



The optimal treatment options for your mitral regurgitation patients - a case-based discussion

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Potential conflict of interest

☑ Prof. Geisler has the following potential conflicts of interest to report:

Boston Scientific: Research grants

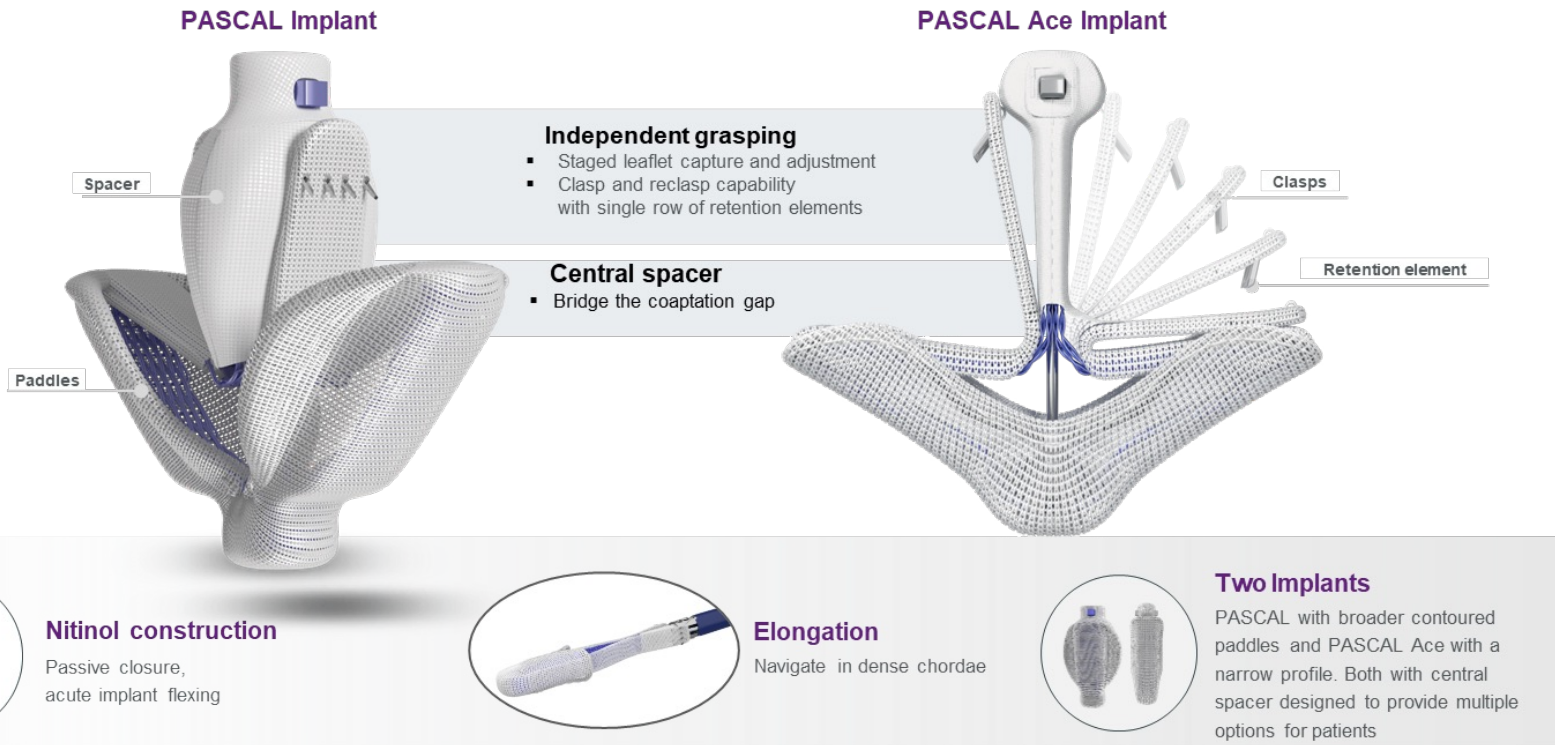
Edwards Lifesciences: Research grants, honoraria

Medtronic: Honoraria

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Edwards PASCAL Transcatheter Valve Repair System*



* Performance, design and simulation data on file
NOTE: Images are not actual size

PASCAL Implant Selection for Mitral Regurgitation

When is the PASCAL implant preferred?

- Restricted / shorter leaflets
- FMR patients



When is the PASCAL Ace implant preferred?

- Commissural jet
- Dense chordae
- Longer leaflets
- DMR patients



When is consensus still needed?

- Calcifications near the grasping zone
- Large flail gap
- $MVA < 4\text{cm}^2$
- Severe tethering
- Clefts



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PASCAL Repair System for mixed etiology

Maurizio Taramasso MD, PhD

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Speaker's name : Maurizio Taramasso

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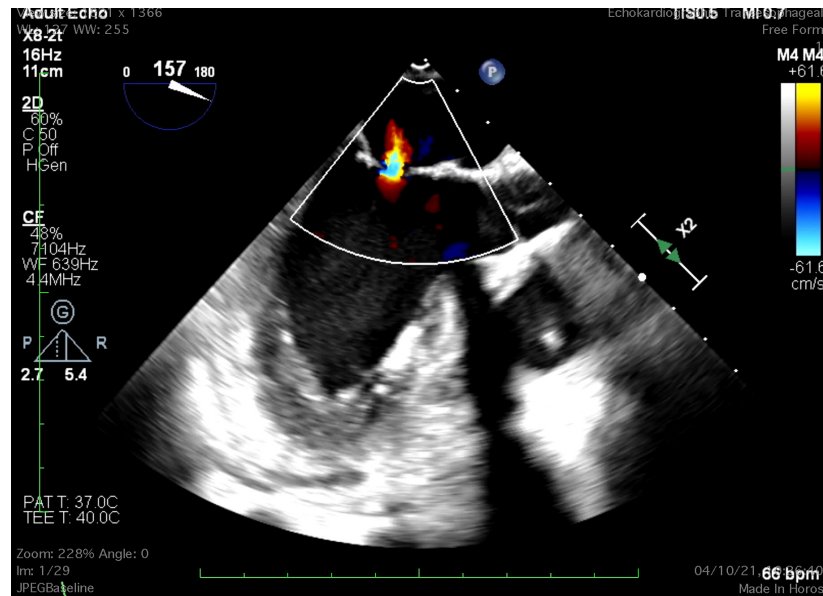
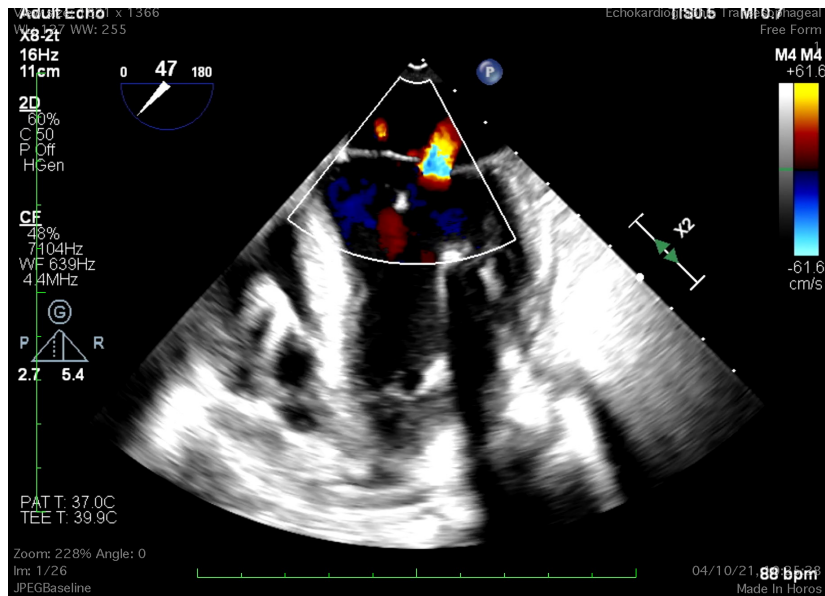
Patient presentation

- 87-year-old lady
- TAVI 6 months prior (SAPIEN 3 valve, 23 mm, no PVL, no increased gradient)
- PM implantation after TAVI
- Severe MR due to mixed etiology: annular dilation and MAC, pressure gradient: 5 mmHg
- Persistent NYHA III-IV after TAVI

TAVI: transcatheter aortic valve implantation; PVL: paravalvular leakage; PM: pacemaker; MR: mitral regurgitation; MAC: mitral annulus calcifications; NYHA: New York Heart Association

