Delivering the outcomes you demand with SAPIEN 3

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Disclosures

I, Jeehoon Kang, declare that I have no conflict of interest or any financial disclosures related to the following presentation.

Contents

- History of TAVI in Severe AS
- Recent publication
  - Room for any improvement?
- Case

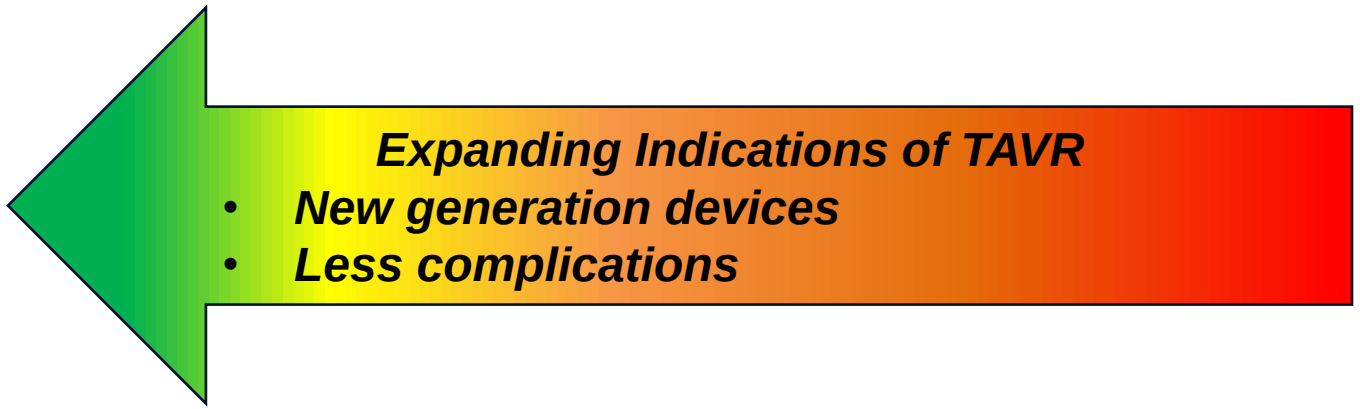
History of TAVI in Severe AS

NOTION All Comer
PARTNER 3
CoreValve Low Risk

PARTNER 2A
PARTNER S3i
SURTAVI
US Pivotal Trial

PARTNER 1A

PARTNER 1B



Low STS <4%	Intermediate STS 4-10%	High STS 10-15%	Extreme STS >15%	Futile
Operable			Inoperable	

History of TAVI in Severe AS

ORIGINAL ARTICLE

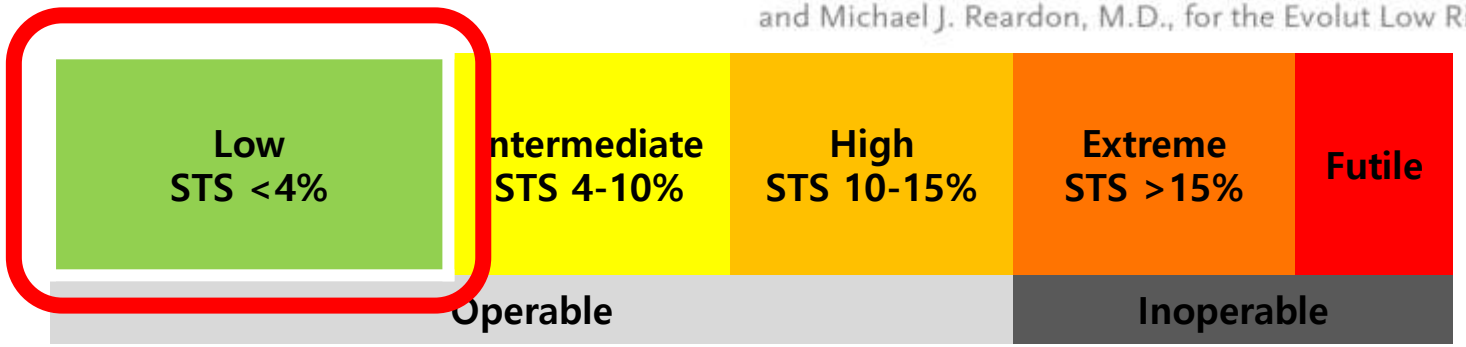
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

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*

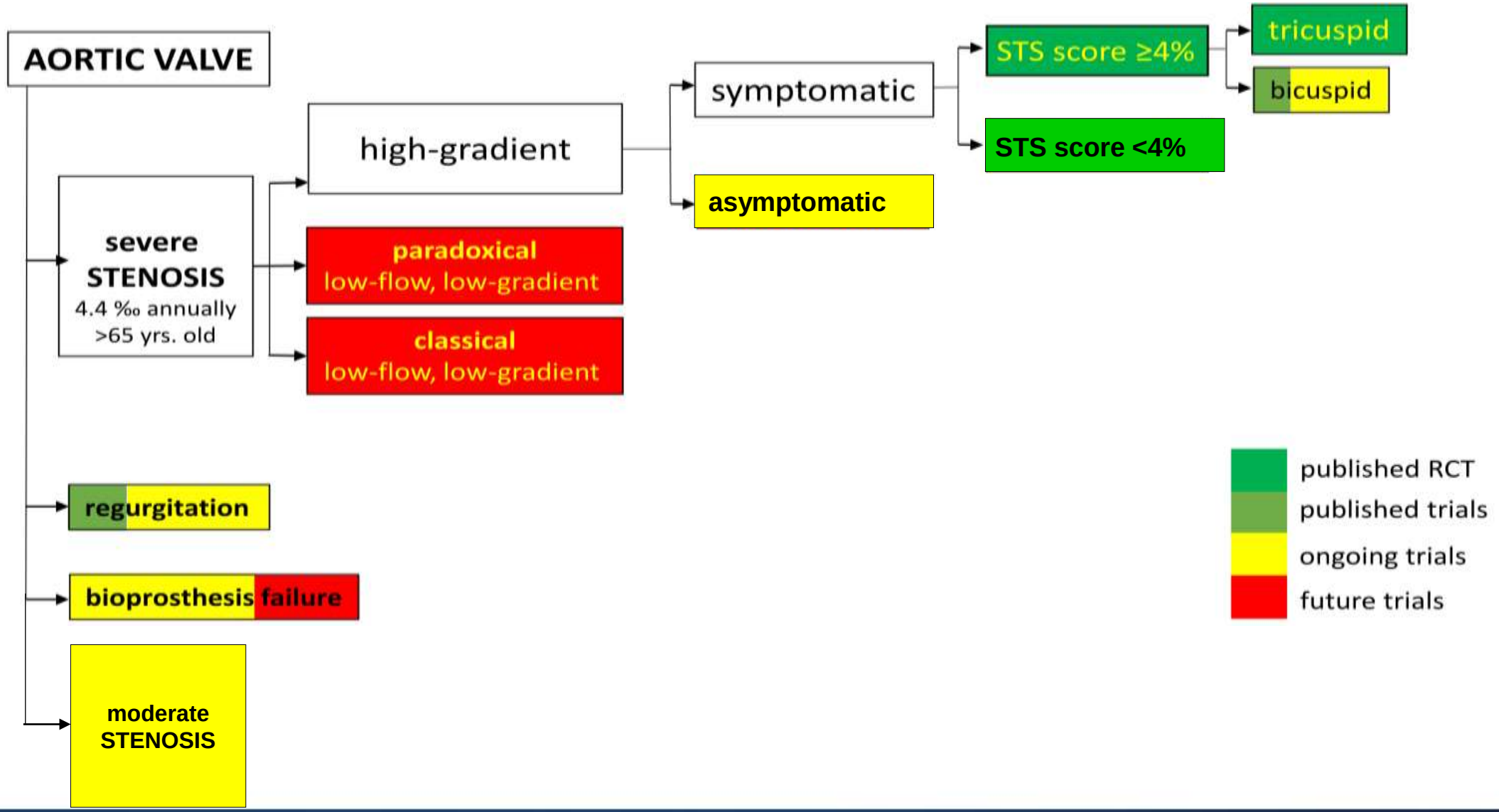
ORIGINAL ARTICLE

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

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators*



History of TAVI in Severe AS



The guideline for Severe AS

ACC/AHA CLINICAL PRACTICE GUIDELINE

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

3.2.4.2. Choice of SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR Is Appropriate

Recommendations for Choice of SAVR Versus TAVI for Patients for Whom a Bioprosthetic AVR Is Appropriate

Referenced studies that support the recommendations are summarized in Online Data Supplement 11 to 13.

COR	LOE	Recommendations
1	A	1. For symptomatic and asymptomatic patients with severe AS and any indication for AVR who are <65 years of age or have a life expectancy >20 years, SAVR is recommended.[1–3]
1	A	2. For symptomatic patients with severe AS who are 65 to 80 years of age and have no anatomic contraindication to transfemoral TAVI, either SAVR or transfemoral TAVI is recommended after shared decision-making about the balance between expected patient longevity and valve durability.[1,4–8]
1	A	3. For symptomatic patients with severe AS who are >80 years of age or for younger patients with a life expectancy <10 years and no anatomic contraindication to transfemoral TAVI, transfemoral TAVI is recommended in preference to SAVR.[1,4–10]

