

The Future Trend in TAVR: The Remaining Hurdles

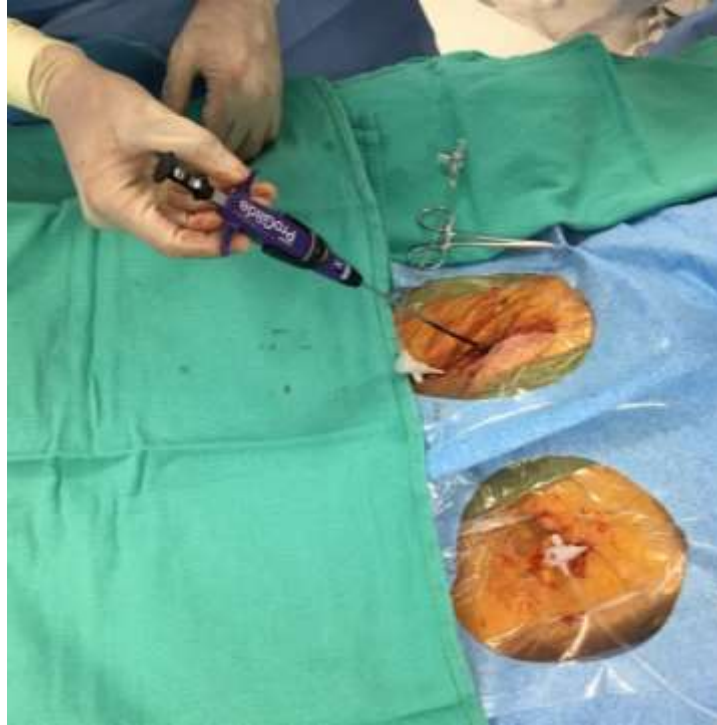
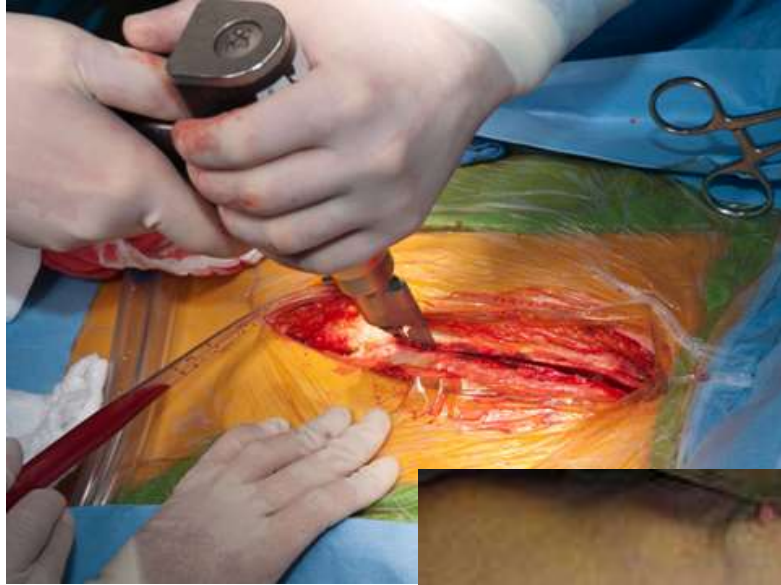
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Professor of Medicine

Chairman, Department of Cardiovascular Medicine

Cleveland Clinic

Change is Real



PARTNER 3 – Low Risk Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

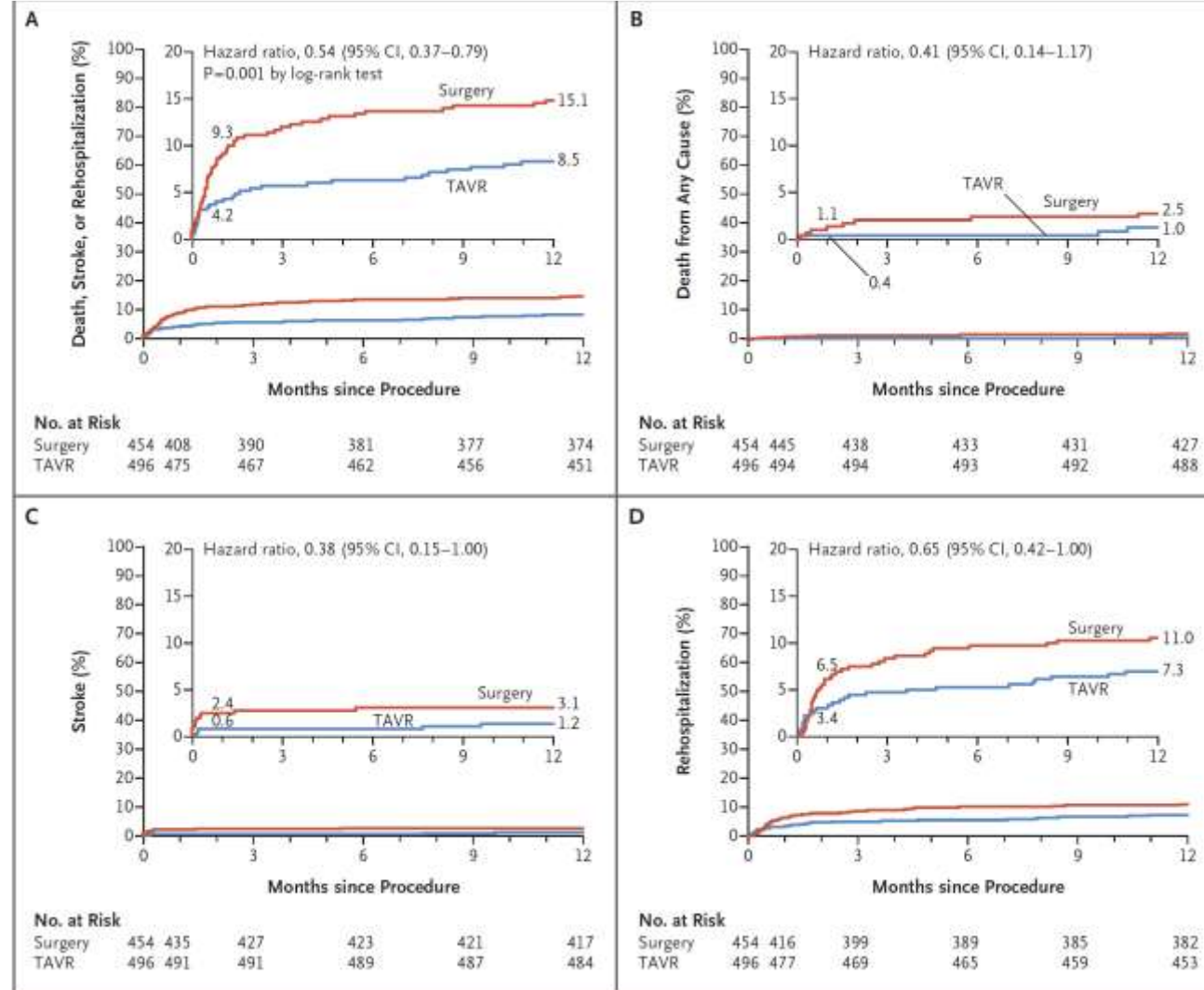
Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

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*

ABSTRACT

BACKGROUND

Among patients with aortic stenosis who are at intermediate or high risk for death with surgery, major outcomes are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. There is insufficient evidence regarding the comparison of the two procedures in patients who are at low risk.



Secondary Endpoints

Outcomes	30 Days			1 Year		
	TAVR (N=496)	Surgery (N=454)	P-value	TAVR (N=496)	Surgery (N=454)	P-value
Bleeding - Life-threat/Major	3.6% (18)	24.5% (111)	<0.001	7.7% (38)	25.9% (117)	<0.001
Major Vascular Complications	2.2% (11)	1.5% (7)	0.45	2.8% (14)	1.5% (7)	0.19
AKI - stage 2 or 3*	0.4% (2)	1.8% (8)	0.05	0.4% (2)	1.8% (8)	0.05
New PPM (incl baseline)	6.5% (32)	4.0% (18)	0.09	7.3% (36)	5.4% (24)	0.21
New LBBB	22.0% (106)	8.0% (35)	<0.001	23.7% (114)	8.0% (35)	<0.001
Coronary Obstruction	0.2% (1)	0.7% (3)	0.28	0.2% (1)	0.7% (3)	0.28
AV Re-intervention	0% (0)	0% (0)	NA	0.6% (3)	0.5% (2)	0.76
Endocarditis	0% (0)	0.2% (1)	0.29	0.2% (1)	0.5% (2)	0.49
Asymp Valve Thrombosis	0.2% (1)	0% (0)	0.34	1.0% (5)	0.2% (1)	0.13

Setup

Common
pump for
OR

Anesthesia
NP

Cardiologist
and Cardiac
surgeon

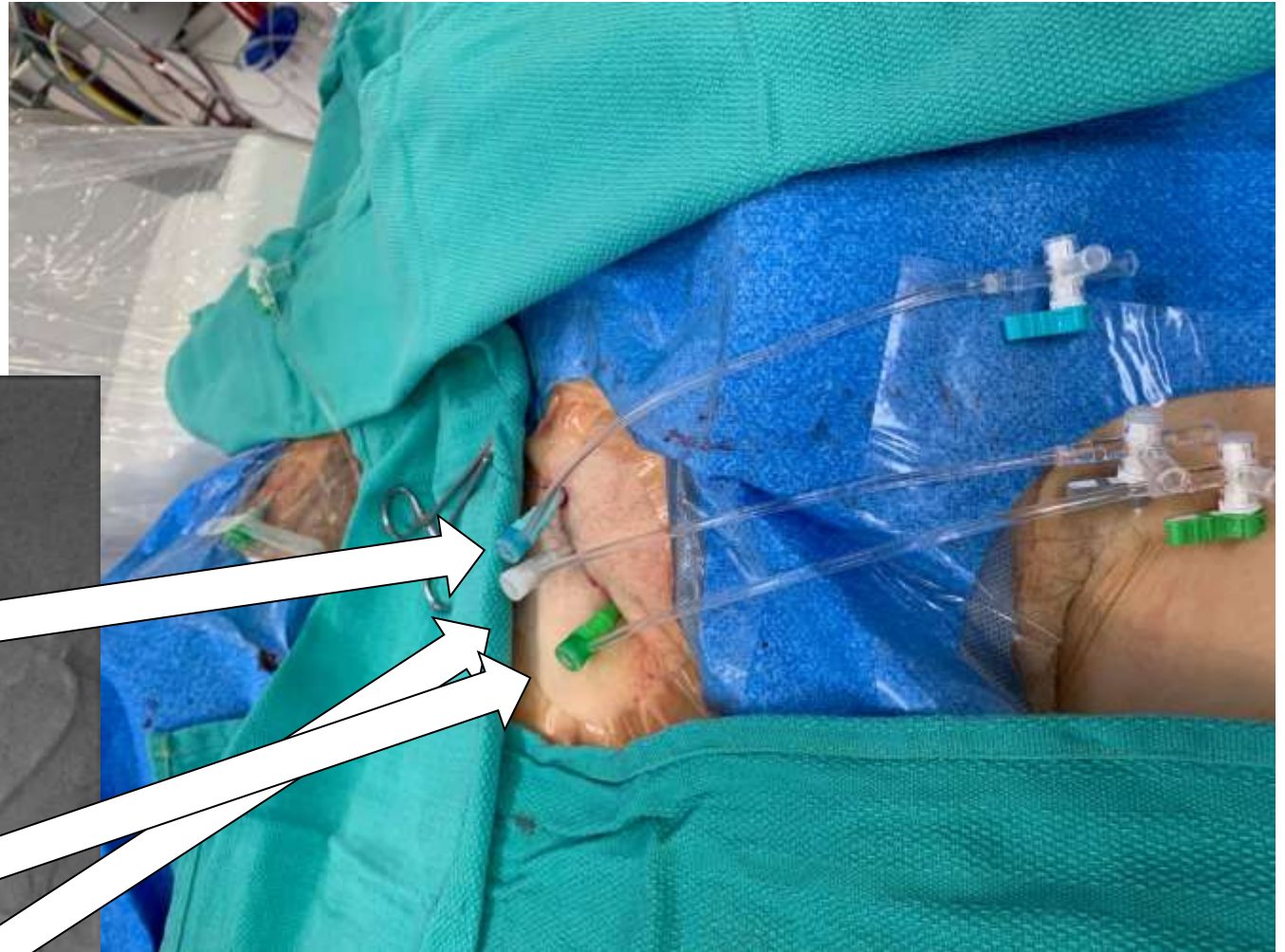
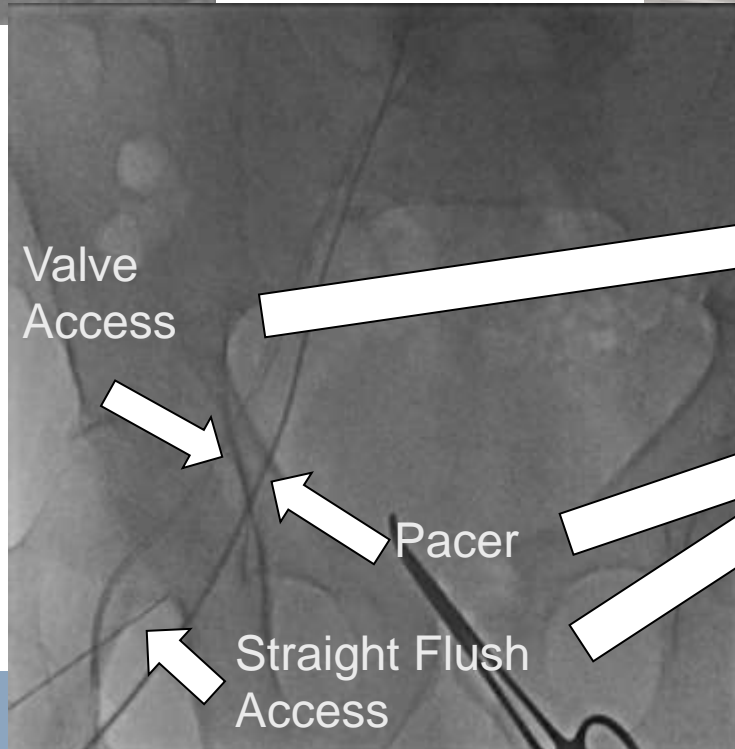
Echo
Technician