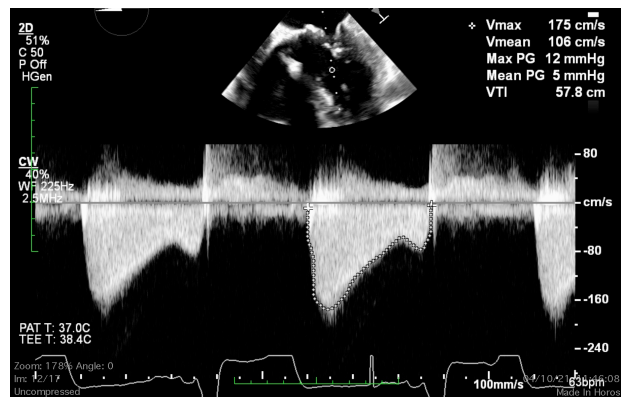
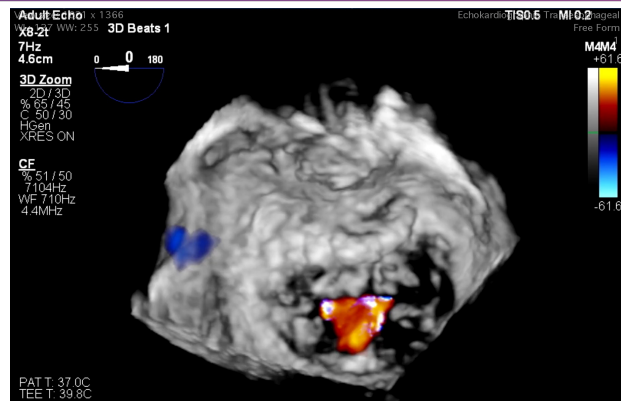
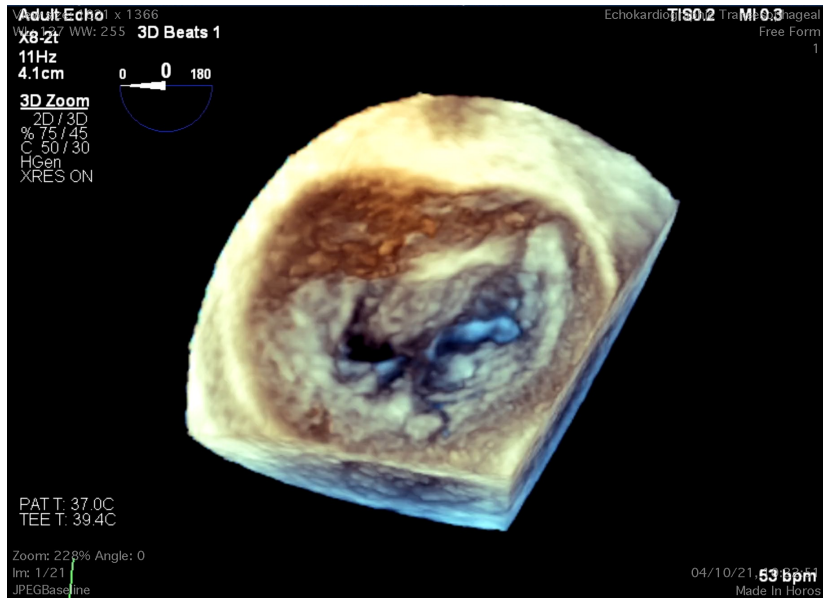
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Baseline: MAC, calcific leaflets, small orifice area



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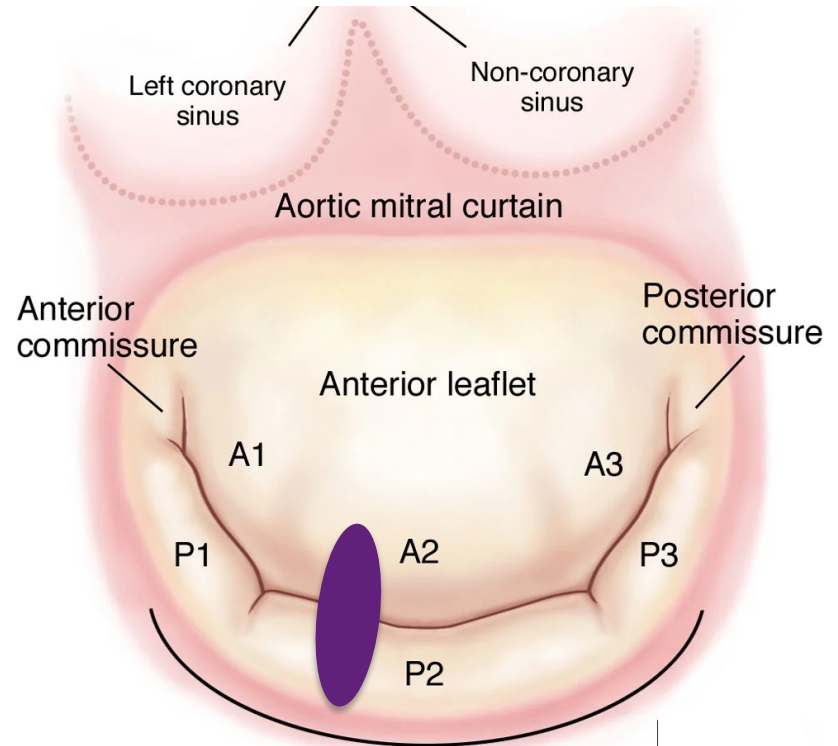
Baseline: reduced leaflets mobility, transvalvular gradient of 5 mmHg



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Strategy

- Posterior TS puncture
- Single device in A2-P2, slightly lateral
- Use of PASCAL implant due to the small orifice area and increased gradient



TS: transeptal

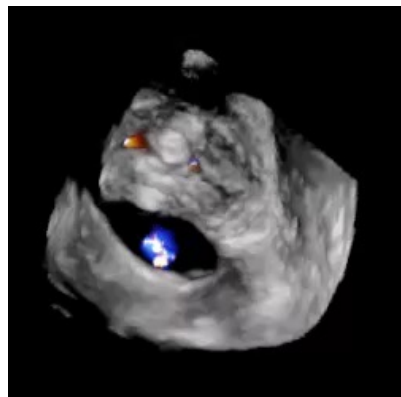
Image modified from Carpentier A, Adams DH, Filsoufi F. *Carpentier's Reconstructive Valve Surgery. From Valve Analysis to Valve Reconstruction*. 2010 Saunders Elsevier.

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PASCAL Implant – Central Spacer

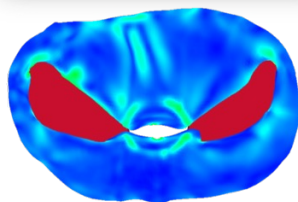
Respect native anatomy to reduce leaflet stress[#]

Central Spacer



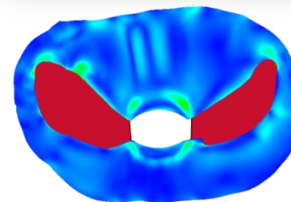
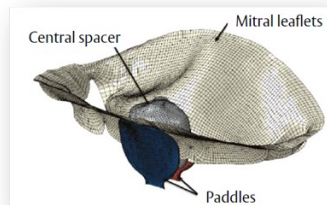
Courtesy of Dr. P. Luedike

Implant without Spacer



Open orifice area = 156.3mm^2 *

PASCAL Implant with Spacer



Open orifice area = 188.1mm^2 *



Reduced stress on leaflets*



20% increase in open orifice area during diastole*

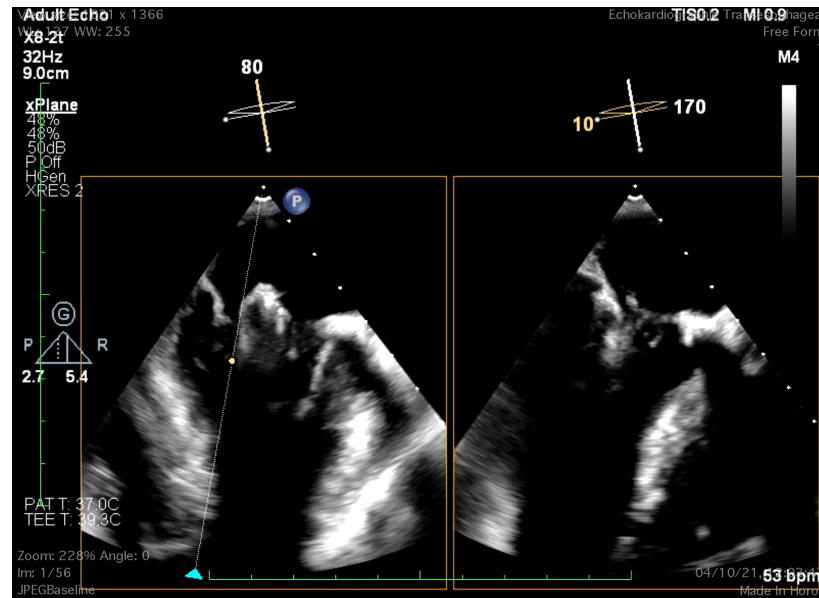
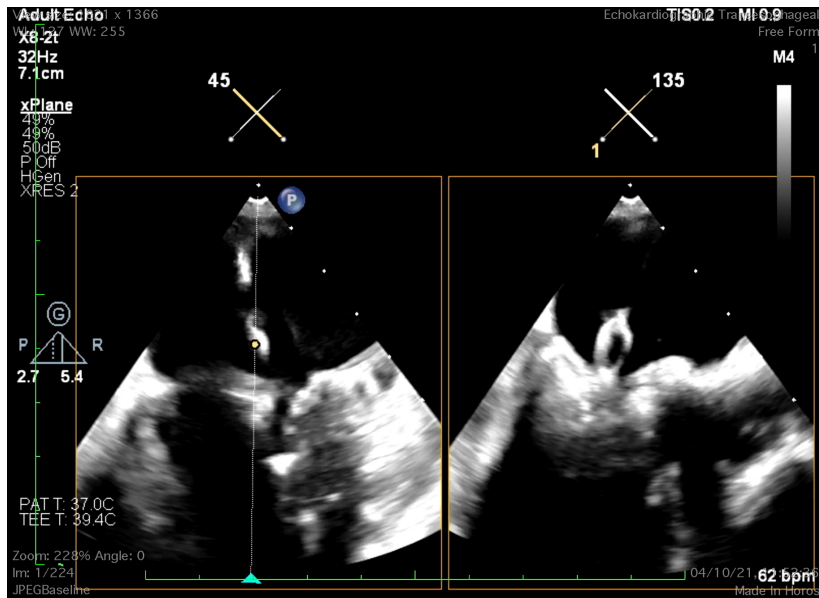
Finite Element Analysis (FEA) in a mitral valve simulates leaflet response to an implant