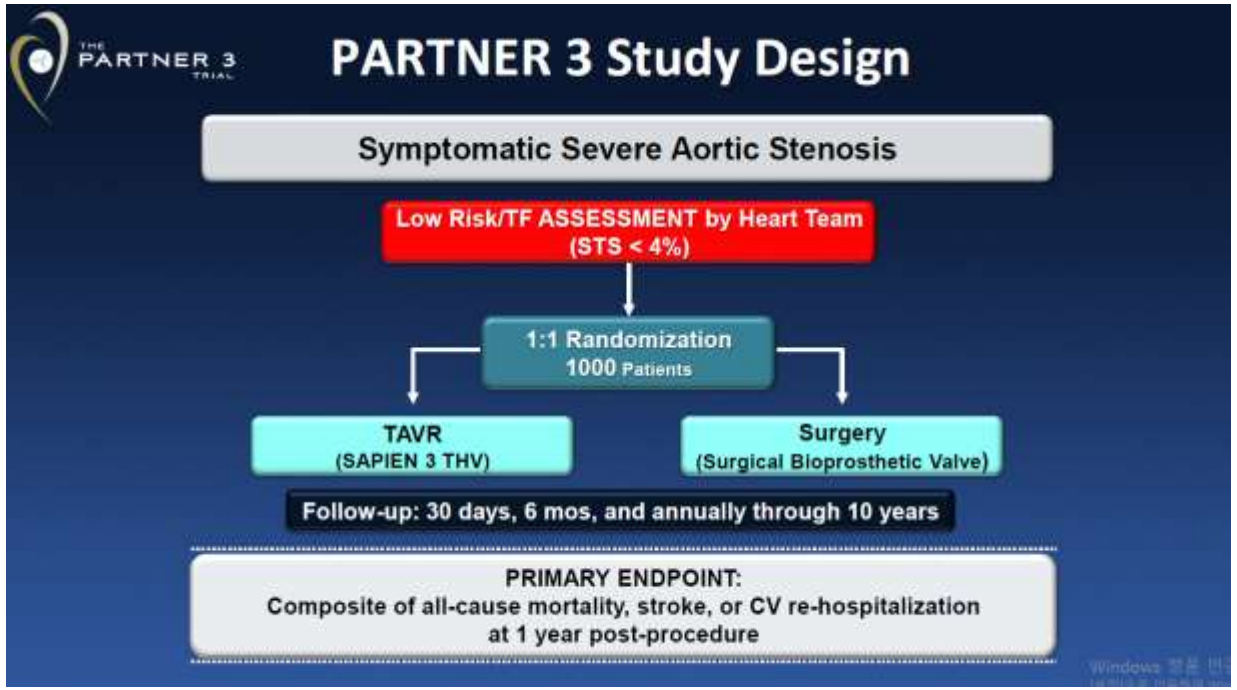
	Favors SAVR	Favors TAVI
Age/life expectancy*	Younger age/longer life expectancy	Older age/fewer expected remaining years of life
Valve anatomy	BAV Subaortic (LV outflow tract) calcification Rheumatic valve disease Small or large aortic annulus†	Calcific AS of a trileaflet valve
Prosthetic valve preference	Mechanical or surgical bioprosthetic valve preferred Concern for patient–prosthesis mismatch (annular enlargement might be considered)	Bioprosthetic valve preferred Favorable ratio of life expectancy to valve durability TAVI provides larger valve area than same size SAVR
Concurrent cardiac conditions	Aortic dilation‡ Severe primary MR Severe CAD requiring bypass grafting Septal hypertrophy requiring myectomy AF	Severe calcification of the ascending aorta ("porcelain" aorta)
Noncardiac conditions		Severe lung, liver, or renal disease Mobility issues (high procedural risk with sternotomy)
Frailty	Not frail or few frailty measures	Frailty likely to improve after TAVI
Estimated procedural or surgical risk of SAVR or TAVI	SAVR risk low TAVI risk high	TAVI risk low to medium SAVR risk high to prohibitive

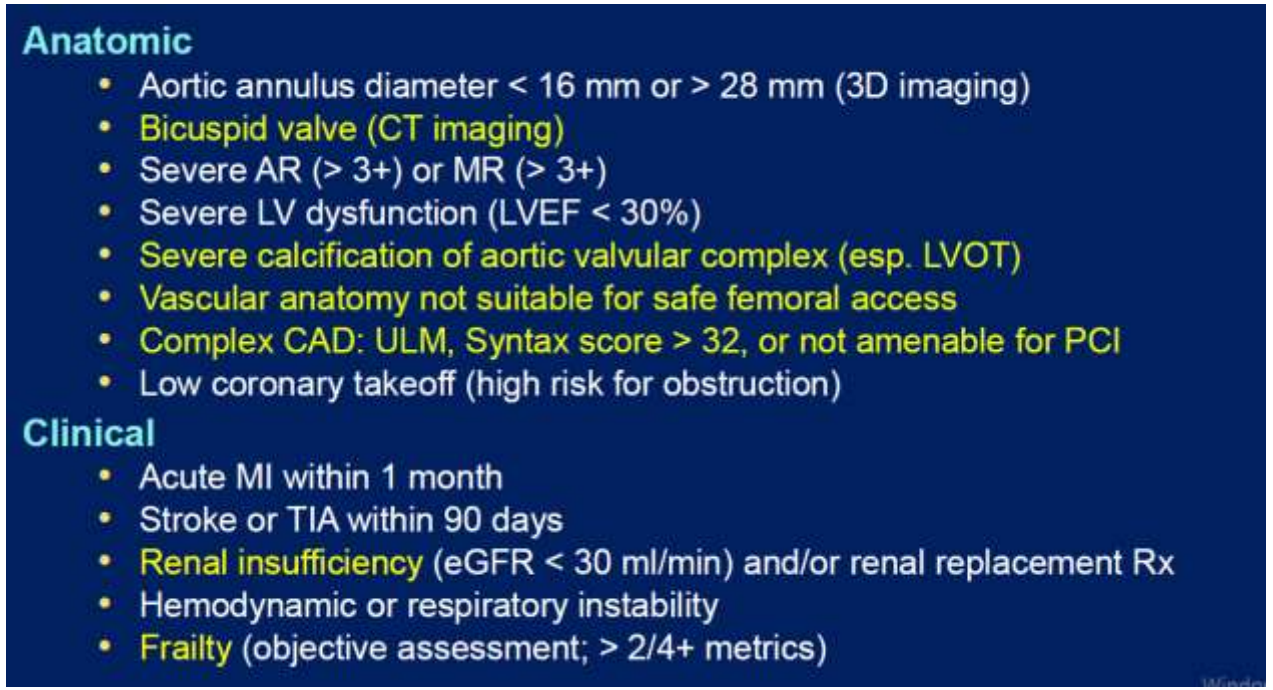
PARTNER3 Trial – 2 YEAR FU

- ***A Recent publication***

Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk

Martin B. Leon, MD,[a,b] Michael J. Mack, MD,[c] Rebecca T. Hahn, MD,[a,b] Vinod H. Thourani, MD,[d] Raj Makkar, MD,[e] Susheel K. Kodali, MD,[f] Maria C. Alu, MS,[a,b] Mahesh V. Madhavan, MD,[a,b] Katherine H. Chau, MD, MS,[a] Mark Russo, MD, MS,[g] Samir R. Kapadia, MD,[h] S. Chris Malaisrie, MD,[i] David J. Cohen, MD, MSc,[j] Philipp Blanke, MD,[k] Jonathon A. Leipsic, MD,[k] Mathew R. Williams, MD,[l] James M. McCabe, MD,[a] David L. Brown, MD,[c] Vasilis Babaliaros, MD,[m] Scott Goldman, MD,[n] Howard C. Herrmann, MD,[o] Wilson Y. Szeto, MD,[p] Philippe Genereux, MD,[q] Ashish Pershad, MD, MS,[r] Michael Lu, PhD,[s] John G. Webb, MD,[t] Craig R. Smith, MD,[a] Philippe Pibarot, DVM, PhD,[u] for the PARTNER 3 Investigators





Key exclusion criteria

MB Leon et al. J Am Coll Cardiol. 2021, 77 (9) 1149–1161

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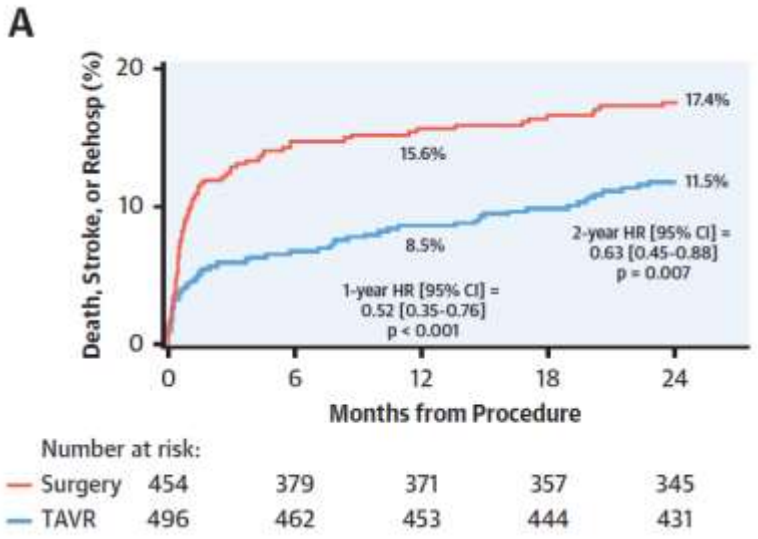