One Nurse

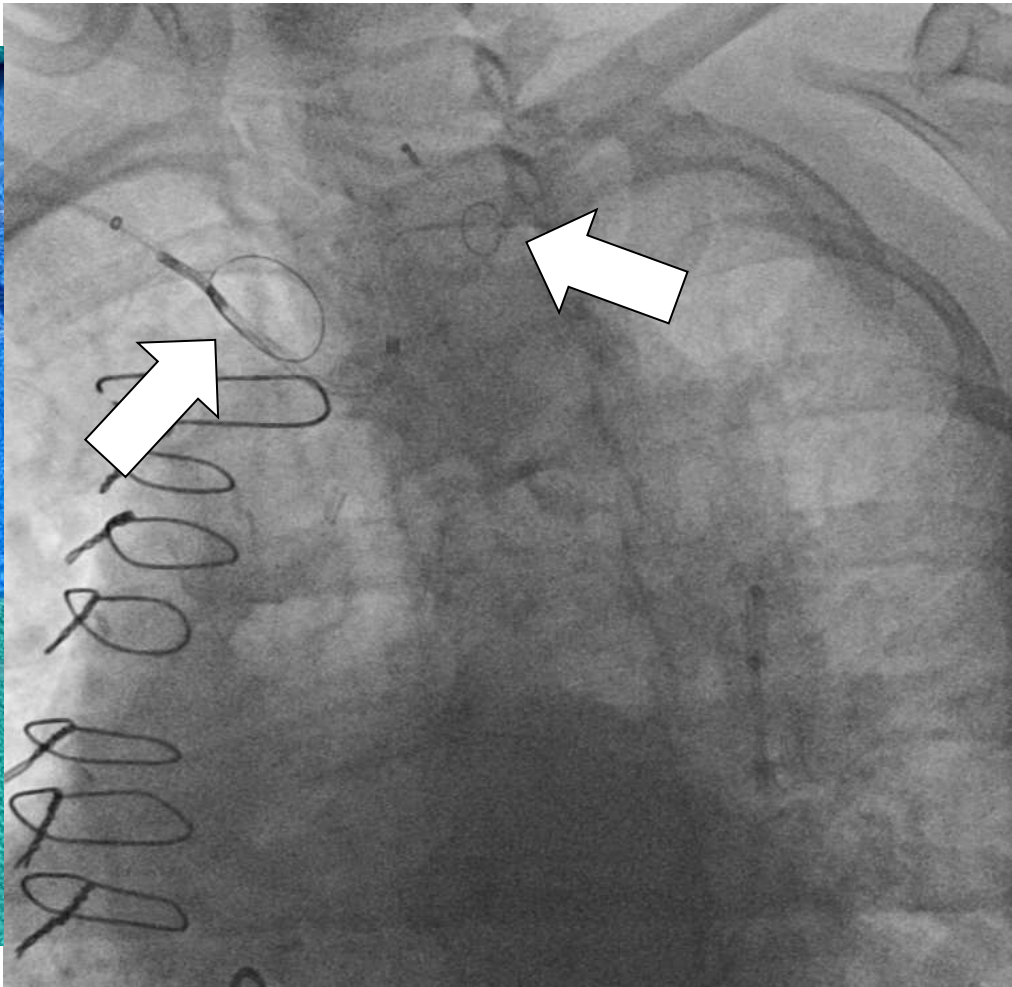
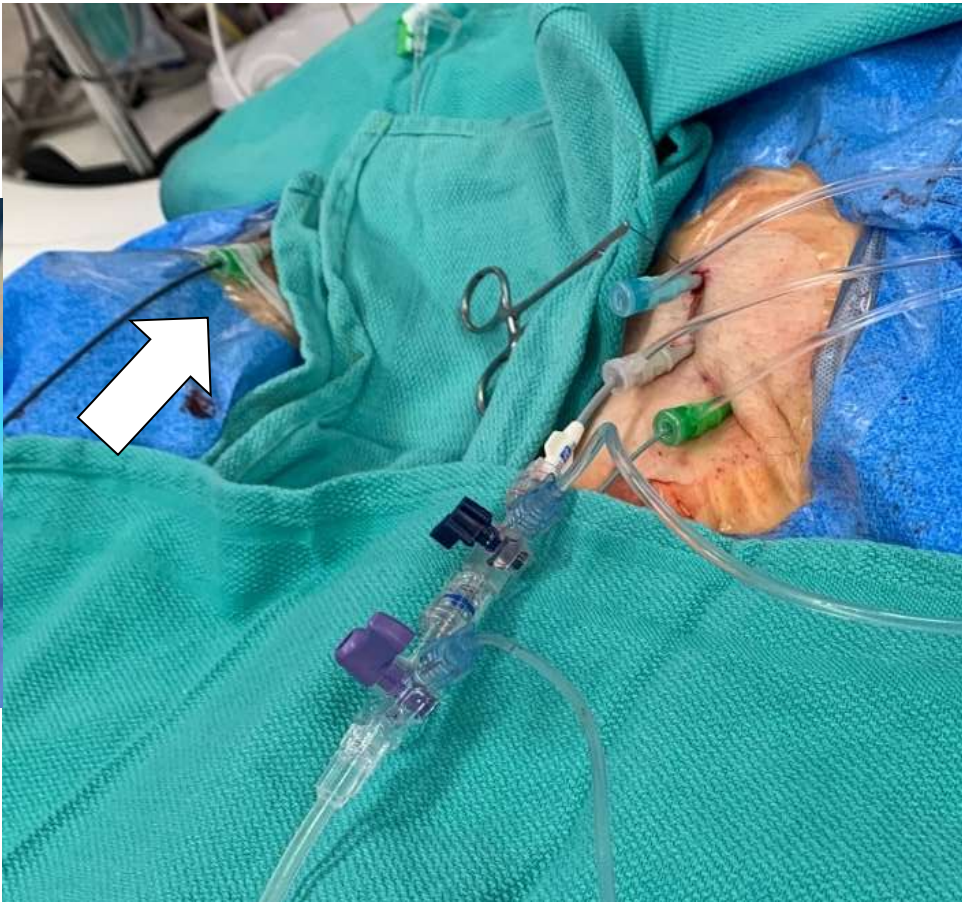
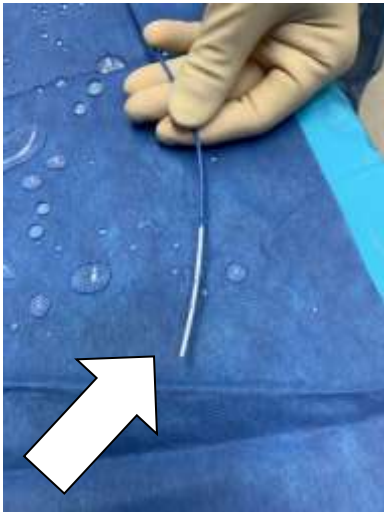


