Late Breaking Clinical Trials

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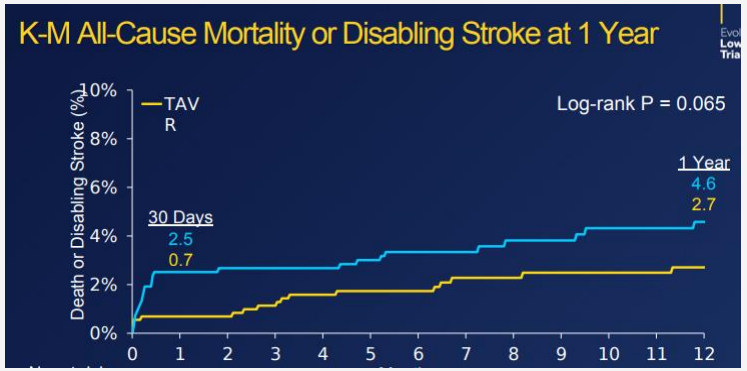
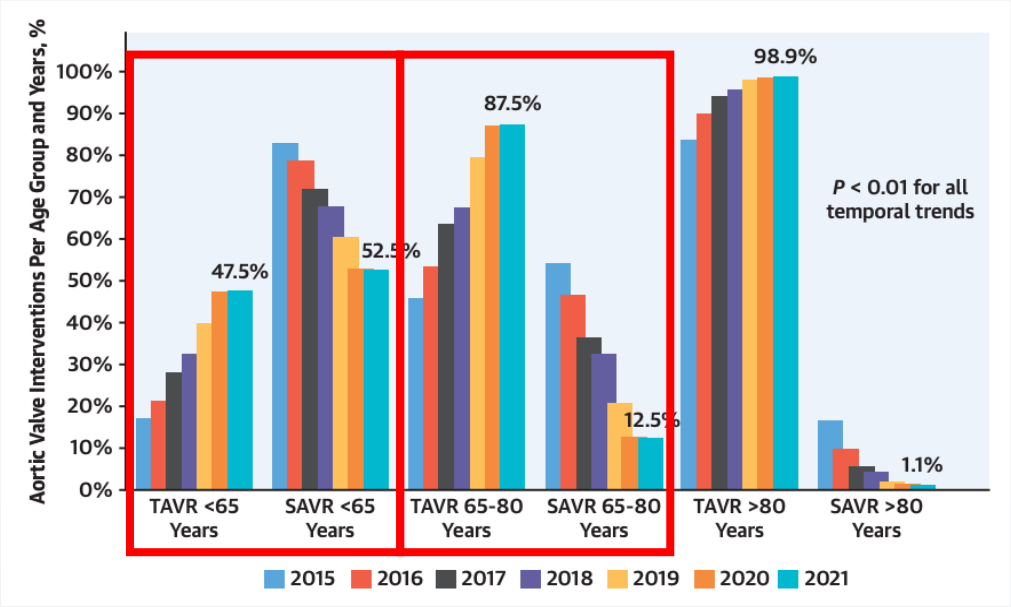
Disclosure

- I have nothing to disclose.

TAVI in low risk



- TAVI is expanding in "*low risk/young*" patients.
- A shift of "**what matters**".



PROCEDURAL SUCCESS METRICS

- Mortality & Stroke
- Quality of Life
- Conduction Disturbance (PPI)

Higher risk + Lower Risk

	Higher risk	Lower Risk
AGE	80+	65+, CAD
ANATOMY	Tri-leaflet	More Bicuspid
ACTIVITY	Low	High(er)

LIFETIME MANAGEMENT METRICS

- Hemodynamics & PPM
- Durability < Life Expectancy
- Coronary Access (PCI) & TAV-in-TAV

Sharma T, et al., JACC 2023;80:2054-2056

TAVI in low risk

ESC European Society of Cardiology
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FASTTRACK CLINICAL RESEARCH
Interventional cardiology

Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial

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See the editorial comment for this article 'Transcatheter vs. surgical treatment of aortic stenosis: long-awaited long-term data, yet a long road to go', by S. Bleiziffer, https://doi.org10.1093/eurheartj/ehad873.

Abstract

Background and Aims Transcatheter aortic valve implantation (TAVI) has become a viable treatment option for patients with severe aortic valve stenosis across a broad range of surgical risk. The Nordic Aortic Valve Intervention (NOTION) trial was the first to randomize patients at lower surgical risk to TAVI or surgical aortic valve replacement (SAVR). The aim of the present study was to report clinical and bioprosthesis outcomes after 10 years.

Methods The NOTION trial randomized 280 patients to TAVI with the self-expanding CoreValve (Medtronic Inc.) bioprosthesis ($n = 145$) or SAVR with a bioprosthesis ($n = 135$). The primary composite outcome was the risk of all-cause mortality, stroke, or myocardial infarction. Bioprosthetic valve dysfunction (BVD) was classified as structural valve deterioration (SVD), non-structural valve dysfunction (NSVD), clinical valve thrombosis, or endocarditis according to Valve Academic Research Consortium-3 criteria. Severe SVD was defined as (i) a transprosthetic gradient of 30 mmHg or more and an increase in transprosthetic gradient of 20 mmHg or more or (ii) severe new intraprosthetic regurgitation. Bioprosthetic valve failure (BVF) was defined as the composite rate of death from a valve-related cause or an unexplained death following the diagnosis of BVD, aortic valve re-intervention, or severe SVD.

Results Baseline characteristics were similar between TAVI and SAVR: age 79.2 ± 4.9 years and 79.0 ± 4.7 years ($P = .7$), male 52.6% and 53.8% ($P = .8$), and Society of Thoracic Surgeons score < 4% of 83.4% and 80.0% ($P = .5$), respectively. After 10 years, the risk of the composite outcome all-cause mortality, stroke, or myocardial infarction was 65.5% after TAVI and 65.5% after SAVR [hazard ratio (HR) 1.0; 95% confidence interval (CI) 0.7–1.3; $P = .9$], with no difference for each individual outcome. Severe SVD had occurred in 1.5% and 10.0% (HR 0.2; 95% CI 0.04–0.7; $P = .02$) after TAVI and SAVR, respectively. The cumulative incidence for severe NSVD was 20.5% and 43.0% ($P < .001$) and for endocarditis 7.2% and 7.4% ($P = 1.0$) after TAVI and SAVR, respectively. No patients had clinical valve thrombosis. Bioprosthetic valve failure occurred in 9.7% of TAVI and 13.8% of SAVR patients (HR 0.7; 95% CI 0.4–1.5; $P = .4$).

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ORIGINAL INVESTIGATIONS

3-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

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ABSTRACT

BACKGROUND Randomized data comparing outcomes of transcatheter aortic valve replacement (TAVR) with surgery in low-surgical risk patients at time points beyond 2 years is limited. This presents an unknown for physicians striving to educate patients as part of a shared decision-making process.

OBJECTIVES The authors evaluated 3-year clinical and echocardiographic outcomes from the Evolut Low Risk trial.

METHODS Low-risk patients were randomized to TAVR with a self-expanding, supra-annular valve or surgery. The primary endpoint of all-cause mortality or disabling stroke and several secondary endpoints were assessed at 3 years.

RESULTS There were 1,414 attempted implantations (730 TAVR; 684 surgery). Patients had a mean age of 74 years and 35% were women. At 3 years, the primary endpoint occurred in 7.4% of TAVR patients and 10.4% of surgery patients (HR: 0.70; 95% CI: 0.49-1.00; $P = 0.051$). The difference between treatment arms for all-cause mortality or disabling stroke remained broadly consistent over time: −1.8% at year 1; −2.0% at year 2; and −2.9% at year 3. The incidence of mild paravalvular regurgitation (20.3% TAVR vs 2.5% surgery) and pacemaker placement (23.2% TAVR vs 9.1% surgery; $P < 0.001$) were lower in the surgery group. Rates of moderate or greater paravalvular regurgitation for both groups were <1% and not significantly different. Patients who underwent TAVR had significantly improved valve hemodynamics (mean gradient 9.1 mm Hg TAVR vs 12.1 mm Hg surgery; $P < 0.001$) at 3 years.

CONCLUSIONS Within the Evolut Low Risk study, TAVR at 3 years showed durable benefits compared with surgery with respect to all-cause mortality or disabling stroke. (Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients; NCT02701283) (J Am Coll Cardiol 2023;81:1663-1674) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus

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ABSTRACT

BACKGROUND
Patients with severe aortic stenosis and a small aortic annulus are at risk for impaired valvular hemodynamic performance and associated adverse cardiovascular clinical outcomes after transcatheter aortic-valve replacement (TAVR).

METHODS
We randomly assigned patients with symptomatic severe aortic stenosis and an aortic-valve annulus area of 430 mm^2 or less in a 1:1 ratio to undergo TAVR with either a self-expanding supraannular valve or a balloon-expandable valve. The coprimary end points, each assessed through 12 months, were a composite of death, disabling stroke, or rehospitalization for heart failure (tested for noninferiority) and a composite end point measuring bioprosthetic-valve dysfunction (tested for superiority).

RESULTS
A total of 716 patients were treated at 83 sites in 13 countries (mean age, 80 years; 87% women; mean Society of Thoracic Surgeons Predicted Risk of Mortality, 3.3%). The Kaplan–Meier estimate of the percentage of patients who died, had a disabling stroke, or were rehospitalized for heart failure through 12 months was 9.4% with the self-expanding valve and 10.6% with the balloon-expandable valve (difference, −1.2 percentage points; 90% confidence interval [CI], −4.9 to 2.5; P<0.001 for noninferiority). The Kaplan–Meier estimate of the percentage of patients with bioprosthetic-valve dysfunction through 12 months was 9.4% with the self-expanding valve and 41.6% with the balloon-expandable valve (difference, −32.2 percentage points; 95% CI, −38.7 to −25.6; P<0.001 for superiority). The aortic-valve mean gradient at 12 months was 7.7 mm Hg with the self-expanding valve and 15.7 mm Hg with the balloon-expandable valve, and the corresponding values for additional secondary end points through 12 months were as follows: mean effective orifice area, 1.99 cm^2 and 1.50 cm^2; percentage of patients with hemodynamic structural valve dysfunction, 3.5% and 32.8%; and percentage of women with bioprosthetic-valve dysfunction, 10.2% and 43.3% (all P<0.001). Moderate or severe prosthesis–patient mismatch at 30 days was found in 11.2% of the patients in the self-expanding valve group and 35.3% of those in the balloon-expandable valve group (P<0.001). Major safety end points appeared to be similar in the two groups.

