Case Studies: Evaluating Post-TAVR PVL

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Trans-catheter Heart Valves

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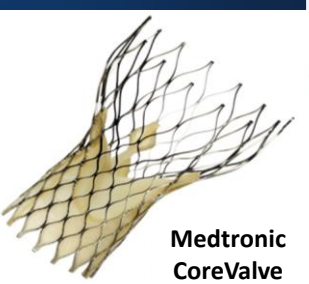
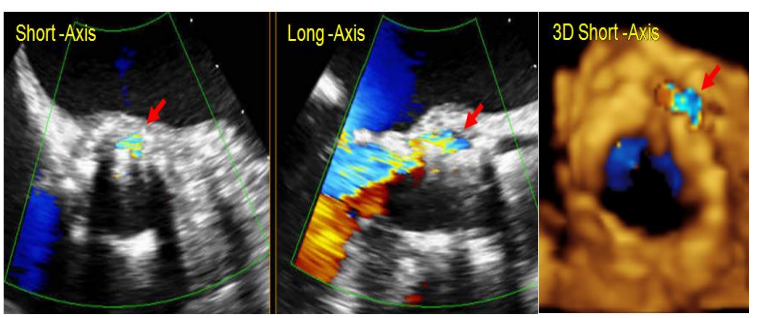
Edwards Sapien Valve

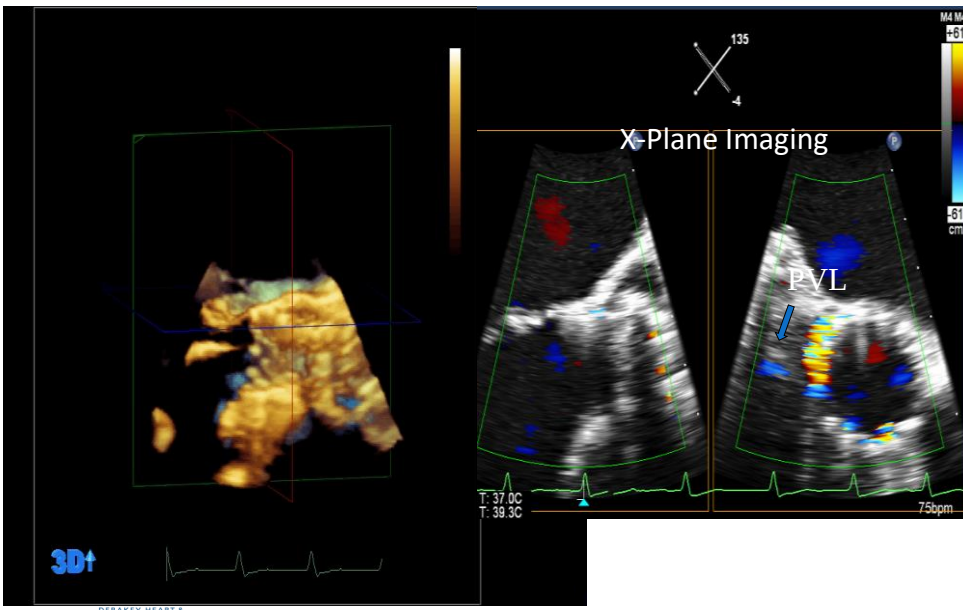


Medtronic CoreValve

SJM Portico Valve



Procedural Success?



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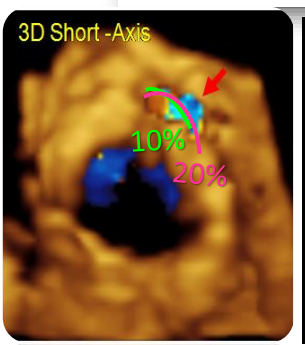
VARC – 2 Definitions: PVL Quantification

	Prosthetic aortic valve regurgitation		
	Mild	Moderate	Severe
Semiquantitative parameters			
Diastolic flow reversal in the descending aorta—PW	Absent or brief early diastolic	Intermediate	Prominent, holodiastolic
Circumferential extent of prosthetic valve paravalvular regurgitation (%)**	<10%	10%-29%	≥30%
Quantitative parameters‡			
Regurgitant volume (mL/beat)	<30 mL	30-59 mL	≥60 mL
Regurgitant fraction (%)	<30%	30-49%	≥50%
EROA (cm^2)	0.10 cm^2	0.10-0.29 cm^2	≥0.30 cm^2



- Adapted from the guidelines for surgical AVR
- Does not consider the height of the PVR jet

- <10% mild PVR
- 10–20% moderate PVR
- >20% severe PVR

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J Thorac Cardiovasc Surg 2013;145:6-23

JACC: CARDIOVASCULAR IMAGING
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Assessment of Paravalvular Regurgitation Following TAVR

A Proposal of Unifying Grading Scheme

Philippe Pibarot, DVM, PhD,* Rebecca T. Hahn, MD,† Neil J. Weissman, MD,‡ Mark J. Monaghan, PhD§

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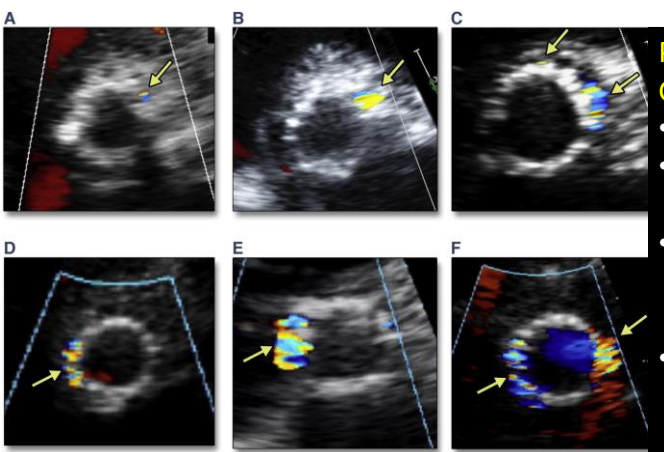
JACC Journals

Assessment of Paravalvular Regurgitation Following TAVR: A Proposal of Unifying Grading Scheme



PVR severity: 5 Grades

- <5%, trace PVR (A);
- 5% to 15%, mild PVR (B);
- 15% to 25%, mild-to-moderate PVR (C and D);
- 15% to 25% but larger jet width, moderate PVR (E);
- >30%, moderate-to-severe PVR (F)

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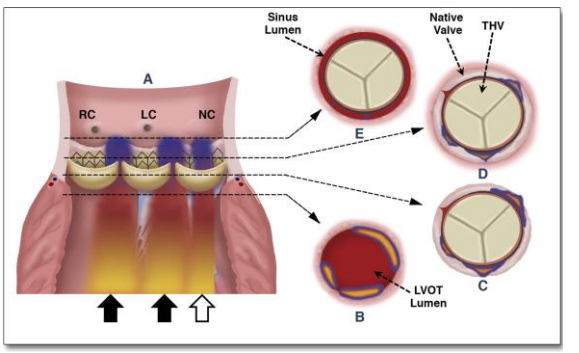
JACC Journals

Assessment of Paravalvular Regurgitation Following TAVR: A Proposal of Unifying Grading Scheme

Doppler Echo

- Color (VCA, circumferential extent, jet length)
- Pulse wave (Holodiastolic flow reversal, LVOT/RVOT SV)
- Beware the many limitations (shielding, Doppler angle)



