1

The Modern Era of TAVR: Asymptomatic Aortic Stenosis and Beyond

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Disclosures

Within the prior 24 months, I have had a relevant financial relationship(s) with an ineligible company(ies) listed below.

Nature of Financial Relationship	Ineligible Company
Grant/Research Support	NA
Consultant Fees/Honoraria	Abbott Structural, AMX, 4C Medical **Technologies**, Alleviant Medical, Edwards Lifesciences, Philips, GE, Valcare Med Ltd, Vdyne, WL Gore, Siemens, Laza, CroiValve
Individual Stock(s)/Stock Options	NA

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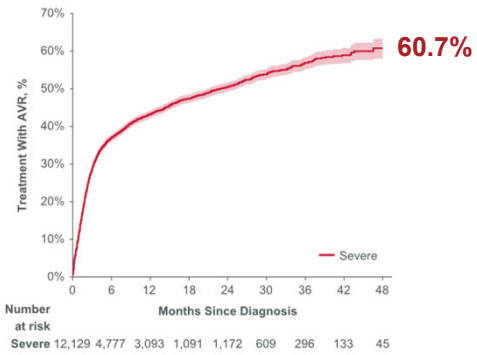
Treatment gaps persist in patients with severe aortic stenosis (AS)[1]

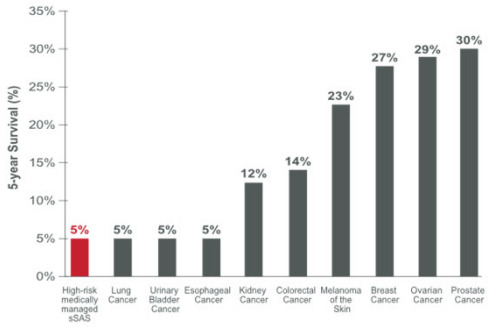
Large contemporary database demonstrates ~40% of patients with severe aortic stenosis remain untreated at 4 years[1]

Treatment Rate by AS Severity[1]



Prognosis of untreated symptomatic severe AS is worse than several metastatic cancers[2,3]

Five-year Survival in Patients with High-Risk sSAS or Metastatic Cancers[2,3]



1. Généreux P, et al. The mortality burden of untreated aortic stenosis. J Am Coll Cardiol. 2023;20:S0735-1097(23)07504-6. 2. Siegel RL, Miller KD, Jemal A (2019) Cancer statistics, 2019. CA Cancer J Clin 69 (1): 7-34. 3. Clark MA, Arnold SV, Duhay FG, Thompson AK, Keyes MJ et al. (2012) Five-year Clinical and Economic Outcomes Among Patients With Medically Managed Severe Aortic Stenosis. Circ Cardiovasc Qual Outcomes 5 (5): 697-704.

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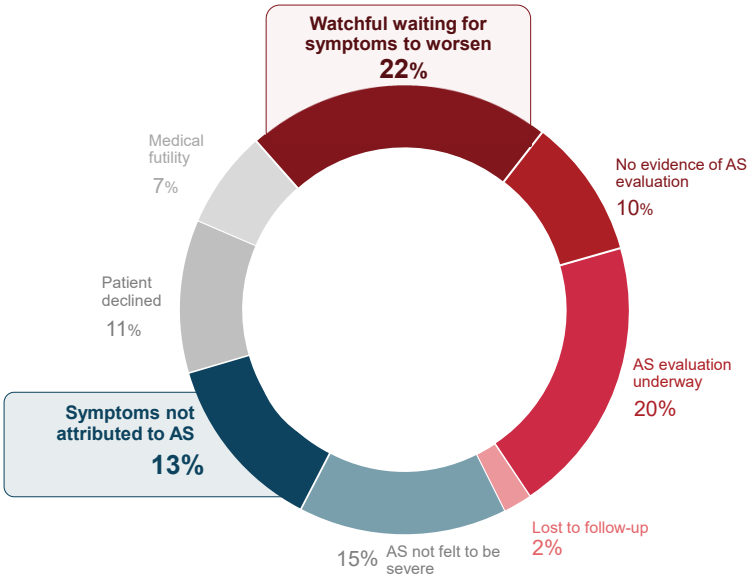
Symptom-related factors are a leading cause of undertreatment[1]



1. Flannery L, Etiwy M, Camacho A, et al. Patient- and Process-Related Contributors to the Underuse of Aortic Valve Replacement and Subsequent Mortality in Ambulatory Patients With Severe Aortic Stenosis. J Am Heart Assoc. 2022;11(11):e025065.

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Severe Aortic Stenosis with no Symptoms: Is it bad?

6

The current state of affairs: two opposing viewpoints for treatment of asymptomatic patients [1,2]

VIEWPOINT Feb 12, 2025

Aortic Valve Replacement for Asymptomatic Severe Aortic Stenosis—The Time Has Come

Brian R. Lindman, MD, MSc; Eugene Braunwald, MD; Patricia A. Pellikka, MD

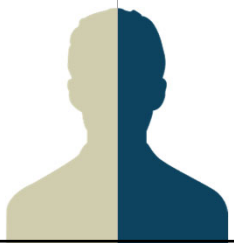
"We believe that the time has come to recommend AVR for asymptomatic patients with severe AS…
It is time to act."

VIEWPOINT March 26, 2025

Aortic Valve Intervention for Asymptomatic Aortic Stenosis

Rick A. Nishimura, MD; Patrick T. O'Gara, MD; Robert O. Bonow, MD

"It may not be time
for routine valve intervention in all patients with asymptomatic severe AS"

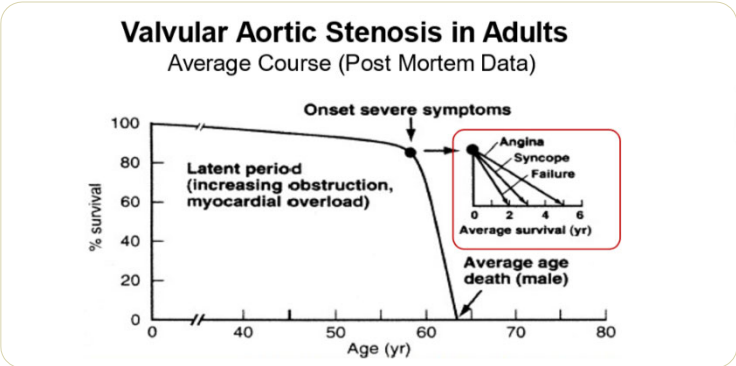


1. Lindman BR, Braunwald E, Pellikka PA. Aortic valve replacement for asymptomatic severe aortic stenosis-the time has come. JAMA Cardiol. 2025.
2. Nishimura RA, O'Gara PT, Bonow RO, Aortic valve intervention for asymptomatic aortic stenosis JAMA Cardiol. 2025.

7

In 1968, the Braunwald Curve was Established – an Illustration that has Defined the Treatment Paradigm for 50+ Years

Ross and Braunwald. Circulation, 1968.



Average age of subjects*:

48 years

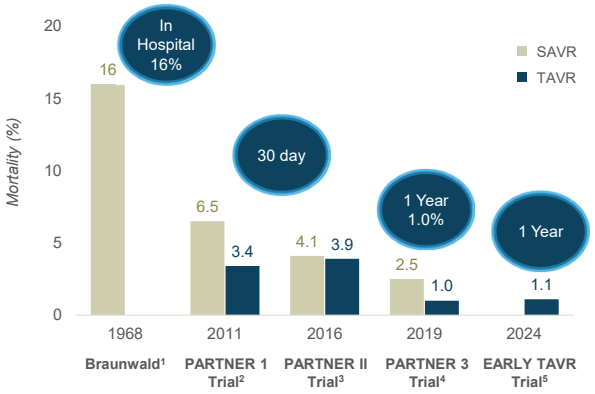
- Many congenitally bicuspid patients
- Data included postmortem studies
- Pre-dates widespread use of echo
- > 80% of deceased patients had symptoms for < 4 years

*Age of time of clinical presentation
1. Ross J Jr, Braunwald E. Aortic stenosis. Circulation.1968;38(1 Suppl):61–67.

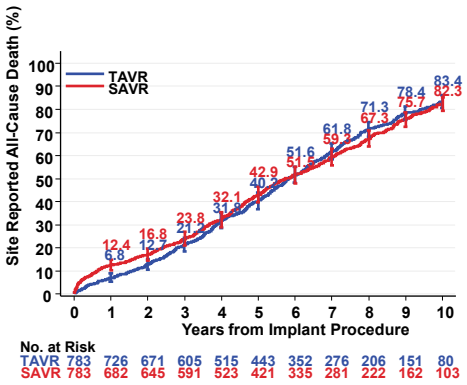
8

The Risk of AVR Has Significantly Reduced Since the Braunwald Curve was Established in 1968 and the TAVR Therapy has been Studied Out to 10 Years

The Braunwald curve was established during the earliest days of AVR, **when the risks of the procedure far outweighed the disease**



All-Cause Mortality in Intermediate Risk Patients with Propensity Score matching from the PARTNER II Trial*[6]



*with Vital Status Check

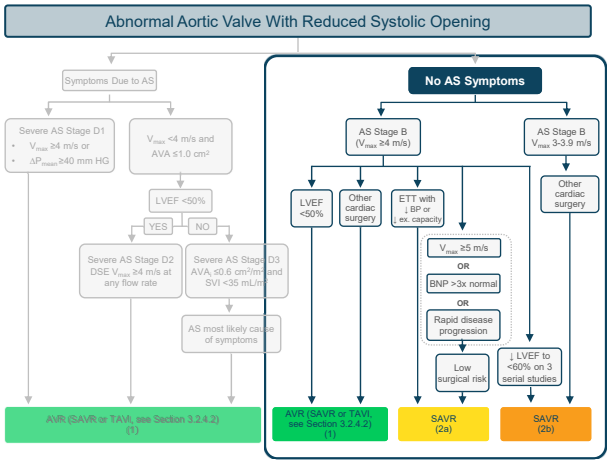
1. Ross J Jr, Braunwald E. Aortic stenosis. Circulation.1968;38(1 Suppl):61–67. 2. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011;364(23):2187-2198 3. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med. 2016;374(17):1609-1620 4. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med 2019;380(18):1695-1705 5. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227. 6. Nazif, T. Can we solve the durability issues? Insights into new valve designs. Presented at New York Valves 2025. New York, NY.

