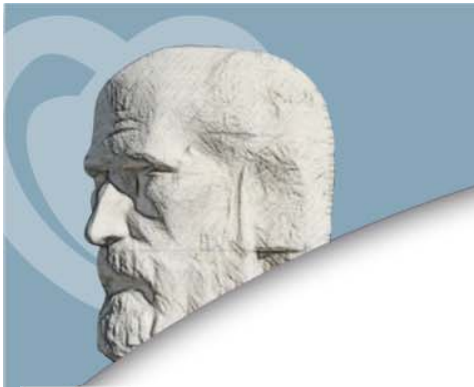


Novedades en diagnóstico y tratamiento de la insuficiencia mitral. Visión a partir de las Guías de la Sociedad Europea de Cardiología en valvulopatías



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2017 ESC/EACTS Guidelines for the management of valvular heart disease

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

Table 1 Classes of recommendations

Classes of recommendations	Definition	Suggested wording to use
Class I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, effective.	Is recommended/is indicated
Class II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.	
<i>Class IIa</i>	<i>Weight of evidence/opinion is in favour of usefulness/efficacy.</i>	Should be considered
<i>Class IIb</i>	<i>Usefulness/efficacy is less well established by evidence/opinion.</i>	May be considered
Class III	Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.	Is not recommended

Table 2 Levels of evidence

Level of evidence A	Data derived from multiple randomized clinical trials or meta-analyses.
Level of evidence B	Data derived from a single randomized clinical trial or large non-randomized studies.
Level of evidence C	Consensus of opinion of the experts and/or small studies, retrospective studies, registries.

ESC CONGRESS

BARCELONA 2017

26 – 30 August

Principales novedades:

- Heart Team.
- Valoración de la fragilidad.
- Intervencionismo percutáneo.

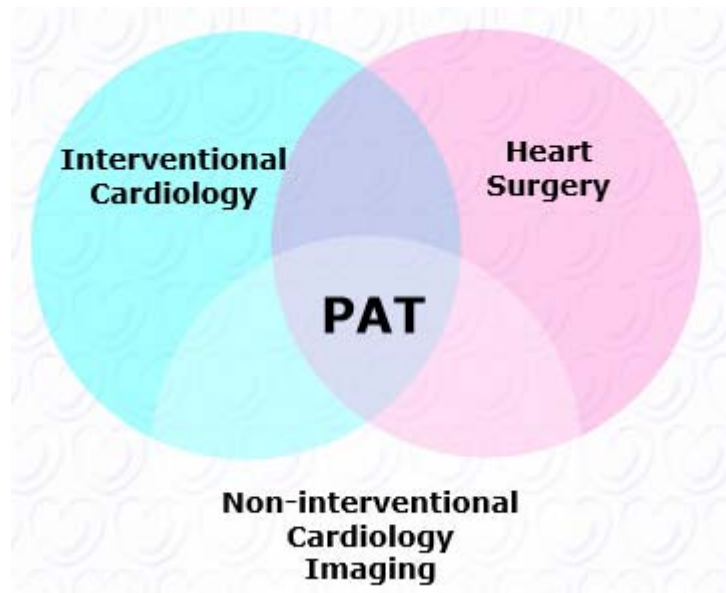
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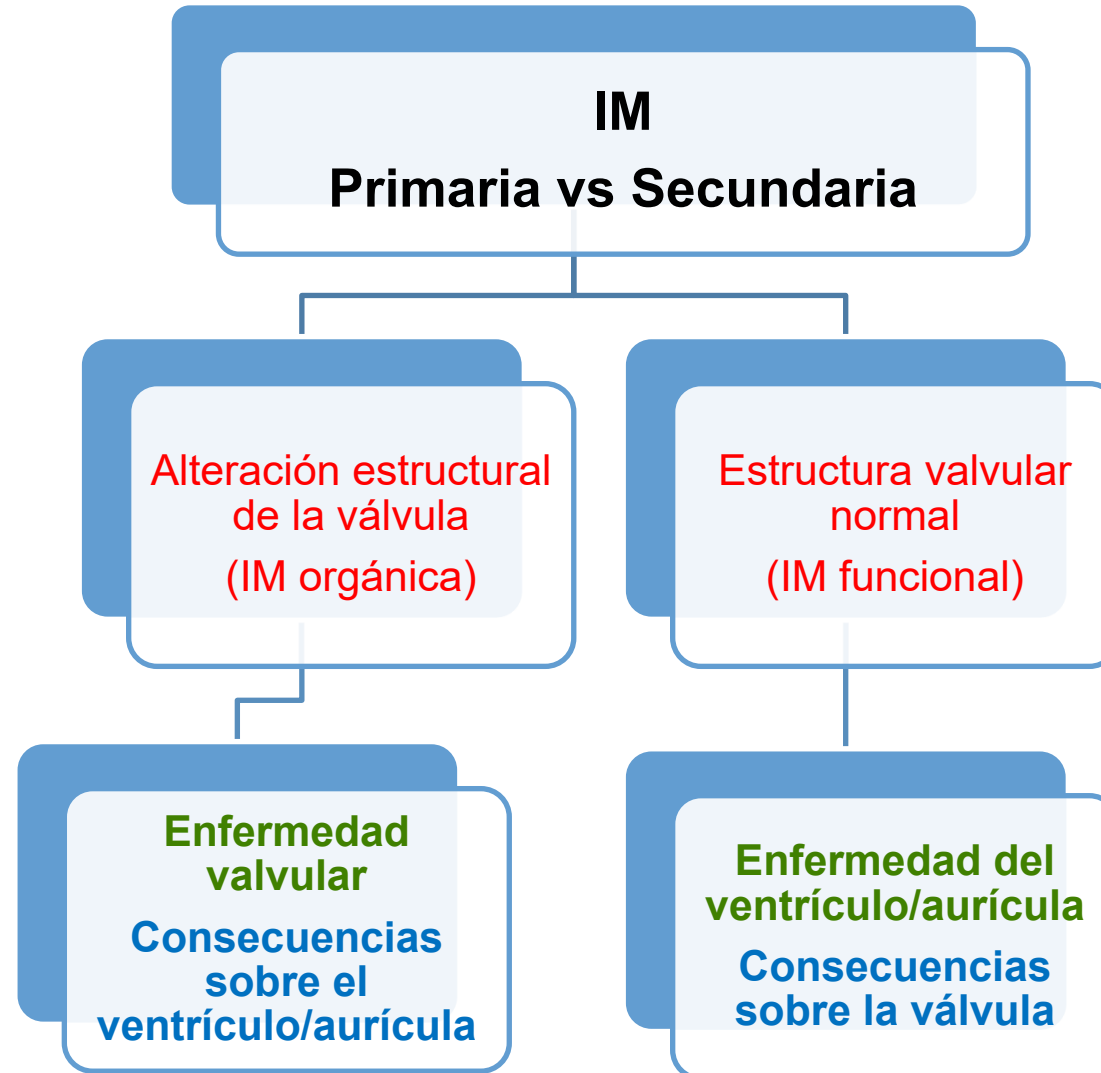
Concepto de “Heart Valve Team y Valve Center”



- Multidisciplinary Teams
- Volume
- Quality Assessment (robust audit)
- Excellence in
 - Imaging
 - Intervention
 - Surgery



