

Use of MitraClip Beyond Everest Criteria

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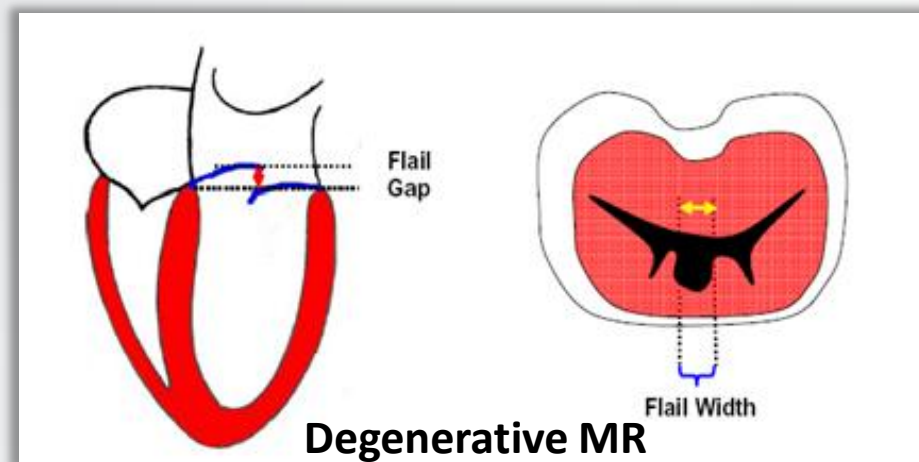
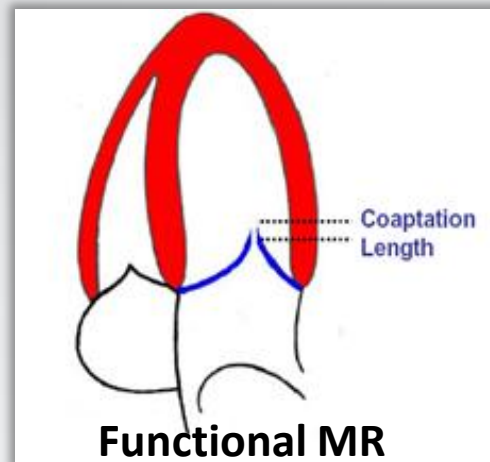
Introduction

- The efficacy and safety of the MitraClip therapy was initially evaluated in the EVEREST II Trial.
- The MitraClip therapy is considered as standard of care for patients with significant mitral regurgitation who are at high risk for surgery.

EVEREST II Trial

Key Eligibility and Exclusion Criteria

- **Non rheumatic MR** originating from a localized area of the valve
- Etiology: degenerative or functional
- Sufficient leaflet tissue for mechanical coaptation
- Valve anatomic exclusions
 - Flail gap >10mm
 - Flail width >15mm
 - Calcified leaflet
- $MVA \geq 4 \text{ cm}^2$



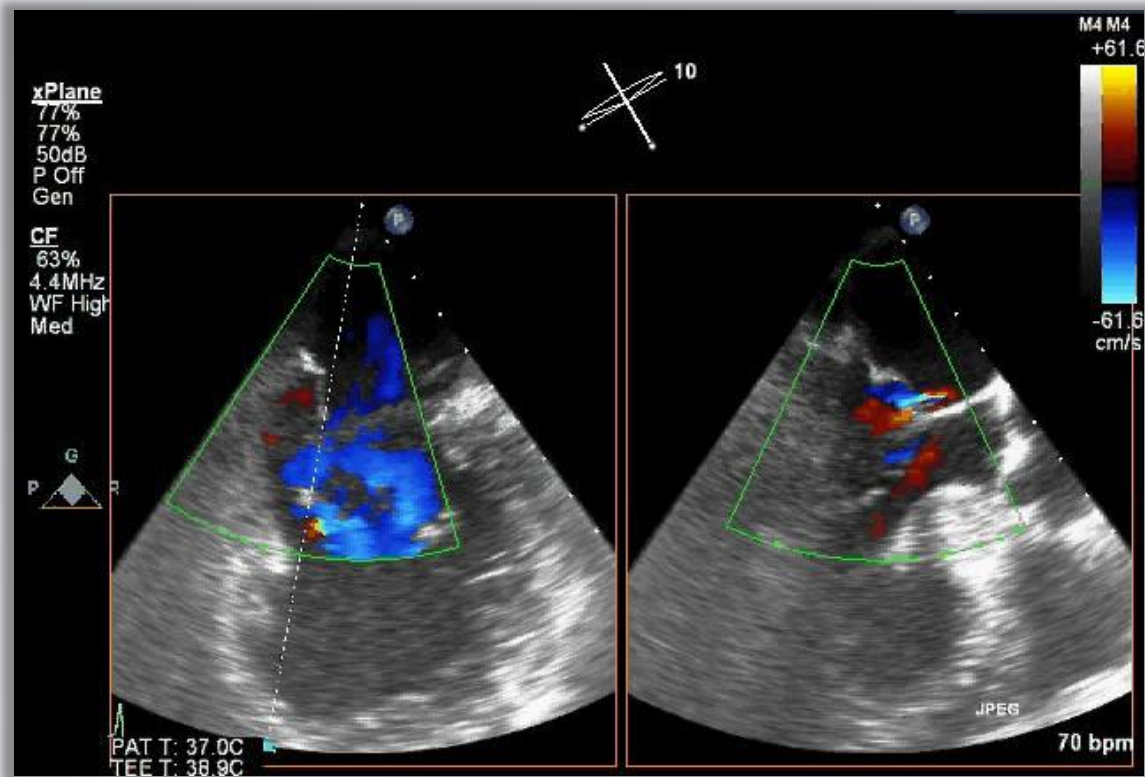
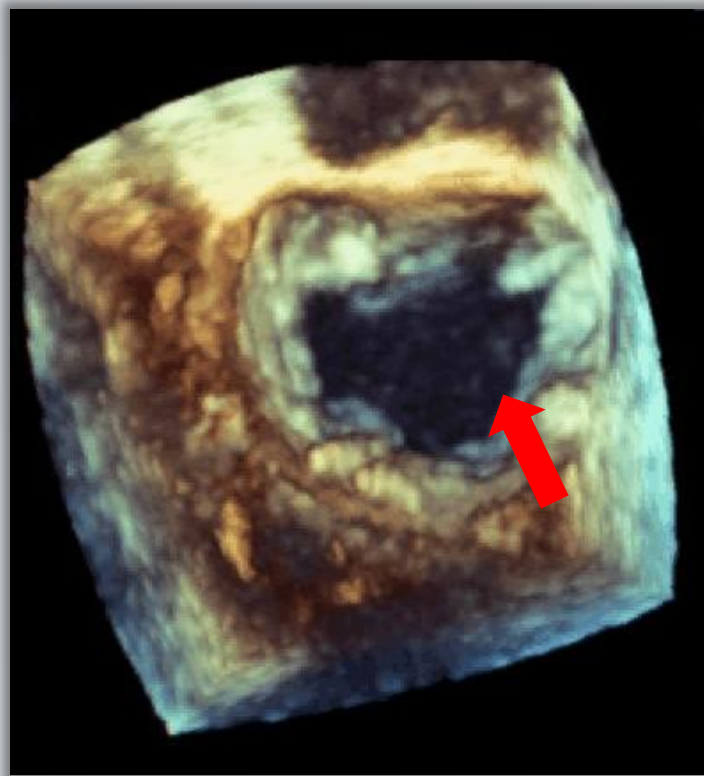
Expanded indications of the MitraClip: Beyond the EVEREST criteria

