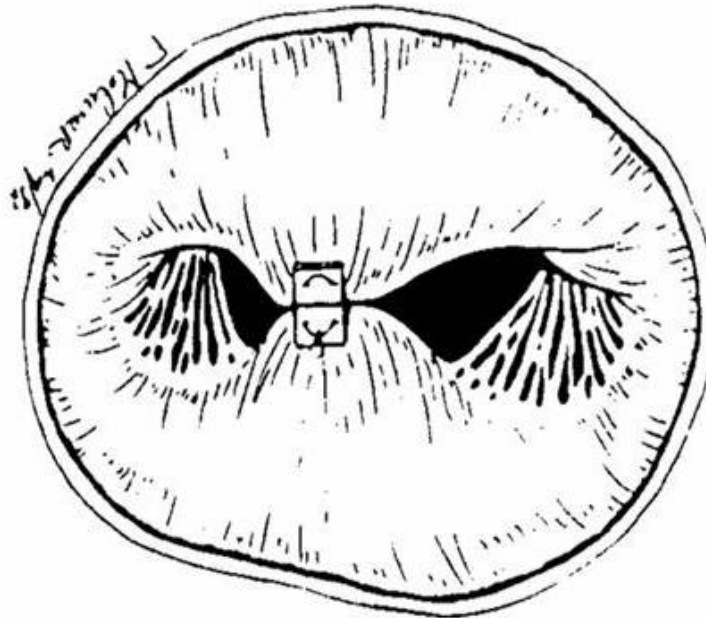


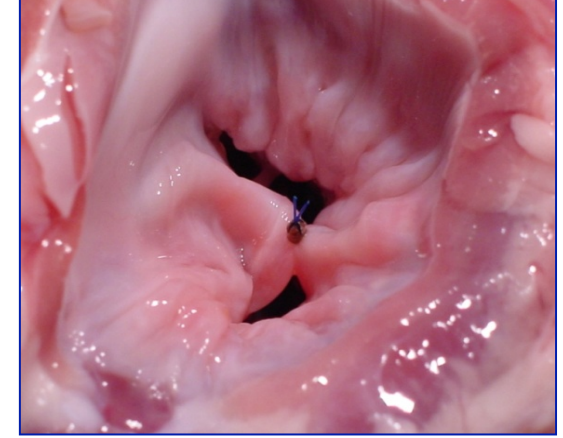
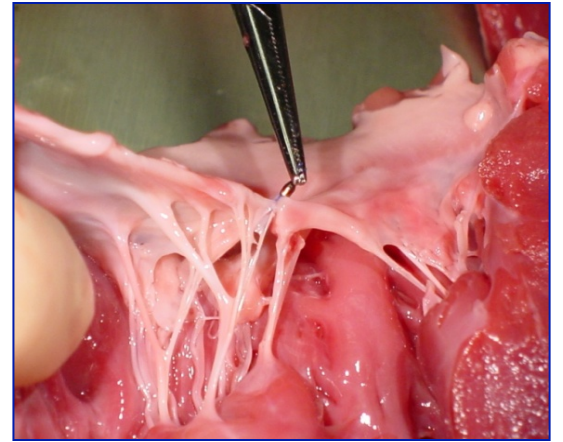
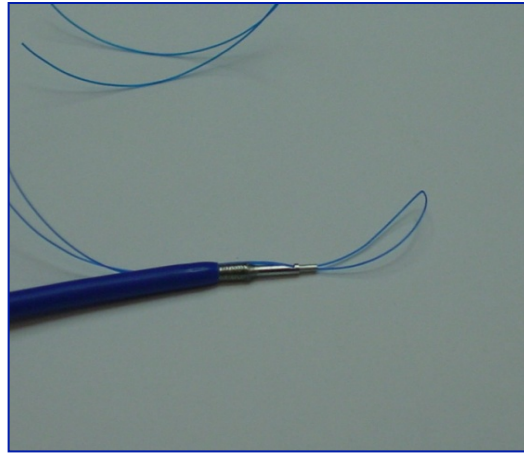
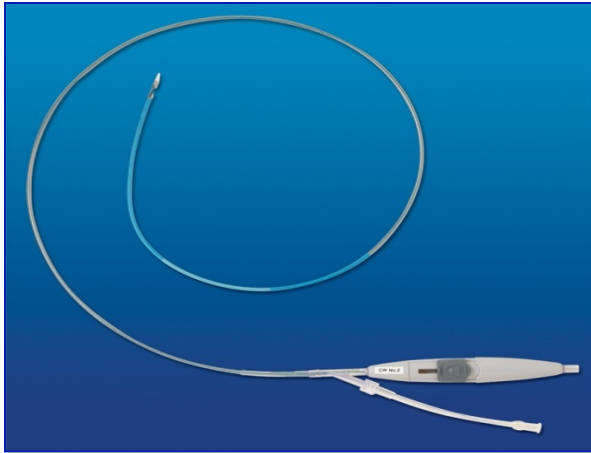
Insuffisance mitrale

MitraClip Procédure et Sélection des patients

Edge to Edge procedure



Mobius System



Courtesy of D. Bobo

Percutaneous suture edge-to-edge repair of the mitral valve

John G. Webb¹, MD; Francesco Maisano², MD; Alec Vahanian³, MD; Brad Munt¹, MD; Tasneem Z. Naqvi⁴, MD; Raoul Bonan⁵, MD; David Zarbatany⁶; Maurice Buchbinder MD⁷

1. St. Paul's Hospital, University of British Columbia, Vancouver, Canada; 2. Istituto Scientifico San Raffaele, Milan, Italy; 3. Hopital Bichat, Paris, France; 4. University of Southern California, Los Angeles, CA, United States; 5. Montreal Heart Institute, Montreal, Canada; 6. SurgiVision, Inc., Irvine, CA, United States; 7. Foundation for cardiovascular medicine, La Jolla, CA, United States

Drs. Buchbinder, Maisano, Munt, Naqvi, Vahanian and Webb are consultants to Edwards Lifesciences, Irvine, CA, United States. David Zarbatany was an employee of Edwards Lifesciences.

KEYWORDS

Mitral, regurgitation, percutaneous, valve

Abstract

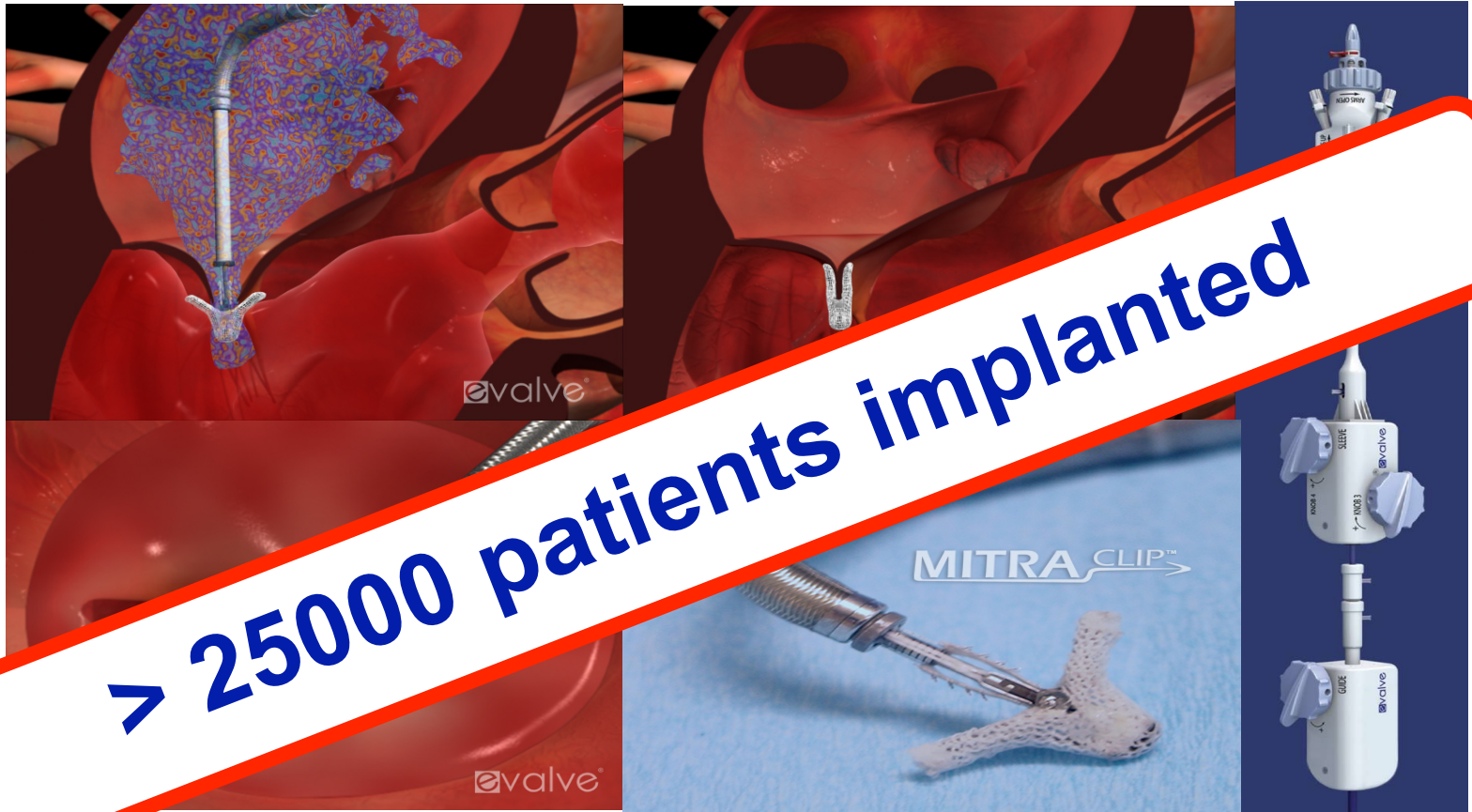
Aims: To describe a new approach to percutaneous mitral valve repair and an illustrative first-in-man experience, we introduce a suture mediated “double orifice”, “edge-to-edge” procedure which can be an effective surgical therapy for mitral regurgitation (MR) in selected patient.

Methods and results: We describe a novel percutaneous approach to double orifice mitral repair utilising an intra-cardiac suture based system. The procedure was performed in 15 patients in four international centres. Endovascular suture based double orifice mitral repair was feasible with an acute reduction in the severity of MR by ≥ 1 grade in nine of 15 patients. At 30 days improvement in MR appeared durable in six patients. Clinical utility was limited by technical difficulties, the inadequacies of current imaging modalities and suture dehiscence.

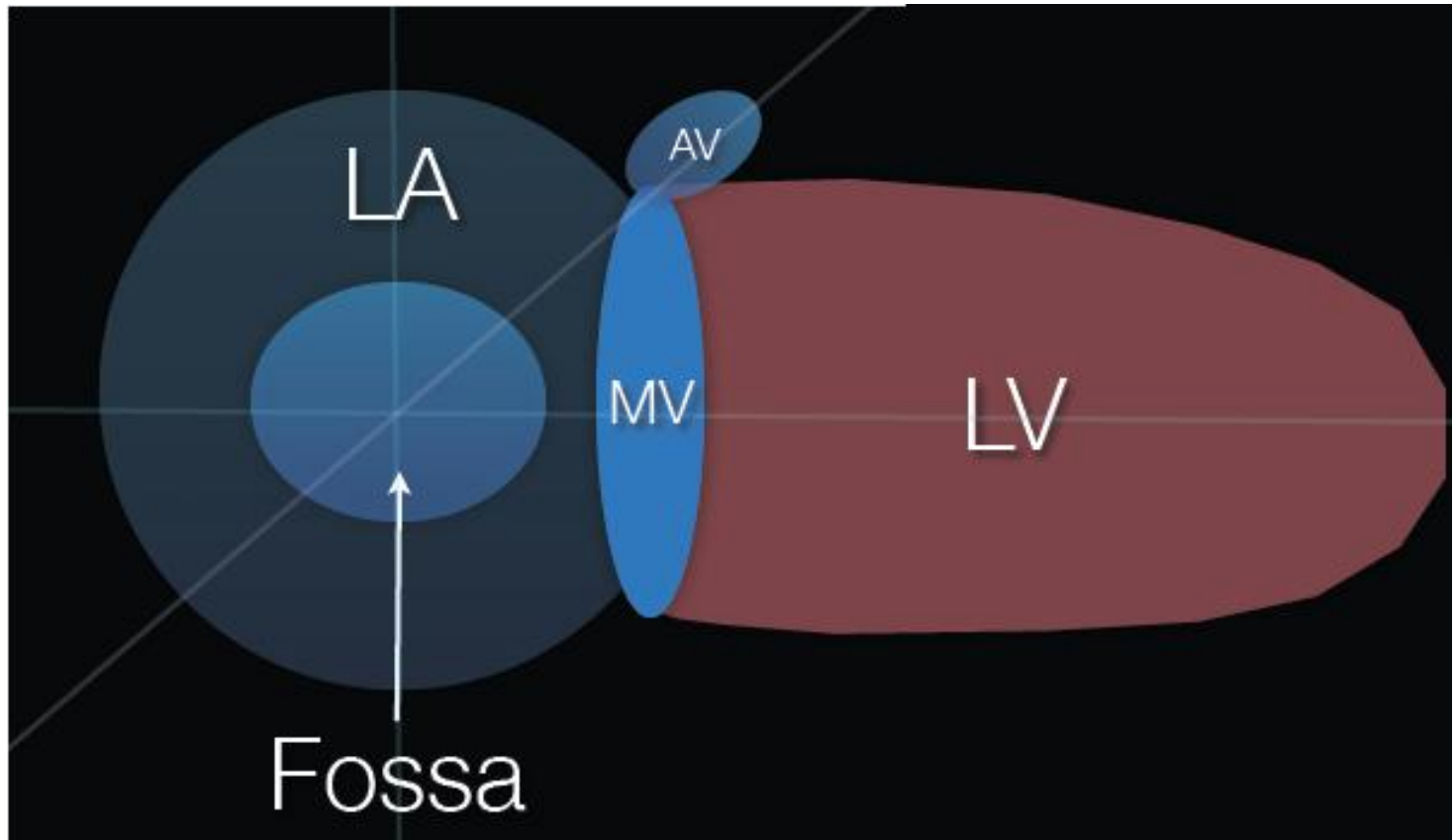
Conclusions: Percutaneous endovascular suture based cardiac repair is feasible. However, in utilising the current device clinical benefit was limited and the repair not durable. In the future, similar endovascular approaches may enable more complex cardiac repair.

Mitraclip

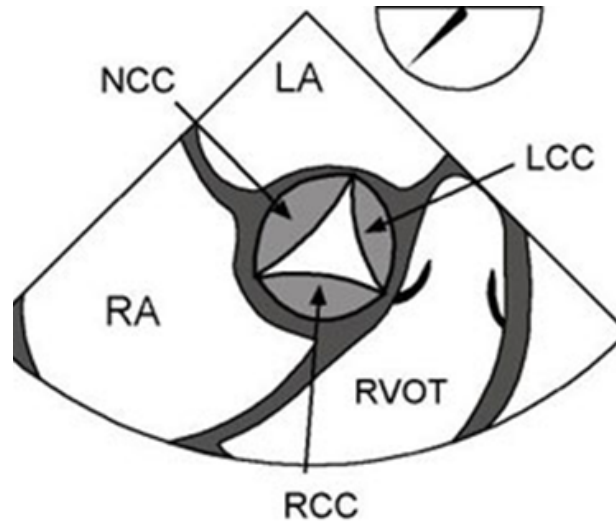
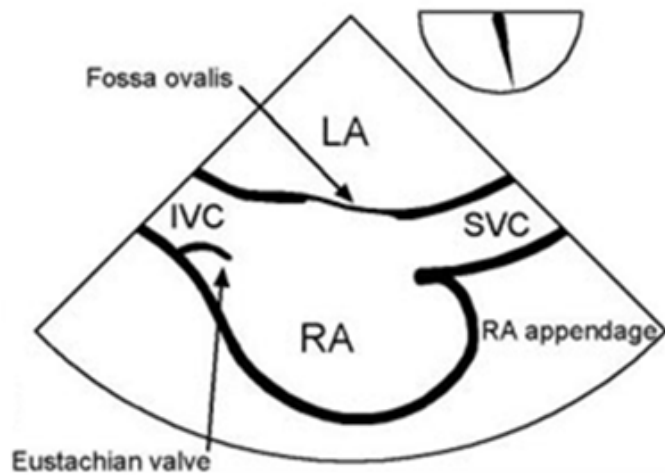
> 25000 patients implanted



Transeptal Puncture

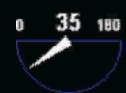


SIA

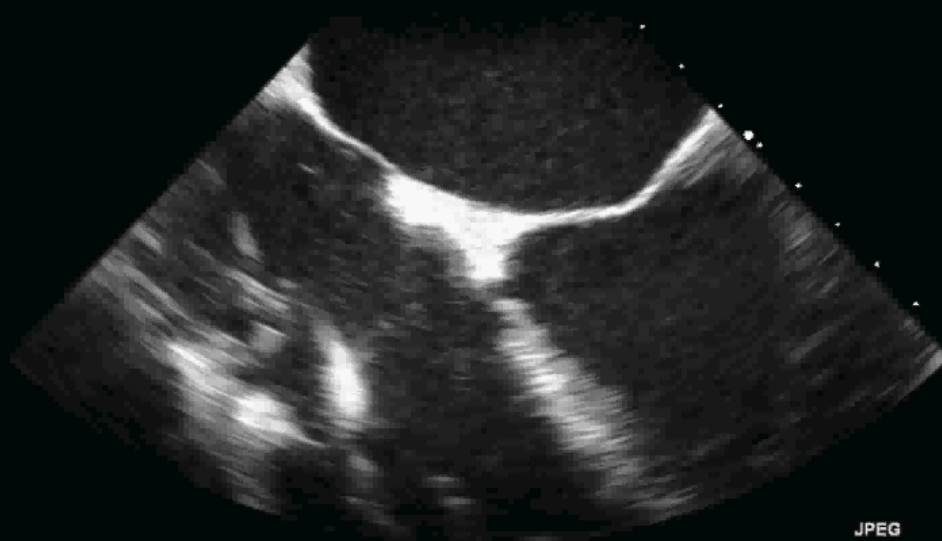
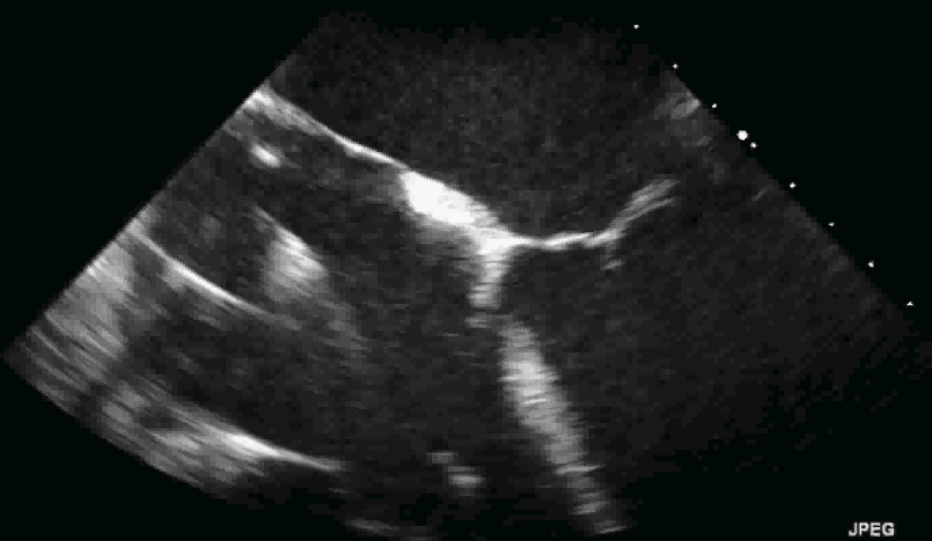




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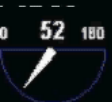