Diagnóstico de la Insuficiencia Mitral

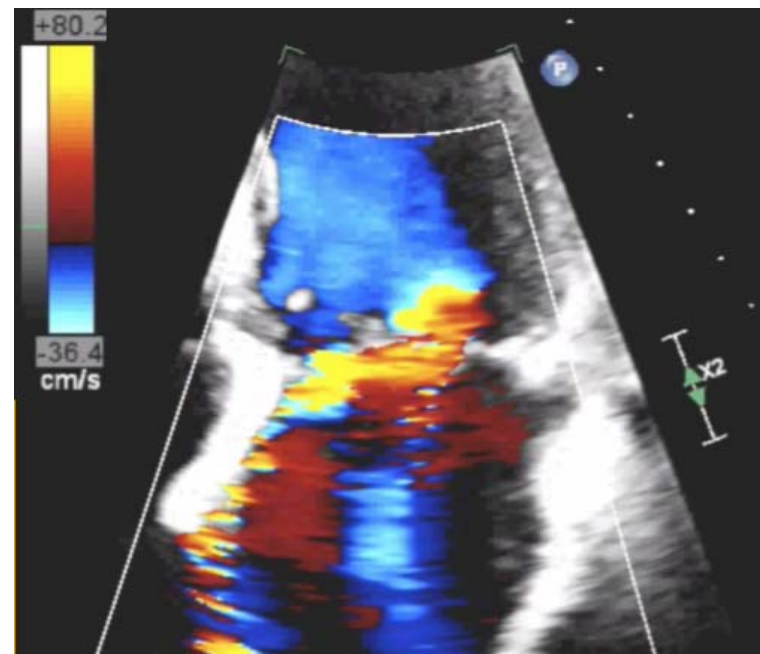
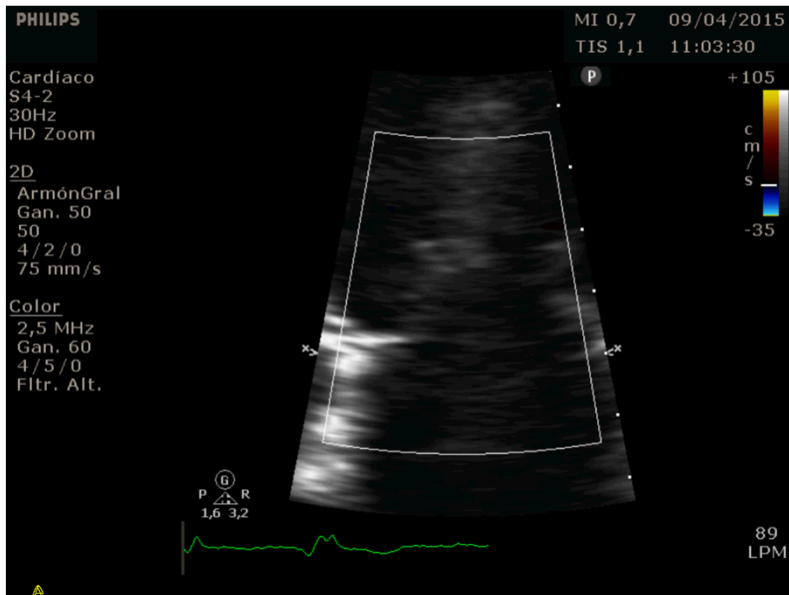
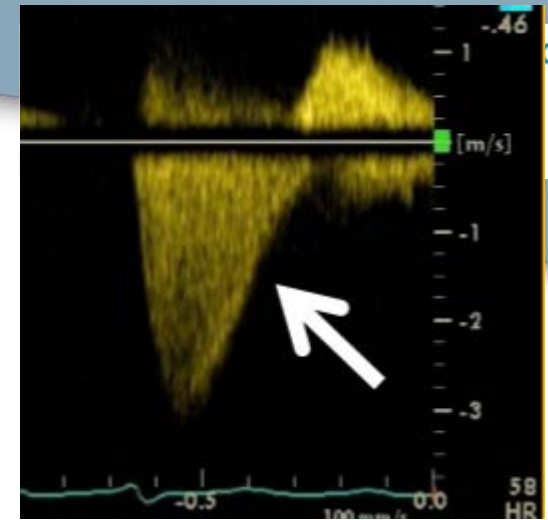
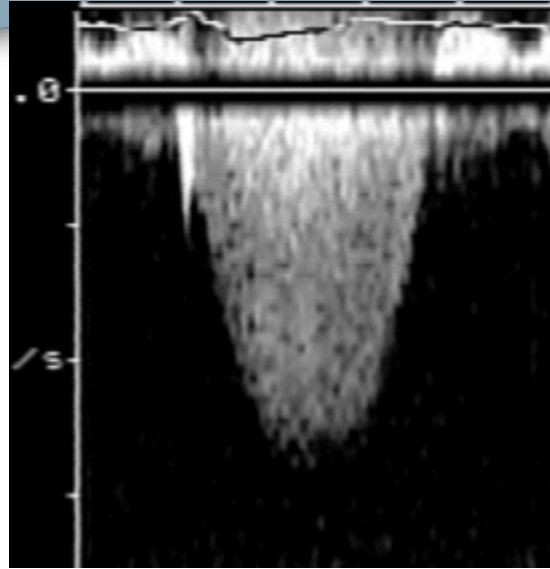
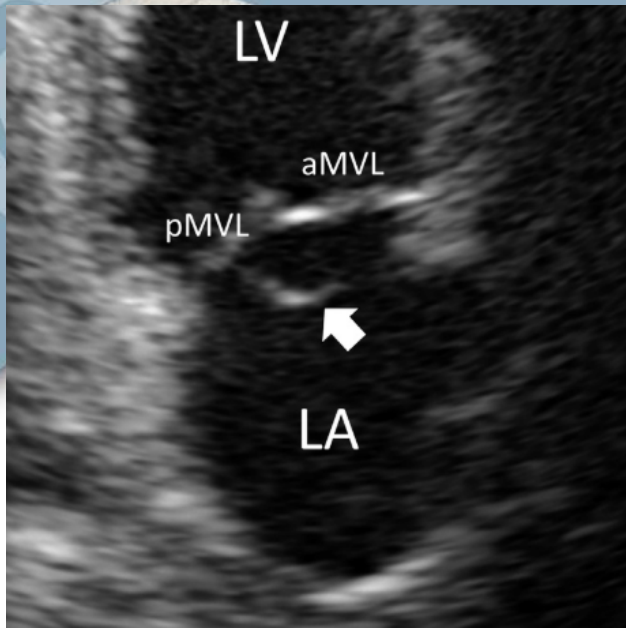




Diagnóstico de la Insuficiencia Mitral

Ecocardiografía

	Mitral regurgitation
Qualitative	
Valve morphology	Flail leaflet/ruptured papillary muscle/large coaptation defect
Colour flow regurgitant jet	Very large central jet or eccentric jet adhering, swirling, and reaching the posterior wall of the LA
CW signal of regurgitant jet	Dense/triangular
Other	Large flow convergence zone

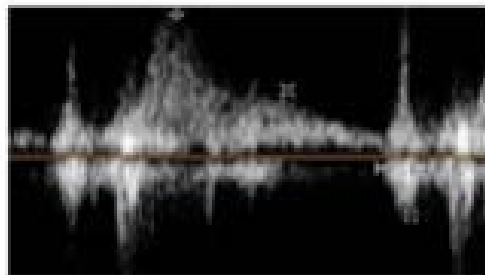
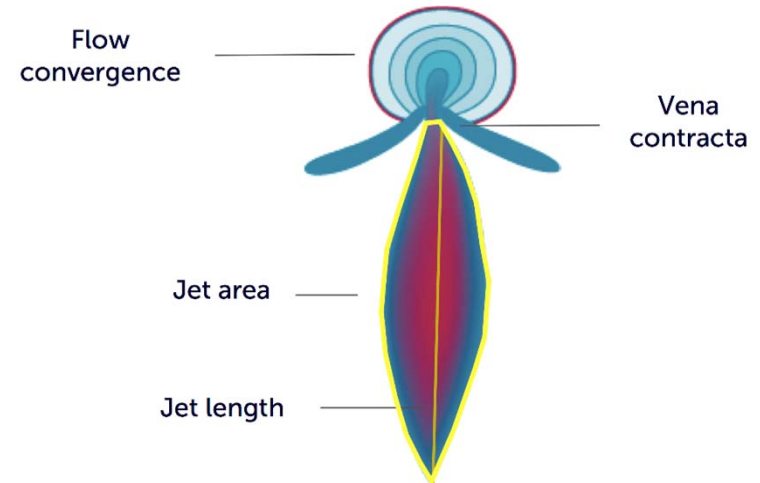
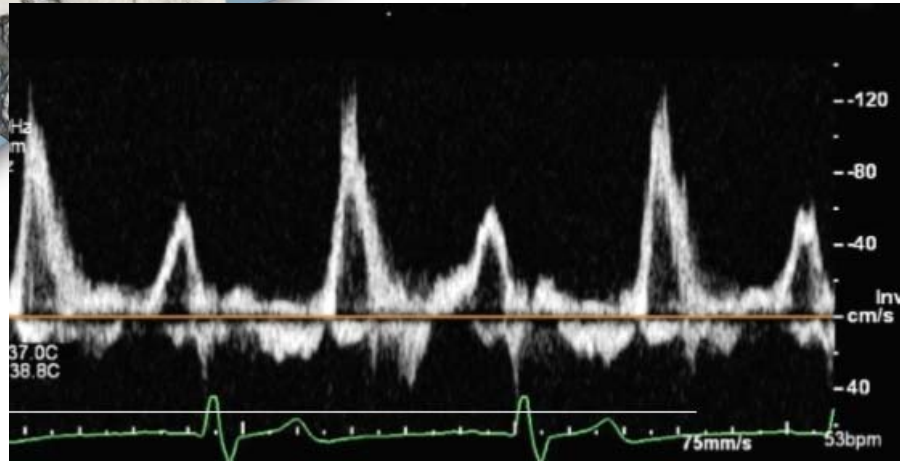




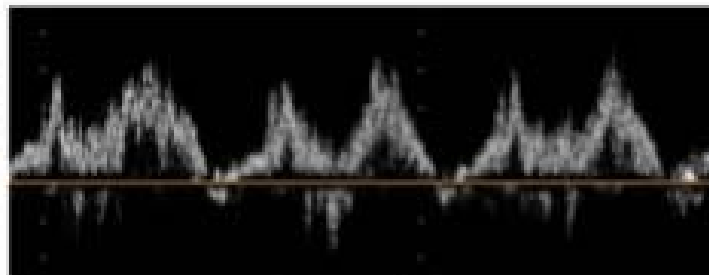
Diagnóstico de la Insuficiencia Mitral

Ecocardiografía

	Mitral regurgitation
Semiquantitative	
<i>Vena contracta</i> width (mm)	≥7 (>8 for biplane)
Upstream vein flow	Systolic pulmonary vein flow reversal
Inflow	E-wave dominant ≥1.5 m/s
Other	TVI mitral/TVI aortic >1.4