CONCLUSIONS
Among patients with severe aortic stenosis and a small aortic annulus who underwent TAVR, a self-expanding supraannular valve was noninferior to a balloon-expandable valve with respect to clinical outcomes and was superior with respect to bioprosthetic-valve dysfunction through 12 months. (Funded by Medtronic; SMART ClinicalTrials.gov number, NCT04722250.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Herrmann can be contacted at howard.herrmann@pennmedicine.upenn.edu or at the Hospital of the University of Pennsylvania, PCAM South Pavilion 11-107, 3400 Civic Center Blvd., Philadelphia, PA 19104.

*A complete list of the SMART trial investigators is provided in the Supplementary Appendix, available at NEJM.org.

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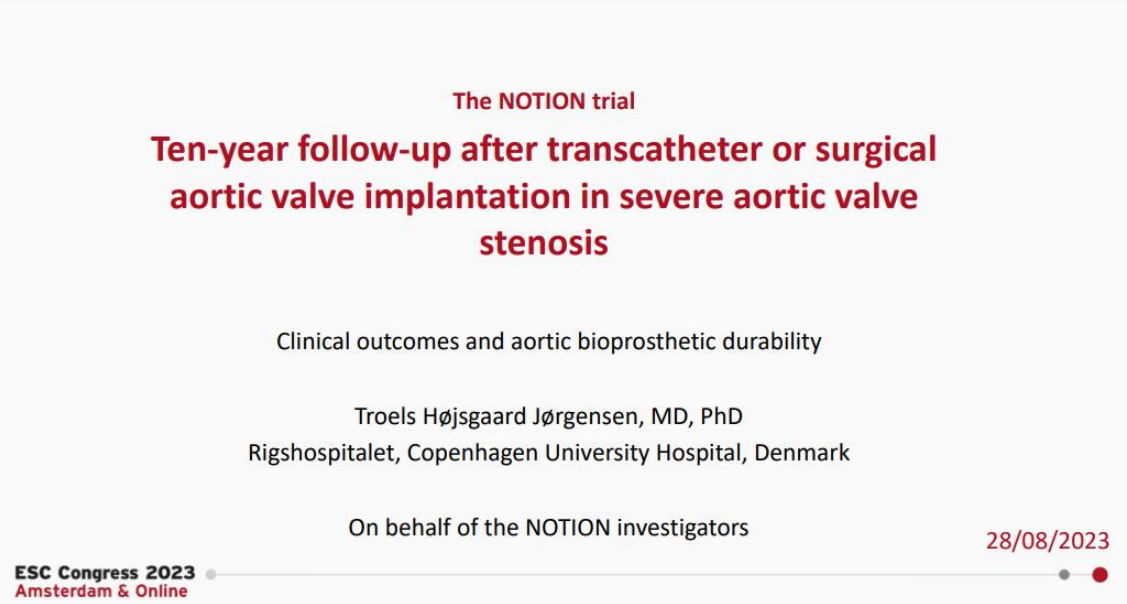
NOTION trial

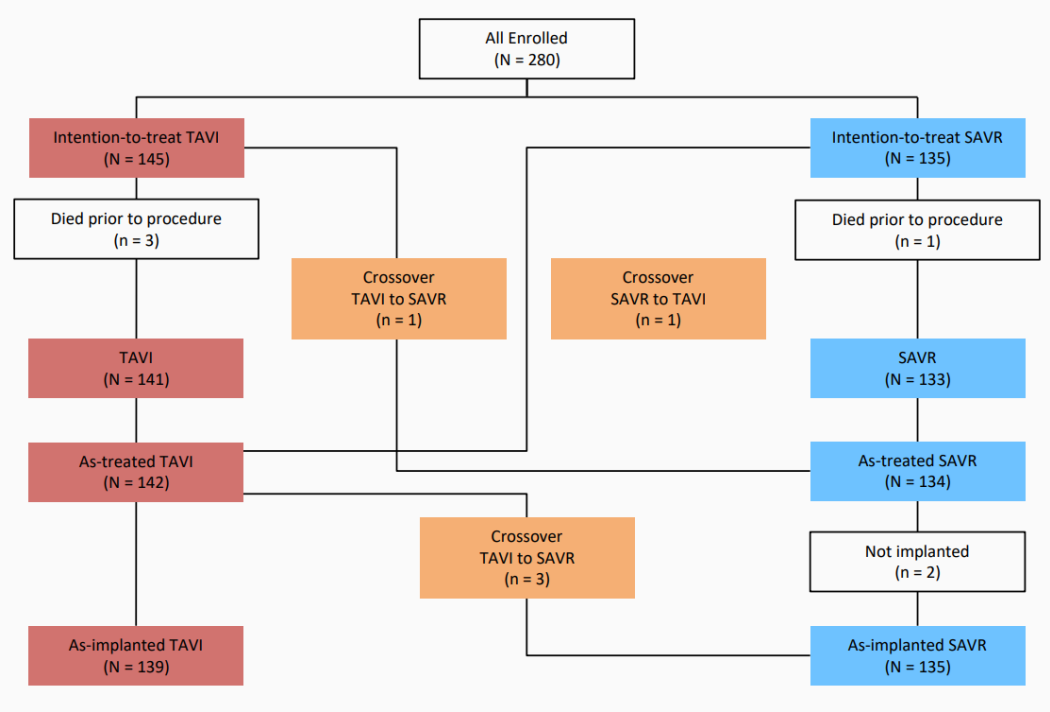
- Nordic Aortic Valve Intervention Trial (NOTION)
- Presented at the ESC 2023



Thyregod et al. EHJ, 2024;45,1116–1124

NOTION trial

- Nordic Aortic Valve Intervention Trial (NOTION)
- Patients diagnosed with severe AS from 2009 to 2013
- Received first- or second-generation CoreValve bioprosthesis

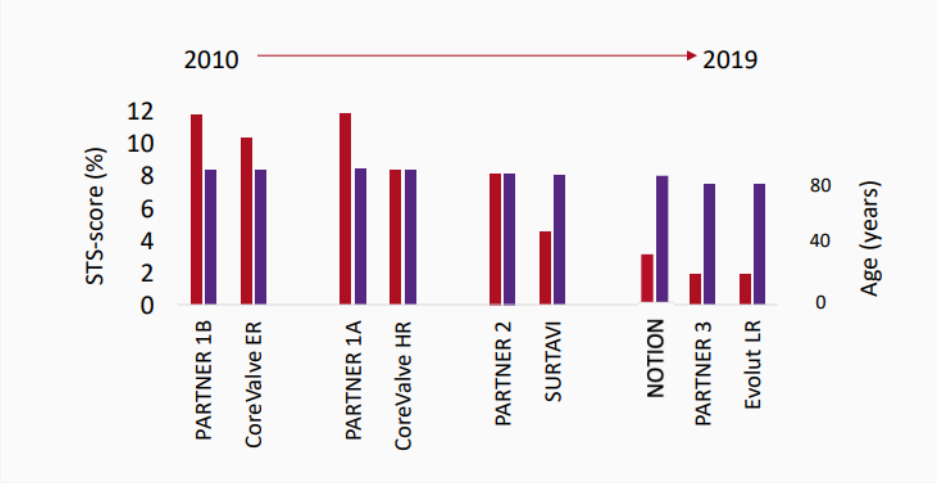


	TAVI (n = 145)	SAVR (n = 135)
Baseline		
Age, Years	79.2 (4.9)	79.0 (4.7)
STS-PROM Score	2.9 (1.6)	3.1 (1.7)
Cerebrovascular incidence	24 (16.6%)	22 (16.3%)
Cardiac Risk factors		
Prior PCI	11 (7.6%)	12 (8.9%)
Pre-existing pacemaker	5 (3.4%)	6 (4.4%)
Prior Myocardial infarction	8 (5.5%)	6 (4.4%)
Known atrial fibrillation/flutter	40/144 (27.8%)	34/133 (25.6%)
Procedure		
Procedure Time*	90.3 (38.6)	177.2 (39.8)
Procedural Success	139/142 (97.9%)	NA
Transfemoral access	137/142 (96.5%)	NA
Subclavian access	5/142 (3.5%)	NA
Valve sizes		
19mm		11/132 (8.3%)
21mm		42/132 (31.8%)
23mm	2/142 (1.4%)	45/132 (34.1%)
25mm		32/132 (24.2%)
26mm	57/142 (40.1%)	
27mm		2/132 (1.5%)
29mm	69/142 (48.6%)	
31mm	14/142 (9.9%)	

