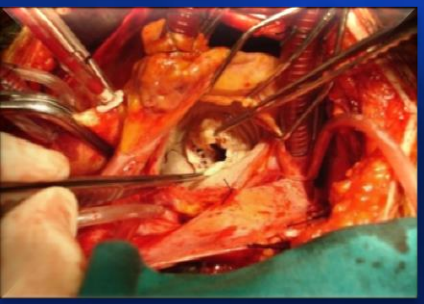
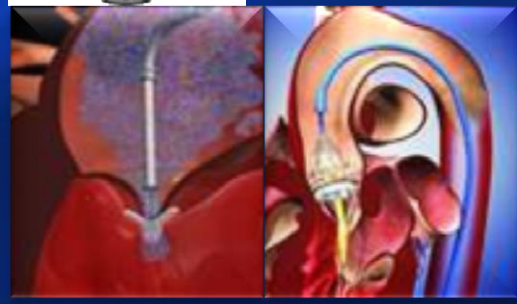
Advances in Valve Therapies



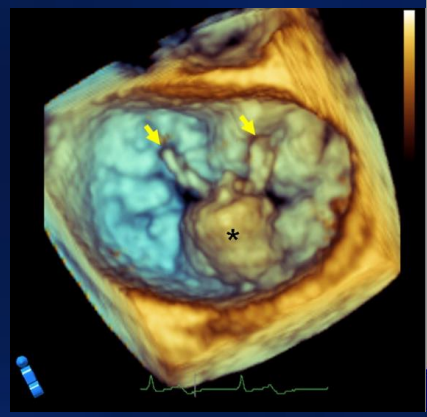


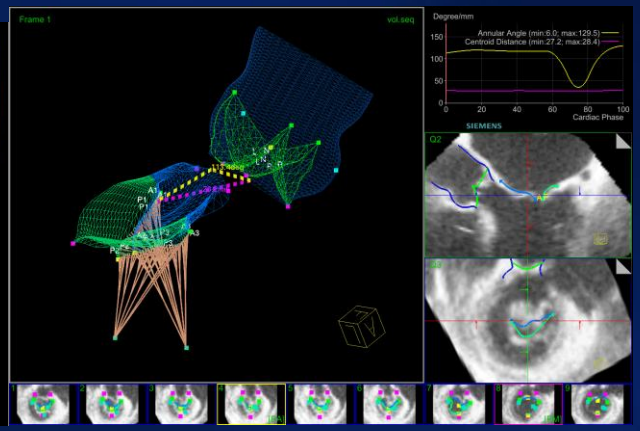
Open Surgical Valve Repair

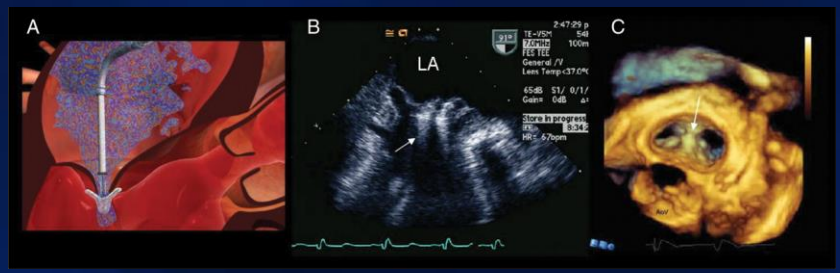
Minimally Invasive Valve Repair

Robotic Valve Repair

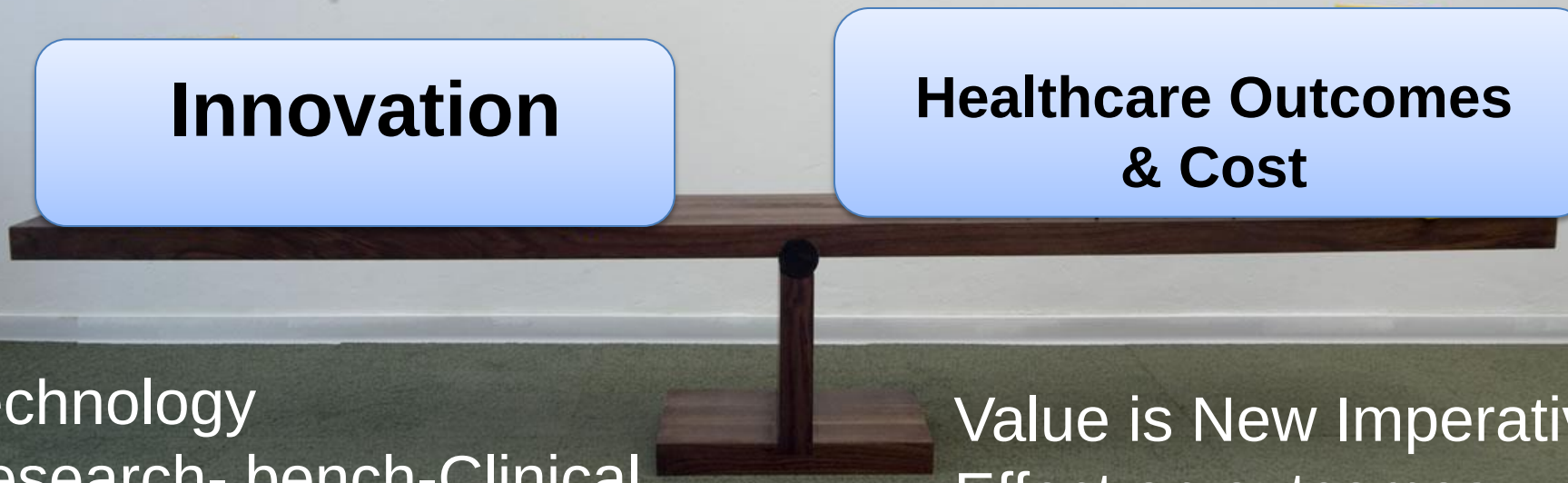
Transcatheter repair







Future of VHD



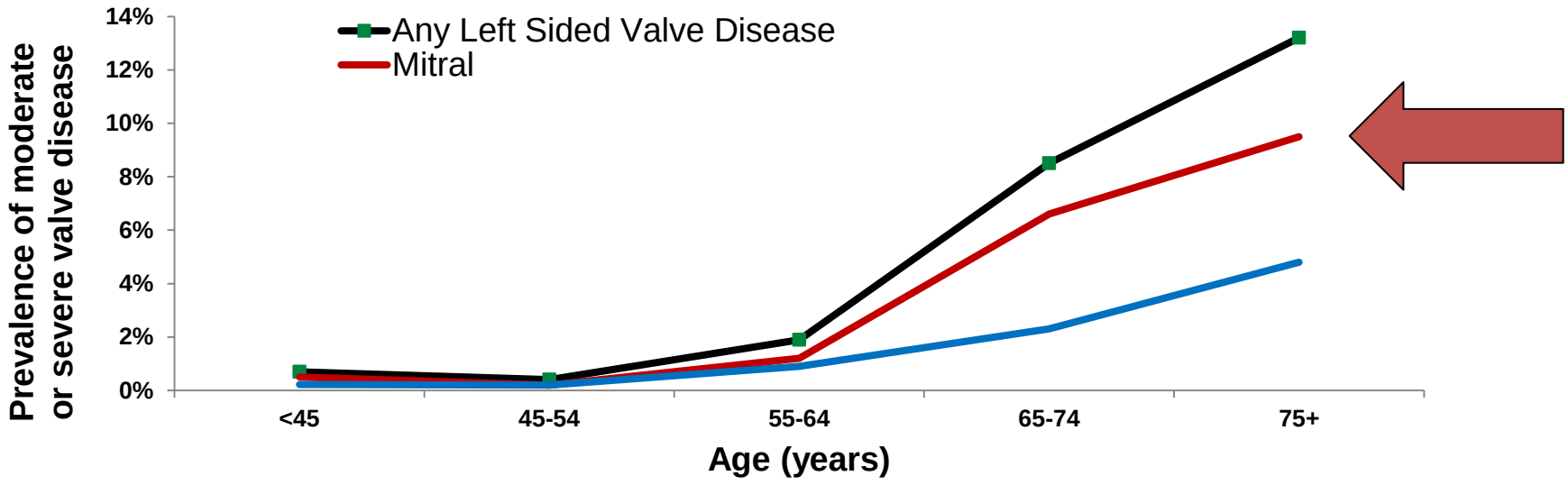
Technology
Research- bench-Clinical
Cost
Communication

VS

Value is New Imperative
Effect on outcomes
- Individual Patient
- Population

Valvular disease is common

- High prevalence of left sided valvular disease in older patient populations
- Mitral regurgitation is the most common type of heart valve disease in the U.S.[1,2-]
- Current Prevalence of significant MR in US is 1.7% but expected to Rise as population ages
- Left Untreated –Severe MR is associated with poor outcomes:
  LV failure,Pulmonary HPT, AF,Stroke,Death



1. Heart Disease and Stroke Statistics 2010 Update: A Report From the American Heart Association. *Circulation.* 2010;121:e46-e215.
2. Nkomo VT et al. *Lancet*. 2006; 368:1005-1011.

PIEDMONT HEART INSTITUTE

Managing MR and the Incorporation of TMVR

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Baylor Scott & White Health
Dallas, TX

Conflict of Interest Disclosure

- Michael Mack
  - Co-PI- COAPT Trial- Abbott Vascular Sponsor
    - Uncompensated

Disclosures

- Speakers Bureau, Abbott Vascular
- Speakers Bureau, Edwards Lifescience
- Speakers Bureau, SORIN Group
- Speakers Bureau,Medtronic Heart Valves

The Dr Mike and Dr Randy Show

- Primary Vs Secondary MR

  Advanced Imaging for diagnosis,directing and assessing Treatments
- Defining High Risks-Fraility etc
- Medical vs SurgicalTreatment in 1 vs 2 MR
- Surgical- Transcatheter Treatment:

  Primary MR-including high risk

  Secondary MR
- The FUTURE

ACC Mitral Regurgitation Needs Assessment *and Gap Analysis*

December 11, 2013

AMERICAN COLLEGE of CARDIOLOGY

Project Overview

- **Purpose:** Gain insight into current clinical practices, gaps in care and emerging best practices in mitral regurgitation diagnosis and management
- **Objective:** Conduct comprehensive analysis of educational and quality improvement needs
- ACC multi-faceted needs assessment "*Understanding Practice-Based Approaches in the Management of Mitral Regurgitation*" with three distinct research components:
  - *Part I: Literature Review and Gap Analysis*
  - *Part II: Expert Interviews*
  - *Part III: Surveys*
- **Summation:** day-long meeting of ACC Experts Advisory Panel to review assessment data findings with these objectives
  - Provide additional insight into gaps and emerging best practices
  - Determine and prioritize most relevant and significant findings
  - Offer recommendations for educational programming and quality improvement interventions

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Key Findings

Confidence in Auscultation (all respondents)

- Majority of physicians no more than moderately confident in ability to detect asymptomatic patient with clinically significant MR by auscultation.
- Cardiologists, in aggregate, more confident in their auscultative skills (mean rating 6.9) than either primary care physicians (mean rating 5.8) or cardiothoracic surgeons (mean rating 4.8).

Perceived Utility of Auscultation versus Echocardiography (all respondents)

- Most primary care physicians and cardiologists perceived auscultation and physical exam as moderately useful in evaluation of possible MR.
- However, they considered standard echocardiogram to be of greater utility.
- More than 10% of physicians perceive auscultation as having limited utility.
- May be barrier to good auscultation and promote over-reliance on imaging.

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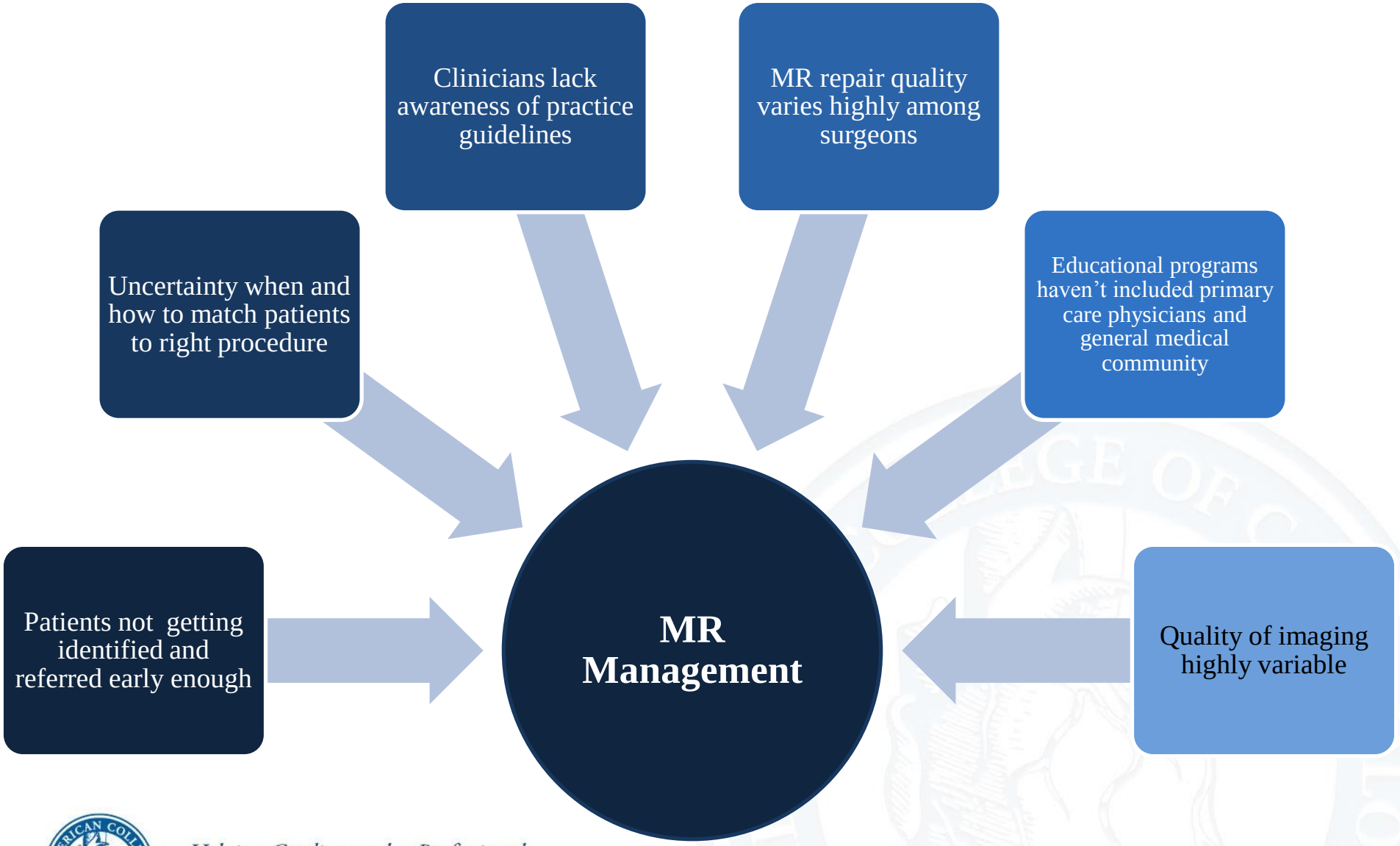
Most Pressing Issues in Management of MR



Helping Cardiovascular Professionals Learn. Advance. Heal.

Q. Given your understanding of evolving best practices, emerging treatment options, and current quality gaps, what are the most pressing issues in the detection, evaluation, and management of MR that the college should target?

Key Findings

Echocardiography Components Assessed and Reported, cont.

- **Quantitative Assessment:**
  - Physicians responses in each survey indicate quantitative assessment inconsistently performed in echocardiography evaluation of patients with MR.
  - Nearly 10% of respondents on Clinical Cardiology and Subspecialist surveys reported that EROA, regurgitant volume, and regurgitant fraction were "Never" reported
  - Suggests significant barriers to accessing infrastructure and skills needed for quantitative assessment
  - Compared to imaging cardiologists, small set of Clinical Cardiologists who read high volume of echocardiograms notably less likely to include vena contracta or EROA measurements in their assessments.

- **Longitudinal strain**–an emerging echocardiogram parameter that may facilitate earlier detection of left ventricular dysfunction.
  - More than 50% of respondents indicate this parameter "Never" assessed or reported
  - Suggests expertise and infrastructure (processes, technique, technology) needed to assess and

Knowledge of Severe MR Criteria (Cardiologists and CT surgeons only)

More than 20% of respondents could not identify important echo criteria of severe degenerative MR

- Only 30% recognized and increase in LVES diameter as Class I indication
- More than 20% DID NOT RECOGNIZE that resting RVSP>50mmhg was guideline based criterion for intervention

ECHO Interpretation (Cardiologists and CT surgeons only)

When asked to interpret 2 echocardiography video clips to ascertain etiology of patient's MR,

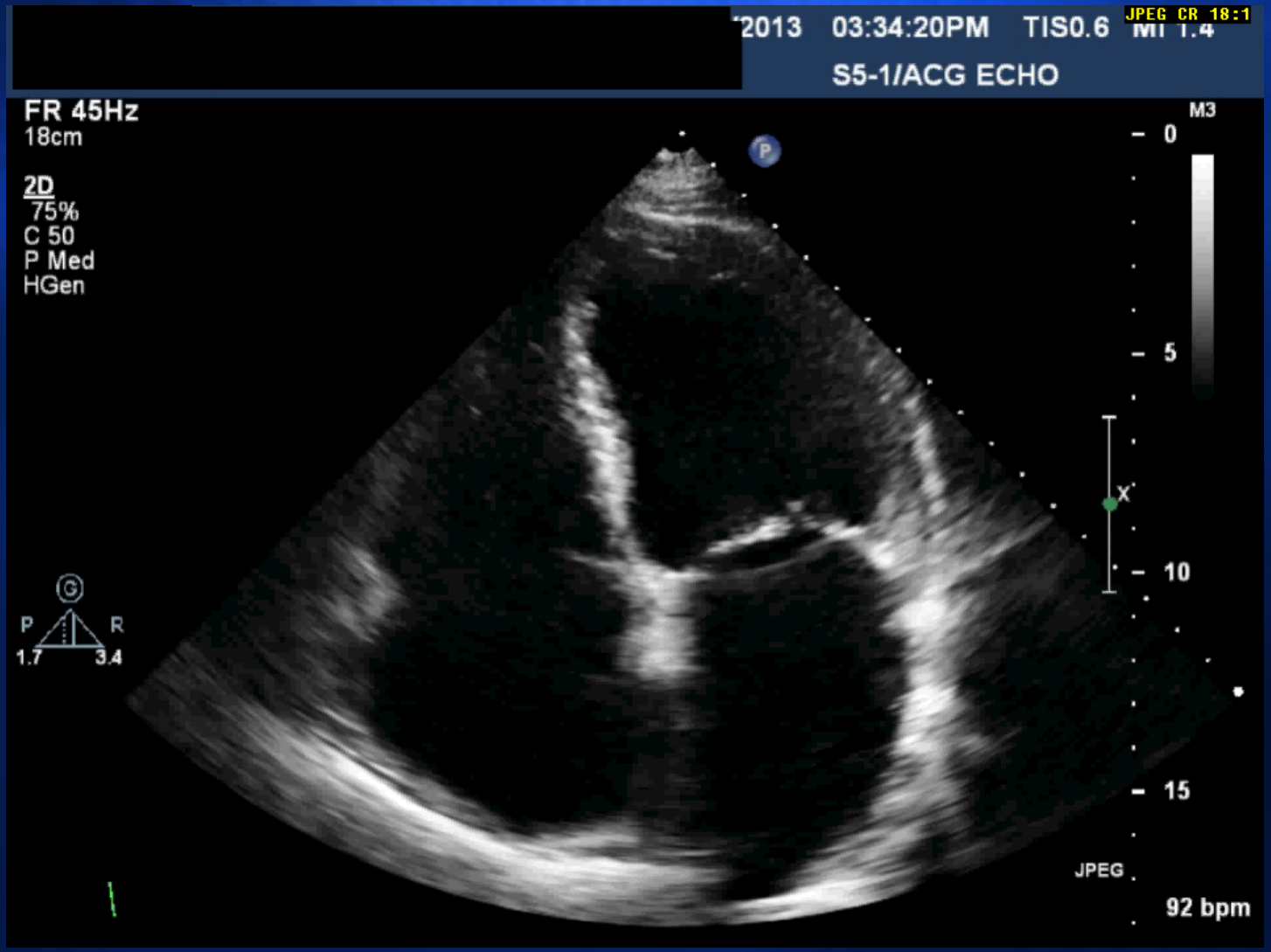
more than 14% respondents did not correctly identify cardiomyopathy with functional MR and

more than 30% did not appropriately interpret posterior leaflet prolapse.

Case

- 72 year old male
- Chronic A-Fib
- Congestive Heart Failure with normal coronaries
- Echo Read as Anterior Leaflet Prolpase

Case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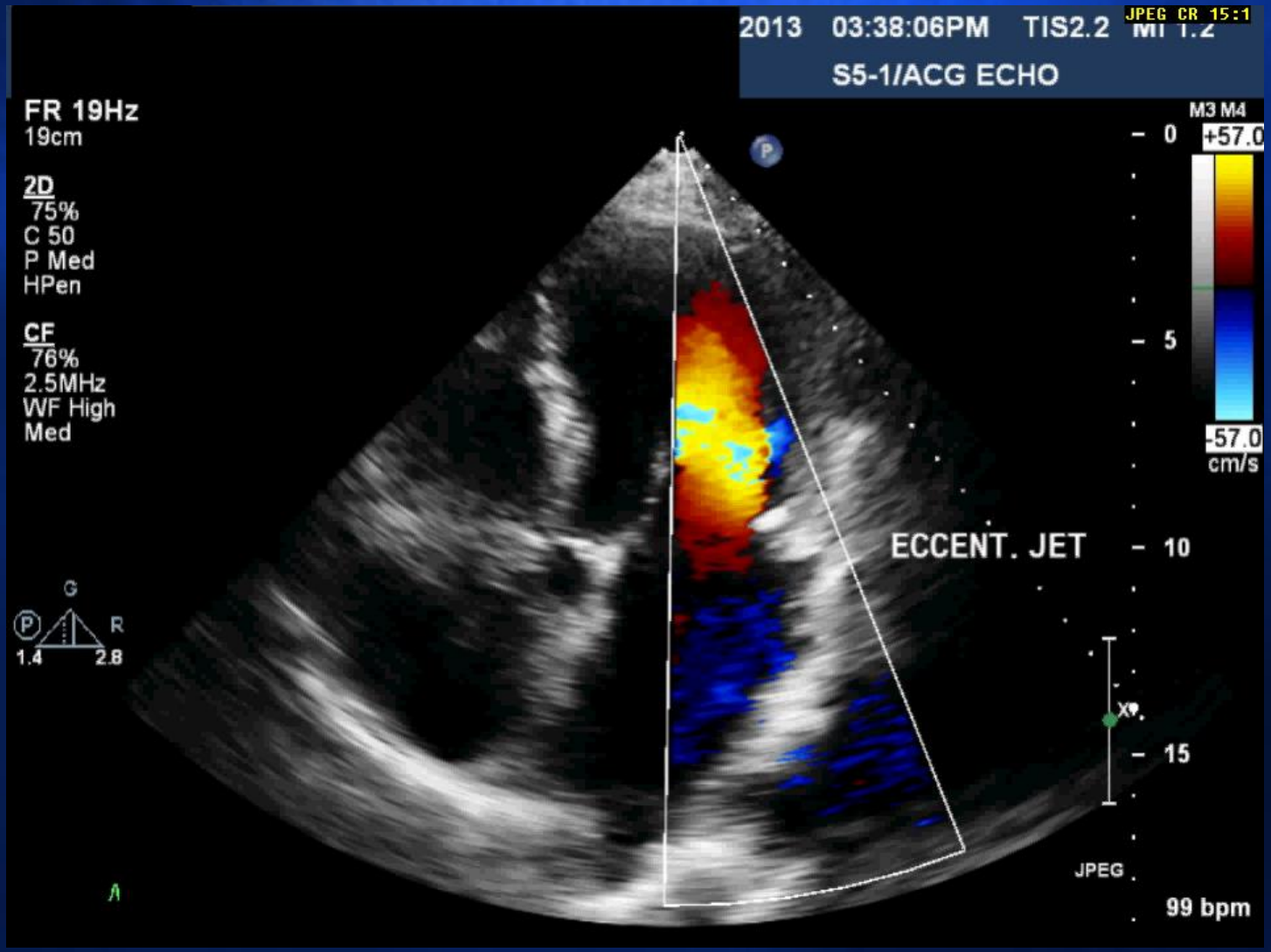
FR 45Hz
18cm
2D
75%
C 50
P Med
HGen
M3
0
5
10
15
P
R
1.7
3.4
JPEG
92 bpm

Case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JPEG CR 15:1
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FR 19Hz
19cm
2D
75%
C 50
P Med
HPen
CF
76%
2.5MHz
WF High
Med
M3 M4
+57.0
-57.0
cm/s
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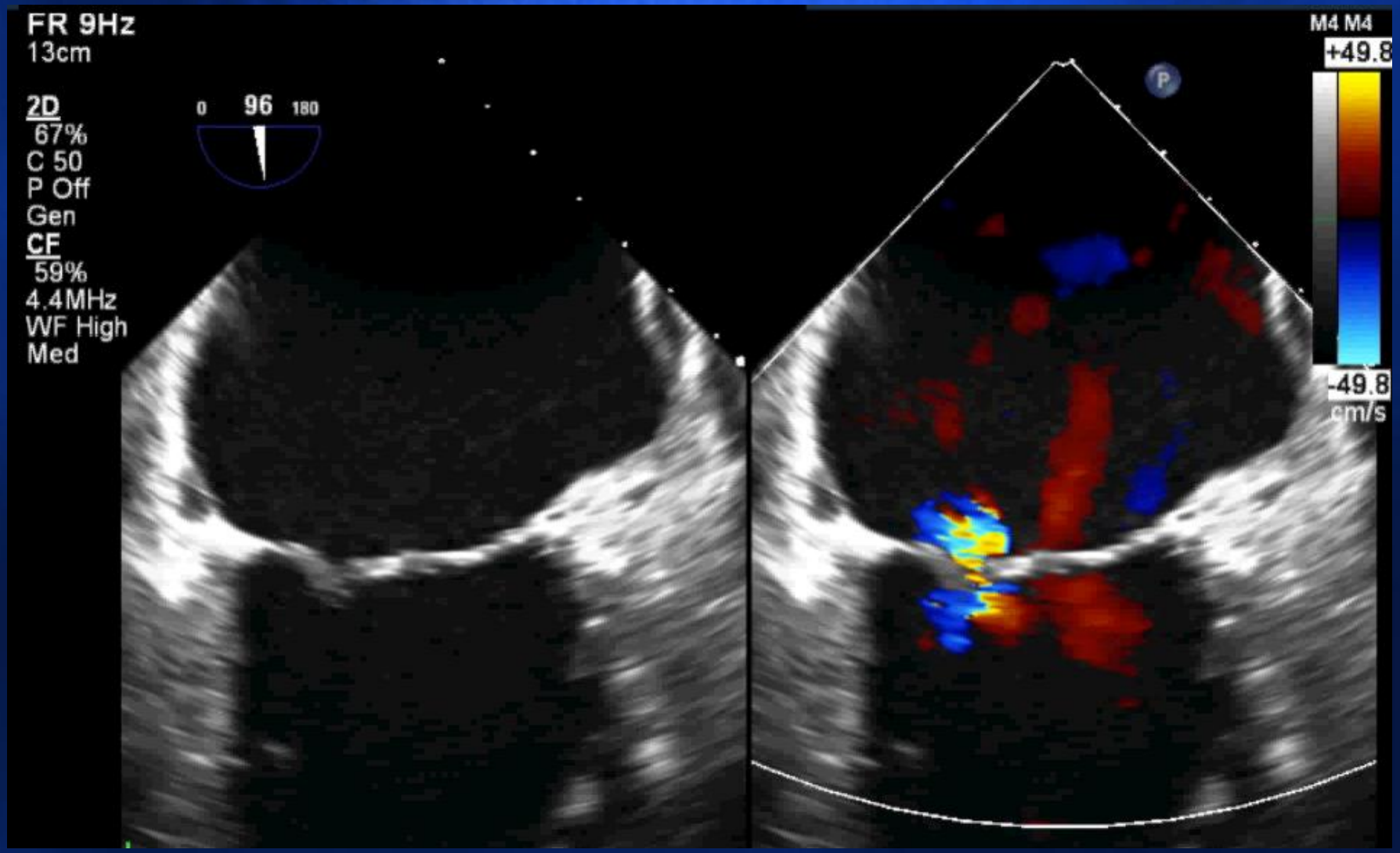
5
10
15
ECCENT. JET
1.4
2.8
JPEG
99 bpm

Case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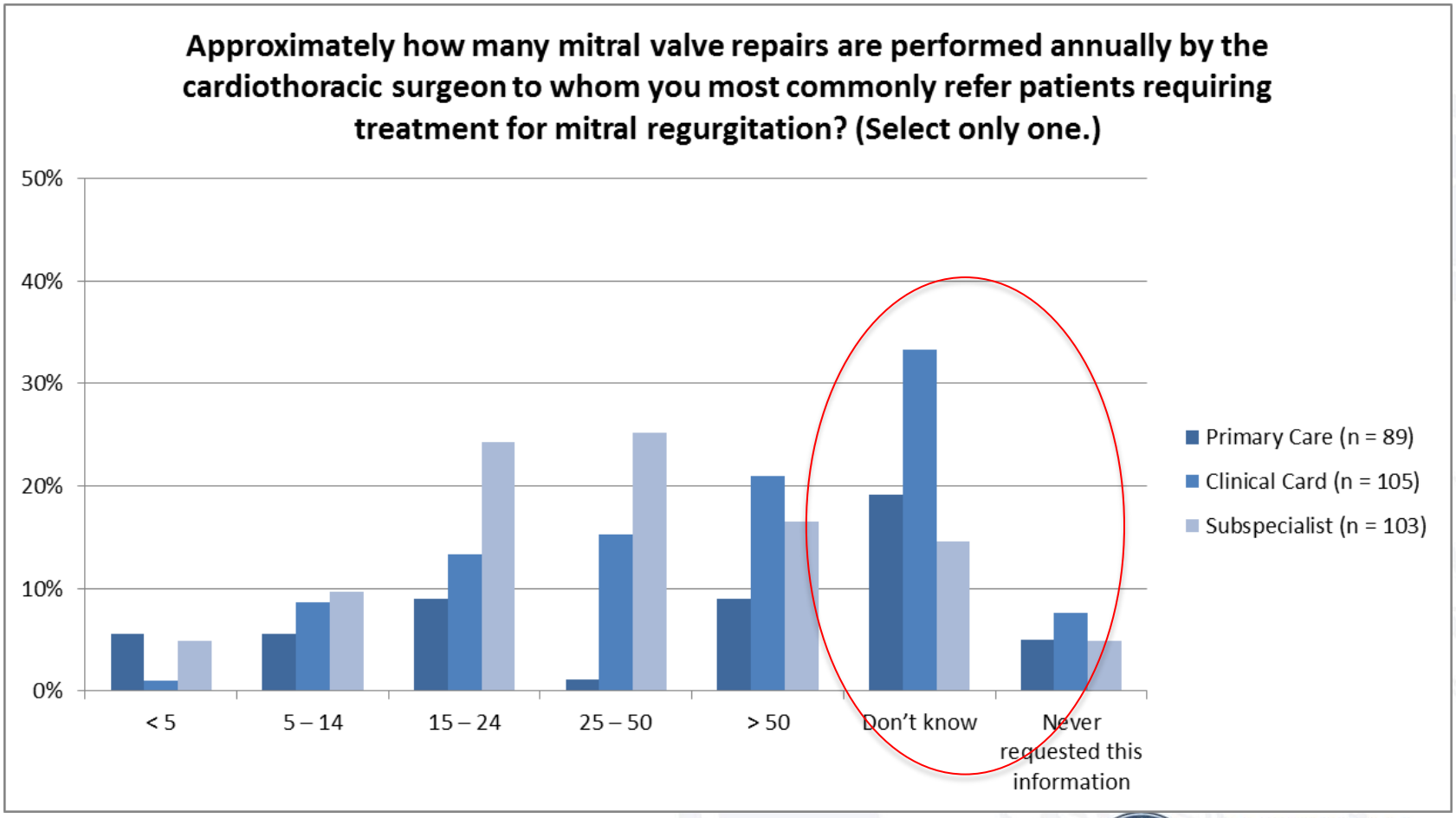
13cm
2D
67%
C 50
P Off
Gen
CF
59%
4.4MHz
WF High
Med
0
96
180
M4 M4
+49.8
-49.8
cm/s

Annual Volume of MR Valve Repairs Performed by Local Surgeons



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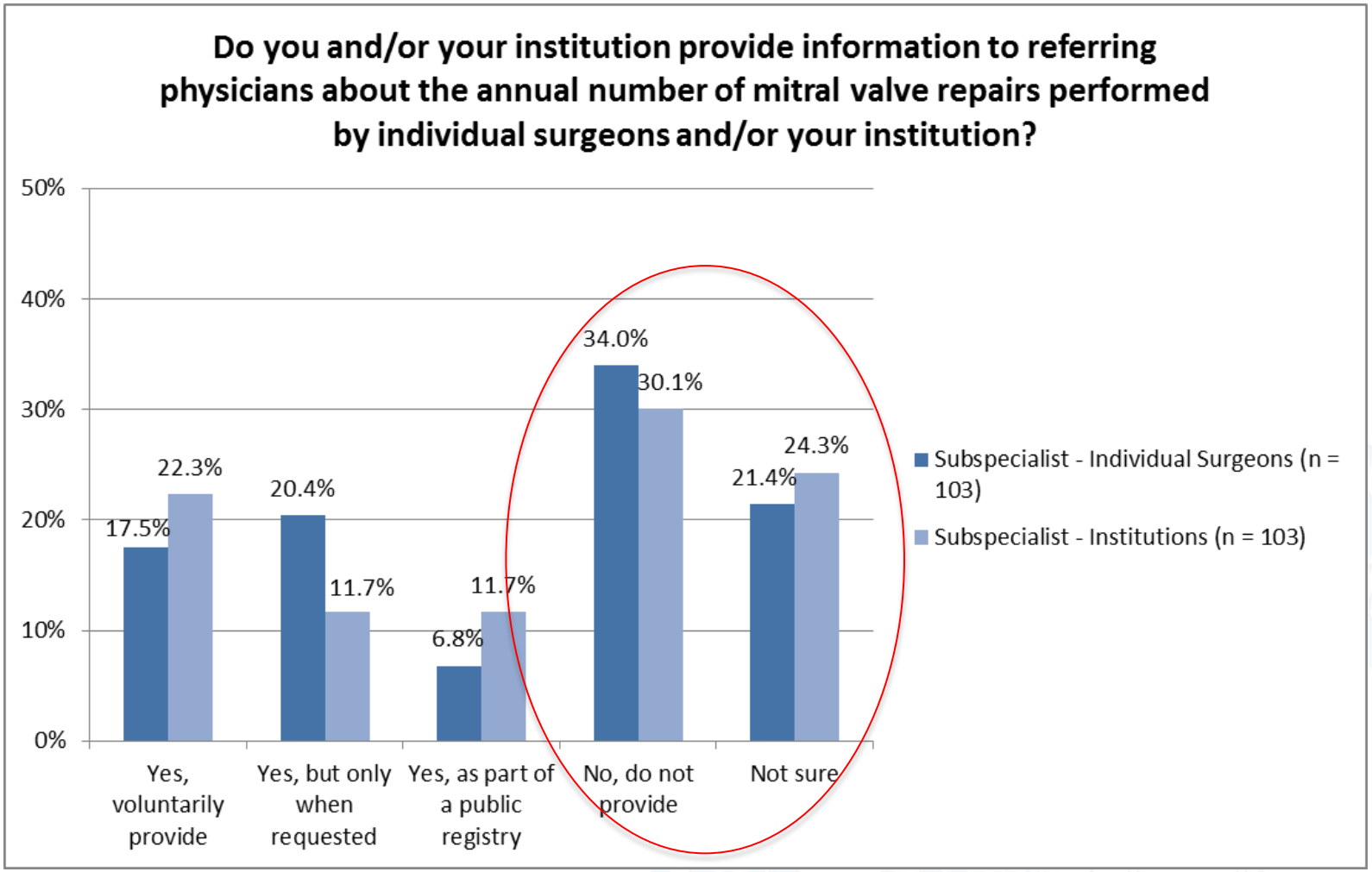
Release of Surgical Volume Statistics



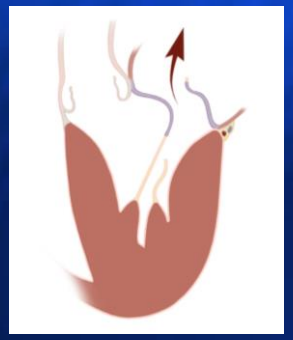
American Heart Journal Feb 2016

Practice gaps in the care of mitral valve regurgitation: Insights from the American College of Cardiology mitral regurgitation gap analysis and advisory panel

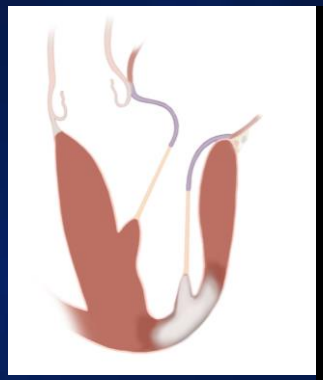
Andrew Wang, MD, Paul Grayburn, MD, Jill A. Foster, MD, MPH, Marti L. McCulloch, MBA, RCS, Vinay Badhwar, MD, James S. Gammie, MD, Salvatore P. Costa, MD, Robert Michael Benitez, MD, Michael J. Rinaldi, MD, Vinod H. Thourani, MD, Randolph P. Martin, MD

Mitral Valve Disease-Basic Question

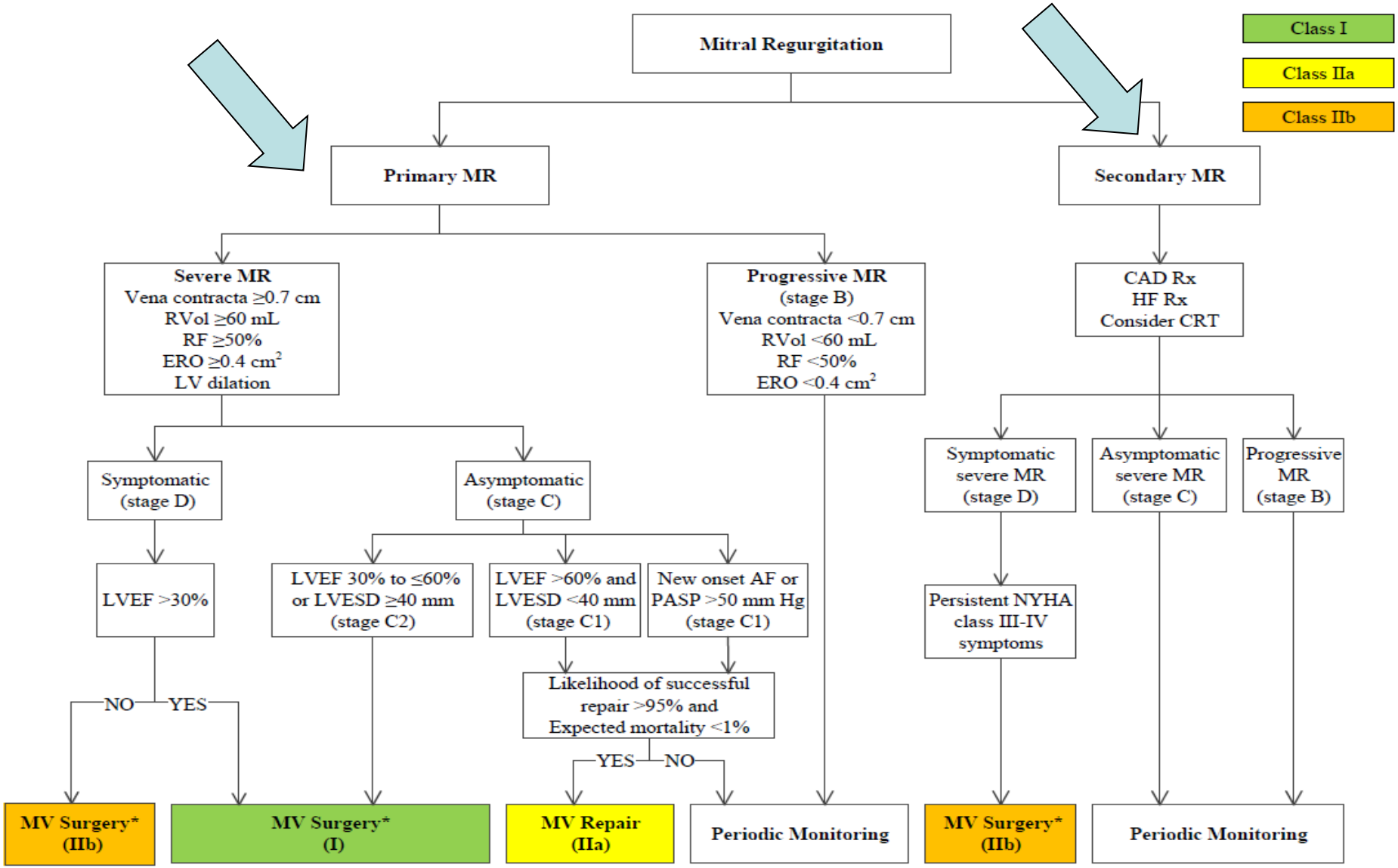
- **Primary Valve Problem** – The valve makes the heart sick



- **Secondary Valve Problem**-The heart makes the valve sick



Indications for Surgery for Mitral Regurgitation



Primary MR and Secondary MR

	Primary MR	Secondary MR
Disease	MR is the Disease Result of ABN of MV Complex •Leaflet •Chordae	MR is consequence of: Abnormal LV contractility LV Remodeling Reduced Closing forces Increased MV tethering MV apparatus is "Normal"
Therapy	MV Repair > MV Replace Trans Catheter- Prohibitive risk	**Treat the Heart Failure:** (Meds, CRT) Surgery??: CABG + MV Replace. CABG + MV Repair Transcatheter
Outcome	**Excellent MV Repair Restores:** **•Lv Fx & Size;** **•QOL;** **•Longevity**	???????