* Simulation data on file

Performance data on file

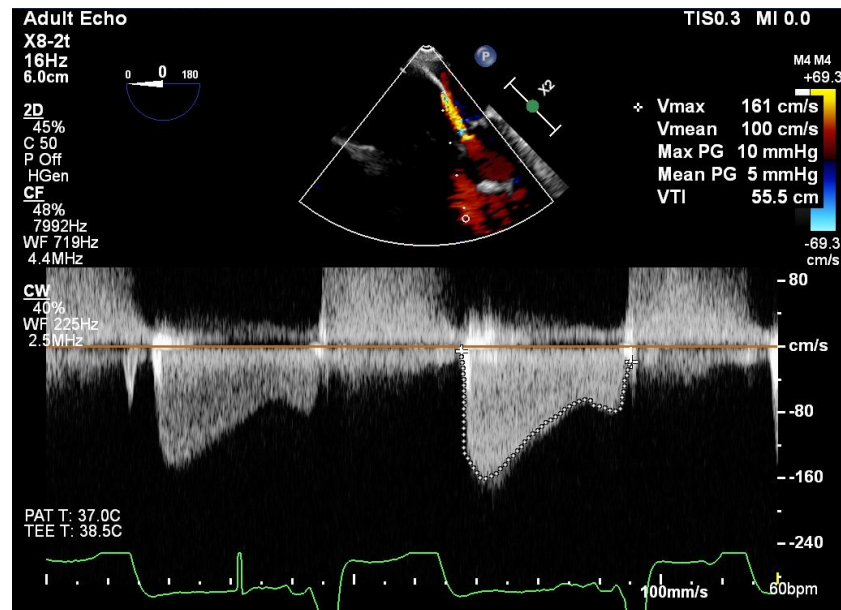
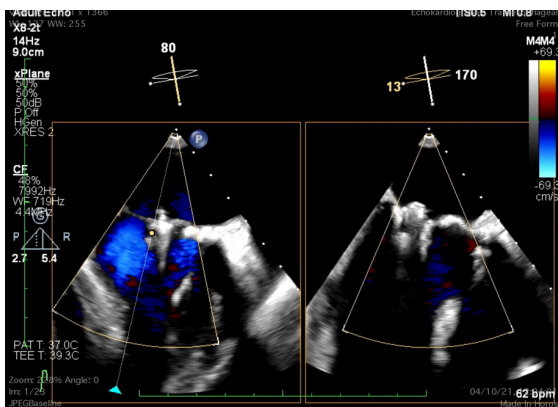
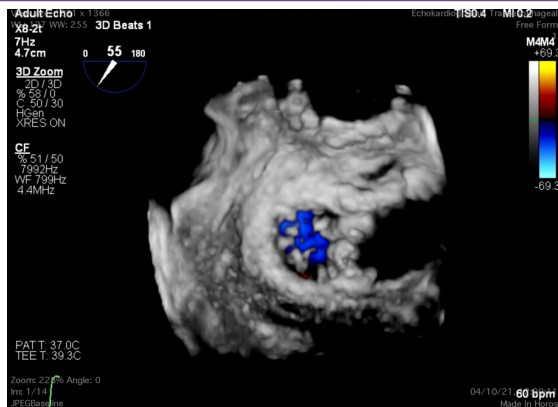
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PASCAL implant released



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Final outcomes: pressure gradient: 5 mmHg; MR: trace



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Conclusions

- Uneventful clinical course
- No re-hospitalization
- NYHA class I-II at 6-months follow-up

→ PASCAL implant proved to be suitable for this patient with high baseline gradient and calcifications

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PASCAL Precision Repair System for bi-commissural mitral regurgitation

Dr. Federico De Marco

Unità Operativa di Cardiologia Interventistica Valvolare e Strutturale

Centro Cardiologico Monzino, Milano (Italy)



Speaker's name : Federico De Marco

☒ I have the following potential conflicts of interest to declare:

Honoraria or consultation fees: Edwards Lifesciences

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Patient Presentation

- **Sex and age:** male, 80 years old
- **Risk factors:** systemic hypertension
- **Past medical history:** permanent AF in Warfarin, no CAD
- **Medical therapy:** Warfarin, Bisoprolol 2,5 mg b.i.d., Furosemid 25 mg b.i.d., Ramipril 2,5 mg/die, Lansoprazole 30 mg/die
- **Clinical presentation:** 2022 admitted for shortness of breath (NYHA III); evidence TTE of severe mitral regurgitation with annular dilation and multi scallop prolapse of both leaflets

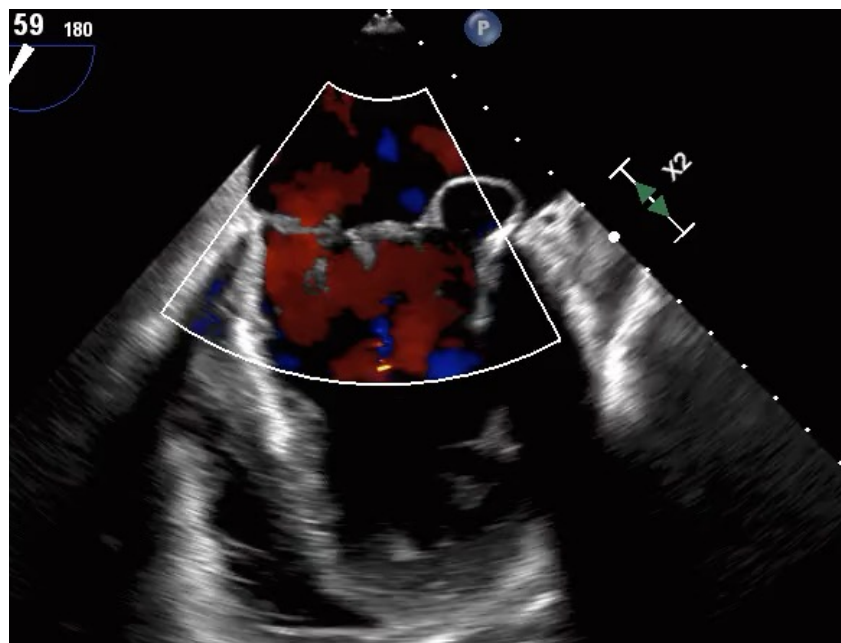
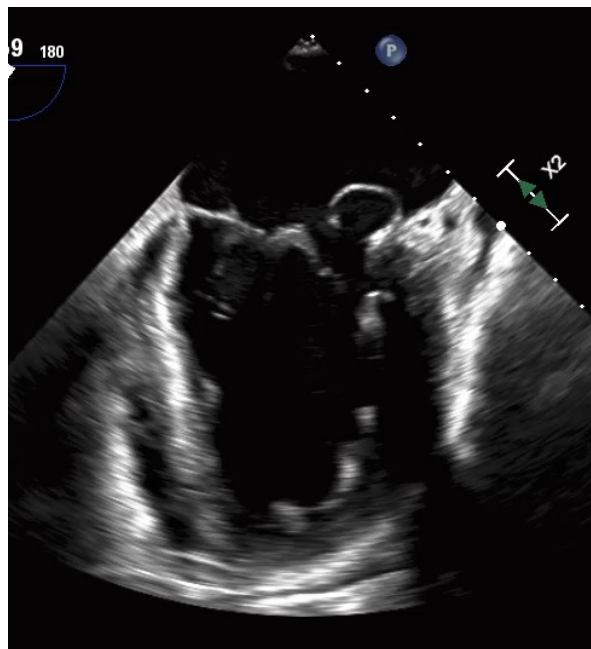
AF: atrial fibrillation; NYHA: New York Heart Association; TTE: Transthoracic echocardiography

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Baseline TEE

Bi-commissural mitral regurgitation (severe)

