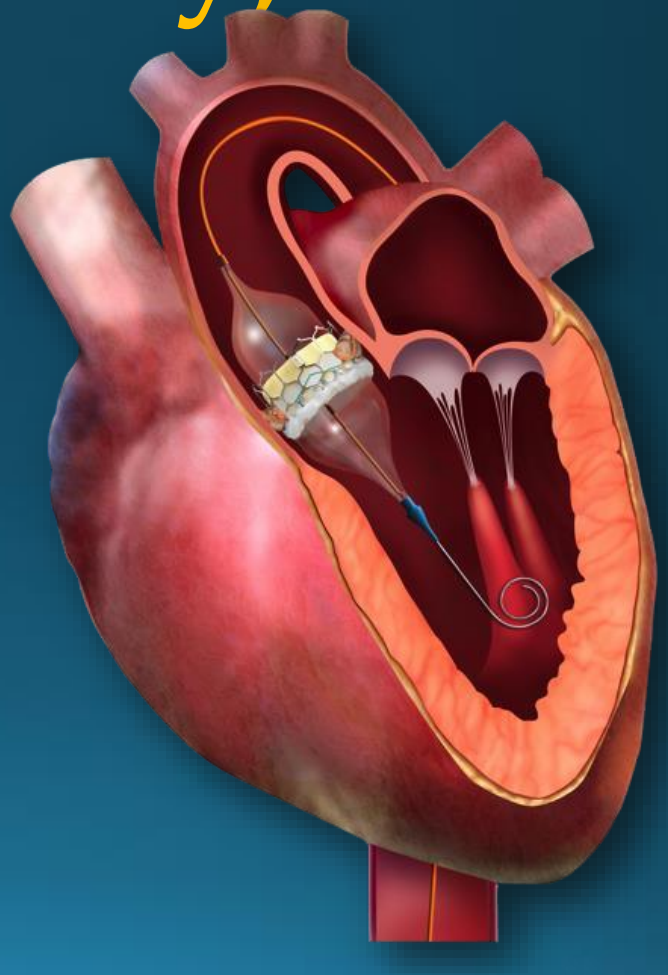
TAVI – General view (boon for severe AS in elderly)

Dr B C Srinivas
Bangalore



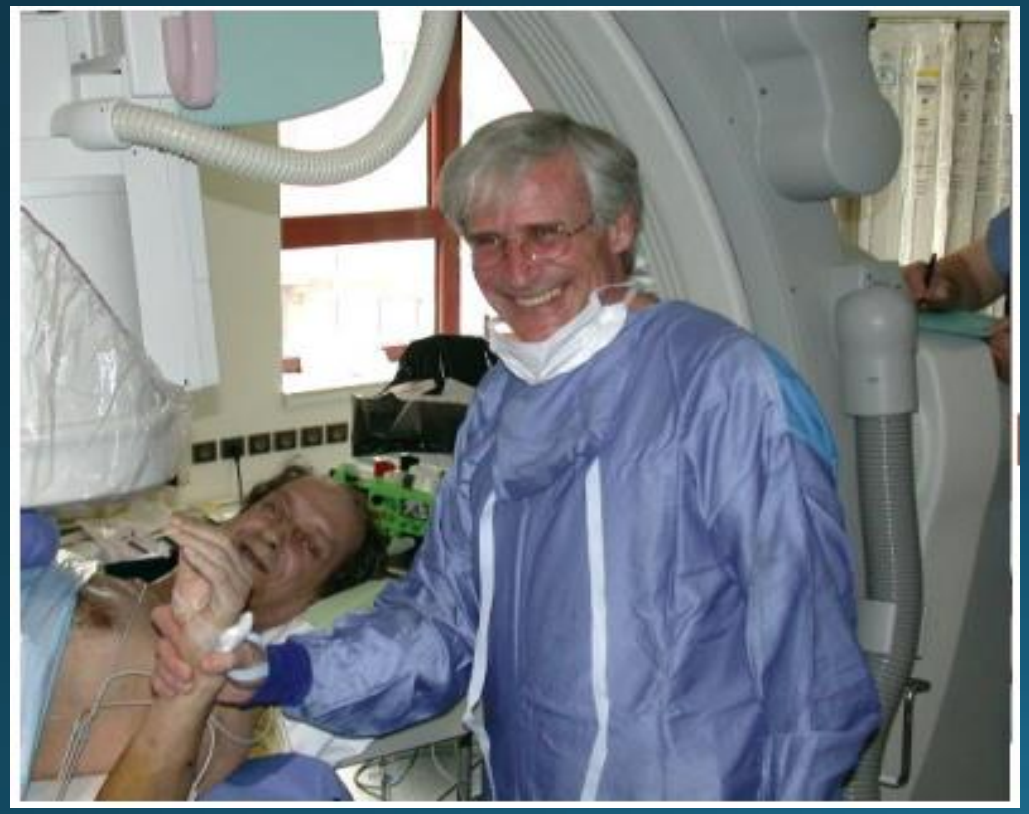
A 22-year journey in TAVI: Evolution to current eminence

- TAVI is the most exciting advancement (an inexorbable march) in the field of interventional cardiology
- 22 years since the first man with TAVI
- We have witnessed an impressive evolution of this technique, with an extension of its use from non-operable patients to high, intermediate and even low-risk patients with aortic stenosis and with a decrease in the incidence of complications.

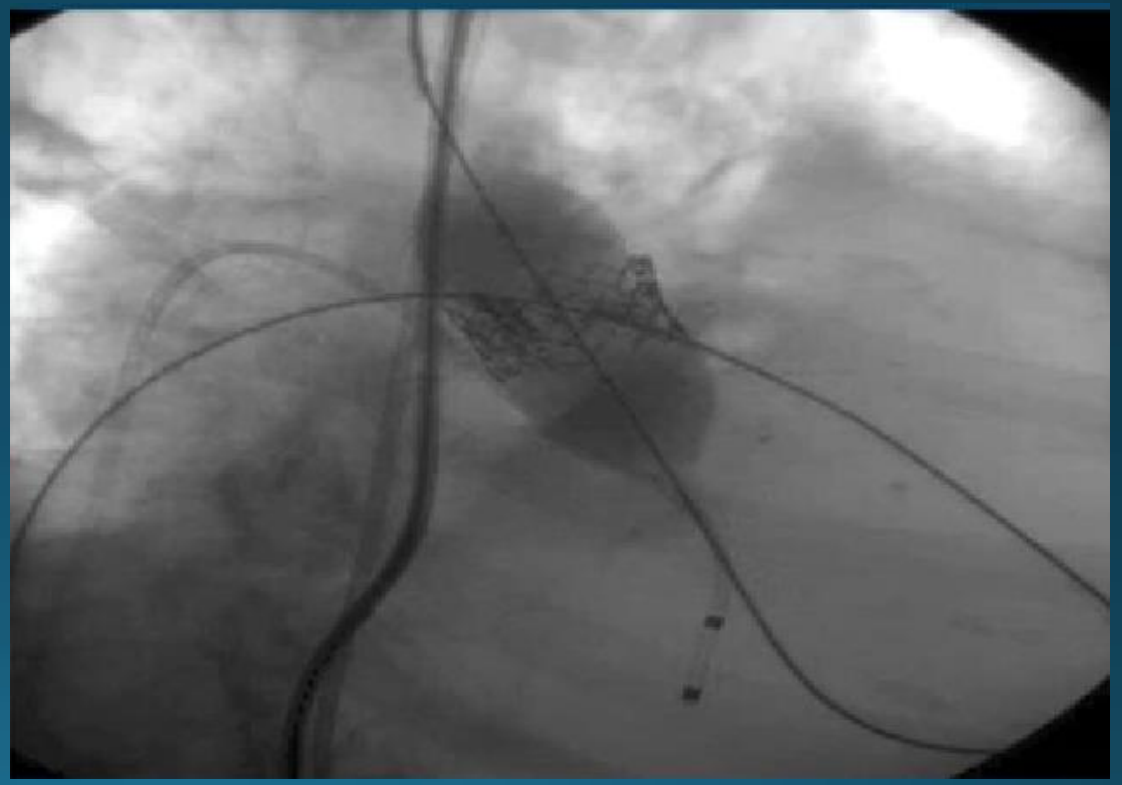
TAVR is maturing 22yrs old technology

1st in man

The Cribier-Edwards valve



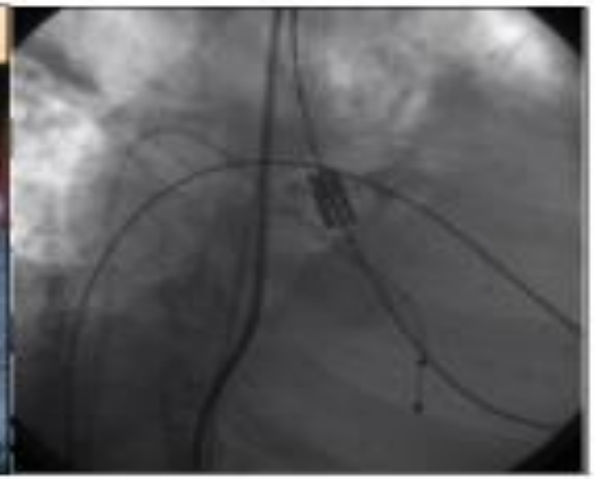
A. Cribier, Rouen, 2002



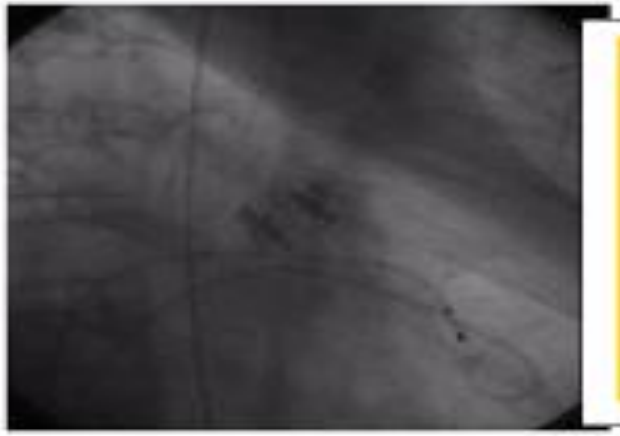
Antegrade transpetal

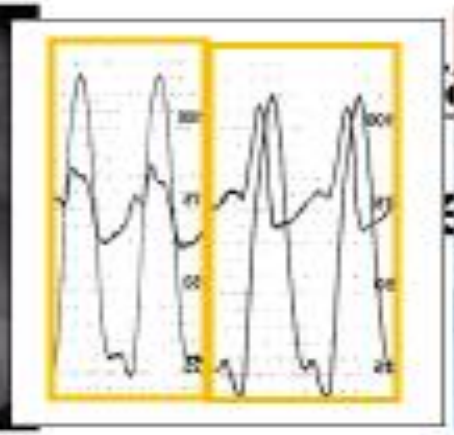
Treatment for Aortic Stenosis

First implantation—from dream to reality



Bail out procedure in very high risk dying patient





Circulation
Volume 106, Issue 24, 10 December 2002; Pages 3006-3008
https://doi.org/10.1161/01.CIR.0000047200.36165.B8

SPECIAL REPORT

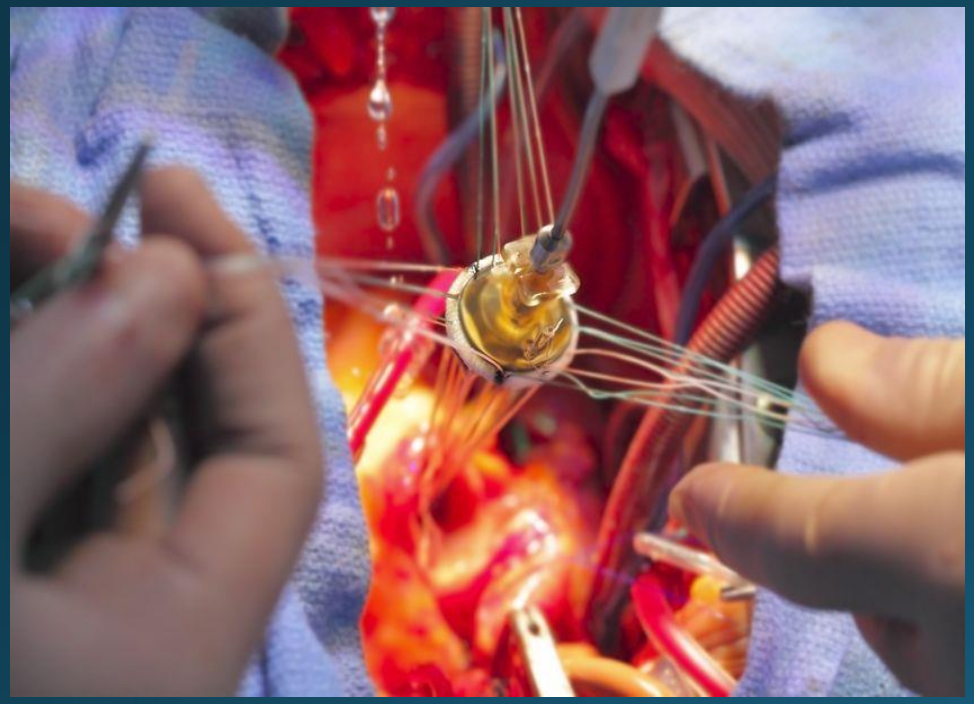
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

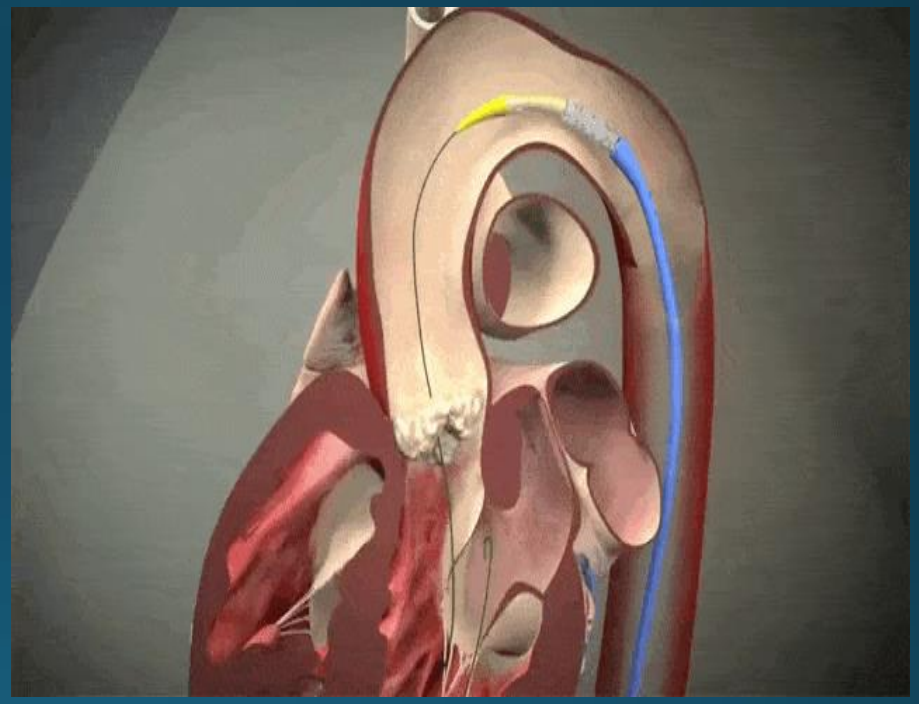
First Human Case Description

Alain Cribier, MD, Helene Eltchaninoff, MD, Assaf Bash, PhD, Nicolas Borenstein, MD, Christophe Tron, MD, Fabrice Bauer, MD, Genevieve Derumeaux, MD, Frederic Anselme, MD, François Laborde, MD, and Martin B. Leon, MD

ABSTRACT: ***Background***— The design of a percutaneous implantable prosthetic heart valve has become an important area for investigation. A percutaneously implanted heart valve (PHV) composed of 3 bovine pericardial leaflets mounted within a balloon-expandable stent was developed. After ex vivo testing and animal implantation studies, the first human implantation was performed in a 57-year-old man with calcific aortic stenosis, cardiogenic shock, subacute leg ischemia, and other associated noncardiac diseases. Valve replacement had been declined for this patient, and balloon valvuloplasty had been performed with nonsustained results.***Methods and Results***— With the use of an antegrade transseptal approach, the PHV was successfully implanted within the diseased native aortic valve, with accurate and stable PHV positioning, no impairment of the coronary artery blood flow or of the

SAVR vs TAVI





CHOOSING THE RIGHT TREATMENT FOT RIGHT PATIENT

PARTNER 3

- RCT 1:1
- Vs Standard Rx
- N =1000 pts

PARTNER 1B

- RCT 1:1
- Vs Standard Rx
- N =358 pts

PARTNER 2A

- RCT 1:1
- Vs. SAVR
- N =2032 pts

PARTNER 1A

- RCT 1:1
- Vs. SAVR
- N =699 pts

Edwards TAVR: Scientific evidences

Registries
(including
SOURCE (EU)
Compassionate,
then Very high Risk

Cribier-Edwards

Edwards-Sapien

2003-2010

Randomized trials

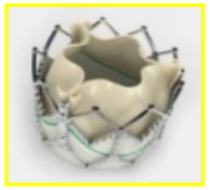
PARTNER 1
(A & B)
Inoperable
High-risk

2012
FDA

Edwards-Sapien

PARTNER 2
Intermediate
Risk

2016
FDA



Sapien XT

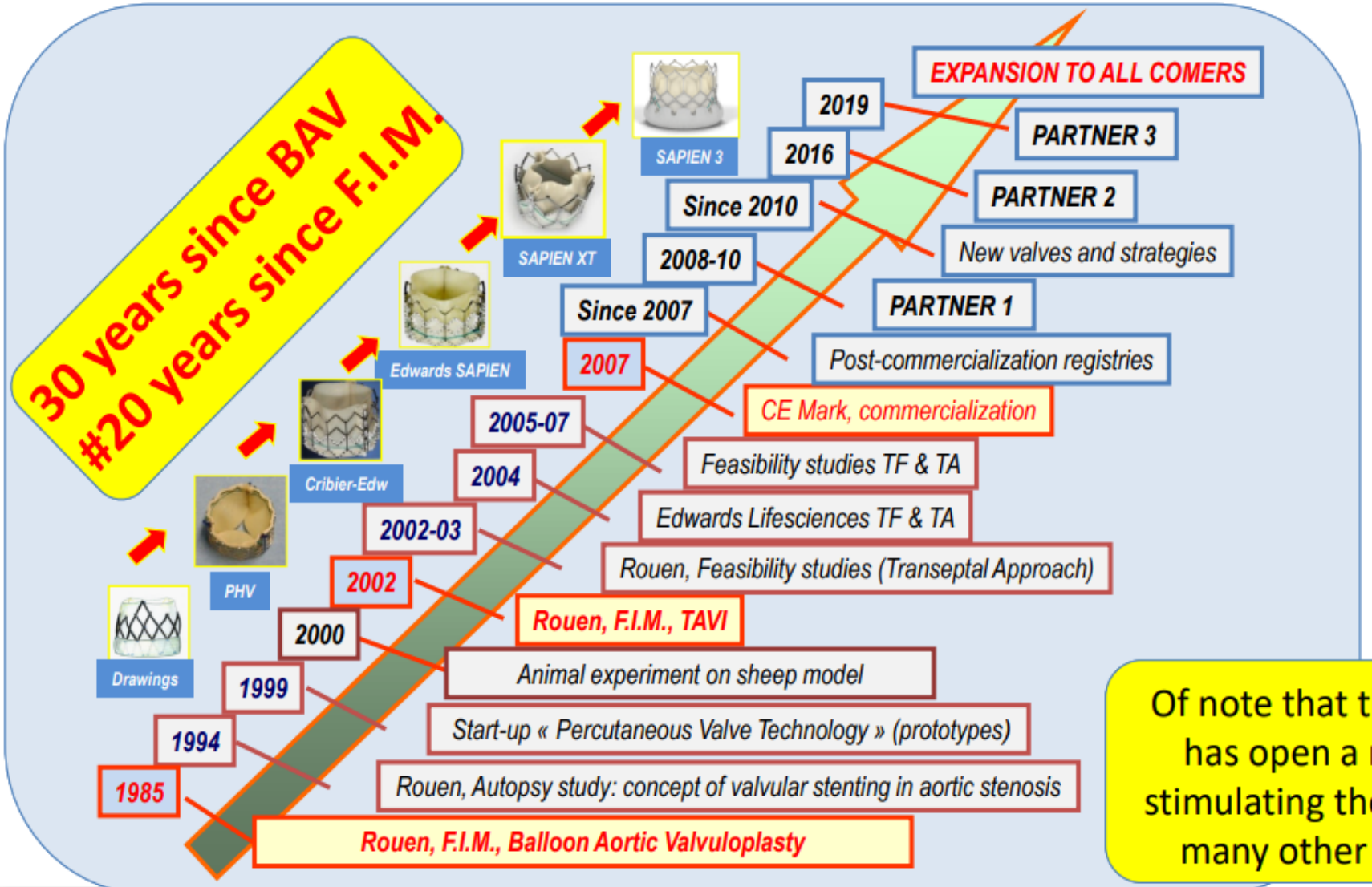
PARTNER 3
Low Risk

2019
FDA

Sapien 3

Similar pathway for
Medtronic CoreValve

Developing TAVI: A long bumpy road



Ongoing extension of TAVR indications

- Valve-in-Valve
- Bicuspid valves
- Asymptomatic AS
- Moderate AS + HF
- High-risk AR
- TAVR with concommittent diseases

Of note that this breakthrough technology has open a new world in cardiology by stimulating the transcatheter treatment of many other valvular and heart diseases

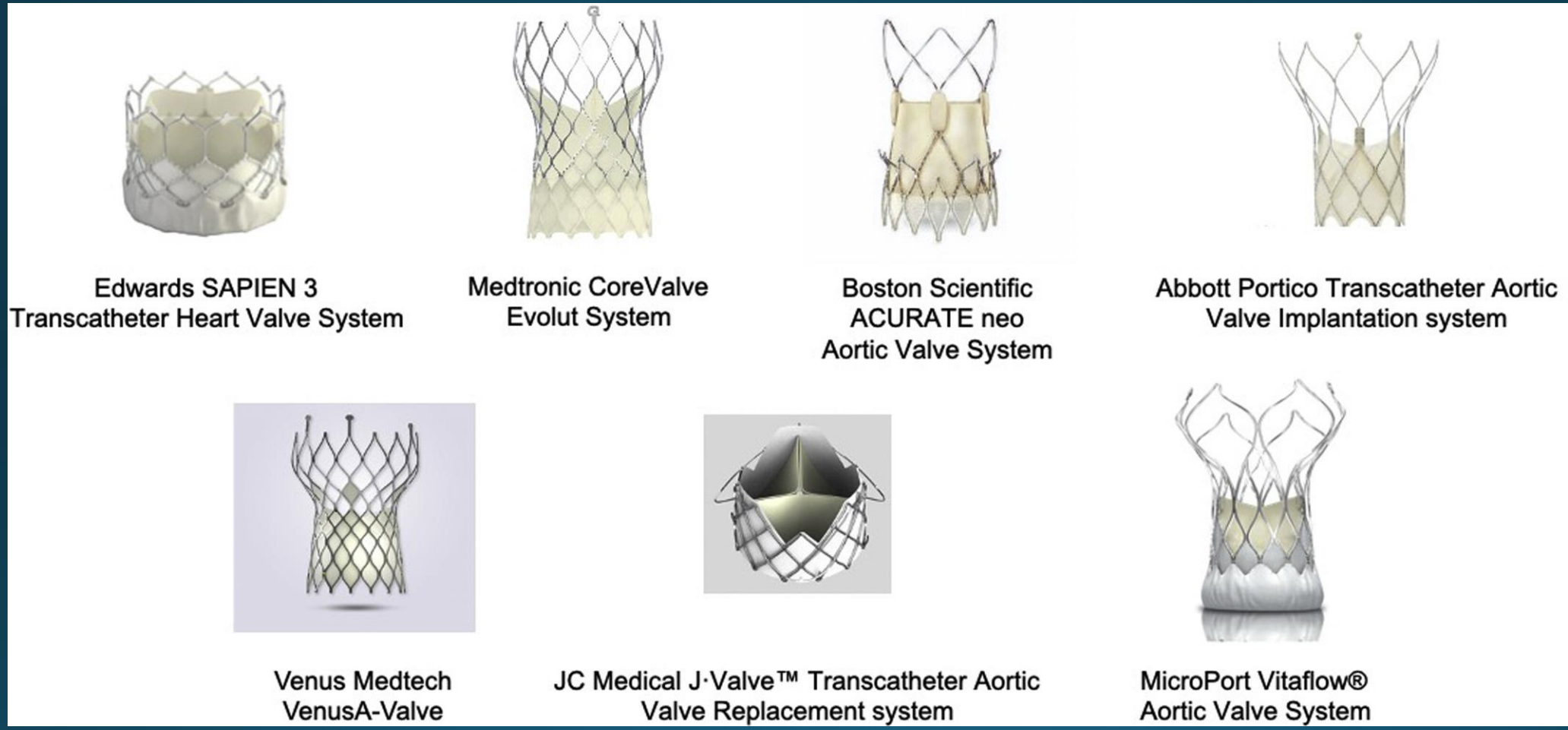


Figure. Currently Available Transcatheter Aortic Valve Replacement Devices in Asian Countries

Myval THV: Designed for Precision in Outcomes

Hybrid Honeycomb Cell Design Concept

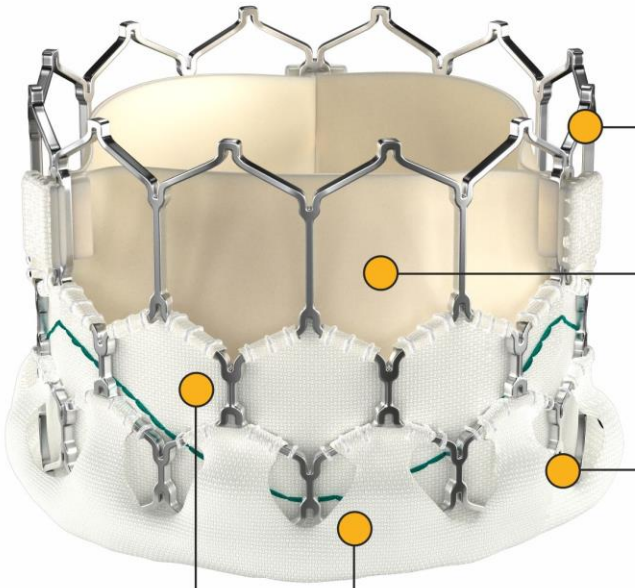
Open cells on upper half to ensure un-jailing of coronary ostia

Closed cells on lower half for high radial strength

≈ 53%

≈ 47%

Frame height 17-21 mm



Cobalt alloy frame for high radial strength & radiopacity

AntiCa[$] treated bovine pericardium tri-leaflet valve

External PET skirting to plug microchannels & further reduce PVL

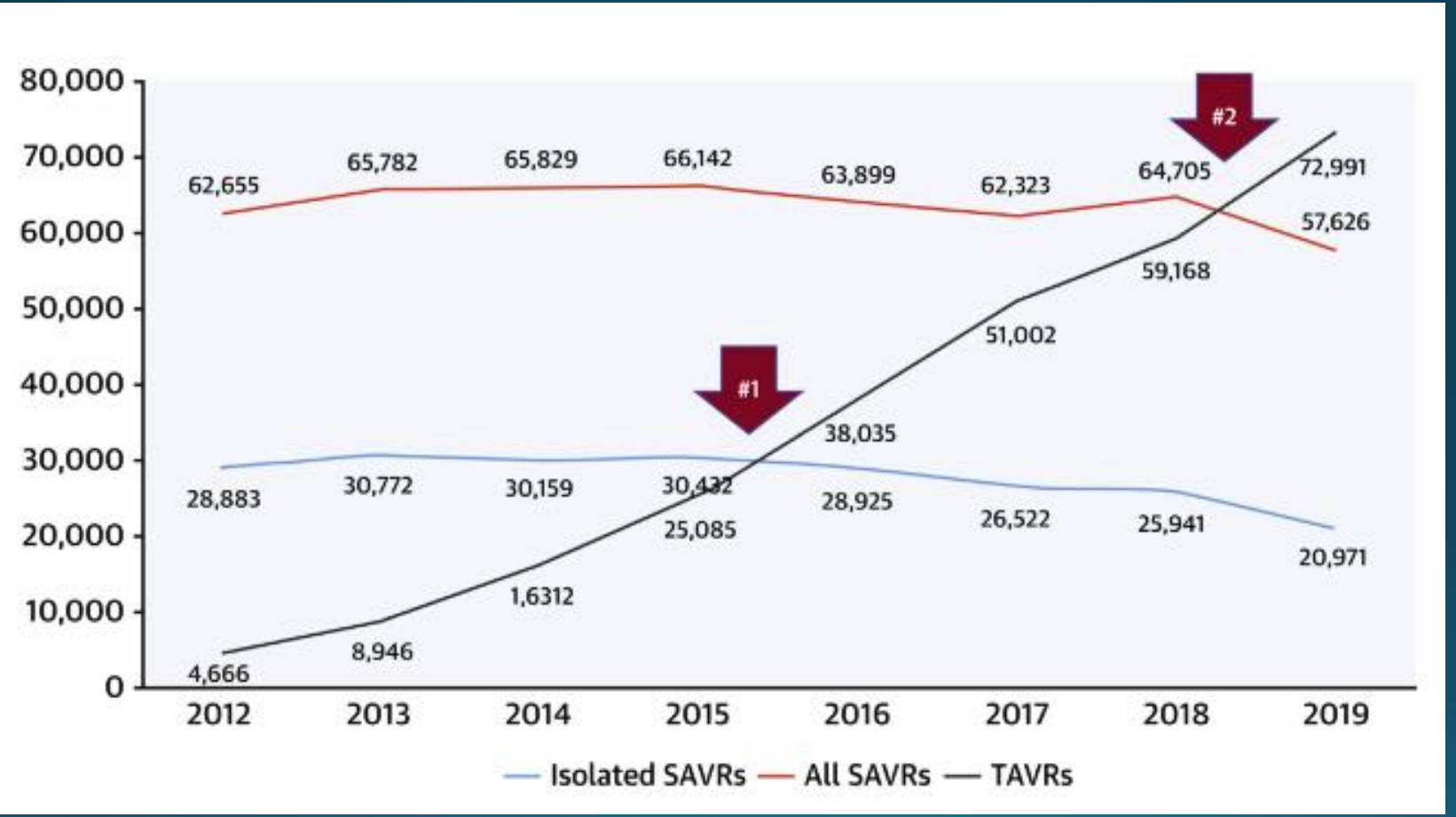
Internal PET sealing cuff for minimizing PVL & puncture resistance

Ø – 20 mm, 21.5 mm, 23 mm, 24.5 mm, 26 mm, 27.5 mm, 29 mm
Ø – 30.5 mm , 32 mm XL Sizes

Myval THV has been indigenously developed by Meril Life Sciences Pvt. Ltd.

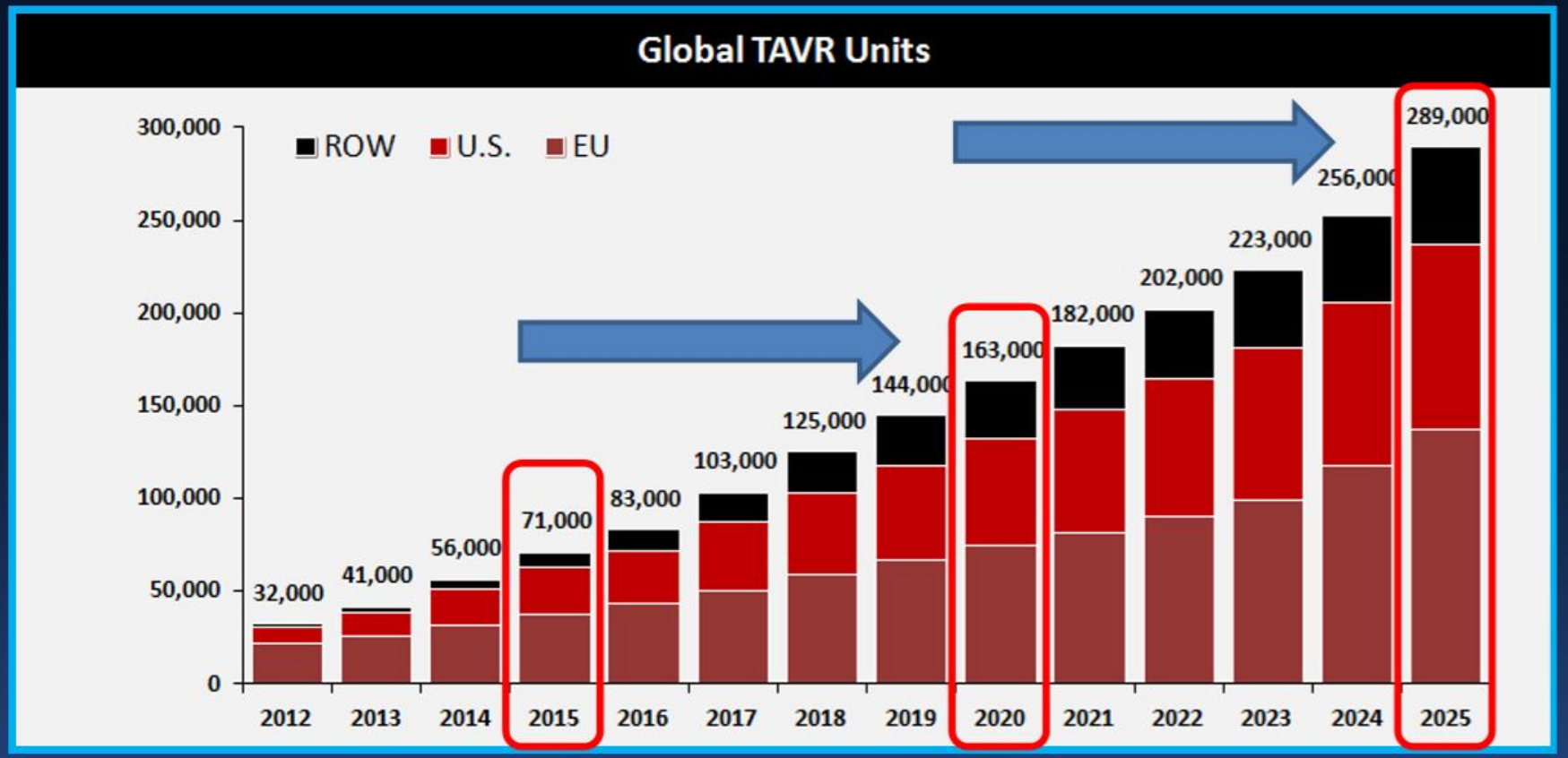
AntiCa[$] - Meril's proprietary anti-calcification treatment technology
All Myval THV sizes are CE approved

TAVR and SAVR Procedure in STS-ACC TVT Registry 2020



*Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. Ann Thorac Surg. 2020; doi: 10. 1016/j.athoracsur.2020.09.002

Estimated Global TAVR Procedure Growth



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

In the next 5 years, TAVR growth will double

In the next 10 years, TAVR will increase X4!

