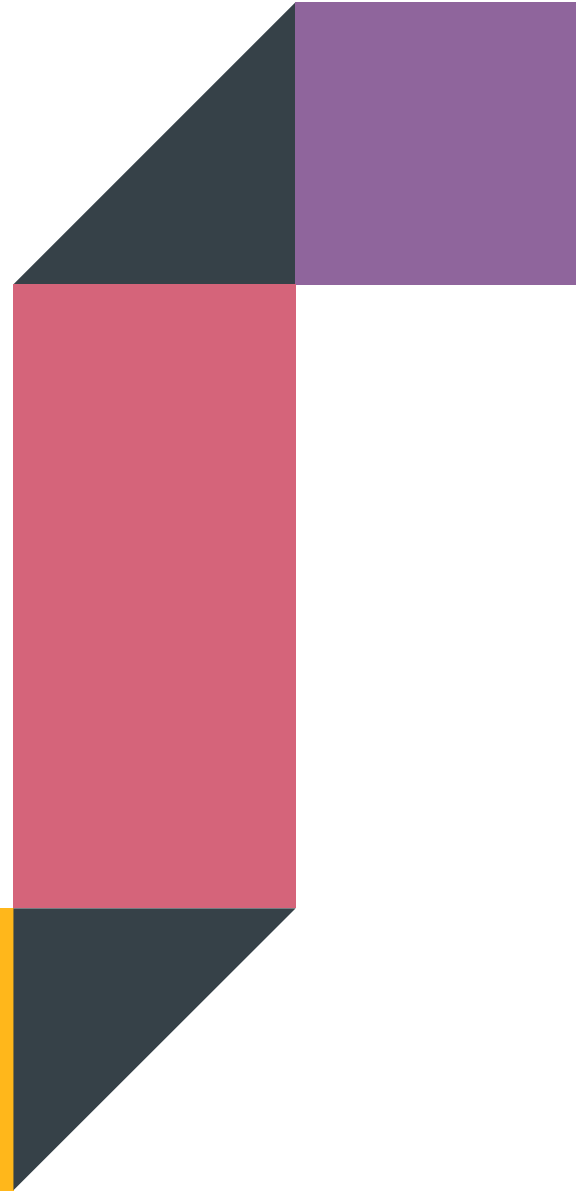




Treatment of the Young Patient with Aortic Stenosis and a Bicuspid Aortic Valve

Michael Mack, MD
Baylor Scott & White Health
Dallas, TX



Conflict of Interest Disclosure

Medtronic

Study Chair Apollo Trial

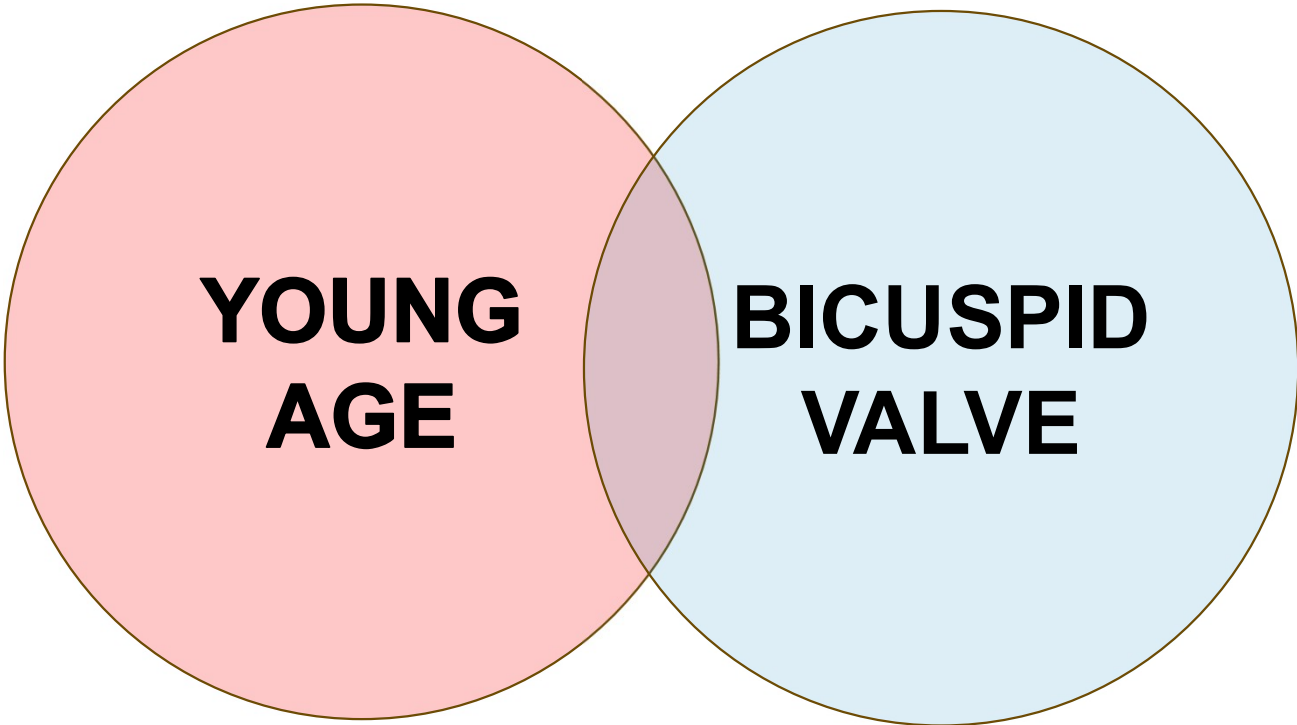
Edwards Lifesciences

Co-PI of PARTNER 3

Foldax

Study Steering Committee





**YOUNG
AGE**

**BICUSPID
VALVE**

Treatment of the Young Patient with Aortic Stenosis and a Bicuspid Aortic Valve

Factors to Consider

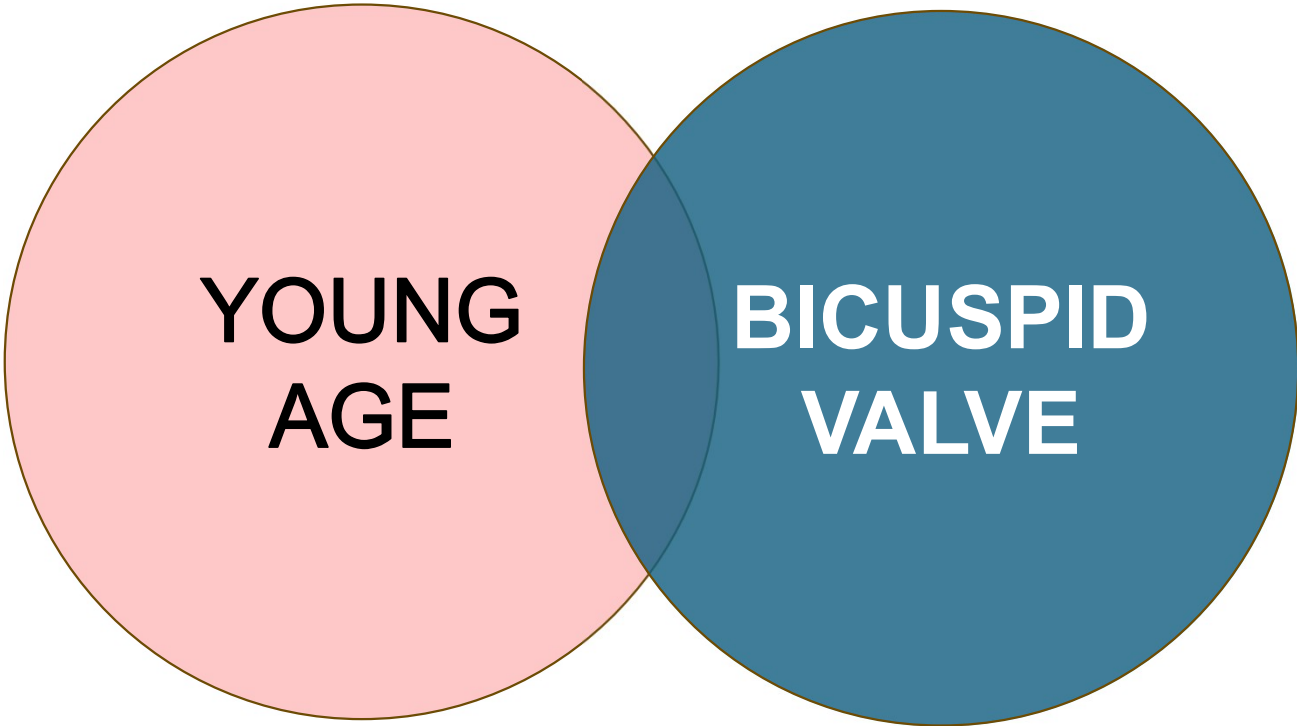


Patient Age-**valve durability**- patient will outlive their valve



Valve-**bicuspid**- how does this affect treatment choice (TAVR vs SAVR)?





**YOUNG
AGE**

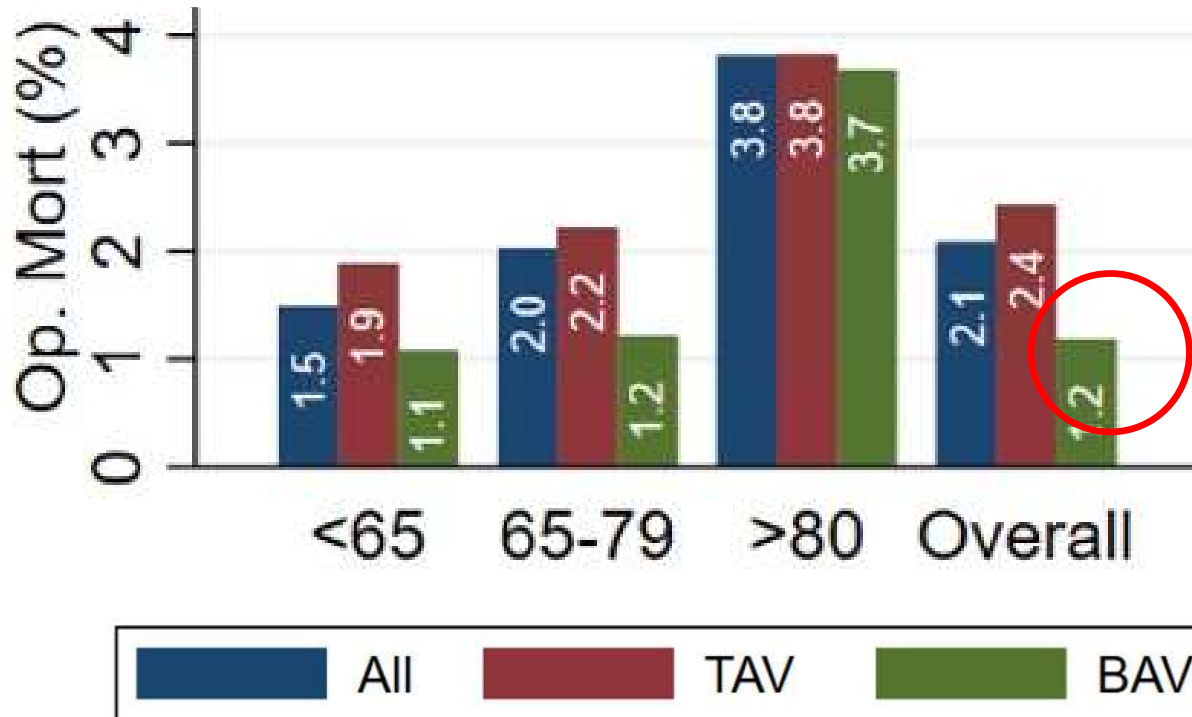
**BICUSPID
VALVE**

Age-Stratified Surgical Aortic Valve Replacement for Aortic Stenosis

Christopher K. Mehta, MD,¹ Tom X. Liu, MD, MS,¹ Levi Bonnell, PhD,² Robert H. Habib, PhD,² Tsuyoshi Kaneko, MD,³ James D. Flaherty, MD,⁴ Charles J. Davidson, MD,⁴ James D. Thomas, MD,⁴ Vera H. Rigolin, MD,⁴ Robert O. Bonow, MD,⁴ Duc Thinkh Pham, MD,¹ Douglas R. Johnston, MD,¹ Patrick M. McCarthy, MD,¹ and S. Chris Malaisrie, MD¹