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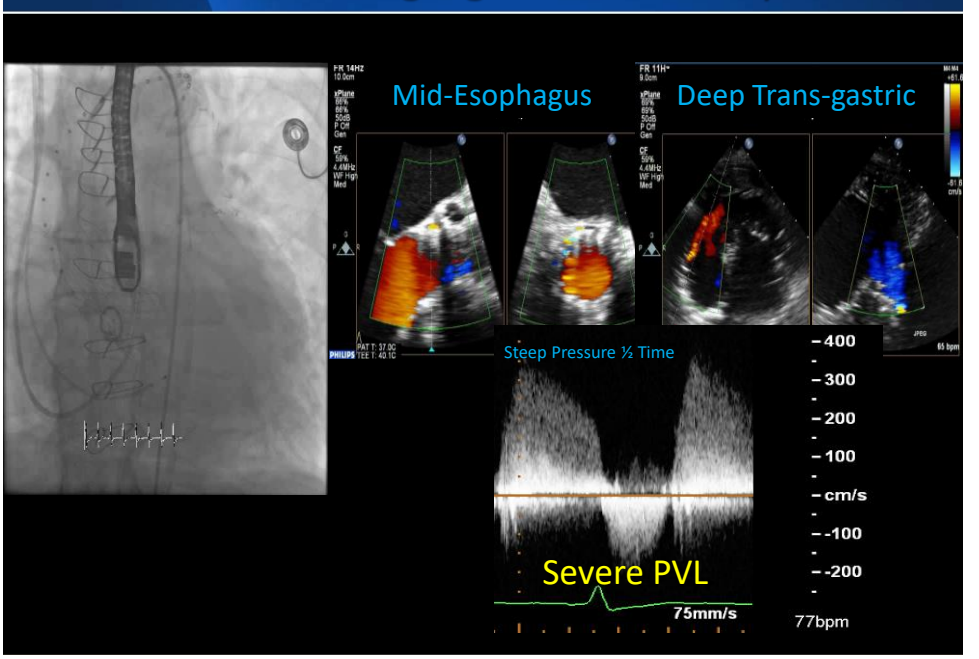
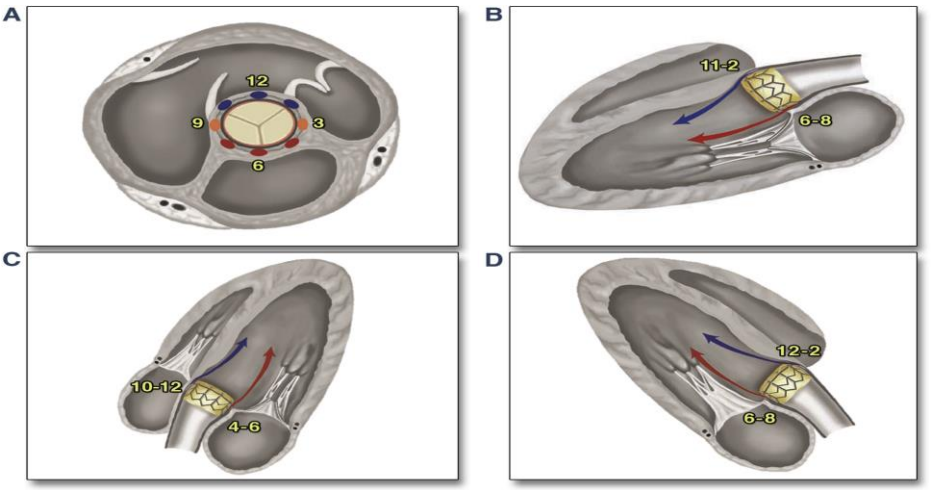
J Am Coll Cardiol Img. 2015;8(3)

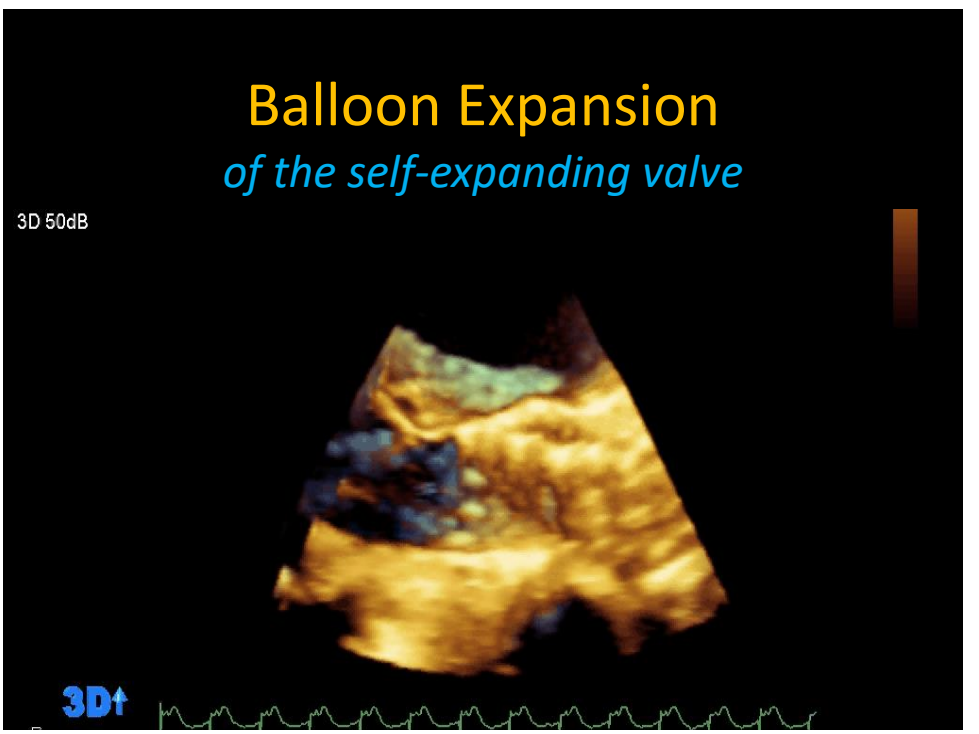
Paravalvular Regurgitation Severity?



Location of the PVR jets in different views

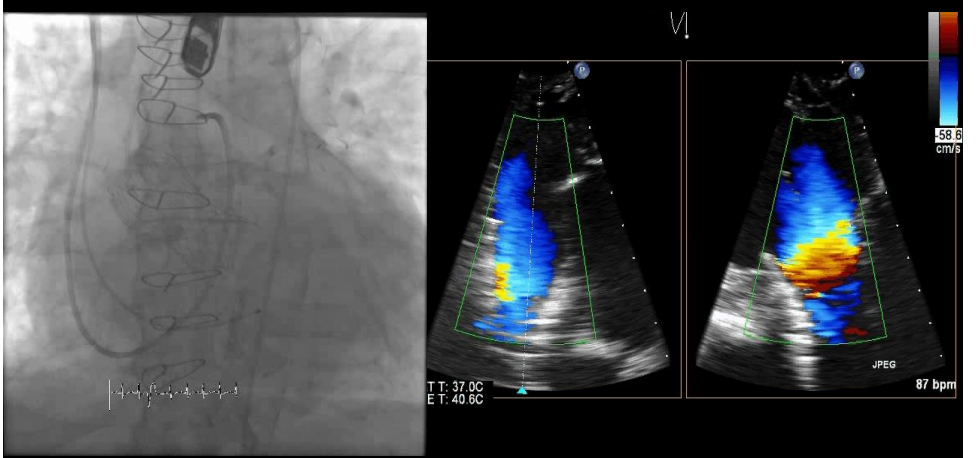


J Am Coll Cardiol Img. 2015;8(3)



