Durability of Transcatheter Bioprosthetic Aortic Valves

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10th
AP VALVES & VIRTUAL
STRUCTURAL HEART

Disclosure

Lars Sondergaard has received consultant fees and/or institutional research grants from

- Abbott
- Boston Scientific
- Medtronic
- SMT

TAVI & patient life-expectancy

Sondergaard. Eur Heart J. 2019;40:1331-3

Surgical aortic valves

De Backer et al. JACC Cardiovasc Interv. 2016;9:1152-8
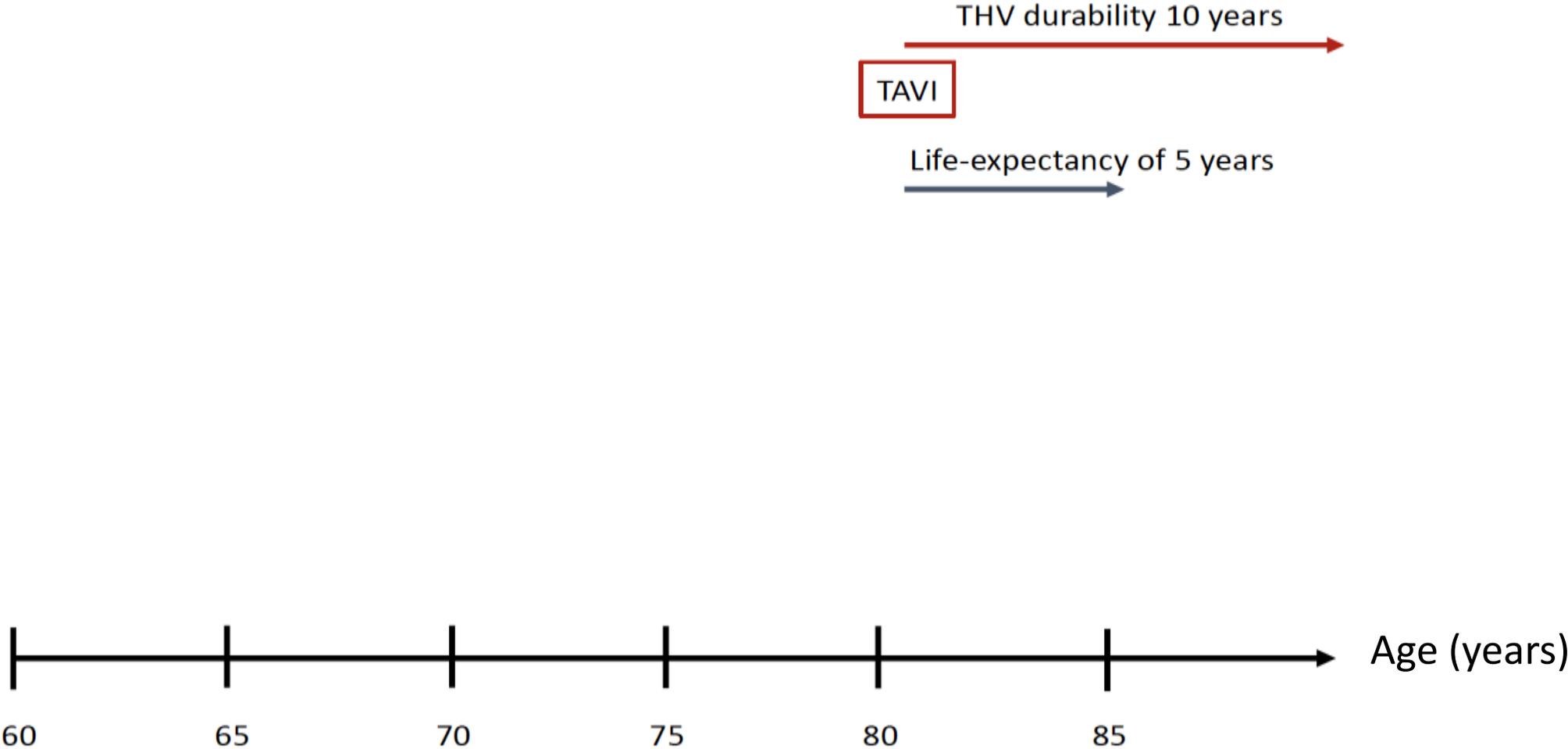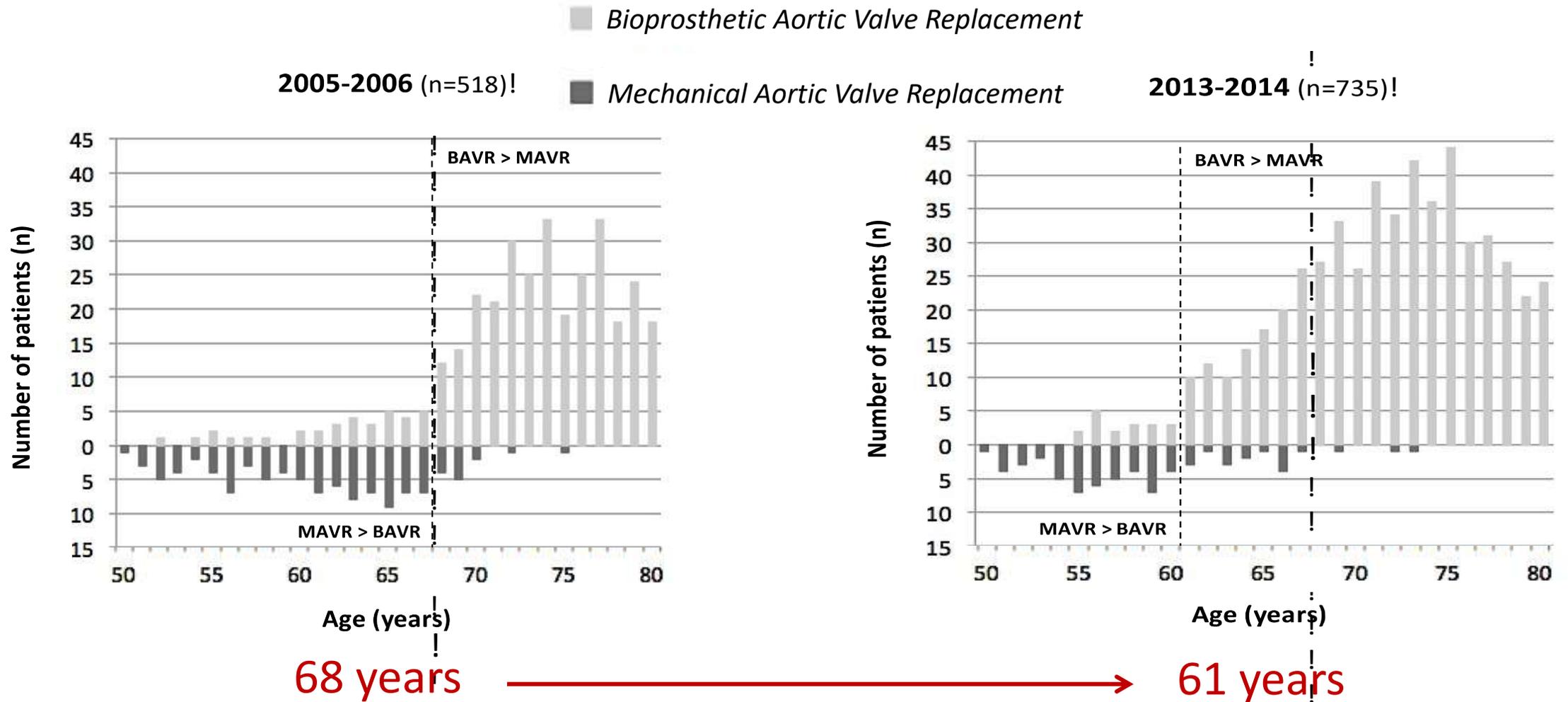
Patients with longer life-expectancy!