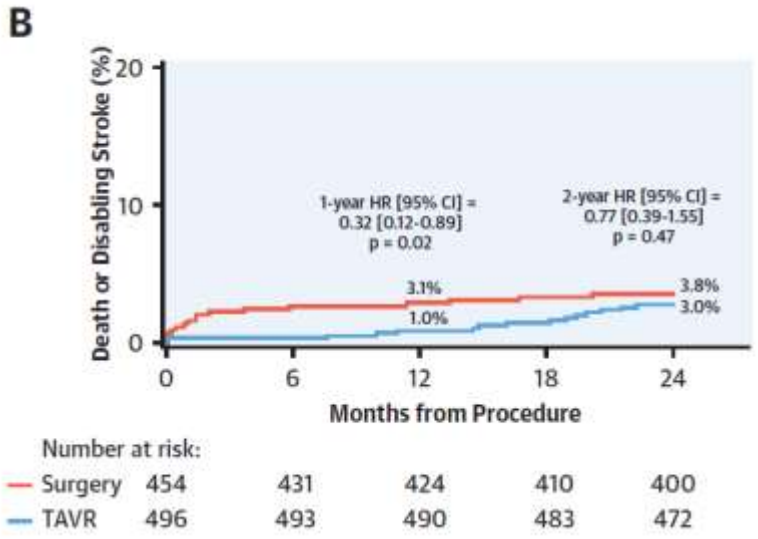


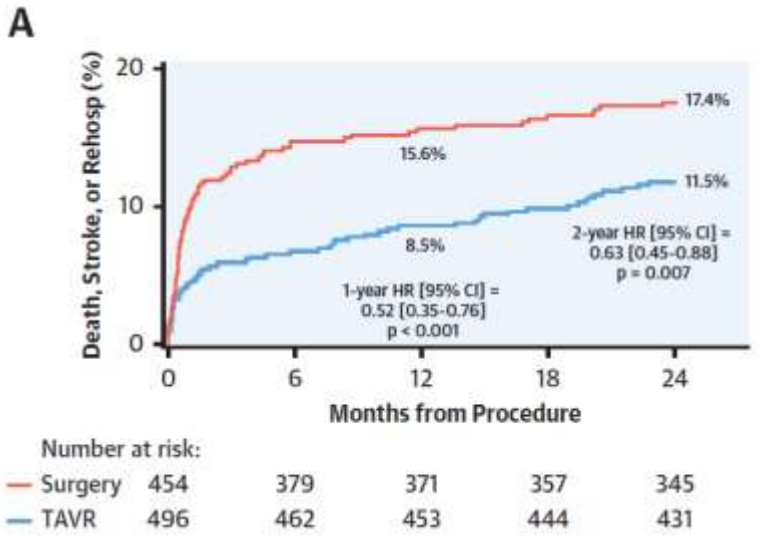
TABLE 2 Key Secondary Endpoints

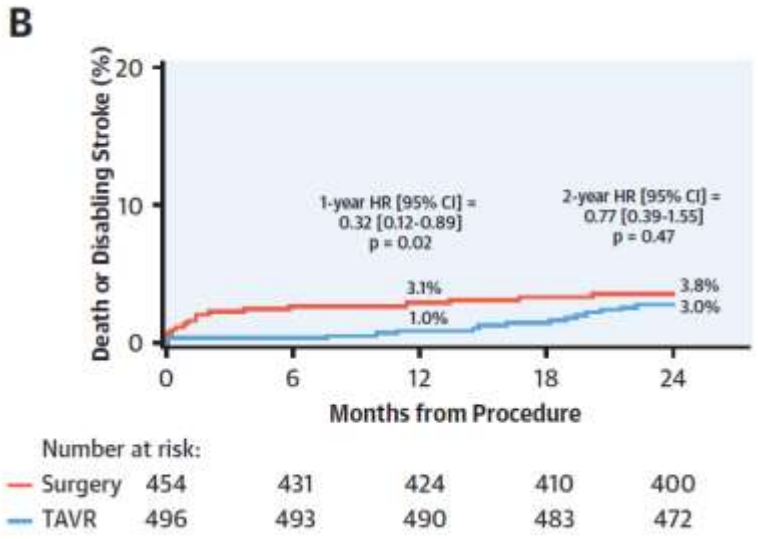
	KM Rate at 1 Year			KM Rate at 2 Years		
	TAVR (n = 496)	SAVR (n = 454)	p Value	TAVR (n = 496)	SAVR (n = 454)	p Value
MI	6 (1.2)	10 (2.2)	0.23	9 (1.8)	12 (2.7)	0.36
New-onset atrial fibrillation	30 (7.2)	150 (40.9)	<0.001	33 (7.9)	153 (41.8)	<0.001
New PPM (excluding baseline)	38 (7.9)	25 (5.8)	0.18	44 (9.1)	30 (7.0)	0.21
New PPM (including baseline)	38 (7.7)	25 (5.6)	0.18	44 (8.9)	30 (6.8)	0.20
New LBBB (excluding baseline)	98 (20.4)	35 (8.0)	<0.001	100 (20.8)	42 (9.7)	<0.001
New LBBB (including baseline)	98 (19.8)	35 (7.7)	<0.001	100 (20.2)	42 (9.4)	<0.001
Coronary obstruction	1 (0.2)	3 (0.7)	0.28	1 (0.2)	3 (0.7)	0.28
AV re-intervention	3 (0.6)	2 (0.5)	0.76	4 (0.8)	4 (0.9)	0.85
Endocarditis	1 (0.2)	2 (0.5)	0.49	1 (0.2)	4 (0.9)	0.13
Valve thrombosis*	5 (1.0)	1 (0.2)	0.13	13 (2.6)	3 (0.7)	0.02

PARTNER3 Trial – 2 YEAR FU

Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk

Martin B. Leon, MD,[a,b] Michael J. Mack, MD,[c] Rebecca T. Hahn, MD,[a,b] Vinod H. Thourani, MD,[d] Raj Makkar, MD,[e] Susheel K. Kodali, MD,[f] Maria C. Alu, MS,[a,b] Mahesh V. Madhavan, MD,[a,b] Katherine H. Chau, MD, MS,[a] Mark Russo, MD, MS,[g] Samir R. Kapadia, MD,[h] S. Chris Malaisrie, MD,[i] David J. Cohen, MD, MSc,[j] Philipp Blanke, MD,[k] Jonathon A. Leipsic, MD,[k] Mathew R. Williams, MD,[l] James M. McCabe, MD,[a] David L. Brown, MD,[c] Vasilis Babaliaros, MD,[m] Scott Goldman, MD,[n] Howard C. Herrmann, MD,[o] Wilson Y. Szeto, MD,[p] Philippe Genereux, MD,[q] Ashish Pershad, MD, MS,[q] Michael Lu, PhD,[r] John G. Webb, MD,[s] Craig R. Smith, MD,[a] Philippe Pibarot, DVM, PhD,[t] for the PARTNER 3 Investigators





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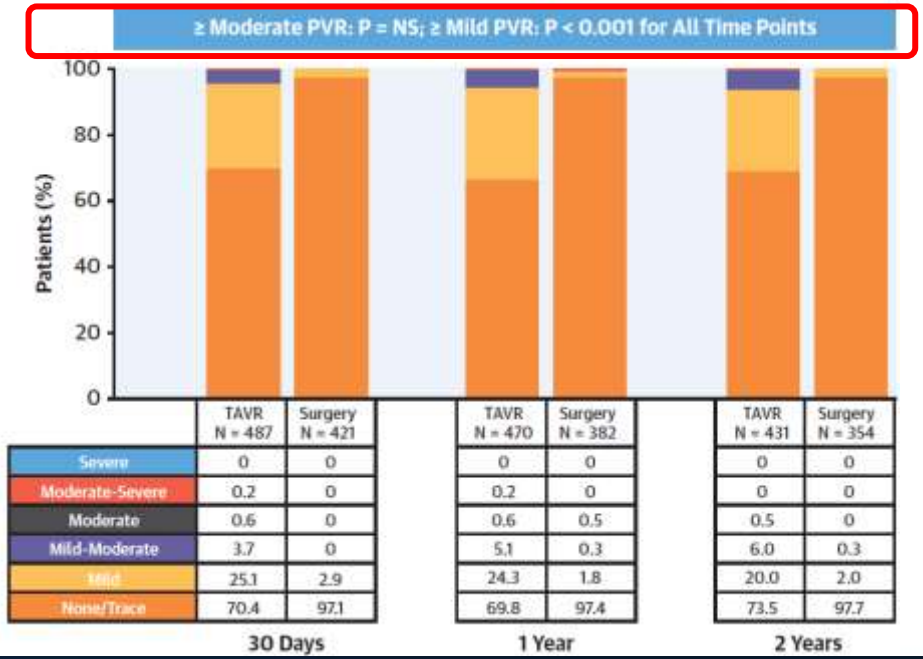


Points to improve

- Rhythm abnormality
  - New onset LBBB and PM implantation
- Valve thrombosis
  - Need of Adequate antithrombotic strategy
- Paravalvular leakage

POINTS TO IMPROVE
: RHYTHM ABNORMALITY

Points to improve: PM implantation

Predictors of Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement With the SAPIEN 3

Victor Mauri, MD,[a] Andreas Reimann,[a] Daniel Stern, MD,[a] Maximilian Scherner, MD,[b] Elmar Kuhn, MD,[b] Volker Rudolph, MD,[a] Stephan Rosenkranz, MD,[a] Kaveh Eghbalzadeh, MD,[b] Kai Friedrichs, MD,[a] Thorsten Wahlers, MD,[b] Stephan Baldus, MD,[a] Navid Madershahian, MD,[b] Tanja K. Rudolph, MD[a]

TABLE 6 Univariate and Multivariate Regression Analysis to Identify Predictors of Permanent Pacemaker Implantation

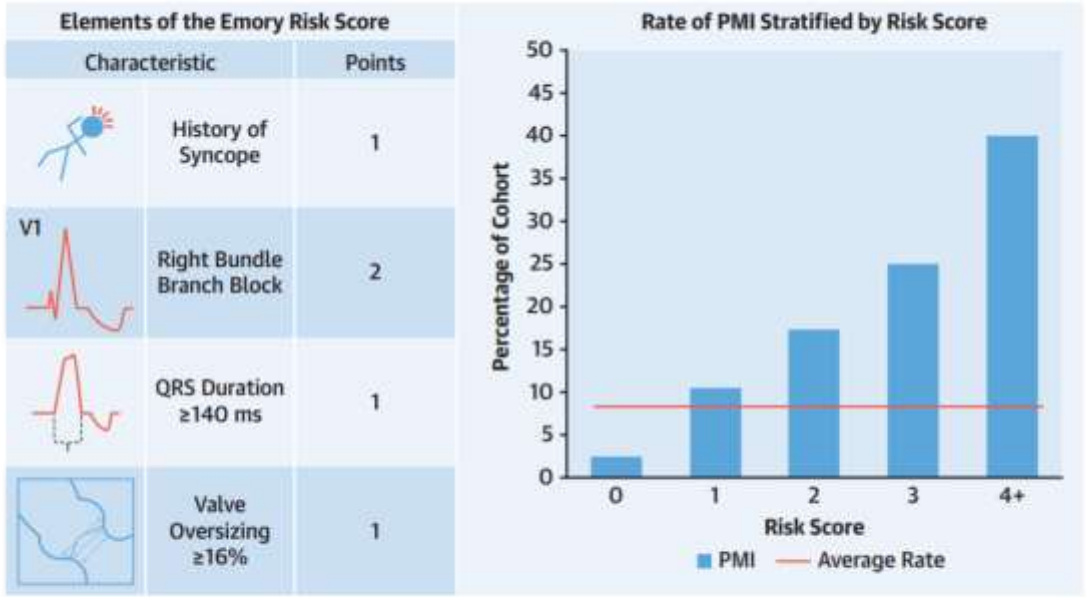
	Univariate Analysis			Multivariate Analysis		
	OR	95% CI	p Value	OR	95% CI	p Value
Age (yrs)	1.1	0.99–1.13	0.094			
Female	1.9	0.89–3.98	0.096			
LVEF	1.0	0.98–1.04	0.618			
Logistic EuroSCORE I	1.0	0.96–1.03	0.619			
Atrial fibrillation	0.9	0.40–1.92	0.749			
AVB grade I	0.8	0.18–3.74	0.787			
LBBB	1.8	0.22–14.42	0.588			
RBBB	8.3	2.11–32.98	0.003	16.9	3.0–95.5	0.001
Incomplete RBBB	2.0	0.38–10.26	0.417			
NCC calcification >790.8 mm^3	3.0	0.97–9.29	0.056			
RCC calcification >203.8 mm^3	0.6	0.29–1.30	0.200			
LCC calcification >131.4 mm^3	2.2	0.93–5.02	0.075			
$LVOT_{NC}$ calcification >3.2 mm^3	2.9	1.20–7.01	0.018	0.8	0.2–2.9	0.736
$LVOT_{RC}$ calcification >4.8 mm^3	4.0	1.83–8.58	<0.001	4.7	1.6–14.1	0.005
$LVOT_{LC}$ calcification >13.7 mm^3	4.4	2.02–9.70	<0.001	3.7	1.3–10.6	0.016
Pre-dilation	1.9	0.90–4.12	0.094			
Post-dilation	2.7	0.66–10.96	0.169			
Out-of-range oversizing	0.4	0.09–1.71	0.210			
Oversizing >20%	0.6	0.17–2.10	0.424			
Implantation depth >25.5% ventricular part of the stent frame	9.7	4.32–21.90	<0.001	15.7	5.7–43.5	<0.001

CI = confidence interval; OR = odds ratio; other abbreviations as in Table 1.