- A1P1 or A3P3 flail or prolapse
- Recurrent MR post MV surgery and the MitraClip therapy
- End stage heart failure with MR
 - Delay heart transplantation or VAD

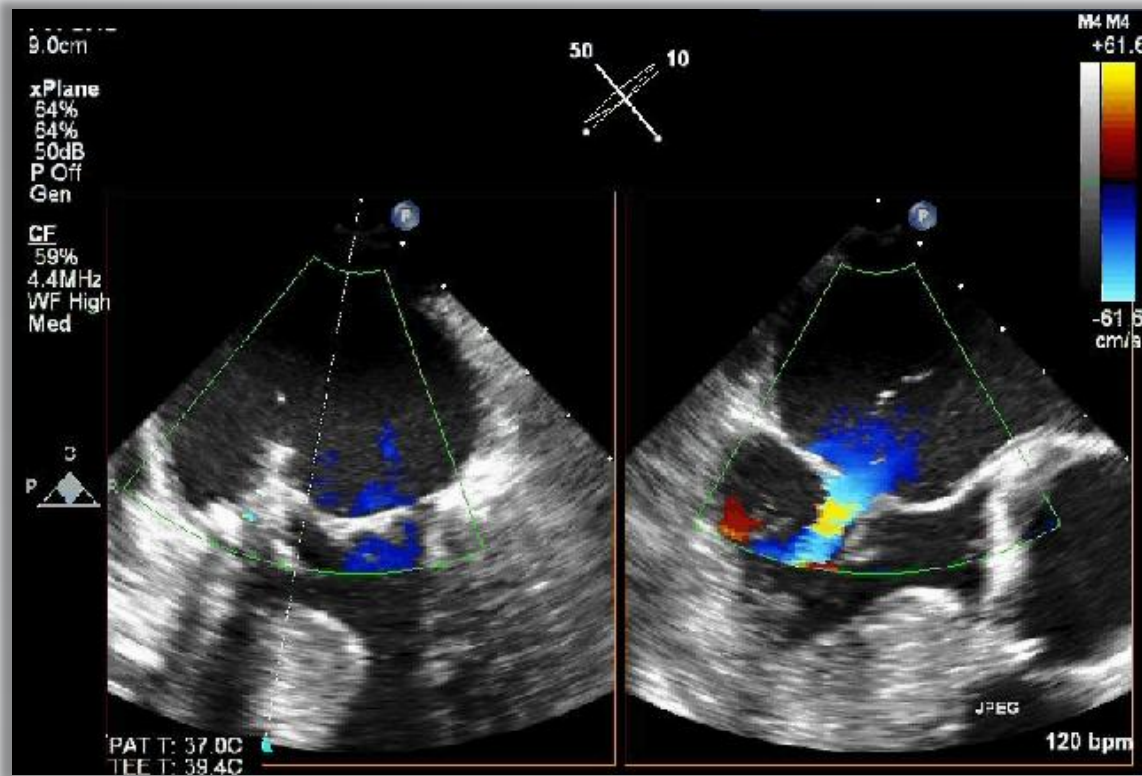
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90-year-old man with P2/P3 flail



90-year-old man with P2/P3 flail



Central vs. Non-central DMR

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Echocardiographic and Clinical Outcomes of Central Versus Noncentral Percutaneous Edge-to-Edge Repair of Degenerative Mitral Regurgitation

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Procedural outcomes

-Central vs. Non-central Degenerative MR-

Table 3 Periprocedural Adverse Events

	Overall (N = 79)	Central (n = 49)	Non-Central (n = 30)	p Value
Clip embolization	0 (0)	0 (0)	0 (0)	—
Partial clip detachment	2 (2.5)	1 (2)	1 (3.3)	1.000
Prolonged clip entanglement	0 (0)	0 (0)	0 (0)	1.000
Chordal rupture	1 (1.2)	1 (2)	0 (0)	1.000
Cardiac tamponade	1 (1.2)	1 (2)	0 (0)	1.000
Gastro-intestinal bleeding	2 (2.5)	1 (2)	1 (3.3)	1.000
Stroke	0 (0)	0 (0)	0 (0)	—
Transient AV block	1 (1.2)	1 (2)	0 (0)	1.000
Pneumonia	1 (1.2)	1 (2)	0 (0)	1.000
Mitral valve surgery	1 (1.2)	1 (2)	0 (0)	1.000
Death	1 (1.2)	0 (0)	1 (3.3)	1.000
All complications	10 (12.6)	7 (14.3)	3 (10)	0.734

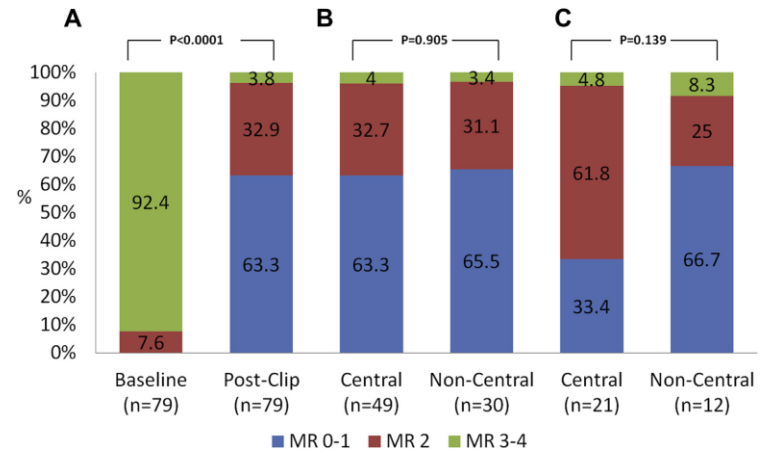


Figure 3 MR Grade at Baseline, 1 Month, and 6 Months Following MitraClip Intervention

Pre- and post-intervention mitral regurgitation (MR) in all patients (A). MR grade at 1-month post-procedure in both groups (B) and MR at 6 months (C). There was a higher proportion of patients with MR grade 0 to 1 in the noncentral group. However, there was no difference between groups with regard to the proportion of MR ≤ 2 (the p value in the figure is for the overall comparison across categories).

