KOCAELİ
ÜNİVERSİTESİ

When is the right time for SAVR or TAVI?

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Potential Conflicts of Interest

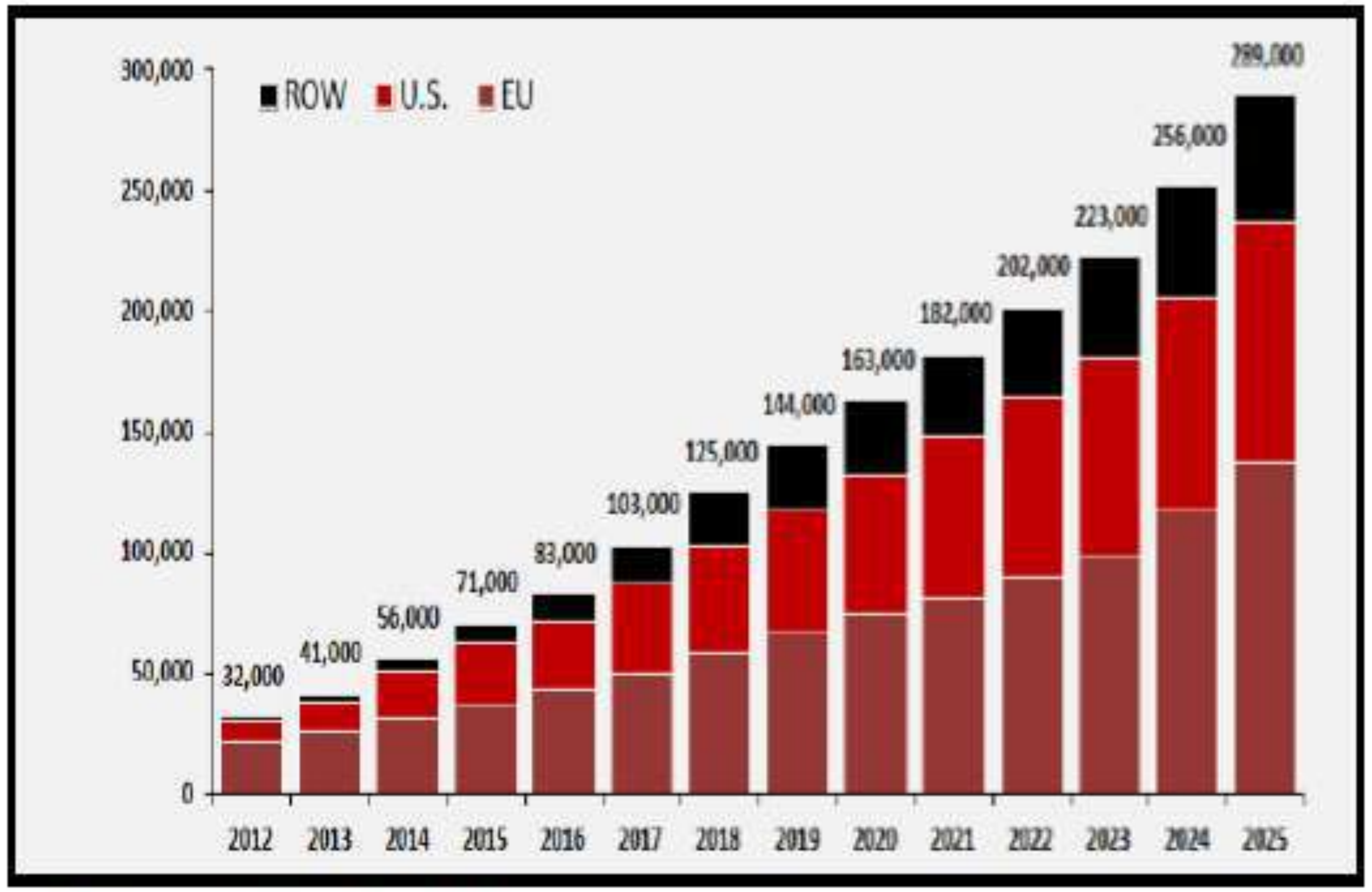
Speaker's Name: Prof Teoman Kilic, MD, FESC

✓ Proctorship for:

- Meril Lifesciences:TAVI
- Medtronic:TAVI
- Abbott: Structural Heart and Congenital Interventions
- Occlutech: Structural Heart and Congenital Interventions

TAVI HISTORY

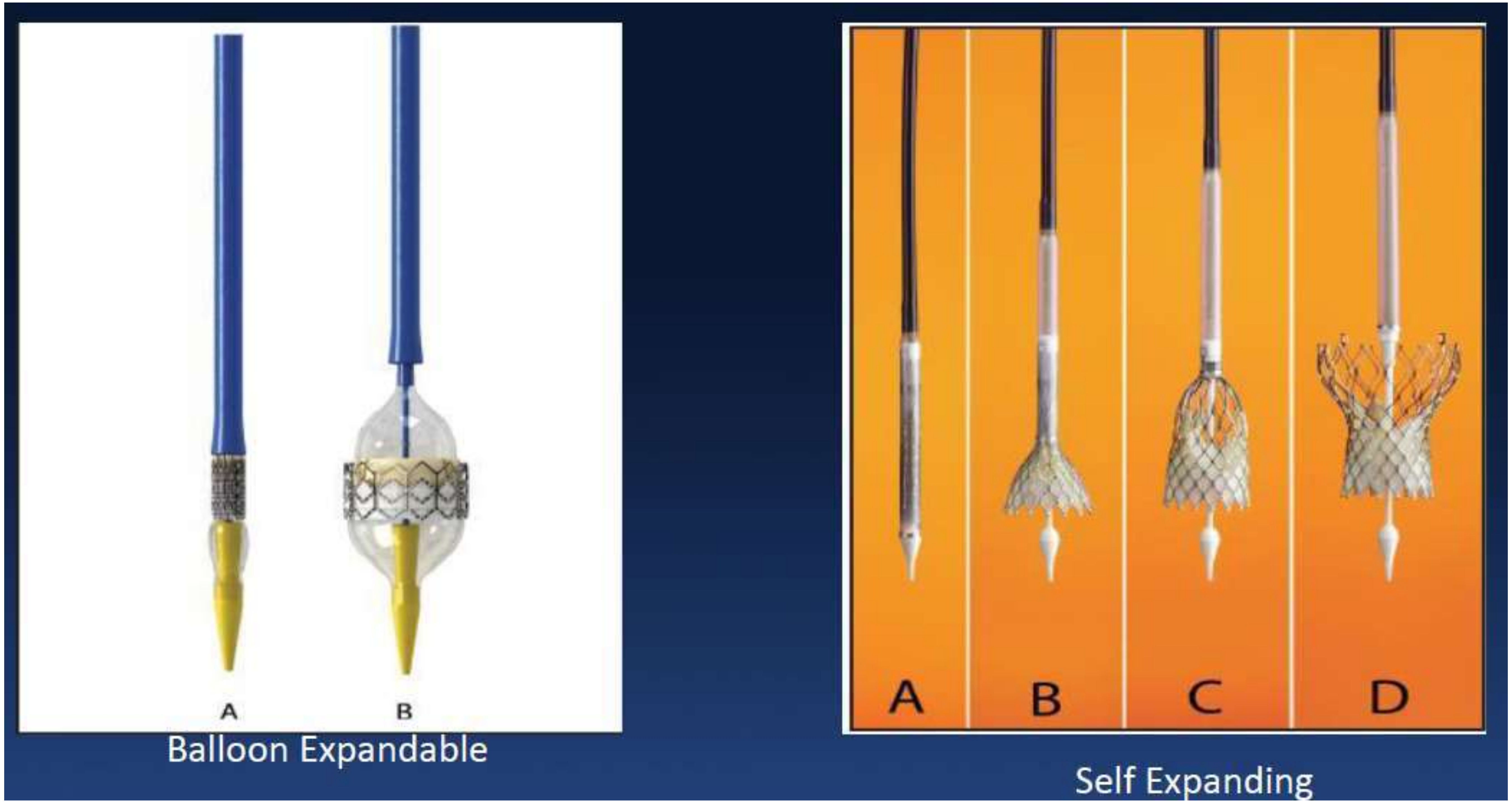
1992		2002	2010	2016
Proof of TAVR Concept in Animals		First TAVR in Humans	PARTNERS Trial of TAVR published	TAVR is routine clinical practice



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

In the next 10 years, TAVI will grow X4

A LOT OF TAVI PROCEDURES WERE DONE WITH OLD GENERATION VALVES



LESSONS LEARNED FROM OLD GENERATION DEVICES

TAVI: A REVOLUTIONIST THERAPY

Journal of Geriatric Cardiology (2017) 14: 204–217

Review · **Open Access** ·

Transcatheter aortic valve implantation: a revolution in the therapy of elderly and high-risk patients with severe aortic stenosis

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Abstract

Transcatheter aortic valve implantation (TAVI) represents a real revolution in the field of interventional cardiology for the treatment of elderly or high-risk surgical patients with severe symptomatic aortic valve stenosis. Today, TAVI seems to play a key and a reliable role in the treatment of intermediate and maybe low-risk patients with severe aortic stenosis. TAVI has also evolved from a complex and hazardous procedure into an effective and safe therapy by the development of new generation devices. This article aims to review the background and future of TAVI, clinical trials and registries with old and new generation TAVI devices and to focus on some open issues related to post-procedural outcomes.

J Geriatr Cardiol 2017; 14: 204–217. doi:10.11909/j.issn.1671-5411.2017.03.002

Keywords: High risk patients; The elderly; Transcatheter aortic valve implantation

TAVI IS SUPERIOR IF TRANSFEMORAL WAY IS USED!

CURRENT OPINION

Latest evidence on transcatheter aortic valve implantation vs. surgical aortic valve replacement for the treatment of aortic stenosis in high and intermediate-risk patients

Fabien Praz[a,], George C.M. Siontis[a,*], Subodh Verma[b], Stephan Windecker[a], and Peter Jüni[c]*

Purpose of review
The goal of this review is to summarize the current evidence supporting the use of transcatheter aortic valve implantation (TAVI) in high and intermediate-risk patients. The focus is on the five randomized controlled trials comparing TAVI with surgical aortic valve replacement (SAVR) published to date, as well as two recent meta-analyses.

Recent findings
TAVI has profoundly transformed the treatment of elderly patients presenting with symptomatic severe aortic stenosis. In experienced hands, the procedure has become well tolerated and the results more predictable. So far, two trials using two different devices [Placement of Aortic Transcatheter Valve (PARTNER) 1A and US CoreValve High Risk] have shown that TAVI is able to compete in terms of mortality with SAVR in high-risk patients. These findings have been extended to the intermediate-risk population in two recently published randomized controlled trials [PARTNER 2 and Nordic Aortic Valve Intervention (NOTION)]. The two meta-analyses suggested improved survival in both high and intermediate-risk patients during the first 2 years following the intervention. The survival benefit was only found in patients treated via the transfemoral access, and appeared more pronounced in women.

Summary
Individual randomized trials enrolling high and intermediate-risk patients have established the noninferiority of TAVI in comparison with SAVR, whereas subsequent meta-analyses suggest superiority of transfemoral TAVI in terms of a sustained survival benefit 2 years after valve implantation irrespective of the surgical risk category. The benefit of TAVI appears more pronounced in women than in men.

Keywords
aortic valve replacement, meta-analysis, surgical aortic valve replacement, transcatheter aortic valve implantation, transcatheter aortic valve replacement

SURVIVAL BENEFIT WAS ONLY FOUND WITH TRANSFEMORAL TAVI

3 Overview of old and new generation transcatheter aortic valves

After the first-in-man case performed in 2002 by Cribier, *et al.*,[5] more than 120,000 TAVI procedures were done worldwide with the chronologically first CE-marked devices: balloon expandable Edwards SAPIEN™/SAPIEN XT™ (Edwards Lifesiences, Irvine, CA, USA) and self expandable Medtronic CoreValve® (Medtronic, Minneapolis, MN, USA).[6] During long-term follow-up (5 years), TAVI with these first generation devices was shown to be superior to medical treatment. Considering both high and intermediate-risk patients and all access routes, pooled randomized trials of these first generation devices show a 13% relative risk reduction of all-cause death in favor of TAVI compared with SAVR at 2-year follow-up. However, the survival benefit was only found with transfemoral TAVI and appeared more pronounced in women than in men.[7] A recent meta-analysis investigated the results of six studies with the usage of these first generation devices, 957 self-expandable valve (SEV) and 947 balloon-expandable valve (BEV, one randomized controlled trial and 5 observational studies). At 30 days follow-up, rates of death did not differ between self-expanding and balloon-expandable valves [odds ratio (OR): 0.74, 95% CI: 0.47–1.17], whereas

Kilic T et al. Journal of Geriatric Cardiology 2017; 14: 204-2017.

KEY POINTS

- Since its appearance in 2002, TAVI has profoundly transformed the treatment of elderly patients presenting with symptomatic severe aortic stenosis.
- During long-term follow-up (5 years), TAVI was shown to be superior to medical treatment.
- Considering both high and intermediate-risk patients and all access routes, pooled randomized trials show a 13% relative risk reduction of all-cause death in favour of TAVI compared with SAVR at 2-year follow-up.
- The survival benefit was only found with transfemoral TAVI and appeared more pronounced in women than in men.
- The estimated numbers needed to treat to prevent one death up to 2 years with transfemoral TAVI as compared with SAVR are 50, 25, and 13 in low, intermediate, and high-risk patients, respectively.

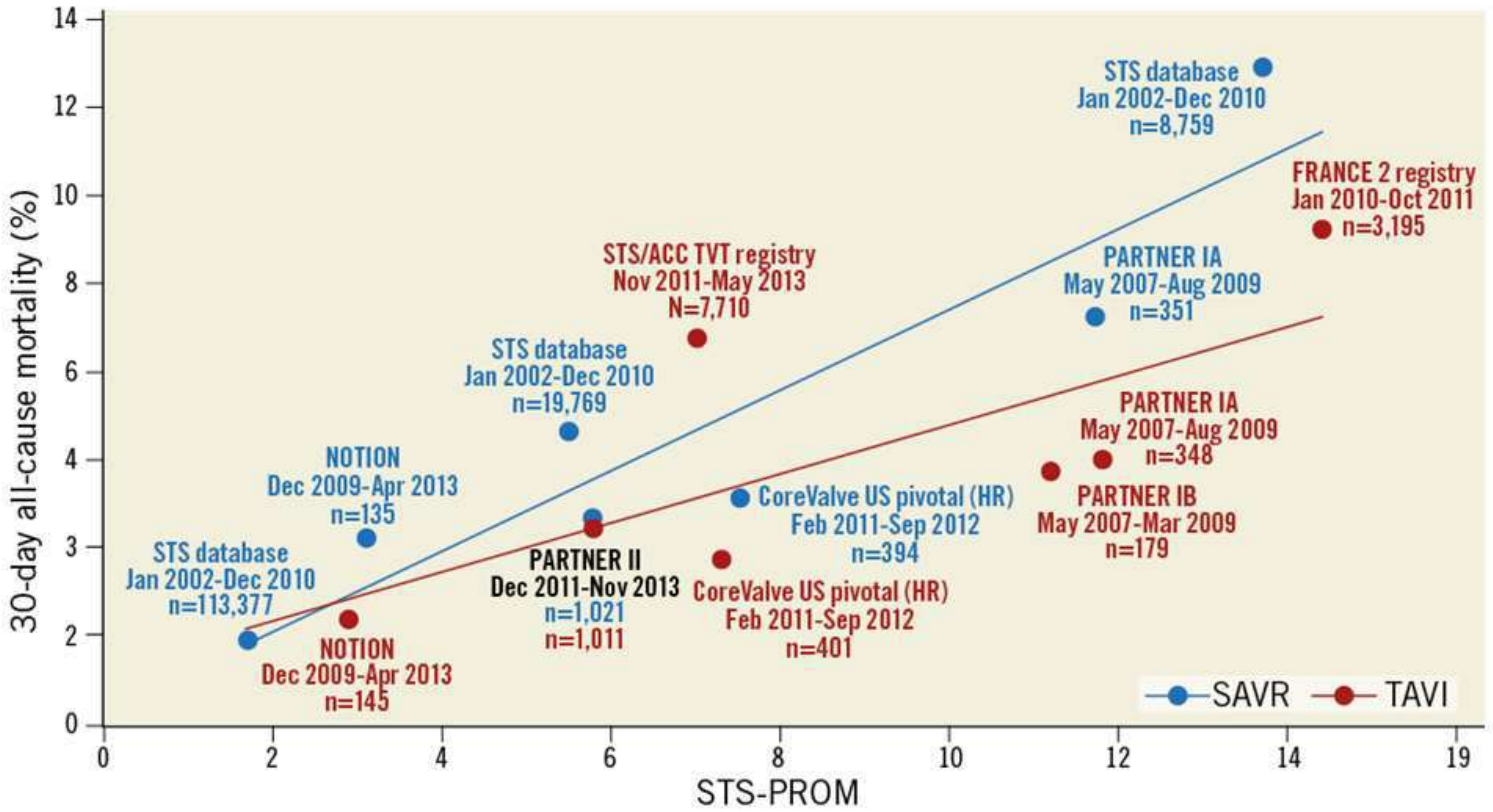
Praz F et al. Curr Opin Cardiol 2017; 32: 117-122.

LESSONS LEARNED FROM OLD GENERATION DEVICES

LIMITATIONS OF OLD GENERATION VALVES

- **PROCEDURAL**
  - TAVI COMPLICATIONS
    - Annulus rupture
    - Coronary occlusion
    - Ventricle rupture
    - Device embolization
- **EARLY PERIPROCEDURAL**
  - PERIPROCEDURAL EVENTS
    - Paravalvular leak
    - PPM
    - Vascular complications
    - Stroke
    - Early valve thrombosis
- **FOLLOW UP**
  - DURABILITY?

LESSONS LEARNED FROM TRIALS AND REGISTRIES



STS database: Thourani et al - *Ann Thorac Surg.* 2015;99:55-61; **NOTION:** Thyregod et al - J Am Coll Cardiol. 2015;65:2184-94; **PARTNER II:** Leon et al - *N Engl J Med.* 2016;374:1609-20; **STS/ACC TVT registry:** Mack et al - *JAMA.* 2013;310:2069-77; **US pivotal (HR):** Adams et al - *N Engl J Med.* 2014;370:1790-8; **PARTNER IB:** Leon et al - *N Engl J Med.* 2010;363:1597-607; **PARTNER IA:** Smith et al - *N Engl J Med.* 2011;364:2187-98

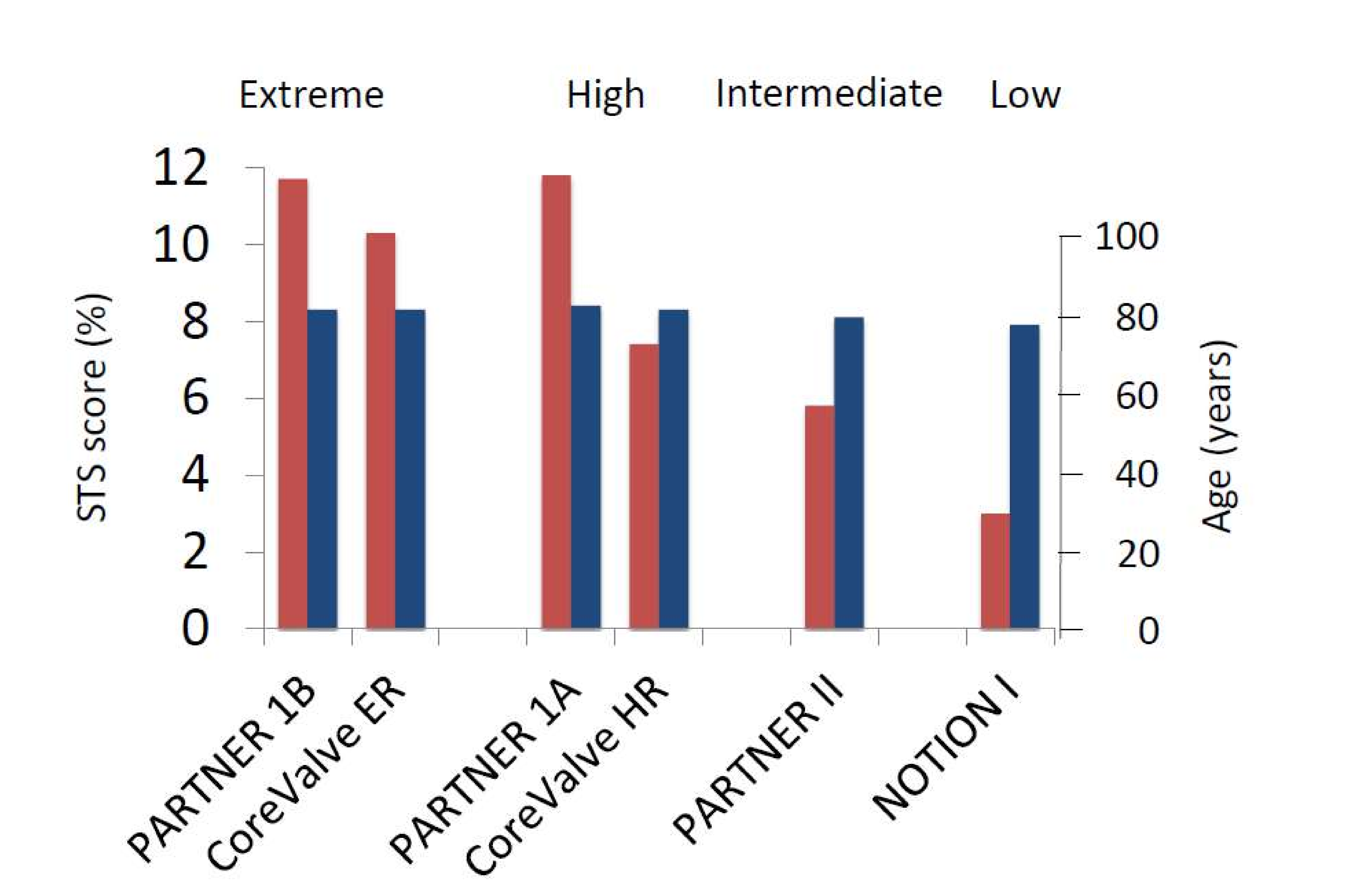
RISK SCORING SYSTEMS FOR TAVI

- Everybody knows;
  - STS
  - Eurocore
  - Logistic Euroscore

- Fragility?
- Chest deformity?
- Malnutrition?
- Porcelain aorta?
- Liver disease?
- Previous radiotherapy?

RANDOMISED CLINICAL TRIALS

Mean age: 80!!!



LIMITATIONS OF RISK SCORES

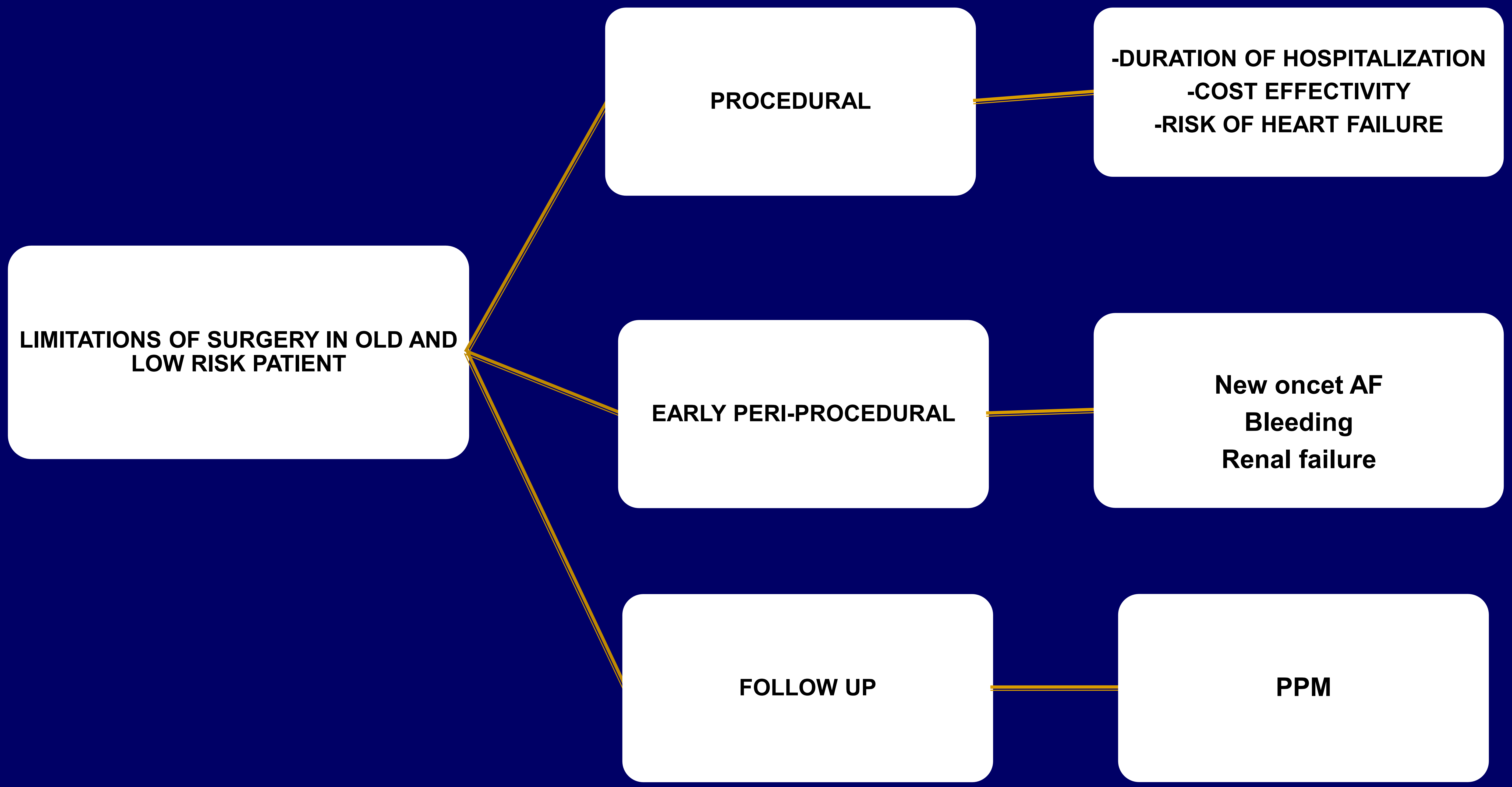
- 85 Years old Man
- Severe aortic stenosis
- No risk factors
- STS score 1.6%

- -> This patient goes to TAVI in many centers

IN REAL PRACTICE, WHAT WE UNDERSTAND FROM LOW RISK ?

