Top 10 Advances in Transcatheter Valve Therapy 2023

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President Mount Sinai Heart Network

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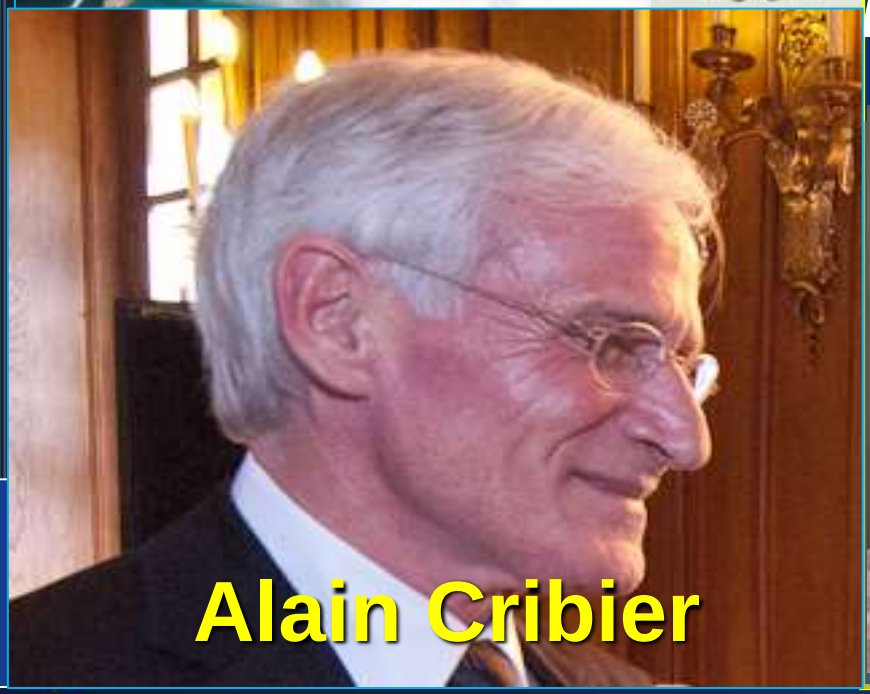
Mount Sinai Hospital, NY

COI: NONE

Start / Father of Transcatheter Valve Therapy

Andersen Stent-Valve
(1989)



Alain Cribier

Percutaneous Valve Technologies (PVT) Aortic Heart Valve

23-24mm max diameter

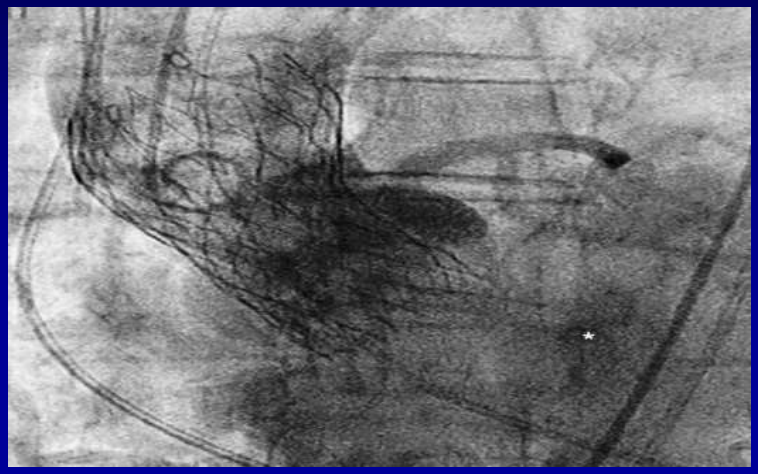
Bovine pericardium / Stainless steel stent

FIM: April 16, 2002

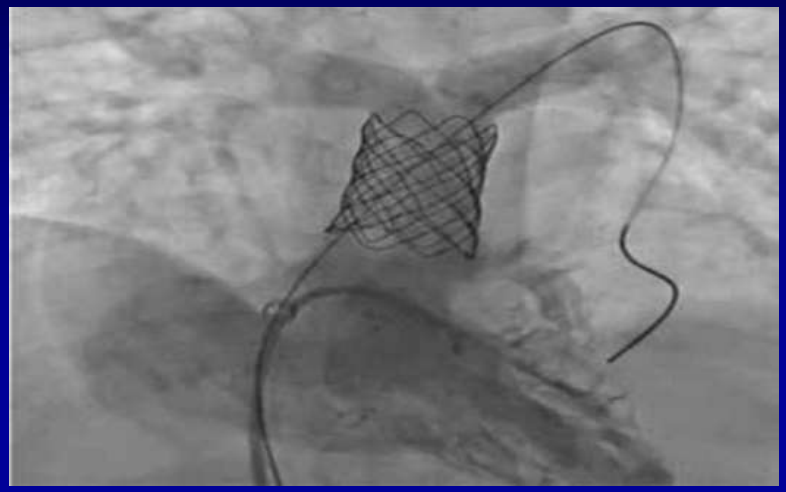
Conclusions: Nonsurgical implantation of a prosthetic heart valve can be safely and successfully achieved with immediate & midterm results

Current Status of Transcatheter Heart Valve Therapy

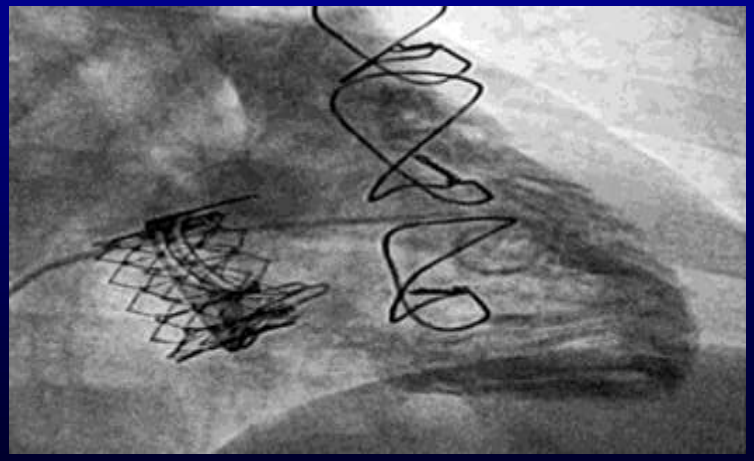
Aortic Valve
Medtronic CoreValve; #2



Pulmonic Valve
Medtronic Melody Valve; #1



Tricuspid Valve
Edwards Perimount Magna; #3

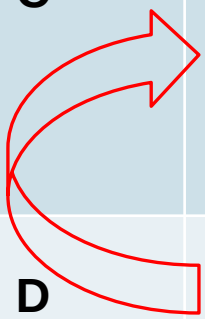


Mitral Valve
Edwards Sapien XT; #4

#2

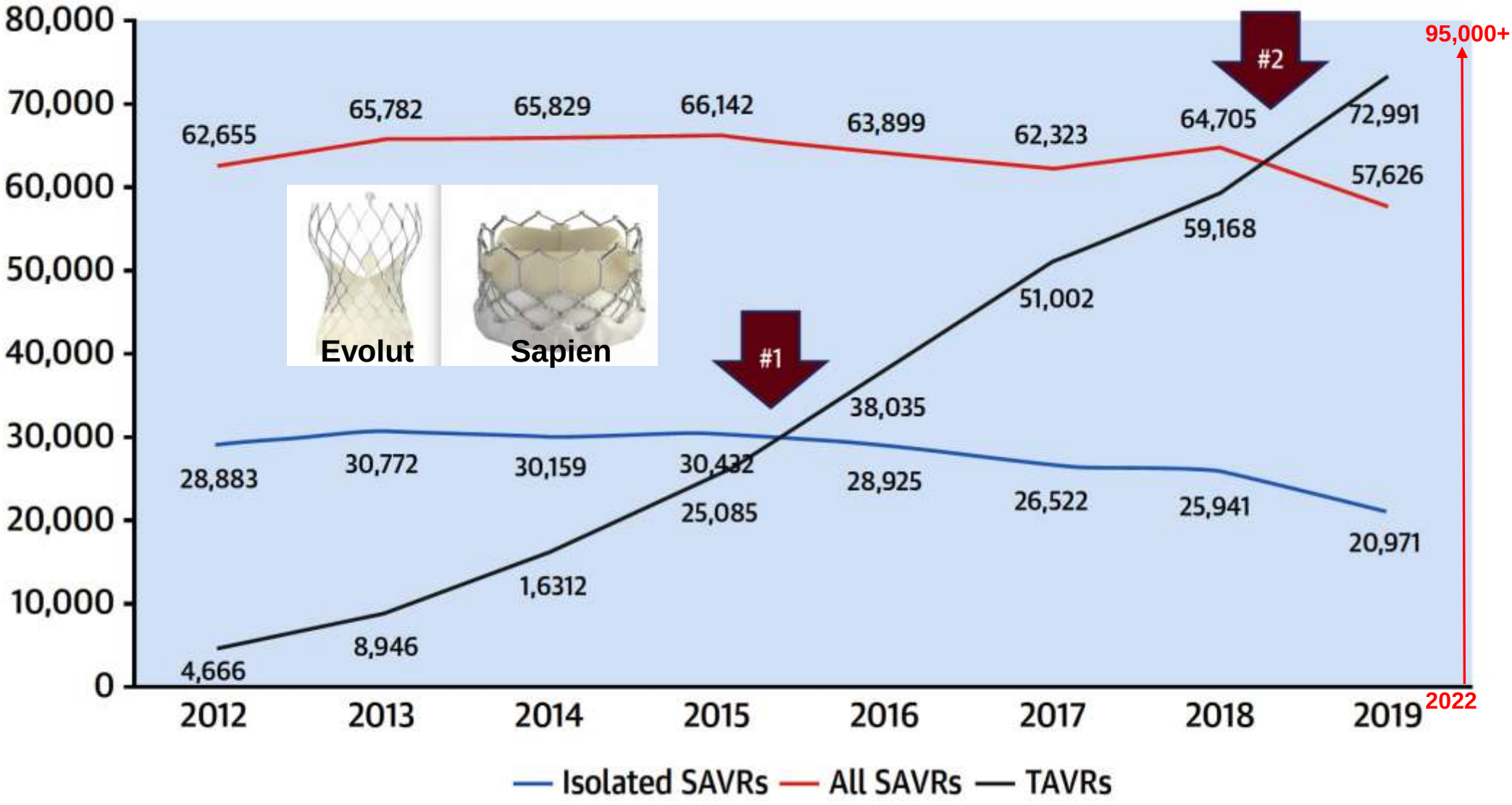
Stages of Progression of Valvular Heart Disease (VHD)

Stage	Definition	Description
A	At risk	Patients with risk of development of VHD
B	Progressive	Patients with progressive VHD (mild-moderate severity and asymptomatic)
C	Asymptomatic severe	Asymptomatic patients who have the criteria for severe VHD: C1: Asymptomatic patients with severe VHD in whom the left or right ventricle remains compensated C2: Asymptomatic patients with severe VHD, with decompensation of the left or right ventricle
D	Symptomatic severe	Patients who have developed symptoms as a result of VHD

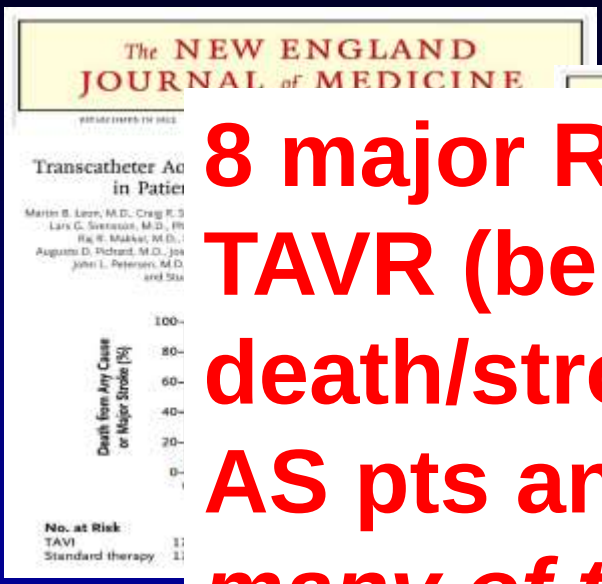


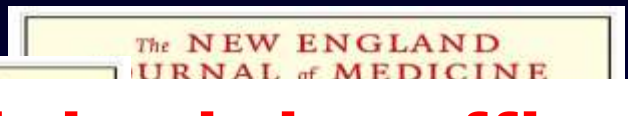
Nishimura et al., Circulation 2014;129:2440

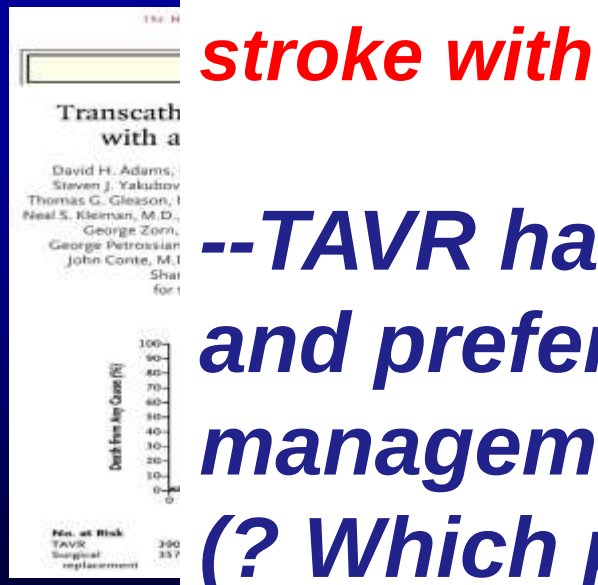
Annual Volumes of TAVR and SAVR in USA



Carroll et al., J Am Coll Cardiol 2020;76:2492







8 major RCT established the efficacy of TAVR (being non-inferior to SAVR for death/stroke) in various STS risk severe AS pts and lower LOS;

many of them showed superior & safer outcomes vs SAVR (except Partner 1A had 2x stroke with TAVR vs SAVR).

…hence

--TAVR has now become the dominant, safe and preferred default strategy in management of severe AS

(? Which pt should get SAVR appropriately)

Balance of Factors Determining Strength of Valve Preference vs. Expected Remaining Years of Life

SAVR

Survival benefit
Valve durability
Avoid permanent pacer
Annular enlargement
Aortic dilation
Concurrent valve disease

TAVI

Survival benefit
Short hospitalization
Transfemoral only
Less pain
Good haemodynamics
Durability less important

Shared decision making
Patient preferences & values

Strength of valve preference

>20 years

<10 years

Life Expectancy

Top 10 Advances in Transcatheter Valve Therapy 2023

Reasons for selection of the study/publication

Revolutionary / significant observation

↓

Widespread acceptance

↓

Change in clinical practice

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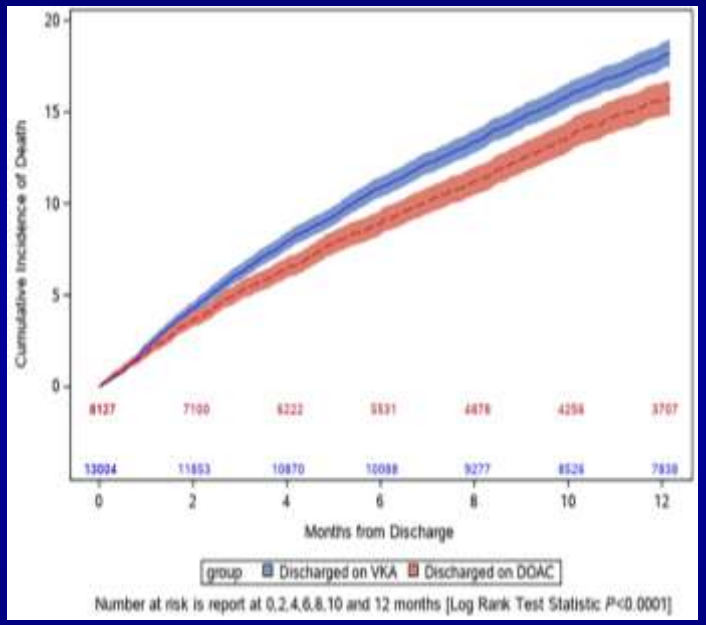
10. LAAO for Afib during TAVR: WATCH TAVR

Concomitant Left Atrial Appendage Occlusion and Transcatheter Aortic Valve Replacement Among Patients with Atrial Fibrillation

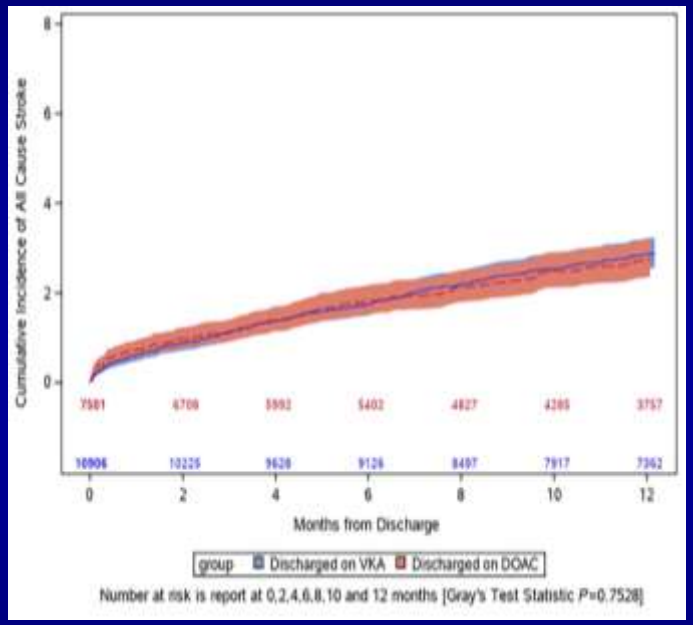
WATCH-TAVR Trial

WATCH-TAVR Study: Mortality, Stroke and Bleeding After TAVR in AF Pts (Occurs in 40-50% AS pts)

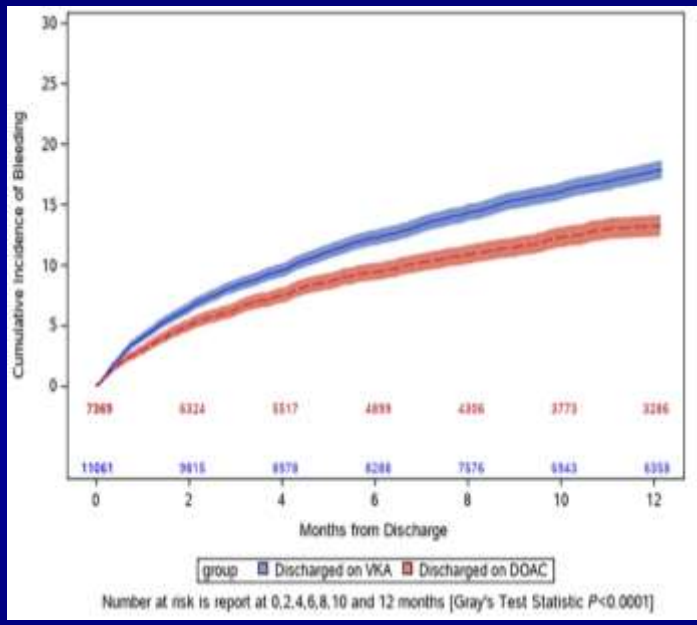
MORTALITY



STROKE



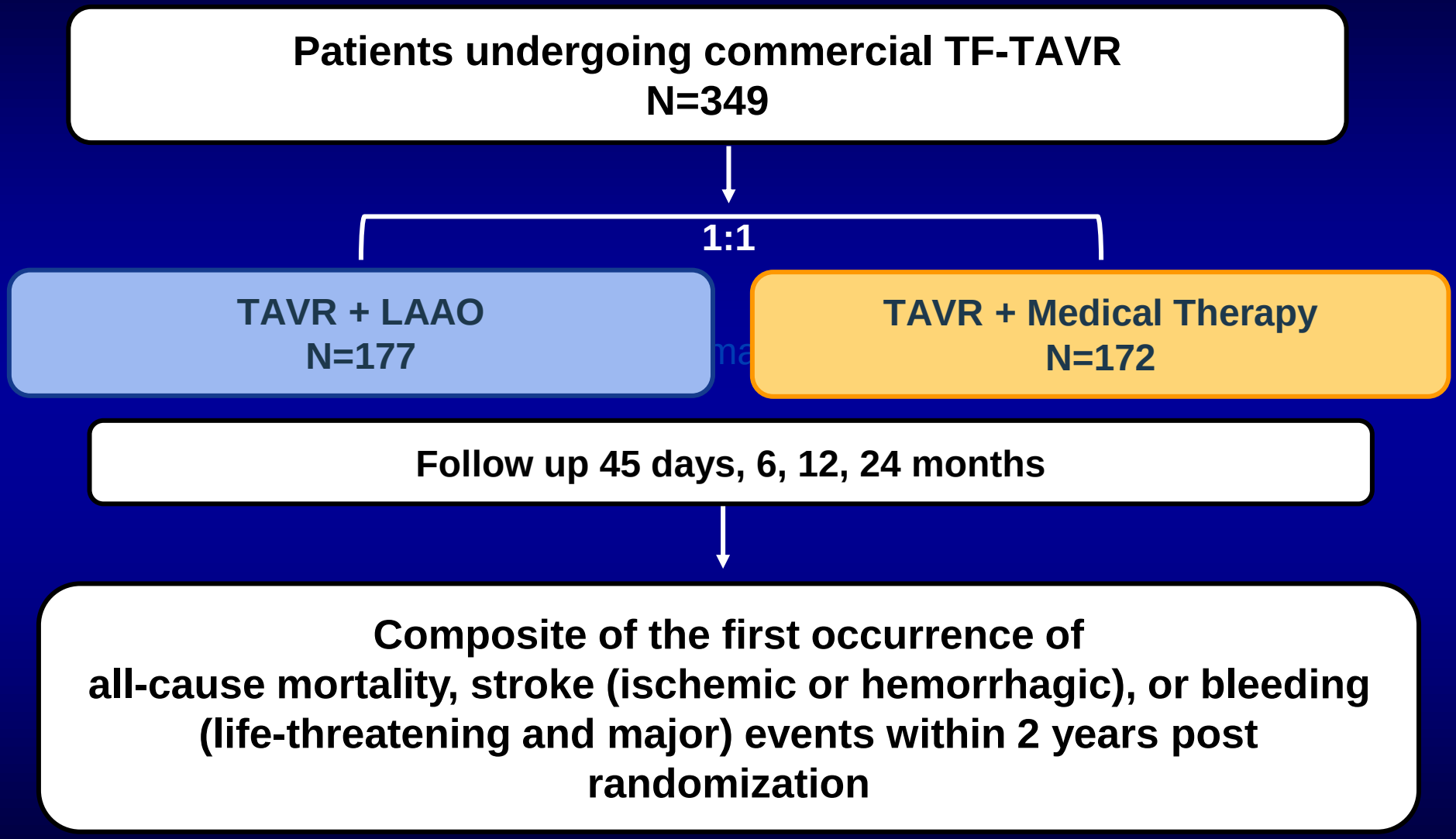
BLEEDING



WARFARIN DOAC

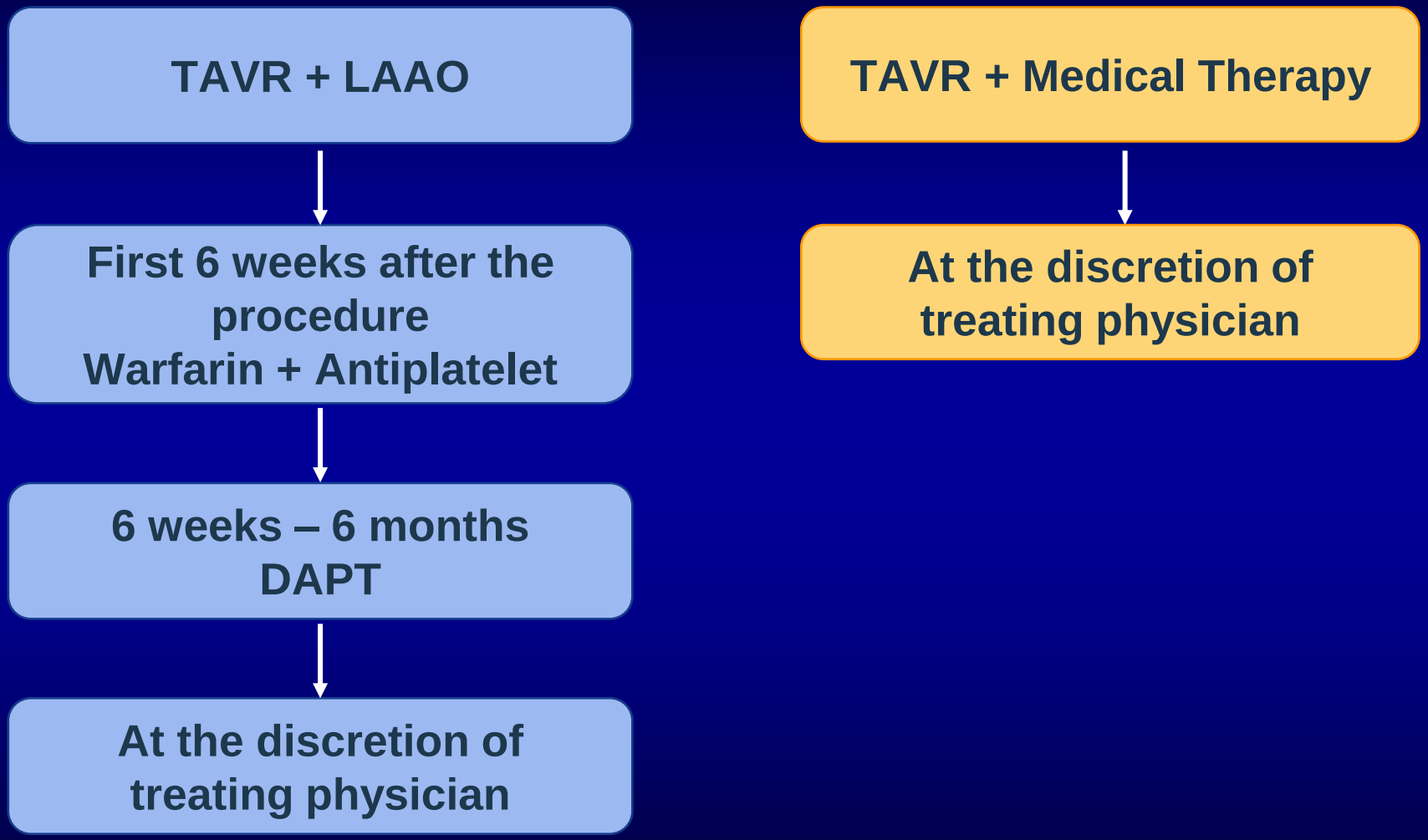
Tanawuttiwat et al, JAHA 2022;11:e023561

WATCH TAVR Study Design



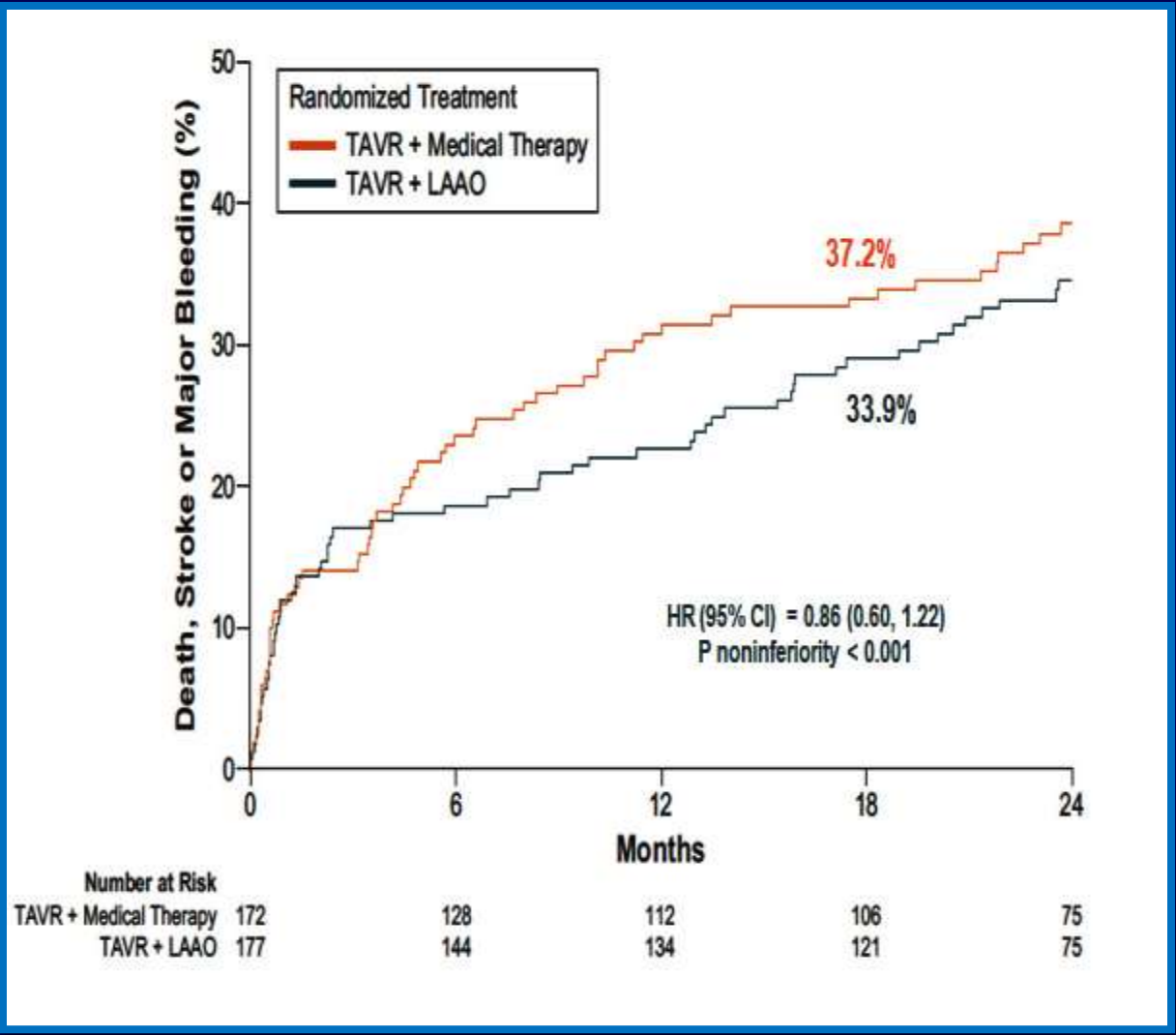
Kapadia et al., Circulation Oct 28, 2023 Epub ahead of print

WATCH-TAVR Study: Medical Therapy

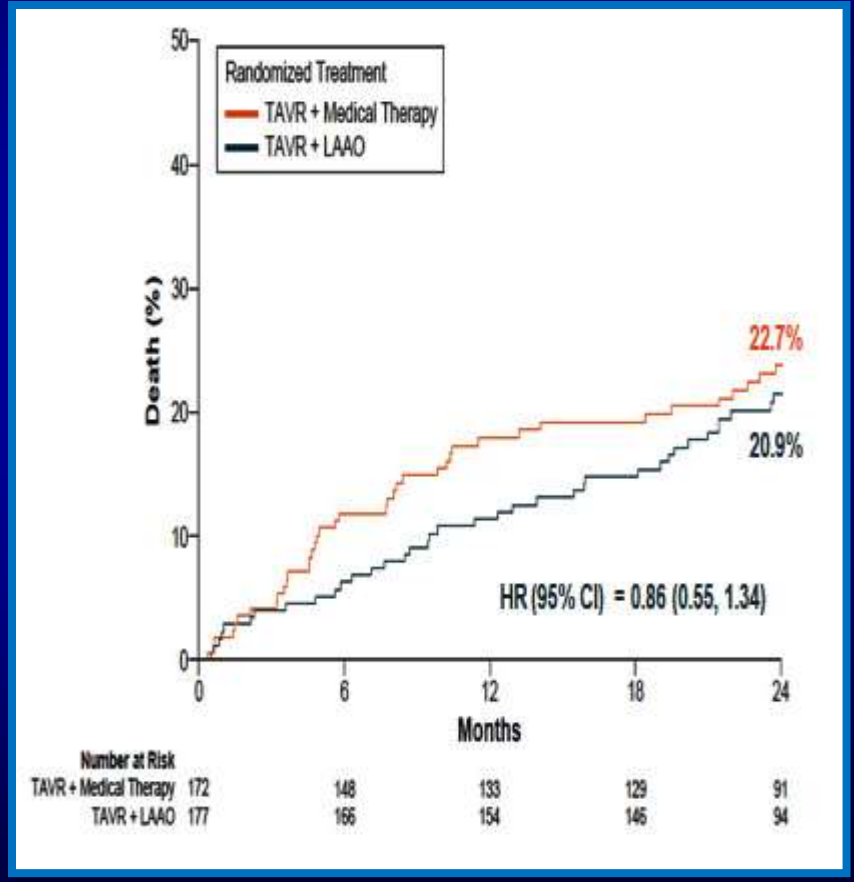


Kapadia et al., Circulation Oct 28, 2023 Epub ahead of print

WATCH TAVR Study: Primary Outcome
Death, Stroke, Major Bleeding



Mortality



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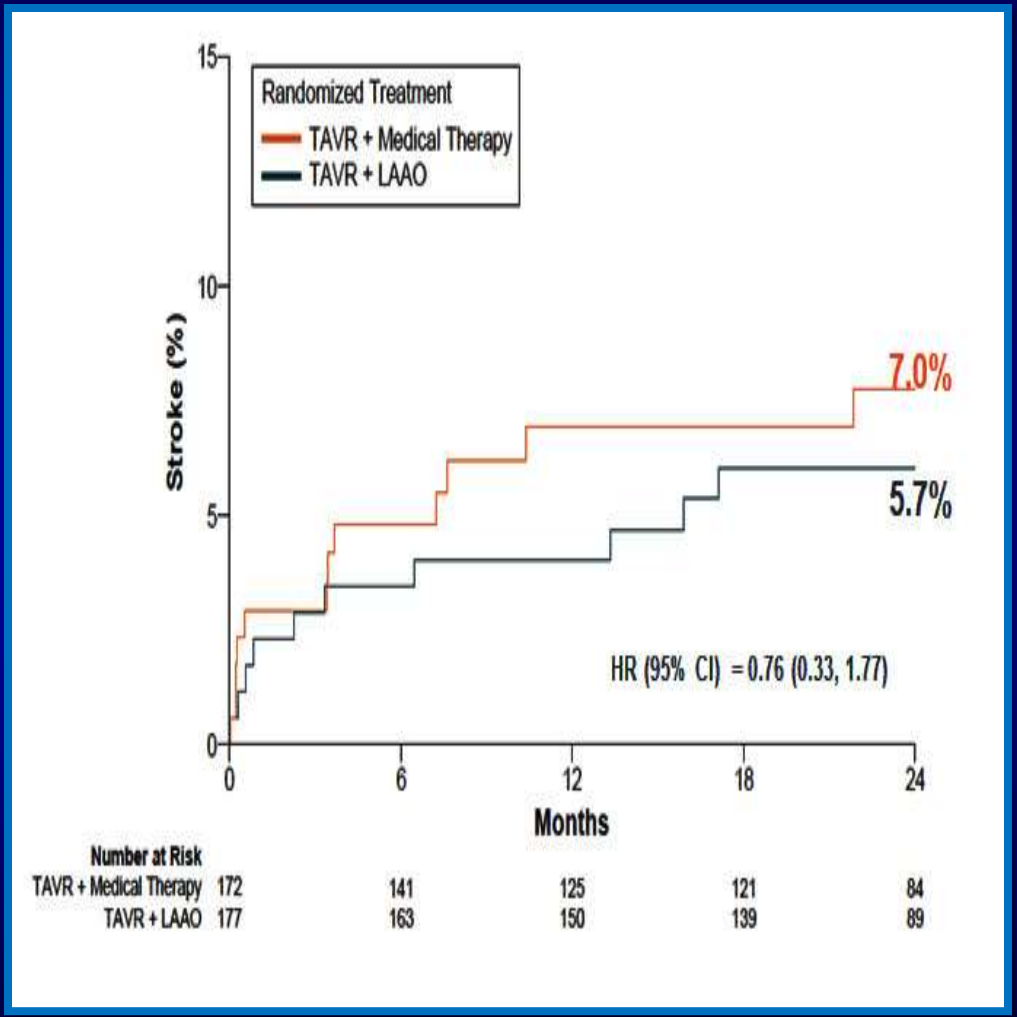
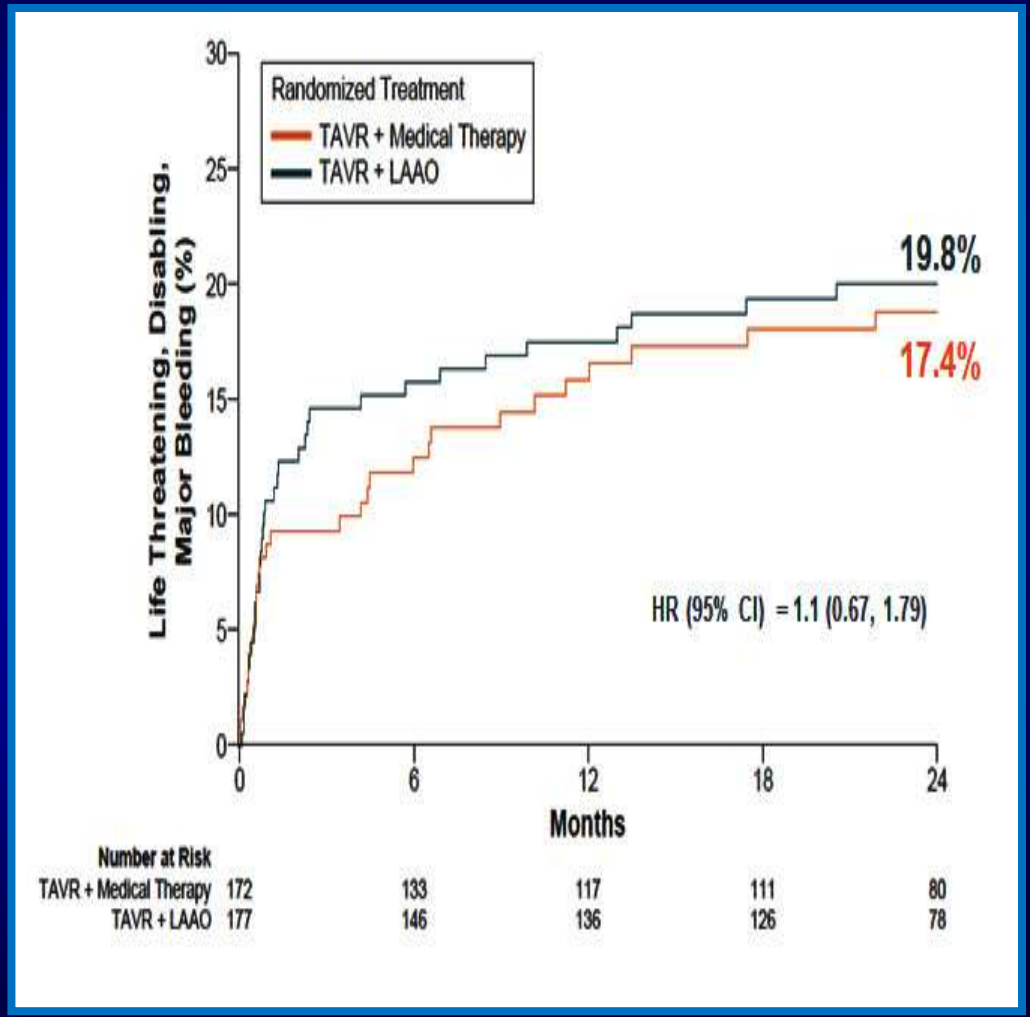
WATCH TAVR Study:

All Strokes



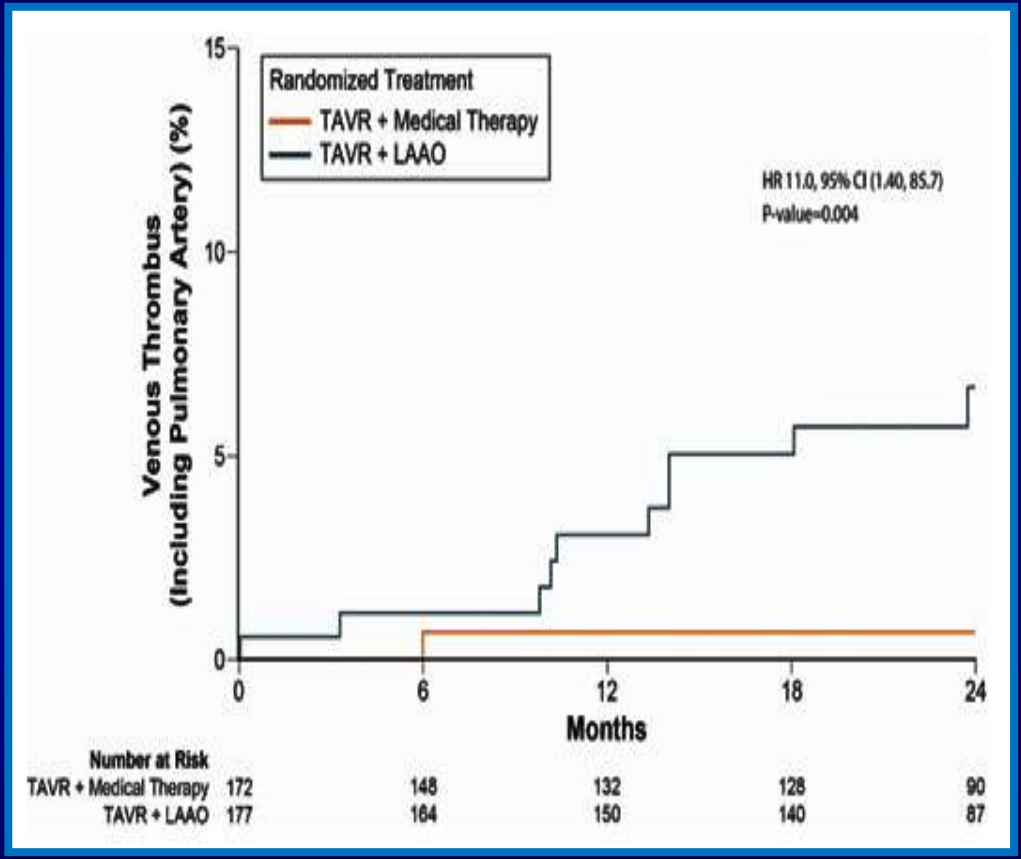
Major Bleeding



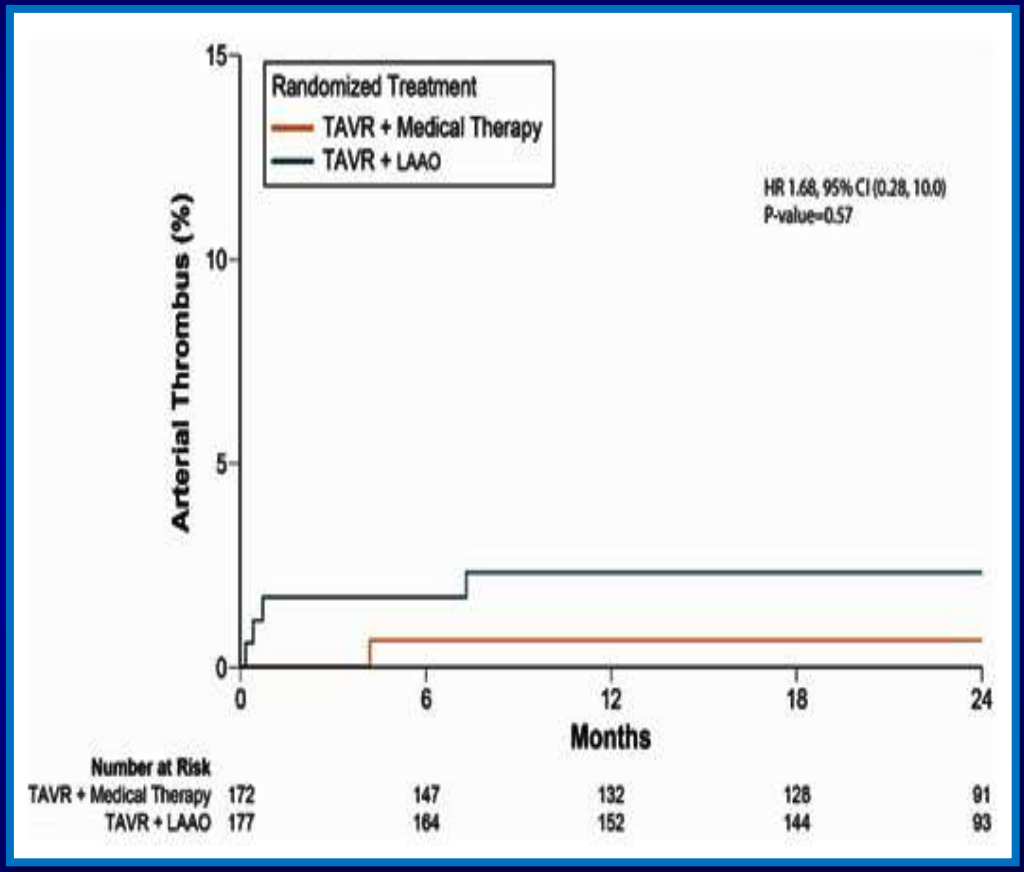
Kapadia et al., Circulation Oct 28, 2023 Epub ahead of print

WATCH TAVR Study: Thrombosis

Venous



Arterial



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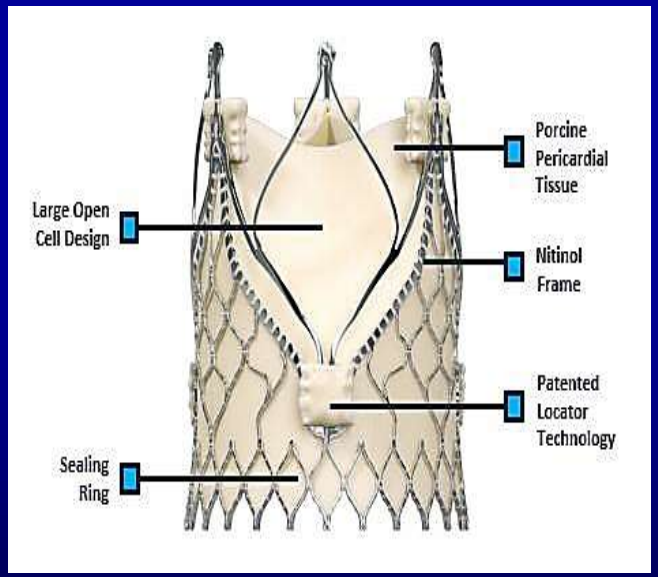
The JenaValve Trilogy™ Heart Valve System in High Surgical Risk Patients with Symptomatic, Severe Aortic Regurgitation: The ALIGN AR Trial

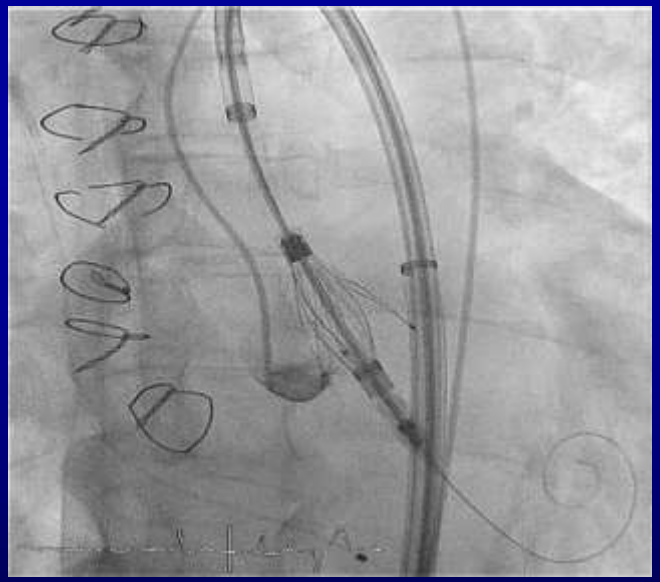
Jenavalve Trilogy TAVI System

- The Trilogy TAVI System features unique locators that align the THV with the native cusps of the valve and ensures anatomically correct alignment

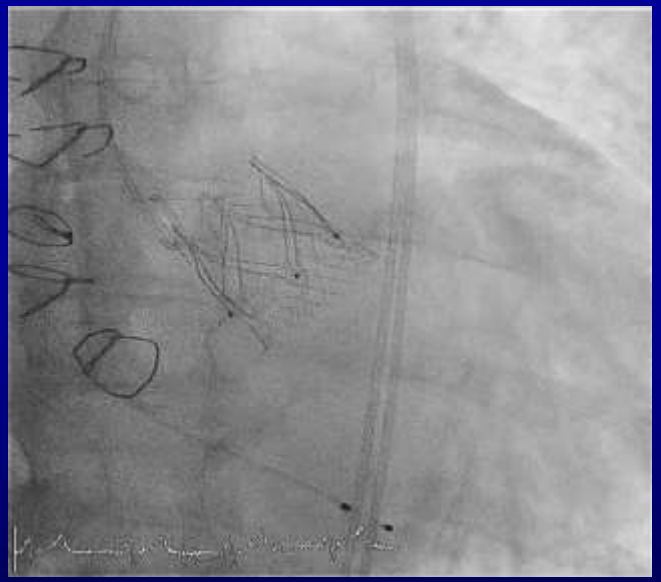
- The locators “clip” onto the native leaflets, enabling anchoring in pure AR patients with non-calcified valves.



