2014 KSC meeting

Optimal Imaging Technique Prior to TAVI -Echocardiography-

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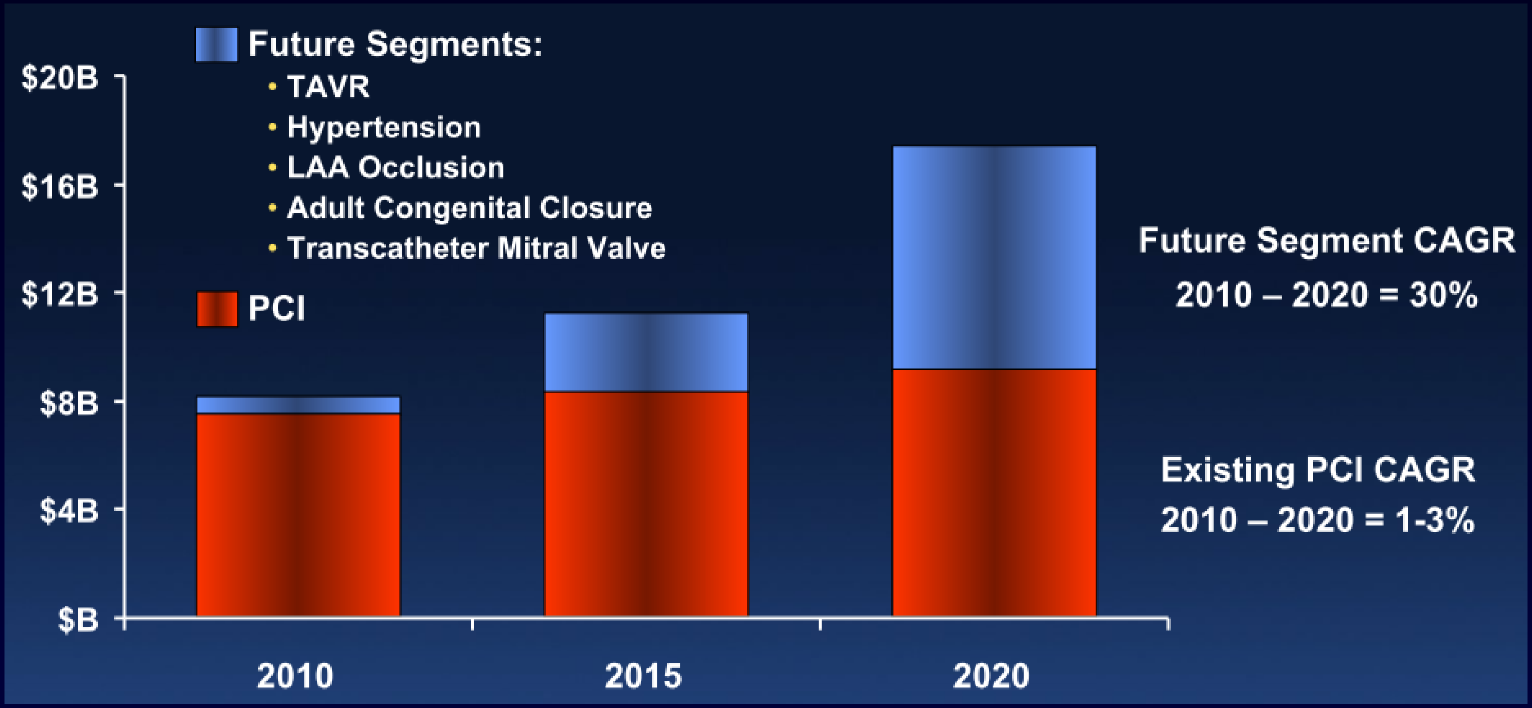
Worldwide Cardiology Market Trends



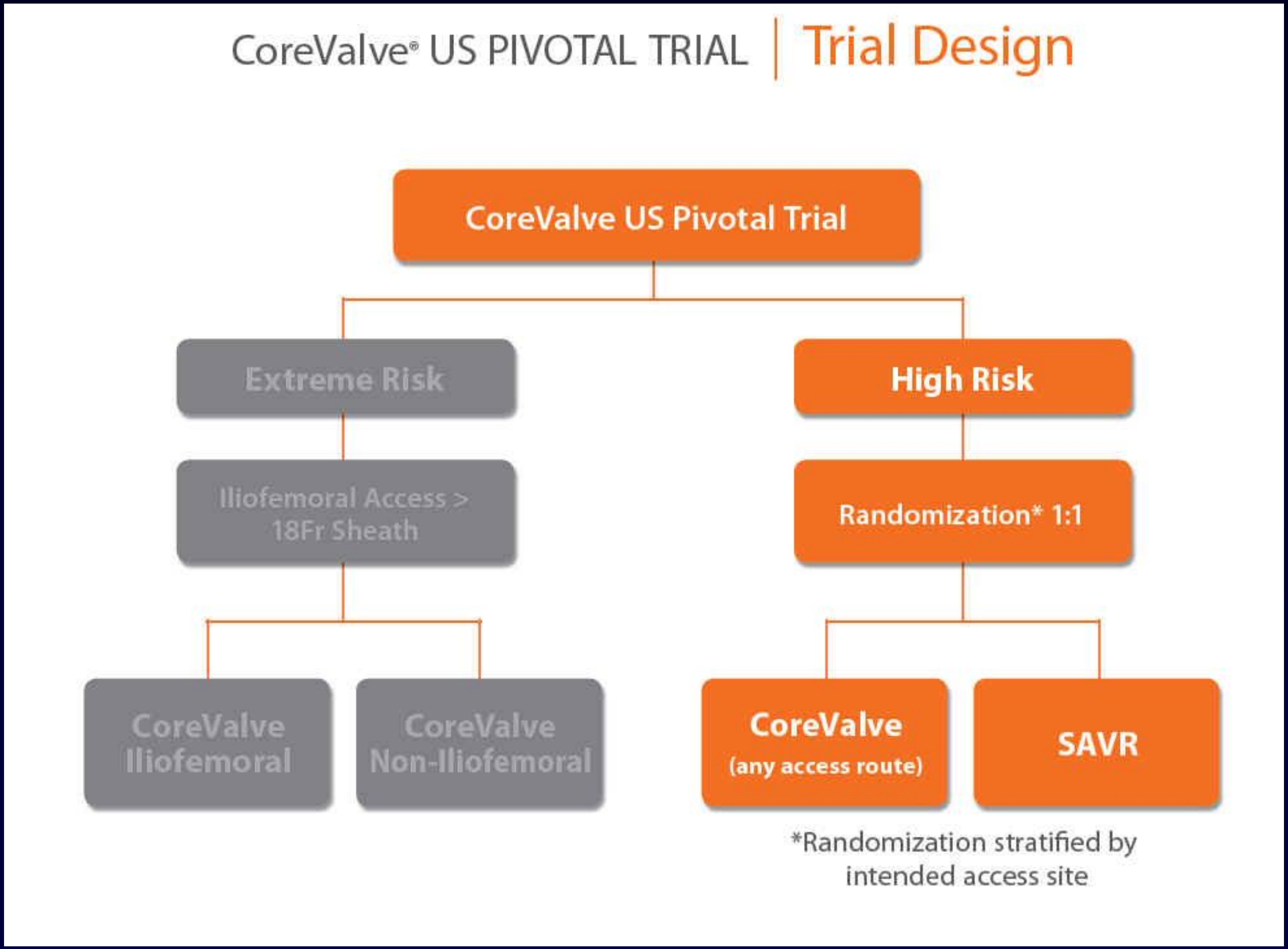
- New market segments may exceed PCI market size by 2020
- Emergence of future segments relies on technology and clinical data
- OUS markets will lead and exceed the size of US markets

Current Generation of Devices

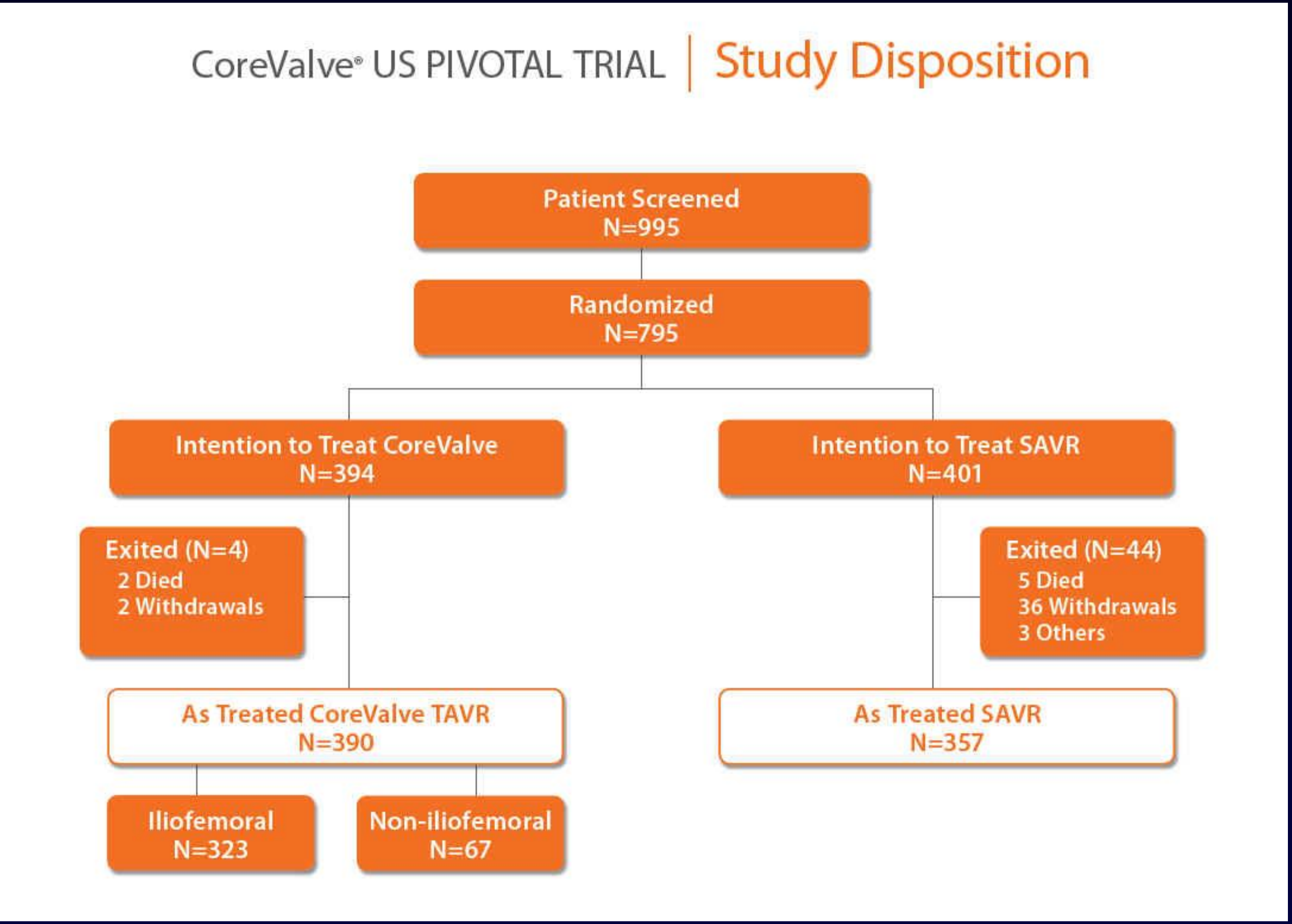
Edward Life sciences
Balloon expandable

Medtronic CoreValve
Self expandable

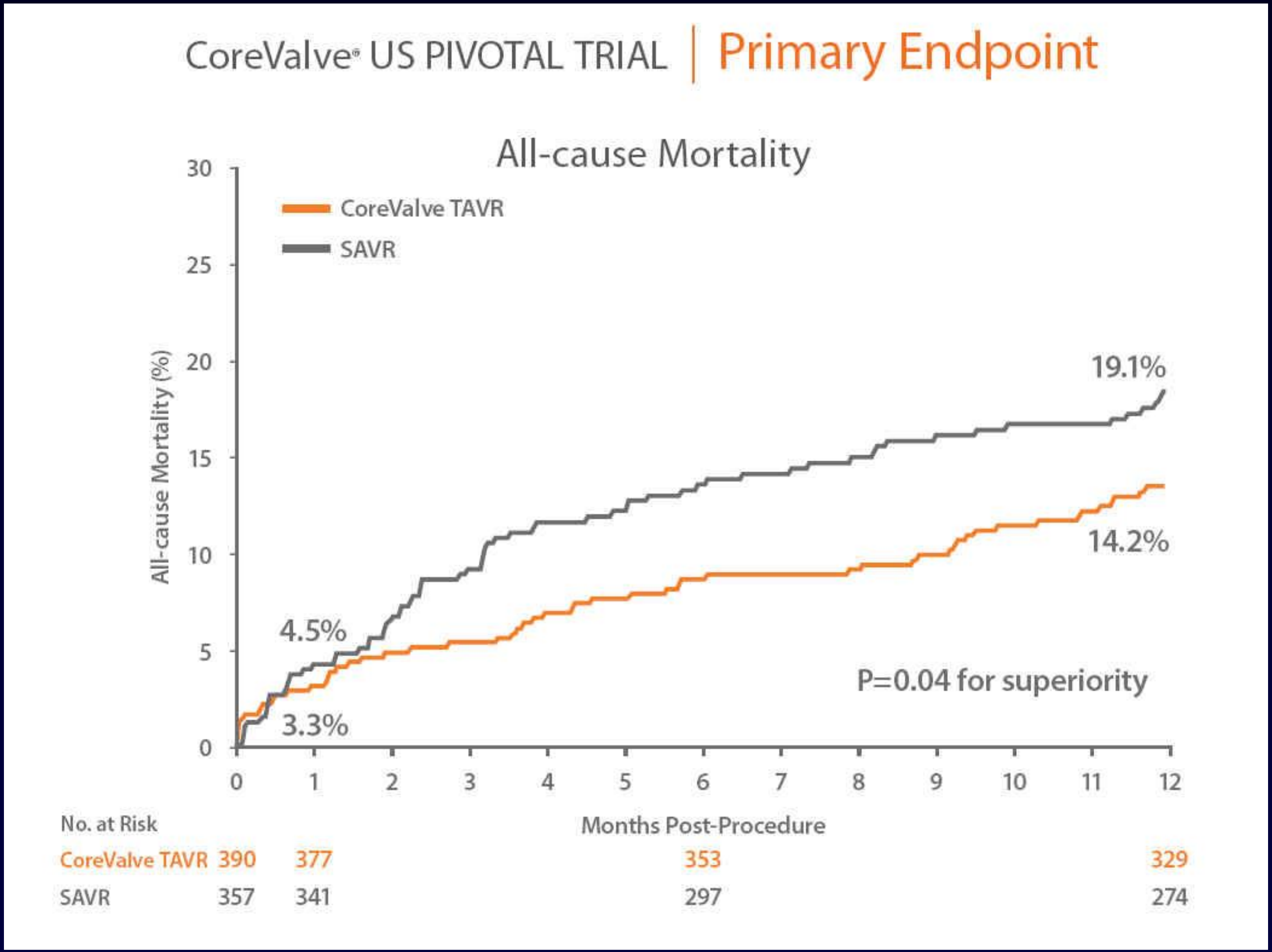
Current State of TAVI



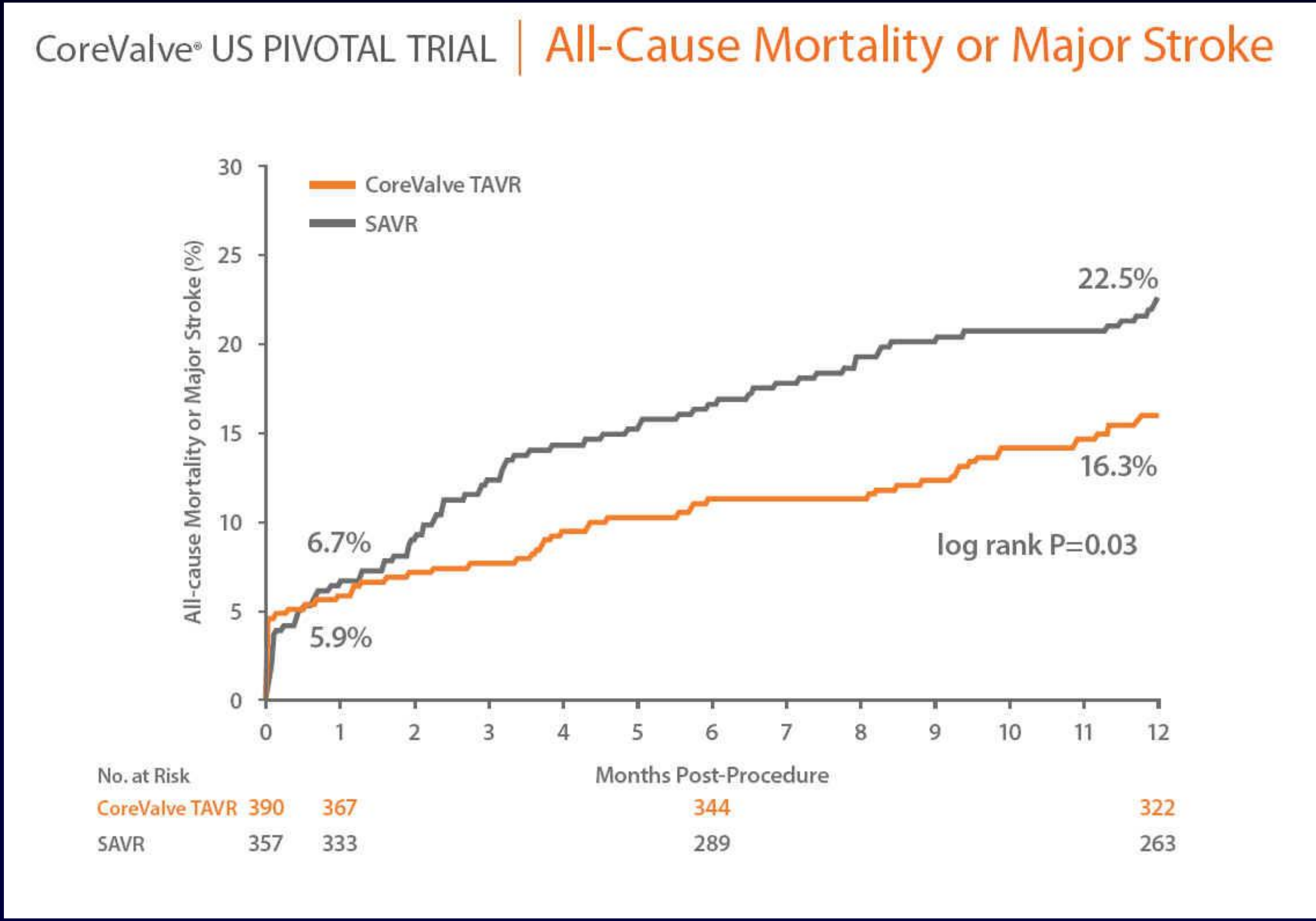
Current State of TAVI



Current State of TAVI



Current State of TAVI



Possible Complication

- Stroke
- Vascular events
- Bleeding
- Paravalvular regulgitation
- Need for new Pacemaker

Indication for TAVI

	Class	Level
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a " heart team" and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a "heart team" based on the individual risk profile and anatomic suitability.	IIa	B

Multidisciplinary Team (Heart team)
- 2 surgeons, 2 interventional cardiologists, 1 cardiac anesthetist and cardiac imaging specialist should agree

Joint Consensus Statement and Guideline on Trans-catheter Aortic Valve Implantation (TAVI) 23 August 2011
Vahanian A, *Eur Heart J*. 2012;33:2451-2496

Imaging is a fundamental component for performing TAVI procedure

Specific Roles of Cardiac Imaging in TAVI

- **Pre-TAVI**
  - Assessment of valvular & LV function (Echo)
  - Iiofemoral evaluation (CT)
  - Aortic size (CT/Echo)
  - Annular sizing (CT/Echo)
  - AV morphological assessment (CT/Echo)
  - Annular/LVOT calcium (CT)
- **During TAVI**
  - Angle of intra-procedural fluoroscopic projection (CT)
  - Monitoring of complications (Echo)
  - Assessment of valvular function-PV leak (Echo)
- **Post TAVI**
  - Follow-up of valvular function (Echo)
  - Long term evaluation: migration/stent fracture (CT)

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Role of Pre-TAVI Imaging

- Patient selection
- Evaluation of severity and morphology of aortic stenosis
  - Aortic root geometry
  - Subaortic geometry
- Iliofemoral assessment
- Evaluation of aorta
- Other valve disease
- Other cardiac/cardiovascular disease