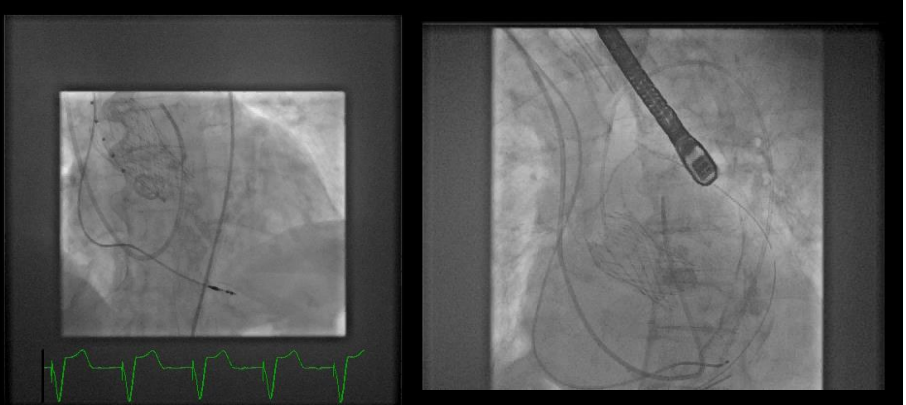
Final Result

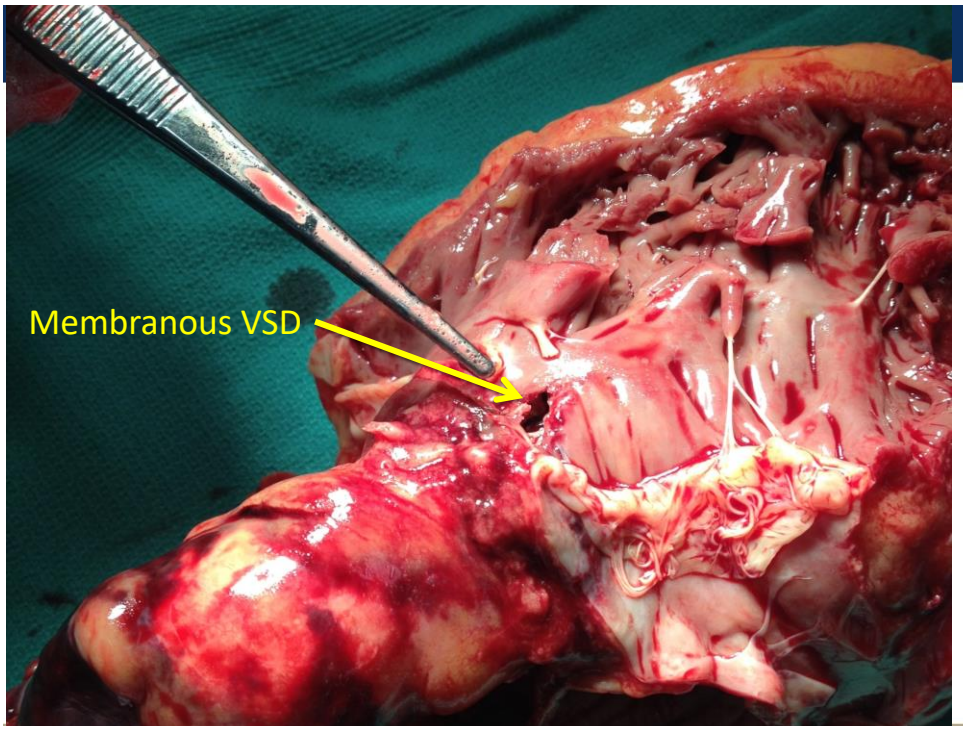
Trace PVL



92 yr male; Post-TAVR

Balloon Inflation for PVL?





77 yr male, severe symptomatic AS. History of CABG and liver dysfunction

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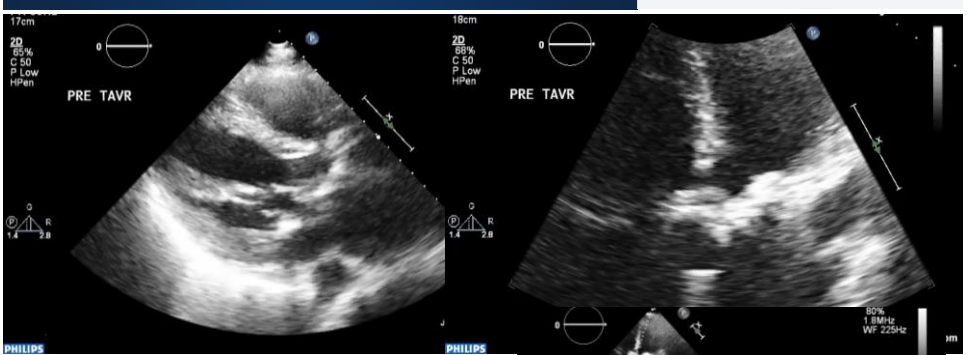

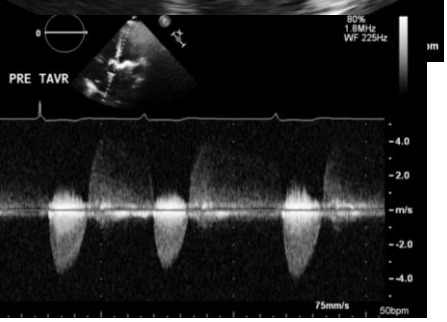

LVEF 35%
AV peak velocity 3.8 m/s
AV mean gradient 35 mmHg
AVA 0.7cm^2

Intra-Procedural TTE

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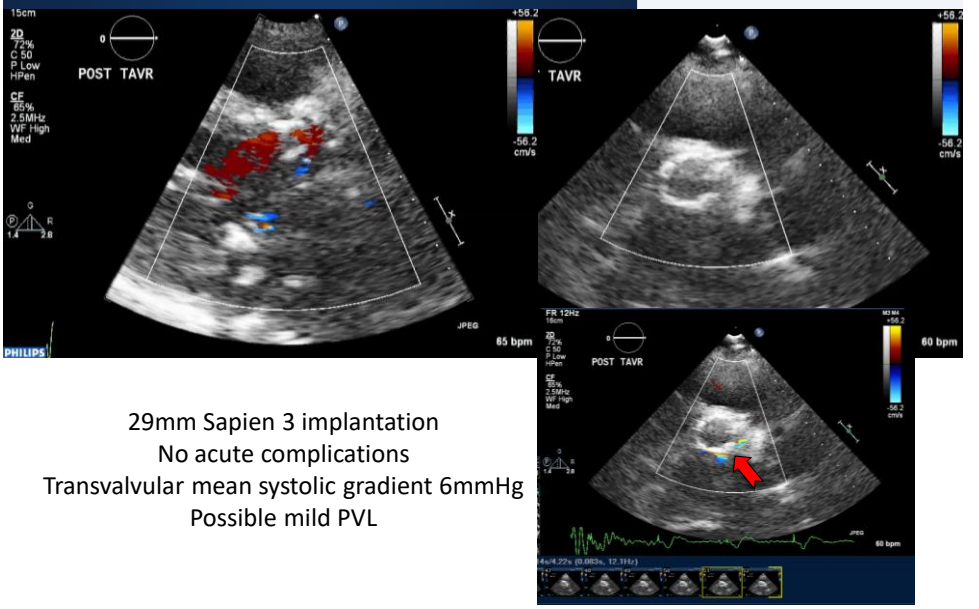

29mm Sapien 3 implantation
No acute complications
Transvalvular mean systolic gradient 6mmHg
Possible mild PVL

Persistent dyspnea after TAVR

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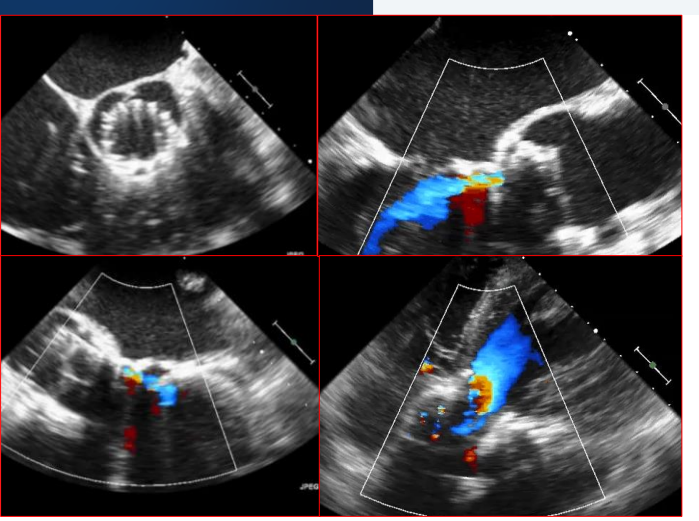
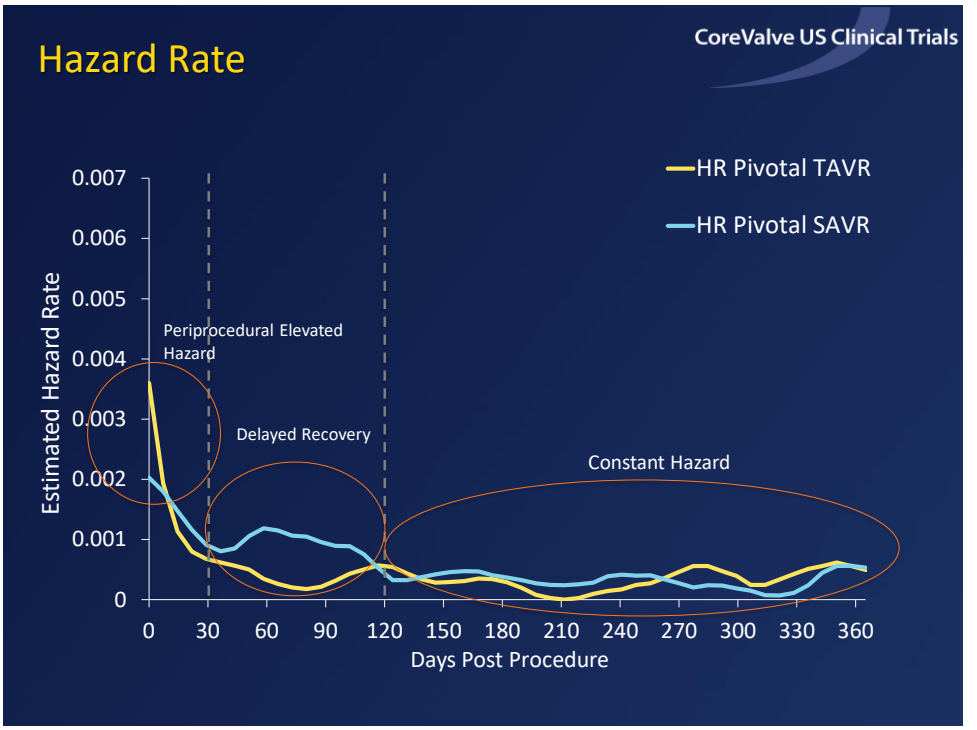
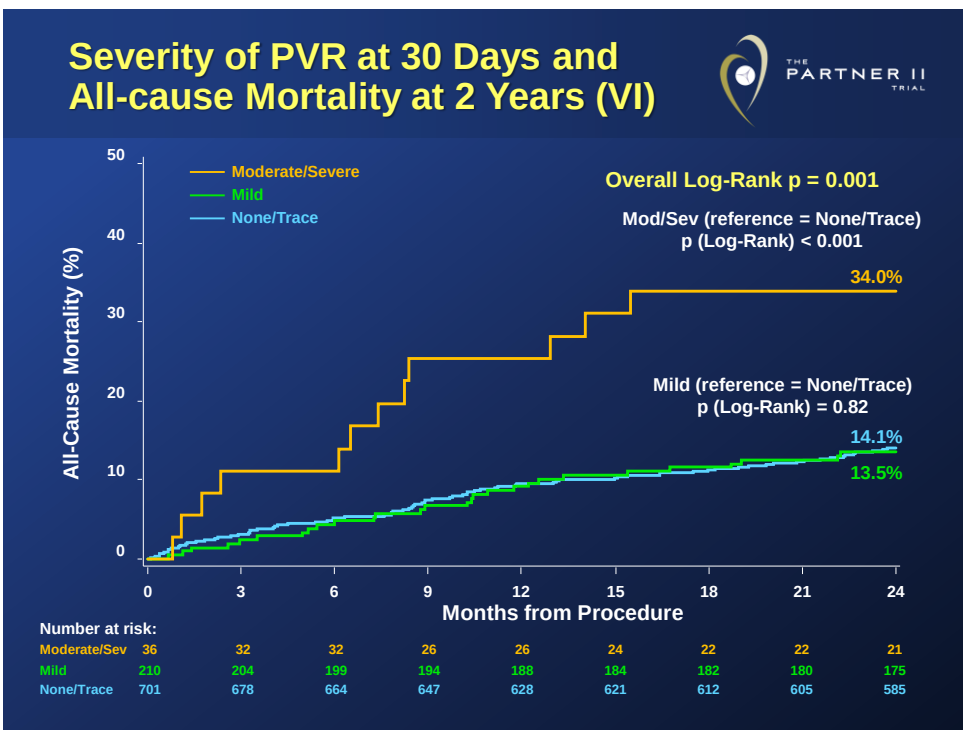
TEE done prior to hospital discharge

