



Reshape/Coapt: do we need more?

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Patient records



- 76 y.o. male
- Hypertension. Dyslipidemia. OPLD. Smoked in the past. Diabetes
- Inferior AMI 2009: stent RC
- Dyspnea on mild exertion.
- Admitted to the hospital with Pulm Edema. NYHA III



Patient records

- **BP 110/70 mmHg**
- **Sinus rhythm. Normal QRS. Inferior Infarction**

Systolic murmur Apex compatible MR

Diastolic murmur compatible Ao Rg

Rales

Cath. Total occlusion RCA



Patient records

- **Echo Questions ?.**
- **LV WM.**
- **Systolic function.**
- **Severity and etiology of MR and AoRg**
- **Pulmonary pressure**

ETE
X7-2t
19Hz
18cm

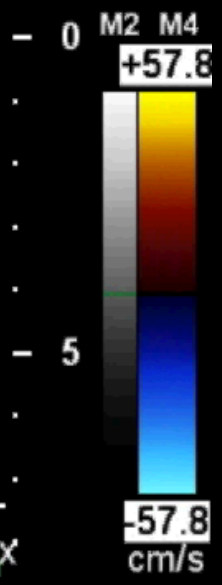
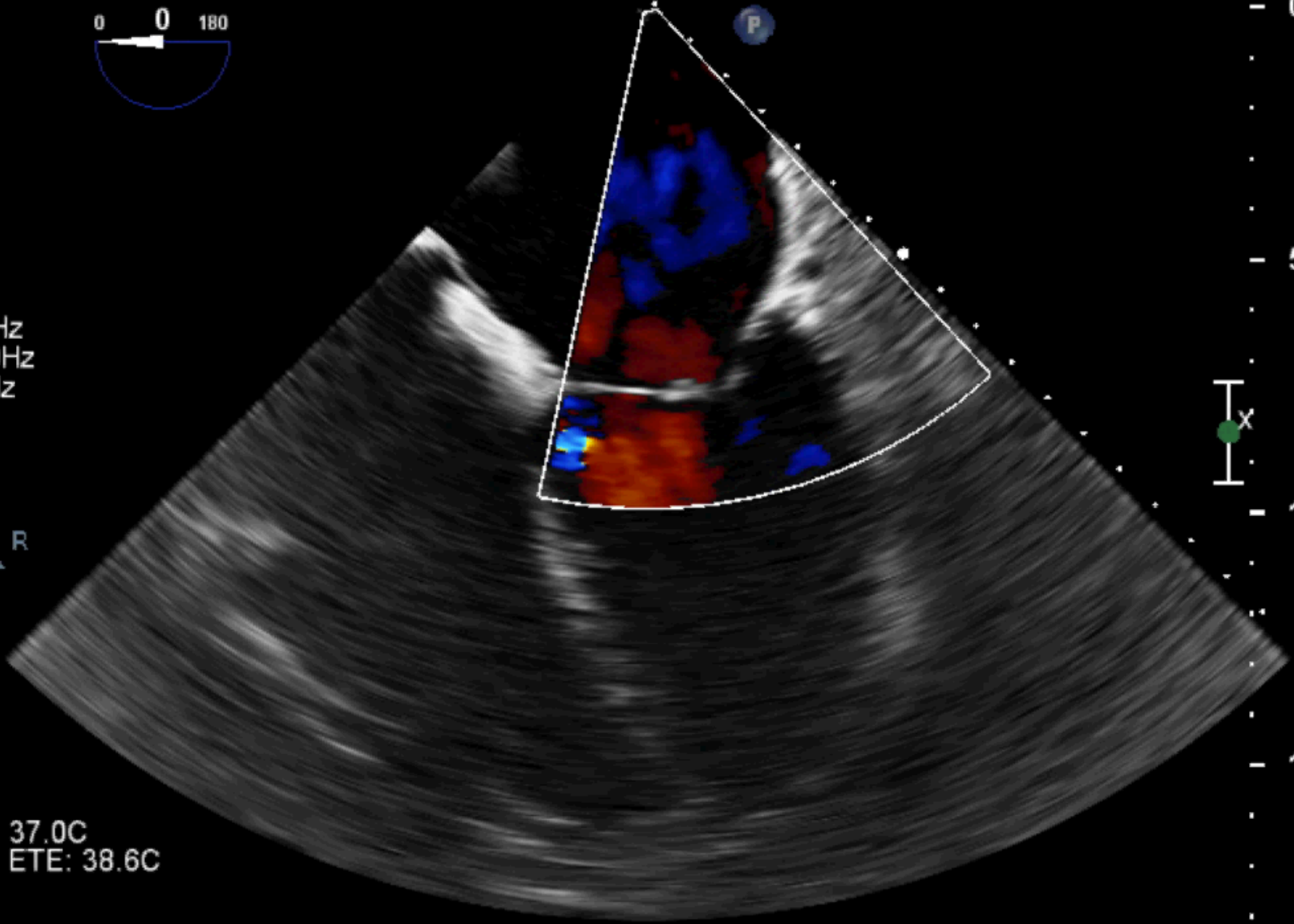
2D
74%
C 46
P Des.
Gral.

FC
48%
6671Hz
FP 600Hz
4.4MHz



PAT T: 37.0C
TEMP. ETE: 38.6C

TISO.6 MI 0.3



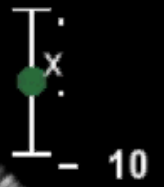
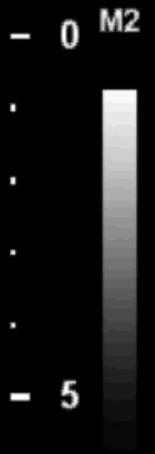
112 lpm

ETE
X7-2t
53Hz
16cm

TIS0.1 MI 0.4



2D
67%
C 46
P Des.
Gral.

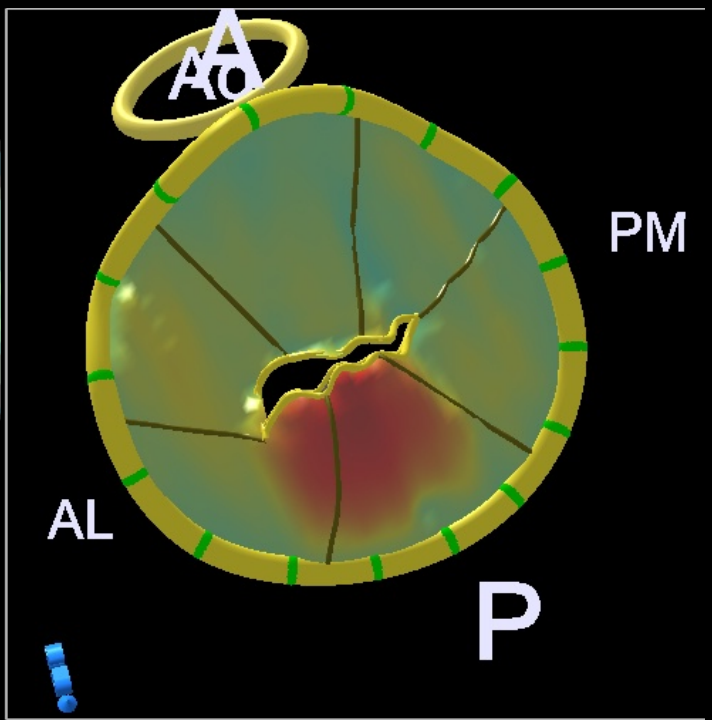
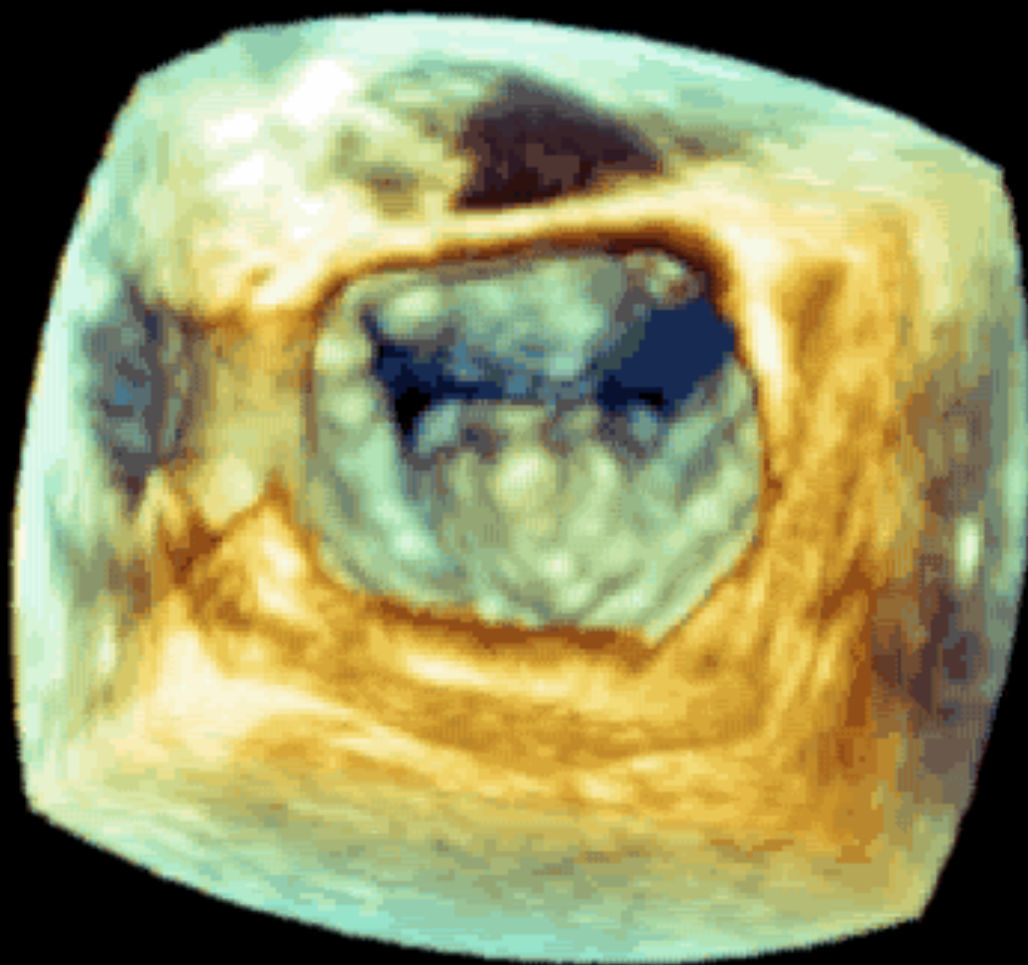