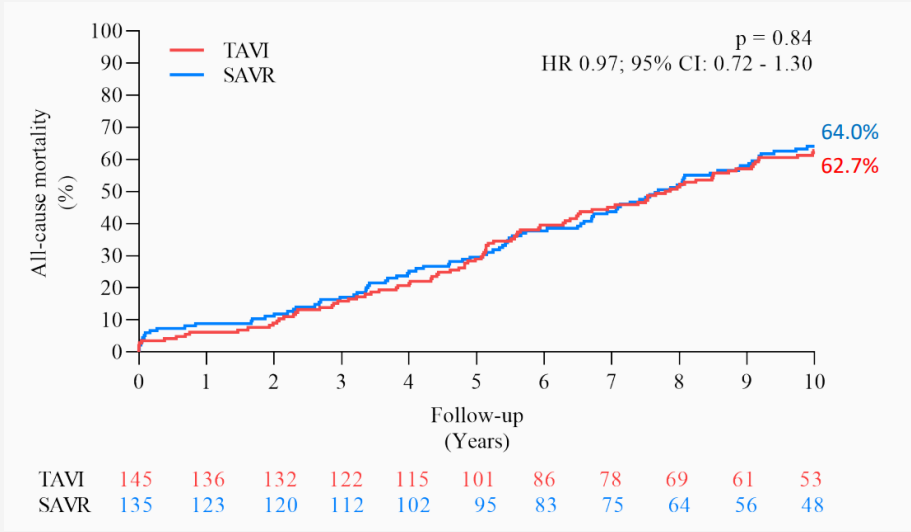
Thyregod et al. EHJ, 2024;45,1116–1124

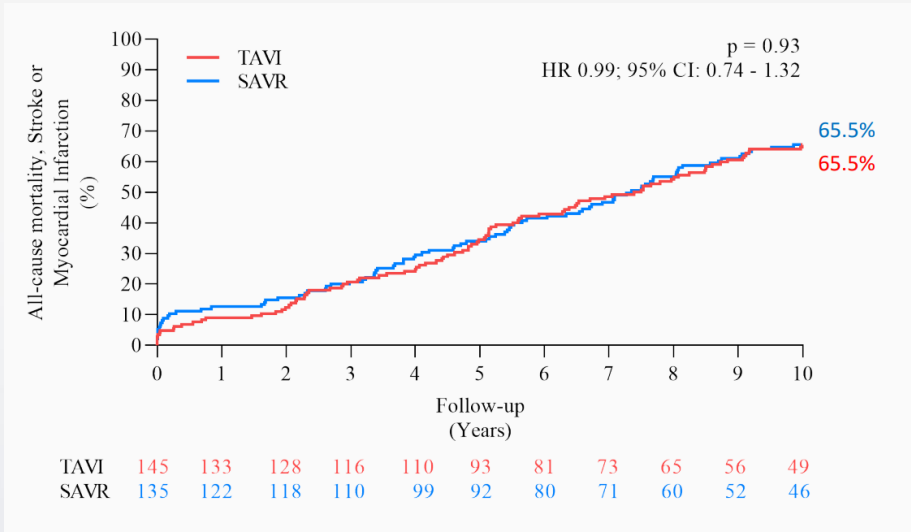
NOTION trial

- Nordic Aortic Valve Intervention Trial (NOTION)



	TAVI ($n = 145$)	SAVR ($n = 135$)	*P*-value
All-cause mortality	62.7	64.0	.8
Cardiovascular death	49.5	51.2	.7
Stroke[a]	9.7	16.4	.1
Stroke with sequelae	6.9	10.4	.3
Transient ischaemic attack	9.7	6.7	.3
Myocardial Infarction	11.0	8.2	.4
New-onset atrial fibrillation	52.0	74.1	<.01
New permanent pacemaker	44.7	14.0	<.01





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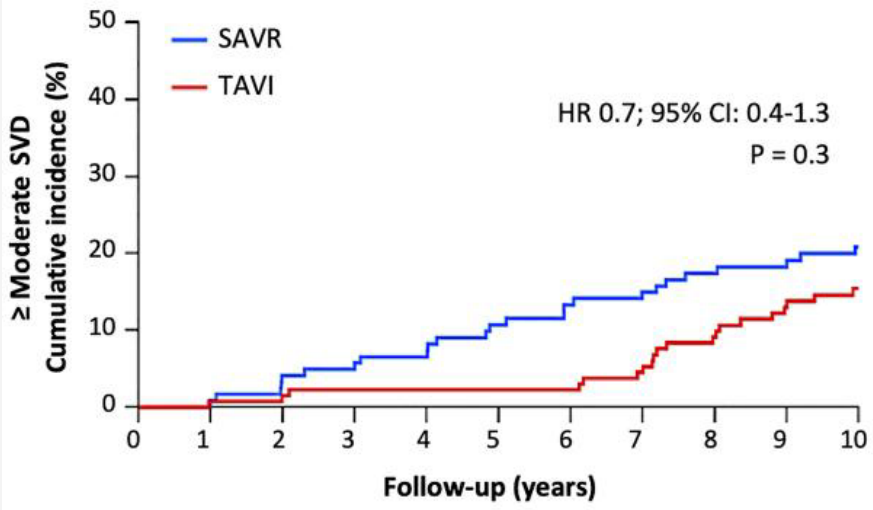
NOTION trial

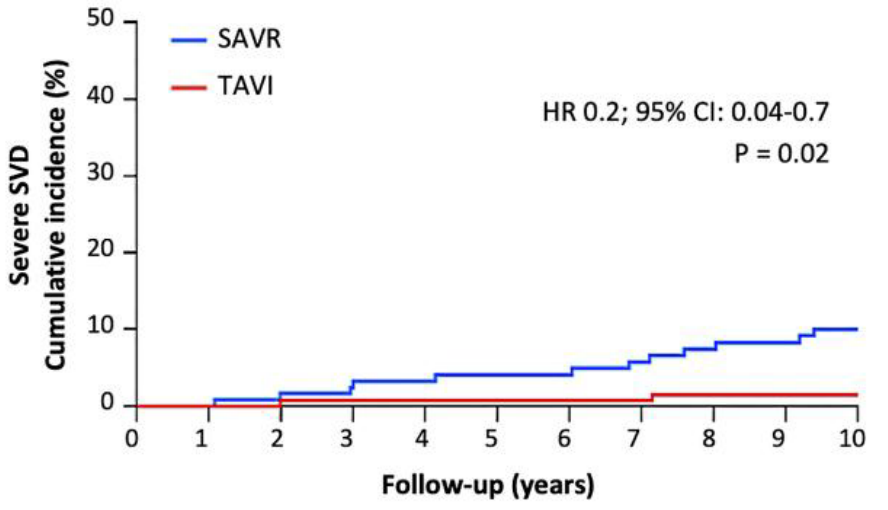
- Nordic Aortic Valve Intervention Trial (NOTION)
- Structural Valve Deterioration (SVD)



Patients at risk

TAVI	134	131	128	117	109	96	82	71	56	44	30
SAVR	123	122	116	107	96	84	69	61	48	41	32

	TAVI	SAVR	p value
≥ Moderate SVD	15.4%	20.8%	0.2
Mean gradient ≥ 20 mmHg; AND Increase in mean gradient ≥ 10 mmHg§	12.3%	20.8%	0.05
Moderate/severe intraprosthetic AR	4.6%	0	0.02



Patients at risk

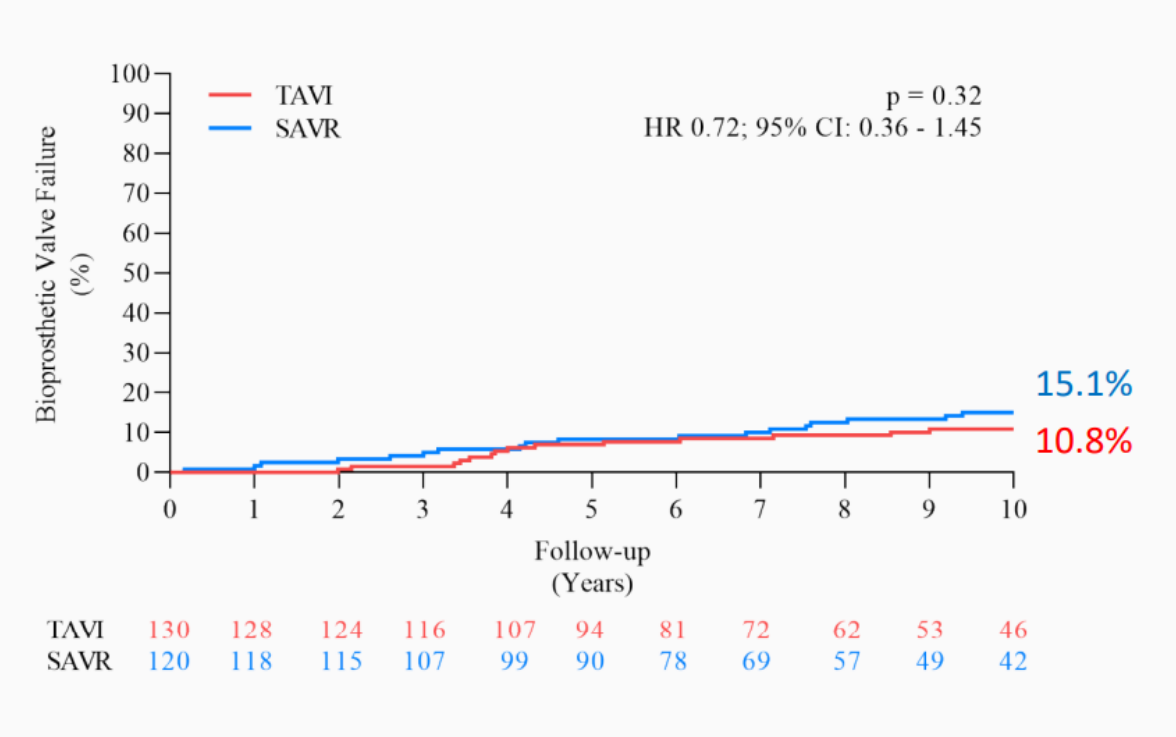
TAVI	134	132	129	118	109	96	82	73	62	51	40
SAVR	123	122	119	110	100	91	79	70	58	50	39

	TAVI	SAVR	p value
Severe SVD	1.5%	10.0%	0.004
Mean gradient ≥ 30 mmHg; AND Increase in mean gradient ≥ 20 mmHg§	1.5%	10.0%	0.004
Severe intraprosthetic AR	0	0	-

Thyregod et al. EHJ, 2024;45,1116–1124

NOTION trial

- Nordic Aortic Valve Intervention Trial (NOTION)



	TAVI (n = 130)	SAVR (n = 120)	p-value
Bioprosthetic valve failure	10.8	15.1	0.32
Valve-related death	5.0	3.7	0.60
Severe structural valve deterioration	3.1	11.0	0.014
Aortic valve re-intervention	4.3	2.2	0.33

Conclusion

In patients with severe AS and lower surgical risk randomized to TAVI or SAVR….

The risk of major clinical outcomes was not different 10 years after treatment.

The risk of severe bioprosthesis SVD was lower after TAVR compared with SAVR, while the risk of BVF was similar.