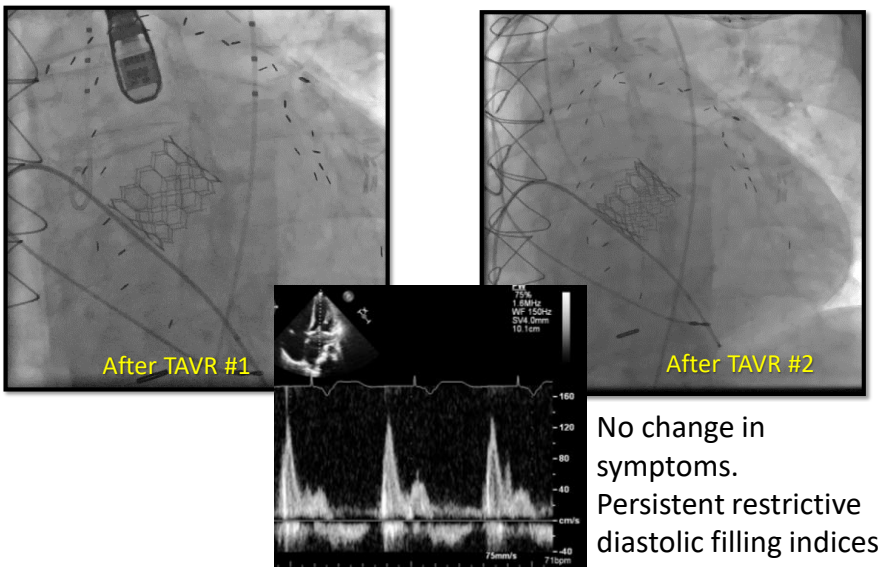
Mild to moderate PVL reported




Hazard Rate
CoreValve US Clinical Trials
HR Pivotal TAVR
HR Pivotal SAVR
Estimated Hazard Rate
0.007
0.006
0.005
0.004
0.003
0.002
0.001
0
Periprocedural Elevated Hazard
Delayed Recovery
Constant Hazard
0 30 60 90 120 150 180 210 240 270 300 330 360
Days Post Procedure


Severity of PVR at 30 Days and All-cause Mortality at 2 Years (VI)
THE PARTNER II TRIAL
Moderate/Severe
Mild
None/Trace
Overall Log-Rank p = 0.001
Mod/Sev (reference = None/Trace)
p (Log-Rank) < 0.001
34.0%
Mild (reference = None/Trace)
p (Log-Rank) = 0.82
14.1%
13.5%
All-Cause Mortality (%)
50
40
30
20
10
0
0 3 6 9 12 15 18 21 24
Months from Procedure
Number at risk:
Moderate/Sev 36 32 32 26 26 24 22 22 21
Mild 210 204 199 194 188 184 182 180 175
None/Trace 701 678 664 647 628 621 612 605 585

Valve-in-Valve procedure successfully treated PVL



No change in symptoms.
Persistent restrictive diastolic filling indices

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Incidence, Predictors, and Outcomes of Aortic Regurgitation After Transcatheter Aortic Valve Replacement

Meta-Analysis and Systematic Review of Literature

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Lars Georg Svensson, MD, PHD,‡ Pedro A. Lemos, MD,§ Chiara Fraccaro, MD, PHD,‖
Giuseppe Tarantini, MD, PHD,‖ Jan-Malte Sinning, MD,‖ Georg Nickenig, MD,¶
Davide Capodanno, MD, PHD,# Corrado Tamburino, MD, PHD,# Azeem Latib, MD,**
Antonio Colombo, MD,** Samir R. Kapadia, MD*
Cleveland, Ohio; São Paulo, Brazil; Padova, Catania, and Milan, Italy; and Bonn, Germany

- 25 studies reported on predictors of post TAVR PVL
- Implant depth, valve under sizing, and calcium score were identified as important predictors

Athappan et. al. JACC 2013

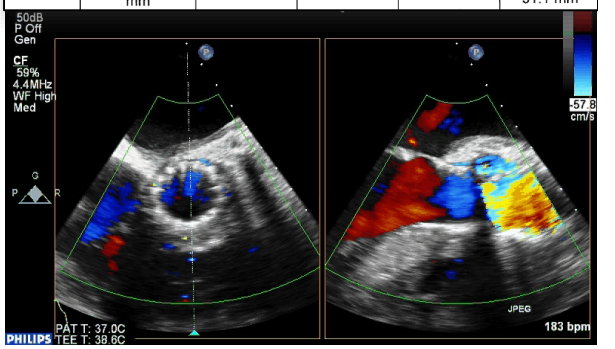
Importance of Correct Valve Size

CT Data:
Aortic annulus:
84 mm perimeter

29 mm CoreValve:
29 mm inflow diameter
Perimeter = 29 x 3.14
91mm/84mm = 1.08
= 8% cover index

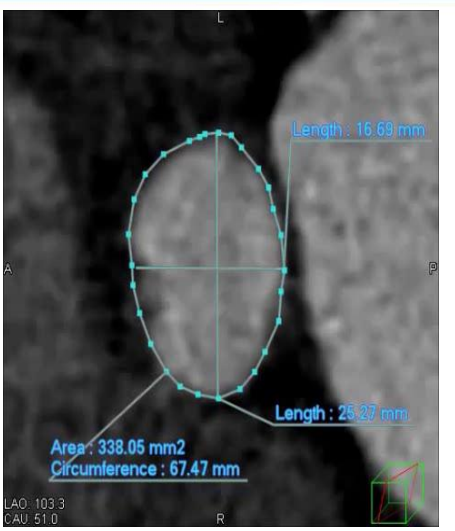
15-20% is ideal

Valve Size	Aortic Annulus Diameter	Ascending Aorta Diameter	Sinus of Valsalva Diameter	Native Leaflet to Sinutubular Junction Length	Perimeter Measurement
23	18 mm – 20 mm	≤ 34 mm	≥ 25 mm	≥ 15mm	56.5 mm – 62.8 mm
26	20 mm – 23 mm	≤ 40 mm	≥ 27 mm	≥ 15mm	62.8 mm – 72.3 mm
29	23 mm – 27 mm	≤ 43 mm	≥ 29 mm	≥ 15mm	72.3 mm – 84.8 mm
31	26 mm – 29 mm	≤ 43 mm	≥ 29 mm	≥ 15mm	81.6 mm – 91.1 mm



The Dynamic Annulus

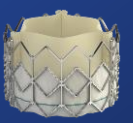
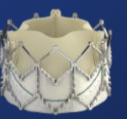
4D multidetector CT image of the aortic annulus in a patient with severe aortic stenosis shows change in measurements during the cardiac cycle.



