TAVI for intermediate risk patients

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The right indication

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SPECIAL ARTICLE

Transcatheter valve implantation for patients with aortic stenosis: a position statement from the European Association of Cardio-Thoracic Surgery (EACTS) and the European Society of Cardiology (ESC), in collaboration with the European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Alec Vaha
Jeroen Ba
Gerard Fo
Francesco
José Luis
Ben van H

Indication for TAVI is:

- **Symptomatic severe aortic stenosis and**
- **HIGH-RISK (LES ≥ 20%, STS ≥ 10%) and/or CONTRAINDICATION for surgical aortic valve replacement**

EACTS/ESC/EAPCI Position statement Eur Heart J 2008

Recommendations for TAVI: no mention of risk

Recommendation	Class	Level
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whomTAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B

Risk Stratification

How to define the risk?

Consider:

1.Risk scores

2.Frailty

3.Anatomical risk

Risk stratification

Limitations of risk scores

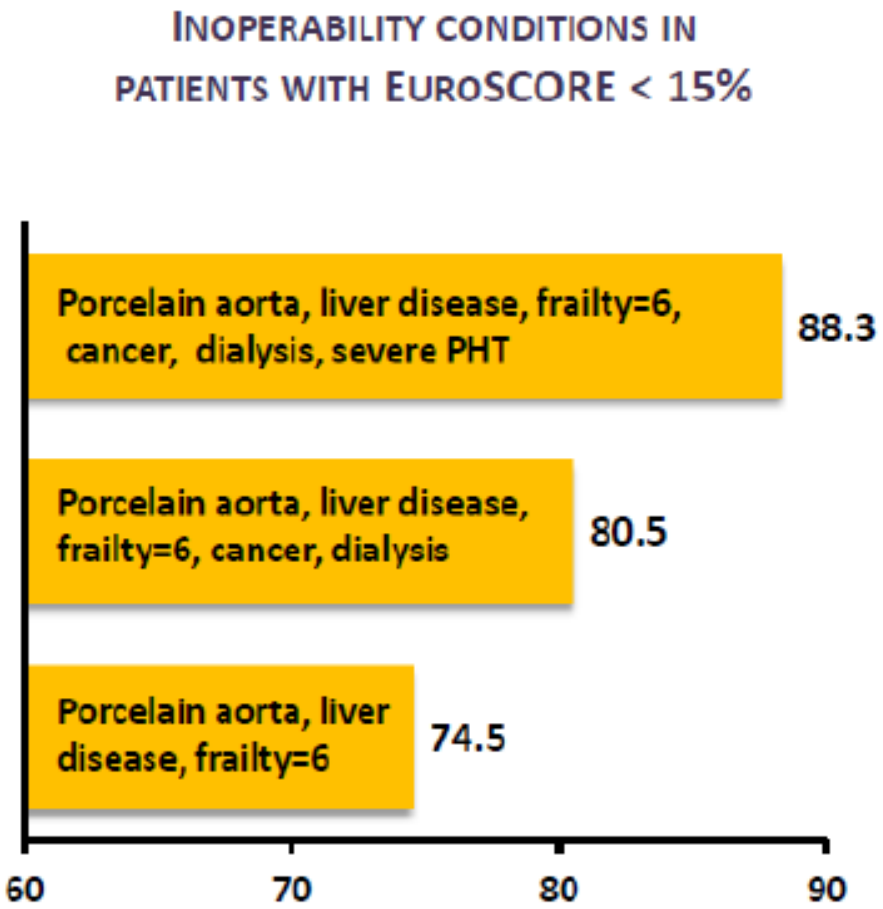
80 year-old male with a previous history of stroke and poor LV function (EF 20%)

Logistic EuroSCORE
18.9%

STS score
1.7%

Highlights the limitations in relying on risk scores to estimate surgical risk

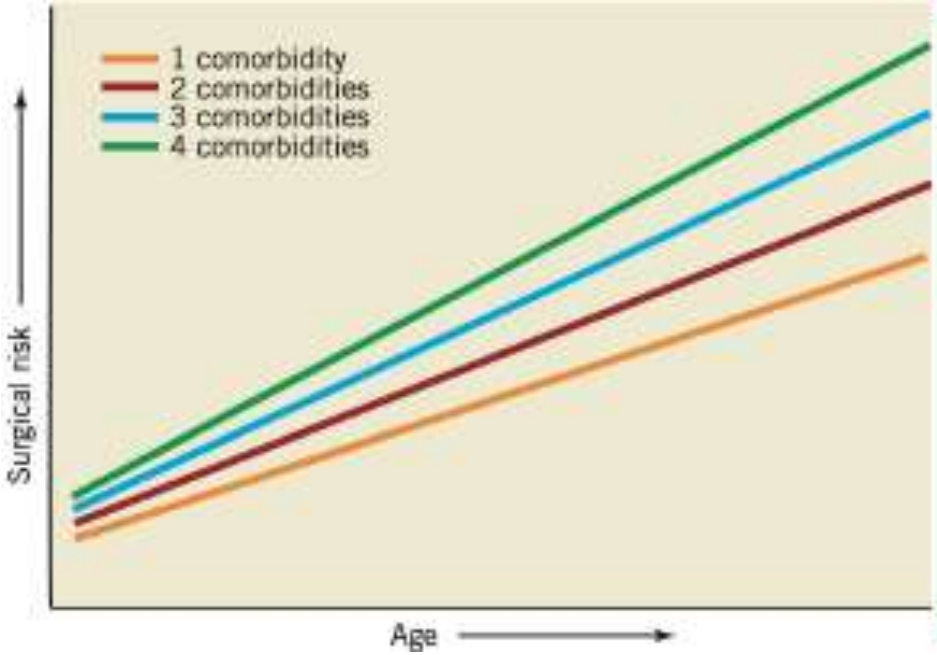
SOURCE XT



M. Thomas, TVT 2013

How can we define the intermediate risk?

SURTAVI model Rationale



Low risk

- ≥70 years and <2 risk factors
- ≥75 years and no risk factors

Intermediate risk

- ≥70 years and 2 or 3 risk factors
- ≥75 years and 1 or 2 risk factors
- ≥80 years and ≤1 risk factor

High risk

- ≥70 years and >3 risk factors
- ≥75 years and >2 risk factors
- ≥80 years and >1 risk factor

Van Mieghem N et al. EuroIntervention 2012;8:258-66

SURTAVI Model Co-Morbidities

- Coronary artery disease requiring revascularization
- Frailty (Katz score + Ambulation Aid + Dementia)
- Left ventricular dysfunction (EF <35% by TTE)
- Neurological dysfunction (with functional impairment)
- Pulmonary disease (GOLD stage II)
- Peripheral vascular disease (including porcelain aorta)
- Renal disease (KDOQI Stage 3, GFR < 60 mL/min)
- Redo cardiac surgery
- Pulmonary hypertension (> 60mmHg)
- Diabetes

Van Mieghem N et al. EuroIntervention 2012;8:258-66

TAVI

Expanding indications?