Development of a Risk Score to Predict New Pacemaker Implantation After Transcatheter Aortic Valve Replacement

Soroosh Kiani, MD,[a] Norihiko Kamioka, MD,[a] George B. Black, MD,[a] Marvin Louis Roy Lu, MD,[a] John C. Lisko, MD,[a] Birju Rao, MD,[b] Andenet Mengistu, BS,[a] Patrick T. Gleason, MD,[a] James P. Stewart, BS,[a] Hope Caughron, MD,[b] Andy Dong, BS,[b] Hima Patel, BS,[b] Kendra J. Grubb, MD,[c] Adam B. Greenbaum, MD,[a] Chandan M. Devireddy, MD,[a] Robert A. Guyton, MD,[c] Bradley Leshnower, MD,[c] Faisal M. Merchant, MD,[a] Mikhael El-Chami, MD,[a] Stacy B. Westerman, MD,[a] Michael S. Lloyd, MD,[a] Vasilis C. Babaliaros, MD,[a] Michael H. Hoskins, MD[a]

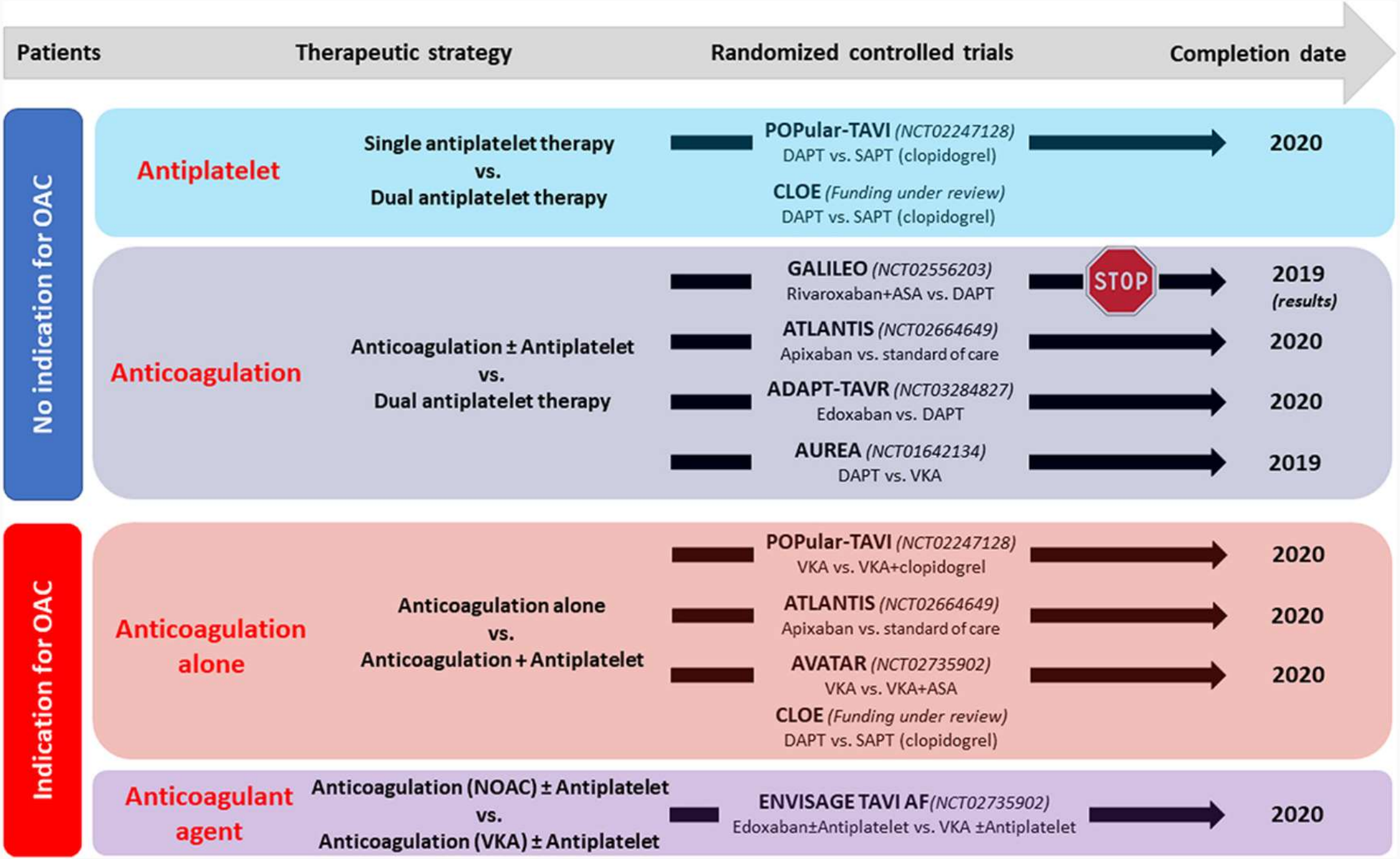
CENTRAL ILLUSTRATION The Emory Risk Score to Predict the Need for Pacemaker Implantation After Transcatheter Aortic Valve Replacement



Kiani, S. et al. J Am Coll Cardiol Intv. 2019;12(21):2133–42.

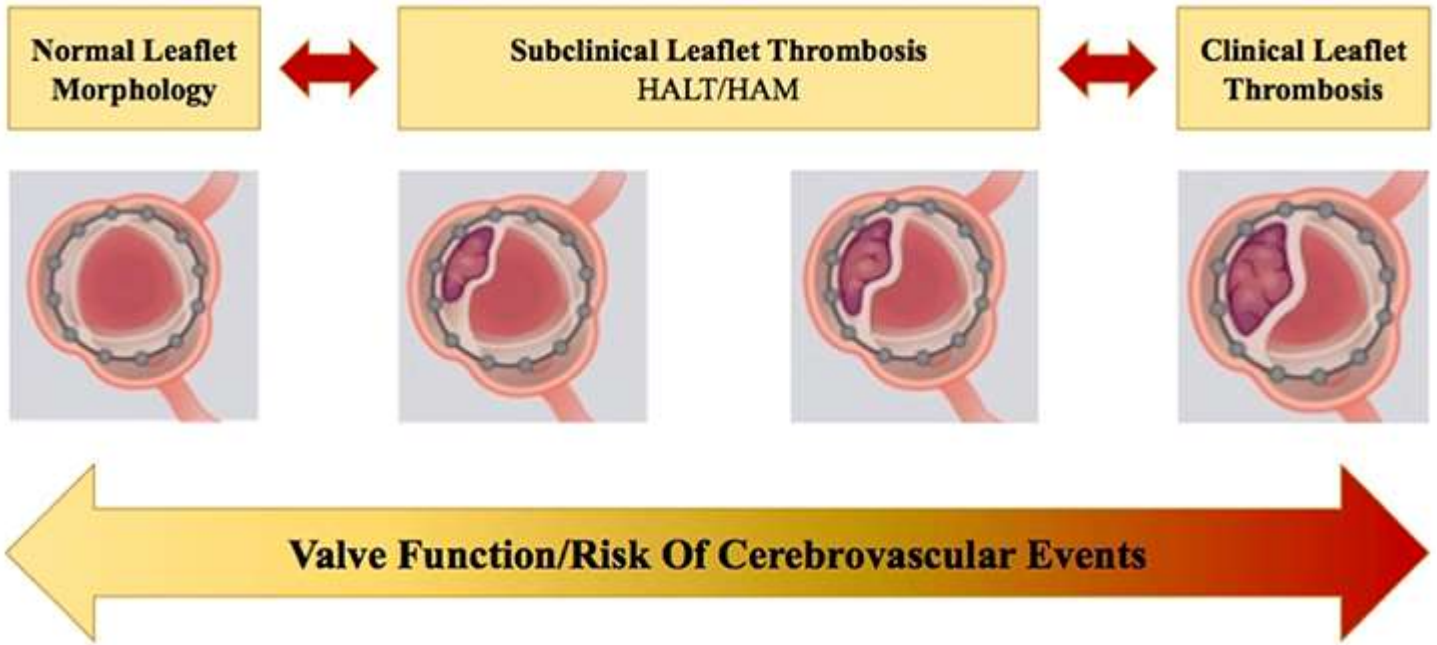
(Left) Elements included in the risk score and points assigned for each when positive. **(Right)** The rate of pacemaker implantation (PMI) at each level of the Emory risk score. The **solid line** denotes the average rate of PMI across the entire cohort (8.2%). Because there was only 1 patient with a risk score >4 (this patient was in the PMI group), these scores were combined into the "4+" category. On 1-way analysis of variance between groups, $p < 0.001$. TAVR = transcatheter aortic valve replacement.

