El Futuro del Implante Percutáneo de Prótesis Aórtica

The Future of TAVI

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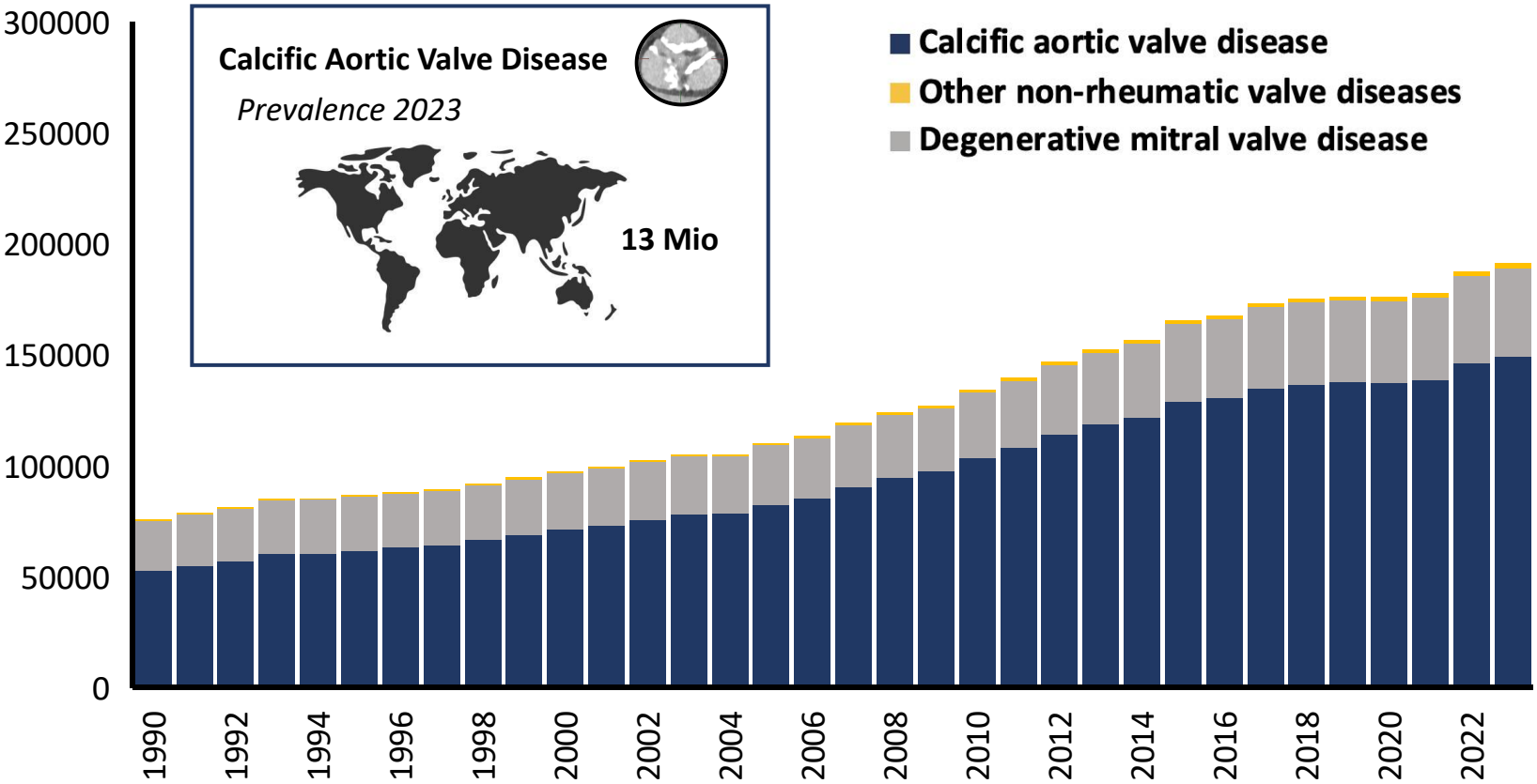
Inselspital, Bern University Hospital

Switzerland

CSC Madrid, November 5 2025

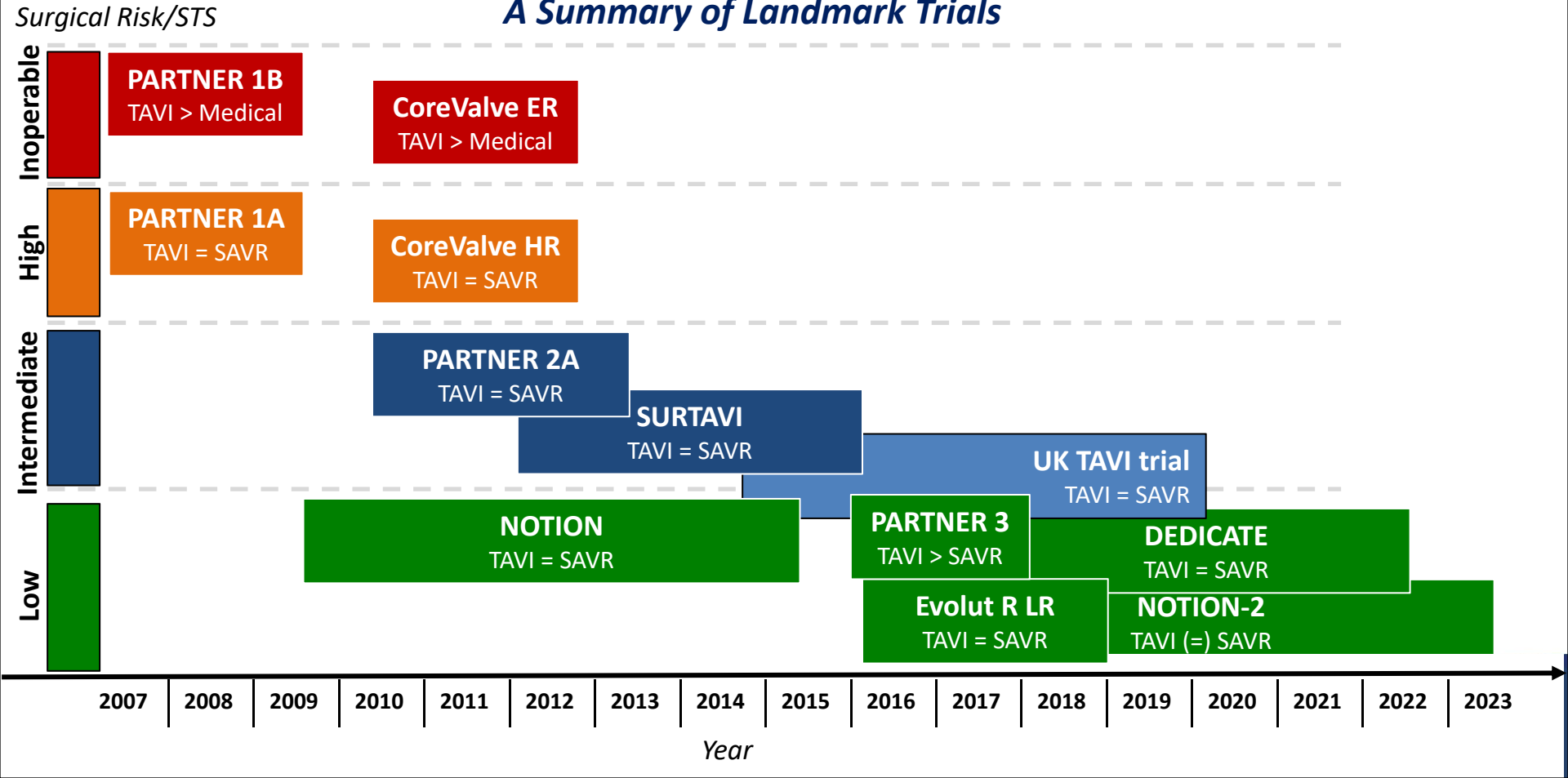
Global Burden of Death from Degenerative Valvular Heart Disease



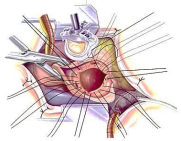
Institute for Health Metrics and Evaluation (IHME). Global Burden of Disease Study (GBD 2023). Available from: http://ghdx.healthdata.org/gbd-results-tool

TAVI - A Paradigm Change in the Treatment of Aortic Stenosis

A Summary of Landmark Trials



Evidence and Guidelines – TAVI vs SAVR



PARTNER 1B (2010) · PARTNER 1A (2011) · CoreValve HR (2014) · PARTNER 2 NOTION (2016) · SURTAVI (2017) · PARTNER 3 Evolut LR (2019) · UK TAVI (2022) · DEDICATE NOTION-2 RHEIA (2024) · 2025

ESC European Society of Cardiology

EACTS European Association For Cardio-Thoracic Surgery

2012 ESC GL

Extreme risk	I	B
High-risk	IIa	B

2017 ESC GL

Extreme risk	I	B
Increased risk	I	B

2021 ESC GL

Age ≥75 years	I	A
Patients according to individual characteristics	I	B

2025 ESC GL

Age ≥70 years	I	A
Asymptomatic AS	IIa	A
Severe bicuspid stenosis at increased surgical risk	IIb	B

American Heart Association.

AMERICAN COLLEGE of CARDIOLOGY

2014 ACC GL

Prohibitive risk	I	B
High-risk	IIa	B

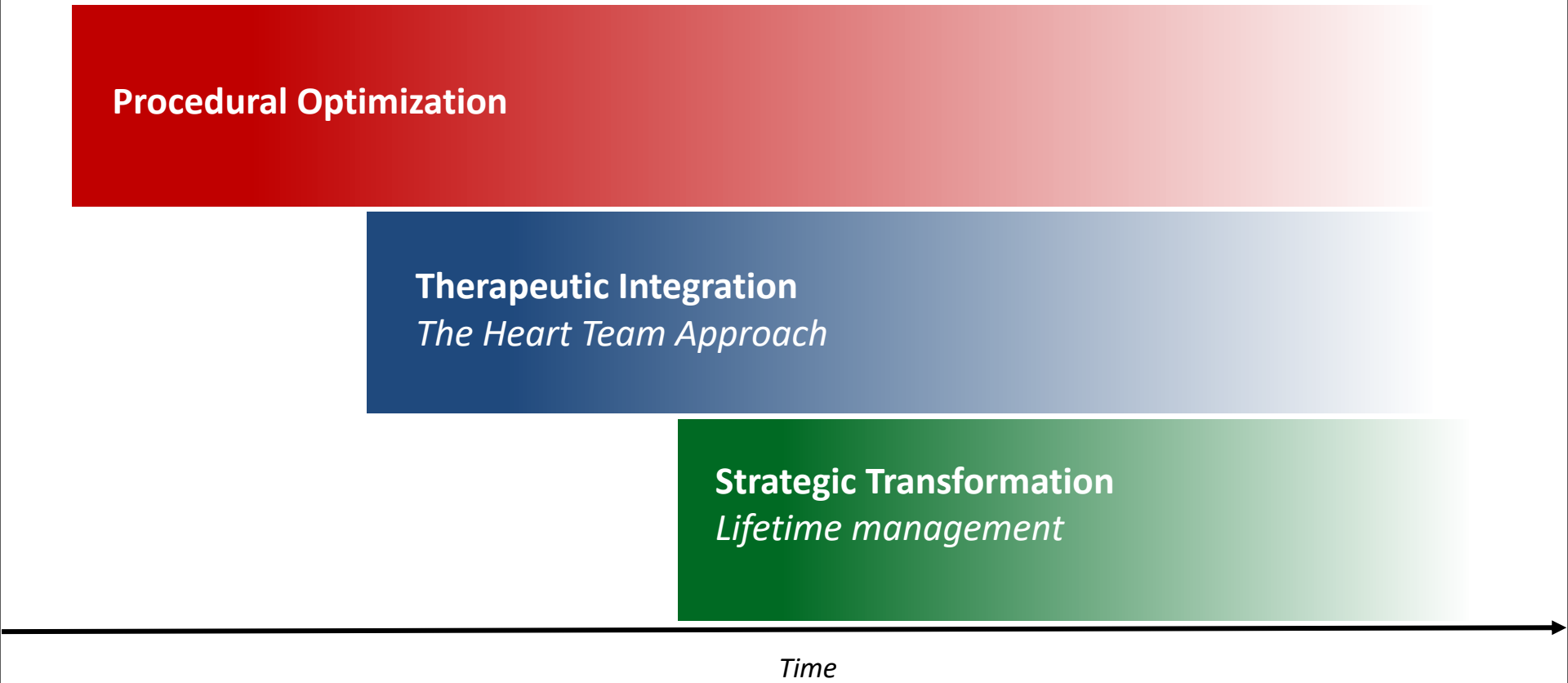
2017 ACC GL

Prohibitive risk	I	A
High risk	I	A
Intermediate risk	IIa	BR

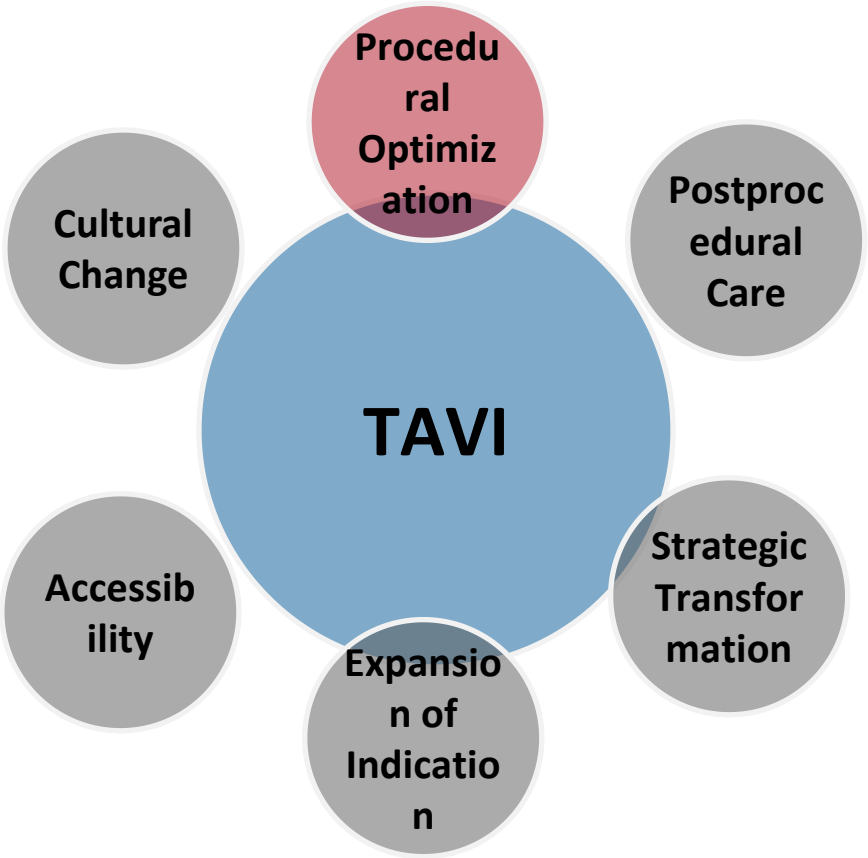
2020 ACC GL

Age 65-80 years based on shared decision making	I	A
Age >80 years	I	A
High/prohibitive risk	I	A

Evolution of TAVI Challenges



The Future of TAVI



Current TAVI Device Landscape

	Balloon-expandable		Self-expanding			
Indication	**Severe AS**				**Pure AR**	
	SAPIEN 3 UR	**Myval Octacor**	**Evolut FX Plus**	**Navitor**	**J-Valve**	**JenaValve Trilogy**
						
