

MitraClip in Mitral Regurgitation

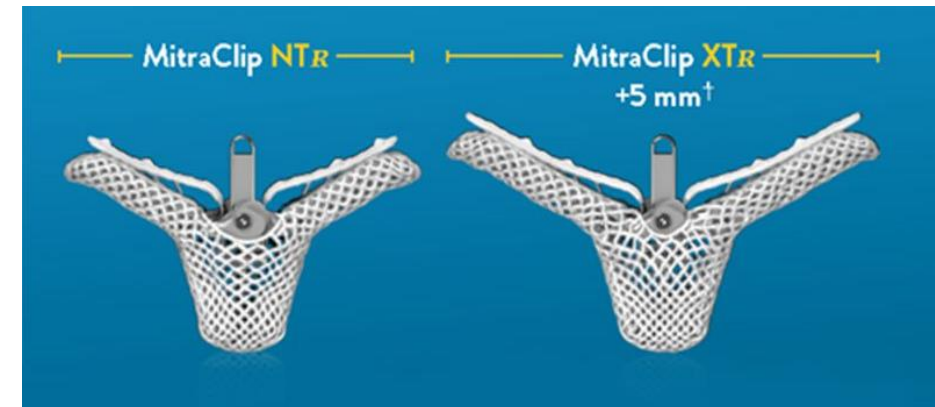
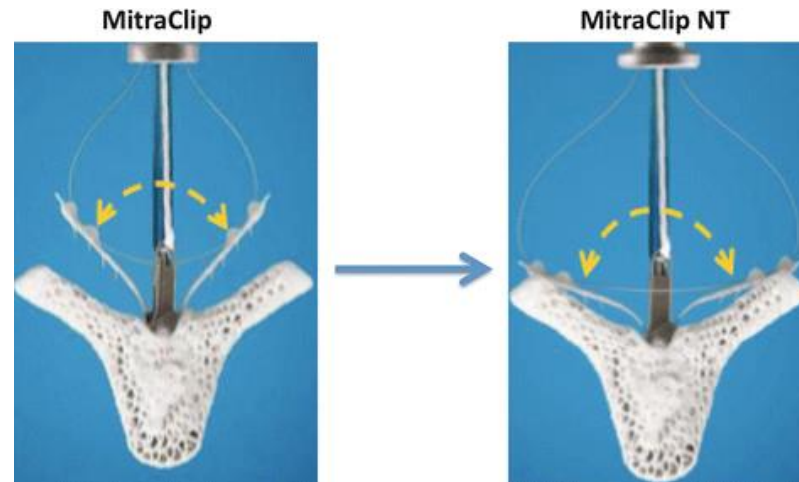
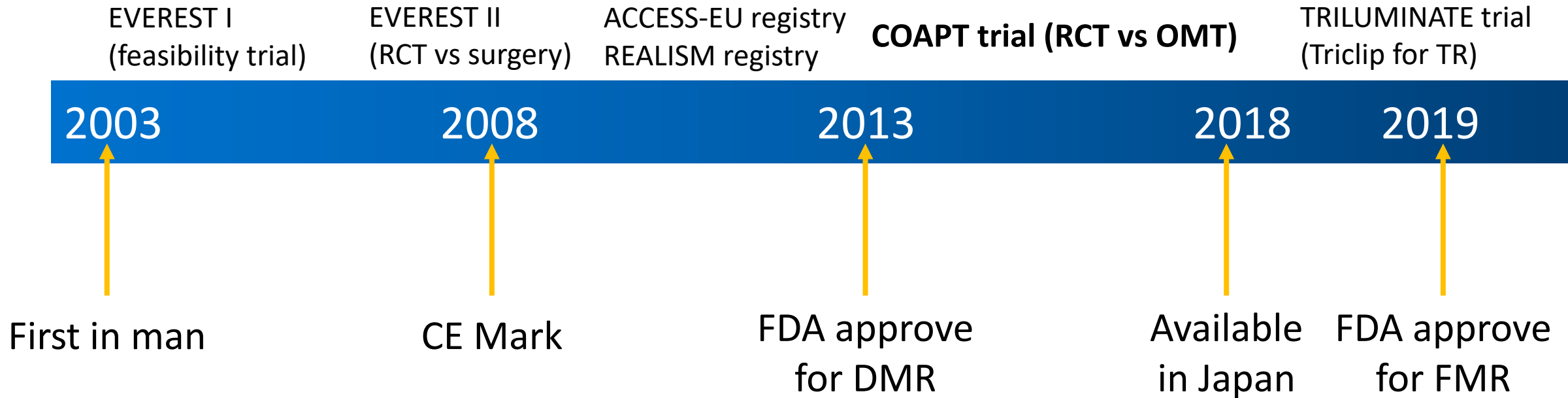
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MitraClip History

