PVL: How to Prevent and How to Treat!

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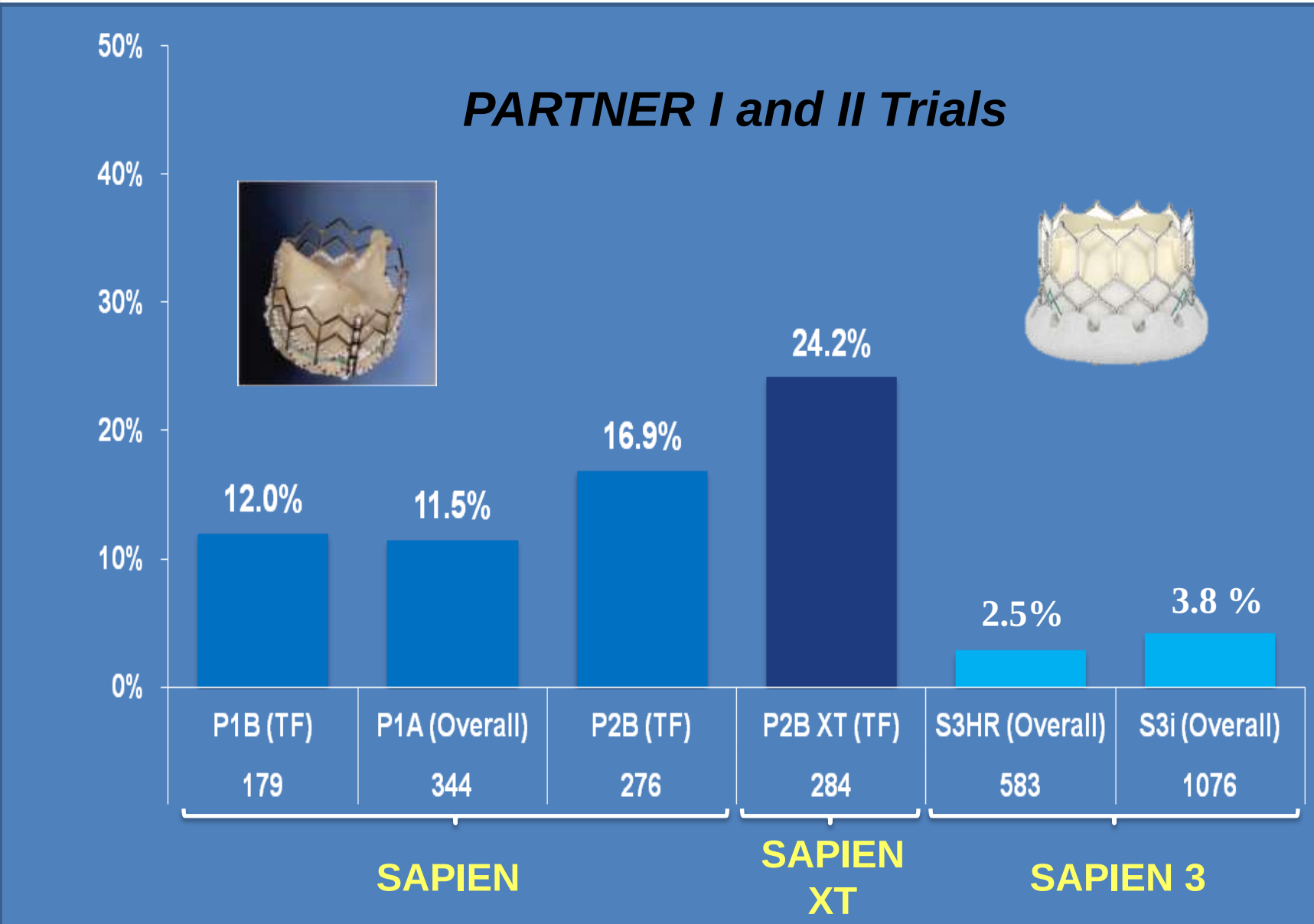
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Edwards Lifesciences
• Grant/Scientific Advisory Board	• Medtronic
• Executive Physician Council	• Boston Scientific Corp

