CASE PRESENTATION: SEVERE FUNCTIONAL MITRAL REGURGITATION

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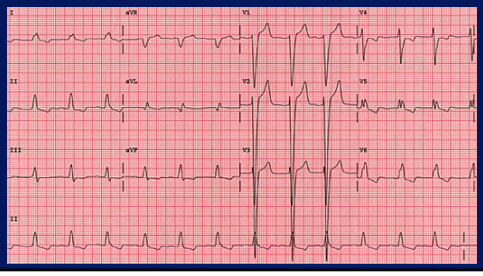
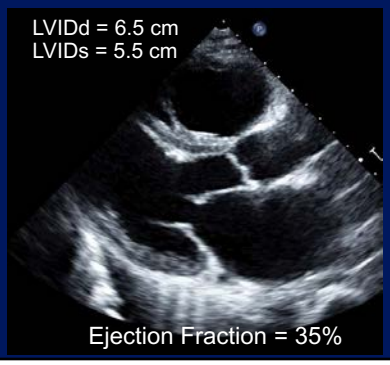
Case Presentation

56 year old with known CAD and S/P MI complicated by VSD, S/P CABG and VSD patch closure, presents with progressive shortness of breath

- On examination:
  - BP = 92/55 mmHg, pulse = 60 bpm
  - Lungs: decreased breath sounds at the bases with bronchial breath sounds in mid lung field
  - Cardiac: normal S1 with prominent S2. 3/6 high pitched "seagull" type early systolic murmur, loudest over the apex but radiating throughout the chest
  - Extremities: 2+ pitting edema at ankles bilaterally
- Medications:
  - Coreg, Lasix, Aldactone, Lisinopril, Lipitor

LBBB
QRS = 148 msec

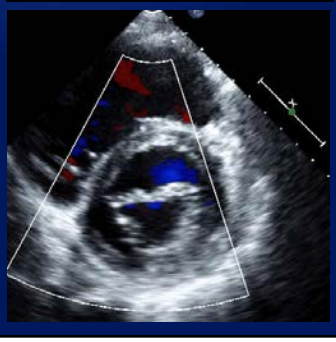




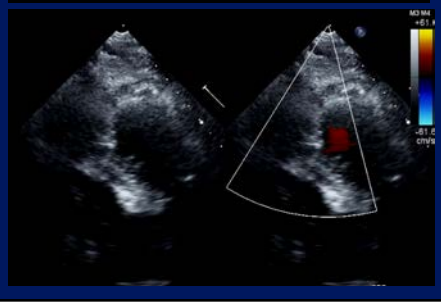
LV Volume
~215 cc

2

Transthoracic Echocardiogram



VSD Patch



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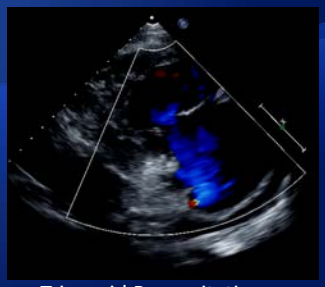
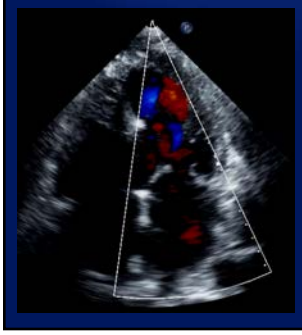
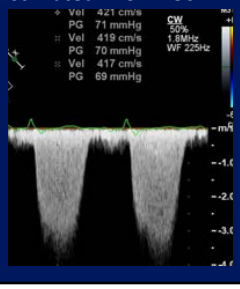
MR Assessment

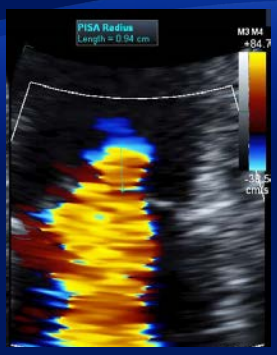
LVOT stroke volume = 56 cc





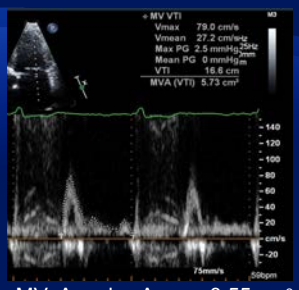
Tricuspid Regurgitation:
Estimated PASP = 80 mmHg



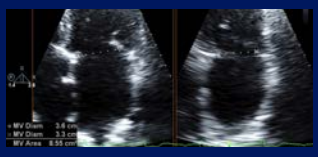


PISA:
1. EROA = 0.42 cm^2
2. Regurgitant volume = 73 cc

MV VTI = 16.6 cm

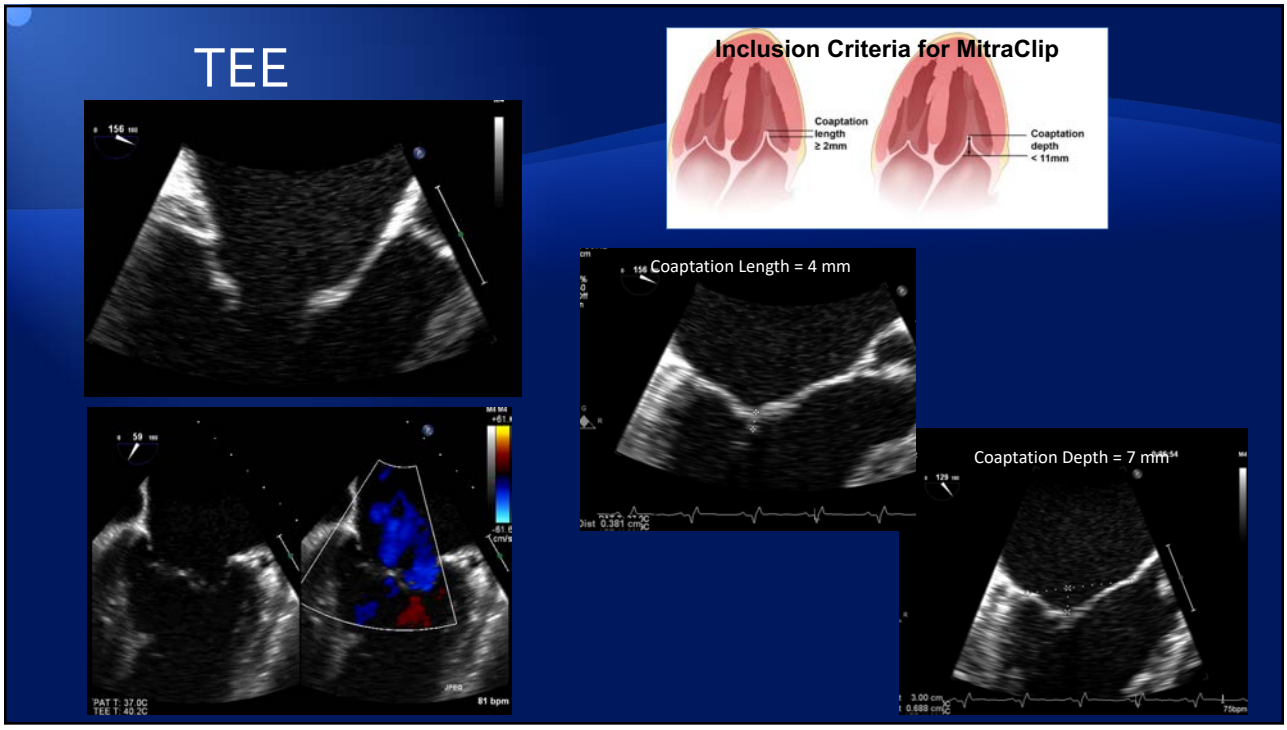


MV Annulus Area = 8.55 cm^2



Quantitative Doppler
1. Regurgitant Volume = 85 cc
2. EROA = 0.49 cm^2
3. Regurgitant Fraction = 60%

4


TEE
Inclusion Criteria for MitraClip
Coaptation length ≥ 2mm
Coaptation depth < 11mm
Coaptation Length = 4 mm
Coaptation Depth = 7 mm

