER) or superior at 2 years (CoreValve)
- The rate of stroke at 3 years is **identical** between TAVR and SAVR
- No evidence of structural valve deterioration at 7 years

2015

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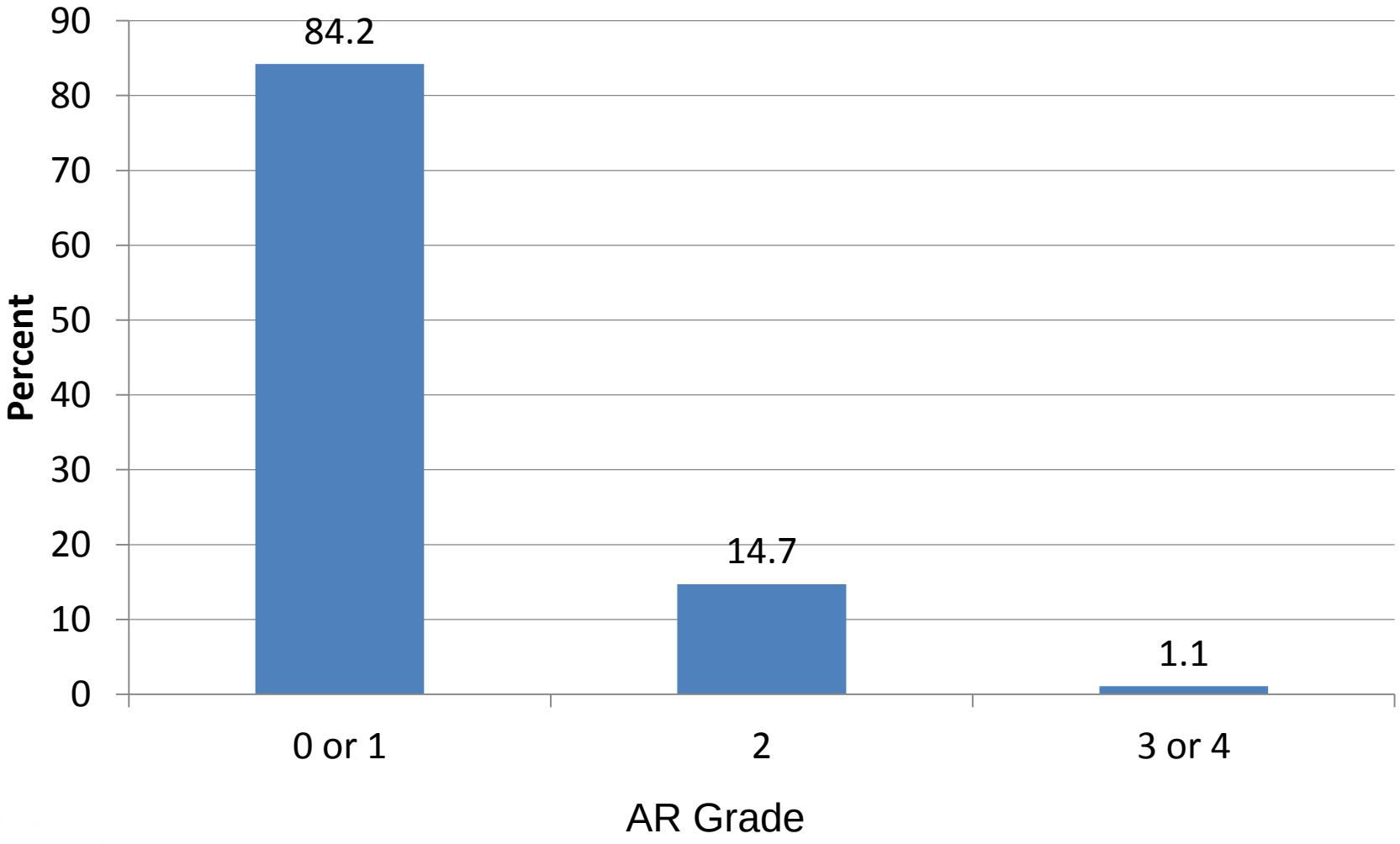
- New Valves
- New patient groups
- Becoming mainstream?

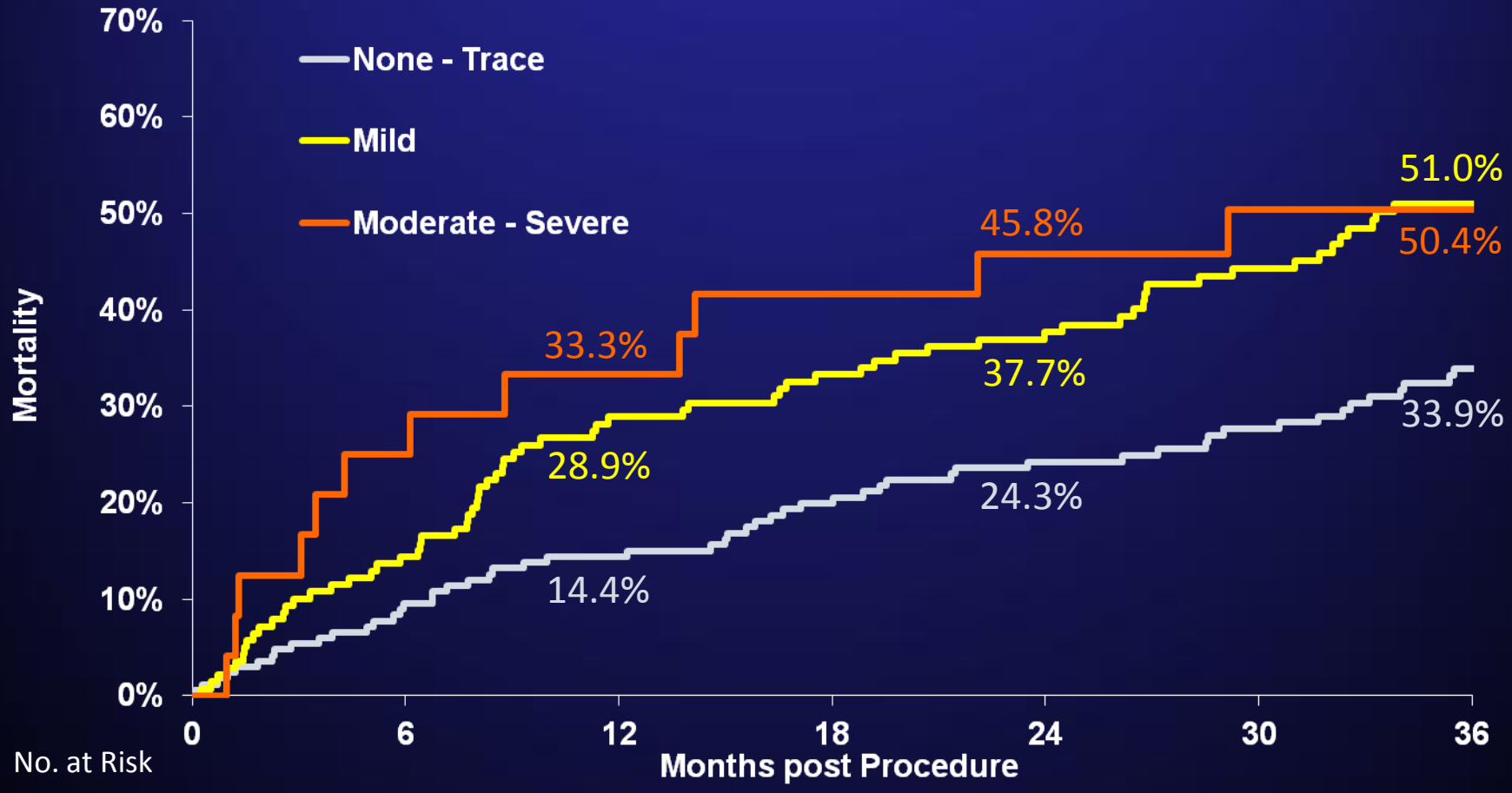
Post Procedural Aortic Regurgitation: FRANCE 2 Registry (N=3195)



Van Belle.Circulation.2014.DOI:10.1161

PARTNER Trial (Edwards SAPIEN Valve)

Impact of Mild Paravalvular Regurgitation on Mortality (TAVI/R Patients-AT)



No. at Risk

None-Tr	168	150	142	130	120	106	81
Mild	139	119	98	91	83	67	42
Mod-Sev	24	18	16	14	13	11	9

Presented by Vinod Thourani, MD at ACC 2013

Association Versus Causation

Relationship Between Valve Sizing and ParaValvular Leak

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Grade of Paravalvular Aortic Regurgitation	Valve Diameter – Mean Annular Diameter (mm)	% Difference Between Valve and Annular Area
None/Trivial	1.5 +/-1. 8	14.2 +/-18.3
Mild	0.4 +/-1.8	4.3 +/-14.2
Moderate/Severe	-0.7 +/-1.4	-7.0 +/-9. 5
P Value	<0.01	<0.01