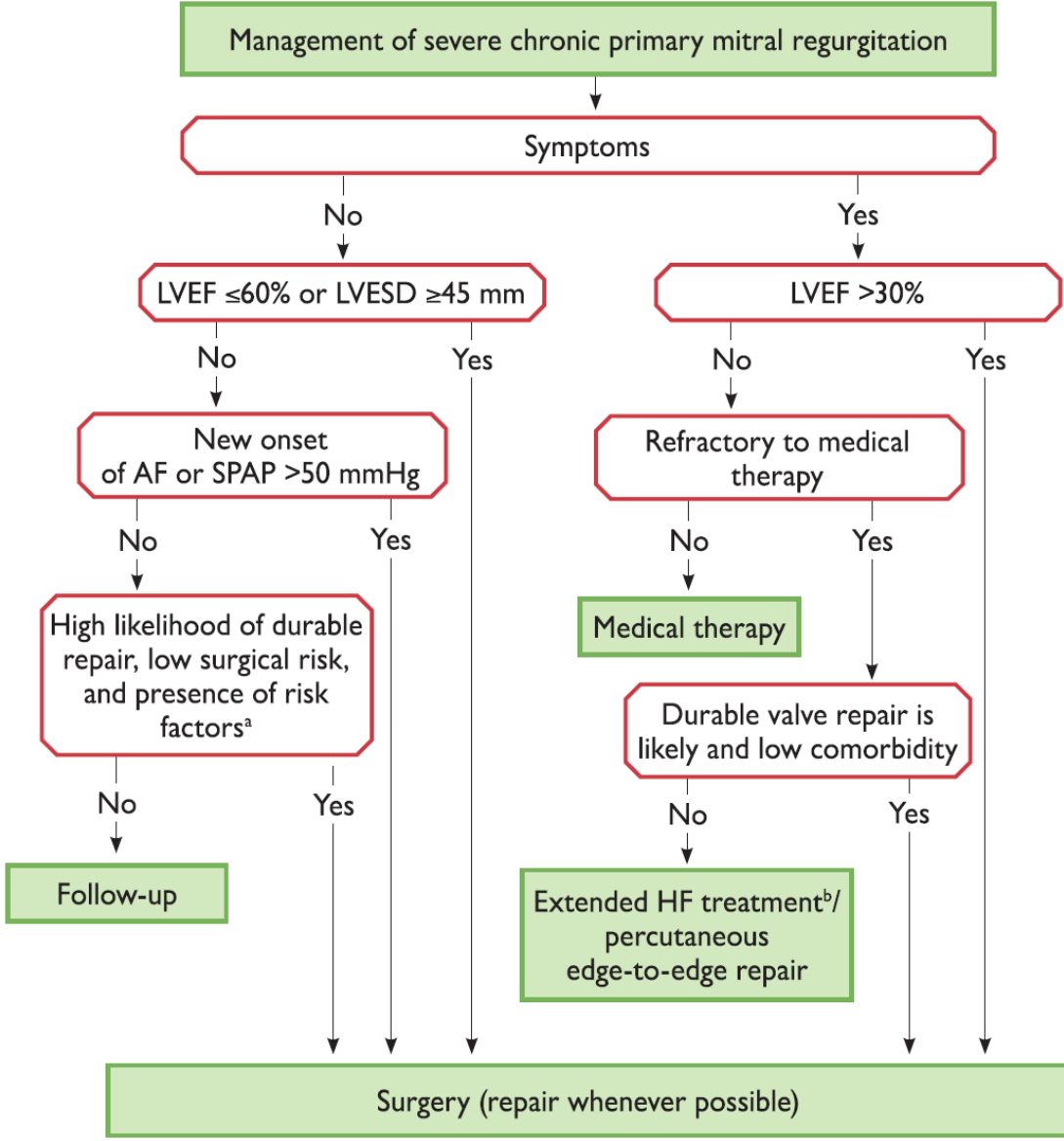


ESC Guideline 2017

- 6. Mitral regurgitation 2758
- 6.1 Primary mitral regurgitation..... 2758
- 6.1.1 Evaluation 2758
- 6.1.2 Indications for intervention 2760
- 6.1.3 Medical therapy..... 2761
- 6.1.4 Serial testing 2761

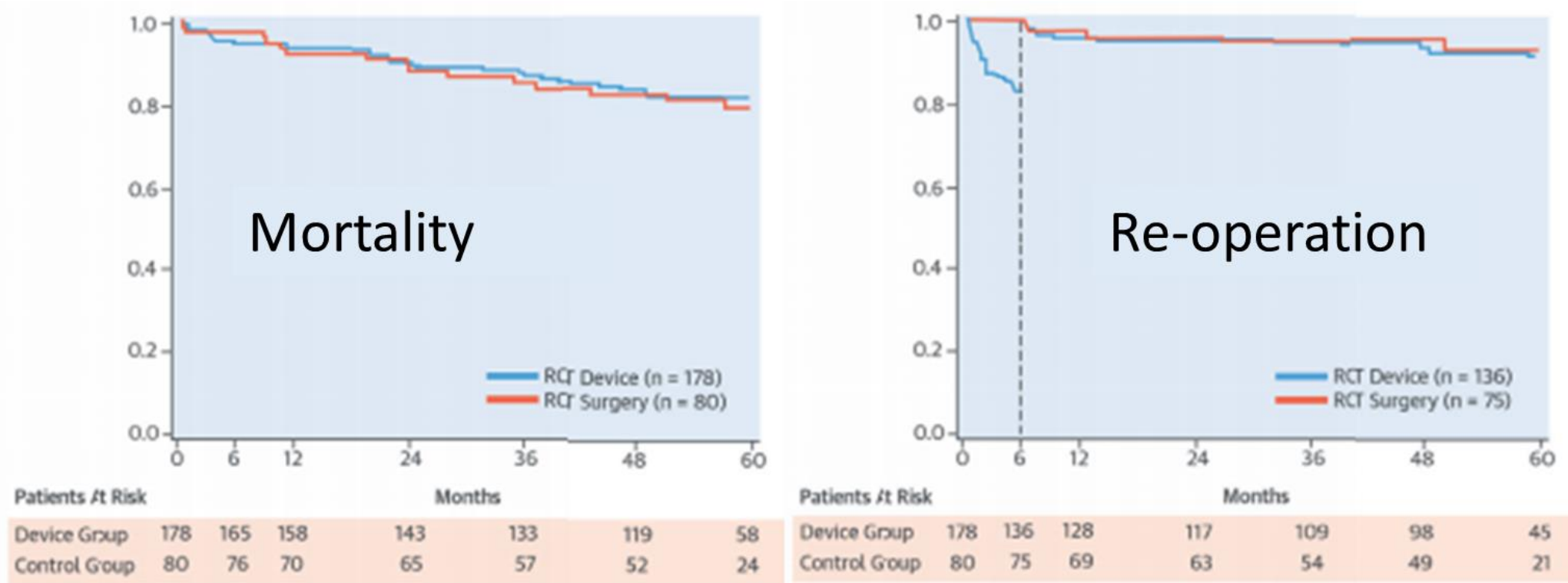
For primary (degenerative) MR...

- Surgery = Class I or IIa
- MitraClip = Class IIb in patients with multiple comorbidity



MitraClip for Degenerative MR

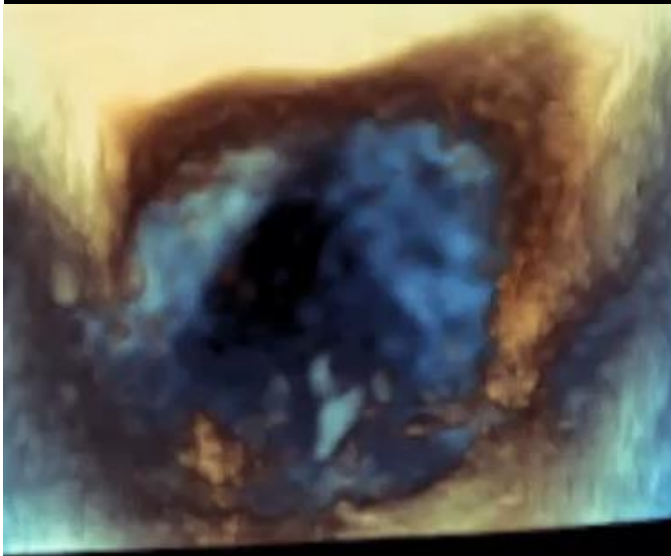
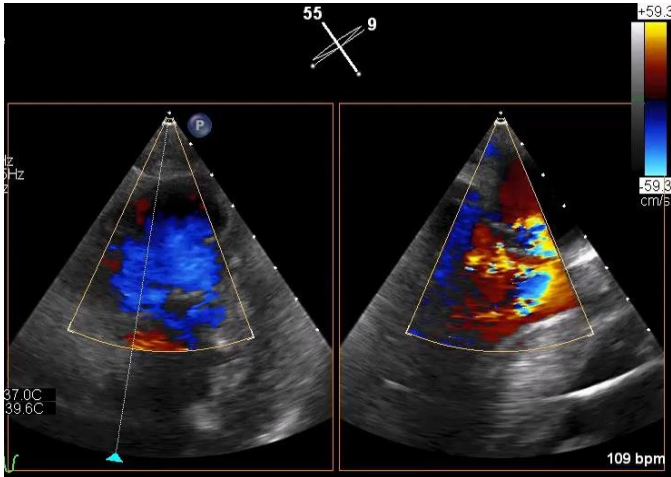
5 Years Follow-up of EVERST II Trial (⇒80% of pts were degenerative MR)