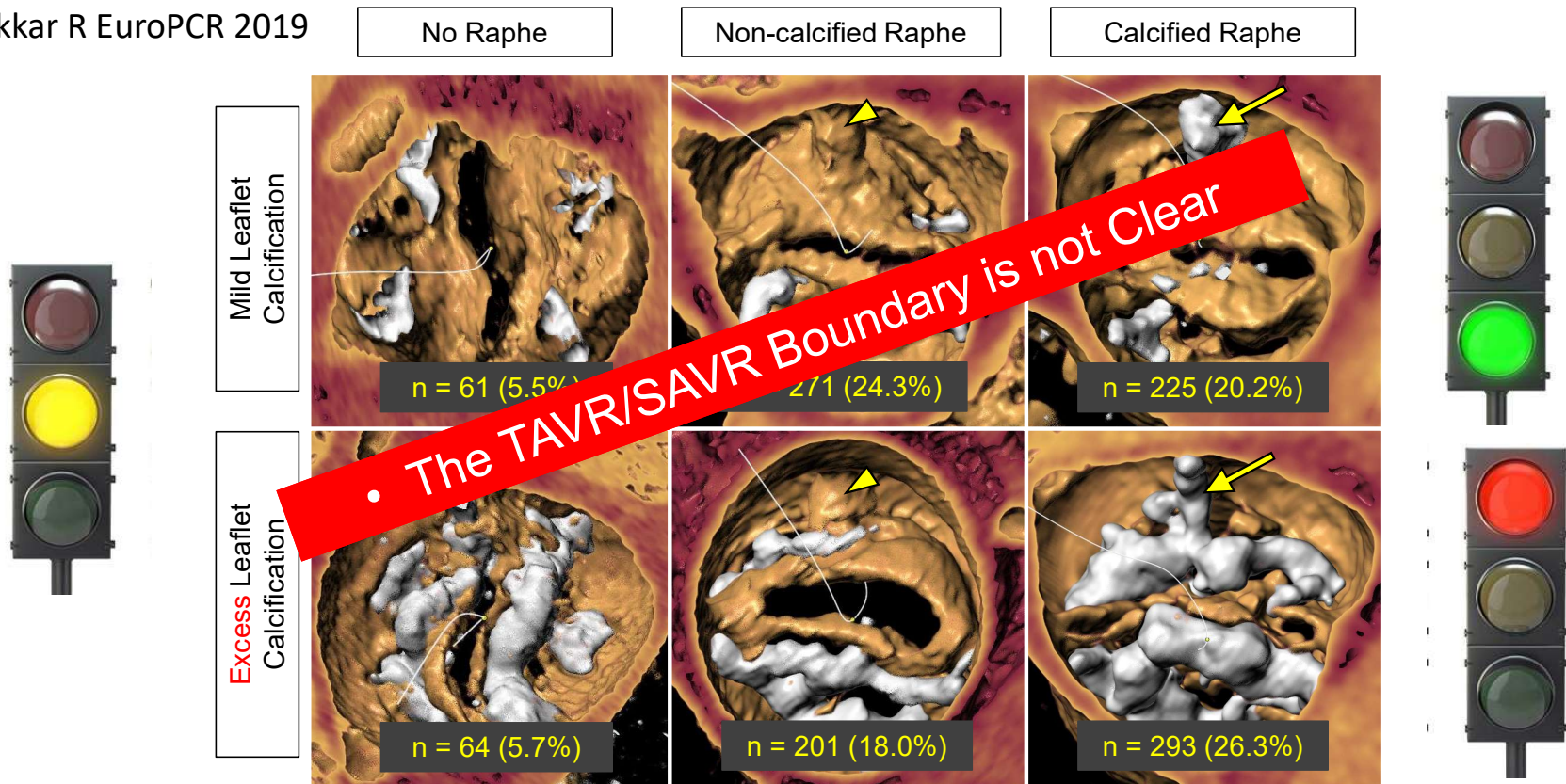
Bicuspid AS

**BAV= 55,326
Operative
Mortality-1.2%**



TAVR in Bicuspid Aortic Stenosis

Yoon S, Makkar R EuroPCR 2019



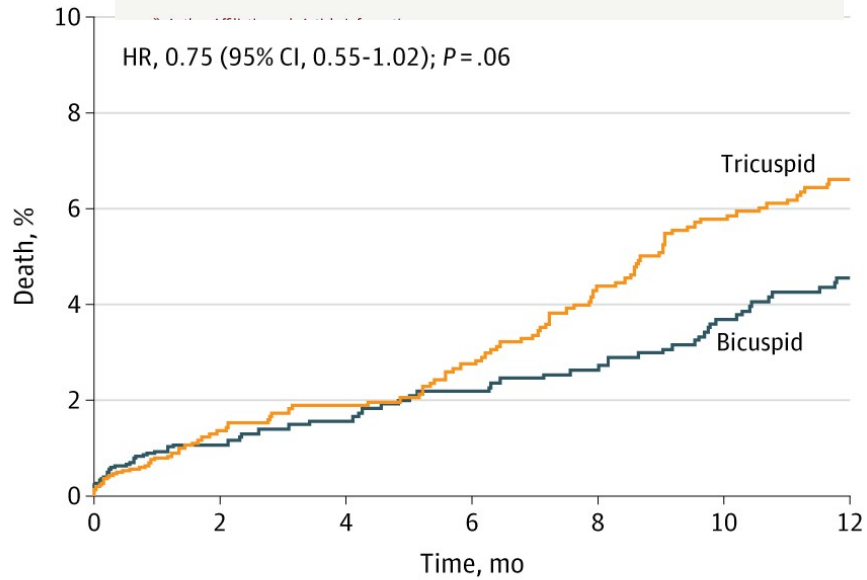
Original Investigation

FREE

Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke Among Patients at Low Surgical Risk

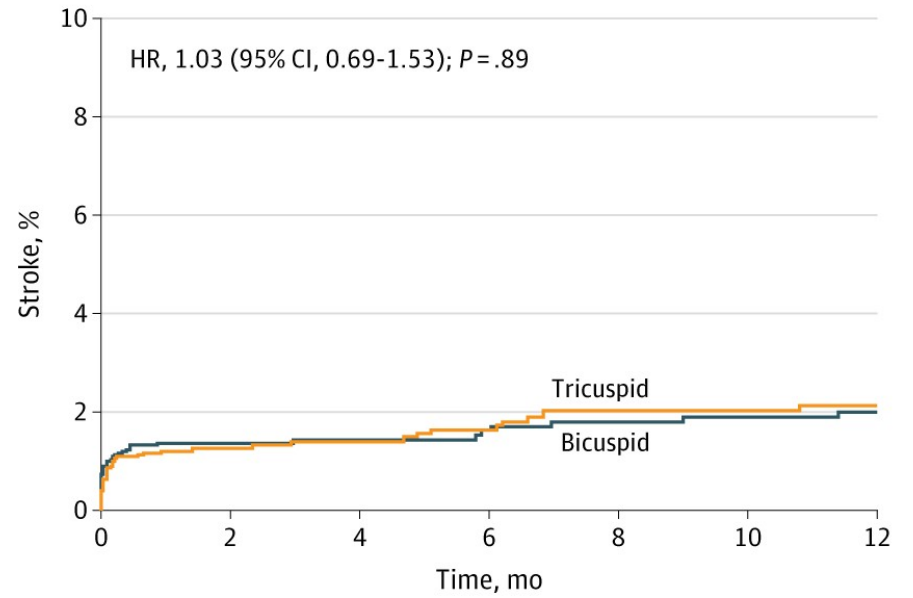
Raj R. Makkar, MD¹; Sung-Han Yoon, MD¹; Tarun Chakravarty, MD¹; et al

A Death



No. at risk	0	2	4	6	8	10	12
Bicuspid	3168	1300	1130	1111	1102	1081	779
Tricuspid	3168	1430	1273	1253	1230	1204	888

B Stroke

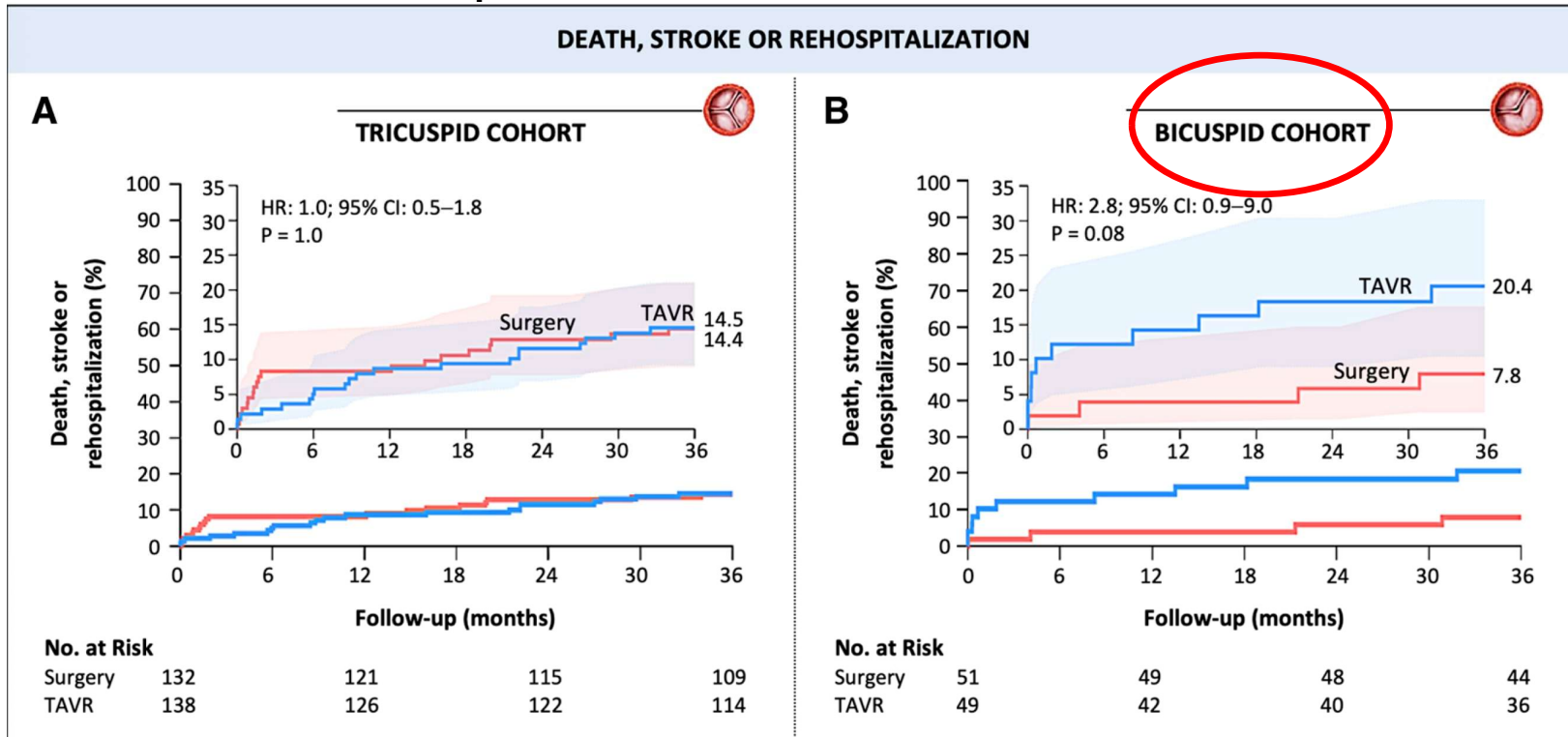


No. at risk	0	2	4	6	8	10	12
Bicuspid	3168	1285	1117	1097	1087	1065	770
Tricuspid	3168	1409	1253	1232	1205	1182	874

