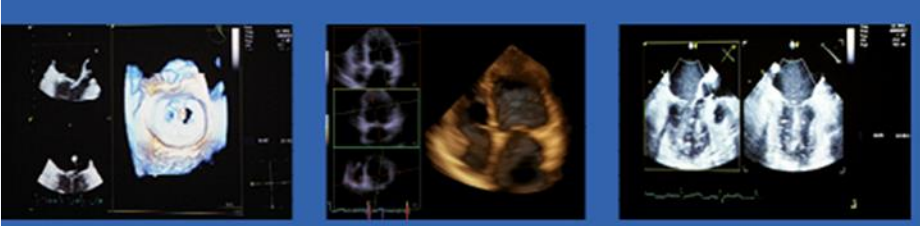


Chronic (Isolated) Tricuspid Regurgitation

Trans-catheter Tricuspid Valve Repair

Xiao Zhou MD PhD

Echocardiography Department

PLA General Hospital

Beijing, China

Conflict of Interest:

Siemens - Research Support

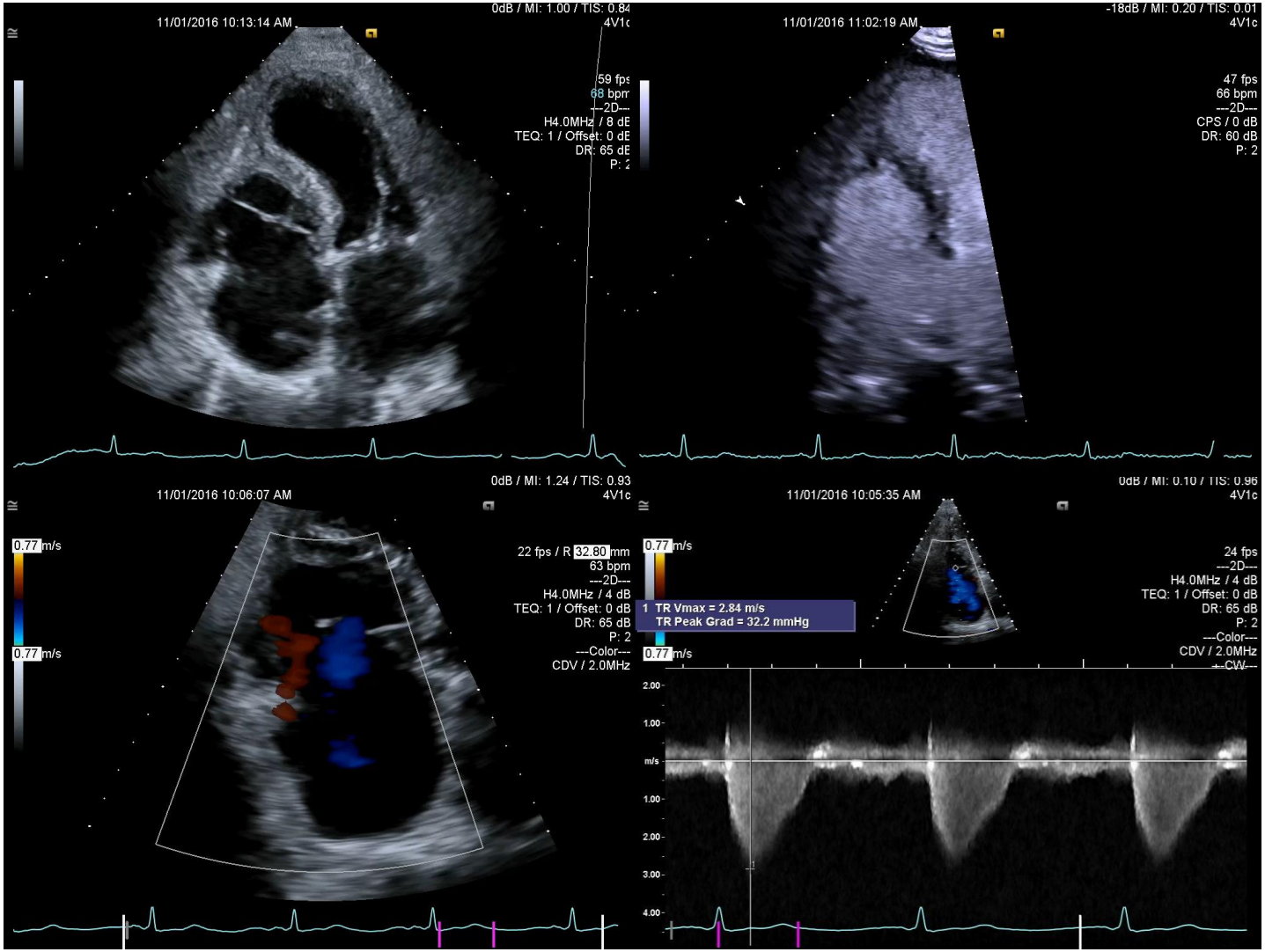
Lady with HF

History

- 74 y/o female history of stage 4 CKD, CLL, and HTN
- CLL found during evaluation for kidney trans
- TR was found when she developed pneumonia as a complication of her CLL treatment and hospitalized
- Abdominal paracentesis for abdominal swelling from fluid retention
- Still feels weak, she experiences abdominal and lower limb edema, and she can walk about 200 ft before feeling short of breath
- She previously experienced about 20 lb weight gain, but she takes Furosemide daily to decrease her fluid retention