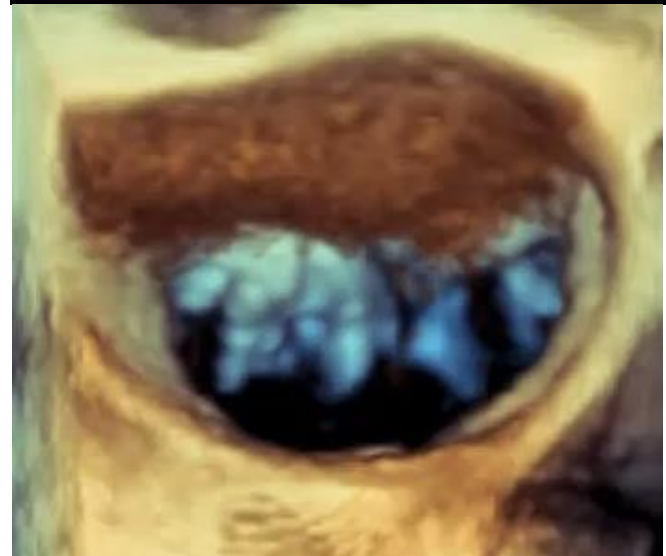
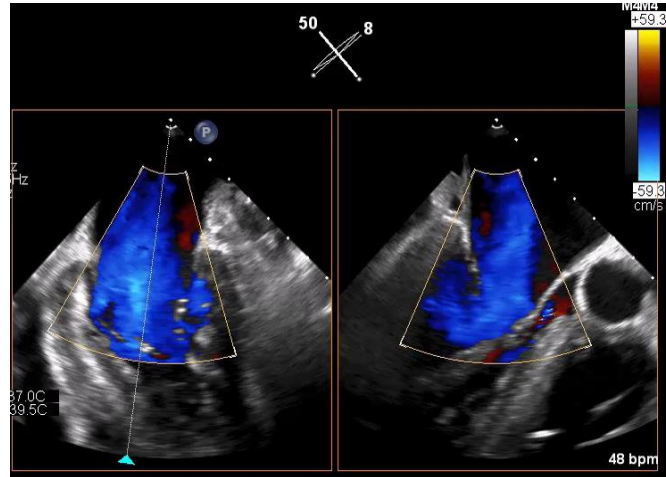
- Equivalent mortality for 5 years
- Equivalent MR recurrence beyond 6 months

Anatomical Consideration in DMR

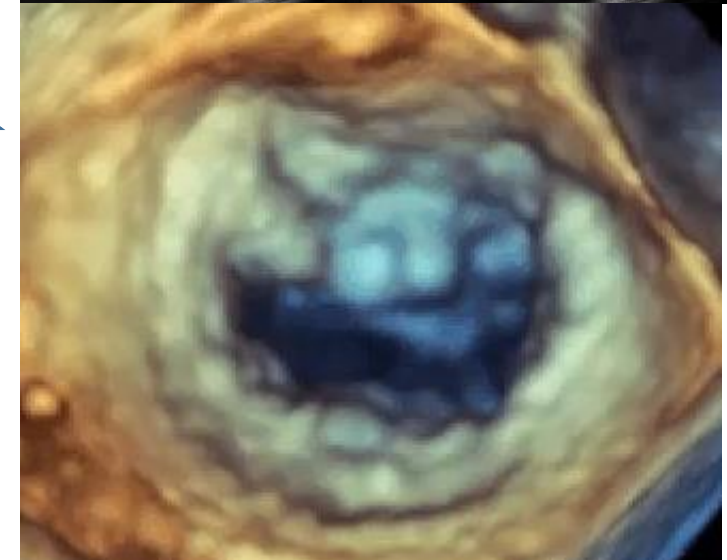
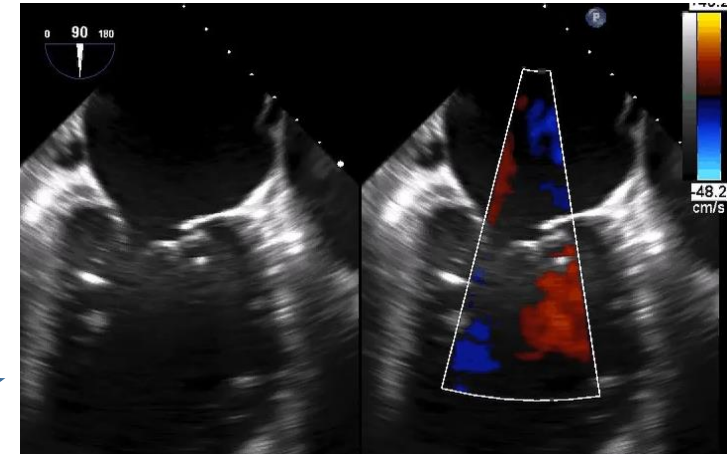
P2 Prolapse