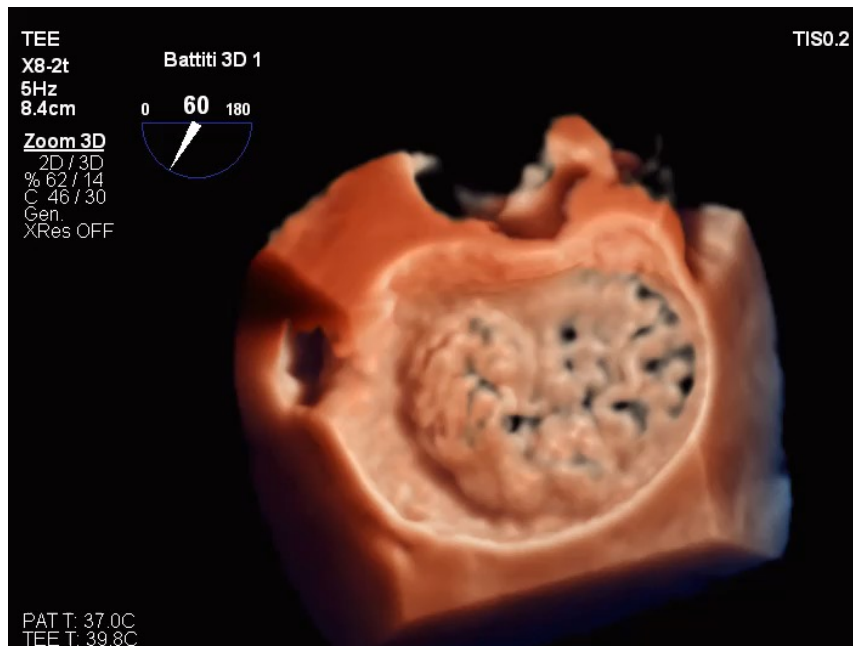
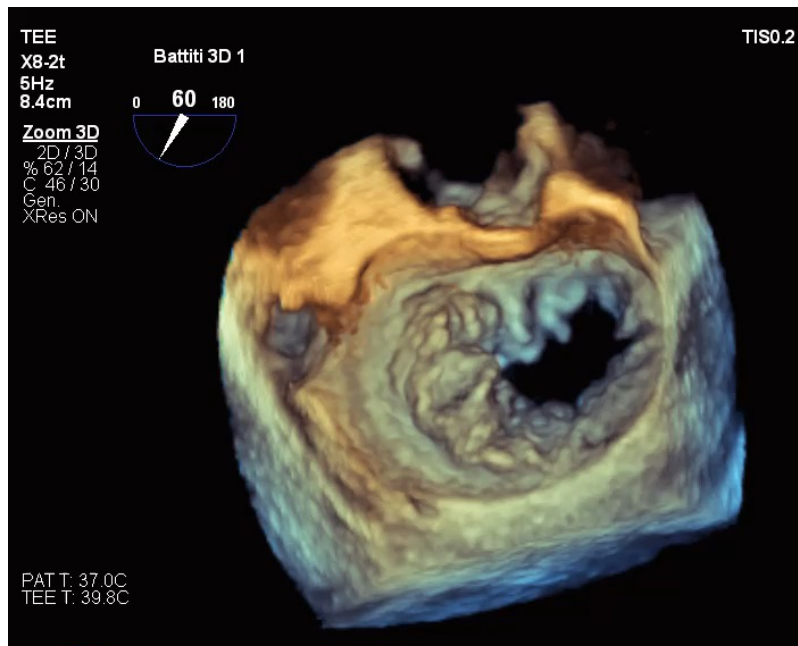
Annular dilation (37x37 mm); lateral commissural bileaflet prolapse + P1-P2 prolapse chordal rupture



TEE: Transesophageal Echocardiography

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Complex disease



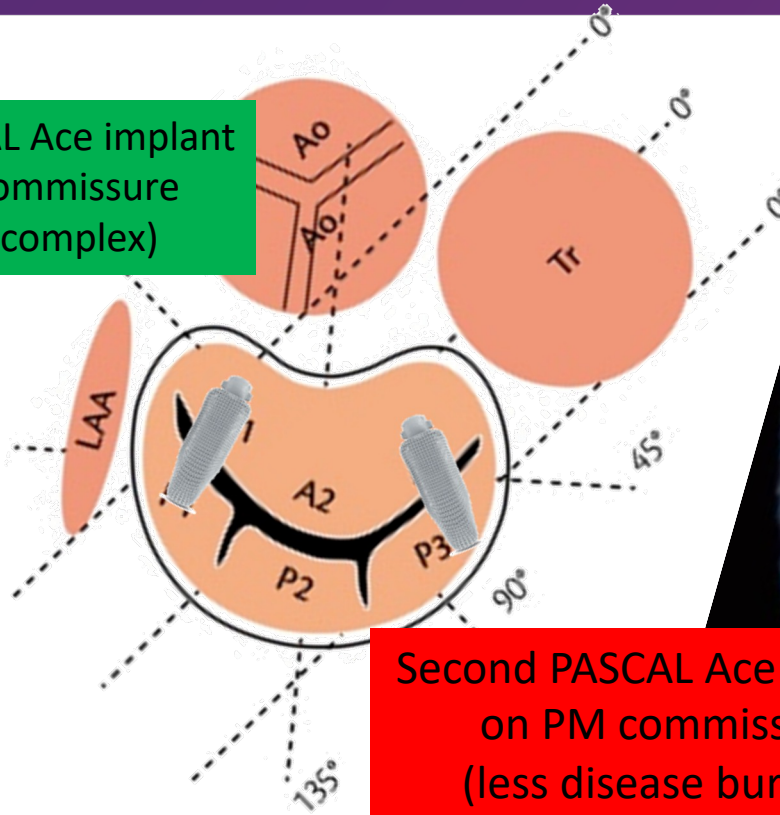
TEE: Transesophageal Echocardiography

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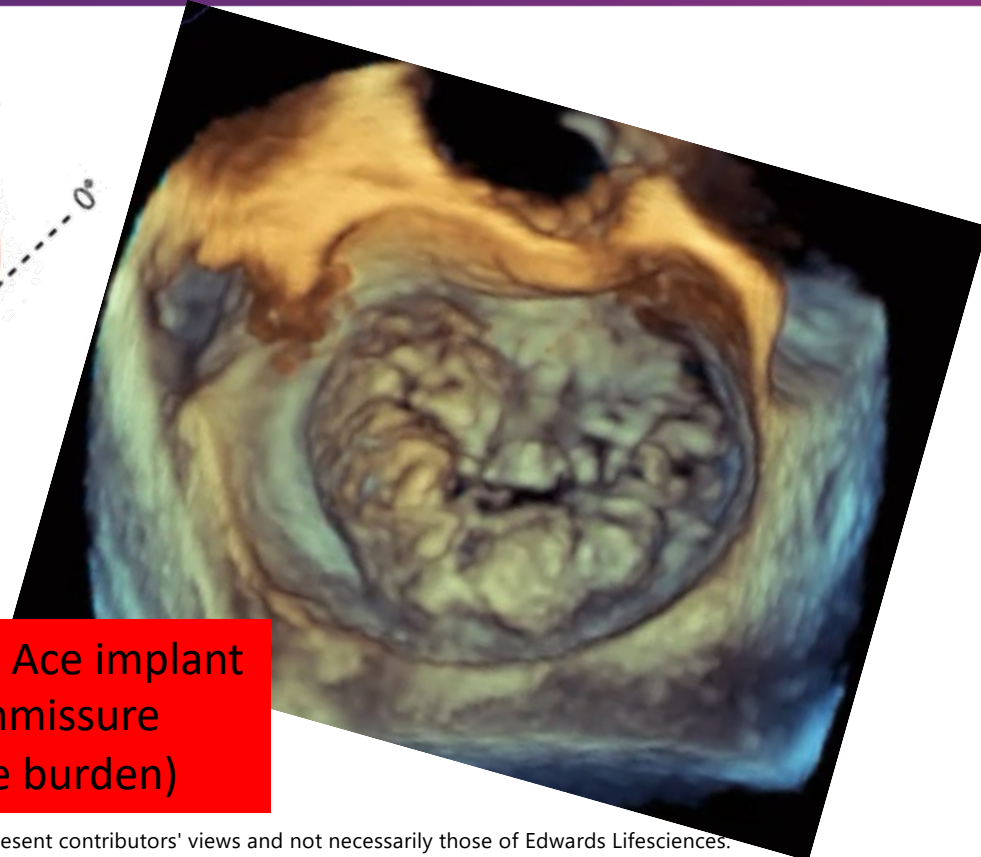
Strategy: PASCAL Precision Repair with 2 commissural PASCAL Ace implants

-> create a single central orifice

First PASCAL Ace implant
on AL commissure
(more complex)

