



TRATAMIENTO PERCUTÁNEO DE LA INSUFICIENCIA MITRAL. MITRACLIP

DABIT ARZAMENDI MD, PhD

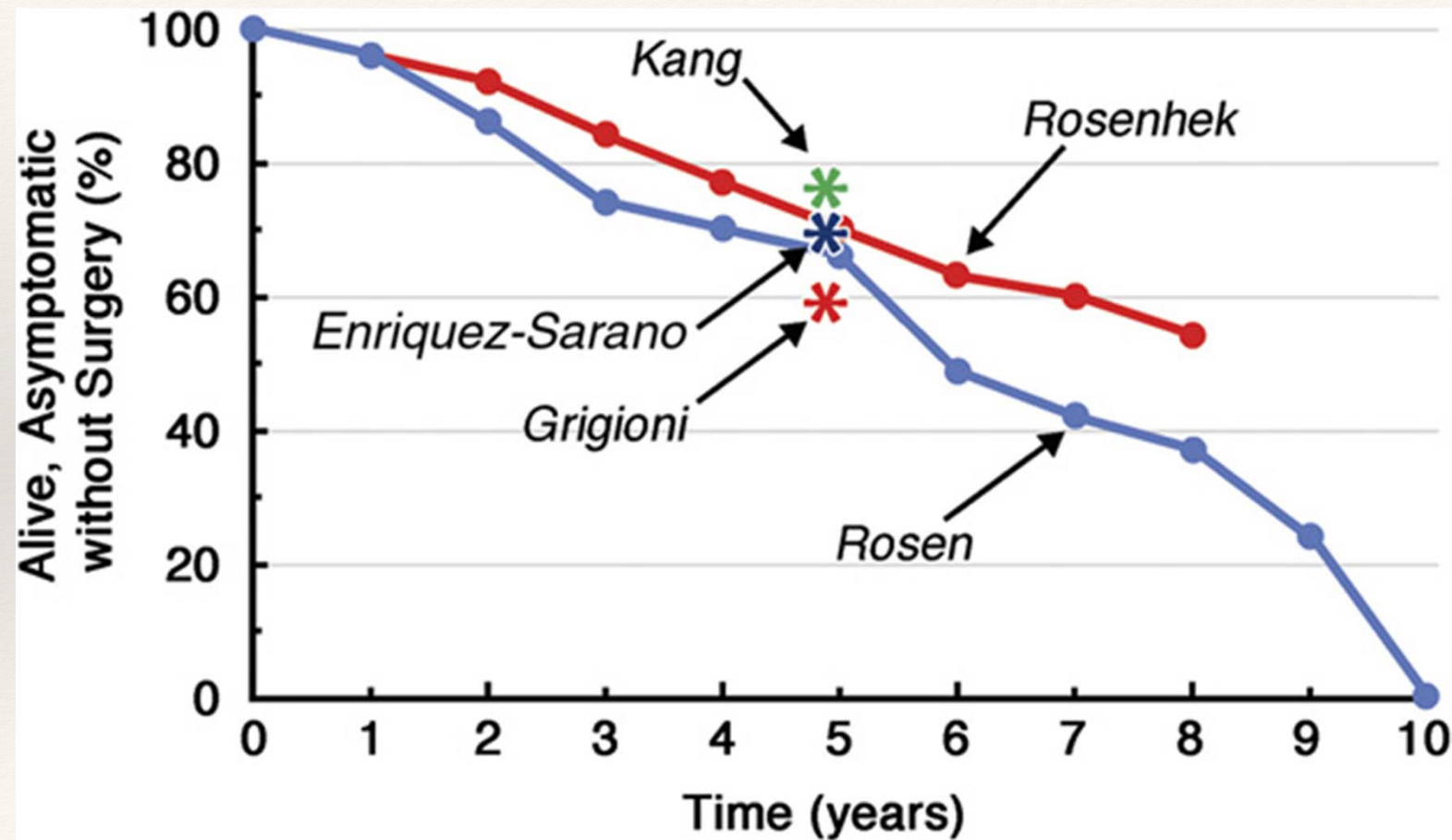


@structuralbcn

IS IT WORTH HAVING A MITRACLIP PROGRAM?