Normal



Systolic Blunting



Flow Reversal



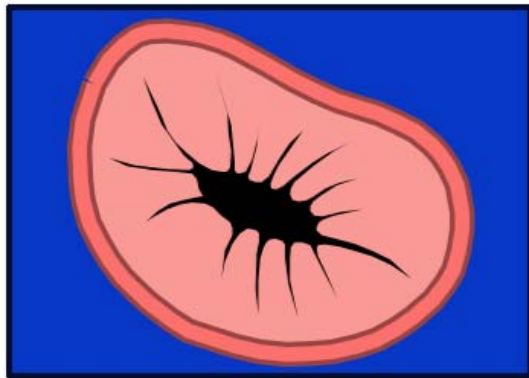
Diagnóstico de la Insuficiencia Mitral

Ecocardiografía

Quantitative	Mitral regurgitation	
	Primary	Secondary
EROA (mm ²)	≥40	≥20
Regurgitant volume (mL/beat)	≥60	≥30
+ enlargement of cardiac chambers/vessels	LV, LA	



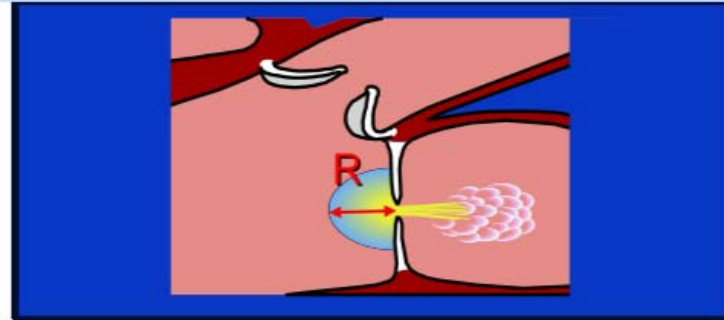
ERO by PISA Method



ERO

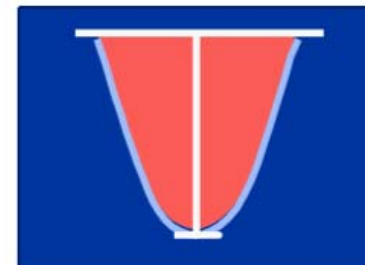
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Flow rate at PISA in cm³/sec



$$6.28 \times (R)^2 \times \text{PISA vel}$$

MR velocity in cm/sec

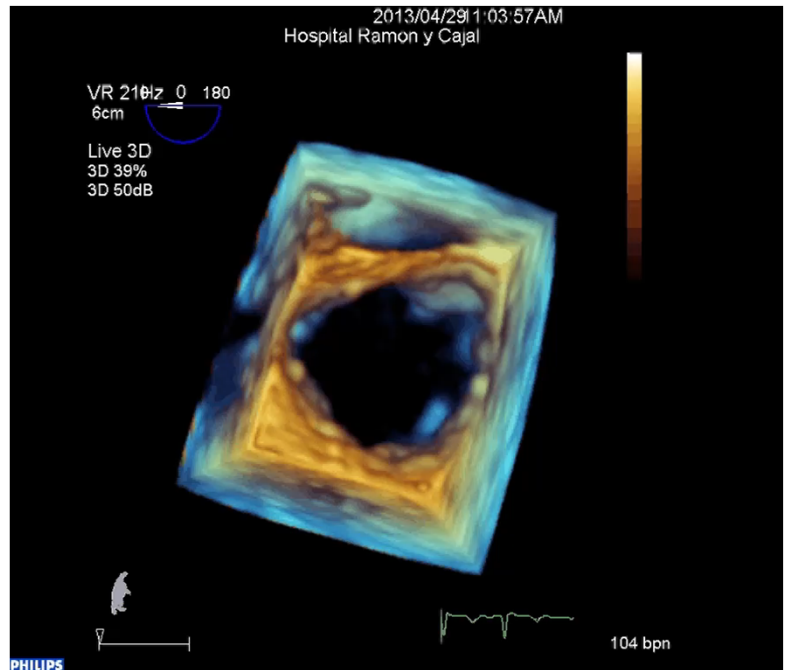
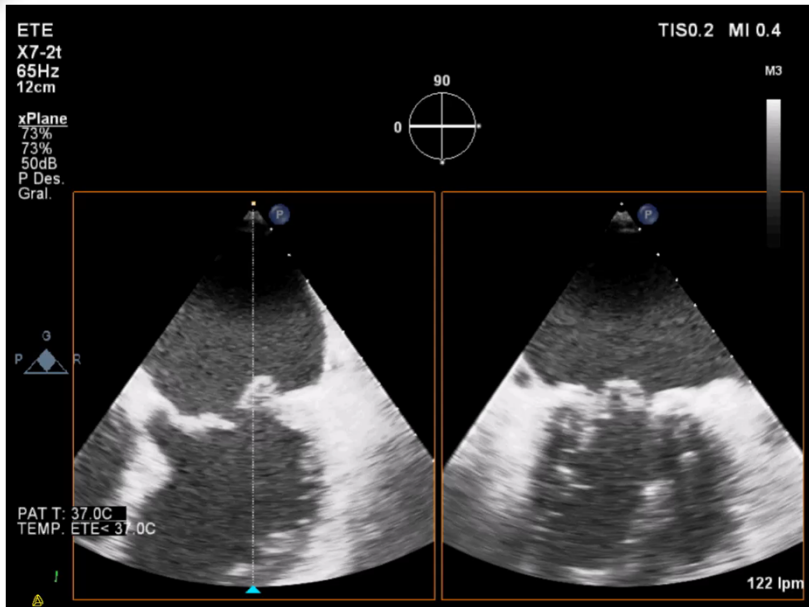
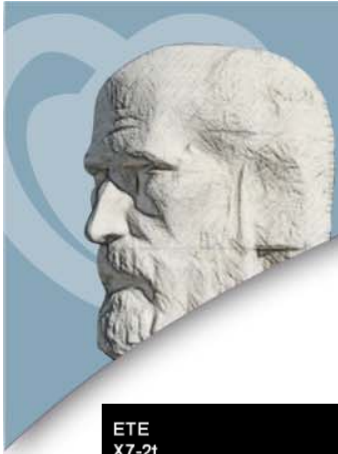




Ecocardiografía

TRANESOFÁGICA Y ECO 3D

- ✓ Permiten entender mejor la anatomía de la valvula y valorar la severidad de la lesión, especialmente en caso de mala ventana TT .
- ✓ ECO 3D permite visualización directa de “vista del cirujano”
- ✓ Muy útil de cara a valorar posibilidad de reparación mitral
- ✓ Guía pre y durante intervencionismo percutáneo.





Seguimiento ecocardiográfico

- Se recomienda un seguimiento ecocardiográfico más frecuente
- Cada 6 meses: IM severa (antes anual), e idealmente en el contexto de un «centro de valvulopatías».
- Cada 1-2 años para los pacientes con IM moderada (antes, cada 2 años).



Imagen multimodalidad

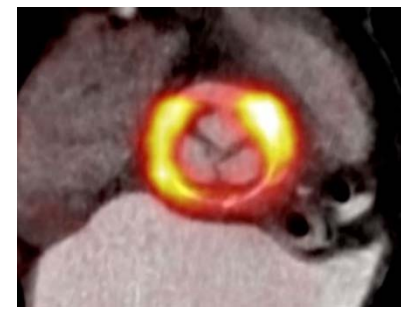
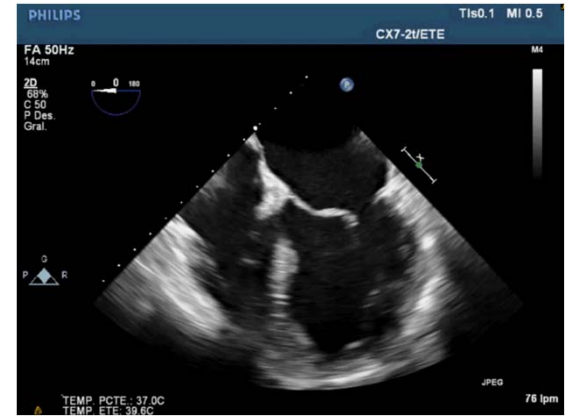
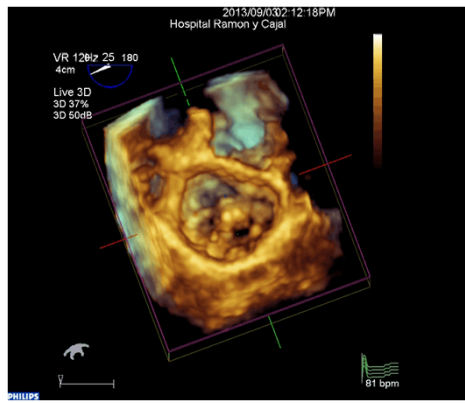
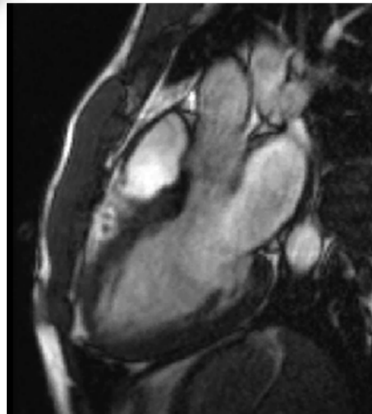


Imagen multimodalidad

EVALUACIÓN INICIAL

ECOCARDIOGRAFÍA: Anatomía VM, Severidad IM, Diámetros y función VI, AI, PSAP.