TAVI & patient life-expectancy

THV durability 10 years

TAVI

Life-expectancy of 5 years

THV durability 10 years
THV durability 10 years
THV durability 10 years

TAVI
TAVI-in-TAVI
TAVI-in-TAVI

Life-expectancy of 25 years

Age (years)

60   65   70   75   80   85

Sondergaard. Eur Heart J. 2019;40:1331-3
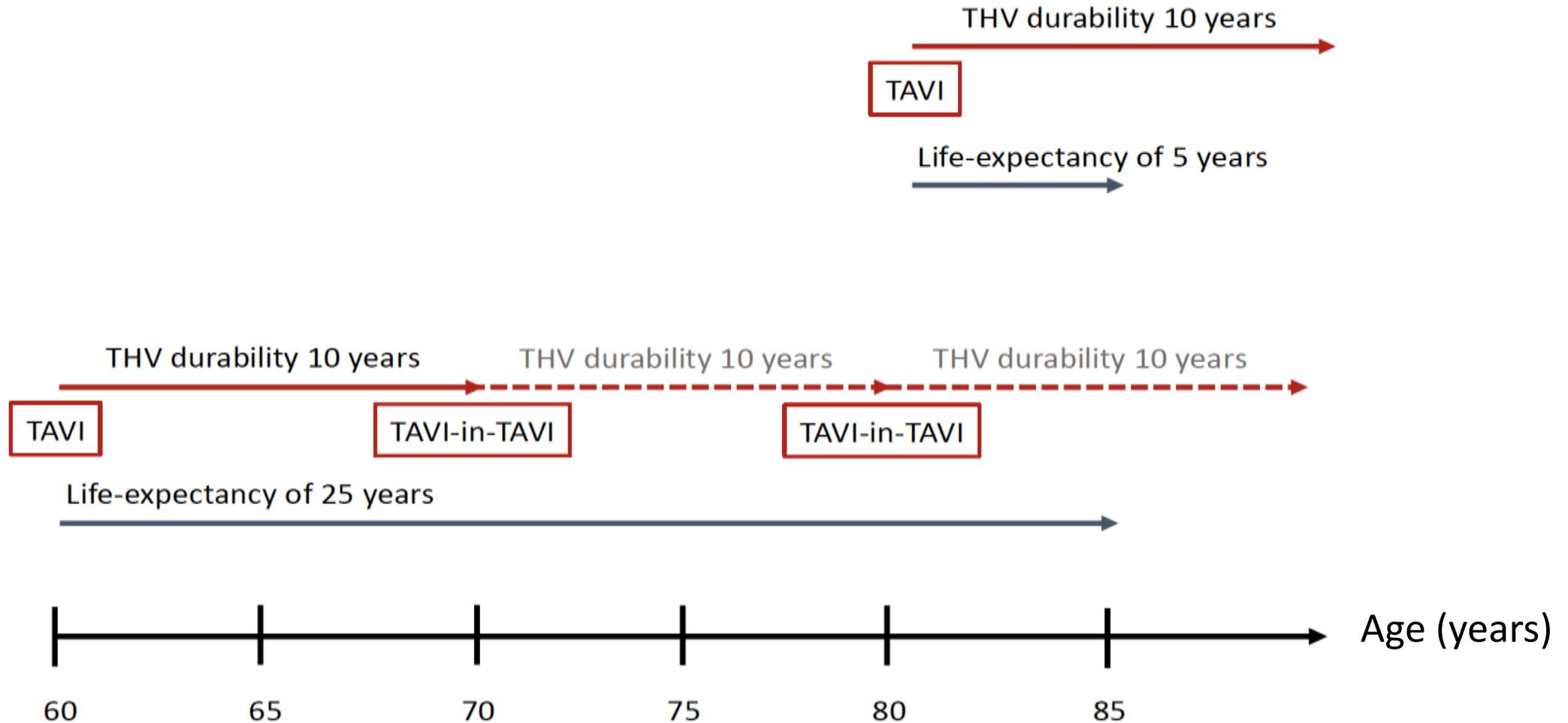
Life-time patient management