Primary MR
Who sees the patients?

- Primary Care Provider
- Clinical Cardiologist
- Echocardiologist
- Surgeons

- AND now the Interventionalist

Secondary MR
Who sees the patients?

- Cardiologist
- Echocardiologist
- Electrophysiologist
- Heart Failure Physician
- Surgeons
- Soon -the Interventionalist

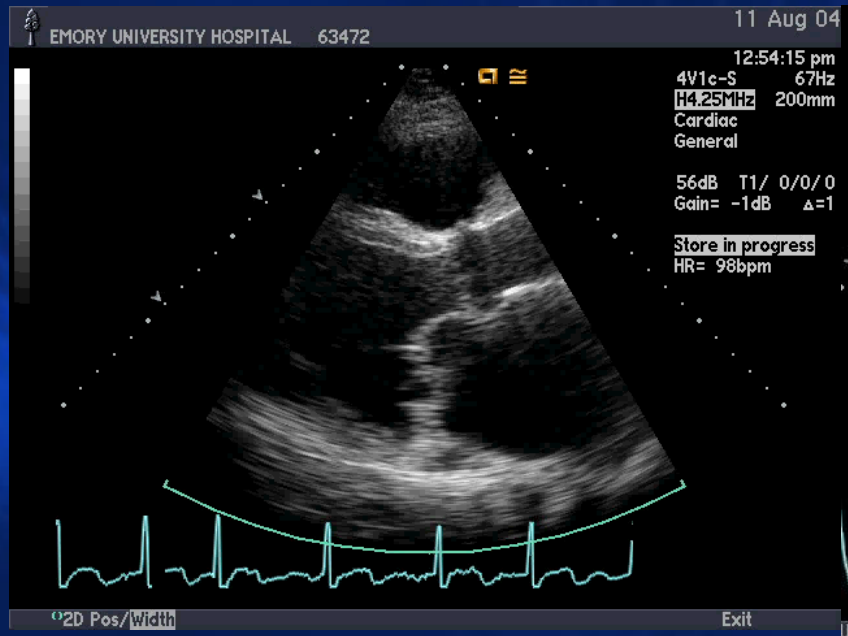
Diagnostic Imaging Assessment of MR-Clinically Available

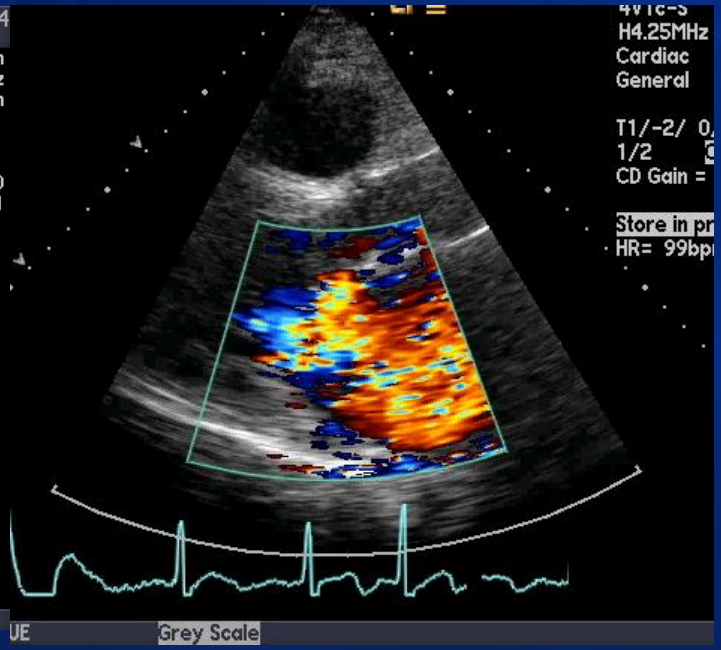
- Echo -Doppler
  - TTE-Rest and Exercise
  - TEE-2D-3D
- CT
- MRI

Mitral Regurgitation – Echo is Your Friend

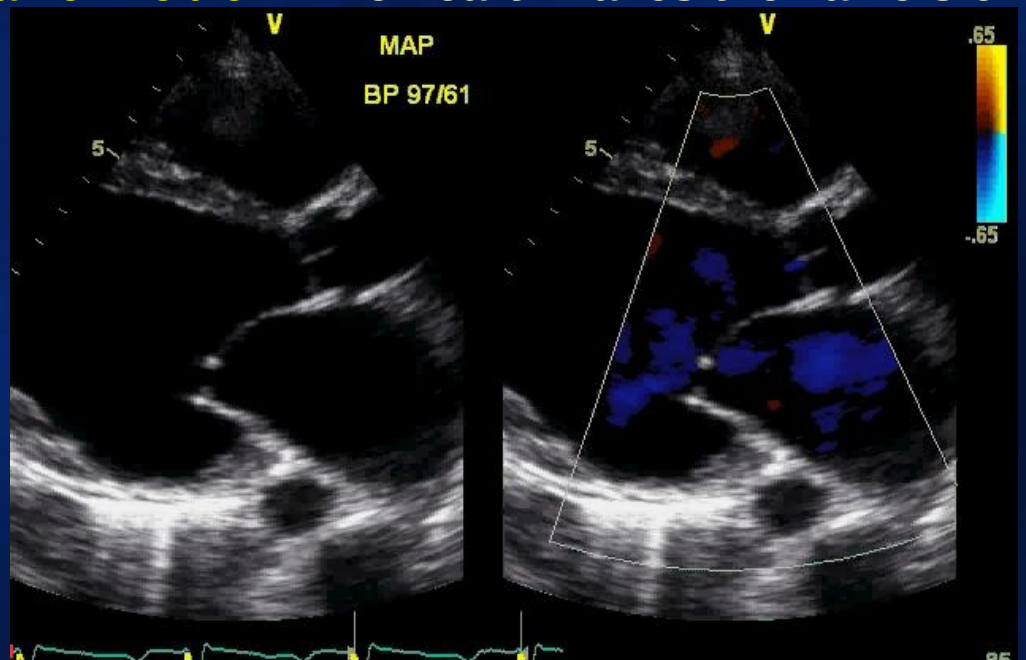
- **Diagnose the cause-Etiology-of MR**
  - **Primary MR**
  - **Secondary MR**
- **Quantitate the severity of MR**
- **Determine impact of MR on:**
  - LV –size and function
  - LA
  - RV & Pulmonary Pressure
  - TV
- **Stress Echo**
- **Aid in planning intervention**
- **Assess outcome of Intervention**

Primary Valve Problem – The valve makes the heart sick

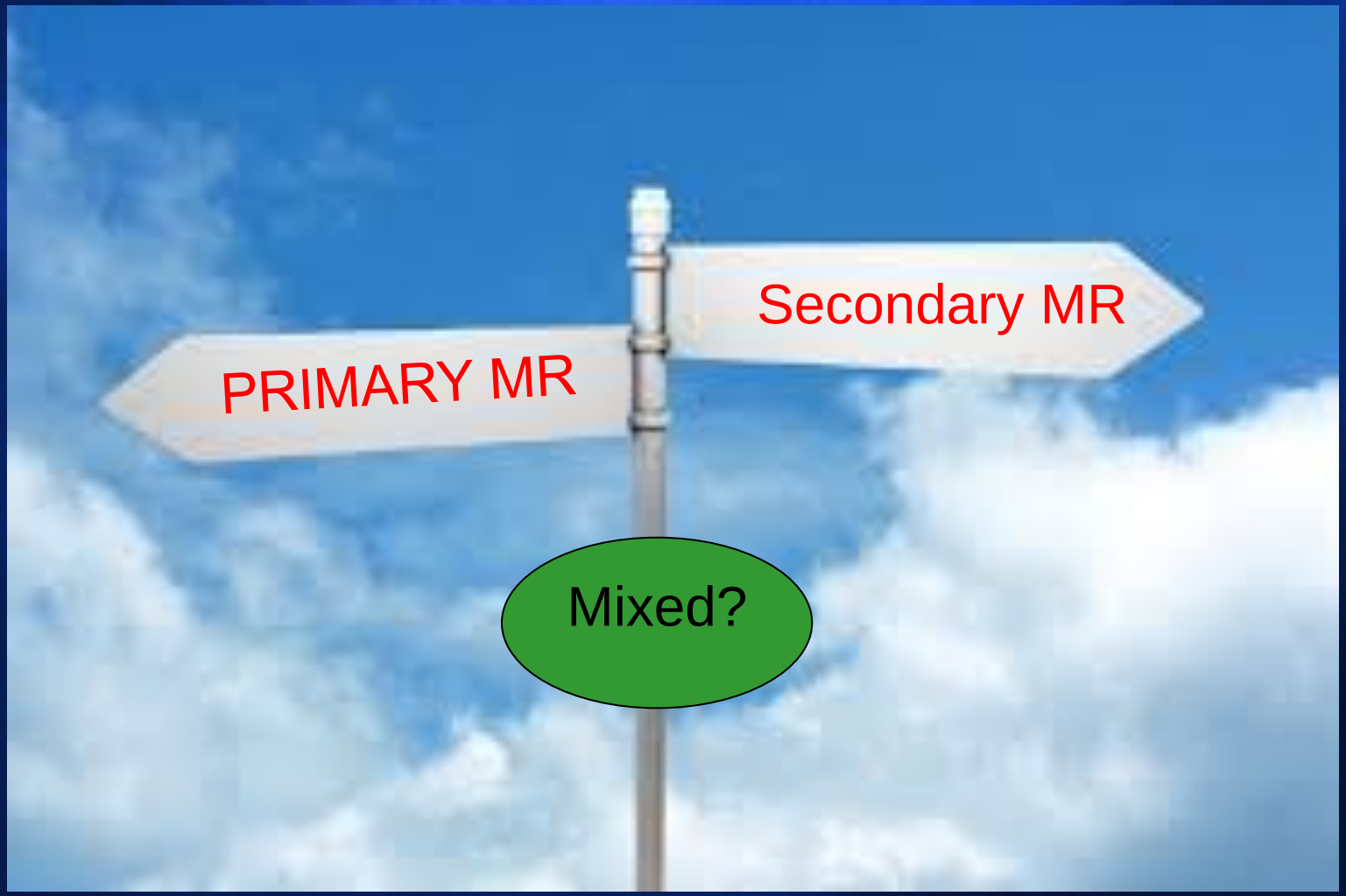




- Secondary Valve Problem-The heart makes the valve sick



Mitral Regurgitation
Primary, Secondary or something in between?

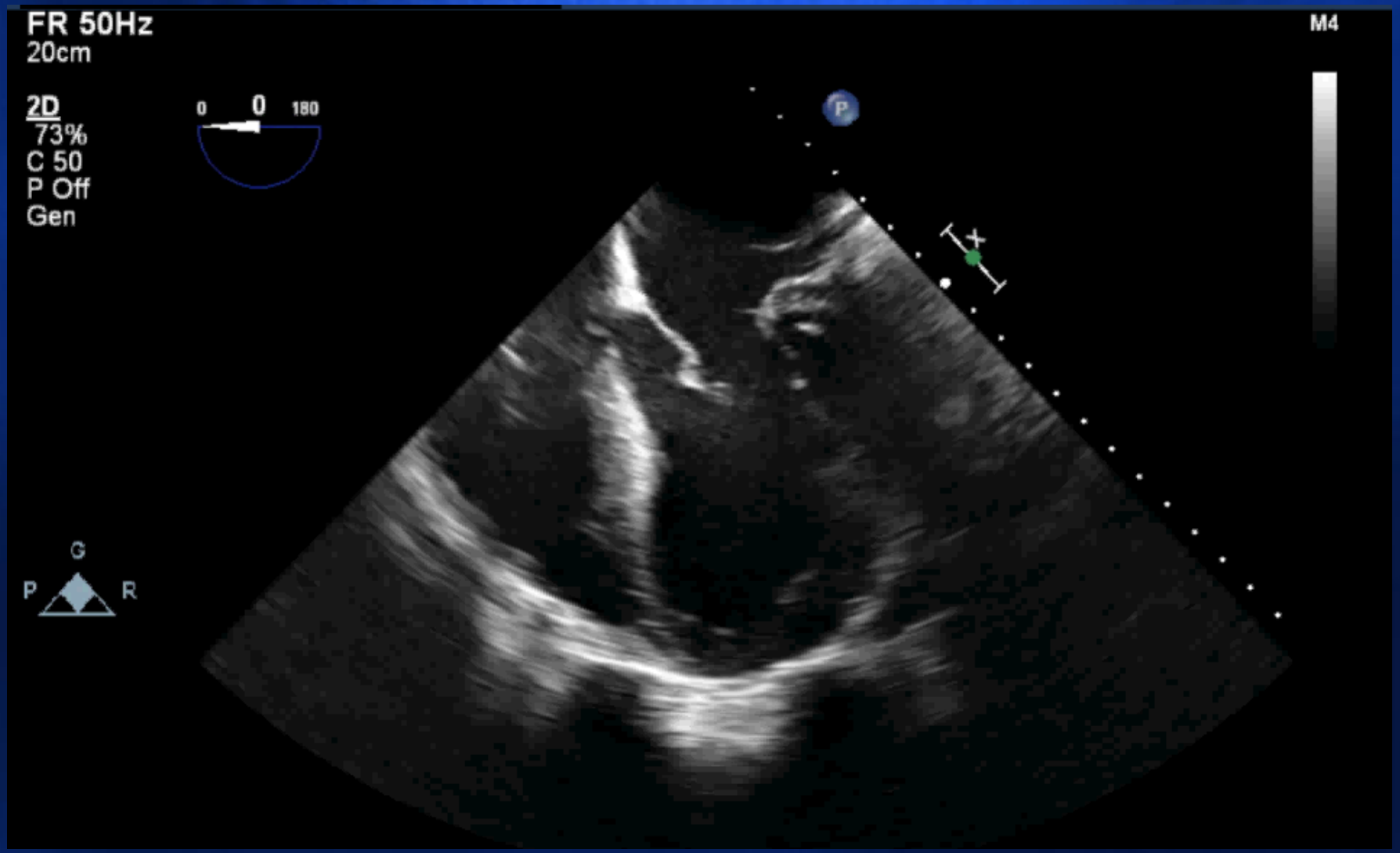


Case

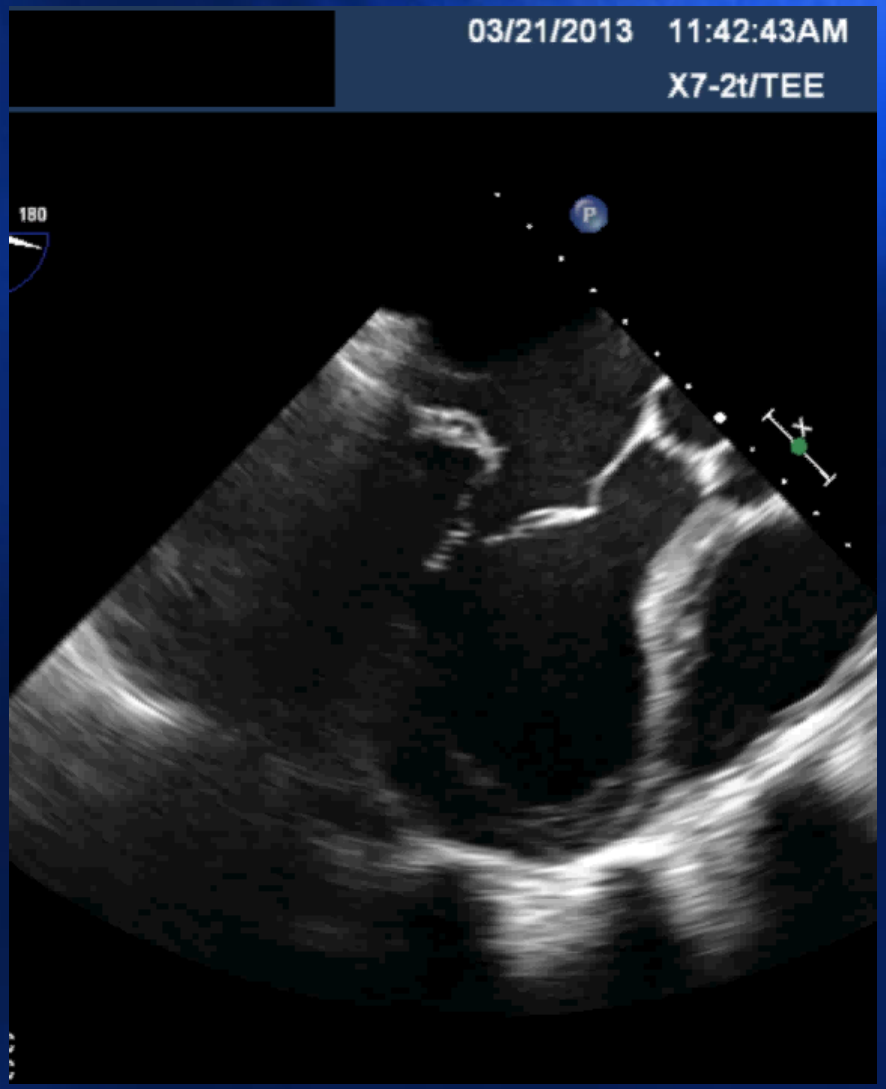
- 79 yo male
- “Ischemic MR” with multivessel CAD
- TEE

What Classification is this?

Case



Case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X7-2t/TEE
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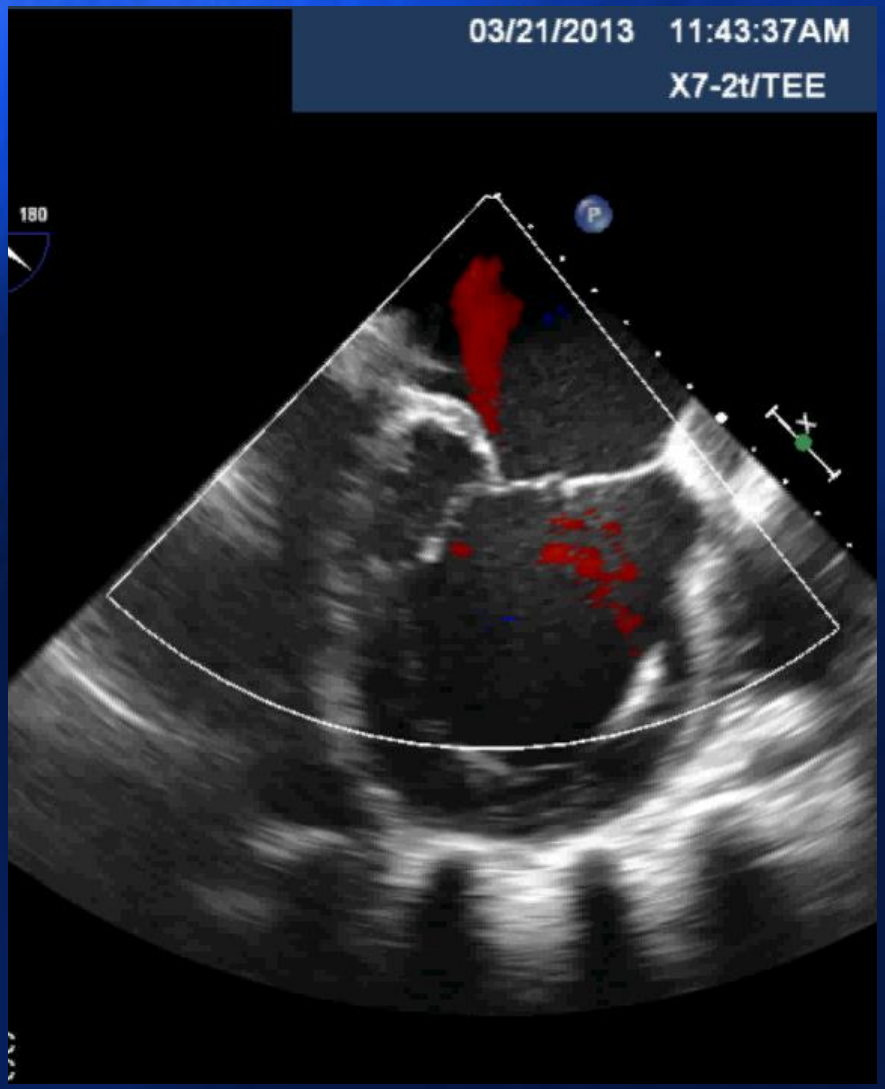
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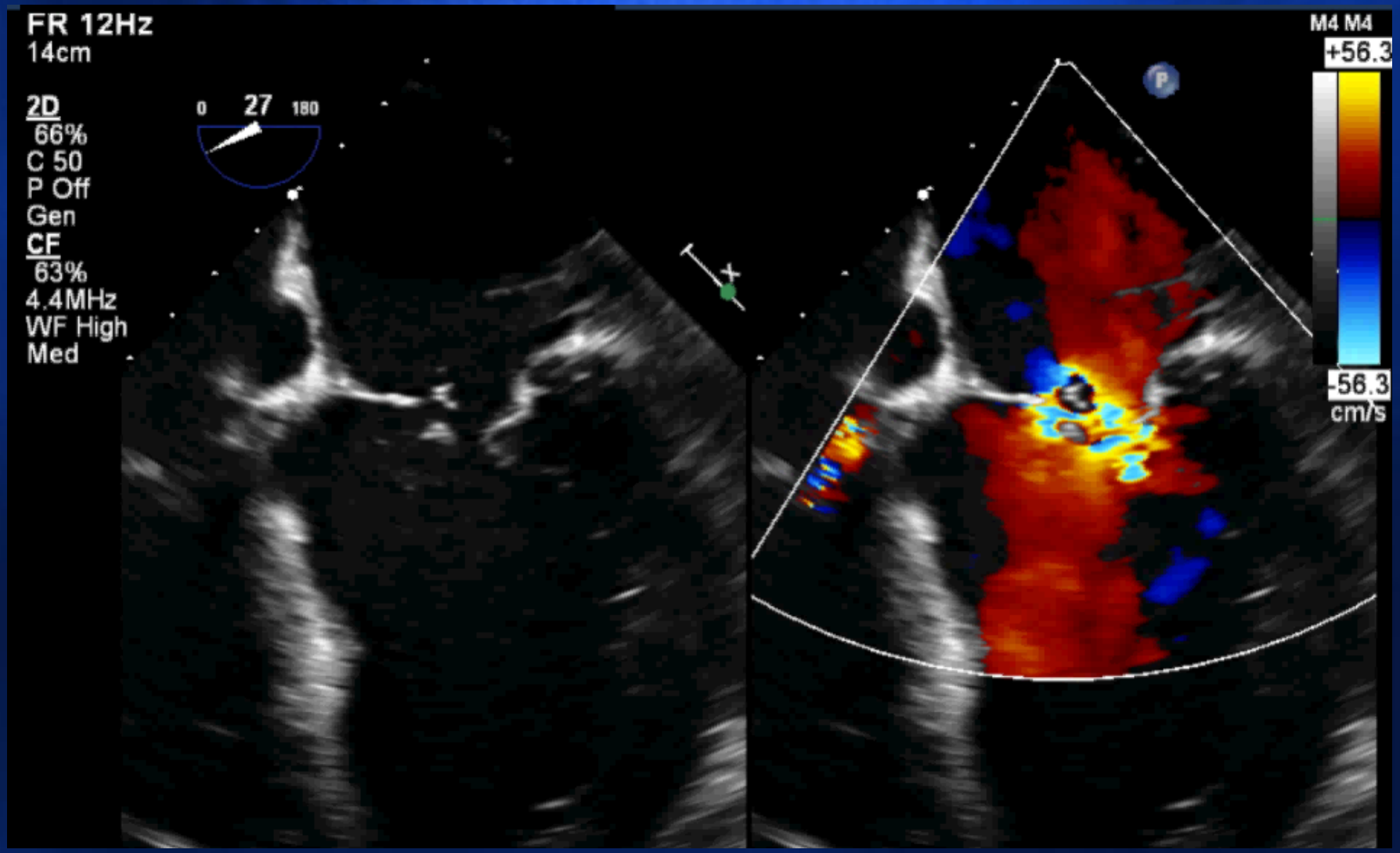
Case


FR 12Hz
14cm
2D
66%
C 50
P Off
Gen
CF
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4.4MHz
WF High
Med
0
27
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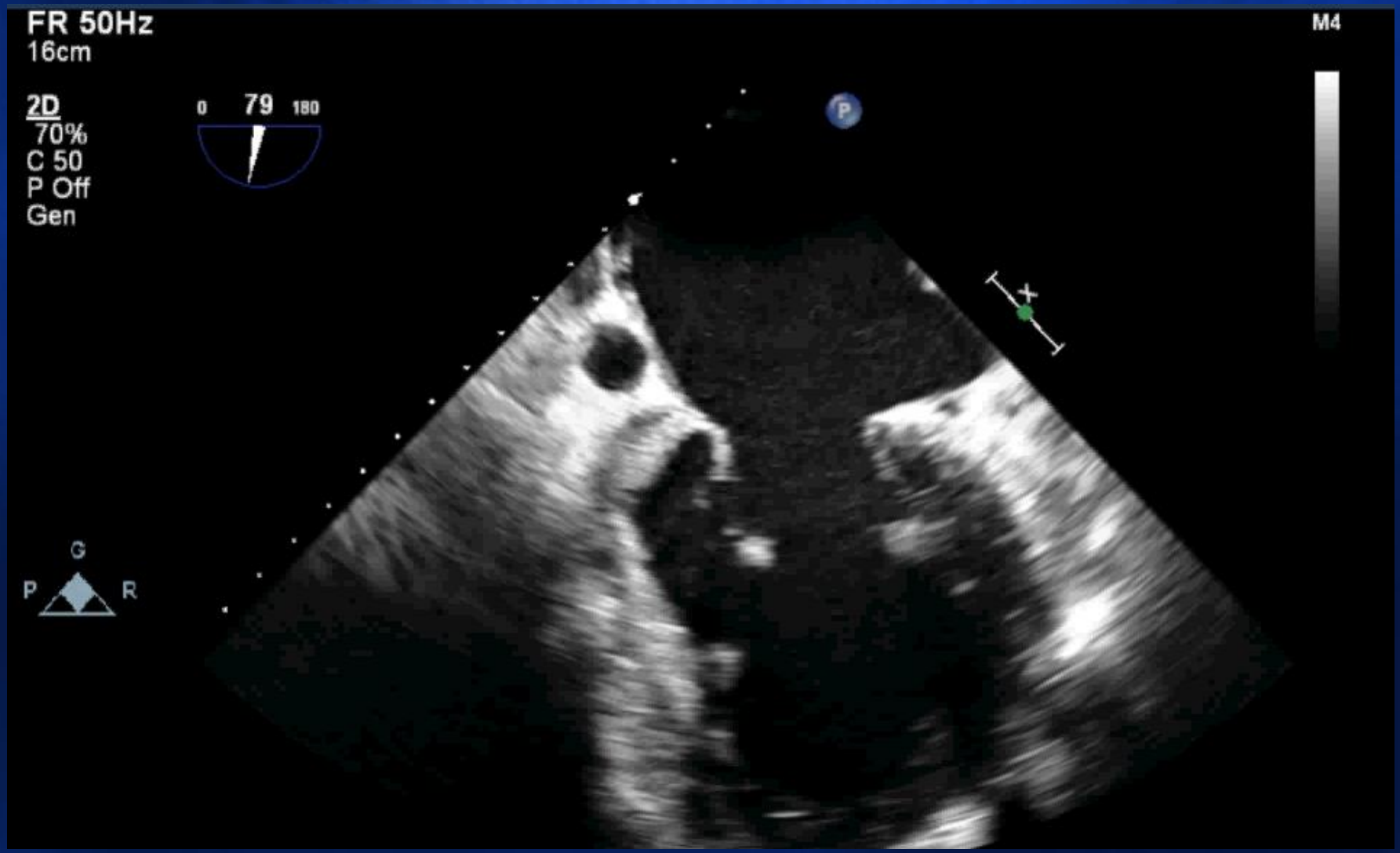
M4 M4
+56.3
-56.3
cm/s

Case



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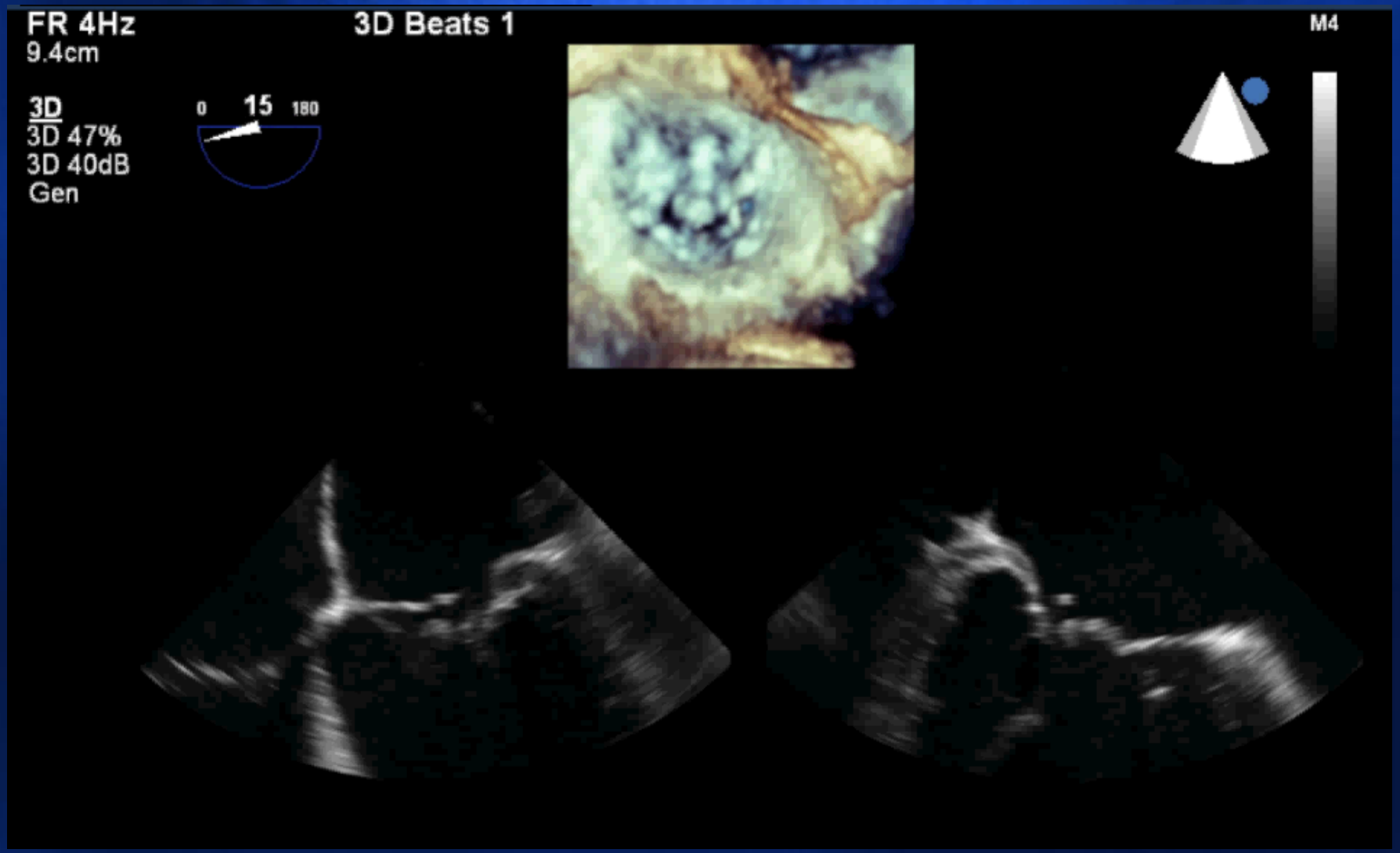


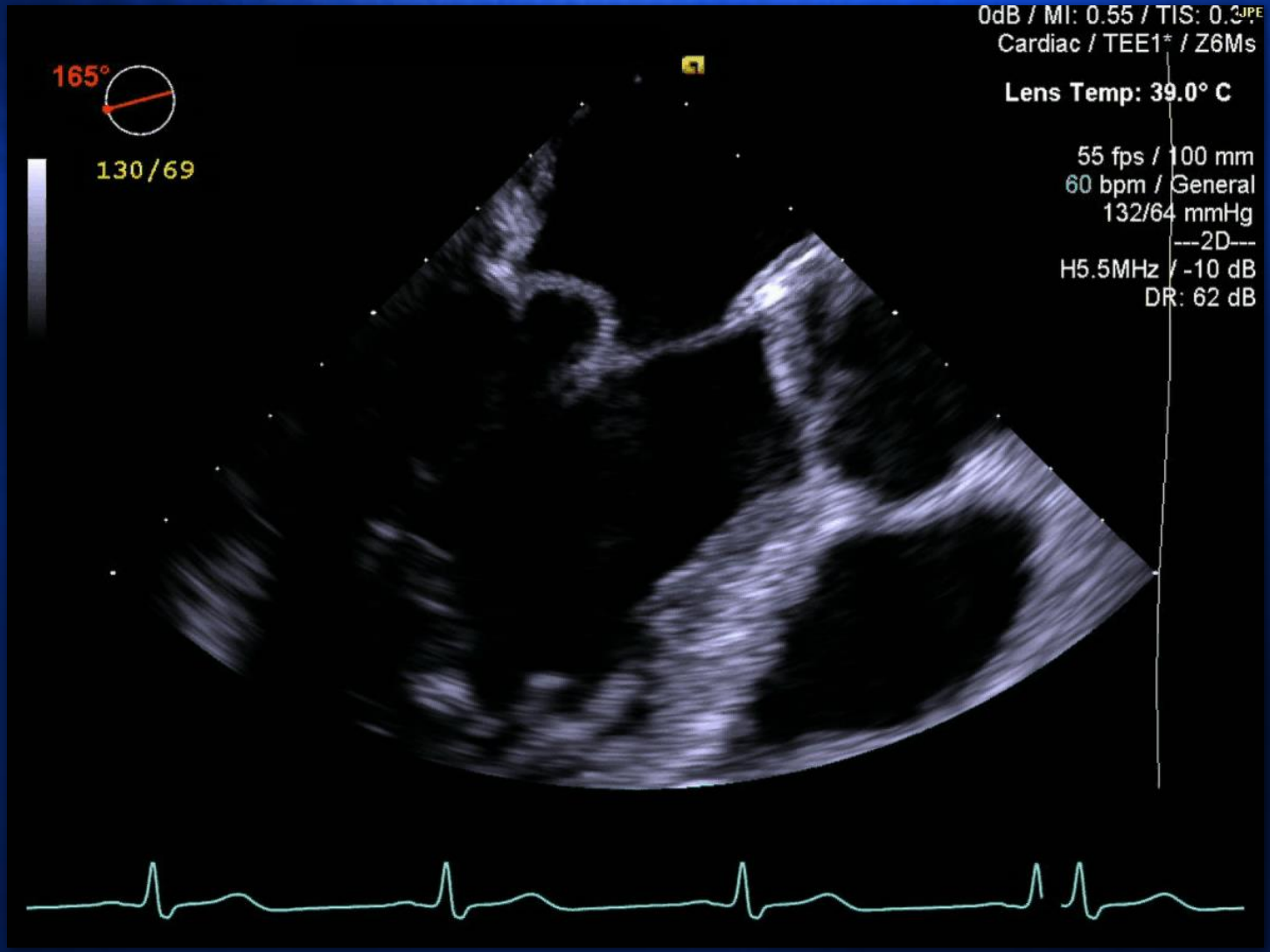
The Dr Mike and Dr Randy Show

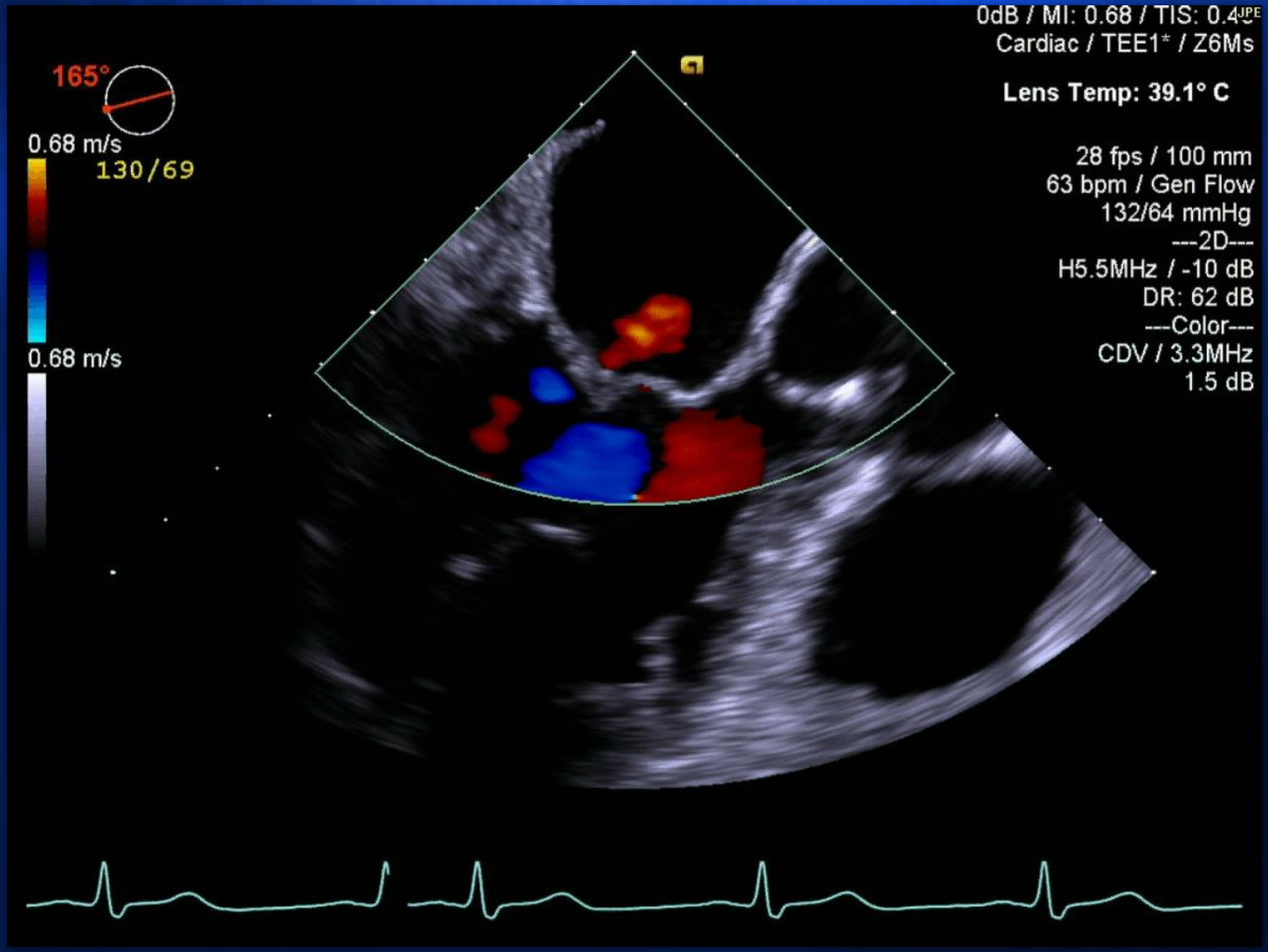
- Primary Vs Secondary MR

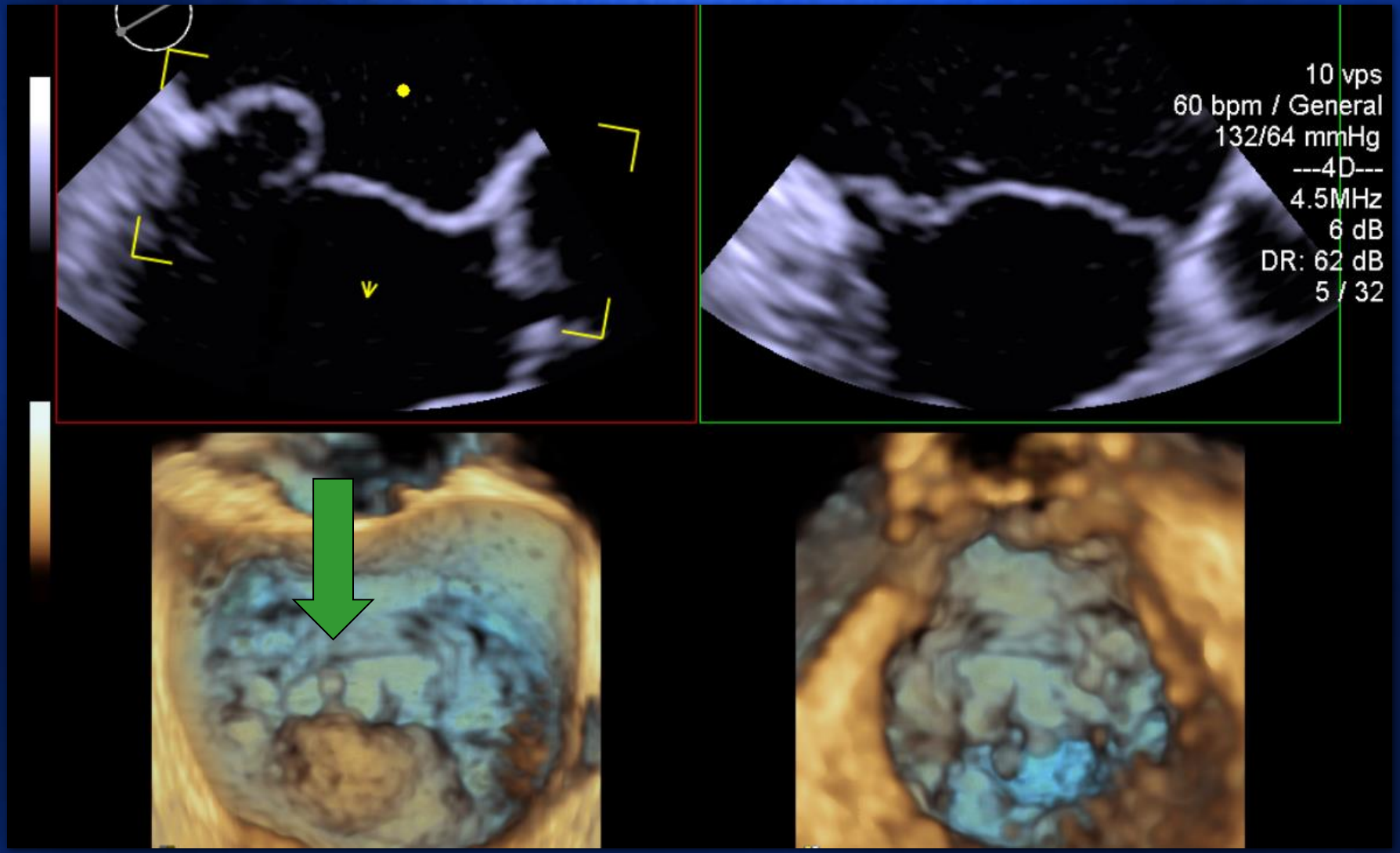
  Advanced Imaging for diagnosis,directing and assessing Treatments
- Defining Risks-Fraility etc
- Medical vs SurgicalTreatment in 1 vs 2 MR
- Surgical- Transcatheter Treatment:

  Primary MR-including high risk

  Secondary MR
- The FUTURE


0dB / MI: 0.55 / TIS: 0.3
Cardiac / TEE1* / Z6Ms
Lens Temp: 39.0° C
55 fps / 100 mm
60 bpm / General
132/64 mmHg
---2D---
H5.5MHz / -10 dB
DR: 62 dB
165°
130/69


0dB / MI: 0.68 / TIS: 0.4
Cardiac / TEE1* / Z6Ms
Lens Temp: 39.1° C
28 fps / 100 mm
63 bpm / Gen Flow
132/64 mmHg
---2D---
H5.5MHz / -10 dB
DR: 62 dB
---Color---
CDV / 3.3MHz
1.5 dB
165°
0.68 m/s
130/69
0.68 m/s


10 vps
60 bpm / General
132/64 mmHg
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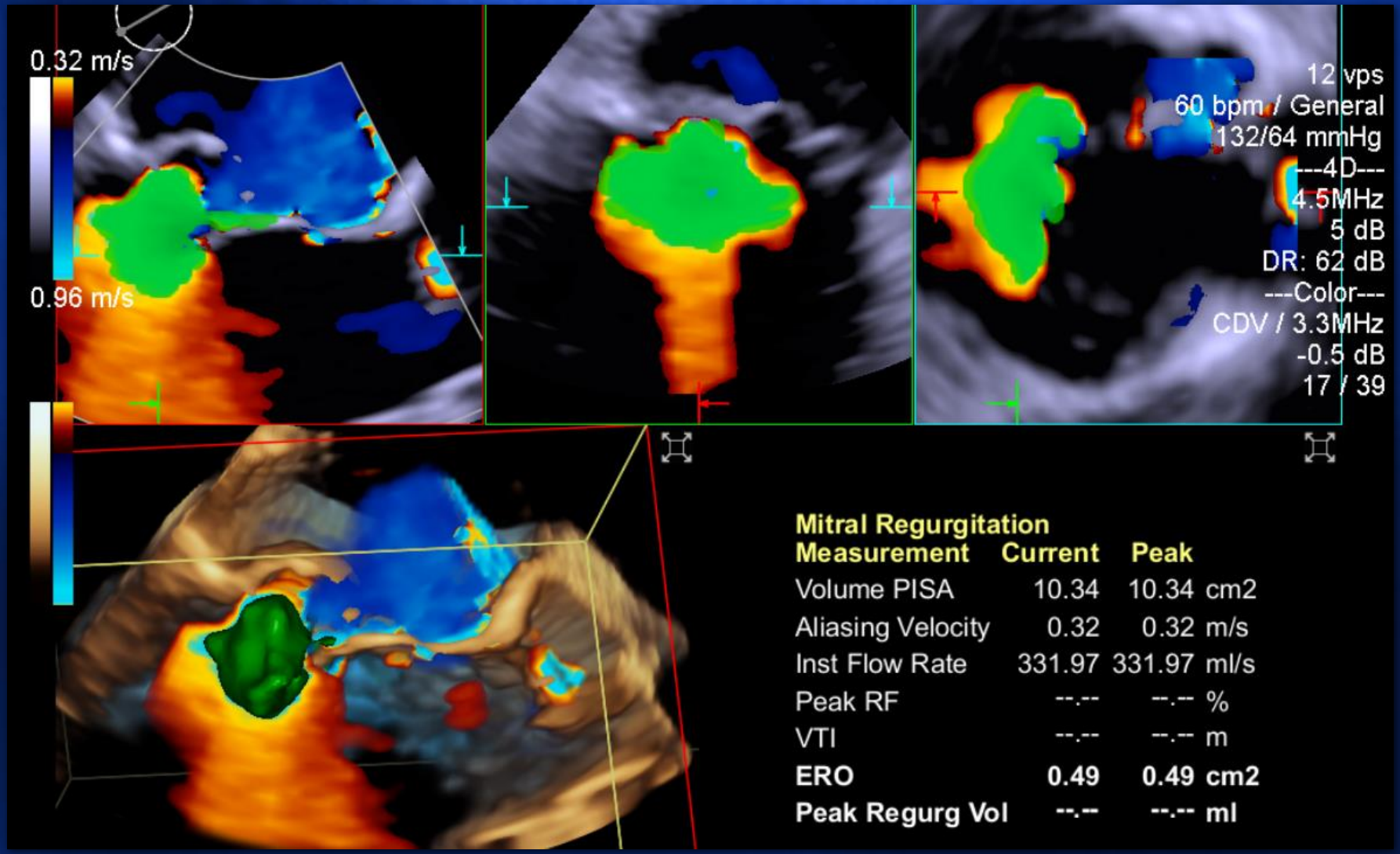
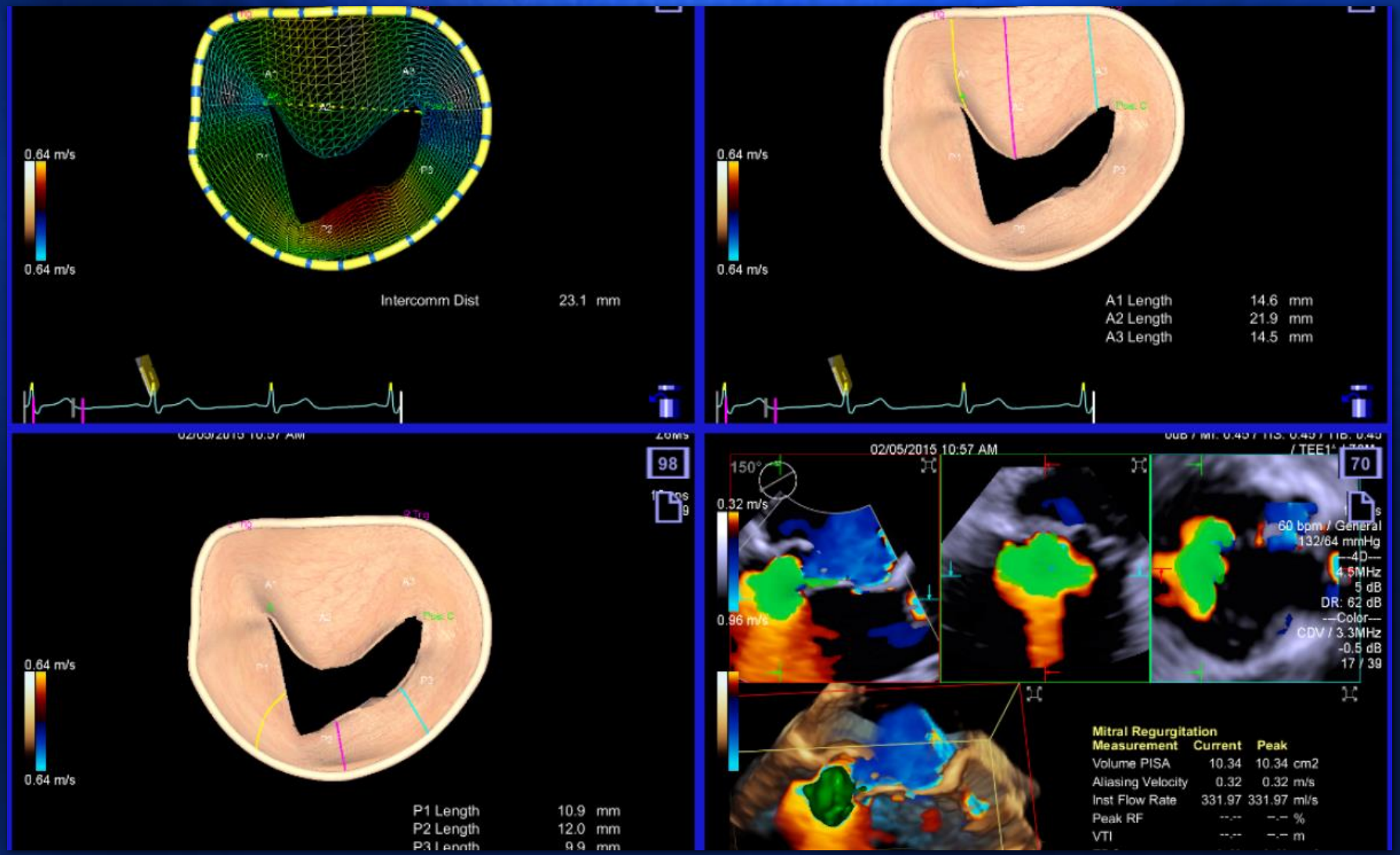
4.5MHz
6 dB
DR: 62 dB
5 / 32

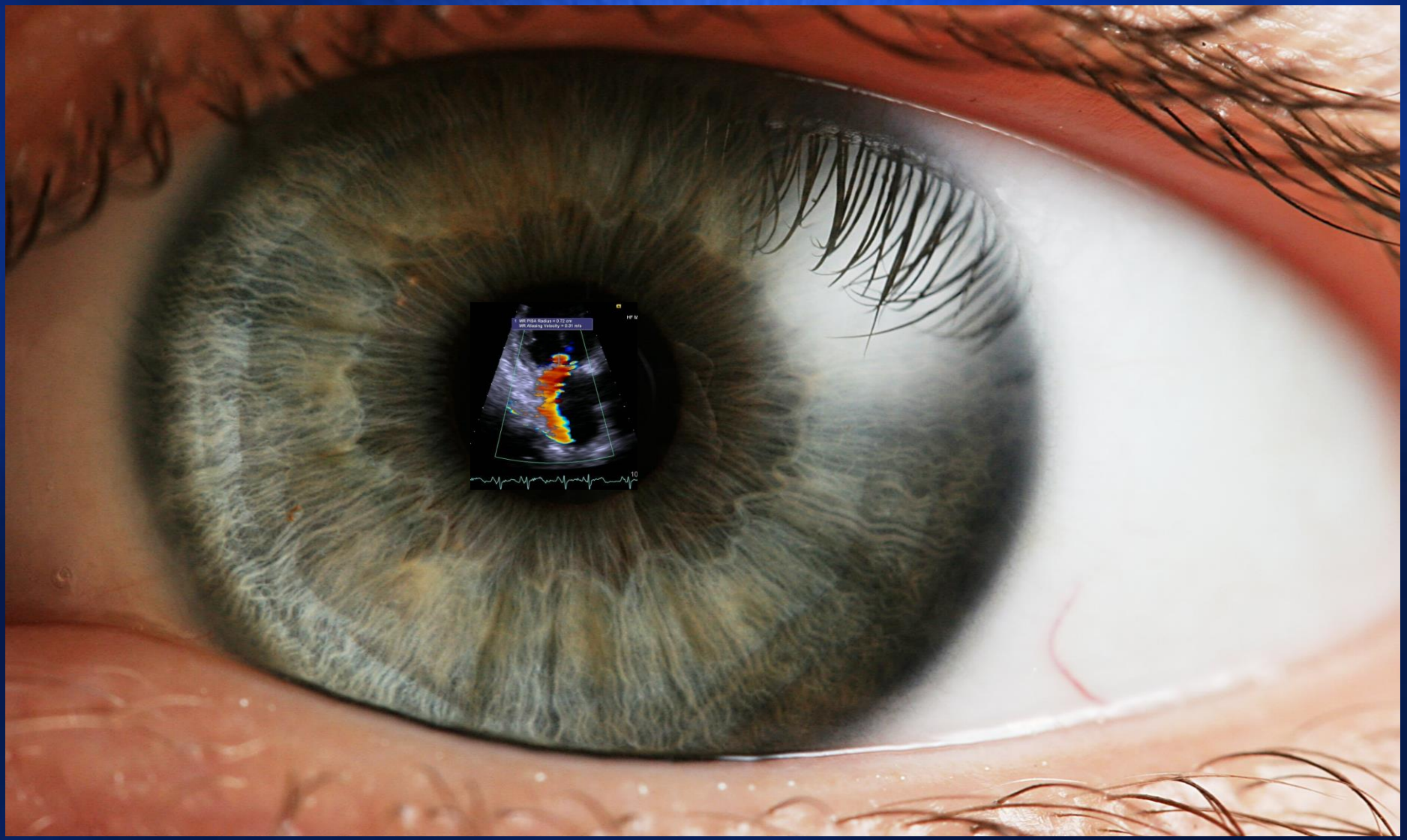
Volumetric PISA and ERO



Composite


0.64 m/s
0.64 m/s
Intercomm Dist 23.1 mm
0.64 m/s
0.64 m/s
A1 Length 14.6 mm
A2 Length 21.9 mm
A3 Length 14.5 mm
98
0.64 m/s
0.64 m/s
P1 Length 10.9 mm
P2 Length 12.0 mm
02/05/2015 10:57 AM
70
150°
0.32 m/s
0.96 m/s
60 bpm / General
132/64 mmHg
4.5MHz
5 dB
DR: 62 dB
CDV / 3.3MHz
-0.5 dB
Mitral Regurgitation
Measurement Current Peak
Volume PISA 10.34 10.34 cm2
Aliasing Velocity 0.32 0.32 m/s
Inst Flow Rate 331.97 331.97 ml/s
Peak RF --.-- --.-- %
VTI --.-- --.-- m

‘Quantitate MR’ – Don’t Eyeball It!



Severe Primary MR
2014 AHA/ACC Guidelines

- Central jet MR > 40% of LA
- Holosystolic eccentric MR jet
- Vena contracta $\geq$ 0.7 cm
- Regurgitant Volume $\geq$ 60 ml
- Regurgitant Fraction $\geq$ 50%
- ERO $\geq$ 0.40 cm^2

Key Findings

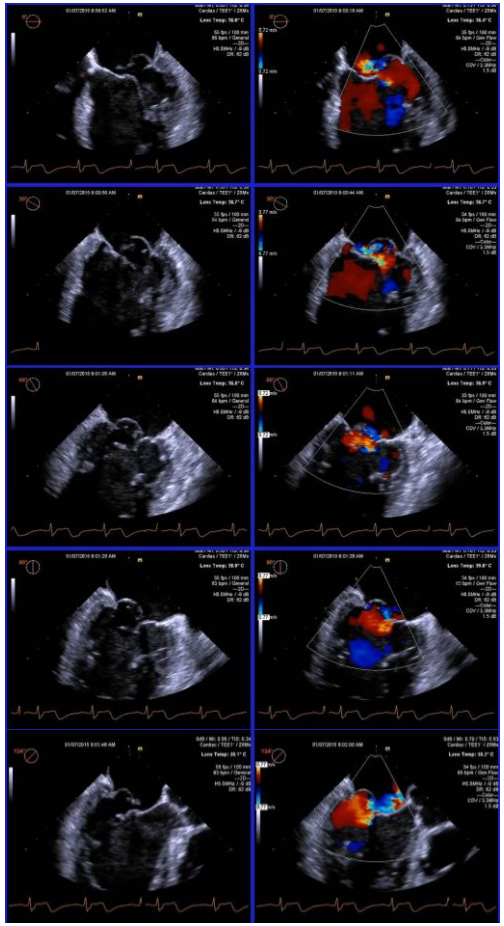
Echocardiography Components Assessed and Reported, cont.

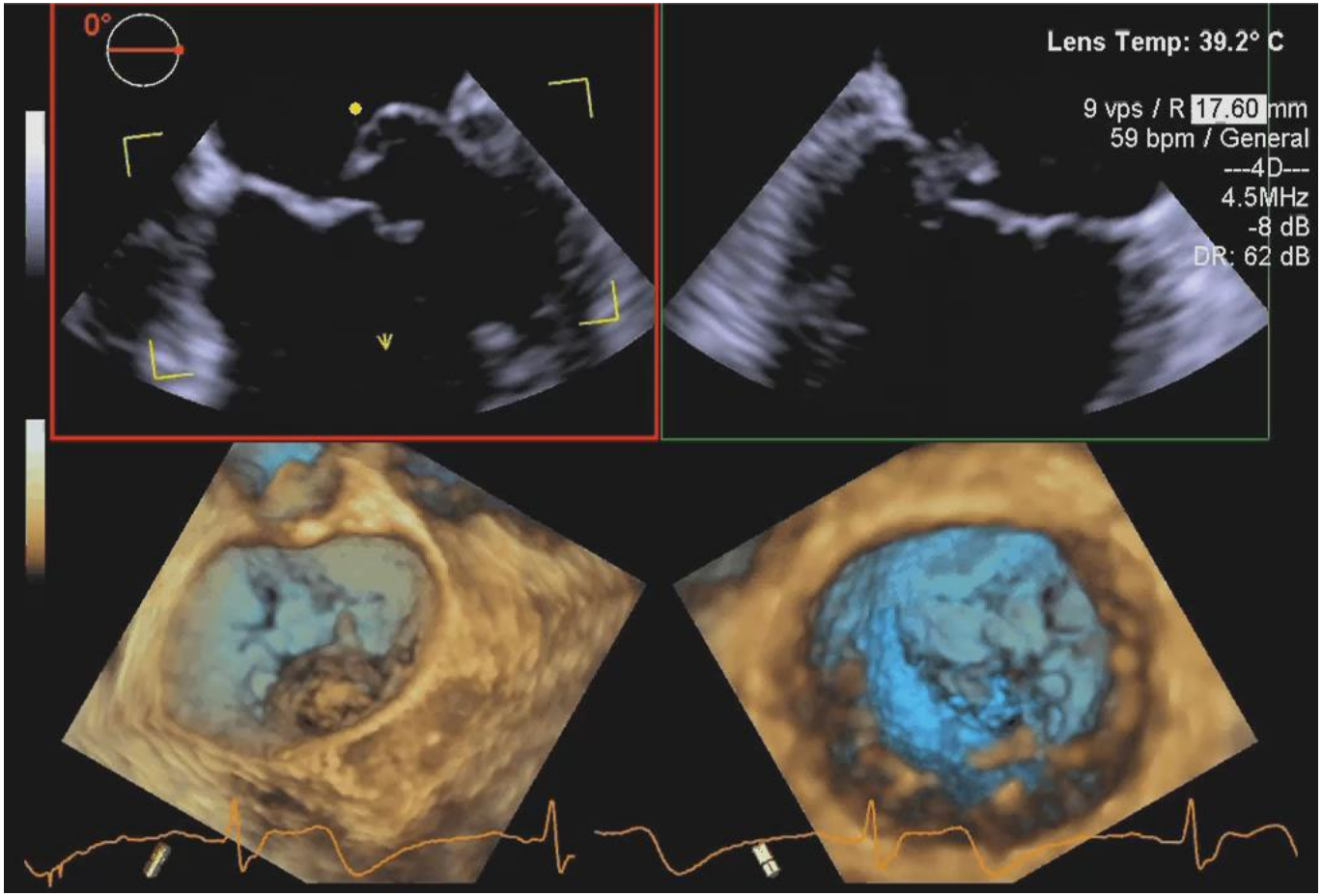
- **Quantitative Assessment:**
  - Physicians responses in each survey indicate quantitative assessment inconsistently performed in echocardiography evaluation of patients with MR.
  - Nearly 10% of respondents on Clinical Cardiology and Subspecialist surveys reported that EROA, regurgitant volume, and regurgitant fraction were "Never" reported
  - Suggests significant barriers to accessing infrastructure and skills needed for quantitative assessment
  - Compared to imaging cardiologists, small set of Clinical Cardiologists who read high volume of echocardiograms notably less likely to include vena contracta or EROA measurements in their assessments.

- **Longitudinal strain**–an emerging echocardiogram parameter that may facilitate earlier detection of left ventricular dysfunction.
  - More than 50% of respondents indicate this parameter "Never" assessed or reported
  - Suggests expertise and infrastructure (processes, technique, technology) needed to assess and

- 60 year old man
- Chronic severe MR
- Degenerative mitral valve
- Normal LV EF 55-60%
- Increasing dyspnea

2-D TEE and Real-Time Volume TEE

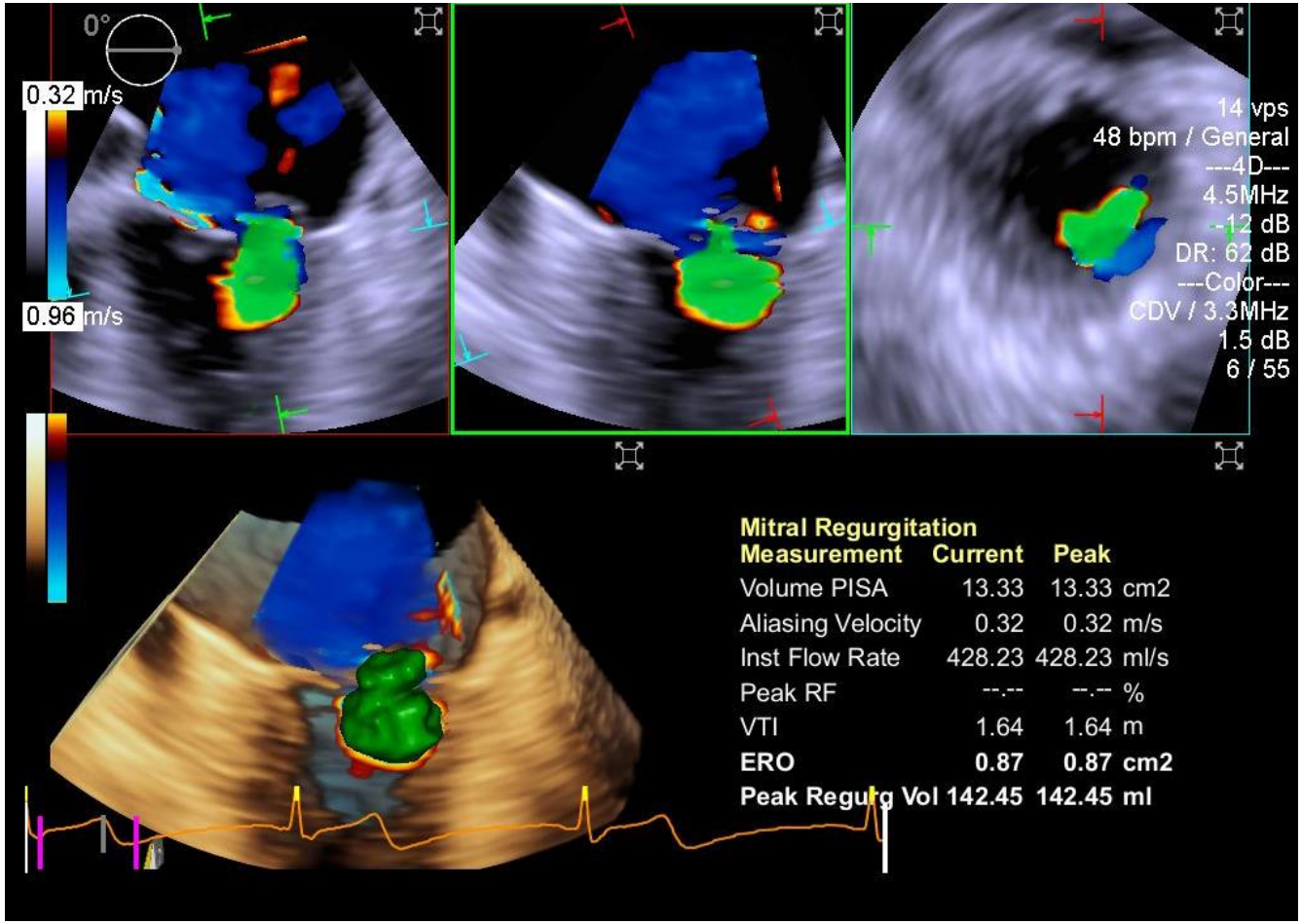




Piedmont HEART

Real-Time Volume Color Doppler TEE

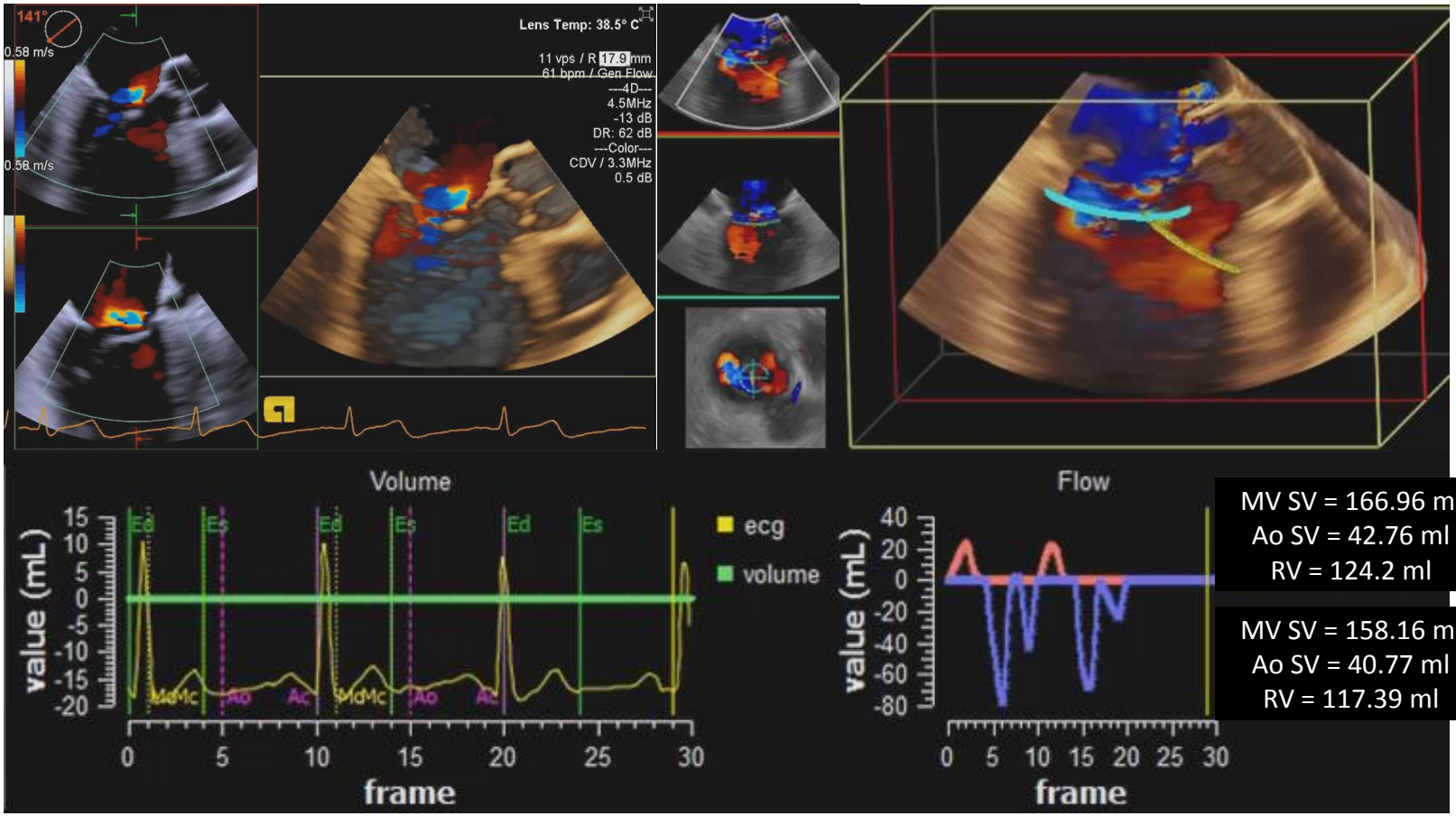
Automated 3-D PISA EROA



Piedmont HEART

Real-Time Volume Color Doppler TEE

Automated Regurgitant Volume

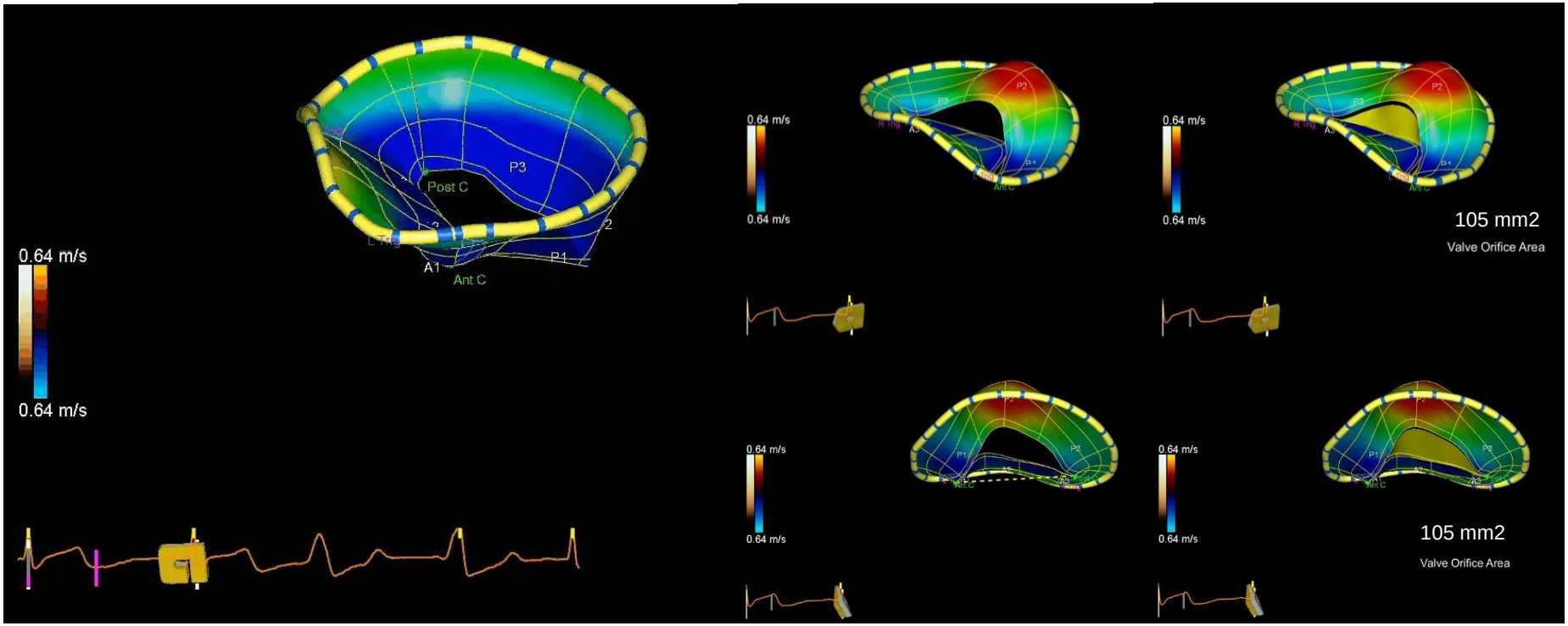


3-D PISA RV = 142.45 ml

Piedmont HEART

Automated Modeling of MV Anatomy

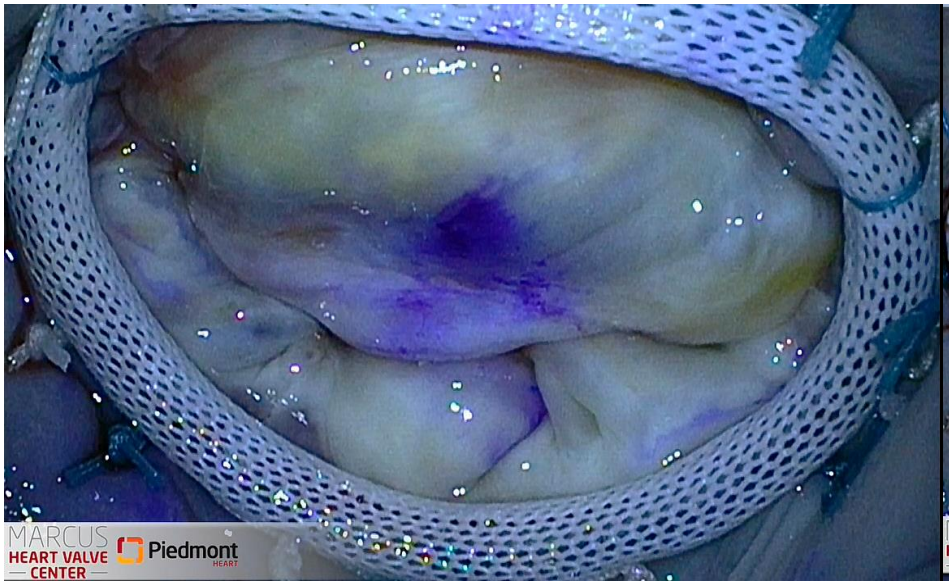
3-D Anatomic ERO

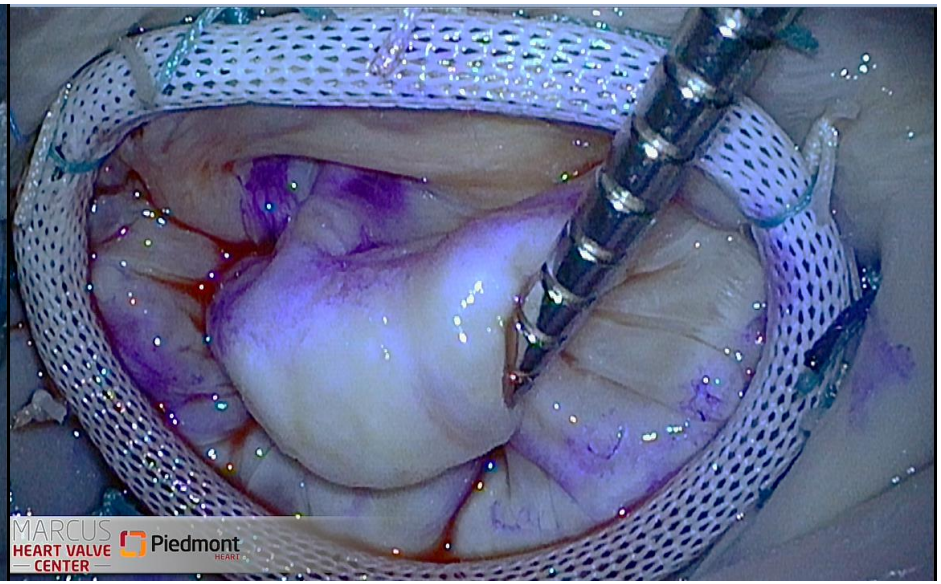


3-D PISA EROA = 0.87 cm^2

Piedmont HEART

Surgical Anatomy
Post- Repair





Piedmont
HEART

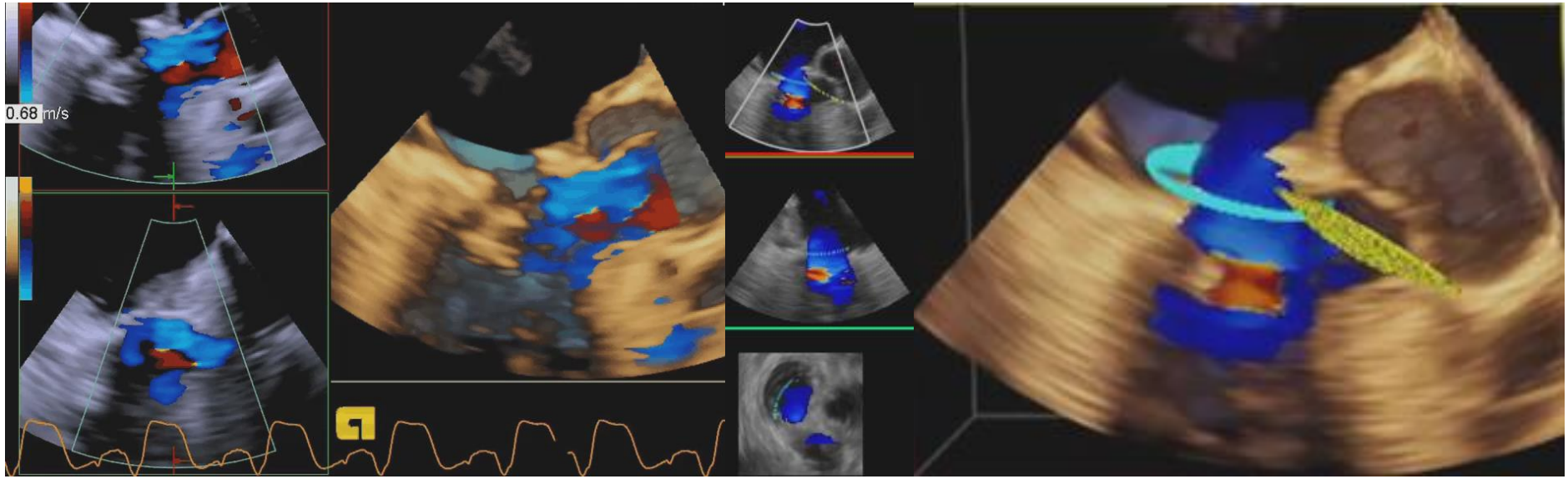
2-D TEE

Post- Repair MR

Piedmont HEART

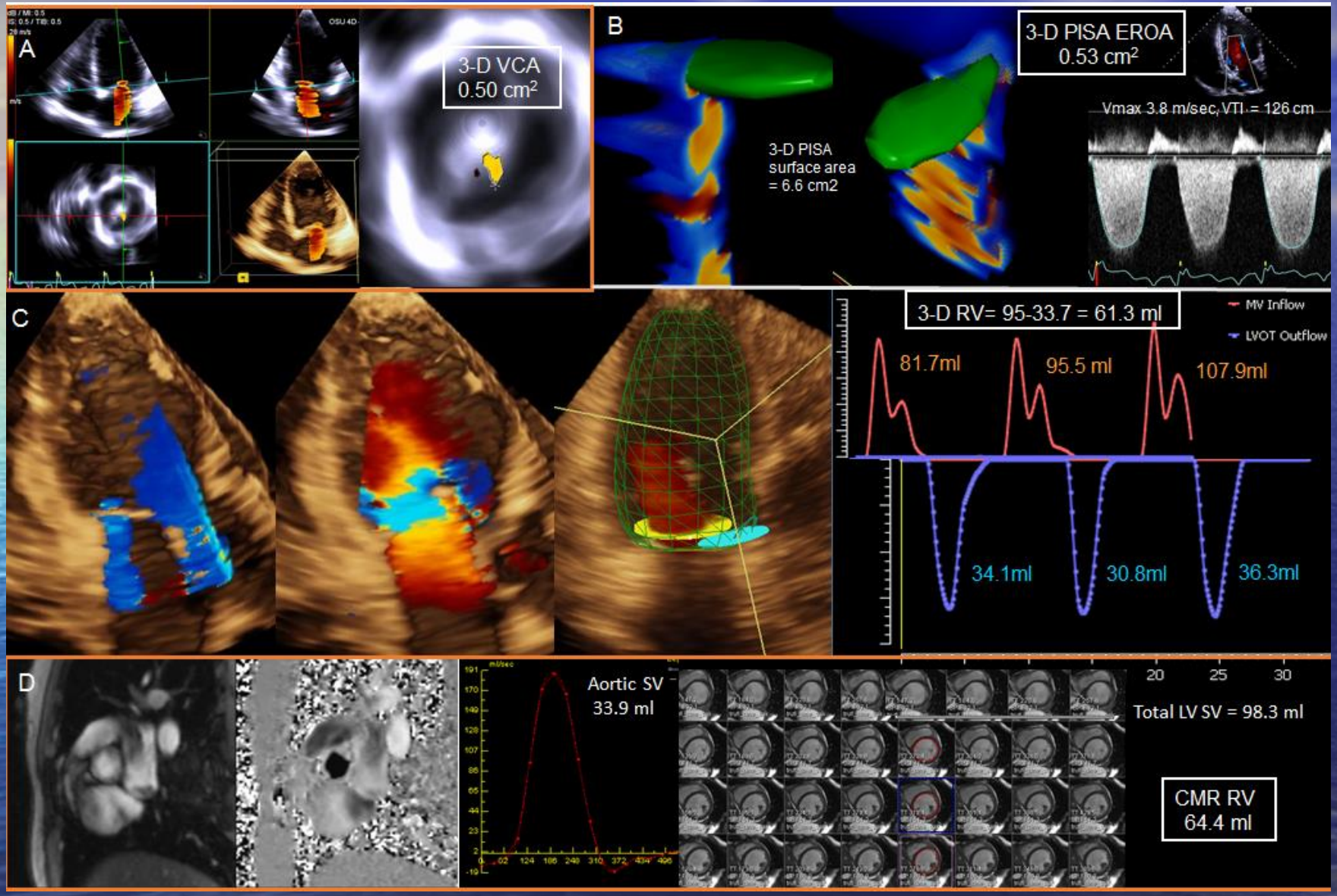
Real-Time Volume Color Doppler TEE

Automated Regurgitant Volume



MV SV = 36.76 ml
Ao SV = 32. 1 ml

Piedmont HEART


A
3-D VCA
0.50 cm²
B
3-D PISA EROA
0.53 cm²
3-D PISA
surface area
= 6.6 cm2
Vmax 3.8 m/sec, VTI = 126 cm
C
3-D RV= 95-33.7 = 61.3 ml
MV Inflow
LVOT Outflow
81.7ml
95.5 ml
107.9ml
34.1ml
30.8ml
36.3ml
D
Aortic SV
33.9 ml
Total LV SV = 98.3 ml
CMR RV
64.4 ml