9

ACC/AHA 2020 Guidelines – What do they currently say?[1]

WHAT DOES THE TREATMENT LOOK LIKE:

Guidelines currently recommend treatment in some asymptomatic patients



WHAT DOES THE MANAGEMENT LOOK LIKE:

Guidelines currently have a class 1 recommendation for severe AS patients to be evaluated by the heart team

2.6. The Multidisciplinary Heart Valve Team and Heart Valve Centers

Recommendations for the Multidisciplinary Heart Valve Team and Heart Valve Centers

COR	LOE	Recommendations
1	C-EO	**1. Patients with severe VHD should be evaluated by a Multidisciplinary Heart Valve Team (MDT) when intervention is considered**
2a	C-LD	2. Consultation with or referral to a Primary or Comprehensive Heart Valve Center is reasonable when treatment options are being discussed for 1) asymptomatic patients with severe VHD, 2) patients who may benefit from valve repair versus valve replacement, or 3) patients with multiple comorbidities for whom valve intervention is considered [1-19]

1. Otto, et al. 2020 AHA/ACC Valvular Heart Disease Guidelines. Circ 2021;143:e72-e227.

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20+ years of evidence investigating progression and treatment of asymptomatic severe aortic stenosis

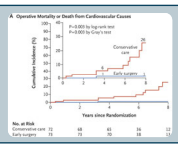
Prospective Study of Asymptomatic Valvular Aortic Stenosis demonstrates increased mortality among some patients with asymptomatic severe AS[1]

Early AVR in asymptomatic SAS compared to no AVR demonstrated **survival of 70% vs 33% at 10 years**[3]

Initial AVR vs conservative strategies in patients with asymptomatic severe AS showed morality of **15.4% vs 26.4%** through 5 years[5]

Impact of valve replacement on long-term survival demonstrated early AVR significantly reduced yearly mortality vs medical management (2.4% vs 9.1% per year)[7]

RECOVERY trial: RCT demonstrates lower mortality in patients treated with early surgery[9]

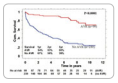


Great debate: all patients with asymptomatic severe aortic stenosis need valve replacement[11]

EVOLVED RCT[13]

RCT Meta-Analysis[14]

1997 2006 2008 2010 2015 2018 2019 2020 2022 2023 2024 2025



Observational analysis demonstrates AVR **dramatically improves survival in asymptomatic SAS.**[2]

Early surgery vs conventional treatment in asymptomatic very severe AS[4]

Asymptomatic Severe AS With Preserved EF Survival: early AVR vs conservative management at 5 yrs (89% vs 63%)[6]

Survival of Severe Asymptomatic AS early AVR vs watchful waiting at 2 years after recommendation (92.5% vs 83.9%)[8]

AVATAR RCT demonstrating improved outcomes with early AVR[10]

EARLY TAVR trial: TAVR RCT[12]

RCT & observational Meta-Analysis[15]

1. Otto CM, Burwash IG, Legget ME, et al. Prospective study of asymptomatic valvular aortic stenosis: clinical, echocardiographic, and exercise predictors of outcome. Circulation. 1997;95(9):2262-70 2. Pai R, et al. Malignant Natural History of Asymptomatic Severe Aortic Stenosis: Benefit of Aortic Valve Replacement. Ann Thorac Surg.. 2006;82(6):2116-2122 3. Brown M, Pellikka P, Schaff H, et al. The benefits of early valve replacement in asymptomatic patients with severe aortic stenosis. J Thorac Cardio Surg. 2008;135(2):308-315 4. Kang D.H., Park S.J, Rim J H, et al. Early surgery versus conventional treatment in asymptomatic very severe aortic stenosis. Circulation. 2010;121(13):1502-9. 5. Taniguchi T, Morimoto T, Shiomi H, et al. Initial Surgical Versus Conservative Strategies in Patients With Asymptomatic Severe Aortic Stenosis. JACC. 2015;66(25):2827–2838. 6. Bohbot Y, Pasquet A, Rusinaru D, et al. Asymptomatic Severe Aortic Stenosis With Preserved Ejection Fraction: Early Surgery Versus Conservative Management. JACC. 2018;72(23):2938-2939. 7. Kim H.J, Kim J.B., Kim H.R., et al. Impact of Valve Replacement on Long-Term Survival in Asymptomatic Patients With Severe Aortic Stenosis. AJC. 2019;123(8): 1321-1328. 8. Campo J, Tsoris A, Kruse J, et al. Prognosis of Severe Asymptomatic Aortic Stenosis With and Without Surgery. Ann Thorac Surg. 2019;108(1):74-79. 9. Kang DH, Park SJ, Lee SA, et al. Early surgery or conservative care for asymptomatic aortic stenosis. N Engl J Med. 2020;382(2):111–119. 10. Banovic M, Putnik S, Penicka M, et al. Aortic valve replacement vs. conservative treatment in asymptomatic severe aortic stenosis: the AVATAR trial. Circ. 2022;145(9):648-658. 11. Lung B, Pierard L, Magne J, et al. Great debate: all patients with asymptomatic severe aortic stenosis need valve replacement. Eur Heart J. 2023;44(33):3136-3148. 12.Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227. 13. Loganath K, Craig N.J., Everett R.J., et al. Early Intervention in Patients With Asymptomatic Severe Aortic Stenosis and Myocardial Fibrosis: the EVOLVED Randomized Clinical Trial. JAMA. 2025;333(3):213-221. 14. Généreux P, Banovic M, Kang DH, et al. Aortic valve replacement vs clinical surveillance in asymptomatic severe aortic stenosis: a systematic review and meta-analysis. J Am Coll Cardiol. 2025;85(9):912-922. 15. Généreux P, Banovic M, Kang D.H., A et al. Aortic Valve Replacement in Asymptomatic Severe Aortic Stenosis:A Systematic Review and Meta-Analysis. JSCAI. 2025.

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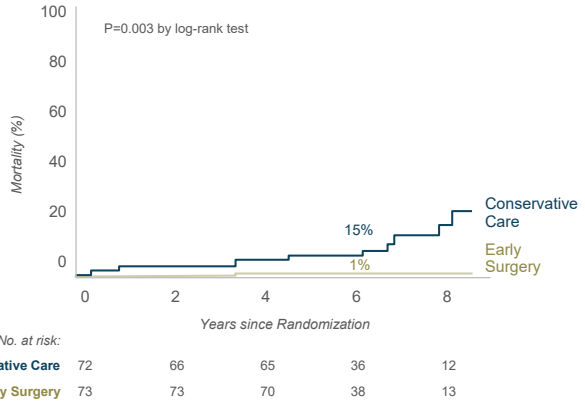
Evidence from SAVR RCTs demonstrate the harm in waiting for an asymptomatic population

RECOVERY Clinical Trial (N = 145)

Operative Mortality or Death from CV Causes in Patients with Asymptomatic SAS[2]



Prompt SAVR **significantly lowered the risk of operative mortality or death** from CV causes compared with conservative care (1% vs 15%) *(median follow-up period of ~6 years).*[1]

1. Kang DH, Park SJ, Lee SA, et al. Early surgery or conservative care for asymptomatic aortic stenosis. N Engl J Med. 2020;382(2):111–119.

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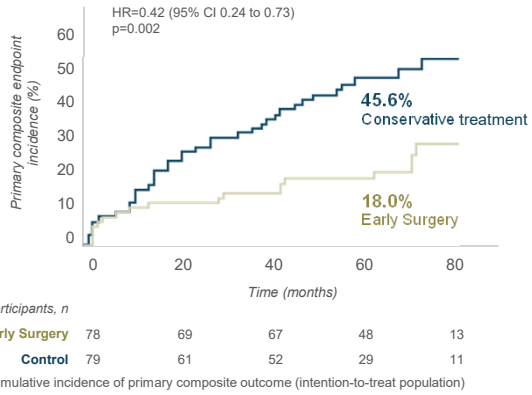
Evidence from SAVR RCTs demonstrate the harm in waiting for an asymptomatic population[1]

AVATAR Clinical Trial (N = 157)

Incidence of All-Cause Mortality or MACE in Patients with Asymptomatic SAS, by Treatment Strategy[3]



Participants, n					
Early Surgery	78	69	67	48	13
Control	79	61	52	29	11

Cumulative incidence of primary composite outcome (intention-to-treat population)

Prompt surgery **significantly reduced all-cause mortality, acute MI, stroke, or HF hospitalization** compared with conservative treatment (18.0% vs 45.6%) *(median follow-up period of 63 months).*[1]

1. Banovic M, Putnik S, Da Costa BR, et al. Aortic valve replacement vs. conservative treatment in asymptomatic severe aortic stenosis: long-term follow-up of the AVATAR trial. Eur Heart J. 2024;45(42):4526–4535.