There was no significant differences in procedural success between central and non-central MR (96% vs. 97%), with similar procedural complication rate and MR grade at follow-up.

Anatomical Specimens of Mitral Valve

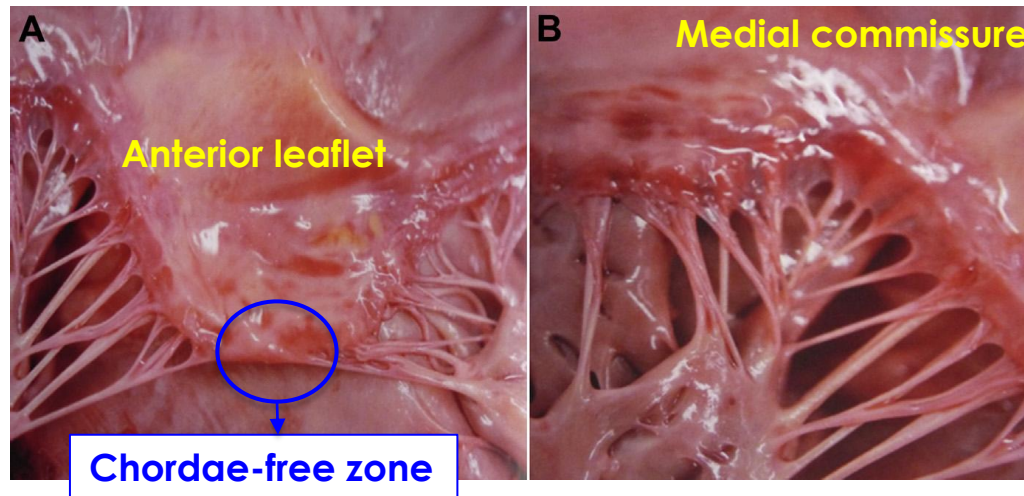


Figure 6 Anatomic Specimen of Mitral Valve Depicting Structure of Chordae Tendineae

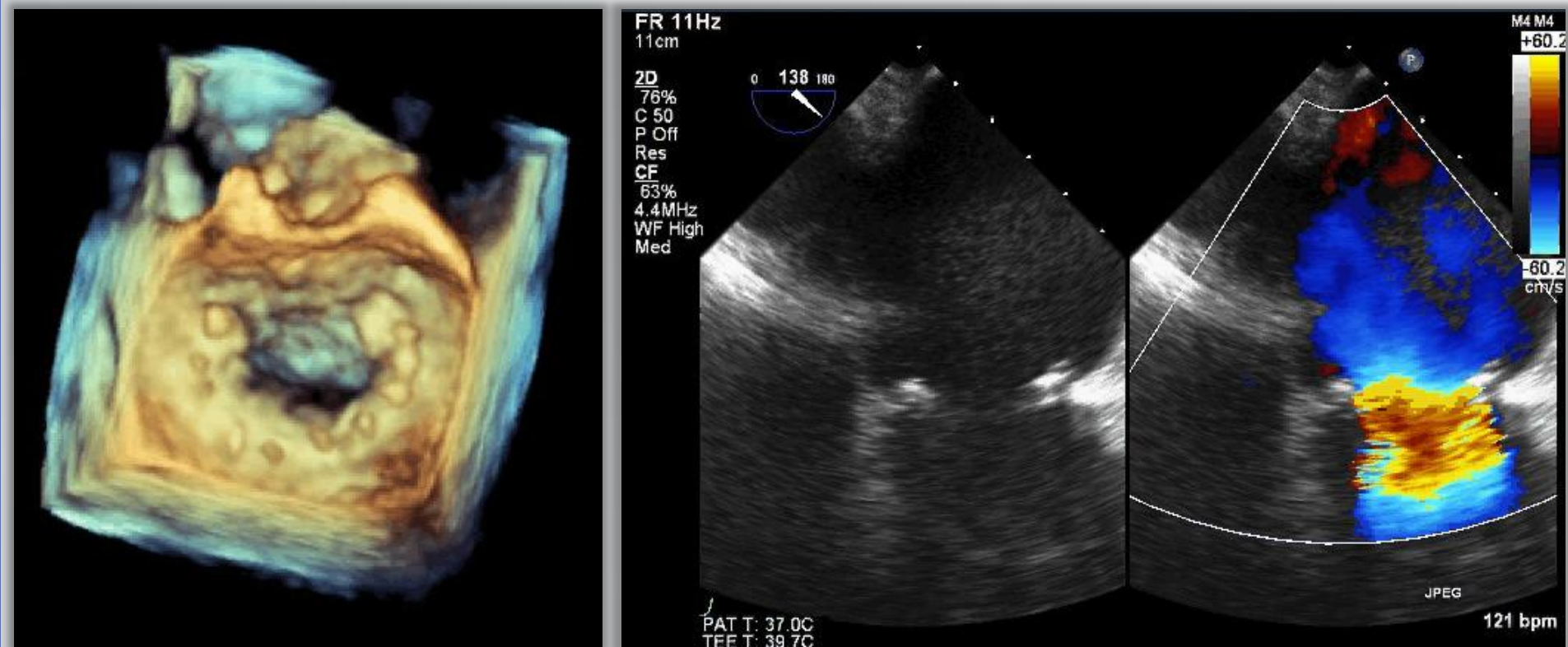
(A) This panel shows the chordae-free zone of the anterior mitral leaflet. (B) Fan-shaped chordae in the medial commissure are shown.

The structure of the chordae tendineae is complex in the medial and lateral commissure. This may impose a higher risk for clip entanglement.

