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HERZ GEFÄSS
ZENTRUM

Update Indikation zum Aortenklappenersatz

Stephan Windecker, Kardiologie

Matthias Siepe, Herzchirurgie

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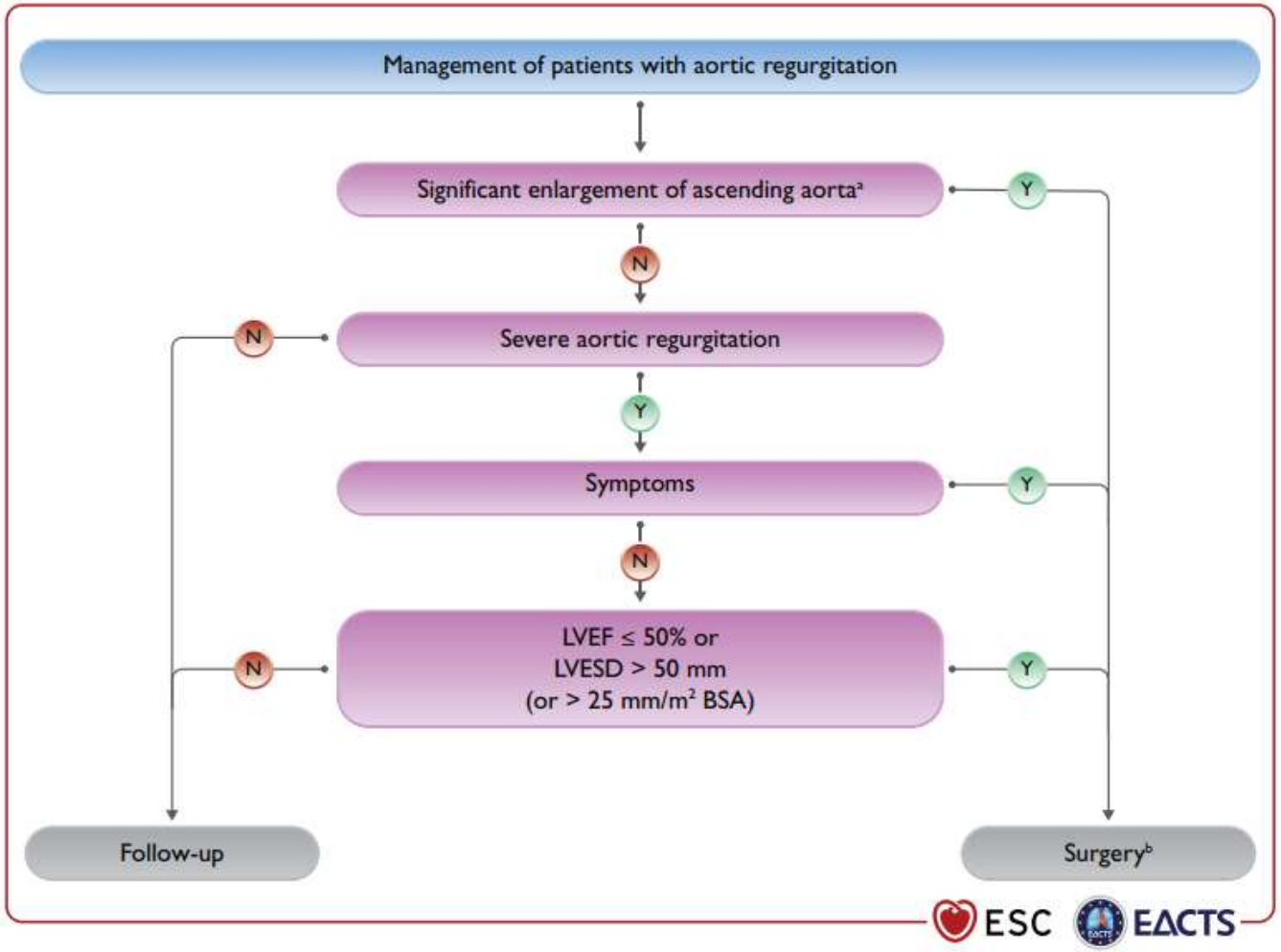
Aortenklappeninsuffizienz

ESC/EACTS Valvular Heart Disease Guideline 2021



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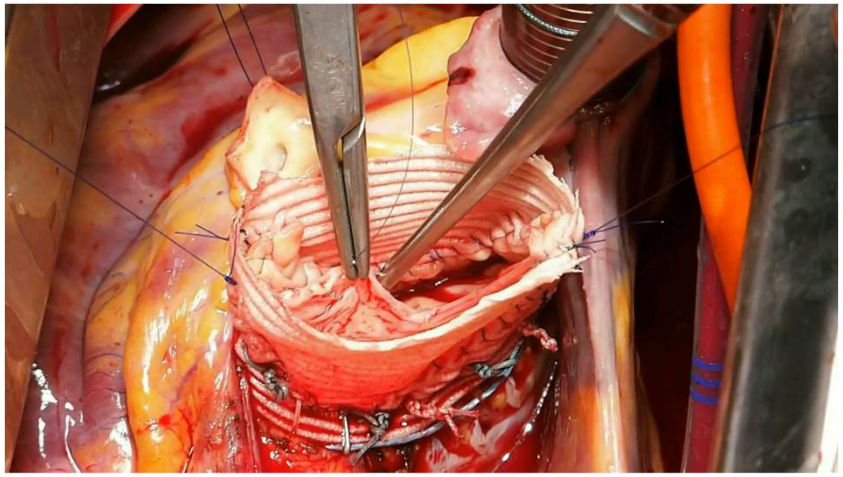
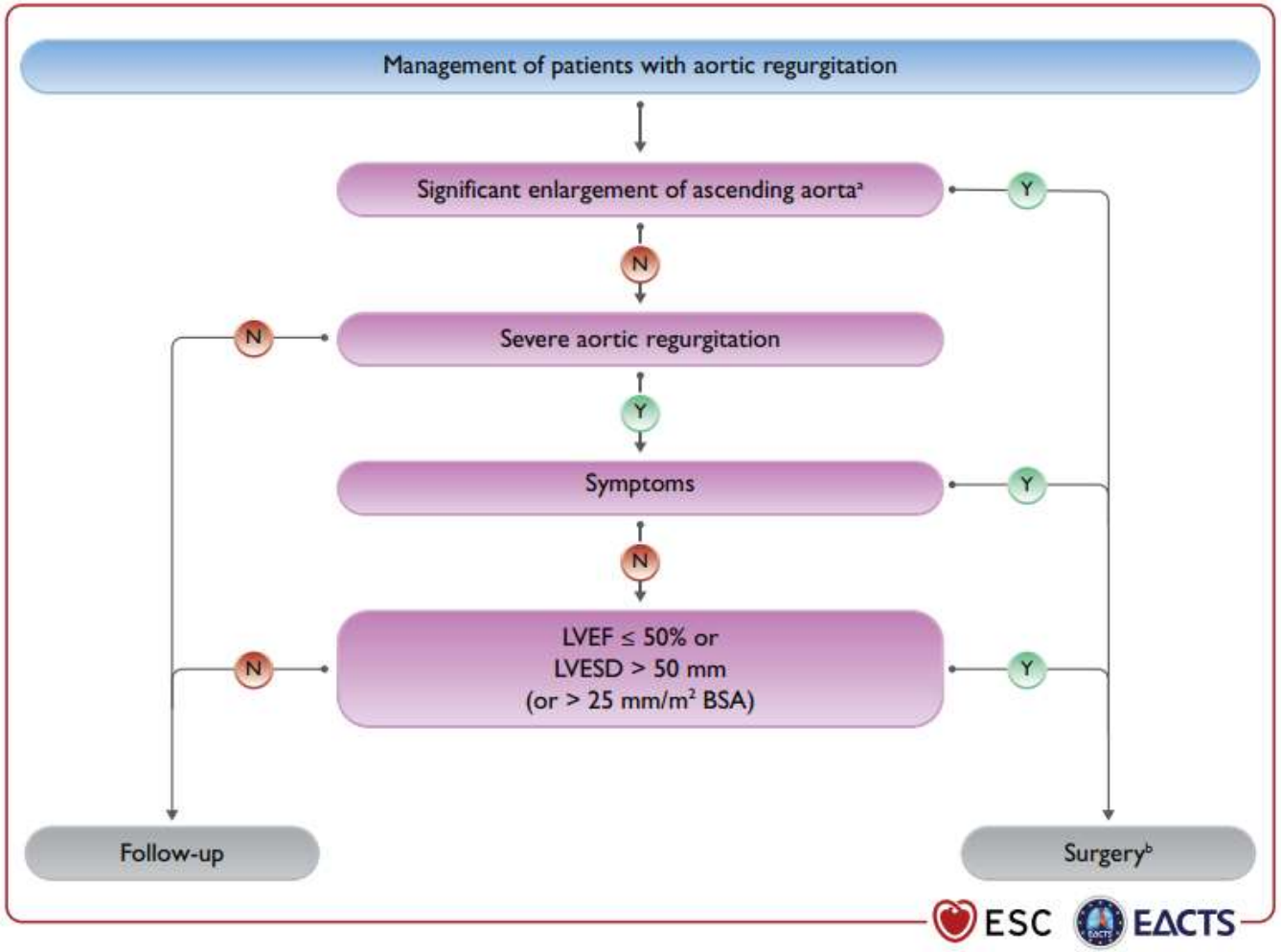
Aortenklappeninsuffizienz



ESC/EACTS Valvular Heart Disease Guideline 2021



In der Regel kein Aortenklappenersatz nötig, sondern Rekonstruktion der Klappen

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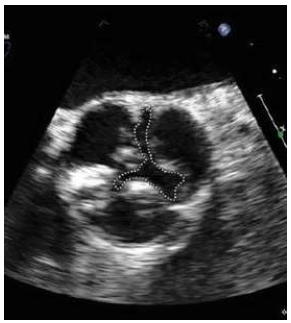
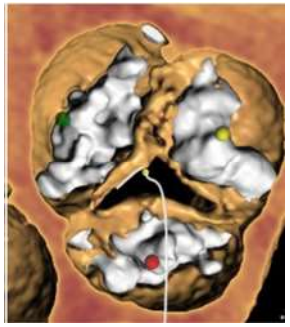
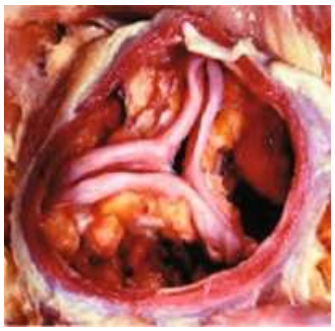
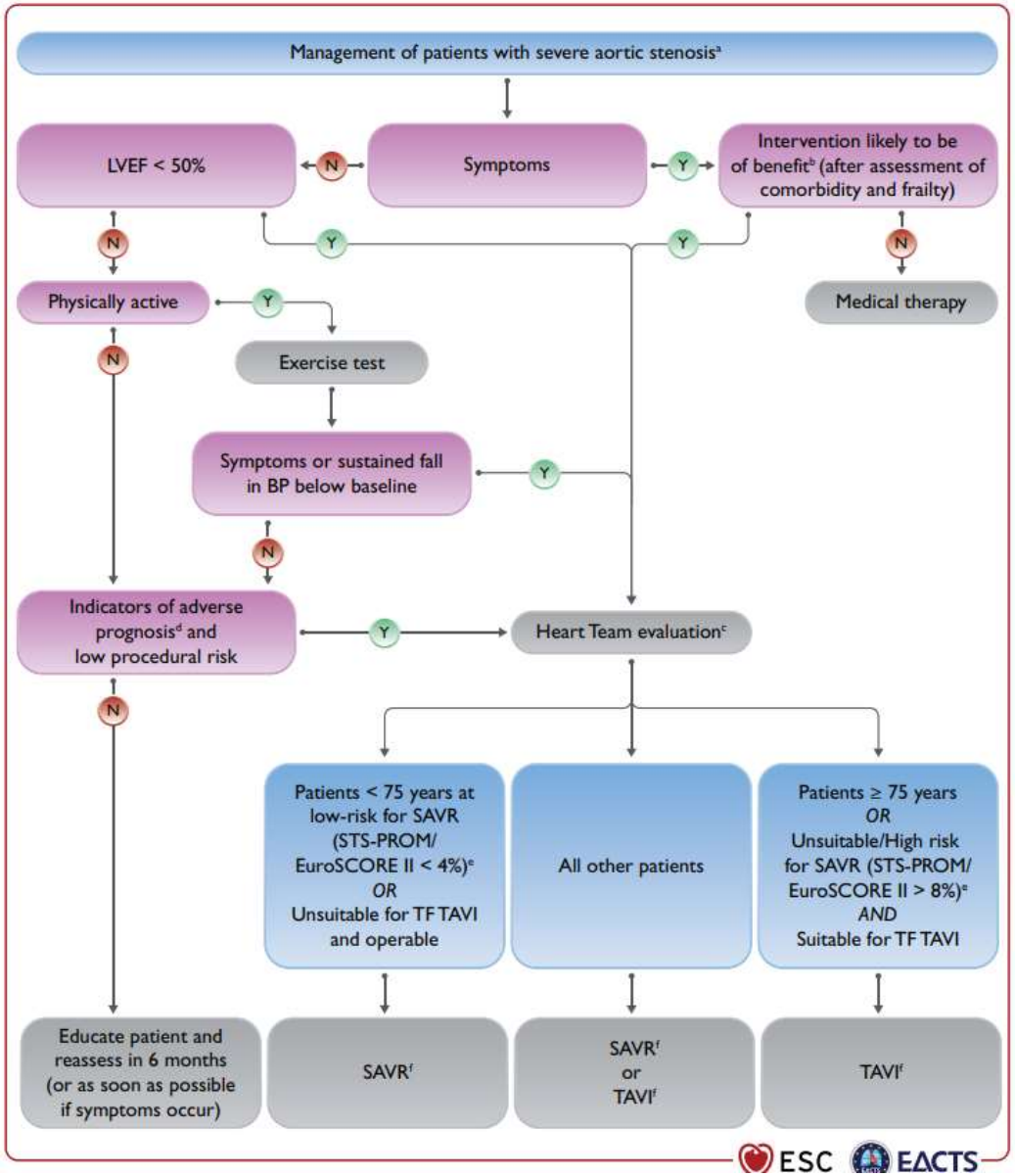
Aortenklappenstenose







ESC/EACTS Valvular Heart Disease Guideline 2021



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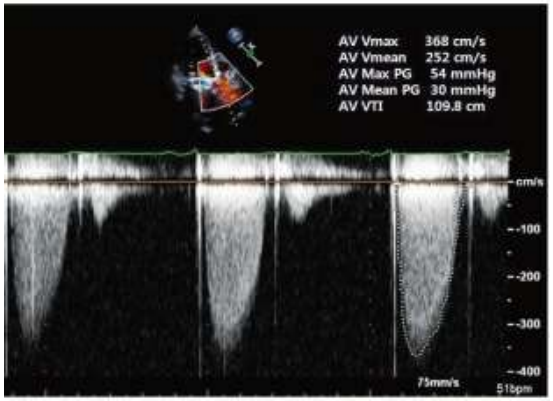
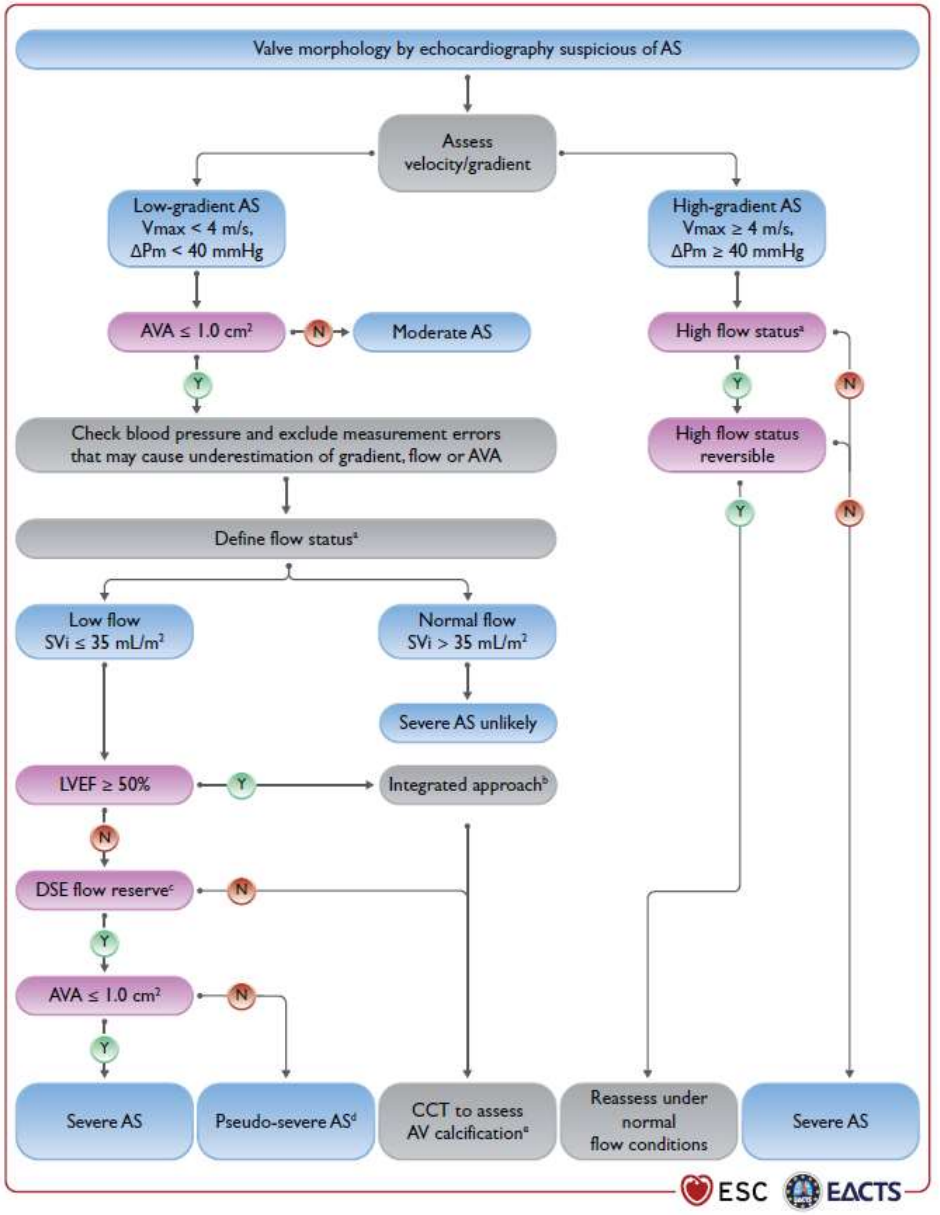
Diagnosestellung: Echo