OLD AND YOUNG PATIENTS

LIMITATIONS OF SURGERY IN PATIENTS WITH OLDER AGE WITH LOW RISK



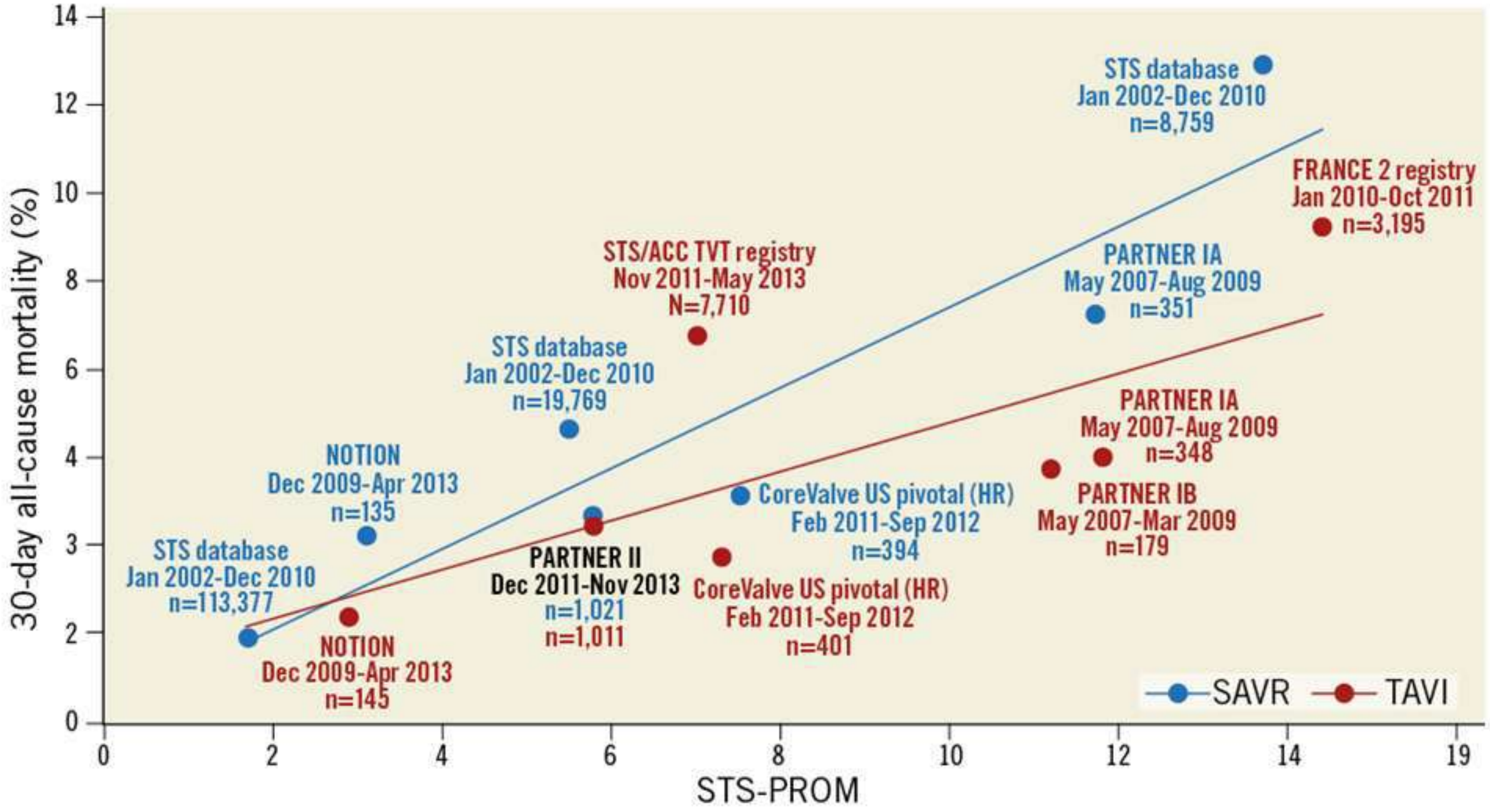
LIMITATIONS OF TAVI IN YOUNG PATIENTS

LIMITATIONS OF TAVI IN YOUNG PATIENTS

- PROCEDURAL
  - COMPLICATIONS OF TAVI
    - Anulus rupture
    - Rısk of coronary oclusıon
    - Risk of ventricular rupture
    - Device embolization
- EARLY PERI-PROCEDURAL
  - PVL
  - PACEMAKER
  - VASCULAR COMPLICATIONS
  - STROKE
  - EARLY VALVE THROMBOSIS
- FOLLOW UP
  - CORONARY REACCESS
  - DURABILITY
  - VALVE IN VALVE TAVI

BICUSPID AORTA
Aortopathy!!!

TAVI VS SURGICAL AVR



STS database: Thourani et al - *Ann Thorac Surg.* 2015;99:55-61; **NOTION:** Thyregod et al - J Am Coll Cardiol. 2015;65:2184-94; **PARTNER II:** Leon et al - *N Engl J Med.* 2016;374:1609-20; **STS/ACC TVT registry:** Mack et al - *JAMA.* 2013;310:2069-77; **US pivotal (HR):** Adams et al - *N Engl J Med.* 2014;370:1790-8; **PARTNER IB:** Leon et al - *N Engl J Med.* 2010;363:1597-607; **PARTNER IA:** Smith et al - *N Engl J Med.* 2011;364:2187-98

TENDENCY TO DO TAVI IN YOUNG AND LOW RISK PATIENTS

- Anatomy transfemoral? Can we achieve surgical like result?
- Paravalvular leak is mild OK?
- LBBB or pacemaker benign?
- Prosthesis patient mismatch does it matter?
- Coronary reaccess for CAD straightforward?
- Lifetime management of aortic valve disease, reintervention feasible?

WHAT IS IMPORTANT IF WE WILL DO TAVI TO LOW RISK & YOUNGER PATIENTS?

Safety
- 0 stroke, 0 complications

Early recovery with no long term adverse events
- Low incidence of new onset LBBB and no PPM

Lifetime management
- Good hemodynamic results
- Durability
- Appropriate implantation of the valve allowing future coronary access (Comissural alignment)
- Providing the ability to perform Redo TAVI

CRF

TCT

OCTOBER 23–26, 2023
MOSCONE CENTER
SAN FRANCISCO, CA

2023 PCR london valves

Five-Year Clinical and Echocardiographic Outcomes from the Partner 3 Low-risk Randomized Trial

Martin B. Leon and Michael J. Mack

on behalf of the Partner 3 Investigators

PCR

EAPCI
European Society of Cardiology

MAIN RESULTS-I

In low-risk severe symptomatic AS patients, treated with either SAPIEN 3 TAVR or Surgery, over 5 years follow-up:

- **BOTH** TAVR and Surgery were associated with similar and low clinical event rates (CV death ~1%/yr, all stroke ~1%/yr, and CV rehospitalization ~3%/yr).
- Differences in the primary composite endpoint rate, which favored TAVR at 1-year, were attenuated after 5 years (Δ 7.1% to Δ 4.3%).
- Other important endpoints were either similar for both therapies (new PM and reintervention), favored TAVR (new AF and serious bleeding), or favored Surgery (mild PVR and valve thrombosis).

MAIN RESULTS-II

- The improvements in antegrade valve hemodynamics were maintained for both therapies at 5 years.
- VARC-3 bioprosthetic valve failure and SVD were similar and infrequent with both therapies (BVF - TAVR 3.3% and Surgery 3.8%; SVD - TAVR 4.2% and Surgery 3.8%), encouraging signs for favorable valve durability; 10-year follow-up is planned.
- Marked 1-year improvements in patient-reported outcomes (esp. KCCQ scores) were maintained and similar for both therapies.

2023 PCR london valves

The Evolut Low Risk Trial: 4 Year Outcomes

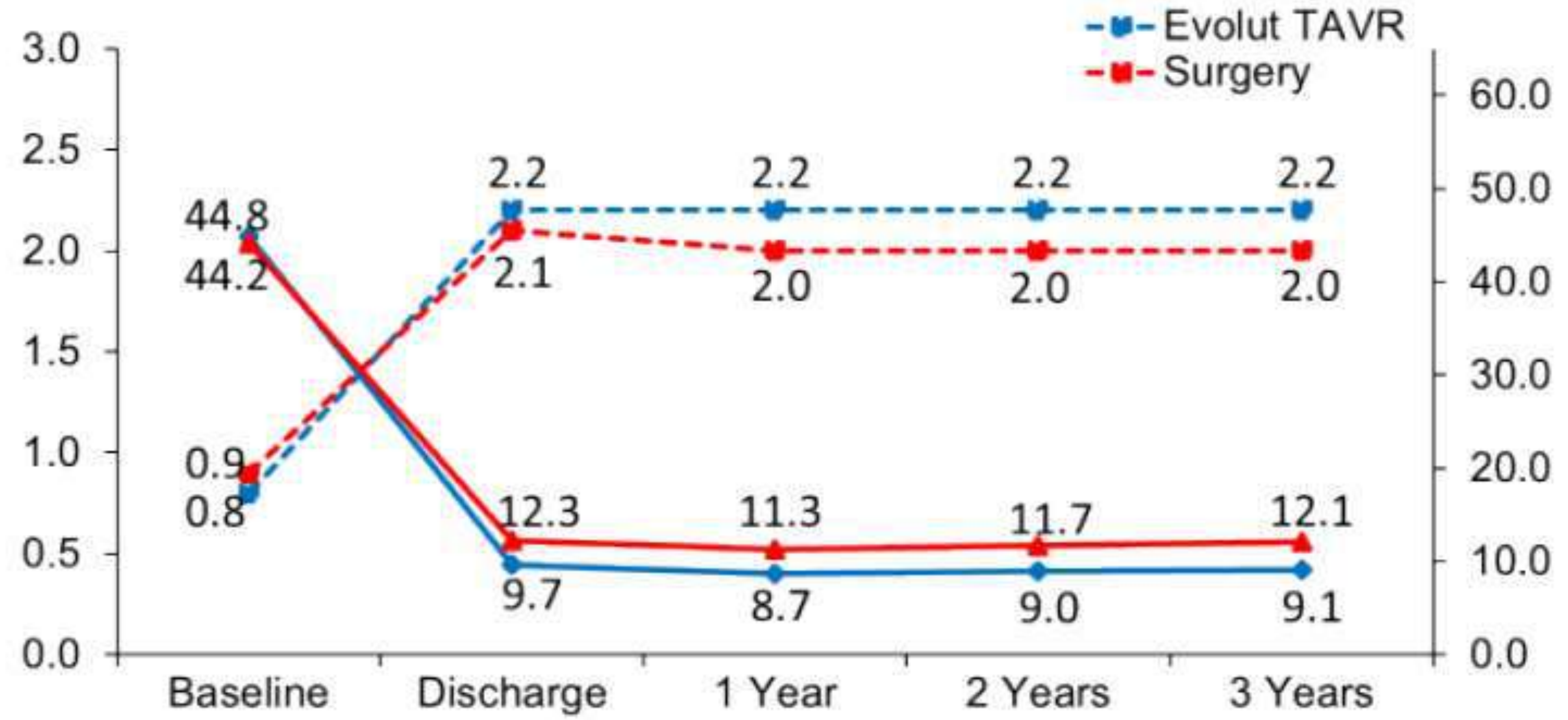
Michael J. Reardon, MD
Methodist DeBakey Heart and Vascular Center, Houston, TX
On behalf of the Evolut Low Risk Trial Investigators

PCR EAPCI European Society of Cardiology

Background | Low Risk Three-Year Haemodynamics

Evolut™ Low Risk Trial

Significantly better MG and EOA with Evolut TAVR at all follow-up timepoints (p < 0.01)



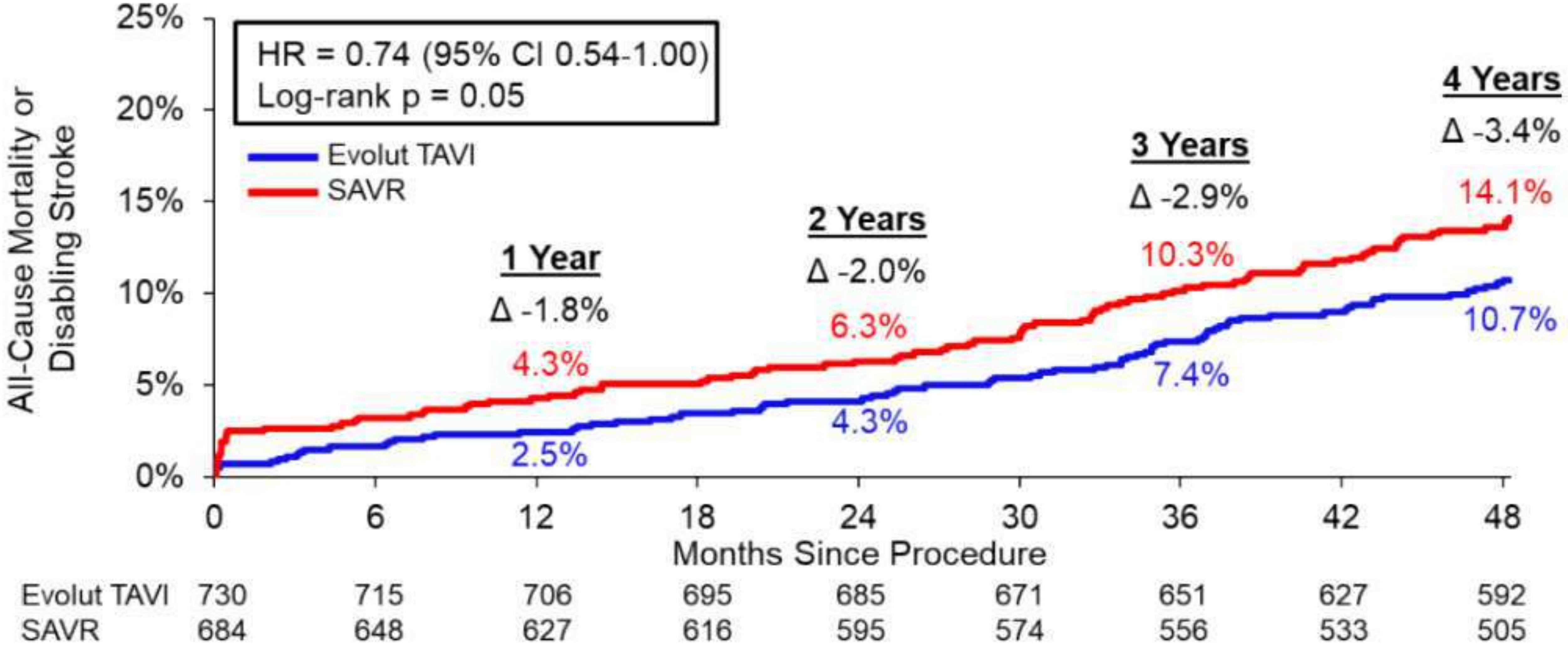
No. of patients	Baseline	Discharge	1 Year	2 Years	3 Years
TAVR EOA	637	576	565	535	493
Surgery EOA	596	406	525	434	396
TAVR MG	717	703	662	607	547
Surgery MG	679	632	597	514	456

Forrest et al. Transcatheter vs. Surgical Aortic Valve Replacement in Low Risk Patients: 3-year Outcomes from the Evolut Low Risk trial. Presented at ACC 2023 in New Orleans, LA.
Forrest et al. J Am Coll Cardiol 2023; 81(17): 1663-1674

Four-Year Results | Primary Endpoint

Evolut™ Low Risk Trial

26% Relative Reduction in Hazard for Death or Disabling Stroke (p = 0.05) with Evolut TAVI vs SAVR and the Curves Continue to Separate Over Time



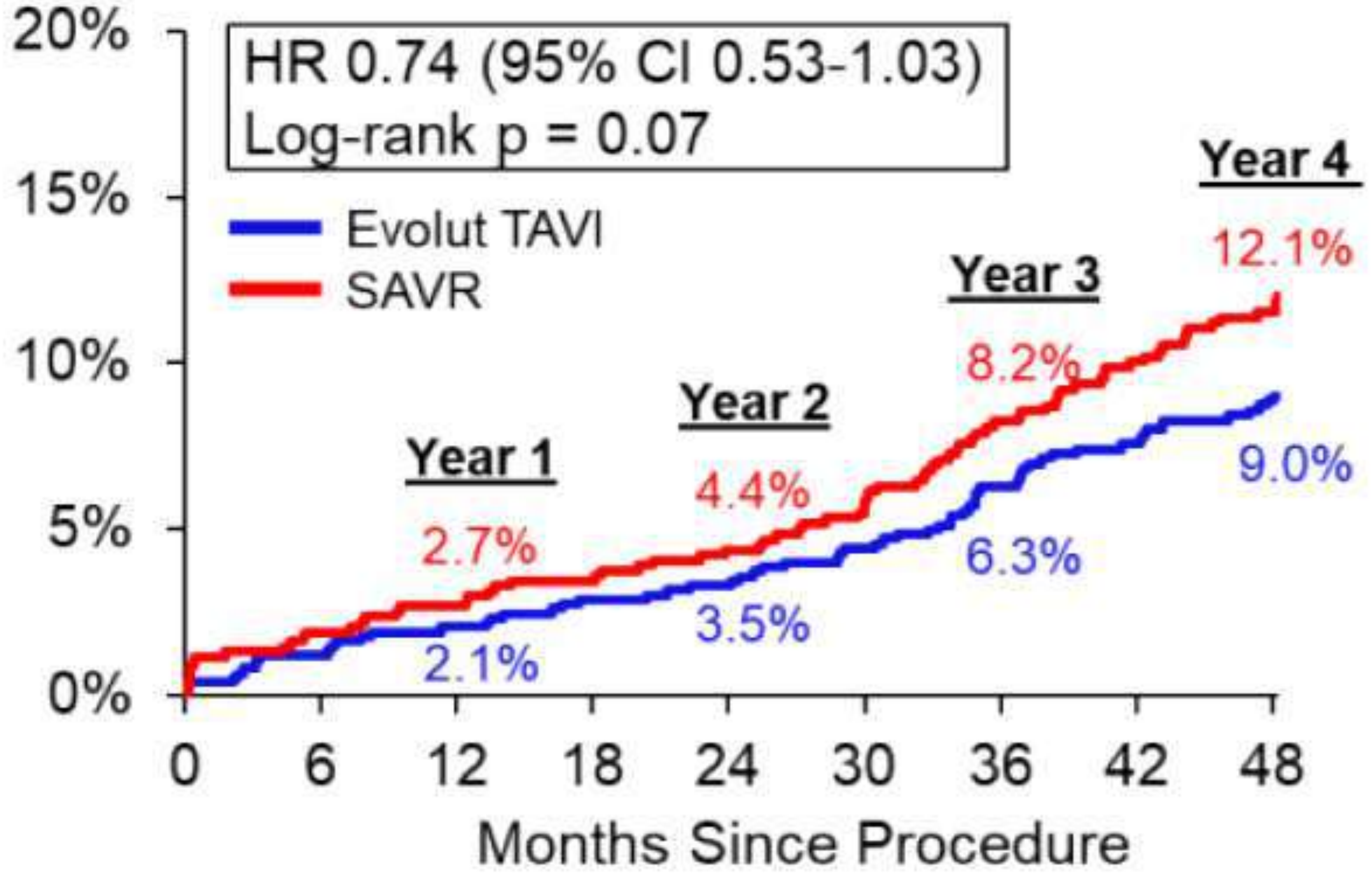
[1]Reardon et al. Four-year outcomes from the Evolut Low Risk trial. Presented at TCT 2023 in San Francisco, CA.
[2]Forrest et al. 4-year outcomes of patients with aortic stenosis in the Evolut Low Risk Trial. *J Am Coll Cardiol* 2023.

Four-Year Results | Primary Endpoint Components

Evolut™ Low Risk Trial

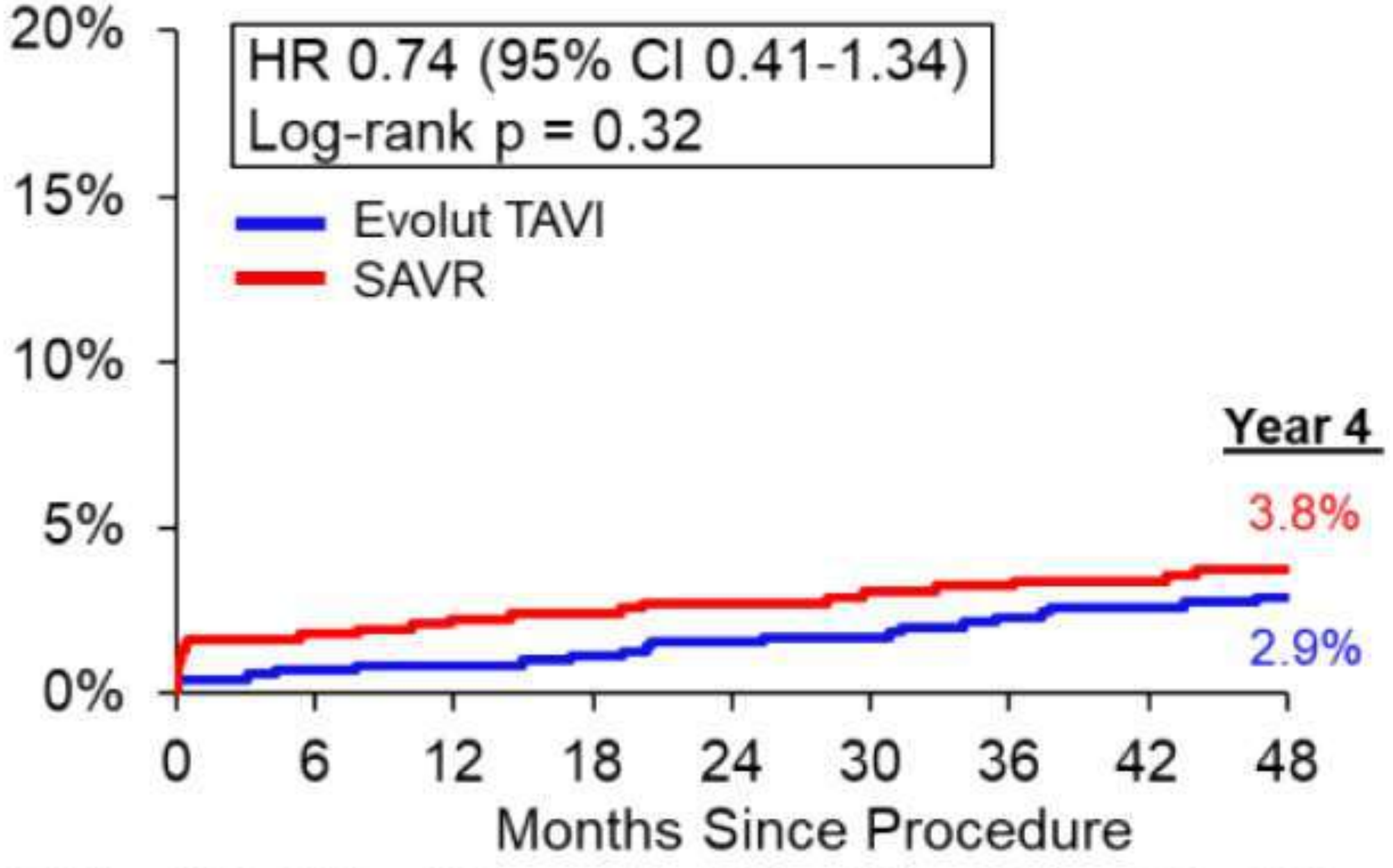
Observed Differences in the Primary Endpoint Driven by Death

All-Cause Mortality



TAVI	730	718	709	699	691	678	659	636	603
SAVR	684	656	636	624	605	585	567	542	516

Disabling Stroke



TAVI	730	715	706	695	685	671	651	627	592
SAVR	684	648	627	616	595	574	556	533	505

Bioprosthetic Valve Performance at 4 Years

Evolut™ Low Risk Trial

Significantly Less Mean Gradient ≥ 20 mmHg and Severe PPM with Evolut TAVI vs SAVR

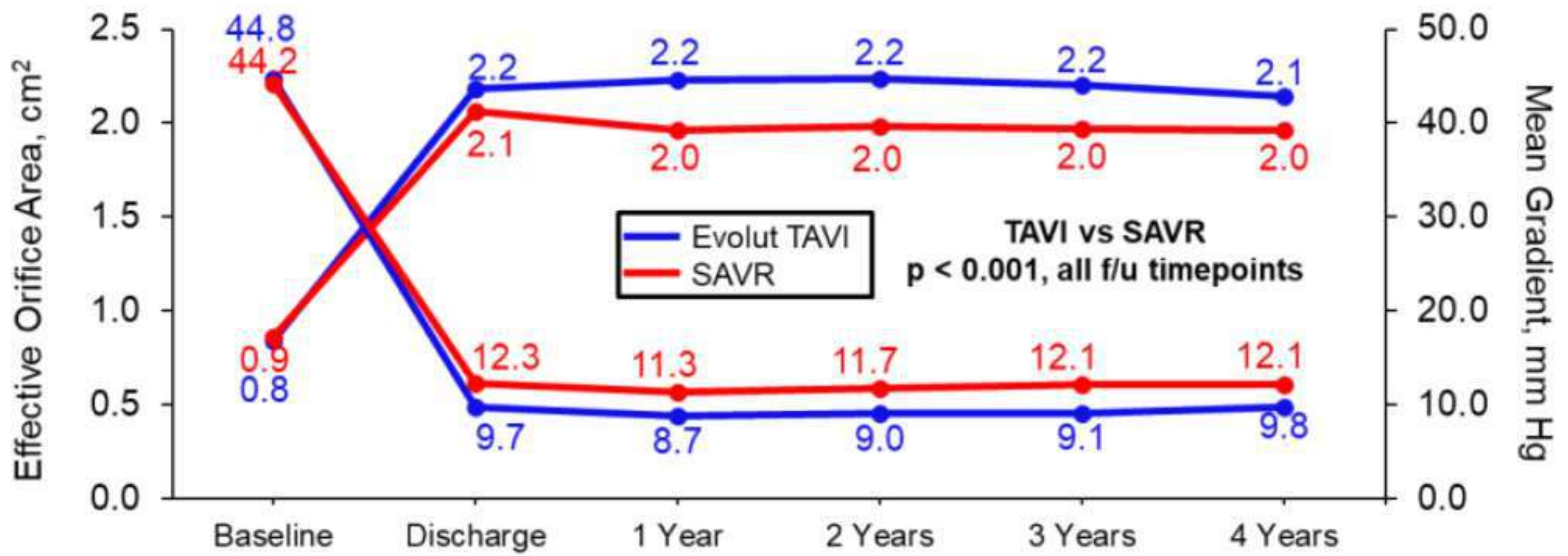
Parameter	Evolut TAVI	SAVR	P Value
Mean gradient ≥ 20 mm Hg[a]	**4.0 (20/497)**	**8.9 (39/438)**	**0.002**
Severe PVR[a], %	0.0 (0/496)	0.0 (0/426)	N/A
Severe PPM (VARC-3)[a], %	**1.1 (7/611)**	**3.5 (19/549)**	**0.008**
Valve endocarditis[b], %	0.9 (6)	2.2 (13)	0.06
Clinical or subclinical valve thrombosis[b], %	0.7 (5)	0.6 (4)	0.84
Clinical thrombosis, %	0.3 (2)	0.2 (1)	0.61
Subclinical thrombosis, %	0.4 (3)	0.5 (3)	0.91

[a]Non-cumulative data based on the 4-year (MG, PVR) or 30-day (PPM) echo, reported as proportion % (n), and compared by chi-square test. [b]Cumulative rates reported as Kaplan-Meier estimates % (n) and compared by log-rank test.
PPM = patient-prosthesis mismatch; PVR = paravalvular regurgitation

Comparative Haemodynamics at 4 Years

Evolut™ Low Risk Trial

Significantly Better Haemodynamics with Evolut TAVI vs SAVR



No. of Patients	Baseline	Discharge	1 Year	2 Years	3 Years	4 Years
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SAVR EOA	596	406	525	434	397	372
TAVI MG	717	703	662	607	547	497
SAVR MG	679	632	597	514	457	438

The DEDICATE-DZHK6 trial

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

Transcatheter or Surgical Treatment of Aortic-Valve Stenosis

Blankenberg S et al. DOI: 10.1056/NEJMoa2400685

CLINICAL PROBLEM

In patients with severe aortic-valve stenosis and low surgical risk, both transcatheter aortic-valve implantation (TAVI) and surgical aortic-valve replacement (SAVR) may be appropriate. However, insufficient evidence exists regarding a comparison of these two strategies in a real-world setting.