P



JPEG

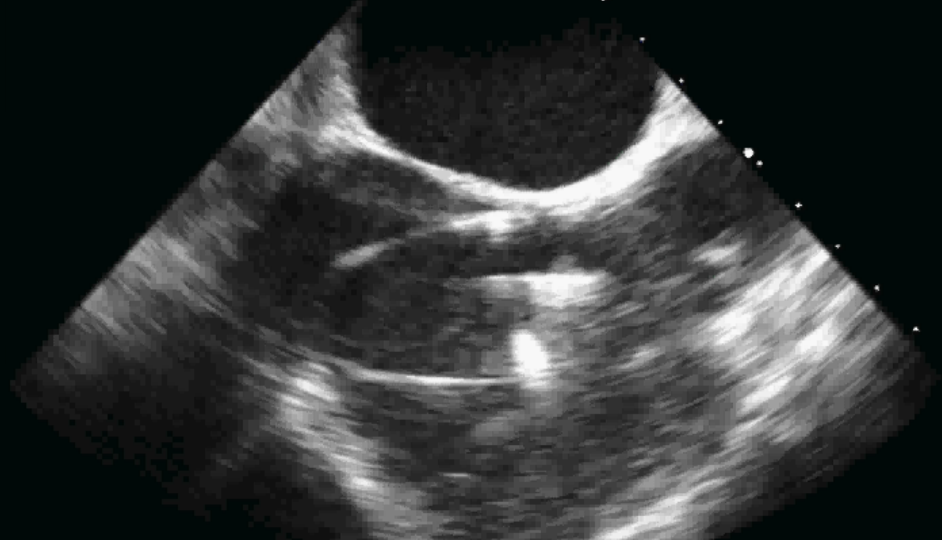
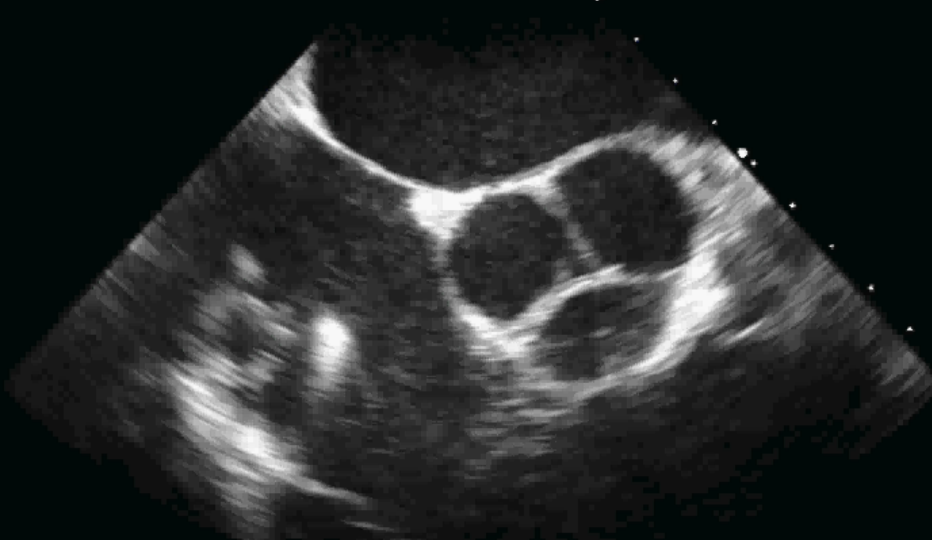
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P



P



JPEG

JPEG



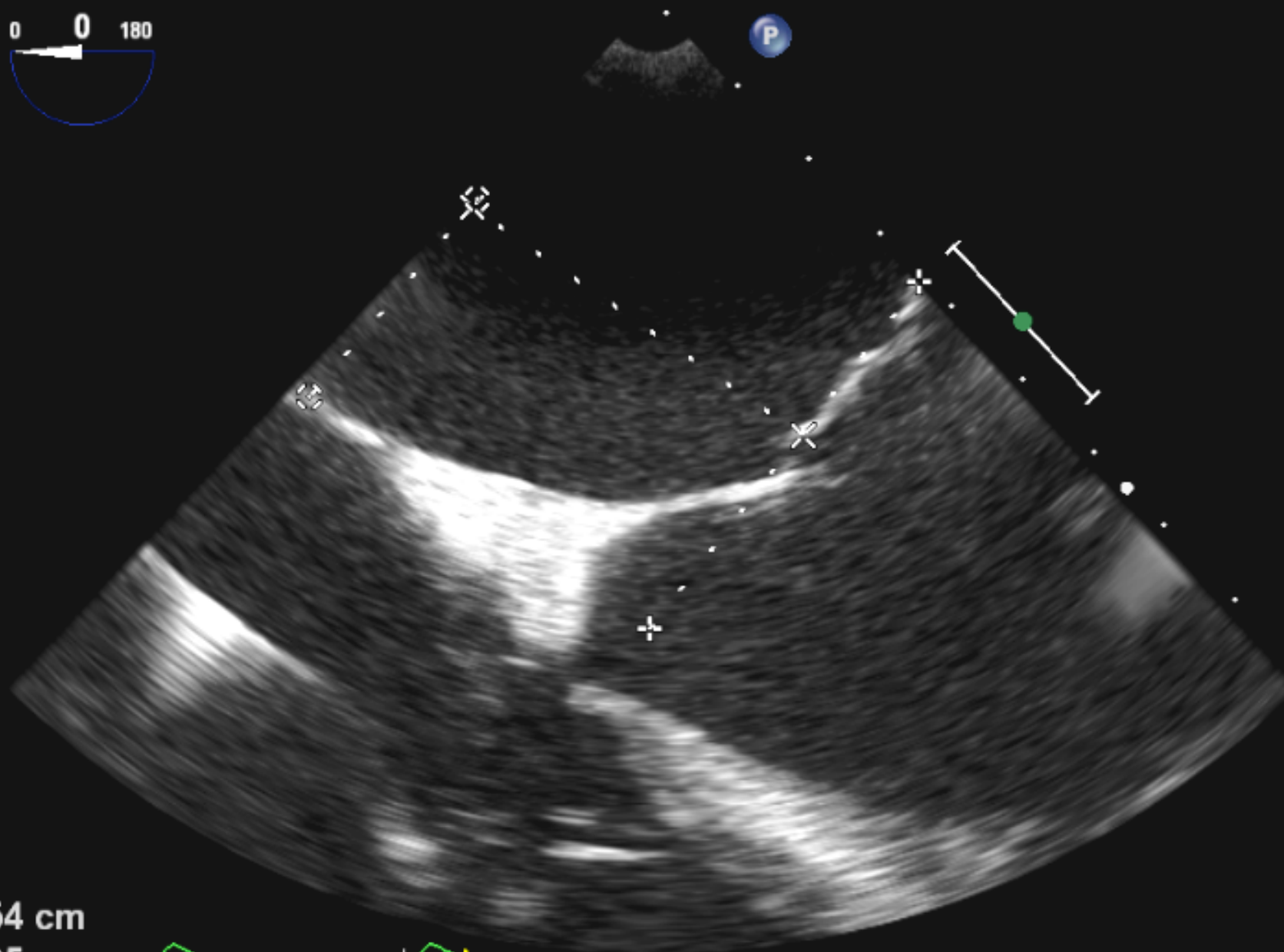
P



JPEG

52Hz
9.0cm

2D
62%
C 50
P Arrêt
Gén

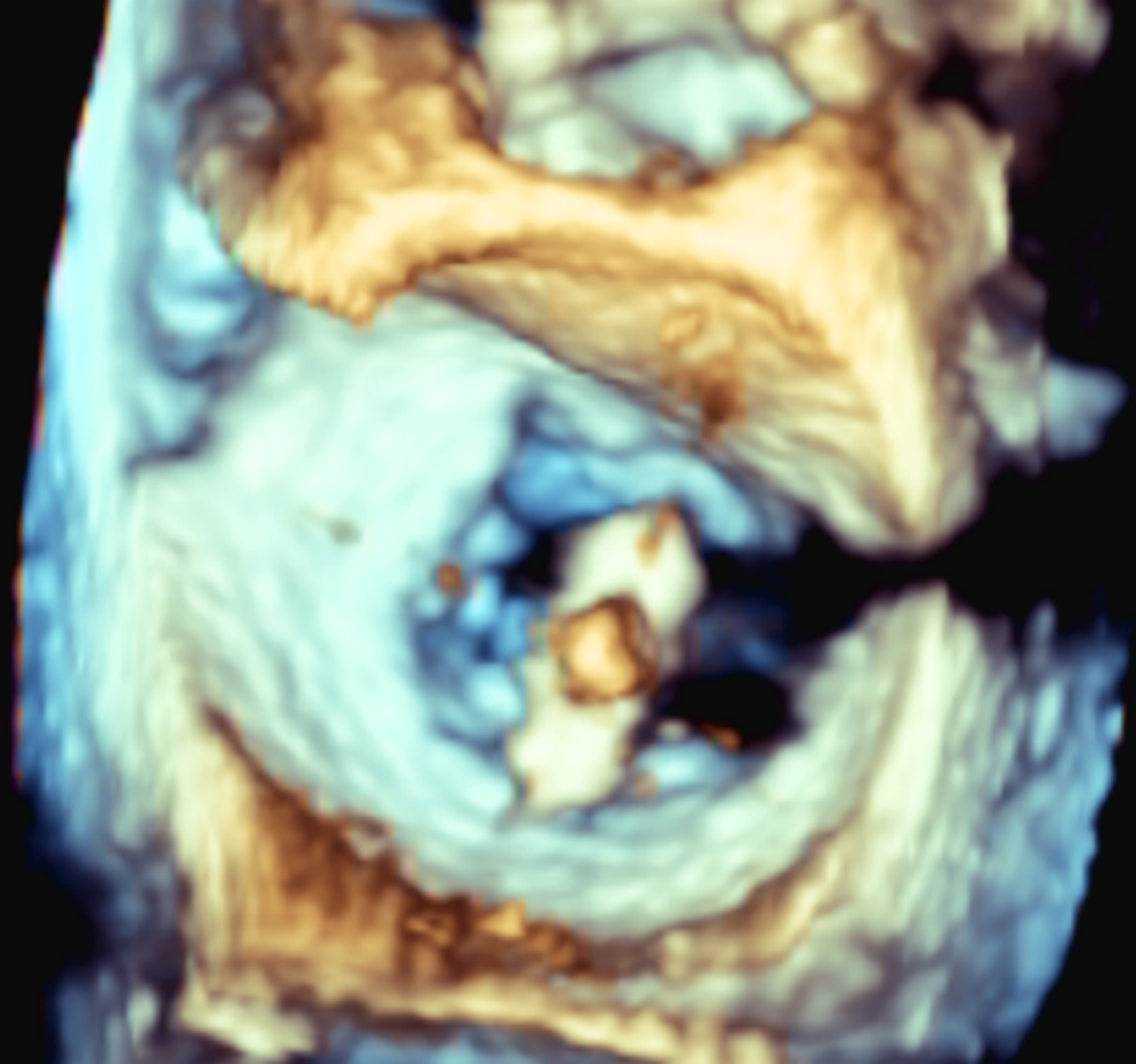


Dist 2.54 cm
Dist 3.95 cm
Dist 4.29 cm



B

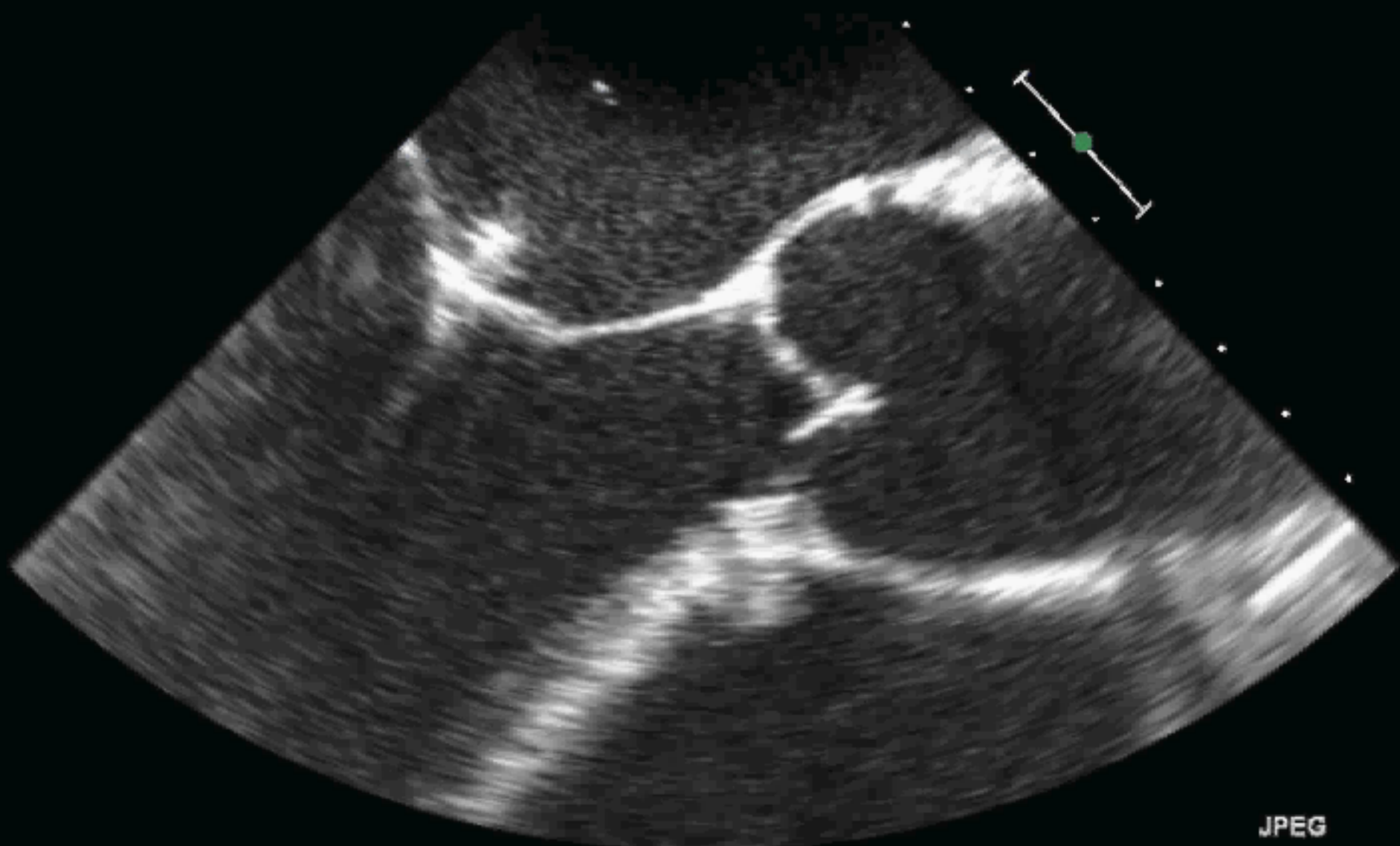
R



0 117 180



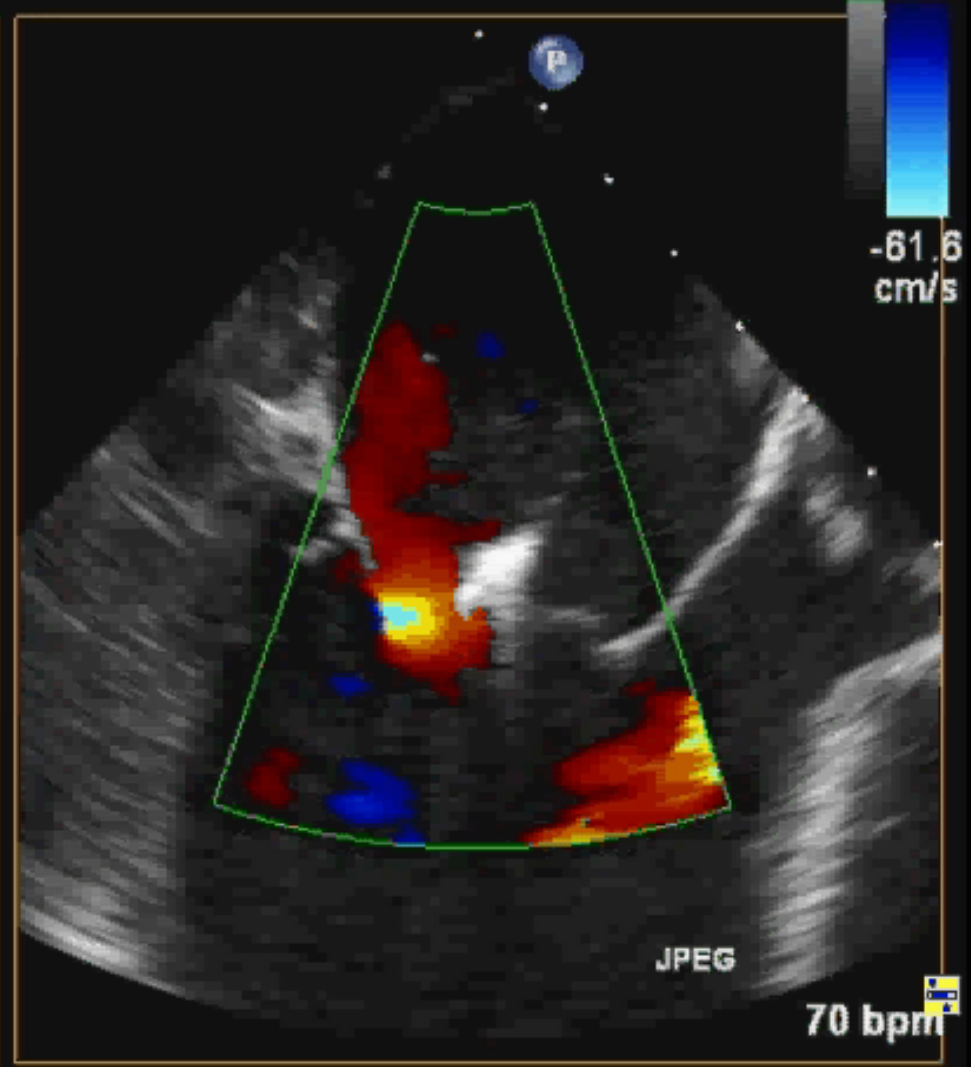
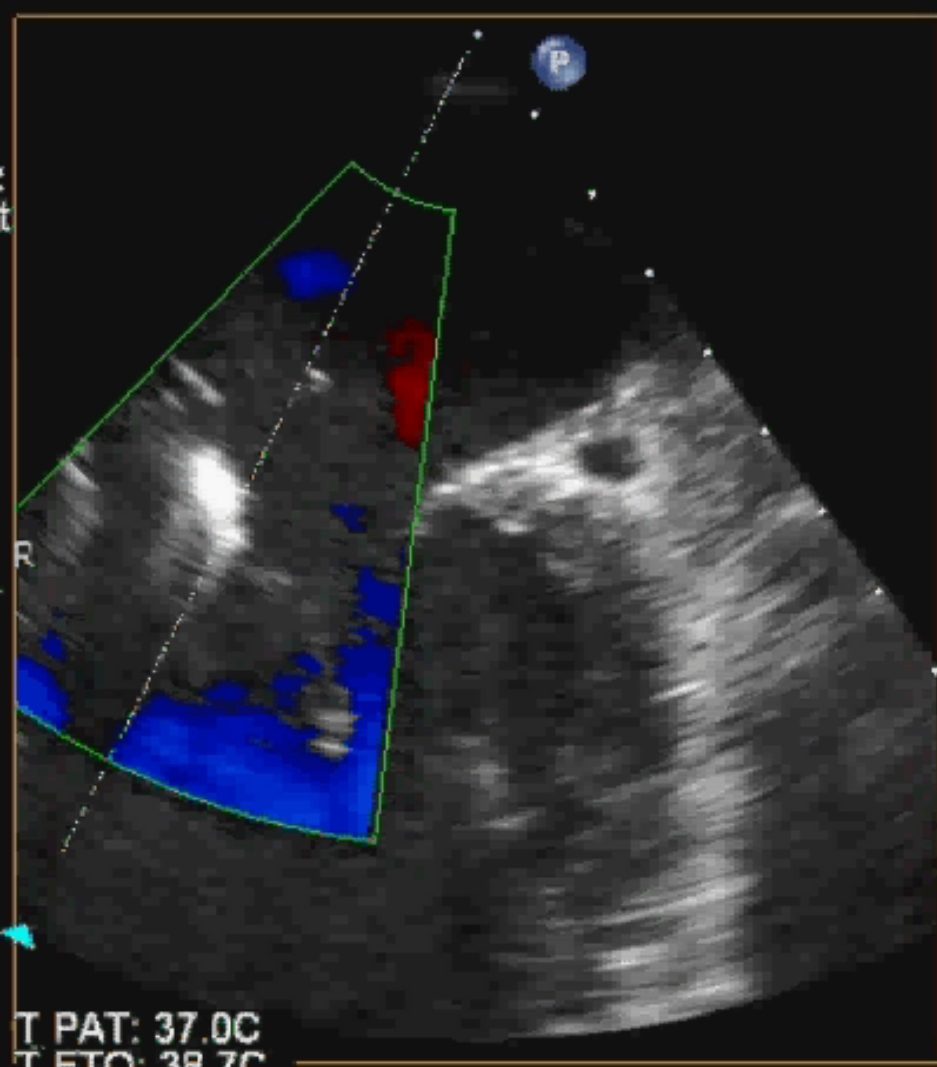
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JPEG