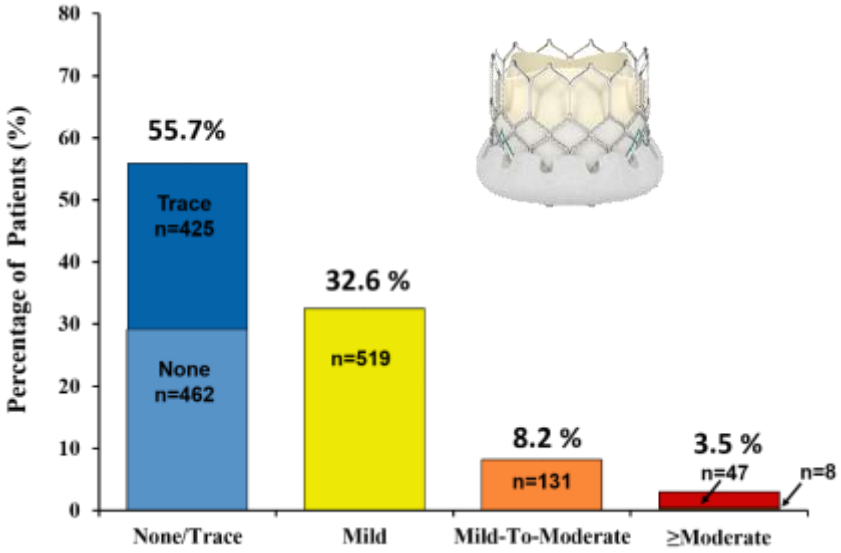
Moderate/Severe PVR at 30 Days

Edwards SAPIEN Valves



Prevalence of Paravalvular Regurgitation with New Generations of THVs

PARTNER 2 – SAPIEN 3 Registry

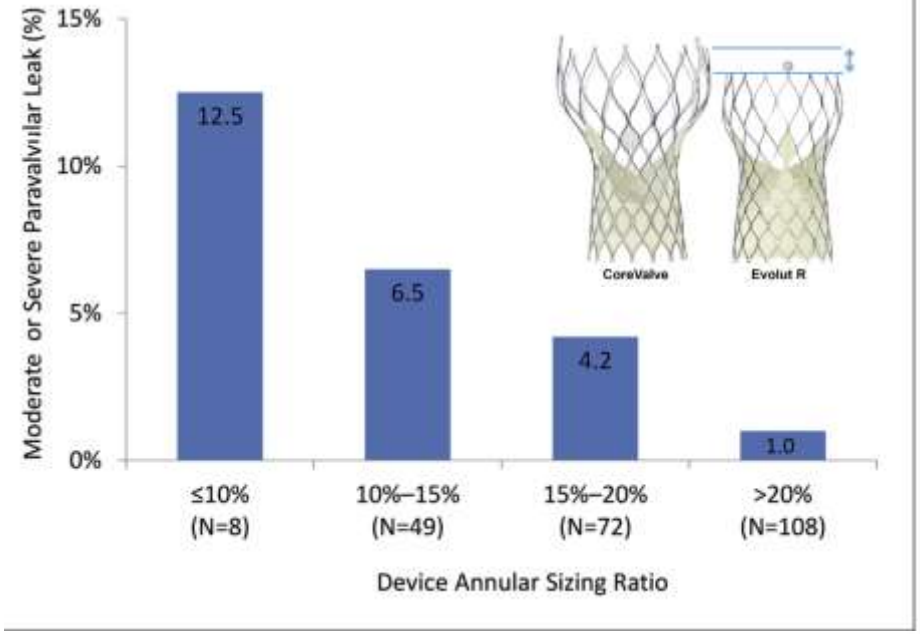


3.5 % ≥ Moderate PVR

40.8% Mild PVR

Pibarot et al. TCT 2016

EVOLUT R US Study

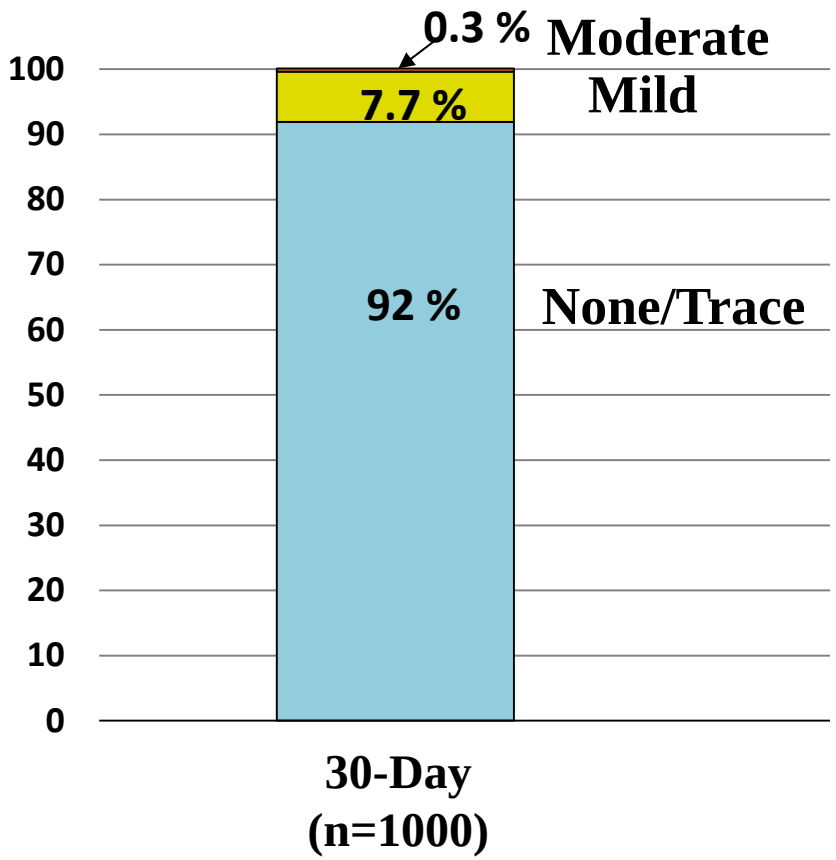


5.7 % ≥ Moderate PVR

32.6 % Mild PVR

Popma, JACC Int 2017; 10: 268-275

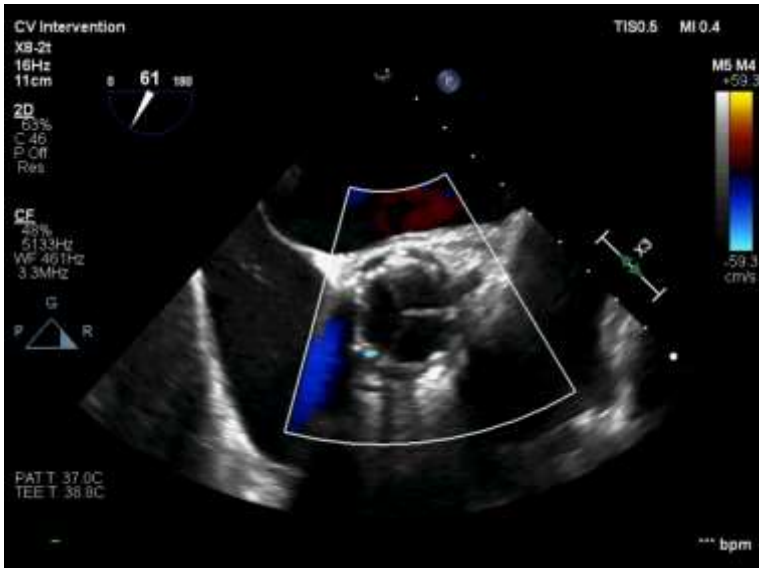
Incidence of PVR at 30 days with LOTUS Valve RESPOND Registry (n=1000 patients)

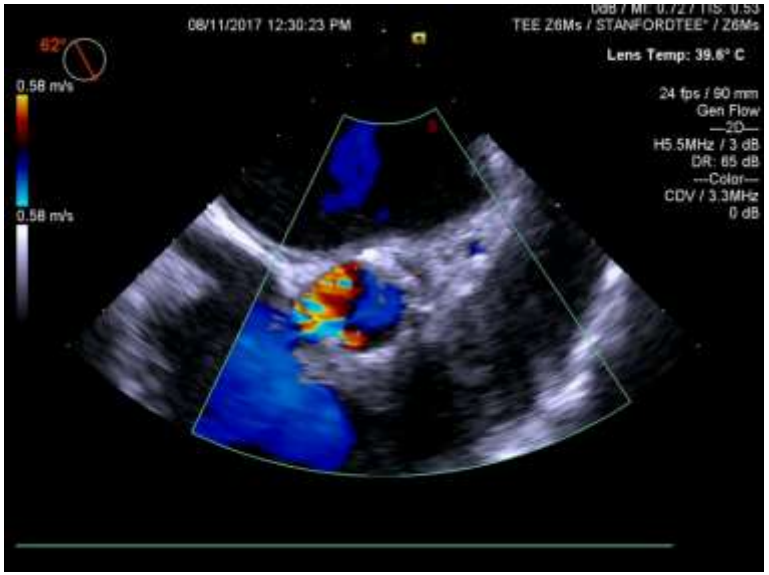


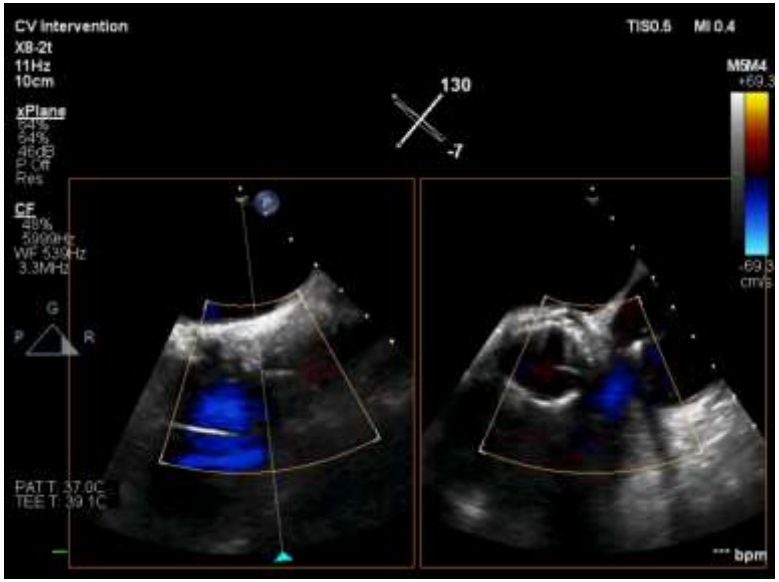
Sizing Strategy and PVL Prevention

- Accurate Sizing: CT
- Upsizing or downsizing
- Intraoperative TEE Verification & Monitoring
- No predilation
- One inflation strategy
- Know the imperfect anatomy

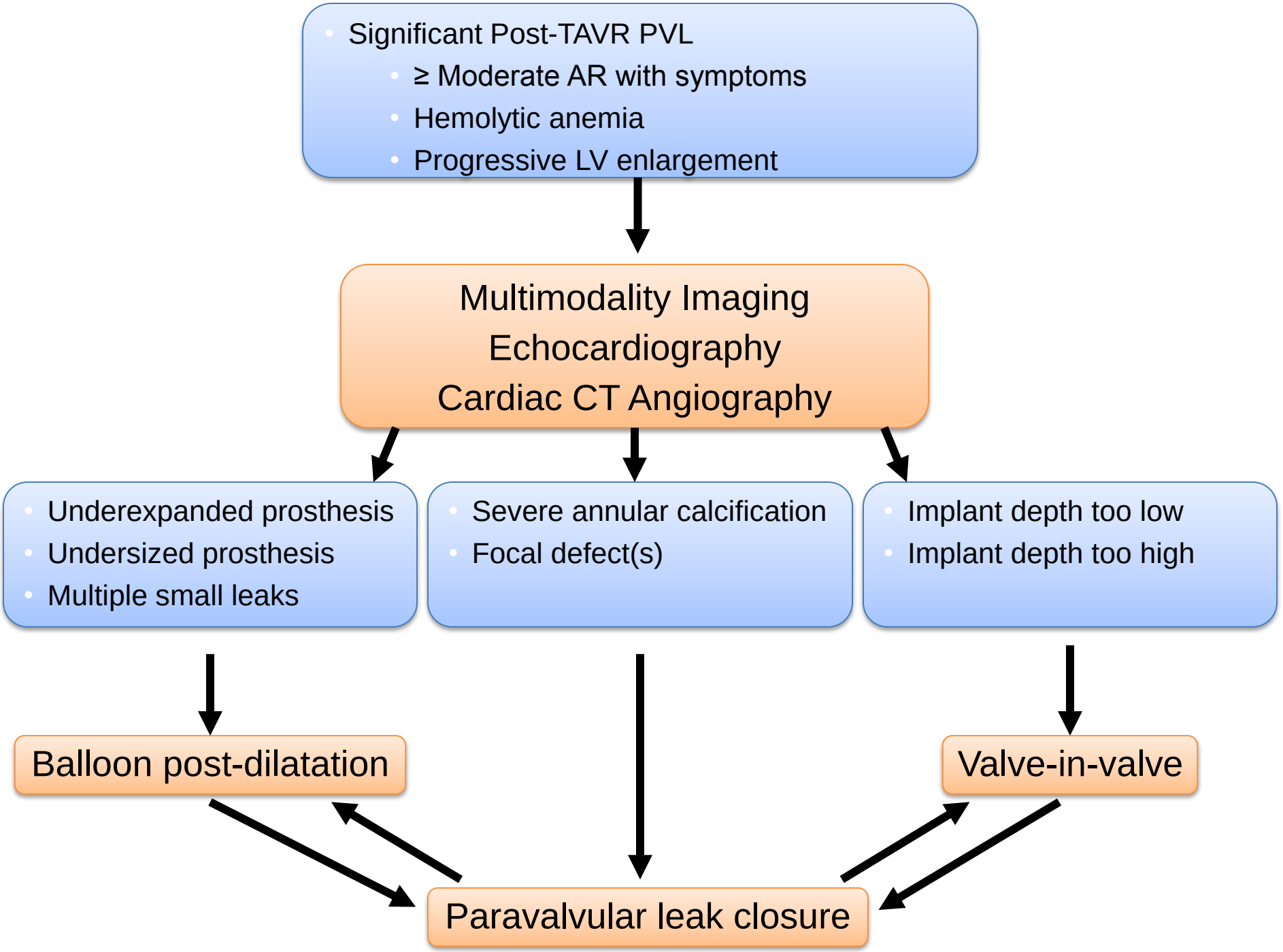
Three iTAVR last Friday…..(4 on Tuesday)



