TAVI 2020: challenges and new horizons

Haim Danenberg, MD

Hadassah Hebrew University Medical Center

Jerusalem, Israel

Clinical Evidence: proven success in extreme, high, and intermediate risk patients with symptomatic, severe aortic stenosis.

Extreme Risk → **High Risk** → **Intermediate Risk**

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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*

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Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery

CrossMark

Jeffrey J. Popma, MD,* David H. Adams, MD,† Michael J. Reardon, MD,† Steven J. Yakubov, MD,‡ Neal S. Kleiman, MD,† David Heimansohn, MD,‖ James Hermiller, Jr, MD,‖ G. Chad Hughes, MD,¶ J. Kevin Harrison, MD,¶ Joseph Coselli, MD,# Jose Diez, MD,# Ali Kafi, MD,** Theodore Schreiber, MD,** Thomas G. Gleason, MD,†† John Conte, MD,†† Maurice Buchbinder, MD,‡‡ G. Michael Deeb, MD,‖‖ Blasé Carabello, MD,¶¶ Patrick W. Serruys, MD, PhD,## Sharla Chenoweth, MS,*** Jae K. Oh, MD,††† for the CoreValve United States Clinical Investigators

Boston, Massachusetts; New York, New York; Houston, Texas; Columbus, Ohio; Indianapolis, Indiana; Durham, North Carolina; Detroit and Ann Arbor, Michigan; Pittsburgh, Pennsylvania; Baltimore, Maryland; Palo Alto, California; Rotterdam, the Netherlands; and Minneapolis and Rochester, Minnesota

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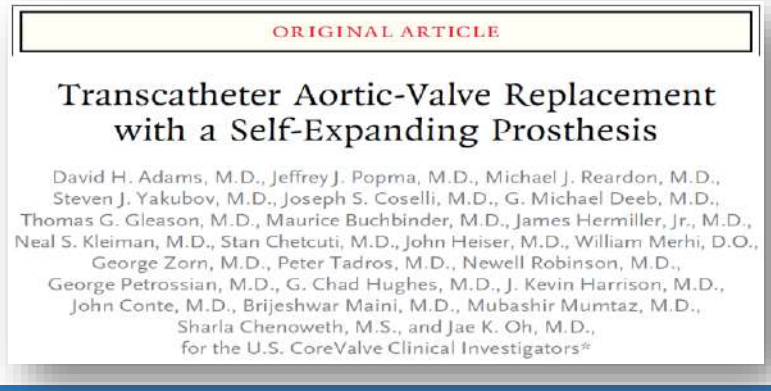
Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

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*



ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*

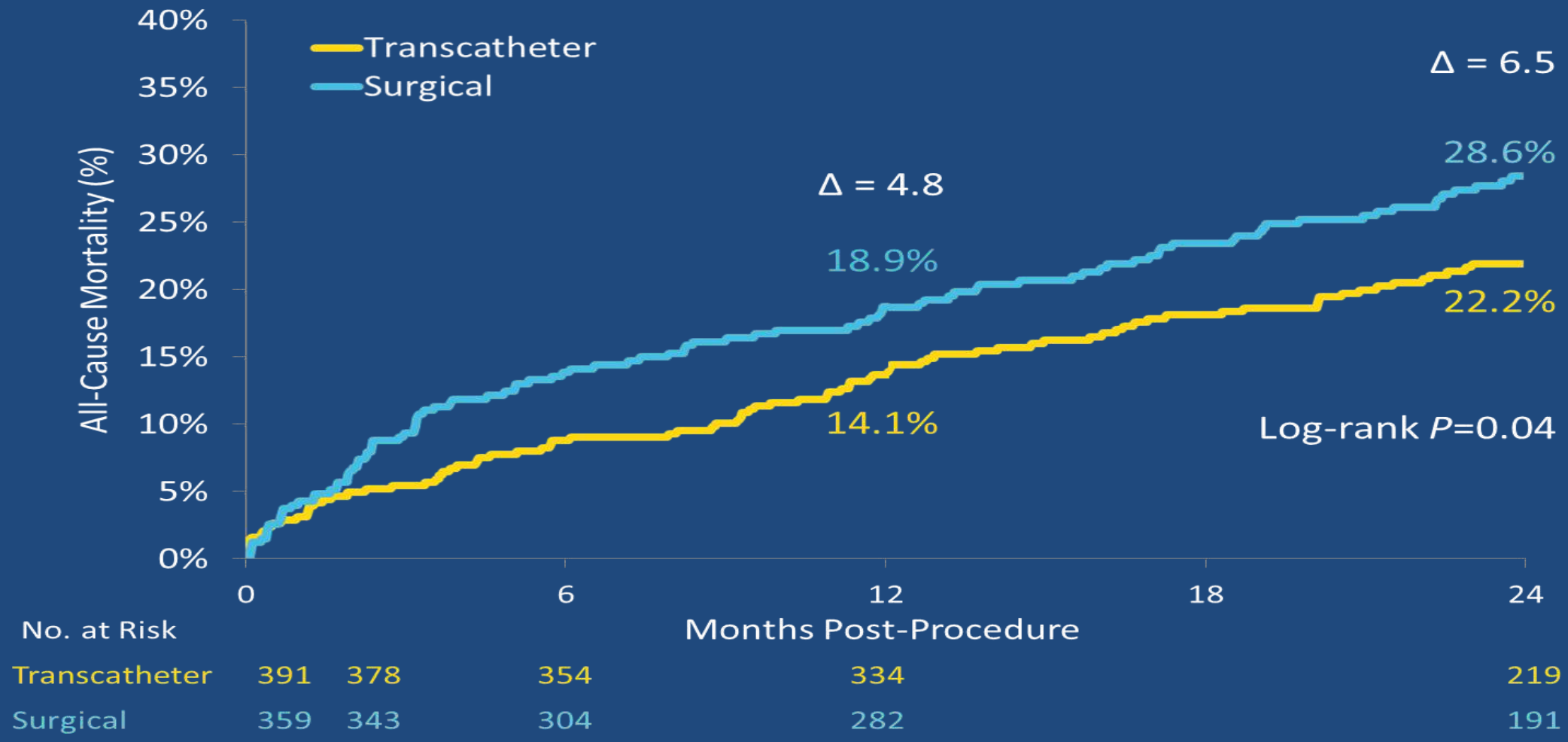
The NEW ENGLAND JOURNAL of MEDICINE

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*

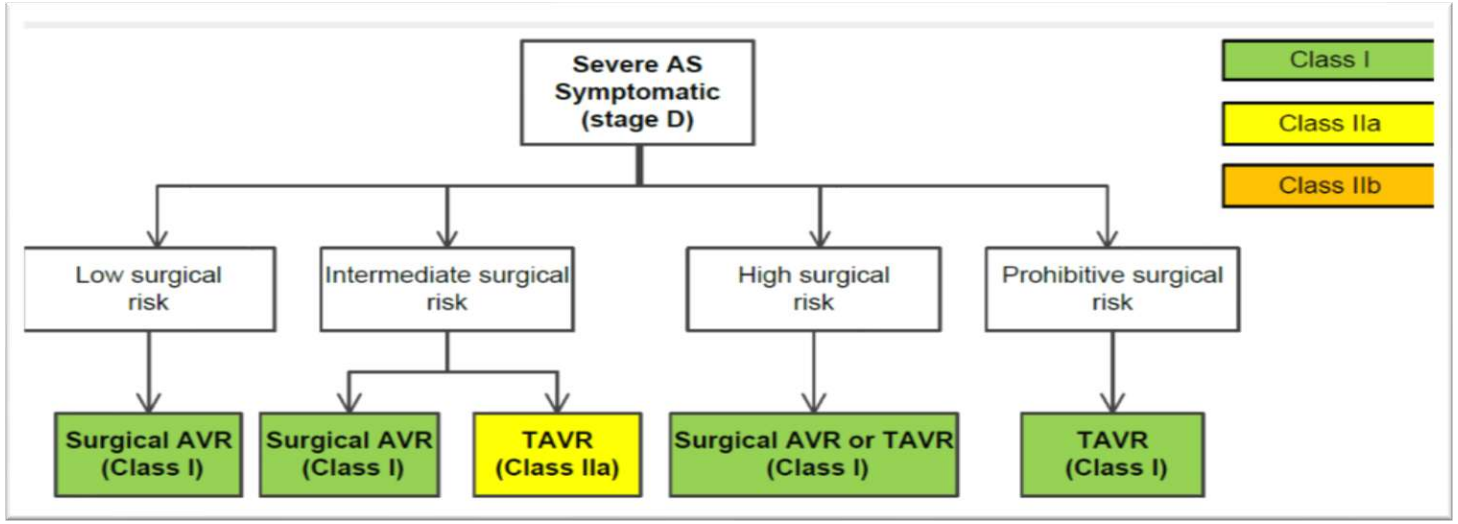
COREVALVE US High Risk Trial: Mortality



Current Guidelines

The ACC/AHA and ESC/EACTS guidelines reflect the success TAVI has demonstrated, and ***TAVI is recommended in extreme risk patients, and considered for both high and intermediate risk*** patients.

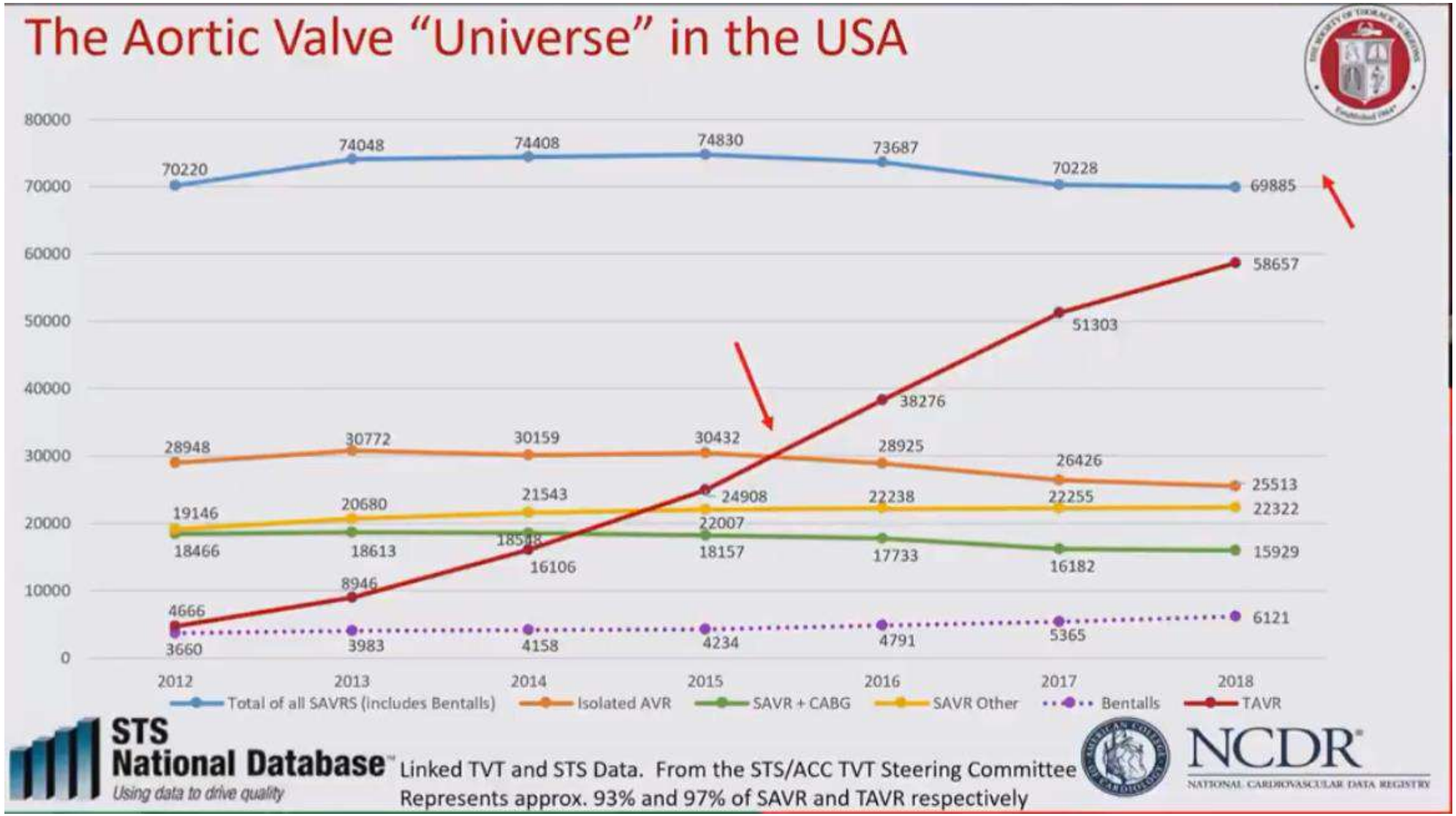
ACC/AHA 2017 Update



ESC/EACTS 2017 Update

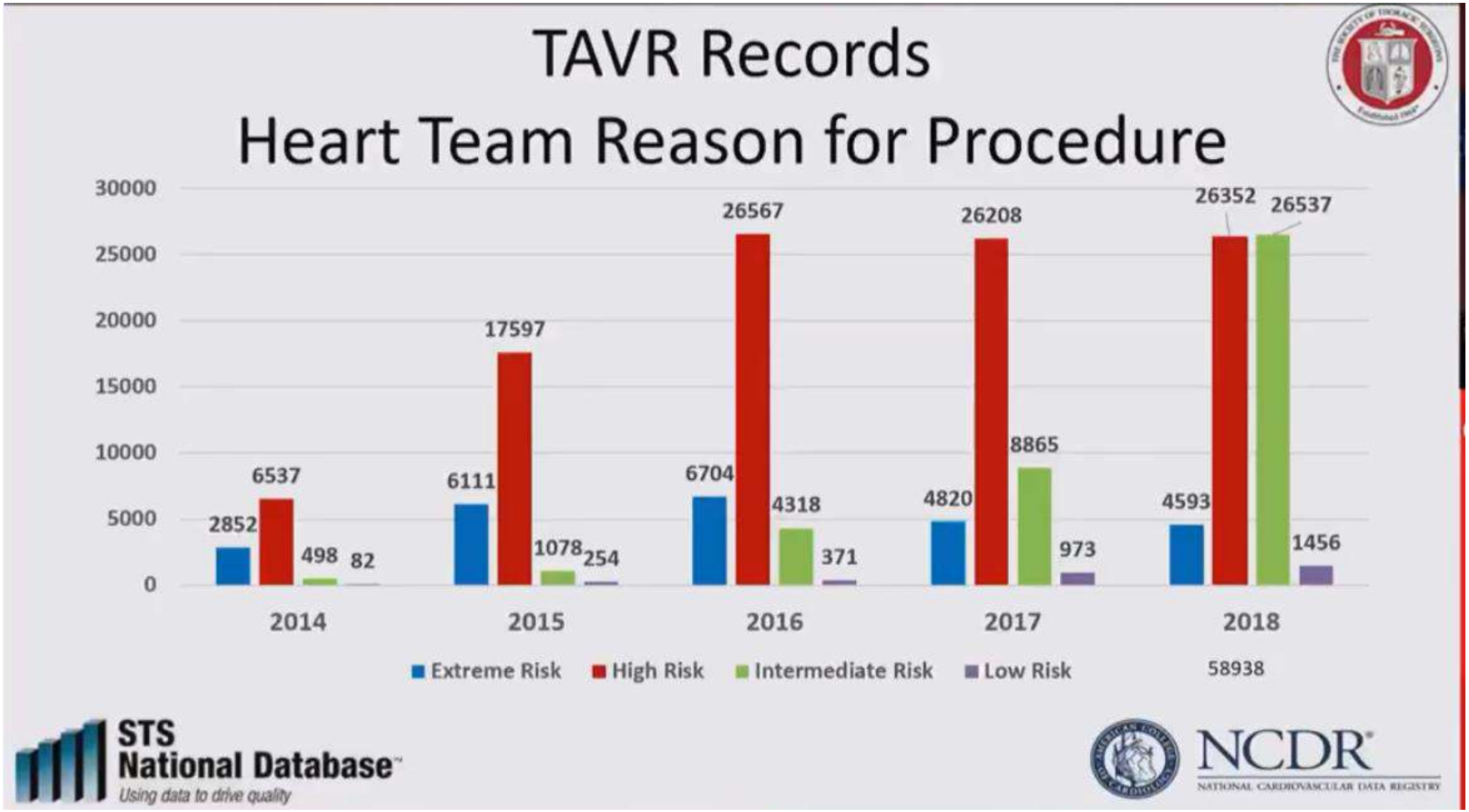
The choice for intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each modality (aspects to be considered are listed in *Table* 7). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see *Table* 7), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B

TAVI in the US



Bavaria et al., presented at EACTS 2019

US: ongoing increase in intermediate/low risk TAVI



Bavaria et al., presented at EACTS 2019

Revolution Vs. Evolution

- Revolution – a sudden, radical or complete change

- Evolution – a process of continuous change from a lower, simple, or worse to a higher, more complex or better state

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ORIGINAL ARTICLE

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

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators*

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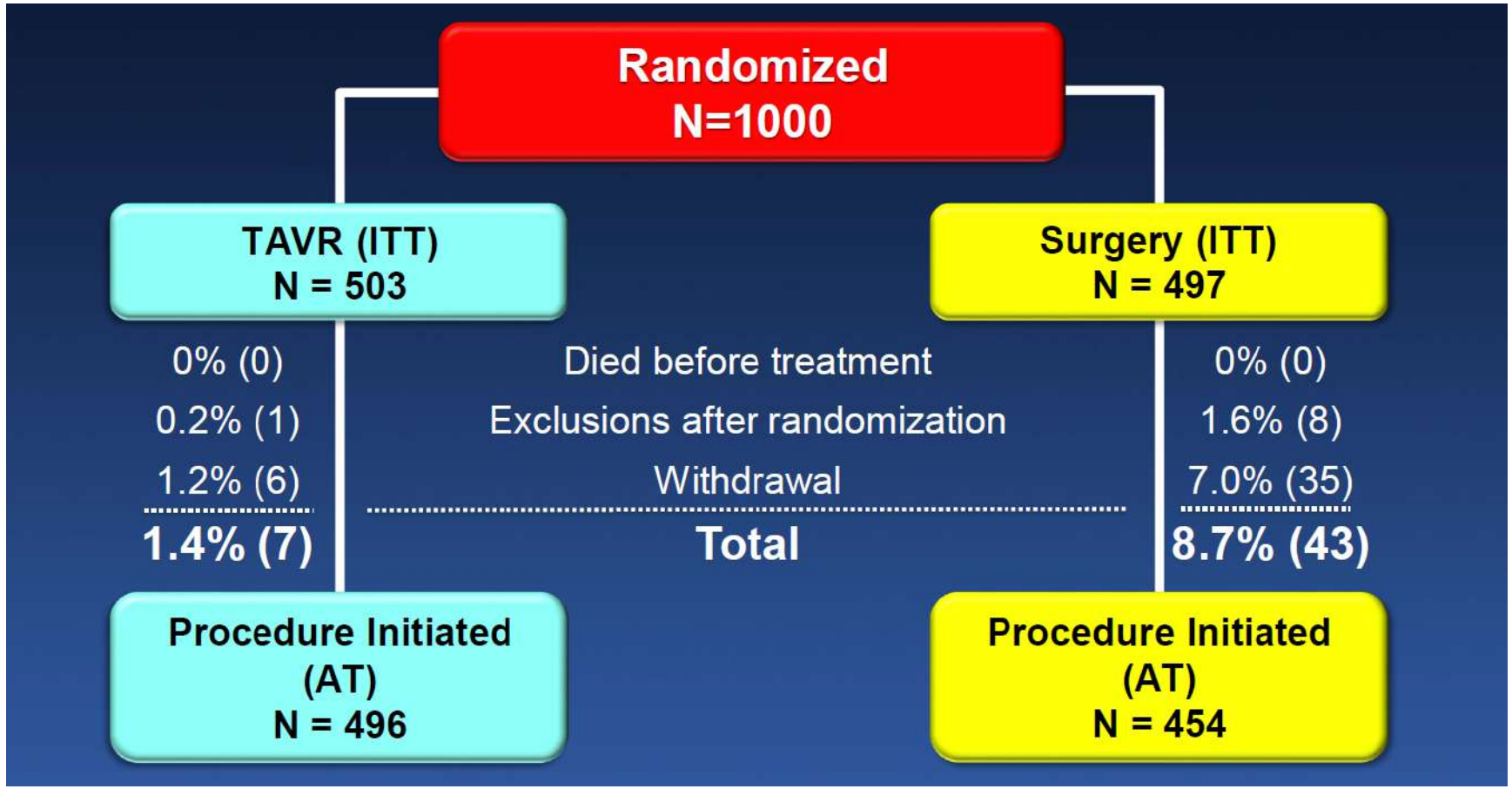
	THE PARTNER 3 TRIAL	Evolut™ Low Risk Trial
Specific exclusion criteria	• Bicuspid valve • Complex CAD (UPLM, SYNTAX>22) • TF only	• Bicuspid valve • Complex CAD (UPLM, SYNTAX>22)
Specific inclusion criteria		Asymptomatic patients Alternative access allowed Embolic protection allowed
Pre-specified primary EP duration	1-year	2-year (2-year data available for <10%)
Patient characteristics	Age 73.5 STS score: 1.9 Concomitant PCI/CABG: 6.5 / 12.8%	Age 74 STS score: 1.9 Concomitant PCI/CABG: ? / 13.6%

Study populations: ITT to AT patient cohorts



✓Major inclusion criteria
- ✓STS PROM ≤ 4
- ✓Eligible for transfemoral placement of SAPIEN 3 THV

✓Major exclusion criteria
- ✓Frailty
- ✓Bicuspid aortic valve
- ✓Complex CAD

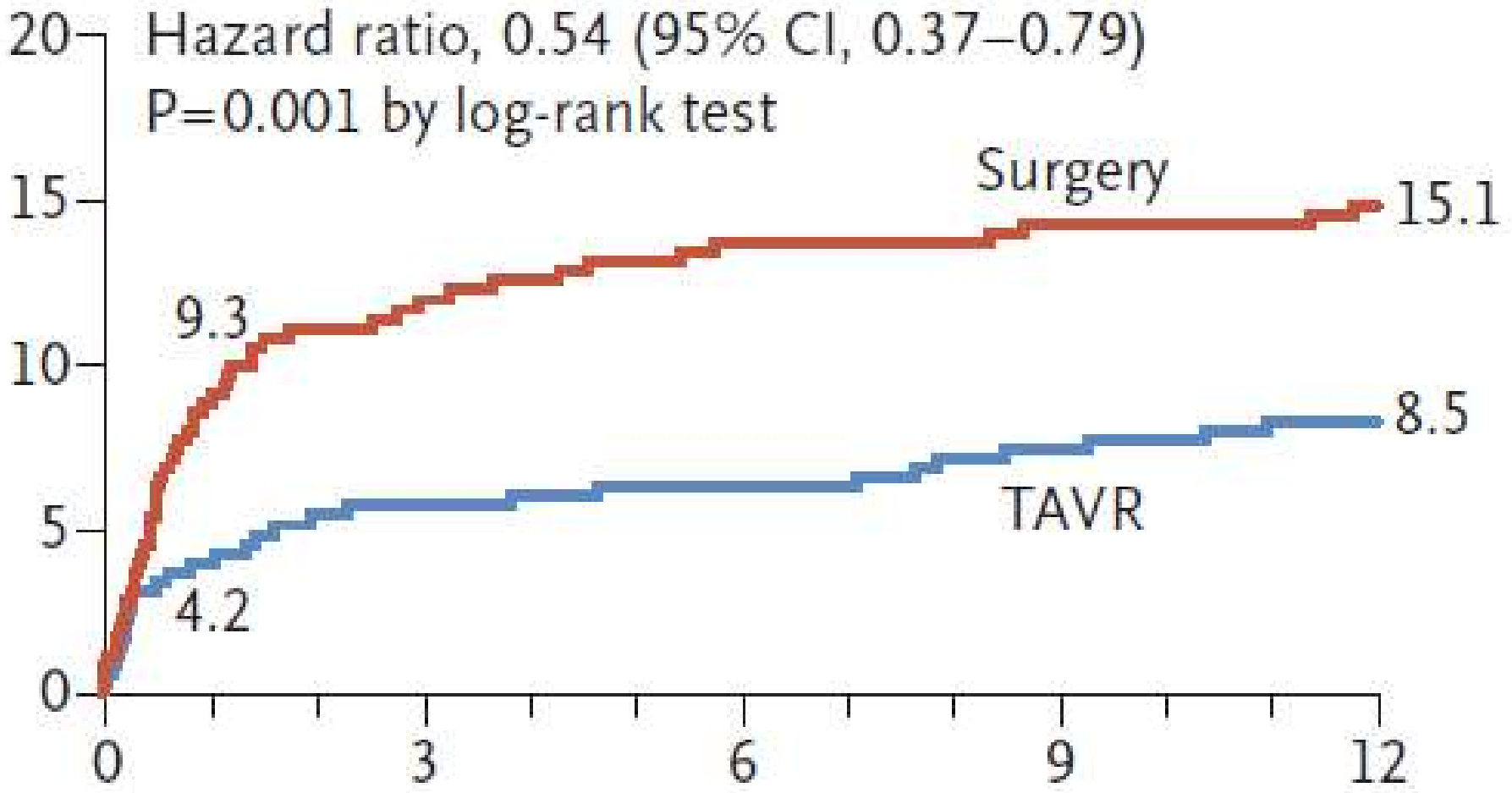
THE PARTNER 3 TRIAL

SAPIEN Valve Evolution

	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility			
Available Valve Sizes	 23 mm, 26 mm	 23 mm, 26 mm, 29 mm	 20 mm, 23 mm, 26 mm, 29 mm