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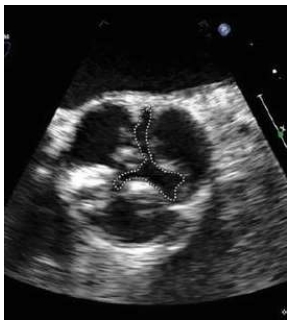
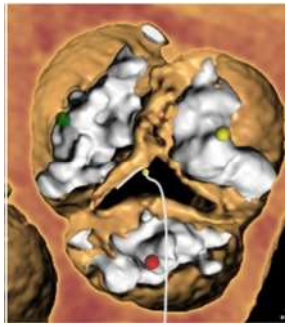
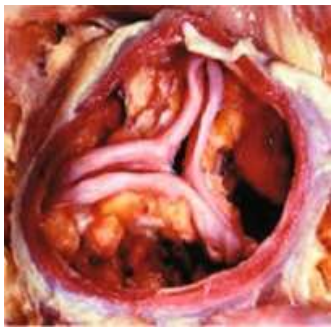
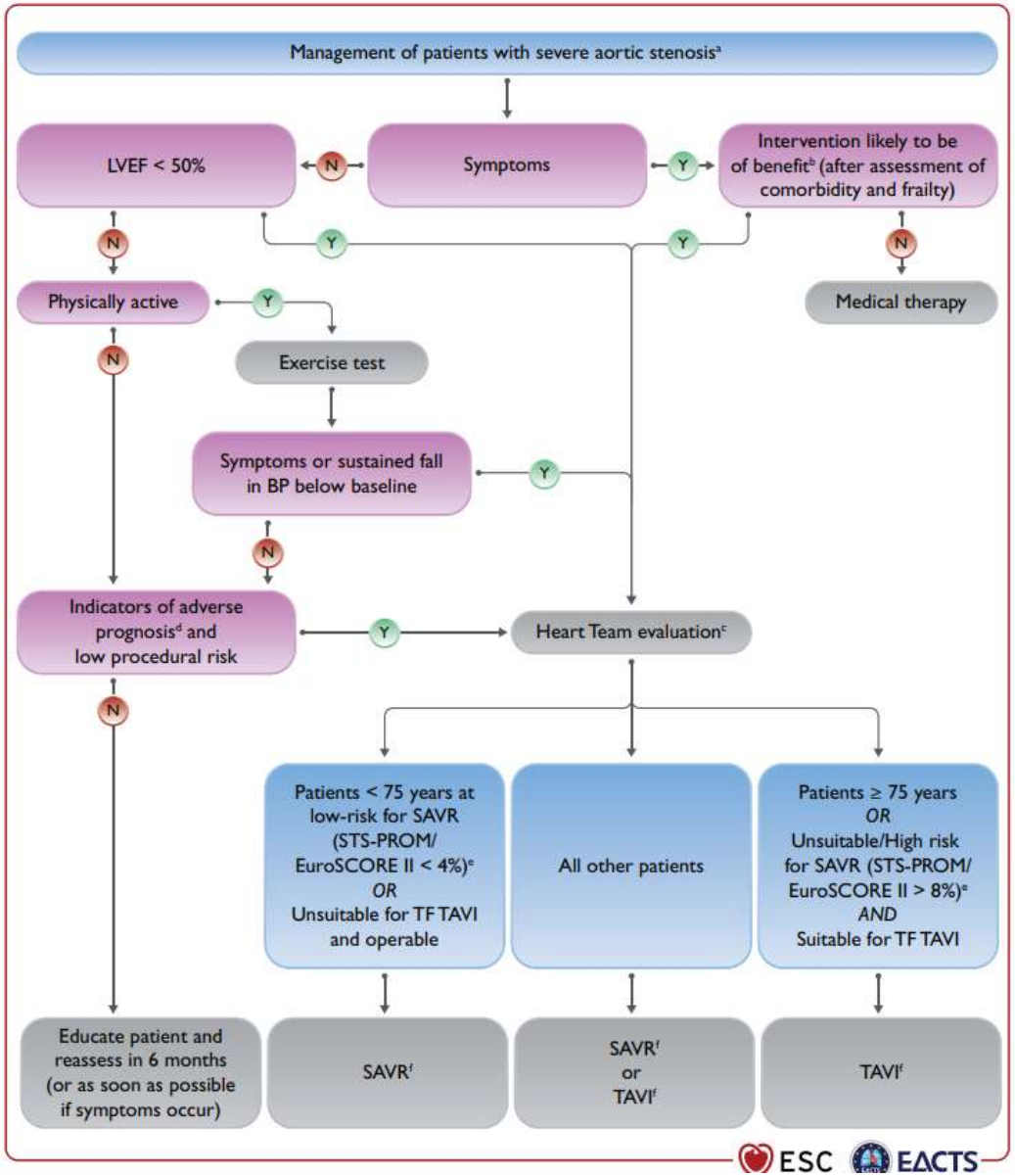
Aortenklappenstenose







ESC/EACTS Valvular Heart Disease Guideline 2021



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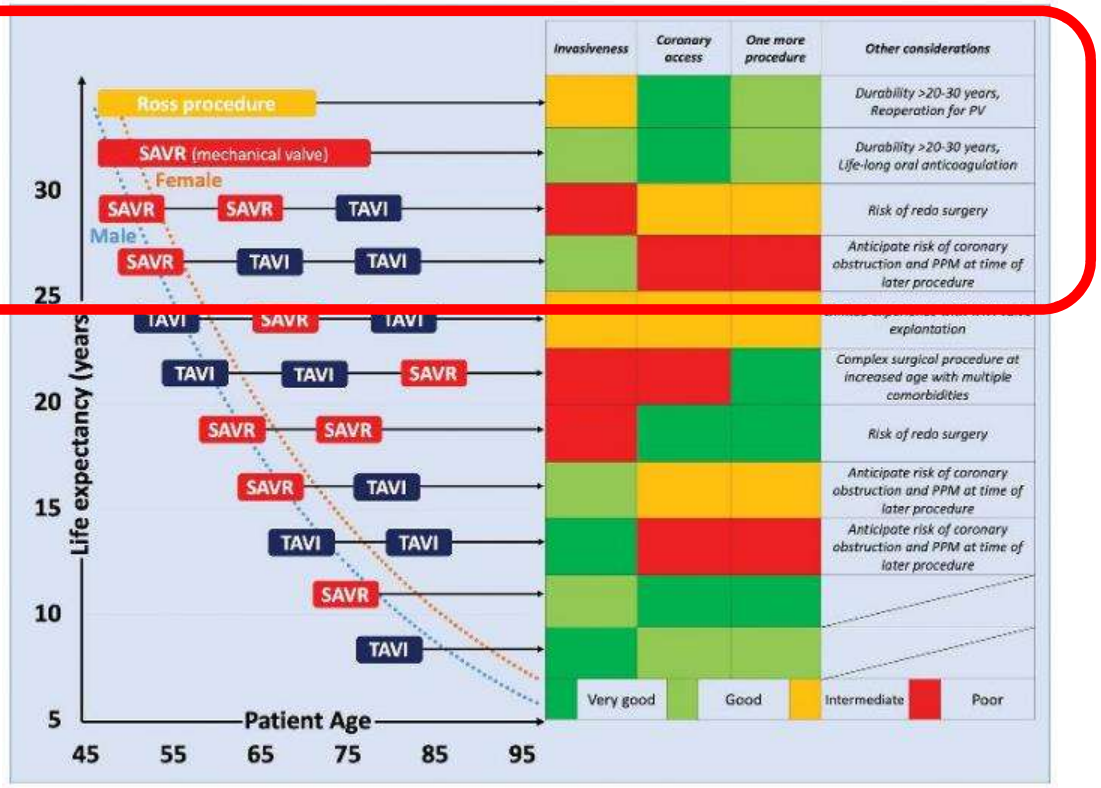
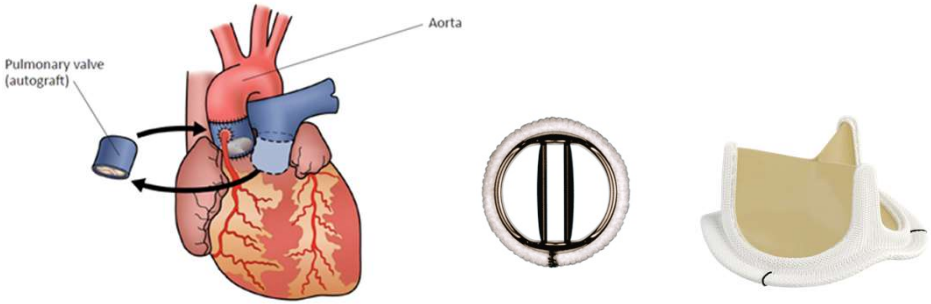
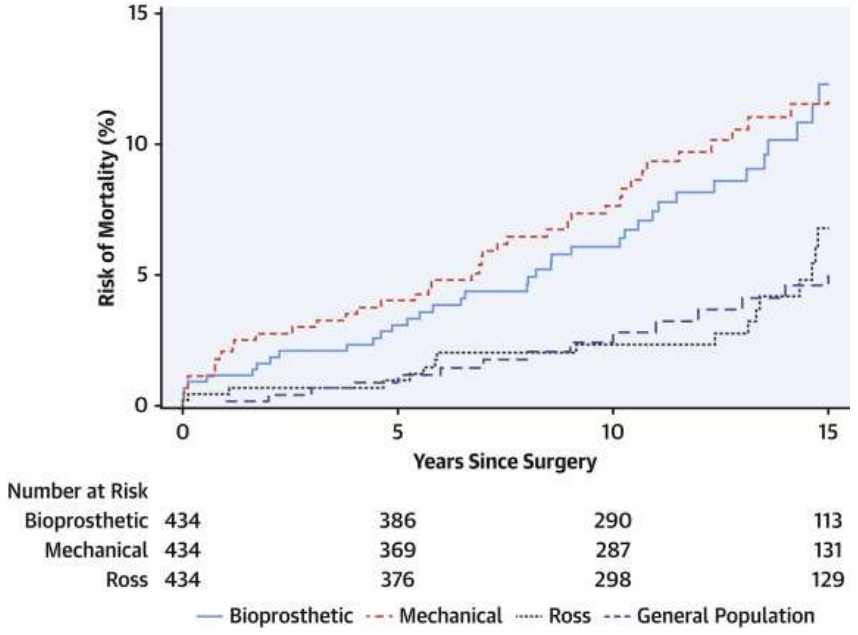
Lifetime management



Windecker S, Eur Heart J, 2022 Apr 25





El-Hamamsy et al. JACC 2022

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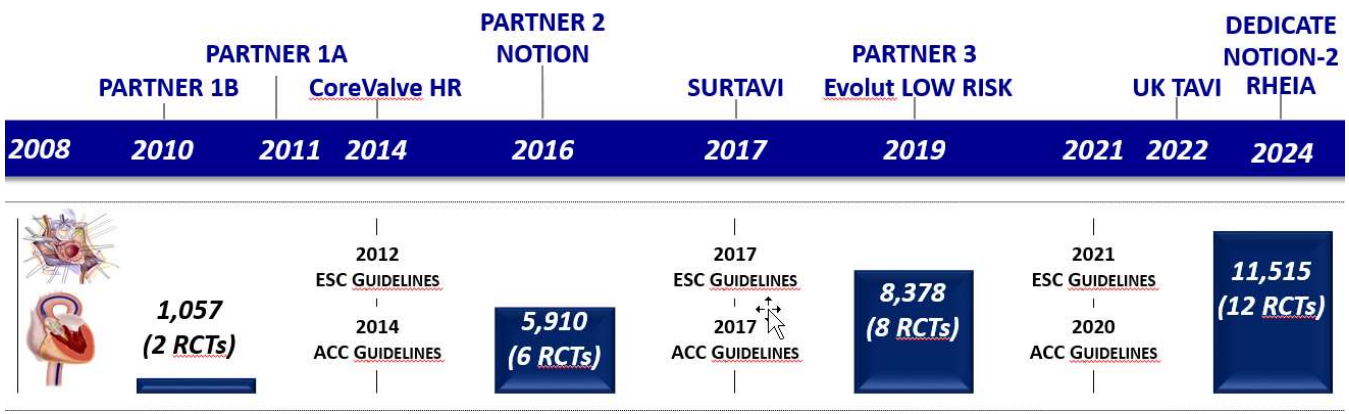
TAVI vs SAVR RCTs



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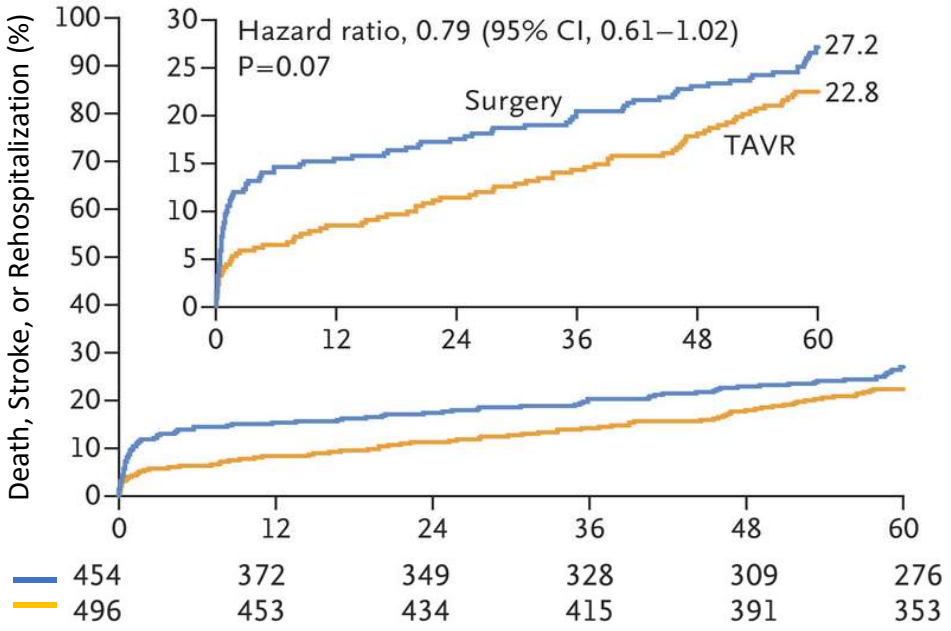
5-Year Outcomes in Low-Risk Pivotal Trials

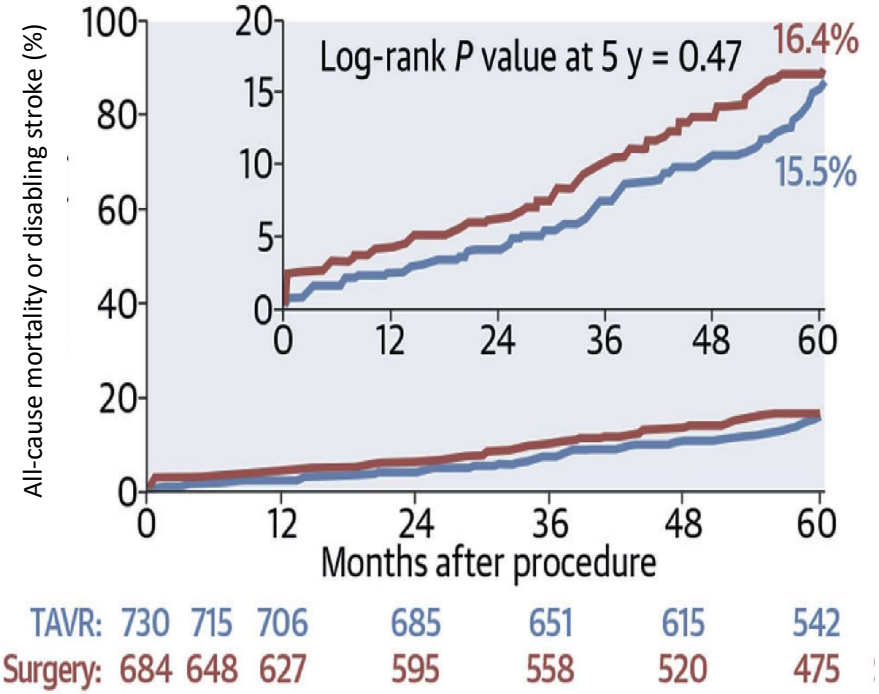
PARTNER 3 and Evolut Low Risk

Mack et al. N Engl J Med 2023;389(21):1949-1960; Forrest et al. J Am Coll Cardiol 2025;85:1523-1532.

PARTNER 3



Evolut Low Risk



SAVR vs. TAVI in patients with severe AS at low surgical risk had similar rates of primary EP at 5 years.

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5-Year Outcomes in Low-Risk Pivotal Trials

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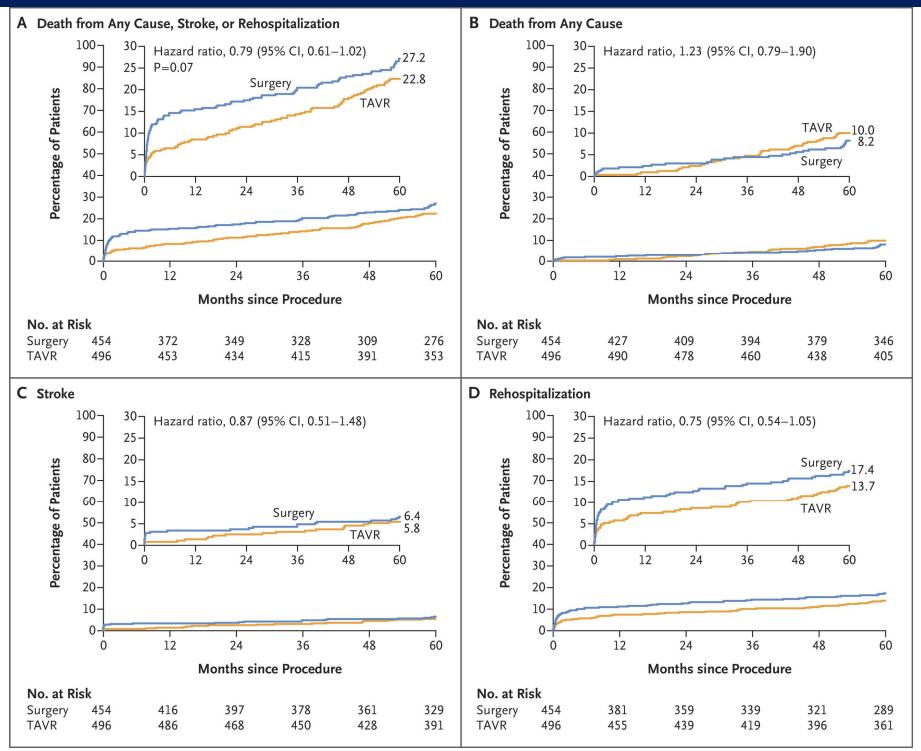
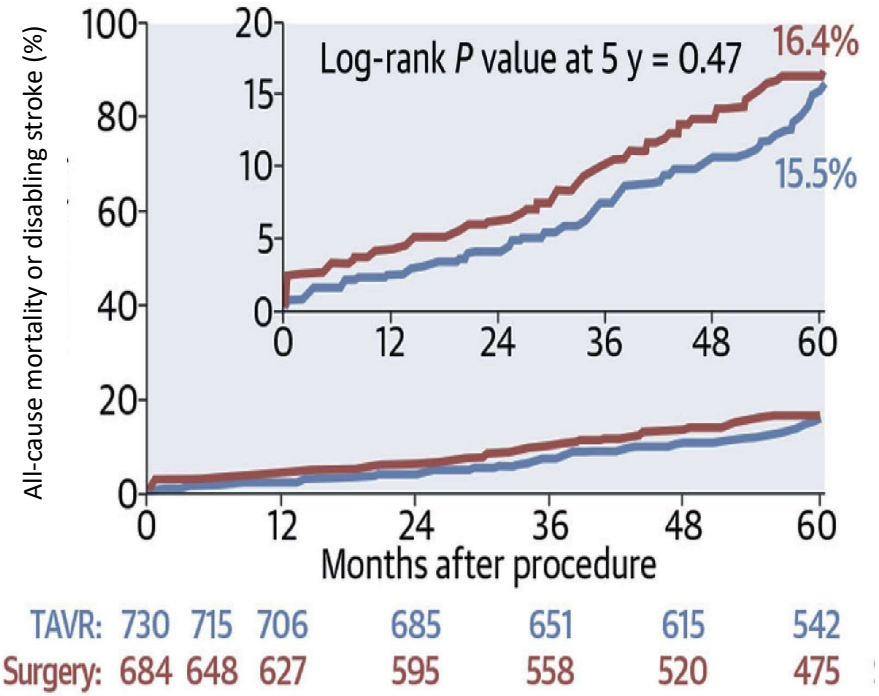