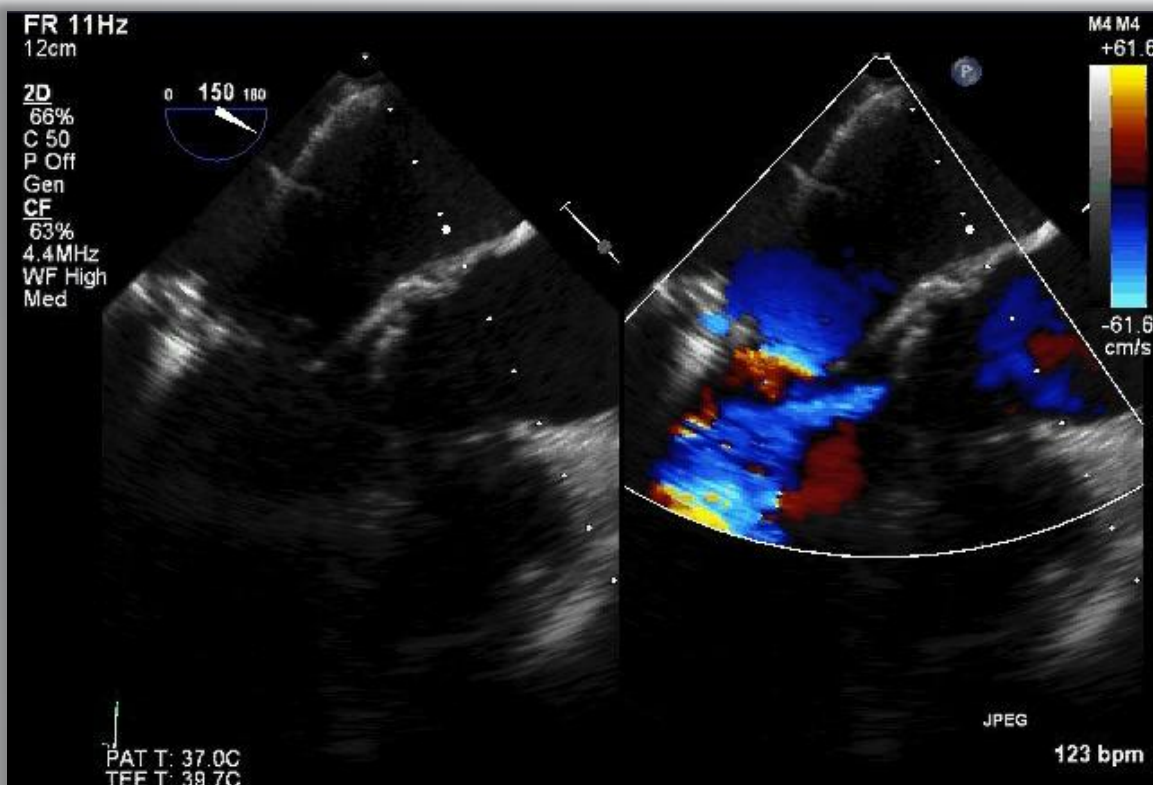
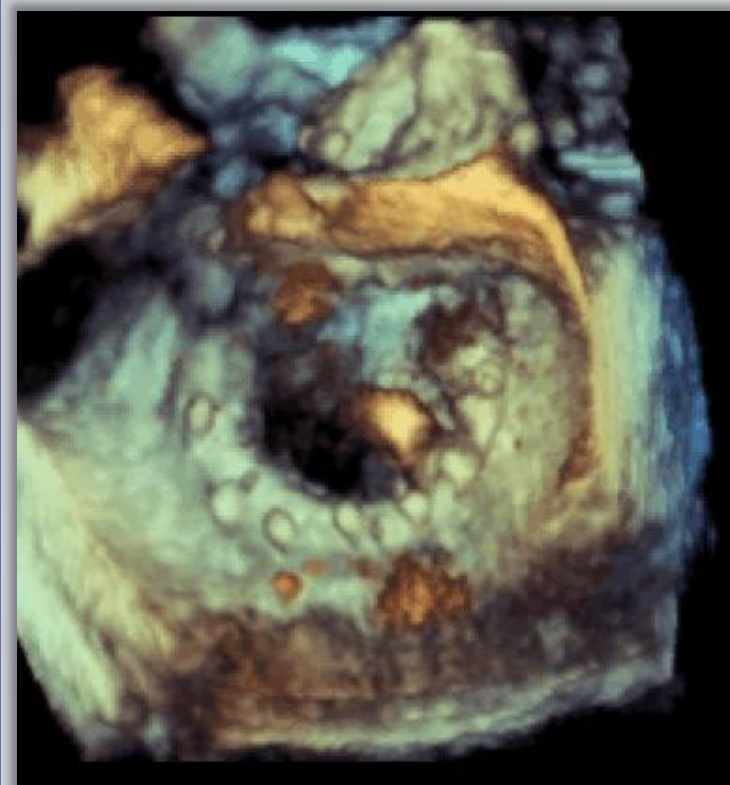
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- A1P1 or A3P3 flail or prolapse
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90-year-old man with recurrent MR post surgical annuloplasty



90-year-old man with recurrent MR post surgical annuloplasty



The MitraClip for recurrent MR post surgical annuloplasty

836 Correspondence

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Percutaneous Mitral Valve Repair With the MitraClip System for Severe Mitral Regurgitation in Patients With Surgical Mitral Valve Repair Failure



To the Editor: Surgical mitral valve repair (SMVR) is the preferred intervention for patients with either symptomatic severe mitral regurgitation (MR) or asymptomatic severe MR and left ventricular dysfunction (1). The rate of freedom from severe MR 10 years after SMVR, however, is reported to be 70% (2), leading to a

considerable number of mitral valve reinterventions, which carry substantial risk, particularly in elderly patients and in those with significant comorbidities.

Percutaneous mitral valve repair (PMVR) with the MitraClip system (Abbott Laboratories, Abbott Park, Illinois) recently emerged as a promising therapeutic alternative to SMVR in patients who are at high risk or are unsuitable for conventional surgery (3). Because of its reduced invasiveness compared with conventional surgery, PMVR could also function as a potential alternative to

reoperation in patients with recurrent MR after SMVR. We report, therefore, the results of transcatheter PMVR with the MitraClip system in patients with recurrent MR after SMVR.

Between August 2011 and August 2012, we treated 10 patients with moderate to severe MR determined by echocardiography at our institution

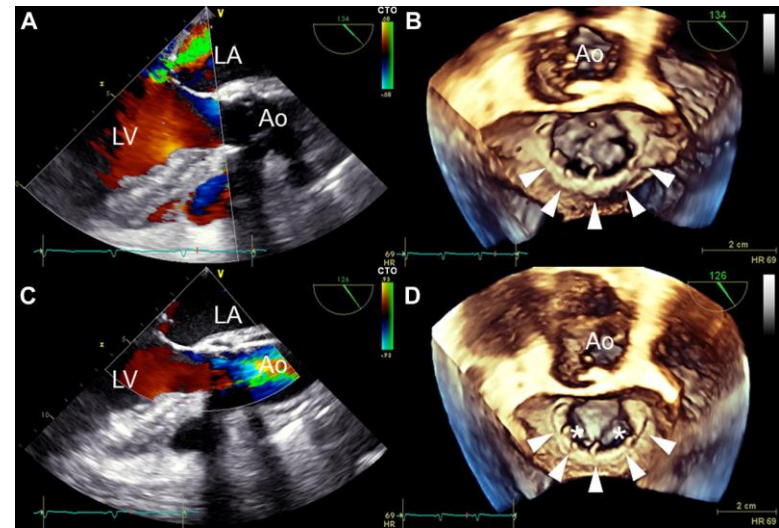


Figure 1 Transesophageal Echocardiography Before and After the Procedure From a Representative Case (Patient #6)

In the long-axis view, mitral regurgitation reduction from severe (A) to trivial (C) is shown, whereas in the 3-dimensional echocardiographic view from the left atrium (LA), the annuloplasty ring (Cosgrove-Edwards; white arrowheads) is clearly demonstrated in the posterior annulus (B,D) with a double orifice (white asterisk) after MitraClip implantation (D). Ao = aorta; LV = left ventricle.