Jenavalve Trilogy Valve



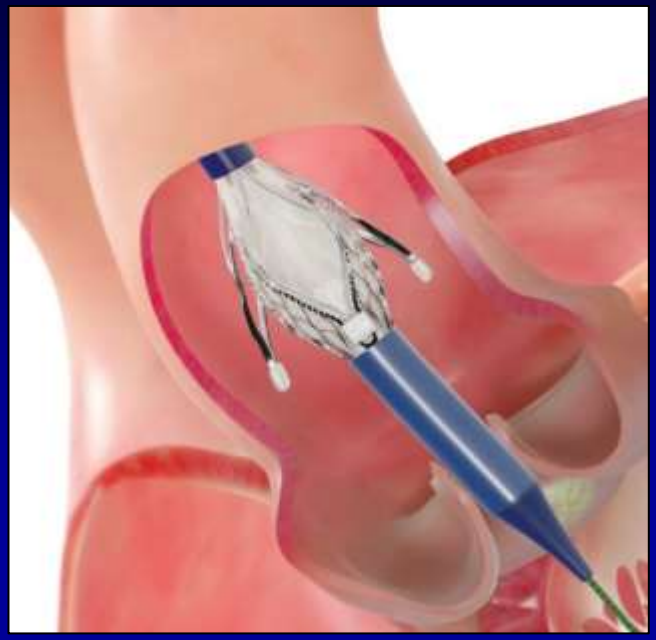
Prosthesis with locators spread during implantation, seating locators in the sinuses



Jenavalve Trilogy valve after implantation with perfect position and no paravalvular regurgitation

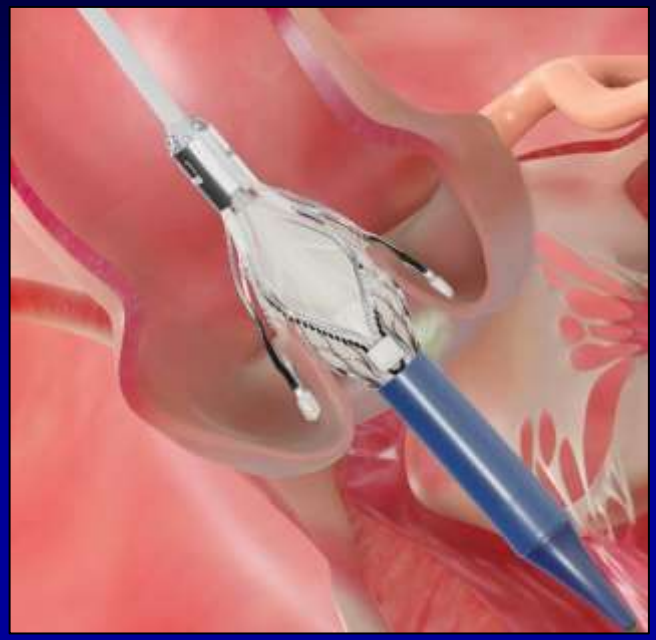
Tamm A, EuroPCR 2022

ALIGN AR Trial: Trilogy THV in AR Anatomy



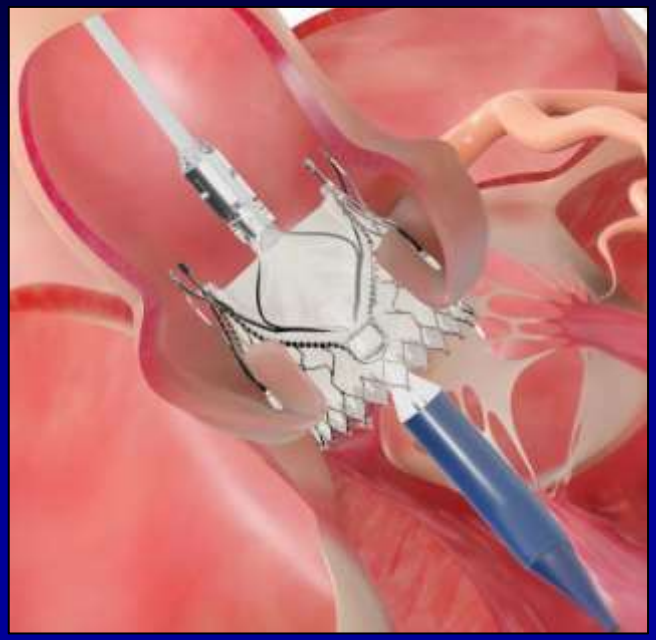
Alignment

- Aligns THV with native cusps



Positioning/Anchoring

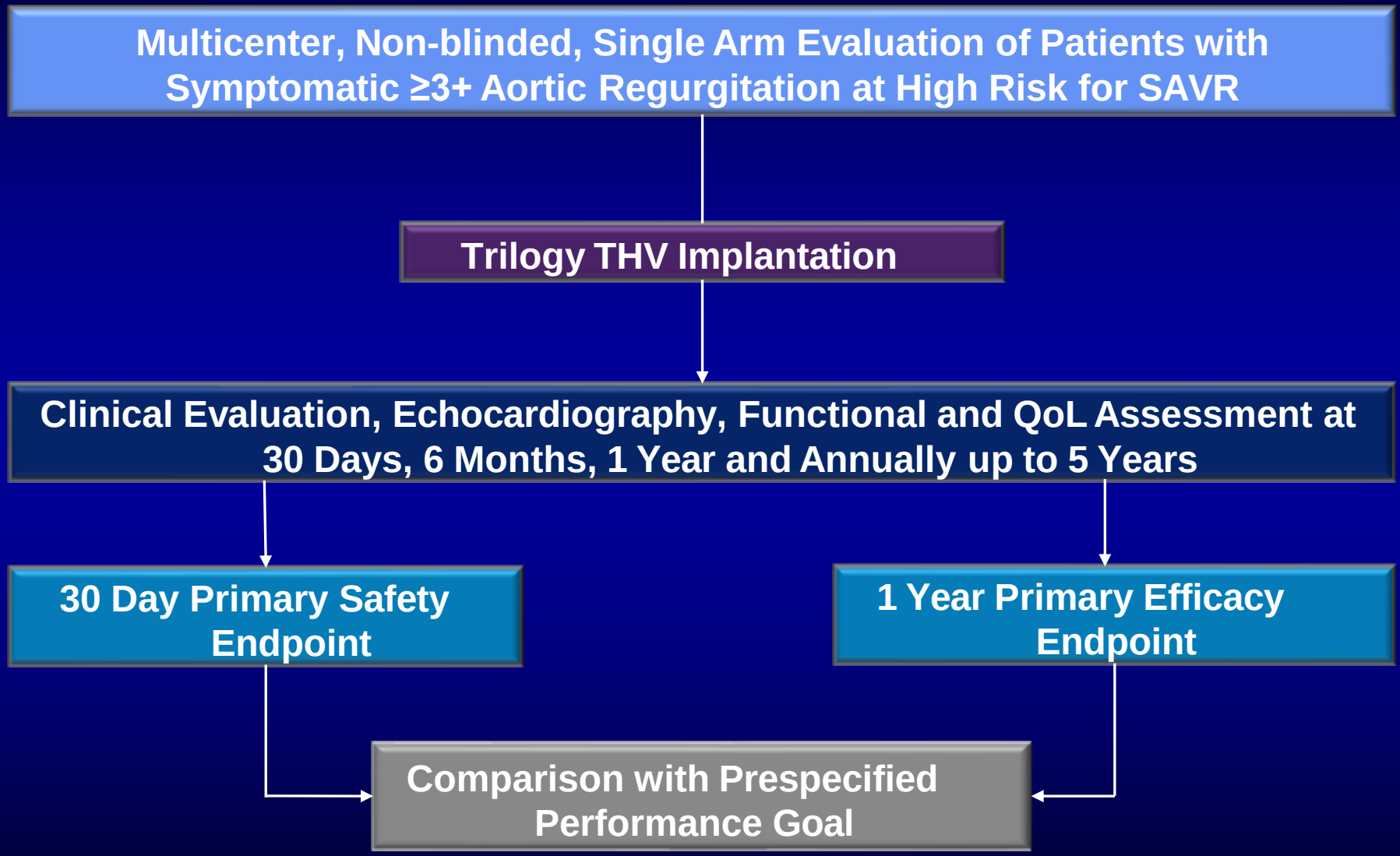
- Locators “clip” onto native leaflets forming a natural seal and stable securement



Deployment

- Large open cells provide access to low coronaries
- Flared sealing ring conforms to annulus

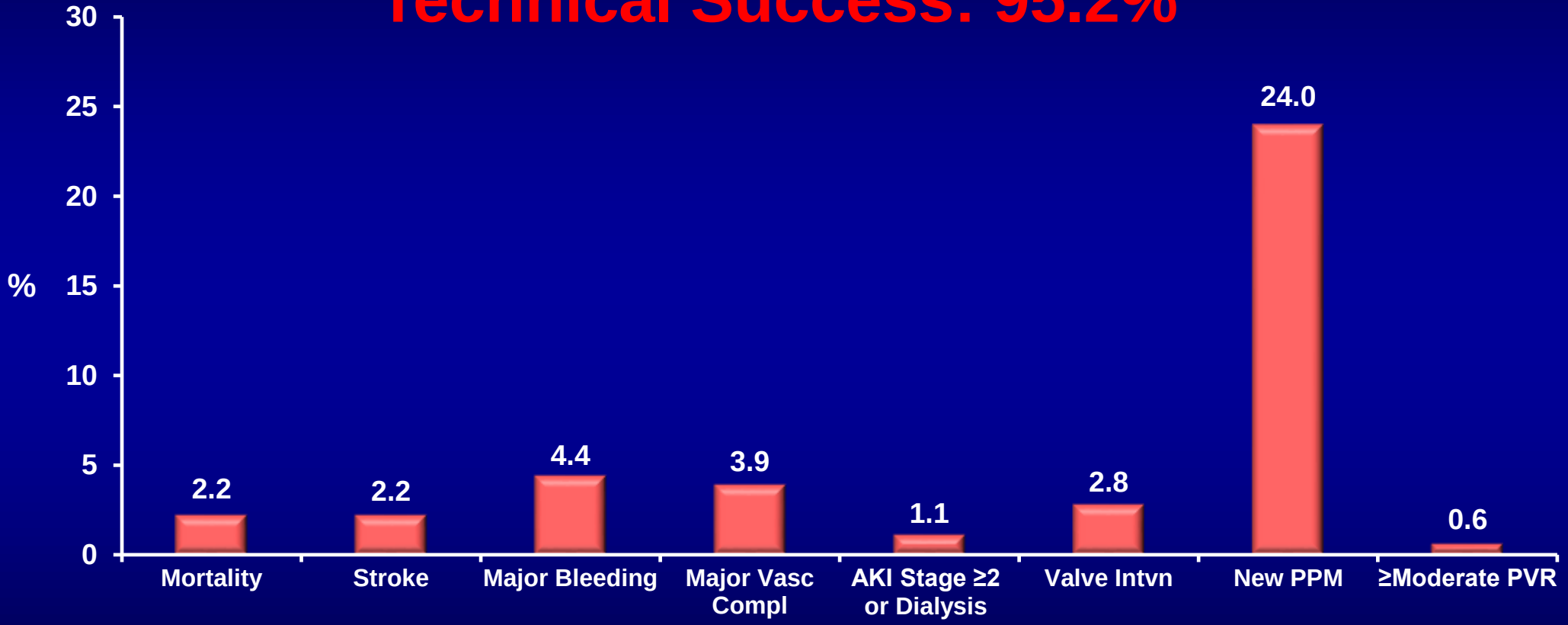
ALIGN AR Study Design



Thourani V and Torsten V, TCT 2023

ALIGN AR Trial: Primary Safety Endpoint at 30 Days (n=170)

Technical Success: 95.2%

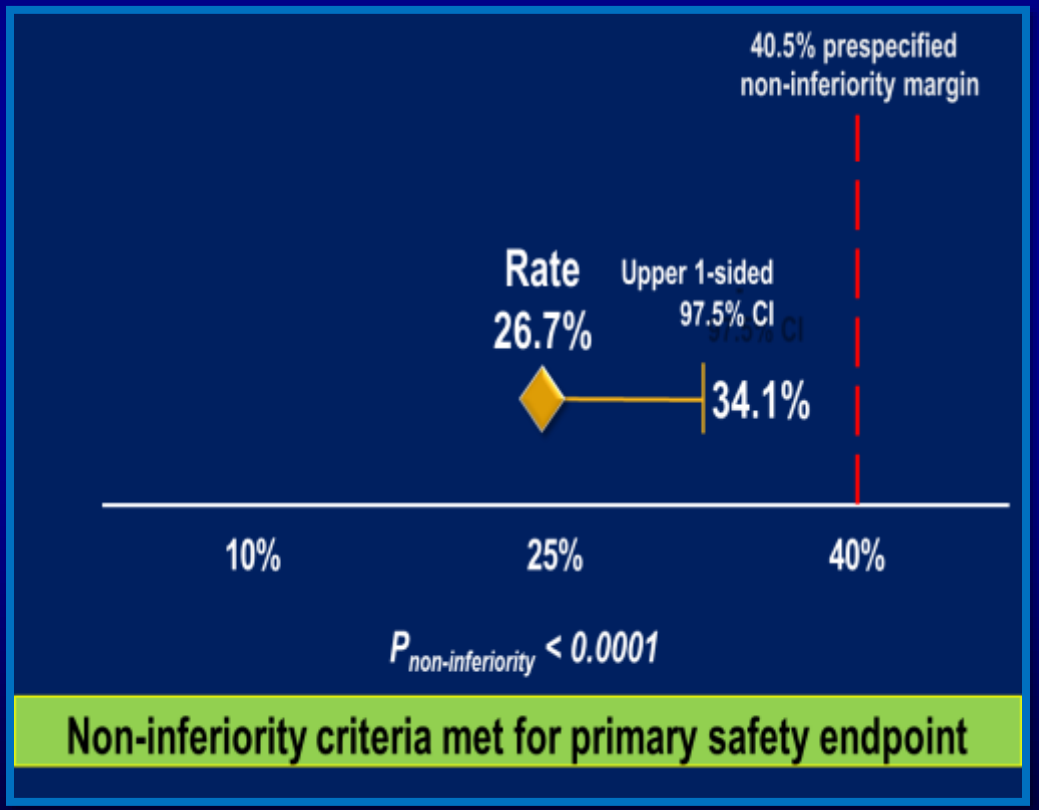


Thourani V and Torsten V, TCT 2023

ALIGN AR Trial: Primary Safety and Efficacy Endpoint

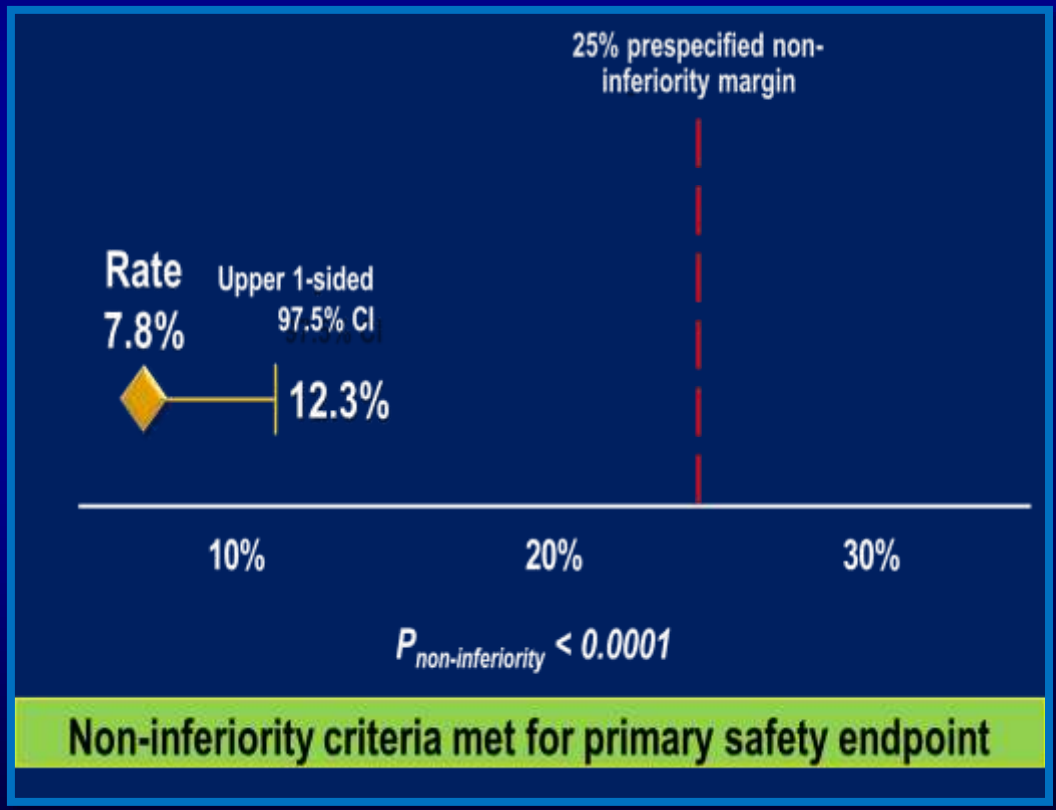
30 Days (n=170)

Composite of 30-day mortality, stroke, major bleeding, major vasc compl, AKI ≥2 or dialysis, valve intervention, PPM, ≥moderate PVR



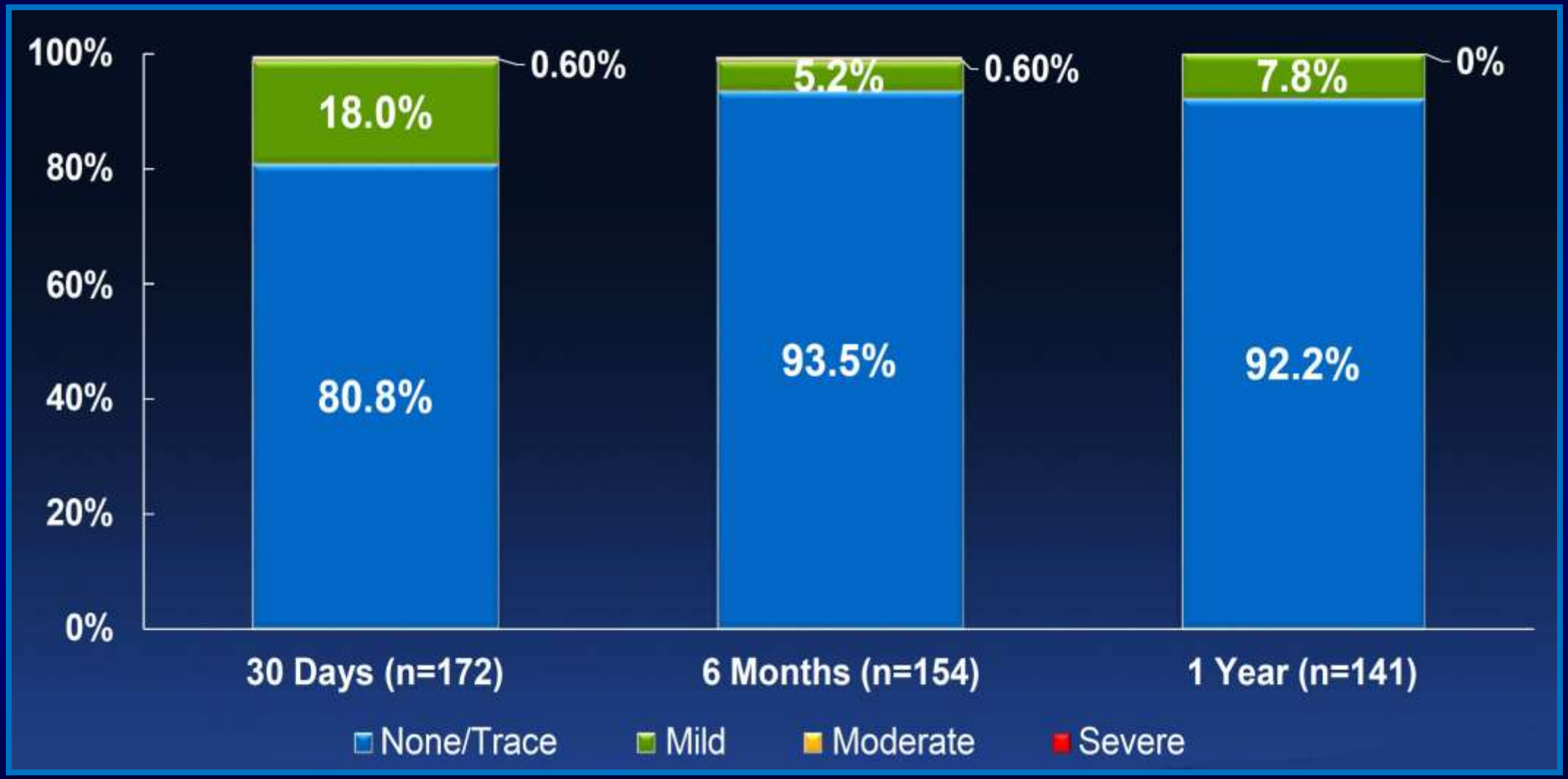
1 Year (n=151)

All-cause mortality



Thourani V and Torsten V, TCT 2023

ALIGN AR Trial: Paravalvular Regurgitation



Thourani V and Torsten V, TCT 2023

Top 10 Advances in Transcatheter Valve Therapy 2022

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8. **PCI Timings with TAVR in AS:** Revasc TAVR, Complete TAVR
9. **TAVR in Pure AR:** ALIGN AR
10. **LAAO for Afib during TAVR:** WATCH TAVR

Comparison of different percutaneous revascularisation timing strategies in patients undergoing transcatheter aortic valve implantation

REVASC-TAVI Registry

Tobias Rheude[1], MD; Giuliano Costa[2], MD; Flavio Luciano Ribichini[3], MD; Thomas Pilgrim[4], MD; Ignacio J. Amat-Santos[5], MD; Ole De Backer[6], MD; Won-Keun Kim[7], MD; Henrique Barbosa Ribeiro[8], MD; Francesco Saia[9], MD; Matjaz Bunc[10], MD; Didier Tchétché[11], MD; Philippe Garot[12], MD; Darren Mylotte[13], MD; Francesco Burzotta[14], MD; Yusuke Watanabe[15], MD; Francesco Bedogni[16], MD; Tullio Tesorio[17], MD; Marco Tocci[18], MD; Anna Franzone[19], MD; Roberto Valvo[20], MD; Mikko Savontaus[21], MD; Hendrik Wienemann[22], MD; Italo Porto[23], MD; Caterina Gandolfo[24], MD; Alessandro Iadanza[25], MD; Alessandro S. Bortone[26], MD, PhD; Markus Mach[27], MD; Azeem Latib[28], MD; Luigi Biasco[29], MD; Maurizio Taramasso[30], MD; Marco Zimarino[31], MD; Daijiro Tomii[4], MD; Philippe Nuyens[6], MD; Lars Sondergaard[32], MD, PhD; Sergio F. Camara[8], MD; Tullio Palmerini[9], MD; Mateusz Orzalkiewicz[9], MD; Klemen Steblovnik[10], MD; Bastien Degrelle[11], MD; Alexandre Gautier[12], MD; Paolo Alberto Del Sole[3], MD; Andrea Mainardi[3], MD; Michele Pighi[3], MD; Mattia Lunardi[3,13], MD, MSc; Hideyuki Kawashima[15], MD; Enrico Criscione[16], MD; Vincenzo Cesario[33], MD; Fausto Biancari[17], MD; Federico Zanin[17], MD; Giovanni Esposito[19], MD; Matti Adam[22], MD; Eberhard Grube[22], MD, PhD; Stephan Baldus[22], MD; Vincenzo De Marzo[23], MD; Elisa Piredda[23], MD; Stefano Cannata[24], MD; Fortunato Iacovelli[26], MD, PhD; Martin Andreas[27], MD, PhD; Valentina Frittitta[20], MD; Elena Dipietro[20], MD; Claudia Reddavid[20], MD; Orazio Strazzieri[20], MD; Silvia Motta[20], MD; Domenico Angellotti[19], MD; Carmelo Sgroi[2], MD; Erion Xhepa[1], MD; Faraj Kargoli[28], MD; Corrado Tamburino[2], MD, PhD; Michael Joner[1*], MD; Marco Barbanti[2,34], MD

EuroIntervention 2023;19-online publish-ahead-of-print July 2023

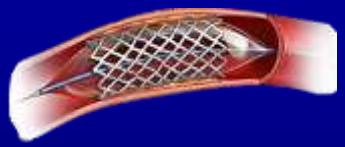
REVASC-TAVI Trial: Study Design

Patients undergoing TAVI with significant, stable CAD at baseline (n=2402)

No follow-up data available (n=231)

No data about the completeness of myocardial revascularization (n=146)

Patients with available data about baseline CAD and PCI performed (n=2025)



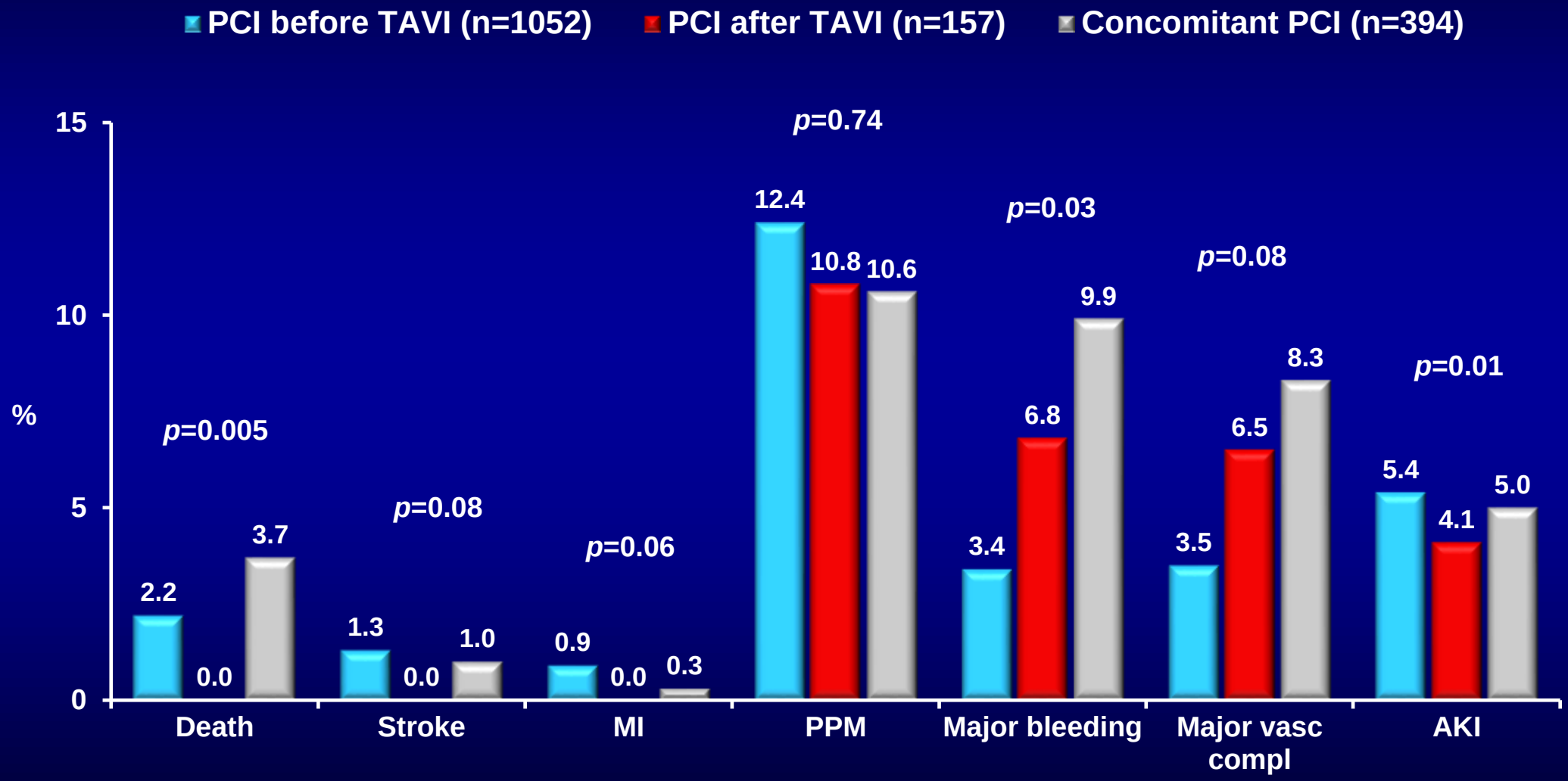
Complete revascularization (n=1310)

Incomplete revascularization (n=715)

675 pairs of patients compared through 1:1 PS matching

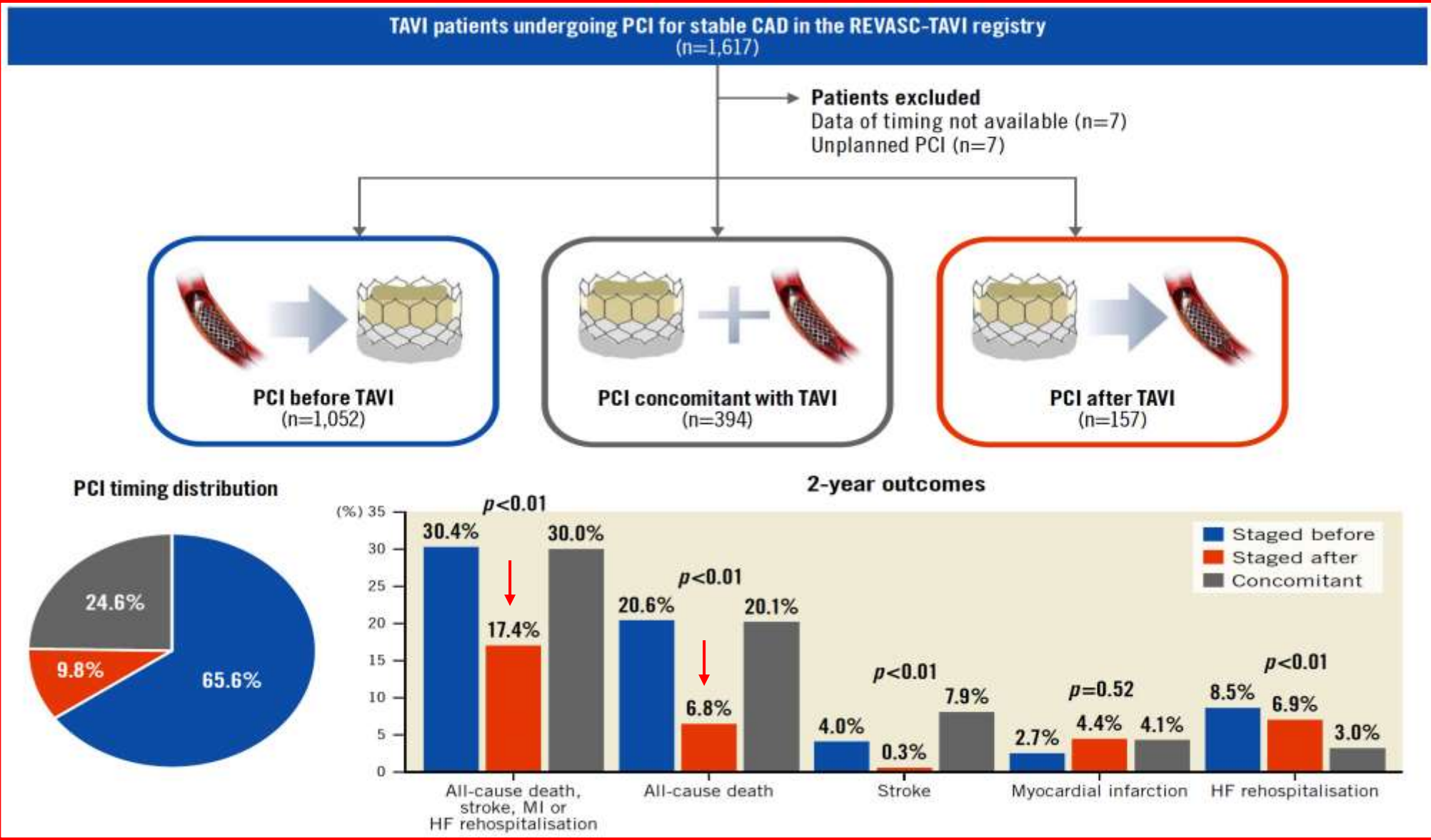
Costa G, EuroPCR 2022

REVASC-TAVI Registry: Procedural In-Hospital Outcomes After IPTW Analysis



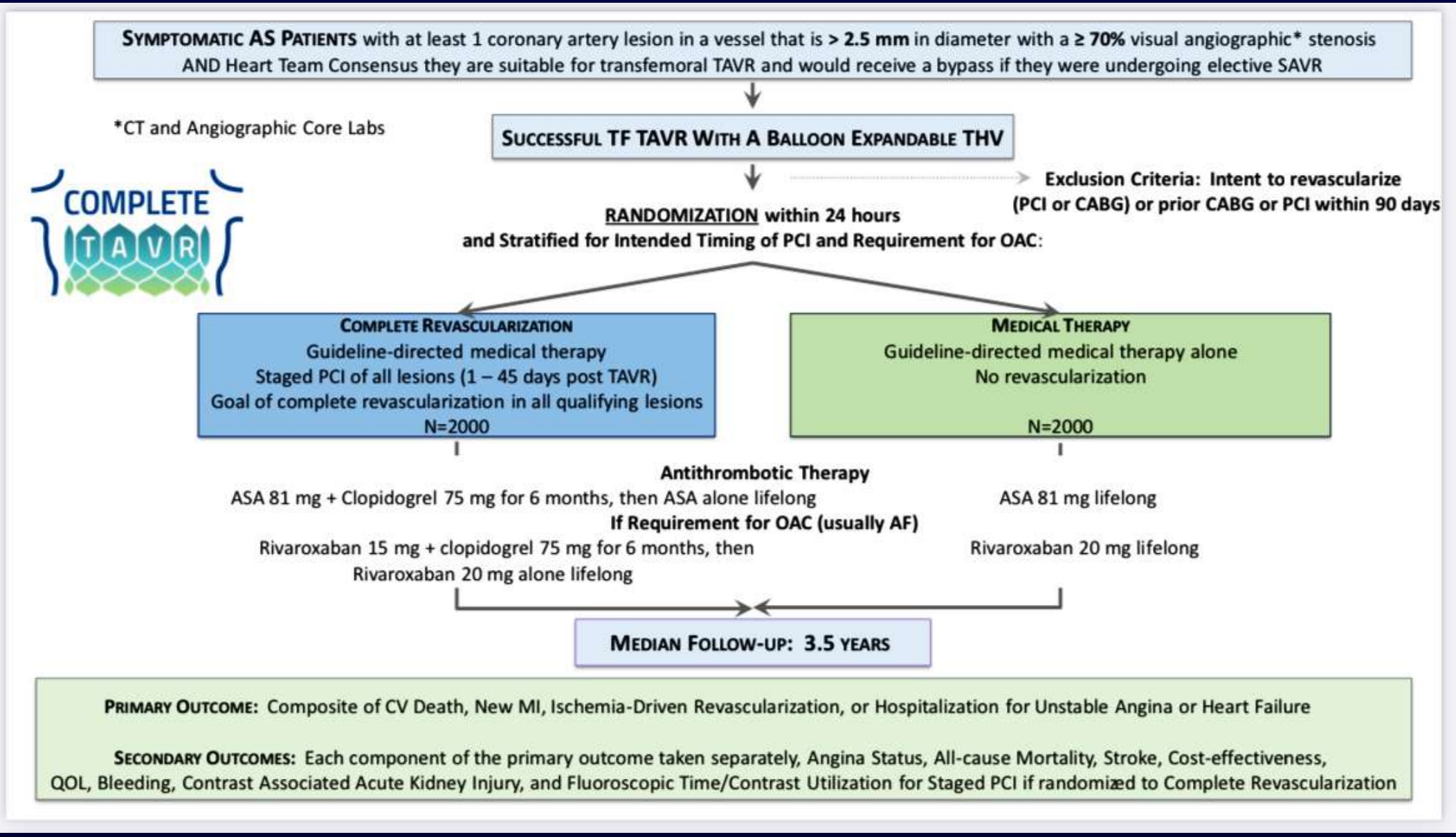
Rheude et al., EuroIntervention 2023 July 19, Epub ahead of print

Outcomes of Pts Undergoing TAVI and PCI for Stable CAD From the International, Multicenter REVASC-TAVI Registry



Rheude et al., EuroIntervention 2023 July 19, Epub ahead of print

COMPLETE TAVR Study Design



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8. **PCI Timings with TAVR in AS:** Revasc TAVR, Complete TAVR
9. **TAVR in Pure AR:** ALIGN AR
10. **LAAO for Afib during TAVR:** WATCH TAVR

Circulation

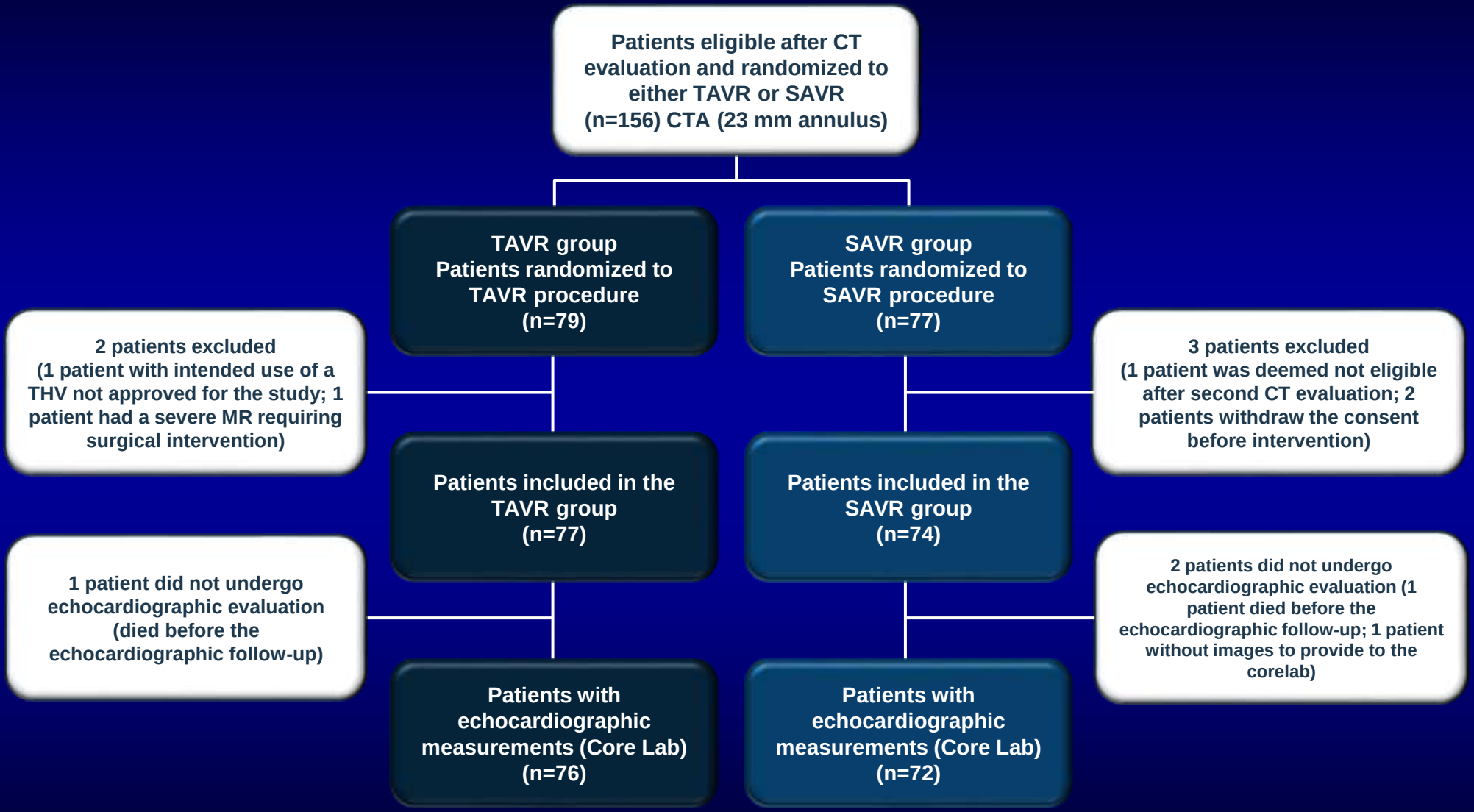
CIRCULATION. 2023; [PUBLISHED ONLINE AHEAD OF PRINT]. DOI:10.1161/CIRCULATIONAHA.123.067326

TRANSCATHETER OR SURGICAL AORTIC VALVE REPLACEMENT IN PATIENTS WITH SEVERE AORTIC STENOSIS AND SMALL AORTIC ANNULUS: A RANDOMIZED CLINICAL TRIAL

JOSEP RODÉS-CABAU, MD, PHD; HENRIQUE RIBEIRO, MD, PHD; SIAMAK MOHAMMADI, MD; VICENÇ SERRA, MD; TALAL AL-ATASSI, MD; ANDRES INIGUEZ, MD; VICTORIA VILALTA, MD, PHD; LUIS NOMBELA-FRANCO, MD, PHD; JOSE IGNACIO SAEZ DE IBARRA, MD; VINCENT AUFFRET, MD, PHD; JESSICA FORCILLO, MD; LENARD CONRADI, MD; MARINA URENA, MD, PHD; CESAR MORIS, MD, PHD; ANTONIO MUÑOZ-GARCIA, MD, PHD; JEAN-MICHEL PARADIS, MD; ERIC DUMONT, MD; DIMITRI KALAVROUZIOTIS, MD; PABLO MARIA POMERANTZEFF, MD, PHD; VITOR EMER EGYPTO ROSA, MD, PHD; MARIANA PEZZUTE LOPES, MD; CARLOS SUREDA, MD; VICTOR ALFONSO JIMENEZ DIAZ, MD; CARLOS GIULIANI, MD; MARISA AVVEDIMENTO, MD; EMILIE PELLETIER-BEAUMONT, MSC; PHILIPPE PIBAROT, PHD ON BEHALF OF THE VIVA TRIAL

INVESTIGATORSHTTPS://WWW.AHAJOURNALS.ORG/DOI/10.1161/CIRCULATIONAHA.123.067326)

VIVA Trial Study Population Flowchart



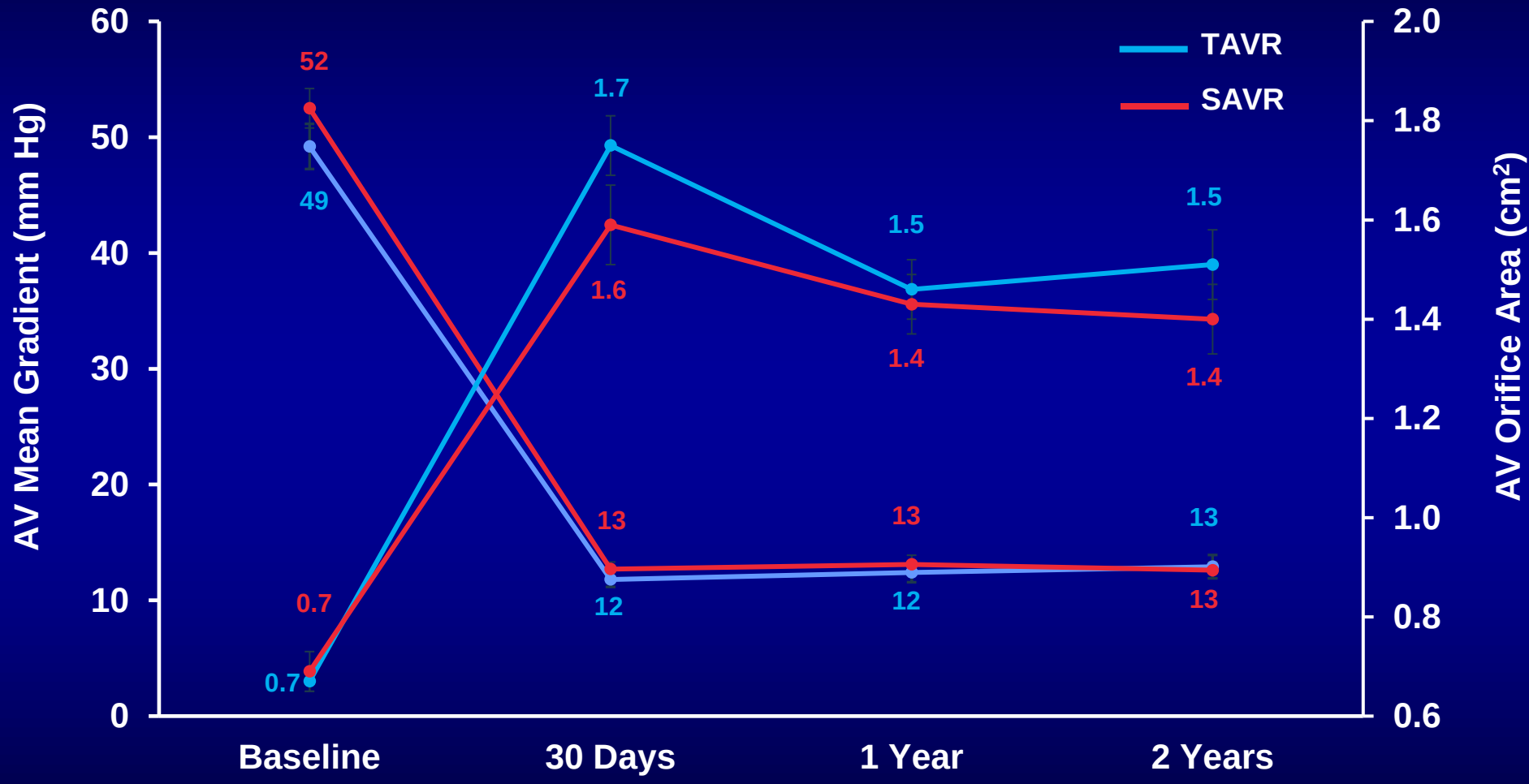
Rodés-Cabau J, TCT 2023

VIVA Trial: Valve Performance at 60 Days

	TAVR n=76	SAVR N=72	Difference TAVR-SAVR (95%CI)	P value
LVEF, %	61±6	61±8	0.30 (-2.27 to 2.87)	0.82
Mean aortic gradient, mmHg	11±5	11±5	0.31 (-1.29 to 1.91)	0.70
Mean gradient >20 mmHg	4 (5.3%)	7 (9.7%)	-4.46 (-13.85 to 3.93)	0.30
Maximal aortic gradient, mmHg	22±9	21±9	0.66 (-2.24 to 3.56)	0.65
Effective orifice area, cm^2	1.63±0.40	1.65±0.45	-0.02 (-0.16 to 0.12)	0.79
Effective orifice area indexed, cm^2/m^2	0.99±0.28	0.98±0.27	0.01 (-0.08 to 0.11)	0.76
Velocity ratio	0.50±0.11	0.50±0.11	0.00 (-0.03 to 0.04)	0.81
Severe PPM or moderate-severe AR (Primary Outcome)	4/72 (5.6%)	7/68 (10.3%)	-4.74 (-13.69 to 4.21)	0.30
Aortic regurgitation*			-	0.48
None-trace	62/75 (82.7%)	59/68 (86.8%)		
Mild	13/75 (17.3%)	9/68 (13.2%)		
Moderate/Severe	0/75 (0%)	0/68 (0%)		
PPM (severe) VARC-2**	4/72 (5.6%)	7/68 (10.3%)	-4.74 (-13.69 to 4.21)	0.30
PPM (severe) VARC-3**	3/72 (4.2%)	5/68 (7.4%)	-3.19 (-10.29 to 4.55)	0.49