P3 Prolapse

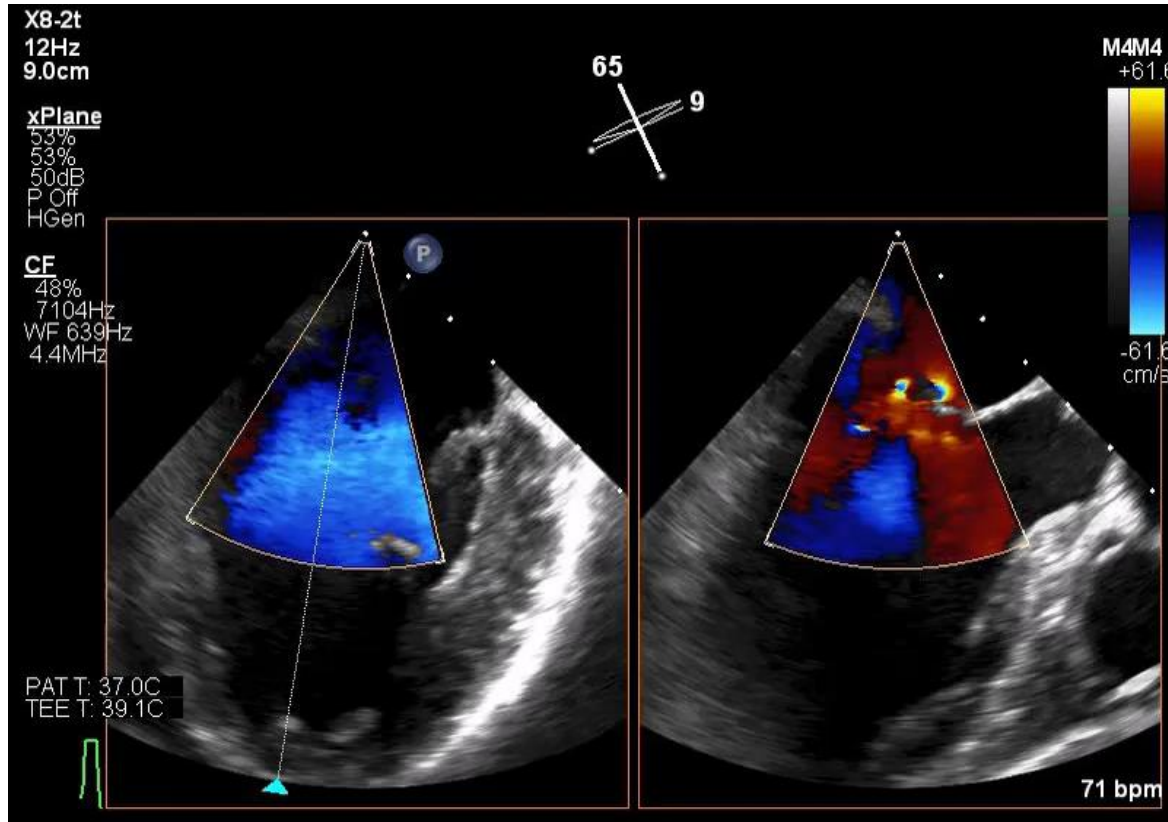


ACOM Prolapse

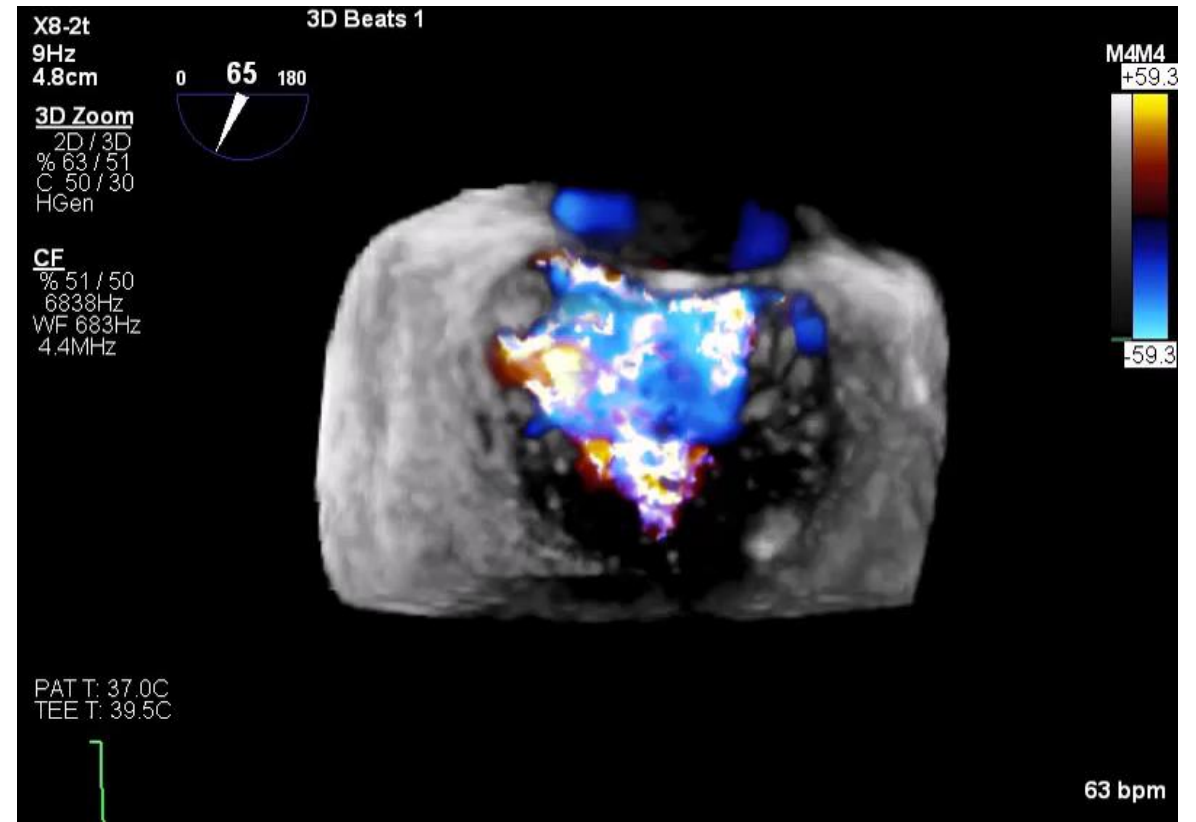


P2 prolapse (90 years, male, STS 9.5, NYHA 2)

“xplane view”

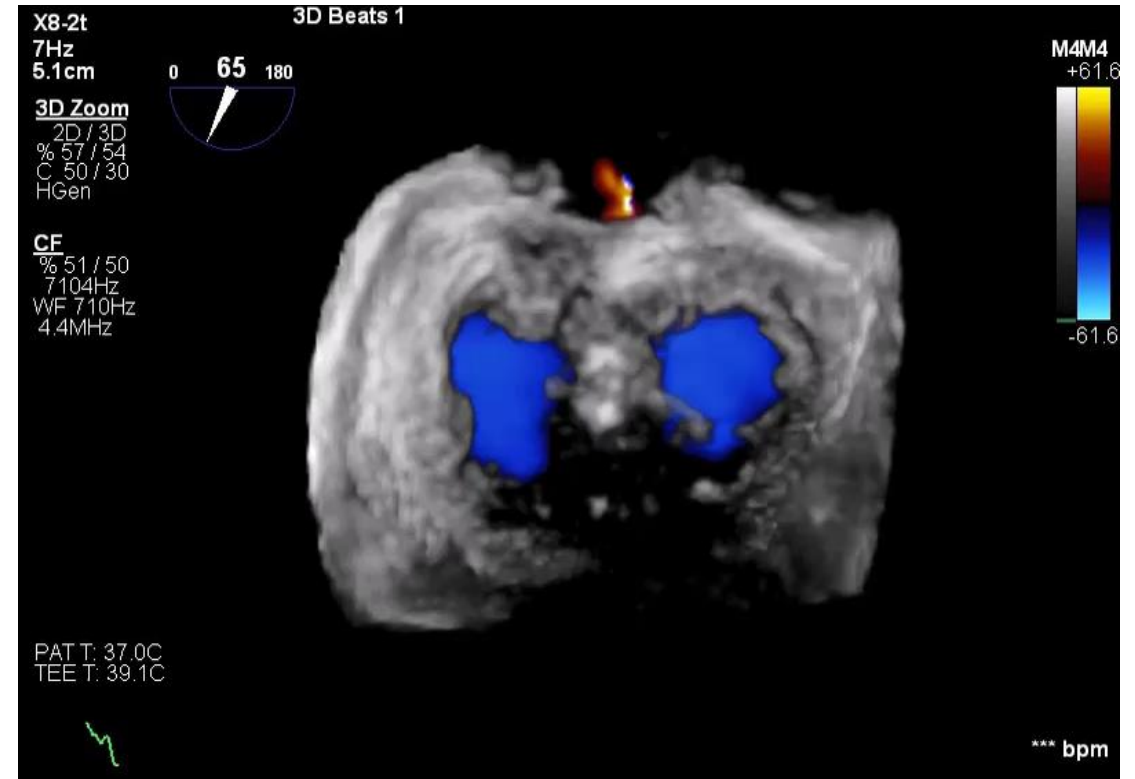
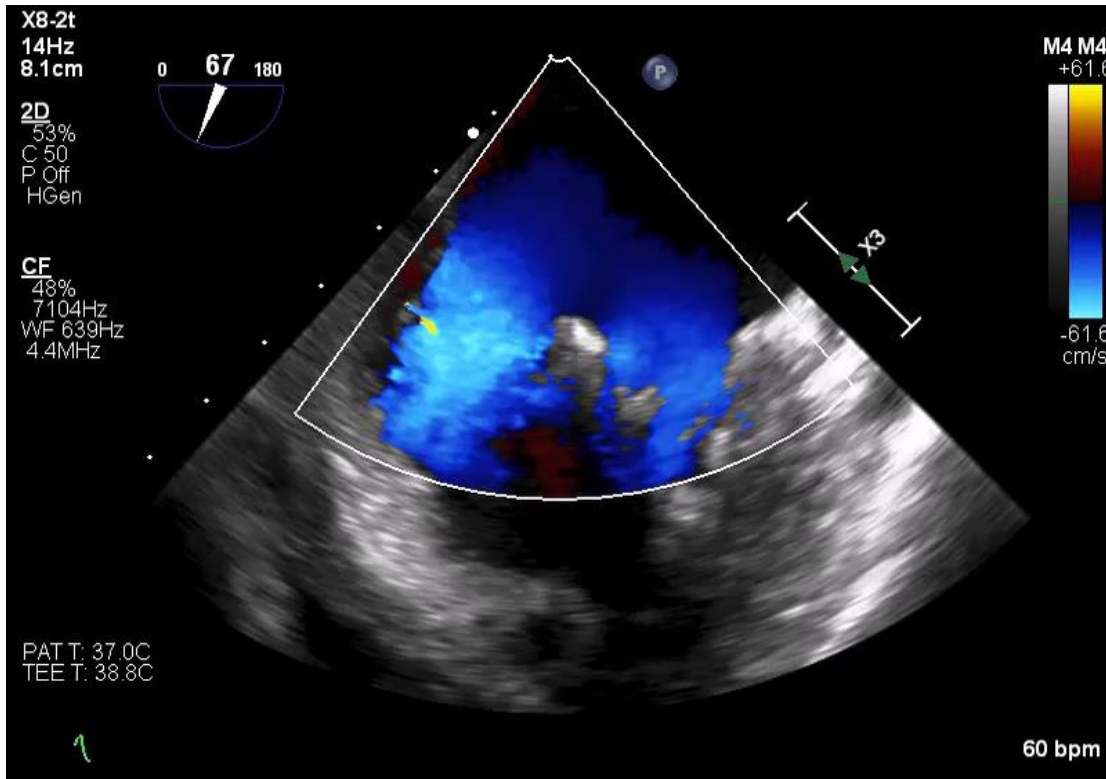