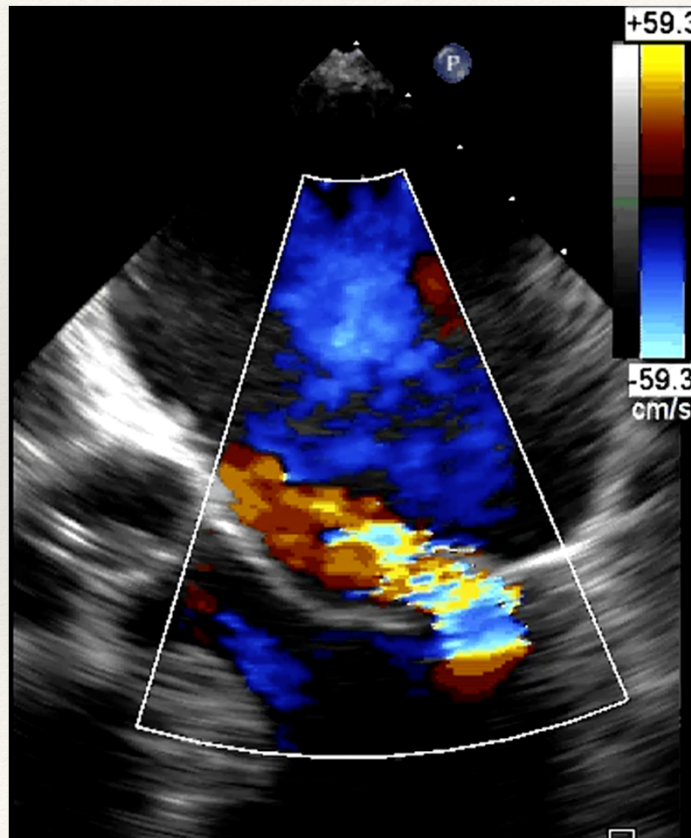
- Mitral regurgitation is the second most prevalent valvular disease (33.6%)
- More prevalent on patients >75yo (13%)
- Younger patients than EAO, but with more comorbidities:
 - ❖ Myocardial infarction 26.1%
 - ❖ Coronary revascularization 13.6%
 - ❖ CKF 4.6%
 - ❖ Heart failure NYHA III-IV 43.3%

IS IT WORTH HAVING A MITRACLIP PROGRAM?

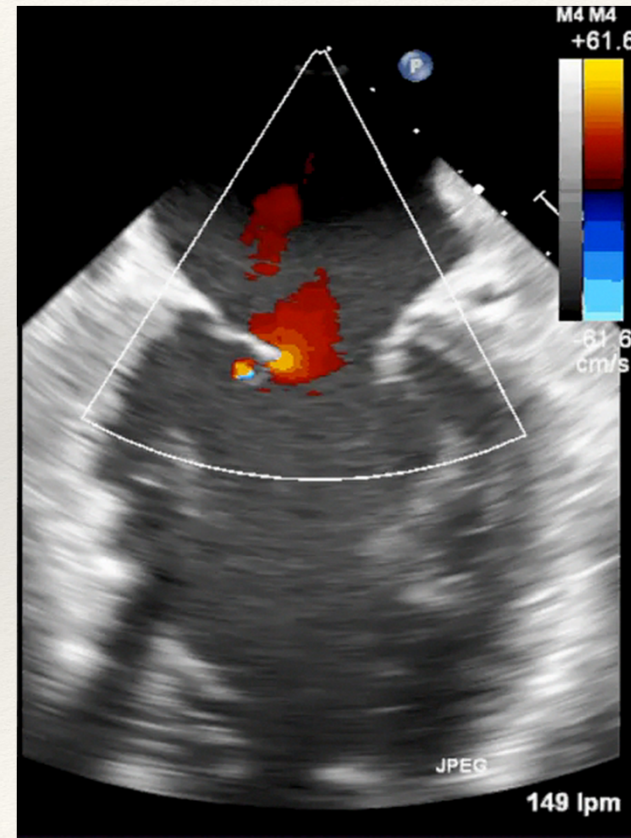


IS IT WORTH HAVING A MITRACLIP PROGRAM?

DEGENERATIVE MR (1ª)