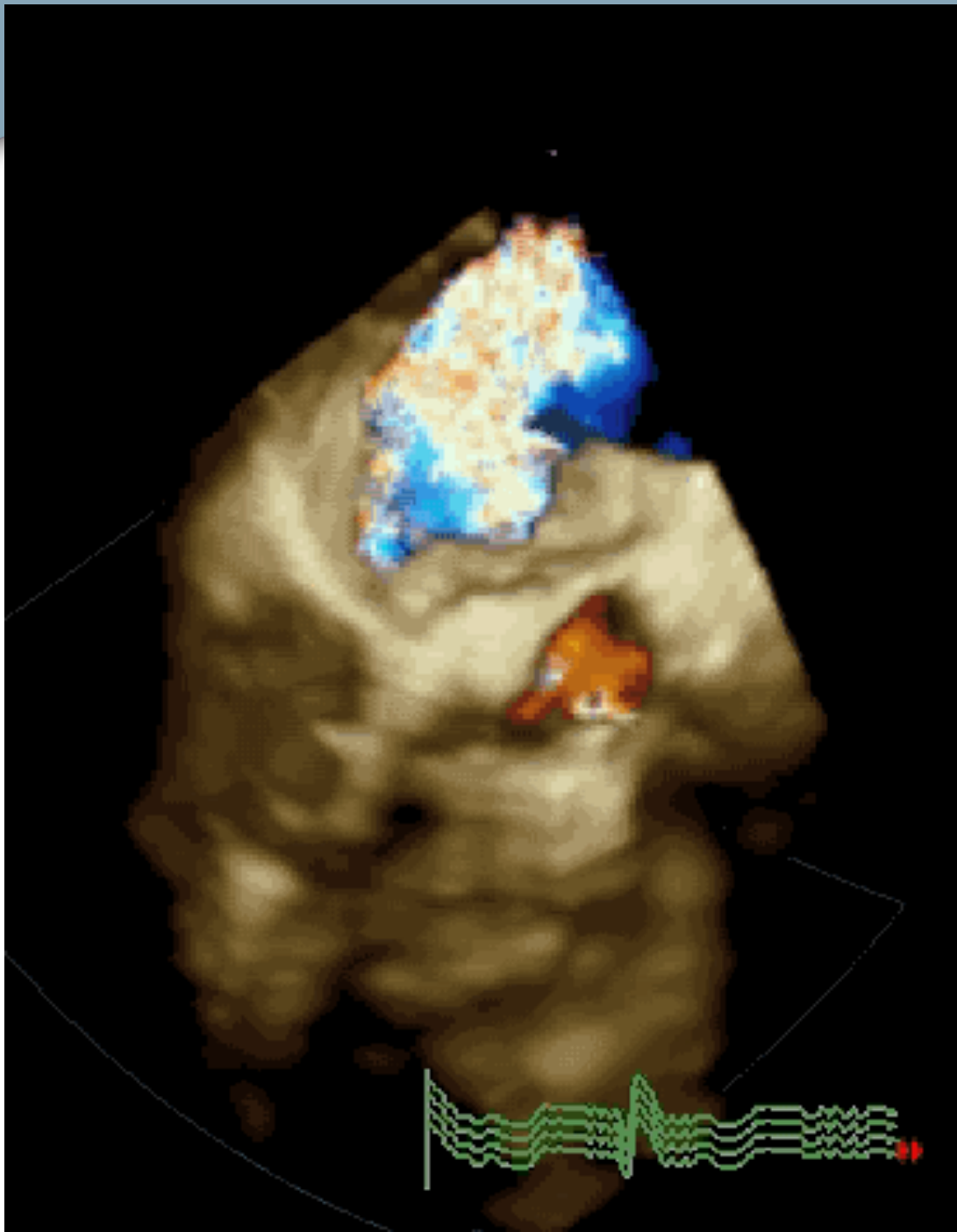
PAT T: 37.0C
TEMP. ETE: 38.8C

15

129 lpm

180



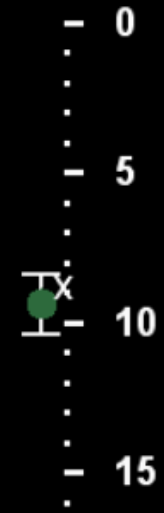
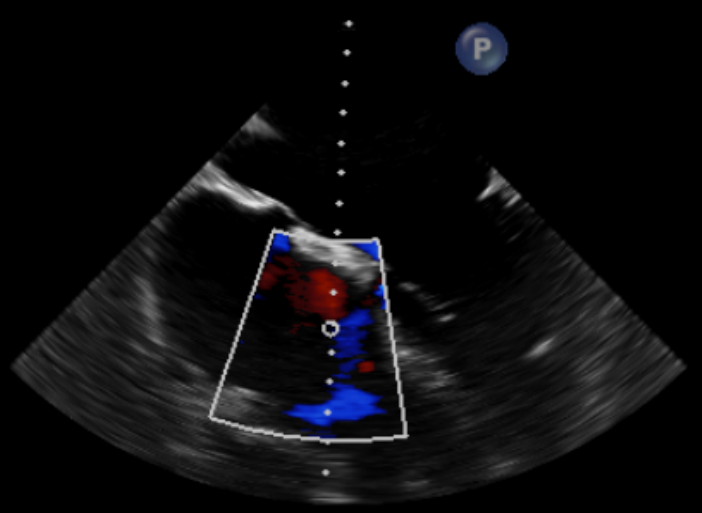