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

Patients with symptomatic severe aortic stenosis

Age <65 years Life-expectancy >20 years ↓ SAVR Class 1, Level A	Age 65-80 years Suitable for TF-TAVR ↓ SAVR or TAVR Life-expectancy vs. durability Class 1, Level A	Age >80 years Life-expectancy <10 years Suitable for TF-TAVR ↓ TAVR Class 1, Level A
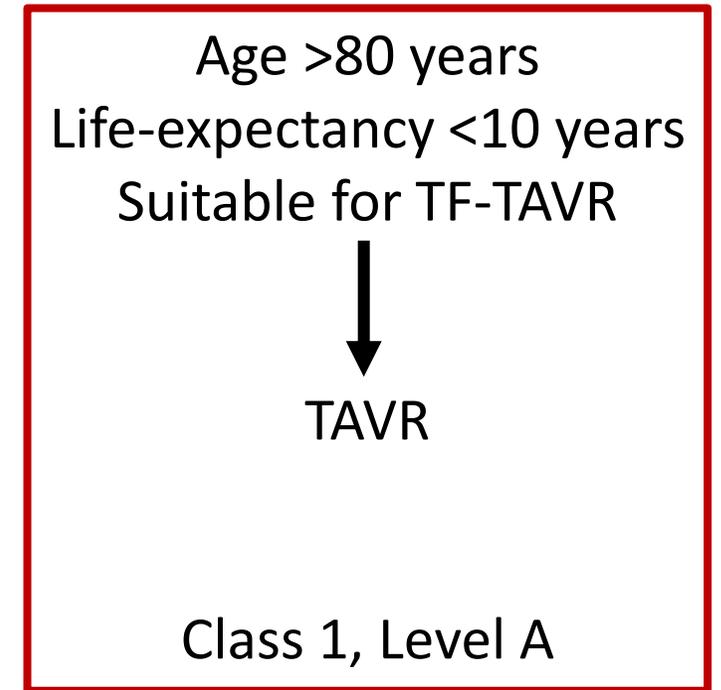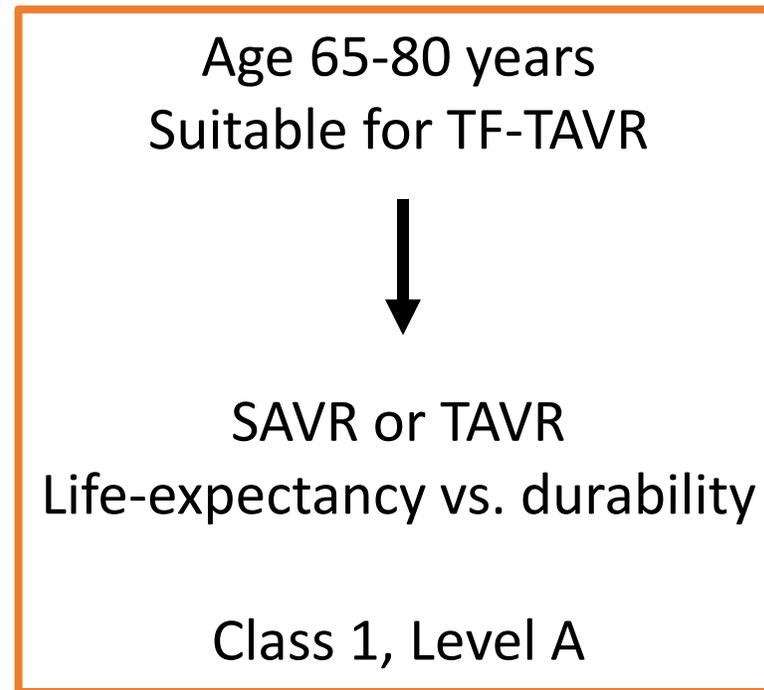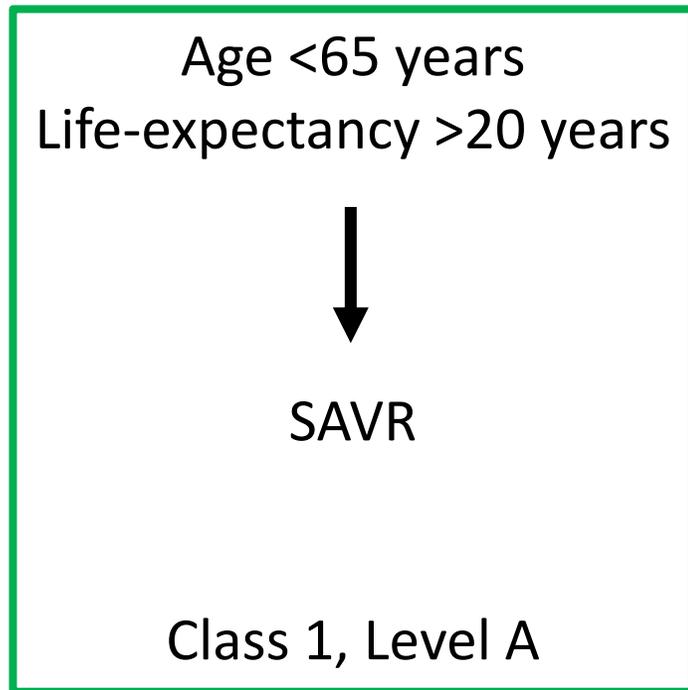
Life-time incidence of re-intervention
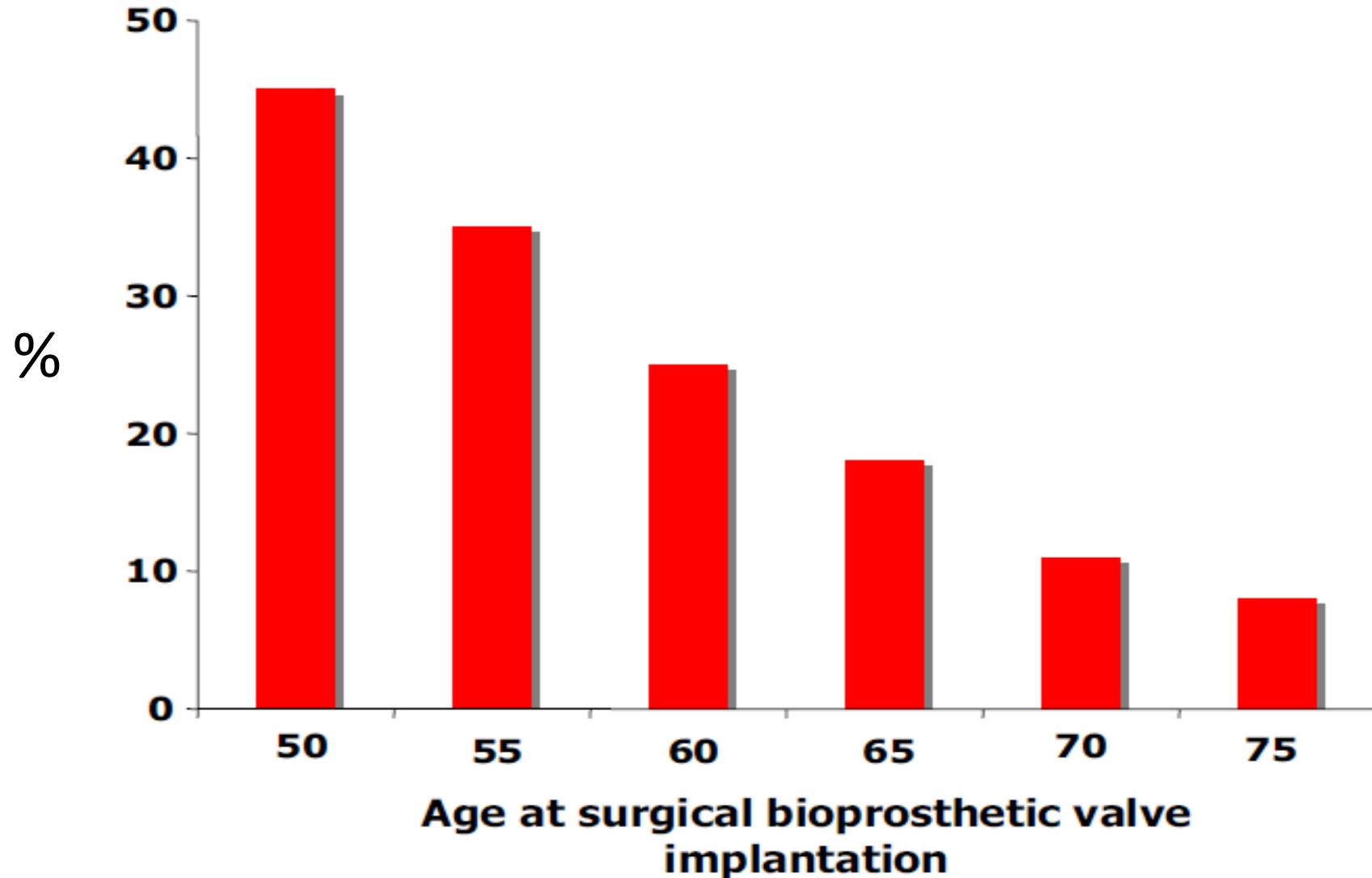
Bioprosthetic aortic valve degeneration

| Author(s) and Year	Sample Size	HR	Low	High		Hazard Ratio [95% CI]
Patient-prosthesis Mismatch						
Senage et al., 2014	617	1.95	1.01	3.74		1.95 [1.01, 3.75]
Flameng et al., 2014	648	1.95	1.52	2.51		1.95 [1.52, 2.51]
Urso et al., 2014	387	2.16	1.08	4.33		2.16 [1.08, 4.33]
De Paulis et al., 2016	205	0.92	0.19	6.98		0.92 [0.15, 5.58]
Random-effect model (I^2= 0%; Egger's test = 0.47)						1.95 [1.56, 2.43]
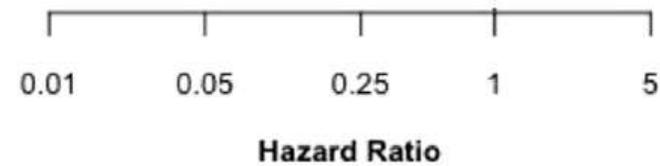
Risk factors:
Patient-prosthesis mismatch (HR 1.95)

Hazard Ratio: 0.01 0.05 0.25 1 5

Ochi et al. Heart, Lung and Circulation 2020;29:668-78

Patient-prosthesis mismatch

Indexed effective orifice area (iEOA)

>0.85 cm^2/m^2:   not present–mild PPM

0.65-0.85 cm^2/m^2:   moderate PPM

≤ 0.65 cm^2/m^2:   severe PPM

Pibarot. J Am Coll Cardiol. 2000;36:1131-41

PPM & cardiac-related mortality

Moderate PPM

Milano 2002	1.27 [0.30, 5.31]	
Mohty 2009	1.32 [1.01, 1.74]	
Ruel 2004	1.28 [0.45, 3.70]	
Total [95% CI]	**1.32 [1.02, 1.71]**	
Heterogeneity: I² = 0%		

HR 1.32

0.01   0.1   10   100
Favours PPM   Favours no PPM
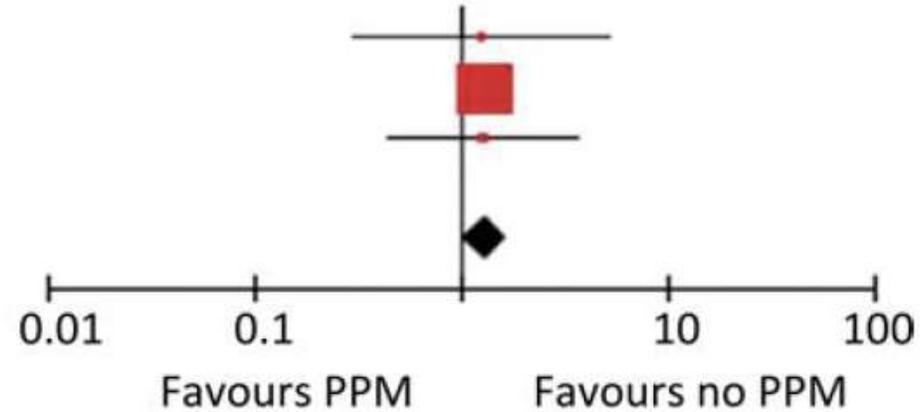
Severe PPM