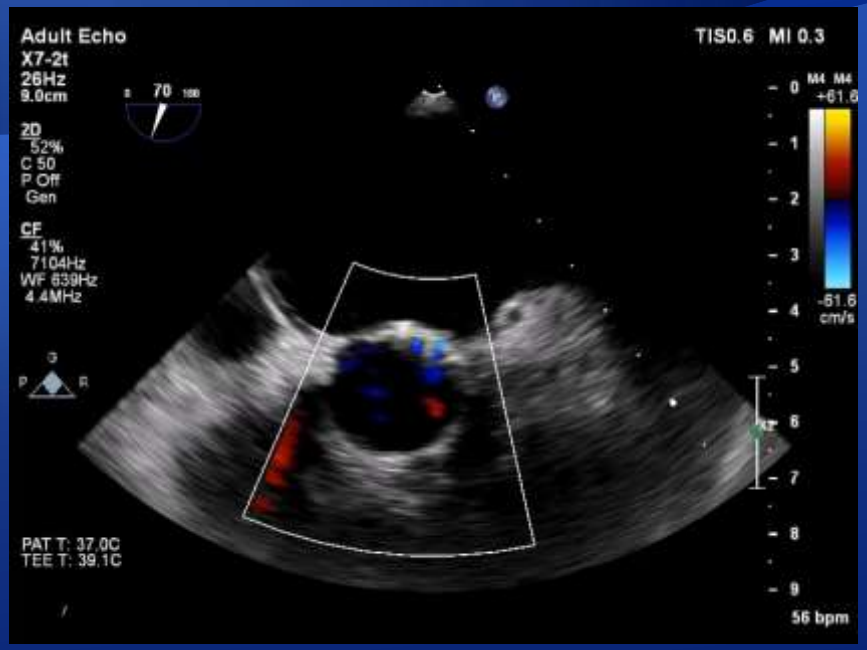




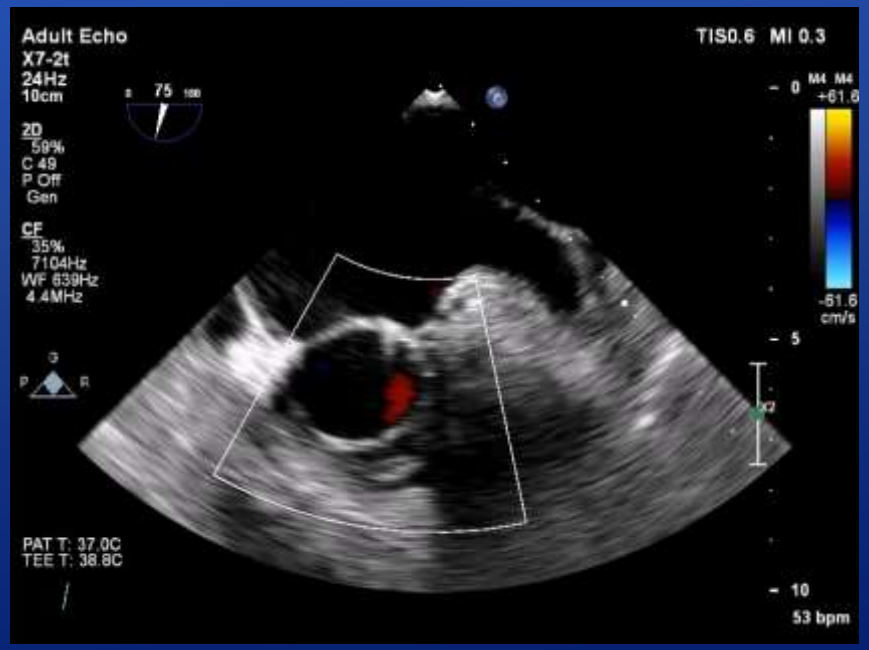
All none or trace PVL (one inflation) !


Significant Post-TAVR PVL
≥ Moderate AR with symptoms
Hemolytic anemia
Progressive LV enlargement
Multimodality Imaging
Echocardiography
Cardiac CT Angiography
Underexpanded prosthesis
Undersized prosthesis
Multiple small leaks
Severe annular calcification
Focal defect(s)
Implant depth too low
Implant depth too high
Balloon post-dilatation
Valve-in-valve
Paravalvular leak closure

Spontaneous Regression



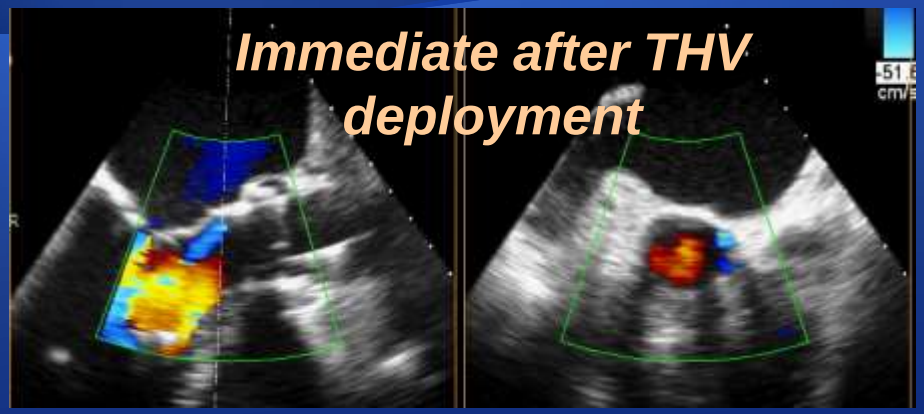
Immediate Post-TAVR

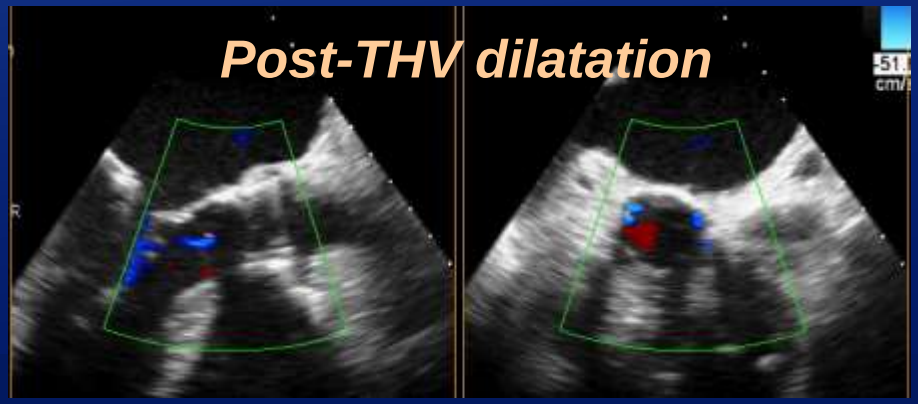


5 minutes Post-TAVR (no intervention)

Small jets seen (frequently between the stent cells) and directed into the center of the LVOT, may regress over the first 5-10 minutes

Post-Dilatation: Reduces PVL and Increases Valve Area





Balloon Expandable

- Use valve delivery balloon
- Never add more than 1-2 cc to balloon
- Perform under rapid pacing

Self Expanding Valve

- Size balloon based on annulus size (Consider non-compliant balloon)
- Use balloon sized to minimum dimension of annulus
- Consider upsizing balloon if necessary
- Perform under rapid pacing

JACC: CARDIOVASCULAR INTERVENTIONS

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Predictive Factors, Efficacy, and Safety of Balloon Post-Dilation After Transcatheter Aorti Valve Implantation With a Balloon-Expandable