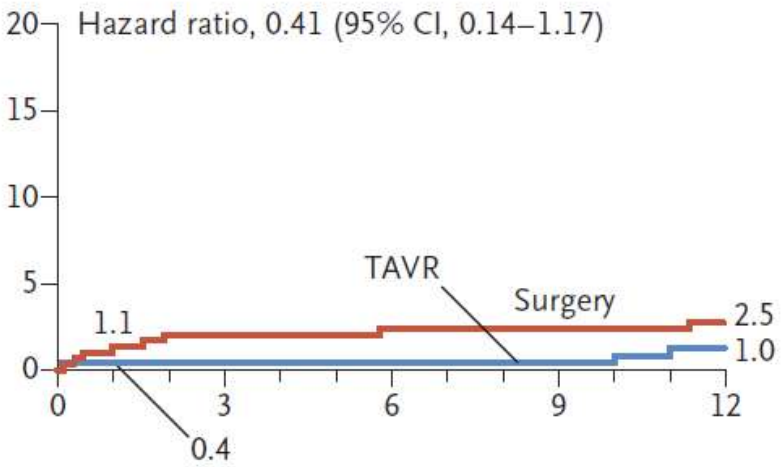
Kaplan–Meier estimates of the rate of the primary composite end point

All cause mortality, all strokes, cardiovascular rehospitalizations

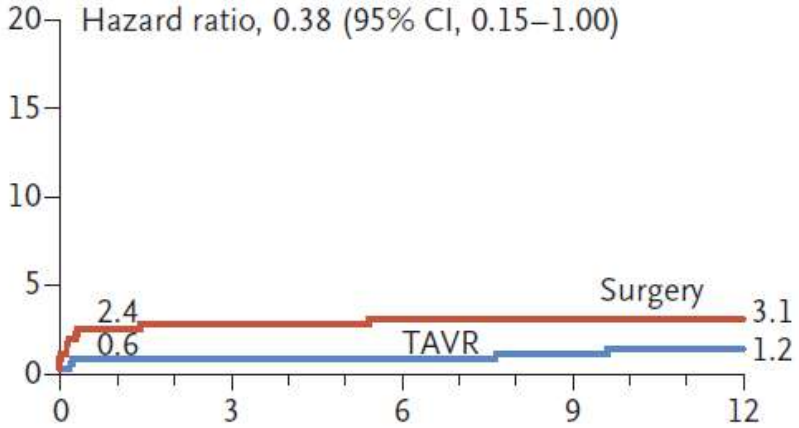


Break-up of primary EP

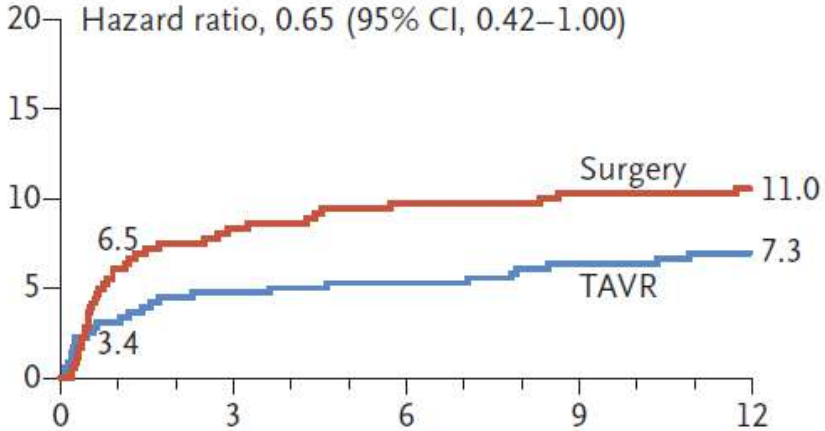
All-cause mortality



All strokes

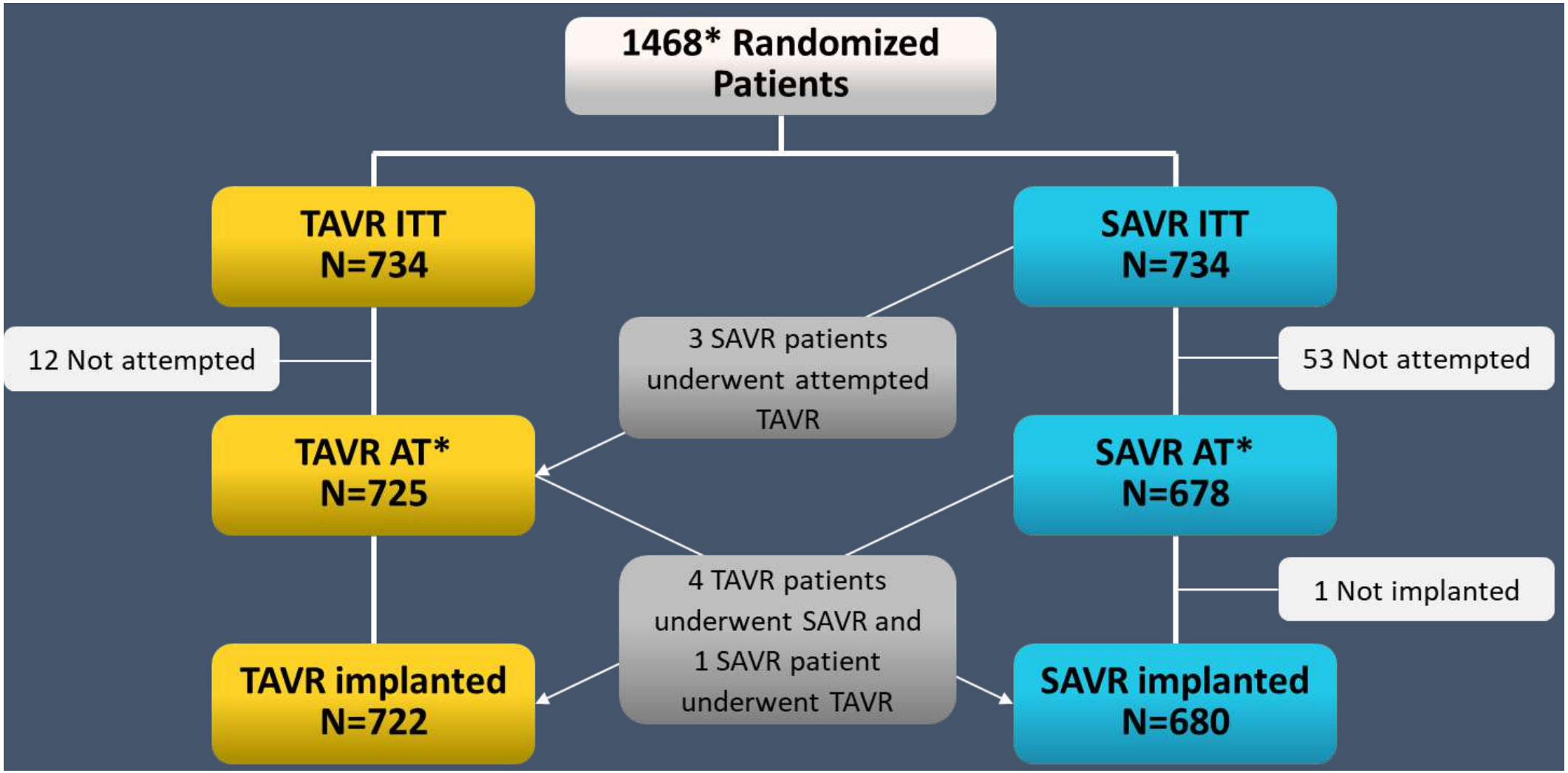


Rehospitalizations



Evolut™ Low Risk Trial

Study population



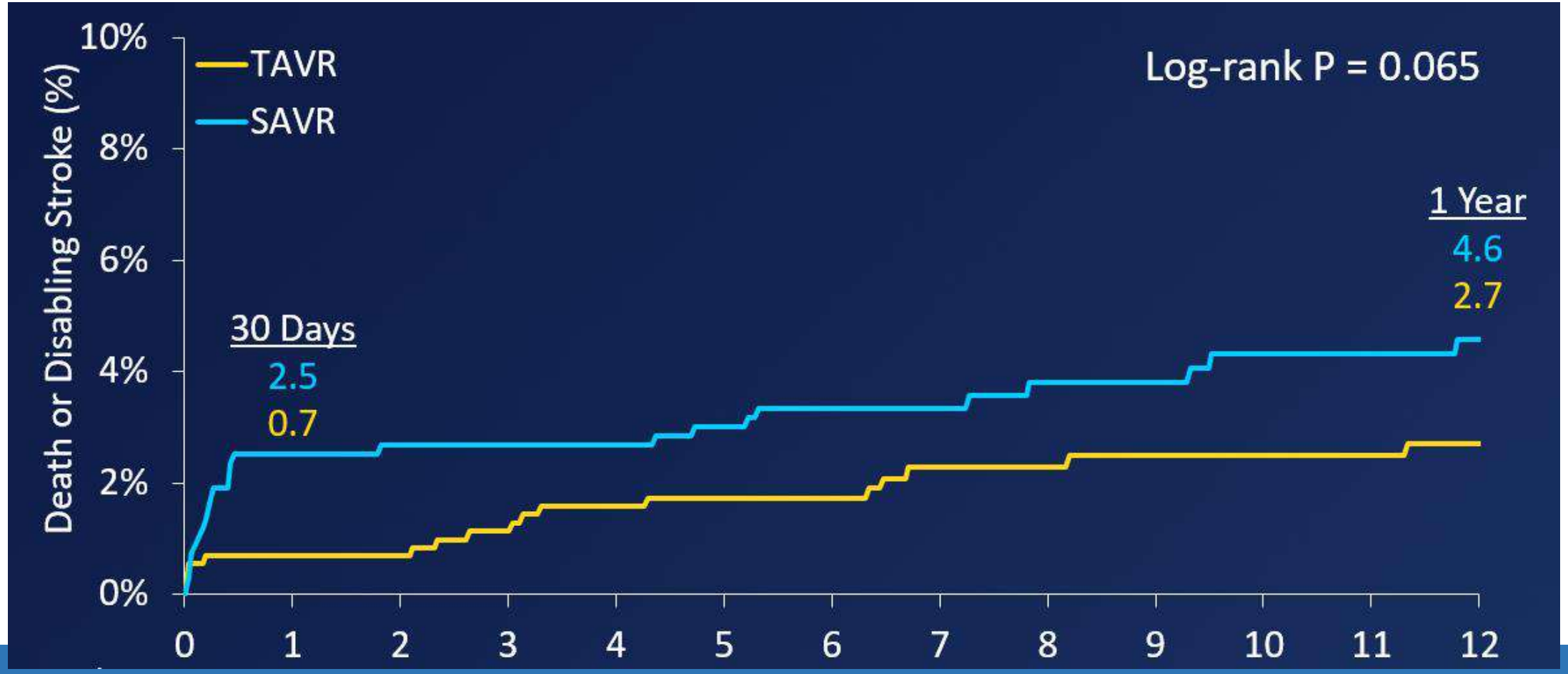
Evolut™ Low Risk Trial

Self-expandable transcatheter heart valve generations

Evolut™ Low Risk Trial

Kaplan–Meier estimates of the rate of the primary composite end point

All cause mortality, disabling strokes

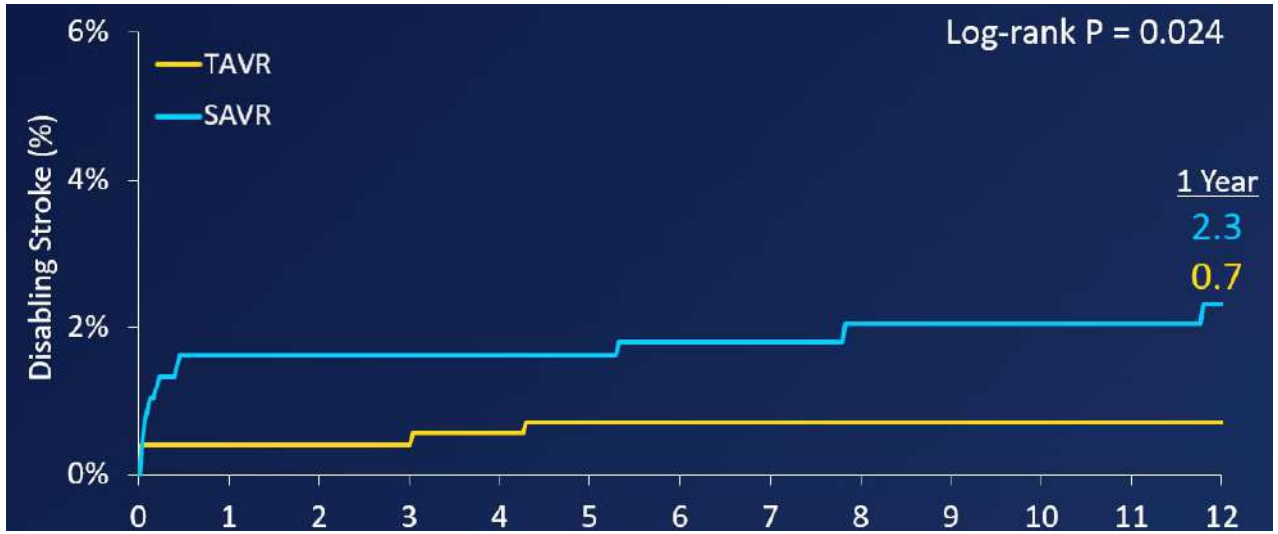


Evolut™ Low Risk Trial

Break-up of primary EP

All-cause mortality

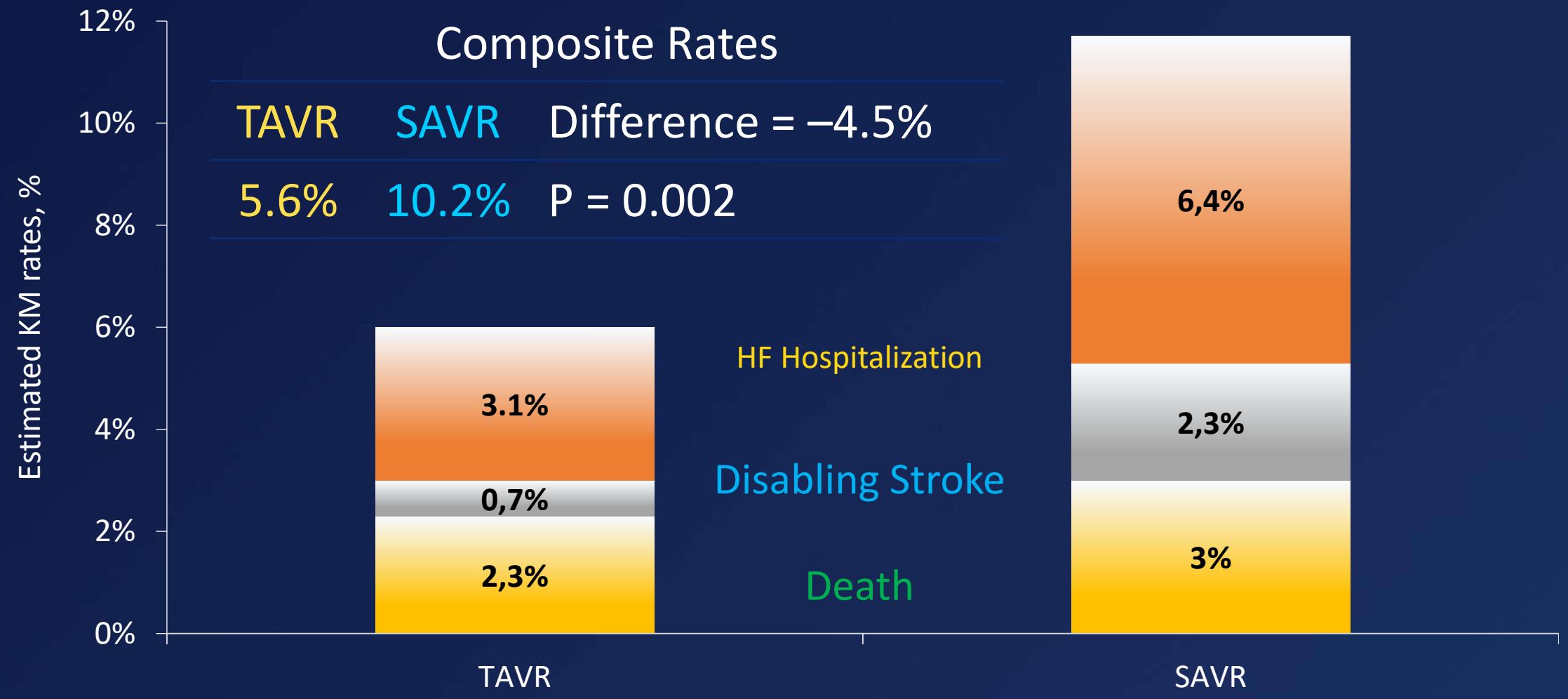
Disabling strokes



Clinical Implications

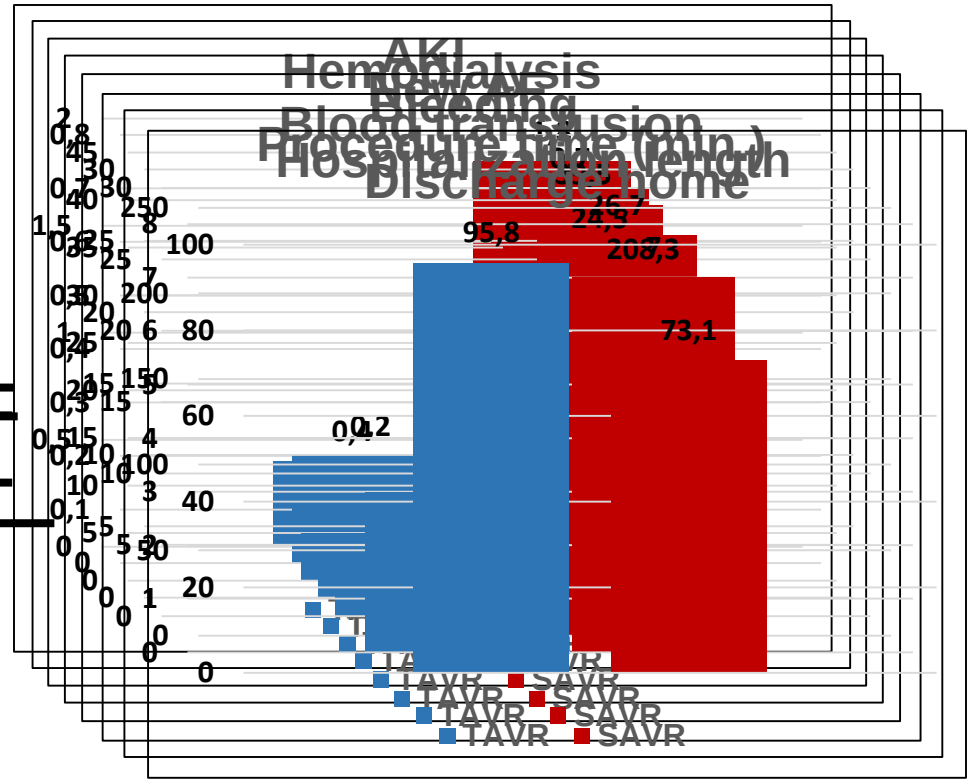
Death, Disabling Stroke and Heart Failure Hospitalizations to 1 Year

Evolut™ Low Risk Trial



Additional important end points in the two* studies

- ✓ Acute kidney injury
- ✓ Hemodialysis
- ✓ New AF
- ✓ Life threatening / major bleeding
- ✓ Need for blood transfusion (>1 unit)
- ✓ Procedure time (min.)
- ✓ Length of hospitalization (days)
- ✓ Discharge to home

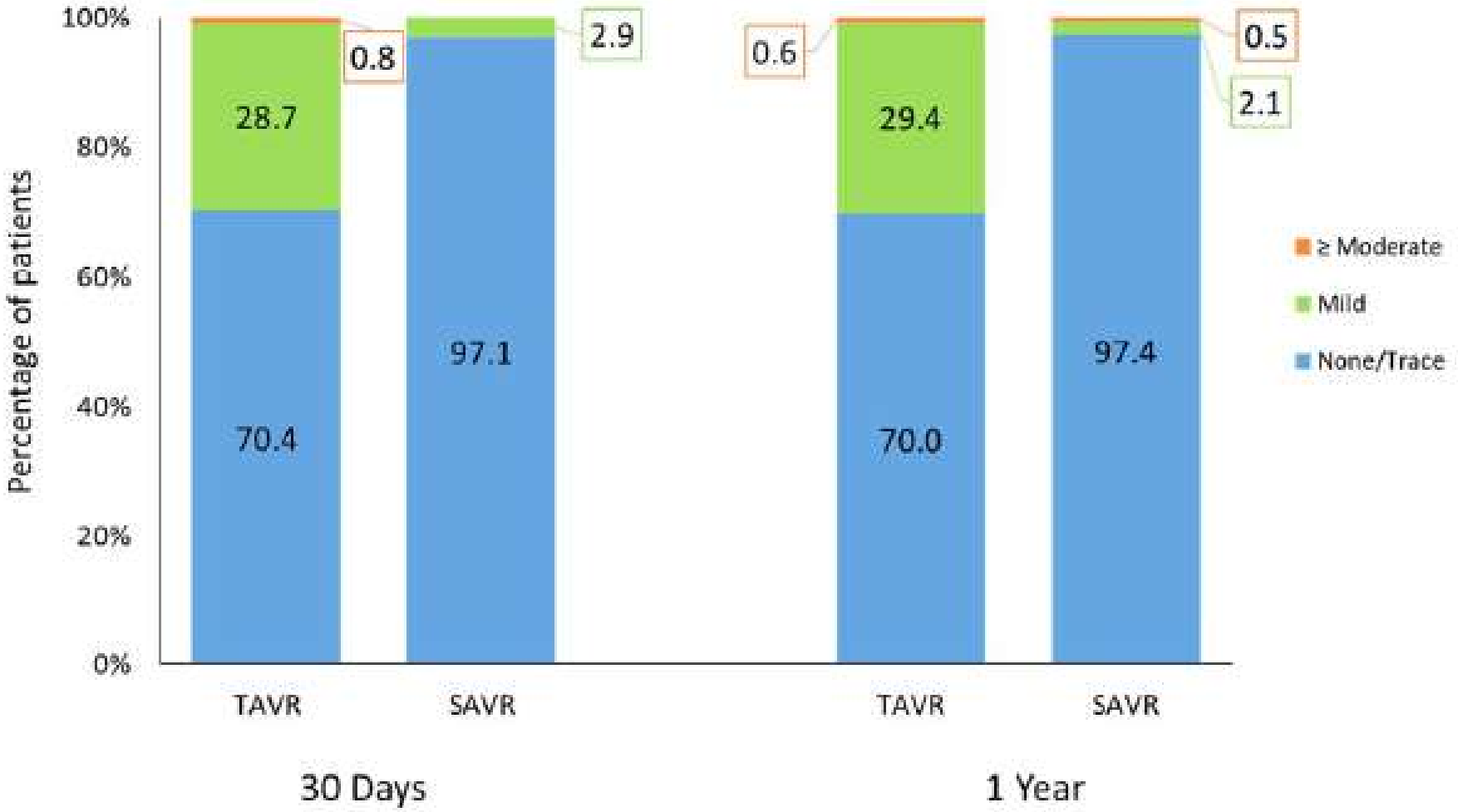


*Where data is available

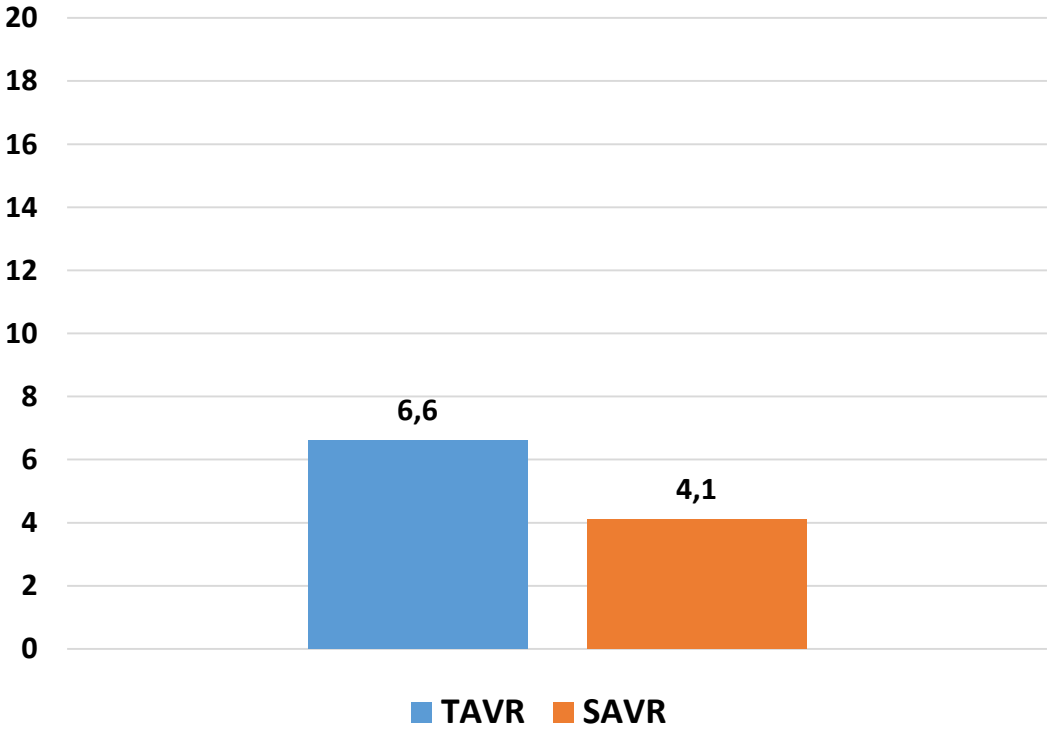
Evolut™ Low Risk Trial

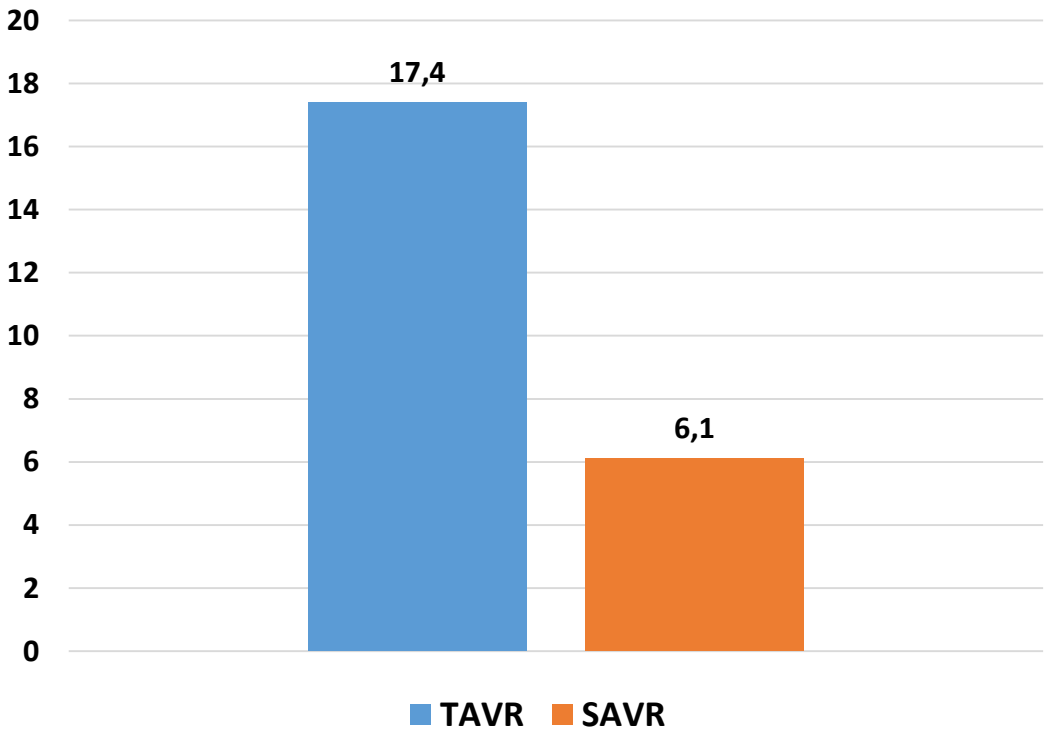
Total aortic regurgitation in Evolut LR study

