

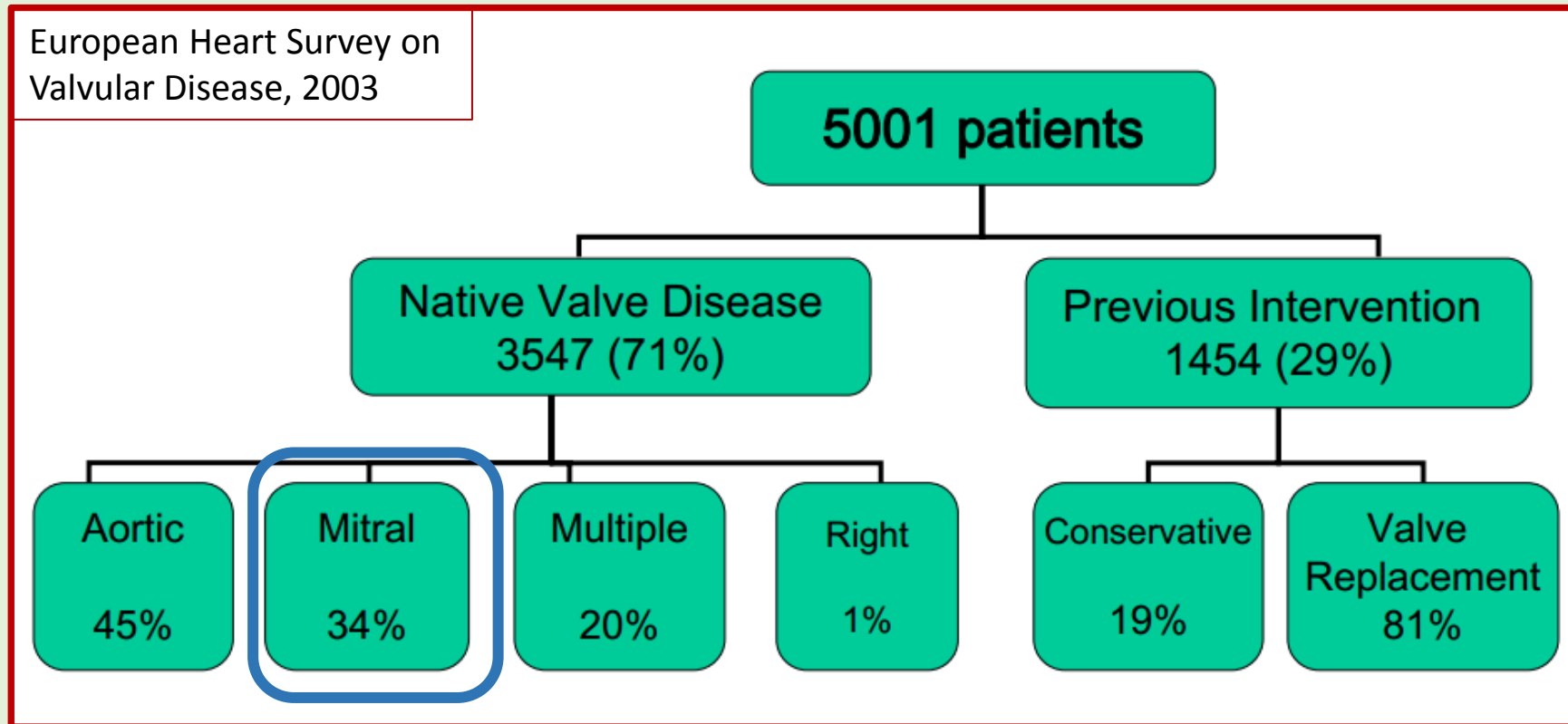
¿En que pacientes y cuando utilizaríamos MITRACLIP?

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Hospital Universitario Virgen de la Victoria. MÁLAGA

INTRODUCCIÓN

La IM es la segunda valvulopatía en frecuencia en Europa...



INTRODUCCIÓN

HF Log Term Registry, 12440 pacientes
(2011-2013)

El 27 % de los pacientes con IC crónica presentaban Regurgitación Mitral (RM)

Al año...	IM	No IM	Valor p
Mortalidad global	11,8	7	<0,0001
Mortalidad cardiovascular	5,8	3,6	<0,0001
Hospitalización	31,2	25,1	<0,0001
Hospitalización IC	15,2	10,3	<0,0001

Datos presentados en Congreso
Europeo Cardiología, Barcelona 2014

INTRODUCCIÓN

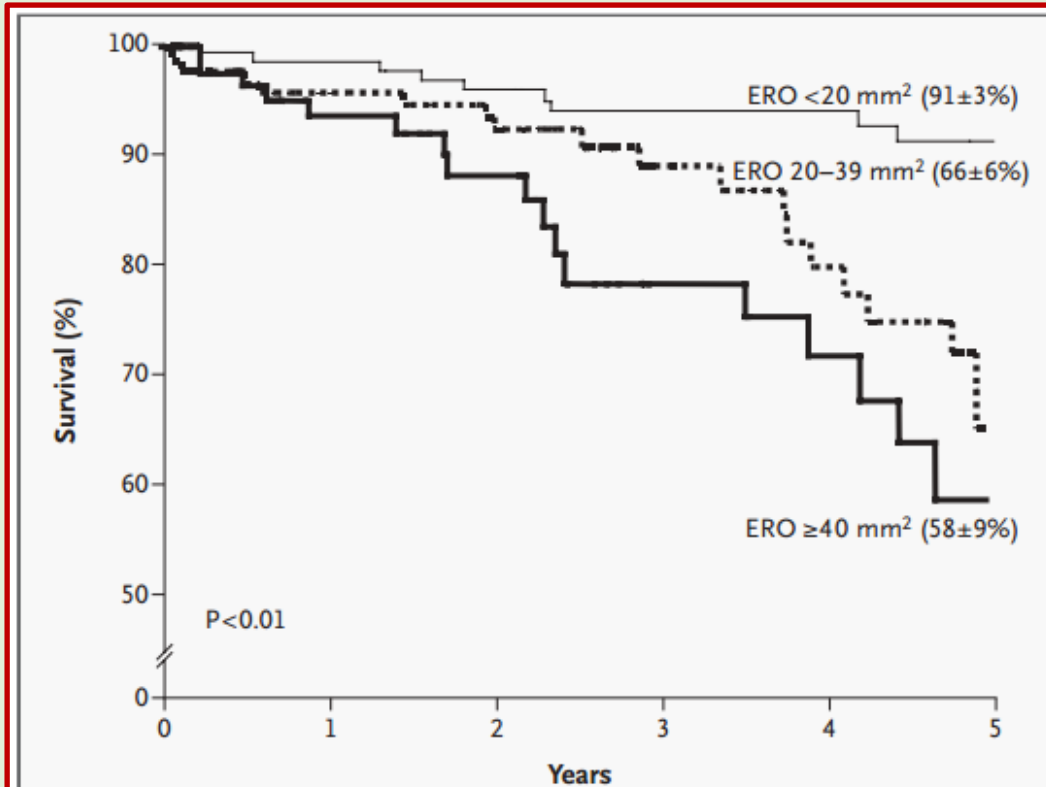
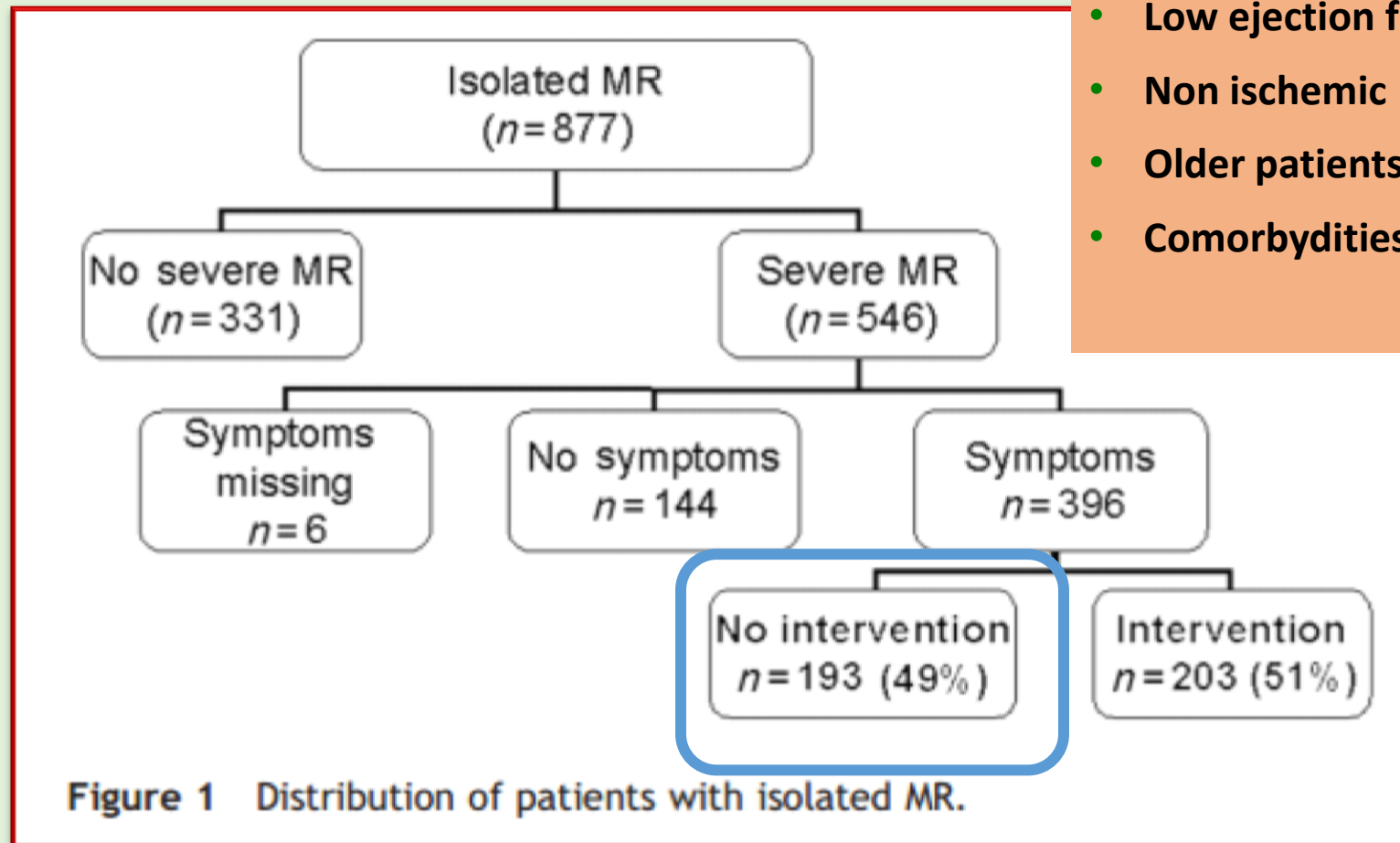


Figure 1. Kaplan–Meier Estimates of the Mean (\pm SE) Rates of Overall Survival among Patients with Asymptomatic Mitral Regurgitation under Medical Management, According to the Effective Regurgitant Orifice (ERO).

Values in parentheses are survival rates at five years.

- Pronóstico desfavorable a medio plazo incluso en pacientes asintomáticos
- Ligado a la severidad (ERO)

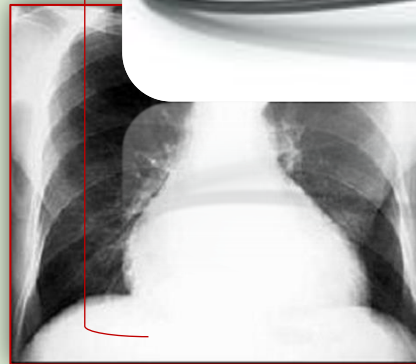
INTRODUCCIÓN



- Low ejection fraction
- Non ischemic
- Older patients
- Comorbidities (Charlson)

PACENTES NO INTERVENIDOS

Dos perfiles
de pacientes
no operados

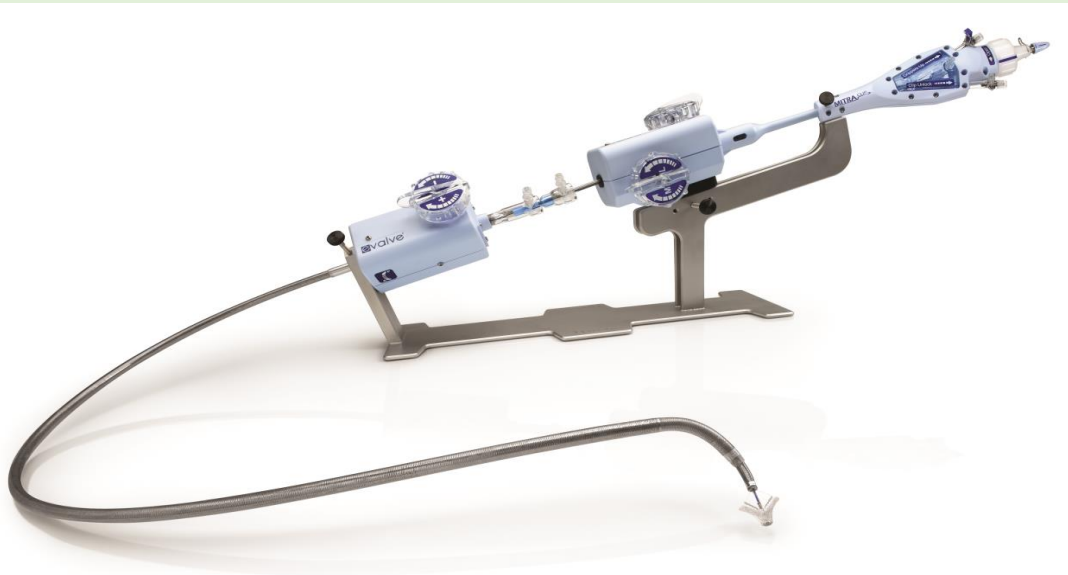
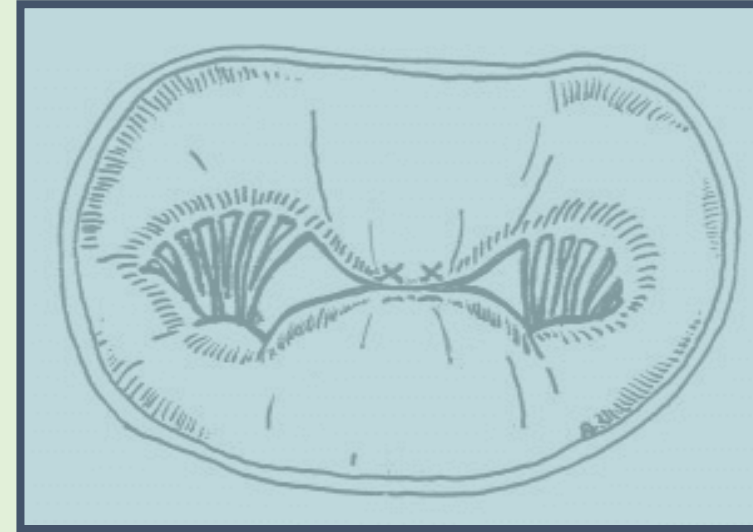