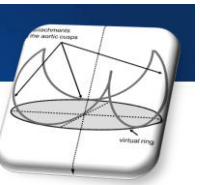
Masri A, Schoenhagen P, Svensson L, Kapadia S, Griffin B, Tuzcu M, Desai M. J Thorac Cardiovasc Surg 2014;147:1847-54.

SAPIEN Platforms in PARTNER
Device Evolution

THE PARTNER II TRIAL

	SAPIEN	SAPIEN XT	SAPIEN 3
Valve Technology			
Sheath Compatibility	22-24F	16-20F	14-16F
Available Valve Sizes	23 mm, 26 mm	23 mm, 26 mm, 29 mm	20 mm, 23 mm, 26 mm, 29 mm

3D Imaging Considerations



- Under sizing increases the risk of PVL.
- The “virtual” annulus is non-circular.
- Single linear measurements (whether directly measured or derived) are less accurate.
- Sizing algorithms for each valve have been defined.
- 3D imaging techniques must be used to accurately measure the annulus.

It’s less important which 3D imaging tool is used!

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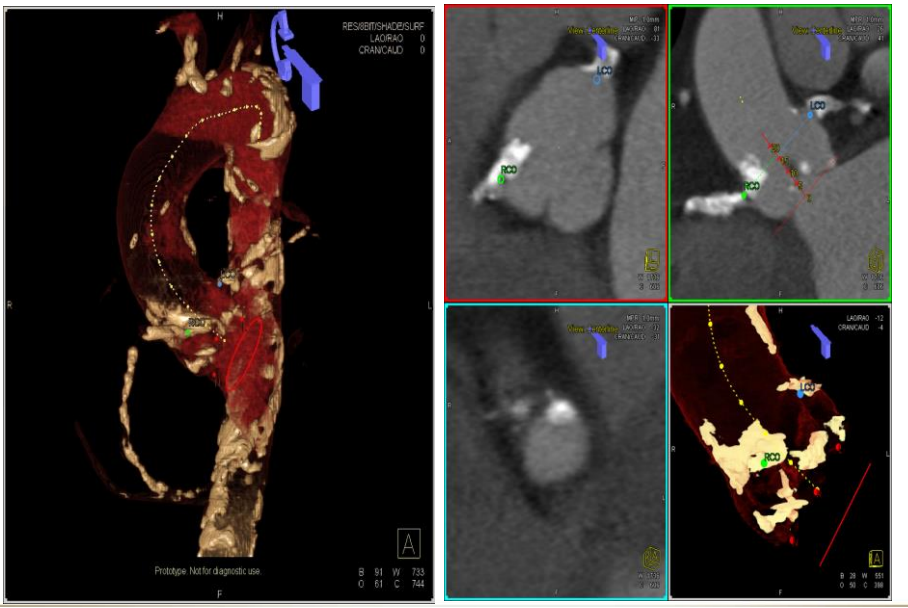
The Hostile Aorta- *Turbulent Flight & Landing*



Para-Valvular Regurgitation after TAVR

Correlation of Device Landing Zone Calcification and Acute Procedural Success in Patients Undergoing Transcatheter Aortic Valve Implantations With the Self-Expanding CoreValve Prosthesis

Daniel John, MD, Lutz Buellesfeld, MD, Seyrani Yuecel, MD, Ralf Mueller, MD, Georg Latsios, MD, Harald Beucher, MD, Ulrich Gerckens, MD, Eberhard Grube, MD

Siegburg, Germany

Methods:

- 100 pts with CoreValve TAVR
- MSCT to assess calcium load in valve and adjacent LVOT
- Calcium levels correlated with PVL by angio and TTE (2 weeks later)

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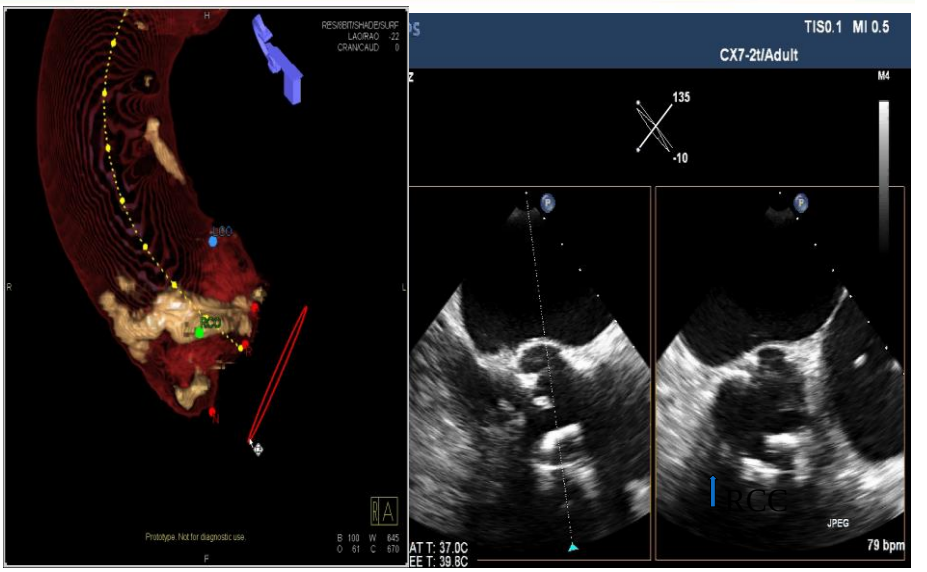
John D, Buellesfeld L, Yuecel S, et al; JACC Intv 2010;3:23-43

Landing Zone Concerns



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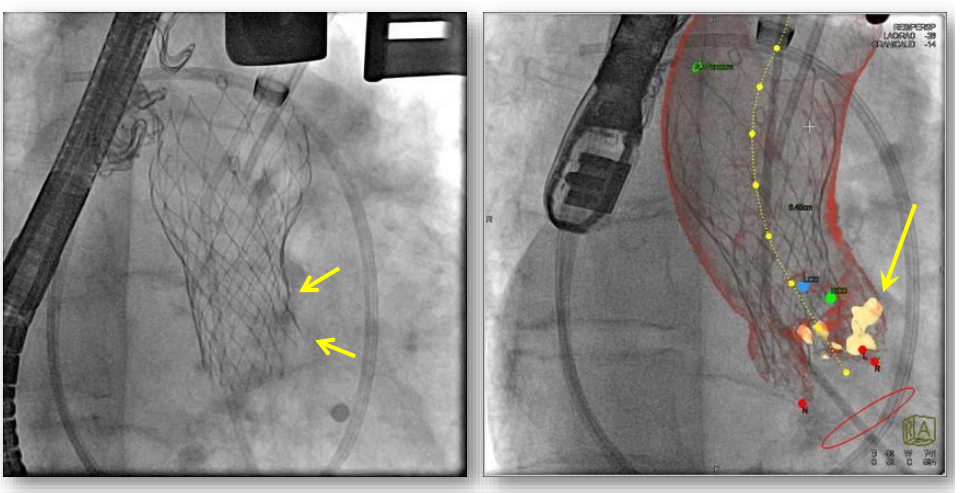
Immediately after Valve deployment