TTE Evaluation of TR

2-D TTE



TTE Evaluation of TR

2-D/3-D TTE

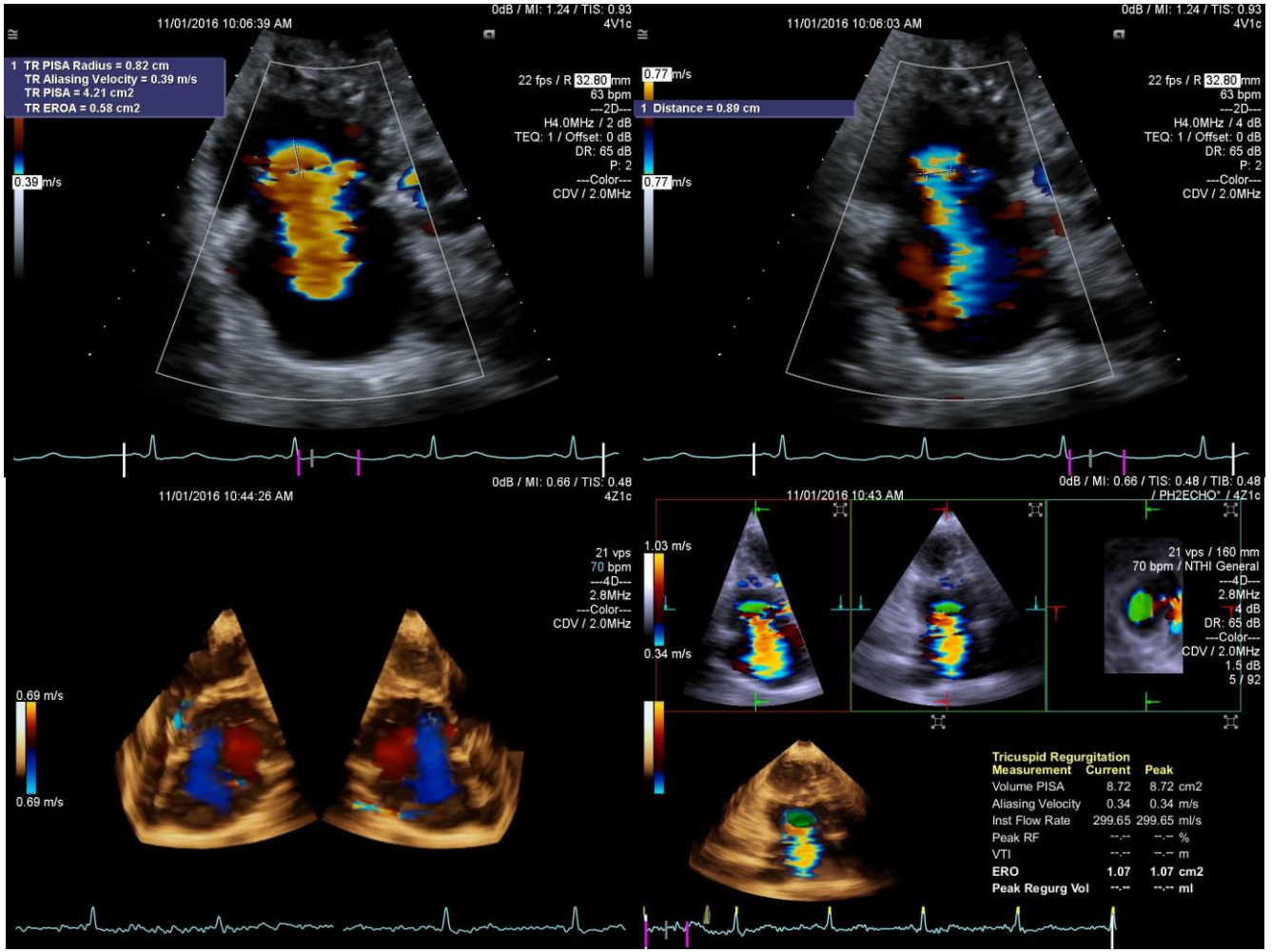


Table 19. Stages of TR

Stage	Definition	Valve Anatomy	Valve Hemodynamics*	Hemodynamic Consequences	Symptoms
A	At risk of TR	**Primary** • Mild rheumatic change • Mild prolapse • Other (e.g., IE with vegetation, early carcinoid deposition, radiation) • Intra-annular RV pacemaker or ICD lead • Postcardiac transplant (biopsy related) **Functional** • Normal • Early annular dilation	• No or trace TR	• None	• None or in relation to other left heart or pulmonary/ pulmonary vascular disease
B	Progressive TR	**Primary** • Progressive leaflet deterioration/destruction • Moderate-to-severe prolapse, limited chordal rupture **Functional** • Early annular dilation • Moderate leaflet tethering	**Mild TR** • Central jet area <5.0 cm^2 • Vena contracta width not defined • CW jet density and contour: soft and parabolic • Hepatic vein flow: systolic dominance **Moderate TR** • Central jet area 5–10 cm^2 • Vena contracta width not defined but <0.70 cm • CW jet density and contour: dense, variable contour • Hepatic vein flow: systolic blunting	**Mild TR** • RV/RA/IVC size normal **Moderate TR** • No RV enlargement • No or mild RA enlargement • No or mild IVC enlargement with normal respirophasic variation • Normal RA pressure	• None or in relation to other left heart or pulmonary/ pulmonary vascular disease
C	Asymptomatic, severe TR	**Primary** • Flail or grossly distorted leaflets **Functional** • Severe annular dilation	• Central jet area >10.0 cm^2 • Vena contracta width >0.7 cm • CW jet density and contour:	• RV/RA/IVC dilated with decreased IVC respirophasic variation • Elevated RA pressure with	• None, or in relation to other left heart or pulmonary/ pulmonary vascular disease
D	Symptomatic severe TR	**Primary** • Flail or grossly distorted leaflets **Functional** • Severe annular dilation (>40 mm or >21 mm/m^2) • Marked leaflet tethering	• Central jet area >10.0 cm^2 • Vena contracta width >0.70 cm • CW jet density and contour: dense, triangular with early peak • Hepatic vein flow: systolic reversal	• RV/RA/IVC dilated with decreased IVC respirophasic variation • Elevated RA pressure with "c-V" wave • Diastolic interventricular septal flattening • Reduced RV systolic function in late phase	• Fatigue, palpitations, dyspnea, abdominal bloating, anorexia, edema

Nishimura RA,et al. J Am Coll Cardiol. 2014 Jun 10;63(22):2438-88.

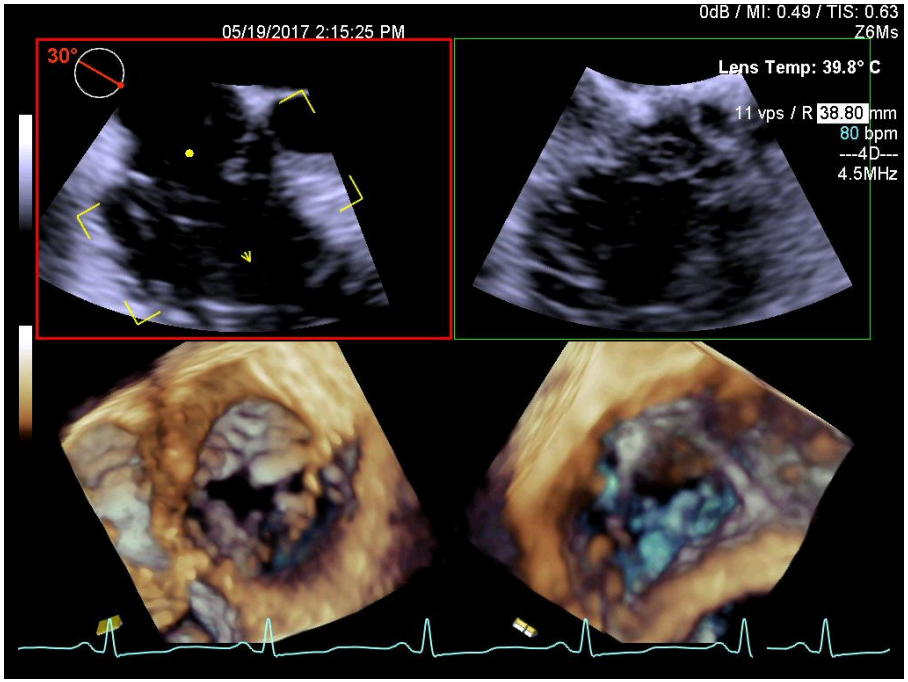
Lady with HF

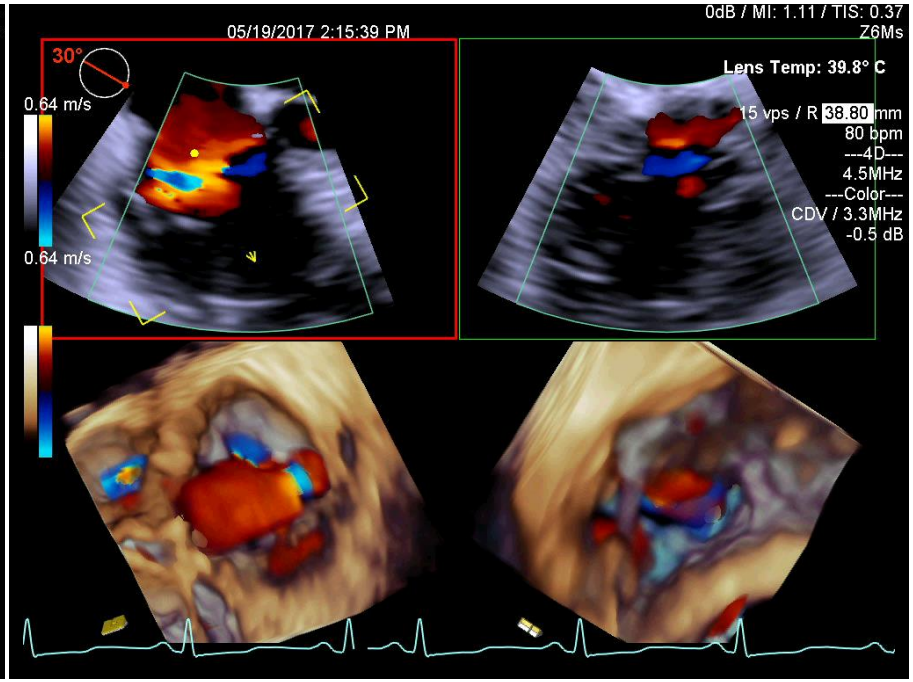
Clinical Decision-Making

- SYMPTOMATIC Severe TR: dilated annulus, good leaflet coaptation, mild AR
- Complex medical history
- High risk for surgery
- Consider trans-catheter TV repair
- Further evaluation of TV anatomy with TEE

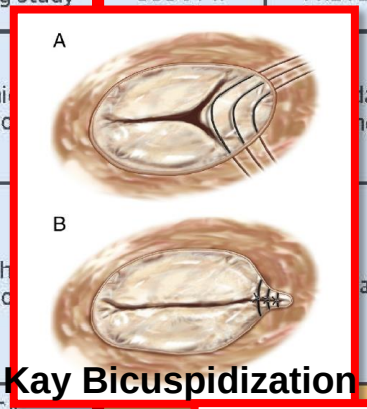
3-D TEE

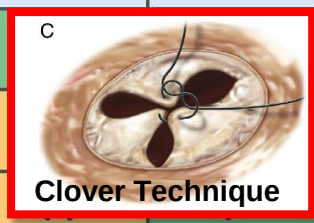
Evaluation of TV leaflets and Annulus





	Trialign	TriCinch	Cardioband	FORMA	TriClip	Millipede	TRAIPTA
							
Mechanism	Annuloplasty	Annuloplasty	Annuloplasty	Coaptation device	Leaflet plasty	Annuloplasty	Annuloplasty
Patients treated	± 50	±27	±19	±18	± 250	2 (surgical)	-
Ongoing Study	SCOUT II	PREVENT	TRI-REPAIR	SPACER	-	-	-
Clini endpo			30-day Safety Endpoint and Serious Adverse Events	30-day Cardiac Mortality	-	-	-
Ech endpo			SL Diameter EROA RVol TR grade	TR grade	-	-	-
RCA damage	✓✓		✓✓			✓/✓✓	✓✓
Device detachment	✓✓		✓✓			✓/✓✓	✓✓
Cardiac perforation	✓		✓✓			✓✓	✓✓✓
Technical difficulty	✓✓			✓	✓✓	✓✓	✓✓✓
Surgical predicate	✓	✓✓		✓✓✓	✓✓✓	✓	✓✓✓