RM funcional: disfunción
ventricular sistólica

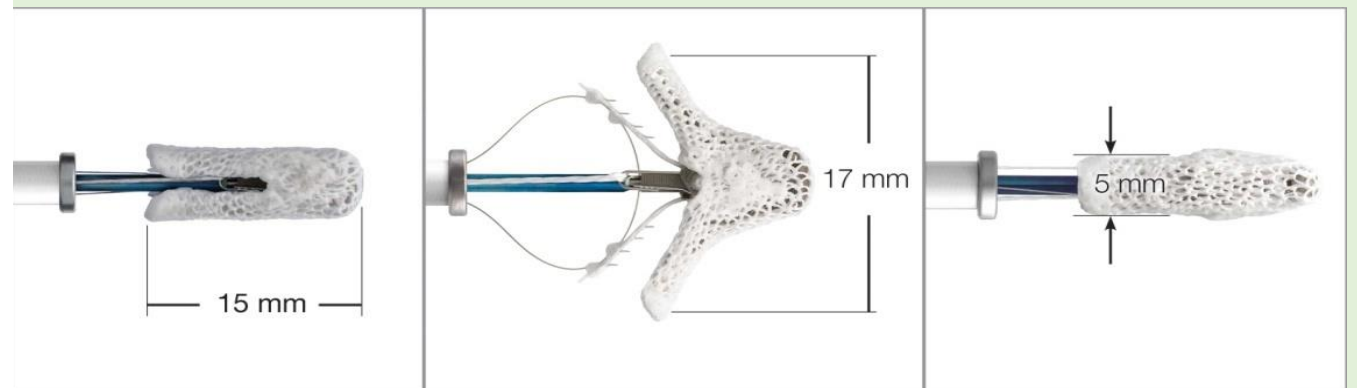


THE MITRACLIP: CONCEPT AND SYSTEM

- Percutaneous repair of the MV
- Beating heart procedure
- Real time MR assessment
- Allow for repositioning of the device



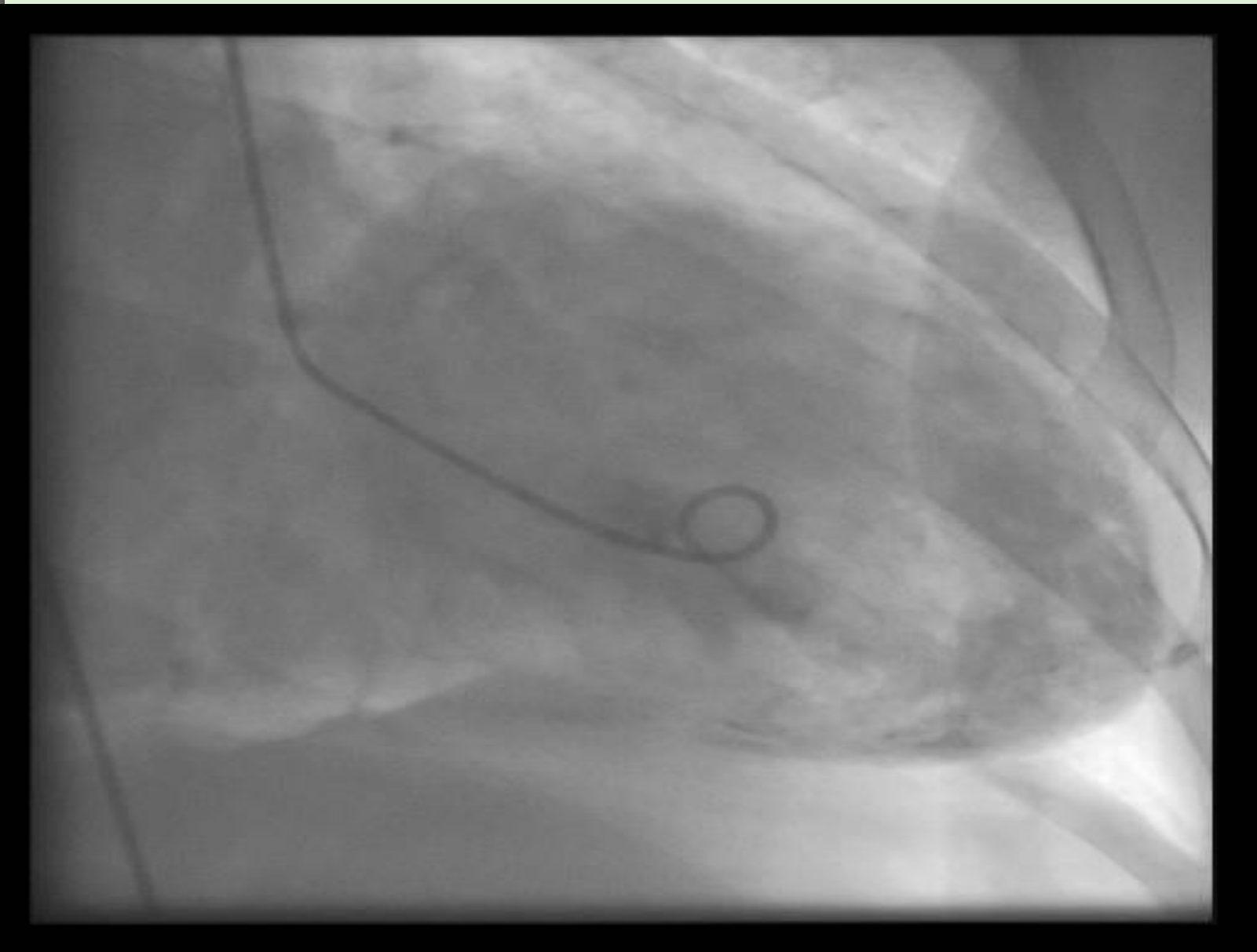
- Double-orifice suture technique developed by Prof. Ottavio Alfieri



Caso 1. IM severa funcional

1. Antecedentes personales

- Varón, 69 años
- HTA
- Diabetes Mellitus en tratamiento con Insulina
- Sin hábitos tóxicos
- Miocardiopatía dilatada idiopática (año 2000) con disfunción ventricular izquierda severa y regurgitación mitral severa
- Portador de DAI-TRC
- Fibrilación auricular permanente



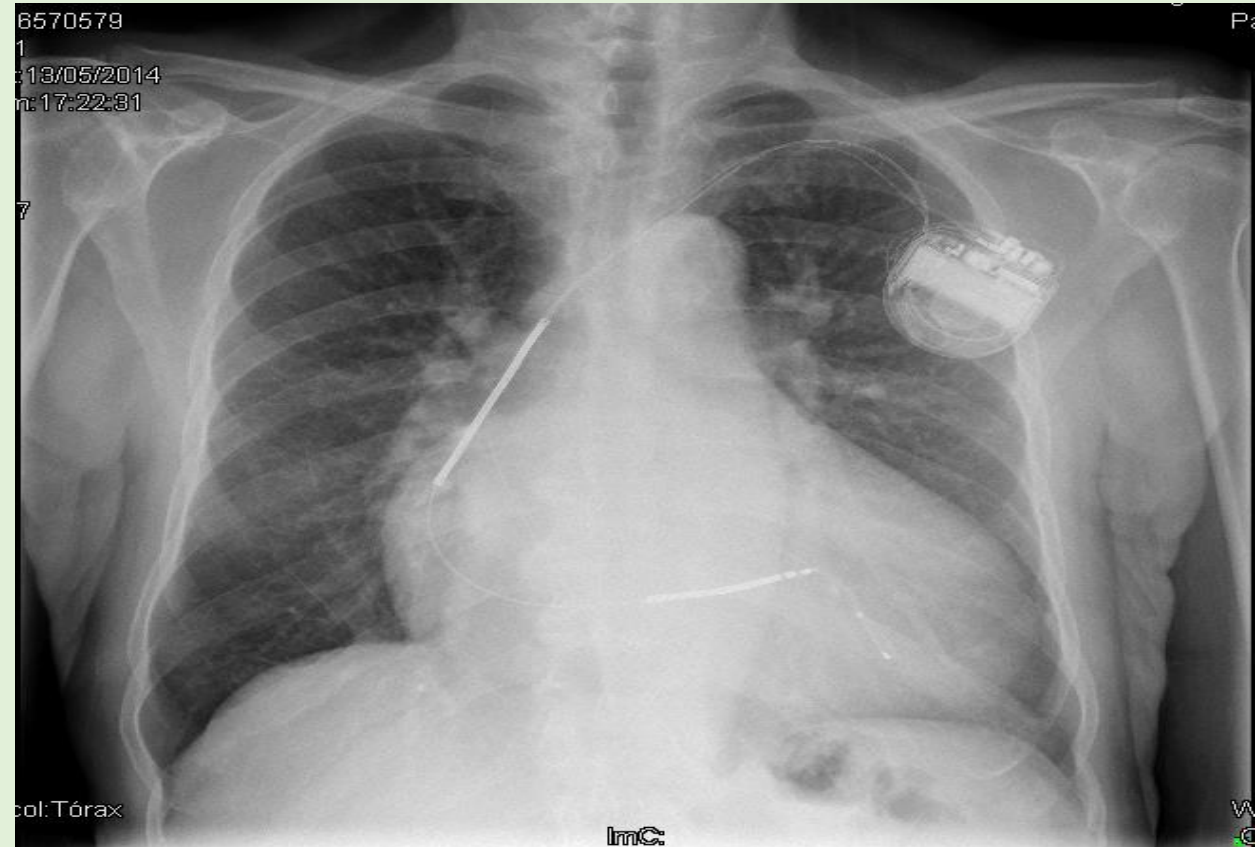
Datos clínicos

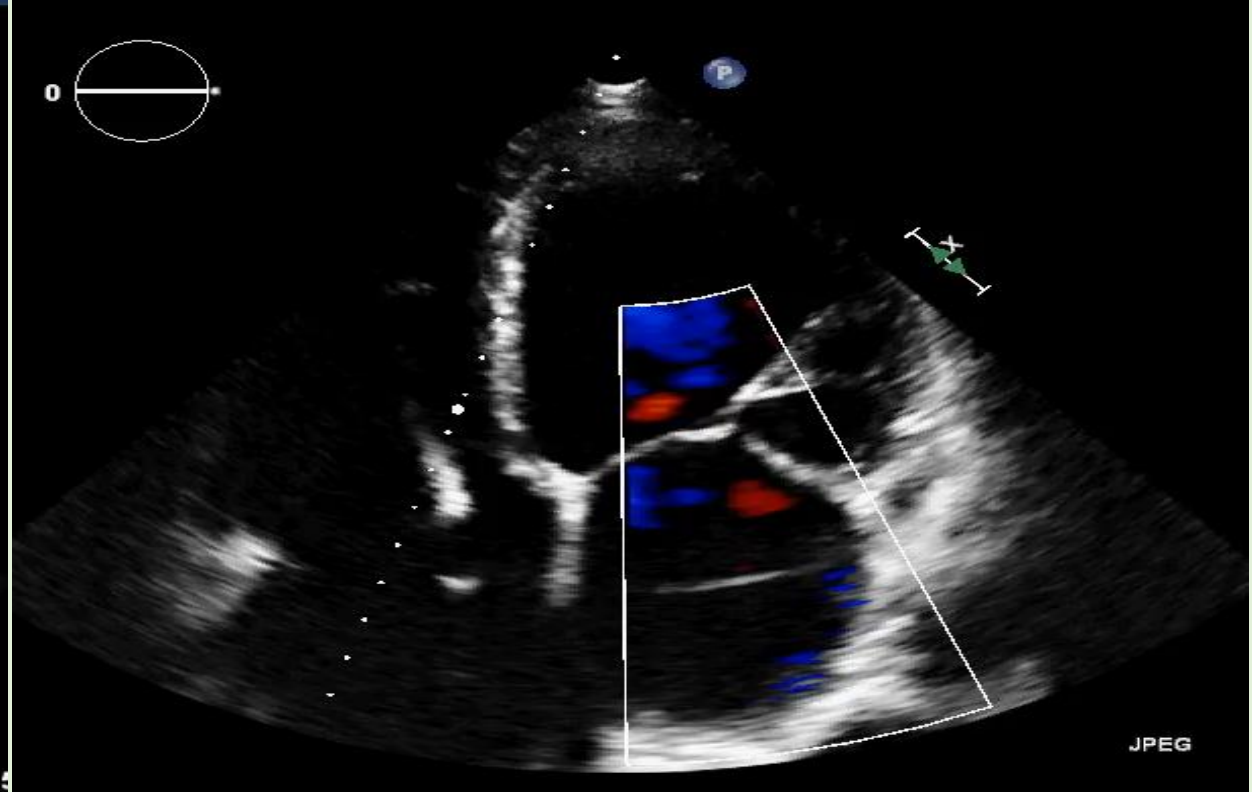
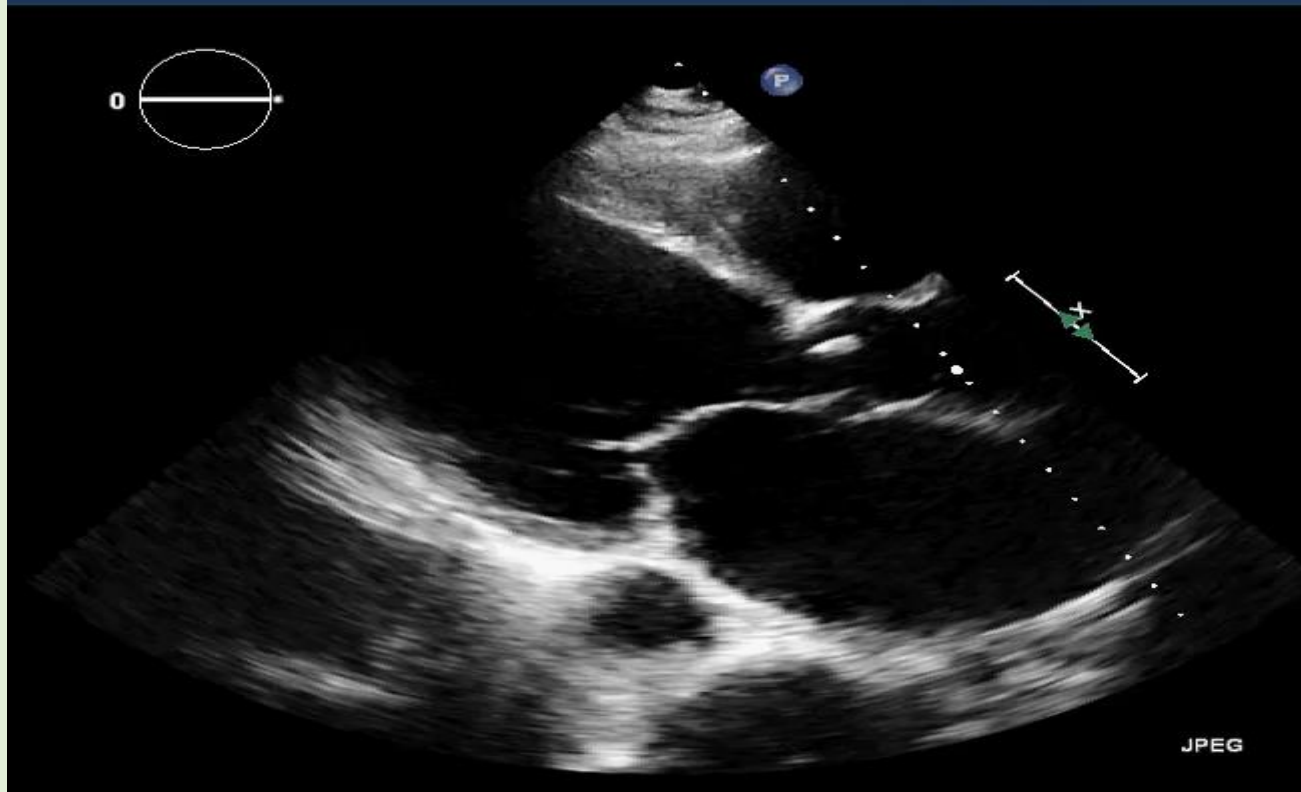
2. Enfermedad actual