Milano 2002	1.00 [0.11, 8.98]	
Ruel 2004	7.54 [3.51, 16.19]	
Mohty 2009	9.58 [3.74, 24.55]	
Total [95% CI]	**6.46 [2.79, 14.97]**	
Heterogeneity: I² = 42%		

HR 6.46

0.01   0.1   10   100
Favours PPM   Favours no PPM

Head et al. Eur Heart J.2012;33:1518-29
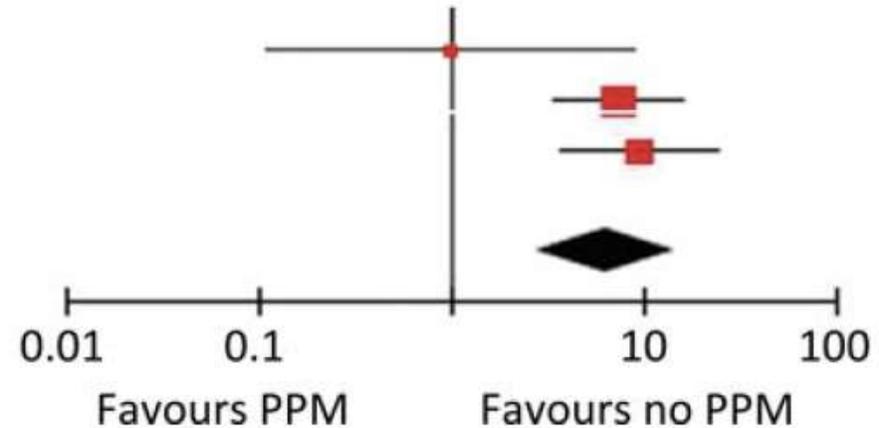
# How to avoid patient-prosthesis mismatch?

PARTNER 3
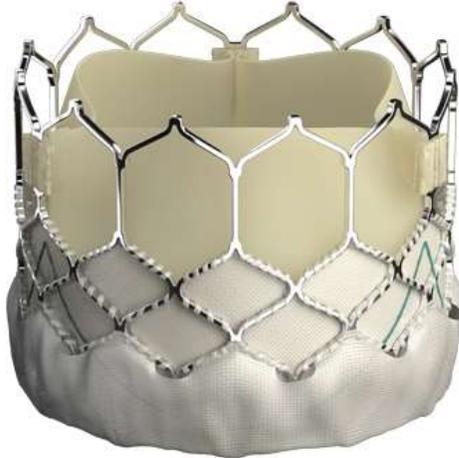
Evolut Low Risk

Sapien 3:
Balloon expandable THV
Intra-annular leaflet position

Evolut:
Self-expandable THV
Supra-annular leaflet position

Severe patient-prosthesis mismatch

Mack et al. NEJM 2019;380:1695-1705 & Popma et al. NEJM 2019;380:1706-15

The Portico IDE study

Makkar et al. Lancet. 2020;396:669-83
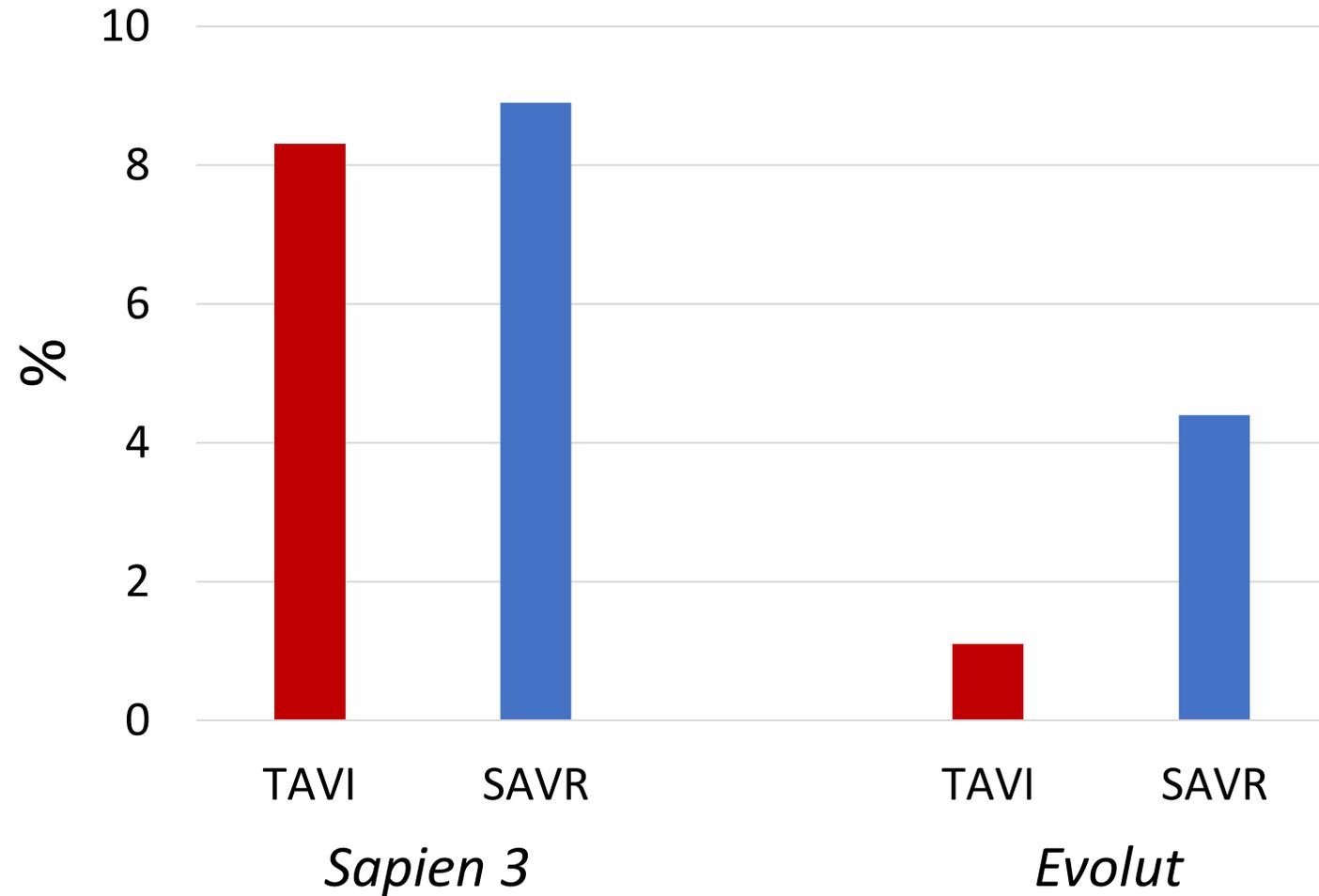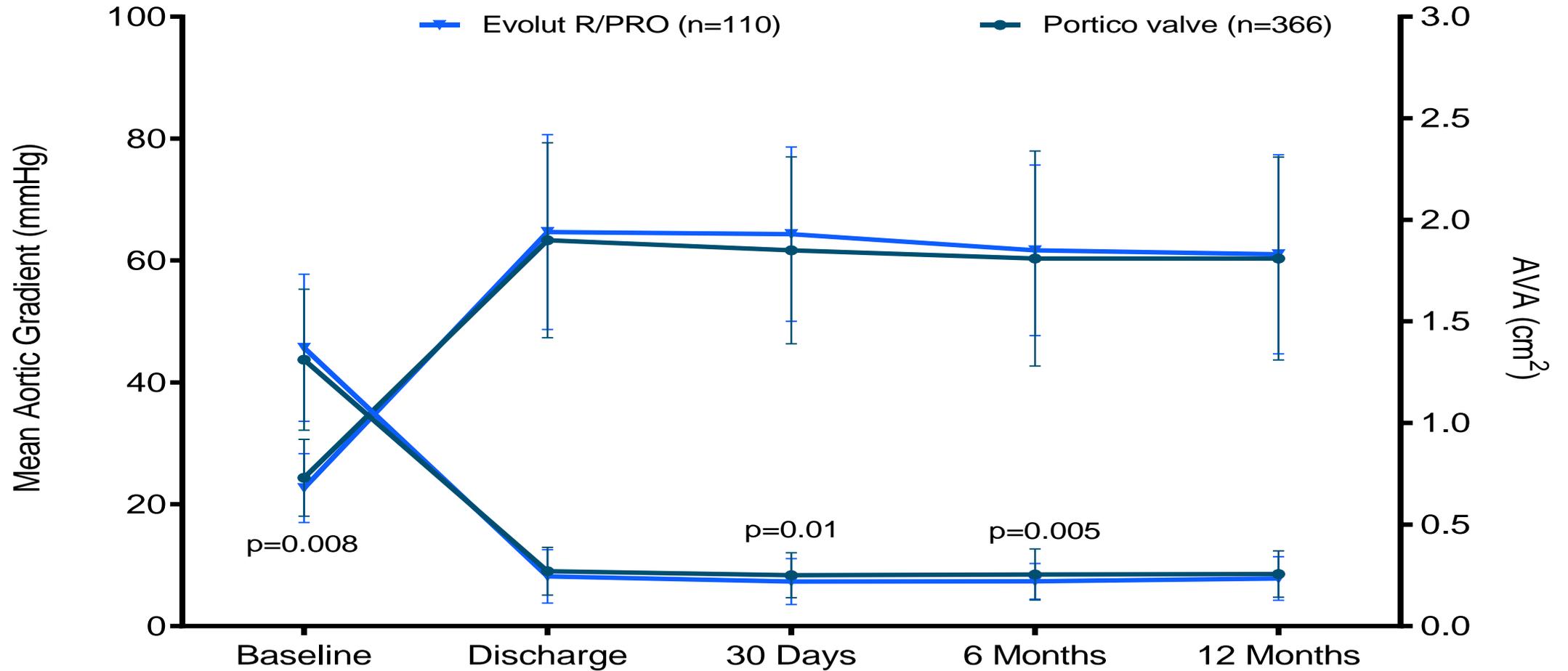
The NOTION trial