Case History

73 Year old Male with Severe symptomatic Aortic stenosis, Moderately Calcified Tricuspid Aortic valve

Echo:

- Trileaflet and Calcific
- Aortic Stenosis, Regurgitation GrII

Parameters	Values
Peak velocity	4.81m/s
Mean gradient	54.76 mmHg
Peak gradient	92.58 mmHg
EF%	50%

CT Analysis

Aortic Annulus

Perimeter:	65.3 mm
Perimeter Derived Ø:	20.8 mm
Area:	328.3 mm²
Area Derived Ø:	20.4 mm

LVOT Ø: 20.4 mm

RCA Height: 10.2 mm

Asc. Aorta Ø: 26.1 mm

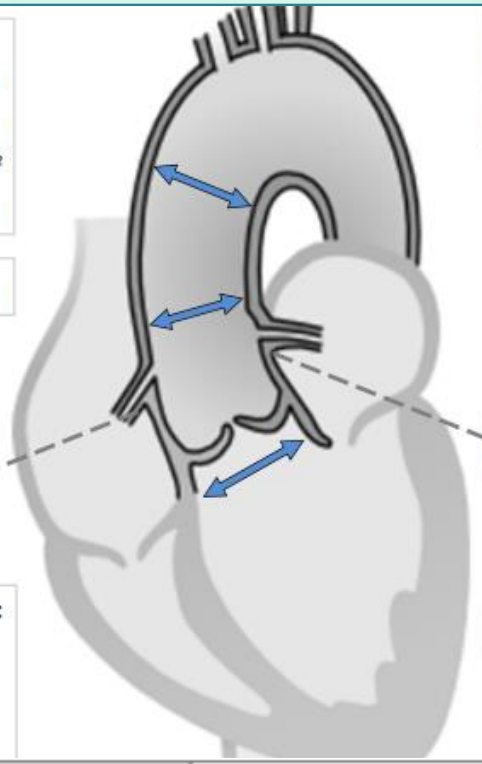
STJ Ø: 21.8 mm

LCA Height: 10.6 mm

Aortic Valve Calcification: Moderate

Sinus Of Valsalva Diameters:

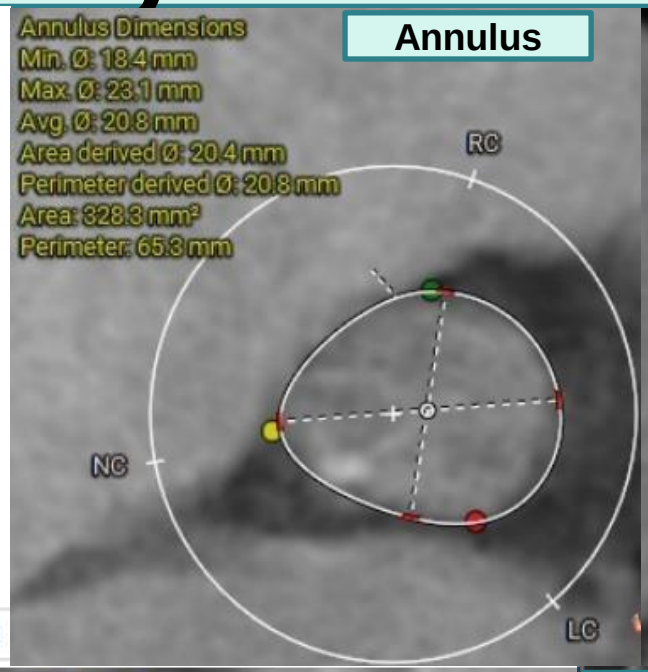
Left:	26.3 mm
Right:	26.0 mm
Non:	25.7 mm



Aortic Annulus

Ascending Aorta Ø	Min: 25.0 mm Max: 27.1 mm Average: 26.1 mm
Aortic Annulus	Min Ø: 18.4 mm Max Ø: 23.1 mm Average Ø: 20.8 mm Eccentricity: 0.20
Sinus of Valsalva Height	8.8 mm
Sinotubular Junction Ø	Min: 19.2 mm Max: 24.3 mm Average: 21.8 mm
LVOT Ø	Min: 17.0 mm Max: 23.8 mm Average: 20.4 mm

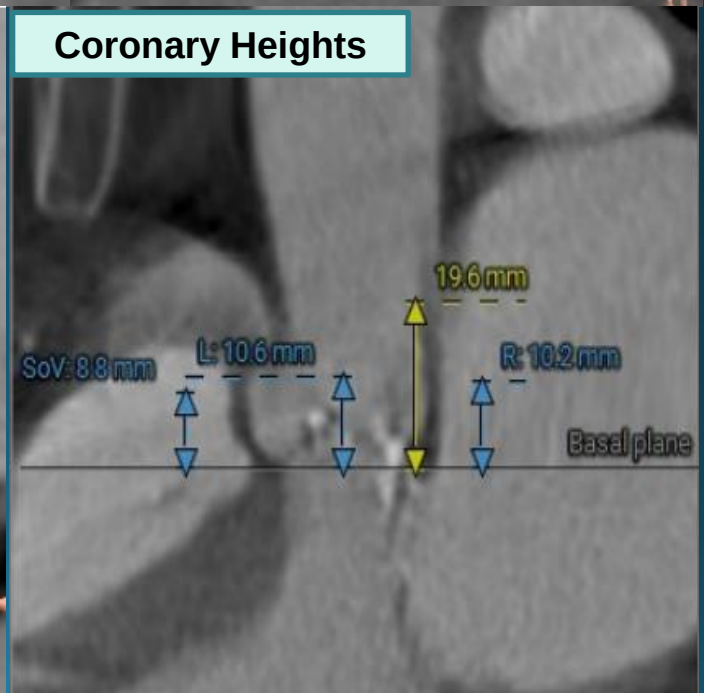
Annulus



LVOT

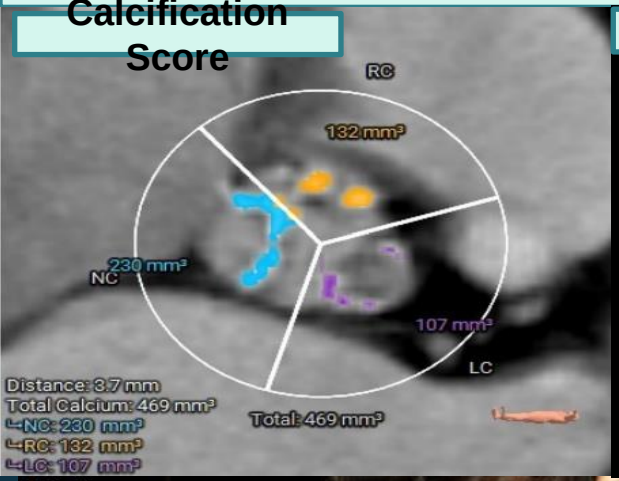
SOV

Coronary Heights



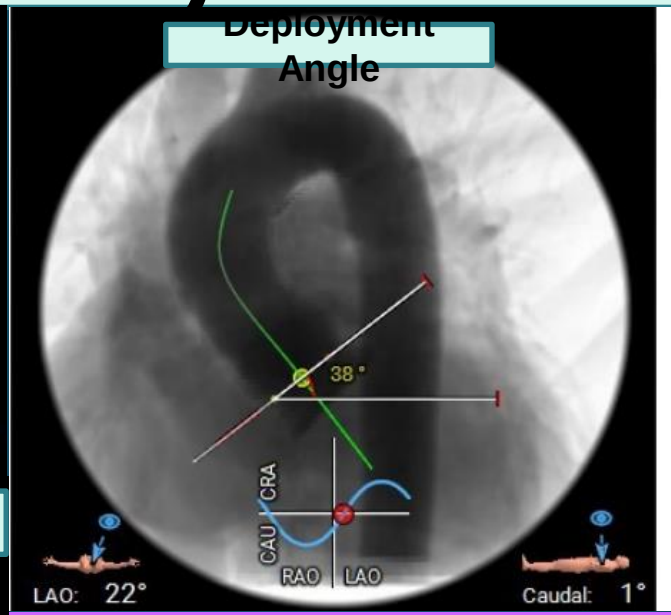
CT Analysis

Calcification Score

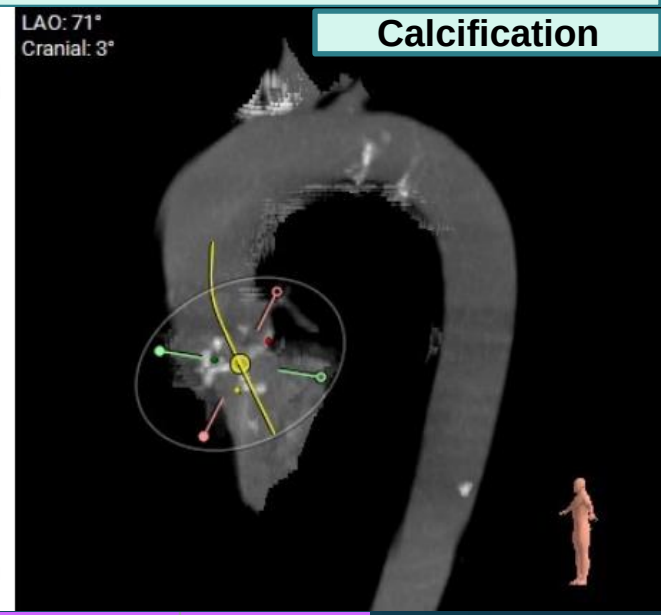


Hockey Puck View

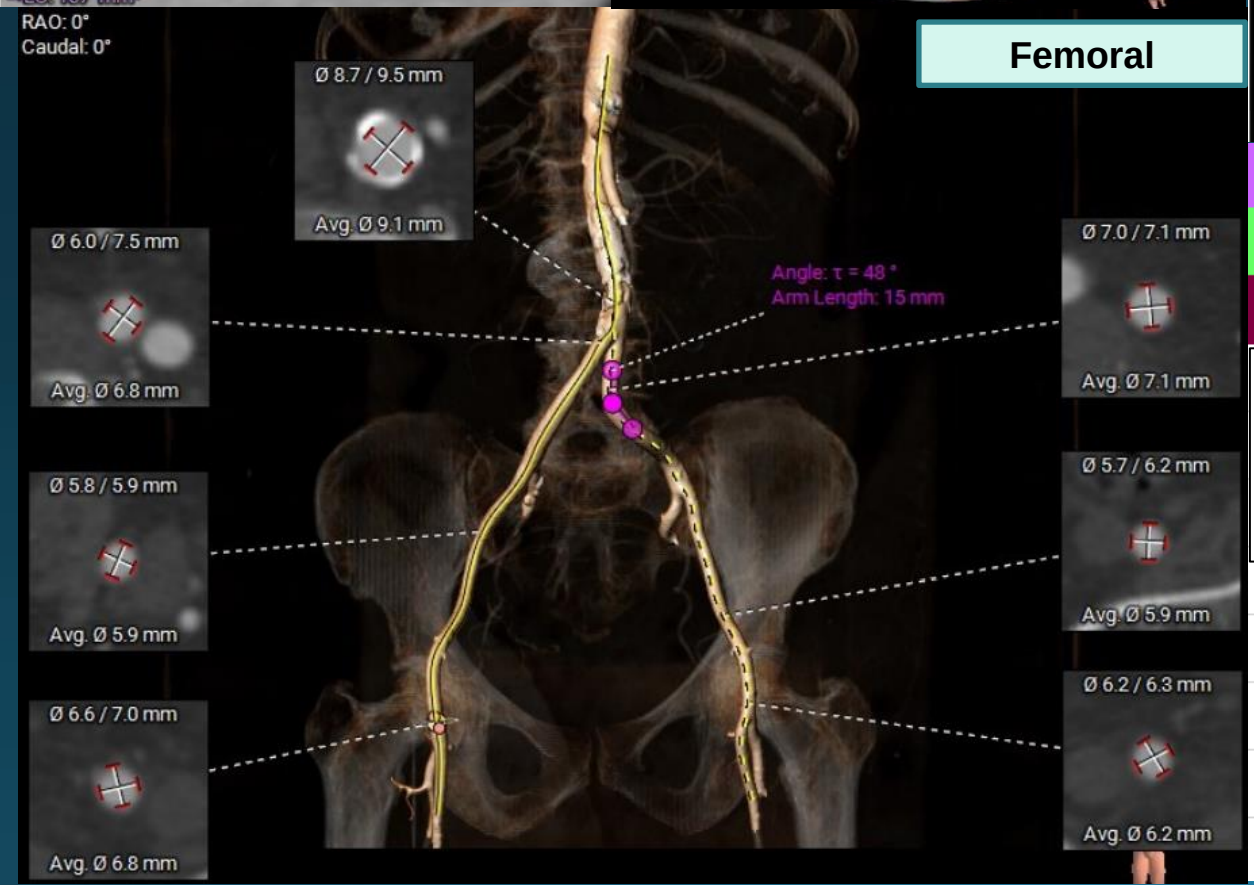
Deployment Angle



Calcification

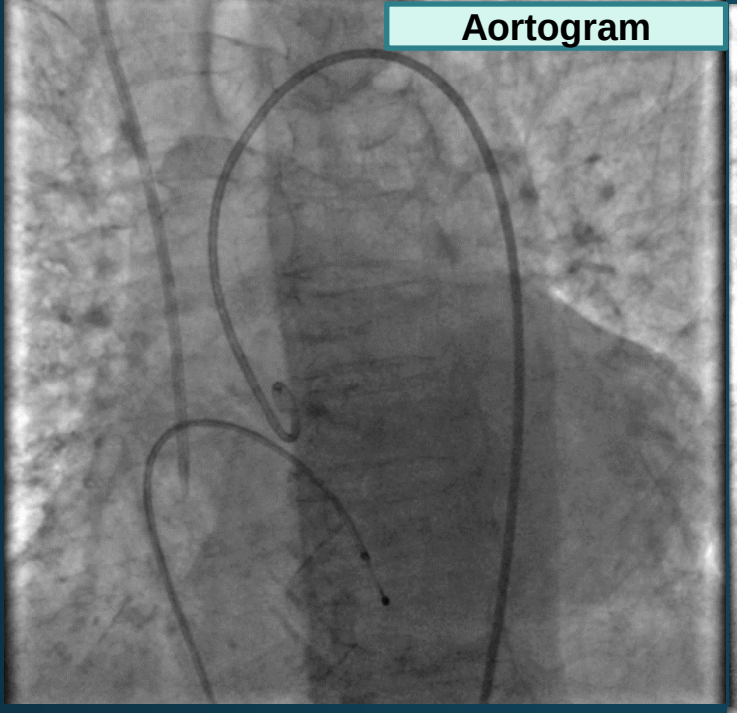


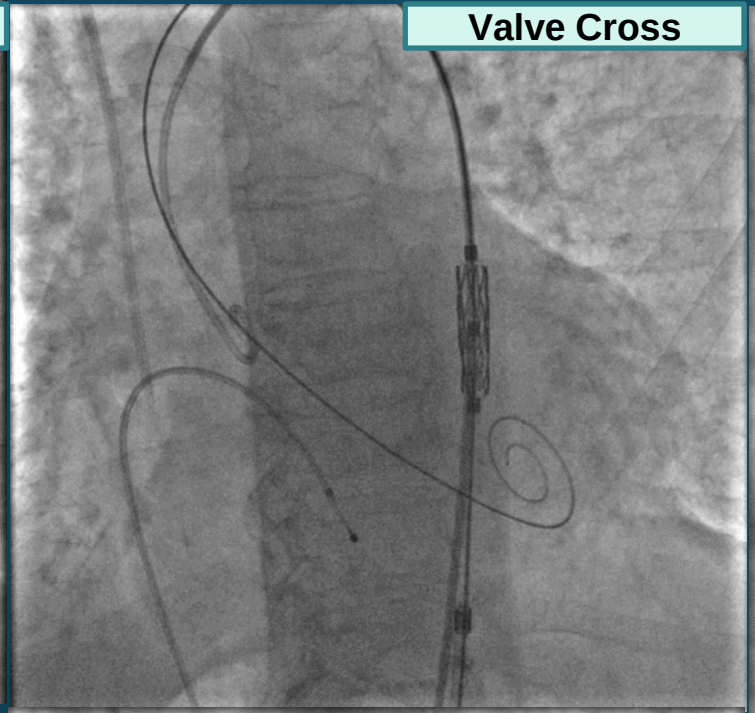
Femoral

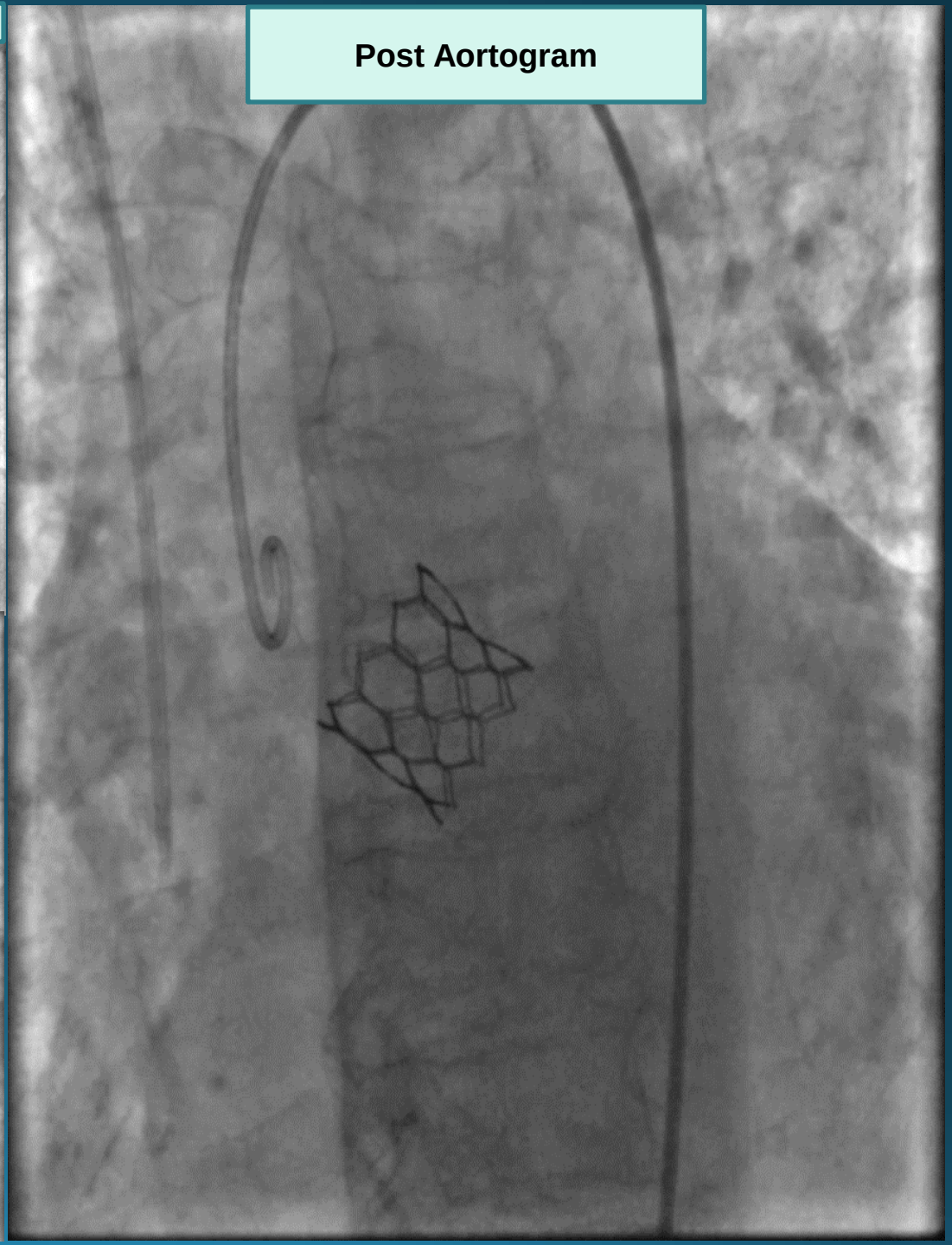


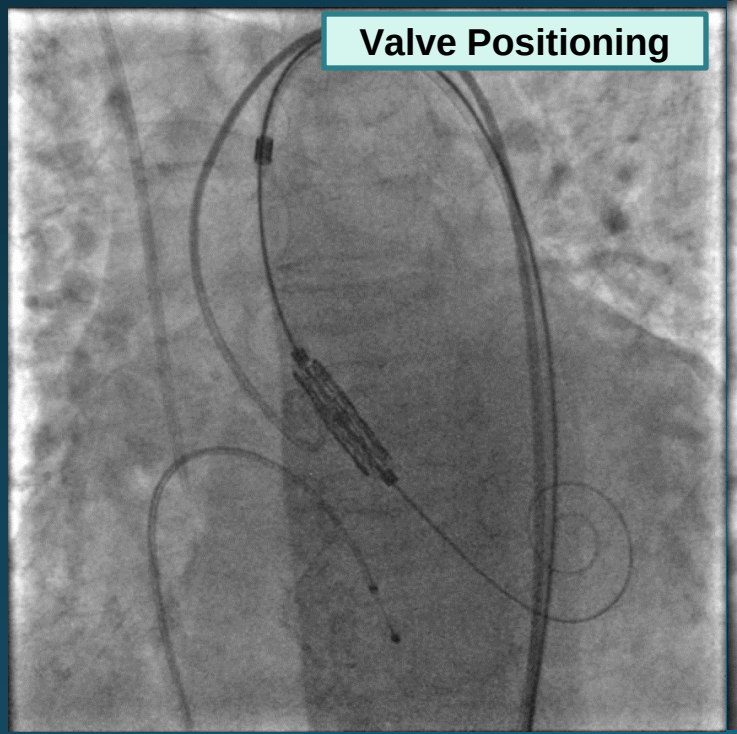
3D Annular area mm²		328.3
3D area derived diameter mm		20.4
% Annlar area over/under	20 mm	-4.3%
	21.5 mm	10.6%
	23 mm	26.6%
	24.5 mm	43.6%
	26 mm	61.7%
	27.5 mm	80.9%
	29 mm	101.2%
	30.5 mm	122.5%
	32 mm	145.0%

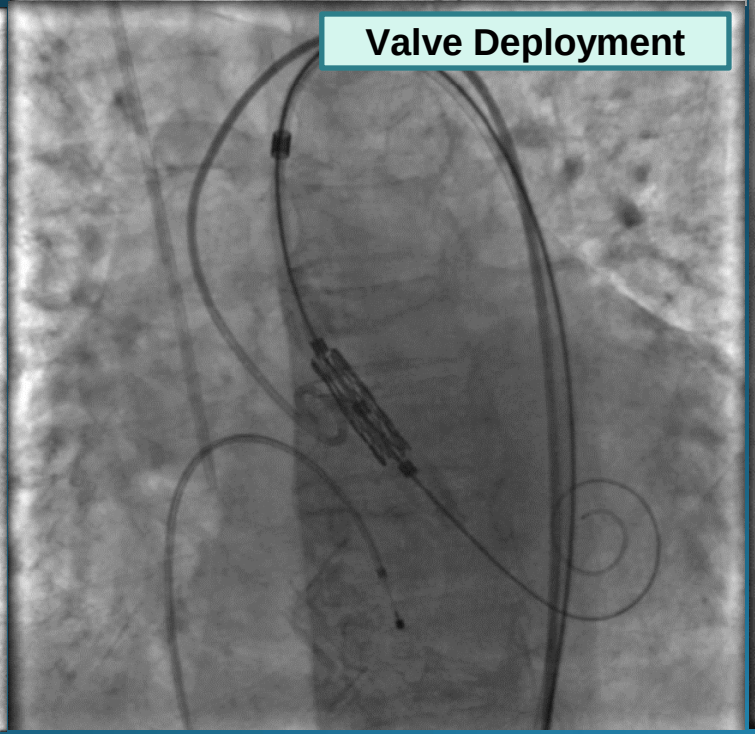
Recommended 21.5 mm size Myval


Aortogram


Valve Cross


Post Aortogram


Valve Positioning


Valve Deployment

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

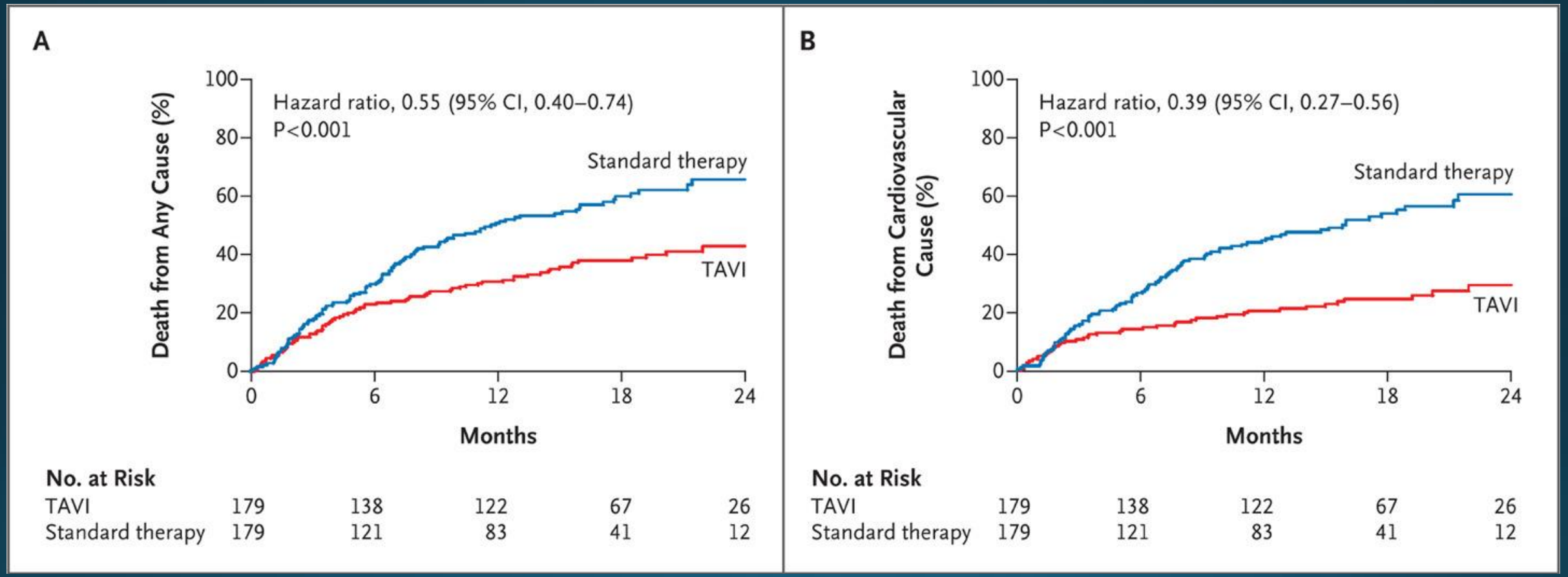
ABSTRACT

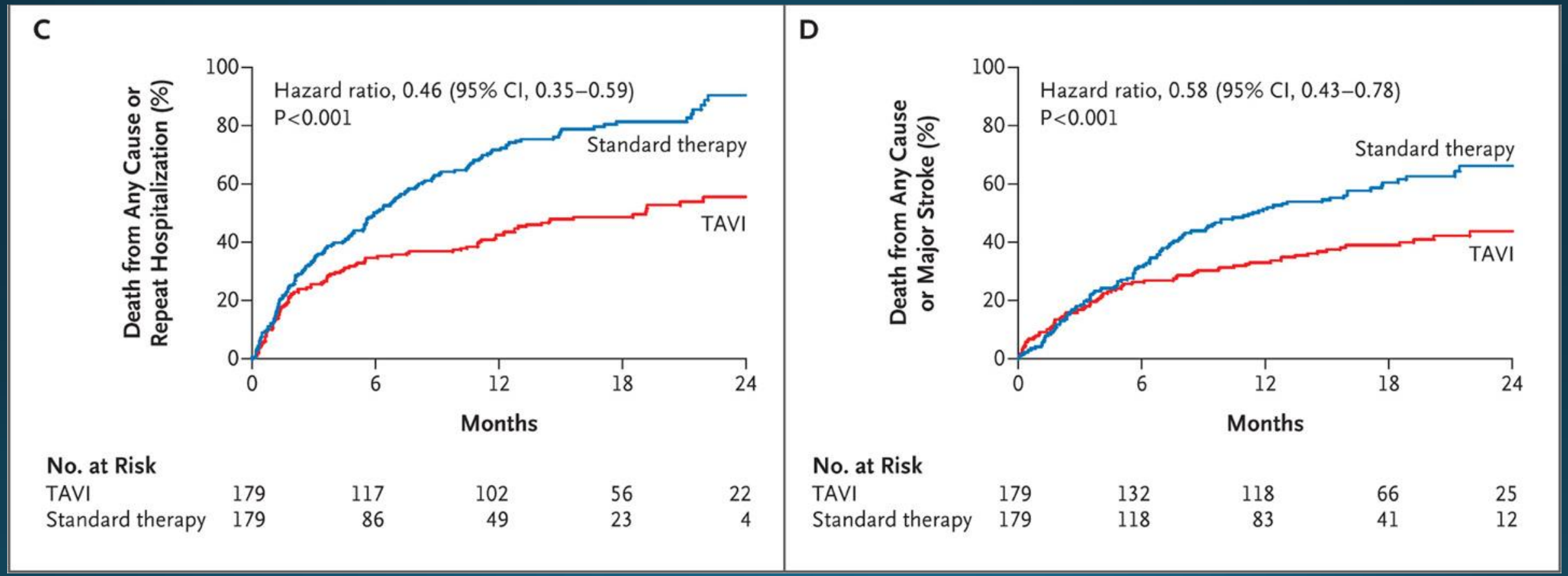
BACKGROUND

Many patients with severe aortic stenosis and coexisting conditions are not candidates for surgical replacement of the aortic valve. Recently, transcatheter aortic-valve implantation (TAVI) has been suggested as a less invasive treatment for high-risk patients with aortic stenosis.

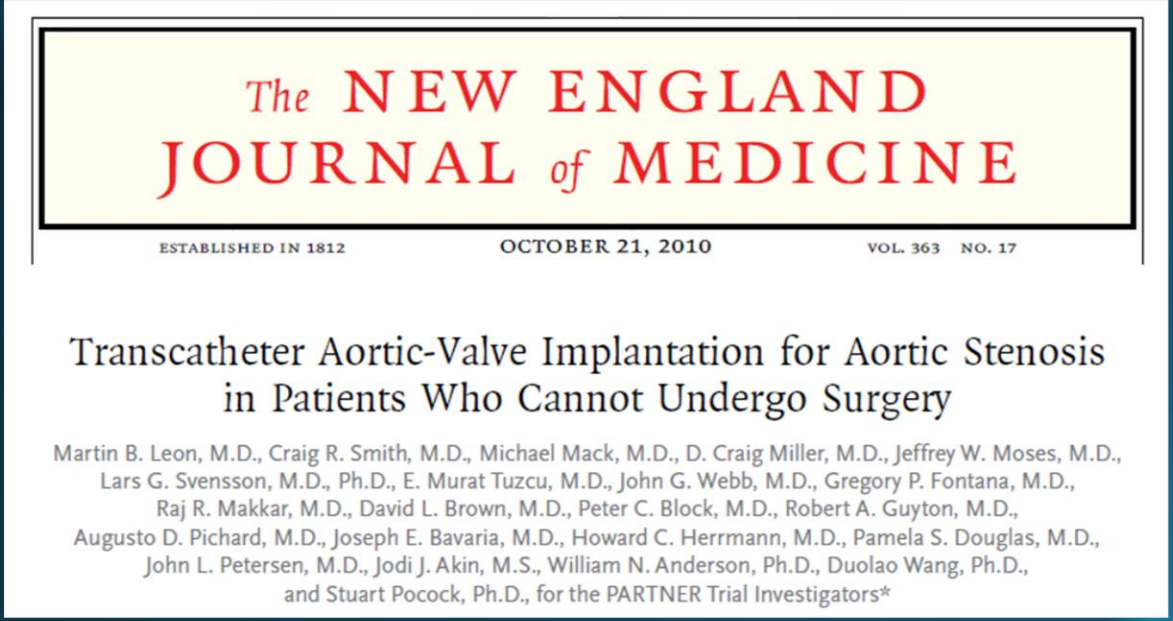
METHODS

From Columbia University Medical Center/NewYork–Presbyterian Hospital, New York (M.B.L., C.R.S., J.W.M.); Medical City Dallas, Dallas (M.M., D.L.B.); Stanford University Medical School, Stanford (D.C.M.), and Edwards Lifesciences, Irvine (J.J.A., W.N.A.) — both in California; Cleveland


A
Death from Any Cause (%)
100
80
60
40
20
0
Hazard ratio, 0.55 (95% CI, 0.40–0.74)
P<0.001
Standard therapy
TAVI
0
6
12
18
24
Months
No. at Risk
TAVI 179 138 122 67 26
Standard therapy 179 121 83 41 12
B
Death from Cardiovascular Cause (%)
100
80
60
40
20
0
Hazard ratio, 0.39 (95% CI, 0.27–0.56)
P<0.001
Standard therapy
TAVI
0
6
12
18
24
Months
No. at Risk
TAVI 179 138 122 67 26
Standard therapy 179 121 83 41 12


C
Death from Any Cause or Repeat Hospitalization (%)
100
80
60
40
20
0
Hazard ratio, 0.46 (95% CI, 0.35–0.59)
P<0.001
Standard therapy
TAVI
0
6
12
18
24
Months
No. at Risk
TAVI 179 117 102 56 22
Standard therapy 179 86 49 23 4
D
Death from Any Cause or Major Stroke (%)
100
80
60
40
20
0
Hazard ratio, 0.58 (95% CI, 0.43–0.78)
P<0.001
Standard therapy
TAVI
0
6
12
18
24
Months
No. at Risk
TAVI 179 132 118 66 25
Standard therapy 179 118 83 41 12

- In PARTNER 1, TAVR was superior to standard therapy in patients with symptomatic severe aortic stenosis who were not candidates for surgery AND was equivalent to surgery in high-risk patients.