DX FINAL

Sí

NO

Sintomático

SVM

TAC enf coronaria?

Reparar

Clip

ETE (2D, 3D)

Asintomático

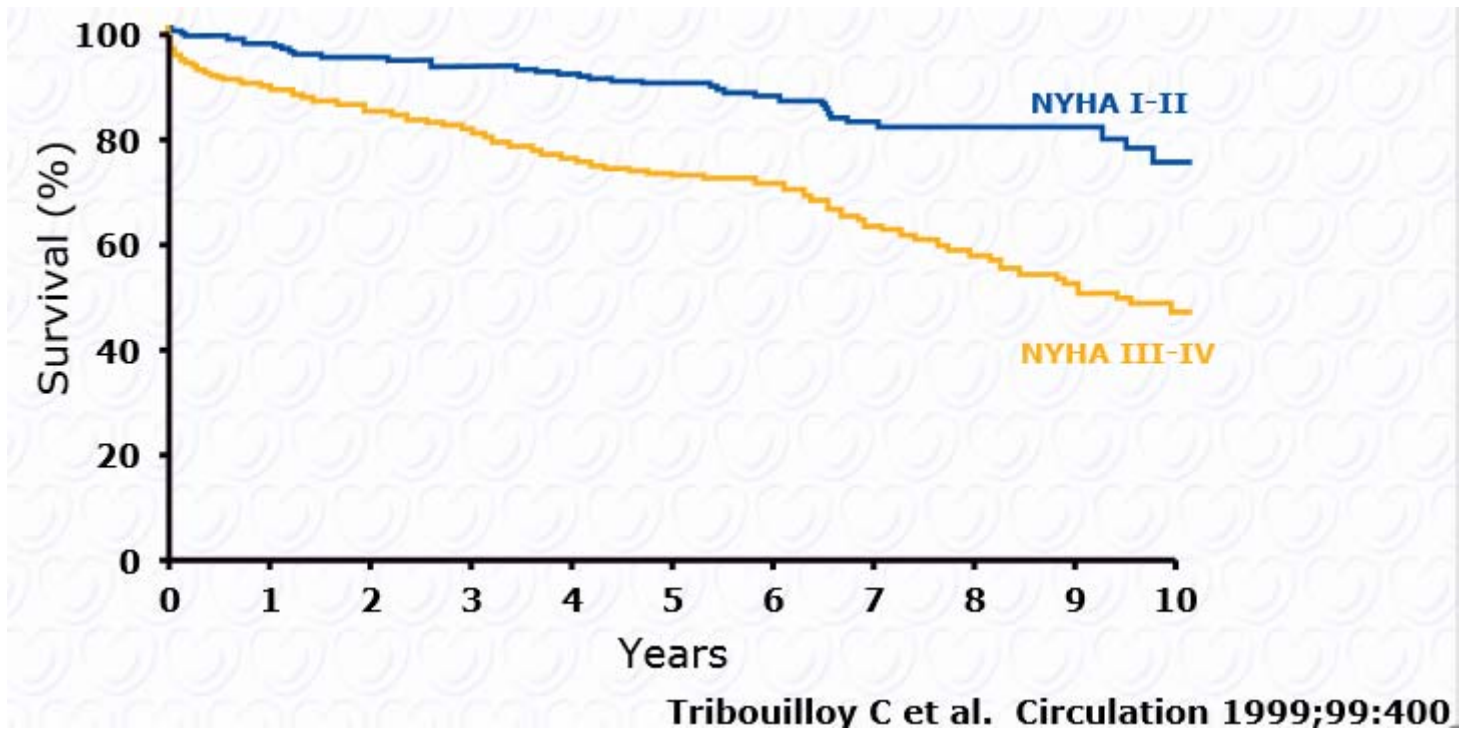
Pronóstico

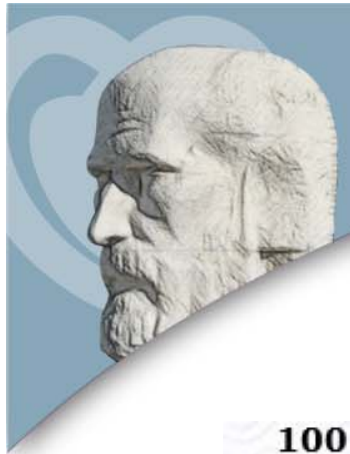
Strain VI, eco ejer

ETE (2D, 3D)
RMC (Severidad IM, FEVI, volúmenes, cicatriz)

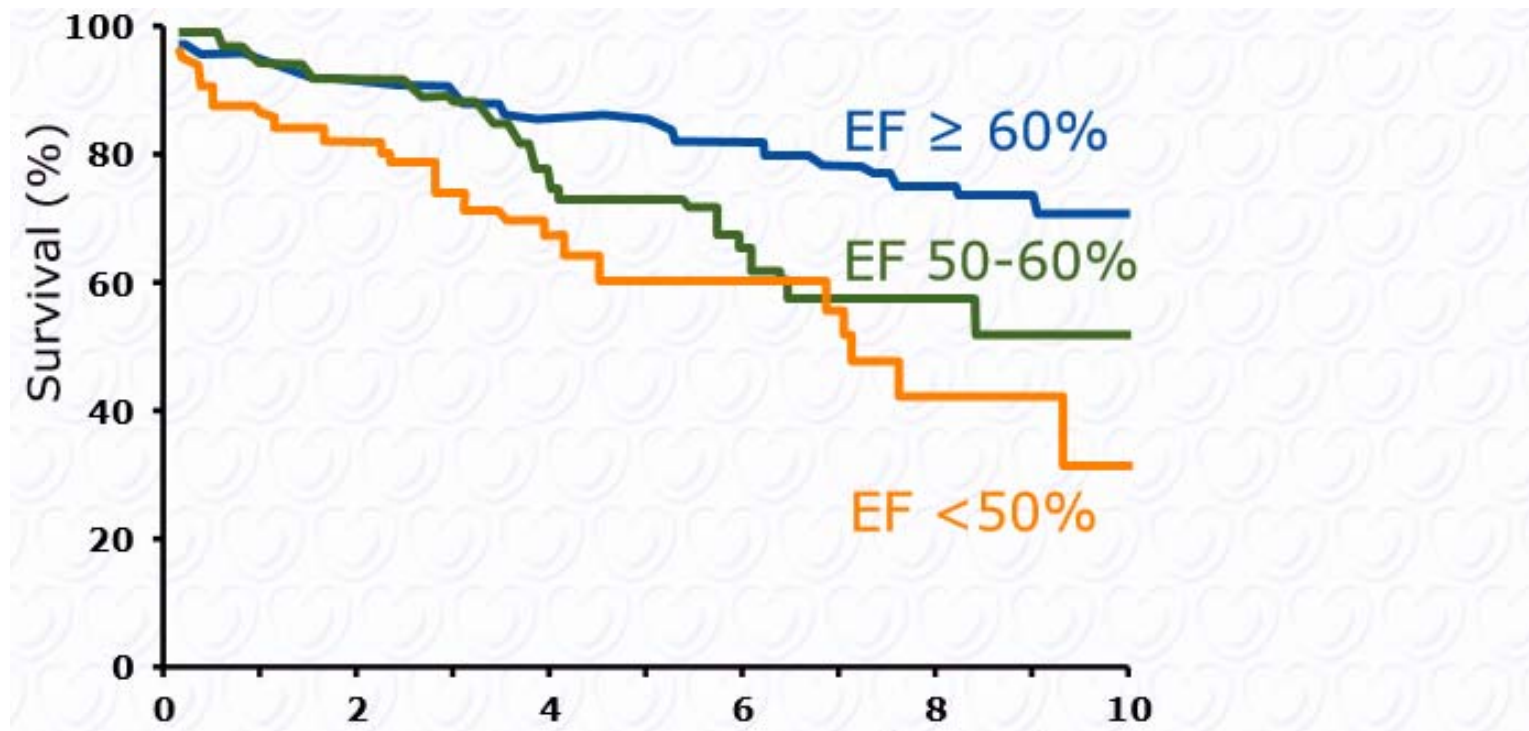


Tratamiento de la insuficiencia mitral





Tratamiento de la insuficiencia mitral

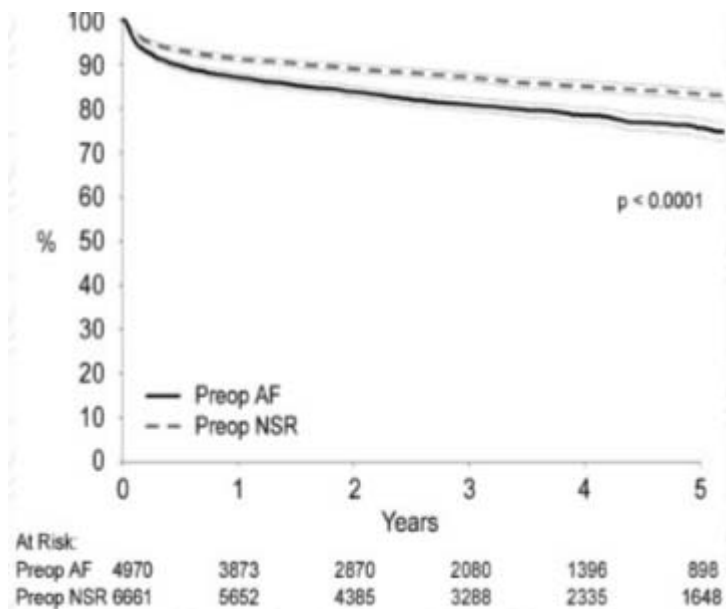


Enriquez-Sarano et al. Circulation 1994;90:830-837.