“3D TEE”



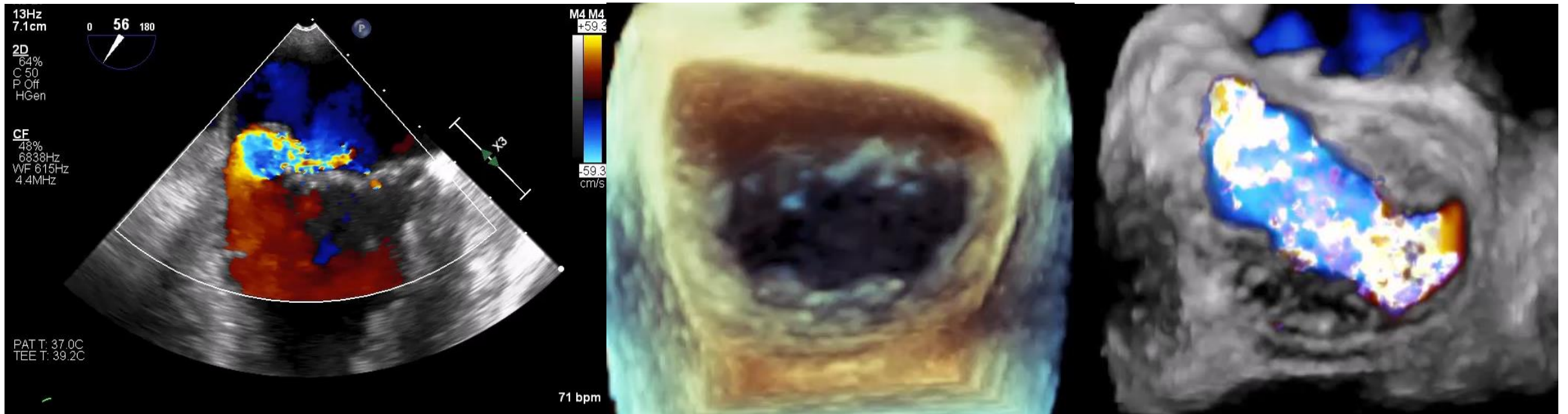
P2 prolapse with chordae rupture

MitraClip Procedure



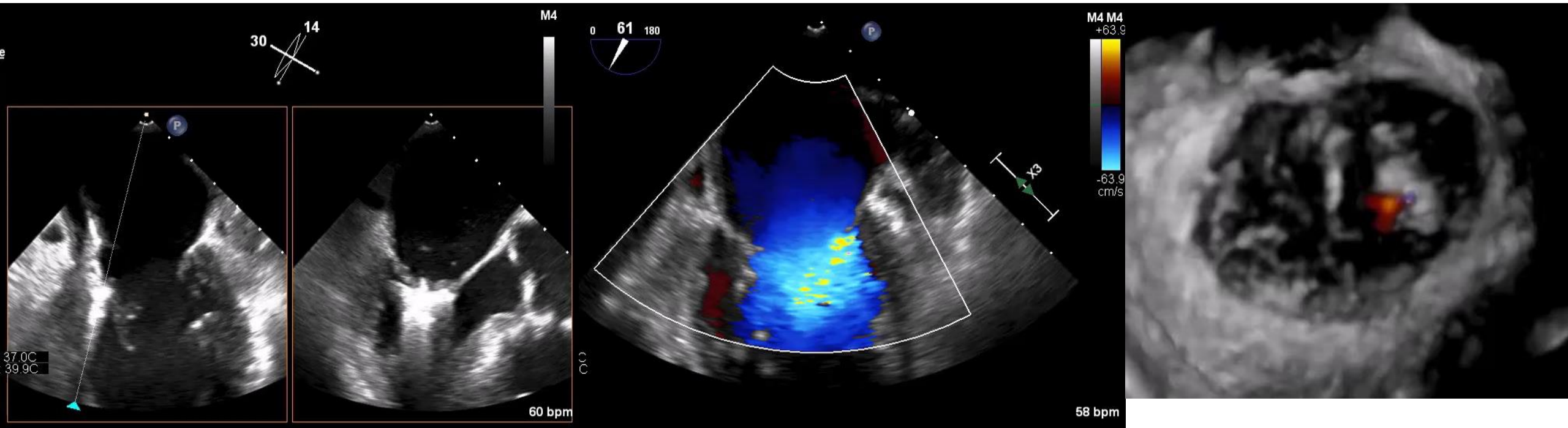
- ✓ Trivial MR after 1 clip deployment
- ✓ Procedure time 67 min, Anesthesia time : 123 min
- ✓ Discharge 3 days after procedure
- ✓ No symptom