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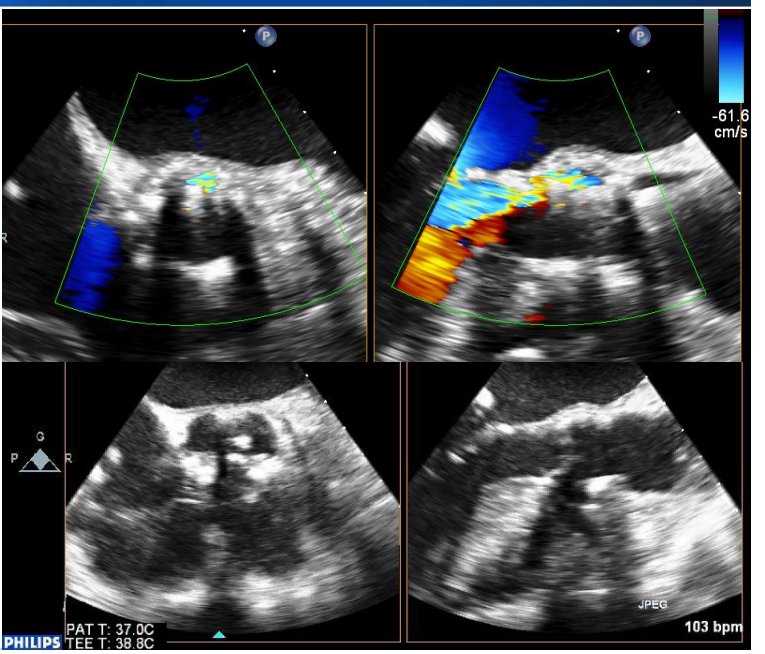
Asymmetric Root Calcium



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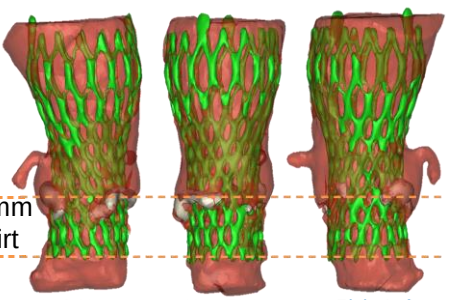
Sealing at Multiple Levels

CoreValve System: sealing can occur along the 12mm sealing skirt—in the aortic root, annulus, and LVOT—including above and below calcification

CT Images Courtesy of Dr. Piazza and Prof. Lange, German Heart Center Munich Germany

Patient Example of 3D Sealing at Multiple Levels



Bright green = CoreValve in contact with tissue
Red = blood volume
White = calcification

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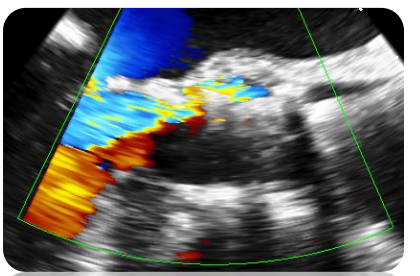
Implantation Depth

- PVL is influenced significantly by implant depth.
- A low CoreValve implantation associated with an OR of 3.67 for moderate or severe AR. (Takagi et al.)

- Sherif et al. optimal device depth 9.5mm (from the NCC)
- Jilaihawi et al. optimal device depth 5- to 10-mm



Valve positioning is based mainly on fluoroscopy with or without echo guidance. Choosing the correct fluoroscopic plane is critical.

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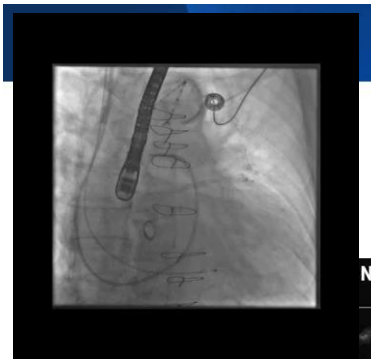
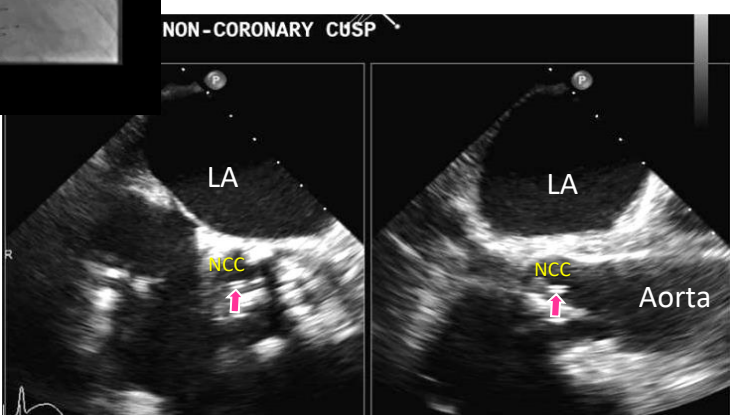
Guiding the Procedure

Confirm the Pig-Tail Catheter Location within the Non-Coronary Cusp (NCC)





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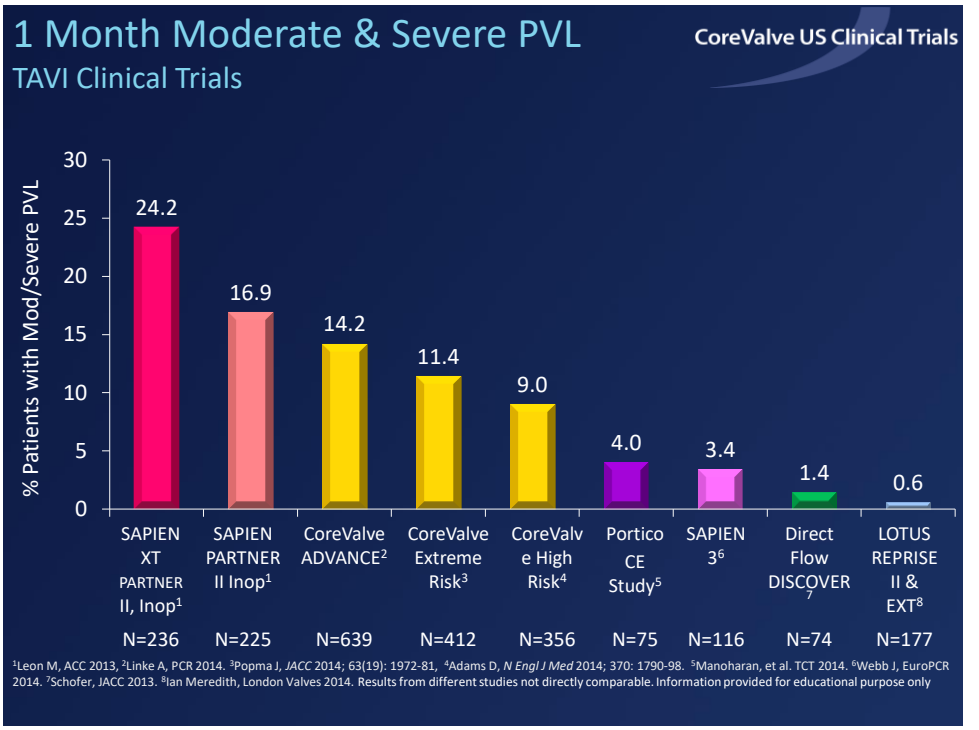

Clinical Presentation

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91 year old man with severe AS

- TAVR 1 month prior
- Now with new onset DOE, NYHA 3

PMHx:

- CAD, Dyslipidemia, HTN, Atrial fibrillation, Pacemaker (prior to TAVR)

Medications:

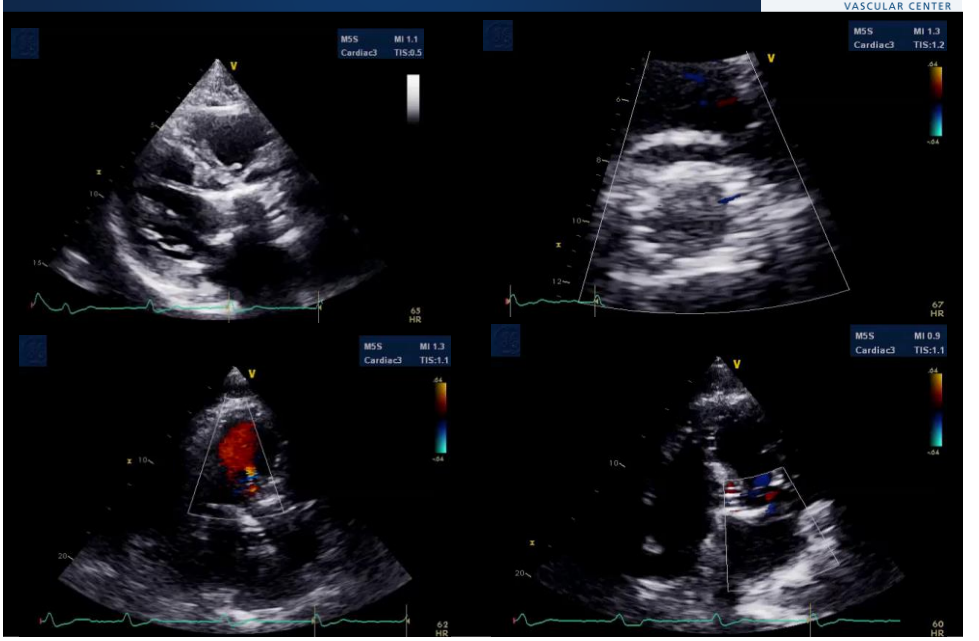
- Furosemide, simvastatin, digoxin, apixaban

Clinical Presentation

Physical Exam:

- BP 154/64, HR 67, RR 18, T 96.7, O2 97% R/A
- No Jugular venous distension, ascites, or peripheral edema
- Decreased breath sounds to bases
- 2/4 diastolic murmur

TTE PVL Severity?