Evolut Low Risk



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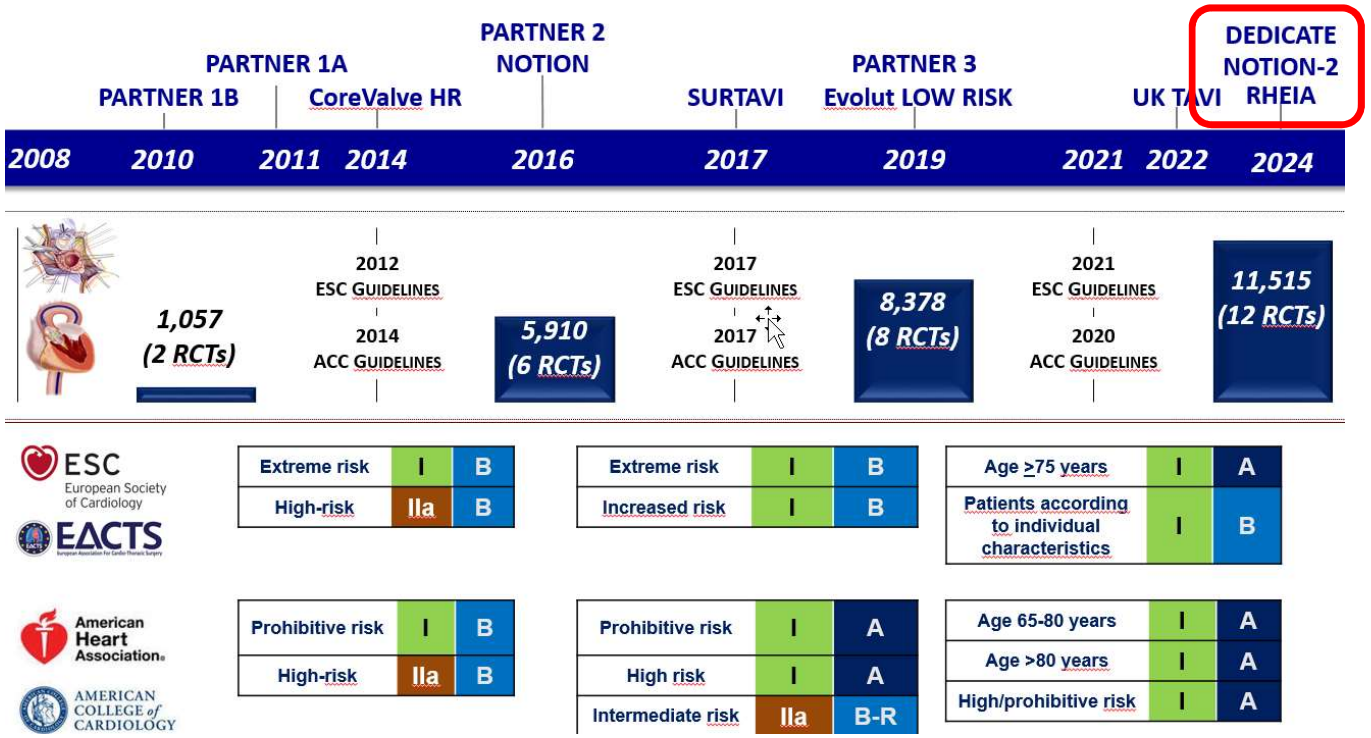
TAVI vs SAVR RCTs



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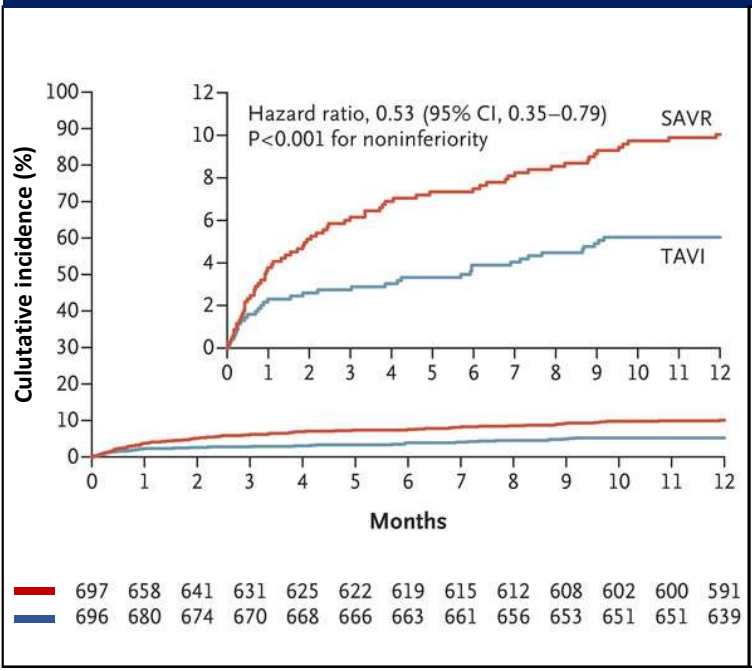
DEDICATE: TAVI vs SAVR

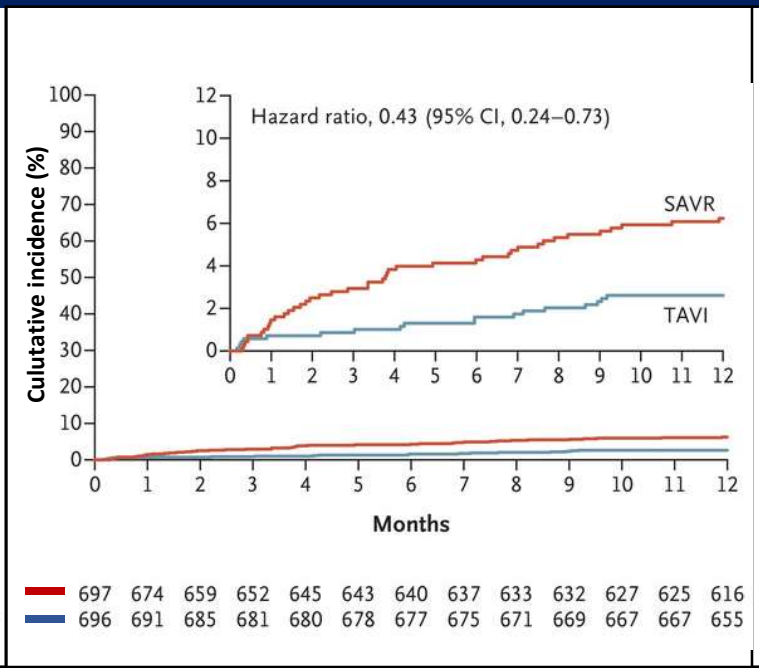
Primary outcome – Death or Stroke (Intention-to-Treat)

Blankenberg S et al. N Engl J Med 2024

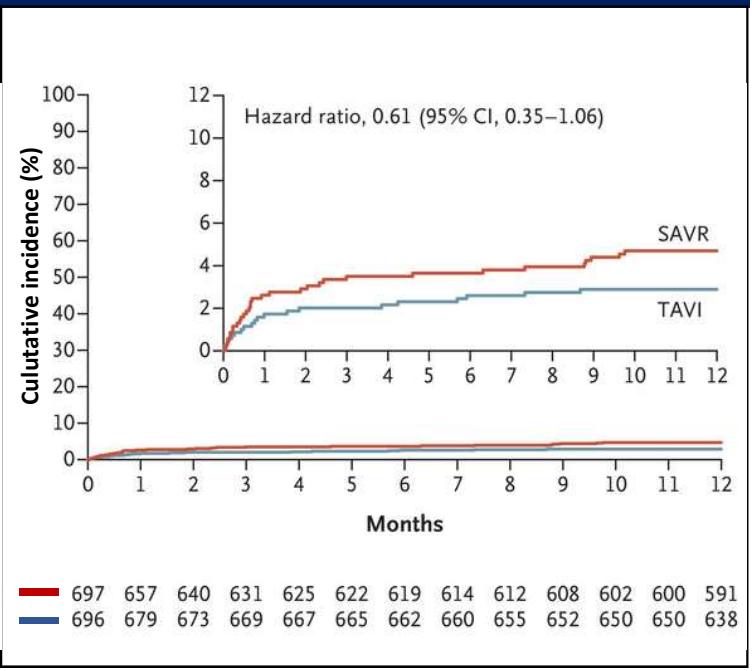
Death or Stroke



All-cause death



Stroke



✓ **In the investigator-initiated randomized trial involving patients with severe, symptomatic aortic-valve stenosis who were at low or intermediate surgical risk, TAVI was noninferior to SAVR with respect to death or stroke at 1 year**

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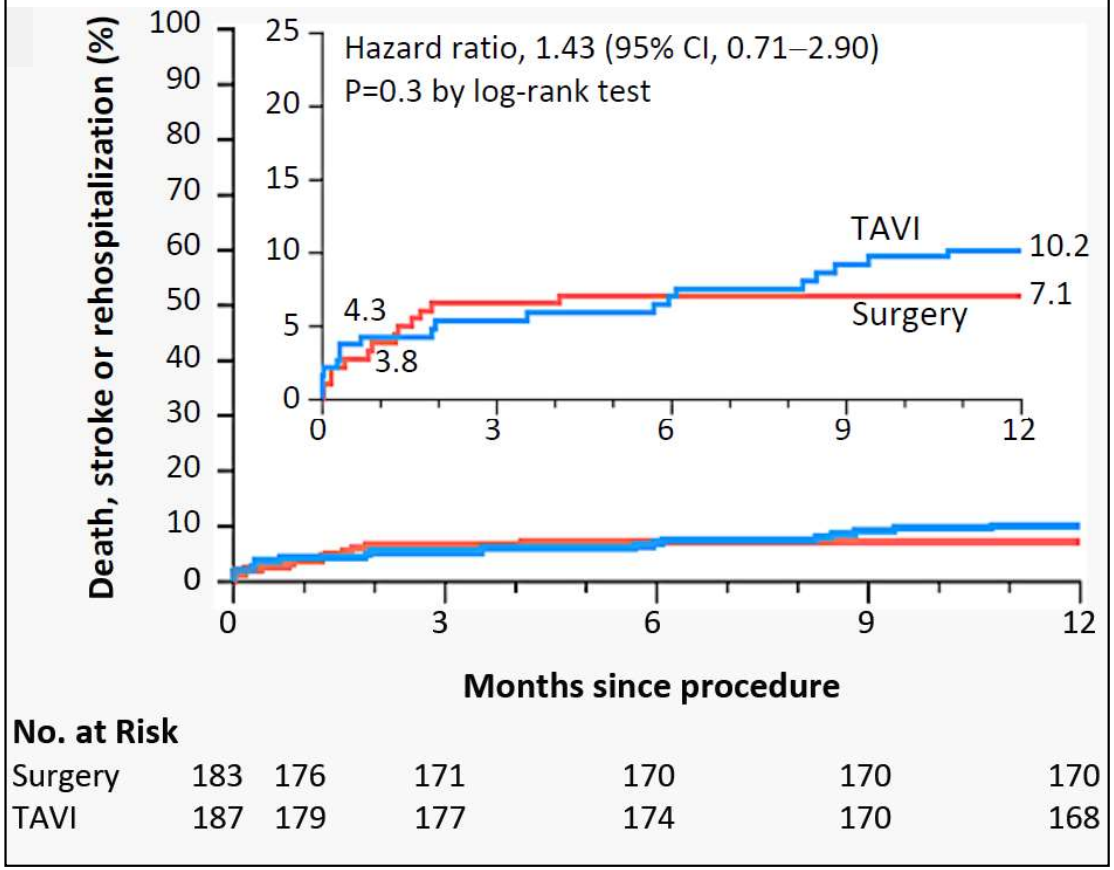
NOTION-2 – Low Risk Patients <75 yo (IICT)

Primary and Key Seconday Endpoint

Jørgensen et al. Eur Heart J 2024.

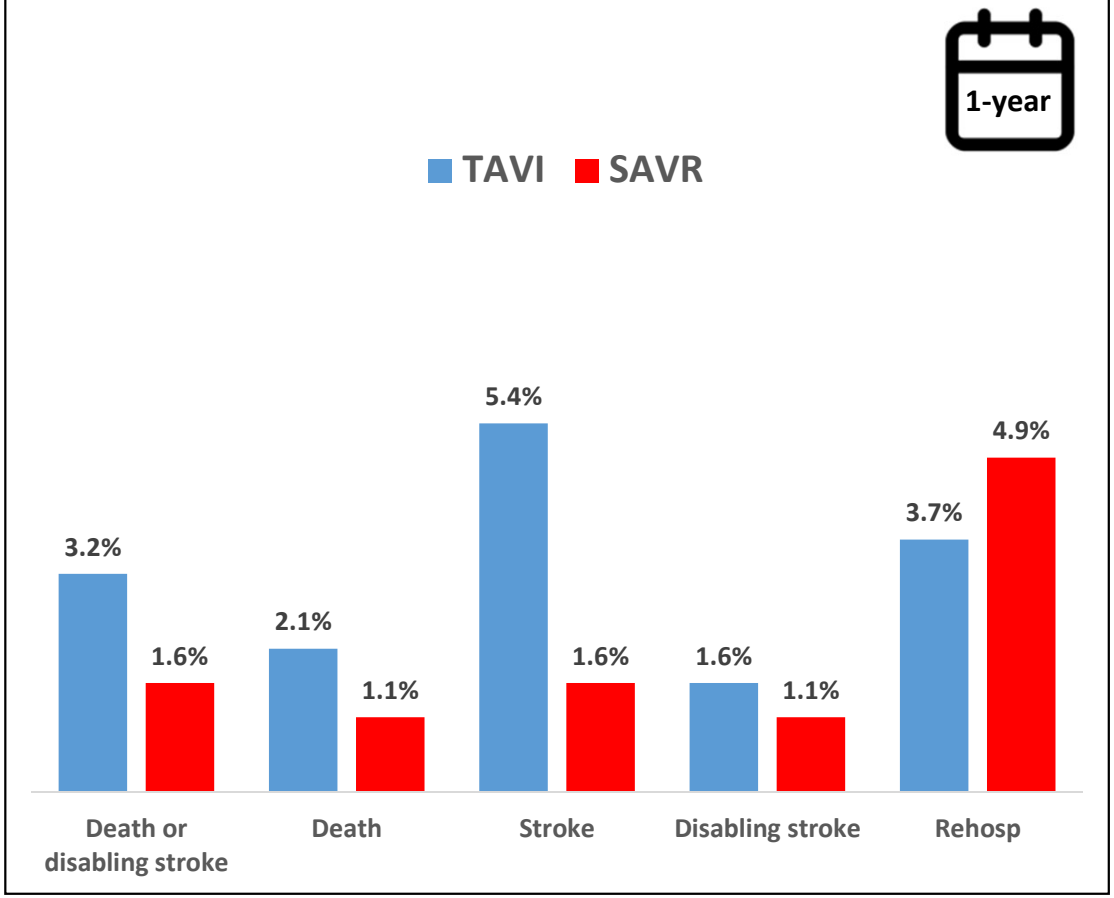
Primary endpoint



No. at Risk

Surgery	183	176	171	170	170	170
TAVI	187	179	177	174	170	168

Key secondary endpoints



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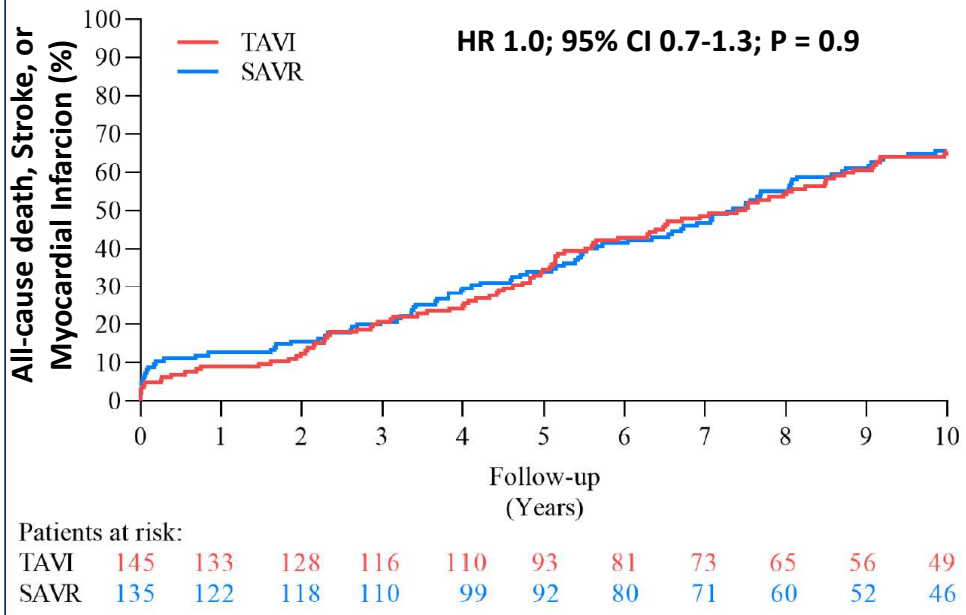
- ✓ **280 patients from 3 Nordic Centers.**
- ✓ **Mean Age: 79.1 years; STS score: 3.0 ± 1.7% (81.8% were considered low-risk patients).**
- ✓ **Clinical and echocardiographic follow-up rates were 98.9% and 81.2%, respectively.**

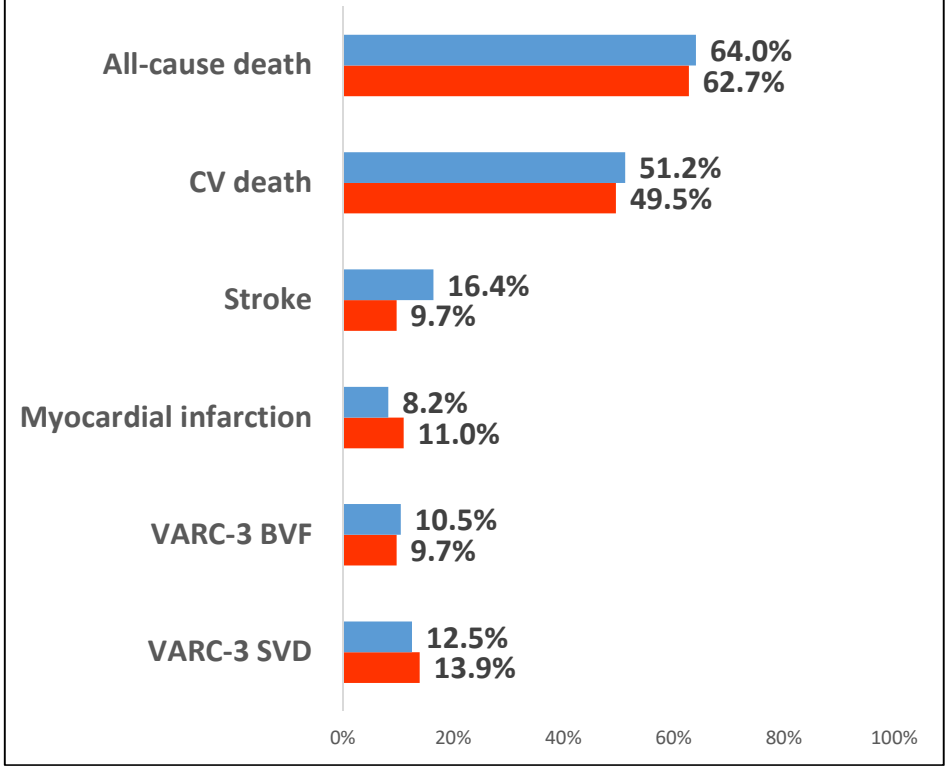
LOW-INTERMEDIATE RISK TRIAL: NOTION @ 10 YEARS F/U

Thyregod et al. Eur Heart J 2023;45(13):1116-1124.

