Considering SAVR in the TAVR era: Surgical Implications of TAVR

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ACC Evolving Valve Management Strategies Roundtable
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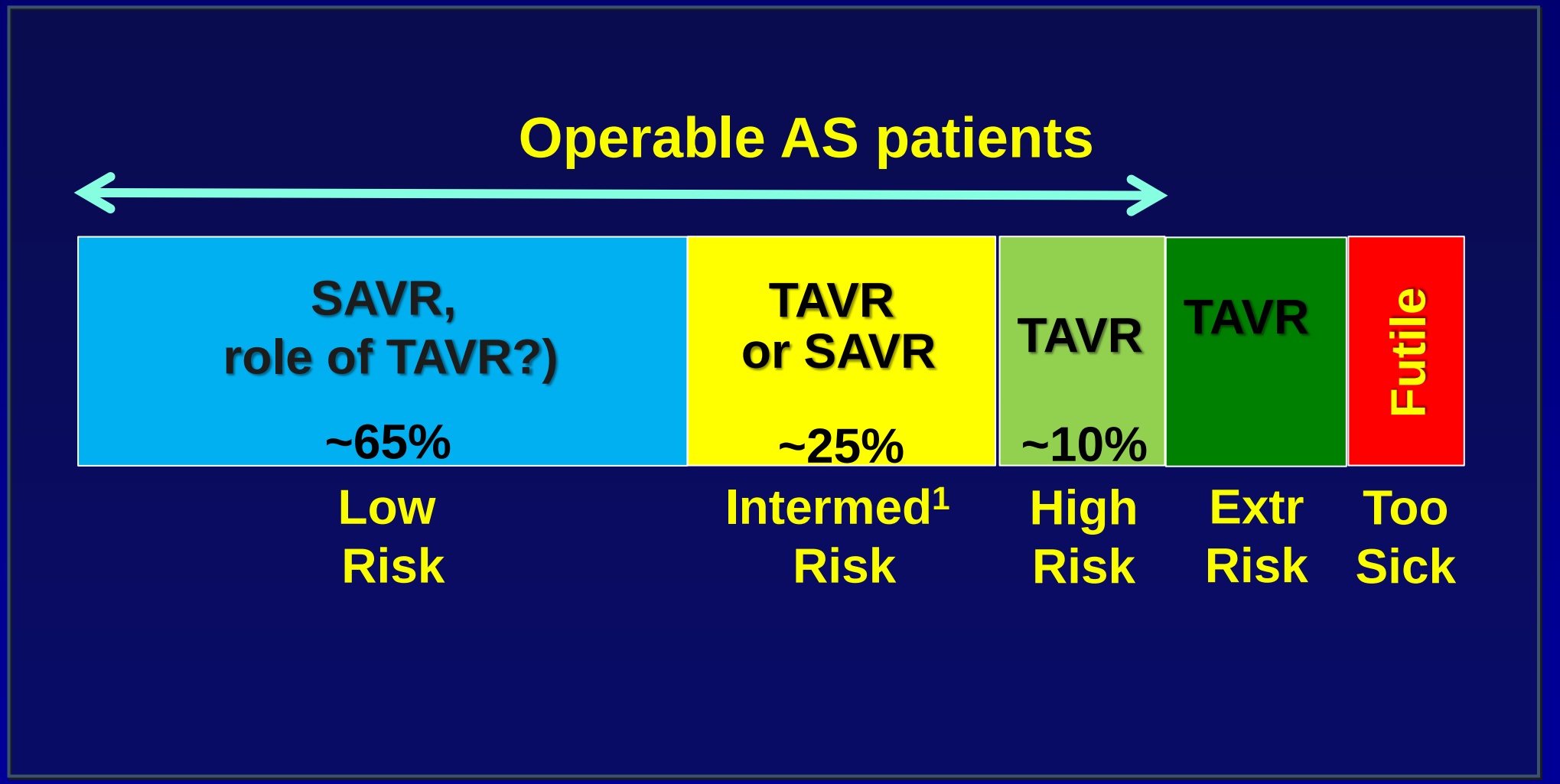
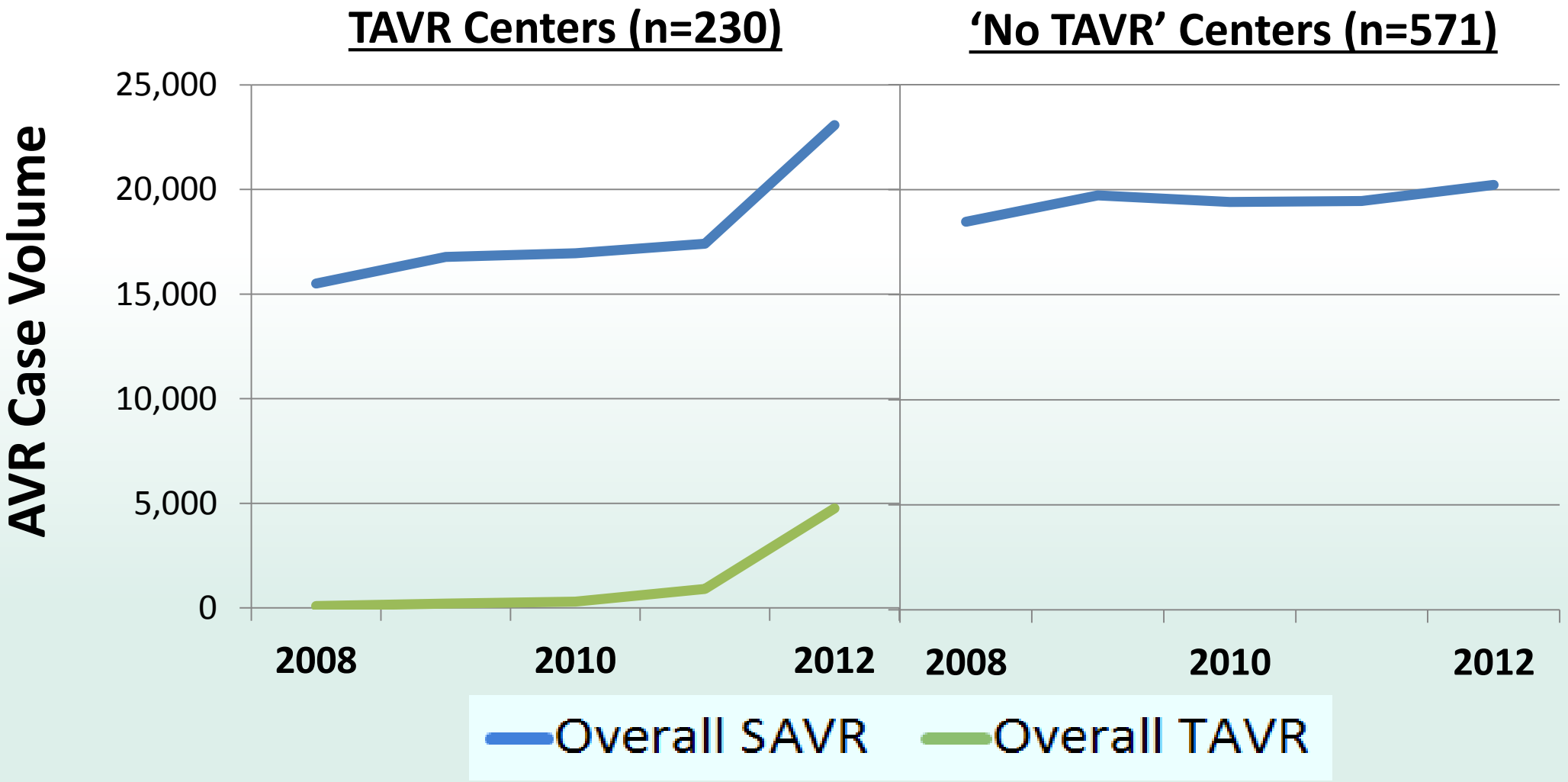
Disclosures