No GA, No Swan Ganz, No Arterial Line, No Foley

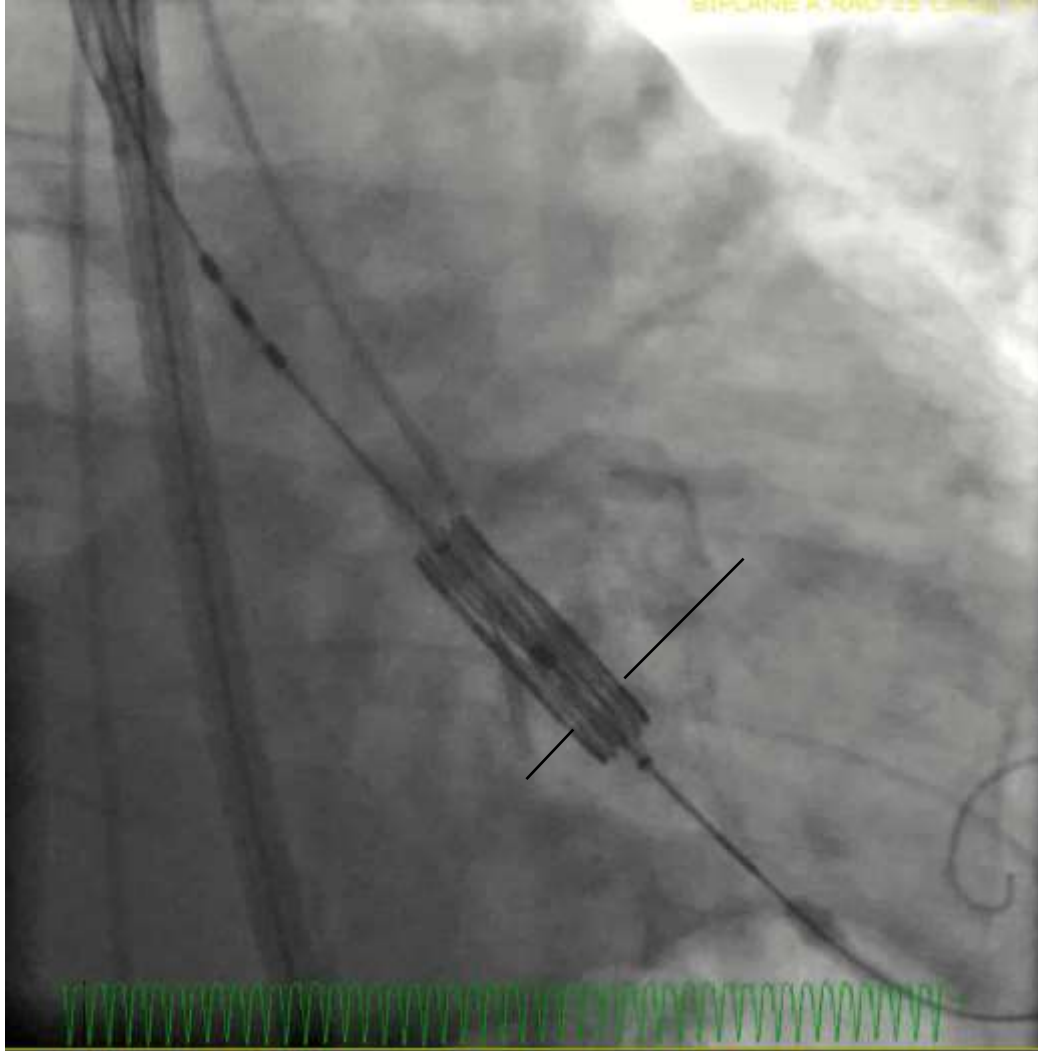
Access



Sentinel

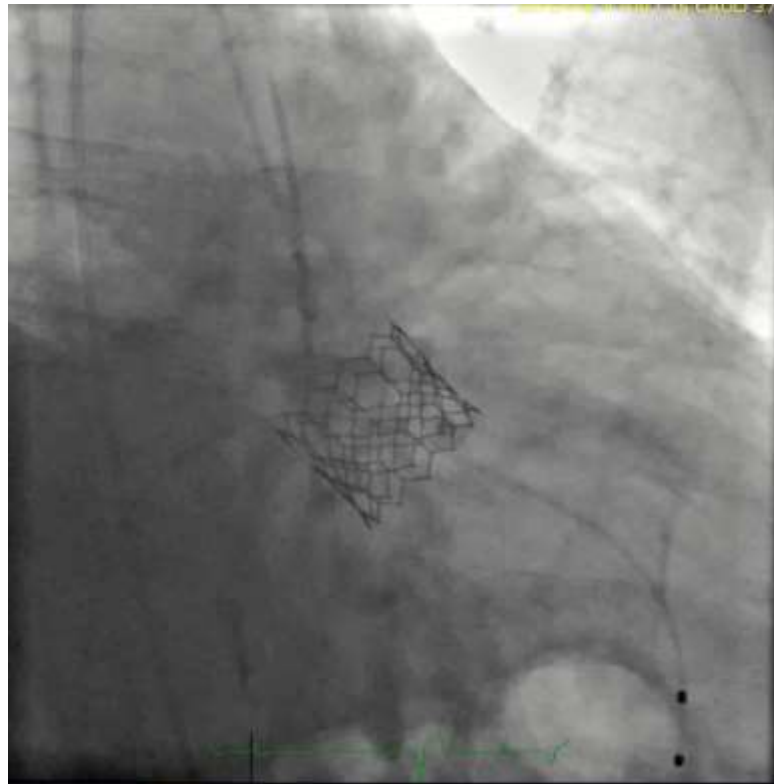


Valve Deployment

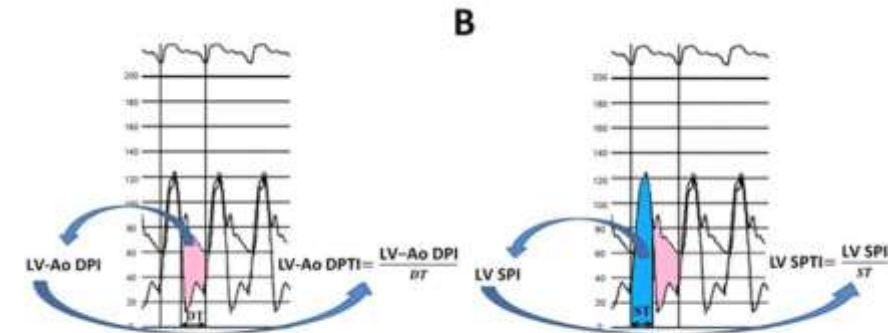


AR Assessment

Angiography

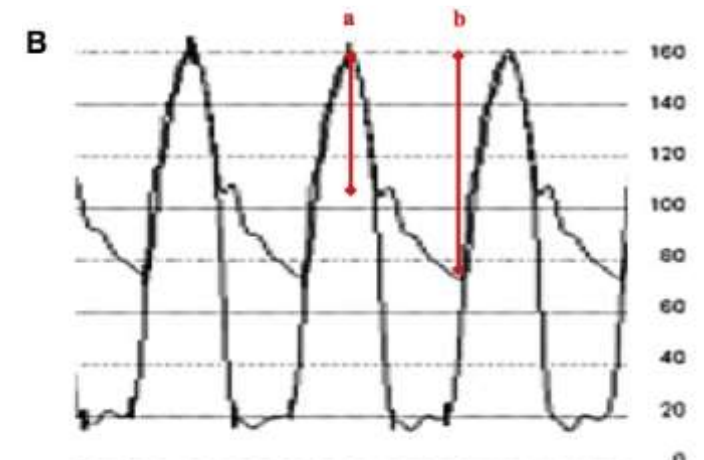


Echo



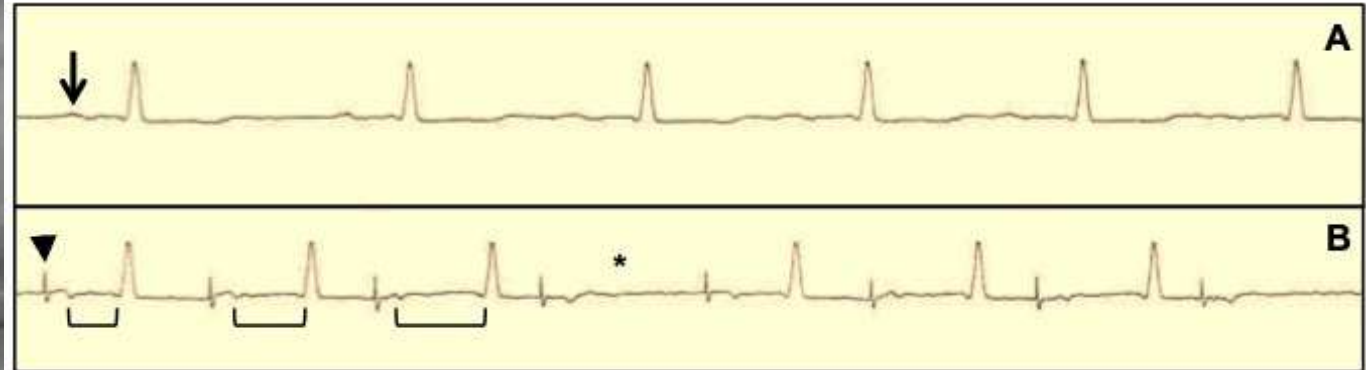
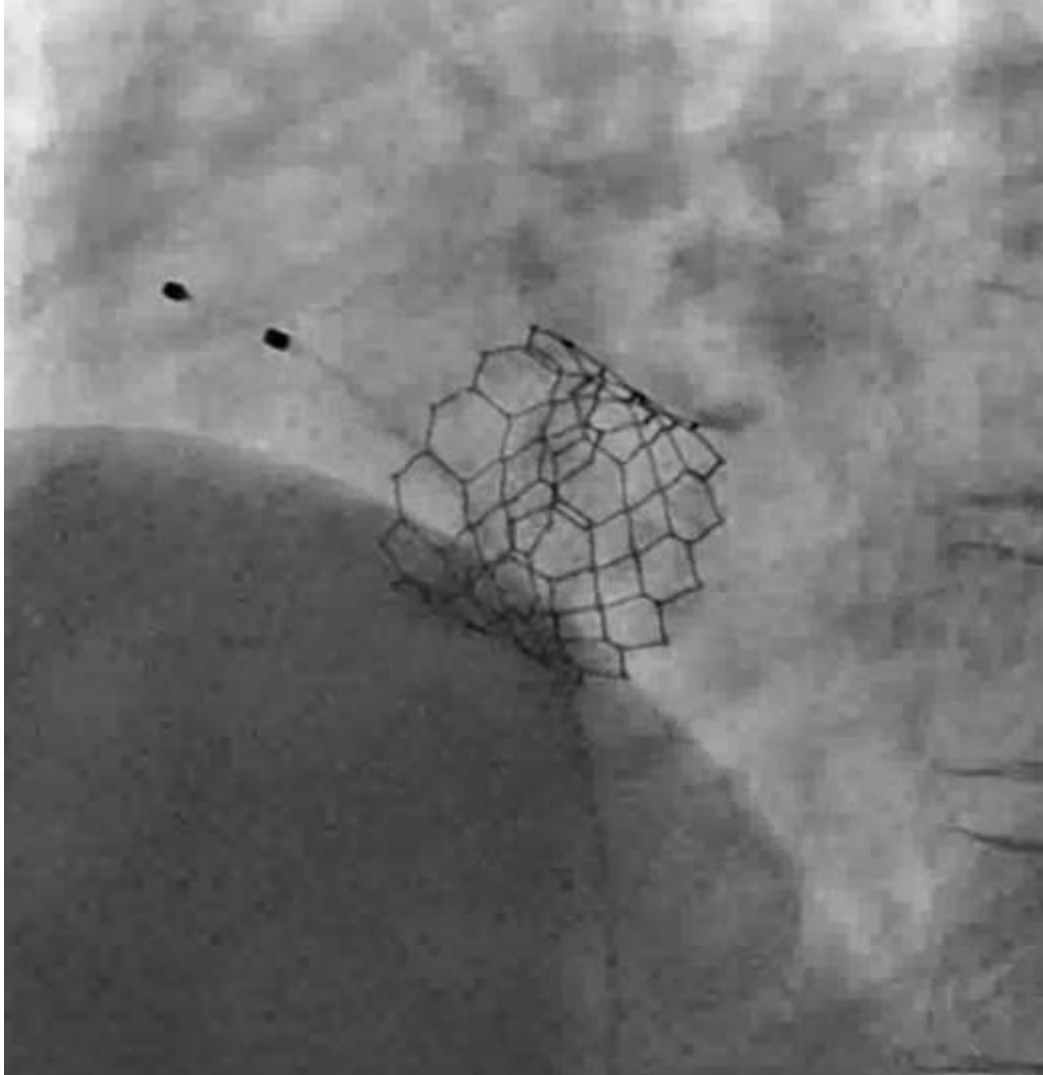
$$\text{TIAR Index} = \frac{\text{LV-Ao DPI}}{\text{LV SPTI}} \times 100$$

<80 ≥ Mild AR



a/b < 0.5 = no AR

Rapid Pacing of RA if in SR



If AVN conducts 1:1 with RA pacing at 120 BPM, less than 2% chances of needing PPM

Manual Pressure



Cleveland Clinic TAVR Outcomes - 2019

- 2019 = 720 patients
- 58% High risk, 40% Int risk
- 91% Conscious Sedation

Mortality - 0%

Stroke - 0.3%

AR($\geq 2+$) - 0.3%

New PPM – 1.2%

Commercially available and investigational devices for TAVI

Balloon Expandable

SAPIEN (Edwards)
*no longer available



SAPIEN XT (Edwards)



S3 (Edwards)



Inovare valve (Braile Biomedica)

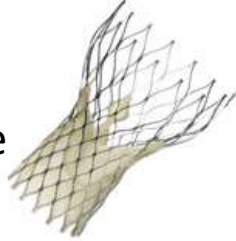


Colibri Heart Valve



Self Expandable

CoreValve (Medtronic)



Evolut R (Medtronic)



Portico (St. Jude Medical)



Centera (Edwards)



Venus (Medtech)



Other Designs

Lotus (Boston Scientific)



Direct Flow Valve (DFM)



Acurate (Symetis Inc)



Engager (Medtronic)



JenaValve



HLT (Heart Leaflet Technologies)