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EXPEDITED PUBLICATION

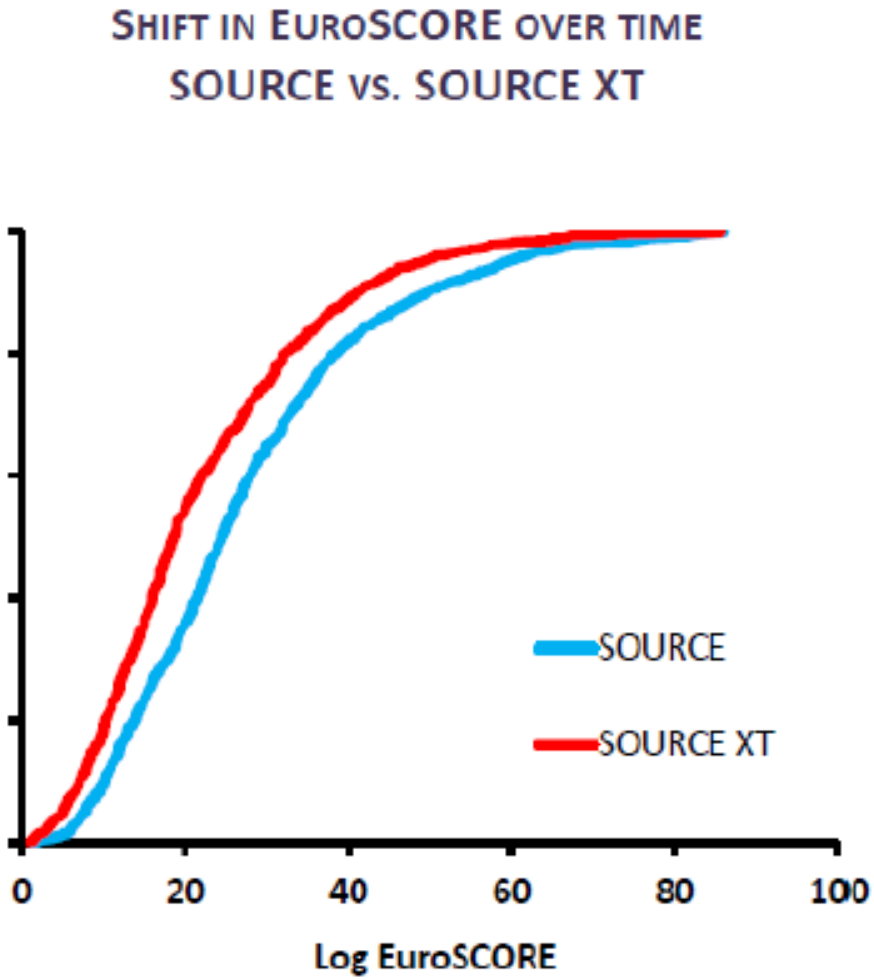
Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

Table 1 Baseline Characteristics for the Overall Cohort and Quartiles 1 to 4

	Overall Cohort	Q1	Q2	Q3	Q4	p Value
Age, yrs	80.3 ± 7.1	81.11 ± 7.00	81.1 ± 7.2	80.19 ± 6.20	78.9 ± 7.9	0.09
Female	265 (63)	58 (55.2)	63 (60)	76 (72.4)	68 (64.8)	0.065
Logistic EuroSCORE, %	20.17 ± 13.00	25.44 ± 16.0	18.9 ± 10.0	18.3 ± 11.0	17.8 ± 12.0	<0.001*
STS-PROM, %	6.1 ± 4.1	7.13 ± 5.4	6.2 ± 3.5	5.8 ± 3.9	4.8 ± 2.6	<0.001†
NYHA functional class III or IV	406 (96.7)	104 (99)	99 (94.3)	101 (96.2)	102 (97.2)	0.27

Change in EuroSCORE over time



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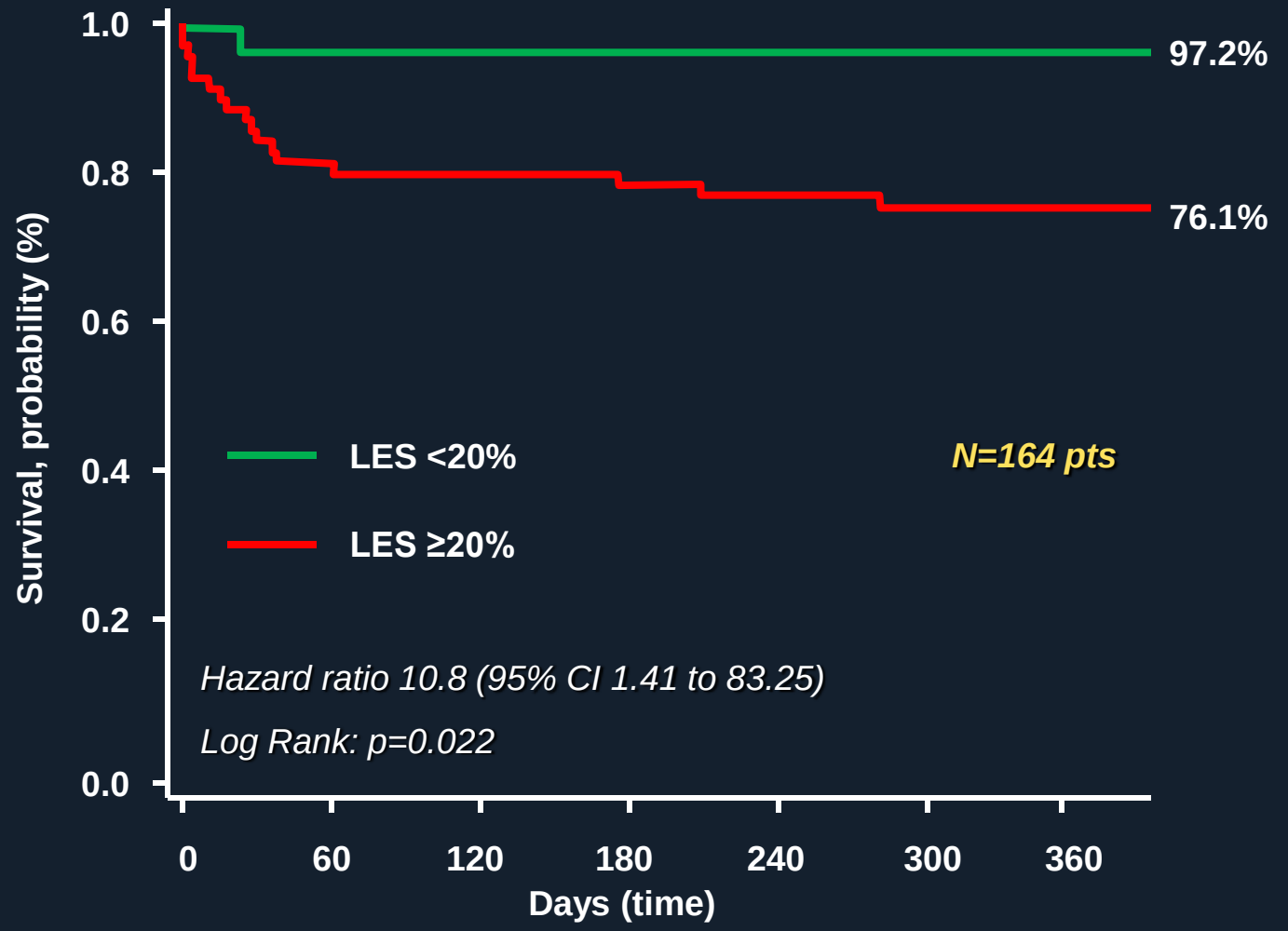
Clinical Results of TAVI in lower risk patients