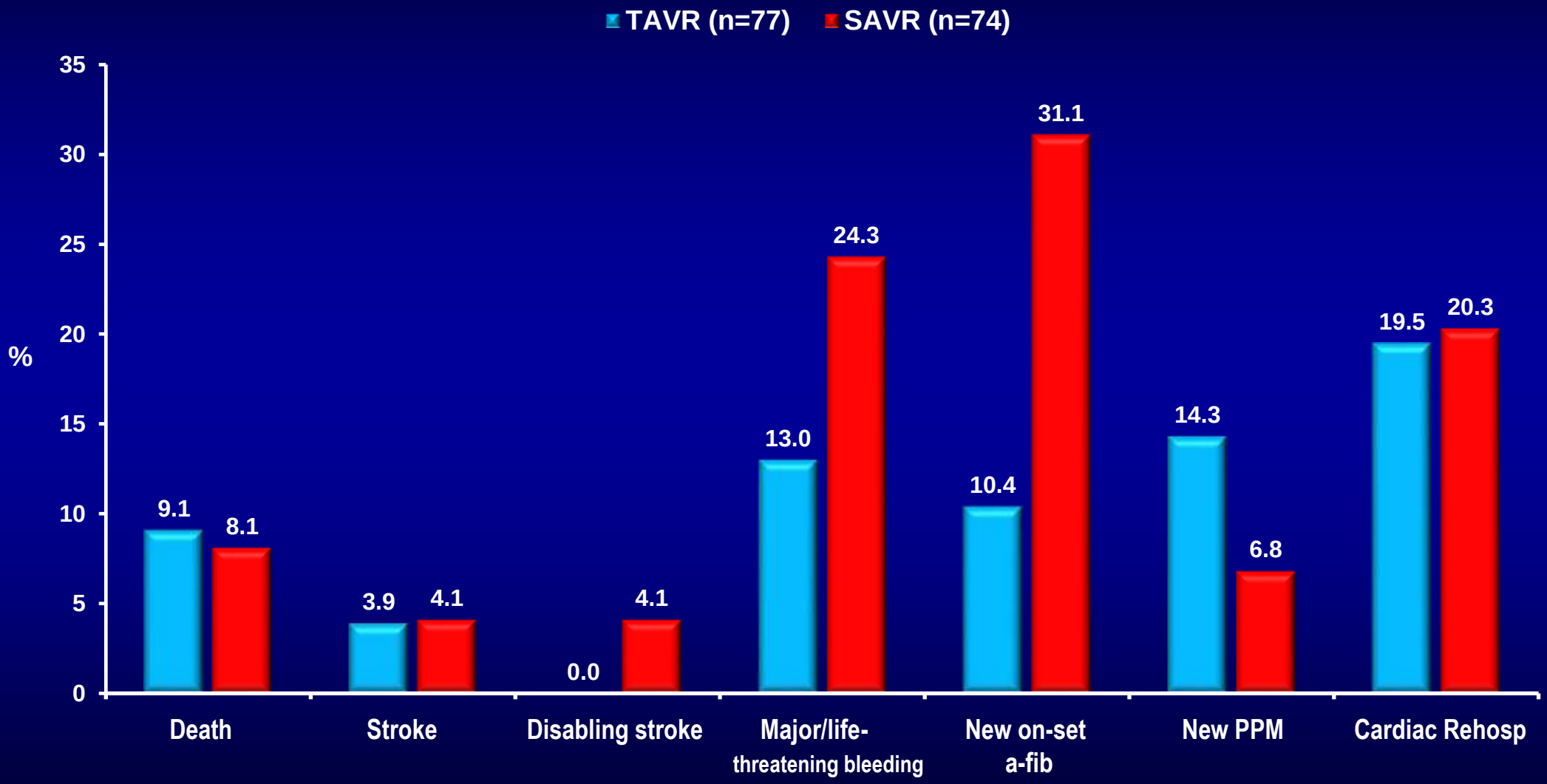
Rodés-Cabau J, TCT 2023

VIVA Trial: Valve Hemodynamics Over Time



Rodés-Cabau J, TCT 2023

VIVA Trial: Follow-Up Outcomes
(median: 2 [1-4] years)



Rodés-Cabau J, TCT 2023

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 4, 2023

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NEW RESEARCH PAPER

STRUCTURAL

5-Year Outcomes With Self-Expanding vs Balloon-Expandable Transcatheter Aortic Valve Replacement in Patients With Small Annuli

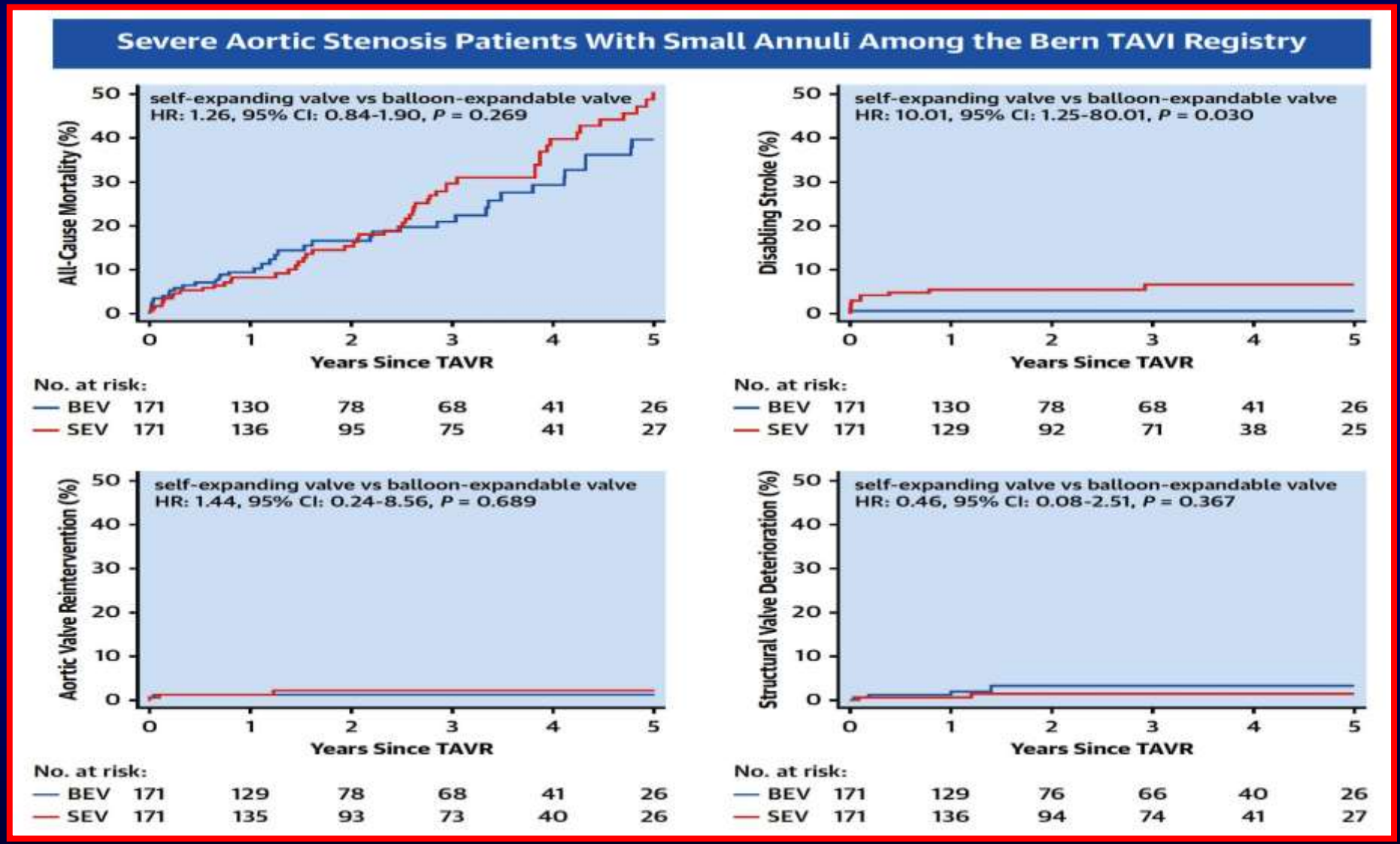
Taishi Okuno, MD,[a] Daijiro Tomii, MD,[a] Jonas Lanz, MD, MSc,[a] Dik Heg, PhD,[b] Fabien Praz, MD,[a] Stefan Stortecky, MD, MPH,[a] David Reineke, MD,[c] Stephan Windecker, MD,[a] Thomas Pilgrim, MD, MSc[a]

Swiss TAVI Registry: Procedural Characteristics and Complications in the Matched Population

Matched Cohort	SEV (n = 171)	BEV (n = 171)	*P* Value
Type of valve			Exact matching
Old generation (SAPIEN XT, CoreValve)	11 (6.4)	11 (6.4)	
Newer generation (SAPIEN 3/3Ultra, Evolut R/PRO/PRO+)	160 (93.6)	160 (93.6)	
Predilation	80 (46.8)	84 (49.1)	0.745
Postdilation	55 (32.2)	34 (19.9)	0.013
Procedural complications			
Valve in series	1 (0.6)	4 (2.3)	0.371
Valve dislocation/embolization	2 (1.2)	4 (2.3)	0.685
Conversion to SAVR	0 (0.0)	2 (1.2)	0.499
Annulus rupture/aortic dissection	0 (0.0)	2 (1.2)	0.499
Coronary artery occlusion	1 (0.6)	1 (0.6)	>0.999
Major vascular complication	18 (10.5)	14 (8.2)	0.578
Technical success	149 (87.1)	150 (87.7)	>0.999
Echocardiographic assessment (discharge)			
Aortic valve area, mm	1.81 ± 0.46	1.49 ± 0.42	<0.001
Transvalvular mean gradient, mm Hg	8.0 ± 4.8	12.5 ± 4.5	<0.001
Transvalvular mean gradient ≥20, mm Hg	5 (2.9)	12 (7.1)	0.087
Paravalvular regurgitation	(n = 171)	(n = 171)	0.015
None/trace	74 (43.3)	98 (57.3)	
Mild	90 (52.6)	71 (41.5)	
Moderate	7 (4.1)	2 (1.2)	
Prosthesis-patient mismatch	(n = 140)	(n = 141)	<0.001
Insignificant	111 (79.3)	68 (48.2)	
Moderate	24 (17.1)	56 (39.7)	
Severe	5 (3.6)	17 (12.1)	
"Predicted" prosthesis-patient mismatch	(n = 171)	(n = 170)	<0.001
Insignificant	161 (94.2)	110 (64.7)	
Moderate	10 (5.8)	60 (35.3)	
Severe	0 (0.0)	0 (0.0)	

Okuno et al., J Am Coll Cardiol Intv 2023;16:429

Swiss TAVI Registry: 5-Yr Clinical Outcomes Between Self-Expanding THVs vs Balloon-Expandable THVs in Pts with Small Annuli



Okuno et al., J Am Coll Cardiol Intv 2023;16:429

SMART Trial: Trial Design

Subjects with severe native aortic valve stenosis with a small annulus (≤430 mm² by MDCT)

Randomization
1:1 Stratified by Site and Sex

Medtronic
Evolut PRO/PRO+/FX

Approximately **700** randomized subjects at approximately **90 sites** in Canada, EMEA and the U.S.

Edwards
SAPIEN 3/SAPIEN 3 Ultra

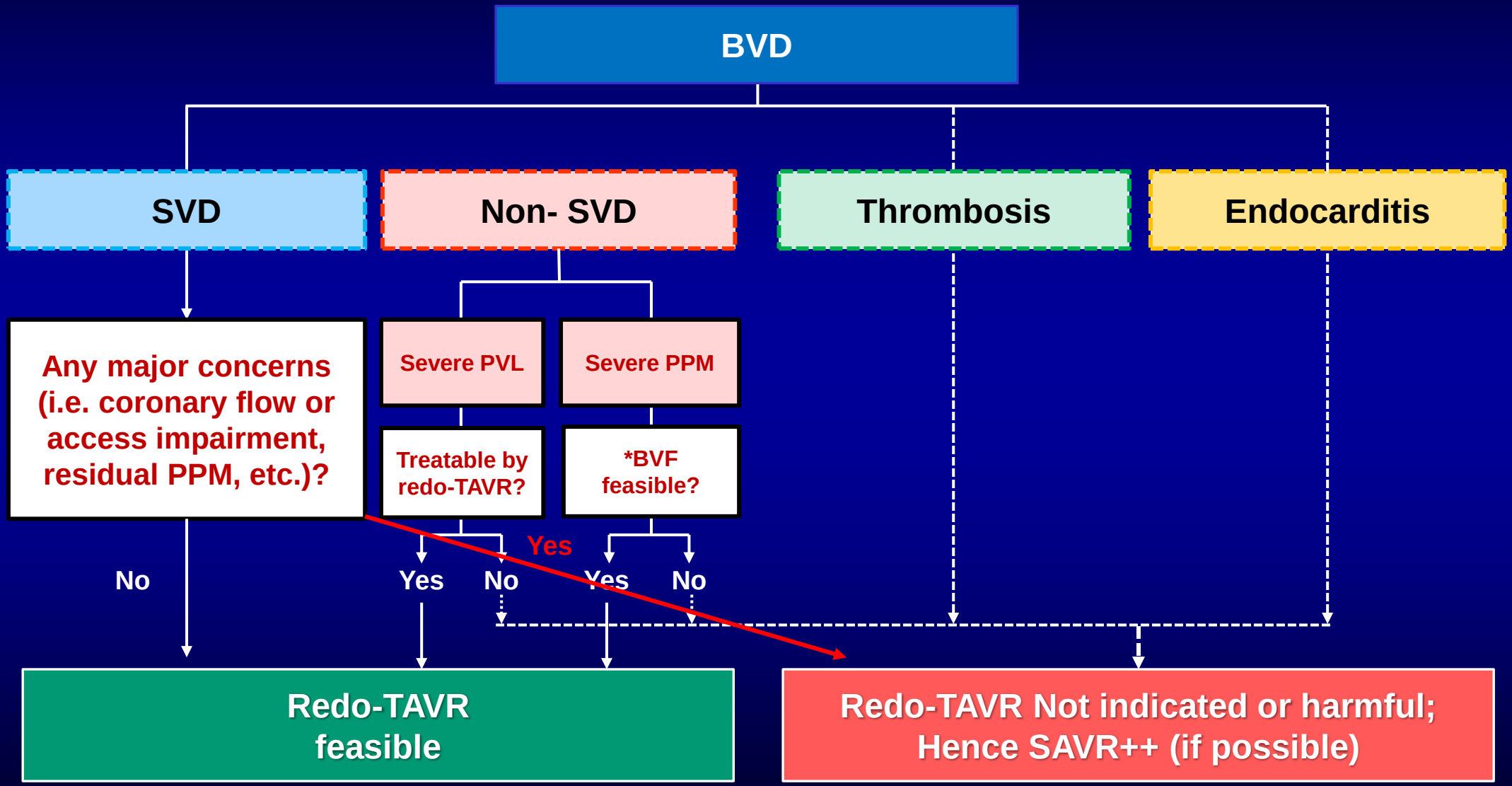
30-Day and annual follow-ups through 5 years for all subjects

Primary Endpoints: - Mortality, disabling stroke or HF rehospitalization at 12 months (non-inferiority)
- Bioprosthetic valve dysfunction (BVD) at 12 months (superiority)

Top 10 Advances in Transcatheter Valve Therapy 2022

1.
2.
3.
4.
5.
6. **TAV or SAV Degeneration:** ViV TAVR, TAV-in-TAV, TAVR Explant
7. **TAVR vs SAVR in Small Annulus AS:** VIVA, SWISS TAVI, SMART
8. **PCI Timings with TAVR in AS:** Revasc TAVR, Complete TAVR
9. **TAVR in Pure AR:** ALIGN AR
10. **LAAO for Afib during TAVR:** WATCH TAVR

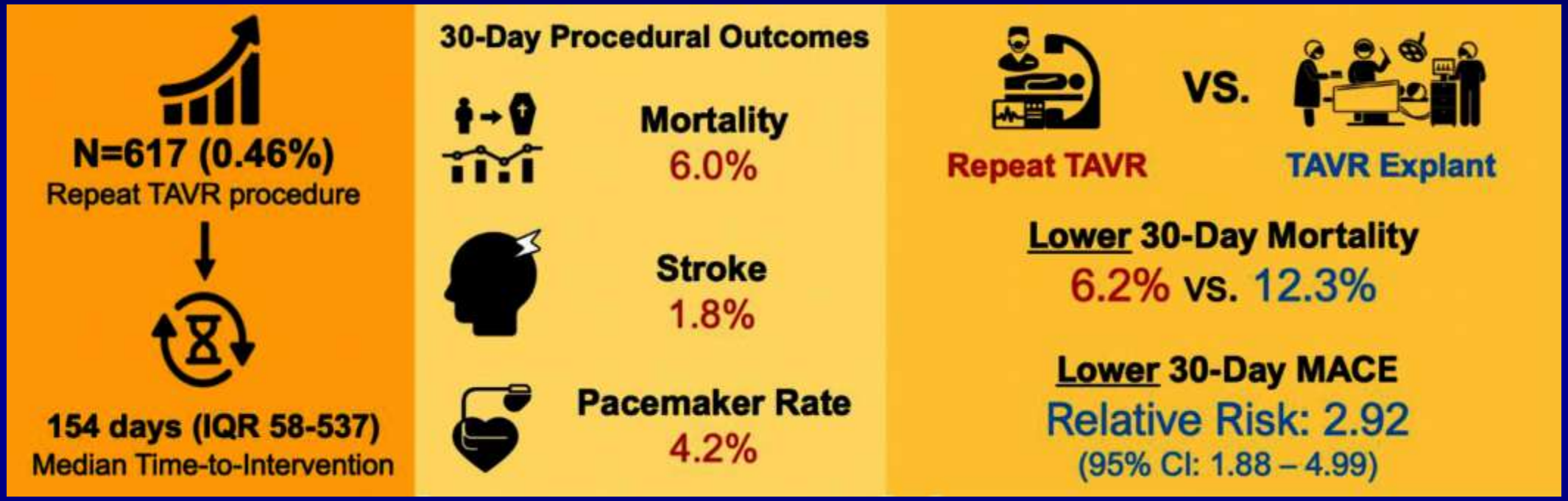
Therapeutic Algorithm for Bioprosthetic Aortic Valve Dysfunction



Tarantini et al., J Am Coll Cardiol Intv 2022;15:1777

TAV-in-TAV vs TAVR Explant-CMS

Contemporary Repeat TAVR Outcomes in the United States



Repeat TAVR **can be performed with acceptable 30-day mortality and may be considered as a potential option in appropriate patients**

Percy et al., J Am Coll Cardiol Intv 2021;14:1717

THE LANCET

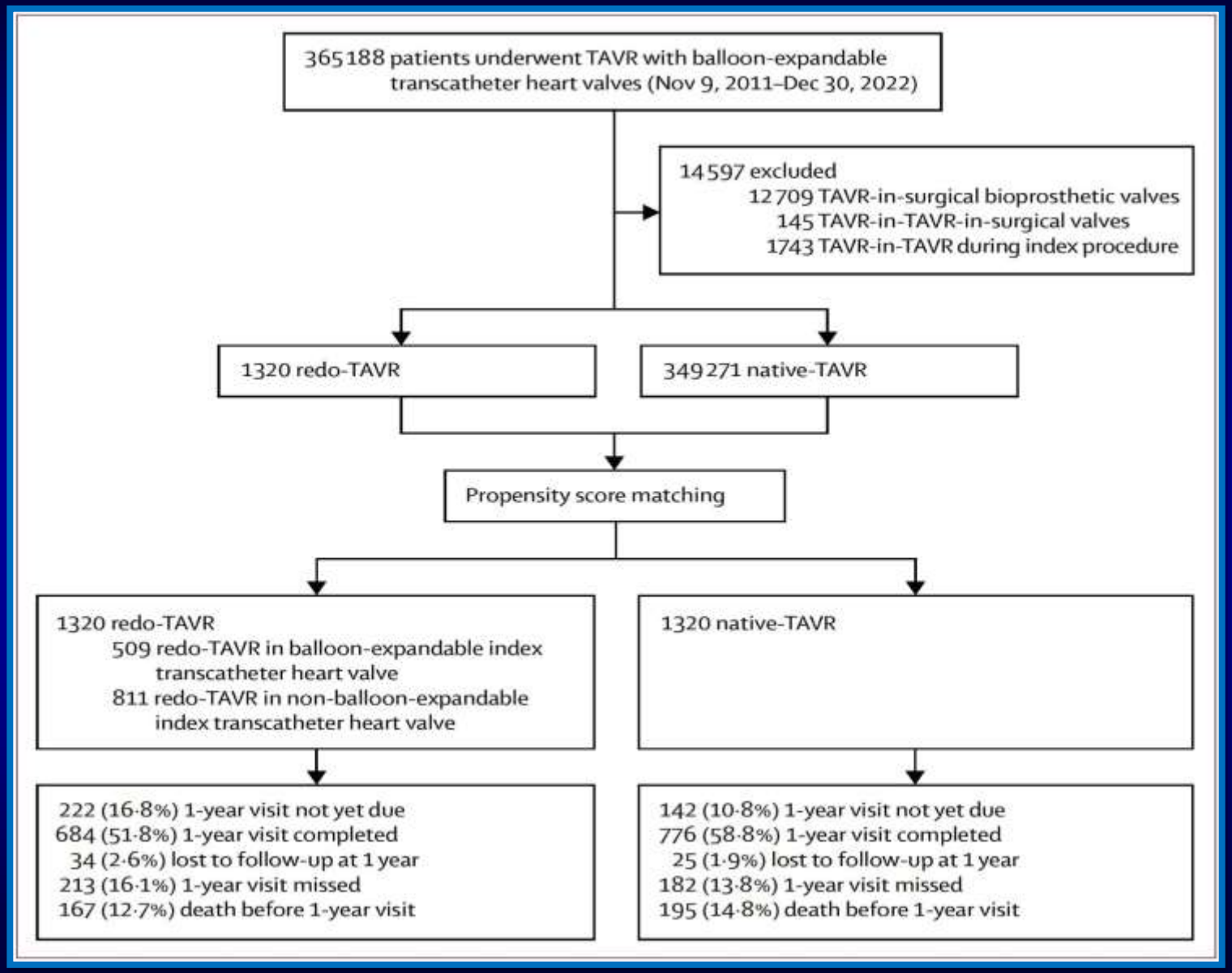
Articles

Lancet 2023; 402: 1529–40

Outcomes of repeat transcatheter aortic valve replacement with balloon-expandable valves: a registry study

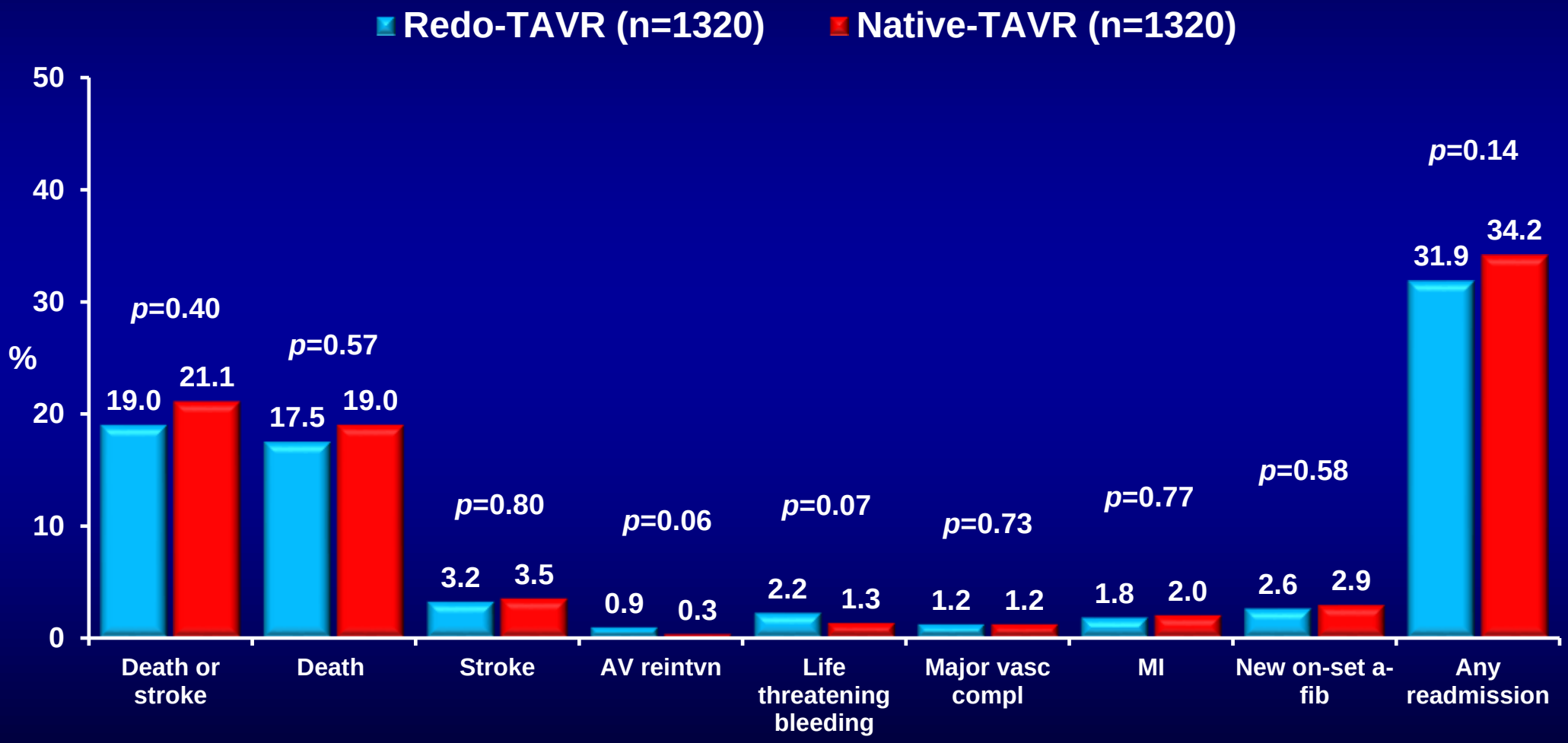
Raj R Makkar, Samir Kapadia, Tarun Chakravarty, Robert J Cubeddu, Tsuyoshi Kaneko, Paul Mahoney, Dhairya Patel, Aakriti Gupta, Wen Cheng, Susheel Kodali, Deepak L Bhatt, Michael J Mack, Martin B Leon, Vinod H Thourani

Redo-TAVR Study Profile



Makkar et al., Lancet 2023;402:1529

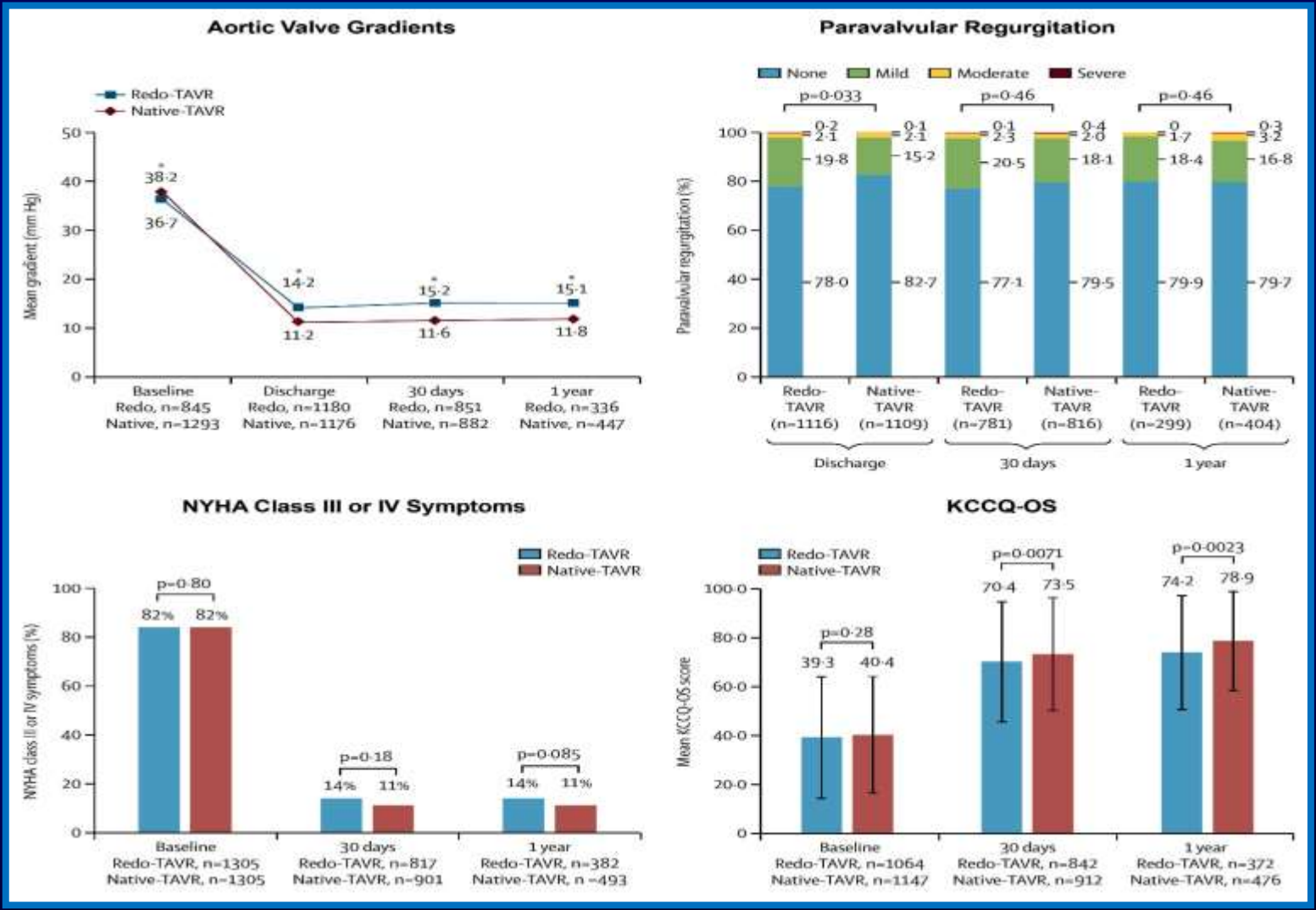
Redo-TAVR Study: 1-Year Outcomes in Propensity Score-Matched Pts Who Underwent Redo-TAVR or Native TAVR



Makkar et al., Lancet 2023;402:1529

Redo-TAVR Study: Echo and Functional Outcomes in Propensity Score-Matched Pts Who Underwent Redo-TAVR or Native TAVR

***Redo-TAVR vs Native TAVR statistically significant, p<0.05**



Makkar et al., Lancet 2023;402:1529

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 8, 2023

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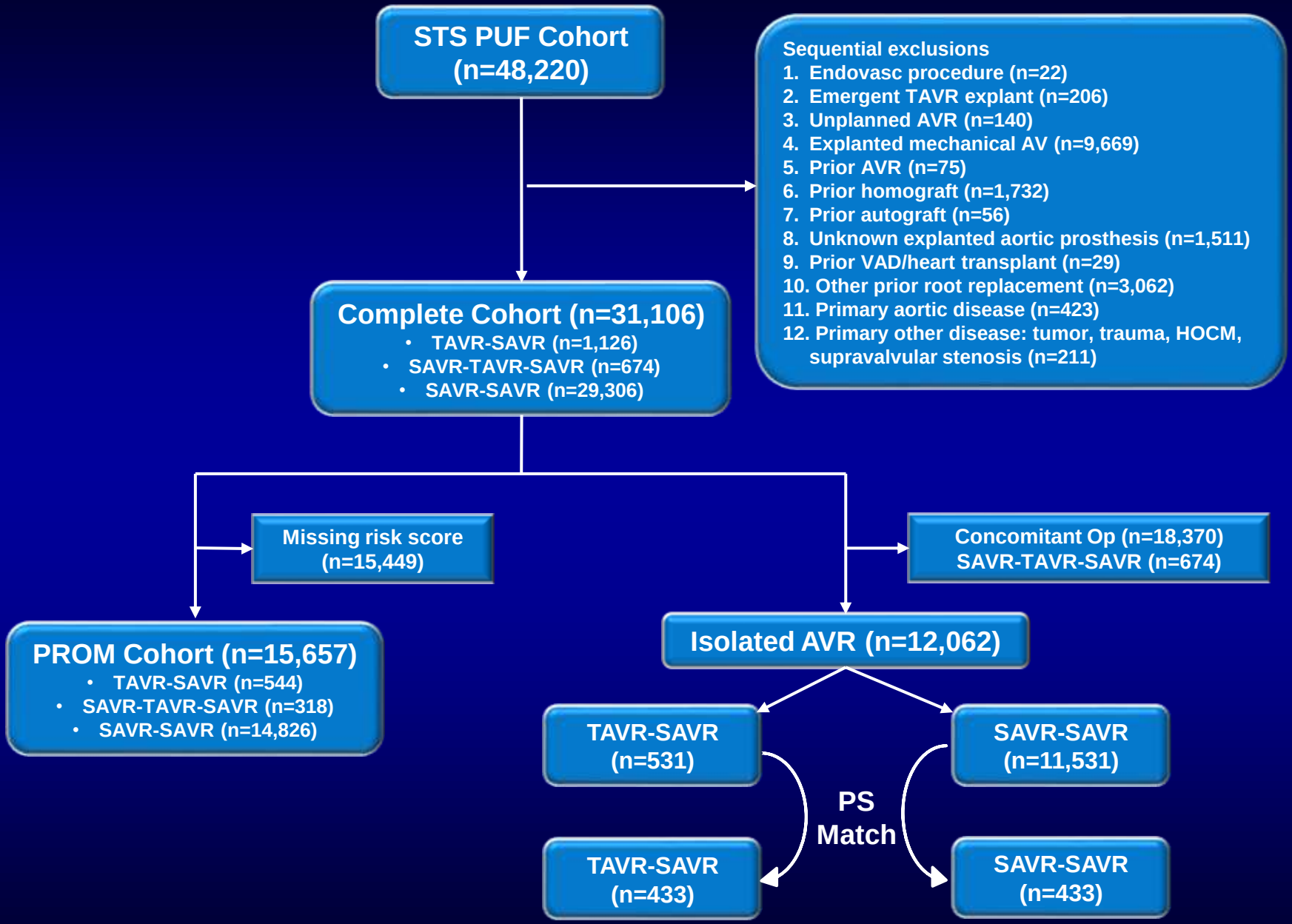
NEW RESEARCH PAPER

STRUCTURAL

Redo Surgical Aortic Valve Replacement After Prior Transcatheter Versus Surgical Aortic Valve Replacement

Robert B. Hawkins, MD, MSc,[a,b] G. Michael Deeb, MD,[a,b] Devraj Sukul, MD, MSc,[a,b] Himanshu J. Patel, MD,[a,b] Sarah K. Gualano, MD,[a,b] Stanley J. Chetcuti, MD,[a,b] P. Michael Grossman, MD,[a,b] Gorav Ailawadi, MD, MBA,[a,b] Shinichi Fukuhara, MD[a,b]

Redo of SAVR After Prior TAVR or SAVR: Consort Diagram



Hawkins et al., J Am Coll Cardiol Intv 2023;16:942

Redo of SAVR After Prior TAVR or SAVR: Short-Term Outcomes for All Pts with Prior SAVR and/or Prior TAVR

	TAVR-SAVR (n=1,126)	SAVR-TAVR-SAVR (n=674)	SAVR-SAVR (n=29,306)	*P* value
Operative mortality	17%	12%	9%	<0.001
Major morbidity	37%	31%	28%	<0.001
Stroke	5%	3%	3%	<0.001
Acute renal failure	12%	11%	7%	<0.001
New Dialysis	10%	9%	5.7%	<0.001
Reoperation	9%	9%	8%	0.083
Prolonged ventilation	32%	28%	24%	<0.001
Transfusion	88%	88%	82%	<0.001
Hours intubated	13 (5-42)	12 (5-37)	10 (5-23)	<0.001
ICU LOS, h	95 (48-169)	77 (45-159)	69 (39-125)	<0.001
Preoperative LOS, d	3 (0-8)	2 (0-8)	0 (0-5)	<0.001
Postoperative LOS, d	9 (7-15)	9 (6-14)	8 (6-12)	<0.001
Discharge to home	51%	63%	73%	<0.001
Readmission	17%	15%	12%	<0.001

Hawkins et al., J Am Coll Cardiol Intv 2023;16:942

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 8, 2023

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NEW RESEARCH PAPER

STRUCTURAL

Redo Surgical Aortic Valve Replacement After Prior Transcatheter Versus Surgical Aortic Valve Replacement

CONCLUSIONS The number of post-TAVR reoperations is increasing and represent a high-risk population. Yet even in isolated SAVR cases, SAVR after TAVR is independently associated with increased risk of mortality. Patients with life expectancy beyond a TAVR valve and unsuitable anatomy for redo-TAVR should consider a SAVR-first approach.
(J Am Coll Cardiol Intv 2023;16:942-953)

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 8, 2023

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NEW RESEARCH PAPER

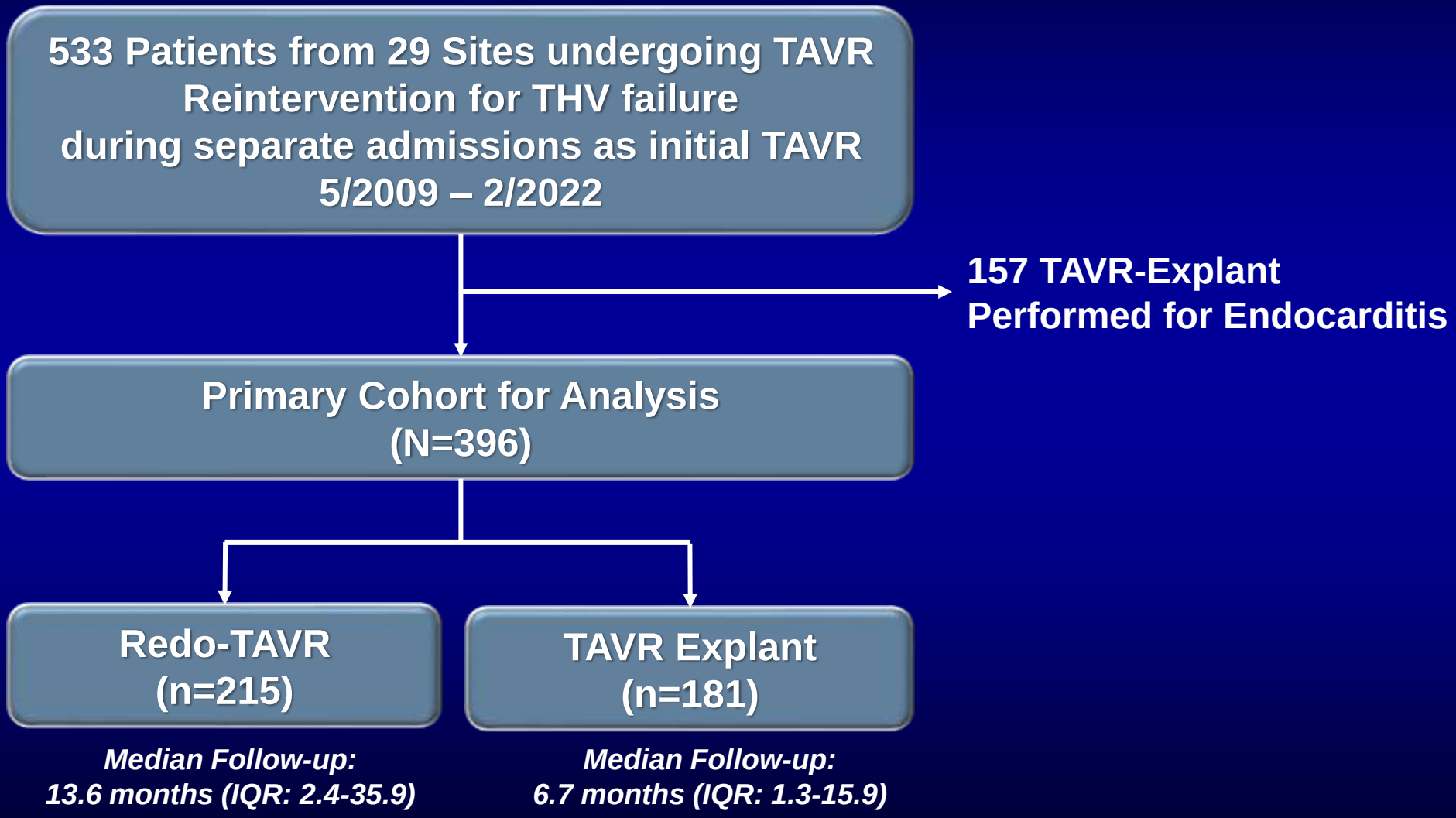
STRUCTURAL

Explant vs Redo-TAVR After Transcatheter Valve Failure

Mid-Term Outcomes From the EXPLANTORREDO-TAVR International Registry

Gilbert H.L. Tang, MD, MSc, MBA,[a,*] Syed Zaid, MD,[b,*] Neal S. Kleiman, MD,[b] Sachin S. Goel, MD,[b] Shinichi Fukuhara, MD,[c] Mateo Marin-Cuartas, MD,[d] Philipp Kiefer, MD,[d] Mohamed Abdel-Wahab, MD,[d] Ole De Backer, MD,[e] Lars Søndergaard, MD,[e] Shekhar Saha, MD,[f] Christian Hagl, MD,[g] Moritz Wyler von Ballmoos, MD, PhD, MPH,[b] Oliver Bhadra, MD,[h] Lenard Conradi, MD,[h] Kendra J. Grubb, MD, MHA,[i] Emily Shih, MD,[j] J. Michael DiMaio, MD,[j] Molly Szerlip, MD,[j] Keti Vitanova, MD,[k] Hendrik Ruge, MD,[k] Axel Unbehaun, MD,[l] Jorg Kempfert, MD, PhD,[l] Luigi Pirelli, MD,[m] Chad A. Kliger, MD,[m] Nicholas Van Mieghem, MD, PhD,[n] Thijmen W. Hokken, MD,[n] Rik Adrichem, MD,[n] Thomas Modine, MD, PhD, MBA,[o] Silvia Corona, MD,[o] Lin Wang, MD,[p] George Petrossian, MD,[p] Newell Robinson, MD,[p] David Meier, MD,[q] John G. Webb, MD,[q] Anson Cheung, MD,[q] Basel Ramlawi, MD,[r] Howard C. Herrmann, MD,[s] Nimesh D. Desai, MD, PhD,[s] Martin Andreas, MD, PhD,[t] Markus Mach, MD,[t] Ron Waksman, MD,[u] Christian C. Schults, MD,[u] Hasan Ahmad, MD,[v] Joshua B. Goldberg, MD,[v] Arnar Geirsson, MD,[w] John K. Forrest, MD,[w] Paolo Denti, MD,[x] Igor Belluschi, MD,[x] Walid Ben-Ali, MD, PhD,[y] Anita W. Asgar, MD,[y] Maurizio Taramasso, MD, PhD,[z] Joshua D. Rovin, MD,[aa] Marco Di Eusanio, MD,[bb] Andrea Colli, MD,[cc] Tsuyoshi Kaneko, MD,[dd] Tamim N. Nazif, MD,[ee] Martin B. Leon, MD,[ee] Vinayak N. Bapat, MBBS, MS, MCh,[ff] Michael J. Mack, MD,[j] Michael J. Reardon, MD,[b] Janarthanan Sathananthan, MBChB, MPH[q]

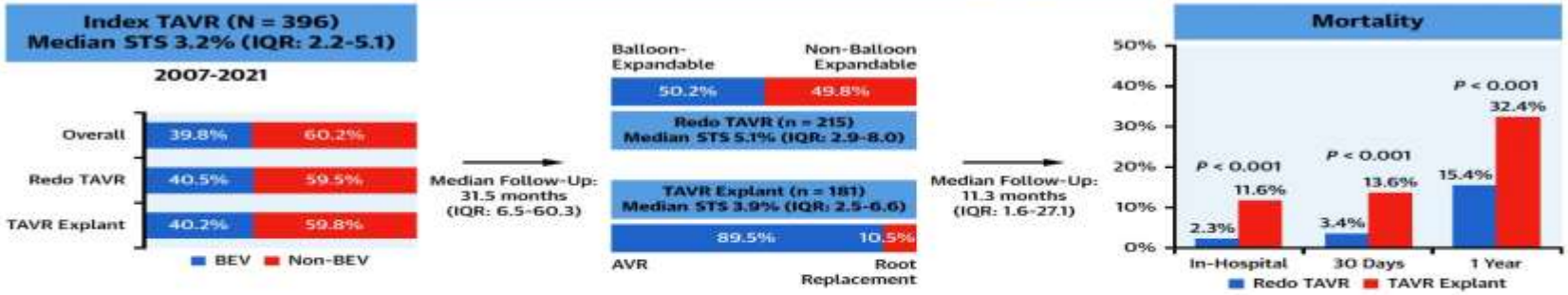
EXPLANTORREDO-TAVR Registry: Study Population