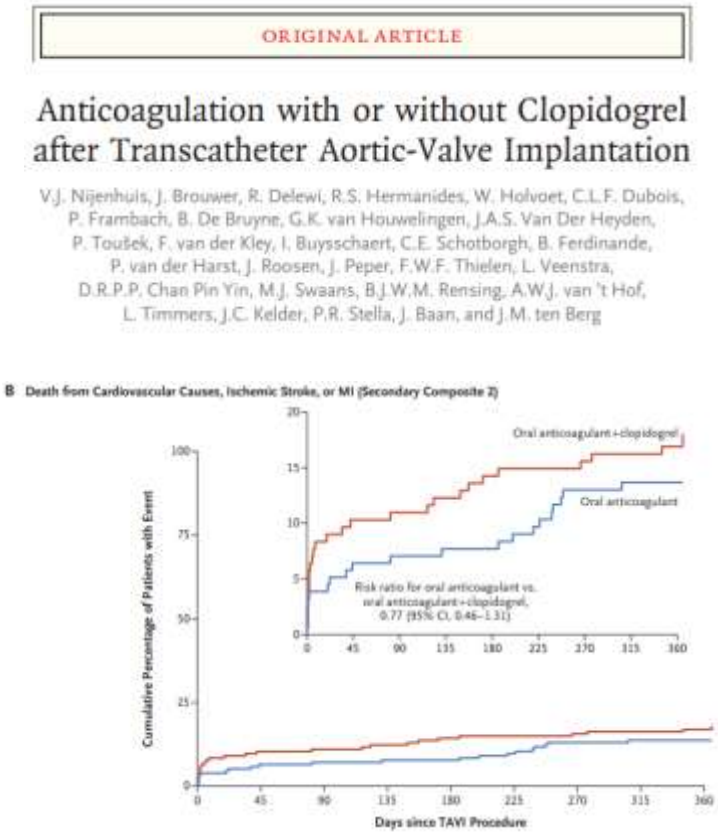
POINTS TO IMPROVE
: VALVULAR THROMBOSIS


Patients
Therapeutic strategy
Randomized controlled trials
Completion date
No indication for OAC
Antiplatelet
Single antiplatelet therapy
vs.
Dual antiplatelet therapy
POPular-TAVI (NCT02247128)
DAPT vs. SAPT (clopidogrel)
2020
CLOE (Funding under review)
DAPT vs. SAPT (clopidogrel)
Anticoagulation
Anticoagulation ± Antiplatelet
vs.
Dual antiplatelet therapy
GALILEO (NCT02556203)
Rivaroxaban+ASA vs. DAPT
STOP
2019
(results)
ATLANTIS (NCT02664649)
Apixaban vs. standard of care
2020
ADAPT-TAVR (NCT03284827)
Edoxaban vs. DAPT
2020
AUREA (NCT01642134)
DAPT vs. VKA
2019
Indication for OAC
Anticoagulation alone
Anticoagulation alone
vs.
Anticoagulation + Antiplatelet
POPular-TAVI (NCT02247128)
VKA vs. VKA+clopidogrel
2020
ATLANTIS (NCT02664649)
Apixaban vs. standard of care
2020
AVATAR (NCT02735902)
VKA vs. VKA+ASA
2020
CLOE (Funding under review)
DAPT vs. SAPT (clopidogrel)
Anticoagulant agent
Anticoagulation (NOAC) ± Antiplatelet
vs.
Anticoagulation (VKA) ± Antiplatelet
ENVISAGE TAVI AF (NCT02735902)
Edoxaban±Antiplatelet vs. VKA ±Antiplatelet
2020

Points to improve: Antithrombotic medication

Document	Year		Recommendations			Duration
ESC/EACTS guidelines	2017	No OAC	DAPT should be considered, followed by SAPT	IIa	C	3–6 months DAPT, then SAPT lifelong
			SAPT may be considered after TAVR in the case of high bleeding risk	IIb	C	No specific recommendation
		OAC	Oral anticoagulation is recommended	I	C	Lifelong
ACC/AHA guidelines	2017	No OAC	Clopidogrel 75 mg daily may be reasonable in addition to aspirin 75-100 mg daily	IIb	C	6 month DAPT, then aspirin lifelong
			Anticoagulation with VKA (INR 2.5) may be reasonable in patients at low risk of bleeding	IIb	B	At least 3 months
		OAC	No specific recommendations			No specific recommendations




ORIGINAL ARTICLE

Anticoagulation with or without Clopidogrel after Transcatheter Aortic-Valve Implantation

V.J. Nijenhuis, J. Brouwer, R. Delewi, R.S. Hermanides, W. Holvoet, C.L.F. Dubois, P. Frambach, B. De Bruyne, G.K. van Houwelingen, J.A.S. Van Der Heyden, P. Toušek, F. van der Kley, I. Buysschaert, C.E. Schotborgh, B. Ferdinande, P. van der Harst, J. Roosen, J. Peper, F.W.F. Thielen, L. Veenstra, D.R.P.P. Chan Pin Yin, M.J. Swaans, B.J.W.M. Rensing, A.W.J. van 't Hof, L. Timmers, J.C. Kelder, P.R. Stella, J. Baan, and J.M. ten Berg

ISSUE OF PARAVALVULAR LEAKAGE

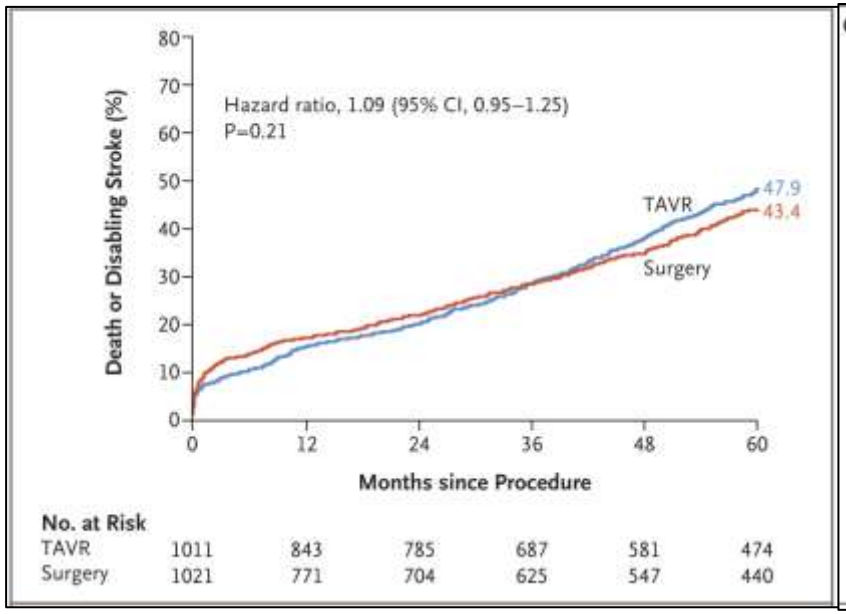
With a case presentation

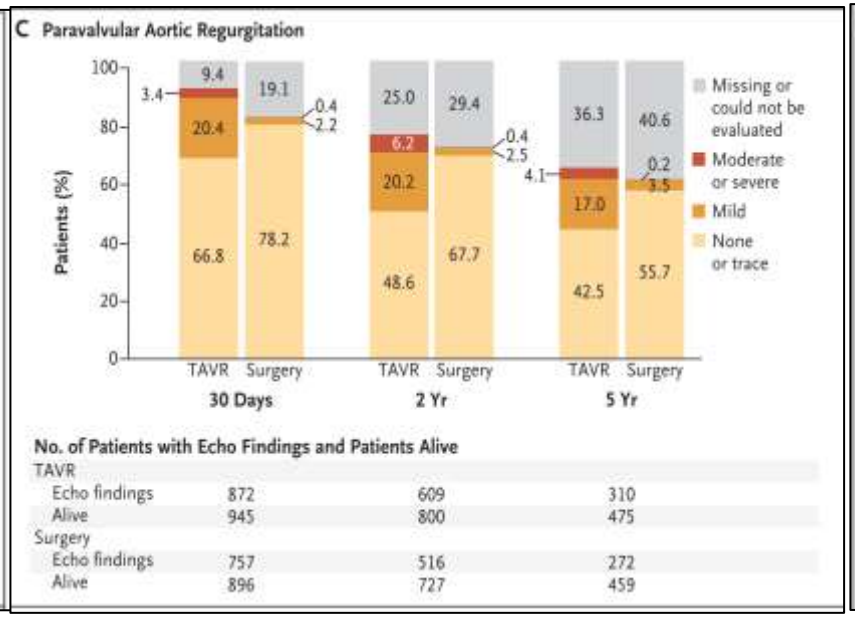
Paravalvular leakage

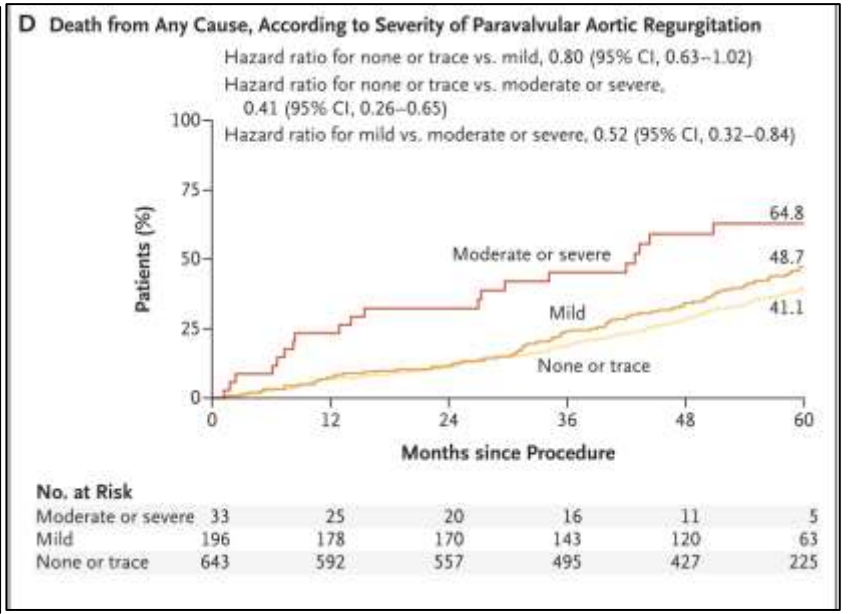
The NEW ENGLAND JOURNAL of MEDICINE

Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement

- PVL is associated with ***increased mortality***. Directly or indirectly? Still unknown.
- Factors associated with PVL
  - **Anatomical, clinical risk factors**
    - AV, aortic annulus calcification, anatomy of the aortic annulus, LVOT-ascending aorta angle
  - **Valvular, Procedural factors**
    - Generation of valve, size of valves, depth of implantation, pre/post balloon angioplasty, etc.