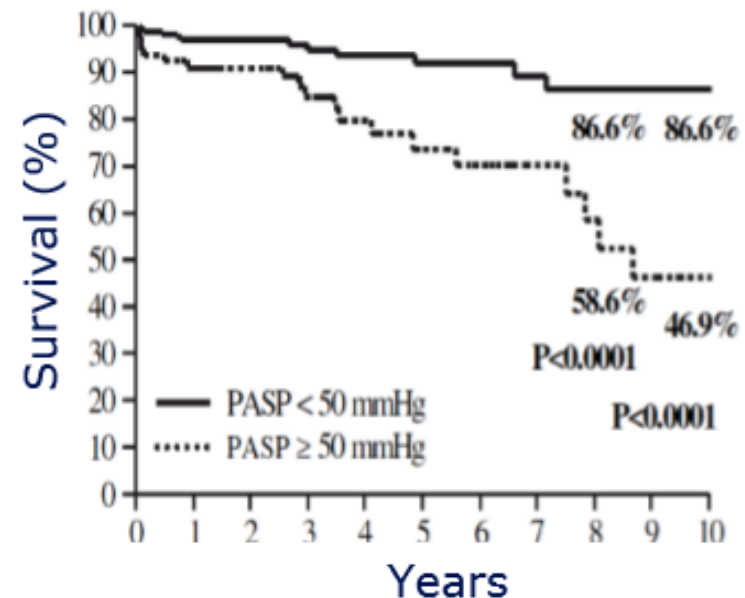


Tratamiento de la insuficiencia mitral

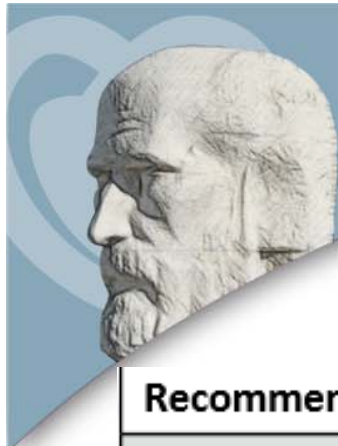
Fibrilación auricular e HTP. *Supervivencia postoperatorio*



Badhwar et al. Ann Thor Surg
2012; 94: 1870-1877



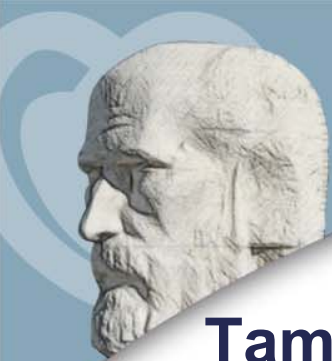
Le Tourneau et al. Heart
2010; 96: 1311-1317



Tratamiento de la insuficiencia mitral

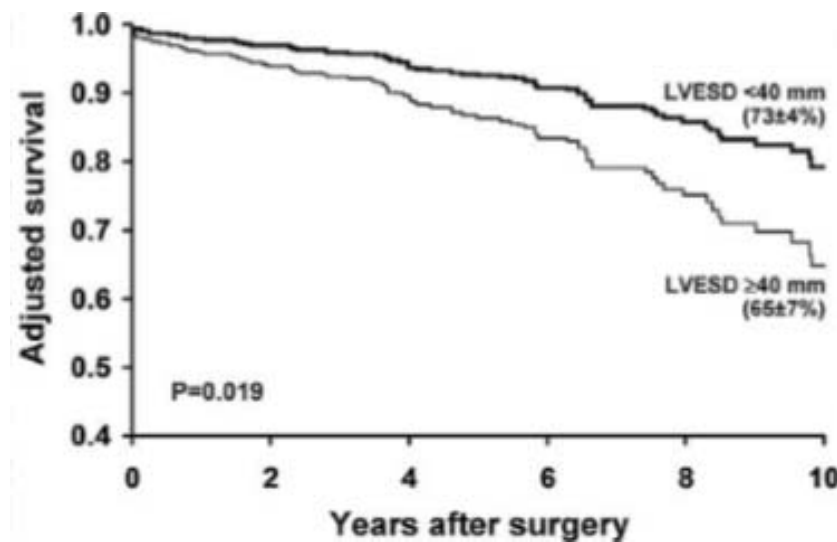
Recommendations	Class	Level
Mitral valve repair should be the preferred technique when the results are expected to be durable.	I	C
Surgery is indicated in <u>symptomatic patients</u> with LVEF >30%.	I	B
Surgery is indicated in <u>asymptomatic patients with LV dysfunction</u> (LVESD ≥45 mm* and/or LVEF ≤60%).	I	B
Surgery should be considered in asymptomatic patients with preserved LV function (LVESD <45 mm and LVEF >60%) and <u>atrial fibrillation secondary to mitral regurgitation</u> or <u>pulmonary hypertension</u> (systolic pulmonary pressure at rest >50 mmHg**).	IIa	B

* Cut-offs refer to average-size adults and may require adaptation in patients with unusually small or large stature
 ** If an elevated SPAP is the only indication for surgery, the value should be confirmed by invasive measurement

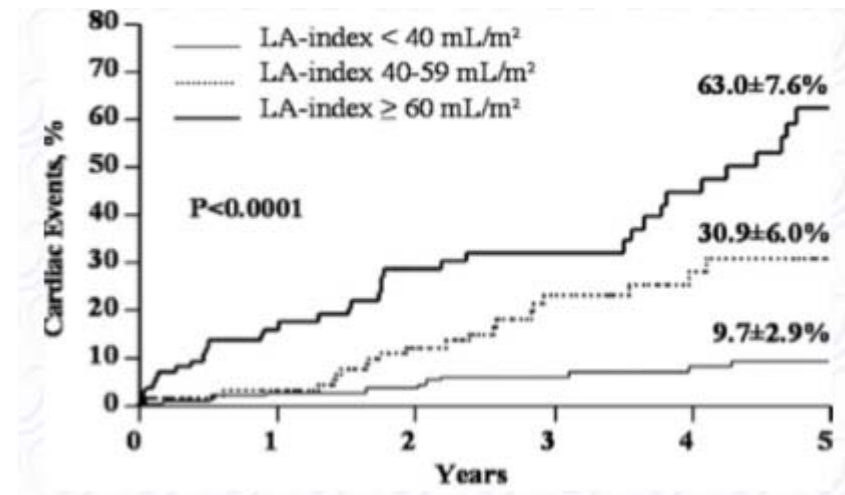


Tratamiento de la insuficiencia mitral

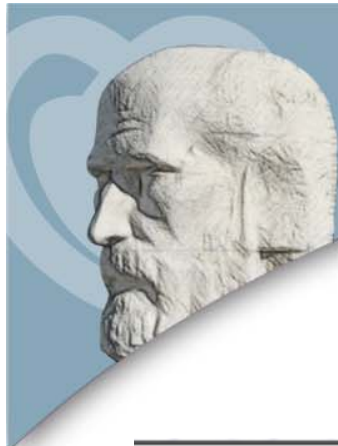
Tamaño del ventrículo izquierdo y aurícula izquierda.
Paciente con "fail leaflet"



Tribouilloy C et al. J Am Coll Cardiol
2009;54:1961-1968



Le Tourneau T. et al. J Am Coll Cardiol
2010;56:570-8



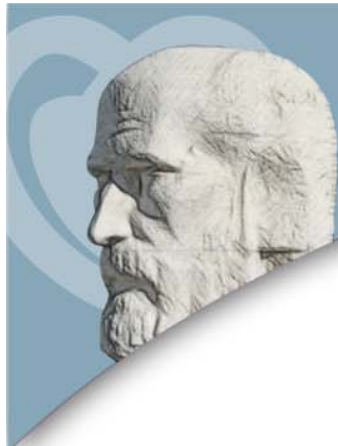
Tratamiento de la insuficiencia mitral

Recommendations	Class	Level
Surgery should be considered in asymptomatic patients with preserved LVEF (>60%) and <u>LVESD 40–44 mm*</u> when a durable repair is likely, surgical risk is low, the repair is performed in heart valve centres, and at least one of the following findings is present: <ul style="list-style-type: none">- <u>flail leaflet</u> or,- <u>presence of significant LA dilatation</u> (volume index ≥ 60 mL/m² BSA) in sinus rhythm.	Ila	C
Mitral valve repair should be considered in symptomatic patients with severe LV dysfunction (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy when likelihood of successful repair is high and comorbidity low.	Ila	C