Tang et al., J Am Coll Cardiol Intv 2023;16:927

Summary of the EXPLANTORREDO-TAVR International Registry

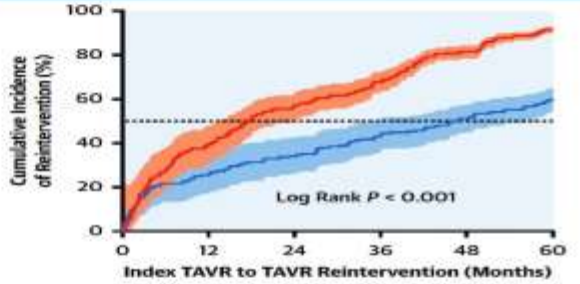
Explant Versus Redo TAVR After THV Failure: Outcomes From the EXPLANTORREDO-TAVR International Registry: 29 Paired Centers, N = 396



Mechanism of TAVR Failure

	Redo TAVR	TAVR Explant	*P* Value
SVD	63.7%	51.9%	0.023
PVL	32.8%	28.7%	0.44
PPM	0.5%	17.1%	<0.001
THV Thrombosis	3.9%	1.7%	0.23
THV Migration	0.5%	3.3%	0.055

Time to TAVR Reintervention



	Redo TAVR	TAVR Explant	*P* Value
Median Interval (months)	45.7 (IQR: 10.6-75.6)	17.6 (IQR: 5.0-40.7)	<0.001

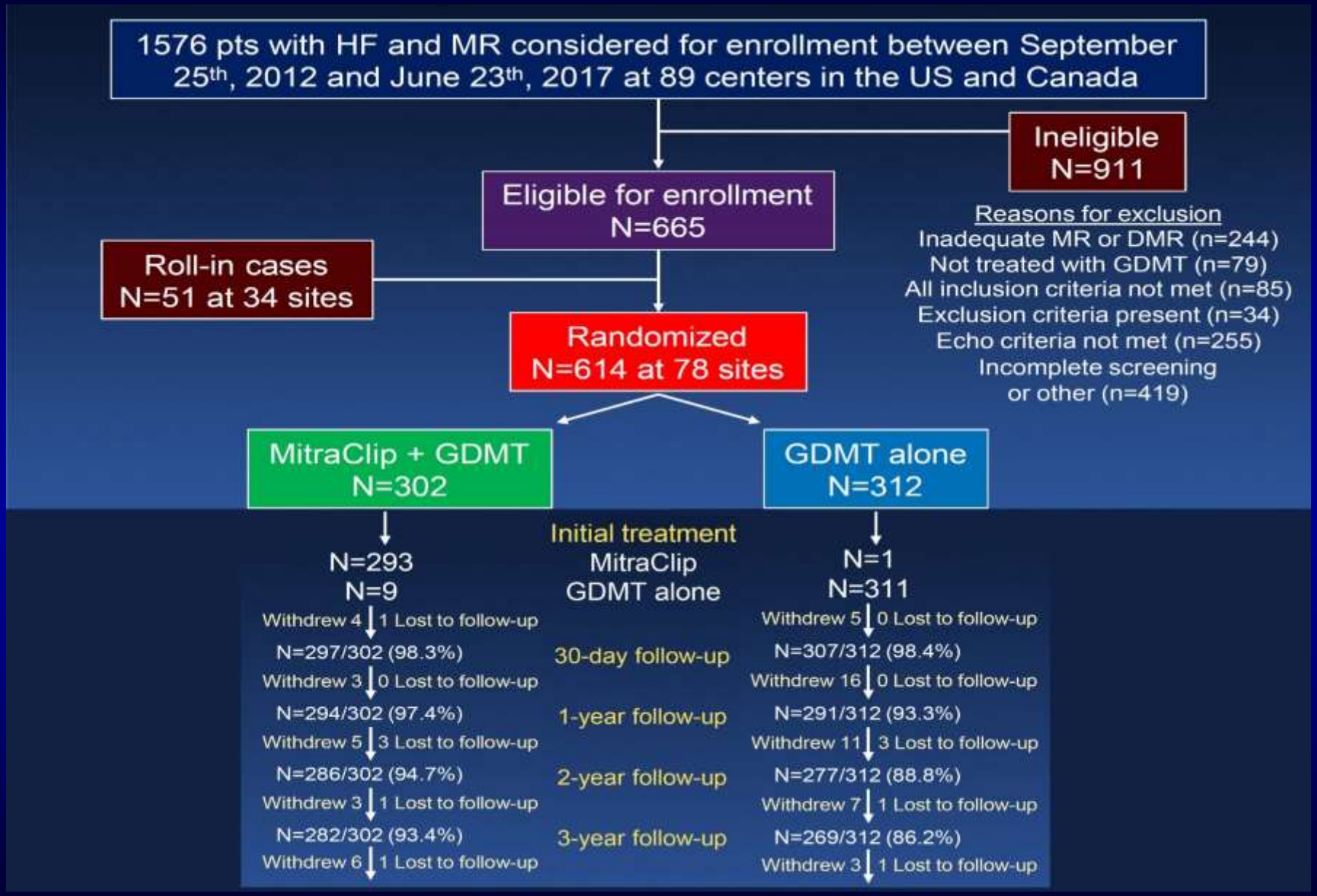
Landmark Analysis: Redo vs Explant TAVR

Tang et al., J Am Coll Cardiol Intv 2023;16:927

Top 10 Advances in Transcatheter Valve Therapy 2022

1.
2.
3.
4.
5. **M-TEER Expanded:** COAPT 5Yr, Expand TEER, TVT Registry, CLASP
6. **TAV or SAV Degeneration:** ViV TAVR, TAV-in-TAV, TAVR Explant
7. **TAVR vs SAVR in Small Annulus AS:** VIVA, SWISS TAVI, SMART
8. **PCI Timings with TAVR in AS:** Revasc TAVR, Complete TAVR
9. **TAVR in Pure Aortic Regurgitation:** ALIGN AR
10. **LAAO for Afib during TAVR:** WATCH TAVR

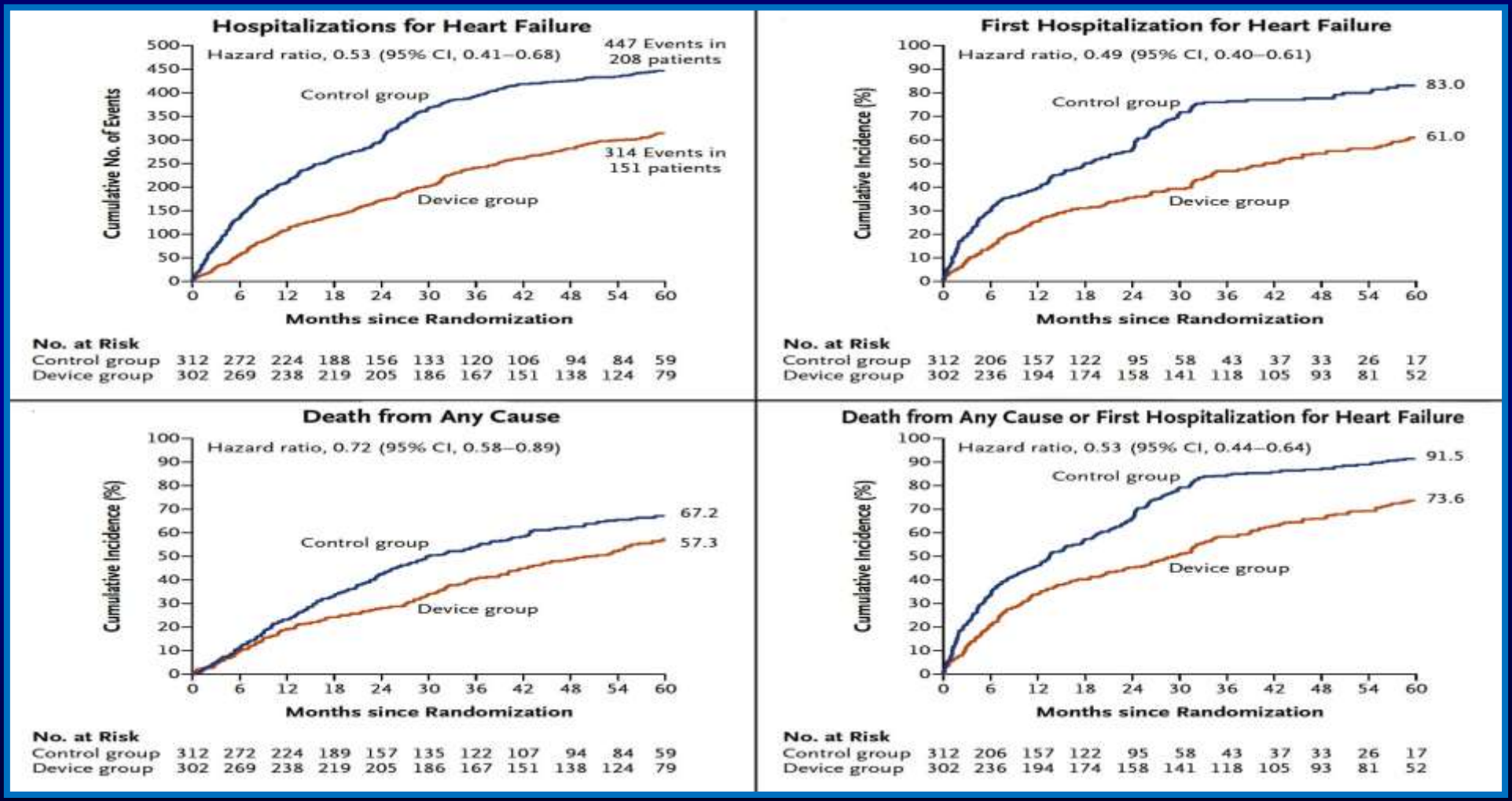
The COAPT Trial Design Through 5 Years



Stone et al., N Engl J Med Mar 5, 2023 Epub ahead of print

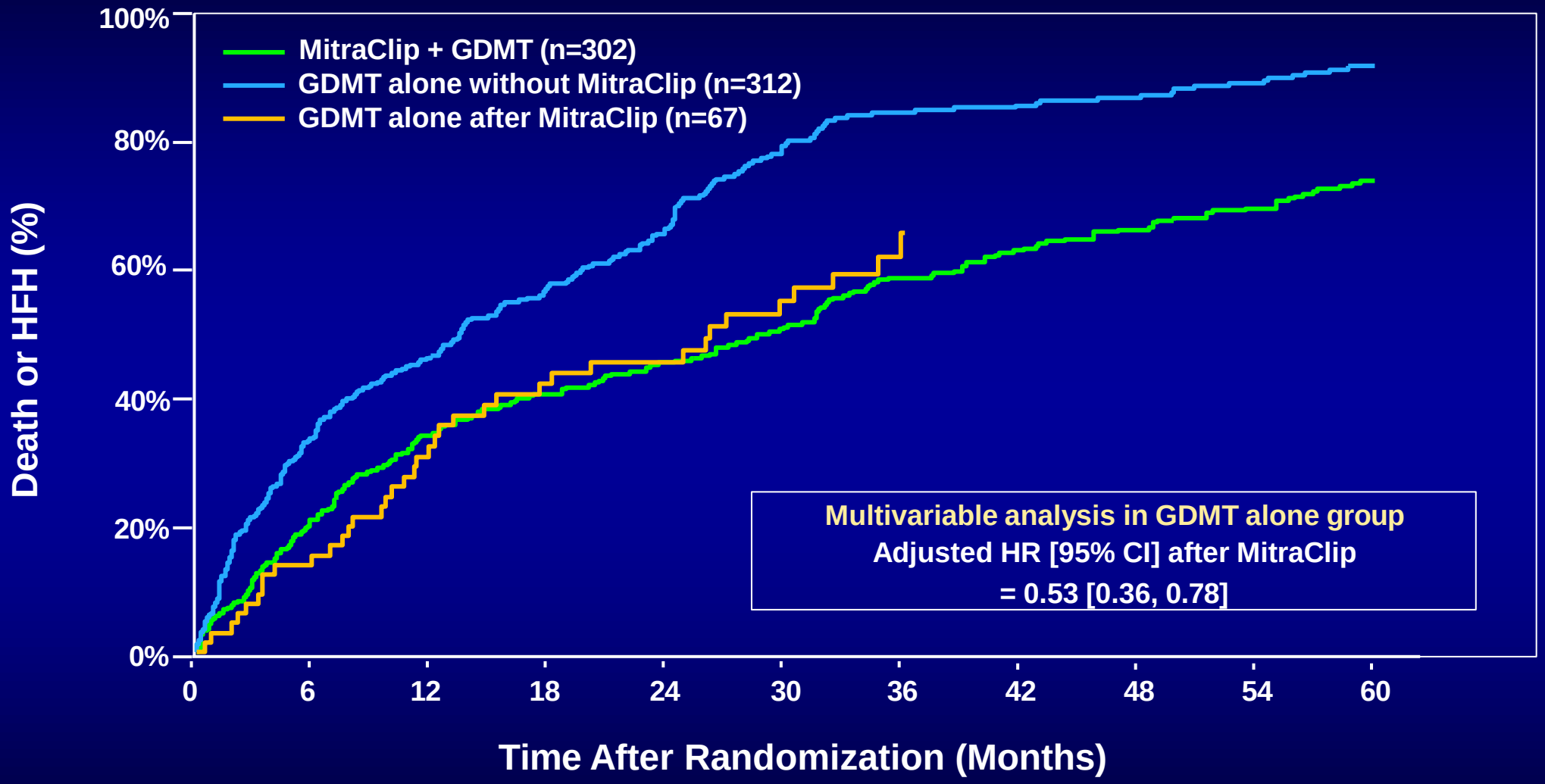
The COAPT Trial: Event Curves for Hosp for HF and Death from Any Cause

- Pts with HF and mod-to-severe or severe MR who had been randomly assigned to undergo TEER + GDMT (device group) or to receive GDMT alone (control group)



Stone et al., N Engl J Med Mar 5, 2023 Epub ahead of print

The COAPT Trial: Death or HFH After Crossovers



Stone et al., N Engl J Med Mar 5, 2023 Epub ahead of print

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 5, 2023

NEW RESEARCH PAPER

STRUCTURAL

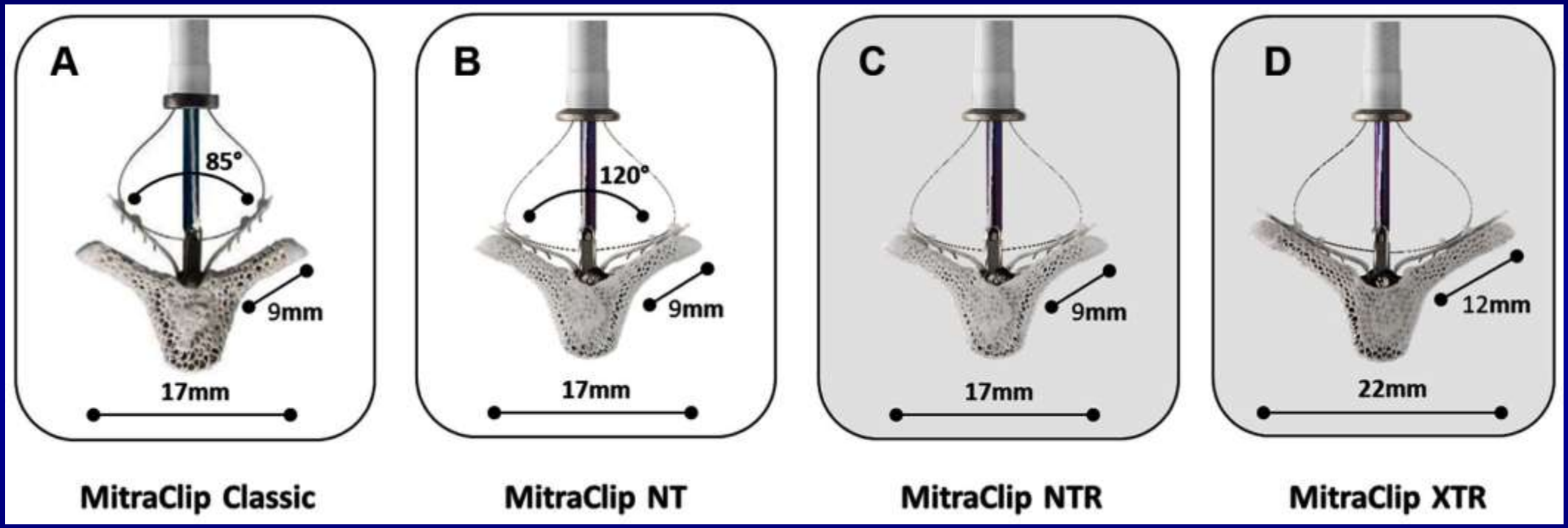
Contemporary Outcomes Following Transcatheter Edge-to-Edge Repair

1-Year Results From the EXPAND Study

Saibal Kar, MD,[a] Ralph Stephan von Bardeleben, MD,[b] Wolfgang Rottbauer, MD,[c] Paul Mahoney, MD,[d] Matthew J. Price, MD,[e] Carmelo Grasso, MD,[f] Mathew Williams, MD,[g] Philipp Lurz, MD,[h] Mustafa Ahmed, MD,[i] Jörg Hausleiter, MD,[j] Bassem Chehab, MD,[k] Jose L. Zamorano, MD,[l] Federico M. Asch, MD,[m] Francesco Maisano, MD[n]

EXPAND Study: MitraClip Implant Evolution

First Generation	Second Generation	Third Generation	

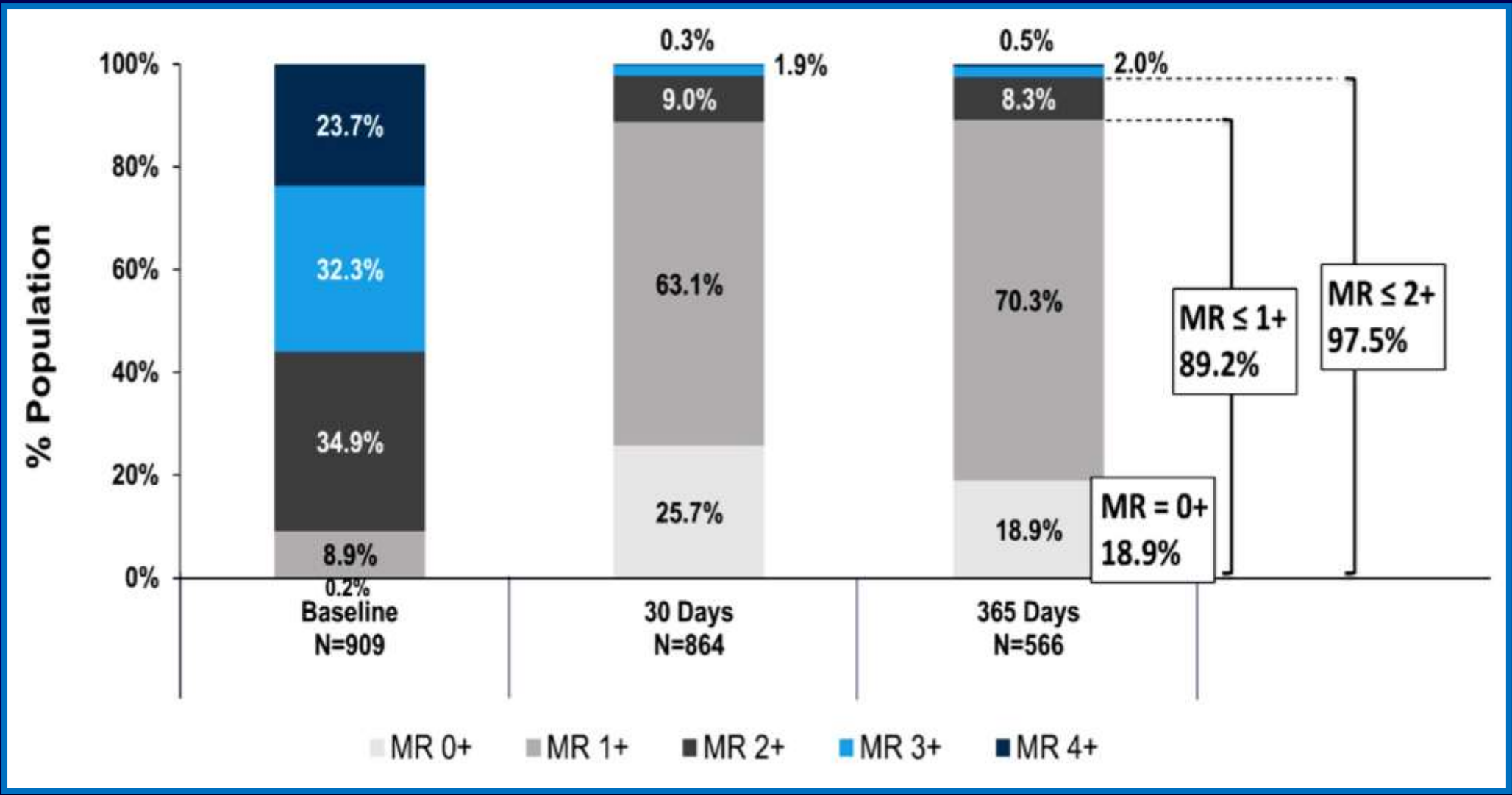


From 1st gen to 2nd gen valve gripper, increased gripper drop angle from 85° to 120°, 2nd gen more efficient leaflet capture on first attempt

3rd gen NTR to XTR, identical size-wise to NT with improved delivery system, increasing precision and predictability during steering. XTR has longer arms for easy grip and better reach.

Kar et al., J Am Coll Cardiol Intv 2023;16:589

EXPAND Study: Change in MR from Baseline Through 1-Year Follow-Up



Kar et al., J Am Coll Cardiol Intv 2023;16:589

EXPAND Study: Procedural Outcomes

	EXPAND	EVEREST II REALISM	TVT Registry	ACCESS-EU
Implantation rate	98.9 (1,030/1,041) (98.1%-99.5%)	94.2 (592/628)	N/A	99.6 (565/567)
Acute procedural success	95.9 (983/1,026) (94.4%-97.0%)	84.1 (528/628)	91.8 (2,709/2,952) Site-reported	91 (514/565) Site-reported
Fluoroscopy time, min	17.2 [11.1-27.0]	33.0 [0-265]	N/A	25 [0-152]
Procedure time, min	80.0 [54.0-115.0]	126.0 [29-448]	N/A	100.0 [15-390]
Length of stay in hospital for index procedure, days	1.0 [1.0-4.0] (U.S. only)	2.0 [N/A-N/A]	2.0 [1.0-5.0]	6.0 [N/A- N/A]

Kar et al., J Am Coll Cardiol Intv 2023;16:589

Safety and Efficacy of Transcatheter Edge-to- Edge Repair in Degenerative Mitral Regurgitation

An Analysis from the STS/ACC TVT Registry

Mitral TEER for Degenerative MR: Study Population

The STS/ACC TVT registry is a national database of all consecutive patients undergoing commercial transcatheter mitral-valve repair in the United States.

TEER with the MitraClip device performed in the US from January 1, 2014 – June 30, 2022
N=60,883

Clinical Exclusion Criteria

- **Ischemic cardiomyopathy N=7098 (17%)**
- **Prior TMV intervention N=236 (0.6%)**
- **Prior SMV intervention N=333 (0.8%)**
- **Cardiogenic shock N=329 (0.8%)**
- **Prior inotropes N=601 (1%)**
- **MV support N=76 (0.2%)**
- **Active endocarditis N=5 (0.01%)**

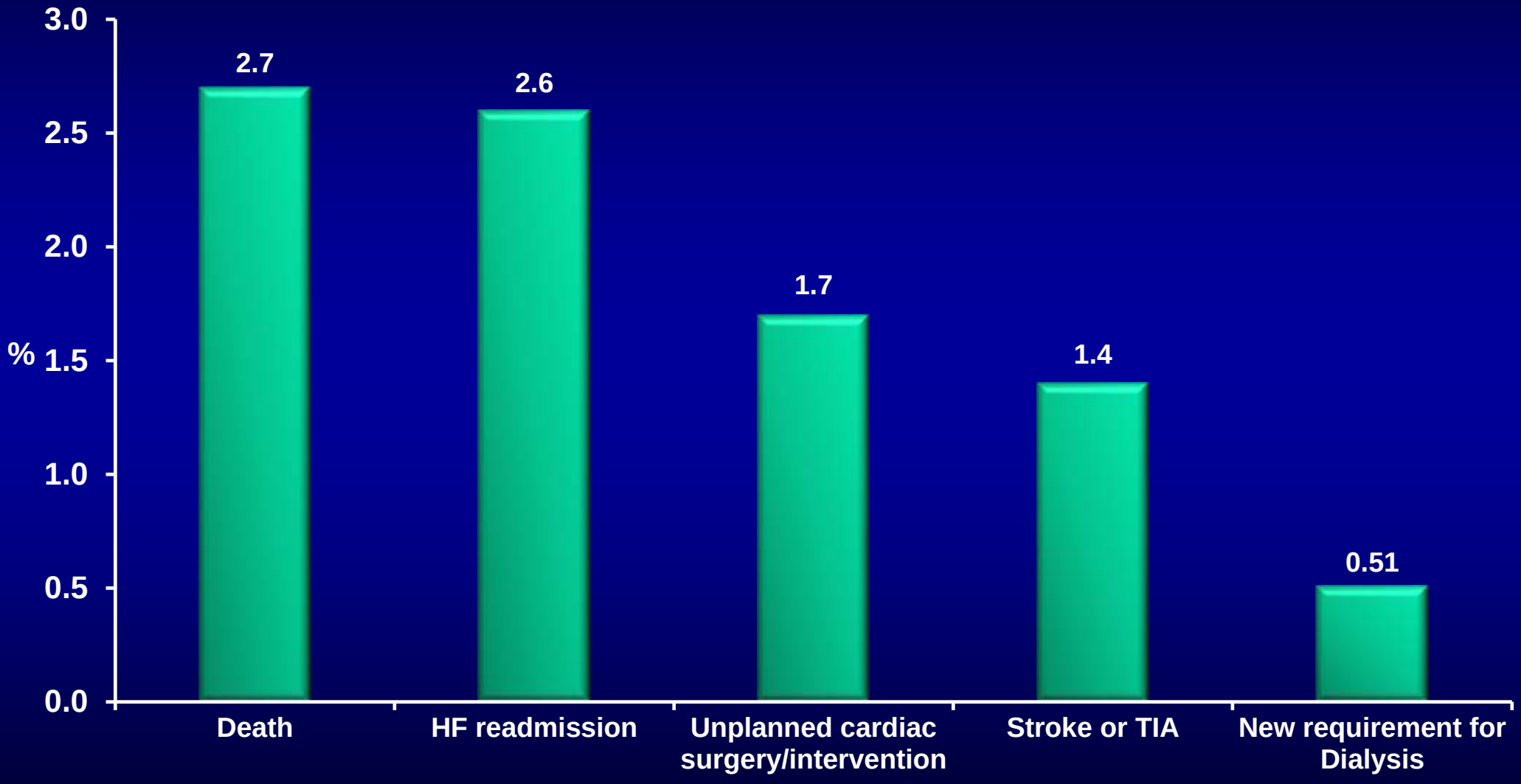
Anatomic/Echo Exclusion Criteria

- **Missing N=415 (1%)**
- **Moderate or less degenerative MR N=2395 (6%)**
- **No degenerative etiology N=21,113 (50%)**
- **Mitral leaflet calcification N=7415 (18%)**
- **Leaflet tethering posterior N=1779 (4%)**

Non-emergent TEER for moderate-severe or severe MR due to "pure" degenerative pathology
N=19,088

Makkar R, ACC 2023

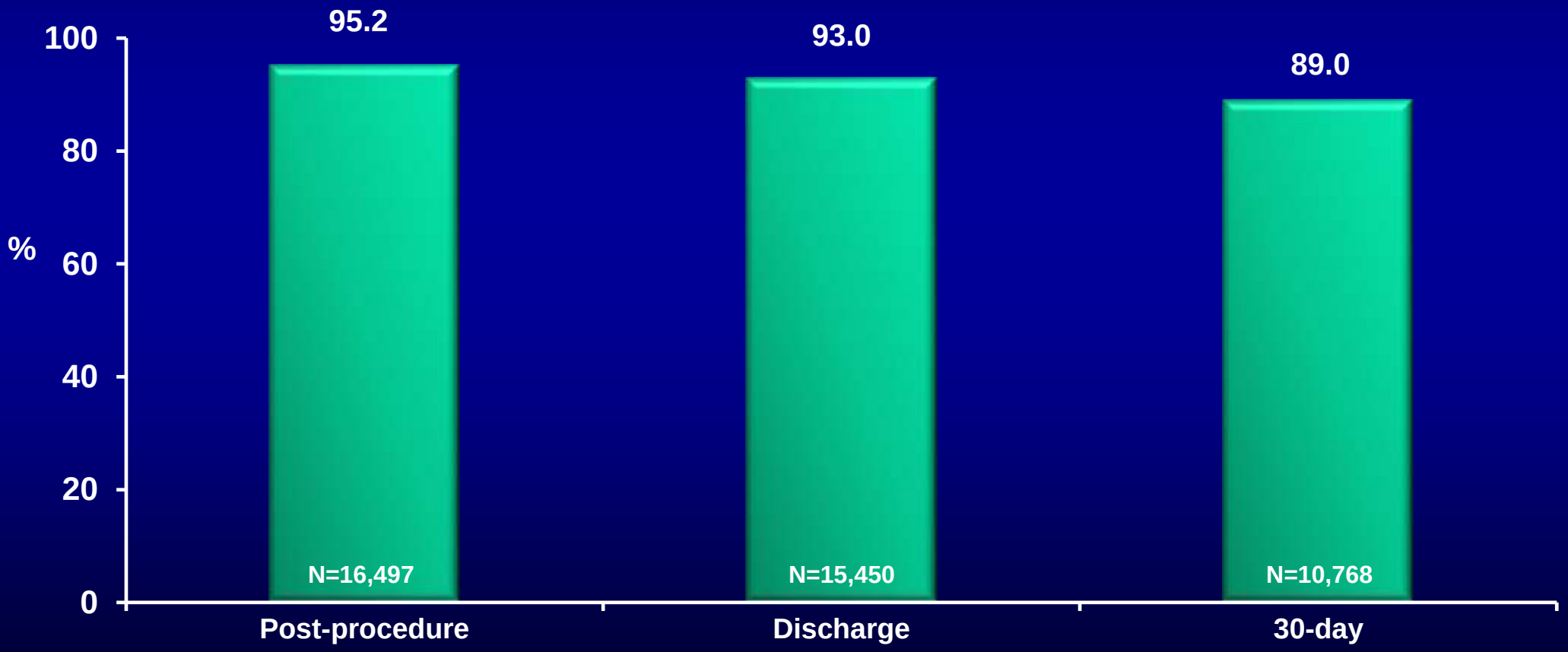
Mitral TEER for Degenerative MR: 30-Day Outcomes (N=19,088)



Makkar R, ACC 2023

Mitral TEER for Degenerative MR: Primary Endpoint

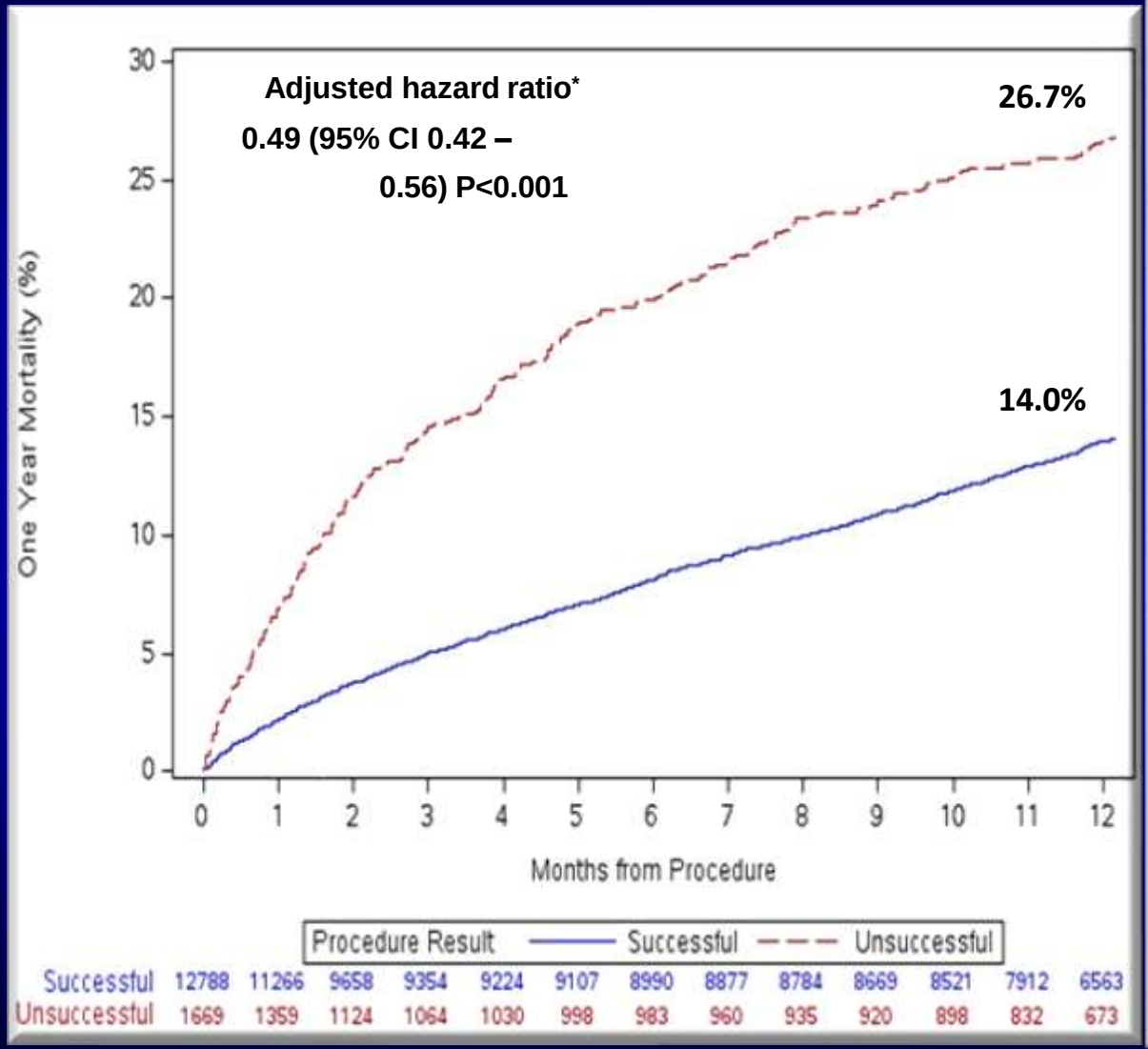
MR Success (MR ≤2+ and Mean Mitral Gradient <10 mmHg)



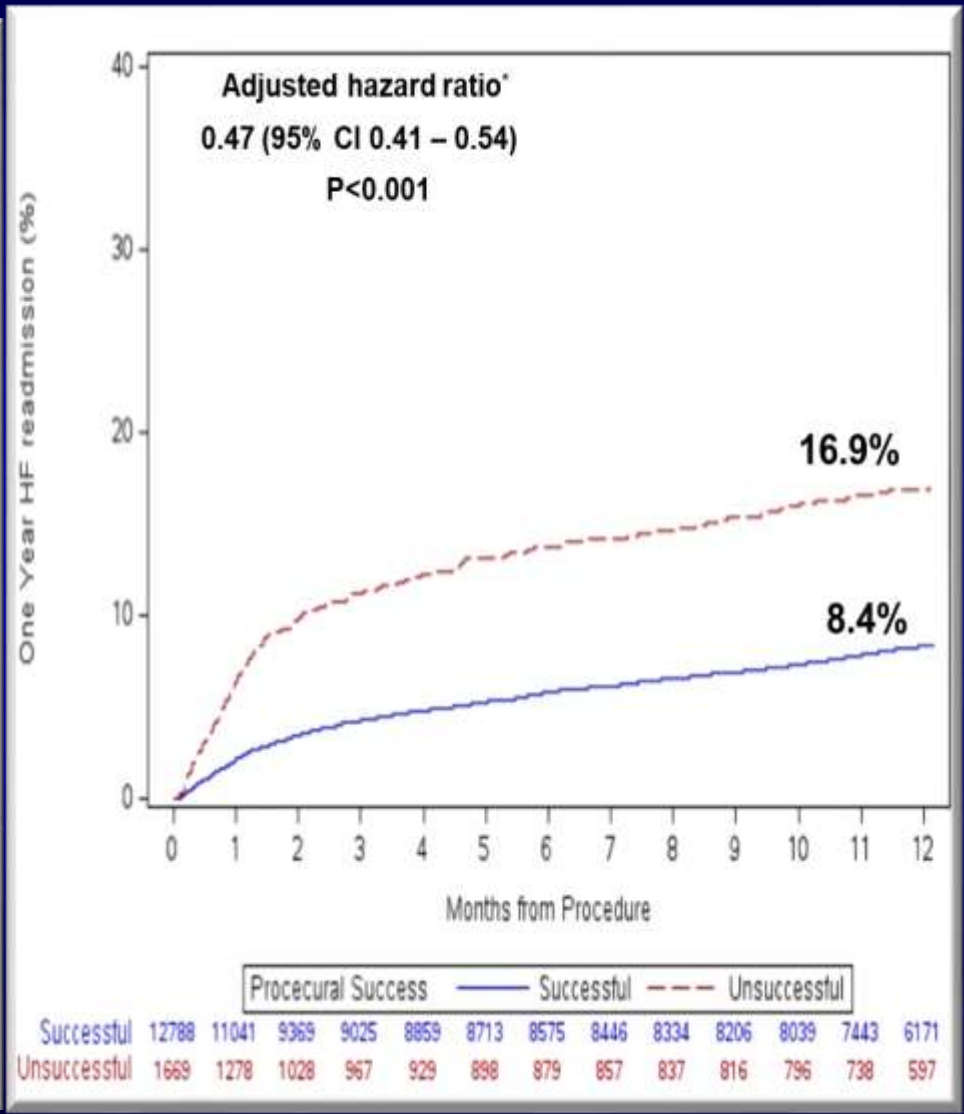
Makkar R, ACC 2023

Mitral TEER for Degenerative MR: 1 Year

Mortality



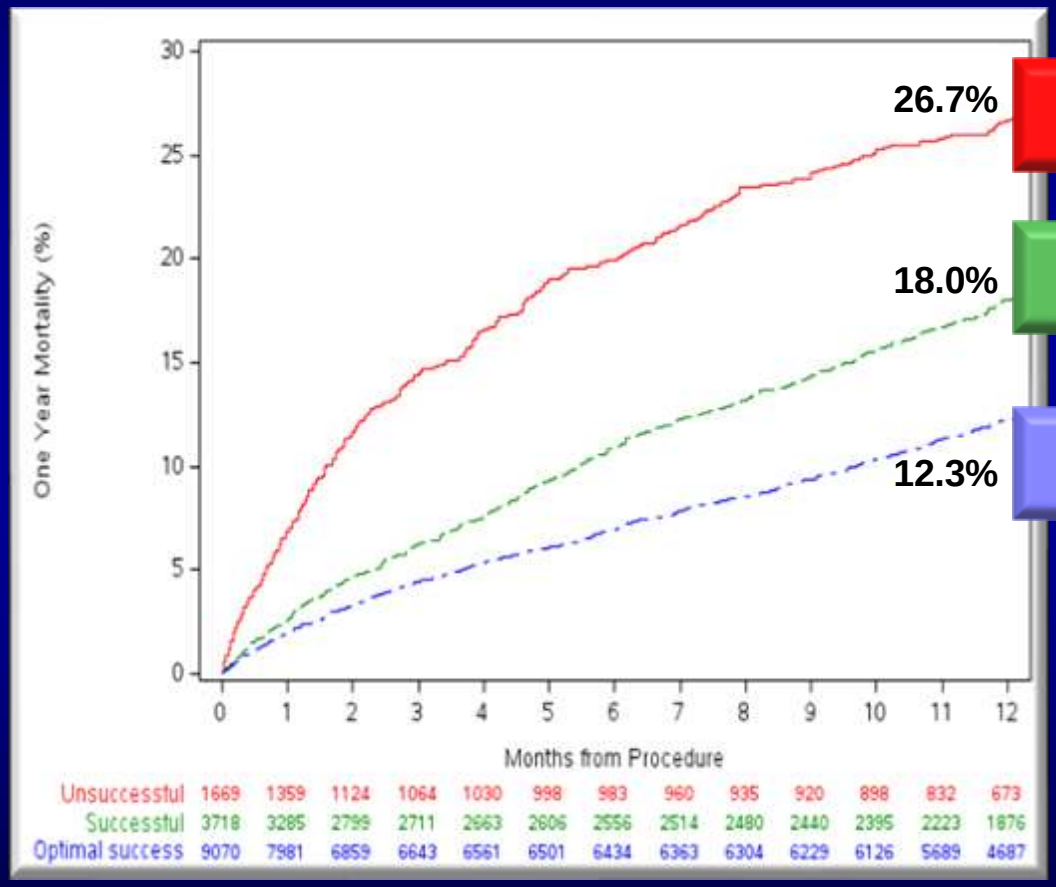
HFH



Makkar R, ACC 2023

Mitral TEER for Degenerative MR: Mild MR vs Mod MR vs Unsuccessful Procedure

Death at 1 Year



26.7% **Unsuccessful procedure**

18.0% **Mod MR/ gradient <10 mmHg**

12.3% **Mild MR/ gradient <10 mmHg**

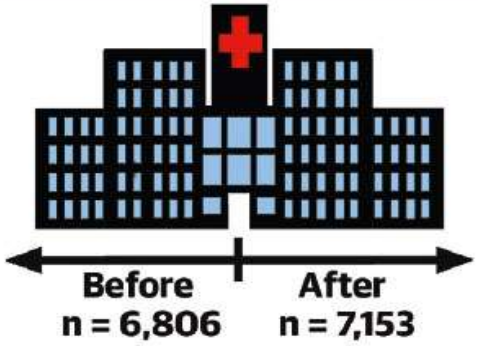
Adjusted HR* 0.73 (0.66 – 0.82)
p < 0.001

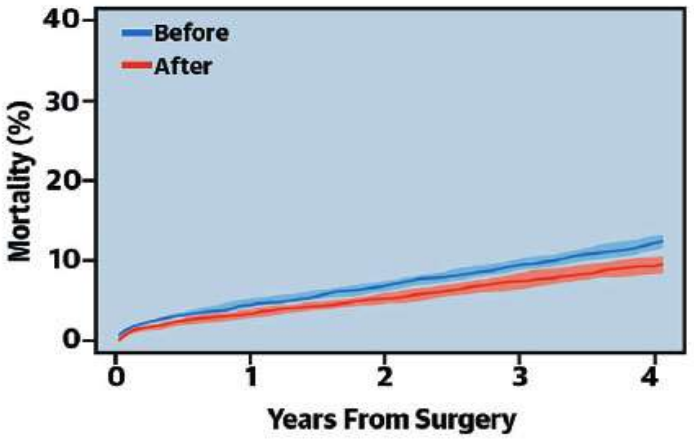
Makkar R, ACC 2023

Assessing the Impact of TEER MVr on Surgical Valve Repair Volume and Outcomes

- Volume and outcomes of surgical MVr compared before vs after the first TEER MVr performed at each institution using STS Adult Cardiac Surgery Database
- Introduction of TEER did not significantly affect MVr volume
- There was an associated downtrend in higher-risk MVr cases, accompanied by improved 30-day and 5-year mortality

Surgical Mitral Valve Repair (MVr):	Comparator:	Results: Surgery After First Transcatheter Edge to Edge Repair (TEER)
n = 13,959 for Degenerative Mitral Regurgitation (DMR) from the Society of Thoracic Surgeons (STS) registry with Centers for Medicare and Medicaid Services (CMS) linkage for long-term outcomes	Surgery performed before vs after date of institution's first transcatheter mitral valve repair	• No significant change in annual MVr volume • Downtrend in higher-risk MVr • Improved risk adjusted 30-day mortality • Improved risk adjusted 5-year mortality



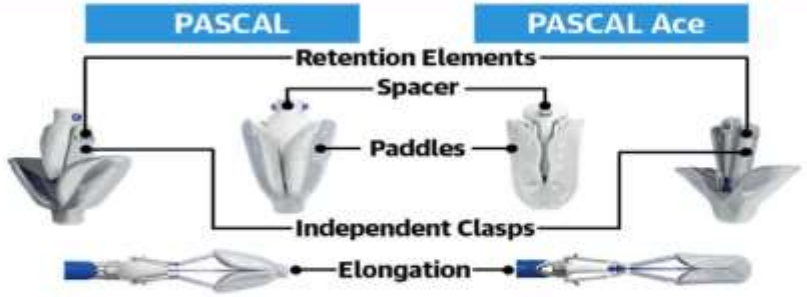


Lowenstern et al., J Am Coll Cardiol 2023;81:521

PASCAL IID Registry Outcomes at 6 Months

A. Anatomical Complexity Criteria

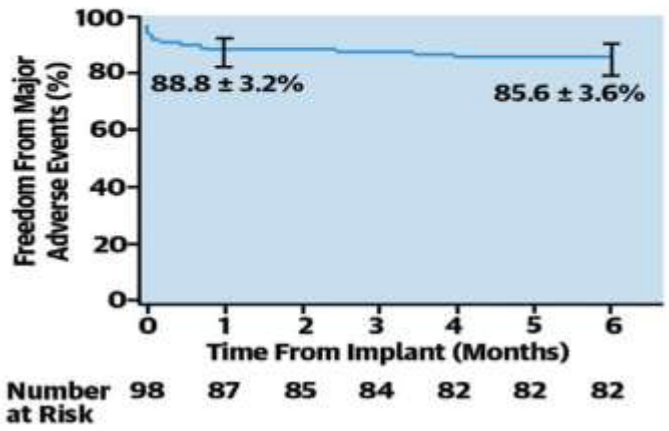
B. PASCAL Implant



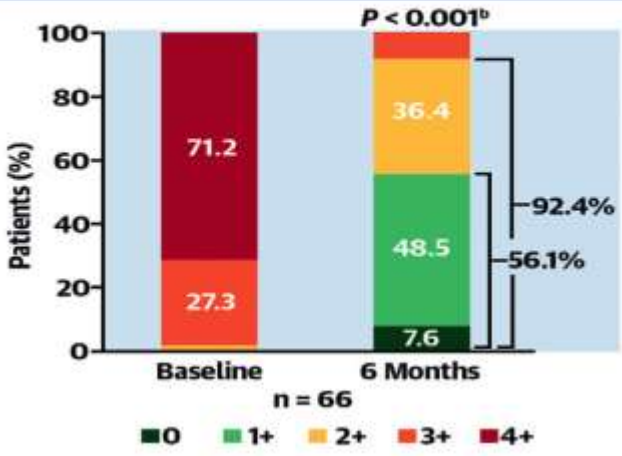
C. Procedural Outcome

Successful implant rate = 92.9% (91/98 patients)