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Quebec City, Quebec, Canada

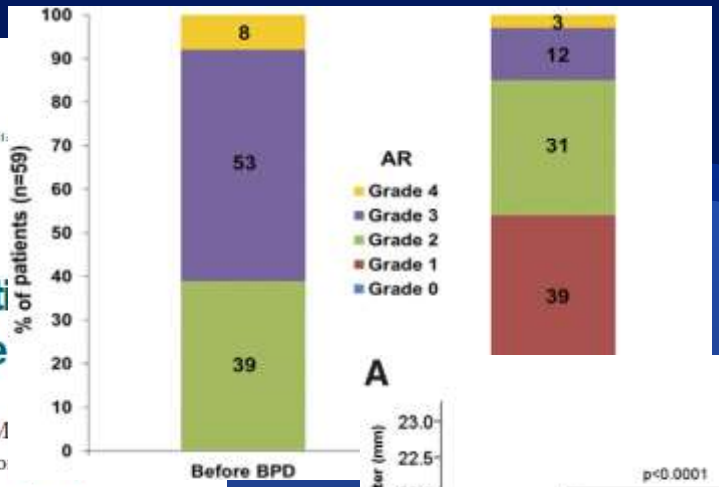
Objectives This study sought to evaluate the predictive factors, effects, and safety of balloon post-dilation (BPD) for the treatment of significant paravalvular aortic regurgitation (AR) after transcatheter aortic valve implantation (TAVI).

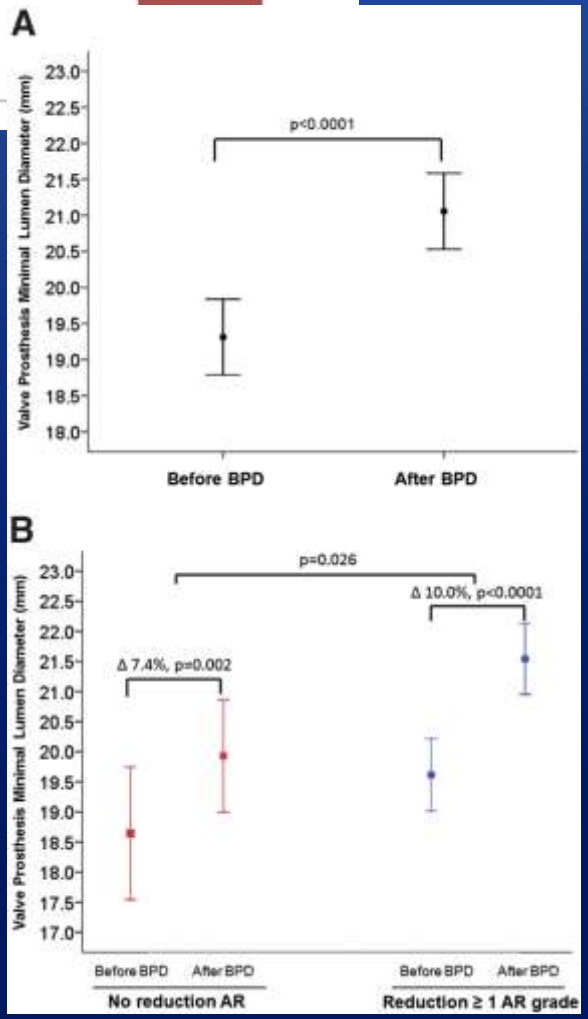
Background Very few data exist on BPD after TAVI with a balloon-expandable valve.

Methods A total of 211 patients who underwent TAVI with a balloon-expandable valve were included. BPD was performed after TAVI if paravalvular AR ≥2 was identified by transesophageal echocardiography. Clinical events and echocardiographic data were prospectively recorded, and median follow-up was 12 (6 to 24) months.

Results BPD was performed in 59 patients (28%) leading to a reduction in at least 1 degree of AR in 71% of patients, with residual AR <2 in 54% of the patients. The predictors of the need for BPD were the degree of valve calcification and transfemoral approach, with valve calcification volume >2,200 and >3,800 mm^3 best determining the need for and a poor response to BPD, respectively. Patients who underwent BPD had a higher incidence of cerebrovascular events at 30 days (11.9% vs. 2.0%, p = 0.006), with most (83%) events within the 24 h after the procedure occurring in patients who had BPD. No significant changes in valve area or AR degree were observed at follow-up in BPD and no-BPD groups.

Conclusions BPD was needed in about one-fourth of the patients undergoing TAVI with a balloon-expandable valve and was successful in about one-half of them. A higher degree of valve calcification and transfemoral approach predicted the need for BPD. BPD was not associated with any deleterious effect on valve function at mid-term follow-up, but a higher rate of cerebrovascular events was observed in patients who had BPD. (J Am Coll Cardiol Intv 2012;5:499–512) © 2012 by the American College of Cardiology Foundation





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STRUCTURAL

Outcomes With Post-Dilation Following Transcatheter Aortic Valve Replacement

The PARTNER I Trial (Placement of Aortic Transcatheter Valve)

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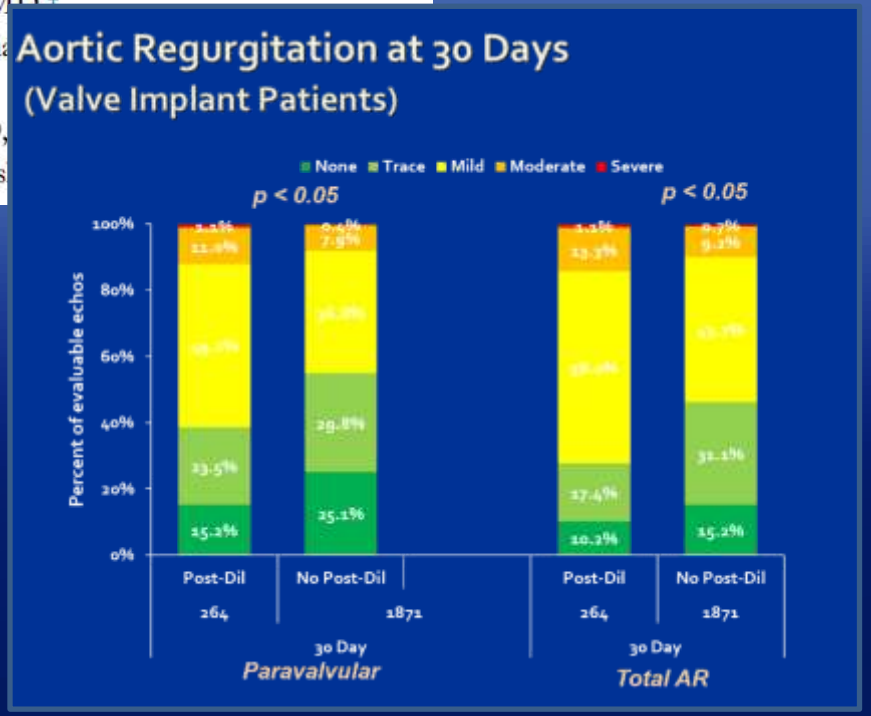
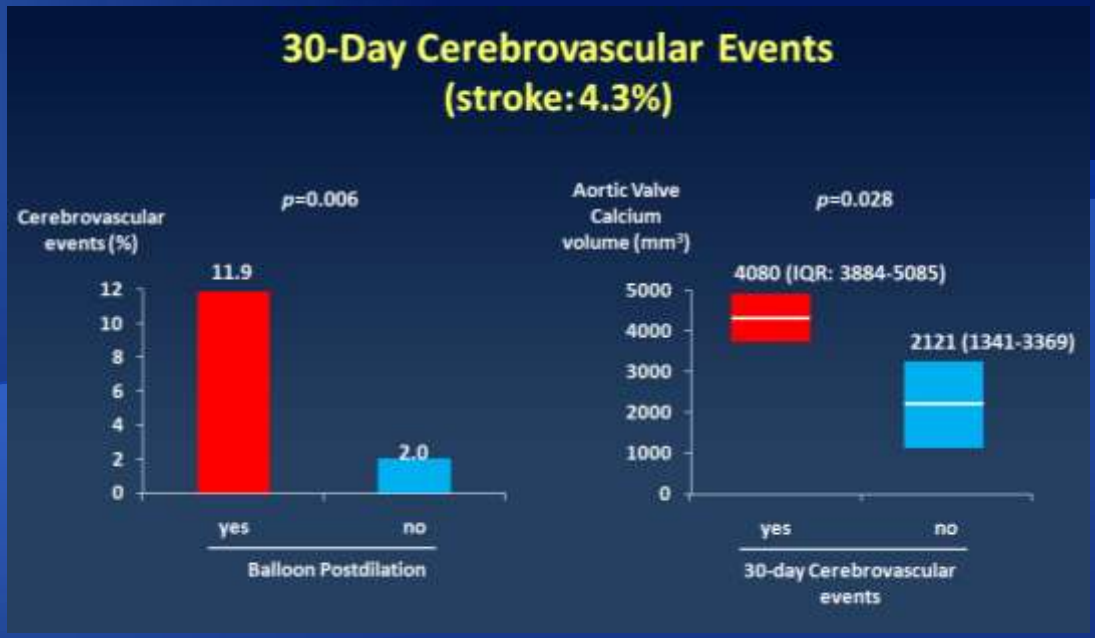
Josep Rodes-Cabau, MD,† Howard C. Herrmann, MD,§ Mathew Willia
Raj Makkar, MD,‖ Wilson Y. Szeto, MD,§ Michael L. Main, MD,¶
Vinod H. Thourani, MD,# E. Murat Tuzcu, MD,** Samir Kapadia, MD,
Thomas McAndrew, MS,‡‡ Ke Xu, PHD,‡‡ Martin B. Leon, MD,* Sus