CLINICAL TRIAL

Design: A multicenter, unblinded, randomized trial in Germany examined whether TAVI would be noninferior to SAVR in patients with severe, symptomatic aortic-valve stenosis who were eligible for both procedures.

Intervention: 1414 patients ≥65 years of age who were at low or intermediate surgical risk and were eligible for TAVI or SAVR were assigned to one of the two procedures. Transcatheter and surgical valve devices were chosen by the patient's heart team. The primary outcome was a composite of death from any cause or fatal or nonfatal stroke at 1 year.

RESULTS

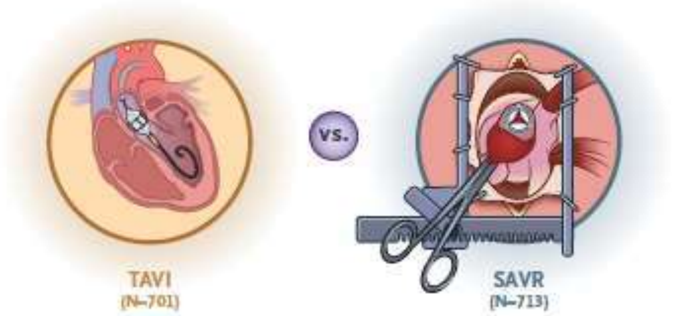
Efficacy: TAVI was noninferior to SAVR with respect to the composite of death or stroke.

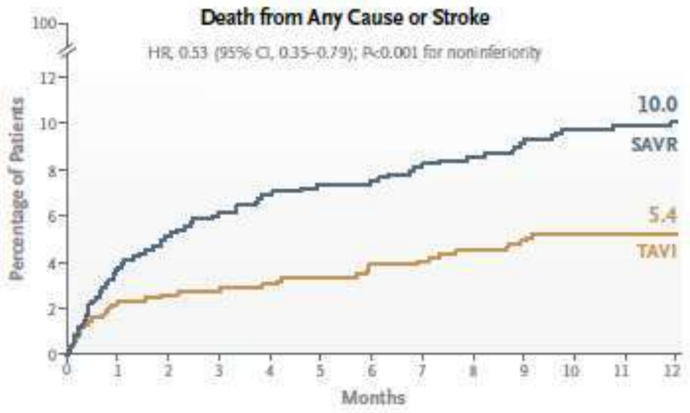
Safety: Patients in the TAVI group were less likely than those in the SAVR group to have major or life-threatening bleeding and were more likely to have vascular access-site complications.

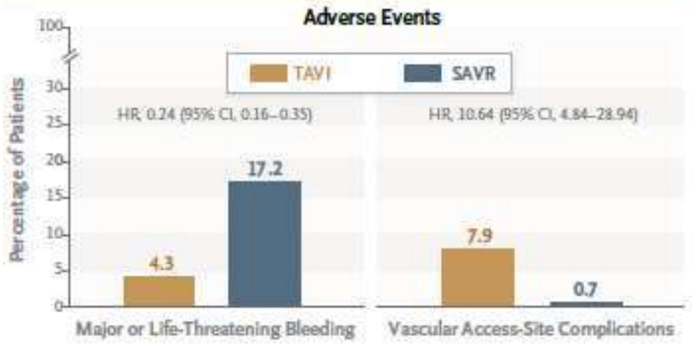
LIMITATIONS AND REMAINING QUESTIONS

- The findings were limited to 1 year of follow-up, so the results cannot be extrapolated to long-term outcomes; the primary outcome will be reevaluated at 5 years.
- 70 patients who were assigned to SAVR were treated with TAVI, usually at the patient's request.
- Patients with bicuspid aortic valves or the need for concomitant surgical procedures were excluded from the trial.

Links: Full Article | NEJM Quick Take | Editorial







CONCLUSIONS

In patients with severe, symptomatic aortic-valve stenosis and low or intermediate surgical risk, TAVI was noninferior to SAVR with respect to a composite outcome of death or stroke at 1 year.

The DEDICATE-DZHK6 trial showed that among low to intermediate risk patients, TAVI is noninferior to SAVR regarding all-cause mortality and stroke.

Principal Findings:

- The primary outcome (all-cause death or stroke) at 1 year was 5.4% in the TAVI group vs. 10.0% in the SAVR group (p for noninferiority < 0.001).

Secondary outcomes:

- All-cause mortality: 2.6% in the TAVI group vs. 6.2% in the SAVR group
- Disabling stroke: 1.3% in the TAVI group vs. 3.1% in the SAVR group
- Atrial fibrillation: 12.4% in the TAVI group vs. 30.8% in the SAVR group
- Major or life-threatening bleeding: 4.3% in the TAVI group vs. 17.2% in the SAVR group
- At least moderate aortic regurgitation: 2.8% in the TAVI group vs. 1.0% in the SAVR group

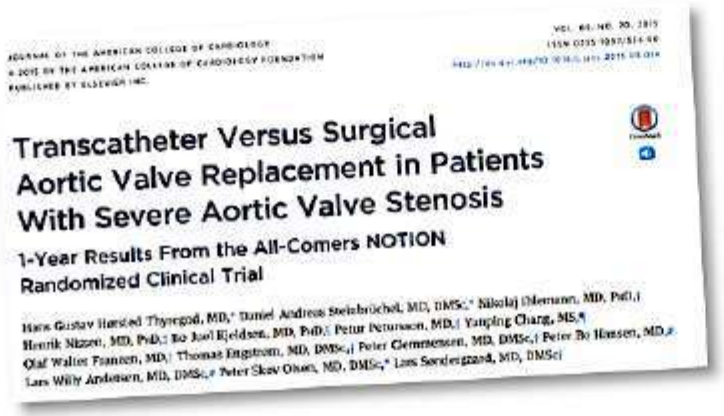
Interpretation:

- Among low to intermediate risk patients with symptomatic severe aortic stenosis, TAVI was noninferior to SAVR.
- TAVI was associated with a lower incidence of all-cause mortality or stroke at 12 months compared with SAVR.
- The incidence of stroke was low in the TAVI group (1.3%) despite infrequent use of cerebral embolic protection.
- Atrial fibrillation and major or life-threatening bleeding was more frequent in the SAVR group.
- In the TAVI group, approximately two-thirds of participants were treated with a balloon-expandable valve.

- This is an important non–industry-sponsored trial, which adds to a growing body of evidence supporting the expanding role of TAVI for treatment of aortic valve disease; however, results do not apply to patients with bicuspid aortic valve disease.

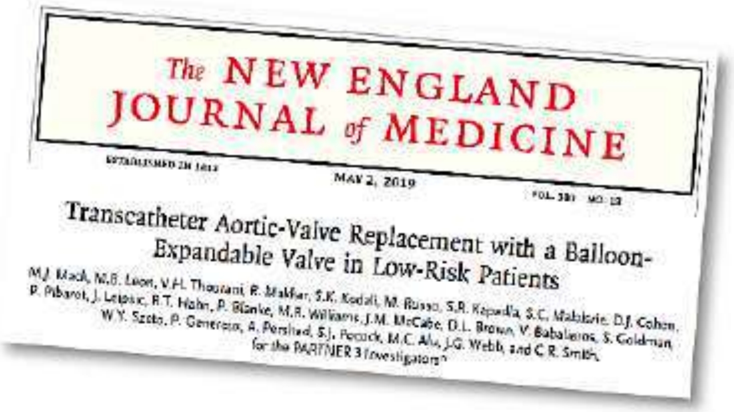
Current RCTs comparing TAVR with SAVR in low surgical risk patients

- Mainly included older patients (> 70-75 years)
- Excluded bicuspid aortic valves


Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis

1-Year Results From the All-Comers NOTION Randomized Clinical Trial

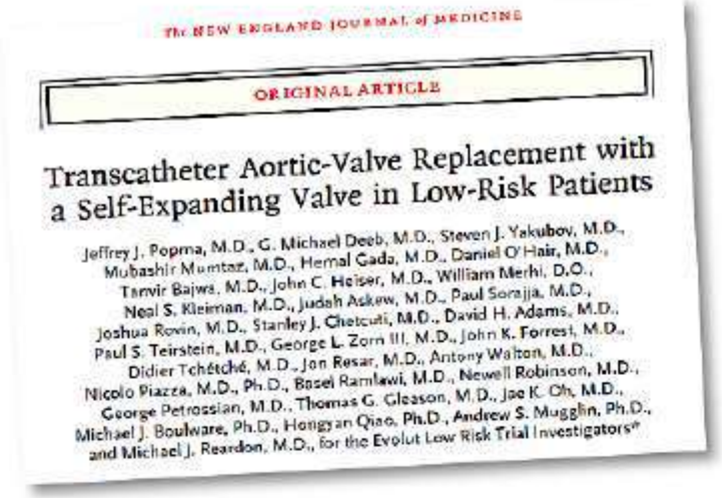
NOTION 1
2015


The NEW ENGLAND JOURNAL of MEDICINE

MAY 2, 2019

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

PARTNER 3
2019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ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Evolut Low Risk
2019


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter or Surgical Treatment of Aortic-Valve Stenosis

DEDICATE
2024

A Randomized Comparison of TAVR and SAVR in Low-Risk Patients Aged 70 years or Younger: Results from the NOTION-2 trial

Ole De Backer, MD, PhD

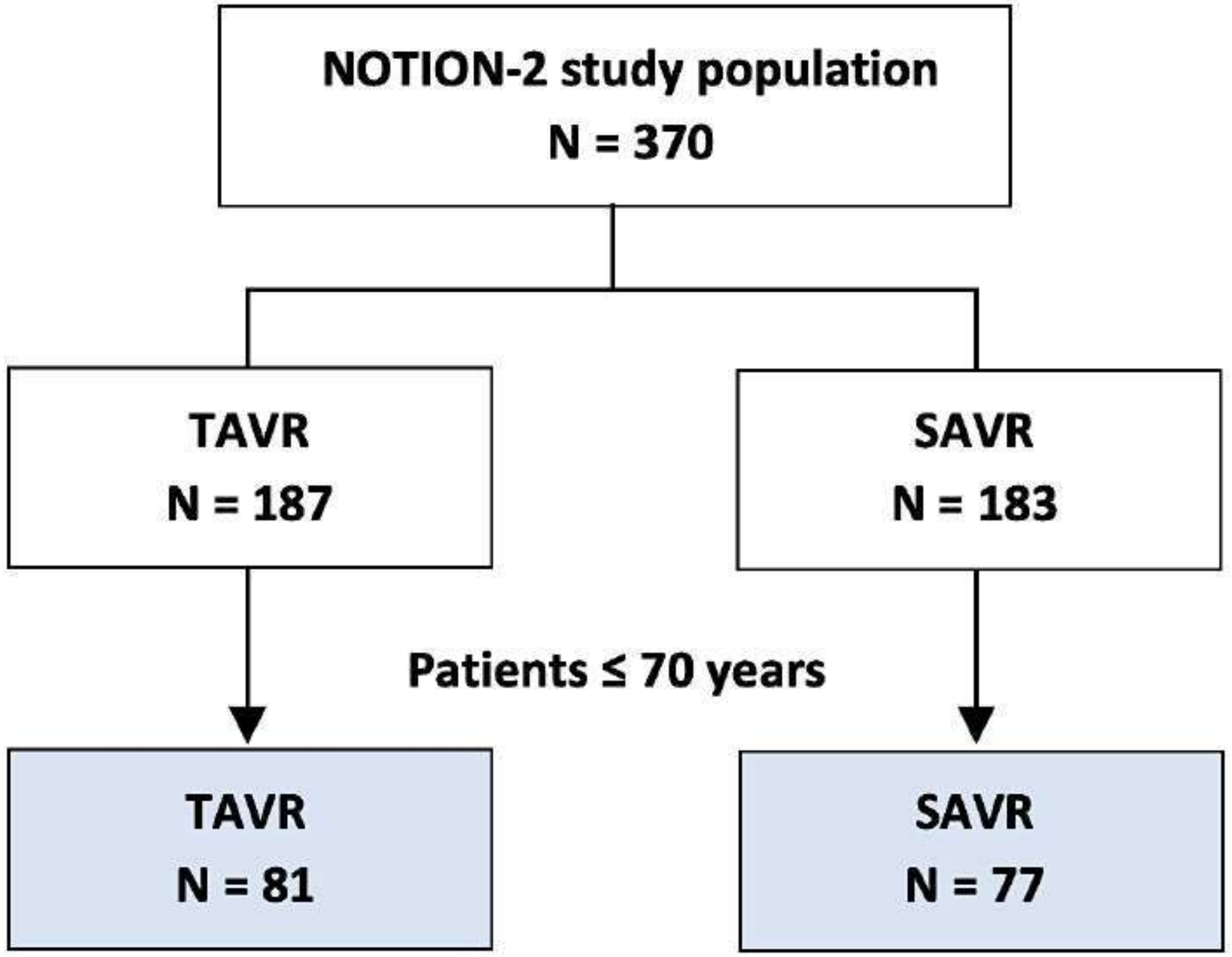
Rigshospitalet, Copenhagen - Denmark

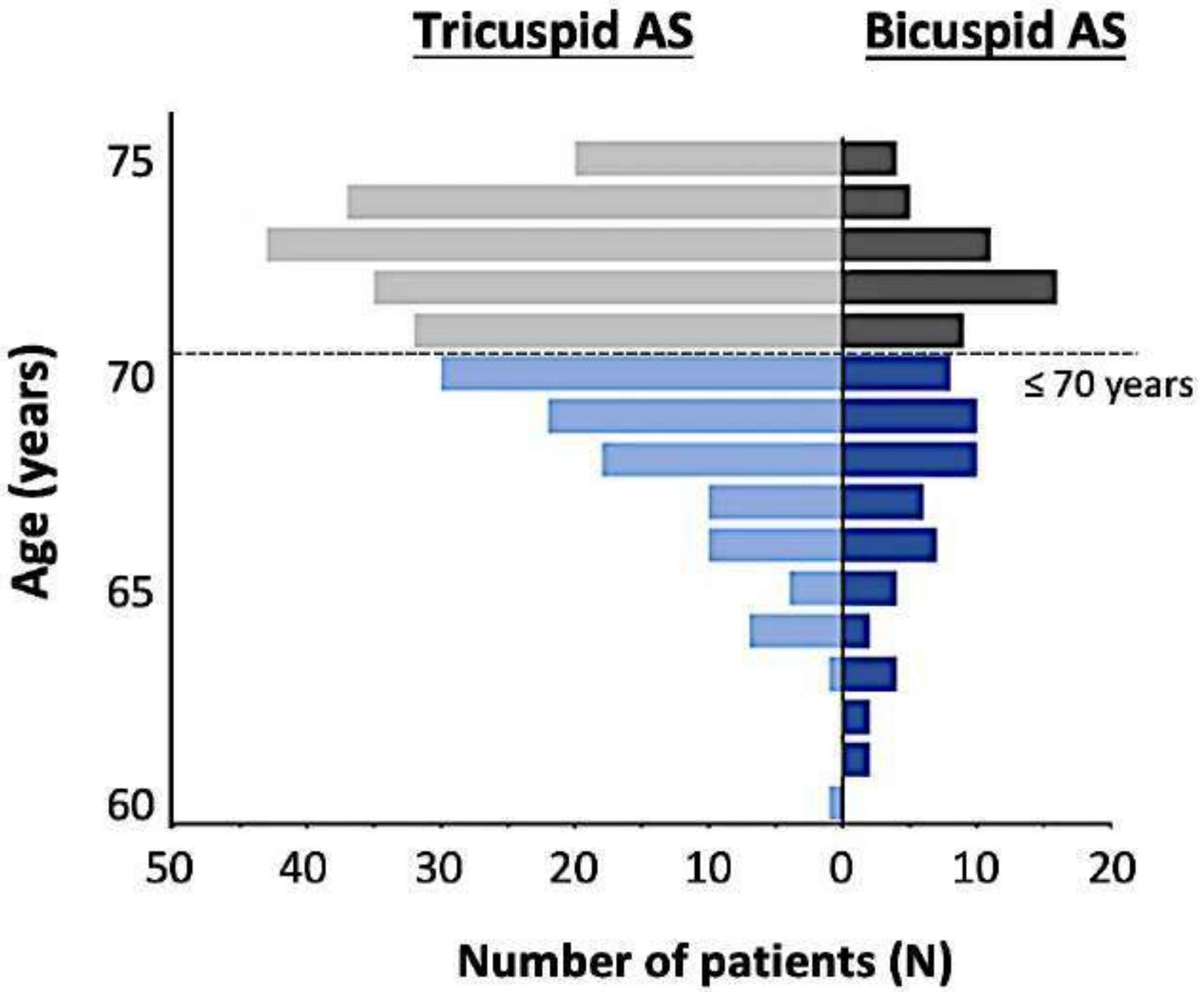
Low surgical risk patients with severe symptomatic aortic stenosis (AS) ≤ 75 years

1:1 randomization

- Stratified by gender, need for coronary revascularization, bicuspid/tricuspid AV -

TAVR **SAVR**


NOTION-2 study population
N = 370
TAVR
N = 187
SAVR
N = 183
Patients ≤ 70 years
TAVR
N = 81
SAVR
N = 77


Tricuspid AS
Bicuspid AS
Age (years)
75
70
65
60
≤ 70 years
50
40
30
20
10
0
10
20
Number of patients (N)

Primary & secondary endpoints

Primary endpoint - at 1 year

- Composite of death, stroke or rehospitalization (procedure, valve-, HF-related)

Secondary endpoints - at 1 year

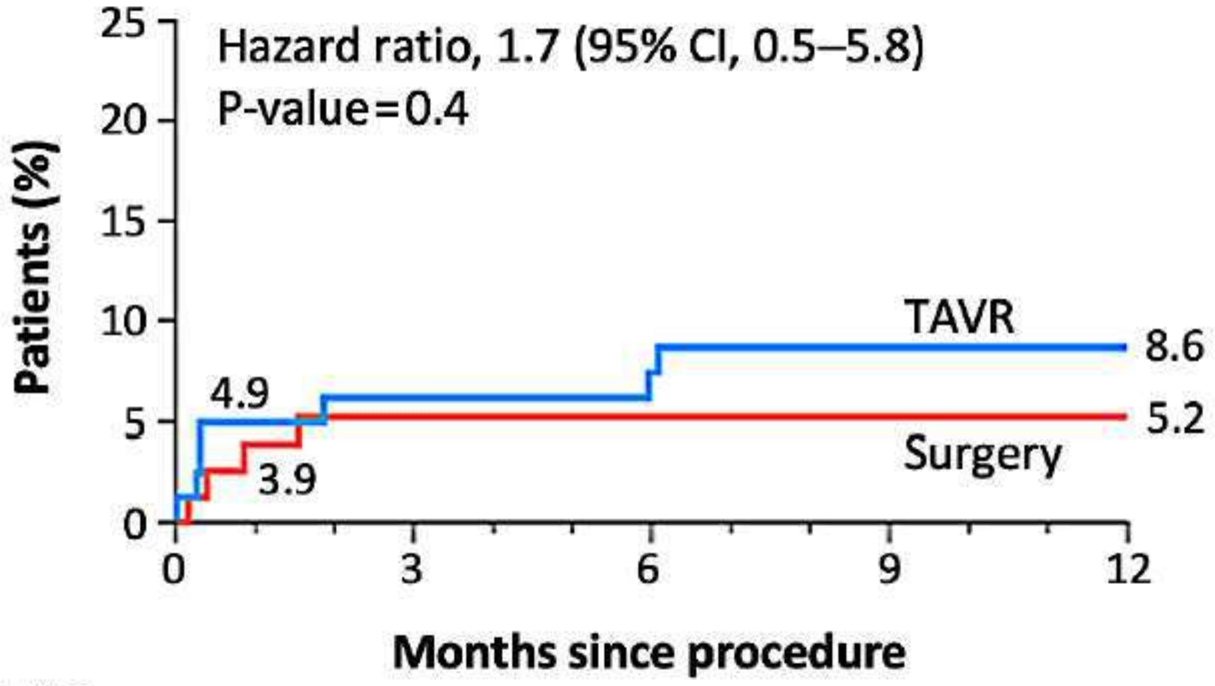
- Composite of death or disabling stroke
- Individual components of primary endpoint
- Major bleeding, new-onset AF, new permanent pacemaker implantation
- Aortic valve performance (gradient, paravalvular regurgitation)
- Functional parameters (NYHA class, KCCQ)

Study population – Baseline characteristics

	TAVR (N = 81)	Surgery (N = 77)
Age, years	68.0 ± 2.2	68.2 ± 2.4
Male sex	57 (70%)	56 (73%)
STS-PROM score, %	1.0 (0.8–1.2)	1.0 (0.8–1.3)
Arterial hypertension	54 (67%)	56 (73%)
Diabetes mellitus	17 (21%)	17 (22%)
Coronary artery disease	8 (10%)	5 (7%)
Atrial fibrillation	11 (14%)	8 (11%)
Previous stroke	3 (4%)	7 (9%)
Bicuspid aortic valve (CT)	29 (36%)	26 (34%)