Severe Secondary MR – 2014 AHA/ACC Guidelines

- ERO $\geq$ 0.20 cm^2
  - PISA by 2D-TEE underestimates true ERO – crescentic shape
- Regurgitant Volume $\geq$ 30 ml
- Regurgitant Fraction $\geq$ 50%

Ischemic

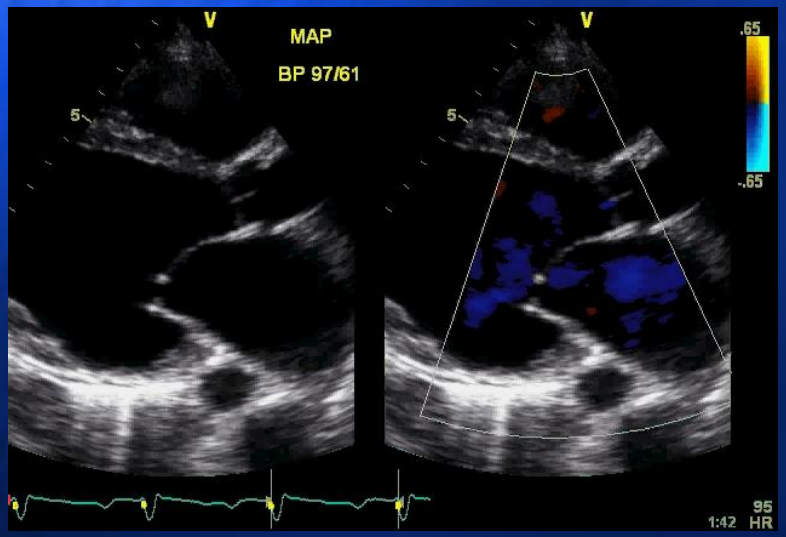
Quantitation of MR severity in 2o MR is challenging

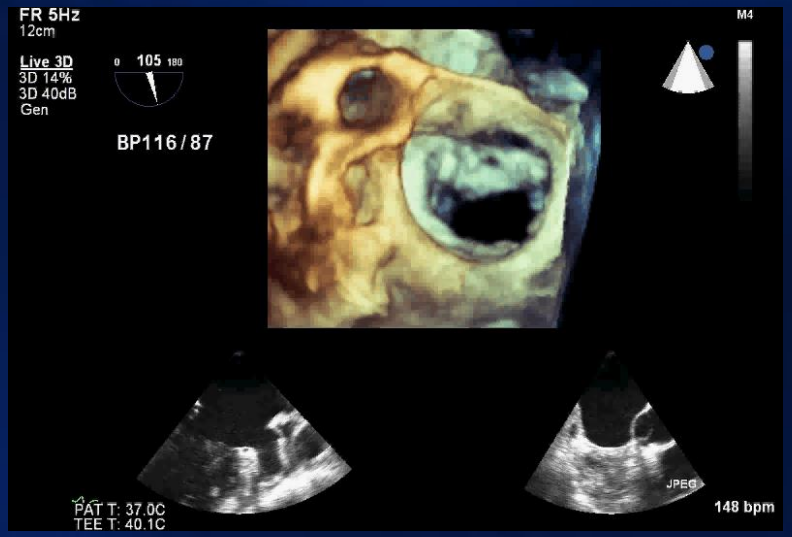
-Because of low flow state

-Regurgitant orifice is crescent-shaped along line of coaptation

-Results in underestimation of EROA & vena contracta width

-Regurgitant orifice changes shape





REVIEW TOPIC OF THE WEEK

Defining "Severe" Secondary Mitral Regurgitation

Emphasizing an Integrated Approach

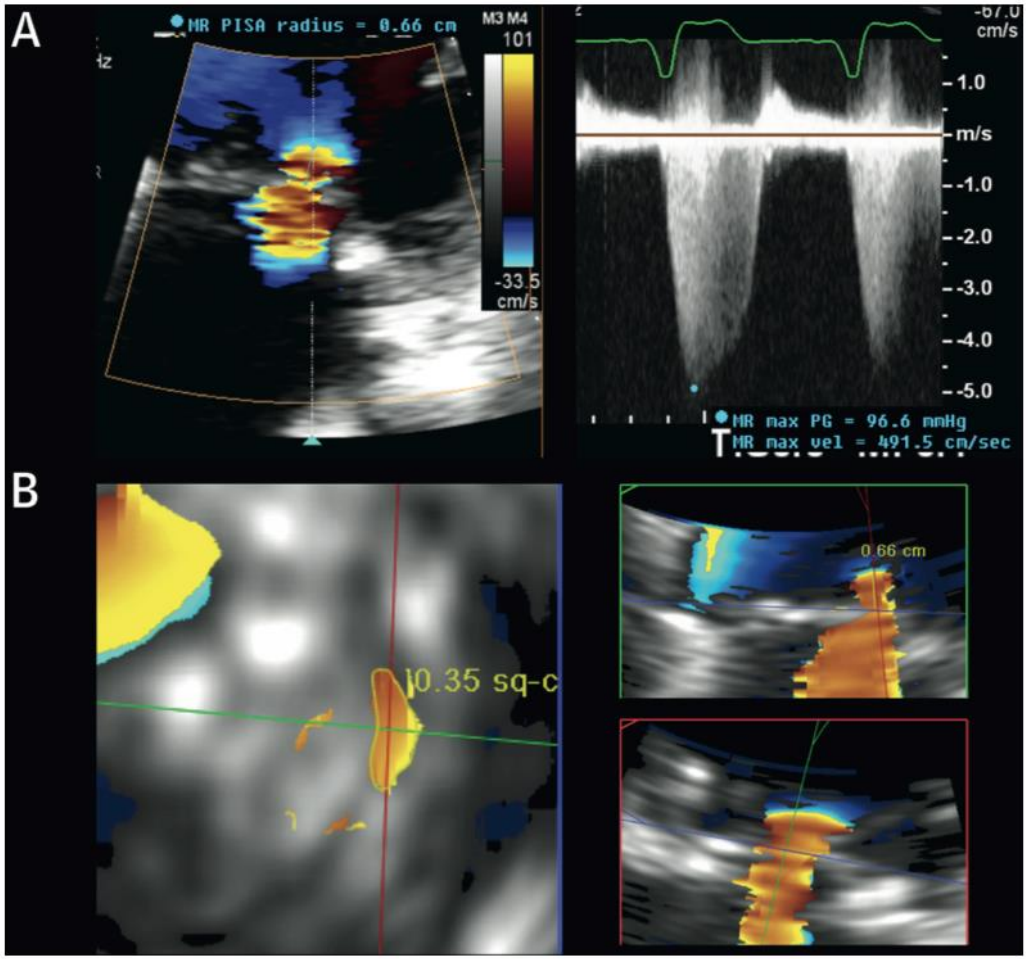
Paul A. Grayburn, MD,*† Blasé Carabello, MD,‡ Judy Hung, MD,§ Linda D. Gillam, MD,‖ David Liang, MD,¶ Michael J. Mack, MD,# Patrick M. McCarthy, MD,** D. Craig Miller, MD,†† Alfredo Trento, MD,‡‡ Robert J. Siegel, MD‡‡

ABSTRACT

Secondary mitral regurgitation (MR) is associated with poor outcomes, but its correction does not reverse the underlying left ventricular (LV) pathology or improve the prognosis. The recently published American Heart Association/American College of Cardiology guidelines on valvular heart disease generated considerable controversy by revising the definition of severe secondary MR from an effective regurgitant orifice area (EROA) of 0.4 to 0.2 cm^2, and from a regurgitant volume (RVol) of 60 to 30 ml. This paper reviews hydrodynamic determinants of MR severity, showing that EROA and RVol values associated with severe MR depend on LV volume. This explains disparities in the evidence associating a lower EROA threshold with suboptimal survival. Redefining MR severity purely on EROA or RVol may cause significant clinical problems. As the guidelines emphasize, defining severe MR requires careful integration of all echocardiographic and clinical data, as measurement of EROA is imprecise and poorly reproducible. (J Am Coll Cardiol 2014;64:2792–801)

Underestimation of EROA in 2nd MR

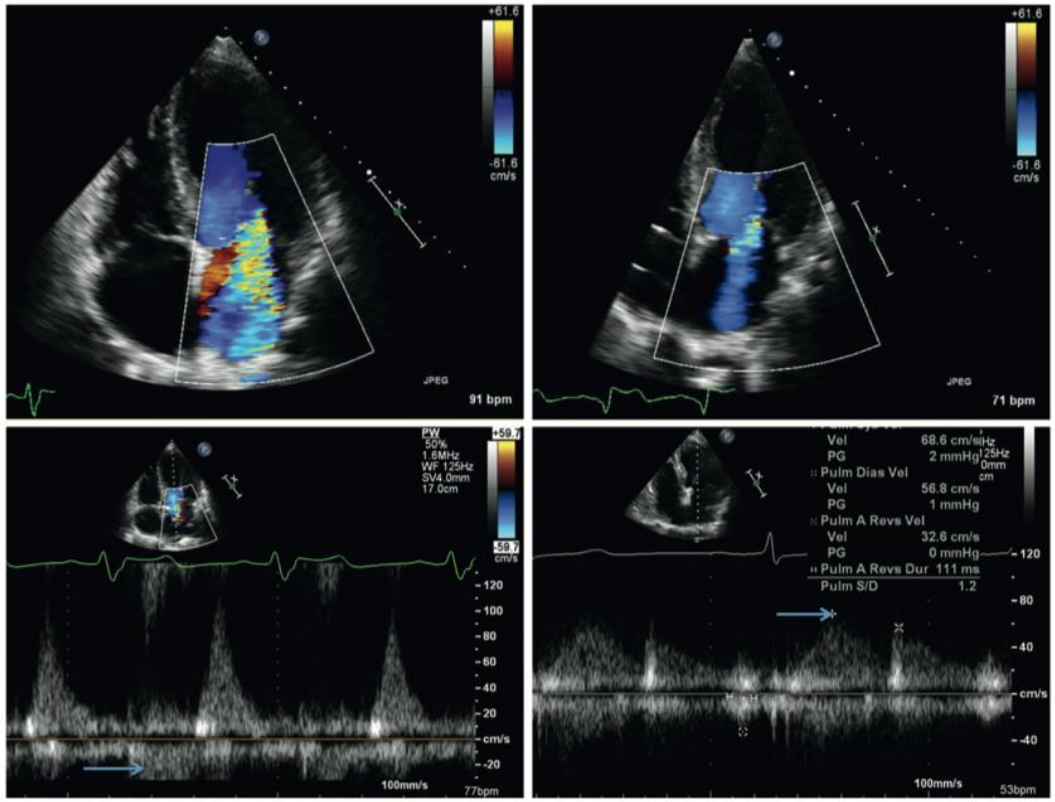
FIGURE 3 Example of EROA Underestimation by PISA Due to Crescentic Orifice Shape



(A) Proximal isovelocity surface area (PISA) radius **(left)** and continuous-wave Doppler **(right)** resulting in a calculated EROA of 0.18 cm^2. **(B)** Direct measurement of the EROA in the same patient at 0.35 cm^2 by 3D color Doppler **(left)**. EROA is crescentic on 3D imaging, with its major and minor axes shown at right. Abbreviations as in Figure 1.

Variabilty of 2nd MR with Medical RX

FIGURE 5 4-Chamber Echocardiographic Images From a Patient With Severe Secondary MR



Baseline **(left)** and 1 month later, after optimizing medical therapy **(right)**. **(Top)** Changes in color-Doppler mitral regurgitation (MR) jet. **(Bottom)** Change from systolic flow reversal **(blue arrow, left)** to normal **(blue arrow, right)**. This case illustrates secondary MR's dynamic nature, which improves or worsens substantially depending on volume status, blood pressure, heart failure exacerbation, ischemia, or medication changes.

Defining "Severe" Secondary Mitral Regurgitation

Emphasizing an Integrated Approach

Paul A. Grayburn, MD,*† Blasé Carabello, MD,‡ Judy Hung, MD,§ Linda D. Gillam, MD,‖ David Liang, MD,¶ Michael J. Mack, MD,# Patrick M. McCarthy, MD,** D. Craig Miller, MD,†† Alfredo Trento, MD,‡‡ Robert J. Siegel, MD‡‡

Specifically, we propose the following:

1. The integrative approach using multiple echocardiographic and clinical variables should continue to be used to grade secondary MR severity;
2. The new definition of severe secondary MR with RVol ≥30 ml and EROA ≥0.2 cm^2 depends on LV size and on the LV-LA pressure gradient and must be used in that context;
3. The quantification method must be specified (2D PISA, 3D planimetry, volumetric);
4. Classification of a patient as having severe secondary MR (Stage C or D) should be deferred until guideline-directed medical therapy, resynchronization, and revascularization are optimized.

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EDITORIAL COMMENT

Current Assessment of Mitral Regurgitation

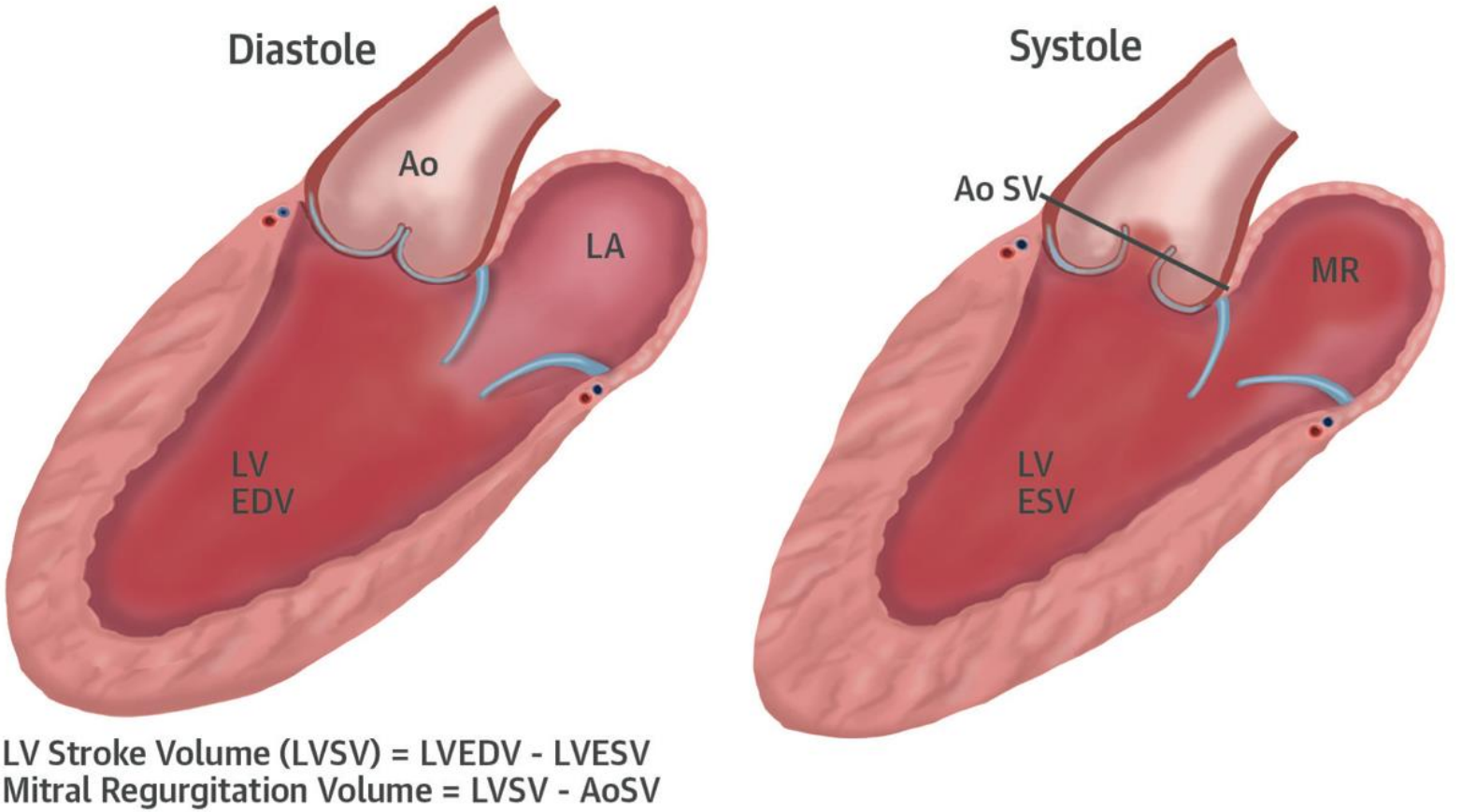
Not Making the Grade*

Saibal Kar, MD, Rahul Sharma, MD

Mitral regurgitation (MR) is a common valvular disorder affecting more than 2 million people in the United States (1). The etiology of MR can be divided into primary MR, caused by pathology of the valve apparatus, and secondary MR, a functional consequence of ventricular dysfunction. The clinical course of MR is generally insidious, and if left untreated, leads to heart failure

STudy), the MitraClip has shown less complete reduction of MR compared with the surgical arm. However, at 4 years, there was equivalent clinical benefit with evidence of favorable remodeling in both groups. It is quite possible that creation of a double orifice resulted in an overestimation of MR grade in the MitraClip arm (4). A further limitation of echocardiography is the significant degree of interob-

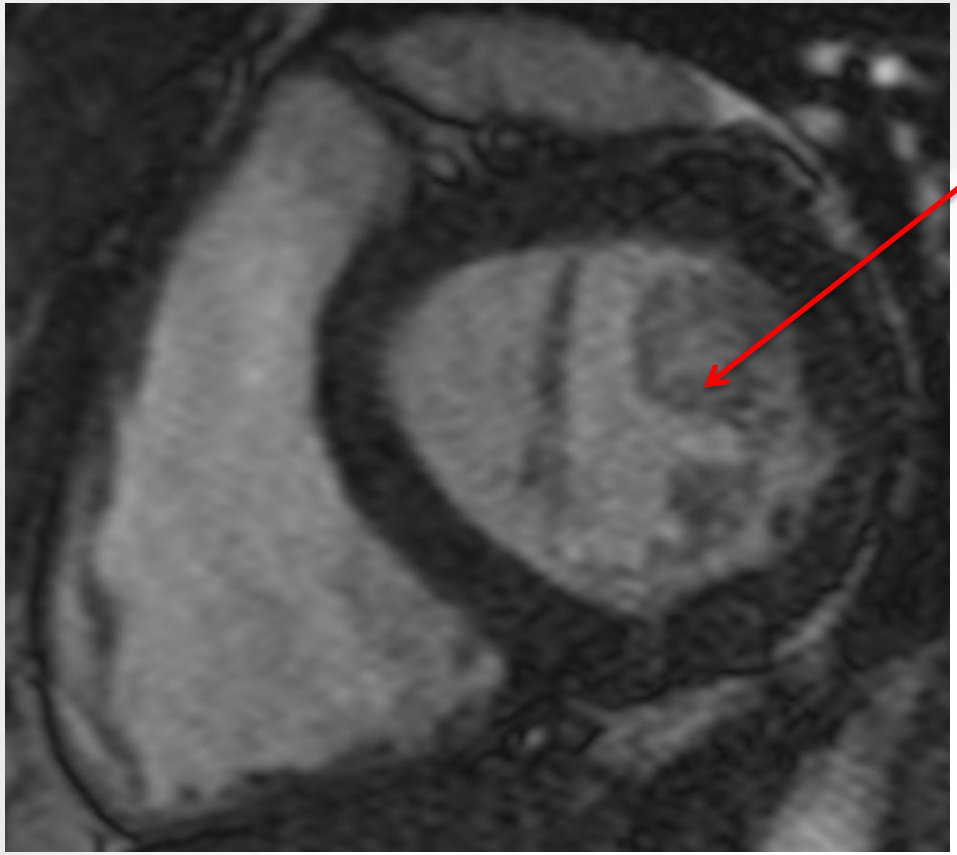
Regurgitant Volume by MRI



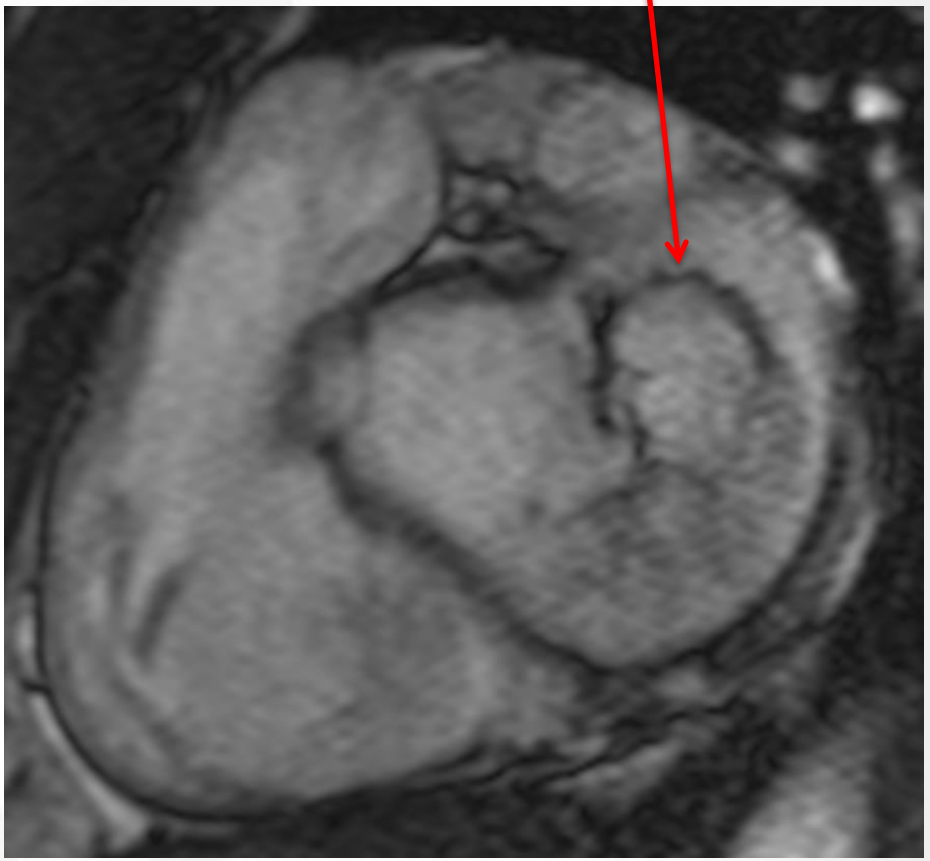
Example of the method used to calculate mitral regurgitant volume (see text for details). Ao = aorta; EDV = end-diastolic volume; ESV = end-systolic volume; LA = left atrium; LV = left ventricular; MR = mitral regurgitation; MRI = magnetic resonance imaging;

Diagnostic Imaging Assessment of MR-Clinically Available

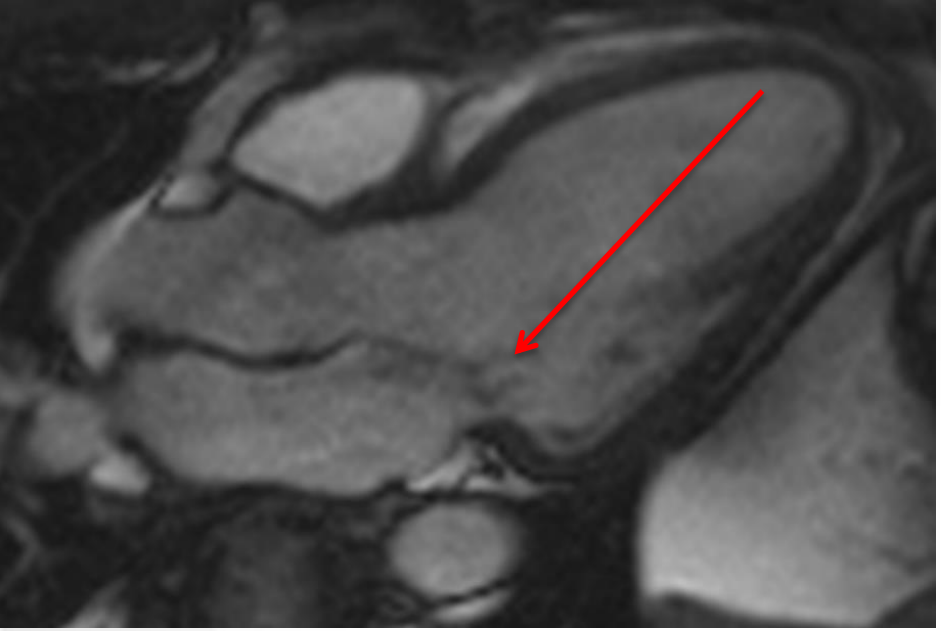
- Echo -Doppler
  - TTE-Rest and Exercise
  - TEE-2D-3D
- CT
- MRI

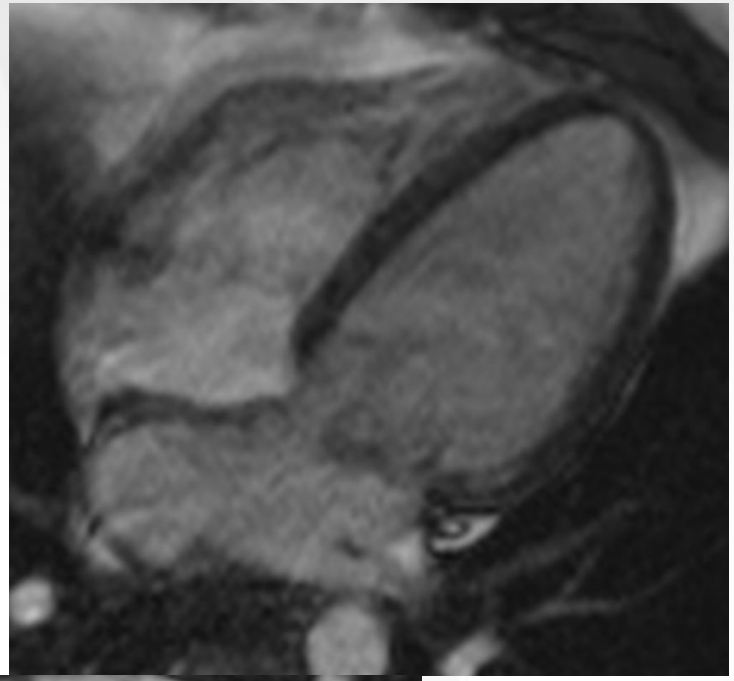


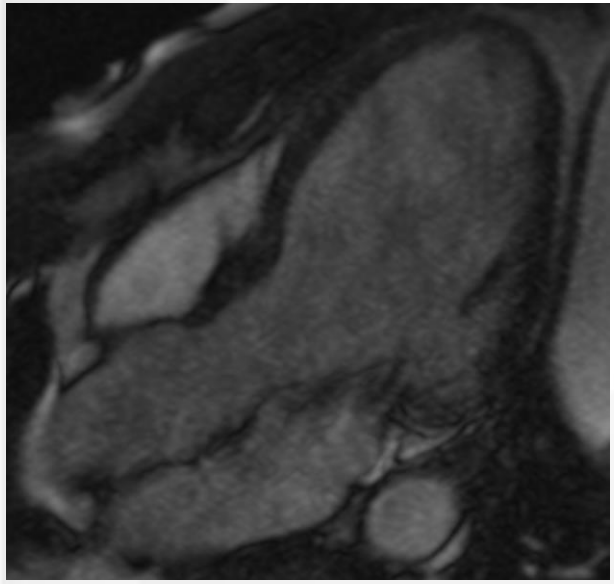
MYXOMATOUS P1/P2 WITH DEEP CLEFT BETWEEM P2 AND P3

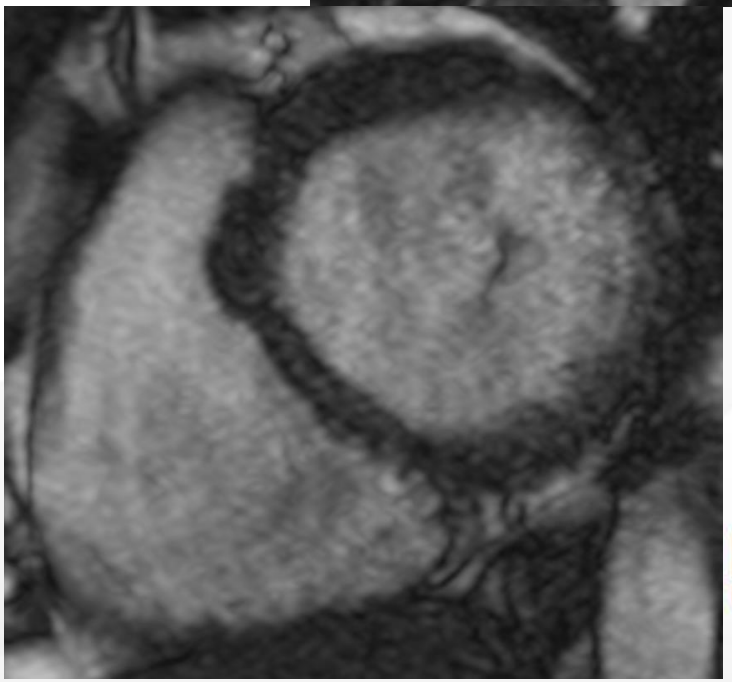


Piedmont HEART



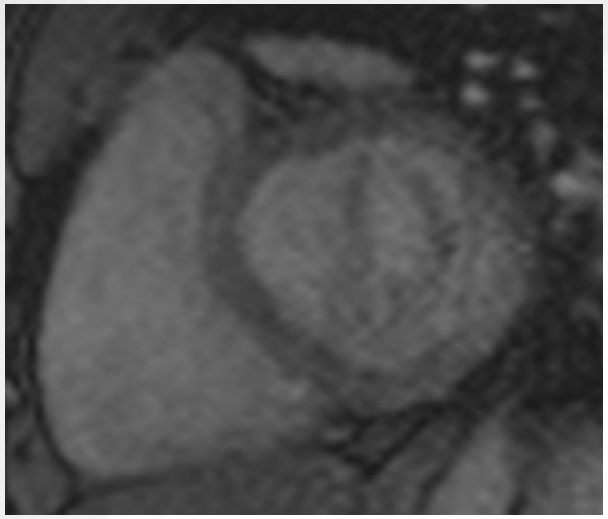


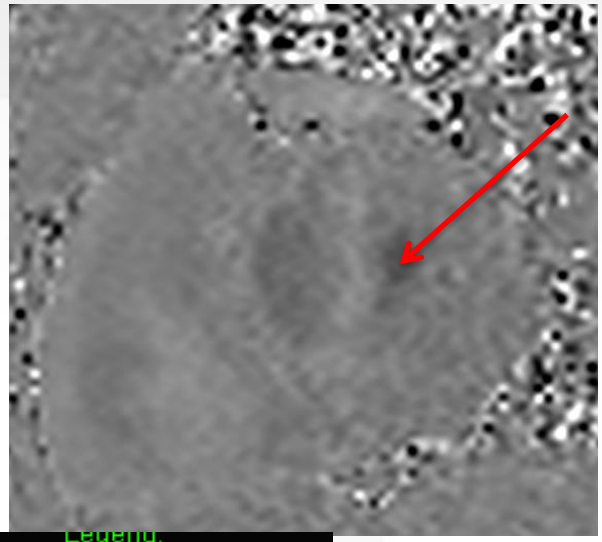


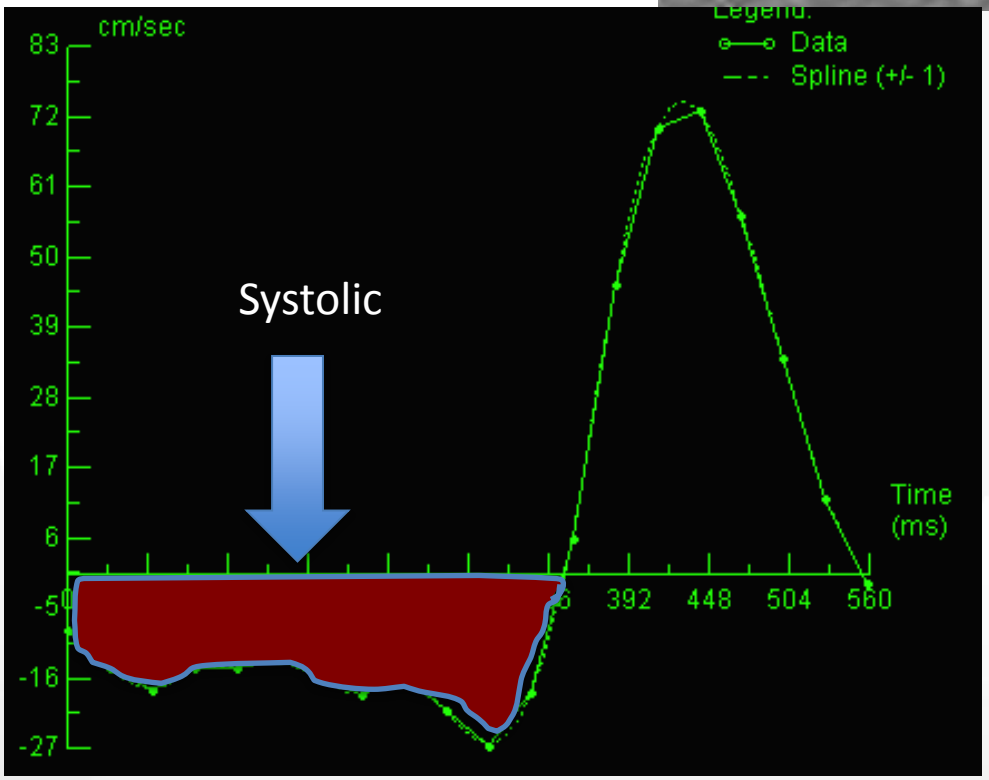


Piedmont HEART

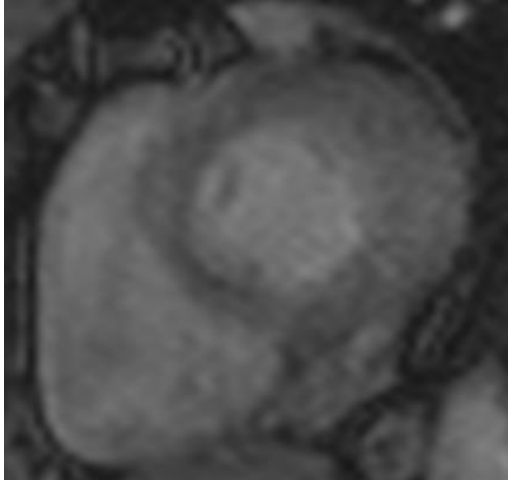
ASSESSMENT OF MITRAL INSUFFICIENCY BY DIRECT THRU PLAINE IMAGING

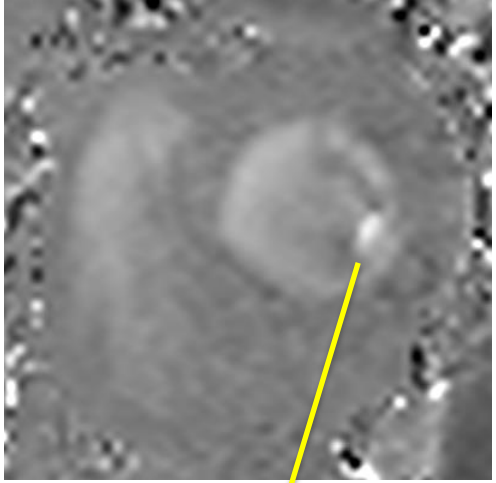


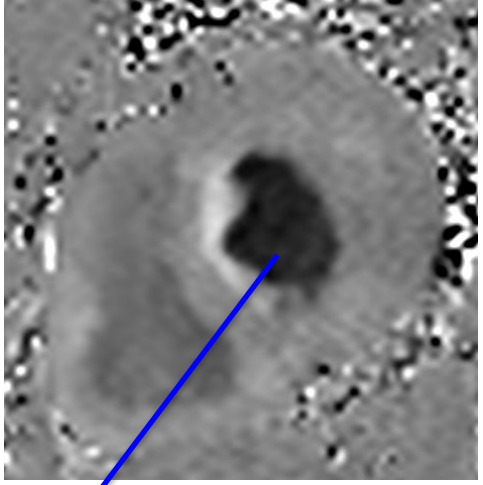




Piedmont HEART



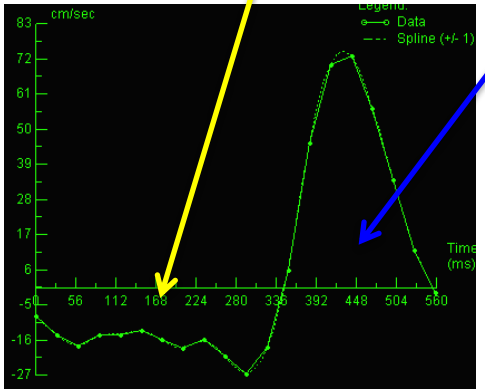




MITRAL INFLOW

MITRAL INSUFFICIENCY

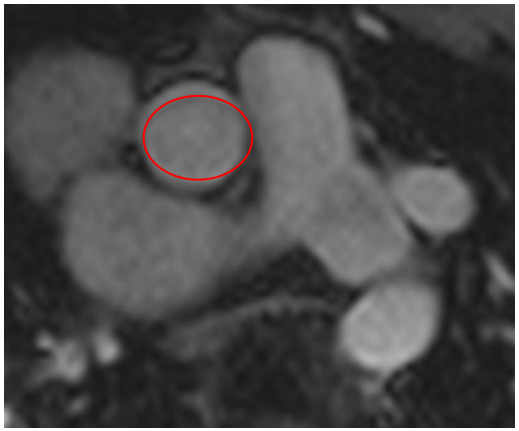
AORTIC FORWARD FLOW

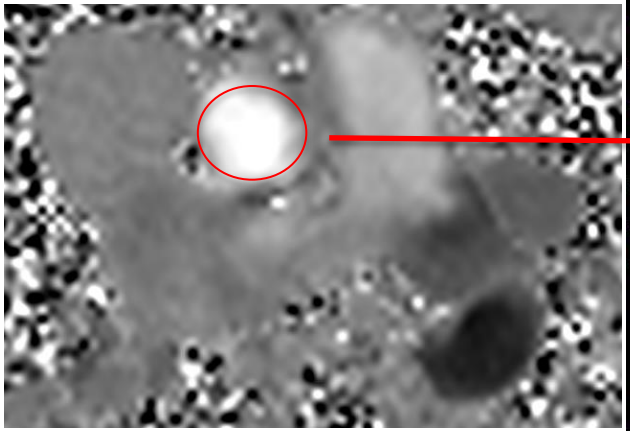


MITRAL INSUFFICIENCY QUANTIFICATION

INDIRECT ASSESSMENT = LV STROKE VOLUME-AO FLOW-> VALIDATED TECHNIQUE

DIRECT ASSESSMENT- MITRAL PHASE CONTRAST- MITRAL INFLOW ASSESSMENT ONLY





LVSV = 110 ML
AO FORWARD FLOW = 59 ML
RV =51 ML, RF =RF 46%

Diagnostic Imaging Assessment of MR-Clinically Available

- Echo -Doppler
  - TTE-Rest and Exercise
  - TEE-2D-3D
- CT
- MRI

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STATE-OF-THE-ART PAPERS

Multimodality Imaging in the Context of Transcatheter Mitral Valve Replacement

Establishing Consensus Among Modalities and Disciplines

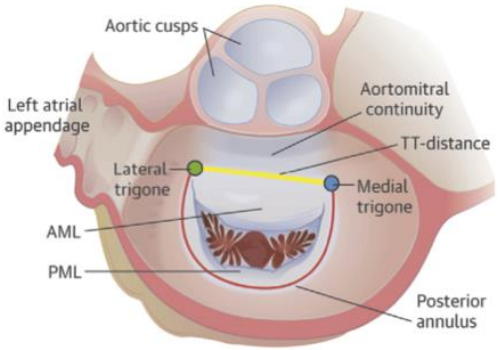
Philipp Blanke, MD,* Christopher Naoum, MBBS,* John Webb, MD,* Danny Dvir, MD,* Rebecca T. Hahn, MD,† Paul Grayburn, MD,‡ Robert R. Moss, MBBS,* Mark Reisman, MD,§ Nicolo Piazza, MD,‖ Jonathon Leipsic, MD*