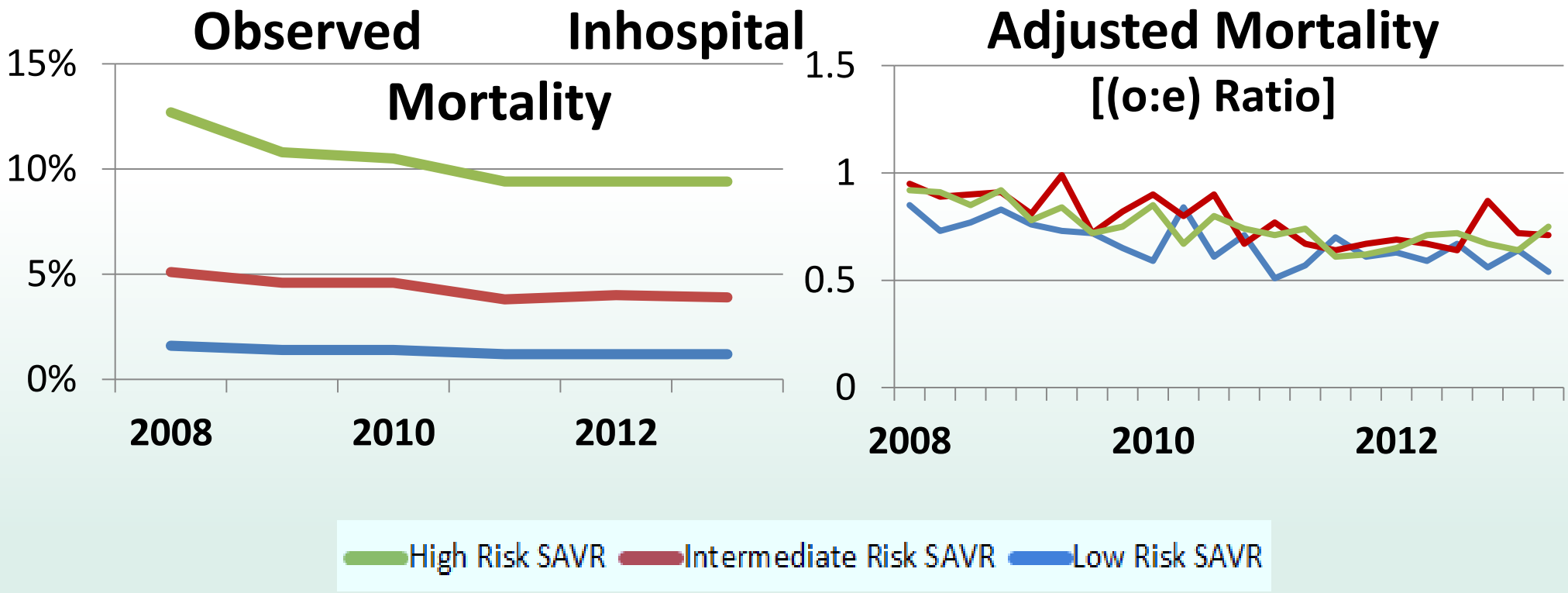
- **Edwards Lifesciences**
  - **Emory Co-PI: PARTNER 1 and 2**
  - **National Co-PI: PARTNER 2 (SAPIEN 3 Trial) with Dr. Susheel Kodali**
- **St. Jude Medical**
  - **Emory PI Portico Trial, Structural Heart Advisory board**
- **Boston Scientific**
  - **Emory PI: REPRISE Trial**
  - **Advisory Board, Executive Comm (Lotus Valve Trial)**
- **Medtronic**
  - **Emory PI: SURTAVI Trial**
- **Jenavalve**
  - **National Co-PI with Drs. Martin Leon and Susheel Kodali**
- **Abbott Medical**
  - **Emory Co-PI: Coapt Trial**
- **Apica Cardiovascular**
  - **IP, co-founder**

TAVR 2015

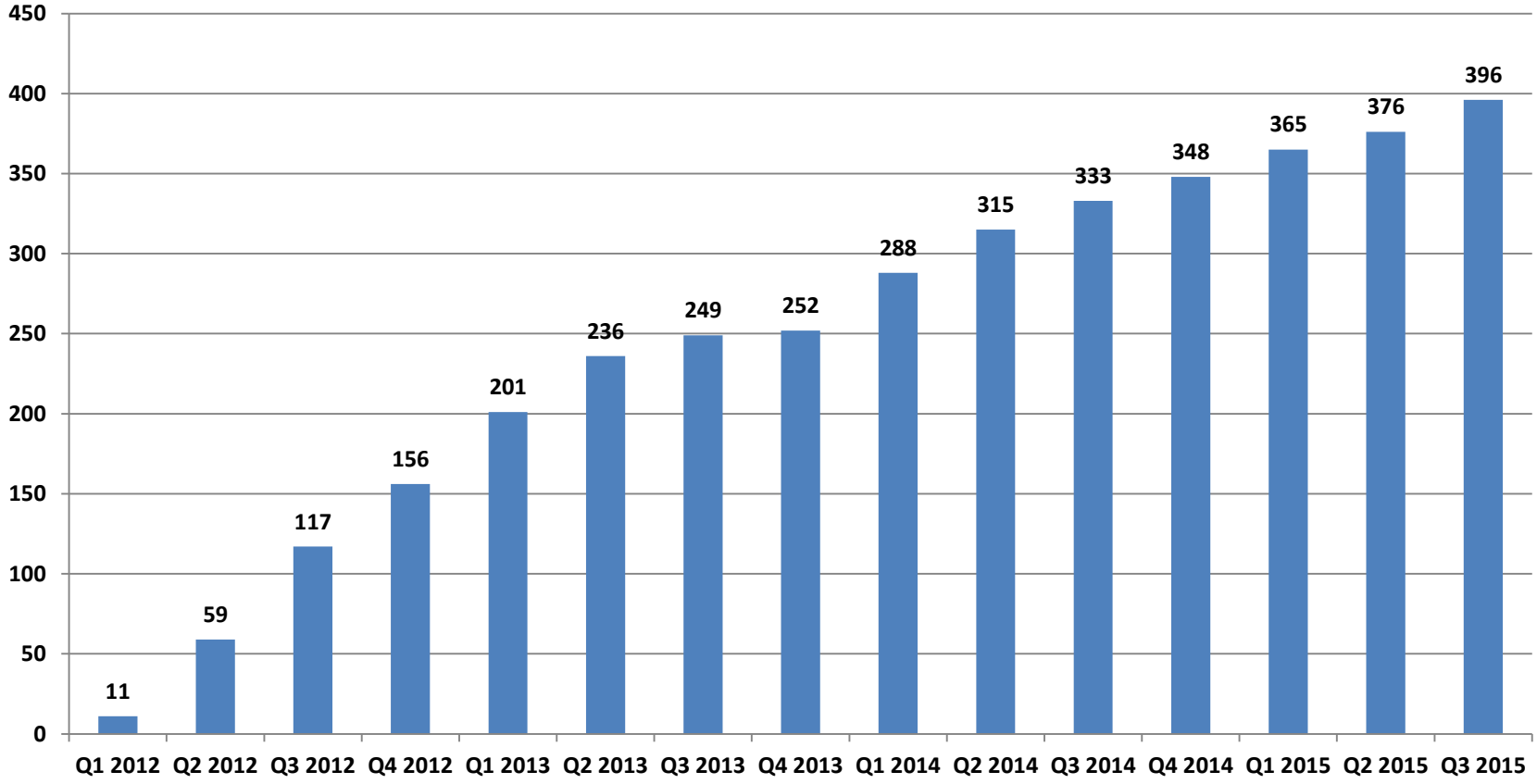


1. Open IDE studies for intermediate risk indication


TAVR Centers (n=230)
'No TAVR' Centers (n=571)
AVR Case Volume
25,000
20,000
15,000
10,000
5,000
0
2008
2010
2012
2008
2010
2012
Overall SAVR
Overall TAVR


Observed Inhospital Mortality
15%
10%
5%
0%
2008
2010
2012
Adjusted Mortality [(o:e) Ratio]
1.5
1
0.5
0
2008
2010
2012
High Risk SAVR
Intermediate Risk SAVR
Low Risk SAVR

Cumulative TVT Sites
2012 to September 2015



STS National Database™
Using data to drive quality

NCDR®
NATIONAL CARDIOVASCULAR DATA REGISTRY

Effect of Availability of Transcatheter Aortic-Valve Replacement on Clinical Practice

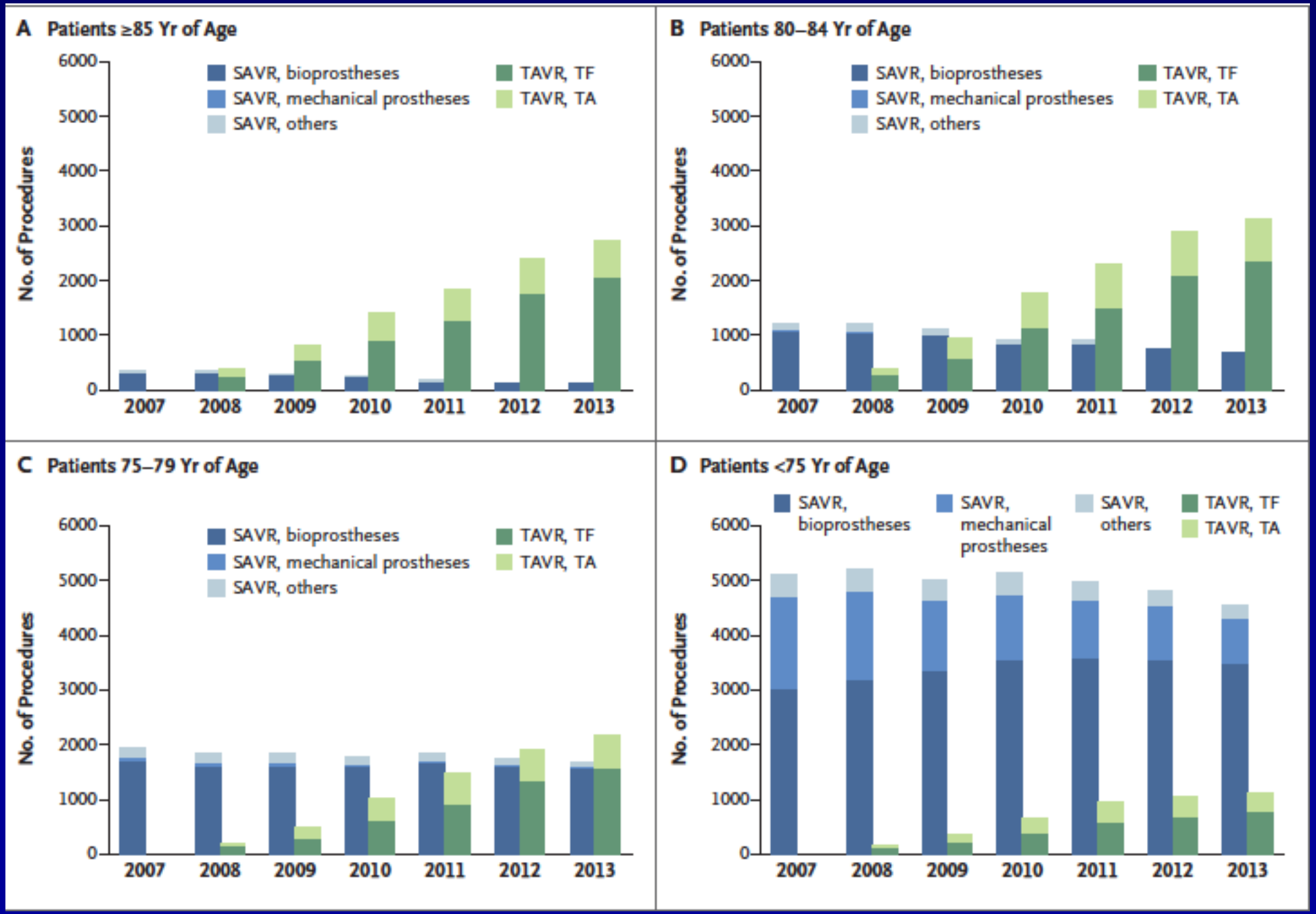
Jochen Reinöhl, M.D., Klaus Kaier, Ph.D., Holger Reinecke, M.D., Claudia Schmoor, Ph.D., Lutz Frankenstein, M.D., Werner Vach, Ph.D., Alain Cribier, M.D., Friedhelm Beyersdorf, M.D., Christoph Bode, M.D., and Manfred Zehender, M.D., Ph.D.