Primary outcomes

Death, stroke or rehospitalization

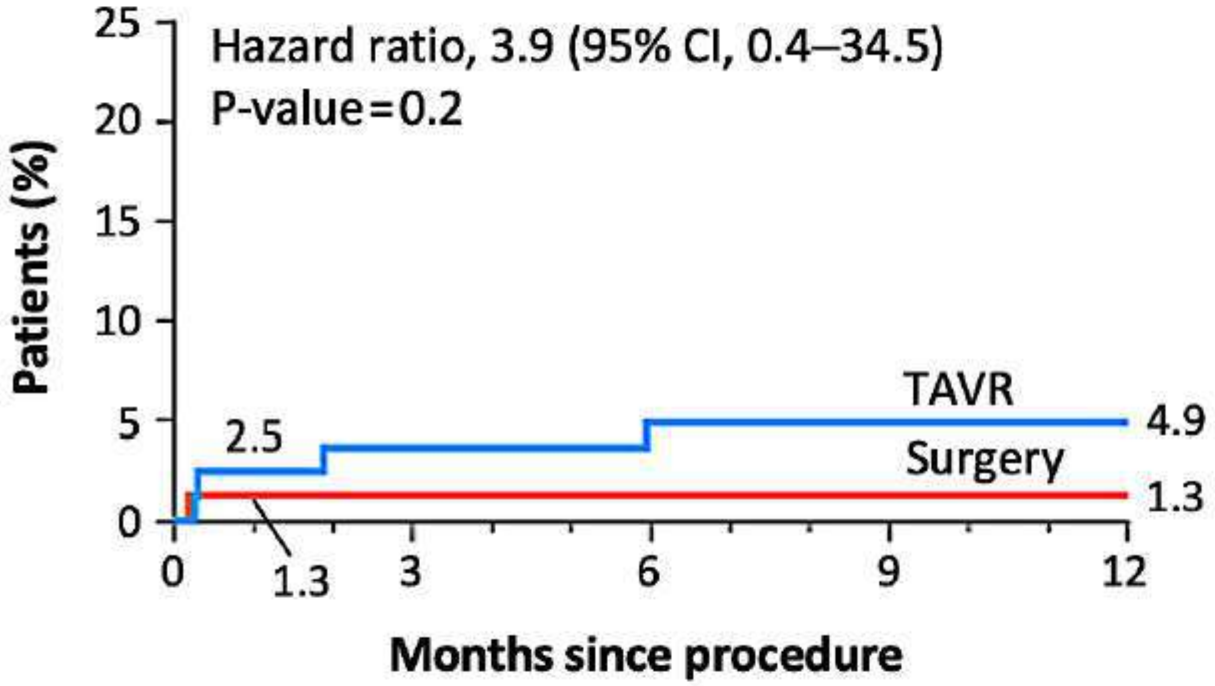


No. at Risk			
Surgery	77	73	73
TAVR	81	75	74

Absolute risk difference

3.4% (95% CI -4.4 to 11.3); P=0.4

Death or disabling stroke



No. at Risk			
Surgery	77	76	76
TAVR	81	78	78

Absolute risk difference

3.6% (95% CI -1.7 to 9.0); P=0.2

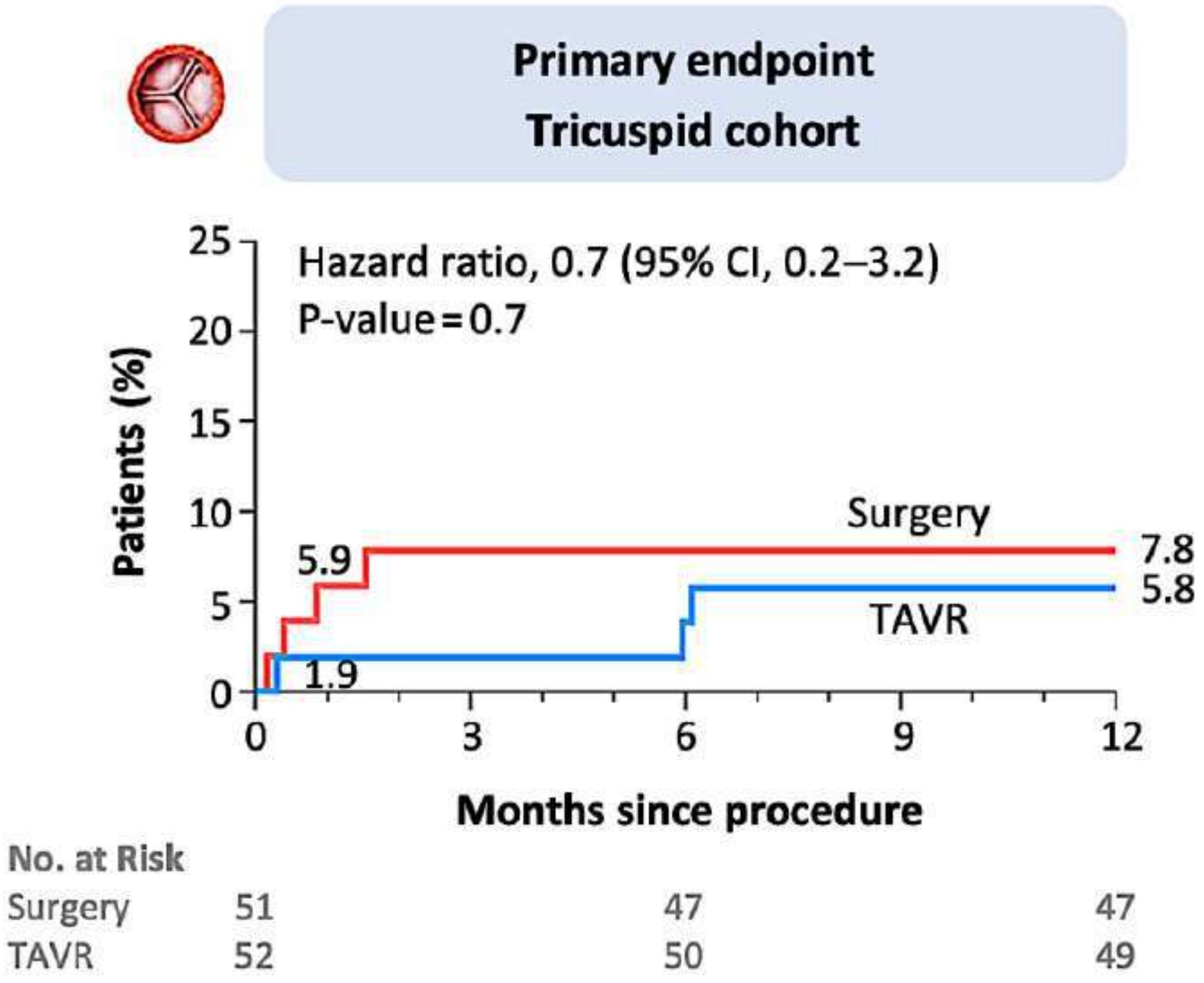
Individual components of primary endpoint

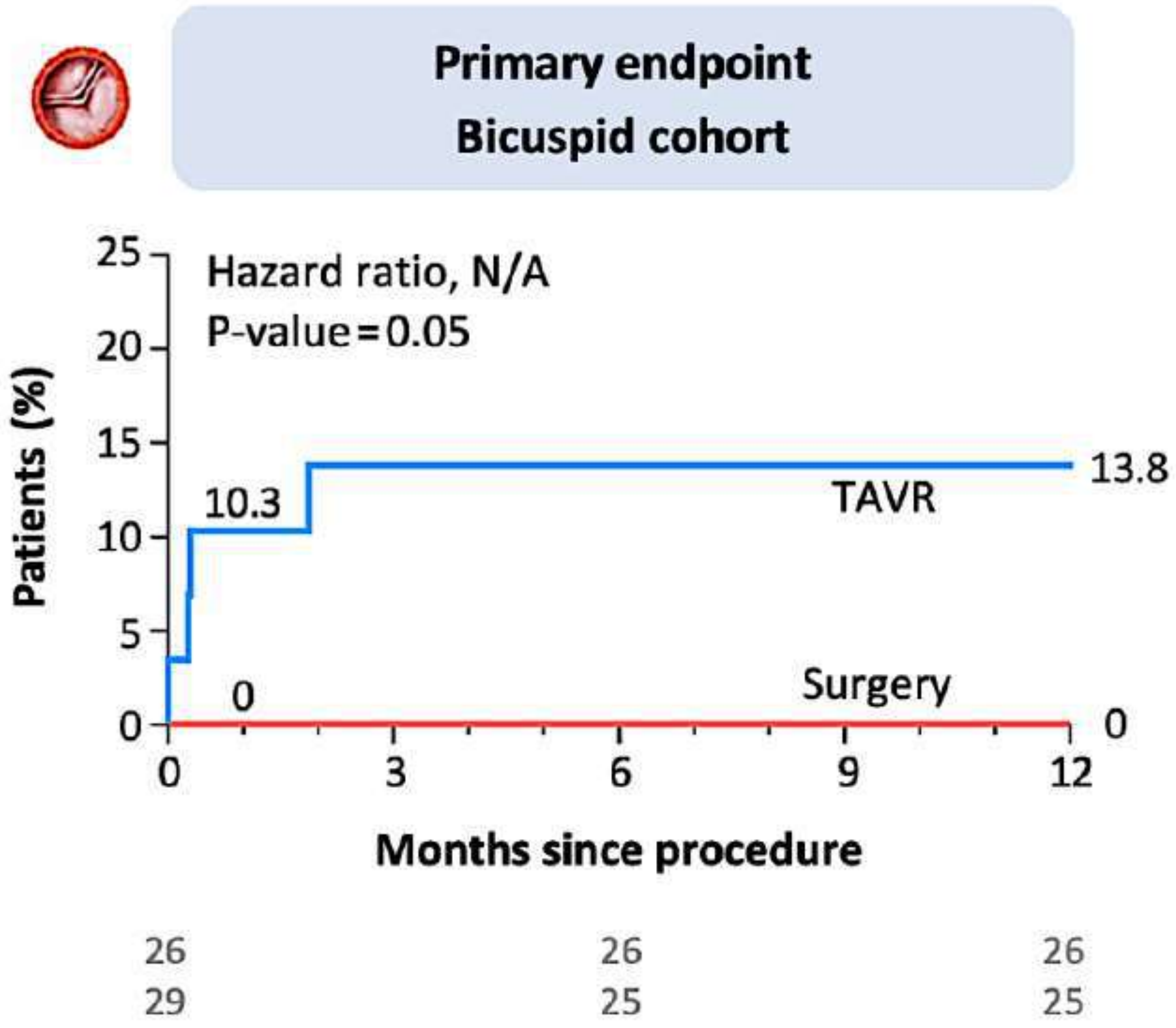
	TAVR	Surgery	TAVR vs. Surgery HR (95% CI)	P Value
	% of patients			
Death, stroke, or rehospitalization	8.6	5.2	1.7 (0.5 to 5.8)	0.4
Death or disabling stroke	4.9	1.3	3.9 (0.4 to 34.5)	0.2
Death from any cause	2.5	1.3	1.9 (0.2 to 21.0)	0.6
Stroke	4.9	1.3	3.9 (0.4 to 34.5)	0.2
Disabling stroke	2.5	1.3	1.9 (0.2 to 21.0)	0.6
Non-disabling stroke	2.5	0	-	0.2
Rehospitalization - procedure-, valve- or HF-related	1.2	3.9	0.3 (0.03 to 3.1)	0.3

Main secondary endpoints

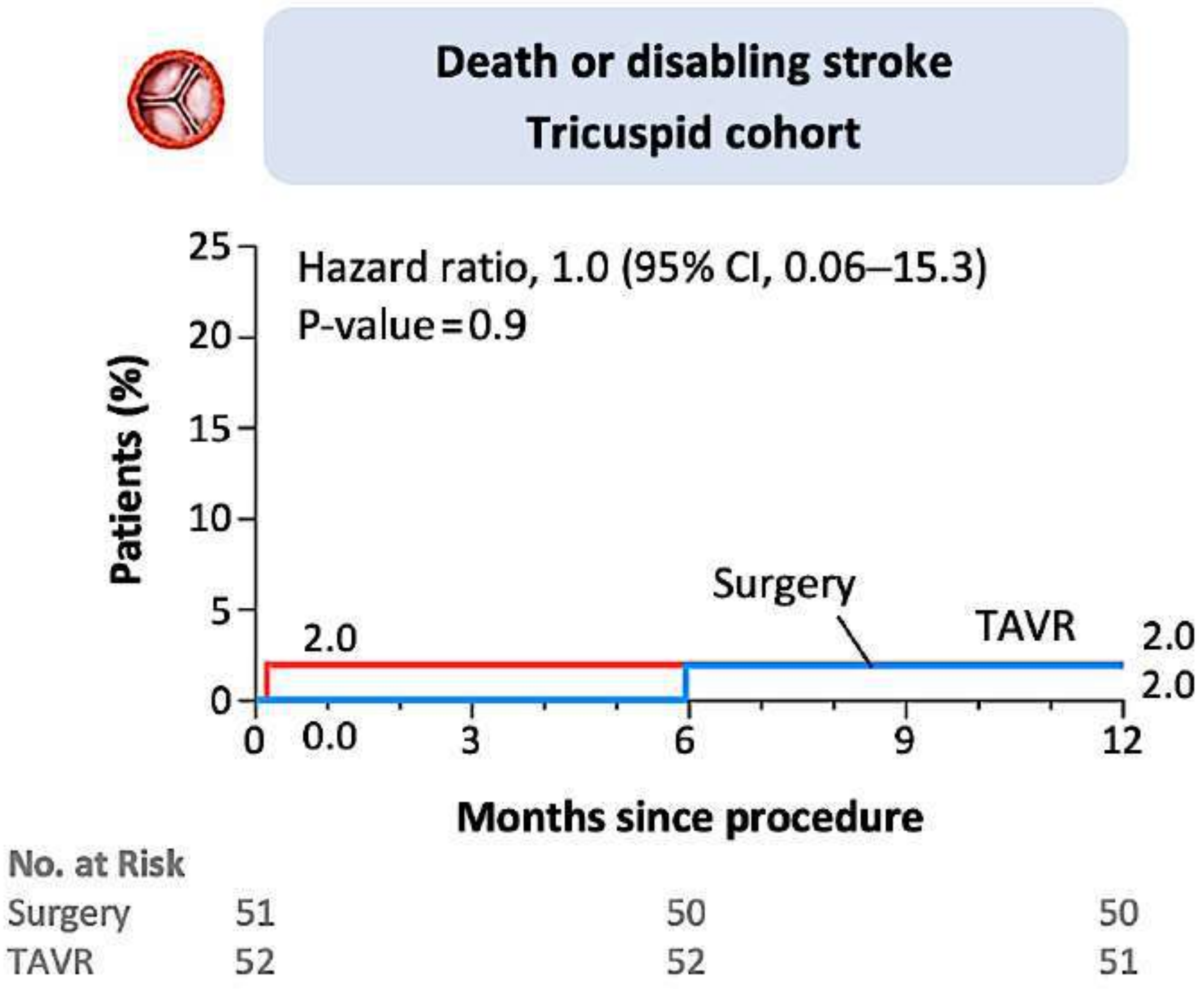
	TAVR	Surgery	TAVR vs. Surgery HR (95% CI)	P Value
	% of patients			
Major or life-threatening bleeding	6.2	16.9	0.4 (0.1 to 1.0)	0.04
Acute kidney injury stage 2 or 3	1.3	1.2	0.9 (0.06 to 15.1)	1.0
Myocardial infarction	3.7	2.6	1.5 (0.2 to 8.7)	0.7
New-onset atrial fibrillation	2.9	27.5	0.09 (0.02 to 0.4)	<0.001
New permanent pacemaker implantation	16.3	8.3	2.1 (0.8 to 5.5)	0.1
Length of index hospitalization – median no. of days	3 (2 to 4)	7 (6 to 9)	4 (3 to 5)	<0.001
Moderate or greater paravalvular regurgitation	5.6	0	5.6 (0.3 to 10.9)	0.05
Severe patient-prosthesis mismatch	9.0	15.5	0.95 (0.4 to 2.6)	0.9
Aortic reintervention	1.2	2.6	0.5 (0.04 to 5.2)	0.5

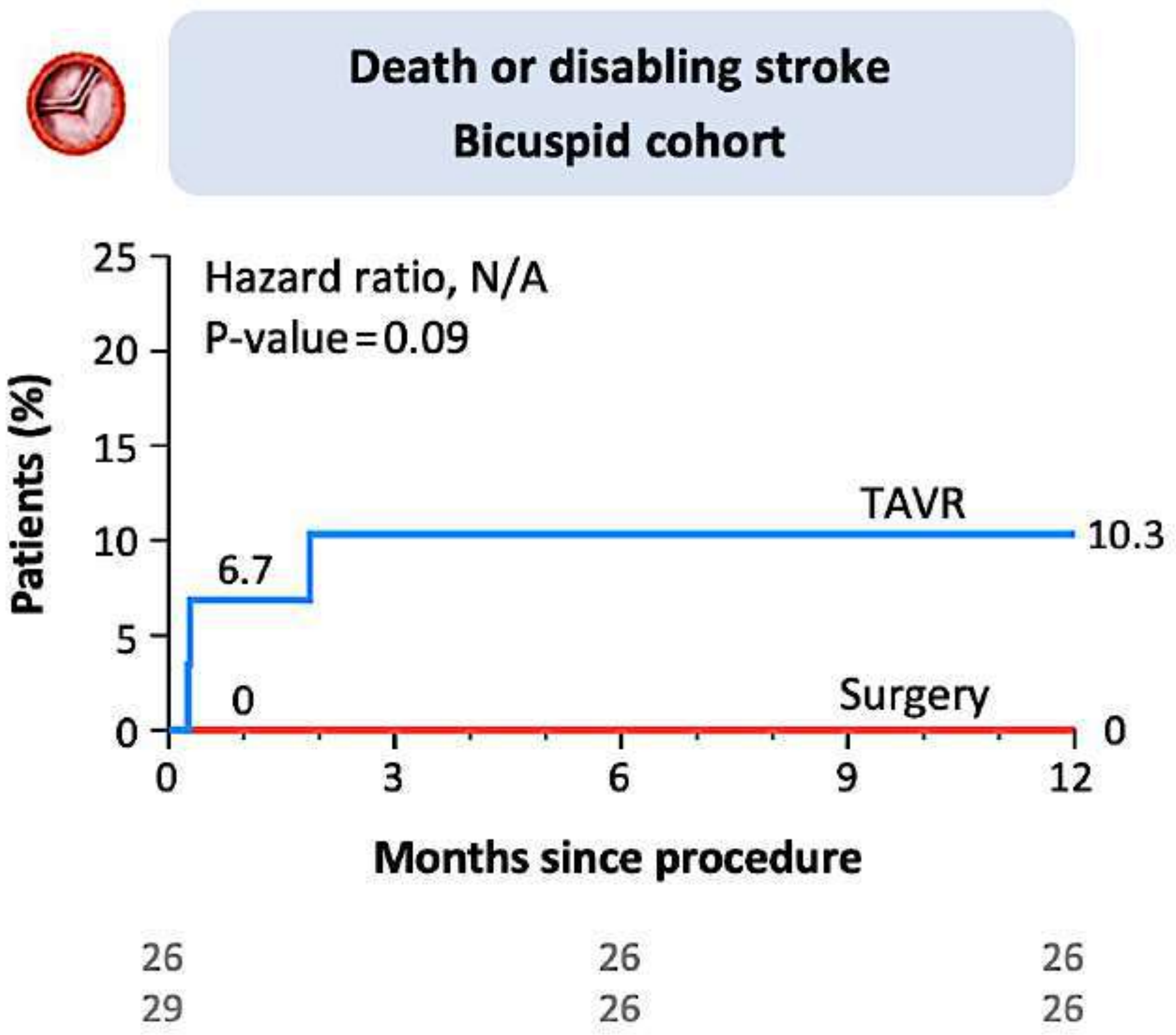
Subanalysis – tricuspid & bicuspid AS cohorts



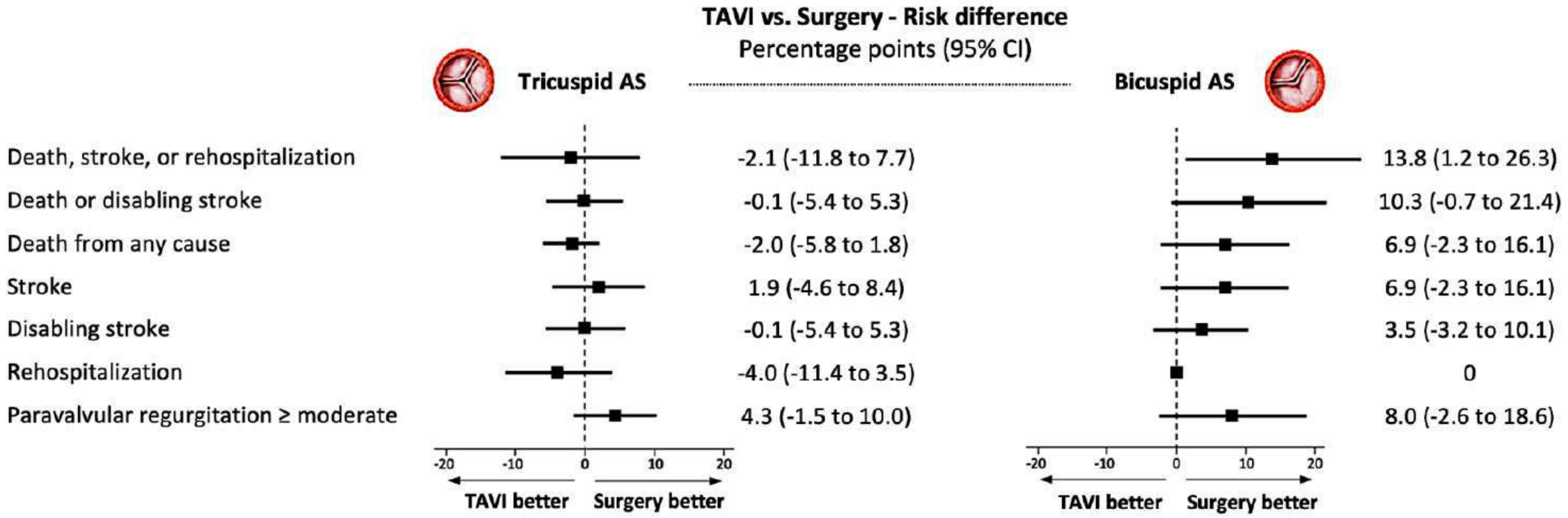


Subanalysis – tricuspid & bicuspid AS cohorts





Subanalysis – tricuspid & bicuspid AS cohorts



NOTION 2

Comparison with other low-risk trials

Baseline characteristics	PARTNER 3	Evolut LR	DEDICATE	NOTION-2	Tricuspid NOTION-2	Bicuspid NOTION-2
Age, years	73.5	73.9	74.5	**71.0**	71.5	69.8
STS-score, %	1.9	1.9	1.9	**1.1**	1.2	1.0
Diabetes mellitus	31%	31%	33%	**21%**	26%	9%
Coronary artery disease	28%	21%	36%	**12%**	14%	4%
Atrial fibrillation	17%	16%	28%	**16%**	16%	16%
Bicuspid aortic valve	0	0	0	**26%**	0	100%
Death or disabling stroke - 1 year						
TAVI	1.0%	2.9%	3.8%	**3.2%**	2.2%	6.1%
SAVR	2.9%	4.6%	8.4%	**1.6%**	1.5%	2.0%

NOTION 2

Take-home messages (1)

Why this study?

Current low-risk TAVR vs. SAVR trials did <u>not</u> include young patients only and excluded bicuspid AS.

What did NOTION-2 ≤ 70 years study?

This is the first-ever RCT comparing TAVR with SAVR in truly young AS patients **≤ 70 years of age** and also including patients with a **bicuspid aortic valve (35%)**.

NOTION 2

Take-home messages (2)

What are the results?

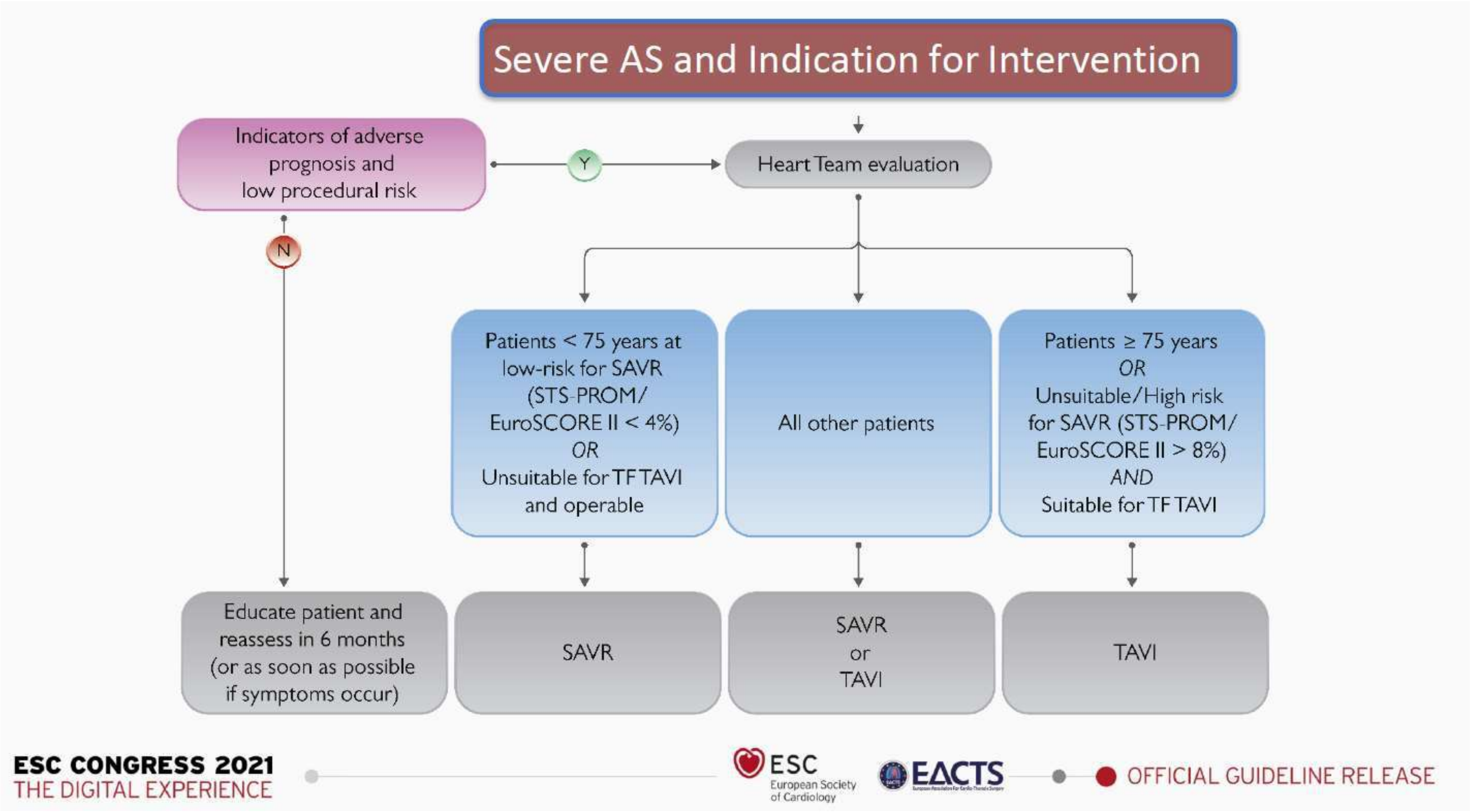
There was **clinical equipoise** for TAVR vs. SAVR in the **tricuspid cohort** with regard to the primary composite endpoint at one year. However, **TAVR outcomes in young bicuspid AS patients** were **less favourable**.

Why is this important?

NOTION-2 study results should encourage & may impact **future RCT designs comparing TAVR with SAVR in bicuspid AS** (e.g., selection of bicuspid phenotypes, use of cerebral embolic protection).

WHAT DO GUIDELINES SAY??

ESC/EACTS 2021 UPDATE



ESC/EACTS RECOMMENDATIONS?