- Disnea progresiva en el último mes, al ingreso en CF IV

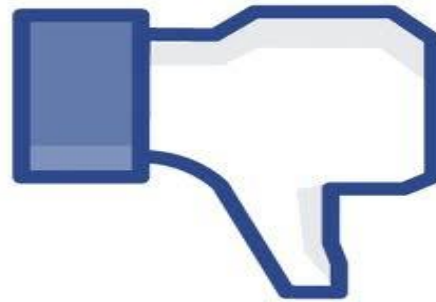
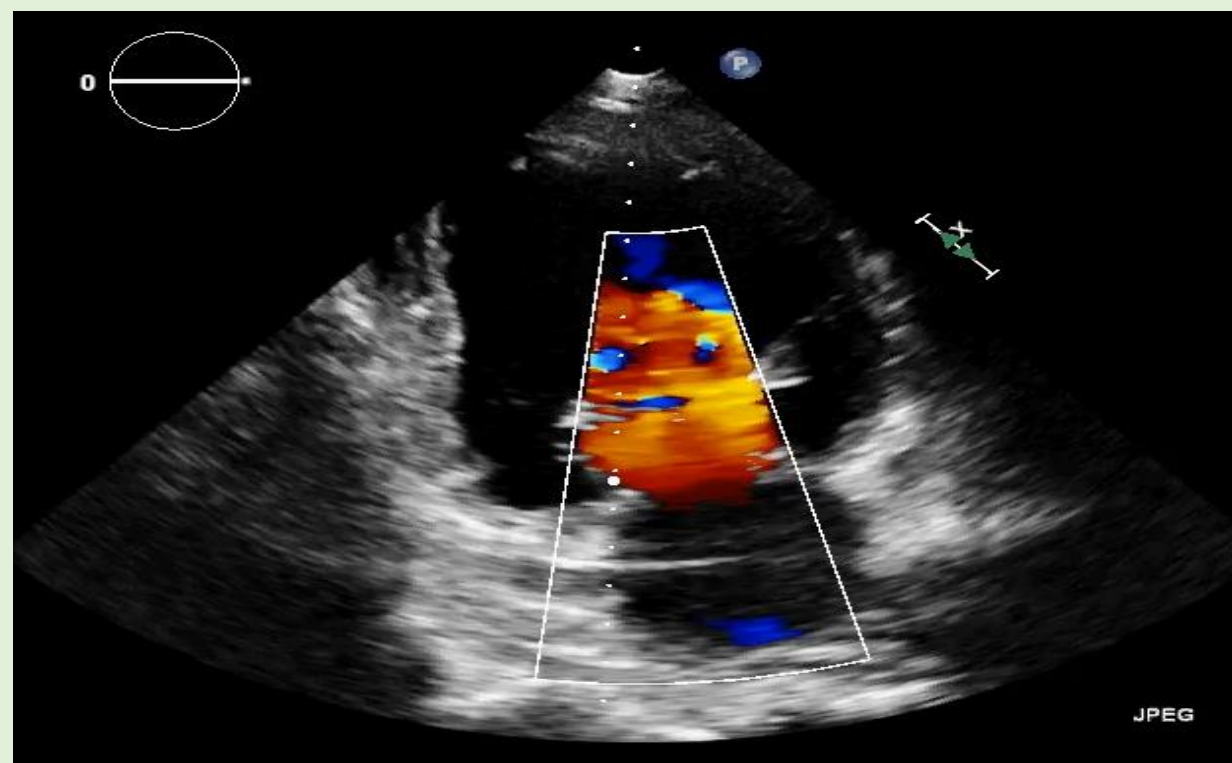
3. Exploración física y pruebas complementarias

- AC: Arrítmico, soplo sistólico apical III/VI
- EEII: Edemas pretibiales con fóvea
- Analítica: NT-proBNP 6491 pg/ml, Creatinina 1.4 mg/dl





- Sin calcio
- No engrosados
- Flexibles
- Movilidad
- Longitud velos
- Area (5,7 cm²)



- Escasa coaptación
- Profundidad de coaptación
- Amplio jet

Cirugía de la I.M.

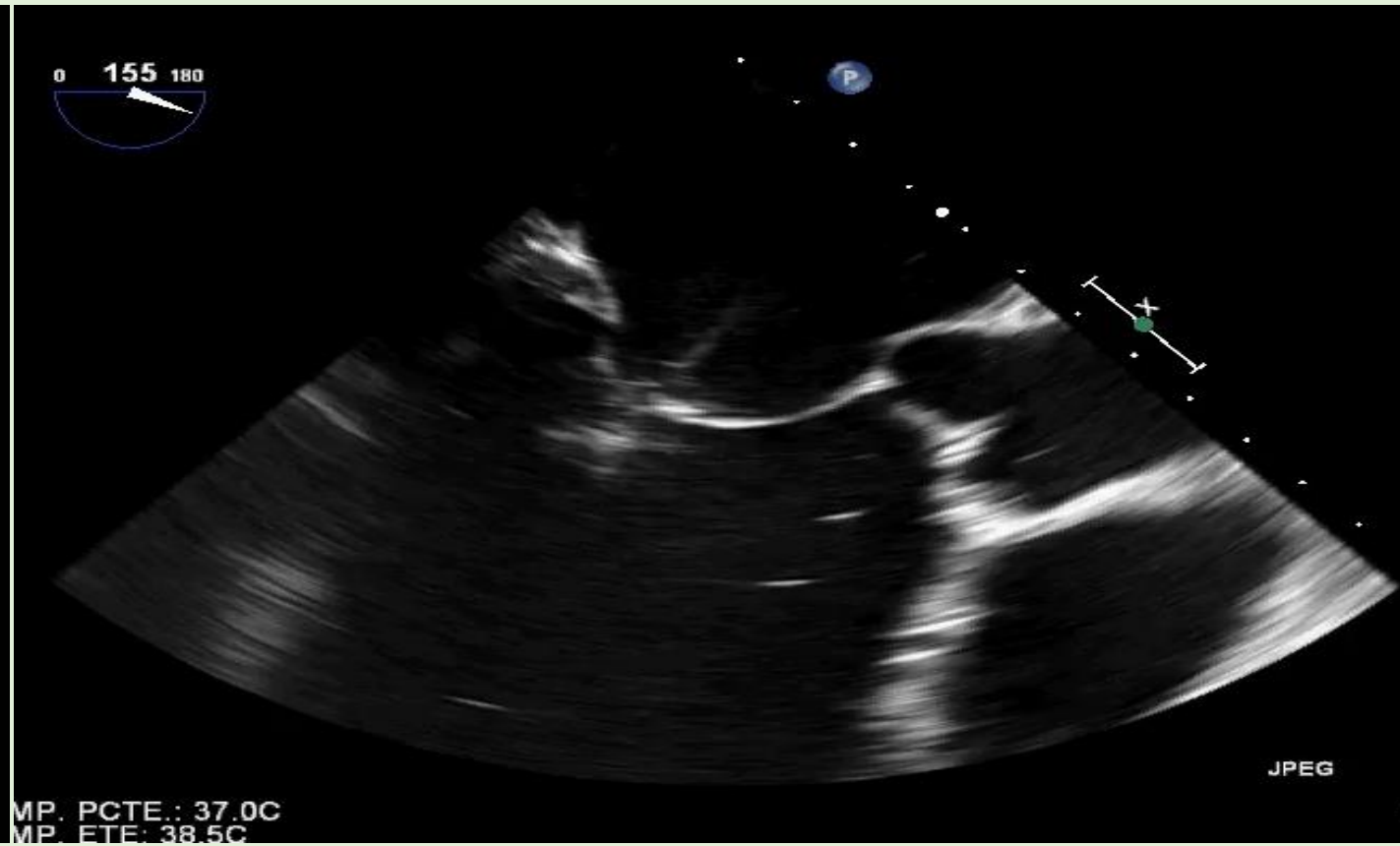
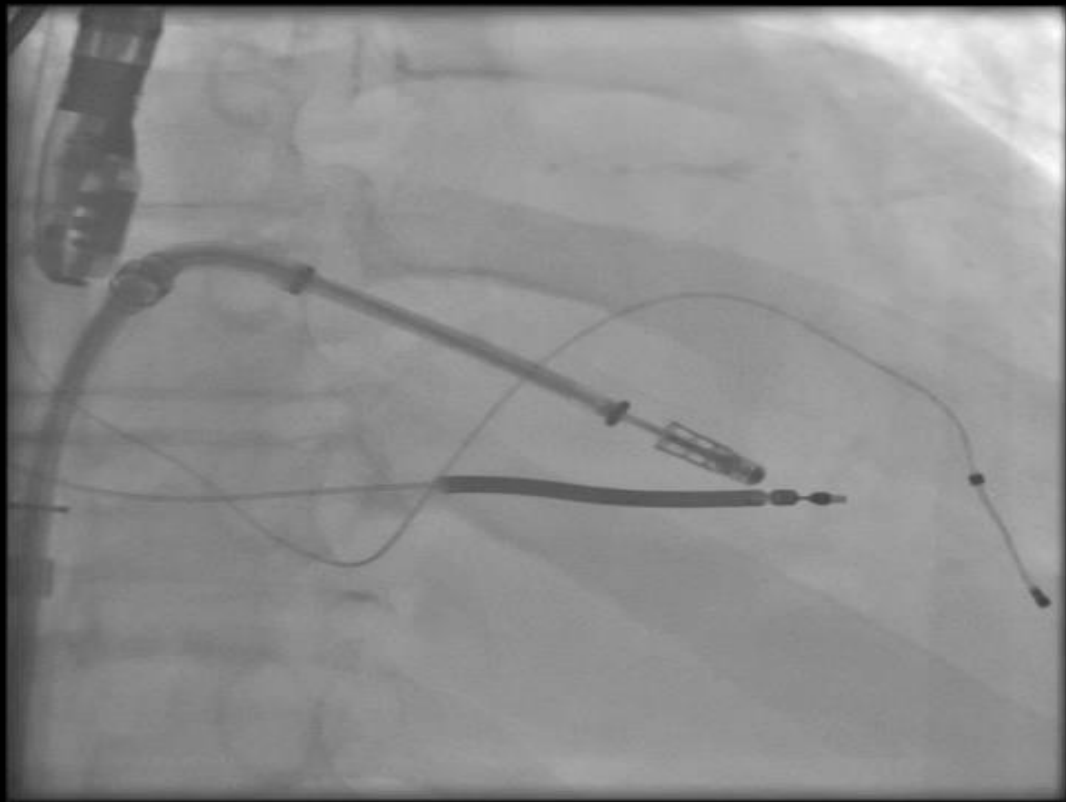
Recomendaciones en INSUFICIENCIA MITRAL FUNCIONAL:

El tratamiento médico es preferido, o al menos utilizado como la primera elección, antes de considerar la cirugía.¹

La cirugía es evitada con frecuencia, pues no hay beneficio claro en la mortalidad a medio/largo plazo.^{2,3,4} La mortalidad quirúrgica es mayor (6-10%).^{5,6}

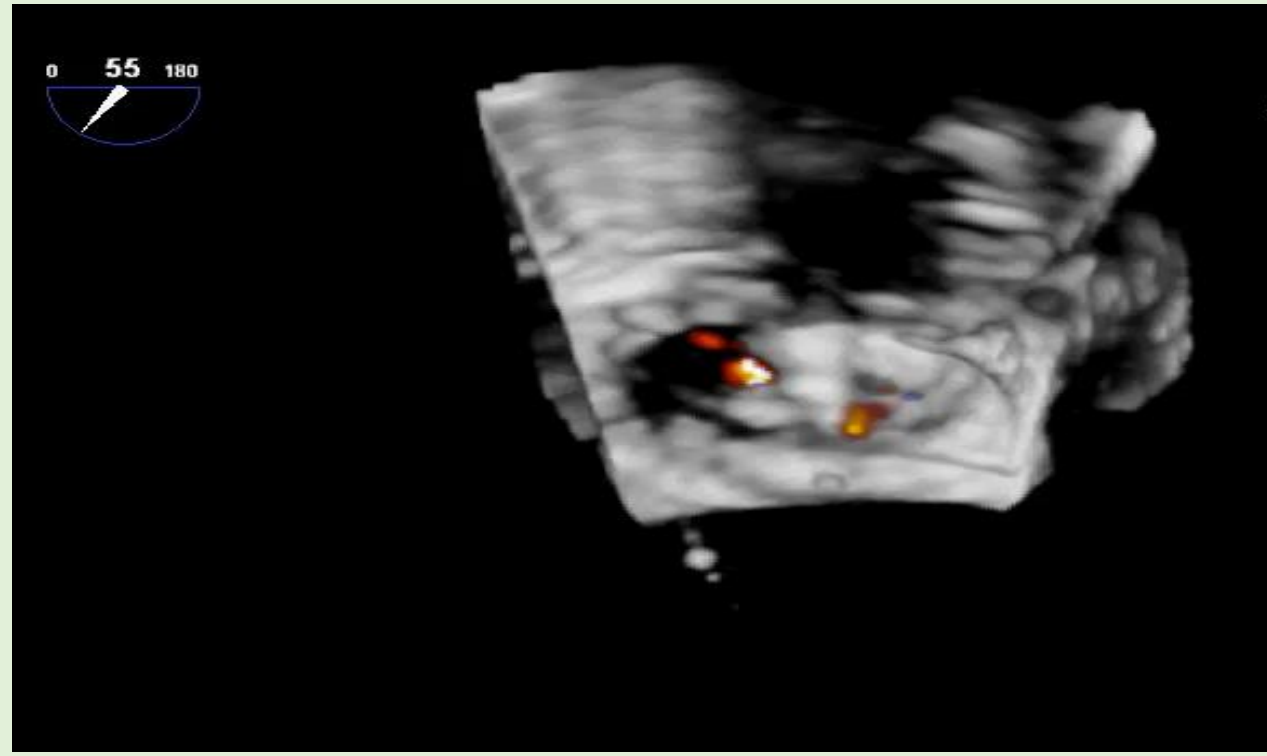
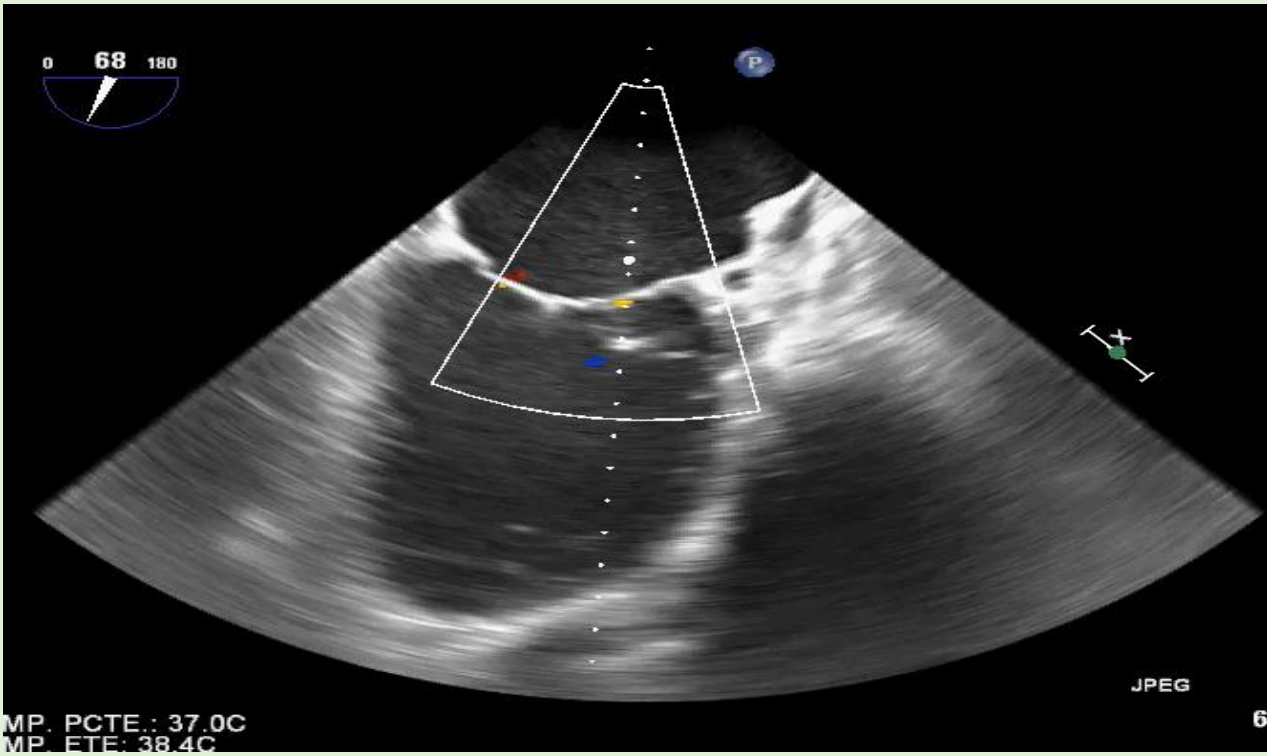
	Class ^a	Level ^b
Surgery is indicated in patients with severe MR ^c undergoing CABG, and LVEF >30%.	I	C
Surgery should be considered in patients with moderate MR undergoing CABG. ^d	IIa	C
Surgery should be considered in symptomatic patients with severe MR, LVEF >30%.	IIa	C
Surgery may be considered in patients with severe MR, LVEF >30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have low comorbidity, when revascularization is not indicated.	IIb	C