Willson. JACC. 2015;59:1287

Valve Oversizing

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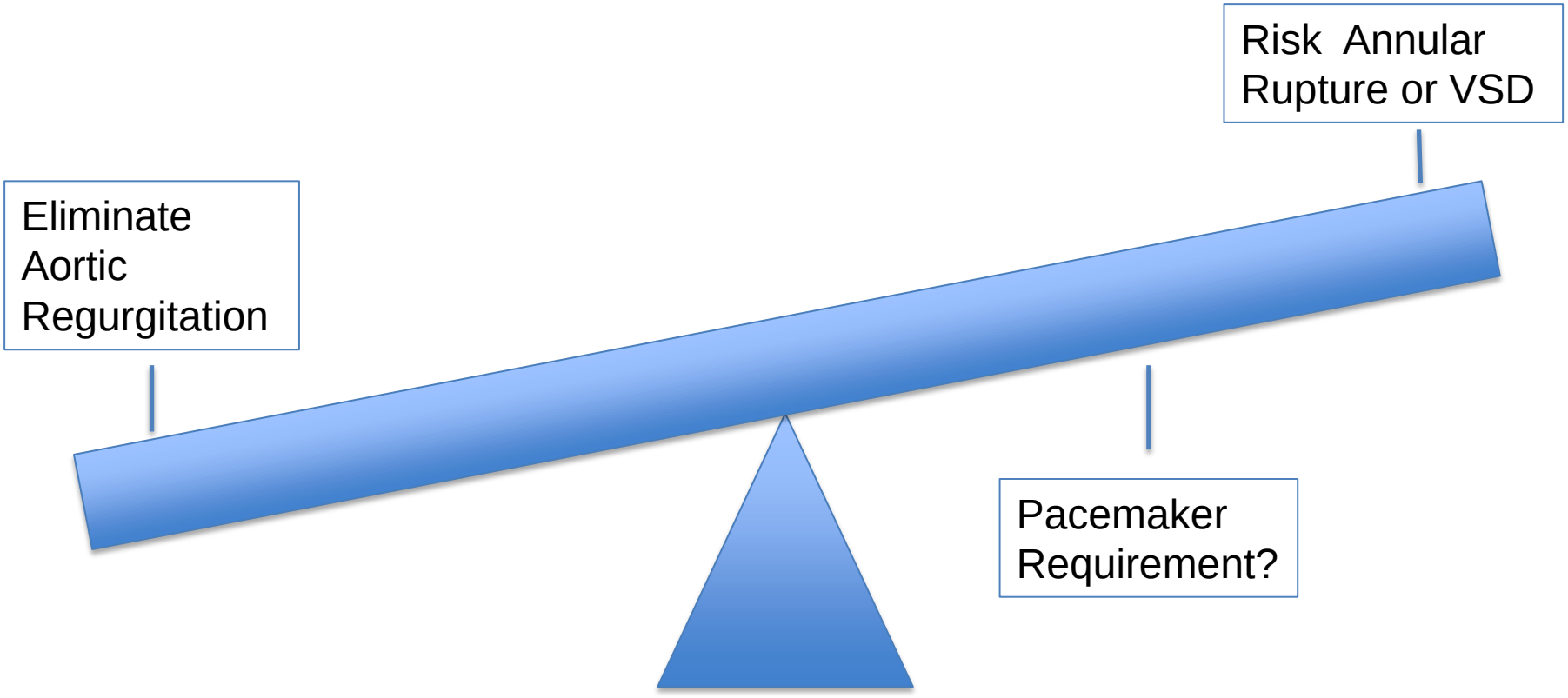

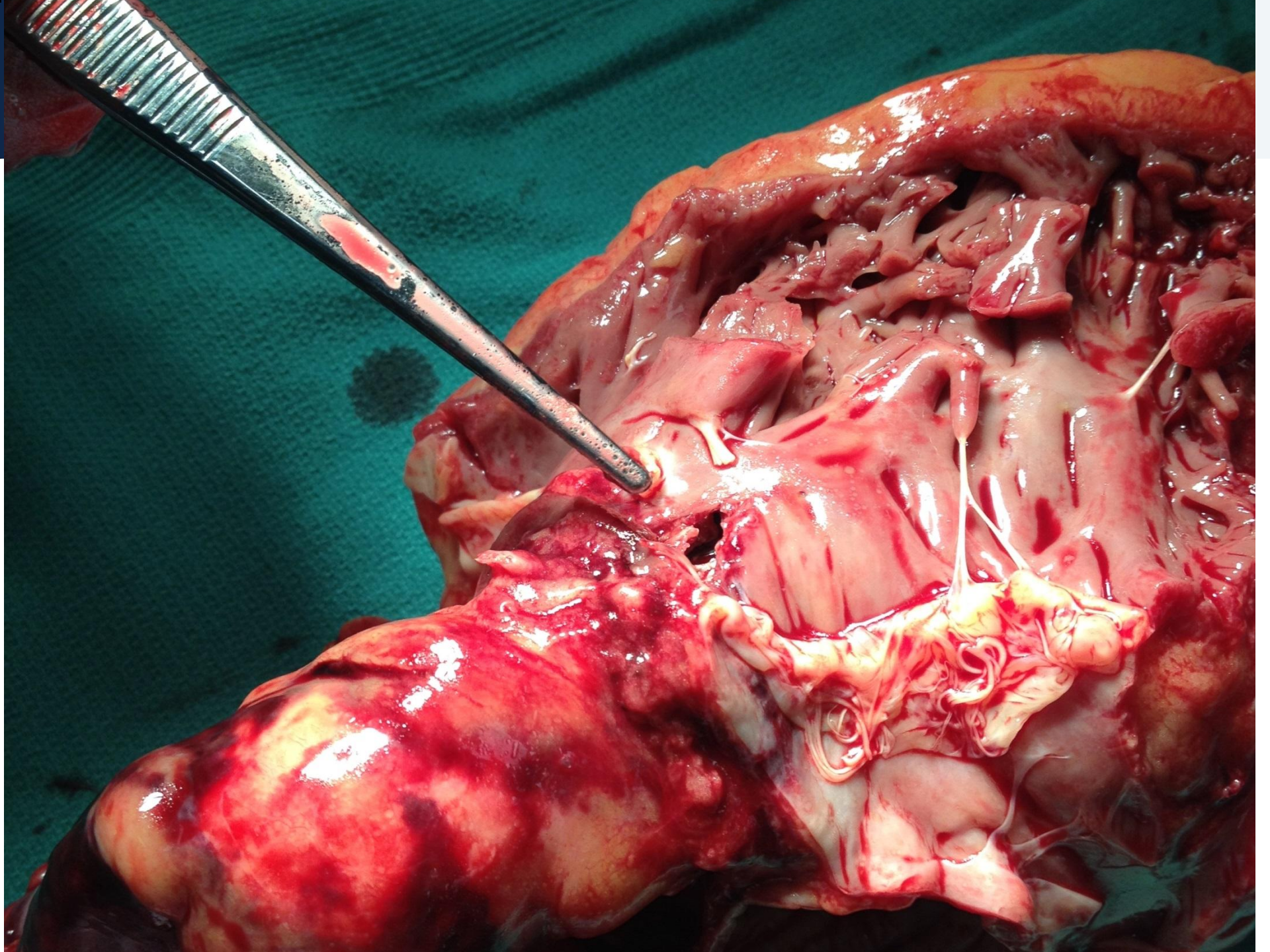

New TAVR Valves

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- ✧Creative approaches to reduce AR
  - – Sealing skirts
  - – Repositionable
- ✧Smaller sheath sizes
- ❖No movement toward larger annulus sizes

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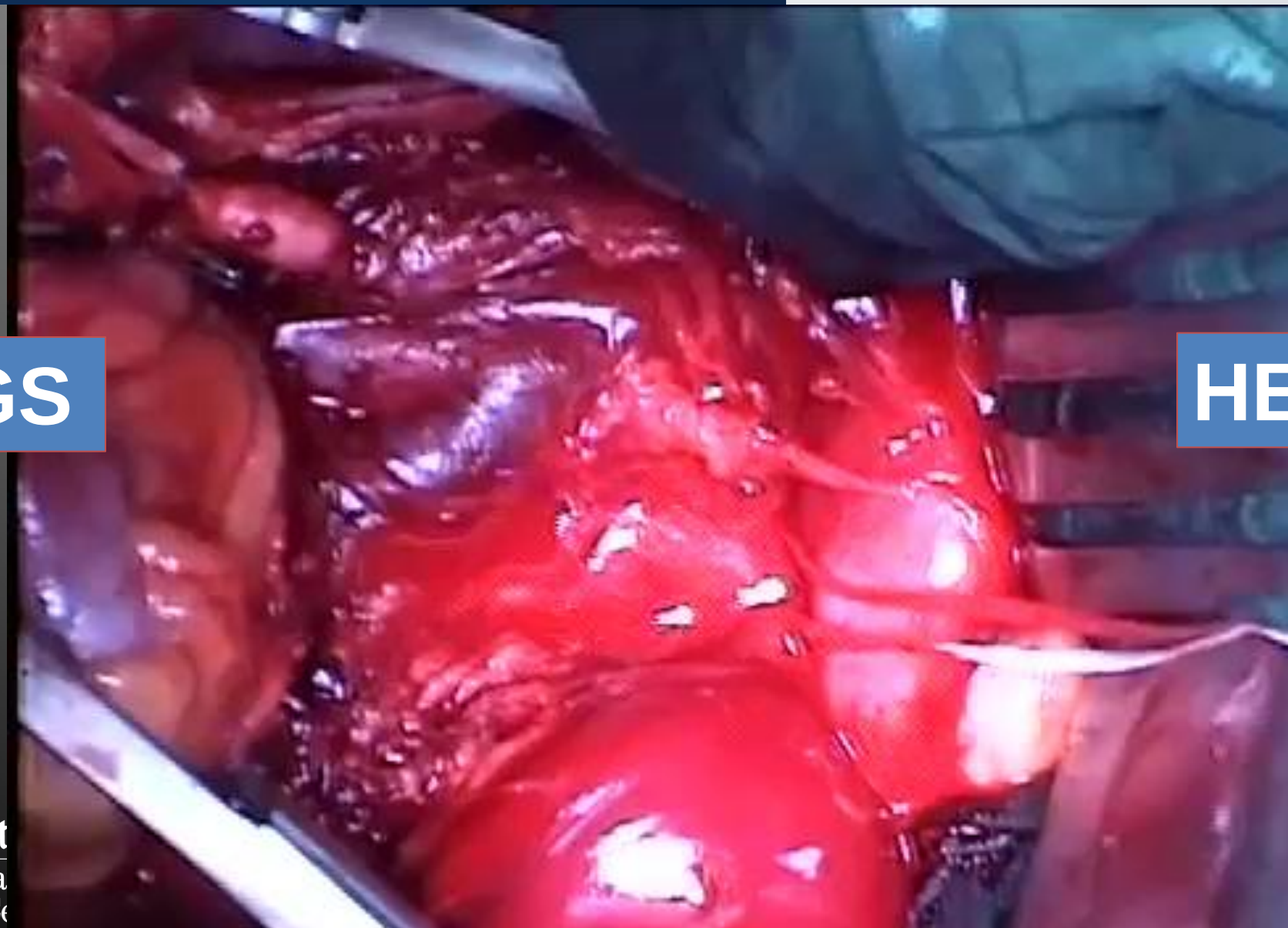

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SAPIEN S3 Valve

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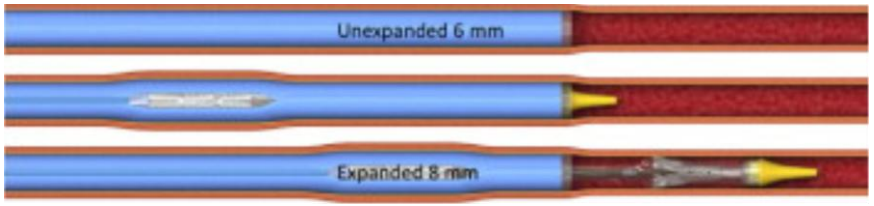