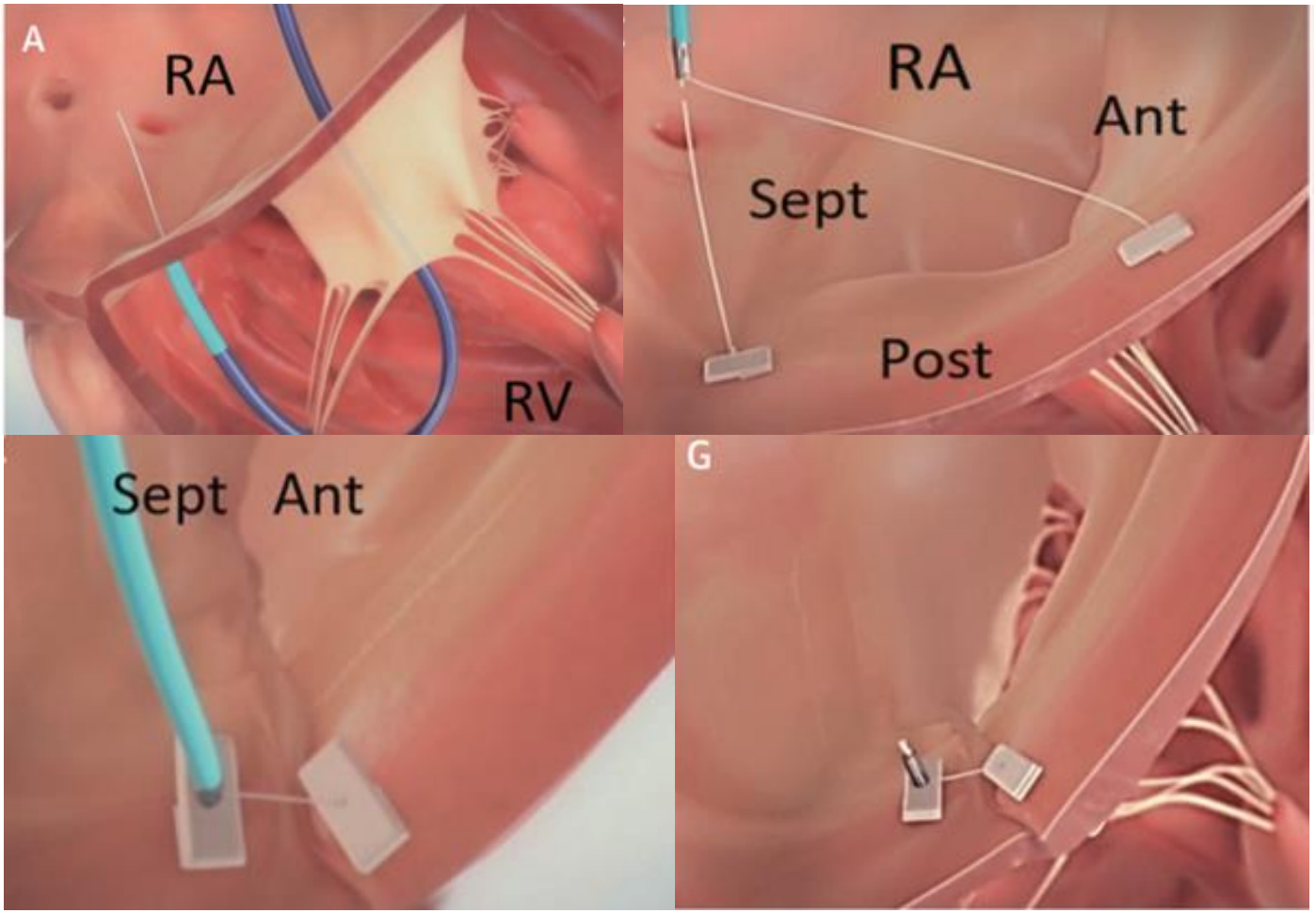




Latib A, Mangieri A. J Am Coll Cardiol. 2017 Apr 11;69(14):1807-1810.