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The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

The PARTNER 2A Trial
NEJM

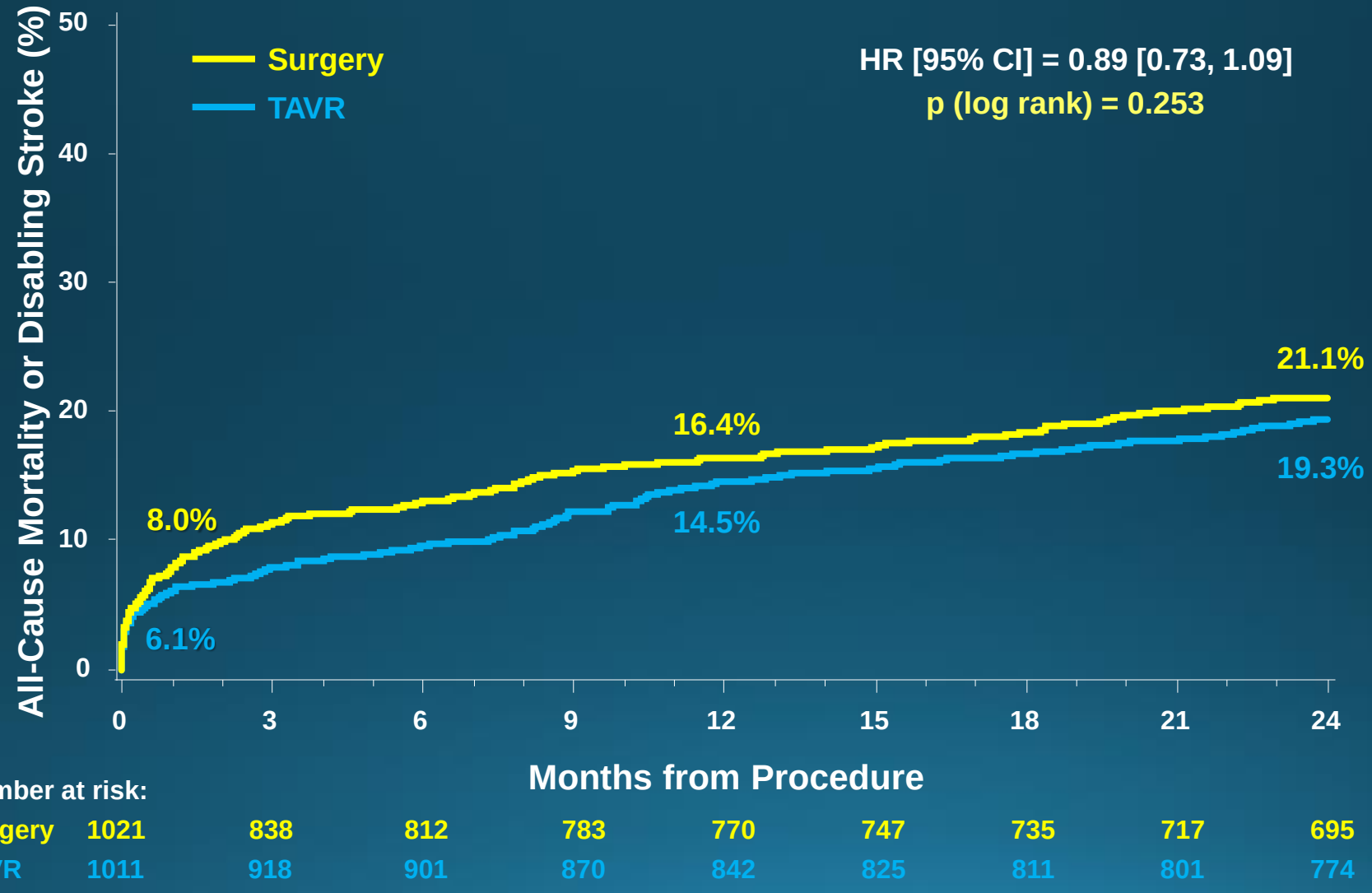
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

Primary Endpoint (ITT)
All-Cause Mortality or Disabling Stroke

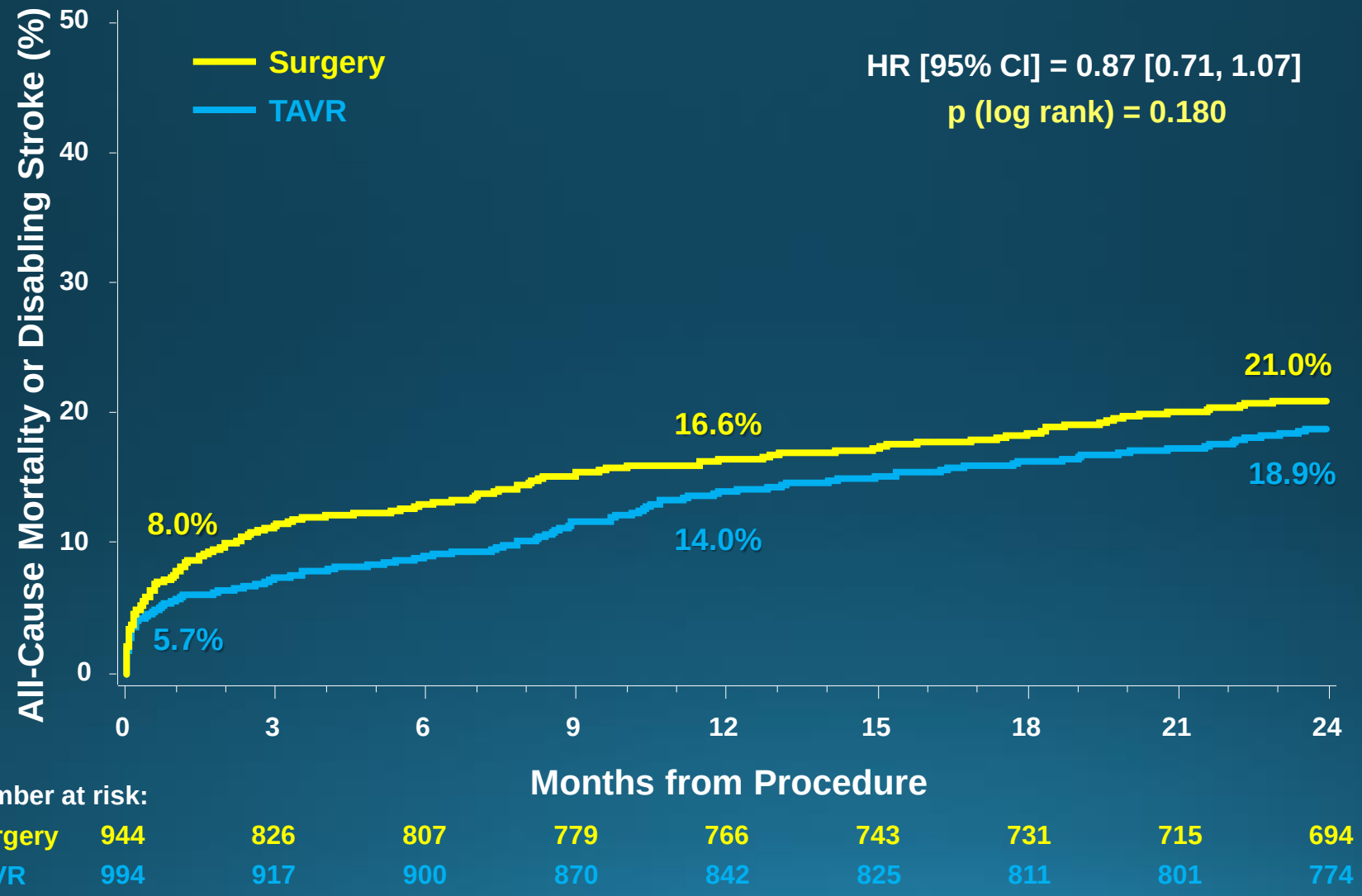


Number at risk:									
Surgery	1021	838	812	783	770	747	735	717	695
TAVR	1011	918	901	870	842	825	811	801	774

Primary Endpoint (AT)

All-Cause Mortality or Disabling Stroke

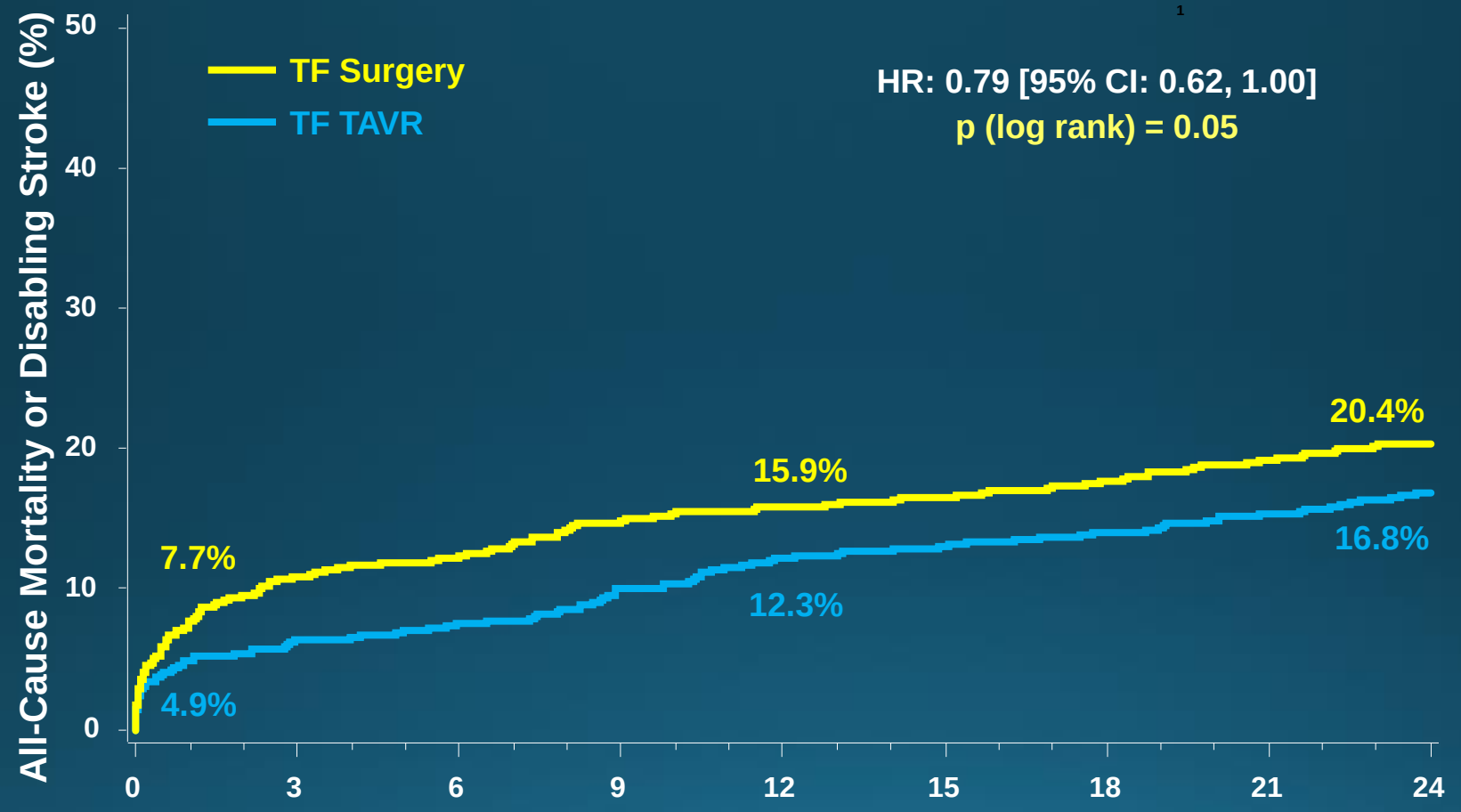
[1]



Number at risk:									
Surgery	944	826	807	779	766	743	731	715	694
TAVR	994	917	900	870	842	825	811	801	774

TF Primary Endpoint (ITT)

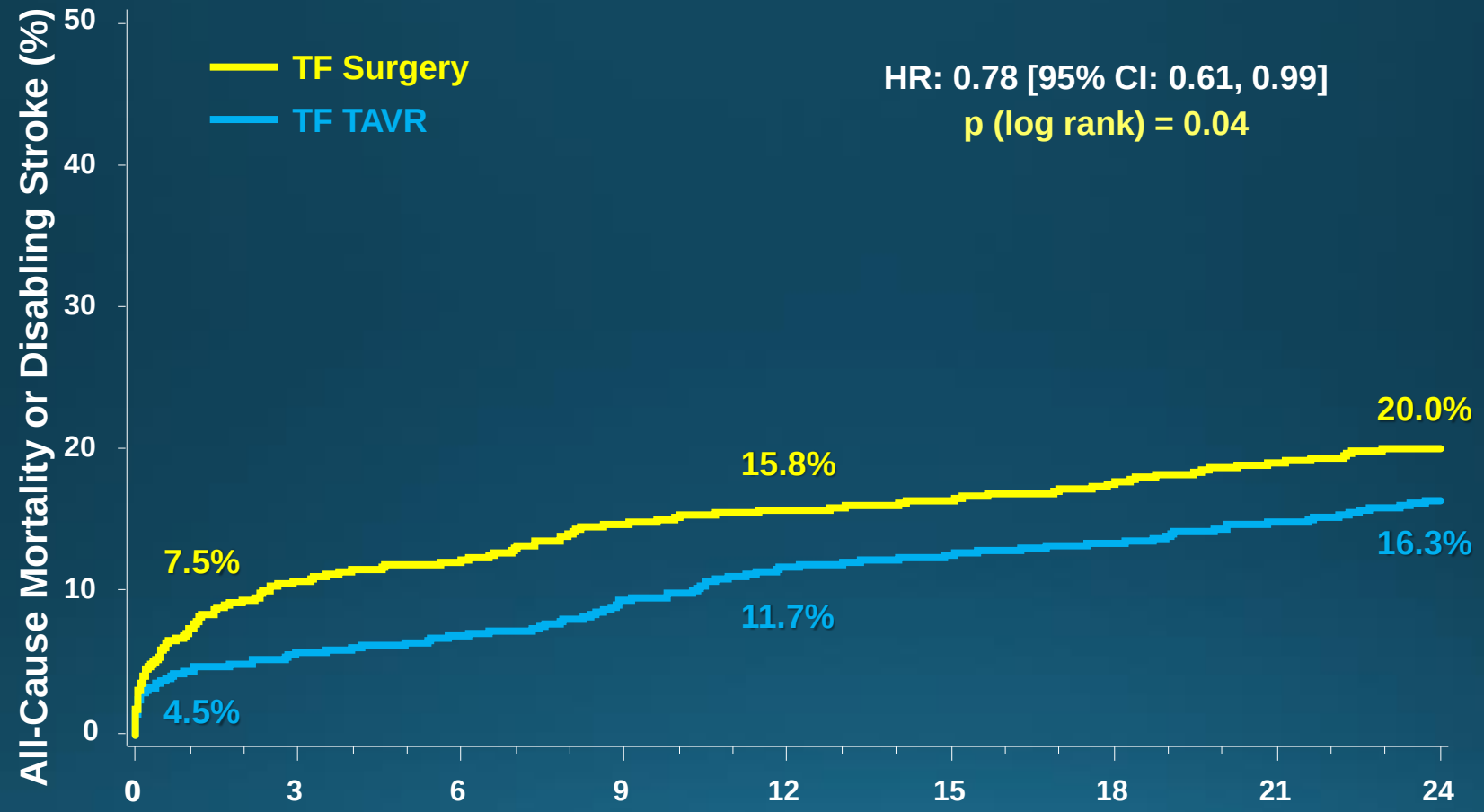
All-cause Mortality or Disabling Stroke



Number at risk:									
TF Surgery	775	643	628	604	595	577	569	557	538
TF TAVR	775	718	709	685	663	652	644	634	612

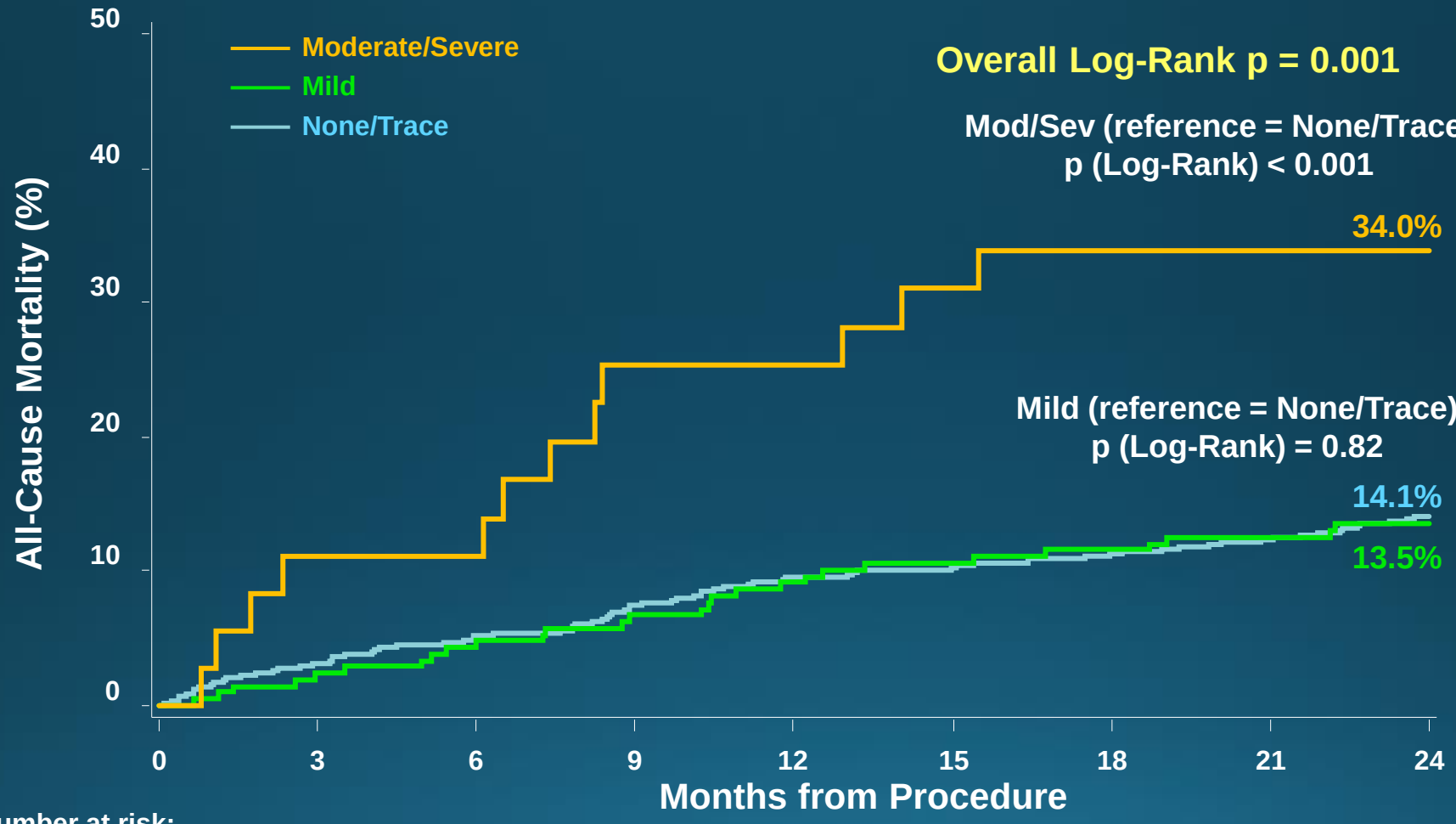
TF Primary Endpoint (AT)

All-Cause Mortality or Disabling Stroke [1]



Number at risk:									
TF Surgery	722	636	624	600	591	573	565	555	537
TF TAVR	762	717	708	685	663	652	644	634	612

Severity of PVR at 30 Days and All-cause Mortality at 2 Years (VI)



Number at risk:

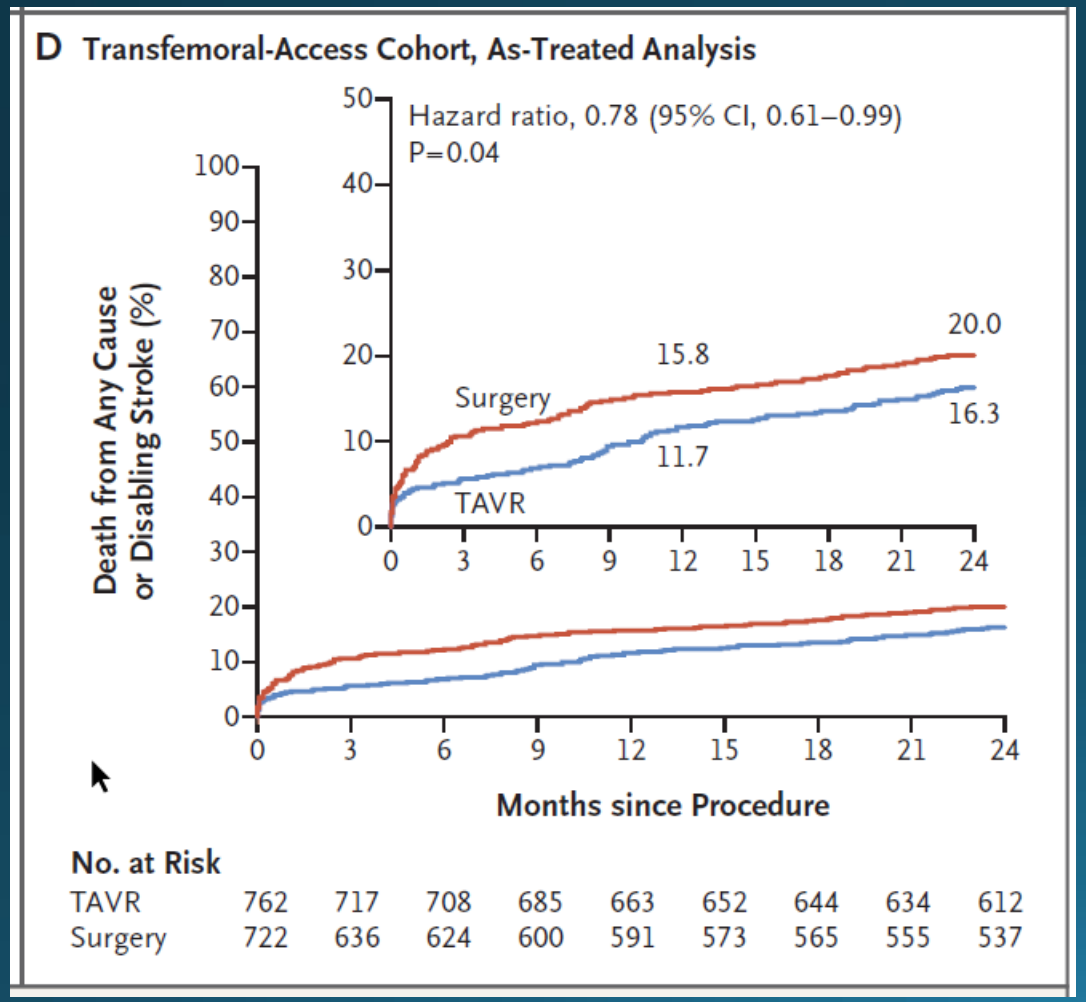
Moderate/Sev	36	32	32	26	26	24	22	22	21
Mild	210	204	199	194	188	184	182	180	175
None/Trace	701	678	664	647	628	621	612	605	585

The PARTNER 2A Trial
Conclusions (1)

In intermediate-risk patients with symptomatic severe aortic stenosis, results from the PARTNER 2A trial demonstrated that...

- TAVR using SAPIEN XT and surgery were similar (non-inferior) for the primary endpoint (all-cause mortality or disabling stroke) at 2 years.
- In the transfemoral subgroup (76% of patients), TAVR using SAPIEN XT significantly reduced all-cause mortality or disabling stroke vs. surgery (ITT: $p = 0.05$, AT: $p = 0.04$).

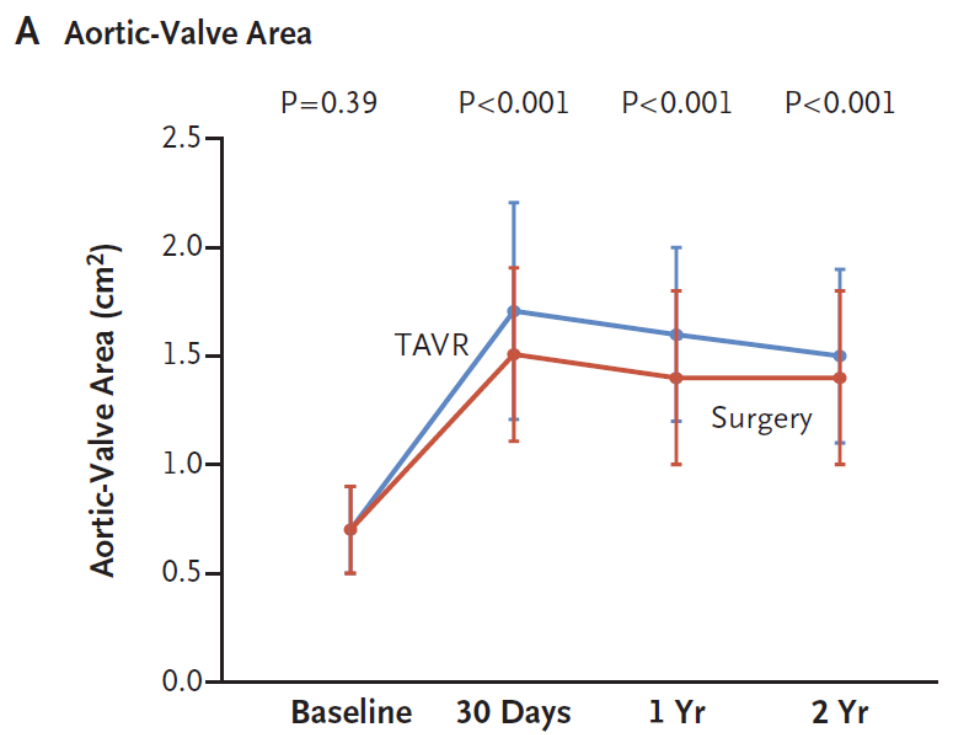
Are TAVI better than SAVR?



- Transfemoral cohort:

TAVI superior to SAVR with reduction in the primary endpoint of 3.7%

TAVI produces Superior Hemodynamics



No. of Patients with Echocardiographic Findings				
TAVR	899	829	695	567
Surgery	861	727	590	488

1. ECHO: superiority of TAVI or SAVR

* persistently larger AVA compared with SAVR

So…

- TAVI has shown good outcome in RCT in prohibitive risk, high risk and intermediate risk
- During this time
  - Devices have evolved
  - Techniques have been refined
  - Role of imaging has been solidified
  - Outcomes of TAVI are excellent

low risk patients?

STUDY PROTOCOL Open Access

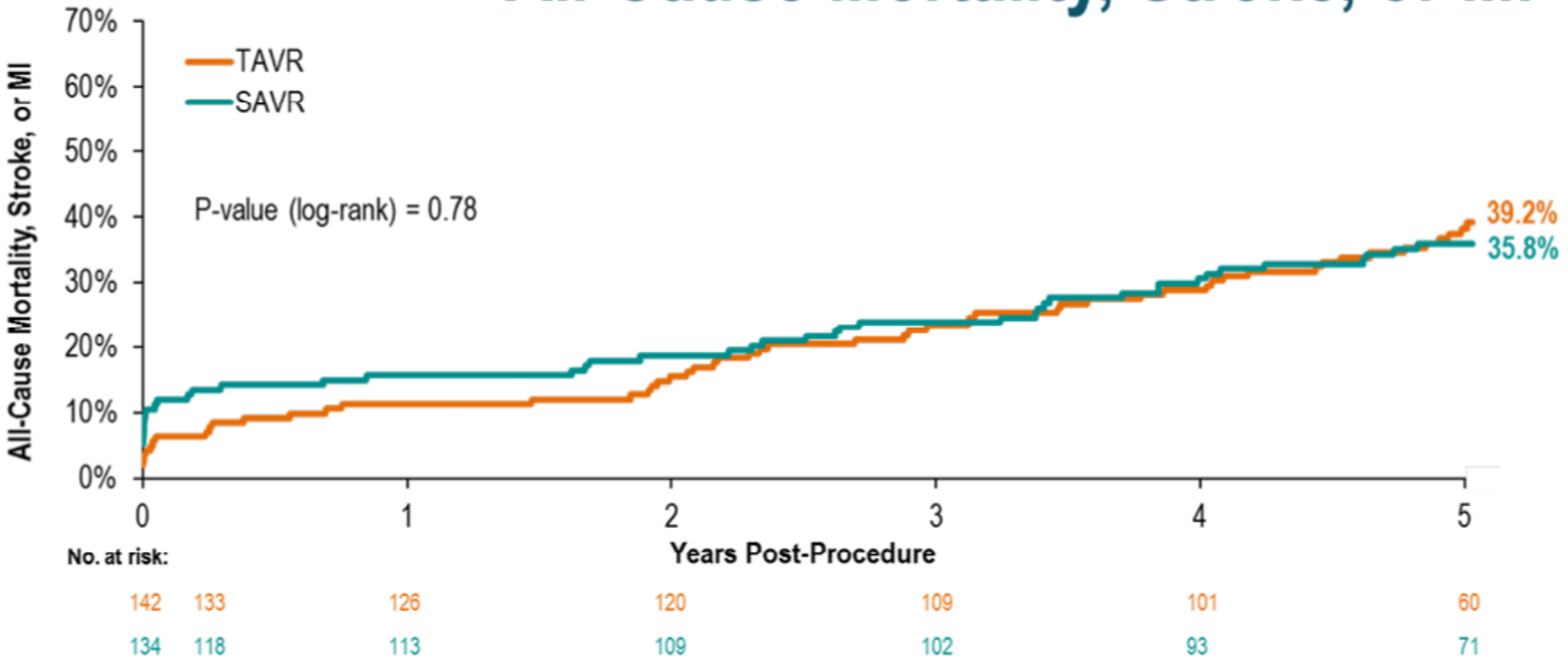
The Nordic Aortic Valve Intervention (NOTION) trial comparing transcatheter versus surgical valve implantation: study protocol for a randomised controlled trial

Hans Gustav Thyregod[1*], Lars Søndergaard[2], Nikolaj Ihlemann[2], Olaf Franzen[2], Lars Willy Andersen[3], Peter Bo Hansen[3], Peter Skov Olsen[1], Henrik Nissen[4], Per Winkel[5], Christian Gluud[5] and Daniel Andreas Steinbrüchel[1]

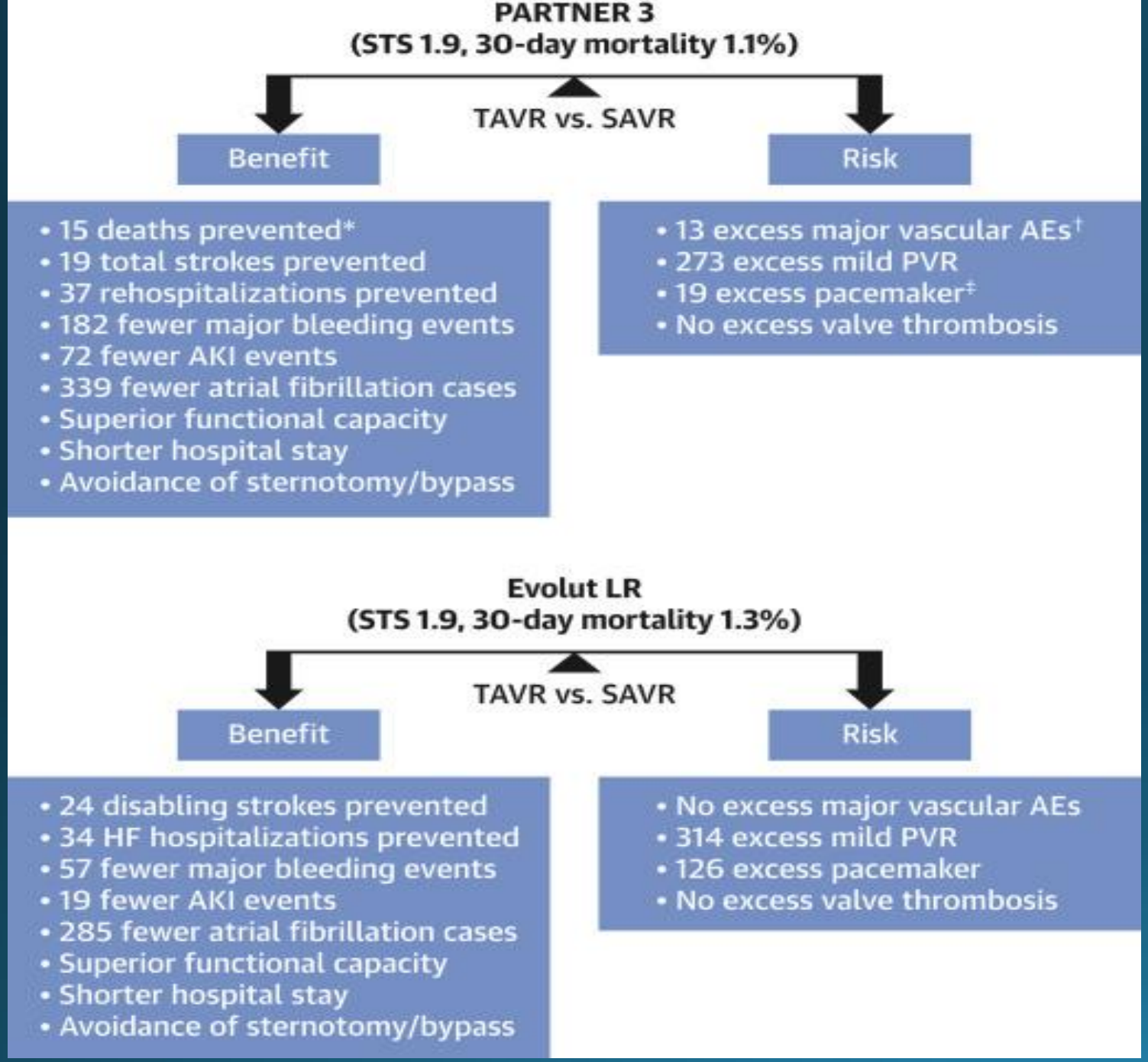
Baseline Characteristics

Characteristic, % or mean ± SD	TAVR n=145	SAVR n=135	p-value
Age (yrs)	79.2 ± 4.9	79.0 ± 4.7	0.71
Male	53.8	52.6	0.84
STS score	2.9 ± 1.6	3.1 ± 1.7	0.30
STS score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 ± 4.0	8.9 ± 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61

All-Cause Mortality, Stroke, or MI



NOTION Trial – 1st Trial with 5 years outcome in LOW RISK – Equally effective as compared to surgery. No difference in Mortality, Stroke or MI



- 1 and 3 year followup
- TAVR superior – death, stroke and rehospitalisation
- Lesser atrial fibrillation and hospital stay

The NEW ENGLAND JOURNAL of MEDICINE

RESEARCH SUMMARY

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

Mack MJ et al. DOI: 10.1056/NEJMoa2307447

CLINICAL PROBLEM

Transcatheter aortic-valve replacement (TAVR) is increasingly being used as an alternative to surgical valve replacement in patients with severe, symptomatic aortic stenosis. In the PARTNER 3 trial comparing TAVR with surgery in patients at low surgical risk, analyses of a composite of death, stroke, or rehospitalization at 1 and 2 years favored TAVR. Longer-term outcomes in these patients are unknown.

CLINICAL TRIAL

Design: This 5-year follow-up of the multicenter, randomized PARTNER 3 trial examined the efficacy of TAVR as compared with surgical aortic-valve replacement in patients with severe, symptomatic aortic stenosis and low surgical risk.

Intervention: 1000 patients were assigned to undergo transfemoral TAVR or surgery. The two primary end points at 5 years were a composite of death from any cause, stroke, or rehospitalization related to the procedure, the valve, or heart failure; and a hierarchical composite that included death, disabling stroke, nondisabling stroke, and the number of rehospitalization days.

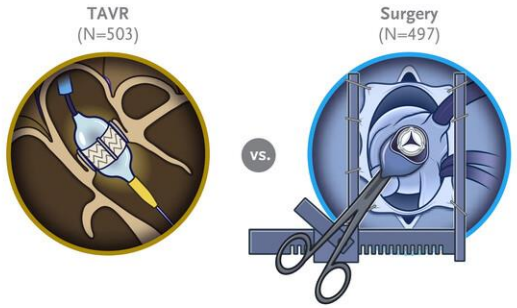
RESULTS

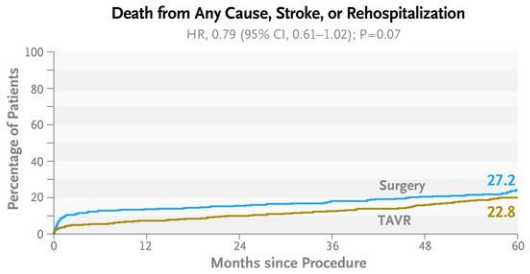
Among the patients with available data, the results for the two primary end points were similar in the two groups at 5 years. The incidence of bioprosthetic-valve failure was also similar in the two groups.