TIS ● GP máx RT = 24,8 mm
Umáx RT = 248,8 cm/s

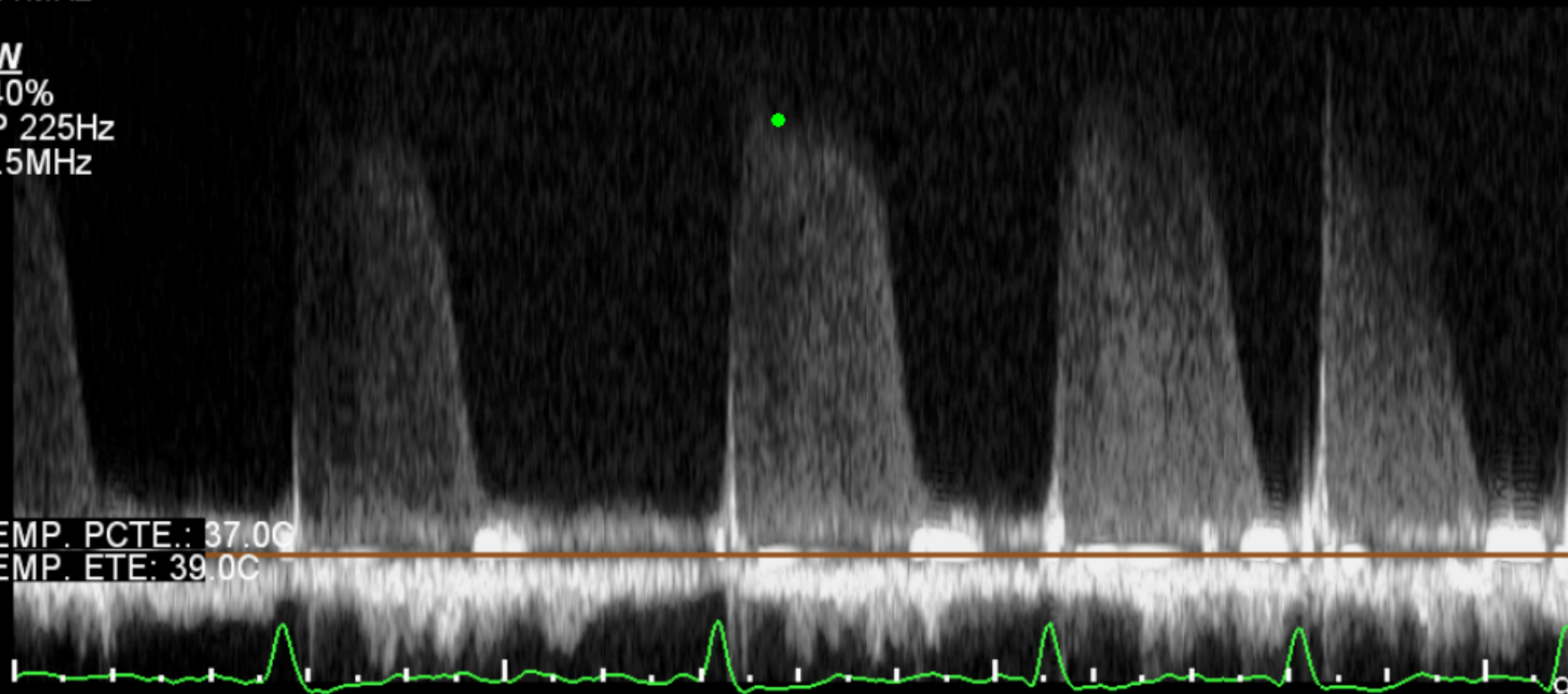
ETE
X7-2t
25Hz
16cm



2D
67%
C 46
P Des.
Gral.
FC
48%
4941Hz
FP 444Hz
4.4MHz



CW
40%
FP 225Hz
2.5MHz



TEMP. PCTE.: 37.0C
TEMP. ETE: 39.0C

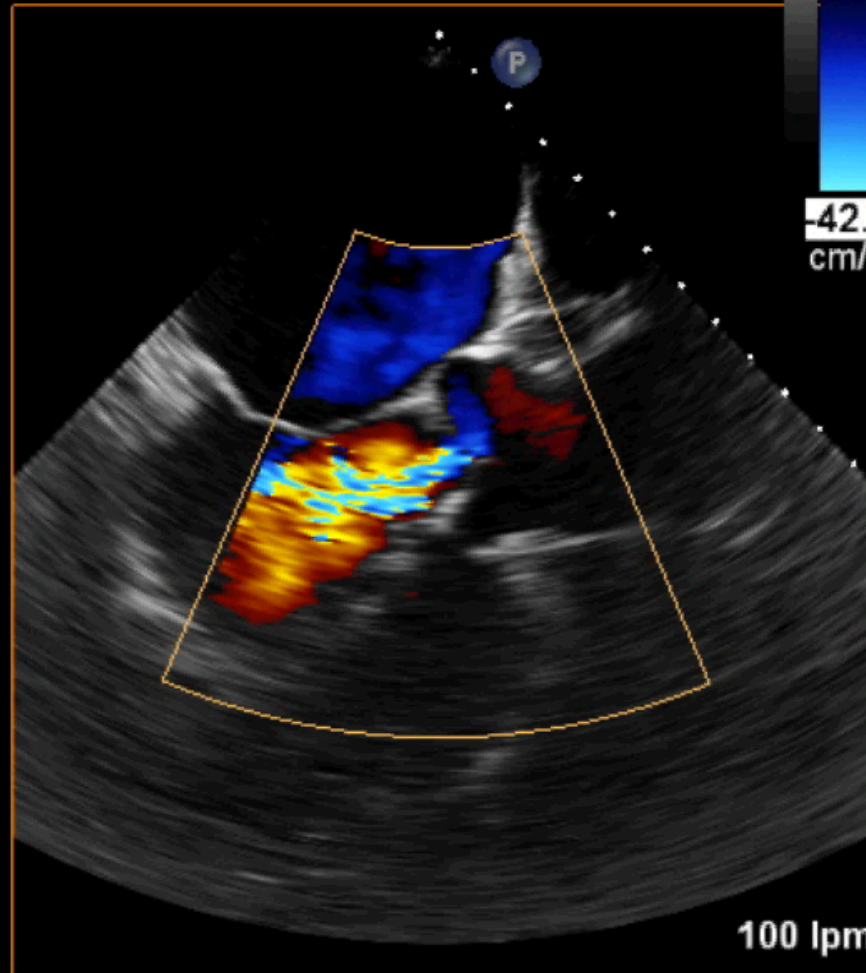
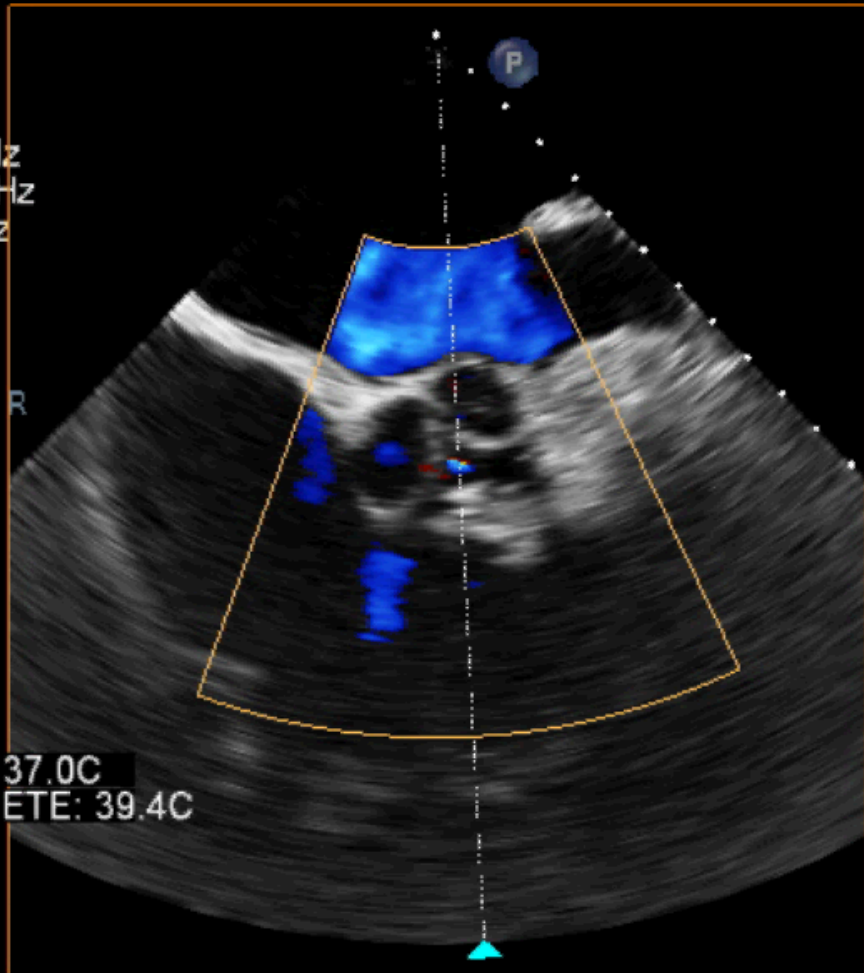
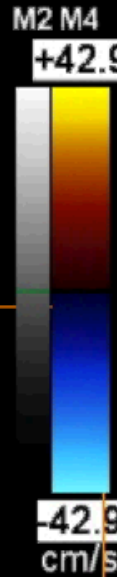
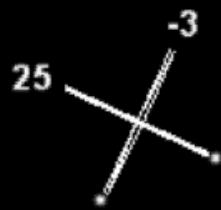
95bpr

TISO.6 MI 0.4

ETE
X7-2t
11Hz
18cm

xPlane
74%
74%
46dB
P Des.
Gral.