TABLE I. Baseline Clinical and Echocardiographic Characteristics

	Overall ($n = 162$)	LES $\geq$ 20% ($n = 78$)	LES < 20% ($n = 84$)	LES $\geq$ 20%/LES < 20% P value
Age, mean ± SD, y	81 ± 5	82 ± 5	80 ± 5	0.011*
Female gender, *n* (%)	96 (59.2)	46 (58.9)	50 (59.2)	0.943
Hypertension, *n* (%)	129 (79.6)	65 (83.3)	64 (76.2)	0.559
Diabetes, *n* (%)	44 (27.1)	21 (26.9)	23 (27.4)	0.799
Peripheral vascular disease, *n* (%)	12 (7.4)	12 (15.4)	0 (0.0)	<0.001*
Porcelain aorta, *n* (%)	30 (18.5)	5 (6.4)	25 (29.7)	0.002*
Congestive heart failure[a], *n* (%)	72 (44.4)	43 (55.1)	29 (34.5)	0.016*
Previous myocardial infarction, *n* (%)	32 (19.7)	21 (26.9)	11 (13.1)	0.039*
Prior stroke, *n* (%)	12 (7.4)	5 (6.4)	7 (8.3)	0.579
Prior TIA, *n* (%)	12 (7.4)	7 (8.9)	5 (5.9)	0.517
Previous CABG, *n* (%)	15 (9.2)	12 (15.4)	3 (3.6)	0.012*
Previous cardiosurgery[b], *n* (%)	3 (1.8)	3 (3.8)	0 (0.0)	0.118
Previous PCI, *n* (%)	49 (30.2)	27 (34.6)	22 (26.2)	0.329
COPD, *n* (%)	34 (20.8)	22 (28.2)	12 (14.3)	0.042*
Liver cirrhosis, *n* (%)	3 (1.8)	0 (0.0)	3 (3.6)	0.118
CRF, *n* (%)	34(20.9)	28 (35.9)	6 (7.1)	<0.001*
Prior aortic valvuloplasty, *n* (%)	65 (40.1)	26 (33.3)	39 (46.4)	0.563
Prior PM, *n* (%)	15 (9.2)	10 (12.8)	5 (5.9)	0.158
NYHA class III and IV, *n* (%)	99 (61.1)	48 (61.5)	51 (60.7)	0.492
Echocardiogram				
Mean Gradient, mean ± SD, mm Hg	55 ± 17	53 ± 1	57 ± 19	0.219
AVA, mean ± SD, cm^2	0.6 ± 0.2	0.6 ± 0.2	0.6 ± 0.2	0.480
LV-EF, mean ± SD, %	51 ± 10	48 ± 12	53 ± 7	0.002*
Logistic EuroSCORE, mean ± SD, %	22.4 ± 14.3	32.8 ± 13.2	12.6 ± 6.5	<0.001*
STS Score, mean ± SD, %	7.3 ± 4	9.9 ± 4	5.0 ± 2	<0.001*