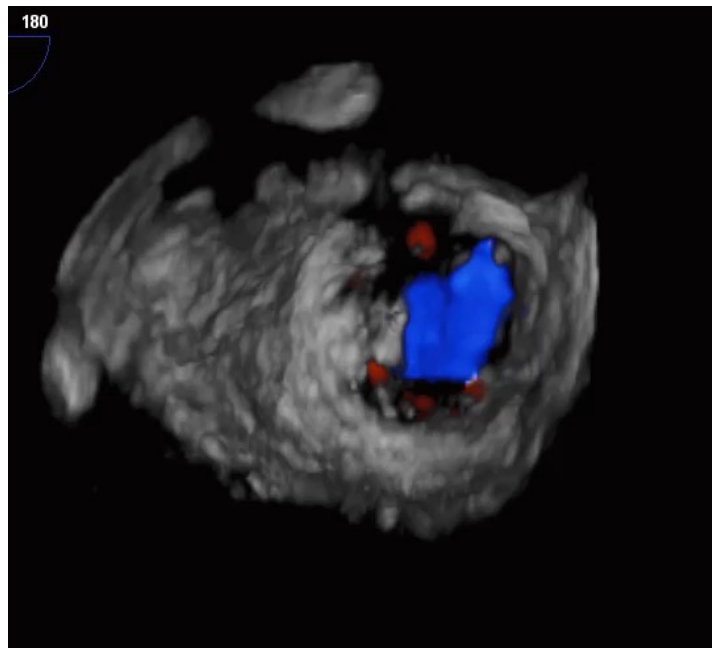
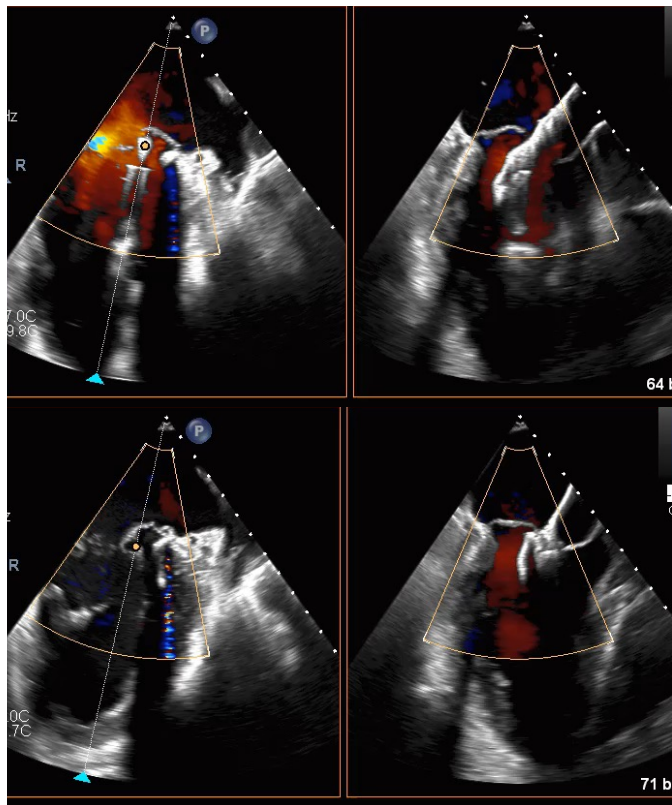


Second PASCAL Ace implant
on PM commissure
(less disease burden)



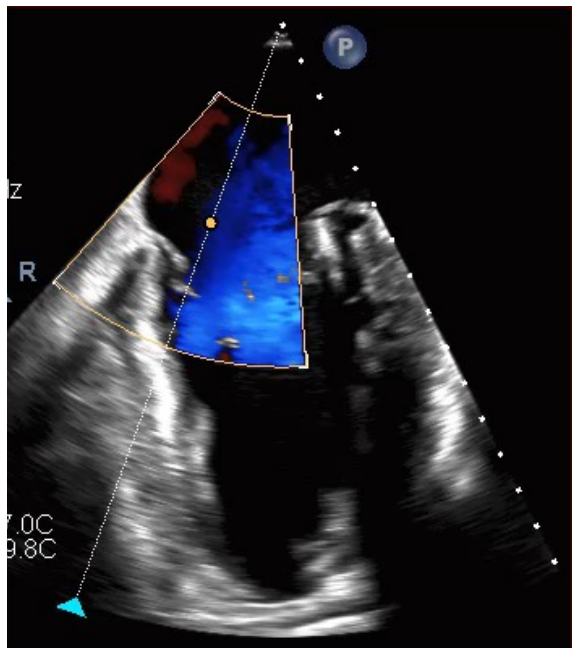
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1st PASCAL Ace implant: crossing by elongation, clasp

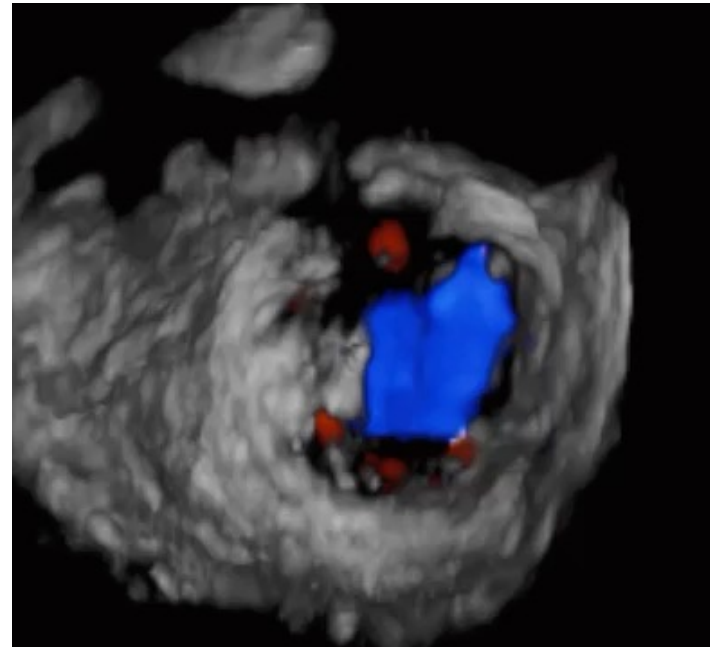
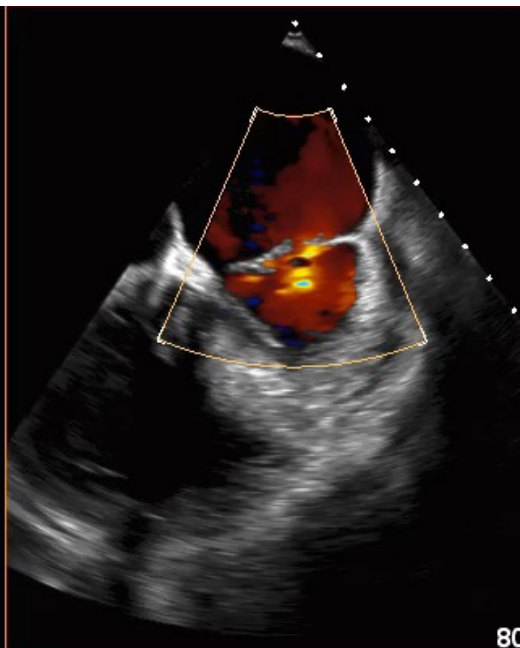


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Second step of the procedure: medial prolapse to be treated



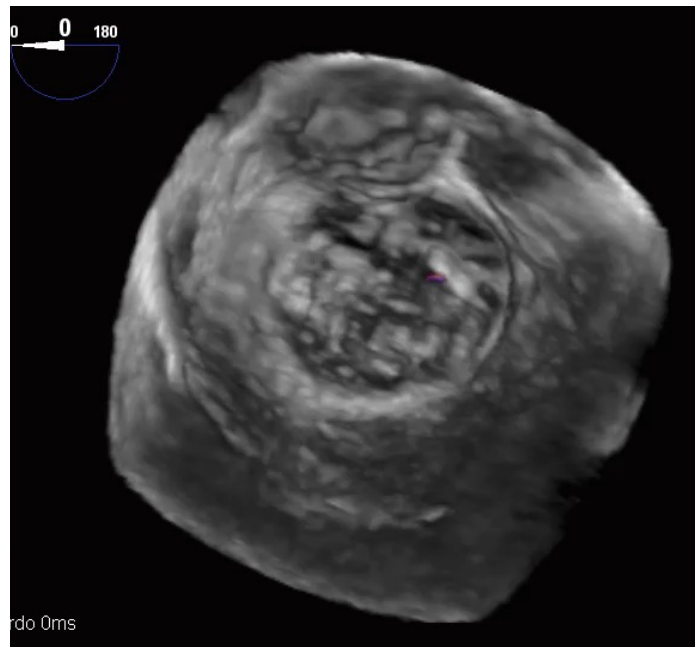
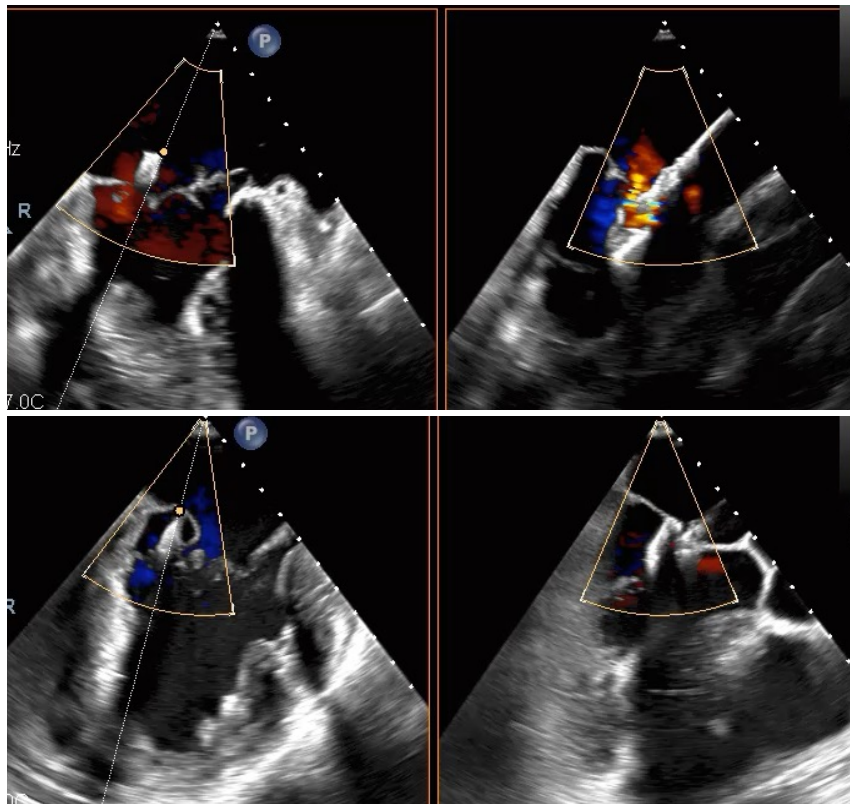
Jet in the medial commissure