Para-valvular leak in PARTNER III study



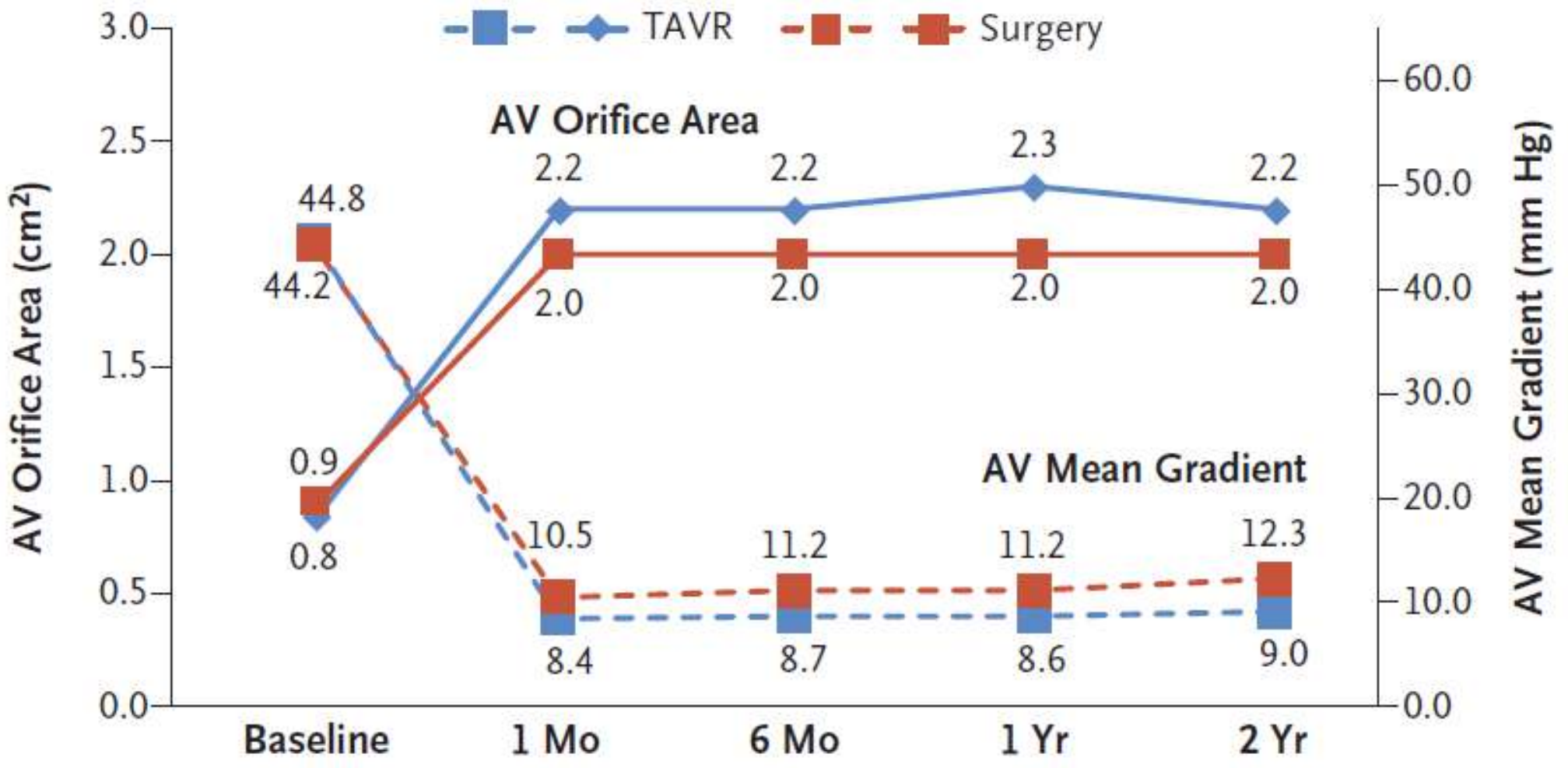
Pacemaker implantation





Evolut™ Low Risk Trial

Aortic Valve Areas over Time for TAVR and Surgery (Echo core-lab)



FDA approval for TAVI in Low risk patients

- August 16, 2019: Evolut and SAPIEN platforms received expanded indication from the US Food and Drug Administration (FDA) to treat symptomatic severe aortic stenosis in patients at low risk for surgical mortality.

- This signals a groundbreaking shift in the future treatment of heart valve disease allowing for younger, more active patients to have this treatment option.

Remaining Controversies:

- TAVI in asymptomatic
- TAVI in bicuspid aortic valve
- TAVI pharmacology
- Device selection
- Coronary access
- Patient-prosthesis mismatch (PPM)
- Permanent pacemaker (PPM..)
- Valve durability

Asymptomatic Aortic Stenosis

Clinical Impact

Sudden Death	Peri-operative Mortality
Severe Asymptomatic AS	*SAVR*
~1-2%/year	*~1-5%*

TAVR may be a better option for Asymptomatic patients

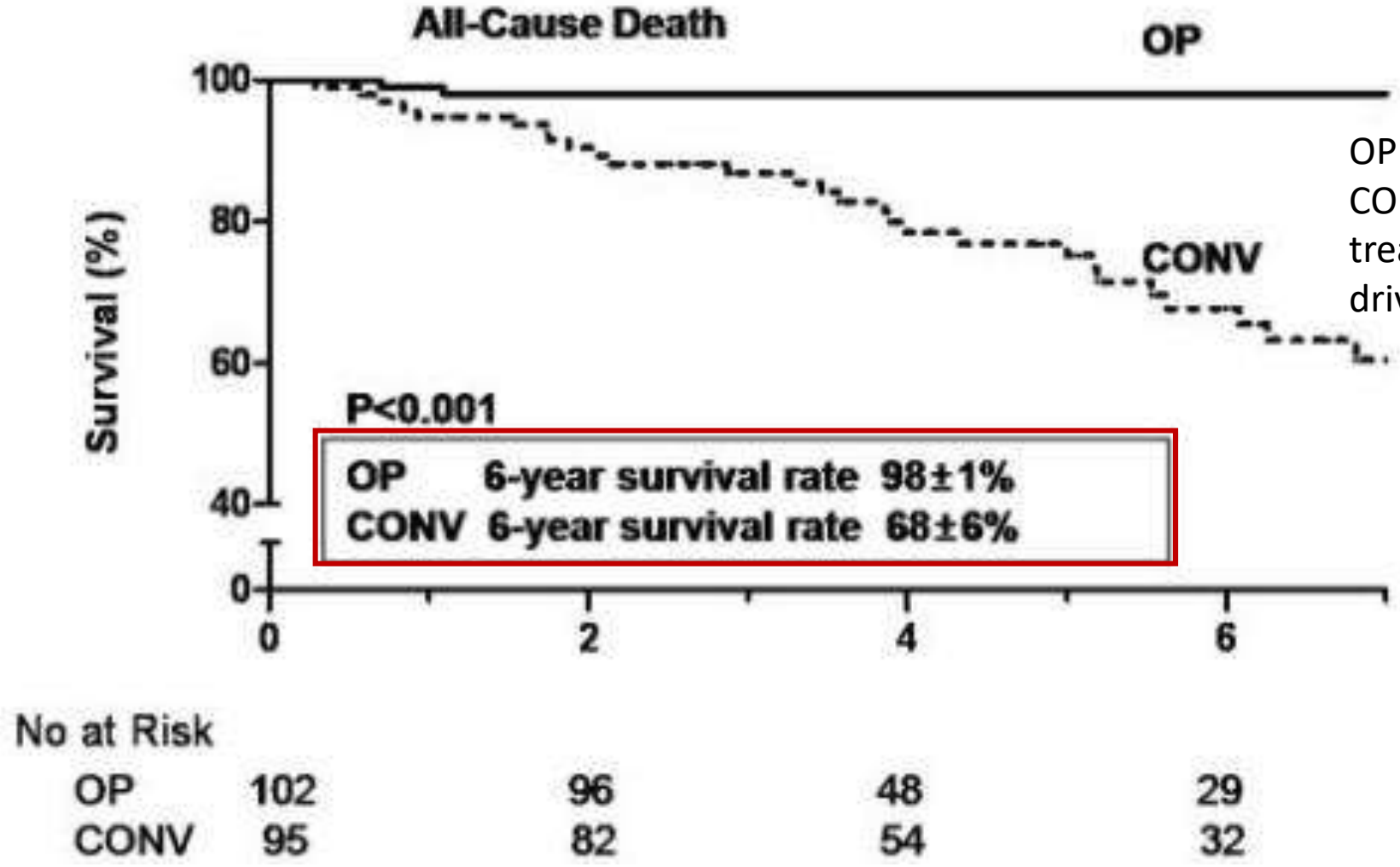
30-day Mortality SURTAVI Intermediate risk	
Core Valve TAVR	SAVR
2.2%	1.7%

30-day Mortality PARTNER trial 2A Intermediate PM	
Sapien 3 TAVR	SAVR
1.1%	4.0%

[1]Genereux et al., presented at TCT 2017; [2]Genereux et al., J Am Coll Cardiol. 2016;67:2263-88; [3]Reardon et al., NEJM 2017; [4]Thourani et al. Lancet 2016; 387:2218-25

Asymptomatic Aortic Stenosis

Clinical Impact



OP = early surgery
CONV = conventional treatment (symptom driven)

[1]Kang et al., circulation 2010:121;1502-1509

Asymptomatic Aortic Stenosis

Guidelines

Recommendations and Levels of Evidence for Diagnosis, Follow-up, and Timing of Aortic Valve Replacement in Patients With Asymptomatic Severe Aortic Stenosis

	ACC/AHA	ESC/EACTS
Indications for aortic valve replacement		
Left ventricular ejection fraction <50%	I, B	I, C
Undergoing other cardiac surgery	I, B	I, C
Symptoms on exercise test clearly related to aortic stenosis	I, B	I, C

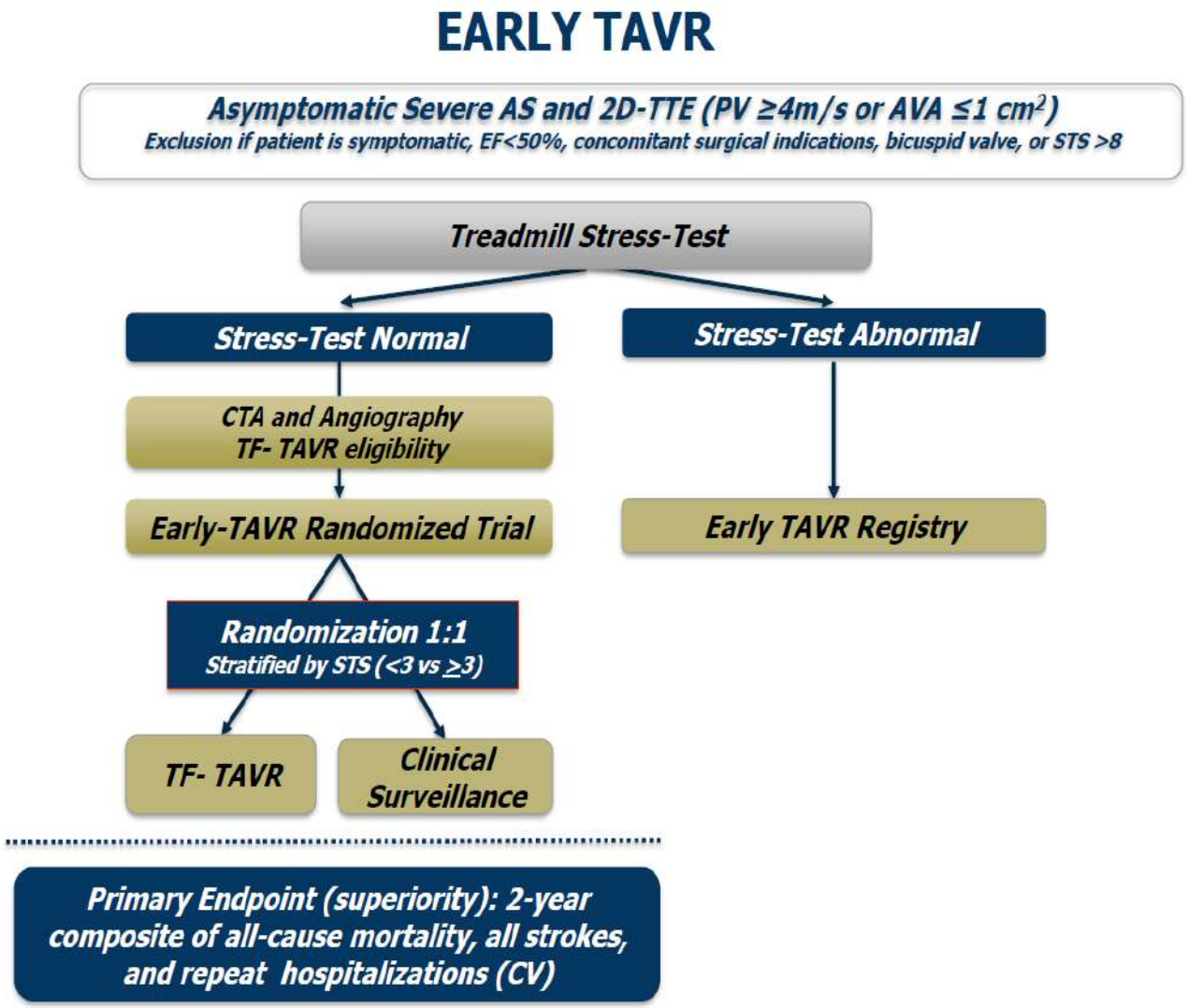
3 Class I indications…6 Class IIa indications…
Level of evidence B or C
No Randomized trial

Repeatedly markedly elevated natriuretic peptide and low surgical risk	-	IIa, C
Severe pulmonary hypertension (>60mmhg) and low surgical risk	-	IIa, C

ACC = American College of Cardiology; AHA = American Heart Association; EACTS = European Association for Cardio-Thoracic Surgery; European ESC = European Society of Cardiology

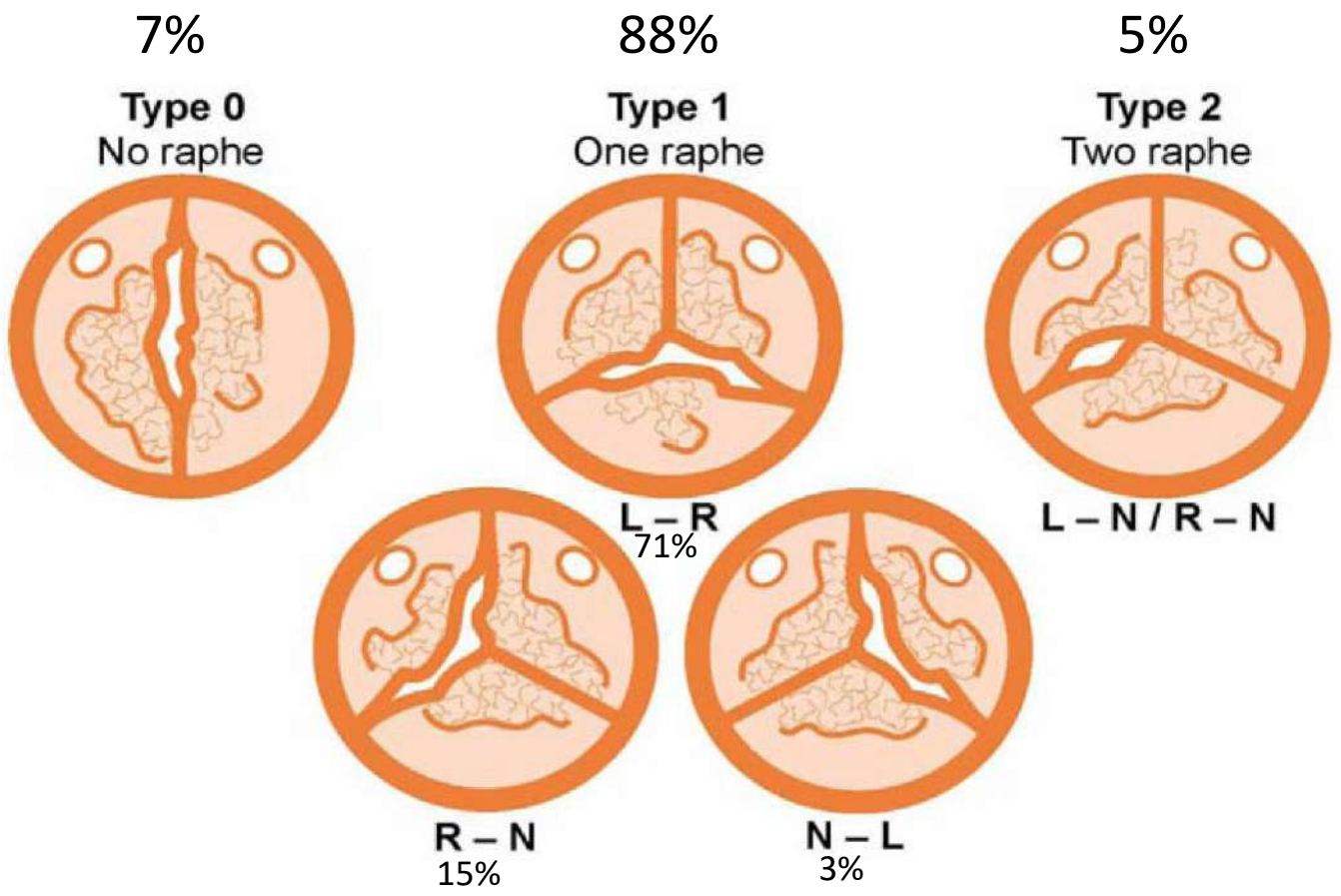
[1]Genereux et al., presented at TCT 2017; [2]Nishimura, et al., K Am Coll Cardiol. 2017 Jul 11;70(2):252-289; [3]Baumgartner et al., Eur Heart J. (2017) 00, 1-53

Asymptomatic Aortic Stenosis: *Early TAVR Trial (ongoing)*



[1]Van Mieghem et al, presented at TCT 2017

Bicuspid aortic valve



Type 0: 2 normally developed cusps, sinuses, and commissures.

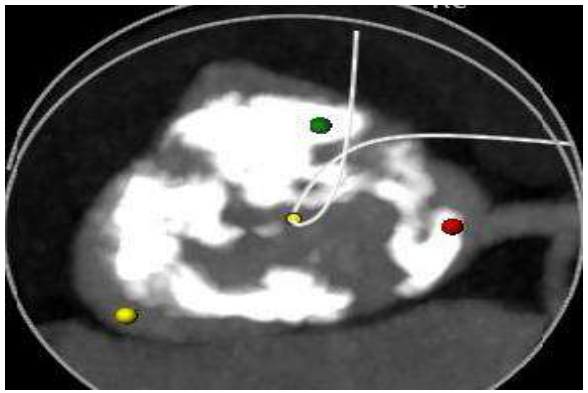
Type 1: 2 underdeveloped and 1 fully developed cusp, 1 underdeveloped and 2 fully developed commissures, and 1 raphe

Type 2: 2 underdeveloped and 1 fully developed cusp, 2 underdeveloped and 1 fully developed commissure, and 2 raphe

[1]Sievers, et al., *J Thorac Cardiovasc Surg* 2007;133:1226-33

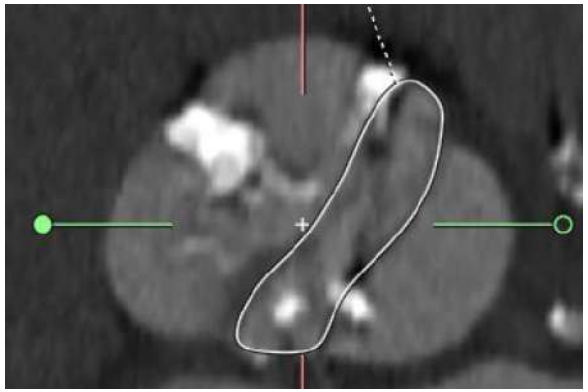
The challenge: Bicuspid TAV Sizing

In addition to the degree of discordance, additional consideration should be given to the following:



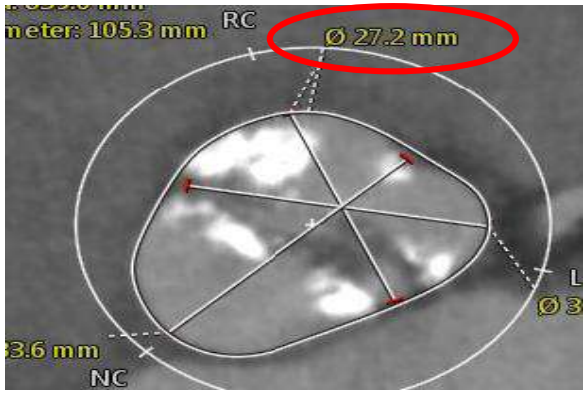
Degree of Calcification

- Will calcium density and location impede TAV frame expansion?



Location and Length of Raphe

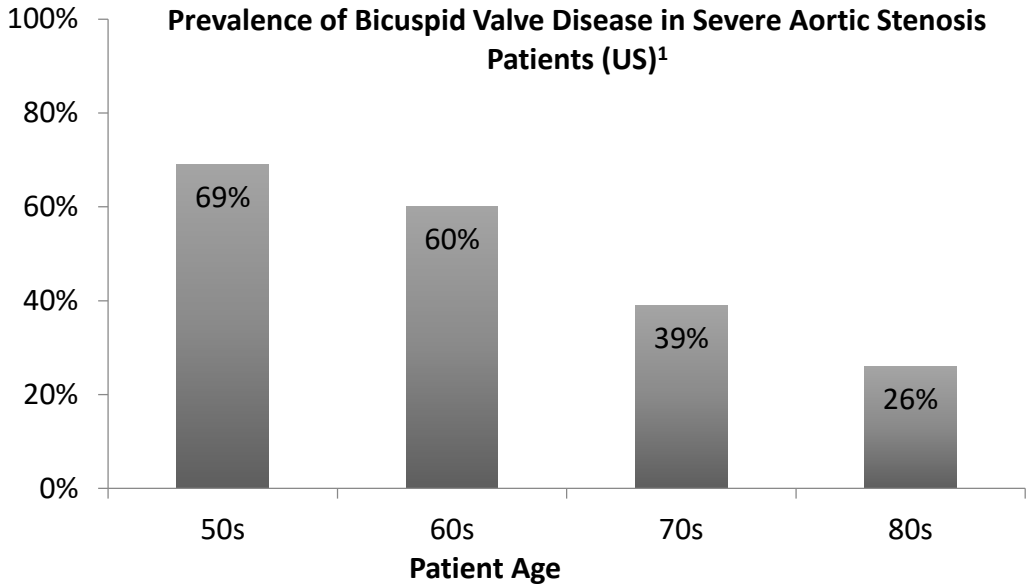
- Does the raphe extend the full length of the commissure?

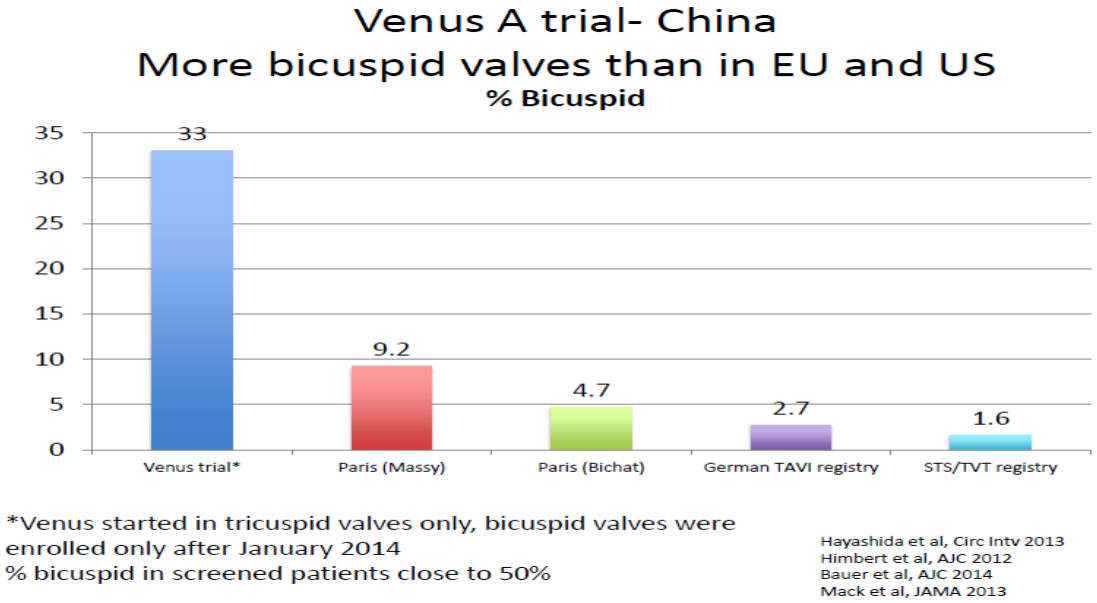


SOV Width and Coronary Height

- Can the SOV width accommodate the TAV size indicated by the annular measurement?
- Is there risk of coronary occlusion due to low coronary arteries?