P3 Prolapse (89 years, female, STS 7.7, NYHA 3)



- ✓ P3 prolapse with chordae rupture
- ✓ Non-central MR

MitraClip Procedure



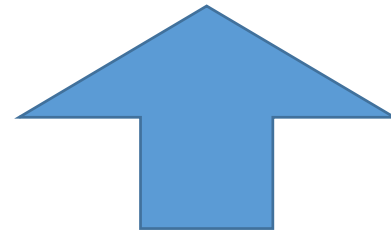
- ✓ Mild MR after 1 clip deployment
- ✓ Procedure time 68 min, Anesthesia time : 130 min
- ✓ Discharge 4 days after the procedure
- ✓ No symptom

Degenerative MR: MitraClip Candidate

Inoperable or high surgical risk patients with suitable anatomy

Surgical risk
Frailty

Anatomical
difficulty



**Heart-team discussion
(almost similar to TAVI)**

- Central or non-central
- Height of Septum
- Flail width
- Flail gap

ESC Guideline 2017: Secondary MR

| | |
|--|------|
| 6. Mitral regurgitation | 2758 |
| 6.2 Secondary mitral regurgitation | 2761 |
| 6.2.1 Evaluation | 2761 |
| 6.2.2 Indications for intervention | 2761 |
| 6.2.3 Medical therapy | 2762 |

For isolated secondary (functional) MR...

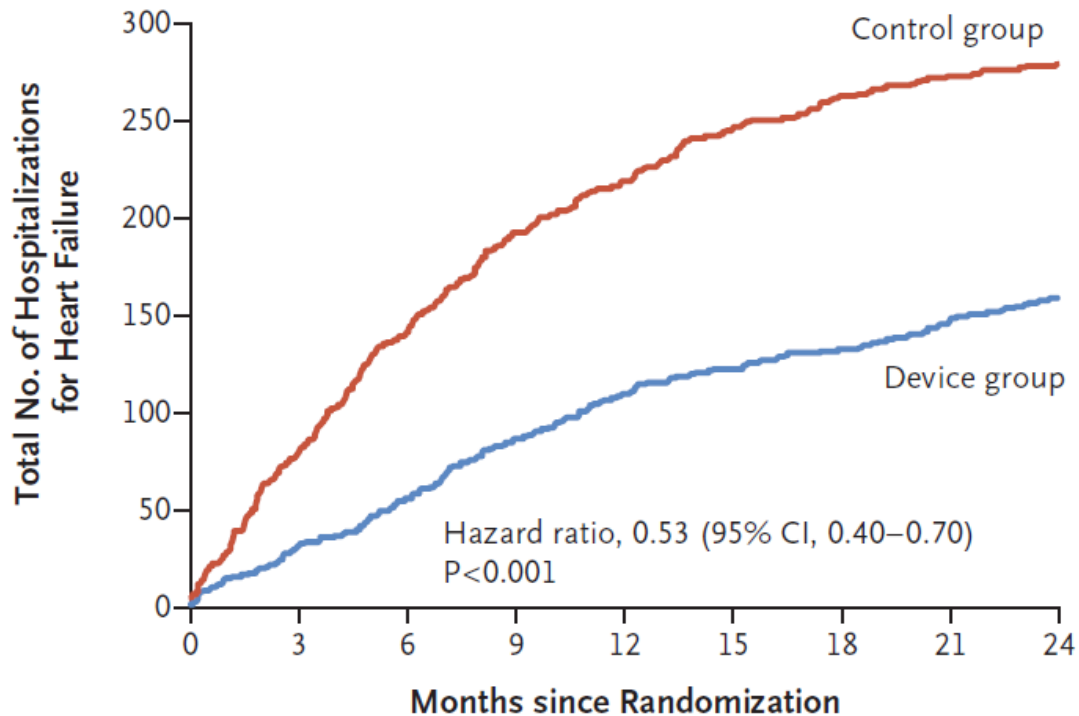
- Surgery = Class IIb in LVEF >30%
- MitraClip = Class IIb regardless of LVEF

Scarce evidence of FMR reduction !

| | | |
|--|-----|---|
| When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and have a low surgical risk. | IIb | C |
| When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility. | IIb | C |
| In patients with severe secondary mitral regurgitation and LVEF <30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have no option for revascularization, the Heart Team may consider a percutaneous edge-to-edge procedure or valve surgery after careful evaluation for a ventricular assist device or heart transplant according to individual patient characteristics. | IIb | C |

COAPT Trial

A Hospitalization for Heart Failure



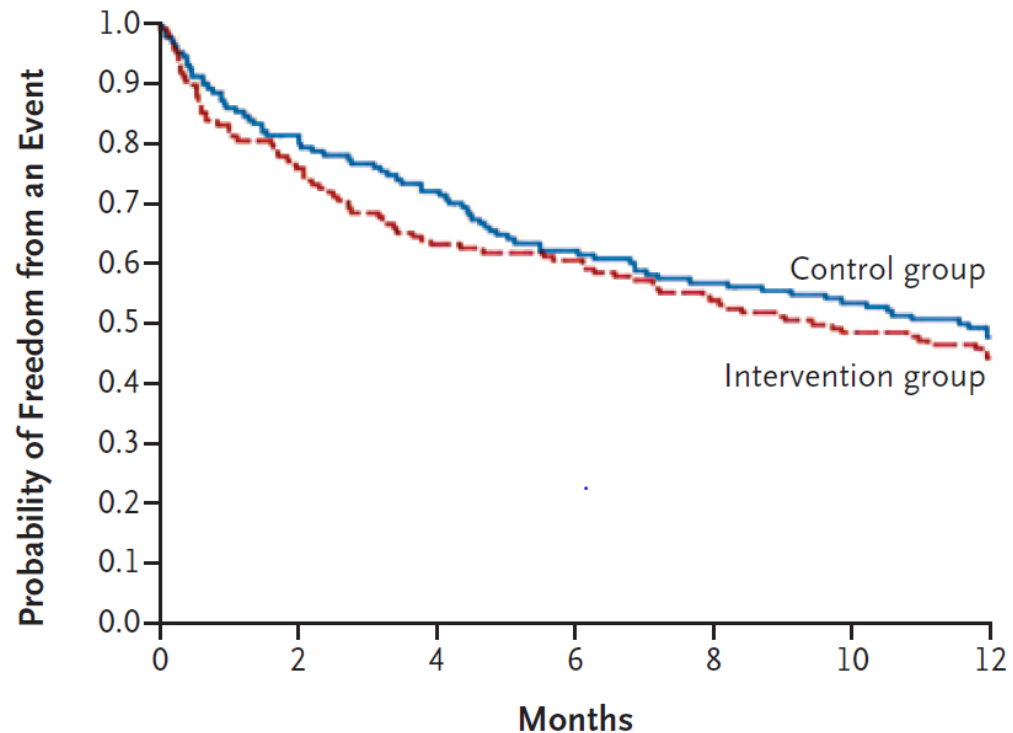
No. at Risk

| | 0 | 3 | 6 | 9 | 12 | 15 | 18 | 21 | 24 |
|---------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Control group | 312 | 294 | 271 | 245 | 219 | 176 | 145 | 121 | 88 |
| Device group | 302 | 286 | 269 | 253 | 236 | 191 | 178 | 161 | 124 |

MitraClip reduce not only HF hospitalization but also all-cause and cardiac mortality.