3D color medial jet

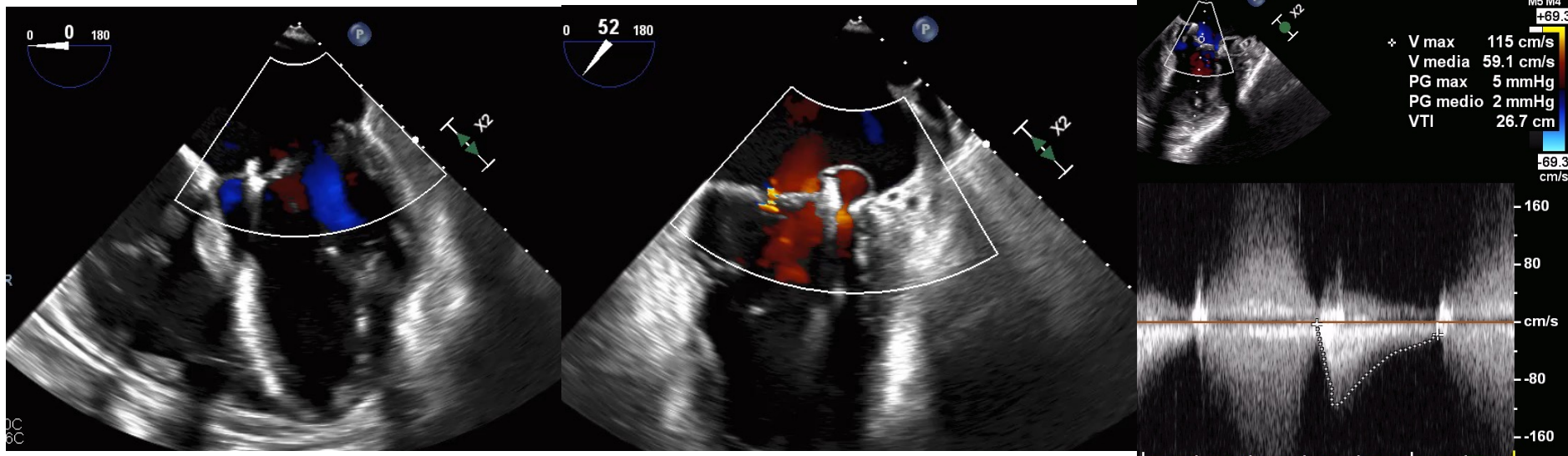
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2nd PASCAL Ace implant: crossing by elongation, closure



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Final result



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Conclusions

- Uneventful clinical course with mild MR
- Patient was asymptomatic at 30-day follow-up

→ PASCAL Precision system with COMMISSURAL PASCAL Ace implants was successful in treating this complex multi scallop, bi-leaflet bi-commissural prolapse

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The PASCAL Precision System for Atrial Functional Mitral Regurgitation

Rodrigo Estevez-Loureiro MD PhD FESC
University Hospital Alvaro Cunqueiro



Speaker's name : Rodrigo Estevez-Loureiro

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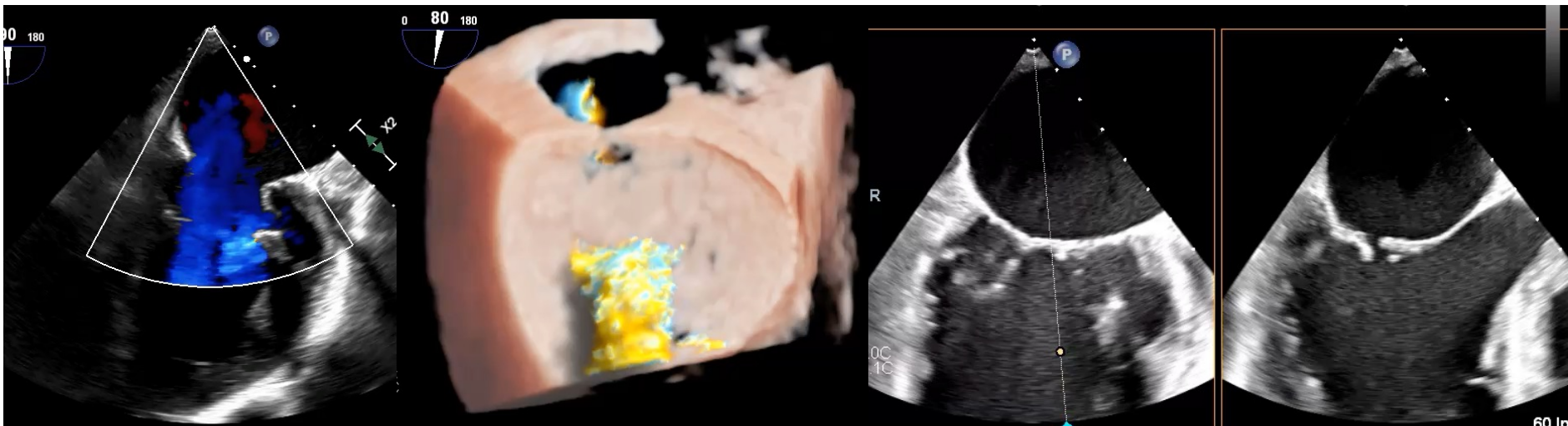
Case presentation

- 77-year-old male
- CVRF: former smoker, dyslipidaemia
- Ischemic heart disease: NSTEMI 2017. PCI to RCA. Moderate disease LCX and LAD.
- Atrial flutter 2018 (2 ablations). Paroxysmal AF
- Nov 21: admission due to APE. Echo: LVD (35-40%) + severe MR
- Moderate COPD.
- Prostatic neoplasm (surgery +RDT)
- Currently: NYHA II. No further admissions. On optimal GDMT

CVRF: Cardiovascular risk factor; NSTEMI: Non-ST-segment Elevation Myocardial Infarction; PCI: Percutaneous Coronary Intervention; RCA: right coronary artery; LCX: Left Circumflex Artery; LAD: Left Anterior Descending; AF: atrial fibrillation; APE: Acute Pulmonary Edema; LVD: Left Ventricular Dysfunction; MR: mitral regurgitation; COPD: Chronic Obstructive Pulmonary Disease; RDT: Regular Dialysis Treatment; NYHA: New York Heart Association; GDMT: Guideline Directed Medical Therapy

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Baseline echo



Central severe MR
Annular dilatation/loss coaptation reserve
Mechanism atrial FMR

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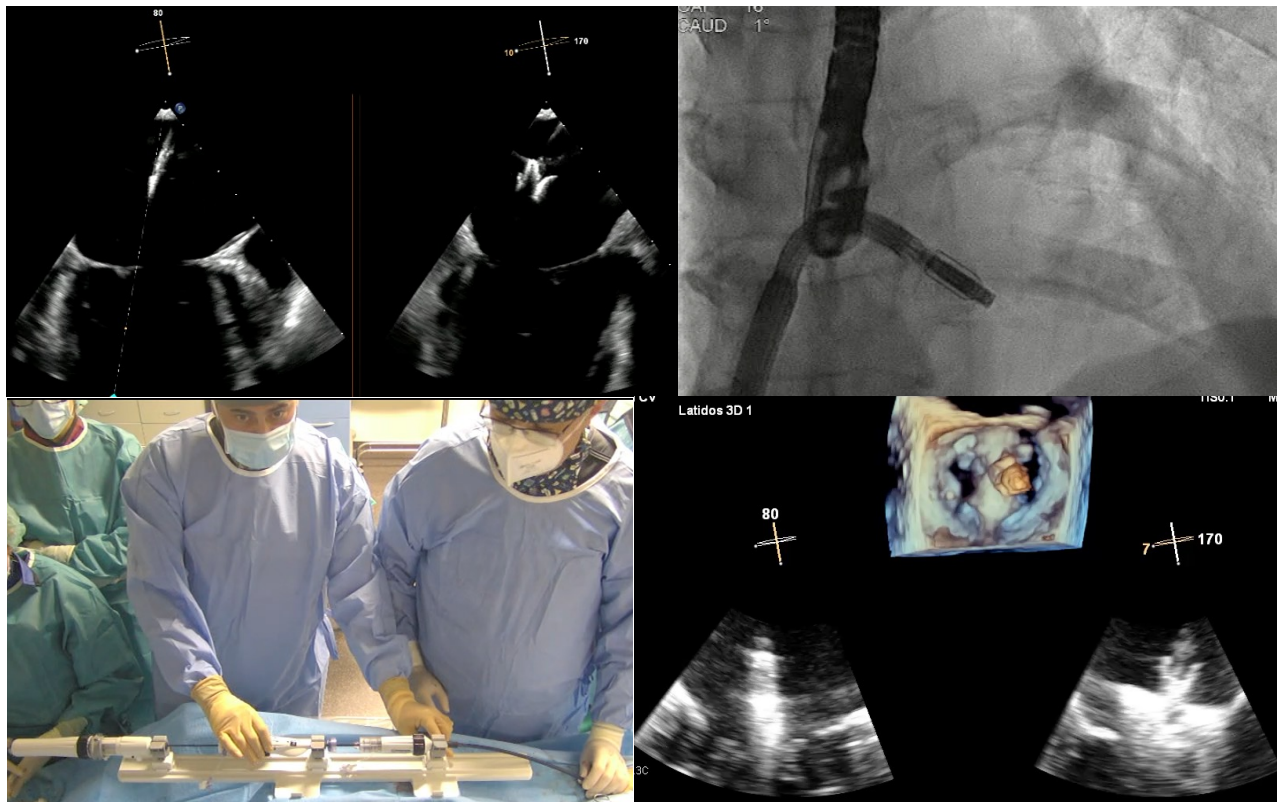
Treatment strategy