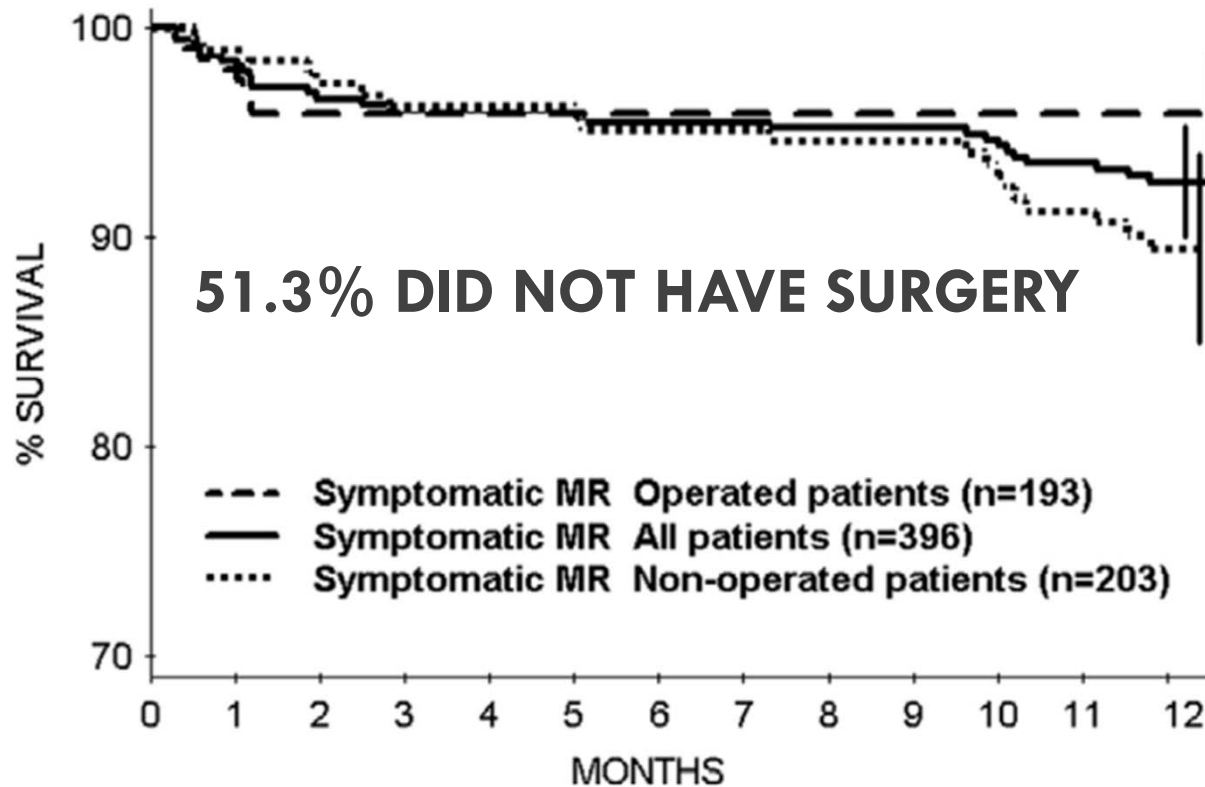


FUNCTIONAL MR (2ª)



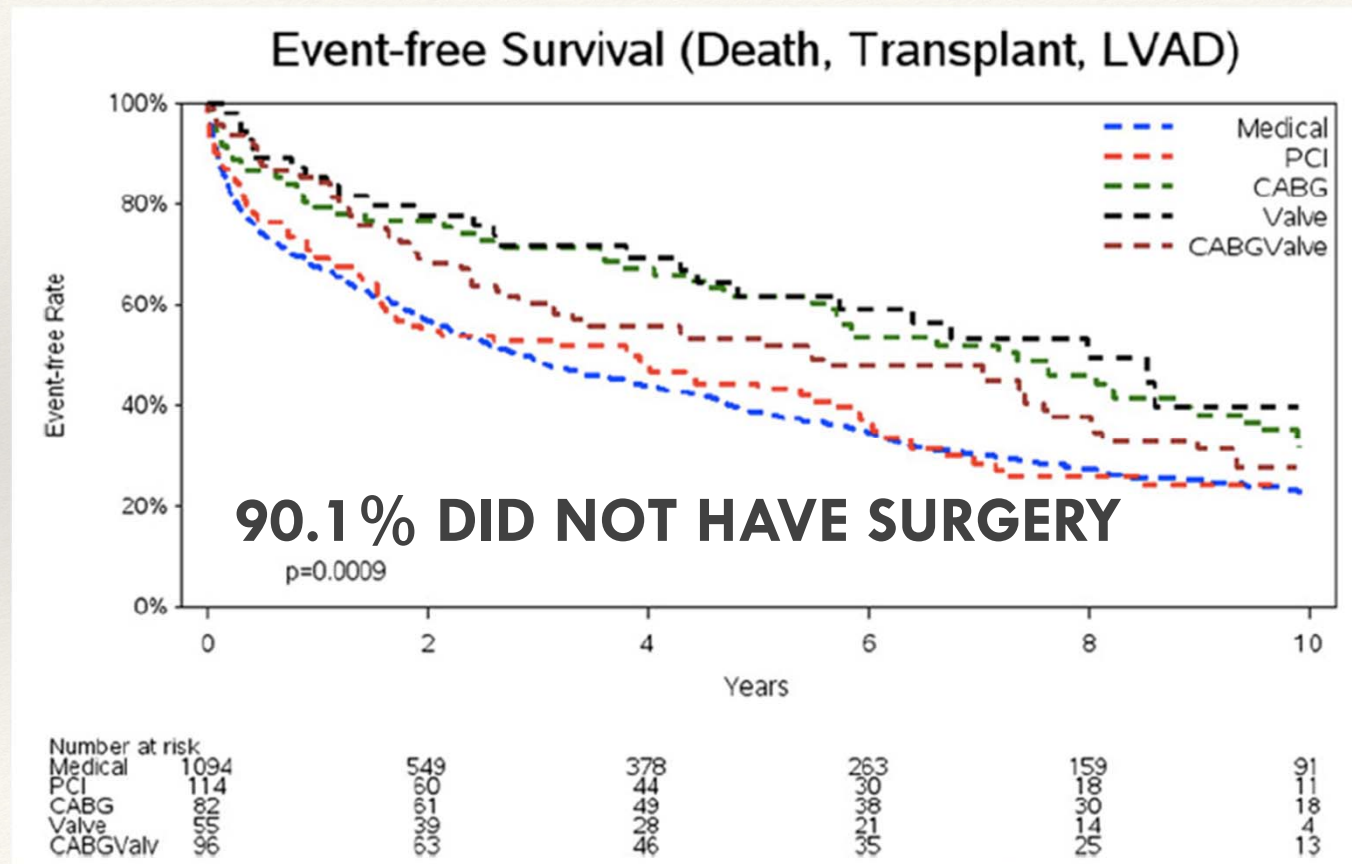
IS IT WORTH HAVING A MITRACLIP PROGRAM?