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EARLY TAVR: The first RCT to study the strategy for treating asymptomatic severe AS with TAVR versus clinical surveillance

1578 "asymptomatic" patients rigorously assessed by protocolized stress test or medical history

901 Patients Confirmed Asymptomatic Randomized 1:1 Across 75 sites

Excluded* from randomization **n=677**

Allocated to early intervention with **TAVR N=455**

Allocated to clinical surveillance **N=446**

Clinical surveillance: adhering to 2020 ACC/AHA guideline recommend treatment timing

Approximately **1 in 6** of patients had unrecognized symptoms with a Class I AVR indication

In real-world practice, this rises to **1 in 3**[3,4]

1. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.
2. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227.
3. Banovic M, Iung B, Putnik S et al. Asymptomatic aortic stenosis: From risk stratification to treatment. Am J Cardiol. 2024; 218: 51–62.
4. Lindman BR, et al. Calcific aortic stenosis. Nat Rev Dis Primers 2016;2:16006. doi: 10.1038/nrdp.2016

THE EARLY TAVR TRIAL

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At the time of randomization, patients had a mean KCCQ score of 92.7, and over 90% confirmed asymptomatic via a negative stress test[1,2]

CHARACTERISTIC	TAVR (N=455)	CS (N=446)	CHARACTERISTIC	TAVR (N=455)	CS (N=446)
Age, y	76.0 ± 6.0	75.6 ± 6.0	Bicuspid valve	8.1%	8.8%
Female sex	28.8%	33.0%	Hx of afib	15.6%	13.2%
BMI, kg/m²	28.4 ± 4.6	28.6 ± 4.8	Pacemaker†	4.6%	2.0%
STS score, %	1.8 ± 1.0	1.7 ± 1.0	Prior MI	5.1%	4.0%
Low-risk per Heart team	83.5%	83.9%	Prior stroke	4.2%	4.5%
Asymptomatic Criteria			CAD	29.2%	25.3%
Treadmill stress test	90.3%	90.8%	PVD	7.3%	4.7%
Clinical history only	9.7%	9.2%	HTN	81.1%	81.8%
KCCQ Score	92.7 ± 8.7	92.7 ± 9.4	Diabetes	26.2%	25.6%
NT-proBNP, pg/mL	276 (139, 599)	297 (148, 608)	eGFR <45 mL/min/ 1.73 m²	6.8%	4.5%

CHARACTERISTIC	TAVR (N=455)	CS (N=446)
AVA, cm²	0.9 ± 0.2	0.8 ± 0.2
Peak velocity, m/s	4.3 ± 0.5	4.4 ± 0.4
Mean gradient, mmHg	46.5 ± 10.1	47.3 ± 10.6
LVEF, %	67.4 ± 6.5	67.4 ± 6.7
LV diastolic dysfunction ≥ Grade II	42.7%	37.3%

*Unable to take the stress test for orthopedic and/or neurologic reasons
1. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.
2. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227.

THE EARLY TAVR TRIAL

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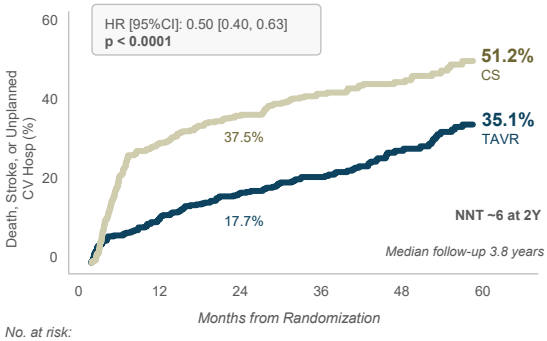
In this trial, prompt intervention was found to be superior to guideline-recommended clinical surveillance for the primary endpoint[1,2]

Primary Endpoint

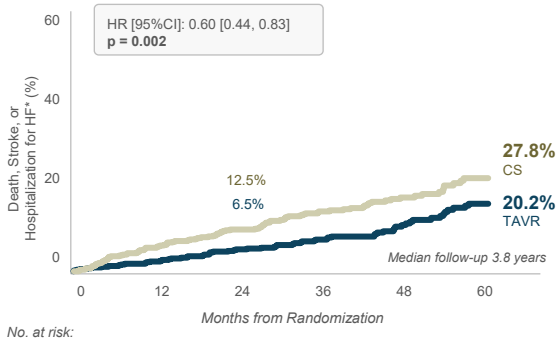


No. at risk:

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

Event rates are Kaplan-Meier estimate
Patients had a minimum follow-up of 2 years

Death, Stroke, or HF Hospitalization*



No. at risk:

TAVR	455	431	412	331	175	128
CS	446	410	376	268	163	77

**Hosp for symptomatic CHF treated with IV diuresis, inotropic therapy, IABP, ventilation for pulmonary edema, or hemodialysis for vol. overload*

*Includes any unplanned cardiovascular hospitalization and any aortic valve intervention or reintervention within 6 months
1. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.
2. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227.

THE EARLY TAVR TRIAL

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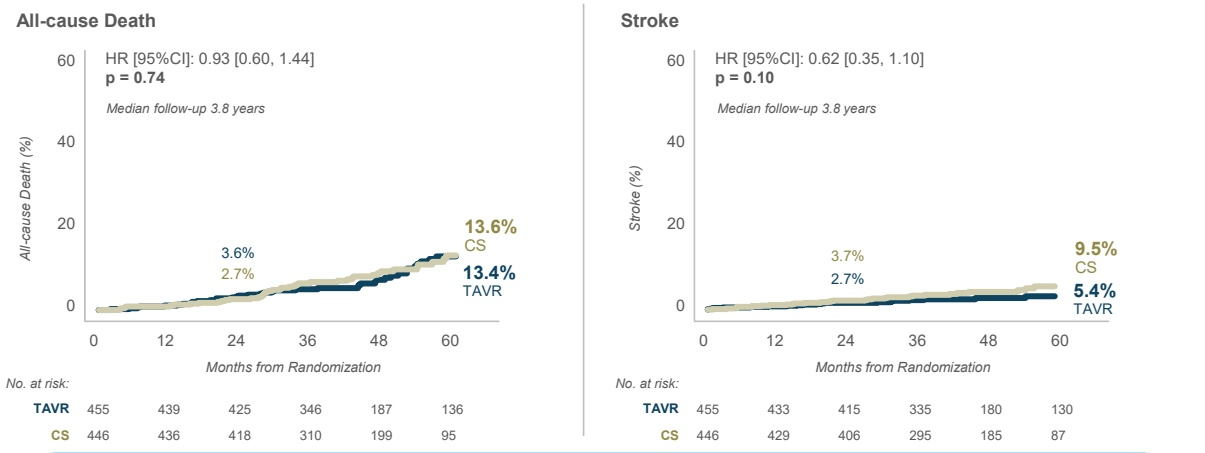
All-cause death and stroke outcomes[1,2]



NO additional mortality or stroke was noted with prompt intervention

Event rates are Kaplan-Meier estimate, Patients had a minimum follow-up of 2 years

1. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.
2. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227.

THE EARLY TAVR TRIAL

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Patients in the guideline-recommended clinical surveillance arm were categorized on symptom onset[1,2]

Patients classified based on acuity and severity of signs/symptoms[1,2]

ASYMPTOMATIC

Patients who may have converted to AVR because they required additional medical procedures and/or had worsened symptoms that were not yet progressive or acute

PROGRESSIVE VALVE SYNDROME

NYHA II

- Dyspnea
- Angina
- Fatigue
- Dizziness

Increase in HF rx from baseline

≥ 1.5- to < 3-fold increase in NT-proBNP from baseline and age-specific threshold*

ACUTE VALVE SYNDROME

NYHA III/VI

- Dyspnea
- Angina
- Fatigue
- Dizziness

Syncope

Atrial fibrillation

Ventricular arrhythmia

Resuscitated sudden death/cardiac arrest

Hospitalization for HF and/or pulmonary edema

LVEF drops to < 50%

≥ 3-fold increase in NT-proBNP from baseline and age-specific threshold*

Under the clinical surveillance protocol, patients were scheduled to be evaluated one year after randomization.

Any patients who developed symptoms within that year were evaluated by their physician and a clinical review board[2]

*For progressive [signs and symptoms], 187.5 pg/ml for patients ≤75 years and 675 pg/ml for > 75 years. For advanced [signs and symptoms], 375 pg/ml for patients ≤75 years and 1350 pg/ml for > 75 years

1. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.
2. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227.

THE EARLY TAVR TRIAL

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AVR outcomes in the clinical surveillance arm are not generalizable to the real world with an expedited time to treatment of 32 days

Early TAVR[1]
Median times

Clinical Surveillance[1]
Median times

In the Real-World, Time to Treatment is Longer[2]

1. Généreux, P et al. Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis, NEJM 2025; 392(3);217-227 2. The Impact of Pre-Procedural Requirements on Time to Aortic Valve Replacement (AVR): Transcatheter AVR vs Surgical AVR. Presented by Curtiss Stinis, TCT 2024.

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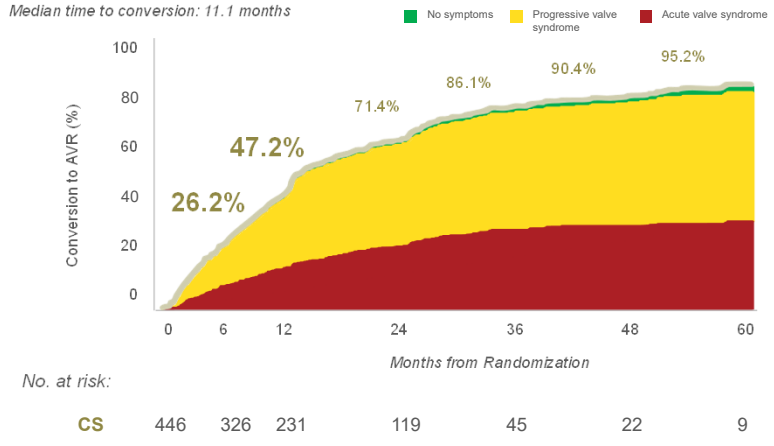
Conversion to a class I indication for AVR was rapid. 25% of patients required AVR within 6 months due to symptom onset.[1]

Conversion to AVR in CS
Median time to conversion: 11.1 months



No. at risk:

CS	446	326	231	119	45	22	9

~40% of patients presented with advanced signs or symptoms[1,2]

1. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227.
2. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.