Prevalence of Bicuspid Valve Disease





*Venus started in tricuspid valves only, bicuspid valves were enrolled only after January 2014
% bicuspid in screened patients close to 50%

Hayashida et al, Circ Intv 2013
Himbert et al, AJC 2012
Bauer et al, AJC 2014
Mack et al, JAMA 2013

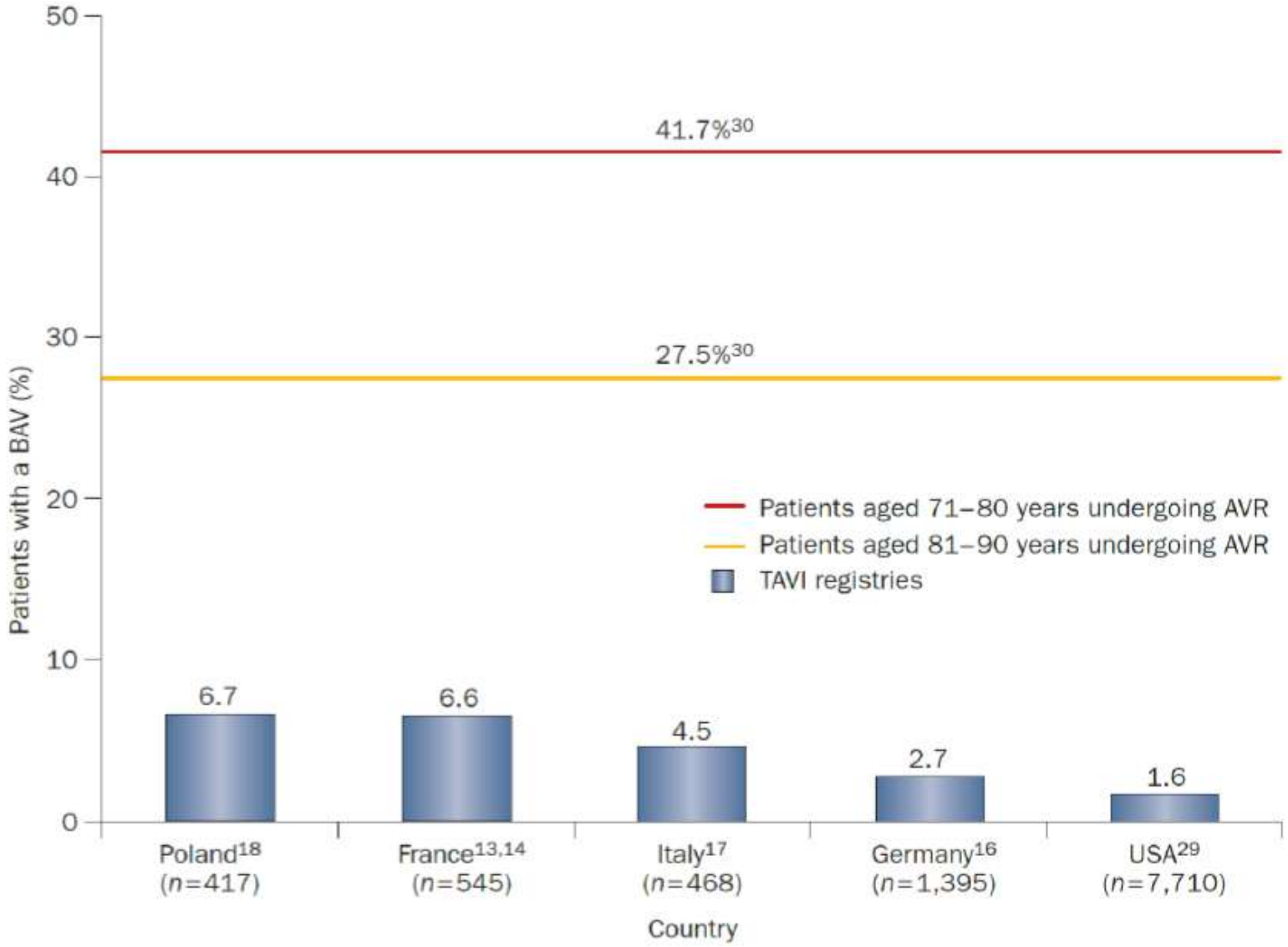
BAV with stenosis or regurgitation is the most common reason for SAVR in patients <70 years of age .

- In the United States, approximately 1 in 5 patients > 80 years undergoing SAVR had BAV[1]
- BAV rates vary according to geography
  - 40% of TAVR patients in China (50% Type 0; 50% Type 1)[2]
  - ~10% of TAVR patients in Japan (Type 0 = 1 – 2%)[3]

[1]Roberts, et al., *Circulation* 2005;111:920-25 [2] Chen, M. EuroPCR, 2016. [3] Wantanbe, 2016.

Bicuspid Aortic Stenosis: TAVI implementation

- TAVI: < 7% of procedures
- SAVR: 42% in 70-80 old
  28% in 80-90 old



[1]Zhao et al, Nature Reviews in Cardiology 2015

Bicuspid Aortic Stenosis

TVT Registry | Self-Expanding TAVI

30-Day Clinical Outcomes

Outcome, No. (%)*	Bicuspid (N=191)	Tricuspid (N=6526)	P
All-cause mortality	4 (2.2)	199 (3.2)	0.49
Stroke	5 (2.6)	220 (3.4)	0.59
Myocardial infarction	0 (0)	22 (0.4)	0.43
Life threatening/major bleeding	16 (8.6)	461 (7.2)	0.45
Major vascular complication	1 (0.5)	102 (1.6)	0.25
Permanent pacemaker	23 (12.6)	1136 (17.8)	0.06
New requirement for dialysis	0 (0)	54 (0.9)	0.21
Aortic valve re-intervention	3 (1.8)	15 (0.2)	<0.01

Popma et al., presented at TCT 2017

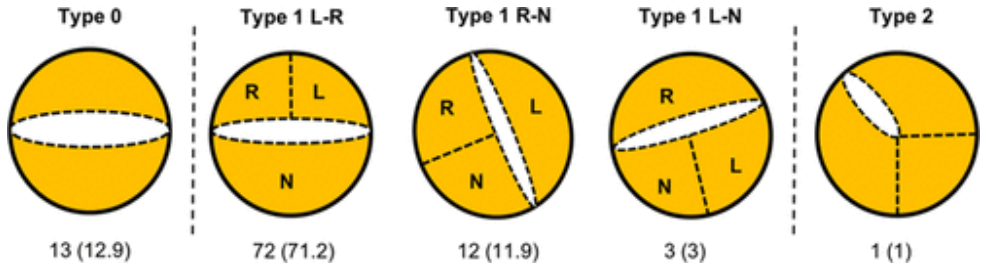
Bicuspid Aortic Stenosis

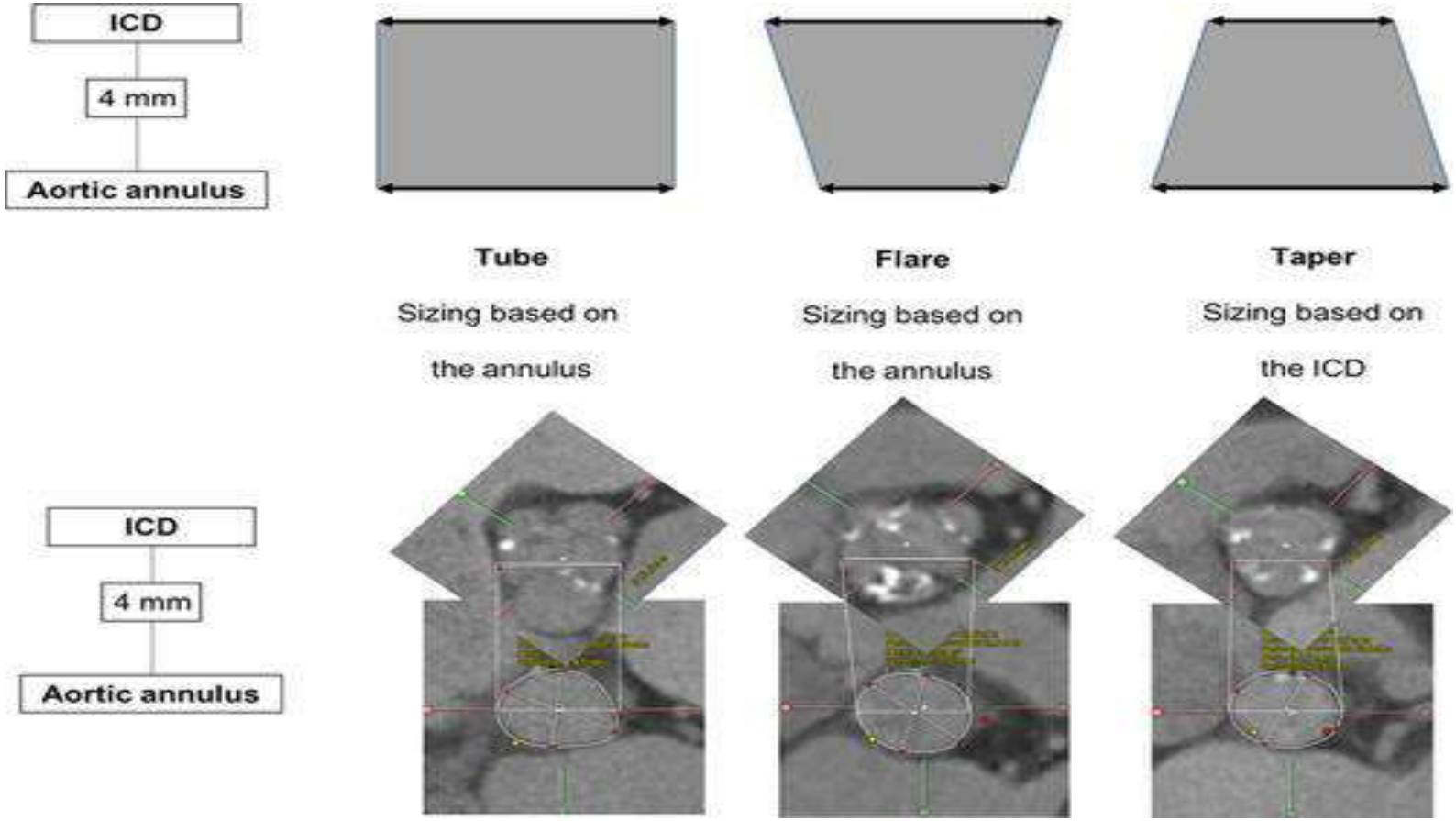
TVT Registry | Comparison of new vs. classic Self-Expanding TAVI

% or mean ± SD	CoreValve (N=319)	Evolut R (N=677)	Evolut PRO (N=236)	CoreValve vs. Evolut R	Evolut R vs. PRO
Procedure time, min	135.5 ± 63.7	117.6 ± 63.1	105.6 ± 55.9	<0.01	<0.01
Length of stay, days	8.1 ± 11.0	5.4 ± 6.6	4.8 ± 6.5	<0.01	0.23
General anesthesia	84.2	63.8	50.6	<0.01	<0.01
Femoral / iliac access	89.0	92.0	91.5	0.12	0.81
Successful device implant	97.2	98.4	98.3	0.21	>0.99
Conversion to open surgery	0.3	0.6	0.8	>0.99	0.65
More than 1 valve used	8.5	2.8	2.1	<0.01	0.57
All-cause mortality	5.4	2.4	3.0	0.01	0.57
Stroke	1.9	3.3	5.6	0.23	0.12
Myocardial infarction	0.3	0.2	0.4	0.58	0.40
Life threatening / major bleeding	7.4	7.1	7.7	0.93	0.77
Major vascular complications	1.9	1.0	1.7	0.27	0.42
Permanent pacemaker	24.7	17.1	11.2	<0.01	0.04
New requirement for dialysis	2.0	1.4	0.0	0.49	0.08
Aortic valve re-intervention	1.7	1.1	0.0	0.46	0.12

Forrest et al., presented at CRT 2019

CT based sizing: the BAVARD study





TAVI in bicuspid valve

Stones in the road? I save every single one, and one day I'll build a castle.

Fernando Pessoa

TAVI pharmacology

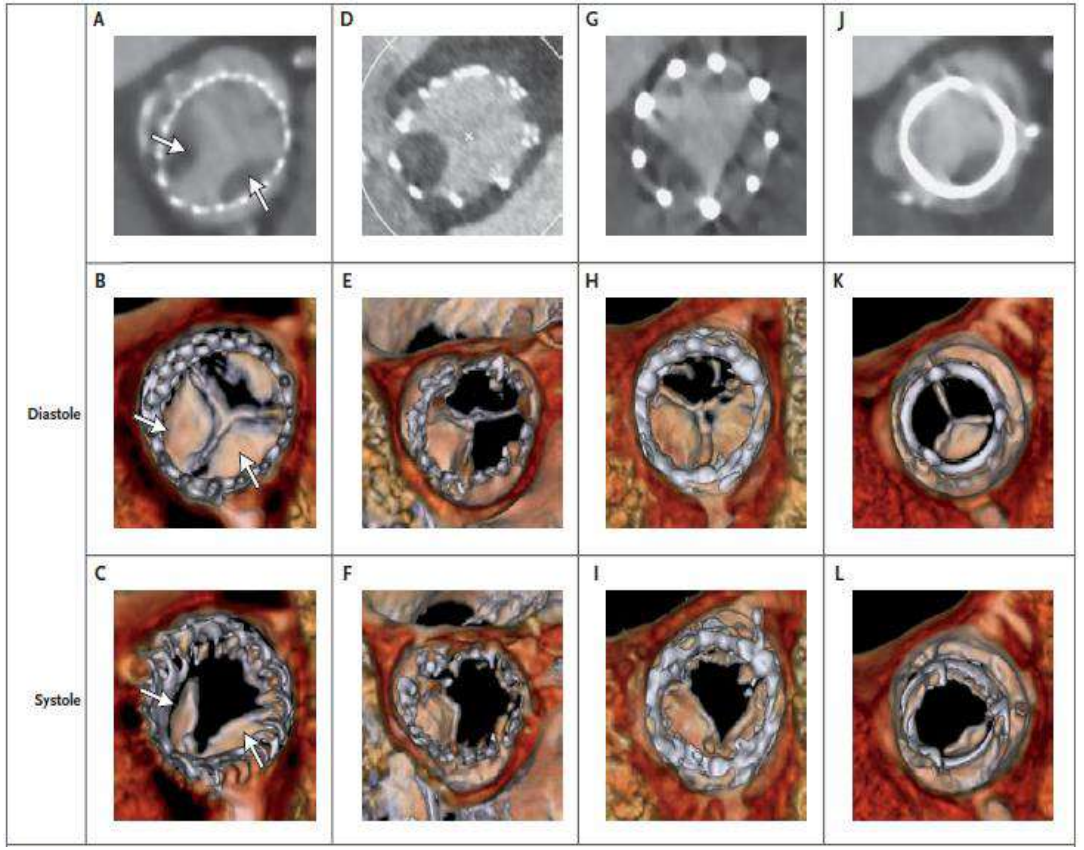
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Possible Subclinical Leaflet Thrombosis in Bioprosthetic Aortic Valves

R.R. Makkar, G. Fontana, H. Jilaihawi, T. Chakravarty, K.F. Kofoed, O. De Backer, F.M. Asch, C.E. Ruiz, N.T. Olsen, A. Trento, J. Friedman, D. Berman, W. Cheng, M. Kashif, V. Jelnin, C.A. Kliger, H. Guo, A.D. Pichard, N.J. Weissman, S. Kapadia, E. Manasse, D.L. Bhatt, M.B. Leon, and L. Søndergaard

ABSTRACT



TAVI pharmacology

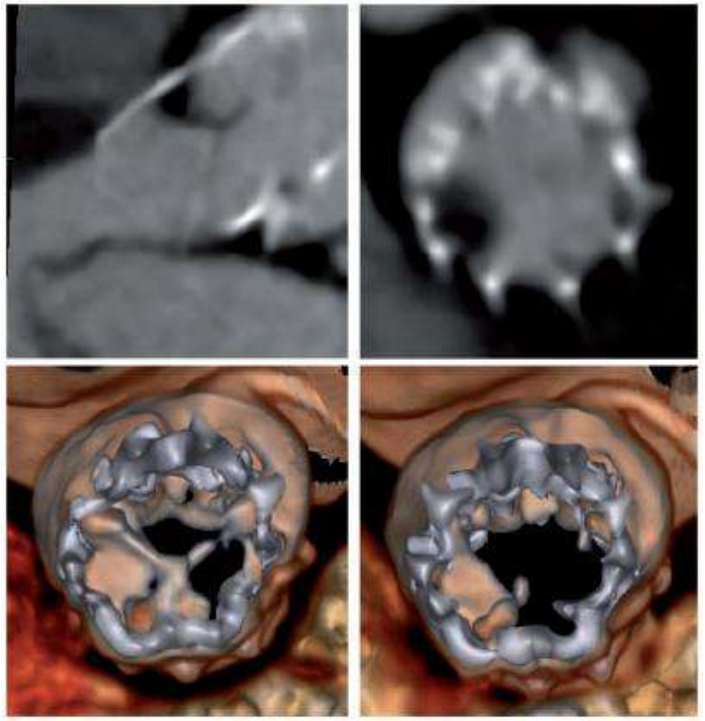
A study in 84 TAVI and SAVR patients found

- Hypo-attenuating leaflet thickening in 38% of patients
- Hypo-attenuation affecting motion in 20% of patients

Table I Evolution pattern of leaflet status between the first and second computed tomography scan

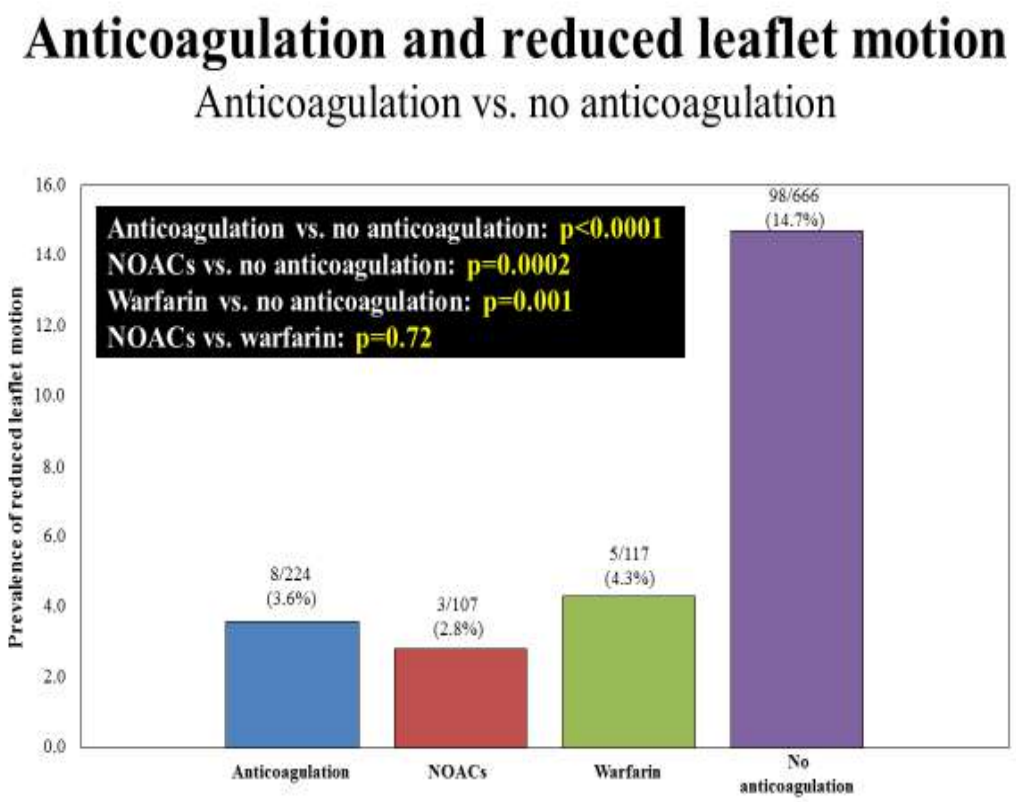
HALT/HAM at first CT	HALT/HAM at second CT			
	HALT− HAM−	HALT+ HAM−	HALT+ HAM+	Total
HALT-HAM-	53	7	4	64
HALT+HAM-	5	3	2	10
HALT+HAM+	2	2	7	11
Total	60	12	13	85

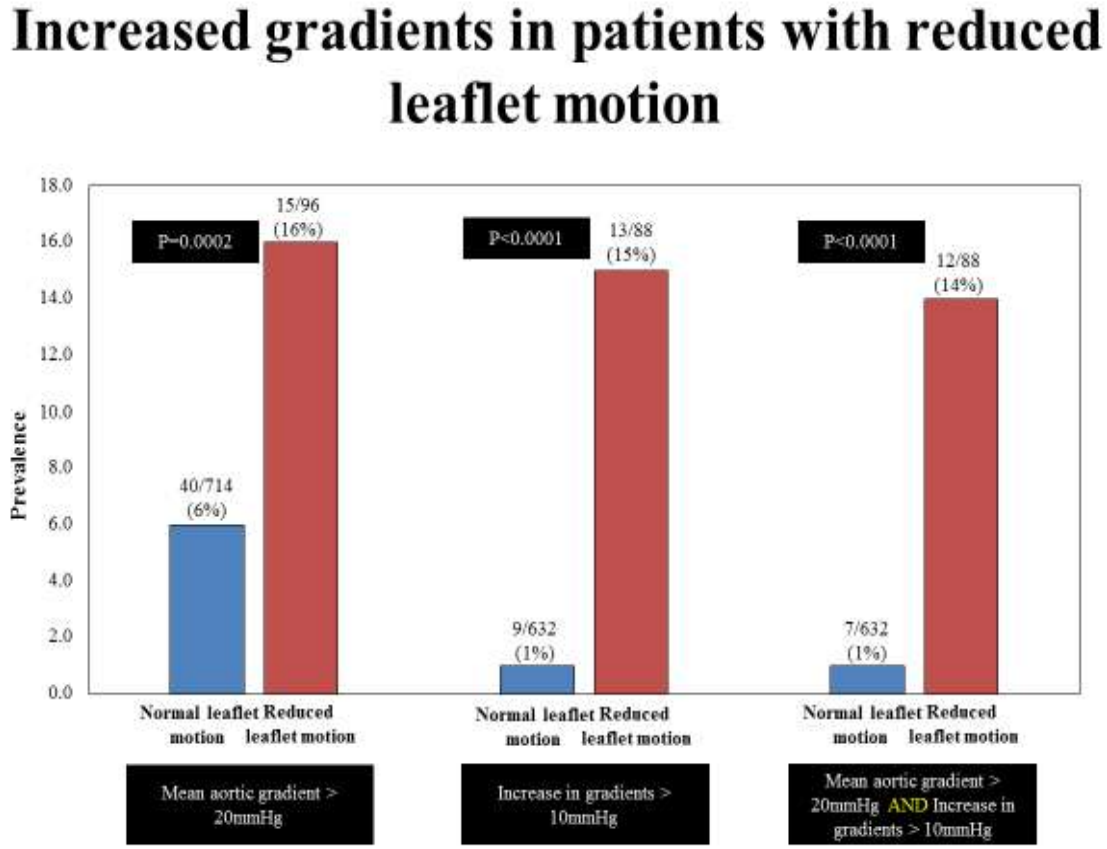
HALT, hypo-attenuating leaflet thickening, HAM, hypo-attenuation affecting motion; Green, regression; orange, progression; CT, computed tomography.



TAVI pharmacology

No anticoagulation and increased gradients have been associated with decreased leaflet motion.