- ***The PARTNER-I trial Cohort A (n= 304) and Cohort B (n= 194) patients randomized to TAVR, and the non-randomized continued access TAVR (n=1637) patients (Total of 2135 patients)***
- ***PD was performed at the discretion of the operator. The overall incidence of PD was 12.4%.***
- ***Clinical events and echocardiographic variables were collected prospectively out to 1 year.***

Hahn RT et al. (J Am Coll Cardiol Intv 2014;7:781–9)



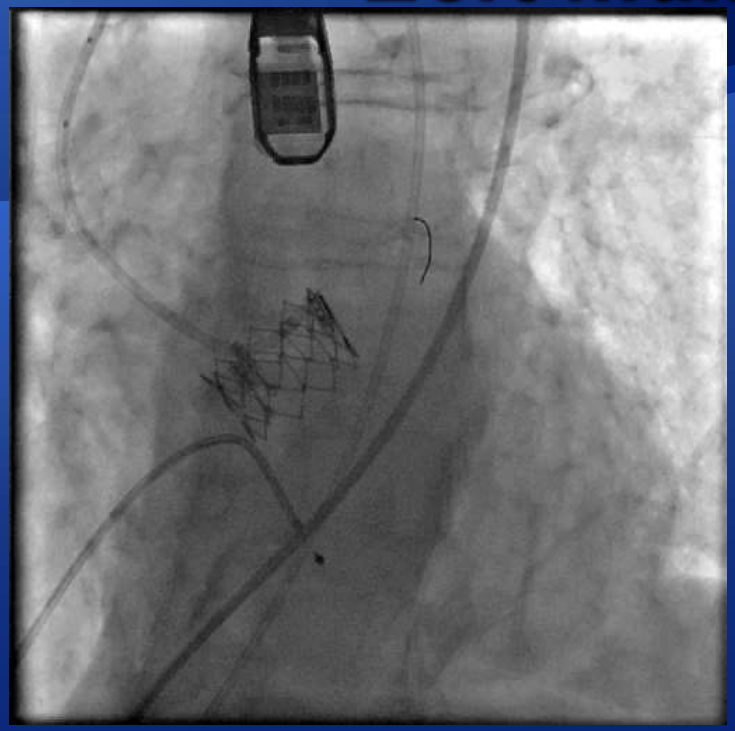
Nombela-Franco L et al. J Am Coll Cardiol Intv 2012;5:499 –512

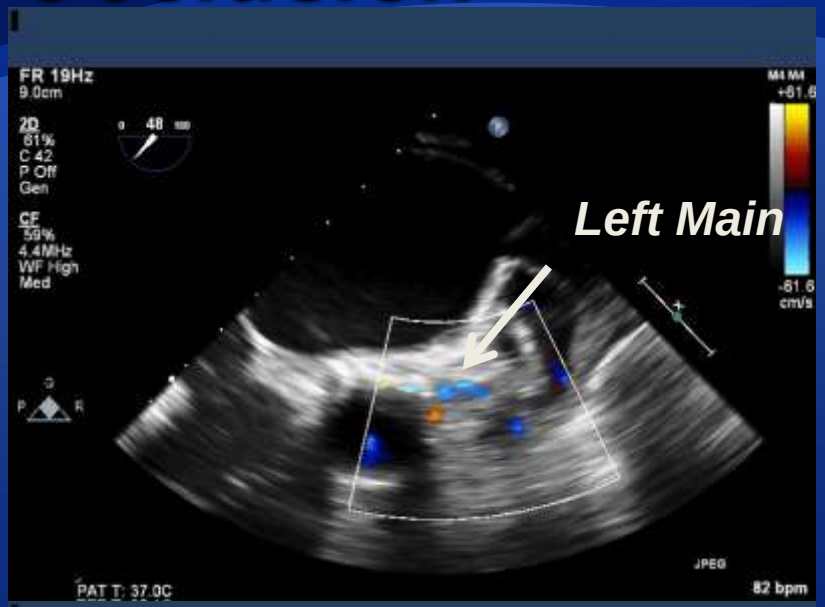
Subacute Stroke (<7 d)	Hazard Ratio	p value
Baseline Annulus Diameter	0.11 [0.01, 1.42]	0.0901
Post-dilatation	1.90 [1.03, 3.50]	0.0409

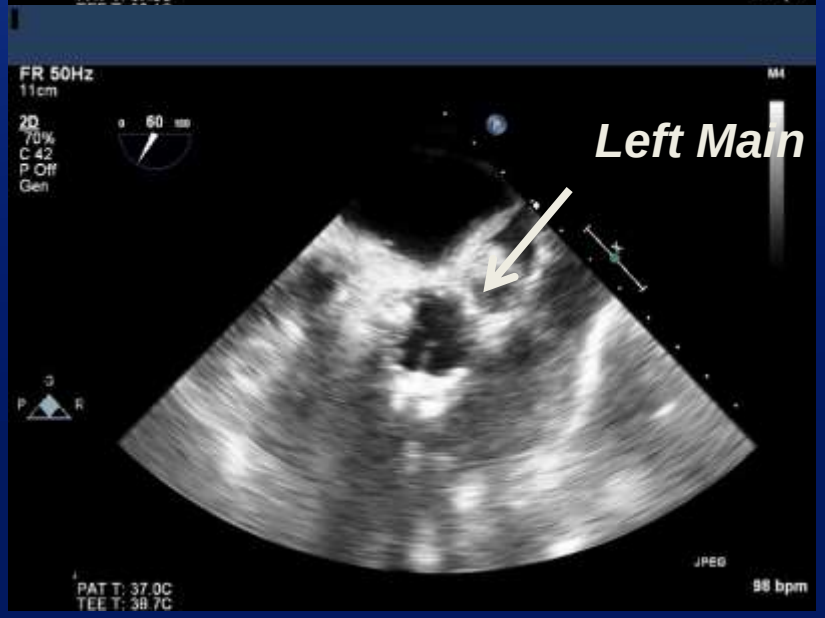
Model:
Potential Covariates included: Baseline annulus diameter, prior CABG, approach (transfemoral vs transapical), major arrhythmia, baseline AV area index
Forced in Covariates: Post-dilatation

Hahn RT et al. (J Am Coll Cardiol Intv 2014;7:781–9)