T 07 00

7



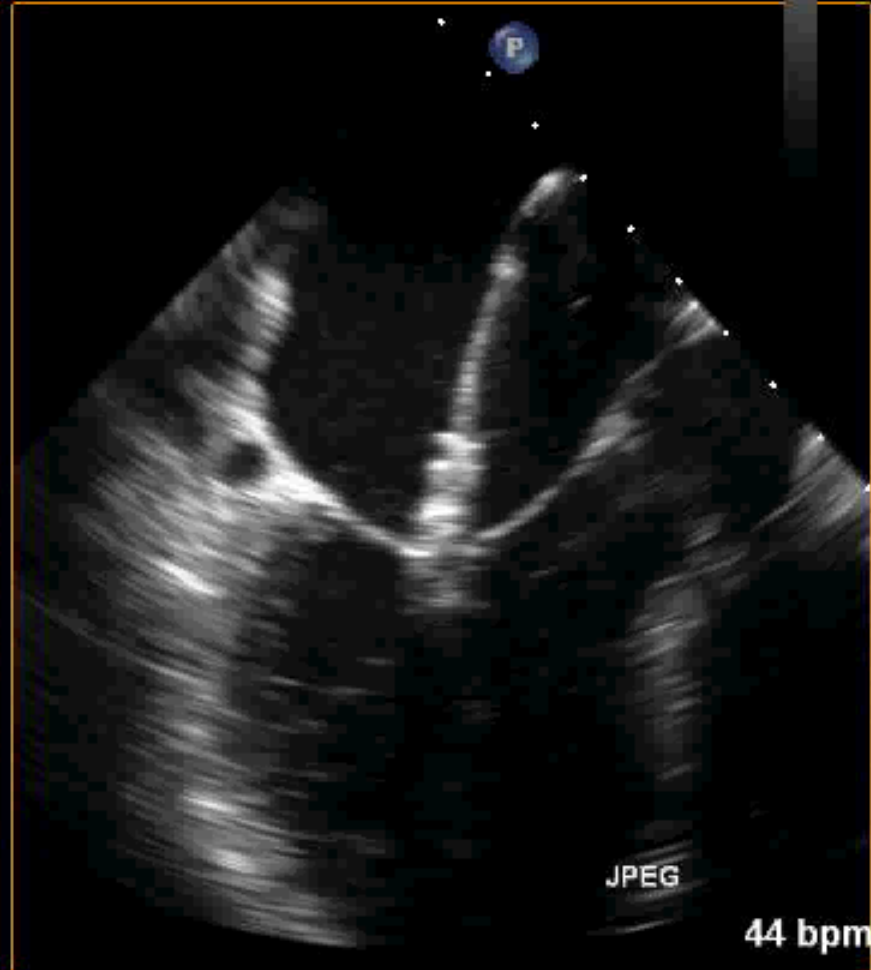
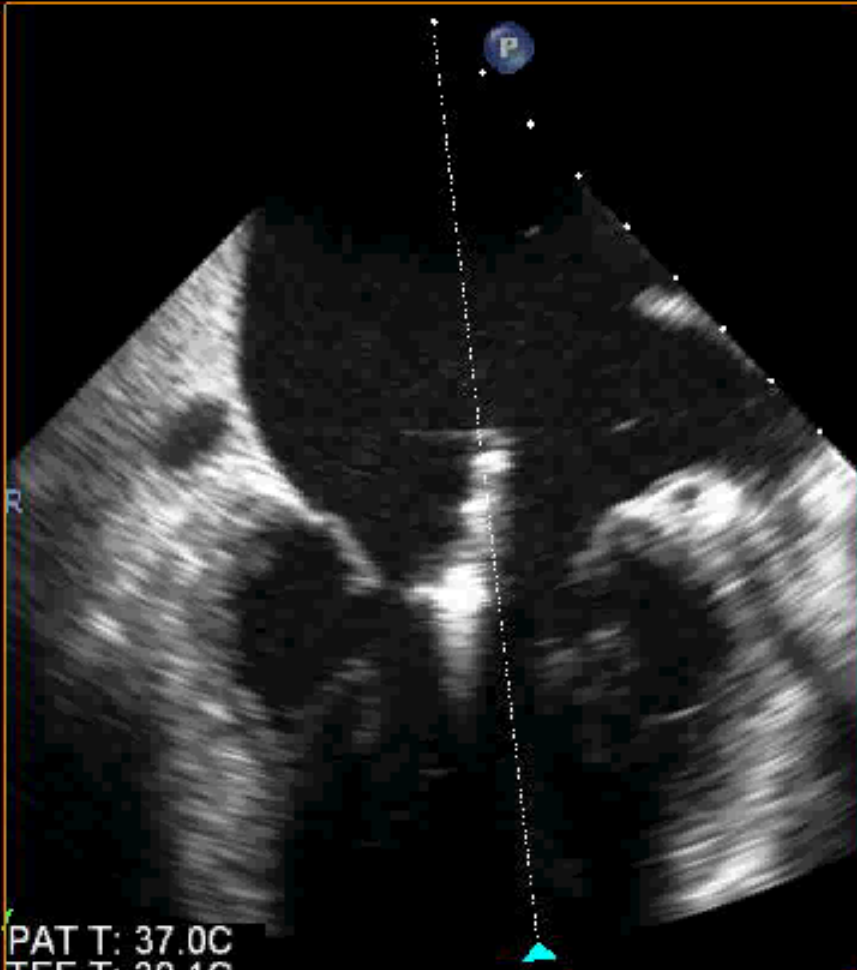
FR 23Hz
13cm