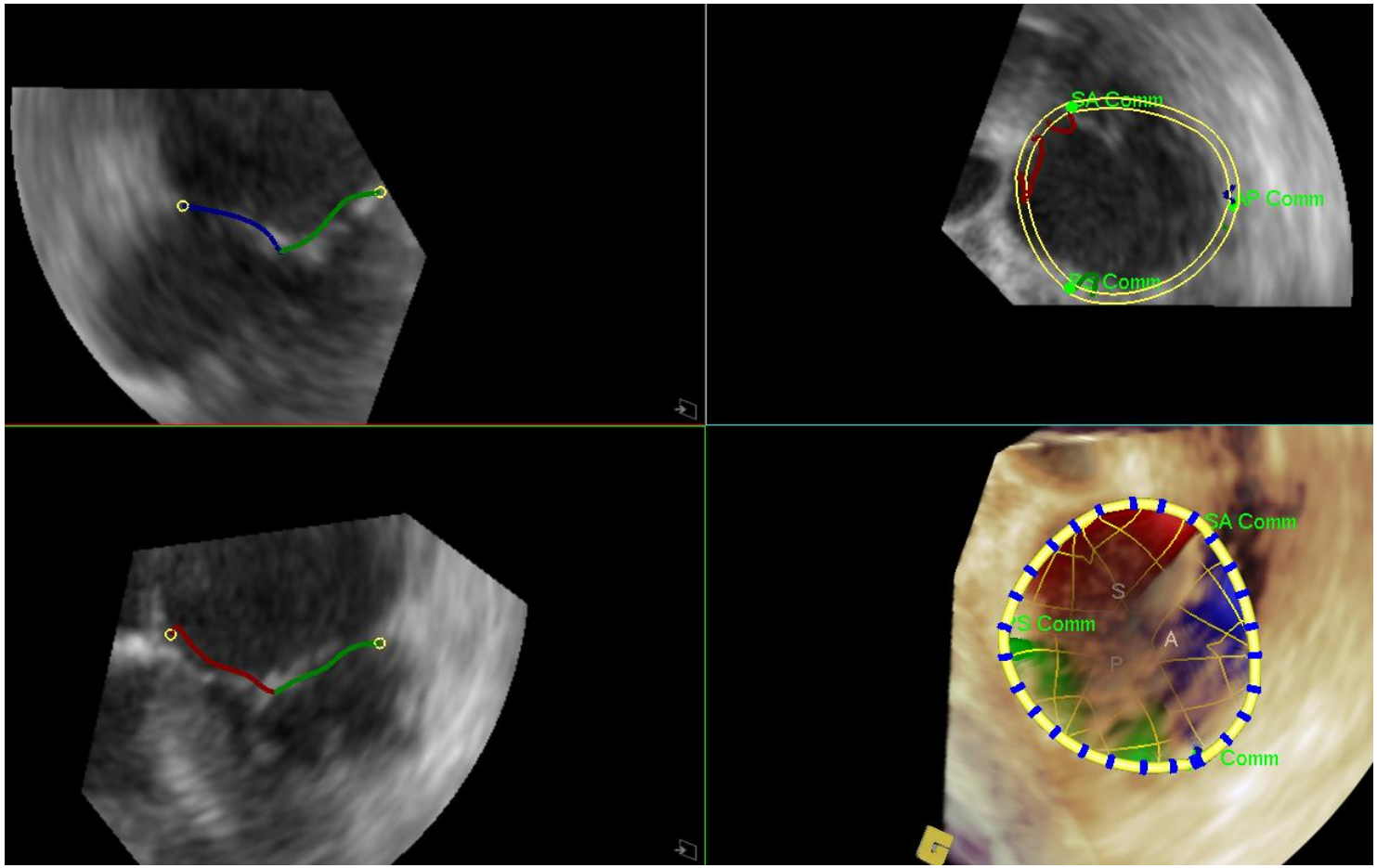
TTVR for Chronic Functional TR

SCOUT



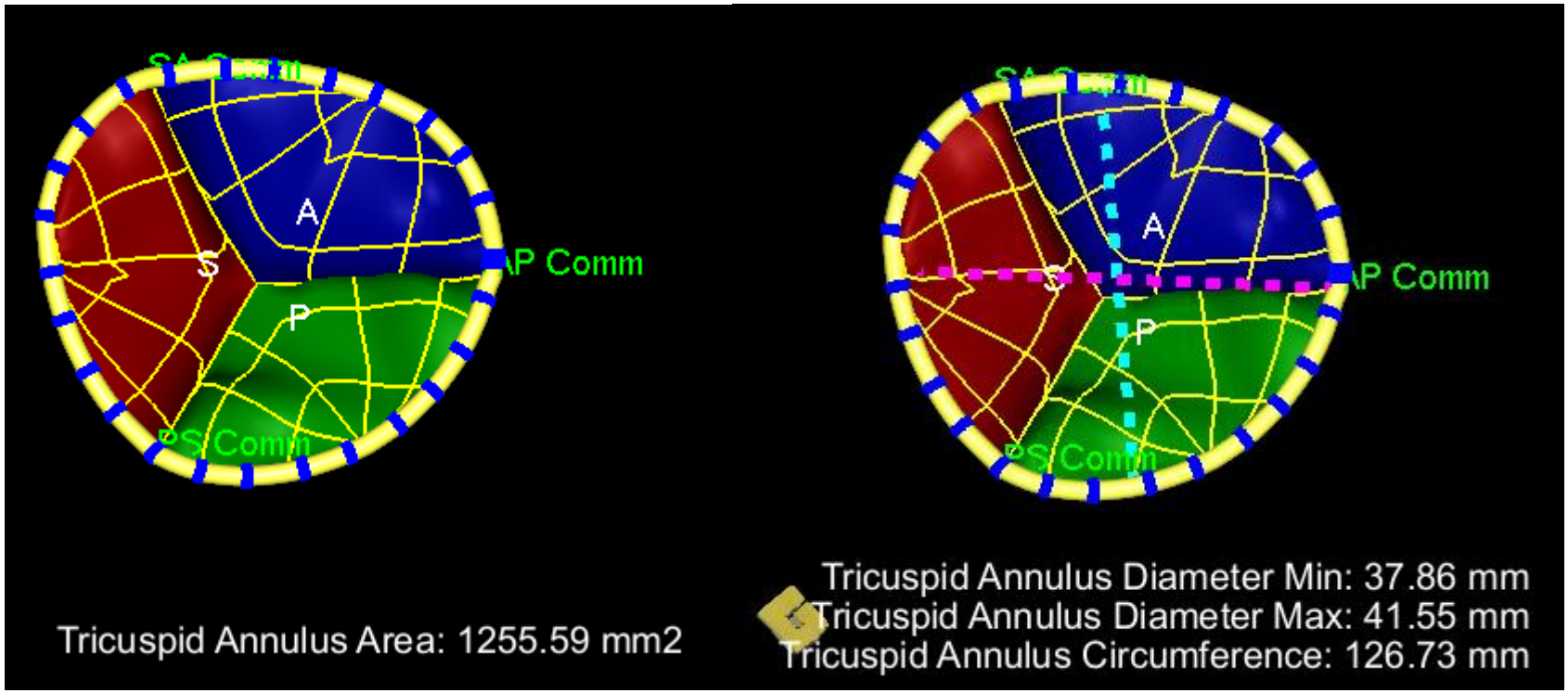
TTVR Planning

3-D TEE for Automated TV Annulus Size



TTVR Planning

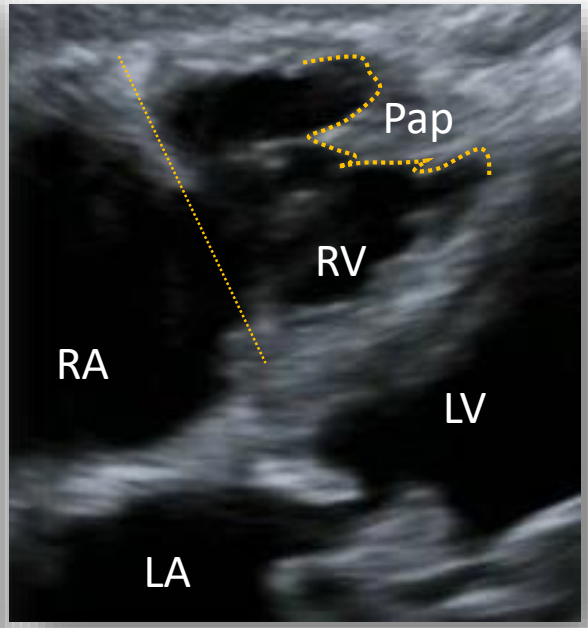
3-D TEE for Automated TV Annulus Size



TTVR Planning

2-D/3-D TTE and TEE

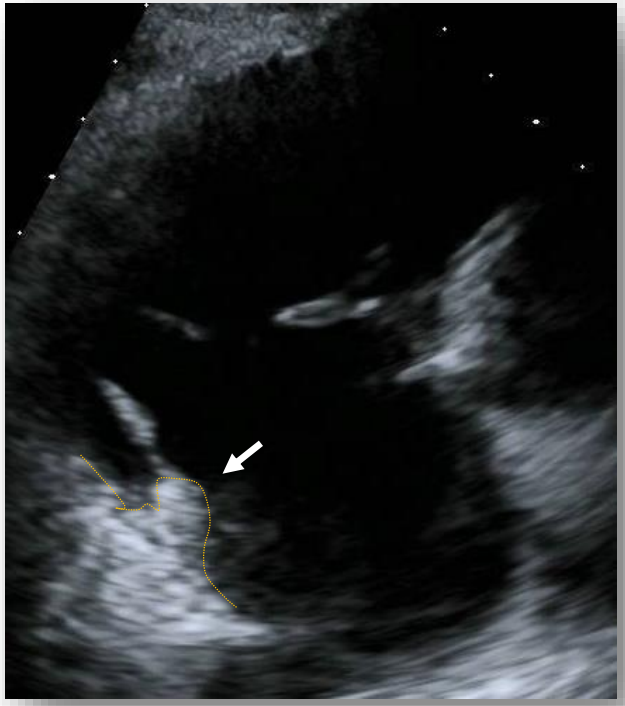
- Extremely short RV height (4-5cm)
- Central and apical papillary muscle
- Good shelf for implantation
- Large ERO considering valve diameter
- Plan: plicate a maximal first pair and see if a second pair is needed



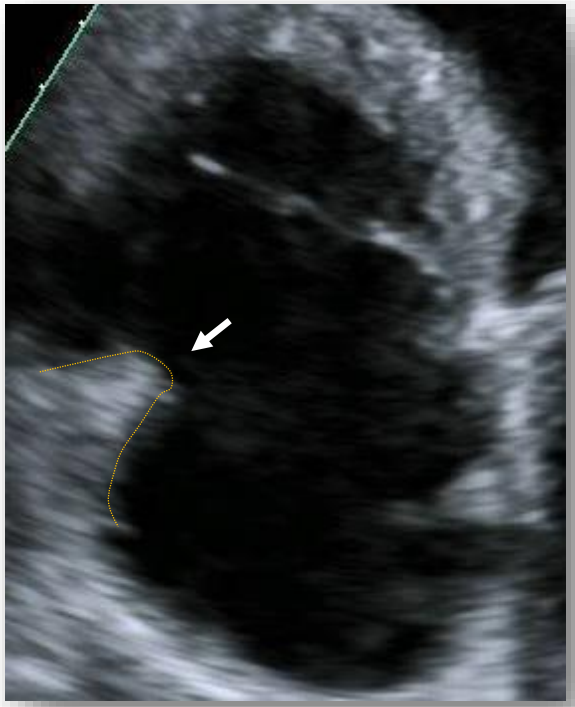
Key Patient Data	
TR Grade	Severe
Diameter dias. (4CH)	3.52 cm
TAPSE	1.62 cm
Tethering Distance	0.51 cm
TR PISA Radius	0.8 cm
EROA by PISA	0.61 cm^2
Quantitative Doppler EROA	0.83 cm^2
Vena Contracta	2.0-1.46 cm
TV Annular Area	13.42 cm^2
PASP (RAP = 8mmHg)	38.1 mmHg

TTVR Planning

Annulus Shelf Size



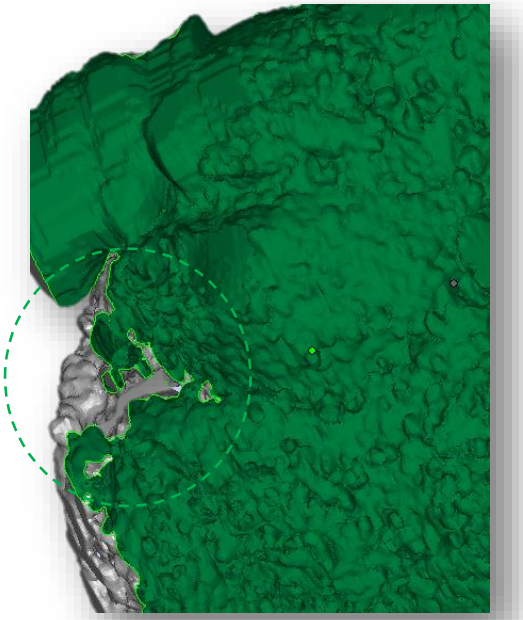
Posterior Septal



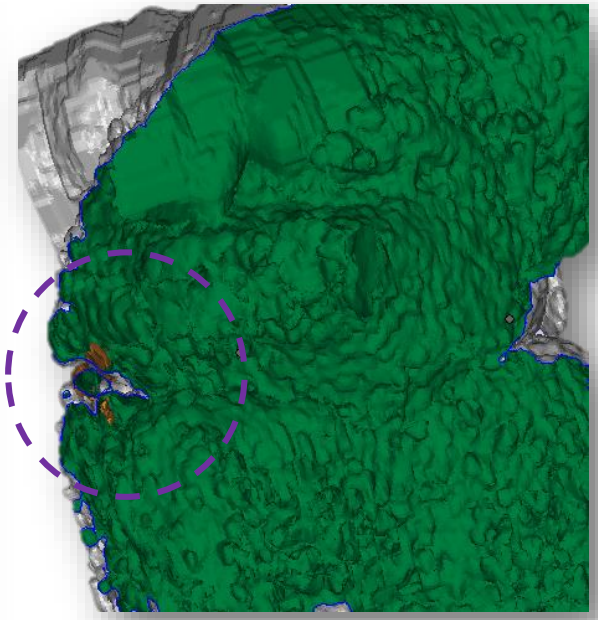
Anterior Posterior

TTVR Planning

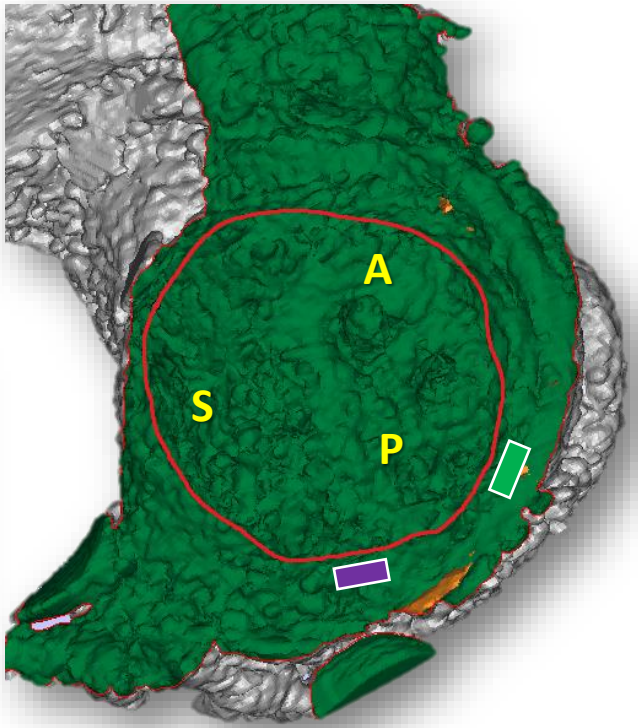
CT for Annulus Shelf Size and Pledget Location