DEGENERATIVE MR



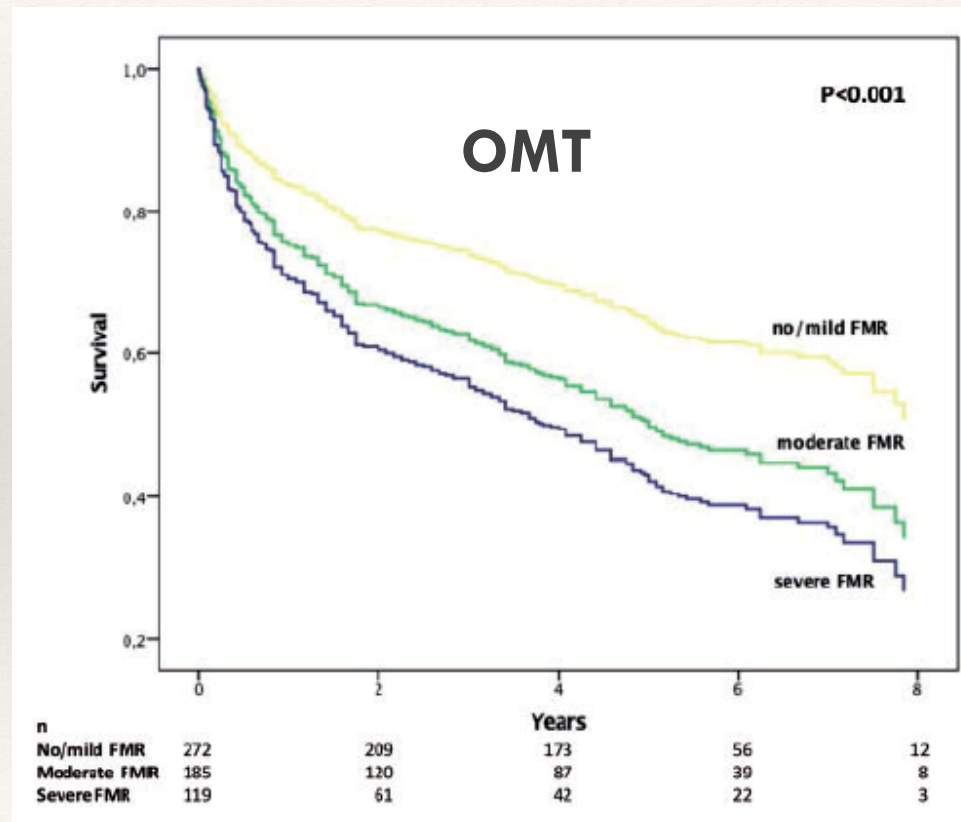
IS IT WORTH HAVING A MITRACLIP PROGRAM?