Tras la revascularización mas de ¾ de los pacientes continúan con IM moderada o grave



0 155 180
MP. PCTE : 37.0C
MP. ETE: 38.5C

JPEG

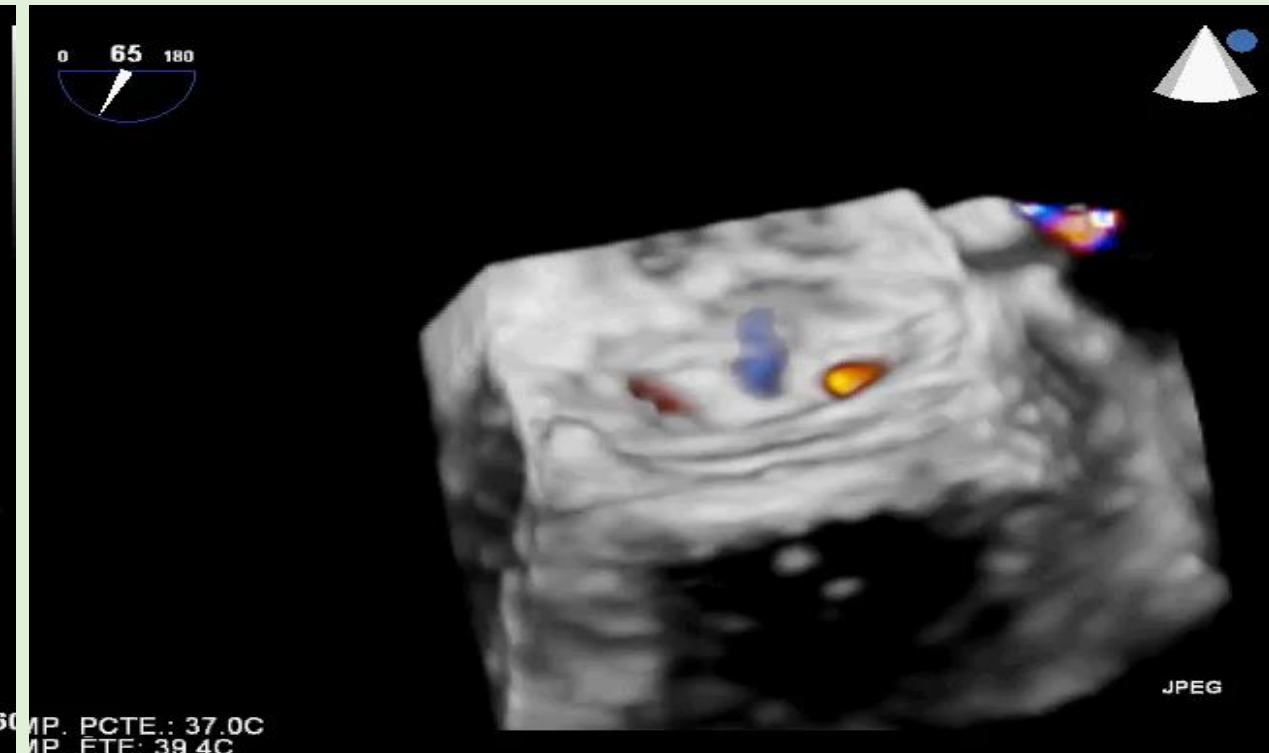
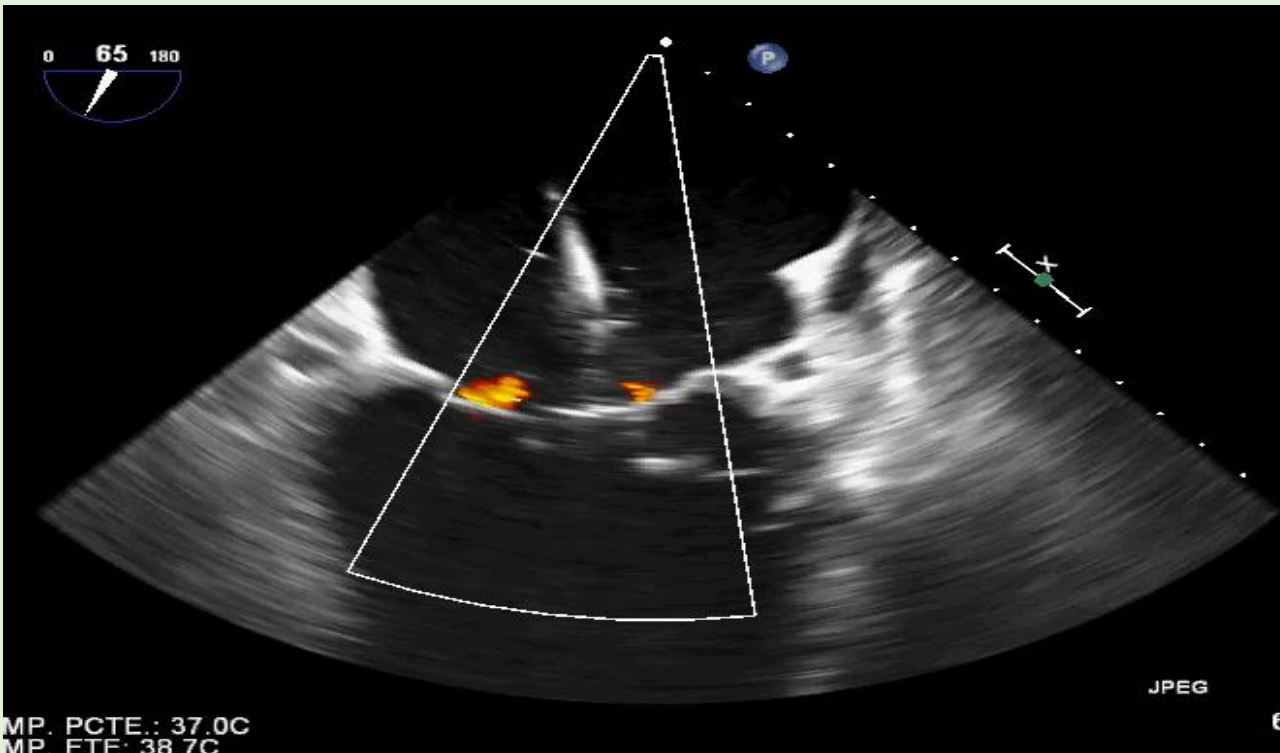




EMP. PCTE.: 37.0C
EMP. ETE: 38.0C

JPEG

60 Ipr



Evolución

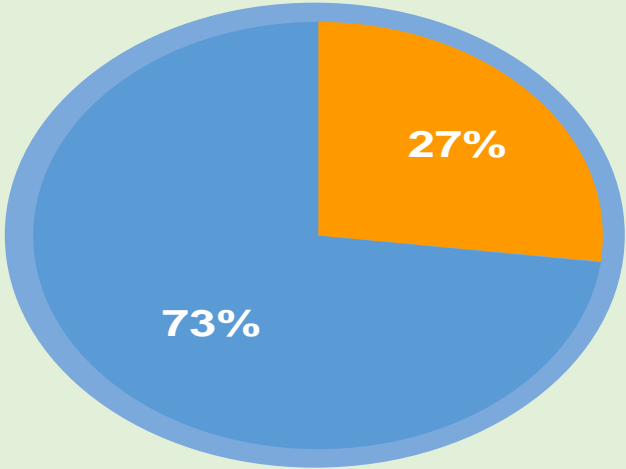
- Al alta:
 - Doble clip mitral normoposicionado (Gradiente medio 3 mm Hg)
 - IM ligera
 - HTP severa
 - Mejoría de CF
 - NT-proBNP 2869 pg/ml, creatinina 0.9 mg/dl
- 2 meses
 - Doble clip mitral normoposicionado (gradiente medio de 2.1 mm Hg)
 - IM leve
 - HTP moderada
 - CF II

MitraClip Therapy

Broad Spectrum of Experience

EVEREST II

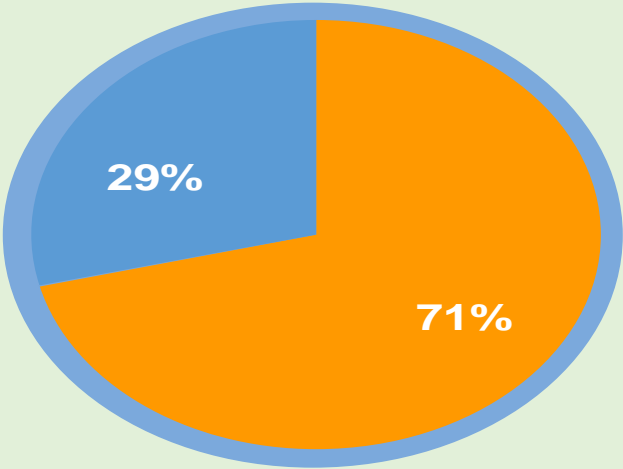
(Randomized Controlled Trial)



- 279 patients
- Device time – 156 minutes
- Implant rate – 87%

EVEREST II

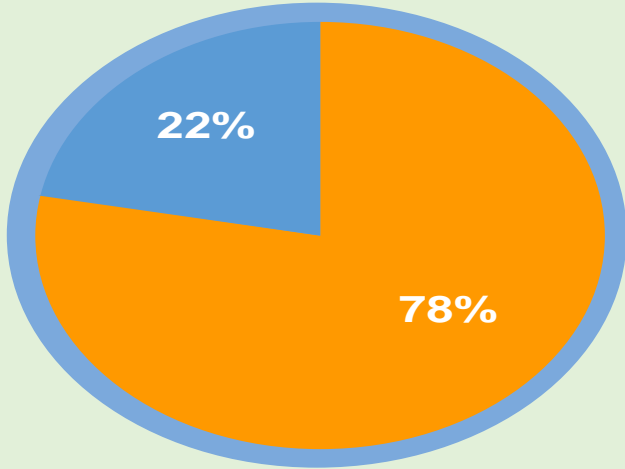
(High Risk Cohort[^])




- 211 patients
- Device time – 128 minutes
- Implant rate – 95%

ACCESS EU

(Europe)



- 529 patients
- Device time – 118 minutes
- Implant rate – 99%

 = DMR

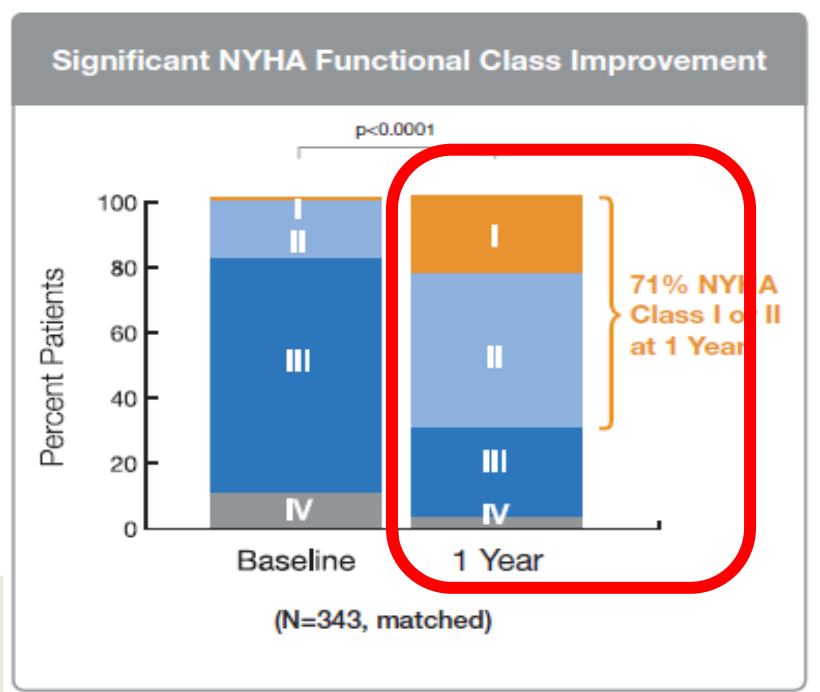
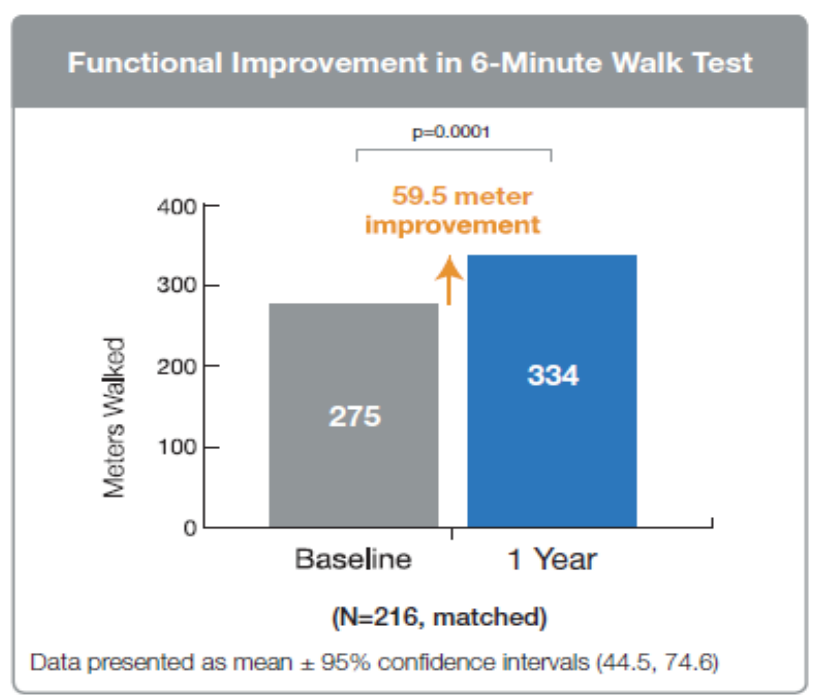
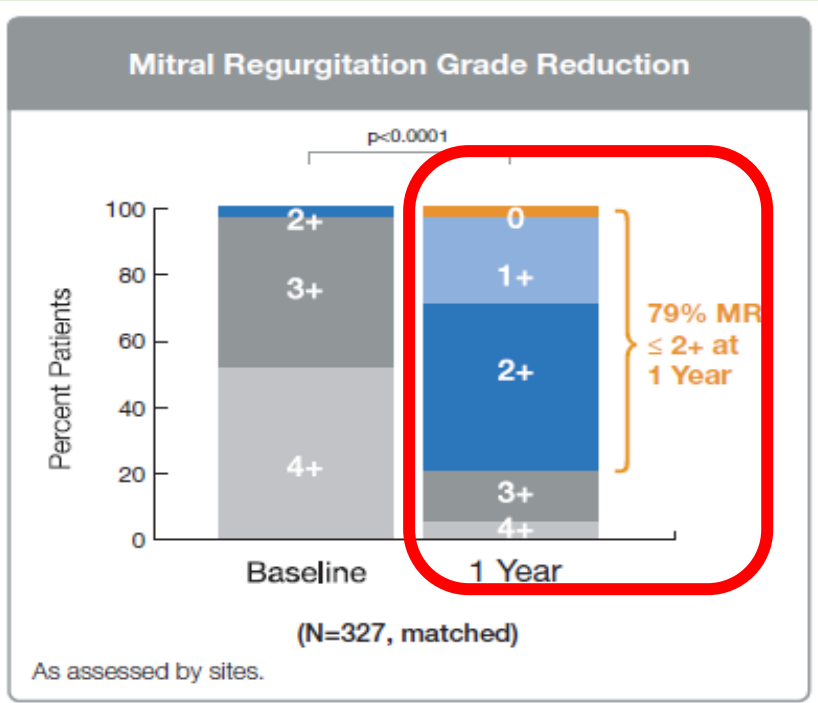
 = FMR