Transthoracic Echocardiogram

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Findings

LV:	LV size is normal LV function is normal. Overall wall motion is normal. Estimated EF is 60-64%.
RV:	RV size is normal. RV function is normal.
LA:	LA size is enlarged.
RA:	RA size is enlarged.
AO:	Aortic root is mildly enlarged.
PERI:	No pericardial effusion.
PLE:	Pleural effusion is present.
AV:	Bioprosthetic aortic valve. Normal prosthetic valve velocity and gradient. Doppler velocity index is 0.57. Mild perivalvular aortic regurgitation
MV:	Moderate thickening and calcification of mitral leaflets. Moderate mitral annular calcification. Thickened and/or calcified chordae. Mild mitral regurgitation.
PV:	Pulmonic valve not well seen. A trace of pulmonic regurgitation.
TV:	No structural TV abnormalities noted. A trace of tricuspid regurgitation
Other:	Estimated PA systolic pressure is 30 mmHg, assuming a mean RAP of 5 mmHg.

2D Measurements

Parasternal Long Axis

Ao Rtd	3.9 cm	LV%fs	49.2 %
IVSd	1.1 cm	LVPWd	0.9 cm
LVIDd	5 cm	LA Ds	3.9 cm
LVIDs	2.5 cm	LVOT	2.2 cm

Doppler Measurements

AV For Flow/AVA

AV pkVel	200.1 cm/s	AV AC/ET	0.3
AV mnVel	113.9 cm/s	AV TVI	29.9 cm
AV pkPG	16 mmHg	AVpkAcRt	2629.8 cm/s²
AV Mean G	6.9 mmHg	AV DeRt	761.3 cm/s²
AV AC	79 msec	AV Area	2.9 cm²
AV ET	263 msec		

LVOT For Flow

LVOT Area	3.8 cm²	LVOT SV	88.1 ml
LVOTpkVel	113.9 cm/s	HR	59.9 bpm
LVOTpkPG	5.2 mmHg	LVOT CO	5.3 l/min
LVOTmnPG	2.7 mmHg	LVOT CI	2.7 l/m/m²
LVOT TVI	23.2 cm		

TEE for PVL severity

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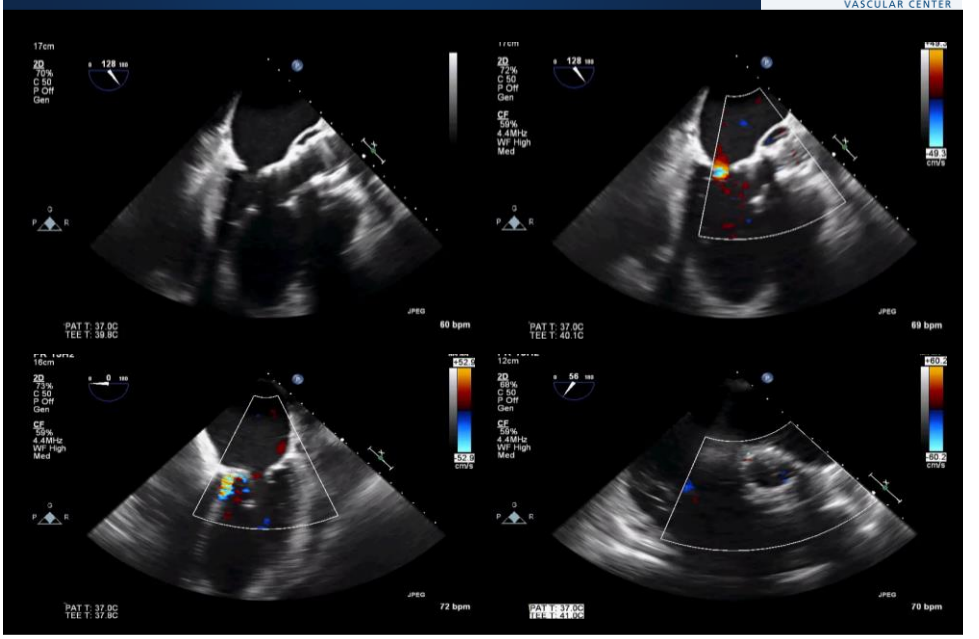
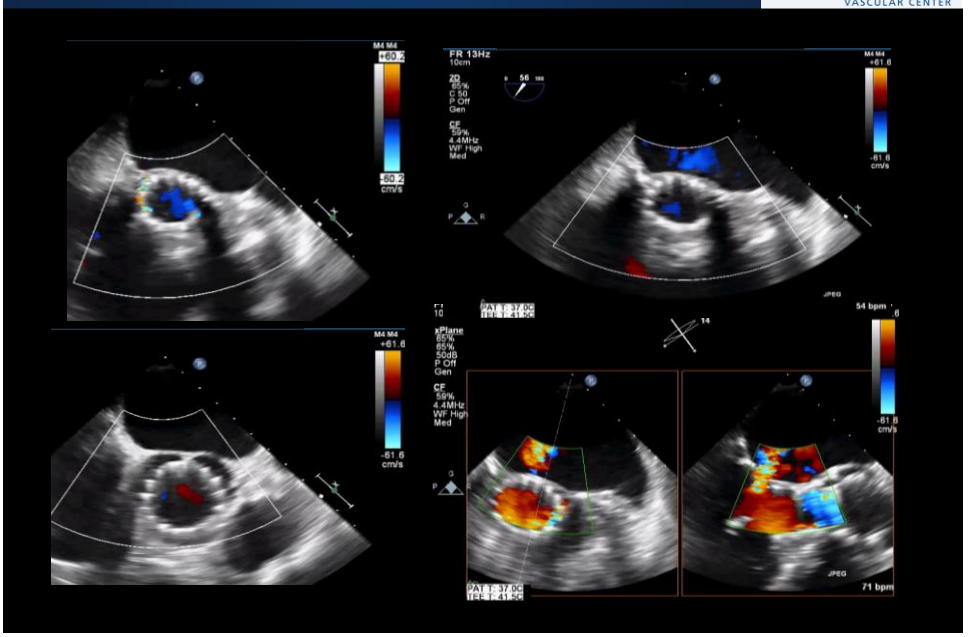


Even more TEE views for PVL



Transesophageal Echocardiogram

LV:	LV size is normal LV function is normal. Overall wall motion is normal. 3D volumetric LVEF is 62%.
RV:	RV size is normal. RV function is normal.
LA:	LA size is enlarged. No thrombus or mass is visualized in the LA or LA appendage. Spontaneous echo contrast is seen in the LA/LA appendage.
RA:	RA size is enlarged.
AO:	Mild atherosclerotic changes seen in the aortic arch and descending aorta.
PERI:	No pericardial effusion.
IAS:	Atrial septum is normal.
AV:	Bioprosthetic Core Valve is visualized.Placement appears lower in LVOT. Mild paravalvular aortic regurgitation with 2 jets located anterior and posteriorly (view 37).
MV:	Moderate thickening and calcification of mitral leaflets. Mild mitral annular calcification. Mild to moderate mitral regurgitation.
PV:	No structural PV abnormalities noted.
TV:	No structural TV abnormalities noted.