ORIGINAL RESEARCH ARTICLE

November 2025

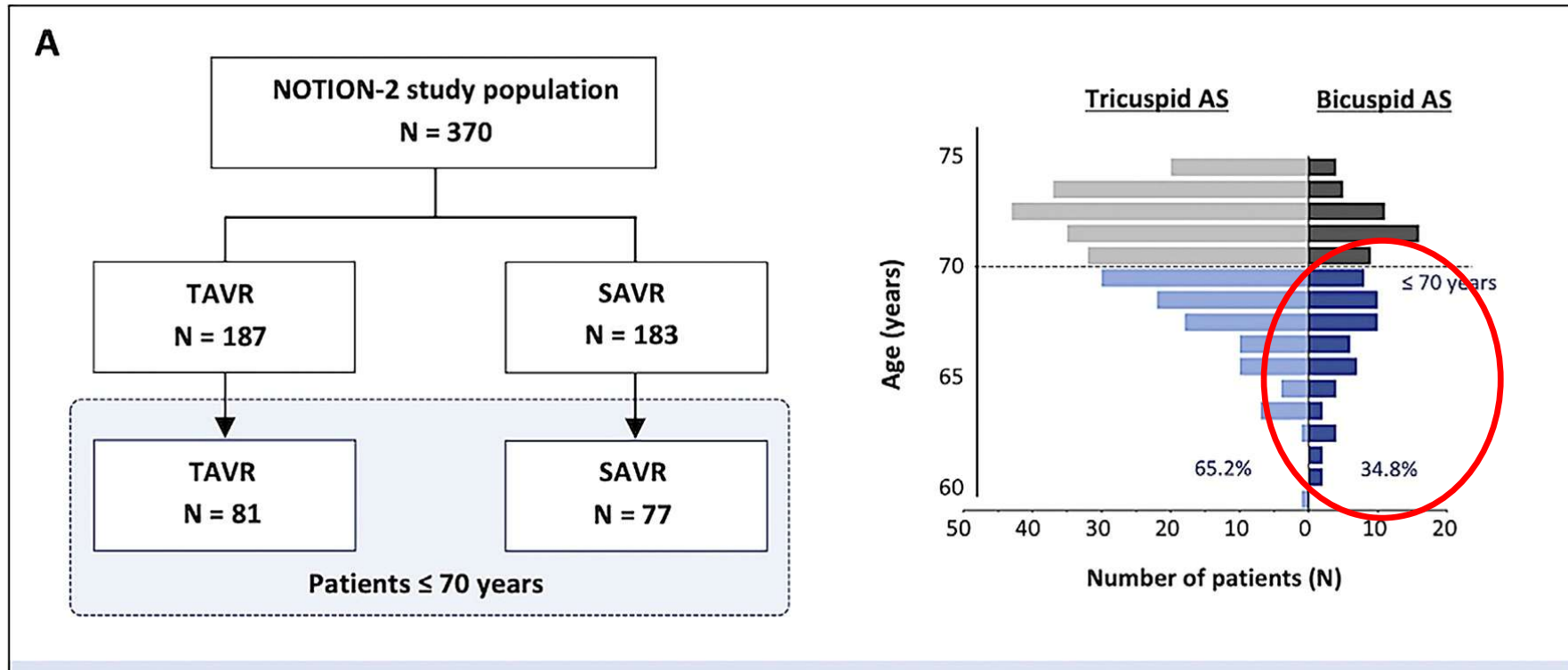
Three-Year Follow-Up of the NOTION-2 Trial: TAVR Versus SAVR to Treat Younger Low-Risk Patients With Tricuspid or Bicuspid Aortic Stenosis



Transcatheter or surgical aortic valve replacement in patients with severe aortic stenosis aged 70 years or younger: A NOTION-2 substudy



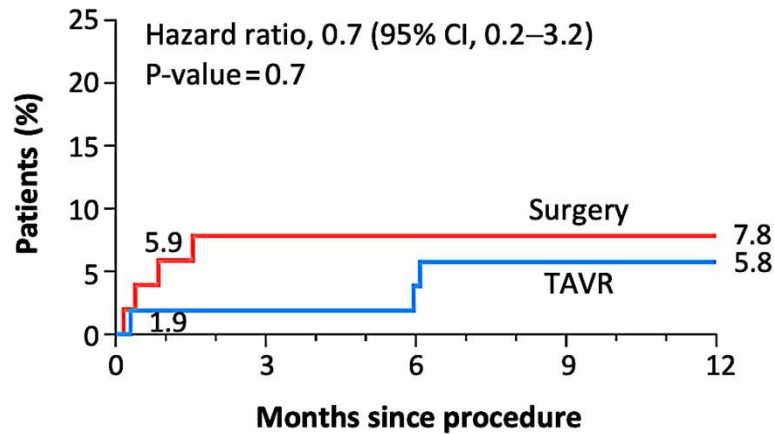
Troels Højsgaard Jørgensen, MD, PhD^a, Hans Gustav Hørsted Thyregod, MD, PhD^a, Mikko Savontaus, MD, PhD^b, Öjvind Bleie, MD, PhD^c, Evald H Christiansen, MD, PhD^d, Matti Niemela, MD, PhD^c, Oskar Angerås, MD, PhD^f, Ingibjörg J. Gudmundsdóttir, MD, DM^g, Mika Laine, MD, PhD^h, Andreas Rück, MD, PhDⁱ, Bernard Prendergast, MD, DMSc^j, Martin Leon, MD, PhD^k, Lars Søndergaard, MD, DMSc^l, and Ole De Backer, MD, PhD^{a,m}, for the NOTION-2 investigators



Subanalysis – Tricuspid & Bicuspid AS cohorts



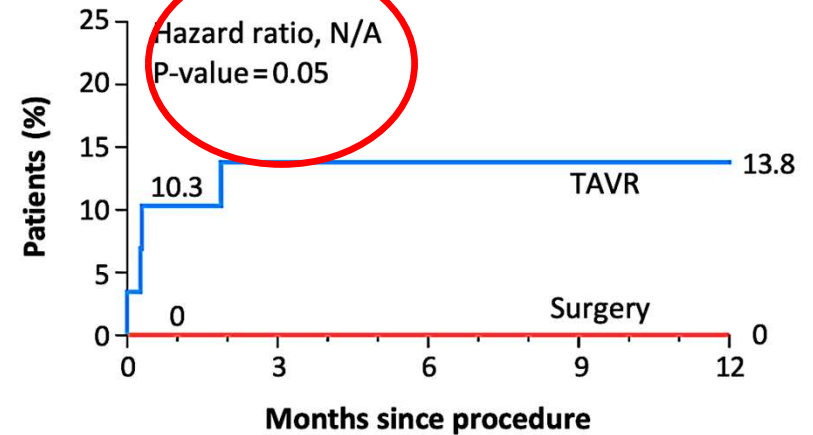
**Primary endpoint
Tricuspid cohort**



No. at Risk			
Surgery	51	47	47
TAVR	52	50	49



**Primary endpoint
Bicuspid cohort**

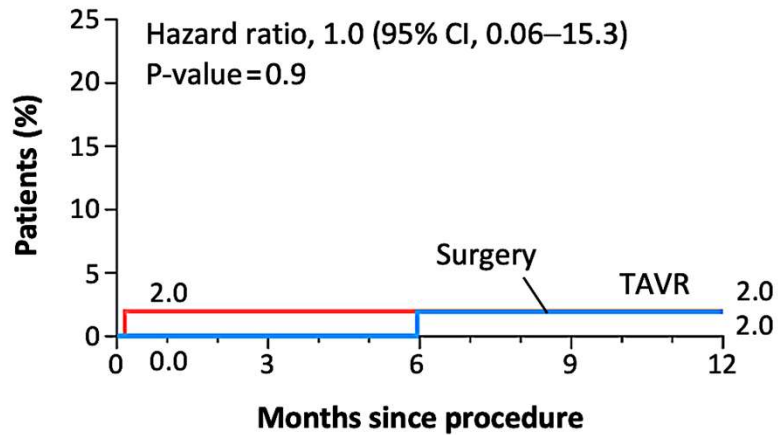


TAVR	26	26	26
Surgery	29	25	25

Subanalysis – tricuspid & bicuspid AS cohorts



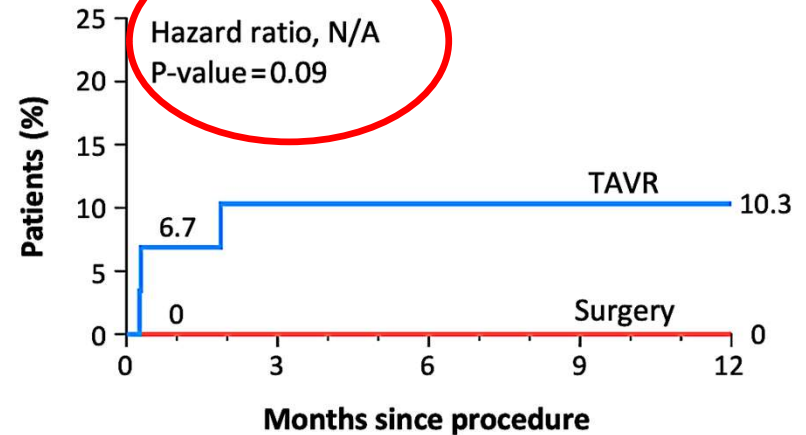
**Death or disabling stroke
Tricuspid cohort**