TAVR: Unknowns and Hurdles

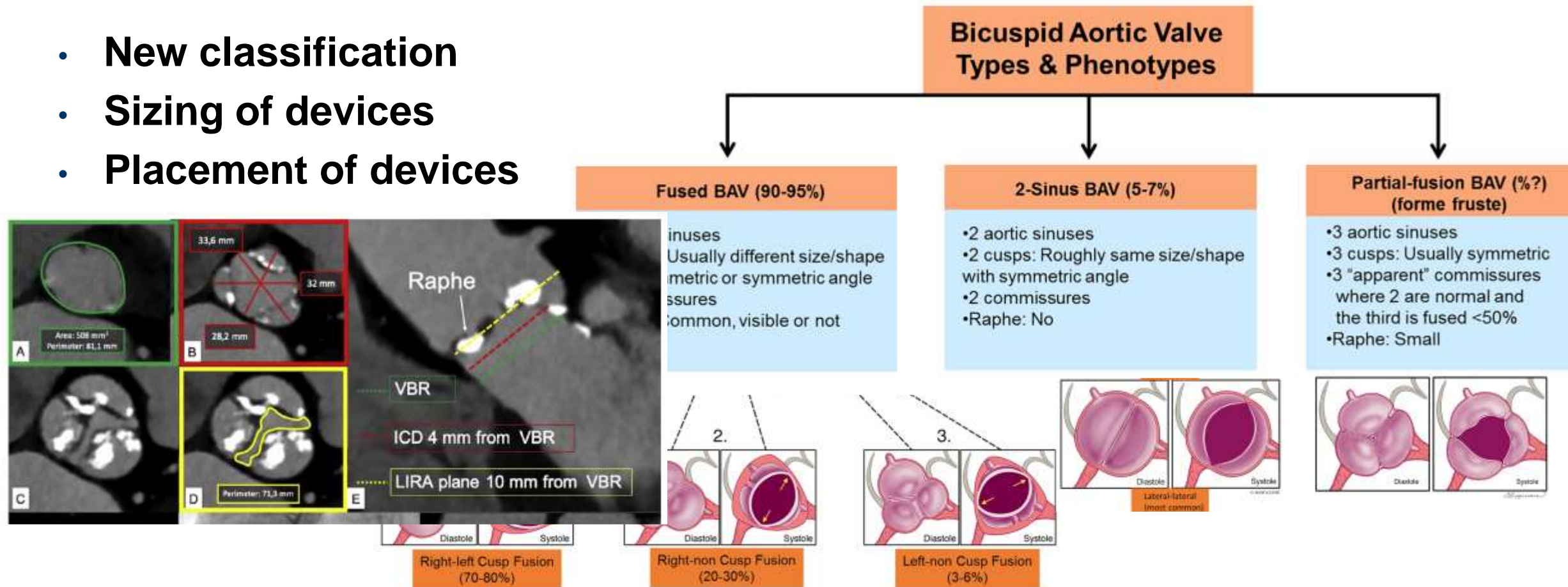
- **Patient and Device Selection**
 - Bicuspid valve
 - Young patients
 - Coronary access
 - Valve in valve
- **Stroke prevention**
- **Minimizing LBBB or need for PPM**
- **Durability**
 - Optimal medical regimen
 - Management of HALT

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Bicuspid Aortic Valve

- New classification
- Sizing of devices
- Placement of devices



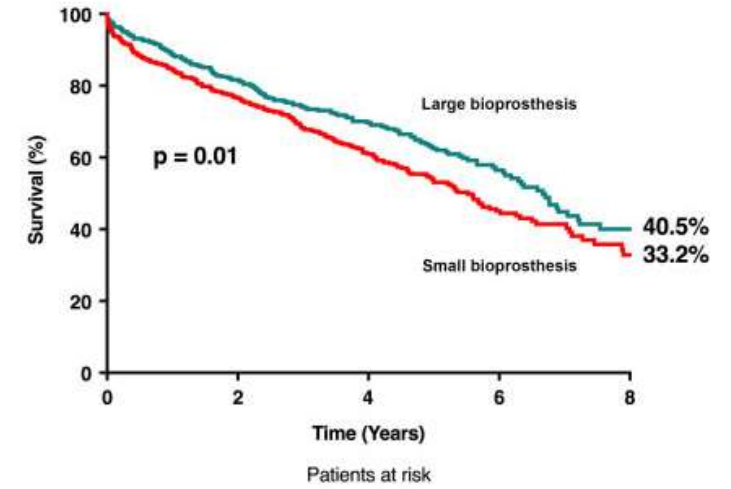
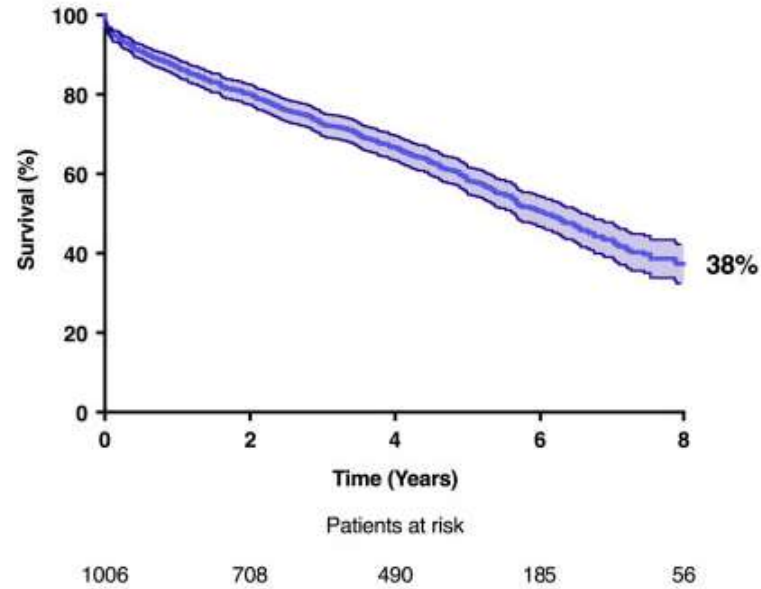
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Young patients

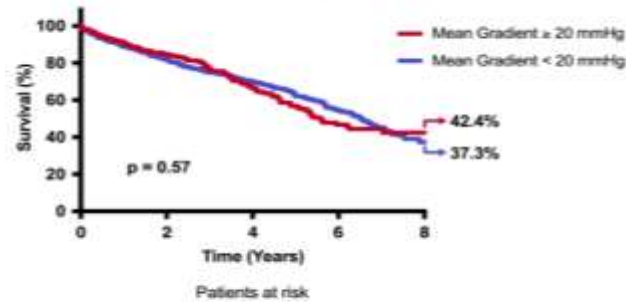
Years	60	→	70	→	80
Option 1	TAVR	→	TAVR	→	TAVR
Option 2	TAVR	→	SAVR	→	TAVR
Option 3	SAVR	→	TAVR	→	TAVR

Valve in Valve: VIVID Registry



Large bioprosthesis	387	279	201	78	27
Small bioprosthesis	450	304	204	75	22

Mean Gradients ≥ 20 mmHg and Survival

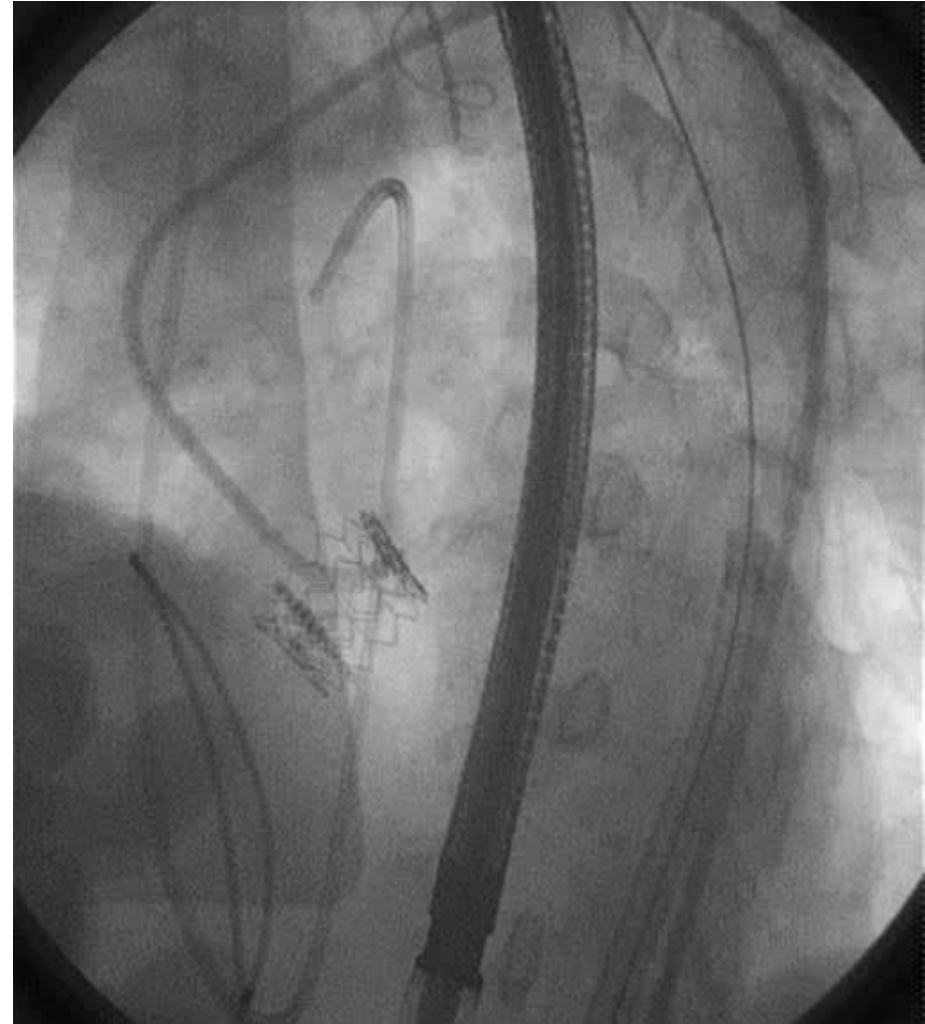


Mean Gradient ≥ 20 mmHg	279	208	135	44	13
Mean Gradient < 20 mmHg	629	452	320	131	40

Coronary Access

- **Valve height**
- **Sinus sequestration**
- **Leaflet alignment**
- **Future Valve in valve options**