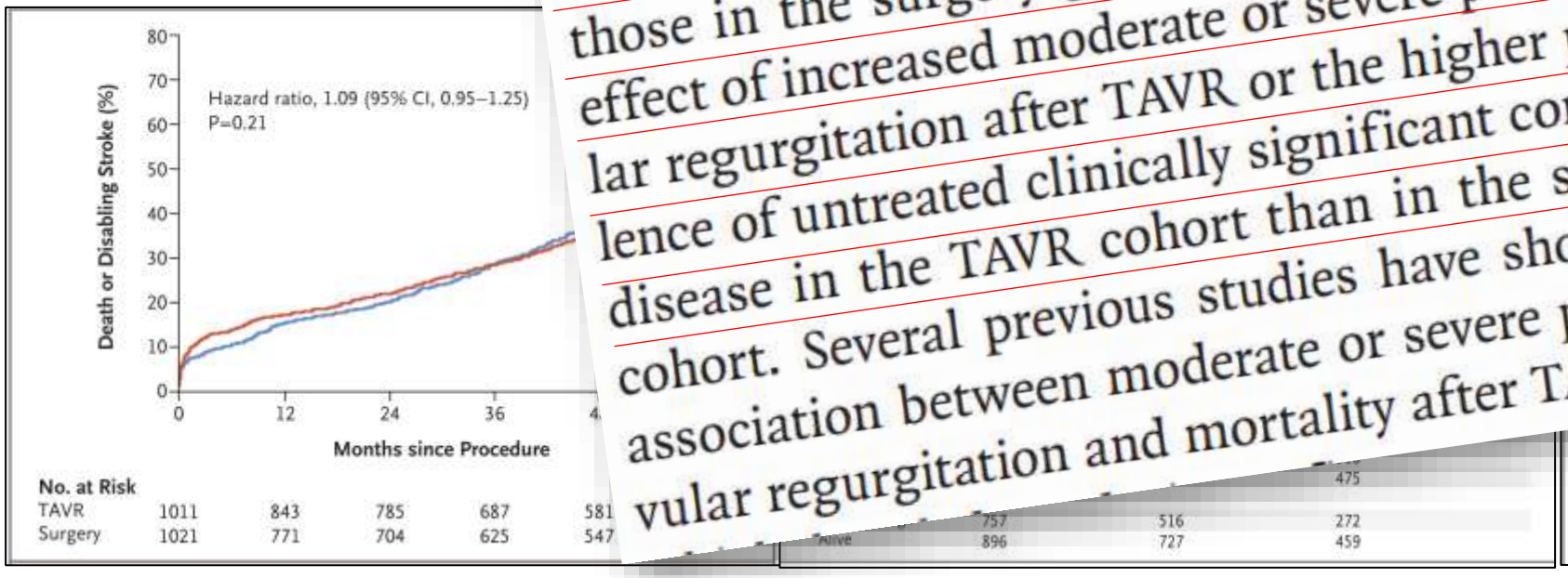
Paravalvular leakage

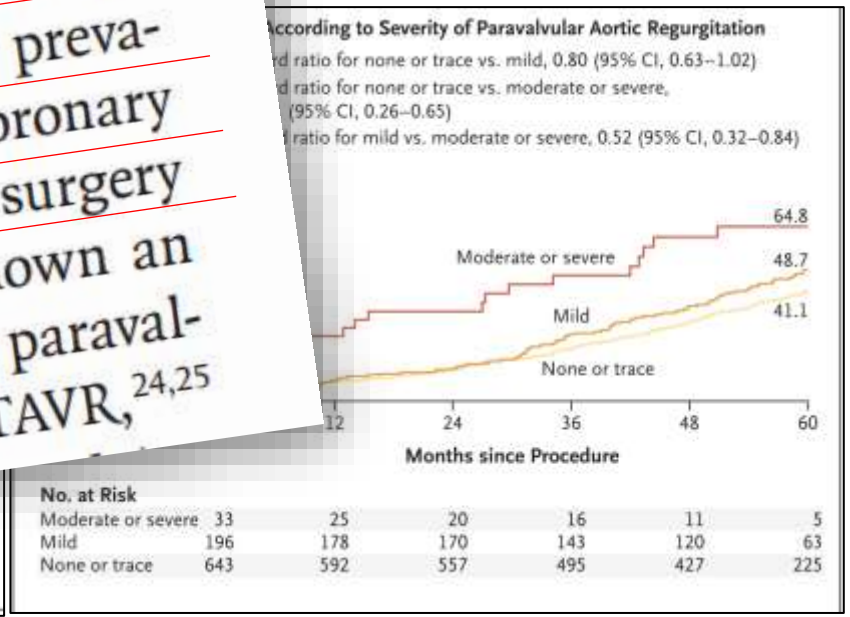
- PVL is associated with ***increased mortality*** ll unknown.
- Factors associat
  - **Anatomical, c**
    - AV, aortic ar a angle
  - **Valvular, Proce**
    - Generation o ty, etc.

The NEW ENGLAND JOURNAL of MEDICINE

Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement

death from any cause or disabling stroke and a higher incidence of death from any cause with TAVR than with surgery. Possible explanations for the higher mortality during this time period among patients in the TAVR group than among those in the surgery group may be the negative effect of increased moderate or severe paravalvular regurgitation after TAVR or the higher prevalence of untreated clinically significant coronary disease in the TAVR cohort than in the surgery cohort. Several previous studies have shown an association between moderate or severe paravalvular regurgitation and mortality after TAVR,[24,25]





Case

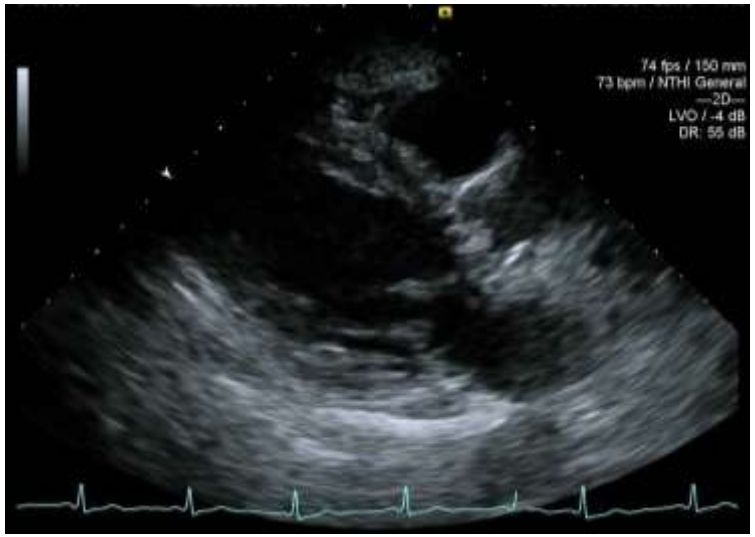
- **72/F**

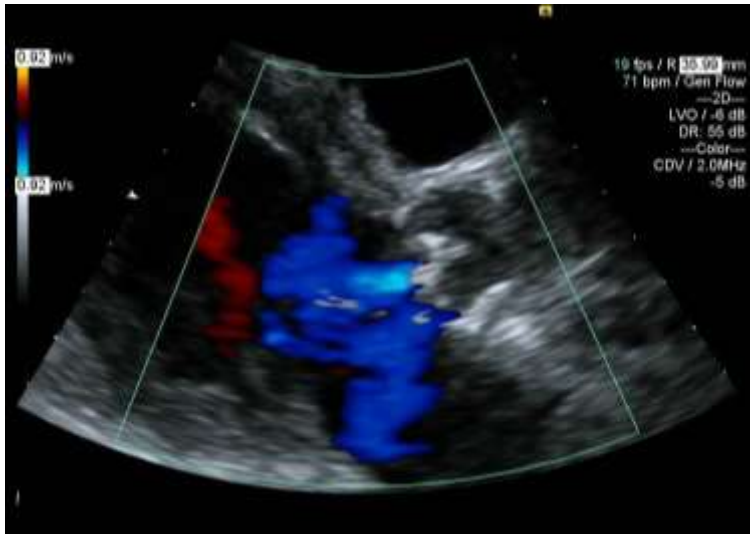
#. Severe AS

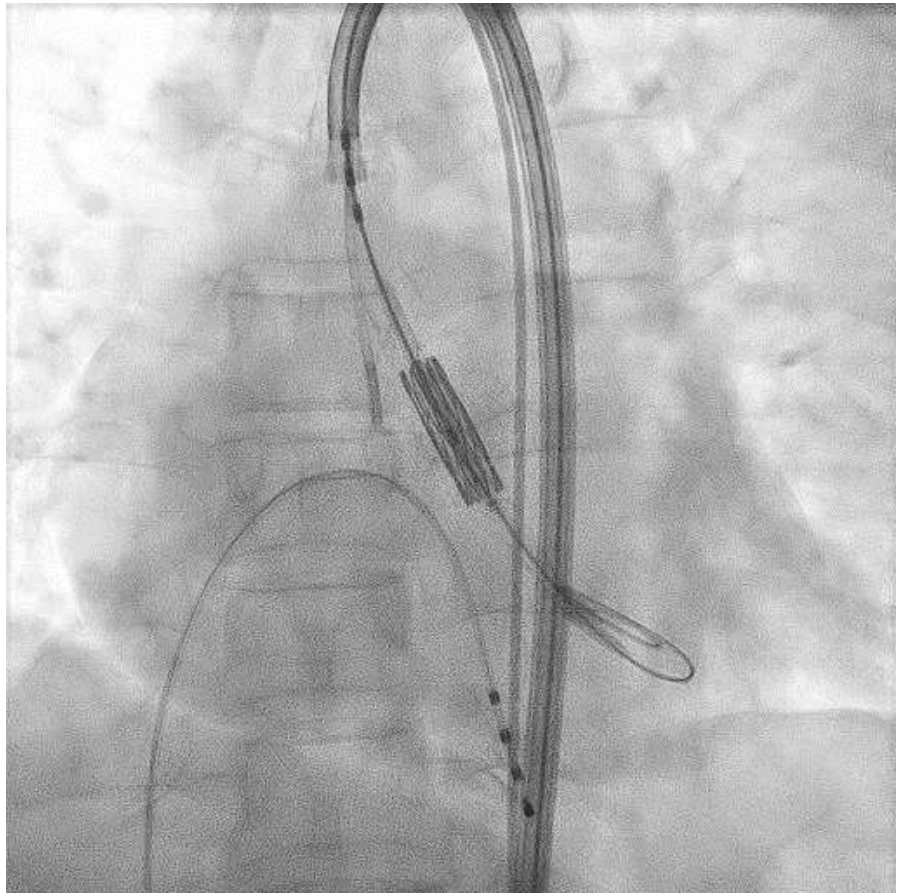
#. h/o cerebral aneurysm rupture (’98) [*Sequelae: Rt side weakness]