Changes in recommendations

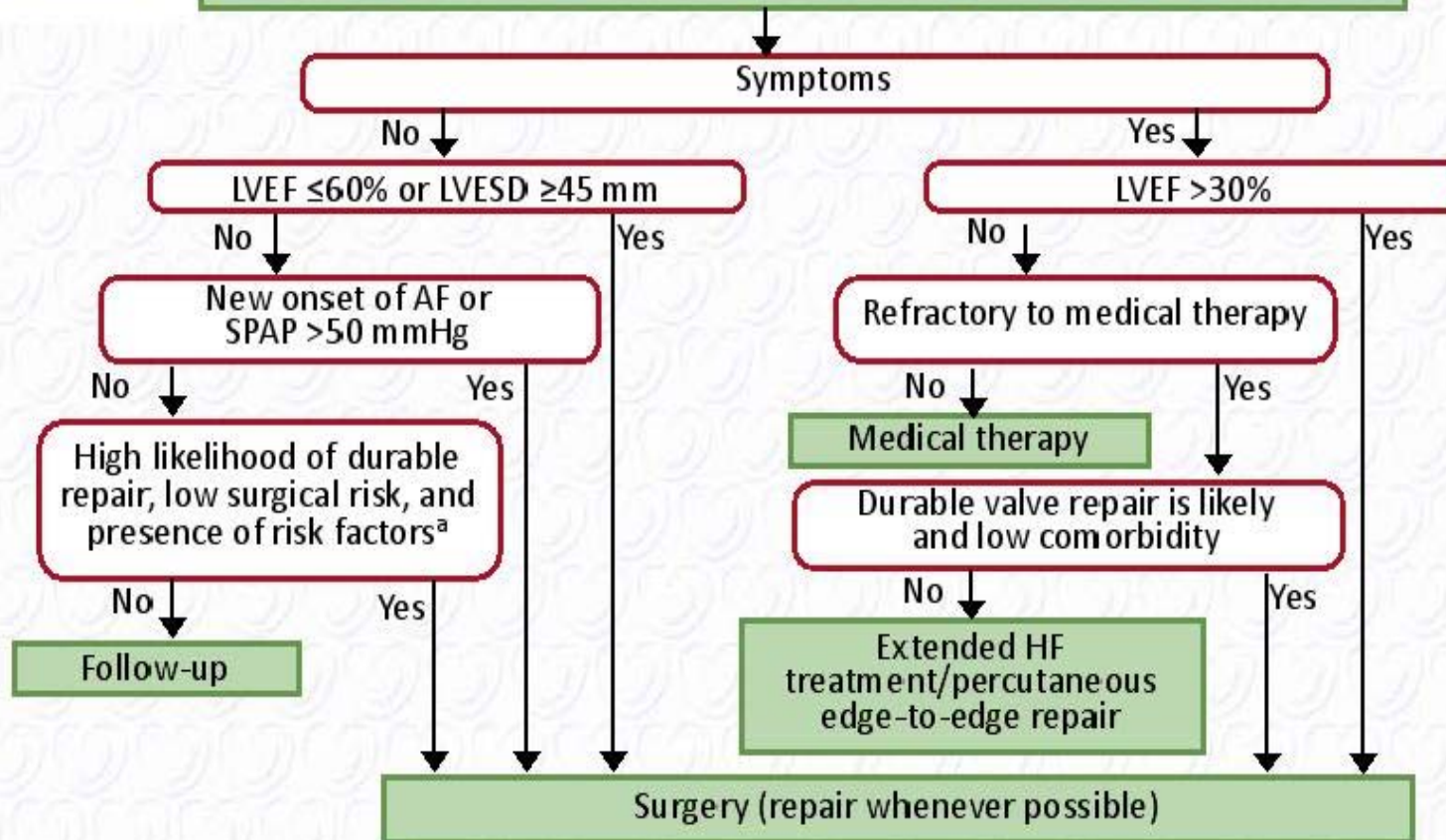
2012	2017
Indications for intervention in asymptomatic severe primary mitral regurgitation	
<p>IIb C Surgery may be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk, and:</p> <ul style="list-style-type: none"> • Left atrial dilatation (volume index ≥ 60 mL/m² BSA) and sinus rhythm. 	<p>IIa C (modified!) Surgery should be considered in asymptomatic patients with preserved LVEF (>60%) and LVESD 40–44 mm when a durable repair is likely, surgical risk is low, the repair is performed in heart valve centres, and the following finding is present: presence of significant LA dilatation (volume index ≥ 60 mL/m² BSA) in sinus rhythm.</p>
Pulmonary hypertension on exercise (SPAP ≥ 60 mmHg at exercise).	Taken out



Tratamiento de la insuficiencia mitral

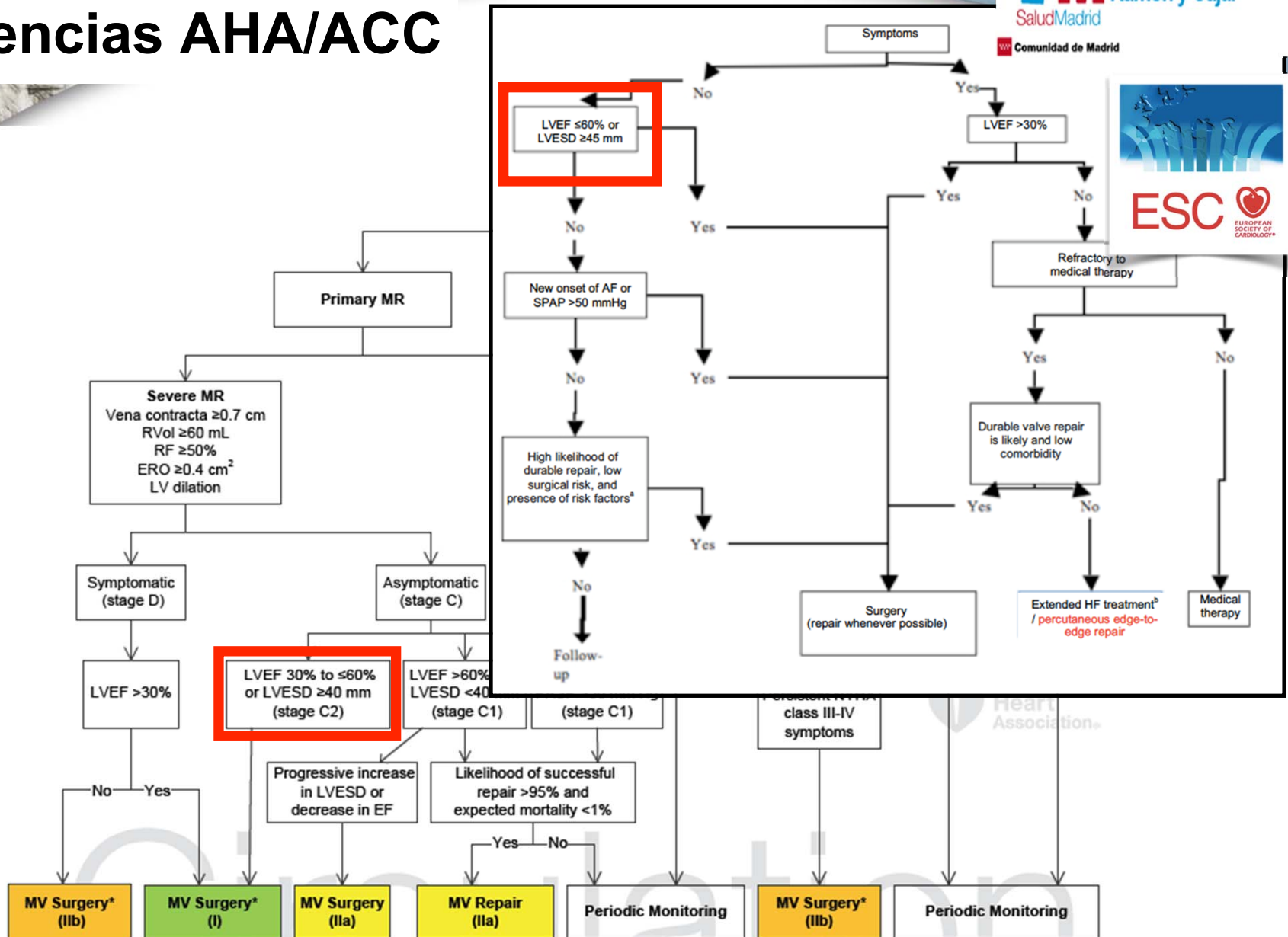
Recommendations	Class	Level
Mitral valve replacement may be considered in <u>symptomatic patients with severe LV dysfunction</u> (LVEF <30% and/or LVESD >55 mm) refractory to medical therapy when <u>likelihood of successful repair is low and comorbidity low</u> .	IIb	C
<u>Percutaneous edge-to-edge procedure</u> may be considered in patients with <u>symptomatic severe primary mitral regurgitation</u> who fulfill the echocardiographic criteria of eligibility and are judged <u>inoperable</u> or at <u>high surgical risk</u> by the Heart Team, avoiding futility.	IIb	C