9.7 +/- 6.9 % Oversizing
No AR > Mild

JACC Int.; Mar, 2013

CoreValve Evolut

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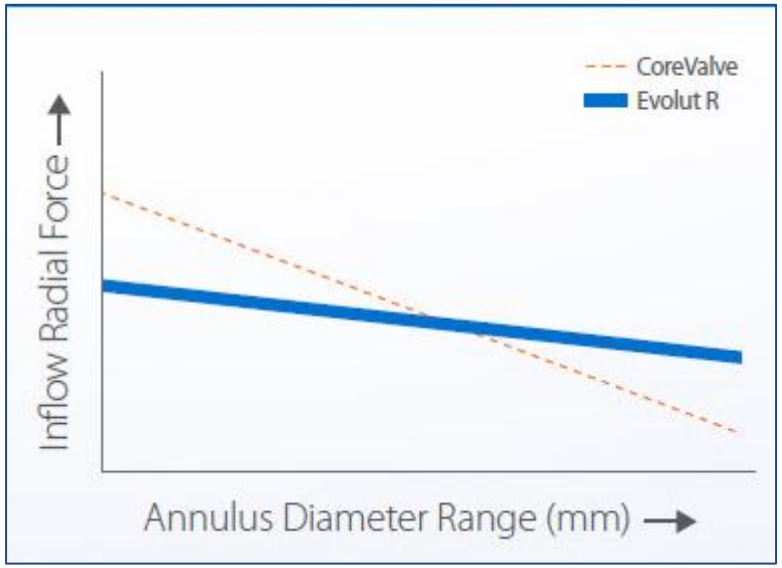

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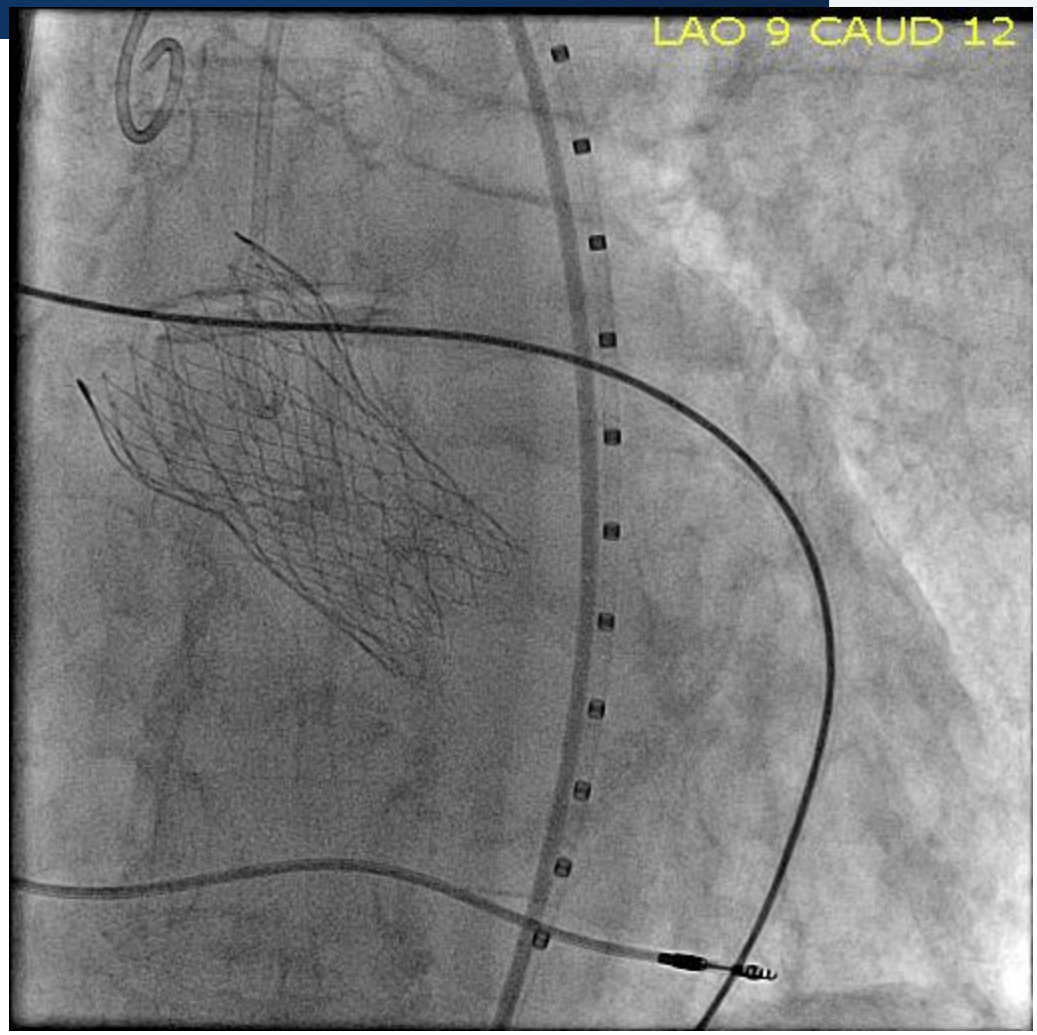

Lotus Valve

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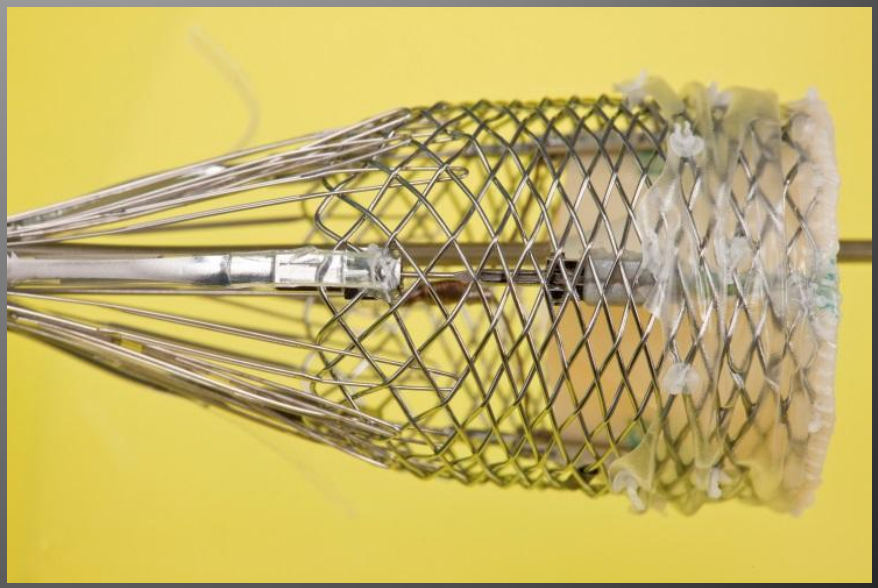