Coronary Occlusion

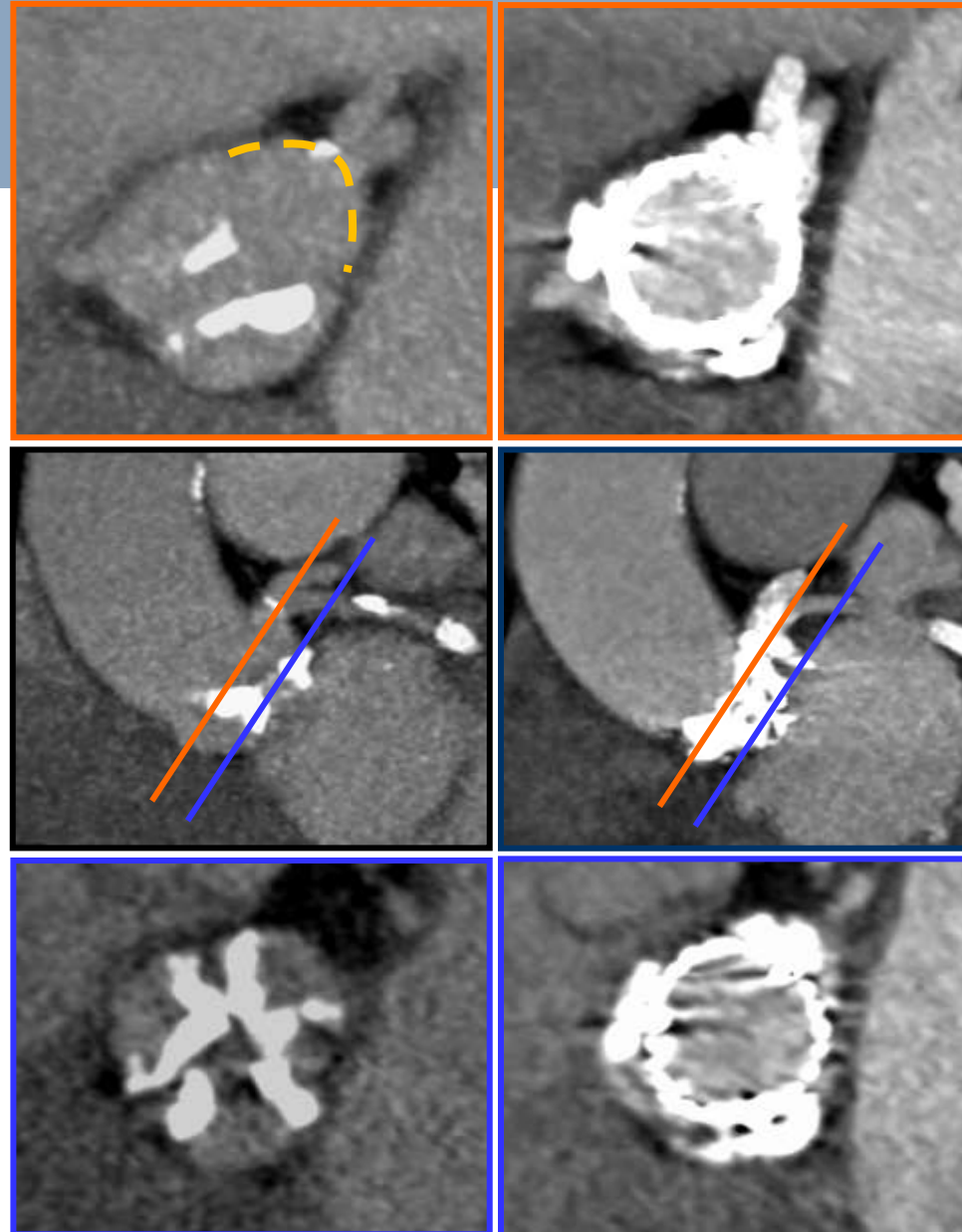


Final Result: Stents in the Left Main

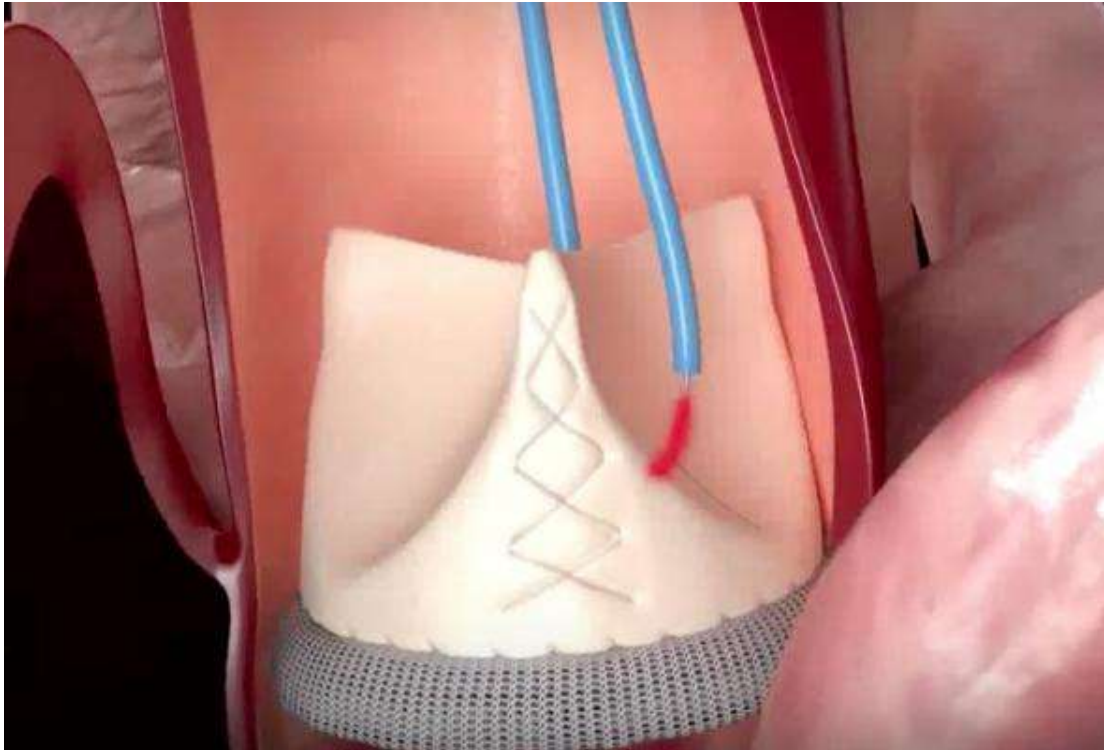


Root Cause Analysis

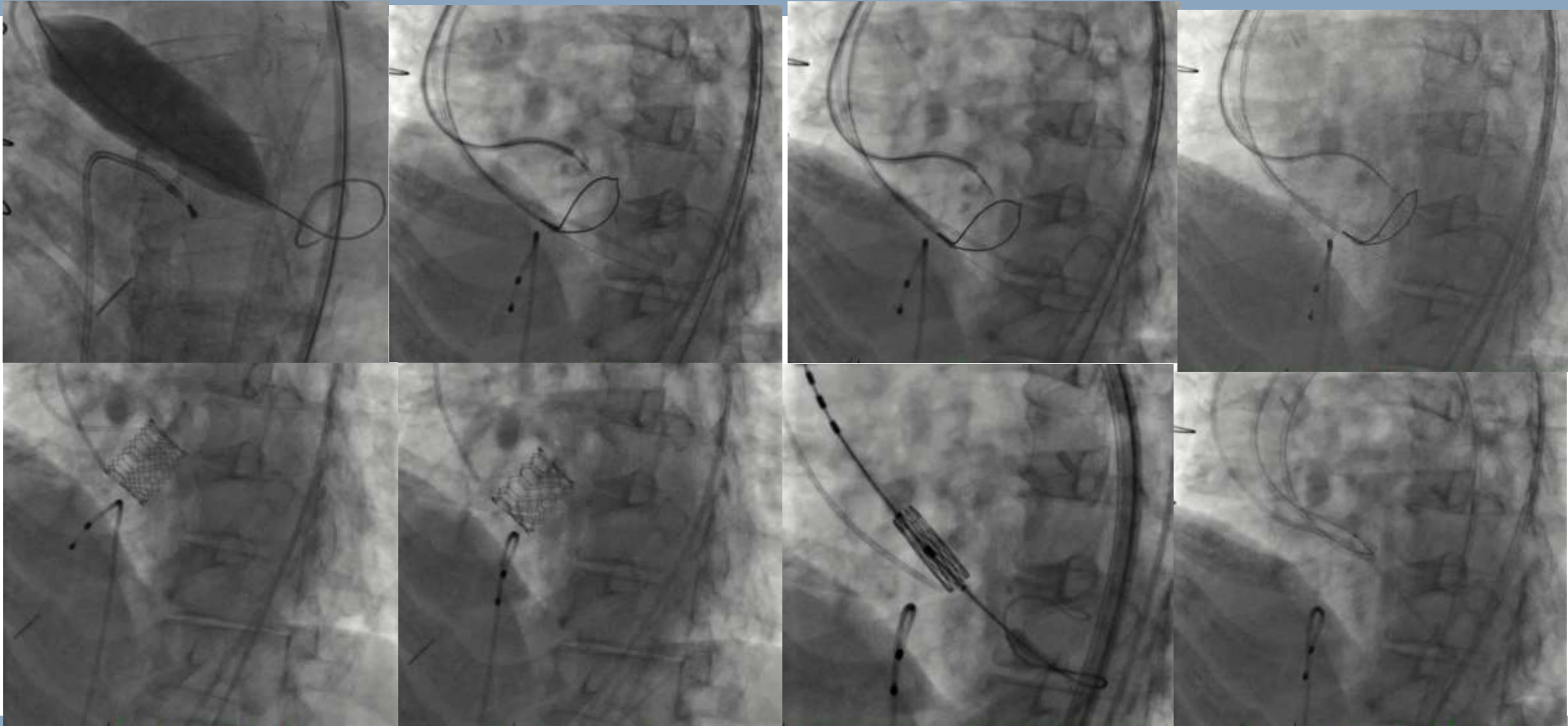
- Small sinuses
- Middle of the cusp
- Low LM origin
- Stent pole next to LMT
- Large amount of Ca



Basilica



Basilica



Results of Basilica Procedure

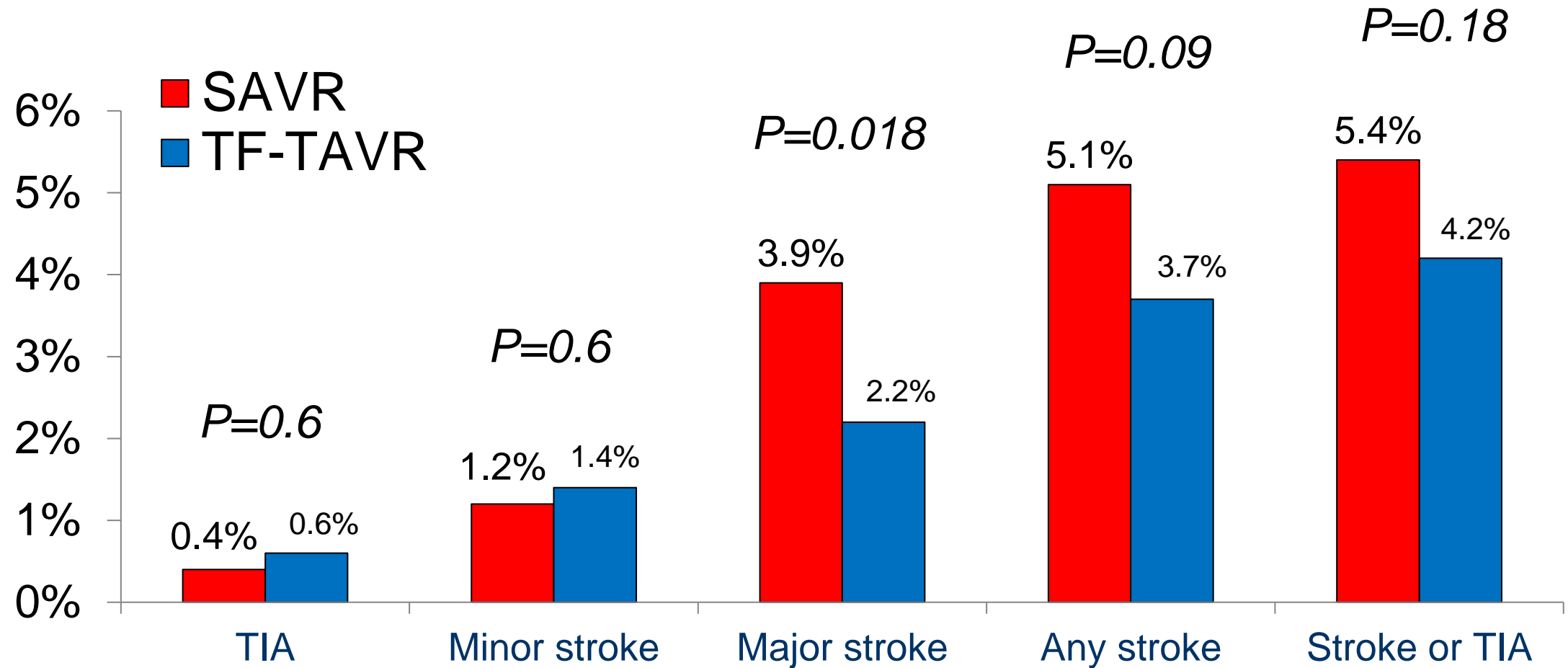
	Total BASILICA (n = 129)	Left BASILICA (n = 102)	Right BASILICA (n = 5)	Double BASILICA (n = 22)	Controls (n = 59)	P Value
Mortality	6.0%	1.6%	0	25.0%	18.9%	0.026
Major Stroke	7.5%	6.4%	0	9.0%	0	0.051
Coronary Obstruction	4.5%	2.0%	0	14.0%	32.2%	< 0.001
Death, Stroke, or Coronary Obstruction	12.3%	8.8%	0	33.0%	35.6%	< 0.001