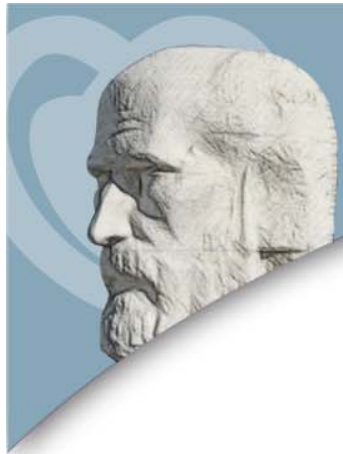
Management of severe chronic primary mitral regurgitation



^a LVEDD ≥40 mm and one of the following present: flail leaflet or LA volume ≥60 mL/m² BSA at sinus rhythm

Diferencias AHA/ACC





Insuficiencia mitral secundaria

Diferencias AHA/ACC

Table 2. Stages of Secondary MR (Table 16 in the 2014 VHD Guideline)

Grade	Definition	Valve Anatomy	Valve Hemodynamics*	Associated Cardiac Findings	Symptoms
A	At risk of MR	<ul style="list-style-type: none"> Normal valve leaflets, chords, and annulus in a patient with coronary disease or cardiomyopathy 	<ul style="list-style-type: none"> No MR jet or small central jet area <20% LA on Doppler Small vena contracta <0.30 cm 	<ul style="list-style-type: none"> Normal or mildly dilated LV size with fixed (infarction) or inducible (ischemia) regional wall motion abnormalities Primary myocardial disease with LV dilation and systolic dysfunction 	<ul style="list-style-type: none"> Symptoms due to coronary ischemia or HF may be present that respond to revascularization and appropriate medical therapy
B	Progressive MR	<ul style="list-style-type: none"> Regional wall motion abnormalities with mild tethering of mitral leaflet Annular dilation with mild loss of central coaptation of the mitral leaflets 	<ul style="list-style-type: none"> ERO <0.40 cm²† Regurgitant volume <60 mL Regurgitant fraction <50% 	<ul style="list-style-type: none"> Regional wall motion abnormalities with reduced LV systolic function LV dilation and systolic dysfunction due to primary myocardial disease 	<ul style="list-style-type: none"> Symptoms due to coronary ischemia or HF may be present that respond to revascularization and appropriate medical therapy
C	Asymptomatic severe MR	<ul style="list-style-type: none"> Regional wall motion abnormalities and/or LV dilation with severe tethering of mitral leaflet Annular dilation with severe loss of central coaptation of the mitral leaflets 	<ul style="list-style-type: none"> ERO ≥0.40 cm²† Regurgitant volume ≥60 mL Regurgitant fraction ≥50% 	<ul style="list-style-type: none"> Regional wall motion abnormalities with reduced LV systolic function LV dilation and systolic dysfunction due to primary myocardial disease 	<ul style="list-style-type: none"> Symptoms due to coronary ischemia or HF may be present that respond to revascularization and appropriate medical therapy
D	Symptomatic severe MR	<ul style="list-style-type: none"> Regional wall motion abnormalities and/or LV dilation with severe tethering of mitral leaflet Annular dilation with severe loss of central coaptation of the mitral leaflets 	<ul style="list-style-type: none"> ERO ≥0.40 cm²† Regurgitant volume ≥60 mL Regurgitant fraction ≥50% 	<ul style="list-style-type: none"> Regional wall motion abnormalities with reduced LV systolic function LV dilation and systolic dysfunction due to primary myocardial disease 	<ul style="list-style-type: none"> HF symptoms due to MR persist even after revascularization and optimization of medical therapy Decreased exercise tolerance Exertional dyspnea

“lower thresholds have been proposed to define severe mitral regurgitation compared with primary mitral regurgitation (20 mm² for effective regurgitant orifice area [EROA] and 30 mL for regurgitant volume)”





Changes in recommendations

2012

2017

Indications for mitral valve intervention in secondary mitral regurgitation (*continued*)

Additional statement:

The lower thresholds defining severe MR compared to primary MR are based on their association with prognosis. However, it is unclear if prognosis is independently affected by MR compared to LV dysfunction. For isolated mitral valve treatment in secondary MR, thresholds of severity of MR for intervention still need to be validated in clinical trials. So far, no survival benefit has been confirmed for reduction of secondary MR.



Tratamiento de la insuficiencia mitral secundaria

Recommendations	Class	Level
Surgery is indicated in patients with severe secondary mitral regurgitation <u>undergoing CABG</u> and <u>LVEF >30%</u> .	I	C
Surgery should be considered in symptomatic patients with severe secondary mitral regurgitation, <u>LVEF <30%</u> but with an <u>option for revascularization</u> , and <u>evidence of myocardial viability</u> .	Ila	C



Changes in recommendations	
2012	2017
Indications for mitral valve intervention in secondary mitral regurgitation	
Ila C Surgery should be considered in patients with moderate secondary mitral regurgitation undergoing CABG	Taken out

Diferencias AHA/ACC

Table 18. Summary of Recommendations for Chronic Severe *Secondary* MR

Recommendations		ESC	IC	E	References
MV surgery is reasonable for patients with chronic severe secondary MR (stages C and D) who are undergoing CABG or AVR					N/A
MV surgery may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe secondary MR (stage D)		IIb		B	439,448–458
MV repair may be considered for patients with chronic moderate secondary MR (stage B) who are undergoing other cardiac surgery		IIb		C	N/A

AVR indicates aortic valve replacement; CABG, coronary artery bypass graft; COR, Class of Recommendation; LOE, Level of Evidence; MR, mitral regurgitation; MV, mitral valve; N/A, not applicable; and NYHA, New York Heart Association.



Tratamiento de la insuficiencia mitral secundaria

Recommendations	Class	Level
When <i>revascularization is not indicated</i> , surgery may be considered in patients with severe secondary mitral regurgitation and LVEF >30% , who remain <u>symptomatic despite optimal medical management</u> (including CRT if indicated) and have a <u>low surgical risk</u> .	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 revascularisation, the <u>Heart Team may consider percutaneous edge-to-edge procedure or valve surgery</u> after careful evaluation for ventricular assist device or heart transplant according to individual patient characteristics.	IIb	C



Tratamiento de la insuficiencia mitral secundaria

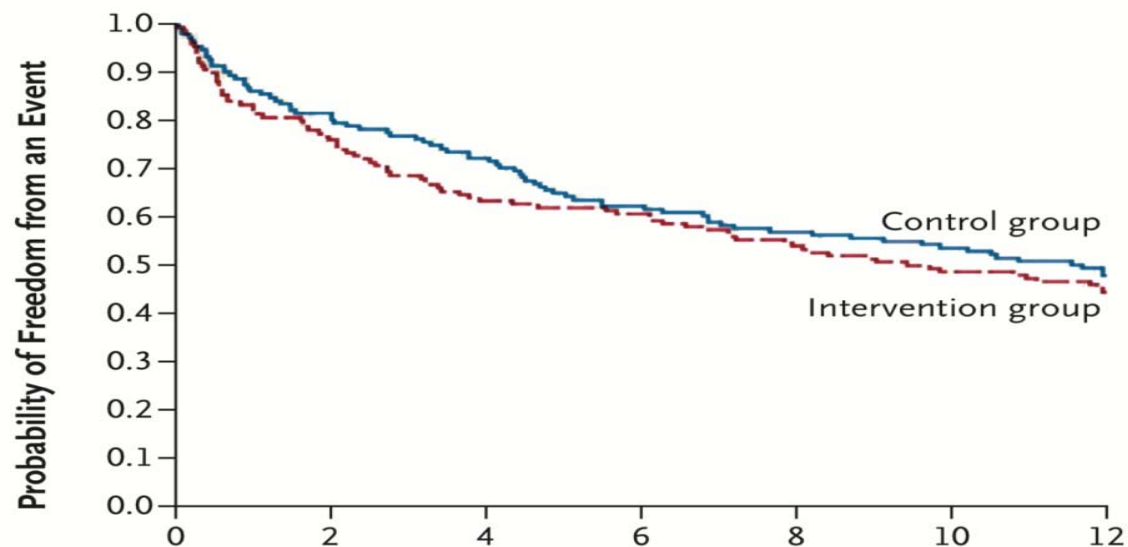
En 2018 se presentan los dos primeros ensayos clínicos aleatorizados en el tratamiento percutáneo de la IM secundaria: MITRA-FR y COAPT.

Mitra-FR Diseño

- Publicly-funded trial.
- 304 patients with severe secondary MR (defined as an effective regurgitant orifice area [**EROA**] > 20 mm² or a regurgitant volume > 30 mL).
- Left ventricular ejection fraction (LVEF) between **15% and 40%**, and **symptomatic HF**.
- 2 groups: Percutaneous mitral valve repair in addition to medical treatment VS medical treatment only.
- The primary outcome was a composite of **death from any cause and first unplanned admission for HF at 1 year**.

Mitra-FR Resultados

No diferencias significativas en el end point primario.



