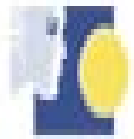


TAVI limitations for low risk patients

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www.eurovalvecongress.com

Potential conflicts of interest

Speaker's name: **Thomas Modine**

☒ I have the following potential conflicts of interest to report:

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees / Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

- Edwards
- Abbott, Boston Scientific, Medtronic, Edwards, Cephea, Microport, GE
- Valmy
- Microport
- Valmy Ltd
- Yes
- Nil

TAVI in the last years
Huge improvements, but...

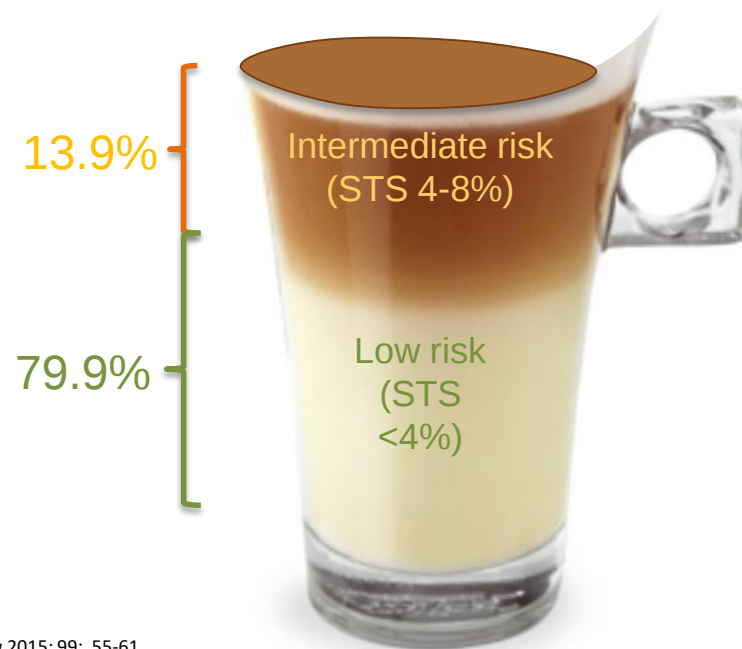
TAVI vs. SAVR – where does the evidence come from?

Observational studies
propensity score matching

Randomized controlled trials

STS database 2002-2010

n=141,905



*Thourani, et al., *Ann Thorac Surg* 2015; 99: 55-61

Similar outcomes between TAVI & SAVR in “matched” intermediate risk . . .

	Piazza ¹			OBSERVANT ²			Latib ³		
	TAVI (n=255)	SAVR (n=255)	p	TAVI (n=133)	SAVR (n=133)	p	TAVI (n=111)	SAVR (n=111)	p
STS (%, mean)	3-8	3-8		na	na		4.6	4.6	
Log EuroSCORE (%, mean)	17.3	17.6		8.9	9.4		23.2	24.4	
30 Day Mortality (%)	7.8	7.1	0.74	3.8	3.8	1.0	1.8	1.8	1.0

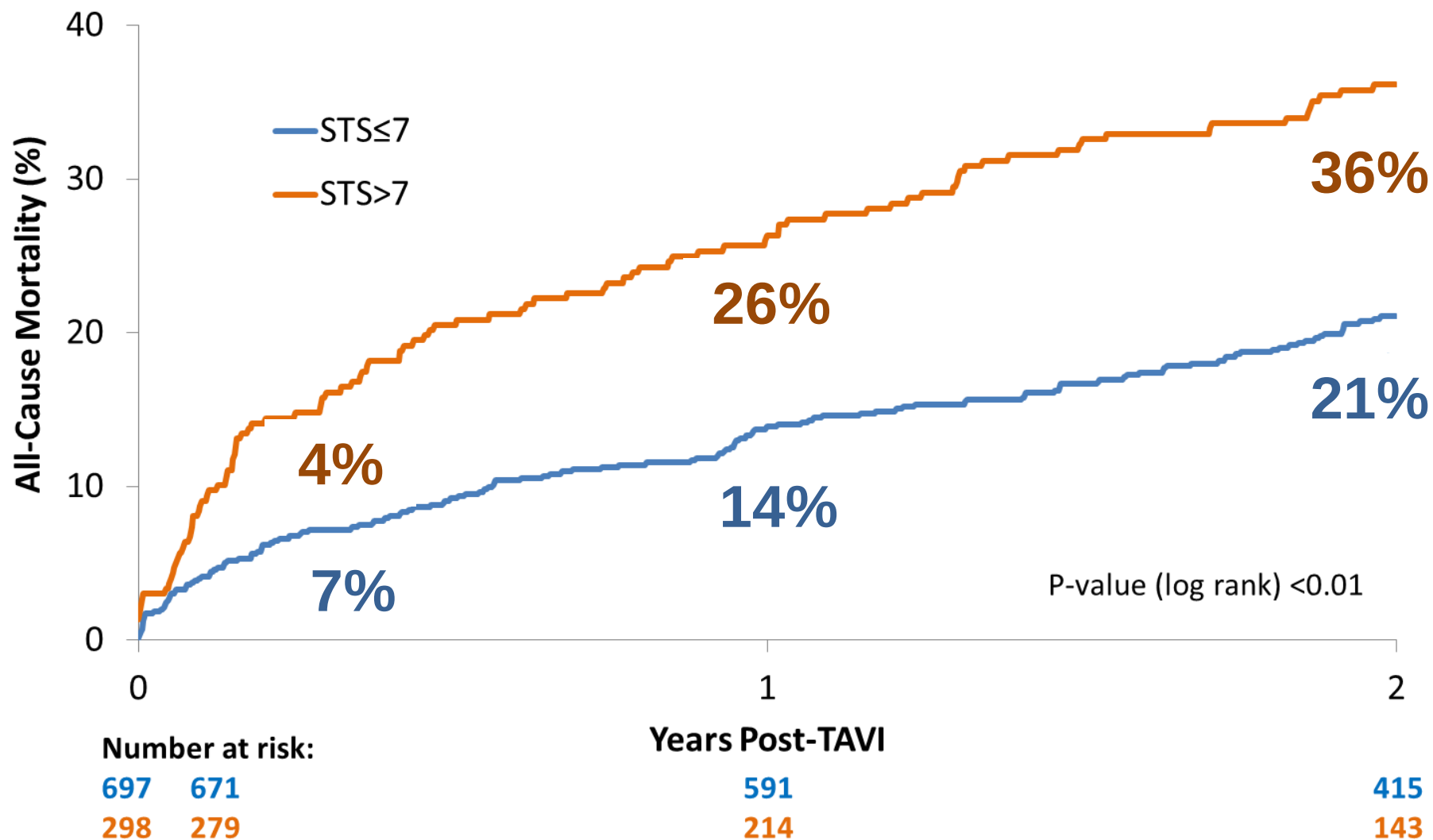
¹Piazza, et al. J Am Coll Cardiol Interv 2013; 6:443-51