FC
48%
4947Hz
FP 445Hz
4.4MHz



PAT T: 37.0C
TEMP. ETE: 39.4C



ETE
X7-2t
14Hz
14cm

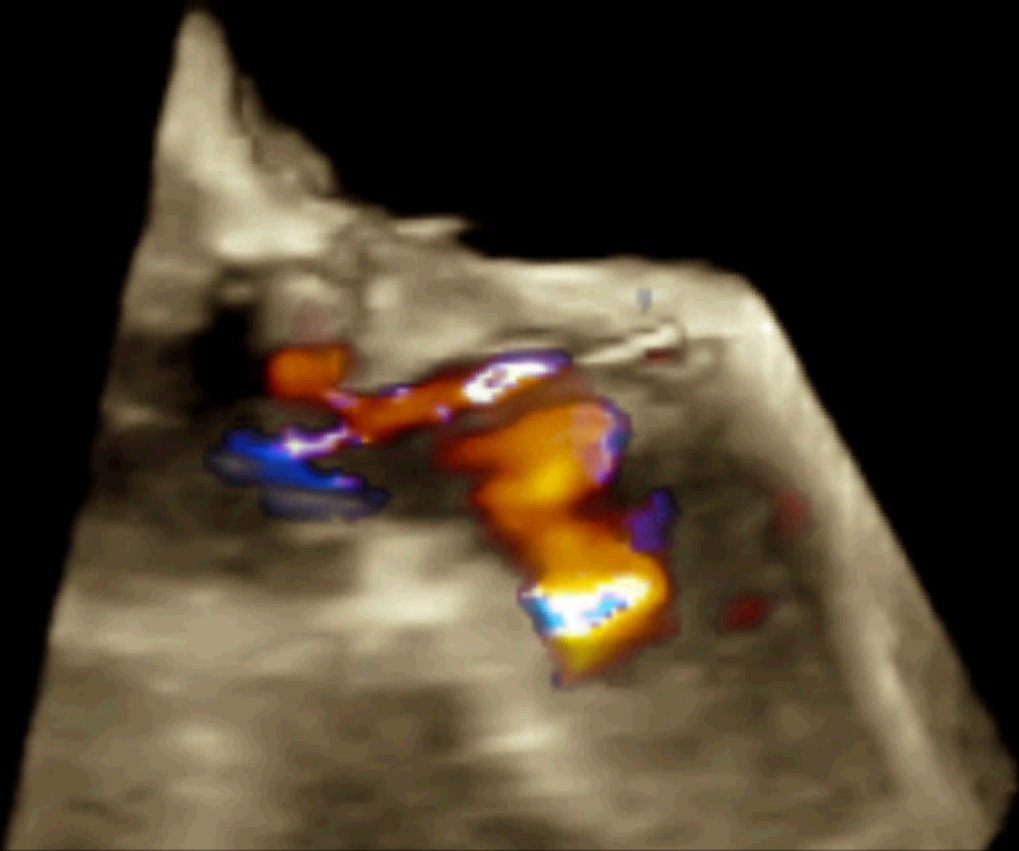
Latidos 3D Alta TVol

TIS0.6 MI 0.3

Live 3D
2D / 3D
% 83 / 43
C 46 / 30
Gral.



FC
% 54 / 50
4872Hz
FP 487Hz
4.4MHz



PAT T: 37.0C
TEMP. ETE: 38.2C

Demora 0ms

106 lpm



- **Severe isquemic MR**
- **Mild TR**
- **Moderate PHT**
- **Moderate Ao reg**
- **LV function 45%**



Patient records

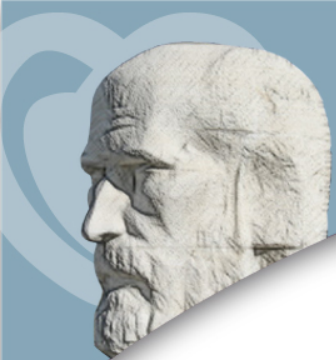
- **HT questions?** . In case severe lesions in severely symptomatic pt with HF
- **Patient risk.**
- **Type of intervention.**
-



• **What to do ?**

- 1.- Mitral & Aortic Valve replacement ?**
- 2.- Mitral valve replacement**
- 3.- Medical Therapy**
- 4.- Mitral clip**





Guidelines



MitraClip as Tx option for high risk surgical patients in ESC Heart Failure 2012 guidelines



ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC

Authors/Task Force Members: John J. V. McMurray (Chairperson), Ulf Erik... (list of names)

ESC Committee for Practice Guidelines (CPG) Group 1: ... (list of names)

Document Reviewers: Theresa McDonagh, ... (list of names)

Writing Group: ... (list of names)

Document Reviewers: ... (list of names)

although its effect on survival is unknown. In this situation, the decision to operate should take account of response to medical therapy, co-morbidity, and the likelihood that the valve can be repaired (rather than replaced).

Secondary mitral regurgitation

This occurs because LV enlargement and remodelling lead to reduced leaflet closing. Effective medical therapy leading to reverse remodelling of the LV may reduce functional mitral regurgitation, and every effort should be made to optimize medical treatment in these patients.

Ischaemic mitral regurgitation is a particular type of secondary mitral regurgitation that may be more suitable for surgical repair. As it is often a dynamic condition, stress testing is important in its evaluation. An exercise-induced increase of effective regurgitant orifice (≥13 mm²) is associated with a worse prognosis. Combined valve and coronary surgery should be considered in symptomatic patients with LV systolic dysfunction, coronary arteries suitable for revascularization, and evidence of viability. Predictors of late failure of valve repair include large interpapillary muscle distance, severe posterior mitral leaflet tethering, and marked LV dilatation (LV end-diastolic diameter >65 mm). In these patients, mitral valve replacement, rather than repair, may be advisable. In the presence of AF, atrial ablation and left atrial appendage closure may be considered at the time of mitral valve surgery.

The role of isolated mitral valve surgery in patients with severe functional mitral regurgitation and severe LV systolic dysfunction who cannot be revascularized or have non-ischaemic cardiomyopathy is questionable, and in most patients conventional medical and device therapy are preferred. In selected cases, repair may be considered in order to avoid or postpone transplantation.

In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms.²⁵⁰

13.4 Heart transplantation

Heart transplantation is an accepted treatment for end-stage HF.^{251,252} Although controlled trials have never been conducted, there is consensus that transplantation—provided that proper selection criteria are applied—significantly increases survival, exercise capacity, quality of life, and return to work compared with conventional treatment.

Apart from the shortage of donor hearts, the main challenges in transplantation are the consequences of the limited effectiveness and complications of immunosuppressive therapy in the long term (i.e. antibody-mediated rejection, infection, hypertension, renal failure, malignancy, and coronary artery vasculopathy). The indications for and contraindications to heart transplantation are summarized in Table 23.

13.5 Mechanical circulatory support

MCS is an umbrella term describing a number of different technologies used to provide both short- and longer term assistance in patients with either chronic HF or AHF. A variety of terms have been used to describe the use of these technologies (Table 24).^{251,253} The most experience is with MCS in end-stage

Table 23 Heart transplantation: indications and contraindications

Patients to consider	End-stage heart failure with severe symptoms, a poor prognosis, and no remaining alternative treatment options Motivated, well informed, and emotionally stable Capable of complying with the intensive treatment required post-operatively
Contraindications	Active infection Severe peripheral arterial or cerebrovascular disease Current alcohol or drug abuse Treated cancer in previous 5 years Unhealed peptic ulcer Recent thrombo-embolism Significant renal failure (e.g. creatinine clearance <30 ml/min) Significant liver disease Systemic disease with multiorgan involvement Other serious co-morbidity with poor prognosis Emotional instability or untreated mental illness High, fixed pulmonary vascular resistance (>4-5 Wood Units and mean transpulmonary gradient >15 mmHg)

HF = heart failure.

Table 24 Terms describing various uses of mechanical circulatory support (MCS)

Bridge to decision (BTDC)	Use of MCS in patients with drug-refractory acute circulatory collapse and at immediate risk of death to sustain life until a full clinical evaluation can be completed and additional therapeutic options can be evaluated.
Bridge to candidacy (BTC)	Use of MCS to improve end-organ function in order to make an ineligible patient eligible for transplantation.
Bridge to transplantation (BTX)	Use of MCS to keep a patient at high risk of death before transplantation alive until a donor organ becomes available.
Bridge to recovery (BTR)	Use of MCS to keep patient alive until intrinsic cardiac function recovers sufficiently to remove MCS.
Destination therapy (DT)	Long-term use of MCS as an alternative to transplantation in patients with end-stage heart failure ineligible for transplantation.

MCS = mechanical circulatory support.

...“In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms.”.....



**Secondary
(Functional) MR**

ACC/AHA 2014 Valve Guidelines

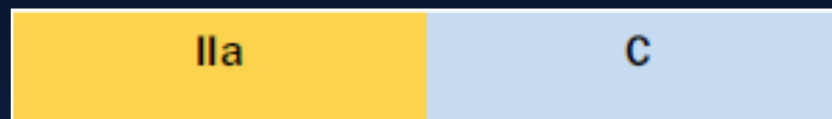
Surgery for Secondary (Functional) MR

In pts undergoing other cardiac surgery

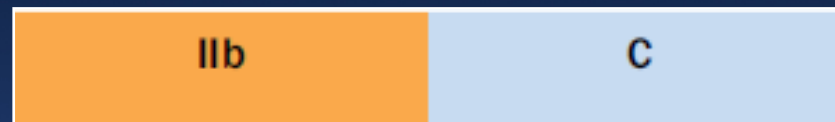
COR

LOE

MV surgery is reasonable for pts with chronic severe secondary MR (stages C and D) who are undergoing CABG or AVR



MV repair may be considered for pts with chronic moderate secondary MR (stage B) who are undergoing other cardiac surgery