Recommended Mode of Intervention in Aortic Stenosis (2)

Recommendations	Class	Level
SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/EuroSCORE II <4%), or in patients who are operable and unsuitable for transfemoral TAVI.	I	B
TAVI is recommended in older patients (≥75 years), or in those who are high risk (STS-PROM/EuroSCORE II >8%) or unsuitable for surgery.	I	A
SAVR or TAVI are recommended for remaining patients according to individual clinical, anatomical, and procedural characteristics.	I	B
Non-transfemoral TAVI may be considered in patients who are inoperable and unsuitable for transfemoral TAVI.	IIb	C
Balloon aortic valvotomy may be considered as a bridge to SAVR or TAVI in haemodynamically unstable patients and (if feasible) in those with severe aortic stenosis who require urgent high-risk NCS.	IIb	C

ESC/EACTS RECOMMENDATIONS?

Clinical, Anatomical and Procedural Factors that Influence the Choice of Treatment Modality for an Individual Patient (1)

	Favours TAVI	Favours SAVR
Clinical characteristics		
Lower surgical risk	-	+
Higher surgical risk	+	-
Younger age	-	+
Older age	+	-
Previous cardiac surgery (particularly intact coronary artery bypass grafts at risk of injury during repeat sternotomy)	+	-
Severe frailty	+	-
Active or suspected endocarditis	-	+

ESC/EACTS RECOMMENDATIONS?

Clinical, Anatomical and Procedural Factors that Influence the Choice of Treatment Modality for an Individual Patient (2)

	Favours TAVI	Favours SAVR
Anatomical and procedural factors		
TAVI feasible via transfemoral approach	+	-
Transfemoral access challenging or impossible and SAVR feasible Transfemoral access challenging or impossible and SAVR inadvisable	- +	+ -
Sequelae of chest radiation	+	-
Porcelain aorta	+	-
High likelihood of severe patient–prosthesis mismatch (AVA <0.65 cm2/m2 BSA)	+	-

ESC/EACTS RECOMMENDATIONS?

Clinical, Anatomical and Procedural Factors that Influence the Choice of Treatment Modality for an Individual Patient (3)

	Favours TAVI	Favours SAVR
Anatomical and procedural factors (continued)		
Severe chest deformation or scoliosis	+	-
Aortic annular dimensions unsuitable for available TAVI devices	-	+
Bicuspid aortic valve	-	+
Valve morphology unfavourable for TAVI (e.g. high risk of coronary obstruction due to low coronary ostia or heavy leaflet/LVOT calcification)	-	+
Thrombus in aorta or LV	-	+

ESC/EACTS RECOMMENDATIONS?

Clinical, Anatomical and Procedural Factors that Influence the Choice of Treatment Modality for an Individual Patient (4)

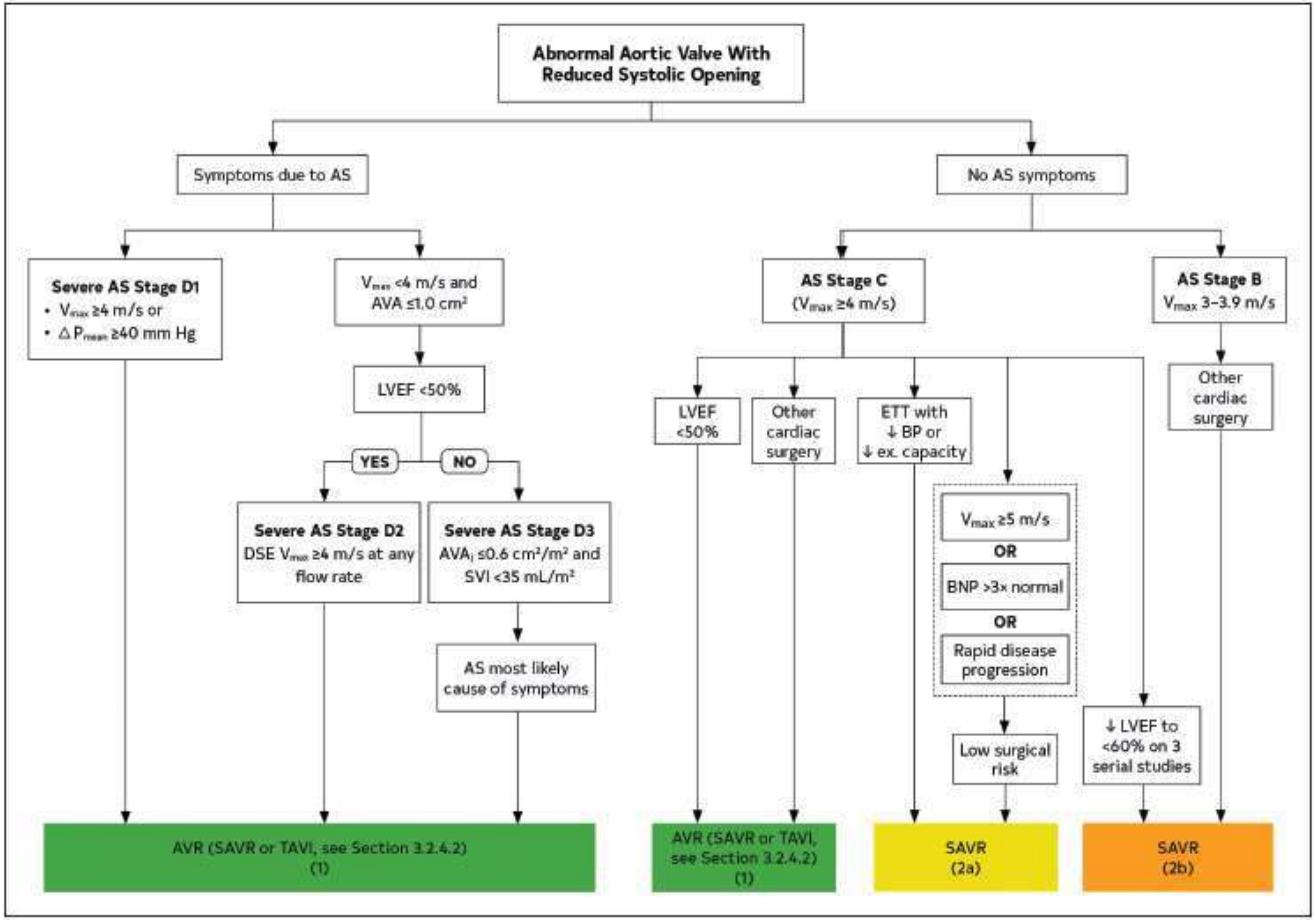
	Favours TAVI	Favours SAVR
Concomitant cardiac conditions requiring intervention		
Significant multi-vessel CAD requiring surgical revascularization	-	+
Severe primary mitral valve disease	-	+
Severe tricuspid valve disease	-	+
Significant dilatation/aneurysm of the aortic root and/or ascending aorta	-	+
Septal hypertrophy requiring myectomy	-	+

WHAT DO GUIDELINES SAY??

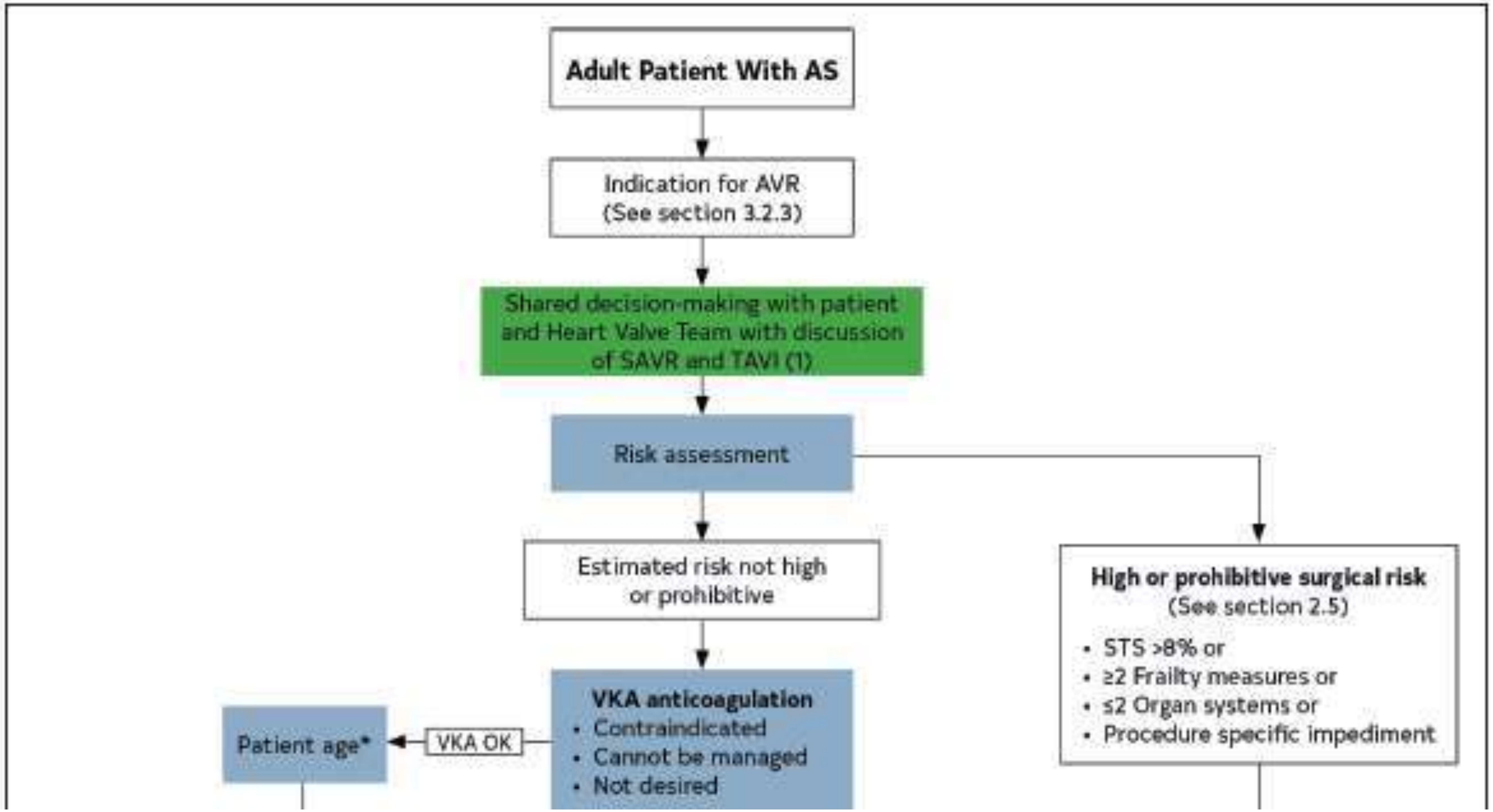
ACC/AHA 2021 GUIDELINE

D: Symptomatic severe AS					
D1	Symptomatic severe high-gradient AS	Severe leaflet calcification/ fibrosis or congenital stenosis with severely reduced leaflet opening	Aortic V_{max} ≥4 m/s or mean ΔP ≥40 mm Hg AVA typically ≤1.0 cm² (or AVAi ≤0.6 cm²/m²) but may be larger with mixed AS/AR	LV diastolic dysfunction LV hypertrophy Pulmonary hypertension may be present	Exertional dyspnea, decreased exercise tolerance, or HF Exertional angina Exertional syncope or presyncope
D2	Symptomatic severe low-flow, low-gradient AS with reduced LVEF	Severe leaflet calcification/ fibrosis with severely reduced leaflet motion	AVA ≤1.0 cm² with resting aortic V_{max} <4 m/s or mean ΔP <40 mm Hg Dobutamine stress echocardiography shows AVA <1.0 cm² with V_{max} ≥4 m/s at any flow rate	LV diastolic dysfunction LV hypertrophy LVEF <50%	HF Angina Syncope or presyncope
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	Severe leaflet calcification/ fibrosis with severely reduced leaflet motion	AVA ≤1.0 cm² (indexed AVA ≤0.6 cm²/m²) with an aortic V_{max} <4 m/s or mean ΔP <40 mm Hg AND Stroke volume index <35 mL/m² Measured when patient is normotensive (systolic blood pressure <140 mm Hg)	Increased LV relative wall thickness Small LV chamber with low stroke volume Restrictive diastolic filling LVEF ≥50%	HF Angina Syncope or presyncope

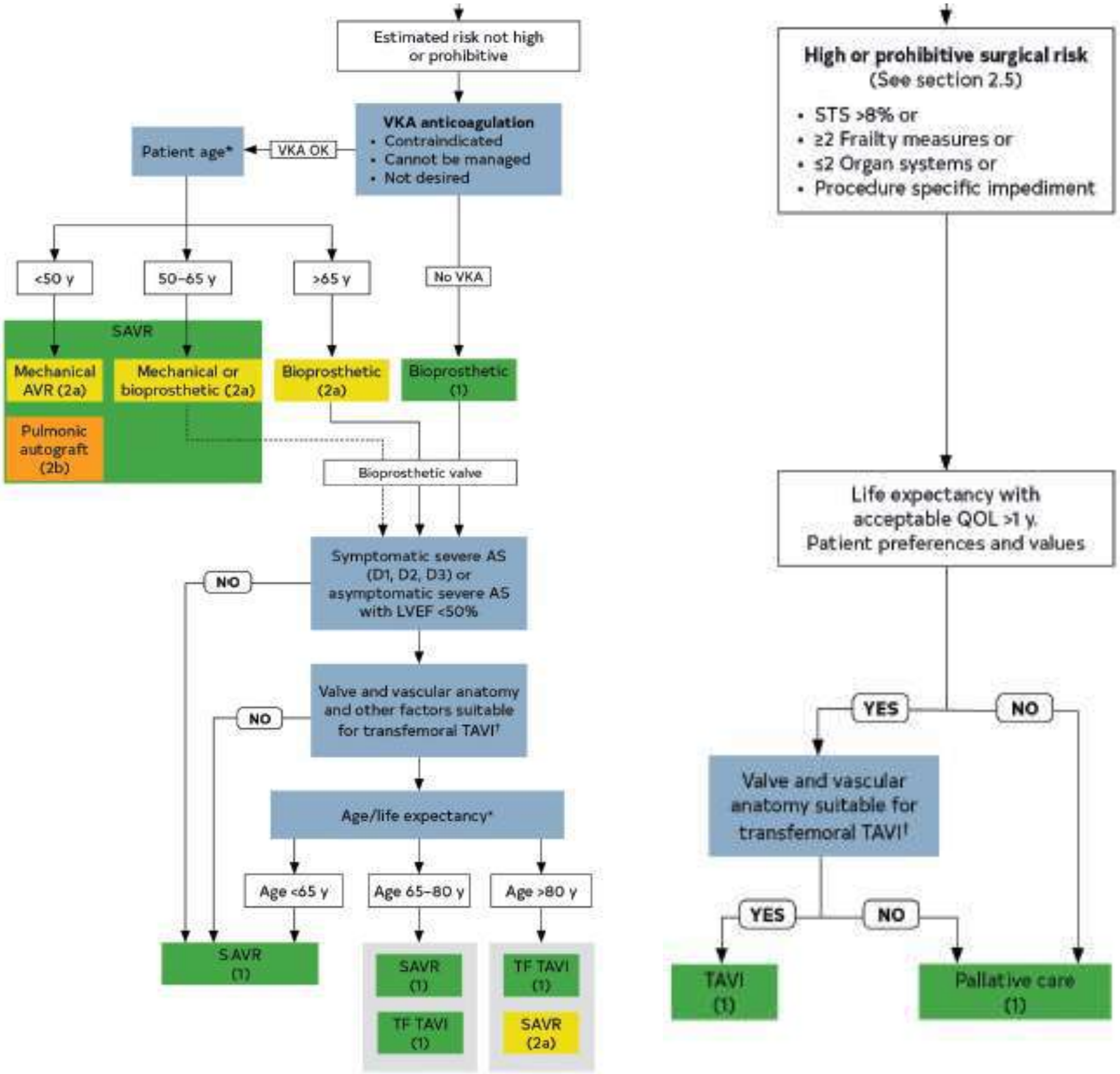
AR indicates aortic regurgitation; AS, aortic stenosis; AVA, aortic valve area circulation; AVAi, AVA indexed to body surface area; BAV, bicuspid aortic valve; ΔP, pressure gradient between the LV and aorta HF, heart failure; LV, left ventricular; LVEF, left ventricular ejection fraction; and V_{max}, maximum velocity.



Abnormal Aortic Valve With Reduced Systolic Opening
Symptoms due to AS
No AS symptoms
Severe AS Stage D1
• Vmax ≥4 m/s or
• ΔPmean ≥40 mm Hg
Vmax <4 m/s and AVA ≤1.0 cm²
LVEF <50%
YES
NO
Severe AS Stage D2
DSE Vmax ≥4 m/s at any flow rate
Severe AS Stage D3
AVAi ≤0.6 cm²/m² and SVI <35 mL/m²
AS most likely cause of symptoms
AS Stage C
(Vmax ≥4 m/s)
AS Stage B
Vmax 3–3.9 m/s
LVEF <50%
Other cardiac surgery
ETT with ↓ BP or ↓ ex. capacity
Vmax ≥5 m/s
OR
BNP >3× normal
OR
Rapid disease progression
Low surgical risk
↓ LVEF to <60% on 3 serial studies
Other cardiac surgery
AVR (SAVR or TAVI, see Section 3.2.4.2) (1)
AVR (SAVR or TAVI, see Section 3.2.4.2) (1)
SAVR (2a)
SAVR (2b)



Adult Patient With AS
Indication for AVR
(See section 3.2.3)
Shared decision-making with patient and Heart Valve Team with discussion of SAVR and TAVI (1)
Risk assessment
Estimated risk not high or prohibitive
High or prohibitive surgical risk
(See section 2.5)
• STS >8% or
• ≥2 Frailty measures or
• ≤2 Organ systems or
• Procedure specific impediment
VKA anticoagulation
• Contraindicated
• Cannot be managed
• Not desired
VKA OK
Patient age*



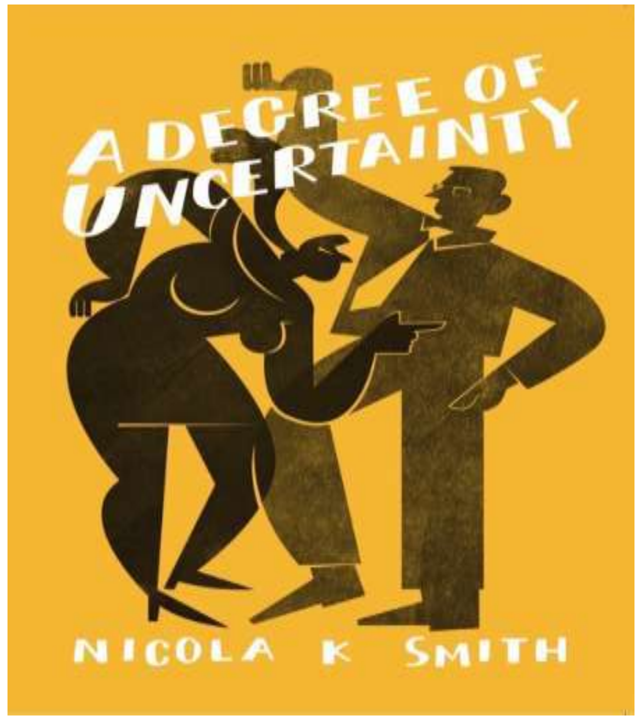
Estimated risk not high or prohibitive
VKA anticoagulation
• Contraindicated
• Cannot be managed
• Not desired
VKA OK
Patient age*
<50 y
50–65 y
>65 y
No VKA
SAVR
Mechanical AVR (2a)
Mechanical or bioprosthetic (2a)
Pulmonic autograft (2b)
Bioprosthetic (2a)
Bioprosthetic (1)
Bioprosthetic valve
Symptomatic severe AS (D1, D2, D3) or asymptomatic severe AS with LVEF <50%
NO
Valve and vascular anatomy and other factors suitable for transfemoral TAVI†
NO
Age/life expectancy*
Age <65 y
Age 65–80 y
Age >80 y
SAVR (1)
SAVR (1)
TF TAVI (1)
TF TAVI (1)
SAVR (2a)
High or prohibitive surgical risk
(See section 2.5)
• STS >8% or
• ≥2 Frailty measures or
• ≤2 Organ systems or
• Procedure specific impediment
Life expectancy with acceptable QOL >1 y.
Patient preferences and values
YES
NO
Valve and vascular anatomy suitable for transfemoral TAVI†
YES
NO
TAVI (1)
Palliative care (1)

Table 14. **A Simplified Framework With Examples of Factors Favoring SAVR, TAVI, or Palliation Instead of Aortic Valve Intervention**

	Favors SAVR	Favors TAVI	Favors Palliation
Age/life expectancy*	Younger age/longer life expectancy	Older age/fewer expected remaining years of life	Limited life expectancy
Valve anatomy	BAV Subaortic (LV outflow tract) calcification Rheumatic valve disease Small or large aortic annulus†	Calcific AS of a trileaflet valve	
Prosthetic valve preference	Mechanical or surgical bioprosthetic valve preferred Concern for patient–prosthesis mismatch (annular enlargement might be considered)	Bioprosthetic valve preferred Favorable ratio of life expectancy to valve durability TAVI provides larger valve area than same size SAVR	
Concurrent cardiac conditions	Aortic dilation‡ Severe primary MR Severe CAD requiring bypass grafting Septal hypertrophy requiring myectomy AF	Severe calcification of the ascending aorta ("porcelain" aorta)	Irreversible severe LV systolic dysfunction Severe MR attributable to annular calcification
Noncardiac conditions		Severe lung, liver, or renal disease Mobility issues (high procedural risk with sternotomy)	Symptoms likely attributable to noncardiac conditions Severe dementia Moderate to severe involvement of ≥2 other organ systems
Frailty	Not frail or few frailty measures	Frailty likely to improve after TAVI	Severe frailty unlikely to improve after TAVI
Estimated procedural or surgical risk of SAVR or TAVI	SAVR risk low TAVI risk high	TAVI risk low to medium SAVR risk high to prohibitive	Prohibitive SAVR risk (>15%) or post-TAVI life expectancy <1 y
Procedure-specific impediments	Valve anatomy, annular size, or low coronary ostial height precludes TAVI Vascular access does not allow transfemoral TAVI	Previous cardiac surgery with at-risk coronary grafts Previous chest irradiation	Valve anatomy, annular size, or coronary ostial height precludes TAVI Vascular access does not allow transfemoral TAVI
Goals of Care and patient preferences and values	Less uncertainty about valve durability Avoid repeat intervention Lower risk of permanent pacer Life prolongation Symptom relief Improved long-term exercise capacity and QOL Avoid vascular complications Accepts longer hospital stay, pain in recovery period	Accepts uncertainty about valve durability and possible repeat intervention Higher risk of permanent pacer Life prolongation Symptom relief Improved exercise capacity and QOL Prefers shorter hospital stay, less postprocedural pain	Life prolongation not an important goal Avoid futile or unnecessary diagnostic or therapeutic procedures Avoid procedural stroke risk Avoid possibility of cardiac pacer

WHAT IS THE OPTIMAL TREATMENT STRATEGY IN PATIENTS WITH CONCOMINANT CAD AND SEVERE AS?

CHALLENGING TOPIC



UNCERTAINTY

RELATIVE PAUCITY OF DATA

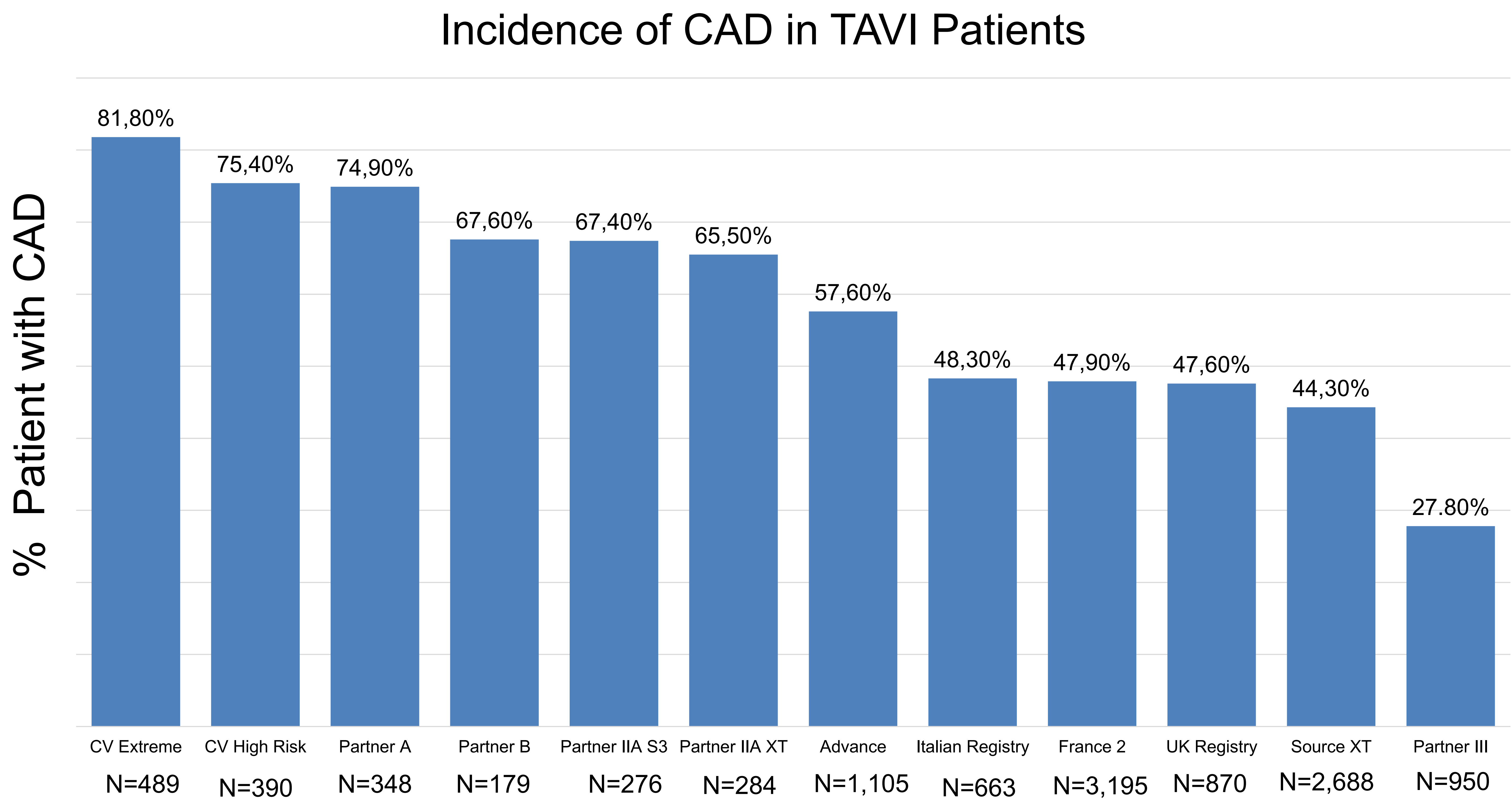
8 Mins!