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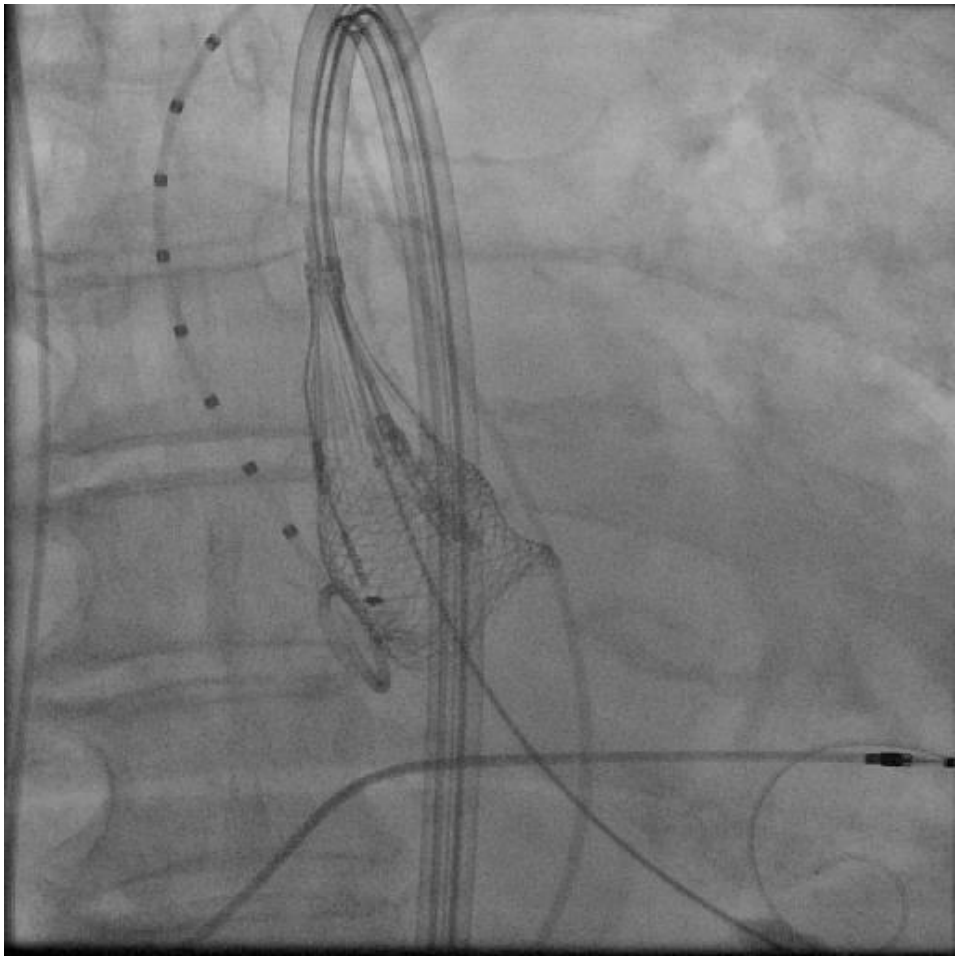
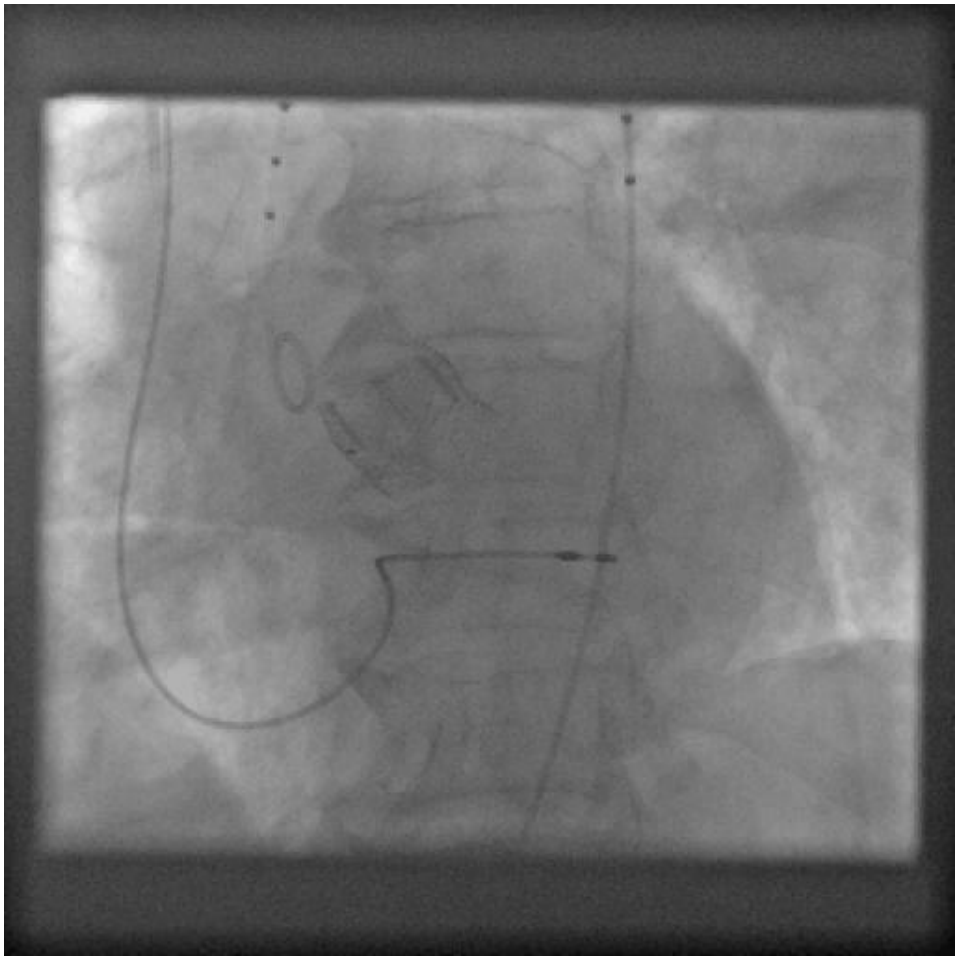
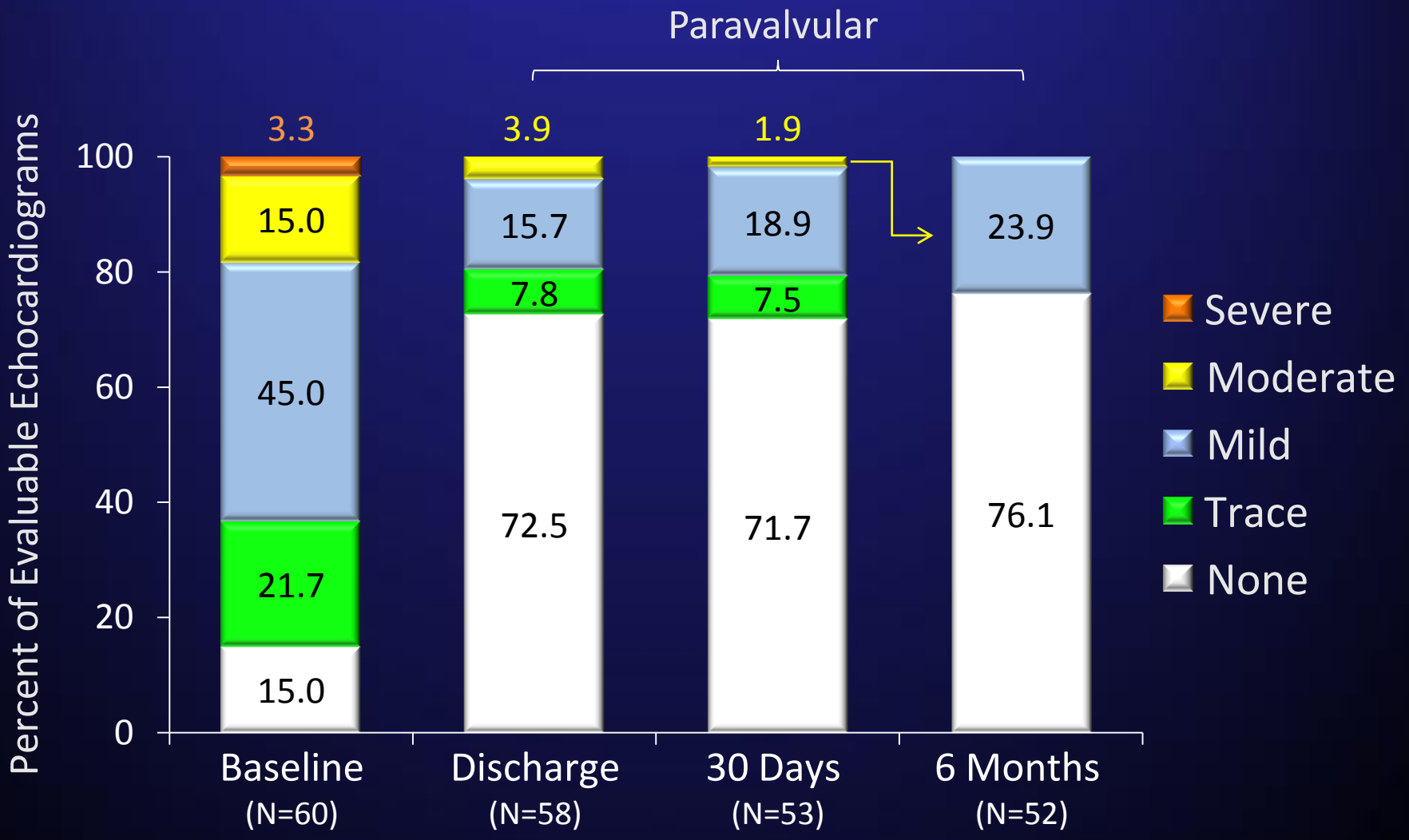




REPRISE II (First 60 Patients)