²D'Errigo, et al. Int J Cardiol 2013; 167:1945-52

³Latib, et al. Am Heart J 2012; 164:910-7

2-Year All-Cause Mortality

CoreValve ADVANCE Registry

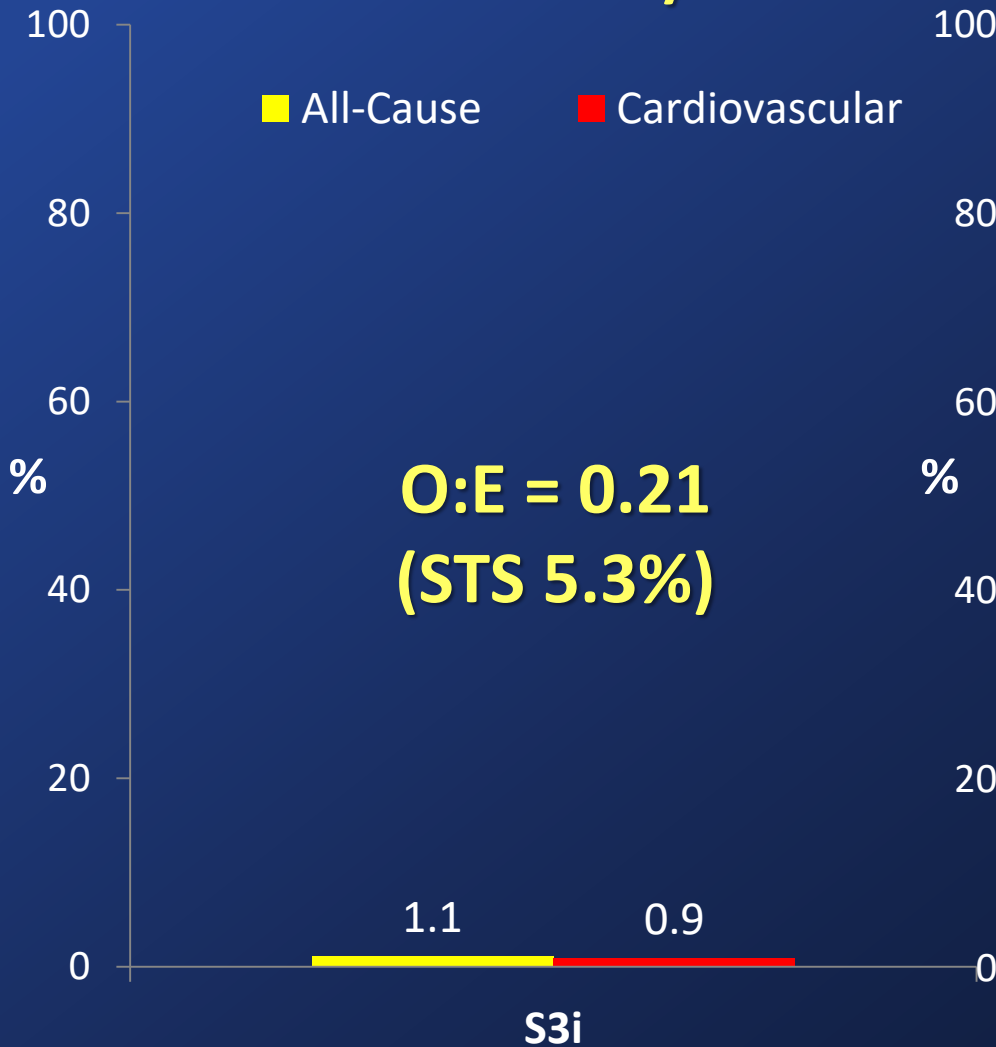


Mortality and Stroke: S3i

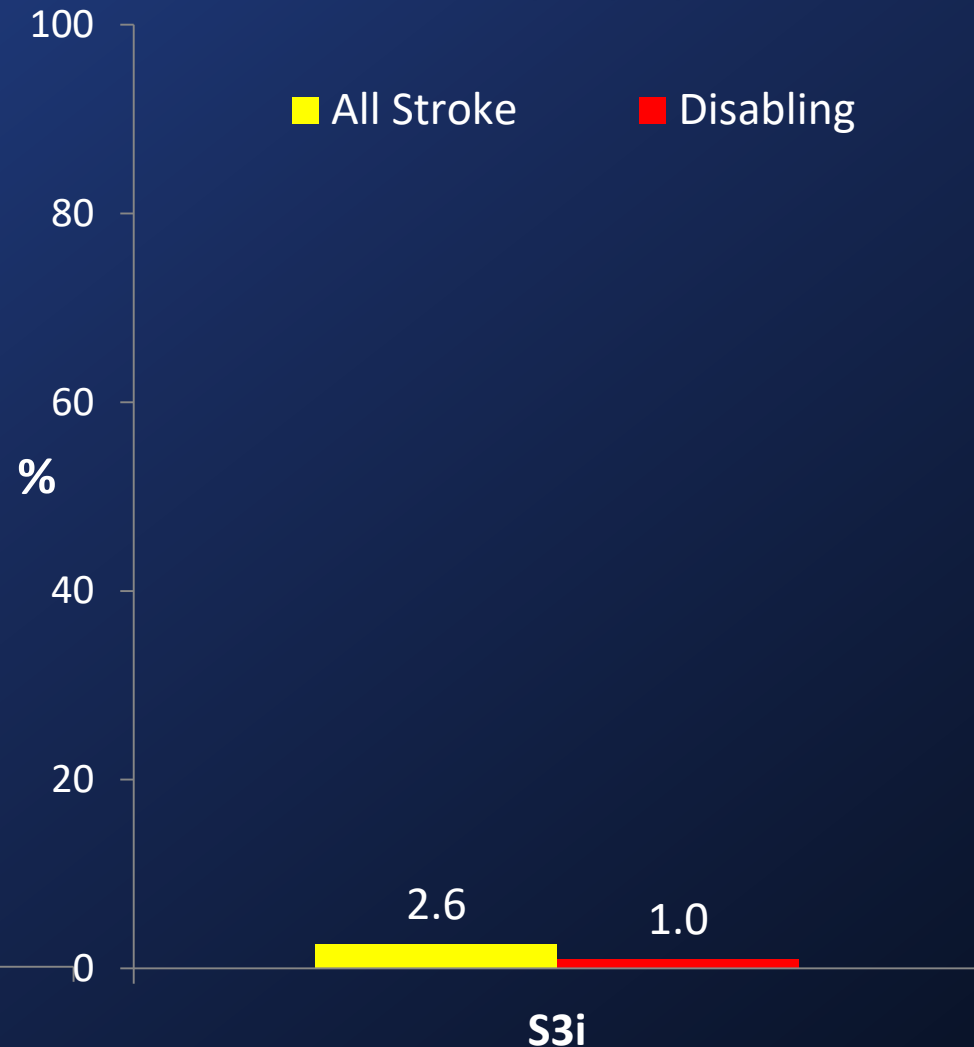
At 30 Days (As Treated Patients)