TAVI in lower risk patients

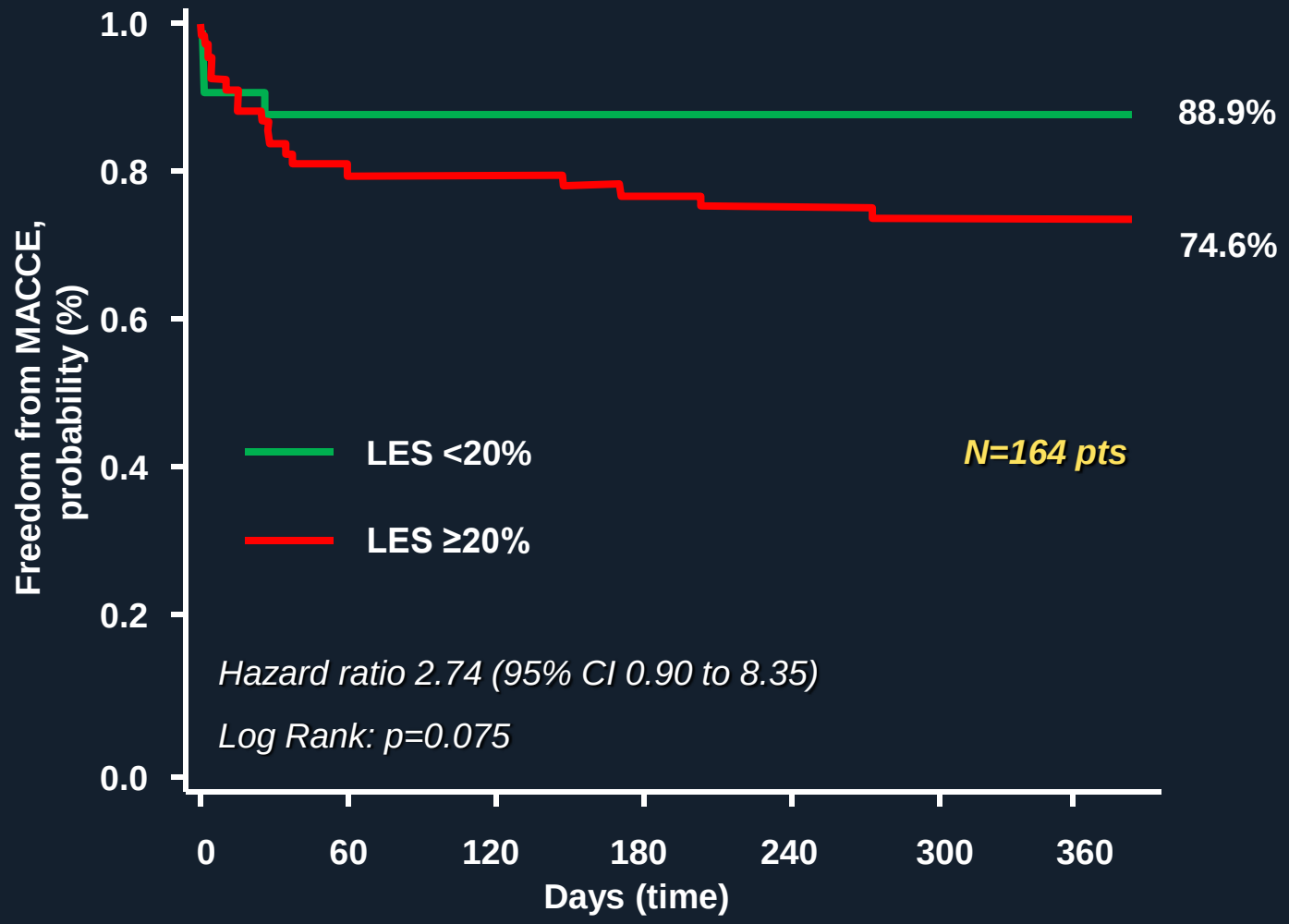
1-year Survival



Tamburino C, et al. CCI 2011

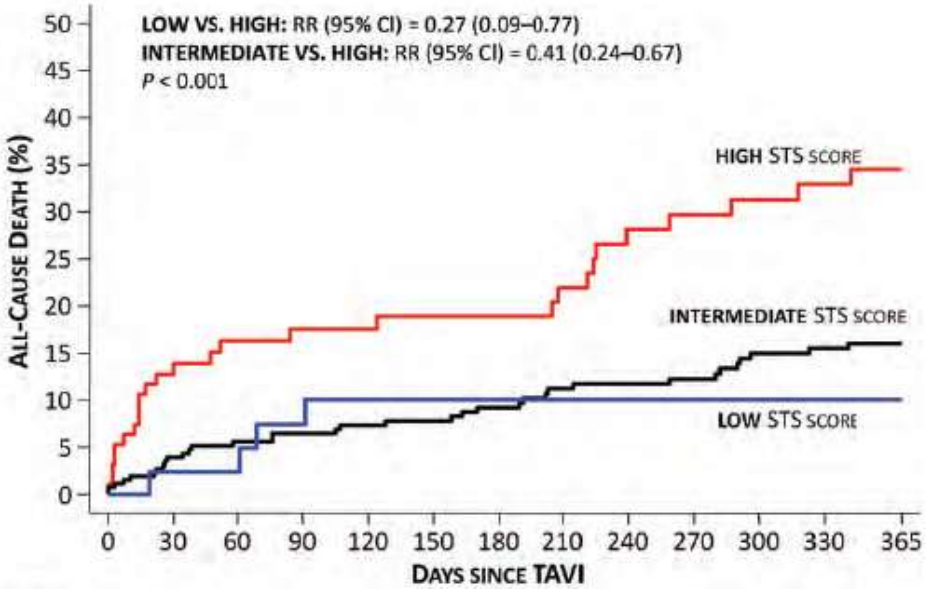
TAVI in lower risk patients

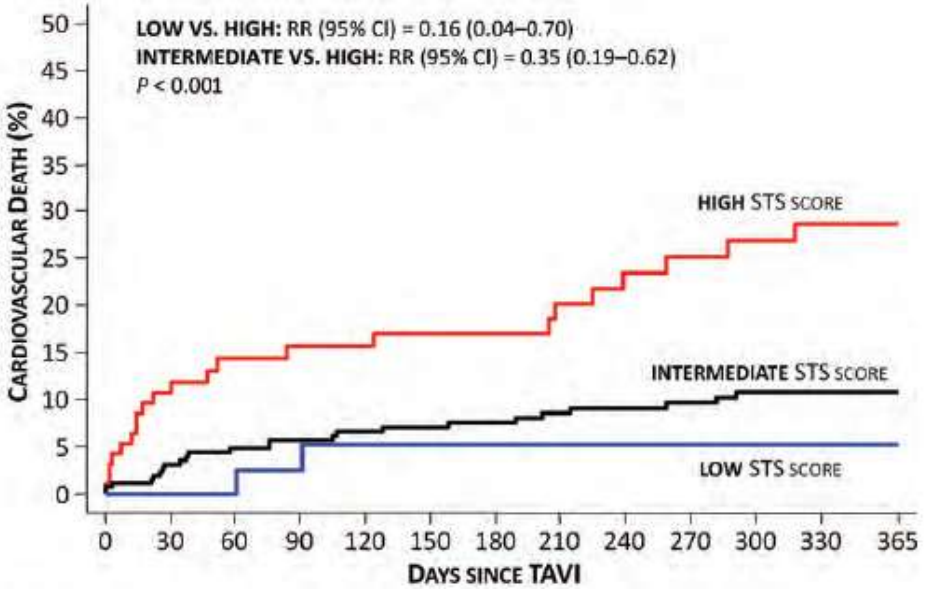
1-year freedom from MACCE



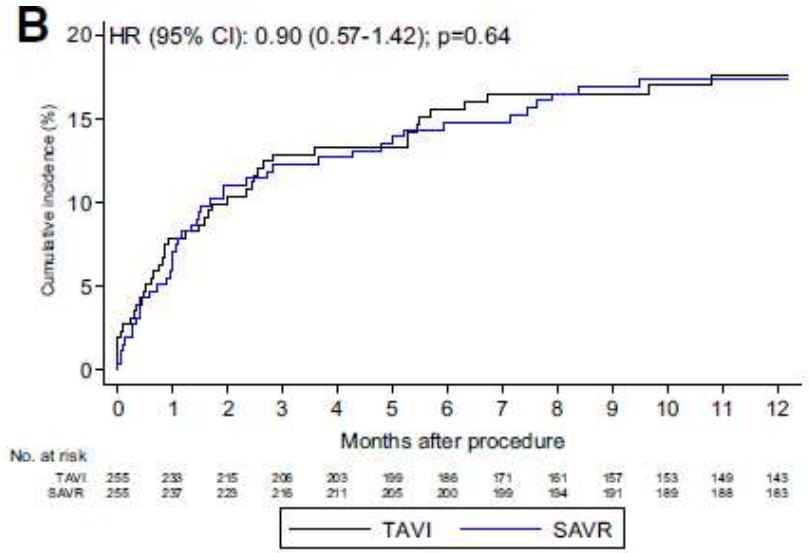
Clinical outcomes of patients with estimated low or intermediate surgical risk undergoing transcatheter aortic valve implantation

Peter Wenaweser[1†*], Stefan Stortecky[1†], Sarah Schwander[1], Dik Heg[2], Christoph Huber[3], Thomas Pilgrim[1], Steffen Gloekler[1], Crochan J. O'Sullivan[1], Bernhard Meier[1], Peter Jüni[2], Thierry Carrel[3], and Stephan Windecker[1,2]





BERMUDA trial



	TAVI, n (IR)	SAVR, n (IR)	HR (95% CI)	P Interaction
Overall	42 (17.5)	43 (17.3)	0.90 (0.57-1.42)	
Age				0.91
≤80	17 (17.5)	17 (17.0)	0.87 (0.41-1.82)	
>80	25 (17.5)	26 (17.6)	0.92 (0.51-1.63)	
Gender				0.024
Male	22 (23.9)	15 (15.7)	1.67 (0.81-3.41)	
Female	20 (13.6)	28 (18.4)	0.56 (0.30-1.04)	
Logistic EuroSCORE				0.91
≤20	26 (16.1)	27 (15.8)	0.88 (0.50-1.56)	
>20	16 (20.7)	16 (20.7)	0.93 (0.44-1.98)	
STS score				0.53
≤4.0	15 (17.9)	17 (18.9)	0.73 (0.34-1.60)	
>4.0	27 (17.4)	26 (16.5)	1.00 (0.57-1.76)	
Diabetes mellitus				0.22
No	32 (19.1)	29 (17.1)	1.08 (0.62-1.86)	
Yes	10 (14.0)	14 (18.0)	0.57 (0.24-1.36)	
Left ventricular function				0.20
<30%	6 (30.9)	2 (9.5)	2.50 (0.49-12.9)	
≥30%	36 (16.3)	41 (18.1)	0.82 (0.50-1.31)	
Cerebrovascular accident				0.93
No	35 (16.2)	35 (15.7)	0.91 (0.55-1.50)	
Yes	7 (30.6)	8 (33.0)	0.86 (0.29-2.55)	
Peripheral vascular disease				0.48
No	40 (17.9)	39 (16.9)	0.94 (0.59-1.52)	
Yes	2 (12.5)	4 (23.6)	0.50 (0.09-2.73)	
Pulmonary hypertension				0.42
No	33 (17.1)	36 (18.1)	0.89 (0.49-1.36)	
Yes	9 (18.1)	7 (14.4)	1.33 (0.46-3.84)	
Prior CABG				
No	40 (18.2)	40 (17.7)	0.92 (0.57-1.47)	0.74
Yes	2 (10.0)	3 (13.6)	0.67 (0.11-3.99)	