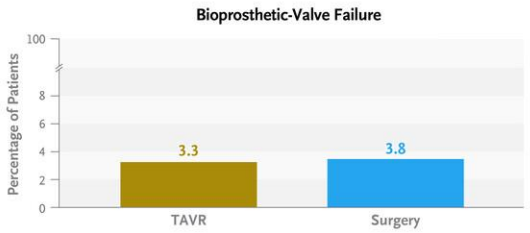
LIMITATIONS AND REMAINING QUESTIONS

- The trial excluded patients who were not candidates for transfemoral access or who had bicuspid aortic valves or other anatomical or clinical features that increased the risk of complications from TAVR or surgery.
- More patients in the surgery group than in the TAVR group withdrew from the trial, which may have biased the findings.
- Whether follow-up during the coronavirus disease 2019 pandemic disproportionately affected adverse outcomes could not be determined.

Links: Full Article | NEJM Quick Take | Editorial







CONCLUSIONS

Among patients with severe, symptomatic aortic stenosis and low surgical risk who underwent TAVR or surgical aortic-valve replacement, the frequency of adverse cardiovascular events appeared to be similar in the two groups at 5 years of follow-up.

Low Risk AS PARTNER 3 Trial

CONCLUSIONS

Among patients with severe, symptomatic aortic stenosis and low surgical risk who underwent TAVR or surgical aortic-valve replacement, the frequency of adverse cardiovascular events appeared to be similar in the two groups at 5 years of follow-up.

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

Study Design

Evolut™ Low Risk Trial

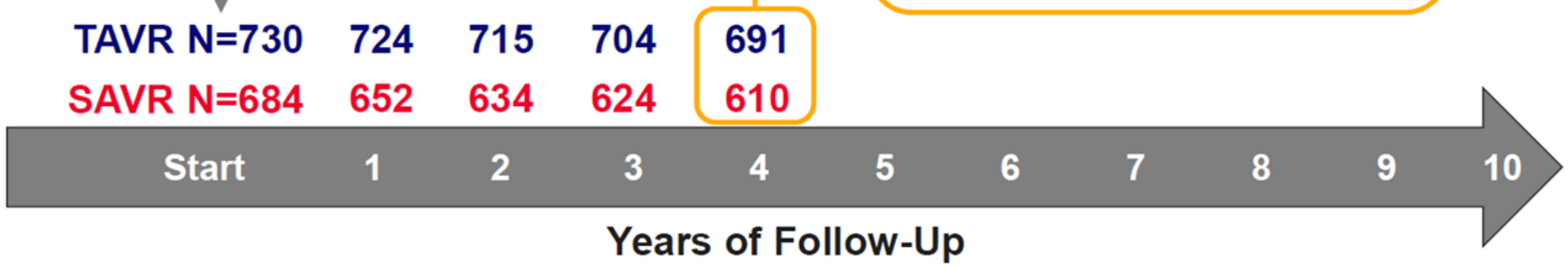
Patients with Severe AS
Low risk of death (<3%) from surgery
Anatomy suitable for both TAVR and SAVR

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.

EVOLUT LOW RISK TRIAL | 4 YEAR RESULTS

SUMMARY

Evolut™ Low Risk Trial

TAVR patients in the Evolut Low Risk trial continue to show durable outcomes for the primary endpoint and significantly better hemodynamics than SAVR through 4 years

- 26% relative reduction in hazard for death or disabling stroke ($p = 0.05$) with Evolut TAVR compared to SAVR at 4 years and the curves continue to diverge over time
- Significantly lower mean gradients and higher EOAs with Evolut TAVR vs SAVR at all follow-up timepoints
- 85% of Evolut TAVR patients had none/trace PVR and there was no difference between groups in moderate or greater PVR (0.4% vs 0.0%, $p = 0.50$)
- Indicators of valve performance, including high gradients at 4 years, severe PPM, and endocarditis overall favored TAVR, with similarly low thrombosis rates in both groups

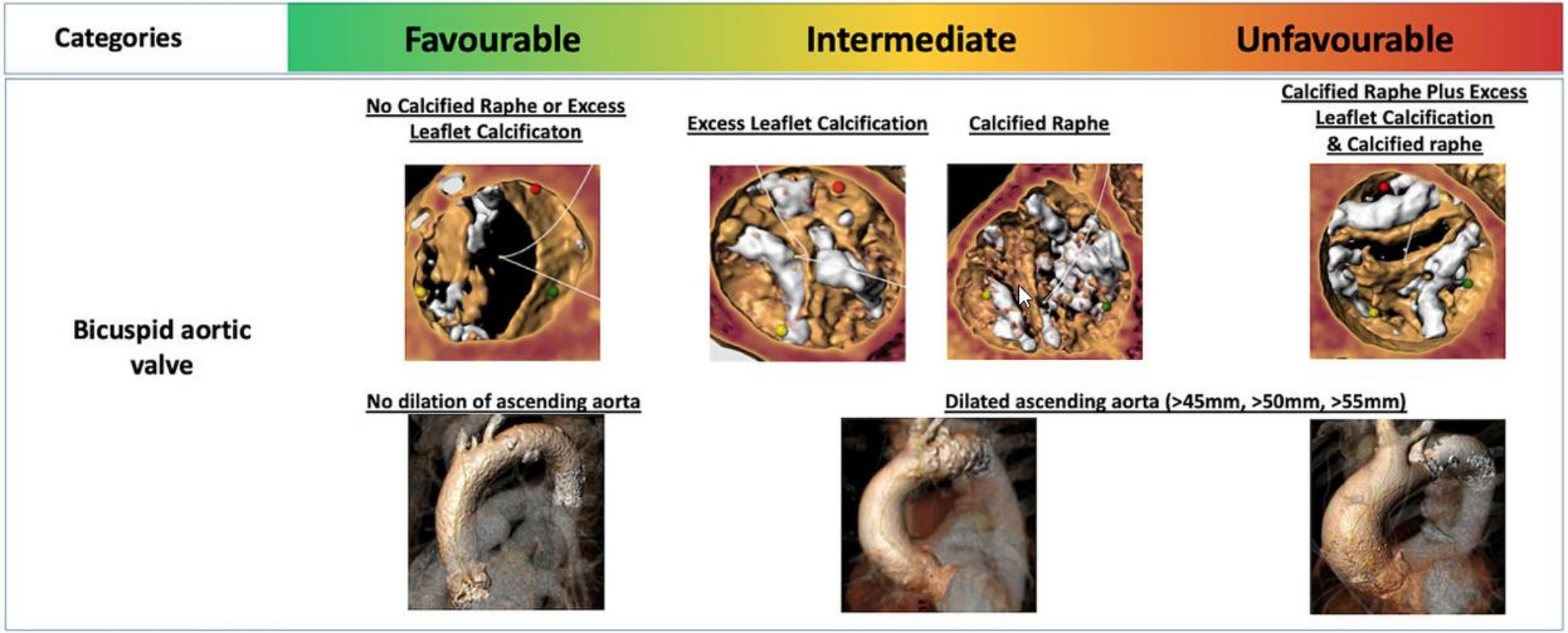
Table. Main Characteristics and Clinical Outcomes of TAVR Low-Risk Trials

	PARTNER 3[1]		Evolut low risk[2]		NOTION[3]	
	TAVR	SAVR	TAVR	SAVR	TAVR	SAVR
Patients, n	496	454	734	734	145	135
Age, y	73.3±5.8	73.6±6.1	74.0±5.9	73.8±6.0	79.2±4.9	79.9±4.7
STS score	1.9±0.7	1.9±0.6	1.9±0.7	1.9±0.7	2.9±1.6	3.1±1.7
Prosthesis	BE	/	SE	/	SE	/
30-d						
PM implantation, %	6.5	4.0	17.4	6.1	34.1	1.6
Moderate/severe PVL	0.8	0	3.5	0.5	15.3	1.8
Mortality	0.4	1.1	0.5	1.3	2.1	3.7
1-y						
PM implantation	7.3	5.4	19.4	6.7	38	2.4
Moderate/severe PVL	0.9	0.5	3.6	0.6	15.7	0.9
Mortality	1.0	2.5	2.9	4.6	4.9	7.5
2-y						
PM implantation	/	/	/	/	/	/
Moderate/severe PVL	0.5	0	5.7	0	15.4	0.9
Mortality	2.4	3.2	4.5	4.5	8.0	9.8

TAVI - issues

- Bicuspid valve antomy
- Paravalvular leak
- Stroke
- Conduction abnormality
- Coronary access
- Valve durability and thrombosis

Figure 6 Anatomical risk stratification of bicuspid aortic valve. The category (favourable, intermediate, ...



Eur Heart J, Volume 43, Issue 29, 1 August 2022, Pages 2729–2750, https://doi.org/10.1093/eurheartj/ehac105

Case2
Patient History

Date of Procedure: 27.06.2022

- 69 Year old Male with Severe symptomatic Aortic stenosis class D3 (Symptomatic, Normal LVEF), Calcified True Bicuspid Aortic valve.
- Mild AR, TR Trace

Baseline ECG

Pre-Procedural Echo cardio graphic Assessment

Parameters	Findings
Peak Δ	105 mm Hg
Mean Δ	68 mm Hg
LVEF	55%

Pre Procedural MSCT Analysis

Aortic Valve

Aortic Annulus

Perimeter:	64.6	mm
Perimeter Derived Ø:	20.6	mm
Area:	319.6	mm²
Area Derived Ø:	20.2	mm

LVOT Ø: 18.9 mm

RCA Height: 18.9 mm

Asc. Aorta Ø: 36.5 mm

STJ Ø: 28.6 mm

LCA Height: 22.9 mm

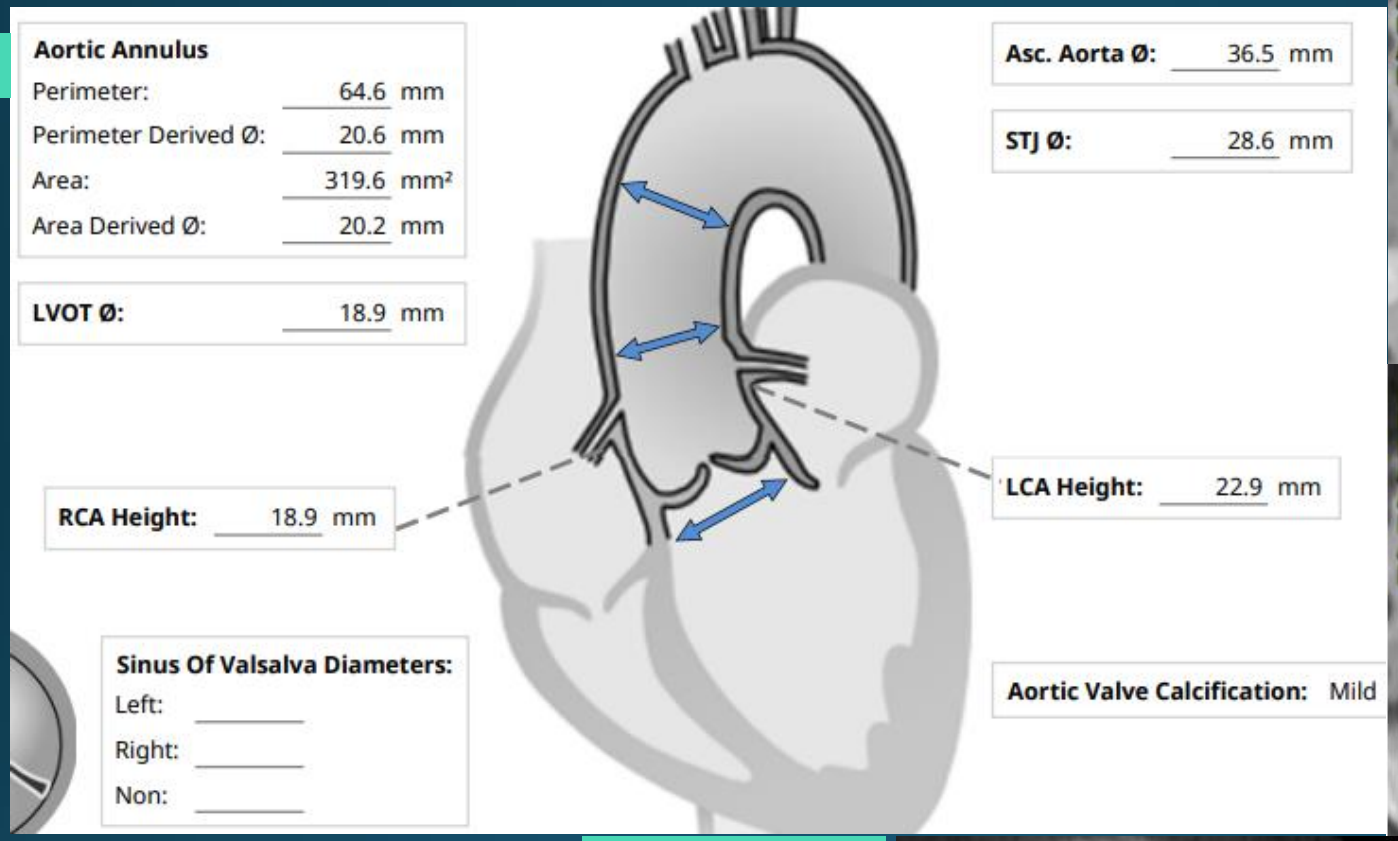
Sinus Of Valsalva Diameters:

Left: _____

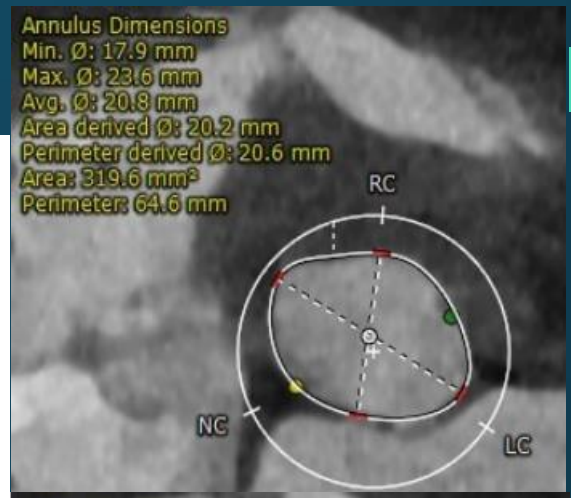
Right: _____

Non: _____

Aortic Valve Calcification: Mild

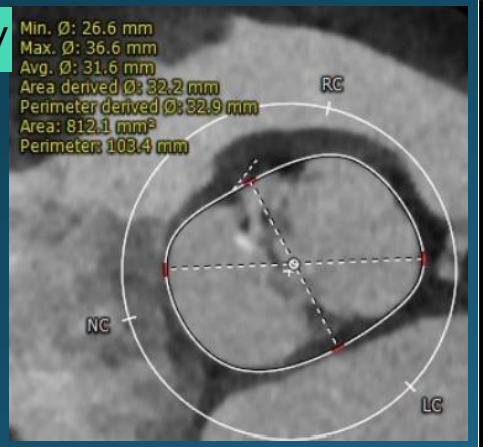


Annulus

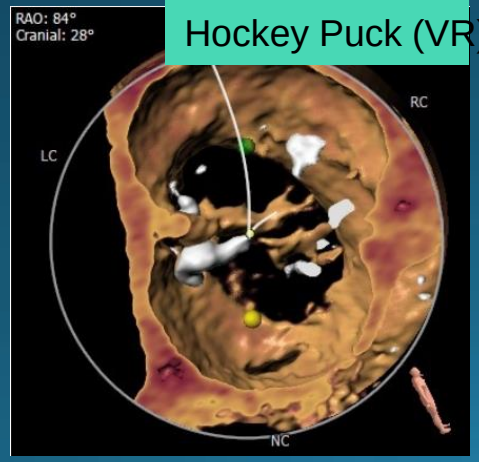


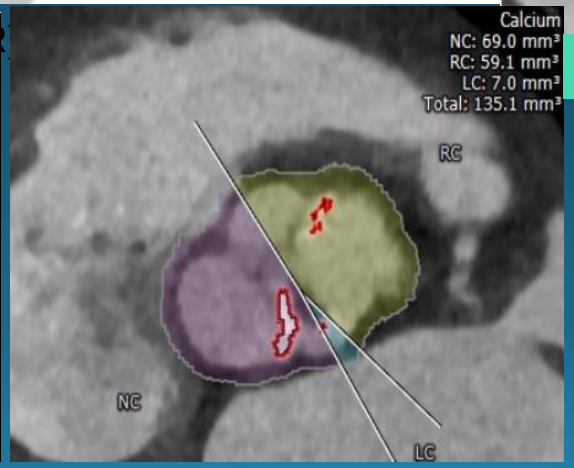
LVOT

SOV



Hockey Puck (VR)



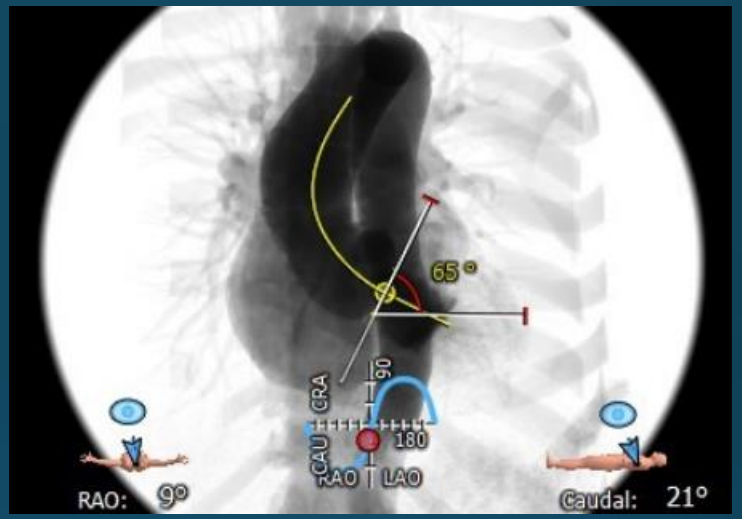


Calcium Quantification

Pre procedural MSCT Analysis

Calcifications

Deployment View

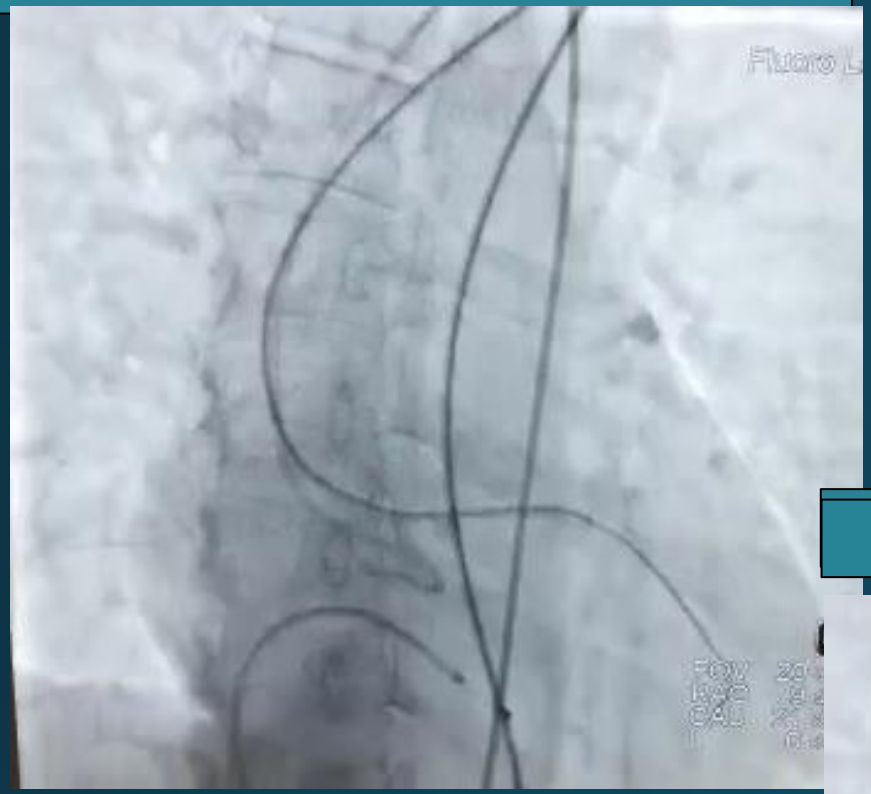


Ascending Aorta Ø	Min: 35.7 mm Max: 37.4 mm Average: 36.5 mm
Sinotubular Junction Ø	Min: 26.5 mm Max: 30.7 mm Average: 28.6 mm
Aortic Annulus	Min Ø: 17.9 mm Max Ø: 23.6 mm Average Ø: 20.8 mm Eccentricity: 0.24
LVOT Ø	Min: 14.5 mm Max: 23.3 mm Average: 18.9 mm
Sinus of Valsalva Height	9.8 mm

3D Annular area mm^2		319.6
3D area derived diameter mm		20.2
% Annlar area over/under	20 mm	-1.7%
Recommended 21.5 mm Intermediate size Myval, 16 mm X 40 mm Mammoth for Predilatation	21.5 mm	13.6%
	23 mm	30.0%
	24.5 mm	47.5%
	26 mm	66.1%
	27.5 mm	85.8%
	29 mm	106.7%
	30.5 mm	128.6%
	32 mm	151.6%

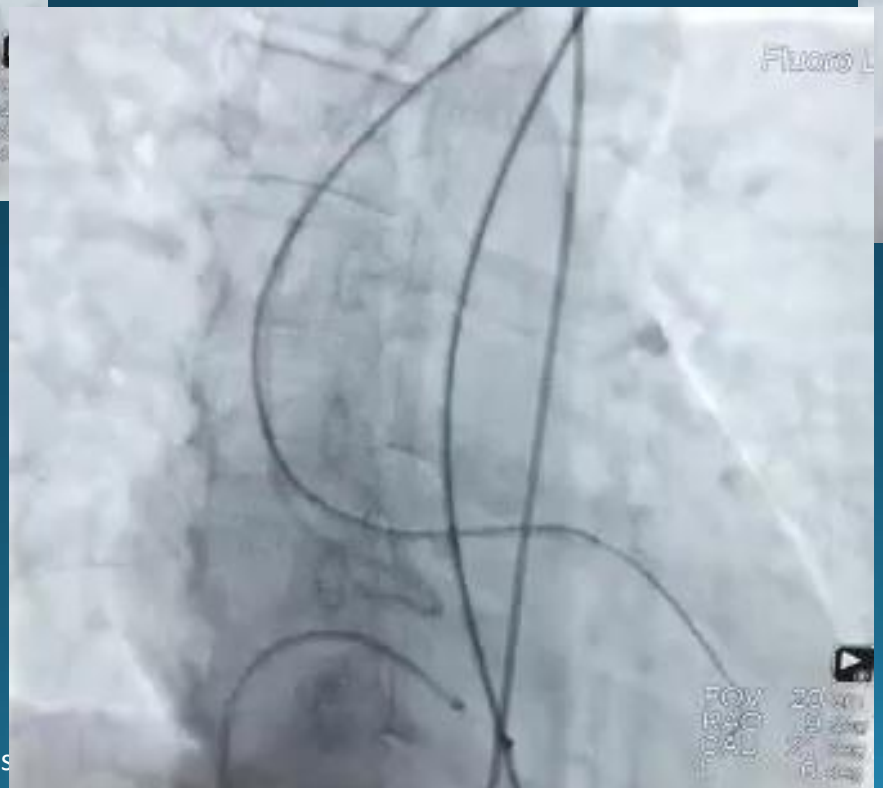
Myval 21.5 mm

Valve Crossing



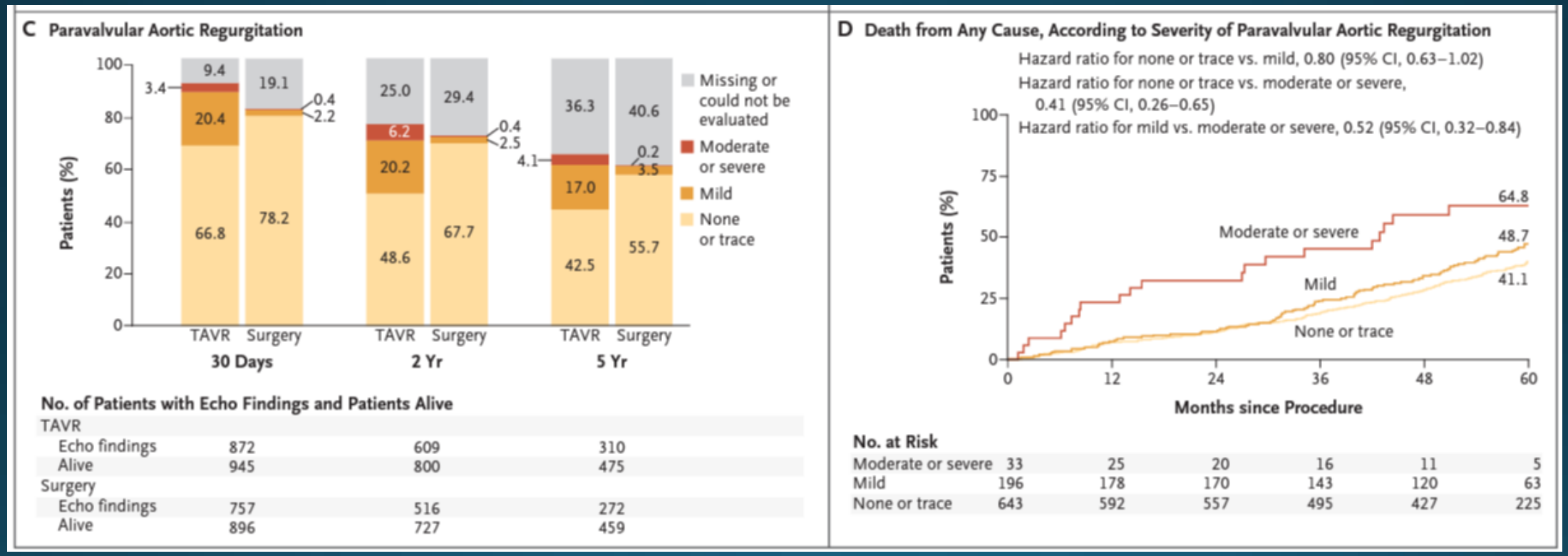
Predilatation

Deployment



Case details, images and video courtes

Paravalvular leak-



No. of Patients with Echo Findings and Patients Alive

TAVR			
Echo findings	872	609	310
Alive	945	800	475
Surgery			
Echo findings	757	516	272
Alive	896	727	459

No. at Risk

Moderate or severe	33	25	20	16	11	5
Mild	196	178	170	143	120	63
None or trace	643	592	557	495	427	225

Moderate or Severe AR- worse longterm outcomes

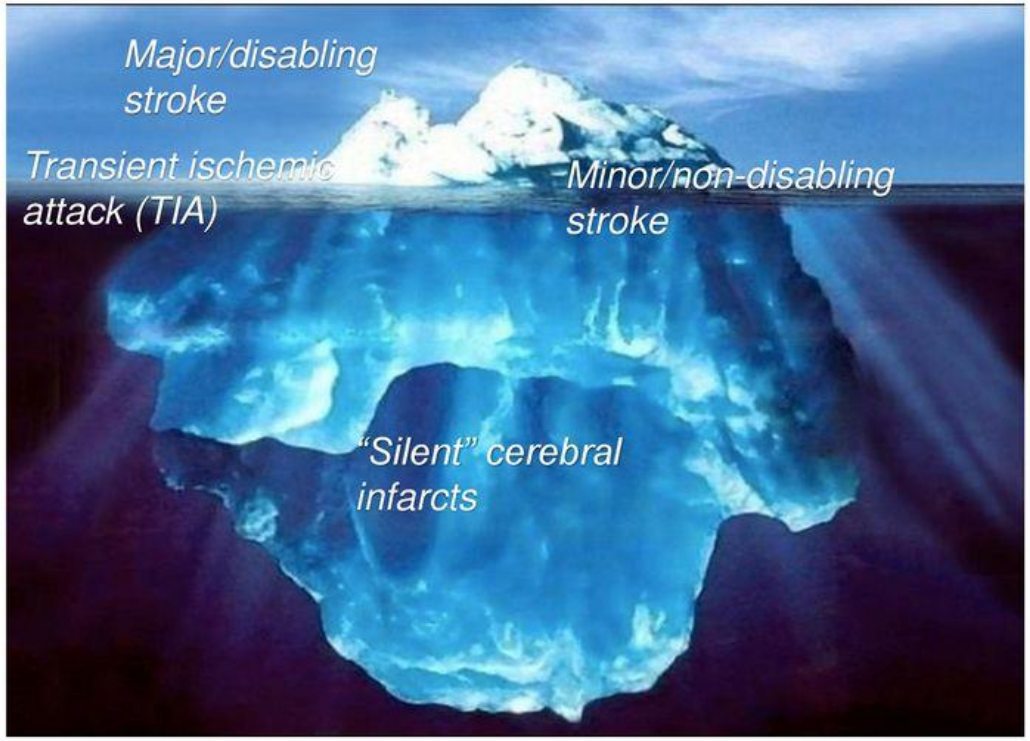
Stroke

In Stroke most damage is unseen

Clinically apparent

Subtle and often undetected

Clinically unrecognized

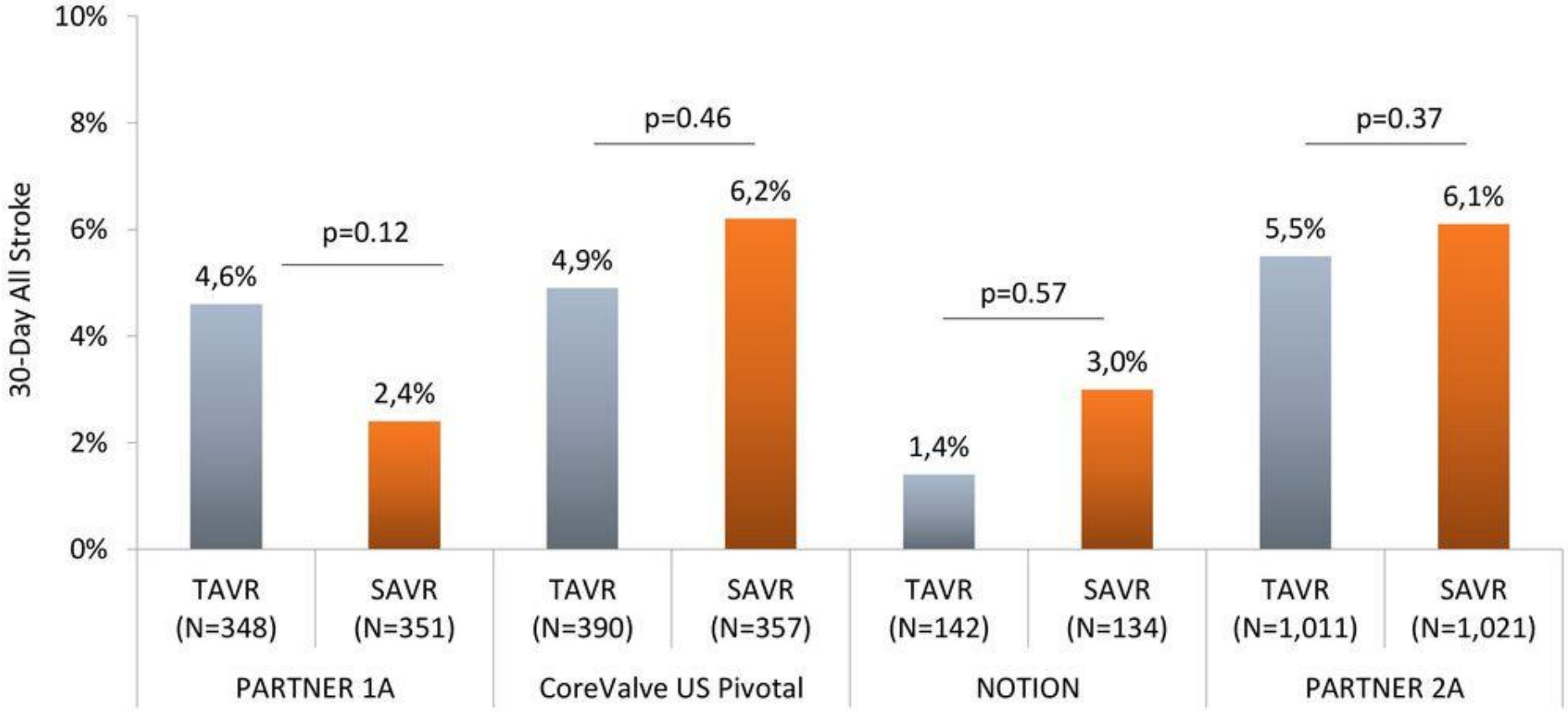


….but can have far-reaching effects

TAVR vs. SAVR

Randomized Trials

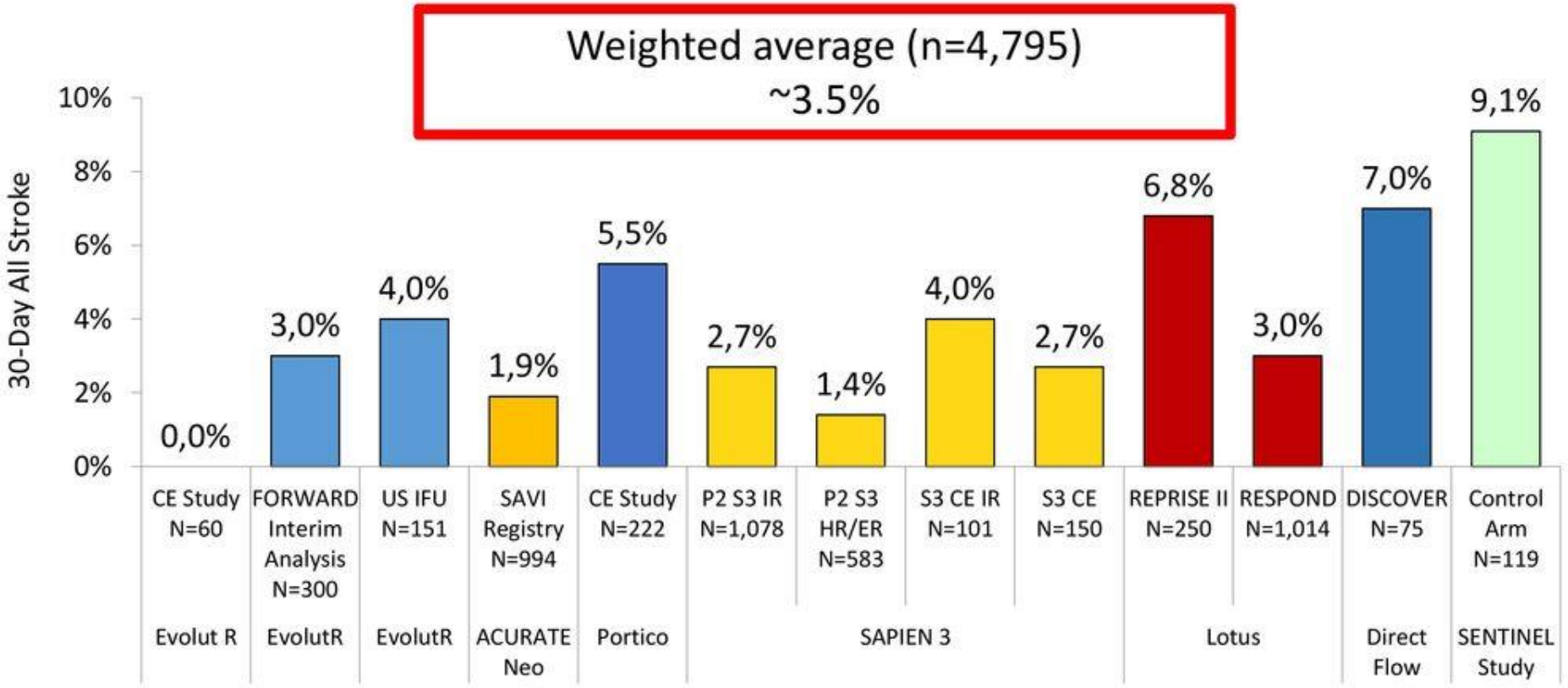
As practice evolved, randomized trials between TAVR and SAVR showed no difference in the rate of 30-day stroke using both self-expanding and balloon-expanding valves