No. at Risk				
Surgery	51		50	50
TAVR	52		52	51

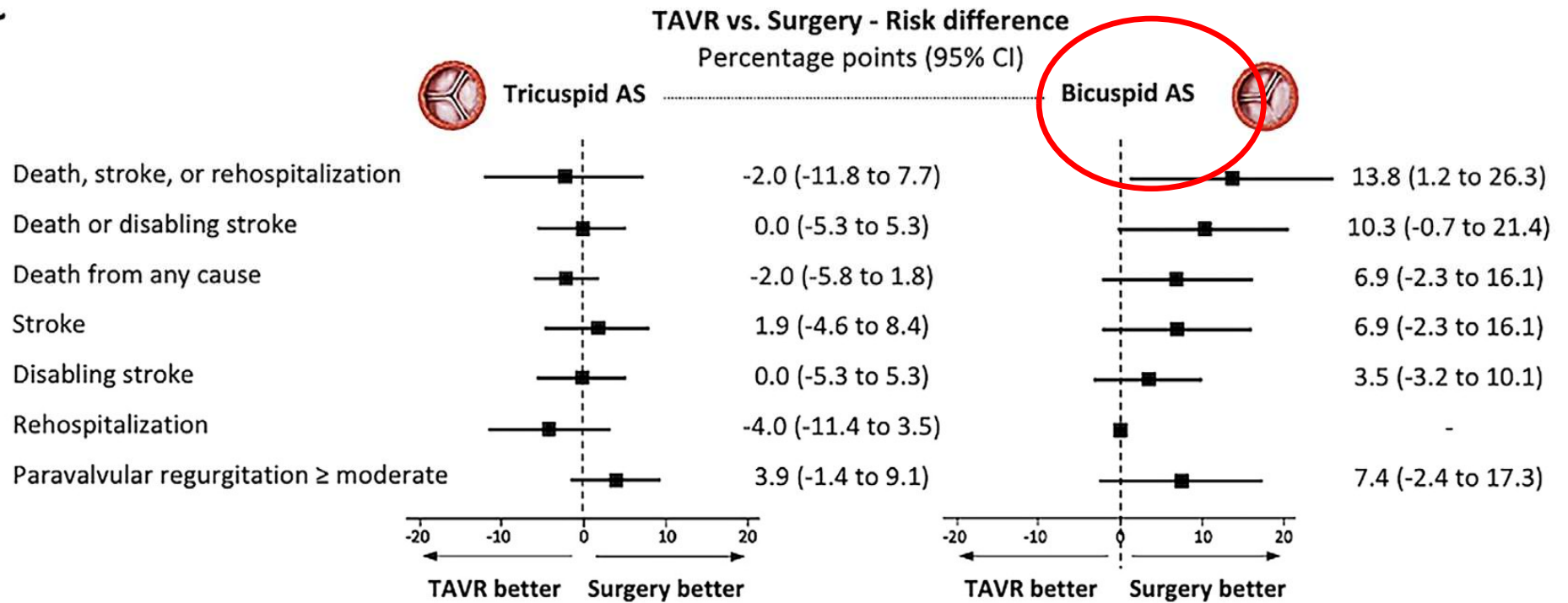


**Death or disabling stroke
Bicuspid cohort**

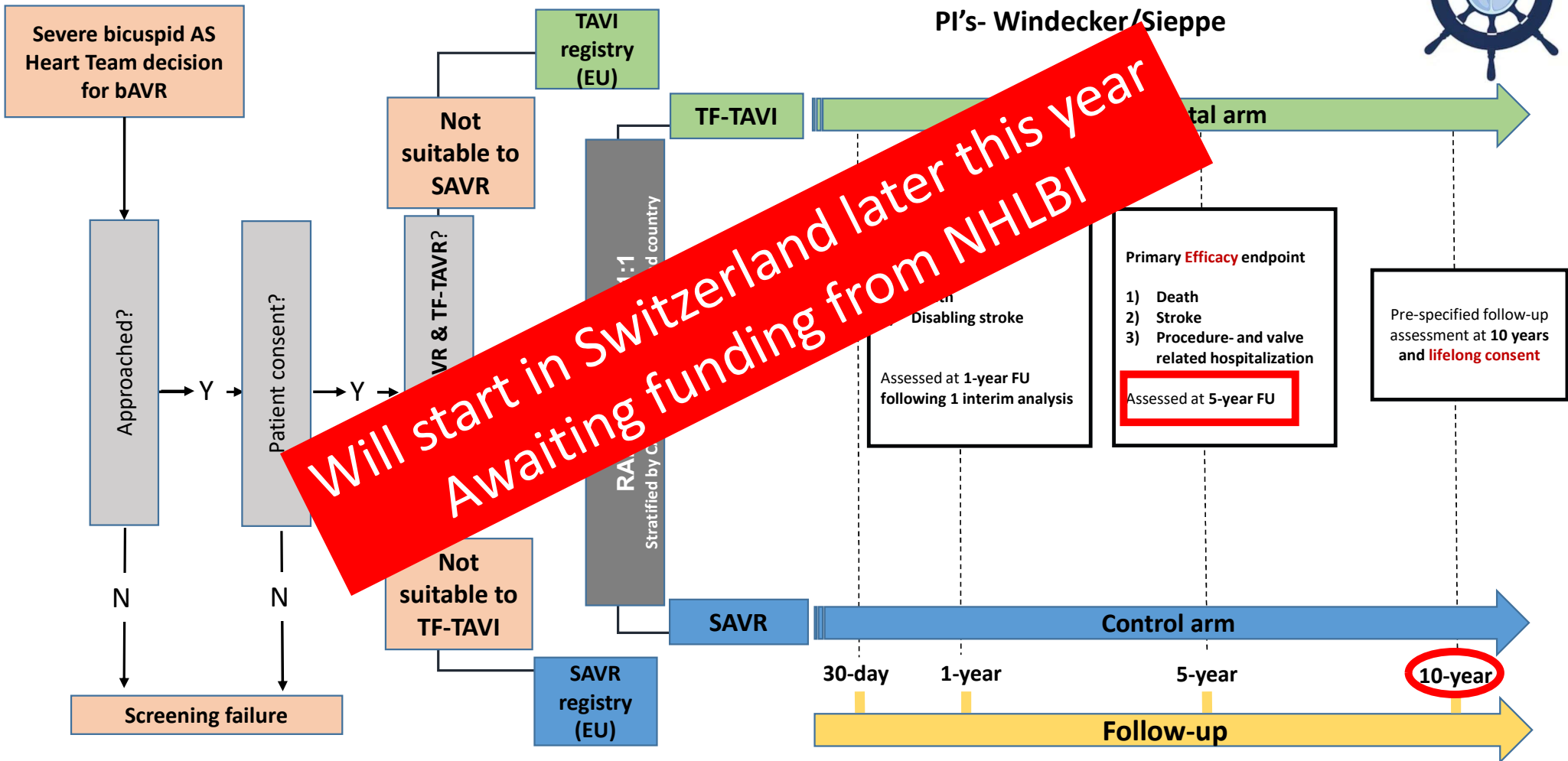
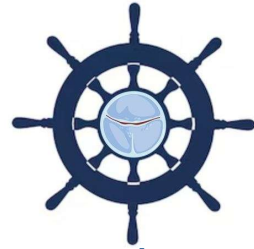


	26		26	26
	29		26	26

C



NAVIGATE BICUSPID – TRIAL FLOW CHART





BELIEVERS trial

Patients with severe Bicuspid Aortic Valve stenosis > 50 years old

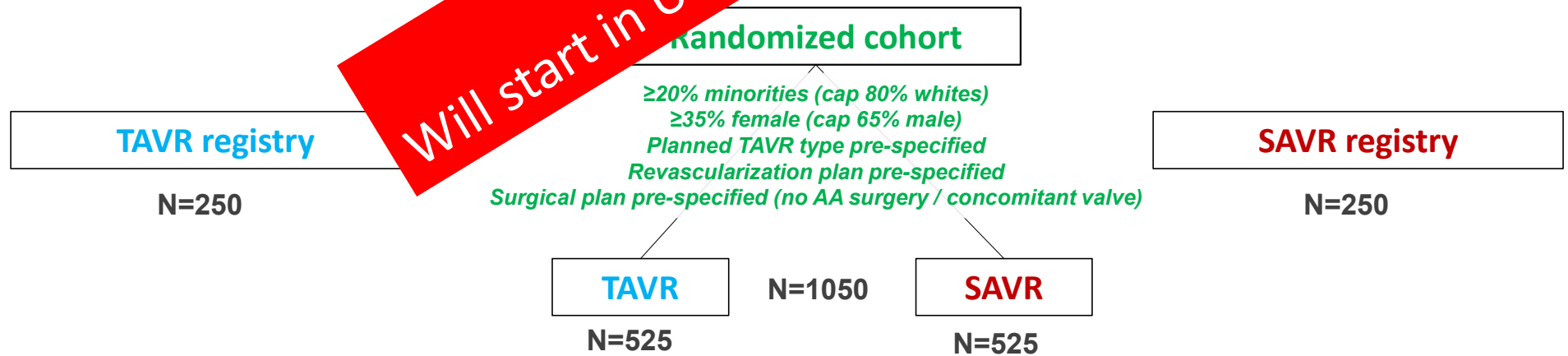
TAVR and SAVR risk determined by committee

Permissibility of randomization will be determined by committee based on perceived equipoise, taking into account risk assessments

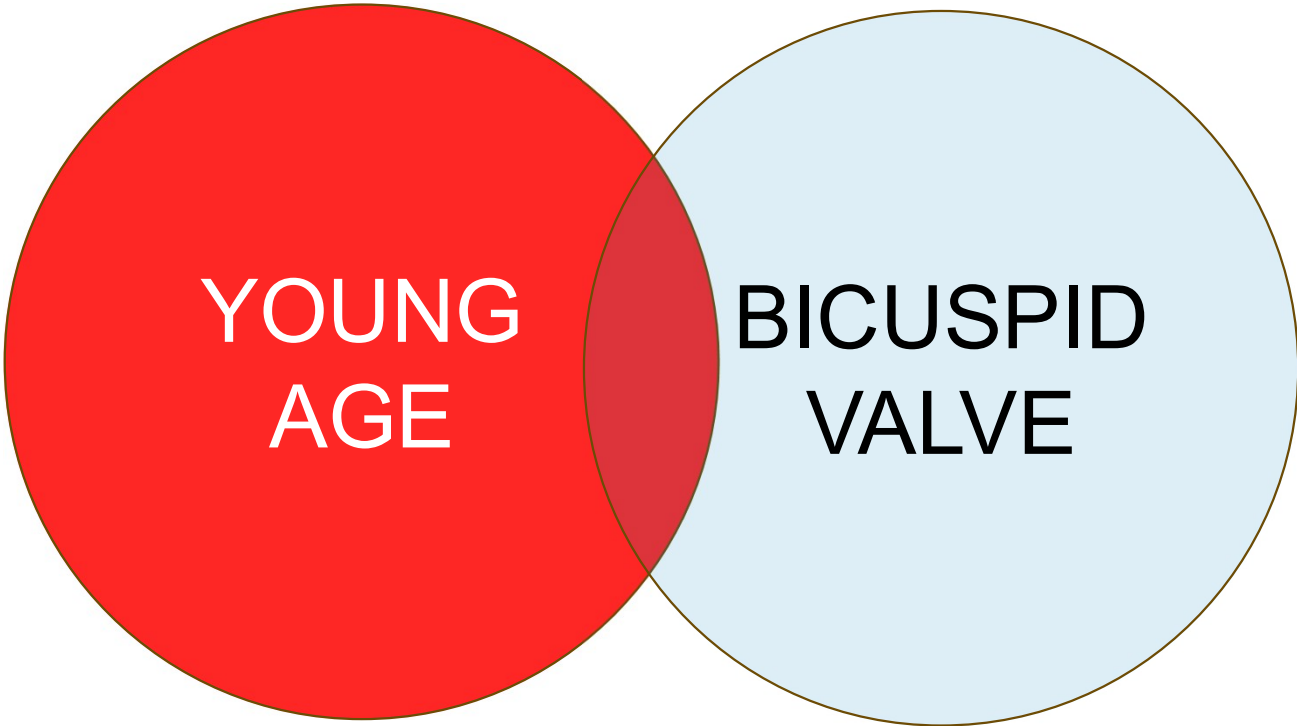
If risk assessment deemed appropriate, randomization to registry still permitted

Key exclusion criteria for randomization:

Concomitant non coronary cardiovascular surgery requiring cardiac surgery; SYNTAX \geq 32; AoMAX \geq 45mm* (not in center registries)



Confidential



**YOUNG
AGE**

**BICUSPID
VALVE**

What Do We Know About Aortic Valve Durability?