Stone GW, et al. N Engl J Med. 2018;379(24):2307-2318.

Mitra-FR Trial



No. at Risk

| | 0 | 2 | 4 | 6 | 8 | 10 | 12 |
|--------------------|-----|-----|-----|----|----|----|----|
| Control group | 152 | 123 | 109 | 94 | 86 | 80 | 73 |
| Intervention group | 151 | 114 | 95 | 91 | 81 | 73 | 67 |

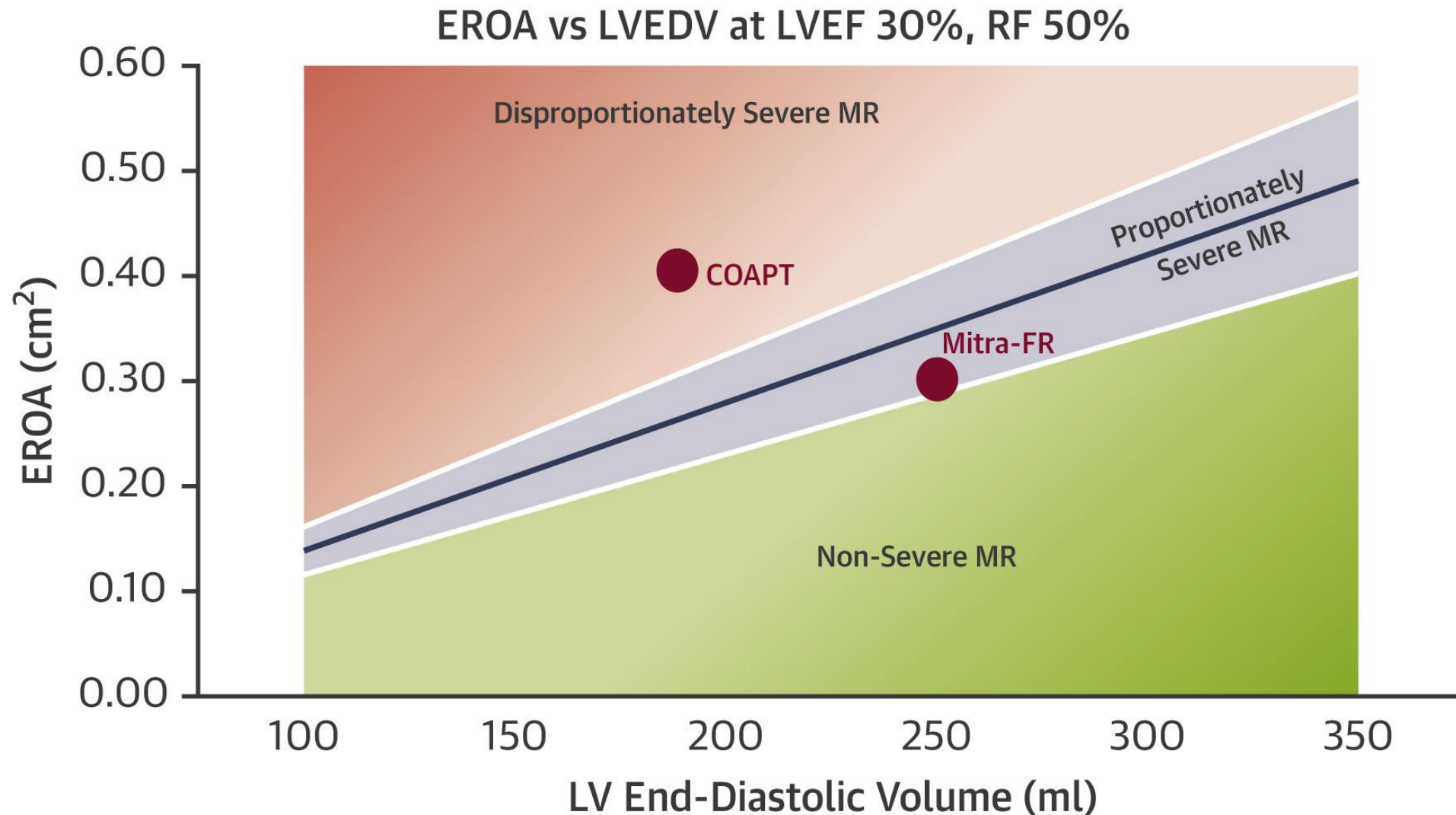
Non significant difference in mortality and HF hospitalization between OMT and MitraClip

Obadia JF, et al. N Engl J Med. 2018;379(24):2297-2306.

Potential Reasons of Difference

| | Mitra-FR (n=304) | COAPT (n=614) |
|------------------------------------|--|---|
| Severe MR Definition | ESC guidelines EROA>0.2cm² or RV>30ml Mean EROA = 0.31 ± 10 cm² | US guidelines EROA>0.3cm² or RV>45ml Mean EROA = 0.41 ± 15 cm² |
| LVEDV (ml) | 135 ± 35 ml/m² | 101 ± 34 ml/m² |
| Guideline directed medical therapy | Real-world practice ⇒ Change of regimen from baseline to Follow-up | CEC confirmed maximum DMT before enroll ⇒ No change from baseline to follow-up |
| Acute results : No clip/≥3+ MR | 9% / 9% | 5% / 5% |
| Procedural complications | 14.6% | 8.5% |
| 12 month f/u MR ≥3+ | 17% | 5% |

Which FMR Should be Treated ?



Ischemic MR: 74 years, male

Clinical Presentation

- Dyspnea (NYHA class 4), Orthopnea

Medial History

- CKD (eGFR = 25)
- AMI (PCI for LAD/LCX with IABP), no apparent ischemia
- 2 times HF hospitalization within 6 months
- STS score = 10.4%

Medication

Enalapril 2.5mg, Carvedilol 10mg, DAPT, Spironolactone 25mg,
Tolvaptan 22.5mg, Azosemide 60mg