TAVR Stroke

Rates with Contemporary Devices

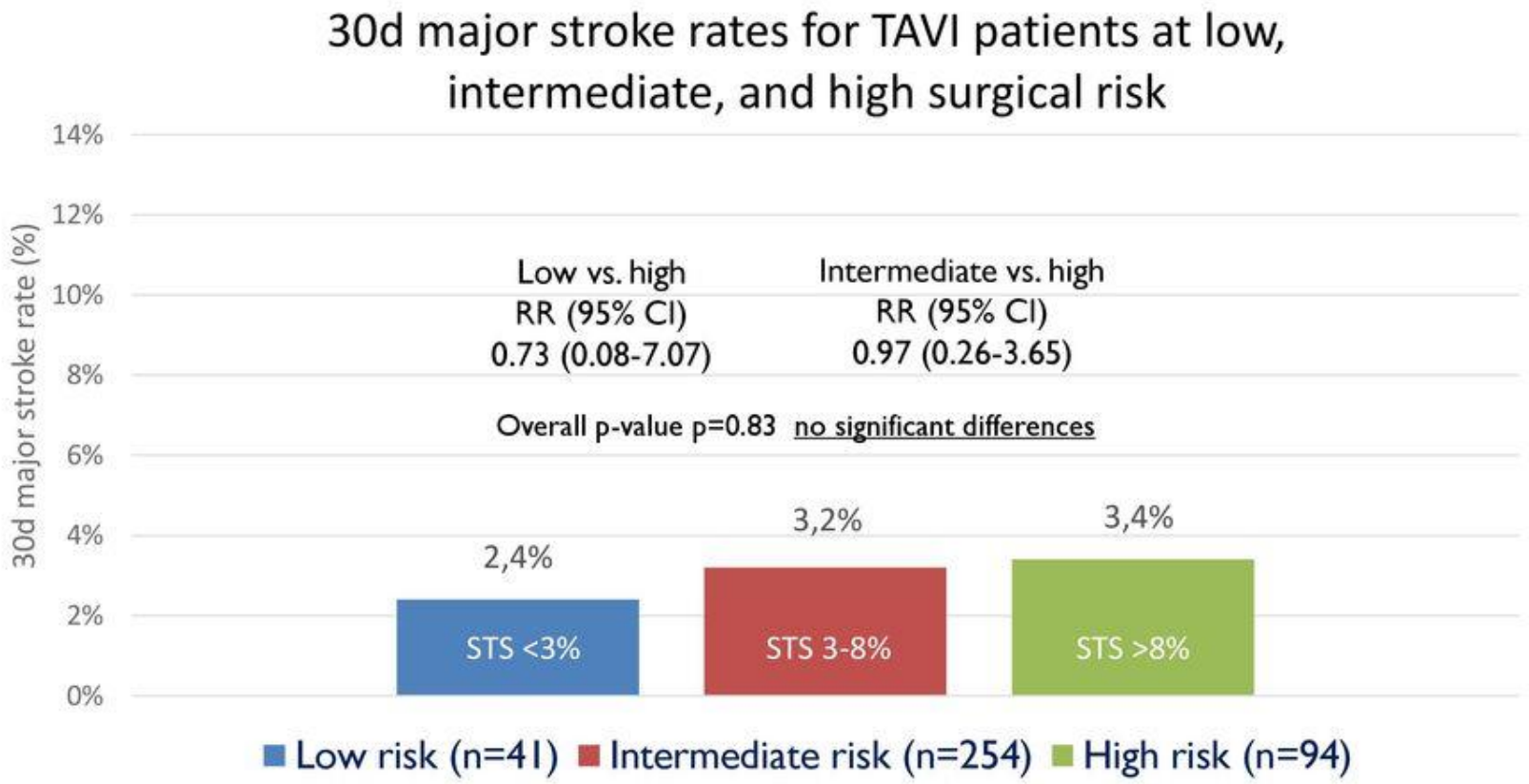
- In contemporary practice, the overall stroke rate remains around 3,5%



[1]Manoharan, et al., *J Am Coll Cardiol Intv* 2015; 8: 1359-67; [2]Moellman, et al., presented at PCR London Valves 2015; [3]Linke, et al., presented at PCR London Valves 2015; [4]Kodali, et al., *Eur Heart J* 2016; doi:10.1093/eurheartj/ehw112; [5]Vahanian, et al., presented at EuroPCR 2015; [6]Webb, et. al. *J Am Coll Cardiol Intv* 2015; 8: 1797-806; [7]DeMarco, et al, presented at TCT 2015; [8]Meredith, et al., presented at PCR London Valves 2015; [10]Falk, et al., presented at EuroPCR 2016; [11]Kodali, presented at TCT 2016

TAVI 30d major stroke rates similar across the surgical risk spectrum

n=389 consecutive TAVI patients treated in Bern

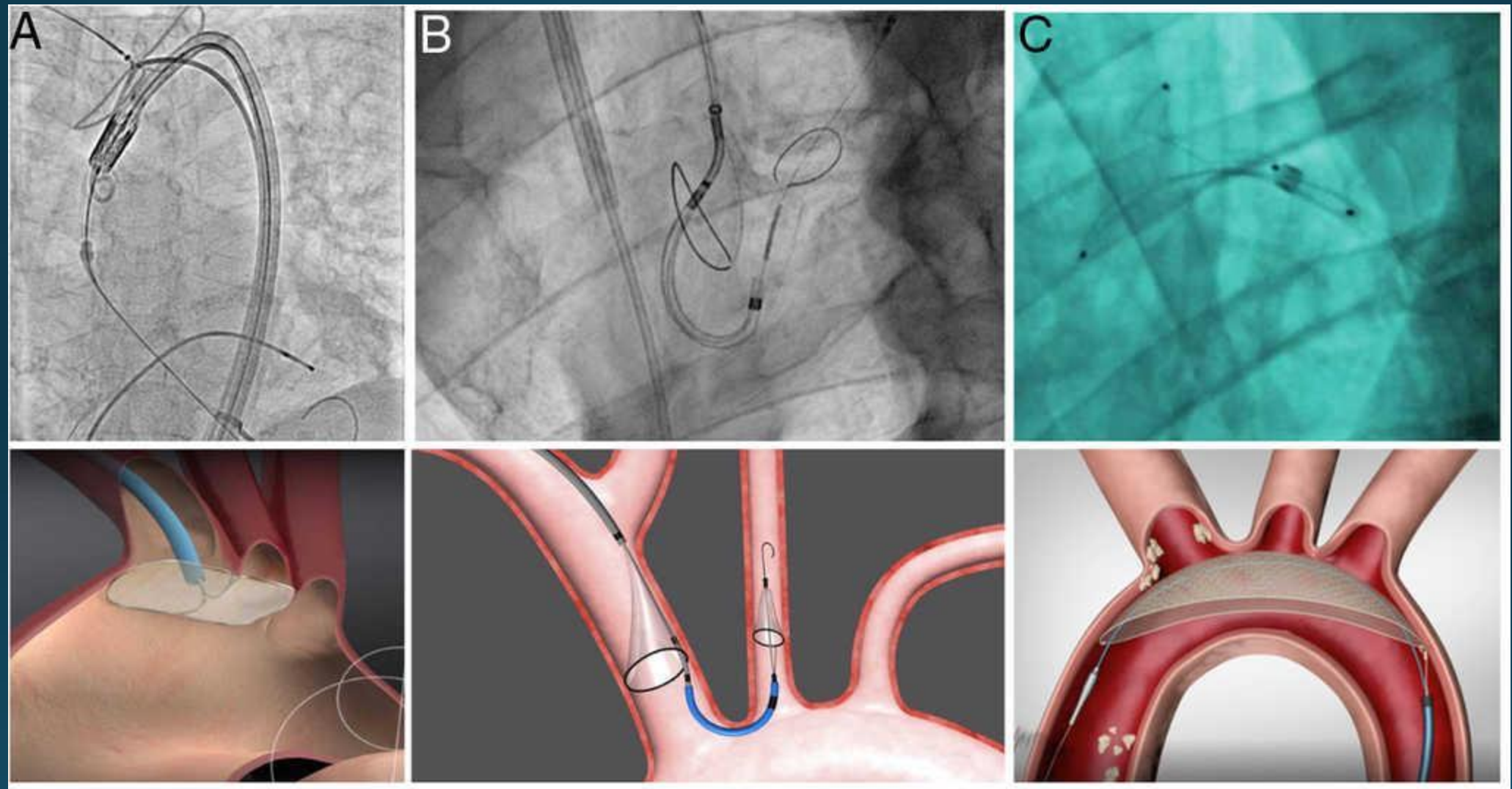


Wenawesser P, et al. Clinical outcomes of patients with estimated low or intermediate surgical risk undergoing transcatheter aortic valve implantation. Eur Heart Journal 2013 34:1894-1905.

Procedural Stroke Prevention

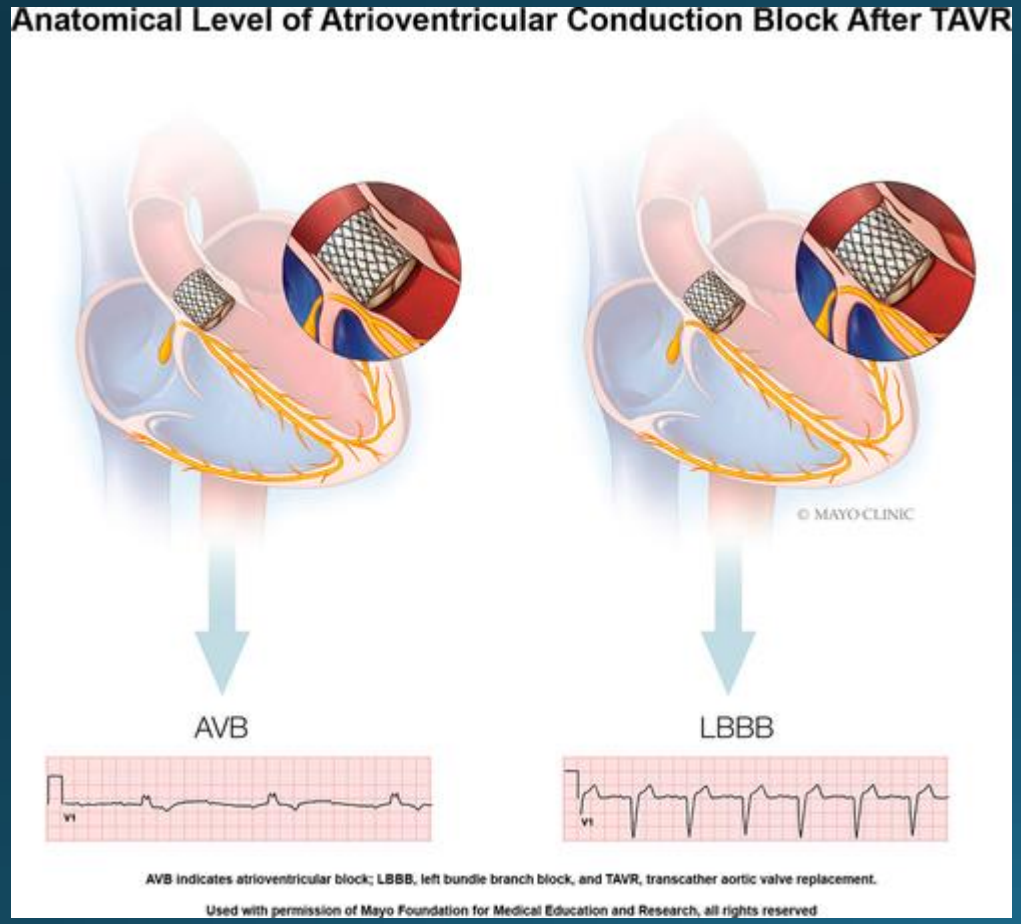
Optimized Anticoagulation

Embolic Protection



Rev Esp Cardiol. 2019;72:664–71

Conduction abnormality



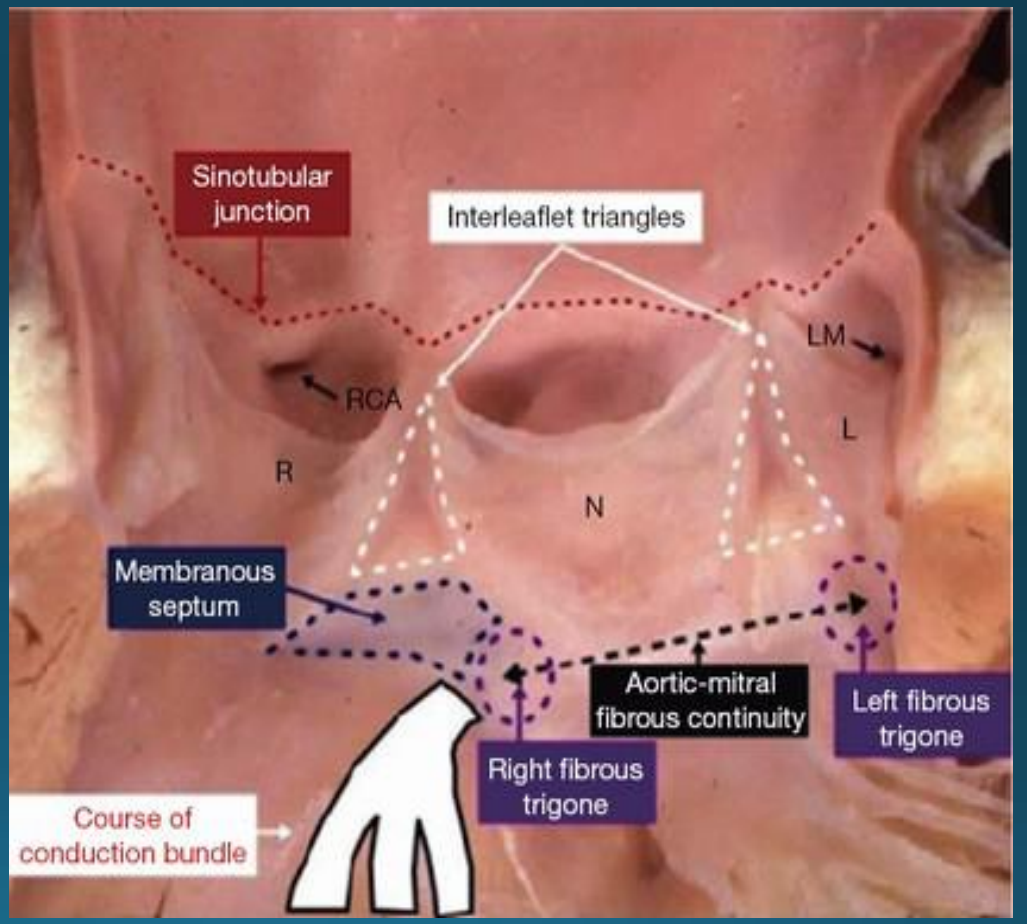
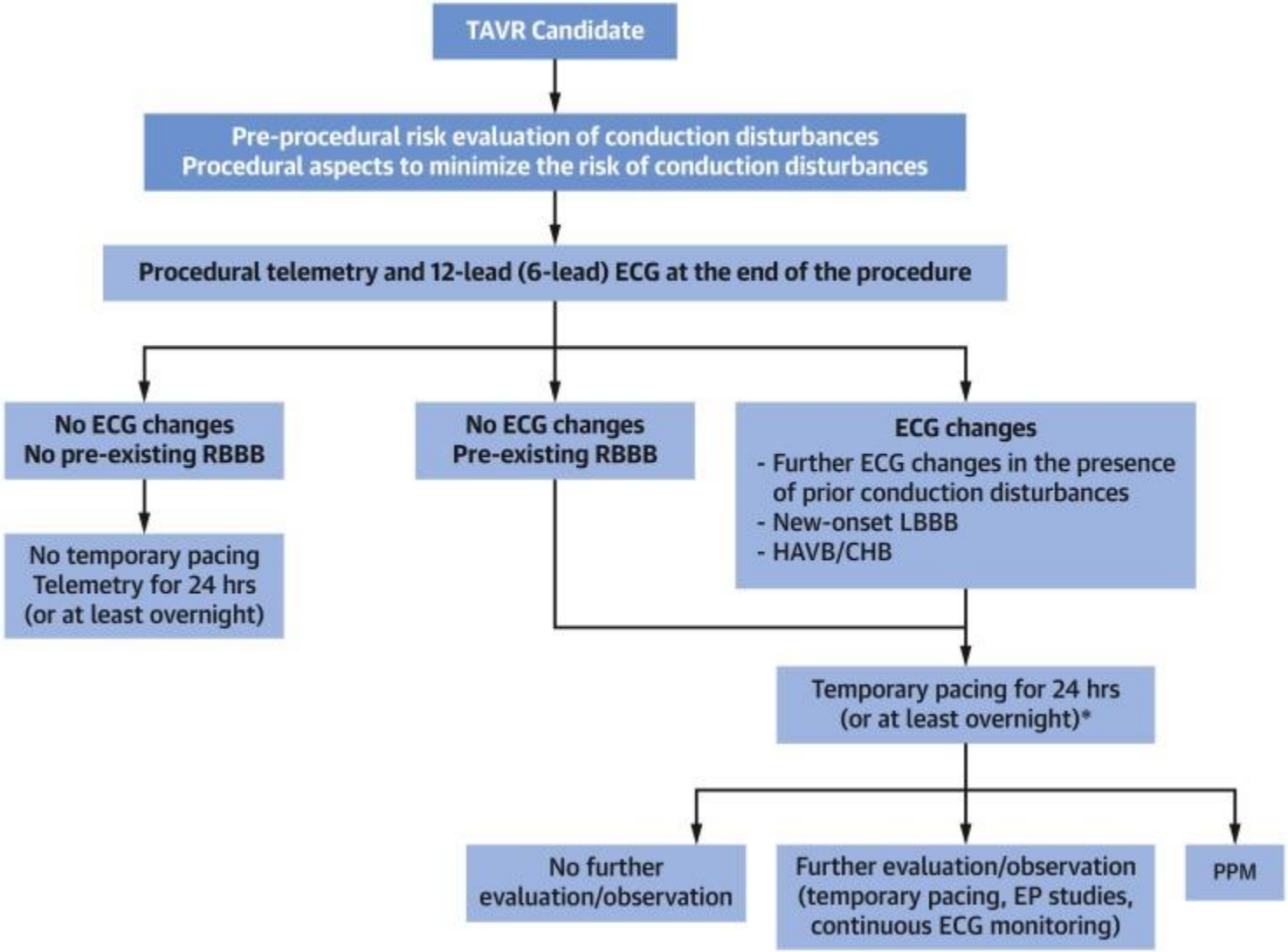


Table 1: Summary of Studies Showing the Incidence of LBBB and PPI Following TAVR and Respective Association with Mortality

Author	Patients (n)	Valve Type	Incidence of LBBB (%)	Incidence of PPI (%)	Risk Factors for LBBB/PPI	Association of TAVR-induced LBBB/PPI and Mortality
Chamandi et al. 2018[90]	1,629	45% ESV 55% MCV	N/A	19.8% at 30 days post-TAVR (26.9% of MCV, 10.9% of ESV)	N/A	PPI was associated with an increased risk of heart failure rehospitalization and lack of LVEF improvement, but not mortality
Fadahunsi et al. 2016[76] (STS/ACC TVT registry)	9,785	ESV MCV	N/A	6.7% at 30 days post-TAVR (25.0% of MCV and 4.3% of ESV)	PPI: age, prior conduction defect, use of self-expanding valve, large prosthesis, valve oversizing	PPI was associated with increased mortality and a composite of mortality or heart failure admission at 1 year
Mauri et al. 2016[47]	229	ESV3	N/A	14.4%	PPI: deep THV implantation, higher LVOT calcium in the area below LCC and RCC, pre-existing RBBB	N/A
Van der Boon et al. 2015[42]	549	ESV MCV	New-onset LBBB 33.7%	13.3% (7.6% of TAVR-induced LBBB patients underwent PPI)	LBBB: Use of MCV, transfemoral approach, deep THV implantation	N/A
Nazif et al. 2015[73] (PARTNER trial and registry)	1,973	ESV	N/A	8.8%	PPI: RBBB, prosthesis/LVOT diameter, LVEDD	PPI was associated with higher repeat hospitalization and mortality or repeat hospitalization at 1 year
Urena et al. 2014[38]	668	ESV	New-onset LBBB 19.2% Persistent LBBB 11.8%	N/A Higher rate of PPI in LBBB group	LBBB: Transapical approach, a 29-mm valve	LBBB did not increase the risk of global or cardiovascular mortality or rehospitalization at 1 year
Nazif at al. 2014[58] (PARTNER trial and registry)	1,307	ESV	New-onset LBBB 10.5%	N/A Higher rate of PPI in LBBB group	LBBB: Prior CABG	LBBB was not associated with 1-year mortality, cardiovascular mortality, repeat hospitalization, stroke, or MI

CENTRAL ILLUSTRATION: Strategy Algorithm Proposal for the Management of Patients With Conduction Disturbances Post-Transcatheter Aortic Valve Replacement



*Consider earlier discontinuation of temporary pacing if regression of ECG changes in <24 h (except for pre-existing RBBB).

Rodés-Cabau, J. et al. J Am Coll Cardiol. 2019;74(8):1086-106.

Coronary artery access

- Coronary artery disease coexists with AS in up to 80% of cases.
- Coronary angiography after TAVR may be unsuccessful in 7.7% of cases or unfavorable in 35% (especially in Self expanding – supra annular THV)
- THV oversizing and higher implantation depth are predictors of unsuccessful coronary cannulation.
- Anatomical features like sino-tubular junction dimension and sinus height impact coronary re-access feasibility.

Coronary artery access

- Prosthesis design with short stent frame, wide cells, and intra-annular design facilitate coronary cannulation post-TAVR.
- Acute and delayed coronary obstruction following TAVR are rare but have high mortality rates.
- Anatomical risk factors for coronary obstruction include coronary ostial height <12 mm and sinus of Valsalva diameter <30 mm.
- Commissural alignment is crucial for successful coronary cannulation after TAVR, especially in younger patients with progressive CAD burden.

Patient History

Date of Procedure:
21.06.2022

- 63 year old male with Severe AS, Calcified Aortic valve, Severe Aortic Stenosis with Trivial AR, Concentric LV Hypertrophy, LV Diastolic Dysfunction, Normal LV Systolic function (EF – 58%), No Regional wall motion Abnormalities at Rest
- True Type 0 Bicuspid Aortic Valve

Pre-Procedure Echo	
Parameters	**Findings**
V_{max}	4.4 m/s
Peak Δ	79 mm Hg
Mean Δ	50 mmHg
AVA	- cm^2
LVEF	58 %

Pre Procedural MSCT Analysis

Aortic Annulus

Perimeter:	67.1 mm
Perimeter Derived Ø:	21.4 mm
Area:	349.5 mm²
Area Derived Ø:	21.1 mm

LVOT Ø: 19.4 mm

RCA Height: 23.4 mm

Asc. Aorta Ø: 38.3 mm

STJ Ø: 34.7 mm

LCA Height: 18.0 mm

Aortic Valve Calcification: Moderate

Sinus Of Valsalva Diameters:

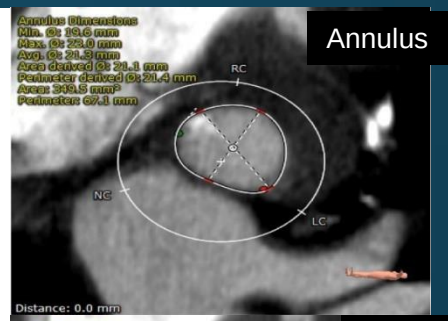
Left: _____

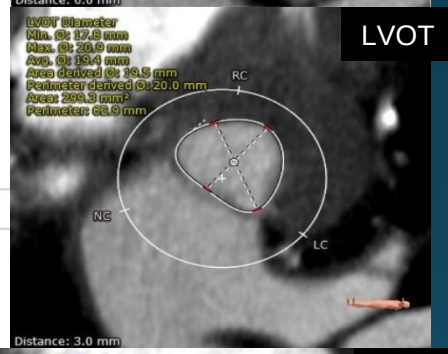
Right: _____

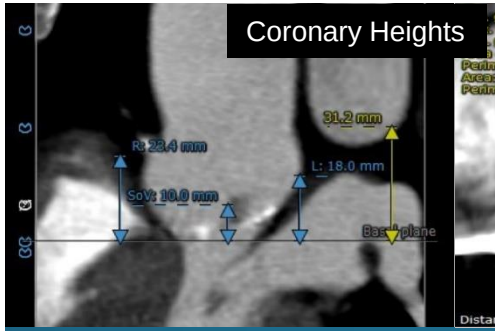
Non: _____

Measurements:

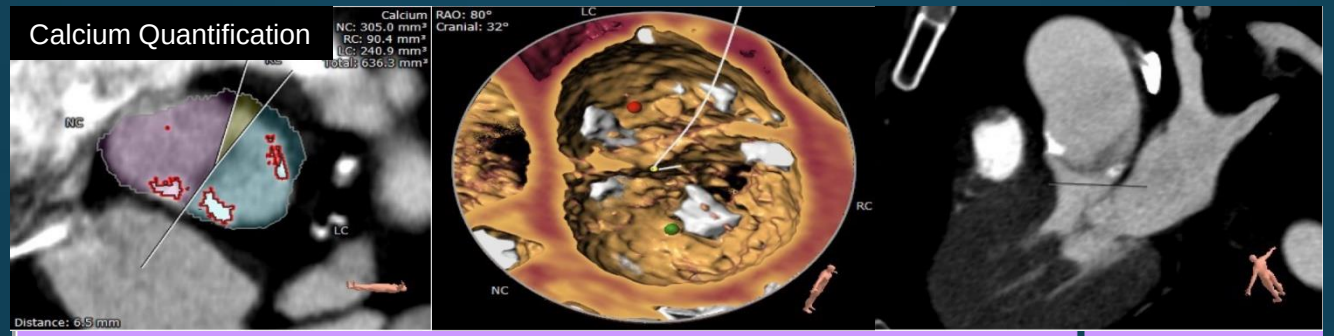
Ascending Aorta Ø	Min: 36.9 mm Max: 39.7 mm Average: 38.3 mm
Sinotubular Junction Ø	Min: 32.4 mm Max: 37.0 mm Average: 34.7 mm
Aortic Annulus	Min Ø: 19.6 mm Max Ø: 23.0 mm Average Ø: 21.3 mm Eccentricity: 0.15
LVOT Ø	Min: 17.8 mm Max: 20.9 mm Average: 19.4 mm
Sinus of Valsalva Height	10.0 mm







Pre Procedural MSCT Analysis

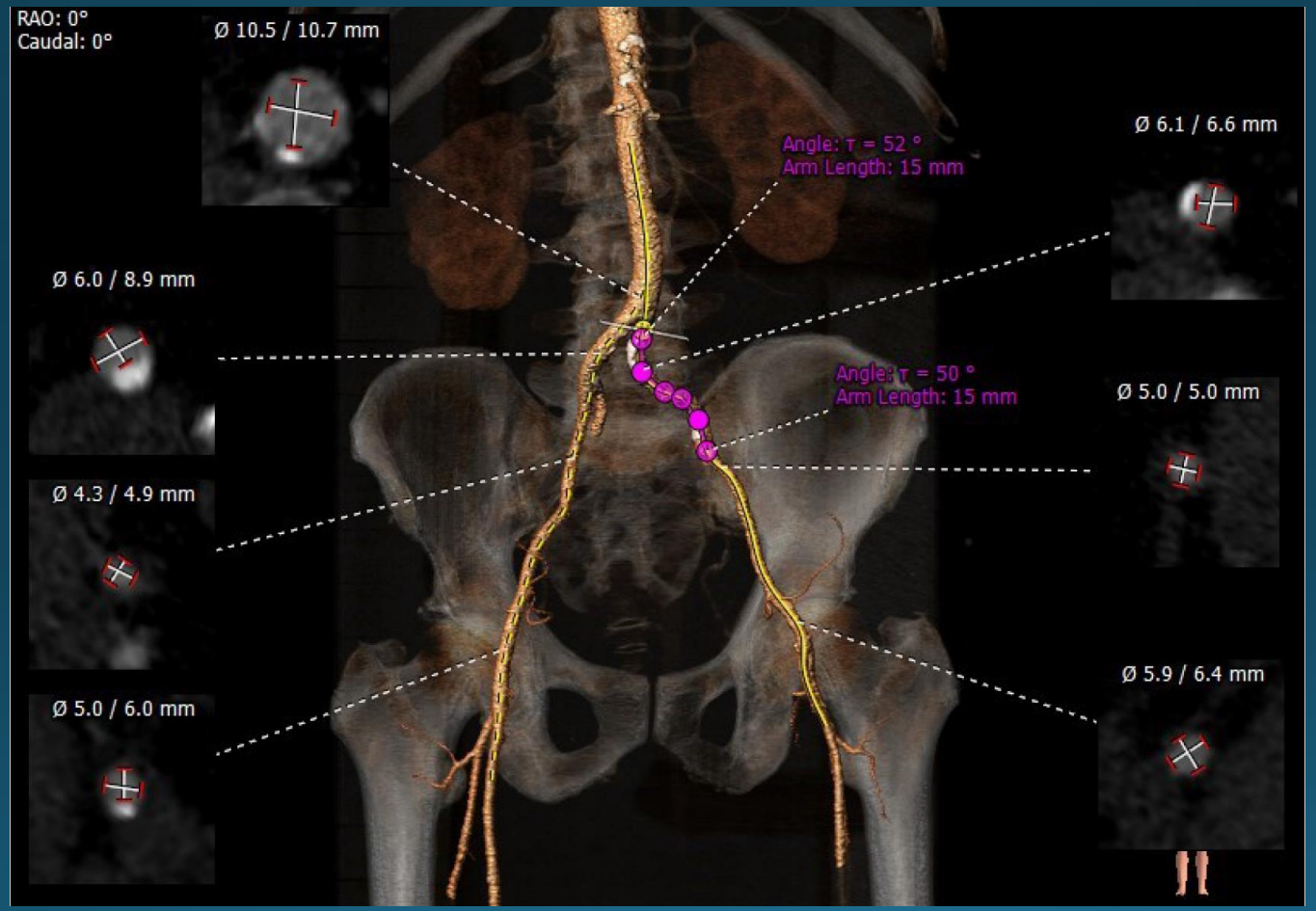


3D Annular area mm^2		349.5
3D area derived diameter mm (annulus area)		21.1
% Annular Area Over/Under	20 mm	-10.1%
	21.5 mm	4%
	23 mm	18.9%
	24.5 mm	34.9%
	26 mm	51.9%
	27.5 mm	69.9%
	29 mm	89.0%
	30.5 mm	109.0%
	32 mm	130.1%

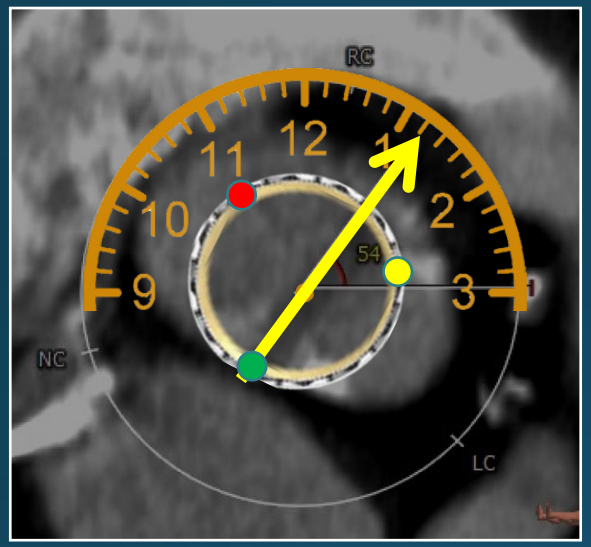
- Bicuspid Type 0 Aortic
- Moderate Aortic Valve
- LVOT is smaller than A
- Mild Calcification is observed at Sinotubular junction.
- Moderate Calcification is observed at Arch of Aorta.
- Mild Calcification is observed at Descending Aorta.