The MitraClip for recurrent MR post surgical annuloplasty

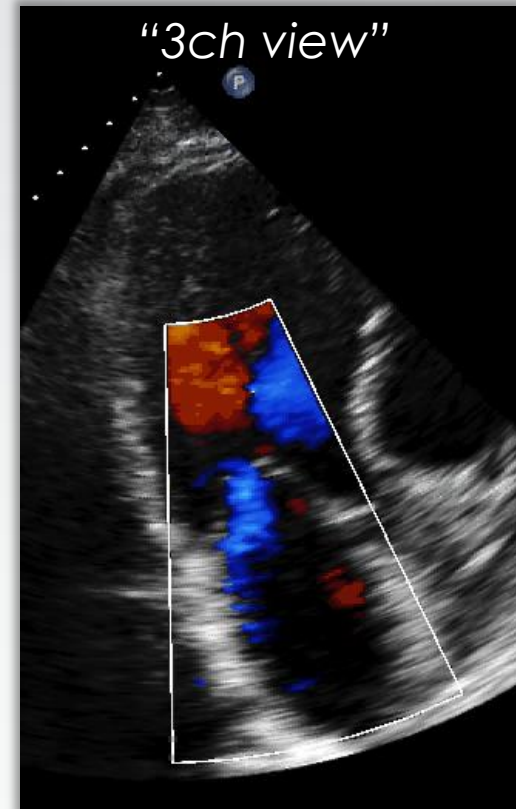
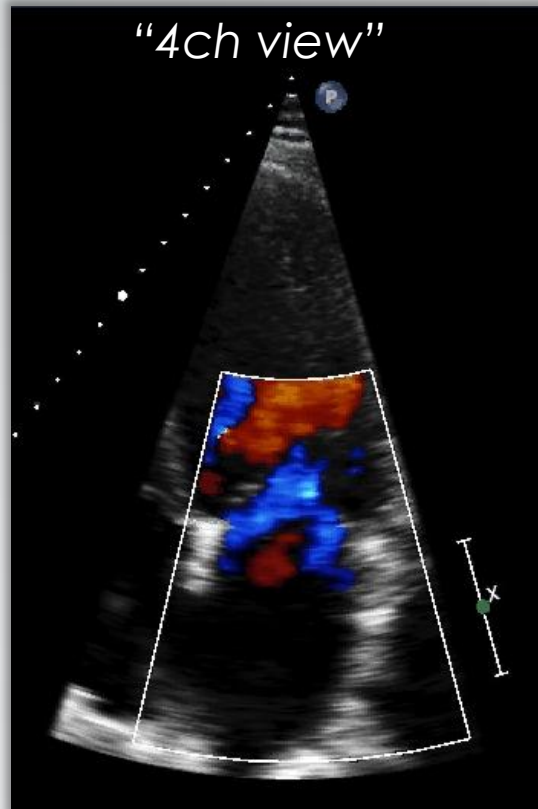
Table 1 Patient Characteristics, Procedural Details, and Follow-Up Data

Variable	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5	Patient #6
Age (yrs)	74	77	79	75	72	72
Sex	Female	Female	Female	Male	Male	Female
NYHA functional class (baseline)	3	3	3	4	2	4
Logistic EuroSCORE (%)	42.9	12.9	13.6	13.0	15.0	20.1
STS score (%)	11.4	4.2	6.0	4.6	5.0	6.0
Interval between SMVR and PMVR	12 yrs	6.5 yrs	5 yrs	10 yrs	8 yrs	7 days
Type of surgical ring	Carpentier-Edwards	Sovering Miniband	Carpentier-Edwards	Carpentier-Edwards	Sovering Miniband	Cosgrove-Edwards
Pre-procedural						
Rhythm	SR	SR	SR	AF	AF	SR
LVEF (%)	30	30	35	35	29	45
MR etiology	Functional	Functional	Functional	Functional	Functional	Functional
Tethering (involved leaflet)	Yes (P)	Yes (P)	Yes (P)	Yes (P)	Yes (A, P)	Yes (A)
MR jets	Central	Central	Central-medial	Central-medial	Central	Central-lateral
MR grade	3	3	3	4	4	4
Systolic PAP (mm Hg)	50	50	35	45	35	60
Mean pressure gradient (mm Hg)	1.8	2.5	2.7	4.5	2.6	3.8
Mitral valve area (cm ²)	4.3	3.3	3.0	3.7	3.7	3.7
Coaptation depth (mm)	9	8	8	10	8	5
Coaptation length (mm)	5	6	4	5	4	3
Procedural details						
Device success	Yes	Yes	Yes	Yes	Yes	Yes
Number of clips needed	1	1	1	1	1	1
Device implantation time (min)	55	33	67	60	75	30
Total fluoroscopy time (min)	27	13	33	28	35	18
Post-procedural						
MR grade	1	1	1	2	1	1
Mean pressure gradient (mm Hg)	5	3.1	5	6	4.8	5
Mitral valve area (cm ²)	2.6	1.9	2.5	1.5	2.4	1.9
Procedural complications	None	None	None	None	None	None
Hospital stay (days)	4	5	2	5	2	NA
Follow-up						
Follow-up (months)	31	12	12	6	3	NA
MR grade	1	1	3	1	1	NA
LVEF improvement	Yes	Yes	No	Yes	Yes	NA
NYHA functional class	2	2	3	2	1	NA

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- A1P1 or A3P3 flail or prolapse
- Recurrent MR post MV surgery and the MitraClip therapy
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**45-year-old man
with endstage non-ischemic cardiomyopathy
hospitalized for acute decompensated heart failure**