TAVR Randomized trials

PARTNER Cohort A Trial

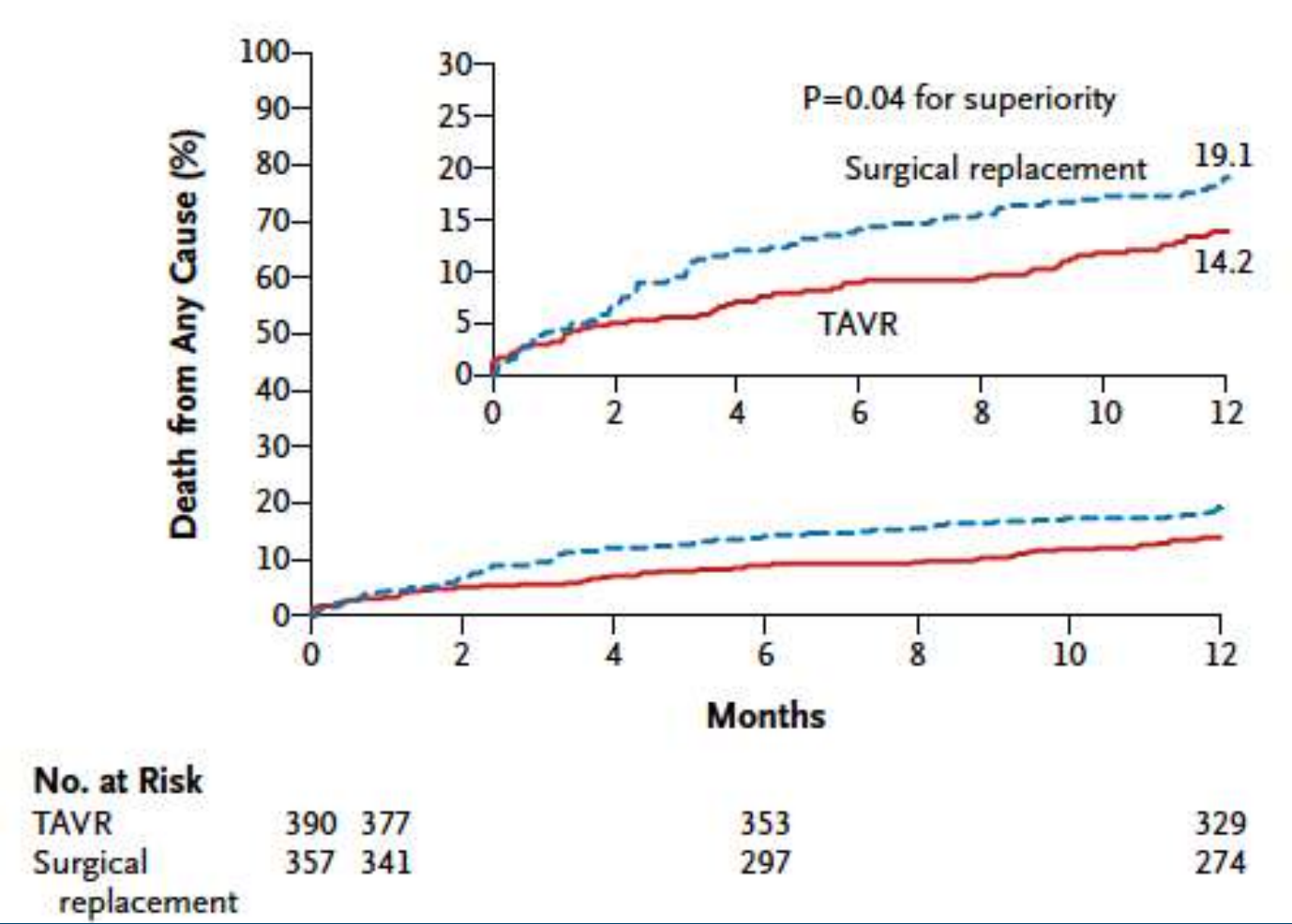
Characteristic	Transcatheter Replacement (N=348)	Surgical Replacement (N=351)	P Value
Society of Thoracic Surgeons score†	11.8±3.3	11.7±3.5	0.61
Logistic EuroSCORE†	29.3±16.5	29.2±15.6	0.93

CoreValve U.S. Pivotal Trial

Characteristic	Intention-to-Treat Population		As-Treated Population	
	TAVR Group (N=394)	Surgical Group (N=401)	TAVR Group (N=390)	Surgical Group (N=357)
STS PROM estimate†				
Mean estimate — %	7.3±3.0	7.5±3.2	7.3±3.0	7.5±3.4
<4% — no. (%)	33 (8.4)	42 (10.5)	33 (8.5)	40 (11.2)
4–10% — no. (%)	308 (78.2)	288 (71.8)	304 (77.9)	251 (70.3)
>10% — no. (%)	53 (13.5)	71 (17.7)	53 (13.6)	66 (18.5)
Logistic EuroSCORE — %‡	17.6±13.0	18.4±12.8	17.7±13.1	18.6±13.0