Frame	Cobalt-chromium	Cobalt-Nickel	Nitinol			
Valve tissue	Bovine pericardium		Porcine pericardium	Bovine pericardium	Porcine Pericardium	
Valve size (mm)	20/23/26/29	20/21.5/23/24.5/26/27.5/29/30.5/32	23/26/29/34	23/25/27/29/35	22/25/28/31/34	23/25/27
Design	Intra-annular		Supra-annular	Intra-annular	Intra-annular	Supra-annular
Repositioning	No		Yes			
Delivery system	14/16 Fr	14 Fr	14/18 Fr	14/15 Fr	18 Fr	

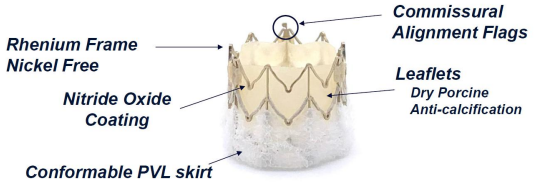
Artificial Intelligence tools to assess anatomical risks and refine patient & device selection

Figures reproduced and modified from Tomii, Windecker, et al. THE PCR-EAPCI TEXTBOOK

Procedural Optimization

Upcoming Devices with New Technology

Siegel

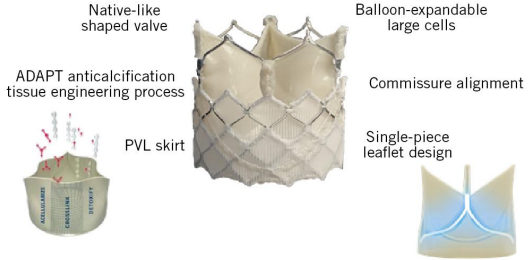


Delivered Crimped On Balloon Through 8 Fr Expandable Sheath

Standout feature:

8F delivery sheath

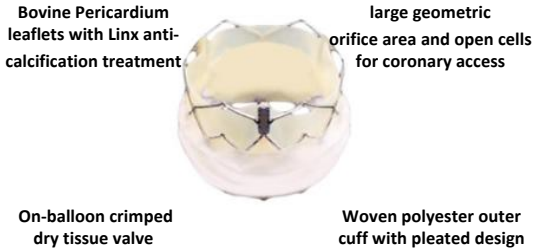
DurAVR



Standout feature:

Single piece native-shaped leaflet structure with superior hemodynamic performance and improved durability

Encantor



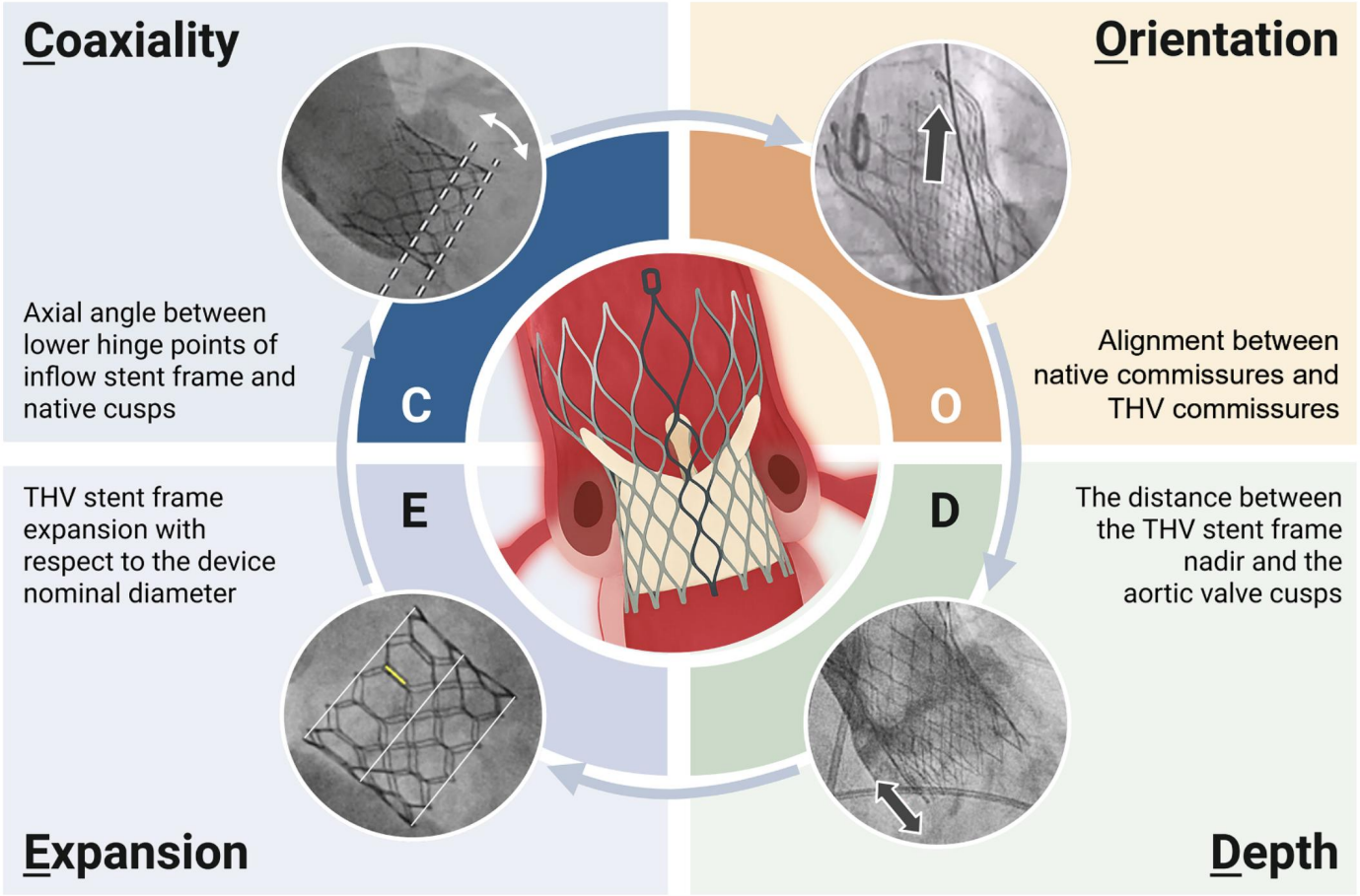
Standout feature:

Balloon-expandable THV with active commissural alignment

Fully repositionable & retrievable THV? THV with a minimized stent frame?

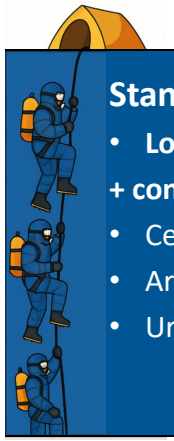
Yadav NY Valves 2025; Kodali et al. EuroIntervention 2023;19:e352-362; Puri 2025; Kodali NY Valves 2025.

Optimization of Implantation: The CODE Framework



Angellotti D et al, JACC Adv 2025;4(10):102181

Minimalist Approach: DOUBLE-CHOICE Trial



Standard of care

- **Local anesthesia**

+ conscious sedation

- Central venous line
- Arterial lines
- Urinary catheter

Minimalist approach

- **Local anesthesia**

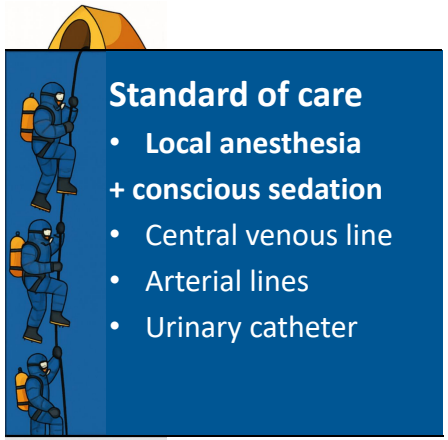
without sedation

- No additional lines

N= 752 patients, median age 83 yrs, 58% female, STS-PROM >4.5%

Double-Choice Trial. Presented at ESC 2025

Minimalist Approach: DOUBLE-CHOICE



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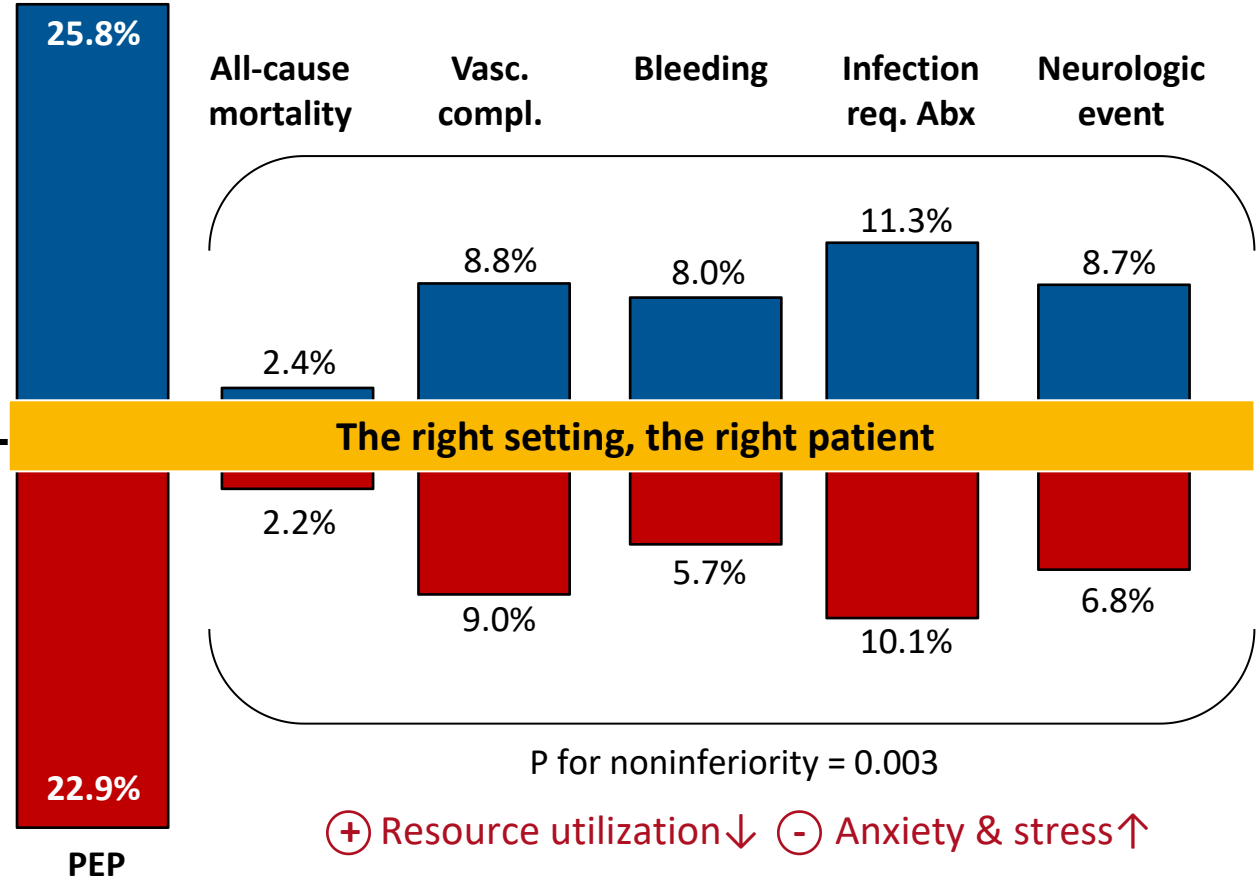
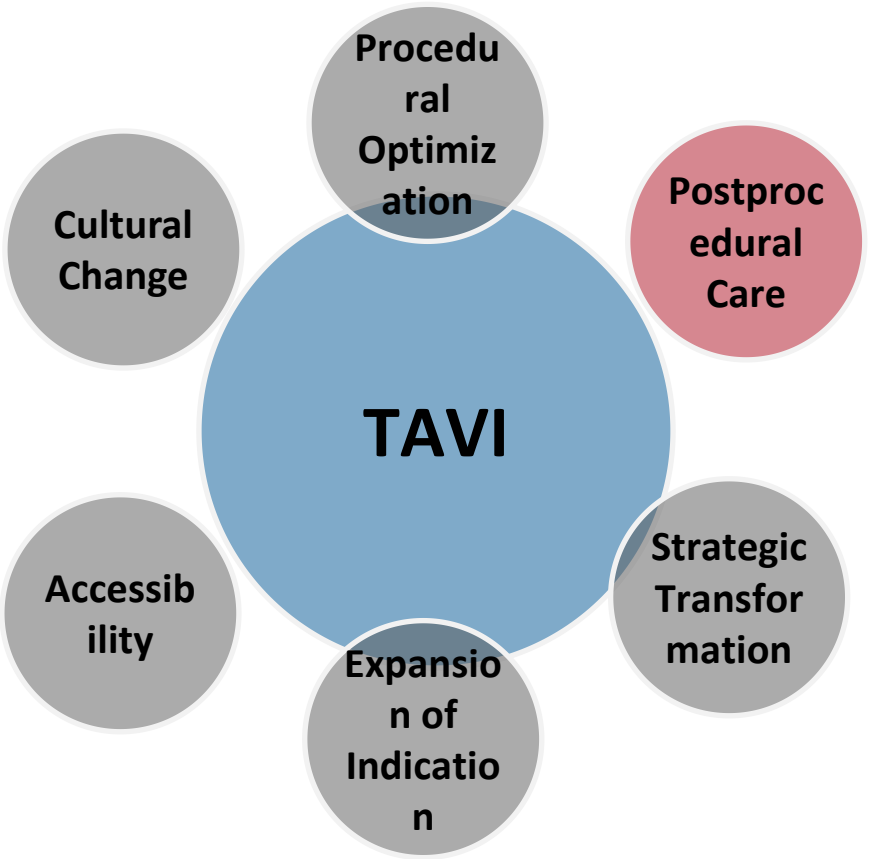


P for noninferiority = 0.003

⊕ Resource utilization↓ ⊖ Anxiety & stress↑

Double-Choice Trial. Presented at ESC 2025

The Future of TAVI



Same-Day Discharge after TAVI

Multicenter PROTECT TAVR Study

2,100 elective transfemoral TAVRs from March 2020 to August 2021 → 1,976 patients (94.1%) excluded from same-day discharge → 124 patients (5.9%) selected for same-day discharge

Clinical characteristics
- Mean age: 78 years
- Median Society of Thoracic Surgeons score: 2.4%
- Baseline permanent pacemaker: 32.3%
- Median pre-TAVR LVEF: 58%

Post-TAVR
- Balloon-expandable valve: 96.8%
- New conduction disease: 0.8%
- Event monitor at discharge: 30%
- Median time to follow-up: 31 days

Same-Day Discharge

100% rate of same-day discharge (n = 124)

30-Day Readmission

2.8% rate of 30-day cardiovascular readmission

Complications

0% vascular access complications
0.8% post-TAVR permanent pacemaker implantation

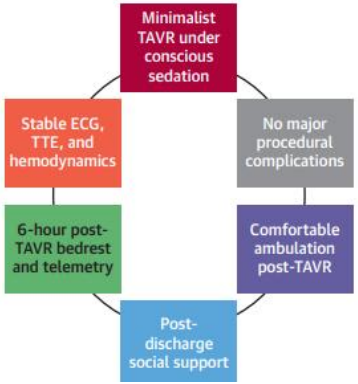
COVID-19 pandemic

Critical care bypassed
Reduction in length of stay
0.9% rate of COVID-19 infection at 30 days

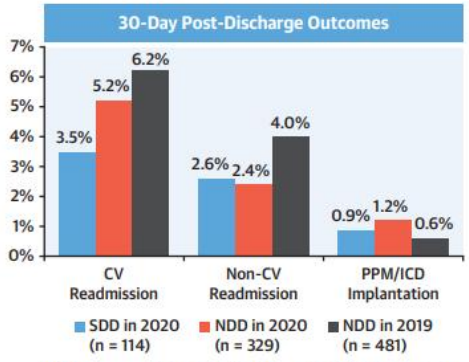
Barker M, et al. J Am Coll Cardiol Intv. 2022;15(6):590-598.