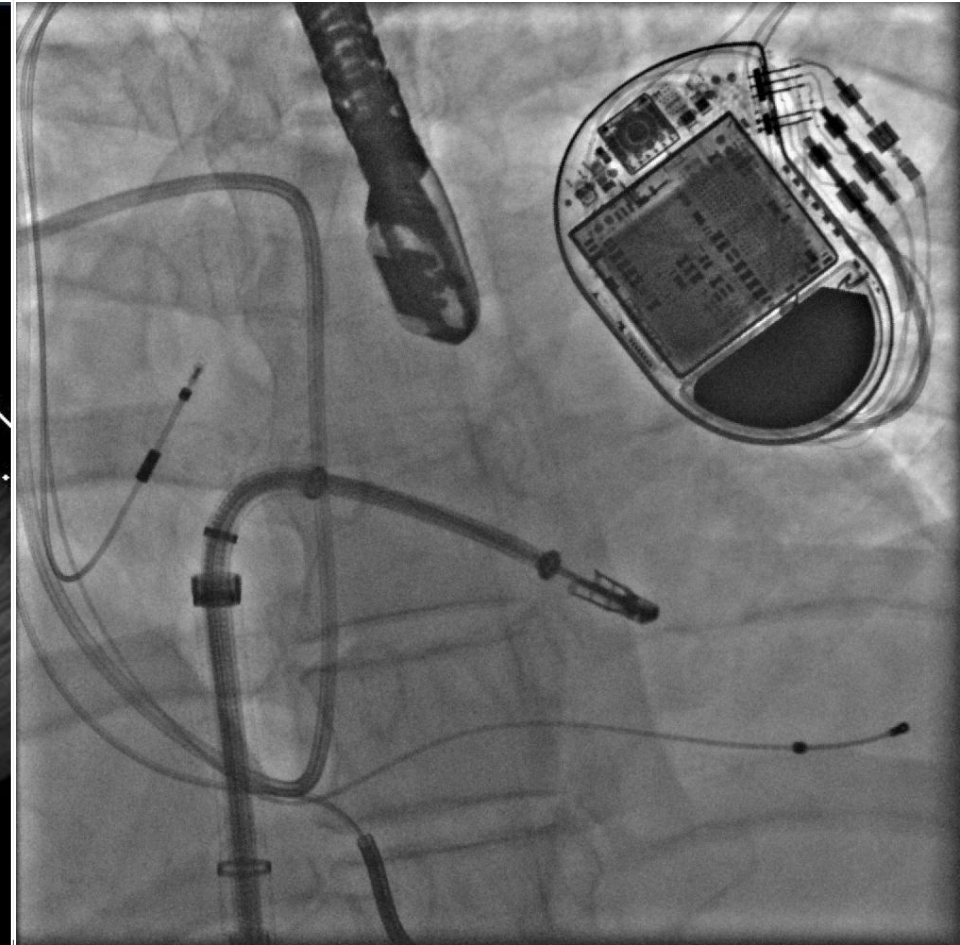
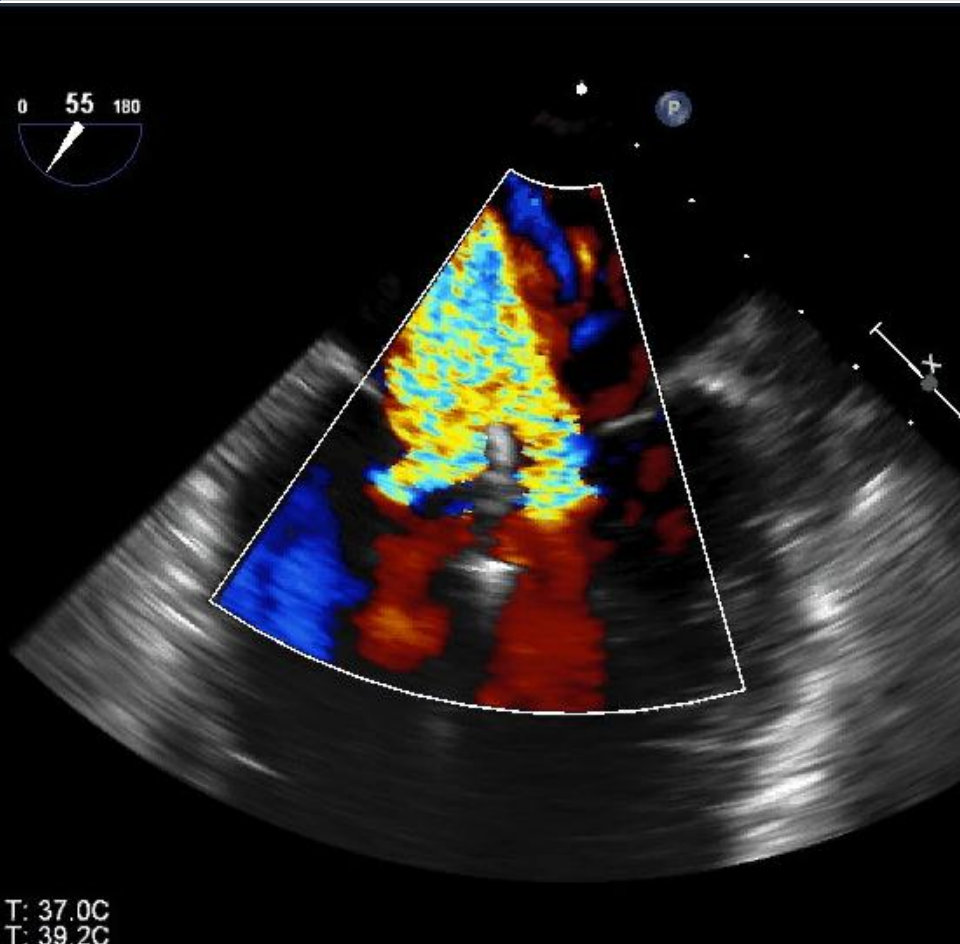


Severe functional MR with LV dysfunction

- ✓ $EROA = 0.46 \text{ cm}^2$
- ✓ $LVEF = 23\%$, $LVID \text{ d/s} = 63/59 \text{ mm}$