Mortality



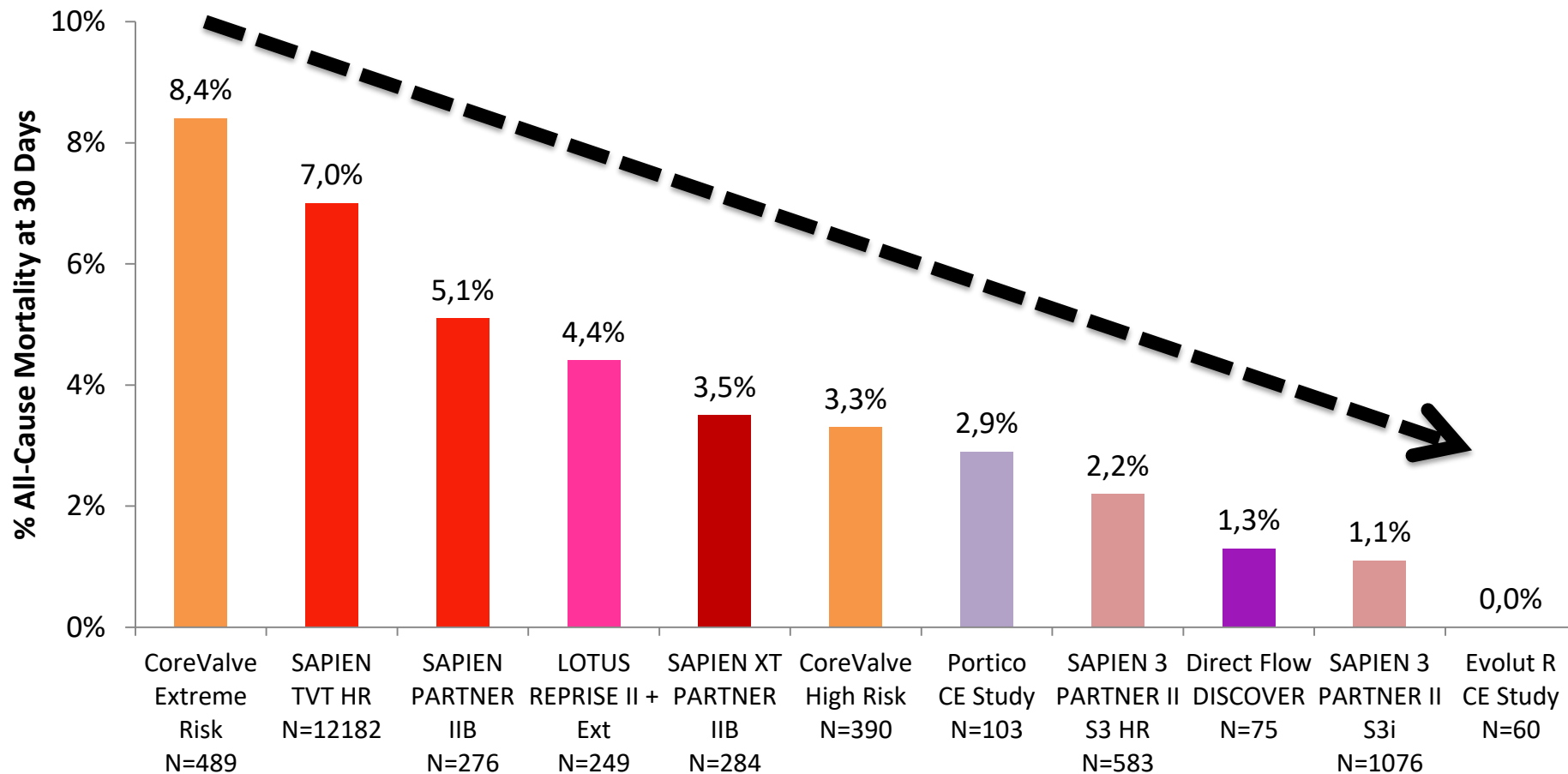
Stroke



TAVI in the last years
Huge improvements, but...