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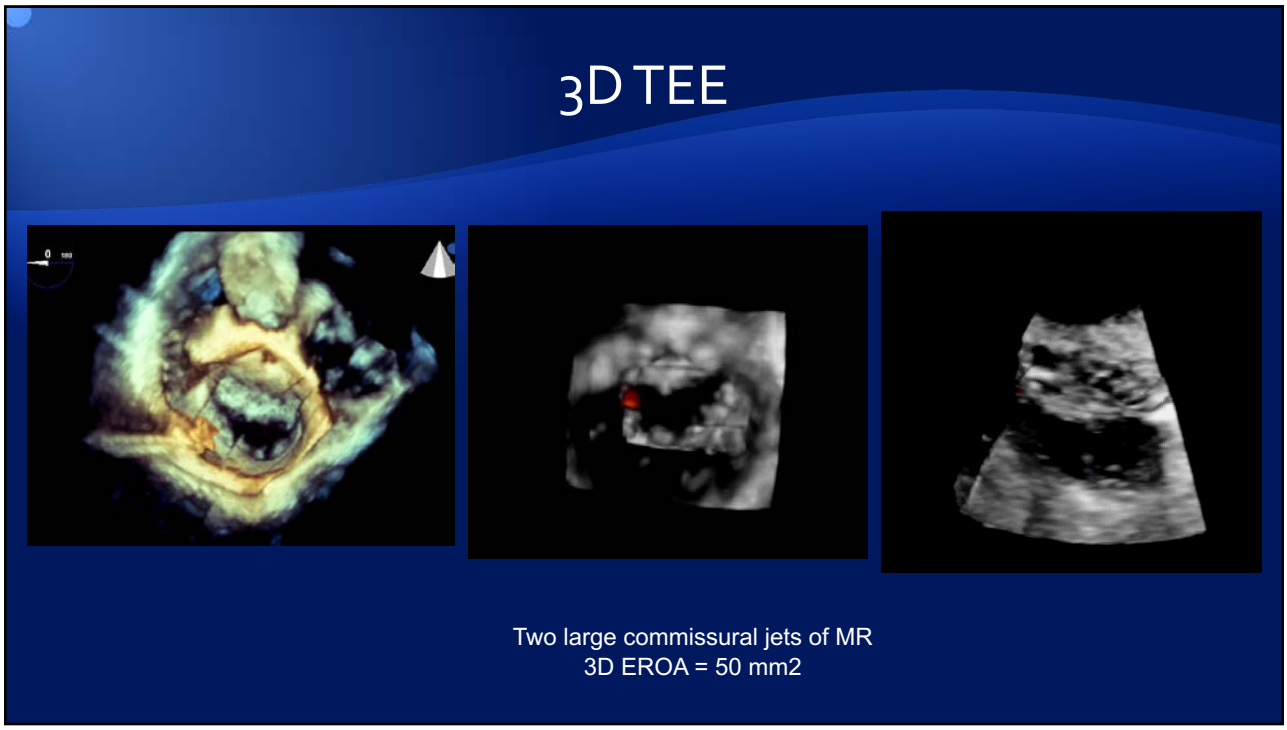
3D TEE
Two large commissural jets of MR
3D EROA = 50 mm2

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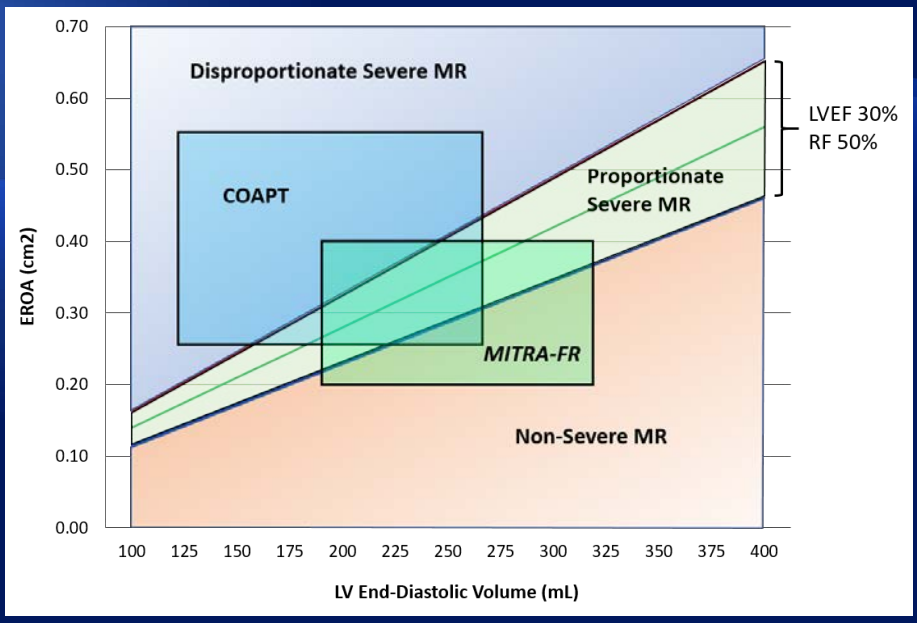

Courtesy of Paul Grayburn

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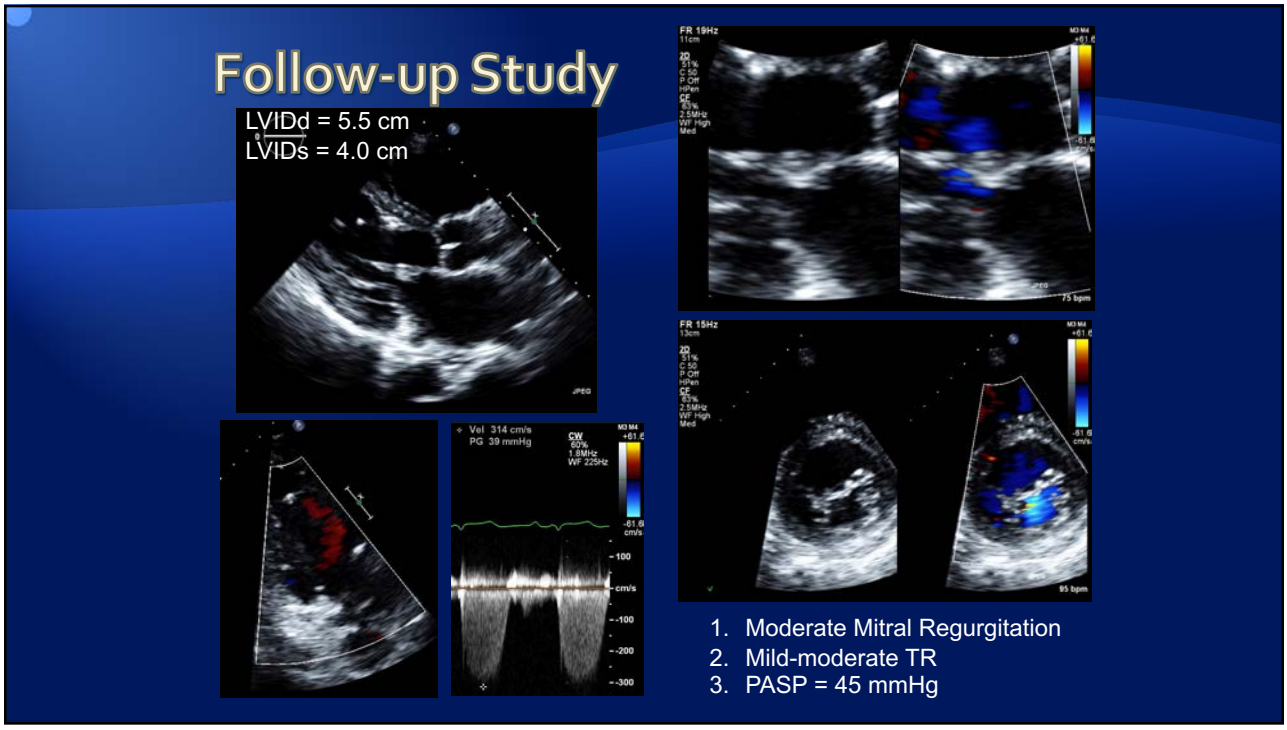
What would you do next?

1. Increase medical therapy
2. Biventricular pacemaker
3. Proceed with Mitral Clip

8


Follow-up Study
LVIDd = 5.5 cm
LVIDs = 4.0 cm
Vel 314 cm/s
PG 39 mmHg
1. Moderate Mitral Regurgitation
2. Mild-moderate TR
3. PASP = 45 mmHg