Bicuspid Type 0 Aortic Valve, Implantation Of 21.5 mm Myval Octacor

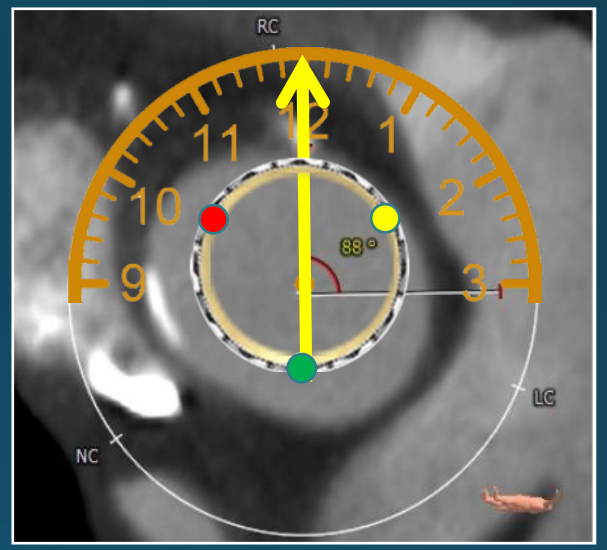
Femoral Access



MSCT derived Clock Angle



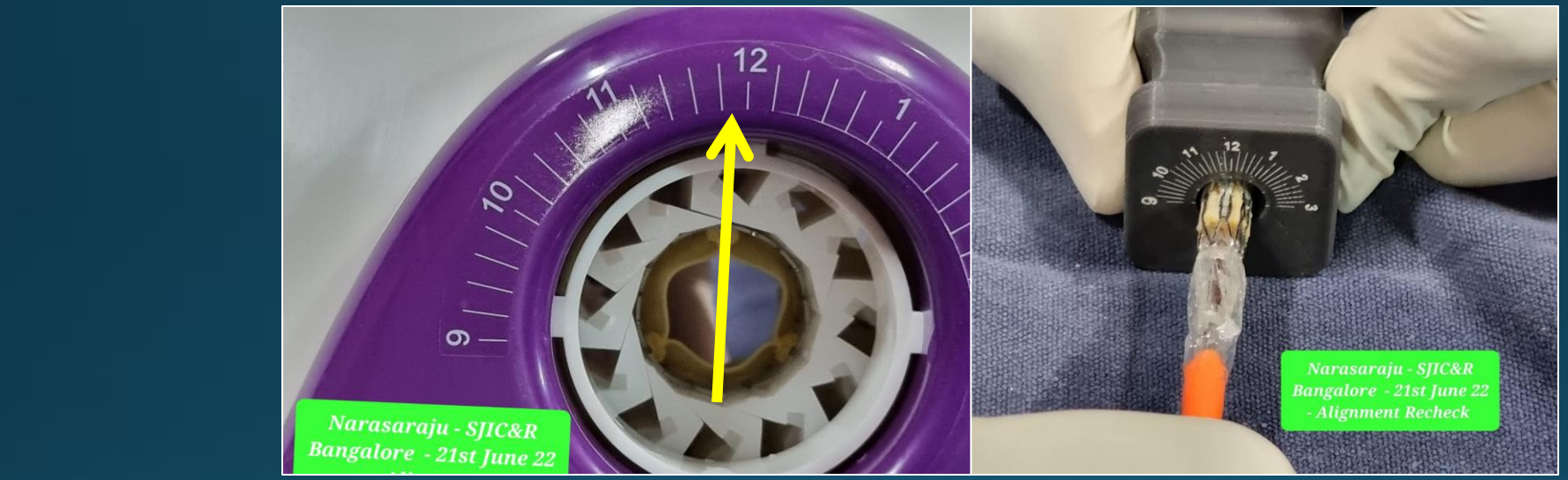
Mid of RCC cusp



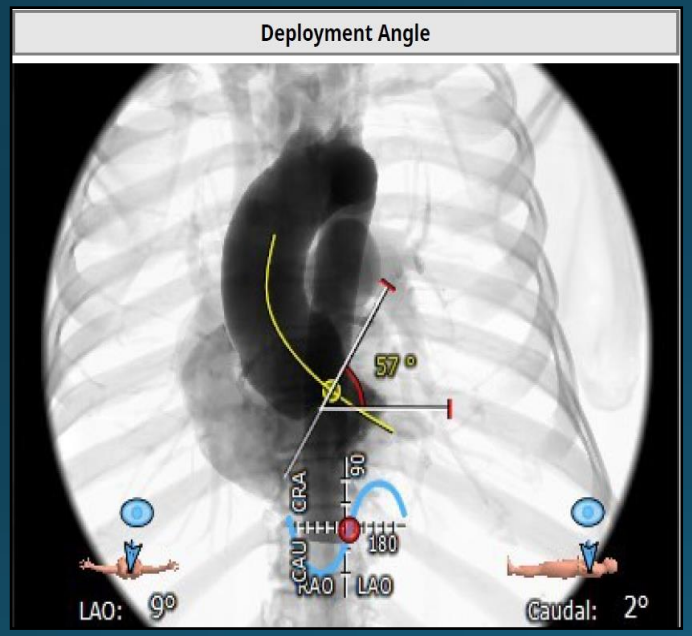
Mid of RCA Origin

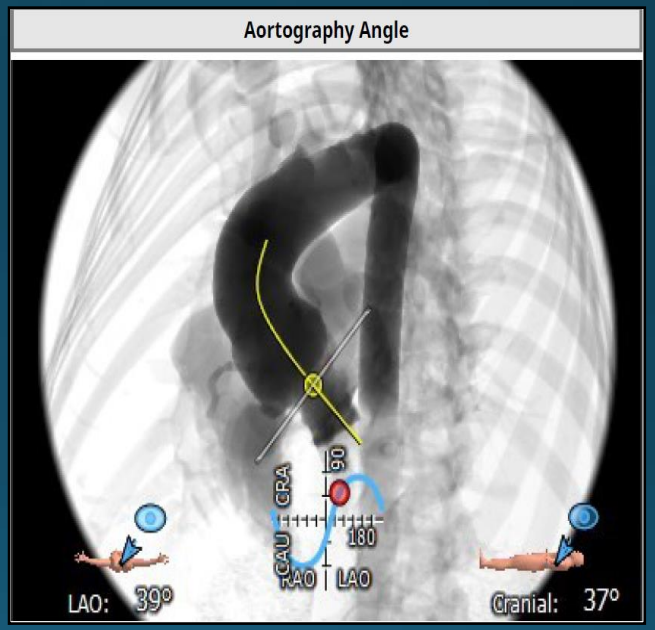
Clock Angle based on Mid of RCA - 03:00 'o'clock

Clock Angle Confirmation



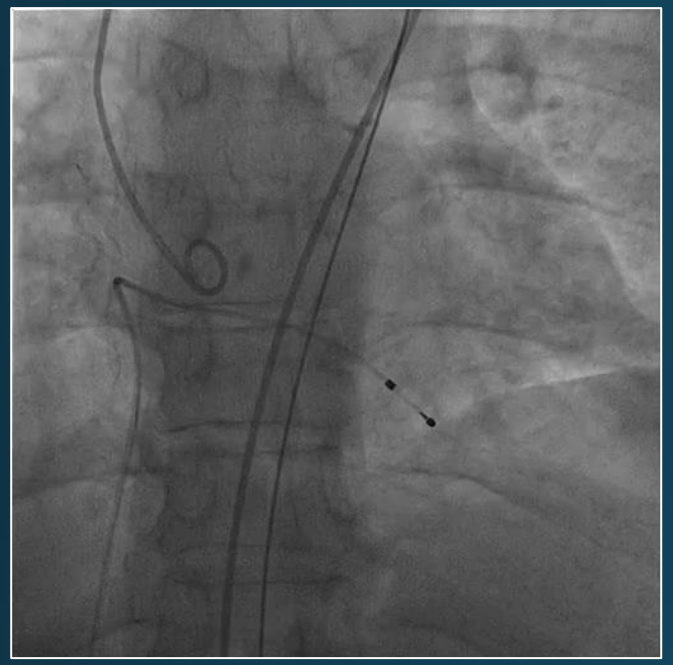
Deployment and Video Densitometry Angles



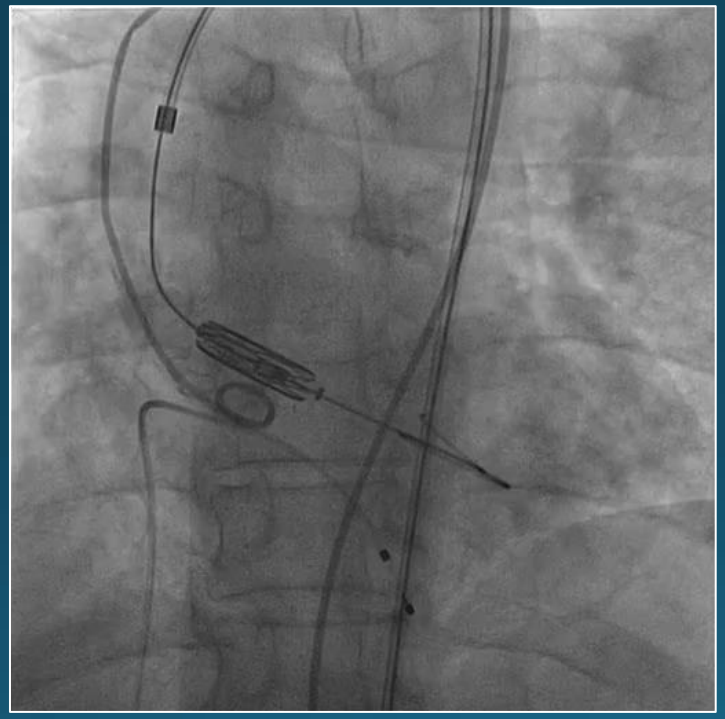


Myval Octacor 21.5 mm

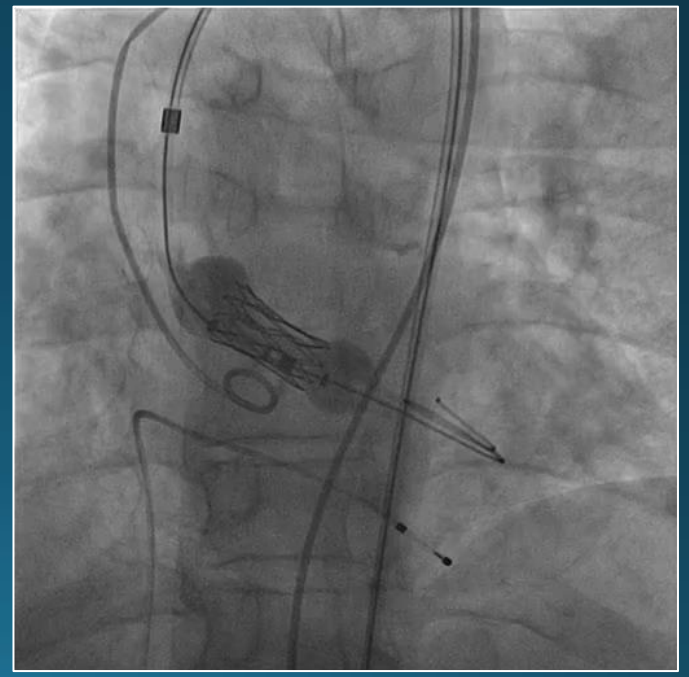
Baseline Aortogram



Positioning

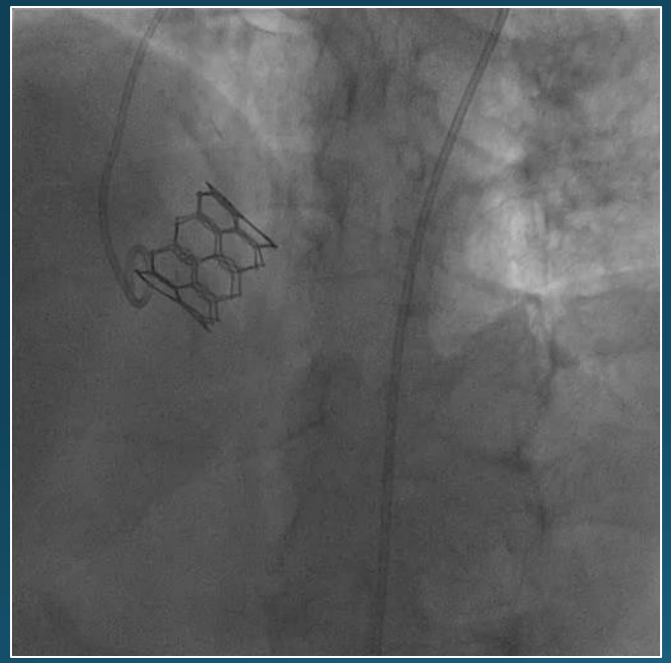
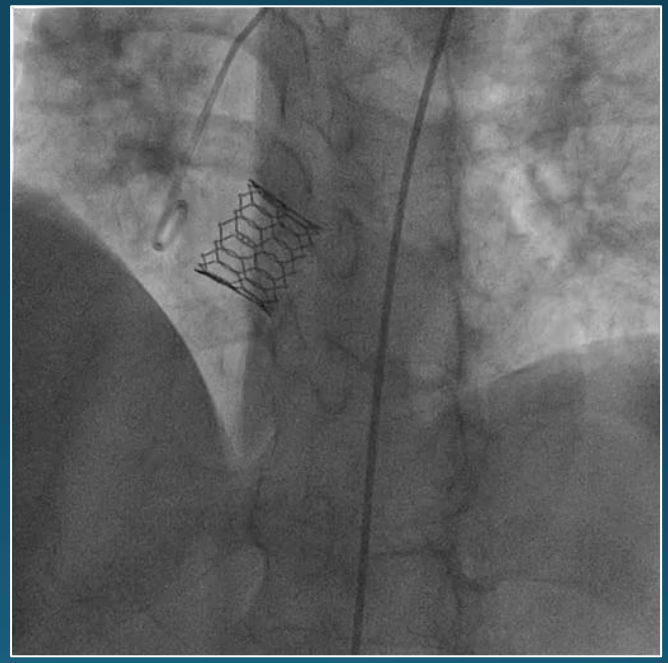


Deployment



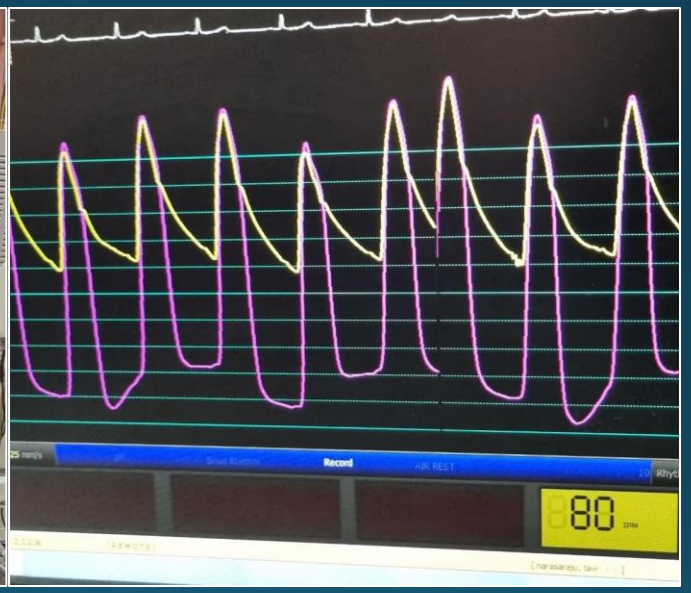
Myval Octacor 21.5 mm

Post Deployment Aortogram and Video Densitometry

Aortogram – Post Deployment	Aortogram – Video Densitometry
	

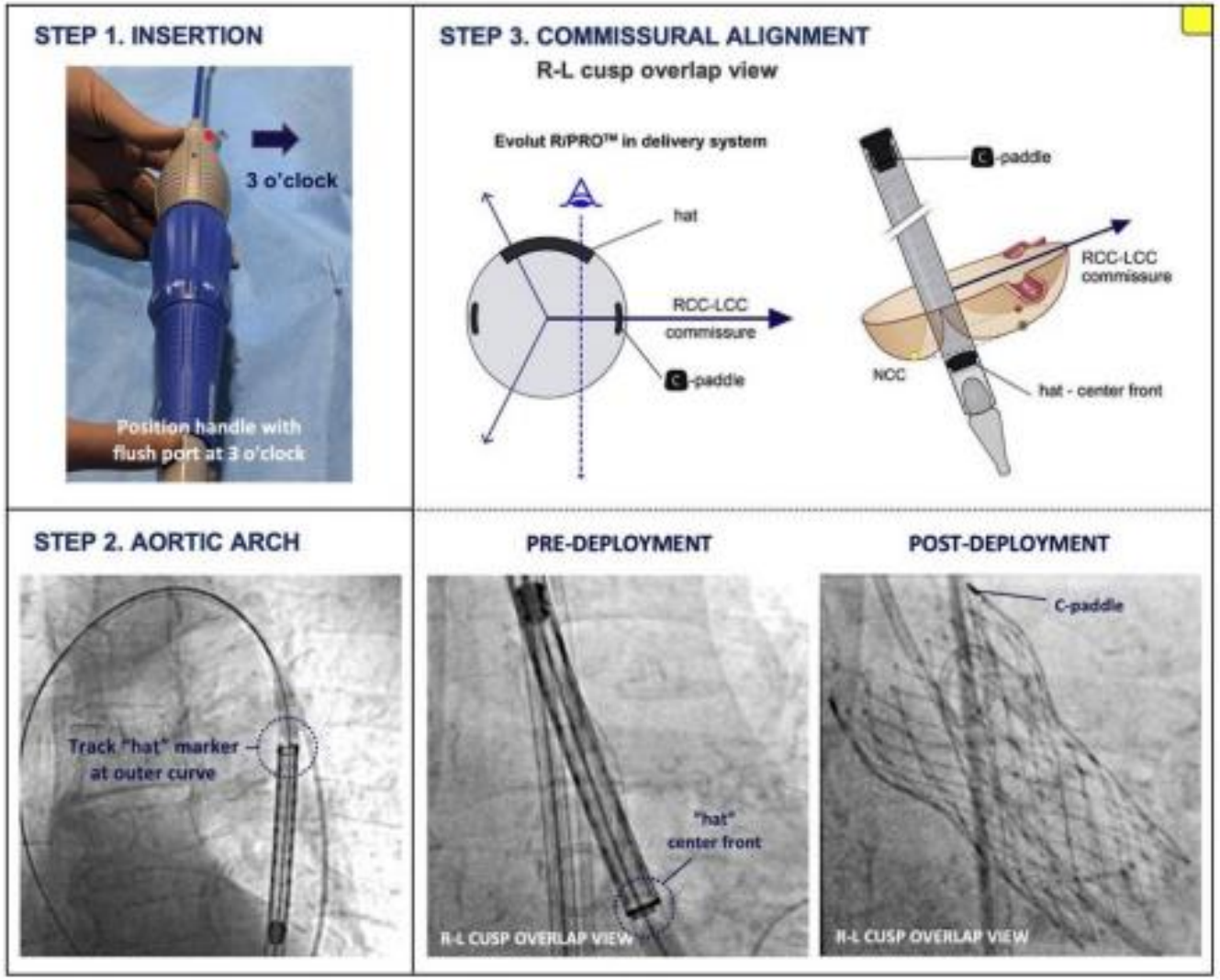
Invasive Gradients

Baseline



Post Procedure

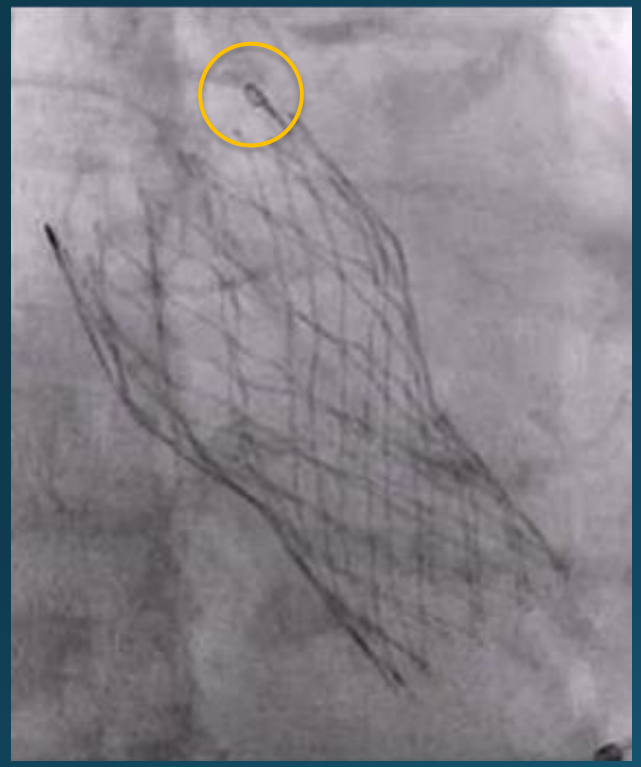
EVOLUT COMMISSURAL ALIGNMENT



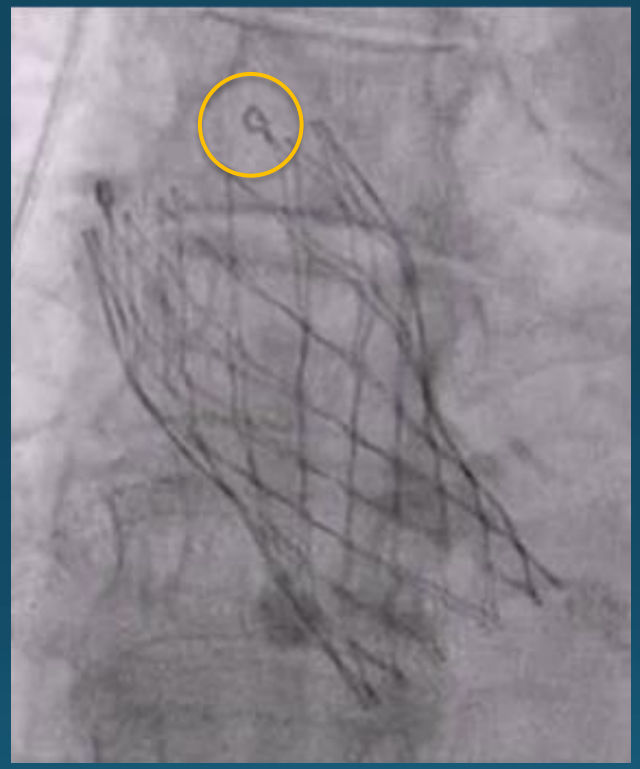
Three procedural steps in order to increase the chances of obtaining commissural alignment with the Evolut system. Abbreviations as in Figures 2 and 3.

"Hat" marker at the center front increased significantly from 70.2% to 97.4% ($P < 0.0001$) at the time of deployment. This improved commissural alignment (C-paddle at inner curve) to 80.4% and resulted in a significant reduction in the incidence of severe coronary overlap with Evolut commissure with the left main coronary artery (31.4%-14.3%, $P < 0.0001$), the right coronary artery (20.7%-14.3%, P ¼ 0.11), both coronaries (14.0%-5.3%, P ¼ 0.0025), or 1 or both coronaries (38.0%-23.3%, P ¼ 0.0021).

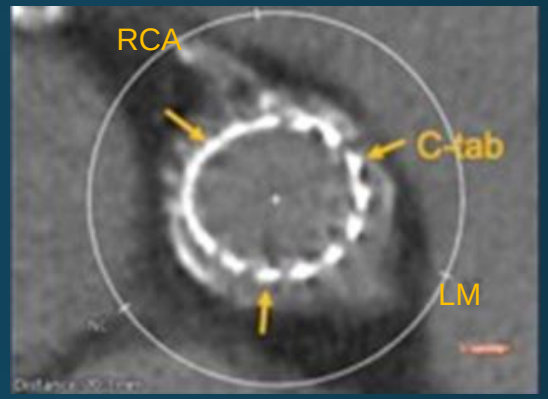
Results

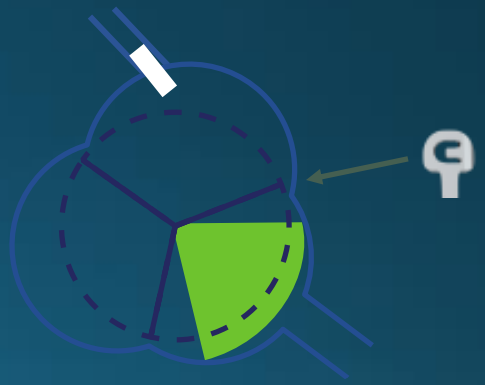


Cusp-overlap View



3-cusp View

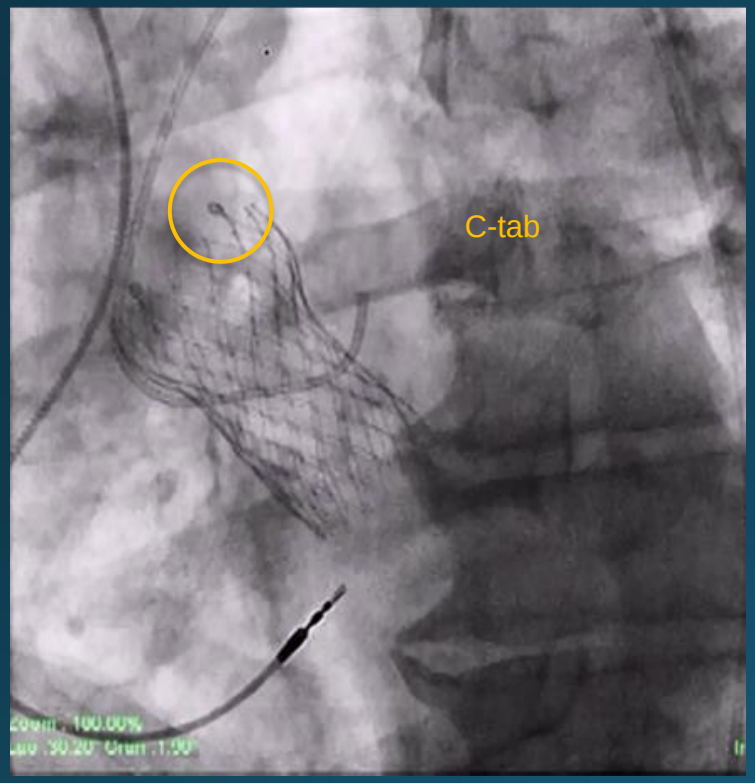


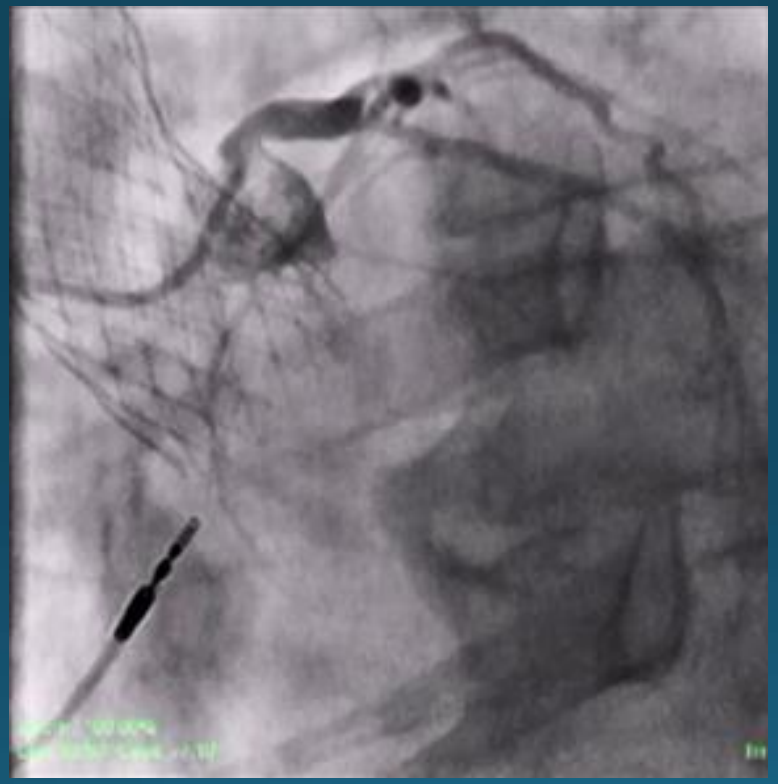


(Favorable C-tab position of Anterior/Inner Curve is shown)

Goal – Post-TAVI Coronary Access

- Commissural alignment helps facilitate coronary access





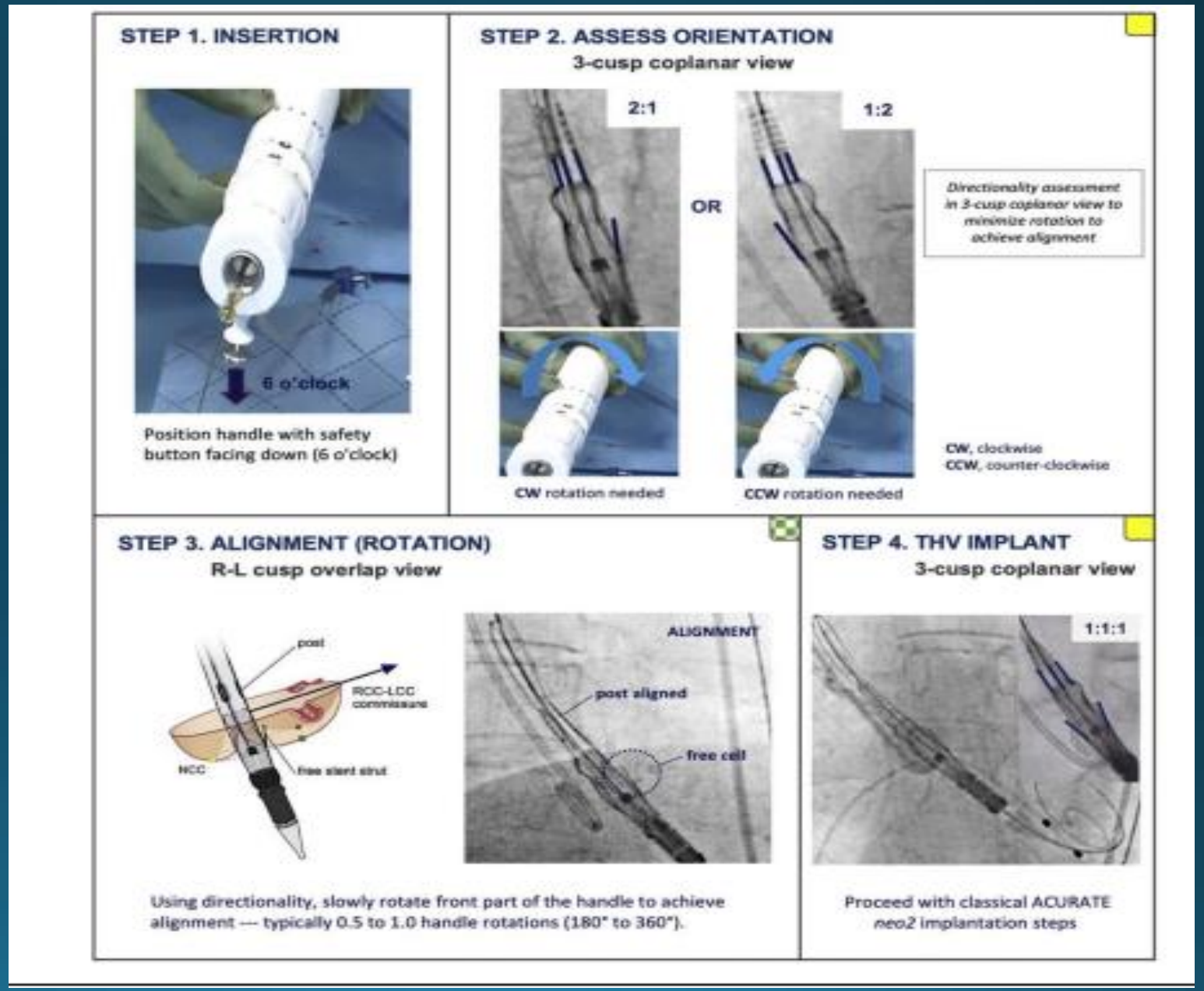
ACURATE-neo2- Commissural alignment

The ACURATE-neo2 valve is a self-expanding THV with supra-annular leaflet position.

The commissures of the ACURATE-neo2 valve can be identified on fluoroscopy by the presence of 3 commissural posts at the base of the stabilizing arches and 3 “free cells” at the level of the upper crown

The delivery system is flexible and allows rotation of the THV delivery system to more than 60◦ .

ACCURATE neo-2 Commisural allignment



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

Hans Gustav Hørsted Thyregod [1*†], Troels Højsgaard Jørgensen [2†], Nikolaj Ihlemann [3], Daniel Andreas Steinbrüchel [1‡], Henrik Nissen [4], Bo Juel Kjeldsen [5], Petur Petursson [6], Ole De Backer [2], Peter Skov Olsen [1], and Lars Søndergaard [2]

DURABLE RESULTS AT 10 Yrs

Key Question

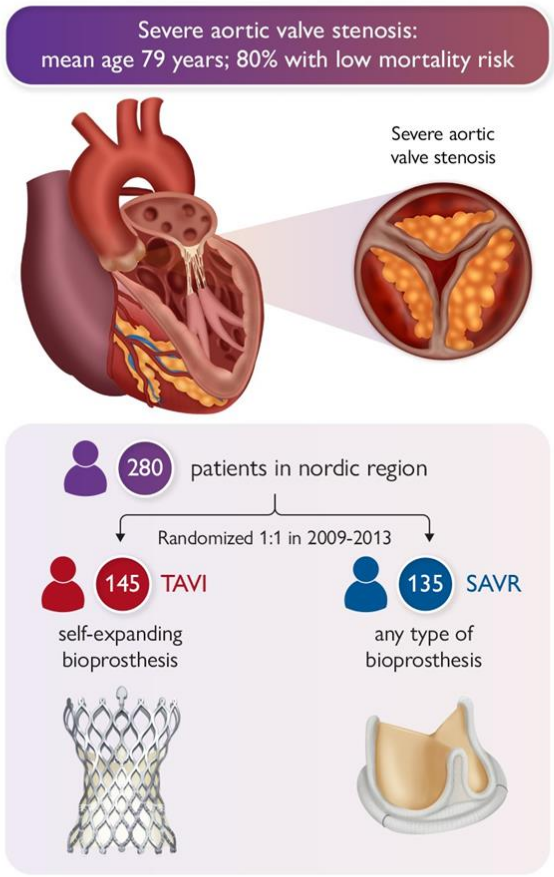
Are there differences in long-term clinical outcomes and durability of transcatheter versus surgical bioprosthetic aortic valves in patients with symptomatic, severe aortic valve stenosis who are at lower surgical risk?

Key Finding

In the NOTION trial at ten years, major clinical outcomes including all-cause mortality, stroke or myocardial infarction were similar after transcatheter aortic valve implantation (TAVI) or surgical aortic valve replacement (SAVR). More SAVR patients had severe structural valve deterioration, while the rates of bioprosthetic valve failure were similar.

Take Home Message

Long-term data for a first generation self-expanding transcatheter aortic valve are comparable to surgical bioprosthetic aortic valves. However, larger studies, including different types of bioprosthetic aortic valves, are warranted to generalize these findings.