OPTIONS? SO MANY PERMUTATIONS!

- Only TAVI?
- PCI+TAVI?
    - In whom? High Risk? Low Risk
    - Optimal Timing? Before? After? Concominant?
- Only isolated AVR?
- CABG+AVR?

PREVALENCE OF CAD IN TAVI PATIENTS

INCIDENCE OF CAD RANGES FROM 27.8% TO 81.8%



- Coronary artery disease is a frequent finding in patients under consideration for TAVI, ranging from 27.8%-81.8% in prior series.
- These studies defined coronary artery disease as the mere presence of coronary artery disease, rather than by the need for coronary revascularization.
- Nevertheless, the presence and extent of ischemic coronary artery disease is often one factor that influences the decision for surgery aortic valve replacement (with CABG) over TAVI with PCI.

GUIDELINES?

- Great uncertainty
- Favors CABG+SAVR in high risk coronary anatomies
- No clear definition of severe CAD
- No clear definition about high risk coronary anatomy
- ESC guidelines focus only the term ‘Multivessel disease’

ESC/EACTS RECOMMENDATIONS?

Clinical, Anatomical and Procedural Factors that Influence the Choice of Treatment Modality for an Individual Patient (4)

	Favours TAVI	Favours SAVR
Concomitant cardiac conditions requiring intervention		
Significant multi-vessel CAD requiring surgical revascularization	-	+
Severe primary mitral valve disease	-	+
Severe tricuspid valve disease	-	+
Significant dilatation/aneurysm of the aortic root and/or ascending aorta	-	+
Septal hypertrophy requiring myectomy	-	+

ACC/AHA RECOMMENDATIONS?

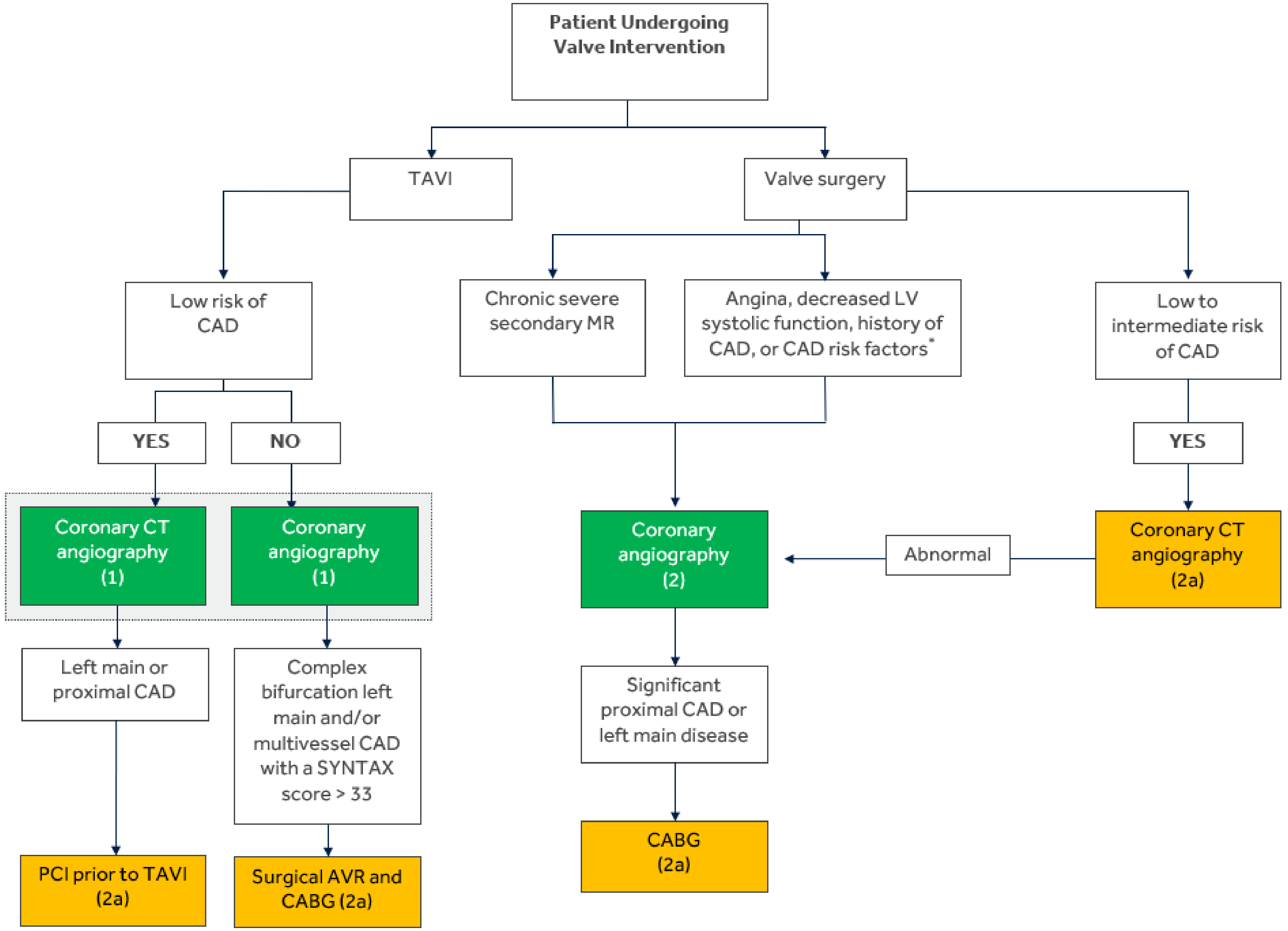
TABLE 14 A Simplified Framework With Examples of Factors Favoring SAVR, TAVI, or Palliation Instead of Aortic Valve Intervention

	Favors SAVR	Favors TAVI	Favors Palliation
Age/life expectancy*	■ Younger age/longer life expectancy	■ Older age/fewer expected remaining years of life	■ Limited life expectancy
Valve anatomy	■ BAV ■ Subaortic (LV outflow tract) calcification ■ Rheumatic valve disease ■ Small or large aortic annulus †	■ Calcific AS of a trileaflet valve	
Prosthetic valve preference	■ Mechanical or surgical bioprosthetic valve preferred ■ Concern for patient-prosthesis mismatch (annular enlargement might be considered)	■ Bioprosthetic valve preferred ■ Favorable ratio of life expectancy to valve durability ■ TAVI provides larger valve area than same size SAVR	
Concurrent cardiac conditions	■ Aortic dilation ‡ ■ Severe primary MR ■ Severe CAD requiring bypass grafting ■ Septal hypertrophy requiring myectomy ■ AF	■ Severe calcification of the ascending aorta ("porcelain" aorta)	■ Irreversible severe LV systolic dysfunction ■ Severe MR attributable to annular calcification

2020 ACC-AHA VALVULAR HEART DISEASE GUIDELINES

Recommendations for PCI Prior to TAVI

Recommendations for Management of CAD in Patients Undergoing TAVI Referenced studies that support the recommendations are summarized in **Online Data Supplement 45.**		
COR	LOE	Recommendations
1	C-EO	1. In patients undergoing TAVI, 1) contrast-enhanced coronary CT angiography (in patients with a low pretest probability for CAD) or 2) an invasive coronary angiogram is recommended to assess coronary anatomy and guide revascularization.
2a	C-LD	2. In patients undergoing TAVI with significant left main or proximal CAD with or without angina, revascularization by PCI before TAVI is reasonable.
2a	C-LD	3. In patients with significant AS and significant CAD (luminal reduction > 70% diameter, fractional flow reserve < 0.8, instantaneous wave-free ratio < 0.89) consisting of complex bifurcation left main and/or multivessel CAD with a SYNTAX (synergy between percutaneous coronary surgery) score > 33, SAVR and CABG are reasonable and preferred over TAVI and PCI.



Otto, et al., Circulation. 2021;143:e72–e227

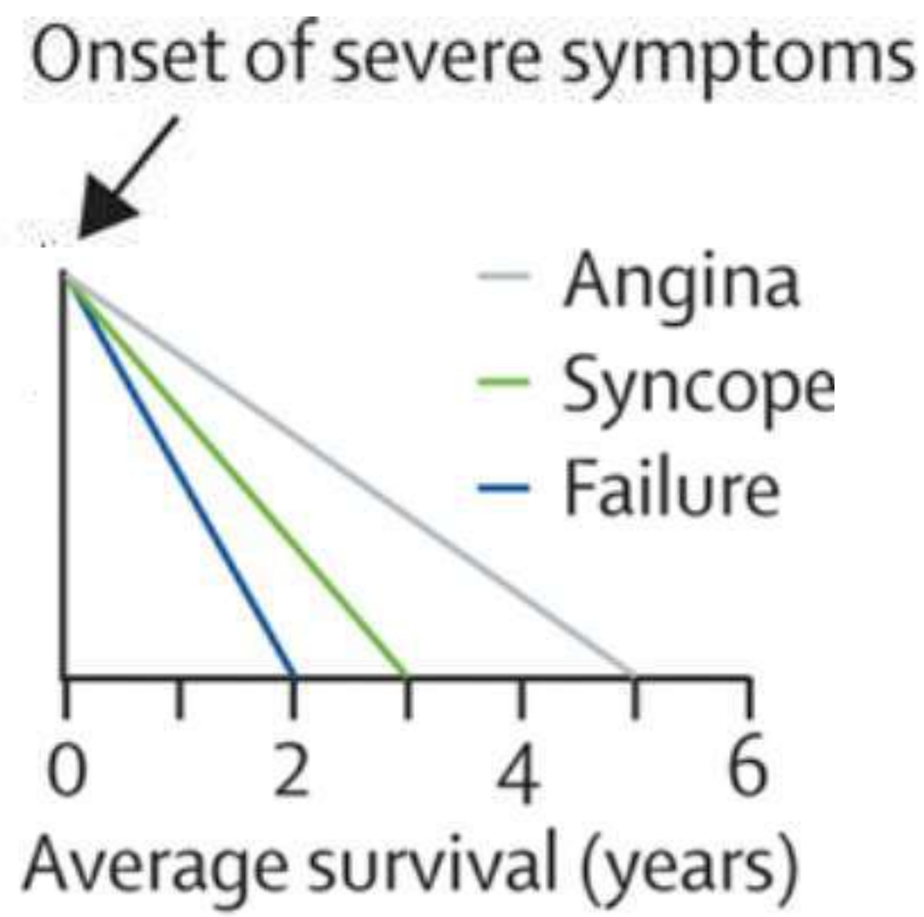
AORTIC STENOSIS

Symptoms: Demarcation in Course of Disease

- Onset of dyspnea and other heart failure symptoms foretell the worst outlook for aortic stenosis patients[1]

SYMPTOMATHIC AORTIC STENOSIS

WE SHOULD CHANGE THE VALVE AS QUICKLY AS POSSIBLE!



Ross J, Braunwald E. Circulation 1968; 38: 61-67.

[1]Carabello BA, Paulus WJ. Lancet 2009; 373: 956-66.

PATIENTS WITH AS AND ACUTE CORONARY SYNDROME

- While it is clear that AS patients presenting with acute coronary syndrome (ACS) should undergo revascularization of the culprit vessel, but:
  - How many patients with severe AS admit to an emergency service with STEMI or NSTEMI?
    - Very low
    - High mortality rate
  - Patients with AS can also have a rest angina unrelated with the presence or absence of CAD

Canadian Journal of Cardiology 38 (2022) 1220–1227

Clinical Research

Long-term Prognosis in Patients With Concomitant Acute Coronary Syndrome and Aortic Stenosis

Nicholas W.S. Chew, MBChB,[a] Audrey Zhang, MBBS,[b] Joy Ong, MBBS,[b] Sophie Koh, MBBS,[b] Gwyneth Kong, MBBS,[c] Yeung Jek Ho, MBBS,[c] Oliver Lim, MBBS,[c] Yip Han Chin, MBBS,[c] Chaoxing Lin, MBBS,[c] Andie Djohan, MBBS,[a] Ivandito Kuntjoro, MD,[a,b] William K.F. Kong, MBChB,[a,b] Jimmy Hon, MBChB,[d] Chi-Hang Lee, MD,[a,b] Mark Y. Chan, PhD,[a,b] Tiong-Cheng Yeo, MBBS,[a,b] Huay-Cheem Tan, MBBS,[b] Kian-Keong Poh, MD,[a,b] and Poay Huan Loh, MBBCh, BAO[a,b]

[a] Department of Cardiology, National University Heart Centre, National University Hospital, Singapore, Singapore
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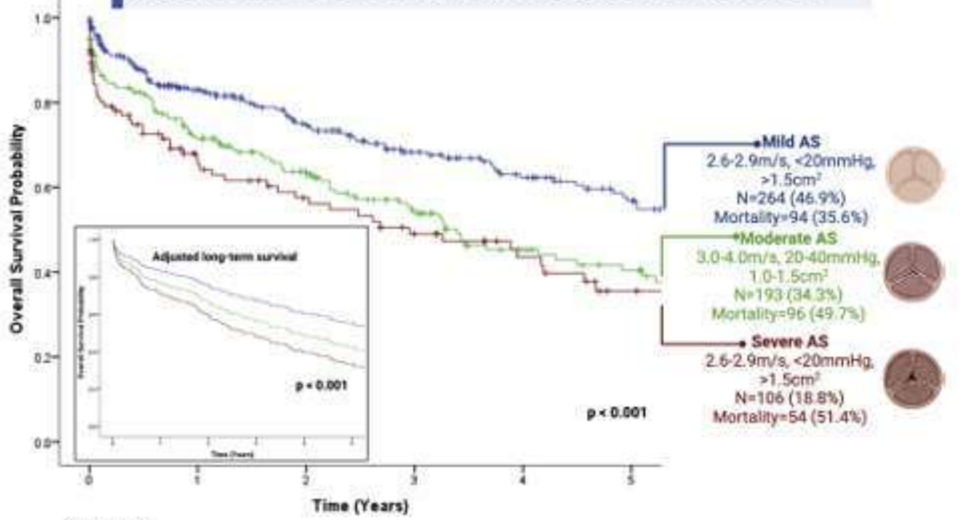
See editorial by Thompson, pages 1130–1131 of this issue.

Impact of AS Severity on Prognosis after ACS



Number at risk

	Baseline	1 year	2 years	3 years	4 years	5 years
Mild AS	264	173	133	98	77	60
Moderate AS	193	120	91	65	40	32
Severe AS	106	52	40	30	22	13

https://doi.org/10.1016/j.cjca.2022.03.010

Prevalence of Aortic Valve Stenosis in Patients With ST-Segment Elevation Myocardial Infarction and Effect on Long-Term Outcome

Gurpreet K. Singh, MD[a], Pieter van der Bijl, MD, PhD[a], Laurien Goedemans, MD[a], E. Mara Vollema, MD[a], Rachid Abou, MD[a], Nina Ajmone Marsan, MD, PhD[a], Jeroen J. Bax, MD, PhD[a,b], and Victoria Delgado, MD, PhD[a,*]

Several studies have shown an association between aortic valve stenosis (AS), atherosclerosis and cardiovascular risk factors. These risk factors are frequently encountered in patients with ST-segment elevation myocardial infarction (STEMI). The aim of this study was to evaluate the prevalence and the prognostic implications of AS in patients presenting with STEMI. A total of 2041 patients (61 ± 12 years old, 76% male) admitted with STEMI and treated with primary percutaneous coronary intervention were included. Patients with previous myocardial infarction and previous aortic valve replacement were excluded. Echocardiography was performed at index admission. Patients were divided in 3 groups: 1) any grade of AS, 2) aortic valve sclerosis and 3) normal aortic valve. Any grade of AS was defined as an aortic valve area ≤2.0 cm². The primary endpoint was all-cause mortality. The prevalence of AS was 2.7% in the total population and it increased with age (1%, 3%, 7% and 16%, in the patients aged <65 years, 65 to 74 years, 75 to 84 years and ≥85 years, respectively). Patients with AS showed a significantly higher mortality rate when compared to the other two groups (p < 0.001) and AS was independently associated with all-cause mortality, with a HR of 1.81 (CI 95%: 1.02 to 3.22; p = 0.04). In conclusion, AS is not uncommon in patients with STEMI, and concomitant AS in patients with first STEMI is independently associated with all-cause mortality at long-term follow up. **(Am J Cardiol 2021;153:30–35)**

Thus, main questions remain regarding the management of **significant stable CAD** in patients undergoing TAVI.

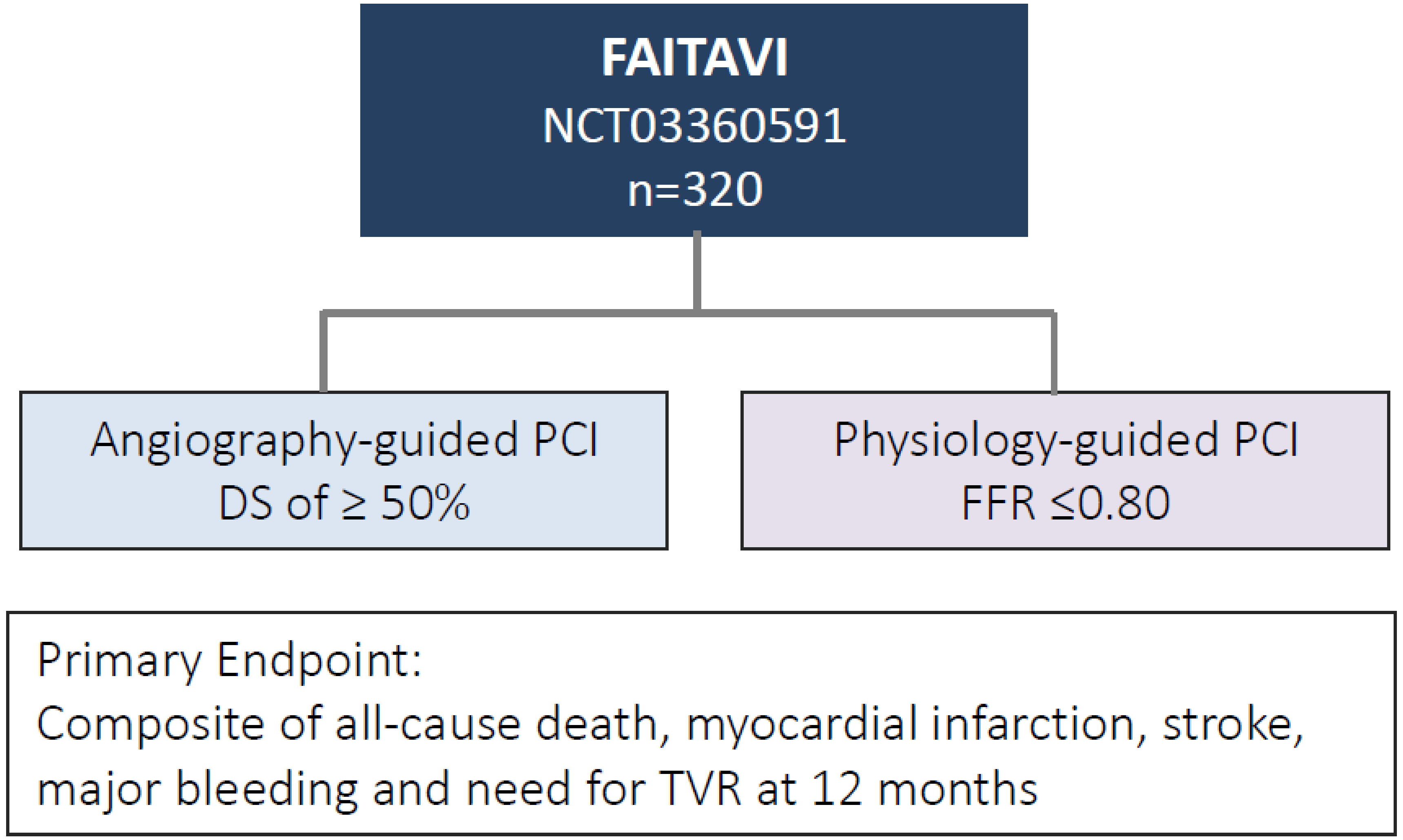
REVASCULARIZATION IN PATIENTS WİTH AS+STABLE CAD?

- Current guidelines aren't particularly clear on how these patients should be treated, but generally recommend two separate procedures, with concomitant procedures only recommended for those with very high degrees of coronary artery stenosis.
- For those with complex CAD, both SAVR and CABG are usually recommended at the same time.
- For PCI and TAVI, there is no direct recommendation but the general consensus in the guidelines seems to favor performing the two procedures as separate interventions.
- However, there is no clear recommendation about PCI+TAVI in patients with AS+stable CAD
  - In whom?
    - Patients with high or low risk for surgery?
    - Patients with higher or lower degree of CAD? More over, no direct recommendation about degree of CAD in the guidelines?
  - When?
    - PCI before TAVI?
    - PCI concominant with TAVI?
    - PCI after TAVI?

- Rather than guidelines, it seems better to focus new trials!!!!!!

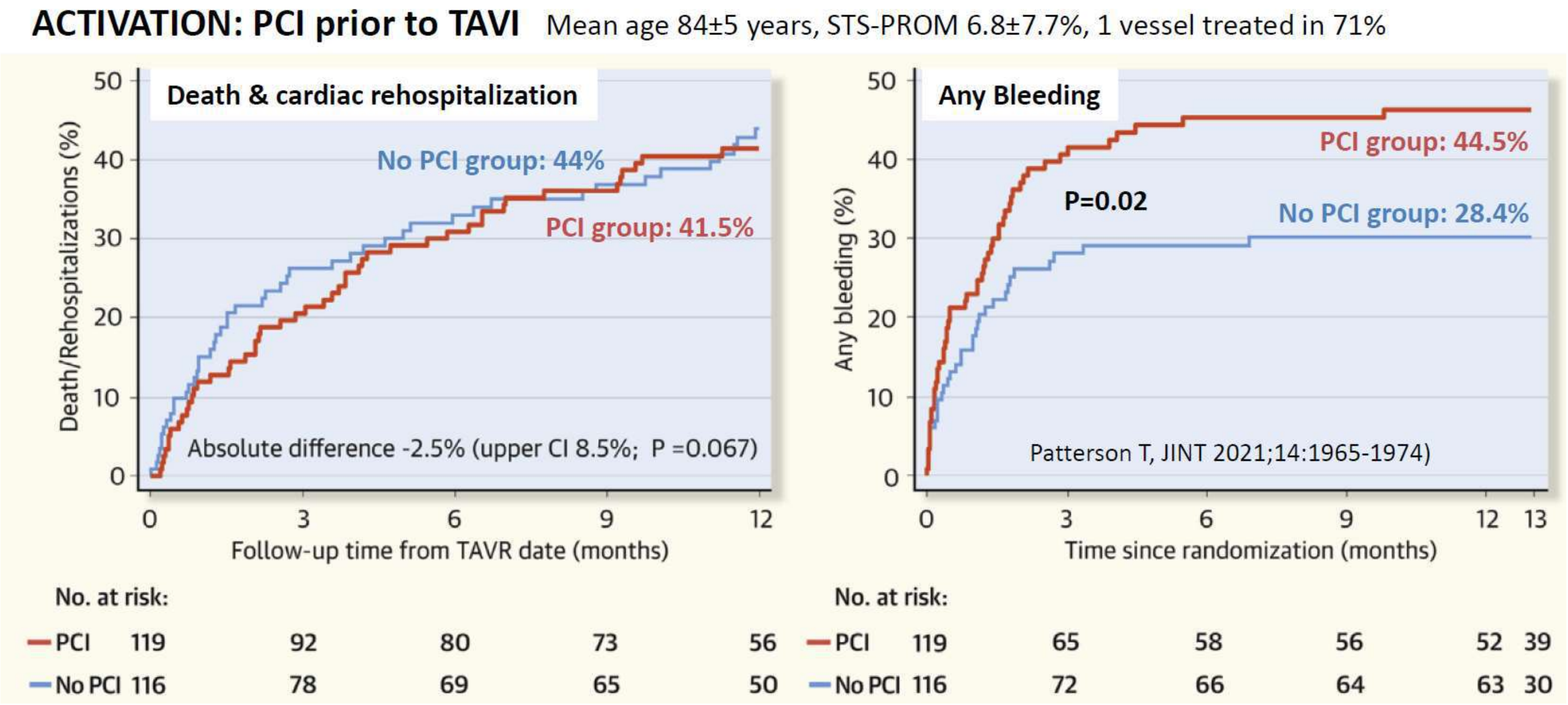
EVALUATION OF CAD IN PATIENTS WITH AS

- Coronary hemodynamics reflects the combined effect of CAD ***and*** the severity of AS.
- Non-invasive stress testing has been discouraged because of risk of arrhythmias.
- Interpretation of FFR can be challenging due to blunted effect of adenosine & change in hyperemic microvacular resistance.