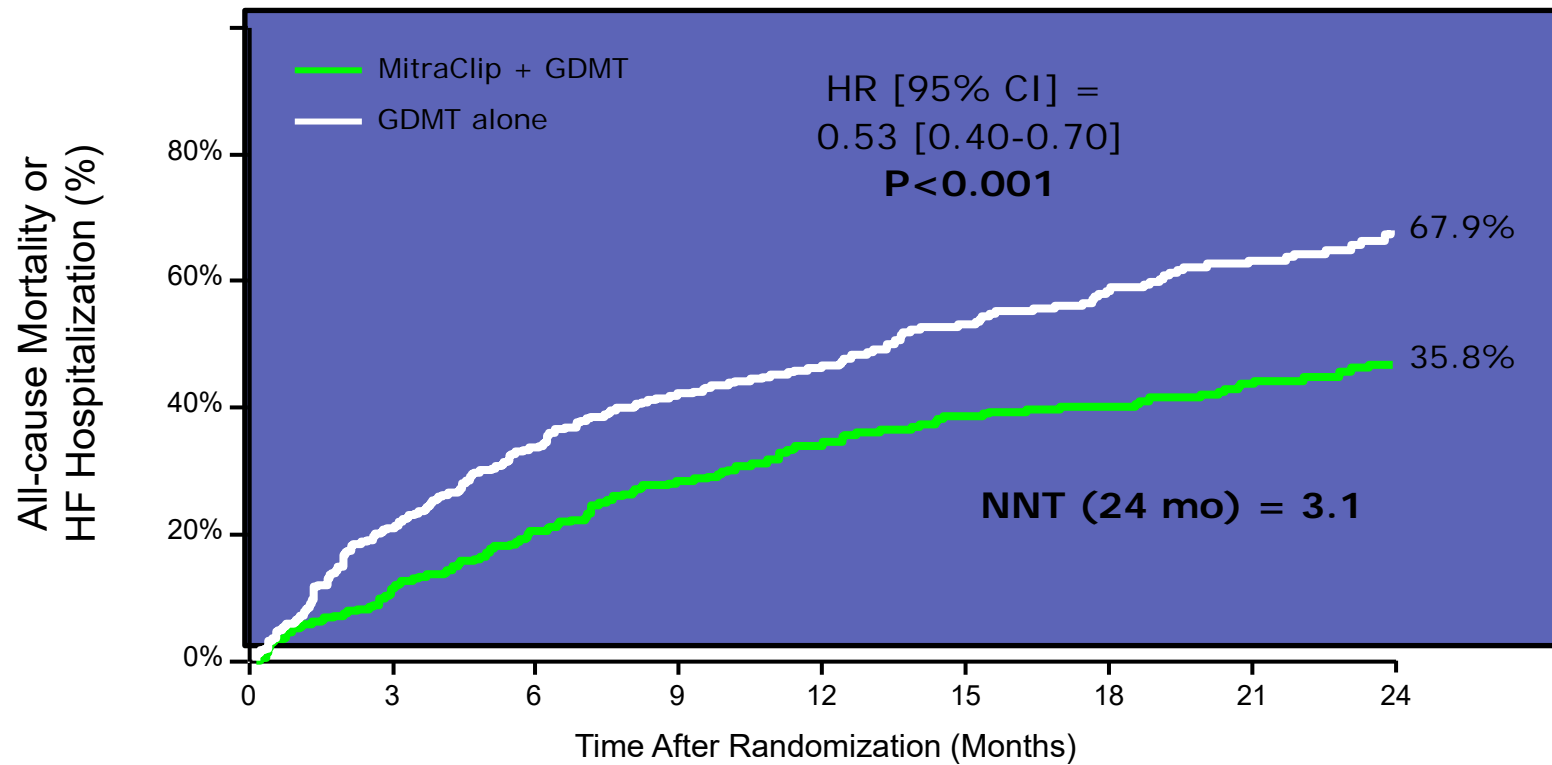


COAPT Diseño

- Trial funded by Abbot Vascular
- 614 patients with severe secondary MR (defined as an **EROA > 30 mm² or a regurgitant volume > 45 mL**)
- An LVEF between **20% and 50%**, and symptomatic HF despite optimal medical treatment.
- 2 groups similarly to the MITRA-FR trial.
- The primary outcome was **admissions for HF at 2 years**.



COAPT Resultados

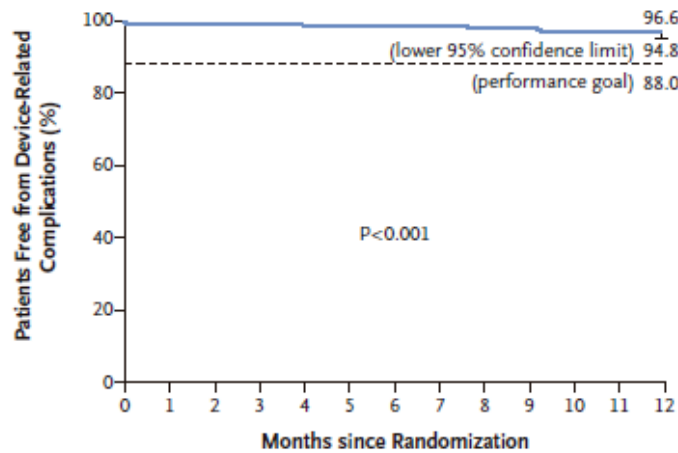




COAPT Resultados

Safety EP

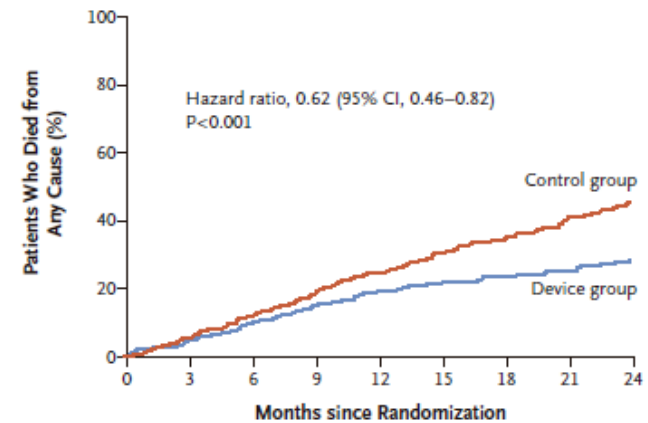
B Freedom from Device-Related Complications



No. at Risk	
Device group	293 283 282 277 272 269 261 258 251 245 241 236 221

Secondary EP

C Death from Any Cause



No. at Risk	
Control group	312 294 271 245 219 176 145 121 88
Device group	302 286 269 253 236 191 178 161 124

Implicaciones para la práctica clínica

- Los resultados de ambos estudios deben interpretarse como complementarios más que contradictorios.
- El estudio COAPT es el primero en demostrar un beneficio en la corrección de la IM secundaria.
- Un NNT de 3 implica un beneficio que no debe ser ignorado, especialmente en un subgrupo de pacientes con una mortalidad al año por encima del 20% a pesar de tratamiento médico óptimo.



Implicaciones para la práctica clínica

En la práctica clínica debemos intentar reproducir el COAPT:

- Selección de pacientes: Disfunción VI (FEVI < 50%) a pesar de tratamiento médico óptimo, TRC si indicada. En las decisiones deben estar implicados un equipo de expertos.
- Evitar futilidad, excluir a pacientes con enfermedad muy avanzada o comorbilidad significativa.
- Evaluación de la IM, teniendo en cuenta las limitaciones del eco 2D, PISA.
- El procedimiento debe realizarse en un centro de referencia con experiencia, objetivo IM \leq grade 2, utilizando los clips que se consideren necesarios para ello.



Conclusiones: PRINCIPALES NOVEDADES

1. En el manejo del paciente con valvulopatía mitral, se apuesta por un equipo multidisciplinar con toma de decisiones consensuadas y preferiblemente en un centro de referencia de valvulopatías
2. En pacientes con insuficiencia mitral primaria, cuando la indicación de cirugía se realiza únicamente en base a la presencia de hipertensión pulmonar en reposo (PSAP >50 mmHg), esta medida debe confirmarse mediante la realización de un cateterismo derecho.
3. Se elimina la indicación de cirugía en caso de hipertensión pulmonar severa con esfuerzo en el paciente con IM primaria asintomática.



Conclusiones: PRINCIPALES NOVEDADES

4. Existe una tendencia a operar antes a los pacientes asintomáticos con IM primaria severa:

Se recomienda la cirugía (recomendación IIa) para pacientes asintomáticos con IM severa aun cuando estén en ritmo sinusal y tengan una FEVI > 60% si la probabilidad de reparación es alta, el diámetro telesistólico del VI se sitúa entre 40 y 44 mm y se cumple uno de estos criterios: la aurícula izquierda está dilatada (≥ 60 ml/m²) en ritmo sinusal o la causa es rotura de cuerdas tendinosas. En caso de alta probabilidad de reparación duradera, bajo riesgo quirúrgico y en un centro de referencia valvular



Conclusiones: PRINCIPALES NOVEDADES

5. Se incorporan los dispositivos percutáneos al tratamiento de la IM secundaria grave (recomendación IIb). Para los pacientes con disfunción ventricular grave que no tienen indicada la revascularización y permanecen sintomáticos a pesar del tratamiento médico óptimo, se puede indicar la cirugía si el riesgo quirúrgico es bajo, y mediante procedimientos percutáneos si el riesgo quirúrgico no es bajo y la morfología valvular es favorable (IIb C).

Probablemente esta recomendación cambie con los resultados de los estudios publicados en 2018.