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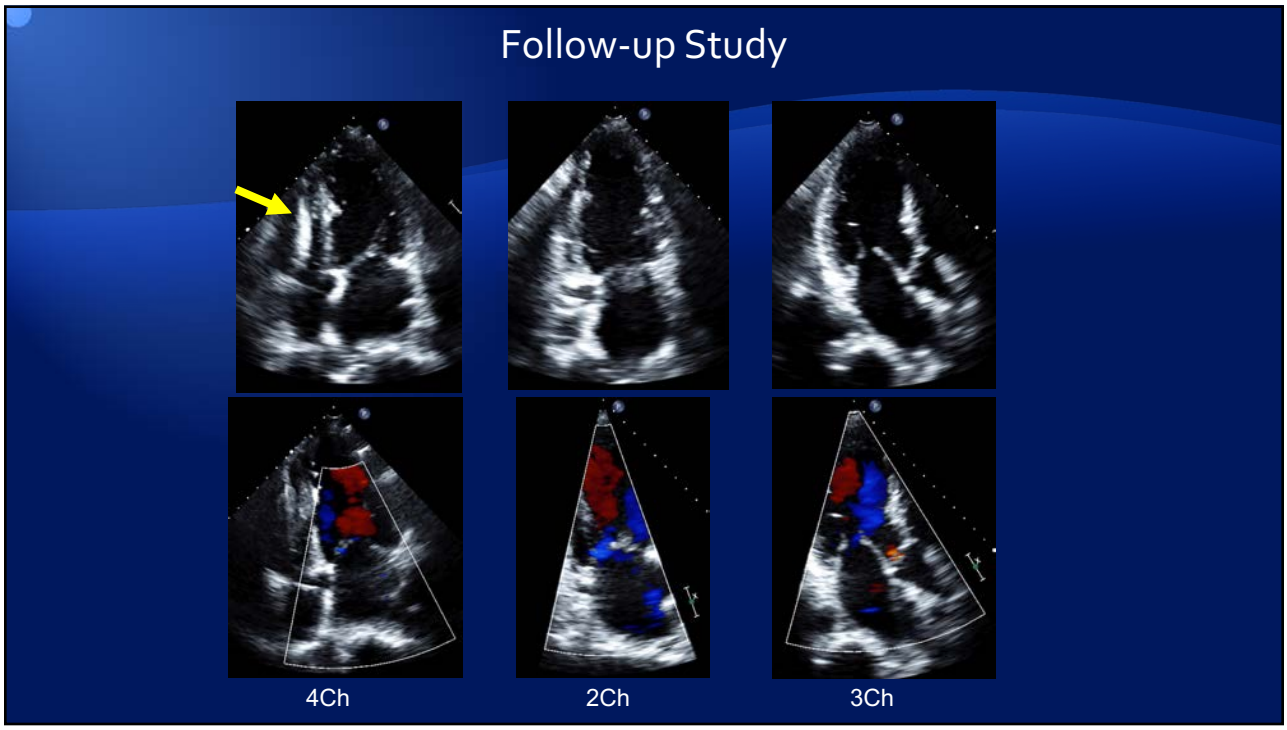
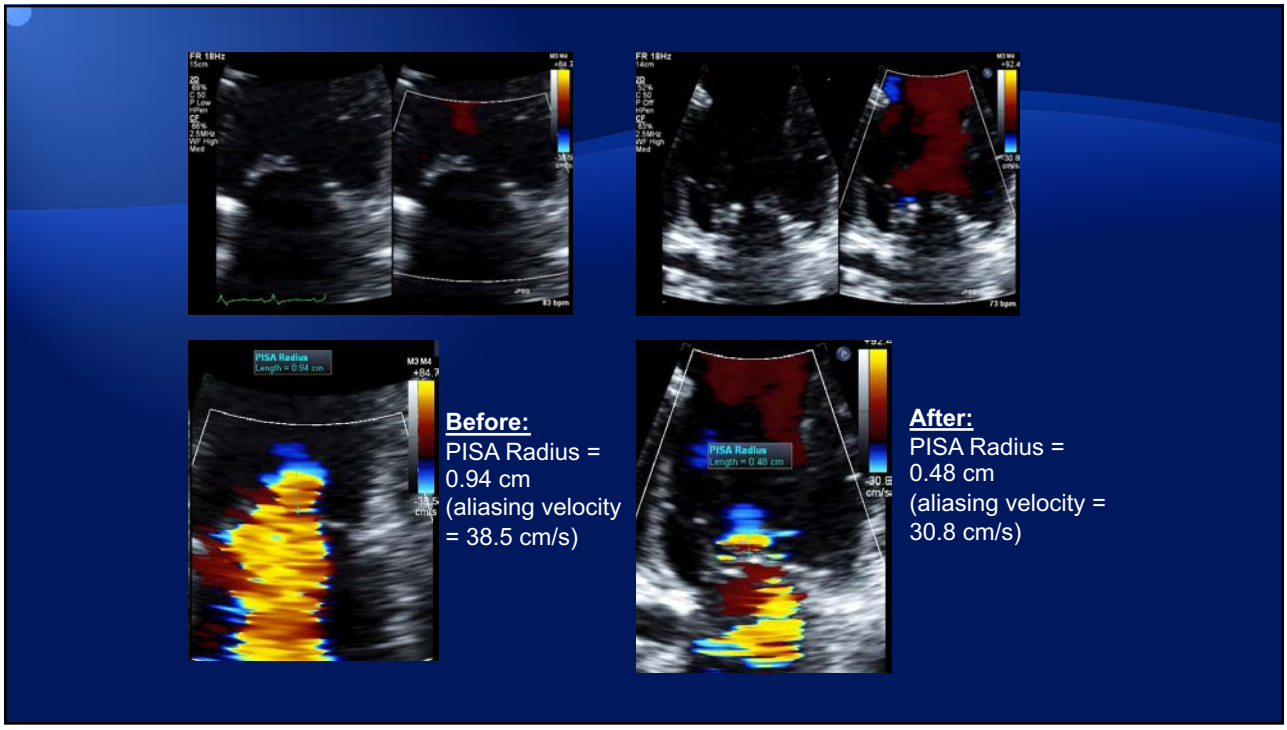

Follow-up Study
4Ch
2Ch
3Ch

10



Before:
PISA Radius = 0.94 cm
(aliasing velocity = 38.5 cm/s)

After:
PISA Radius = 0.48 cm
(aliasing velocity = 30.8 cm/s)

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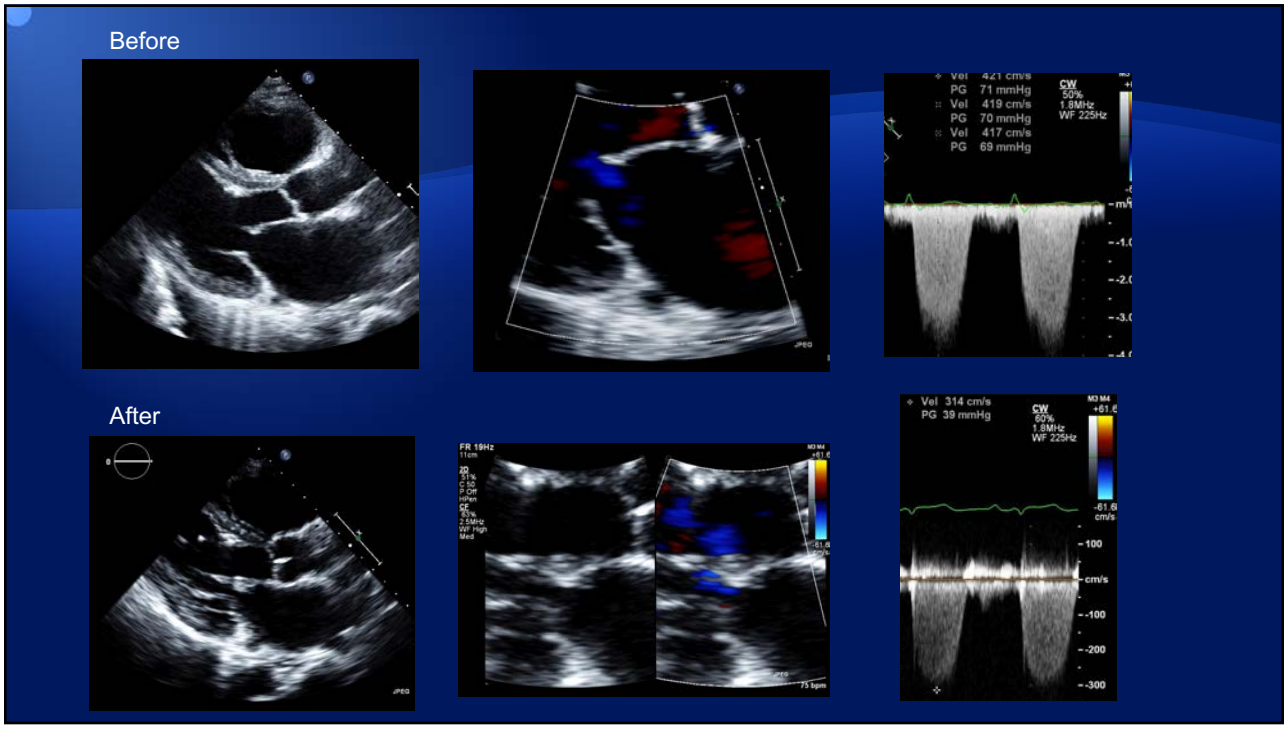

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JACC: HEART FAILURE VOL. 6, NO. 4, 2018
APRIL 2018:308–16

Indications for Cardiac Resynchronization Therapy

A Comparison of the Major International Guidelines

Camilla Normand, BM BCh,[a,b] Cecilia Linde, MD, PhD,[c] Jagmeet Singh, MD, PhD,[d] Kenneth Dickstein, MD, PhD[a,b]

TABLE 1 Recent International Guidelines on CRT Implantation Recommendations and Indications

Society	Guideline (Ref. #)	Year
ESC Heart Failure Association	Guidelines for the diagnosis and treatment of acute and chronic HF (15)	2016
ESC European Heart Rhythm Association	Guidelines on cardiac pacing and CRT (14)	2013
American College of Cardiology Foundation/ American Heart Association	Guidelines for the management of HF (37)	2013
Canadian Cardiovascular Society	Comprehensive update of the Canadian Cardiovascular Society Guidelines for the Management of HF (16)	2017
National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand	Update to guidelines for the prevention, detection and management of chronic HF in Australia, 2006 (20)	2011
National Institute of Health and Care Excellence	ICD and CRT for arrhythmia and HF (38)	2014

CRT = cardiac resynchronization therapy; ESC = European Society of Cardiology; HF = heart failure; ICD = implantable cardioverter-defibrillator.