In pts NOT undergoing other cardiac surgery

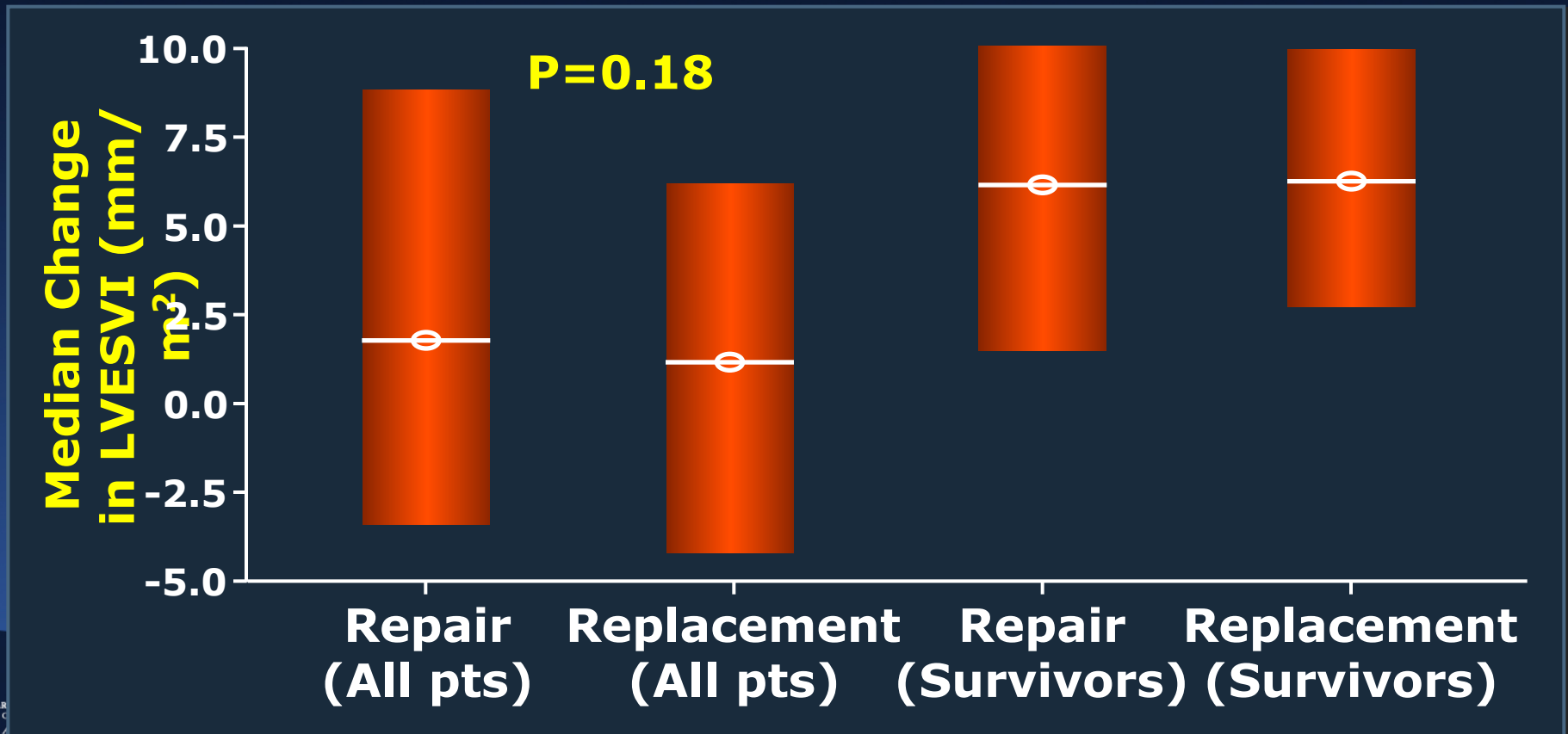
MV surgery may be considered for severely symptomatic pts (NYHA class III/IV) with chronic severe secondary MR (stage D)



SMR Trial: Primary Endpoint

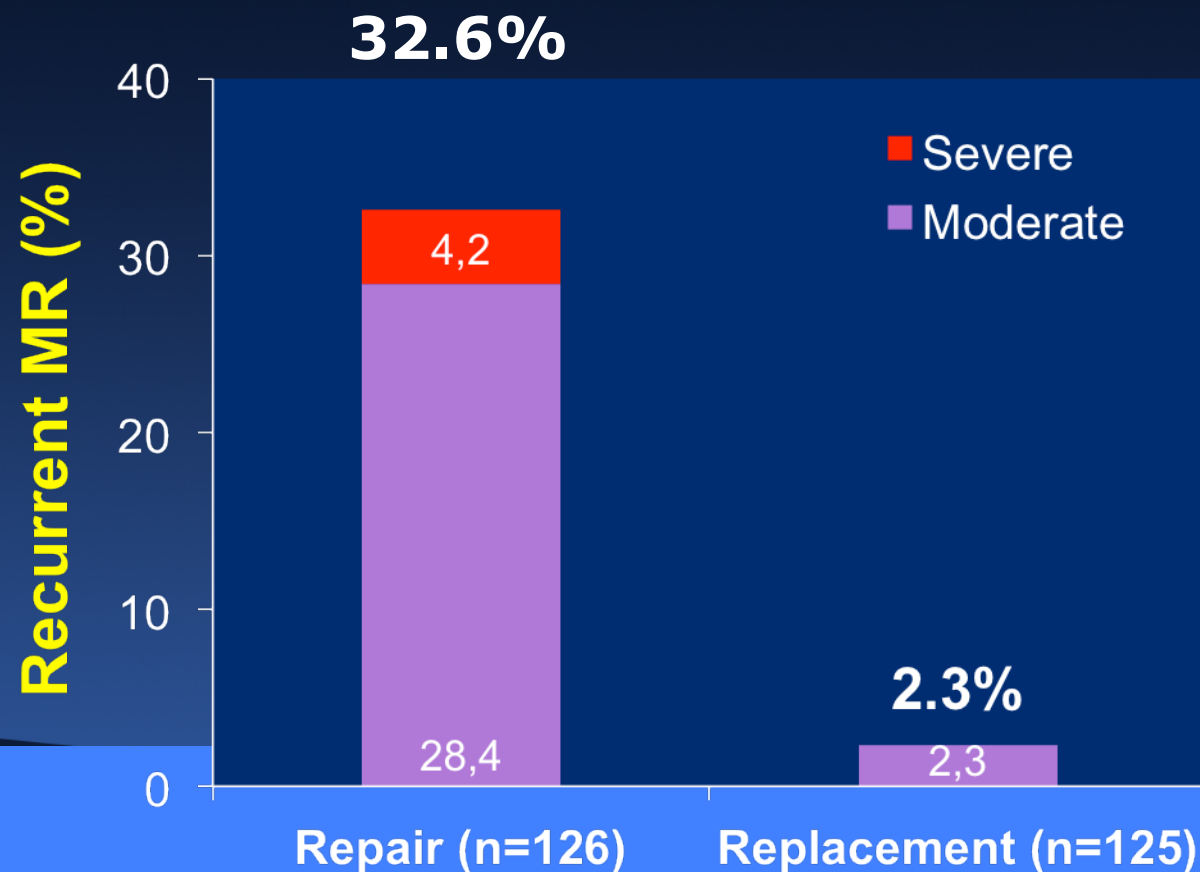
251 pts with severe ischemic FMR were randomized to MV repair with complete rings vs. chordal-sparing MV replacement; mean EROA $\sim 0.40 \text{ cm}^2$; 86% concomitant procedures (75% CABG, TV repair, Maze)

1° EP = Median Change in LVESVI from baseline to 1 year



Severe MR Trial: Recurrent MR

Recurrent MR at 1 year



There were no significant 1-year differences in:

- LVESVI
- NYHA
- SF-36 scores
- MLHF scores
- MV reoperation
- Death
- MACE

MitraClip RCTs in Functional MR

	COAPT	RESHAPE-HF	Mitra-Fr
N patients, sites	430 @ 75 US sites	800 @ 50 EU sites	288 @ 18 French sites
Control arm	Medical Rx	Medical Rx	Medical Rx
FMR grade	≥3+ (EROA ≥30 mm ² and/or Rvol >45 mL by ECL)	≥3+ (EROA ≥30 mm ² and/or Rvol >45 mL by ECL)	Sev (EROA >20 mm ² + Rvol >30 mL) by ECL
NYHA class	II, III, or ambulatory IV	III or ambulatory IV	II - IV
Other inclusion criteria	HF hosp within 12 months or BNP ≥300 pg/ml or nT-proBNP ≥1500 pg/ml within 12 months; MV surgery is not local standard of care	HF hosp within 12 months or BNP ≥350 pg/ml or nT-proBNP ≥1400 pg/ml within 90 days; not eligible for MV surgery	HF hosp within 12 months; not eligible for MV surgery
LVEF	≥20% - ≤50%	≥15% - ≤40%	≥15% - ≤40%
LV volumes	LVEDD ≤70 mm	LVEDD ≥55 mm	-
Primary efficacy endpoint (superiority)	Recurrent HF hospitalization at 12 months	Death or recurrent HF hospitalization at 12 months	Death or recurrent HF hospitalization at 12 months
Primary safety endpoint (noninferiority)	SLDA, device embolizations, endocarditis/MS/device-related complications requiring non-elective CV surgery, LVAD, OHT	-	-
Health economics	Assessed	Assessed	-
Follow-up	5 years	2 years	2 years