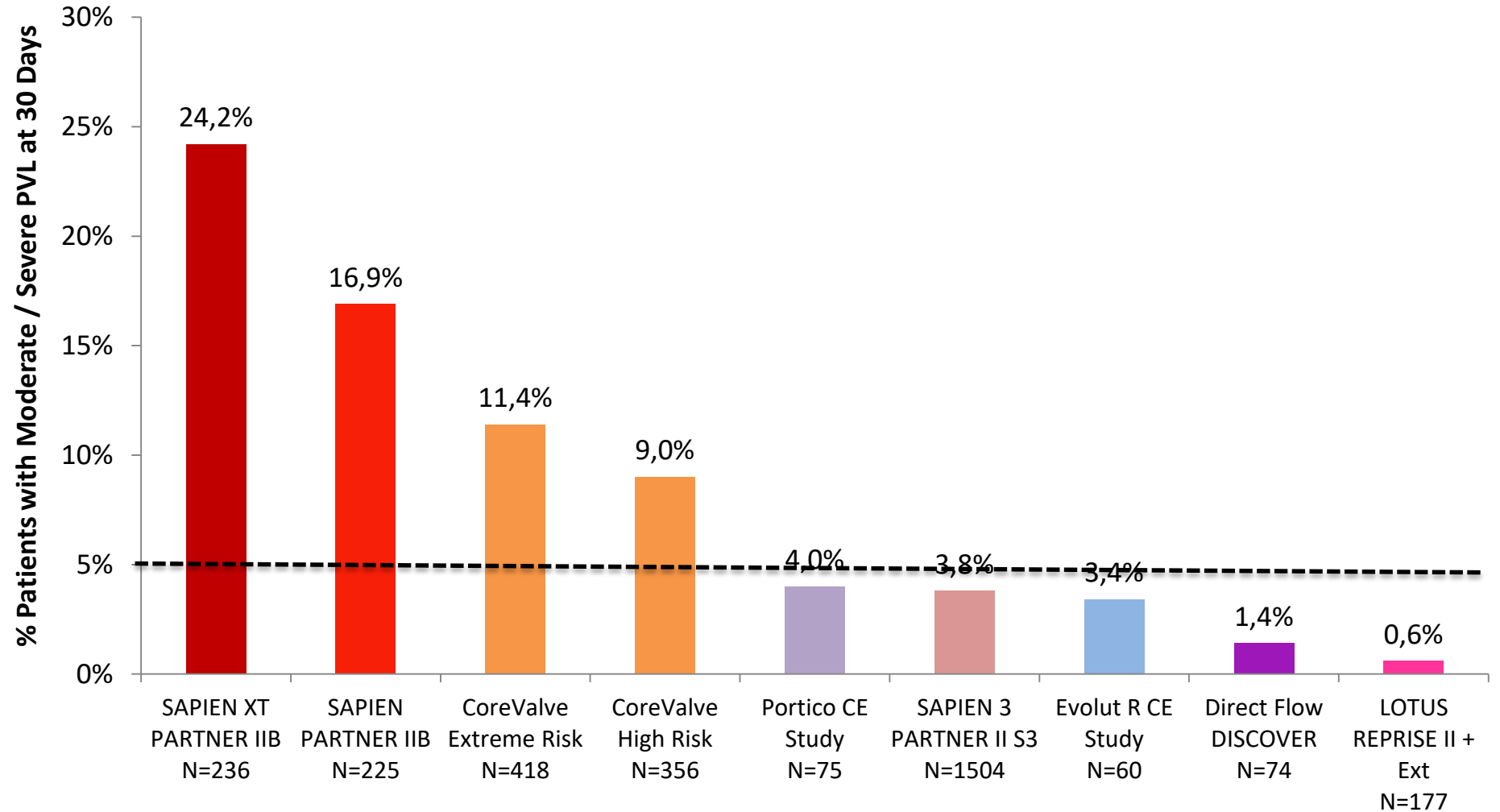
Matter of debate
Complications rate reduction