Normand C et al. J Am Coll Cardiol HF 2018;6:308–16

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Normand C et al. J Am Coll Cardiol HF 2018;6:308–16

TABLE 2 Comparison of Recommendations for LBBB

Guideline (Year)	QRS ≥150 ms		QRS 130-149 ms		QRS 120-129 ms	
	NYHA Functional Class III/IV	NYHA Functional Class II	NYHA Functional Class III/IV	NYHA Functional Class II	NYHA Functional Class III/IV	NYHA Functional Class II
ESC HFA (2016)*	I, A	I, A	I, B	I, B	III, A	III, A
ESC EHRA (2013)	I, A	I, A	I, B	I, B	I, B	I, B
ACC/AHA/HRS (2013)	I, A	I, B	IIa, B	IIa, B	IIa, B	IIa, B
CCS (2017)	I, High	I, High	I, High	I, High	III, Moderate	III, Moderate
Australian Guidelines (2011)	A		A		A	
NICE (2014)	CRT-P or CRT-D†	CRT-D	CRT-P or CRT-D†	CRT-D	CRT-P or CRT-D†	CRT-D

Values are Class of Recommendation, Level of Evidence, unless otherwise indicated. Australian guidelines provide only grade of recommendation (A), not evidence level for these recommendations. NICE guidelines provide guidance on type of device rather than recommendation or evidence level. *The ESC HFA guidelines do not specify NYHA functional class, rather they state that the guidelines refer to symptomatic patients with heart failure. †Not for NYHA functional class IV.

ACC/AHA/HRS = American College of Cardiology/American Heart Association/Heart Rhythm Society; CCS = Canadian Cardiology Society; CRT-D = cardiac resynchronization therapy-defibrillator; CRT-P = cardiac resynchronization therapy-pacemaker; ESC EHRA = European Society of Cardiology European Heart Rhythm Association; ESC HFA = European Society of Cardiology European Heart Rhythm Association; LBBB = left bundle branch block.

TABLE 3 Comparison of Recommendations for Non-LBBB

Guidelines (Year)	QRS ≥150 ms		QRS 130-149 ms		QRS 120-129 ms	
	NYHA Functional Class III/IV	NYHA Functional Class II	NYHA Functional Class III/IV	NYHA Functional Class II	NYHA Functional Class III/IV	NYHA Functional Class II
ESC HFA (2016)*	IIa, B	IIa, B	IIb, B	IIb, B	III, A	III, A
ESC EHRA (2013)	IIa, B	IIa, B	IIb, B	IIb, B	IIb, B	IIb, B
ACC/AHA/HRS (2013)	IIa, A	IIb, B	IIb, B	III, B	IIb, B	III, B
CCS (2017)	IIb, Low	IIb, Low			III, Moderate	III, Moderate
Australian Guidelines (2011)	A		A		A	
NICE (2014)	CRT-P or CRT-D†	CRT-D	CRT-P‡		CRT-P‡	

Values are Class of Recommendation, Level of Evidence, unless otherwise indicated. Australian guidelines provide only grade of recommendation (A), not evidence level for these recommendations. NICE guidelines provide guidance on type of device rather than recommendation or evidence level. *The ESC HFA guidelines do not specify NYHA class, rather they state that the guidelines refer to symptomatic patients with heart failure. †Not for NYHA functional class IV. ‡Only for NYHA functional class IV.

Abbreviations as in Table 1 and 2.

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TRICUSPID REGURGITATION CASE

Rebecca T. Hahn
Susheel Kodali
Vinnie Bapat
Isaac George
Columbia University

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Mrs VG

- 92 year-old female
- History of presenting illness
  - Worsening fatigue and exertional dyspnea in the 18 months prior to index admission
  - No episodes of acute decompensated right-sided heart failure

1

Past Medical History

- Hypertension, hyperlipidemia
- Type II diabetes mellitus (on oral hypoglycemics)
- Hypothyroidism
- Persistent atrial fibrillation
  - on Apixaban
- CABG 1992 (SVG-LAD, SVG-OM)
  - Unstable angina with BMS to SVG of OM on 7/6/2017
  - 30 days of dual antiplatelet therapy
- Chronic kidney disease (baseline creatinine 1.6mg/dL)
- Severe TR, mild MR and moderate AS

Physical Exam

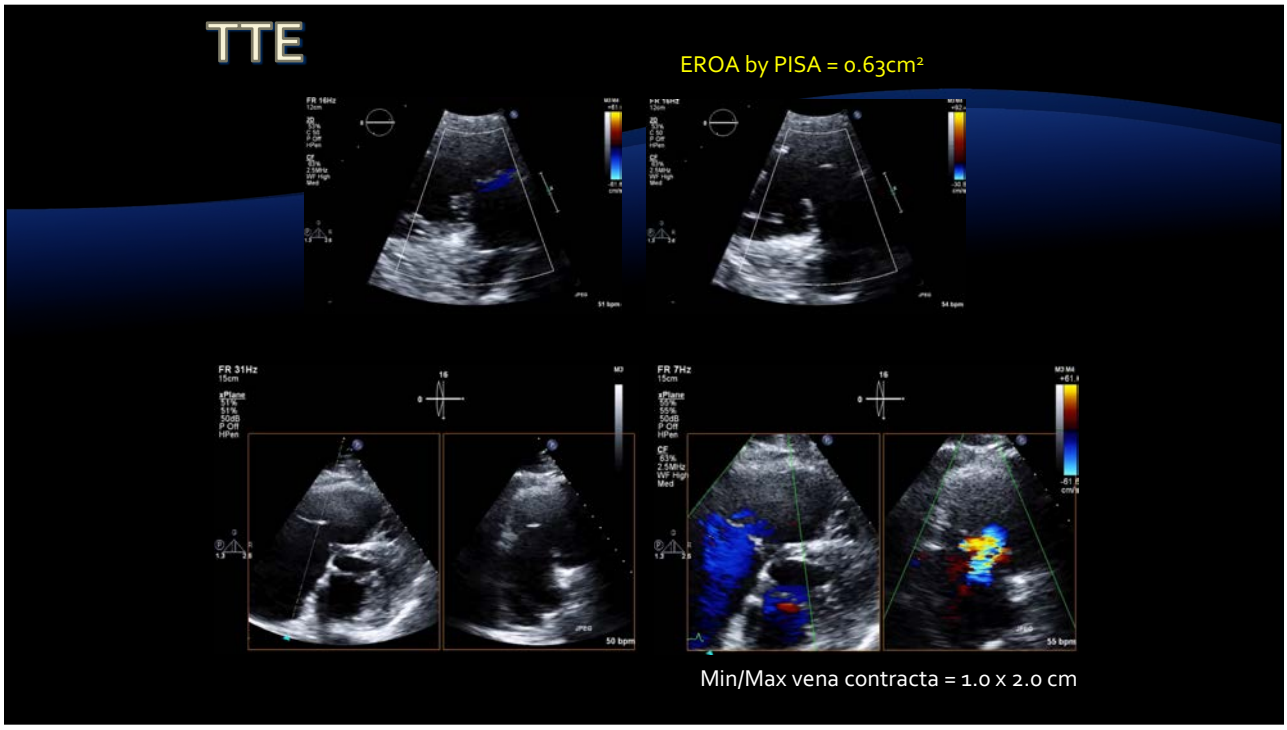
- Marked JVD
- Hepatomegly
- Peripheral edema

2

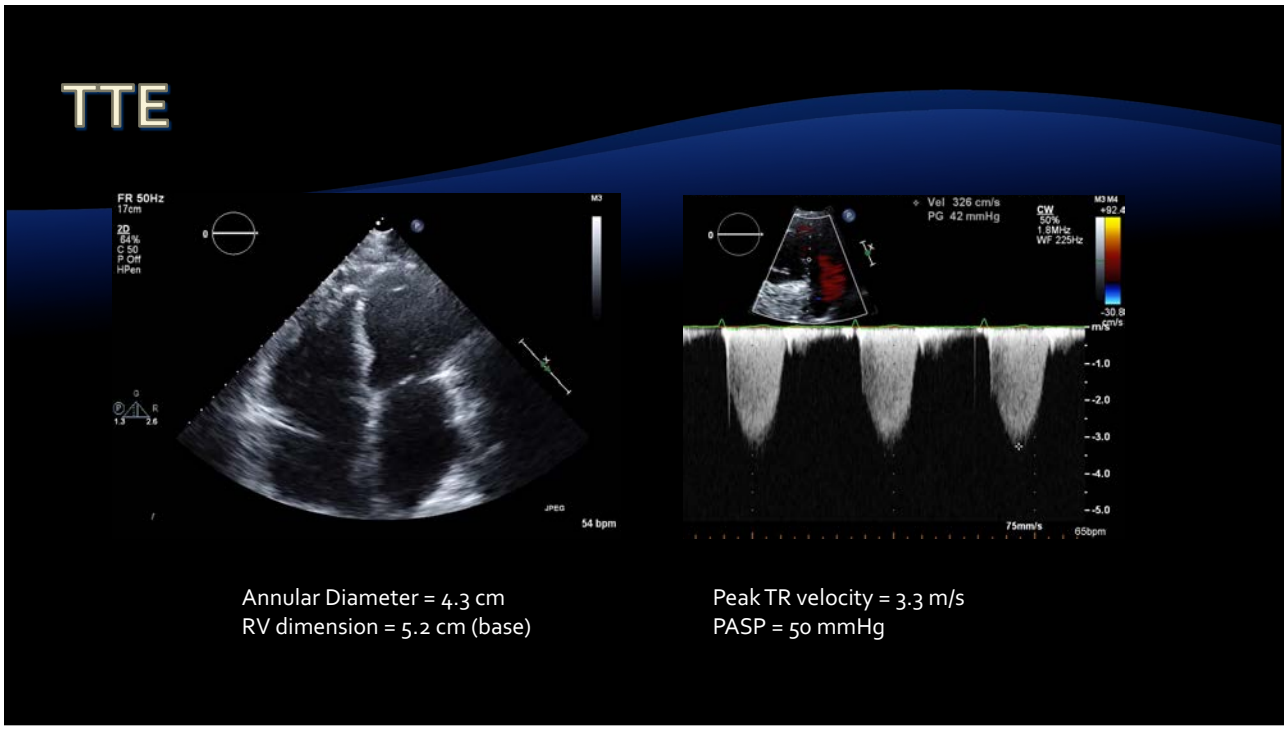
Transthoracic echocardiography NYPH/CUMC 10/11/2017