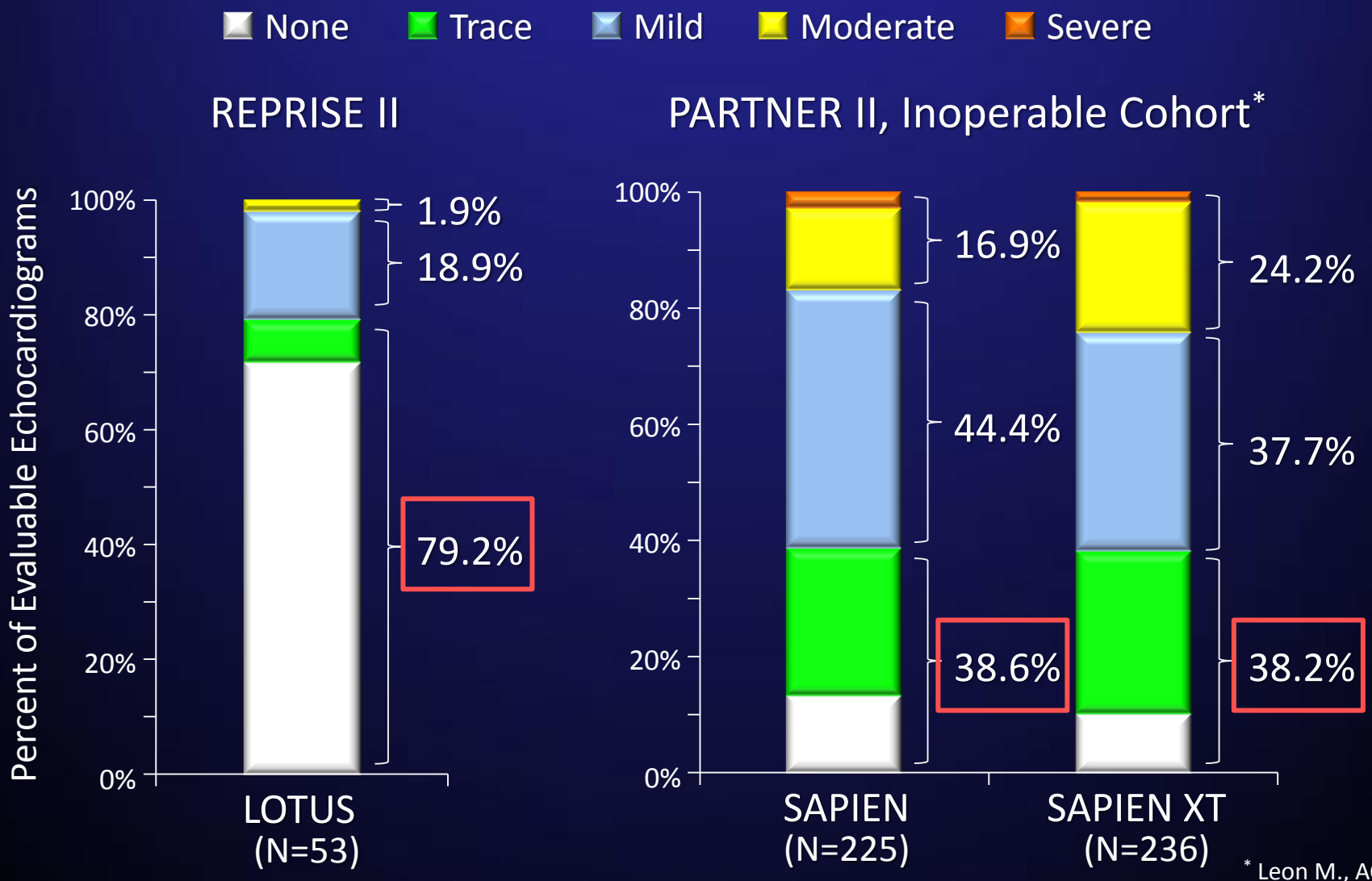
Paravalvular Aortic Regurgitation



No moderate or severe paravalvular aortic regurgitation at 6 months

REPRISE II Comparison with Edwards Valves

Paravalvular Aortic Regurgitation – 30 Days



* Leon M., ACC 2013

30-Day results presented at EuroPCR 2013

Direct Flow Medical: Valve Concept

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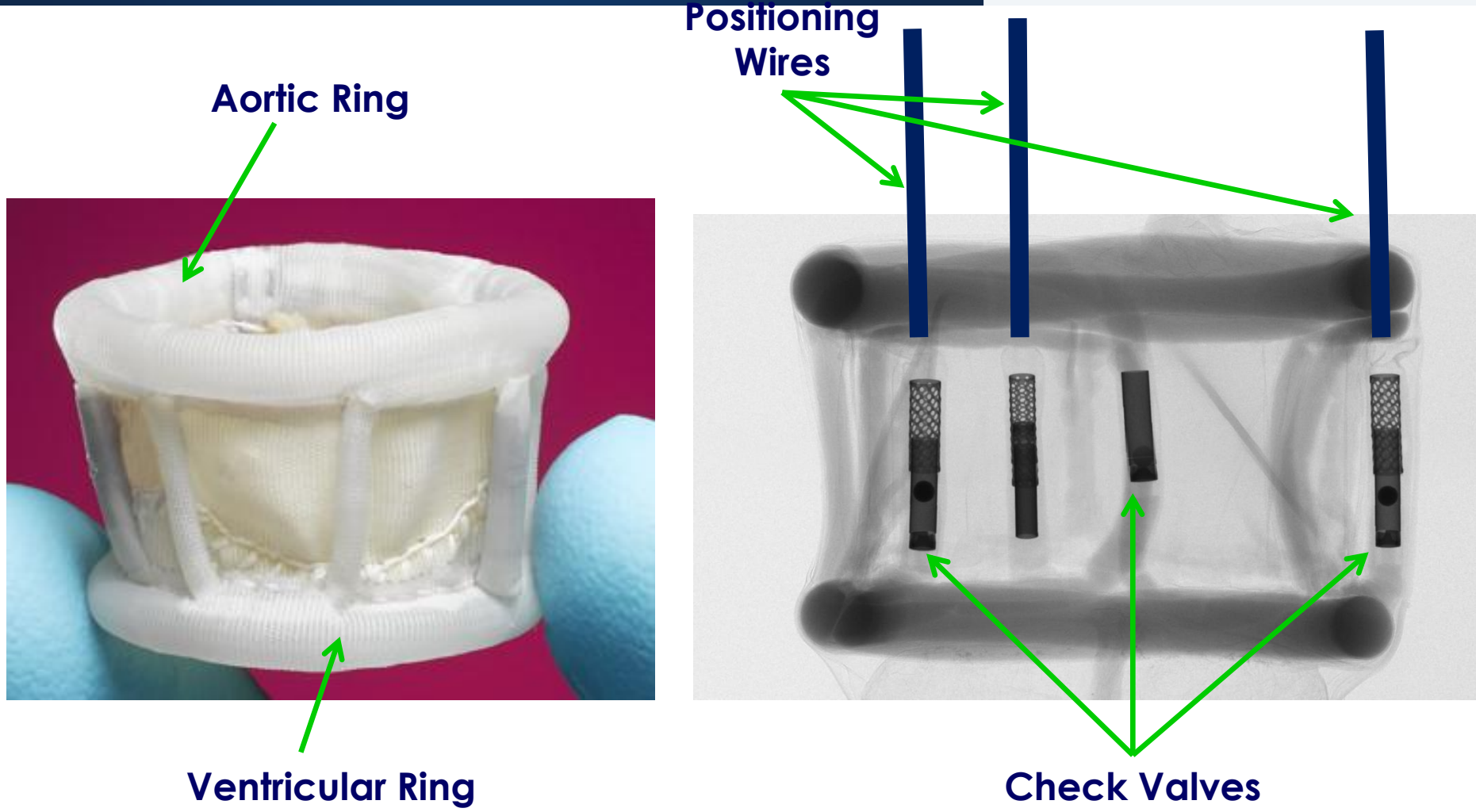

Investigational device not for sale in or outside the United States

2 Year Data *(EU Feasibility Trial)*

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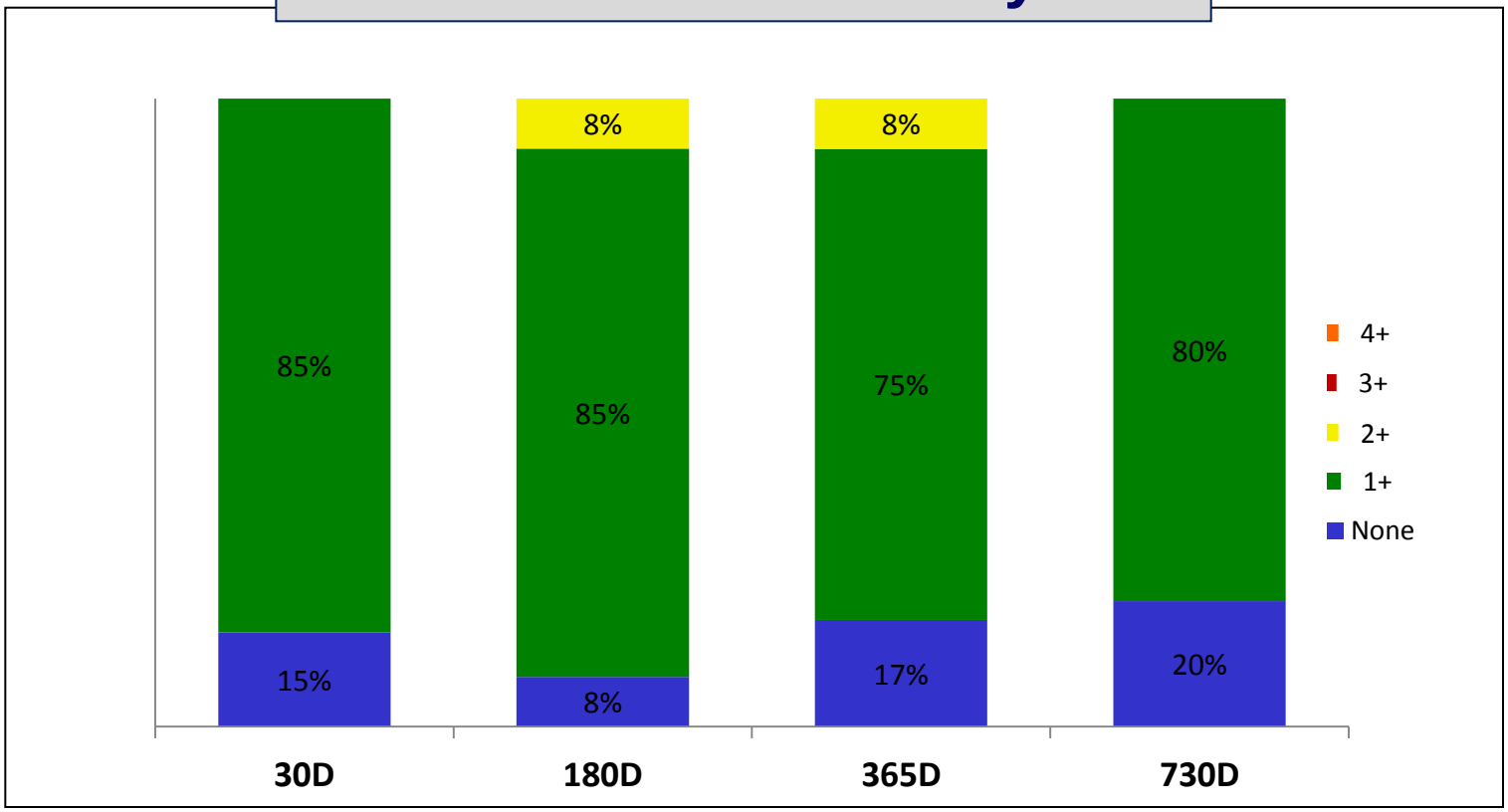
Aortic Insufficiency



* As measured by TTE

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- New Valves
- New patient groups
- Taming stroke
- Becoming mainstream?