COREVALVE

THE REVALVING TECHNOLOGY

Patient Selection Matrix

	NON-INVASIVE		ANGIOGRAPHY				SELECTION CRITERIA		
Anatomy	Echo	CT / MRI	LV	AO	Coro	AO & Runoffs	**Preferred**	**Borderline**	**Not Acceptable**
Atrial or Ventricular Thrombus	X						Not Present		Present
Mitral Regurgitation	X						≤ Grade 1	Grade 2	> Grade 2
LV Ejection Fraction	X		X				> 50%	30% to 50%	< 20% (w/o cardiac support)
LV Hypertrophy (wall thickness)	X						Normal to Mild (0.6 to 1.3 cm)	Moderate (1.4 to 1.6cm)	Severe (≥ 1.7cm)
Sub-Aortic Stenosis	X	X					Not Present		Present
Annulus width [A]	X	X					20 to 23mm → 26mm device 23 to 27mm → 29mm device		< 20mm or > 27mm
AO Root width [B]		X	X	X			≥ 27mm → 26mm device ≥ 28mm → 29mm device		< 27mm
Coronary Ostia [D] (from native leaflet)					X		≥ 14mm	13mm w/ mod. Ca^{2+} 10 to 13mm w/o Ca^{2+}	< 14mm w/ severe Ca^{2+} < 13mm w/ mod. Ca^{2+} < 10mm w/o Ca^{2+}
Coronary Disease					X		None	Mid or Distal Stenosis < 70%	Proximal Stenosis ≥ 70%
Annulus-to-Aorta (angle) †		X	X	X			< 45°	45° to 70°	> 70°
Ascending AO width [C]	X	X	X	X			≤ 40mm → 26mm device ≤ 43mm → 29mm device		> 43mm
AO Arch Angulation		X		X		X	Large-Radius Turn		High Angulation or Sharp Bend
Aorta & Runoff Vessels (Disease) ‡		X				X	None	Mild	Moderate to Severe
Iliac & Femoral Vessels (diameter)		X				X	≥ 7mm	Non-Diabetic Non-Dialyzed ≥ 6mm	< 6mm

† [illegible]
‡ [illegible]

[illegible]

Patient selection

- **Four steps**

  - Confirmation the severity of AS

  - Evaluation of symptoms

  - Analysis of the risk of surgery and evaluation of life expectancy and quality of life

  - Assessment of the feasibility and exclusion of contraindications for TAVI

European Heart Journal (2008) 29, 1463–1470

Confirmation of severe AS

- Echocardiography
  - Valve area
  - Flow-dependent indices (Peak / mean pressure gradient)

- 'pseudo severe' AS
  - Low-dose dobutamine echocardiography is useful to differentiate

European Heart Journal (2008) 29, 1463–1470

Risks of surgery
Life expectancy and Quality of life

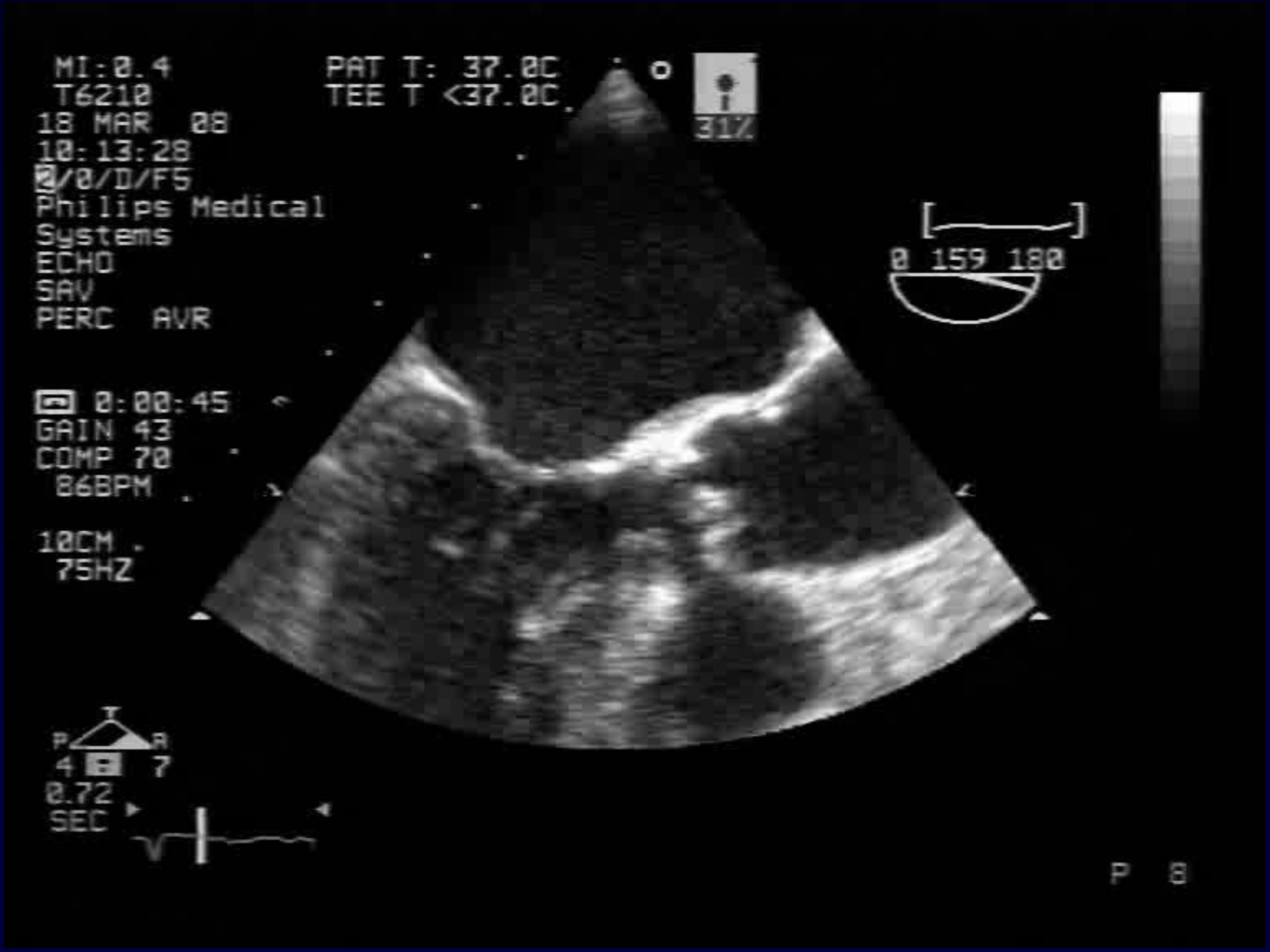
- Risk of surgery
  - The EuroScore (or logistic EuroScore)
  - The STS Predicted Risk of Mortality score
  - the Ambler score
  - Not yet specifically established

- Life expectancy
  - <1 year; contraindication

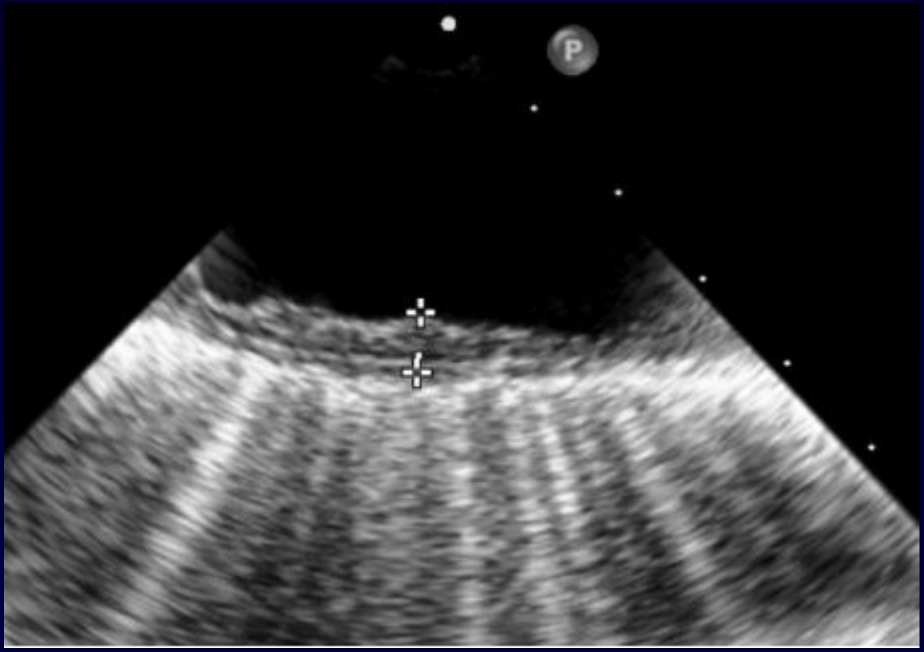
Echo in TAVI

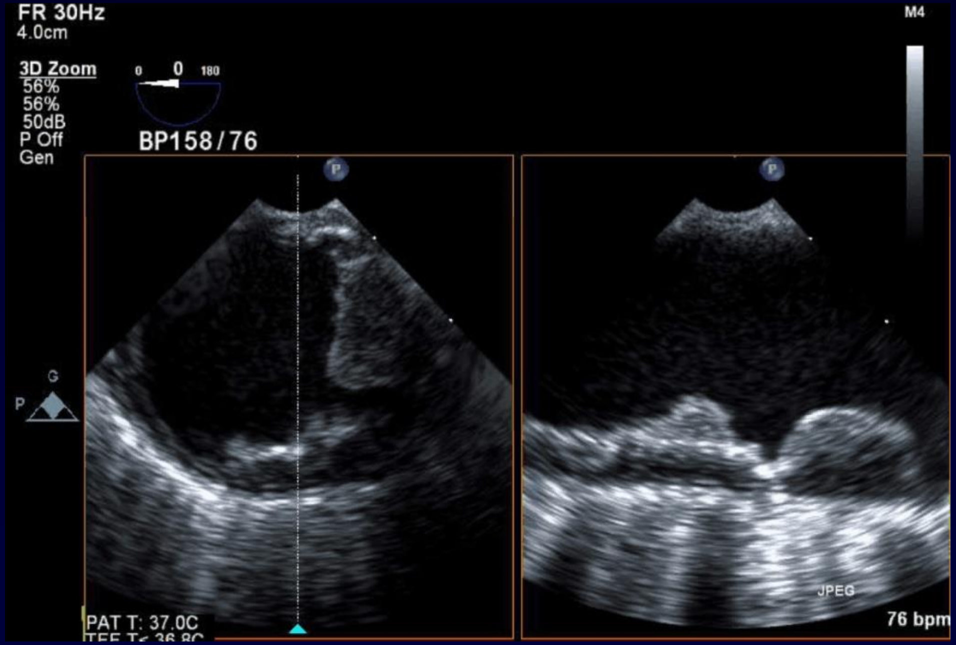
- Determining severity
- Assessing etiology
- Excluding other cause of LV outflow tract obstruction
- Device selection
  - Annular sizing
  - Aortic root and STJ sizing
  - Position of the coronary arteries

Structural Heart



Aortic Atheroma - TEE





Echo in TAVI

- Determining severity
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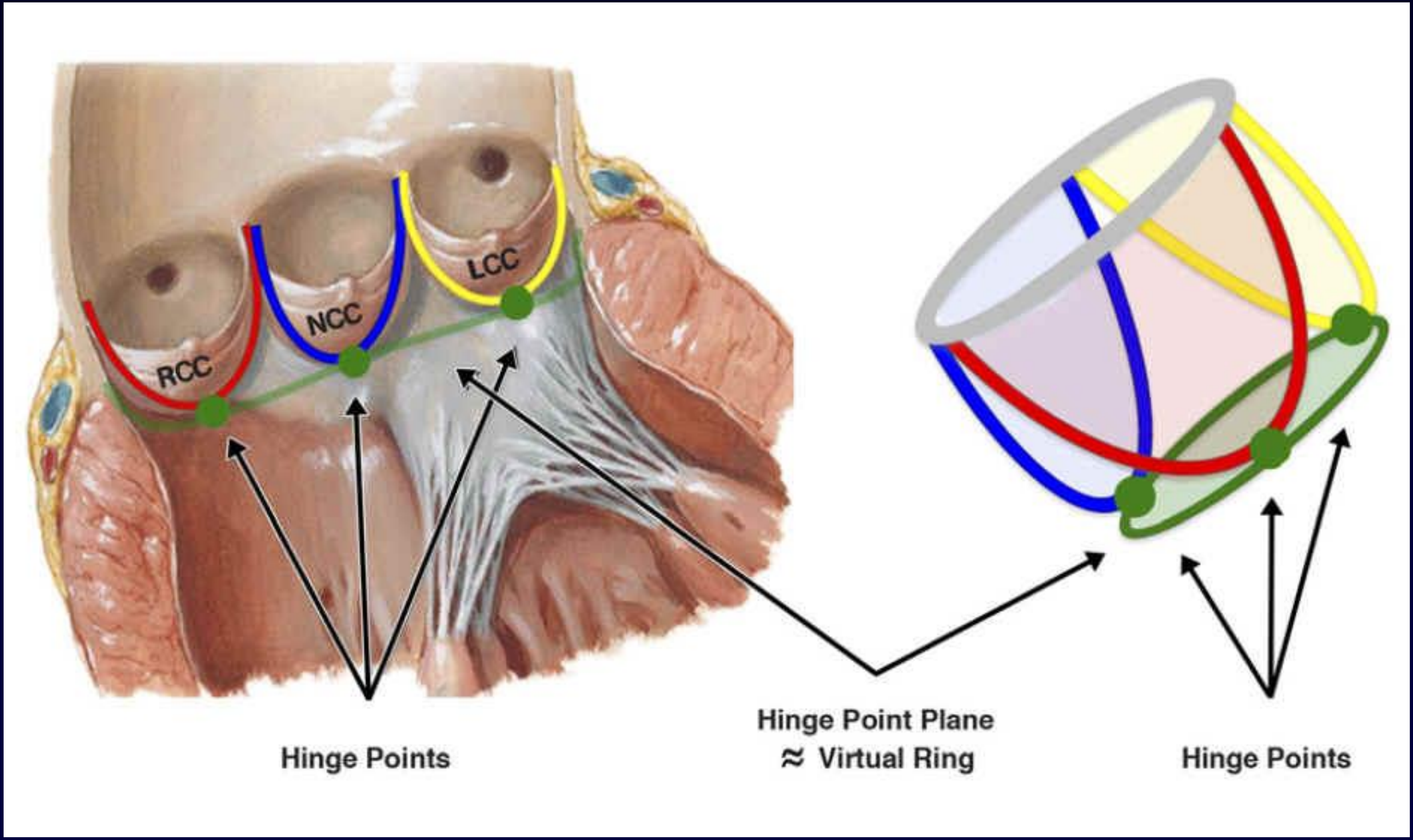
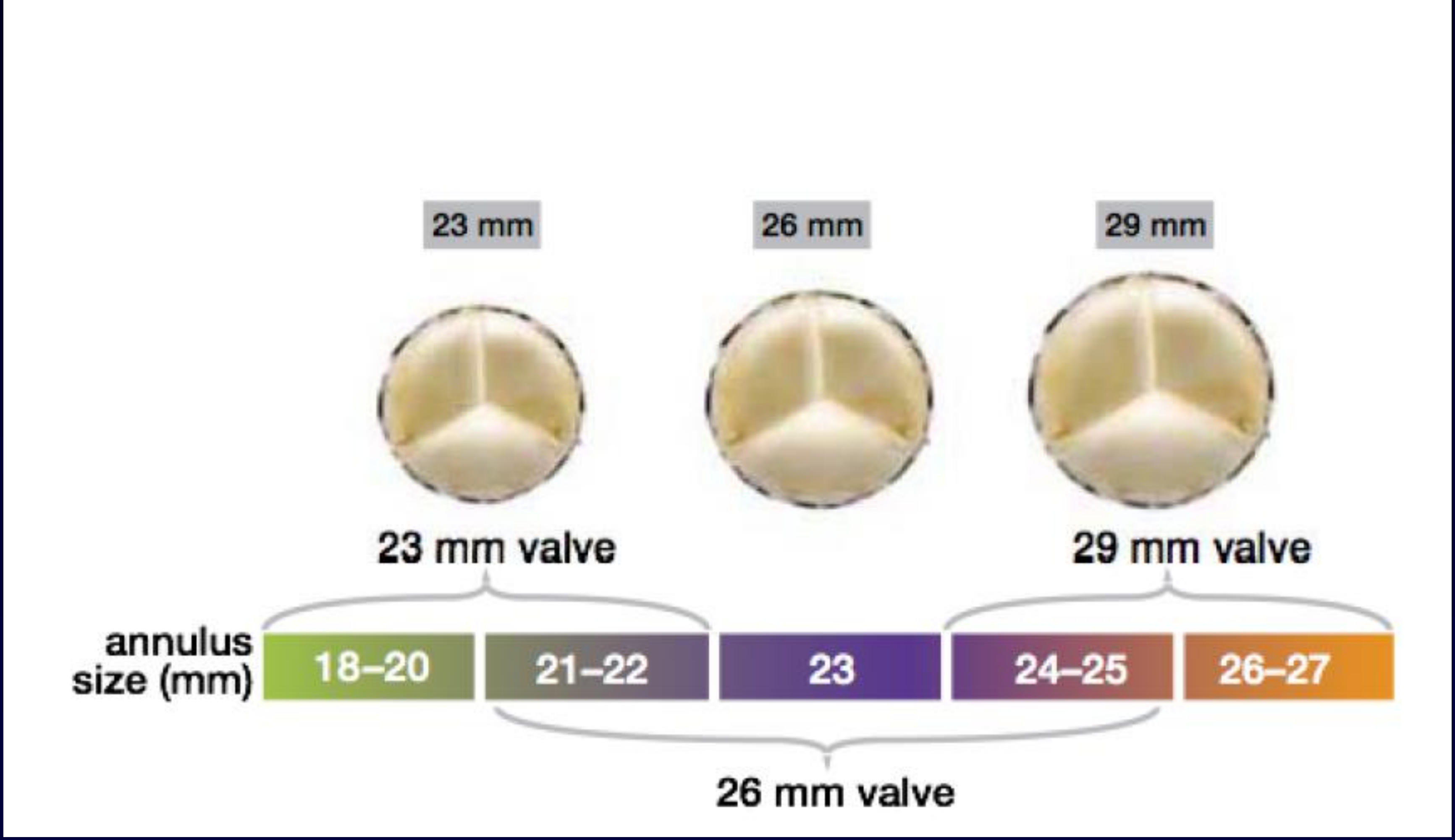
Normal Anatomy of Aortic Valve