Primary endpoint



Key clinical outcomes



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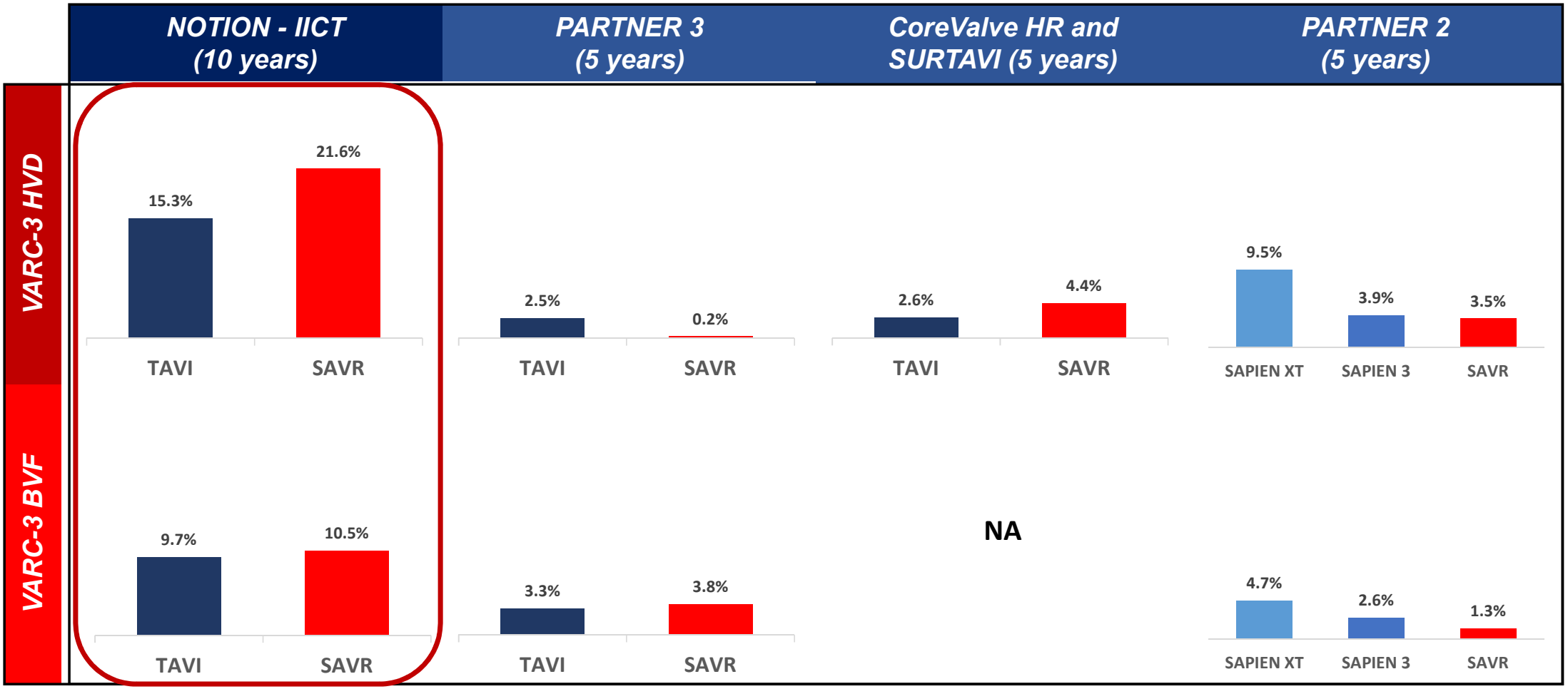
VALVE DURABILITY COMPARING TAVI AND SAVR IN MAJOR RCTS (AT 5-10 YEARS)

Thyregod et al. Eur Heart J 2023;45(13):1116-1124; Mack MJ et al. N Engl J Med 2023;389(21):1949-1960; O'Hair et al. JAMA Cardiol 2023;8(2):111-119; Pibarot et al. J Am Coll Cardiol 2020.



TAVI vs SAVR – Tricuspid Aortic Stenosis

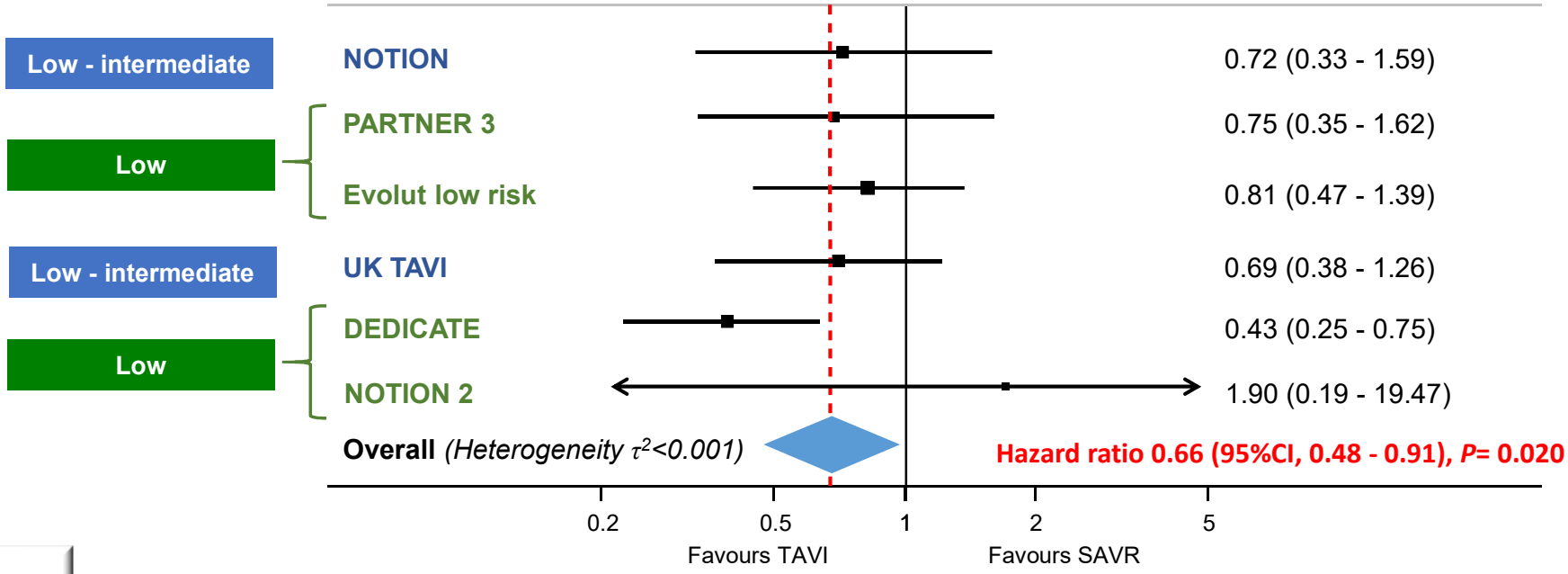
Meta-analysis of 6 RCTs @ 2 Years

Mortality

2-year

Low/intermediate risk RCTs

NOTION, PARTNER 3, EVOLUT low risk, UK TAVI, DEDICATE, NOTION 2 (tricuspid cohort)



34% relative risk reduction up to 2 years

TAVI vs SAVR – Tricuspid Aortic Stenosis

Mortality

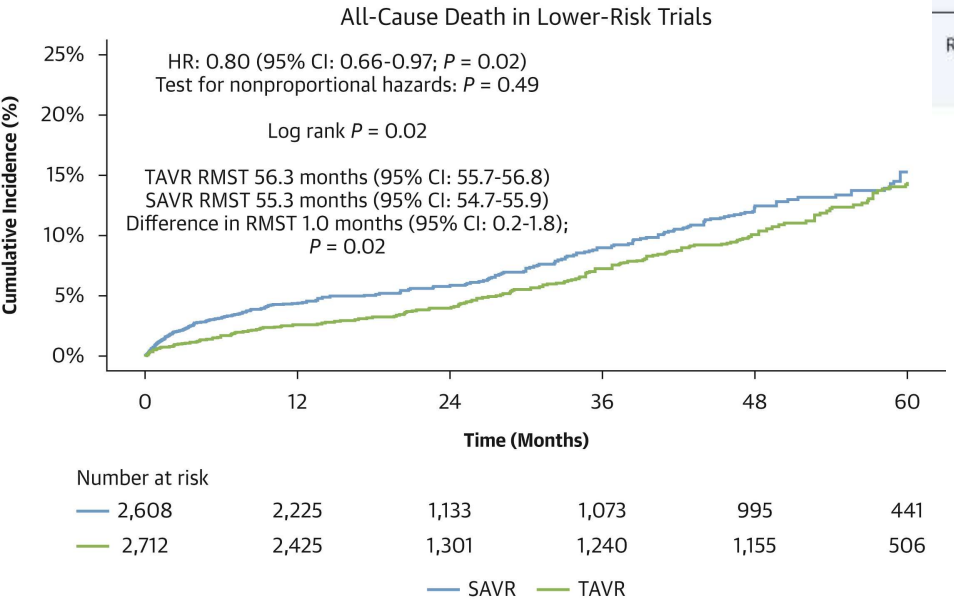
Meta-analysis of 6 RCTs @ 5 Years

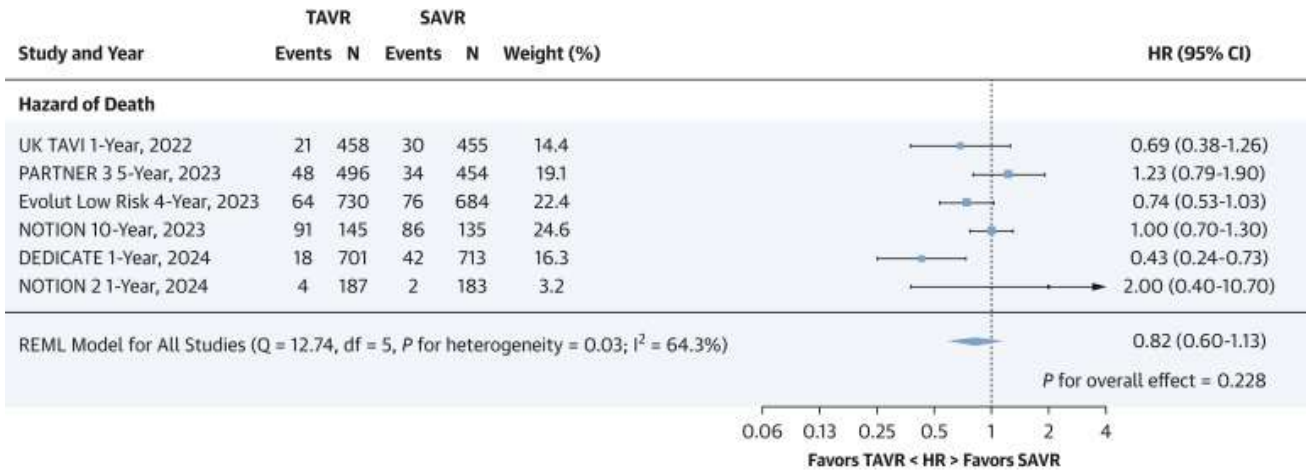
Reddy et al. JACC 2025

Low/intermediate risk RCTs

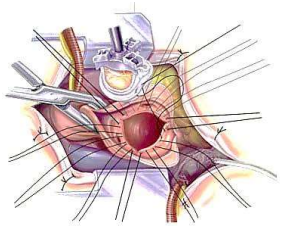
NOTION, PARTNER 3, EVOLUT low risk, UK TAVI, DEDICATE, NOTION 2 (tricuspid cohort)

5-year





At 5 years no difference in mortality



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AORTIC VALVE INTERVENTION (TAVI VS SAVR) IN SEVERE SYMPTOMATIC AORTIC STENOSIS

	Favours SAVR		Favours TAVI
Age	65	75	85
Surgical risk	Low	Intermediate	High - Prohibitive
Frailty	Low	Moderate	Severe
Valve morphology	Unfavourable	Intermediate	Favourable
Femoral access	Unfavourable	Intermediate	Favourable
Concomitant valve disease	• Severe AR • Severe primary MR • Severe TR	• Severe secondary MR • Moderate/severe MS • Moderate AR/MR/TR	Mild AR/MR/MS/TR
Coronary artery disease	• 3-vessel disease and SYNTAX>22 • LM disease and SYNTAX>32	• 3-vessel disease and SYNTAX≤22 • LM disease and SYNTAX≤32	• 1 or 2-vessel disease • LM disease and SYNTAX≤22
Other factors	• Aortic disease requiring surgery • Septal hypertrophy requiring surgery • Active endocarditis		• Porcelain aorta • Previous cardiac surgery • Previous chest irradiation • Chest malformation • Multiple comorbidities

Windecker S et al.
Eur Heart J 2022

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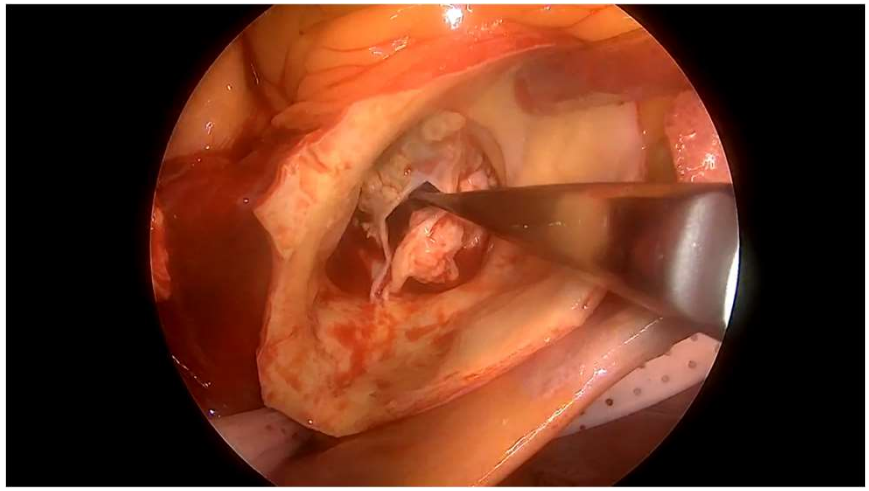
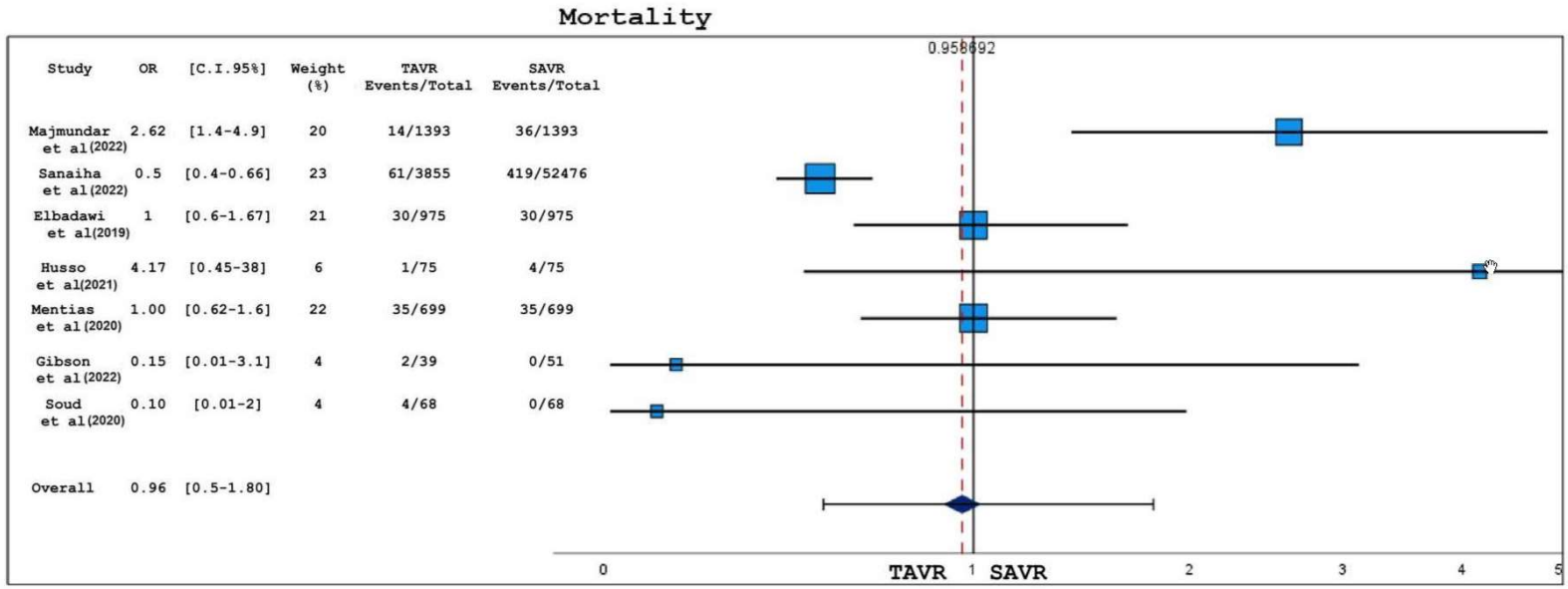


Meta-analysis of retrospective data

Improta et al. J Clin Med 2023



Random Effects Model
Heterogeneity: I-squared = 0.81
Homogeneity: Q= 31.77, df = 6, p value = 0.90
Effect Size test: z=-0.13, Sig 2 tails p = 0.90

Schwer degenerierte bikuspide AK

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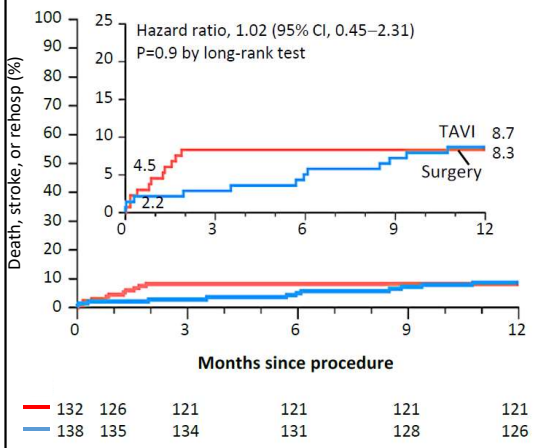
NOTION-2:

TRICUSPID AND BICUSPID COHORTS

Jørgensen et al. Eur Heart J 2024.