Cardiac Magnetic Resonance

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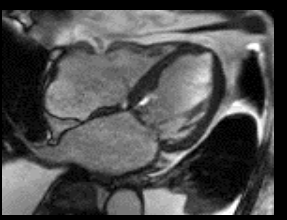

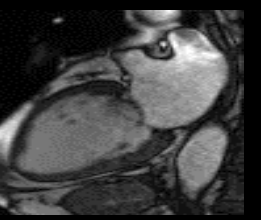

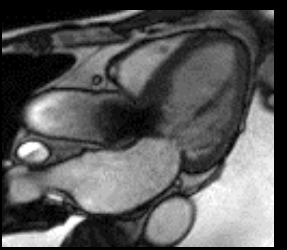

LV	
End Diastolic Volume	152.1 ml
End Systolic Volume	29 ml
Cardiac Output	8.62 L/min
Myocardial Mass	154.7 g
Stroke Volume	123.10 ml
Ejection Fraction	80.93 %

Cardiac Magnetic Resonance

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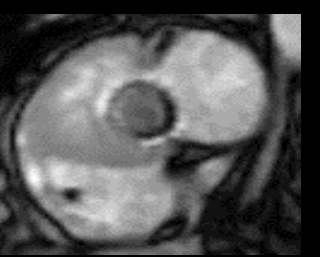
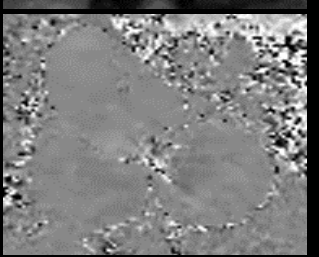
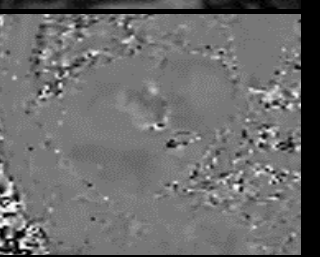
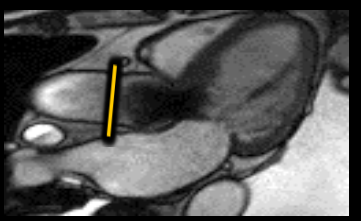
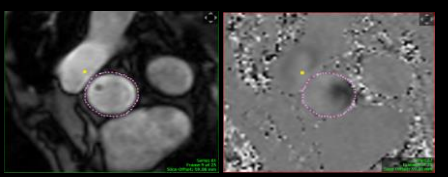


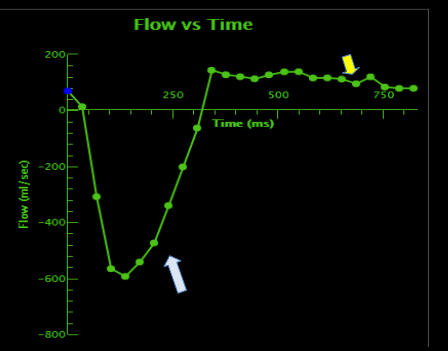




Cardiac Magnetic Resonance

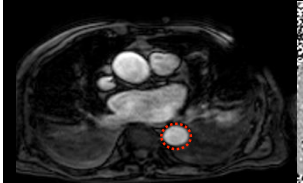


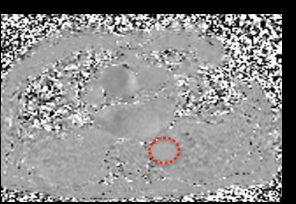


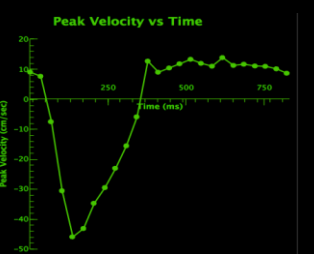


RF = Rvol (50 mL) / AOFF (100 mL) = 50%

Cardiac Magnetic Resonance







DESCENDING AORTA: HOLODIASTOLIC FLOW REVERSAL

Cardiac Magnetic Resonance Report

1. Normal LV and RV sizes. Severe bi-atrial enlargement. NO thrombus in LA or RA appendages.

2. Hyperdynamic LV and normal RV systolic function (LVEF 81%, RVEF 50%).

3. Subendocardial scarring in the basal-mid anterolateral wall, total scar burden 2%.

4. Self expanding transcatheter valve in low aortic/LVOT position. Severe paravalvular aortic regurgitation (RV 50 ml, RF 50%) with holodiastolic flow reversal in the descending aorta. Position of bioprosthesis limits anterior mitral leaflet excursion resulting in mild mitral stenosis (planimetered MVA 2.0 cm2). Mild-moderate mitral regurgitation (RV 23 ml, RF 32%).

5. Enlarged ascending aorta (4.5 cm) without dissection. Enlarged pulmonary artery (MPA 3.0 cm). Normal pulmonary venous anatomy.

6. Large bilateral pleural effusions. Small inferior pericardial effusion.

FINAL IMPRESSION: SELF EXPANDING TRANSCATHETER IN LOW AORTIC/LVOT POSITION WITH SEVERE PARAVALVULAR AORTIC REGURGITATION. MILD-MODERATE MITRAL REGURGITATION.

Clinical Decision Making

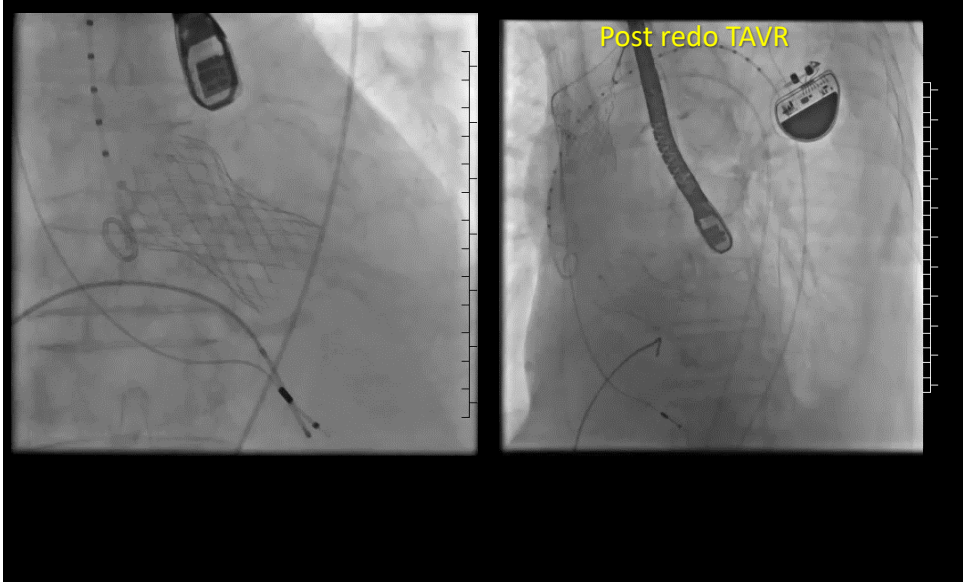
Clinical Summary

- 91M NYHA III
- Post-TAVR (Core Valve) 1 month ago

CMR Findings

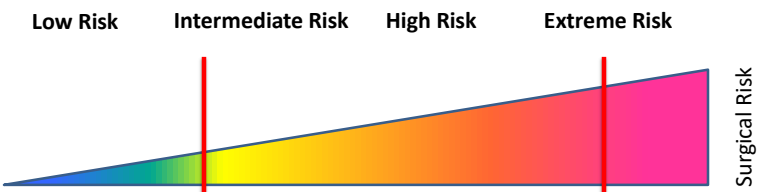
- Low implant in LVOT
- Severe (RF 50%)paravalvular AI with holodiastolic reversal
- Mild-moderate mitral regurgitation

Interventional Lab



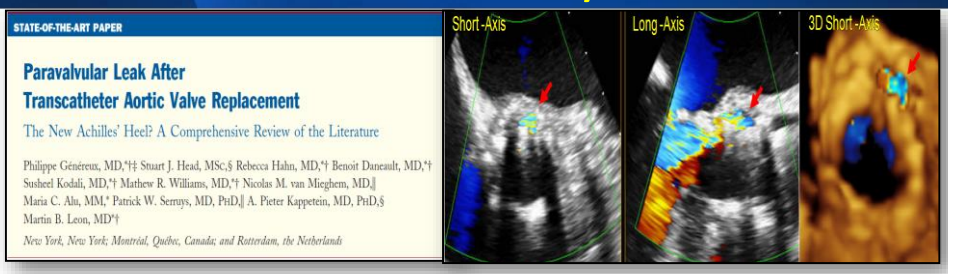
PREDICTIONS FOR 2020

All risk categories will be TAVR candidates



Both dividing lines moving to the left

In Summary



- Underestimation of PAR with may be significant.
- Accurate annulus sizing is a key step to prevent PVR.
- 3D imaging is superior to 2-D imaging techniques.
- Innovations designed to improve sealing.
- Improvement in the range of available device sizes, accurate annular sizing, and precise positioning will help minimize AR after TAVR.

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