Annulus Sizing is Crucial



Annulus Sizing is Crucial

- **Undersizing**

  - Paravalvular regurgitation

  - Valve embolization

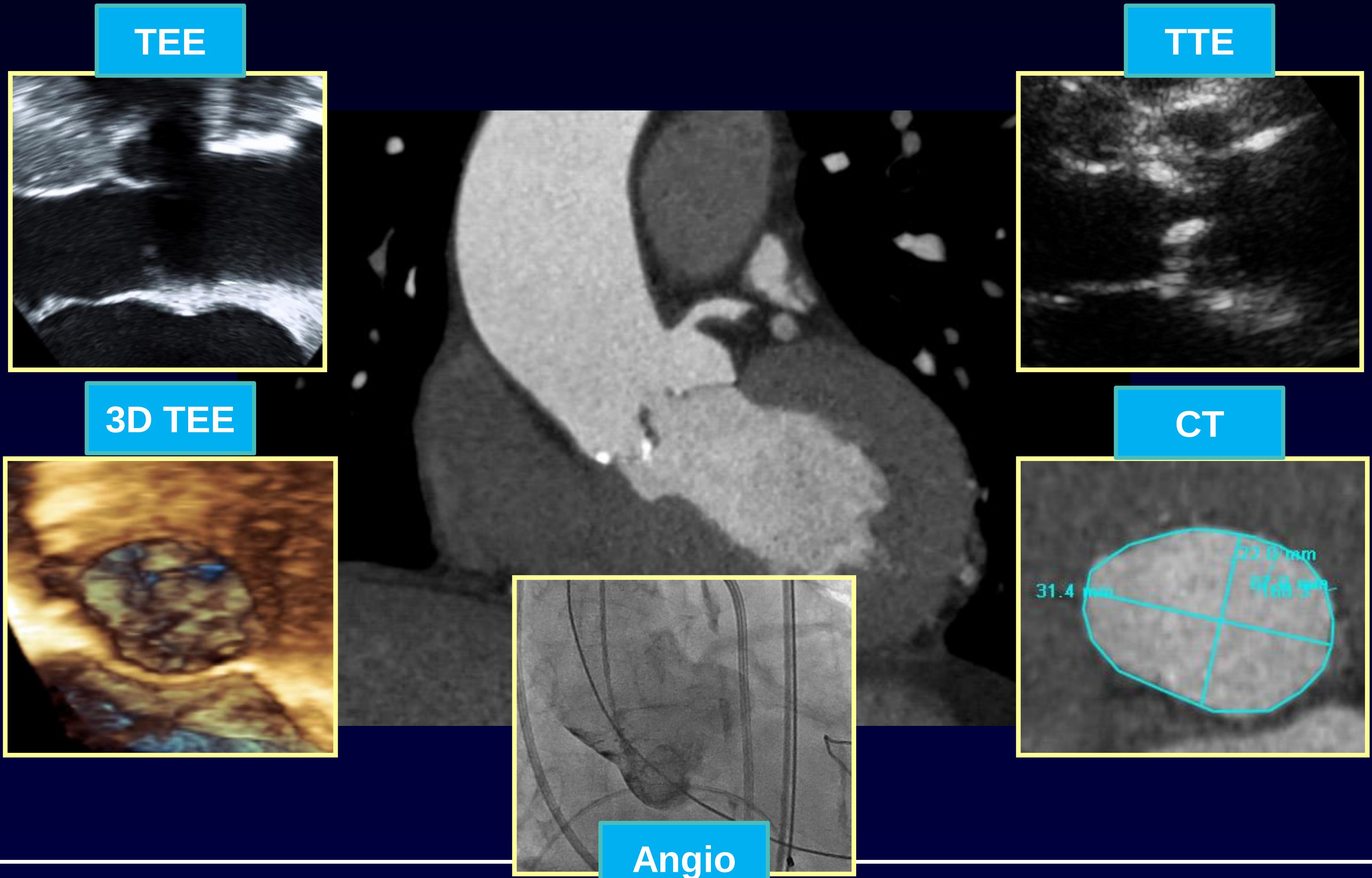
- **Oversizing**

  - Reduce valve durability

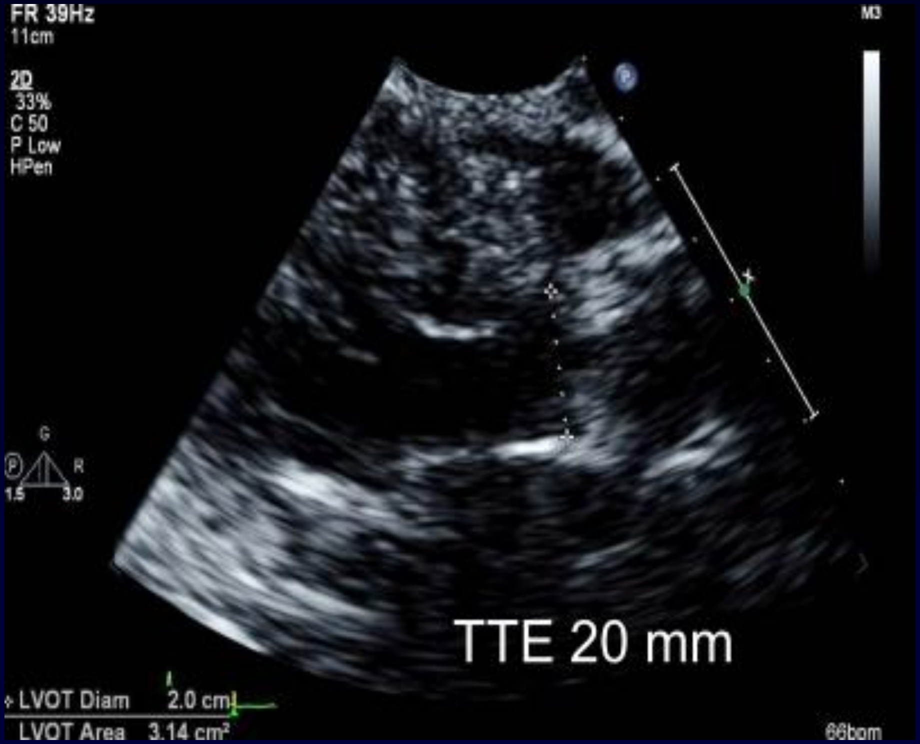
  - Conduction disturbance

  - Annular rupture

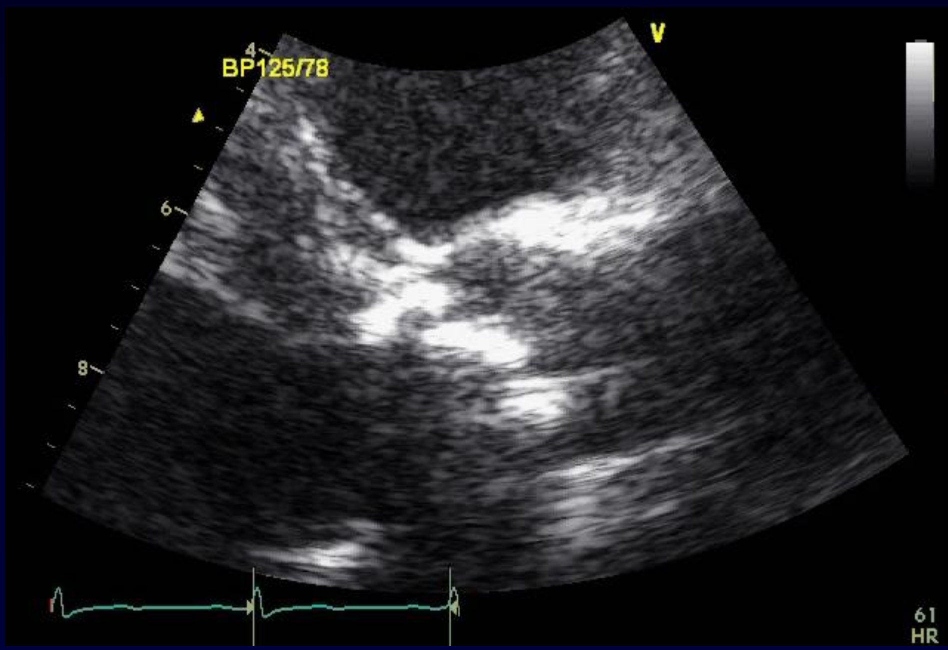
TAVI-Annulus measurement

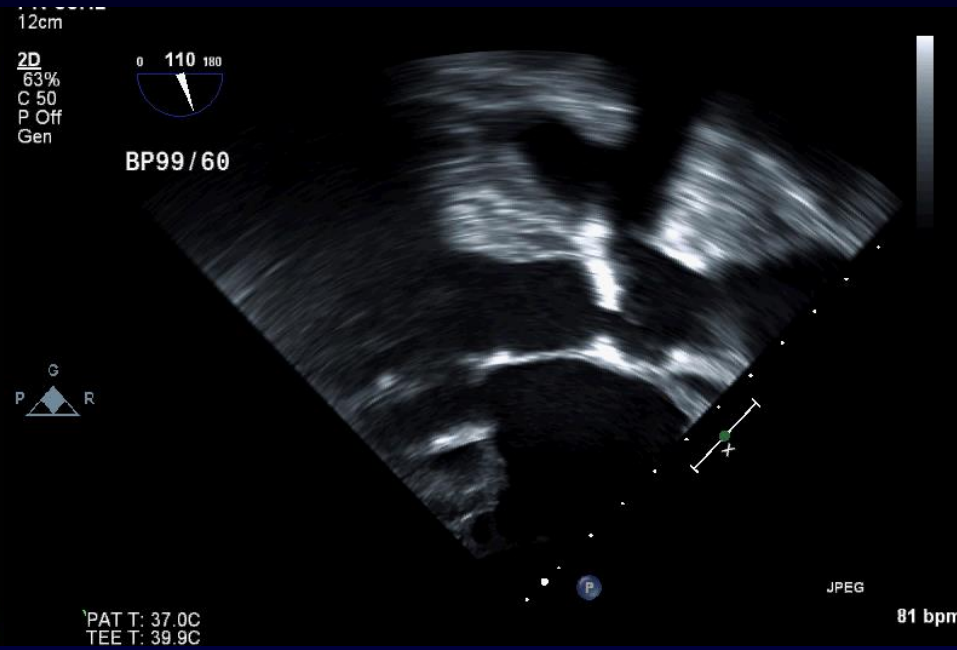


Annulus Measurement by Echo

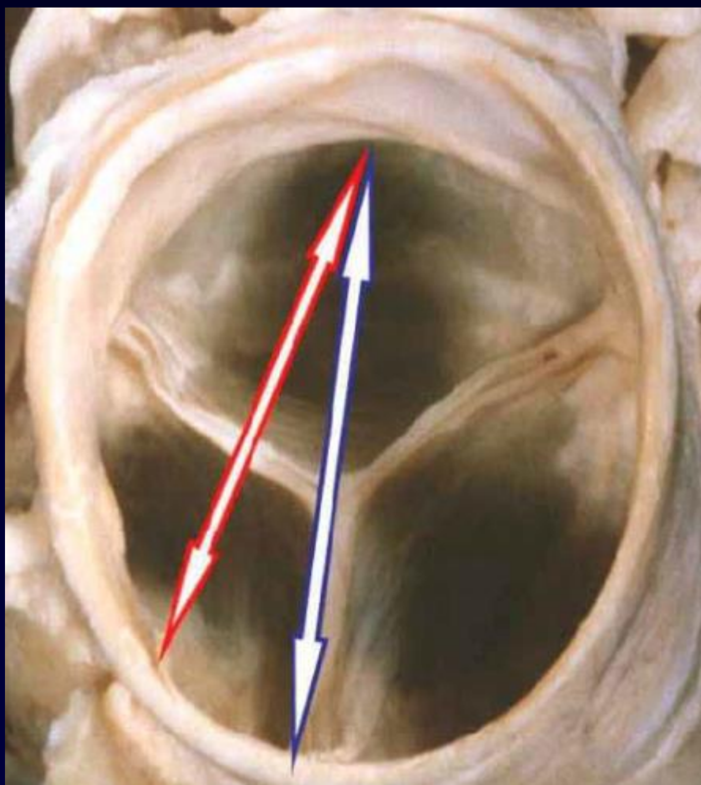


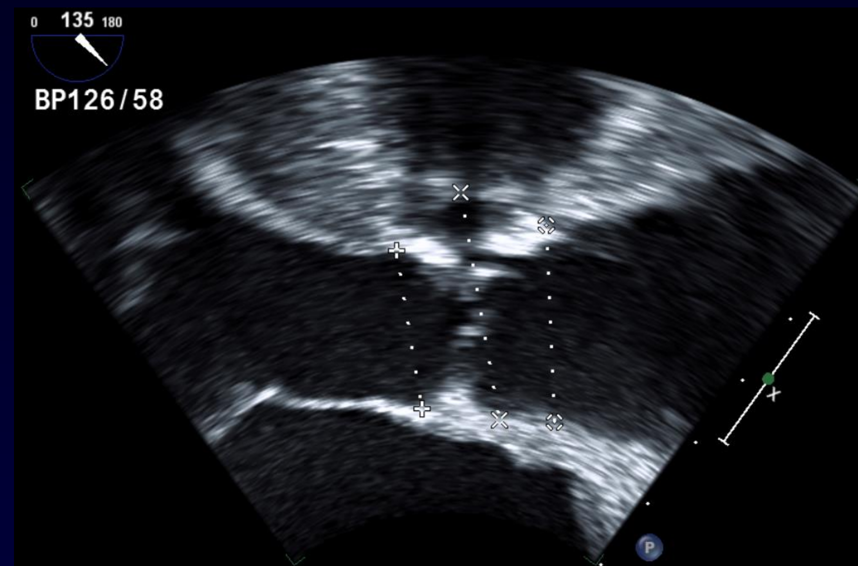
2D TTE / TEE


BP125/78
V
61
HR


12cm
2D
63%
C 50
P Off
Gen
0 110 180
BP99/60
G
P R
PAT T: 37.0C
TEE T: 39.9C
JPEG
81 bpm

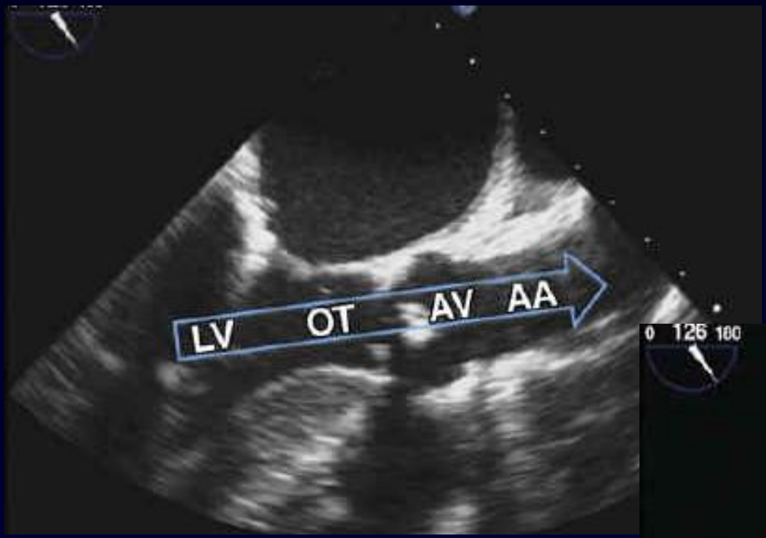
Annulus

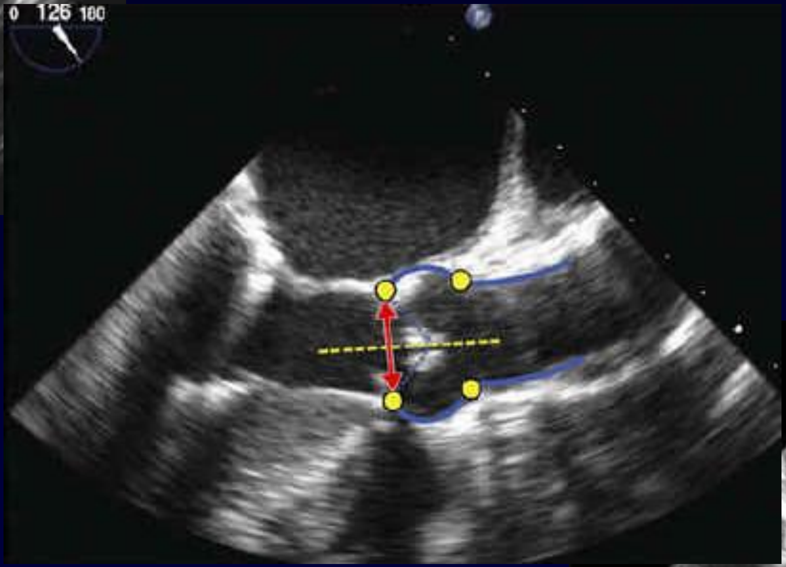


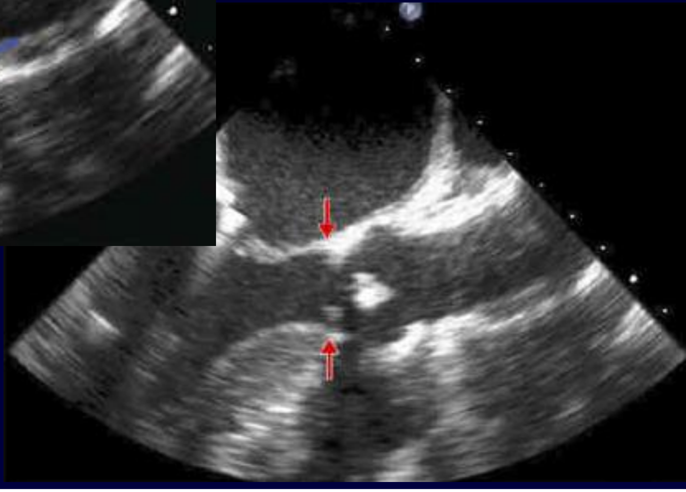


Easy to underestimate the annulus diameter

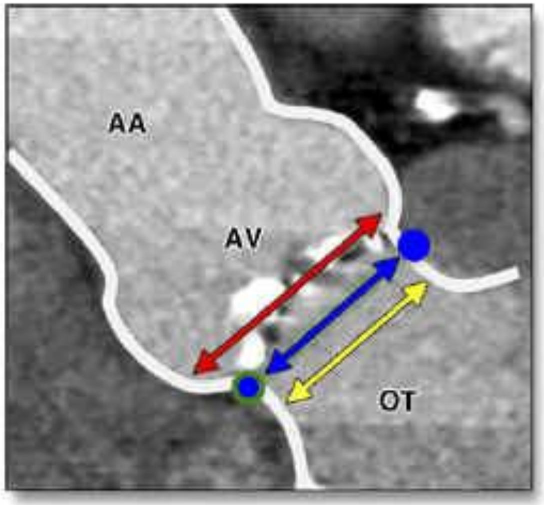
Aortic Annular View with TEE

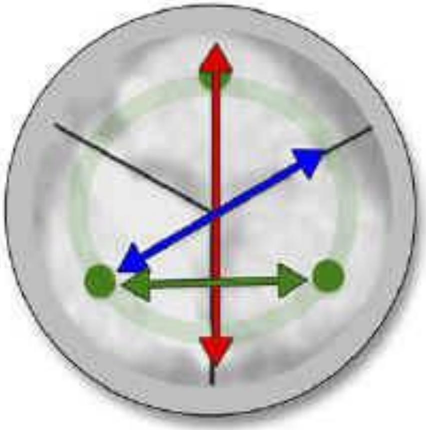






Errors Annulus Sizing





AA = Ascending Aorta

AV = Aortic Valve

OT = Outflow Tract

= Annulus

= Hinge Points

= Virtual Ring

= True measurement at the level of the virtual ring.

= Measurement at the level of the upper outflow tract shows a good correlation with the hinge point plane.

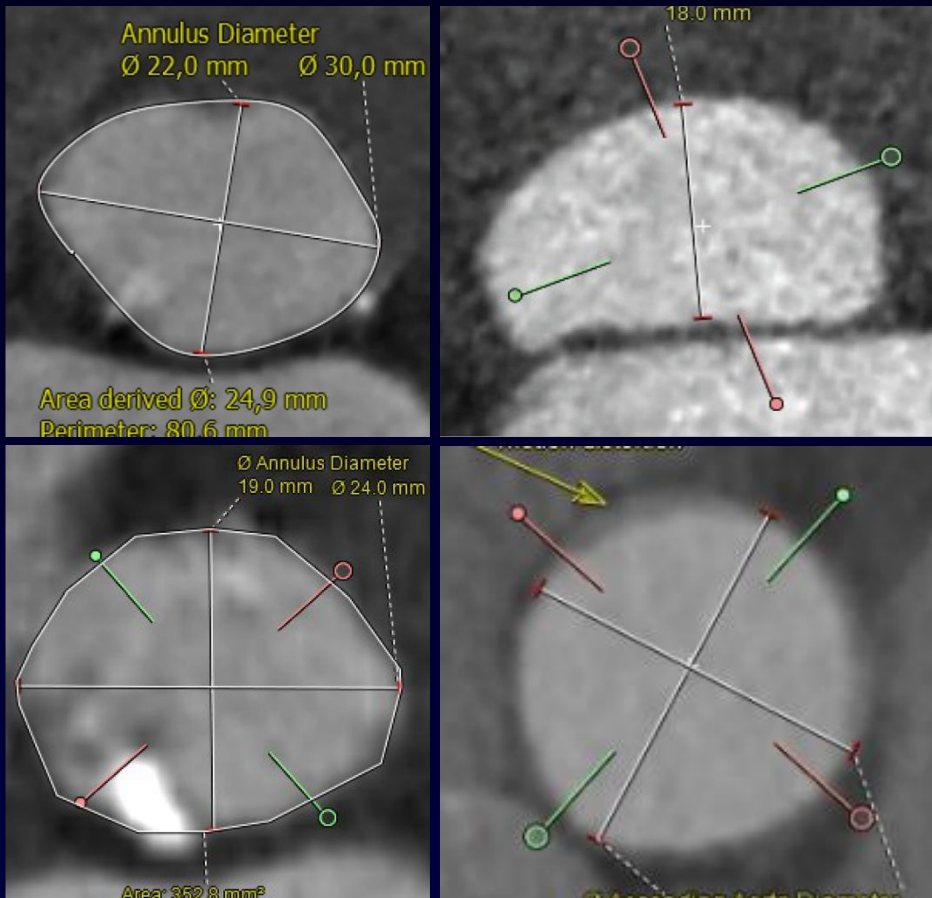
= Off-center measurement between two hinge points underestimates the annulus size.

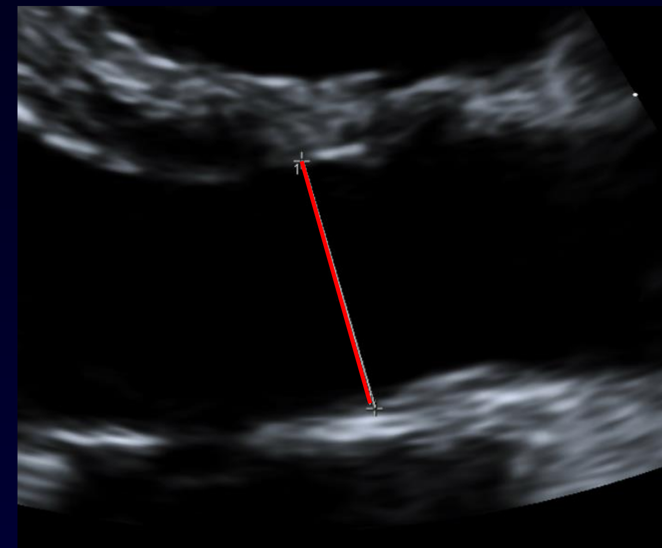
= Measurement upward in the aortic sinus overestimates the annulus size.