Thyregod et al. EHJ, 2024;45,1116–1124

Evolut Low Risk trial

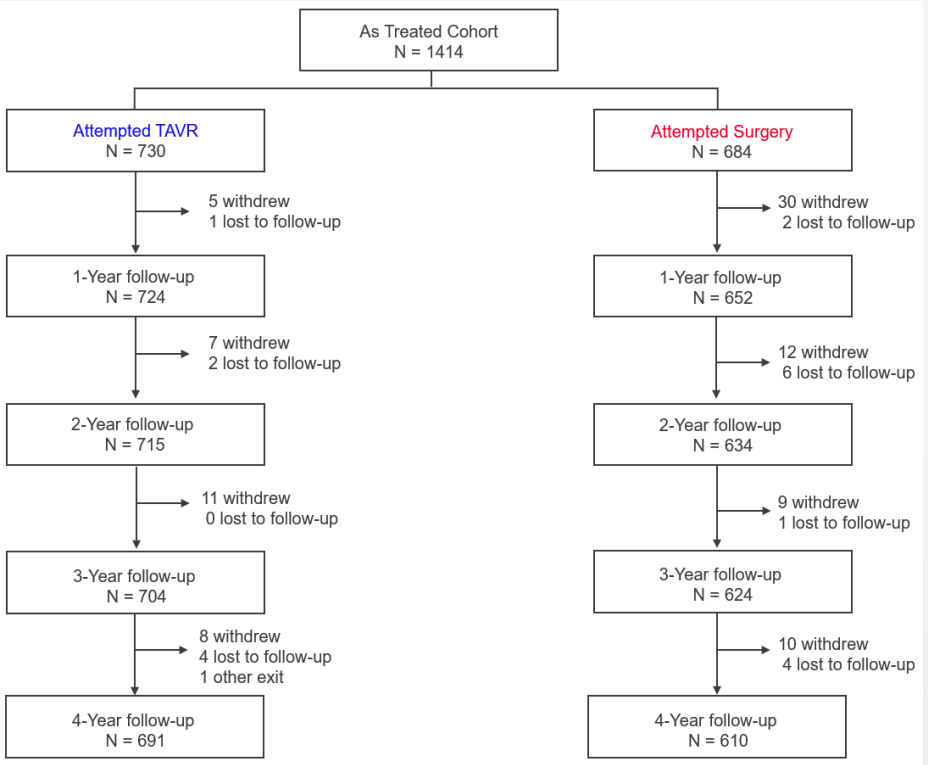
- Intermediate term follow-up of the Evolut Low risk trial
- Lack of intermediate-term data for low-risk patients in regards of paravalvular regurgitation, hemodynamics, coronary access, structural valve deterioration,and need for new pacemaker.

ORIGINAL ARTICLE

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

3-Year Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

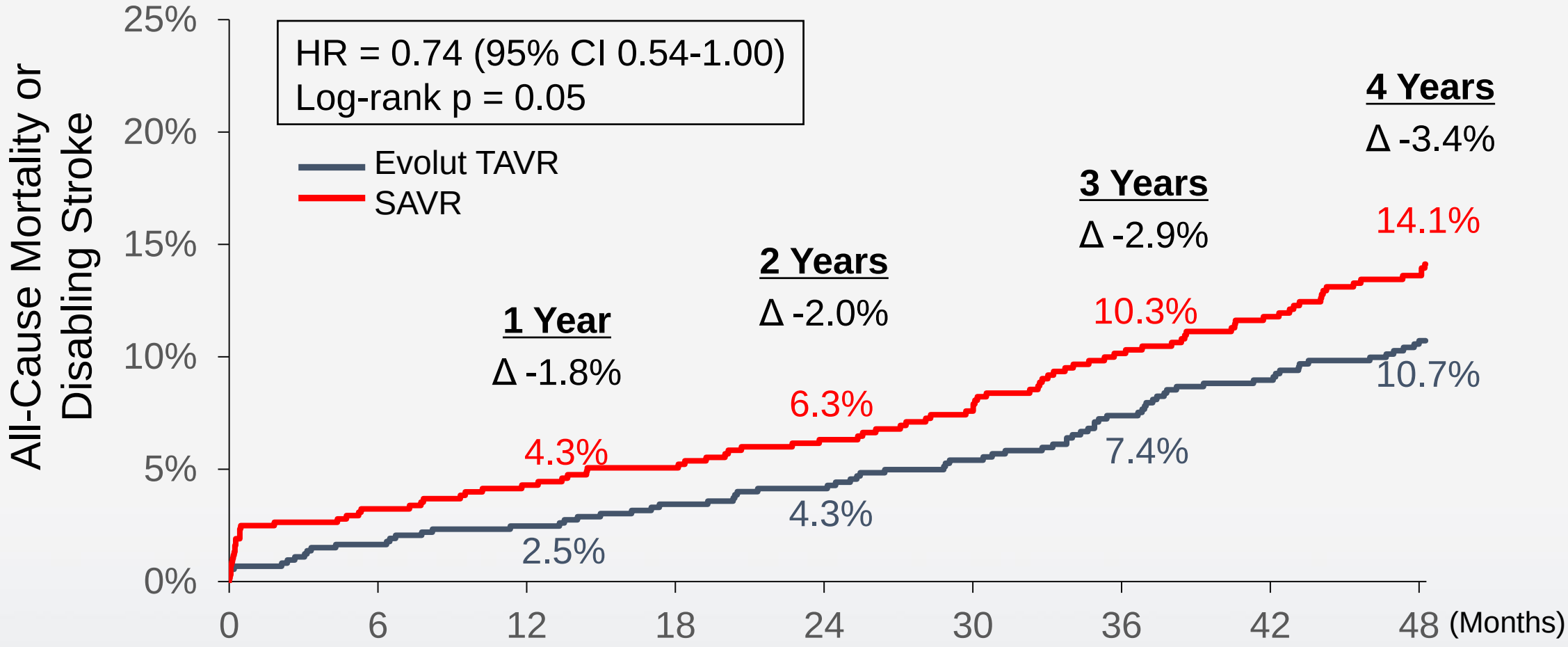
John K. Forrest, MD,[a] G. Michael Deeb, MD,[b] Steven J. Yakubov, MD,[c] Hemal Gada, MD,[d] Mubashir A. Mumtaz, MD,[d] Basel Ramlawi, MD,[e] Tanvir Bajwa, MD,[f] Paul S. Teirstein, MD,[g] Michael DeFrain, MD,[h] Murali Muppala, MD,[h] Bruce J. Rutkin, MD,[i] Atul Chawla, MD,[j] Bart Jenson, MD,[j] Stanley J. Chetcuti, MD,[b] Robert C. Stoler, MD,[k] Marie-France Poulin, MD,[l] Kamal Khabbaz, MD,[l] Melissa Levack, MD,[m] Kashish Goel, MD,[m] Didier Tchétché, MD,[n] Ka Yan Lam, MD,[o] Pim A.L. Tonino, MD,[o] Saki Ito, MD,[p] Jae K. Oh, MD,[p] Jian Huang, MD, MSc,[q] Jeffrey J. Popma, MD,[q] Neal Kleiman, MD,[r] Michael J. Reardon, MD,[r] on behalf of the Low Risk Trial Investigators*



Forrest et al., JACC, 2023:81:1663–1674. Forrest et al., JACC, 2023:22:2163-2165

Evolut Low Risk trial

Primary Endpoint: All-Cause Mortality and Disabling Stroke



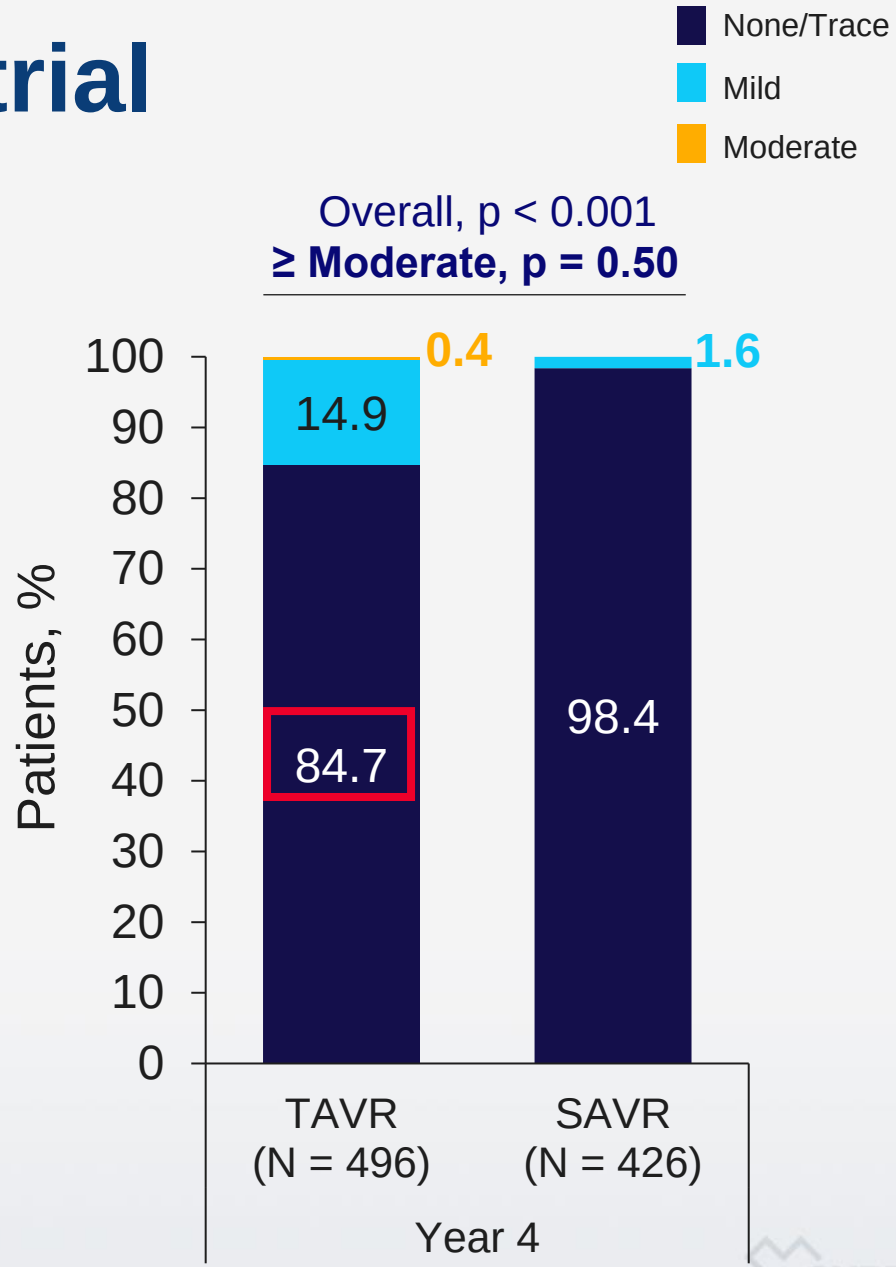
Evolut TAVR	730	715	706	695	685	671	651	627	592
SAVR	684	648	627	616	595	574	556	533	505