- Normal left ventricular size and systolic function
- Moderately increased right ventricular size with preserved systolic function
- Severe tricuspid incompetence
- Moderate aortic stenosis (AVA 1.4 cm^2)

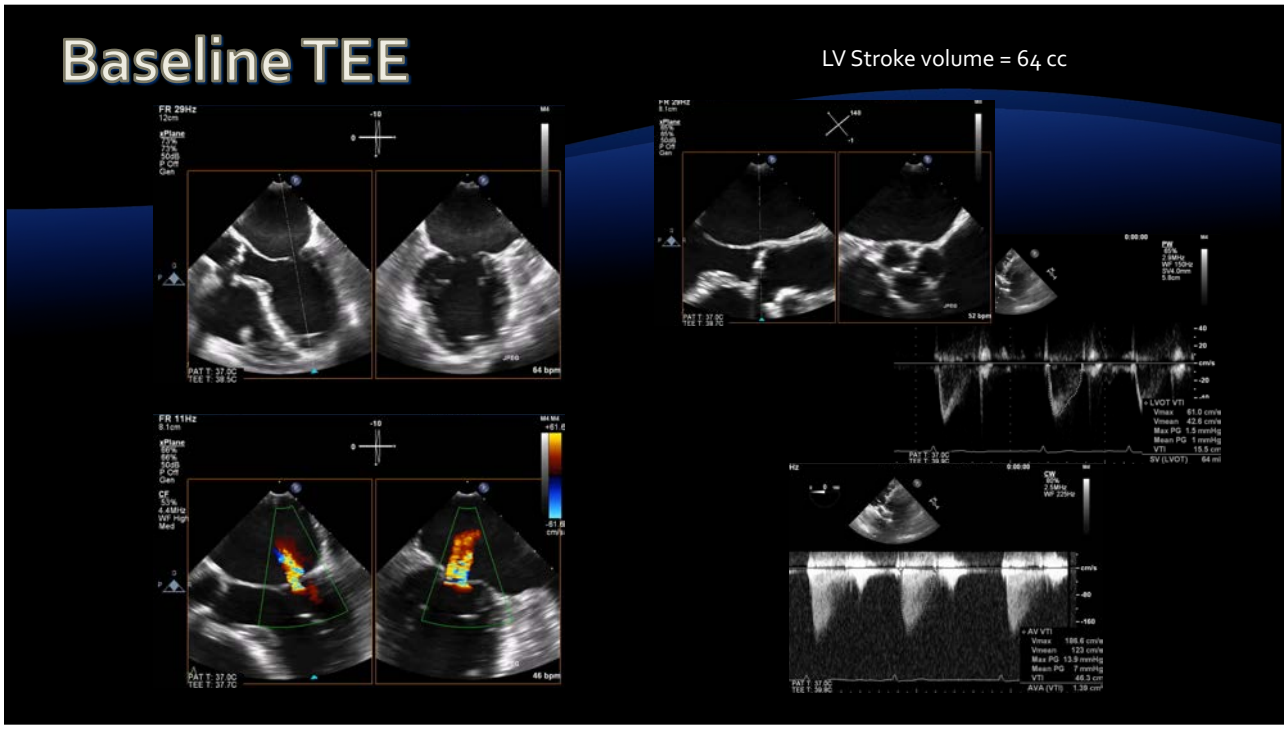
3


TTE
EROA by PISA = 0.63cm²
Min/Max vena contracta = 1.0 x 2.0 cm

4


TTE
Annular Diameter = 4.3 cm
RV dimension = 5.2 cm (base)
Peak TR velocity = 3.3 m/s
PASP = 50 mmHg

5


Baseline TEE
LV Stroke volume = 64 cc

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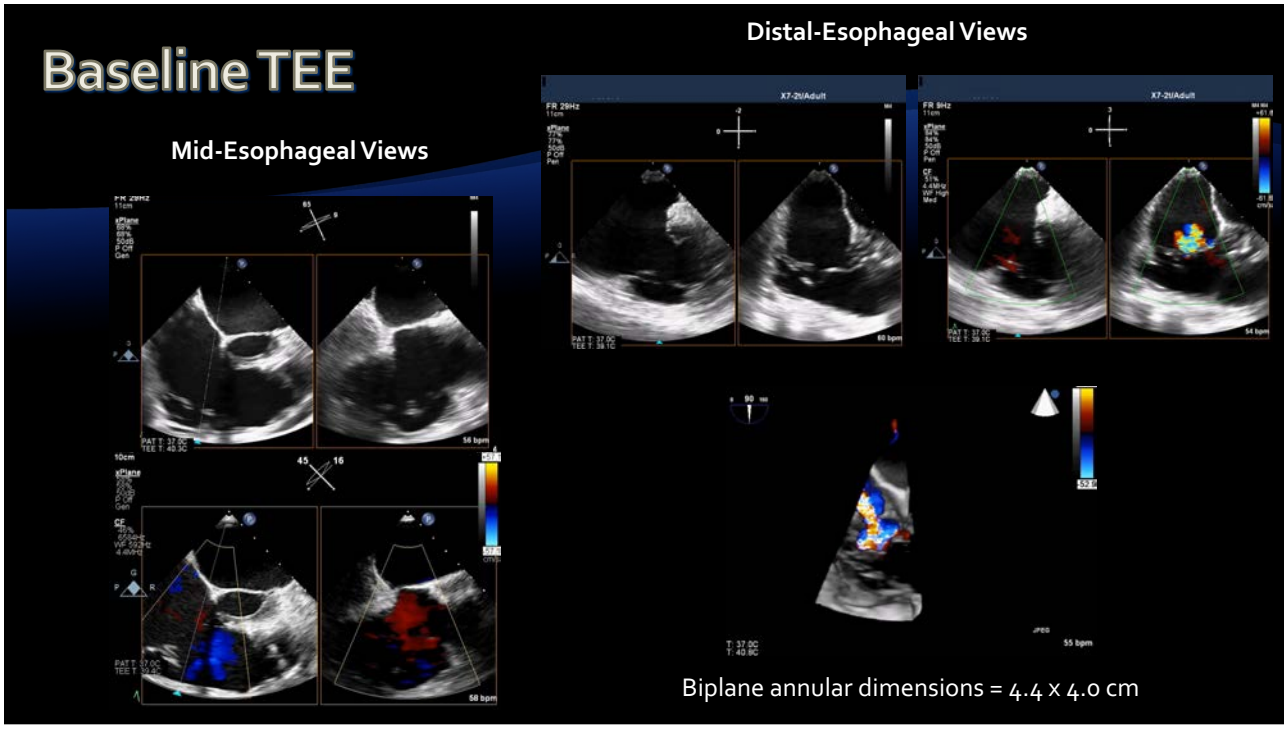
Baseline TEE
Distal-Esophageal Views
Mid-Esophageal Views
Biplane annular dimensions = 4.4 x 4.0 cm

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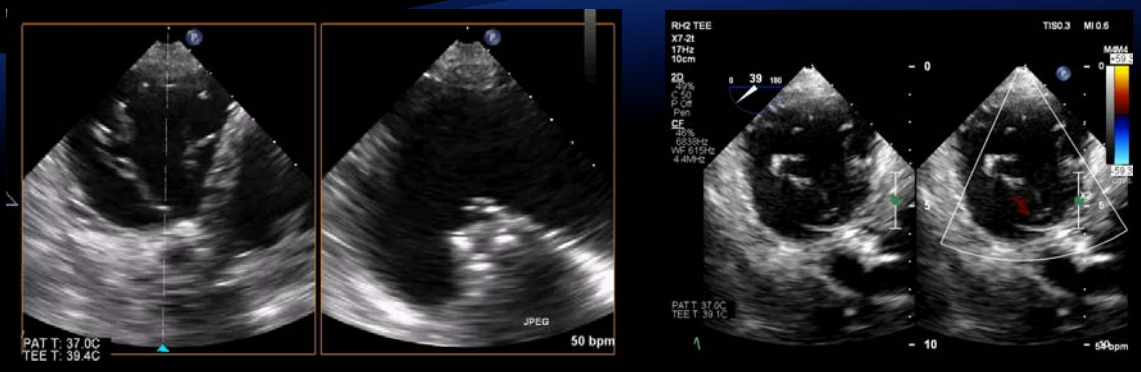
Baseline TEE