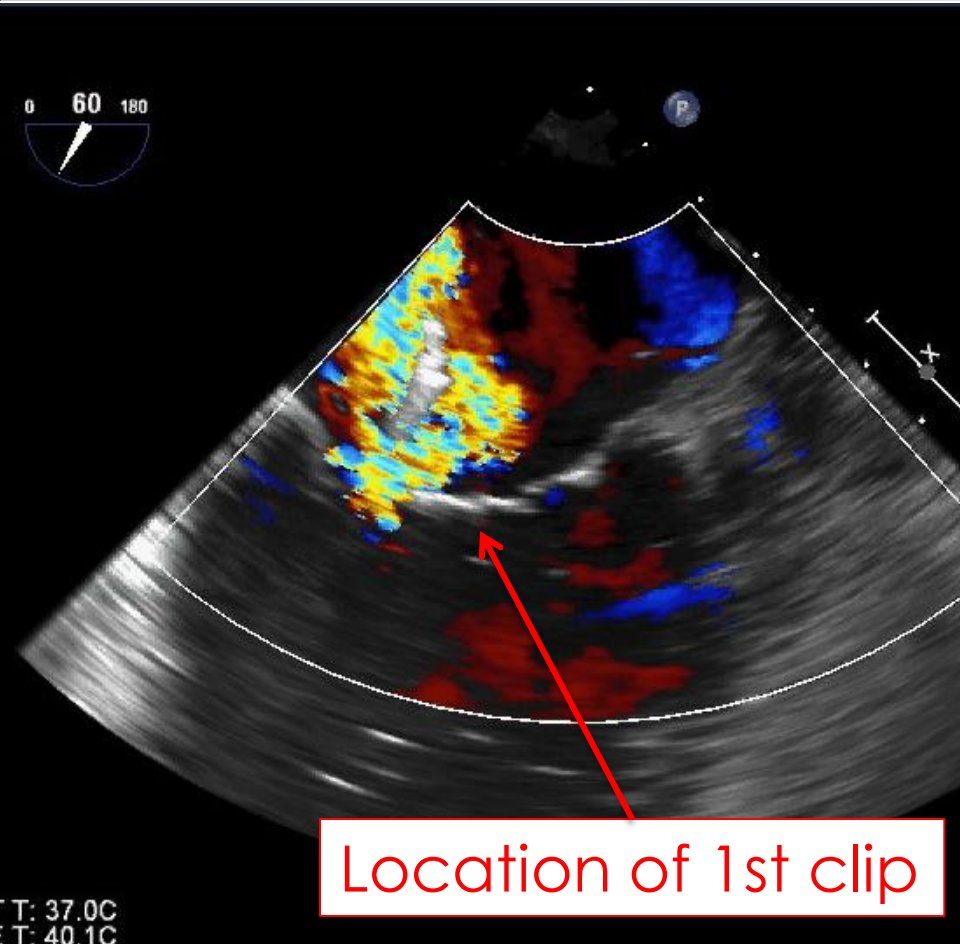
MitraClip procedure

“1st clip deployment”



MitraClip procedure

“2nd clip deployment”