30-day All-cause Mortality



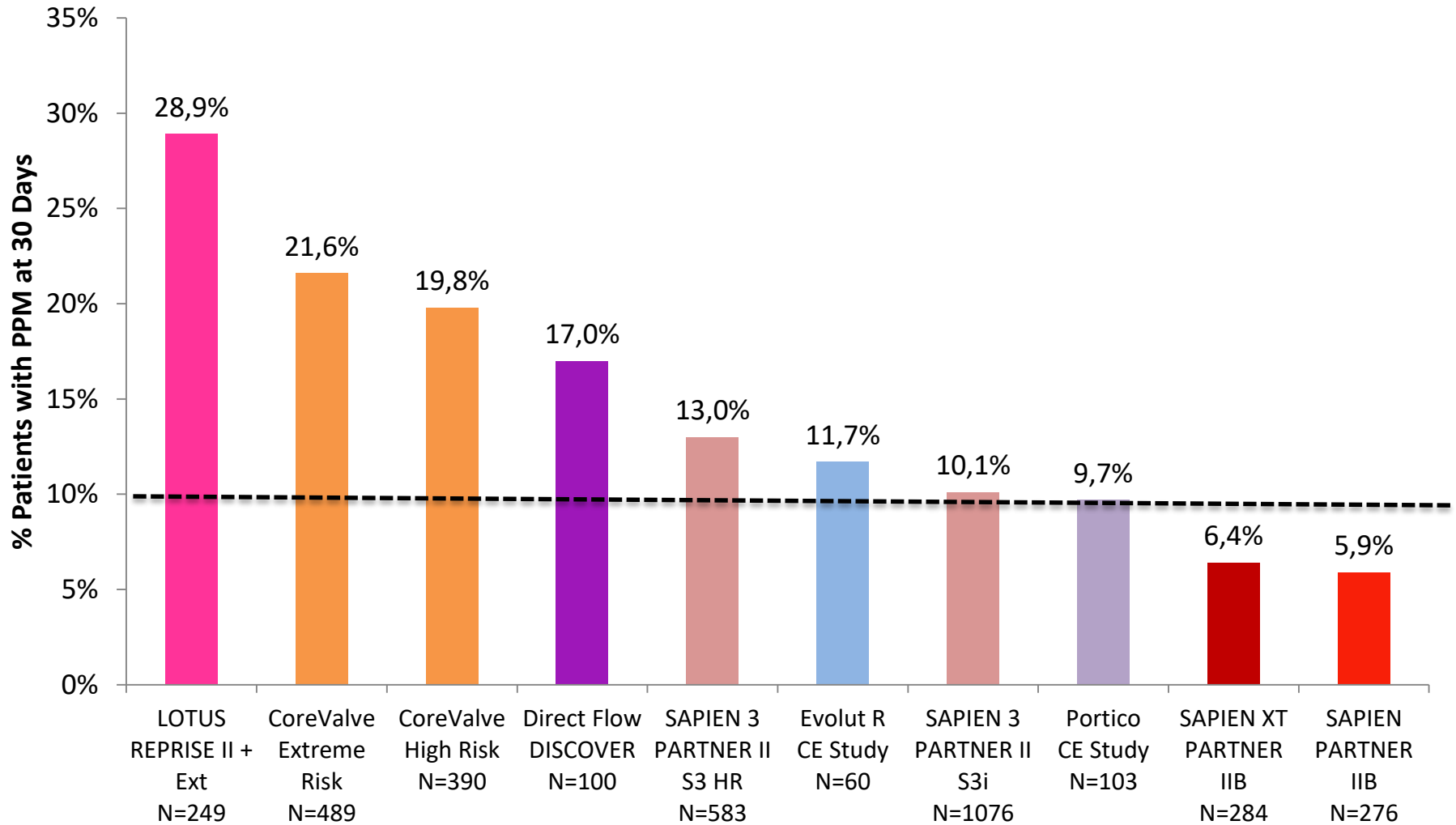
¹Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ²Holmes, et al., *JAMA* 2015; 313: 1019-28; ³Leon, et. al. presented at ACC 2013; ⁴Meredith, et al., presented at PCR London Valves 2014; ⁵Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ⁶Manoharan, et al., et. al. presented at TCT 2014; ⁷Kodali, et al., presented at ACC 2015; ⁸Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ⁹Meredith, et al., presented at ACC 2015