Posterior Septal



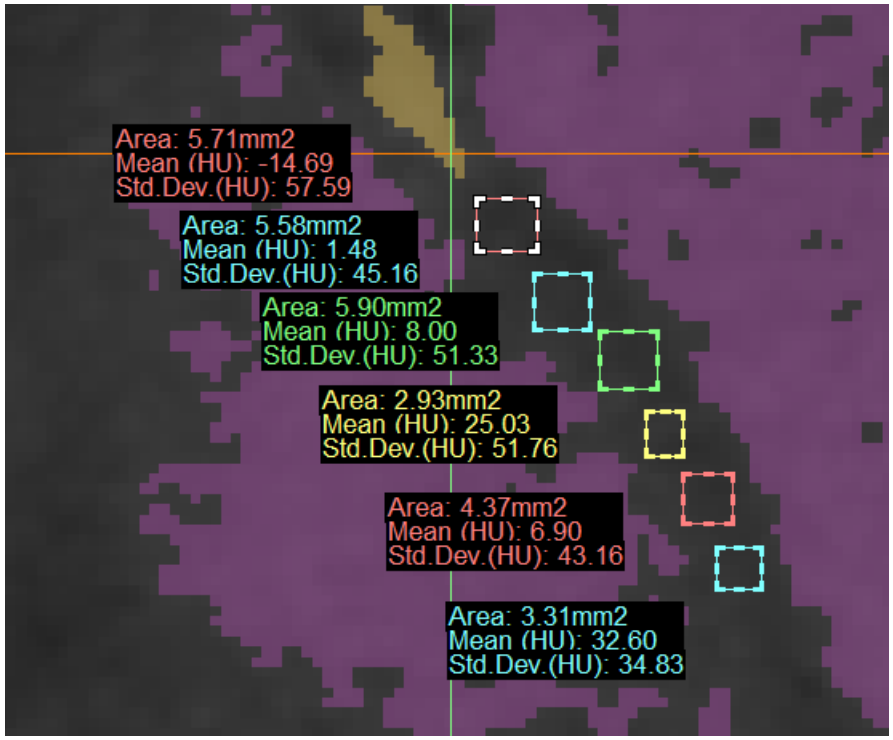
Anterior Posterior



TTVR Planning

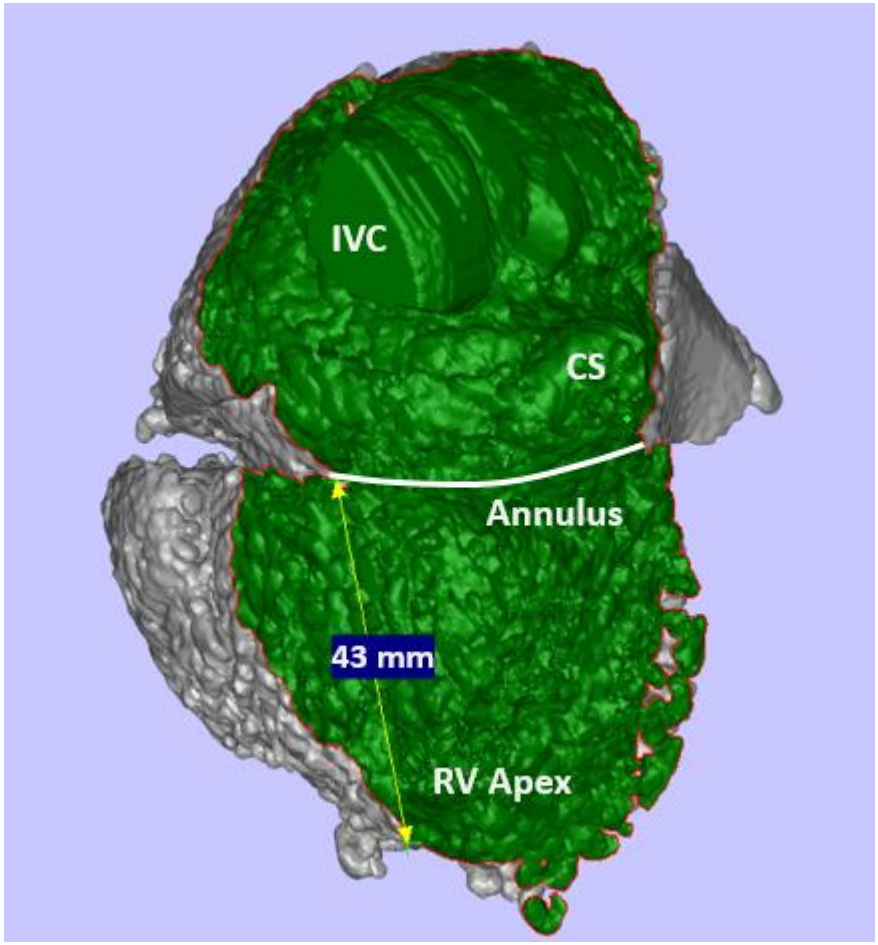
CT for Annulus Shelf Tissue “Quality/Density”

- Tissue density varies along posterior annulus
- Density decreases as you go more anterior