EPD in Stroke Prevention: Controversies

- **Risk of Stroke**
 - Is this really a problem in current practice?
 - Can we identify “high risk” patients?
- **Efficacy of EPD**
 - Do they really work?
 - What are “trade-offs”
 - Cost, Time, Contrast, Complications

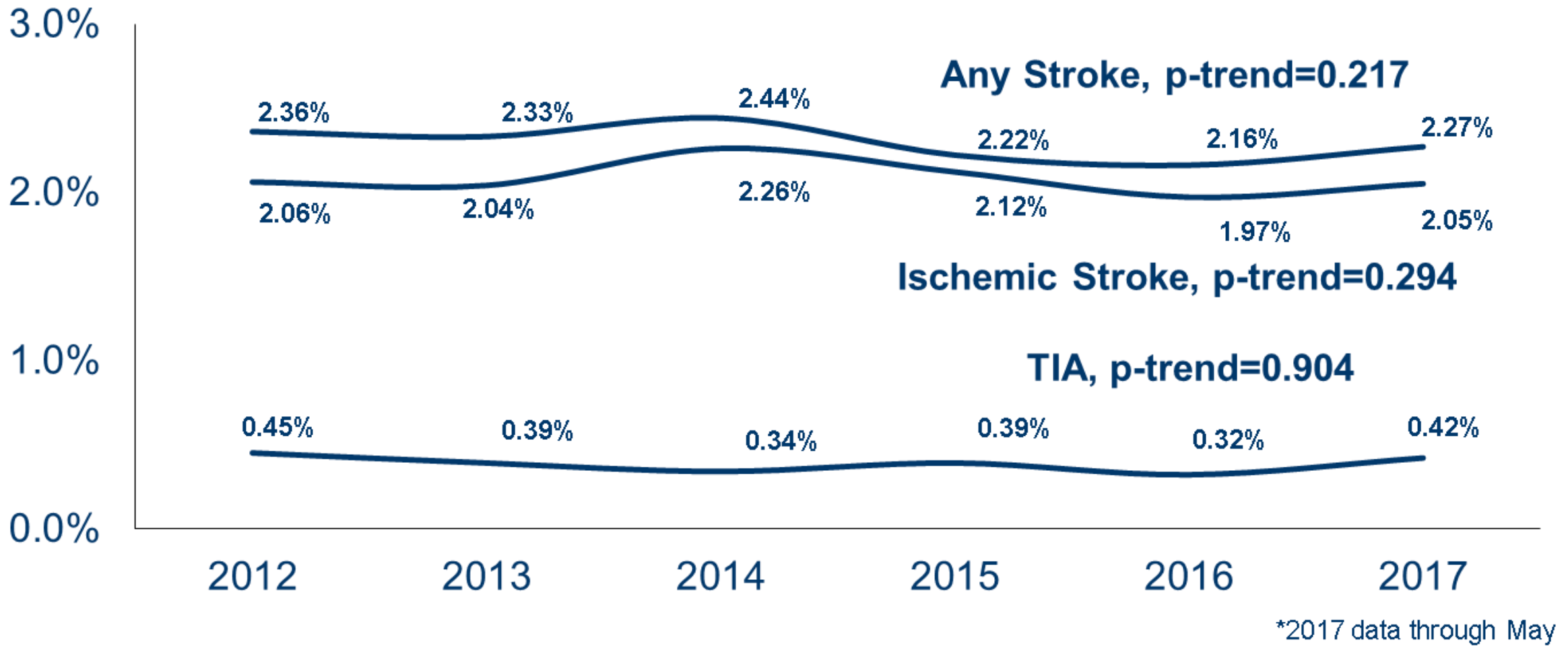
TAVR Stroke Risk Compared To SAVR

Is this the Gold Standard?