Reinöhl J, et al. NEJM. 2015; 373:2438

Table 1. Numbers of Surgical Aortic-Valve Replacement (SAVR) and Transcatheter Aortic-Valve Replacement (TAVR) Procedures, According to Year.*

Procedure	2007	2008	2009	2010	2011	2012	2013	Total
SAVR								
Total — no. (frequency)†	8622 (10.5)	8603 (10.5)	8259 (10.1)	8109 (9.9)	7899 (9.7)	7452 (9.1)	7048 (8.7)	55,992 (9.8)
Bioprostheses — no. (%)	6128 (71.1)	6196 (72.0)	6284 (76.1)	6266 (77.3)	6296 (79.7)	6050 (81.2)	5838 (82.8)	43,058 (76.9)
Mechanical prostheses — no. (%)	1810 (21.0)	1708 (19.8)	1333 (16.1)	1228 (15.1)	1104 (14.0)	1013 (13.6)	847 (12.0)	9,038 (16.1)
Other prostheses — no. (%)‡	689 (8.0)	712 (8.3)	645 (7.8)	621 (7.7)	505 (6.4)	391 (5.2)	365 (5.2)	3,928 (7.0)
TAVR								
Total — no. (frequency)†	144 (0.2)	1122 (1.4)	2599 (3.2)	4806 (5.9)	6523 (8.0)	8240 (10.1)	9147 (11.3)	32,581 (5.7)
Transfemoral — no. (%)	NA	825 (73.5)	1618 (62.3)	3051 (63.5)	4283 (65.7)	5881 (71.4)	6794 (74.3)	22,452 (68.9)
Transapical — no. (%)	NA	302 (26.9)	986 (37.9)	1772 (36.9)	2253 (34.5)	2363 (28.7)	2367 (25.9)	10,043 (30.8)
All procedures — no.	8766	9725	10,858	12,915	14,422	15,692	16,195	88,573

Reinöhl J, et al. NEJM. 2015; 373:2438



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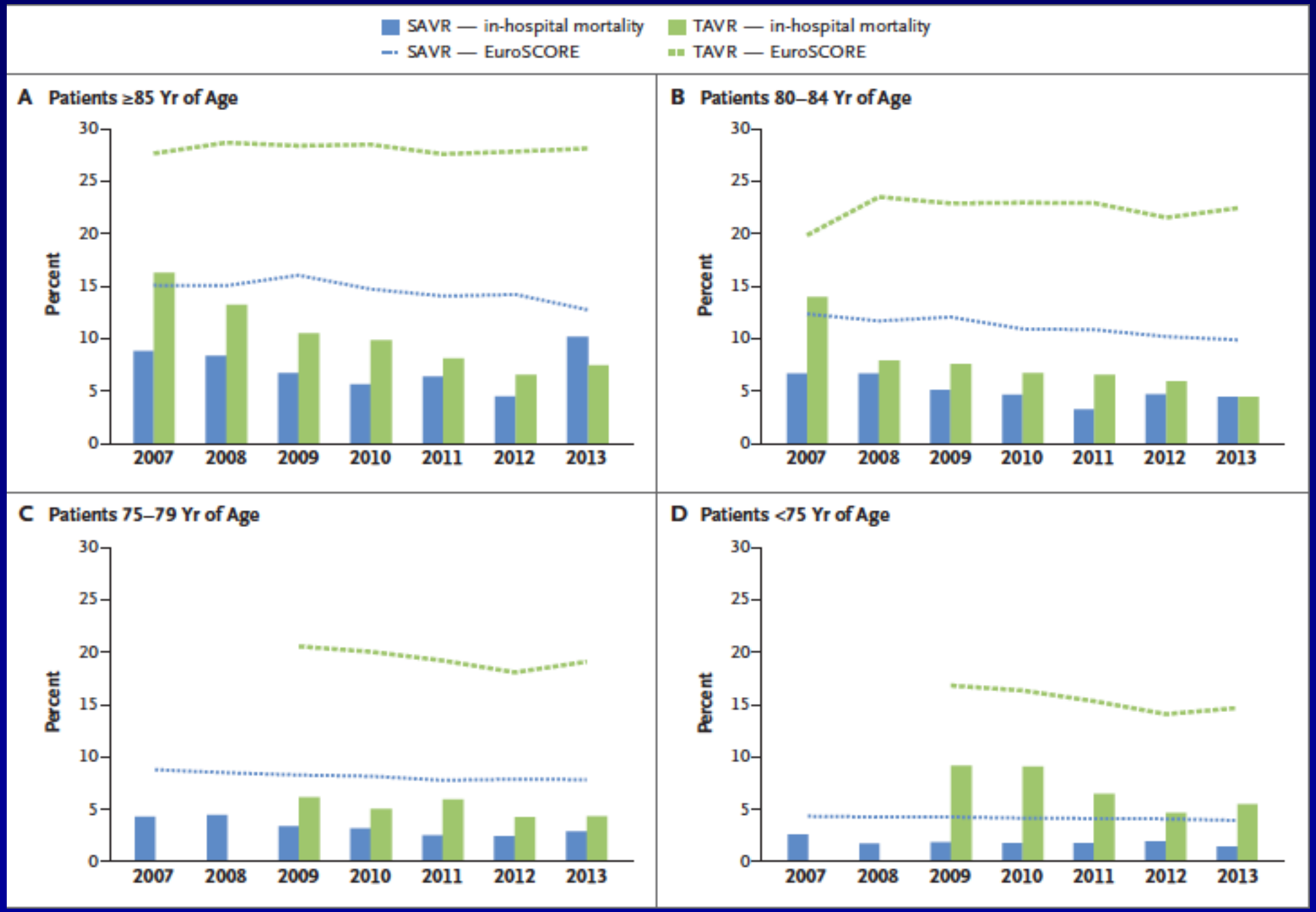