M4

3D Zoom



62%
62%
50dB
P Off
Gen



PAT T: 37.0C
TEE T: 39.1C

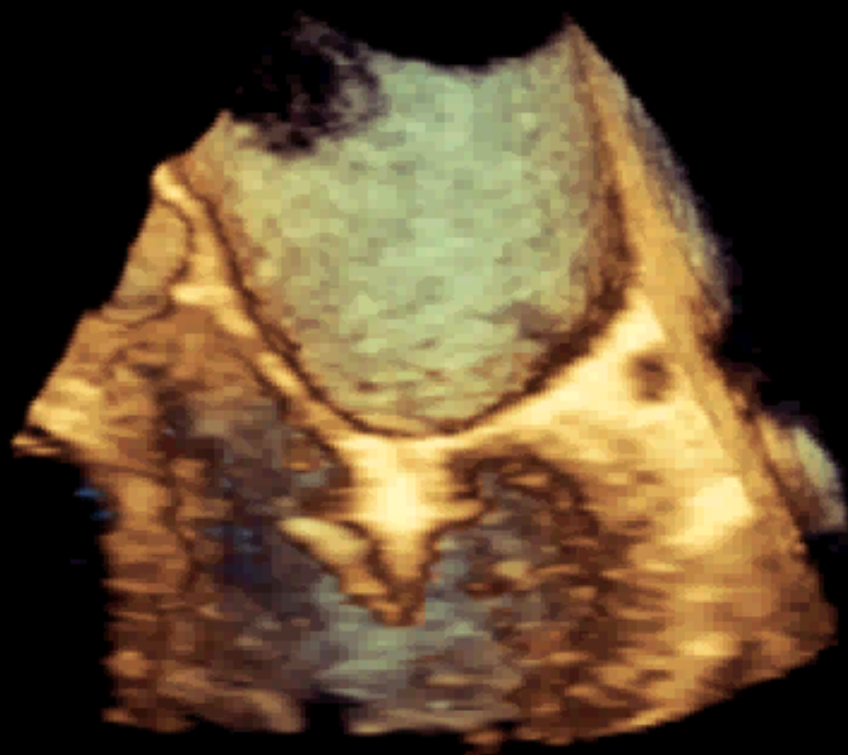
44 bpm

FR 12Hz
11cm

Live 3D
3D 26%
3D 40dB
Gen



M4



JPEG

PAT T: 37.0C
TEE T: 38.6C

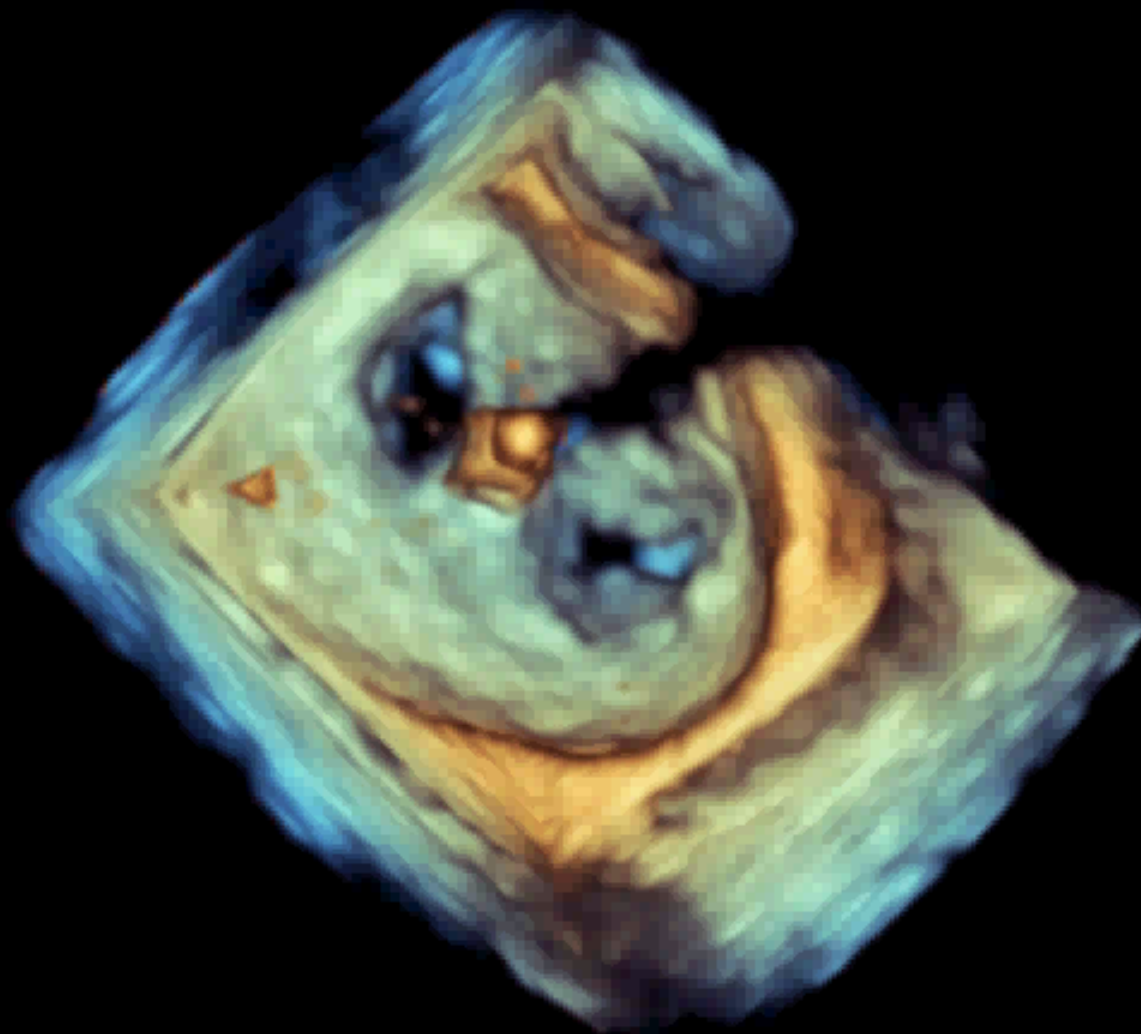
39 bpm

FR 13Hz
10cm

Live 3D
3D 19%
3D 40dB
Gen



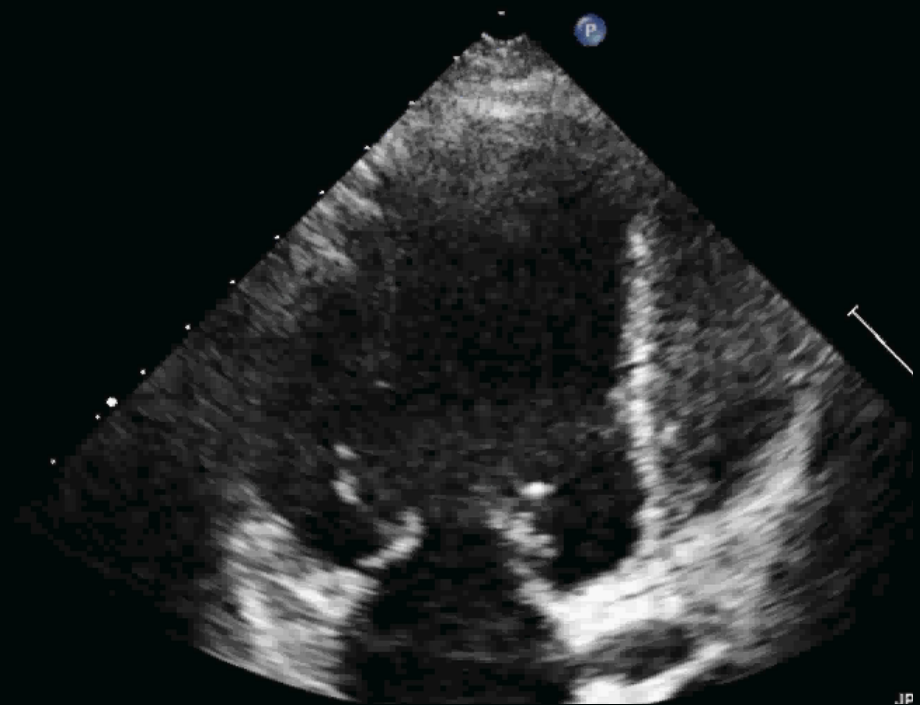
M4



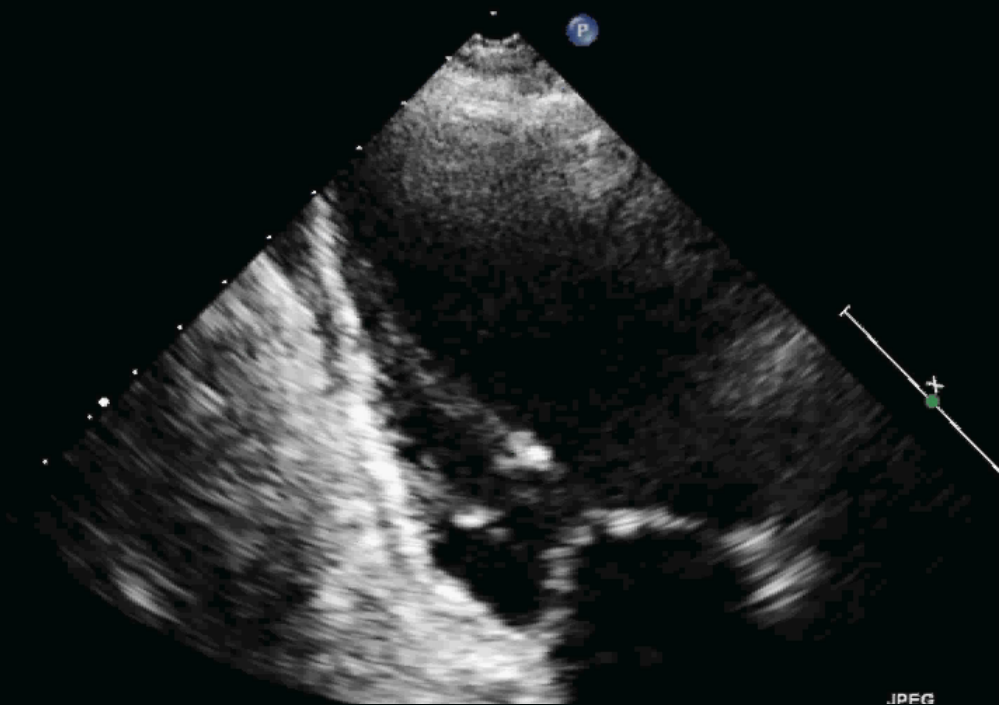
JPEG

PAT T: 37.0C
TEE T: 39.0C

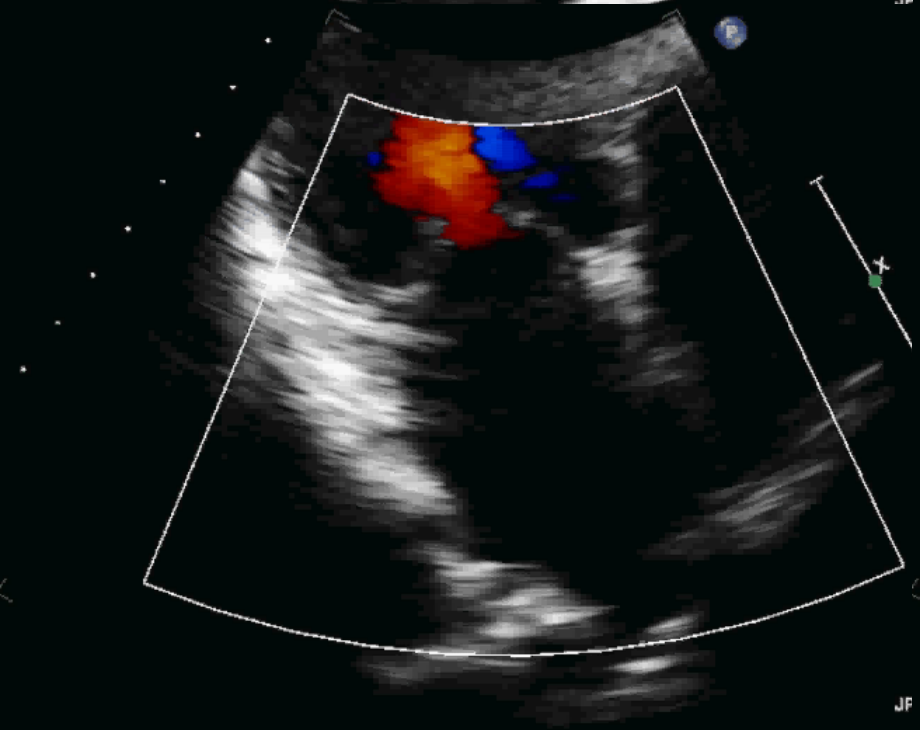
50 bpm



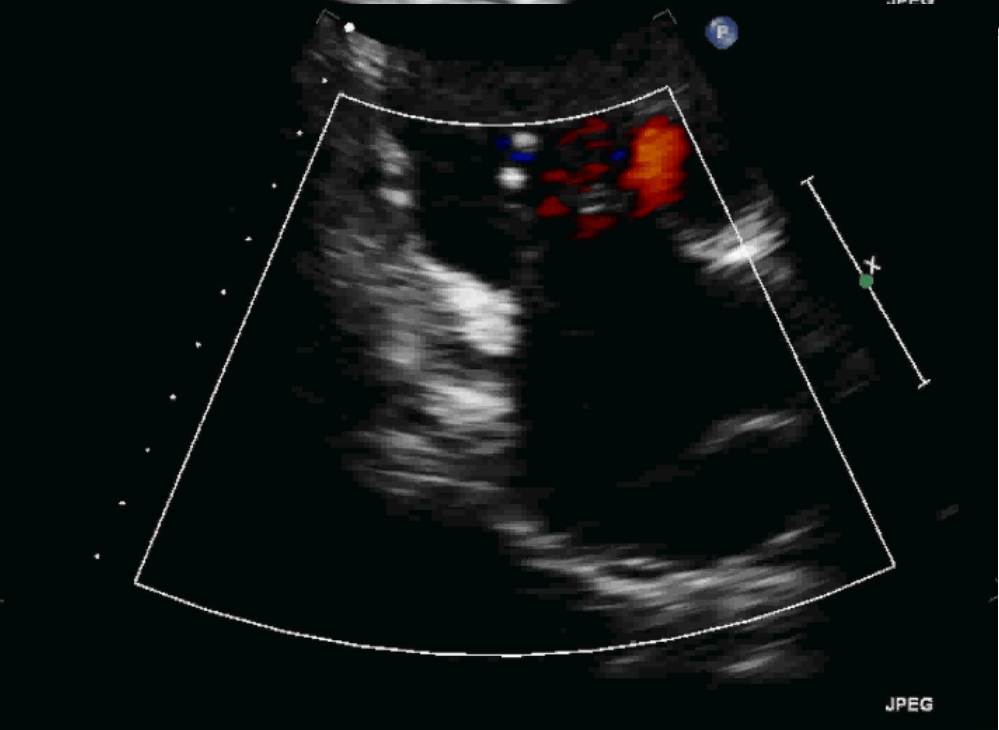
.JP



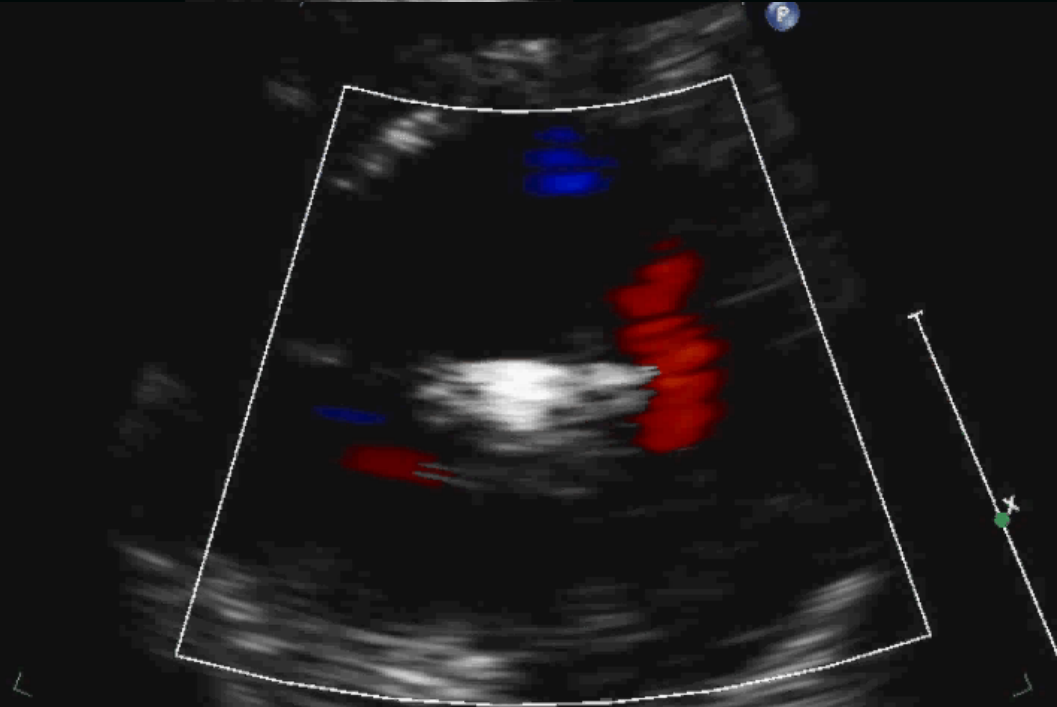
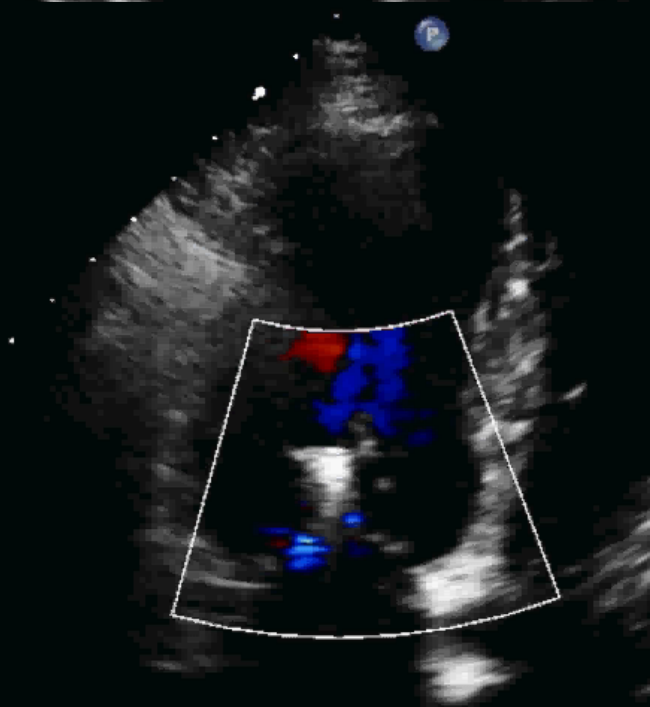
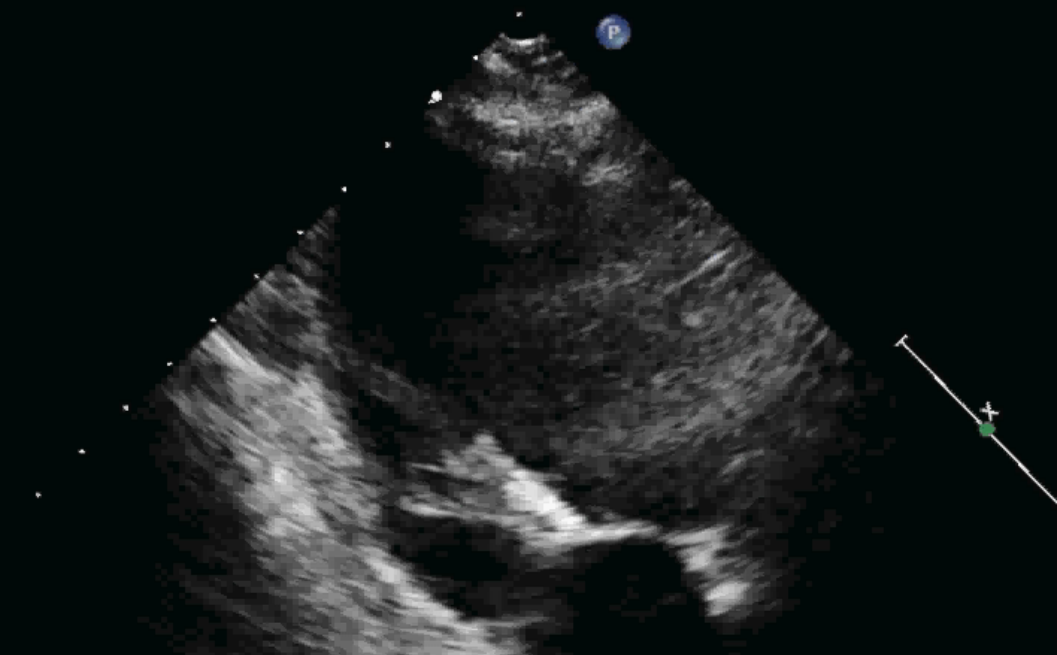
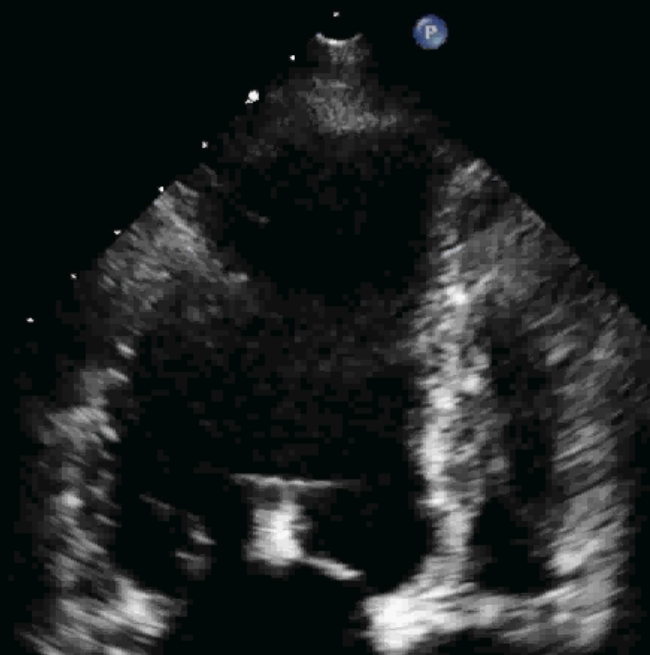
.JPEG



.JF



.JPEG



MitraClip Screening

Listes des incidences requises ETT

1. PS grand axe

- Vue globale VG, Aorte et OG sans et avec couleur
- Zoom PS grand axe sans et avec couleur sur la chambre de chasse et la valve aortique
- Vue centrée sur la valve mitrale sans et avec couleur
- Large zoom sur la partie proximale du jet régurgitant pour mesure de la vena contracta (cycle et non image fixe ; ne pas modifier la ligne de base ni la limite de Nyquist)
- TM du ventricule gauche

2. PS petit axe

- Vue parasternale petit axe au niveau de l'orifice mitral sans et avec couleur. En cas de MitraClip chaque orifice devra pouvoir être visualisé séparément et une planimétrie de chaque orifice effectuée. Une attention particulière devra être donnée à la localisation de l'origine des jets régurgitants avant MtraClip et résiduels après MitraClip.
- Vue parasternale petit axe au niveau des piliers
- Vue parasternale petit axe au niveau de la valve aortique sans et avec couleur

3. Apicale 4 cavités

- Vue globale des 4 cavités (VG et VD, OG et OD) sans et avec couleur
- Vue centrée sur VG (pour mesure des volumes par Simpson ; garder la même profondeur entre les 4C, 3C et 2C)
- Zoom sur OG sans et avec couleur (prendre soin de bien inclure le jet s'il est excentré). Après MitraClip, une attention particulière devra être donnée à la mise en évidence de chaque jet
- Zoom sur la valve mitrale sans et avec couleur
- Zoom sur la valve tricuspide sans et avec couleur
- Flux régurgitant tricuspide en Doppler continu (pour mesure de la pression artérielle pulmonaire systolique)
- Flux mitral antérograde en Doppler pulsé à l'extrémité des feuillets
- Vitesses et gradient transmitral en Doppler continu
- Flux veineux pulmonaire en Doppler pulsé
- DTI mitral anneau latéral et septal
- DTI tricuspide

4. Apicale 3cavités

- Vue globale (VG, OG et Aorte) sans et avec couleur

- Vue centrée sur VG
- Zoom sur OG sans et avec couleur
- Zoom sur la valve mitrale sans et avec couleur
- VTI sous aortique mesurée en Doppler pulsé pour calcul du volume d'éjection systolique
- VTI aortique et gradient transaortique en Doppler continu

Apicale 2 cavités

- o Vue globale (VG et OG) sans et avec couleur
- o Vue centrée sur VG
- o Zoom sur OG sans et avec couleur
- o Zoom sur la valve mitrale sans et avec couleur

Sous-costale

- Dimension de la veine cave en inspiration et expiration (2D et TM)

Quantification IM

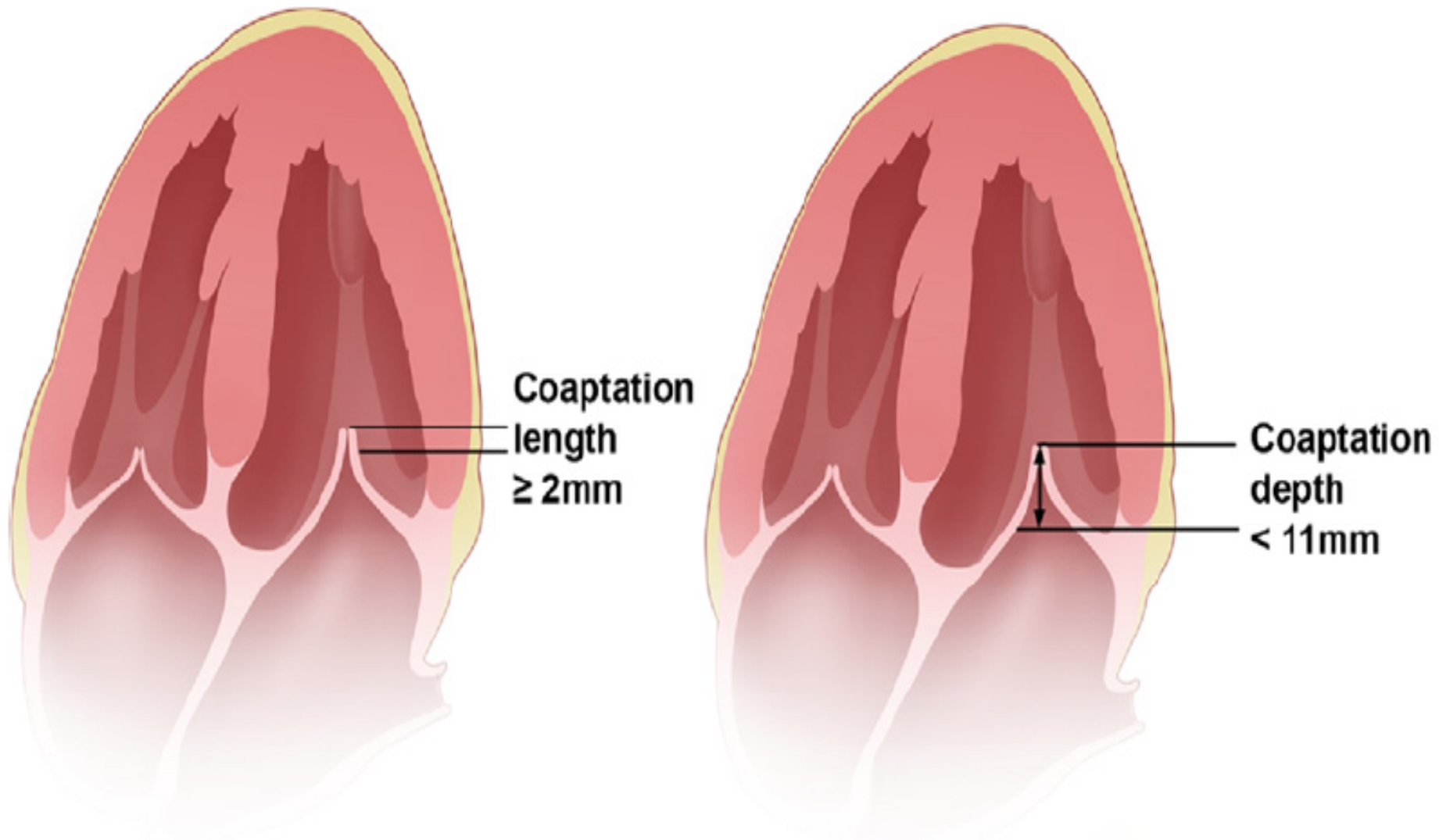
- Flux doppler continu de la régurgitation mitrale (idéalement enregistrement en utilisant la sonde Pedof) dans l'incidence la plus appropriée en fonction de la direction du jet.
- Zone de convergence. La mesure du rayon de la zone de convergence sera effectuée dans l'incidence permettant d'obtenir la zone de convergence la plus large et la mieux définie. La vitesse d'aliasing est abaissée dans le sens de la régurgitation. La vitesse d'aliasing sera également celle qui permettra d'obtenir une zone de convergence hémisphérique et bien définie (habituellement entre 30 et 40 cm/sec). Il est crucial d'utiliser un large zoom.

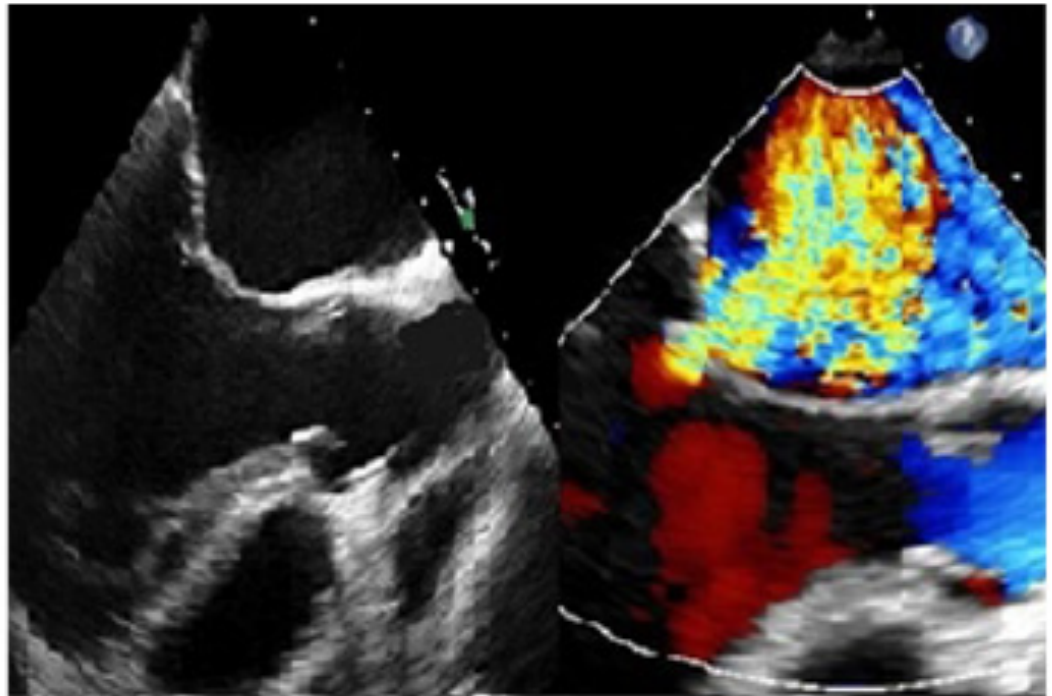
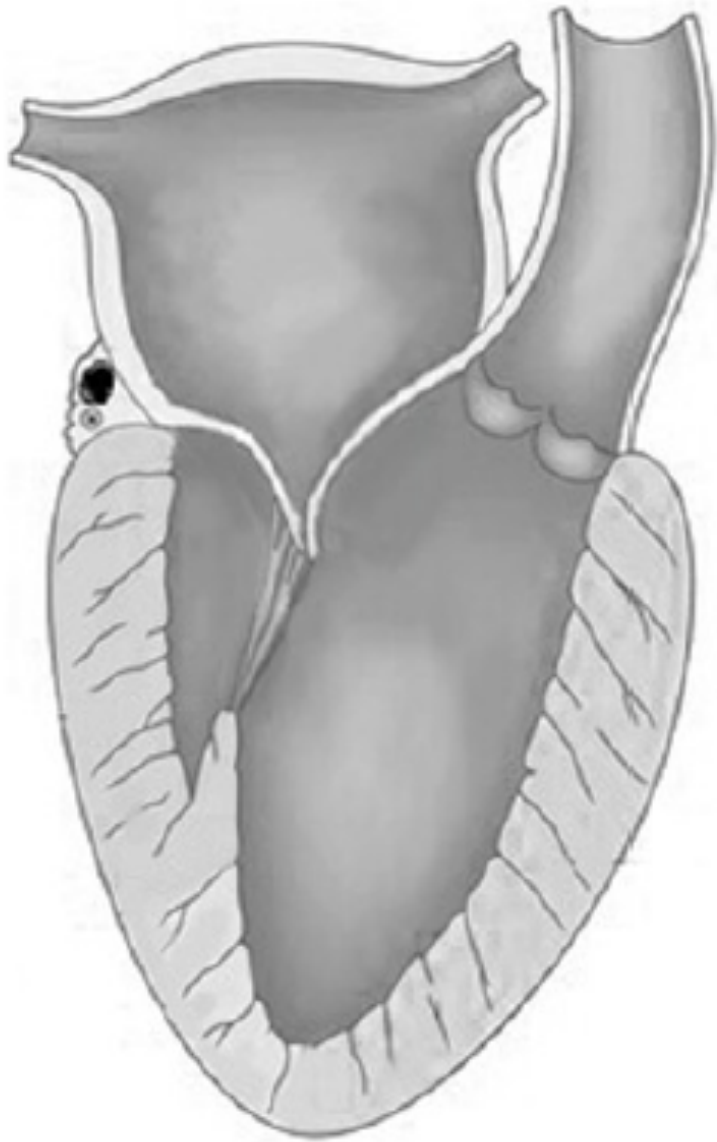
Listes des incidences requises ETO

1. 0 degré (incidences 4C)
 - Vue globale larges avec les 4 cavités sans et avec couleur
 - Zoom sur la valve mitrale sans et avec couleur
2. 45 degrés (petit axe sur la valve aortique) sans et avec couleur
3. 60 degrés (incidence bicommissurale)
 - Vue globale large avec OG et VG sans et avec couleur
 - Zoom sur la valve mitrale sans et avec couleur
4. 120 degrés (LVOT view)
 - Vue globale large avec VG, OG et aorte sans et avec couleur
 - Zoom sur la valve mitrale sans et avec couleur
5. Incidence bicavale (120°), petit axe (45-60°) et 4 cavités du septum interauriculaire
6. Xplane 0 degré et incidence perpendiculaire « long axis additional 90 degrees » sans et avec couleur
7. Boucles dans au moins 2 incidences de l'auricule
8. Si possible valve mitrale en petit axe et grand axe trans-gastrique
9. Acquisitions 3D (optionnelles)
 - zoom sur la valve mitrale avec orientation chirurgicale (aorte en haut, commissure externe à gauche et commissure interne à droite)
 - Full volume