MitraClip RCTs in Functional MR

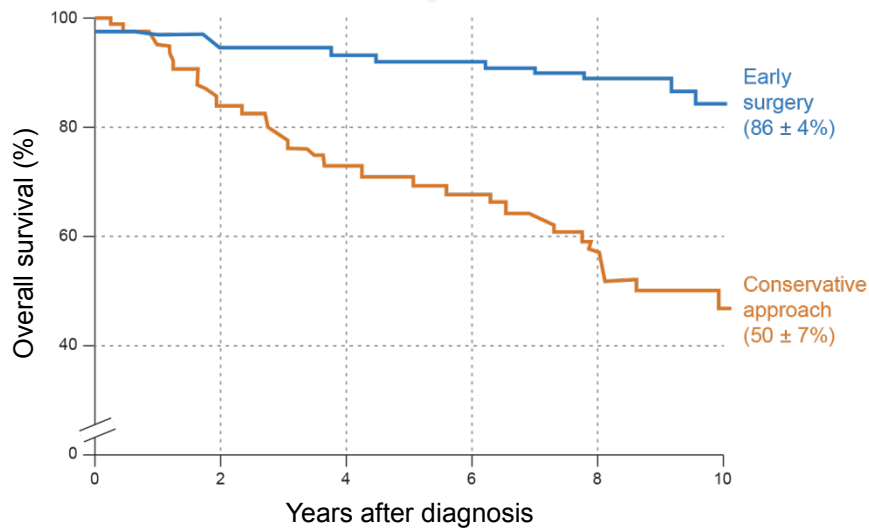
	COAPT	RESHAPE-HF	Mitra-Fr
N patients, sites	430 @ 75 US sites	800 @ 50 EU sites	288 @ 18 French sites
Contra			
F			
N			
C			
L			
L			
F			
e			
(non			
	LVAD, OHT		
Health economics	Assessed	Assessed	-
Follow-up	5 years	2 years	2 years

- **3 trials randomizing 1,518 patients with heart failure and secondary (functional) MR to MitraClip vs. GDMT**

Early surgical intervention improves outcomes



10-year overall survival of asymptomatic MR patients was significantly greater with early Surgery vs. medical management



Otto, C. Heart 2003

“early intervention to prevent left ventricular systolic dysfunction or pulmonary hypertension provides optimal clinical outcomes”.

1. Otto, C. – Timing of surgery in mitral regurgitation - Heart 2003;89:100–105

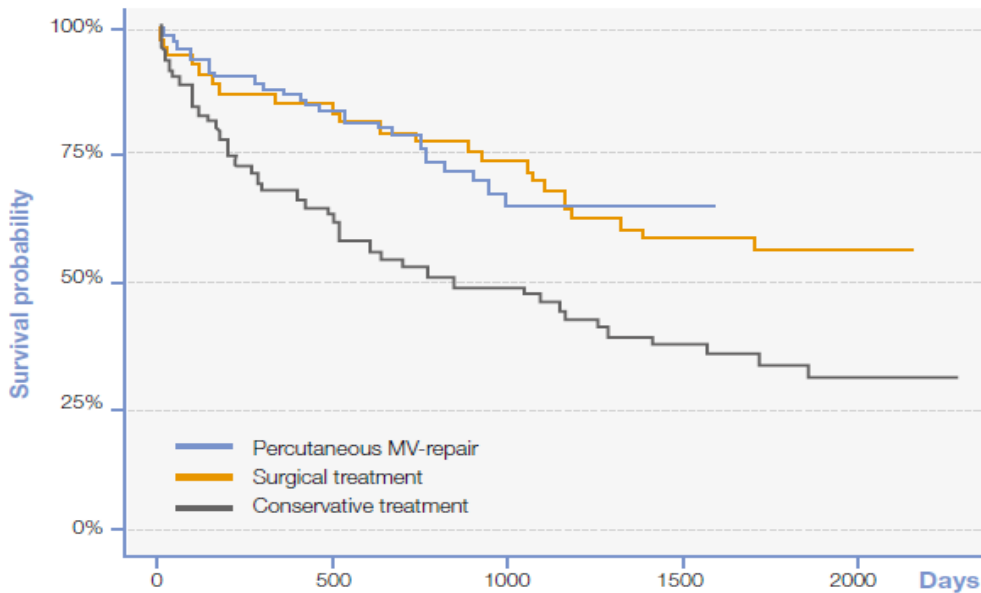
Montant P, Chenot F, Robert A, et al. Long-term survival in asymptomatic patients with severe degenerative mitral regurgitation: a propensity score-based comparison between an early surgical strategy

and a conservative treatment approach. J Thorac Cardiovasc Surg. 2009;138(6):1339-1348.



MitraClip intervention improves survival

Kaplan-Meier Survival Curves



n at risk	0	500	1000	1500	2000
Percutaneous MV-repair	139	78	20	2	0
Surgical treatment	53	44	39	30	7
Conservative treatment	59	36	29	22	7

MitraClip therapy*
is superior to
 conservative
 treatment and
 survival rates are
 comparable to
 surgery in high-
 surgical-risk patients
 with symptomatic MR
 (DMR and FMR)

*Swaans - Survival of Transcatheter Mitral Valve Repair Compared With Surgical and Conservative Treatment in High-Surgical-Risk Patients – JACC, 2014(7); 8 : 875-881

Let us implant a MitraClip. BEFORE....



- MR severe,
- Symptoms NYHA III
-

High Surgical risk

CLINICAL DATA



Let us make it easy



Basic Factors of MR

Mechanical function depends on its material's properties

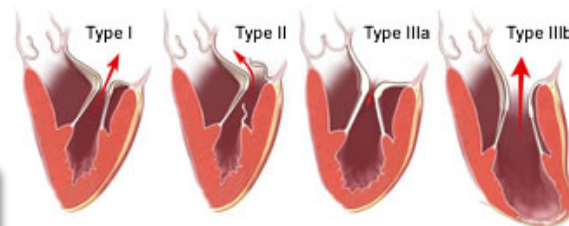
- ECD – CAVC – Ceft
- Accessory Valve
- Arcade - Parachute
- Short Chordae

Congenital

Organic

Degenerative

- Myxomatous (Marfan, etc)
- Fibro-Elastic-Deficiency
- Rheumatic
- Post-Endocarditis
- Drug-induced
- Connective Tissue Disorders
- Annular Calcification



Mitral regurgitation type	Leaflet anatomy	Annulus	Etiology
Type I	Normal or perforated	Dilated	Endocarditis
Type II	Proximal	Normal	Myxomatous disease; papillary muscle rupture or elongation
Type IIIa	Restricted motion	Normal	Rheumatic disease
Type IIIb	Tethering/restricted motion from dilated left ventricle	Dilated	Ischemic or idiopathic cardiomyopathy

- DCM
- HOCM

Myocardial-Cell Dysfunction

Functional

Ischemic

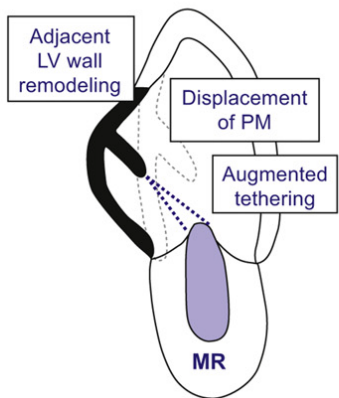
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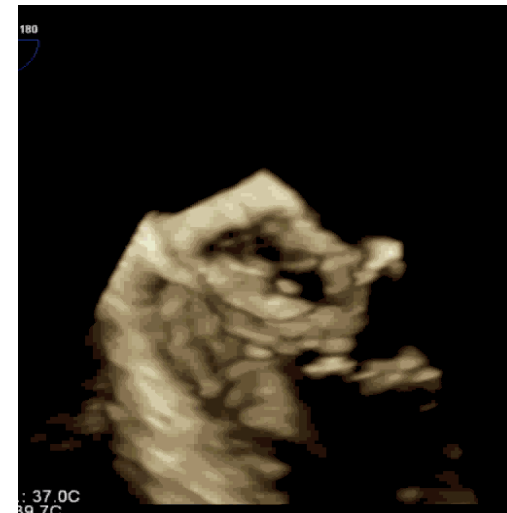
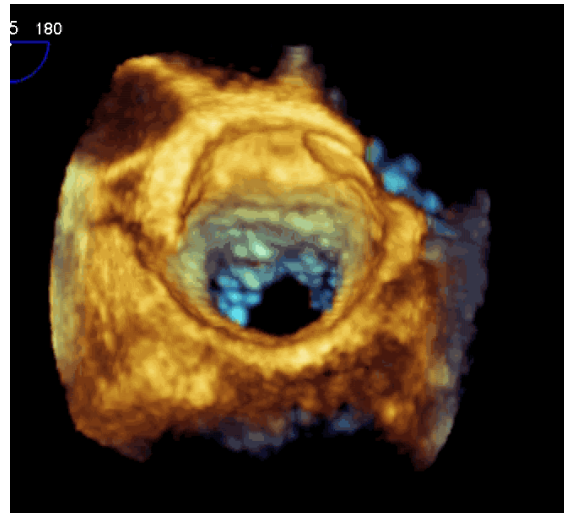
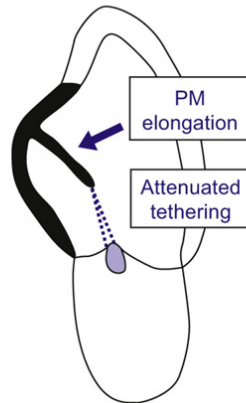
Functional Mi Reg