JACC: CARDIOVASCULAR IMAGING CME

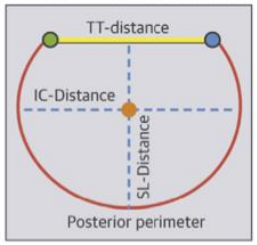
CENTRAL ILLUSTRATION **Multimodality Imaging for TMVI: Pre-Procedural Screening, Periprocedural Guidance and Post-Procedural Assessment**

Anatomical Assessment for TMVI Eligibility and Device Sizing

3D ANNULAR SEGMENTATION (CT/3D TEE)



Pertinent Annular Measurements



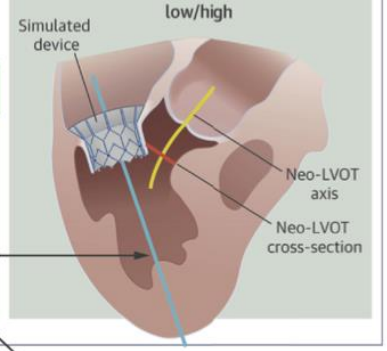
- Annular area
- Perimeter
- SL-Distance
- IC-Distance

→ Device Size

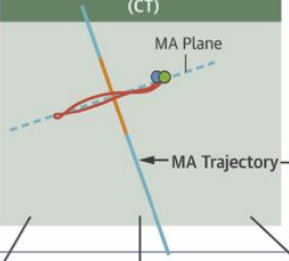
DEVICE SIMULATION FOR LVOT OBSTRUCTION PREDICTION (CT)

- Embedded geometry in CT data set
- Trajectory determines device orientation
- Quantification of Neo-LVOT area

→ Risk of LVOT Obstruction: low/high



2D MA PLANE + MA TRAJECTORY (CT)



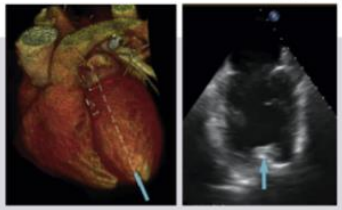
LANDING ZONE CHARACTERISTICS (CT/2D AND 3D TEE)

- Annular calcium
- MVP/mitral annular disjunction
- Myocardial shelf
- Leaflet length
- Directly inserting papillary muscles

→ Adequate Landing Zone: yes/no

Peri-procedural Guidance

Ideal LV puncture site (CT)
Correlation with Intraoperative TEE (x-plane)



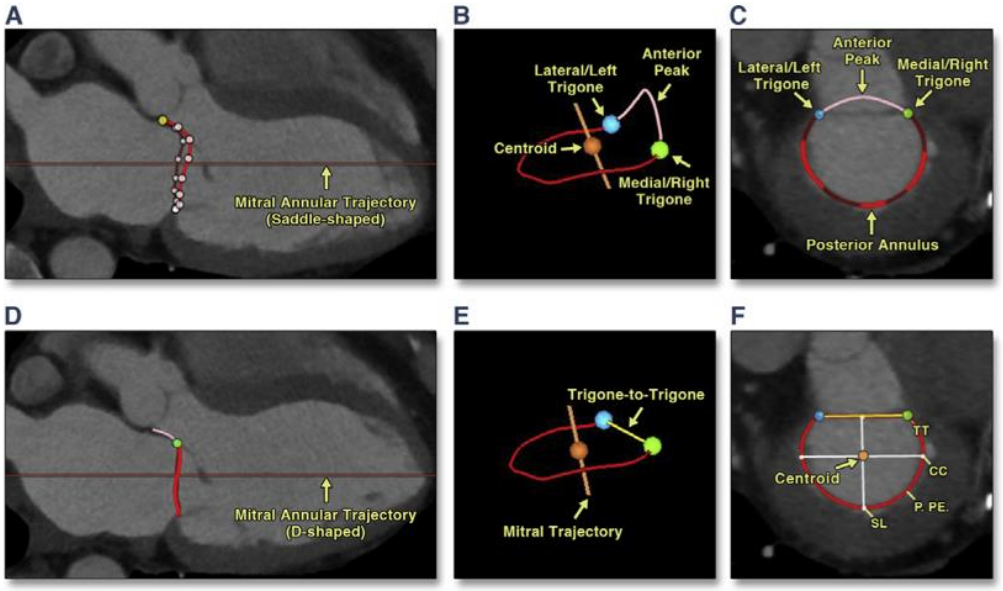
Ideal Intercostal Access

Prediction of Fluoroscopic Angulation for Coplanar View

INTRAOPERATIVE 2D AND 3D TEE AND FLUOROSCOPY

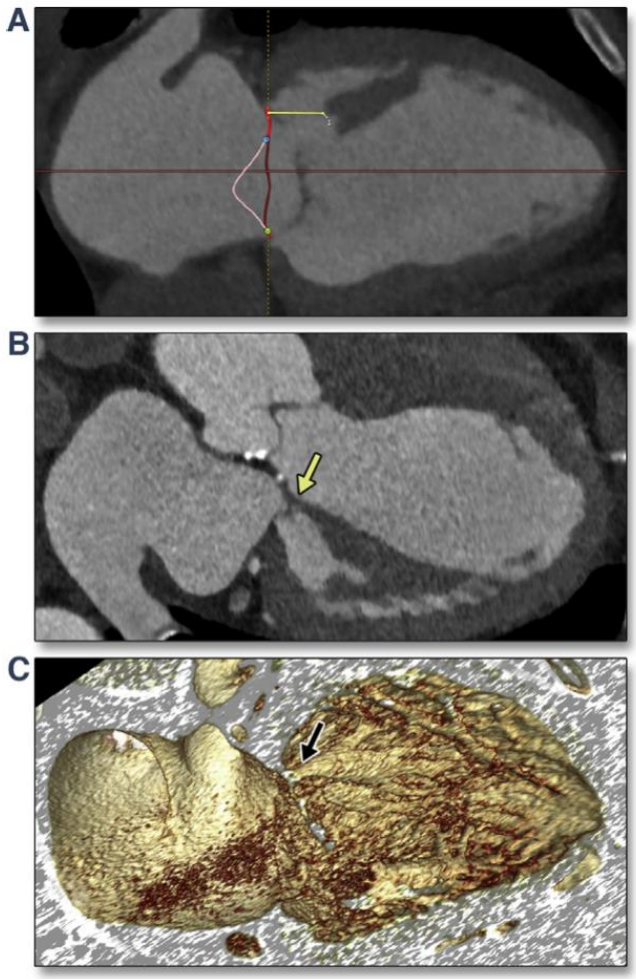
- Guide wire advancement and positioning
- Delivery system advancement and positioning
- Rotational alignment
- Device anchoring
- Device deployment

FIGURE 6 3D-Mitral Annular Segmentation on CT



(A) Saddle-shaped MA segmentation as a cubic spline interpolation. **(B) Pink line** = anterior peak; **red line** = posterior peak (PML insertion); **green** and **blue dots** = fibrous trigones. Importantly, the anterior peak projects into the LVOT (short-axis view **[C]** and long-axis view **[D]**). The more planar D-shaped annular contour is created by truncating the saddle-shaped contour at the trigone-to-trigone distance **(yellow lines [E and F])**. Important measurements are the projected area septal-to-lateral (SL) and inter-commissural (IC) distances; the latter is oriented perpendicularly to SL while transecting through the centroid **(F)**. Abbreviations as in Figures 1 and 3.

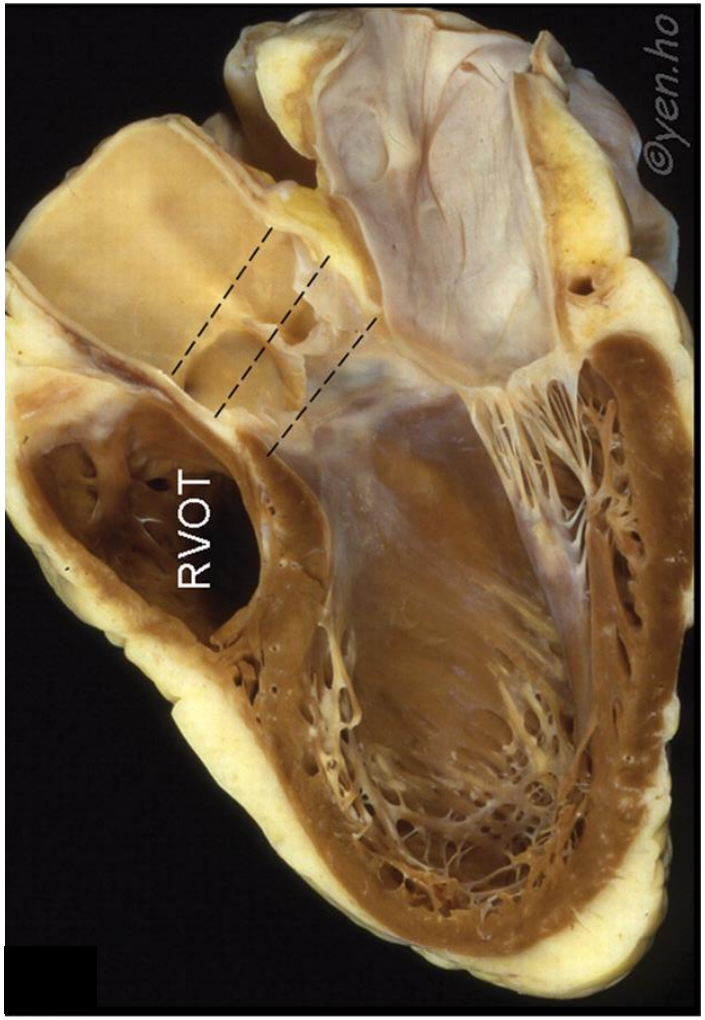
FIGURE 8 Assessment of Papillary Muscle Anatomy



(A) Distance measurement from the anteromedial papillary muscle tip to the annular plane **(yellow line)**. The red line indicates the annular trajectory. **(B and C)** Multiplanar reformat and endovascular volume rendered image demonstrating direct insertion of the anteromedial papillary muscle into the AML **(yellow arrow in B, black arrow in C)**. Abbreviations as in Figure 1.

Mitral Annulus-LVOT

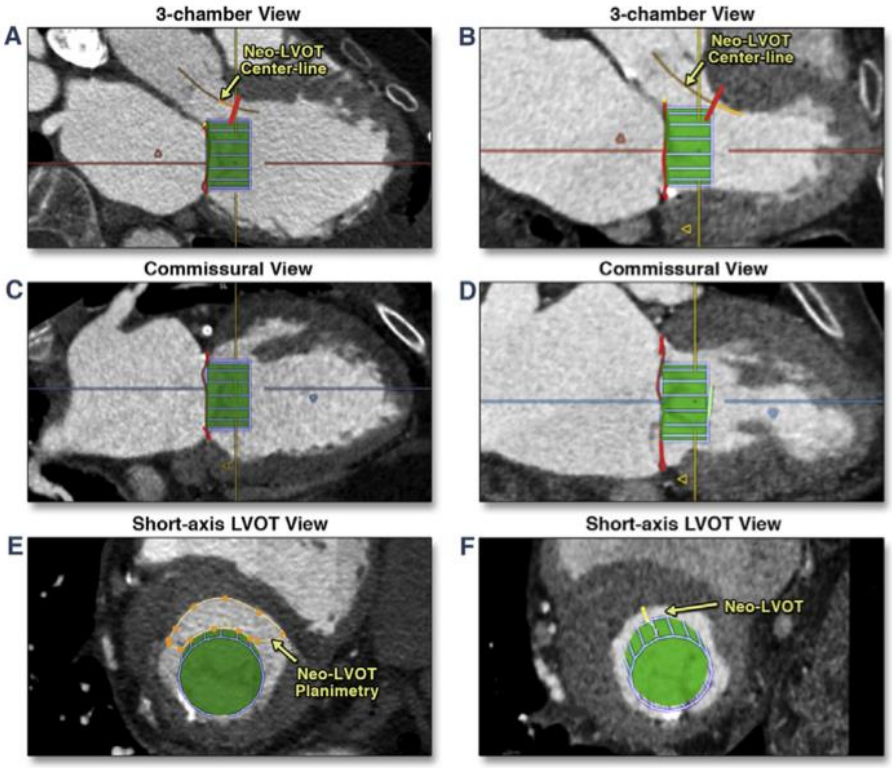
Orientation of the mitral annulus and LVOT



MARCUS HEART VALVE CENTER

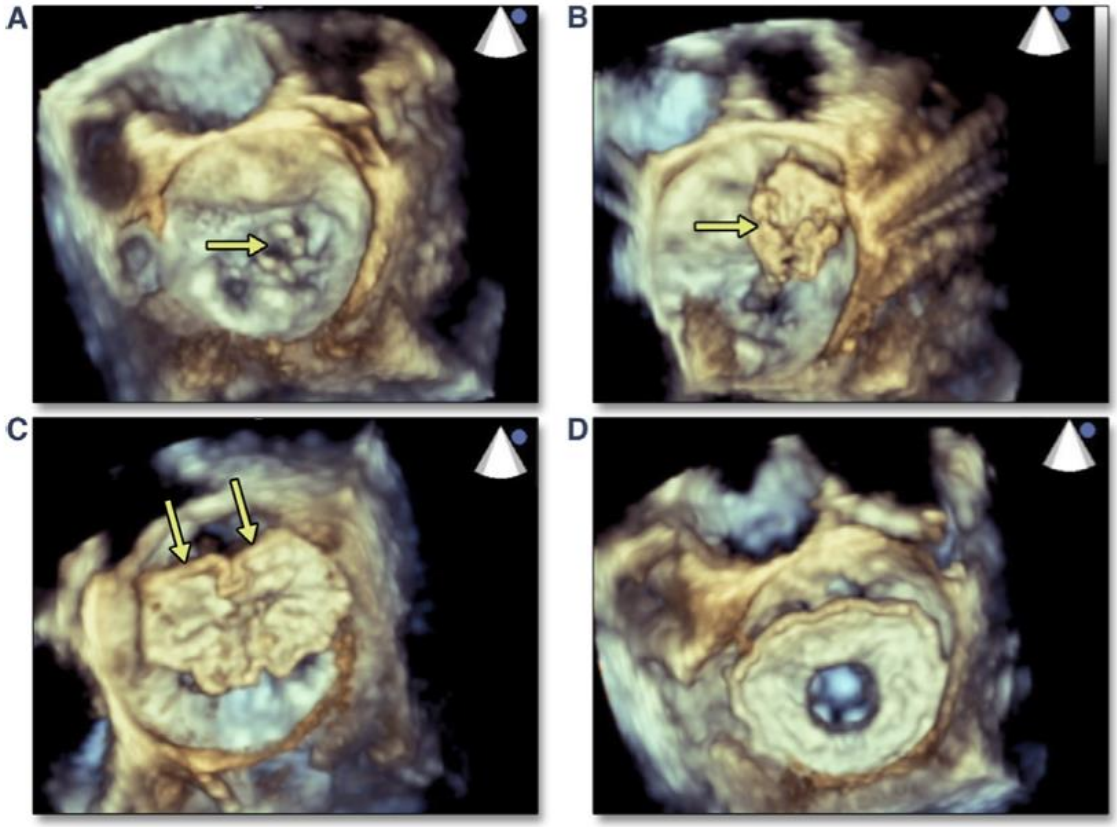
Piedmont HEART

FIGURE 10 **Prediction of Neo-LVOT Dimensions**



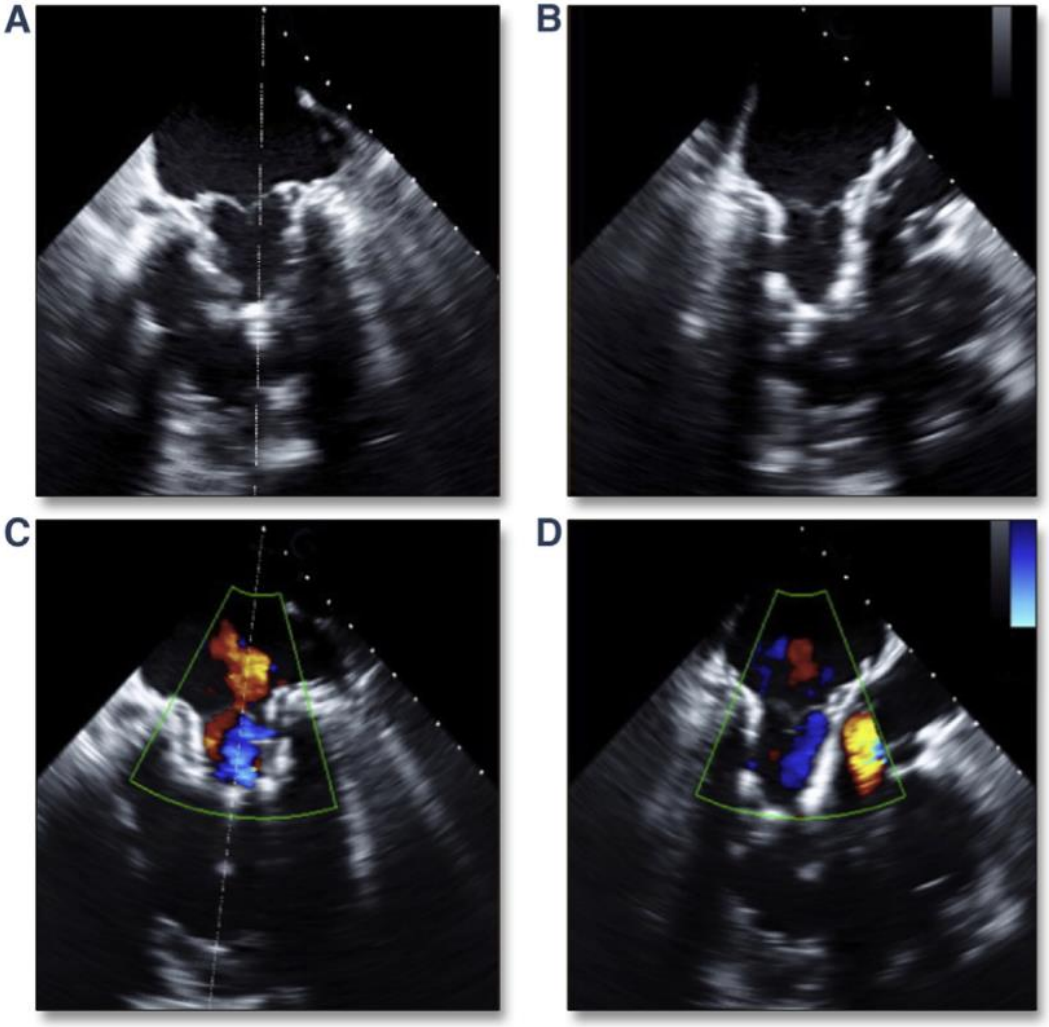
End-systolic CT-datasets in FMR with an anterolateral/lateral myocardial scar **(A, C, E)** and in DMVD **(B, D, E)**. **(A and B)** Three-chamber views and commisural views **(C and D)** showing the annular segementation and a simulated cylindrical device (29 mm), oriented perpendicularly to the annular plane. The neo-LVOT formed by the septal myocardium and the device is segmented (center line technique, **orange line**). The **red bar** indicates the position of the short-axis LVOT view **(E and F)**, which allows for planimetric assessment of the neo-LVOT, yielding 3.5 cm^2 at end-systole **(E)**, indicating low risk for LVOT obstruction, and a slit-like neo-LVOT **(F)** suggests high risk for LVOT obstruction. LVOT = left ventricular outflow tract.

FIGURE 18 Deployment of Tendyne Valve Using 3D Zoom Surgical Views



(A) Sheath **(arrow)** is seen in the LA above native leaflets. **(B)** Valve flange **(arrow)** is released and begins to appear in LA. **(C)** Valve flange is rotated, aligning the flat part of the D-shaped mitral annulus with the aortic-mitral curtain **(arrows)**. **(D)** Flange is fully opened, and the bioprosthesis is seen in the center. Online Videos 1 and 2. Abbreviations as in **Figure 1**.

FIGURE 19 TEE Images Immediately After Implantation of Tendyne Valve



X-plane view shows mid-commissural **(A)** and long-axis **(B)** views. Valve leaflets are in closed position (mid-systole). Color Doppler images in same views showing LVOT preservation and no paravalvular leakage **(C and D)**. Abbreviations as in Figures 4 and 10.

Pre procedure

Periprocedure

Post Procedure

TABLE 2 Role and Contribution of Imaging Modalities in the Context of TMVI

Plan	TTE	2D TEE/X-Plane 3D*	3D TEE	CT	Fluoroscopy
Pre-procedural planning					
Quantification of MR	+++	++	+++	NA	+
Annular dimensions	+	+	++	+++	NA
Leaflet morphology	++	+++	+++	++	NA
Annular and leaflet calcifications	++	++	+	+++	+
Chordae	++	++	++	+	NA
Papillary muscle anatomy	++	++	++	+++	NA
LV Size and function	+++	++	NA	++	++
LVOT anatomy	+	++	+++	+++	NA
Periprocedural imaging					
Localization of ventricular puncture	NA	+++*	+	NA	+
Guidewire advancement and positioning	NA	++*	+++†	NA	++
delivery system advancement and positioning	NA	+++*	+++	NA	++
Device deployment	NA	+++*	+++	NA	++
Rotational alignment	NA	+§	+++†‡	NA	+
Device anchoring	NA	+++*	++	NA	+
Post-TMVR					
Valvular competency/ para-valvular regurgitation	++	++	+++‖	+	+
Trans-mitral gradient	+++	+++	NA	NA	NA
LVOT anatomy	++	++	+++	+++	NA
LVOT gradient	+++	++	NA	NA	+++#
Device apposition/seating	++	++	+++	+++	NA
Device stability	+++	+++	++	++	+++
Leaflet mobility/thrombus	+	+++	++	+++	NA
Stent fracture	NA	NA	NA	+	+++

*X-plane mode. †Live 3D mode. ‡Zoom 3D mode. §Transgastric view. ‖Color 3D and vena contracta area. #Catheter-based direct gradient measurement.

LV = left ventricle; LVOT = left ventricular outflow tract; MR = mitral regurgitation; NA = not applicable; TMVI = transcatheter mitral valve implantation.

The Dr Mike and Dr Randy Show

- Primary Vs Secondary MR

  Advanced Imaging for diagnosis,directing and assessing Treatments
- Defining High Risks-Fraility etc
- Medical vs SurgicalTreatment in 1 vs 2 MR
- Surgical- Transcatheter Treatment:

  Primary MR-including high risk

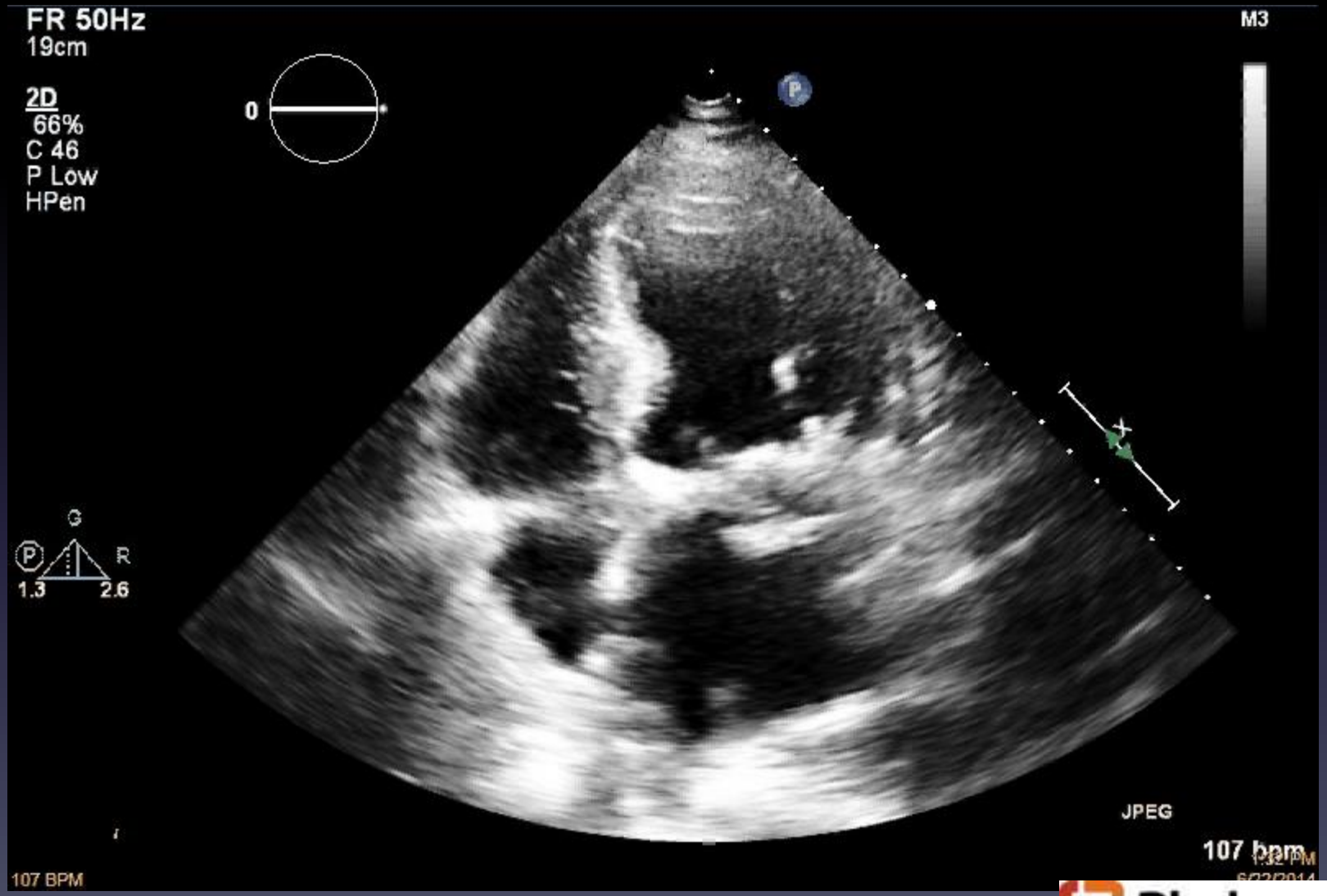
  Secondary MR
- The FUTURE

Case

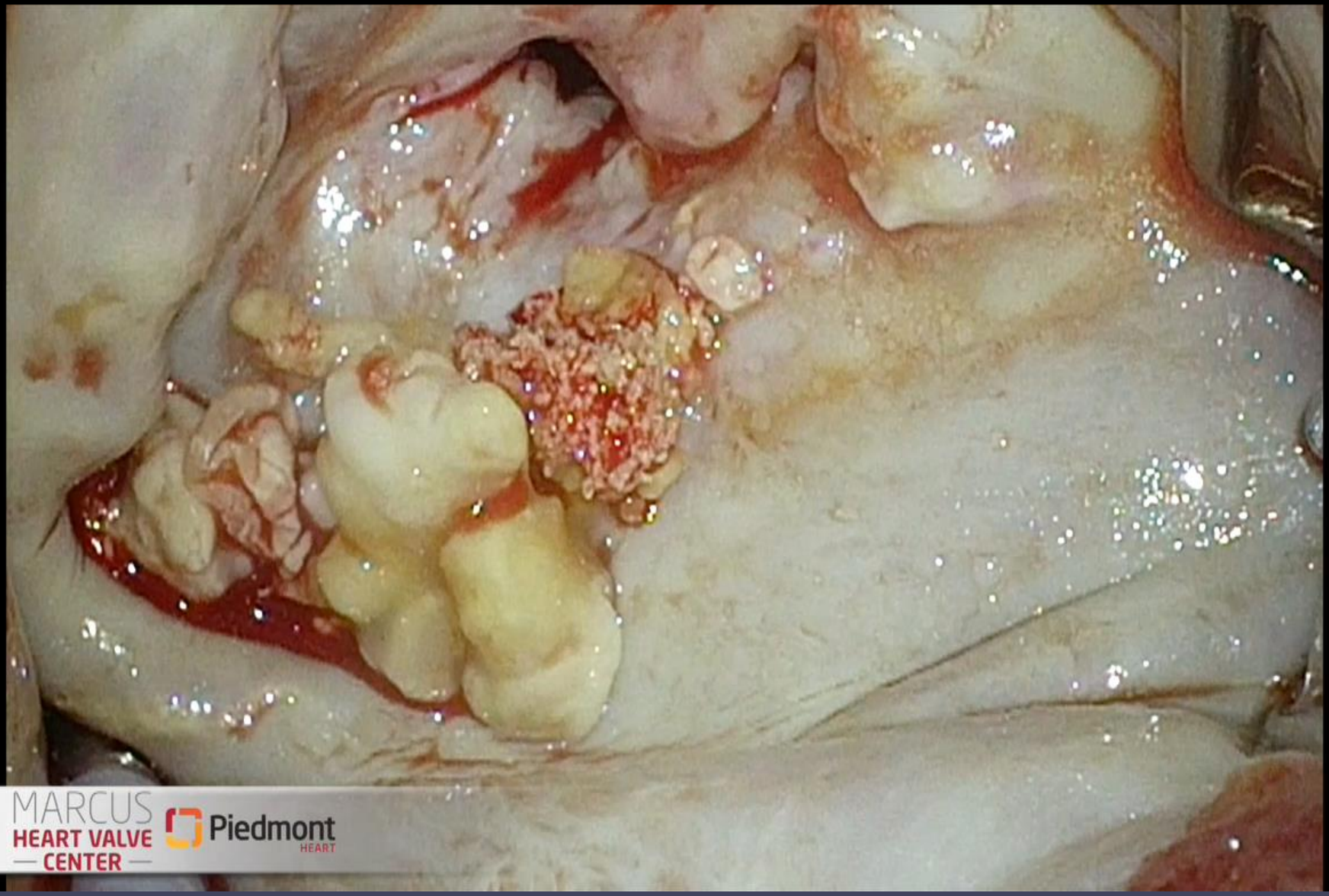
- 46 yo WF with ESRD on PD,
- CAD s/p NSTEMI with PCI x 2 to RCA 7/2013,
- HTN who presented with DOE and loud systolic mumur
- TTE
- Subsequent TEE

Piedmont HEART

Transthoracic Echo




FR 6Hz
11cm
3D Beats 1
M4
3D
3D 42%
3D 40dB
0
45
180
JPEG
92 bpm
PAT T: 37.0C
TEE T: 39.5C
92 BPM
6/23/2014


MARCUS
HEART VALVE
CENTER
Piedmont
HEART

Valve in MAC

Recommendations for Chronic Primary MR

Recommendations	COR	LOE
MV surgery is recommended for symptomatic patients with chronic severe primary MR (stage D) and LVEF >30%	I	B
MV surgery is recommended for asymptomatic patients with chronic severe primary MR and LV dysfunction (LVEF 30%–60% and/or LVESD ≥40 mm, stage C2)	I	B
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR limited to the posterior leaflet	I	B
MV repair is recommended in preference to MVR when surgical treatment is indicated for patients with chronic severe primary MR involving the anterior leaflet or both leaflets when a successful and durable repair can be accomplished	I	B
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B
repair without residual MR is >95% with an expected mortality rate of <1% when performed at a Heart Valve Center of Excellence		
MV repair is reasonable for asymptomatic patients with chronic severe nonrheumatic primary MR (stage C1) and preserved LV function in whom there is a high likelihood of a successful and durable repair with 1) new onset of AF or 2) resting pulmonary hypertension (PA systolic arterial pressure >50 mm Hg)	IIa	B
Concomitant MV repair is reasonable in patients with chronic moderate primary MR (stage B) undergoing cardiac surgery for other indications	IIa	C
MV surgery may be considered in symptomatic patients with chronic severe primary MR and LVEF ≤30% (stage D)	IIb	C
MV repair may be considered in patients with rheumatic mitral valve disease when surgical treatment is indicated if a durable and successful repair is likely or if the reliability of long-term anticoagulation management is questionable	IIb	B
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities	IIb	B
MVR should not be performed for treatment of isolated severe primary MR limited to less than one half of the posterior leaflet unless MV repair has been attempted and was unsuccessful	III: Harm	B

Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities | IIb | B

Baylor Scott & White HEALTH

Nishimura, RA et al. 2014 AHA/ACC Valvular Heart Disease Guideline

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http://dx.doi.org/10.1016/j.jacc.2013.09.070

JACC WHITE PAPER

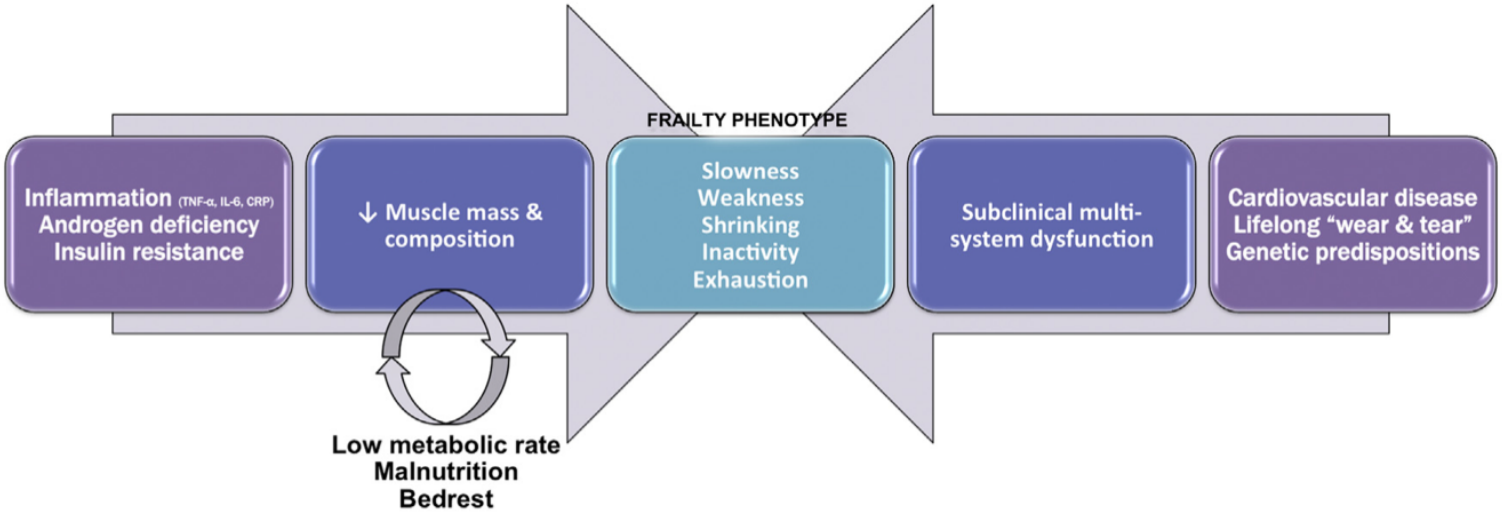
Frailty Assessment in the Cardiovascular Care of Older Adults

Jonathan Afilalo, MD, MSc,* Karen P. Alexander, MD,† Michael J. Mack, MD,‡ Mathew S. Maurer, MD,§ Philip Green, MD,§ Larry A. Allen, MD, MPH,‖ Jeffrey J. Popma, MD,¶ Luigi Ferrucci, MD, PhD,# Daniel E. Forman, MD**

Montreal, Quebec, Canada; Durham, North Carolina; Plano, Texas; New York, New York; Aurora, Colorado; Boston, Massachusetts; and Baltimore, Maryland

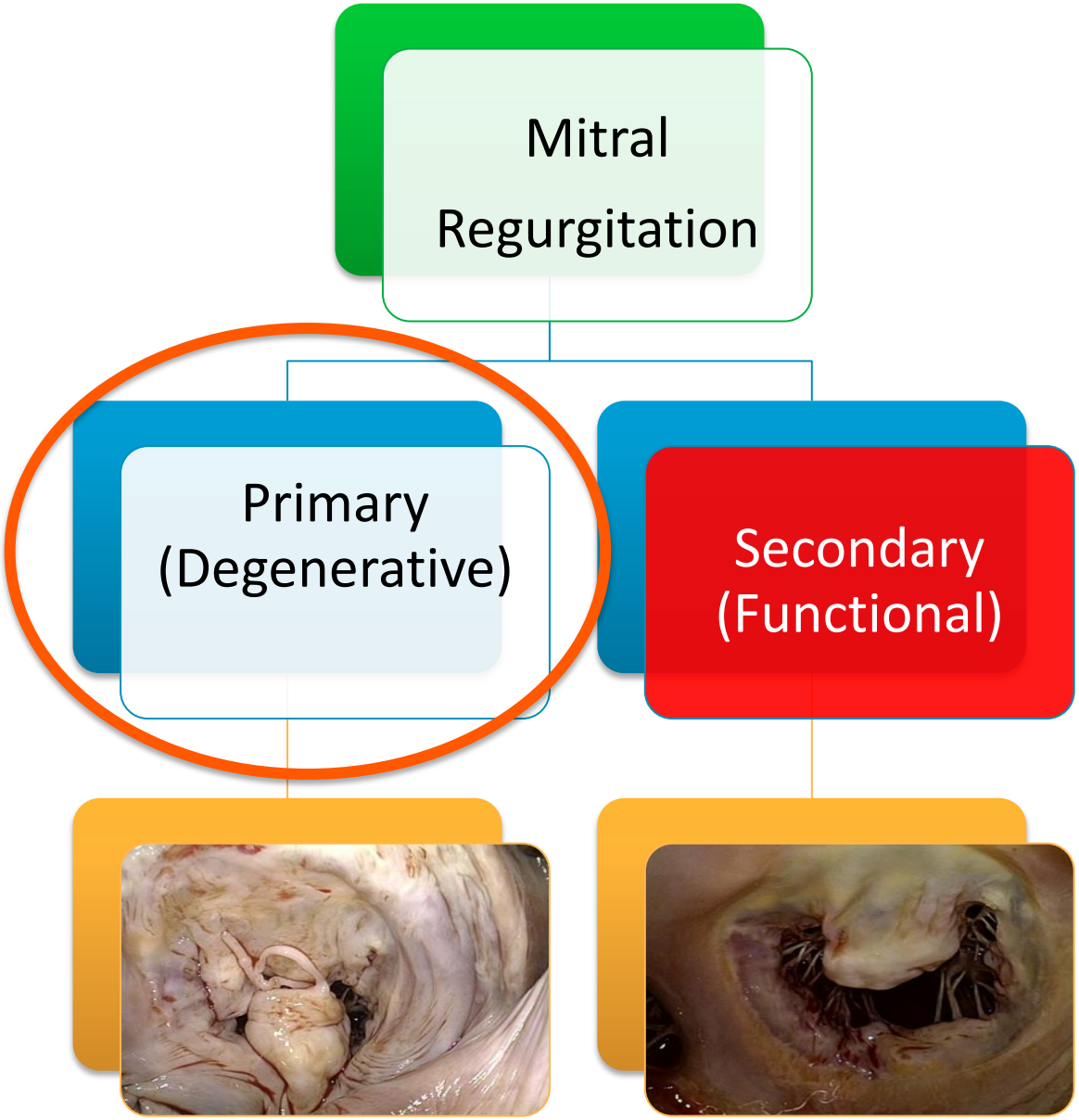
Figure 1

Two of the Pathways Leading Toward the Phenotype of Frailty



(Left) The age-associated activation of inflammatory cells and decline in androgen hormones upset the balance between catabolic and anabolic stimuli, respectively, leading to a decline in muscle mass and composition known as sarcopenia. This detrimental response is aggravated in patients with insulin resistance and metabolic syndrome. Addition of bed rest and malnutrition initiates a vicious cycle of further decline in muscle mass, limiting the necessary mobilization of amino acids in times of stress. **(Right)** The accumulation of subclinical impairments in multiple organ systems resulting from cardiovascular disease, lifelong "wear and tear," and/or genetic predispositions lead to decreased homeostatic reserve and resiliency to stressors. Other pathophysiological pathways have been proposed. Biological pathways may manifest clinically as slow walking speed, weakness, weight loss, physical inactivity, and exhaustion—termed the phenotype of frailty. CRP = C-reactive protein; IL = interleukin; TNF = tumor necrosis factor.