Expected Survival After Bioprosthetic SAVR

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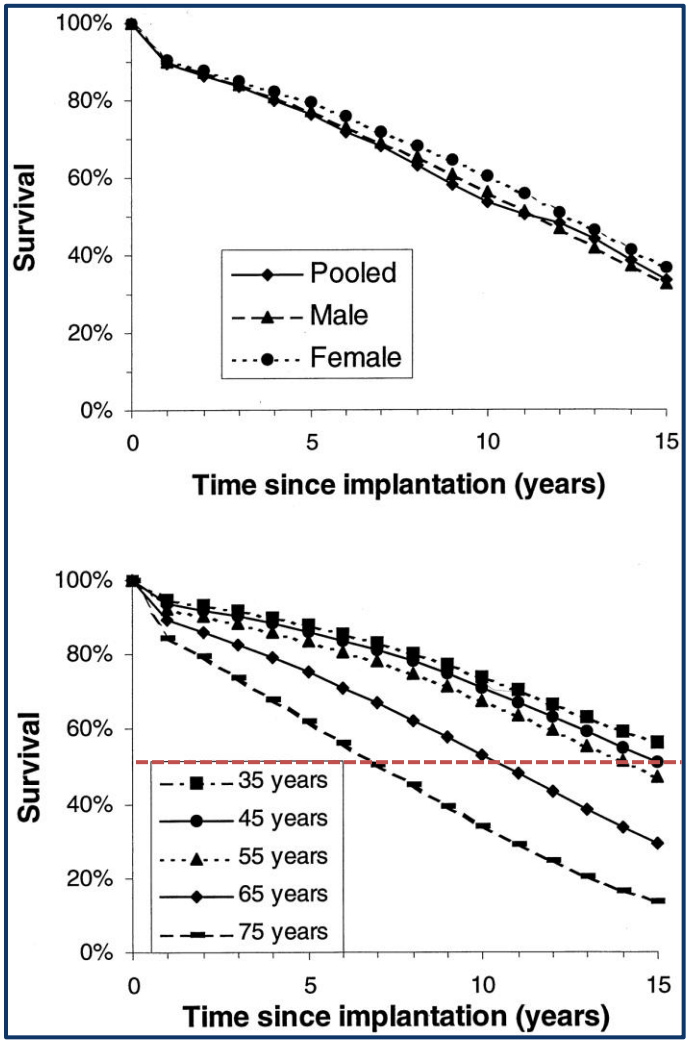
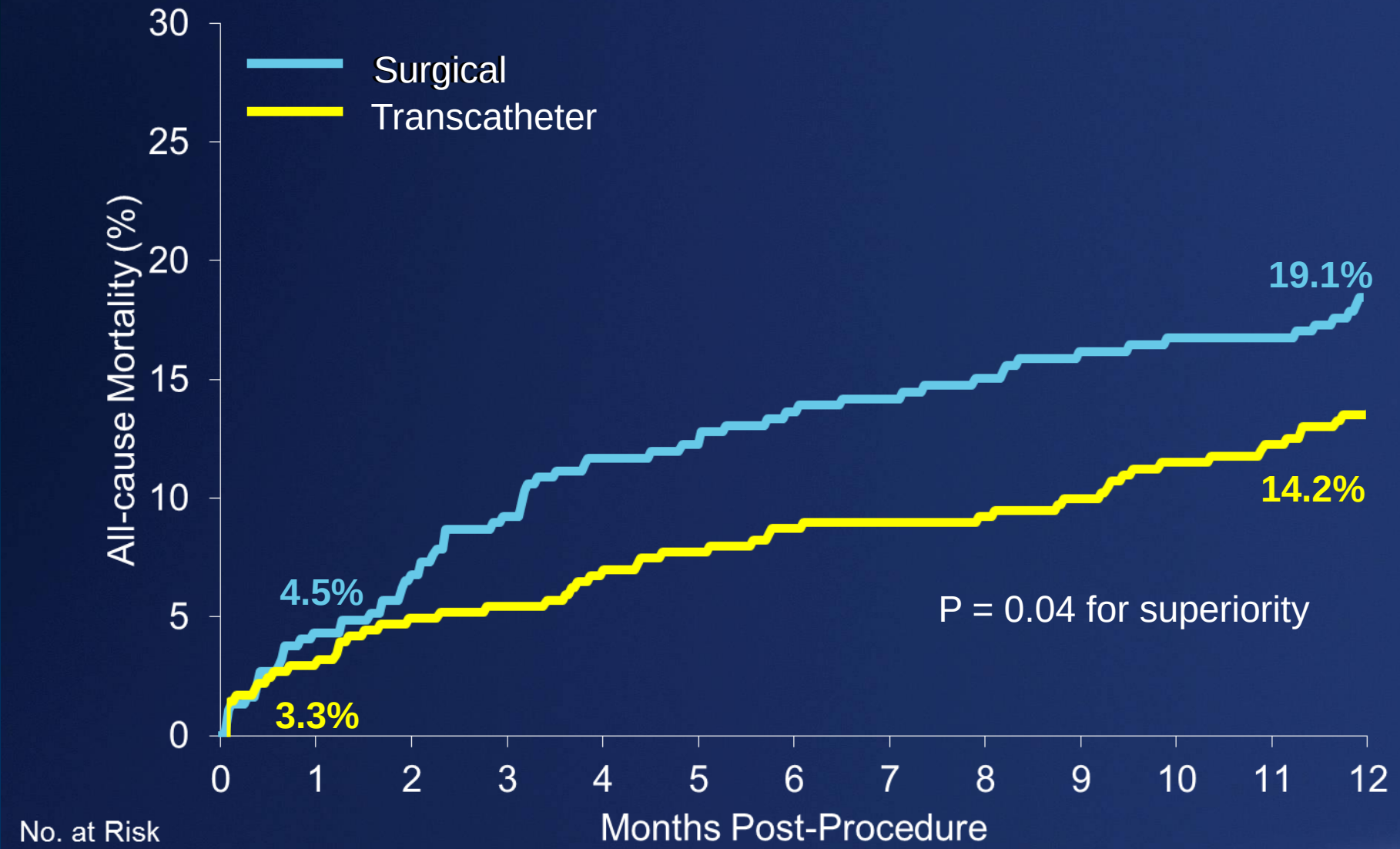
- Meta-analysis of 9 studies
- 5,837 valve recipients with 31,874 years of follow-up
- Standardized definitions of events
- Microsimulation model producing 10,000 life histories



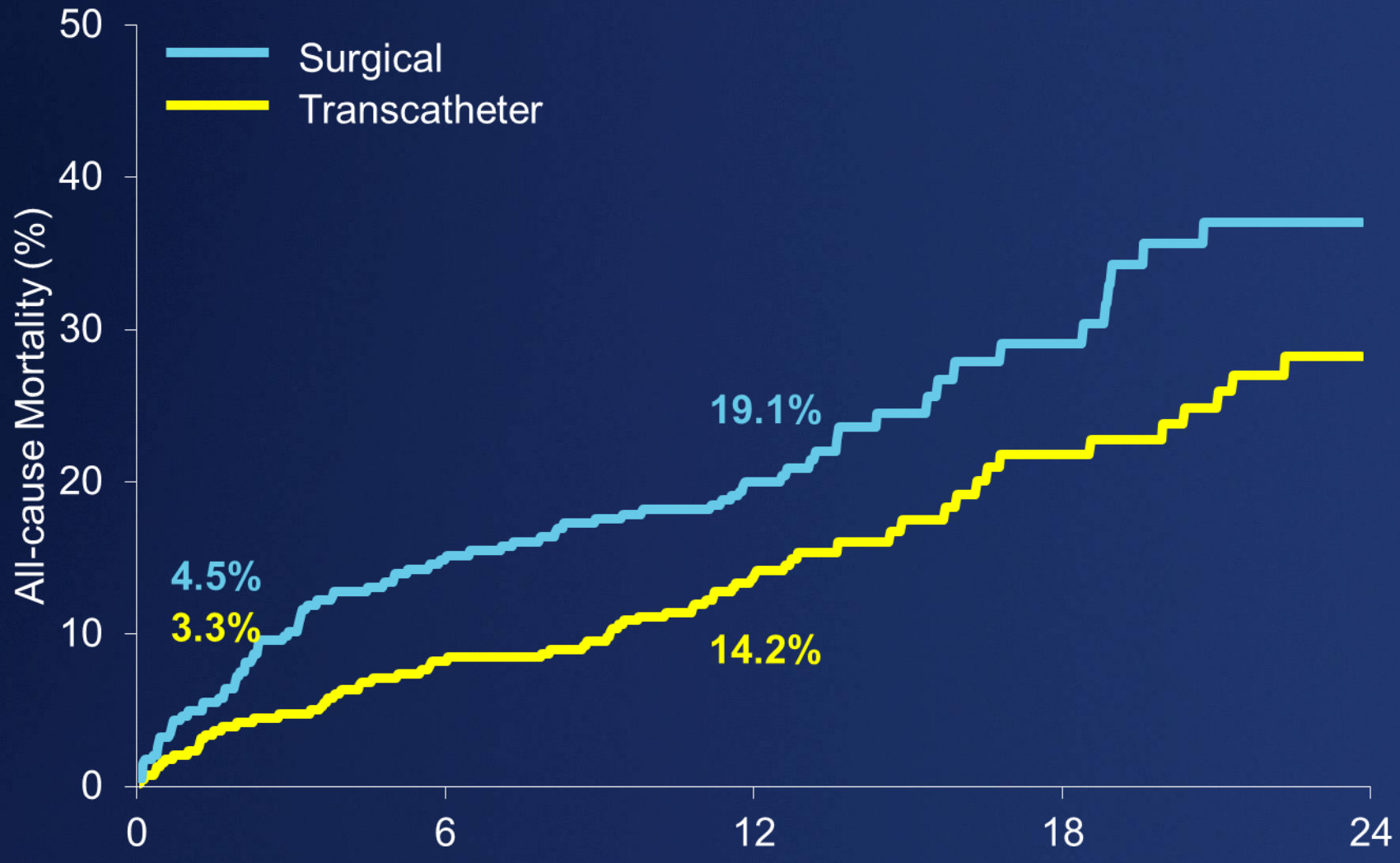
Puvimanasinghe J P A et al. Circulation 2001;103:1535-1541

Primary Endpoint: 1 Year All-cause Mortality



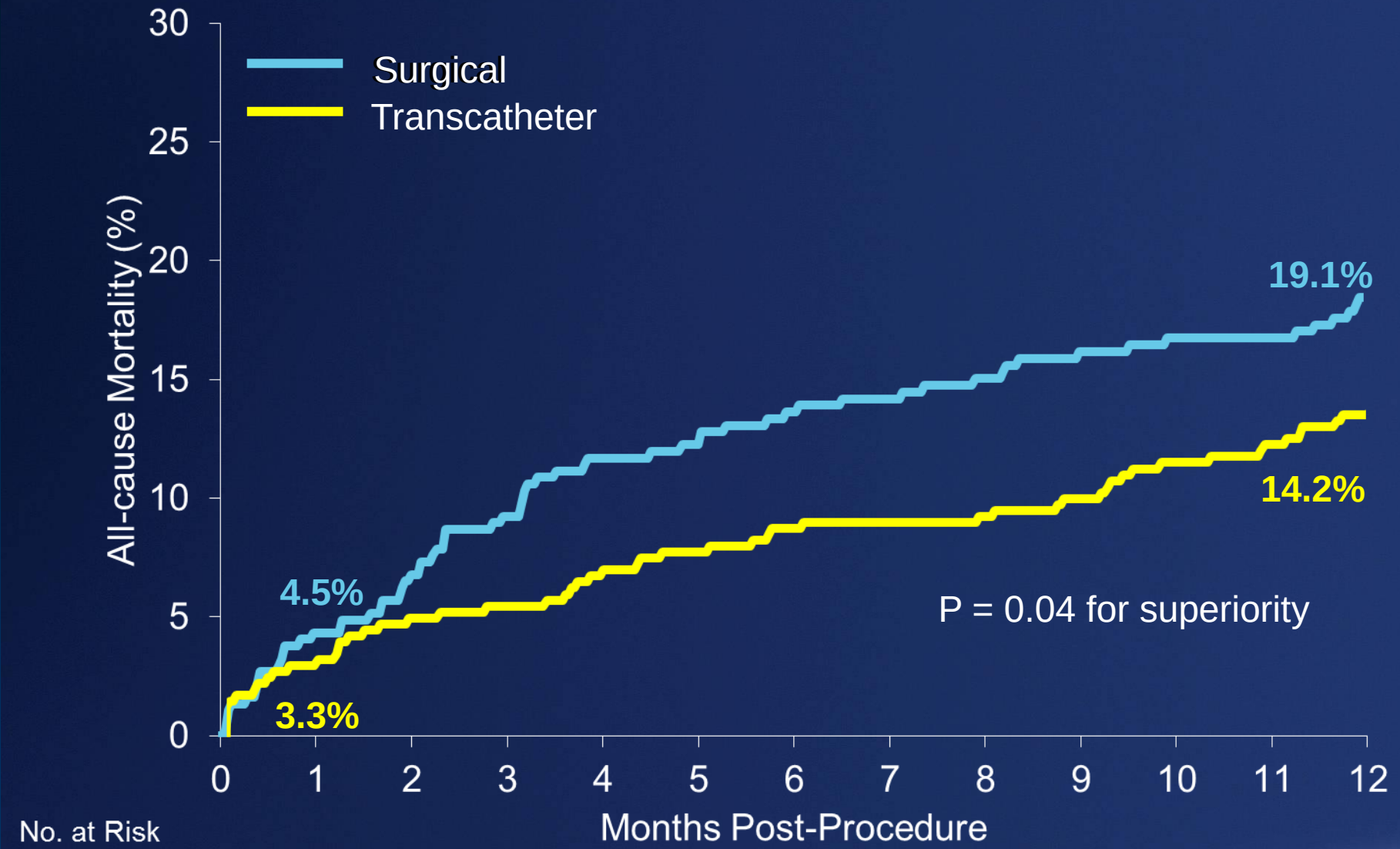
No. at Risk					
Surgical	357	341	297	274	
Transcatheter	390	377	353	329	