Barker M et al, JINT 2022

Cleveland experience



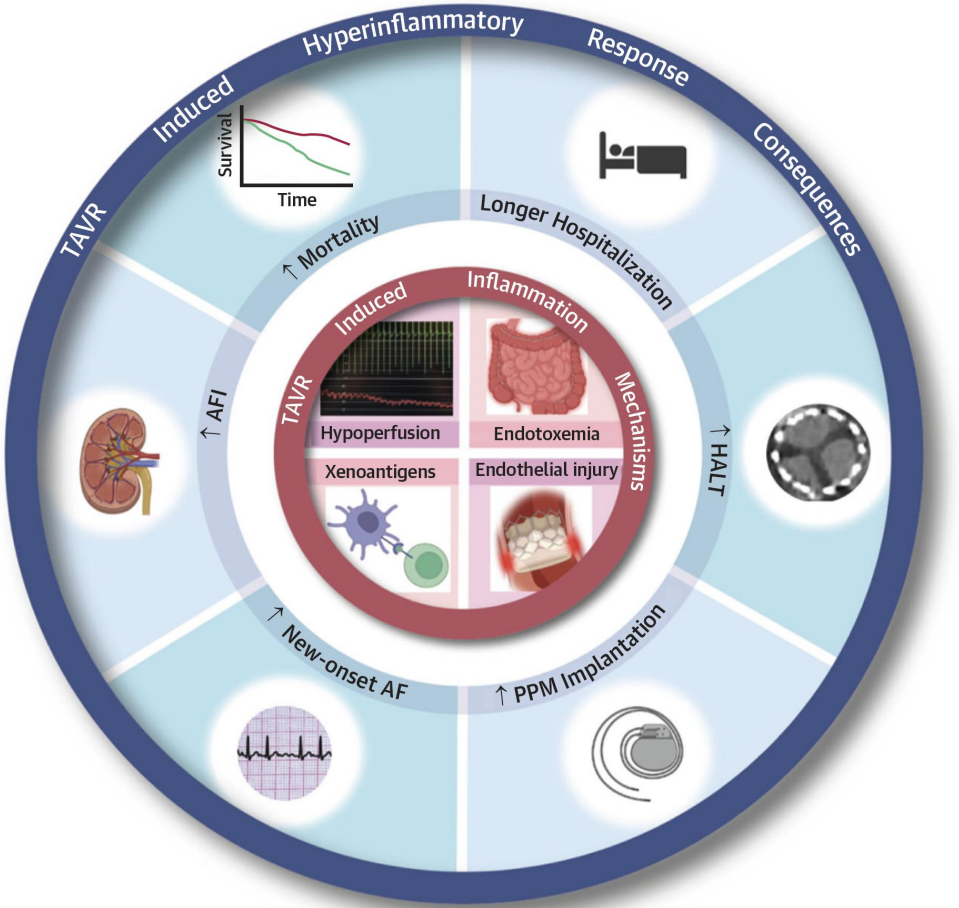
Same-day discharge (SDD): 8.7%
Next-day discharge (NDD): 61.6%



CV Readmissions Within 30 Days After SDD (n = 4)
- Rapid atrial fibrillation (POD 1) → Spontaneous resolution
- Pulmonary edema (POD 7) → IV diuresis and antihypertensives
- GI bleed related to DAPT (POD 15) → EGD and changed to SAPT
- Intermittent CHB (POD 25) → PPM Implantation

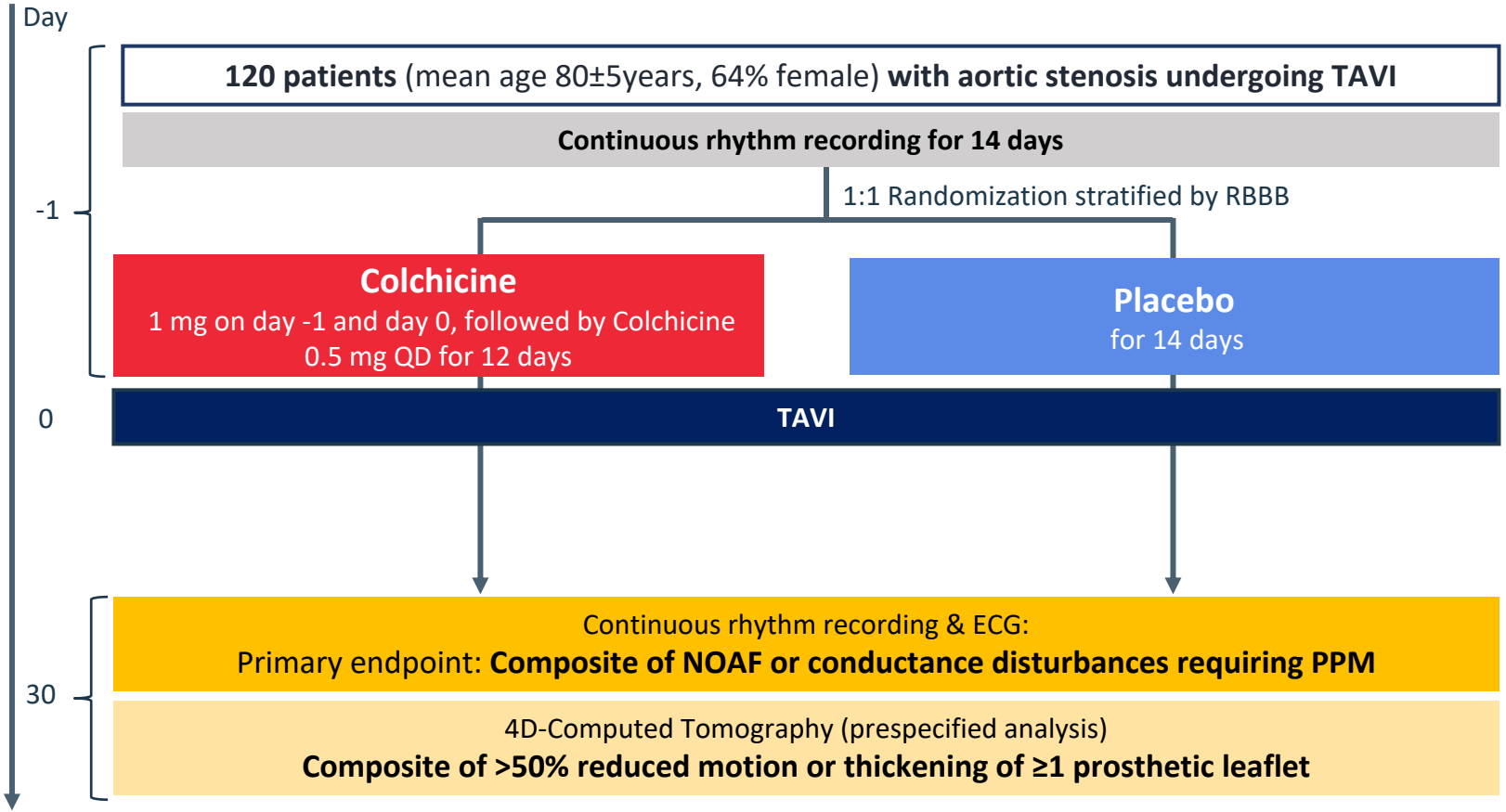
Krishnaswamy A et al, JINT 2022

Antiinflammatory Treatment after TAVI



Colchicine in Patients with Aortic Stenosis Undergoing TAVI

Investigator-initiated, double-blind, placebo-controlled, randomised trial



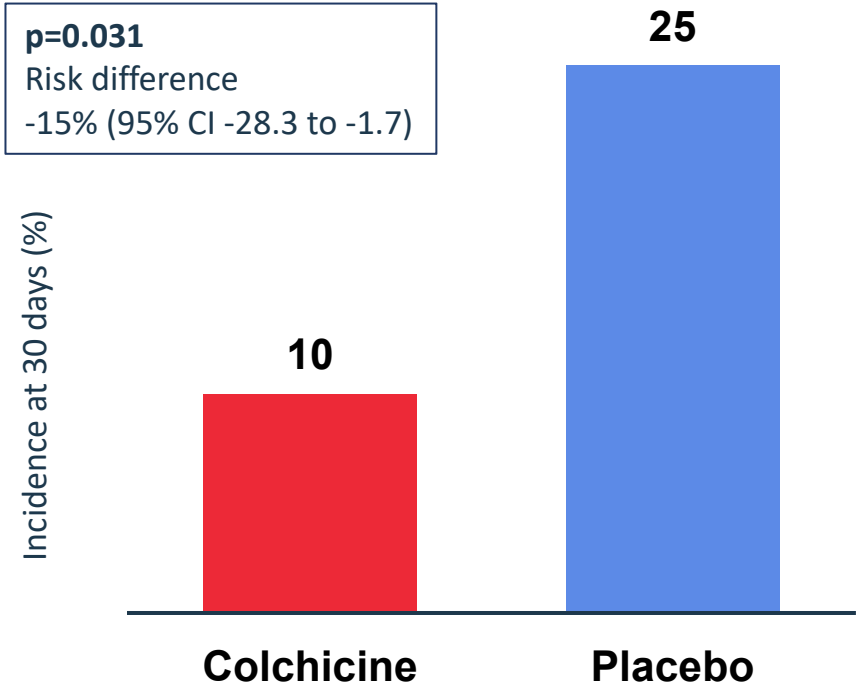
Ryffel C et al, Nat Commun 2025;16(1):6501

Colchicine in Patients with Aortic Stenosis Undergoing TAVI

Primary Endpoint

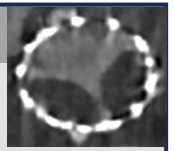
New-onset atrial fibrillation or new PPM implantation at 30 days

p=0.031
Risk difference
-15% (95% CI -28.3 to -1.7)

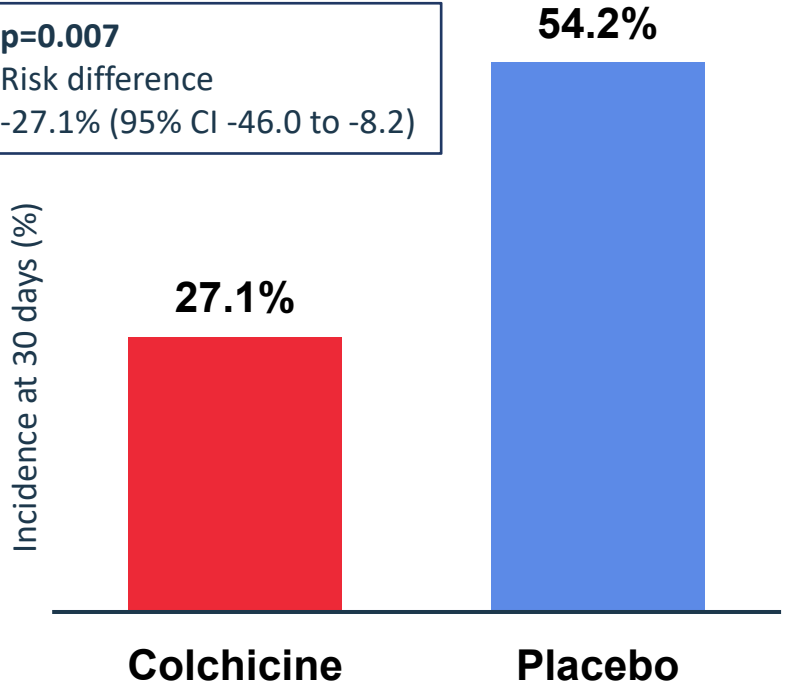


Pre-specified 4D-CT Endpoint

>50% reduced motion or thickening of ≥1 prosthetic leaflet at 30 days



p=0.007
Risk difference
-27.1% (95% CI -46.0 to -8.2)



Ryffel C et al, Nat Commun 2025;16(1):6501

Antithrombotic Therapy post TAVI

TAVR

No indication for antithrombotic therapy

Indication for **antithrombotic therapy**

POPular TAVI cohort B
ENVISAGE-TAVI AF
1

Antiplatelet therapy

Ussia et al
SAT-TAVI
ARTE
POPular TAVI cohort A

Antithrombotic t

GALILEO
Low Risk Trial 2
ATLANTIS strat
ADAPT-TAVR

Non-Antithrombotic Therapy after TAVI (NAPT) Trial

360 TAVI patients

<5 days post TAVI

ASA 75-100 mg

NAPT

Primary endpoint: Death, MI, stroke, bleeding at 1 year

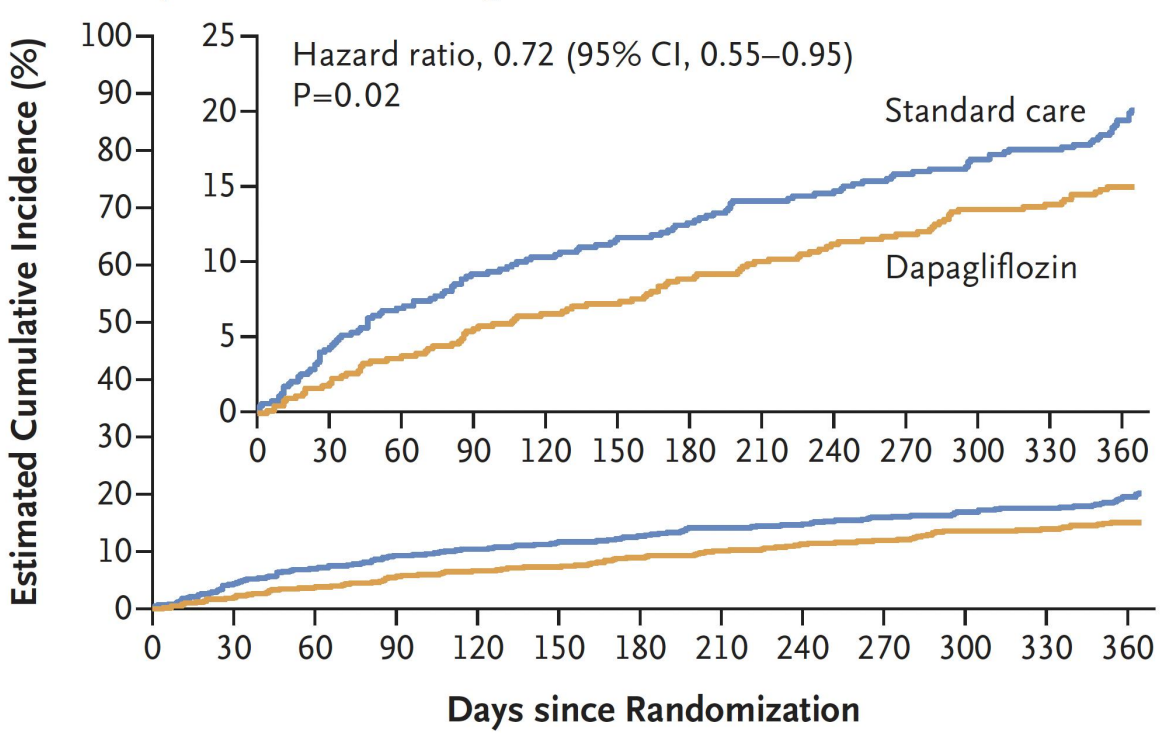
Anticipated event rates; 23% vs 18%; 6%, non-inferiority margin 6%