MITRAL VALVE DISEASE


Mitral Regurgitation
Primary (Degenerative)
Secondary (Functional)

Degenerative Leaflet Repair

Edge to Edge
MitraClip

Artificial Chords
Neochord
Harpoon

Transcatheter Mitral Valve Repair

MitraClip System

Recommendations for Chronic Primary MR

Recommendations	COR	LOE
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MV repair may be considered in patients with rheumatic mitral valve disease when surgical treatment is indicated if a durable and successful repair is likely or if the reliability of long-term anticoagulation management is questionable	IIb	B
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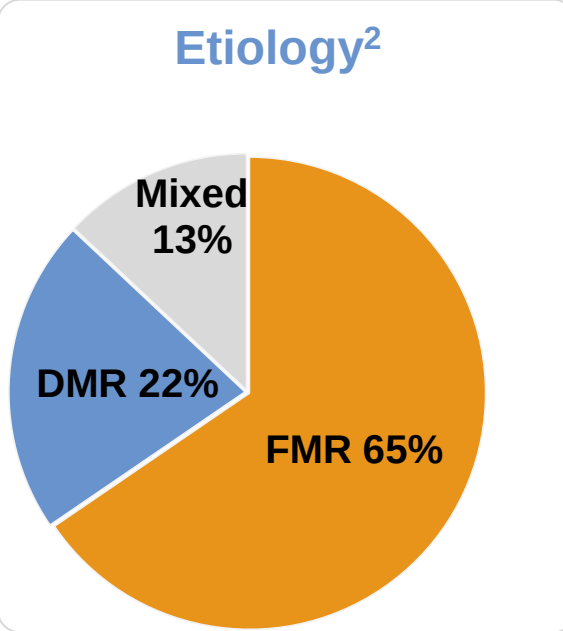
Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities | IIb | B

Baylor Scott & White HEALTH

Nishimura, RA et al. 2014 AHA/ACC Valvular Heart Disease Guideline

Commercial MitraClip Implant Worldwide Experience

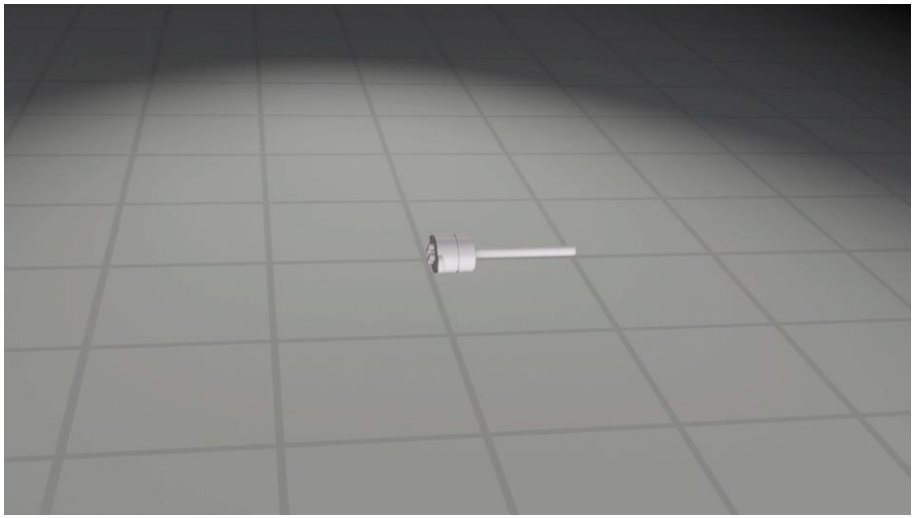
- Treating Centers: 463
- Patients[1]: 25,508
- Implant Rate[1]: 96%
- Etiology[2]
  - Functional MR 65%
  - ***Degenerative MR 22%***
  - Mixed 13%



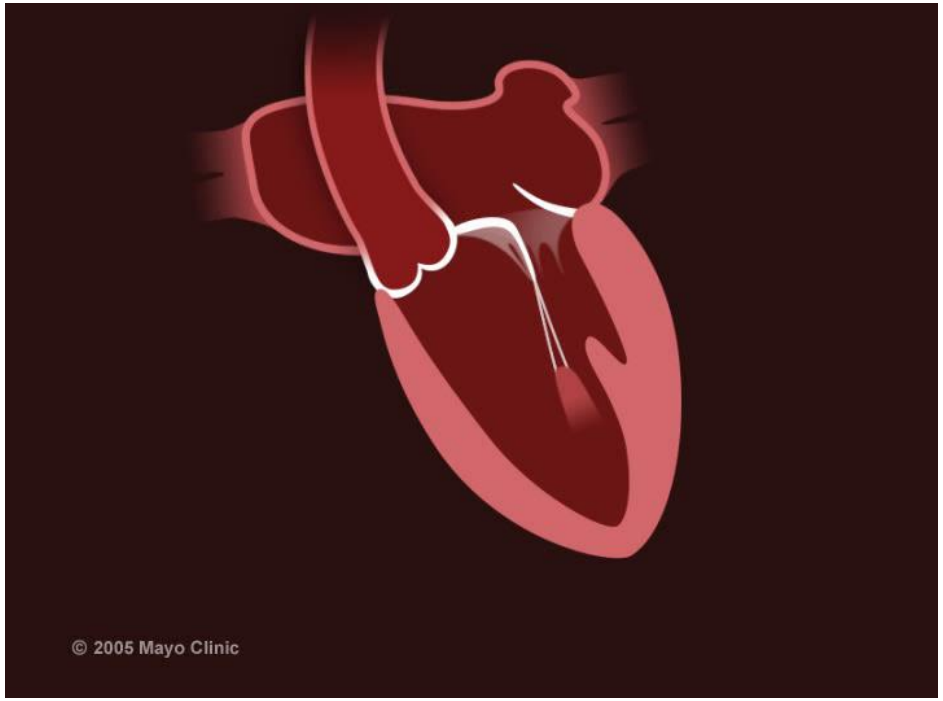
Data as of 01/31/2015. Source: Abbott Vascular.

Transapical Off-Pump Artificial Chord Implantation

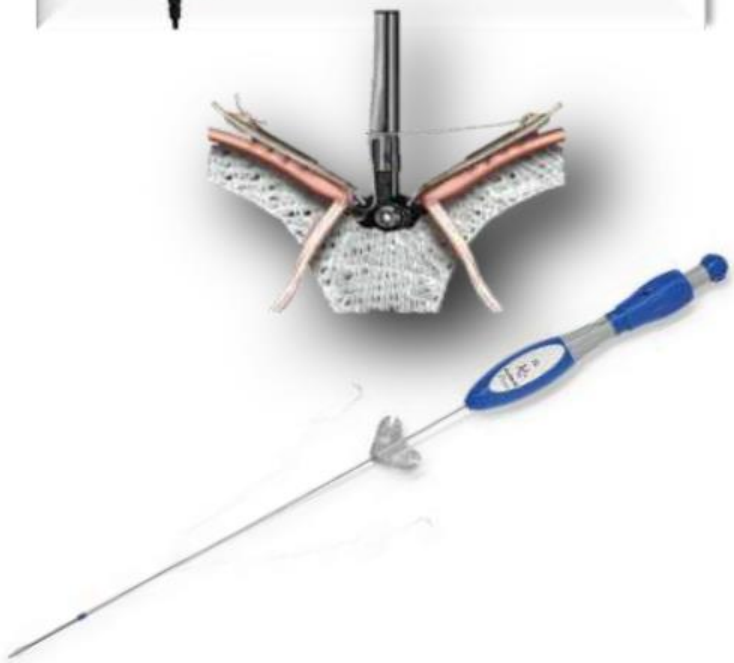
Harpoon



Neochord



Combination of Techniques



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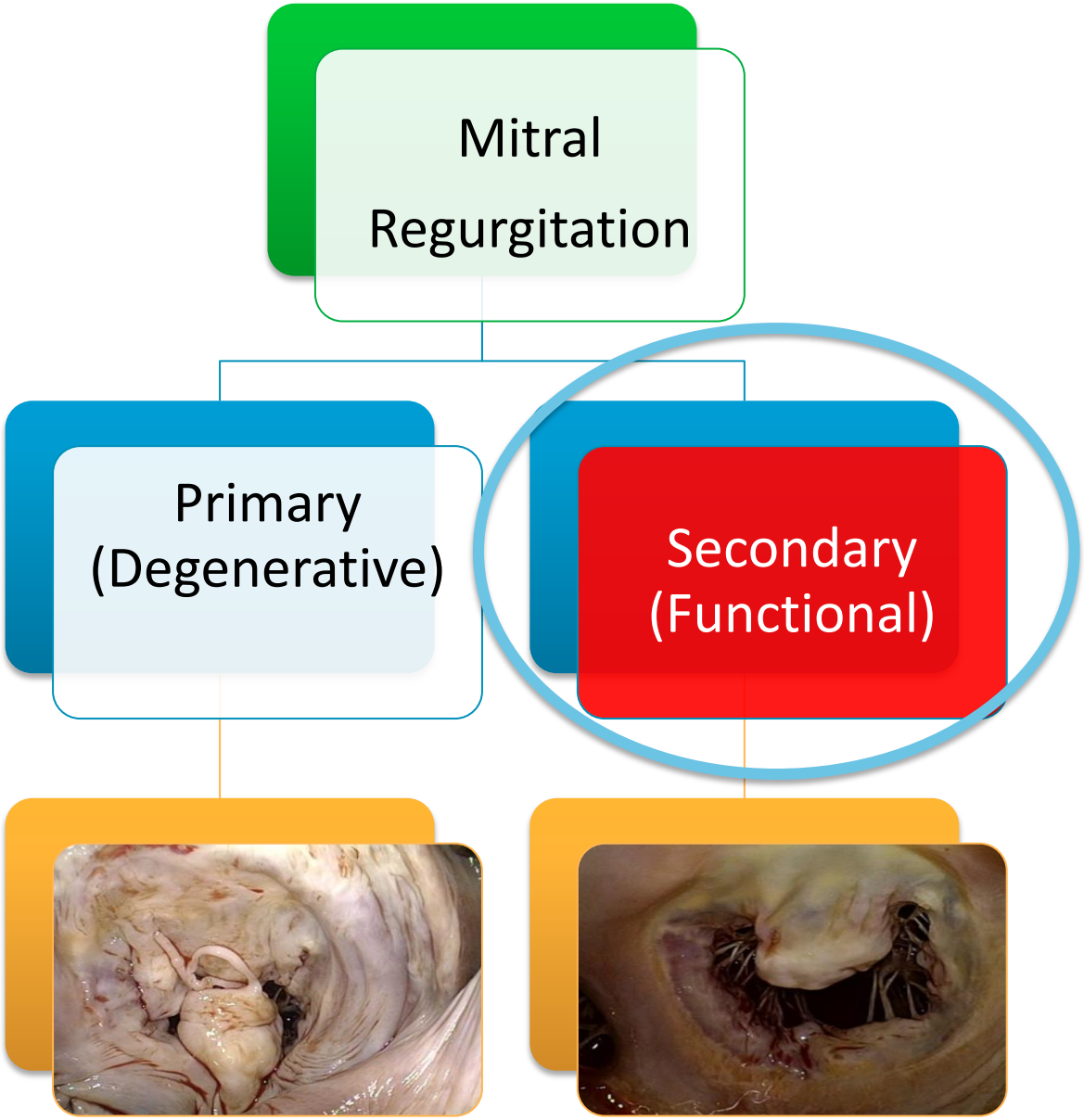
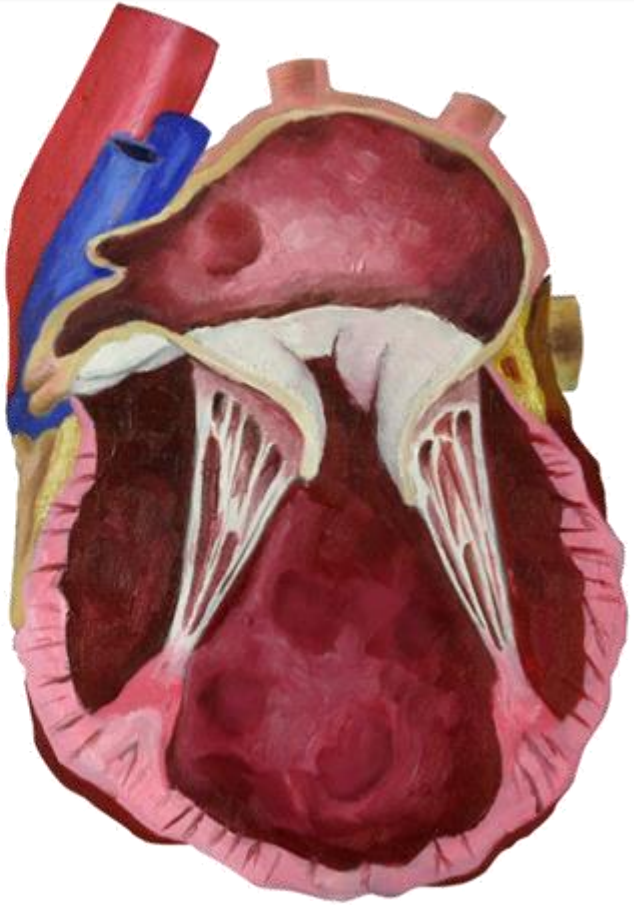
Fully Percutaneous Mitral Repair


Mitral Regurgitation
Primary (Degenerative)
Secondary (Functional)

Secondary MR

Disease of the Left Ventricle NOT the Mitral Valve

Normal LV



Dilated LV tethering one or both leaflets

Why Do We Care About Secondary MR?

It is Associated with Advanced CHF !

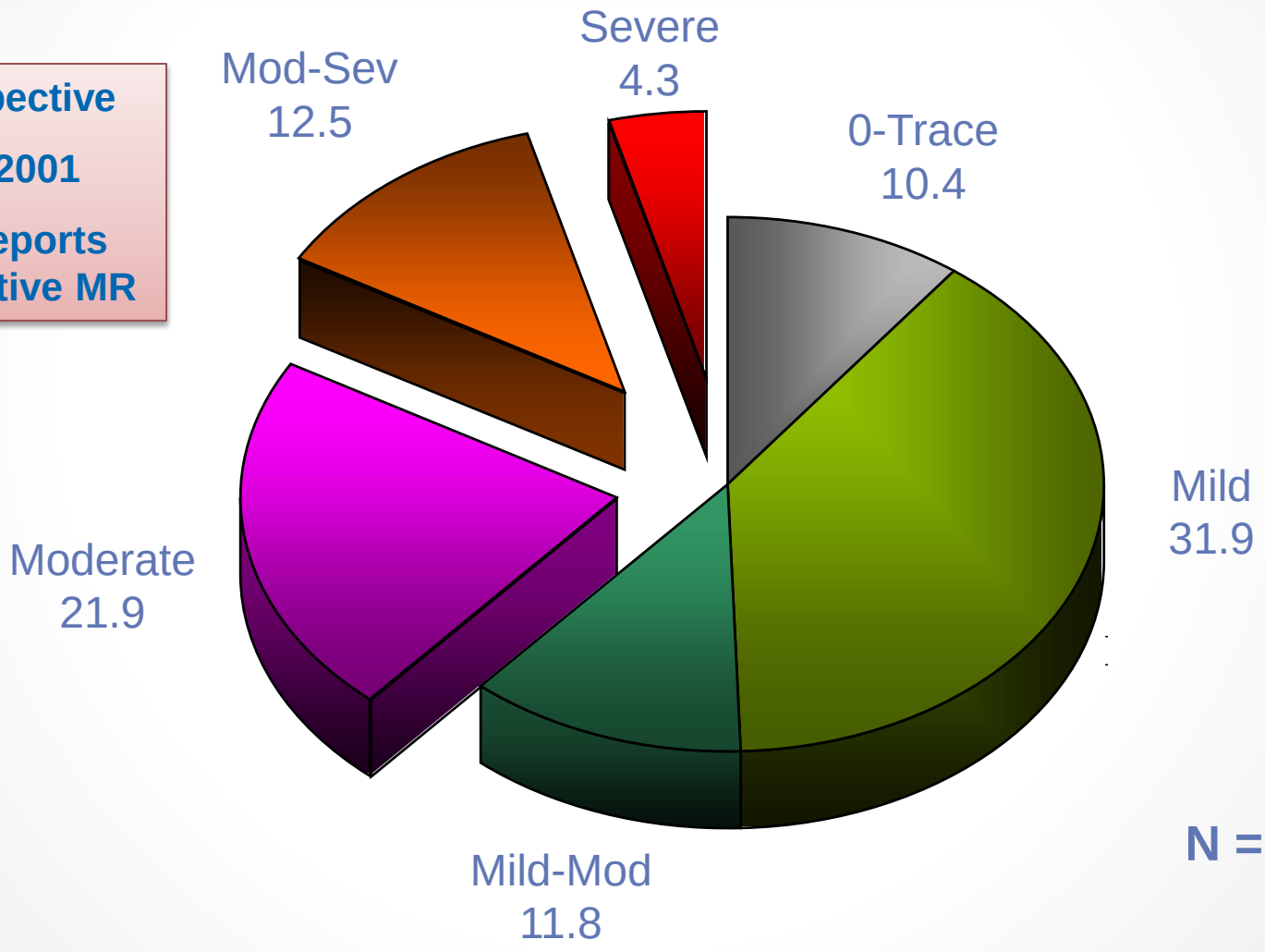
Frequency of MR in a CHF population=90%

Heart failure clinic, EF≤35%, Class III-IV

Retrospective

1996-2001

Echo reports Quantitative MR

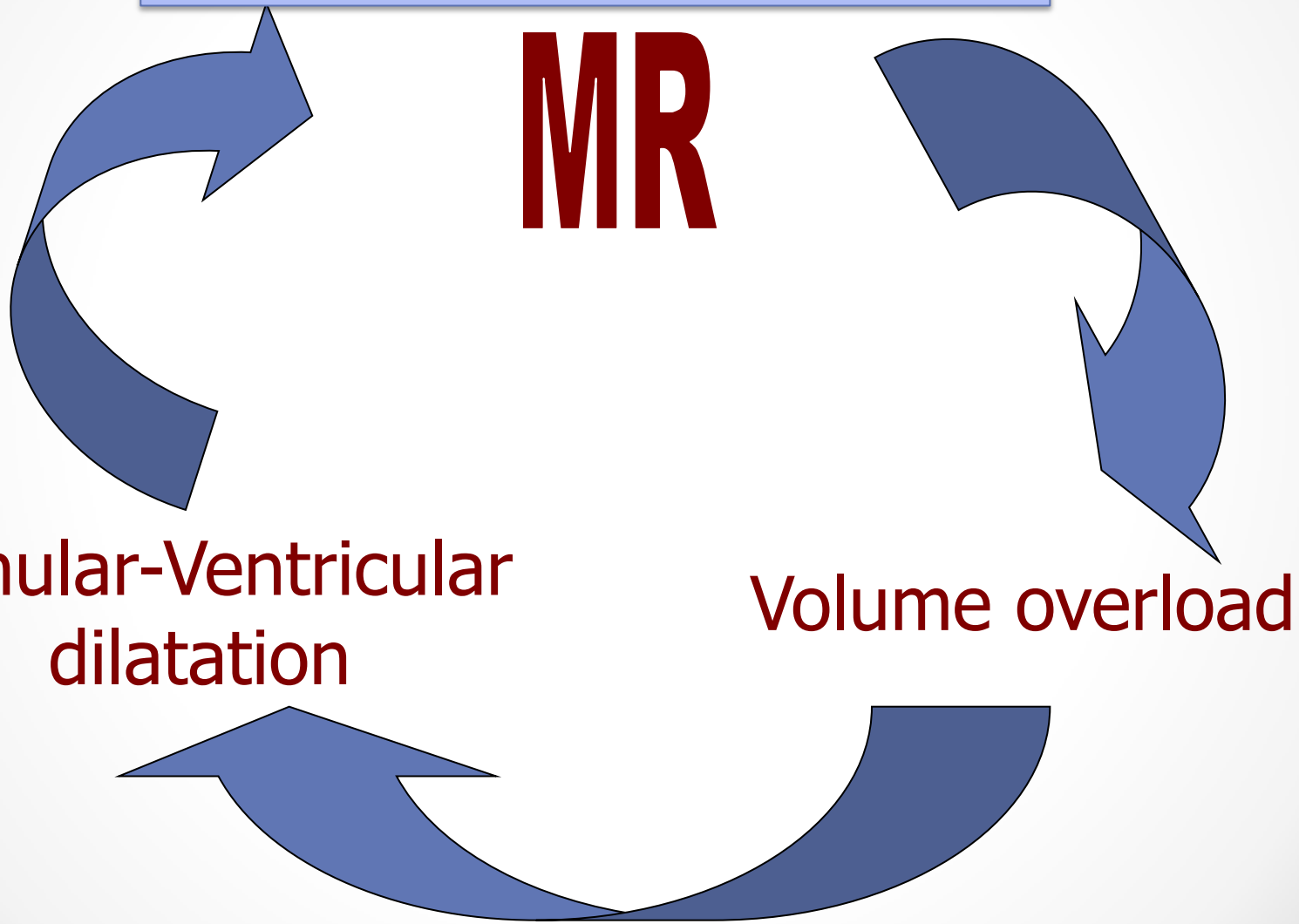


N = 558

Patel JB- J Cardiac Failure 10:285, 2004

FMR

A Vicious Cycle

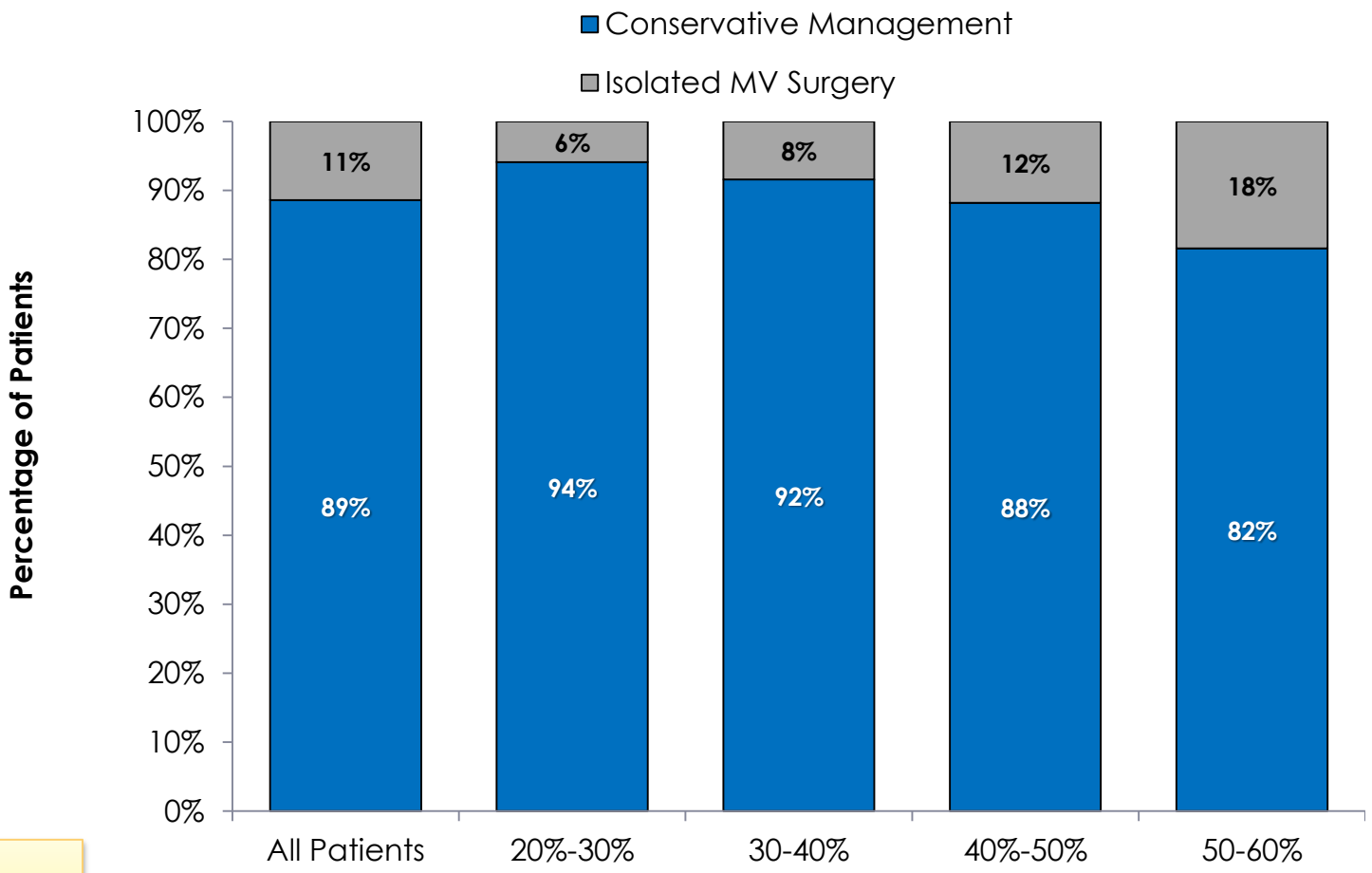


Chronic Severe *Secondary* Mitral Regurgitation: Intervention

Recommendations	COR	LOE
MV surgery is reasonable for patients with chronic severe secondary MR (stages C and D) who are undergoing CABG or AVR	IIa	C
MV surgery may be considered for severely symptomatic patients (NYHA class III-IV) with chronic severe secondary MR (stage D)	IIb	B
MV repair may be considered for patients with chronic moderate secondary MR (stage B) who are undergoing other cardiac surgery	IIb	C

Repair or Replacement not stipulated

Treatment of Patients with 3-4+ FMR, LVEF≥20%, no CABG from 2000-2010 *(n=1,538*)*

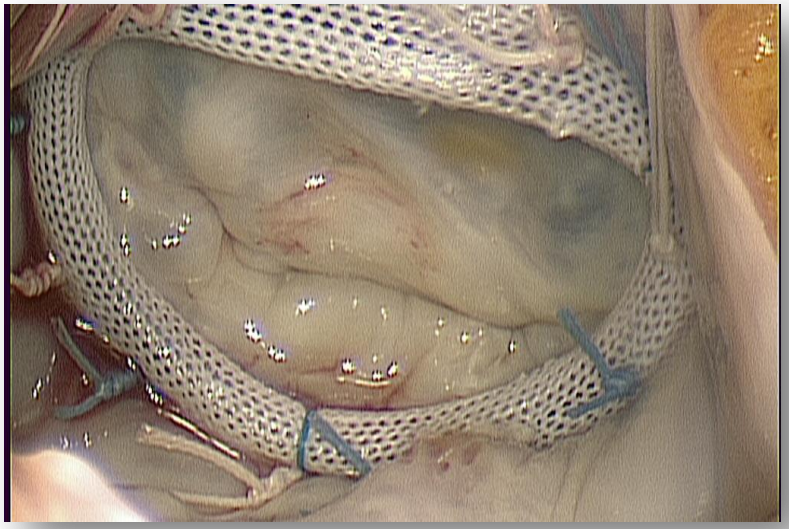


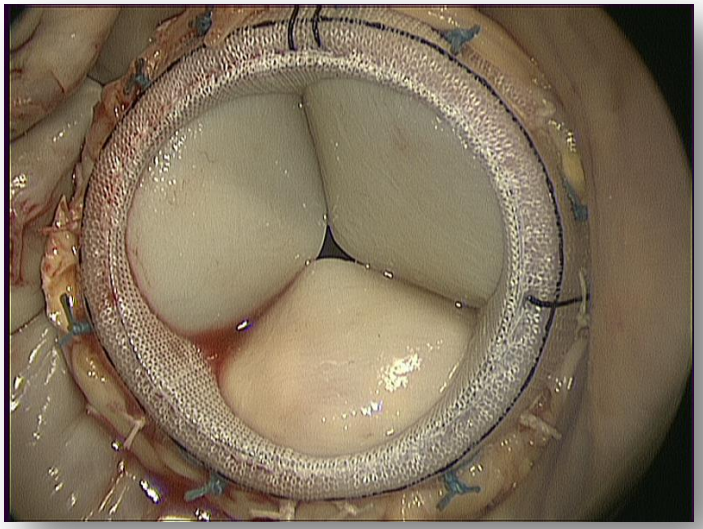
Duke Database

Left Ventricular Ejection Fraction (LVEF)

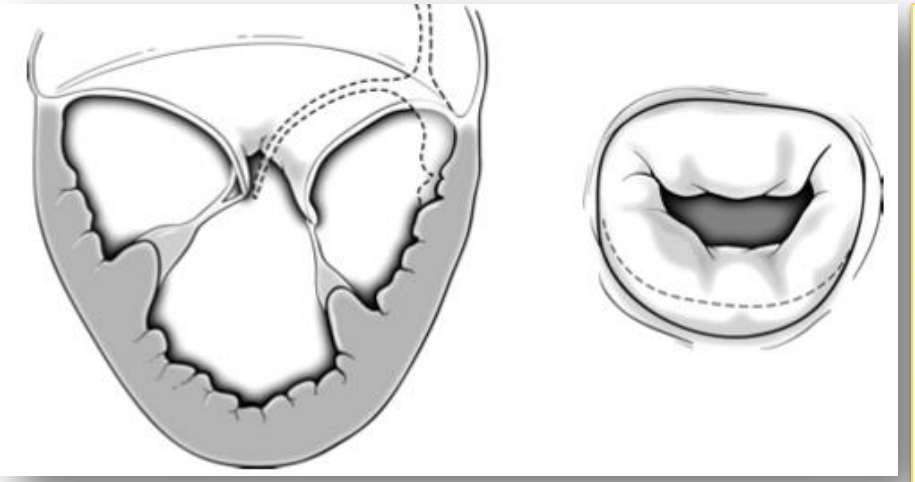
Surgical Options to Correct Secondary MR

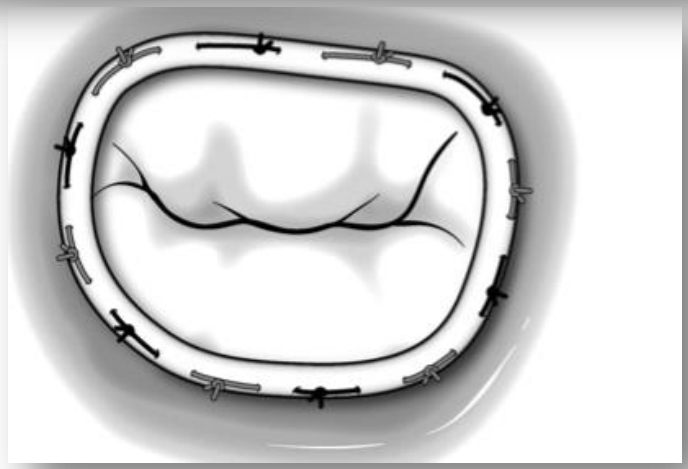
After GDMT and Resynchronization When Appropriate





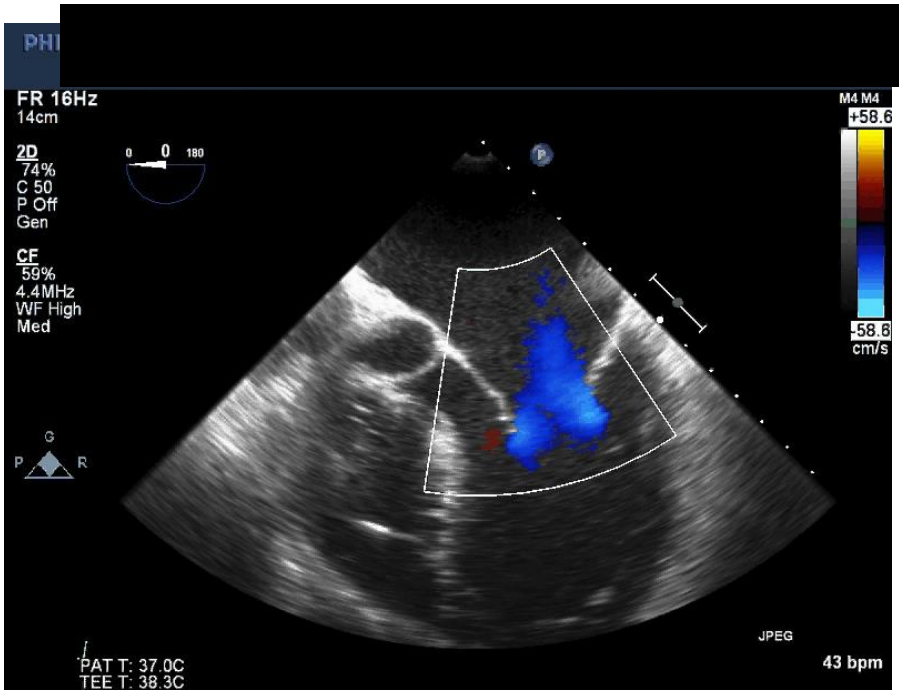
Secondary MR
Undersized Annuloplasty

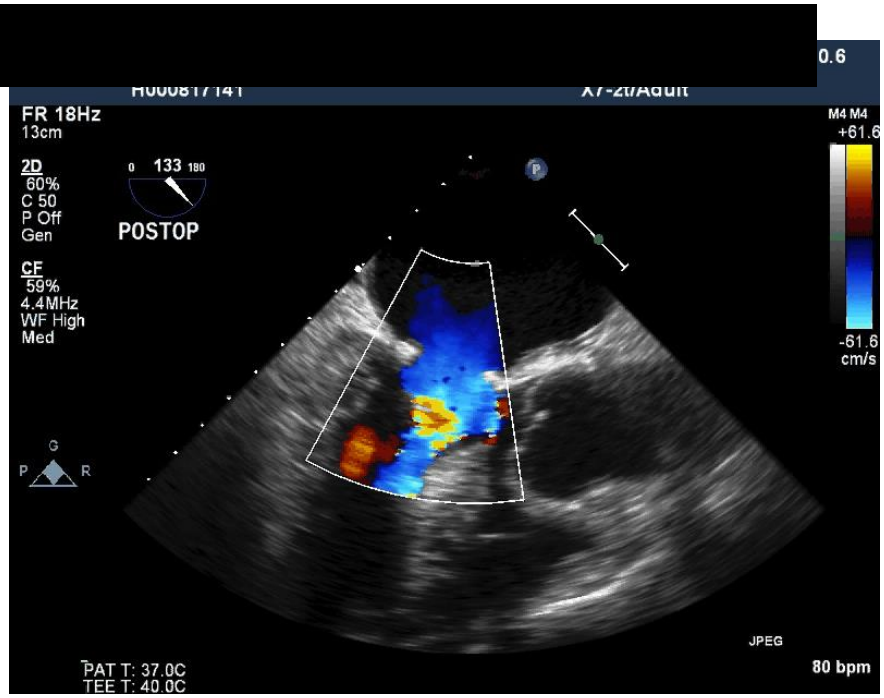




- Disease of the left ventricle NOT of the mitral valve
- MR caused by apical lateral distraction of the papillary muscles tethering the leaflets
- Annular dilation is secondary and occurs greatest in the septal-lateral (anterior-posterior) dimension
- Surgical repair based on over correction of the annular dilation

Secondary MR Before and After Mitral Valve Annuloplasty





The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Mitral-Valve Repair versus Replacement for Severe Ischemic Mitral Regurgitation

Michael A. Acker, M.D., Michael K. Parides, Ph.D., Louis P. Perrault, M.D., Alan J. Moskowitz, M.D., Annetine C. Gelijns, Ph.D., Pierre Voisine, M.D., Peter K. Smith, M.D., Judy W. Hung, M.D., Eugene H. Blackstone, M.D., John D. Puskas, M.D., Michael Argenziano, M.D., James S. Gammie, M.D., Michael Mack, M.D., Deborah D. Ascheim, M.D., Emilia Bagiella, Ph.D., Ellen G. Moquete, R.N., T. Bruce Ferguson, M.D., Keith A. Horvath, M.D., Nancy L. Geller, Ph.D., Marissa A. Miller, D.V.M., Y. Joseph Woo, M.D., David A. D'Alessandro, M.D., Gorav Ailawadi, M.D., Francois Dagenais, M.D., Timothy J. Gardner, M.D., Patrick T. O'Gara, M.D., Robert E. Michler, M.D., and Irving L. Kron, M.D., for the CTSN*

251 Patients Randomized
Primary endpoint- LVESVI at One Year

November 18, 2013, at NEJM.org.