Options



Ross Procedure- restores life expectancy; highly operator dependent; not widely available



Mechanical- survival advantage at 15 years in patients <65 years; patients strongly resistant to anticoagulation



Bioprosthetic- all valves subject to structural valve deterioration



SAVR

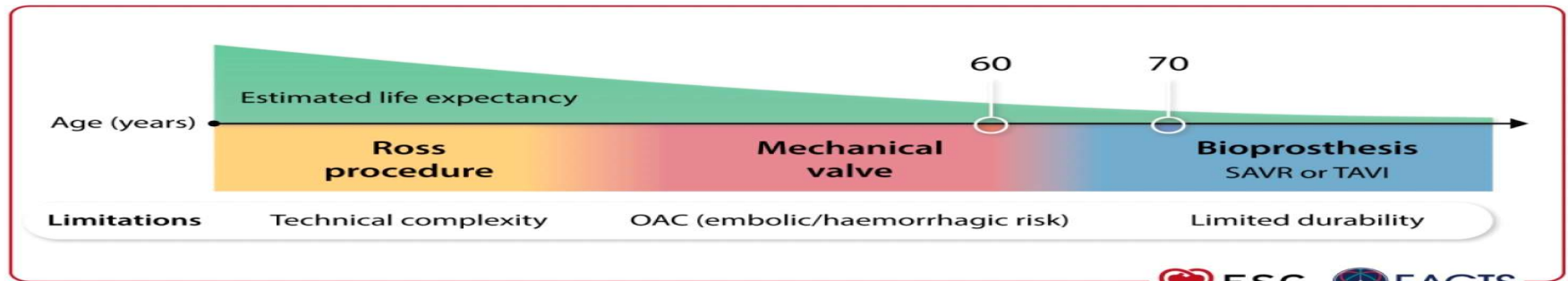


TAVR

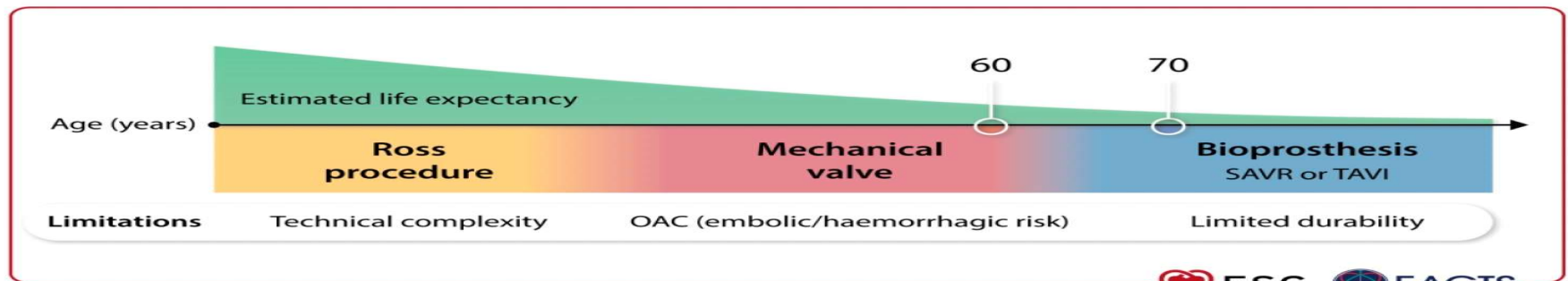


2025 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the task force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)



ESC EACTS



ESC EACTS

What Data Do We Have Regarding Comparative Outcomes and Bioprosthetic Valve Durability with TAVR and SAVR?



PARTNER 3 Trial -7 Year Outcomes



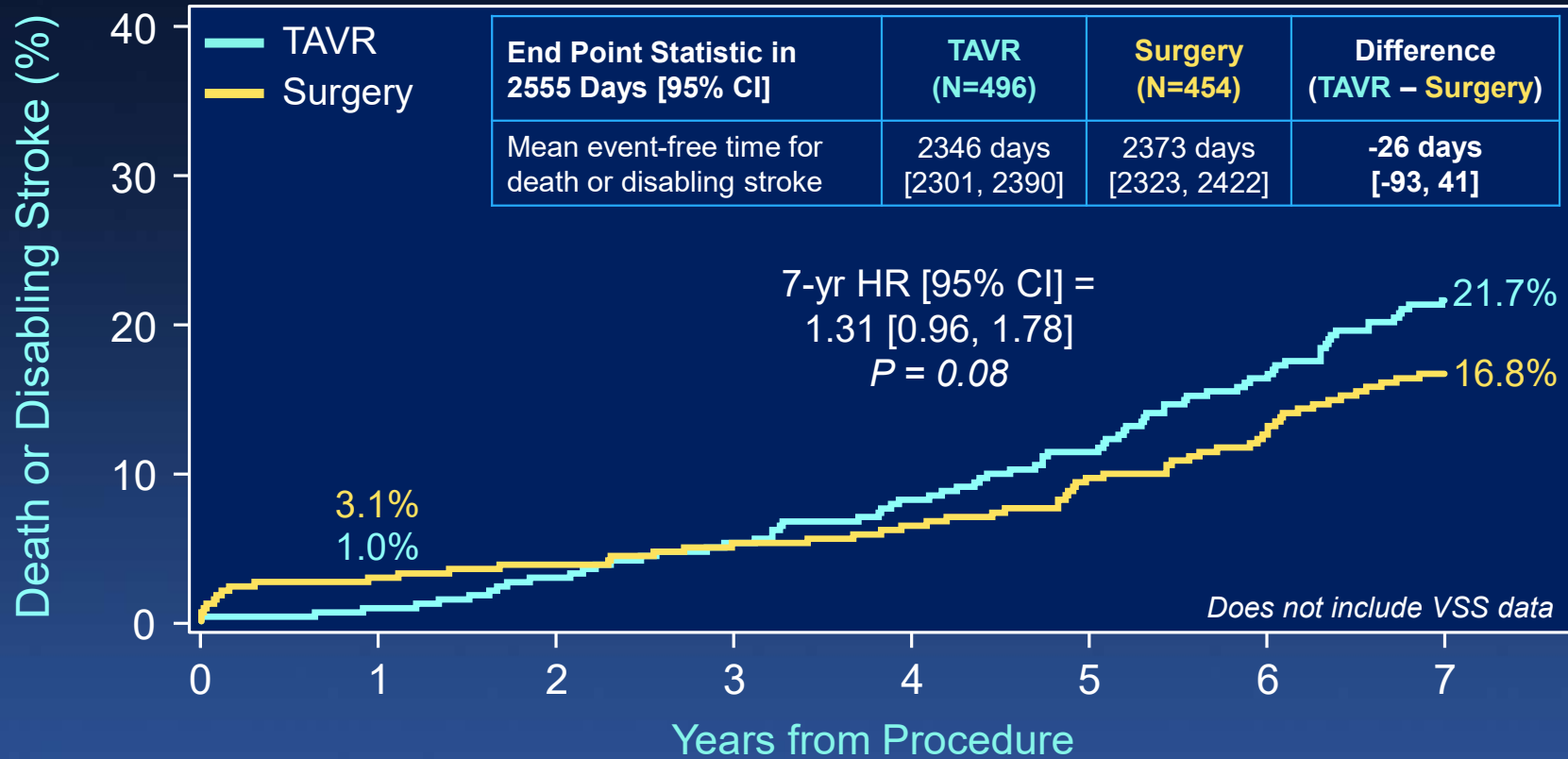
The NEW ENGLAND
JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Low-Risk Patients at 7 Years

Martin B. Leon, M.D.,^{1,2} Michael J. Mack, M.D.,³ Philippe Pibarot, D.V.M., Ph.D.,⁴
Rebecca T. Hahn, M.D.,^{1,2} Vinod H. Thourani, M.D.,⁵ S.H. Kodali, M.D.,^{1,2}
Philippe G n reux, M.D.,⁶ Samir R. Kapadia, M.D.,⁷ David J. Cohen, M.D.,^{2,8}
Stuart J. Pocock, Ph.D.,^{2,9} Yiran Zhang, M.S.,¹⁰ Molly Szerlip, M.D.,³
Julien Ternacle, M.D., Ph.D.,¹¹ S. Chris Malaisrie, M.D.,¹²
Howard C. Herrmann, M.D.,¹³ Wilson Y. Szeto, M.D.,¹³ Mark J. Russo, M.D.,¹⁴
Vasilis Babaliaros, M.D.,¹⁵ Tamim Nazif, M.D.,^{1,2} John G. Webb, M.D.,¹⁶ and
Raj R. Makkar, M.D.,¹⁷ for the PARTNER 3 Investigators*

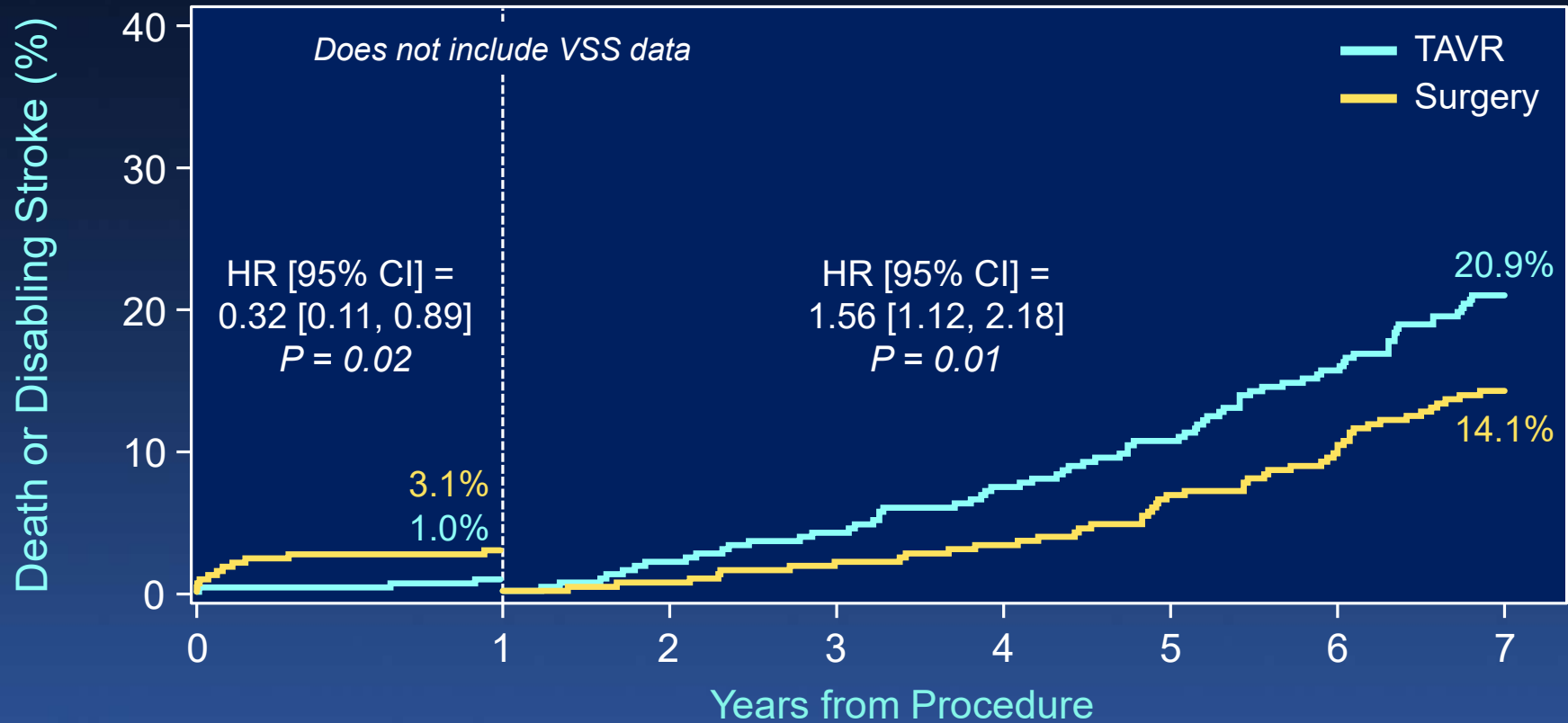
Death or Disabling Stroke



Number at risk:

TAVR	496	490	477	461	441	417	382	344
Surgery	454	425	408	392	379	357	339	306

Death or Disabling Stroke



Number at risk:

	0	1	2	3	4	5	6	7
TAVR	496	490	477	461	441	417	382	344
Surgery	454	425	408	392	379	357	339	306

Site-reported MI

No. of events

Diagnostic/Therapeutic Intervention	0 – 5 Years		>5 – 7 Years		0 – 7 Years	
	TAVR	Surgery	TAVR	Surgery	TAVR	Surgery
Total No. of MI Events	10	19*	16*	4	26*	23*
With Intervention	3 (30%)	9 (47%)	8 (50%)	1 (25%)	11 (42%)	10 (43%)
PCI/Coronary Stent	3	9	7	1	10	10
CABG	0	0	1	0	1	0
Without Intervention	7 (70%)	10 (53%)	8 (50%)	3 (75%)	15 (58%)	13 (57%)
Coronary Cath. Only	2	3	1	0	3	3
No Intervention Attempted	5	7	7	3	12	10

*2 patients had 2 events (1 in the TAVR arm and 1 in the Surgery arm)

Valve Thrombosis

No. of events

Clinically Significant Valve Thrombosis	0 – 7 Years	
	TAVR	Surgery
Valve Thrombosis Events	14 events in 13 pts ^{*†}	2 events in 2 pts [†]
Clinical Sequelae Related to Thrombosis		
Death	0	0
Stroke (all ischemic)	3	0
Disabling	1	0
Non-disabling	2	0
Stage 2 or 3 HVD	10	1
Resolved with Anticoagulation	7	0

*1 patient had 2 events (both Stage 1 HVD)

†There was 1 new event in each arm from 5-7 years (both Stage 3 HVD)

Ten-year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Aortic Stenosis: PARTNER 2A Trial

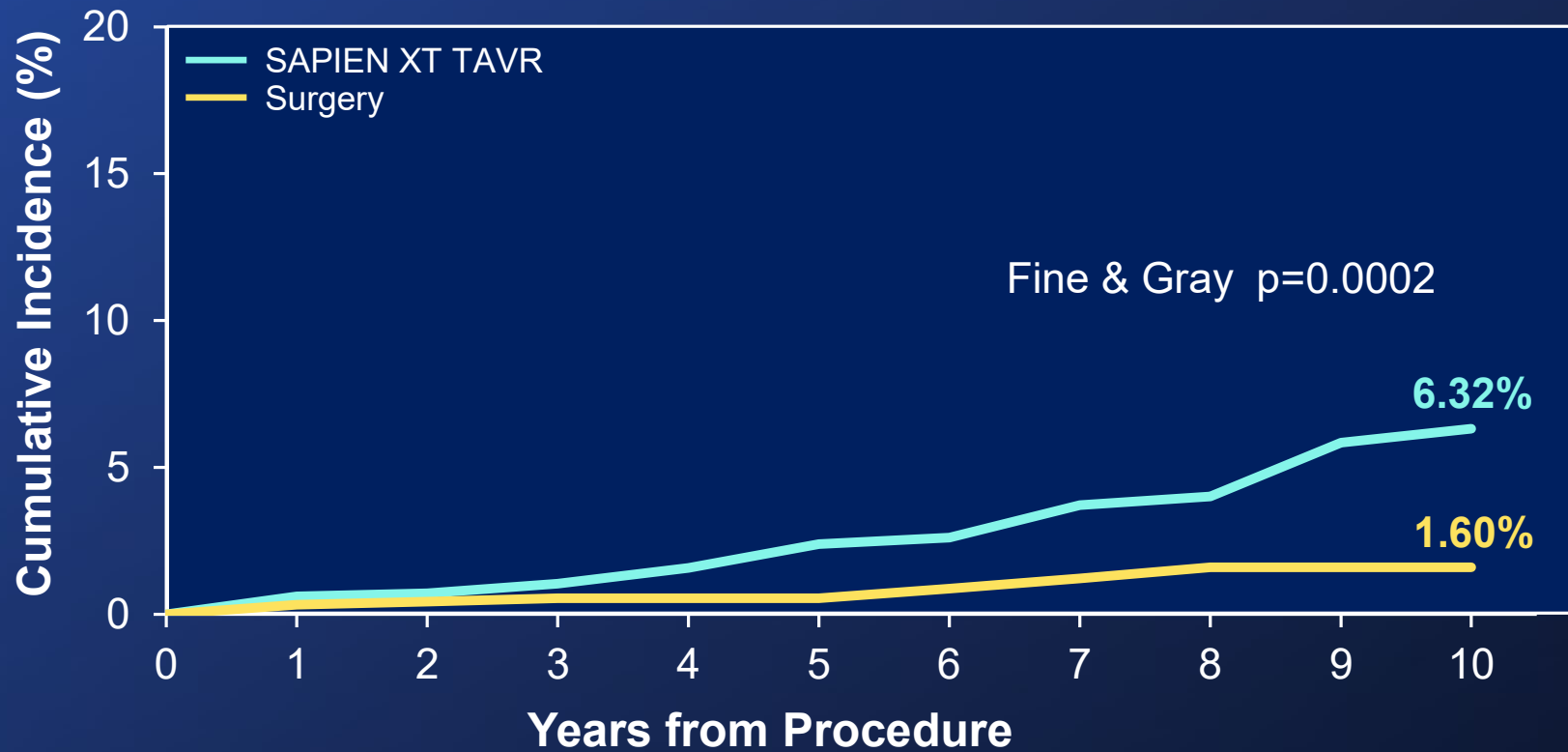
Vinod H. Thourani, MD

on behalf of The PARTNER 2 Trial Investigators

TCT | San Francisco | October 27th, 2025



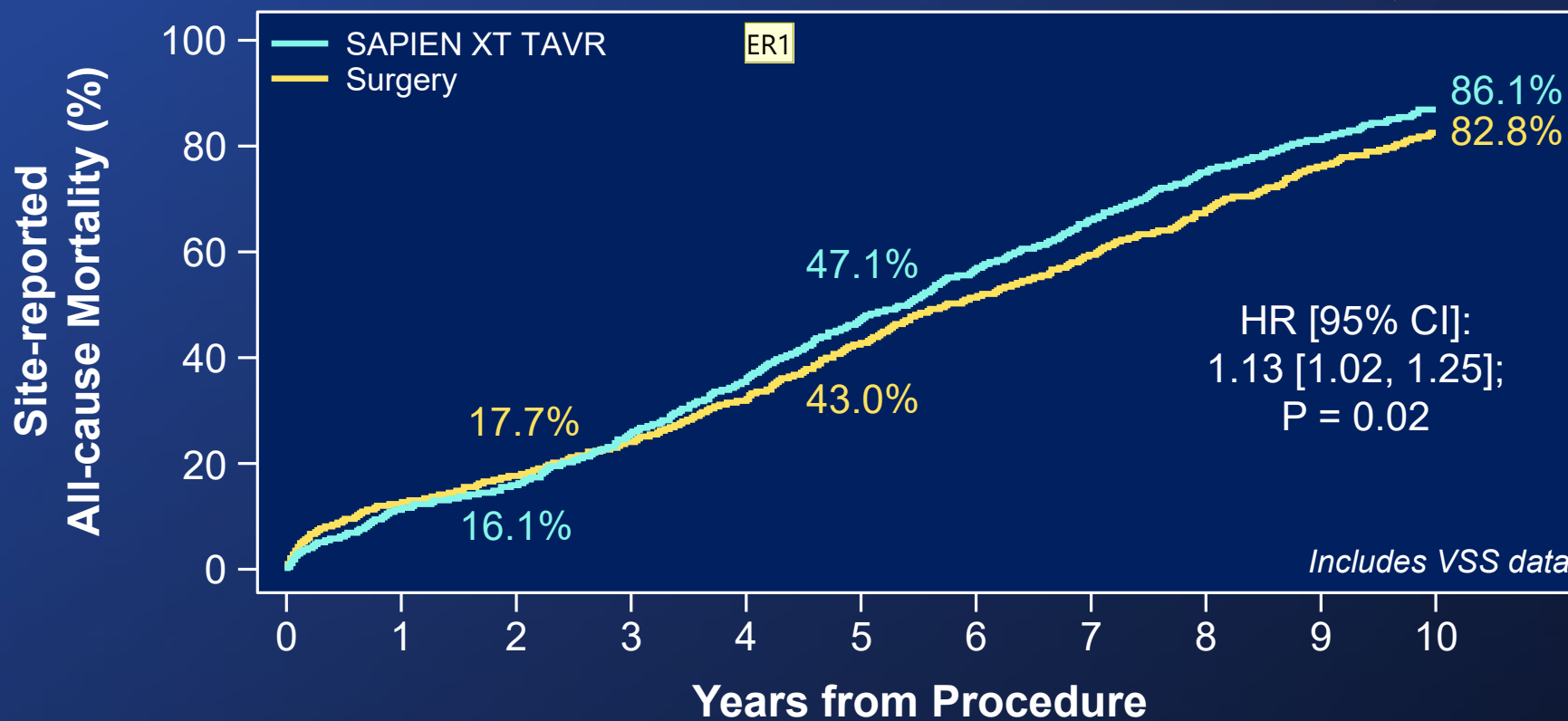
AV Reintervention With Competing Risk of Death



No. at Risk

XT TAVR	974	848	794	689	581	353	174	130	100	65	25
Surgery	936	796	727	649	566	355	159	130	105	78	34

All-cause Mortality



No. at Risk

XT TAVR	974	858	810	716	619	485	380	292	213	159	97
Surgery	936	813	763	701	624	503	396	327	254	184	120

Slide 27

ER1

Just taking a look at the legends between the figures. Some have the writing in white, so in the respective colors.