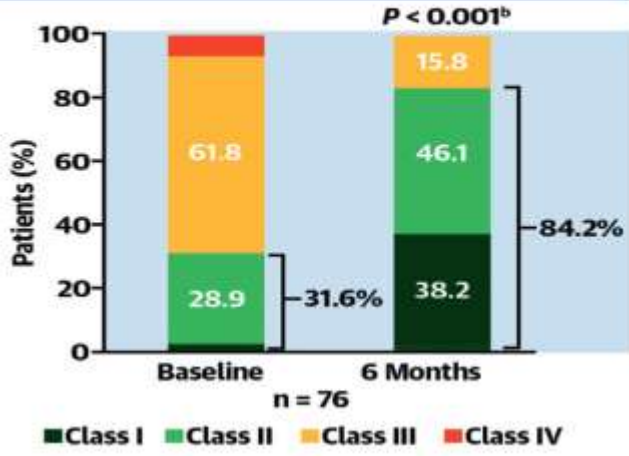
D. Major Adverse Events



E. MR Reduction

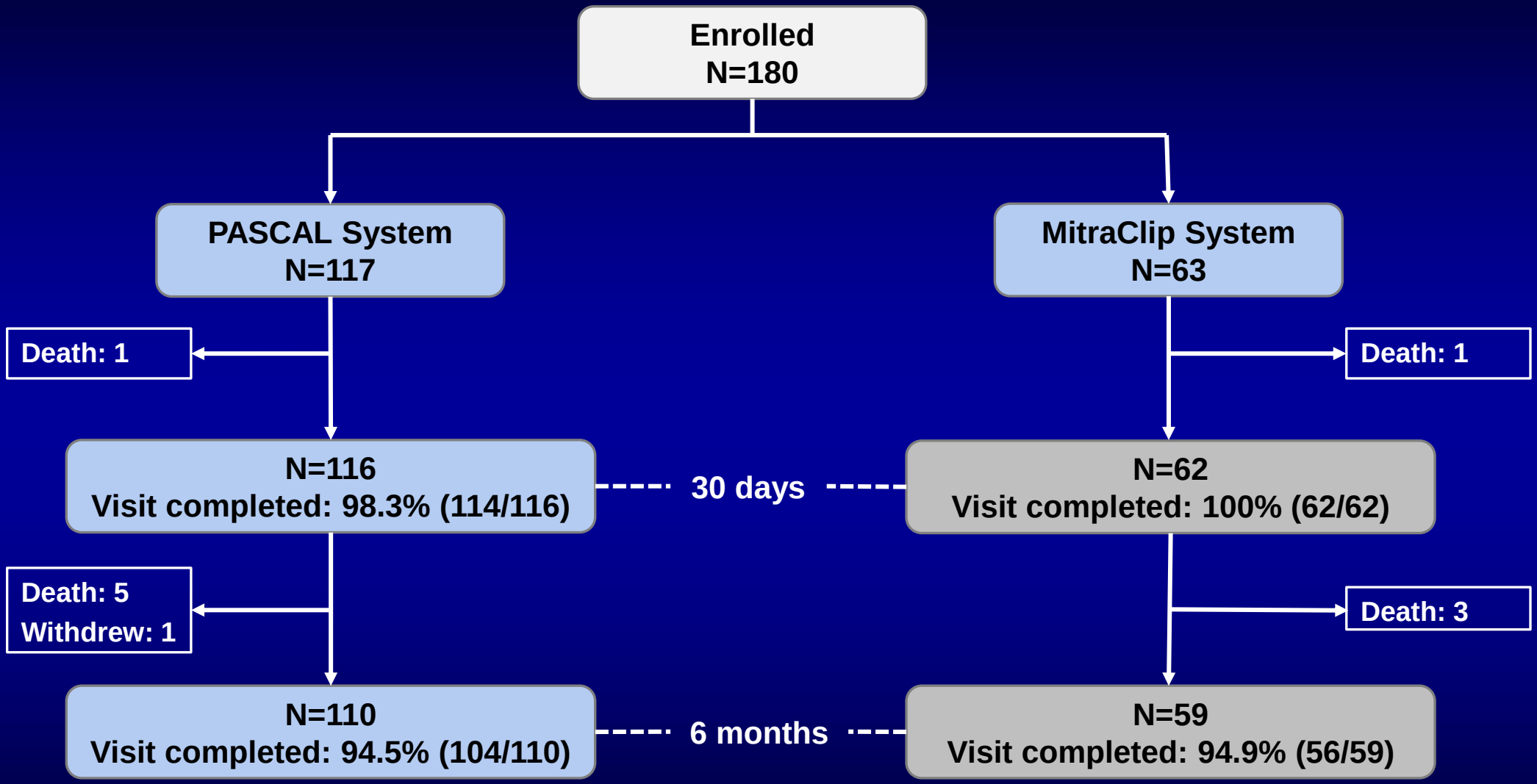


F. New York Heart Association Functional Class



Hausleiter et al., J Am Coll Cardiol 2023;81:431

CLASP IID Trial: Patient Disposition and Flow

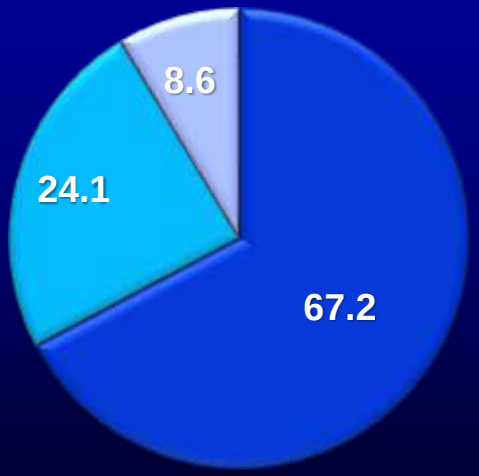


Lim et al., J Am Coll Cardiol Intv 2022 Sept 8 Epub ahead of print

CLASP IID Trial: Procedural Outcomes

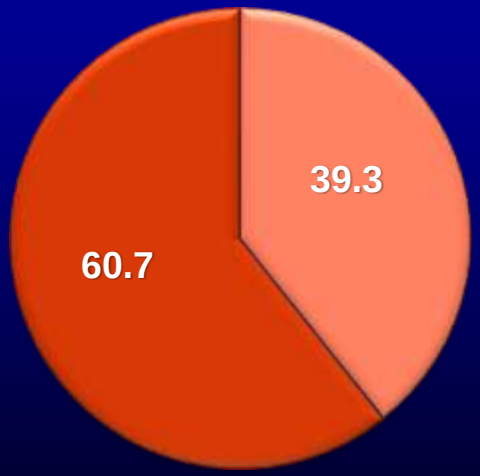
	PASCAL (N=117)	MitraClip (N=63)	p value
Successful implant rate	99.1%	100.0%	1.000
Procedure time (min)	88.0 [68.5, 122.0]	79.0 [58.0,106.0]	0.023
Device Time (min)	60.0 [38.0, 96.0]	41.0 [26.0, 67.0]	<0.001
Mean number of devices	1.5± 0.6	1.6 ± 0.7	0.215
Total length of stay for the index procedure (days)	1.0 [1.0, 2.0]	1.0 [1.0, 2.0]	0.505

Endpoint	PASCAL (n=117)	MitraClip (n=63)	Difference	95% CI
Safety	3.4%	4.8%	- 1.3%	+ 5.1%
Effectiveness	96.5%	96.8%	-0.3%	-6.2%



Device Type

- PASCAL
- PASCAL Ace
- PASCAL and PASCAL Ace



- MitraClip NT, NTR or XTR
- MitralClip NT, NTW, XT or XTW (G4)

Lim et al., J Am Coll Cardiol Intv 2022 Sept 8 Epub ahead of print

REPAIR MR Trial Overview

Patient Population:

- **Subject is symptomatic (NYHA Class II/III/IV) or asymptomatic (LVEF ≤60%, Pulmonary Artery Systolic Pressure >50 mmHg, or LVESD >40 mm)**
- **Subject is at least 75 years of age, OR if younger than 75 years, then has:**
  - **STS-PROM Score ≥2%, OR**
  - **Presence of other comorbidities which may introduce a potential surgical specific impediment.**

Severe Primary Mitral Regurgitation (Grade III/IV per ASE Criteria)

↓

Cardiac surgeon of the site Heart Team concurs that the subject's mitral valve is conducive to Mitral Valve Repair Surgery

No → **Exclude Subject**

↓ YES

Subject meets all inclusion/exclusion criteria and Eligibility Committee confirms that MR can be reduced to ≤ Mild with MitraClip or Mitral Valve Repair Surgery

No → **Exclude Subject**

↓ YES

Randomization (1:1) (n=500)

↓

Transcatheter Repair – MitraClip *(Device)*

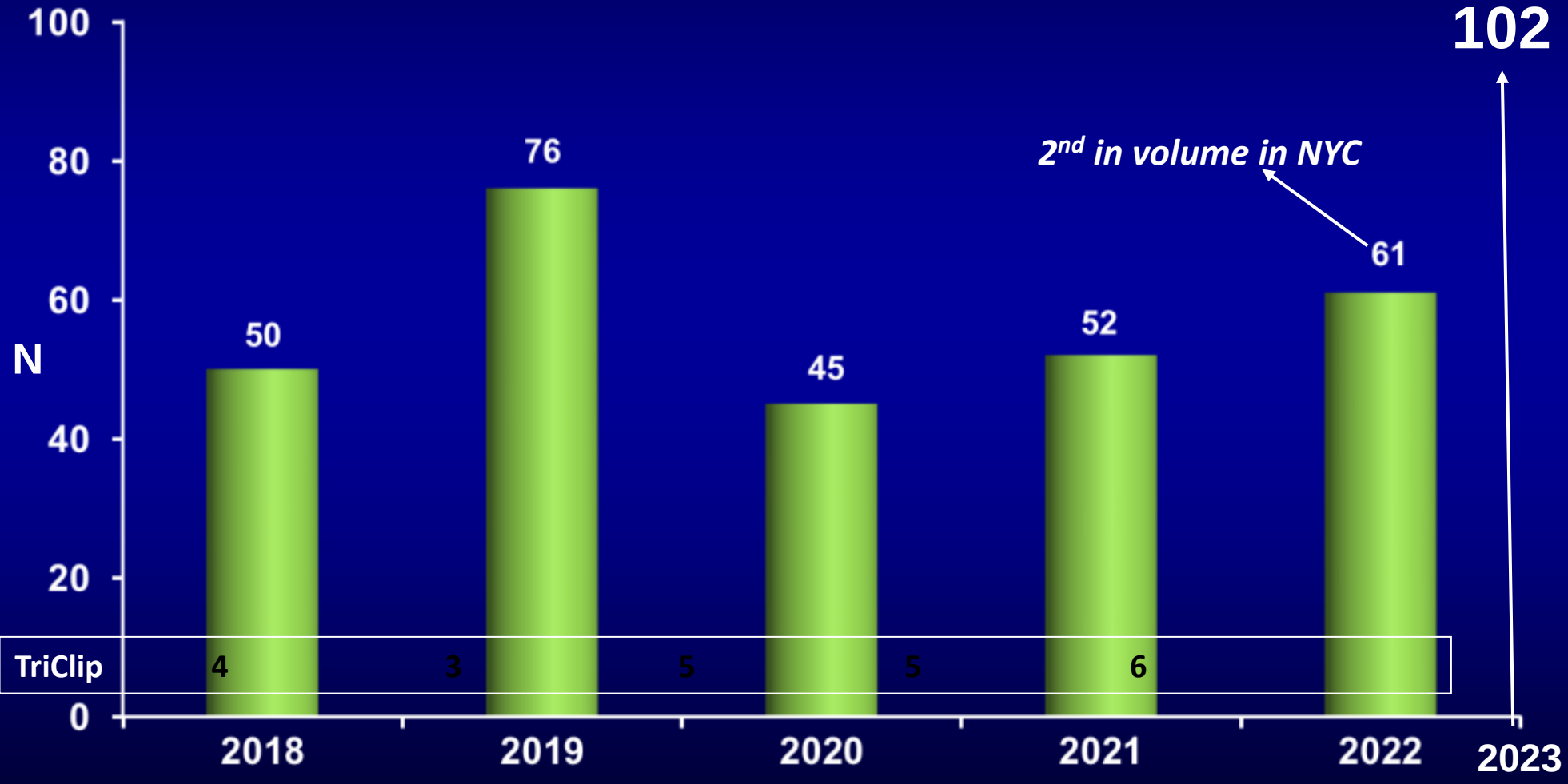
Surgical Mitral Valve Repair *(Control)*

- **Co-Primary Endpoint #1:** All-cause mortality, stroke, cardiac hospitalization, or acute kidney injury requiring renal replacement therapy at 2 years (any cardiac hospitalizations in the first 30 days post treatment will be excluded)
- **Co-Primary Endpoint #2:** Proportion of subjects with moderate or less MR (≤2+), without mitral valve replacement, and without recurrent mitral valve intervention (surgical or percutaneous) from the time of index procedure through 2 years.

MitraClip / TriClip Procedures at MSH

2018 to 2022

In-Hospital Death: N =	*3*	*2*	*2*	*1*	*2*



MitraClip TEER Clinical Parameters

Site Specific Metrics – Averages Over the Past 6 Months
MSH vs National Data- TVT Registry

Average MR Reduction	
2.9 MSH	2.7 Nation

Average MR Post Procedure	
1.1 MSH	1.3 Nation

Average Gradient Post Procedure	
2.6 MSH	3.3 Nation

Average Device Time	
25 mins MSH	55 mins Nation

30-day/1-Yr Mortality	
0/5% MSH	2.9/16.6% Nation

Top 10 Advances in Transcatheter Valve Therapy 2022

1.
2.
3.
4. **TMVR Updated:** INTREPID EFS 1Yr, MITRAL 5Yr
5. **M-TEER Expanded:** COAPT 5Yr, Expand TEER, TVT Registry, CLASP II
6. **TAV or SAV Degeneration:** ViV TAVR, TAV-in-TAV, TAVR Explant
7. **TAVR vs SAVR in Small Annulus AS:** VIVA, SWISS TAVI, SMART
8. **PCI Timings with TAVR in AS:** Revasc TAVR, Complete TAVR
9. **TAVR in Pure Aortic Regurgitation:** ALIGN AR
10. **LAAO for Afib during TAVR:** WATCH TAVR

1-Year Outcomes Following Transfemoral Transseptal Transcatheter Mitral Valve Replacement: Intrepid TMVR Early Feasibility Study Results (U.S. Multicenter))

Firas Zahr, MD[1]; Howard K. Song, MD PhD[1]; Scott Chadderdon, MD[1]; Hemal Gada, MD[2]; Mubashir Mumtaz, MD[2]; Timothy Byrne, MD[3]; Merick Kirshner, MD[3]; Samin Sharma, MD[4]; Susheel Kodali, MD[5]; Isaac George, MD[5]; John Heiser, MD[6]; William Merhi, DO[6]; Leora Yarboro, MD[7]; Paul Sorajja, MD[8]; Vinayak Bapat, MD[8]; Tanvir Bajwa, MD[9]; Eric Weiss, MD[9]; Jeremy J. Thaden, MD[10]; Elizabeth Gearhart[11]; Scott Lim, MD[7]; Michael Reardon, MD[12]; David Adams, MD[4]; Michael Mack, MD[13]; Martin B. Leon, MD[5]

1-Year Outcomes from the Intrepid Transcatheter Mitral Valve Replacement Early Feasibility Study

Intrepid Valve

A

Delivery System

B

Survival

C

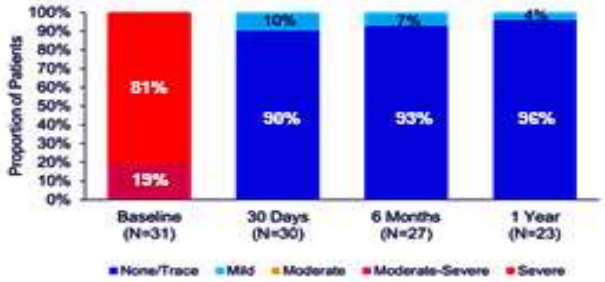
Clinical Outcomes

D

	30 Days	1 Year
Stroke	0%	0%
MVARC major vascular complications	24%	24%
Re-operation (or re-intervention)	3%	3%
CV hospitalization	6%	22%

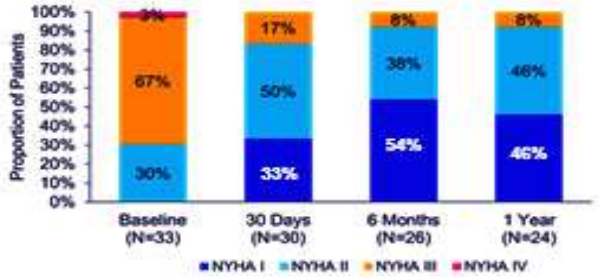
Mitral Regurgitation

E



NYHA Classification

F



(A) Intrepid transfemoral bioprosthesis. The Intrepid bioprosthesis, available in 42- and 48-mm valve sizes, is composed of an inner Nitinol stent, an outer Nitinol fixation ring, and a woven polyester skirt attached at the top of the fixation ring that flares outward to form an atrial brim. Reproduced with permission from Medtronic. (B) Intrepid delivery system. Reproduced with permission from Medtronic. (C) Survival free of all-cause mortality. (D) Key clinical outcomes. (E) Mitral regurgitation over time. Echocardiographic data are on implanted patients only and core laboratory adjudicated. (F) New York Heart Association classification over time.

Zahr, Byrne, Sharma et al.

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 16, NO. 18, 2023

PUBLISHED BY ELSEVIER

NEW RESEARCH PAPER

STRUCTURAL

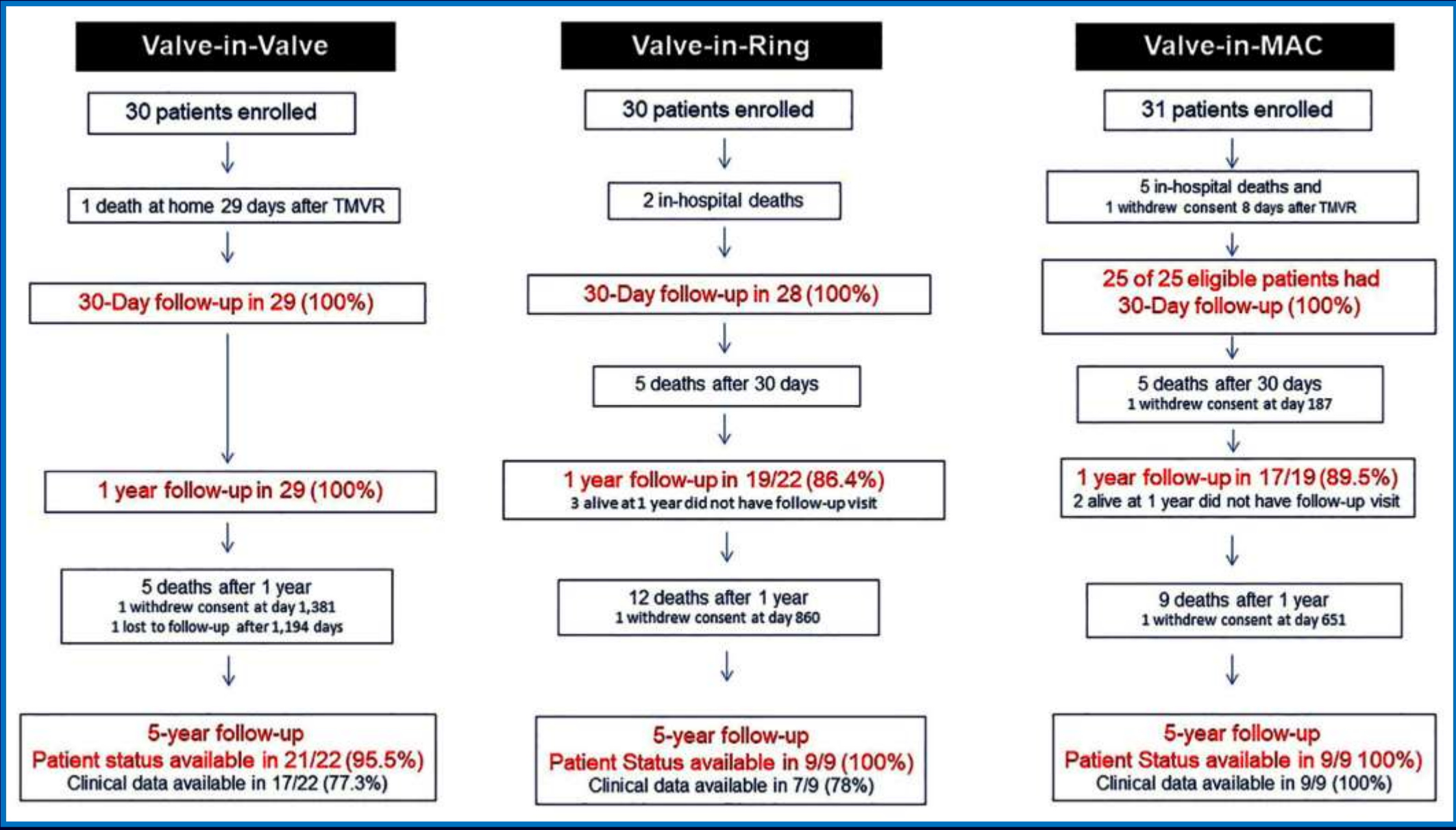
5-Year Prospective Evaluation of Mitral Valve-in-Valve, Valve-in-Ring, and Valve-in-MAC Outcomes

MITRAL Trial Final Results (U.S.)

(Mitral Implantation of Transcatheter Valves)

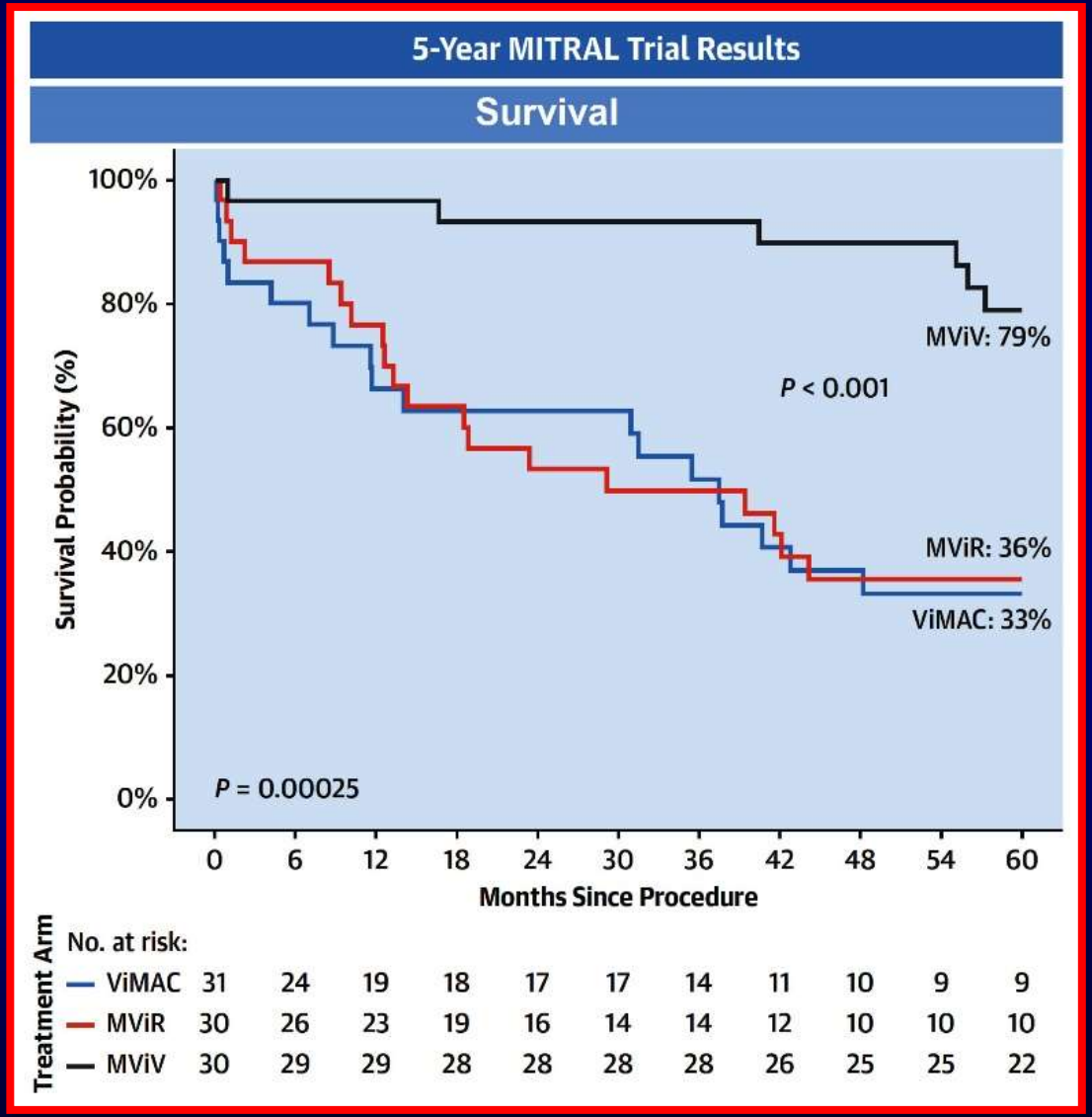
Mayra E. Guerrero, MD,[a] Mackram F. Eleid, MD,[a] Dee Dee Wang, MD,[b] Amit Pursnani, MD,[c] Susheel K. Kodali, MD,[d] Isaac George, MD,[e] Igor Palacios, MD,[f] Hyde Russell, MD,[g] Raj R. Makkar, MD,[h] Saibal Kar, MD,[i] Lowell F. Satler, MD,[j] Vivek Rajagopal, MD,[k] George Dangas, MD,[l] Gilbert H.L. Tang, MD, MSc, MBA,[m] James M. McCabe, MD,[n] Brian K. Whisenant, MD,[o] Kenith Fang, MD,[p] Prakash Balan, MD,[p] Richard Smalling, MD,[q] Tatiana Kaptzan, PhD,[r] Bradley Lewis, MS,[s] Pamela S. Douglas, MD,[t] Rebecca T. Hahn, MD,[d] Jeremy Thaden, MD,[a] Jae K. Oh, MD,[a] Martin Leon, MD,[d] William O'Neill, MD,[b] Charanjit Rihal, MD[a]

MITRAL Trial: Patient Flow



Guerrero et al., J Am Coll Cardiol Intv 2023;16:2211

MITRAL Trial: 5-Year Outcomes of Mitral Valve-in-Valve, Valve-in-Ring, and Valve-in-MAC



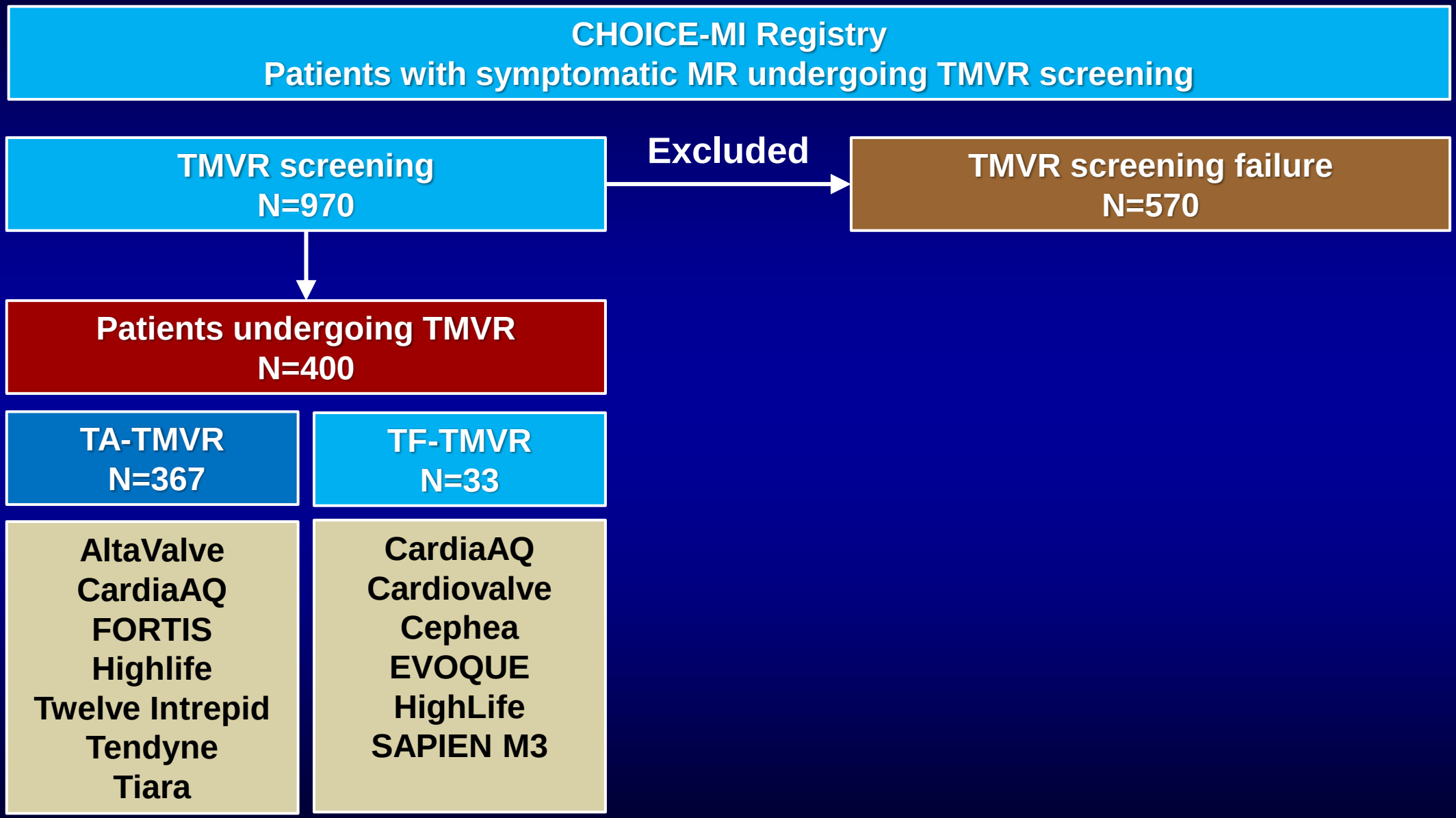
Guerrero et al., J Am Coll Cardiol Intv 2023;16:2211

EuroIntervention 2023;19-online publish-ahead-of-print May 2023

Clinical outcomes of transcatheter mitral valve replacement: two-year results of the CHOICE-MI Registry

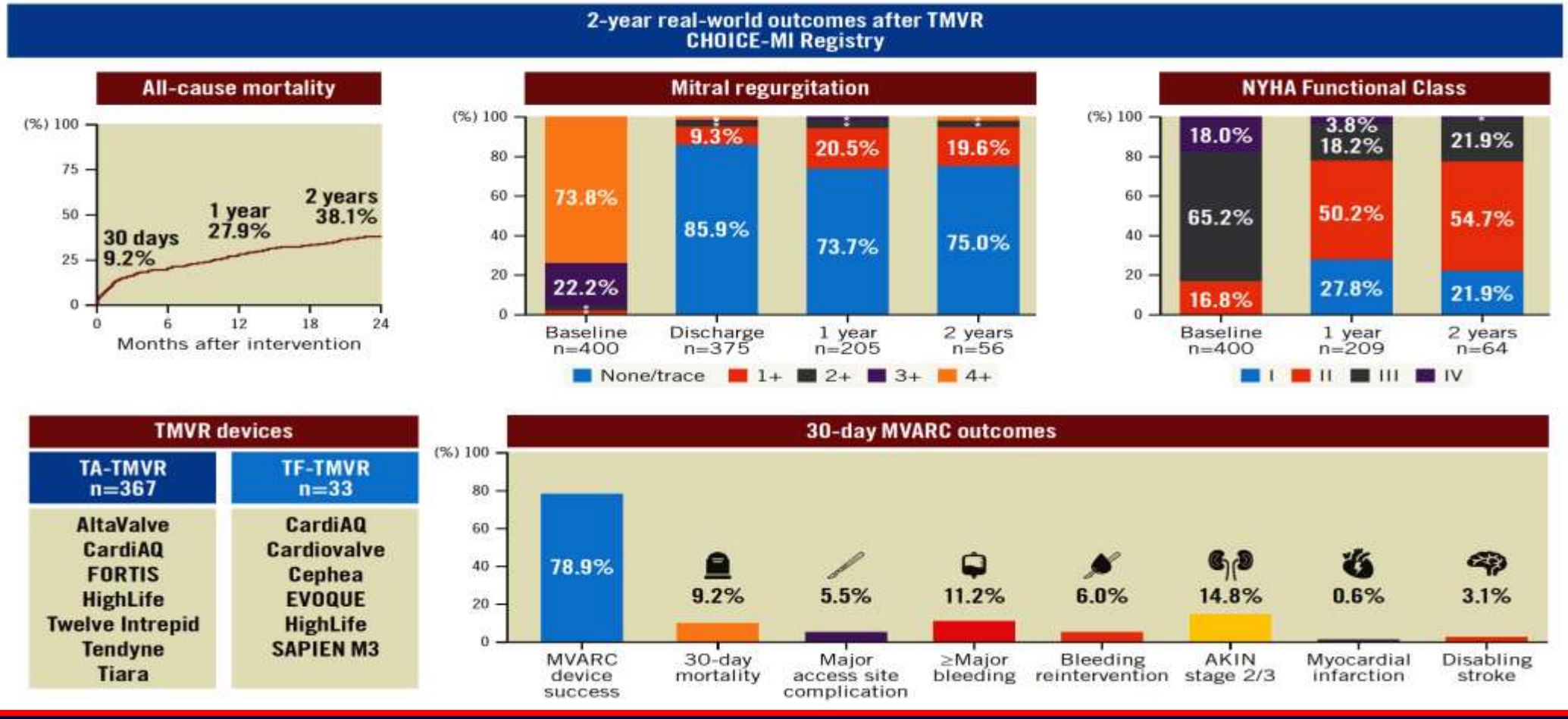
Sebastian Ludwig[1,2,3], MD; Nils Perrin[4], MD; Augustin Coisne[3,5], MD, PhD; Walid Ben Ali[4], MD, PhD; Jessica Weimann[1], MSc; Alison Duncan[6], MD; Mariama Akodad[7], MD; Andrea Scotti[3,8], MD; Daniel Kalbacher[1,2], MD; Sabine Bleiziffer[9], MD; Georg Nickenig[10], MD; Jörg Hausleiter[11], MD; Hendrik Ruge[12,13], MD; Matti Adam[14], MD; Anna S. Petronio[15], MD; Nicolas Dumonteil[16], MD; Lars Sondergaard[17], MD; Marianna Adamo[18], MD; Damiano Regazzoli[19], MD; Andrea Garatti[20], MD; Tobias Schmidt[21], MD; Gry Dahle[22], MD, PhD; Maurizio Taramasso[23], MD; Thomas Walther[24], MD; Joerg Kempfert[25], MD; Jean-François Obadia[26], MD; Omar Chehab[27], MD; Gilbert H.L. Tang[28], MD, MSc, MBA; Azeem Latib[8], MD; Sachin Goel[29], MD; Neil Fam[30], MD; Martin Andreas[31], MD, PhD; David W. Muller[32], MD; Paolo Denti[33], MD; Fabien Praz[34], MD; Ralph Stephan von Bardeleben[35], MD; Juan F. Granada[3], MD; Thomas Modine[36], MD, PhD; Lenard Conradi[37]*, MD; CHOICE-MI Investigators (collaborators)

CHOICE-MI Registry: Study Flowchart



Ludwig et al., EuroIntervention 2023 May 19, Epub ahead of print

Real-World Outcomes After TMVR – Results from the CHOICE-MI Registry



- Clinical and echo outcomes of 400 patients undergoing TMVR with 11 different devices
- Treatment with TMVR was associated with predictable and durable resolution of MR and functional improvement in the majority of patients

Ludwig et al., EuroIntervention 2023 May 19, Epub ahead of print

Top 10 Advances in Transcatheter Valve Therapy 2022

1.
2.
3. **TTVR Emerging:** TRILUMINATE 1Yr, bRIGHT Pass, TRANSCEND
4. **TMVR Updated:** INTREPID EFS 1Yr, MITRAL 5Yr
5. **M-TEER Expanded:** COAPT 5Yr, Expand TEER, TVT Registry, CLASP II
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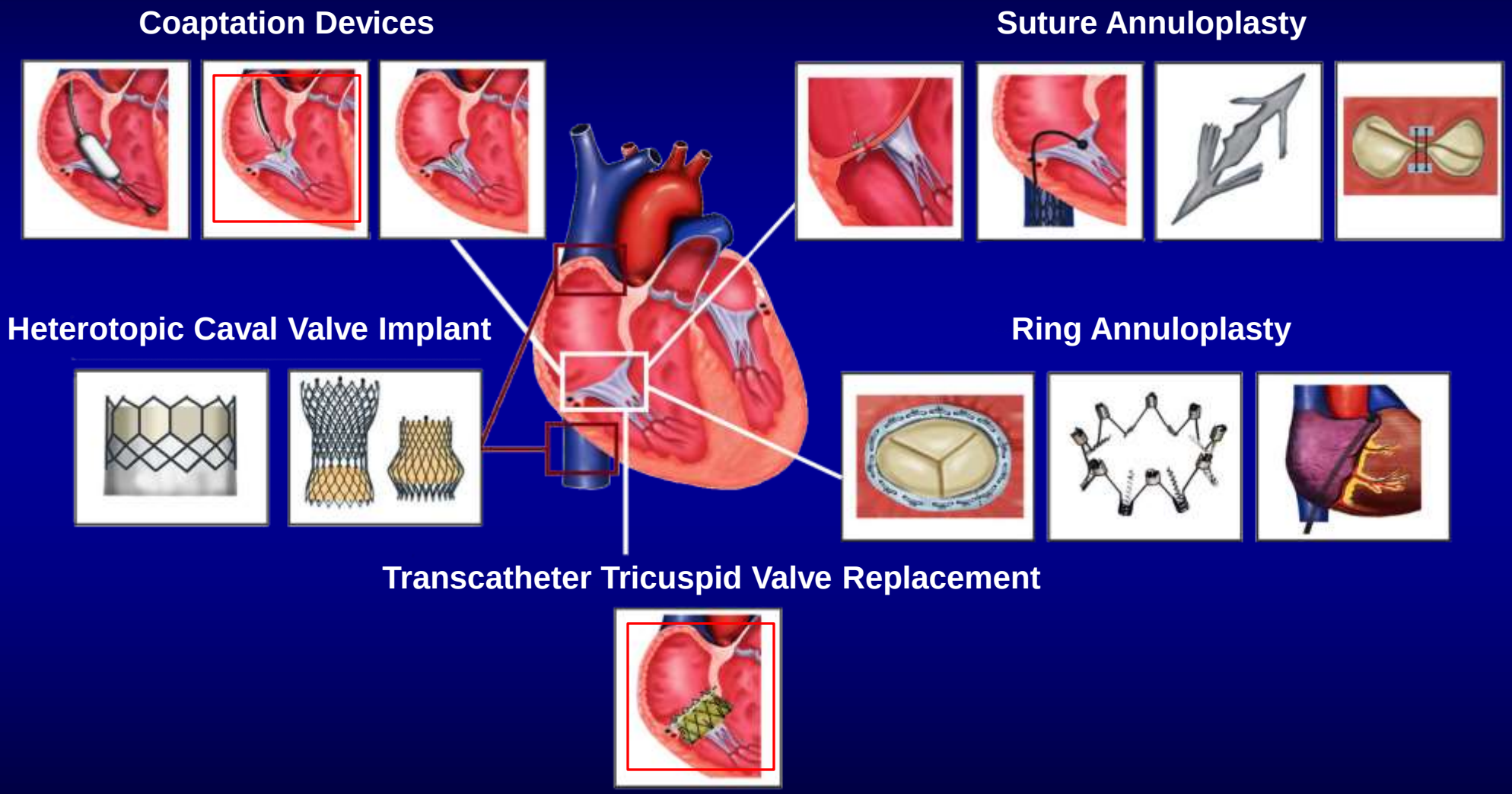
8. **PCI Timings with TAVR in AS:** Revasc TAVR, Complete TAVR
9. **TAVR in Pure Aortic Regurgitation:** ALIGN AR
10. **LAAO for Afib during TAVR:** WATCH TAVR

Transcatheter Tricuspid Landscape



The NEW ENGLAND JOURNAL of MEDICINE

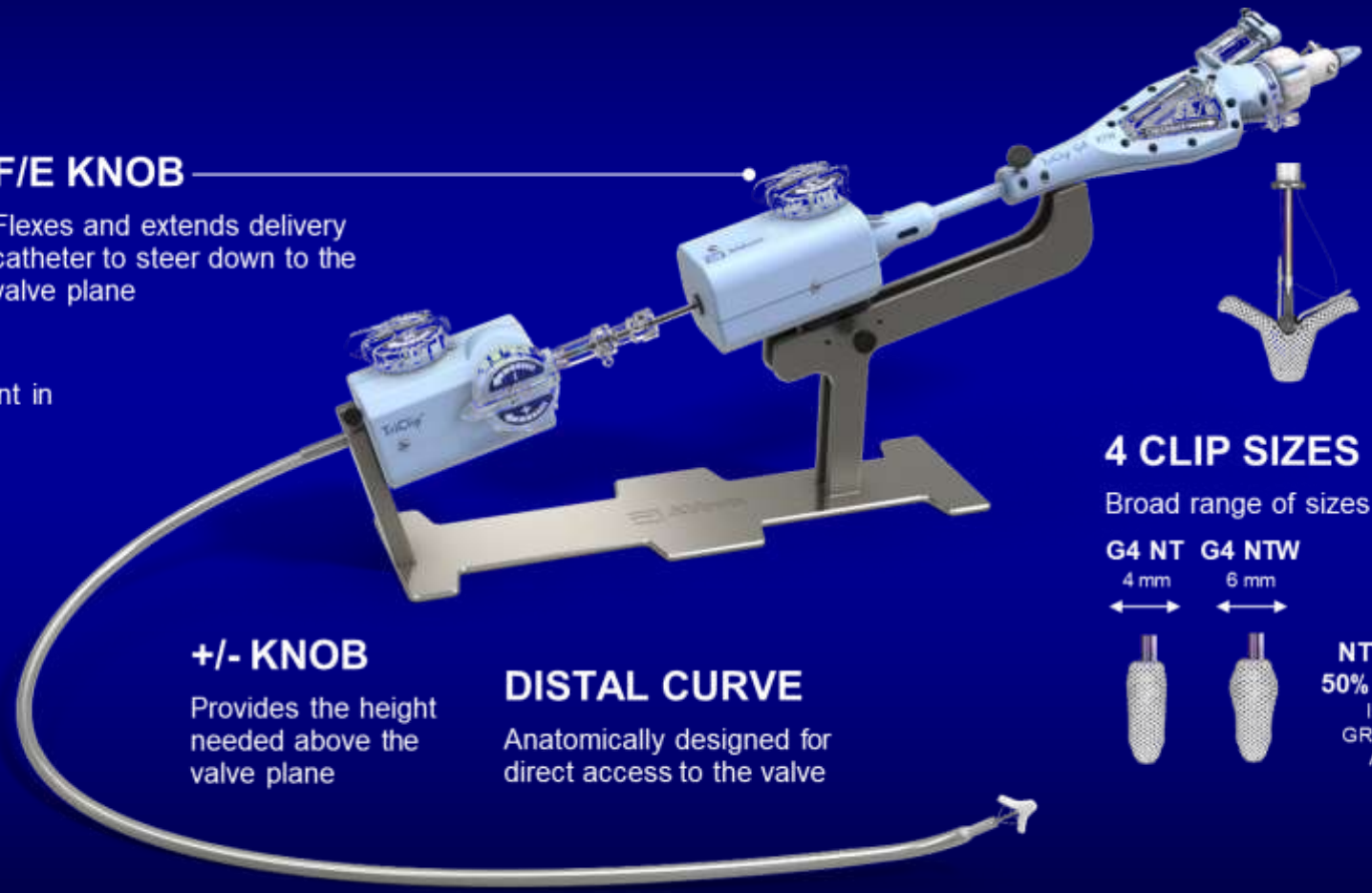
ORIGINAL ARTICLE

Transcatheter Repair for Patients with Tricuspid Regurgitation

Paul Sorajja, M.D., Brian Whisenant, M.D., Nadira Hamid, M.D., Hursh Naik, M.D., Raj Makkar, M.D., Peter Tadros, M.D., Matthew J. Price, M.D., Gagan Singh, M.D., Neil Fam, M.D., Saibal Kar, M.D., Jonathan G. Schwartz, M.D., Shamir Mehta, M.D., Richard Bae, M.D., Nishant Sekaran, M.D., Travis Warner, M.D., Moody Makar, M.D., George Zorn, M.D., Erin M. Spinner, Ph.D., Phillip M. Trusty, Ph.D., Raymond Benza, M.D., Ulrich Jorde, M.D., Patrick McCarthy, M.D., Vinod Thourani, M.D., Gilbert H.L. Tang, M.D., Rebecca T. Hahn, M.D., and David H. Adams, M.D., for the TRILUMINATE Pivotal Investigators*

TriClip™ G4 Delivery System

TRILUMINATE™
PIVOTAL TRIAL



F/E KNOB

Flexes and extends delivery catheter to steer down to the valve plane

S/L KNOB

Enables movement in septal or lateral direction

+/- KNOB

Provides the height needed above the valve plane

DISTAL CURVE

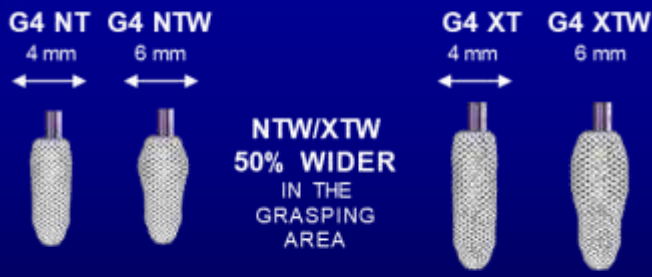
Anatomically designed for direct access to the valve

CONTROLLED GRIPPER ACTUATION

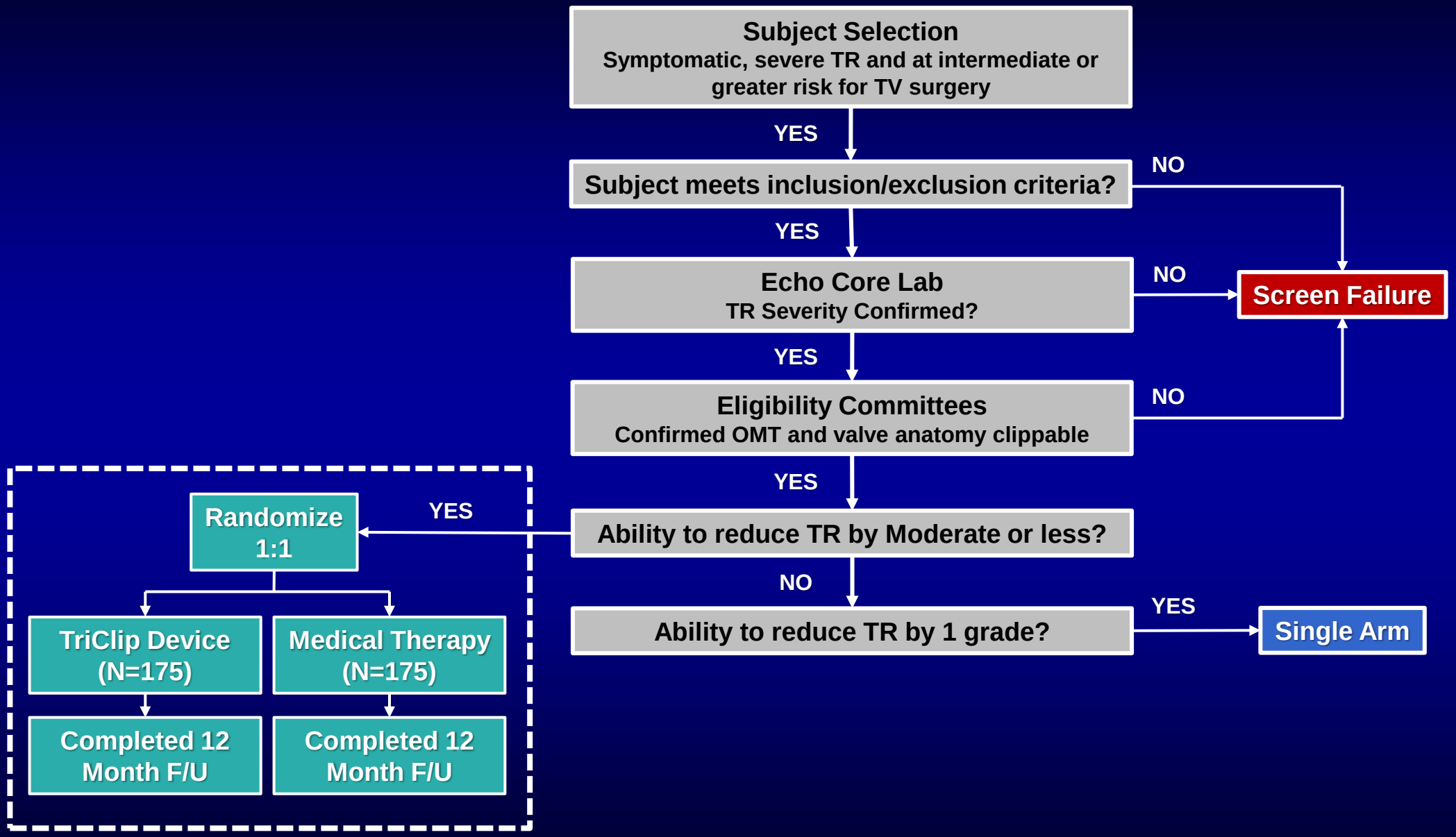
Ability to optimize leaflet grasping if needed