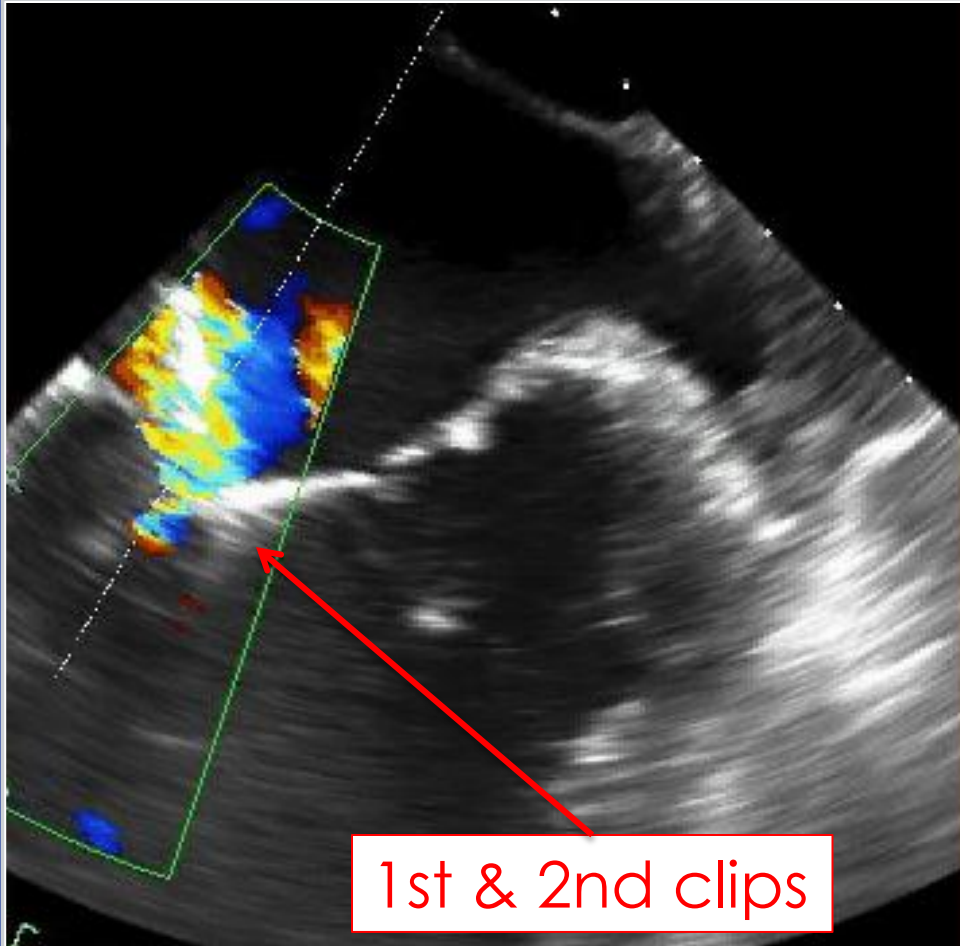


Location of 1st clip



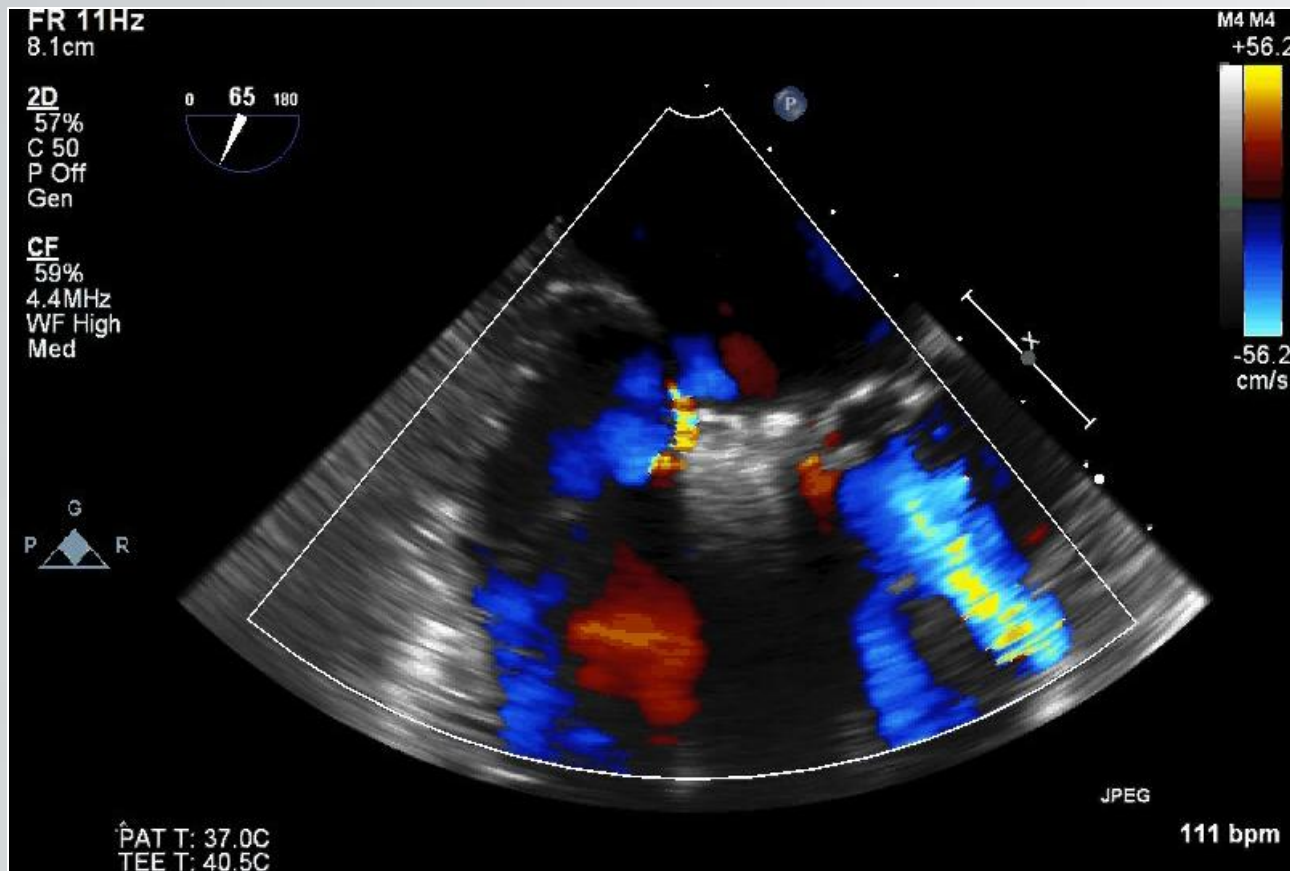
MitraClip procedure

“3rd clip deployment”



MitraClip procedure

“Post 3rd clip deployment”



“Cardiac output increased from 2.9 to 3.7 L/min”

MitraClip for FMR

- Is sudden reduction of MR in patients with LV dysfunction dangerous?
- Is there a sudden increase in LV afterload, which cause hemodynamic deterioration?

Hemodynamics pre and post MitraClip

Table 2. Hemodynamic Variables

	Before MitraClip	After MitraClip	Median Difference	P
Pressures and volumes				
EDV, mL	147 (106 to 183)	138 (104 to 185)	-9 (-21 to 5)	0.18
ESV, mL	57 (39 to 112)	84 (43 to 118)	11 (0 to 25)	0.006
EDP, mm Hg	14 (11 to 17)	11 (8 to 14)	-3 (-4 to 0)	0.002
MAP, mm Hg	64 (56 to 72)	68 (60 to 77)	9 (0 to 14)	0.02
mPAP, mm Hg	28 (24 to 32)	25 (22 to 29)	-3 (-5 to 0)	0.001
mPCWP, mm Hg	15 (12 to 20)	12 (10 to 13)	-5 (-8 to -2)	<0.001
vPCWP, mm Hg	22 (16 to 30)	14 (13 to 16)	-7 (-18 to -2)	<0.001
mLAP, mm Hg	15 (10 to 21)	11 (9 to 14)	-3 (-7 to 0)	0.001
Afterload and preload				
WS _{ES} , mm Hg	184 (140 to 200)	209 (176 to 232)	30 (10 to 58)	0.001
WS _{ED} , mm Hg	48 (28 to 58)	34 (21 to 46)	-8 (-19 to 2)	0.005
Load-independent parameters of LV contractility				
SCI, mm Hg·mL ⁻¹ ·s ⁻¹	4.8 (3.1 to 8.9)	5.8 (3.7 to 9.2)	0.2 (-0.5 to 1)	0.23
ESPVR, mm Hg/mL	1.6 (0.7 to 2.6)	1.2 (0.8 to 2.1)	-0.1 (-0.3 to 0.1)	0.12
PRSW, mm Hg	41 (29 to 60)	30 (24 to 52)	-3 (-13 to 1)	0.001
LV myocardial energetics				
eSW, mm Hg·mL	6357 (3756 to 7671)	4490 (2957 to 6754)	-579 (-2287 to 228)	0.004
PVA, mm Hg·mL	9169 (6691 to 12 033)	8634 (6951 to 10 717)	-52 (-1937 to 1181)	0.66
Forward output and resistances				
CO, L/min	4.4 (3.5 to 5.6)	5.6 (4.6 to 6.5)	0.9 (0.3 to 1.9)	<0.001
CI, L·min ⁻¹ ·m ⁻²	2.6 (2.2 to 3.0)	3.2 (2.6 to 3.8)	0.5 (0.2 to 1.1)	<0.001
SVR, dynes·s·cm ⁻⁵	995 (796 to 1261)	995 (633 to 1092)	-95 (-209 to 12)	0.03
PVR, dynes·s·cm ⁻⁵	174 (129 to 282)	176 (99 to 286)	-20 (-65 to 19)	0.27

CI indicates cardiac index; CO, cardiac output; EDP, end-diastolic pressure; EDV, end-diastolic volume; ESPVR, end-systolic pressure-volume relationship; ESV, end-systolic volume; eSW, external stroke work; LV, left ventricular; MAP, mean arterial pressure; mPAP, mean pulmonary artery pressure; mPCWP, mean pulmonary capillary wedge pressure; mLAP, mean left atrial pressure; PRSW, preload-recruitable stroke work; PVA, pressure-volume area; PVR, pulmonary vascular resistance; SCI, Starling contractile index; SVR, systemic vascular resistance; vPCWP, pulmonary capillary wedge pressure v-wave; WS_{ED}, end-diastolic wall stress; and WS_{ES}, end-systolic wall stress. All values are given as median (interquartile range).

Take home message

The safety and efficacy of the MitraClip therapy was initially evaluated in the EVEREST trial

Expanded indication of the MitraClip

- ✓ Non-central MR
- ✓ Recurrent MR post MV surgery and MitraClip
- ✓ FMR in patient with end-stage cardiomyopathy

These subset of patients are sometimes challenging, but can be treated with the MitraClip

Conclusions

- In real world setting, we expanded the indication of the MitraClip therapy beyond the criteria of EVEREST trial
- Specific caution should be exercised to achieve optimal procedural results for this expanded indication