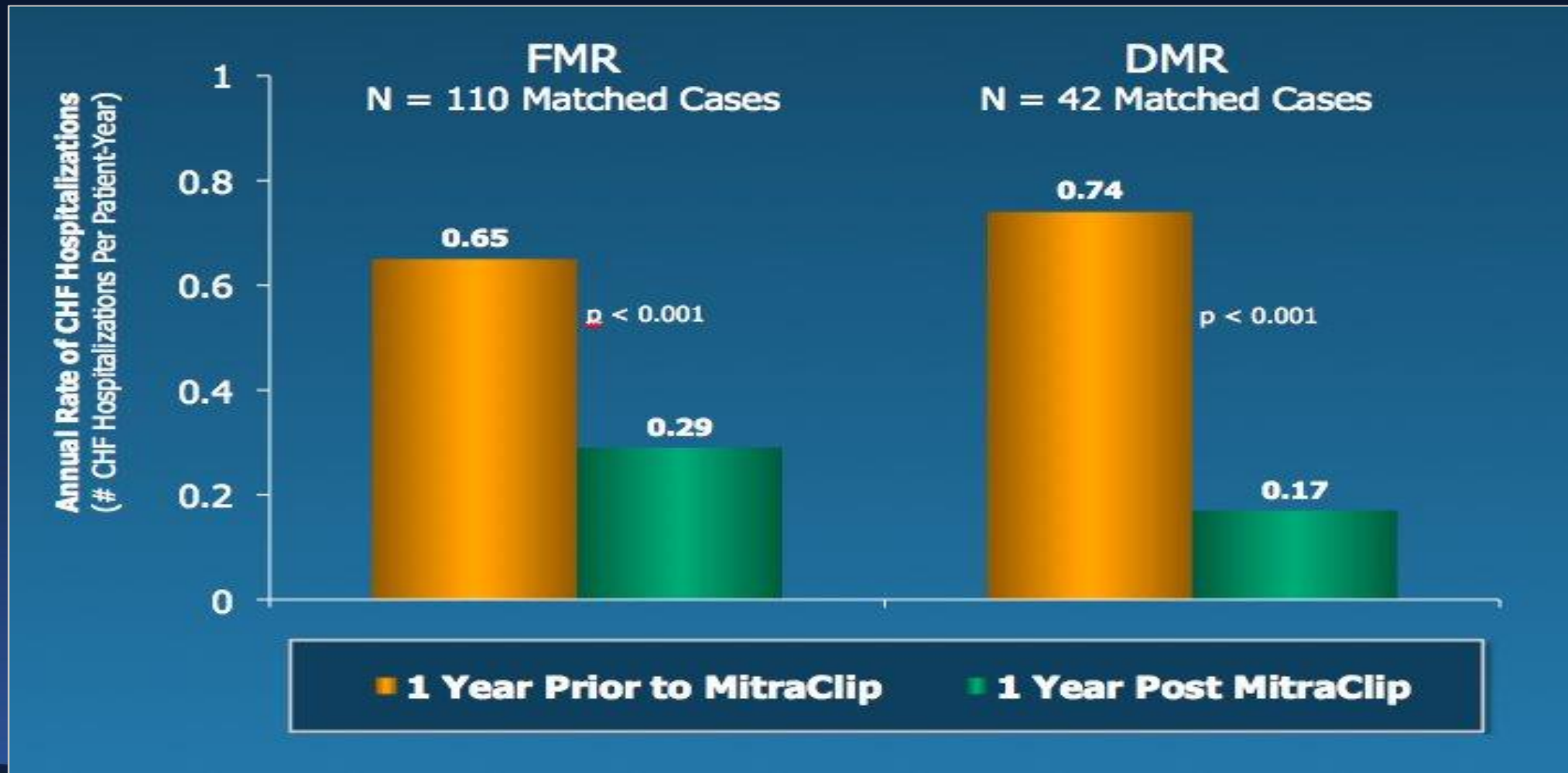
[^] Enrolled by February 28, 2010

Source: Data on file Abbott Vascular, April 12, 2011

ACCESS EU: REAL WORLD CLINICAL EXPERIENCE



Hospitalizations for CHF EVEREST II High Surgical Risk Cohort



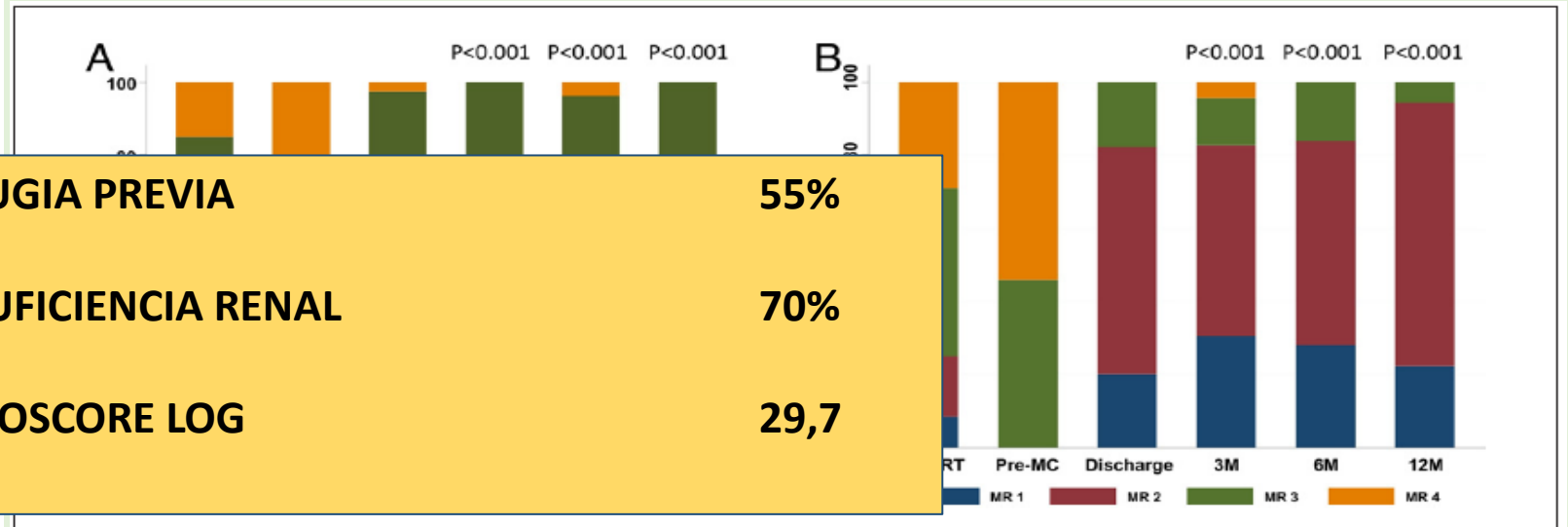
RESULTADOS DEL TRATAMIENTO

PERMIT CARE: MITRACLIP IN CRT NON RESPONDERS

- Prospectively conducted survey reporting outcomes in 51 symptomatic patients with FMR classified as “CRT nonresponders” who remained at NYHA III or IV and were treated with the MitraClip

Table 1 Demographic Characteristics (N = 51)

Age (yrs)	70.26 ± 9.16
Male	44 (86)
Etiology (%)	
Ischemic cardiomyopathy	37 (73)
Nonischemic cardiomyopathy	14 (27)
Previous interventions (%)	
CABG or PCI	24 (47)
Valve surgery	4 (8)
New York Heart Association functional class	
III	32 (63)
IV	17 (33)
Previous CRT-D (%)	47 (92)
CRT-P	4 (8)
Comorbidities	
Previous stroke	8 (16)
Diabetes	11 (22)
COPD	15 (29)
Renal insufficiency	36 (70)
Logistic EuroSCORE	29.7 ± 19.4
STS score	13.9 ± 14.6
Laboratory findings	
Creatinine (μmol/l)	149.5 ± 63.2
Sodium (mmEq/l)	139.74 ± 4.2
Potassium (mmEq/l)	4.25 ± 0.41
Hemoglobin (g/dl)	12.34 ± 1.5
NT-proBNP (ng/l)	3,702 (1,794–8,148)
Month since CRT	32.9 ± 25.7



CIRUGIA PREVIA 55%

INSUFICIENCIA RENAL 70%

EUROSCORE LOG 29,7

“Treatment with the MitraClip in CRT non-responders was feasible, safe, and demonstrated improved functional class, increased LVEF, and reduced ventricular volumes in about 70% of these study patients.”

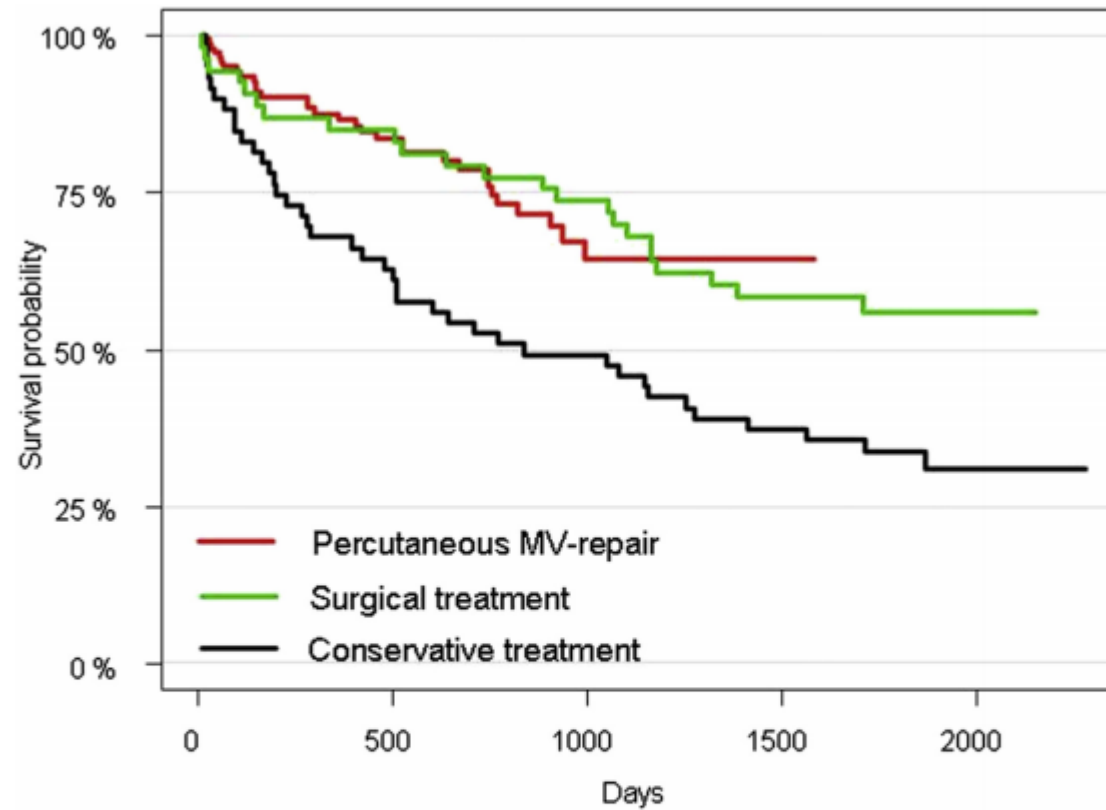
Survival of Transcatheter Mitral Valve Repair Compared With Surgical and Conservative Treatment in High-Surgical-Risk Patients

Martin J. Swaans, MD,* Annelies L. M. Bakker, MD,* Arash Alipour, MD, PhD,* Martijn C. Post, MD, PhD,* Johannes C. Kelder, MD, PhD,* Thom L. de Kroon, MD,† Frank D. Eefting, MD,* Benno J. W. M. Rensing, MD, PhD,* Jan A. S. Van der Heyden, MD, PhD*

- 139 pacientes de alto riesgo quirúrgico tratados con Mitraclip hasta abril 2013
- Comparado con cohorte de pacientes de alto riesgo quirúrgico previa a la introducción de Mitraclip (2009)

TABLE 1 Baseline Characteristics

Characteristic	MitraClip	High-Risk Surgery	Conservative Treatment	p Value
No.	139	53	59	
Age, yrs	74.6 ± 9.4	70.2 ± 9.5	71.7 ± 9.6	0.009
Male, %	94 (67.6)	27 (50.9)	32 (54.2)	0.051
BMI, kg/m ²	25.9 ± 4.7	26.7 ± 5.3	26.5 ± 4.5	0.53
LVEF, %	36.8 ± 15.3	43.9 ± 14.4	34.5 ± 16.5	0.003
Log EuroSCORE, %	23.9 ± 16.0	14.2 ± 8.9	18.7 ± 13.2	<0.0001



n at risk:	139	78	20	2	0
	53	44	39	30	7
	59	36	29	22	7

Supervivencia al año %	
Cirugía	85,8
Mitraclip	85,2
T. médico	67,7

FIGURE 1 Kaplan-Meier Survival Curves

After 1-year follow-up, the transcatheter mitral valve (MV) repair and the high-risk surgery group had similar survival rates (85.8% vs. 85.2%, respectively), whereas only 67.7% of the patients in the conservatively treated group survived. The same trend was observed during the second and third year of follow-up.