FUNCTIONAL MR



IS IT WORTH HAVING A MITRACLIP PROGRAM?

FUNCTIONAL MR



IS IT WORTH HAVING A MITRACLIP PROGRAM?

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Artículo especial

Registro Español de Hemodinámica y Cardiología Intervencionista. XXVII Informe Oficial de la Sección de Hemodinámica y Cardiología Intervencionista de la Sociedad Española de Cardiología (1990-2017)

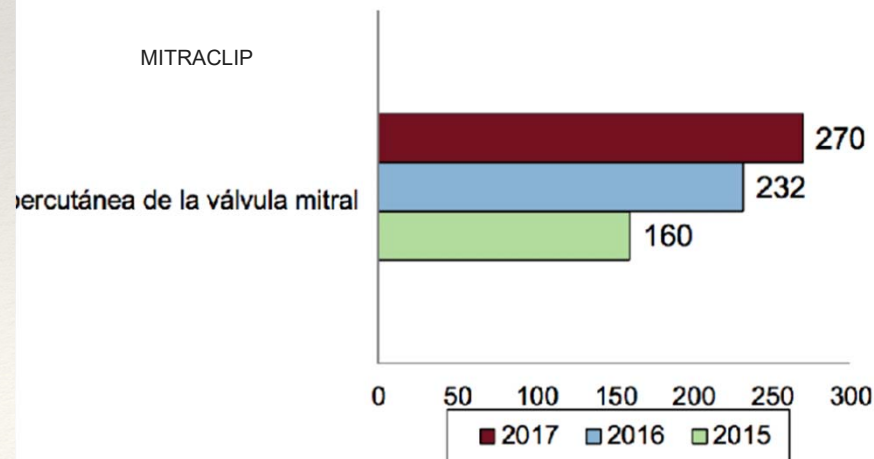
Ana Belén Cid Álvarez^{a,*}, Oriol Rodríguez Leor^b, Raúl Moreno^c y Armando Pérez de Prado^d

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POTENTIAL FOR TCT

940K*

Aortic Stenosis (M/S)

14% treated**

1.6M^{2,3}

Tricuspid Regurgitation (M/S)

0.4% treated^{1***}

4M*

Mitral Regurgitation (M/S)

1.5% treated****

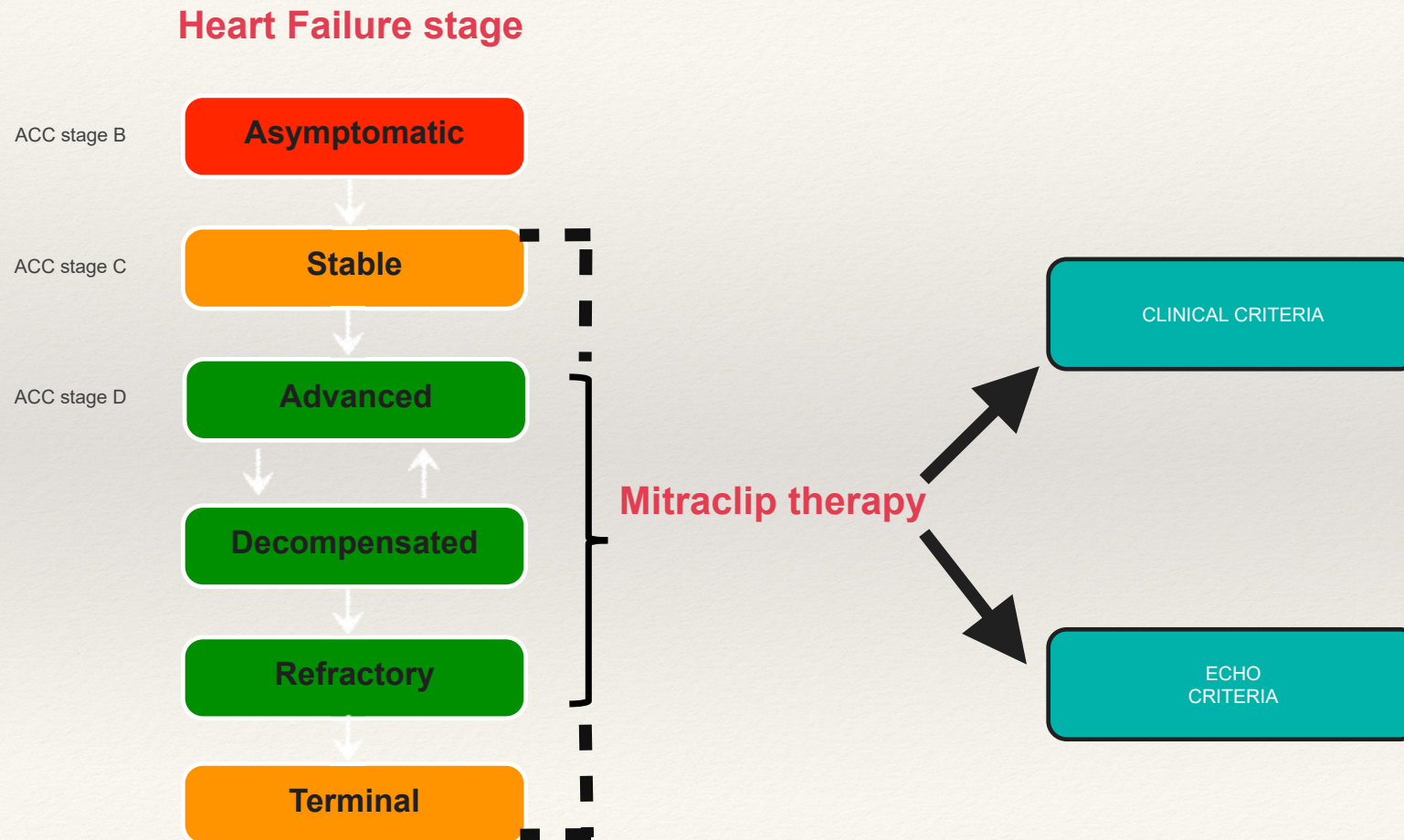
1. CMS MedPark Data File 2016, 2. Topilsky et al Burden of TR in Patients Diagnosed in the Community Setting JACC: CV Imaging 2018, 3. Topilsky, J. Tricuspid valve regurgitation: epidemiology and pathophysiology, Minerva Cardioangiologica 2018.
Calculations made based on data from refs 2 and 3. **Calculation made based at Abbott based on ref from 1, 2, 3.