Largest coaptation gap = 8 mm

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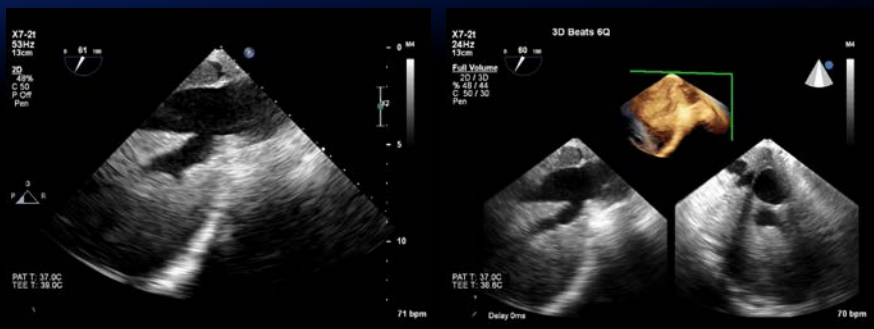
IVC



IV Diameter = 3.5 cm

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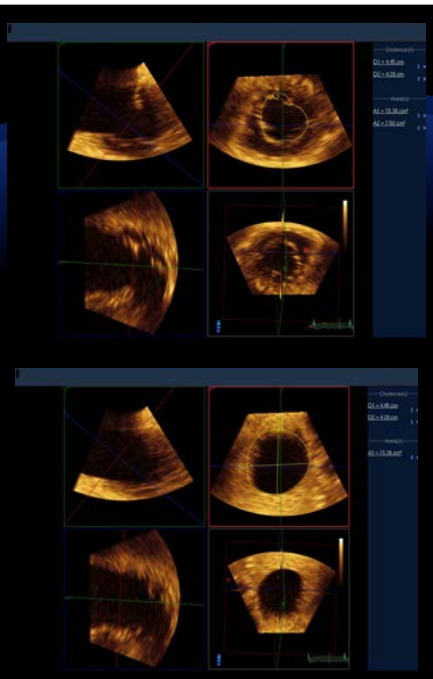
3D Assessment



3D annular area = 15.38cm²
(dimensions = 4.45cm by 4.28cm)

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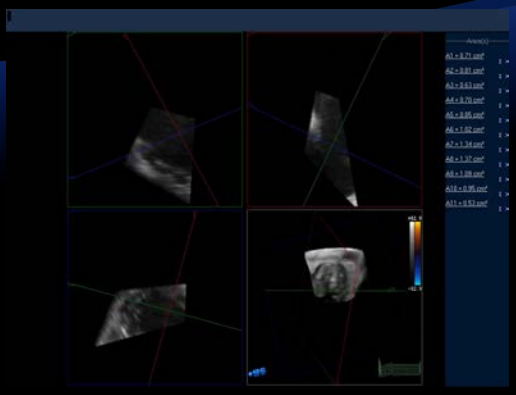
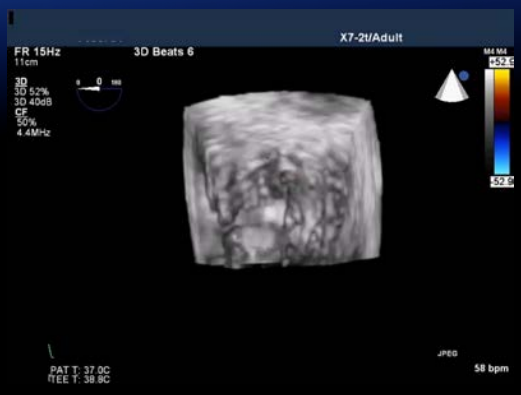
3D Color Doppler





3D color Doppler EROA (averaged over 11 frames) = 0.91cm²

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Grading of Tricuspid Regurgitation

Grading the Severity of Chronic TR by Echocardiography[1]

Parameters	Mild	Moderate	Severe
Structural			
TV morphology	**Normal or mildly abnormal leaflets**	Moderately abnormal leaflets	**Severe valve lesions** (e.g., flail leaflet, severe retraction, large perforation)
RV and RA size	Usually normal	Normal or mild dilation	Usually dilated[2]
Inferior vena cava diameter	Normal <2cm	Normal or mildly dilated 2.1-2.5cm	Dilated >2.5cm
Qualitative Doppler			
Color flow jet area[3]	**Small, narrow, central**	Moderate central	**Large central jet** or eccentric wall-impinging jet of variable size
Flow convergence zone	**Not visible, transient or small**	Intermediate in size and duration	**Large throughout systole**
CWD jet	**Faint/partial**/parabolic	Dense, parabolic or triangular	Dense, often triangular
Semiquantitative			
Color flow jet area (cm^2)[3]	Not defined	Not defined	>10
VCW (cm)[3]	<0.3	0.3-0.69	≥0.7
PISA radius (cm)[4]	≤0.5	0.6-0.9	>0.9
Hepatic vein flow[5]	Systolic dominance	Systolic blunting	**Systolic flow reversal**
Tricuspid inflow[6]	**A-wave dominant**	Variable	E-wave >1.0m/sec
Quantitative			
EROA (cm^2)	<0.20	0.20-0.39[8]	≥0.40
RVol (mL/beat)	<30	30-44[8]	≥45

2D/3D Imaging

Color Flow/ CW Doppler

Color Flow/ PW Doppler

2D/CW/ PW Doppler

Zoghbi WA et al. J Am Soc Echocardiogr 2017; 30: 303-371.

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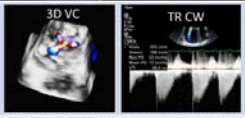
TR Grading: Work in Progress

Quantitation Method	Measurements Required	Example	Calculation
PISA	1. PISA radius [r] 2. PISA aliasing velocity [v] (approximately 28 cm/s) 3. TR peak velocity [v_c] 4. TR velocity time integral [TR_{VTI}]		$Q = 2\pi r^2 v$ $ROA = Q/v_c$ Reg Vol = ROA x TR_{VTI}
Quantitative Doppler	1. TV velocity time integral [TV_{VTI}] • PW Doppler sample volume at the annulus 2. Diastolic $TV_{annulus}$ Area • 3D annular area OR • Biplane annular area	 	Diastolic Stroke Volume = $TV_{annulus}$ Area x TV_{VTI} RegVol = Diastolic Stroke Volume – Forward Stroke Volume $ROA = RegVol \div TR_{VTI}$ Note: Forward stroke volume may be either the left ventricular or right ventricular stroke volume
3D color Doppler	1. 3D Color Doppler planimetered vena contracta area [VC_{area}] 2. TR velocity time integral [TR_{VTI}]		$ROA = Vc_{area}$ $RegVol = VC_{area}$ x TR_{VTI}

Abbreviations: PISA = proximal isovelocity surface area, TR = tricuspid regurgitation, Q = flow, ROA = regurgitant orifice area, TV = tricuspid valve, PW = pulsed wave, 3D = three dimensional, RegVol = regurgitant volume, VC = vena contracta

SCOUT 1 is the first tricuspid valve device trial to use Doppler quantitative measures of disease severity

Hahn RT. *Circ Cardiovasc Imaging*. 2016 Dec;9(12)

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TR Quantitation

- Mean VC = 1.5 cm
- EROA by PISA = 0.63cm² and calculated regurgitation volume = 70.4cc
- 2D Quantitation: annular area = 13.8 cm² calculated diastolic stroke volume = 156 cc,regurgitation volume = 106.8 cc, EROA = 0.96 cm²
- 3D Quantitation: annular area = 15.38cm² (dimensions = 4.45cm by 4.28cm) calculated diastolic stroke volume = 173.8cc, regurgitation volume = 120.7cc, EROA =1.08cm²
- 3D color Doppler EROA (averaged over 11 frames) = 0.91cm² calculated regurgitation volume = 101.6cc.
- 3D TV EOA = 7.50cm²

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New Grading Scheme for Severe TR

Table 1 Proposed expansion of the 'Severe' grade

Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7–13 mm	14–20 mm	≥21 mm
EROA (PISA)	<20 mm²	20–39 mm²	40–59 mm²	60–79 mm²	≥80 mm²
3D VCA or quantitative EROA[a]			75–94 mm²	95–114 mm²	≥115 mm²

VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.
[a]3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.

Rebecca T. Hahn, and Jose L. Zamorano. "The Need for a New Tricuspid Regurgitation Grading Scheme." European Heart Journal - Cardiovascular Imaging 2017

Severe ***Massive*** ***Torrential***

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Assessment/Plan

- 92F with severe symptomatic TR; prohibitive risk for open surgical repair or replacement (age, previous sternotomy, and multiple co-morbidities) with MASSIVE TR

- OPTIONS:
  - Caval valve(s) — ? IVC too large
  - Trialign, Cardioband — ?annulus too large
  - FORMA — Not Available
  - MitraClip — ?coaptation gap too broad
  - Other?