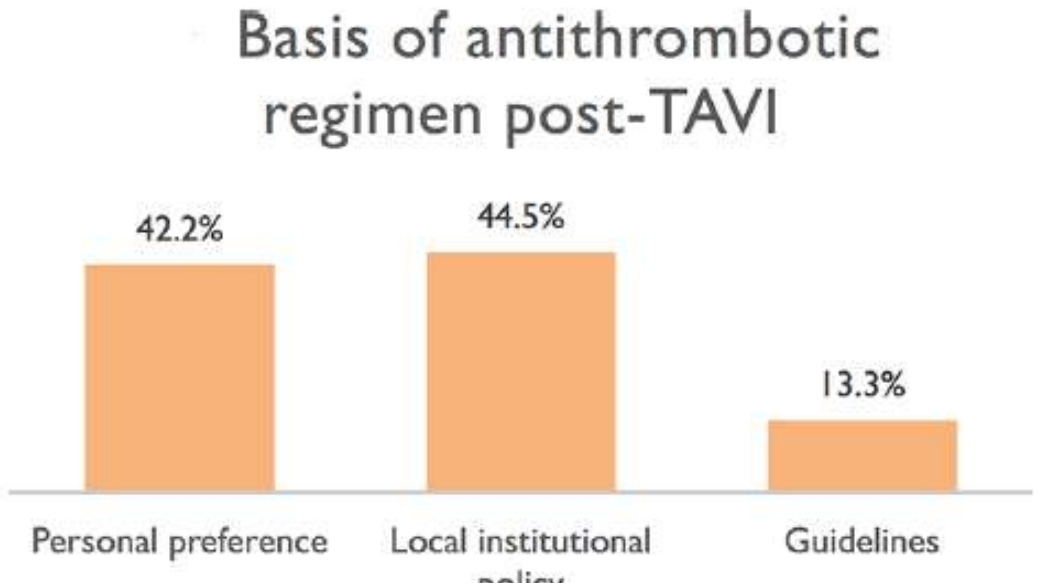


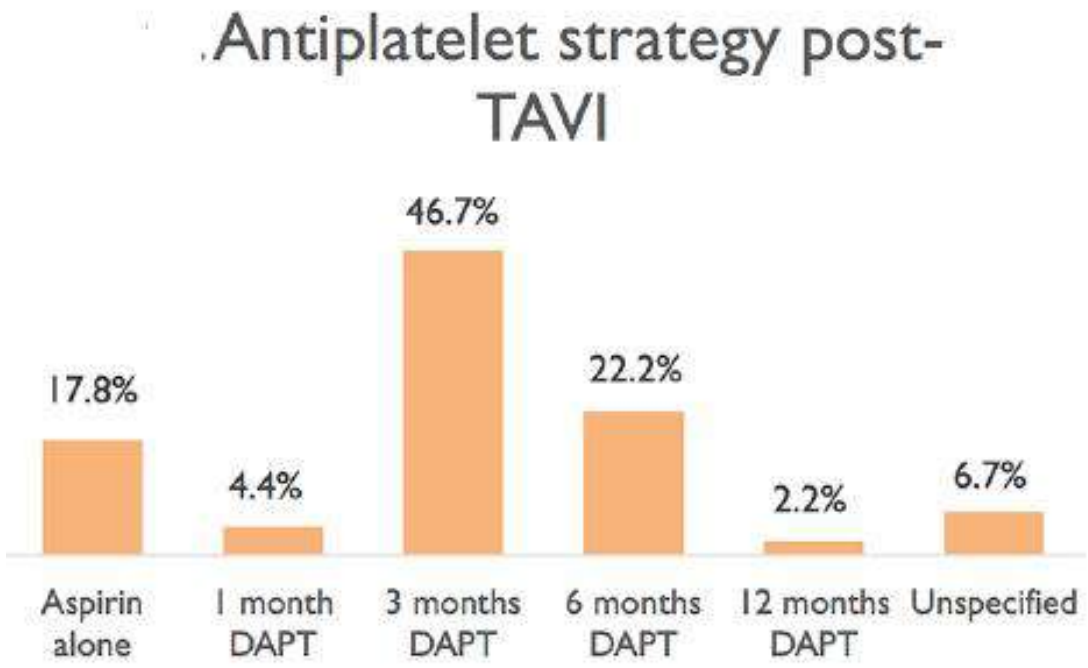


Makkar et al., presented at TCT 2017

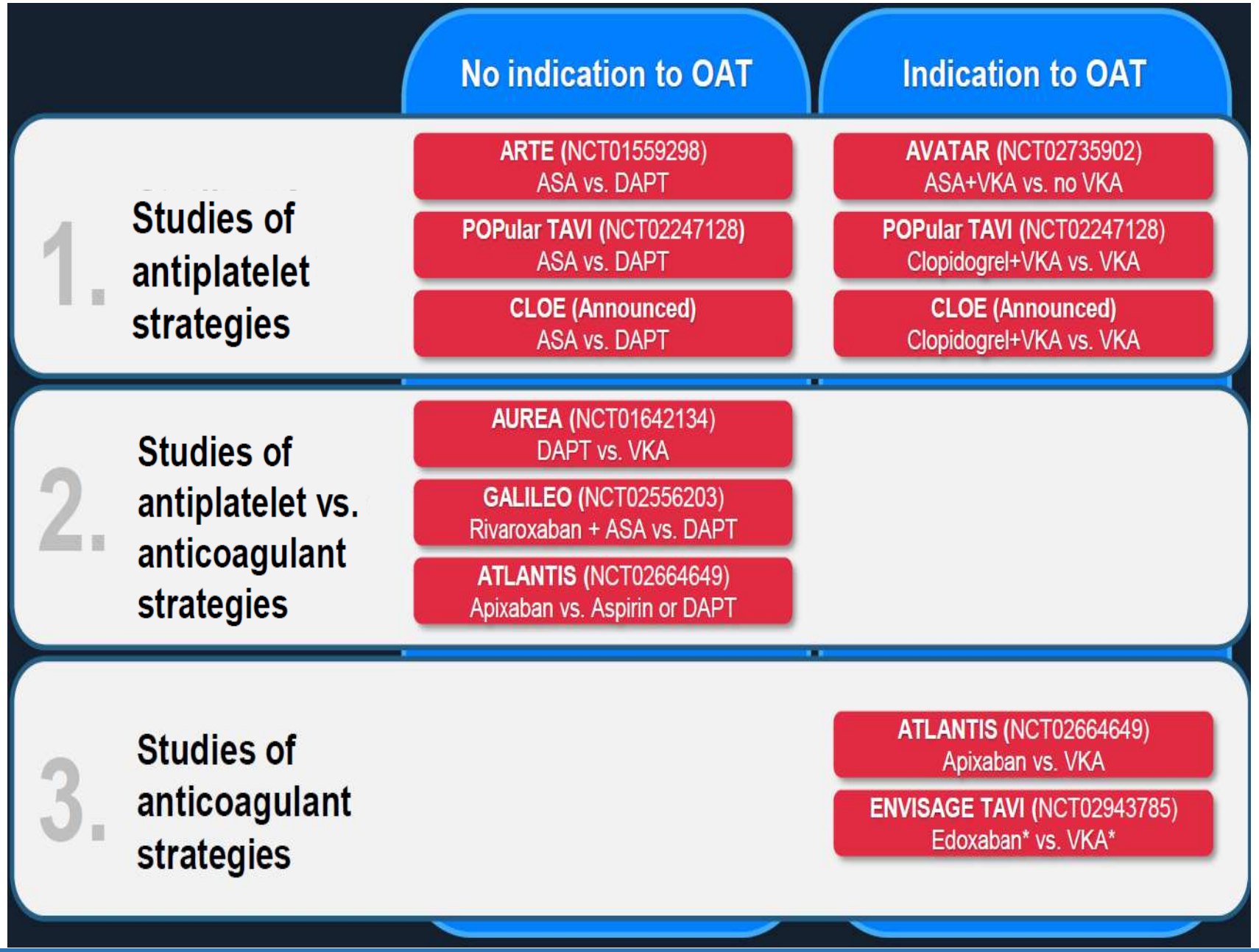
TAVI pharmacology

➢ Oral anticoagulation is recommended lifelong for patients with surgical or transcatheter implanted bioprostheses who have other indications for anticoagulation	I	C
➢ DAPT should be considered for the first 3-6 months after TAVR, followed by lifelong SAPT in patients who do not need OAC for other reasons.	IIa	C
➢ SAPT may be considered after TAVR in the case of high bleeding risk.	IIb	C





TAVI pharmacology



Capodanno, et al., presented at London Valves 2017

TAVI Device Selection - which valve should I take today?

TAVI Device Selection

- Sapien 3/S3 Ultra
- Evolut R/PRO

Current Industry Standard

- Lotus/Lotus Edge
- Acurate Neo
- Portico

Next in Line/Increasing Clinical Use

- Direct Flow
- Engager
- Centera

May they Rest in Peace..

- Jena Valve
- Venus A Valve

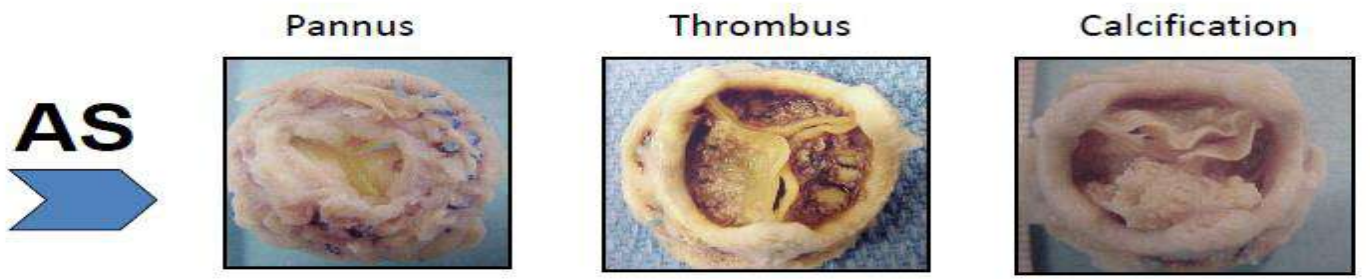
Rebooting and/or Increasing Momentum

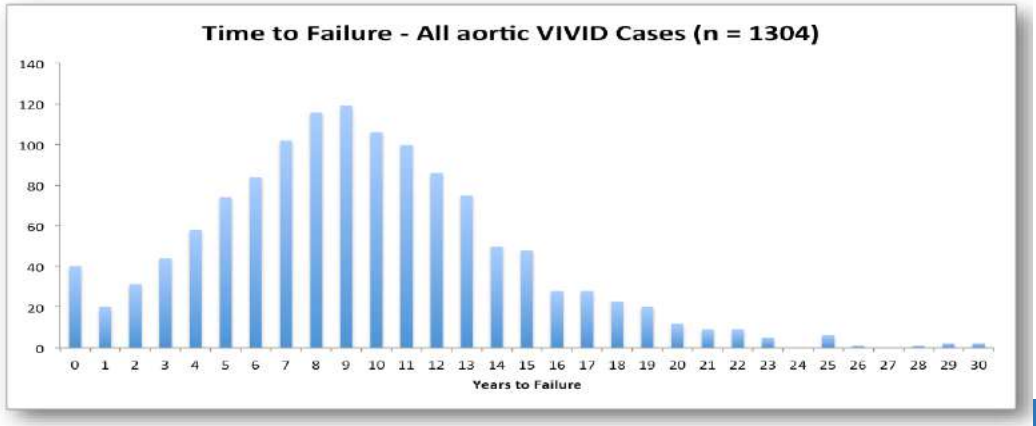
All of the Rest!

- J-Valve
- VitaFlow
- Taurus One
- Trinity
- Colibri
- Inovare
- Thubrikar
- Valve Medical
- Triskele
- BioValve
- MyVal
- HLT Meridian
- NVT
- Xeltis
- Zurich TEHV

Expansion of technology to lower risk population → shifting the focus from mortality and morbidity to durability and performance

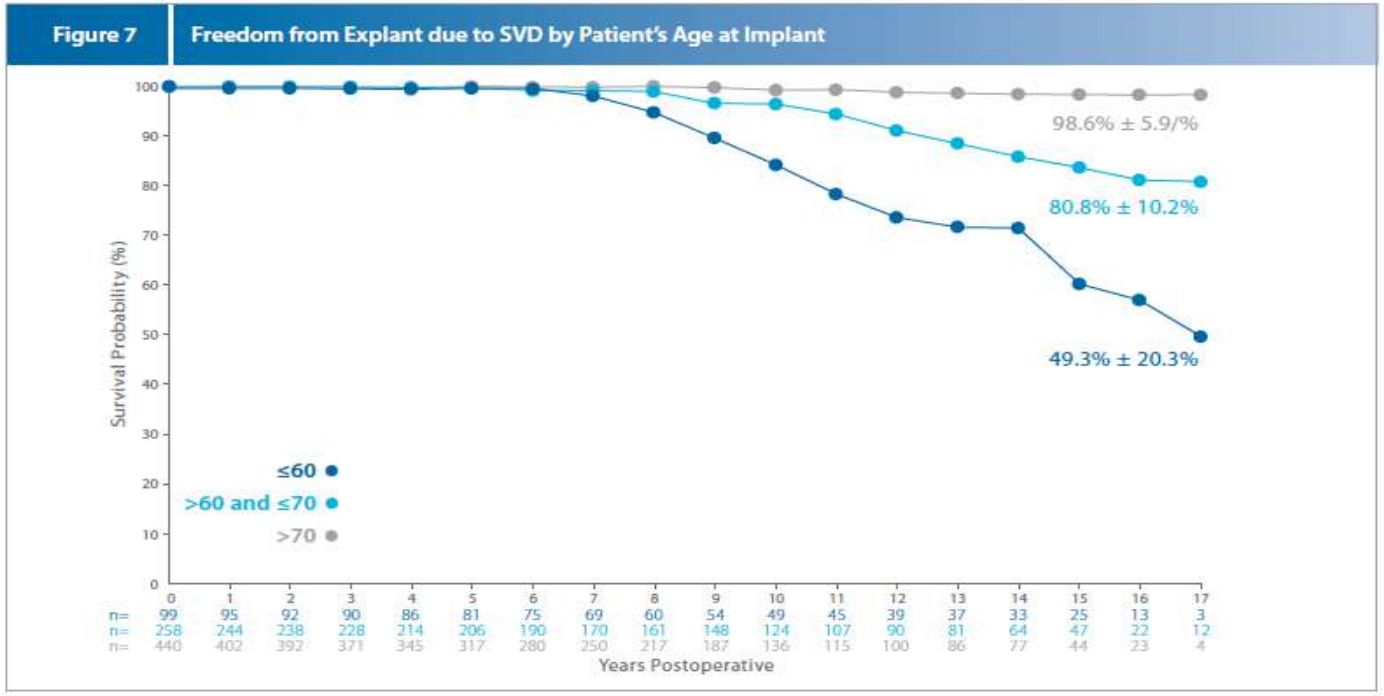
Bioprosthetic valve failure

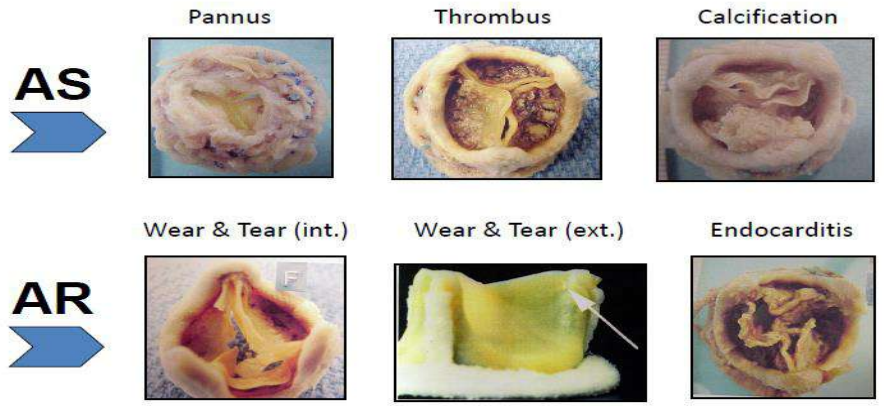




Bioprosthesis Durability

Bioprosthesis durability is age dependent with the risk of failure decreasing with increasing patient age.[1] Durability may vary by valve model with fewer than 10% of patients ≥ 65 years requiring reoperation at 15 years.[2]

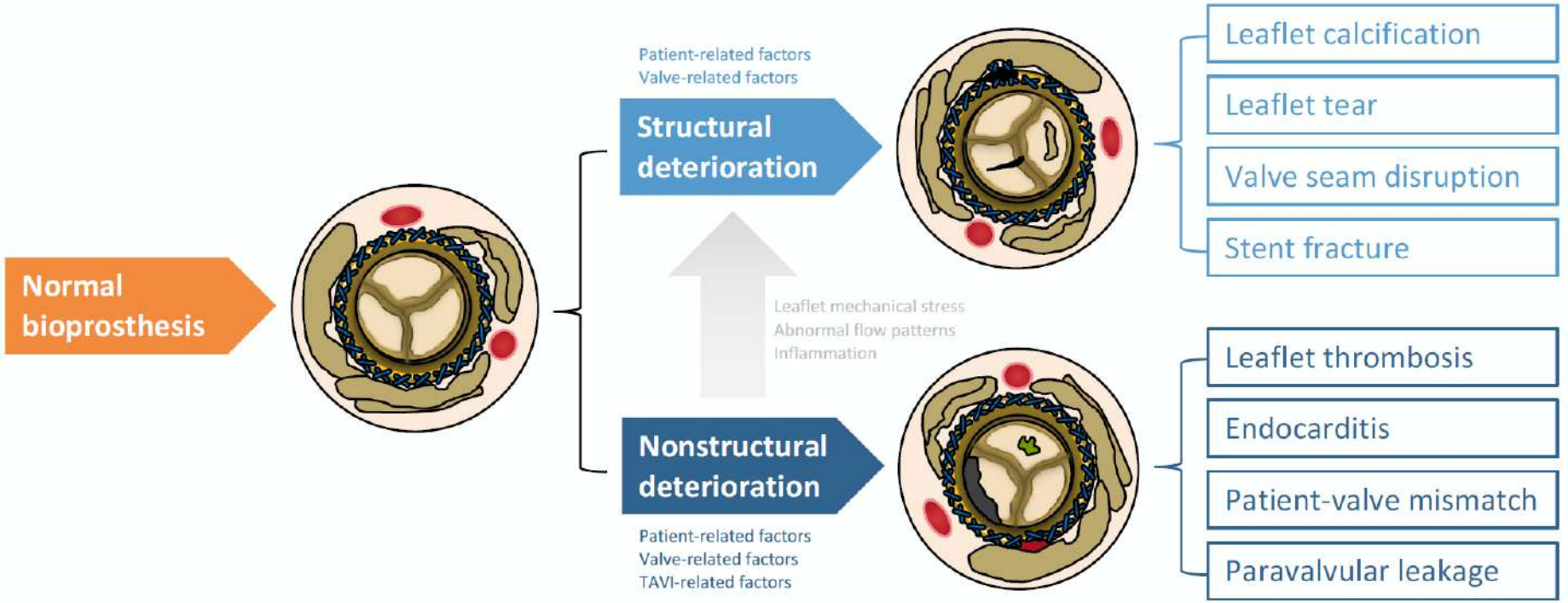




An example of contemporary aortic valve durability by age group[3]

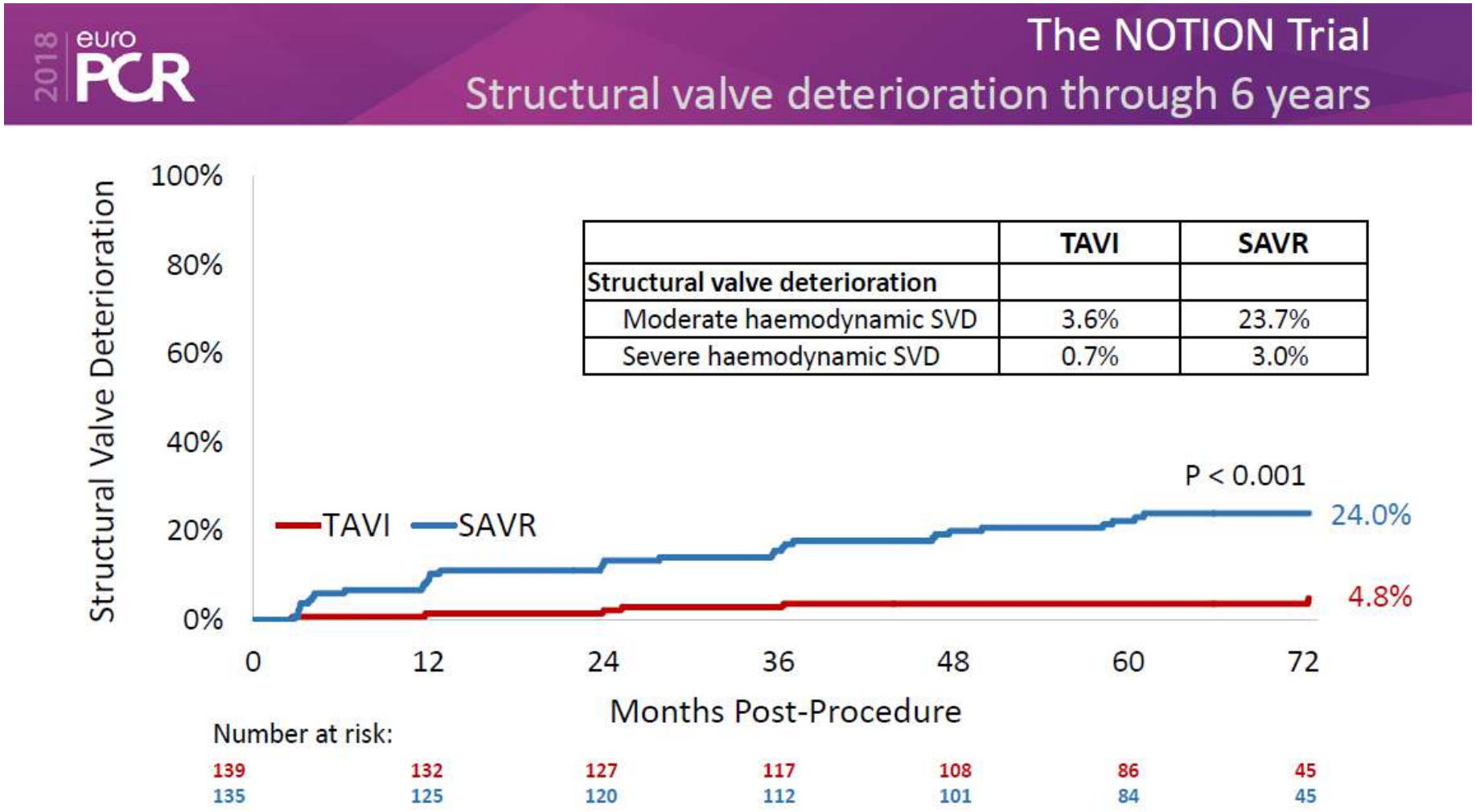
1. *Rahimtoola S. Choice of Prosthetic Heart Valve In Adults An Update. J Am Coll Caridiol 2010;55:2413-26.*
2. *Bonow R, Carabello B, Chatterjee K, et al. ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease J Am Coll Cardiol 2006;48:1-148.*
3. *Mosaic® Aortic Bioprosthesis. Medtronic, Inc. 2014 UC201503587EN*

Mechanisms of prosthetic valve deterioration



Adapted from Bagur R, et al. Heart 2017;103:1756–9

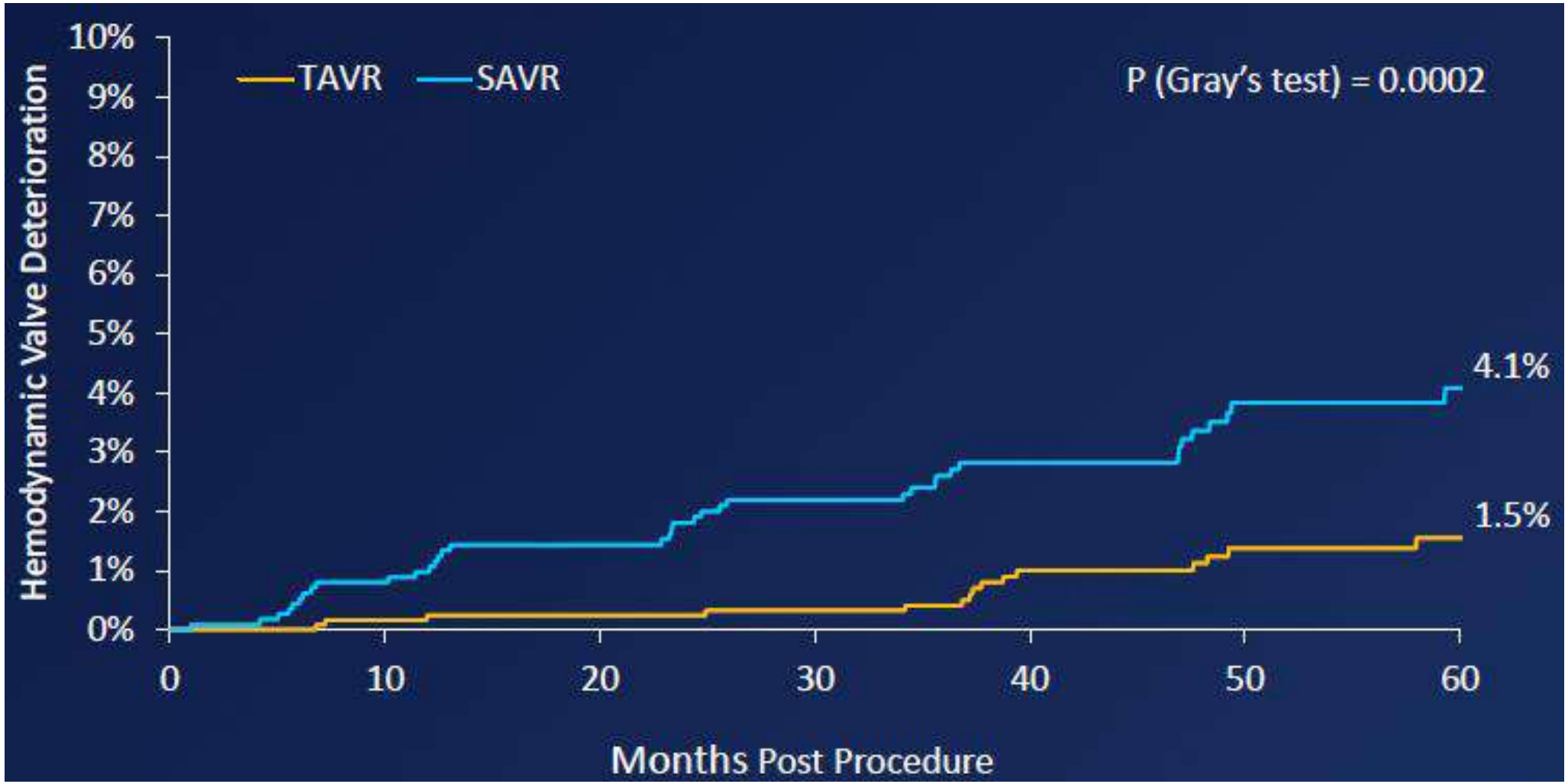
Durability: Notion



	TAVI	SAVR
Structural valve deterioration		
Moderate haemodynamic SVD	3.6%	23.7%
Severe haemodynamic SVD	0.7%	3.0%

[1]Sondergaard et all., presented at EuroPCR 2018; [2]Petrossian et al., presented at ACC 2018

Durability: Corevalve Pivotal Trials



O'Hair, et al. presented at TCT 2019

Durability: CHOICE trial comparing Sapien and Corevalve

	Balloon-expandable valve (n=121)	Self-expanding valve (n=120)	p-value
Bioprosthetic valve dysfunction	28 (22.5%)	26 (20.9%)	0.91
Components			
Structural valve deterioration	6 (6.6%)	0 (0%)	0.018
Moderate SVD	4 (5.6%)	0 (0%)	0.047
Severe SVD	2 (0.9%)	0 (0%)	0.20
NSVD	17 (17.8%)	23 (26.7%)	0.20
Moderate/severe PPM	14 (15.9%)	13 (16.0%)	1.0
Moderate/severe PVL	3 (2.5%)	10 (8.5%)	0.08
Valve thrombosis	6 (7.3%)	1 (0.8%)	0.06
Endocarditis	2 (1.6%)	4 (3.4%)	0.39

Abdel-Wahab et al., presented at EuroPCR 2019

The Problem of Valve Prosthesis-Patient Mismatch

SHAHBUDIN H. RAHIMTOOLA, M.D.