NCT06007222

SGLT2-Inhibitors in Patients Undergoing TAVI

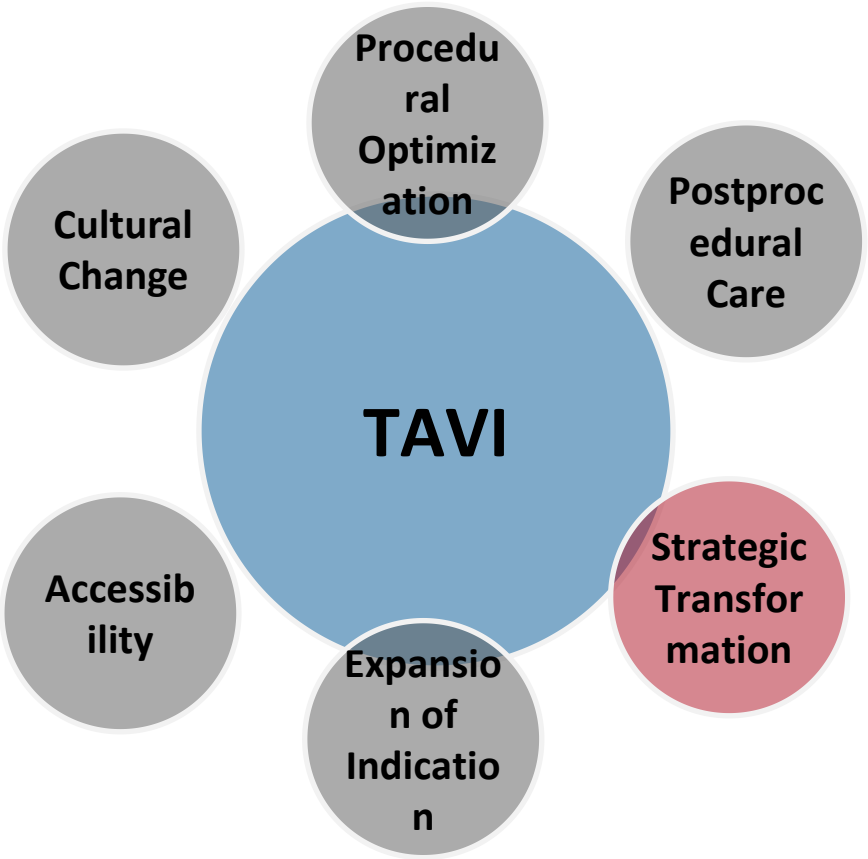
1257 patients s/p TAVI with a Hx of HF plus CKD, diabetes, or LVEF↓ (mean age 82±6 yrs, 49% female)

Death from any cause or worsening heart failure

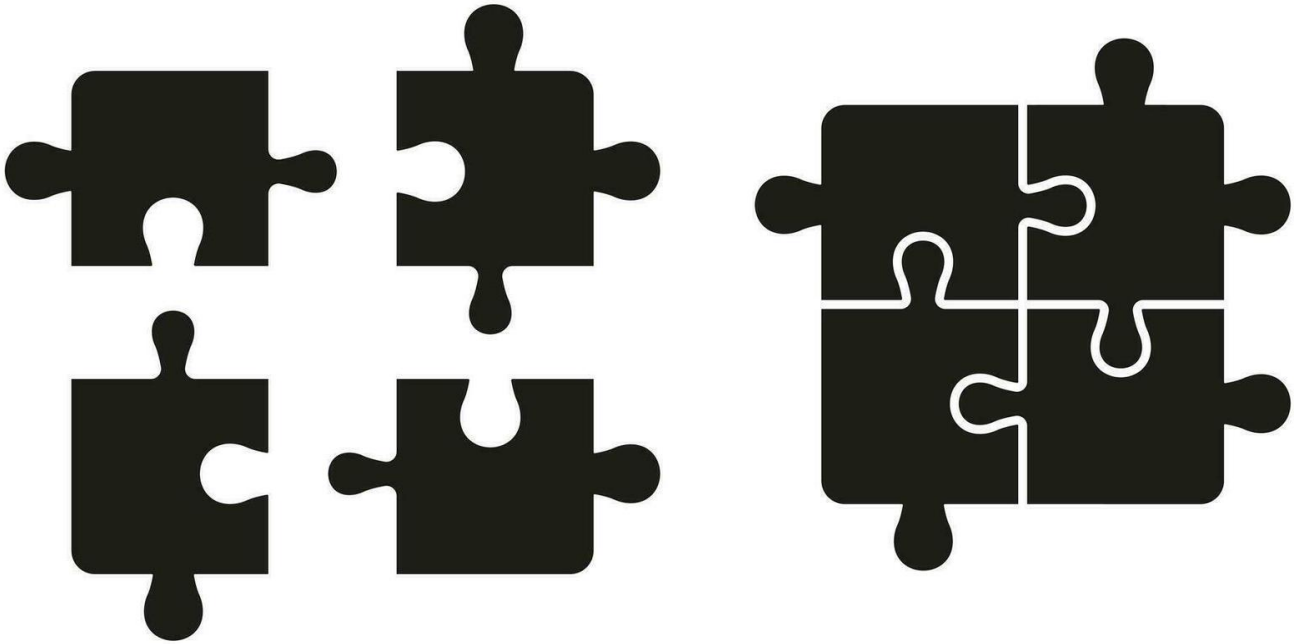


Raposeiras-Roubin S et al, N Engl J Med 2025

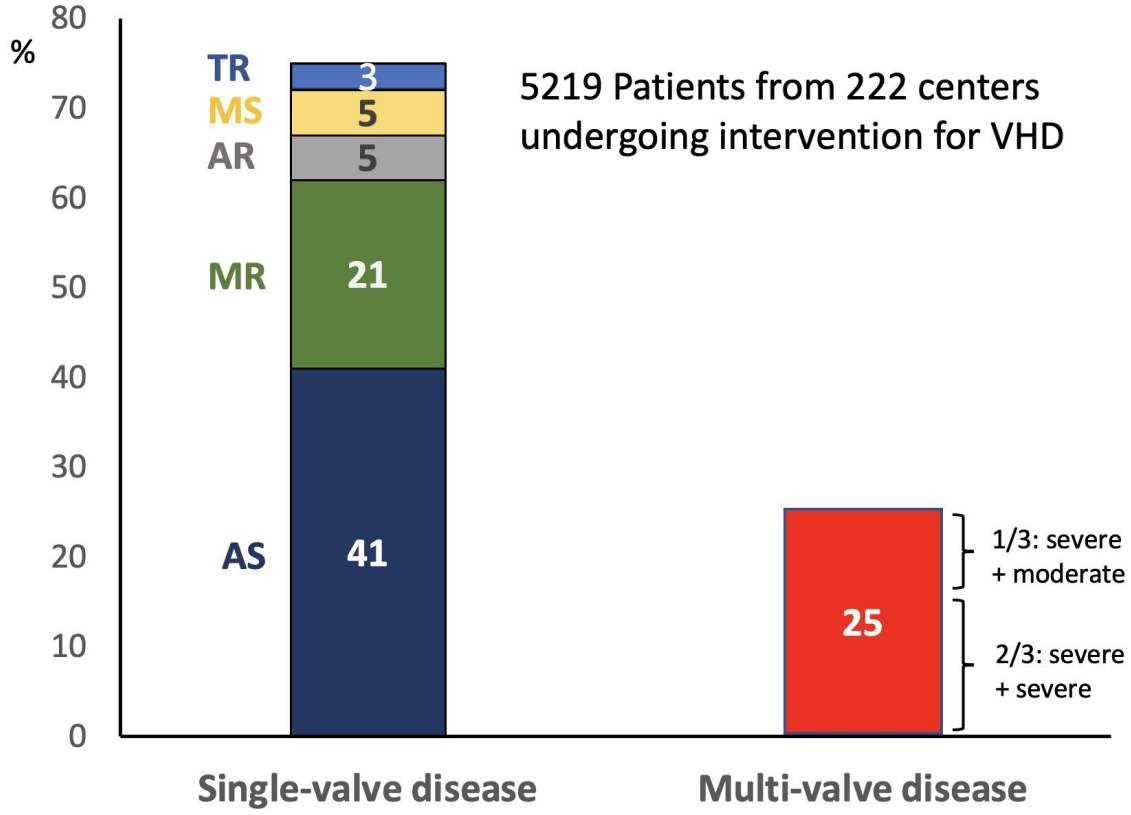
The Future of TAVI



Aortic Stenosis and Multivalve Disease



Prevalence of Multivalve Disease

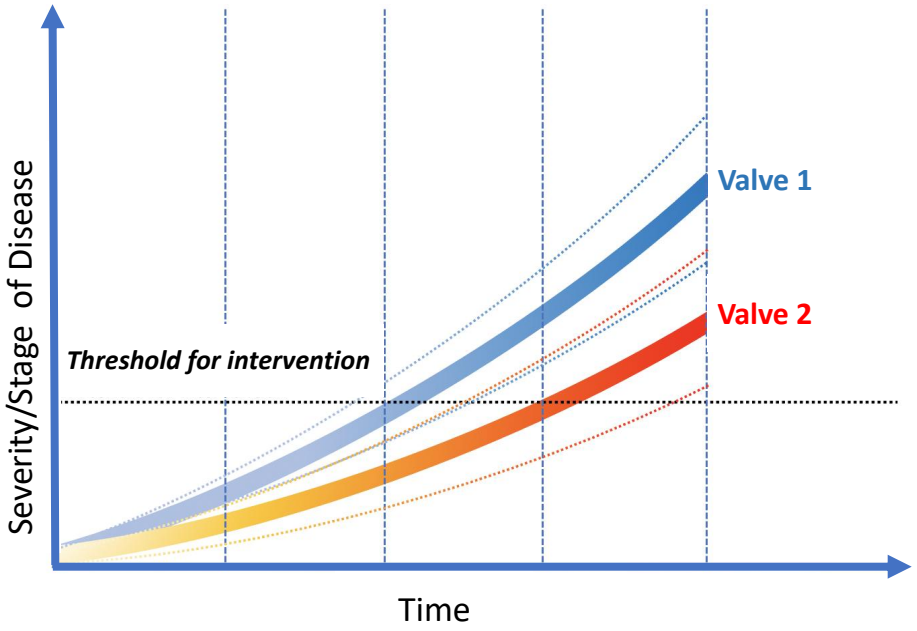


Iung B et al, Circulation 2019

Strategic Transformation

Aortic Stenosis and Concomitant Valvular Heart Disease

Asynchronous Progression of Concomitant VHD



Alaour B, Nakase M, Pilgrim T. Can J Cardiol 2023

Strategic Transformation

Aortic Stenosis and Coronary Artery Disease

1	**Revascularization vs conservative Management** *Severity of CAD*	ACTIVATION, NOTION 3, COMPLETE TAVR (NCT04634240), PRO-TAVI (NCT05078619)
2	**PCI + TAVI vs CABG + SAVR** *Complexity of CAD*	TCW
3	**PCI before, during or after TAVI** *Timing of revascularization*	TAVI-PCI (NCT04310046))

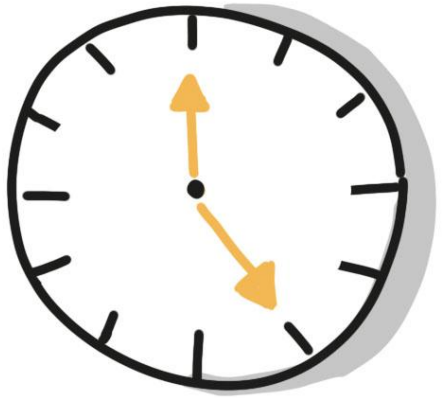
From one-size-fits-all approach to a tailored/individualized approach to patients with aortic stenosis and coronary artery disease.

Timing of Intervention in Aortic Stenosis

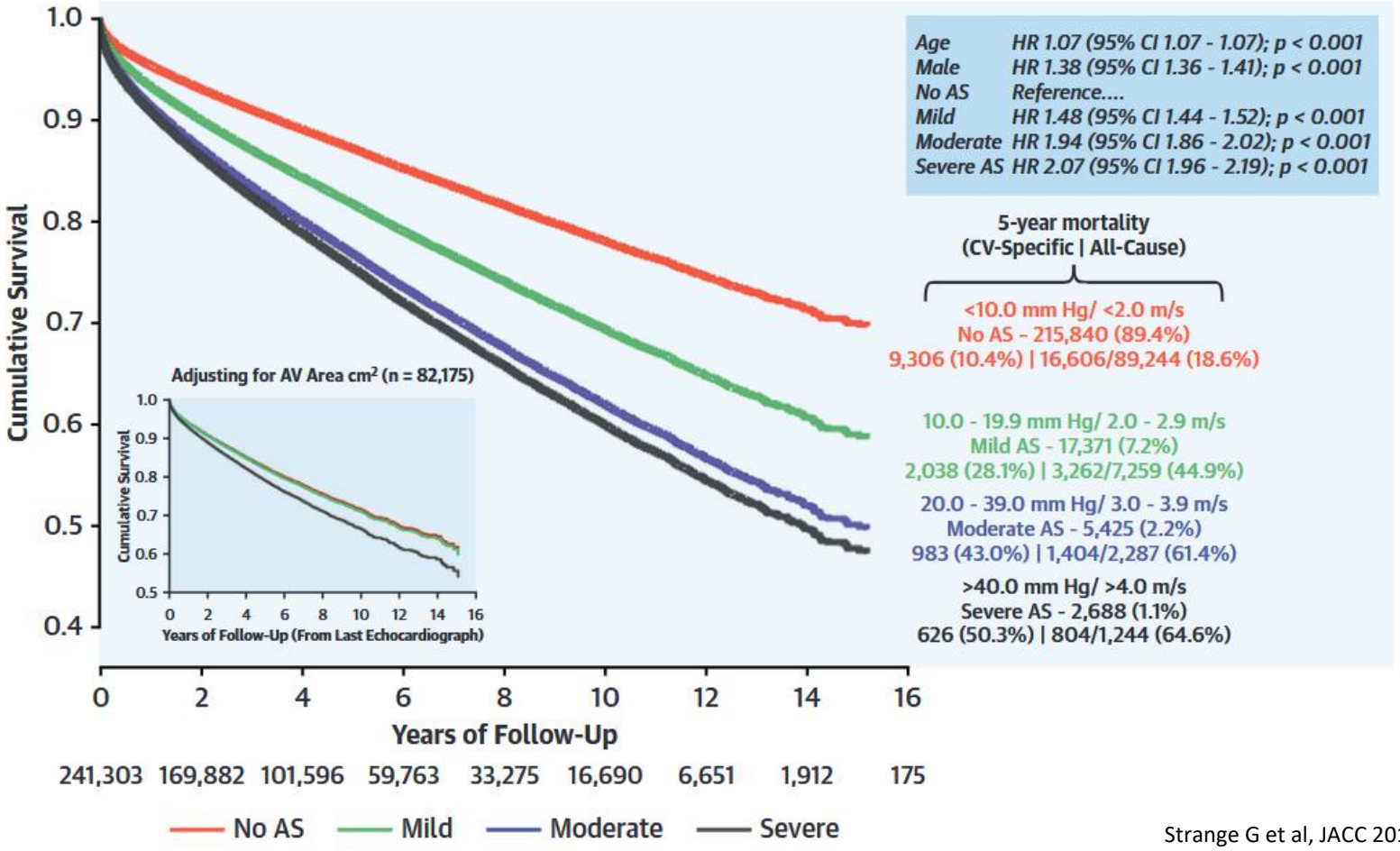
Earlier intervention in aortic stenosis is supported by two key insights:

1. Mortality risk in aortic stenosis increases gradually rather than abruptly.

2. Shift from grading of aortic stenosis to staging of aortic stenosis (integrating markers of cardiac damage)



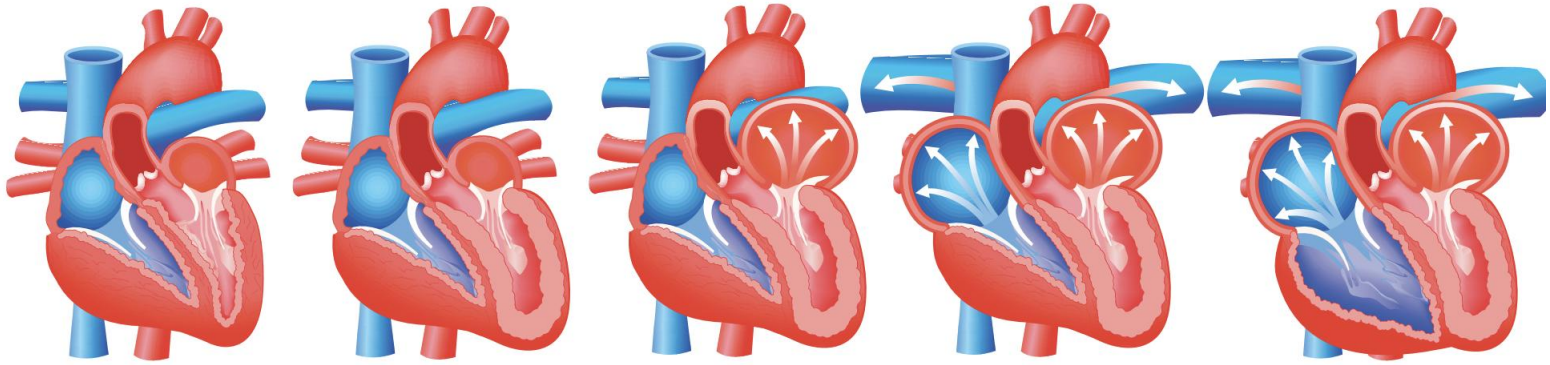
1. Mortality Risk According to Severity of AS



Strange G et al, JACC 2019;74:1851-63

Strategic Transformation

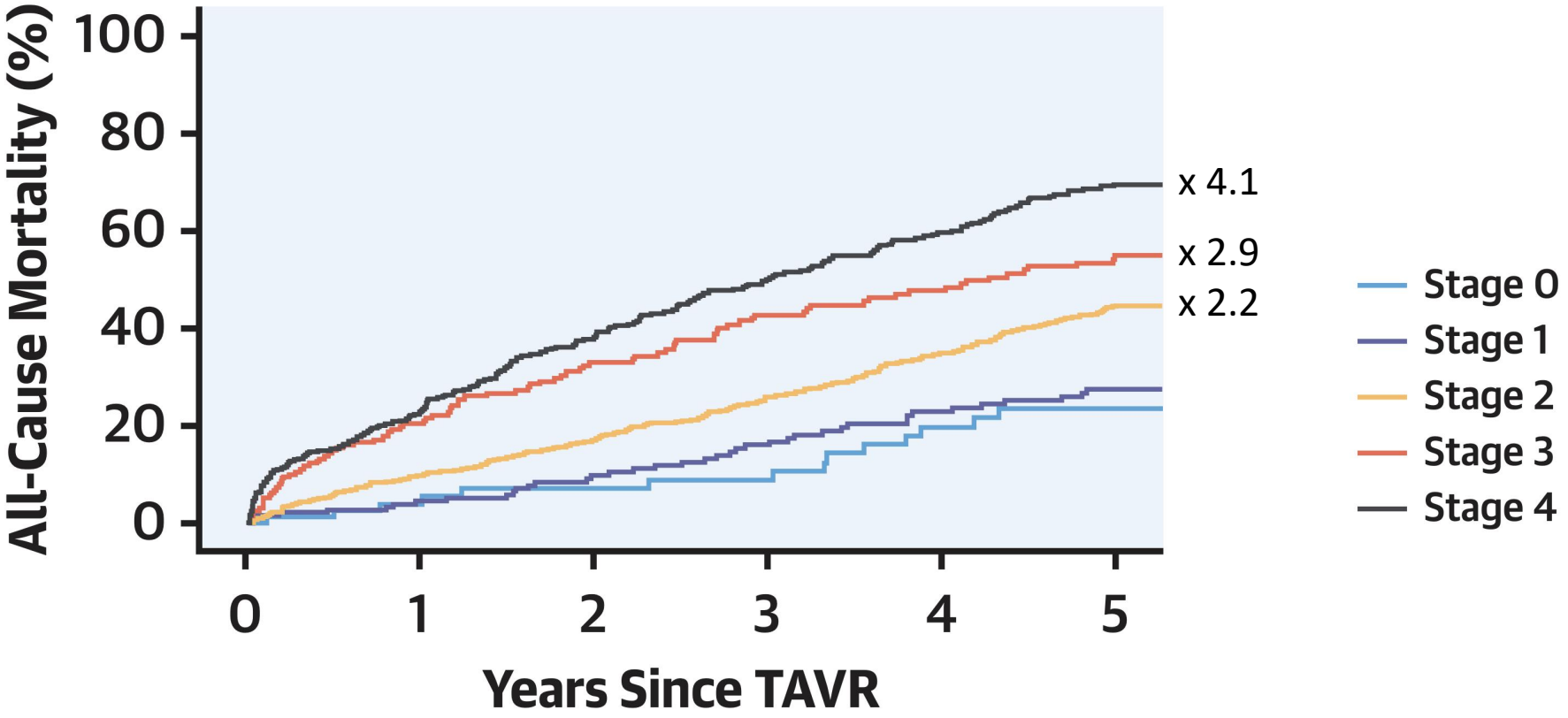
2. Cascade of Secondary Cardiac Damage due to AS



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/m^2 (Male) >95 g/m^2 (Female)	Indexed left atrial volume >34mL/m^2	Systolic Pulmonary hypertension ≥60 mmhg	Moderate-Severe right ventricular dysfunction
		E/e' >14	Moderate-Severe mitral regurgitation	Moderate-Severe tricuspid regurgitation	
		LV Ejection Fraction <50%	Atrial Fibrillation		

Généreux P et al, Eur Heart J 2017

2. Long-Term Impact of Cardiac Damage Following TAVI



Nakase M, et al. J Am Coll Cardiol Intv. 2024;17(8):992–1003

Strategic Transformation

Metaanalysis of RCTs: AVR vs Medical Tx in Asymptomatic Severe AS

N=1427 patients, mean age 73.3 years, average duration of follow-up 4.1 years

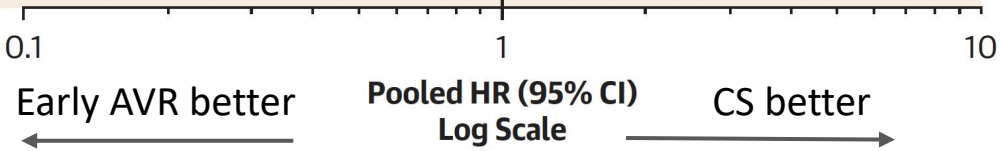
RECOVERY (2010-2015)	AVATAR (2015-2023)	EARLY TAVR (2017-2021)	EVOLVED (2017-2022)
N=145 SAVR=73 Age 64.5 years	N=157 SAVR=78 Age 67.0 years	N=901 TAVR=455 Age 75.8 years	N=224 SAVR= 80; TAVR=26 Age 73.4 years
Low-level stress test in 17%	Low-level stress test in 100%	Low-level stress test in 90.6%	No stress test reported
mG 63 mmHg	mG 50 mmHg	mG 47 mmHg	mG 45 mmHg
FUP ~ 6.2 years	FUP ~ 5.3 years	FUP ~ 3.8 years	FUP ~ 3.5 years

Généreux P et al, JACC 2025;85(9):912-922

Strategic Transformation

Metaanalysis of RCTs: AVR vs Medical Tx in Asymptomatic Severe AS

	Early AVR n/N (%)	Clinical Surveillance n/N (%)	Pooled HR* (95% CI)	*P* Value
All-Cause Mortality	70/719 (9.7%)	97/708 (13.7%)	0.68 (0.40-1.17)	0.17
Cardiovascular Mortality	37/719 (5.1%)	59/708 (8.3%)	0.67 (0.35-1.29)	0.23
Heart Failure Hospitalization	18/606 (3.0%)	65/597 (10.9%)	0.28 (0.17-0.47)	<0.01
Unplanned CV or HF Hospitalization	105/719 (14.6%)	226/708 (31.9%)	0.40 (0.30-053)	<0.01
Stroke	32/719 (4.5%)	51/708 (7.2%)	0.62 (0.40-0.97)	0.03



Généreux P et al, JACC 2025;85(9):912-922

Strategic Transformation

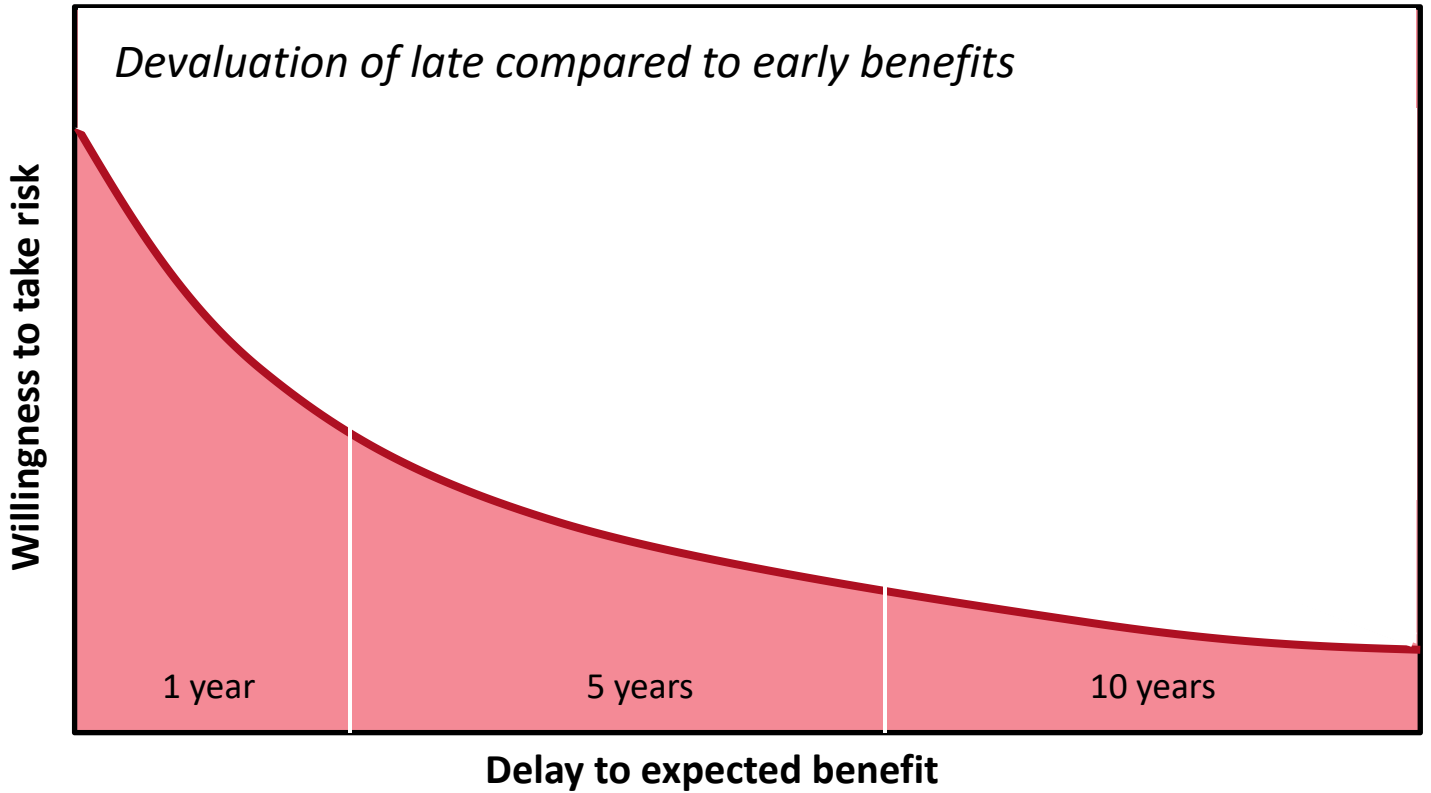
TAVI in Moderate Aortic Stenosis

PROGRESS (NCT04889872) N=1294 (complete)	TAVI (Sapien) vs Clinical surveillance	Moderate AS Symptoms OR signs of cardiac systolic or diastolic dysfunction	**Safety:** Composite of death, stroke, bleeding, AKI, hospitalization due to complication, reintervention at 30 days **Efficacy:** Composite of all-cause mortality, stroke, CV hospitalization at 2 years
EXPAND TAVR II (N05149755) N=650 (complete)	TAVI (Evolut) + OMT vs OMT + clinical surveillance	Moderate AS + risk features: symptoms OR cardiac dysfunction, ↑NT-proBNP, Afib, ↑AV calcium, previous HF event	**Safety:** Composite of all-cause mortality, stroke, bleeding, AKI, hospitalization due to complication, reintervention at 30 days **Efficacy:** Composite of all-cause mortality, HF, AV reintervention at 2 years

The „Dark Side“ of Early Intervention for Aortic Stenosis

- Rhythm disturbances
- Premature prosthetic valve degeneration and ↑risk of repeat procedures
- Prosthetic valve endocarditis
- Challenging coronary access

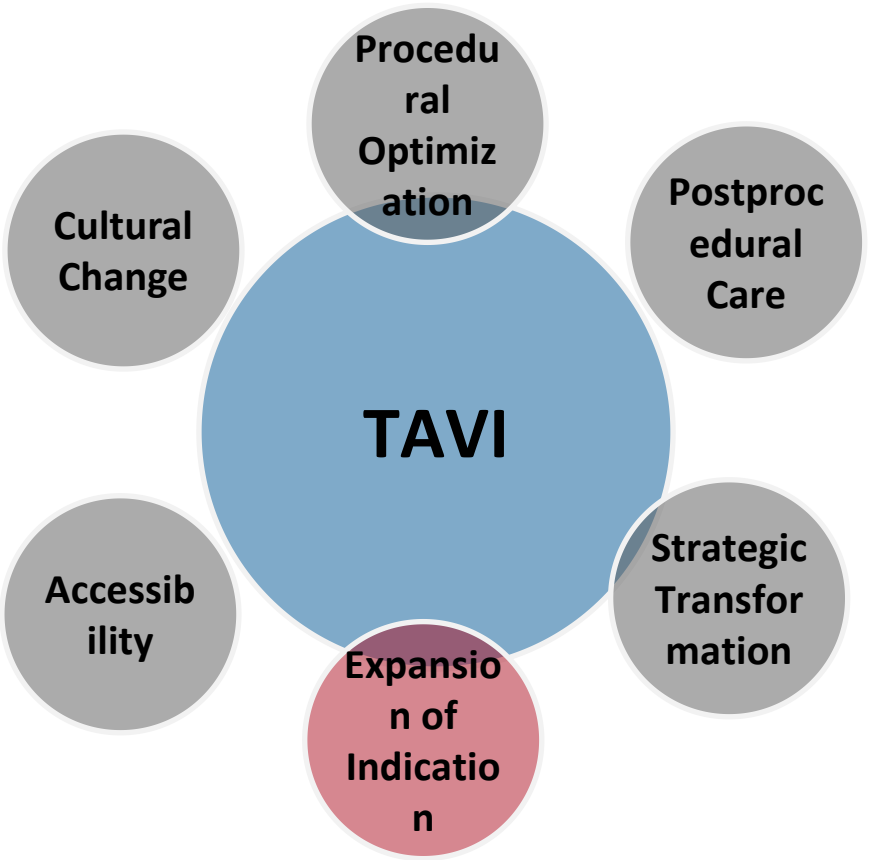
Time Preference for Now – Discount of Late Benefits