Moderate to severe PVL



¹Leon, et. al. presented at ACC 2013; ²Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ³Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ⁴Manoharan, et al., et. al. presented at TCT 2014; ⁵Kodali, et al., presented at ACC 2015; ⁶Meredith, et al., presented at ACC 2015; ⁷Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ⁸Meredith, et al., presented at PCR London Valves 2014

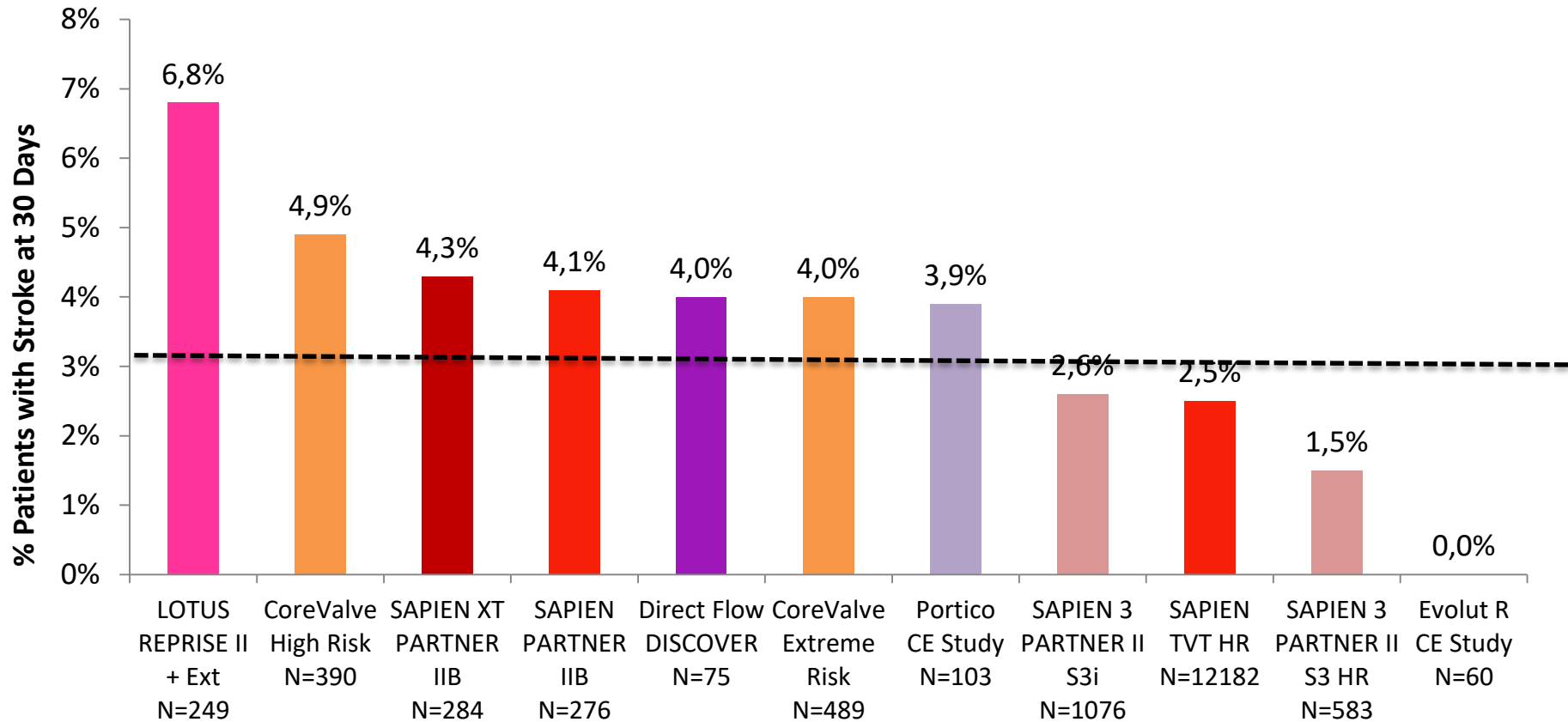
30-day Permanent Pacemaker



¹Meredith, et al., presented at PCR London Valves 2014; ²Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ³Adams, et al., *N Engl J Med* 2014; 370: 1790-8;

⁴Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ⁵Kodali, et al., presented at ACC 2015; ⁶Meredith, et al., presented at ACC 2015; ⁷Manoharan, et al., et. al. presented at TCT 2014; ⁸Leon, et. al. presented at ACC 2013

30-day stroke rate



¹Meredith, et al., presented at PCR London Valves 2014; ²Adams, et al., *N Engl J Med* 2014; 370: 1790-8; ³Leon, et. al. presented at ACC 2013; ⁴Schofer, et al., *J Am Coll Cardiol* 2014; 63: 763-8; ⁵Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; ⁶Manoharan, et al., et. al. presented at TCT 2014; ⁷Kodali, et al., presented at ACC 2015;