MITRACLIP

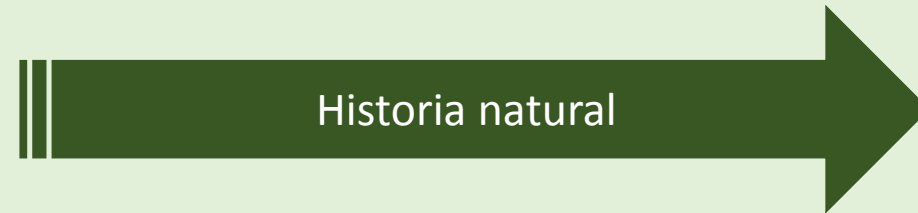
RESULTADOS ACTUALES

TABLE 1 Baseline Characteristics

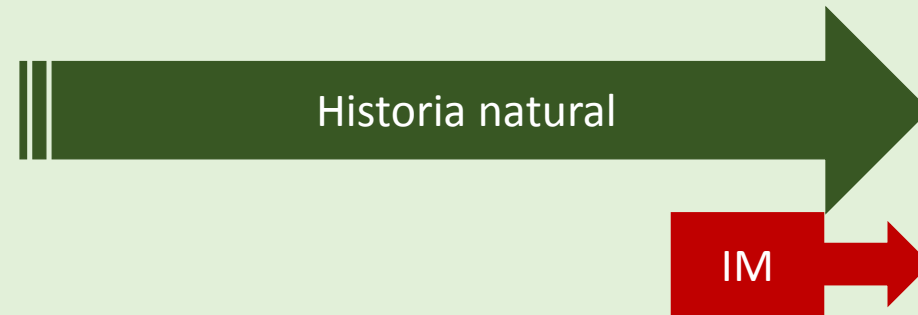
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Log EuroSCORE, %	23.9 ± 16.0	14.2 ± 8.9	18.7 ± 13.2	<0.0001
Comorbidities				
Hypertension	74 (53.2)	28 (52.8)	25 (42.4)	0.35
Diabetes mellitus	32 (23)	10 (18.9)	17 (28.8)	0.46
Atrial fibrillation	74 (53.2)	27 (50.9)	24 (40.7)	0.27
COPD	31 (22.3)	15 (28.3)	19 (32.2)	0.31
Known CAD	89 (64.0)	28 (52.8)	45 (76.3)	0.03
Previous				0.004
History of				0.002
History of				<0.0001
History of				<0.0001
Renal insufficiency*	55 (39.6)	9 (17.0)	18 (30.5)	0.01
Pulmonary hypertension†				0.005
No	15 (10.8)	11 (20.8)	14 (23.7)	
Moderate	99 (71.2)	28 (52.8)	26 (44.1)	
Severe	25 (18.0)	14 (26.4)	19 (32.2)	
NYHA functional class				0.74
II	16 (11.5)	6 (11.3)	8 (13.6)	
III	91 (65.5)	38 (71.7)	35 (59.3)	
IV	32 (23.0)	9 (17.0)	16 (27.1)	
Etiology				0.005
FMR	107 (77.0)	31 (58.5)	48 (81.3)	
DMR	25 (18.0)	17 (32.1)	4 (6.8)	
Mixed	7 (5.0)	5 (9.4)	7 (11.9)	

IM 3+/4+ = 6,6%

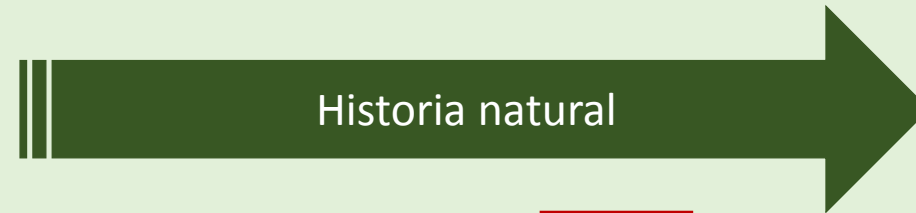
Criterios clínicos: etiología funcional



Criterios clínicos: etiología funcional



Crterios clnicos: etiología funcional



IM

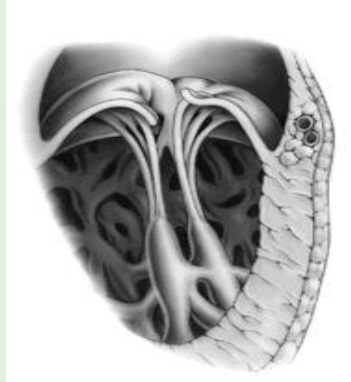


Criterios clínicos: etiología funcional



Mitral Regurgitation Disease Progression

DEGENERATIVE
Valve Disease



FUNCTIONAL
Heart Disease



Mitral
Regurgitation

Volume
Overload

LV
Dysfunction

LV
Dilation

Remodeling

Remodeling



- Patients improve when mitral regurgitation is reduced
- Without intervention progress to heart failure

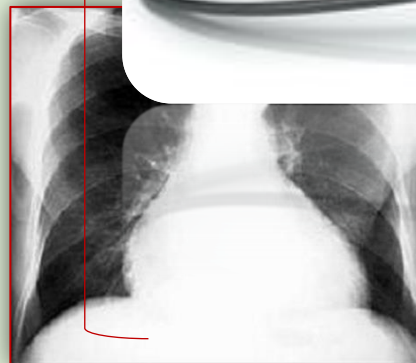
MITRACLIP

INSUFICIENCIA MITRAL FUNCIONAL

	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	LVESD ≤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
Health economics	Assessed	Assessed	-
Follow-up	5 years	2 years	2 years

PACIENTES NO INTERVENIDOS

Dos perfiles
de pacientes
no operados



RM funcional: disfunción
ventricular sistólica

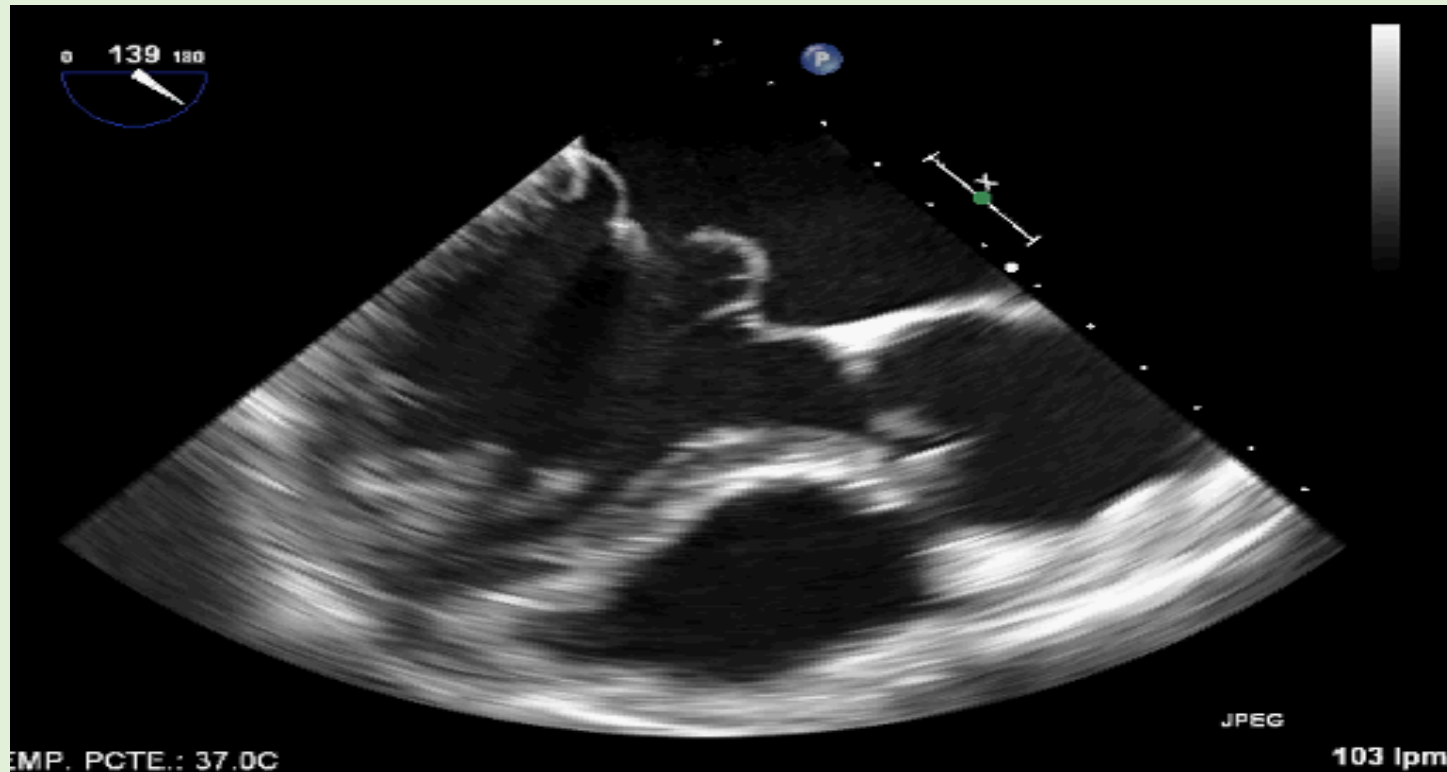
CASO 2. IM DEGENERATIVA.

HISTORIA CLÍNICA

- 38 años,
- Tetralogía de Fallot. Arco aórtico derecho
- Fístula de Watterston en periodo neonatal
- Corrección con parche transanular y ampliacion de TSVD con dos años.
- Pulmón derecho hipoplásico. Estenosis de la rama pulmonar derecha tratada con stent en 2009
- Regurgitación pulmonar severa siendo preciso implante quirúrgico de prótesis biológica Shelhig 21 por dilatación y deterioro de FEVD

ENFERMEDAD ACTUAL

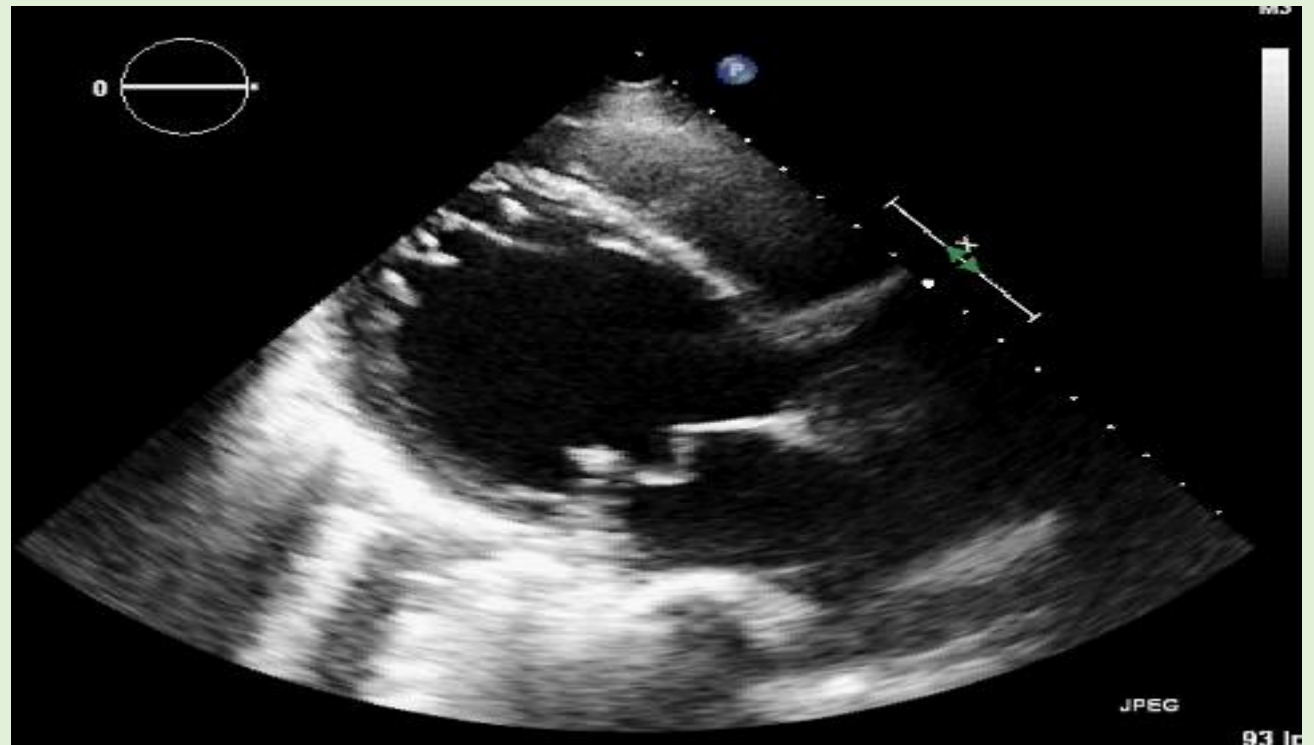
Desarrollo de regurgitación mitral severa pocos meses después de la cirugía de la válvula pulmonar



ENFERMEDAD ACTUAL

Durante los primeros años actitud expectante, hasta observarse progresiva dilatación y disminución de la FEVI. GF II, el paciente autolimita su actividad física

DTS 47 mm
FEVI 49 %



SESIÓN MEDICO QUIRÚRGICA

Se plantean varias opciones:

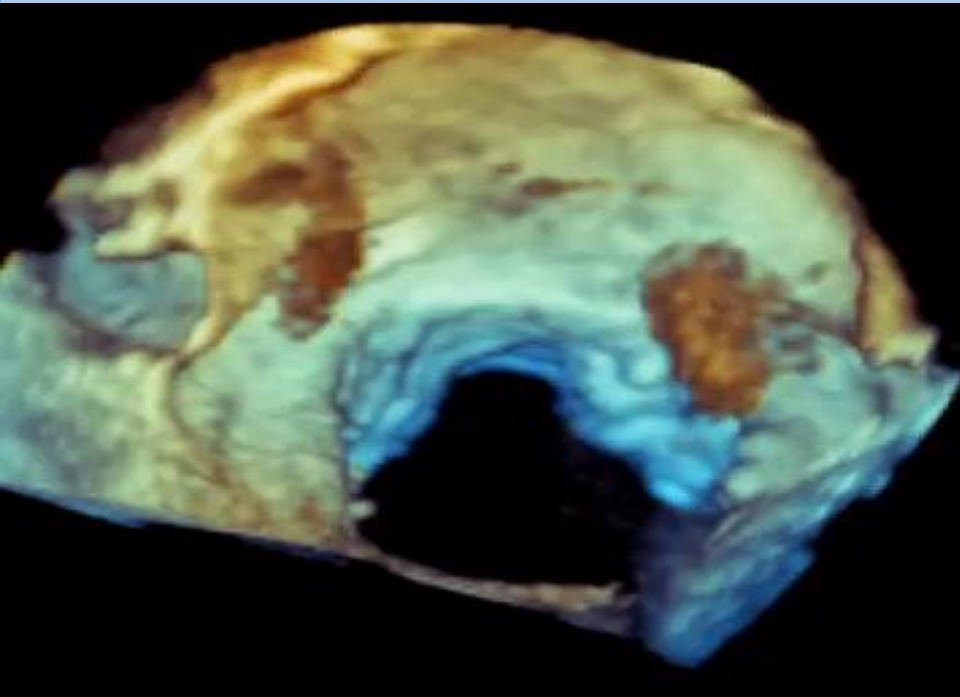
Reparación Quirúrgica (cuarta intervención), riesgo de precisar una prótesis en el futuro (quinta cirugía)