SUMMARY Valve prostheses have played an important part in the past two decades in the management of patients with valvular heart disease. However, many of the devices used in valve replacement have introduced new clinical problems. This paper deals with some of the problems associated with valve replacement, including one not previously emphasized — valve prosthesis-patient mismatch, which may cause obstruction to ventricular outflow and/or inflow.

clinical medicine, so that in effect, the patient is exchanging one disease process for another. Many com-

broadened.[37] Mismatch can be considered to be present when the effective prosthetic valve area, after insertion into the patient, is less than that of a normal human valve. The reduced prosthetic valve area is

SEVERITY OF PPM

DEFINITION IN THE AORTIC VALVE POSITION

Indexed EOA (cm^2/m^2)	0.65	0.85
EOA_i in obese (cm^2/m^2)	0.6	0.7

Kappetein, A. Pieter, et al. *European heart journal* 33.19 (2012): 2403-2418.

European Heart Journal (2012) 33, 1518–1529
doi:10.1093/eurheartj/ehs003

CLINICAL RESEARCH
Cardiac surgery

The impact of prosthesis–patient mismatch on long-term survival after aortic valve replacement: a systematic review and meta-analysis of 34 observational studies comprising 27 186 patients with 133 141 patient-years

Stuart J. Head[1]*, Mostafa M. Mokhles[1], Ruben L.J. Osnabrugge[1,2], Philippe Pibarot[3], Michael J. Mack[4], Johanna J.M. Takkenberg[1], Ad J.J.C. Bogers[1], and Arie Pieter Kappetein[1]

Conclusion: Prosthesis–patient mismatch is associated with an increase in all-cause and cardiac-related mortality over long-term follow-up. We recommend that current efforts to prevent PPM should receive more emphasis and a widespread acceptance to improve long-term survival after AVR.

PPM is associated with mortality

Prosthesis–Patient Mismatch in Patients Undergoing Transcatheter Aortic Valve Replacement

From the STS/ACC TVT Registry

Howard C. Herrmann, MD,[1] Samuel A. Daneshvar, MD,[2] Gregg C. Fonarow, MD,[3] Amanda Stebbins, MPH,[4] Sreekanth Vemulapalli, MD,[5] Nimesh D. Desai, MD,[6] David J. Malenka, MD,[7] Vinod H. Thourani, MD,[8] Jennifer Rymer, MD,[1] Andrzej S. Kosinski, PhD[4]

ABSTRACT

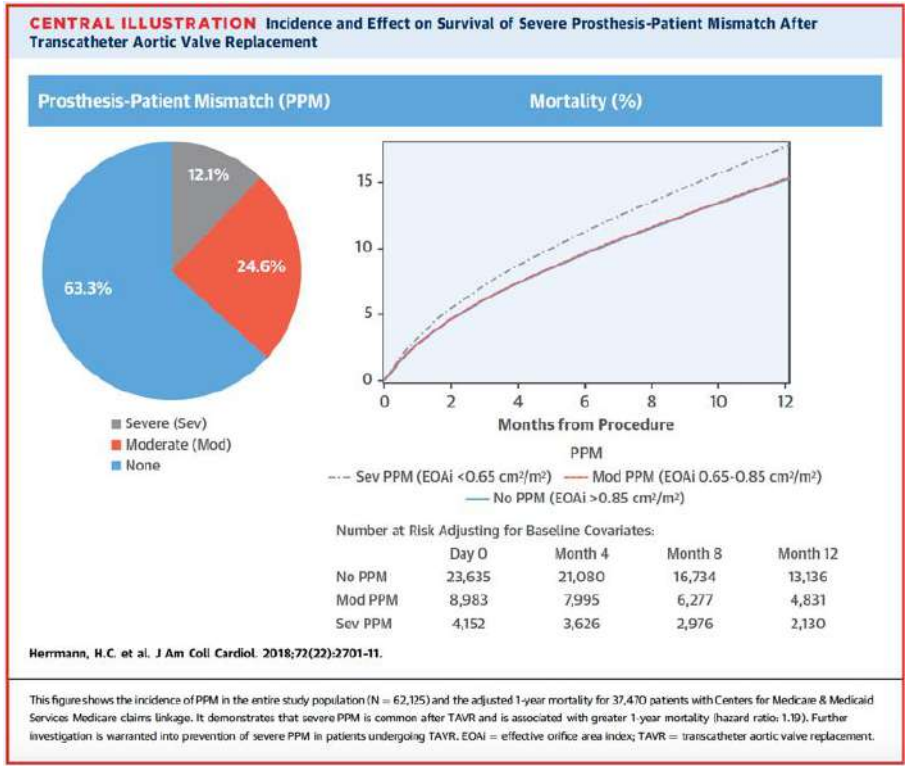
BACKGROUND Prosthesis-patient mismatch (PPM) after surgical aortic valve replacement (AVR) for aortic stenosis is generally associated with worse outcomes. Transcatheter AVR (TAVR) can achieve a larger valve orifice and the effects of PPM after TAVR are less well studied.

OBJECTIVES The authors utilized the Society of Thoracic Surgeons/American College of Cardiology TVT (Transcatheter Valve Therapy) registry to examine the frequency, predictors, and association with outcomes of PPM after TAVR in 62,125 patients enrolled between 2014 and 2017.

METHODS On the basis of the discharge echocardiographic effective valve area indexed to body surface area, PPM was classified as severe (<0.65 cm^2/m^2), moderate (0.65 to 0.85 cm^2/m^2), or none (>0.85 cm^2/m^2). Multivariable regression models were utilized to examine predictors of severe PPM as well as adjusted outcomes, including mortality, heart failure (HF) rehospitalization, stroke, and quality of life, at 1 year in 37,470 Medicare patients with claims linkage.

RESULTS Severe and moderate PPM were present following TAVR in 12% and 25% of patients, respectively. Predictors of severe PPM included small (≈23-mm diameter) valve prosthesis, valve-in-valve procedure, larger body surface area, female sex, younger age, non-white/Hispanic race, lower ejection fraction, atrial fibrillation, and severe mitral or tricuspid regurgitation. At 1 year, mortality was 17.2%, 15.6%, and 15.9% in severe, moderate, and no PPM patients, respectively ($p = 0.02$). HF rehospitalization had occurred in 14.7%, 12.8%, and 11.9% of patients with severe, moderate, and no PPM, respectively ($p < 0.0001$). There was no association of severe PPM with stroke or quality-of life score at 1 year.

CONCLUSIONS Severe PPM after TAVR was present in 12% of patients and was associated with higher mortality and HF rehospitalization at 1 year. Further investigation is warranted into the prevention of severe PPM in patients undergoing TAVR. (J Am Coll Cardiol 2018;72:2701-11) © 2018 by the American College of Cardiology Foundation.



Herrmann HC, J Am Coll Cardiol. 2018 Dec 4;72(22):2701-2711

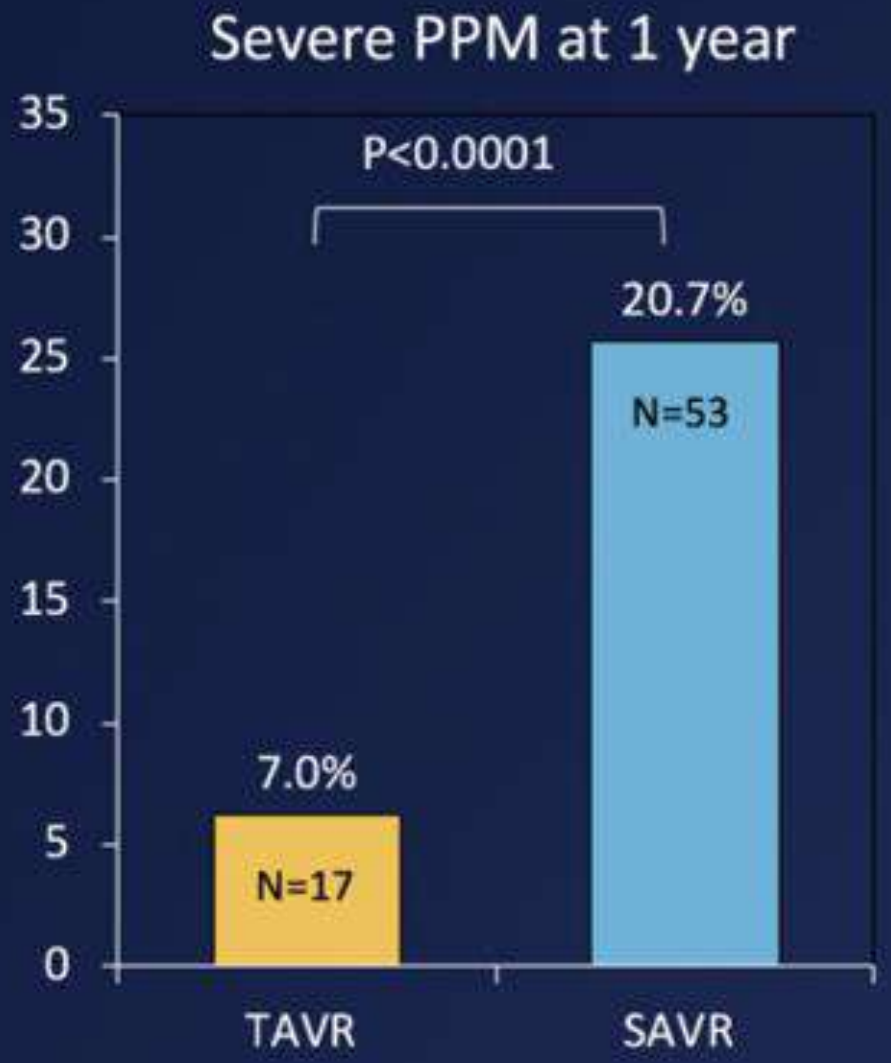
PPM predicts SVD

Table 3. Single-Predictor Analysis of Late Survival (Cox) and SVD (Cox With Multiple Imputation Method)

	Late Survival			SVD		
	Hazard Ratio	95% CI	*P*	Hazard Ratio	95% CI	*P*
Age, y	1.05	1.02–1.09	0.0004	1.00	0.94–1.07	0.99
Female gender	0.99	0.77–1.28	0.98	2.05	1.07–3.93	0.03
Body surface area	0.96	0.48–1.91	0.91	0.11	0.02–0.60	0.01
NYHA class	1.22	0.99–1.50	0.07	3.70	0.38–35.97	0.44
Ejection fraction	0.99	0.97–1.01	0.08	1.02	0.99–1.05	0.31
AS	0.96	0.52–1.76	0.88	0.76	0.18–3.22	0.71
AI	1.08	0.96–1.21	0.22	1.04	0.76–1.43	0.79
Rhythm (SR/non-SR)	1.24	0.97–1.49	0.06	1.09	0.26–4.62	0.90
Concomitant CABG	1.31	1.02–1.70	0.03	0.87	0.47–1.64	0.67
Design (stented/stentless)	1.14	0.87–1.49	0.32	1.51	0.78–2.91	0.22
Size ≤21	1.41	1.08–1.84	0.01	2.93	1.57–5.46	0.0007
Tissue (porcine aortic/pericardial)	0.94	0.72–1.23	0.66	0.69	0.37–1.29	0.24
Anticalcification treatment	0.81	0.62–1.06	0.13	0.49	0.25–0.94	0.03
EOA index	0.98	0.95–1.02	0.42	0.07	0.01–0.62	0.02
Discharge peak gradient	0.99	0.98–1.01	0.52	1.02	0.98–1.05	0.39
P-PtM	1.15	0.89–1.50	0.30	2.54	1.30–4.95	0.006

CI indicates confidence interval; NYHA, New York Heart Association; AS, aortic stenosis or mixed aortic valve disease; AI, pure aortic insufficiency; SR, sinus rhythm; and CABG, coronary artery bypass grafting.

Prosthesis-Patient Mismatch

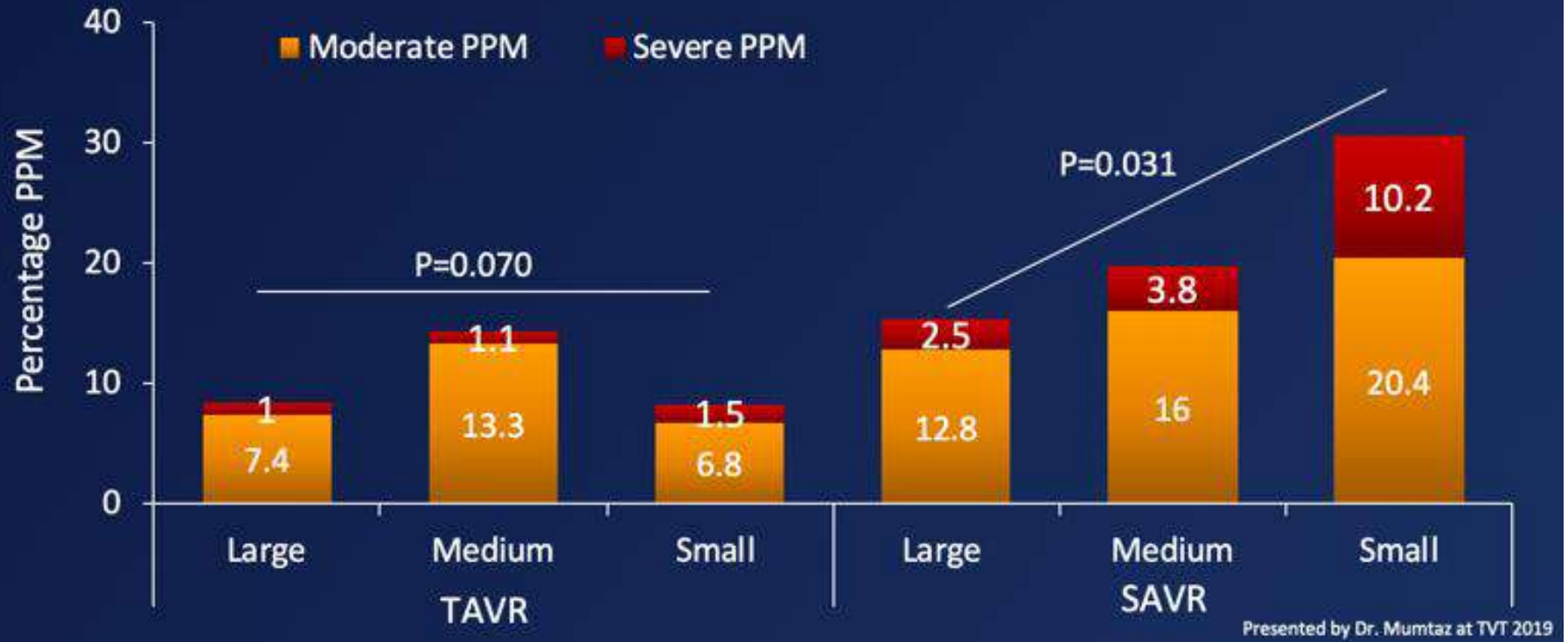


- Severe PPM occurs significantly more after SAVR than TAVR
  - At 1 month rates are 7.0% for TAVR and 20.7% for SAVR (P<0.001)
- Moderate PPM occurred in 20.8% of TAVR and 30.6% of SAVR patients at 1 year

Low Risk

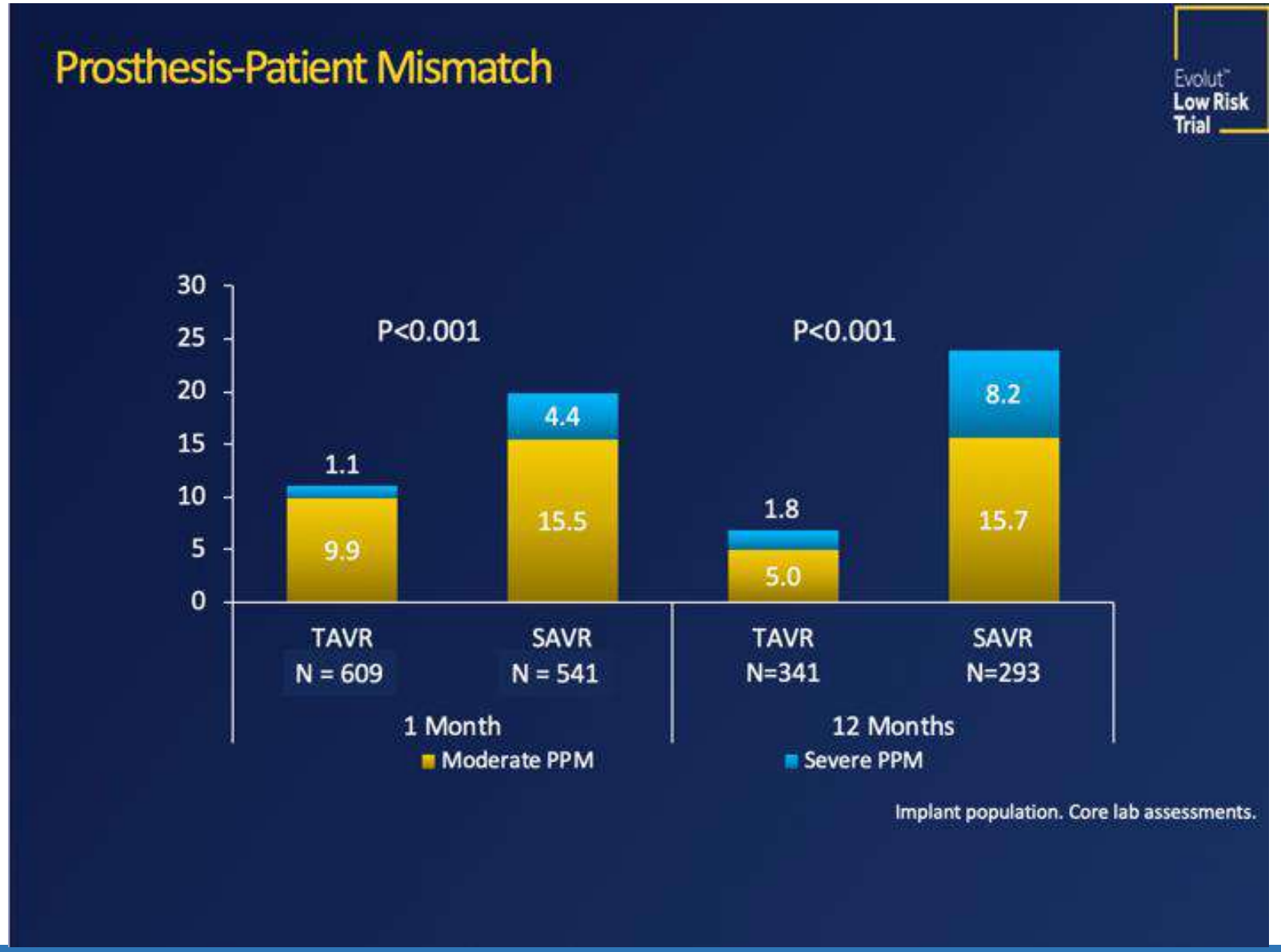
Hemodynamics

30-day PPM by Annular Size



Presented by Dr. Mumtaz at TVT 2019

Evolut Low Risk PPM



Ann Thorac Surg. 2015 April ; 99(4): 1239–1247. doi:10.1016/j.athoracsur.2014.10.070.

Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, **Edward G. Soltesz, MD**, **Nakul Vakil, MD**, **Jeevanantham Rajeswaran, PhD**, **Eric E. Roselli, MD**, **Joseph F. Sabik III, MD**, **Nicholas G. Smedira, MD**, **Lars G. Svensson, MD, PhD**, **Bruce W. Lytle, MD**, and **Eugene H. Blackstone, MD**
Department of Thoracic and Cardiovascular Surgery, Heart and Vascular Institute, and Department of Quantitative Health Sciences, Research Institute, Cleveland Clinic, Cleveland, Ohio

We found that gradients increased slowly with time for the whole patient group, consistent with previous studies [22]. Of particular importance, however, is that for patients with the highest initial gradients early after AVR, risk of explant for SVD rose exponentially faster.

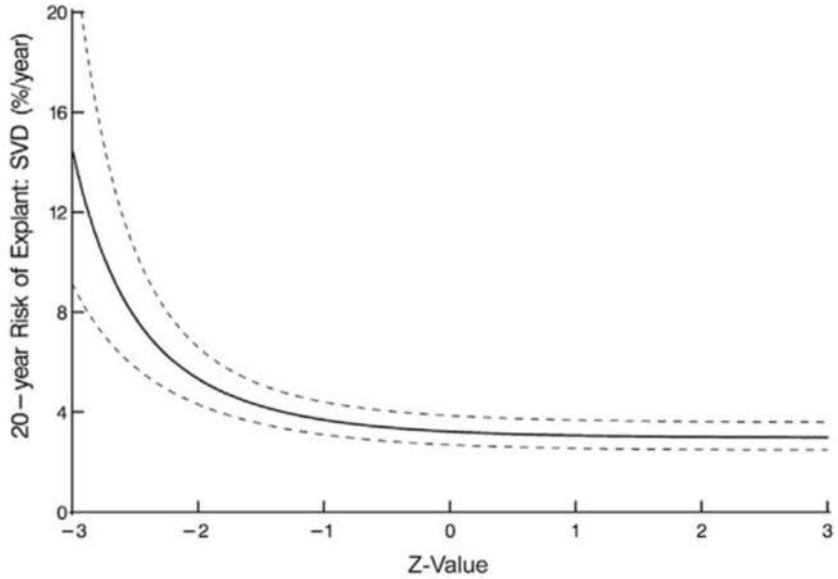


Fig 4.
Structural valve deterioration (SVD) at 20 years and prosthesis–patient mismatch, represented by the number of standard deviations the geometric size of the aortic prosthesis deviates from normal. Nomogram is based on preoperative variables alone.

Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function

Rebecca T. Hahn, MD,[a] Jonathon Leipsic, MD,[b] Pamela S. Douglas, MD,[c] Wael A. Jaber, MD,[d] Neil J. Weissman, MD,[e] Philippe Pibarot, DVM, PhD,[f] Philipp Blanke, MD,[b] Jae K. Oh, MD[g]

METHODS We collected the Echocardiography Core Lab measured mean gradients and effective orifice area (EOA) from discharge or 30-day echocardiograms from randomized trials; the PARTNER (Placement of Aortic Transcatheter Valves) trials for the balloon-expandable valves and the Medtronic CoreValve US Pivotal trial and Medtronic CoreValve Evolut R United States IDE Clinical Study for the self-expanding valves.

RESULTS For all SAPIEN (Edwards Lifesciences, Irvine, California) valve sizes, mean EOA = 1.70 ± 0.49 cm^2 with mean gradient of 9.36 ± 4.13 mm Hg. For all SAPIEN XT valve sizes, mean EOA = 1.67 ± 0.46 cm^2 with mean gradient of 9.52 ± 3.64 mm Hg. For all SAPIEN 3 valve sizes, the mean EOA = 1.66 ± 0.38 cm^2 with mean gradient of 11.18 ± 4.35 mm Hg. For all CoreValve valve sizes, the mean EOA = 1.88 ± 0.56 cm^2 with mean gradient of 8.85 ± 4.14 mm Hg. For all Evolut R valve sizes, the mean EOA = 2.01 ± 0.65 cm^2 with mean gradient of 7.52 ± 3.19 mm Hg. The SAPIEN 3 post-implant EOA was progressively larger for each quintile of baseline annular area by computed tomography ($p < 0.001$). Similarly, for the Evolut R valve, post-implantation EOA was significantly larger for each quintile of baseline annular perimeter ($p < 0.001$).

Balloon Expandable: Sapien family

TABLE 2 Mean Gradient and EOA for Balloon-Expandable SAPIEN Valves

Valve Iteration	Prosthetic Valve Size, mm					
	20	23	26	29	All Sizes	p Value
SAPIEN						
EOA, cm^2	NA	1.56 ± 0.43 (1,212)	1.84 ± 0.52 (1,130)	NA	1.70 ± 0.49 (2,342)	<0.001
Mean gradient, mm Hg	NA	9.92 ± 4.27 (1,212)	8.76 ± 3.89 (1,130)	NA	9.36 ± 4.13 (2,342)	<0.001
DVI	NA	0.53 ± 0.13 (1,212)	0.53 ± 0.13 (1,130)	NA	0.53 ± 0.13 (2,342)	0.64
SAPIEN XT						
EOA, cm^2	NA	1.41 ± 0.30 (545)	1.74 ± 0.42 (675)	2.06 ± 0.52 (251)	1.67 ± 0.46 (1471)	<0.001
Mean gradient, mm Hg	NA	10.41 ± 3.74 (545)	9.24 ± 3.57 (675)	8.36 ± 3.14 (251)	9.52 ± 3.64 (1,471)	<0.001
DVI	NA	0.52 ± 0.10 (545)	0.54 ± 0.11 (675)	0.53 ± 0.11 (251)	0.53 ± 0.11 (1,471)	0.004
SAPIEN 3						
EOA, cm^2	1.22 ± 0.22 (47)	1.45 ± 0.26 (471)	1.74 ± 0.35 (626)	1.89 ± 0.37 (326)	1.66 ± 0.38 (1,470)	<0.001
Mean gradient, mm Hg	16.23 ± 5.01 (47)	12.79 ± 4.65 (471)	10.59 ± 3.88 (626)	9.28 ± 3.16 (326)	11.18 ± 4.35 (1,470)	<0.001
DVI	0.42 ± 0.07 (47)	0.43 ± 0.08 (471)	0.43 ± 0.09 (626)	0.40 ± 0.09 (326)	0.43 ± 0.09 (1,470)	<0.001

Values are mean ± SD (n). This table shows the mean gradients and EOA for each balloon-expandable valve iteration by valve size implanted. All mean valve areas and EOAs were significantly different for each valve size for a given valve type (range $p < 0.03$ to $p < 0.0001$).

DVI = Doppler velocity index; EOA = effective orifice area; NA = not available.