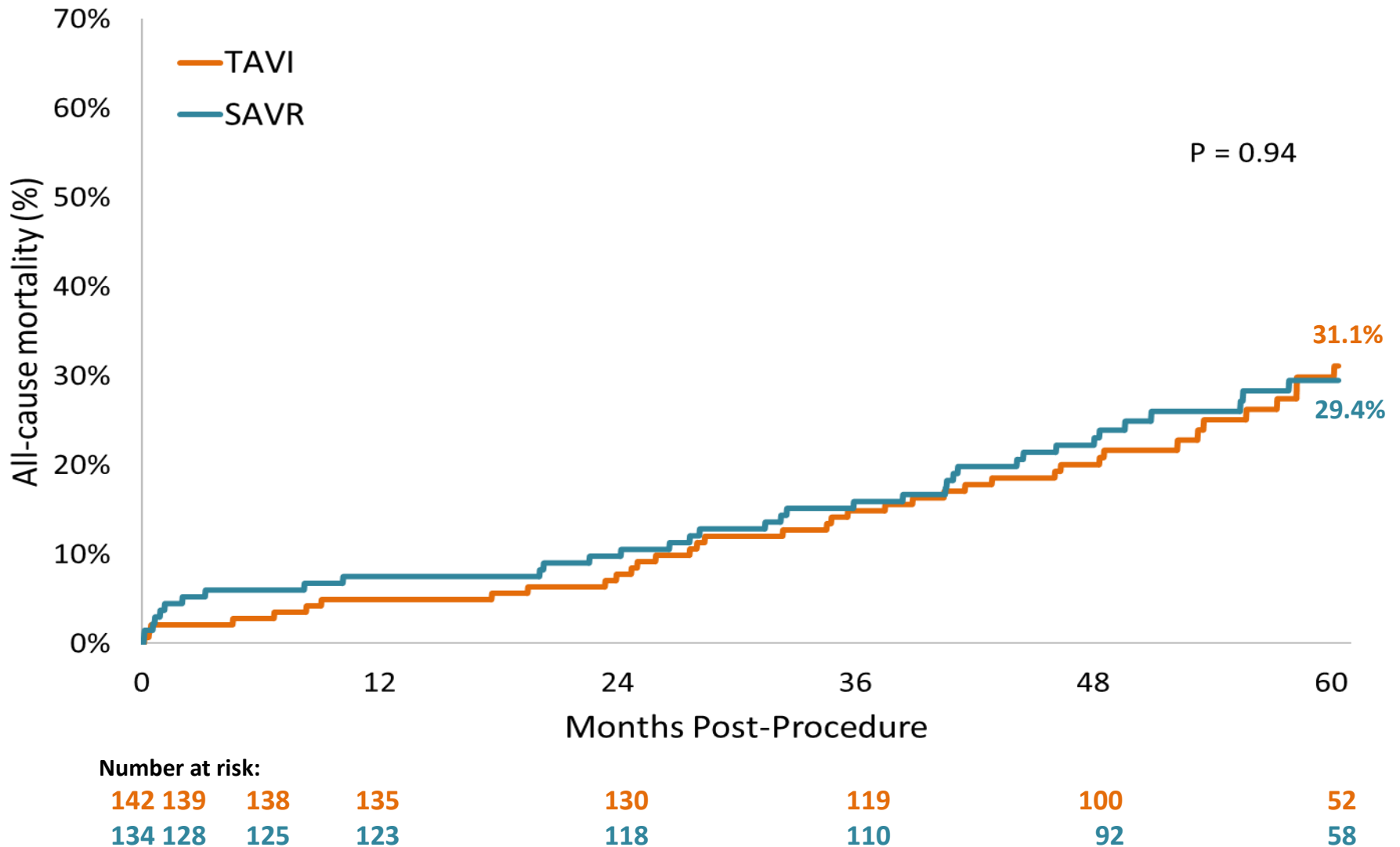
⁸Holmes, et al., *JAMA* 2015; 313: 1019-28 ⁹Meredith, et al., presented at ACC 2015