2-Year All-cause Mortality



No. at Risk				
Surgical	357	341	274	28
Transcatheter	390	377	329	38

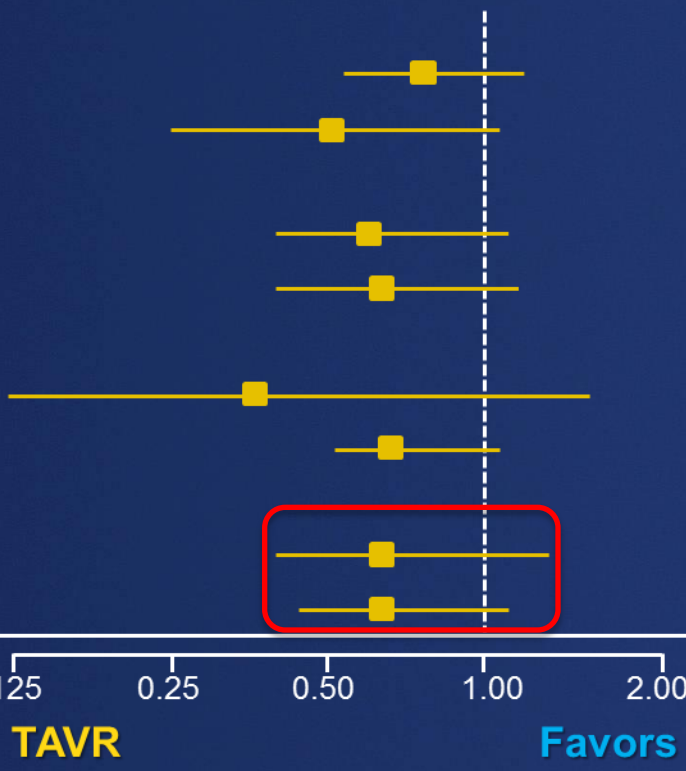
Primary Endpoint: 1 Year All-cause Mortality

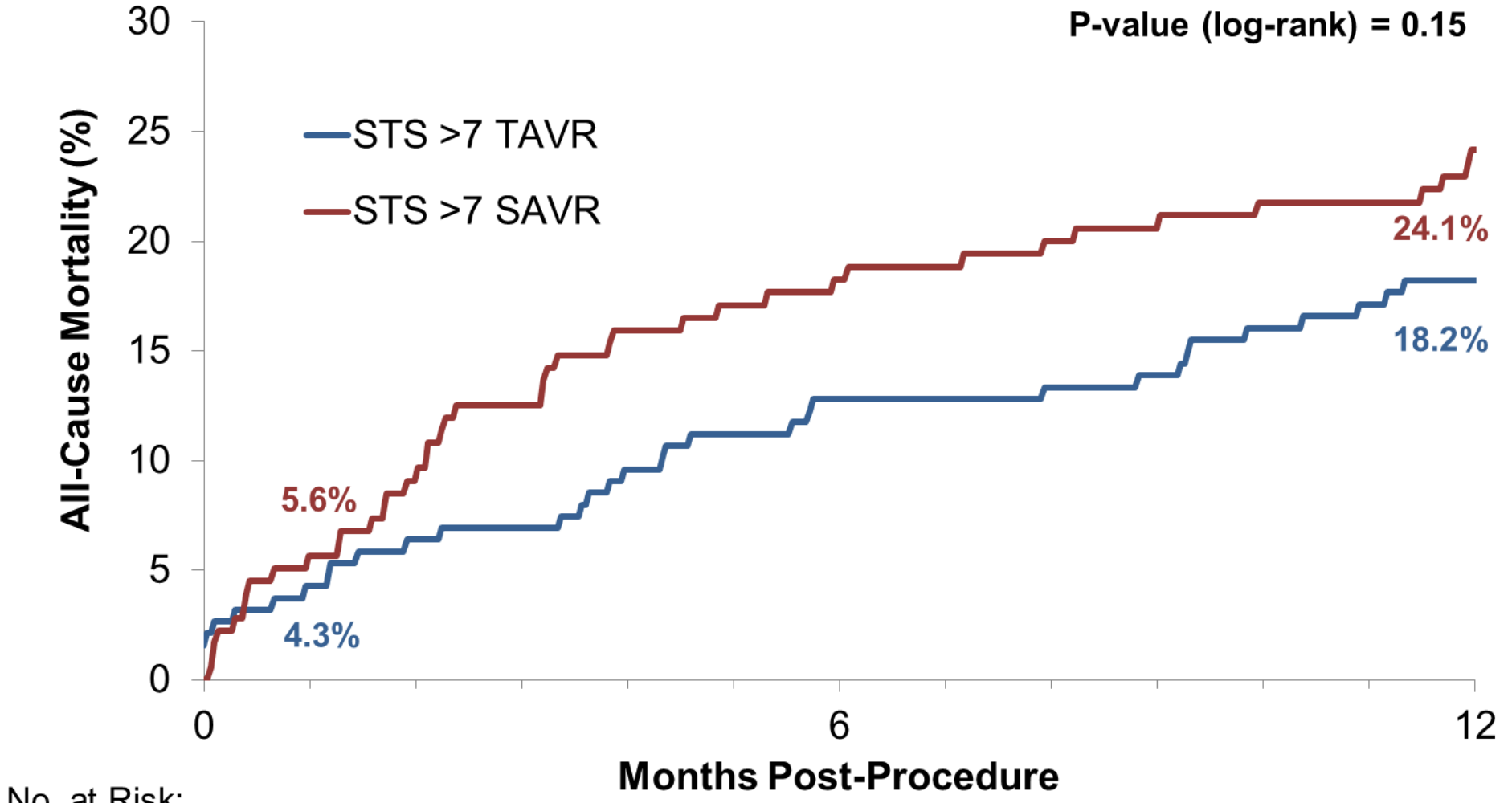


No. at Risk					
Surgical	357	341	297	274	
Transcatheter	390	377	353	329	

Subgroup Analysis for 1 Year Mortality

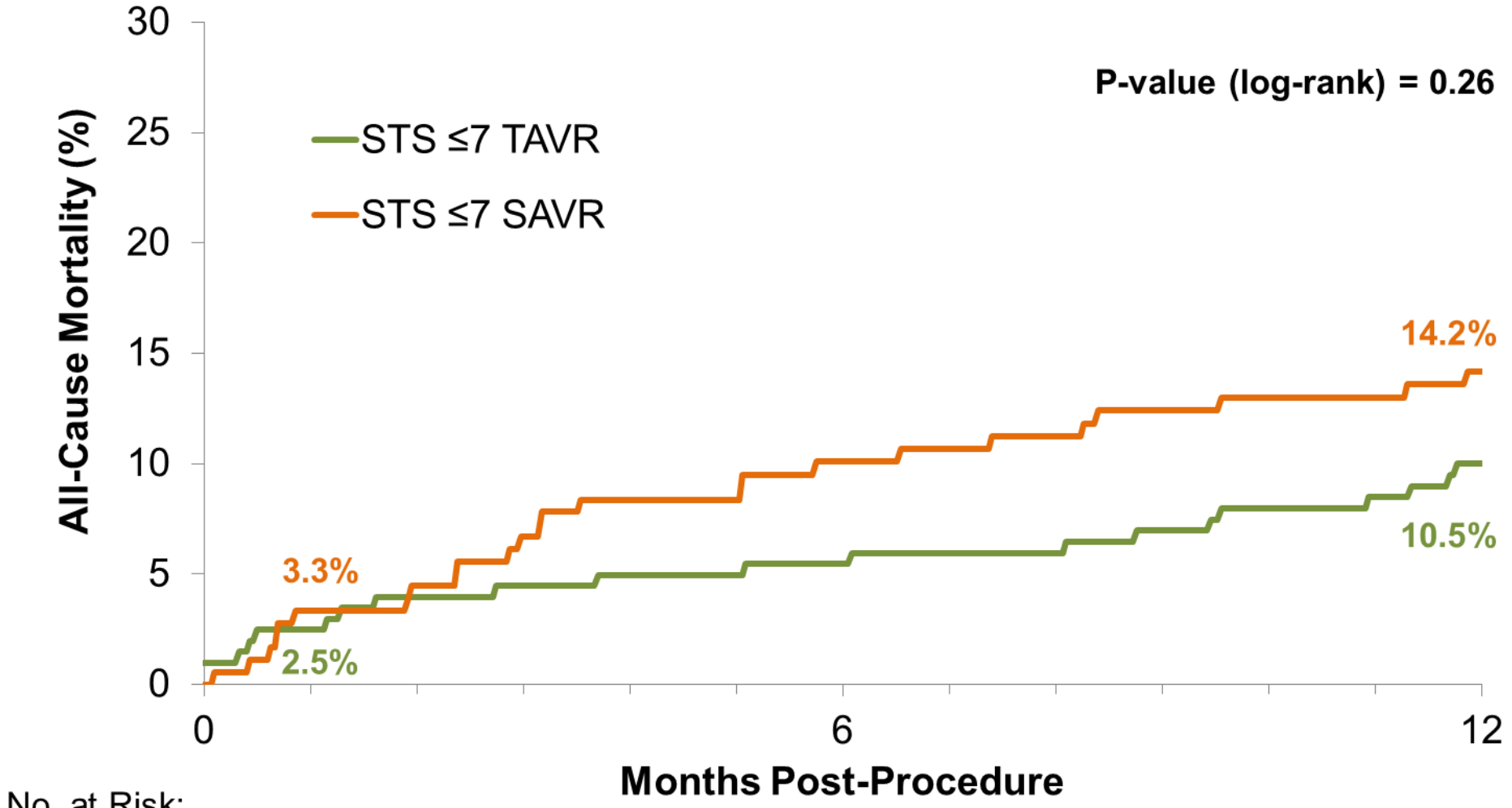
Subgroup	All-cause Death at 1 Year K-M Rates		Hazard Ratios (95% CI)	P Value
	TAVR	SAVR		
Prior CABG				0.27
No	16.2	19.6	0.80 (0.53, 1.21)	
Yes	9.6	18.1	0.50 (0.24, 1.04)	
PVD				0.95
No	12.8	17.8	0.68 (0.42, 1.11)	
Yes	15.3	21.2	0.70 (0.41, 1.19)	
Hypertension				0.35
No	15.8	36.5	0.37 (0.09, 1.54)	
Yes	14.1	18.4	0.74 (0.51, 1.07)	
STS Score				>0.99
≤7%	10.5	14.2	0.72 (0.40, 1.29)	
>7%	18.2	24.1	0.72 (0.46, 1.13)	