Forrest et al., JACC, 2023:81:1663–1674. Forrest et al., JACC, 2023:22:2163-2165

Evolut Low Risk trial

Secondary endpoints

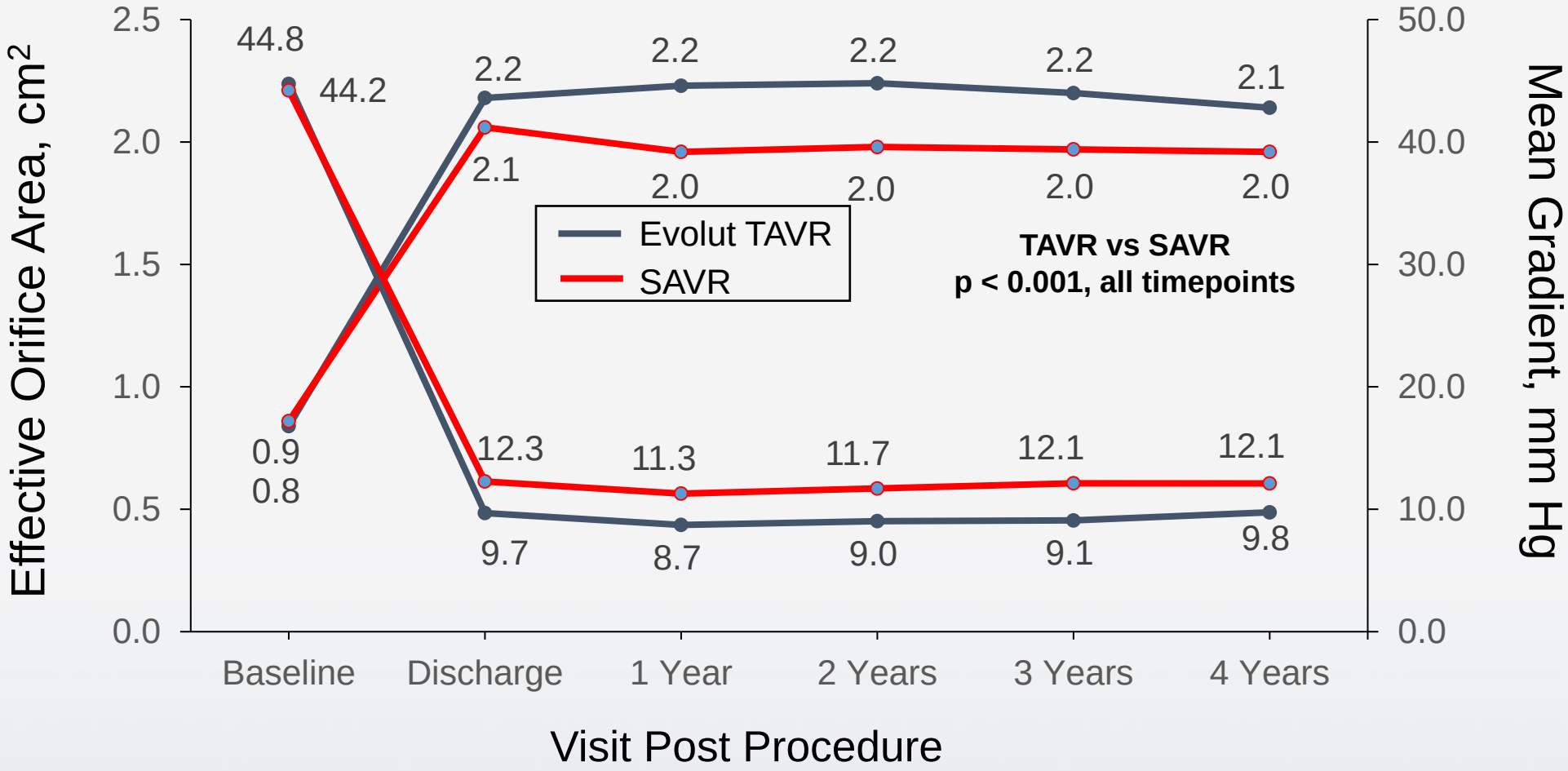
Secondary Endpoint	Evolut TAVR	SAVR	P Value
All-cause mortality, %	9.0 (64)	12.1 (76)	0.07
Cardiovascular mortality, %	5.3 (37)	7.3 (46)	0.12
Disabling stroke, %	2.9 (20)	3.8 (24)	0.32
AV hospitalization[a], %	10.3 (71)	12.1 (75)	0.27
All-cause mortality, disabling stroke, or AV rehospitalization	18.0 (128)	22.4 (144)	0.04
Myocardial infarction, %	4.8 (33)	2.6 (17)	0.06
Permanent pacemaker implant[b], %	24.6 (171)	9.9 (62)	<0.001
Permanent pacemaker implant[c], %	23.8 (171)	9.7 (63)	<0.001
Atrial fibrillation, %	14.0 (100)	40.8 (276)	<0.001
Reintervention, %	1.3 (9)	1.7 (10)	0.63



Forrest et al., JACC, 2023:81:1663–1674. Forrest et al., JACC, 2023:22:2163-2165

Evolut Low Risk trial

Hemodynamics



Forrest et al., JACC, 2023:81:1663–1674. Forrest et al., JACC, 2023:22:2163-2165

Evolut Low Risk trial

	TAVR	Surgery	HR or Risk Difference[a] (95% CI)	*P* Value[b]
Valve performance				
Reintervention	7 (1.0)	6 (0.9)	1.06 (0.36 to 3.15)	0.92
PVR[d]				<0.001
None/trace	426 (78.7)	435 (97.3)	-	
Mild	110 (20.3)	11 (2.5)	-	
Moderate	4 (0.7)	1 (0.2)	-	
Severe	1 (0.2)	0 (0.0)	-	
≥Mild	115/541 (21.3)	12/447 (2.7)	18.6% (14.8 to 22.3)	<0.001
≥Moderate	5/541 (0.9)	1/447 (0.2)	0.7% (−0.2 to 1.6)	0.16
PPM[d]				<0.001
None	437/489 (89.4)	295/394 (74.9)	-	
Moderate	45/489 (9.2)	80/394 (20.3)	-	
Severe	7/489 (1.4)	19/394 (4.8)	-	
≥Moderate	52/489 (10.6)	99/394 (25.1)	−14.5% (−19.6 to −9.4)	<0.001
Total valve thrombosis	5 (0.7)	4 (0.6)		0.84
Clinical[e]	2 (0.3)	1 (0.2)	1.84 (0.17 to 20.25)	0.61
Subclinical[f]	3 (0.4)	3 (0.5)	0.91 (0.18 to 4.50)	0.91

** From 3 years data*

Conclusion

From intermediate f/u of patients with severe AS and lower surgical risk…

The risk of major clinical outcomes was not different.

Hemondynamics was superior after TAVR, and the thrombosis rates were low.

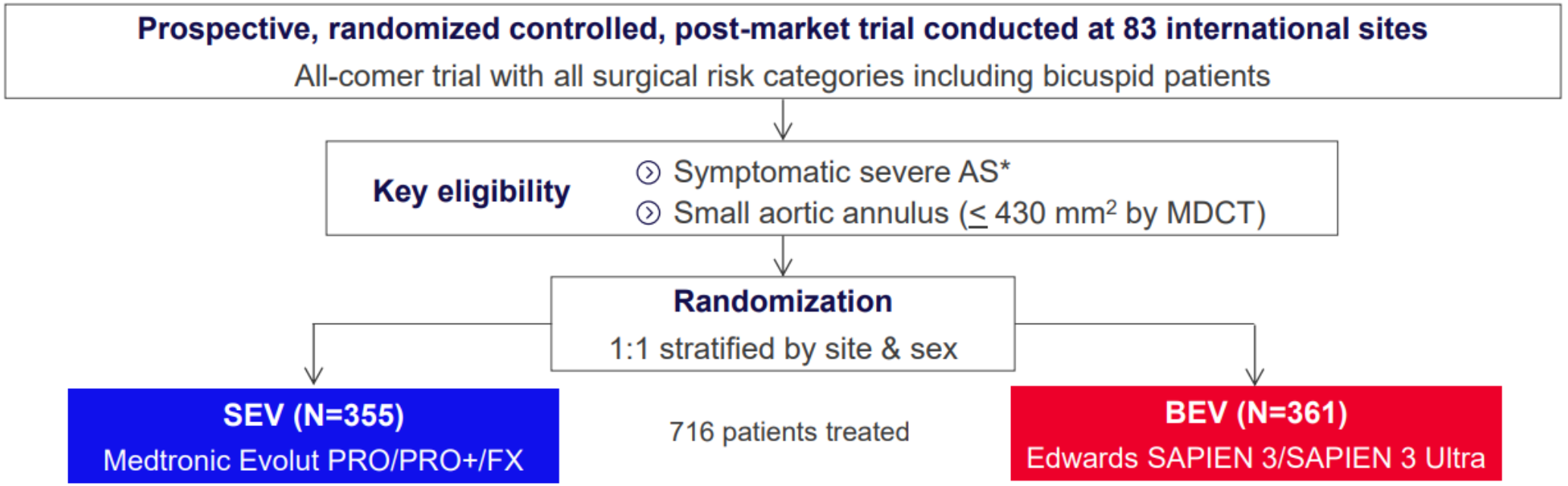
Forrest et al., JACC, 2023:81:1663–1674. Forrest et al., JACC, 2023:22:2163-2165