Distorsion of subvalvular apparatus due to remodeling or dilatation

Effects of Associated LV Remodeling



Effects of PM lengthening

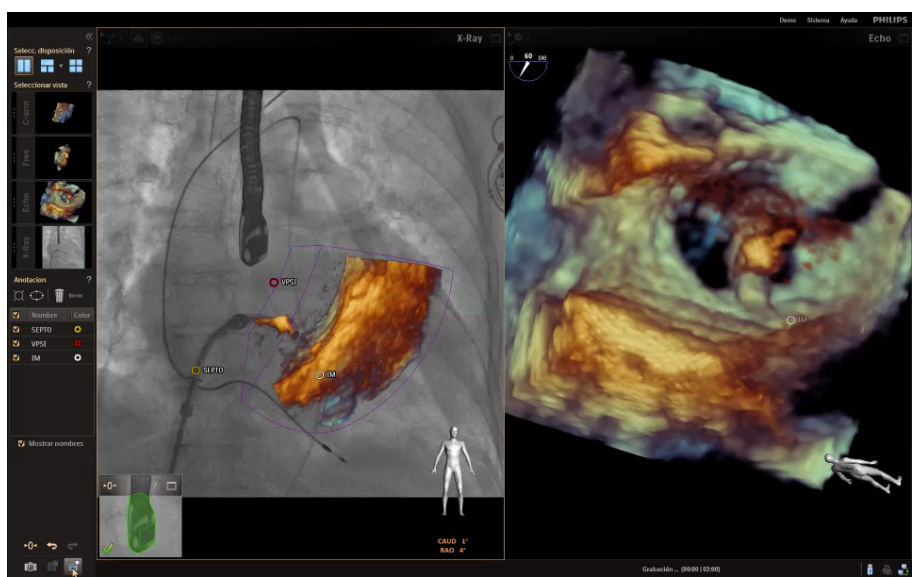
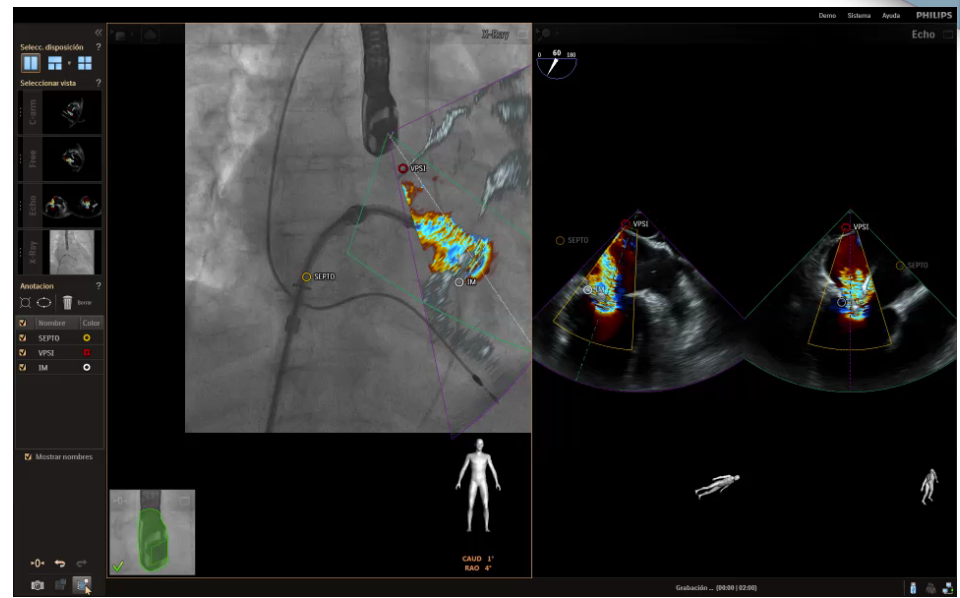


TEE is a MUST

- MiRg > Moderate ? : **YES**
- Severe calcification I? : NO
- Severe leaflet movement restriction ? : NO
- Flail ? : NO

High likelihood of success

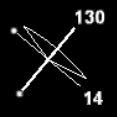
- Previous surgery ? : NO
- Thrombus ? : NO
- Mitral Stenosis ? : NO
- Can we see ALL TEE images of mitral valve ? : **YES**



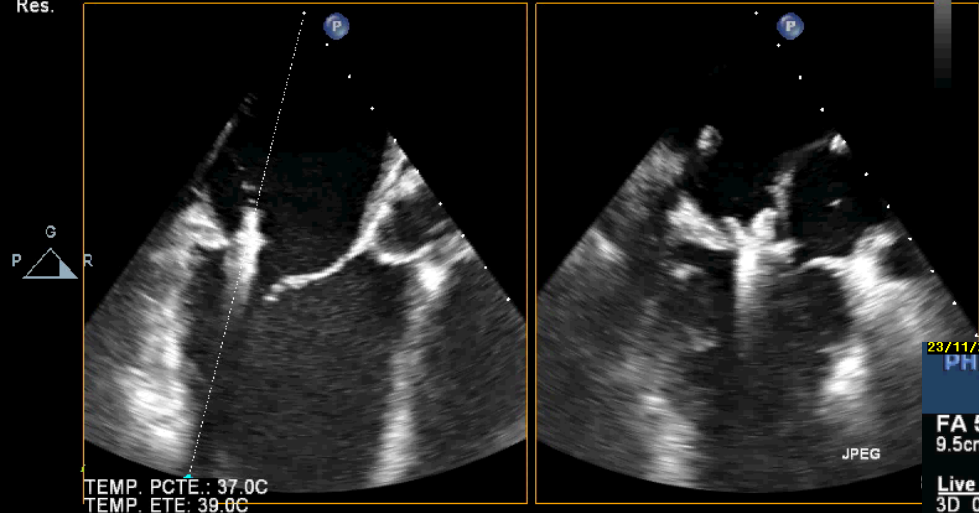


FA 36Hz
12cm

xPlane
69%
69%
50dB
P Des.
Res.



M4



TEMP. PCTE.: 37.0C
TEMP. ETE: 39.0C

23/11/2010 09:15
PHILIPS

1945160

23/11/2010 11:38:35 TIs0.2 JPEG CR 10:1 MI 0.5

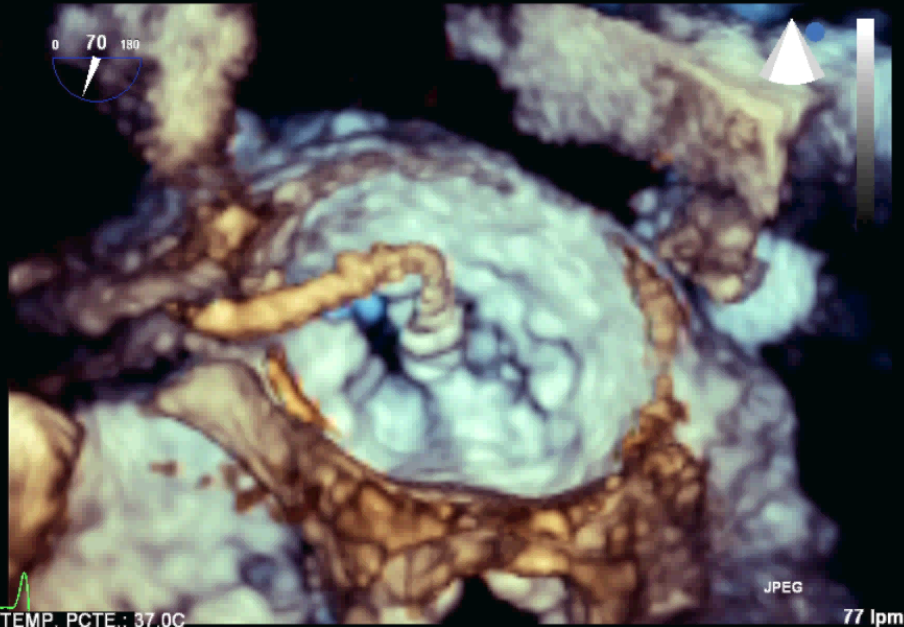
X7-2t/ETE

FA 5Hz
9.5cm

Live 3D
3D 0%
3D 2dB
Res.