The Annulus: Facts

- Systolic > diastolic
- Eccentric shape
- Calcification: important for leak

Annulus CT

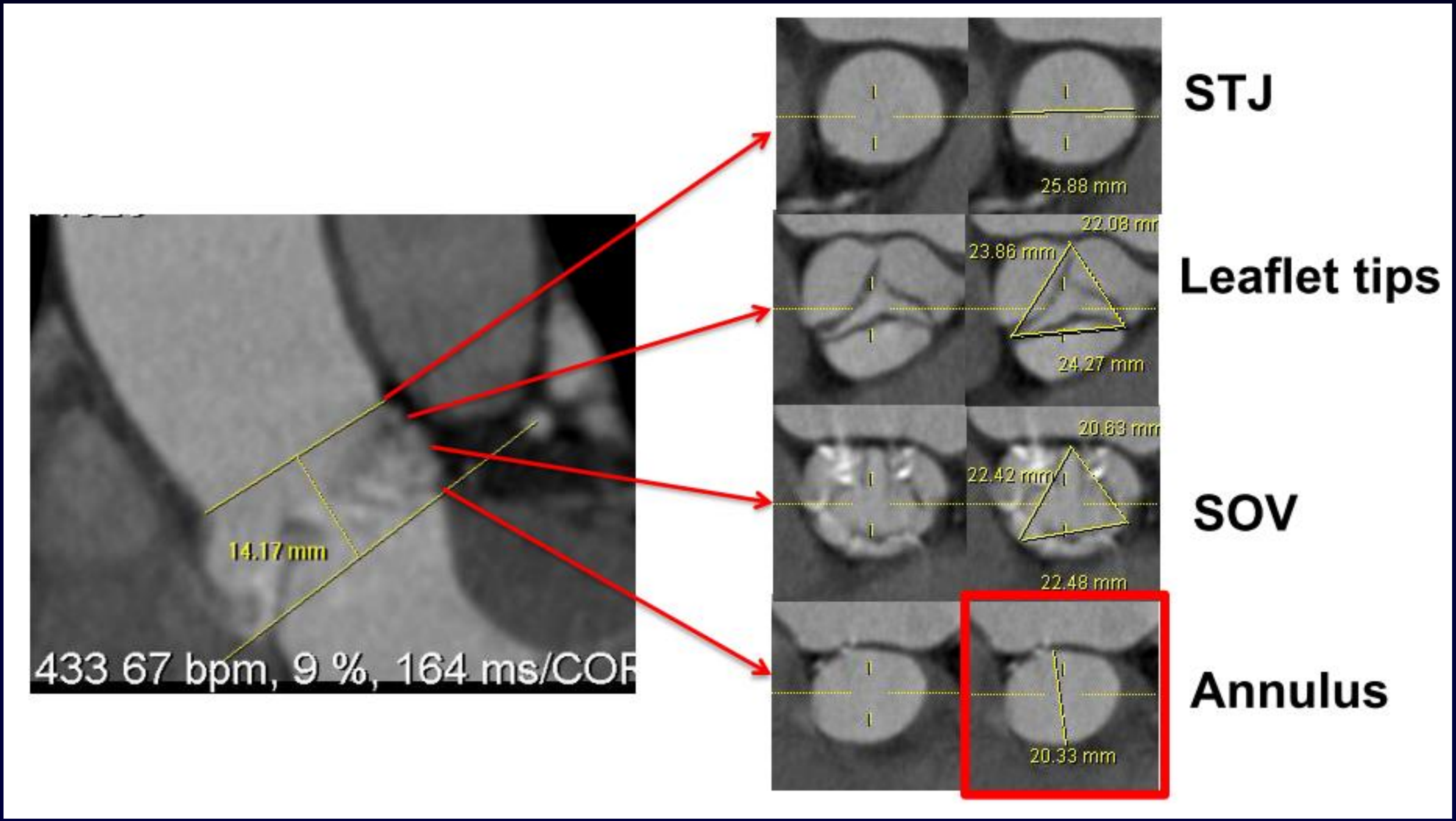




- Mostly oval shape
- Shortest at AP diameter

- 2D measurement is hard to assess true annulus size

CT: Axial cuts at multiple levels



CT sizes annulus larger than TEE

- 50 patients after TAVI
- Different THV size would be selected in 44-40% of cases, when a strategy of valve-sizing is undertaken using CT
- CT > TEE: 1.5mm

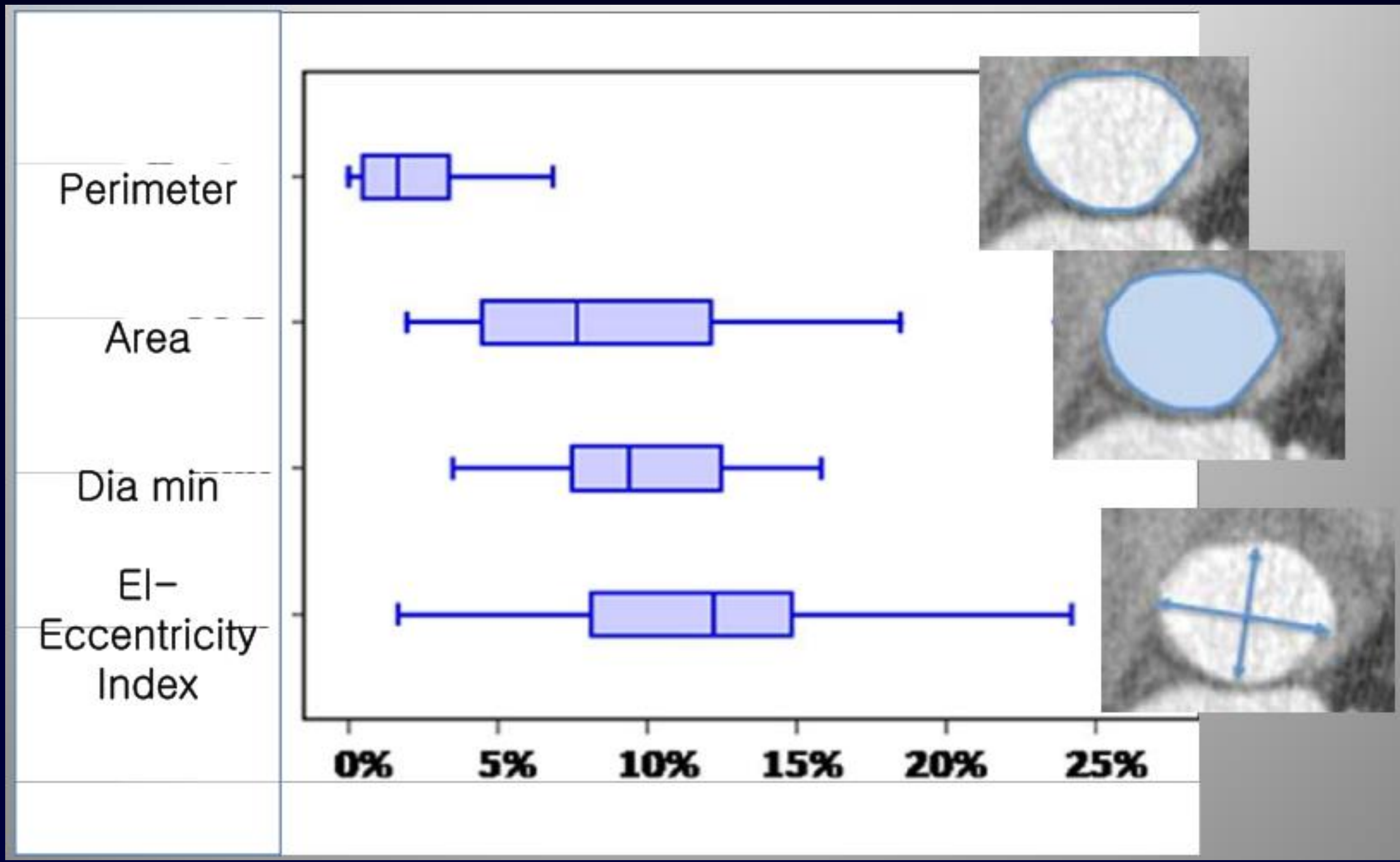
Gurvitch et al. JACC Intv 2011

Correlation Between TTE, TEE, MDCT

	Mean Annulus Diameter (mm)	p Value vs. TEE	R vs. TEE
Echocardiographic measurements			
TTE	23.9 ± 2.1	0.13	0.89
TEE	24.1 ± 2.1	—	—
MSCT measurements			
Virtual basal ring			
Long-axis	27.5 ± 3.1	<0.0001	0.67
Short-axis	21.7 ± 2.3	<0.0001	0.69
Mean	24.6 ± 2.4	0.07	0.77
3-chamber view	23.8 ± 2.6	0.26	0.70

Messika-Zeitoun et al, JACC 2010

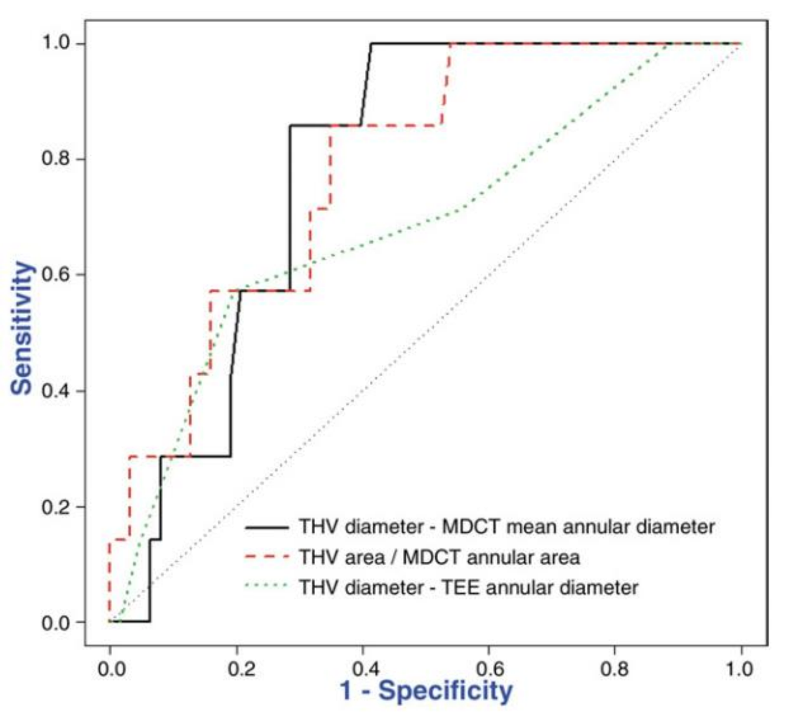
4D Change in Annulus Dimensions over Cardiac Cycle



Hamdan et al. JACC 2012

3-Dimensional Aortic Annular Assessment by Multidetector Computed Tomography Predicts Moderate or Severe Paravalvular Regurgitation After Transcatheter Aortic Valve Replacement

A Multicenter Retrospective Analysis



Area Under the Receiver-Operating Characteristic Curves for Prediction of PAR

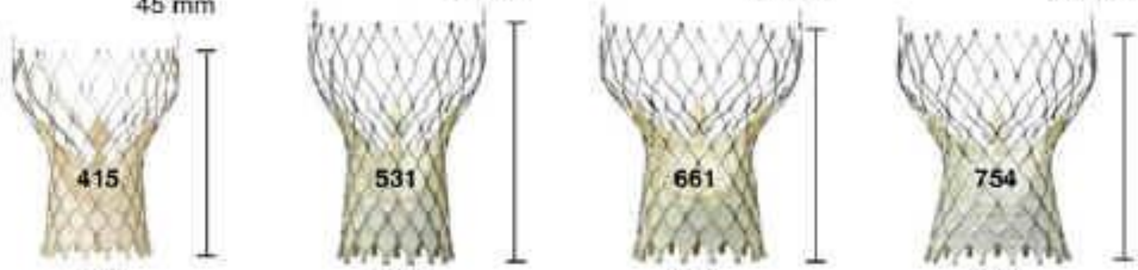
- 109 pts imaged pre-TAVR (CT)
- Moderate or severe regurgitation (12.7%) was associated with device undersizing ($p<0.01$)
- Difference on CT between valve and annulus size was predictive of regurgitation
- 3D aortic annular measurement are predictive of moderate or severe regurgitation post TAVR

Wilson AB, J Am Coll Cardiol, 2012 Apr 3;59(14):1287-94

Annulus size measurement

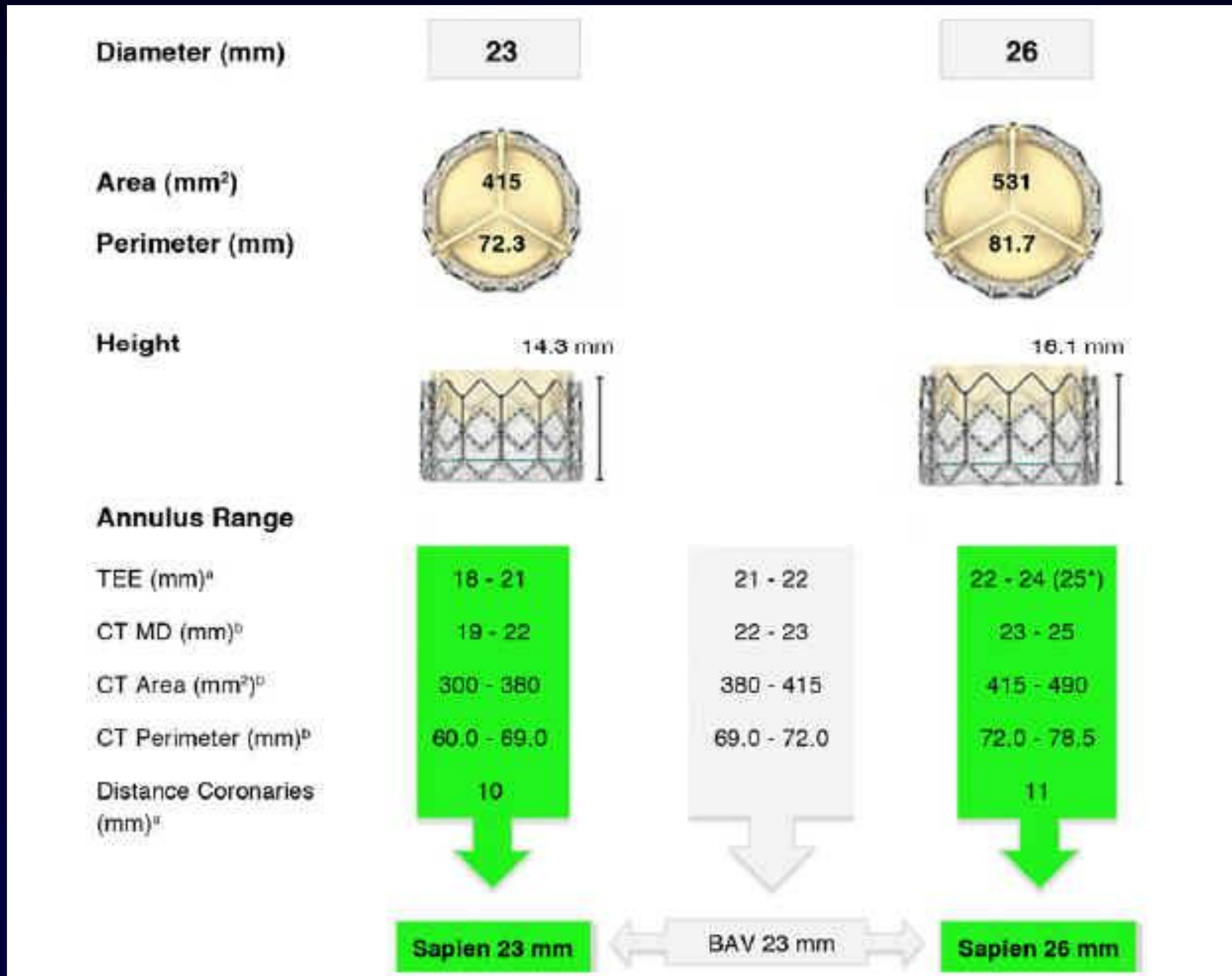
- Measurement of “annulus” is very critical for successful TAVI
- 3D Data set provides the most useful information because the “annulus” is not circular
- Decision making is evolving with increasing experience and availability of different sizes

CoreValve Sizing



Diameter (mm)	23		26		29		31
Height	45 mm		55 mm		53 mm		52 mm
Area (mm^2)	415		531		661		754
Perimeter (mm)	72.3		81.6		91.1		97.4
Annulus Range							
TEE (mm)[b]	17 - 19		19 - 22		22 - 26		25 - 28
CT MD (mm)[a]	18 - 20		20 - 23		23 - 27		26 - 29
CT Area (mm^2)[a]	254.5 - 314.2		314.2 - 415.5		415.5 - 572.6		530.9 - 660.5
CT Perimeter (mm)[a]	56.5 - 62.8		62.8 - 72.3		72.3 - 84.8		81.7 - 91.1
AsAo Width (mm)[a]	≤34		≤40		≤43		≤43
Sinus Height (mm)[a]	15		15		15		15
Sinus Width (mm)[a]	25		27		29		29
		BAV 20 mm		BAV 23 mm		BAV 26 mm	
	CoV 23		CoV 26		CoV 29		CoV 31