- Heart team: MR TEER
- PASCAL Precision system with PASCAL Ace implant:
 - Long leaflets
 - Insert maximum tissue
 - Aim for 1 device strategy

MR: mitral regurgitation; TEER: transcatheter edge-to-edge repair

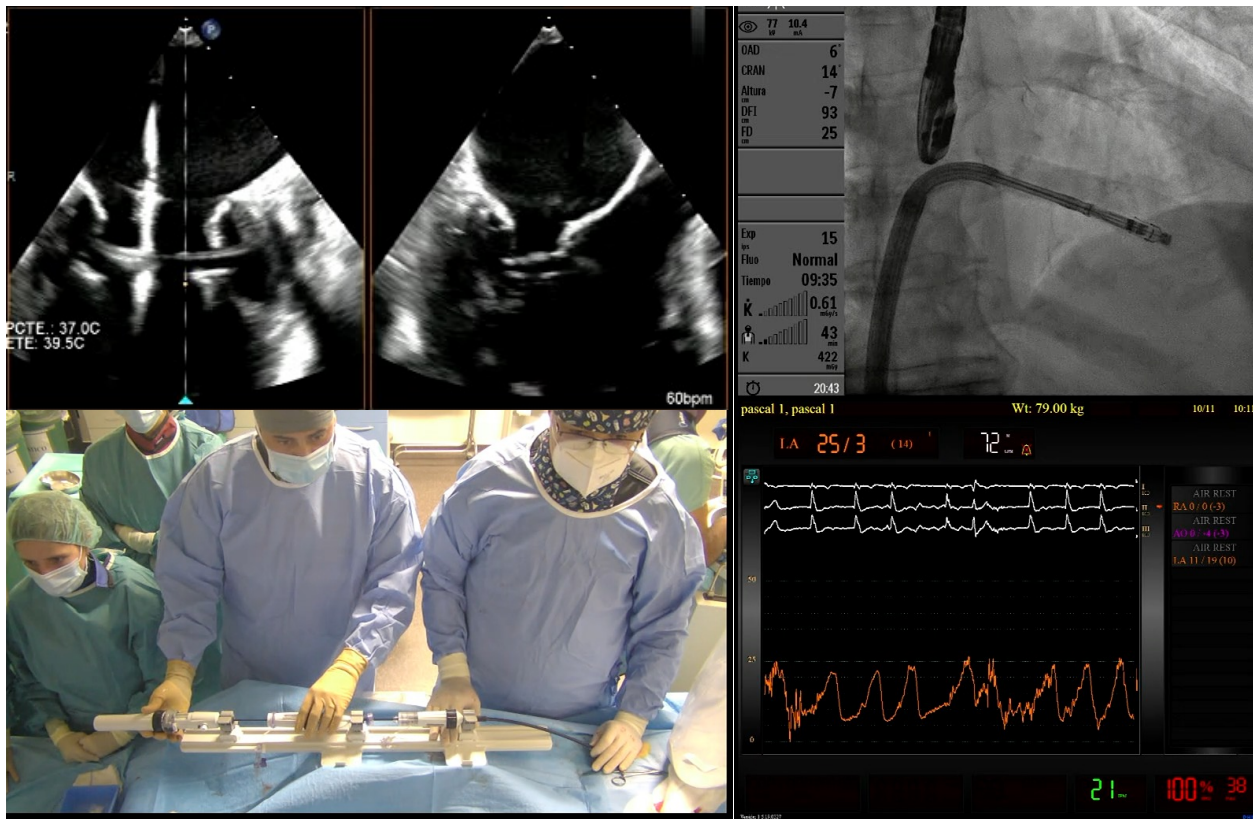
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Steering and positioning



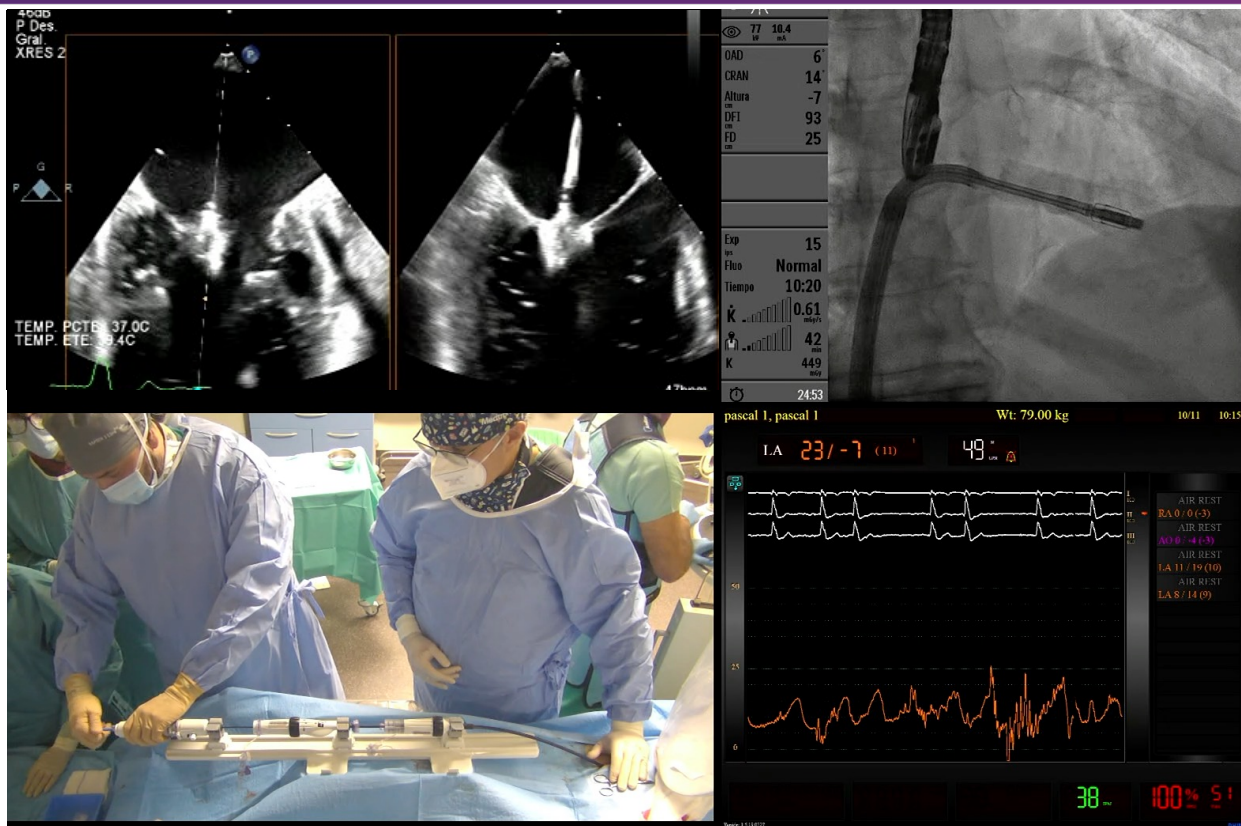
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Entering LV and clasp