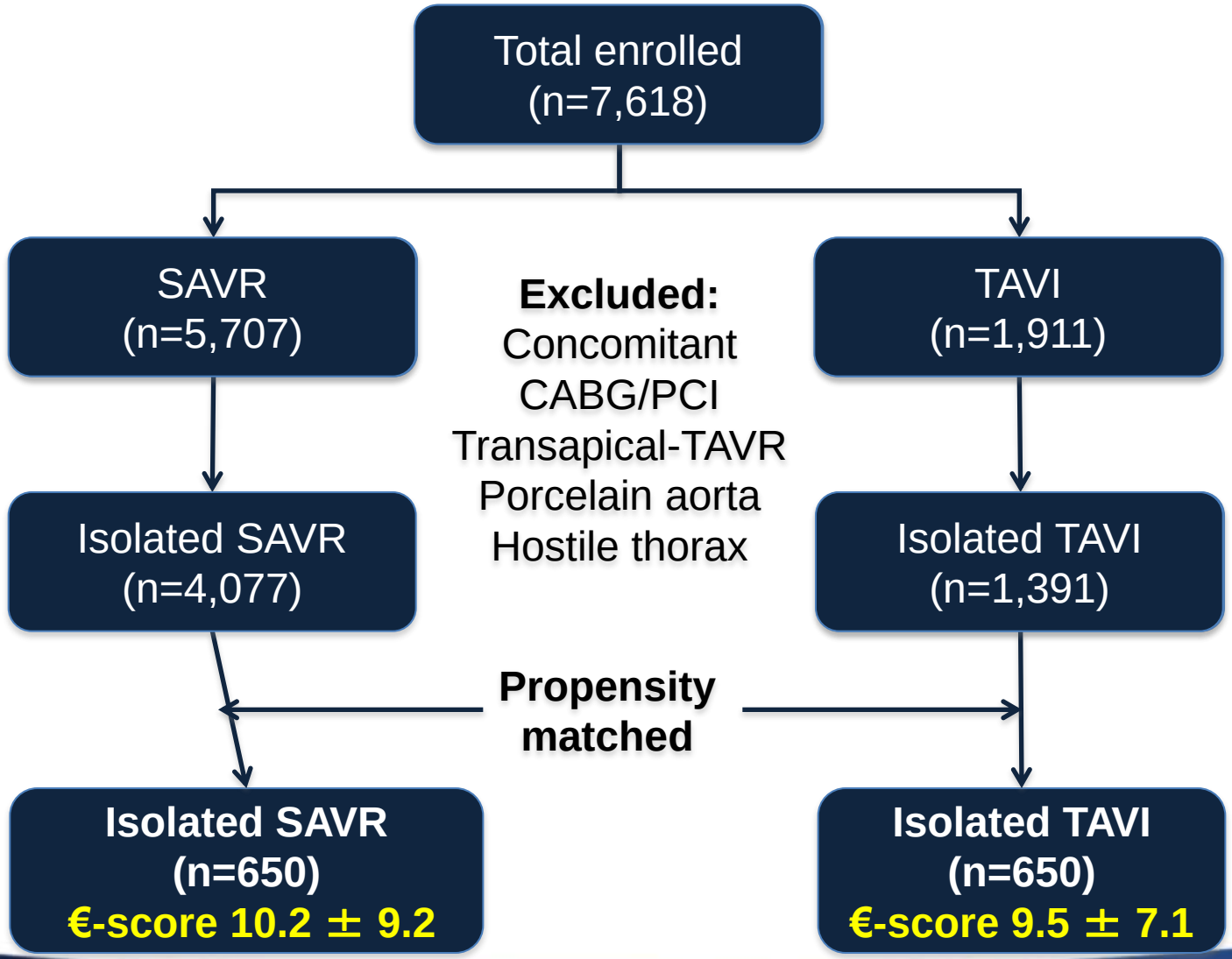
CoreValve U.S. Pivotal Trial

High-risk arm



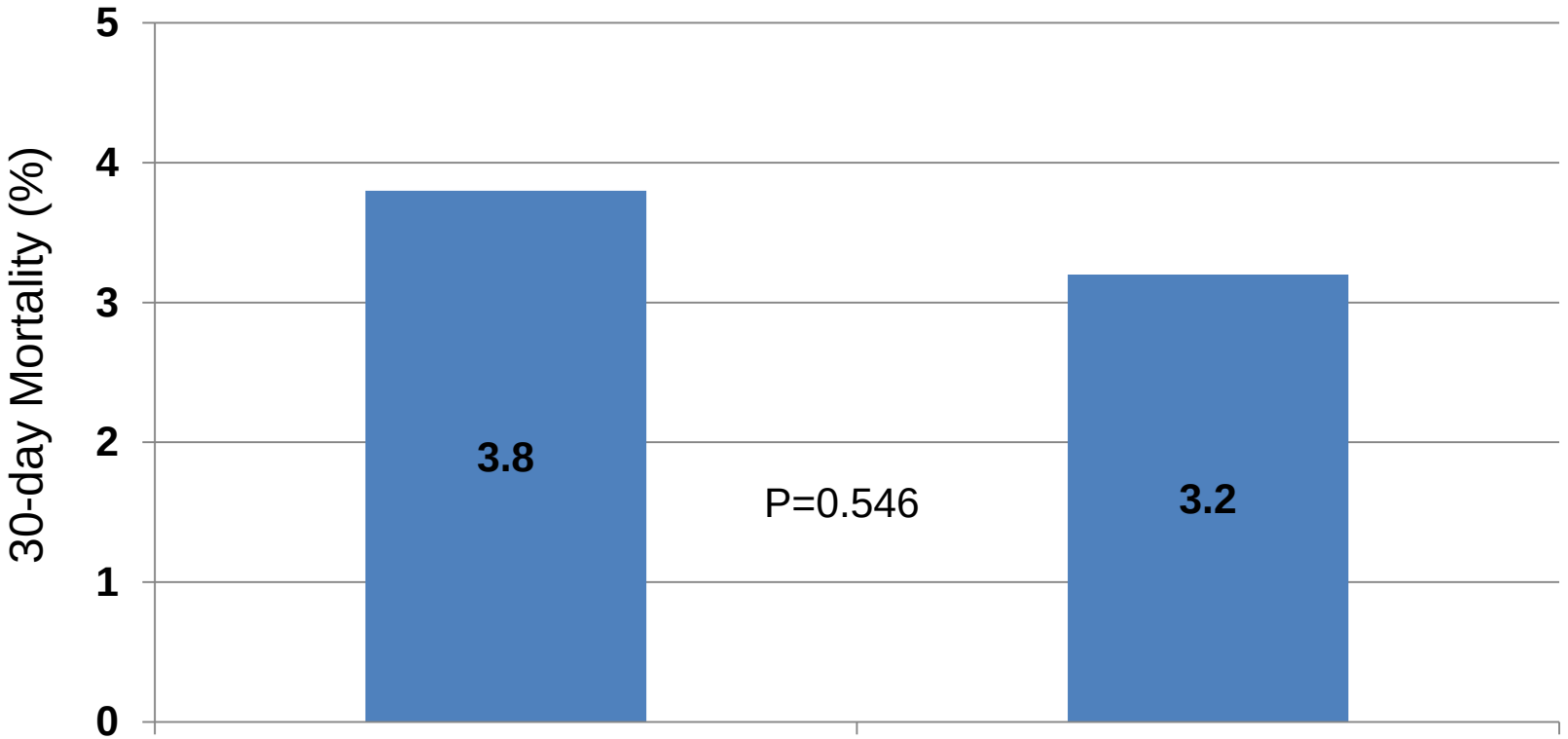
Adams DH. NEJM 2014

OBSERVANT – *Flow chart*



Tamburino, unpublished data

OBSERVANT – *Matched population*

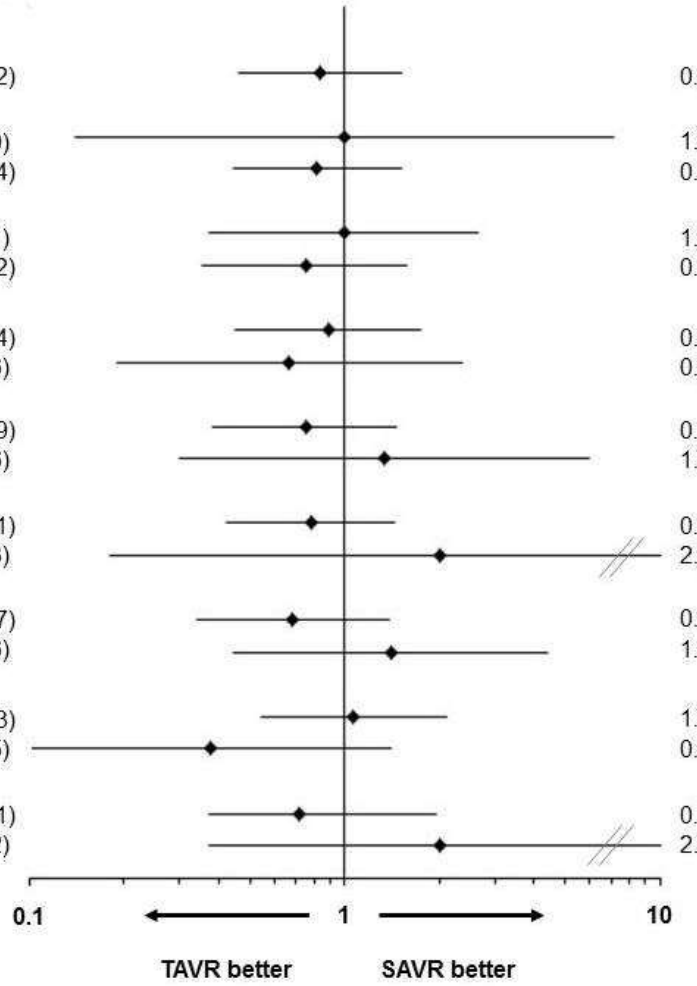


	SAVR	TAVI	
Log EuroSCORE (%)	10.2±9.2	9.5±7.1	p = 0.104

Tamburino, unpublished data

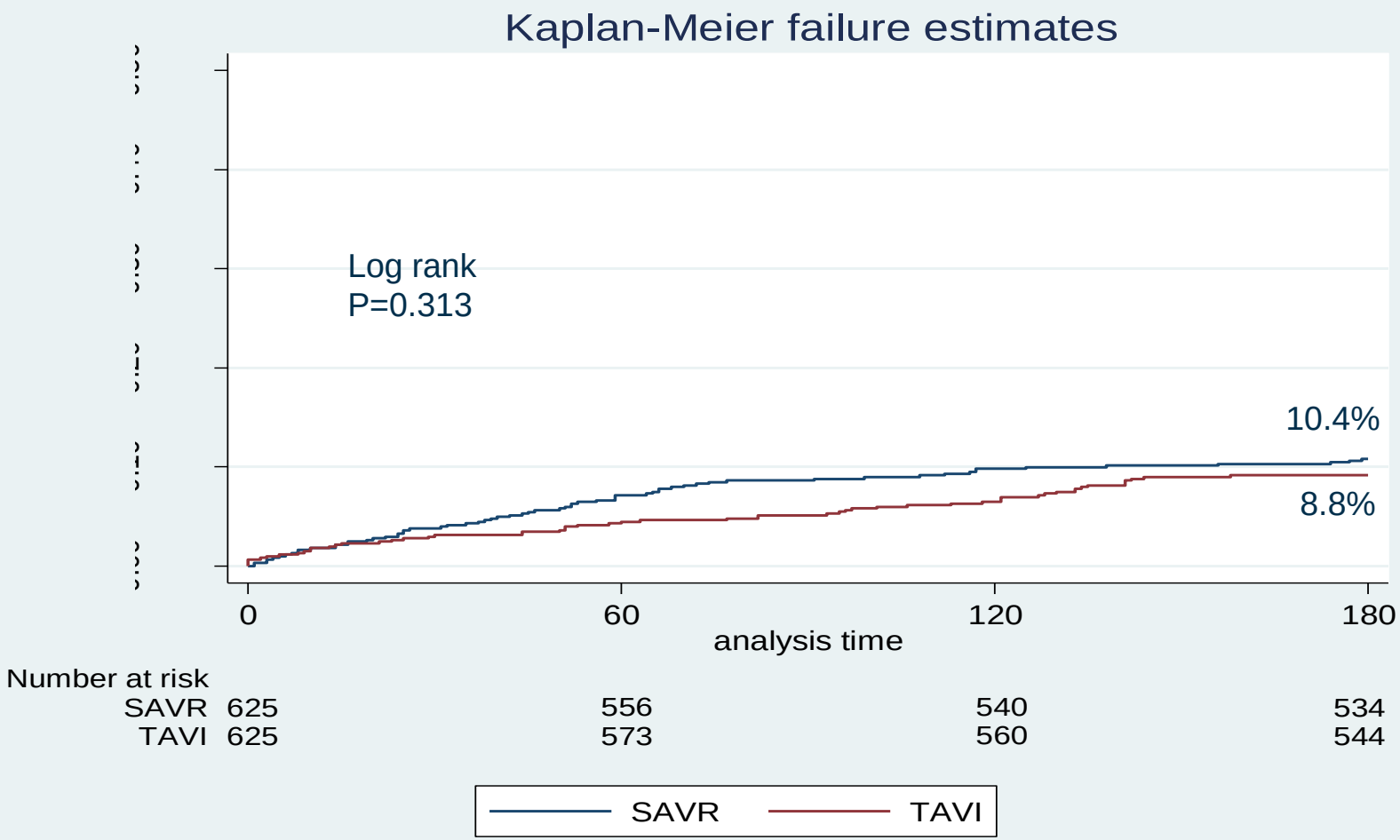
OBSERVANT – *Matched population*

Subgroups	Death from any cause		Risk ratio (95% CI)	P value for interaction
	SAVR	TAVR		
	n (%)			
Overall	24 (3.8)	20 (3.2)	0.83 (0.46-1.51)	
Age				0.848
≤75	2 (1.9)	2 (1.9)	1.00 (0.14-7.10)	
>75	22 (4.1)	18 (3.4)	0.82 (0.44-1.52)	
Gender				0.647