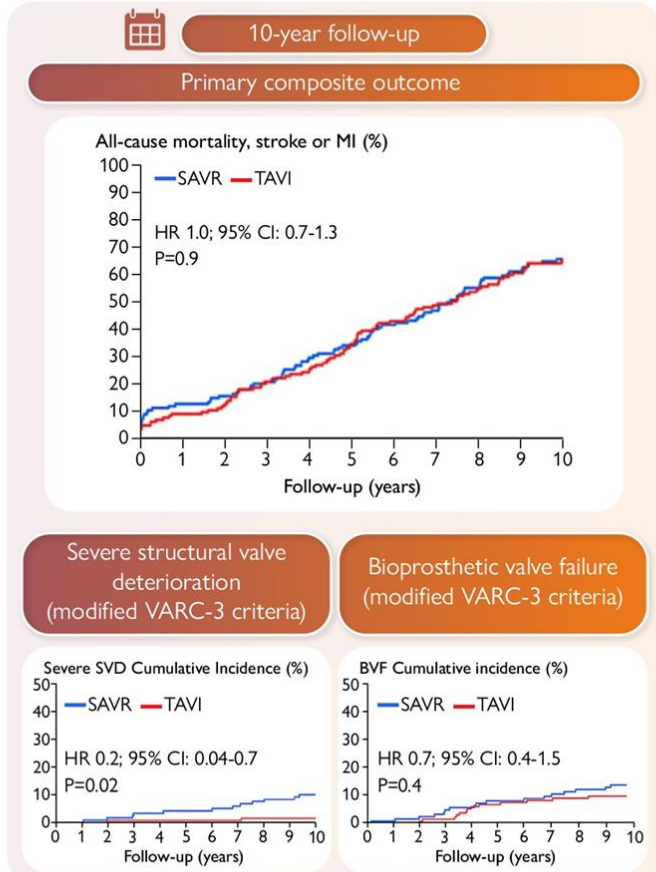


Table 1 **Guideline recommendations: choice of surgical aortic valve replacement vs. transcatheter aortic valve implantation for whom a bioprosthesis is appropriate**

Recommendations	TAVI		SAVR	
	Classa	Levelb	Classa	Levelb
2020 ACC/AHA Guideline for the Management of Valvular Heart Disease				
Symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy over 20 years			I	A
Symptomatic patients with severe AS who are 65–80 years of age and have no anatomical contraindication to transfemoral TAVI	I	A	I	A
Symptomatic patients with severe AS who are >80 years of age or younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI	I	A	IIa	A
Asymptomatic patients with severe AS and an LVEF <50% who are 65–80 years of age and have no anatomic contraindication to transfemoral TAVI	I	B-NR	I	B-NR
Asymptomatic patients with severe AS and an abnormal exercise test, very severe AS, rapid progression, or an elevated BNP			I	B-NR
Patients with an indication for AVR but valve or vascular anatomy or other factors are not suitable for transfemoral TAVI			I	A
Symptomatic patients of any age with severe AS and a high or prohibitive surgical risk (estimated life expectancy >12 months)	I	A		
2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease				
Younger (<75 years) patients who are low risk for surgery (STS-PROM/EuroSCORE II <4%), or patients who are operable and unsuitable for transfemoral TAVI			I	B
Older (≥75 years) patients, or in those who are high risk (STS-PROM/EuroSCORE II >8%) or unsuitable for surgery	I	A		
Remaining patients according to individual clinical, anatomical, and procedural characteristics	I	B	I	B

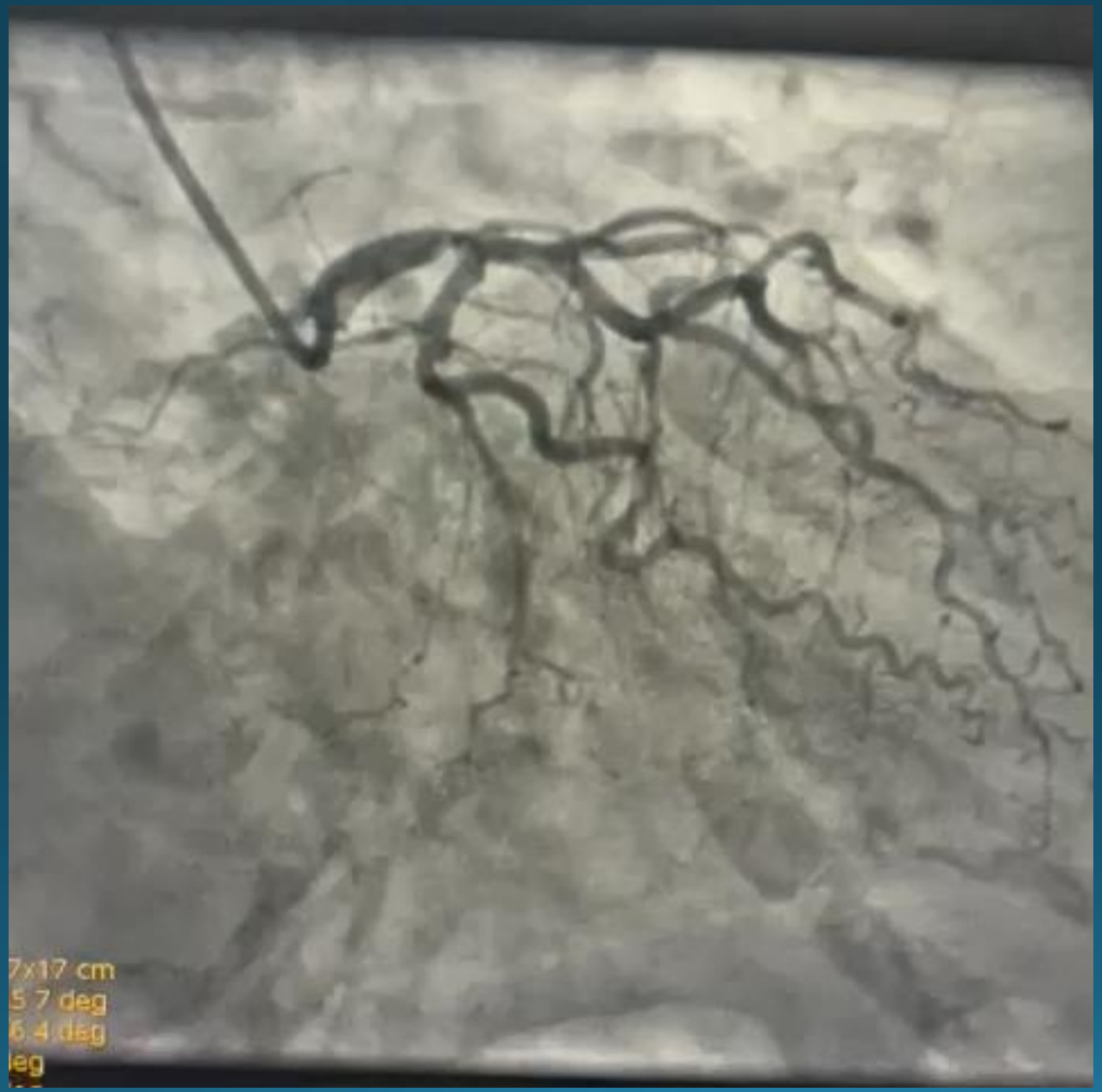
Hybrid therapy- in high risk patient

Patient History

- 84 Year old Female with NSTEMI, LVF.
- With medical treatment LVF resolved, chest pain, ECG changes resolved.
- She also had Severe Aortic stenosis, moderate AR, MAC with MR Gr II. Moderately Calcified Tricuspid Aortic valve

Pre-Procedural Echo cardio graphic Assessment

Parameters	Findings
Peak Δ	75 mm Hg
Mean Δ	45 mm Hg
LVEF	50%


7x17 cm
5 7 deg
6 4 deg
eg

Pre Procedural MSCT Analysis

Aortic Valve

Aortic Annulus

Perimeter:	66.0	mm
Perimeter Derived Ø:	21.0	mm
Area:	332.2	mm²
Area Derived Ø:	20.6	mm

LVOT Ø: 22.1 mm

RCA Height: 13.2 mm

Asc. Aorta Ø: 29.8 mm

STJ Ø: 24.5 mm

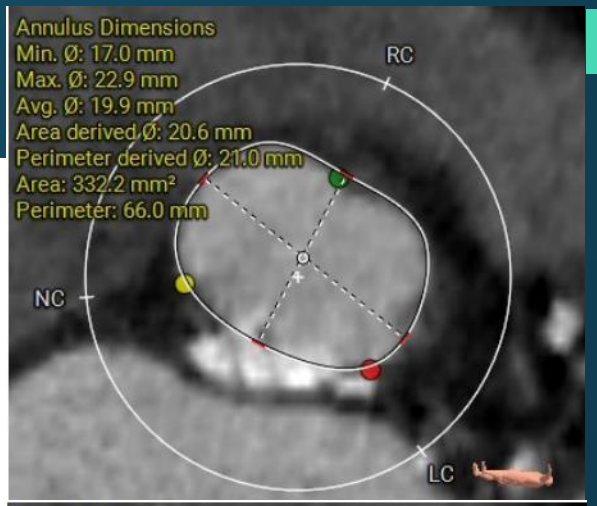
LCA Height: 9.0 mm

Aortic Valve Calcification: Moderate

Sinus Of Valsalva Diameters:

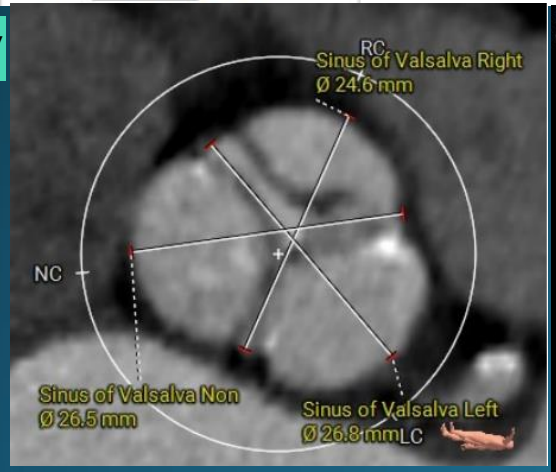
Left:	26.8	mm
Right:	24.6	mm
Non:	26.5	mm

Annulus

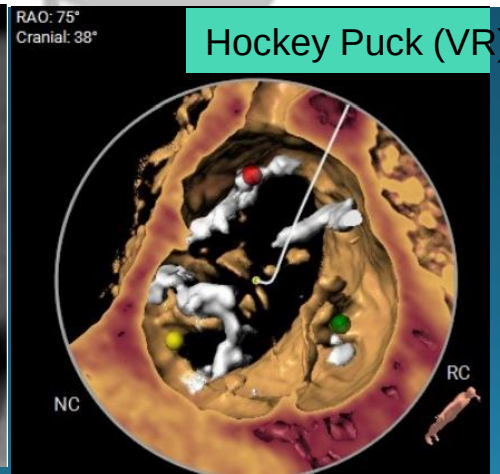


LVOT

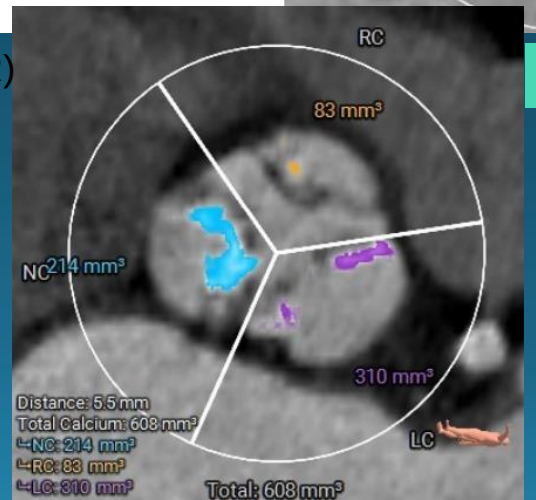
SOV



Hockey Puck (VR)

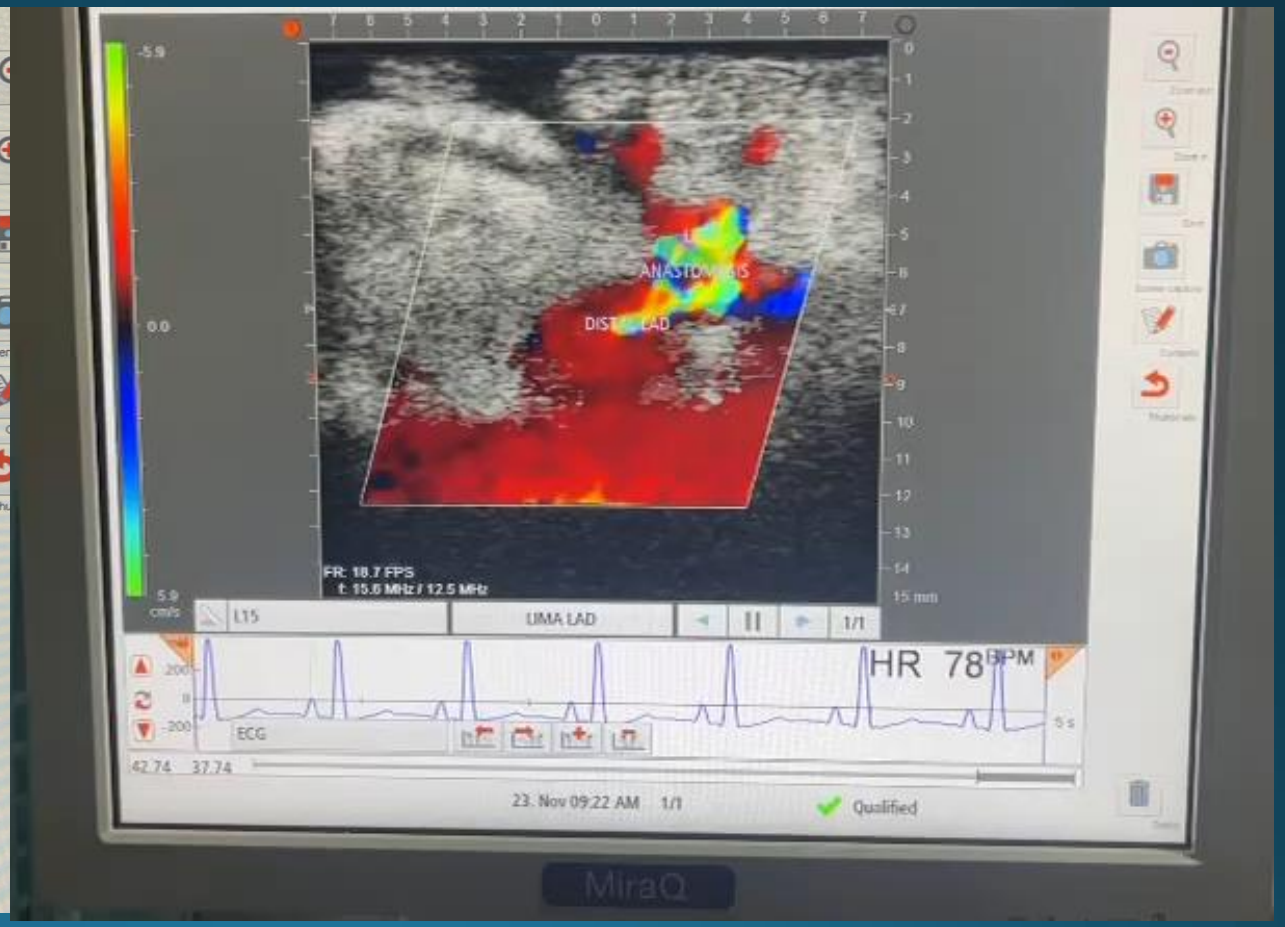


Calcium Quantification



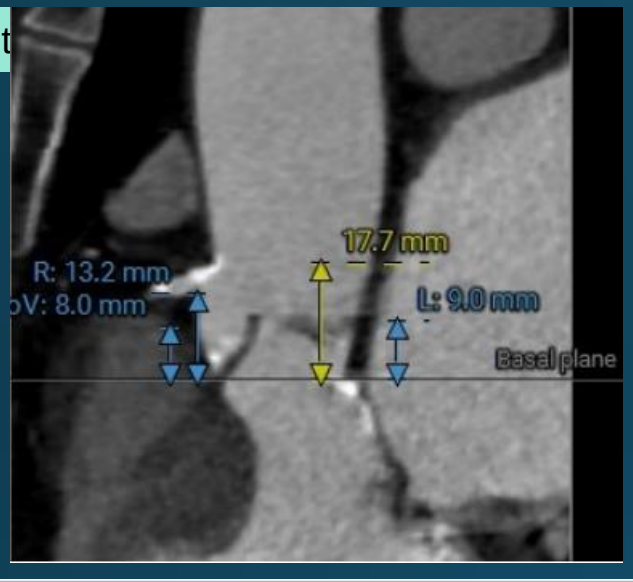
MICAS- LIMA to LAD done

LIMA Flow into LAD

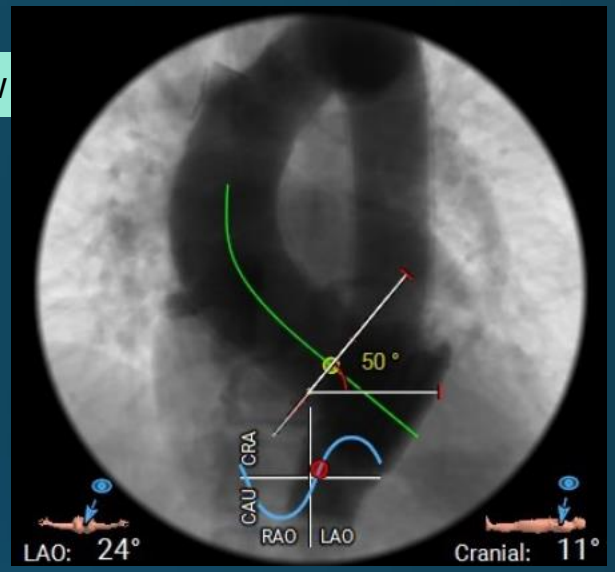


Pre procedural MSCT Analysis

Coronary Height



Deployment View



Ascending Aorta Ø	Min: 29.1 mm Max: 30.4 mm Average: 29.8 mm
Aortic Annulus	Min Ø: 17.0 mm Max Ø: 22.9 mm Average Ø: 19.9 mm Eccentricity: 0.26
Sinus of Valsalva Height	8.0 mm
Sinotubular Junction Ø	Min: 23.8 mm Max: 25.1 mm Average: 24.5 mm
LVOT Ø	Min: 19.8 mm Max: 24.4 mm Average: 22.1 mm

3D Annular area mm^2		332.2
3D area derived diameter mm		20.6
% Annlar area over/under	20 mm	-5.4%
Recommended 21.5 mm Intermediate size Myval, 18 mm X 40 mm Mammoth for Predilatation	21.5 mm	9.3%
	23 mm	25.1%
	24.5 mm	41.9%
	26 mm	59.8%
	27.5 mm	78.8%
	29 mm	98.8%
	30.5 mm	119.9%
	32 mm	142.1%

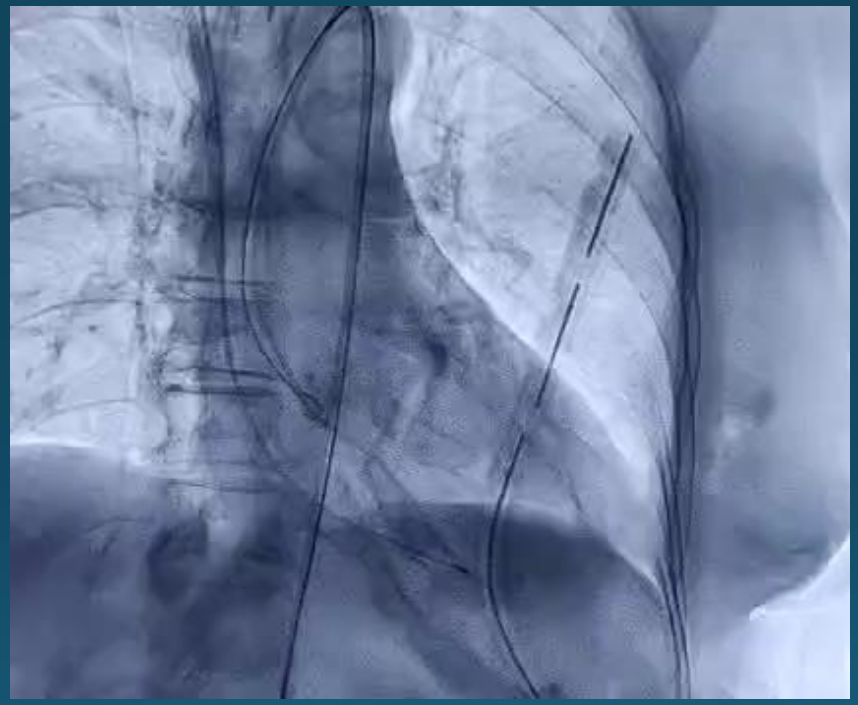
Myval 21.5 mm

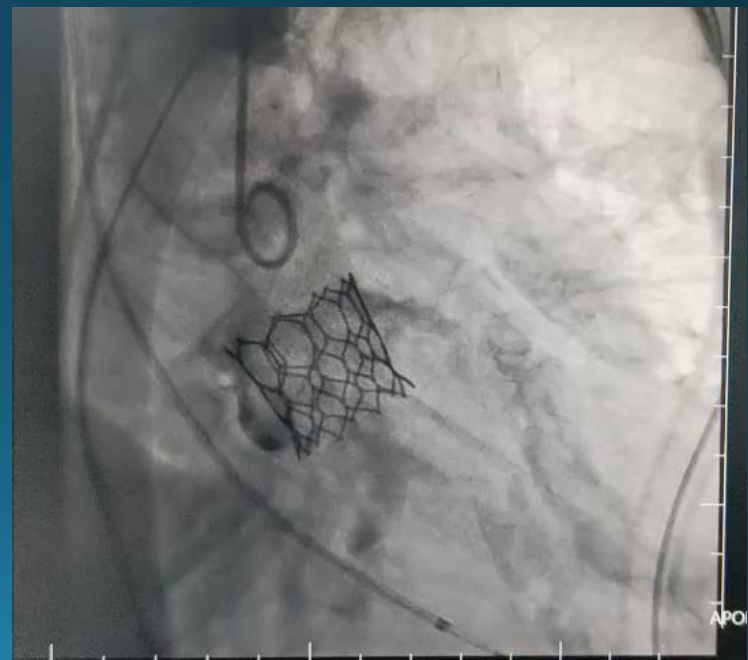
Valve Check

Navigation through aortic arch

Myval 21.5 mm

Positioning and Deployment





Myval 21.5 mm
Final Result

Case History

72 Year old Male with Symptomatic Aortic stenosis, Mild to Moderate Calcified Tricuspid Aortic valve. Post CABG, Type 2DM, Systemic Hypertension, AVA 0.8cm^2

Parameters	Values
Peak velocity	4.5 m/s
Mean gradient	44.7 mmHg
Peak gradient	70 mmHg
EF%	55%

CT Analysis

Aortic Annulus

Perimeter:	70.5 mm
Perimeter Derived Ø:	22.4 mm
Area:	390.6 mm²
Area Derived Ø:	22.3 mm

LVOT Ø: 22.4 mm

RCA Height: 13.0 mm

Asc. Aorta Ø: 29.5 mm

STJ Ø: 24.3 mm

Aortic Annulus

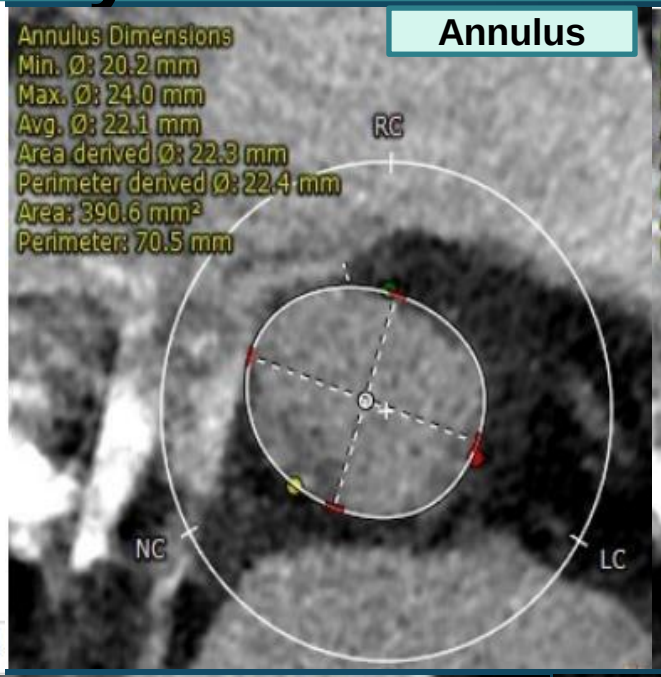
LCA Height: 10.3 mm

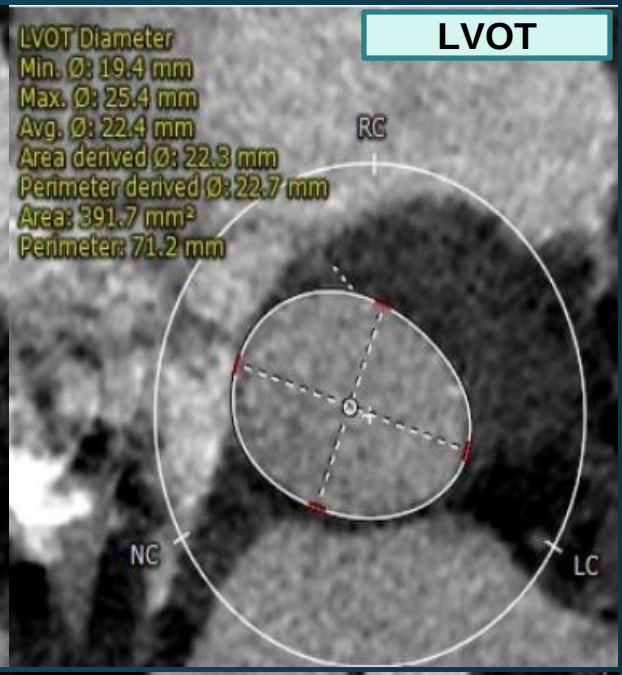
Aortic Valve Calcification: Mild

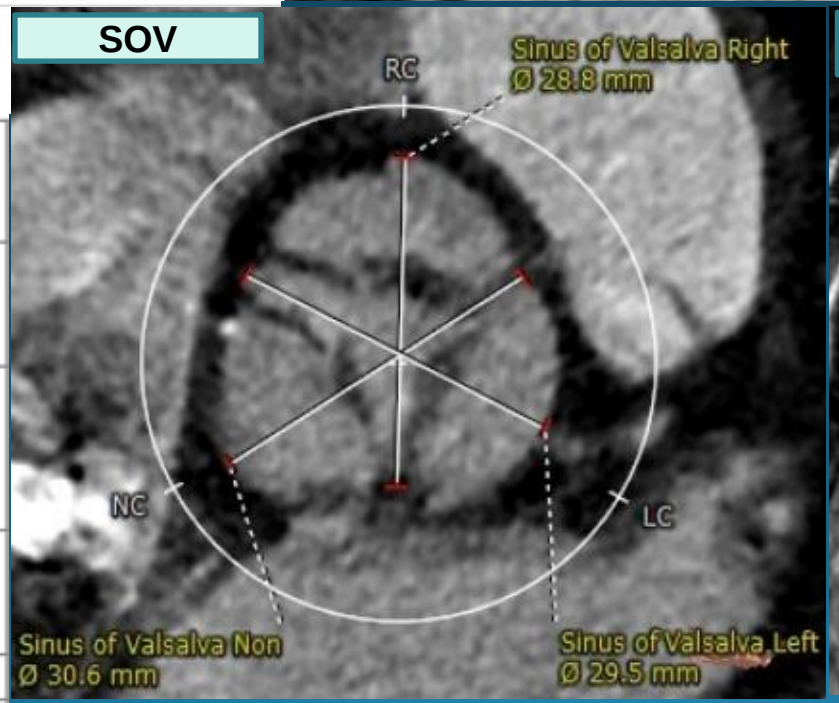
Sinus Of Valsalva Diameters:

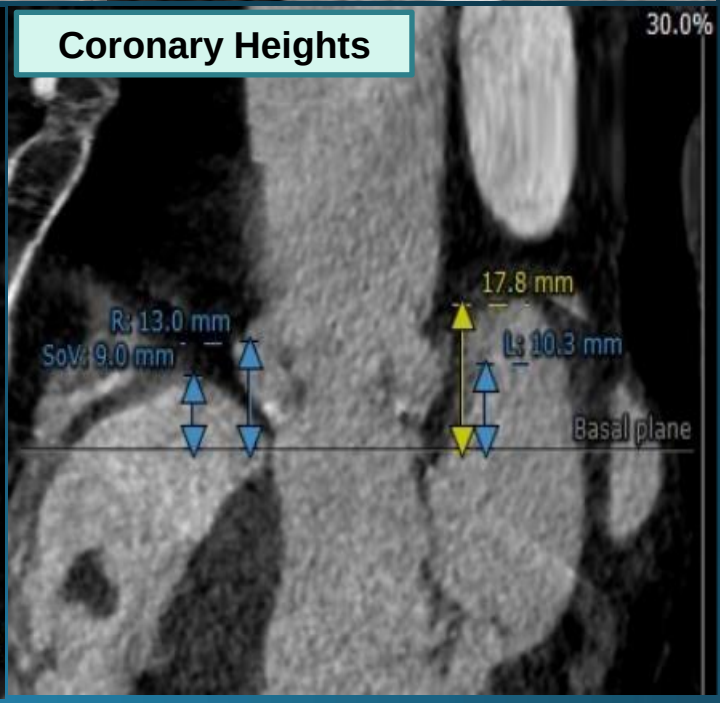
Left:	29.5 mm
Right:	28.8 mm
Non:	30.6 mm

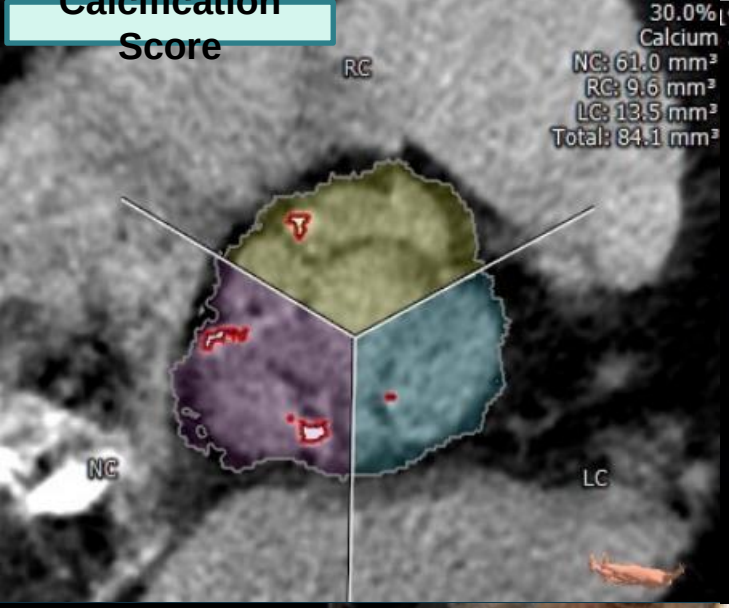
Ascending Aorta Ø	Min: 29.2 mm Max: 29.8 mm Average: 29.5 mm
Sinotubular Junction Ø	Min: 24.1 mm Max: 24.5 mm Average: 24.3 mm
Aortic Annulus	Min Ø: 20.2 mm Max Ø: 24.0 mm Average Ø: 22.1 mm Eccentricity: 0.16
LVOT Ø	Min: 19.4 mm Max: 25.4 mm Average: 22.4 mm
Sinus of Valsalva Height	9.0 mm

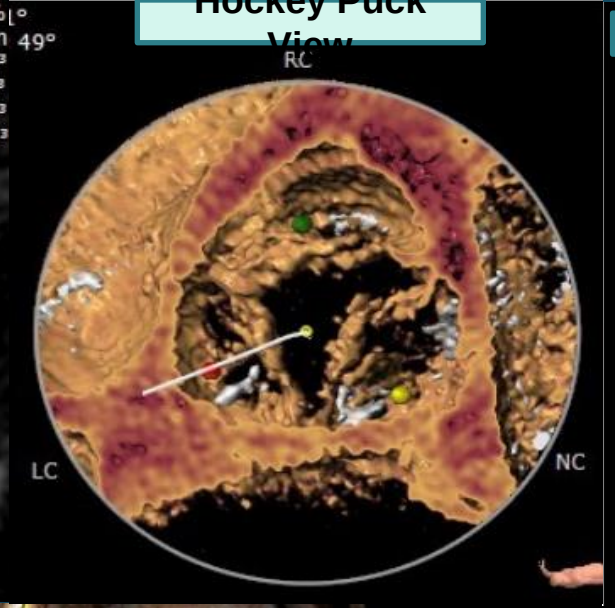


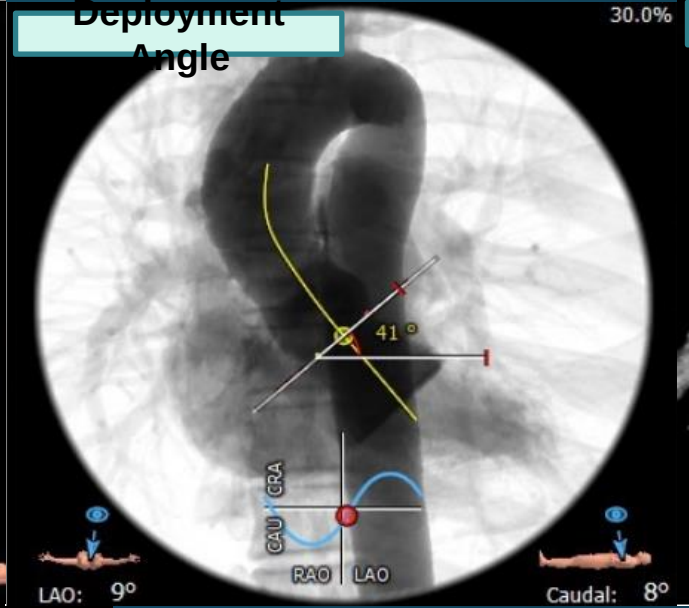


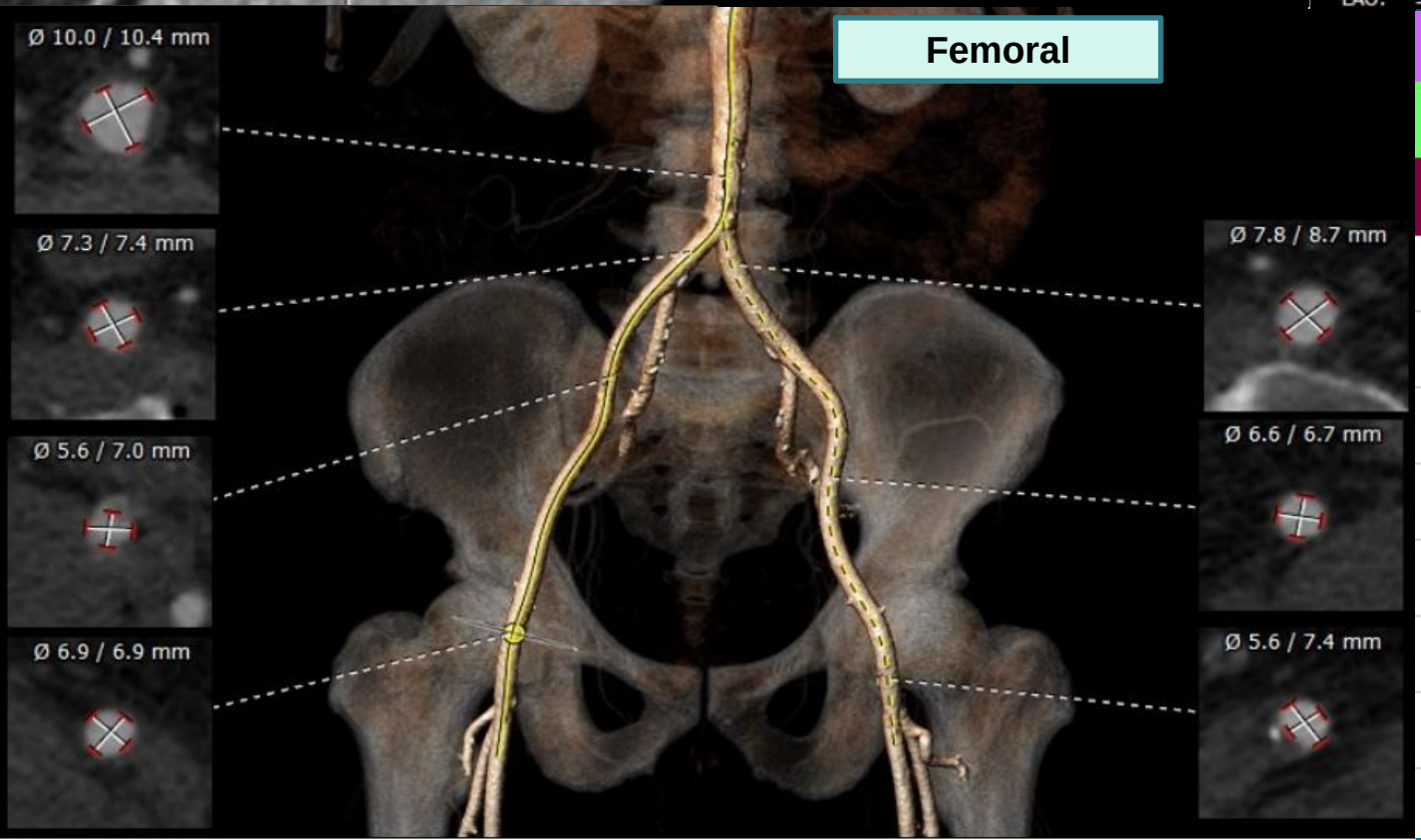






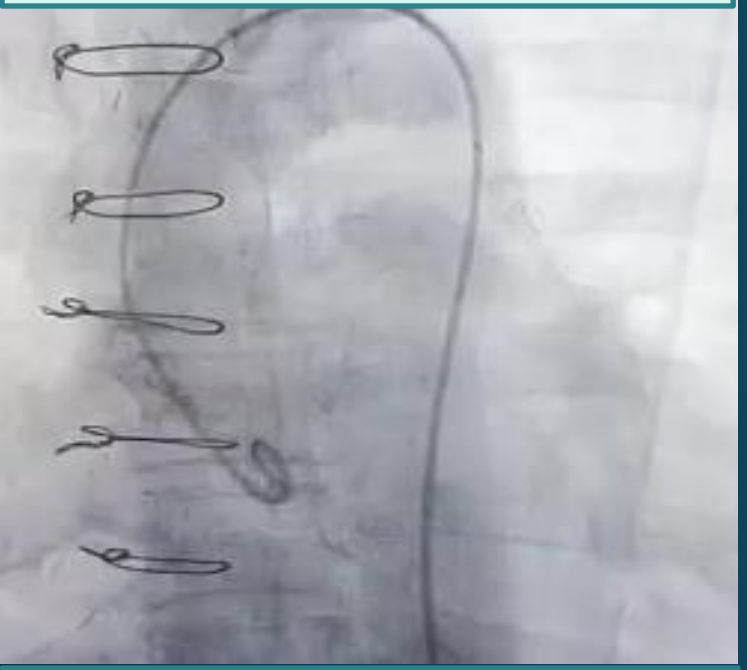




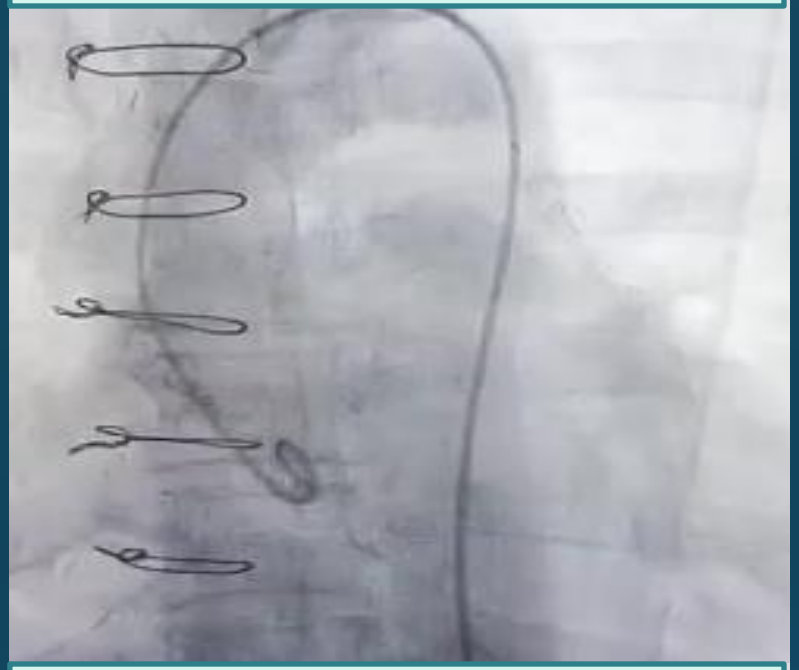


3D Annular area mm²		390.6
3D area derived diameter mm		22.3
% Annlar area over/under	20 mm	-19.6%
	21.5 mm	-7.1%
Recommended 23 mm size Myval	23 mm	6.4%
	24.5 mm	20.7%
	26 mm	35.9%
	27.5 mm	52.1%
	29 mm	69.1%
	30.5 mm	87.0%
	32 mm	105.9%