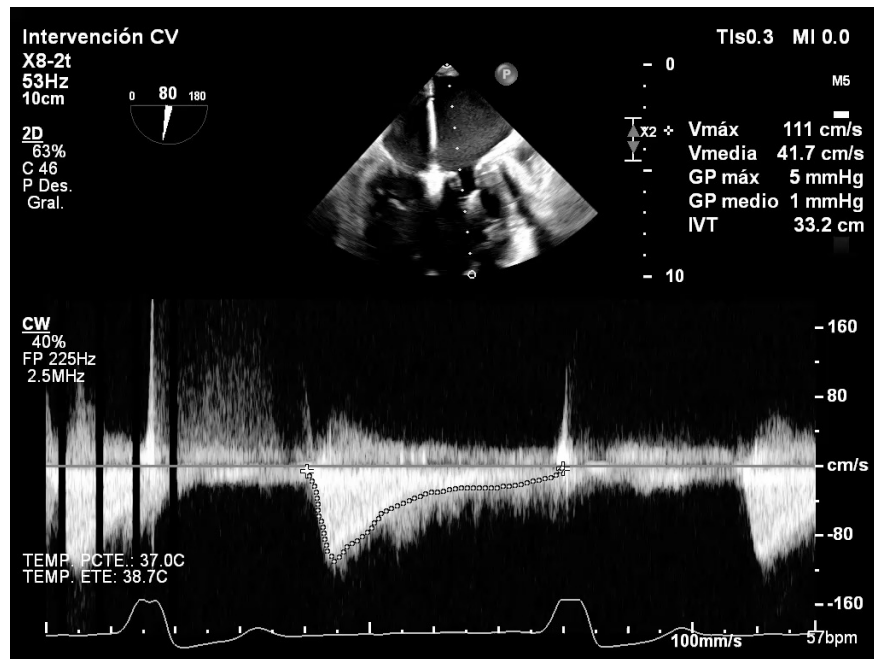
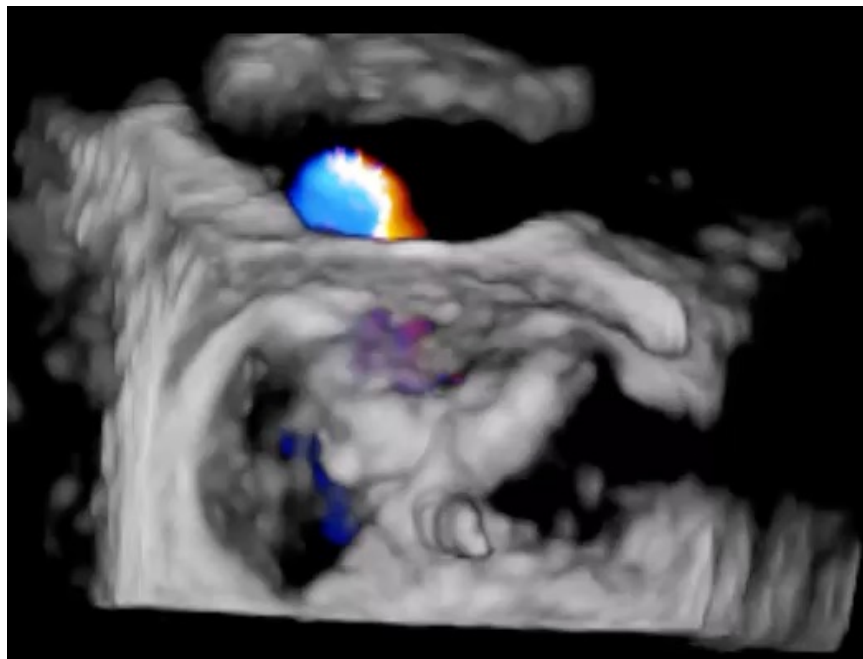
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Implant release and Final Result



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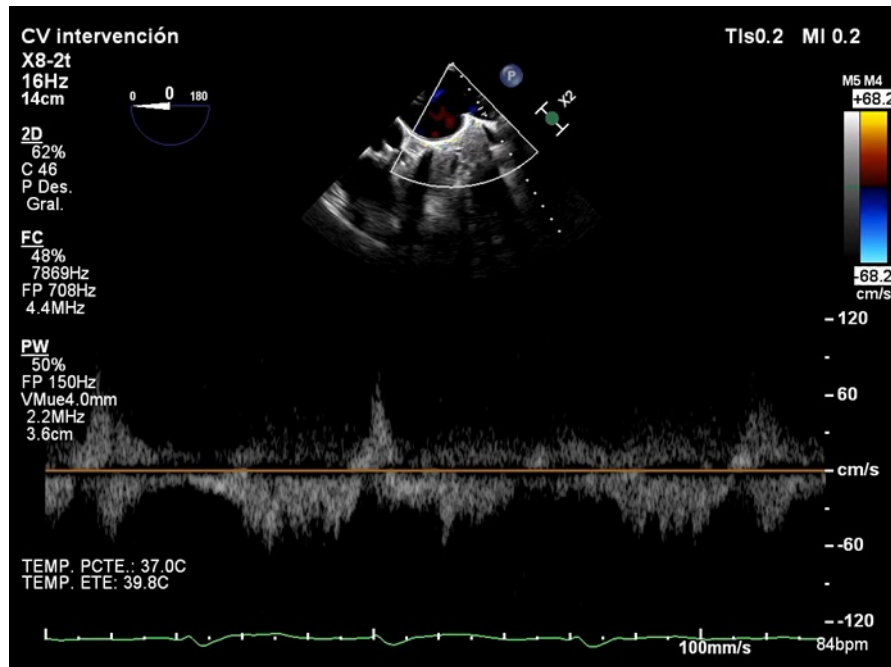
Final Result



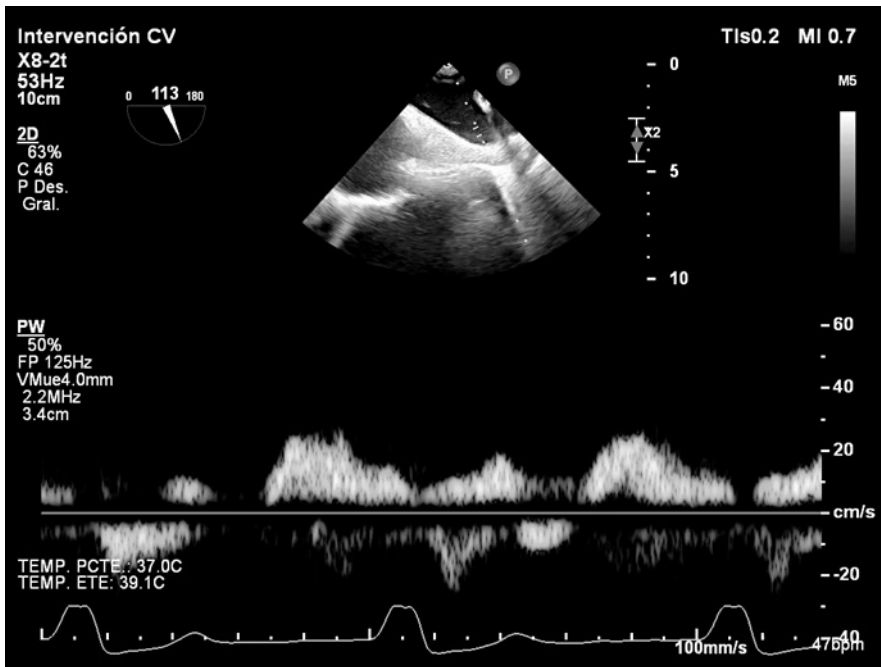
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Final Result

PV Flow pre



PV Flow post

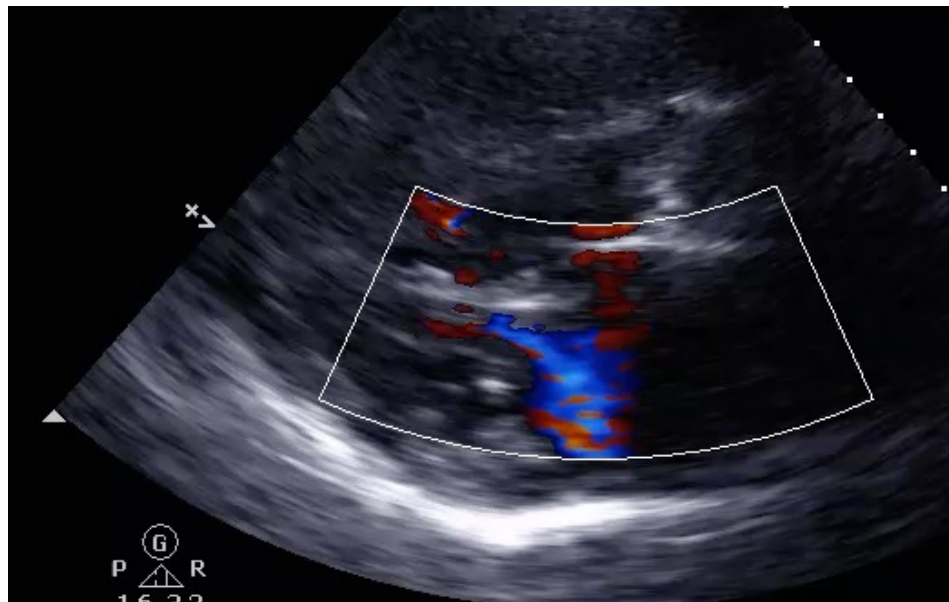


PV: pulmonary venous

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Discharge echo & conclusions

- Uneventful clinical course with trace MR
- Patient was asymptomatic at 1 month follow-up



MR: mitral regurgitation; FMR: functional MR

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