Reinöhl J, et al. NEJM. 2015; 373:2438

Evolution of the Treatment of Aortic Stenosis

Surgery is the only treatment

Surgery is the gold standard treatment

Surgery is the preferred treatment for low and intermediate risk patients

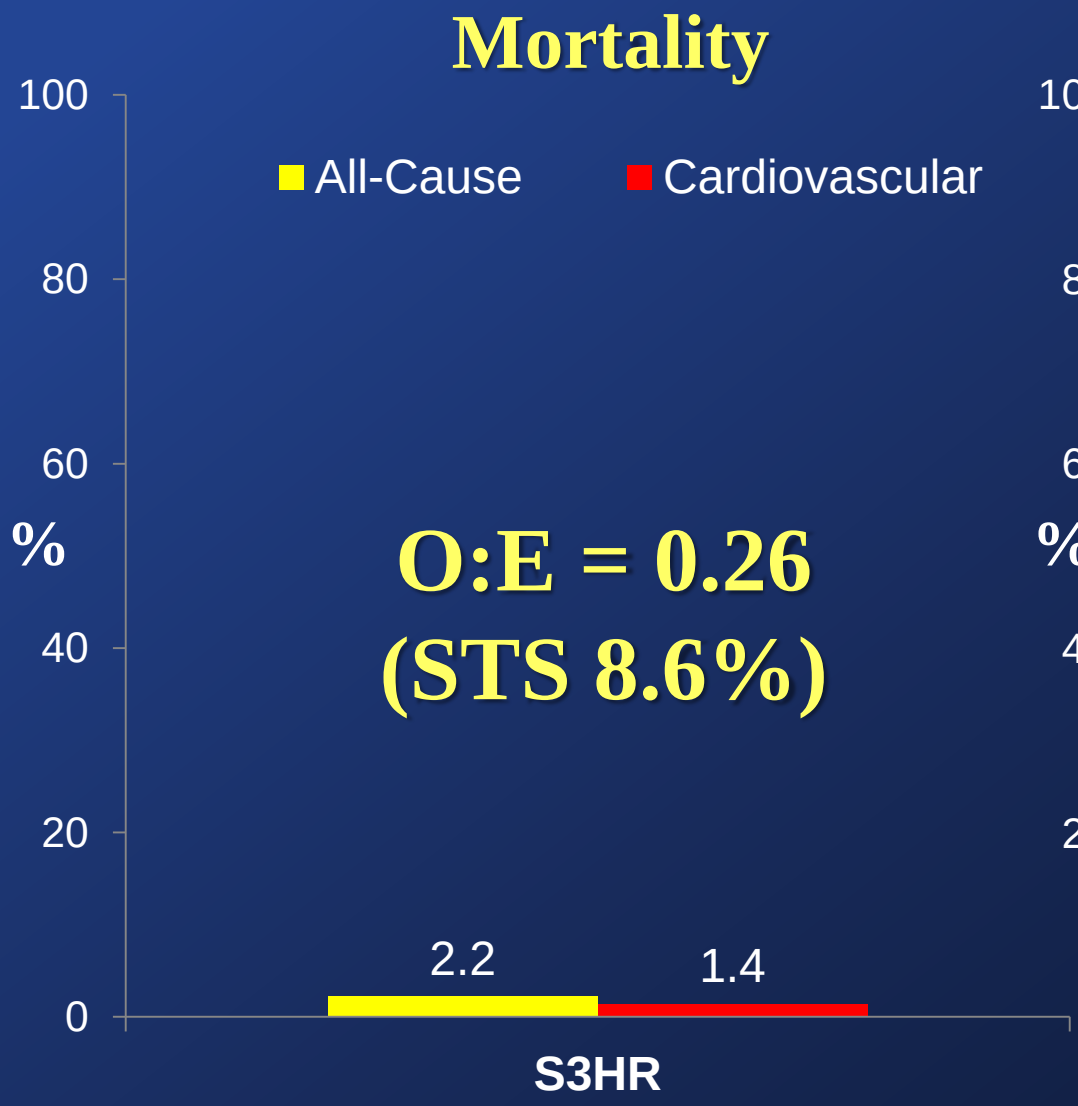
Transcatheter interventions are performed in intermediate risk patients

Surgery is performed in patients with contraindication to transcatheter approach

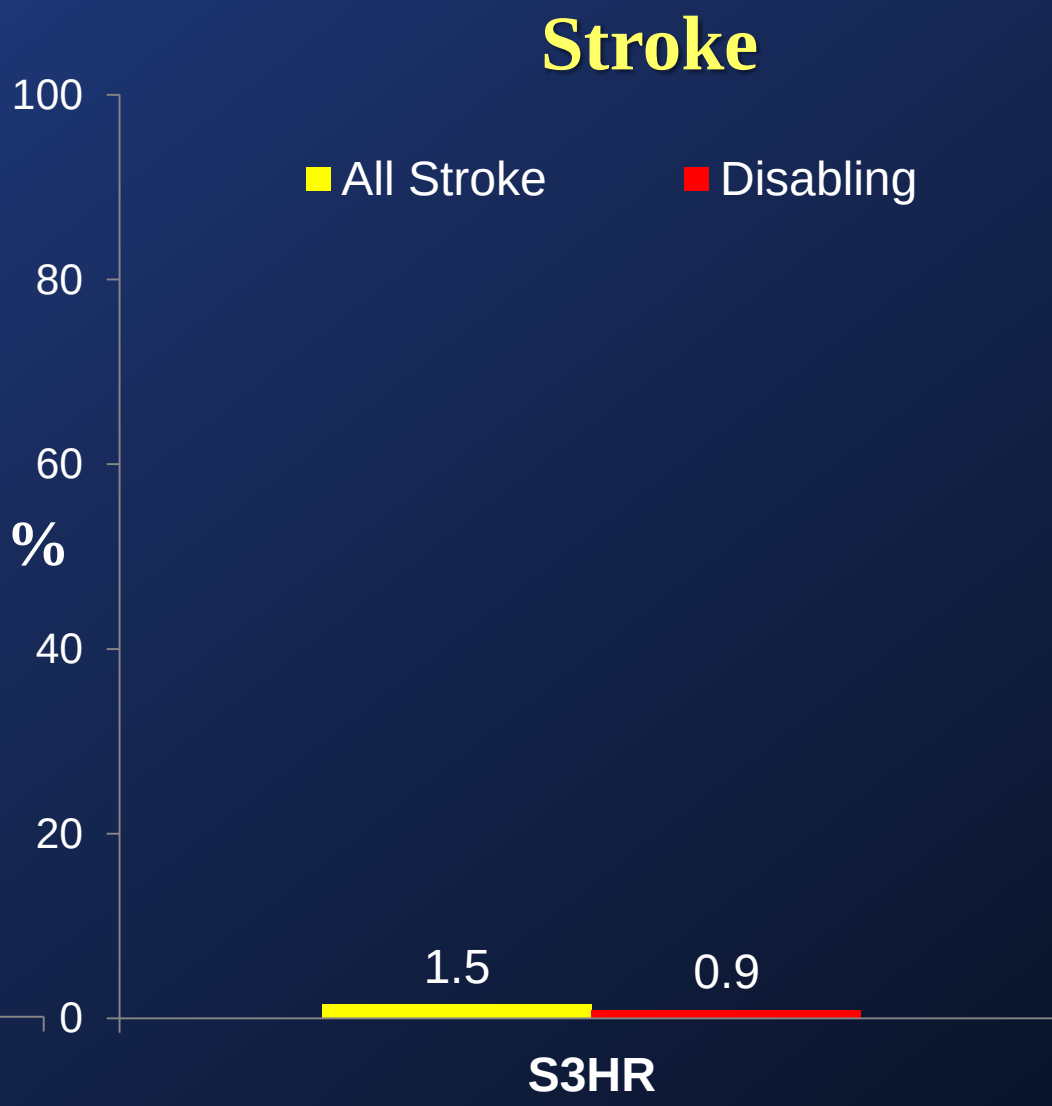
Mortality and Stroke: S3HR

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL



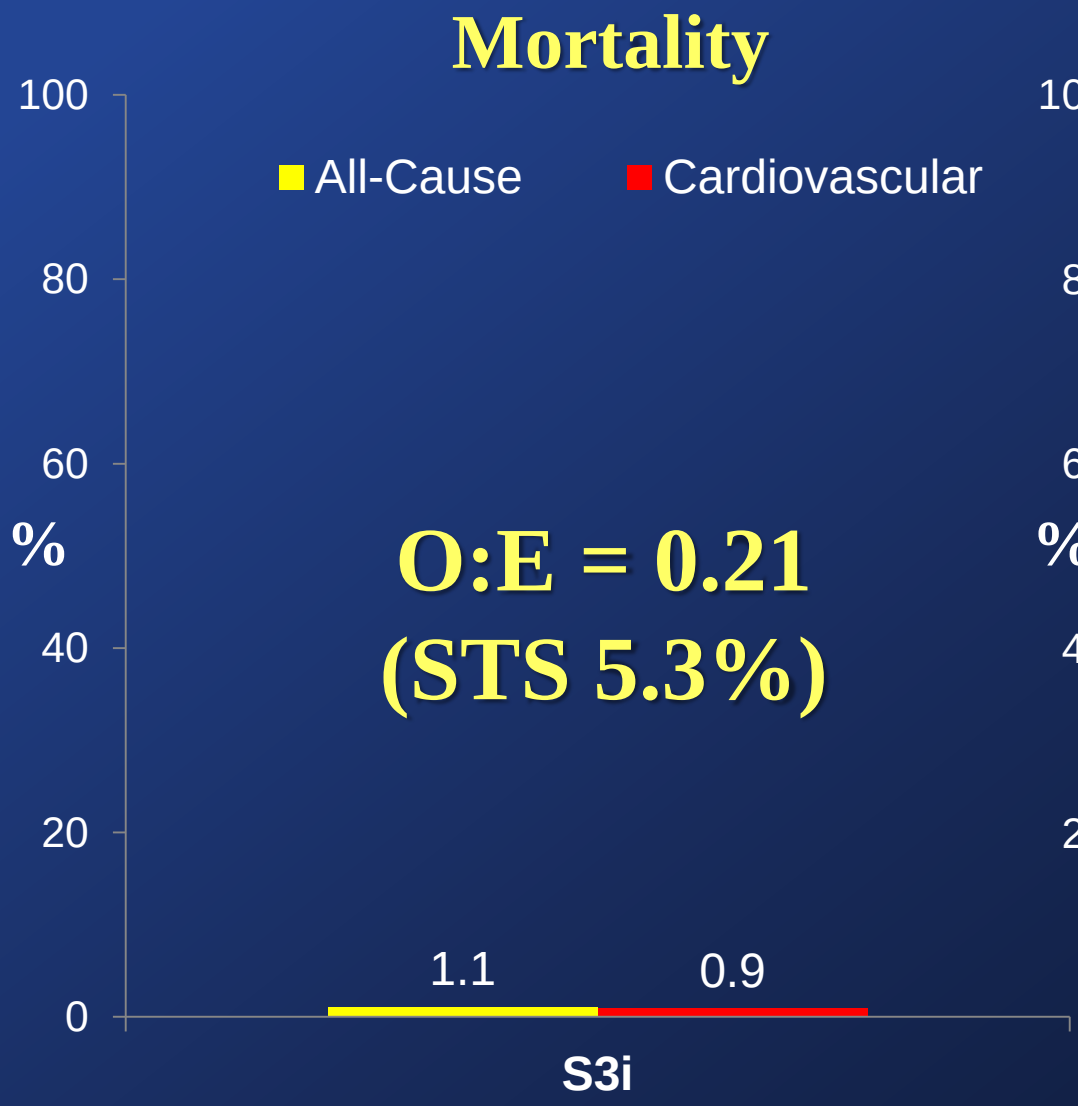
O:E = 0.26
(STS 8.6%)