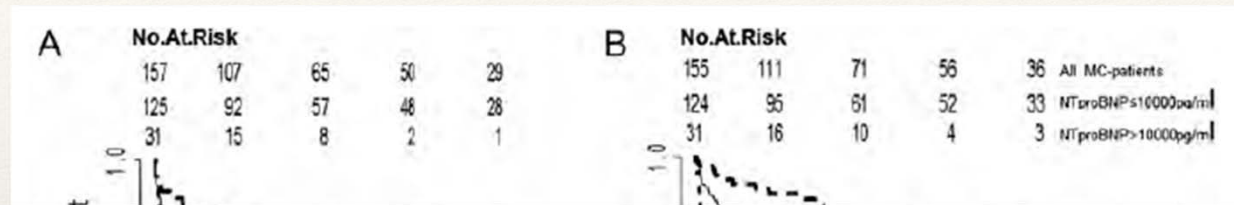
CLINICAL AND ANATOMICAL SELECTION FOR FUNCTIONAL MR

- PATIENT SELECTION FOR MITRACLIP: THE KEY TO SUCCESS

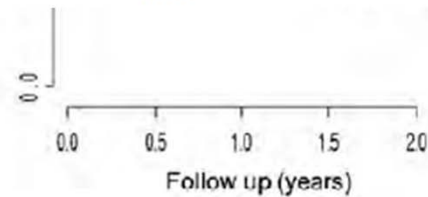
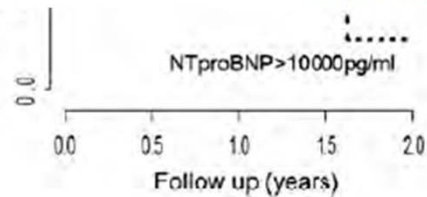
FUNCTIONAL MR. PATIENT SELECTION