Edward Sapien Sizing

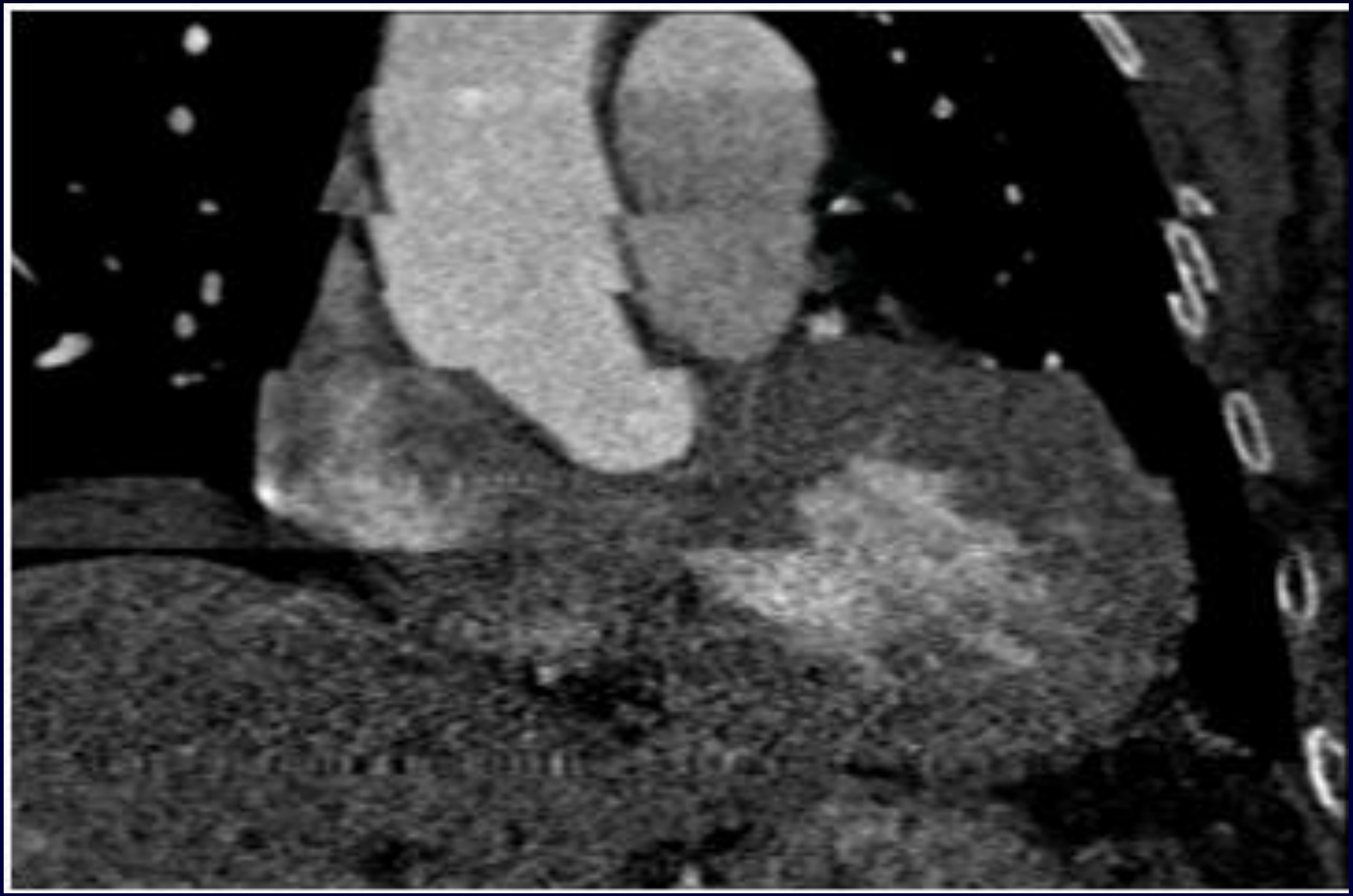


Annulus size by 2D TEE

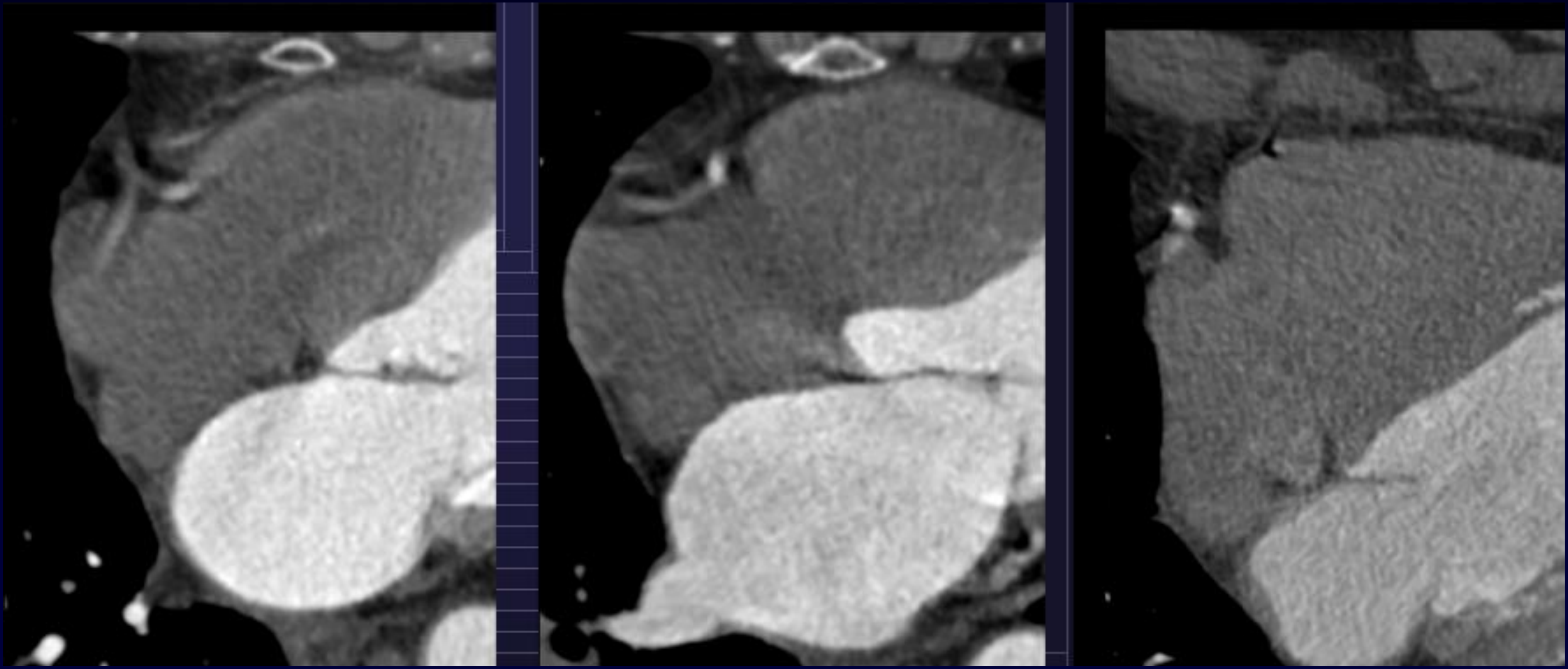
	N=42
Mean annulus diameter	22.44 mm
Mean sinus of Valasalva diameter	31.4 mm

		TEE derived size determination (mm)				
		23	26	29	31	total
Actual valve size (mm)	23	1	0	0	0	1
	26	3	15	2	0	20
	29	1	2	15	1	19
	31	0	0	1	1	2
	total	5	17	18	2	42

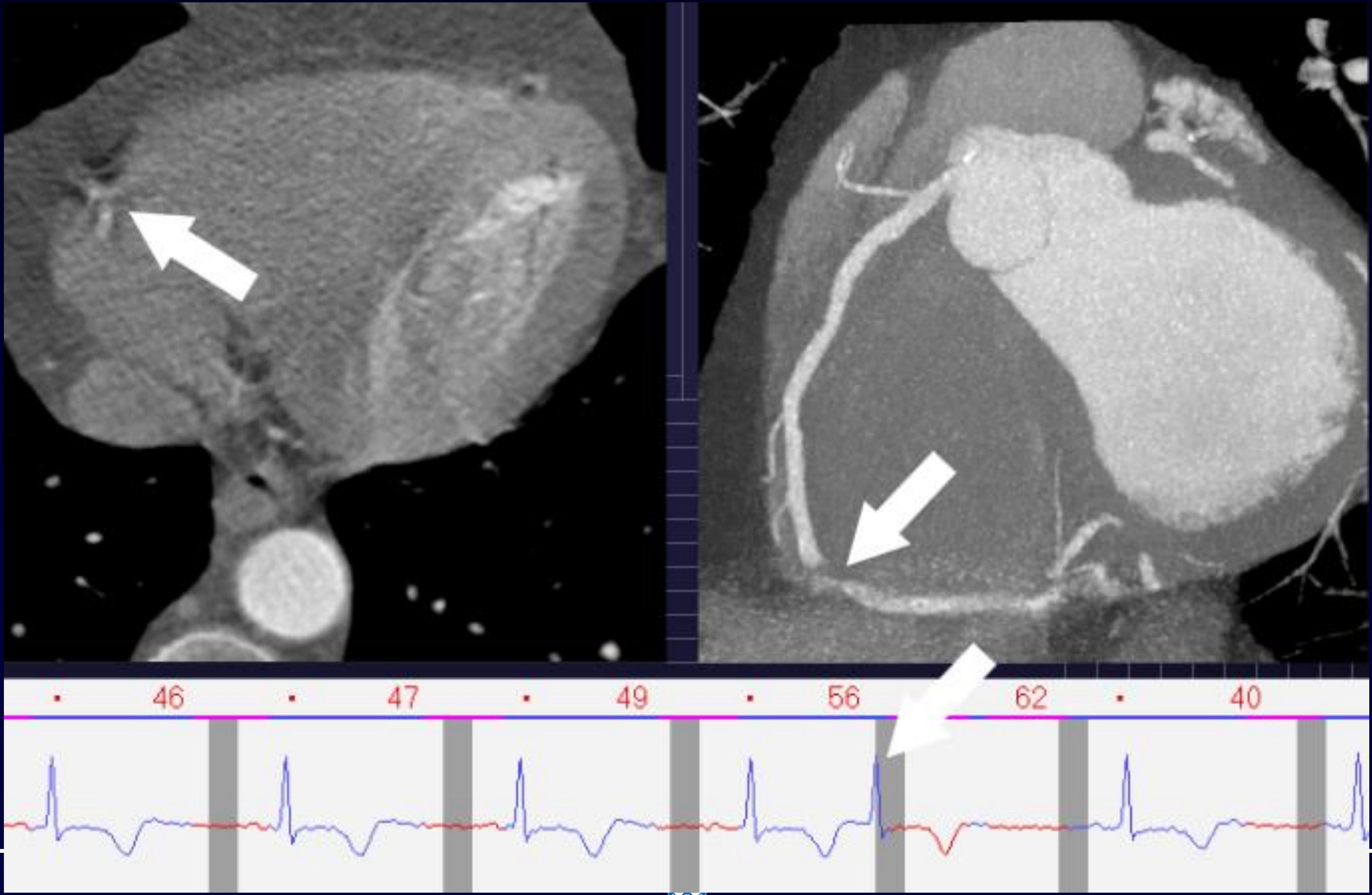
Breathing Artifacts



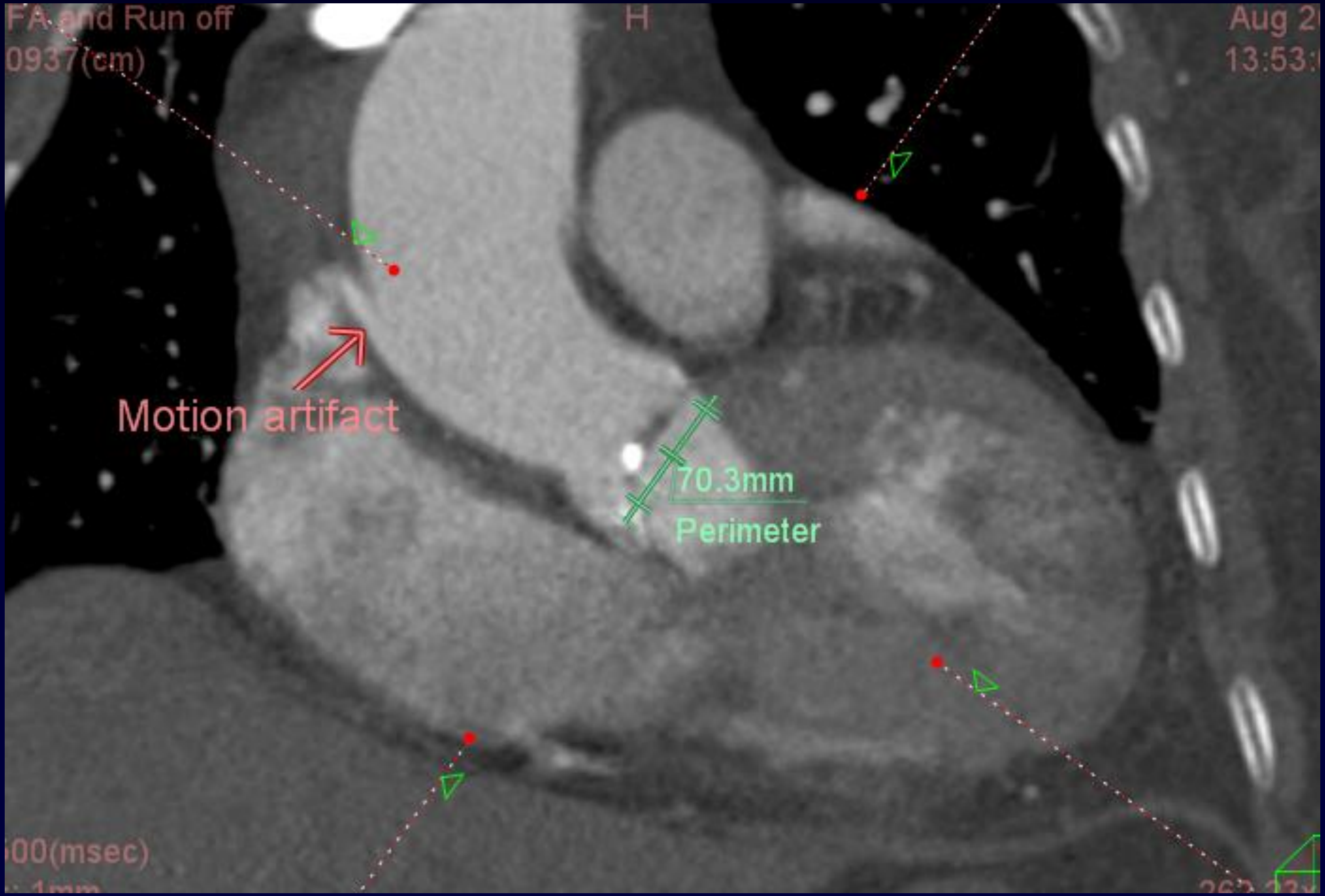
Cardiac Motion



PVC



Motion artifact on aorta



New Imagings for TAVI

Improving TAVI outcomes

Reducing the risk of complications

Pursuit of Perfection

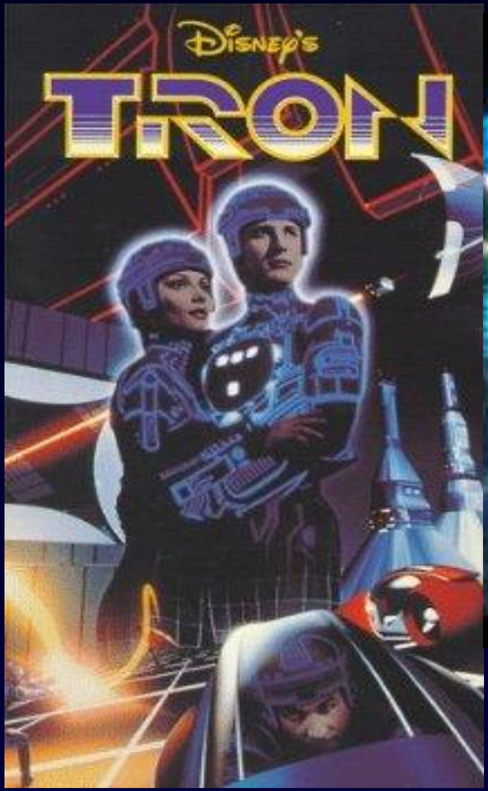
3D

Quantatative

Automated

Real-time

Why 3D ?

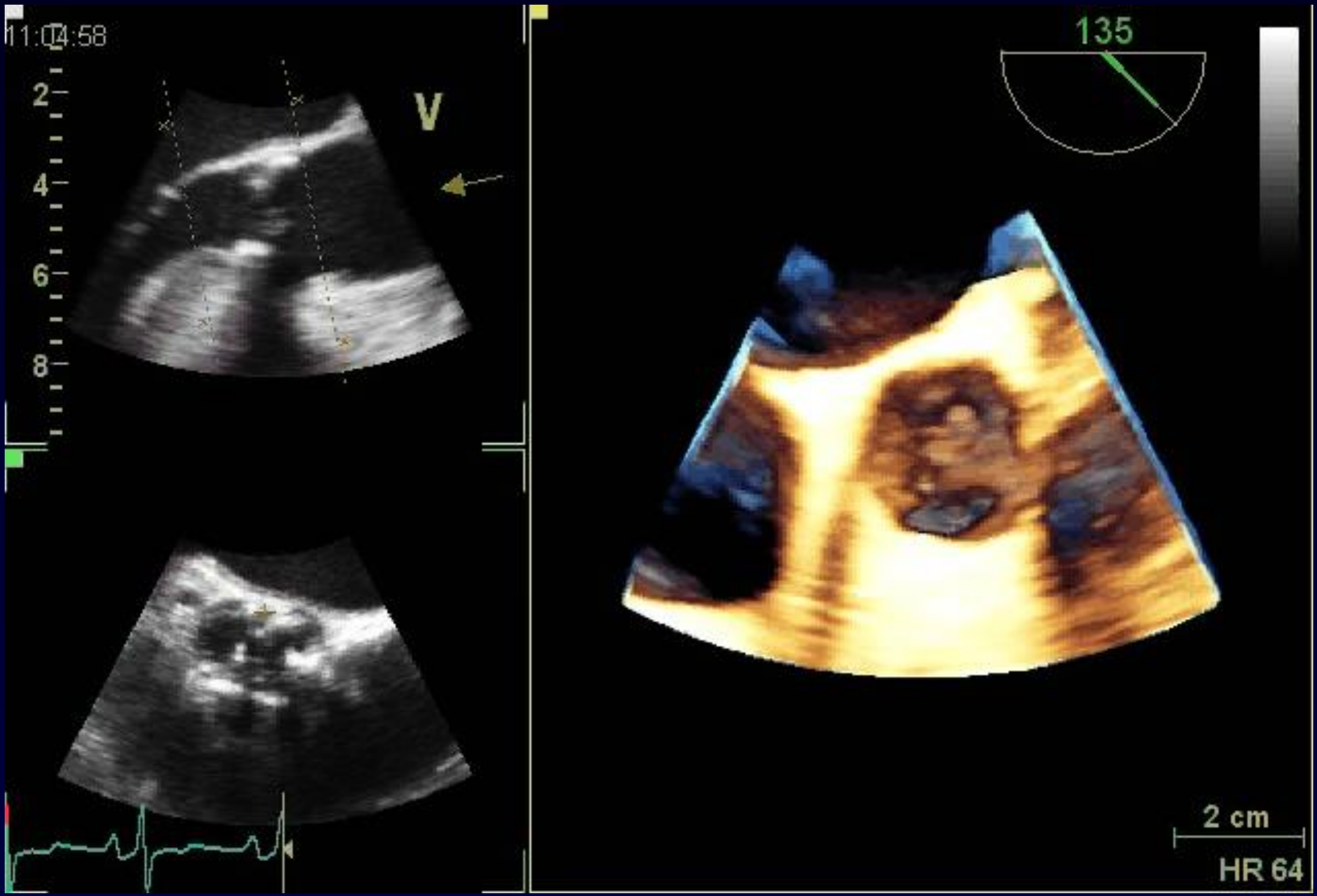


1982 Tron

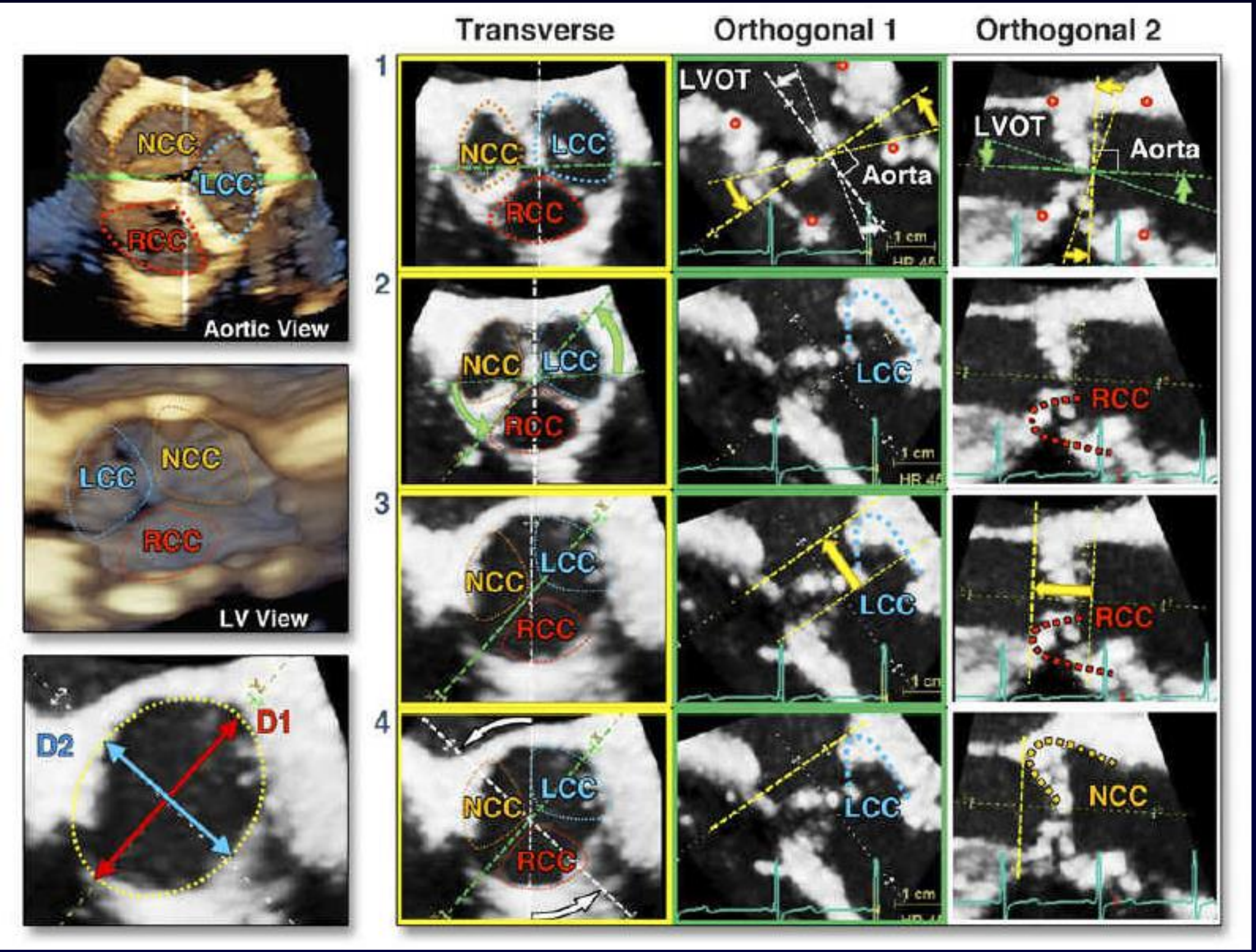
2010 Avatar

2013 Ironman3

3D measurement

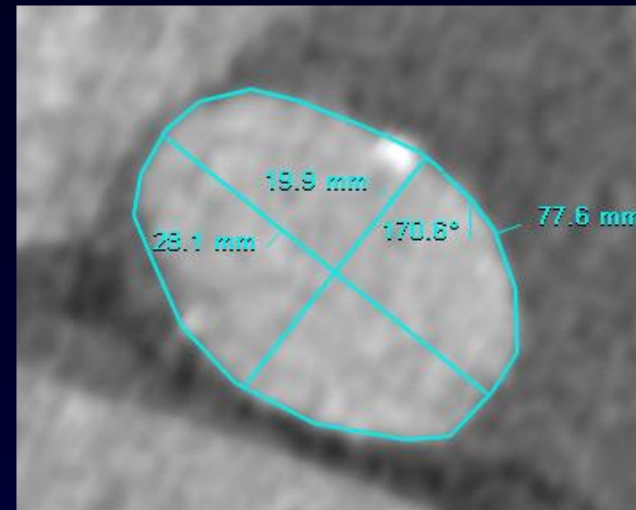


Alignment of Aortic Root with 3D-TEE

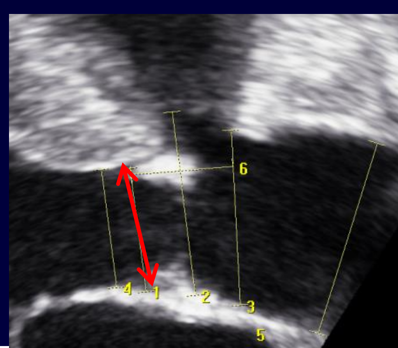


3D TEE vs. CT

Perimeter: 78 (24.8 π) mm
Area: 440 mm^2 (23.7 mm)