No. at Risk:

TAVR	188	163	151
SAVR	177	140	128



No. at Risk:

TAVR	202	190	178
SAVR	180	157	146

Original Investigation

Outcomes Following Transcatheter Aortic Valve Replacement in the United States

Michael J. Mack, MD; J. Matthew Brennan, MD, MPH; Ralph Brindis, MD, MPH; John Carroll, MD; Fred Edwards, MD; Fred Grover, MD; David Shahian, MD; E. Murat Tuzcu, MD; Eric D. Peterson, MD, MPH; John S. Rumsfeld, MD, PhD; Kathleen Hewitt, MSN; Cynthia Shewan, PhD; Joan Michaels, RN; Barb Christensen, RN; Alexander Christian; Sean O'Brien, PhD; David Holmes, MD; for the STS/ACC TVT Registry

IMPORTANCE Transcatheter aortic valve replacement (TAVR) was approved by the US Food and Drug Administration for the treatment of severe, symptomatic aortic stenosis and inoperable status (in 2011) and high-risk but operable status (starting in 2012). A national registry (the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy [STS/ACC TVT] Registry) was initiated to meet a condition for Medicare coverage and also facilitates outcome assessment and comparison with other trials and international registries.

OBJECTIVE To report the initial US commercial experience with TAVR.

DESIGN, SETTING, AND PARTICIPANTS We obtained results from all eligible US TAVR cases (n=7710) from 224 participating registry hospitals following the Edwards Sapien device commercialization (November 2011–May 2013).

Editorial page 2045

Author Video Interview at jama.com

Supplemental content at jama.com

TAVR implantation un the US: TVT Registry

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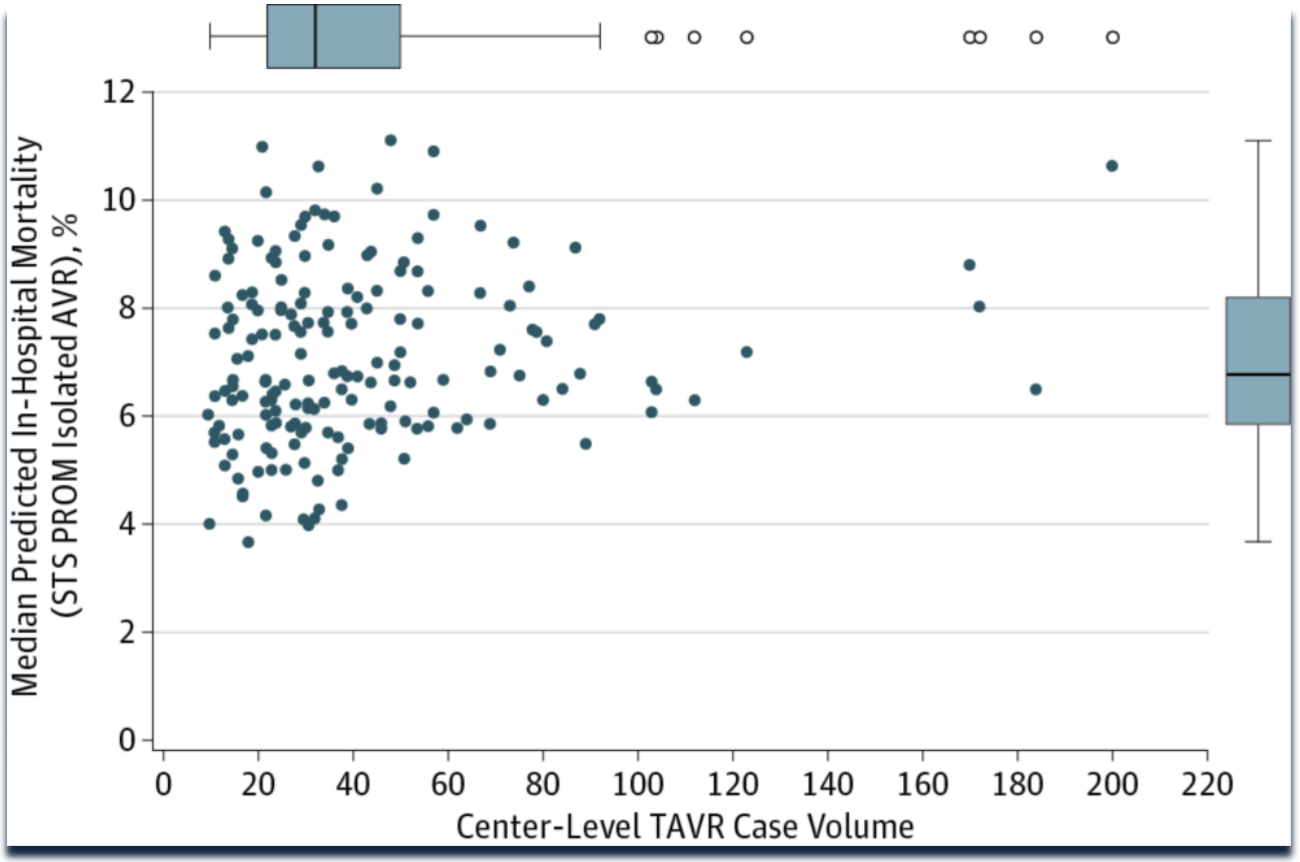
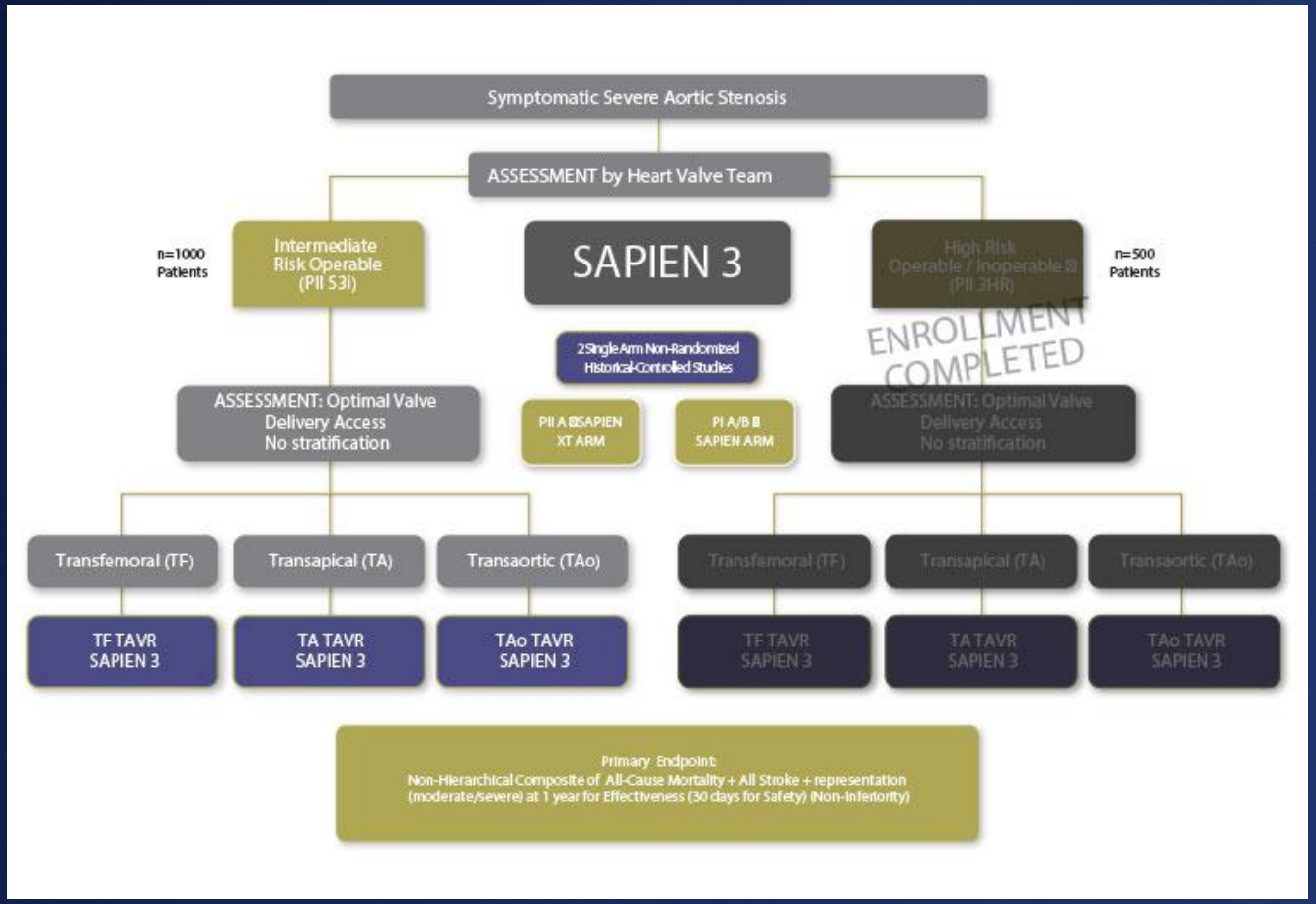


JAMA. 2013;310(19):2069-2077. doi:10.1001/jama.2013.282043

PARTNER IIA Trial



CoreValve® SURTAVI Trial