Implante de prótesis mecánica mitral

Intentar tratamiento percutáneo, aunque pueda precisar una prótesis en el futuro

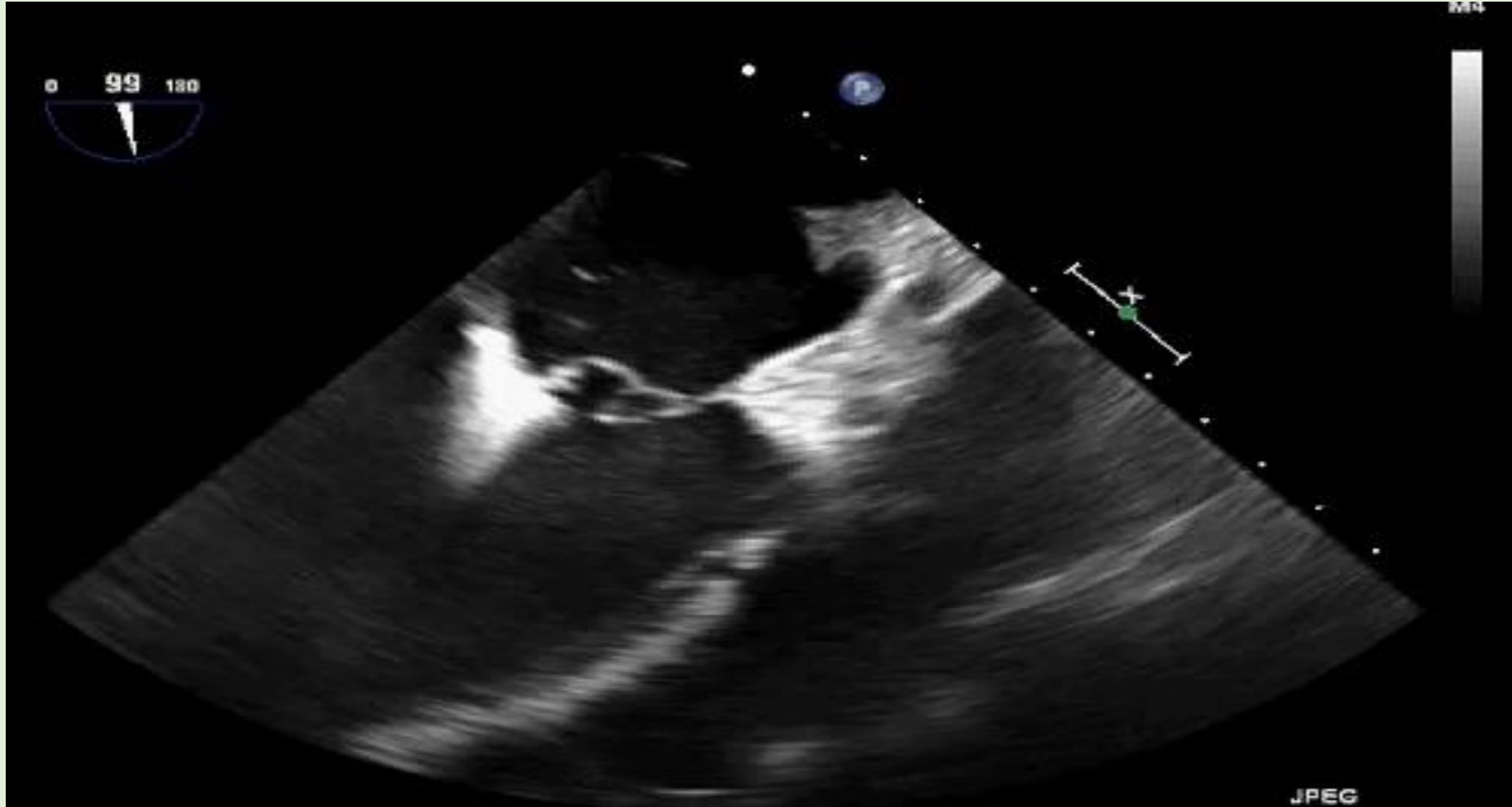
VALORACIÓN ECOCARDIOGRÁFICA

Las valvas no están engrosadas, ausencia de calcio, suficiente cantidad de tejido y buen área valvular.....



..... altura del prolapso, anchura del prolapso

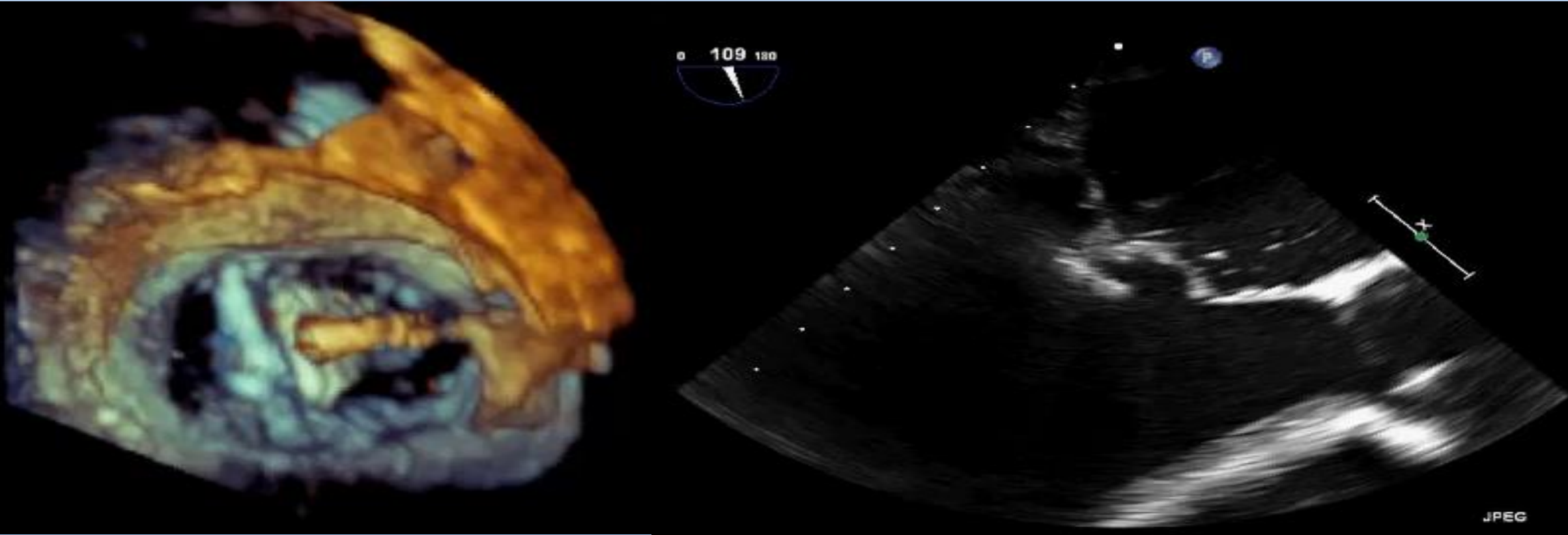
TRATAMIENTO CON MITRACLIP



Implante de dispositivo en segmentos medios de la válvula

TRATAMIENTO CON MITRACLIP

Segundo dispositivo



Grasping del segundo clip, bolo de adenosina

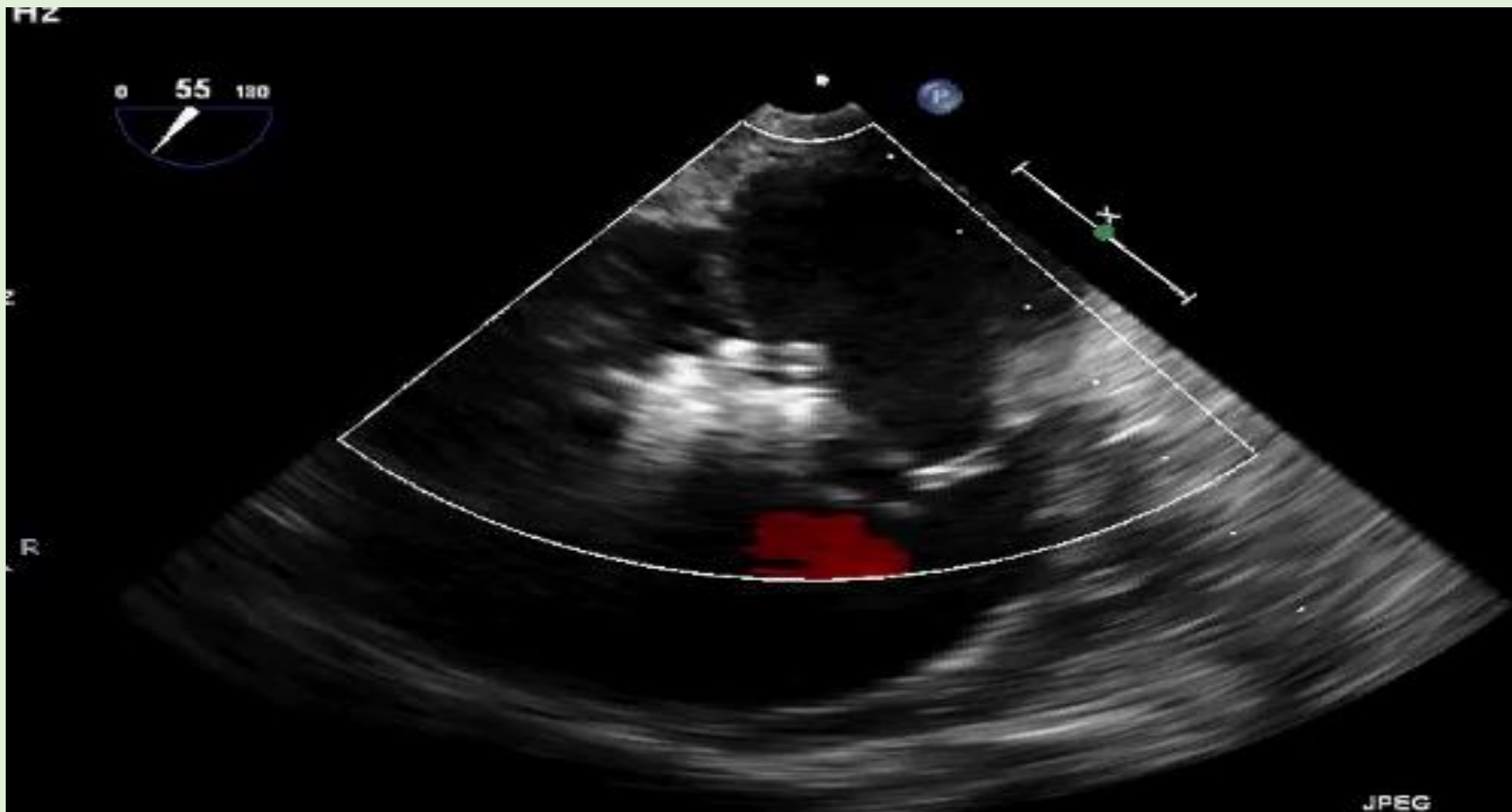
TRATAMIENTO CON MITRACLIP

Tercer dispositivo



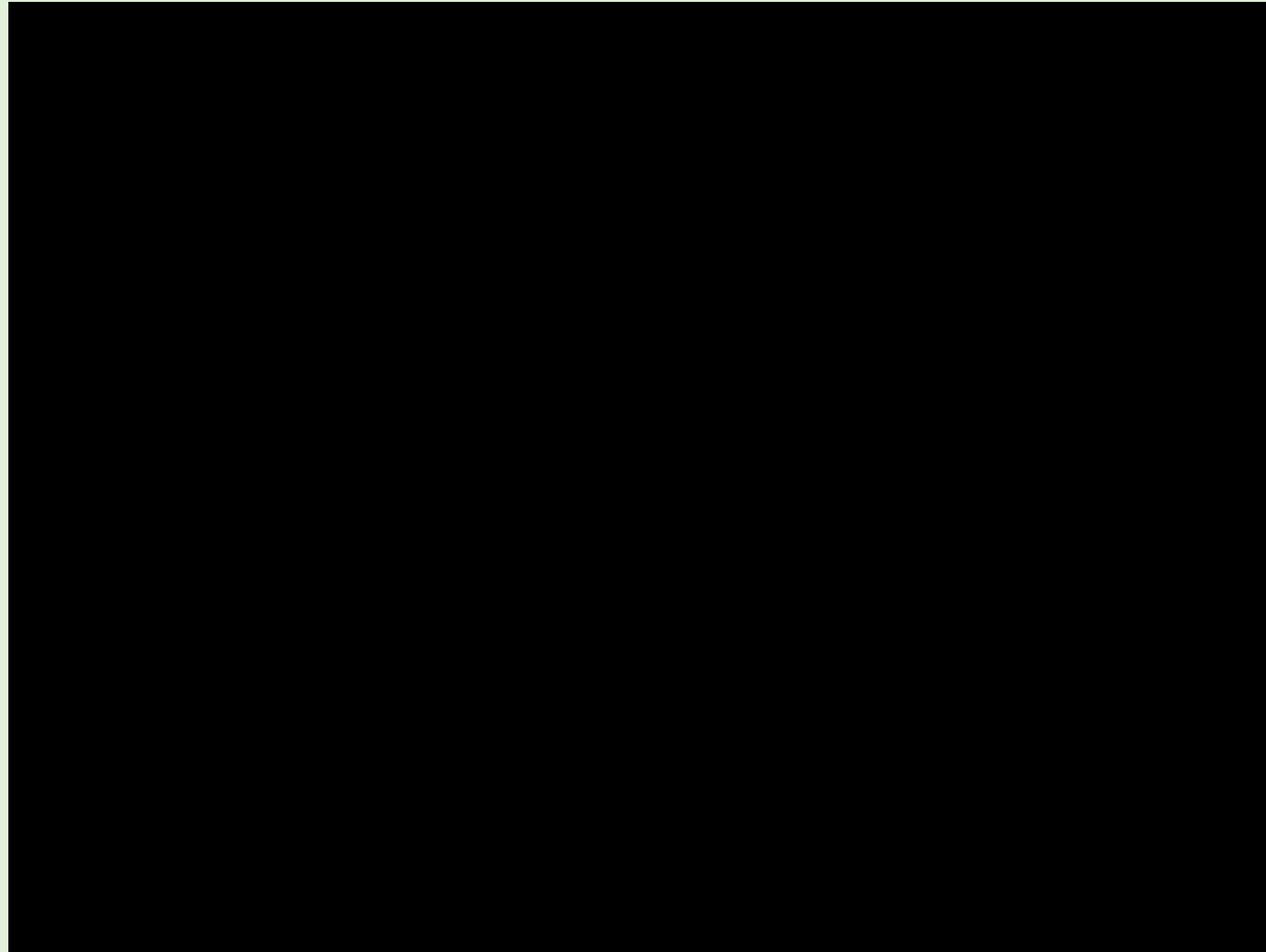
TRATAMIENTO CON MITRACLIP

Tercer dispositivo



TRATAMIENTO CON MITRACLIP

Tercer dispositivo



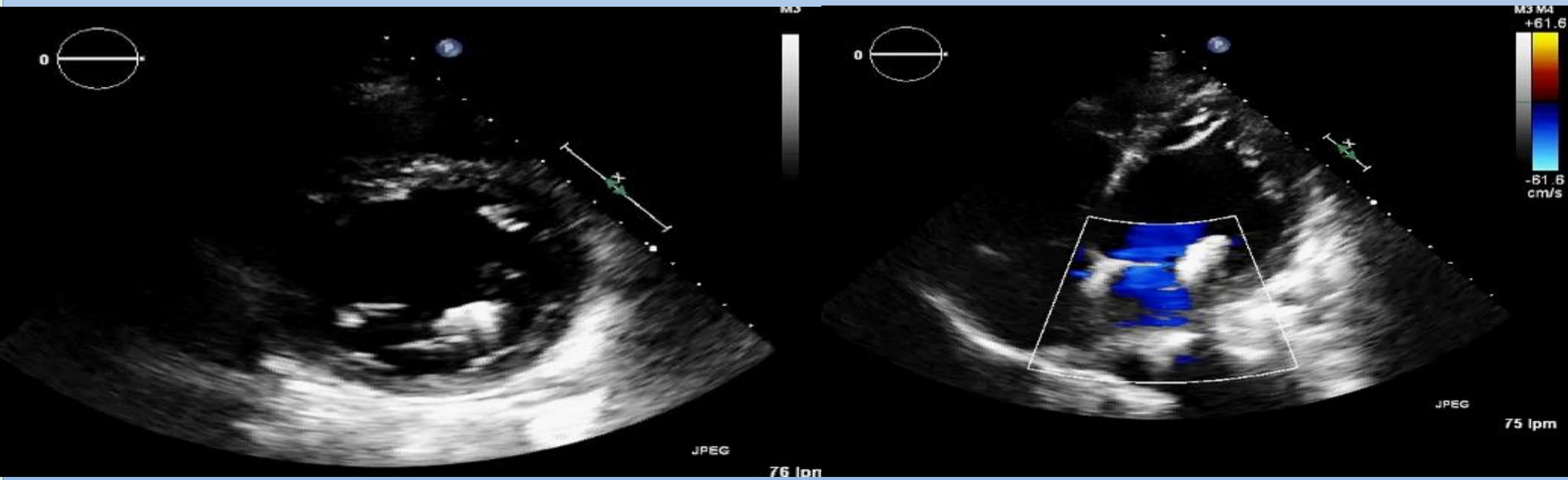
TRATAMIENTO CON MITRACLIP

Tercer dispositivo



SEGUIMIENTO

Ecocardiografía al mes



SEGUIMIENTO

- Buena tolerancia hemodinámica
- Extubación precoz
- Alta a planta al día siguiente
- Regurgitación mitral leve en eco previo al alta, con gradiente medio de 2 mmHG a 83lpm
- Mejoría clínica subjetiva tras los primeros meses de tratamiento

CIRUGÍA DE LA I.M.