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Assessment/Plan

TRANSATRIAL, TRANSCATHETER TRICUSPID VALVE REPLACEMENT WITH THE 48MM NAVIGATE SYSTEM

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TTVR: First-in-Human

NaviGate
CARDIAC STRUCTURES, Inc.

News Release

FOR IMMEDIATE RELEASE
Contact: Ronald Trahan, APR, Ronald Trahan Associates, +1-508-359-4005, x108

NaviGate Cardiac Structures Inc. ("NCSI") reports world's first transcatheter tricuspid valved stent is successfully implanted

LAKE FOREST, Calif., Dec. 30, 2016 — NaviGate Cardiac Structures Inc. ("NCSI") announced today that a novel valved stent that can capture the enlarged annulus in patients suffering from functional tricuspid regurgitation (FTR) was implanted in a patient presenting with massive incompetence of the tricuspid valve.

The patient, a 64-year-old female with an extensive history of severe tricuspid regurgitation (TR 4+) that invariably results in right heart failure (RHF), a lethal condition, was successfully treated with the **GATE™** tricuspid Atrioventricular Valved Stent (AVS) from NCSI. The cardiac team from the Cleveland Clinic, recognized as the number-one cardiac medicine center in the USA for 22 consecutive years, implanted the AVS with catheter-guided technique under a compassionate plea from the patient. (A compassionate plea allows a special permission for medical procedures deemed to be the last resort for patients with conditions for which no approved device or medicine exists.)

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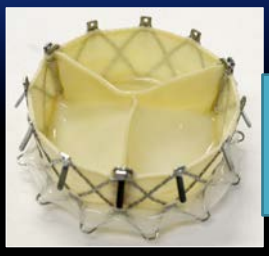
The Solution: NAVIGATE
Transcatheter Valved Stent Replacement Technology



The larger sized valves are *ideal for the dilated Tricuspid Valve*. (TV 48 ± 4mm Ø)

Components Specifications

- Temperature Shape Memory NiTinol Tapered Stent (Inflow=30mm/Outflow=40mm)
- Height profile 21 mm, Truncated Cone configuration with a Diffuser effect.
- Annular Winglets for secure anchoring of annulus and tricuspid valve leaflet.
- Chemically Preserved Xenogeneic Pericardium.

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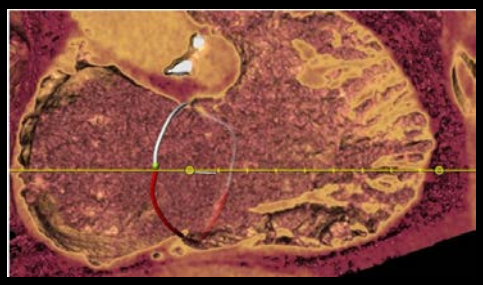
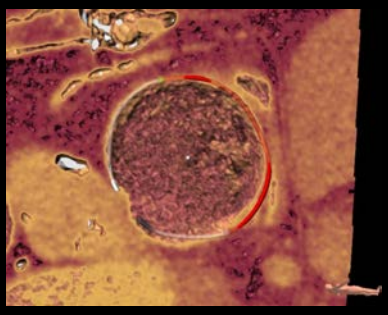
Assessment/Plan

- 92F with severe symptomatic tricuspid incompetence, at prohibitively high risk of surgical intervention because of age, previous sternotomy, and co-morbidities

- **Sagittal view**



- **Transverse view**



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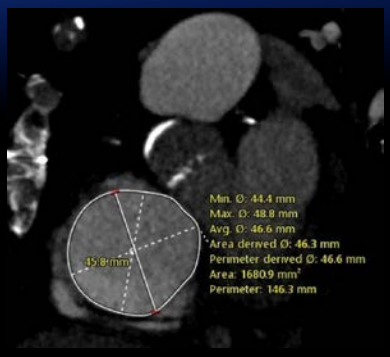
Pre-procedural CT planning
Tricuspid annular area by 2D imaging

Systolic phase:

44 x 54 mm



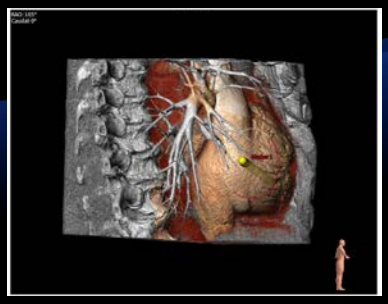
Diastolic phase

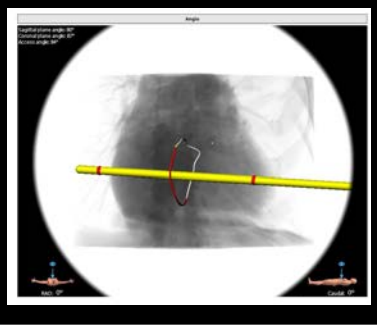
44 x 49 mm

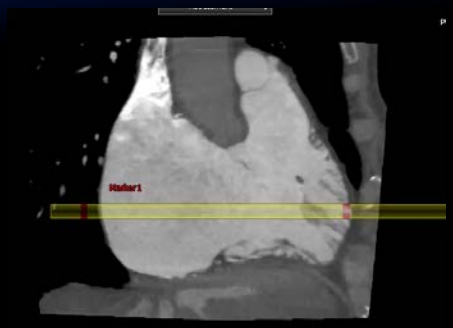
Decision: 48 vs 52 mm valve

21

Access







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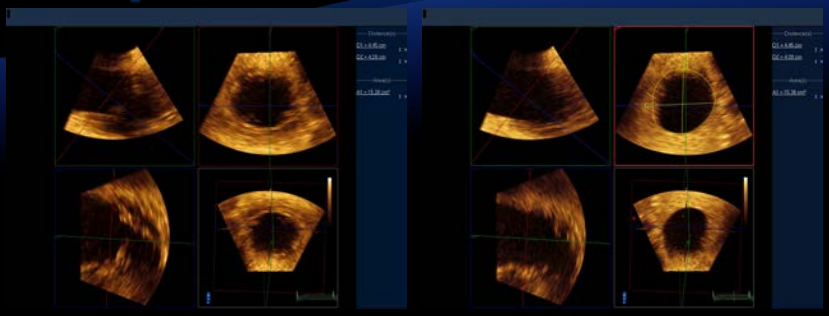
Intra-procedural 3D Echo



Diastolic phase

43 x 45 mm

Plan for transcatheter tricuspid valve replacement with a 48mm NaviGate tricuspid valve bioprosthesis

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Procedural plan

- Right atrial approach via a lateral right-sided mini-thoracotomy at the 5th intercostal space under general anesthesia in a hybrid operating room
- 48mm Navigate transcatheter valve deployment under fluoroscopic and transesophageal guidance and rapid pacing
- Femoral venous access for right ventriculography
- Femoral arterial access for selective angiography of the right coronary artery during tricuspid valve advancement and deployment
- Temporary pacing achieved with Confida wire in left ventricle and pacing electrodes mounted on wire

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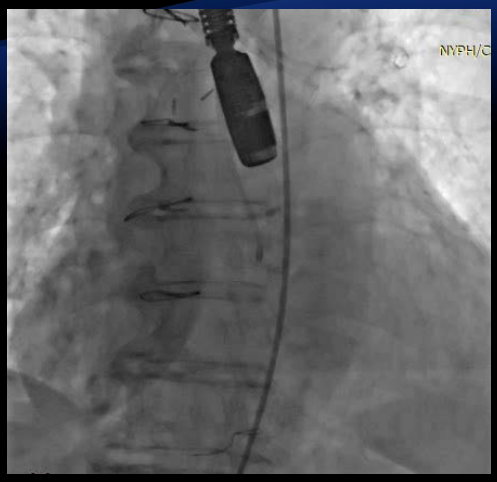
Pre-procedural selective angiography of the right coronary system



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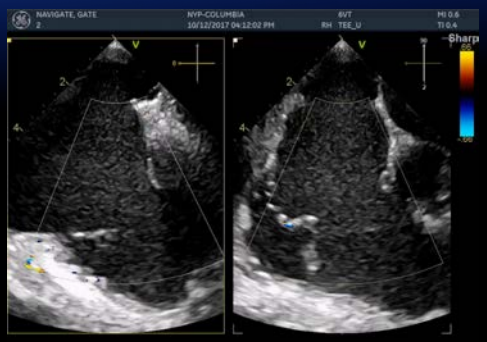
Torrential tricuspid incompetence

Simultaneous Echo and Fluoro Guidance is KEY



Temporary pacing achieved with Confida wire in left ventricle and pacing electrodes mounted on wire

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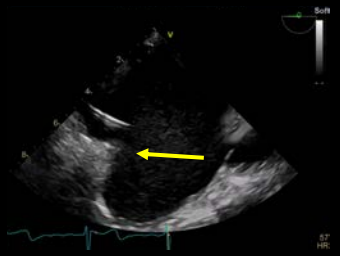
Positioning the Transatrial Puncture