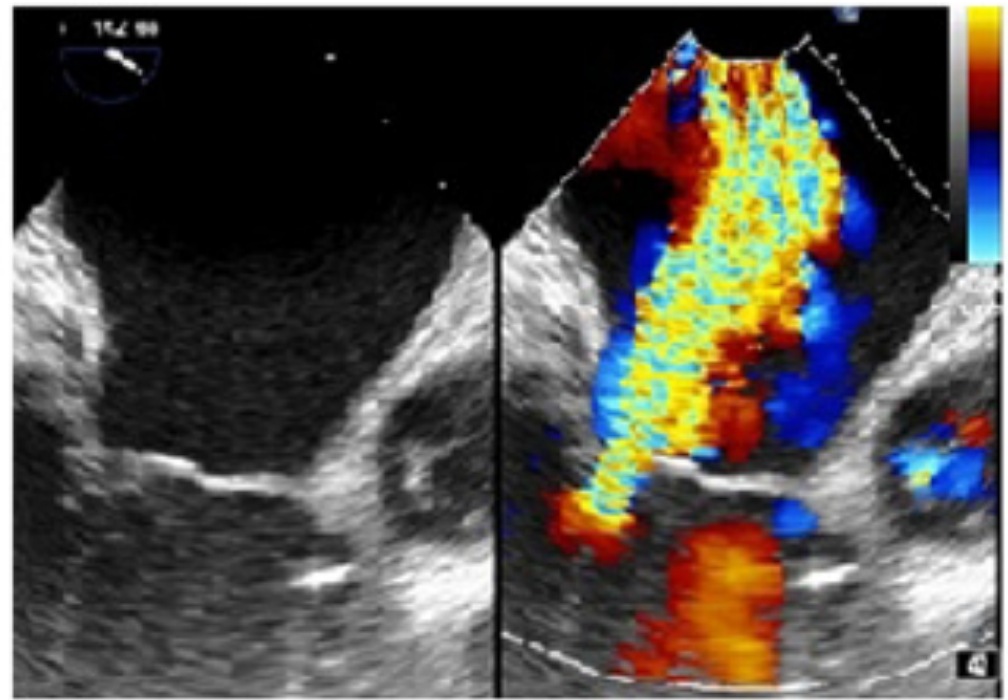
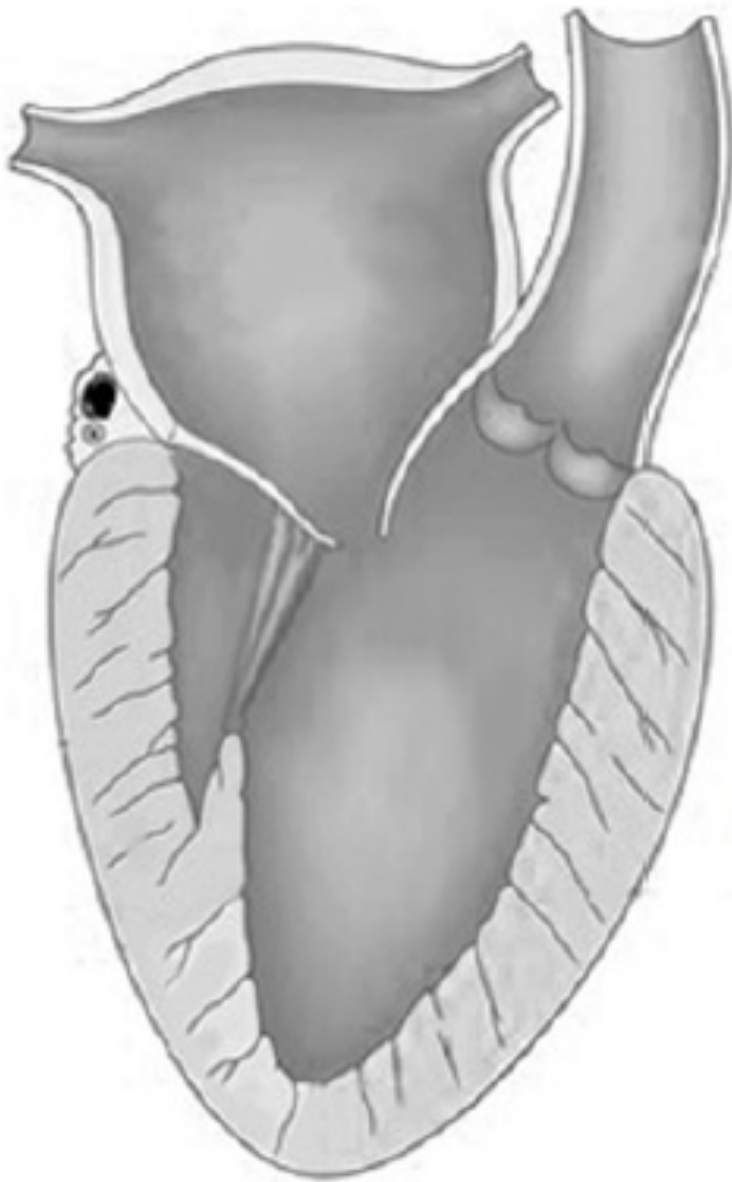
Selection of Candidates

Functional Mitral Regurgitation

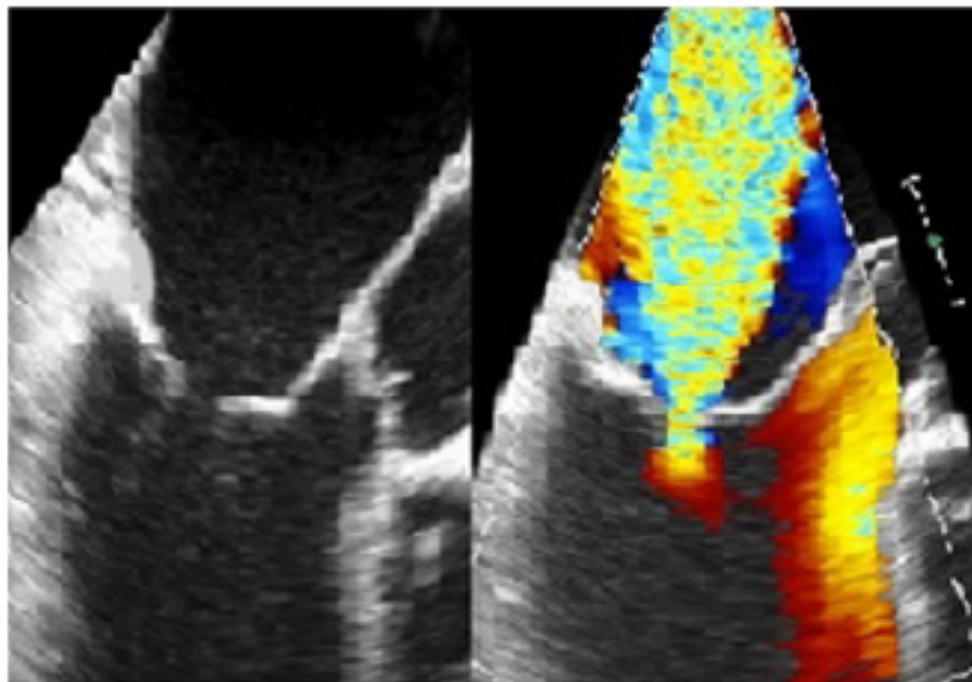
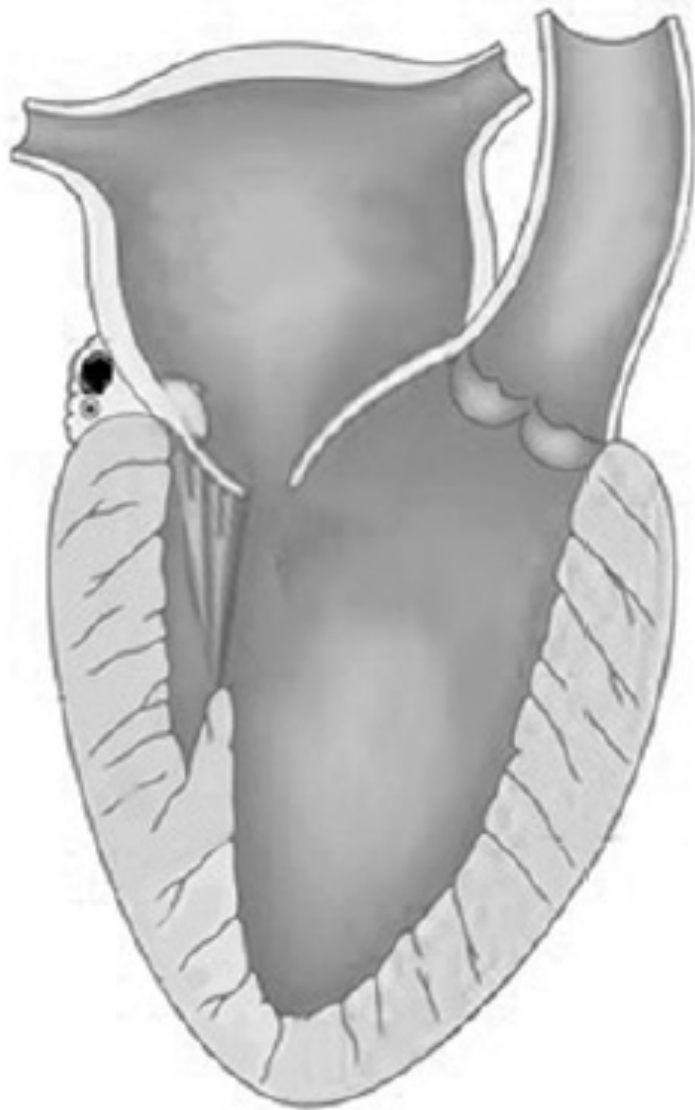




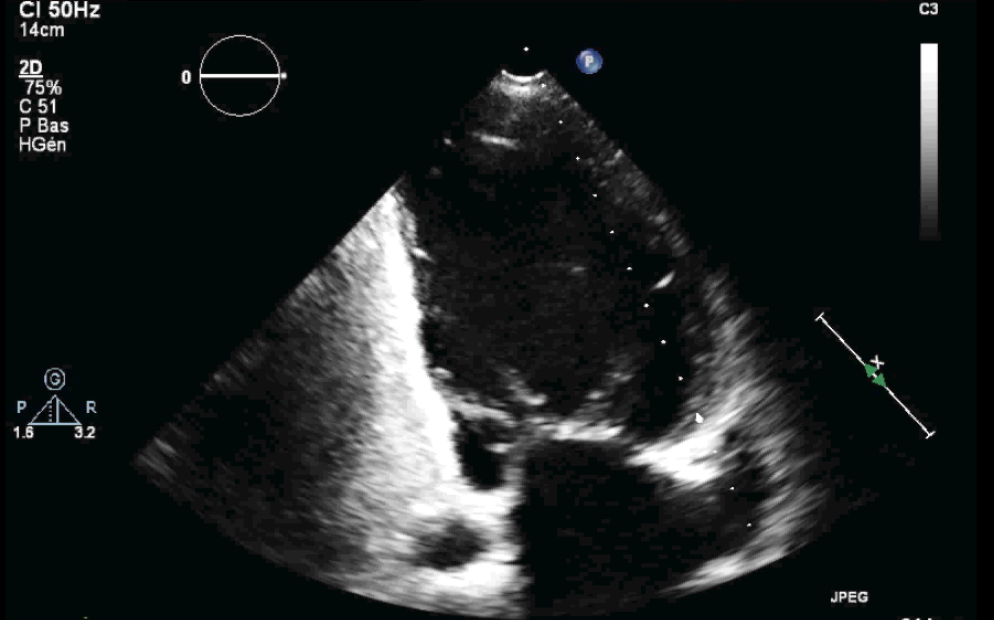
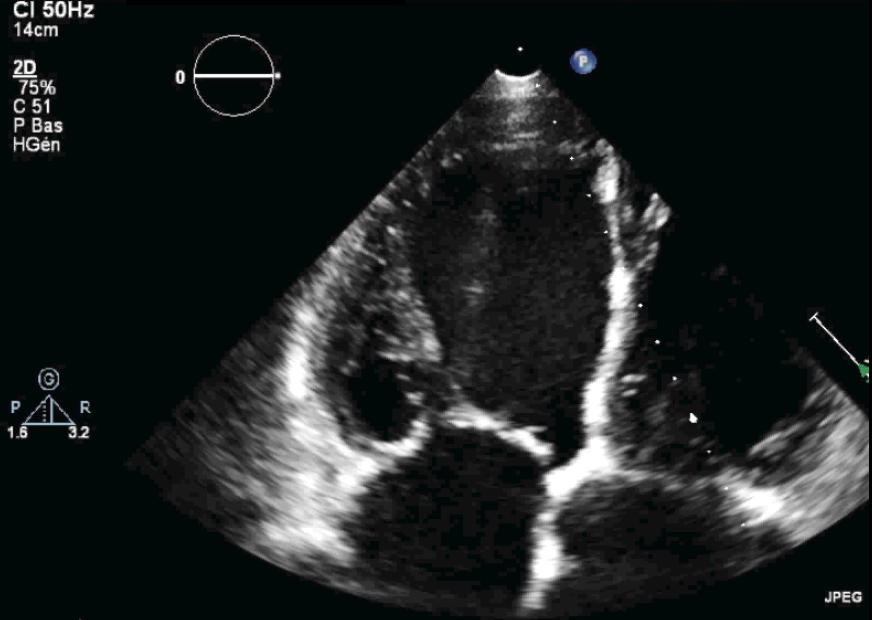
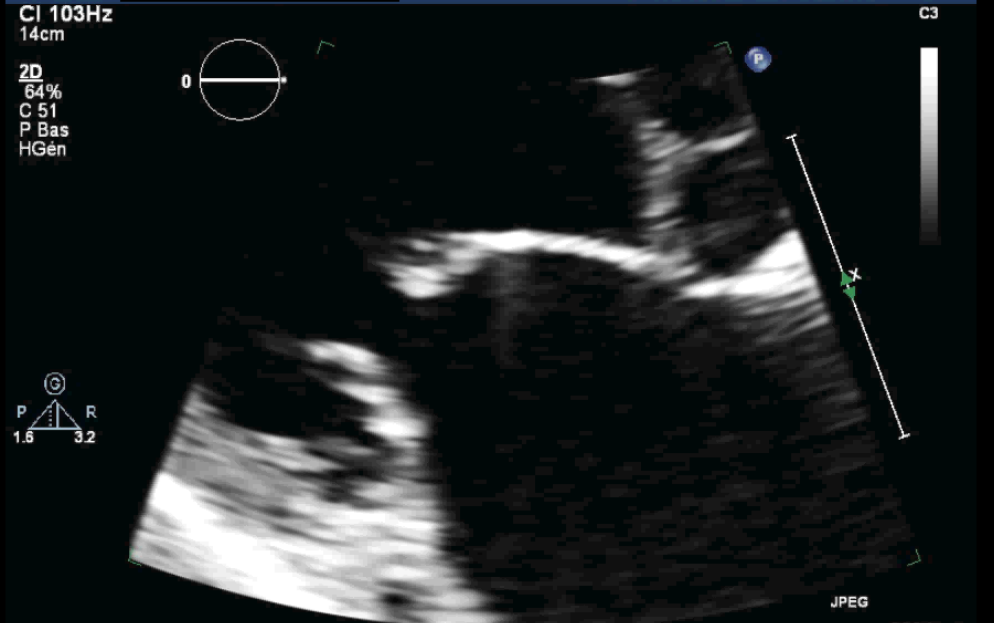
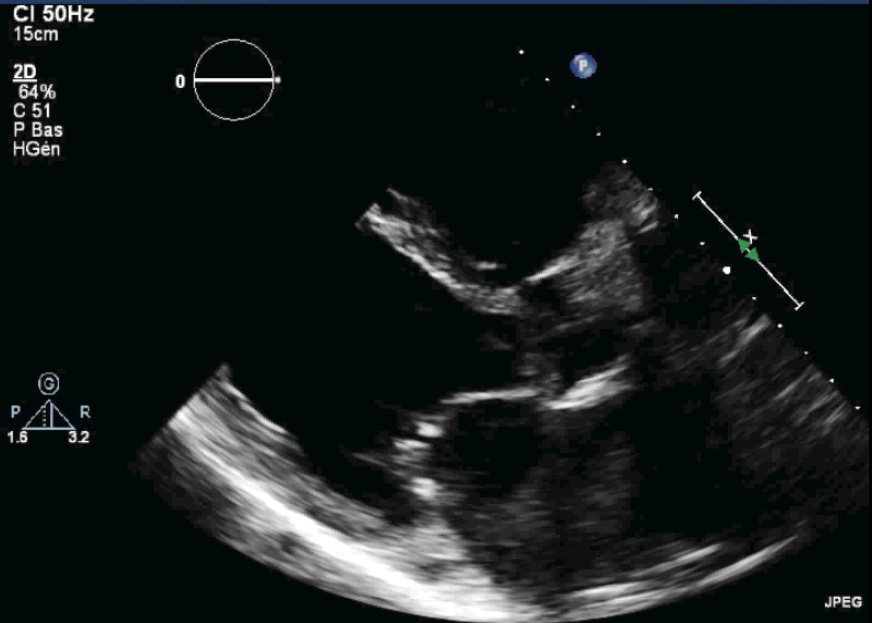
Optimal valvular lesion anatomy