#. h/o ESWL for Renal stone

#. TAVI with Sapien3 **(+1.5cc, 11.7% oversizing)**

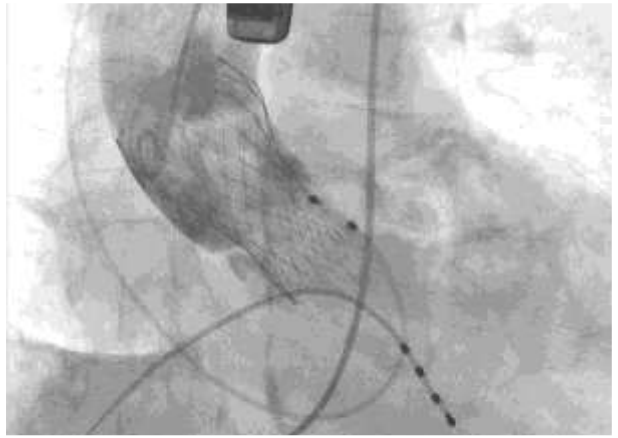
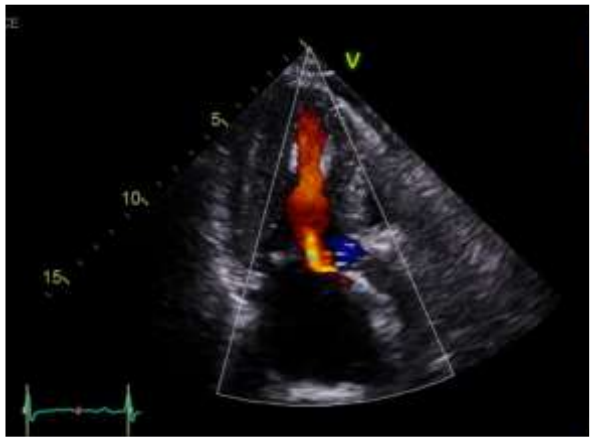






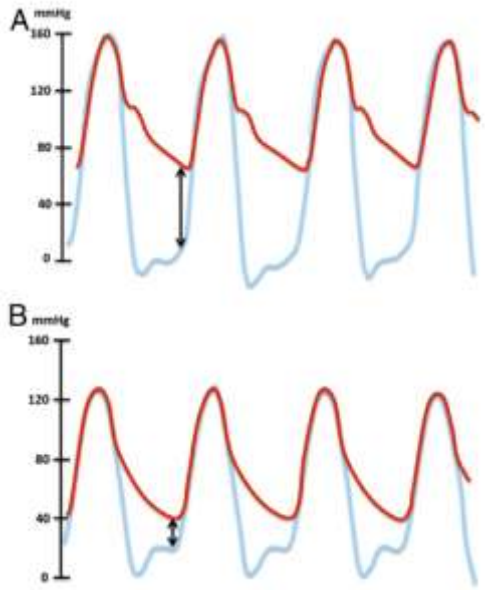
Case

- **How can we assess PVL**

Angiography	Echocardiography	Hemodynamic index
		
Reproducible Peri-procedural assessment	Most accurate	Reproducible Quantitative Investigator independent
Highly subjective Iodine contrast use	Investigator dependent Sedation is necessary for TEE	False positive and false negative

Case

- **How can we assess PVL**
  - **AR index:** A simple, reproducible, and point-of-care assessment of periAR during TAVI
  - Patients (N=146) who underwent TAVI with CoreValve Prosthesis
  - Primary End point: 1 year all-cause mortality



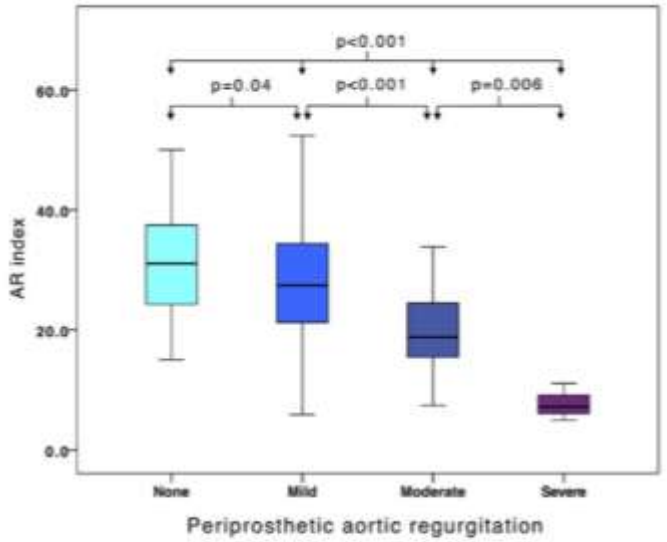


Figure 2 AR Index According to Degree of PeriAR

The AR index according to the degree of periAR as assessed by echocardiography after transcatheter aortic valve implantation. Abbreviations as in Figure 1.

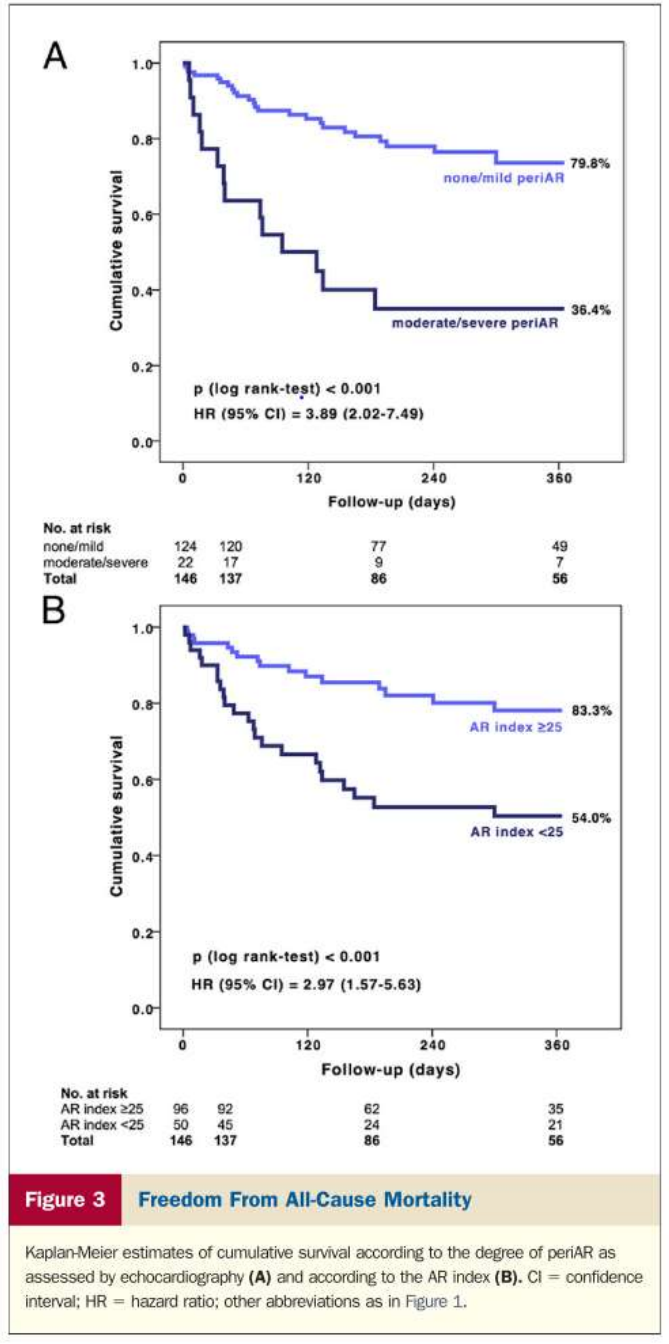


Figure 3 Freedom From All-Cause Mortality

Kaplan-Meier estimates of cumulative survival according to the degree of periAR as assessed by echocardiography **(A)** and according to the AR index **(B).** CI = confidence interval; HR = hazard ratio; other abbreviations as in Figure 1.

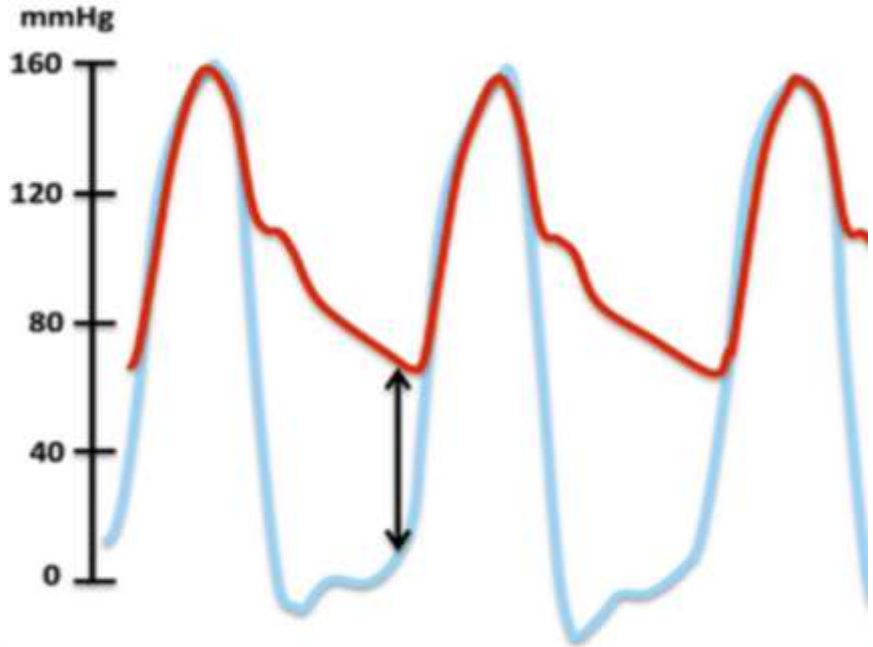
Sinning, J.M., et al., J Am Coll Cardiol, 2012