Other Risks of PD: Left Main Occlusion

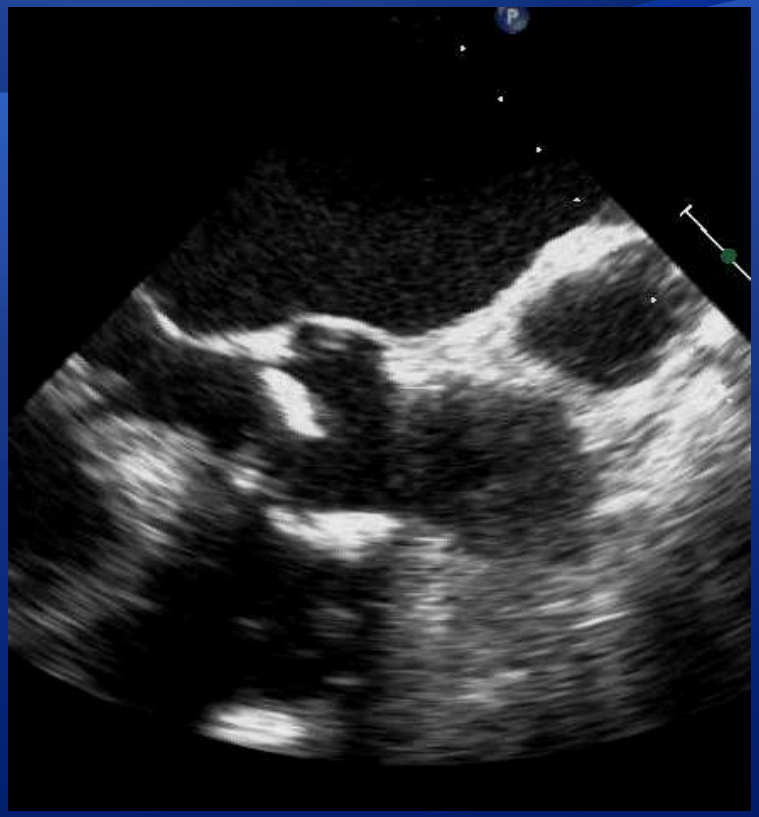


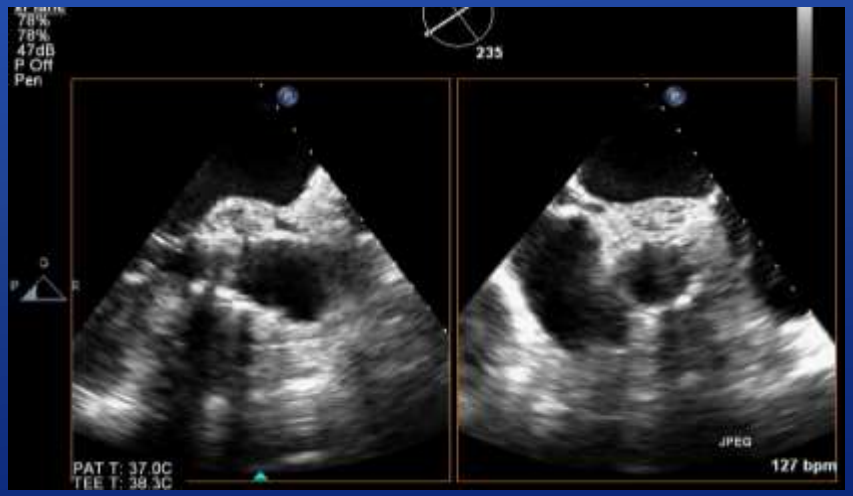


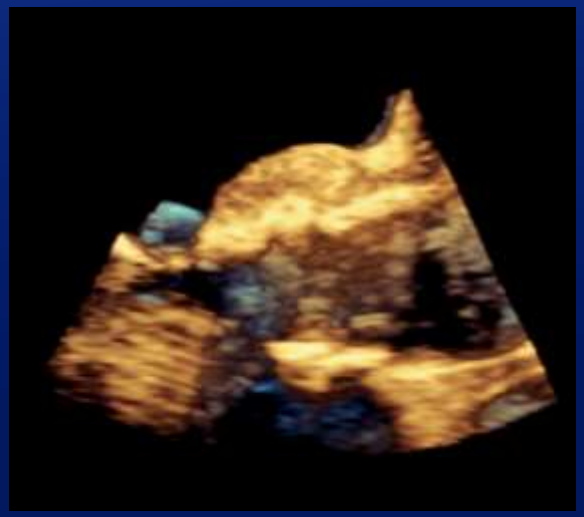


Due to effaced sinuses and threatened left main, decision was made not to post-dilate