Durability

Just be patient to see how old it will GROW

The NOTION Trial

all-cause mortality



The NOTION Trial

conclusions

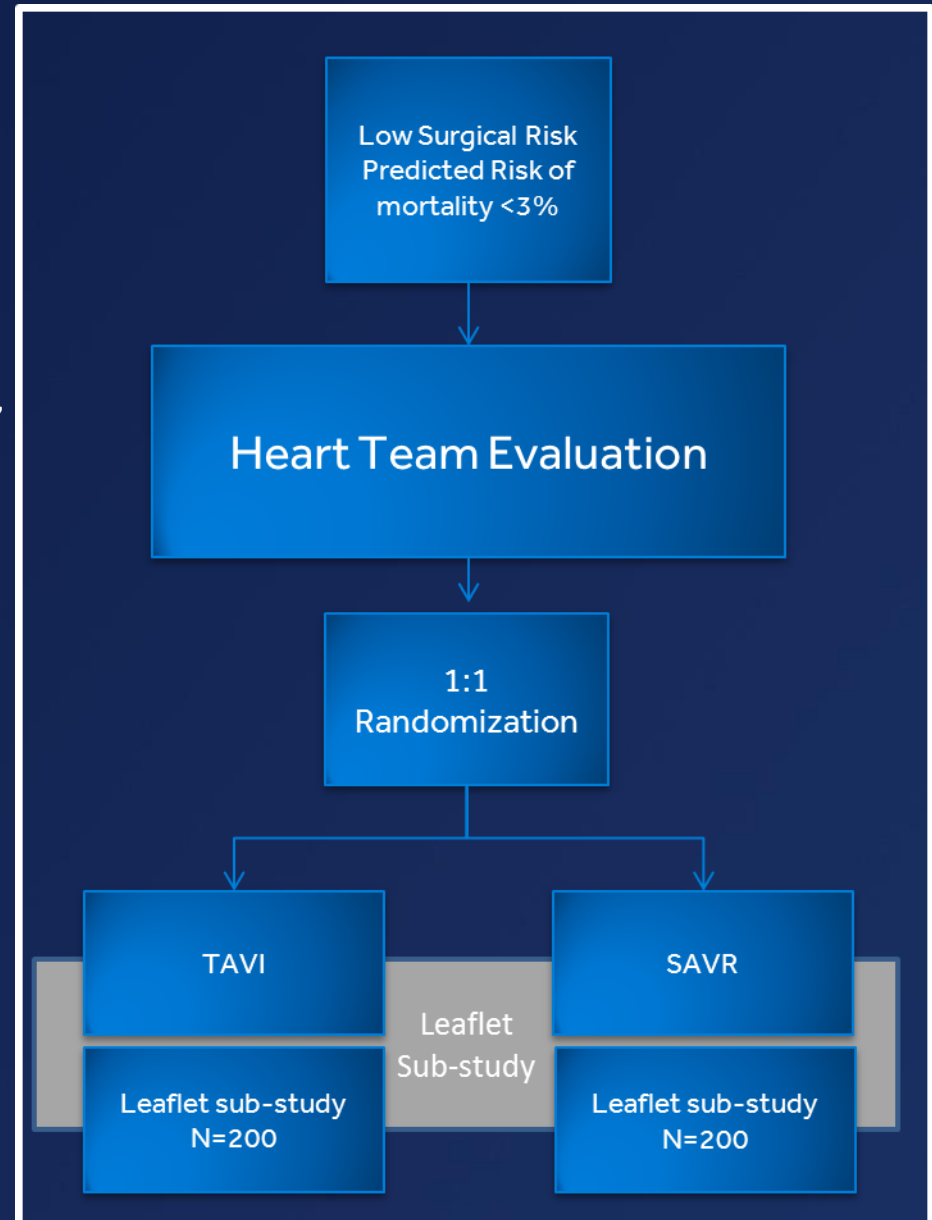
Through 5 years follow-up of the NOTION trial:

- Excellent haemodynamic valve performance was maintained
- Bioprosthetic failure was low and similar for the self-expanding transcatheter (CoreValve) and the surgical valves implanted
- Structural valve deterioration was significantly greater for SAVR compared with TAVI
- There was no valve thrombosis and similar rates of endocarditis for both groups

Medtronic TAVR in Low Risk Patients

Trial Design

- **Patient Population: Low Risk Cohort**
 - Determined by Heart Team to be low surgical risk
- **Primary Endpoint:**
 - Safety: Death, all stroke, life-threatening bleeding, major vascular complications, or AKI at 30 days
 - Efficacy: Death or major stroke at 2 years
 - (One year analysis for early FDA submission)
- **Sample Size: ~1200 Subjects**
- **Follow-up Evaluations:**
 - 30-days, 6-month, 18-month, and 1 Through 5 years
- **Number of Sites: Up to 80**



PARTNER 3 – Low Risk

Study Design & Registries

Severe Calcific Aortic Stenosis

Low Risk ASSESSMENT by Heart Team AND
STS < 4

1:1 Randomization
(n = 1,228)

TF - TAVR
(SAPIEN 3)

CT Imaging sub-study (n =
200)

Actigraphy/QoL sub-study

SAVR (Any approved Surgical
Bioprosthetic Valve)

CT Imaging sub-study
(n = 200)

Actigraphy/QoL sub-study

PRIMARY ENDPOINT:

Composite of all-cause mortality, all stroke, or re-hospitalization at 1 year post procedure

Follow-up: Annually through 10 years

PARTNER 3 Registries

Alternative Access
Registry
(TA/TAo/Subclavian)
(n = 100)

Aortic ViV
(n = 100)

Mitral ViR
(n = 50)

Mitral ViV
(n = 50)

TAVR in Low-Risk Patients

- ***TAVR is now the preferred therapy*** in AS patients :
 - Inoperable
 - High-risk
 - Some intermediate-risk
- ***Secondary benefits associated with TAVR***
 - Reduced ICU and hospital LOS,
 - More rapid QOL recovery,
 - Lower frequency of AKI, bleeding, and post-operative AF
 - Improved valve hemodynamics.
- ***TAVR is now being studied in low-risk AS patients in randomized clinical trials!***

Conclusions

- A systematic fall in surgical risk scores is evident (Europe > US)
- “Lower” risk patients are currently being treated (Europe > US)
- Clinical outcomes in patients with lower surgical risk scores are excellent
- Risk scores need to be reconsidered: AGE as a decision factor?
- RCT: Partner III, EvolutR low risk, NOTION II