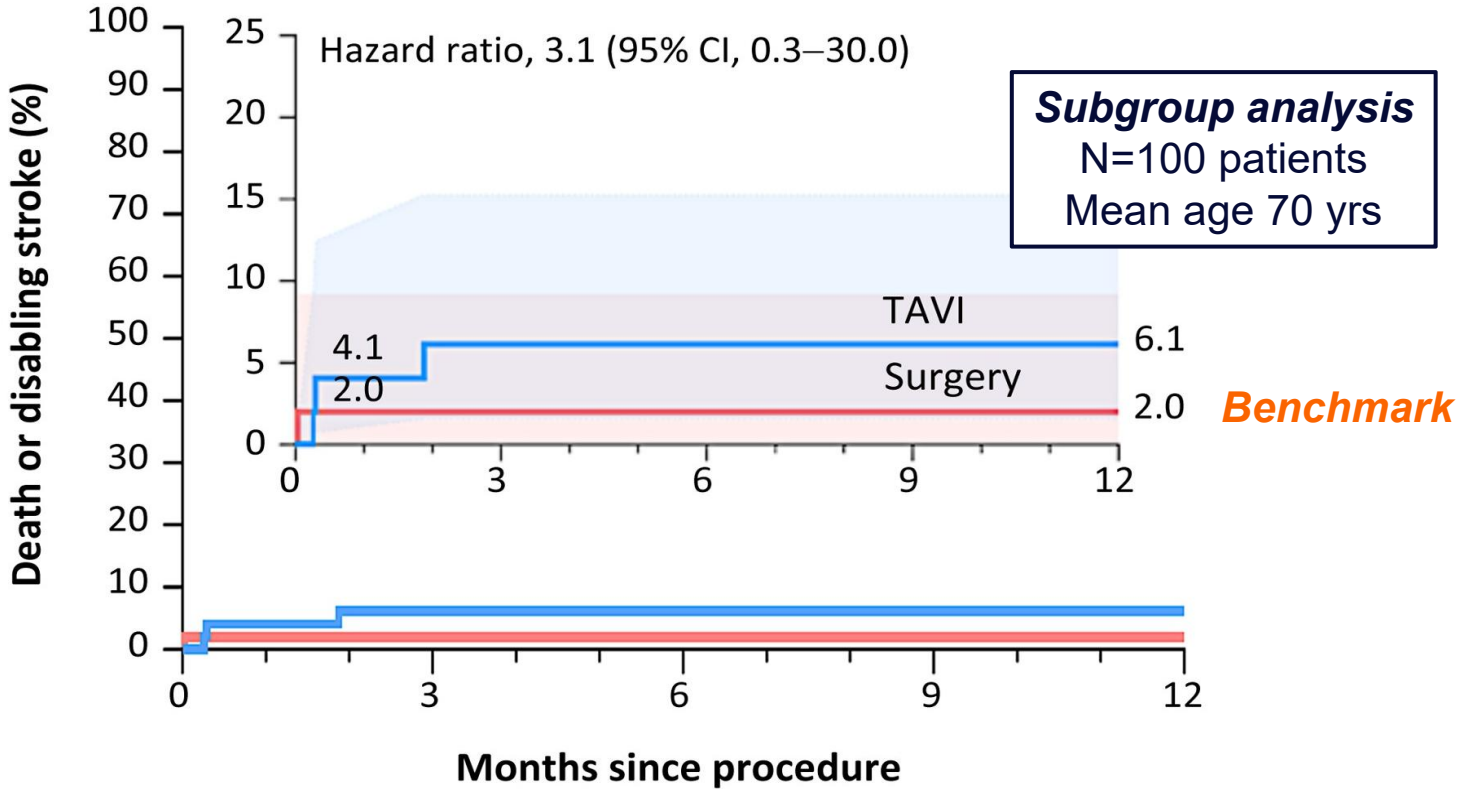
RE-VALVE Interventions

Techniques and devices that ***modify, split, lacerate, or partially remove*** **valve leaflets** to allow safe repeat TAVI.

The Future of TAVI



TAVR versus SAVR in Bicuspid Aortic Stenosis (NOTION-2)

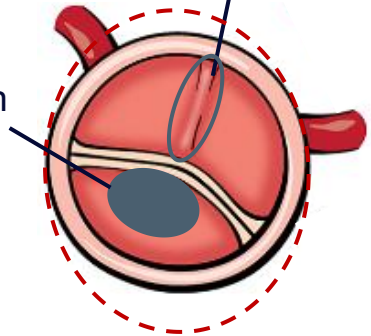


Jorgensen TH et al, Eur Heart J 2024

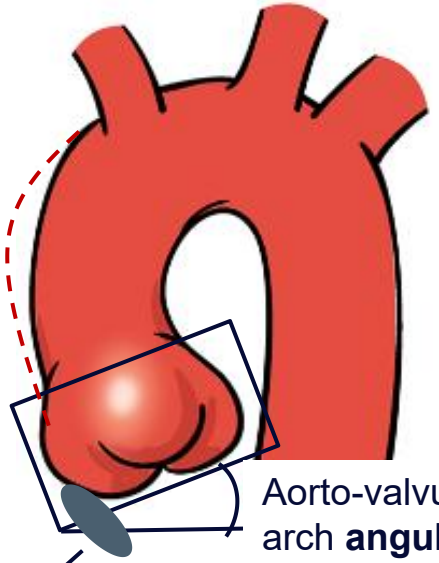
Bicuspid Anatomy - a Cocktail of Risks for TAVI

Raphe: Number, type & configuration of fusion, length, calcification

Cusp calcification: volume & distribution



Annular **Dimension & Ellipticity**



Ascending aorta **dilatation**

Aortovalvular **configuration**

Aorto-valvular arch **angulation**

LVOT calcification

RCTs in Patients with Bicuspid Aortic Stenosis

BELIEVERS

1050 patients with BAV stenosis

- TF TAVI
- SAVR

Primary endpoint:
Composite of all-cause **mortality**, all **stroke**, **CV rehospitalization**, or valve **reintervention** at 3 years post-procedure

NAVIGATE

1500 patients with BAV stenosis

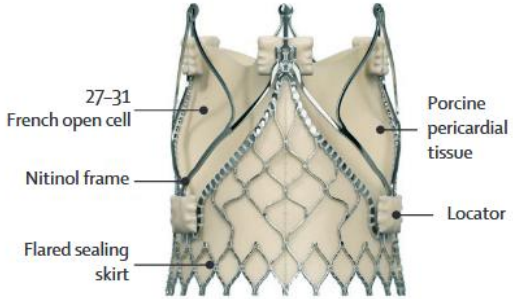
- TF TAVI
- SAVR

Safety endpoint: **Death** and disabling **stroke** assessed at 1-year FUP

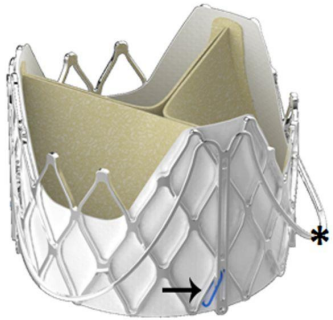
Primary efficacy endpoint:
Composite of **death**, **stroke**, **re-hospitalization** (procedure-, valve-, heart failure-related) assessed at 5-year FUP

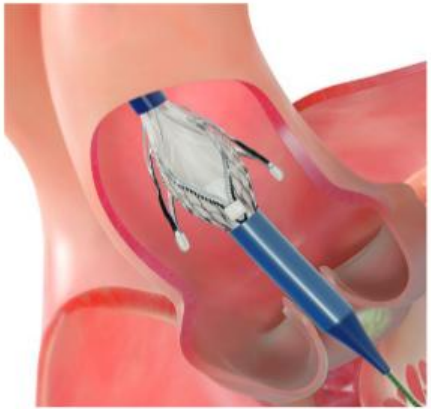
TAVI for Pure Native Aortic Regurgitation

JenaValve Trilogy

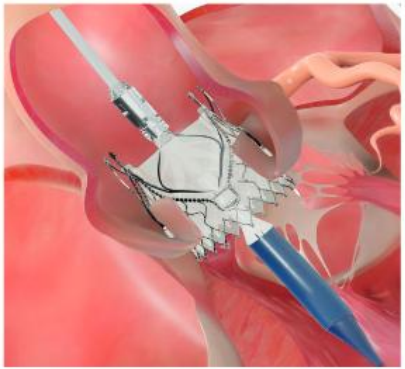


J-Valve

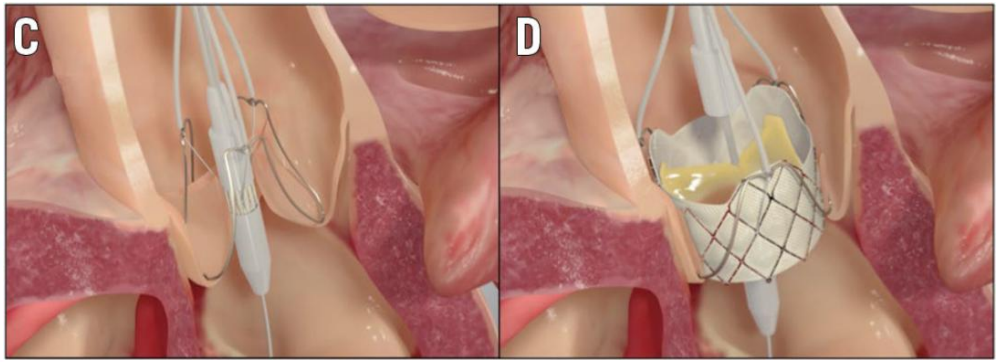




Alignment and positioning



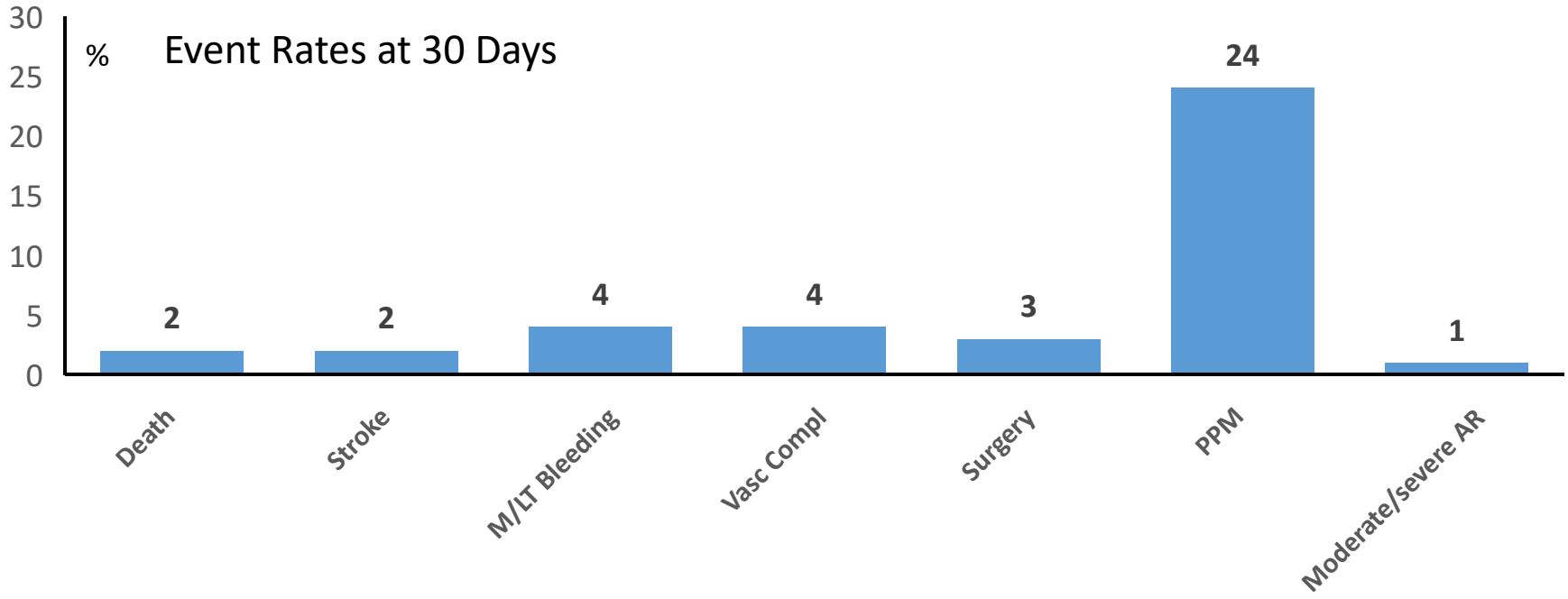
Anchoring and sealing



Wei L et al, JACC Cardiovasc Interv 2015;8:1831-45; Hensey M et al, EuroIntervention 2019;14(5):e1553-e1555

TAVI for Pure Native Aortic Regurgitation

N=180, mean age 75.5 years



Vahl TP et al, Lancet 2024;403(10435):1451-1459

Expanding Indications

TAVI for Pure Native Aortic Regurgitation

ARTIST

NCT06608823

Patient with 3-4+ Native Valve AR Requiring Class I or II Indication for AVR
N = 1,016

- **TAVI with Trilogy**
- **SAVR**

Primary endpoint
Noninferiority endpoint at 12 months: 1) Death, 2) Any stroke, 3) Unplanned cardiac rehospitalization

Secondary outcome:

- Superiority analysis for primary EP;
- MACE at 1-10 yrars;
- EOA
- Prosthetic-patient mismatch:
- KCCQ-OS;
- Atrial fibrillation:

JOURNEY

NCT06455787

Patients with symptomatic, severe AR who are deemed at high risk for surgery
N = 194

- **TAVI with J-Valve TF system**

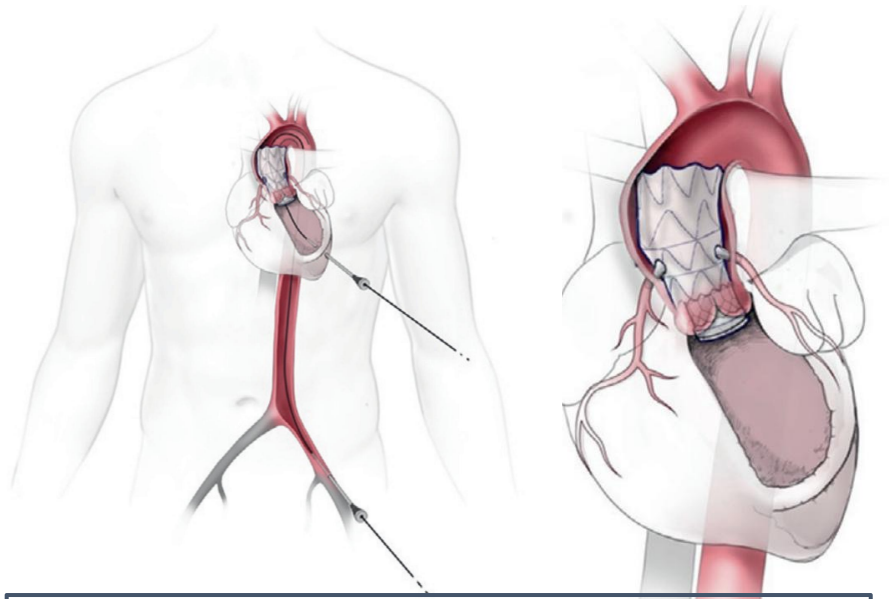
Primary outcome	
VARC-3 early safety at 30 days	All-cause mortality at 1 year