4 CLIP SIZES

Broad range of sizes for tailored treatment

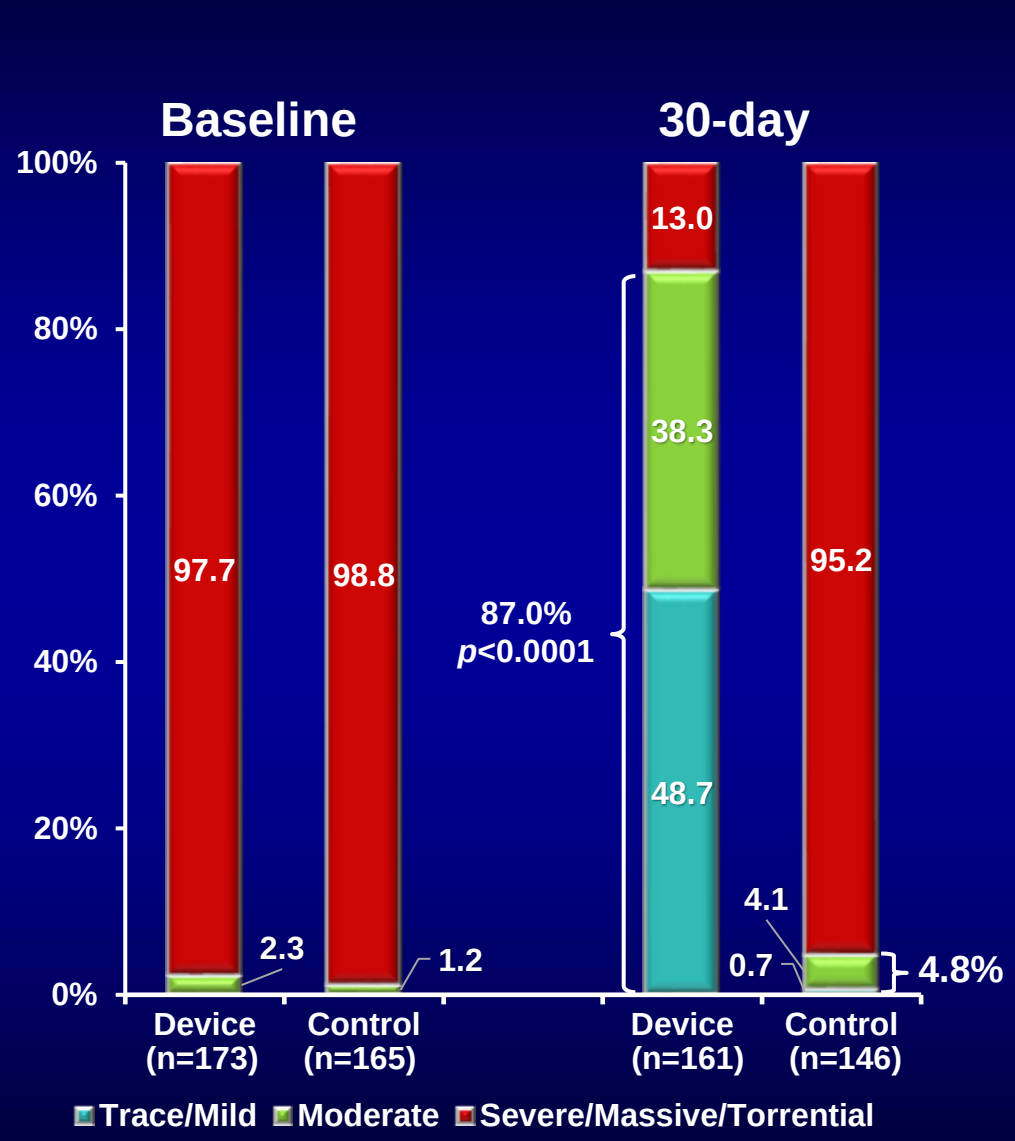


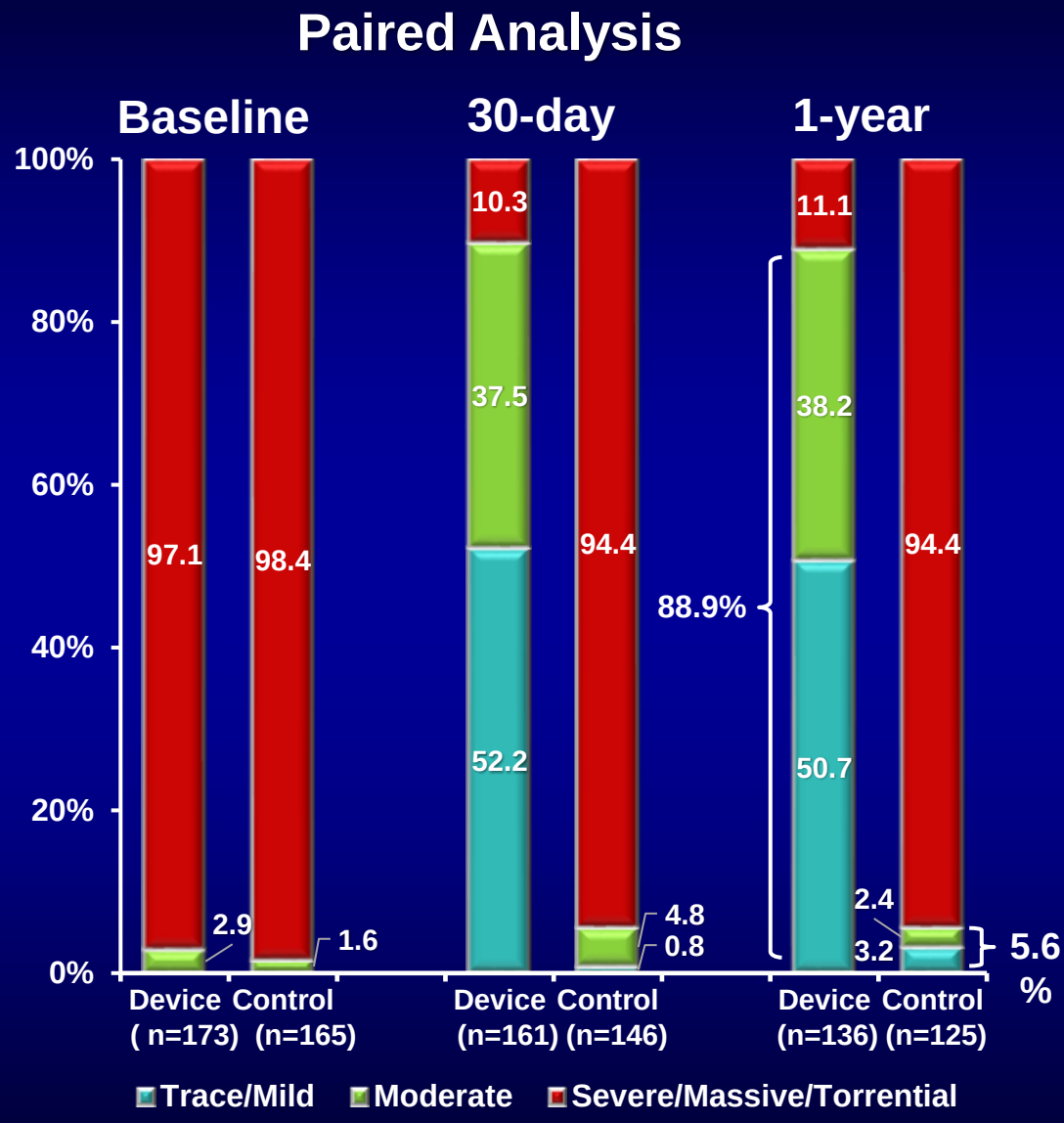
TRILUMINATE Trial: Enrollment and Treatment Pathway



Sorajja et al., N Engl J Med Mar 4, 2023 Epub ahead of print

TRILUMINATE Trial: Reduction in TR Severity

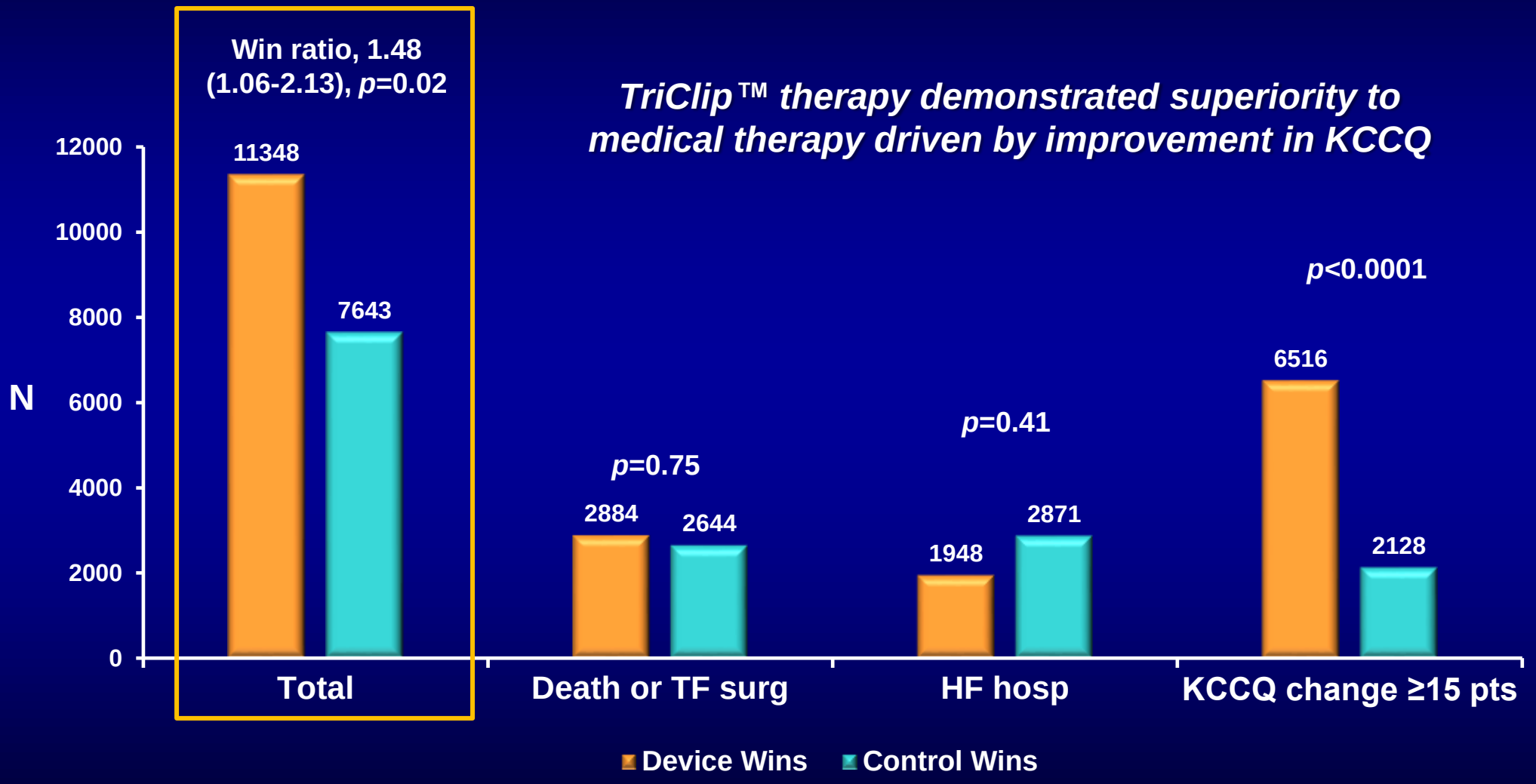




Sorajja et al., N Engl J Med Mar 4, 2023 Epub ahead of print

TRILUMINATE Trial: Primary Endpoint

Finkelstein-Schoenfeld Analysis

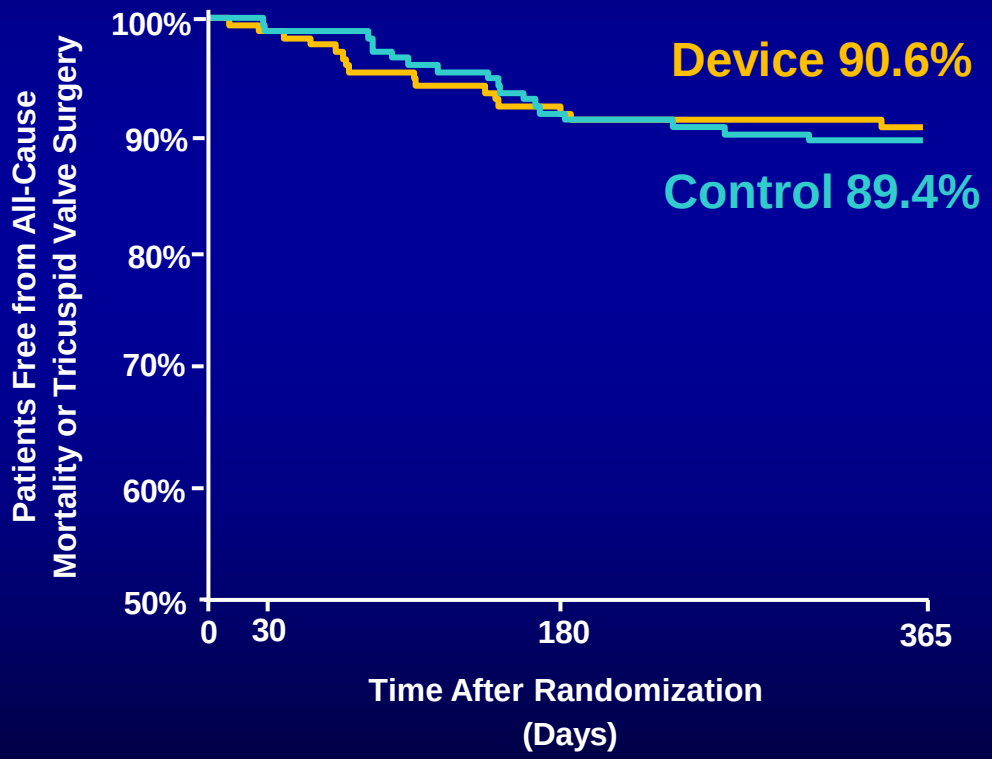


Sorajja et al., N Engl J Med Mar 4, 2023 Epub ahead of print

TRILUMINATE Trial: Individual Component Analysis

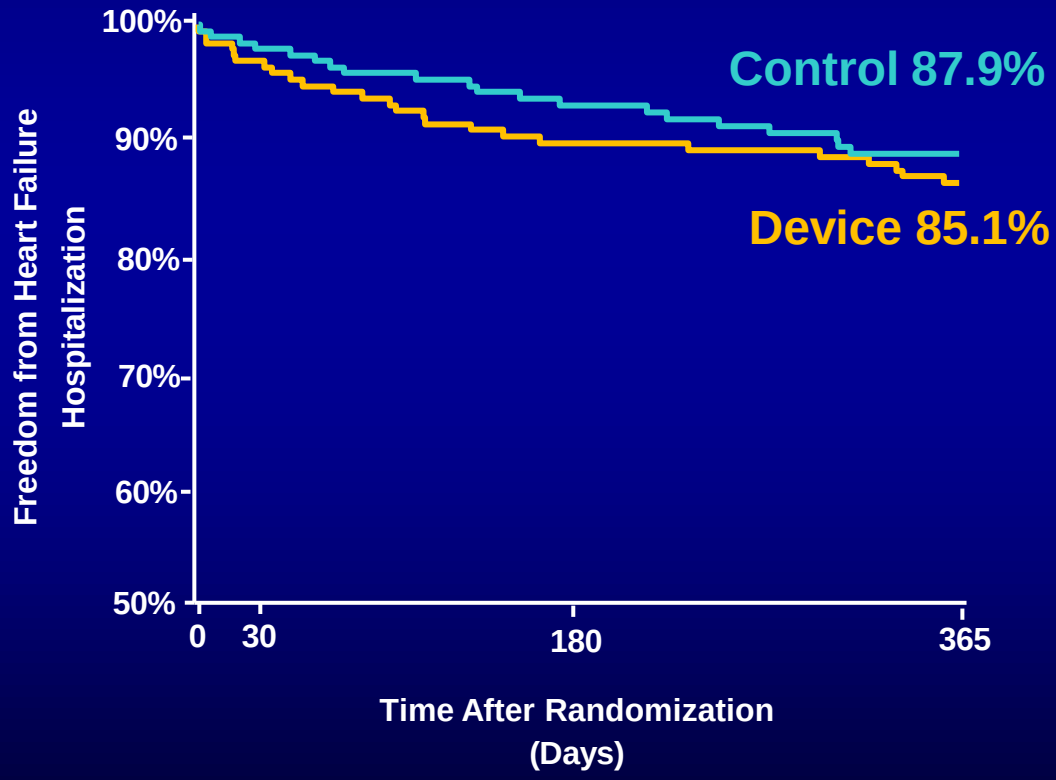
1st Component: Mortality or TV Surgery

p=0.75



2nd Component: Heart Failure Hospitalization

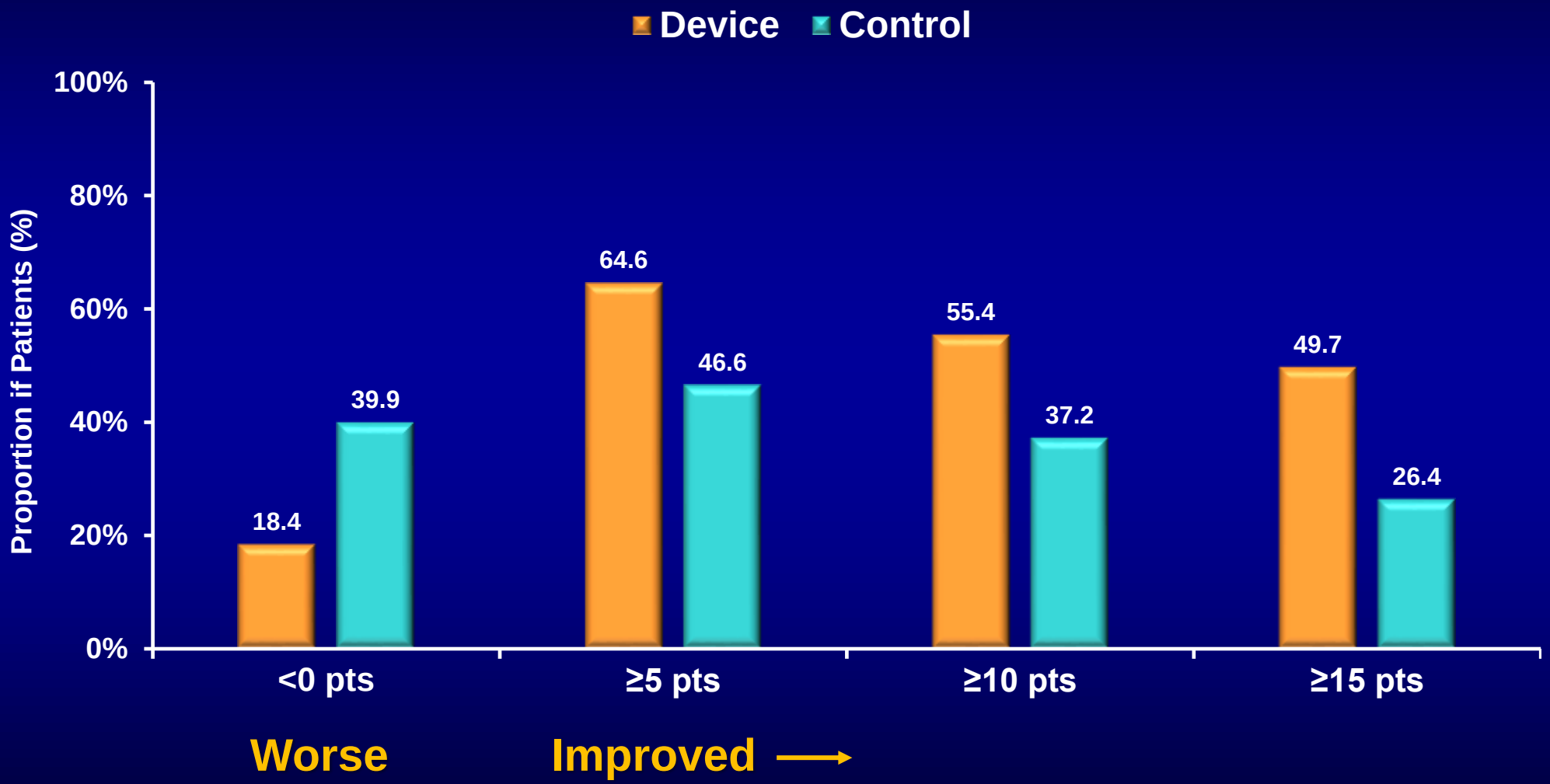
p=0.41



Sorajja et al., N Engl J Med Mar 4, 2023 Epub ahead of print

TRILUMINATE Trial: Quality of Life Improvement

KCCQ change ≥15 Patients, Baseline to 1 Year



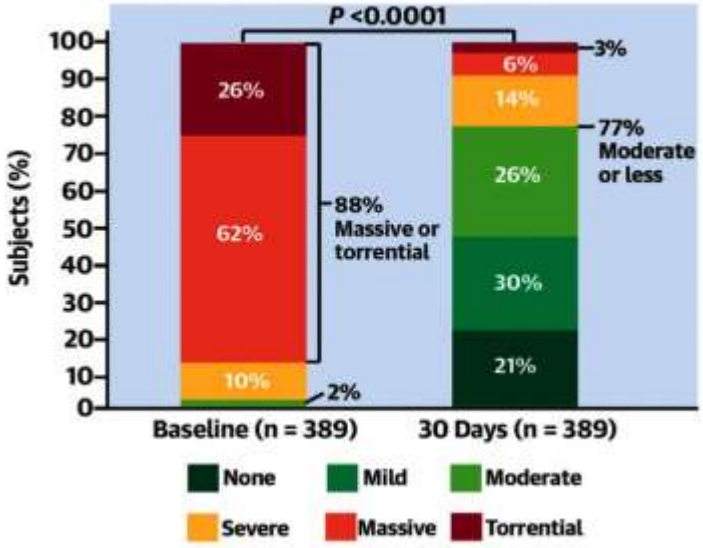
Sorajja et al., N Engl J Med Mar 4, 2023 Epub ahead of print

bRIGHT PAS Study: TTVR Safe and Effective in Real-World Population

Real-World Population

- Mean age: 78.9 years
- Mean LVEF 55.8%
- NYHA functional class III/IV: 88%
- Male: 44%
- Prior HF Hospitalization: 40.3%
- Baseline KCCQ score: 44.52

Reduction in TR at 30 Days



Safety Profile at 30 Days

Major Adverse Event	2.7%
• Cardiovascular mortality	0.8%
• Myocardial infarction	0.0%
• Stroke	0.4%
• New onset renal failure	1.4%
• Endocarditis requiring surgery	0.0%
• Nonelective CV surgery for device-related AE	0.2%

MAEs adjudicated by independent clinical events committee

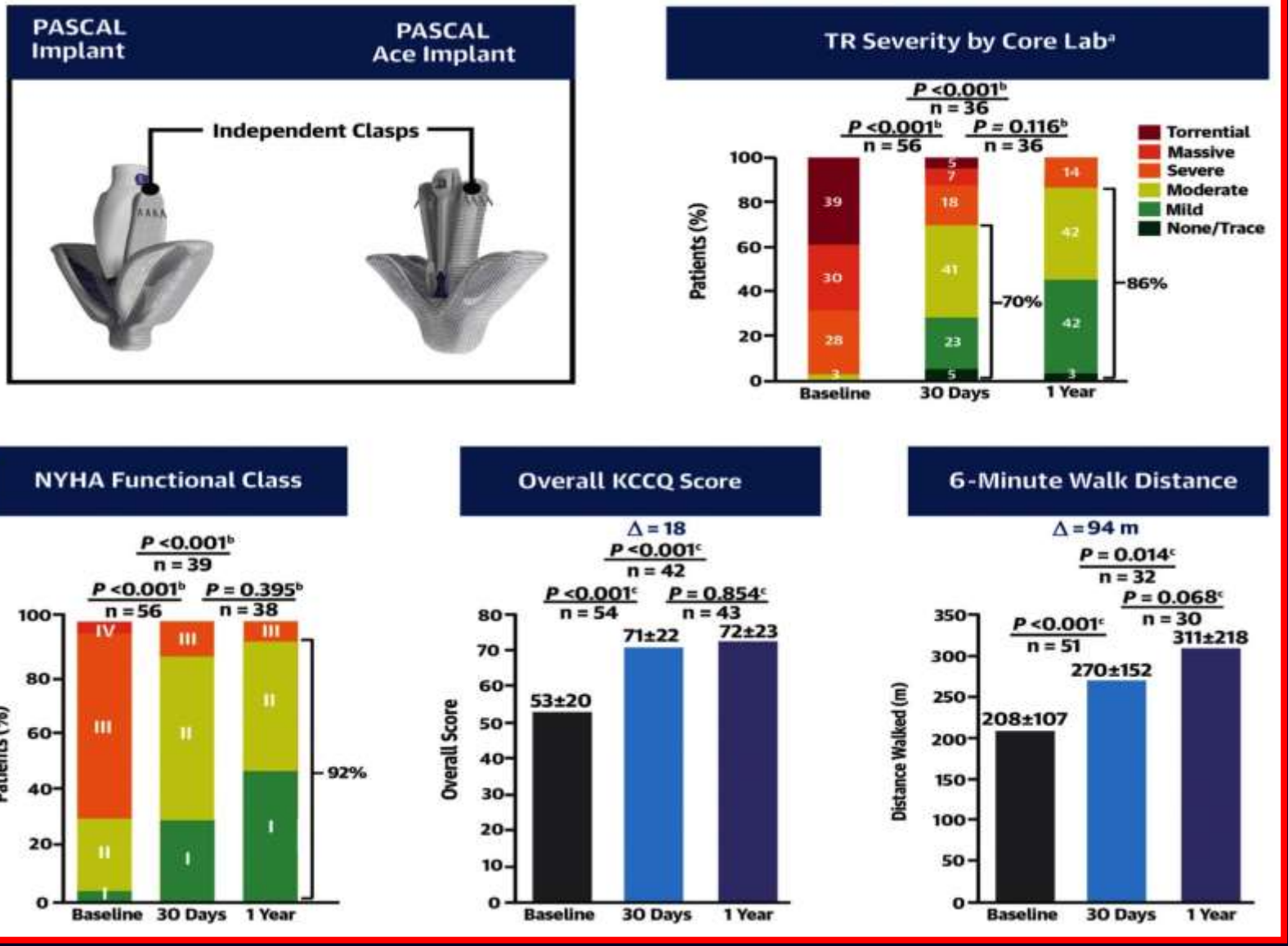
Lurz et al., J Am Coll Cardiol 2023;82:281

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 81, NO. 18, 2023

1-Year Outcomes of Transcatheter Tricuspid Valve Repair

Susheel K. Kodali, MD,[a] Rebecca T. Hahn, MD,[a,b] Charles J. Davidson, MD,[c] Akhil Narang, MD,[c] Adam Greenbaum, MD,[d] Patrick Gleason, MD,[d] Samir Kapadia, MD,[e] Rhonda Miyasaka, MD,[e] Firas Zahr, MD,[f] Scott Chadderdon, MD,[f] Robert L. Smith, MD,[g] Paul Grayburn, MD,[g] Robert M. Kipperman, MD,[h] Leo Marcoff, MD,[h] Brian Whisenant, MD,[i] Mike Gonzales, MD,[i] Raj Makkar, MD,[j] Moody Makar, MD,[j] William O'Neill, MD,[k] Dee Dee Wang, MD,[k] William A. Gray, MD,[l] Sandra Abramson, MD,[l] James Hermiller, MD,[m] Lucas Mitchel, MD,[m] D. Scott Lim, MD,[n] Dale Fowler, MD,[n] Mathew Williams, MD,[o] Sorin V. Pislaru, MD,[p] Abdellaziz Dahou, MD,[b] Michael J. Mack, MD,[g] Martin B. Leon, MD,[a] Mackram F. Eleid, MD[p]

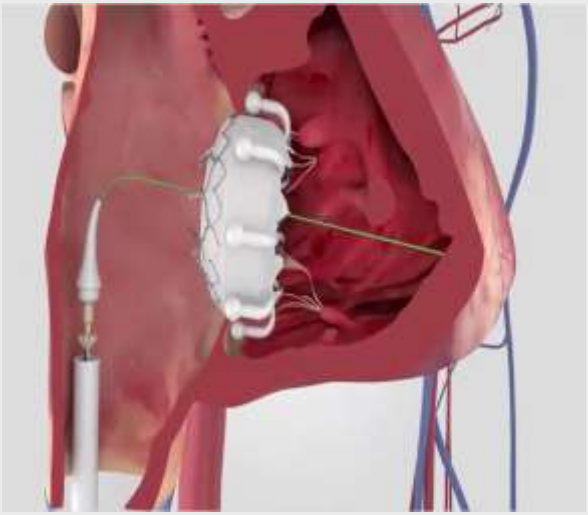
CLASP TR Study: The PASCAL Transcatheter Valve Repair System with Echo and Clinical Outcomes



Kodali et al., J Am Coll Cardiol 2023;81:1766

TRISCEND: EVOQUE Tricuspid Valve Replacement System

***Unique valve design* engages leaflets, chords, and annulus to achieve secure placement**



Anchors compatible with pre-existing leads and respect the native anatomy

Conforming frame designed to achieve optimal retention force

Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (44, 48, 52 mm)

28F transfemoral delivery system compatible with all valve sizes

Patients with symptomatic ≥moderate tricuspid regurgitation

↓

Heart team assessment

- Functional or degenerative TR
- Signs and/or symptoms or prior heart failure hospitalizations from TR despite optimal medical therapy

↓

EVOQUE valve replacement system

Endpoints:
Device and procedural success
Composite of major adverse events (MAEs) at 30 days TR reduction

Follow-up: 30 days, 6 months, 1 year, and annually up to 5 years

NCT04221490

The 28-F EVOQUE Tricuspid Delivery System

Kodali S, TCT 2021

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 15, NO. 5, 2022

PUBLISHED BY ELSEVIER

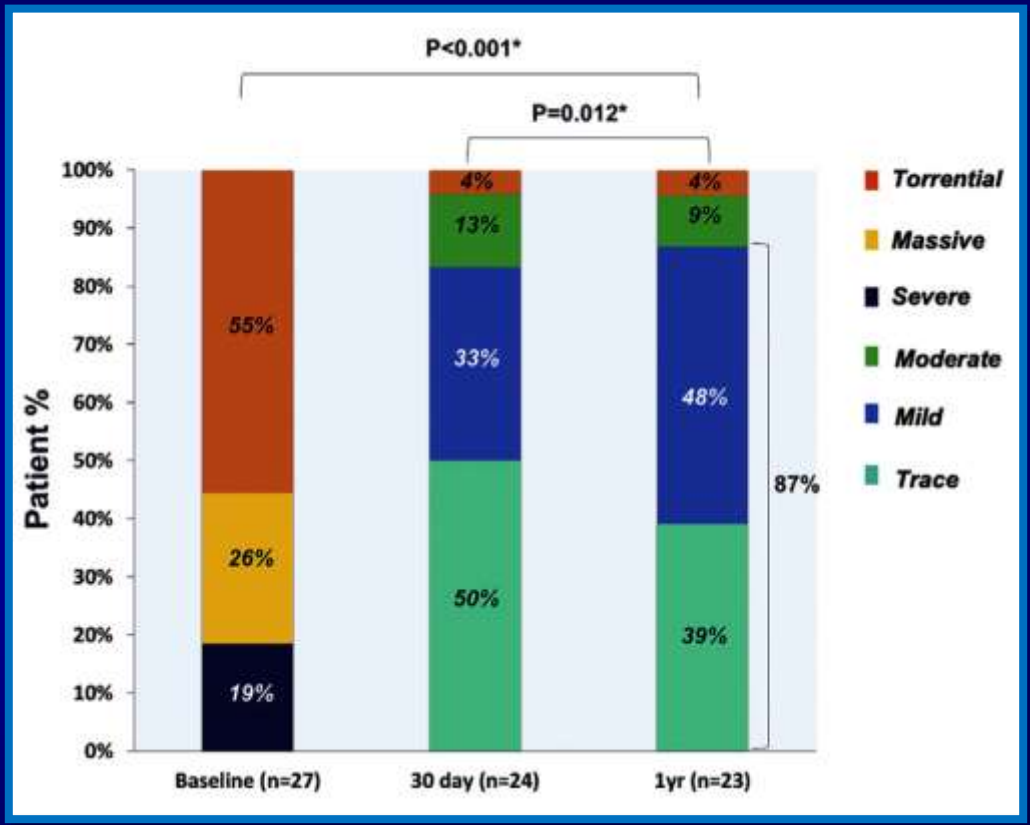
Transcatheter Tricuspid Valve Replacement With the EVOQUE System

1-Year Outcomes of a Multicenter, First-in-Human Experience

John G. Webb, MD,[a] Anthony (Ming-yu) Chuang, MBBS, MMED,[a] David Meier, MD,[a] Ralph Stephan von Bardeleben, MD,[b] Susheel K. Kodali, MD,[c] Robert L. Smith, MD,[d] Jörg Hausleiter, MD,[e,f] Geraldine Ong, MD,[g] Robert Boone, MD,[a] Tobias Ruf, MD,[b] Isaac George, MD,[c] Molly Szerlip, MD,[d] Michael Näbauer, MD,[e,f] Faeez M. Ali, MD,[g] Robert Moss, MD,[a] Felix Kreidel, MD,[b] Vinayak Bapat, MD,[d] Katharina Schnitzler, MD,[e,f] Jian Ye, MD,[a] Mirjam Wild, MD,[e,f] Mariama Akodad, MD, PHD,[a] Djeven P. Deva, MD,[g] Andrew G. Chatfield, MD,[a] Michael J. Mack, MD,[d] Paul A. Grayburn, MD,[d] Mark D. Peterson, MD,[g] Raj Makkar, MD,[h] Martin B. Leon, MD,[c] Rebecca T. Hahn, MD,[c] Neil P. Fam, MD, MSc[g]

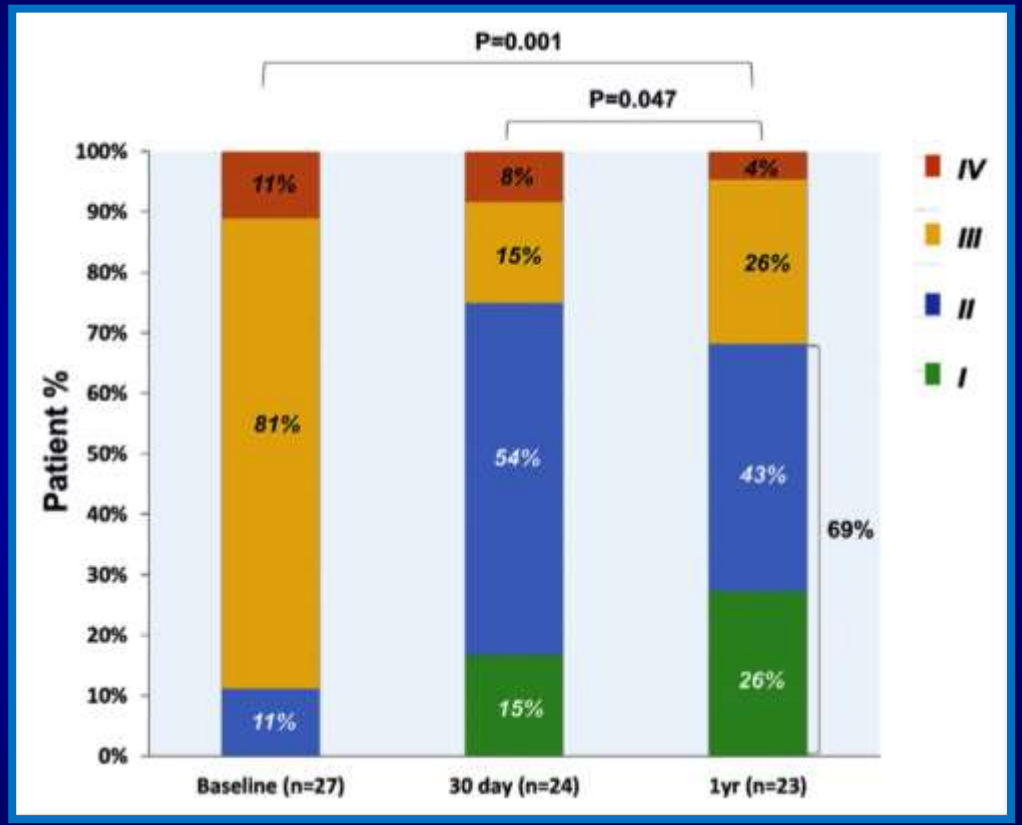
EVOQUE System: Comparison of TR Severity and NYHA Functional Class at Baseline, 30 Days and 1 Year

TR Severity



Sustained TR reduction observed with TR grade ≤2+ in 96% and ≤1+ in 87% at 1 year

NYHA Functional Class



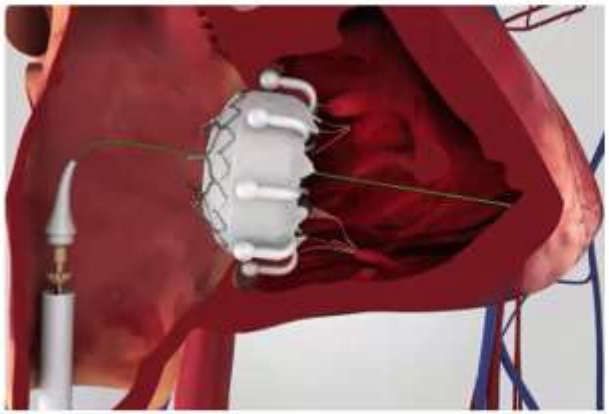
Functional class improvements occurred mostly within the first month postprocedure; no significant differences in NYHA class between 30-day and 1-year F/U

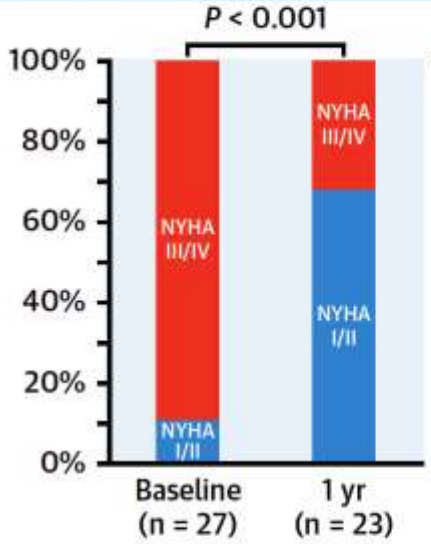
Webb et al., J Am Coll Cardiol Intv 2022;15:481

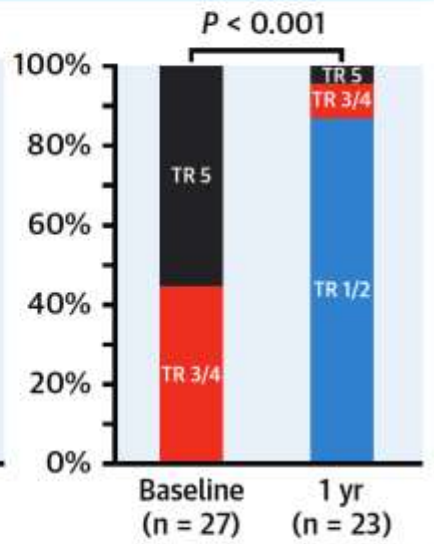
EVOQUE System: 1-Year Transfemoral TTVR for Severe TR

EVOQUE Transfemoral Tricuspid Replacement

1-Year Clinical and Echocardiographic Outcomes







27 patients with severe TR
treated with the EVOQUE system
7 sites (Canada, Europe, U.S.)
May 2019 to July 2020

All-cause mortality: 7%
HF hospitalization: 7%
New pacemaker: 7% within 30 days,
4% beyond 30 days

Sustained improvement in NYHA functional class as well as improvement in TR degree suggesting that the EVOQUE System is a promising treatment option for this population

- EVOQUE TTVR system found to be safe and effective
- Low mortality and HF rehospitalization observed in fragile-high-risk population
- TR significantly reduced with 96% of subjects achieving TR grade of <2+
- Associated with sustained functional improvement with proportion of pts classified as NYHA functional class I/II from 11% at baseline to 70% at 1 year

Webb et al., J Am Coll Cardiol Intv 2022;15:481

TRISCEND II Pivotal Trial

Edwards EVOQUE Transcatheter Tricuspid Valve Replacement: Pivotal Clinical Investigation of Safety and Clinical Efficacy Using a Novel Device (NCT04482062)

Summary	**Multicenter, randomized controlled pivotal clinical trial to evaluate the safety and effectiveness of the EVOQUE System with optimal medical therapy (OMT) compared to OMT alone in the treatment of patients with at least severe tricuspid regurgitation (TR). Patients will be followed at discharge, 30 days, 3 months, 6 months and annually through 5 years.**
Primary Outcome	**• TR Grade reduction and composite endpoint including: KCCQ improvement, NYHA functional class improvement, and 6MWD improvement** **• Rate of Major Adverse Events (MAE)** **• Composite endpoint including all-cause mortality, RVAD implantation or heart transplant, tricuspid valve intervention, HF hospitalizations, KCCQ improvement, NYHA functional class improvement, and 6MWD improvement**
Secondary Outcome	**Composite endpoint including reduction in TR grade, change in QoL from baseline, death and HF hospitalization, all-cause hospitalization, all-cause mortality, and change in right ventricular end diastolic volume index**

Top 10 Advances in Transcatheter Valve Therapy 2022

1.
2. **Mid-longterm TAVR vs SAVR:** NOTION, PARTNER-3, EVOLUT LR
3. **TTVR Emerging:** TRILUMINATE 1Yr, bRIGHT Pass, TRANSCEND
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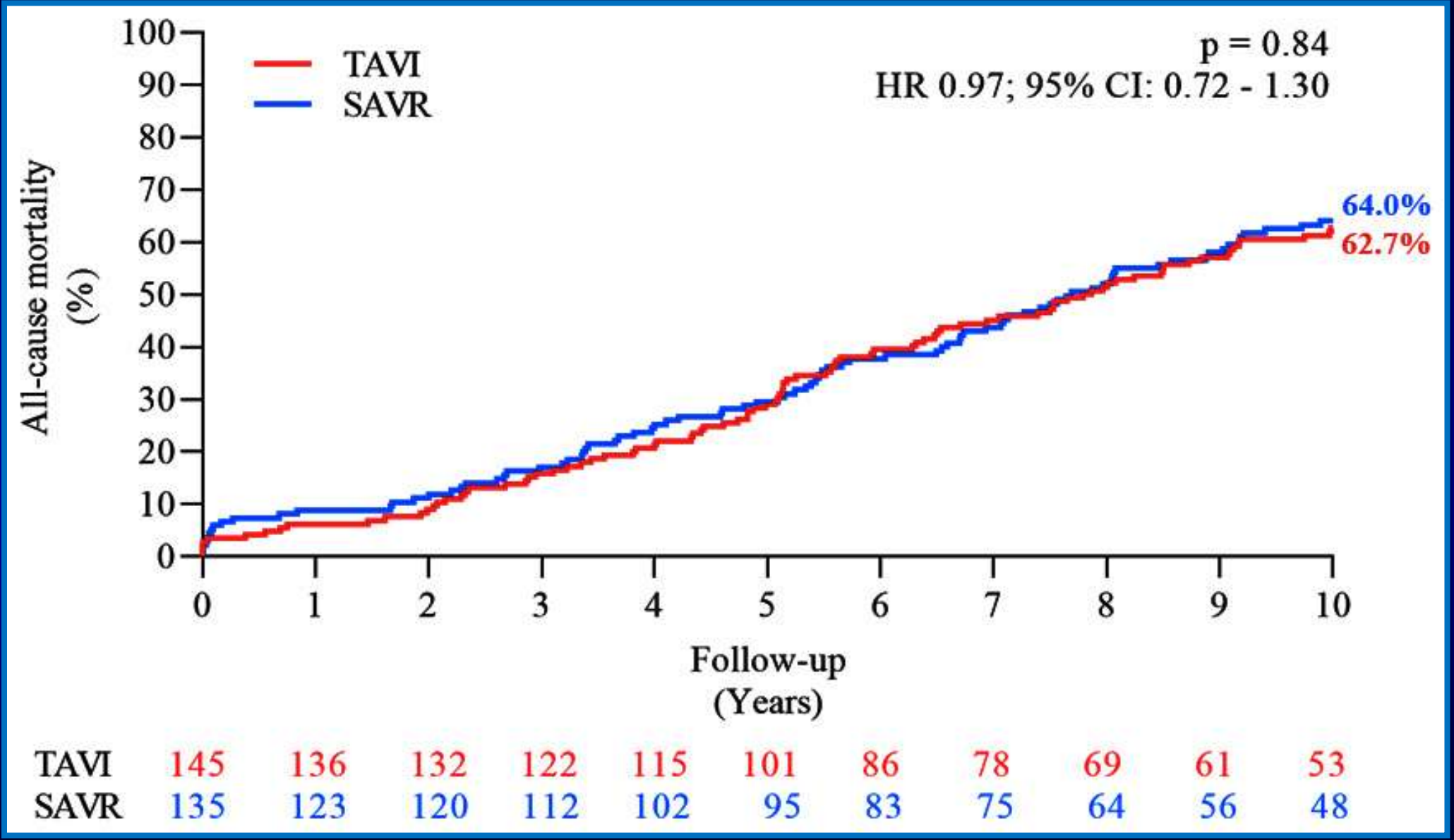
10. **LAAO for Afib during TAVR:** WATCH TAVR