TTVR Planning

CT for Posterior Annulus to RV Apex Distance

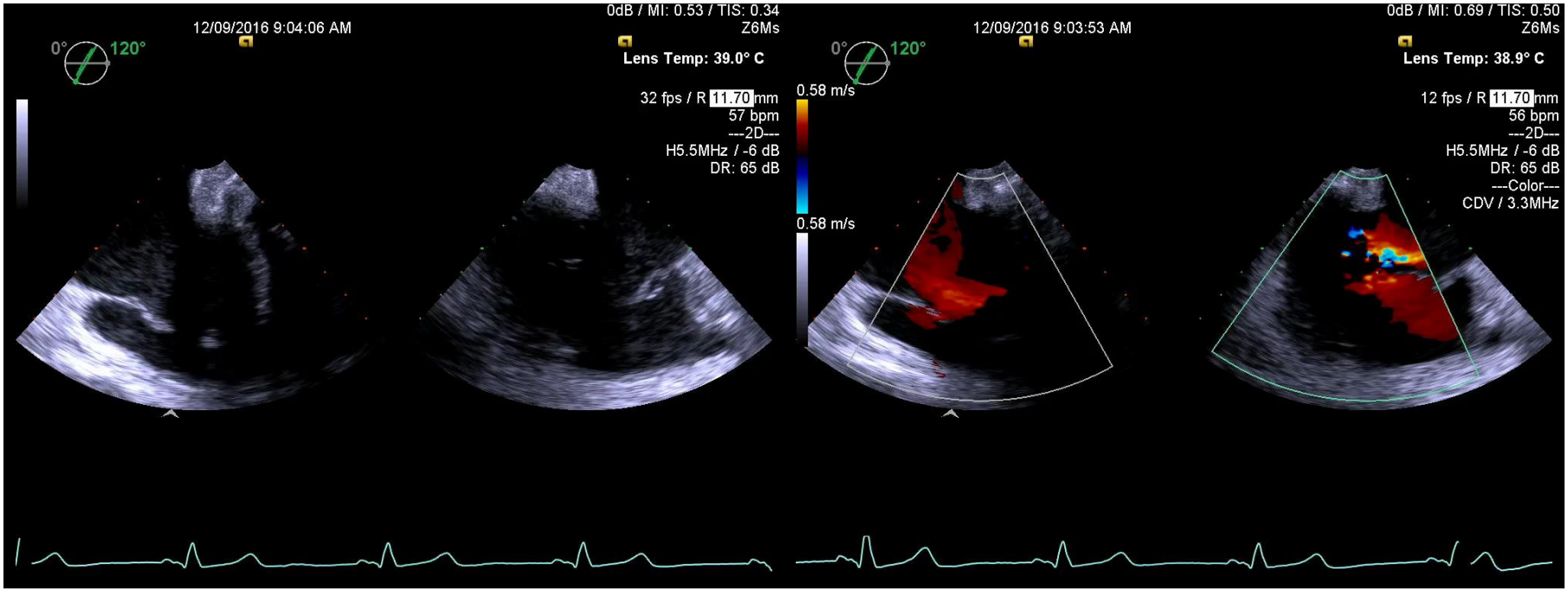


TTVR Planning

3-D Printing for Shelf Size and Pledget Location

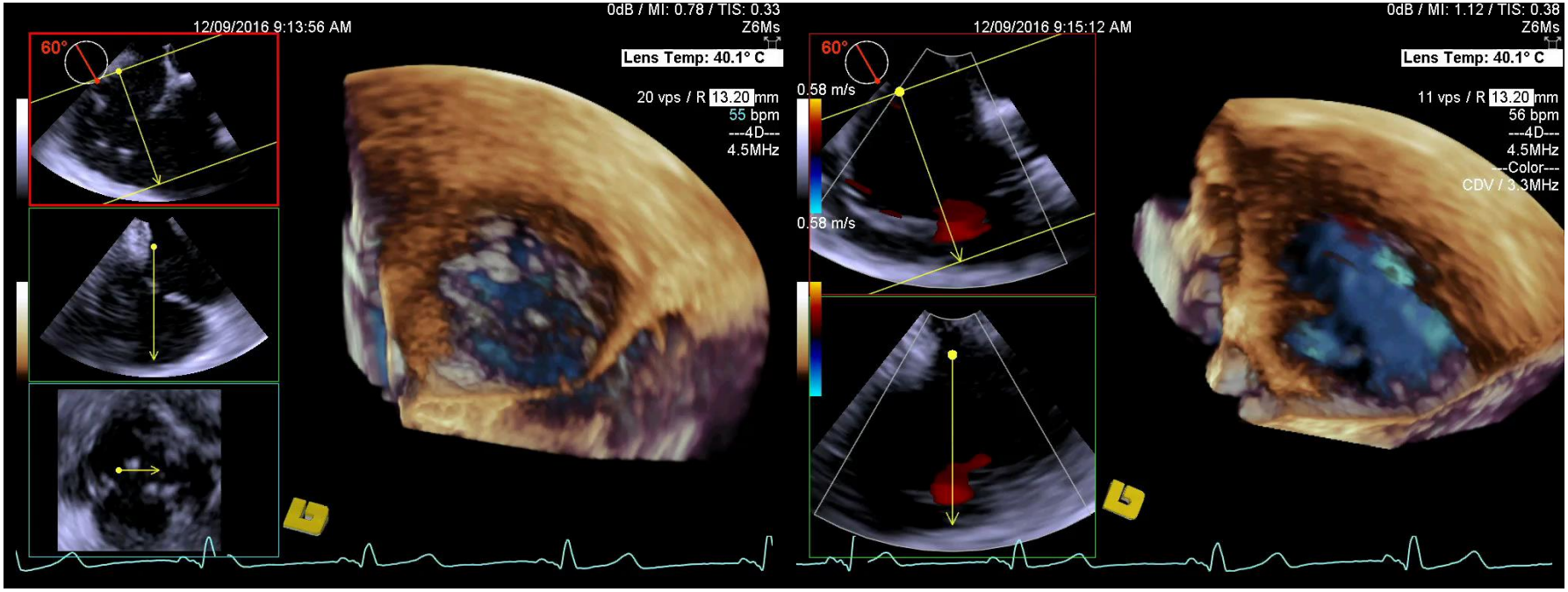
Pre-TTVR

2-D TEE



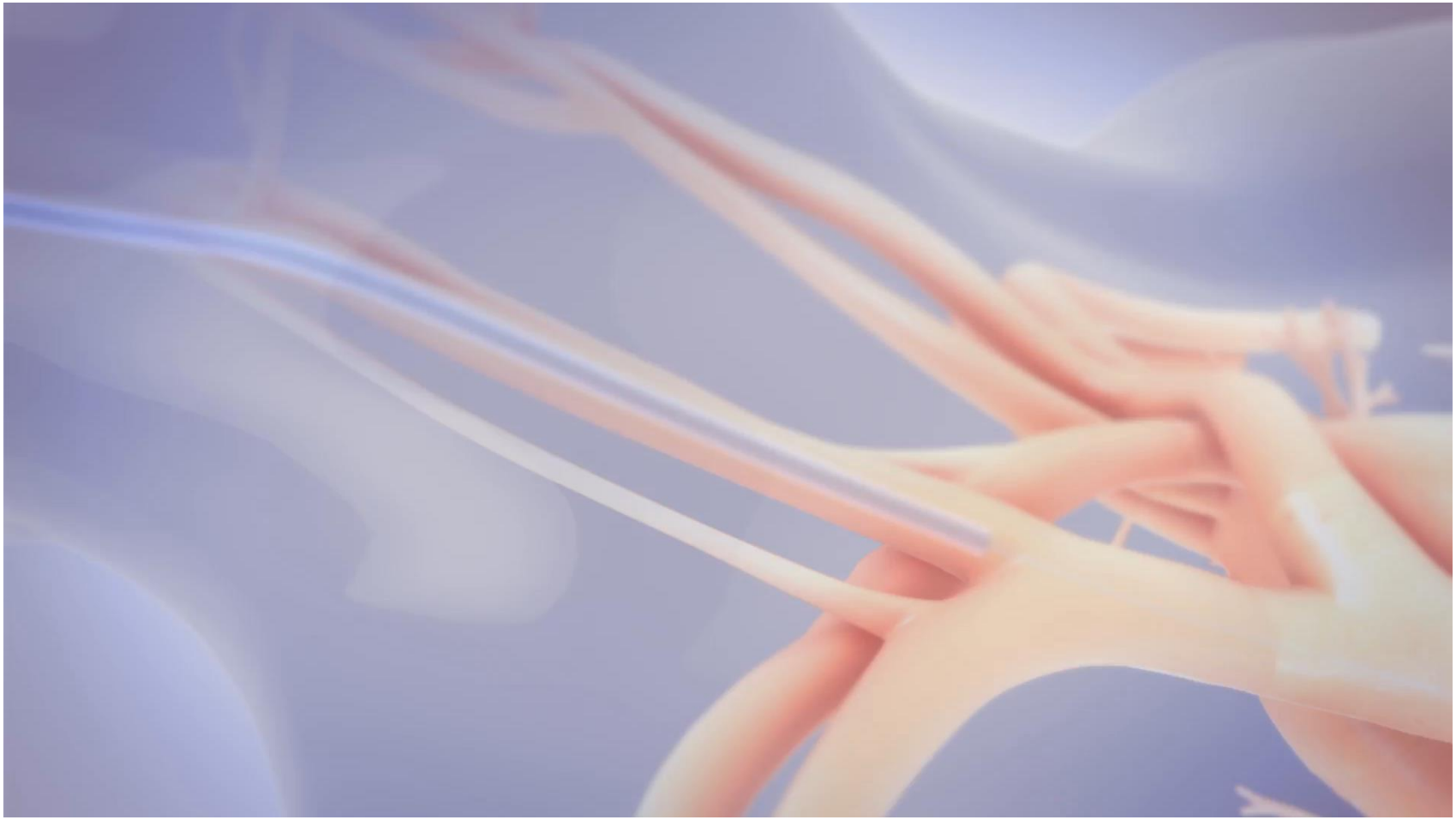
Pre-TTVR

3-D TEE



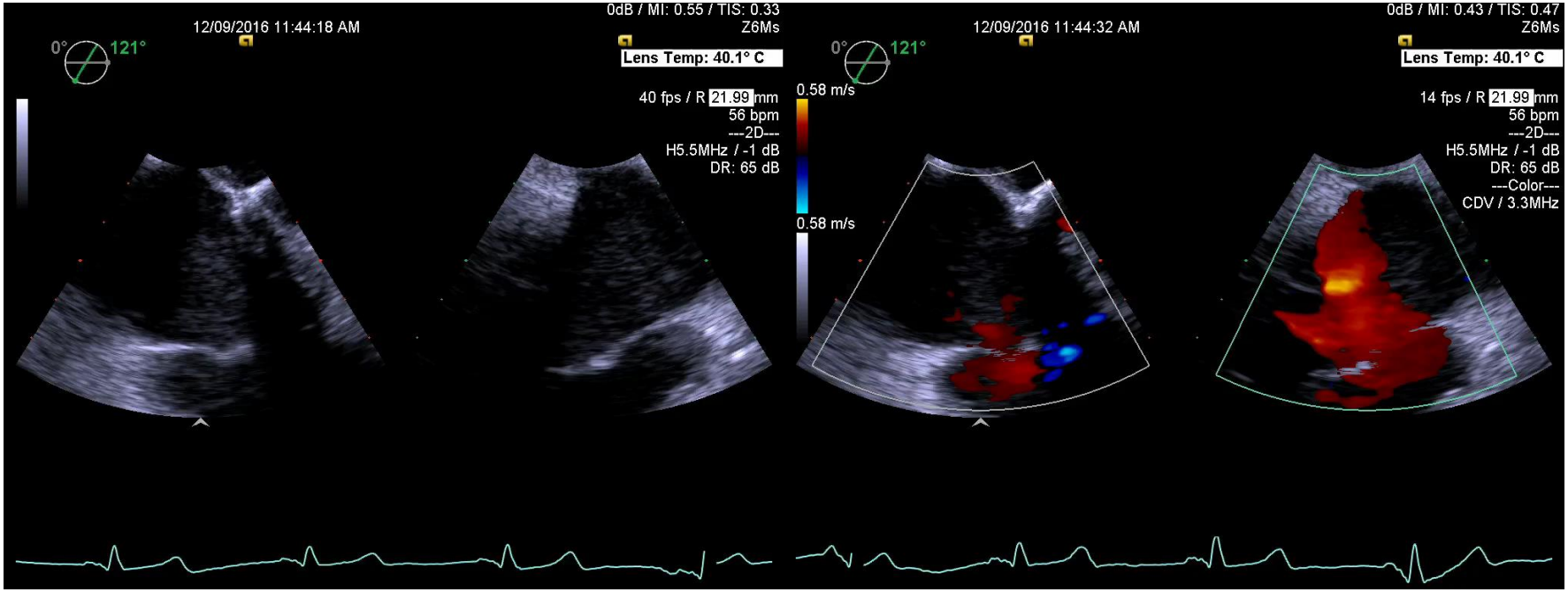
TTVR for Chronic Functional TR

SCOUT



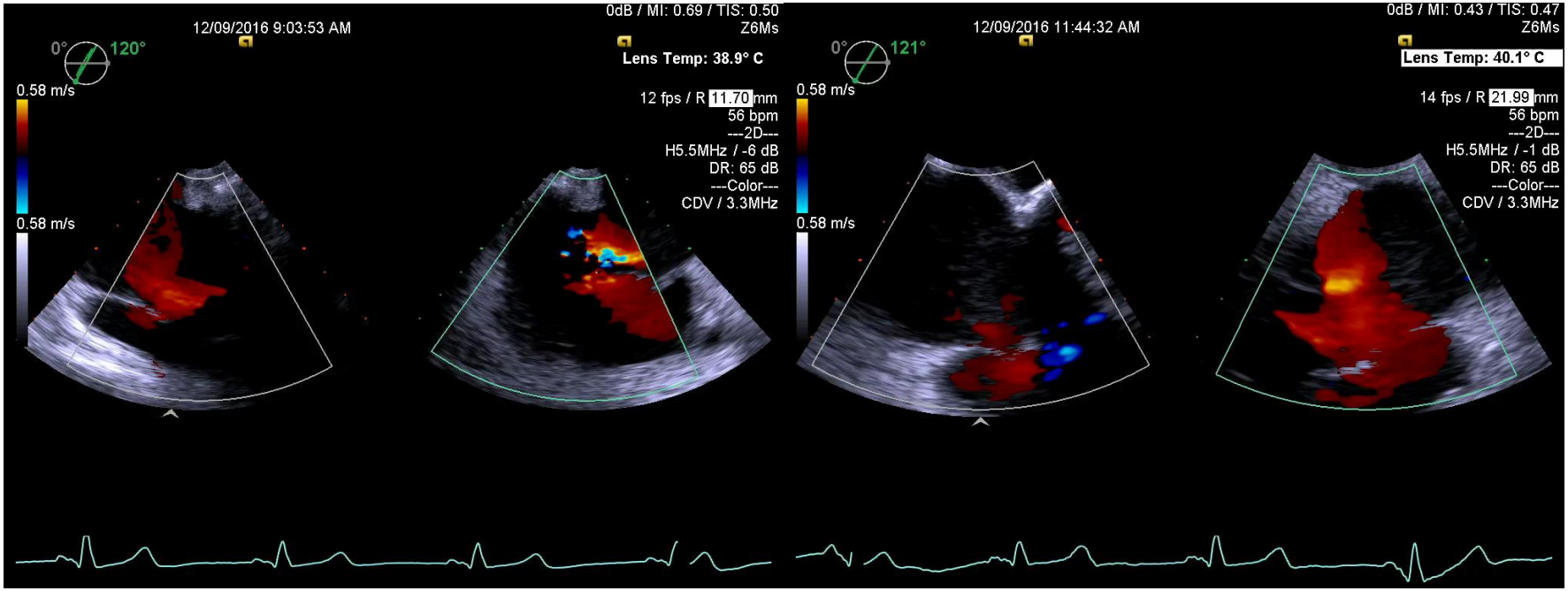
Post-TTVR

2-D TEE



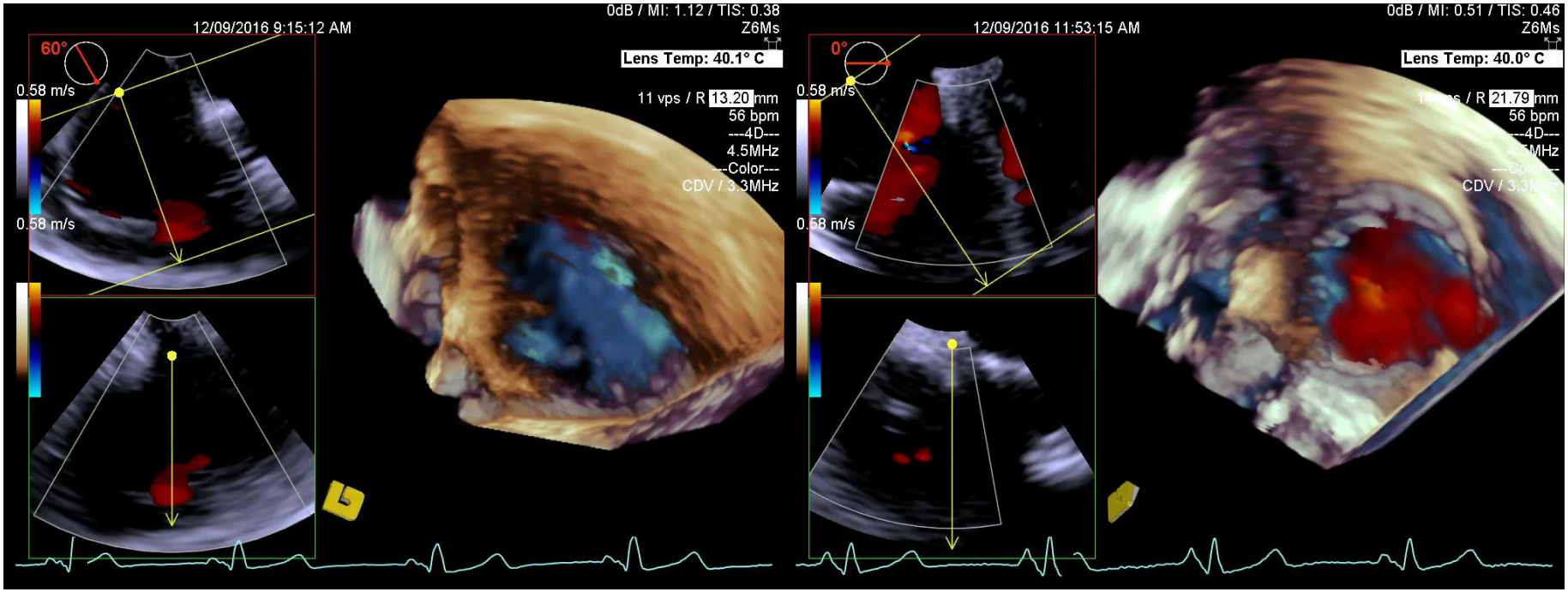
Pre/Post-TTVR

2-D TEE



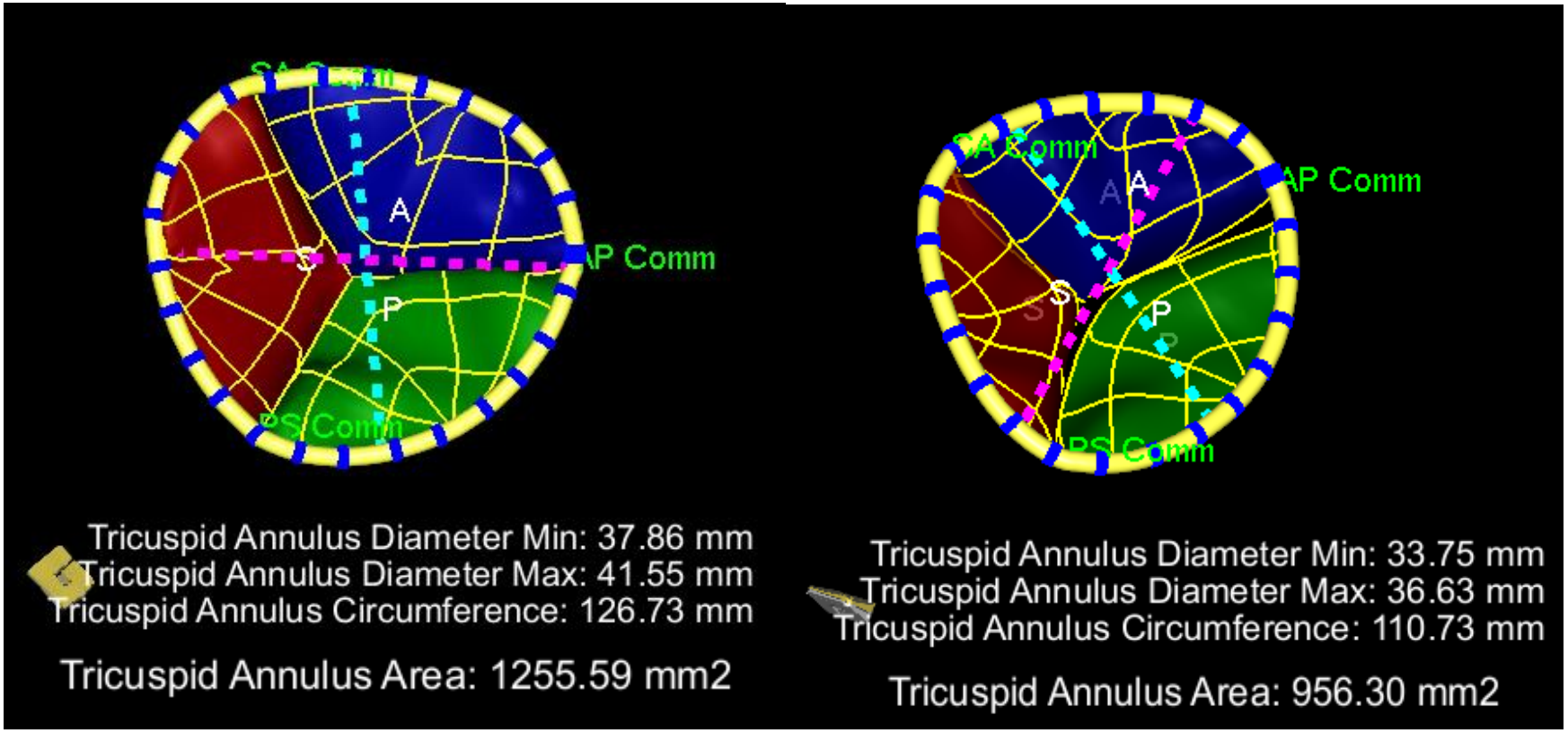
Pre/Post-TTVR

3-D TEE



Pre/Post- TTVR

3-D TEE for Automated TV Annulus Size



TTVR for Chronic Functional TR

SCOUT

Early Feasibility Study of a Transcatheter Tricuspid Valve Annuloplasty

SCOUT Trial 30-Day Results

Rebecca T. Hahn, MD,[a,b] Christopher U. Meduri, MD,[c] Charles J. Davidson, MD,[d] Scott Lim, MD,[e] Tamim M. Nazif, MD,[a] Mark J. Ricciardi, MD,[d] Vivek Rajagopal, MD,[d] Gorav Ailawadi, MD,[e] Mani A. Vannan, MBBS,[c] James D. Thomas, MD,[d] Dale Fowler, MD,[e] Stuart Rich, MD,[d] Randy Martin, MD,[c] Geraldine Ong, MD,[b] Adam Groothuis, PhD,[f] Susheel Kodali, MD[a]

ABSTRACT

BACKGROUND The SCOUT (Percutaneous Tricuspid Valve Annuloplasty System for Symptomatic Chronic Functional Tricuspid Regurgitation) trial is a prospective, single-arm, multicenter, early feasibility study of a novel transcatheter device to plicate the tricuspid annulus (TA) and reduce tricuspid regurgitation (TR).

OBJECTIVES This study tested the feasibility and safety of a novel transcatheter device and assessed its early performance and functional outcomes.