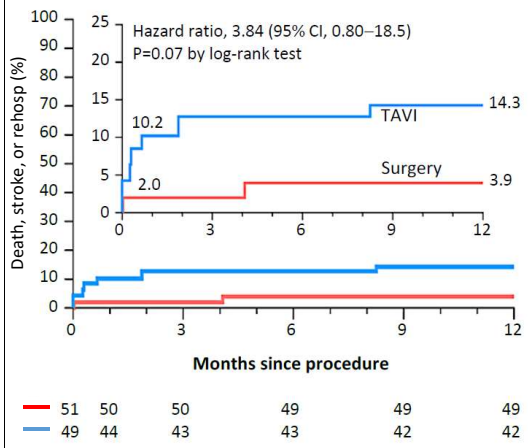
Primary endpoint

Tricuspid cohort



	TAVI vs. SAVR
Incidence	8.7% vs. 8.3%
Risk difference	0.4% (-6.3%, 7.0%)
Hazard ratio	1.02 (0.45-2.31)

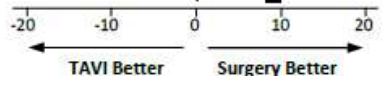
Bicuspid cohort



	TAVI vs. SAVR
Incidence	14.3% vs. 3.9%
Risk difference	10.4% (-0.8%, 21.5%)
Hazard ratio	3.84 (0.80-18.5)

Key secondary endpoints

Subgroup	No. of Patients	TAVI	Surgery	TAVI vs. Surgery Risk difference (95% CI)
		*% of patients**		*Percentage points*
Death or disabling stroke				
Tricuspid	270	2.2	1.5	0.7 (-2.5 to 3.9)
Bicuspid	100	6.1	2.0	4.1 (-3.6 to 11.9)
Death from Any Cause				
Tricuspid	270	1.5	0.8	0.7 (-1.8 to 3.2)
Bicuspid	100	4.1	2.0	2.1 (-4.6 to 8.8)
Stroke				
Tricuspid	270	5.1	2.3	2.8 (-1.7 to 7.3)
Bicuspid	100	6.1	0	6.1 (-0.6 to 12.8)
Disabling stroke				
Tricuspid	270	1.5	1.5	0 (-3.0 to 2.8)
Bicuspid	100	2.0	0	2.0 (-1.9 to 6.0)
Non-disabling stroke				
Tricuspid	270	3.6	0.8	2.8 (-0.6 to 6.3)
Bicuspid	100	4.1	0	4.1 (-1.5 to 9.6)
Rehospitalization				
Tricuspid	270	3.6	6.1	-2.5 (-7.6 to 2.7)
Bicuspid	100	4.2	2.0	2.2 (-4.6 to 8.8)
Major- or life-threatening bleeding				
Tricuspid	270	5.1	18.9	-13.8 (-21.5 to -6.3)
Bicuspid	100	4.1	13.7	-9.6 (-20.6 to 1.3)
New permanent pacemaker implantation				
Tricuspid	270	15.2	7.8	7.4 (-0.3 to 15.0)
Bicuspid	100	14.6	8.5	6.1 (-6.7 to 18.9)
Moderate or greater paravalvular regurgitation§				
Tricuspid	270	3.1	0	3.1 (0.1 to 6.1)
Bicuspid	100	9.1	0	9.1 (0.6 to 17.6)



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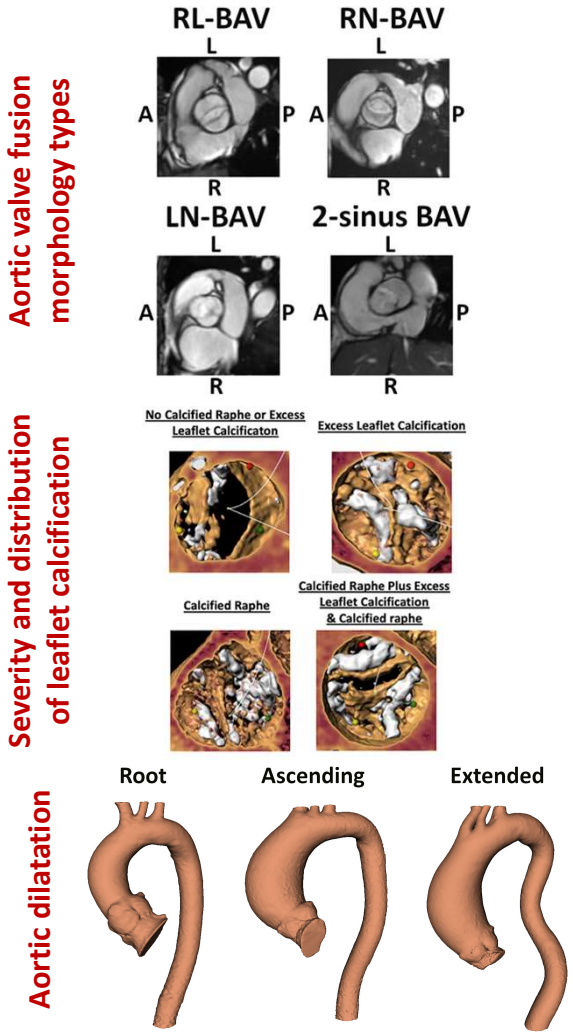
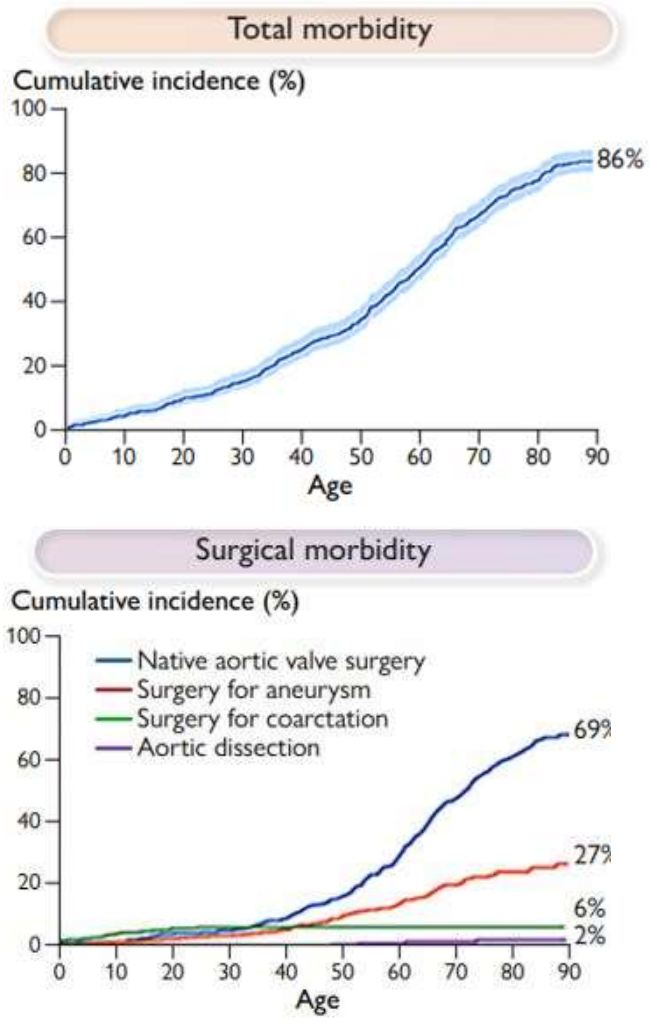
BICUSPID AORTIC VALVE STENOSIS – DISTINCT VALVE LESION

Yang LT et al. Eur Heart J 2023; Windecker et al. Eur Heart J 2022 ; Elbadawi et al. JACC Cardiovasc Interv 2019; Rodríguez-Palomares et al. J Am Coll Cardiol 2023

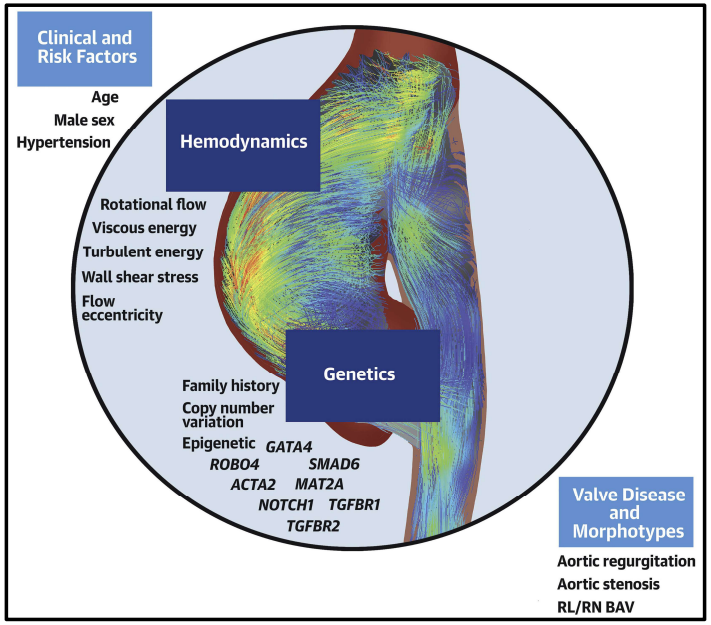
Anatomical Considerations



Lifetime Cumulative Morbidity



Future Progression of Aortopathy

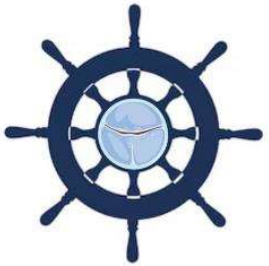


BAV Stenosis

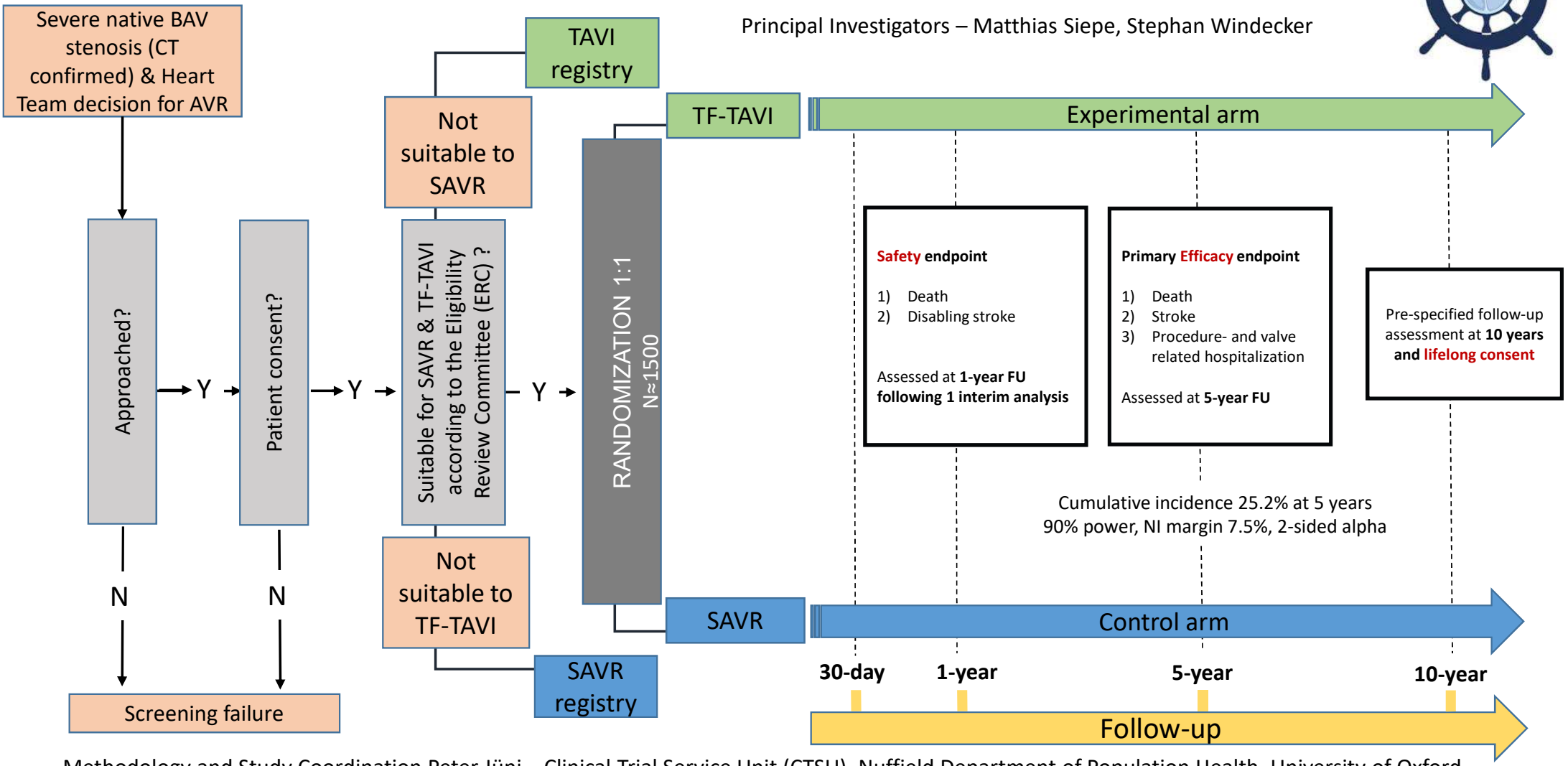
- Younger patients
- More complex, non-circular anatomy
- Prosthetic hemodynamic outcomes
- Risk of stroke, annulus rupture
- Aortopathy

No randomized clinical trial compared TAVI and SAVR to date

NAVIGATE BICUSPID – INVESTIGATOR INITIATED TRIAL



Principal Investigators – Matthias Siepe, Stephan Windecker



Methodology and Study Coordination Peter Jüni – Clinical Trial Service Unit (CTSU), Nuffield Department of Population Health, University of Oxford

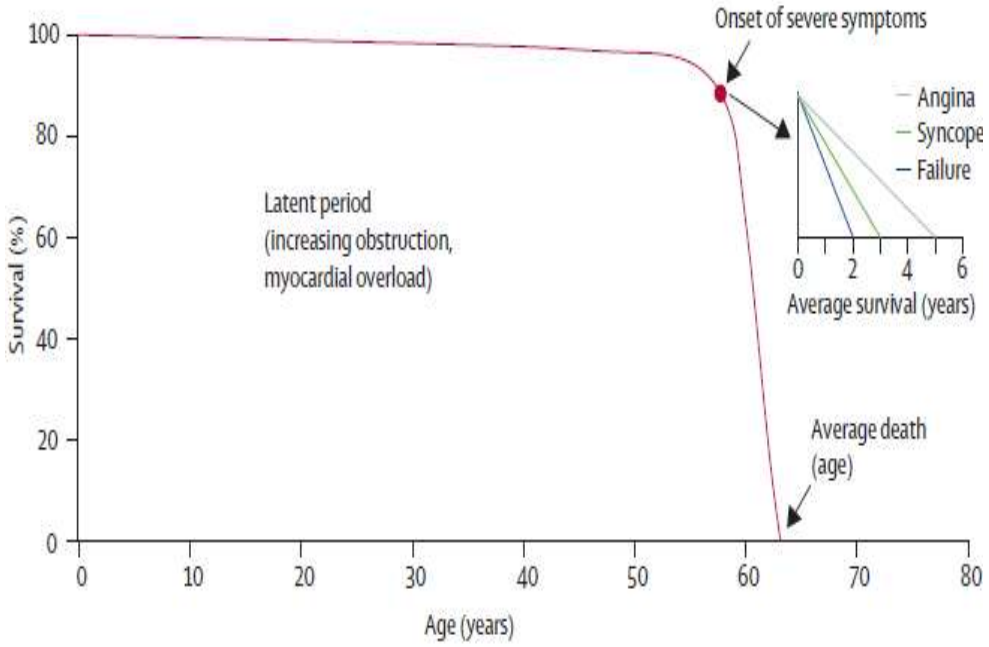
Natural History of Aortic Stenosis

Ross and Braunwald. Circulation 1968;37/38(suppl V):V-61-V-67; Bonow and Greenland Circulation 2015;131:969-71.

Ross and Braunwald in 1968

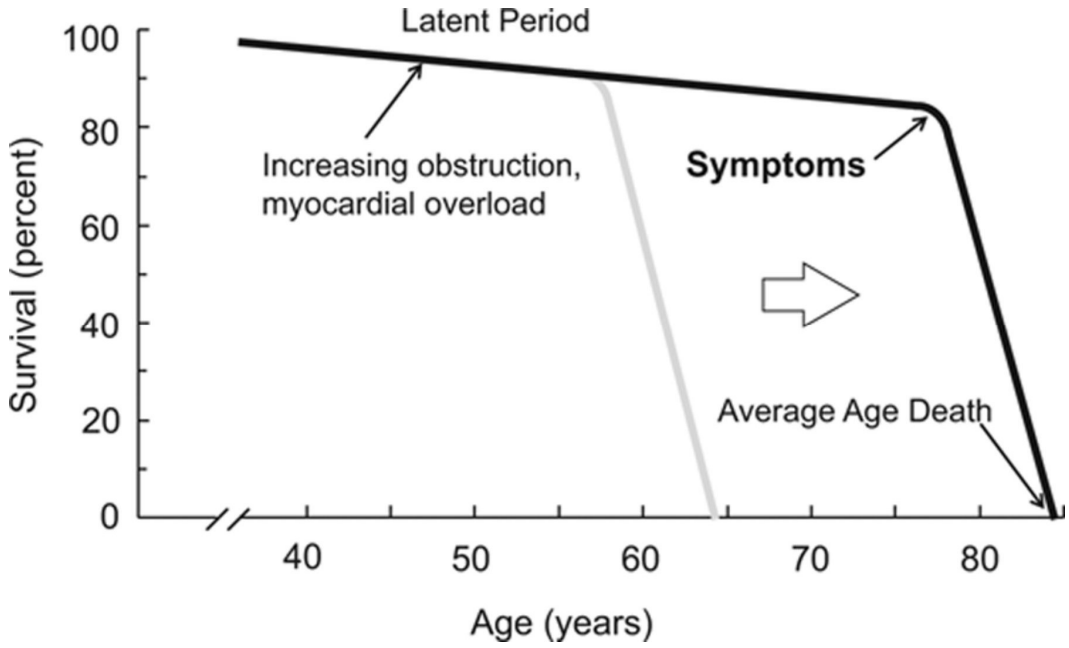
Post Mortem data from 11 patients

- Age: 30-60 years
- Etiology: Rheumatic and bicuspid AS
- Operative mortality 10-15% in 1960s



Review in contemporary era

- 13.3 milion cases with non-rheumatic calcific AS (2021)
- Majority of patients are older with degenerative cause



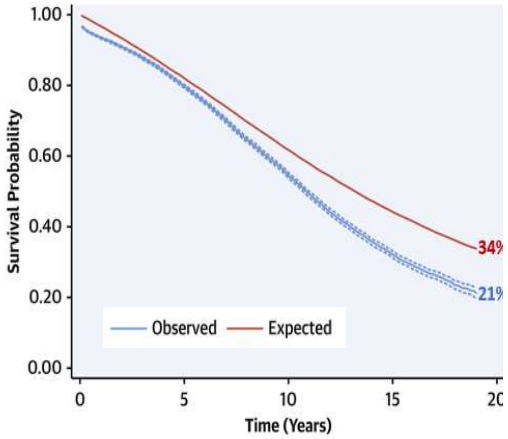
Early Intervention versus Watchful Waiting

Glaser et al. J Am Coll Cardiol 2019; 74(1):26-33.