	Class ^a	Level ^b	Ref ^c
Mitral valve repair should be the preferred technique when it is expected to be durable.	I	C	
Surgery is indicated in symptomatic patients with LVEF >30% and LVESD <55 mm.	I	B	127, 128
Surgery is indicated in asymptomatic patients with LV dysfunction (LVESD ≥45 mm and/or LVEF ≤60%).	I	C	
Surgery should be considered in asymptomatic patients with preserved LV function and new onset of atrial fibrillation or pulmonary hypertension.	IIa	C	

Recomendaciones en INSUFICIENCIA MITRAL DEGENERATIVA

La cirugía valvular en la INSUFICIENCIA MITRAL DEGENERATIVA ofrece una mortalidad baja (2.3-2.6%) y buen pronóstico a largo plazo.^{1, 2, 3}

La **REPARACION VALVULAR** es preferida sobre el reemplazo valvular, pues ha demostrado menor mortalidad (registros).^{4, 5}

Surgery may be considered in patients with severe LV dysfunction (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy with low likelihood of durable repair and low comorbidity.	IIb	C	
Surgery may be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk, and: <ul style="list-style-type: none"> • left atrial dilatation (volume index ≥60 ml/m² BSA) and sinus rhythm, or • pulmonary hypertension on exercise (SPAP ≥60 mmHg at exercise). 	IIb	C	

En mas de 1/3 de los pacientes no se repara la válvula

Criterios clínicos: etiología



DEGENERATIVA

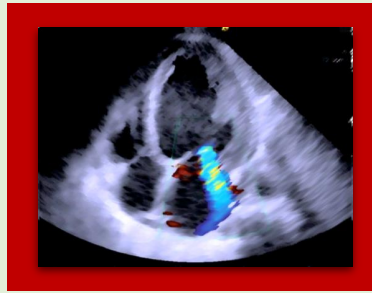
- Principalmente degeneración fibroelástica
- No es posible tratar:
 - - enfermedad reumática
 - - degeneración mixoide (Barlow)
 - - Endocarditis
 - - Congénitas: cleft mitral, válvula en paracaídas...

FUNCIONAL

La gran mayoría de los casos tratados son funcionales

- Mayor facilidad para cumplir criterios ecocardiográficos
- La cirugía ofrece peores resultados cuando hay disfunción ventricular.

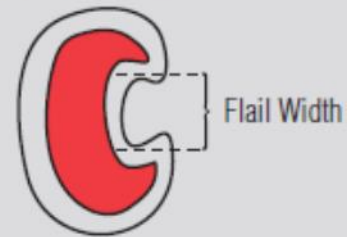
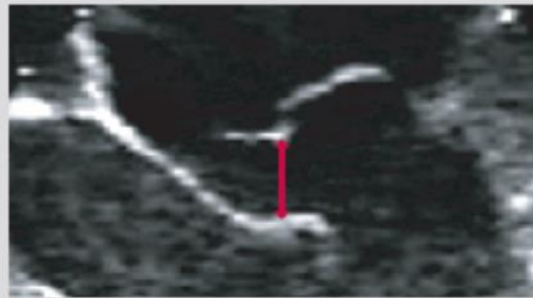
Cracterios ecocardiográficos: degenerativa



Prolapso valvular

Flail Gap

Flail Width

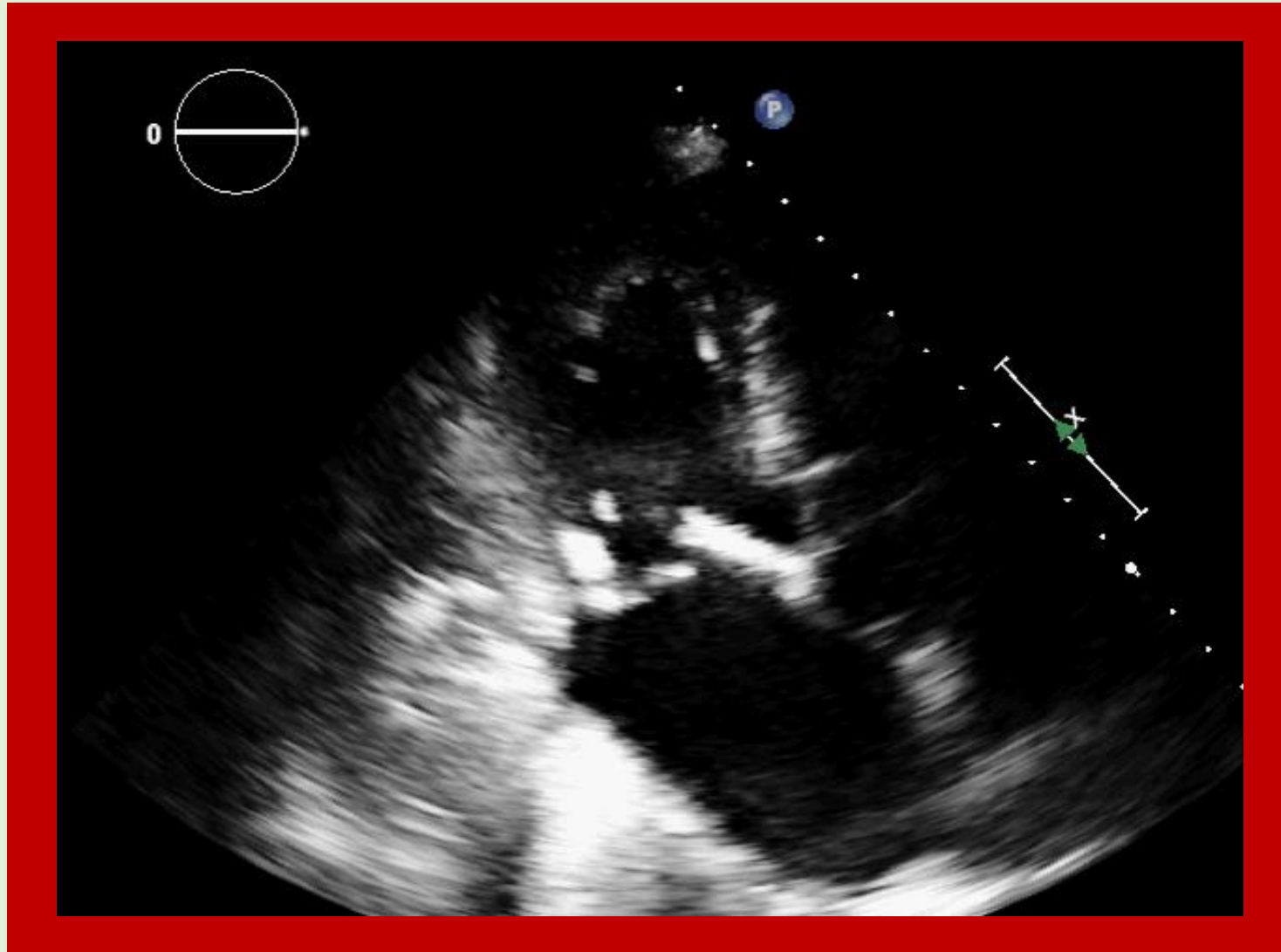
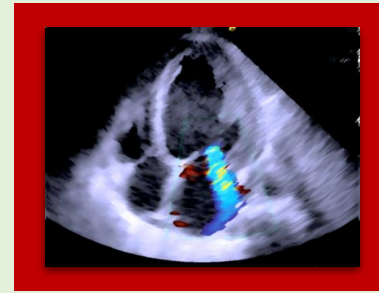


SELECCIÓN DE PACIENTES. IM DEGENERATIVA

CASO IDÓNEO	ACEPTABLE	INAPROPIADO
Patología central (A2/P2)	Patología en segmentos 1 ó 3	Perforación, cleft mitral
Libre de calcificación	Calcio fuera zona grasping	Calcificación zona grasping
Área > 4 cm ²	Área > 3 cm ²	Área < 3 cm ² o GM > 5 mmHG
Longitud móvil velo >10 mm	Longitud móvil velo 7-10 mm	Longitud móvil velo < 7 mm
Profundidad coaptación < 11	Profundidad coaptación > 11	
Movilidad normal	Restricción sistólica (Carpentier IIIa)	Restricción sistodiastólica (Carpentier IIIb)
Anchura del prolapso < 15 mm	Anchura mayor si es posible varios clips	Prolapso con engrosamiento (Barlow)
Altura del prolapso < 10 mm		

Adaptado de D.Braun. Herz 2013

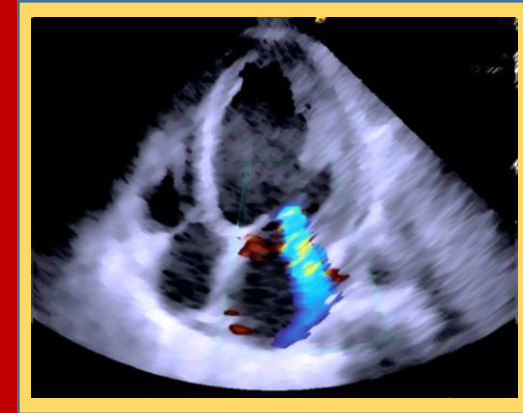
Criterios ecocardiográficos: degenerativa



SELECCIÓN DE PACIENTES

ECOCARDIOGRAFÍA TRANSTORÁCICA

Permite *descartar* la mayoría de los casos en los que no es posible realizar el tratamiento



ECOCARDIOGRAFÍA TRANSESOFÁGICA

Necesaria antes del procedimiento para *confirmar* que es posible realizarlo

All commercial TMVR cases with MitraClip enrolled in TVT registry through August 31, 2014 were identified (n=564)

Examined in-hospital and 30-day outcomes for procedure success, complications, and device-related events.

Outcome Definitions

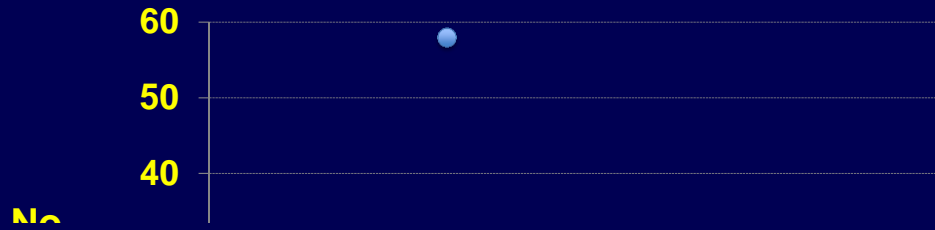
Procedure success

Post-implant MR grade ≤ 2 , without CV surgery and without in-hospital mortality

Procedure complications

cardiac perforation, major bleeding, stroke, MI, mitral injury, or death

564 patients at 61 hospitals



LV ejection fraction.....	56% (45, 63%)
MR severity grade 3 or 4.....	94.0%
LV EDD.....	5.2 cm (4.6, 5.8 cm)
LV ESD.....	3.6 cm (3.0, 4.5 cm)
<u>Degenerative MR.....</u>	85.5%
• Posterior prolapse.....	28.9%
• Posterior flail.....	28.0%
Functional MR.....	14.4%
Diabetes.....	25.0%
Prior CABG.....	32.4%
Prior MI.....	24.6%
Creatinine \geq 2 g/dl.....	16.7%

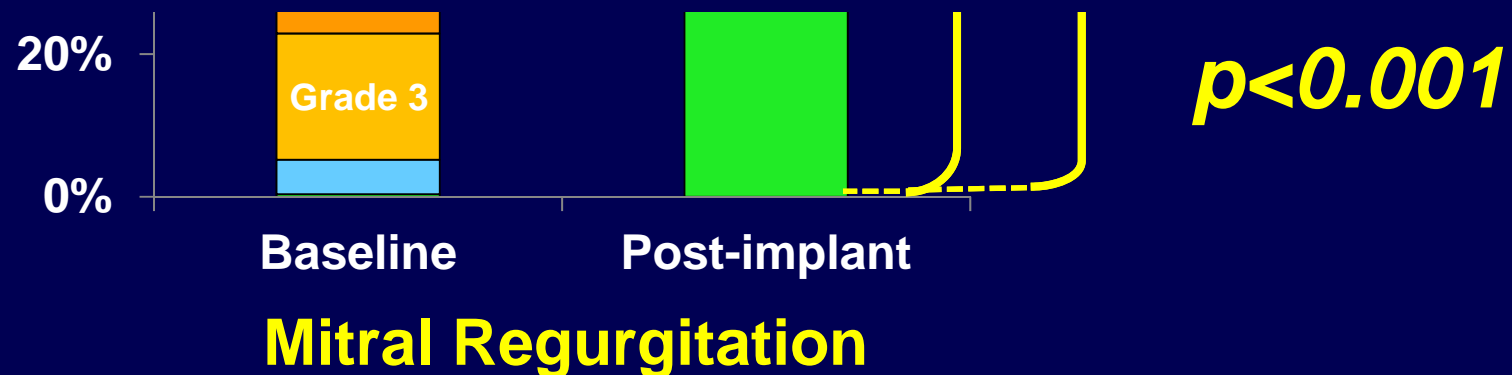
Change in Mitral Regurgitation

Clip implantation occurred in 94%

Procedure success.... 91.8%

Complications..... 7.8%

Length-of-stay..... 3 d (1,6 d)



Adverse Events

- In-hospital mortality..... 2.3%
- 30-day mortality..... 5.8%
- Cardiac surgery..... 0.5%
- Stroke..... 1.8%
- Myocardial infarction..... 0%
- Major bleeding..... 3.9%
- Cardiac perforation..... 0.7%
- Device-related events..... 2.7%
 - Single leaflet device attachment.... 1.1%
 - Device embolization..... 0.4%
 - Other..... 1.2%

ESC/EACTS 2012 Guidelines on the Management of Valvular Heart Disease



European Heart Journal
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES



Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

“**Indication for primary MR:** Percutaneous edge-to-edge procedure may be considered in patients with symptomatic severe primary MR who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a ‘heart team’, and have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C).” (page 21)

“**Indication for secondary MR:** The percutaneous mitral clip procedure may be considered in patients with symptomatic severe secondary MR despite optimal medical therapy (including CRT if indicated), who fulfill the echo criteria of eligibility, are judged inoperable or at high surgical risk by a team of cardiologists and cardiac surgeons, and who have a life expectancy greater than 1 year (recommendation class IIb, level of evidence C).” (page 25)