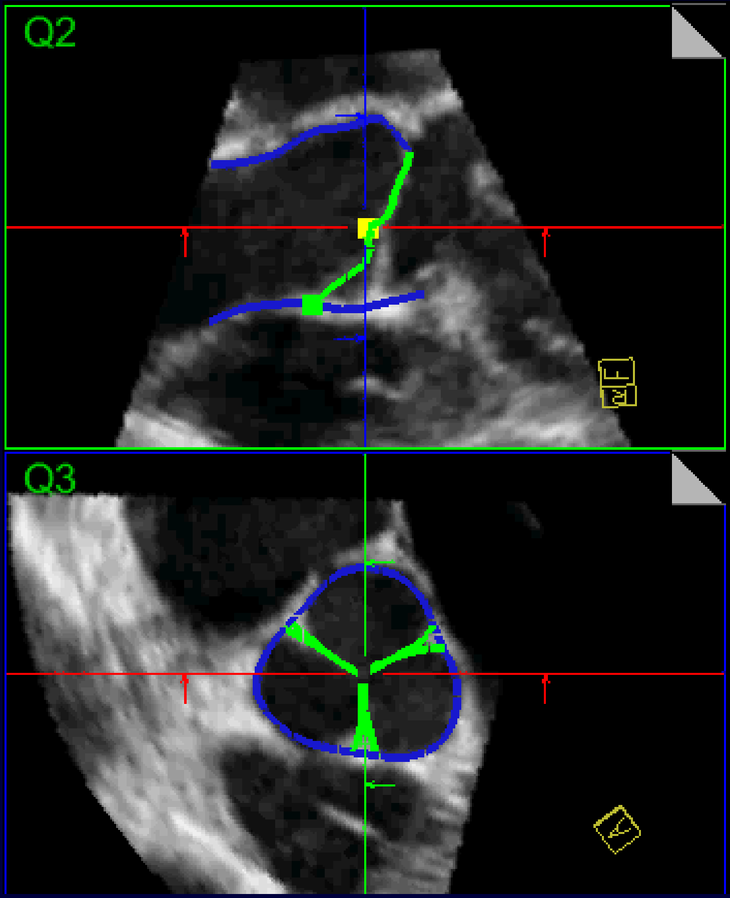
Perimeter: 77.6 (24.7 π) mm
Area: 443 mm^2 (23.8 mm)



Annulus	**21 mm**

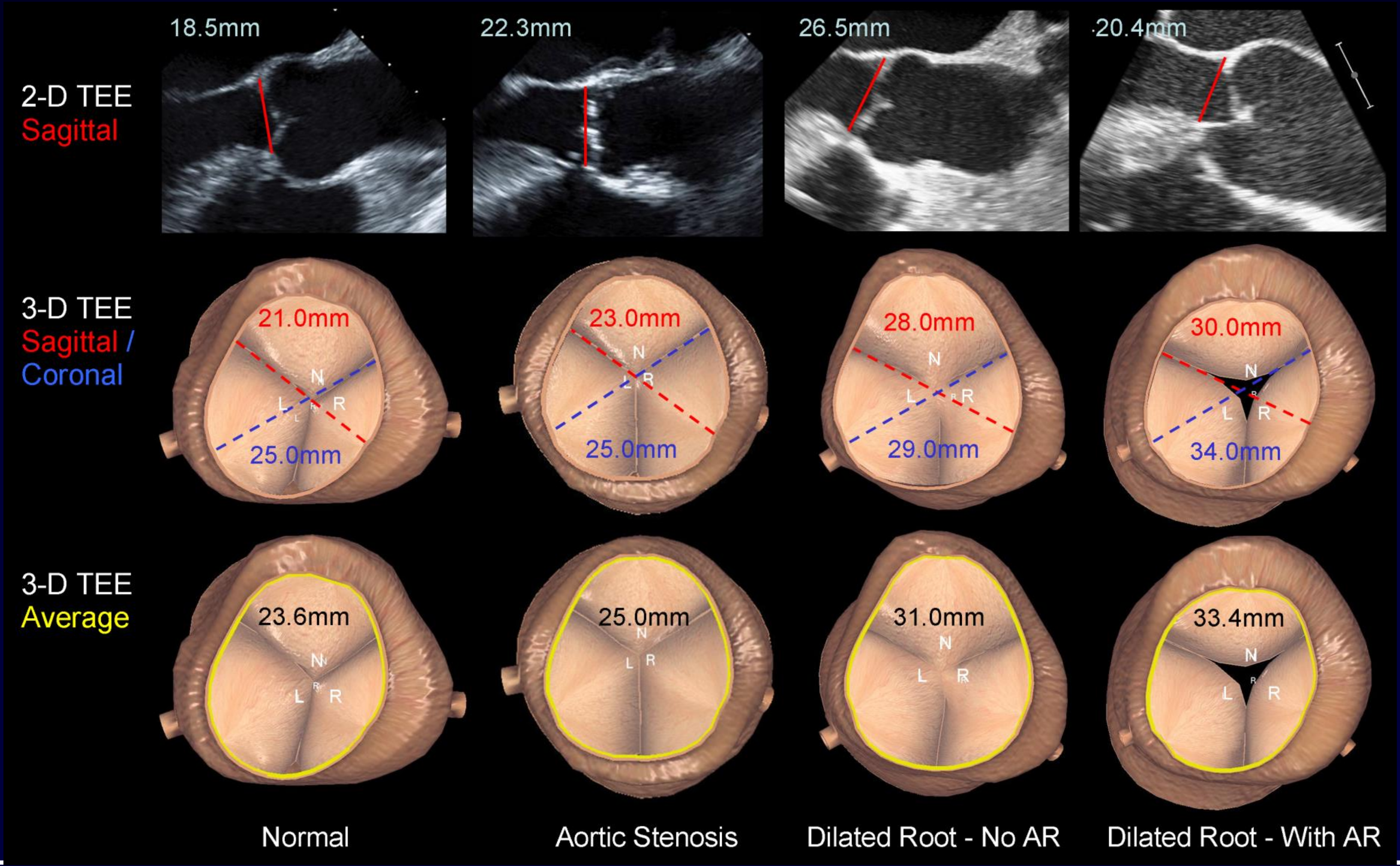
Aortic Annulus

Automated Quantitative Modeling - Echo



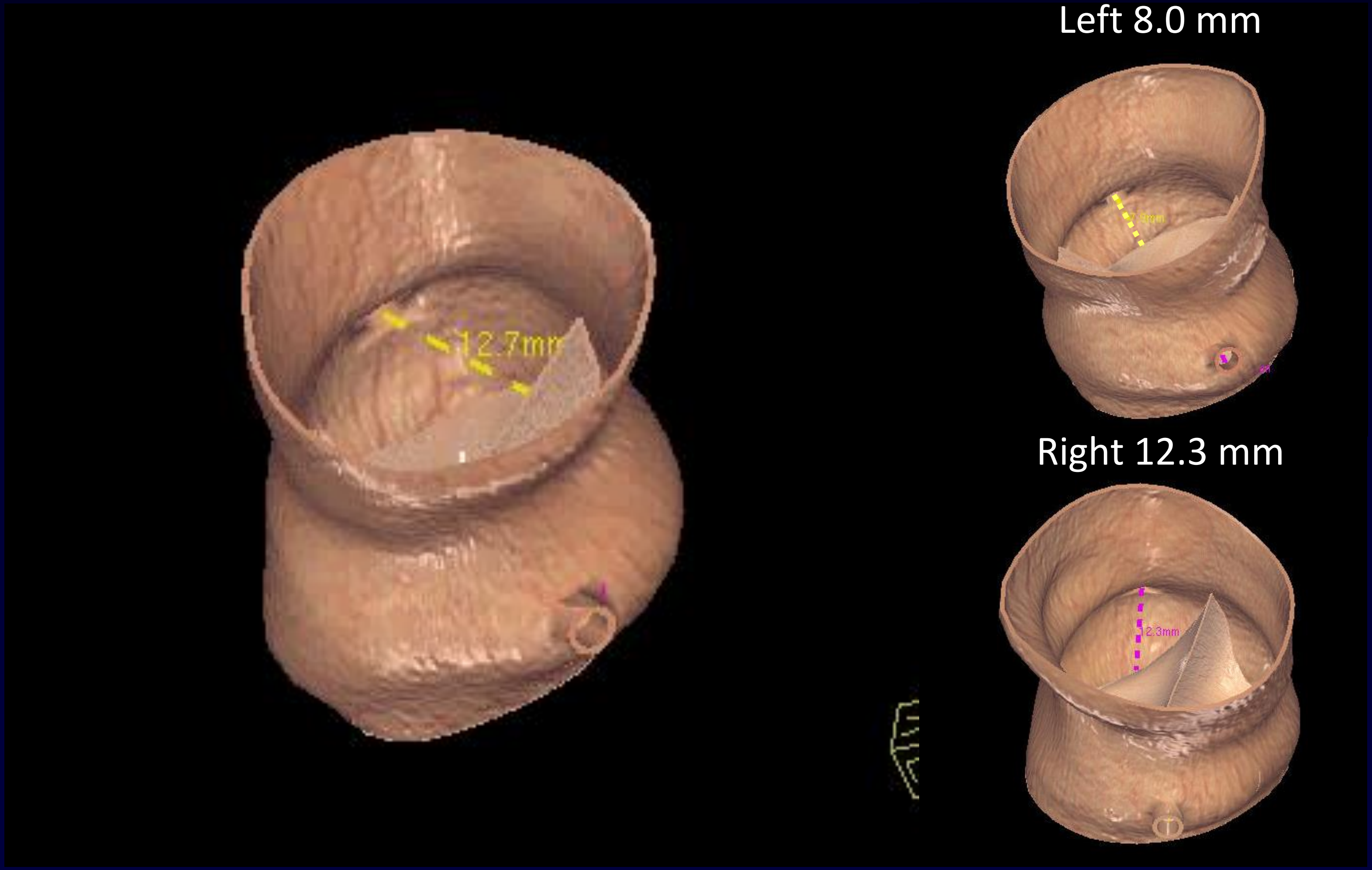
Aortic Annulus

2-D versus Automated 3-D TEE



Automated 3-D TEE of Aortic Root

Annulus to Ostia Distances

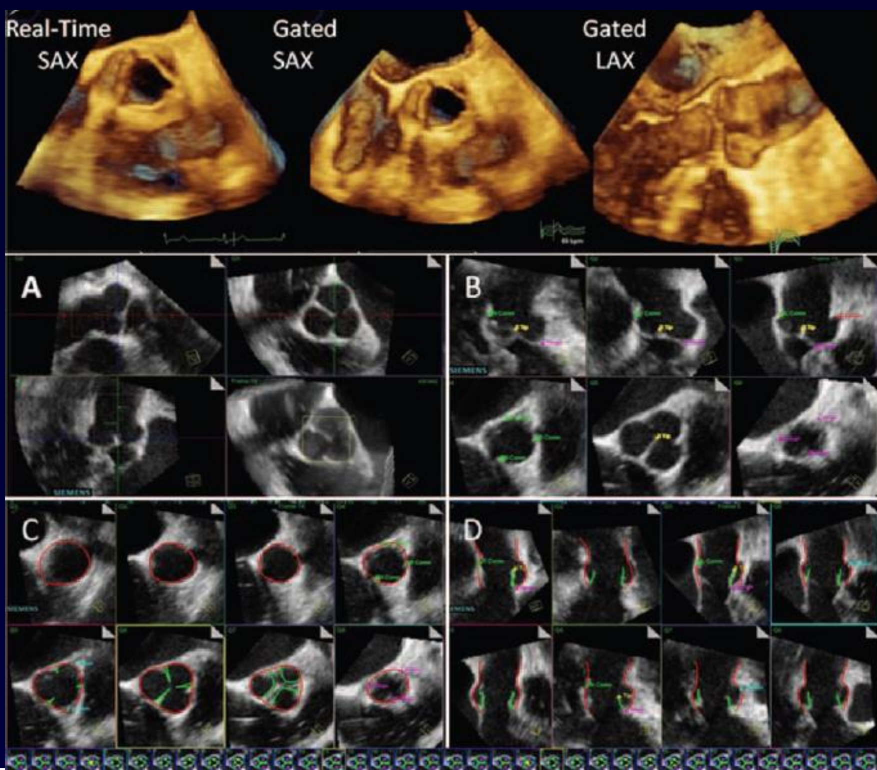


Automated Quantitative 3-Dimensional Modeling of the Aortic Valve and Root by 3-Dimensional Transesophageal Echocardiography in Normals, Aortic Regurgitation, and Aortic Stenosis

Comparison to Computed Tomography in Normals and Clinical Implications

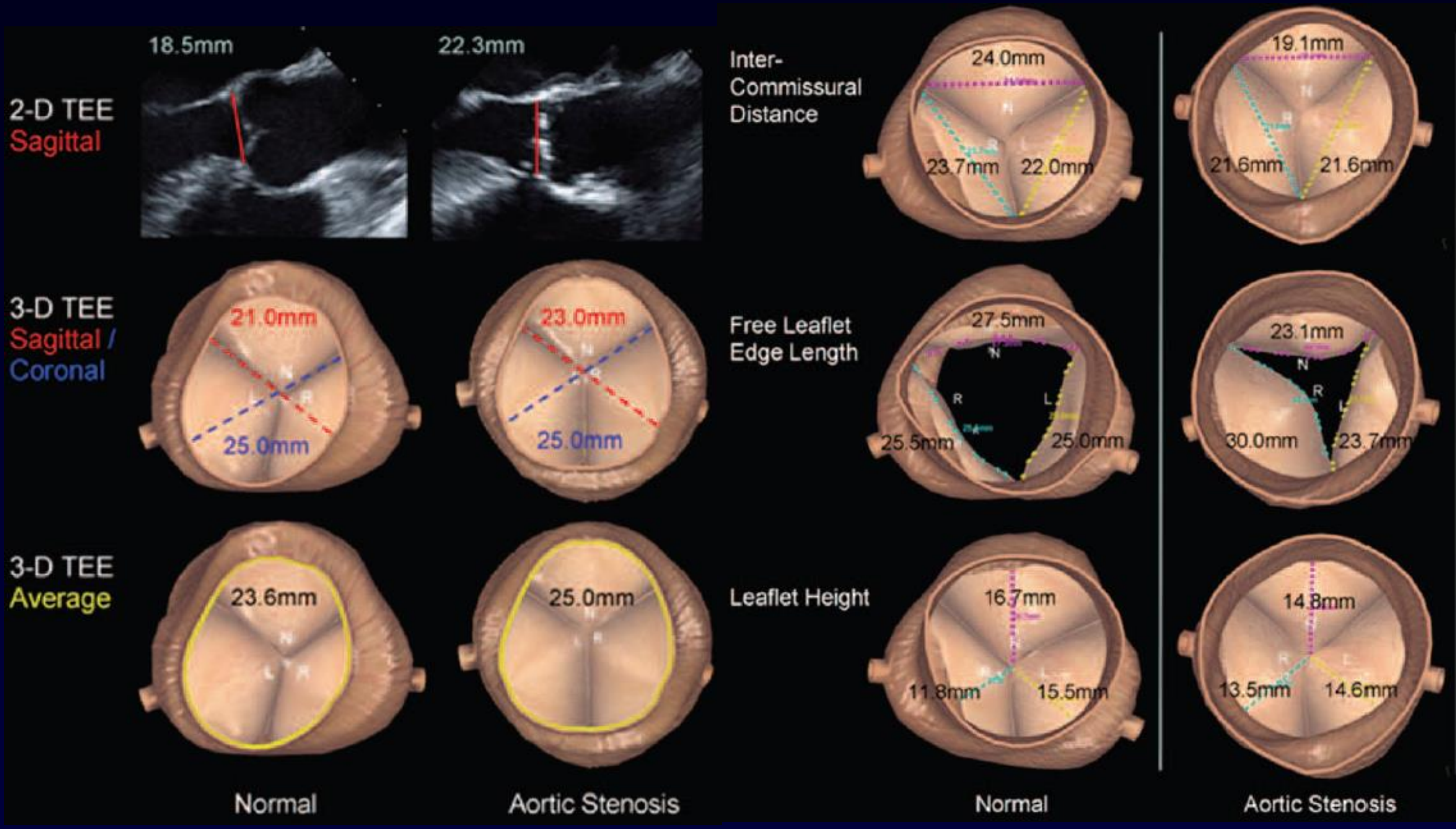
Anna Calleja, MD*; Paaladinesh Thavendiranathan, MD, Msc*; Razvan Ioan Ionasec, PhD; Helene Houle, RDCS, RVT; Shizhen Liu, MD, PhD; Ingmar Voigt, MSc; Chittoor Sai Sudhakar, MD; Juan Crestanello, MD; Thomas Ryan, MD; Mani A. Vannan, MBBS

Circ Cardiovasc Imaging 2013;6:99-108.



Automated 3D modeling TEE compared with 2D TEE and 3D CT

- iE33 system (Philips)
- X72t-TEE probe



Circ Cardiovasc Imaging 2013;6:99-108.

Comparison of two-dimensional and three-dimensional imaging techniques for measurement of aortic annulus diameters before transcatheter aortic valve implantation

Ertunc Altiok,[1] Ralf Koos,[1] Jörg Schröder,[1] Kathrin Brehmer,[1] Sandra Hamada,[1] Michael Becker,[1] Andreas H Mahnken,[2] Mohammad Almalla,[1] Guido Dohmen,[3] Rüdiger Autschbach,[3] Nikolaus Marx,[1] Rainer Hoffmann[1]

Heart 2011;97:1578–84.

- 49 consecutive patients with severe AS undergoing TAVI

< Methods>

2D TTE

2D TEE

3D TEE

Dual-source CT

Angiography

< Parameters>

Aortic annulus diameters

- coronal

- sagital

Distance between

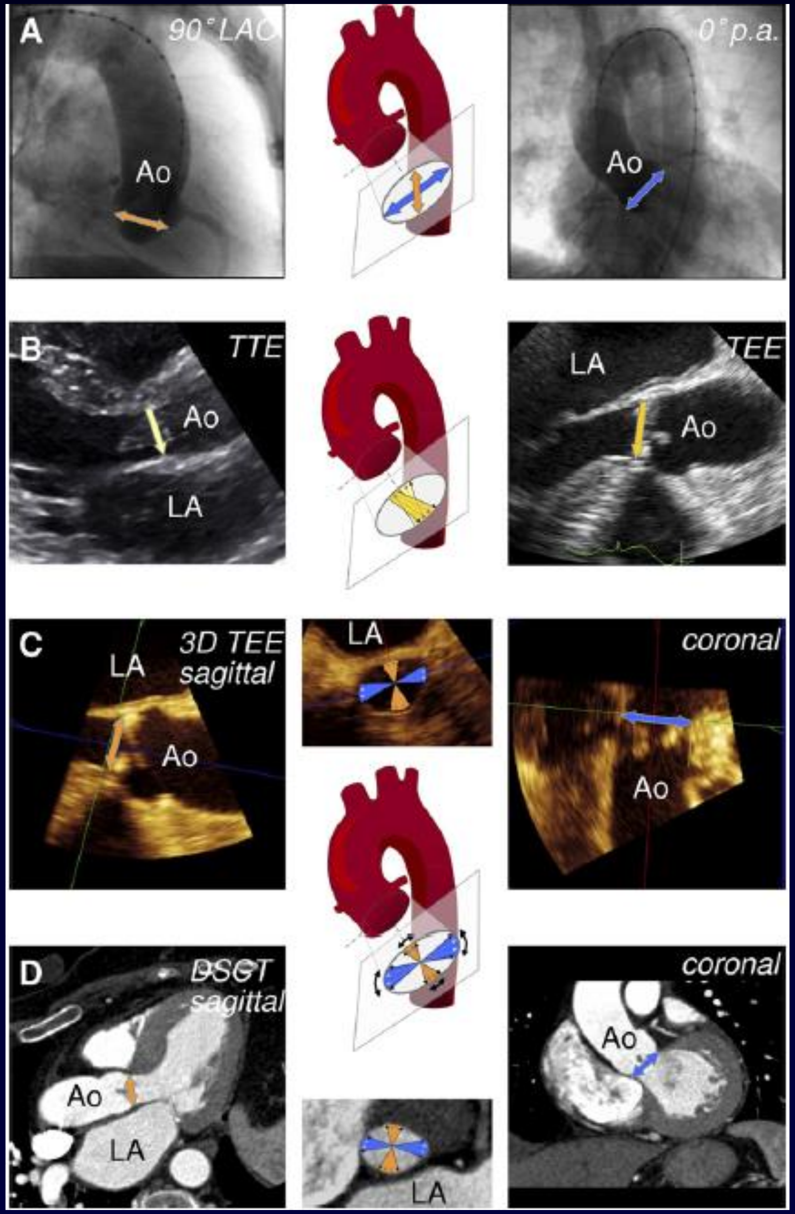
aortic annulus & LM os.