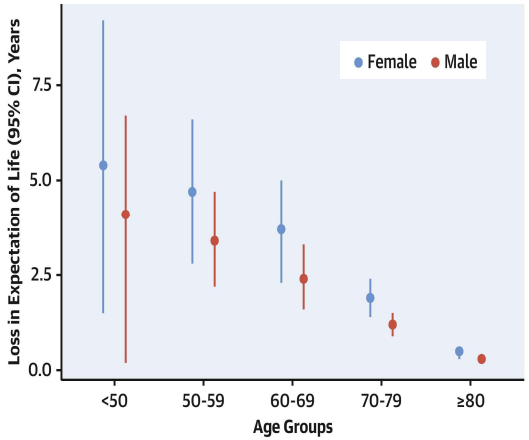
Loss in life expectancy after AVR

Age-, sex-, and year of SAVR-matched analysis of 23,528 SAVR patients in SWEDEHEART with general population

Survival after AVR

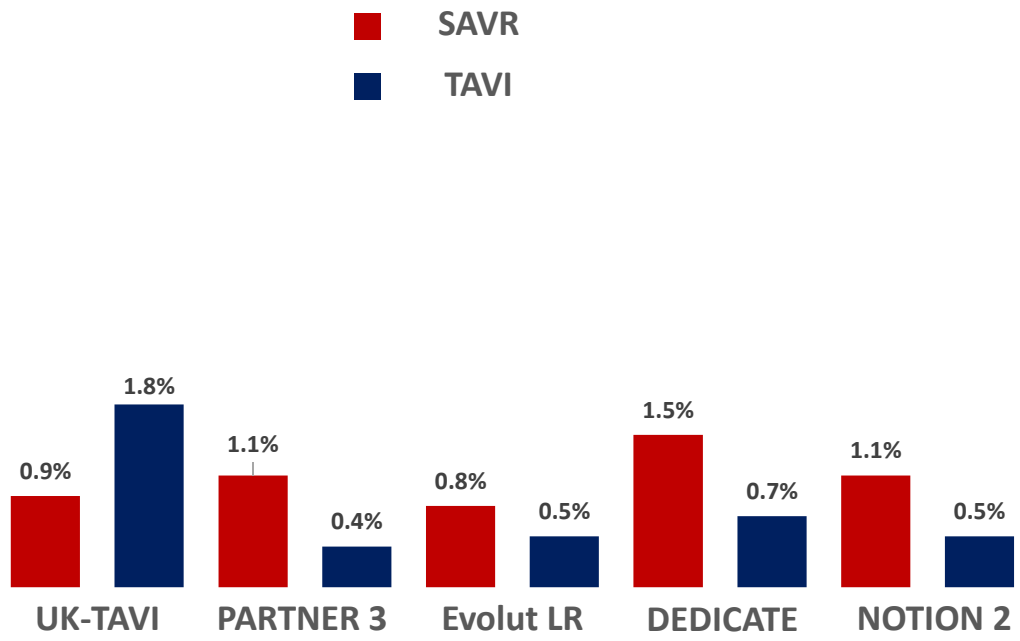


Loss in life expectancy after AVR



Even after successful surgery, life expectancy does not fully restore to normal.

Periprocedural death in contemporary RCTs



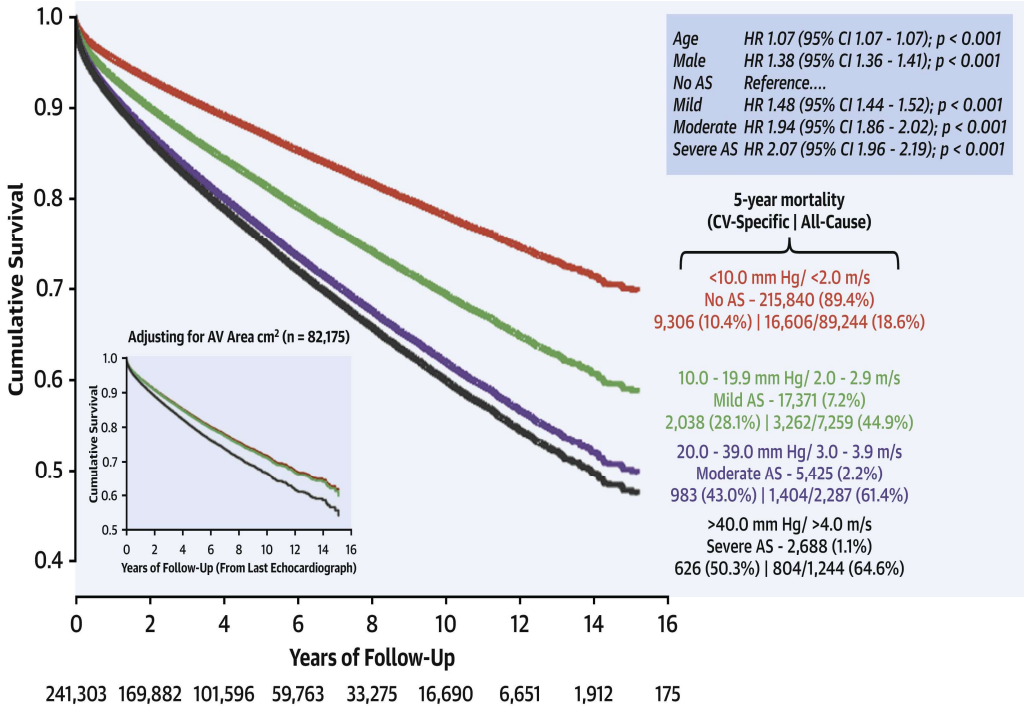
Risk of mortality are consistently low (<3%) in contemporary TAVI-SAVR RCTs

NATURAL HISTORY OF UNTREATED AS ACROSS DISEASE CONTINUUM

Strange et al. J Am Coll Cardiol 2019;74:1851-1863; Généreux et al. J Am Coll Cardiol 2023;82(22):2101-2109.

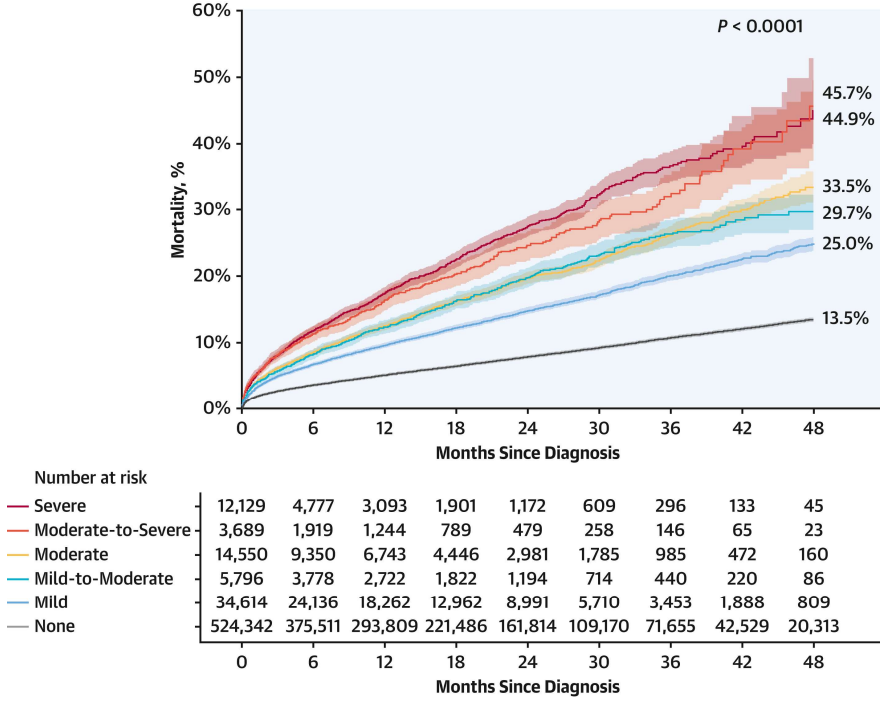
National Echocardiographic Database of Australia

241,303 individuals from the NEDA



Echocardiographic claims data From 24 US Hospitals

595,120 patients from 24 US hospitals

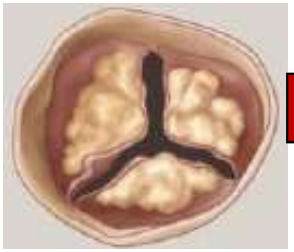


Untreated AS had a higher mortality across the full spectrum of AS severity.

Optimal Time Point of Intervention in Aortic Stenosis

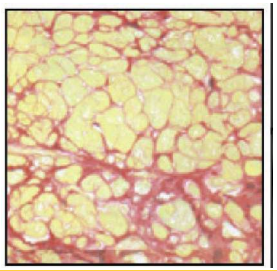
Otto et al. N Engl J Med 2008;359:1395-98; Bing et al. JACC Cardiovasc Imaging 2019;12(2):283-296; Généreux et al. J Am Coll Cardiol 2022;80:783-800.

Aortic Stenosis



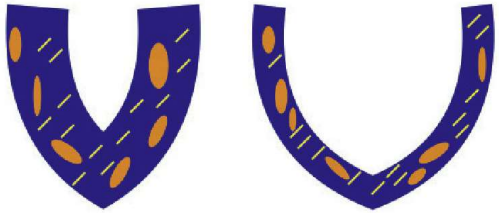
Pressure overload

Replacement fibrosis



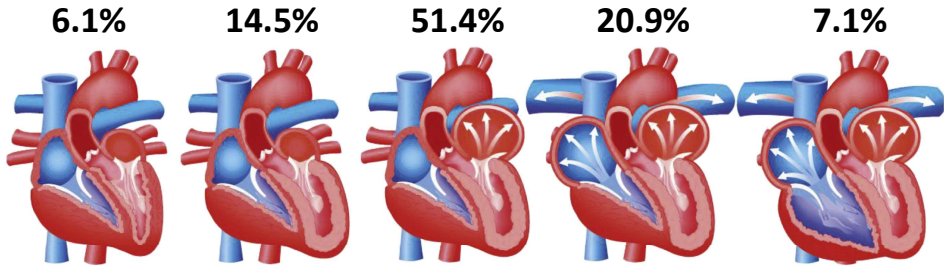
Myocyte death

Anatomical and functional cardiac damage

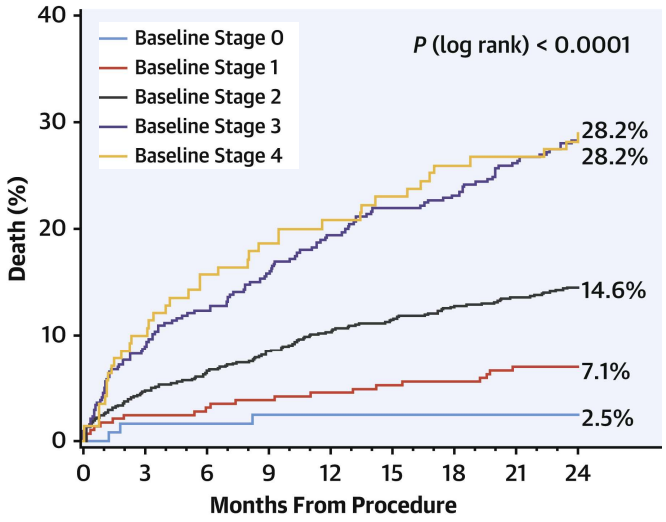


Extravalvular Cardiac Damage in Symptomatic Severe Aortic Stenosis

1,974 patients from the PARTNER 2 and 3 trials



Stages/Criteria	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
	No Cardiac Damage	LV Damage	LA or Mitral Damage	Pulmonary Vasculature or Tricuspid Damage	RV Damage
Echocardiogram		Increased LV Mass Index >115 g/m² (Male) >95 g/m² (Female)	Indexed LA Volume >35 mL/m²	Systolic Pulmonary Hypertension >60 mm Hg	Moderate-Severe Right Ventricular Dysfunction
		E/e' >14	Moderate-Severe Mitral Regurgitation	Moderate-Severe Tricuspid Regurgitation	
		LV Ejection Fraction <50%	Atrial Fibrillation		



Indications for Aortic Valve Interventions: Timing of Intervention

Recommendations	AHA/ACC 2020		ESC/EACTS 2021	
	COR	LOE	COR	LOE
Symptomatic, severe high-gradient AS	1	A	I	B
Symptomatic, classical low-flow low-gradient AS				
With flow reserve.	1	B-NR	I	B
Positive DSE (true severe setenosis)			I	C
Without flow reserve, calcium on CT			IIa	C
Symptomatic, paradoxical low-flow low-gradient AS				
Positive on careful confirmation (high likelihood of true severe stenosis)	1	B-NR	IIa	C
Asymptomatic, severe high-gradient AS				
LVEF <50%	1	B-NR	I	B
Symptoms on exercise test	2a	B-NR	I	C
A decrease in blood pressure on exercise test			IIa	C
LVEF <55% without another cause			IIa	B
Very severe AS (V_{max} >5.0m/s), low-surgical risk	2a	B-NR	IIa	B
Rapid progression (V_{max} progression ≥0.3m/s/year), low-surgical risk	2a	B-NR	IIa	B
Markedly elevated BNP, low-surgical risk	2a	B-NR	IIa	B
Indications for other cardiac surgery	1	B-NR	I	C
Moderate AS				
Indications for other cardiac surgery	2b	C-EO	IIa	C

Management Asymptomatic Severe Aortic Stenosis

Class I Recommendation

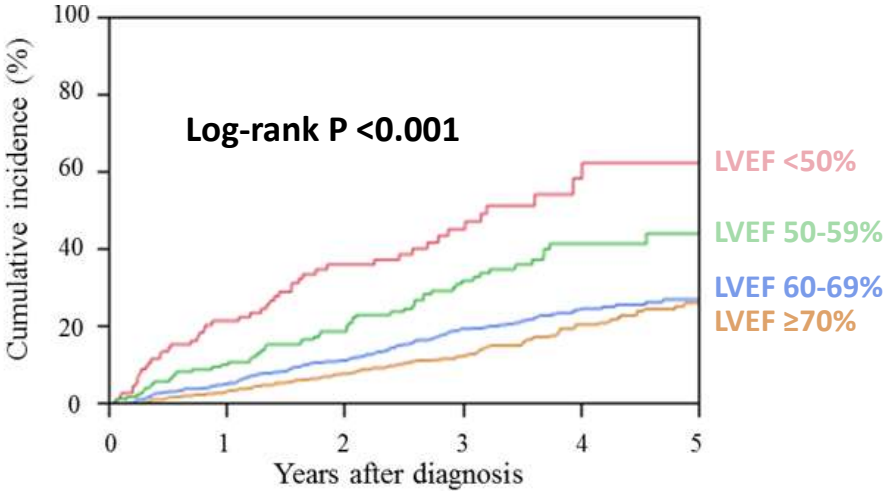
Taniguchi et al. JACC Cardiovasc Interv 2018;11:145-157; Das et al. Eur Heart J 2005;26:1309-1313.

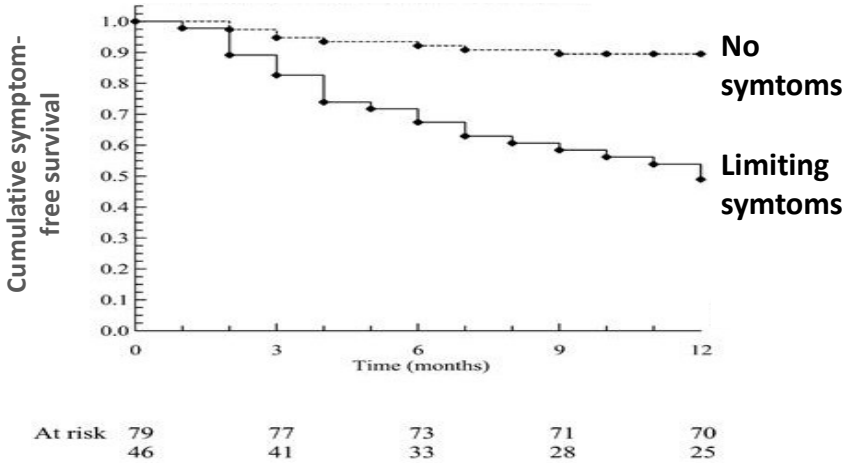
LVEF <50% without another cause				Symptoms on excercise test			
ACC/AHA (COR/LOE)		ESC/EACTS (COR/LOE)		ACC/AHA (COR/LOE)		ESC/EACTS (COR/LOE)	
1	B-NR	I	B	1	A	I	C

- ✓ 3,794 patients with severe AS.
- ✓ Composite of aortic valve-related death or HF hospitalization according to LVEF.