Secondary outcome:

- Rate of improvement in cardiovascular-specific health status (KCCQ)
- Improvement in left ventricular end diastolic diameterindex (LVEDDi)
- Improvement in left ventricular end diastolic volume index (LVEDVi)

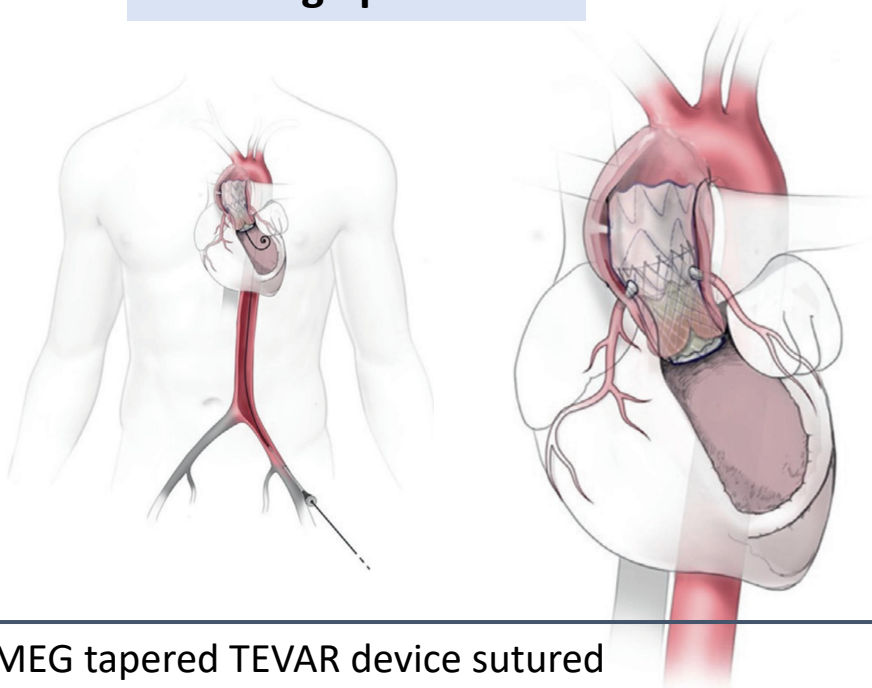
Endo-Bentall Procedures for Aortic Dissection

Two-stage procedure



Fenestrated physician-modified endograft devices (PMEG) combined with a TAVI valve

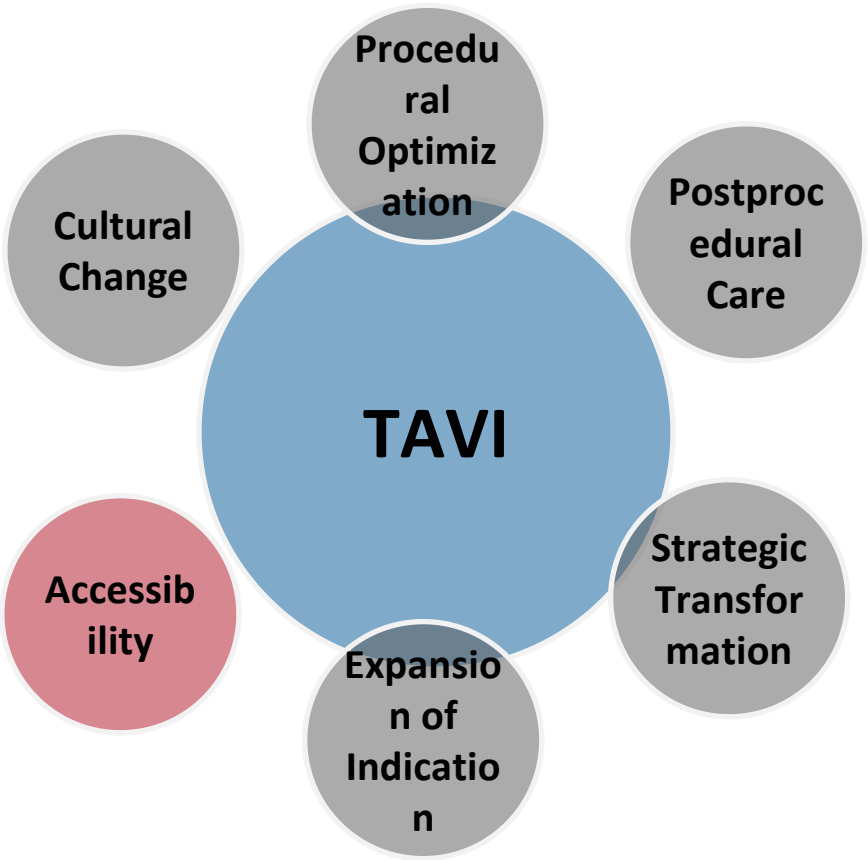
One-stage procedure



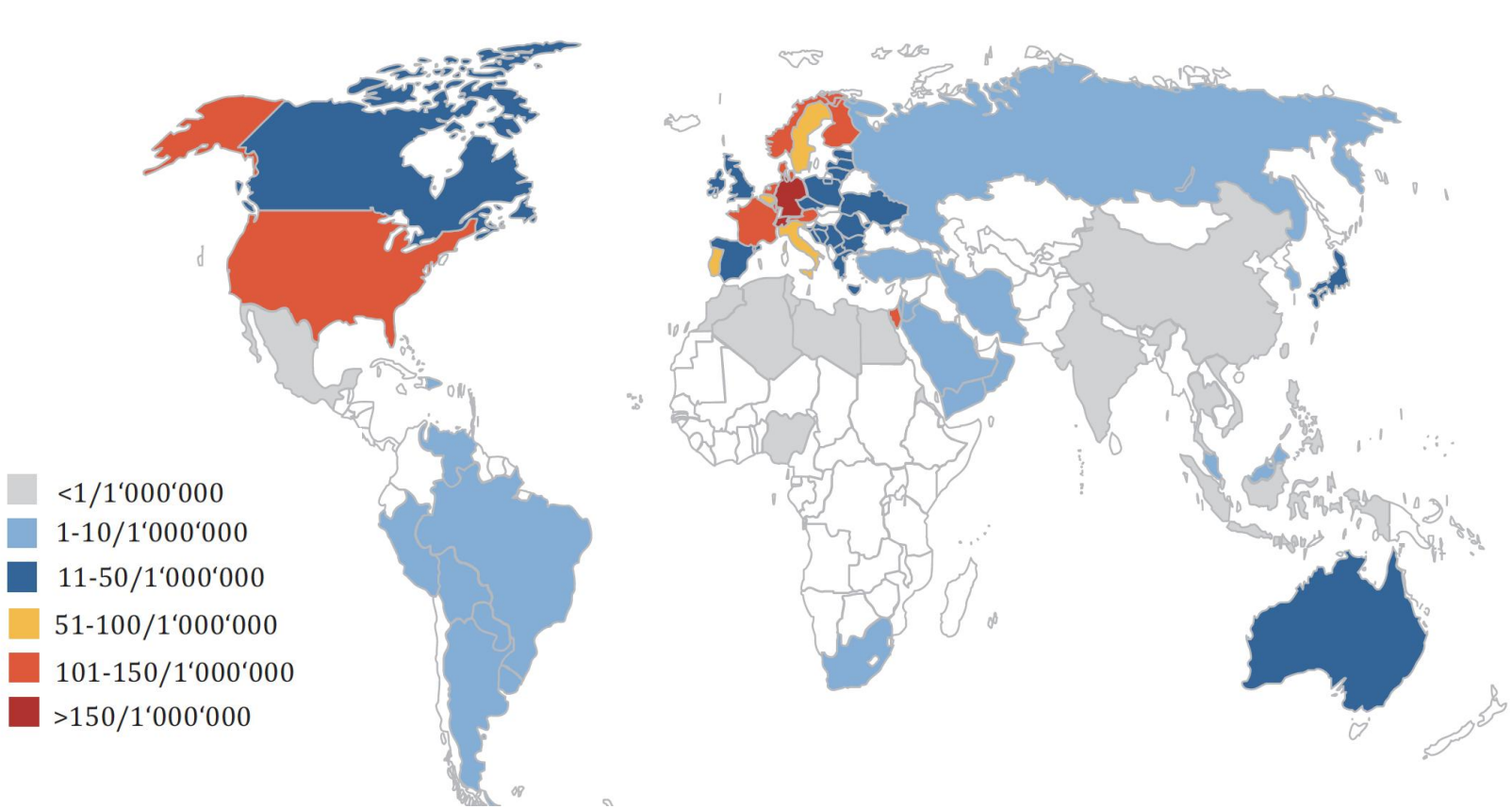
PMEG tapered TEVAR device sutured circumferentially to a self expandable TAVI device

Shehab M et al, Eur J Vasc Endovasc Surg. 2025:S1078-5884(25)00689-6

The Future of TAVI



Geographical Dispersion of TAVI

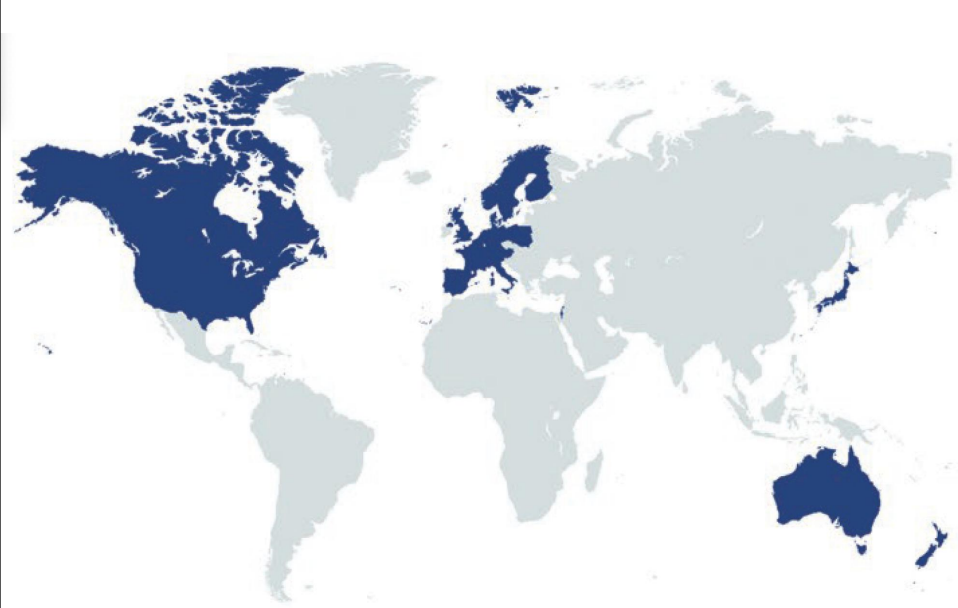


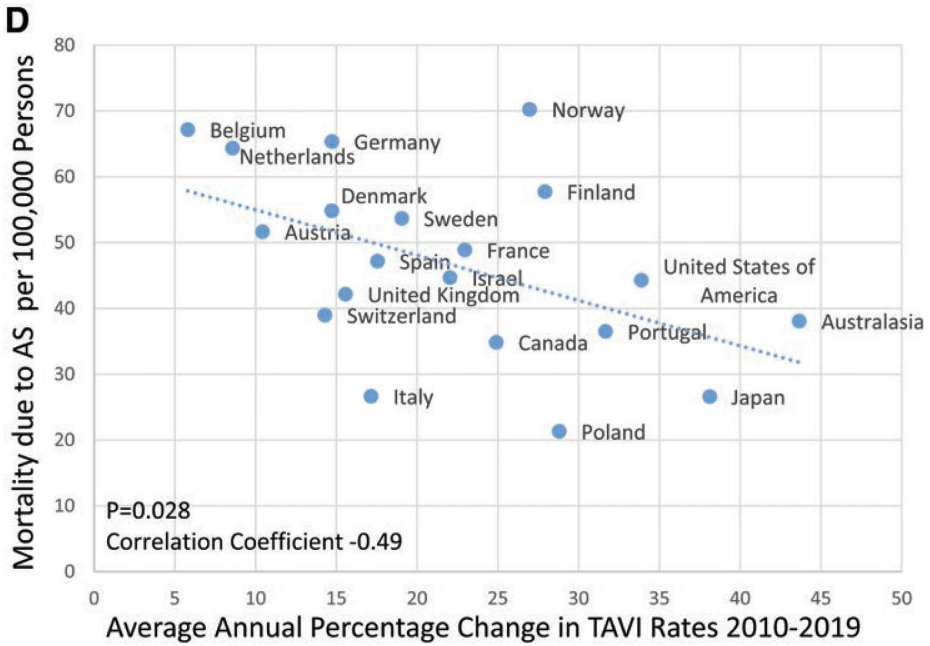
Pilgrim T, Windecker S, Eur Heart J 2018

Accessibility

Expansion of TAVI and Mortality from Aortic Stenosis

Global Burden of Disease Study 2010-2019





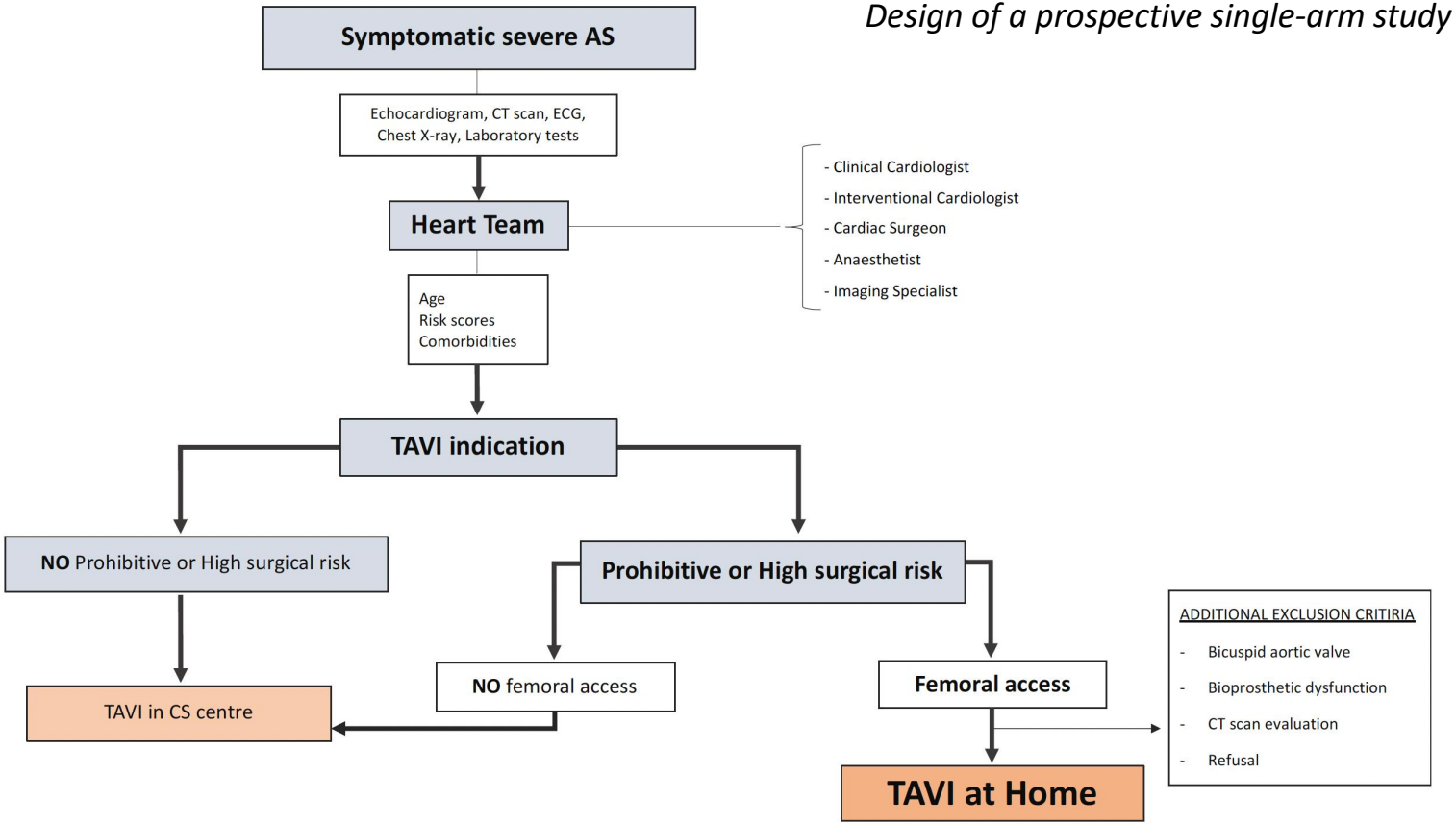
We need affordable TAVI systems for all of us.