The SMART trial

Herrmann HC et al. NEJM. 2024

The SMART trial

Trial design



Co-Primary Endpoints at 1 year with planned 5-year follow-up

Co-Primary Endpoint 1: Composite of mortality, disabling stroke, or heart failure rehospitalization through 12 months
Co-Primary Endpoint 2: Bioprosthetic valve dysfunction through 12 months

Estimated event rate: 16% for the primary endpoint & 14% (SEV) vs. 36% (BEV) for the Secondary endpoint

Herrmann HC et al. NEJM. 2024

The SMART trial

Trial outcomes

Co-primary endpoint #1

Clinical outcome composite through 12 months

- Mortality
- Disabling stroke
- Heart failure rehospitalization

Noninferiority (margin 8%)
As treated population

Co-primary endpoint #2

Bioprosthetic valve dysfunction through 12 months

- Hemodynamic structural valve dysfunction:
  Mean gradient ≥20 mmHg
- Nonstructural valve dysfunction:
  Severe PPM (VARC-3), ≥moderate total AR
- Clinical valve thrombosis (VARC-2)
- Endocarditis (Duke criteria)
- Aortic valve reintervention

Superiority
As treated population

If both primary endpoints were met, a hierarchical testing of secondary endpoints in a prespecified order for superiority

Hypothesis-tested secondary endpoints
1 Hemodynamic mean gradient at 12 months
2 Effective orifice area at 12 months
3 Hemodynamic SVD (mean gradient ≥20 mmHg) through 12 months
4 BVD in women through 12 months
5 Moderate/severe prosthesis-patient mismatch at 30 days

Estimated event rate: 16% for the primary endpoint & 14% (SEV) vs. 36% (BEV) for the Secondary endpoint

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Baseline characteristics

Table 1. Characteristics of the Patients at Baseline (As-Treated Population).*

Characteristic	SEV (N=355)	BEV (N=361)
Age — yr	80.1±6.3	80.3±6.1
Body-surface area — m^2	1.8±0.2	1.8±0.2
Female sex — no. (%)	312 (87.9)	309 (85.6)
STS-PROM — %	3.3±1.9	3.2±1.7
STS-PROM category — no. (%)		
<3%	182 (51.3)	191 (52.9)
3 to <5%	122 (34.4)	123 (34.1)
≥5%	51 (14.4)	47 (13.0)
NYHA functional class — no. (%)†		
I	4 (1.1)	6 (1.7)
II	197 (55.5)	211 (58.4)
III	150 (42.3)	144 (39.9)
IV	4 (1.1)	0
Diabetes — no. (%)	104 (29.3)	123 (34.1)
Hypertension — no. (%)	293 (82.5)	313 (86.7)
COPD or chronic lung disease — no./total no. (%)	61/339 (18.0)	62/353 (17.6)
Cerebrovascular disease — no./total no. (%)	42/351 (12.0)	41/360 (11.4)
Previous CABG — no./total no. (%)	12/354 (3.4)	18/361 (5.0)
Previous PCI — no./total no. (%)	60/353 (17.0)	84/360 (23.3)
Previous myocardial infarction — no. (%)	19 (5.4)	29 (8.0)
Arrhythmia — no./total no. (%)	83/355 (23.4)	85/360 (23.6)
Atrial fibrillation or flutter — no./total no. (%)	69/349 (19.8)	65/353 (18.4)
History of right bundle-branch block — no. (%)	21 (5.9)	25 (6.9)
Site-reported LVEF at screening — %‡	61.6±7.6	61.2±8.7
Coronary artery disease — no. (%)	125 (35.2)	148 (41.0)
Preexisting pacemaker or defibrillator — no. (%)	30 (8.5)	25 (6.9)
Tricuspid aortic-valve morphology — no. (%)	341 (96.1)	346 (95.8)
Treatment with vitamin K antagonist — no. (%)	16 (4.5)	16 (4.4)
Treatment with direct oral anticoagulant — no. (%)	54 (15.2)	57 (15.8)
Aortic annulus area — mm^2	380.9±34.2	382.8±33.9

Average age: Low risk is not equivalent to young

Definition of the STS-PROM

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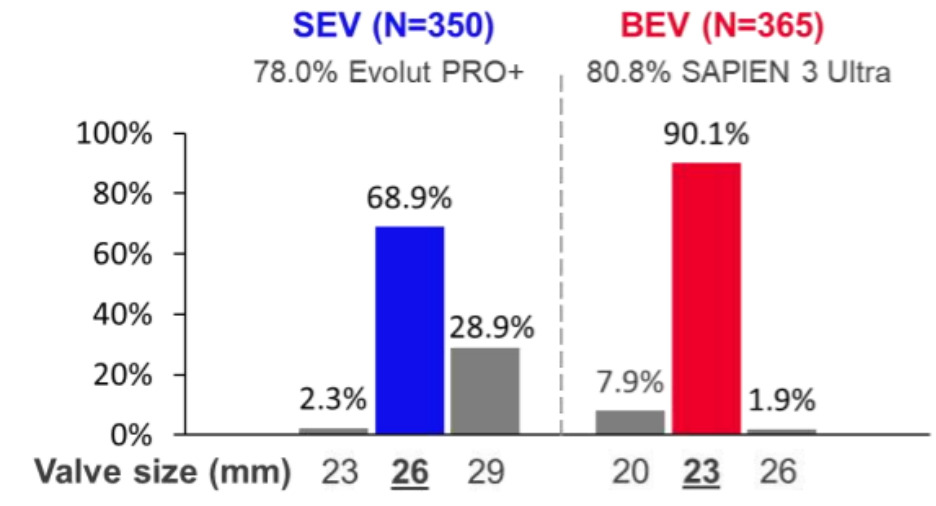
The SMART trial

Valve size and procedures

Aortic annulus size	SEV (N=355)	BEV (N=361)
Mean area (mm^2)	380.9 ± 34.2	382.8 ± 33.9
Mean perimeter (mm)	70.3 ± 3.2	70.4 ± 3.2



Annulus Sizing		20 mm	23 mm	26 mm	29 mm
Native Valve Annulus Size (CT)	Area	273 - 345 mm^2	338 - 430 mm^2	430 - 546 mm^2	540 - 683 mm^2
	Area Derived Diameter	18.6 - 21 mm	20.7 - 23.4 mm	23.4 - 26.4 mm	26.2 - 29.5 mm
Native Valve Annulus Size TEE		16 - 19 mm	18 - 22 mm	21 - 25 mm	24 - 28 mm

	Valve size	Aortic annulus measurements		Sinus of valsalva diameter	Sinus of valsalva height
		Diameter	Perimeter		
Evolut™ PRO and Evolut™ R valves	23 mm	17†/18–20 mm	53.4†/56.5–62.8 mm	≥ 25 mm	≥15 mm
	26 mm	20–23 mm	62.8–72.3 mm	≥ 27 mm	≥15 mm
	29 mm	23–26 mm	72.3–81.7 mm	≥ 29 mm	≥15 mm
Evolut™ R valves	34 mm	26–30 mm	81.7–94.2 mm	≥ 31 mm	≥16 mm

314~415 mm^2

415~530 mm^2

- Different cutoff values and different oversizing

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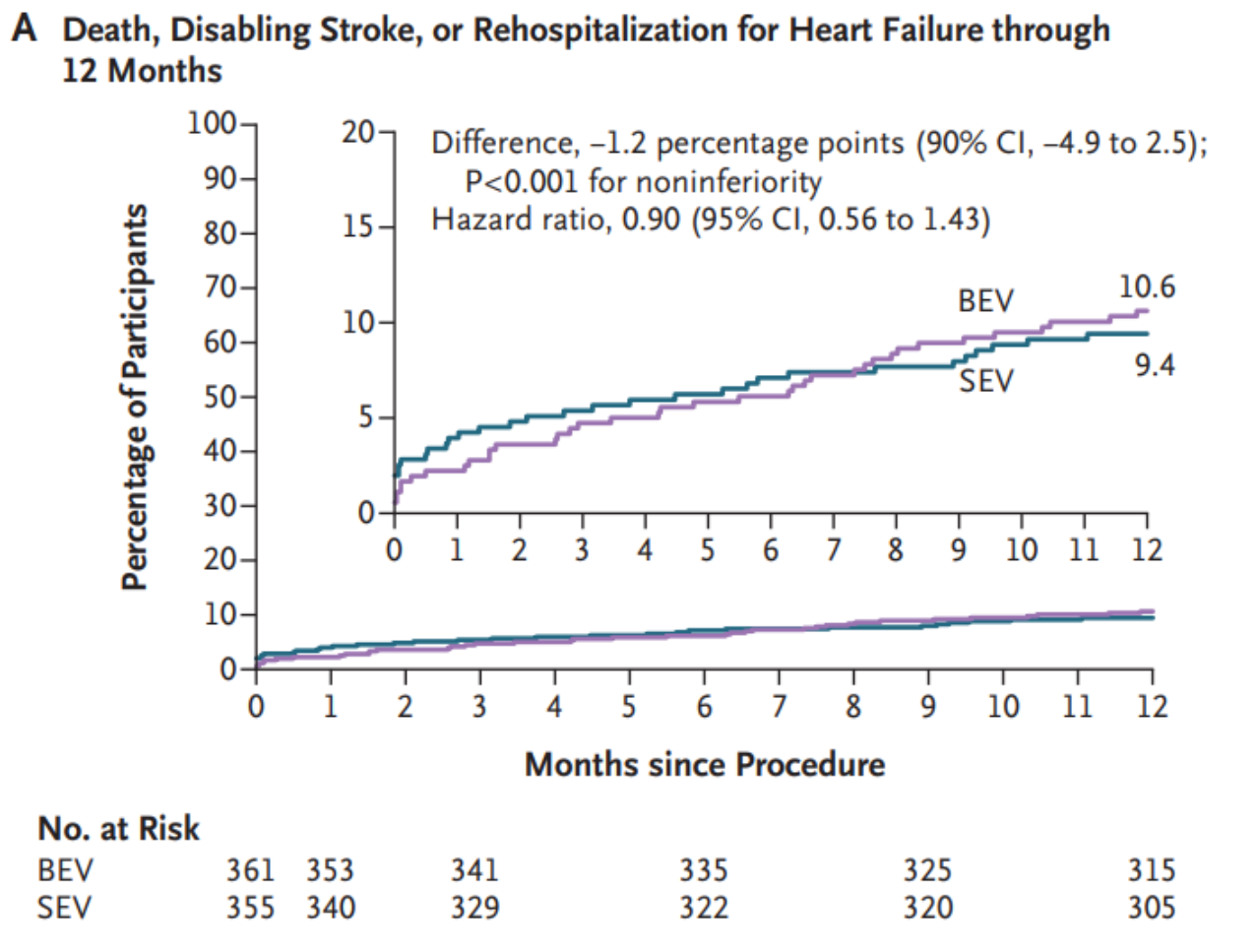
The SMART trial