M4



TEMP. PCTE.: 37.0C
TEMP. ETE: 39.5C

77 bpm



PHILIPS

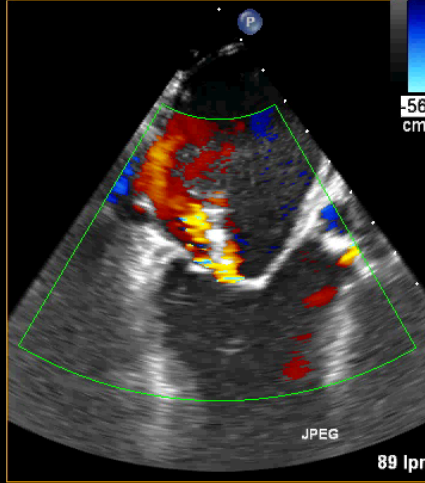
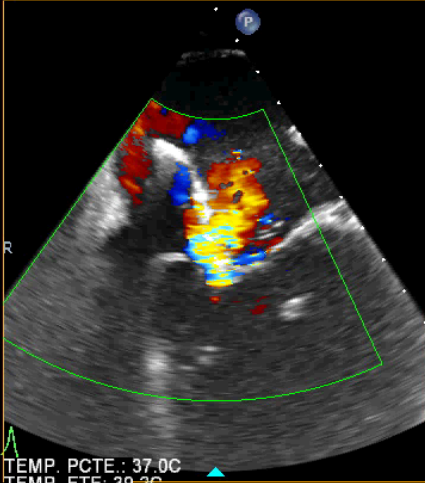
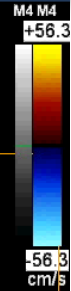
23/11/2010 11:37:52 TIs0.8 MI 0.4

X7-2t/ETE

FA 7Hz
12cm

xPlane
78%
78%
50dB
P Des.
Res.

FC
59%
4.4MHz
FP Alt.
Med.



TEMP. PCTE.: 37.0C
TEMP. ETE: 39.2C

89 lpm



23/11/2010 09:15

PHILIPS

1945160

23/11/2010 11:39:16

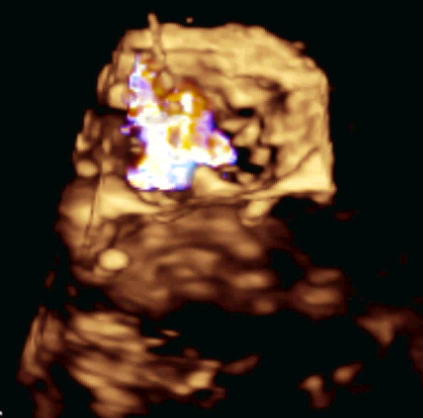
TIs1.0

JPEG CR 16:1
MI 0.4

X7-2t/ETE

FA 18Hz
12cm

Volumen complete 60
3D 0%
3D 2dB
FC
50%
4.4MHz



TEMP. PCTE.: 37.0C
TEMP. ETE: 38.4C

JPEG

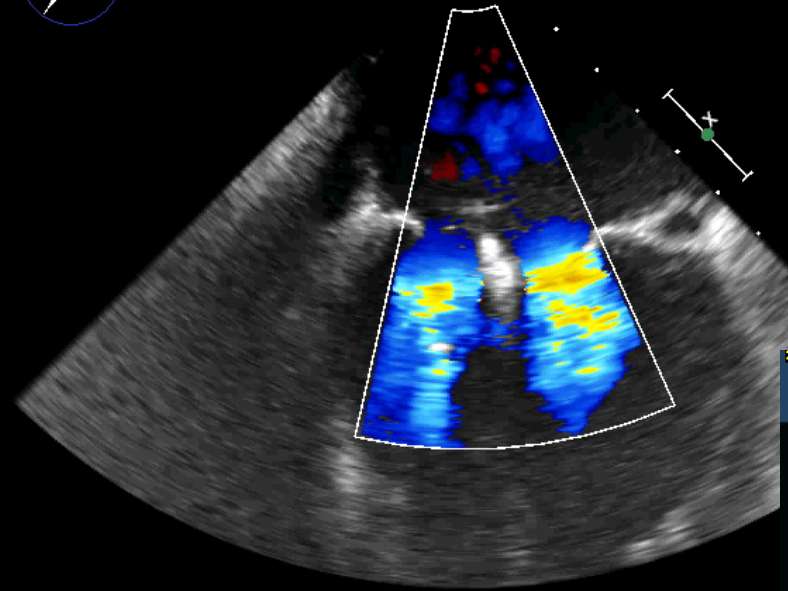
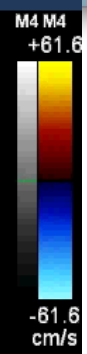
71 lpm



FA 18Hz
11cm

2D
69%
C 50
P Des.
Res.

FC
59%
4.4MHz
FP Alt.
Med.



TEMP. PCTE.: 37.0C
TEMP. ETE: 39.4C

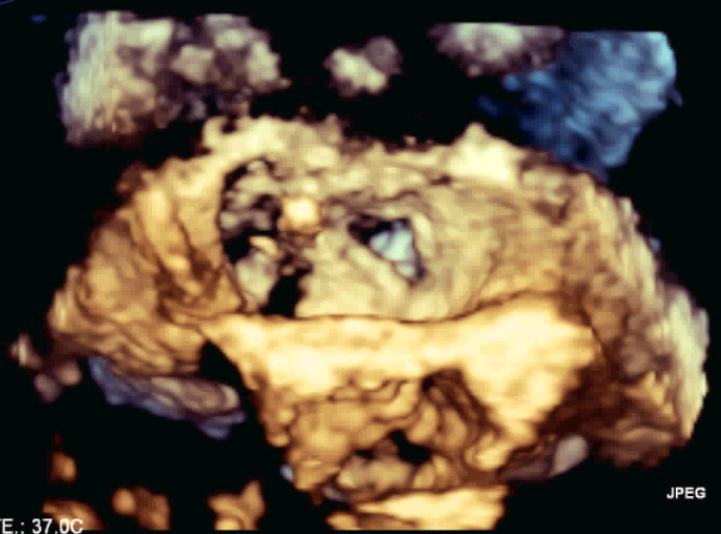
23/11/2010 09:15

1945160

X7-2t/ETE

FA 8Hz
8.9cm

Live 3D
3D 0%
3D 0dB
Res.



TEMP. PCTE.: 37.0C
TEMP. ETE: 39.8C

JPEG

74 lpm

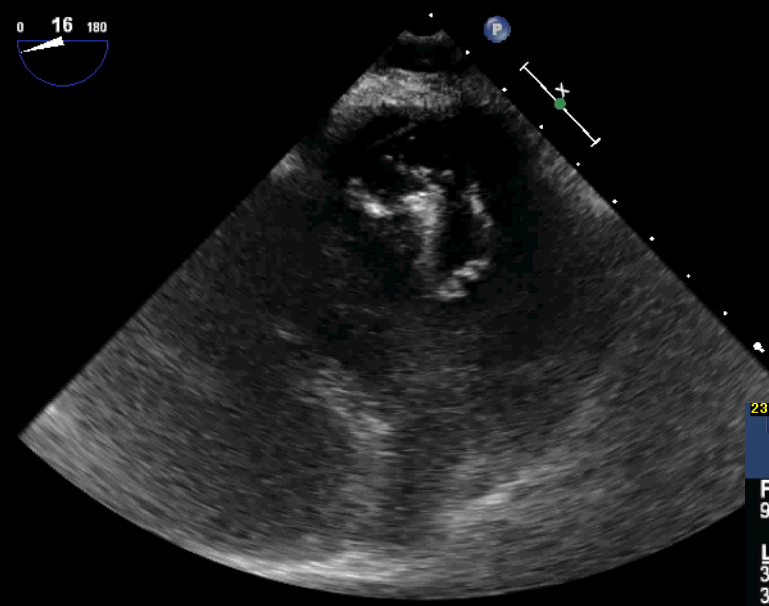
FA 52Hz
11cm

2D
74%
C 50
P Des.
Res.



M4

G
P R



23/11/2010 09:15

PHILIPS

1945160

23/11/2010

13:24:53

TIs0.2

JPEG CR 12:1
MI 0.5

X7-2t/ETE

FA 8Hz
9.1cm

Live 3D
3D 0%
3D 0dB
Res.



M4

TEMP. PCTE.: 37.0C
TEMP. ETE: 38.1C



TEMP. PCTE.: 37.0C
TEMP. ETE: 40.1C

JPEG

77 lpm



Conclusions

- High prevalence of MR. Prognostic impact
- Dynamic behavior, screening and risk stratification with exercise echocardiography
- Importance of severity assessment (3D echo) and anatomical evaluation to decide best therapeutic option
- MitraClip is an alternative safe procedure in selected patients with good short and mid term results. **BUT HT IS A MUST IN SELECTION**