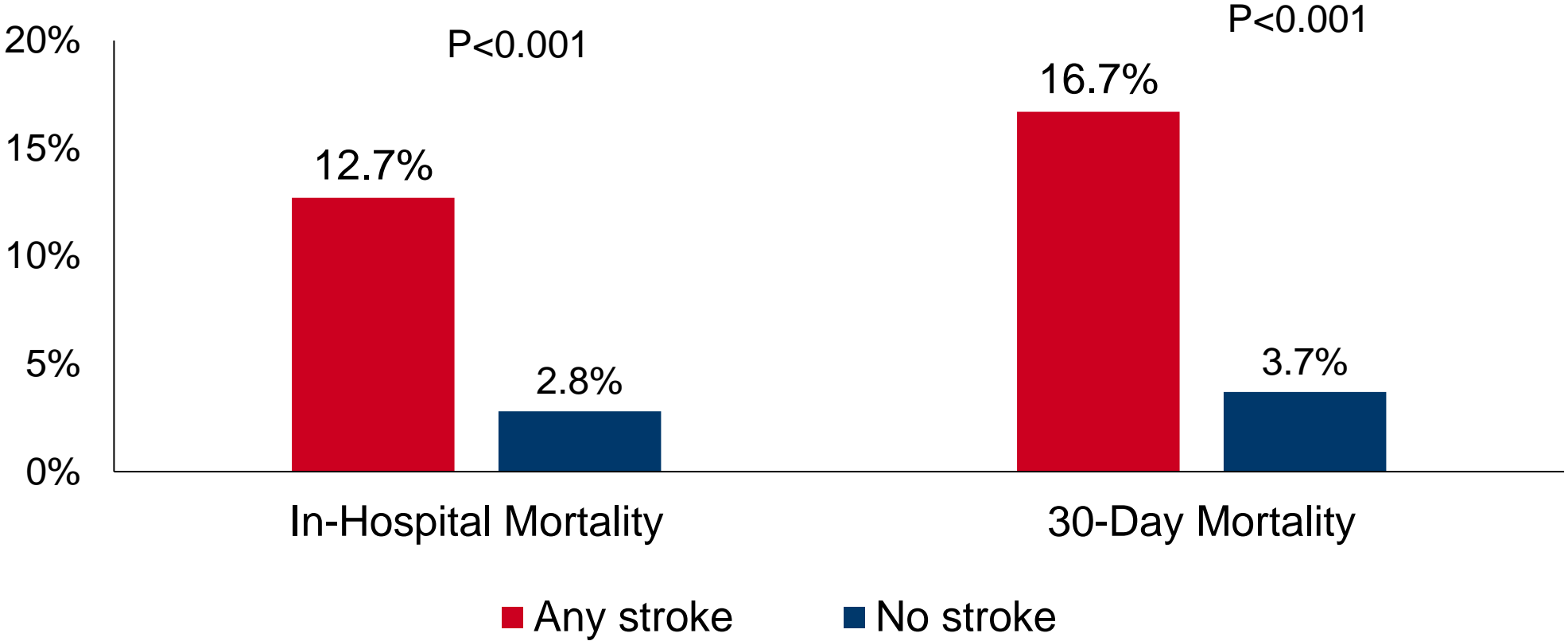


Trends in Post-TAVR Neurologic Event Rates

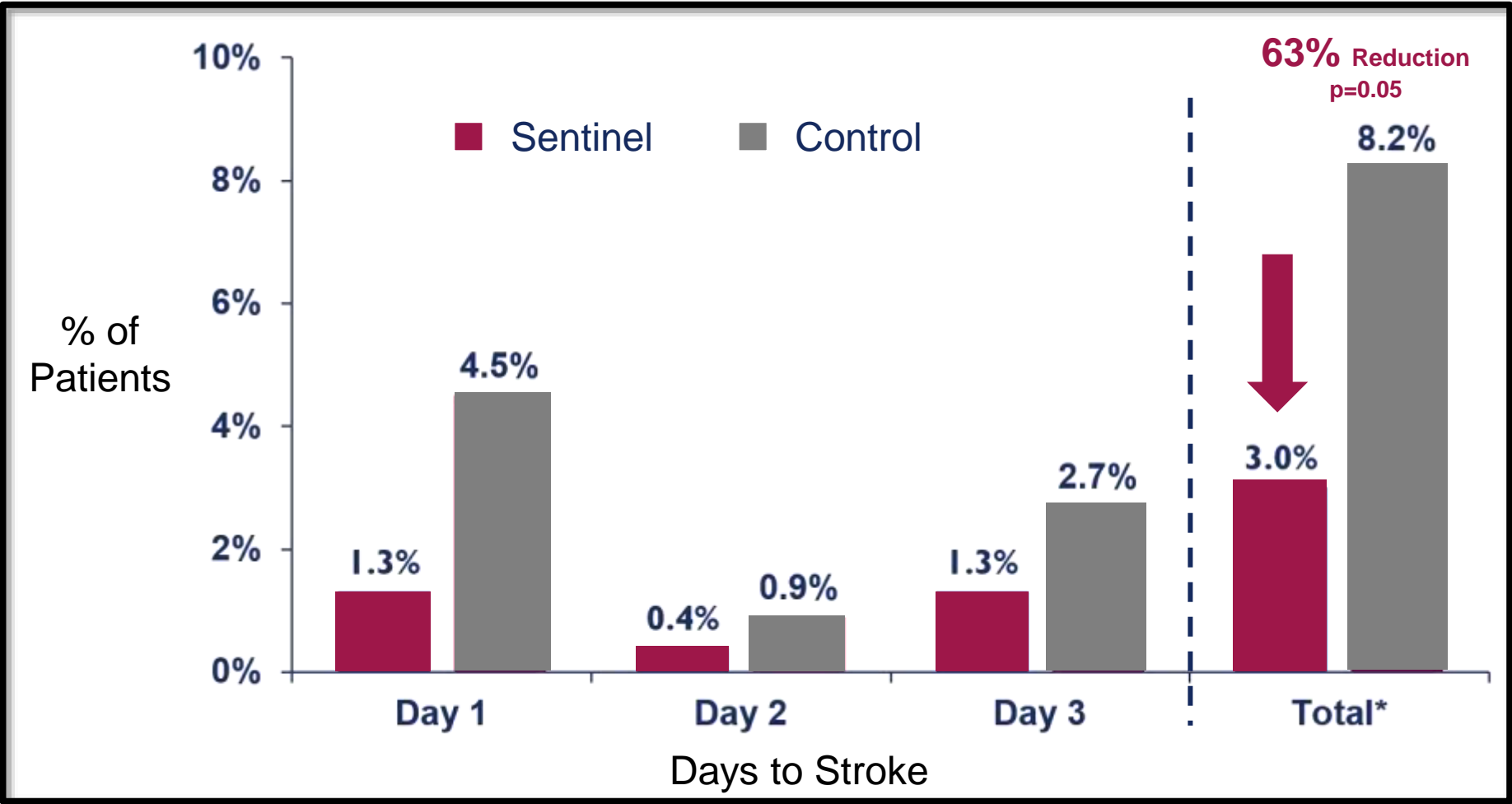
n=101,430



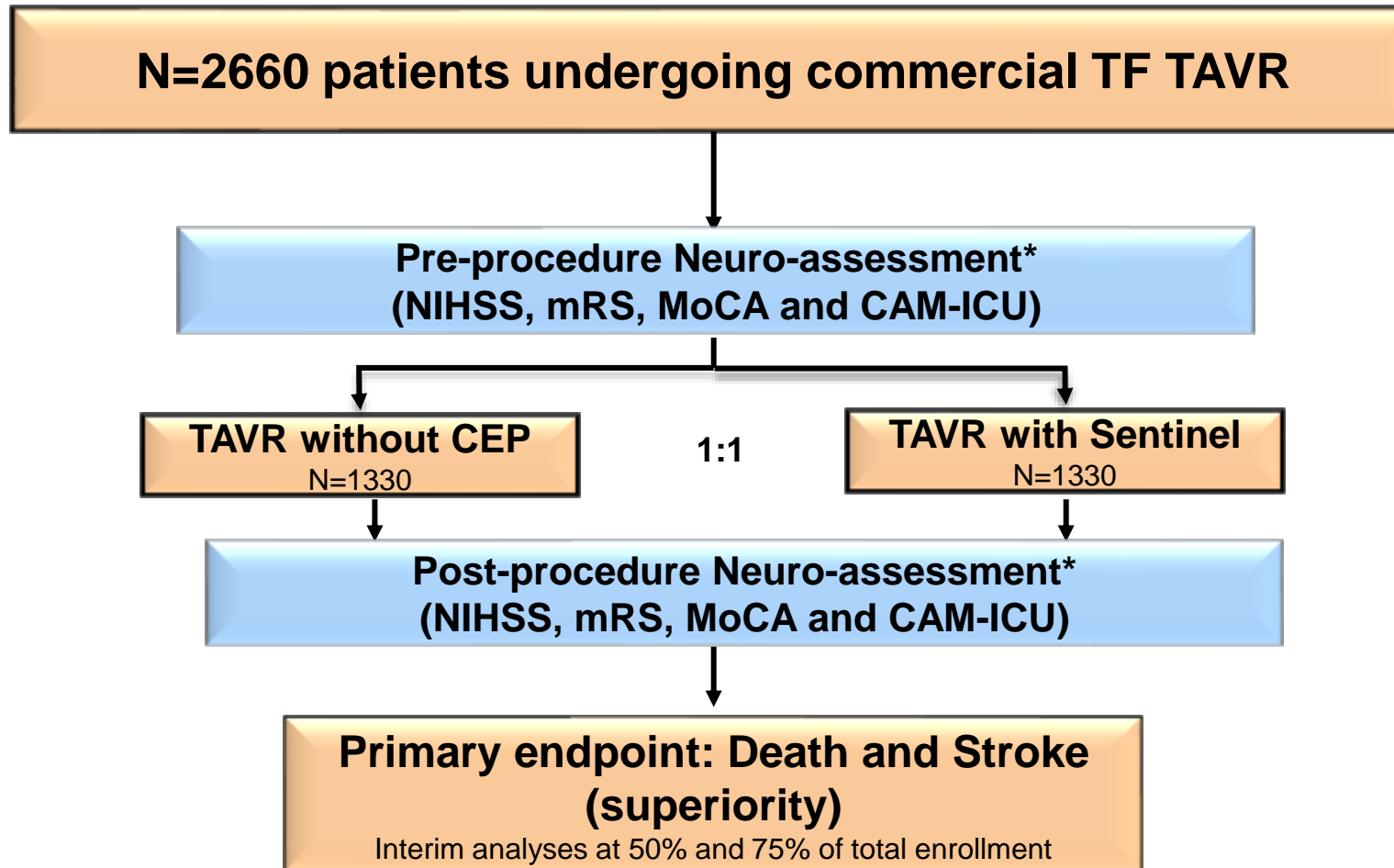
Association of Post TAVR Stroke with Mortality



Significant Procedural Stroke Reduction with Sentinel



PROTECTED TAVR

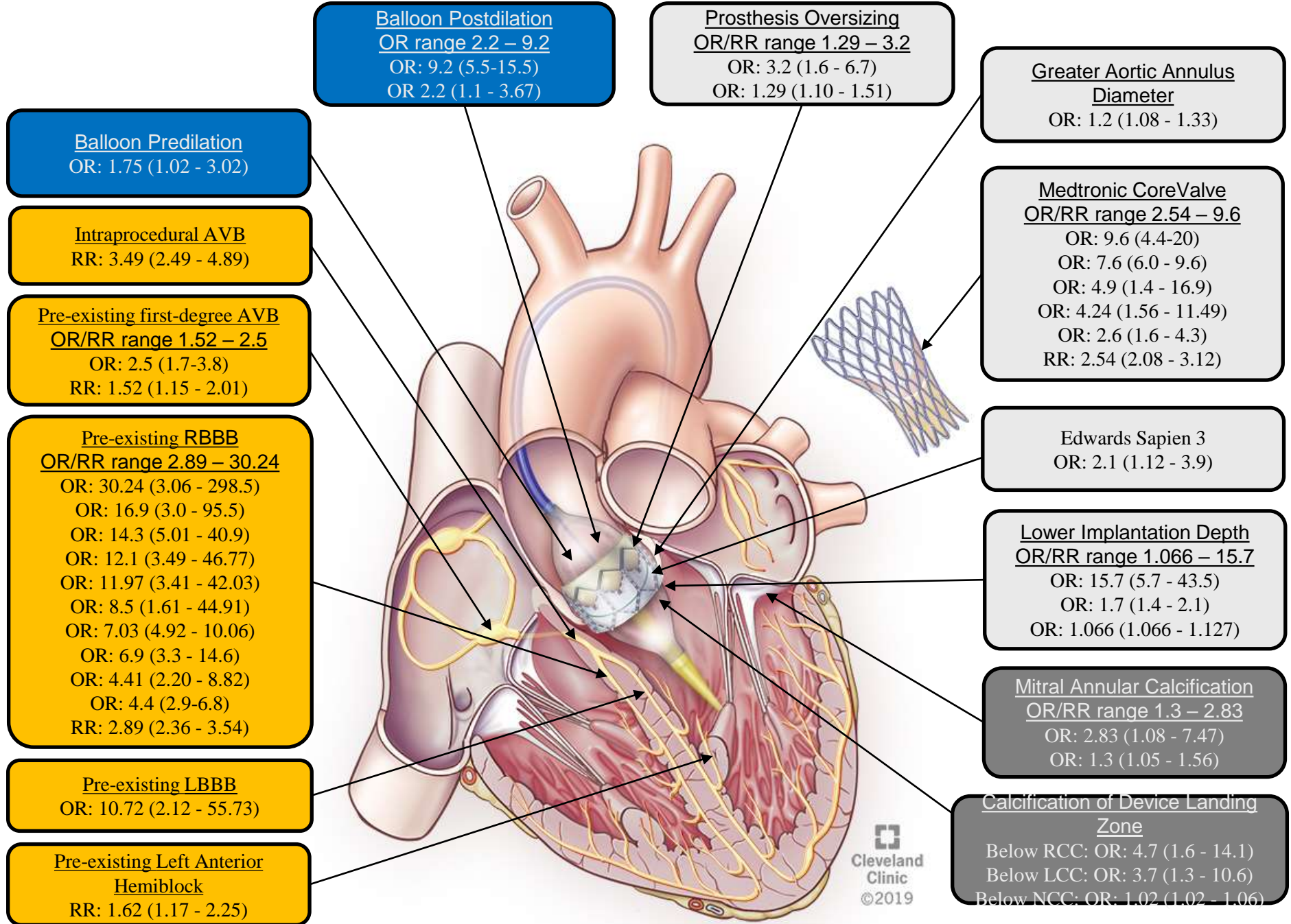
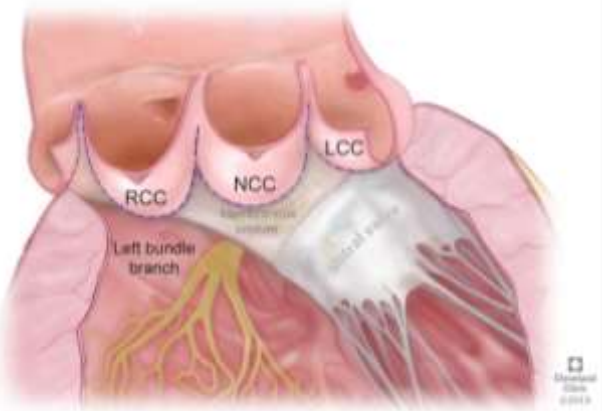


*Must be a neurologist, neurology fellow, neurology physician assistant, or neurology nurse practitioner

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Conduction Abnormality



Balloon Predilation
OR: 1.75 (1.02 - 3.02)

Intraprocedural AVB
RR: 3.49 (2.49 - 4.89)

Pre-existing first-degree AVB
OR/RR range 1.52 – 2.5
OR: 2.5 (1.7-3.8)
RR: 1.52 (1.15 - 2.01)

Pre-existing RBBB
OR/RR range 2.89 – 30.24
OR: 30.24 (3.06 - 298.5)
OR: 16.9 (3.0 - 95.5)
OR: 14.3 (5.01 - 40.9)
OR: 12.1 (3.49 - 46.77)
OR: 11.97 (3.41 - 42.03)
OR: 8.5 (1.61 - 44.91)
OR: 7.03 (4.92 - 10.06)
OR: 6.9 (3.3 - 14.6)
OR: 4.41 (2.20 - 8.82)
OR: 4.4 (2.9-6.8)
RR: 2.89 (2.36 - 3.54)

Pre-existing LBBB
OR: 10.72 (2.12 - 55.73)

Pre-existing Left Anterior Hemiblock
RR: 1.62 (1.17 - 2.25)

Balloon Postdilation
OR range 2.2 – 9.2
OR: 9.2 (5.5-15.5)
OR 2.2 (1.1 - 3.67)

Prosthesis Oversizing
OR/RR range 1.29 – 3.2
OR: 3.2 (1.6 - 6.7)
OR: 1.29 (1.10 - 1.51)

Greater Aortic Annulus Diameter
OR: 1.2 (1.08 - 1.33)

Medtronic CoreValve
OR/RR range 2.54 – 9.6
OR: 9.6 (4.4-20)
OR: 7.6 (6.0 - 9.6)
OR: 4.9 (1.4 - 16.9)
OR: 2.6 (1.6 - 4.3)
RR: 2.54 (2.08 - 3.12)

Edwards Sapien 3
OR: 2.1 (1.12 - 3.9)

Lower Implantation Depth
OR/RR range 1.066 – 15.7
OR: 15.7 (5.7 - 43.5)
OR: 1.7 (1.4 - 2.1)
OR: 1.066 (1.066 - 1.127)

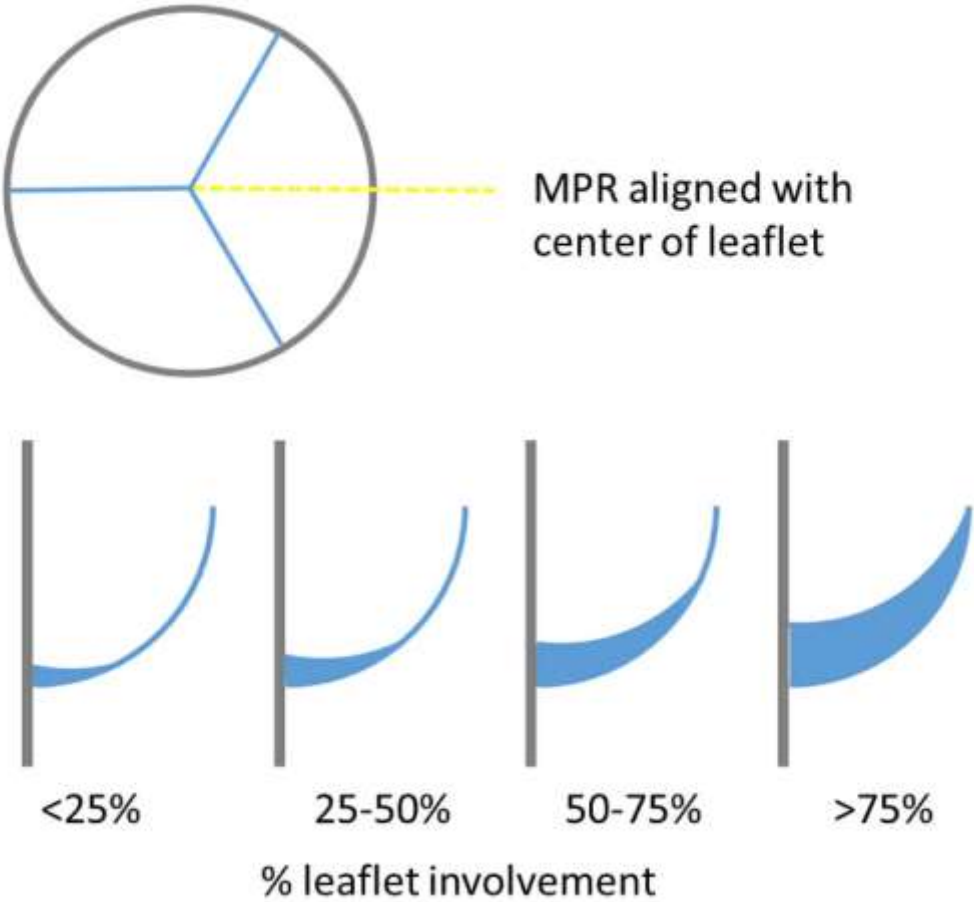
Mitral Annular Calcification
OR/RR range 1.3 – 2.83
OR: 2.83 (1.08 - 7.47)
OR: 1.3 (1.05 - 1.56)