Objective:	Compare TAVI vs. SAVR in lower risk patients $\geq$70 years
Primary outcome:	Composite rate of all-cause mortality, stroke or myocardial infarction at 1 year (VARC II-defined)
Secondary outcomes:	Safety, efficacy, and echocardiographic outcomes (VARC II-defined)
Design:	Prospective, multi-centre, non-blinded, randomised
Enrollment period:	December 2009 - April 2013

The NOTION trial: All-cause mortality (CoreValve)

Jorgensen et al. European Heart Journal. In press
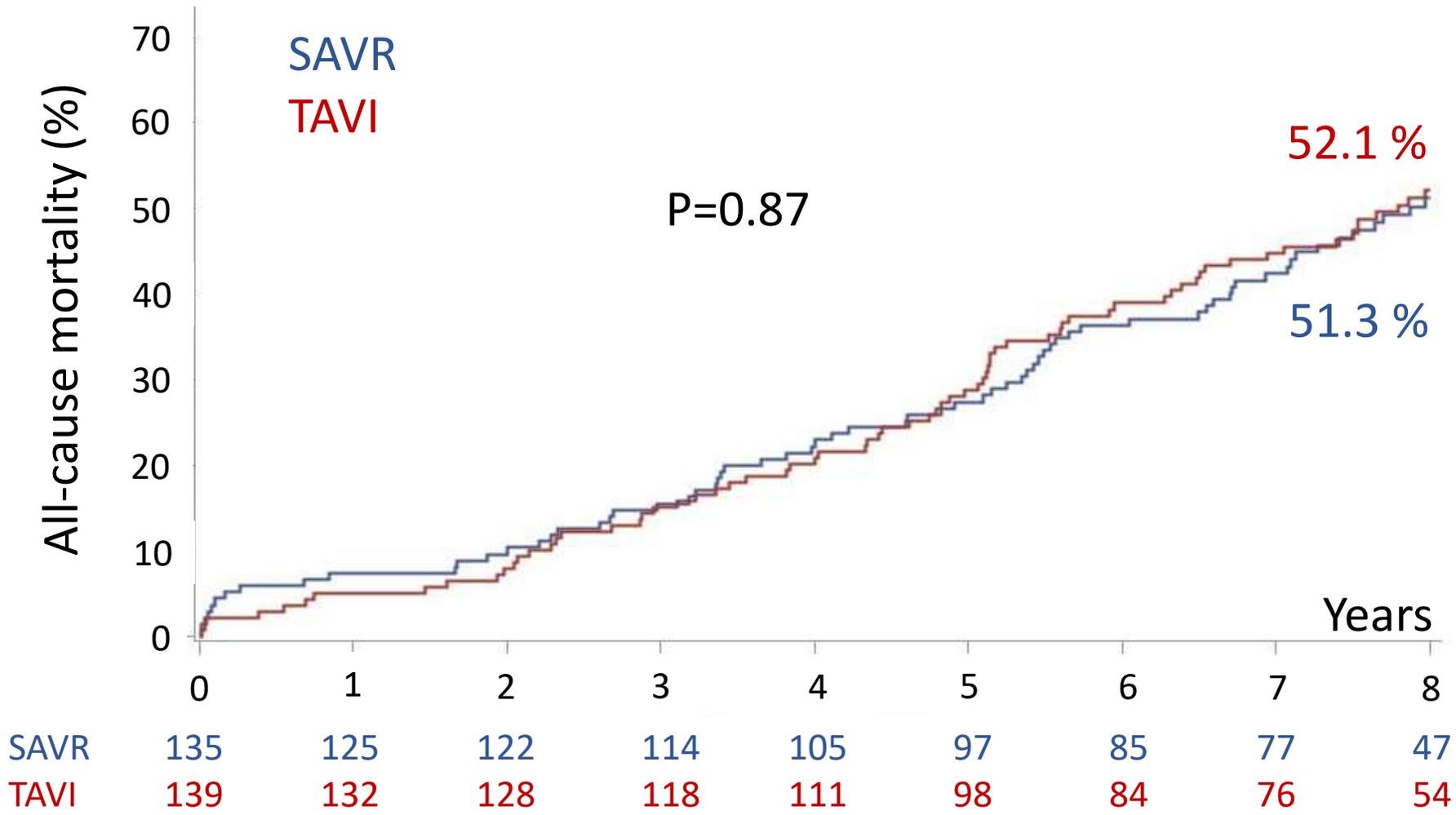
European consensus on durability

Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Capodanno et al . Eur Heart J. 2017; 38:3382-90

Bioprosthetic valve dysfunction

Structural Valve Deterioration	Nonstructural Valve Deterioration	Thrombosis	Endocarditis
Intrinsic permanent changes of the prosthetic valve (i.e., calcification, leaflet fibrosis, tear or flail) leading to degeneration and/or haemodynamic dysfunction	Any abnormality not intrinsic to the prosthetic valve itself (i.e., intra- or para-prosthetic regurgitation, prosthesis malposition, patient-prosthesis mismatch, late embolization) leading to degeneration and/or dysfunction	Thrombus development on any structure of the prosthetic valve, leading to dysfunction with or without thrombo-embolism	Infection involving any structure of the prosthetic valve, leading to perivalvular abscess, dehiscence, pseudo-aneurysms, fistulae, vegetations, cusp rupture or perforation

Capodanno et al . Eur Heart J. 2017; 38:3382-90

# Structural valve deterioration

Moderate or severe haemodynamic SVD

- Mean gradient ≥20 mmHg *OR*

- Mean gradient ≥10 mmHg change from baseline *OR*

- Moderate/severe intra-prosthetic aortic regurgitation *(new or worsening from baseline)*

Capodanno et al. Eur Heart J. 2017; 38:3382-90

Modified criteria

- Mean gradient ≥20 mmHg *AND*

 mean gradient ≥10 mmHg change from baseline

Structural valve deterioration

Structural valve deterioration (%)