Primary outcome



12 Months	SEV (N=355)	BEV (N=361)	HR (95% CI)
All-cause mortality	5.1%	5.9%	0.88 (0.47, 1.65)
Disabling stroke	3.1%	2.6%	1.26 (0.52, 3.03)
HF rehosp	3.8%	3.5%	1.11 (0.51, 2.44)

Estimated event rate: 16% for the primary endpoint

Noninferiority (margin 8%)

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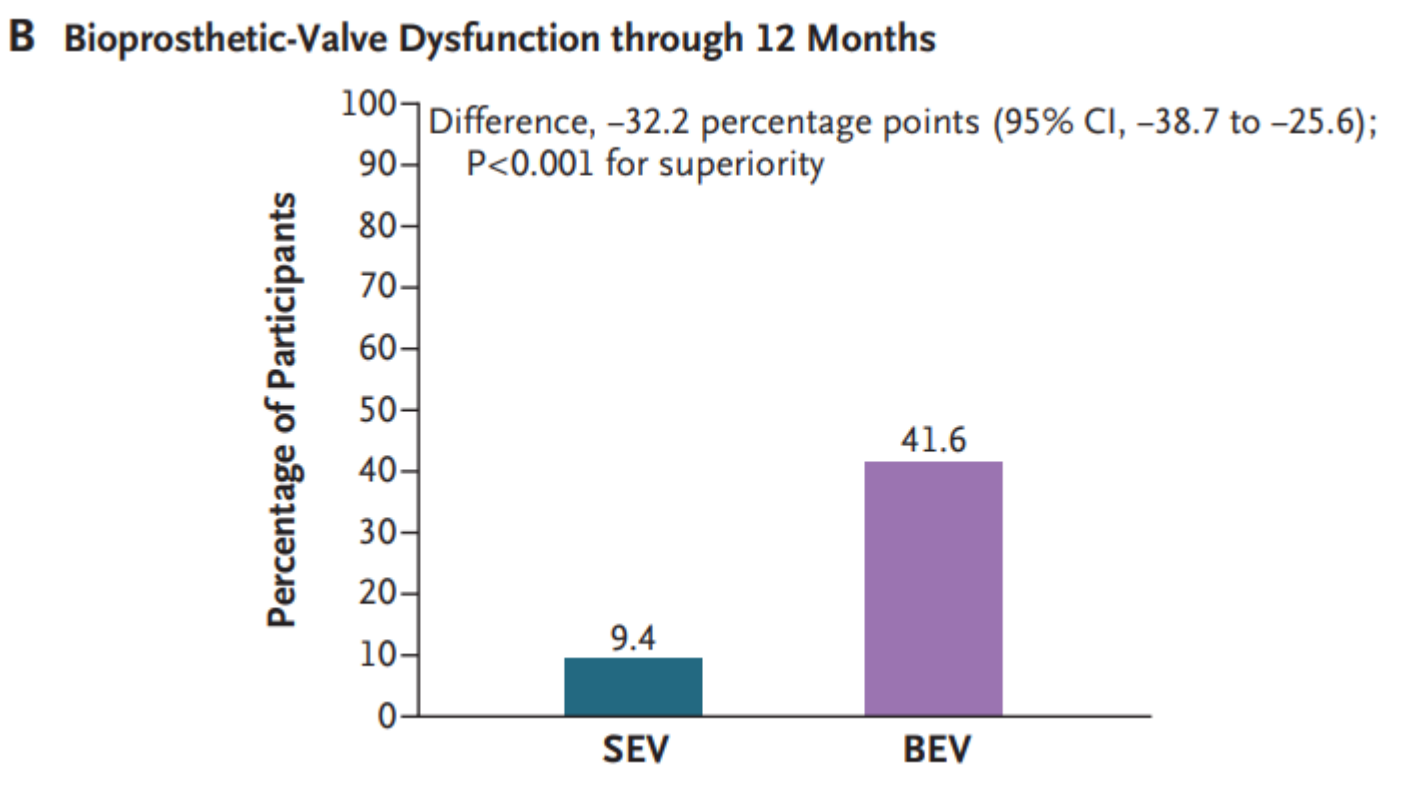
The SMART trial

Primary outcome



	SEV (N=350)	BEV (N=365)	P Value
BVD composite	**9.4%**	**41.6%**	**<0.001**
HSVD	3.2%	32.2%	
NSVD	5.9%	18.2%	
Thrombosis (clinical)	0.3%	0.3%	
Endocarditis	0.6%	2.3%	
AV Reintervention	0.9%	0.6%	

HSVD = Mean gradient ≥ 20 mmHg
NSVD = Severe PPM per VARC-3 or ≥moderate total AR

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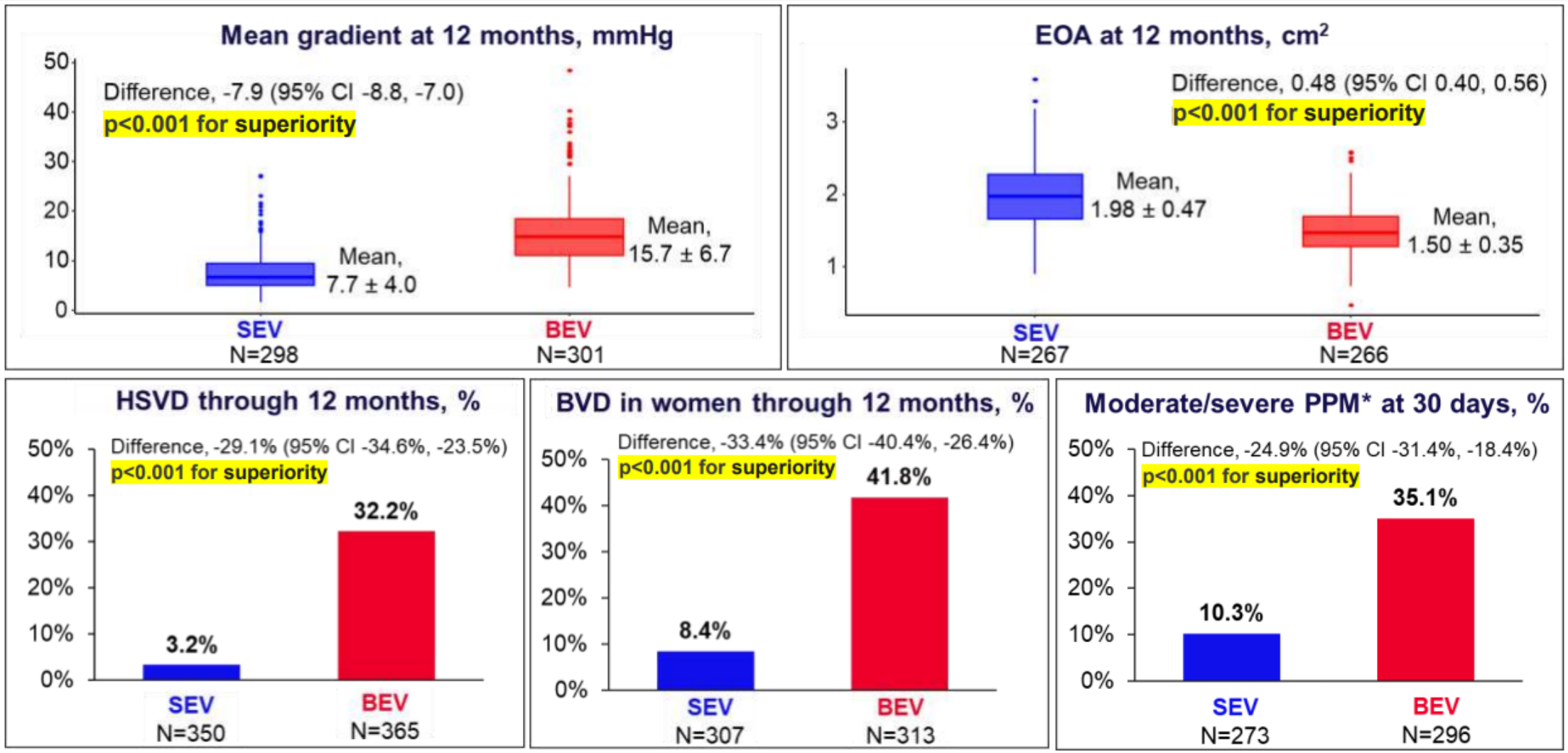
Secondary outcomes



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Other observatory outcomes

KM%	30 Days			12 Months		
	SEV (N=355)	BEV (N=361)	Log-Rank P Value	SEV (N=355)	BEV (N=361)	Log-Rank P Value
Pacemaker implant[a]	12.1%	7.8%	0.055	14.0%	9.3%	0.051
Pacemaker implant	11.1%	7.2%	0.067	12.8%	8.7%	0.063
Prosthetic valve endocarditis	0.0%	0.0%	NA	0.6%	2.3%	0.063
Coronary artery obstruction	0.6%	0.3%	0.55	0.6%	0.3%	0.55
Acute kidney injury stage 2/3	0.3%	0.3%	0.99	0.3%	0.3%	0.99
Cardiovascular hospitalizations	4.9%	5.3%	0.77	15.7%	16.6%	0.79
Hospital readmission	8.6%	11.2%	0.25	29.7%	32.1%	0.50
Clinical valve thrombosis	0.0%	0.0%	NA	0.3%	0.3%	0.99