Emma Robinson, 2025-10-13T16:31:06.744

Ten-year Outcomes of the PARTNER 2 Intermediate-Risk Studies:

A Propensity-matched Analysis of P2S3i TAVR and P2A Surgery

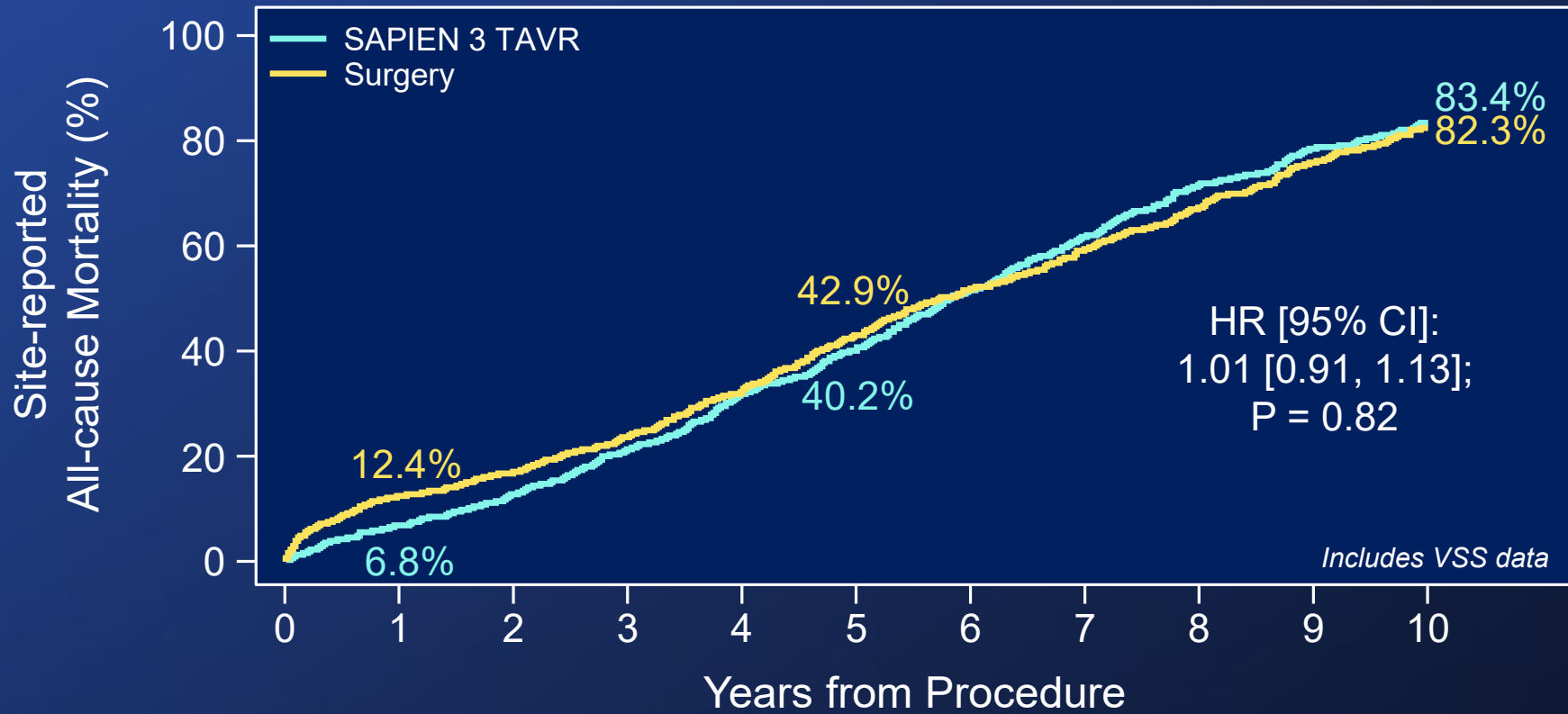
Raj Makkar, MD

on behalf of The PARTNER 2 Trial Investigators

TCT | San Francisco | October 27th, 2025



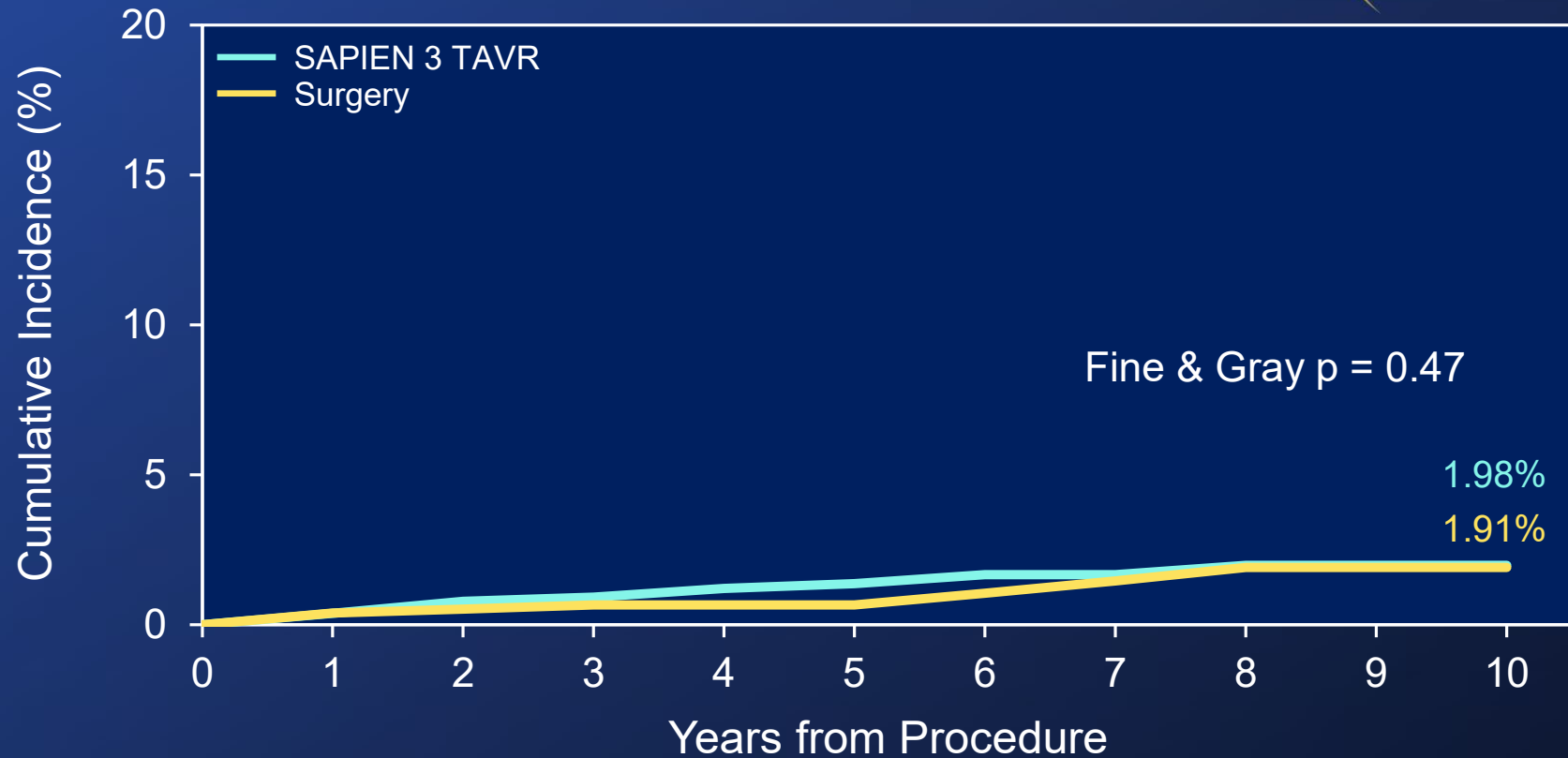
All-cause Mortality



No. at Risk

S3 TAVR	783	726	671	605	515	443	352	276	206	151	80
Surgery	783	682	645	591	523	421	335	281	222	162	103

AV Reintervention With Death as a Competing Risk



No. at Risk

S3 TAVR	783	712	647	566	458	310	165	125	101	75	32
Surgery	783	667	613	544	472	296	134	111	90	68	29

Six-Year Outcomes After Transcatheter vs Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

JACC
February 2026

John K. Forrest, MD,^a Steven J. Yakubov, MD,^b G. Michael Deeb, MD,^c Michael J. Reardon, MD,^d on behalf of the Evolut Low Risk Trial Investigators*

CONCLUSIONS The 6-year results from the Evolut Low Risk trial show no significant difference in the composite endpoint of all-cause mortality or disabling stroke. At 6 and 7 years, the TAVR arm had a higher reintervention rate compared with surgery, driven by an increased incidence of aortic regurgitation. (Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients; [NCT02701283](#)) (JACC. 2026;■:■-■) © 2026 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/>).