Other Risks of PD: Aortic Perforation

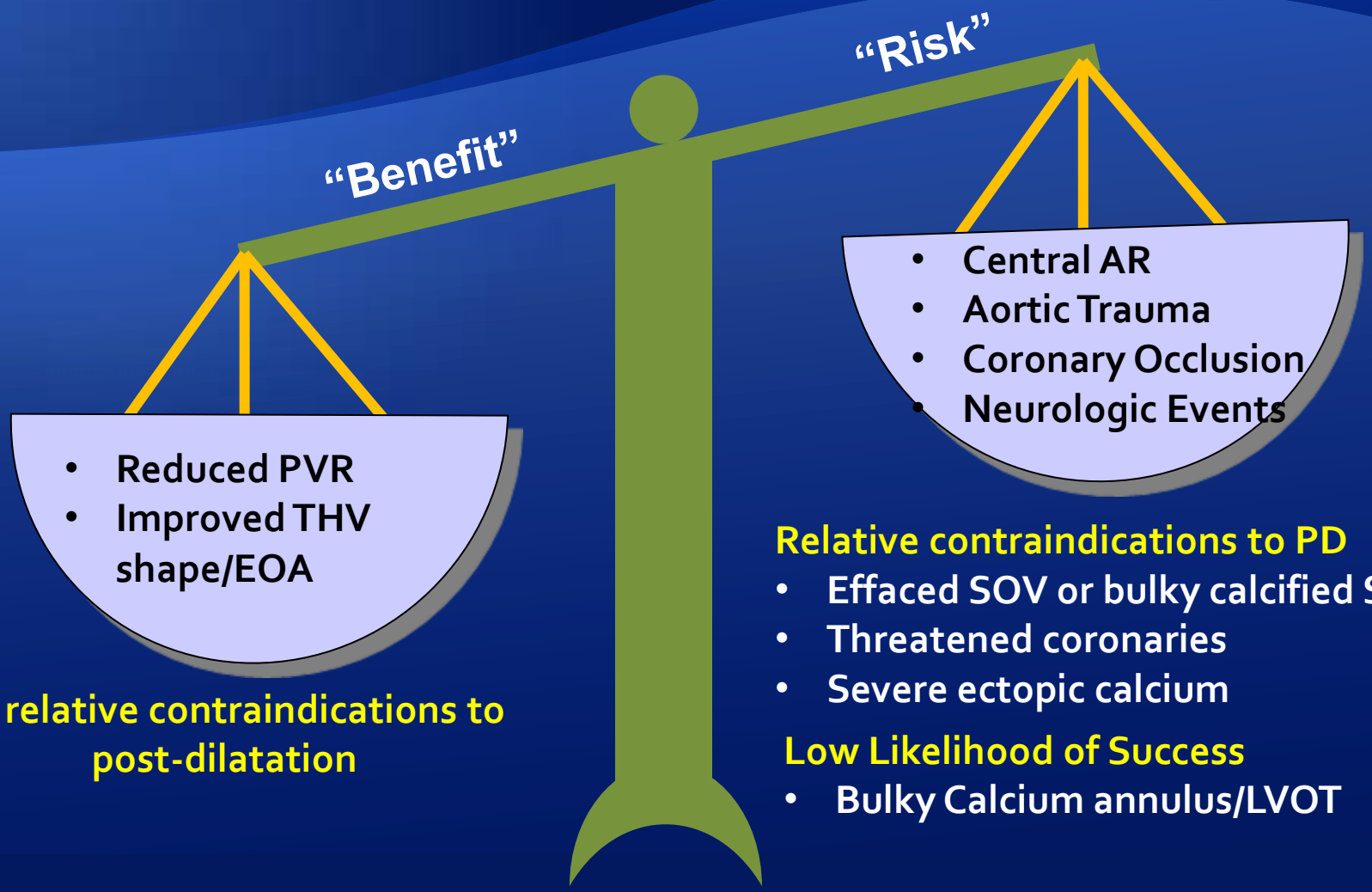






Annulus – 18mm
SOV = 26.3 mm
ST Junction – 19mm

Post-dilatation Risk-Benefit Analysis



No relative contraindications to post-dilatation

Relative contraindications to PD

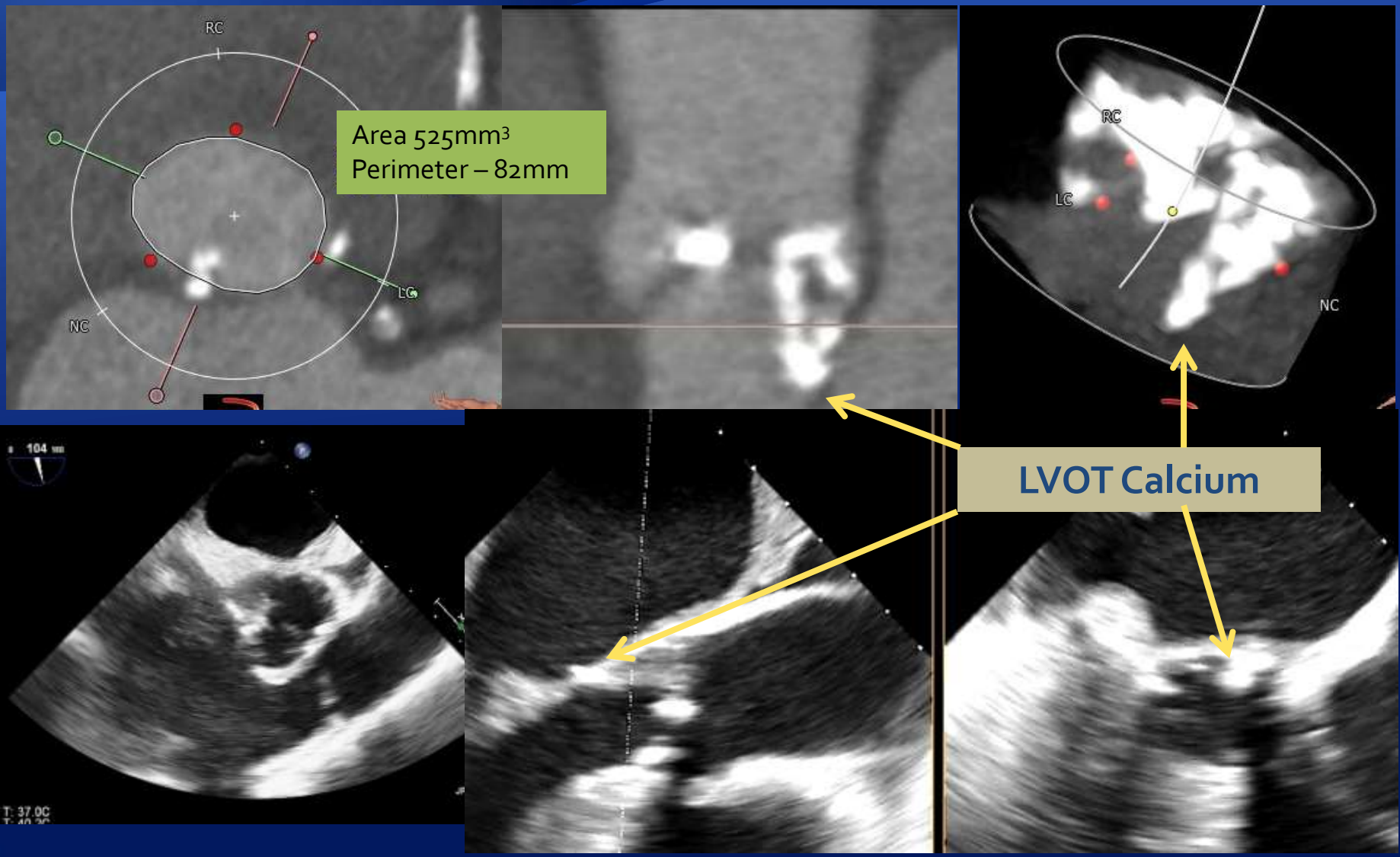
- Effaced SOV or bulky calcified STJ
- Threatened coronaries
- Severe ectopic calcium

Low Likelihood of Success

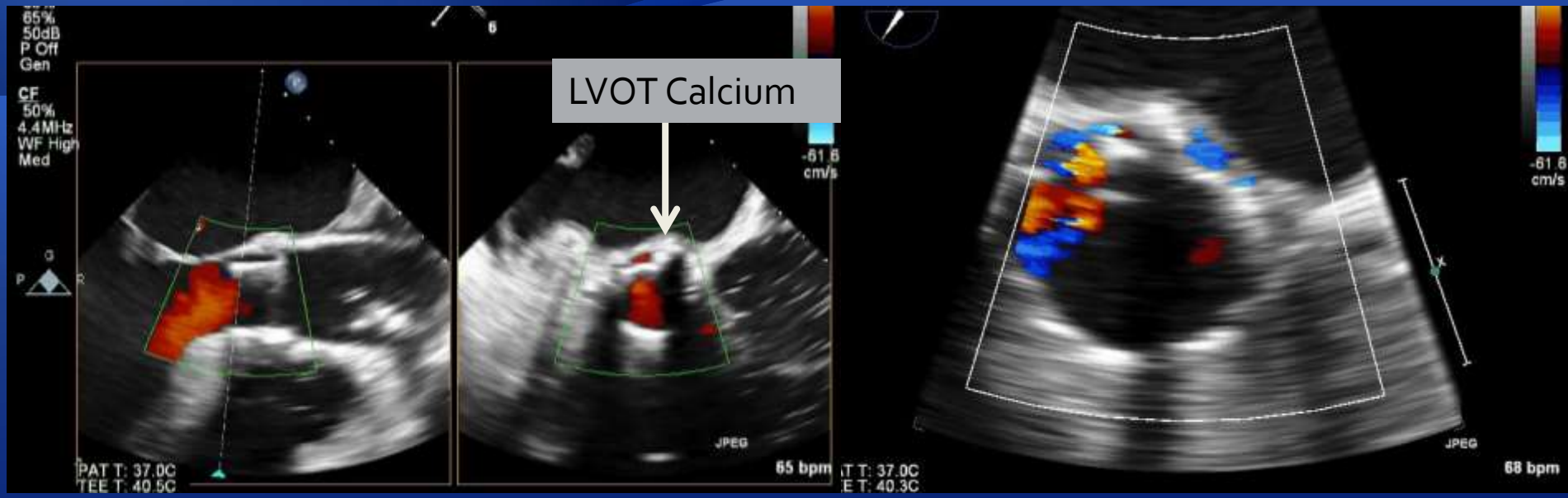
- Bulky Calcium annulus/LVOT

Risk-Benefit of PVL Closure Device or Second THV

Other Solutions to PVL: Paravalvular Closure Device

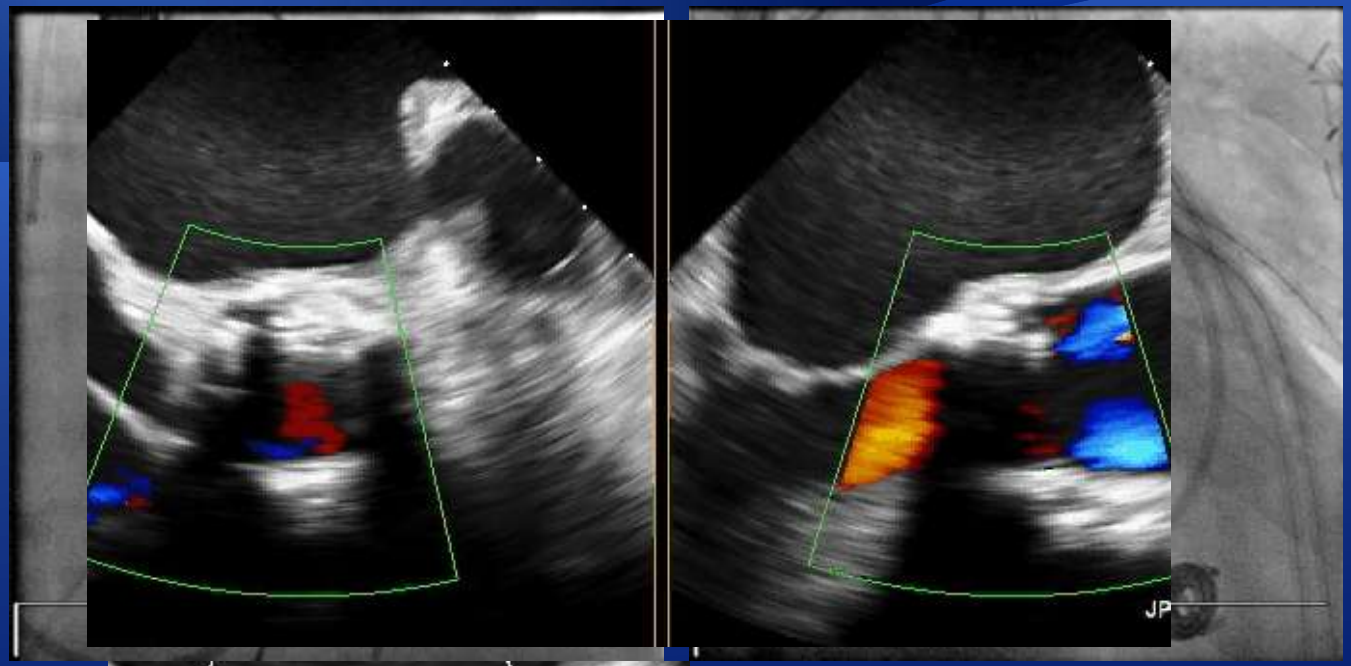


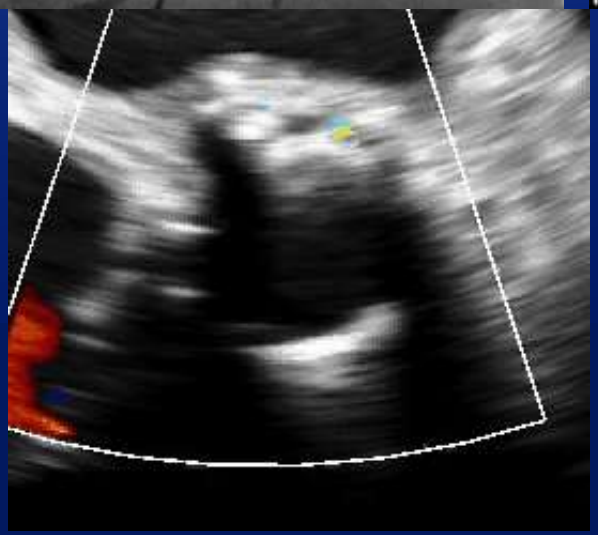
Other Solutions to PVL: Paravalvular Closure Device