FUNCTIONAL MR. PATIENT SELECTION

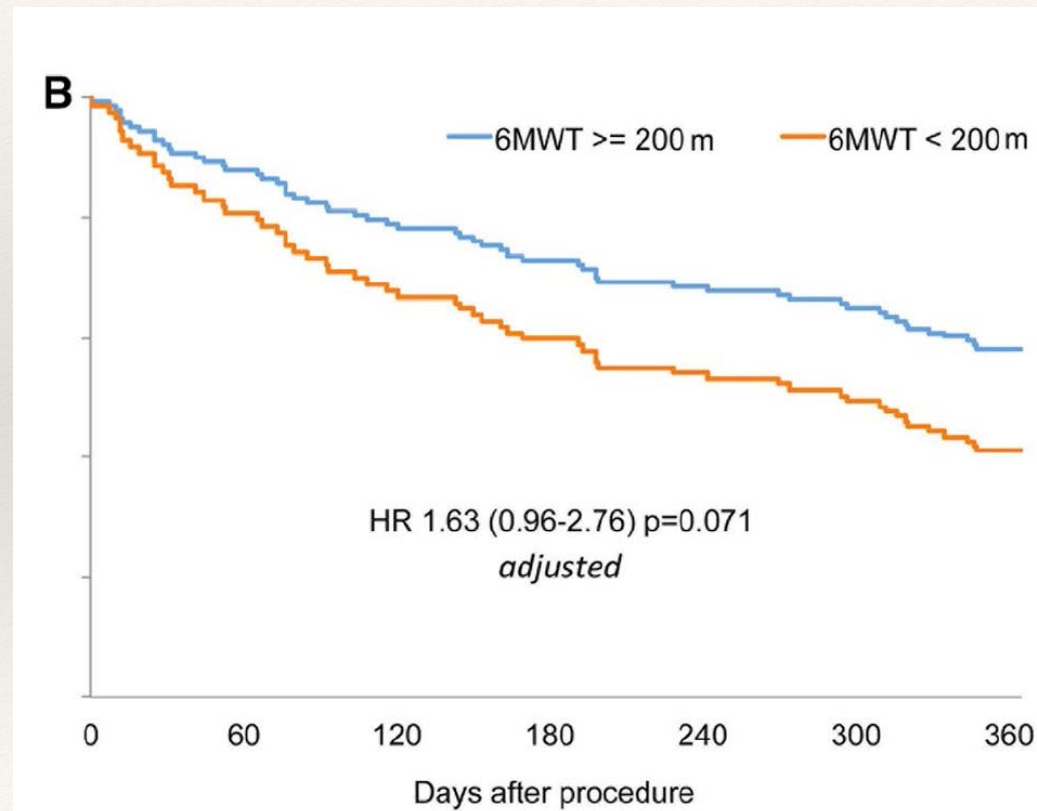


Parameter	Univariate analysis		Multivariate analysis: optimized model	
	HR (95% CI)	P-value	HR (95% CI)	P-value
NT-proBNP >10 000 pg/mL	4.6 (2.6–8.2)	<0.001	3.5 (1.9–6.7)	<0.001
Age >80 years	1.8 (1.0–3.3)	0.046	2.2 (1.2–4.2)	0.008
Serum creatinine >150 mmol/L	2.4 (1.4–4.3)	0.002		
NYHA class IV	2.1 (1.2–3.7)	0.008	1.7 (1.0–3.2)	0.049
TAPSE <15 mm	3.2 (1.8–5.6)	<0.001	1.9 (1.0–3.6)	0.038
TR grade >2+	2.0 (1.0–4.0)	0.052		