THE EARLY TAVR TRIAL

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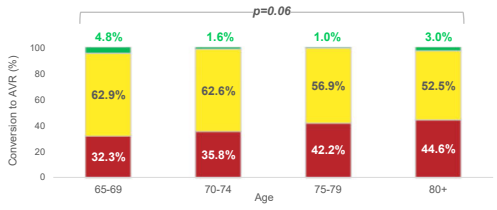
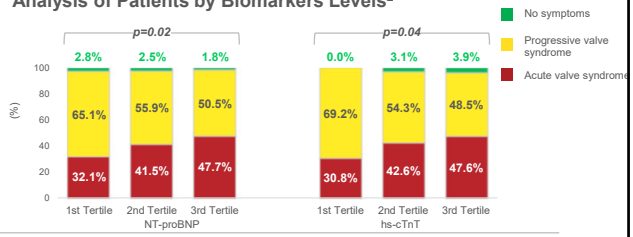
There is no clinical, reliable way to predict which patients will present with acute valve syndrome[1-4]

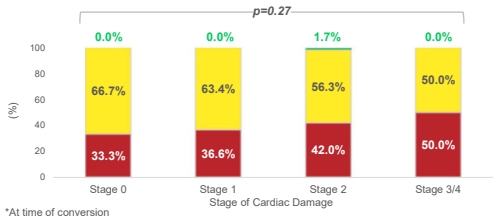
Analysis of Patients by Age[1]



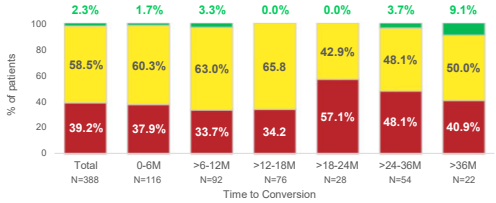
Analysis of Patients by Biomarkers Levels[2]



Analysis of Patients by Stages of Cardiac Damage*[3]



Analysis of Patients by Time to Conversion[4]



*At time of conversion

1. Impact of Age on Timing and Outcomes for Asymptomatic Severe Aortic Stenosis: Results from the EARLY TAVR Trial. Presented by P Généreux, SCAI 2025. 2.Cardiac Biomarkers in Patients with Asymptomatic Severe Aortic Stenosis: Biomarker Analysis from the EARLY TAVR Trial. Presented by B Lindman, ACC 2025. 3. Incidence, Evolution and Impact of Cardiac Damage in Asymptomatic Severe Aortic Stenosis: Results from the EARLY TAVR trial . Presented by P Généreux, EuroPCR 2025. 4. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024

THE EARLY TAVR TRIAL

21

EARLY TAVR trial case studies highlight the sudden and severe onset of symptoms

At randomization:

85 y/o female	STS: **3.50** NYHA Class: **I** KCCQ: **98.6** EF: **50%**	2 MONTHS	Dyspnea, Hospitalization for acute HF, EF:30-35% BAV performed – symptoms persisted	76 days
76 y/o female	STS: **0.89** NYHA Class: **I** KCCQ: **97.9** EF: **65%**	19 DAYS 79 DAYS	Syncope Syncope & VT arrest, EF:55%	84 days
82 y/o male	STS: **1.40** NYHA Class: **I** KCCQ: **95.8** EF: **55%**	309 DAYS	Progressive fatigue, hospitalization, global hypokinesis, KCCQ: 62.5, EF 44%	332 days
79 y/o male	STS: **3.00** NYHA Class: **I** KCCQ: **74.5**	79 DAYS	Syncope, Sudden cardiac arrest, CV death	✖

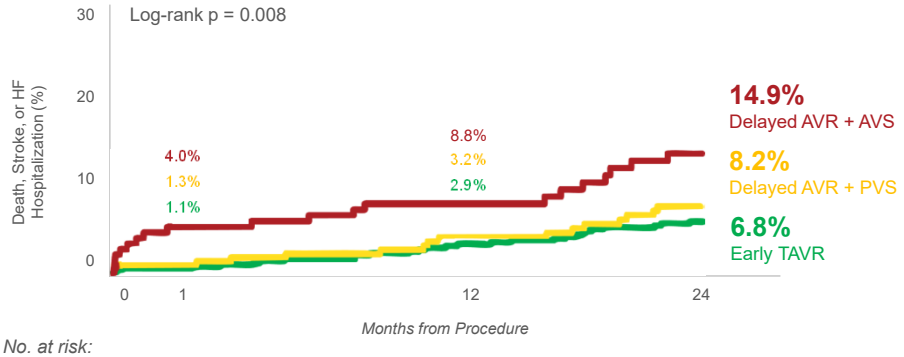
Minor changes to patient demographic details have been made to ensure patients confidentiality is maintained

THE EARLY TAVR TRIAL

22

Acute Valve Syndrome was associated with a higher rate of death, stroke or HF hospitalization[1]

Death, Stroke, or HF Hospitalization*



No. at risk:				
Early TAVR	444	439	430	409
Delayed AVR + PVS	227	222	207	175
Delayed AVR + AVS	152	144	125	96

Acute valve syndrome is associated with an increased risk of death, stroke or heart failure hospitalization after AVR[1]

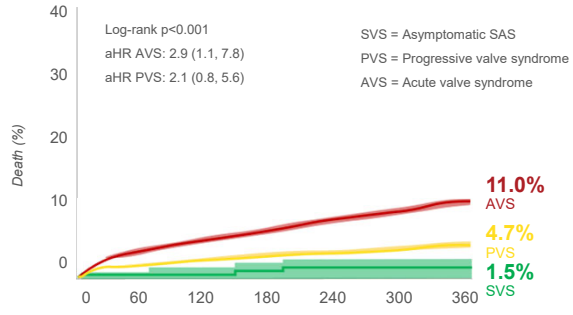
*Hosp for symptomatic CHF treated with IV diuresis, inotropic therapy, IABP, ventilation for pulmonary edema, or hemodialysis for volume overload
1. Incidence and Impact of Acute Valve Syndrome Before Aortic Valve Replacement: Insights from the EARLY TAVR trial. Presented by P Généreux, ACC 2025.

THE EARLY TAVR TRIAL

23

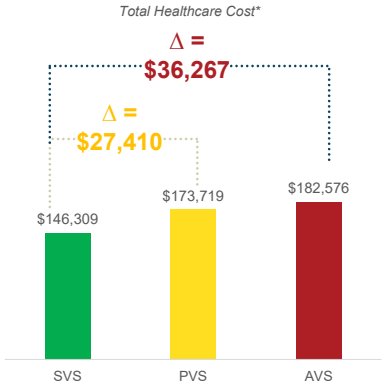
Real-world evidence of over 24,000 patients demonstrate Acute Valve Syndrome is associated with worse clinical outcomes and higher resources costs[1]

Compared to asymptomatic severe AS, patients with acute valve syndrome face a higher mortality rate **(1.5% vs 11.0%)[1]**



No. at risk:							
SVS	269	261	255	251	241	228	220
PVS	10,183	9,808	9,535	9,240	8,977	8,705	8371
AVS	13,572	12,712	12,165	11,641	11,126	10,647	10,084

Treating asymptomatic severe AS with AVR can **save up to $36,000 per patient** through 1 year compared to waiting for symptom onset.[1]



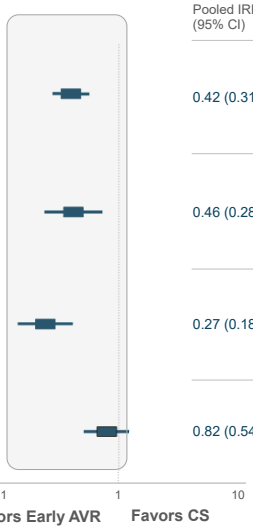
*includes total cost of AVR and up to one year after AVR
1. Acute Valve Syndrome and its Association with Health Care Cost and Resources Utilization During and After Aortic Valve Replacement. Presented by P Généreux, EuroPCR 2025.

THE EARLY TAVR TRIAL

24

Pooled analysis of 5,346 patients across 16 studies shows significantly improved outcomes with prompt intervention versus clinical surveillance

	Early AVR n/N (%)	Clinical Surveillance n/N (%)	Pooled IRR (95% CI)	P-Value
All-cause mortality	297/2273 (13.1%)	871/2718 (32.0%)	0.42 (0.31-0.58)	<0.01
Cardiovascular mortality	88/1333 (6.6%)	197/1341 (14.7%)	0.46 (0.28-0.78)	<0.01
HF hospitalizations	30/1118 (2.7%)	118/1135 (10.4%)	0.27 (0.18-0.41)	<0.01
Stroke	59/1257 (4.7%)	71/1246 (5.7%)	0.82 (0.54-1.24)	0.35



Pooled Incidence Rate Ratio (95% CI)
Log Scale

Patients under clinical surveillance experienced significantly worse outcomes than those with prompt AVR for

ALL-CAUSE MORTALITY
32.0% vs 13.1%, p<0.01

CV MORTALITY
14.7% vs 6.6%, p<0.01

HF HOSPITALIZATION
10.4% vs 2.7%, p<0.01

THE EARLY TAVR TRIAL

1. Généreux P, Banovic M, Kang D.H., A et al. Aortic Valve Replacement in Asymptomatic Severe Aortic Stenosis:A Systematic Review and Meta-Analysis. JSCAI. 2025.

25

Clinical implications from the EARLY TAVR trial

A major reset in the approach to severe asymptomatic management is now recommended:[2]

1. Watchful waiting is **no longer appropriate**[2]
2. Earlier diagnosis and preparation for intervention[2]
3. Educational initiatives across referral networks **are needed**[2]
4. Updated international guidelines **are anticipated**[2]

Given the **benefits observed and the lack of harm, prompt TAVR may be preferred to clinical surveillance in patients with asymptomatic severe AS,** especially when combined with the challenges of timely symptom recognition and prompt treatment in real-world settings[1]

1. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024.
2. The EARLY TAVR Trial Commentary. Presented by B Prendergast, TCT 2024.