- *CT-Angiography rather than coronary angiography may be the default clinical practice pattern in the future.*

CAN WE USE ONLY TAVI STRATEGY?
REVASCULARIZATON VS CONSERVATIVE TREATMENT

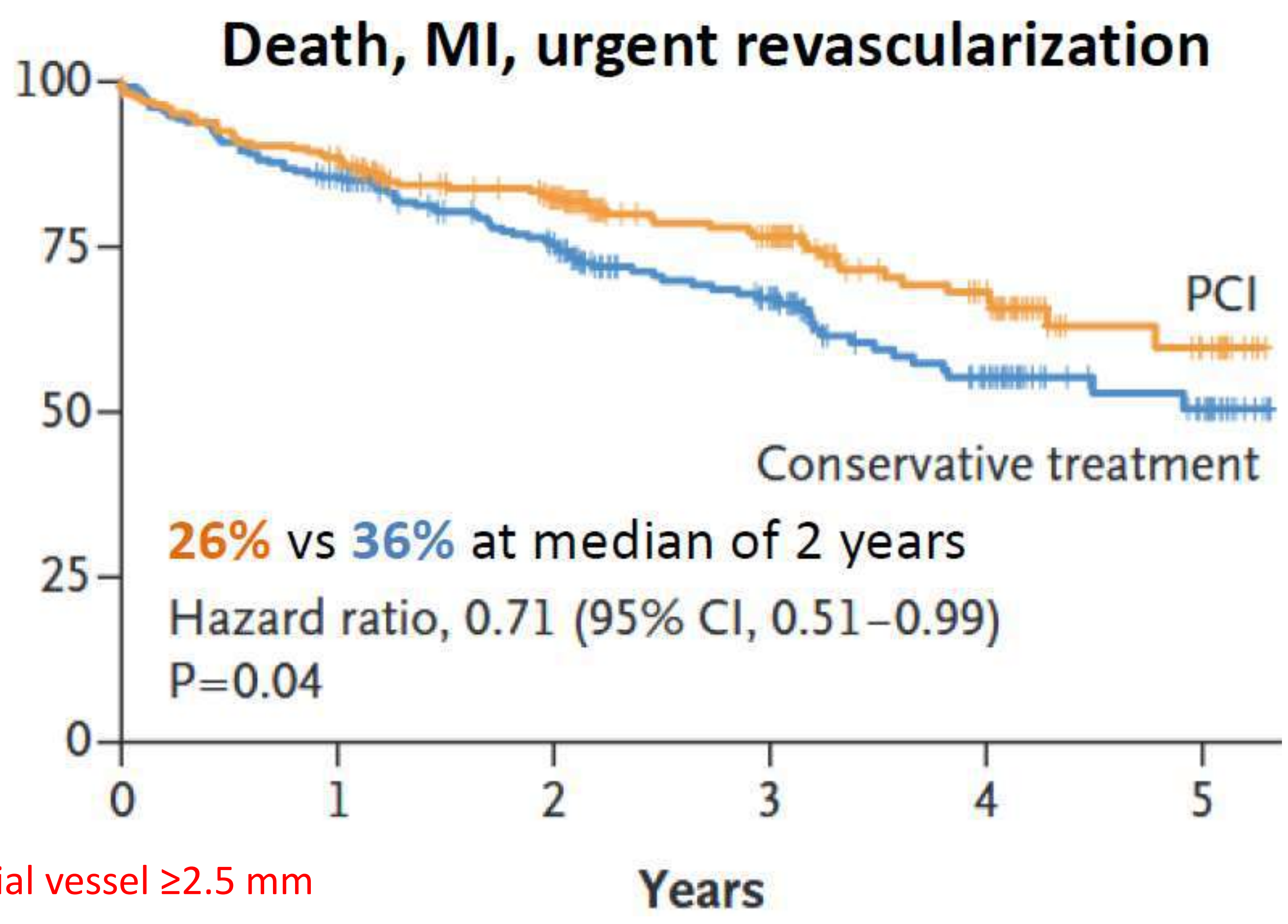


[5] Nevertheless, this study was underpowered and included only patients with stable CAD—of whom 69% were completely asymptomatic—and more than two-thirds of patients had single-vessel CAD

CAN WE USE ONLY TAVI STRATEGY?
REVASCULARIZATON VS CONSERVATIVE TREATMENT

NOTION-3: PCI vs conservative management in CAD with FFR ≤0.80 or 90% DS

N=455	TAVI & PCI	TAVI & Conservative
	227	228
Median age	82 (78-85)	81 (78-85)
Female sex	32%	33%
STS-PROM	3 (2-4)	3 (2-4)
Lesion with ≥90% stenosis	**61%**	**58%**
Multivessel disease	21%	20%
SYNTAX Score	9 (6-14)	9 (5-14)
LAD stenosis	63%	58%
Complete revascularization	89%	-



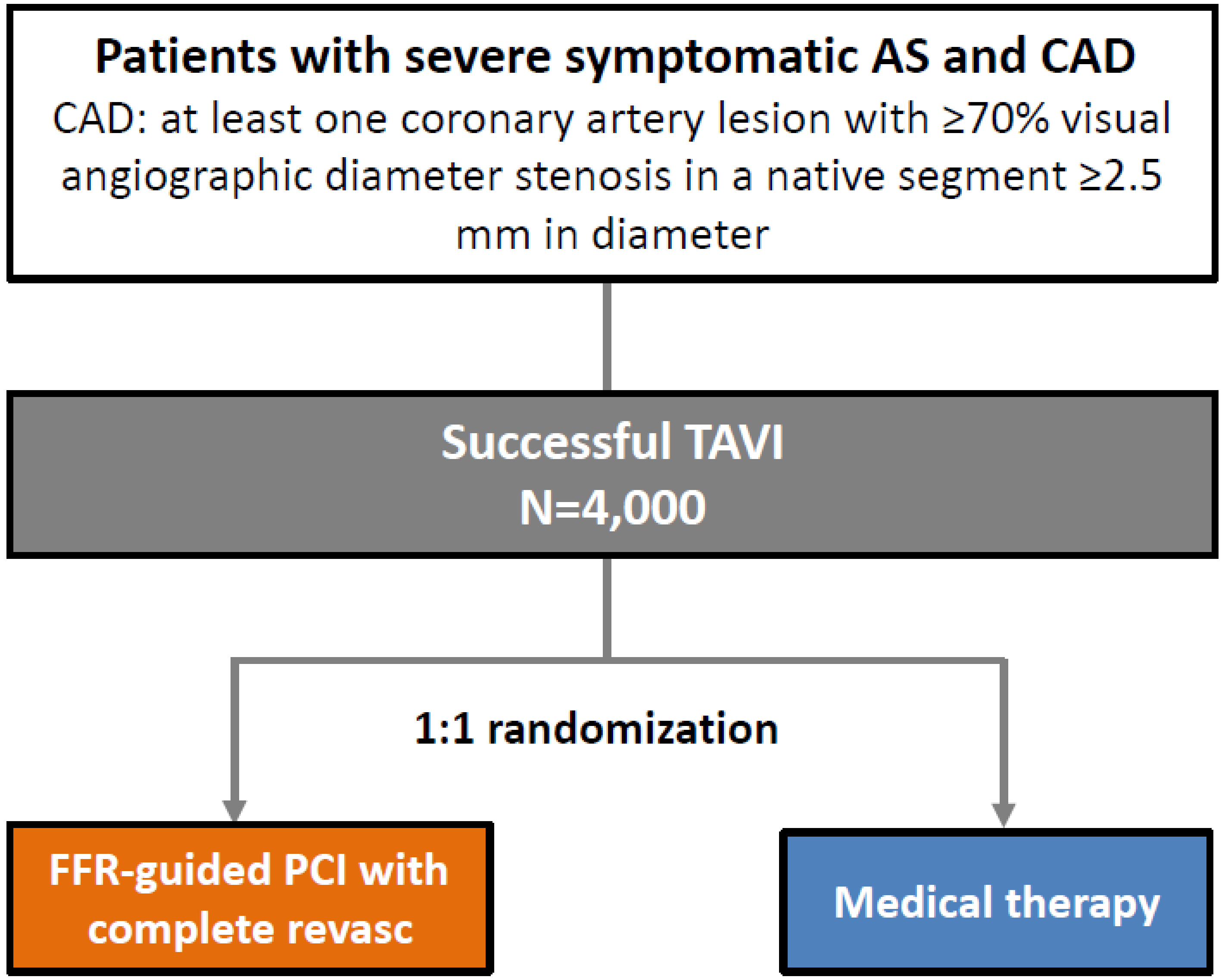
Obstructive coronary artery disease: FFR≤0.80 or ≥90% stenosis in an epicardial vessel ≥2.5 mm

Patients with symptomatic severe aortic stenosis with obstructive coronary artery disease in at least one vessel were randomized to PCI (n = 227) versus conservative therapy (n = 228). PCI was strongly recommended to be performed before TAVI, but could also be performed during or within 2 days after the procedure.

Lonborg J et al, NEJM, 2024

CAN WE USE ONLY TAVI STRATEGY?
REVASCULARIZATON VS CONSERVATIVE TREATMENT

COMPLETE TAVR



Key inclusion criteria

- Severe AS with NYHA ≥II OR positive exersize test
- CAD
- Successful transfemoral TAVR

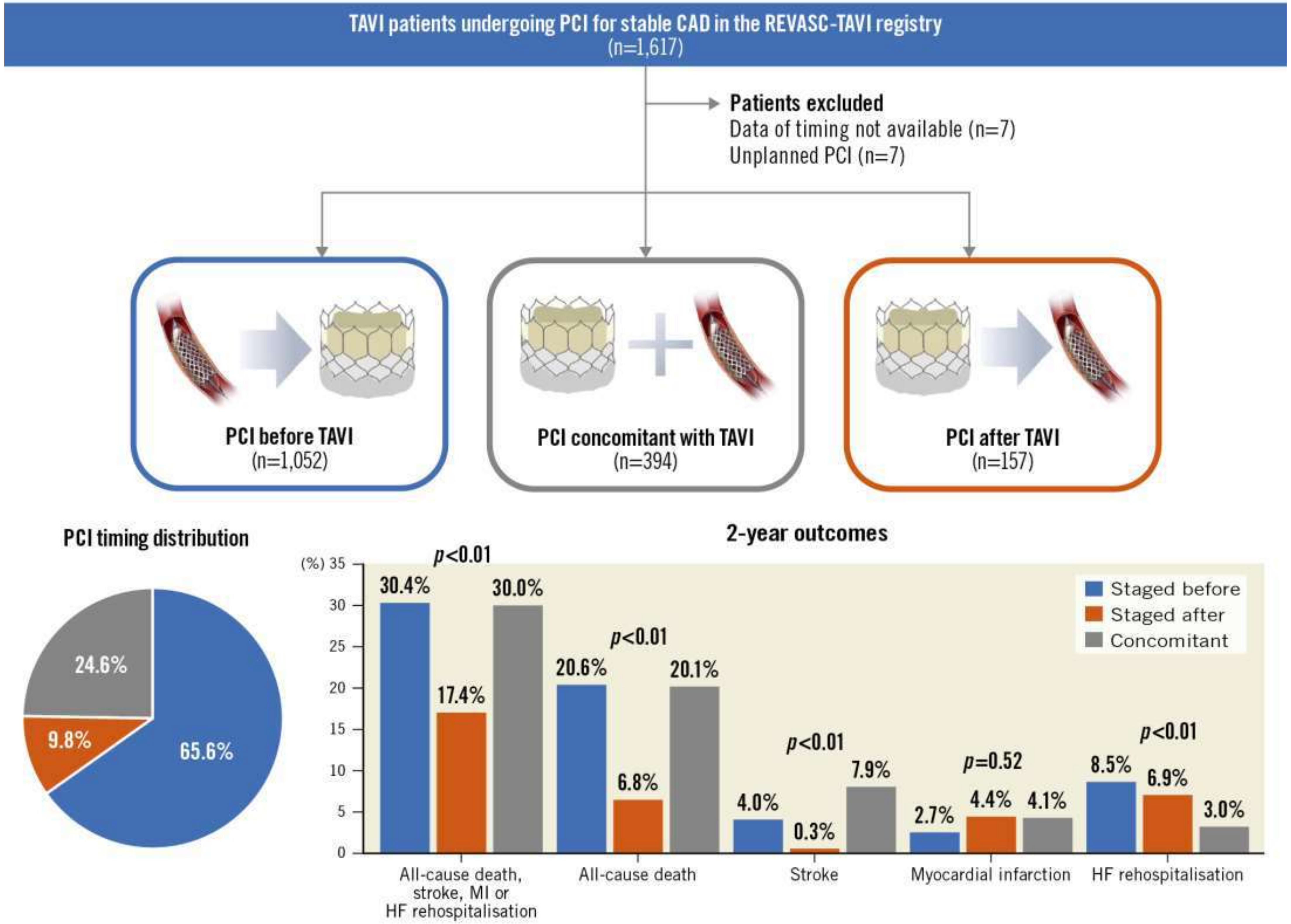
Key exclusion criteria

- PCI or AMI within 90 days prior to TAVI
- Planned revascularization
- Non-CV comorbidities with life expectancy <5 years
- Prior CABG or SAVR
- Severe MR
- LVEF <30%
- Low coronary takeoff
- eGFR <30 mL/min

Primary endpoint

Composite of cardiovascular death or new myocardial infarction or ischemia-driven revascularization or hospitalization for unstable angina or heart failure at a median follow-up of 3.5 years

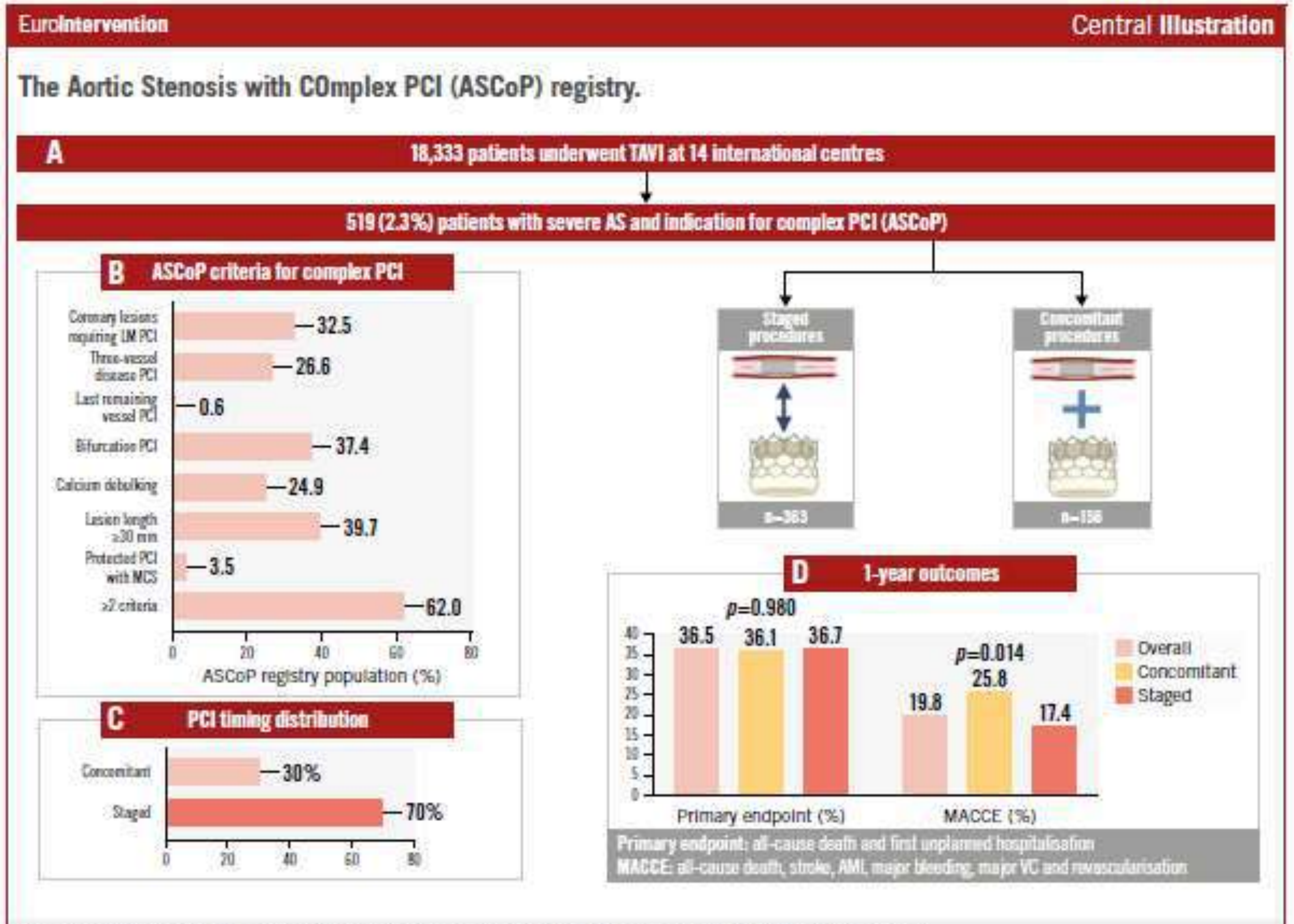
IF WE USE PCI+TAVI STRATEGY, WHAT IS THE OPTIMAL TIMING?



EuroIntervention 2023 Sep 18;19(7):589-599. doi: 10.4244/EIJ-D-23-00186

IF WE USE PCI+TAVI STRATEGY, WHAT IS THE OPTIMAL TIMING?

Complex PCI and TAVI: the ASCoP registry



Claudio Montalto *et al.* • *EuroIntervention* 2025;21:e426-e436 • DOI: 10.4244/EIJ-D-24-00933

A) Flowchart illustrating the study; (B) the population in terms of ASCoP criteria for complex PCI; (C) PCI timing distribution; and (D) the main results at 1 year. AMI: acute myocardial infarction; LM: left main; MACCE: major adverse cardiac and cerebrovascular events; MCS: mechanical circulatory support; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation; VC: vascular complication

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published online e-edition April 2025
DOI: 10.4244/EIJ-D-24-00933

ORIGINAL RESEARCH

Outcomes of complex, high-risk percutaneous coronary intervention in patients with severe aortic stenosis: the ASCoP registry

Claudio Montalto[1,2]*, MD; Andrea R. Munafò[1], MD; Francesco Soriano[1], MD; Ketina Arslani[3,4], MD; Stephanie Brunner[5], MD; Sarah Verhemel[6], MD; Ottavia Cozzi[7], MD; Antonio Mangieri[7], MD; Andrea Buono[8], MD; Mattia Squillace[9], MD; Stefano Nava[1], MD; José Luis Díez Gil[10], MD; Andrea Scotti[11], MD; Marco Foroni[12], MD; Giuseppe Esposito[1], MD, PhD; Alessandro Mandurino-Mirizzi[13], MD; David Bauer[14], MD; Benjamin De Ornelas[8], MD; Pablo Codner[15], MD; Kerstin Piayda[16], MD; Italo Porto[17], MD, PhD; Federico De Marco[18], MD, PhD; Horst Sievert[16], MD; Ran Kornowski[15], MD; Petr Toušek[14], MD; Dionigi Fischetti[13], MD; Azeem Latib[11], MD; Jorge Sanz Sanchez[10], MD; Diego Maffeo[8], MD; Francesco Bedogni[9], MD; Bernhard Reimers[7], MD; Damiano Regazzoli[7], MD; Nicolas van Mieghem[6], MD, PhD; Lars Sondergaard[19], MD; Francesco Saia[12], MD; Stefan Toggweiler[5], MD; Ole De Backer[3,20], MD, PhD; Jacopo A. Oreglia[1], MD

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This paper also includes supplementary data published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-24-00933

ABSTRACT

BACKGROUND: There is a lack of evidence to guide treatment of patients with a concomitant indication for transcatheter aortic valve implantation (TAVI) and complex, high-risk percutaneous coronary intervention (PCI).

AIMS: We aimed to assess different strategies of PCI timing in this high-risk TAVI cohort.

METHODS: The ASCoP registry retrospectively included patients with a clinical indication for both TAVI and PCI with at least 1 criterion of complex or high-risk PCI. The primary endpoint was a composite of all-cause death and unplanned rehospitalisation for cardiovascular causes. The secondary endpoint was a composite of all-cause death, stroke, acute myocardial infarction, major bleeding, major vascular complication and unplanned revascularisation. Multivariable analysis was used to adjust for possible confounders.

RESULTS: A total of 519 patients were included: 363 (69.9%) underwent staged procedures and 156 (30.1%) concomitant TAVI and PCI. After 441 (interquartile range 182-824) days, the primary endpoint occurred in 151 (36.5%) cases, without any significant difference between the 2 groups (p=0.98), while the secondary endpoint occurred more frequently in the concomitant group (n=36 [25.8%] vs n=57 [17.4%]; p=0.014).

CONCLUSIONS: In patients undergoing TAVI and complex/high-risk PCI, a concomitant strategy is associated with a higher rate of adverse events and increased procedural risk. (ClinicalTrials.gov: NCT05750927)

Supplementary Table 6. Sensitivity analysis excluding patients treated with staged PCI after TAVI.

	Concomitant Strategy (n= 156)	Staged Strategy (excluding PCI after TAVI) (n= 333)	*p* value[a]
	In-hospital Events		
Death	2 (1.3)	4 (1.2)	0.940
Acute kidney injury	12 (7.7)	22 (6.6)	0.660
Vascular complications	26 (16.7)	31 (9.3)	**0.018**
Minor	19 (12.2)	25 (7.5)	0.092
Major	7 (4.5)	6 (1.8)	0.085
Bleedings	21 (13.5)	30 (9)	0.133
Minor	4 (2.6)	17 (5.1)	0.196
Major	17 (10.9)	13 (3.9)	**0.003**
Stroke	4 (2.6)	5 (1.5)	0.415
TIA	0 (0)	4 (1.2)	0.169
	1-year follow-up		
Primary endpoint	41 (35.8)	97 (34.6)	0.636
MACCE	36 (25.8)	50 (16.1)	**0.007**
All-cause death	10 (8.8)	24 (8.3)	0.966
CV death	3 (2.9)	11 (3.9)	0.526
All-cause rehospitalization	34 (30.7)	82 (30.4)	0.923
CV rehospitalization	15 (14.6)	42 (16.7)	0.370
Stroke	7 (5)	7 (2.3)	0.134
Major bleedings	18 (11.8)	14 (4.4)	**0.001**
Major vascular complications	8 (5.7)	7 (2.3)	**0.046**
Myocardial infarction	5 (4.9)	5 (1.6)	0.161
Repeat PCI	5 (4.3)	6 (2.2)	0.354

DAPT, Dual Antiplatelet Therapy; OAC, Oral Anticoagulant Therapy; SAPT, Single Antiplatelet Therapy

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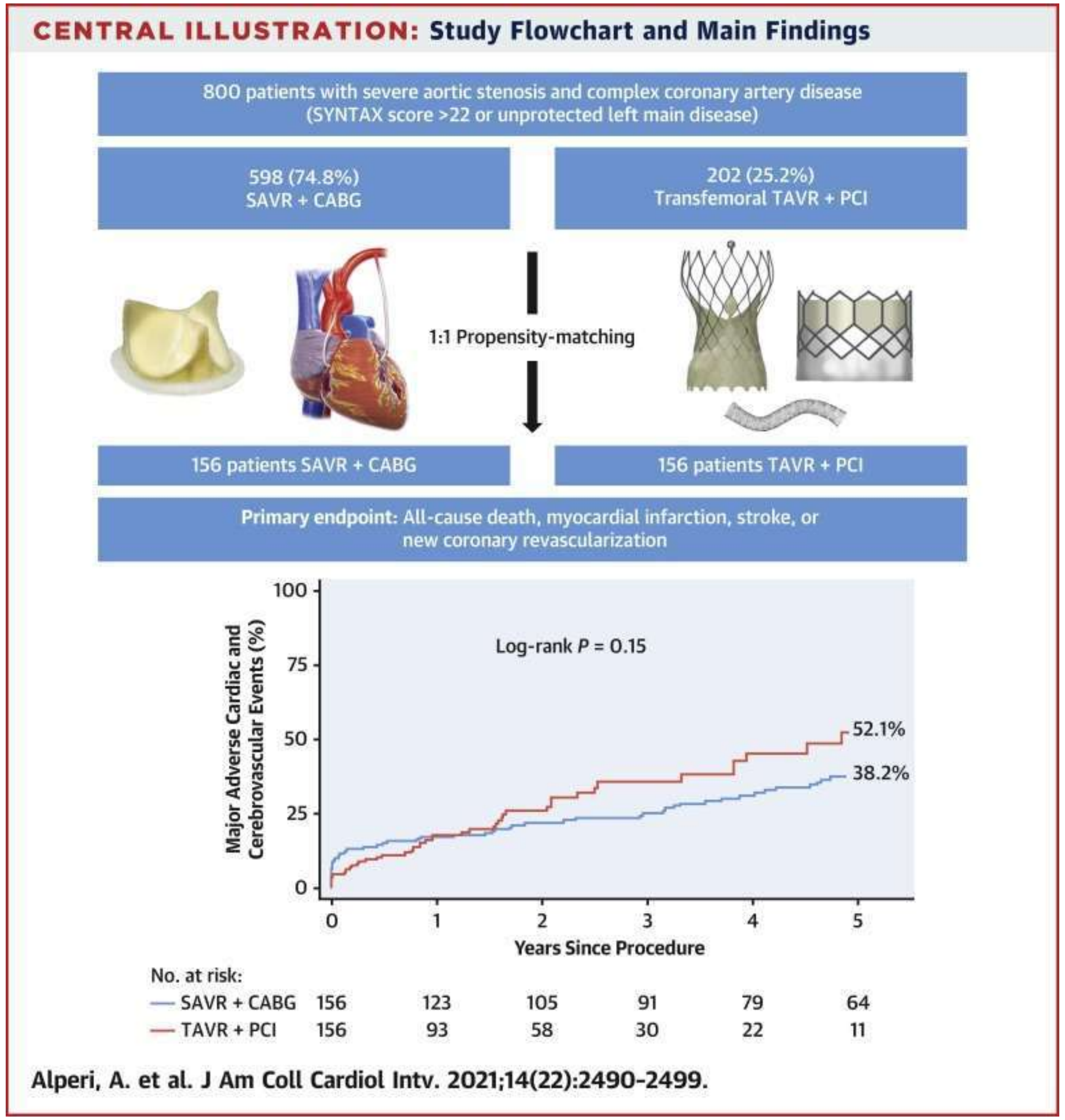
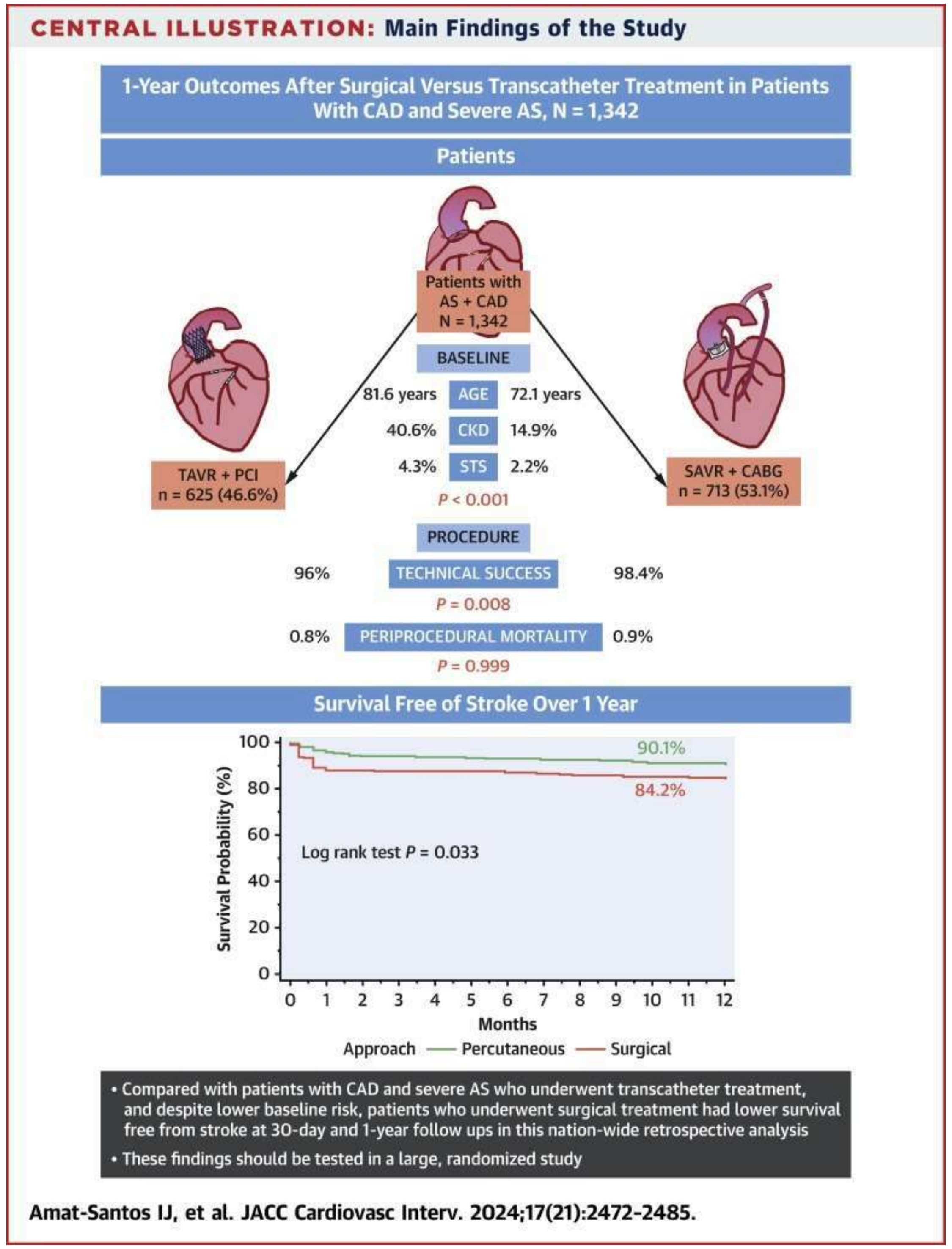
CONCLUSIONS: In patients undergoing TAVI and complex/high-risk PCI, a concomitant strategy is associated with a higher rate of adverse events and increased procedural risk. (ClinicalTrials.gov: NCT05750927)

ONE OF THE OTHER MAIN QUESTIONS:
SURGICAL VS TRANSCATHETER STRATEGY?