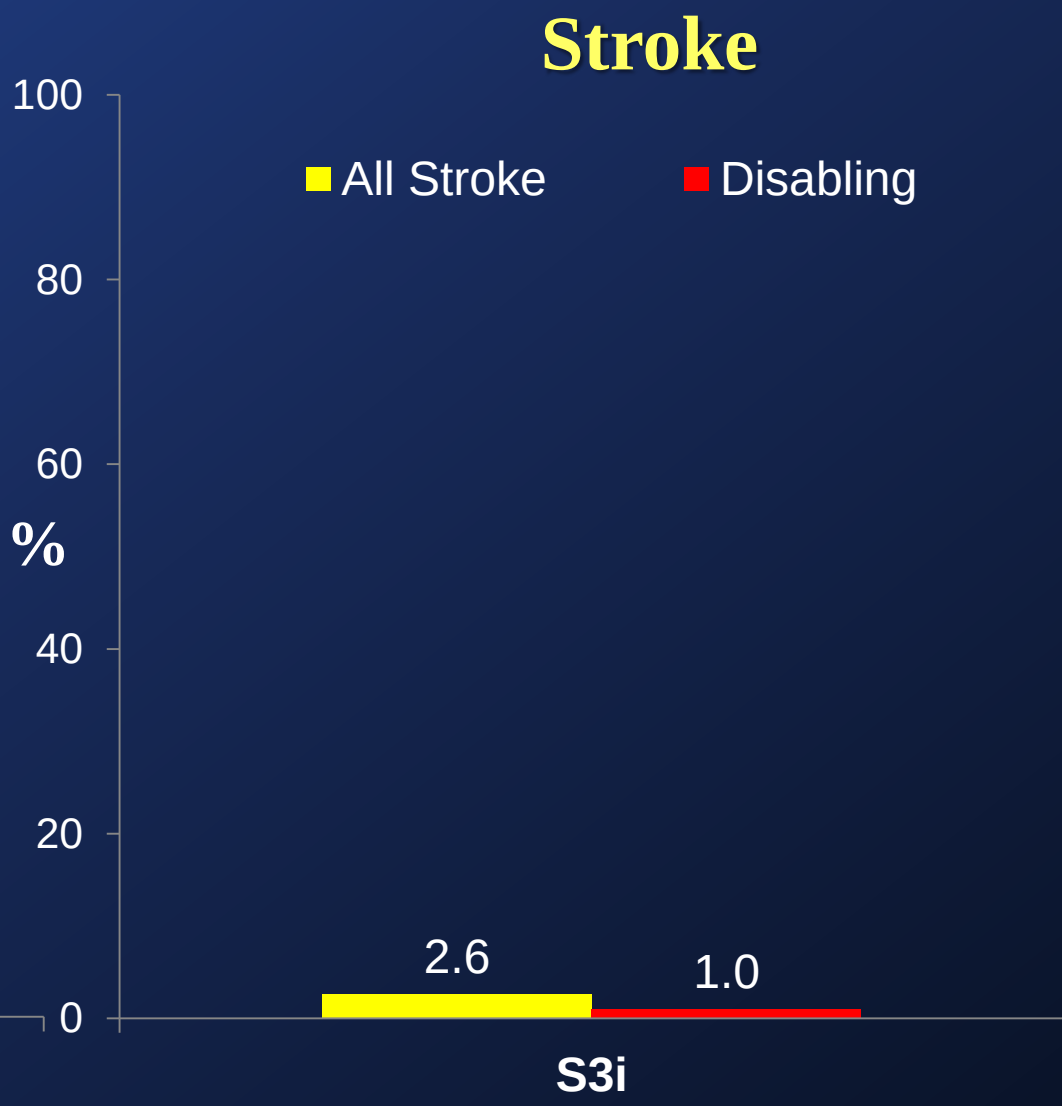
Mortality and Stroke: S3i

At 30 Days (As Treated Patients)

THE PARTNER II TRIAL



O:E = 0.21
(STS 5.3%)



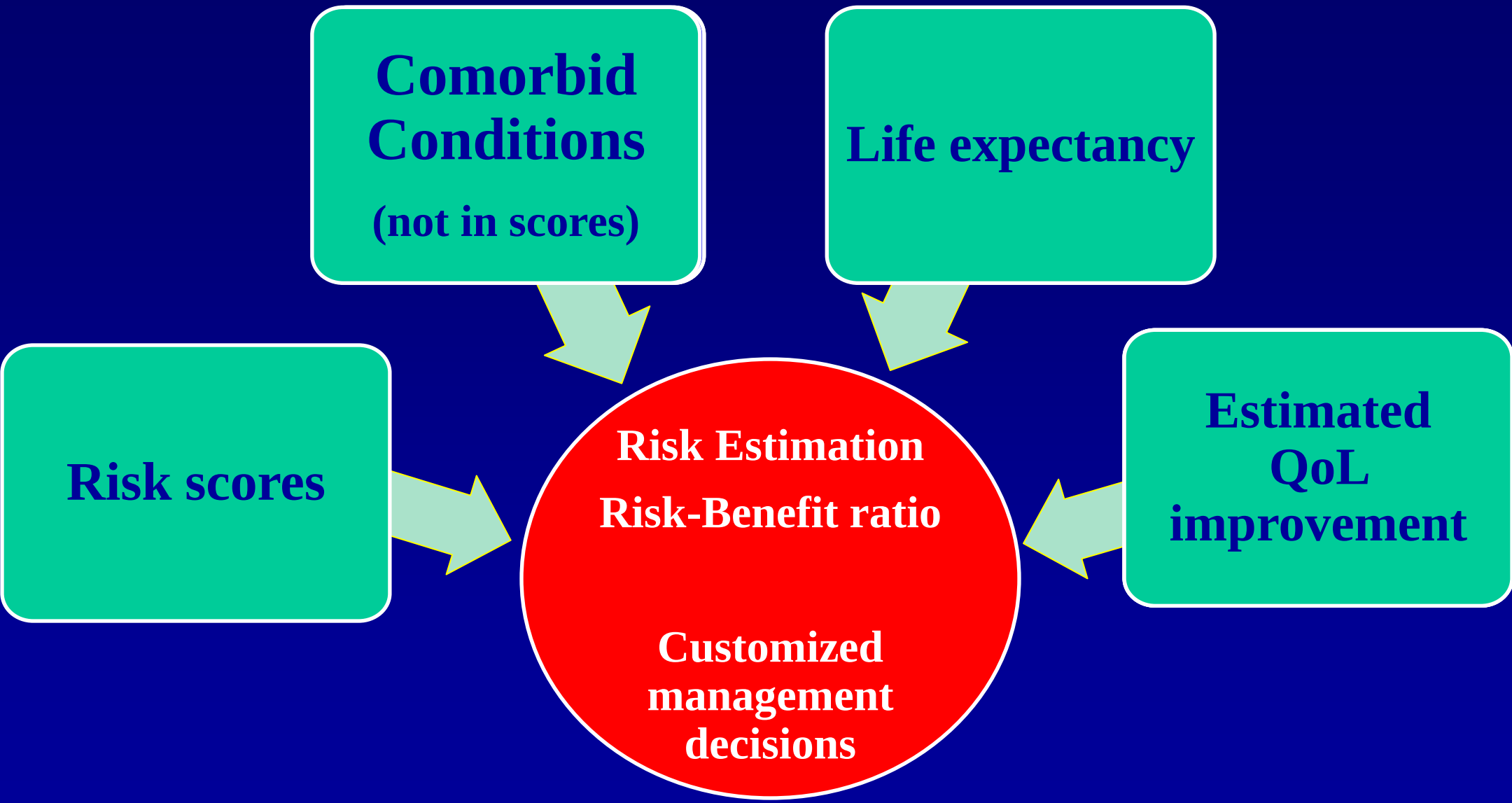
Impact on mortality of paravalvular leakage Comprehensive literature review