Balloting the Atrium

Poor Position (non-coaxial)



Good Position (coaxial)

Atrial Poke: Distance 7.5 cm

Positioning of stiff guidewire into right ventricle over a pigtail catheter, and through transatrial incision

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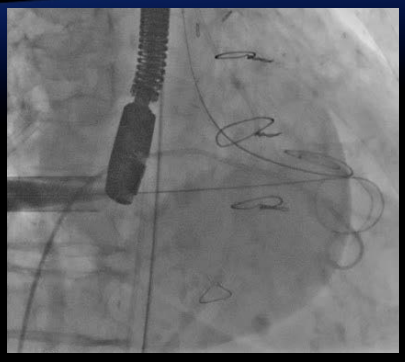
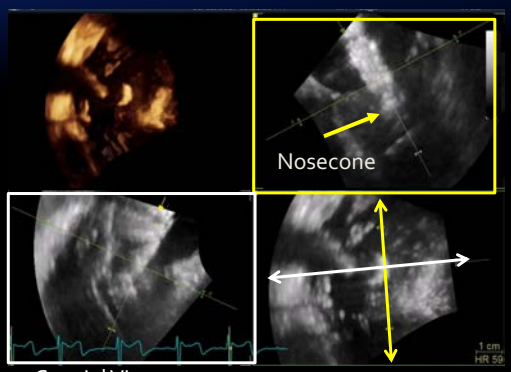
Advancement of the NaviGate tricuspid system into right ventricle over stiff wire, and through the right atrial incision





3D Flexi-slice to image long-axis of device

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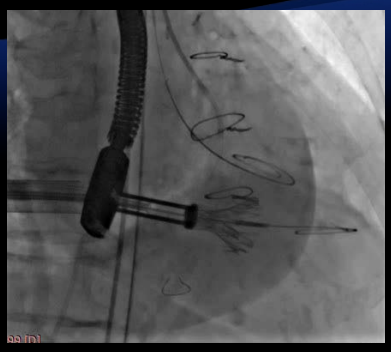
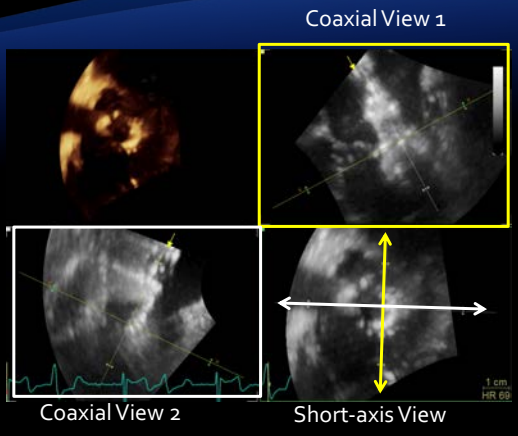
Initial valve deployment with RCA injection





Retracting the capsule:
Exposing Ventricular Tines

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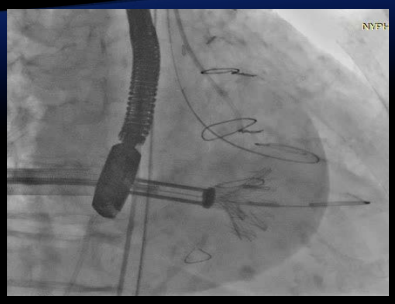
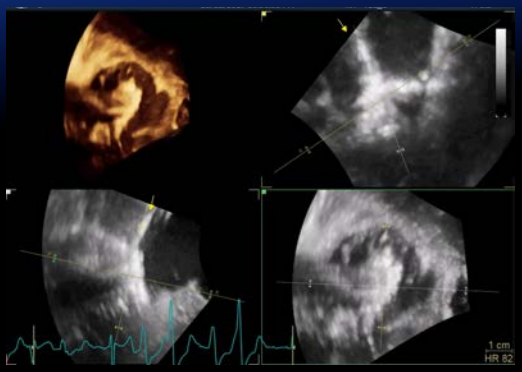
Valve deployment (continued)





- Ventricular aspect fully exposed
- Atrial aspect restrained

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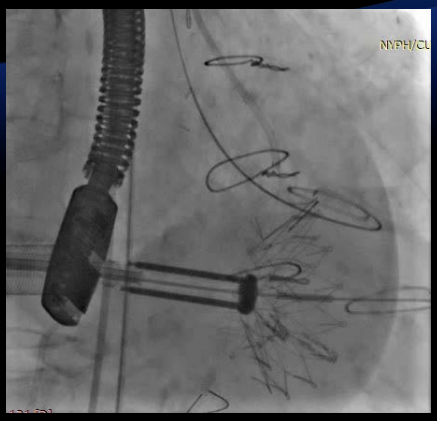
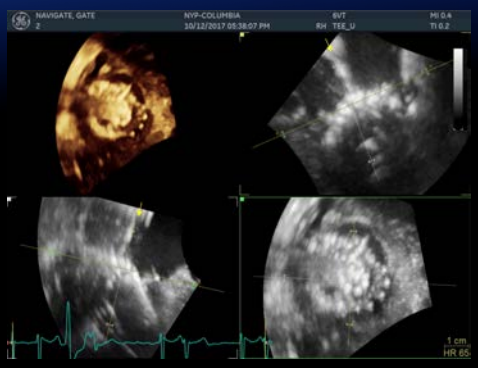
Intra-procedural TEE – initial valve deployment





Atrial brim exposed

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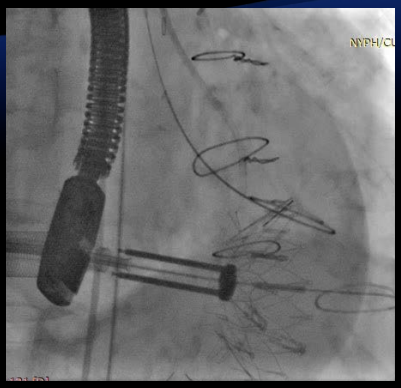
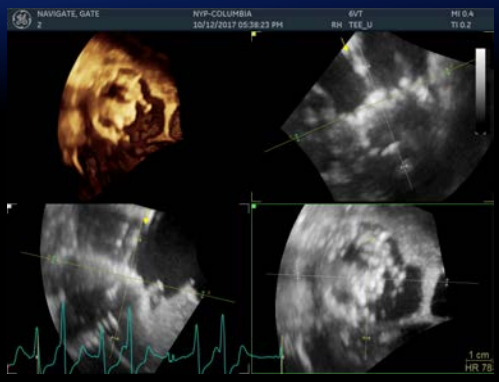
Valve Release: Complete Deployment





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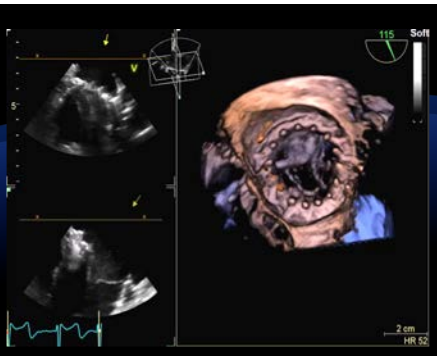
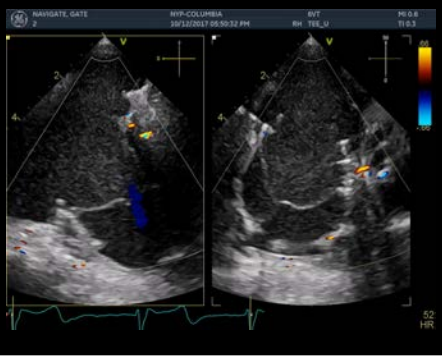
Final Result





- Trivial central and trivial paravalvular regurgitation
- Peak/mean transtricuspid gradient = 1.5 and 0.3 mmHg

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Post procedural course

- Pledgeted purse-string suture in lateral right atrial wall closed
- Single right pleural Blake drain left in situ
- Extubated in the operating room
- Hemodynamically stable on milrinone infusion for RV support

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Post procedural course

- Two nights in the intensive care unit, 2 nights on the general ward
- Milrinone ceased on day 2 post procedure
- Chest tube removed on day 2 post procedure
- Discharged home in excellent condition on day 5 post procedure

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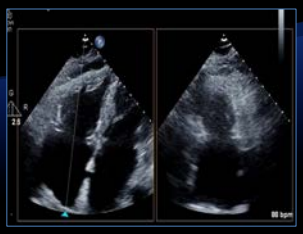
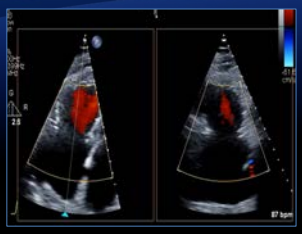
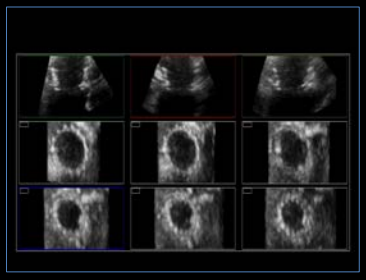
NaviGate
30 day follow-up







Conformable Valve
No significant regurgitation

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