Angiography

2D echo

3D TEE

DSCT

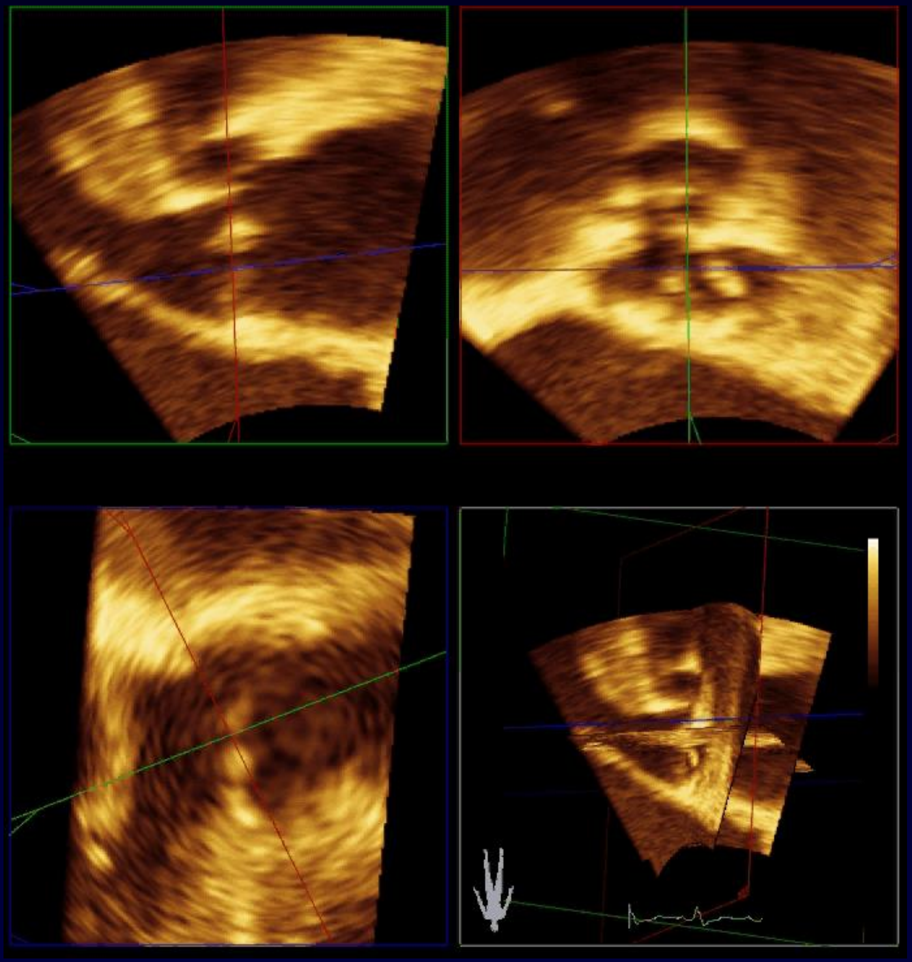


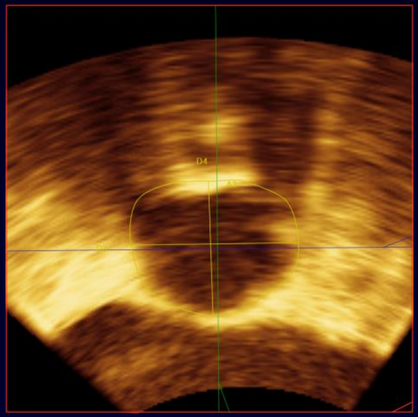
3D imaging techniques should be used to evaluate aortic annulus diameters

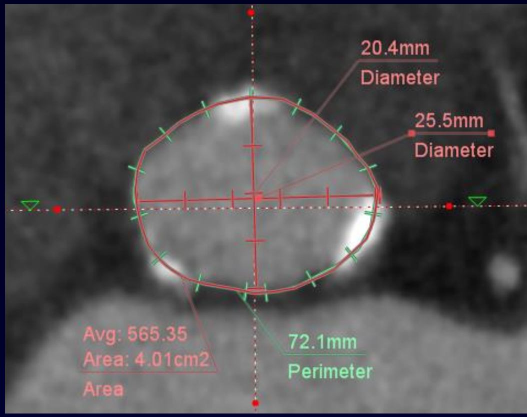
3D TEE provides measurements of aortic annulus diameters similar to those obtained by DSCT.

Heart 2011;97:1578-84.

3D Echocardiography (Philips)

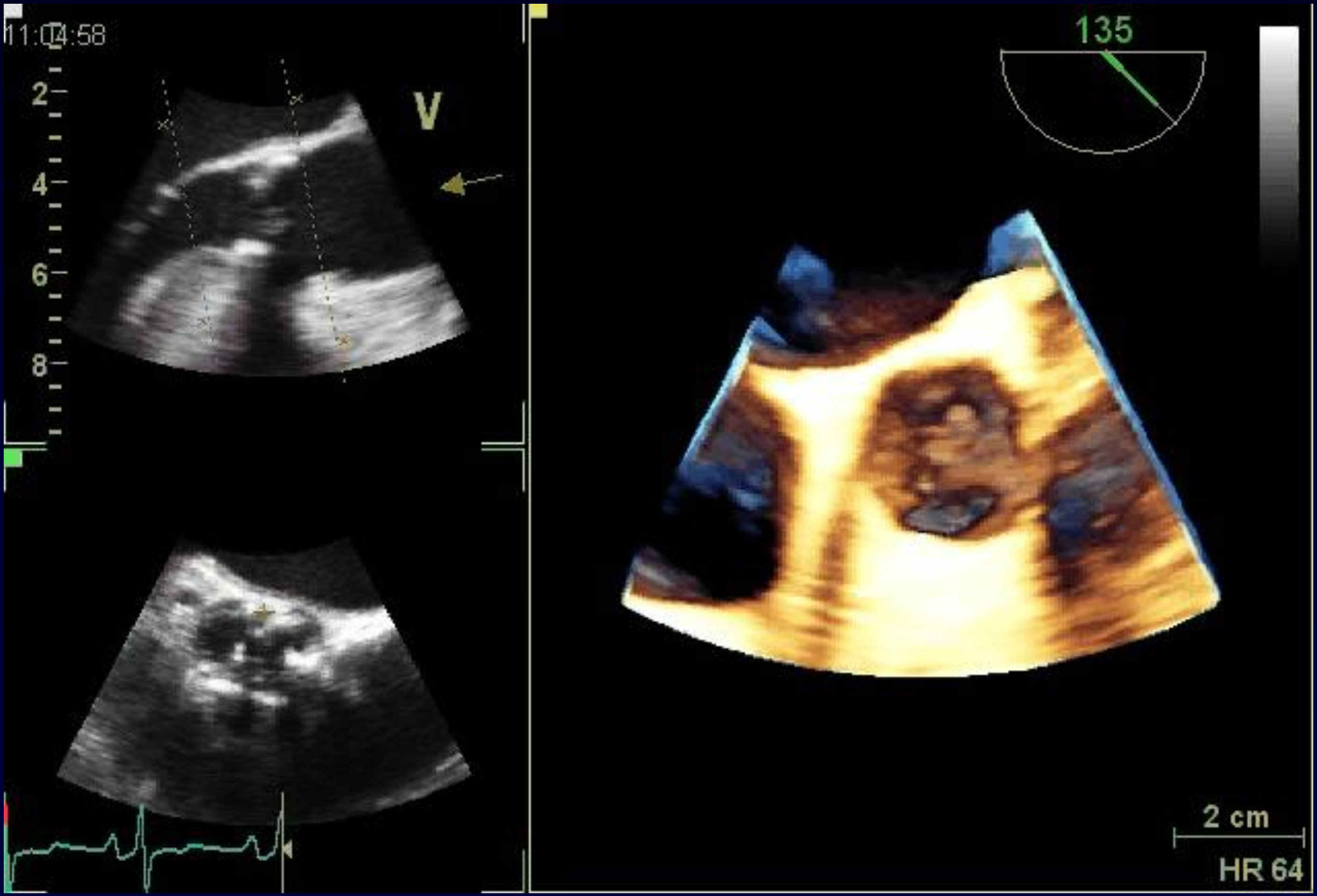




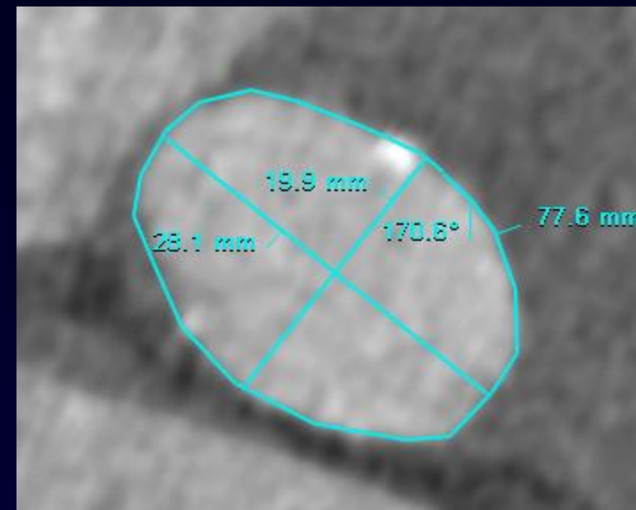


	3D TEE	CT
Perimeter		72.1 mm
Diameter	24.3 x 19.8	25.5 x 20.4
Area	4.06 cm^2	4.01 cm^2

3D Echocardiography (GE)

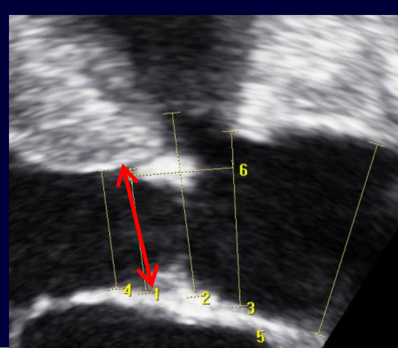


3D TEE vs. CT



Perimeter: 78 (24.8 π) mm
Area: 440 mm² (23.7 mm)

Perimeter: 77.6 (24.7 π) mm
Area: 443 mm² (23.8 mm)

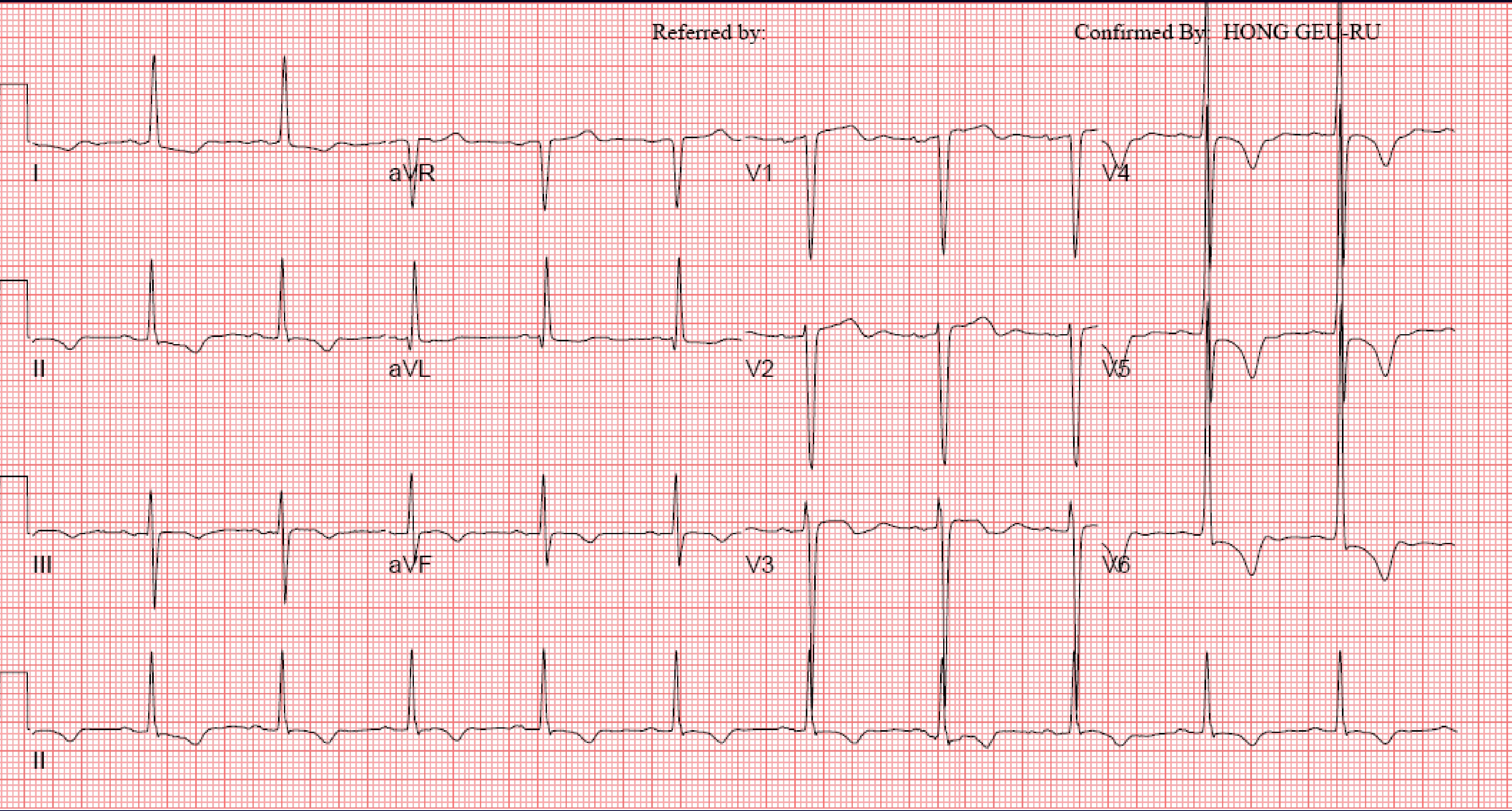


Annulus	**21 mm**

87 year old Female with Dyspnea

- C.C
  - ✓ Dyspnea for 10 days
  - ✓ Chest discomfort for 6 months
- History
  - ✓ Hypertension on medication
  - ✓ Chronic renal failure