Ryffel C, Windecker S, Pilgrim T. Circ Cardiovasc Interv. 2023;16(12):e013104

Accessibility

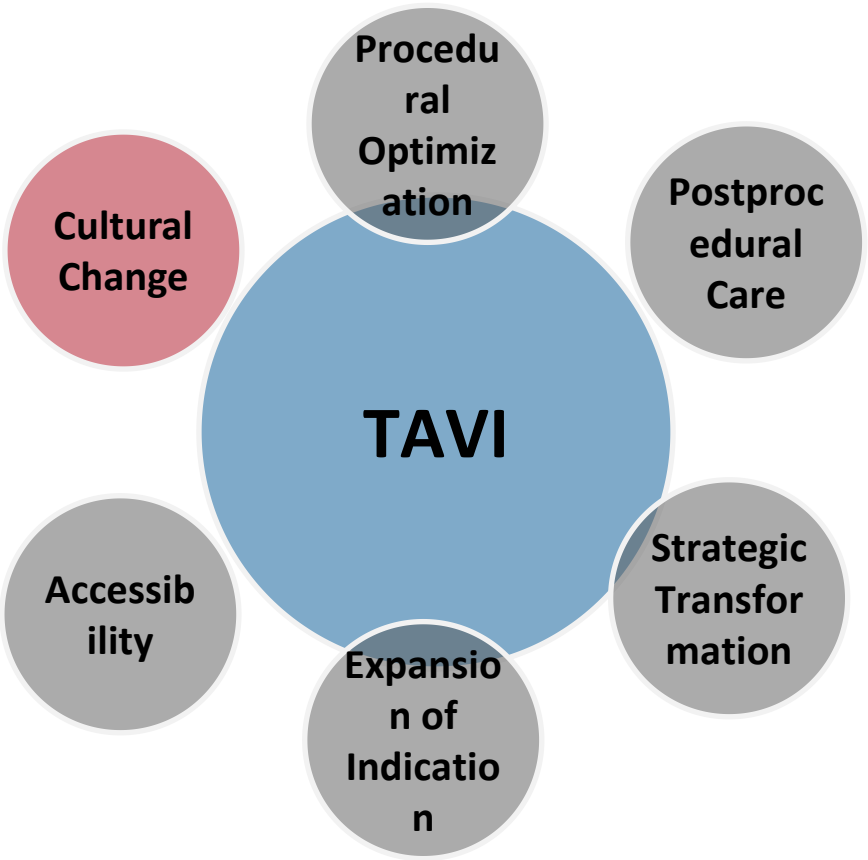
TAVI at Hospitals Without On-Site Cardiac Surgery

Design of a prospective single-arm study



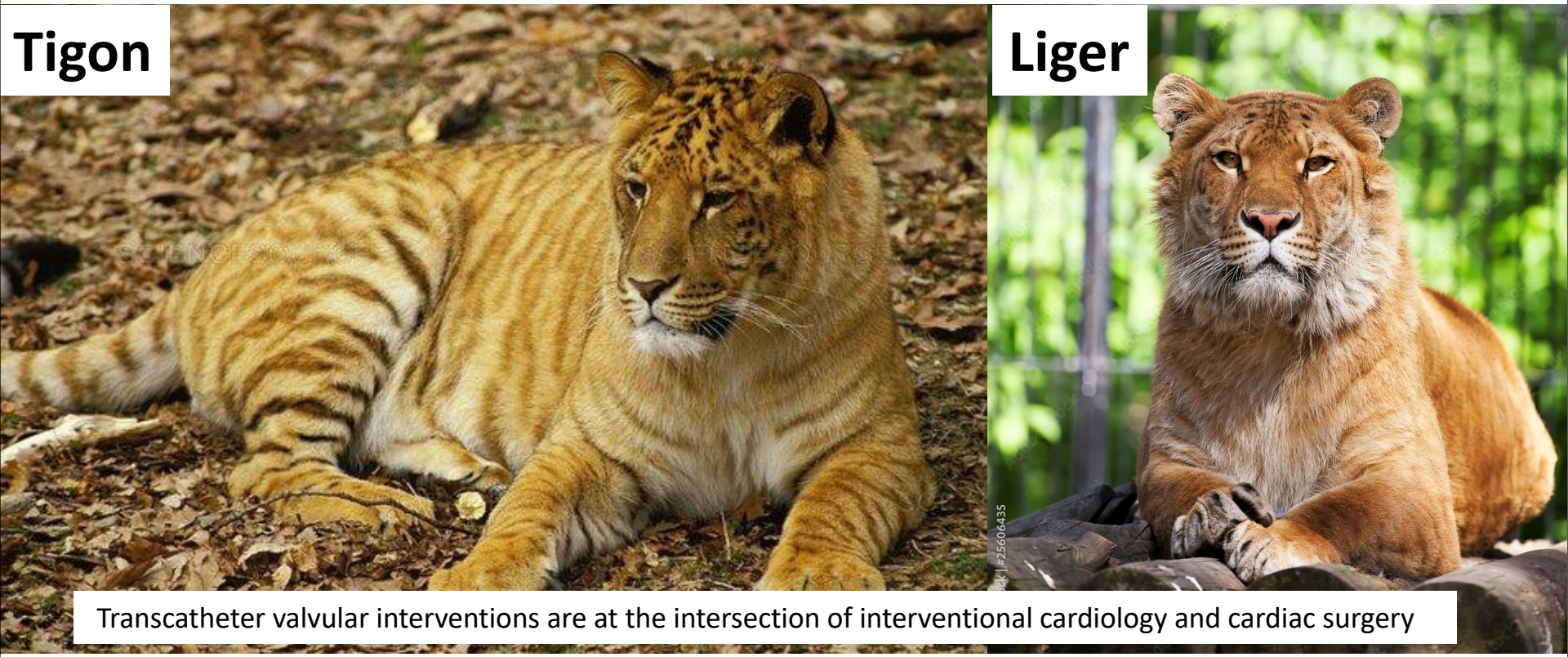
Compagnone M et al, JCDD 2025

The Future of TAVI



Cultural Change

Evolution of a Chimeric Speciality

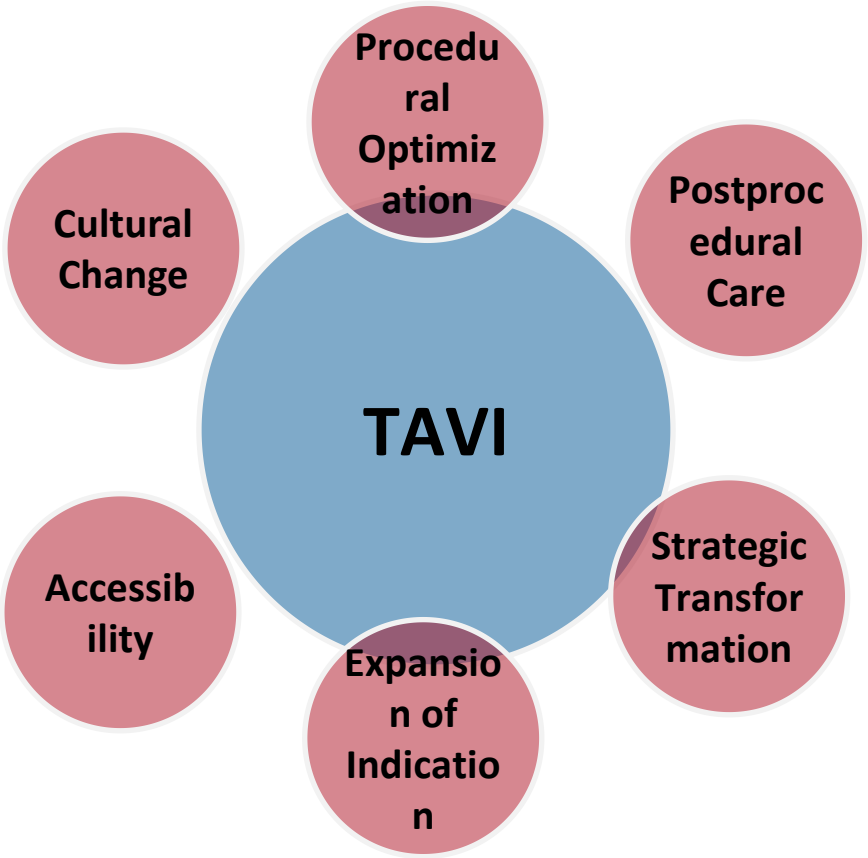


Transcatheter valvular interventions are at the intersection of interventional cardiology and cardiac surgery

TAVI has been bringing the specialties together much more than driving them apart.

Pilgrim T, Siontis GCM, Windecker S. Eur Heart J 2023

The Future of TAVI



~~The Future of TAVI~~

The Future of Degenerative Aortic Stenosis

Effect of Sodium-Glucose Cotransporter-2 Inhibitors on the Progression of Aortic Stenosis

Target Trial Emulation of Nonsevere Aortic Stenosis Patients

Patient Population

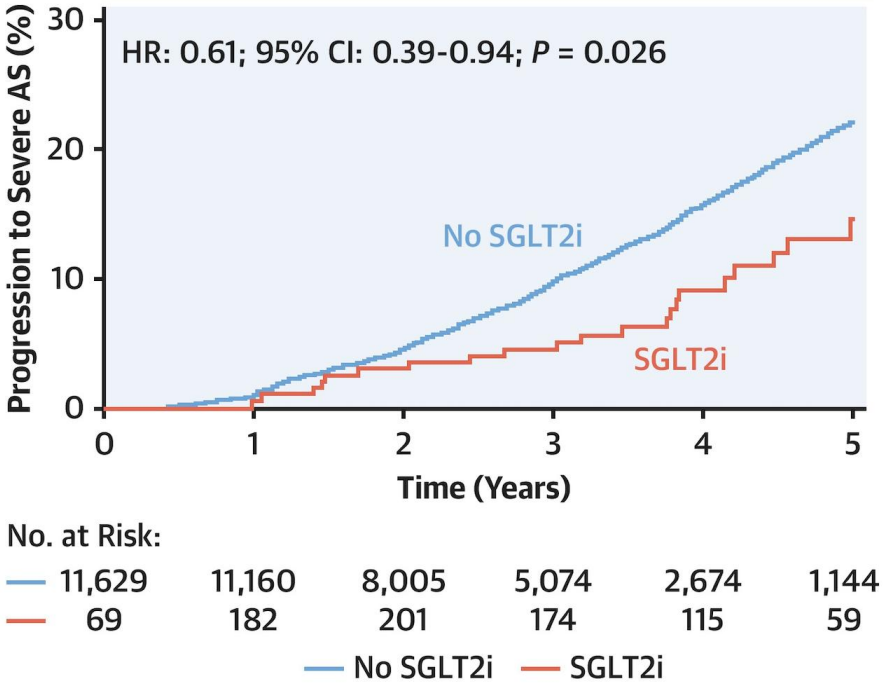
Yale New Haven Health System,
January 2016 to September 2022

Recent SGLT2i initiators (n = 458) vs Non-SGLT2i users (n = 11,240)

No differences between groups in baseline AS severity

SGLT2i patients were younger with higher rates of diabetes, chronic kidney disease, coronary artery disease, and heart failure, which are all associated with more rapid AS progression

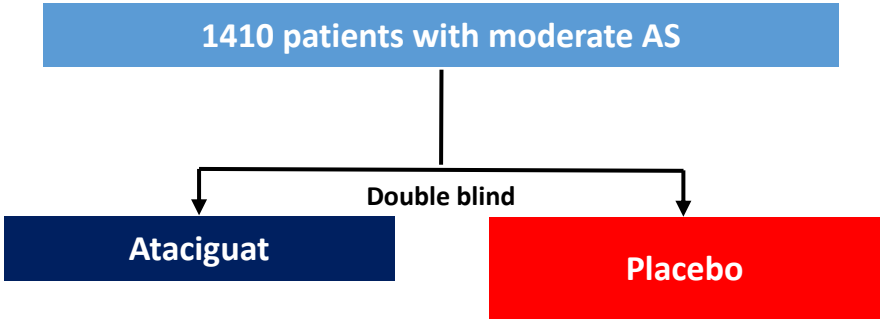
Progression to Severe AS



Tayyab Shah et al. *J Am Coll Cardiol Intv* 2025; 18:738-748

Prevention of Progression of Aortic Stenosis

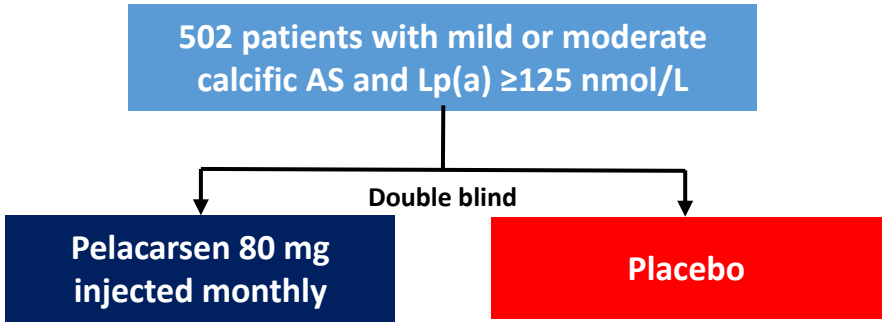
Reactivation of Oxidized Guanylate Cyclase



Primary outcome
Part A: Change in Aortic Valve Calcium (AVC) from baseline to Week 24 Part B: Percent change in AVA as measured by echocardiogram from baseline to Week 48 Part C: Change in peak VO2 from baseline to Week 48

NCT07001800

Lipoprotein(a) Lowering



Primary outcome	
Change in peak aortic jet velocity at 36 months	**Change in aortic valve calcium score at 36 months**

NCT05646381

SUMMARY The Future of TAVI

- *Procedural optimization:* **technological refinement** of THV systems; **AI tools** to assess anatomical risk and refine patient selection; optimization of THV; minimalist approach & **streamlined patient pathways**.
- *Postprocedural care:* early discharge, medical management
- *Strategic transformation:* **tailored timing of intervention** for multivalve disease; refined management of patients with AS and CAD; timing of intervention
- ***Expansion of indications****:* BAV, pure native AR; aortic dissection
- *Global* ***accessibility*** in less affluent geographies
- *Cultural change:* evolution of a **chimeric speciality**
- And maybe there will be a future when TAVI will no longer be needed at all.