- Post-deployment angiography revealed 3+ PVL
- Post-dilatation performed with additional 1cc (2cc total) with no change in PVL
- Unable to expand valve due to LVOT calcium

Other Solutions to PVL: Paravalvular Closure Device

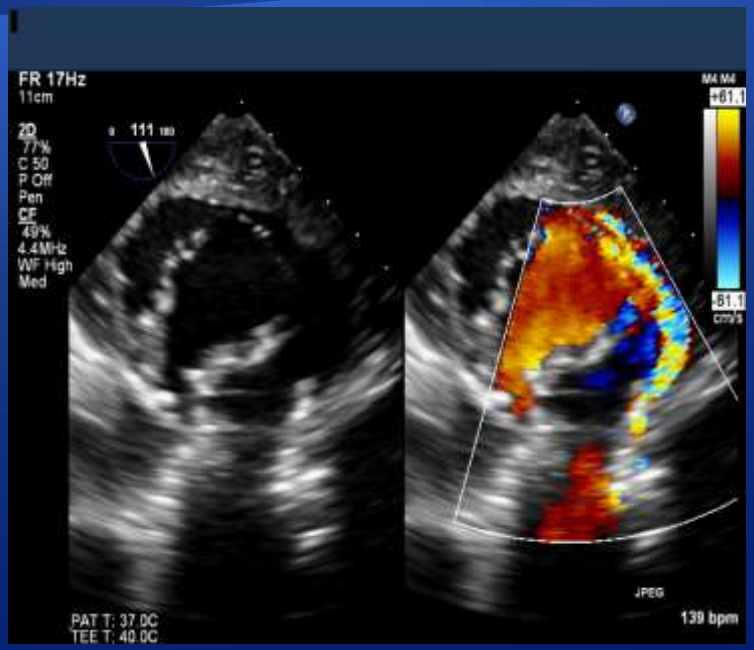


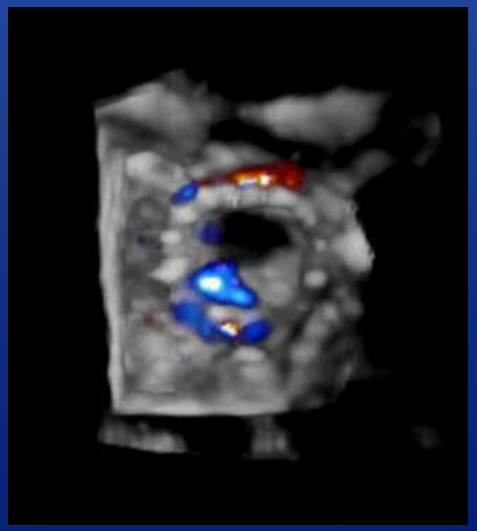


- In same setting, PVL was crossed with a glide wire and a 4F sheath
- AVP 4 device was advanced through the 4F glide cath
- Using echo and fluoroscopic guidance, it was deployed across the defect
- Echo post revealed reduced PVL

Other Solutions to PVL: Valve-in-Valve

Deep Gastric Views



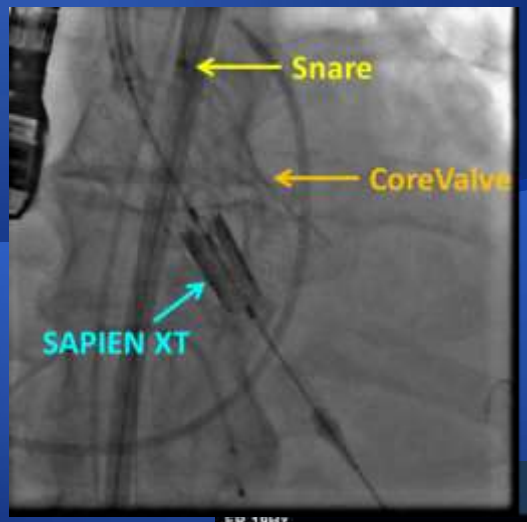


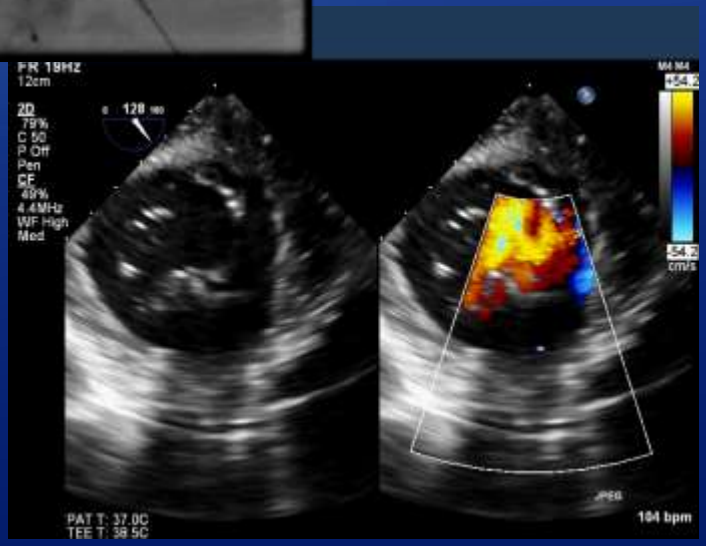
- *Large posterior PVL 13mm² with multiple jets*
- *Total 3D EROA = 19mm²*
- *AR VTI = 95cm, Regurgitation Volume = 18cc*

89 year old with severe symptomatic aortic stenosis

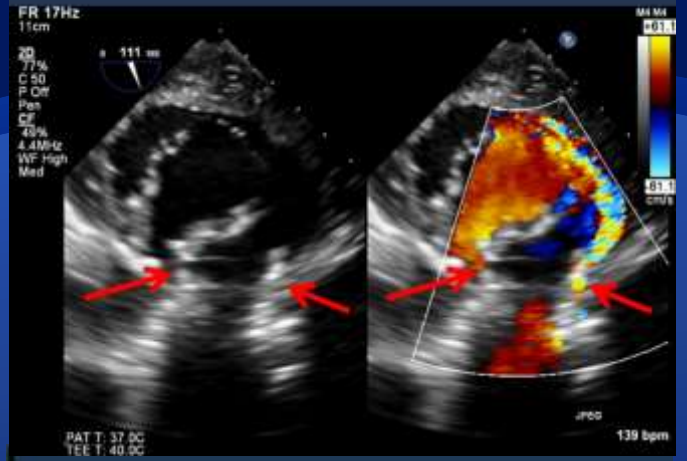
- *Annular perimeter = 85 cm*
- *31 mm CoreValve delivered however valve was resulting position was low resulting in severe aortic regurgitation*

THV in THV

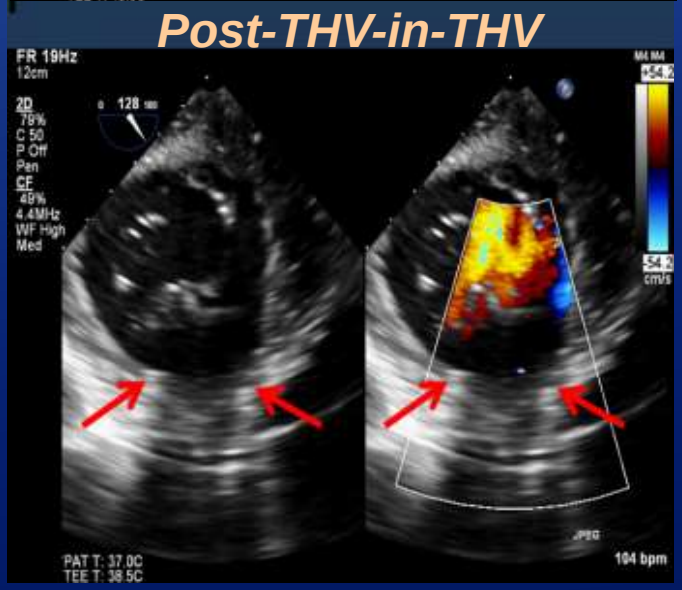




Pre-THV-in-THV



Post-THV-in-THV



SAPIEN in CoreValve salvage: CoreValve was snared and SAPIEN XT positioned at the anatomic anulus

- ***Final AVA = 1.9 cm2***
- ***Trivial residual paravalvular regurgitation***

One oz of PVL Prevention is worth a ton of Post-dilatation, Plug or V-in-V !


100