Calcification of Device Landing Zone
Below RCC: OR: 4.7 (1.6 - 14.1)
Below LCC: OR: 3.7 (1.3 - 10.6)
Below NCC: OR: 1.02 (1.02 - 1.06)

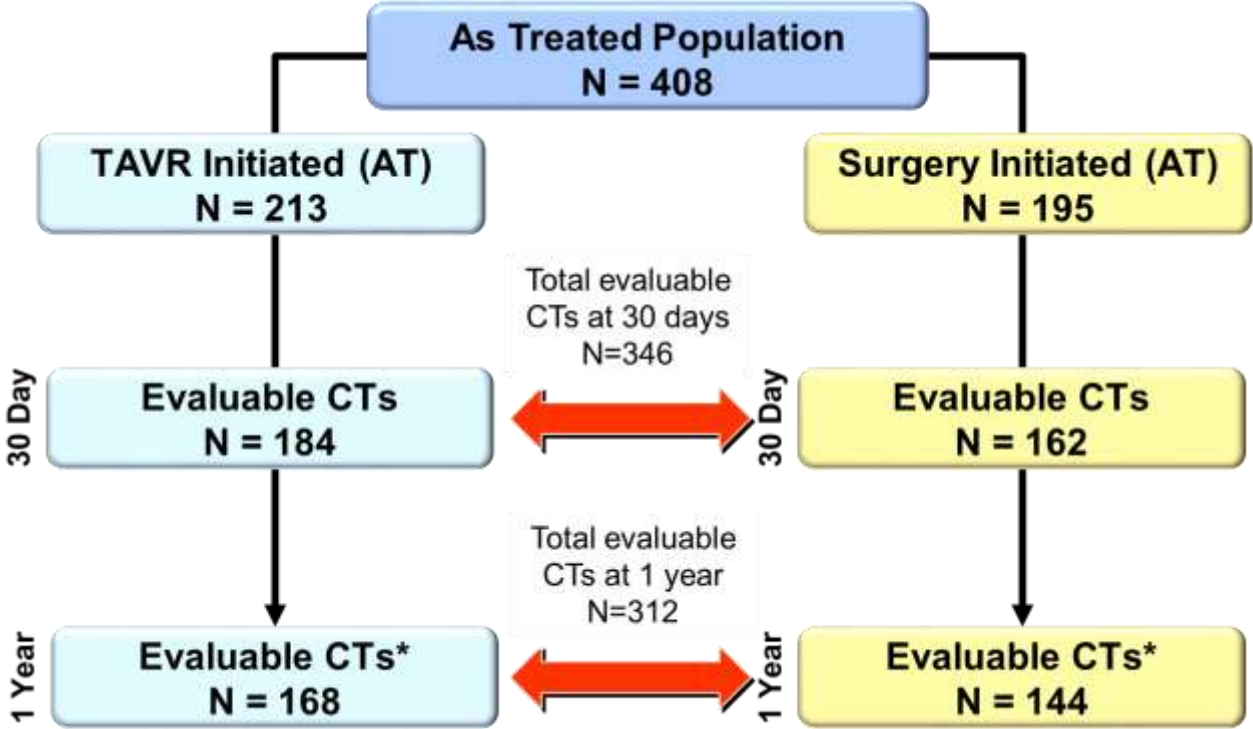
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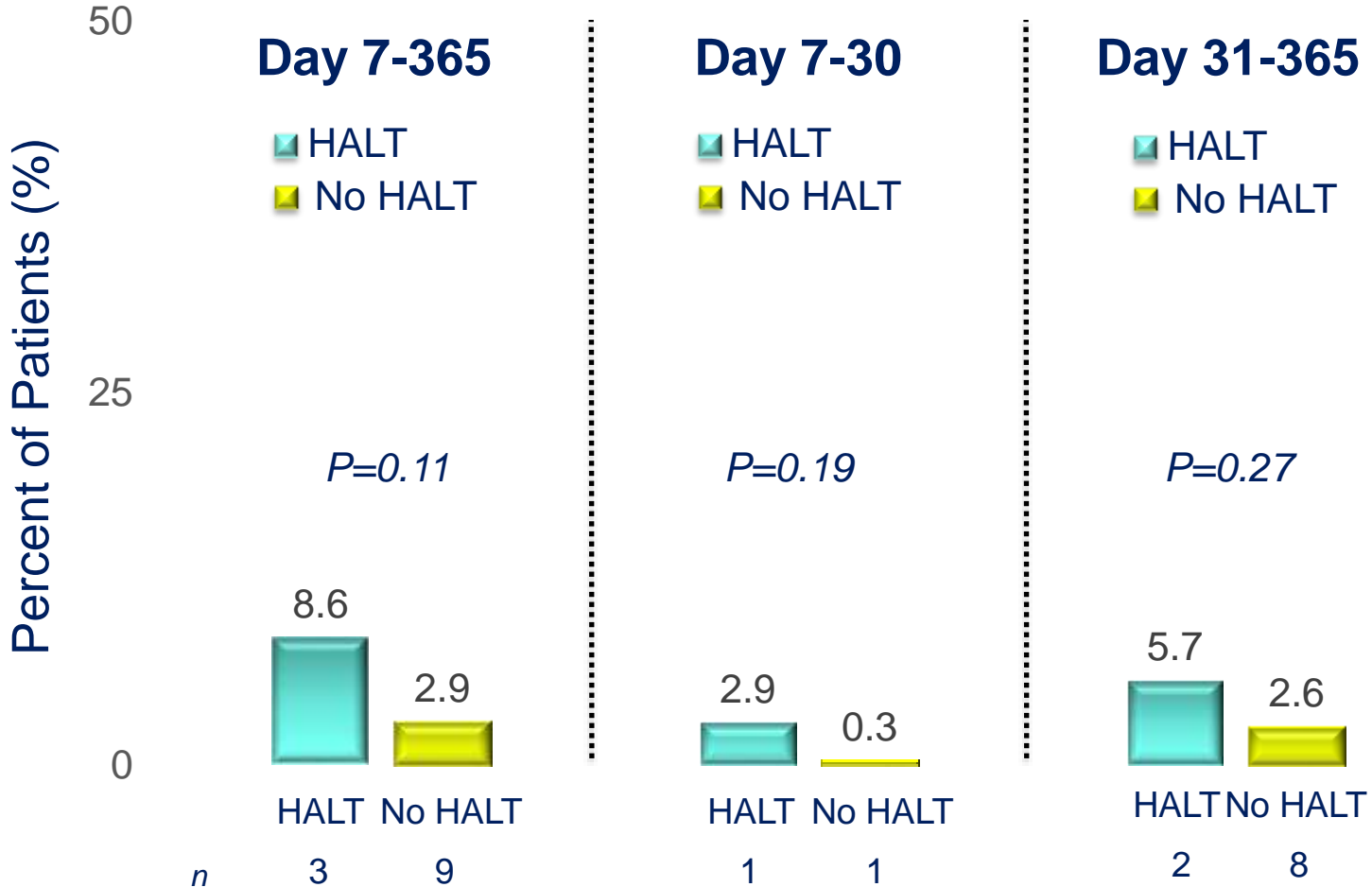
PARTNER CT Substudy



Blanke P. et al. Journal of Cardiovascular Computed Tomography 2019

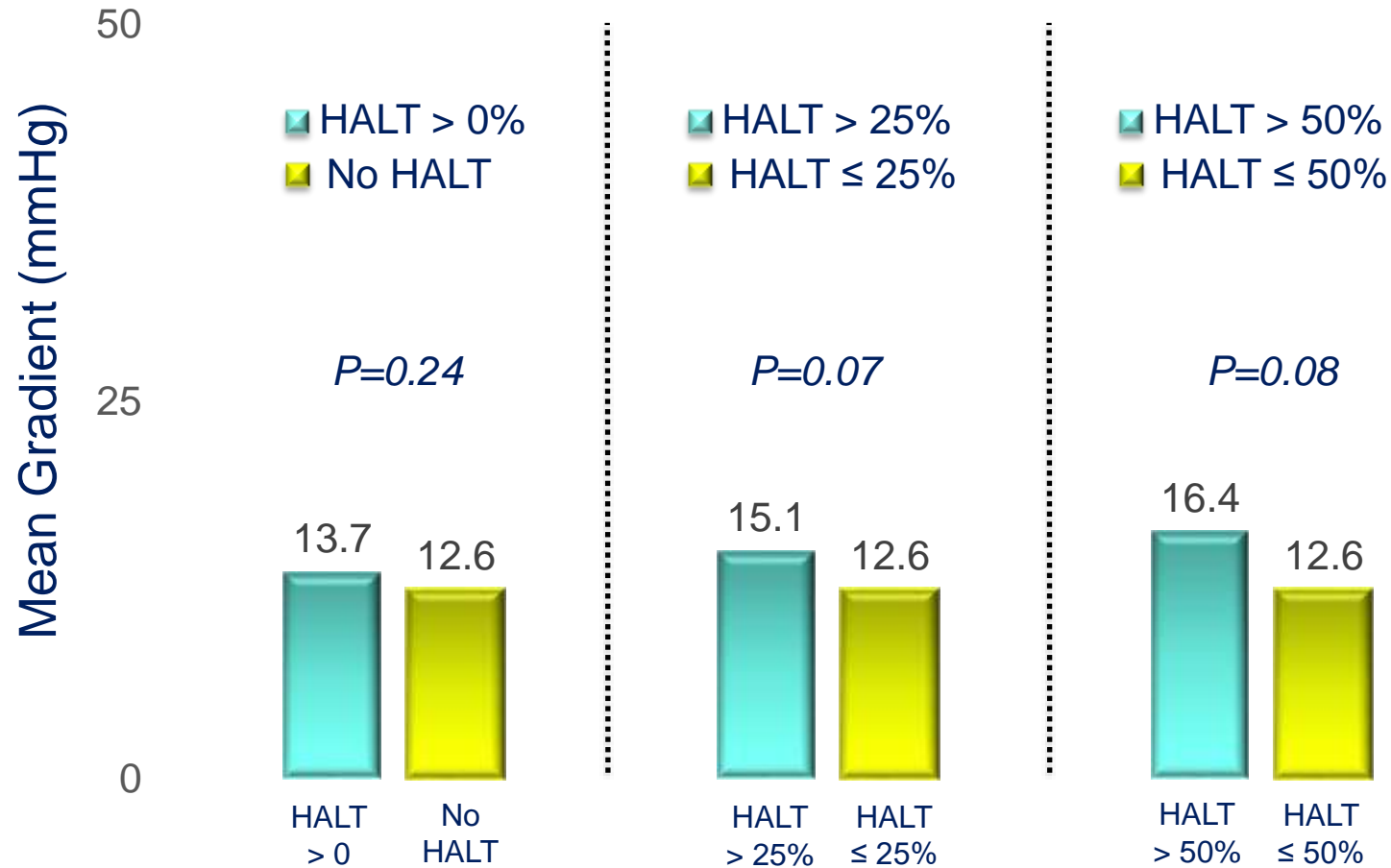


Death / Stroke / TIA / Thromboembolic Events and 30-day HALT TAVR & SAVR



Mean Aortic Valve Gradient and Severity of HALT 1 year

All Patients with Evaluable CTs – TAVR & SAVR



Unanswered Questions

- **DAPT is probably not needed**
- **Anticoagulation may not help all (Galileo, Atlantis....)**
- **Anticoagulation for VIV?**
- **NOACS versus Coumadin**
- **Treatment for HALT and how long**

New Trials

- **EARLY TAVR** – TAVR in asymptomatic severe AS
- **UNLOAD LV** – TAVR in patients with poor EF and moderate AS
- **WATCH-TAVR** – TAVR and Watchman in patients with AS and AF
- **PROTECTED TAVR** – Sentinel in TAVR (Death and stroke as endpoints)