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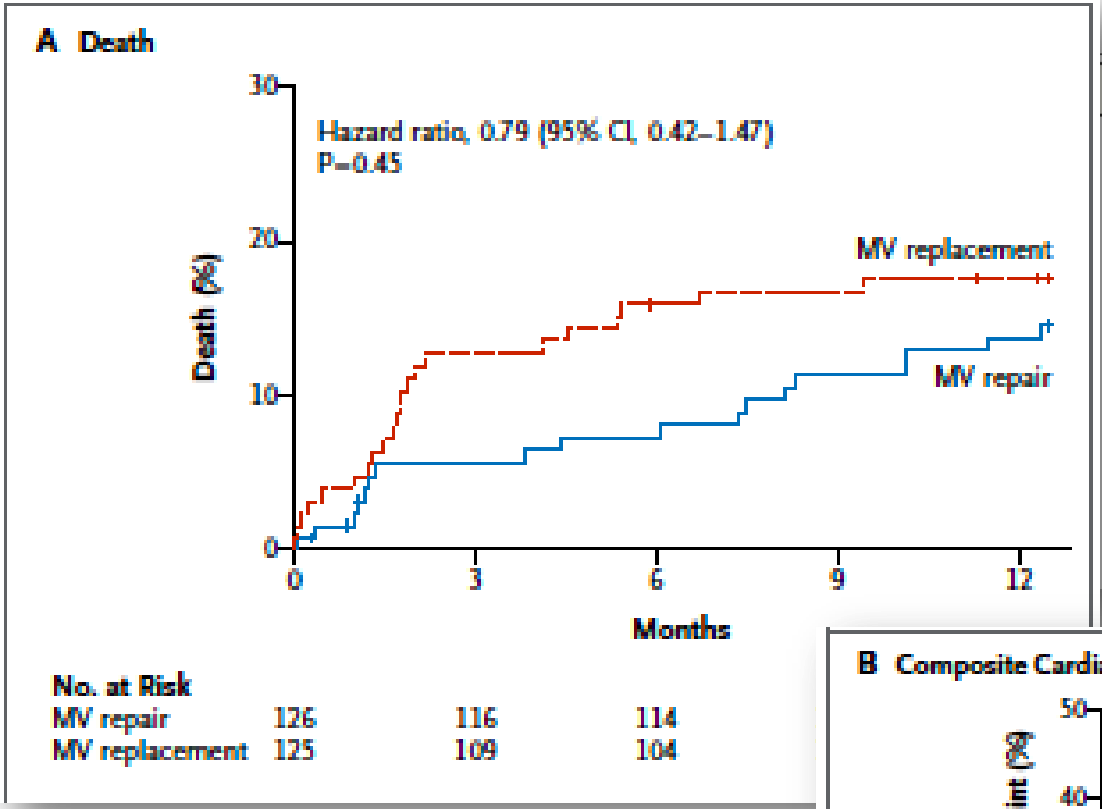
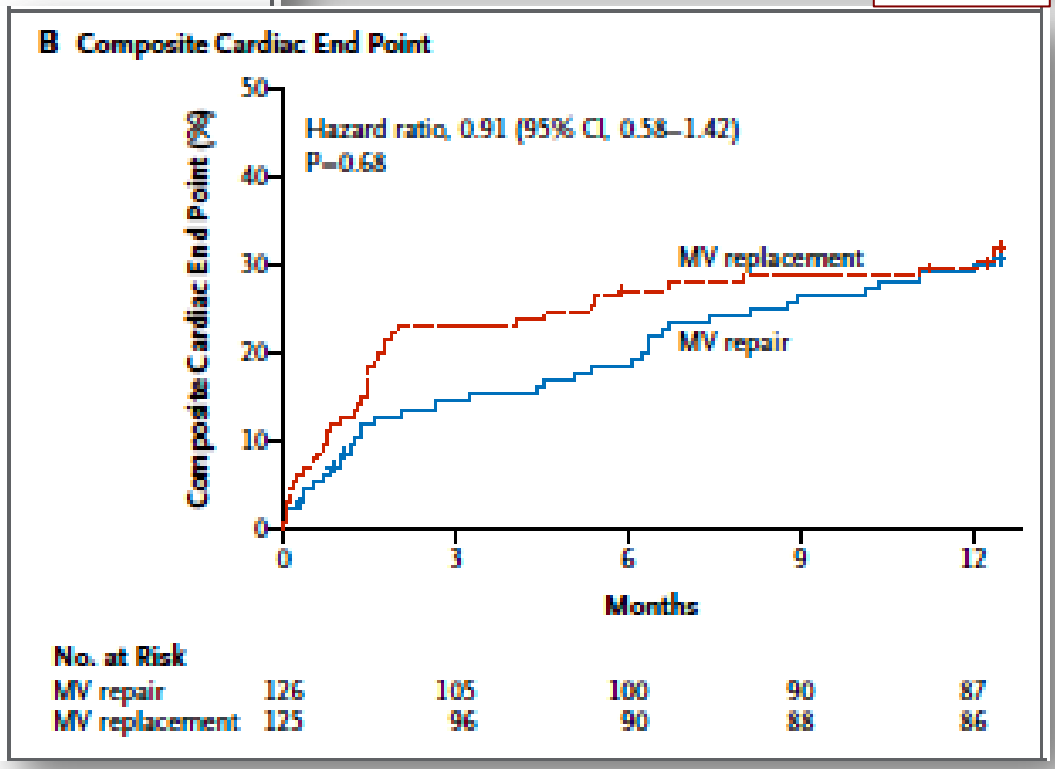
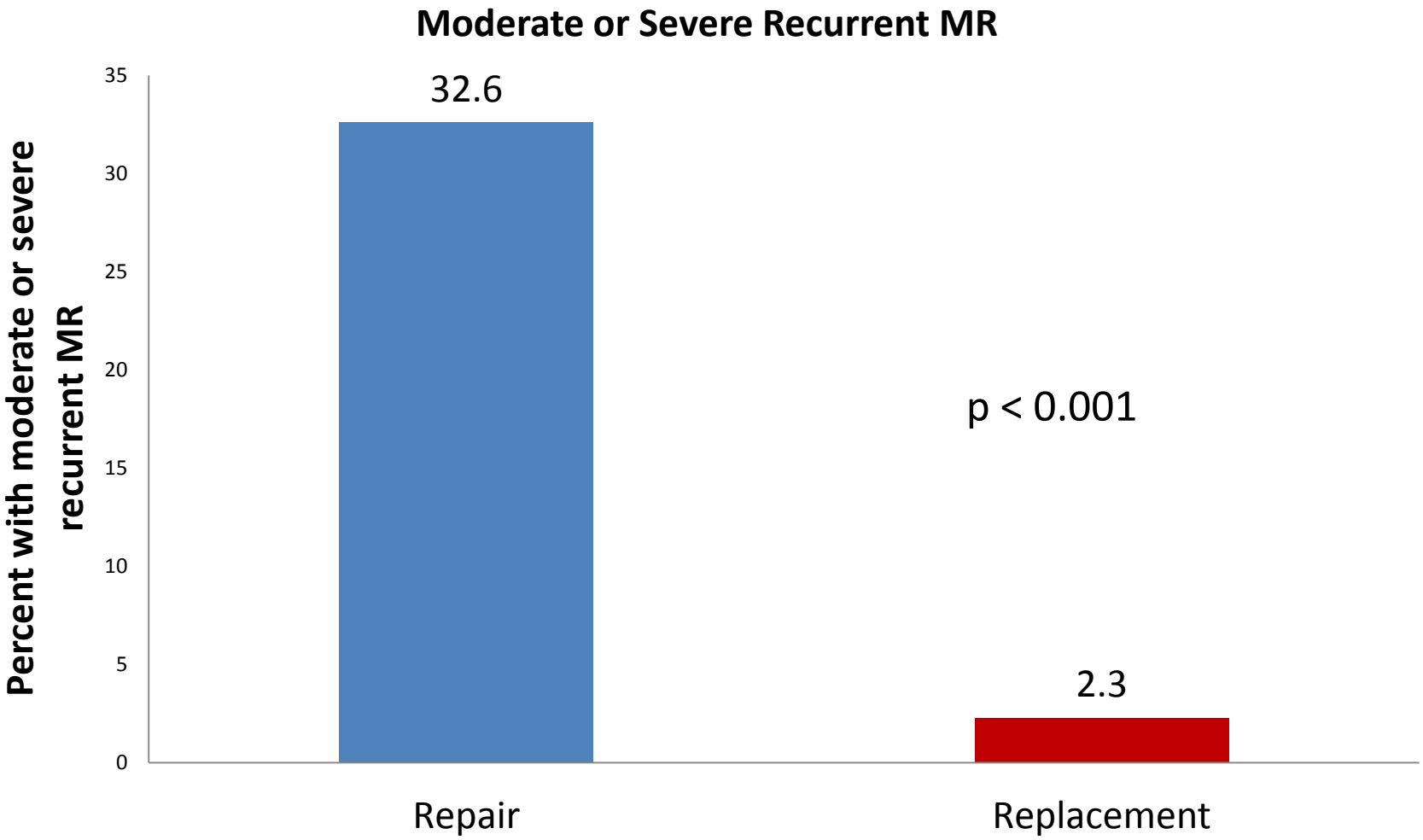
N=251





Recurrent MR at 1 year



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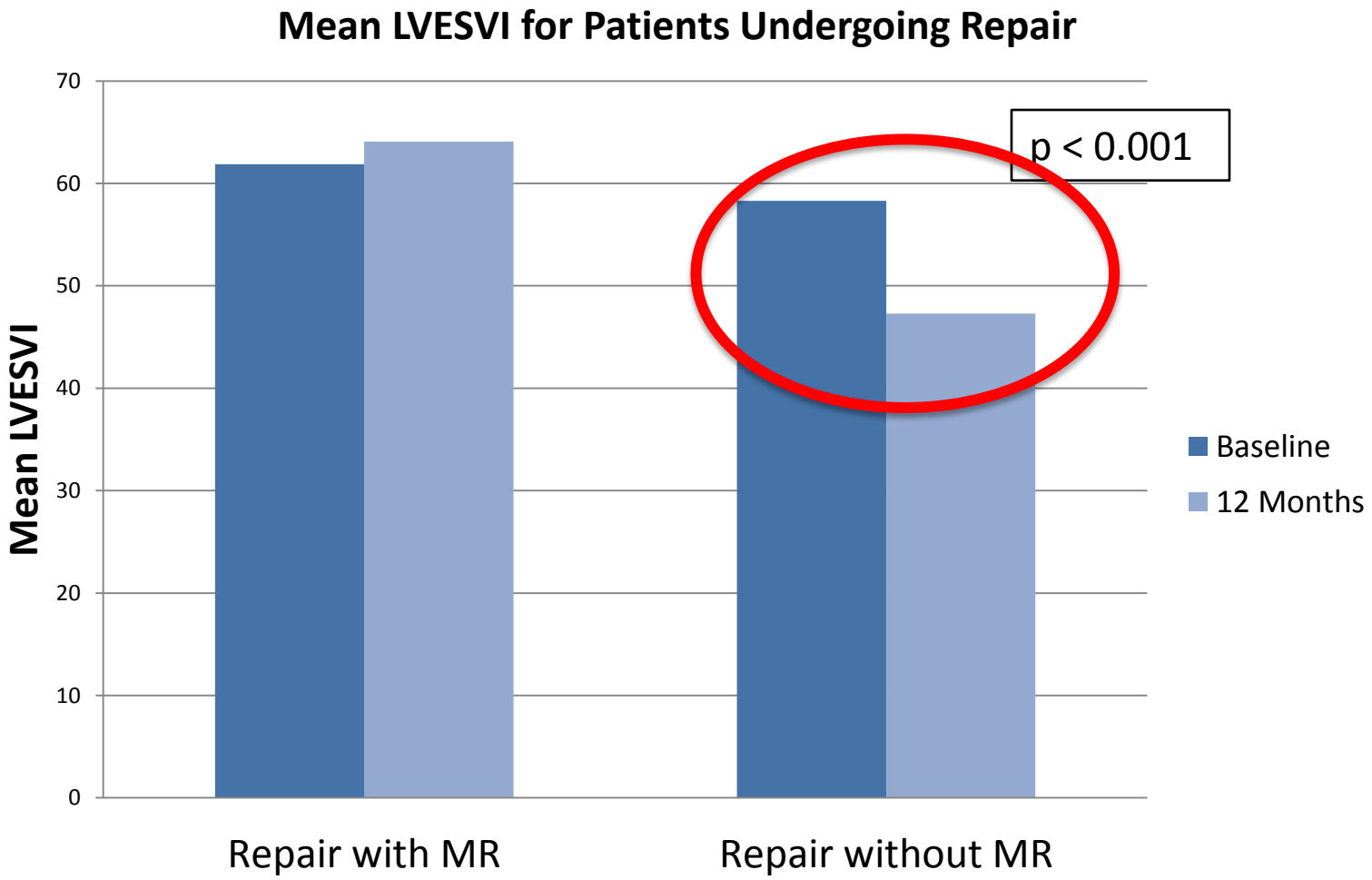
November 18, 2013, at NEJM.org.

CONCLUSIONS

We observed no significant difference in left ventricular reverse remodeling or survival at 12 months between patients who underwent mitral-valve repair and those who underwent mitral-valve replacement. Replacement provided a more durable correction of mitral regurgitation, but there was no significant between-group difference in clinical outcomes. (Funded by the National Institutes of Health and the Canadian Institutes of Health; ClinicalTrials.gov number, NCT00807040.)

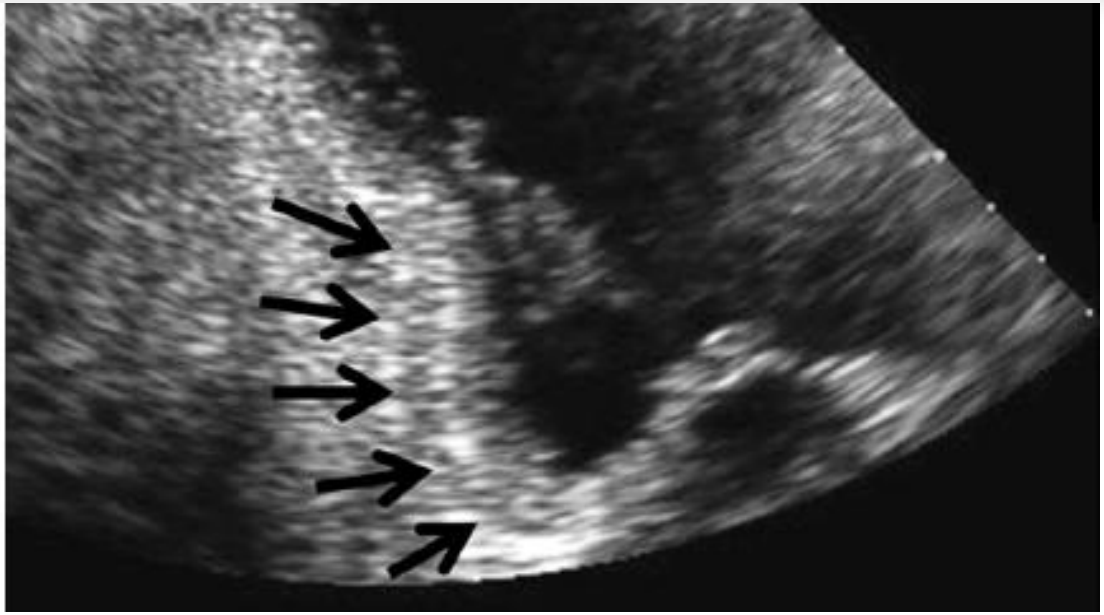
LVESVI with Recurrent MR



CTSN SMR Trial

Predicting recurrent mitral regurgitation after mitral valve repair for severe ischemic mitral regurgitation

Irving L. Kron, MD,[a] Judy Hung, MD,[b] Jessica R. Overbey, MS,[c] Denis Bouchard, MD,[d] Annetine C. Gelijns, PhD,[c] Alan J. Moskowitz, MD,[c] Pierre Voisine, MD,[e] Patrick T. O'Gara, MD,[f] Michael Argenziano, MD,[g] Robert E. Michler, MD,[h] Marc Gillinov, MD,[i] John D. Puskas, MD,[j] James S. Gammie, MD,[k] Michael J. Mack, MD,[l] Peter K. Smith, MD,[m] Chittoor Sai-Sudhakar, MD,[n] Timothy J. Gardner, MD,[o] Gorav Ailawadi, MD,[a] Xin Zeng, MD,[b] Karen O'Sullivan, MPH,[c] Michael K. Parides, PhD,[c] Roger Swayze, RN, BSN,[h] Vinod Thourani, MD,[j] Eric A. Rose, MD,[c] Louis P. Perrault, MD,[d] and Michael A. Acker, MD,[p] for the CTSN Investigators

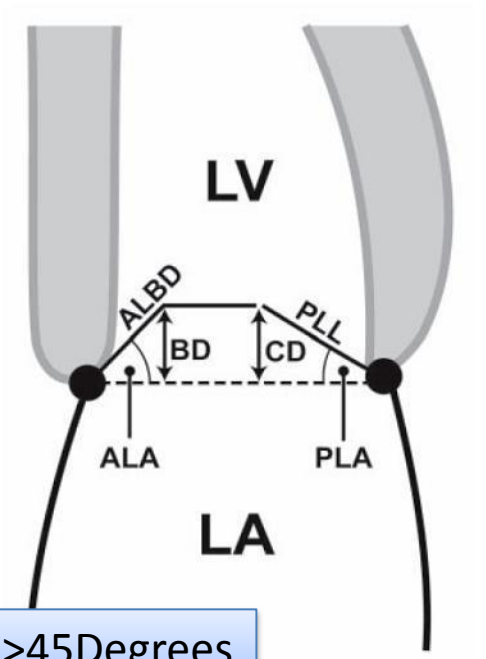


Baylor Scott & White HEALTH

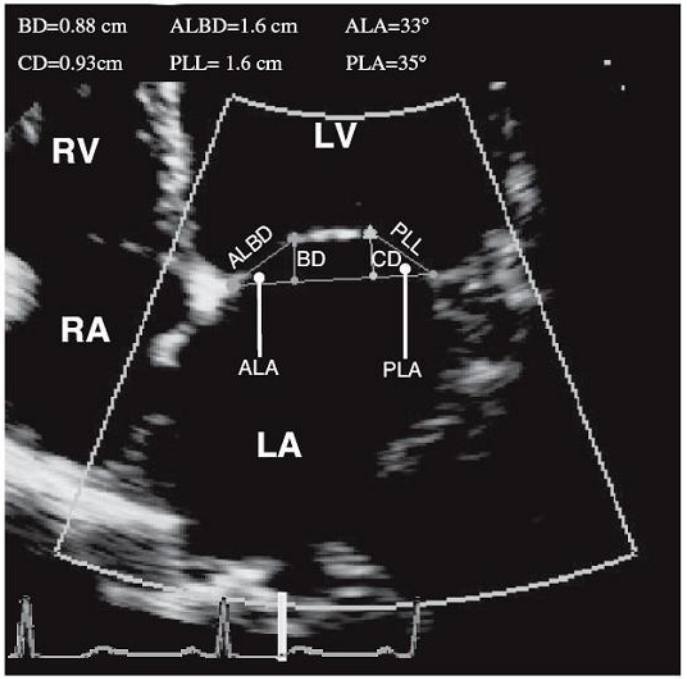
- J Thorac Cardiovasc Surg 2015;149:752-61)

Preoperative Posterior Leaflet Angle Accurately Predicts Outcome After Restrictive Mitral Valve Annuloplasty for Ischemic Mitral Regurgitation

Julien Magne, MSc; Philippe Pibarot, DVM, PhD; François Dagenais, MD, FRCS; Zeineb Hachicha, MD; Jean G. Dumesnil, MD, FRCPC; Mario Sénéchal, MD, FRCPC

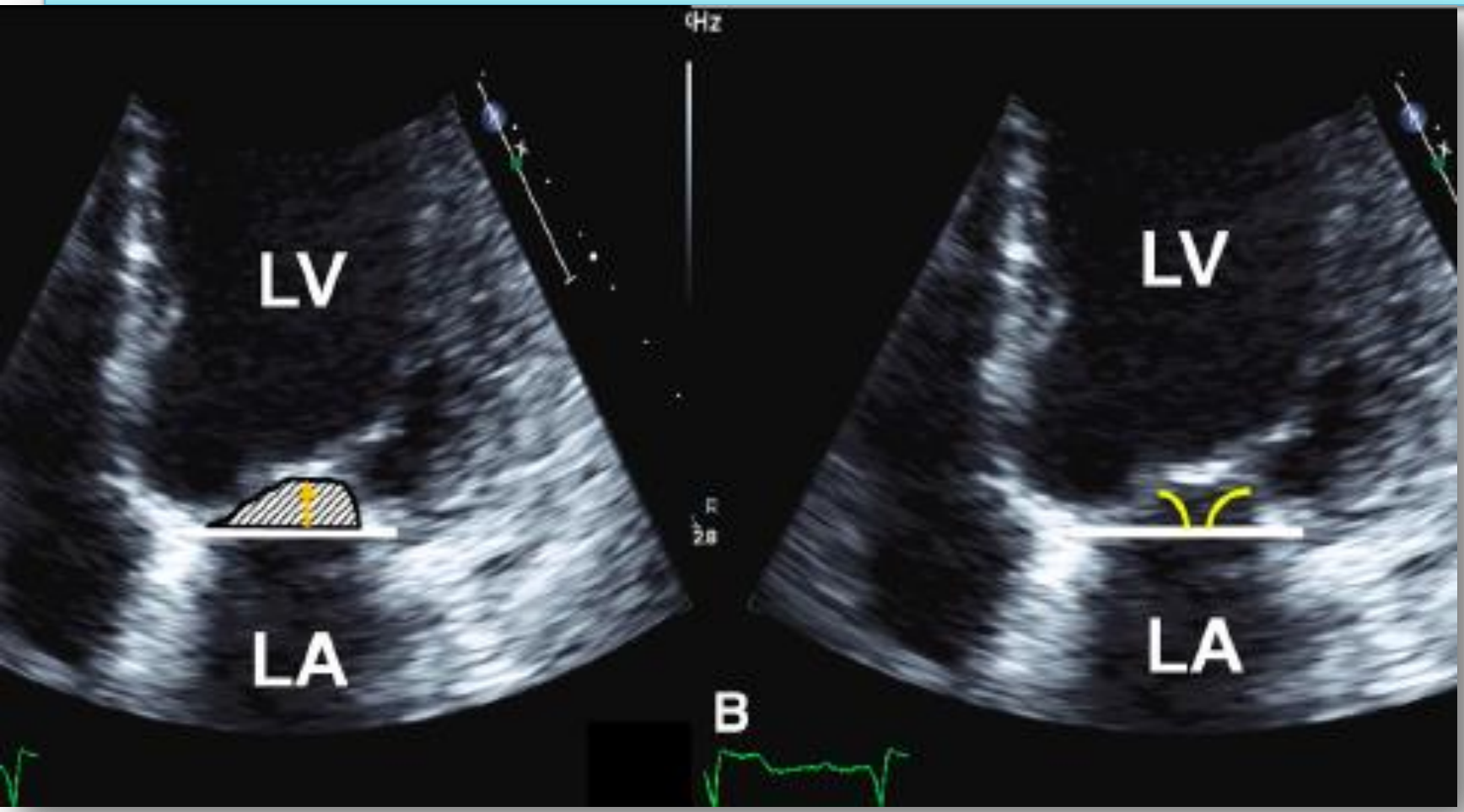


PLA >45Degrees



Magne et al. Circulation 2007; 115: 782-91

Predictors of Recurrence



Tenting Area Tenting Height

Anterior and Posterior Leaflet Angles

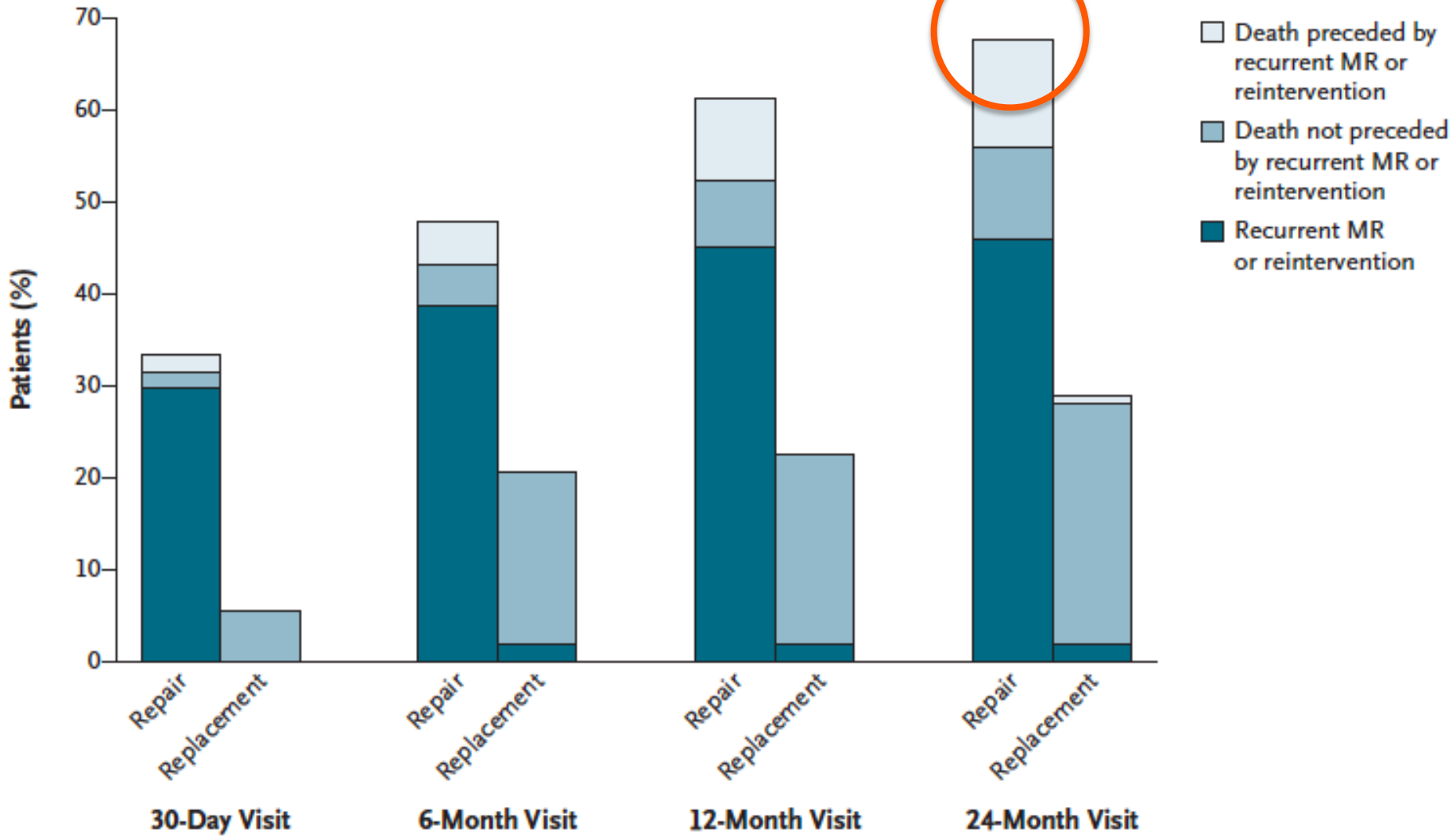


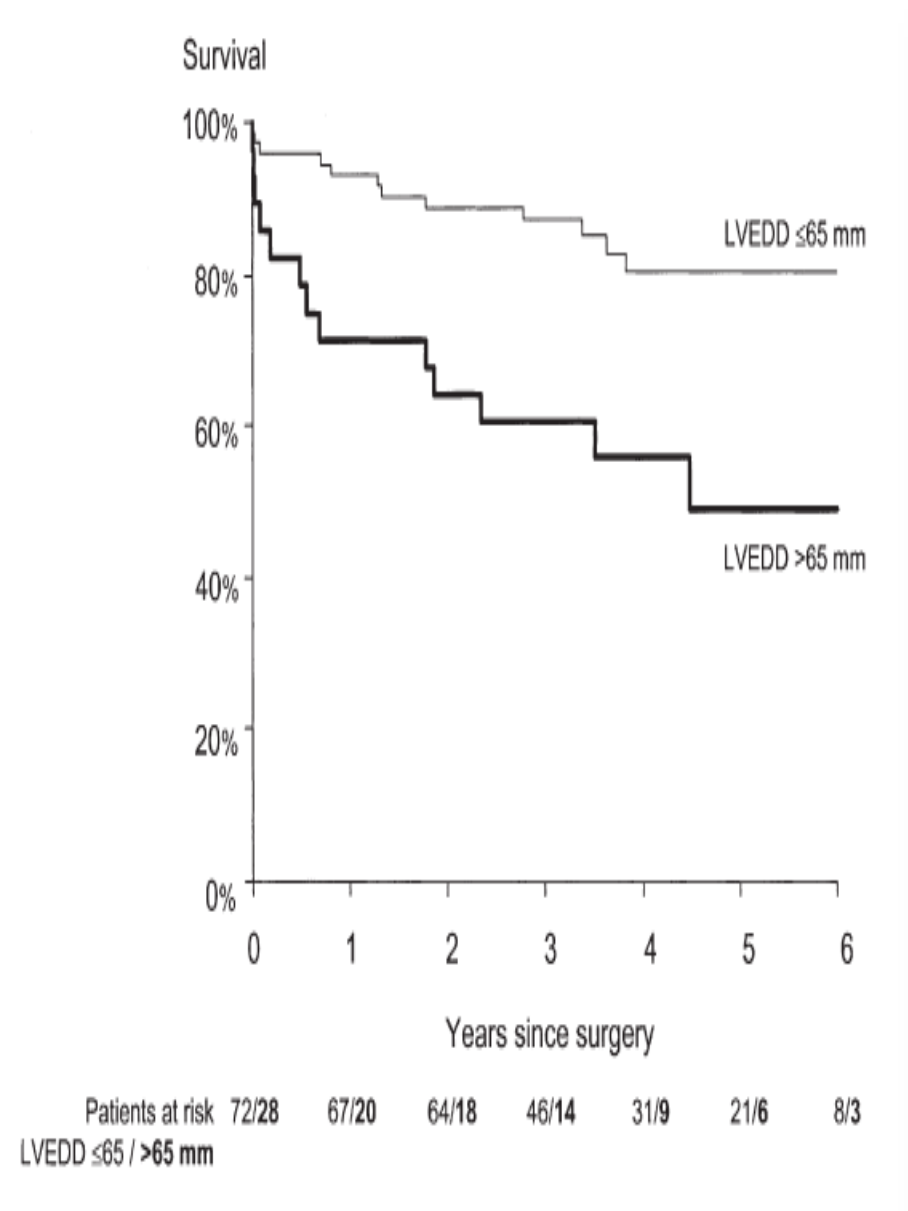
Figure 2. Cumulative Failure of Mitral-Valve Repair or Replacement.

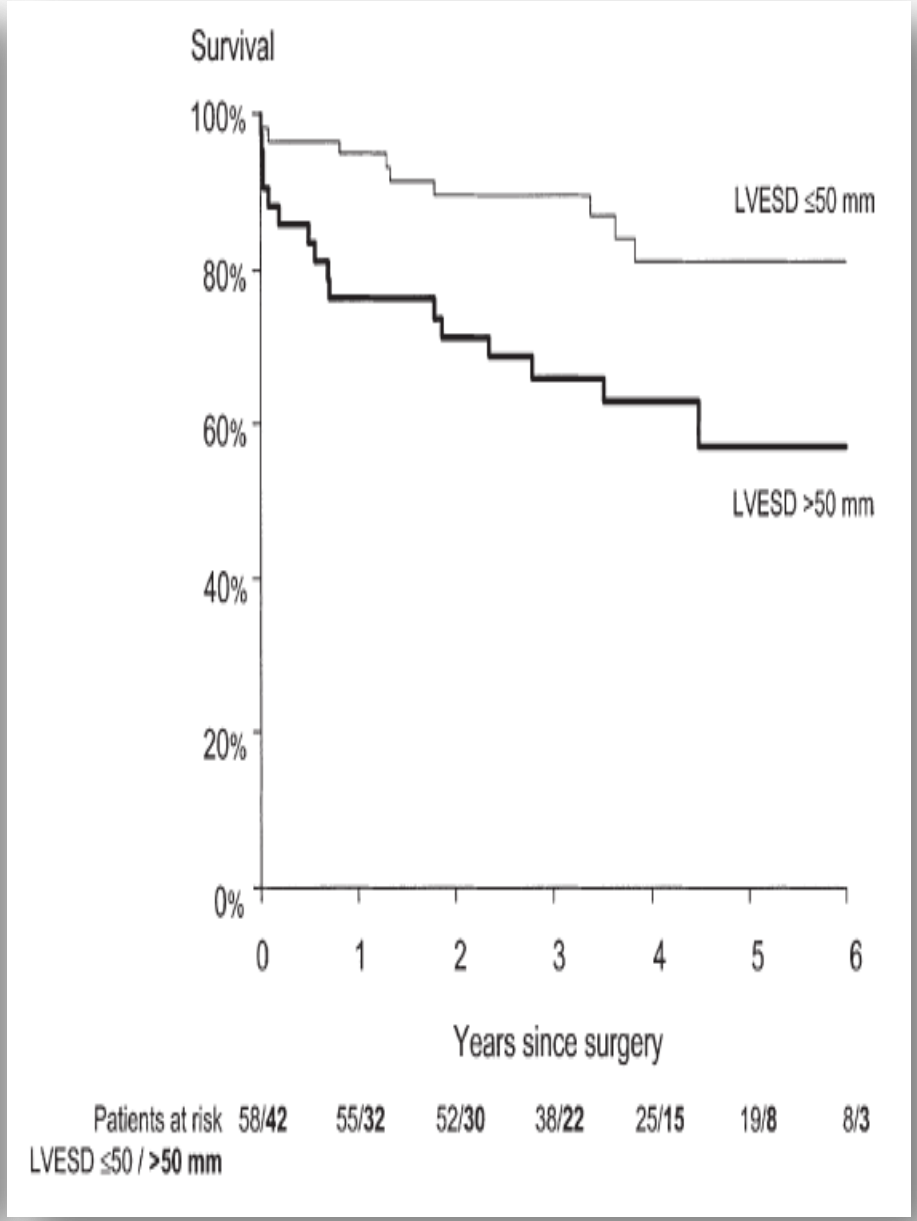
Restrictive Mitral Annuloplasty Cures Ischemic Mitral Regurgitation and Heart Failure

Jerry Braun, MD, Nico R. van de Veire, MD, Robert J. M. Klautz, MD, PhD, Michel I. M. Versteegh, MD, Eduard R. Holman, MD, PhD, Jos J. M. Westenberg, PhD, Eric Boersma, PhD, Ernst E. van der Wall, MD, PhD, Jeroen J. Bax, MD, PhD, and Robert A. E. Dion, MD, PhD

Conclusions. At 4.3 years' follow-up, intermediate-term cutoff values for left ventricular reverse remodeling proved to be predictors for late mortality. For patients with preoperative LVEDD of 65 mm or less, restrictive mitral annuloplasty with revascularization provides a cure for ischemic mitral regurgitation and heart failure; however, when LVEDD exceeds 65 mm, outcome is poor and a ventricular approach should be considered.

(Ann Thorac Surg 2008;85:430–7)


Survival
100%
80%
60%
40%
20%
0%
LVEDD ≤65 mm
LVEDD >65 mm
0
1
2
3
4
5
6
Years since surgery
Patients at risk 72/28 67/20 64/18 46/14 31/9 21/6 8/3
LVEDD ≤65 / >65 mm


Survival
100%
80%
60%
40%
20%
0%
LVESD ≤50 mm
LVESD >50 mm
0
1
2
3
4
5
6
Years since surgery
Patients at risk 58/42 55/32 52/30 38/22 25/15 19/8 8/3
LVESD ≤50 / >50 mm

Repair vs. Replacement for Secondary MR: *Replacement Always?*

Not always, but when recurrence is predictable…

- Severe tethering
  - -PLA, ALA, Tenting Height, Tenting Area
- Severely depressed LV function
  - -EF<0.35
- Severely dilated LV
  - -LVEDD >65
- Inferobasal aneurysm, dyskinesis

Why is the Benefit of MR Reduction So Hard to Find?

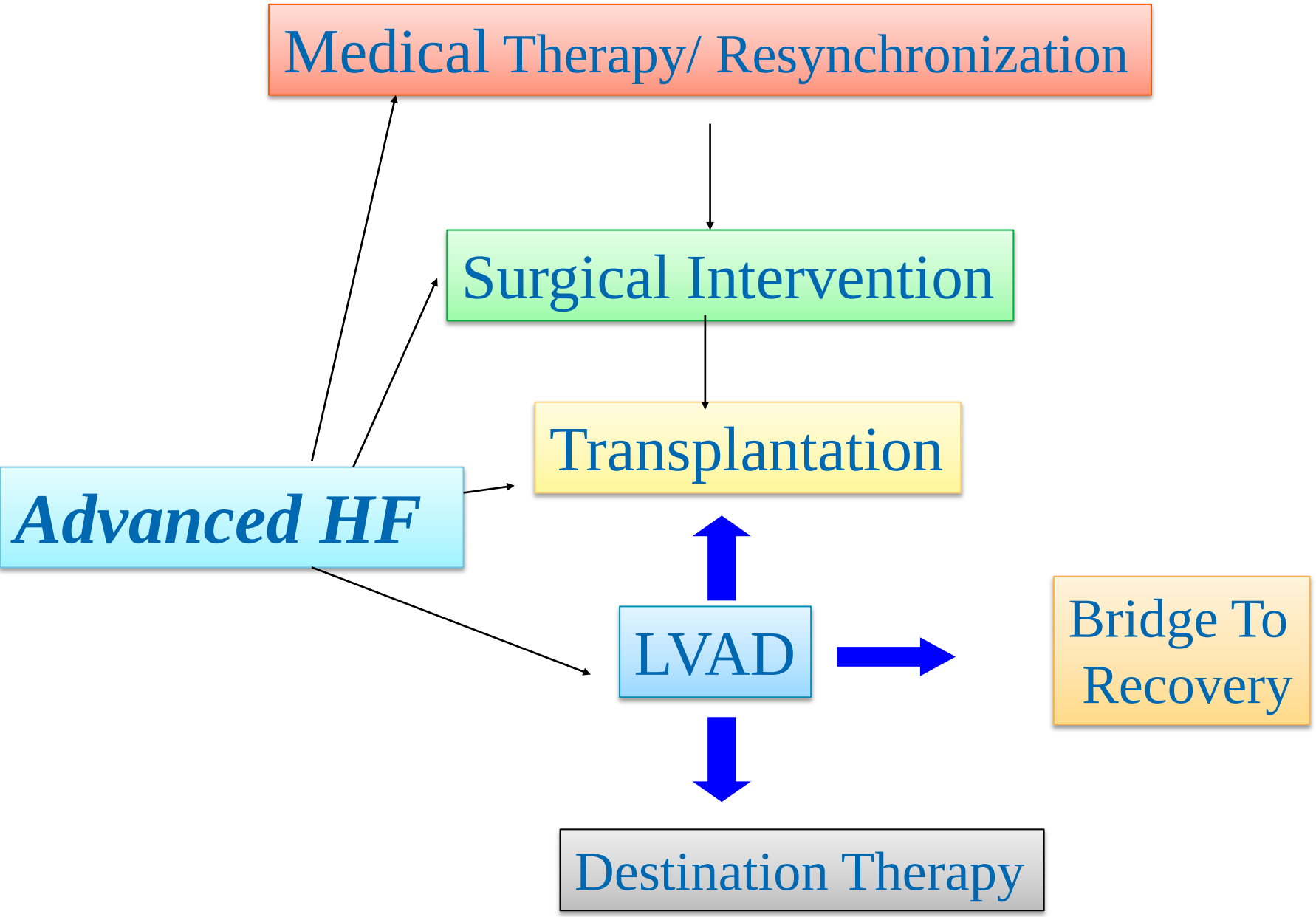
1- MR Recurrence (≥ 20%) and operative mortality (1.5-15%) counterbalance a benefit.

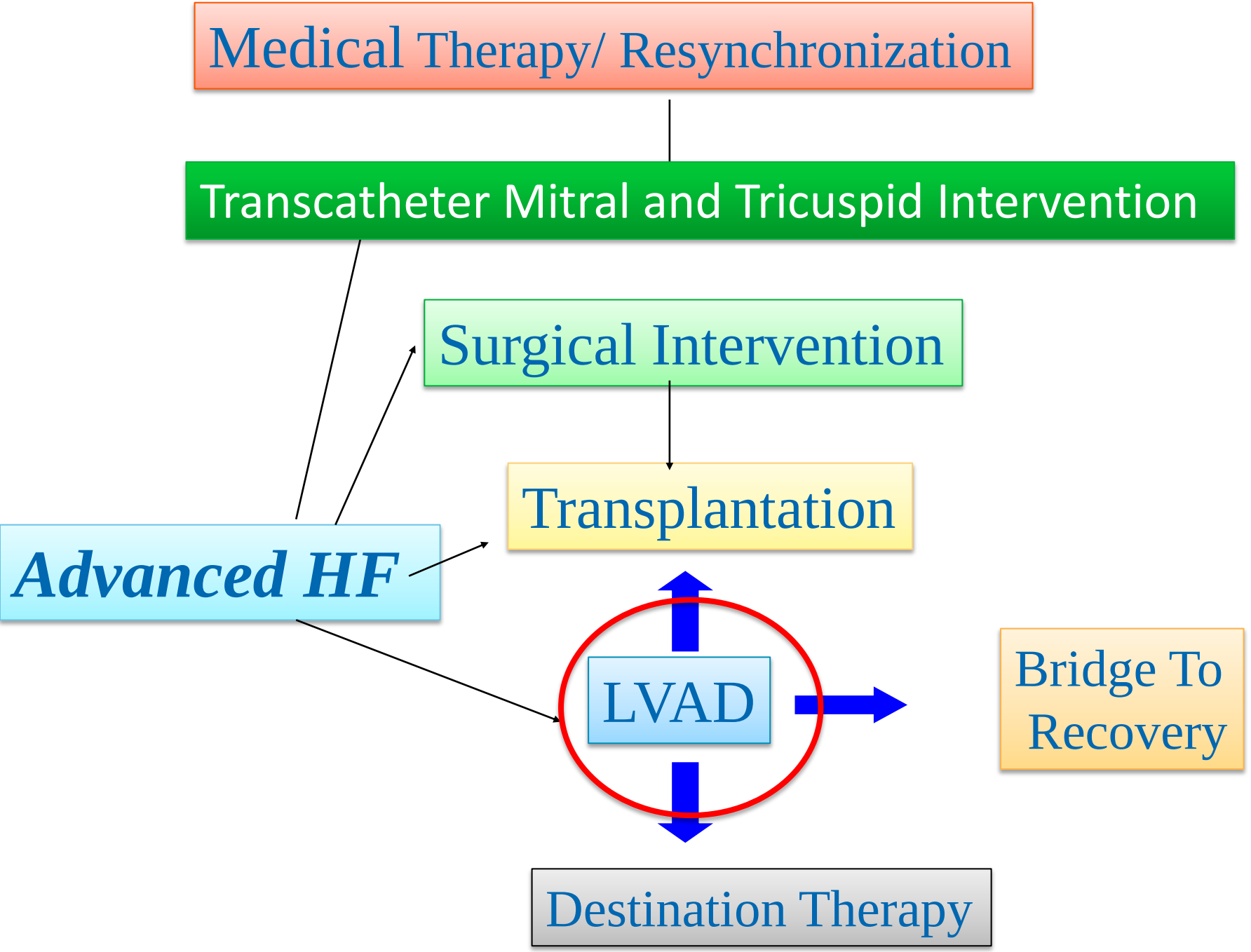
2- The benefit is limited to specific patient subgroups that have not been pre-defined in the current data sets (etiology, duration of MR, LVEF, functional class etc)-like treating all anemia with Vit B12 and saying it doesn't work!