THE EARLY TAVR TRIAL

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Updated 2025 ESC Valvular Guidelines

Symptomatic patients with severe aortic stenosis		
Intervention is recommended in symptomatic patients with severe, high-gradient AS [mean gradient ≥40 mmHg, V_{max} ≥4.0 m/s, AVA ≤1.0 cm^2 (or ≤0.6 cm^2/m^2 BSA)].[388,471–474]	I	B
Intervention is recommended in symptomatic patients with low-flow (SVi ≤35 mL/m^2), low-gradient (<40 mmHg) AS with reduced LVEF (<50%) after careful confirmation that AS is severe.[342,345,346,348,475]	I	B
Intervention should be considered in symptomatic patients with low-flow (SVi ≤35 mL/m^2), low-gradient (<40 mmHg) AS with normal LVEF (≥50%) after careful confirmation that AS is severe.[c 293,348,349,476–481]	IIa	B
Asymptomatic patients with severe aortic stenosis		
Intervention is recommended in asymptomatic patients with severe AS and LVEF <50% without another cause.[14,354–359]	I	B
Intervention should be considered in asymptomatic patients (confirmed by a normal exercise test, if feasible) with severe, high-gradient AS and LVEF ≥50% as an alternative to close active surveillance, if the procedural risk is low.[360–363,367,368]	IIa	A
Intervention should be considered in asymptomatic patients with severe AS and LVEF ≥50% if the procedural risk is low and one of the following parameters is present: • Very severe AS (mean gradient ≥60 mmHg or V_{max} >5.0 m/s).[14,362,363,482–484] • Severe valve calcification (ideally assessed by CCT) and V_{max} progression ≥0.3 m/s/year.[303,353,364] • Markedly elevated BNP/NT-proBNP levels (more than three times age- and sex-corrected normal range, confirmed on repeated measurement without other explanation).[97,365] • LVEF <55% without another cause.[14,354,356–359]	IIa	B
Intervention should be considered in asymptomatic patients with severe AS and a sustained fall in BP (>20 mmHg) during exercise testing.	IIa	C

Fabien Praz et al. EHJ 2025

27

Aortic Stenosis Management

Life Journey Considerations

- Improved Dx – AI/DL, biomarkers
- Access to care
- Pre-emptive AVR
- Delay CAVD - pharma

UPSTREAM

- Minimalist procedure
- Enhanced technology
- Expanding indications
- Patient preferences (SDM)

INDEX AVR

- AV Durability
- Therapy sequencing
- Rx concomitant CV disease
- Adjunctive pharma

DOWNSTREAM

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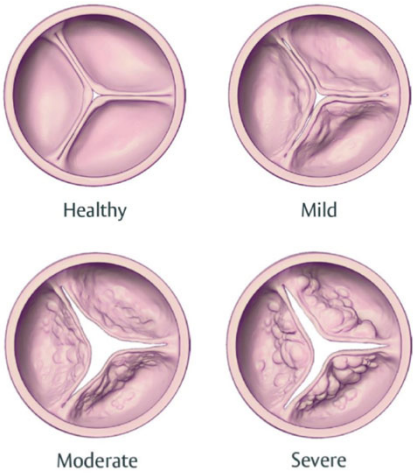
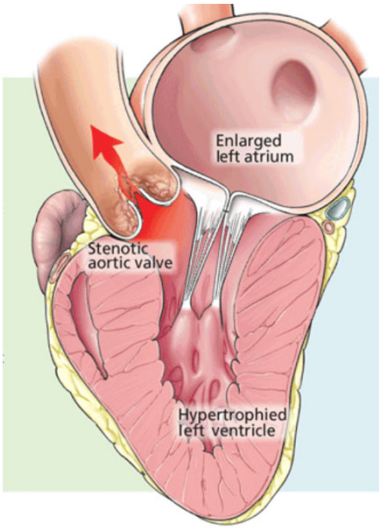
Severity of Aortic Stenosis

Valve criteria

Dogma: AVA <1cm² or PV ≥4m/s = AVR



Cardiac Consequences?



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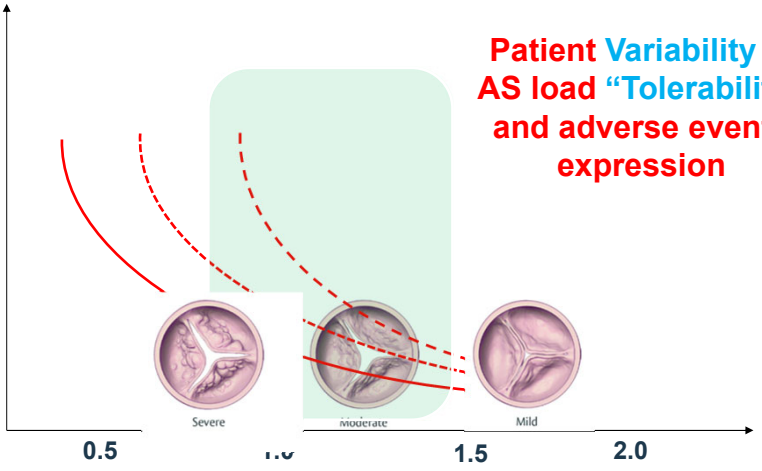
At What Severity of Aortic Stenosis Adverse Cardiac Events Occur?

Adverse Events
-Mortality
-Valve-related symptoms
-Cardiac damage



Patient Variability in AS load "Tolerability" and adverse events expression

Aortic Valve Area (AVA cm²)

30

European Heart Journal (2017) 00, 1–9
doi:10.1093/eurheartj/ehx381

FASTTRACK CLINICAL RESEARCH

Staging classification of aortic stenosis based on the extent of cardiac damage

Philippe Généreux[1,2,3], Philippe Pibarot[4], Björn Redfors[1,5], Michael J. Mack[6], Raj R. Makkar[7], Wael A. Jaber[8], Lars G. Svensson[8], Samir Kapadia[8], E. Murat Tuzcu[8], Vinod H. Thourani[9], Vasilis Babaliaros[9], Howard C. Herrmann[10], Wilson Y. Szeto[10], David J. Cohen[11], Brian R. Lindman[12], Thomas McAndrew[1], Maria C. Alu[13], Pamela S. Douglas[14], Rebecca T. Hahn[1,13], Susheel K. Kodali[1,13], Craig R. Smith[13], D. Craig Miller[15], John G. Webb[16], and Martin B. Leon[1,13]*

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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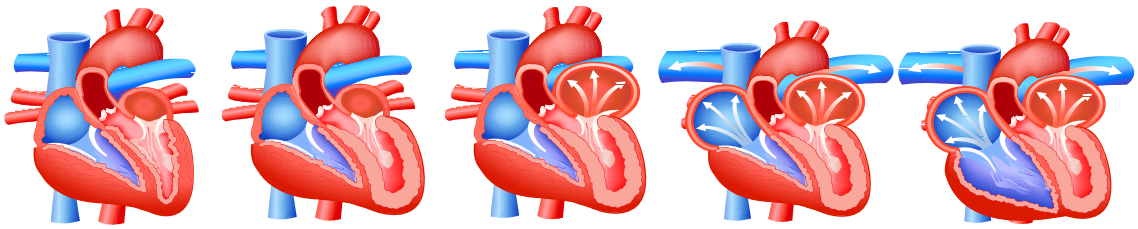
Staging Classification of Patients with AS: Specific Criteria



Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
No damage	LV damage	LA/Mitral damage	PA/Tricuspid damage	RV damage
	Increased LV Mass Index >115 g/m² Male >95 g/m² Female	Indexed left atrial volume >34mL/m²	PASP ≥60mmhg	Moderate-Severe RV dysfunction
	E/e' >14	Moderate-Severe MR	Moderate-Severe TR	
	EF <50%	Atrial Fibrillation		

Patients hierarchically classified based on the presence of at least one variable in the highest stage (independent, not additive)

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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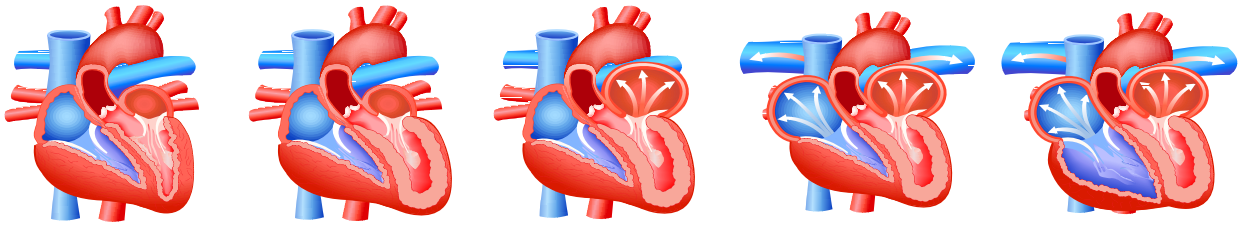
Staging Classification of Patients with AS



Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
N=121 (6.1%)	N=287 (14.5%)	N=1014 (51.4%)	N=412 (20.9%)	N=140 (7.1%)

Total N = 1974 patients

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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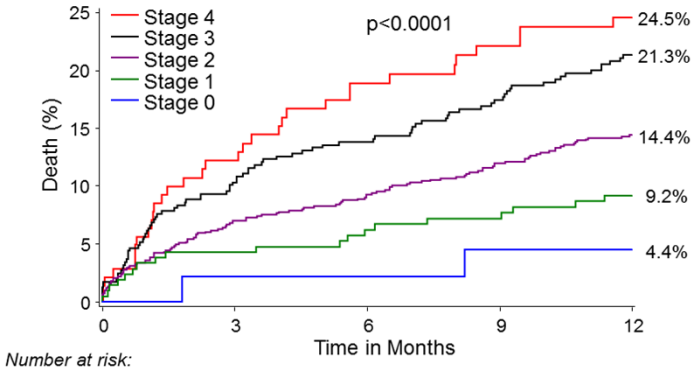
Extent of Cardiac Damage
1-Year Death After AVR; N=1,661 pts.



Number at risk:

Stage 4	145	118	108	96	93
Stage 3	413	360	337	320	303
Stage 2	844	755	720	679	652
Stage 1	212	199	195	186	180
Stage 0	47	45	45	42	42

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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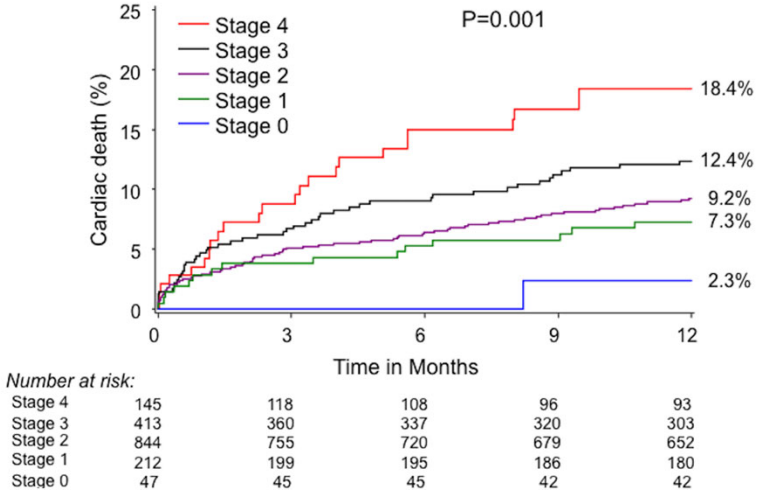
Extent of Cardiac Damage
1-Year Cardiac Death After AVR; N=1,661 pts.