METHODS Between November 2015 and June 2016, 15 patients with New York Heart Association (NYHA) functional class ≥II and moderate or greater functional TR were enrolled. Primary performance and safety endpoint outcomes were technically successful at 30 days with no reintervention. Echocardiographic measurements (TA diameter, effective regurgitant orifice area [EROA], left ventricular stroke volume [LVSV]) and quality-of-life (QoL) measurements (NYHA functional class, Minnesota Living with Heart Failure Questionnaire [MLHFQ], and 6-min walk test [6MWT]) were performed at baseline and 30 days.

RESULTS All patients (mean 73.2 ± 6.9 years of age, 87% female) underwent successful device implantation with no deaths, strokes, bleeding, tamponade, or valve reintervention. Technical success rate at 30 days was 80%, with 3 single-pledget annular detachments without reintervention. In the remaining 12 patients, there were significant reductions in TA (12.3 ± 3.1 cm^2 to 11.3 ± 2.7 cm^2, respectively; $p = 0.019$) and EROA (0.51 ± 0.18 cm^2 vs. 0.32 ± 0.18 cm^2, respectively; $p = 0.020$), with significant increase in LVSV (63.6 ± 17.9 ml vs. 71.5 ± 25.7 ml, respectively; $p = 0.021$). In the intention-to-treat cohort, there were significant improvements in NYHA functional class (≥1 class, $p = 0.001$), MLHFQ (47.4 ± 17.6 to 20.9 ± 14.8; $p < 0.001$), and 6MWT (245.2 ± 110.1 to 298.0 m ± 107.6 m; $p = 0.008$).

CONCLUSIONS The 30-day results of the SCOUT trial confirmed the safety of the novel transcatheter device, which reduced TA and EROA, increased LVSV, and improved QoL. (Early Feasibility of the Mitralign Percutaneous Tricuspid Valve Annuloplasty System (PTVAS) Also Known as TriAlign [SCOUT]; NCT02574650.) (J Am Coll Cardiol 2017;69:1795-806) © 2017 by the American College of Cardiology Foundation.