Table 3 Outcomes Associated With Aortic and/or Paravalvular Regurgitation

Author, Year (Ref. #)	n	Variable	Outcome	Univariate Analysis	Multivariate Analysis
Abdel-Wahab, 2011 (3)	690	AR ≥2	In-hospital mortality	OR = 2.50 (1.37–4.55)	OR = 2.43 (1.22–4.85)
Gotzmann, 2011 (4)	122	AR ≥2	6-month mortality No clinical improvement	—	OR = 4.26 (1.59–11.45) OR = 10.1 (3.20–31.94)
Takagi, 2011 (15)	41	AR ≥2	6-month mortality	12.2% vs. 25.0% (p = 0.25)	—
Hayashida, 2012 (89)	260	AR ≥2	Median 217 days (IQR: 54–401)	HR = 1.97 (1.19–3.28)	—
Leber, 2011 (90)	69	AR >2	1-year mortality	9% vs. 37.5% (p = 0.07)	—
Moat, 2011 (5)	870	AR ≥2	1-year mortality	HR = 1.49 (1.00–2.21)	HR = 1.66 (1.10–2.51)
Sinning, 2012 (91)	152	PVL ≥2	1-year mortality	HR = 4.0 (2.1–7.5)	HR = 4.9 (2.5–9.6)
Tamburino, 2011 (6)	663	PVL ≥2	Late mortality	—	HR = 3.79 (1.57–9.10)
Sinning, 2012 (41)	146	Moderate/severe PVL	1-year survival	HR = 3.9 (2.0–7.5)	HR = 2.4 (1.0–5.4)
Unbehaun, 2012 (26)	358	No vs. trace vs. mild AR	2-year survival	66% vs. 72% vs. 67% (p = 0.77)	—
Kodali, 2012 (8)	158	Mild to severe AR	2-year survival	HR = 1.75 (1.17–2.61)	Not significant
		Mild to severe PVL	2-year survival	HR = 2.11 (1.43–3.10)	Not significant

Genereux & Head et al. *JACC* 2013;61:1125-36

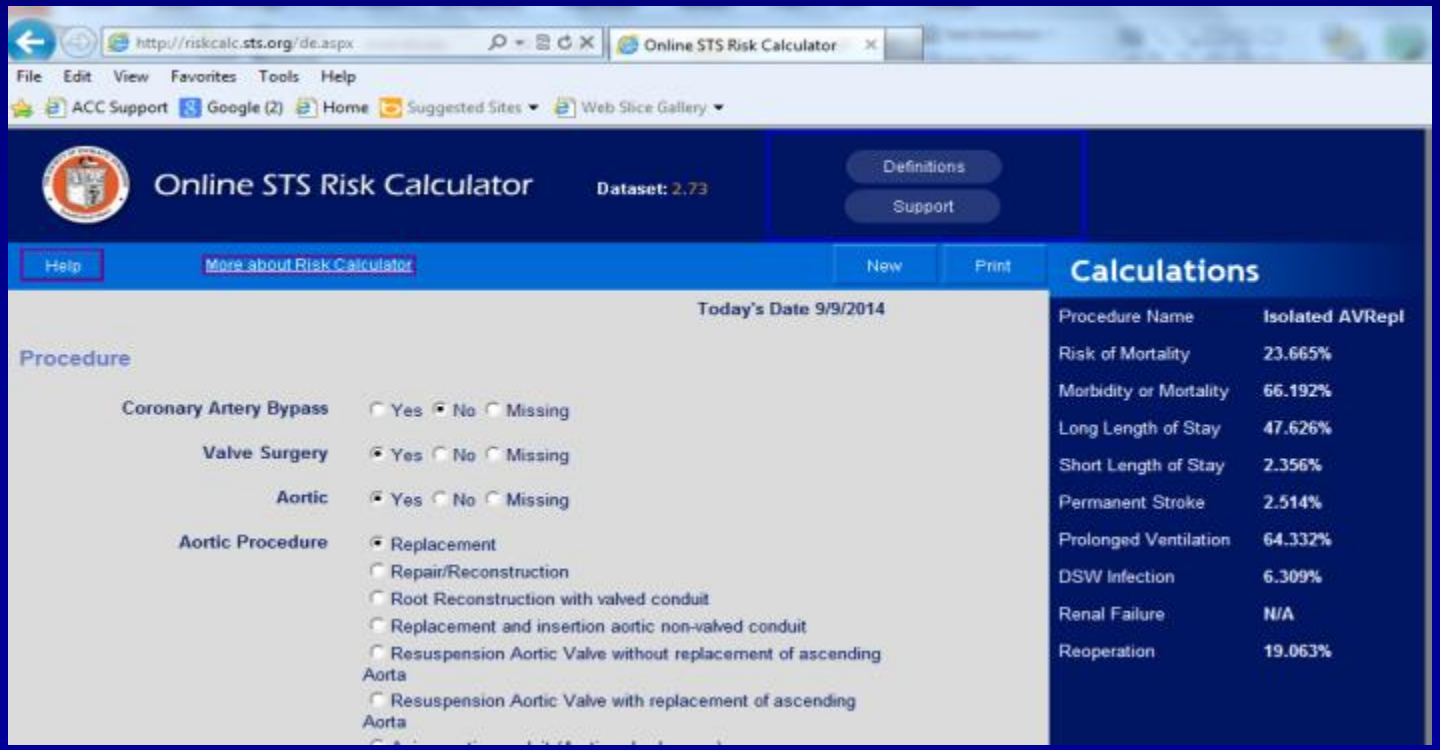
Heart Team



Adapted from Dr. Kappetein

Risk Model Workgroup

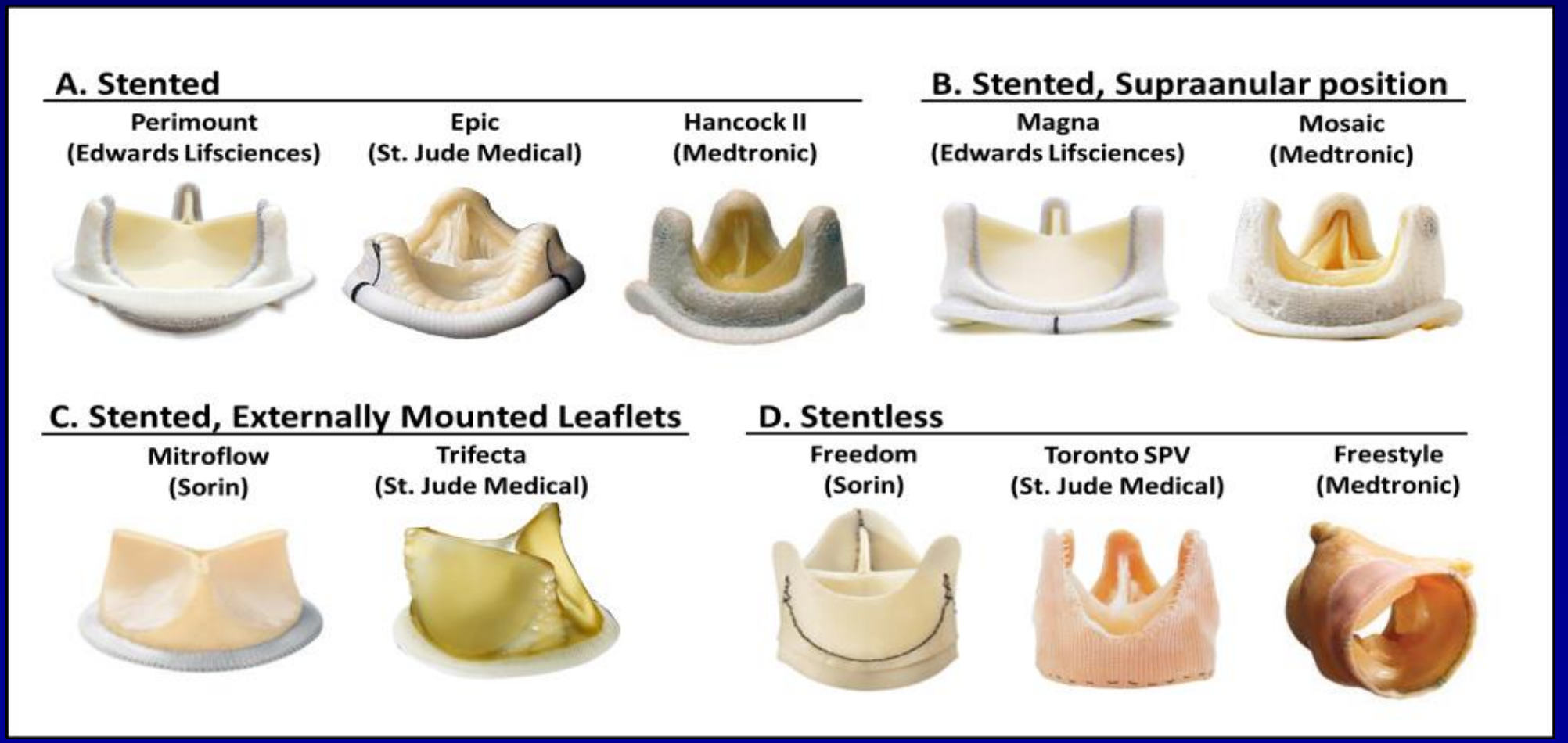
- Develop a predictive tool to calculate in-hospital mortality at the patient level (a patient risk score similar to the online STS risk calculator).