SAVR
TAVI

Mean gradient ≥20 mmHg *OR*

Mean gradient ≥10 mmHg change from baseline *OR*

Moderate central aortic regurgitation

P=0.001

28.5 %

14.1 %

Years

	0	1	2	3	4	5	6	7	8
SAVR	135	113	105	97	84	75	62	54	30
TAVI	139	130	126	115	107	94	80	68	44

Jorgensen et al. European Heart Journal. In press
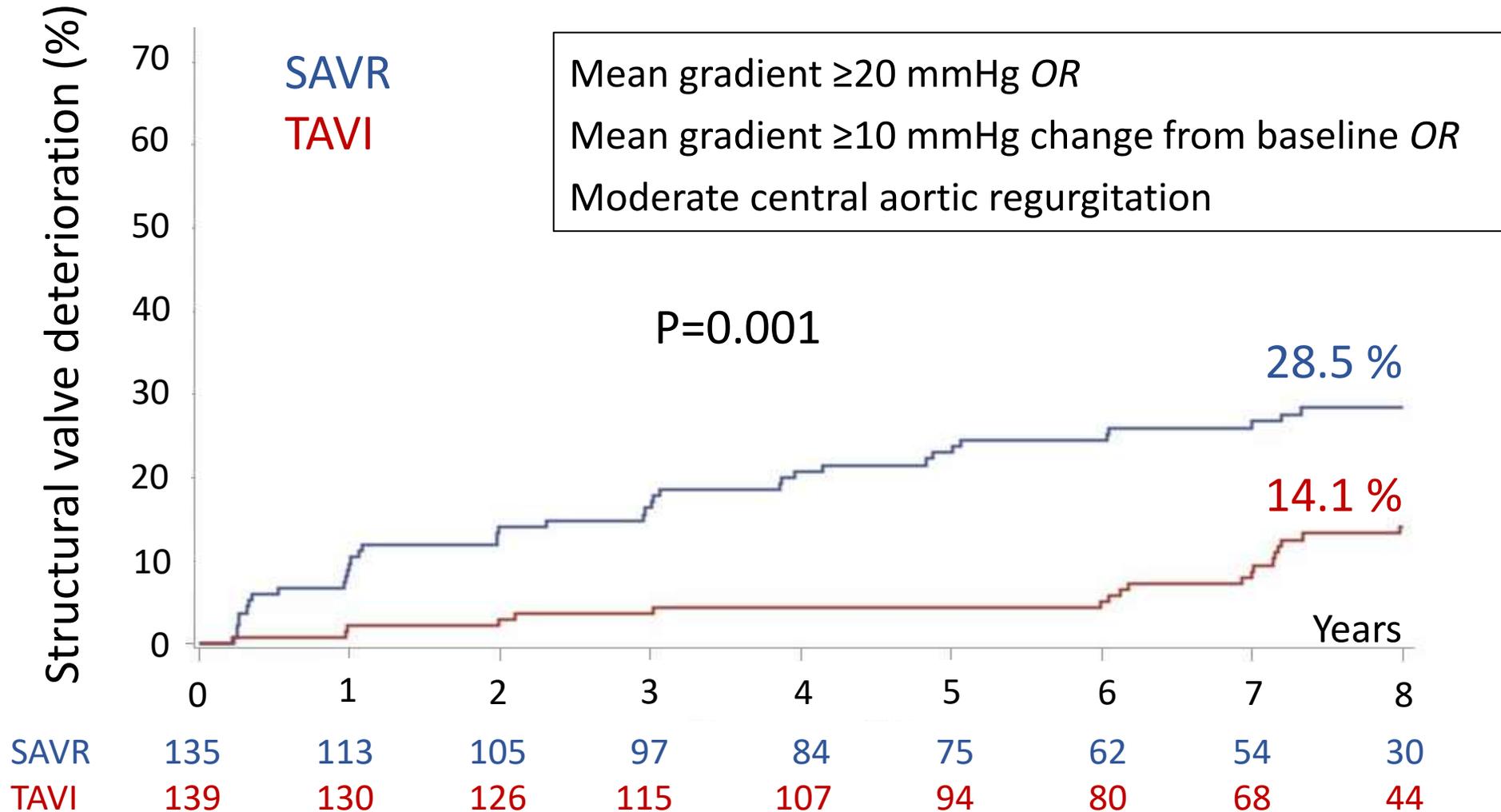
NOTION: Structural valve deterioration (CoreValve)

Jorgensen et al. European Heart Journal. In press
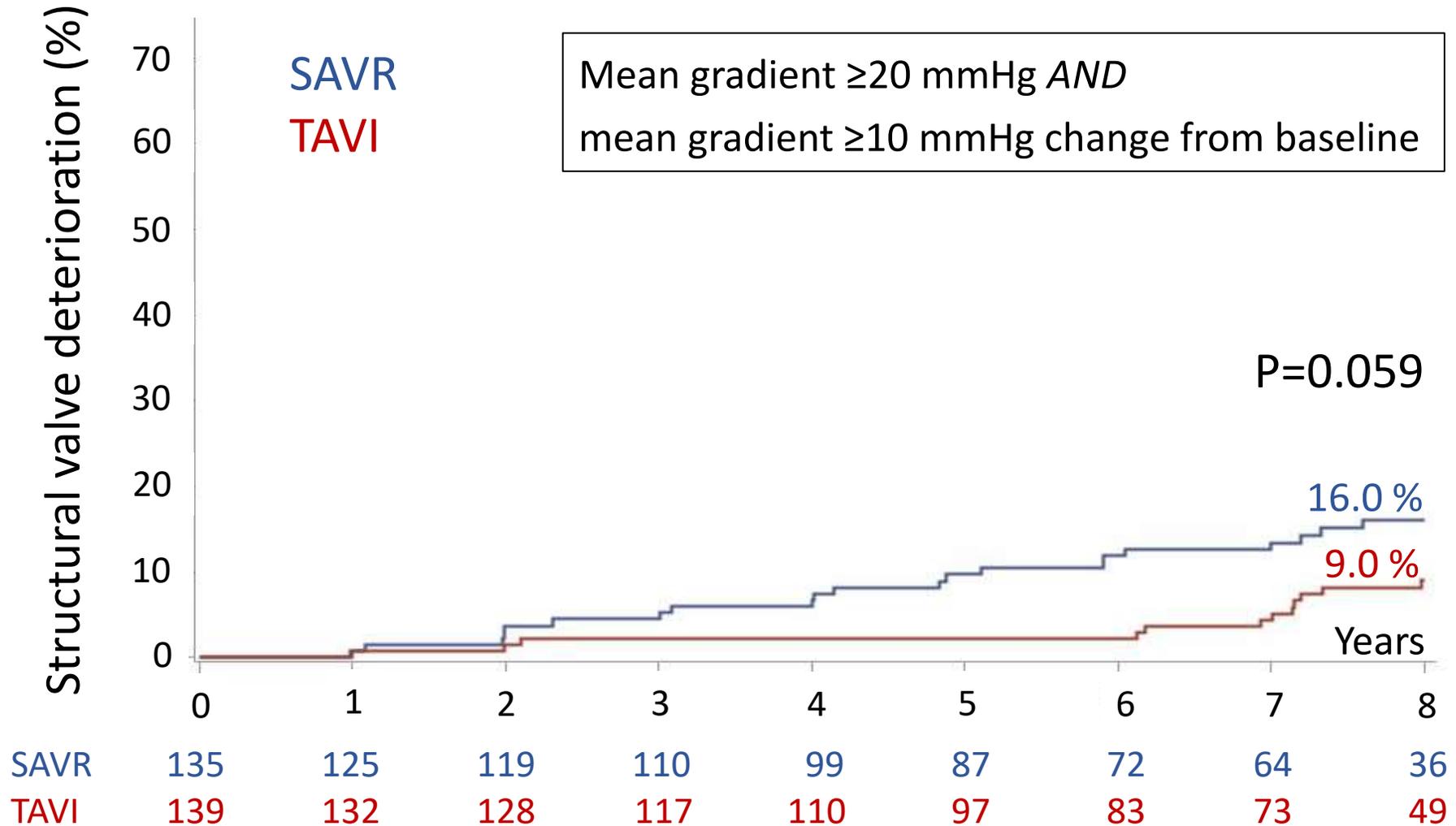
PARTNER 2: Structural valve deterioration (SAPIEN)