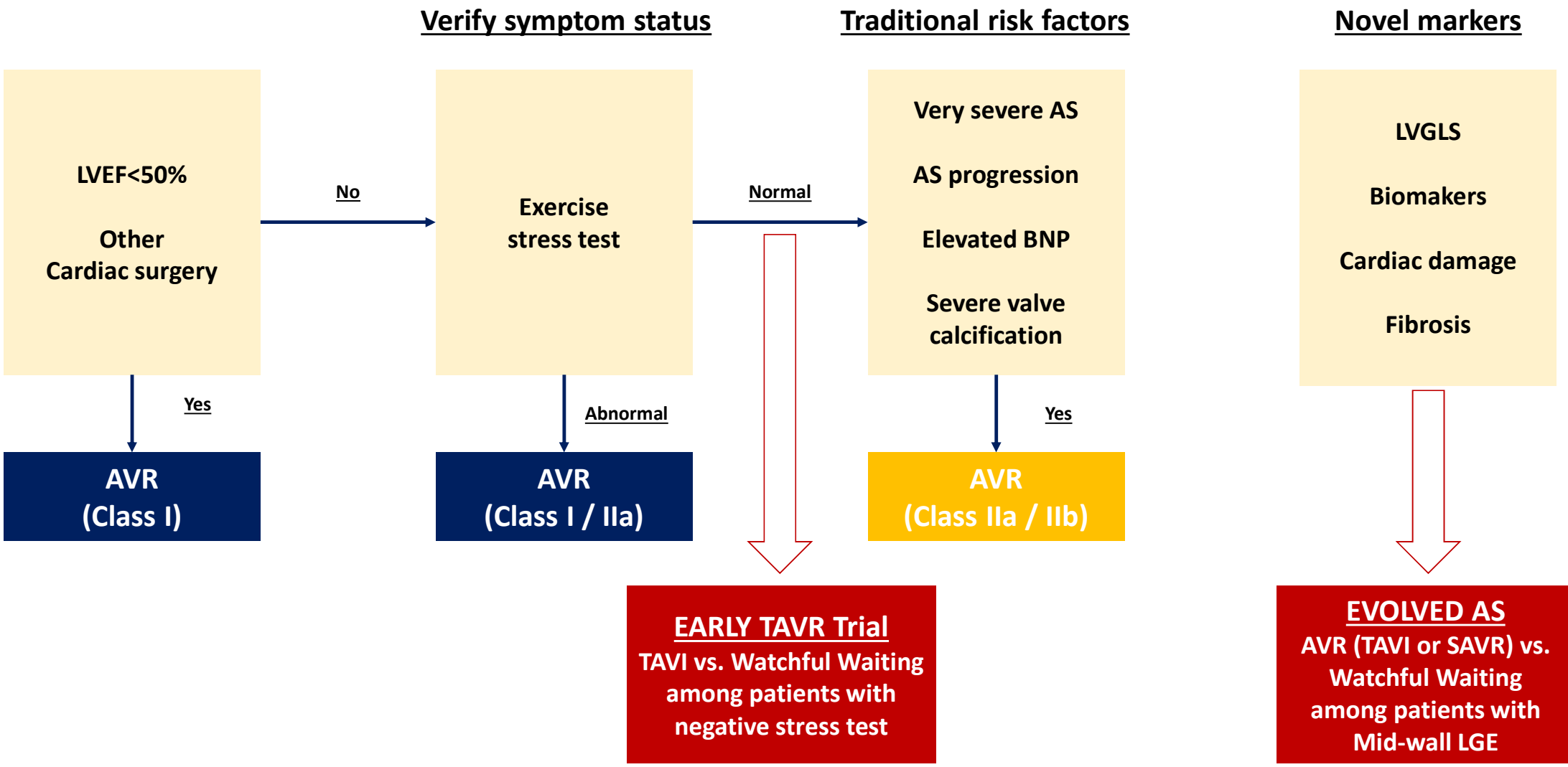
- ✓ 125 patients with severe asymptomatic AS.
- ✓ Treadmill exercise testing using the modified Bruce protocol was performed.

Asymptomatic Pts with conservative therapy



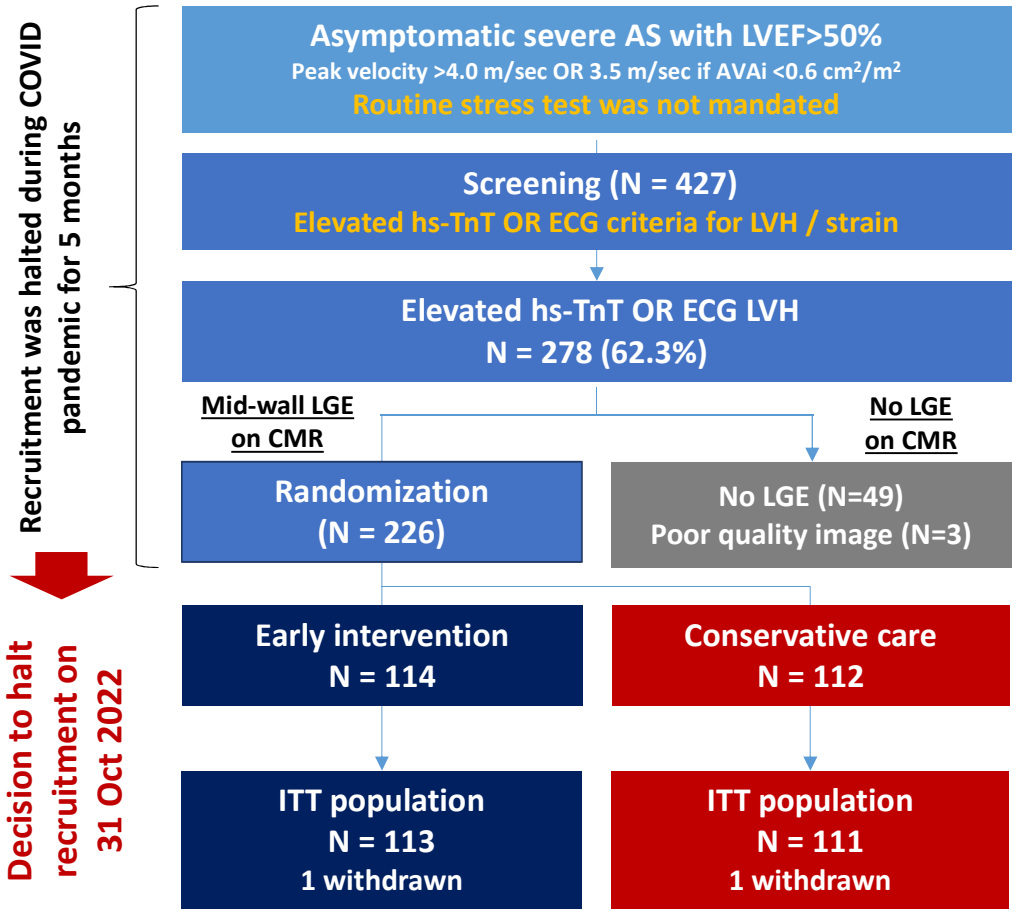


MANAGEMENT ASYMPTOMATIC SEVERE AORTIC STENOSIS



EVOLVED TRIAL - TAVI IN ASYMPTOMATIC SEVERE AS

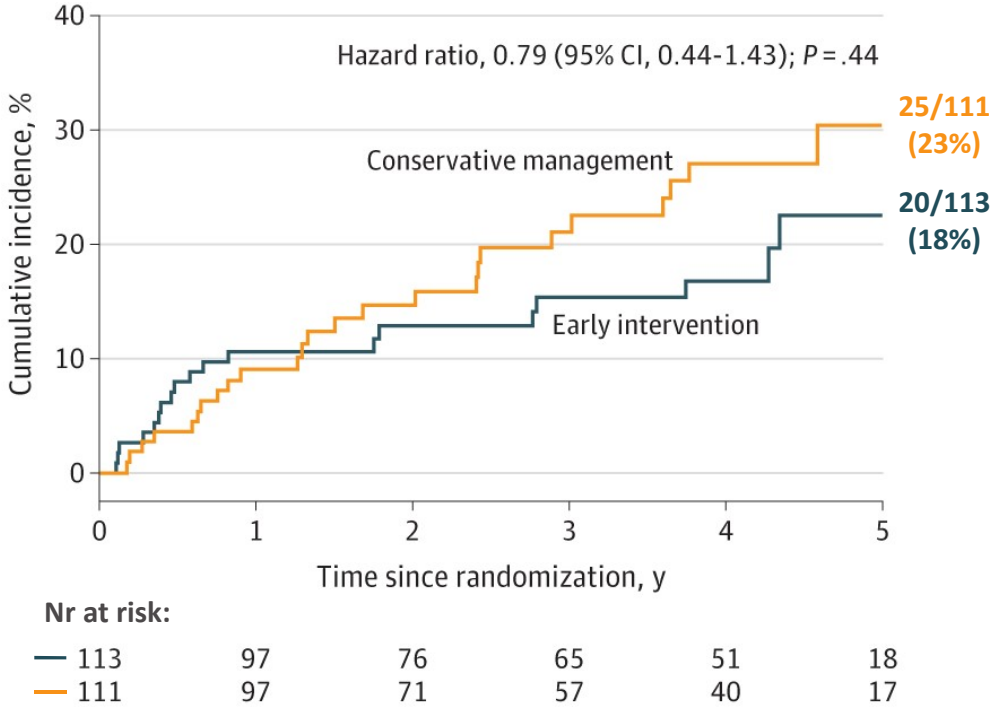
Loganath al. JAMA 2025;333:213-221.



Primary endpoint

All-cause death or unplanned AS-related hospitalization

(any unplanned admission before or after AVR with syncope, heart failure, chest pain, ventricular arrythmia, or second- or third-degree heart block attributed to AV disease)

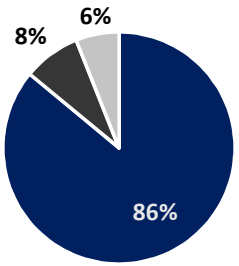


EVOLVED TRIAL - TAVI IN ASYMPTOMATIC SEVERE AS

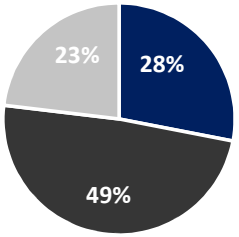
Loganath al. JAMA 2025;333:213-221.

AVR rate

Early intervention
N = 113

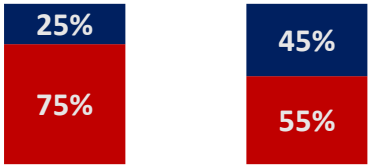


Conservative management
N = 111

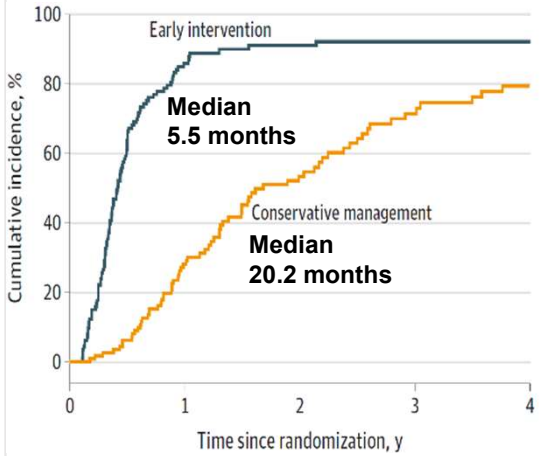


AVR within 12 mo
AVR after 12 mo
No AVR or died before AVR

SAVR TAVR



Time to intervention

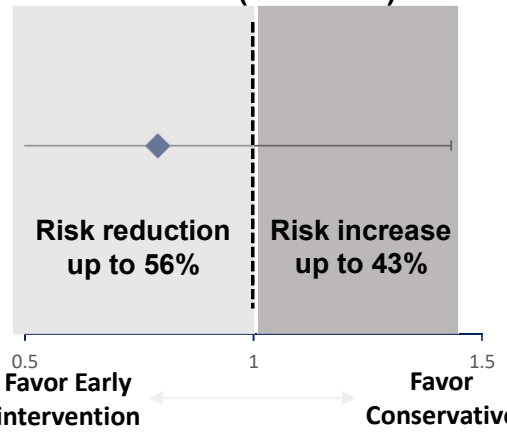


✓ 6 Pts in the early intervention group died before AVR.

Primary EP

All-cause death or AS-related hospitalization

HR 0.79 (0.44-1.43)

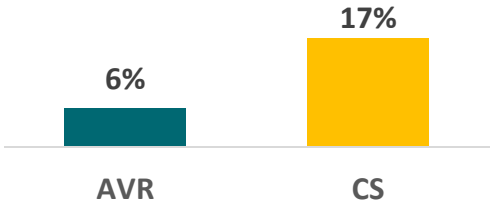


✓ Very wide 95% CI resulting in imprecise estimates of potential benefit or harm of early intervention.

Hypothesis

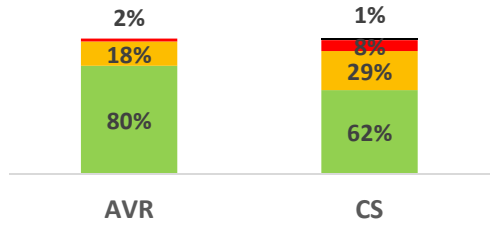
Unplanned AS-hosp

HR 0.37 (0.16-0.88)



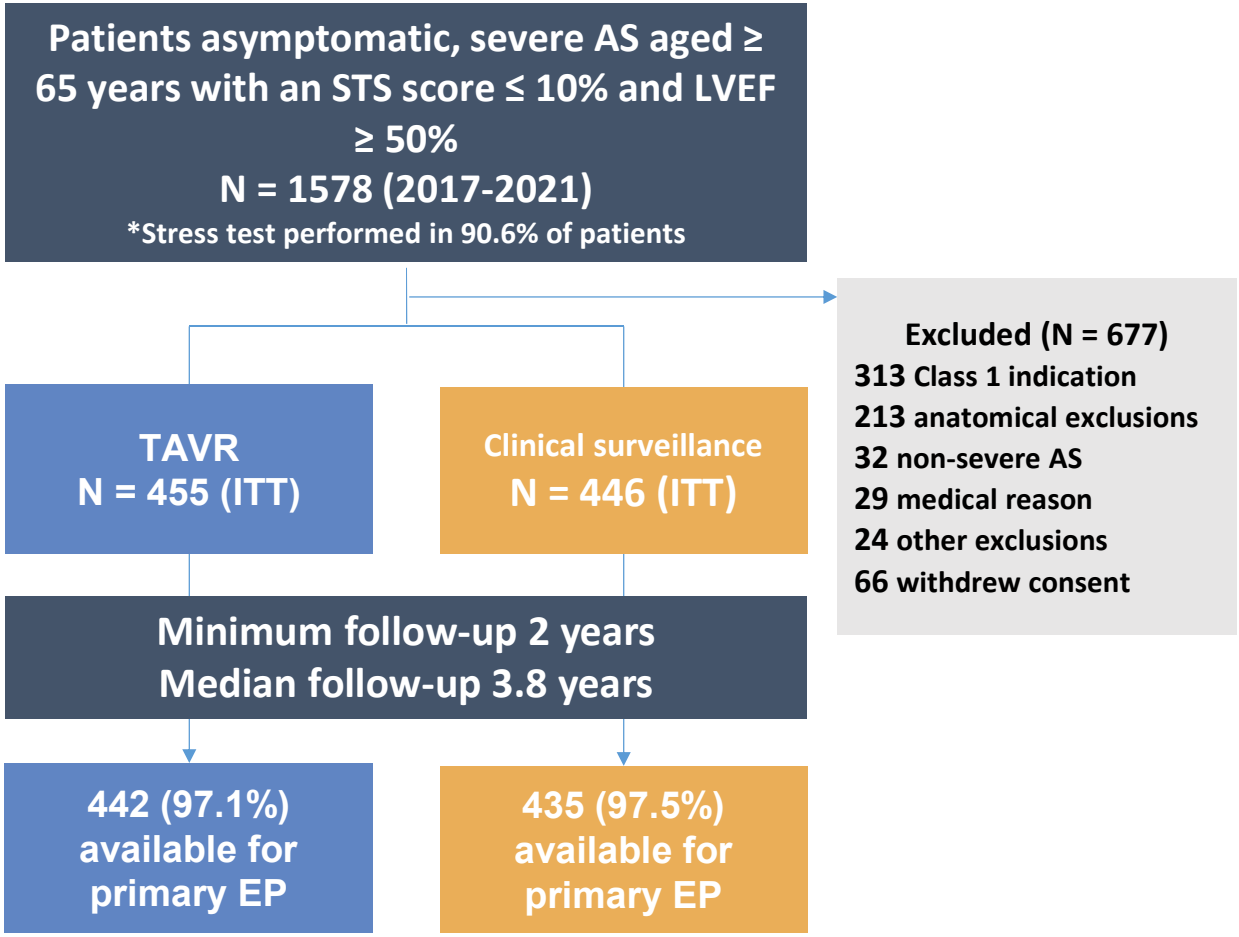
NYHA at 1 year

OR 0.37 (0.20-0.70)



EARLY TAVR TRIAL - TAVR IN ASYMPTOMATIC SEVERE AS

Généreux et al. N Engl J Med 2025;392:217-227.



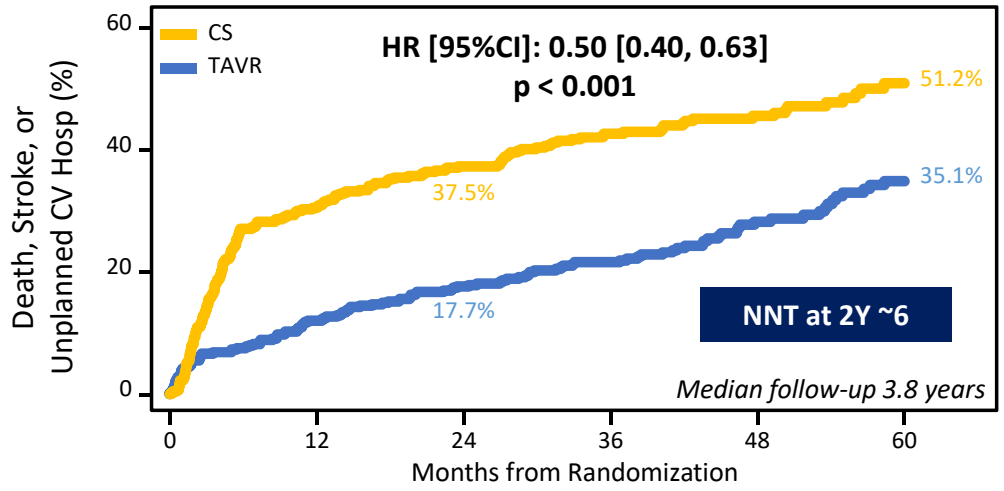
Characteristic	TAVR (N=455)	CS (N=446)
Age, y	76.0 ± 6.0	75.6 ± 6.0
Female sex	28.8%	33.0%
BMI, kg/m^2	28.4 ± 4.6	28.6 ± 4.8
STS score, %	1.8 ± 1.0	1.7 ± 1.0
Low-risk per Heart team	83.5%	83.9%
Asymptomatic Criteria		
By stress test	90.3%	90.8%
By clinical history only*	9.7%	9.2%
KCCQ Score	92.7 ± 8.7	92.7 ± 9.4
NT-proBNP, pg/mL	276 (139, 599)	297 (148, 608)

EARLY TAVR TRIAL - TAVR IN ASYMPTOMATIC SEVERE AS PRIMARY EP

Généreux et al. N Engl J Med 2025;392:217-227.