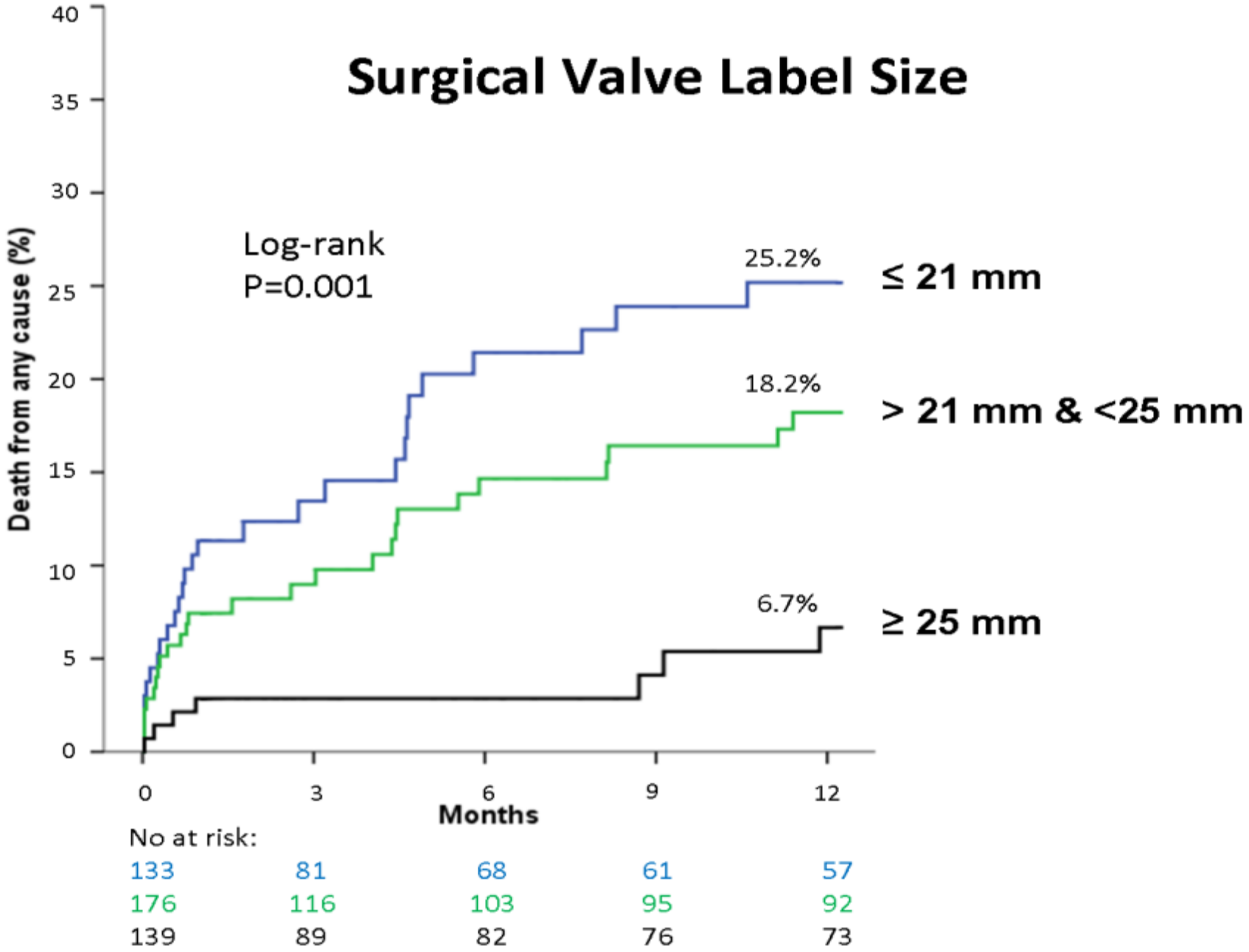


Main issues
Aortic-valve-in-valve procedures

- Malpositioning
- Ostial coronary occlusion
- Residual stenosis

Bioprosthetic Valves



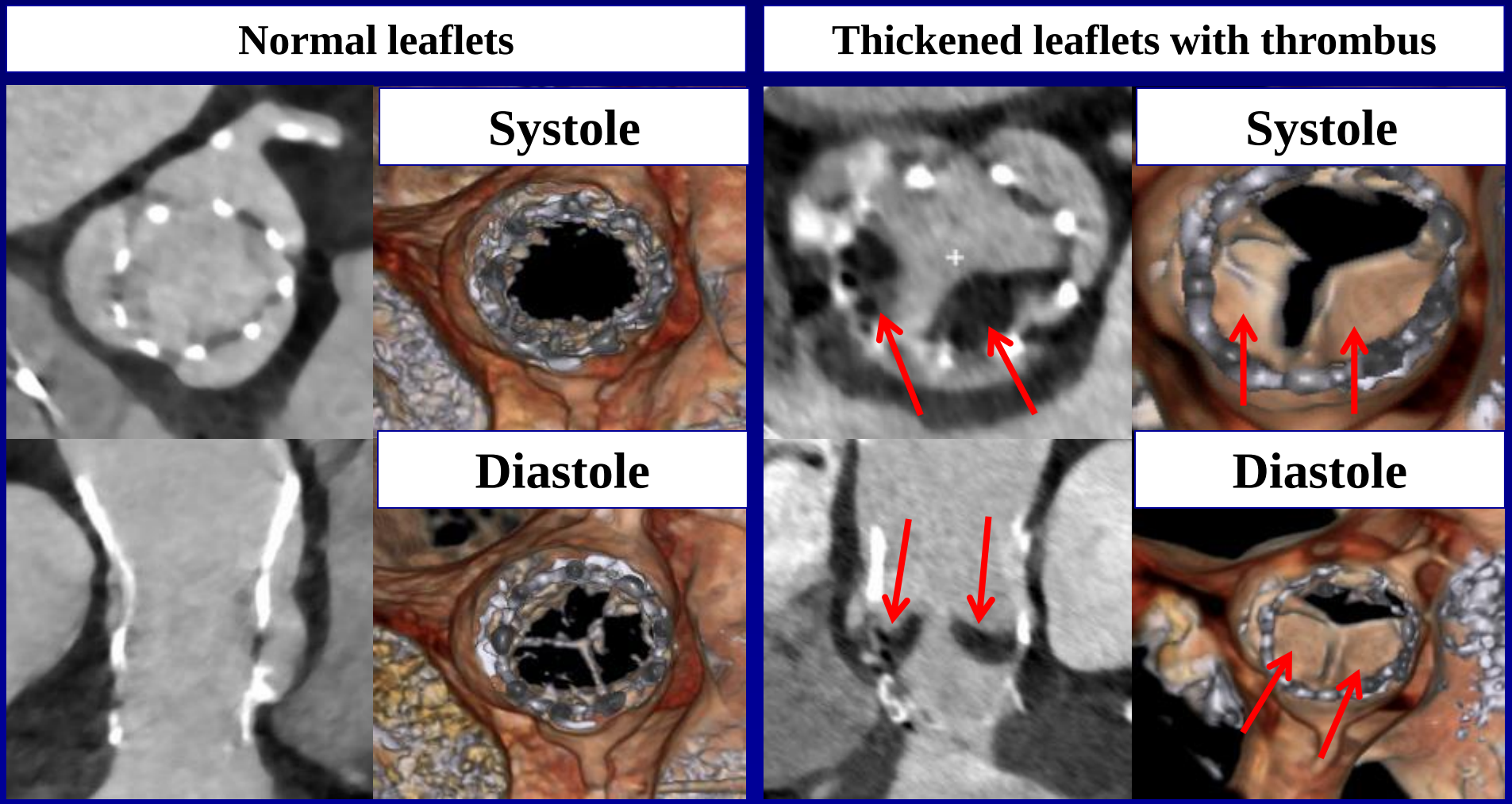

Surgical Valve Label Size
Death from any cause (%)
40
35
30
25
20
15
10
5
0
Log-rank
P=0.001
25.2%
18.2%
6.7%
≤ 21 mm
> 21 mm & <25 mm
≥ 25 mm
0
3
6
9
12
Months
No at risk:
133 81 68 61 57
176 116 103 95 92
139 89 82 76 73

ORIGINAL ARTICLE

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. de Backer, F.M. Asch, C.E. Ruiz, N.T. Olsen, A. Trento, J. Friedman, D. Berman, W. Cheng, M. Kashif, V. Jelnin, C.A. Kliger, H. Guo, A.D. Pichard, N.J. Weissman, S. Kapadia, E. Manasse, D.L. Bhatt, M.B. Leon, and L. Søndergaard

Volume rendered CT images of bioprosthetic valves



An All-comers Randomized Clinical Trial Comparing TAVR with SAVR in Patients with Aortic Valve Stenosis

Lars Søndergaard

The Heart Center, Rigshospitalet, Copenhagen, Denmark

- on behalf of the NOTION Investigators

Enrollment Criteria

Main inclusion criteria

- Severe AS
- Age ≥70 years
- Life expectancy ≥ 1 year
- Suitable for TAVR & SAVR