Male	8 (3.1)	8 (3.1)	1.00 (0.37-2.66)	
Female	16 (4.2)	12 (3.2)	0.75 (0.35-1.58)	
Diabetes mellitus				0.694
No	18 (3.8)	16 (3.4)	0.89 (0.45-1.74)	
Yes	6 (3.9)	4 (2.6)	0.67 (0.19-2.36)	
Pulmonary hypertension				0.492
No	20 (3.8)	15 (2.9)	0.75 (0.38-1.46)	
Yes	3 (3.5)	4 (4.6)	1.33 (0.30-5.96)	
NYHA class 4				0.458
No	23 (4.0)	18 (3.1)	0.78 (0.42-1.45)	
Yes	1 (1.7)	2 (3.3)	2.00 (0.18-22.06)	
Moderate/severe MR				0.298
No	19 (3.9)	13 (2.7)	0.68 (0.34-1.39)	
Yes	5 (3.3)	7 (4.6)	1.40 (0.44-4.41)	
Coronary artery disease				0.171
No	16 (3.1)	17 (3.3)	1.06 (0.54-2.10)	
Yes	8 (6.6)	3 (2.5)	0.38 (0.10-1.41)	
Logistic Euroscore				0.268
≤5%	21 (4.3)	15 (3.1)	0.71 (0.37-1.39)	
>5%	2 (1.6)	4 (3.2)	2.00 (0.37-10.92)	