Suboptimal valvular lesion anatomy

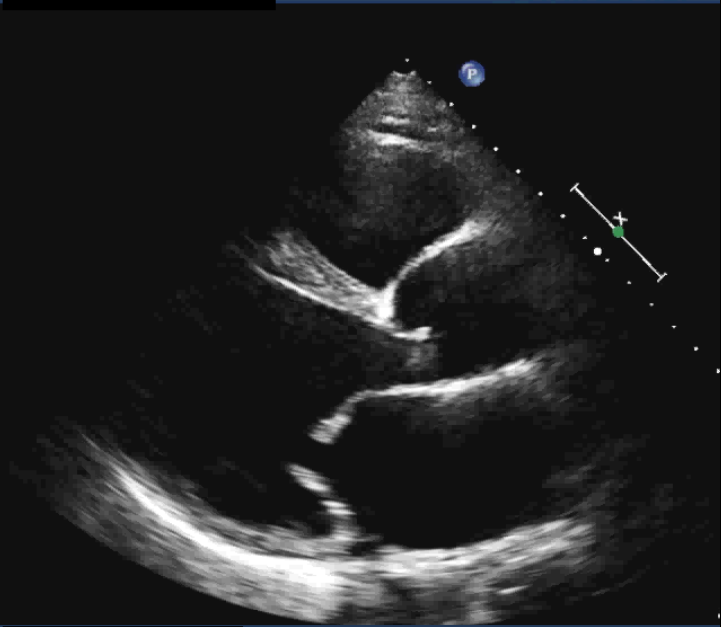


Adverse valvular lesion anatomy



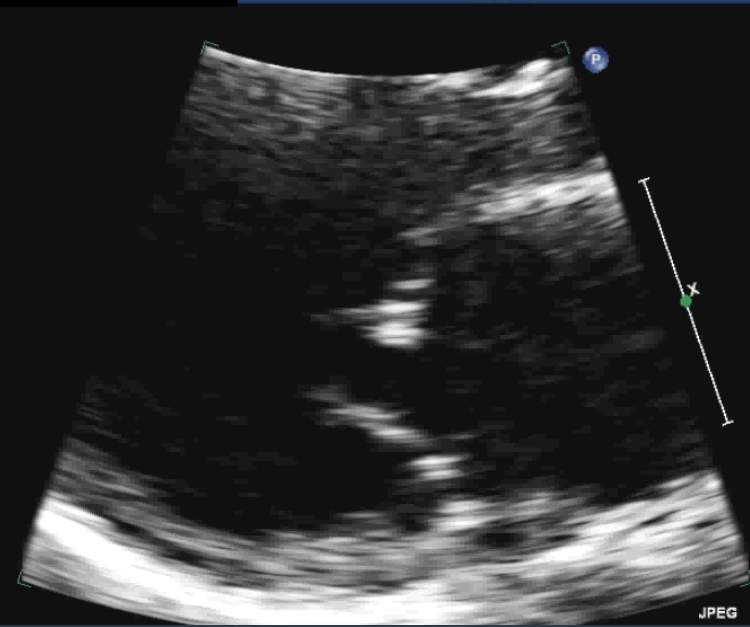
CI 45Hz
18cm

2D
61%
C 50
P Bas
HGen



CI 103Hz
17cm

2D
64%
C 50
P Bas
HGen

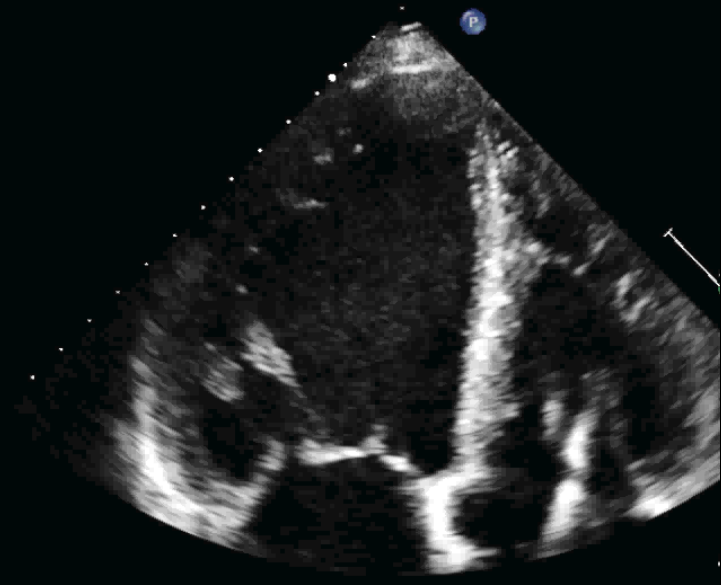


C3

JPEG

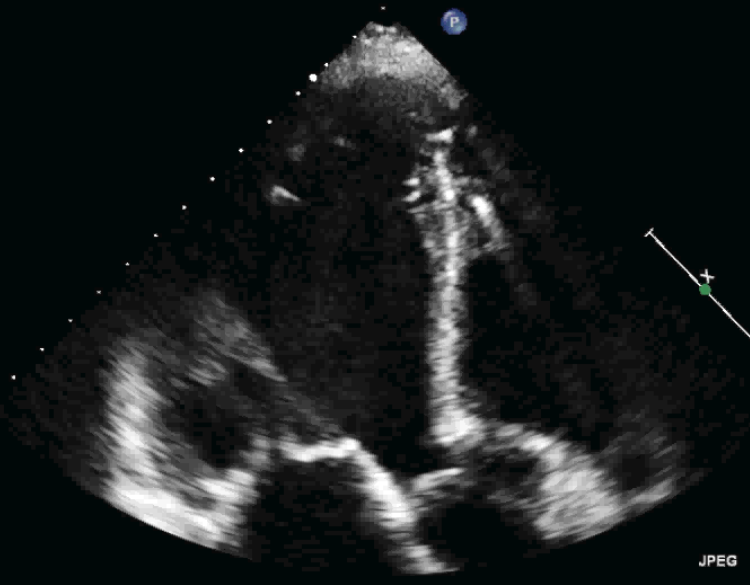
CI 33Hz
14cm

2D
58%
C 50
P Bas
HGen



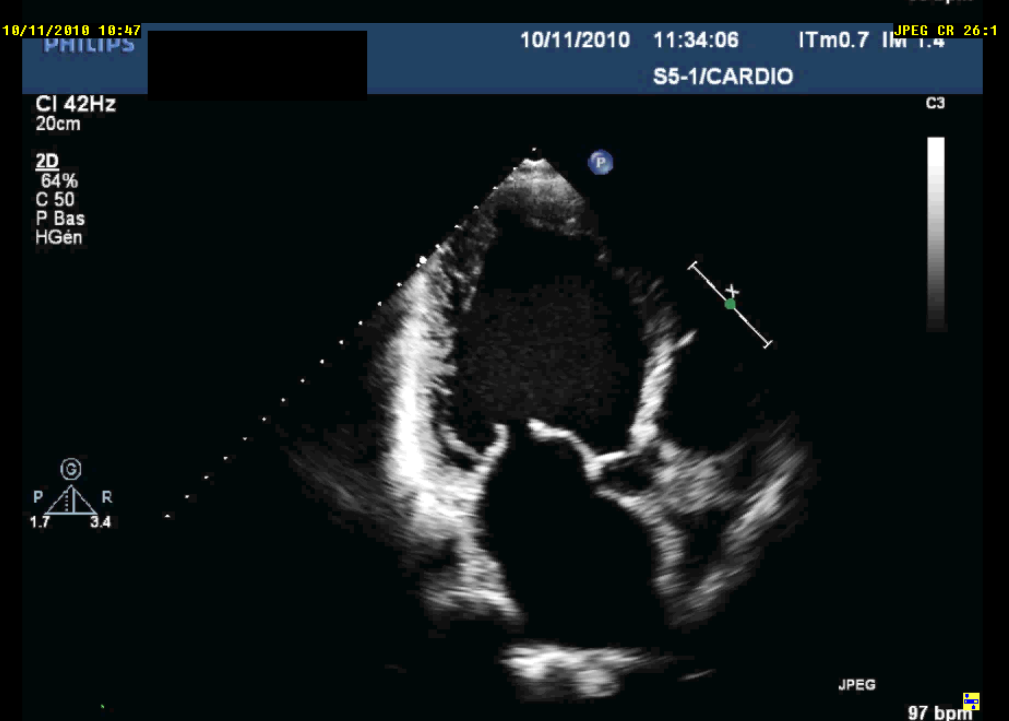
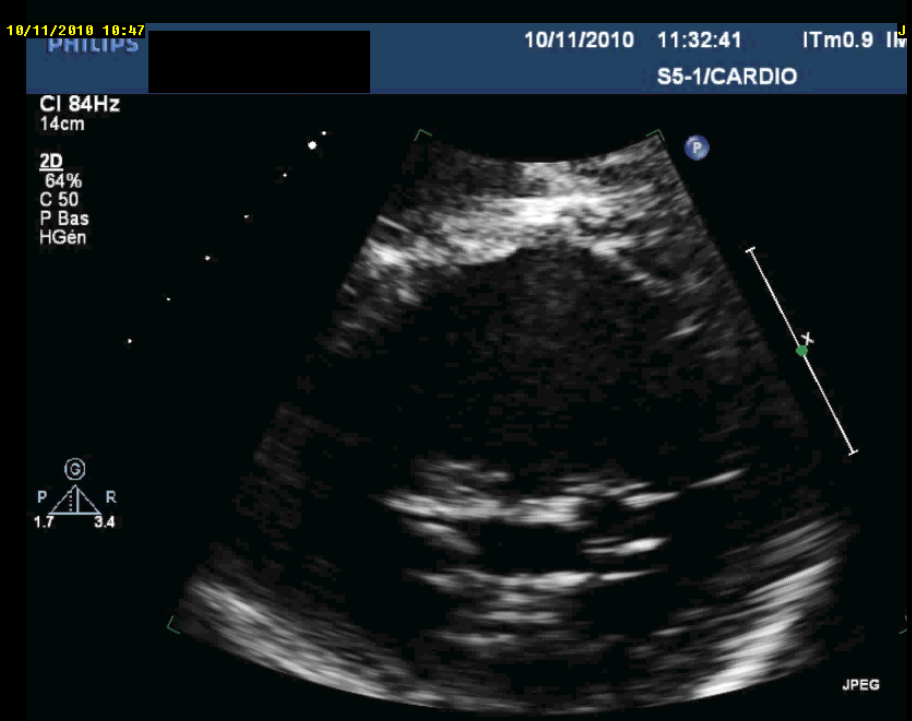
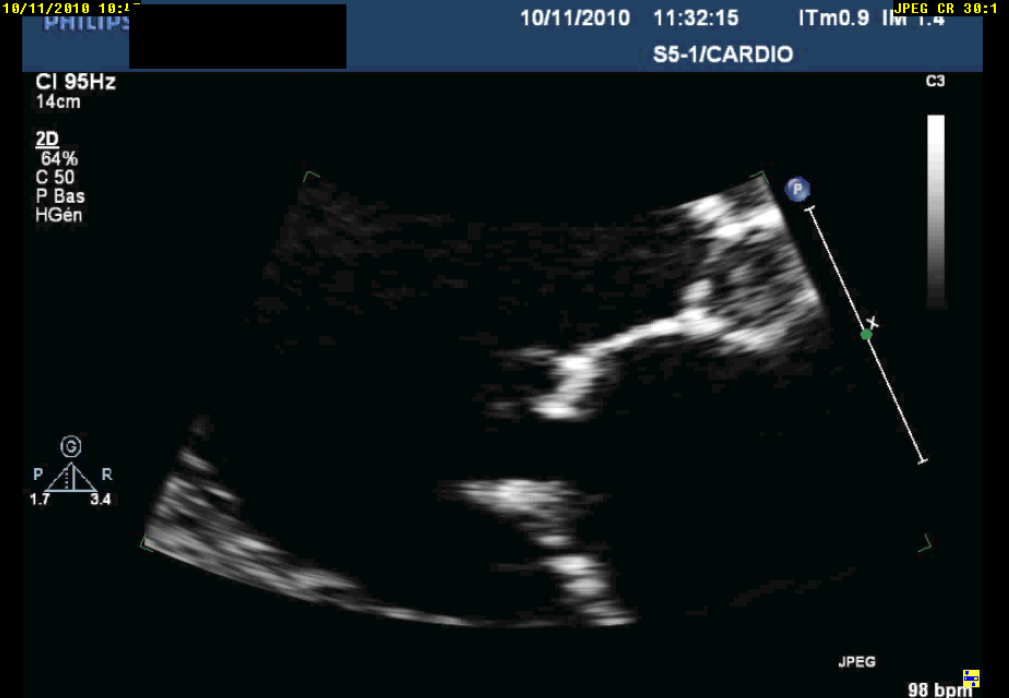
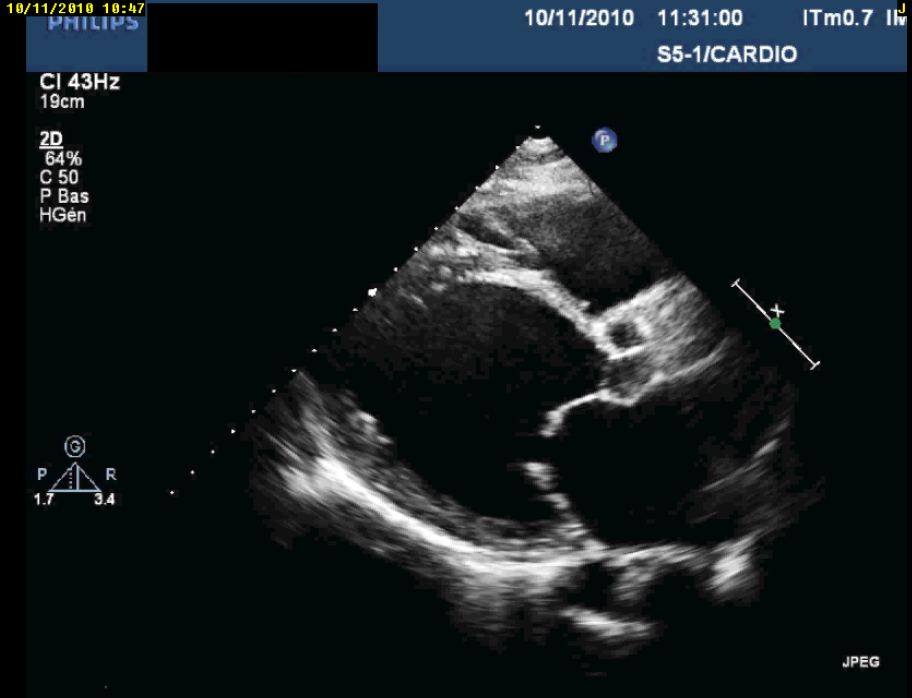
CI 33Hz
14cm

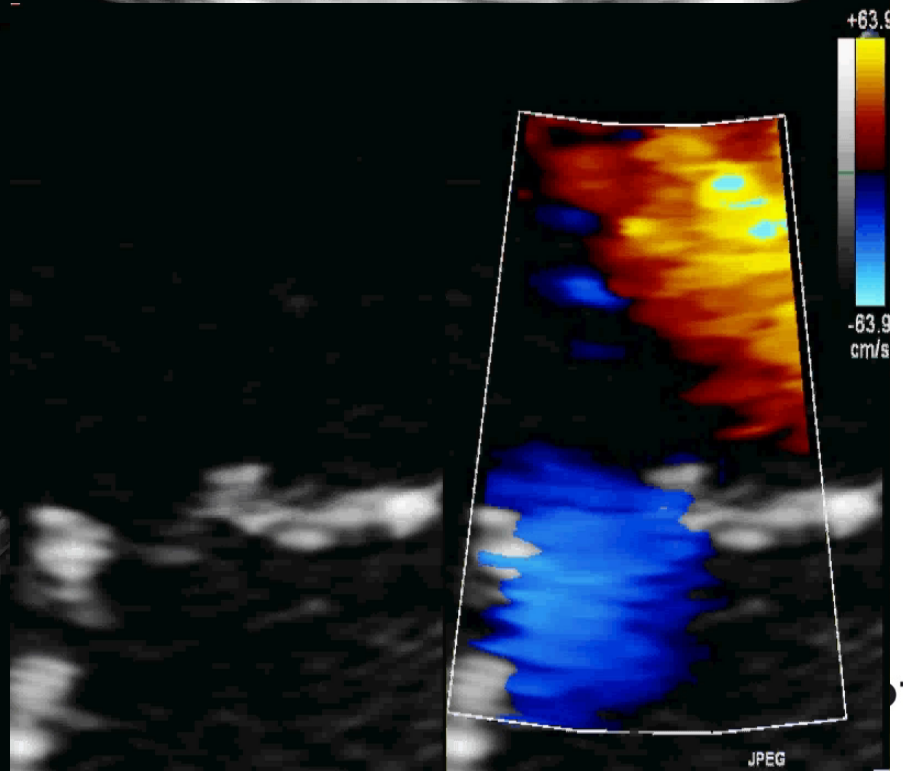
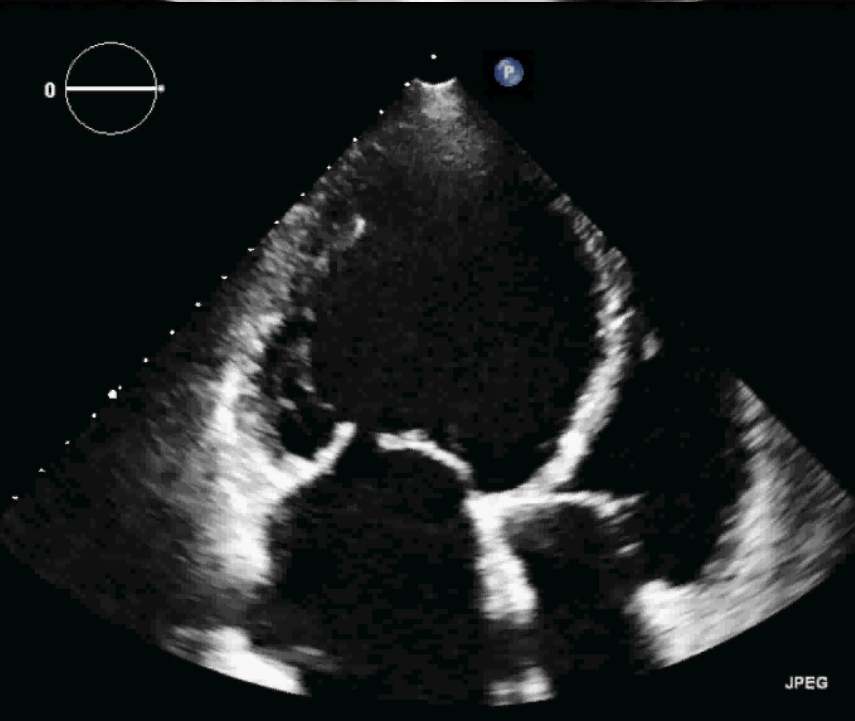
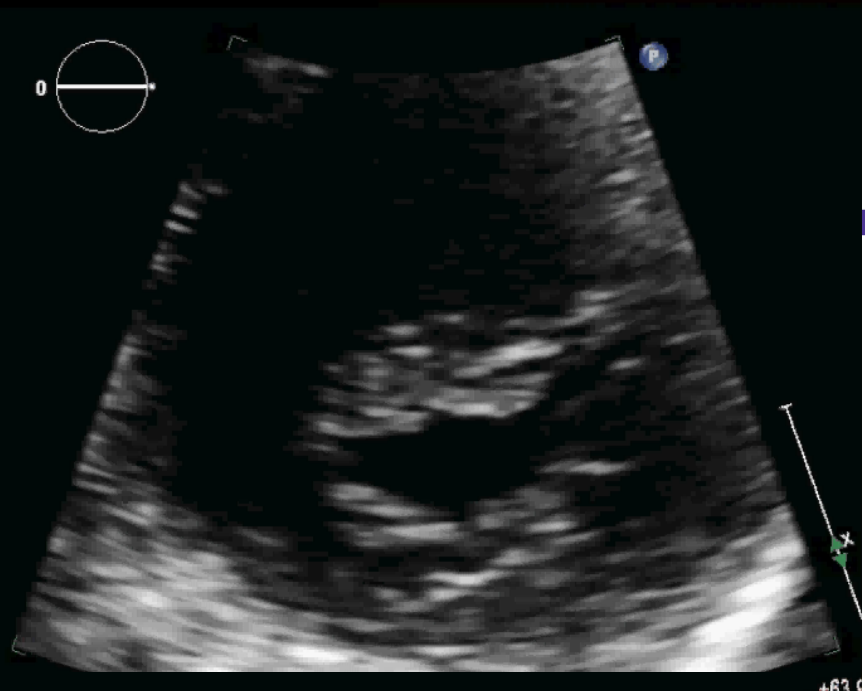
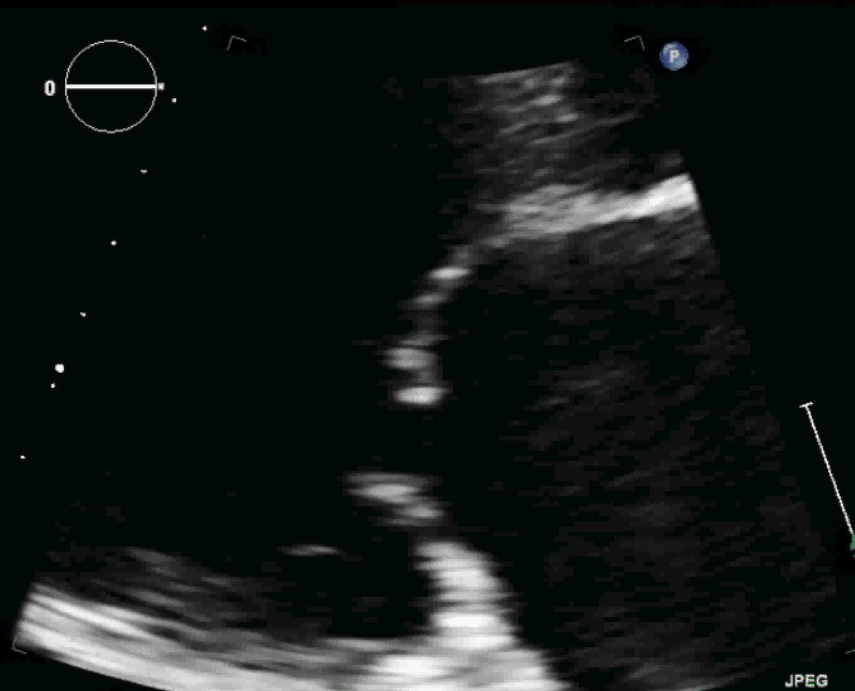
2D
59%
C 50
P Bas
HGen