3- No randomized trials with appropriate controls and core-lab assessment of MR.

4- Maybe there is no benefit.

(MR is a surrogate marker not causally related to outcome)

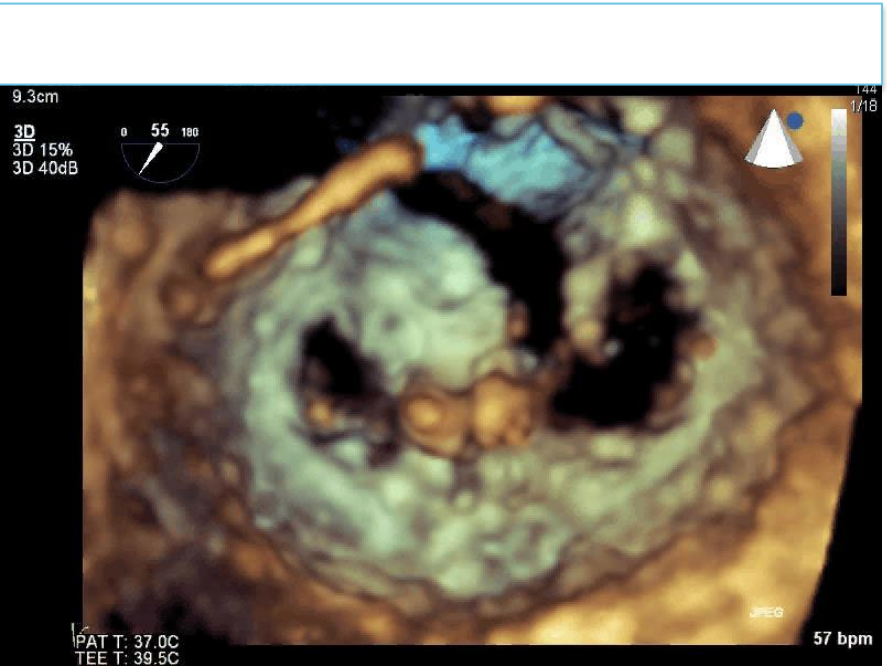

Medical Therapy/ Resynchronization
Surgical Intervention
Transplantation
Advanced HF
LVAD
Bridge To Recovery
Destination Therapy

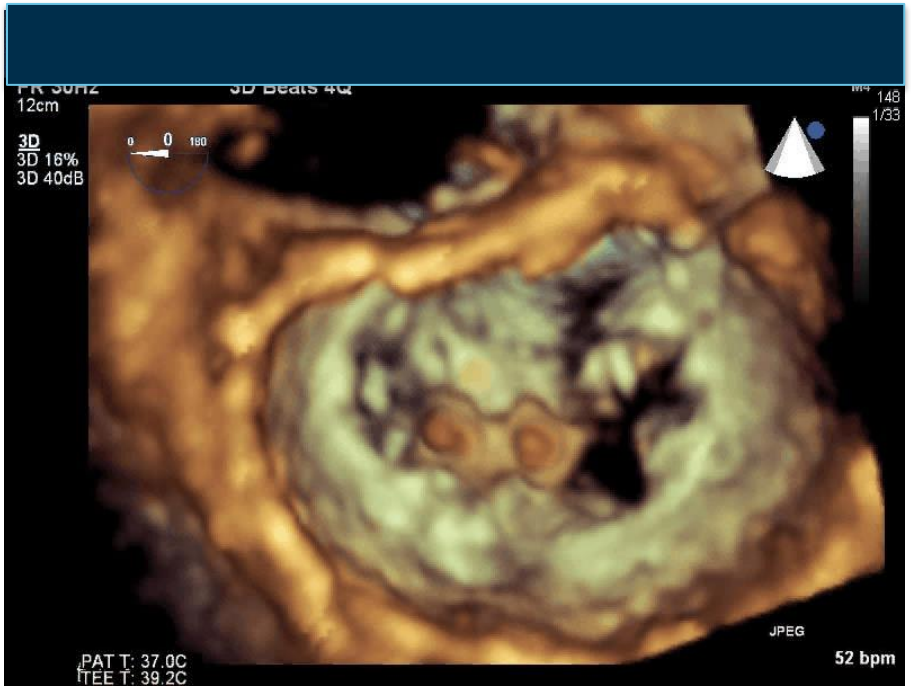

Medical Therapy/ Resynchronization
Transcatheter Mitral and Tricuspid Intervention
Surgical Intervention
Transplantation
Advanced HF
LVAD
Bridge To Recovery
Destination Therapy

Transcatheter Mitral Valve Repair

MitraClip System

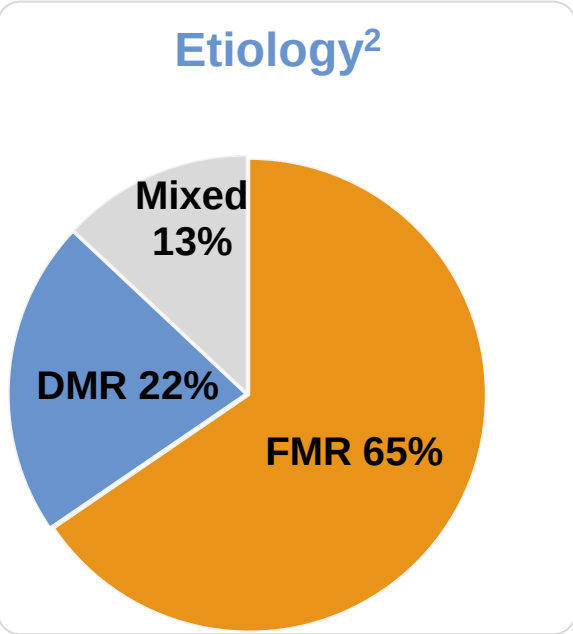
MitraClip for Secondary MR





Commercial MitraClip Implant Worldwide Experience

- Treating Centers: 463
- Patients[1]: 25,508
- Implant Rate[1]: 96%
- Etiology[2]
  - ***Functional MR 65%***
  - Degenerative MR 22%
  - Mixed 13%



Data as of 01/31/2015. Source: Abbott Vascular.

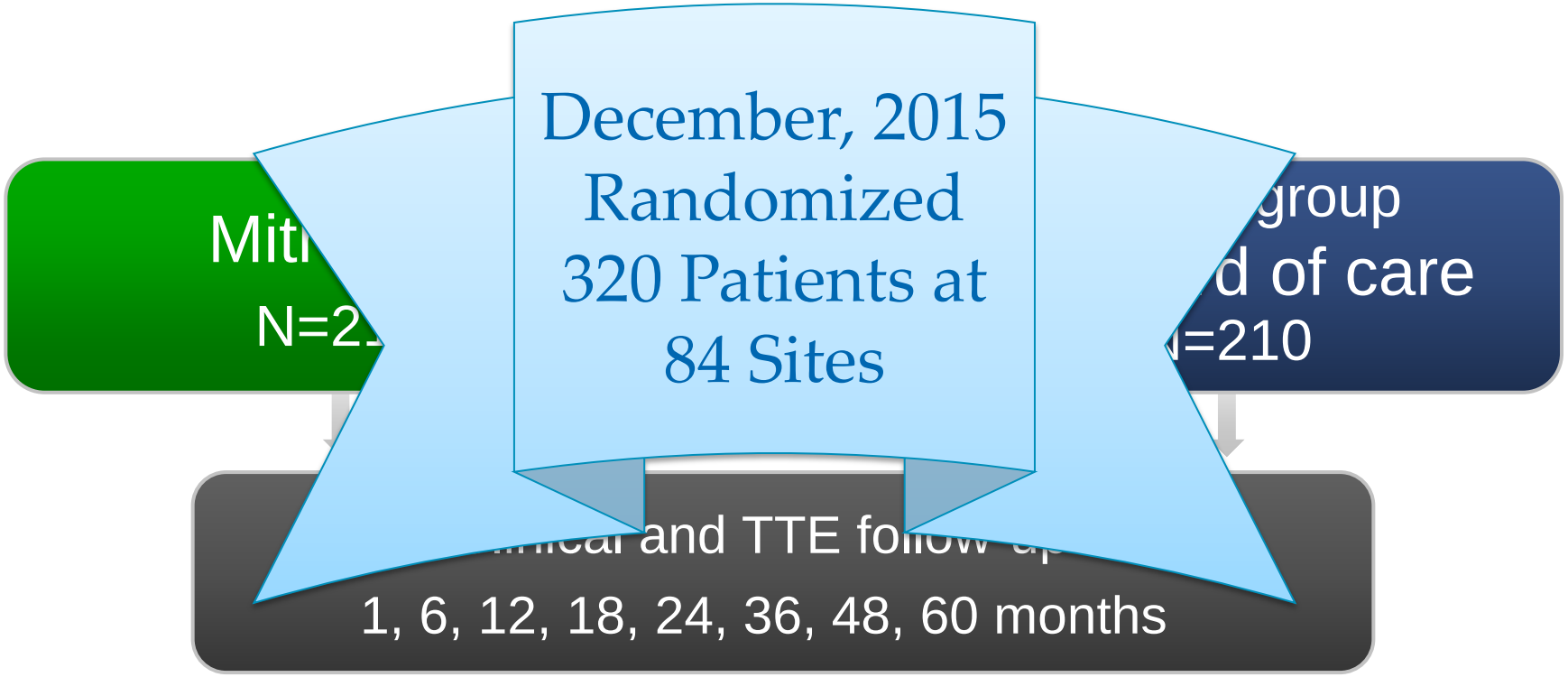
COAPT: Trial design

~420 patients enrolled at up to 75 US sites

Significant FMR (≥3+ by core lab)

Not appropriate for mitral valve surgery (local heart team)

Specific anatomical criteria



COAPT Trial
Summary

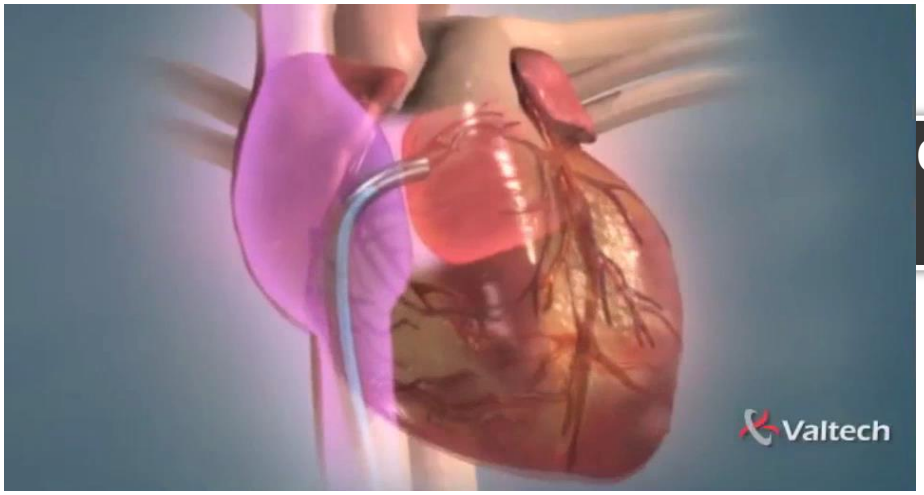
- First trial of correction of MR in secondary MR randomized vs. medical therapy
- Trial enrollment will complete in March 2016
- Results will be available late 2017
- These results will significantly “inform the field” and impact both surgery and transcatheter valve repair and replacement

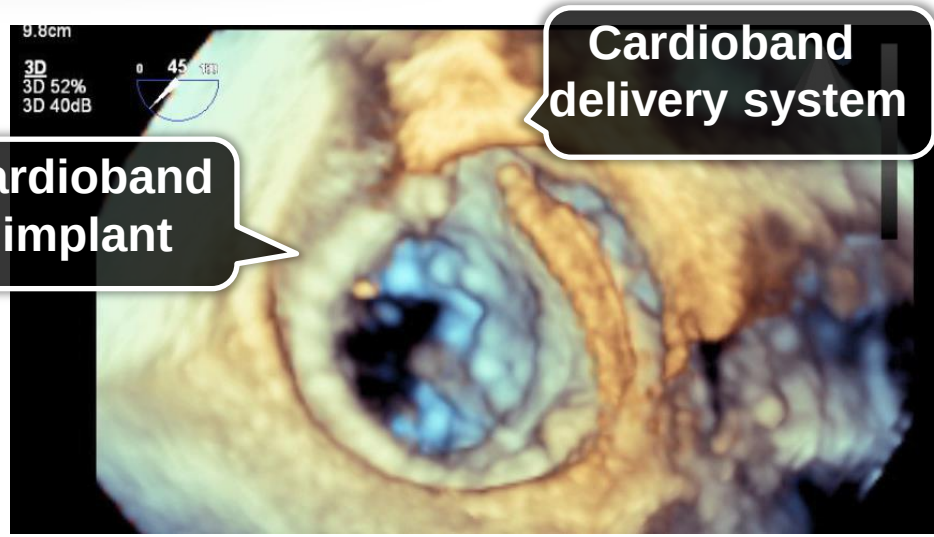
Cardioband Valtech

- Surgical band delivered via transfemoral venous access
- Implanted on the supra-annular position, similar to the surgical treatment
- Controlled adjustment of the posterior annulus for optimal hemodynamic results

Cardioband Delivery System

Transcatheter Mitral Annuloplasty
Posterior Band Deployed Trigone to Trigone

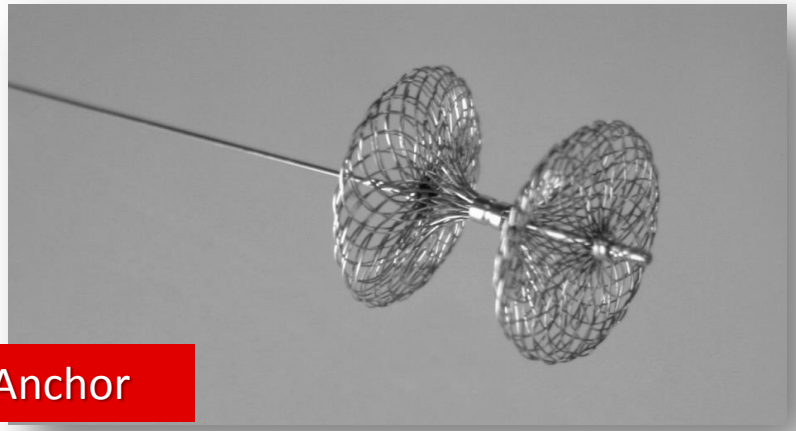




Mitra Spacer

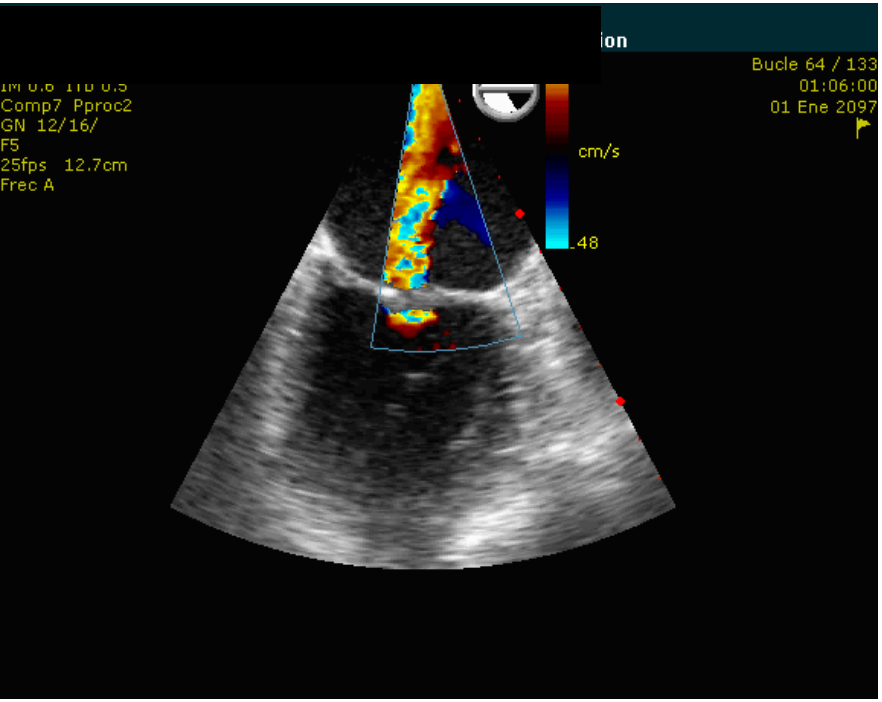
Mitra-Spacer™

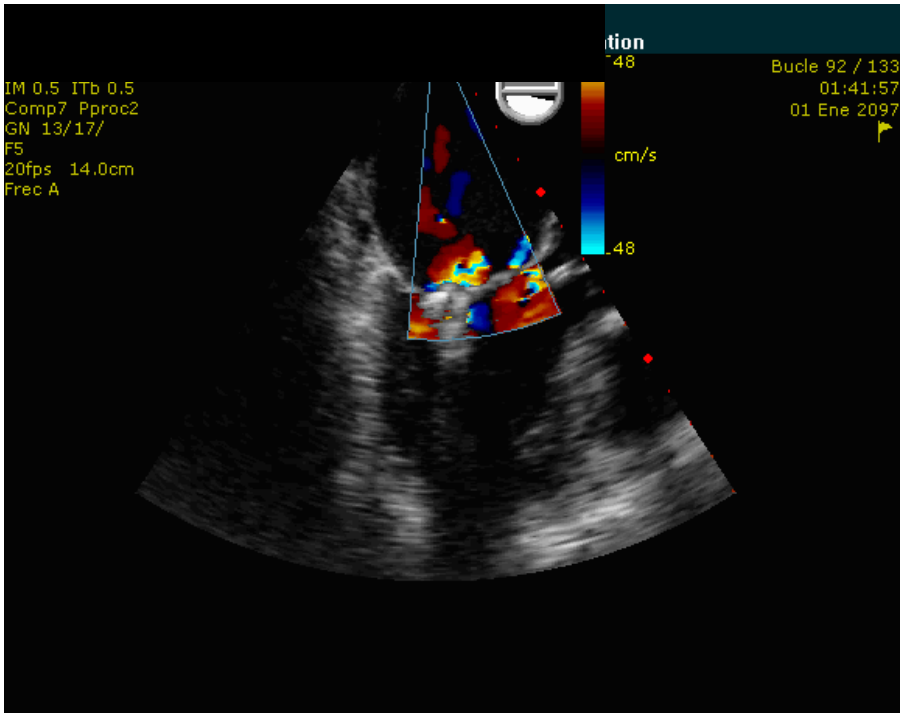
14Fr Delivery Catheter



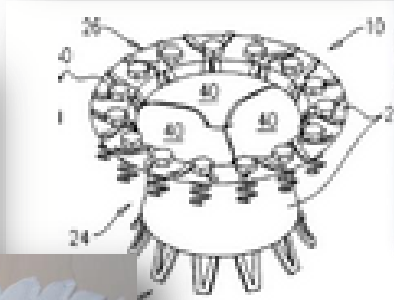
Anchor

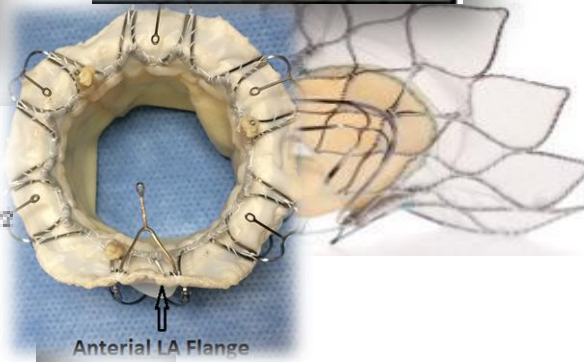
Mitra Spacer

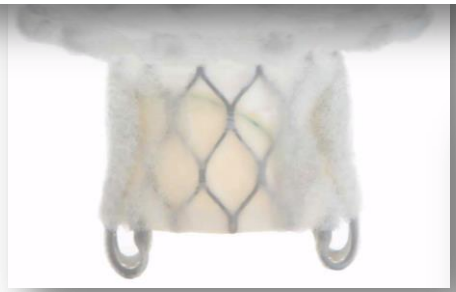


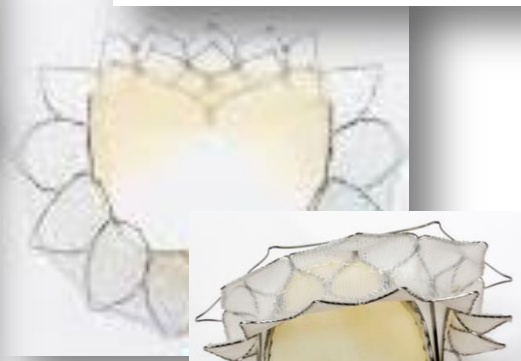


Transcatheter Mitral Valve Replacement-TMVR









Baylor Scott & White HEALTH

TMVR

Approved For Early Feasibility Trials in U.S.
(When <30 Cases Performed OUS)

CardiaQ

Tendyne

Edwards Fortis

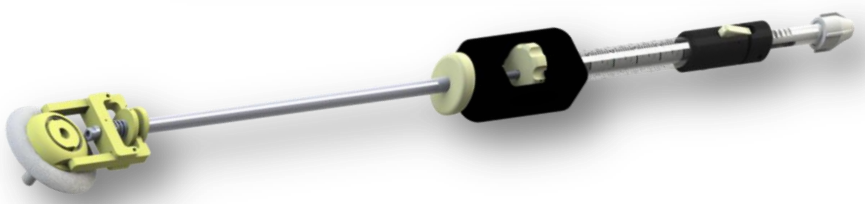
Neovasc Tiara

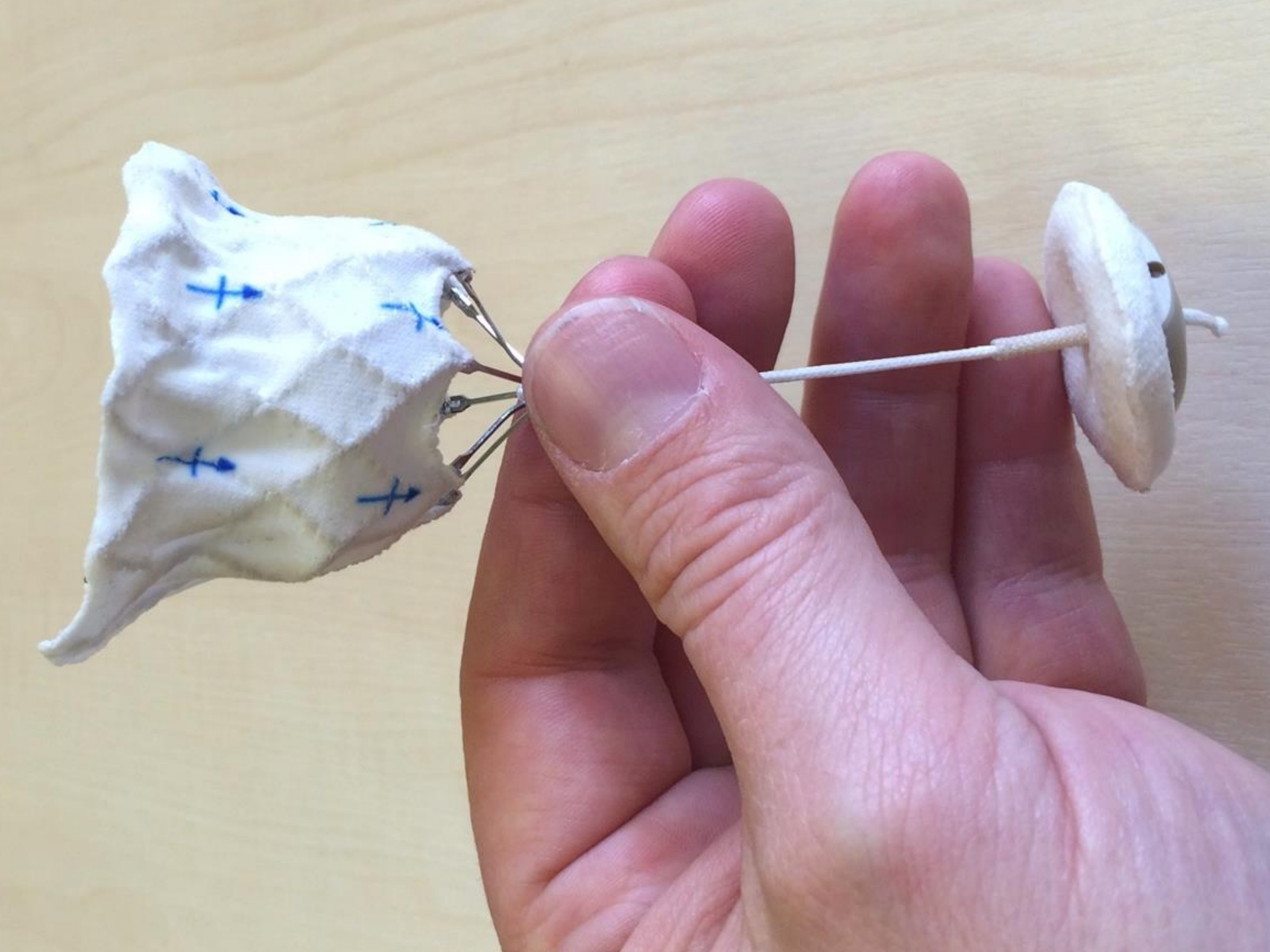
Tendyne Transcatheter Mitral Valve

Tendyne Device

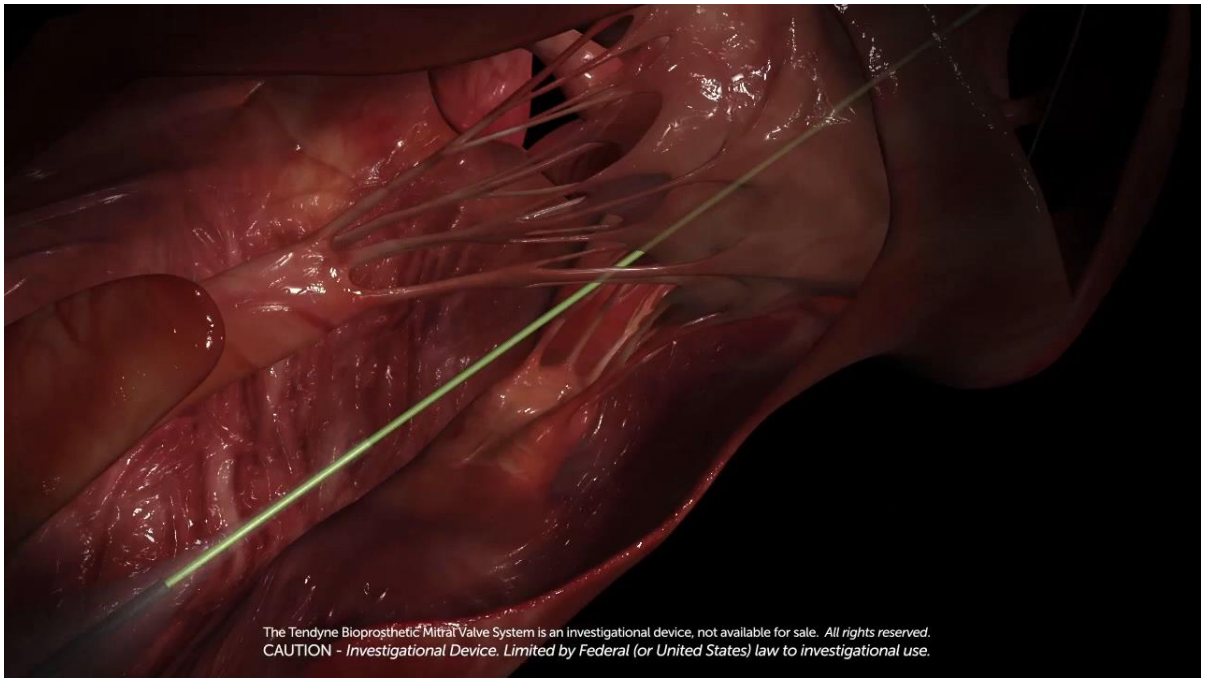
- Inner circular and outer D-Shaped Self-Expanding Nitinol Frame
- Porcine Pericardial Tri-Leaflet Valve
- Large EOA
- Tether to Left Ventricular Apex
- Numerous Valve Sizes

- **Tendyne Procedure**
- Trans-apical
- Fully Repositionable and Retrievable
- No Rapid Pacing or CPB Required



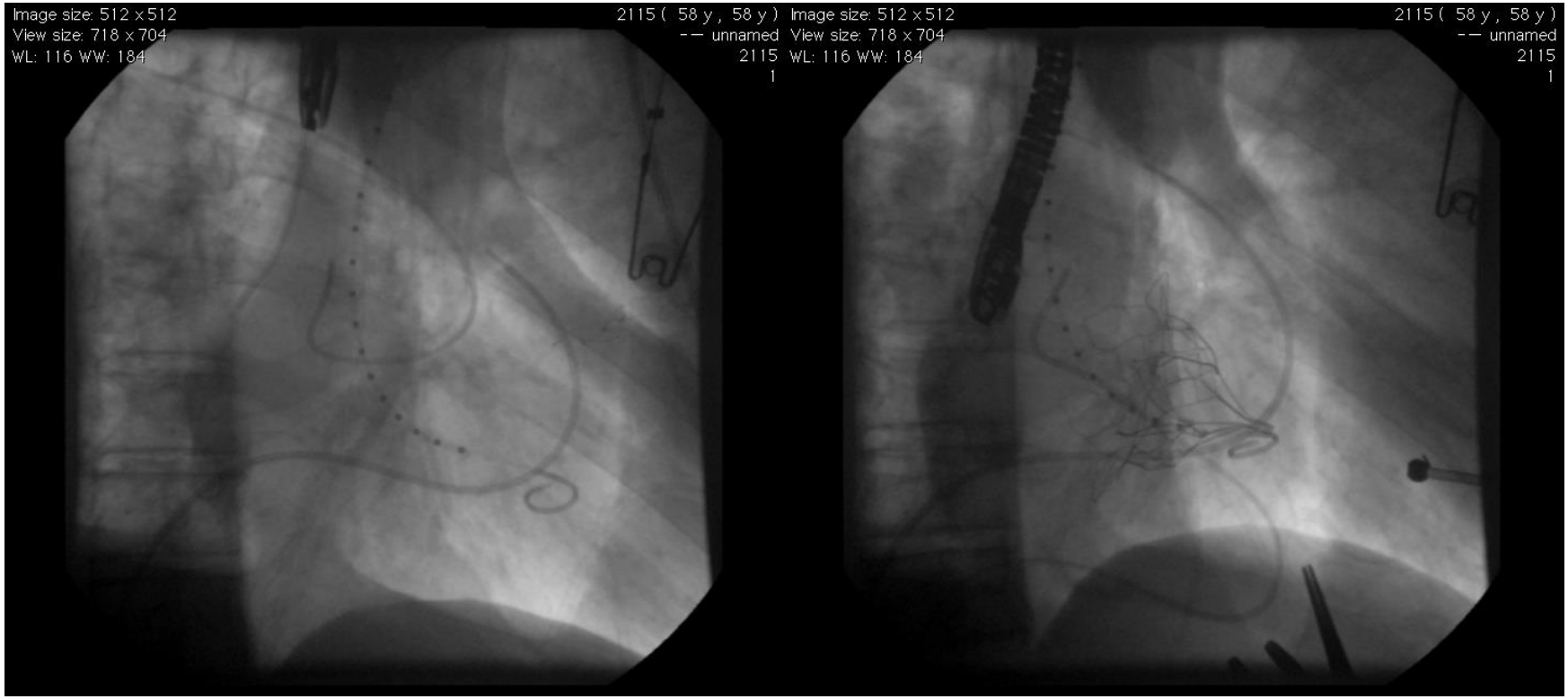


Tendyne Transcatheter Mitral Valve

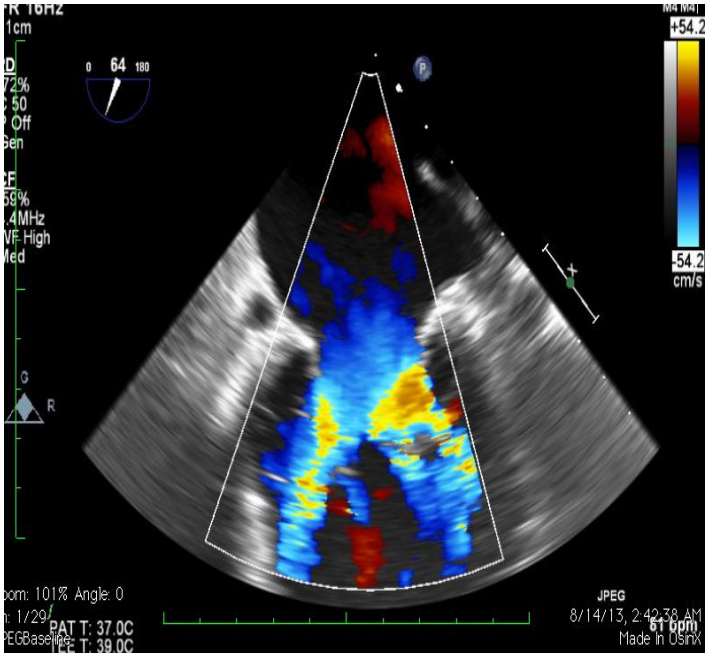


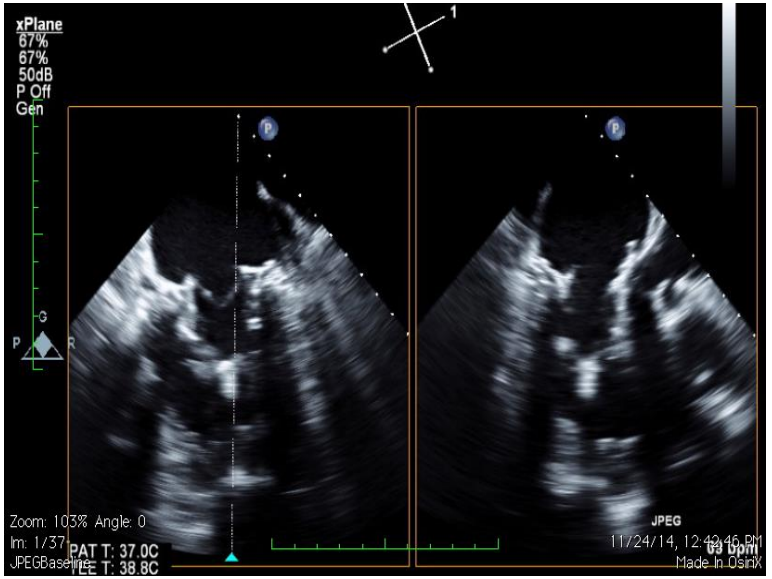
Tendyne

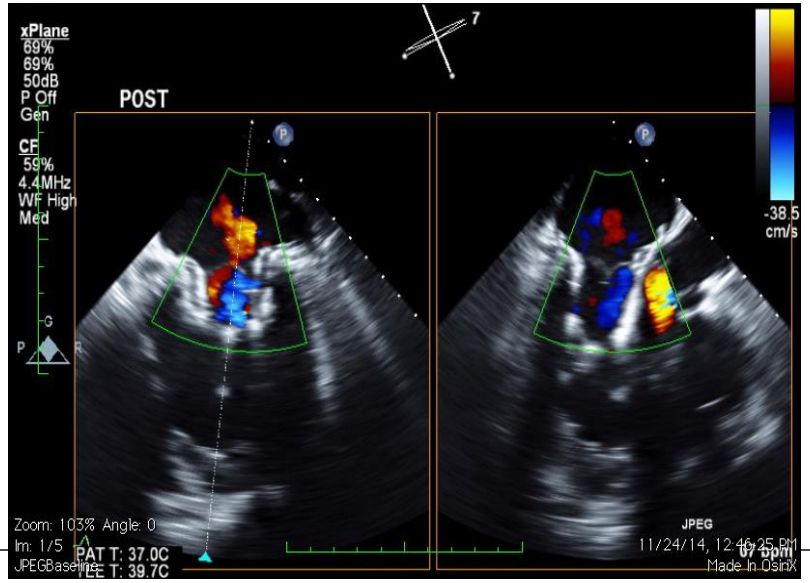
Baseline Post-valve



Tendyne Transcatheter Mitral Valve







Edwards buy of CardiAQ for $350M a bet on tra

July 1

HeartWare Spends $800M For Mitral Valve Repair Company Valtech

By Jof Enriquez

HeartWare International Inc., maker of left ventricular assist devices (LVADs) for the treatment of heart failure, has agreed to acquire Israeli firm Valtech Cardio Inc., a developer of non-invasive transcatheter mitral and tricuspid valve repair and replacement technologies, in an all-stock, no-cash deal that is expected to close late in 2015.

Boston Scientific announces $200M option to purchase Israeli transcatheter mitral valve player

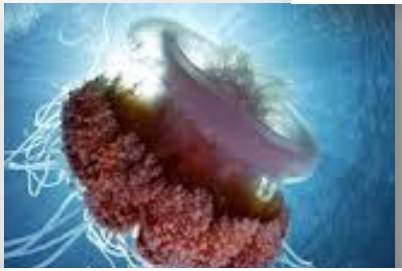
Boston Scientific ($BSX) announced that it has obtained an exclusive $200 million option to acquire Israel's MValve Technologies, maker of a transcatheter mitral valve replacement (TMVR) system for mitral regurgitation. Boston Scientific also said it is providing additional financing to the company in anticipation of a first in-human clinical trial. The bigwig has been financing MValve since 2012.

The official announcement of the option came just now, though Israeli newspaper paper *Globes* broke the news last year. Such a transaction would add to the $1 billion-plus spent by competitors Abbott ($ABT), Medtronic ($MDT) and Edwards ($EW) in recent months, as they place their bets on different companies in the hopes of winning the battle for

Transcatheter Mitral Valve Replacement TMVR

>$2.5 Billion spent in last 3 months for 6 companies with a combined total of ~50 cases !

twelve



Baylor Scott & White HEALTH

TMVR

Discussion Questions

- 1. What is the role of advanced imaging modalities for MR? When are they incorporated?
- 2. What is the optimal therapy for patients with symptomatic severe primary MR? What about for symptomatic severe secondary MR? Ischemic MR? When is valve replacement preferred over repair in patients referred for surgery?
- 3. When is transcatheter mitral valve repair appropriate (extreme risk patient, degenerative, functional)? Do you consider a transcatheter mitral repair attempt before sending patients to surgery? What factors are key in determining if your patient is a reasonable transcatheter mitral repair candidate?
- 4. Where do you envision transcatheter mitral valve replacement (TMVR) will fit into the management of patients with severe MR? Is it likely to better suit patients with primary or secondary MR? Should the adoption of TMVR technologies depend on efficacy in improving survival or is reduction in heart failure hospitalizations sufficient?
- 5. What is the appropriate frequency and methods that should be used in following patients with MR initially, during active medical treatment, and post-surgery/post-intervention?