Primary Endpoint

Non-hierarchical composite of all-cause death, any stroke, or unplanned CV hospitalization* at a minimum follow-up of 2 years

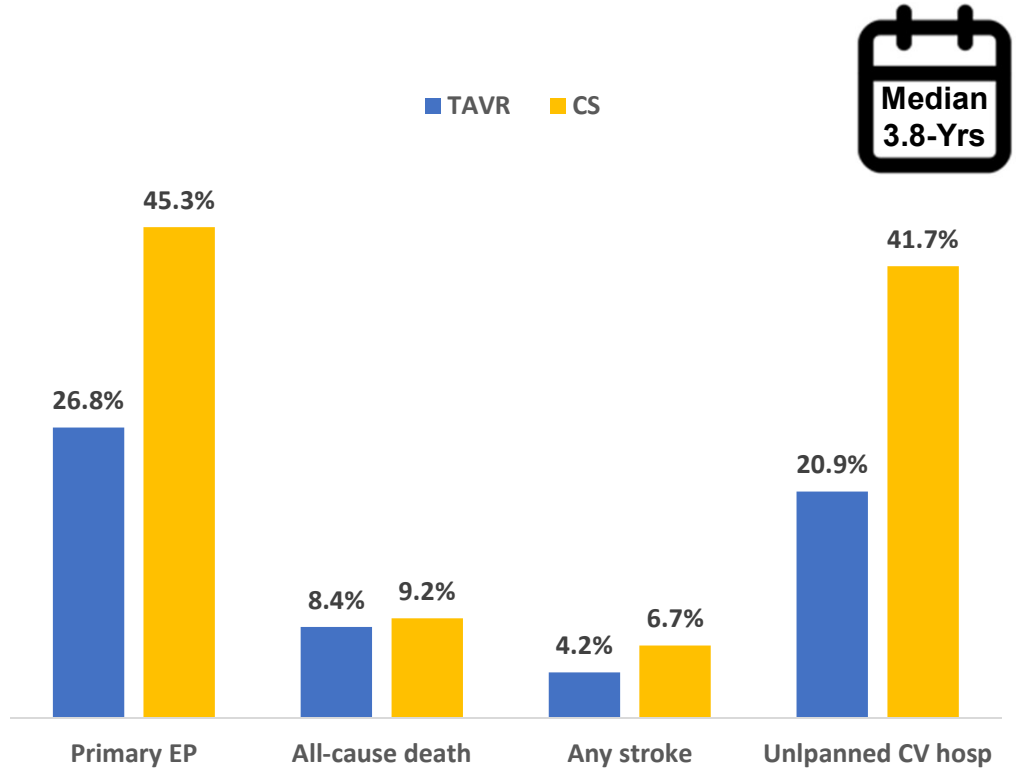


No. at risk:

TAVR	455	390	363	285	142	103
CS	446	305	266	187	117	46

*Unplanned hospitalization for cardiovascular (CV) causes includes aortic-valve interventions (e.g., conversion to aortic-valve replacement) within 6 months after randomization in the clinical surveillance group or aortic-valve reintervention within 6 months after the trial procedure in the TAVR group.

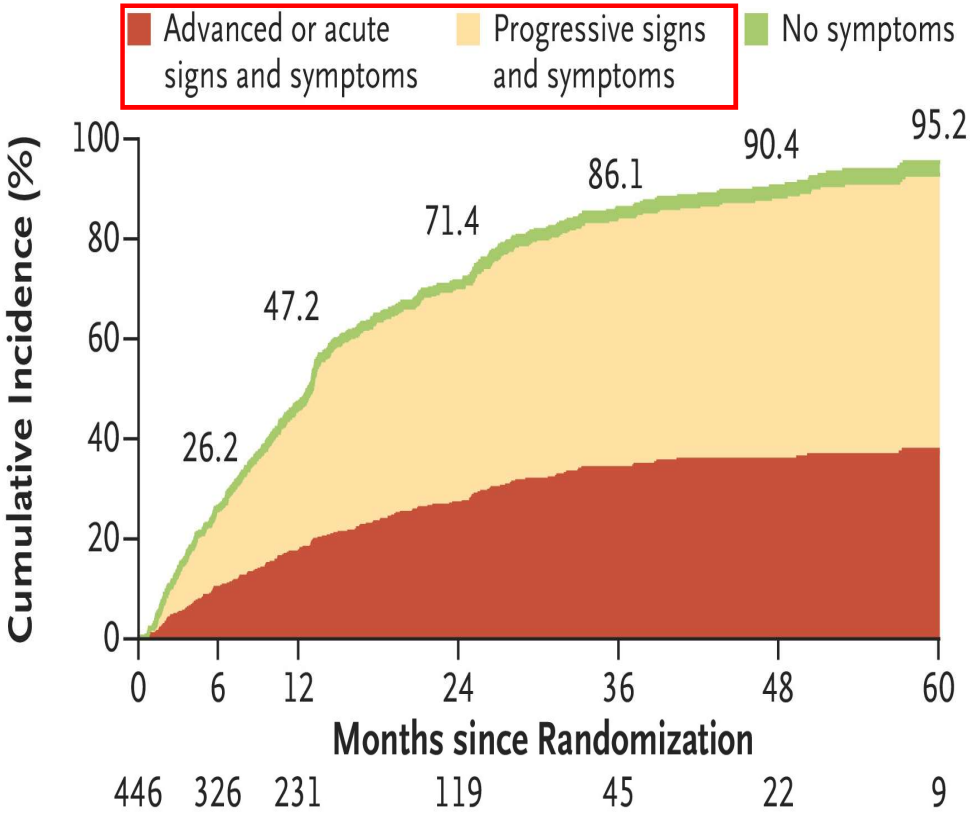
Death, Stroke, or Unplanned CV Hosp



EARLY TAVR TRIAL - TAVR IN ASYMPTOMATIC SEVERE AS

Généreux et al. N Engl J Med 2025;392:217-227.

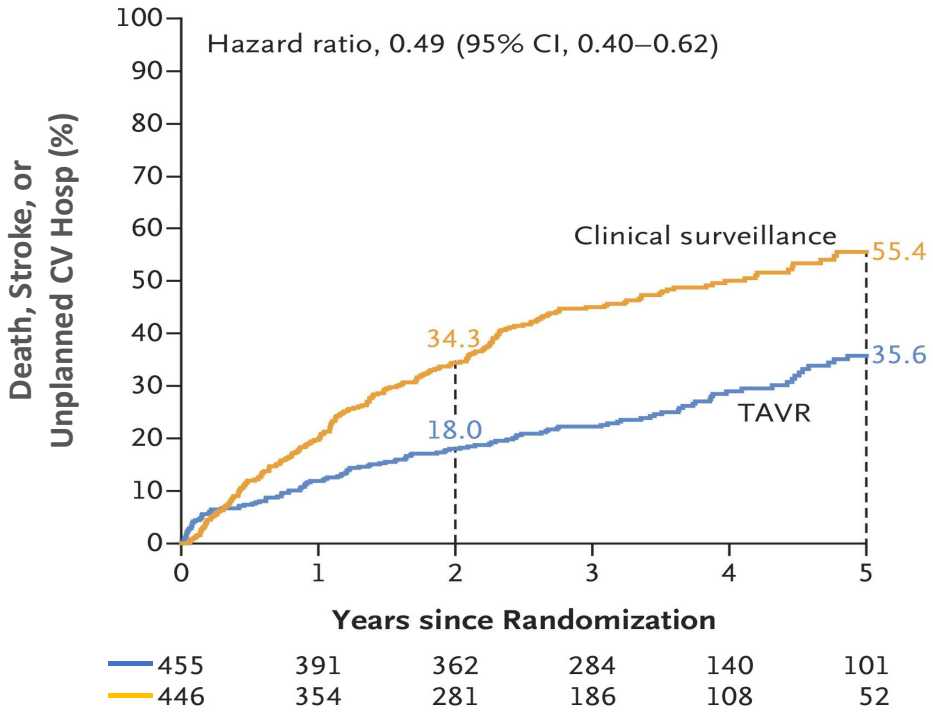
Time to conversion to AVR



Median time from randomization to conversion: 11.1 months
Median time from symptom onset to conversion: 32 days

Exploratory analysis of the primary EP

Including only interventions resulting from advanced signs and symptoms, regardless of timing of intervention



The results of the primary EP remained consistent with those of the primary analysis.

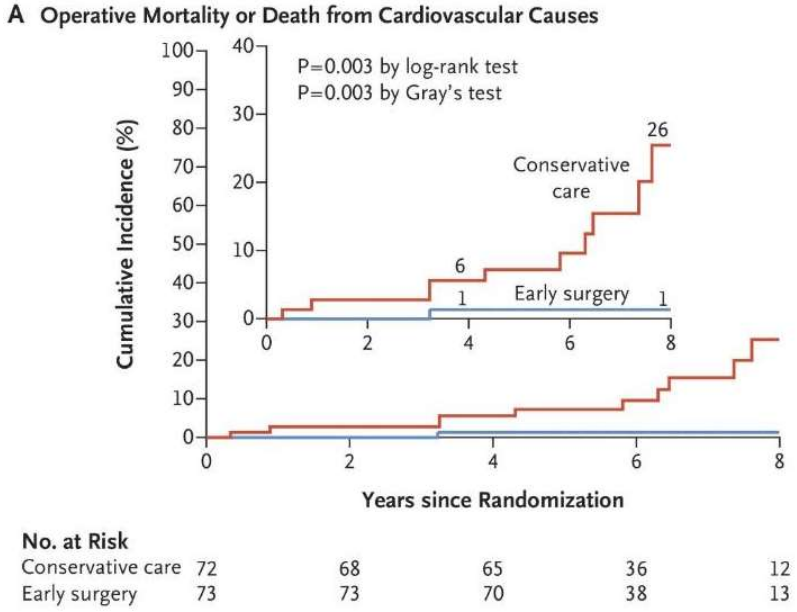
UPSTREAM TREATMENT:

ASYMPTOMATIC SEVERE AORTIC STENOSIS

RECOVERY

Kang et al. N Engl J Med. 2020;382:111-119

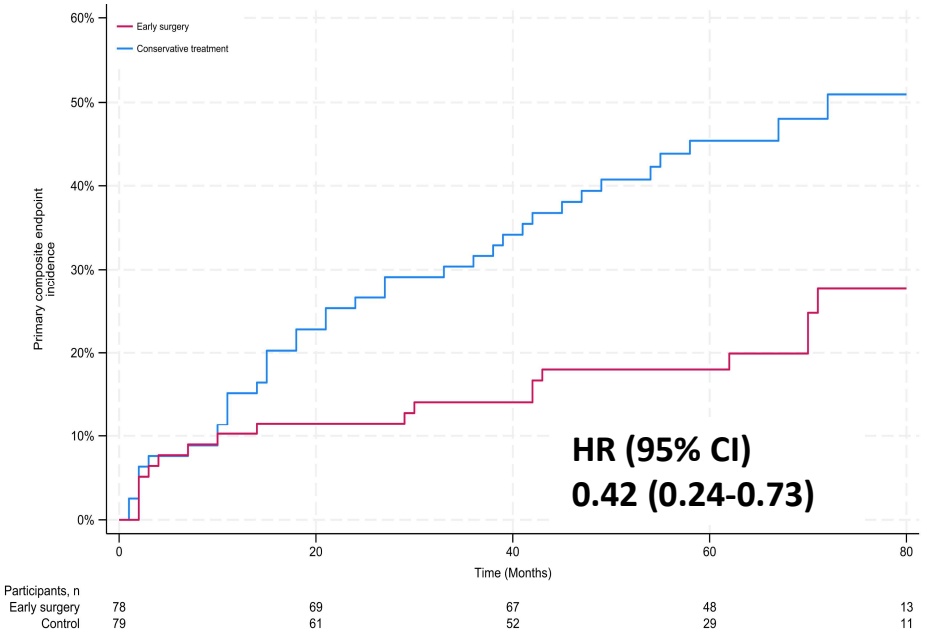
Randomized Trial (n=145)
Early surgery vs. conservative care
(Asymptomatic patients with very severe AS)



AVATAR

Banovic et al. Eur Heart J 2024;45:4526-4535

Randomized Trial (n=157)
Early surgery vs. conservative care
(Asymptomatic patients with severe AS, neg ETT)



EARLY INTERVENTION IN PATIENTS WITH ASYMPTOMATIC SEVERE AS TRIAL CHARACTERISTICS

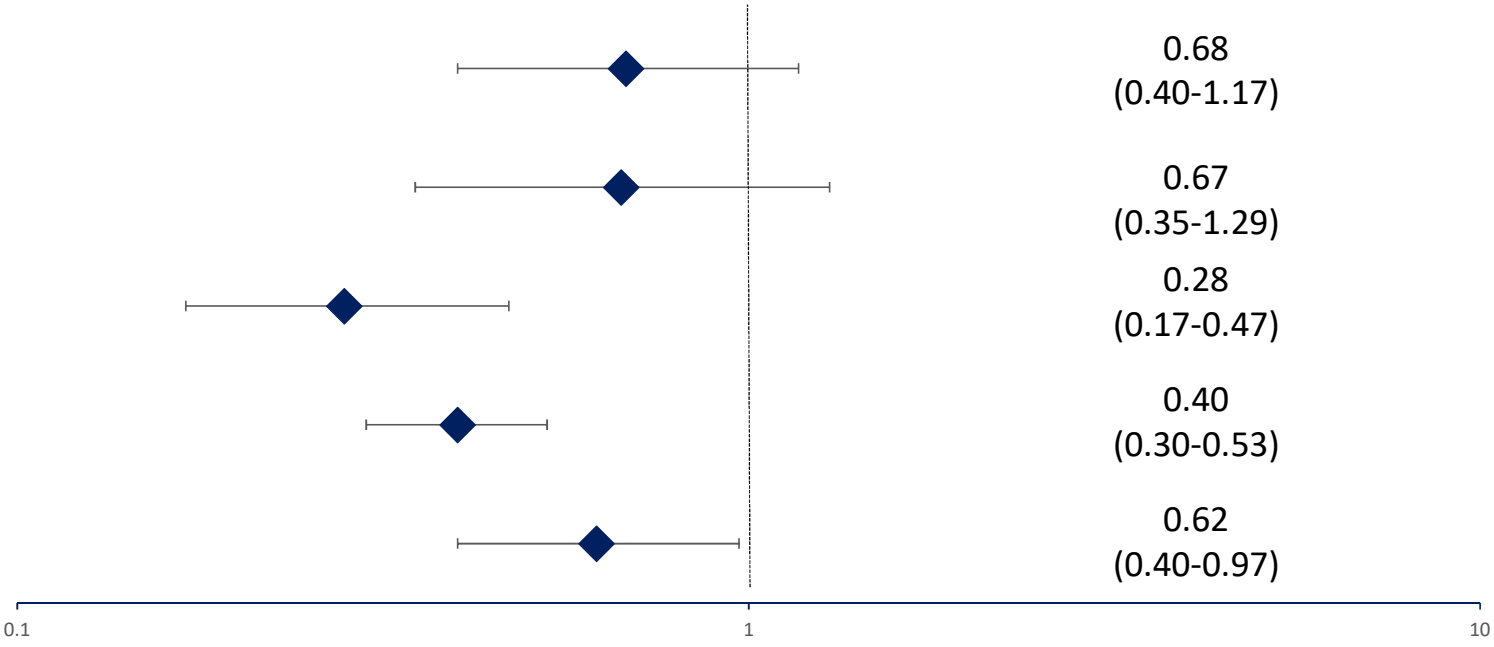
	RECOVERY		AVATAR		EARLY-TAVR		EVOLVED	
Total Nr of patients	145		157		901		224	
Key patient demographics (mean)	age 64 yrs, Female 51%, EuroScore II 0.9%		age 67 yrs, Female 43%, STS-PROM 1.7%		age 76 yrs, Female 31%, STS-PROM 1.8%		age 75 yrs, Female 27%, unknown	
Stress test performed	16.6%		100%		90.6%		Not mandatory	
Key baseline echo results (mean)*	V_{max} 5.1 m/sec; Mean PG 62.7 mmHg;		V_{max} 4.3 m/sec; Mean PG 50.7 mmHg;		V_{max} 4.3 m/sec; Mean PG 46.5 mmHg;		V_{max} 4.3 m/sec; Mean PG 45.2 mmHg;	
Bicuspid etiology	61%		14%		8.4%		29%	
AVR (actual rate)	Intervention (100%)	CS (74%)	Intervention (92.3%)	CS (44.3%)	Intervention (97.6%)	CS (87.0%)	Intervention (94%)	CS (77%)
Time from randomization to intervention (median)	23 days	700 days	55 days	476 days	14 days	11.1 months (≈333 days)	5.5 months (≈165 days)	20.2 months (≈606 days)
Time from indication to intervention (median)	-	NA	-	123 days (90-297 days)	-	32 days (18-58 days)	-	100 days (43-146 days)
AVR modality	SAVR 100%	SAVR 98.1%; TAVI 1.9%	SAVR 100%	SAVR 88.6%; TAVI 11.4%	TAVI 100%	SAVR 1.8%; TAVI 98.2%	SAVR 75%; TAVI 25%	SAVR 45%; TAVI 55%

EARLY INTERVENTION IN PATIENTS WITH ASYMPTOMATIC SEVERE AS
META-ANALYSIS OF 4 RCTS

Généreux et al. J Am Coll Cardiol 2025;85:912-922.

Study-level meta-analysis of early AVR vs. Clinical surveillance in patients with asymptomatic severe AS

	AVR	CS	Pooled HR (95%CI)
All-cause mortality	70/719 (9.7%)	97/708 (13.7%)	0.68 (0.40-1.17)
CV mortality	37/719 (5.1%)	59/708 (8.3%)	0.67 (0.35-1.29)
HF hosp	18/606 (3.0%)	65/597 (10.9%)	0.28 (0.17-0.47)
Unplanned CV or HF hosp	105/719 (14.6%)	226/708 (31.9%)	0.40 (0.30-0.53)
Stroke	32/719 (4.5%)	51/708 (7.2%)	0.62 (0.40-0.97)



EARLY INTERVENTION IN PATIENTS WITH ASYMPTOMATIC SEVERE AS

adapted from Iung B et al. Eur Heart J 2023;44:3136–3148.

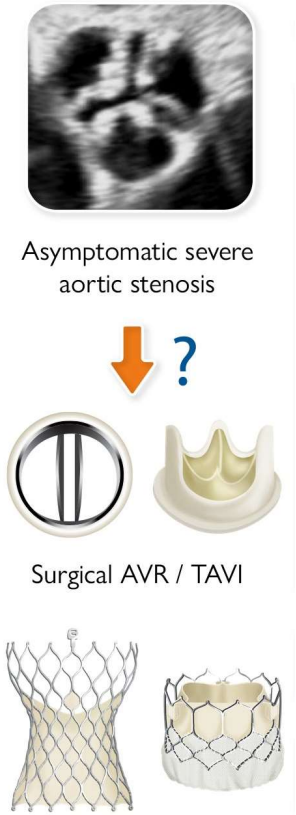
Pro

Major limitations of watchful waiting

- Intervention unavoidable
- F/U suboptimal in real life
- Assessment of symptoms challenging
- Risk of sudden death
- Risk of late referral with associated risk of increased morbidity or mortality
- Risk of irreversible consequences
- Waiting time for intervention when symptoms occur

Risk of intervention is low

4 RCTs demonstrate improved outcomes with earlier intervention



Contra

Major risks of intervention

- Interventional mortality/complications
- Bleeding
- Paravalvular regurgitation
- Risks related to permanent pacemaker
- Structural valve deterioration
- Eariler intervention with biological valves may imply need for earlier reintervention

Irreversible cardiac damage may be detected early by careful clinical F/U

Limited generalizability of RCTs performed in highly selected populations