TTVR for Chronic Functional TR

SCOUT

TABLE 5 Summary of TTE Findings in the As-Treated Study Group

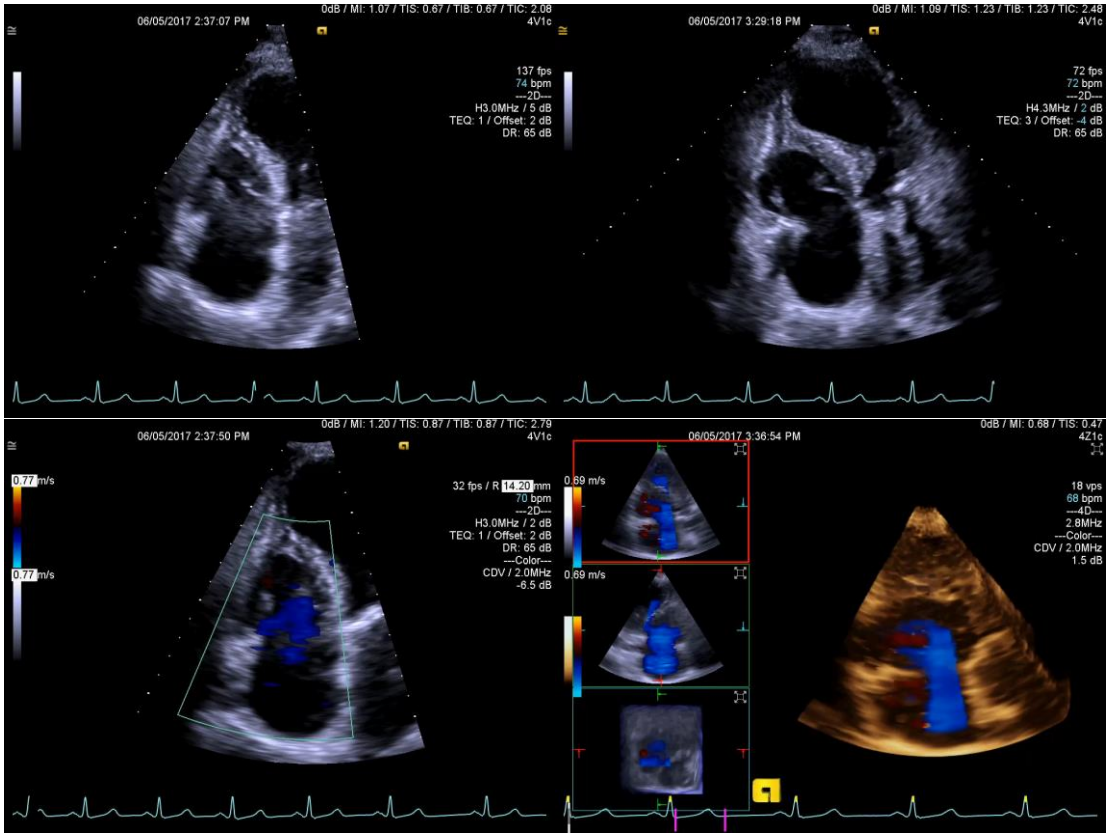
Echo Variable	Baseline	30-Day	Change*	p Value†
LVEF, %	59.8 ± 12.7 (12) 66.0 (39.2, 73.8)	59.1 ± 12.9 (11) 60.7 (37.6, 81.3)	−0.3 ± 7.3 (11) −1.6 (−12.7, 12.4)	0.904
RV TAPSE, cm	1.7 ± 0.4 (12) 1.7 (1.1, 2.1)	1.6 ± 0.2 (10) 1.6 (1.3, 1.9)	−0.1 ± 0.4 (10) 0.0 (−0.6, 0.3)	0.308
LVOT Doppler stroke volume, ml	63.6 ± 17.9 (11) 59.6 (38.5, 92.4)	71.5 ± 25.7 (11) 66.6 (40.9, 124.5)	11.7 ± 13.2 (10) 8.7 (−6.0, 32.1)	0.021
TR vena contracta mean, cm	1.3 ± 0.4 (11) 1.2 (0.8, 2.2)	1.0 ± 0.3 (12) 1.0 (0.6, 1.4)	−0.3 ± 0.3 (11) −0.3 (−0.9, 0.3)	0.022
PISA EROA, cm^2	0.51 ± 0.18 (12) 0.50 (0.30, 0.88)	0.32 ± 0.18 (12) 0.28 (0.13, 0.78)	−0.20 ± 0.25 (12) −0.24 (−0.49, 0.42)	0.020
PASP estimated, mm Hg	44.1 ± 10.2 (12) 46.0 (25.6, 56.4)	42.0 ± 9.5 (12) 39.9 (29.2, 57.5)	−2.1 ± 6.6 (12) −0.5 (−20.2, 5.9)	0.327
TV annular diameter, cm	4.0 ± 0.5 (12) 4.0 (3.1, 5.0)	3.8 ± 0.6 (12) 3.9 (2.9, 4.8)	−0.2 ± 0.4 (12) −0.3 (−0.6, 1.1)	0.038
Tethering distance, cm	0.7 ± 0.1 (12) 0.7 (0.3, 0.8)	0.6 ± 0.1 (12) 0.6 (0.4, 0.7)	−0.1 ± 0.2 (12) −0.1 (−0.4, 0.4)	0.116
TV annulus area (2D), cm^2	12.3 ± 3.1 (12) 11.6 (8.5, 17.4)	11.3 ± 2.7 (12) 10.0 (8.1, 15.2)	−1.0 ± 1.3 (12) −0.9 (−2.7, 1.5)	0.019
TR regurgitant volume, ml	79.6 ± 17.5 (11) 88.0 (52.0, 97.9)	57.1 ± 29.0 (11) 51.1 (31.0, 136.3)	−18.1 ± 27.2 (10) −27.6 (−49.0, 44.2)	0.065
Quantitative Doppler TR EROA, cm^2	0.85 ± 0.22 (12) 0.87 (0.42, 1.14)	0.63 ± 0.29 (11) 0.62 (0.32, 1.37)	−0.22 ± 0.29 (11) −0.28 (−0.59, 0.53)	0.045

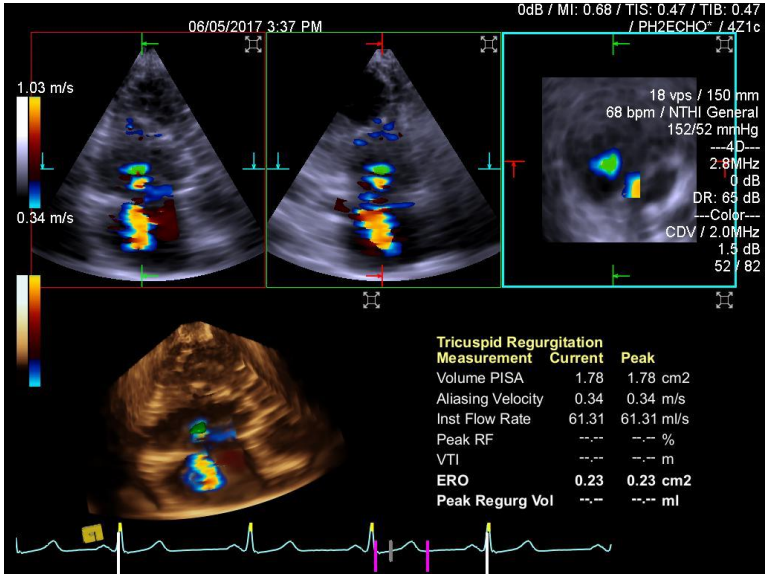
Values are mean ± SD (N) and median (minimum, maximum). *Change from baseline to 30 days computed on paired data. †p value by paired Student *t*-test or Wilcoxon signed-rank test when normality assumptions are violated.

TTE = transthoracic echocardiography; other abbreviations as in Table 4.

Post-TTVR (~7 months)

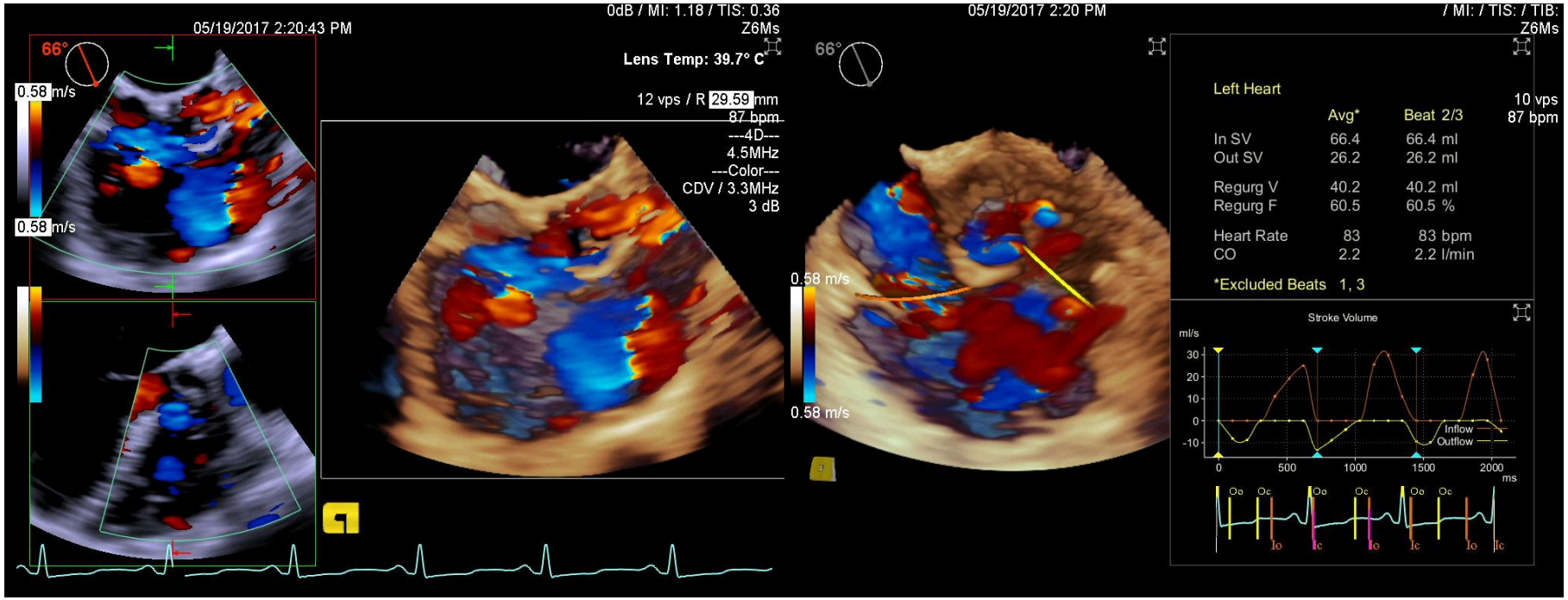
TTE





Quantification of TR

Automated 3-D TR Regurgitant Volume




thank
you!