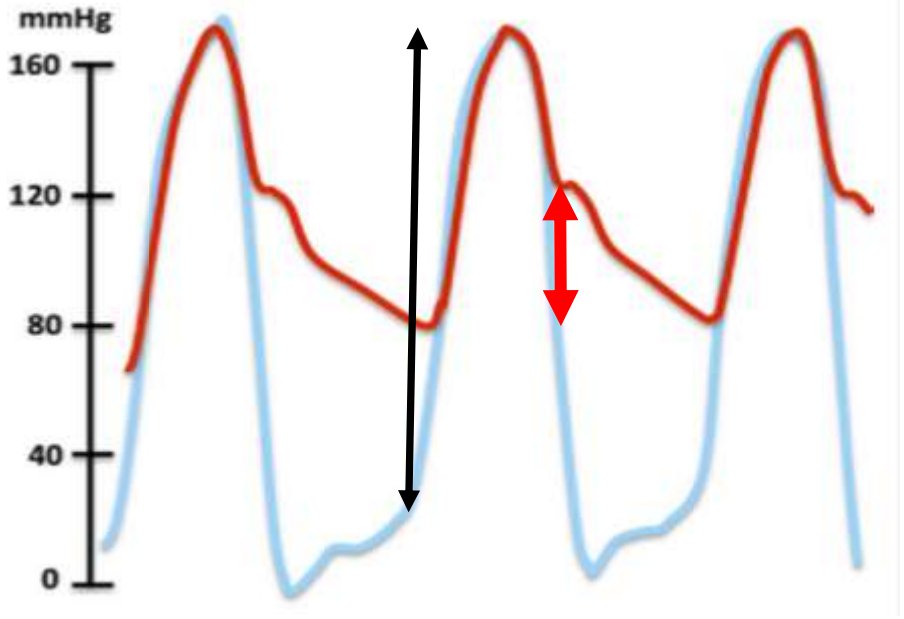
Case

- **How can we assess PVL: Proposal of a new AR index**
  - During the cardiac cycle, AR occurs after the dicrotic notch (RED arrow)
  - The relative pressure drop, compensated by the aortic pressure gradient may be associated with AR

AR index= $\frac{AoDBP-LVEDP}{AoSBP}$ x 100

New AR index= $\frac{AoSBP-LVEDP}{Dicrotic-AoDBP}$



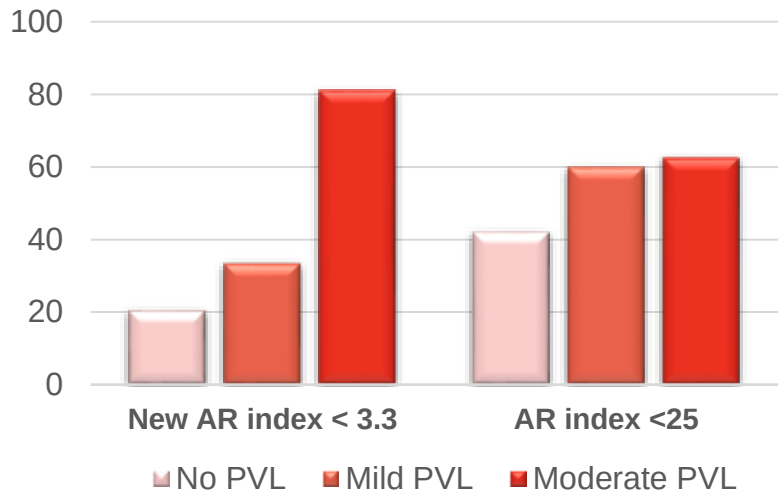


Kang J, Kim HS et al. JACC Cardiovasc Interv. 2020

Case

- **How can we assess PVL: Proposal of a new AR index**
  - Analysis of 287 patients who underwent TAVI and SNUH, with a accurate hemodynamic record, with 1-year follow-up EchoCG..

✓ **Cut of value of 3.3 for the "new AR index"**



$$\text{New AR index} = \frac{AoSBP - LVEDP}{Dicrotic - AoDBP}$$

- **New AR index < 3.3**

Sensitivity 81.2% Specificity 75.3%

PPV 31.7% NPV 96.6%

- **AR index < 25**

Sensitivity 62.5% Specificity 52.0%

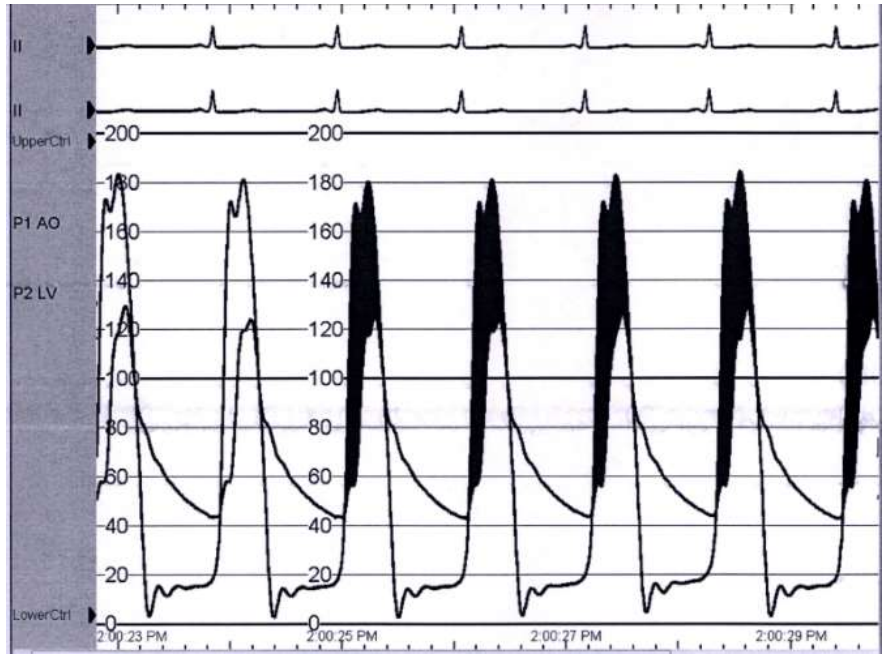
PPV 15.5% NPV 90.7%

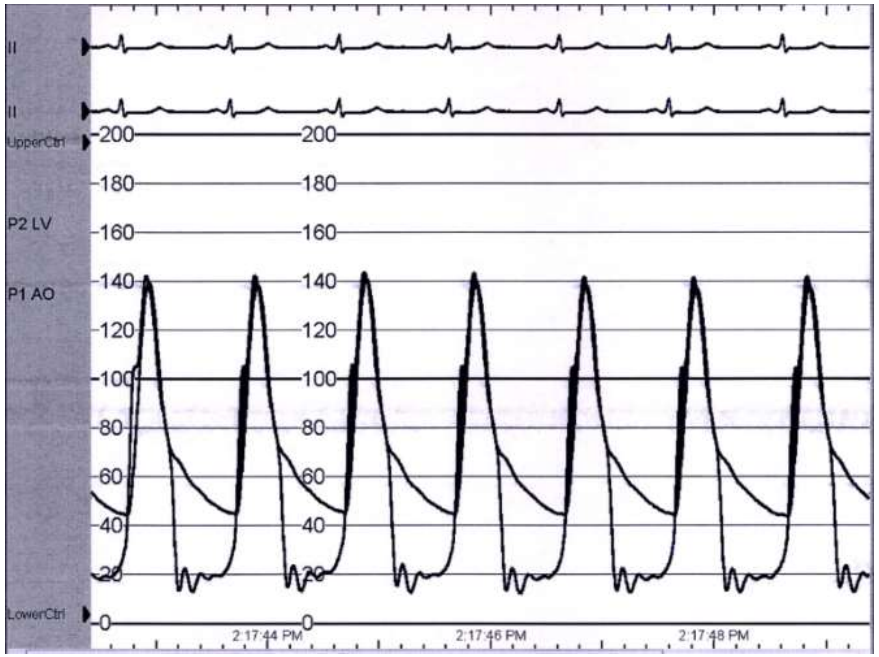
Kang J, Kim HS et al. JACC Cardiovasc Interv. 2020

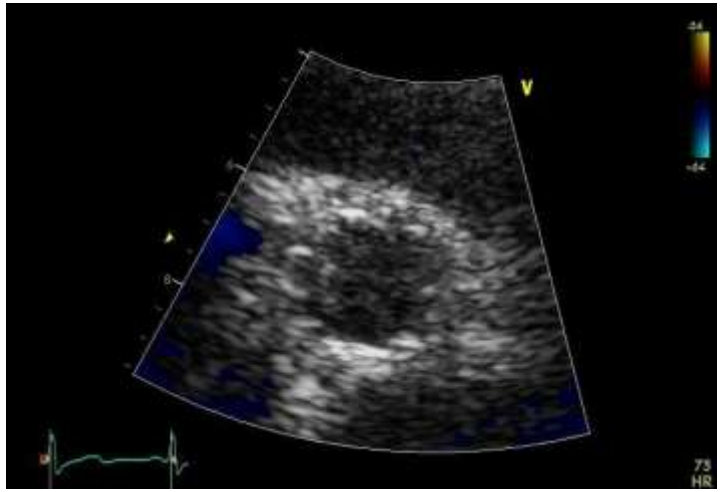
Case

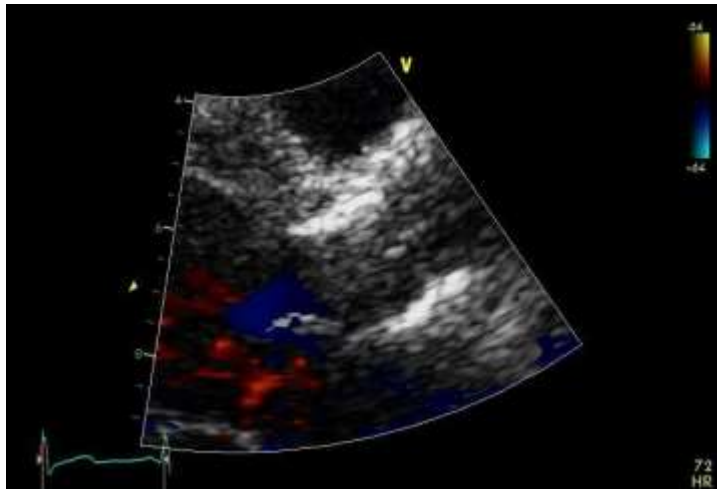
#. TAVI with Sapien3 (+1.5cc, 11.7% oversizing)

- Post TAVI Ao/LV pressure double tracing
- SBP 150 mmHg, DBP 48mmHg
- Dicrotic notch 73mmHg, LVEDP 22mmHg
- **AR index 17.3, new AR index: 5.1**









Take home message and Summary

#. TAVI is expanding its indication for Severe AS treatment

Treating more low risk patients requires more clinical excellency.

#. Compared to the traditional treatment, there are still points to improve.

Rhythm abnormality

Optimal Antithrombotic agent

Paravalvular leakage

#. The '**New AR index**' may be a simple, reproducible and quantitative index to predict PVL during TAVI.

Thank you for your attention