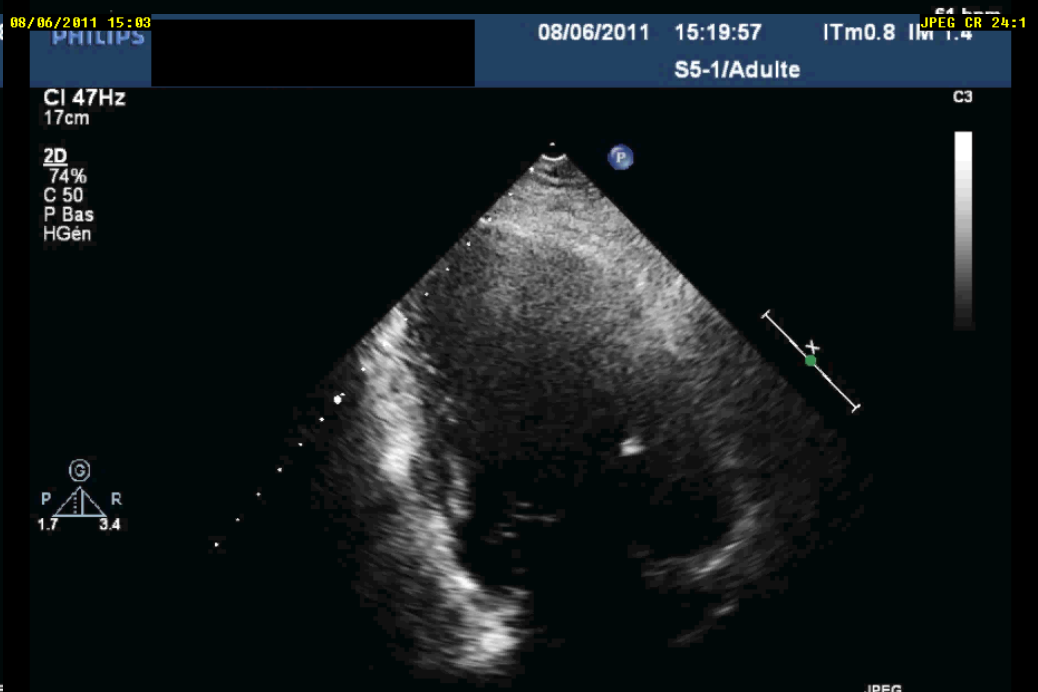
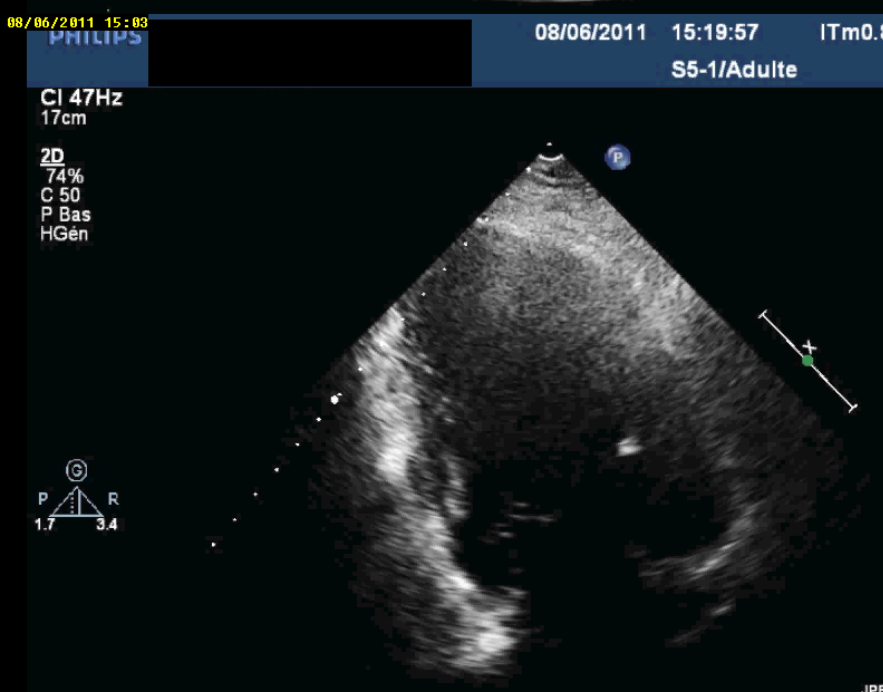
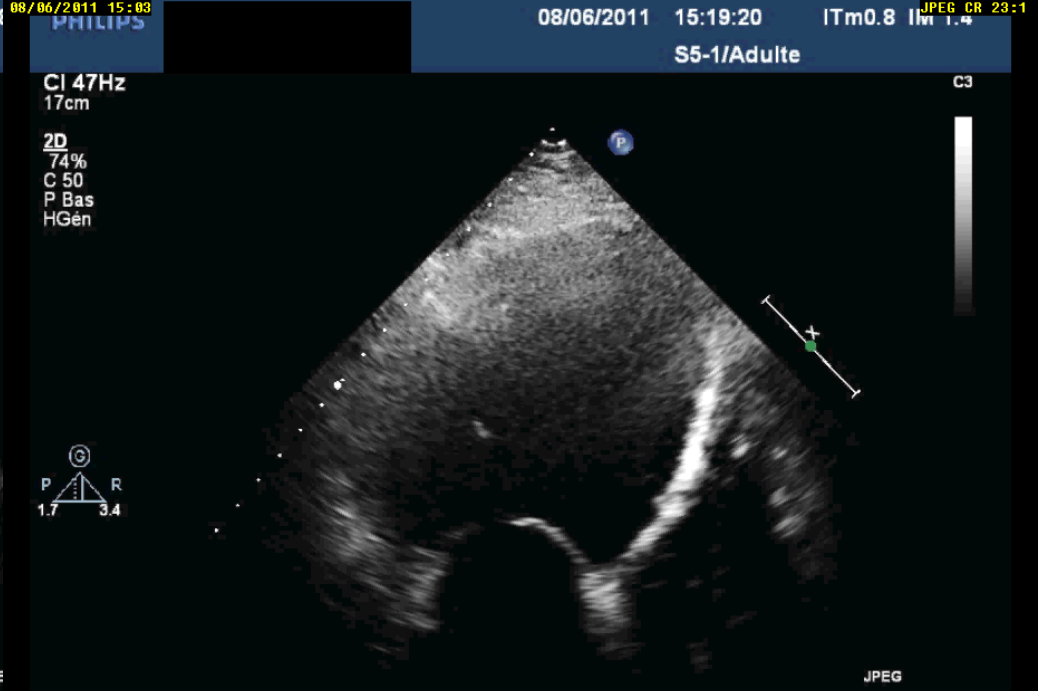
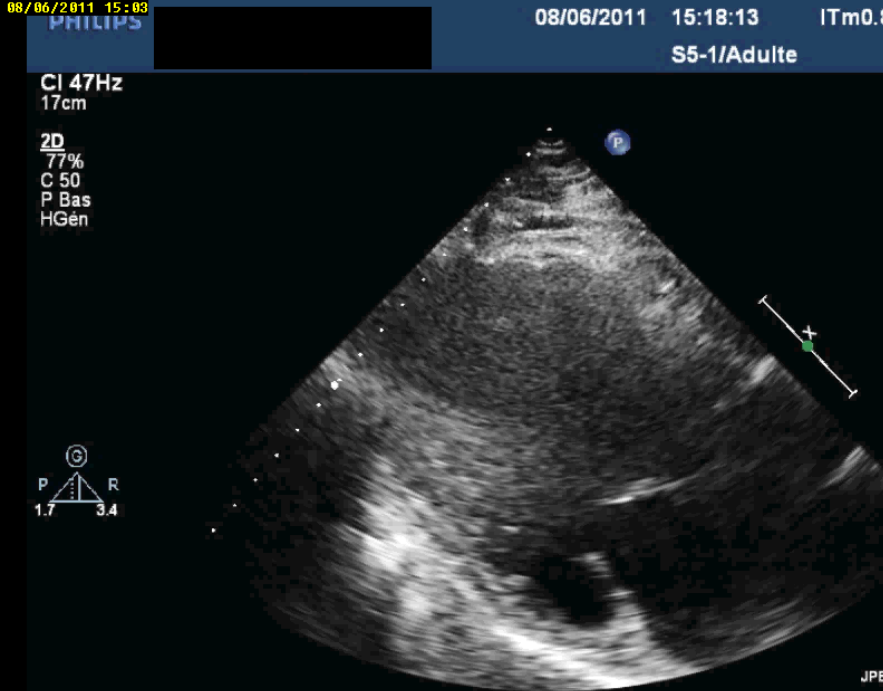


C3

JPEG



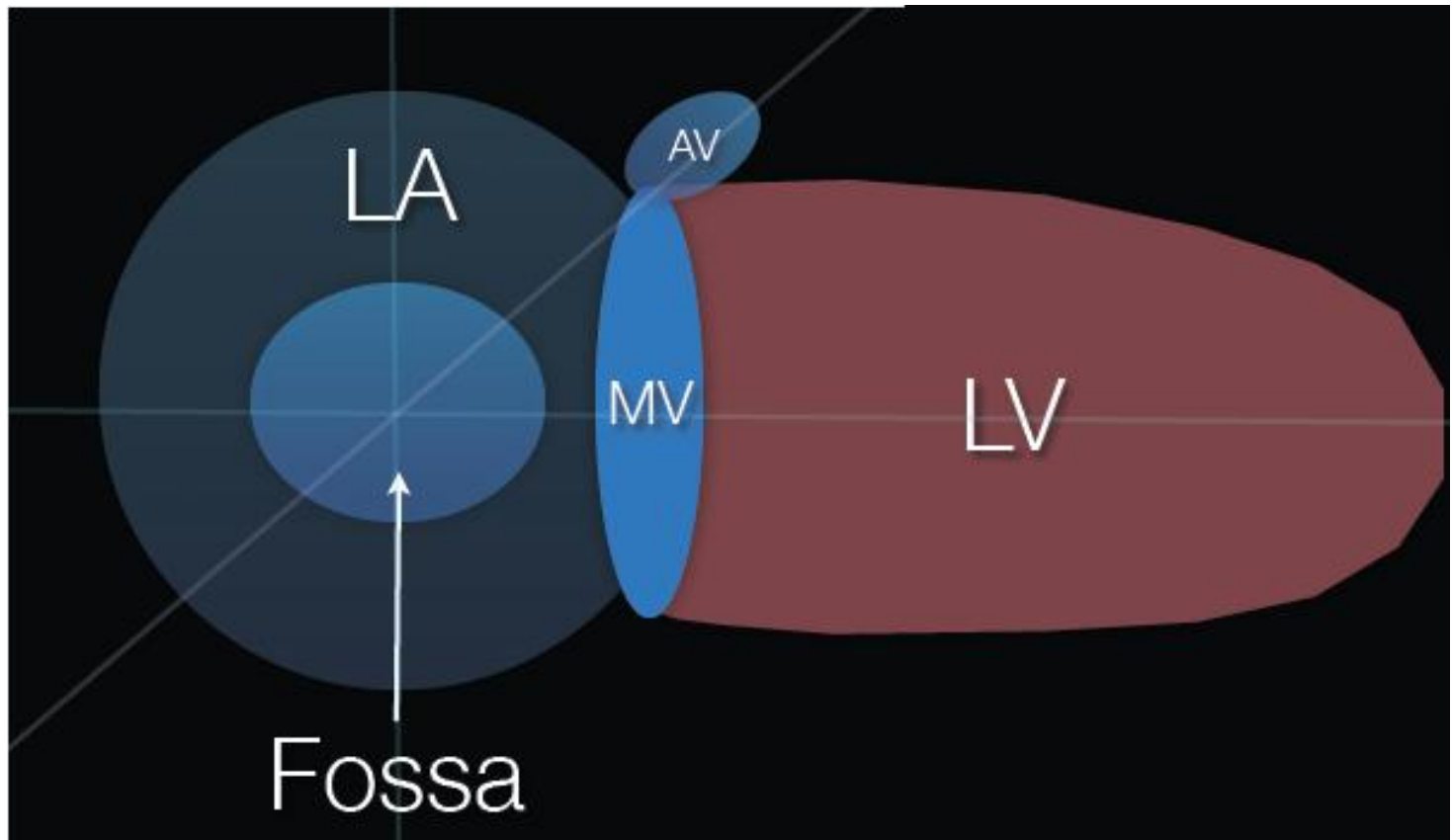




Maybe too Late...

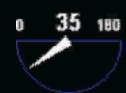
- **Very low ejection fraction**
- **Severe left ventricular enlargement**
- **End-Stage heart failure**
- **Right ventricular dysfunction**
- **Severe TR**

Transeptal Puncture

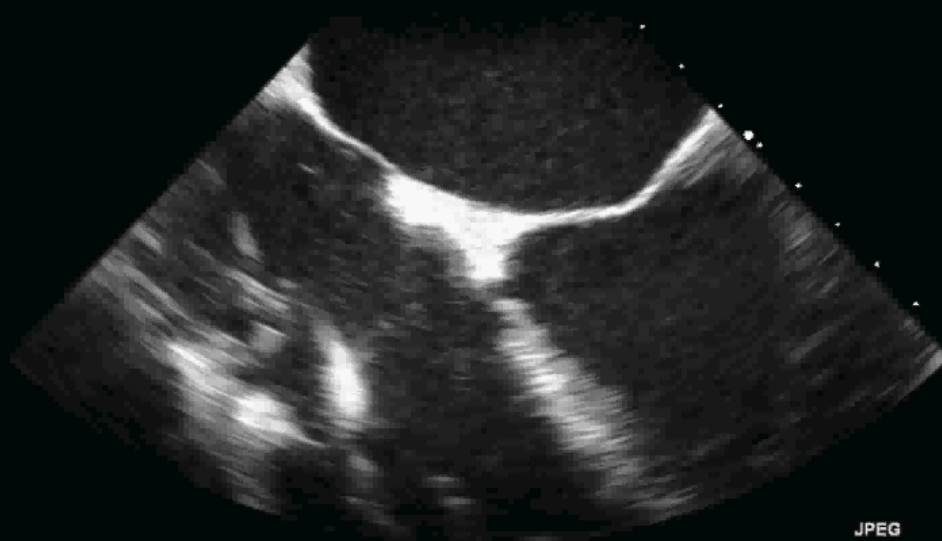
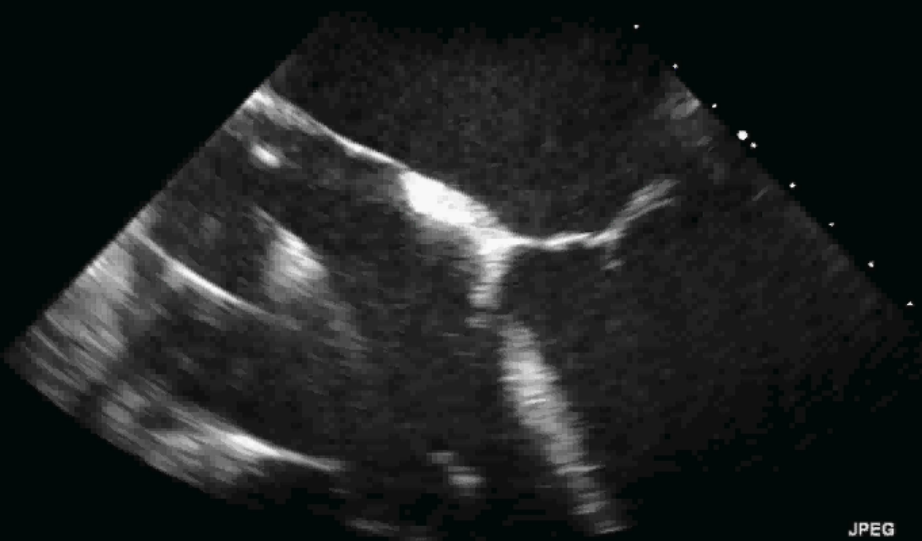




P

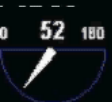


P



JPEG

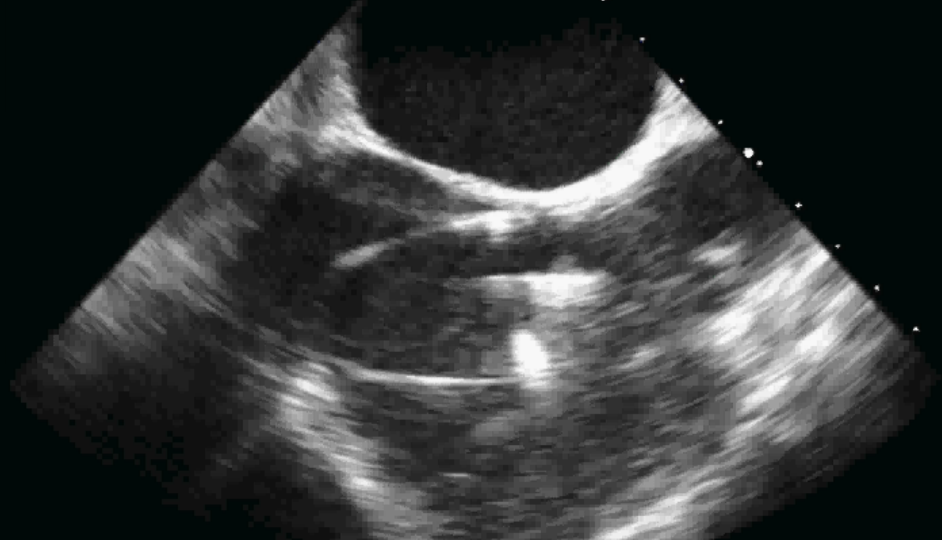
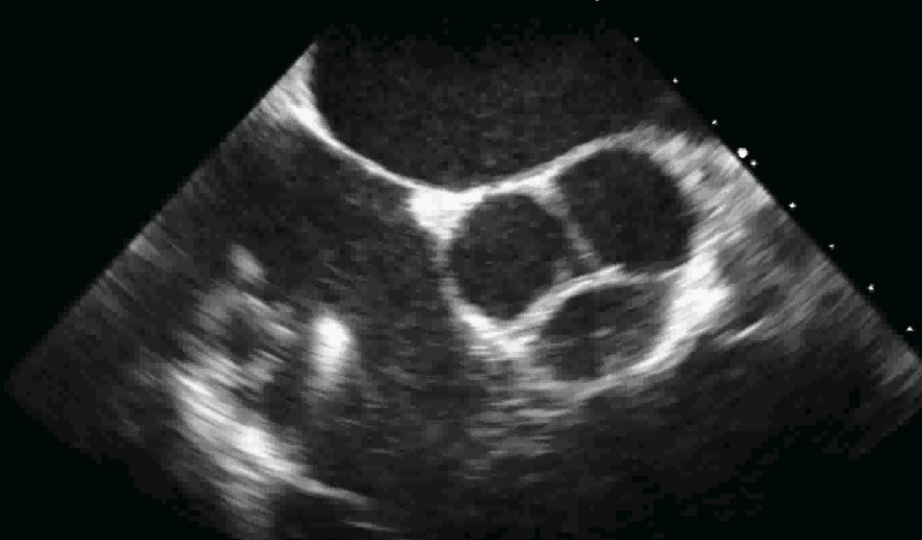
JPEG



P

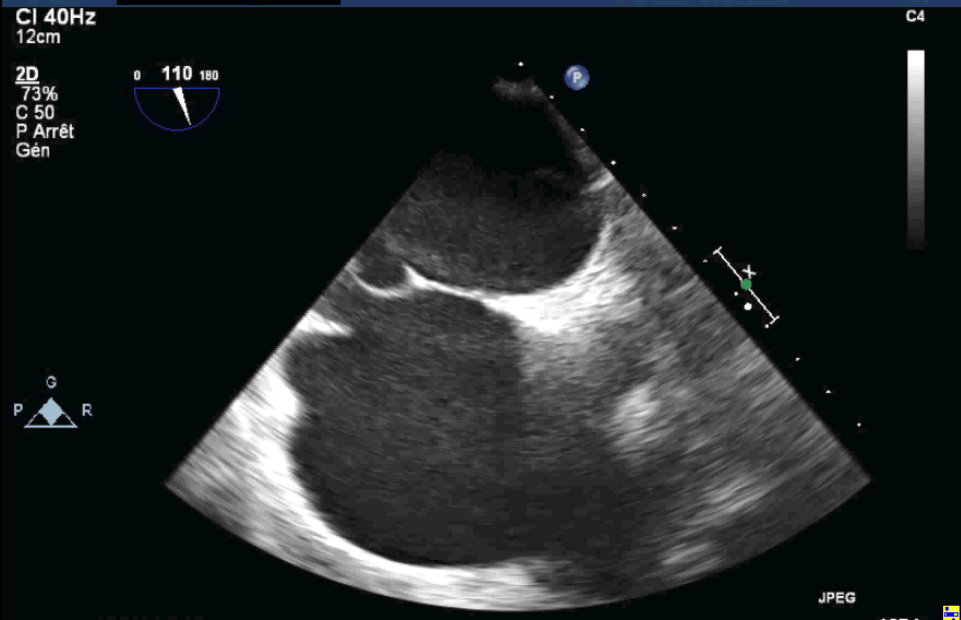
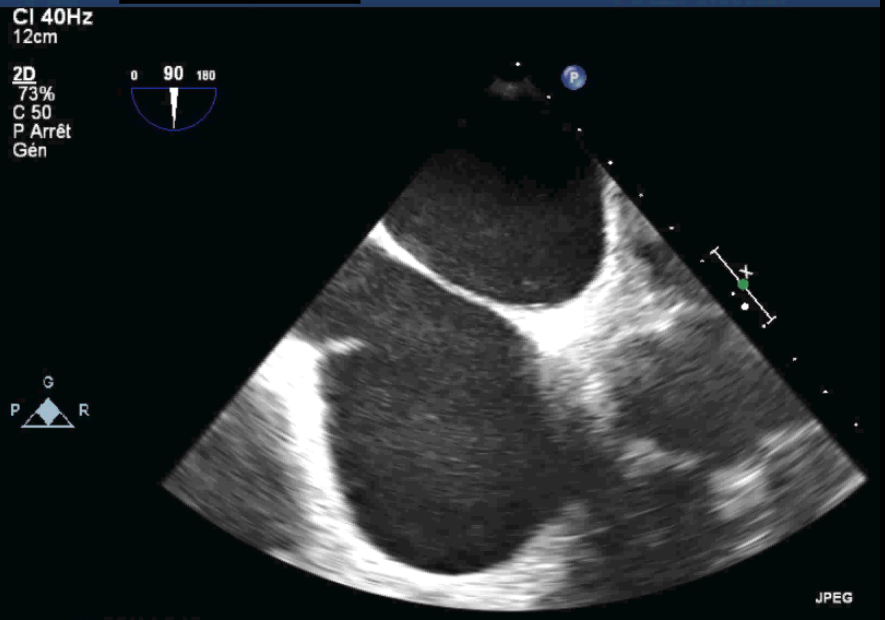
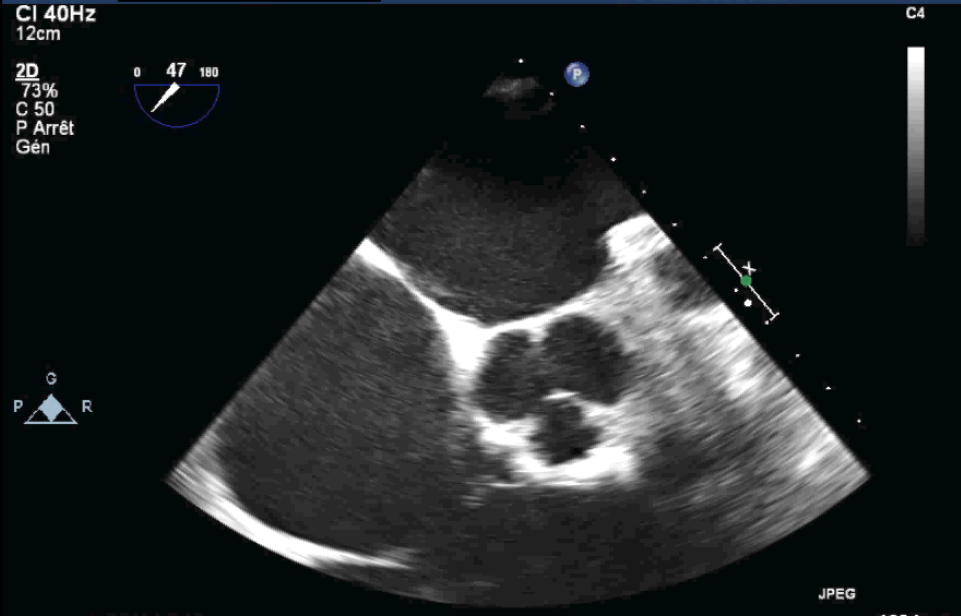
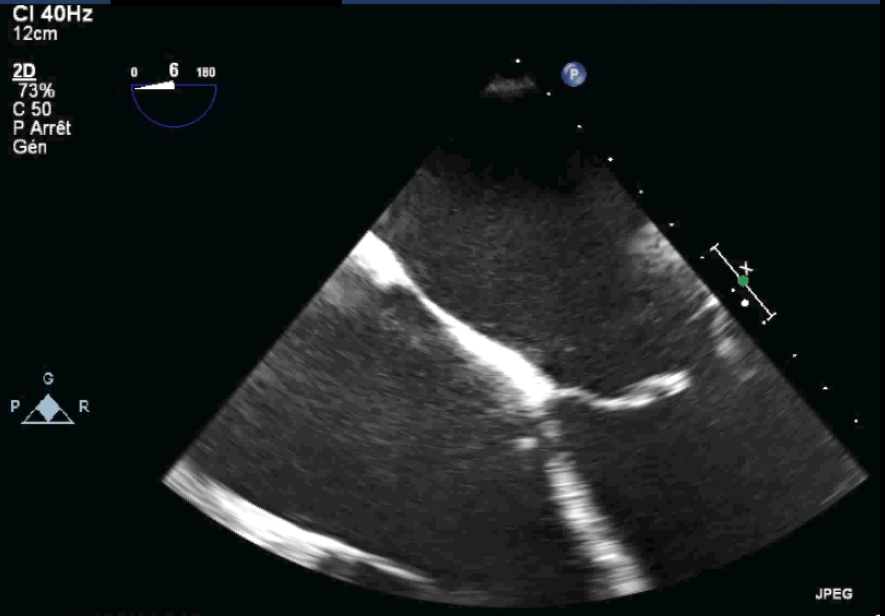