Self-Expanding: CoreValve family

TABLE 5 Normal Reference Values for the CoreValve and Evolut R Valves by Native Annular Diameter Quintiles at 30 Days

Quintiles	≤22.8 mm	>22.8 to 24.5 mm	>24.5 to 25.9 mm	>25.9 to 27.6 mm	>27.6 to 41.5 mm	p Value for Trend
CoreValve						
EOA, cm^2	1.71 ± 0.55 (166)	1.80 ± 0.53 (141)	1.92 ± 0.48 (167)	1.94 ± 0.52 (165)	2.06 ± 0.66 (160)	<0.001
EOAi, cm^2/m^2	1.03 ± 0.33 (166)	1.02 ± 0.30 (141)	1.04 ± 0.29 (167)	1.01 ± 0.30 (165)	1.07 ± 0.36 (160)	0.34
Mean gradient, mm Hg	9.01 ± 4.06 (180)	8.96 ± 4.71 (151)	8.75 ± 3.99 (179)	9.16 ± 4.50 (170)	8.75 ± 3.61 (171)	0.75
DVI	0.59 ± 0.15 (172)	0.55 ± 0.13 (145)	0.54 ± 0.11 (173)	0.53 ± 0.12 (167)	0.55 ± 0.14 (170)	0.001
Quintiles	**≤22.3 mm**	**>22.3 to ≤23.2 mm**	**>23.2 to ≤24.7 mm**	**>24.7 to ≤26.2 mm**	**>26.2 to ≤30.2 mm**	**p Value for Trend**
Evolut R						
EOA, cm^2	1.66 ± 0.42 (53)	1.82 ± 0.43 (38)	1.98 ± 0.56 (62)	1.98 ± 0.59 (49)	2.56 ± 0.77 (53)	< 0.001
EOAi, cm^2/m^2	0.99 ± 0.27 (53)	1.09 ± 0.26 (38)	1.10 ± 0.32 (62)	1.06 ± 0.34 (49)	1.29 ± 0.37 (53)	< 0.001
Mean gradient, mm Hg	7.94 ± 3.10 (58)	6.91 ± 2.58 (43)	7.66 ± 2.94 (63)	8.53 ± 3.49 (56)	6.40 ± 3.34 (57)	0.21
DVI	0.61 ± 0.11 (57)	0.61 ± 0.14 (41)	0.61 ± 0.15 (63)	0.56 ± 0.14 (51)	0.58 ± 0.15 (55)	0.07

Values are mean ± SD (n). Trend test p value from generalized linear modeling with quintiles as independent ordinal variable.

Abbreviations as in Tables 1 and 3.

TAVI Device Selection

Predicted PPM reference tables

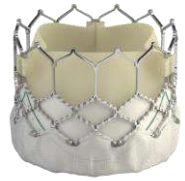
Hahn Chart

Evolut™ Hemodynamic Reference Values[1]

Annular Diameter (mm)	≤22.3	>22.3 to ≤23.2	>23.2 to ≤24.7	>24.7 to ≤26.2	>26.2 to ≤30.2
Diameter-derived Annular Area (mm²)	≤391	391-423	423-479	479-539	539-716
EOA Ref Data (cm²)	1.66 ± 0.42 (n = 53)	1.82 ± 0.43 (n = 38)	1.98 ± 0.56 (n = 62)	1.98 ± 0.59 (n = 49)	2.56 ± 0.77 (n = 53)
Patient BSA (m²)	*In Vivo* Indexed Effective Orifice Area (IEOA)				
1.3	1.28	1.40	1.52	1.52	1.97
1.4	1.19	1.30	1.41	1.41	1.83
1.5	1.11	1.21	1.32	1.32	1.71
1.6	1.04	1.14	1.24	1.24	1.60
1.7	0.98	1.07	1.16	1.16	1.51
1.8	0.92	1.01	1.10	1.10	1.42
1.9	0.87	0.96	1.04	1.04	1.35
2	0.83	0.91	0.99	0.99	1.28
2.1	0.79	0.87	0.94	0.94	1.22
2.2	0.75	0.83	0.90	0.90	1.16
2.3	0.72	0.79	0.86	0.86	1.11
2.4	0.69	0.76	0.83	0.83	1.07
2.5	0.66	0.73	0.79	0.79	1.02
2.6	0.64	0.70	0.76	0.76	0.98
2.7	0.61	0.67	0.73	0.73	0.95
2.8	0.59	0.65	0.71	0.71	0.91

Sapien 3™* Hemodynamic Reference Values[1]

Area-derived Annular Diameter (mm)	≤22.1	>22.2 to ≤23.64	>23.65 to ≤24.9	>24.9 to ≤26.2	>26.2 to ≤29.4
Annular Area (mm²)	248-384	385-439	440-488	489-537	538-678
EOA Ref Data (cm²)	1.41 ± 0.27 (n = 189)	1.58 ± 0.33 (n = 191)	1.73 ± 0.36 (n = 192)	1.79 ± 0.35 (n = 191)	1.91 ± 0.42 (n = 188)
Patient BSA (m²)	*In Vivo* Indexed Effective Orifice Area (IEOA)				
1.3	1.08	1.22	1.33	1.38	1.47
1.4	1.01	1.13	1.24	1.28	1.36
1.5	0.94	1.05	1.15	1.19	1.27
1.6	0.88	0.99	1.08	1.12	1.19
1.7	0.83	0.93	1.02	1.05	1.12
1.8	0.78	0.88	0.96	0.99	1.06
1.9	0.74	0.83	0.91	0.94	1.01
2	0.71	0.79	0.87	0.90	0.96
2.1	0.67	0.75	0.82	0.85	0.91
2.2	0.64	0.72	0.79	0.81	0.87
2.3	0.61	0.69	0.75	0.78	0.83
2.4	0.59	0.66	0.72	0.75	0.80
2.5	0.56	0.63	0.69	0.72	0.76
2.6	0.54	0.61	0.67	0.69	0.73
2.7	0.52	0.59	0.64	0.66	0.71
2.8	0.50	0.56	0.62	0.64	0.68



The analysis provided above assesses data from separate clinical studies. These charts are not intended to be a direct comparison of these devices as there is no head-to-head clinical study, but rather are intended to illustrate an analysis of similar trials. Multiple factors, including the use of different echo corelabs, contribute to clinical study outcomes and need to be considered in making any assessments across different studies. Where measurements are derived, conversions assume circularity.

Indexed Effective Orifice Area (IEOA) = EOA/BSA²

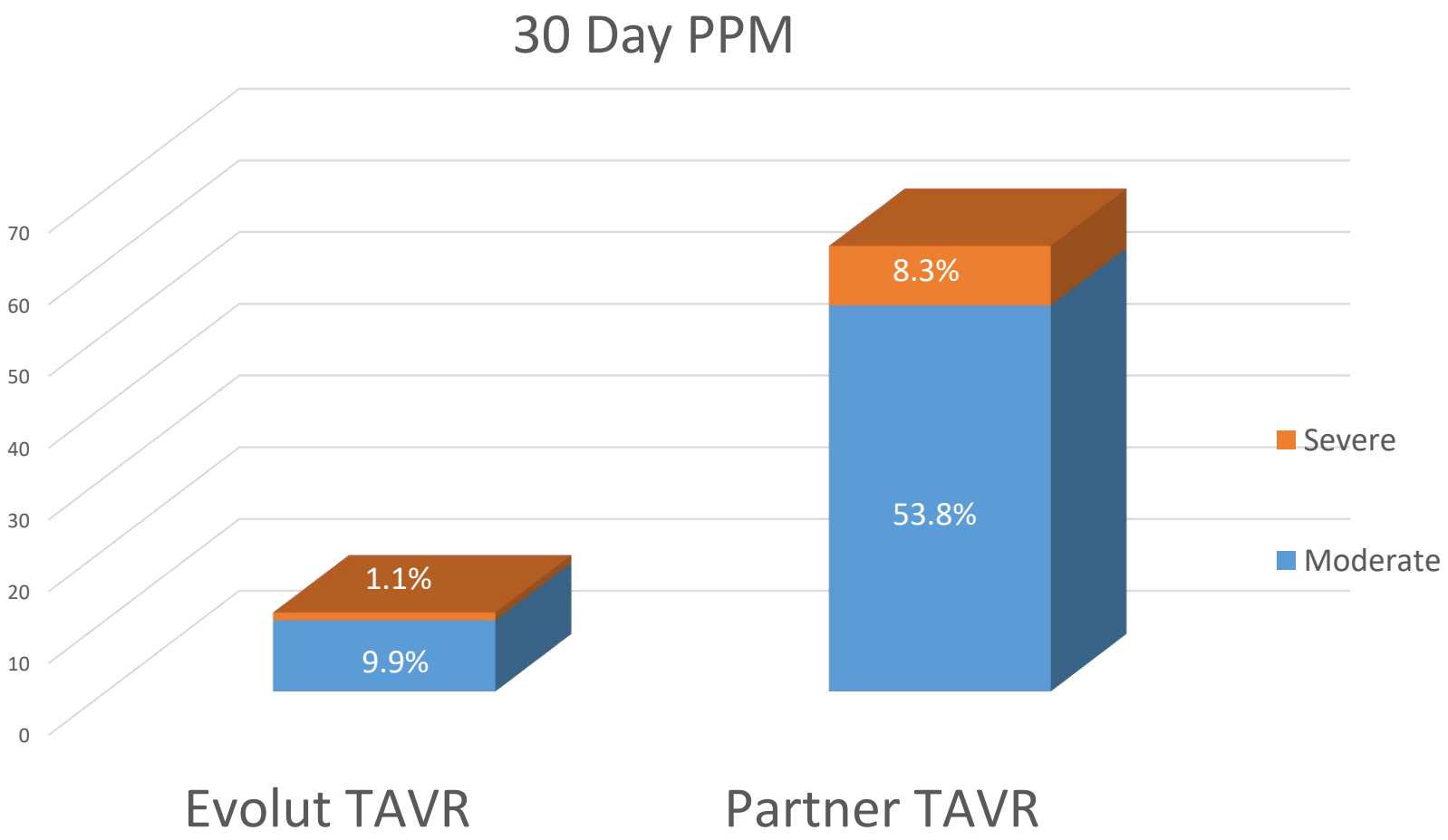
IEOA > 0.85 cm²/m²	mild
IEOA ≤ 0.85 cm²/m²	moderate
IEOA ≤ 0.65 cm²/m²	severe

References

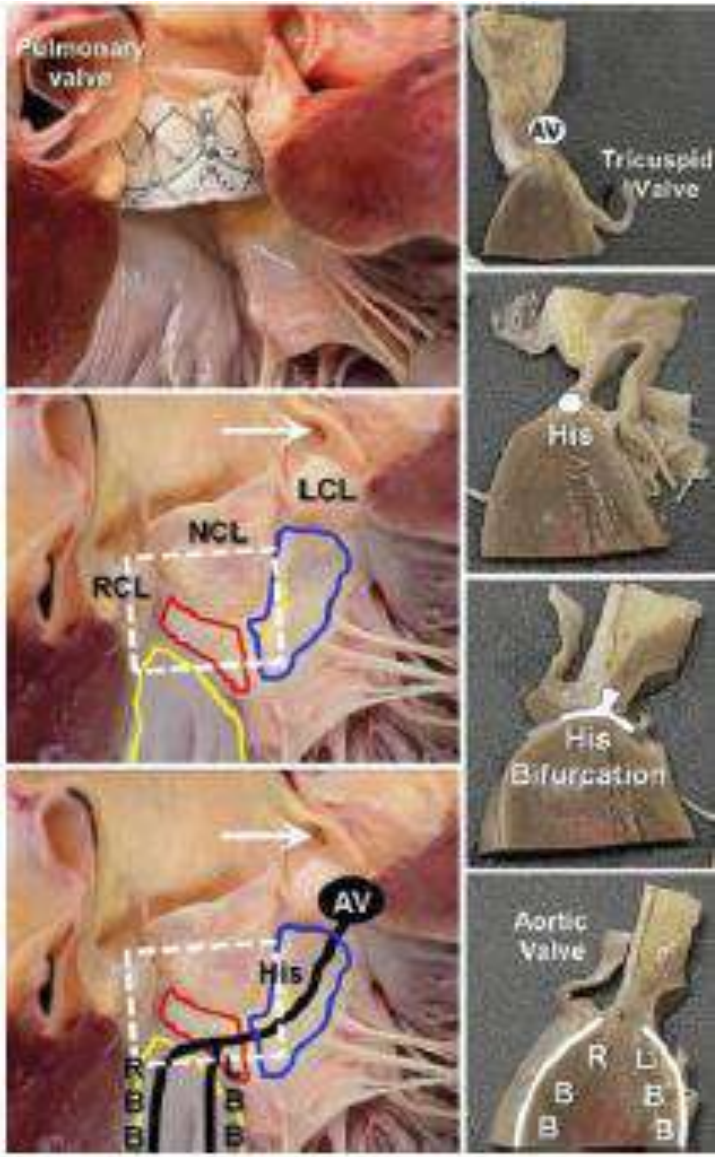
[1] Hahn RT, Leipsic J, Douglas PS, et al. Comprehensive Echocardiographic

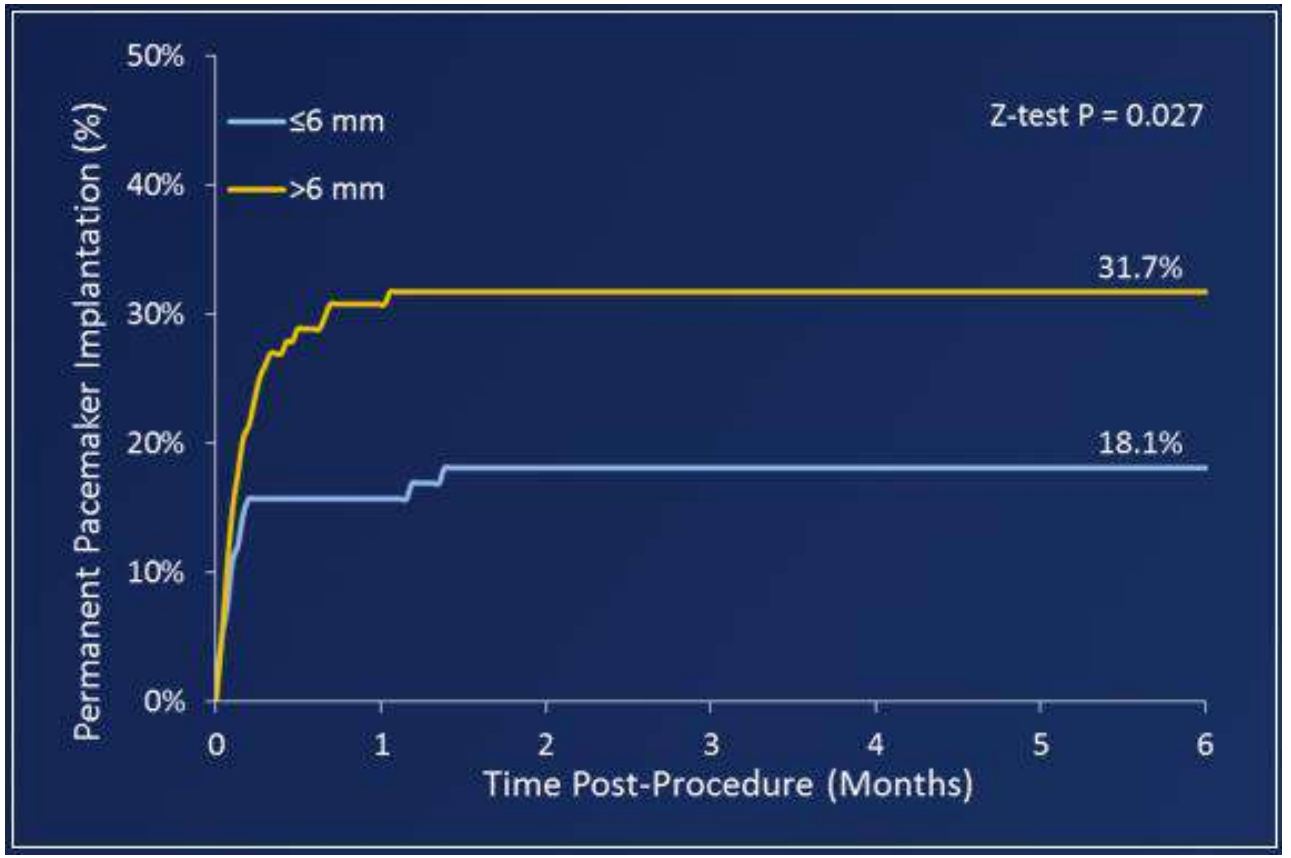
Hahn et al., JACC Cardiovasc Imaging. 2018 Jun 8

30 Day PPM


30 Day PPM
70
60
50
40
30
20
10
0
1.1%
9.9%
8.3%
53.8%
Severe
Moderate
Evolut TAVR
Partner TAVR

Permanent Pacemakers
Why Do They Happen?

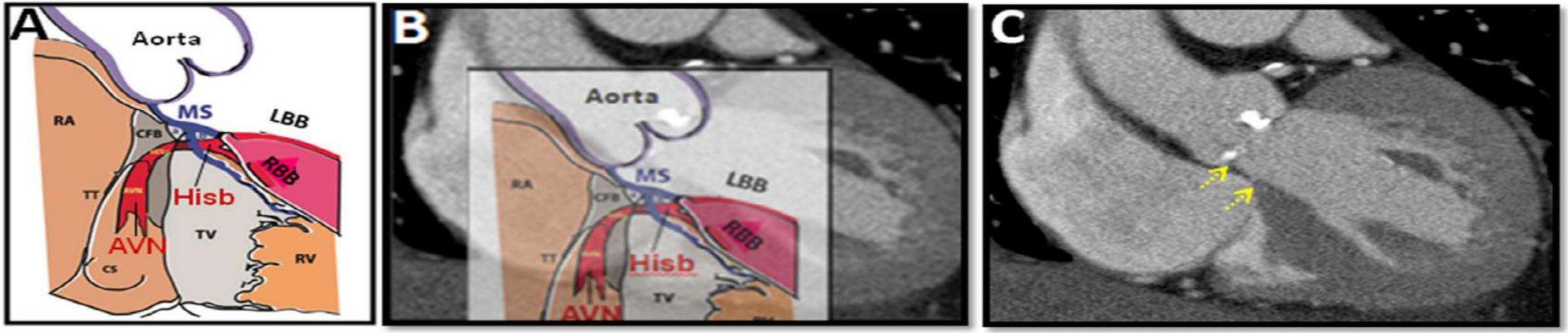




[1]Bax, et al., *Eur Heart J* 2014; 35:2639-54; [2]Petronio, et al., presented at EuroPCR 2014

Inverse Relationship Between Membranous Septal Length and the Risk of Atrioventricular Block in Patients Undergoing Transcatheter Aortic Valve Implantation

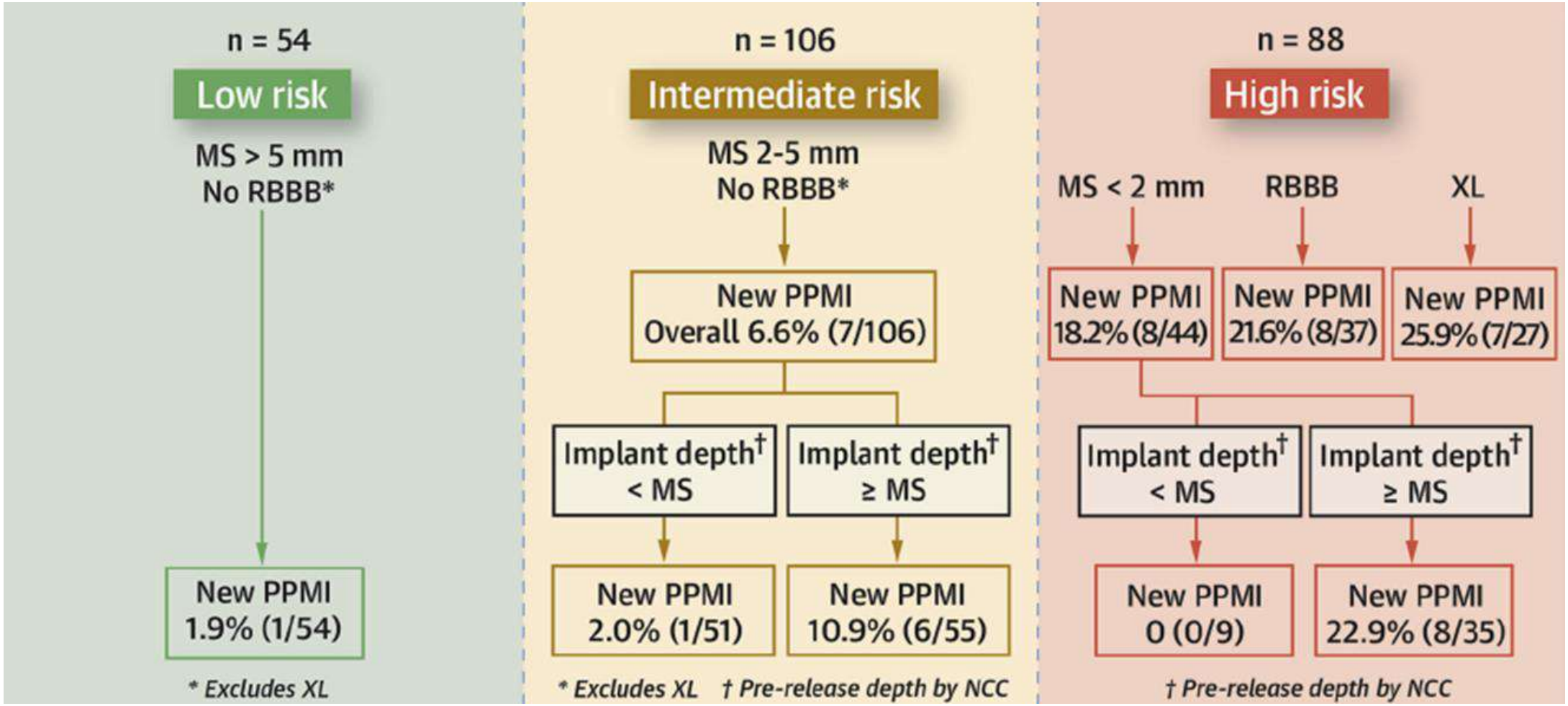
Ashraf Hamdan, MD,*† Victor Guetta, MD,* Robert Klempfner, MD,* Eli Konen, MD,† Ehud Raanani, MD,‡ Michael Glikson, MD,* Orly Goitein, MD,† Amit Segev, MD,* Israel Barbash, MD,* Paul Fefer, MD,* Dan Spiegelstein, MD,‡ Ilan Goldenberg, MD,* Ehud Schwammenthal, MD, PHD*



Hamdan et al; JACC Intv 2015;8:1218–2

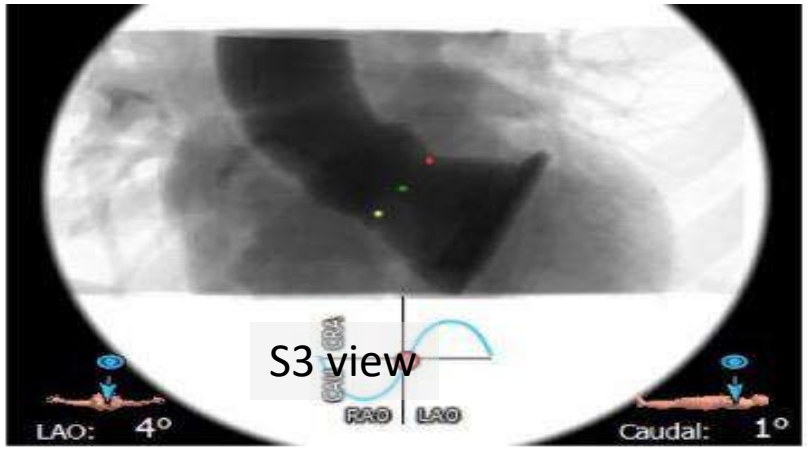
TAVI Device Selection

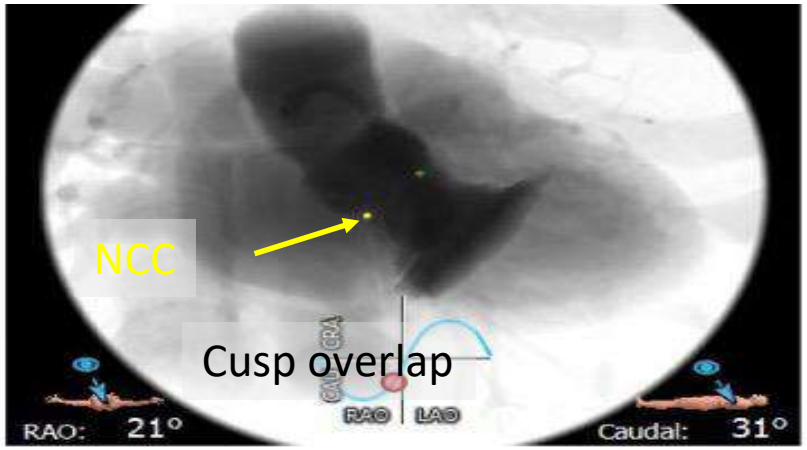
Minimizing conduction defects in self-expandable valves

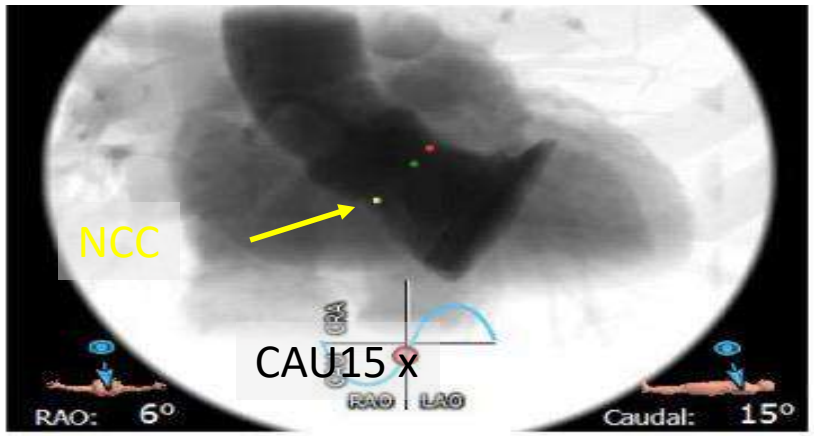


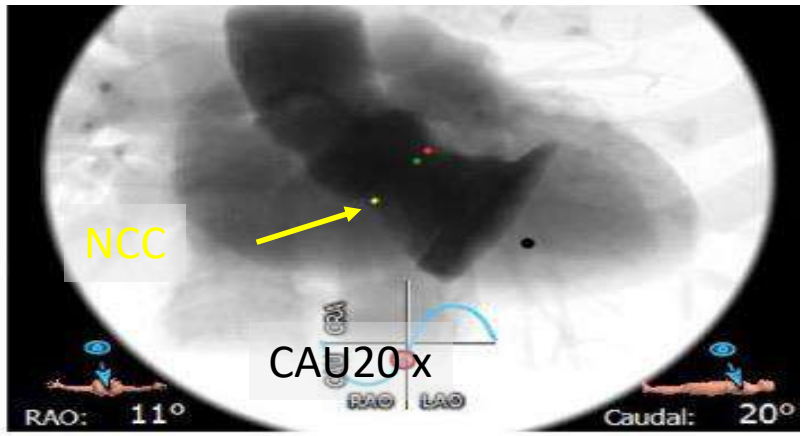
Jilaihawi, et al., JACC Cardiovasc Interv. 2019 Aug 22. pii: S1936-8798(19)31425-6.