SAPIEN XT vs. SAVR (5 years)
HR: 2.61 [95% CI: 1.45-4.69]
p < 0.001

9.5% [7.0%-12.7%]

3.5% [2.1%-5.8%]
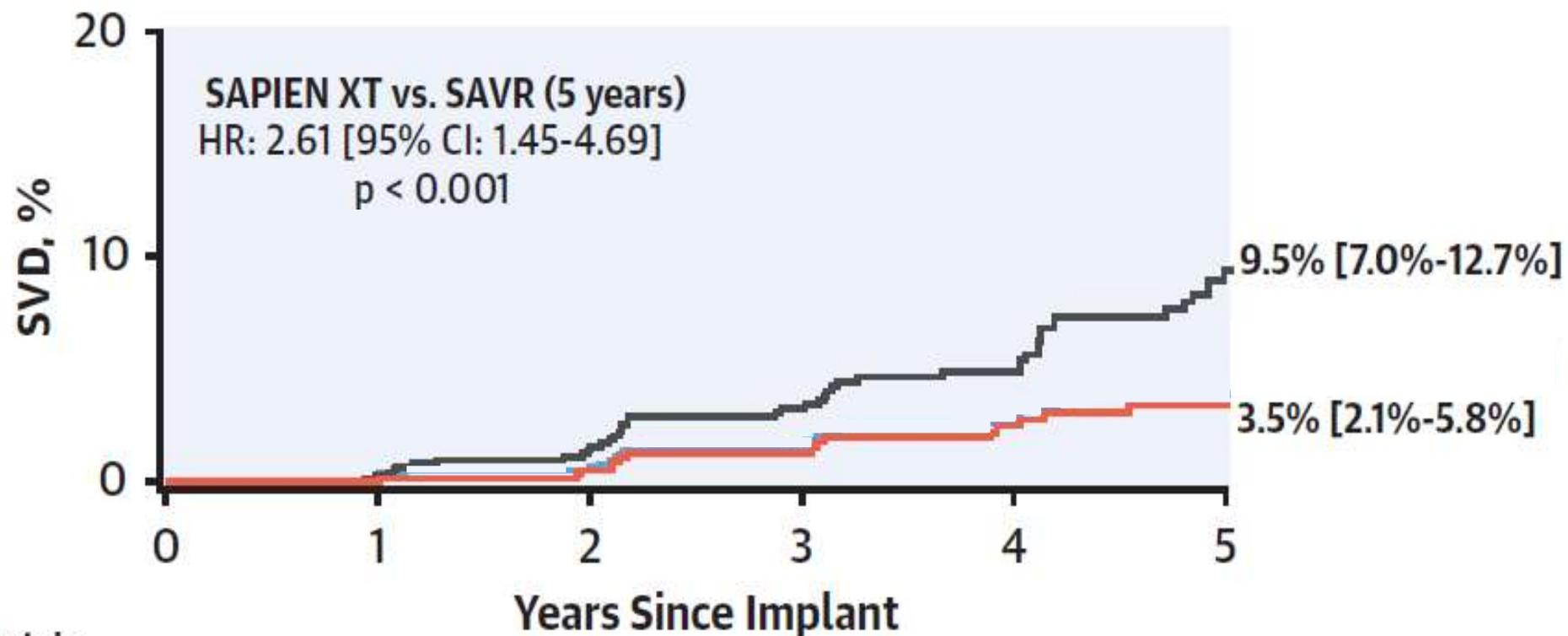
No. at risk:

SAVR	664	625	538	449	346	265
SAPIEN XT	774	733	622	505	368	297

Bioprosthetic valve failure

Severe structural valve deterioration

Valvular re-intervention

Valve-related death

Capodanno et al . Eur Heart J. 2017; 38:3382-90
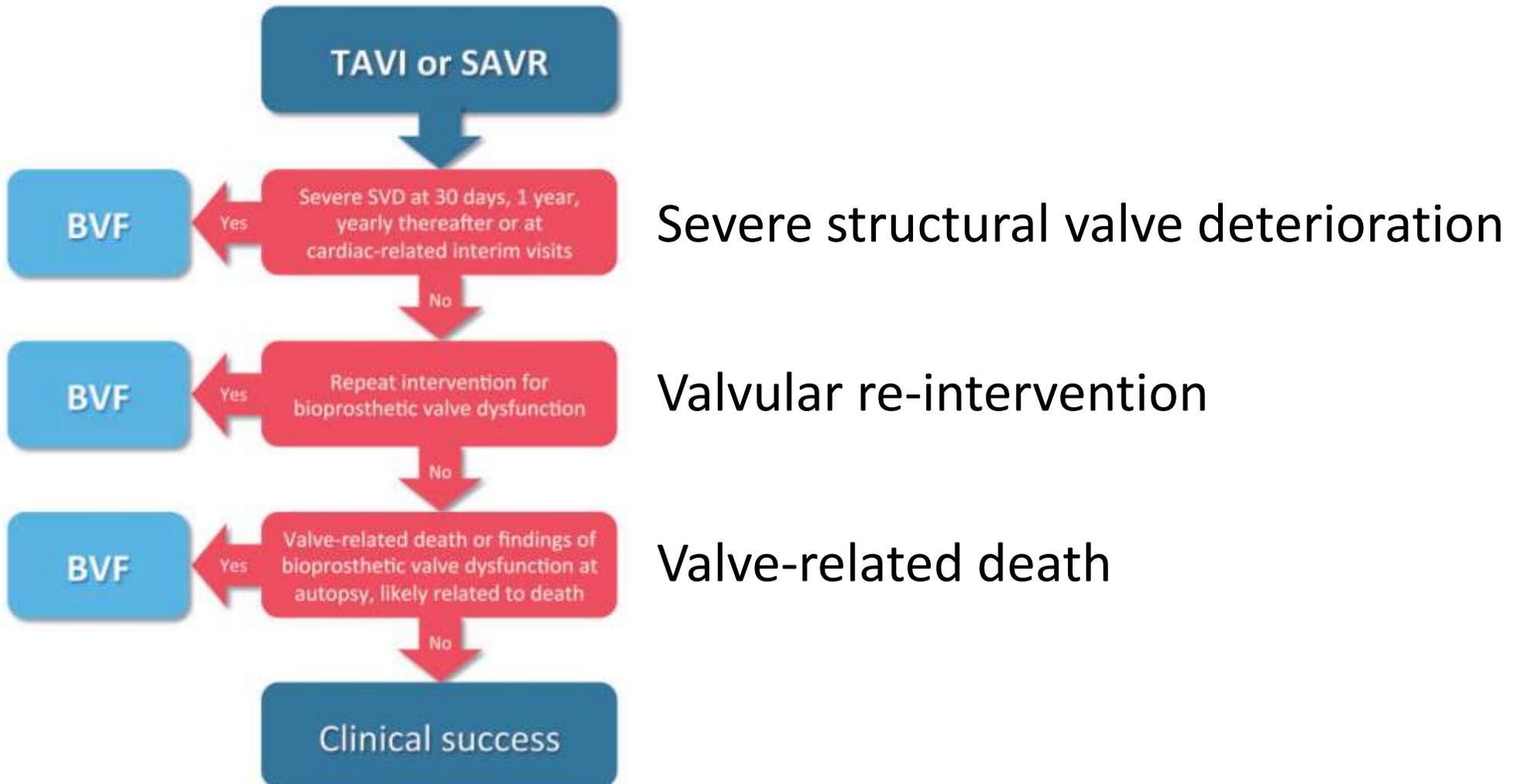
NOTION: Bioprosthetic valve failure (CoreValve)

Bioprosthetic valve failure (%)