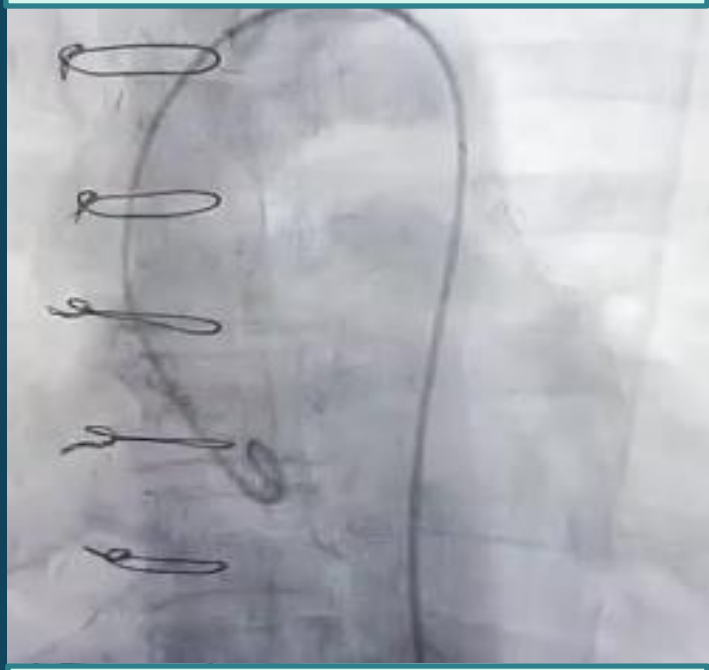
Aortogram



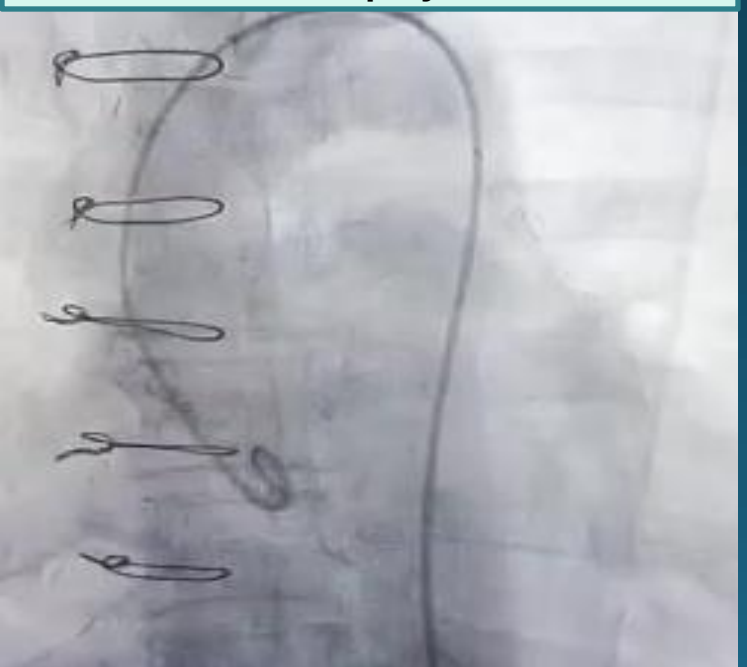
Valve Cross



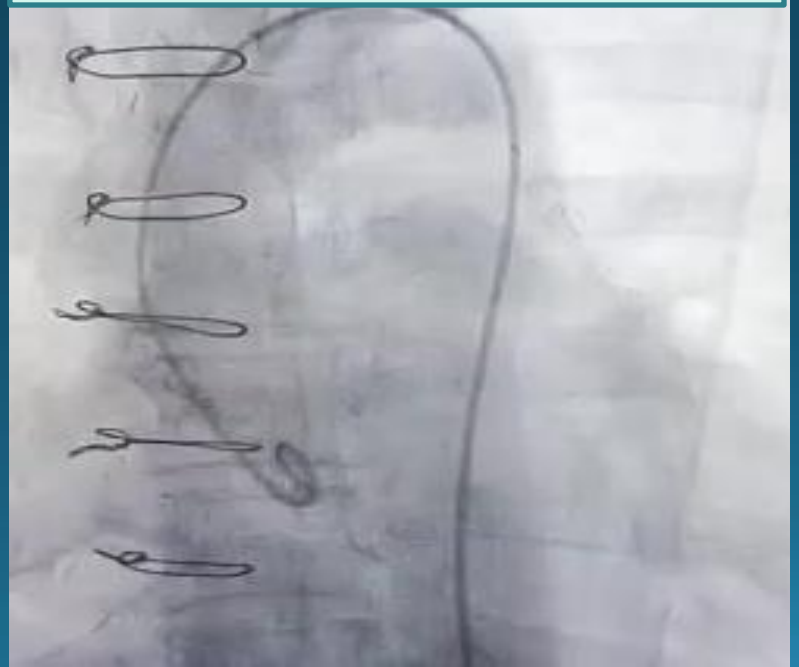
Valve Positioning



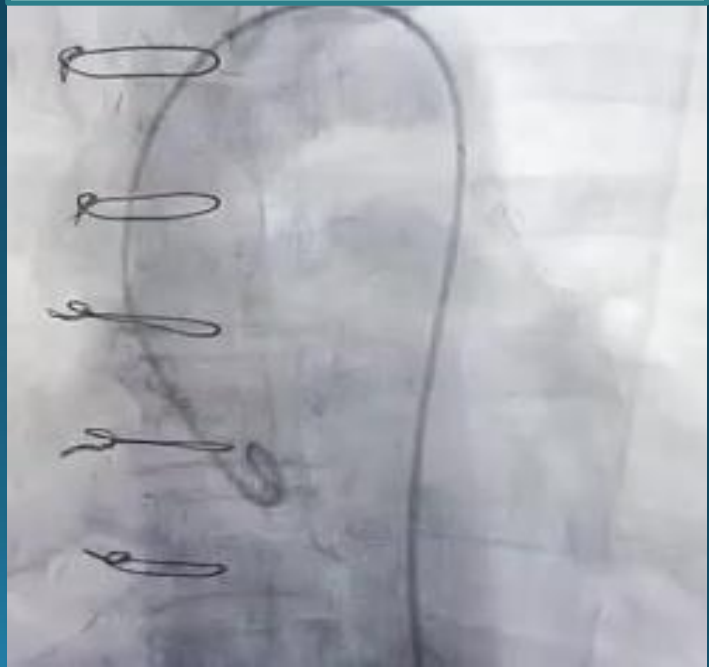
Valve Deployment



Post Aortogram



Femoral



Post TAVI

Parameters	Values
Peak velocity	1.19m/s
Mean gradient	3 mmHg
Peak gradient	10 mmHg
EF%	55%

JACC: ASIA VOL. 1, NO. 3, 2021

STATE-OF-THE-ART REVIEW

Transcatheter Aortic Valve Replacement in Asia

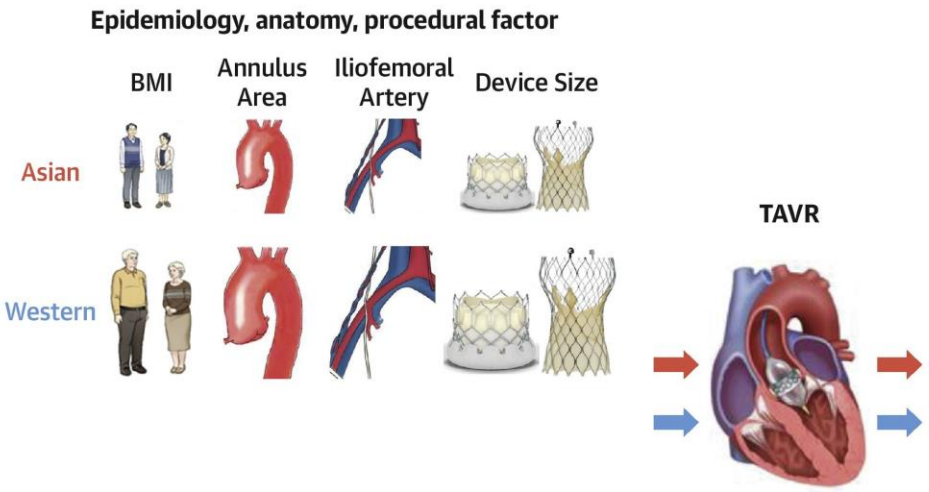
Present Status and Future Perspectives

Cheol Hyun Lee, MD, PhD,[a,*] Taku Inohara, MD, PhD,[b,*] Kentaro Hayashida, MD, PhD,[b] Duk-Woo Park, MD, PhD[c]

ABSTRACT

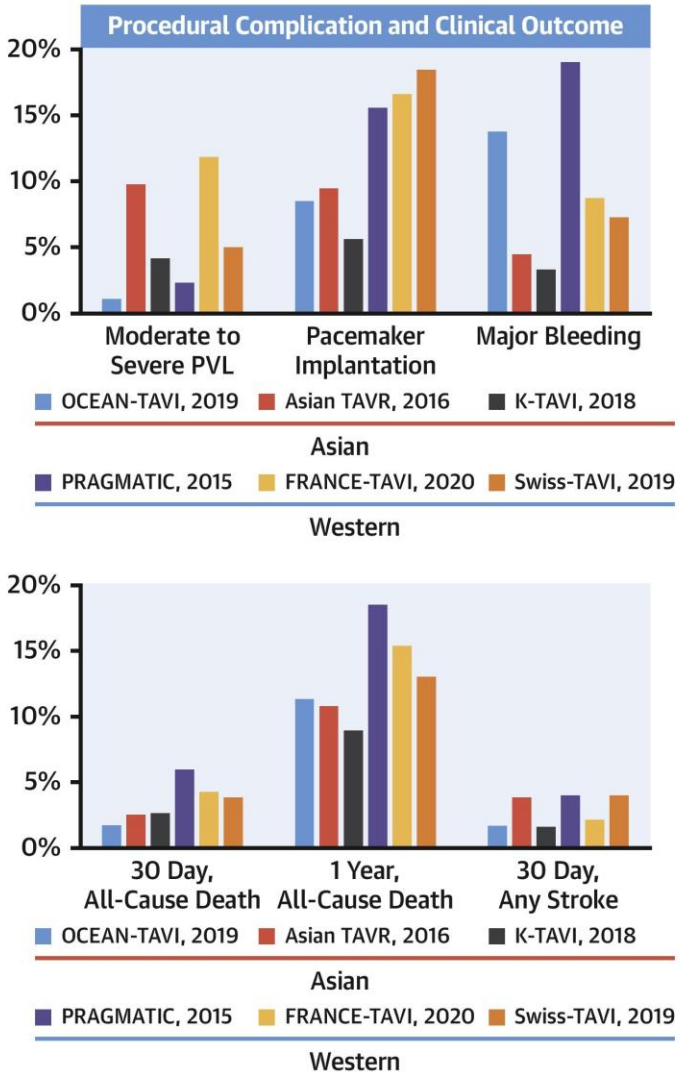
Over the last decade, based on evidence from multiple randomized clinical trials, transcatheter aortic valve replacement (TAVR) has become the established treatment for patients with symptomatic severe aortic stenosis. Despite the overwhelming expansion of TAVR in Western countries, the initial uptake and widespread adoption of this procedure have been relatively delayed in Asian countries, owing to the high cost of devices; limited local health and reimbursement policies; and lack of specific training/proctoring program, specialized heart team, or dedicated infrastructure. Furthermore, it has not yet been determined whether there are substantial interracial and ethnic differences in the clinical characteristics, comorbidities, and anatomic features, as well as procedural and long-term outcomes, in patients receiving TAVR. In this review, we provide not only a comprehensive look at the current status and outcomes of TAVR in Asian populations compared with those of Western populations but also a perspective on the future of TAVR in Asia. (JACC: Asia 2021;1:279–293) © 2021 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/).

CENTRAL ILLUSTRATION: Specific Clinical and Anatomic Features and Outcomes of Transcatheter Aortic Valve Replacement in Asian Populations



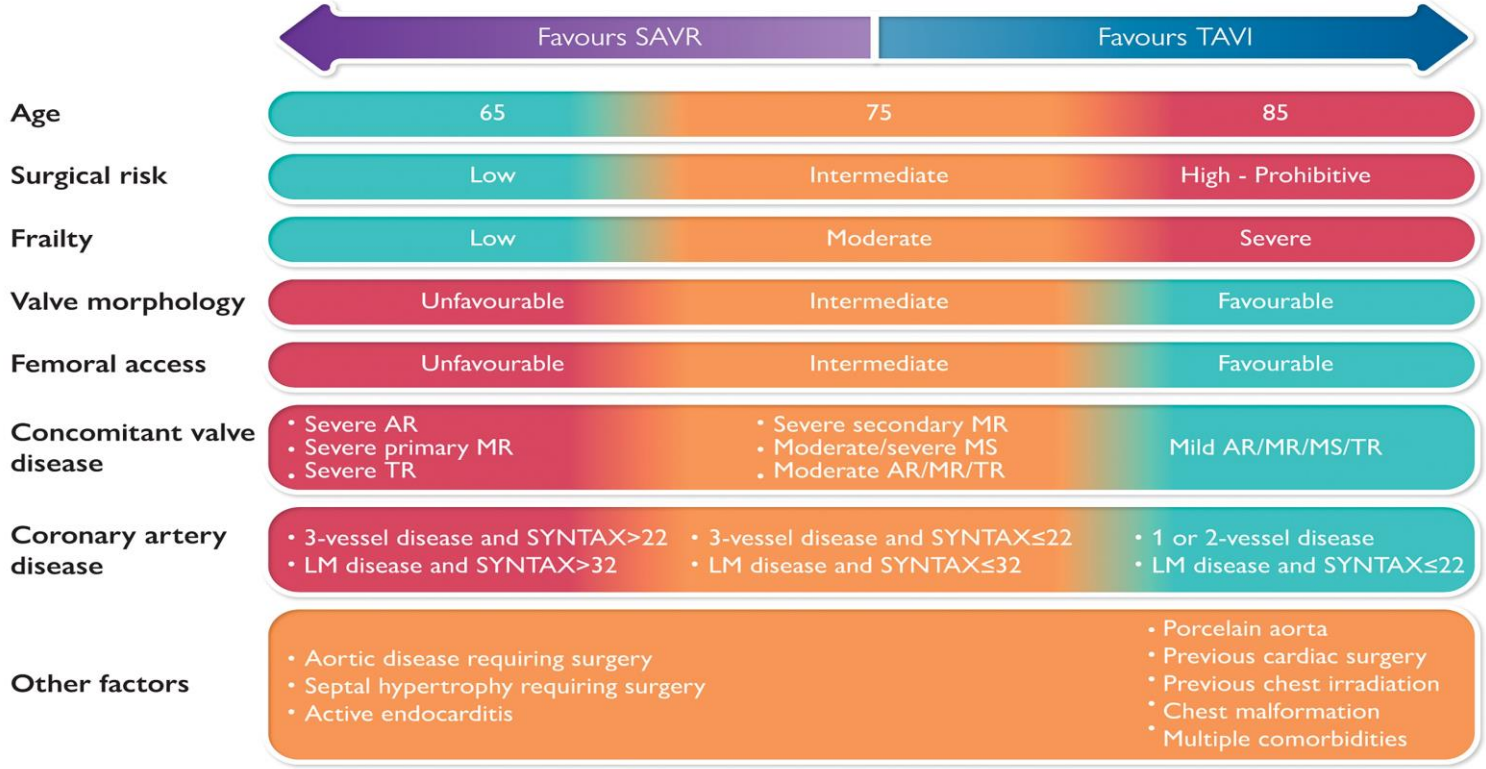
	Age	Male	BMI	LVEF	STS score
Asian	◄►	◄►		◄►	◄►
Western	◄►	◄►	▲	◄►	◄►

	Valve area	Annulus area	Bicuspid	Device size	Transfemoral
Asian	◄►		▲		◄►
Western	◄►	▲		▲	◄►



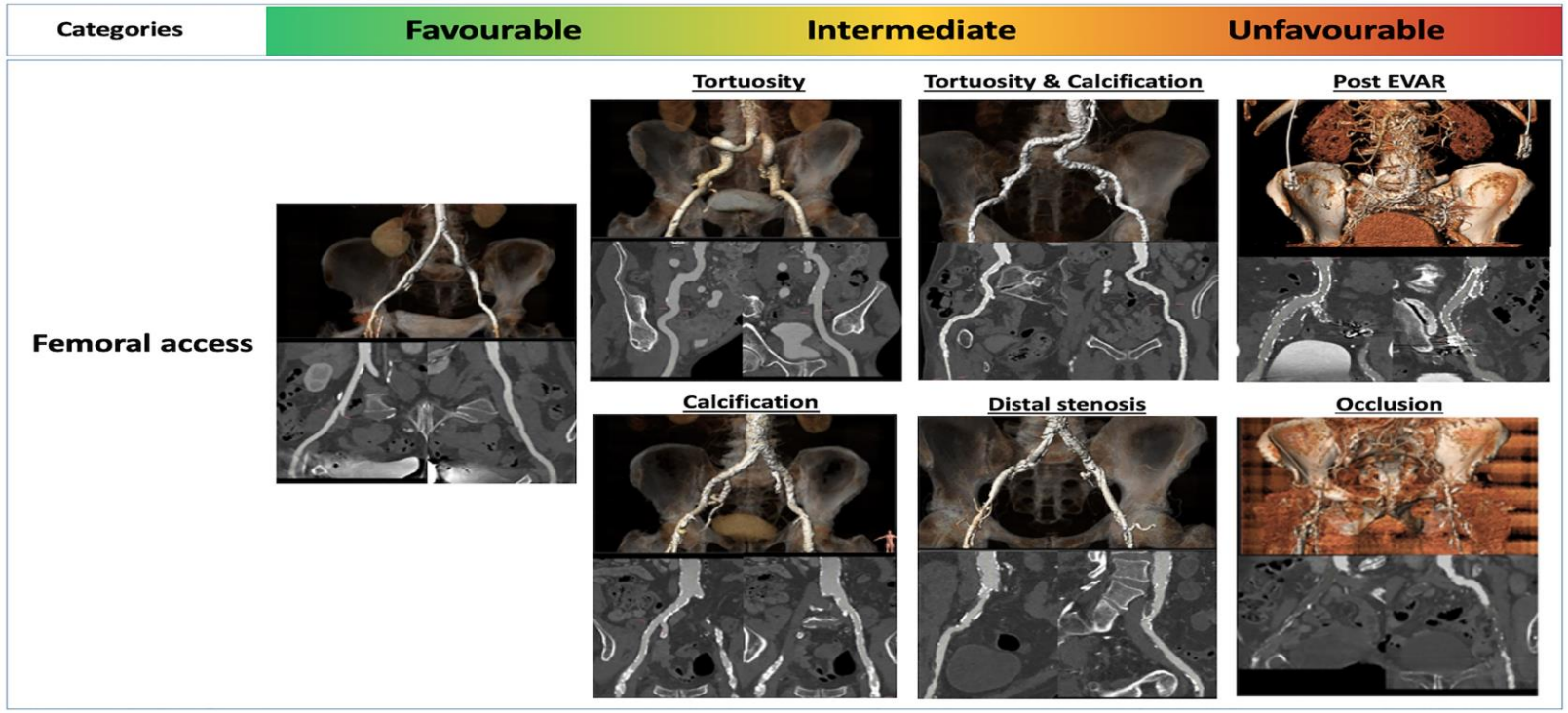
Lee, C.H. et al. JACC: Asia. 2021;1(3):279–293.

Graphical Abstract Decision-making process between TAVI and SAVR. Refer to Figures 2, 4, and 6 for details of the valve ...



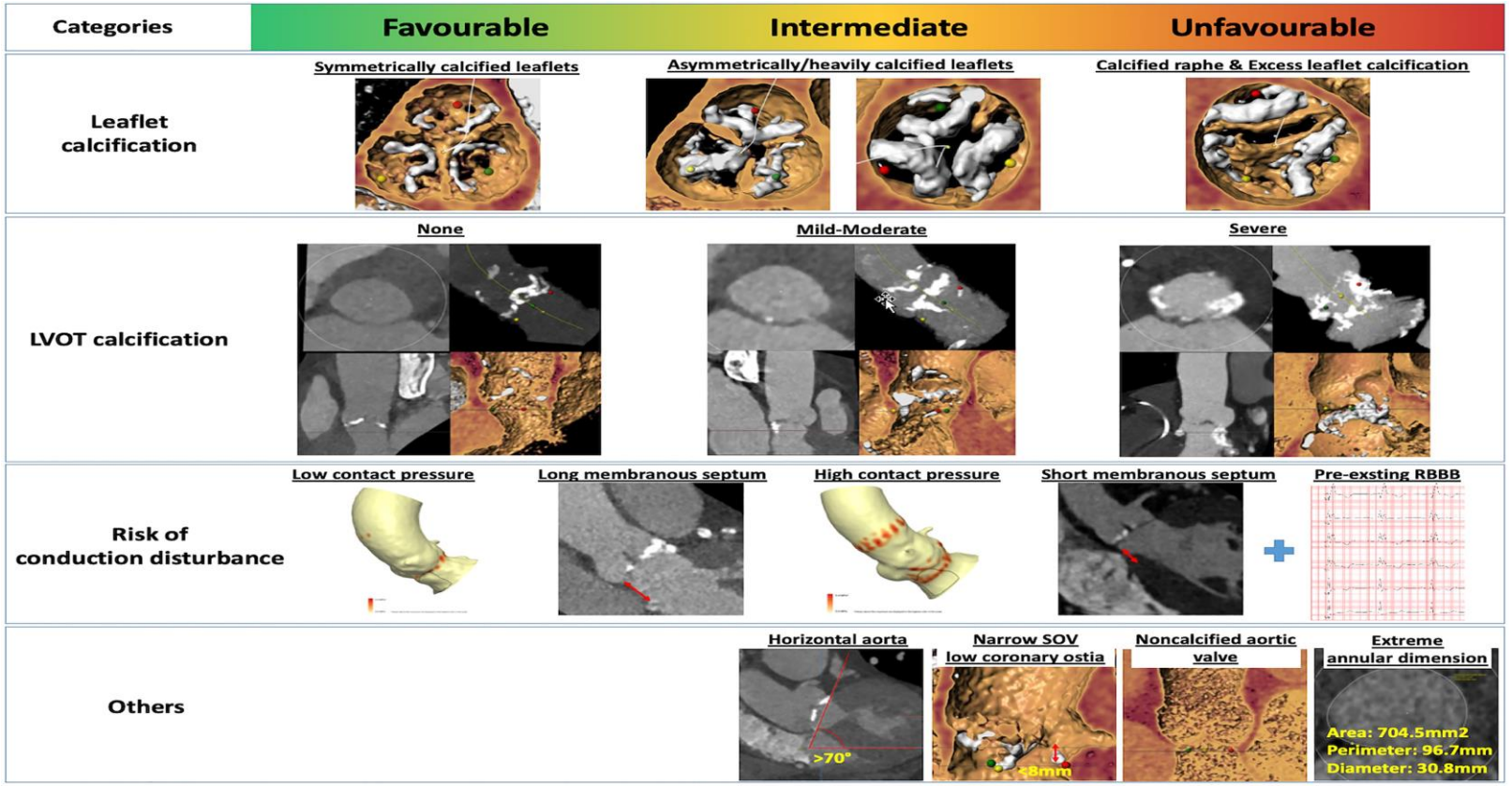
Eur Heart J, Volume 43, Issue 29, 1 August 2022, Pages 2729–2750, https://doi.org/10.1093/eurheartj/ehac105

Figure 3 Anatomical risk stratification of femoral access. The category (favourable, intermediate, unfavourable) ...



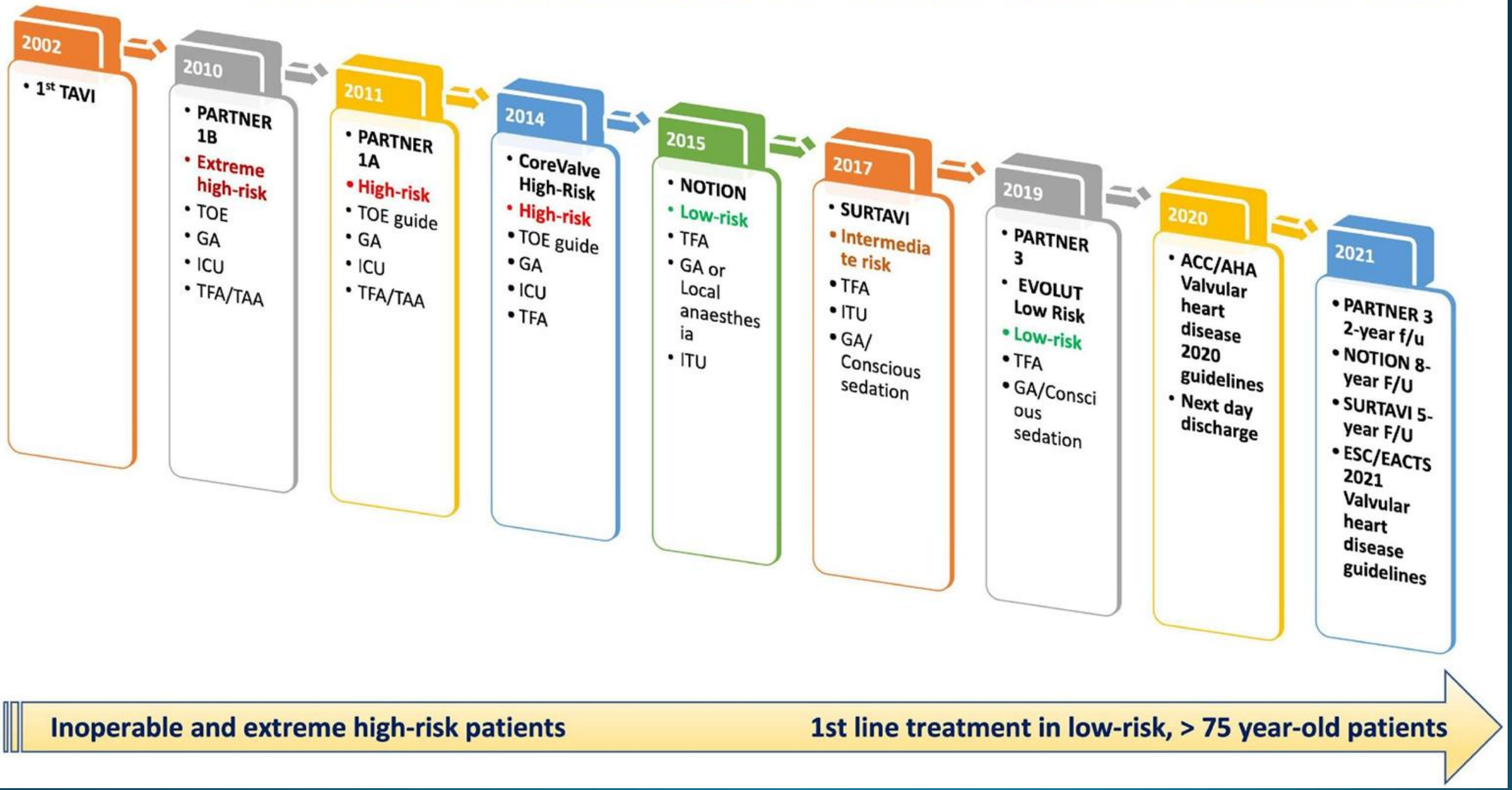
Eur Heart J, Volume 43, Issue 29, 1 August 2022, Pages 2729–2750, https://doi.org/10.1093/eurheartj/ehac105

Figure 2 Anatomical risk stratification of native aortic valve morphology. The category (favourable, intermediate, ...

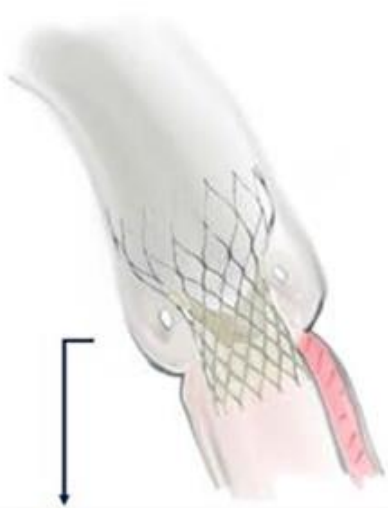


Eur Heart J, Volume 43, Issue 29, 1 August 2022, Pages 2729–2750, https://doi.org/10.1093/eurheartj/ehac105

TAVI: A 20-YEAR JOURNEY OF TRANSFORMATIVE EVOLUTION



Lifetime management –AS in young



1st procedure	TAVR		SAVR		Ross	
2nd procedure	TAVR	TAVR explant + SAVR	TAVR	Redo SAVR	TAVR	Redo SAVR
	Minimally invasive procedure	Possible 3rd procedure	Wide experience with TAVR-in-SAVR Easy Coronary reaccess after SAVR Surgery at young age	Possible 3rd procedure	Minimally invasive procedure Possible 3rd procedure	Complex procedure
	Risk of coronary obstruction Difficult coronary reaccess Few options for 3rd procedure	Poor experience with TAVR explant Possible concomitant aortic repair	Few options for 3rd procedure	Higher operative risk	Possible need for two valves intervention	

Figure 4. Possible advantages and limitations of all possible strategies for a lifetime management of aortic stenosis.
SAVR indicates surgical aortic valve replacement; and TAVR, transcatheter aortic valve replacement.

Supplemental Table 4. Ongoing major clinical trials

Clinical Trial (Unique Identifier)	N	Population	Intervention	Primary outcome	Follow-up period	Estimated Completion
Trials of early intervention in patients with aortic stenosis						
AVATAR	312	Asymptomatic severe AS patients with low or intermediate surgical risk	SAVR	All-cause mortality and MACE*[1]	5 years	2021
ESTIMATE	360	Asymptomatic severe AS patients with normal exercise test, LVEF >50%, and low surgical risk	SAVR	All-cause mortality and cardiac morbidity*[2]	1 year	2019
EARLY-TAVR	1109	Asymptomatic severe AS with age ≥65 years	TAVI	All-cause mortality, stroke, and rehospitalization*[3]	2 years	2032
EVOLVED	1000	Asymptomatic severe AS patients	SAVR/TAVI	All-cause mortality and rehospitalization*[4]	3 years	2024
TAVR UNLOAD	300	Moderate AS patients with reduced LVEF (<50%) and heart failure	TAVI	All-cause mortality, disabling stroke, rehospitalization*[5], and change in KCCQ	1 year	2024
Trials of TAVI vs. SAVR						
PARTNER 3	1000	Severe AS patients with an operative mortality < 4%	TAVI (SAPIEN 3) vs. SAVR	All-cause mortality, all stroke, and rehospitalization	10 years	2029
Evolut Low Risk	2223	Severe AS patients with an operative mortality <3%	TAVI (Evolut R) vs. SAVR	All-cause mortality and disabling stroke	10 years	2026
NOTION	280	Severe AS patients older than 70 years of age	TAVI (CoreValve) vs. SAVR	All-cause death, myocardial infarction, and stroke	10 years	2023
NOTION-2	372	Severe AS patients under 75 years of age	TAVI vs. SAVR	All-cause death, stroke, and rehospitalization	10 years	2029
DEDICATE	1404	“All-comers” severe AS patient population with a low to intermediate surgical risk	TAVI vs. SAVR	All-cause mortality and stroke	5 years	2027
Trials in patients with mixed valve disease						
MITAVI	1162	Patients with concomitant moderate or severe mitral regurgitation after successful TAVI	MitraClip	All-cause mortality and heart failure hospitalization	1 year	2023
Trials in patients with severe AS and concomitant coronary artery disease						
TCW	328	Severe AS patients with multivessel disease	TAVI + FFR-guided PCI vs. SAVR + CABG	All-cause mortality, myocardial infarction, disabling stroke, clinically-driven target vessel revascularization, valve re-intervention, and life-threatening or disabling bleeding	1 year	2023
NOTION-3	452	Severe AS patients with coronary artery disease	TAVI + FFR-guided PCI vs. TAVI	All-cause mortality, myocardial infarction, or urgent revascularization	1 year	2027
COMPLETE TAVR	4000	Severe AS patients with coronary artery disease	TAVI + PCI vs. TAVI + medical therapy	Cardiovascular death, myocardial infarction, or ischemia-driven revascularization or hospitalization for unstable angina or heart failure	3.5 years	2026

Concluding remarks

- TAVI is now standard of care for high risk Severe AS
- Trials shows equivalence in intermediate and low risk pateints
- Rapid advances in technology & implantation technique make it a safer procedure with predictable outcomes
- Clincal trails are evaluating in younger patients, bicuspid anatomy, low risk groups, aortic regurgitation, Moderate AS
- It is a boon for elderly severe aortic stenosis

The TAVR train has left the station for multiple new stops

EXPANDING INDICATIONS

LOW RISK
BICUSPID VALVES
ASYMPTOMATIC AS
MODERATE AS IN CHF
AUTOLOGOUS VALVES

THANK YOU