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Stage 1	212	199	195	186	180
Stage 0	47	45	45	42	42

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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Evolution and Prognostic Impact of Cardiac Damage After Aortic Valve Replacement

Philippe Généreux, MD,[a] Philippe Pibarot, DVM, PHD,[b] Björn Redfors, MD, PHD,[c,d,e] Jeroen J. Bax, MD, PHD,[f] Yanglu Zhao, MD, PHD,[g] Raj R. Makkar, MD,[h] Samir Kapadia, MD,[i] Vinod H. Thourani, MD,[j] Michael J. Mack, MD,[k] Tamim M. Nazif, MD,[d] Brian R. Lindman, MD,[l] Vasilis Babaliaros, MD,[m] Flavien Vincent, MD,[c,n] Mark Russo, MD,[o] James M. McCabe, MD,[p] Linda D. Gillam, MD, MPH,[a] Maria C. Alu, MS,[c,d] Rebecca T. Hahn, MD,[c,d] John G. Webb, MD,[q] Martin B. Leon, MD,[c,d] David J. Cohen, MD, MSc[c,r]

JACC

Généreux et al. J Am Coll Cardiol 2022;80:783–800.

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Evolution of Cardiac Damage

1120 patients were alive and had paired TTE assessment at baseline AND 1 year.

Among survivors at 1 year, compared to baseline:

- **15.6% of patients improved at least 1 Stage.**
- **57.9% remained in the same Stage.**
- **26.5% deteriorated at least 1 Stage.**

Independent predictors of Stage deterioration at 1-year:

- **Hypertension (OR 1.73; 95% CI 1.01-2.96; P = 0.044).**
- **Index procedure performed with SAVR (OR 2.04; 95% CI 1.52-2.74; P < 0.0001).**

Généreux et al. J Am Coll Cardiol 2022;80:783–800.

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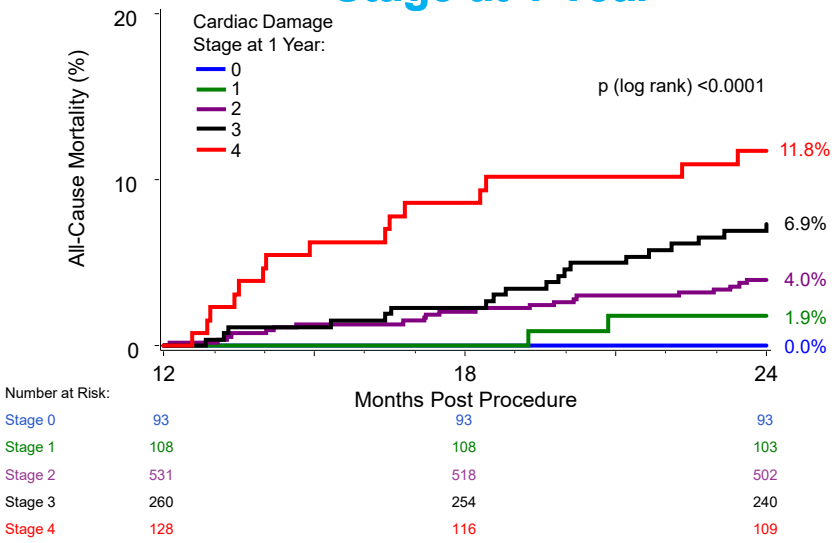
2-Year Mortality Stratified by Cardiac Damage Stage at 1 Year



Généreux et al. J Am Coll Cardiol 2022;80:783–800.

38

Cardiac Damage and Quality of Life After Aortic Valve Replacement in the PARTNER Trials

Philippe Généreux, MD,[a] David J. Cohen, MD, MSc,[b,c] Philippe Pibarot, DVM, PhD,[d] Björn Redfors, MD, PhD,[b,e,f] Jeroen J. Bax, MD, PhD,[g] Yanglu Zhao, MD, PhD,[h] Heather Prince, PhD,[h] Raj R. Makkar, MD,[i] Samir Kapadia, MD,[j] Vinod H. Thourani, MD,[k] Michael J. Mack, MD,[l] Tamim M. Nazif, MD,[e] Brian R. Lindman, MD,[m] Vasilis Babaliaros, MD,[n] Mark Russo, MD,[o] James M. McCabe, MD,[p] Linda D. Gillam, MD, MPH,[a] Maria C. Alu, MS,[b,e] Rebecca T. Hahn, MD,[b,e] John G. Webb, MD,[q] Martin B. Leon, MD,[b,e] Suzanne V. Arnold, MD, MHA[r,s]

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Généreux et al. J Am Coll Cardiol 2023;81:743–752

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KCCQ-OS Score According to Baseline Cardiac Damage

KCCQ-OS Score	Stage 0 (N=121)	Stage 1 (N=287)	Stage 2 (N=1014)	Stage 3 (N=412)	Stage 4 (N=140)	*P* value
Baseline	65.6 ± 21.5	60.6 ± 23.9	58.4 ± 22.7	49.6 ± 23.3	47.0 ± 24.9	<0.0001
1-Year	87.8 ± 13.1	82.0 ± 19.2	80.5 ± 19.1	74.1 ± 21.2	79.1 ± 19.7	<0.0001
Δ at 1-Year	21.8 ± 21.7	20.0 ± 21.9	20.6 ± 21.4	22.7 ± 21.7	28.4 ± 28.4	0.011

values are mean ± SD

Généreux et al. J Am Coll Cardiol 2023;81:743–752

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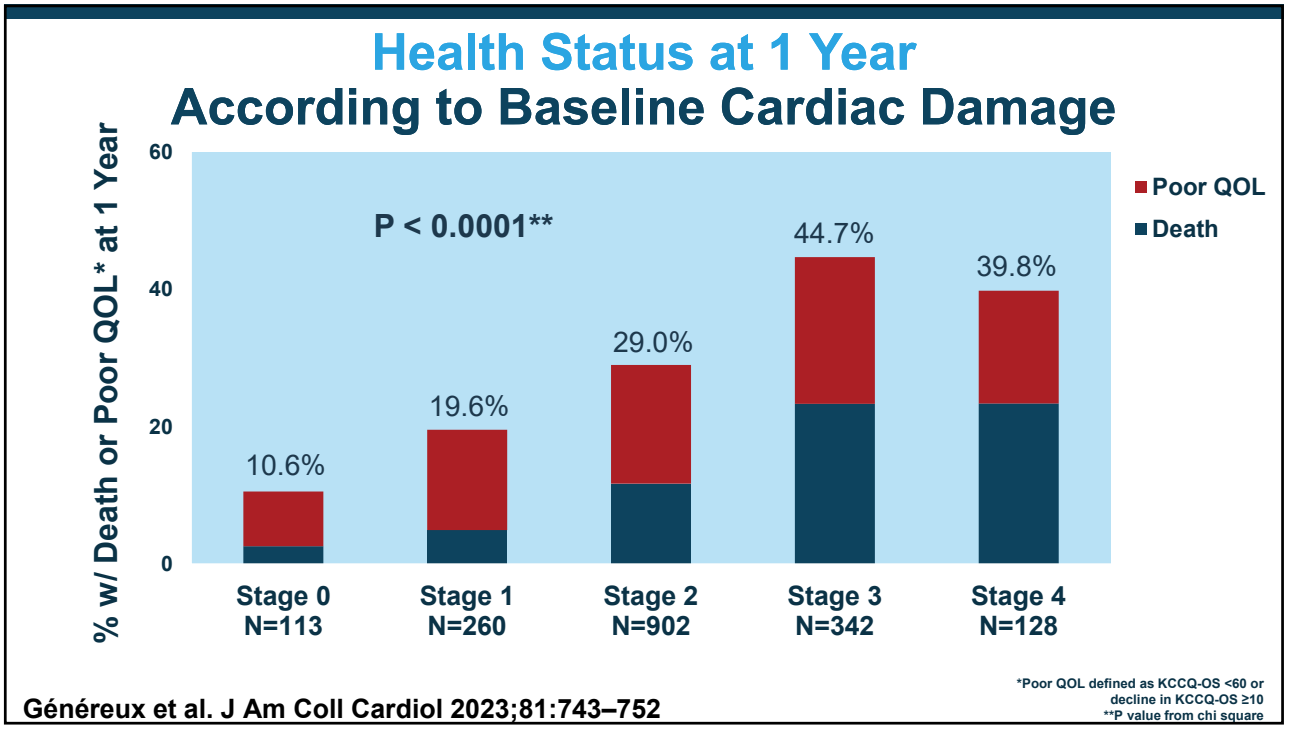
Health Status at 1 Year
According to Baseline Cardiac Damage
% w/ Death or Poor QOL* at 1 Year
60
40
20
0
P < 0.0001**
10.6%
19.6%
29.0%
44.7%
39.8%
Poor QOL
Death
Stage 0 N=113
Stage 1 N=260
Stage 2 N=902
Stage 3 N=342
Stage 4 N=128
*Poor QOL defined as KCCQ-OS <60 or decline in KCCQ-OS ≥10
**P value from chi square
Généreux et al. J Am Coll Cardiol 2023;81:743–752