SAVR
TAVI

Severe structural valve deterioration *or*
Re-intervention *or*
Valve-related death

P=0.34

10.6 %

7.3 %

Years

	0	1	2	3	4	5	6	7	8
SAVR	135	125	121	113	103	94	82	73	45
TAVI	139	133	128	118	111	98	84	75	53
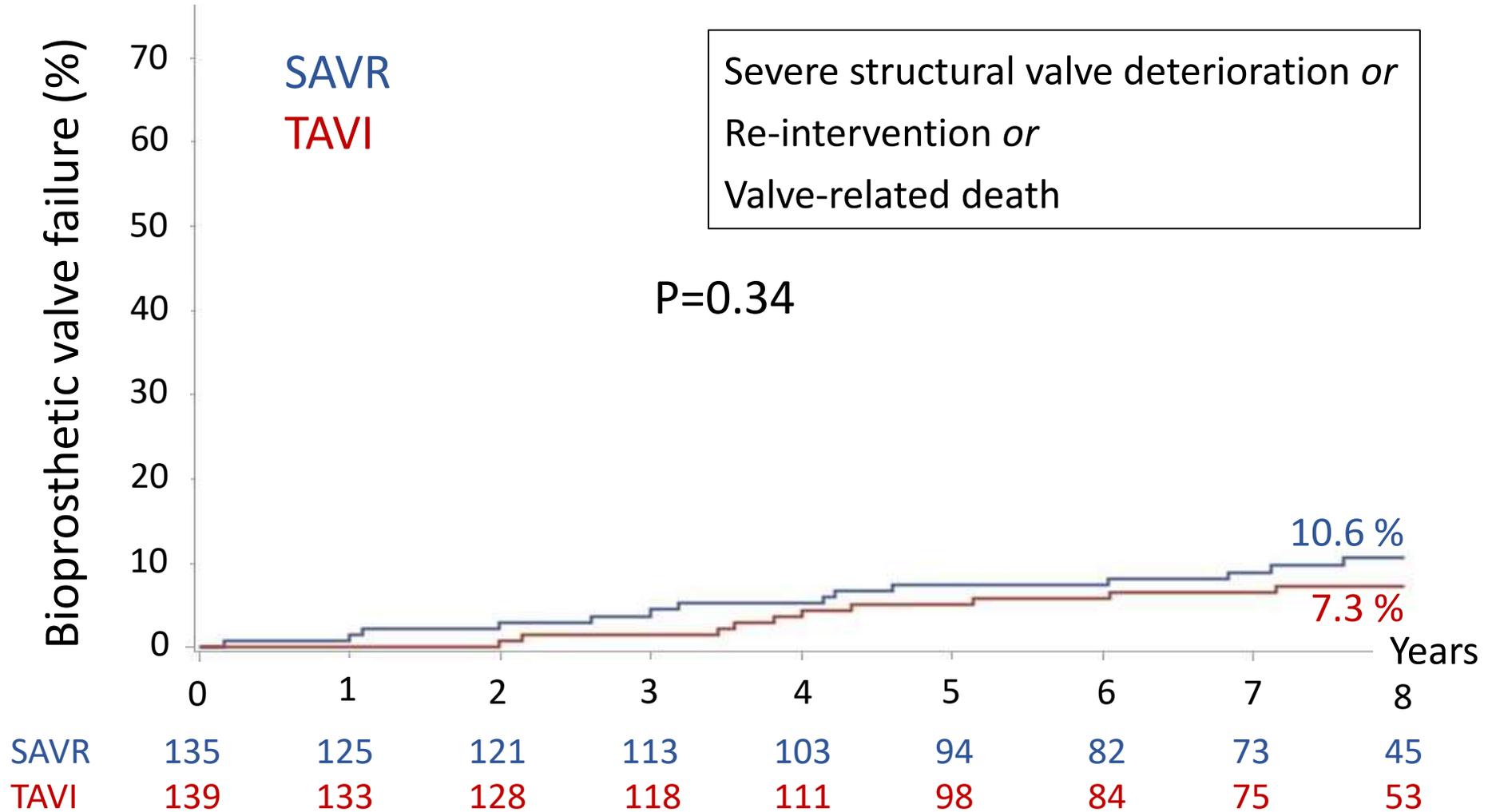
PARTNER 2: Bioprosthetic valve failure (SAPIEN)
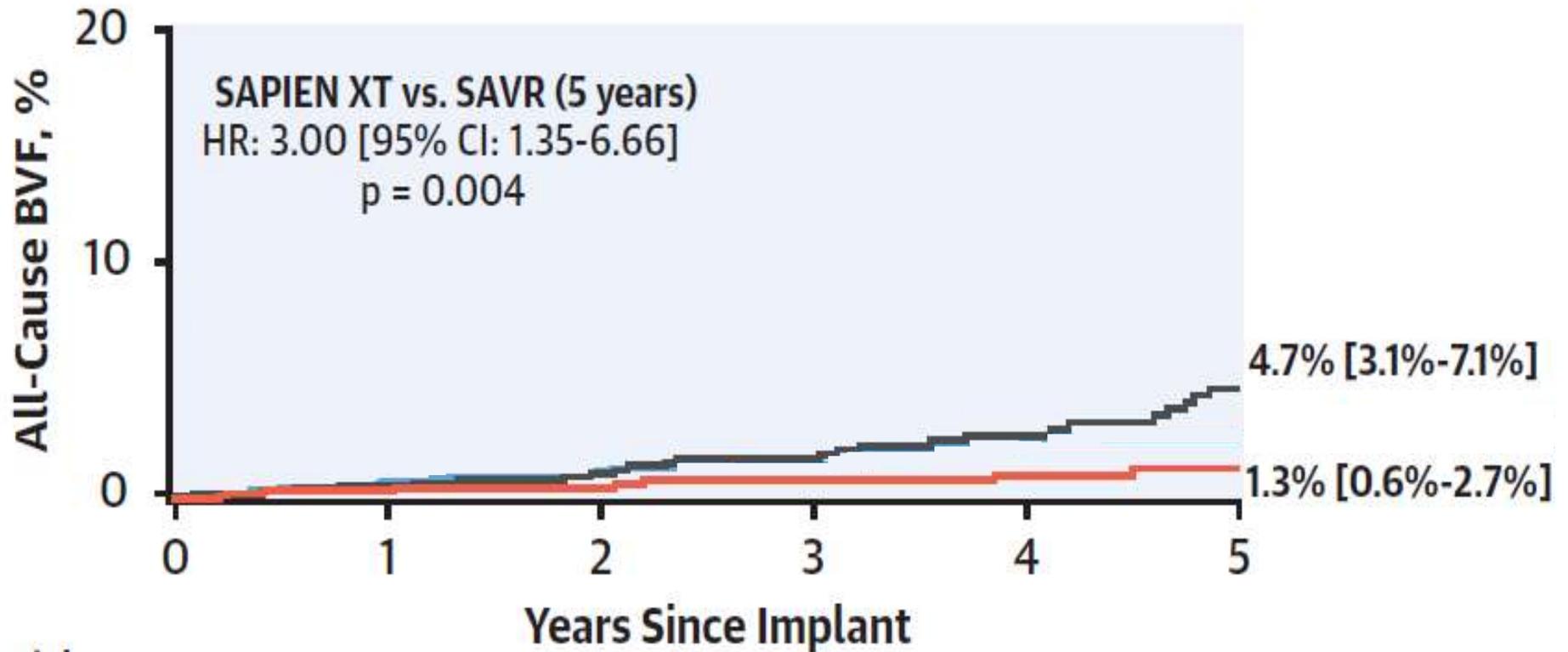
Durability of bioprosthetic aortic valves

- Durability of bioprosthetic aortic valves is important - particular in patients with longer life-expectancy

- Self-expandable THV offer largest EOA and lowest transvalvular gradient

- This may transform into lower rate of structural valve deterioration and valve failure as compared to both balloon expandable THV and surgical bioprosthetic aortic valves

- Similar, the lower rate of severe patient-prosthesis mismatch with SE THV may improve the survival rate after TAVI