Tamburino, unpublished data

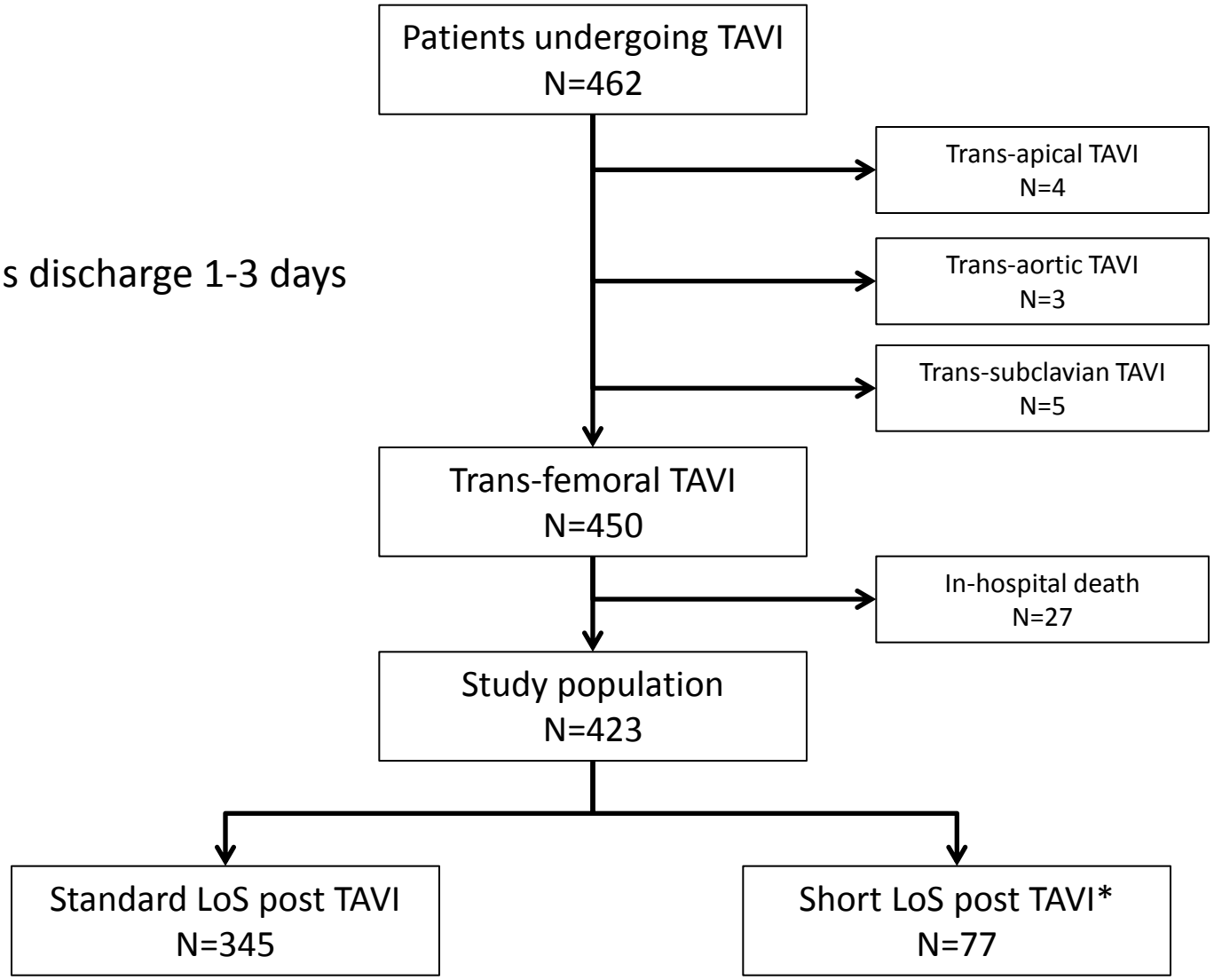
OBSERVANT – *Matched population*



Early discharge after transfemoral TAVI

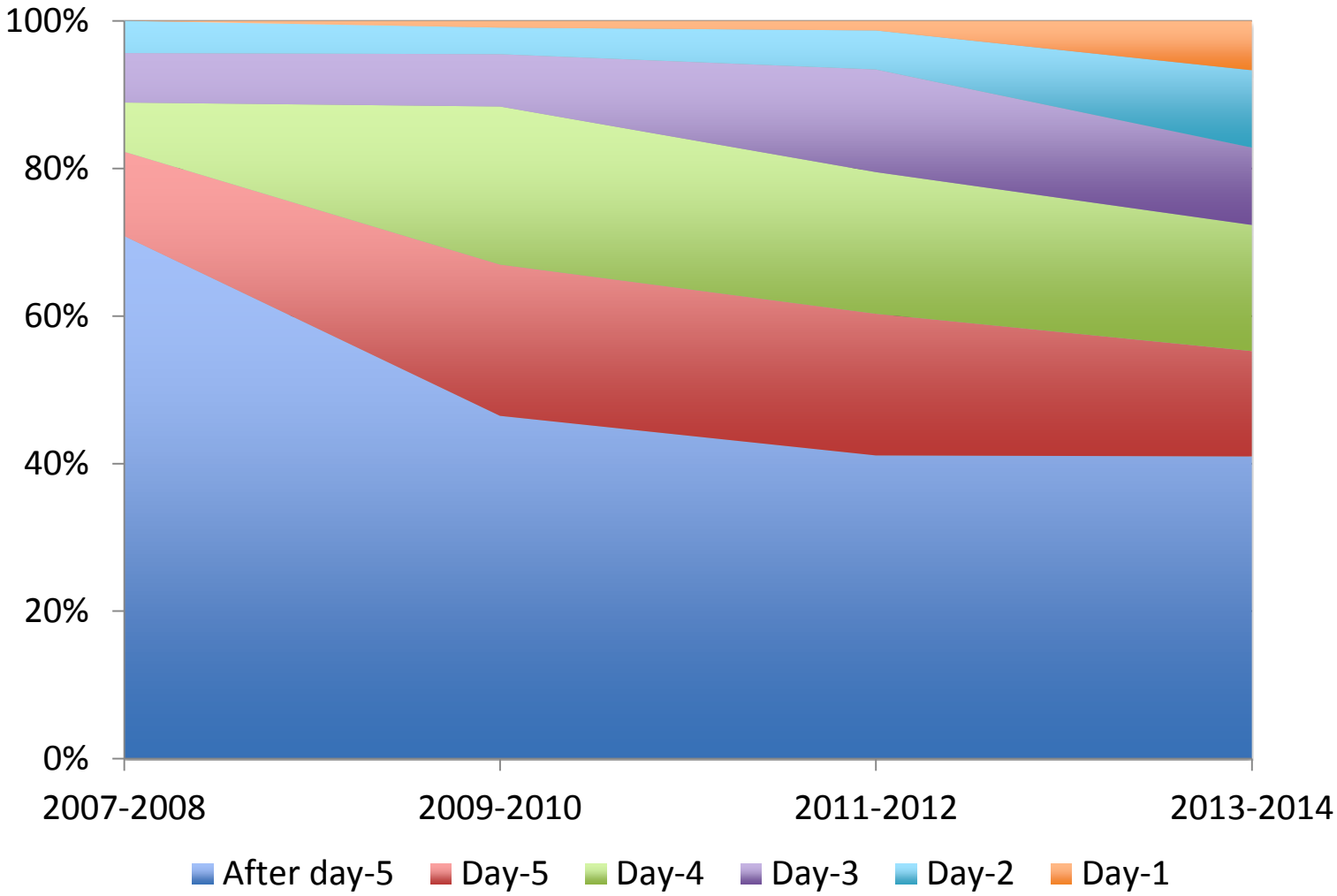
Proof of concept

*Defined as discharge 1-3 days post-TAVI



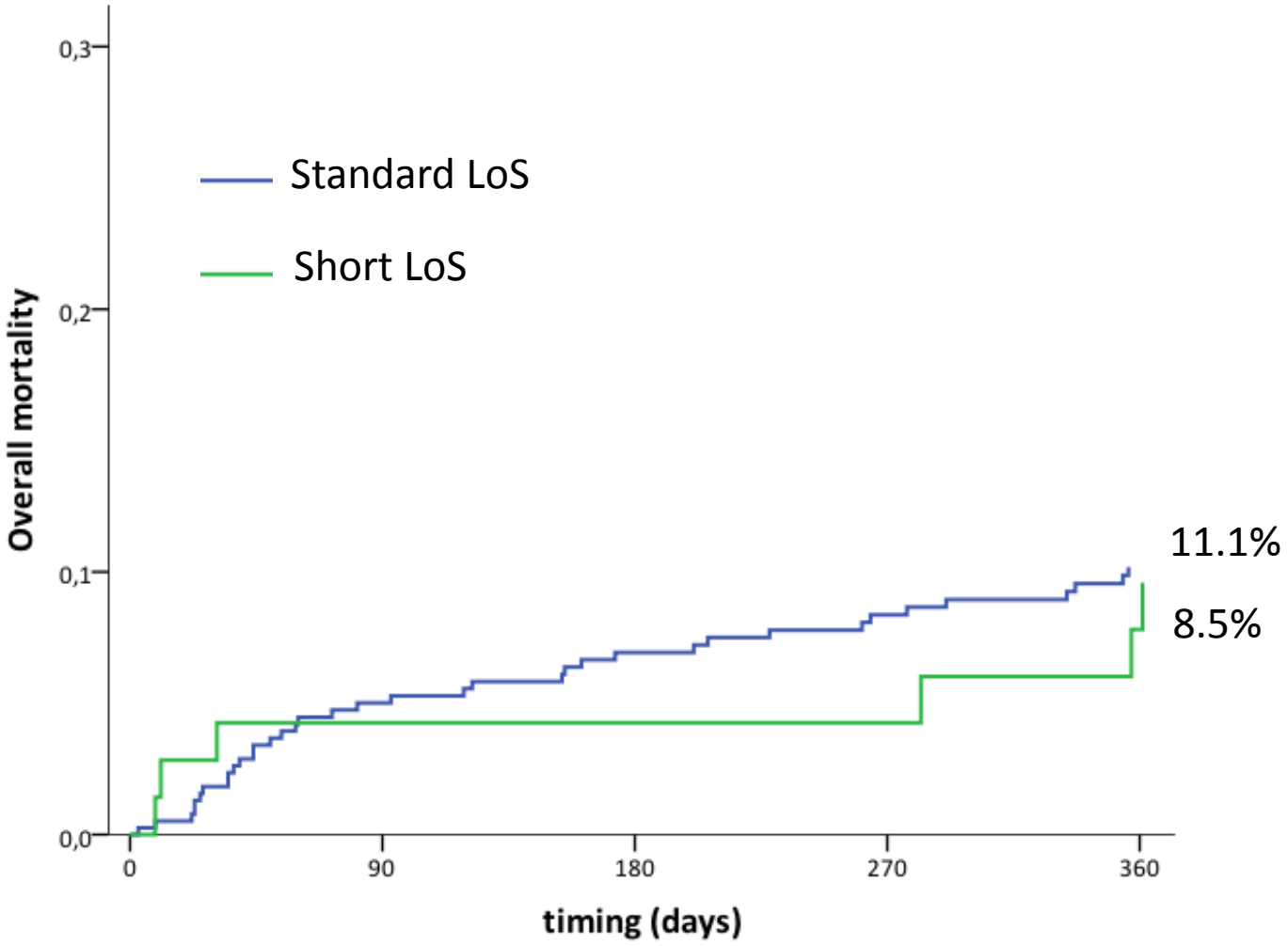
Ferrarotto experience

Days hospitalization post-TAVI overtime



Ferrarotto experience

Adjusted Kaplan-Meier – all cause mortality



Closing Remarks

- Current indications for TAVR in high-risk AS patients are well established, informed by rigorous evidence-based medicine clinical trials.
- TAVI should not be used in LOW RISK patients, unless under special and unusual circumstances.
- TAVI is already being used in MODERATE RISK patients in EU (and elsewhere); early indications suggest similar results compared with SAVR.
- Ongoing randomized trials (PARTNER 2A and SURTAVI) will determine clinical use of TAVR in moderate risk AS patients in the future.