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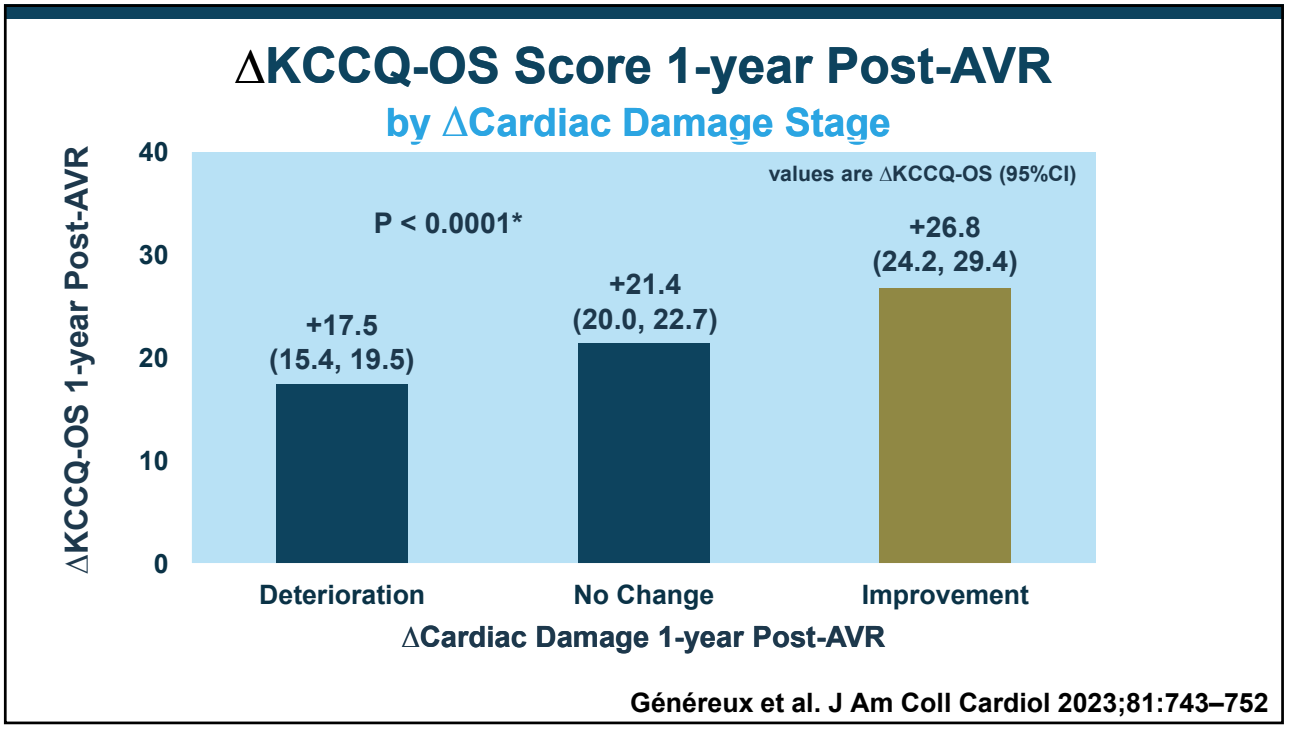
ΔKCCQ-OS Score 1-year Post-AVR
by ΔCardiac Damage Stage
ΔKCCQ-OS 1-year Post-AVR
40
30
20
10
0
values are ΔKCCQ-OS (95%CI)
P < 0.0001*
+17.5 (15.4, 19.5)
+21.4 (20.0, 22.7)
+26.8 (24.2, 29.4)
Deterioration
No Change
Improvement
ΔCardiac Damage 1-year Post-AVR
Généreux et al. J Am Coll Cardiol 2023;81:743–752

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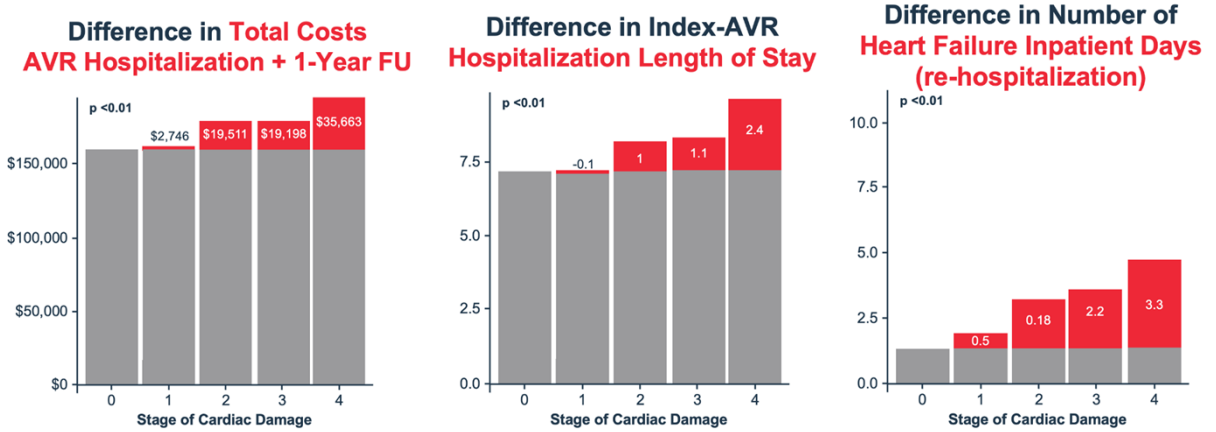
Cost and Health Care Resources Utilization
1-Year post AVR Per Stage of Cardiac Damage



Généreux et al. TCT 2024

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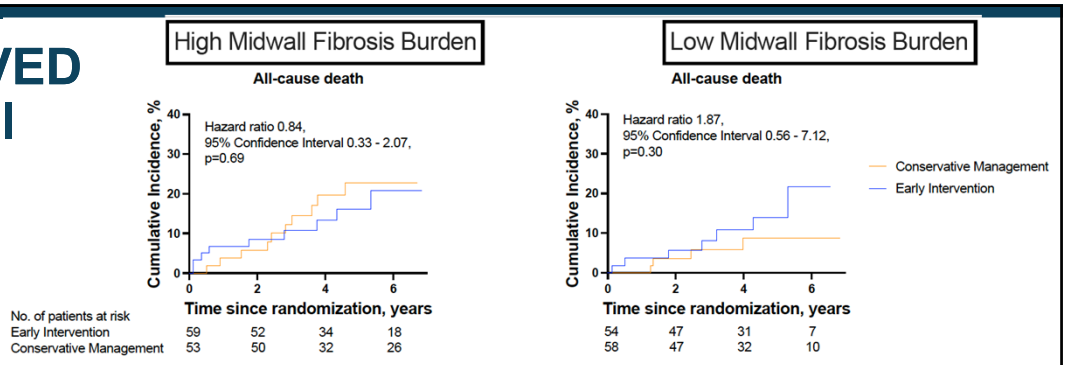
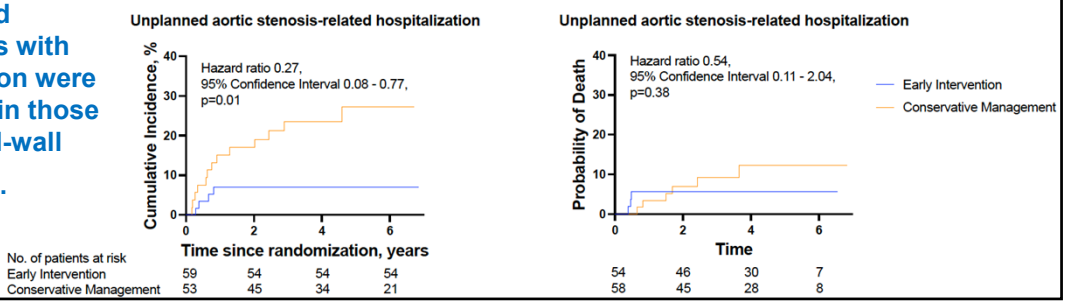
EVOLVED Trial



Reductions in aortic stenosis-related hospitalisations with early intervention were most apparent in those with higher mid-wall fibrosis burden.



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VOL. ■, NO. ■, 2021

NEW RESEARCH PAPER

Prognostic Implications of Associated Cardiac Abnormalities Detected on Echocardiography in Patients With Moderate Aortic Stenosis

Mohammed Rizwan Amanullah, MBBS,[a,*] Stephan Milhorini Pio, MD,[b,*] Arnold C.T. Ng, MBBS, PhD,[c] Kenny Y.K. Sin, MBBS,[d] Nina Ajmone Marsan, MD, PhD,[b] Zee Pin Ding, MBBS,[a] Martin B. Leon, MD,[e] Philippe Généreux, MD,[f] Victoria Delgado, MD, PhD,[b] See Hooi Ewe, MBBS, PhD,[a] Jeroen J. Bax, MD, PhD[b]

Amanullah et al. JACC Imaging 2021

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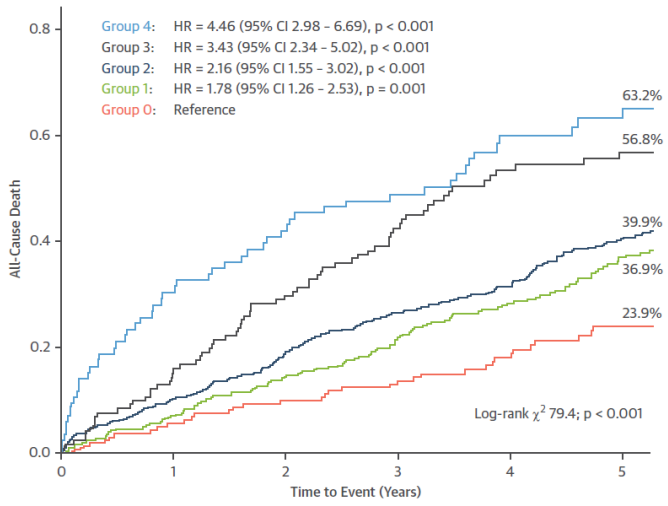
Extent of Cardiac Damage Among Moderate AS
5-Year Death; N=1,245 pts.



Amanullah et al. JACC Imaging 2021

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What is 'at-risk' Moderate AS?