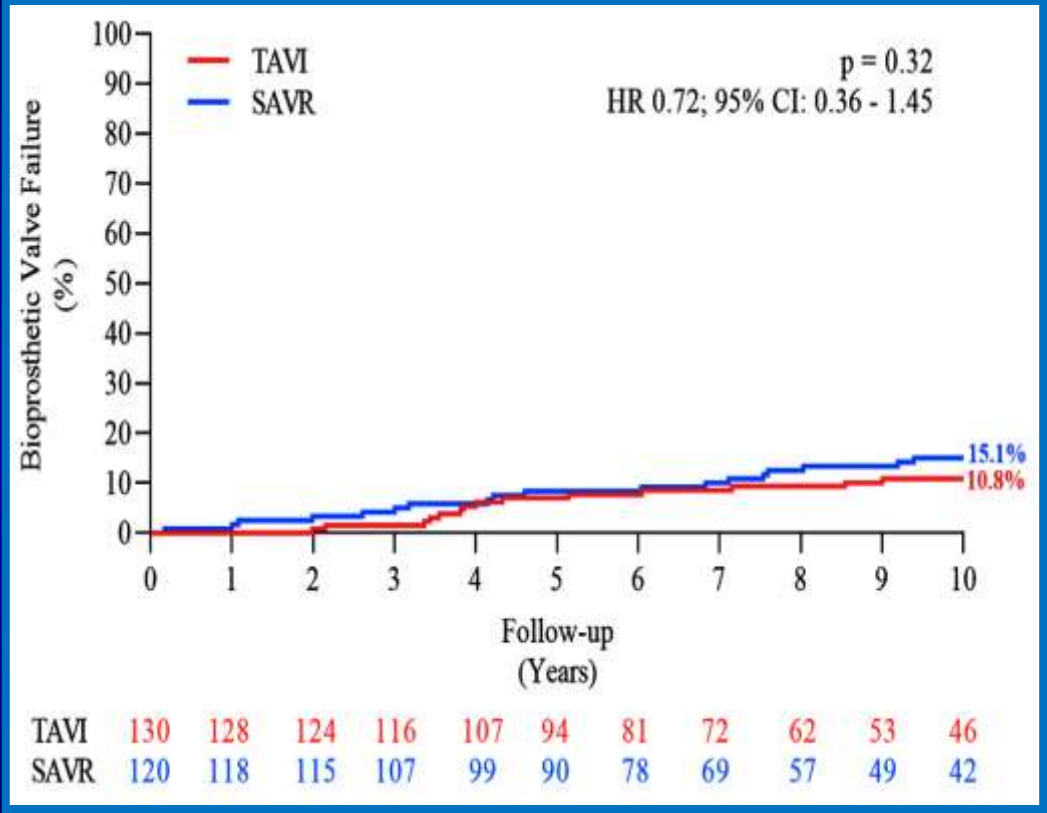
The NOTION Trial (Denmark)
Ten-Year Follow-Up After Transcatheter or Surgical Aortic Valve Implantation in Severe Aortic Valve Stenosis

NOTION Trial: All-Cause Mortality at 10 Years



Jorgensen T, EuroPCR 2023

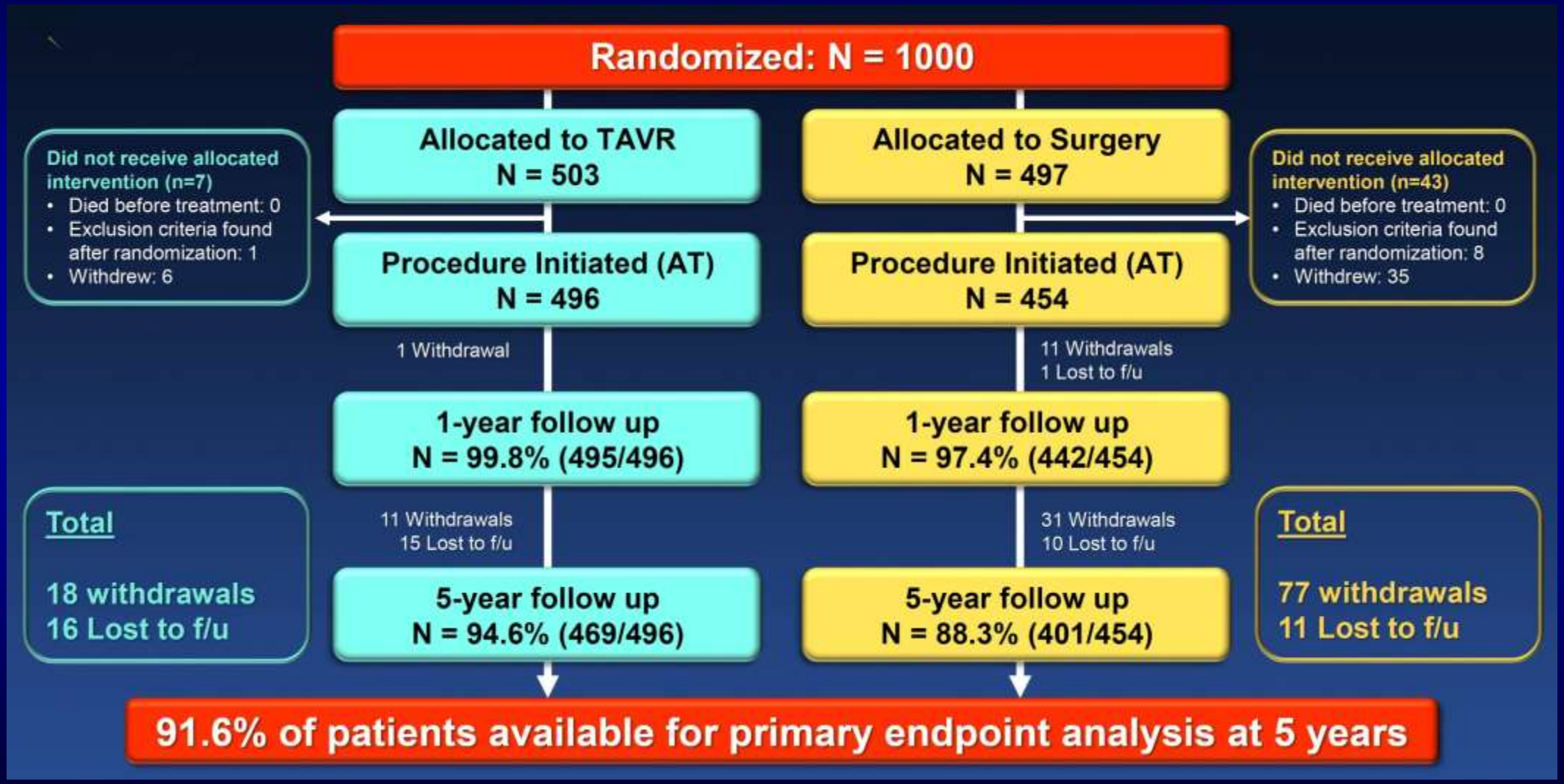
NOTION Trial: Bioprosthetic Valve Failure at 10 Years



	TAVR (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

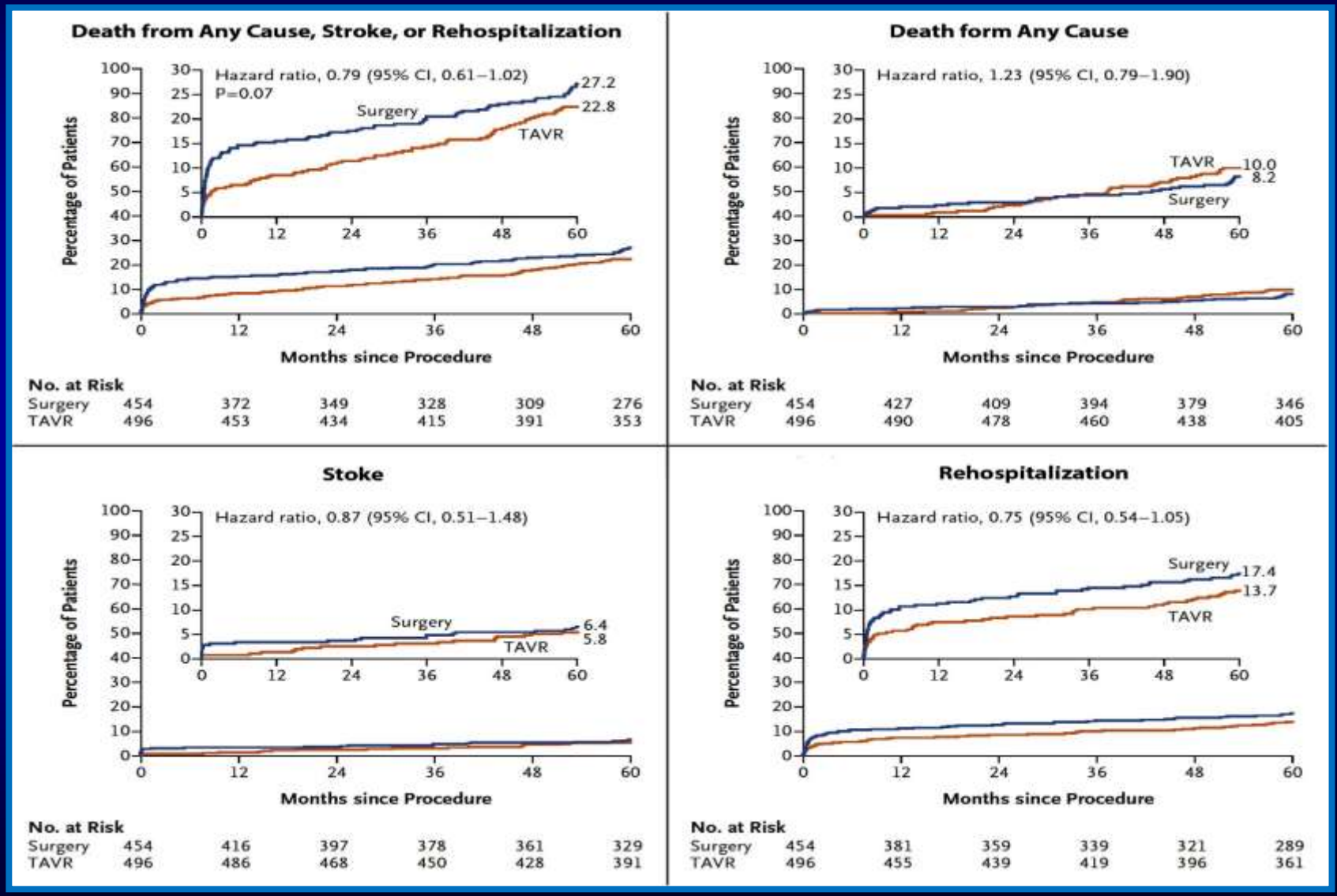
Jorgensen T, EuroPCR 2023

PARTNER 3 Trial: Patient Disposition to 5 Years



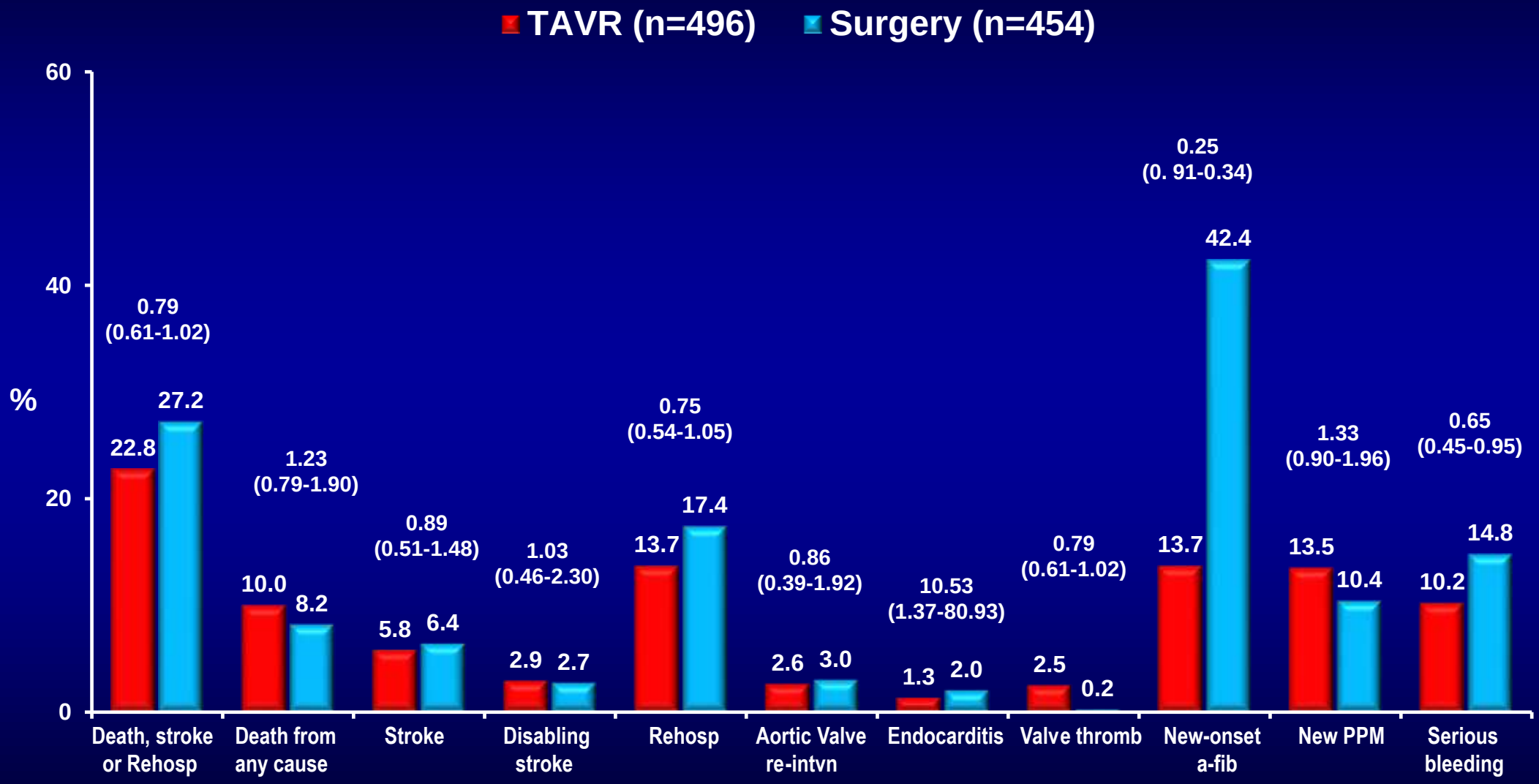
Mack et al., N Engl J Med 2023;389:1949

PARTNER 3 Trial: Primary Endpoint and Its Components



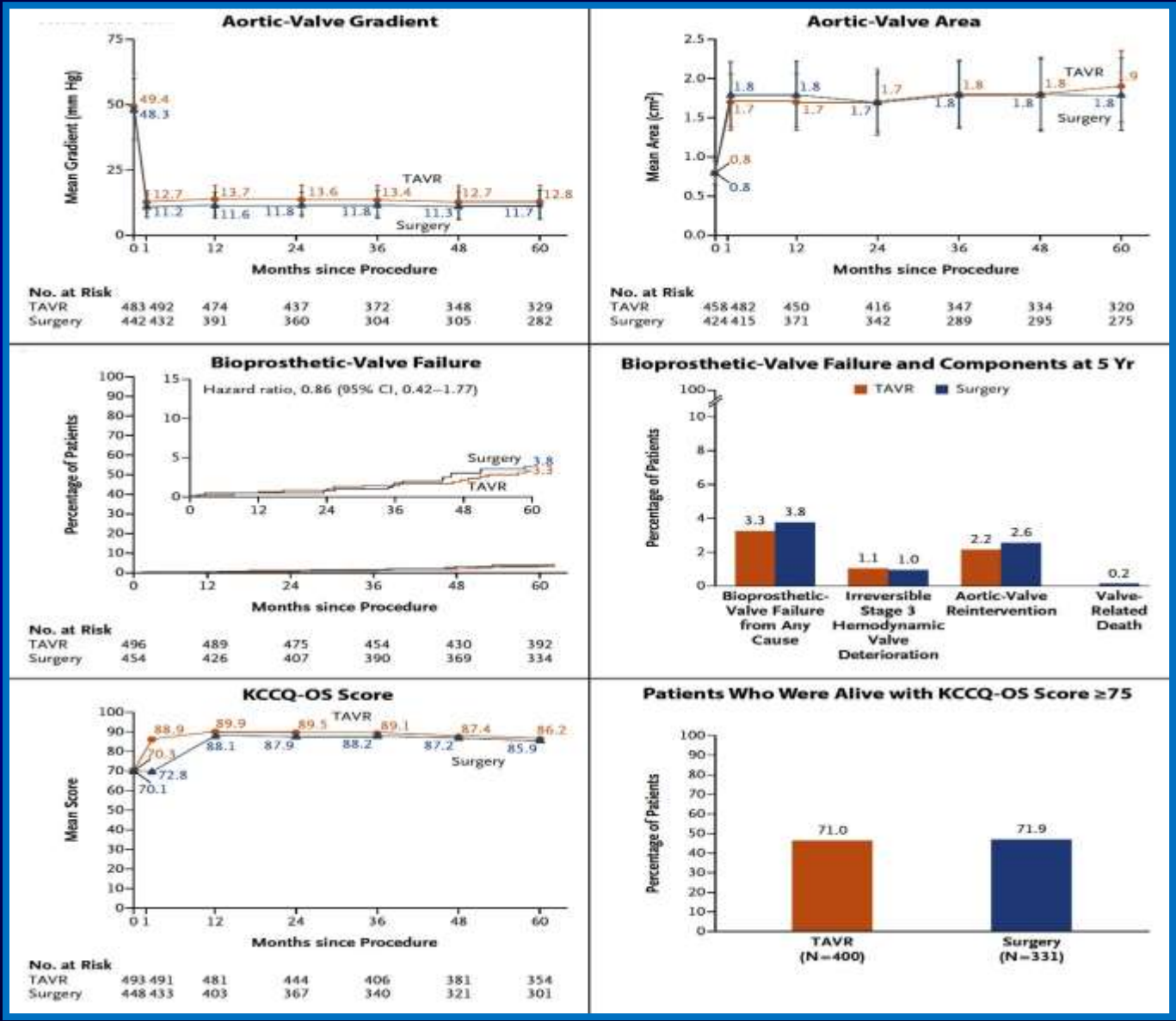
Mack et al., N Engl J Med 2023;389:1949

PARTNER 3 Trial: Key Clinical Endpoints



Mack et al., N Engl J Med 2023;389:1949

PARTNER 3 Trial: Echo Outcomes, Bioprosthetic-Valve Failure, and QoL Outcomes



Mack et al., N Engl J Med 2023;389:1949

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

CONCLUSIONS

Among low-risk patients with severe, symptomatic aortic stenosis who underwent TAVR or surgery, there was no significant between-group difference in the two primary composite outcomes. (Funded by Edwards Lifesciences; PARTNER 3 ClinicalTrials.gov number, NCT02675114.)

Evolut Low Risk Trial: 4-Year Results

Study Design

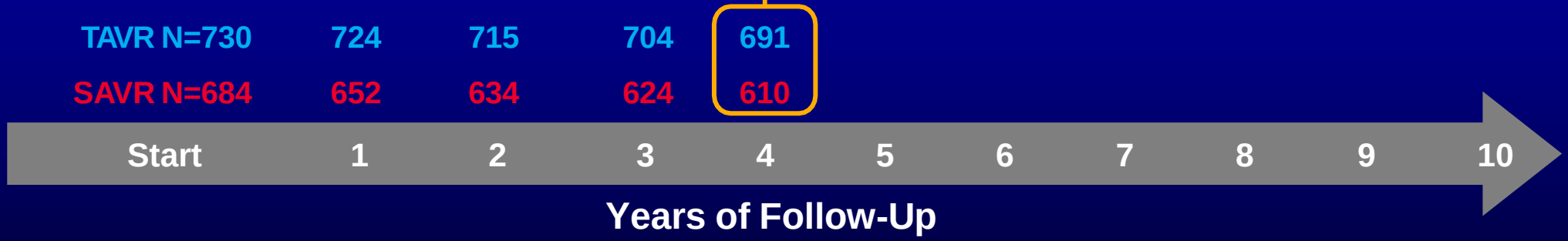
Patients with Severe AS
Low risk death (<3%) from surgery
Anatomy suitable for both TAVR and SAVR

Screening Committee
Confirmed eligibility

1:1 Randomization
May 2016 to May 2019
1414 Patients

Clinical Events Committee
Echo Core Laboratory

Evaluable status[a] at 4Y
94.7% TAVR
89.2% Surgery



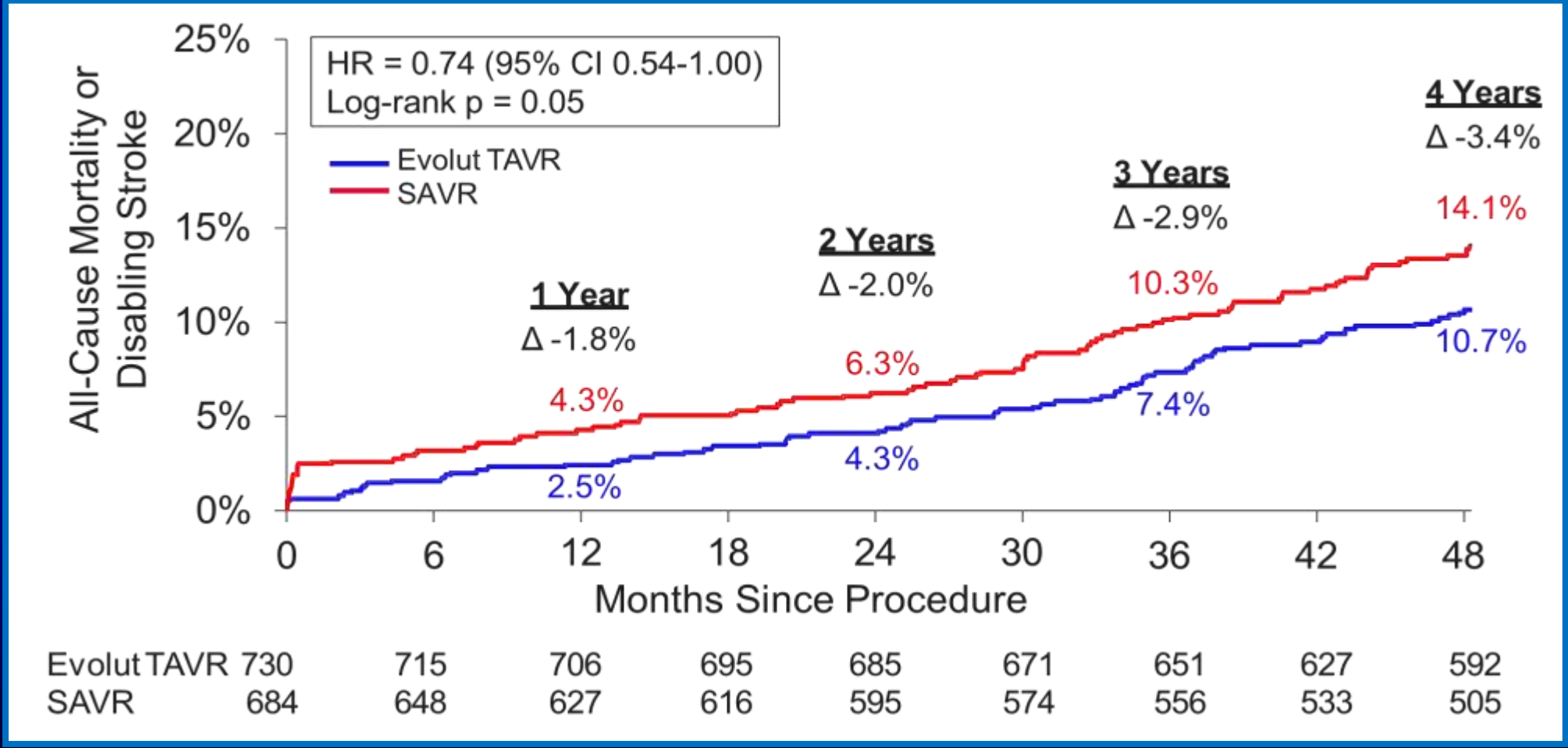
[a]Evaluable status was calculated as the number of patients expected after withdrawal and loss to follow-up, and included death as known status for each time point.

Reardon M, TCT 2023

Evolut Low Risk Trial: 4-Year Results

Primary Endpoint: All-Cause Mortality and Disabling Stroke

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



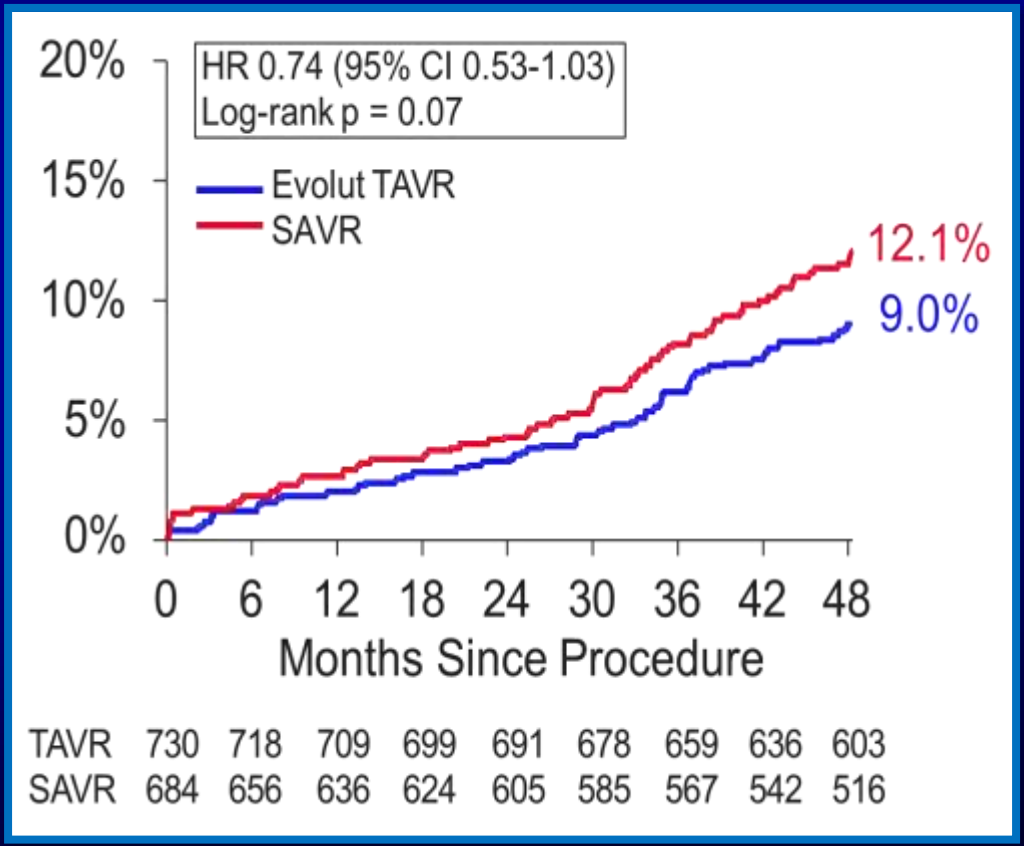
Reardon M, TCT 2023

Evolut Low Risk Trial: 4-Year Results

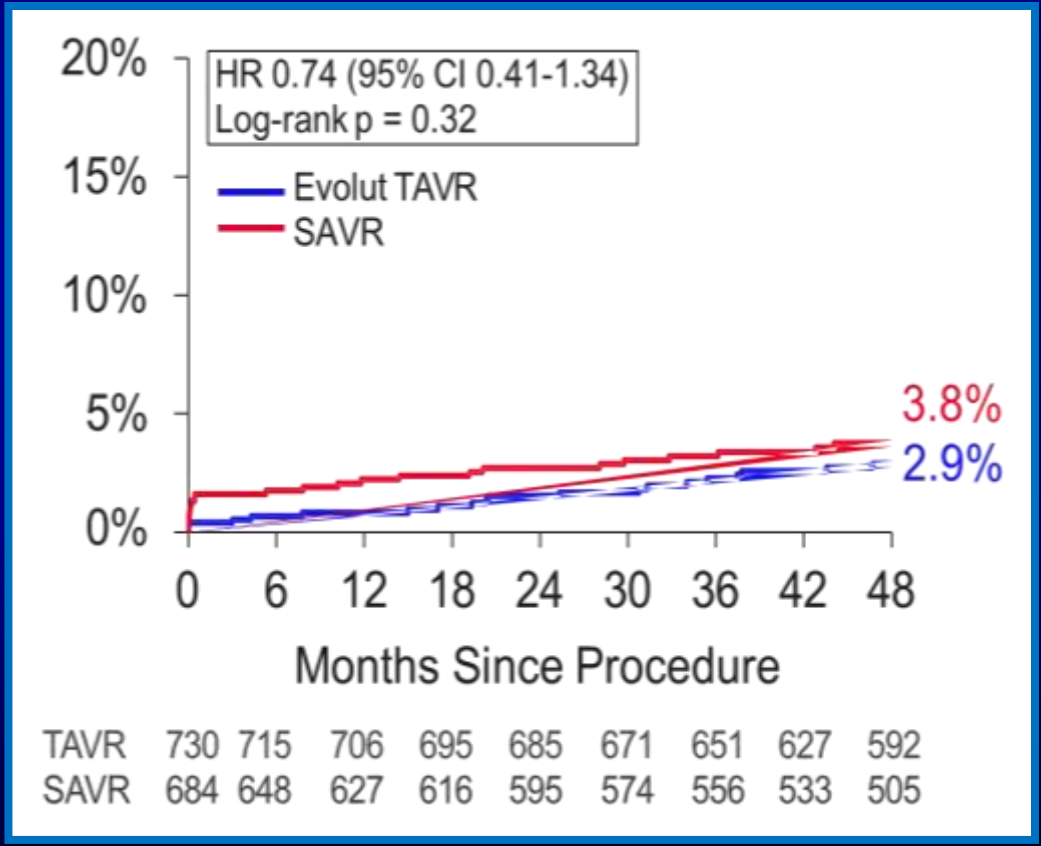
All-Cause Mortality and Disabling Stroke

Observed Differences in the Primary Endpoint Driven by Death

All-Cause Mortality



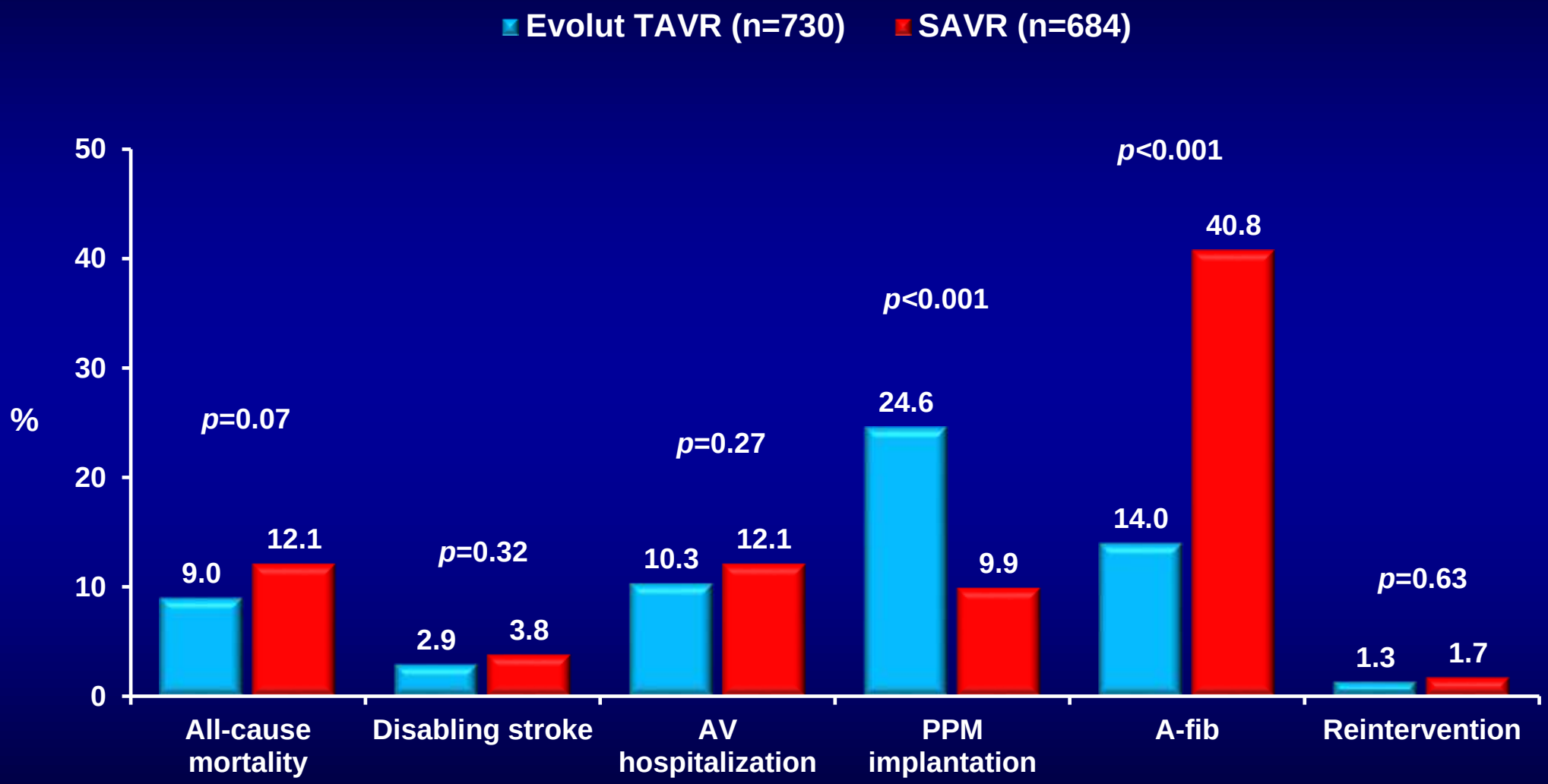
Disabling Stroke



Reardon M, TCT 2023

Evolut Low Risk Trial: 4-Year Results

Secondary Endpoints

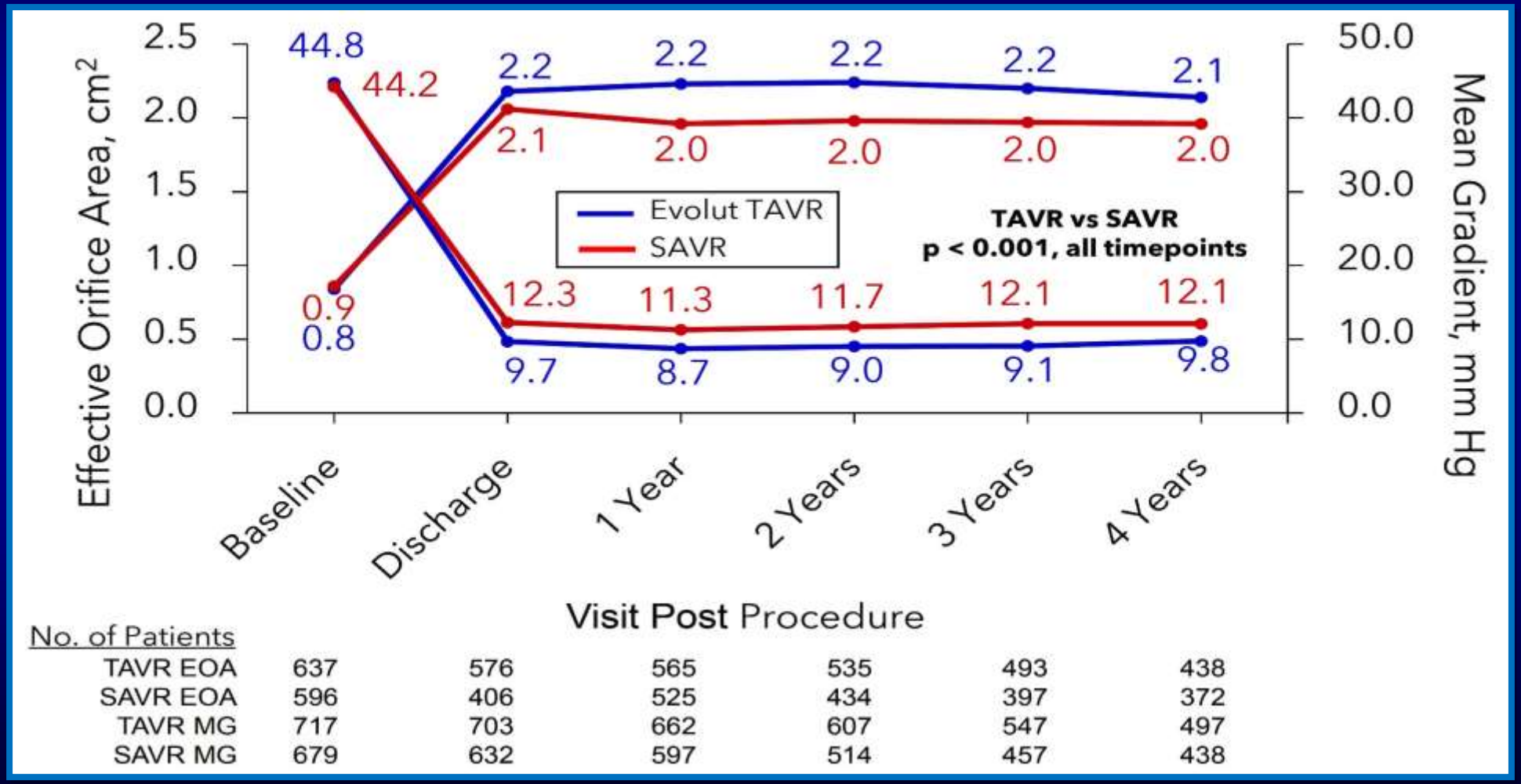


Reardon M, TCT 2023

Evolut Low Risk Trial: 4-Year Results

Comparative Hemodynamics

Significantly Better Hemodynamics with Evolut TAVR vs SAVR



No. of Patients						
TAVR EOA	637	576	565	535	493	438
SAVR EOA	596	406	525	434	397	372
TAVR MG	717	703	662	607	547	497
SAVR MG	679	632	597	514	457	438

Reardon M, TCT 2023

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JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 82, NO. 8, 2023

PUBLISHED BY ELSEVIER

THE PRESENT AND FUTURE

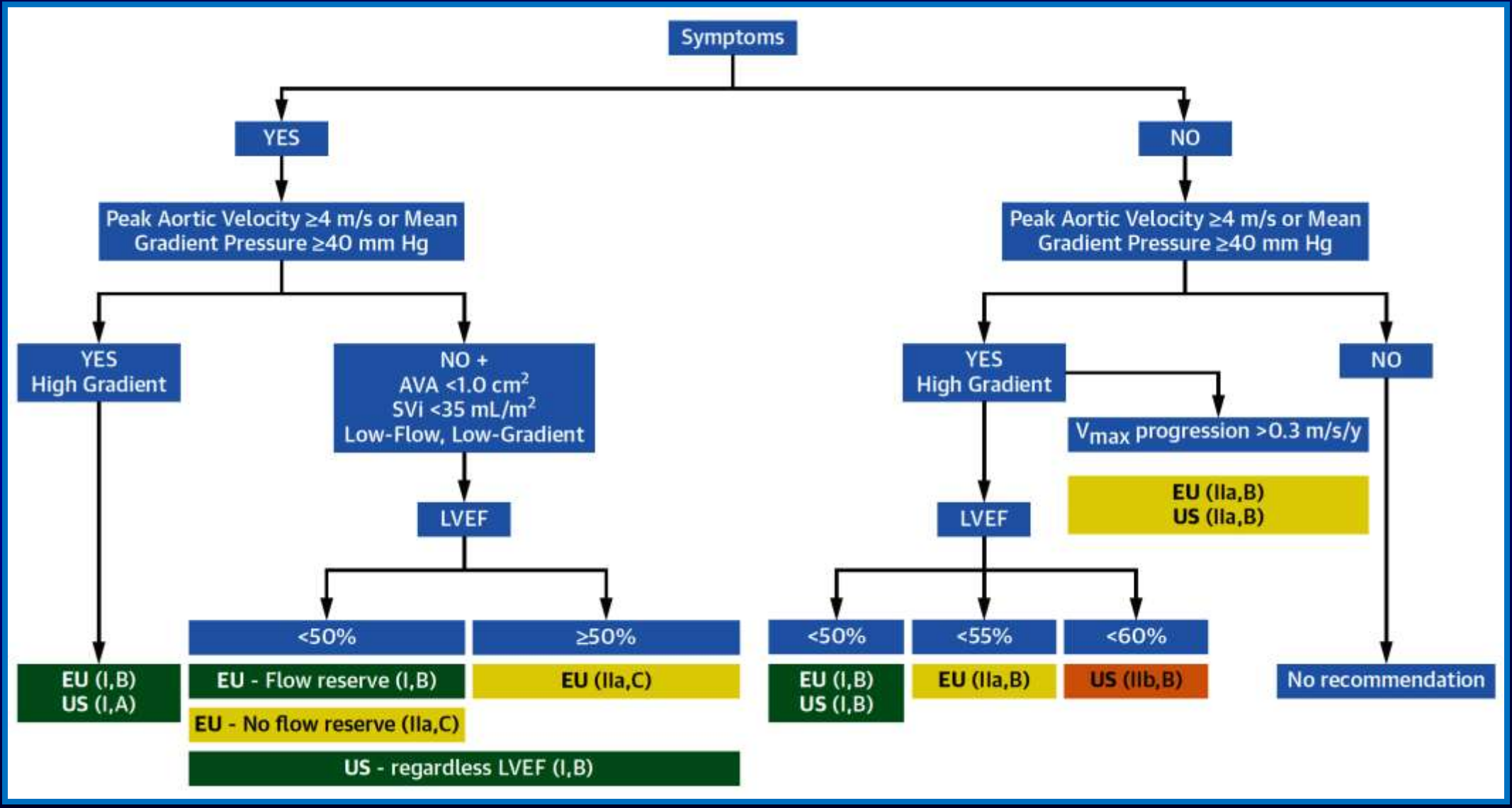
JACC GUIDELINE COMPARISON

ACC/AHA and ESC/EACTS Guidelines for the Management of Valvular Heart Diseases

JACC Guideline Comparison

Augustin Coisne, MD, PhD,[a,b] Patrizio Lancellotti, MD, PhD,[c,d] Gilbert Habib, MD, PhD,[e] Madalina Garbi, MD,[f] Jordi Sanchez Dahl, MD, PhD,[g] Marco Barbanti, MD,[h] Mani A. Vannan, MD,[i] Vassilios S. Vassiliou, MD,[j] Dariusz Dudek, MD,[k] Ovidiu Chioncel, MD,[l,m] Johannes L. Waltenberger, MD, PhD,[n,o] Victoria L. Johnson, MD,[p] Ruggero De Paulis, MD,[q] Rodolfo Citro, MD, PhD,[r,s] Philippe Pibarot, DVM, PhD,[t]
on behalf of the EuroValve Consortium

Management of Patients with Severe Aortic Stenosis



Coisne et al., J Am Coll Cardiol 2023;82:721

Mode of Intervention When Aortic Valve Replacement Is Indicated for Aortic Stenosis

Age 75 years

SAVR
AND STS-Prom / EuroScore <4 (I-B)

TAVR
STS-Prom / EuroScore <8 OR non SAVR candidates (I-A)

Age

SAVR
AND life expectancy >20 y (I-A)

SAVR or TAVR
after shared-decision making

TAVR
OR life expectancy <10 years AND femoral access (I-A)

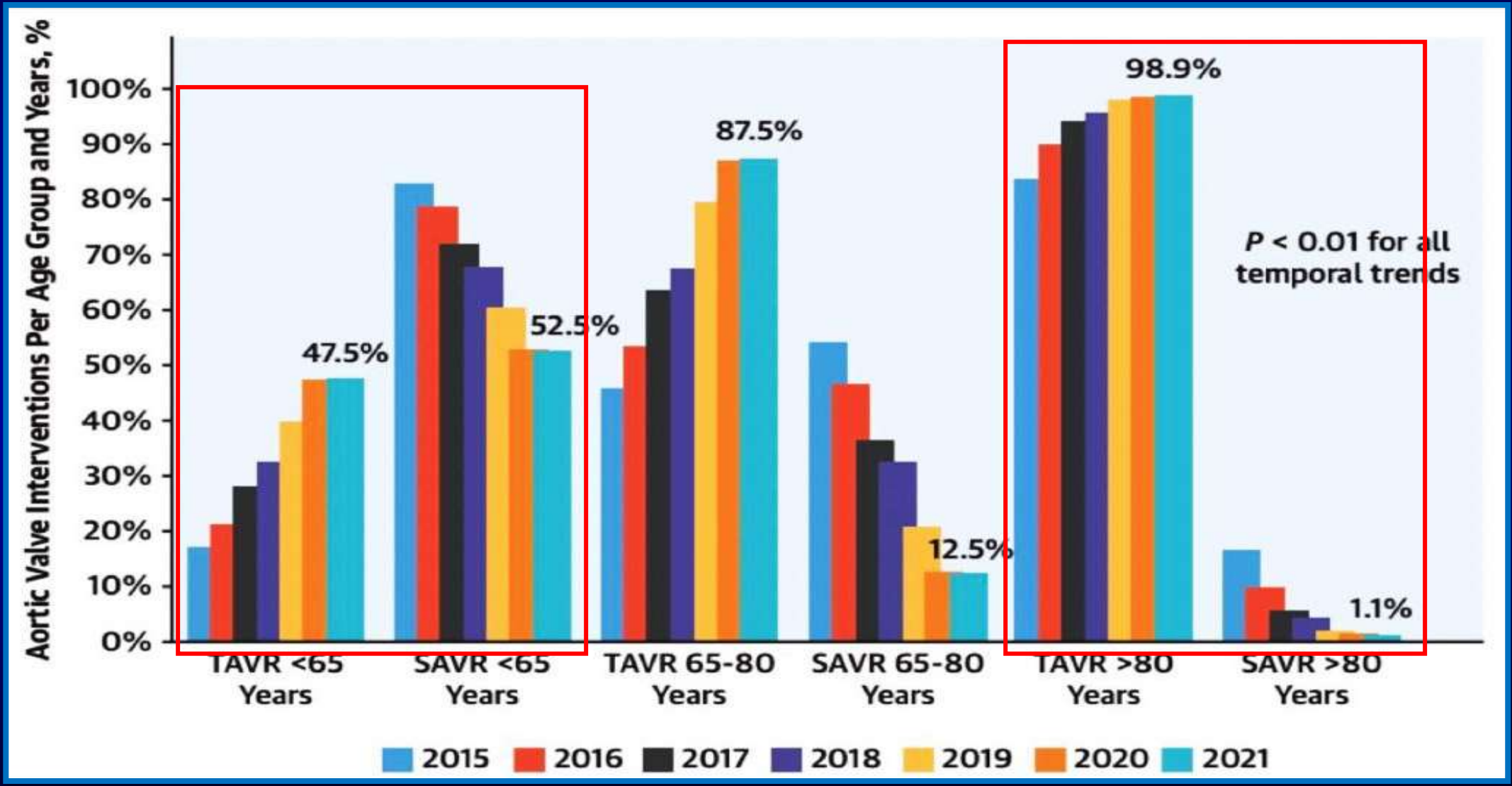
Age 65 years

Age 80 years

Coisne et al., J Am Coll Cardiol 2023;82:721

Aortic Valve Interventions Per Age Group & Years

National Vizient Clinical Database; N=279,066 pts undergoing alone TAVR or SAVR from 10/2015 to 12/2021 in >300 US centers