Key TTE data

LVEDV=126 ml/m², EF31%, MVA=5.56cm², EROA=0.56cm²

MitraClip Procedure

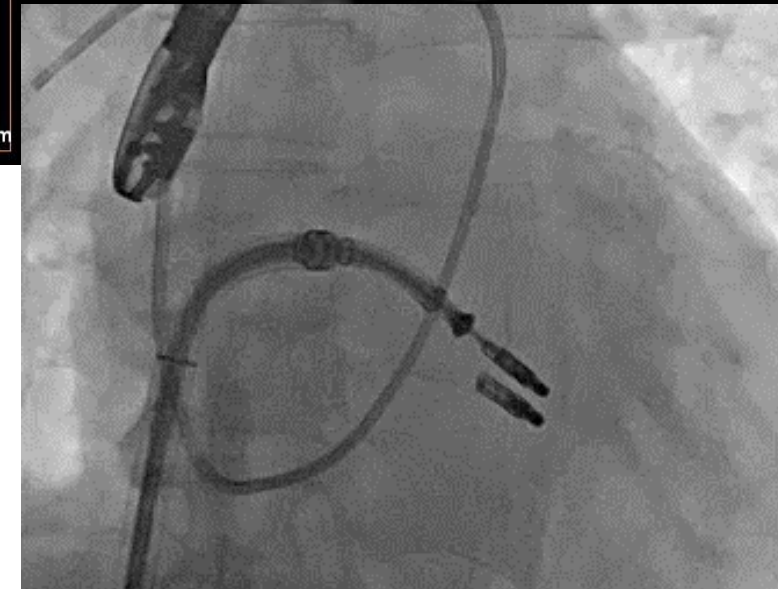
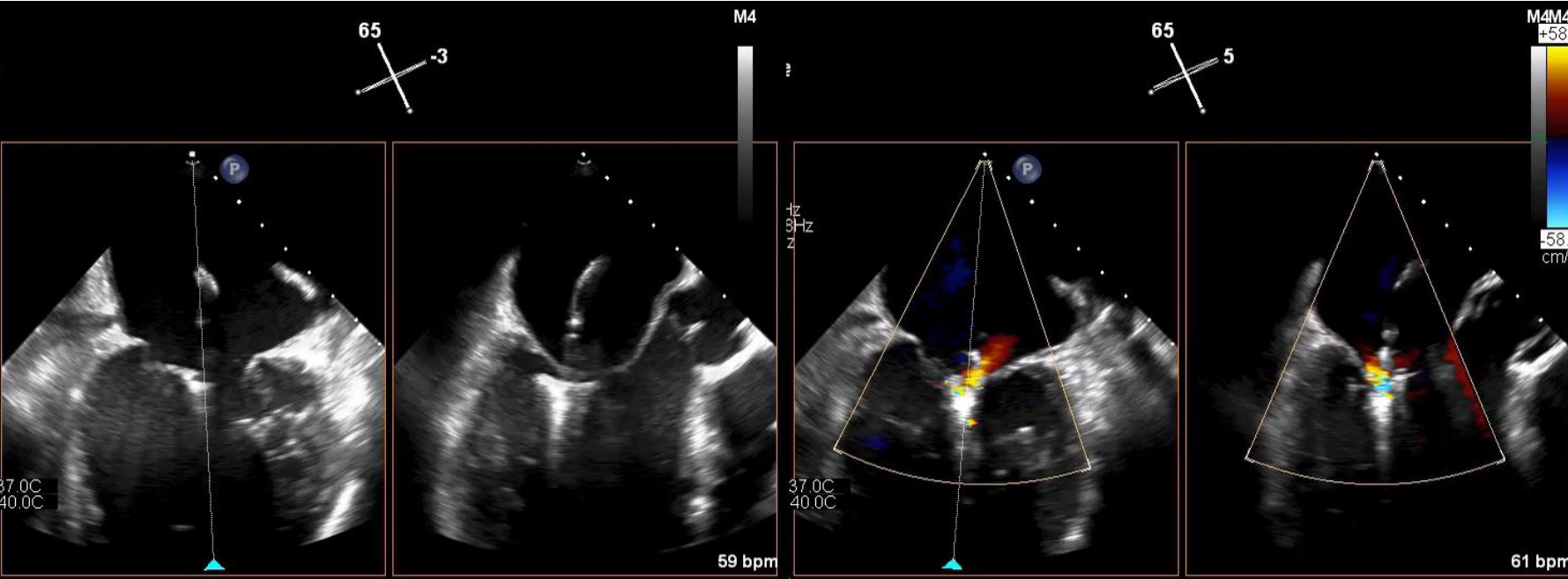
“1st Clip Implantation”



Deploy the 1st clip medial A2/P2.
MR improved from severe to moderate.
No MS and prepare the 2nd clip.

MitraClip Procedure

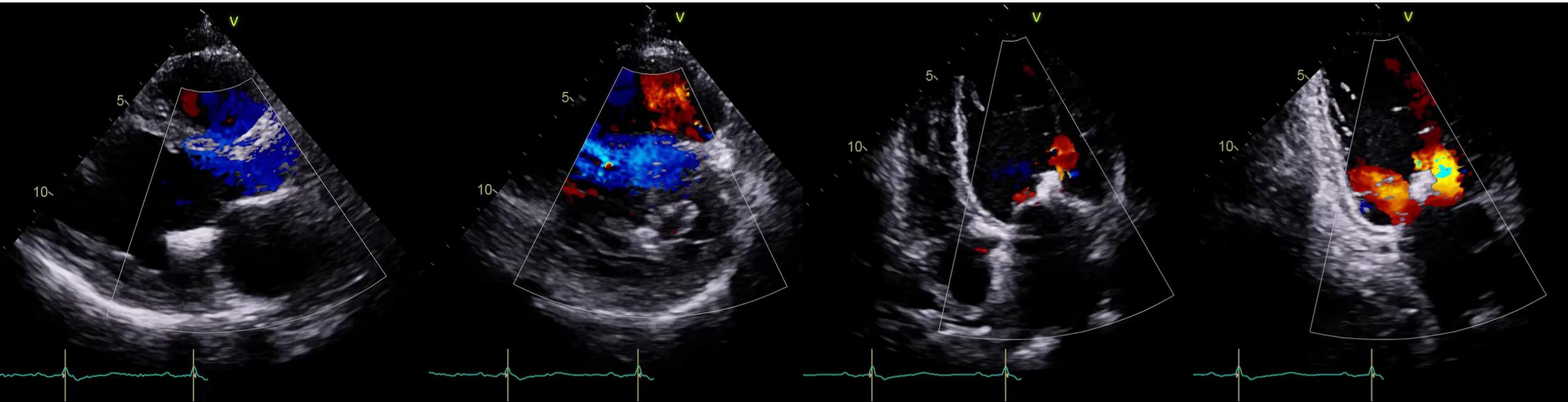
“2nd Clip Implantation”



Deploy the 2nd clip just lateral to the 1st clip
MR decreased to trivial
Mean PG = 3mmHg

Follow-up TTE

Dyspnea and orthopnea disappeared after the procedure
Discharged 1 week after the procedure.
NYHA class I at 1 year follow-up.



Trivial- MR, MS (-), LVEF = 24%

FMR : MitraClip Candidate

“True” severe MR patients assessed by quantitative PISA method
LV/RV disease is not so advanced

Anatomical
difficulty

- PML length and tethering
- Height of septum
- Annular dilatation

Surgical risk
Frailty



Other treatment
option

- Degree of OMT
- CRT indication
- Heart transplantation
- LVAD

Heart-team discussion

(Interventionalist ▪ HF specialist ▪ EP specialist ▪ Cardiac surgeon ▪ Imaging specialist, etc)

Summary

- MitraClip therapy is effective for the high risk degenerative MR, but technical difficulty depends of the anatomy.
- COAPT and Mitra-FR trials provided us the optimal patient selection of the MitraClip for functional MR.
- If patient selection and procedural quality are optimal, patient will have a good clinical course.