In patients with severe AS and complex CAD, TAVR + PCI and SAVR + CABG were associated with similar rates of MACCE after a median follow-up period of 3 years, but TAVR + PCI recipients exhibited a higher risk for repeat coronary revascularization.



Despite a lower baseline risk, CABG + SAVR in patients with severe AS and CAD was associated with a higher rate of death and stroke compared with PCI + TAVR, highlighting the necessity for a large, randomized analysis

ONE OF THE OTHER MAIN QUESTIONS: SURGICAL VS TRANSCATHETER STRATEGY?

Transcatheter Valves and Vessels trial

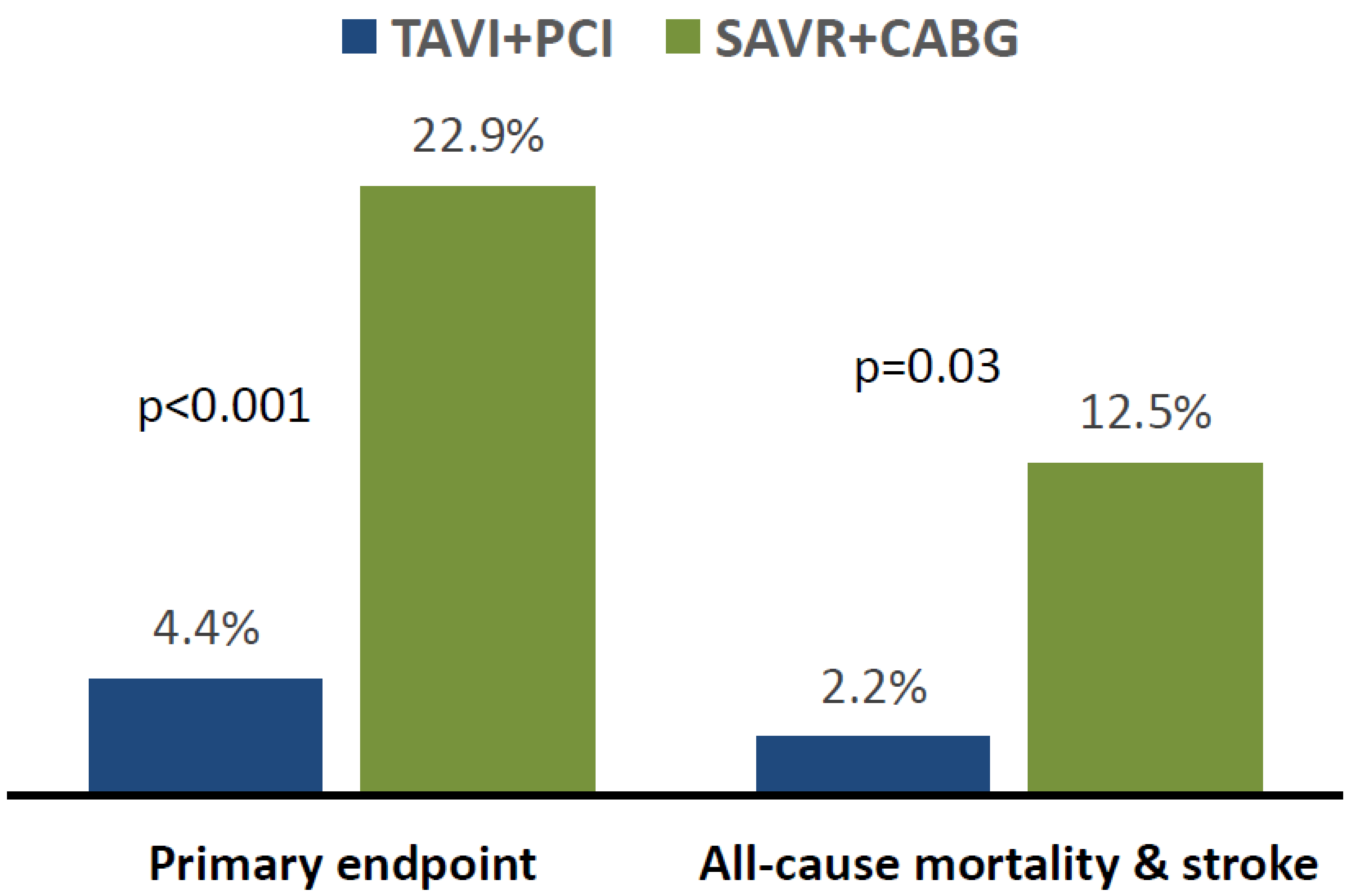
N=172 patients with AS an CAD (69% male)

1:1 randomization

TAVI + FFR-guided PCI
N=91

SAVR + CABG
N=81

- Mean age 76 years
- Mean STS-PROM 3.4%
- Two or more de novo lesions with a 50% of greater diameter stenosis (or single LAD lesion ≥ 20 mm length or involving a bifurcation
- SYNTAX score 13.4%



Primary endpoint: All-cause mortality, MI, disabling stroke, clinically driven TVR, valve reintervention, and life-threatening or disabling bleeding at 1 year

THE STUDY IS STOPPED DUE TO HIGHER MORTALITY AMONG SAVR+CABG GROUP!!!!!.

ONE OF THE OTHER MAIN QUESTIONS: SURGICAL VS TRANSCATHETER STRATEGY?

0003-4975/$36.00 843
https://doi.org/10.1016/j.athoracsur.2024.12.016

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Transcatheter vs Surgical Aortic Valve Replacement in Medicare Beneficiaries With Aortic Stenosis and Coronary Artery Disease

Check for updates

Vikrant Jagadeesan, MD,[1,*] J. Hunter Mehaffey, MD, MS,[2,*] Mohammed A. Kawsara, MD,[1] Dhaval Chauhan, MD,[2] J W. Awori Hayanga, MD, MPH,[2] Christopher E. Mascio, MD,[2] J. Scott Rankin, MD,[2] Ramesh Daggubati, MD,[1] and Vinay Badhwar, MD[2]

ABSTRACT

BACKGROUND As percutaneous therapeutic options expand, the optimal management of severe aortic stenosis (AS) and concomitant coronary artery disease (CAD) is being questioned between coronary artery bypass grafting with surgical aortic valve replacement (CABG+SAVR) and percutaneous coronary intervention with transcatheter aortic valve replacement (PCI+TAVR). This study sought to compare perioperative and longitudinal risk-adjusted outcomes between patients undergoing CABG+SAVR and patients undergoing PCI+TAVR.

METHODS Using the Centers for Medicare & Medicaid Services inpatient claims database, the study evaluated all patient aged 65 years and older with AS and CAD who were undergoing CABG+SAVR or PCI+TAVR (from 2018 to 2022). Comorbidities and frailty were accounted for using validated metrics with doubly robust risk adjustment using inverse probability weighting, multilevel regression, and competing-risk time to event analyses. The primary end point was a 5-year composite of stroke, myocardial infarction (MI), valve reintervention, or death.

RESULTS A total of 37,822 patients formed the study cohort (PCI+TAVR, n = 17,413; CABG+SAVR, n = 20,409). Accounting for age, comorbidities, frailty, and number of vessels revascularized, PCI+TAVR was associated with lower procedural mortality (1.1% vs 3.6%; odds ratio [OR], 0.29; *P* <.001) but higher vascular complications (OR, 6.02; *P* <.001) and new permanent pacemaker (OR, 1.92; *P* <.001). However, the longitudinal 5-year primary end point favored CABG+SAVR (20.4% vs 14.2%; OR, 1.44, *P* <.001). Subgroup analyses demonstrated a benefit in the use of arterial conduit in CABG+;AVR in patients with single-vessel CAD.

CONCLUSIONS Among Medicare beneficiaries with severe AS and CAD, CABG+SAVR was associated with higher procedural mortality than PCI+TAVR but lower 5-year risk-adjusted stroke, MI, valve reintervention, and death.

(Ann Thorac Surg 2025;119:843-51)

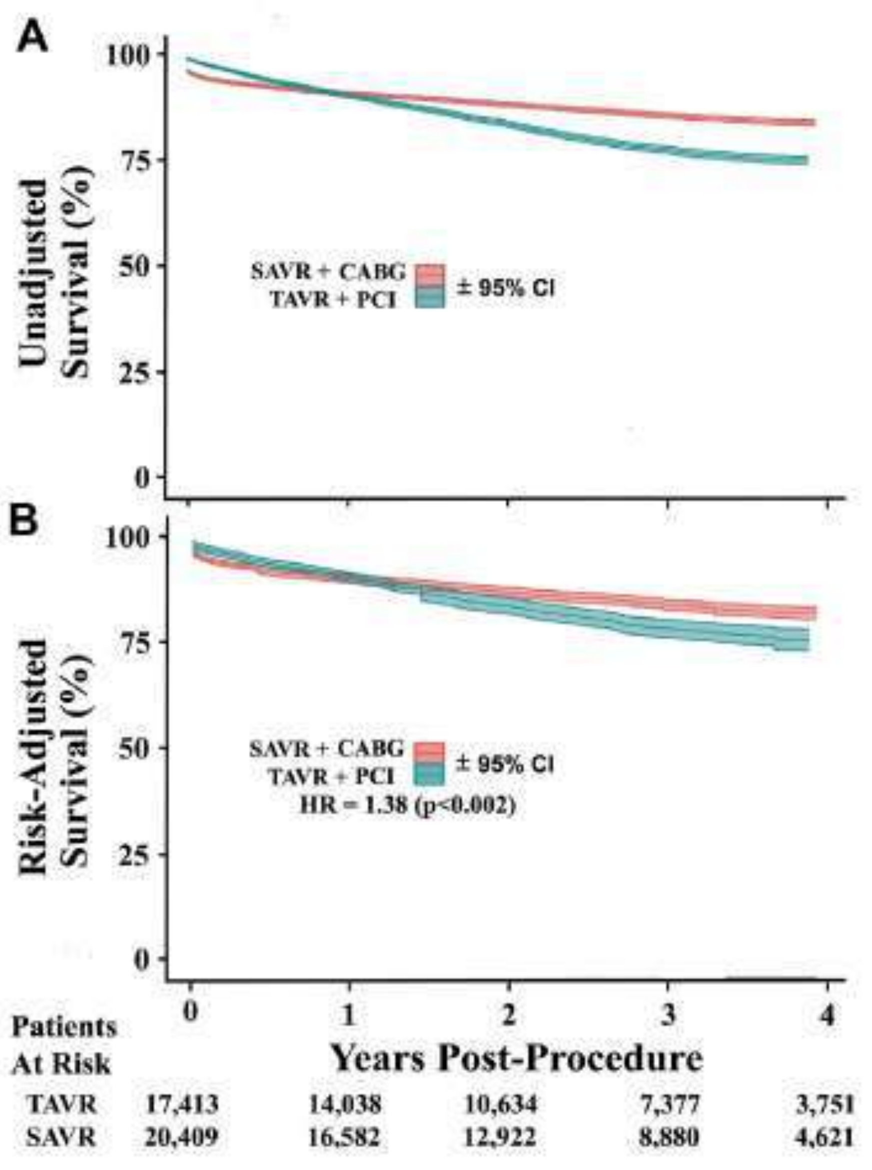


FIGURE 1 (A) Unadjusted all-cause mortality curves stratified by treatment group percutaneous coronary intervention with transcatheter aortic valve replacement (PCI+TAVR) (red) and coronary artery bypass grafting with surgical aortic valve replacement (CABG+SAVR) (blue). (B) Risk-adjusted all-cause mortality curves stratified by treatment group PCI+TAVR (red) and CABG+SAVR (blue). (HR, hazard ratio.)

HOW TO INTERPRETE THE AVAILABLE EVIDENCE?

Circulation

IN DEPTH

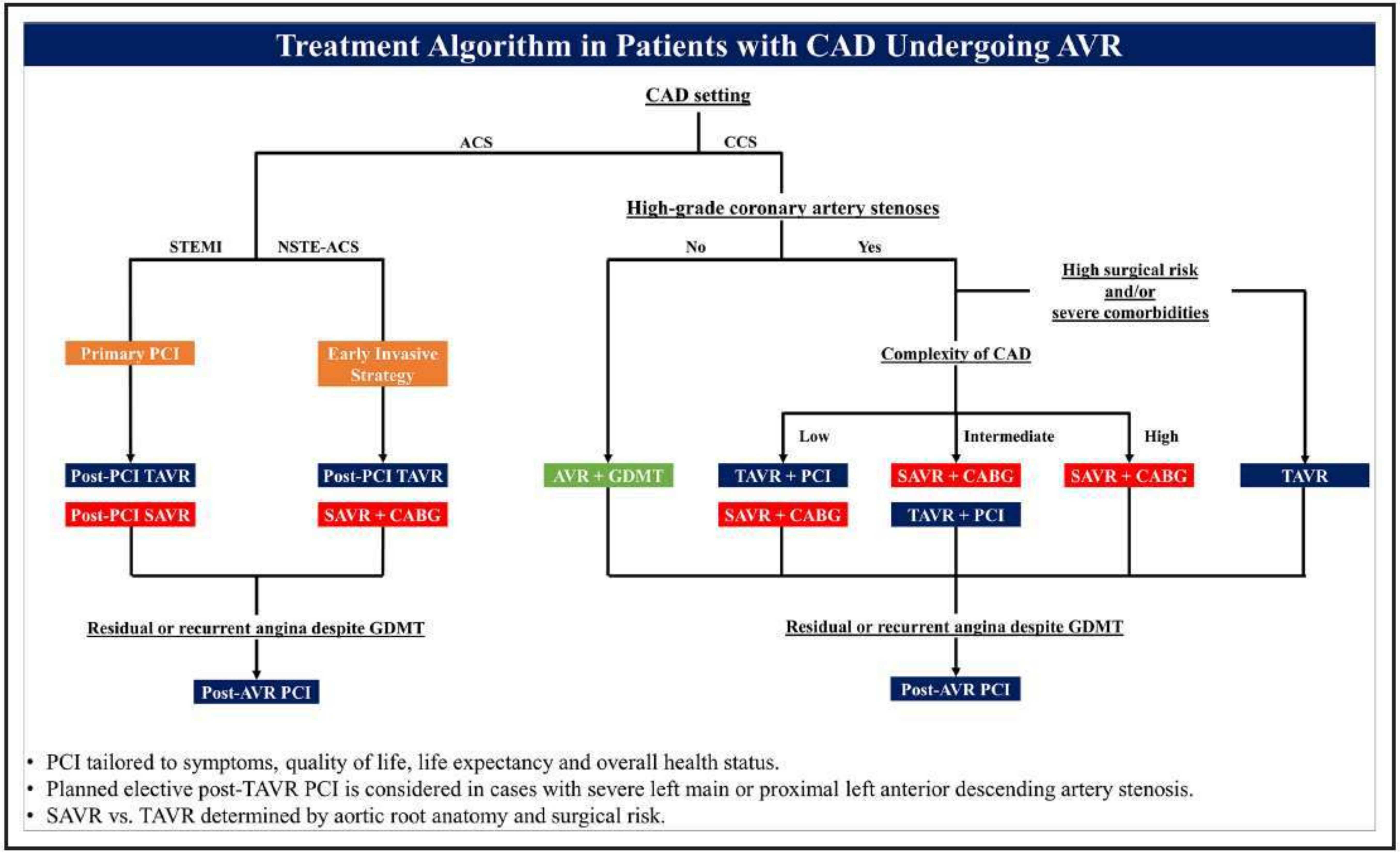
Aortic Stenosis and Coronary Artery Disease: Decision-Making Between Surgical and Transcatheter Management

Daijiro Tomii, MD; Thomas Pilgrim, MD, MSc; Michael A. Borger, MD, PhD; Ole De Backer, MD, PhD; Jonas Lanz, MD, MSc; David Reineke, MD; Matthias Siepe, MD; Stephan Windecker, MD

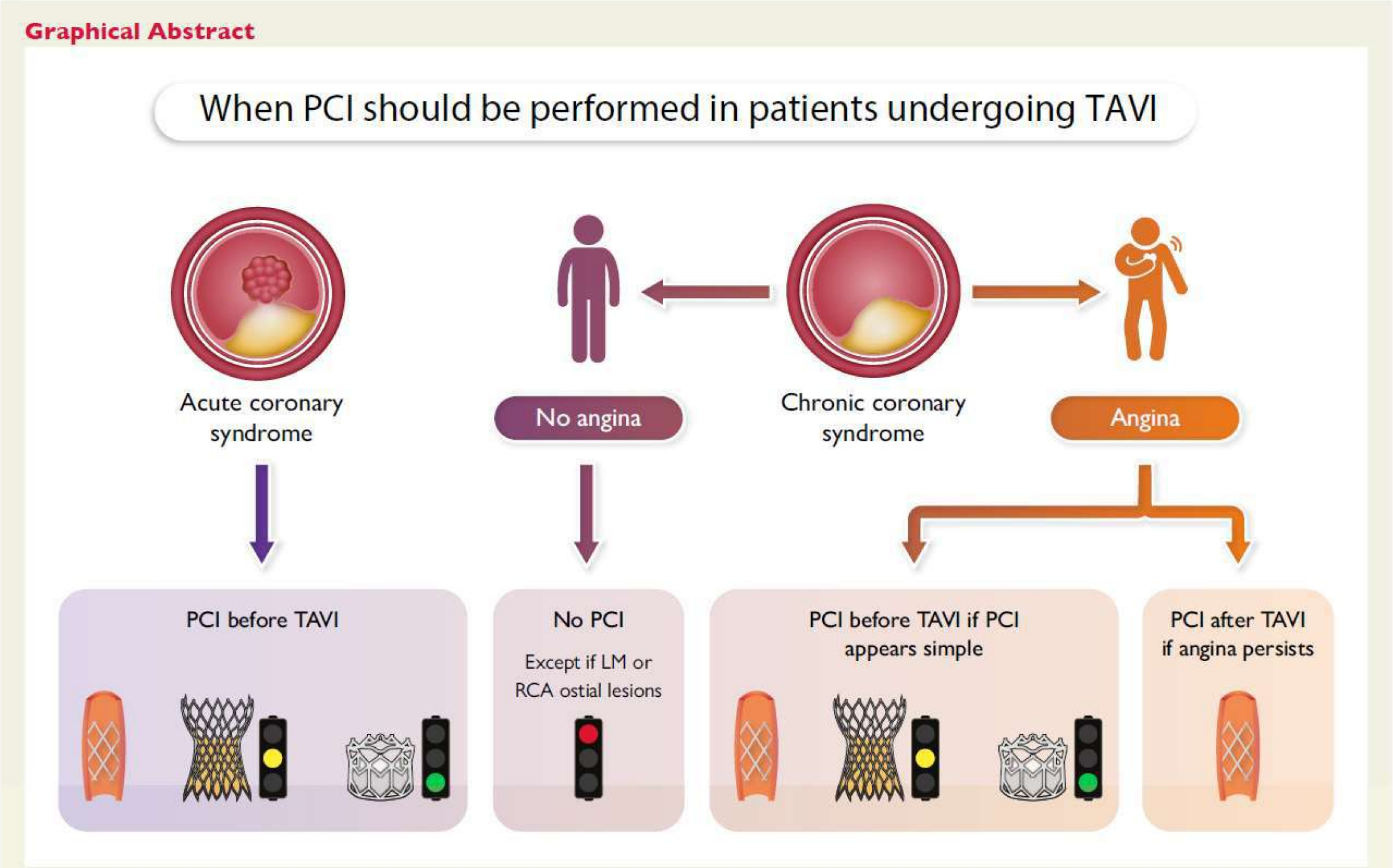
ABSTRACT: Aortic stenosis (AS) and coronary artery disease (CAD) frequently coexist and share pathophysiological mechanisms. The proportion of patients with AS and CAD requiring revascularization varies widely because of uncertainty about best clinical practices. Although combined surgical aortic valve replacement and coronary artery bypass grafting has been the standard of care, management options in patients with AS and CAD requiring revascularization have expanded with the advent of transcatheter aortic valve replacement (TAVR). Potential alternative treatment pathways include revascularization before TAVR, concomitant TAVR and percutaneous coronary intervention, percutaneous coronary intervention after TAVR and deferred percutaneous coronary intervention or hybrid procedures. Selection depends on underlying disease severity, antithrombotic treatment strategies, clinical presentation, and symptom evolution after TAVR. In patients undergoing surgical aortic valve replacement, the addition of coronary artery bypass grafting has been associated with improved long-term mortality, especially if CAD is complex. although it is associated with higher periprocedural risk. The therapeutic impact of percutaneous coronary intervention in patients with TAVR is less well-established. The multitude of clinical permutations and remaining uncertainties do not support a uniform treatment strategy for patients with AS and CAD. Therefore, to provide the best possible care for each individual patient, heart teams need to be familiar with the available data on AS and CAD. Herein, we provide an in-depth review of the evidence supporting the decision-making process between transcatheter and surgical approaches and the key elements of treatment selection in patients with AS and CAD.

Key Words: aortic stenosis ■ computed tomography ■ coronary artery bypass grafting ■ coronary artery disease ■ percutaneous coronary intervention ■ surgical aortic valve replacement ■ transcatheter aortic valve replacement

HOW TO INTERPRETE THE AVAILABLE EVIDENCE?



Tomii D, Pilgrim T, Borger MA, et al. Aortic Stenosis and Coronary Artery Disease: Decision-Making Between Surgical and Transcatheter Management. Circulation. 2024;150:2046-2069.



When PCI should be performed in patients undergoing TAVI

Eltchaninoff H, Durand E. Transfemoral aortic valve implantation and concomitant CAD: the jury is out. Eur Heart J. 2024

WHAT IS THE OPTIMAL TREATMENT STRATEGY IN PATIENTS WITH CONCOMINANT CAD AND SEVERE AS?

Decision making process between surgical and transcatheter intervention in patients with severe AS and significant CAD requiring intervention

Patient characteristics	Patient vulnerability	Low	Intermediate	High
	Diabetes	Yes		No
Coronary artery characteristics	Distribution and complexity of CAD	3 vessel disease with SYNTAX Score >22 LM disease with SYNTAX Score >32	3 vessel disease with SYNTAX Score ≤22 LM disease with SYNTAX Score ≤32	1 or 2 vessel disease
Post AVR considerations	Coronary Access after TAVR	Hostile	Intermediate	Favorable
	Treatment Options	SAVR + CABG	SAVR + CABG TAVR + PCI	TAVR ± PCI

ESC/EACTS TAKE HOME MESSAGES

- SAVR and TAVI are both excellent treatment options for AS
- The choice between TAVI and SAVR must be based upon Heart Team evaluation for all patients
- Basic scenarios
  - SAVR: younger patients (<75 yrs) at low surgical risk
  - SAVR: unsuitable for TF TAVI and operable
  - TAVI: older patients (≥ 75 yrs)
  - TAVI: inoperable or high surgical risk
- The mode of intervention in all other scenarios should be determined by careful consideration of the clinical, anatomical and procedural characteristics of each individual patient
- The Heart Team recommendation should be discussed with the patient who can then make an informed treatment choice