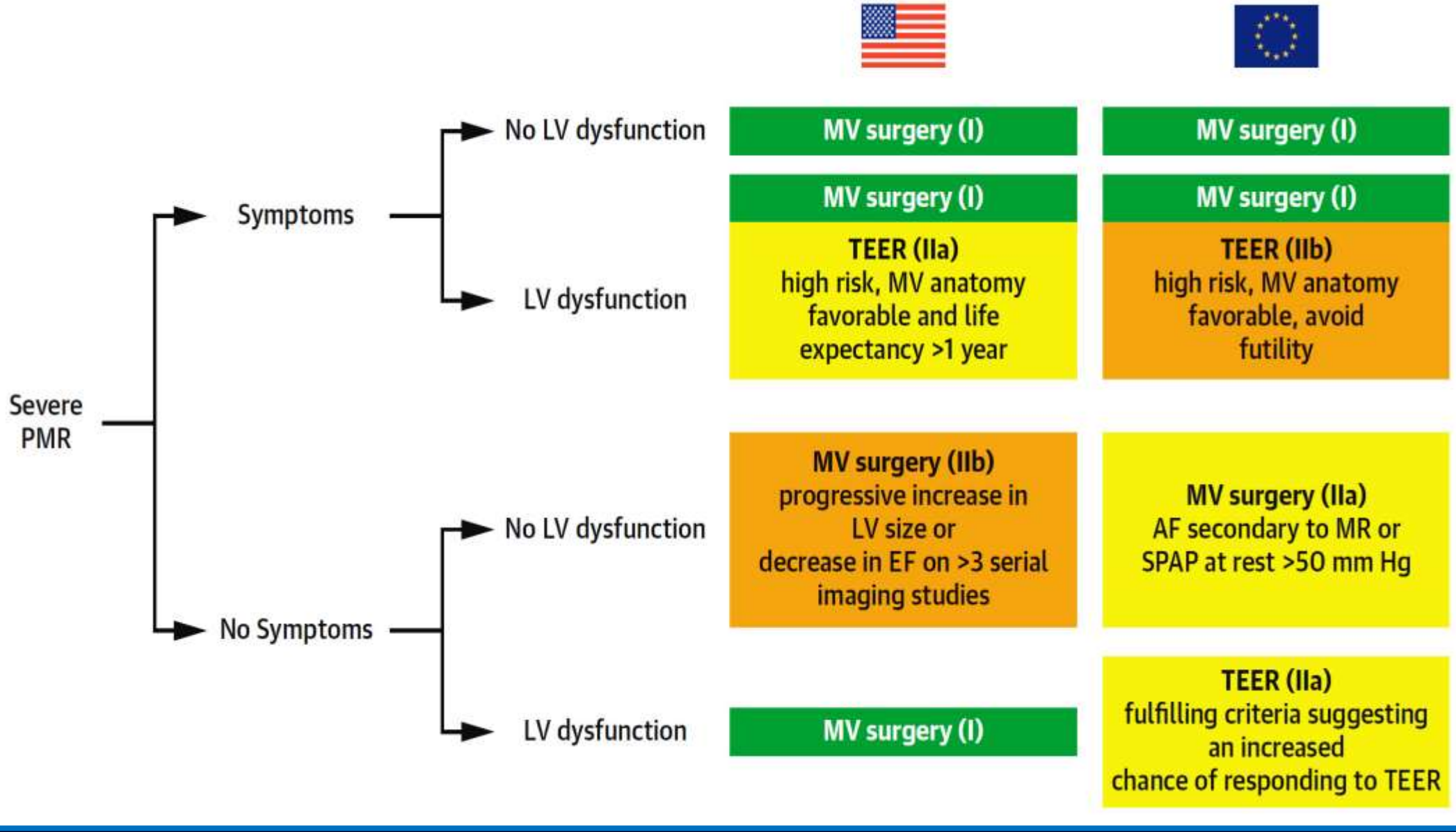
Sharma T et al., J Am Coll Cardiol 2022;80:2054

Selected Recommendations on Management of AR

Recommendation	American	European
Symptoms	I-B	I-B
No symptoms and		
LVEF ≤55%	I-B	IIb-C
LVEF ≤50%	I-B	I-B
Progressive decline in LVEF to 55%-60% on 3 serial studies	IIb-B	
LVESD >50 mm or >25 mm/m^2	IIa-B	I-B
LVESD >20 mm/m^2 if low risk		IIb-B
Severe AR undergoing other cardiac surgery	I-C	I-C
Moderate AR undergoing other cardiac surgery	IIa-C	
Aortic valve repair in selected patients at experienced centers when durable results are expected		IIb-C

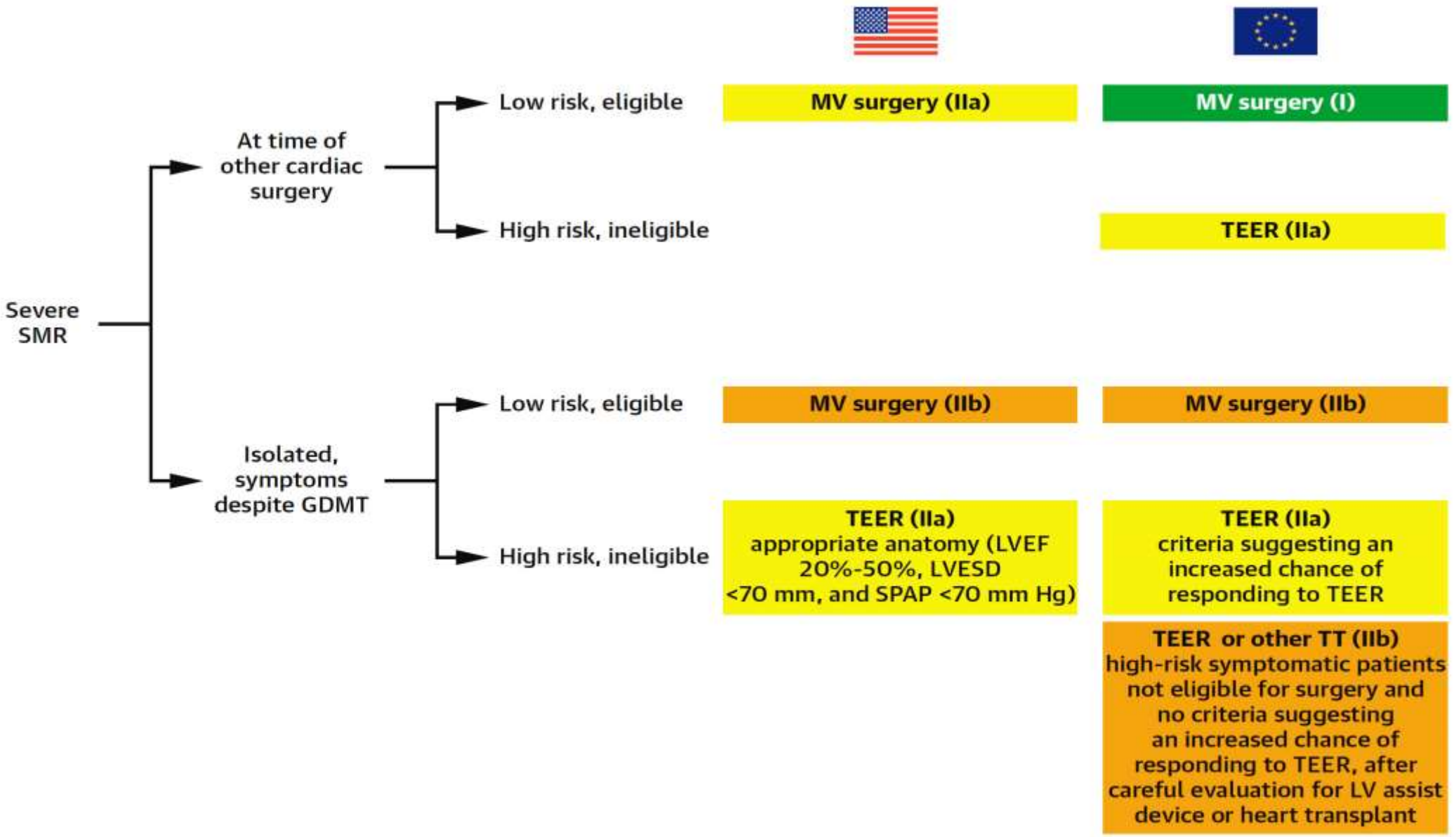
Coisne et al., J Am Coll Cardiol 2023;82:721

Management of Patients With Severe Primary MR



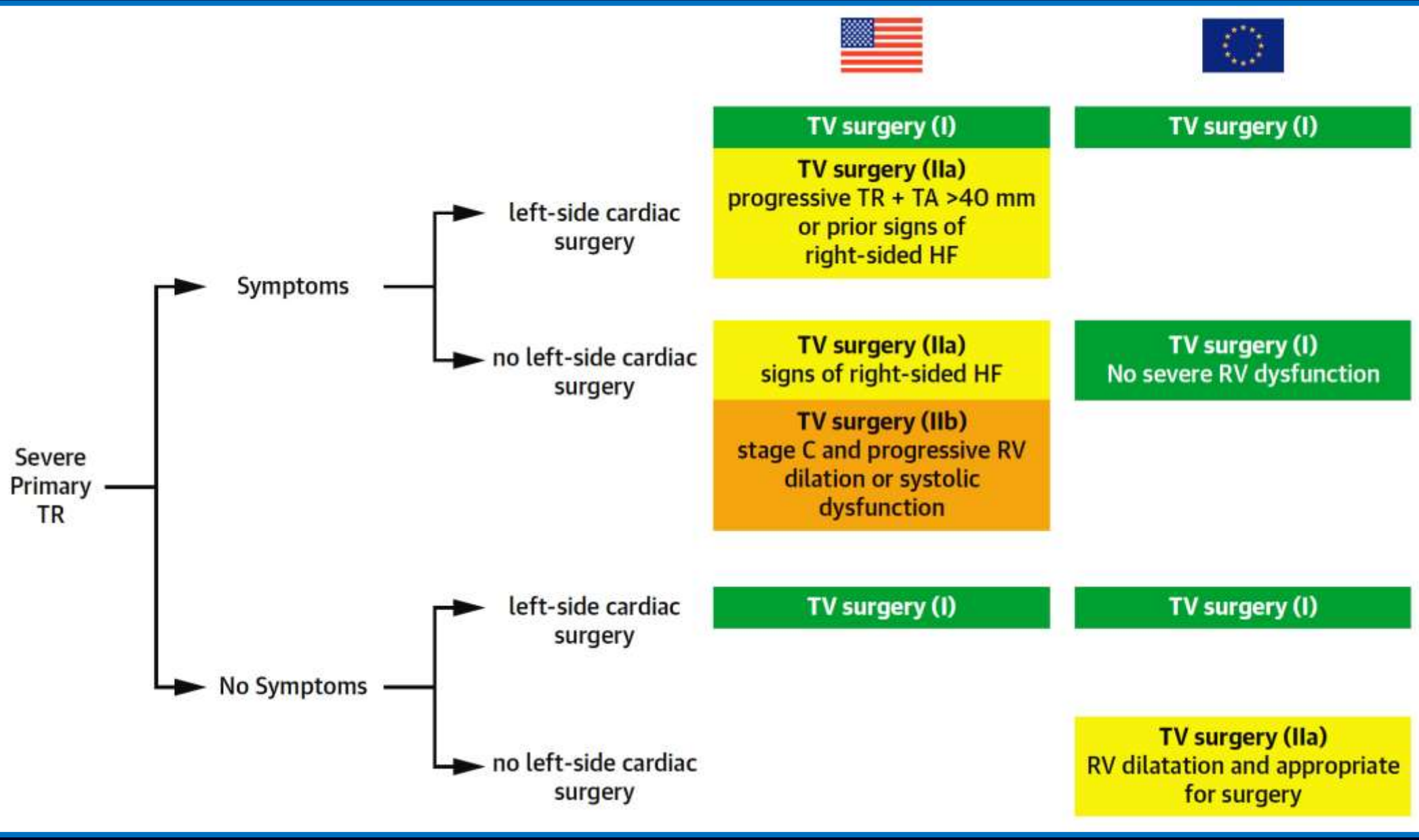
Coisne et al., J Am Coll Cardiol 2023;82:721

Management of Patients With Severe Secondary MR



Coisne et al., J Am Coll Cardiol 2023;82:721

Management of Patients With Severe Primary TR



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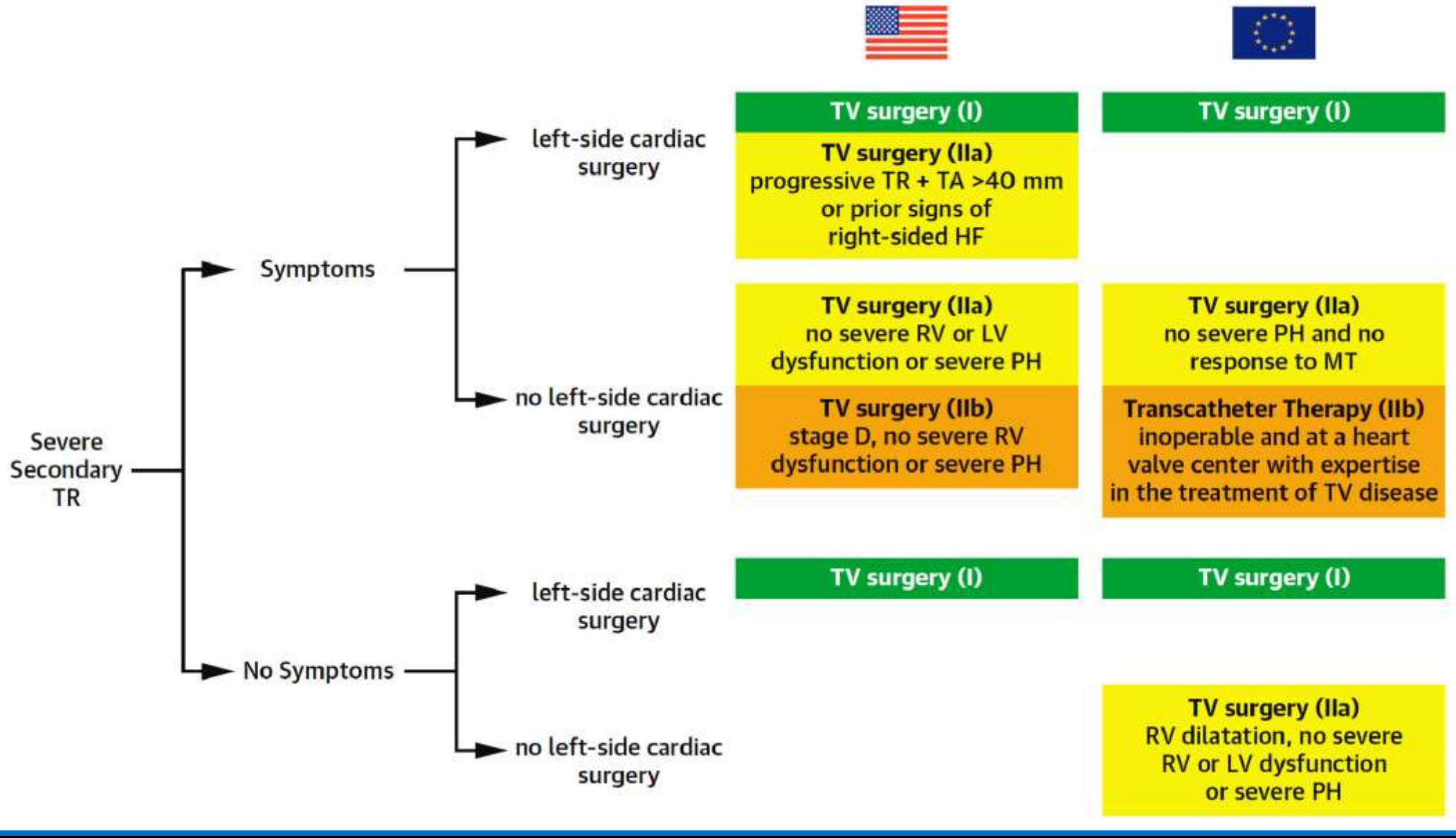
Management of Patients With Severe Secondary TR



Coisne et al., J Am Coll Cardiol 2023;82:721

Comparison Between Guidelines in the Management of Valvular Heart Disease

Aortic Stenosis	
AVR if symptoms and high gradient (I) – AVR if asymptomatic and LV dysfunction or other cardiac surgery (I) – AVR if asymptomatic and Vmax >5 m/s or >0.3 m/s/y, exercise intolerance (IIa)	AVR in AG (I) vs AVR in EG (IIa) for preserved EF low-flow, low-gradient severe AS – TAVR considered vs SAVR in patient >65 y of age (AG) vs >75 y of age (EG)

Aortic Regurgitation	
AVR if symptoms (I) – AVR if asymptomatic and LV dysfunction or other cardiac surgery (I)	LV dysfunction = LVESD >50 mm or LVESD >25 mm/m^2 or LVEF ≤50% in EG vs LVEF ≤55% in AG – – AVR if moderate AR and other cardiac surgery (IIa) in AG vs no recommendation in EG

Mitral Stenosis	
PMC if symptoms and favorable anatomy (I) – Surgery if PMC is not suitable (I)	PMC at a Comprehensive Valve Center (I) in AG vs no recommendation in EG

Primary Mitral Regurgitation	
MV surgery if symptoms (I) – MV repair if asymptomatic and LV dysfunction (I) – Repair > Replacement	TEER for high-risk patients IIa for AG vs IIb for EG – MV surgery if asymptomatic and high probability of successful and durable repair in AG (IIa) vs watchful waiting except if AF or SPAP >50 mm Hg in EG (IIa)

Secondary Mitral Regurgitation	
MV intervention if symptoms after GDMT (I) – MV surgery if symptoms and low-risk after GDMT (IIb)	MV surgery if symptoms at time of CABG I for EG vs IIa for AG – TEER if symptoms and ineligible for surgery in EG (IIa) vs no surgical consideration (only anatomy and COAPT criteria) in AG (IIb)

Tricuspid Regurgitation	
TV surgery in TR undergoing left-sided valve surgery if severe (I) or if mild-to-moderate and TA dilatation or prior signs and symptoms of right-sided HF	TV surgery if symptoms and severe primary TR (I in EG vs IIa in AG) – TTVI if symptoms, anatomically eligible and not amenable for surgery in EG (IIb) vs no recommendation in AG

Consistencies between guidelines	Discrepancies between guidelines

Coisne et al., J Am Coll Cardiol 2023;82:721

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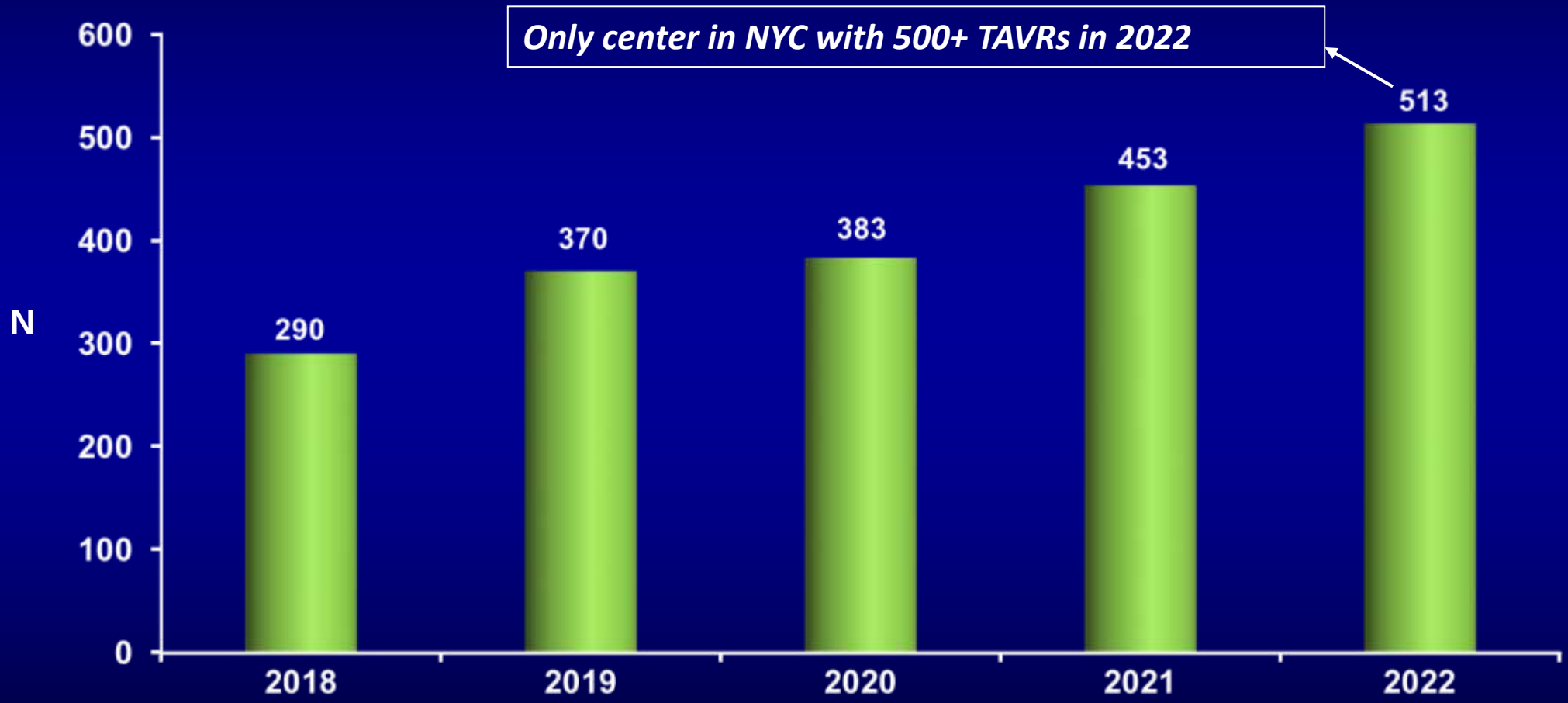
Growing Structural Transcatheter Heart Interventions

TAVR Procedures at MSH: 2018 to 2022

Major complication: N =	*8*	*10*	*14*	*15*	*9*



Length of Stay in Days:	*4.1*	*3.1*	*3.2*	*3.4*	*3.5*
O/E Mortality Ratio:	*0.75*	*0.85*	*0.81*	*0.48*	*0.58*

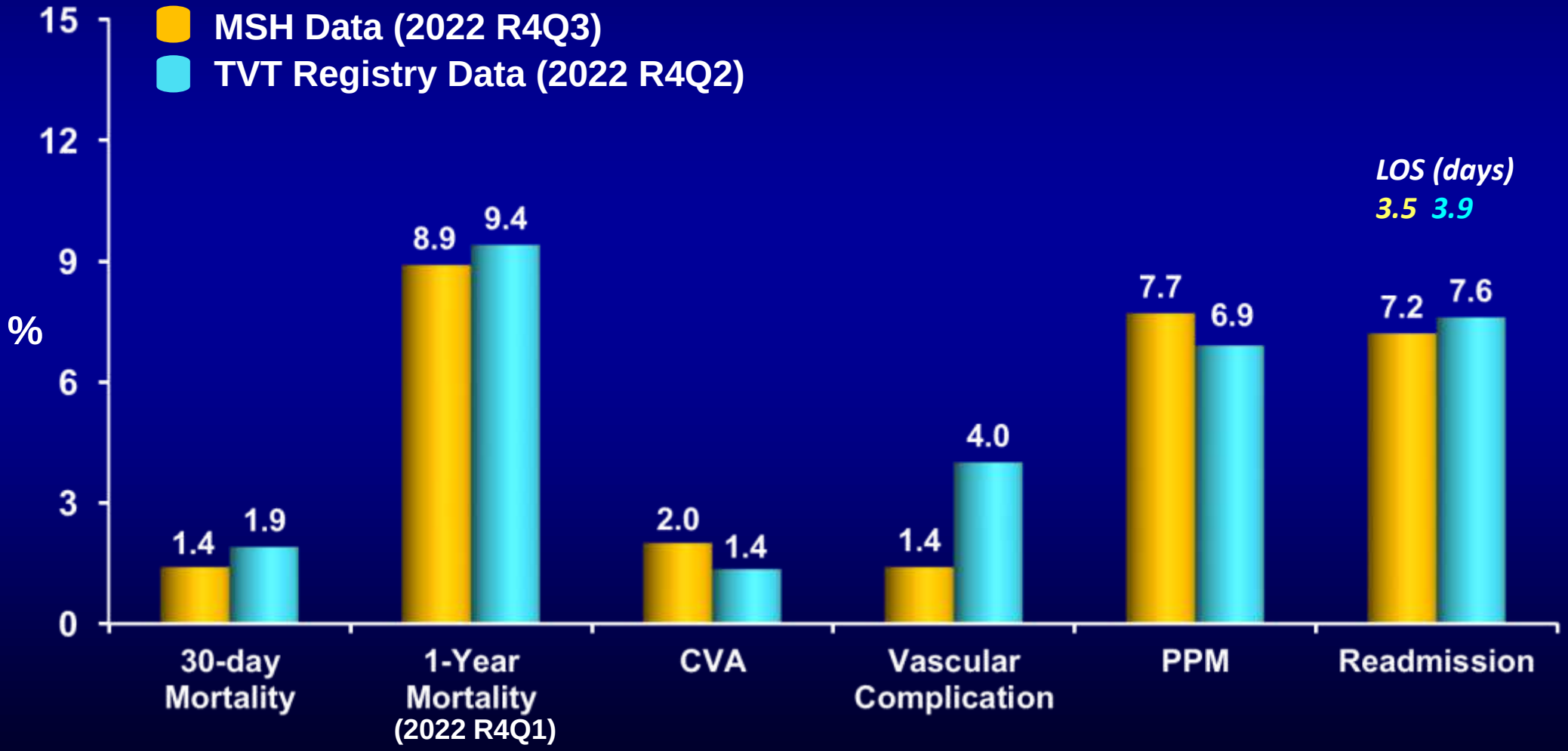
Excellent TAVR Outcomes 2022

***N=513** (62% SAPIEN-3, 38% Evolut-R/Fx CoreValve, 0.2% ACURATE)*

89.7% Conscious Sedation;10.3% GA. 38.6% Sentinel

92.6% Perc Femoral; 7.2% Cutdown Femoral; 0.2% Transcarotid. 6.2% ViV (N=32; 27 TAV-in-SAV, 5 TAV-in-TAV)

100% TF TAVR at MSH in 2022 (except 1)

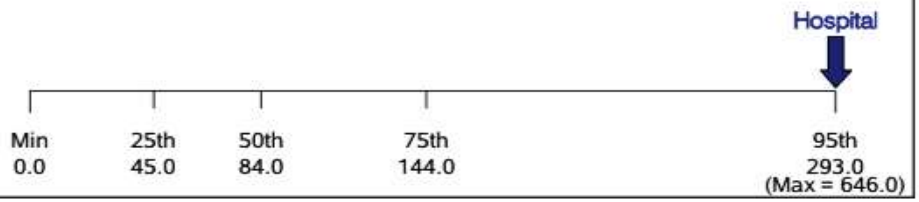


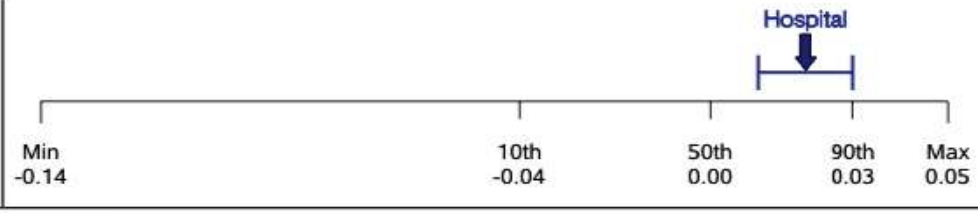
The Society of Thoracic Surgeons

STS/ACC TVT Registry
Public Reporting Metrics

Patients with TAVR as of 2021 q3
Hospital 974296

AMERICAN COLLEGE of CARDIOLOGY

Timeframe First TAVR Procedure Performed	My Hospital TAVR Volume[1] (commercial procedures only)		Distribution of Annual Hospital TAVR Volumes (Across all TVT Registry Hospitals)
	Cumulative	Annual volume (Oct 1, 2020 - Sep 30, 2021)	
May, 2012	**2353**	**447**	

My Hospital TAVR 30 Day Composite Site Difference[1,2,3] (95% Confidence Interval)	Eligible Patients (Oct 1, 2018 - Sep 30, 2021)	Participant Rating	Distribution of Participant Estimates
0.02 (0.01 to 0.03)	**1128**	★★★	

[1] Missing value (--) indicates that hospital does not meet eligibility criteria for reporting.

[2] 30 Day Composite consists of six ordered categories based on the worst possible outcome (30-day death) to the best possible outcome (e.g. alive and free of major complications) during hospitalization and the 30-day follow-up period as defined below:

1. 30-day death
2. 30-day stroke
3. 30-day life-threatening or major bleeding
4. Acute kidney injury (stage III)
5. 30-day moderate to severe paravalvular aortic regurgitation (PVL)
6. None of the above

[3] The TAVR 30-day mortality/morbidity composite is reported as a "site difference":
>0 implies "My Hospital" has better than expected performance
<0 implies "My Hospital" has worse than expected performance

Top 10 Advances in Transcatheter Valve Therapy 2023

Central Illustration

Trials/Studies leading to change in Transcatheter valve Interventional Therapy

LAAO with TAVR, TMVR in MAC. PCI with TAVR: 

TAVR vs SAVR in small annulus, TAV-in-TAV: 

TAVR in pure AR, PCI post TAVR, TTVR-Evoque: 

M-TEER Expanded data, Triclip: 

5-10Yrs TAVR vs SAVR durability in severe AS: 

Final result → BETTER Interventional Outcomes/ Improved SURVIVAL

Growing Structural Heart Intervention Team

Big Boss With no title!!

Samin Sharma, MD

Interventional Director
The Mount Sinai Health System

Annapoorna Kini, MD

Interventional Director, MSH

Sahil Khera, MD

Associate Director, MSH

Parasuram Krishnamoorthy, MD

Surgical Director
The Mount Sinai Health System

Gilbert Tang, MD

Director Imaging

Stamatios Lerakis, MD

Attending Imaging

Malcolm Anastasius, MD

2022 Structural Heart Intervention Fellows

Anoop Koshy, MD

Negar Salehi, MD

Combined Interv+ Structural

Prashant Dwivedi, MD

Manish Vinayak, MD

Structural Attendings

Sunny Goel, MD

Amit Hooda, MD

Yumiko Kanei, MD

Schedulers/Liasion

Angela Gratereaux

Adriana Batista

Derek Fernandez, PCA

Director of Nursing, Structural Heart Pogram

Hyo Jin Kang, NP

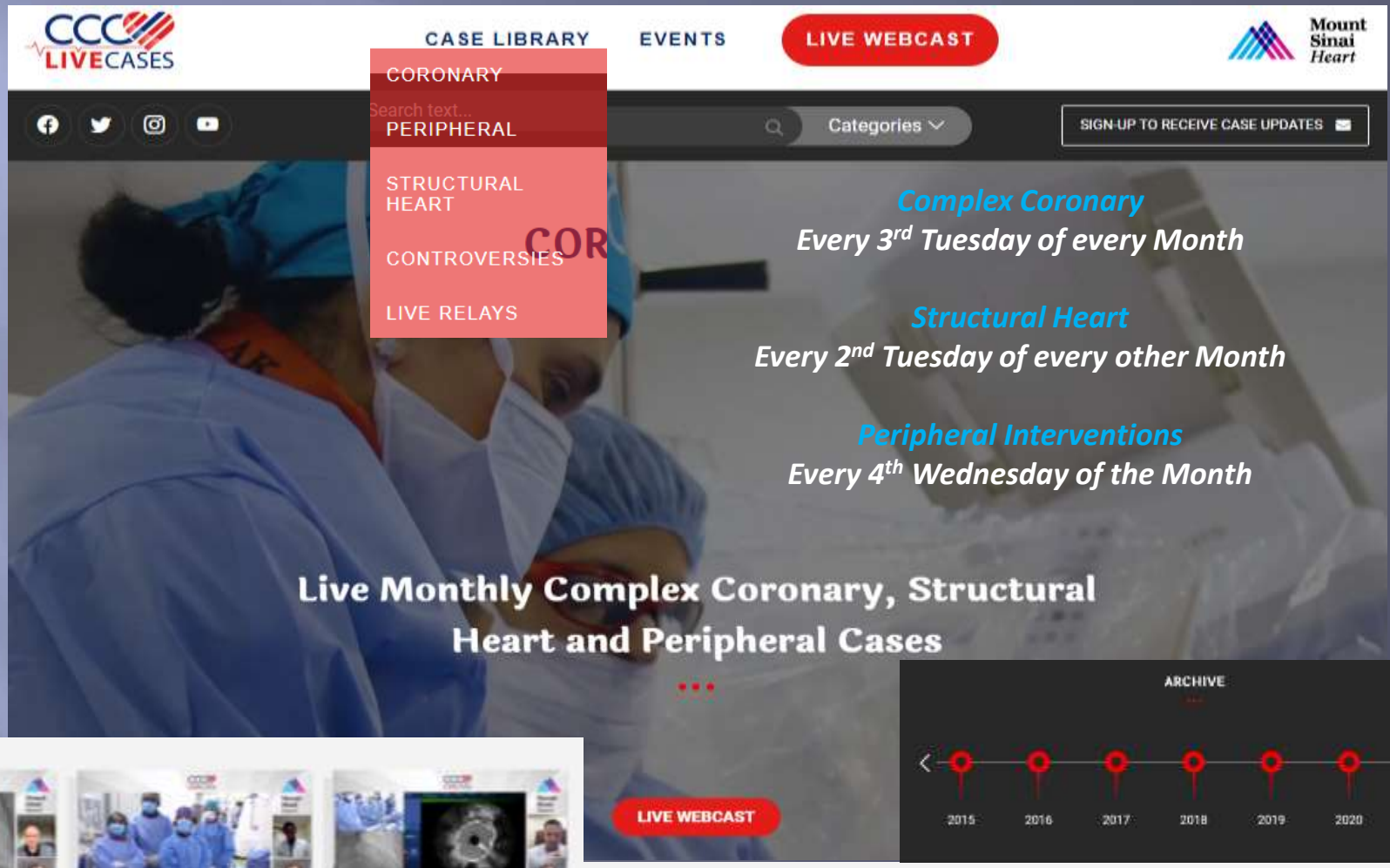
Dedicated Structural NP's

Dana Leichter, NP

Maryam Akhtar, NP

Shuk F Lau-McKee, NP

New Website! www.ccclivecases.org



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DR. SAMEER MEHTA
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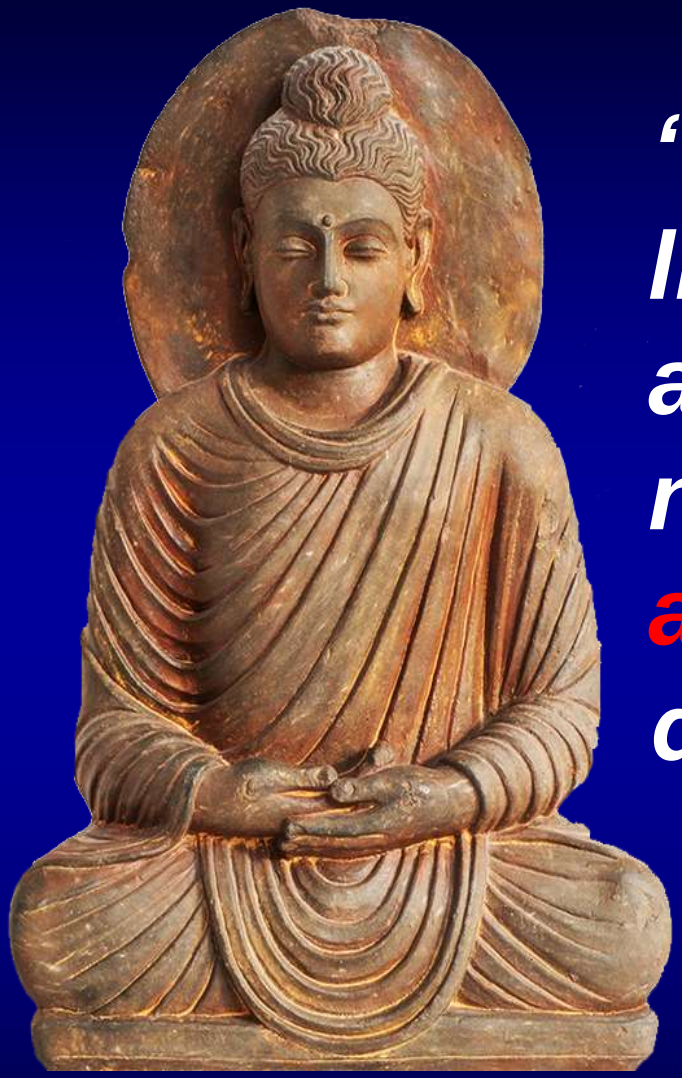
Lifetime Pageviews = 1,972,326

Users on CCC Live Website

	New Users	Sessions
	185,987 % of Total: 100.05% (185,886)	316,162 % of Total: 100.00% (316,162)
1. India	102,514 (55.12%)	149,710 (47.35%)
2. United States	53,951 (29.01%)	100,845 (31.90%)
3. Germany	2,433 (1.31%)	5,037 (1.59%)
4. United Kingdom	2,264 (1.22%)	4,392 (1.39%)
5. China	1,605 (0.86%)	1,886 (0.60%)
6. Turkey	1,341 (0.72%)	4,379 (1.39%)
7. Canada	1,193 (0.64%)	2,562 (0.81%)
8. Australia	1,084 (0.58%)	1,896 (0.60%)
9. Japan	1,028 (0.55%)	1,805 (0.57%)
10. Italy	853 (0.46%)	1,761 (0.56%)

Views by Country on YouTube

Geography	Views	Watch time (hours)	Average view duration
Total	817,652	166,955.7	12:15
United States	237,512 29.0%	57,582.7 34.5%	14:32
India	124,372 15.2%	21,534.1 12.9%	10:23
Germany	7,361 0.9%	1,440.1 0.9%	11:44
Turkey	3,770 0.5%	740.1 0.4%	11:46
Egypt	2,963 0.4%	406.3 0.2%	8:13
United Kingdom	2,757 0.3%	493.9 0.3%	10:44
Pakistan	2,743 0.3%	504.3 0.3%	11:01
Saudi Arabia	2,155 0.3%	345.3 0.2%	9:36
Japan	1,983 0.2%	253.2 0.2%	7:39
Russia	1,884 0.2%	228.3 0.1%	7:16
Spain	1,111 0.1%	18.2 0.0%	0:59
South Korea	963 0.1%	215.9 0.1%	13:27



"Thousands of candles can be lighted from a single candle, and the life of the candle will not be shortened. Happiness and knowledge never decreases by being shared."

- Buddha

The Year in Valvular Heart Disease: Ten Papers That Could Become Game Changers

Lp(a) associated with AS occurence but not AS progression

RCT: No effect of Vitamin K on AS progression

Aortic stenosis

RCT

Early SAVR intervention was associated with better outcome than watchful waiting

RCT

TAVI was non-inferior to SAVR in elderly patients with severe AS and moderately increased operative risk

RCT

Sentinel cerebral protection device did not reduce the rate of stroke during transfemoral TAVI

RCT: During MV surgery, combined TV repair was associated with lower rate of reoperation for TR, TR progression, or death at the expense of higher pacemaker rate

Mitral regurgitation

Tricuspid regurgitation

In elderly patients with severe degenerative MR at increased surgical risk, TEER was superior to conservative management

TRI-SCORE accurately predicted in-hospital mortality rate after isolated tricuspid valve surgery

RCT: VKA was associated with lower event rates than rivaroxaban in patients with rheumatic heart disease in AF

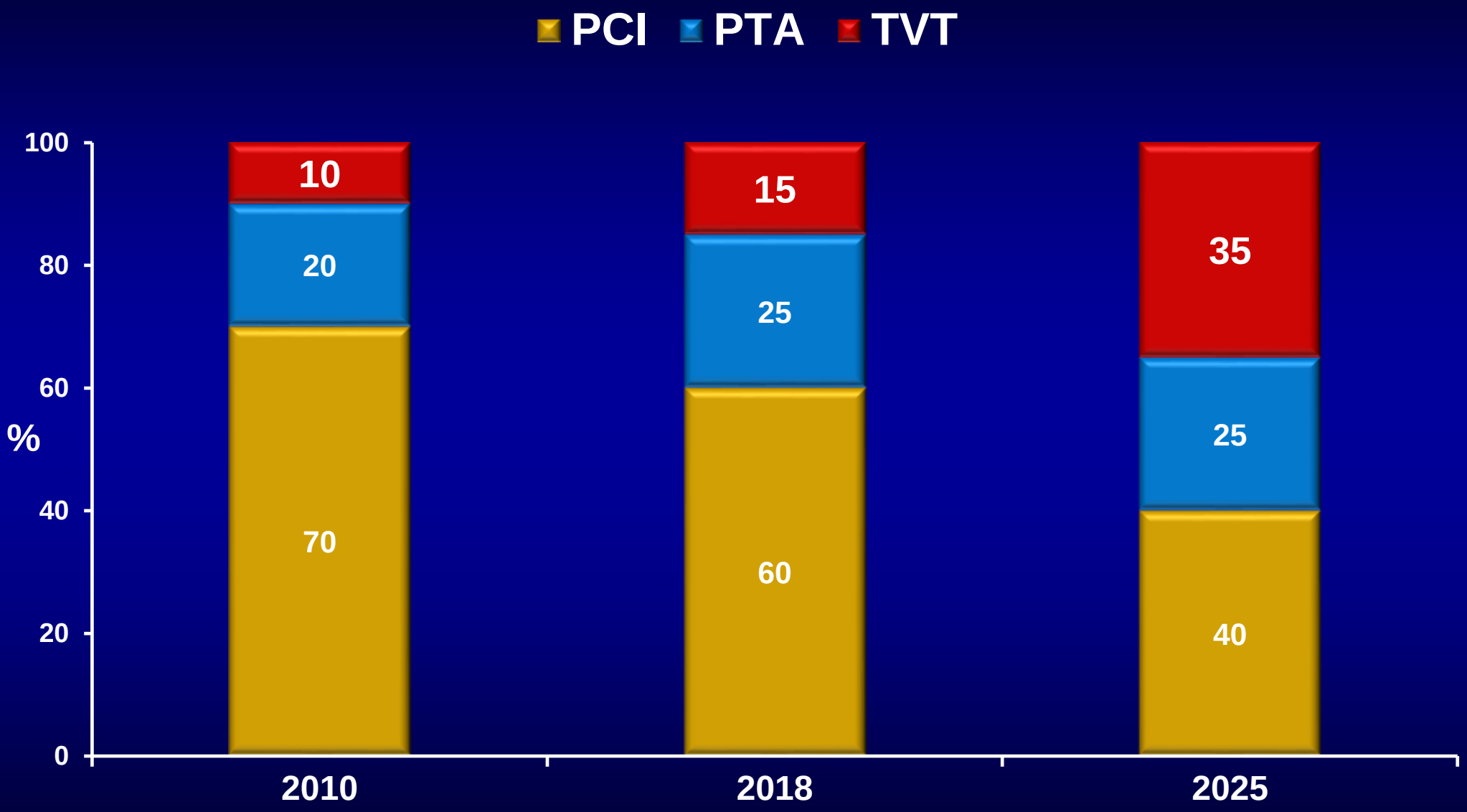
Rheumatic heart disease

Mechanical valve thrombosis

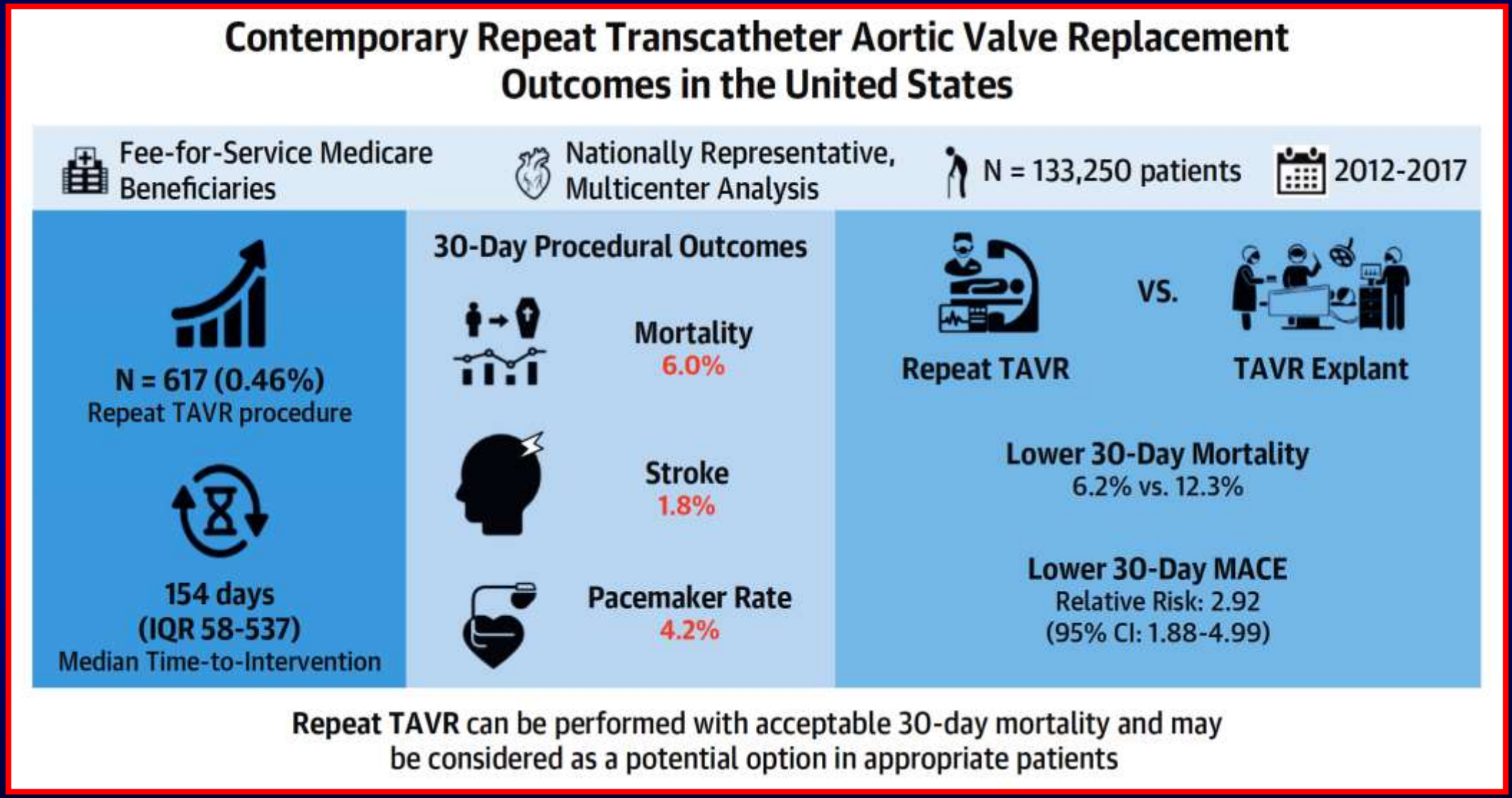
Ultraslow infusion of low-dose thrombolytic therapy was associated with high success rate and low complication rate in obstructive mechanical valve thrombosis

Published on behalf of European Society of Cardiology

Changing Landscape of Interventional Cardiology



Contemporary Outcomes of Repeat TAVR in the US Medicare Database



Percy et al., J Am Coll Cardiol Intv 2021;14:1717