P



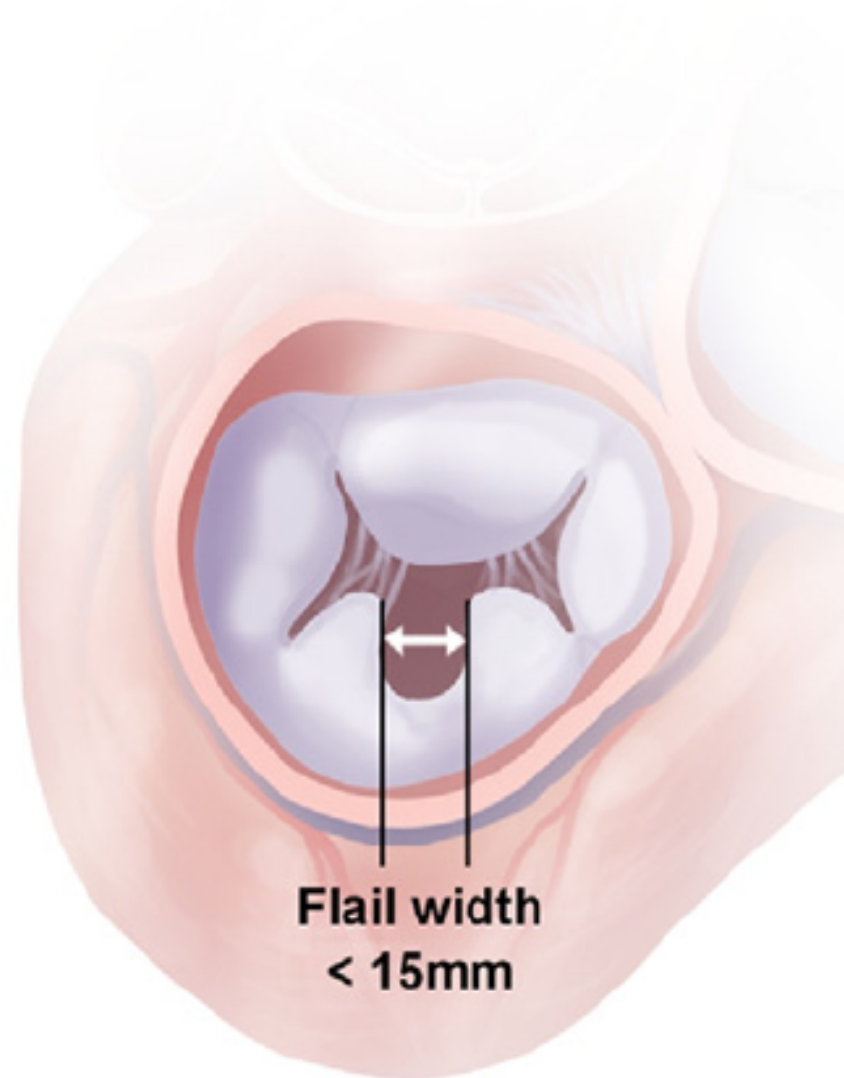
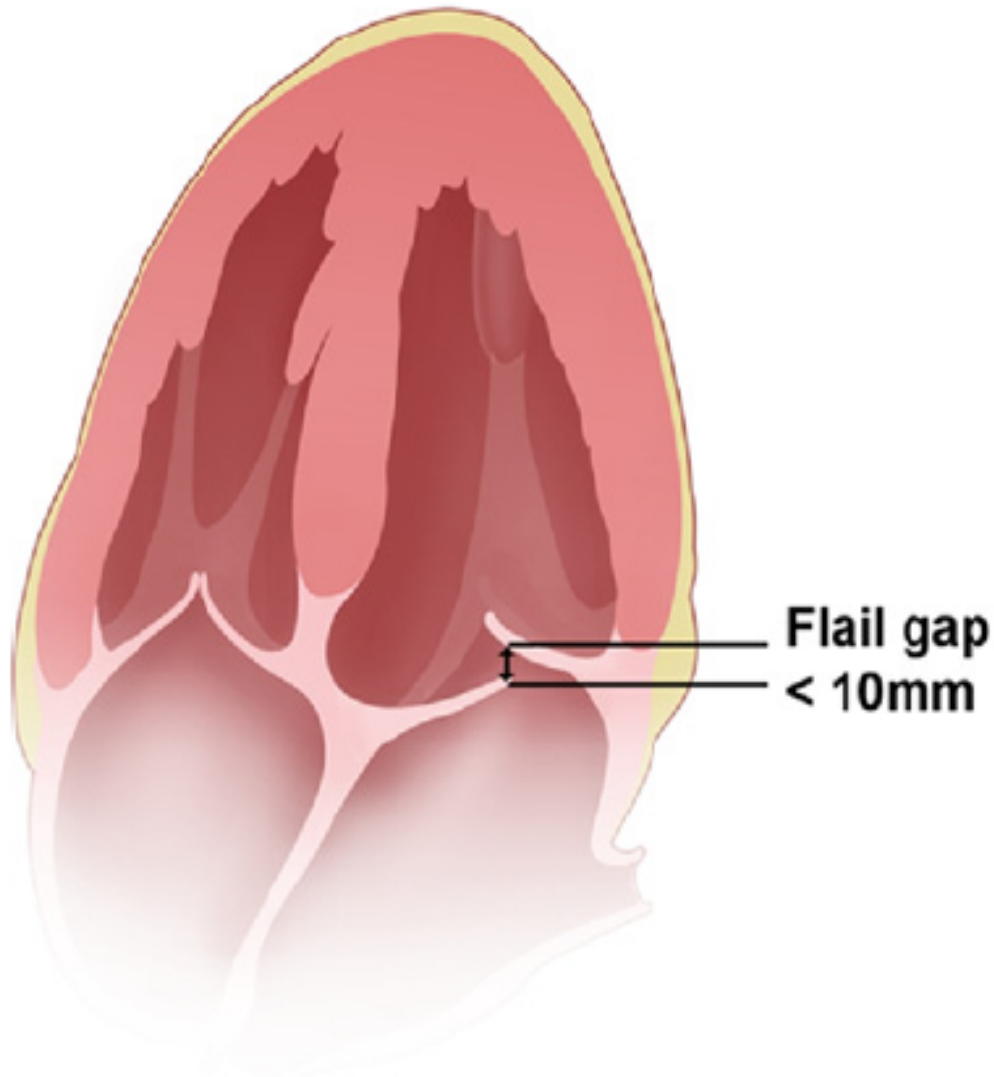
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JPEG



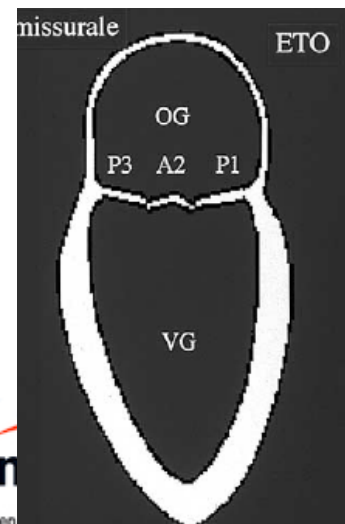
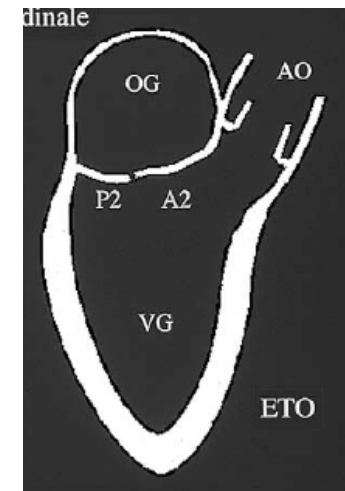
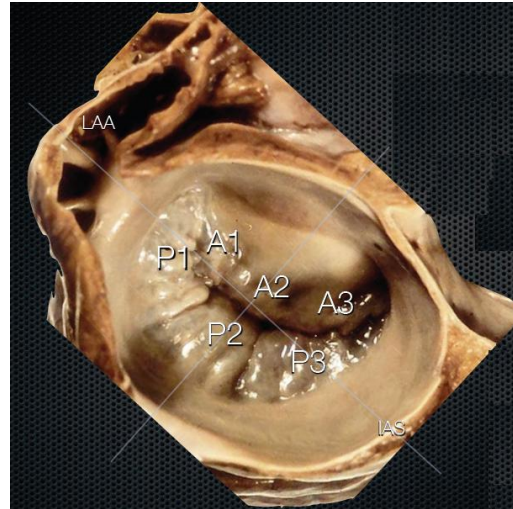
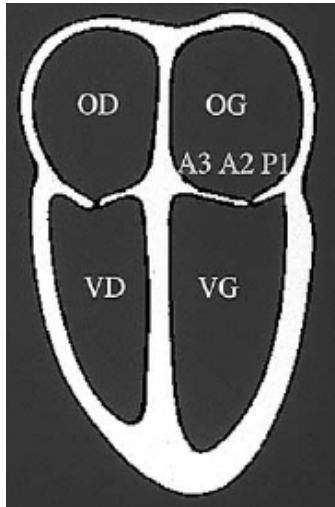
Selection of Candidates

Organic Mitral Regurgitation

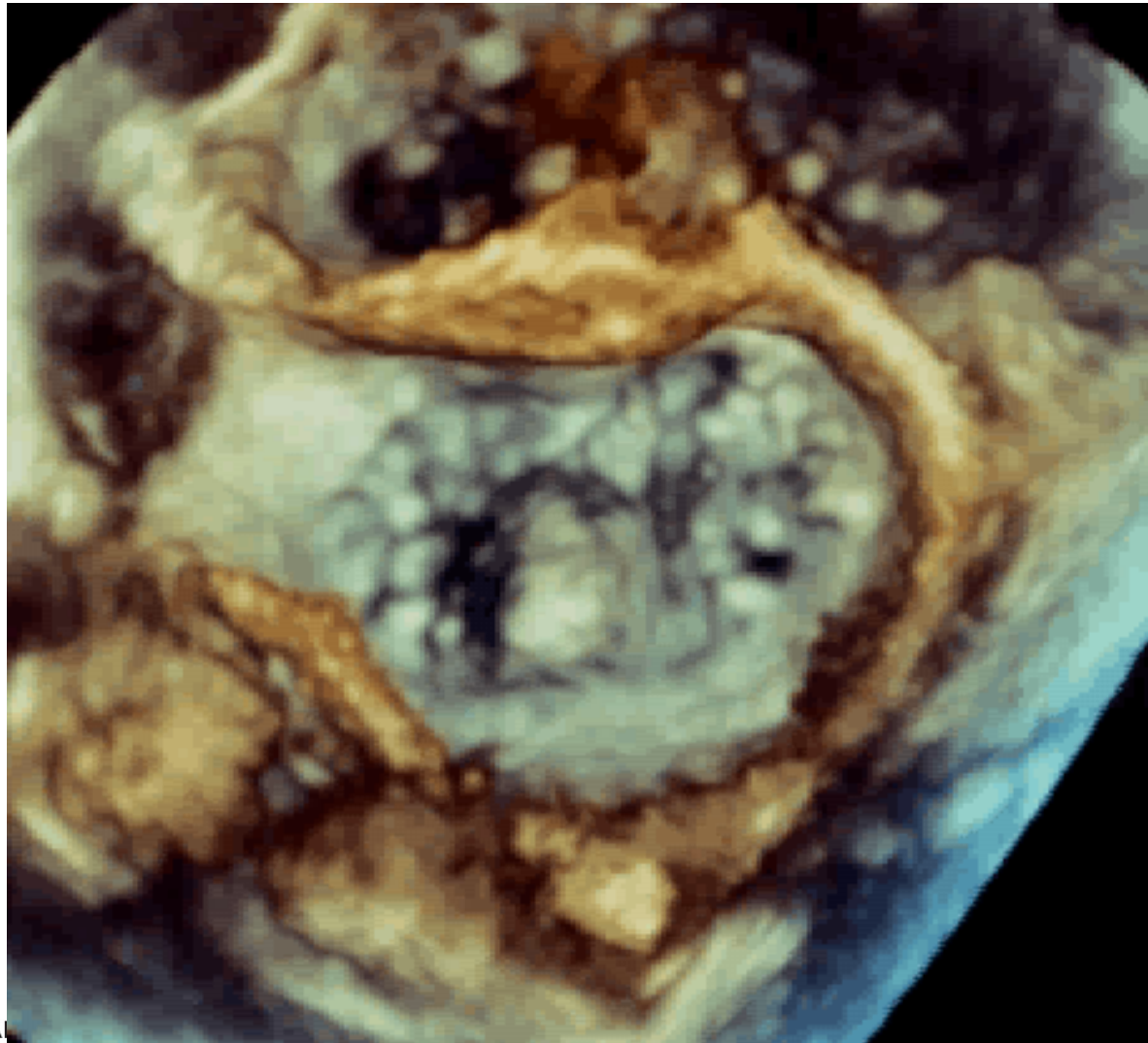


Mitral Valve Lesion

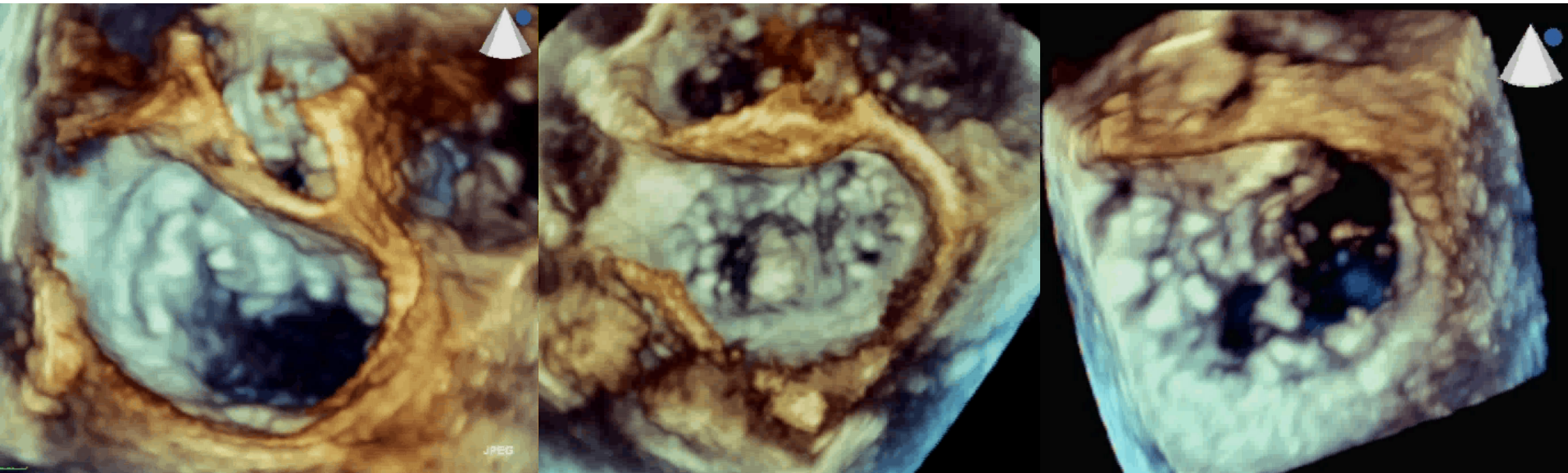
2D Transesophageal Echocardiography



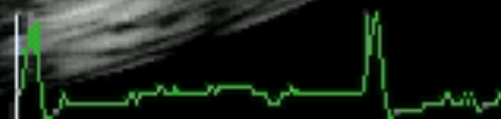
3D Transesophageal Echocardiography



3D Transesophageal Echocardiography



PHILIPS



1 cm

Theoretical Concerns

- **Mitral stenosis**
- **Tensions forces and distortion of the mitral valve**
- **No associated annuloplasty**
- **Feasibility of bail out repair**

EVEREST II randomized clinical trial: Predictors of mitral valve replacement in de novo surgery or after the MitraClip procedure

Donald Glower, MD,^a Gorav Ailawadi, MD,^b Michael Argenziano, MD,^c Michael Mack, MD,^d Alfredo Trento, MD,^e Andrew Wang, MD,^a D. Scott Lim, MD,^b William Gray, MD,^c Paul Grayburn, MD,^d John Dent, MD,^b Linda Gillam, MD,^c Barathi Sethuraman, MD,^f Ted Feldman, MD,^g Elyse Foster, MD,^h Laura Mauri, MD,ⁱ and Irving Kron, MD,^b on behalf of the EVEREST II Investigators

Objective: The Endovascular Valve Edge-to-Edge Repair Study (EVEREST II) is a prospective, multicenter, randomized controlled trial comparing percutaneous repair with the MitraClip device to mitral valve (MV) surgery in the treatment of mitral regurgitation. The present study analyzed the patient characteristics and treatment effects on mitral repair versus replacement.

Methods: Of 279 patients enrolled, 80 surgical patients underwent 82 MV operations and 178 underwent an initial MitraClip procedure, of whom 37 underwent a subsequent MV operation within 1 year of their index the MitraClip procedure. A logistic regression model was used to predict MV replacement according to valve pathology, etiology of mitral regurgitation, age, previous cardiac surgery, and treatment group.

Results: The rate of percutaneous or surgical MV repair at 1 year was 89% (158/178) in patients initially receiving the MitraClip device versus 84% (67/80) in the surgical patients ($P = .36$). Surgical repair was performed after the MitraClip procedure in 20 (54%) of 37 patients ($P < .001$ vs surgery). In both the MitraClip device and surgery groups, MV replacement was significantly associated with anterior leaflet pathology ($P = .035$). Logistic regression analysis showed that anterior leaflet pathology predicted MV replacement. In 5 (13.5%) of 37 patients undergoing surgery after MitraClip therapy, replacement was performed in part because of MV injury associated with the MitraClip procedure.

Conclusions: These data suggest that anterior leaflet pathology is strongly associated with MV replacement in patients undergoing either de novo MV surgery or surgery after MitraClip therapy. MitraClip therapy has a repair rate similar to surgery through 1 year but also imparts a risk of replacement of a potentially repairable valve. (J Thorac Cardiovasc Surg 2012;143:S60-3)

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Donald Glower, MD,^a Gorav Ailawadi, MD,^b Michael Argenziano, MD,^c Michael Mack, MD,^d 37 patients underwent subsequent MV surgery, of whom 20 (54%) underwent MV repair. The planned repair rate for the 37 patients who underwent surgery after the MitraClip procedure (92%) was significantly greater than the actual repair rate (54%, $P = .005$). The number of MitraClip devices implanted (17 with no clip, 7 with 1 clip,

Of the 37 cases of MV surgery after the MitraClip procedure, valve injury was reported by the surgeon in 11 (30%); 6 cases were reported to be related to the MitraClip procedure and the remaining 5 were reported to be related to difficulty in removing the device during explantation. In 6 of

Conclusions: These data suggest that anterior leaflet pathology is strongly associated with MV replacement in patients undergoing either de novo MV surgery or surgery after MitraClip therapy. MitraClip therapy has a repair rate similar to surgery through 1 year but also imparts a risk of replacement of a potentially repairable valve. (J Thorac Cardiovasc Surg 2012;143:S60-3)