FIGURE 1 Clinical Outcomes Through 6 Years in the Evolut Low Risk Trial

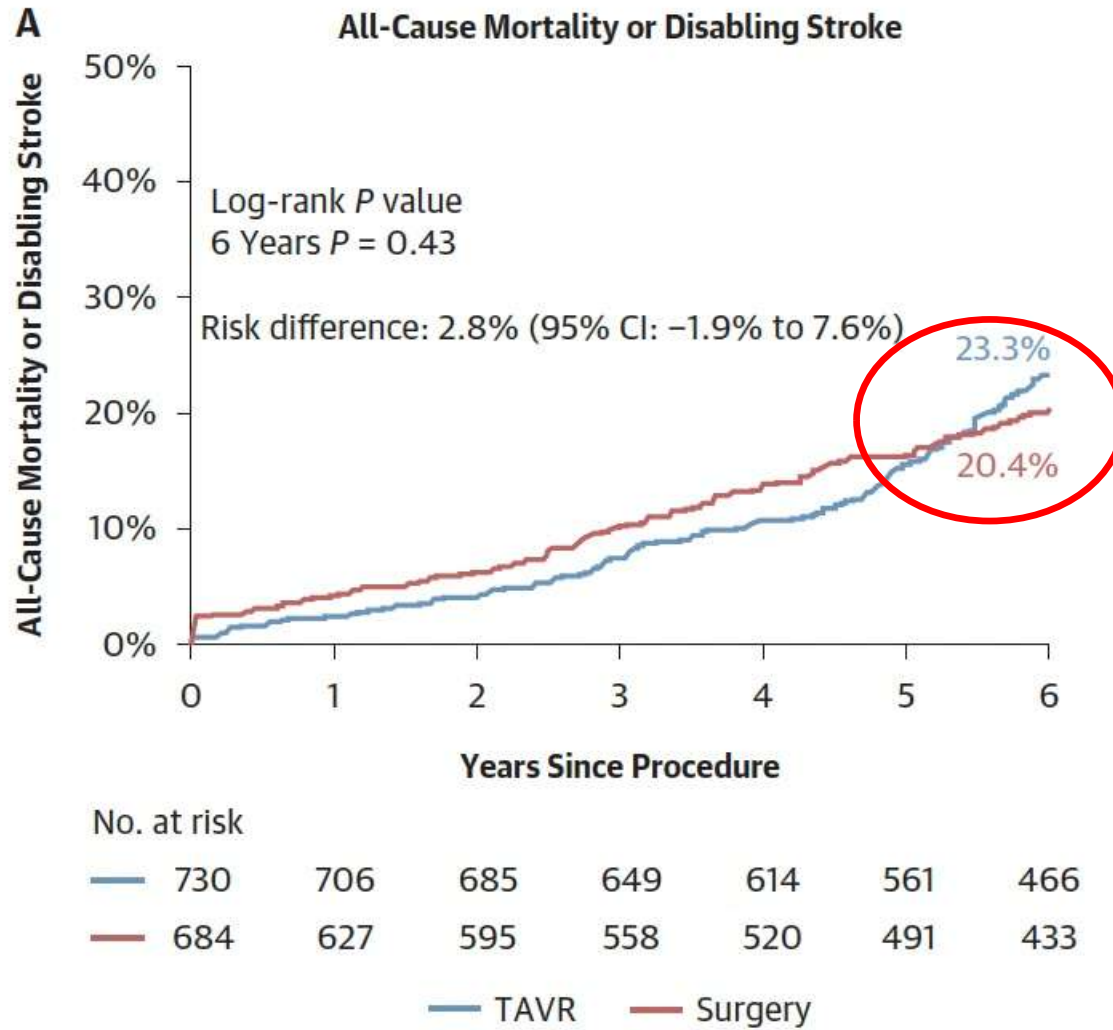
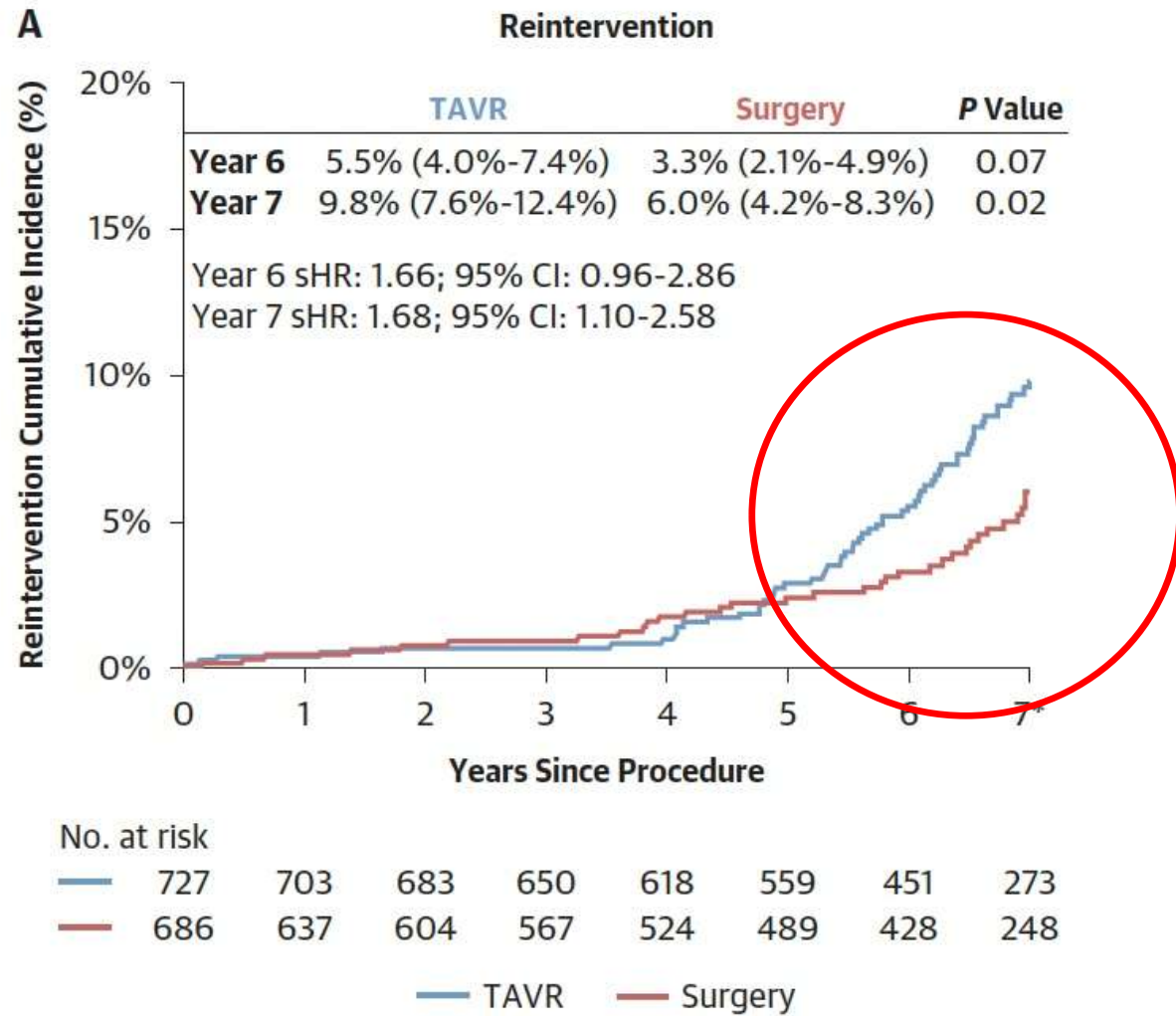


FIGURE 2 Reintervention—Cumulative Incidence Through 7 Years



Early Structural Valve Degeneration of Trifecta Bioprosthesis



Shinichi Fukuhara, MD, Suzuna Shiomi, BS, Bo Yang, MD, PhD, Karen Kim, MD, MS, Steven F. Bolling, MD, Jonathan Haft, MD, Paul Tang, MD, Francis Pagani, MD, PhD, Richard L. Prager, MD, Stanley Chetcuti, MD, P. Michael Grossman, MD, Himanshu J. Patel, MD, and G. Michael Deeb, MD

Department of Cardiac Surgery, University of Michigan, Ann Arbor, Michigan; and Division of Cardiovascular Medicine, University of Michigan, Ann Arbor, Michigan



SVD

Trifecta vs. Non-Trifecta

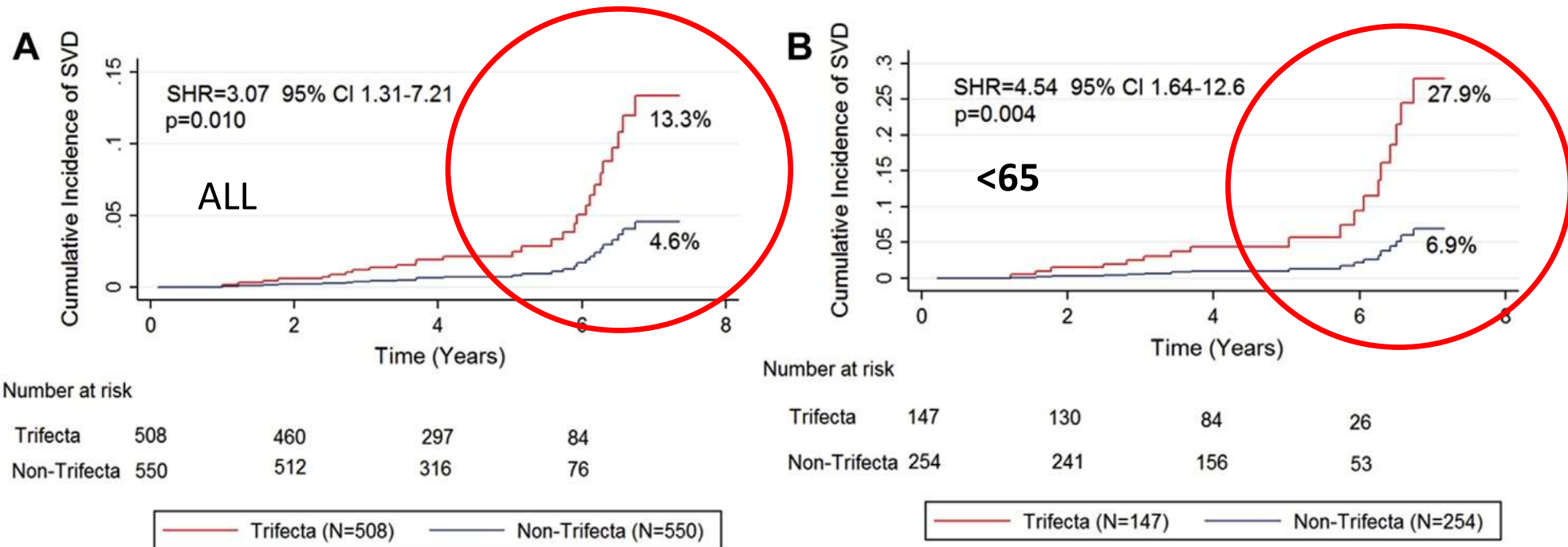


Figure 3. Cumulative incidence of structural valve degeneration: Trifecta (Abbott Vascular, Santa Clara, CA) vs non-Trifecta. Death and prosthetic valve endocarditis were considered as competing events. (A) Entire cohort. (B) Younger cohort (age ≤ 65 years). (CI, confidence interval; SHR, subdistribution hazard ratio; SVD, structural valve degeneration.)



Reintervention Trifecta vs. Non-Trifecta

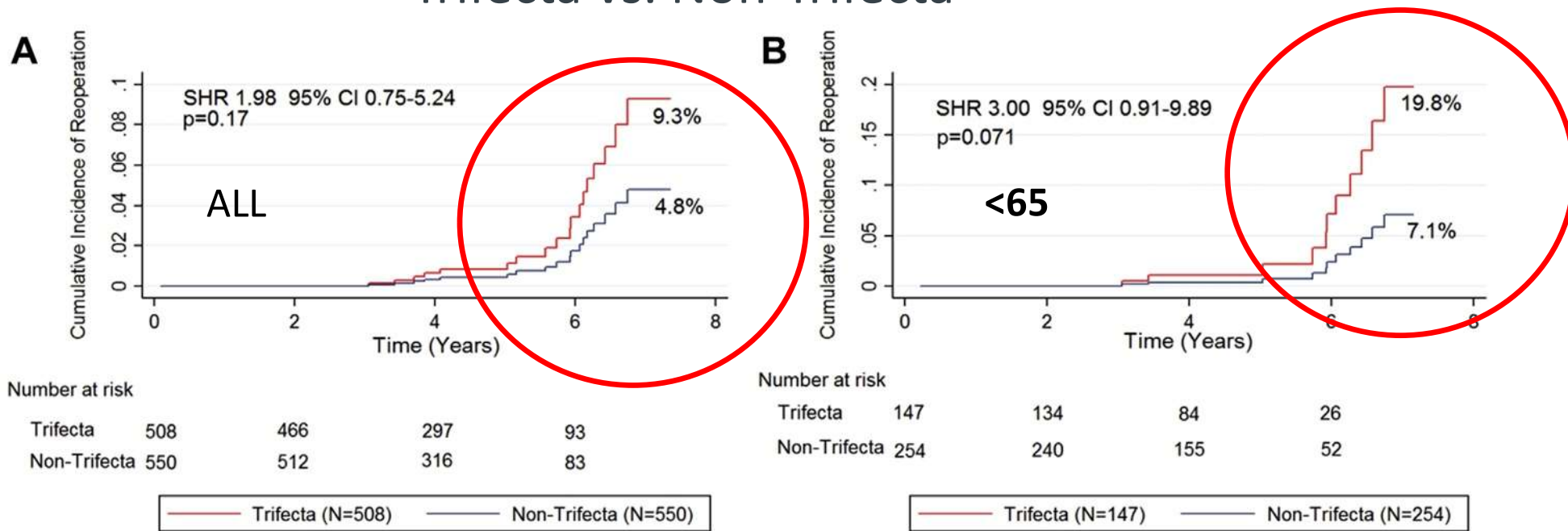


Figure 4. Cumulative incidence of reoperation (surgical or transcatheter aortic valve replacement): Trifecta (Abbott Vascular, Santa Clara, CA) vs non-Trifecta. (A) Entire cohort. (B) Younger cohort (age ≤ 65 years). (CI, confidence interval; SHR, subdistribution hazard ratio; SVD, structural valve degeneration.)



Treatment of the Young Patient with Aortic Stenosis and a Bicuspid Aortic Valve

Conclusions

Patients < 70 years should preferentially receive SAVR

TAVR in patients with a bicuspid valve should be reserved for older patients with favorable anatomy

Patients < 65 years should be informed about the Ross Procedure and mechanical valve options and outcomes

ACC/AHA Guidelines will be published later this year

We need 10-year valve durability and outcome data in low-risk patients

Similar to surgical valves, there may be differences in durability of TAVR valves