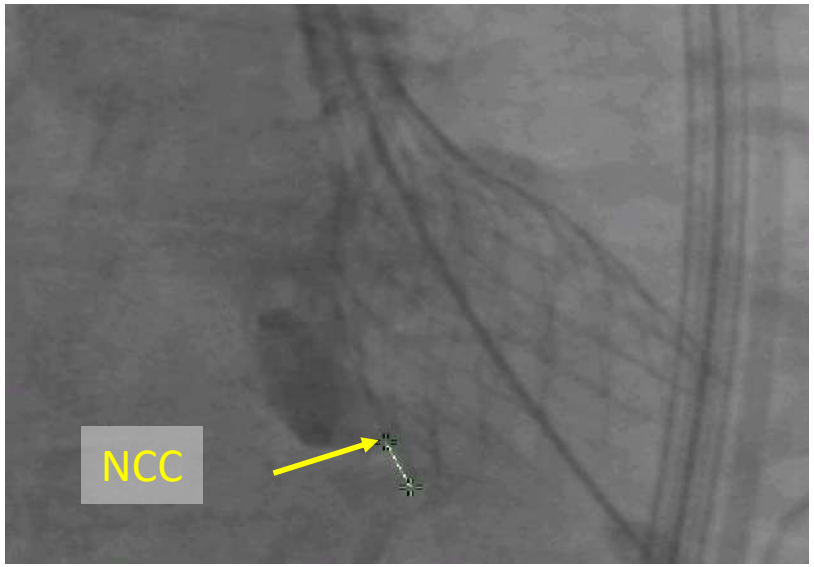
MIDAS: intraprocedural; device positioning









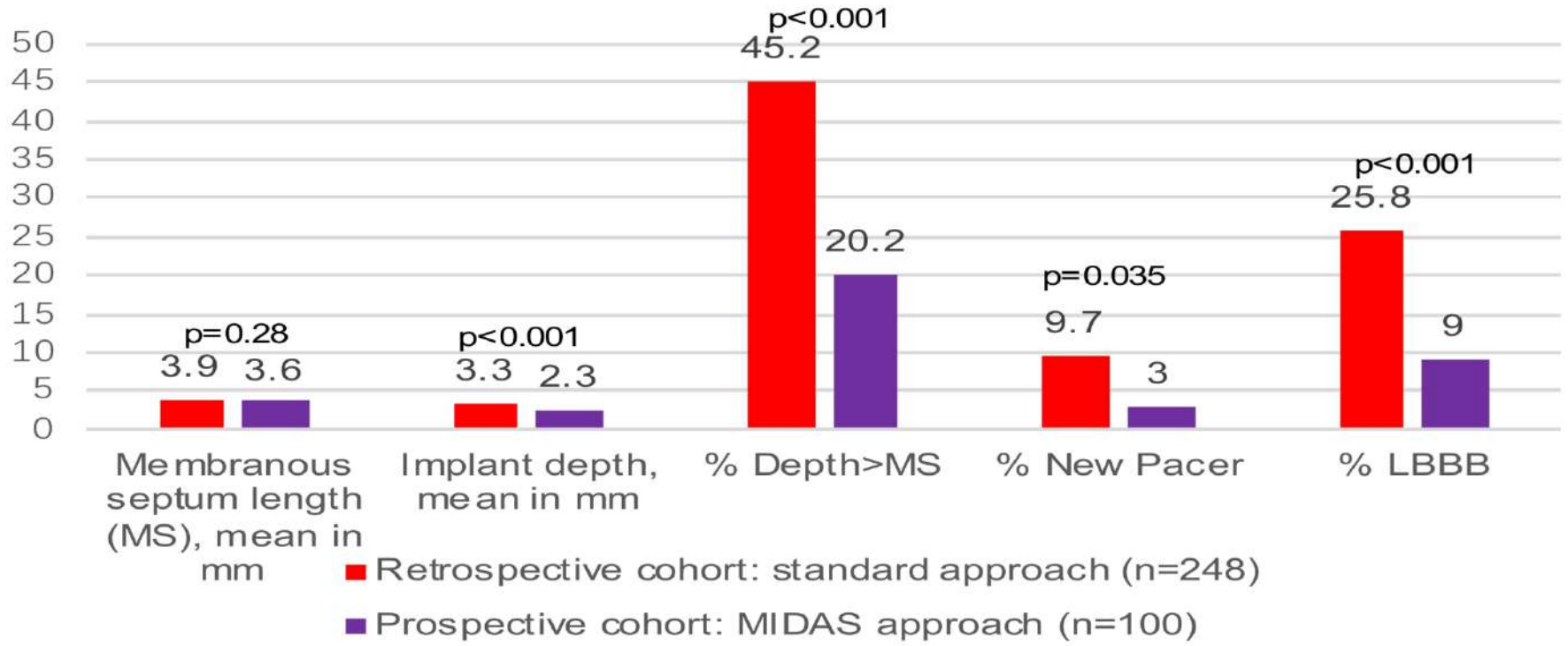


1. NYU approach: start at CAU15 / LAO X or RAO X based on CTA
2. Come to 80% and remove any parallax by coming LAO
3. Assess implant depth according to NCC and decide: release vs re-capture
    - Implant higher than length of MS

MIDAS approach: Outcomes

Reduction in PPMI

9.7%>>3%

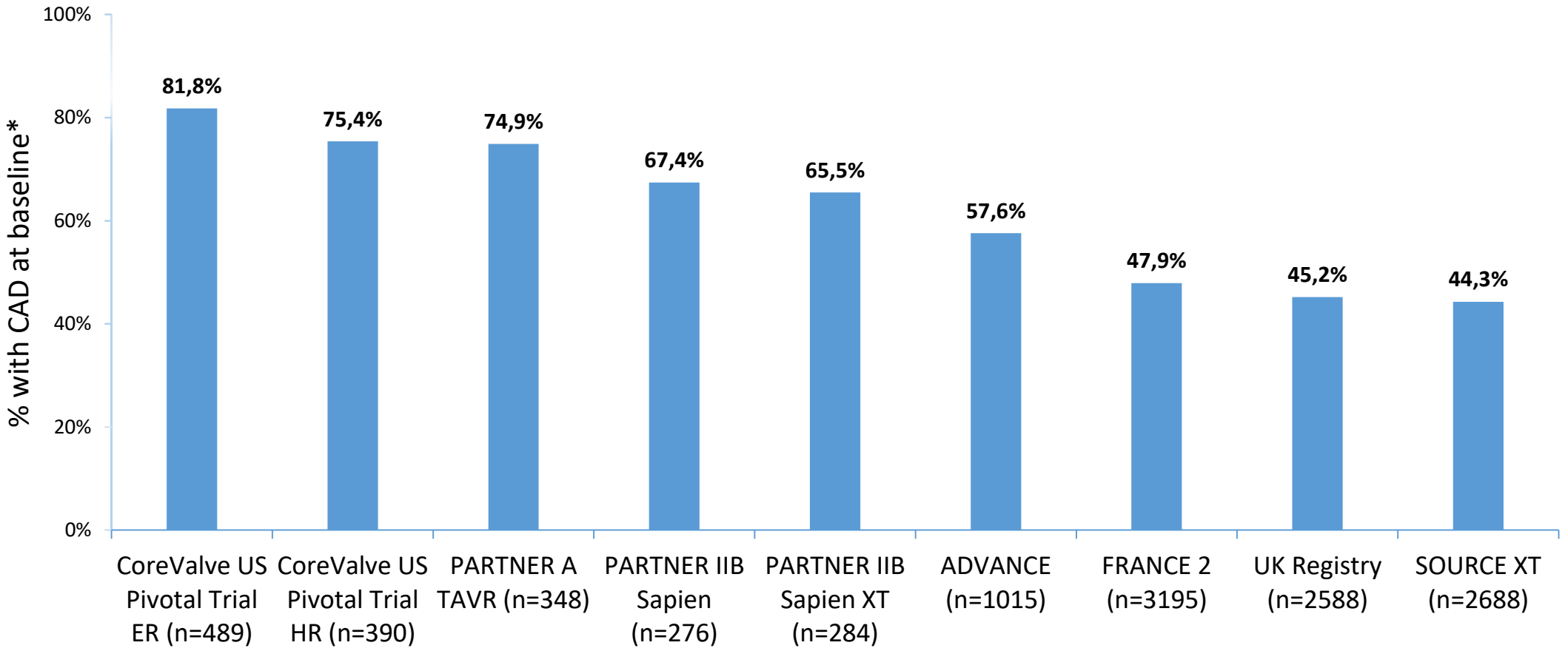


Reduction in LBBB

25.8%>>9%

TAVI Device Selection

Coronary Access

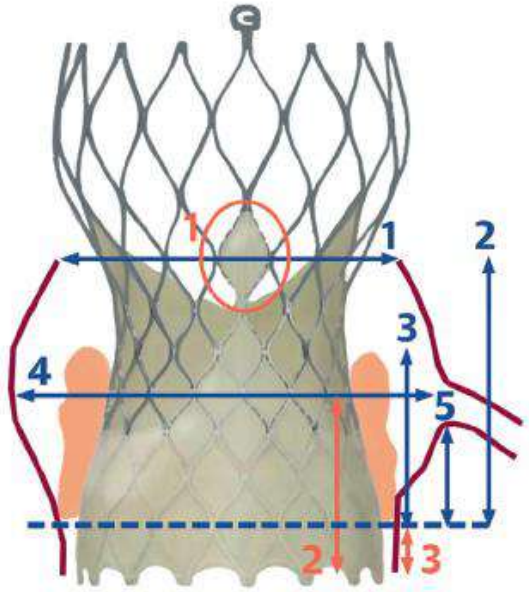


1. Popma JJ, et al. J Am Coll Cardiol 2014;63:1972-1981. 2. Adams, et al., NEJM 2014; 370: 1790-8; 3. Smith GR, et al. NEJM 2011;364:2187-98. 4&5. Webb, et. al. J ACC Cardiovasc Interv 2015;8:1797-806; 6. Gerckens U, et al. Eur Heart J 2017;38(36):2729-2738. 7. Gilard M, et al. NEJM 2012;366:1705-15. 8. Snow TM, et al. Int J Cardiol 2015;199:253-60; 9. Schymik G, et al. JACC Cardiovasc Interv 2015;8:657-69.

TAVI Device Selection

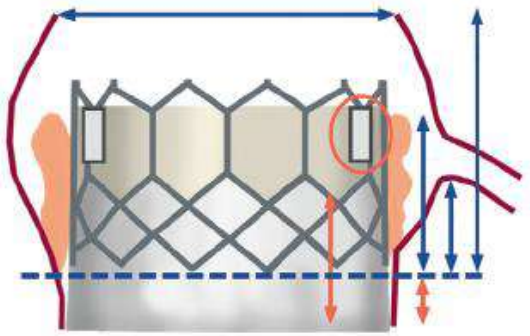
Coronary Access

Factors Impacting Coronary Access



Anatomical

1. Sinotubular junction dimensions
2. Sinus height
3. Leaflet length and bulkiness
4. Sinus of Valsalva width
5. Coronary height

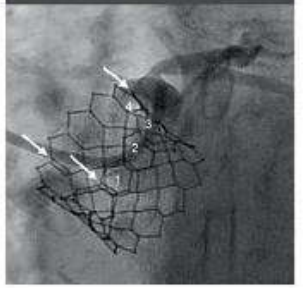


Device and Procedural

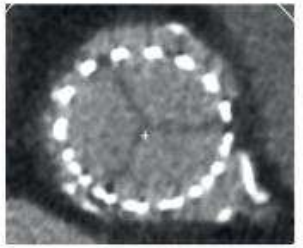
1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth

Imaging Evaluation

Fluoroscopy



MDCT



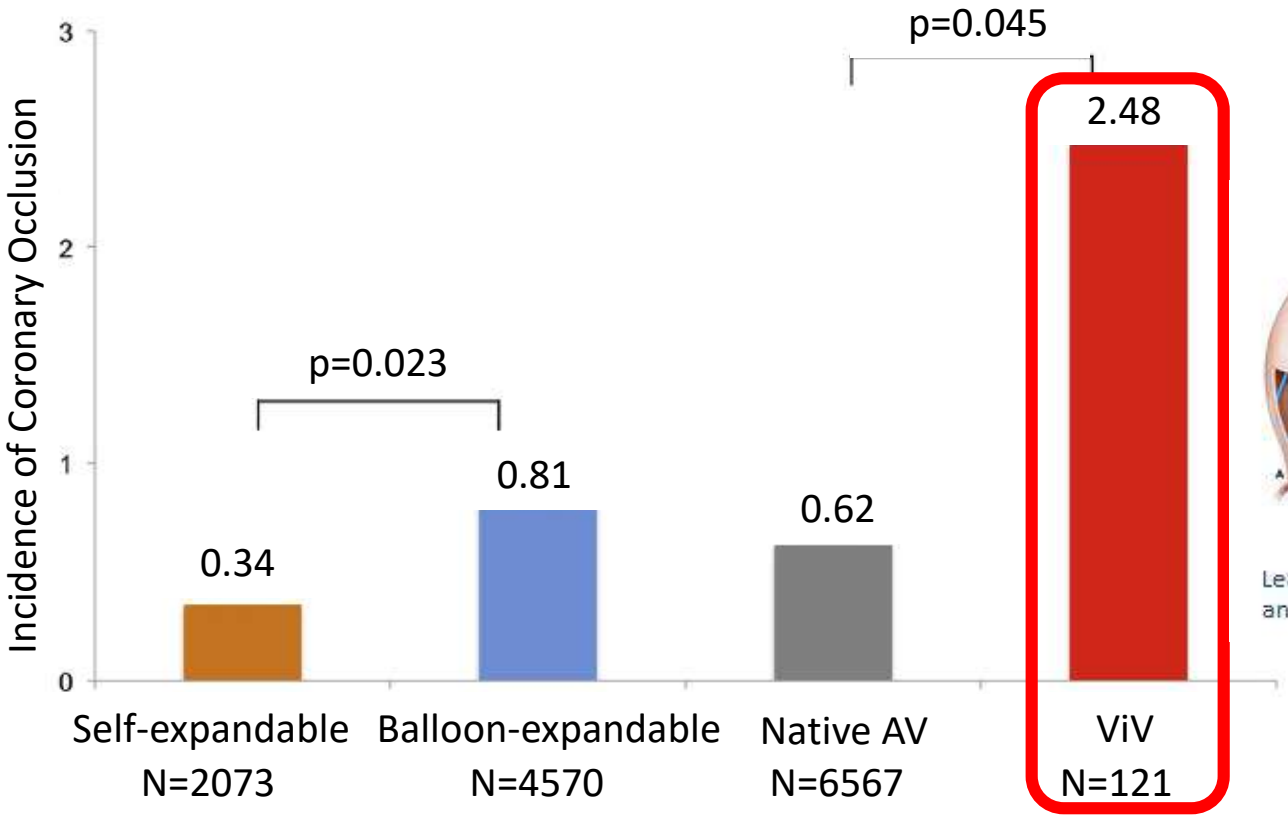
TAVI Device Selection

Coronary Access

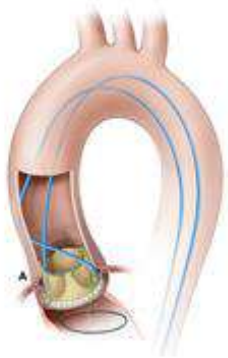
	Kerckhoff-Klinik[1] (n = 1,000)	Segeberg Registry[2] (n = 296)	UK Registry[3] (n = 2,588)	TAVR-LM Registry[4] (n = 6,405)	Tanaka[5] (n = 2,170)
Post-TAVI PCI Incidence	3.5%	5.7%	0.7%	0.1%	1.4%
Time to PCI Post-TAVR	233 ± 158 days	17.7 months (range: 1-72)	136 days (range: 1-1092)	368 days (IQR: 204-534)	Not reported
Type of TAV Implanted					
CoreValve/Evolut R	29%	100%	48%	44%	100%
SAPIEN XT	45%		52%	55%	
JenaValve	3%				
Symetis	11%				
Portico	3%				
Procedural Success	74%	95.8%	Not Reported	100%	93.3%

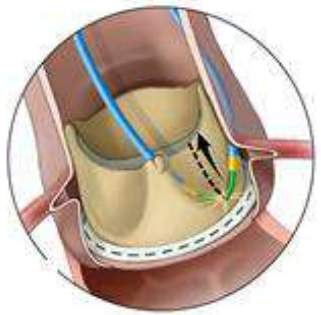
[1]Blumenstein, et al., *Clin Res Cardiol* 2015; 104:632-39; [2]Allali, et al., *Cardiovasc Revasc Med* 2016;17:391-8; [3]Snow, et al., *Int J Cardiol* 2015; 199:253-60; [4]Chakravarty, et al., *J Am Coll Cardiol* 2016; 67:951-60. 5. Tanaka et al. Incidence, technical safety and feasilbility of coronary angiography and intervention following self-expanding transcatheter aortic valve replacement. Cardiovasc Revasc Med 2019; ePub ahead of print.

TAVR Complications
Coronary Obstruction

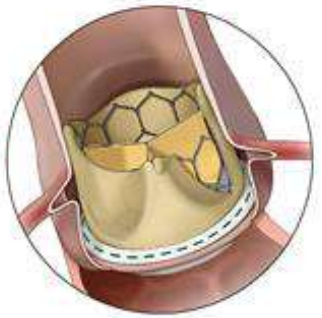


BASILICA


Leaflet wire traversal and snaring

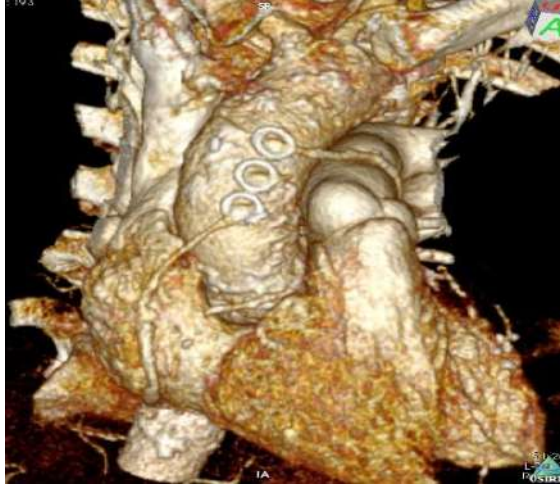

Leaflet slicing

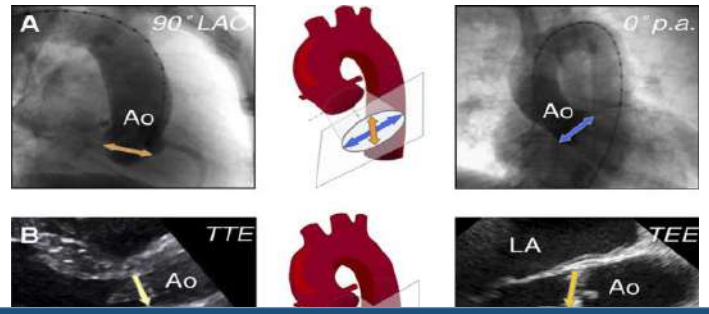

Sliced leaflet


Valve-in-Valve

[1]Ribeiro, et al., *J Am Coll Cardiol* 2013; 62: 1552-62

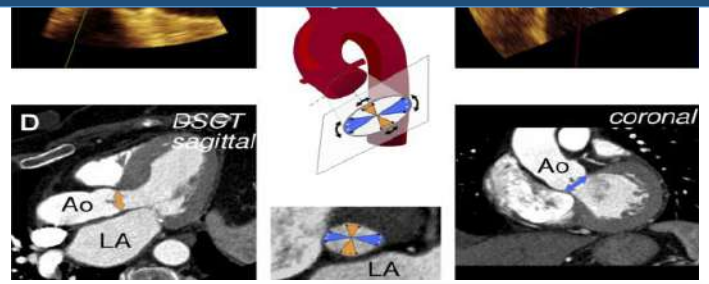
The key to success:
meticulous preparation & heart team discussion

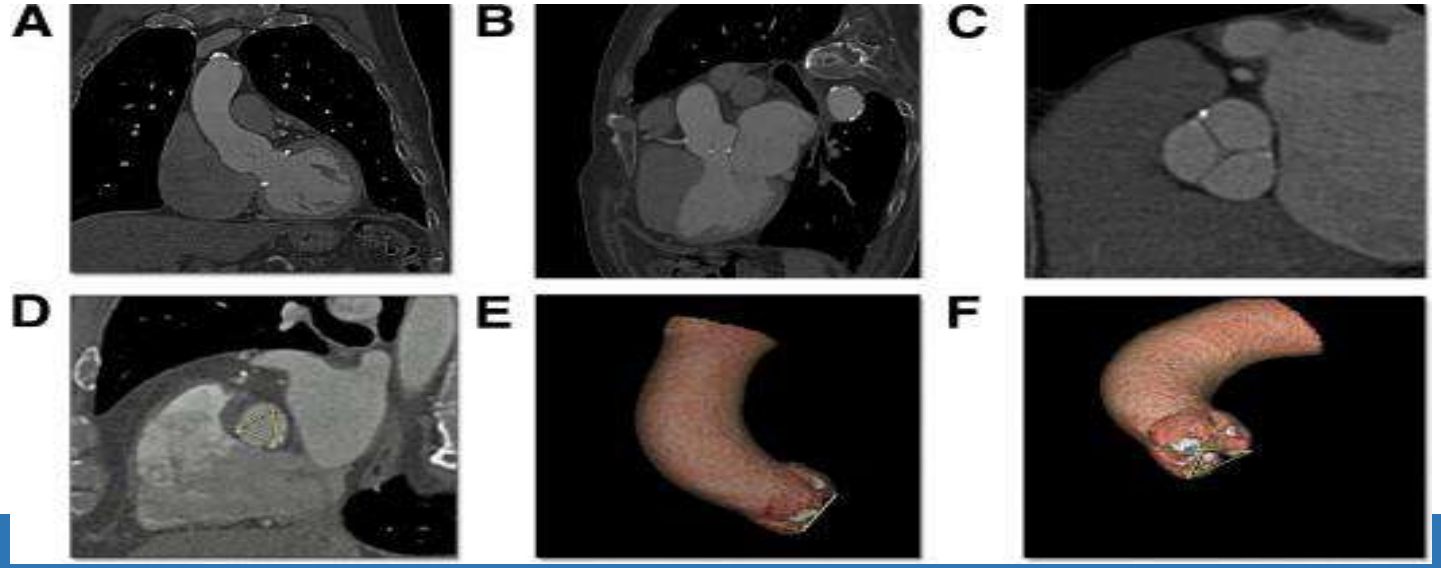


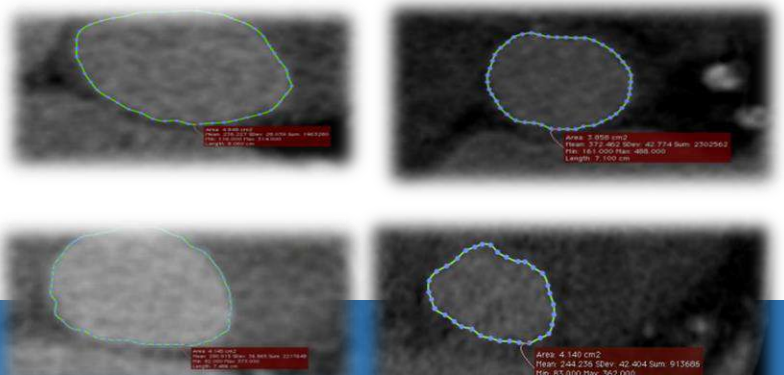


If I had eight hours to chop down a tree, I'd spend six sharpening my ax

Abraham Lincoln







We need to carefully select our TAVI patients

- **Anatomy favorable for optimal result (TAVI suitability vs. surgical risk..)**
- **Match the ideal valve to the specific patient**
- **Inform and involve the patient as for the short- and long-term objectives : set up the expectations!**

Summary

- TAVI has evolved tremendously since the first case in 2002, showing great success and becoming the gold standard in extreme- high- and intermediate- surgical risk aortic stenosis patients

- Recent results from the PARTNER 3 and Evolut Low Risk Trials show excellent outcomes in low risk patients

- The proper therapy for asymptomatic severe AS patients and bicuspid aortic valve disease as well as the optimal antithrombotic/anticoagulant therapy post TAVI and valve selection for specific cohorts will be determined shortly

- Valve and technical modifications will further improve procedural safety&efficacy (ie, pacemaker need..)

- TAVI will soon evolve as the default therapy for isolated AS patients requiring a bioprosthetic valve

Is this the end of the TAVolution?

- **Revolution: a sudden, radical or complete change**

- **Evolution: a process of continuous change from a lower, simple, or worse to a higher, more complex or better state**

This is not the end, this is not even the beginning of the end but it may be the end of the beginning..

W. Churchill


Muito Obrigado!

STS score	1.9	1.9
CAD	27.7	28
Prior stroke	3.4	5.1
PVD	6.9	7.3
Creatinine > 2	0.2	0.2
Any BBB	13.3	17
LVEF	66	66
NYHA III/IV *	31	24
Concomitant PCI/CABG	6.5	12.8
Concomitant mitral / tricuspid intervention	0	2.2%
Procedure time (min)	58.6 ± 36.50	208.3 ± 62.15
Minimal invasive	N/A	24%
General anesthesia	33%	100%
Valve ≥ 23 mm	98%	79.9%
Median ICU stay (days)	2	3
Median LOS (days)	3	7