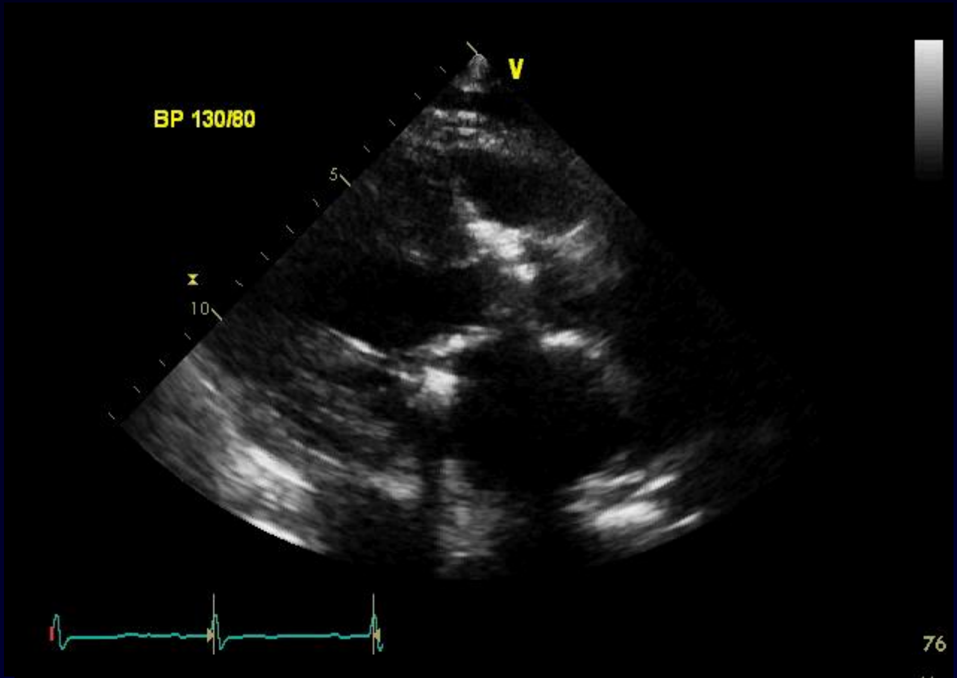
EKG

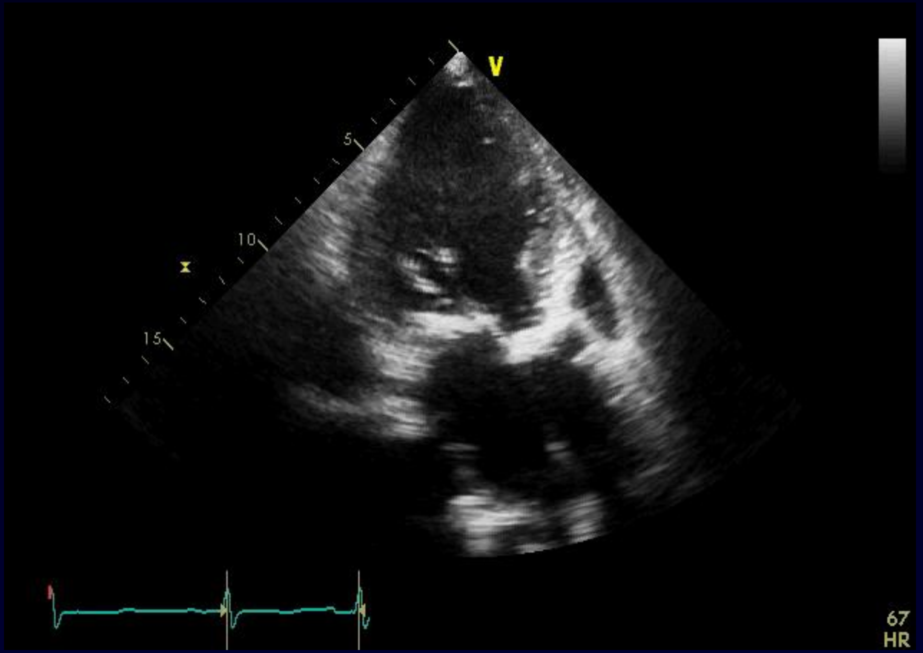

Referred by:
Confirmed By: HONG GEU-RU
I
aVR
V1
V4
II
aVL
V2
V5
III
aVF
V3
V6
II

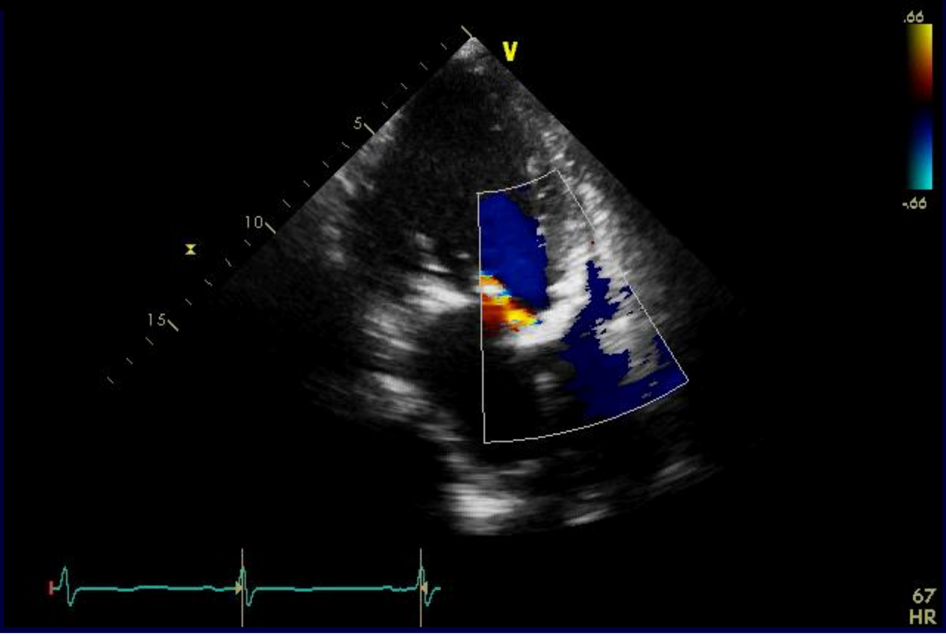
CXR

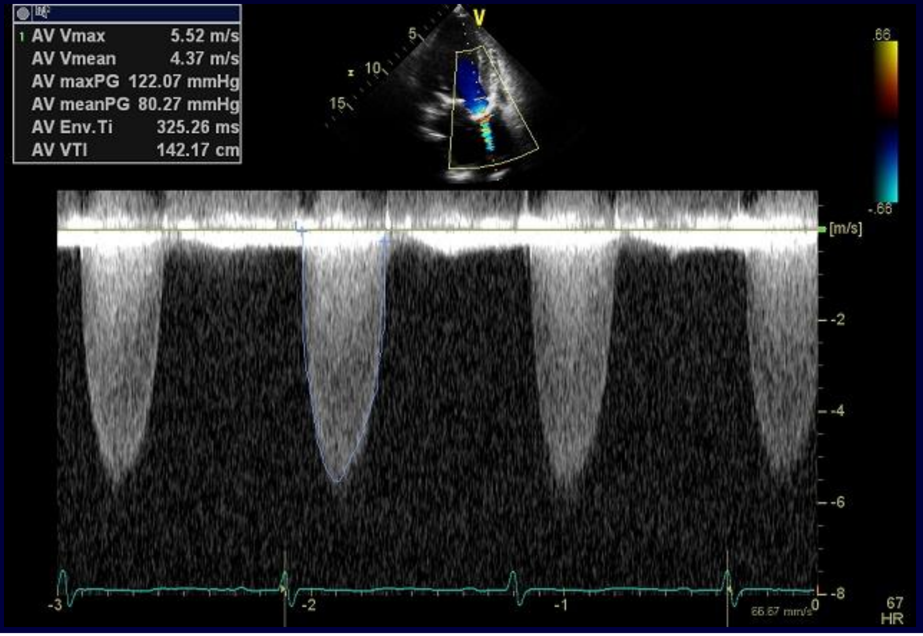
Lab

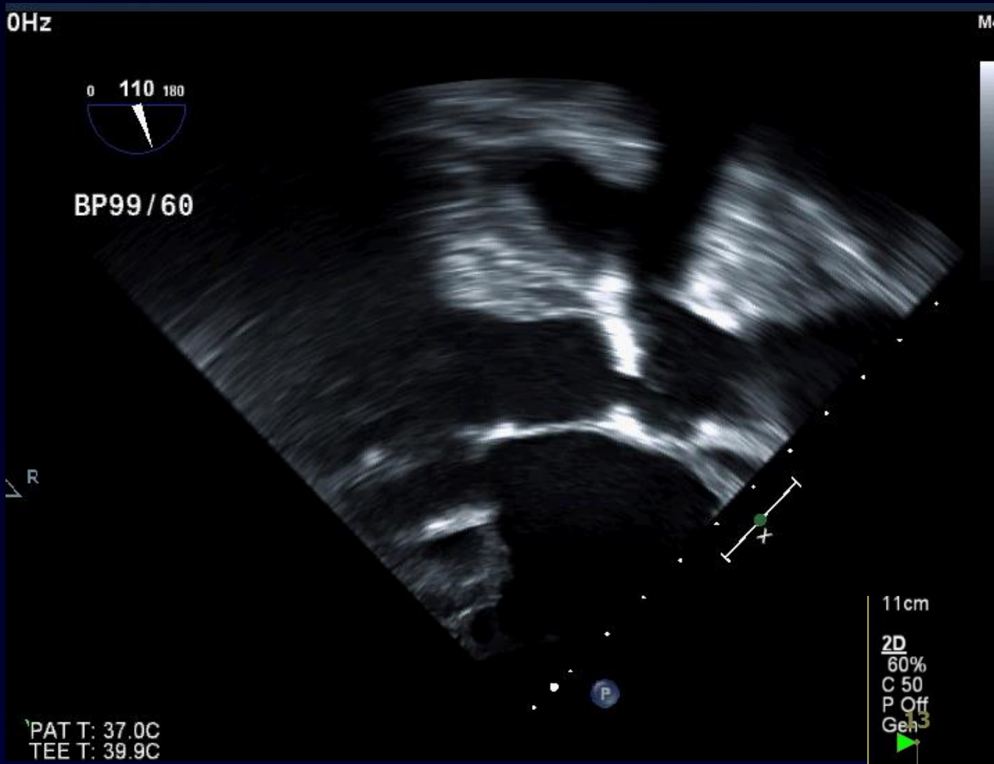
CBC (WBC-Hb-Plt)	**5470 (54.6%)-10.8-135k**
BUN/Creatinie	35.2/1.92
Glucose	111
Electrolyte (Na/K/Cl/tCO_2)	137-4.0-99-26
OT/PT/T.bil	18-9-0.4
CK/CK-MB	44-3.0
NT-proBNP	20923
CRP	3.0

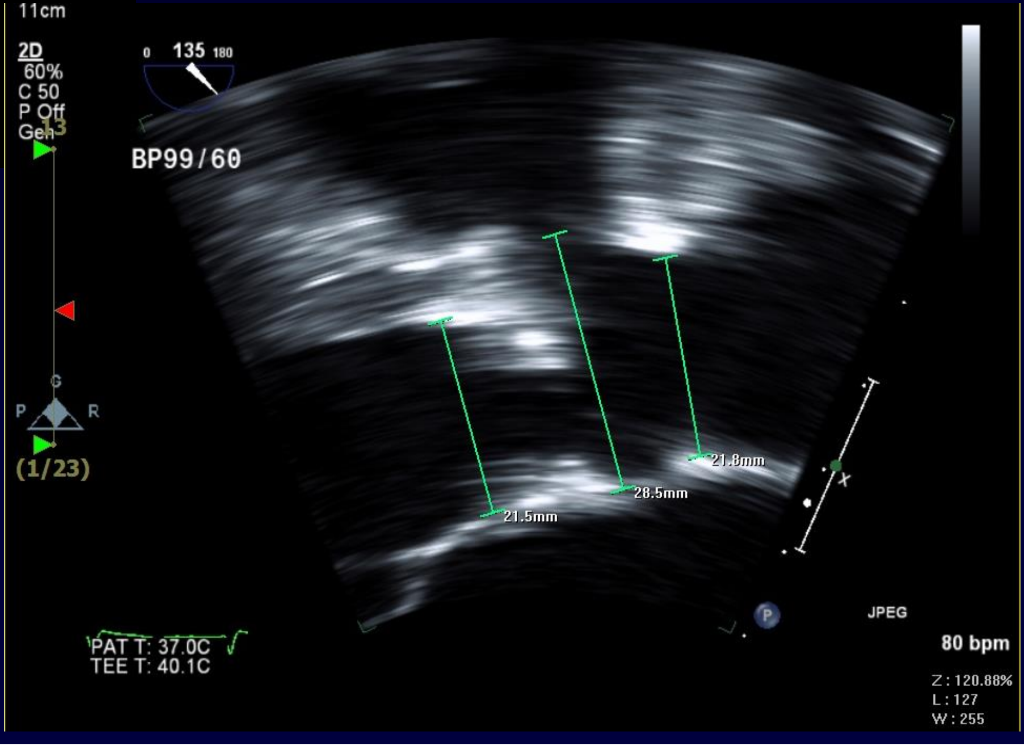

BP 130/80
76


67
HR

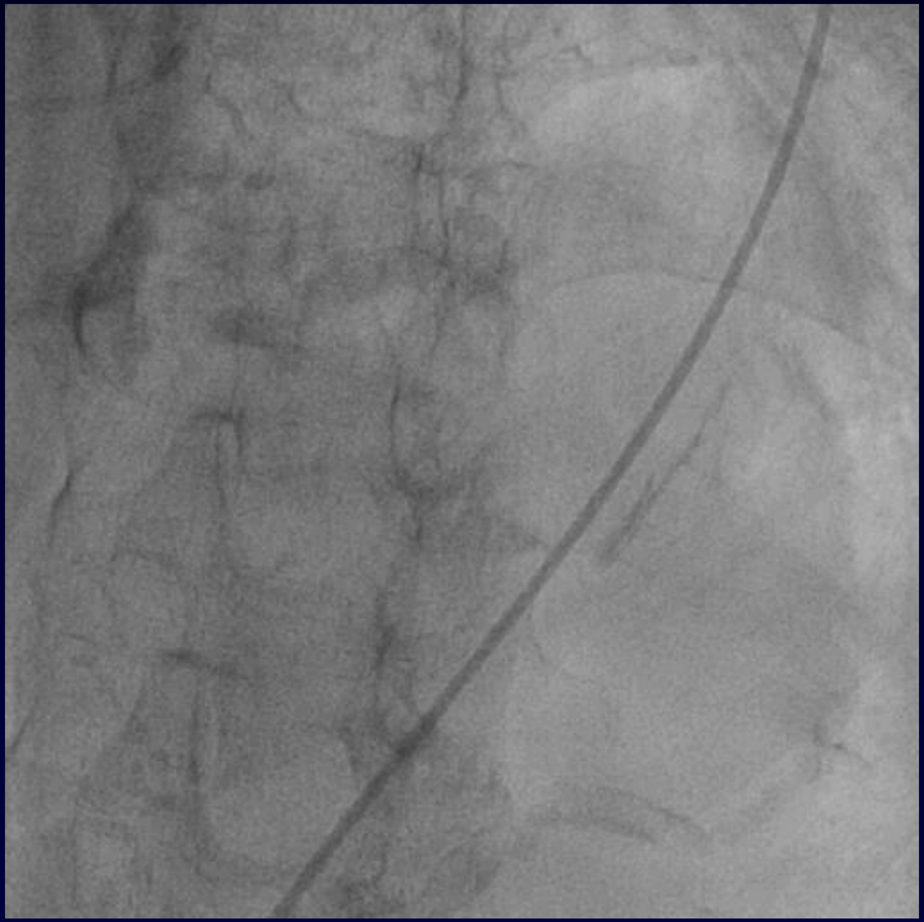

67
HR

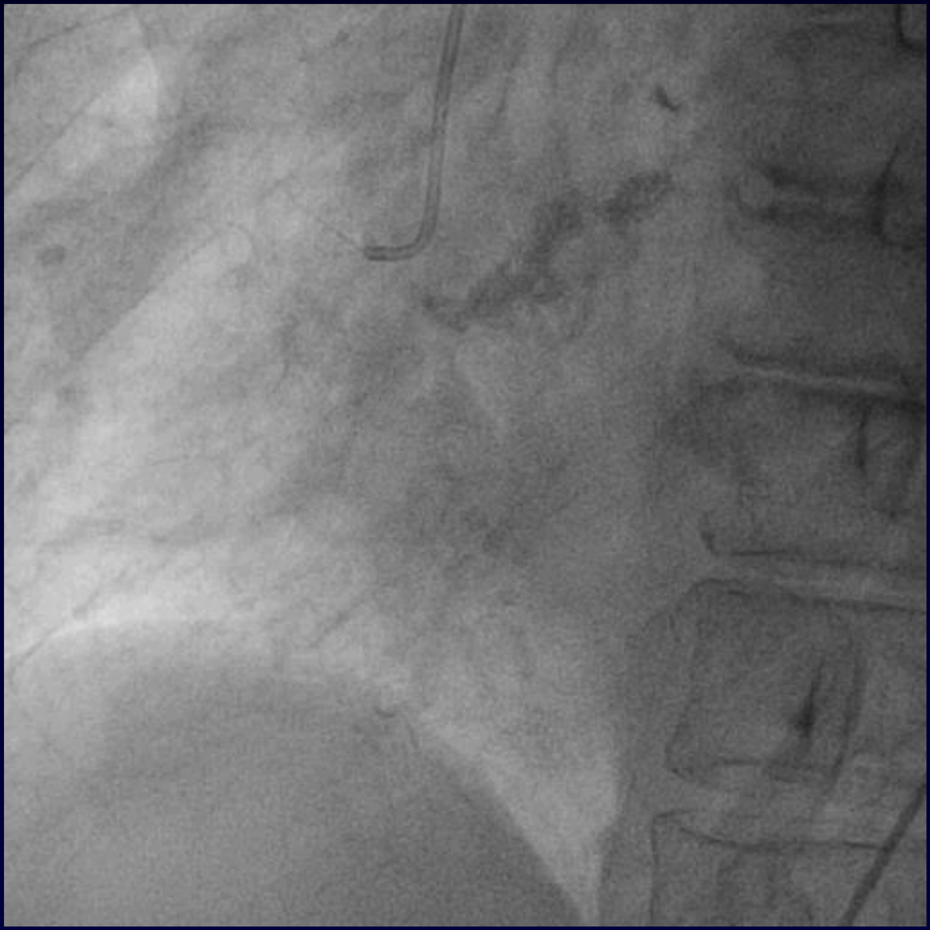

AV Vmax 5.52 m/s
AV Vmean 4.37 m/s
AV maxPG 122.07 mmHg
AV meanPG 80.27 mmHg
AV Env.Ti 325.26 ms
AV VTI 142.17 cm
[m/s]
67
HR


0Hz
M4
0 110 180
BP99/60
R
P
PAT T: 37.0C
TEE T: 39.9C


11cm
2D
60%
C 50
P Off
Gen
0 135 180
BP99/60
P
R
(1/23)
21.8mm
28.5mm
21.5mm
P
JPEG
80 bpm
PAT T: 37.0C
TEE T: 40.1C
Z: 120.88%
L: 127
W: 255

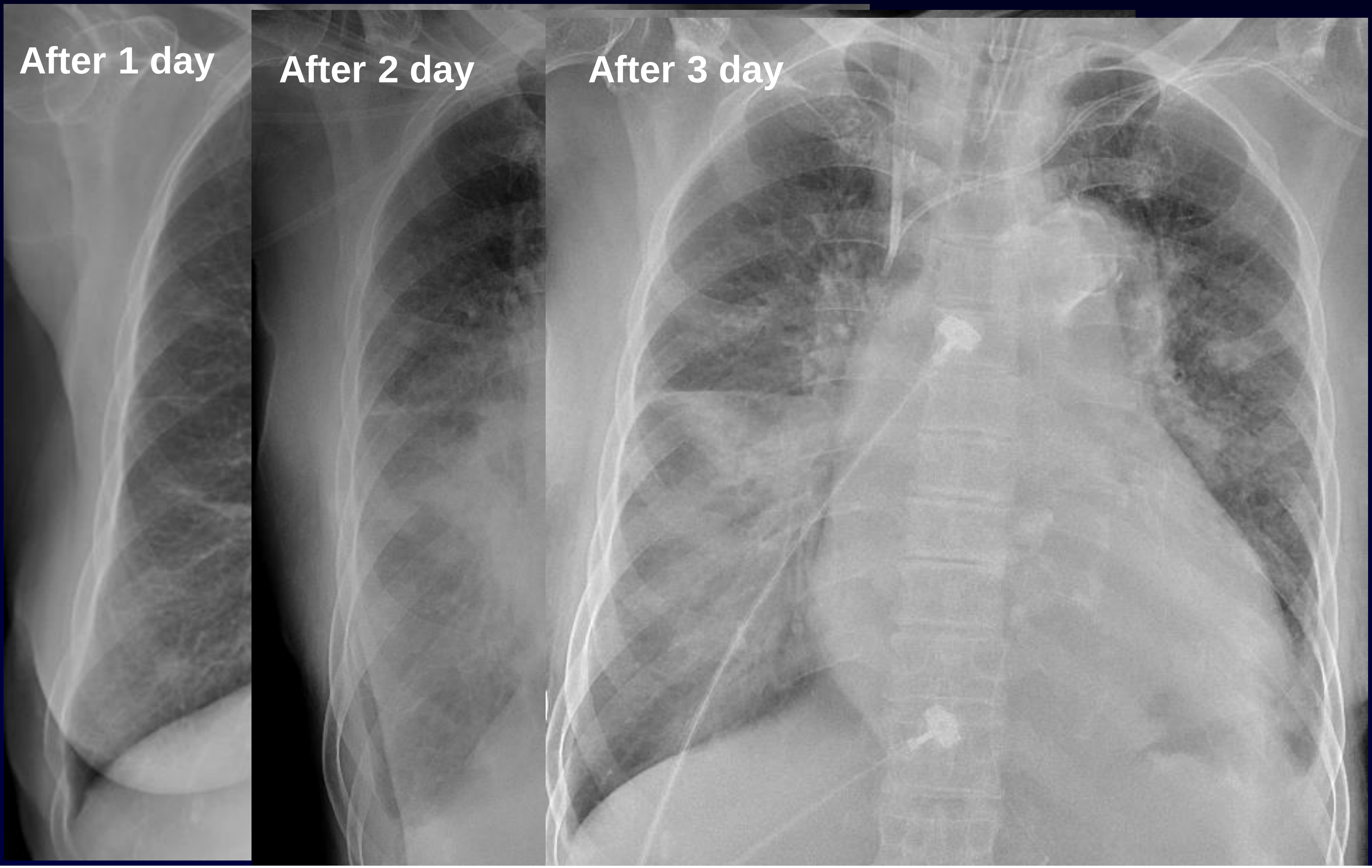
CAG





Cardiac CT for pre-procedure (TAVI) screening

After CT scan



Advantage of Echo

- Inexpensive
- Safe
- Portable
- Repeat
- Hemodynamic information

- Do not require offline analysis

Pitfalls of Echocardiography

- **Image quality**
  - Good vs poor
- **Subjective**
- **Machine factor**
- **Operator dependent**
  - Expert vs beginner

COREVALVE
THE REVALVING TECHNOLOGY

Patient Selection Matrix

	NON-INVASIVE		ANGIOGRAPHY				SELECTION CRITERIA		
Anatomy	Echo	CT / MRI	LV	AO	Coro	AO & Runoffs	Preferred	Borderline	Not Acceptable
Atrial or Ventricular Thrombus	X						Not Present		Present
Mitral Regurgitation	X						≤ Grade 1	Grade 2	> Grade 2
LV Ejection Fraction	X		X				> 50%	30% to 50%	< 20% (w/o cardiac support)
LV Hypertrophy (wall thickness)	X						Normal to Mild (0.6 to 1.3 cm)	Moderate (1.4 to 1.6cm)	Severe (≥ 1.7cm)
Sub-Aortic Stenosis	X	X					Not Present		Present
Annulus width [A]	X	X					20 to 23mm → 26mm device 23 to 27mm → 29mm device		< 20mm or > 27mm
AO Root width [B]		X	X	X			≥ 27mm → 26mm device ≥ 28mm → 29mm device		< 27mm
Coronary Ostia [D] (from native leaflet)					X		≥ 14mm	13mm w/ mod. Ca^{2+} 10 to 13mm w/o Ca^{2+}	< 14mm w/ severe Ca^{2+} < 13mm w/ mod. Ca^{2+} < 10mm w/o Ca^{2+}
Coronary Disease					X		None	Mid or Distal Stenosis < 70%	Proximal Stenosis ≥ 70%
Annulus-to-Aorta (angle) †		X	X	X			< 45°	45° to 70°	> 70°
Ascending AO width [C]	X	X	X	X			≤ 40mm → 26mm device ≤ 43mm → 29mm device		> 43mm
AO Arch Angulation		X		X		X	Large-Radius Turn		High Angulation or Sharp Bend
Aorta & Runoff Vessels (Disease) ‡		X				X	None	Mild	Moderate to Severe
Iliac & Femoral Vessels (diameter)		X				X	≥ 7mm	Non-Diabetic Non-Dialyzed ≥ 6mm	< 6mm

† Within the first 7cm of the ascending aorta versus a perpendicular line across the aortic valve.
‡ Evaluate for evidence and degree of calcification, obstruction, tortuosity, and ulceration.

PN 000404 V4 July 2008

Conclusion

- Cardiac imaging has an essential role in the planning and provision of TAVI
- Echocardiography allows appropriate case selection, correct choice of prosthetic size and type, guides successful implantation, and facilitates the treatment of complications
- The imaging specialist must possess procedural knowledge, and precision in quantification, and communication in order to be part of a team that delivers good outcomes

Thank you for your attention

Aortic Annular Measurement