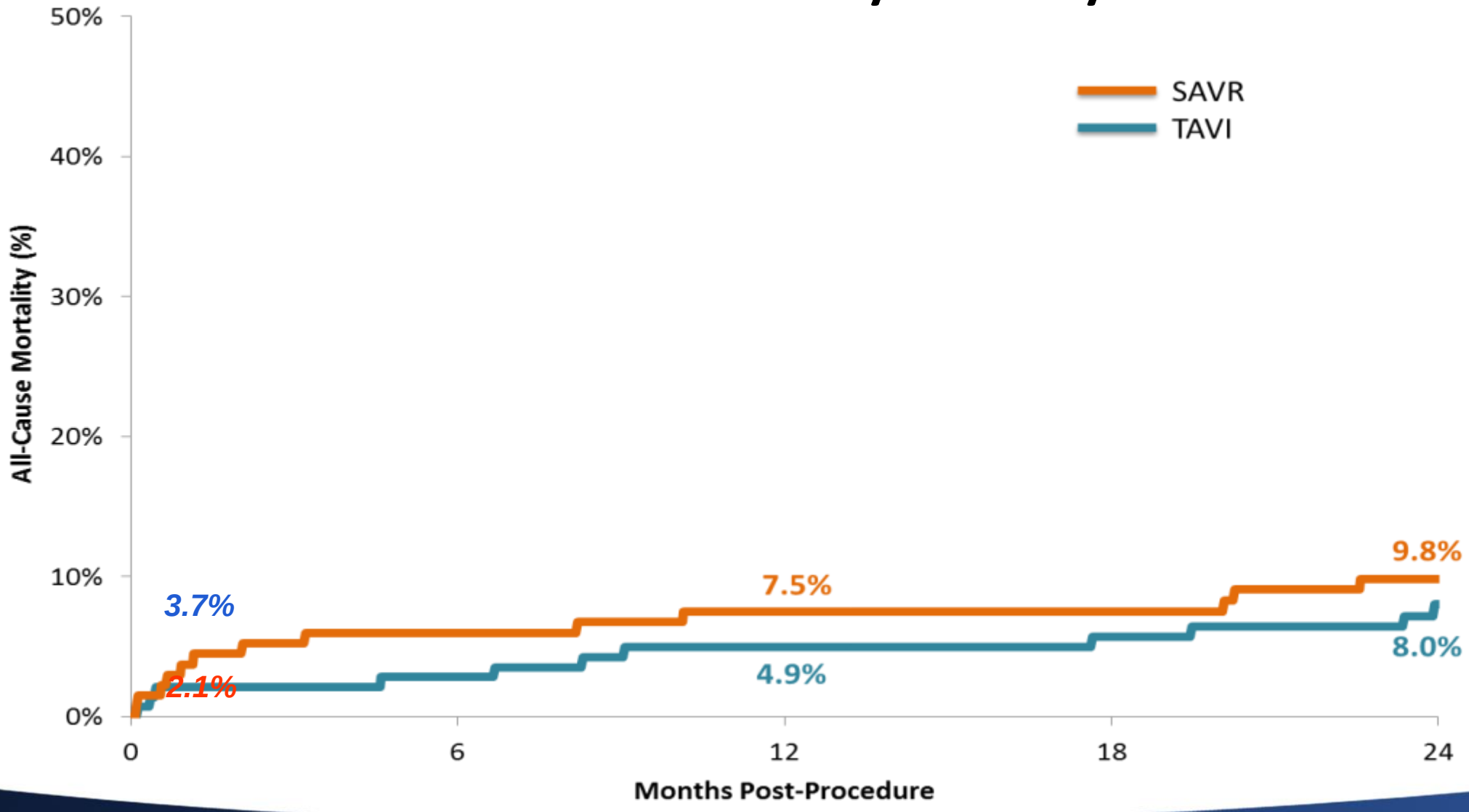
Main exclusion criteria

- Severe CAD
- Severe other valve disease
- Prior heart surgery
- Need for acute treatment
- Recent stroke or MI
- Severe lung disease
- Severe renal failure

Baseline Characteristics

Characteristic, % or mean ± SD	TAVR n=145	SAVR n=135	p-value
Age (yrs)	79.2 ± 4.9	79.0 ± 4.7	0.71
Male	53.8	52.6	0.84
STS Score	2.9 ± 1.6	3.1 ± 1.7	0.30
STS Score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 ± 4.0	8.9 ± 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61

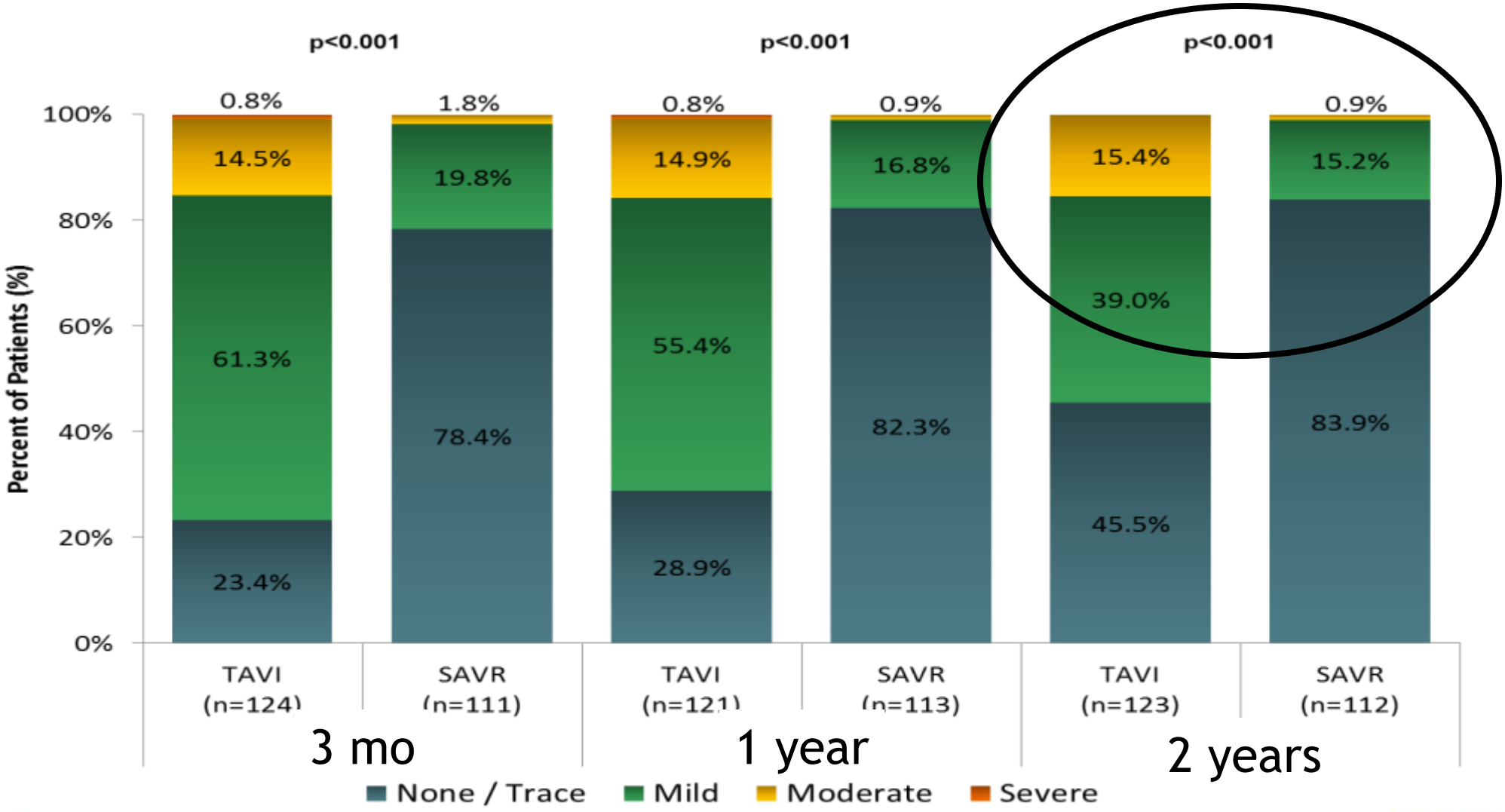
All-Cause Mortality at 2-years



Secondary Outcomes at 2 Years

	1 Year			2 Years		
Outcome, %	TAVR	SAVR	p-value	TAVR	SAVR	p-value
Death, any cause	4.9	7.5	0.38	8.0	9.8	0.54
Death, cardiovascular	4.3	7.5	0.25	6.5	9.1	0.40
Stroke	2.9	4.6	0.44	3.6	5.4	0.46
TIA	2.1	1.6	0.71	6.0	3.3	0.30
Myocardial infarction	3.5	6.0	0.33	5.1	6.0	0.69
Atrial fibrillation	21.2	59.4	<0.001	22.7	60.2	<0.001
Pacemaker	38.0	2.4	<0.001	41.3	4.2	<0.001
Aortic valve re-intervention	0.0	0.0	N/A	0.0	0.0	N/A

Aortic Valve Regurgitation



Discussion Points

- **How do we decide between SAVR or TAVR?**
  - **Heart Team, Scores (which score: EuroSCORE II, STS, TVT…)**
- **Are we ready for TAVR in low-risk pts, in light of PV leak, pacemaker rates, thrombosis… Should we mandate a randomized trial?**
- **Are we comfortable with the long-term durability data to implant in younger patients?**
- **Will TAVR in it's current scheme, be cost-prohibitive?**
- **Should patient's over 65 yrs always have a 23 valve implanted?**
- **Are certain pt populations better served with mini-AVR: bicuspid, low-risk, those with prior 21 valve, low-lying coronaries, etc…**

Thanks

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