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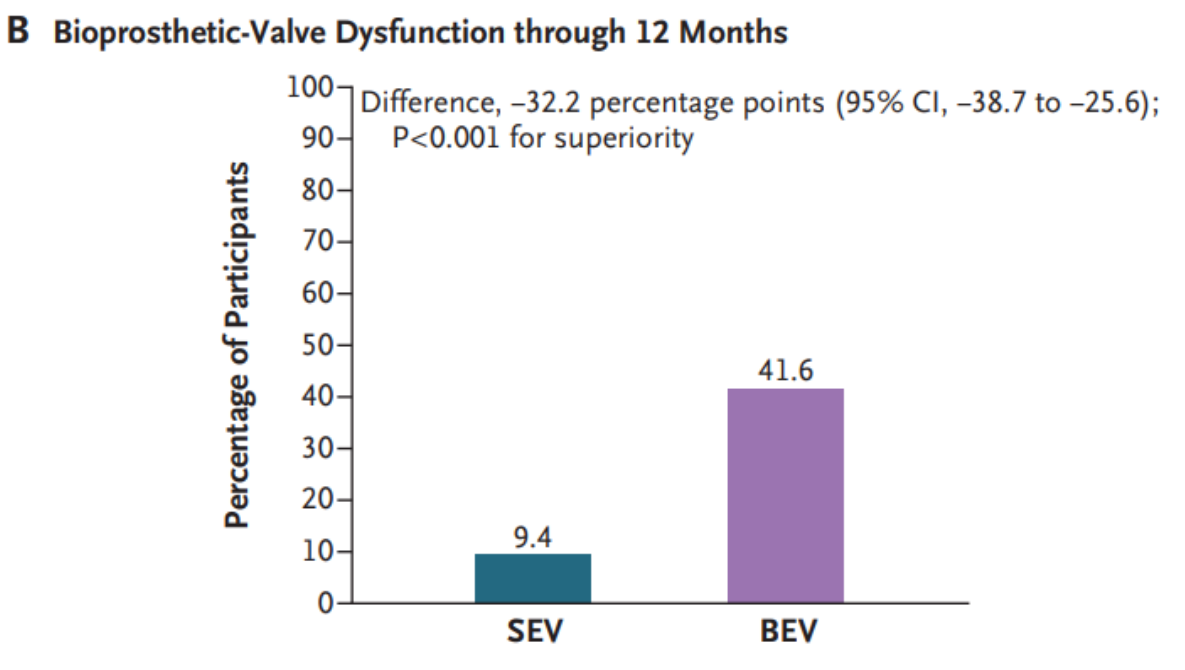
Other observatory outcomes

- Was there an issue in the definition of BVD?

Alternative definition	SEV (N=350)	BEV (N=365)	Difference	P Value (Superiority)
BVD composite				
ESC (Capodanno)[1]	11.5%	43.7%	-32.2%	<0.001
VARC-3[2]	7.4%	22.4%	-15.0%	<0.001
SMART (primary endpoint with 12 mo echo only)[3]	6.3%	28.3%	-22.0%	<0.001
HSVD				
Playford (NEDA)[4]	1.3%	22.0%	-20.8%	<0.001
O'Hair[5]	0.4%	6.7%	-6.4%	<0.001
SMART (HSVD w 12 mo echo only)[6]	2.0%	20.3%	-18.3%	<0.001



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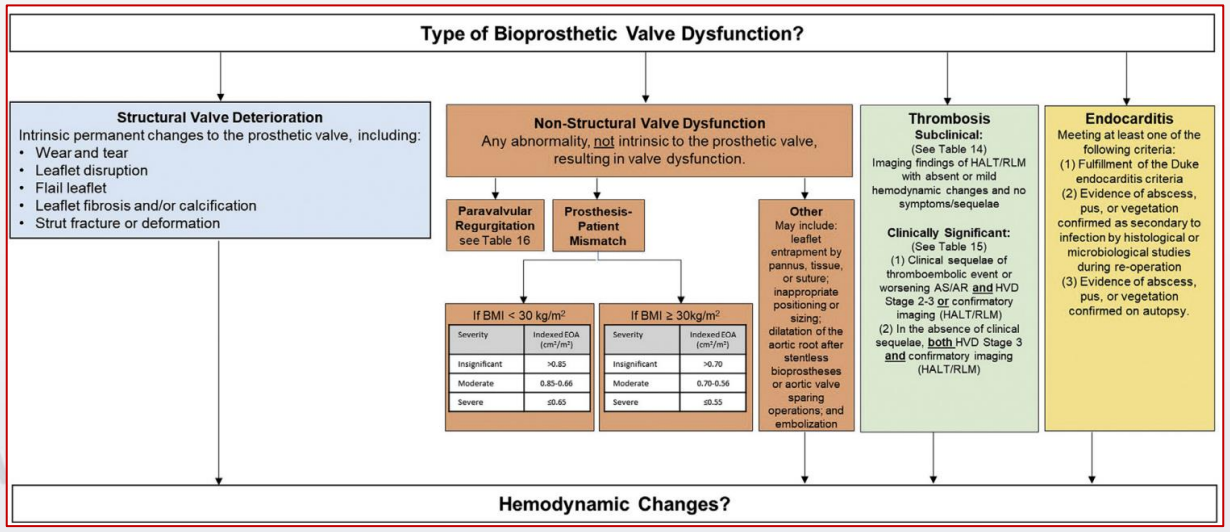

Table 3: Structural valve deterioration

Moderate haemodynamic SVD (any of the following)
- Mean transprosthetic gradient ≥20 mmHg and <40 mmHg
- Mean transprosthetic gradient ≥10 and <20 mmHg change from baseline
- Moderate intra-prosthetic aortic regurgitation, new or worsening (>1+/4+) from baseline

Severe haemodynamic SVD (any of the following)
- Mean transprosthetic gradient ≥40 mmHg
- Mean transprosthetic gradient ≥20 mmHg change from baseline
- Severe intra-prosthetic aortic regurgitation, new or worsening (>2+/4+) from baseline

Morphological SVD (any of the following)
- Leaflet integrity abnormality (i.e. torn or flail causing intra-frame regurgitation)
- Leaflet structure abnormality (i.e. pathological thickening and/or calcification causing valvular stenosis or central regurgitation)
- Leaflet function abnormality (i.e. impaired mobility resulting in stenosis and/or central regurgitation)
- Strut/frame abnormality (i.e. fracture)

Haemodynamic and morphological SVD

SVD: structural valve deterioration.

(1) HVD showing an increase in mean gradient >20 mmHg from discharge or 30-day echoCG to last available echoCG
(2) new occurrence or increase of 2 grades or more of intraprosthetic AR resulting in severe AR

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The SMART trial

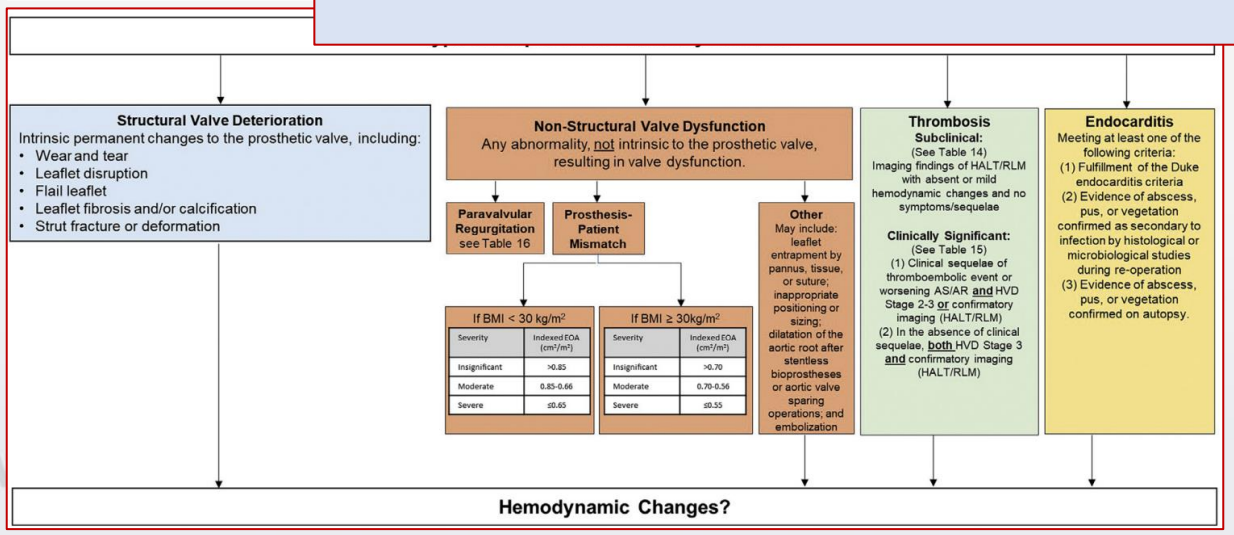
Other observatory outcomes

- Was there an issue in the definition of BVD?

Alternative definition	SEV (N=350)	BEV (N=365)	Difference	P Value (Superiority)
BVD composite				
ESC (Capodanno)[1]				
VARC-3[2]				
SMART (primary endpoint with 12 mo echo only)[3]				
HSVD				
Playford (NEDA)[4]				
O'Hair[5]				
SMART (HSVD w 12 mo echo only)[6]				

Conclusion

Among patients with severe aortic stenosis and a small aortic annulus who underwent TAVR, a self-expanding supraannular valve was noninferior to a balloon-expandable valve with respect to clinical outcomes and was superior with respect to bioprosthetic-valve dysfunction through 12 months.



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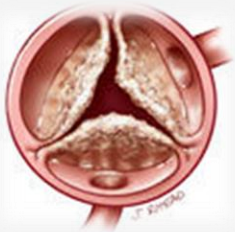
Conclusion

From results of clinical trials presented in 2023, we can now have confidence in…



Performing TAVI in low risk patients, in whom

- The clinical outcomes are similar to the counterpart treatment,
- Have superior hemodynamics.
- Without an issue of valve failure.

Conclusion

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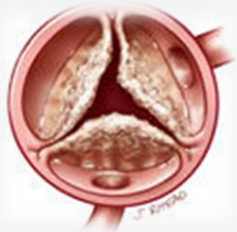

Performing TAVI in low risk patients, in whom

- The clinical outcomes are similar to the counterpart treatment,
- Have superior hemodynamics.
- Without an issue of valve failure.

- *Especially, in those who have a small annulus size,*
  - *A supraannular type valve will maximize the strongpoints of TAVI*