Dimension	Examples of "at-risk" thresholds	Rationale
Symptoms / function	NYHA ≥ II, 6-MWT <300 m	Symptom-limited functional reserve despite only moderate gradients
Systolic pump function	LVEF < 60 % or GLS worse than –16 %	EF declines late; strain picks up earlier contractile loss
Flow & filling pressures	Stroke-volume index <35 mL m², E/e' ≥ 14, PASP > 50 mm Hg	Identify low-flow / diastolic-dysfunction phenotype
Remodelling	LV mass index >115/95 g m², LA volume index >34 mL m²	Maladaptive hypertrophy & LA stretch predict HF
Valve calcification	CT calcium above sex-specific severe cut-offs	Surrogate for rapid haemodynamic progression
Biomarkers / rhythm	NT-proBNP ≥ 600 pg mL⁻¹, recent AF, high-sensitivity troponin	Reflect wall stress, fibrosis and atrial myopathy
Clinical HF burden	≥1 HF hospitalization in prior year	Signals imminent decompensation

Khan KR, et al. J Am Coll Cardiol. 2023;81(13):1235-1244
Lee HJ, et al. JACC Cardiovasc Imaging. 2025;18(2):180-191
Zhu D, et al. Circ Cardiovasc Imaging. 2020;13(4):e009958
Truong VT, et al. Korean Circ J. 2022;52(12):878-886

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JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 2, 2023
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EDITORIAL COMMENT

Staging the Extent of Cardiac Damage Among Patients With Valve Disease

Growth of Evidence Continues*

Philippe Généreux, MD

>32 manuscripts
>37,000 patients
validating the concept of Staging of Cardiac Damage

TABLE 1 Staging of Cardiac Damage in Valve Disease and Other Cardiovascular Pathology: Currently Published Evidence

First Author, Year	N	Study Population	Modality Used to Characterize Cardiac Damage
Aortic stenosis			
Genereux et al,[1] 2017	1,661	Severe symptomatic AS undergoing TAVR or SAVR	TTE
Fukui et al,[2] 2019	689	Severe symptomatic AS undergoing TAVR	TTE
Vollema et al,[3] 2019	1,189	Severe symptomatic AS	TTE
Tastet et al,[4] 2019	735	Moderate-severe asymptomatic AS	TTE
Berkovitch et al,[5] 2020	2,608	Severe symptomatic AS undergoing TAVR	TTE
Maeder et al,[6] 2020	421	Severe AS with complete invasive hemodynamics obtained before AVR	Invasive hemodynamic assessment
Baz et al,[7] 2020	94	Severe AS undergoing TAVR	TTE and biomarkers
Vollema et al,[8] 2020	616	Severe symptomatic AS with available LV GLS	TTE
Lloyd et al,[9] 2021	44	Severe AS patients referred for TAVR with biomarkers assessment	TTE and biomarkers
Park et al,[10] 2021	145	Severe asymptomatic AS randomized to SAVR vs clinical surveillance	TTE
Schewel et al,[11] 2021	1,400	Severe symptomatic AS with invasive hemodynamic assessment before TAVR	Invasive hemodynamic assessment
Okuno et al,[12] 2021	1,133	Severe AS undergoing TAVR	TTE
Amanullah et al,[13] 2021	1,245	Moderate AS	TTE
Snir et al,[14] 2021	12,013	Severe AS	TTE
Okuno et al,[15] 2021	1,156	Severe AS undergoing TAVR	TTE
Avvedimento et al,[16] 2021	262	Severe AS undergoing TAVR	TTE before and 30-day post-TAVR
Baz et al,[17] 2021	224	Severe symptomatic AS undergoing TAVR	TTE
Zhu et al,[18] 2022	427	Severe AS undergoing TAVR	TTE
Hirasawa et al,[19] 2022	405	Severe AS undergoing TAVR	Computed tomography
Shamekhi et al,[20] 2022	933	Severe AS undergoing TAVR	TTE
Gutiérrez et al,[21] 2022	496	Severe AS undergoing TAVR	TTE
Genereux et al,[22] 2022	1,974	Severe symptomatic AS undergoing TAVR or SAVR	TTE before and 1-year post-TAVR
Aortic regurgitation			
Silva et al,[23] 2022	571	Moderate-severe aortic regurgitation	TTE
Mitral regurgitation			
Bernard et al,[24] 2022	338	Asymptomatic primary MR	TTE
Singh et al,[25] 2022	325	Secondary MR	TTE
Cavalcante et al,[26] 2022	387	Secondary MR	TTE
Shamekhi et al,[27] 2022	929	Patients undergoing TEER	TTE
Van Wijngaarden et al,[28] 2022	1,106	Severe primary MR undergoing surgery	TTE
Tricuspid regurgitation			
Dietz et al,[29] 2020	1,311	Significant TR	TTE
Galloo et al,[30] 2022	278	Significant TR undergoing surgery	TTE
Hypertension			
Seko et al,[31] 2019	1,639	Patients with hypertension	TTE
Heart failure			
Stassen et al,[32] 2022	844	Patients with heart failure undergoing CRT placement	TTE

AS = aortic stenosis; CRT = cardiac resynchronization therapy; GLS = global longitudinal strain; LV = left ventricular; MR = mitral regurgitation; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement; TEER = transcatheter edge-to-edge repair; TR = tricuspid regurgitation; TTE = transthoracic echocardiography.

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AS Severity Grading and Cardiac Staging

Grade or Stage	Stage 0 None	Stage 1 LV	Stage 2 LA-mitral	Stage 3 PA-tricuspid	Stage 4 RV
Grade 0 V_{max} <2m/s					
Grade 1 V_{max} 2-2.9m/s					
Grade 2 V_{max} 3-3.9m/s					
Grade 3 V_{max} ≥.4m/s					

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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AS Severity Grading and Cardiac Staging

Grade or Stage	Stage 0 None	Stage 1 LV	Stage 2 LA-mitral	Stage 3 PA-tricuspid	Stage 4 RV
Grade 0 V_{max} <2m/s					
Grade 1 V_{max} 2-2.9m/s					
Grade 2 V_{max} 3-3.9m/s	PROGRESS	PROGRESS EXPAND II TAVR-UNLOAD	PROGRESS EXPAND II TAVR-UNLOAD	PROGRESS EXPAND II TAVR-UNLOAD	PROGRESS EXPAND II TAVR-UNLOAD
Grade 3 V_{max} ≥.4m/s	EARLY TAVR	AVR	AVR	AVR	AVR

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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AS Severity Grading and Cardiac Staging

Grade or Stage	Stage 0 None	Stage 1 LV	Stage 2 LA-mitral	Stage 3 PA-tricuspid	Stage 4 RV
Grade 0 V_{max} <2m/s	Medical Rx				
Grade 1 V_{max} 2-2.9m/s					
Grade 2 V_{max} 3-3.9m/s	PROGRESS	PROGRESS EXPAND II TAVR-UNLOAD	PROGRESS EXPAND II TAVR-UNLOAD	PROGRESS EXPAND II TAVR-UNLOAD	PROGRESS EXPAND II TAVR-UNLOAD
Grade 3 V_{max} ≥.4m/s	EARLY TAVR	AVR	AVR	AVR	AVR

Généreux et al. Eur Heart J 2017;38(45):3351-3358

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Conclusion from multiple robust bodies of evidence

1. A robust body of evidence demonstrates **significant patient benefits for proactive disease management of severe AS**[1-3]

2. **~40% of patients present with acute valve syndrome** which was associated with a higher rate of death, stroke or HF hospitalization[2,3,9]

3. It is **difficult to predict** disease progression and 1 in 3 'asymptomatic' patients are symptomatic[2-8]

Prompt referral for evaluation and work-up of all severe AS patients is recommended to improve patient outcomes.[2,3]

1. Généreux P, Banovic M, Kang D.H., A et al. Aortic Valve Replacement in Asymptomatic Severe Aortic Stenosis: A Systematic Review and Meta-Analysis. JSCAI. 2025. 2. TAVR for Asymptomatic Severe Aortic Stenosis: Results of The EARLY TAVR Trial. Presented by P Généreux, TCT 2024. 3. Généreux P, Schwartz A, Oldemeyer JB, et al. Transcatheter aortic-valve replacement for asymptomatic severe aortic stenosis. N Engl J Med. 2025;392(3):217-227. 4. Cardiac Biomarkers in Patients with Asymptomatic Severe Aortic Stenosis: Biomarker Analysis from the EARLY TAVR Trial. Presented by B Lindman, ACC 2025. 5. Lindman B, Pibarot P, Schwartz A et al. Cardiac Biomarkers in Patients with Asymptomatic Severe Aortic Stenosis: Analysis from the EARLY TAVR Trial. Circ. 2025. 6. Impact of Age on Timing and Outcomes for Asymptomatic Severe Aortic Stenosis: Results from the EARLY TAVR Trial. Presented by P Généreux, SCAI 2025. 7. Banovic M, Iung B, Putnik S et al. Asymptomatic aortic stenosis: From risk stratification to treatment. Am J Cardiol. 2024; 218: 51–62. 8. Lindman BR, et al. Calcific aortic stenosis. Nat Rev Dis Primers 2016;2:16006. doi: 10.1038/nrdp.2016. 9. Incidence and Impact of Acute Valve Syndrome Before Aortic Valve Replacement: Insights from the EARLY TAVR trial. Presented by P Généreux, ACC 2025.

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The Modern Era of TAVR
Treating Aortic Stenosis Earlier

To prevent death

To prevent irreversible symptoms

To prevent irreversible lost of quality of life

To prevent irreversible cardiac damage

Treat/Prevent Cardiac Damage before Symptoms or Another Cardiac Disease Occurs!

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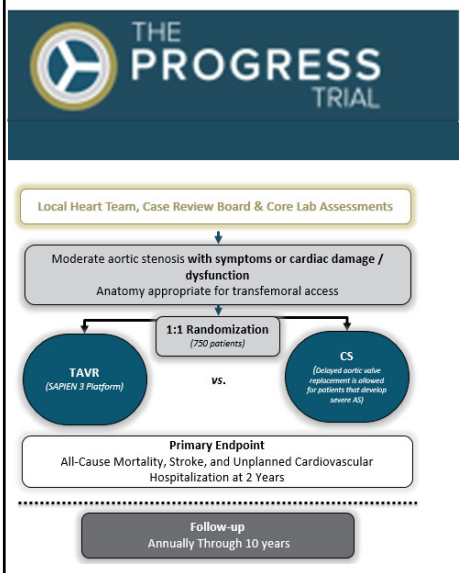
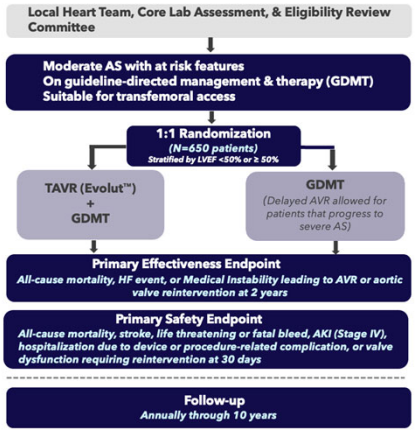
The Future of TAVR – Preventing Cardiac Damage



Evaluate if the benefits of intervention with TAVR before AS becomes severe outweigh the risks of the intervention



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Thank you!

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