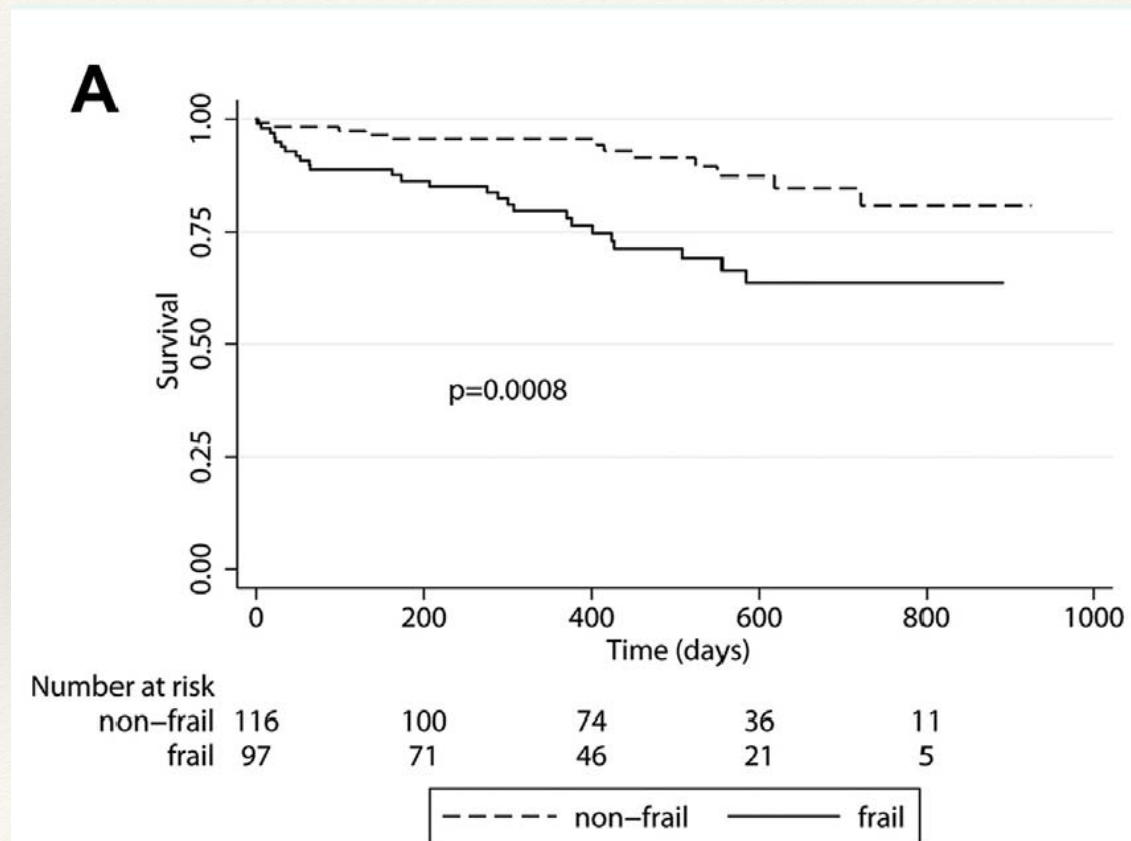
FUNCTIONAL MR. PATIENT SELECTION

6MWT



FUNCTIONAL MR. PATIENT SELECTION

FRAILITY



FUNCTIONAL MR. PATIENT SELECTION

OPTIMAL PATIENT

1. Symptomatic secondary mitral regurgitation (3+ or 4+ by independent echocardiographic core laboratory assessment) due to cardiomyopathy of either ischemic or non-ischemic etiology
2. Subject has been adequately treated per applicable standards, including for coronary artery disease, LV dysfunction, mitral regurgitation and heart failure
3. NYHA functional class II, III or ambulatory IV
4. Subject has had at least one hospitalization for heart failure in the 12 months prior to enrollment and/or a corrected* BNP ≥ 300 pg/ml or a corrected NT-proBNP ≥ 1500 pg/ml

FUNCTIONAL MR. ANATOMICAL CRITERIA

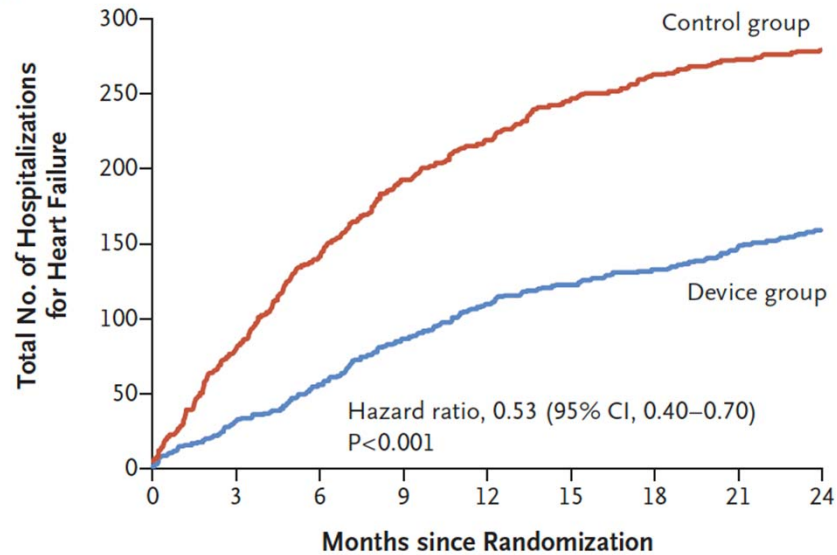
OPTIMAL PATIENT

1. Left ventricular ejection fraction $\geq 20\%$ and $\leq 50\%$.
2. Left ventricular end-systolic dimension ≤ 70 mm
3. The primary regurgitant jet is non-commissural, and in the opinion of the MitraClip implanting investigator can be successfully be treated by the MitraClip (if a secondary jet exists, it must be considered clinically insignificant)

FUNCTIONAL MR. OPTIMAL PATIENT

OPTIMAL RESULT

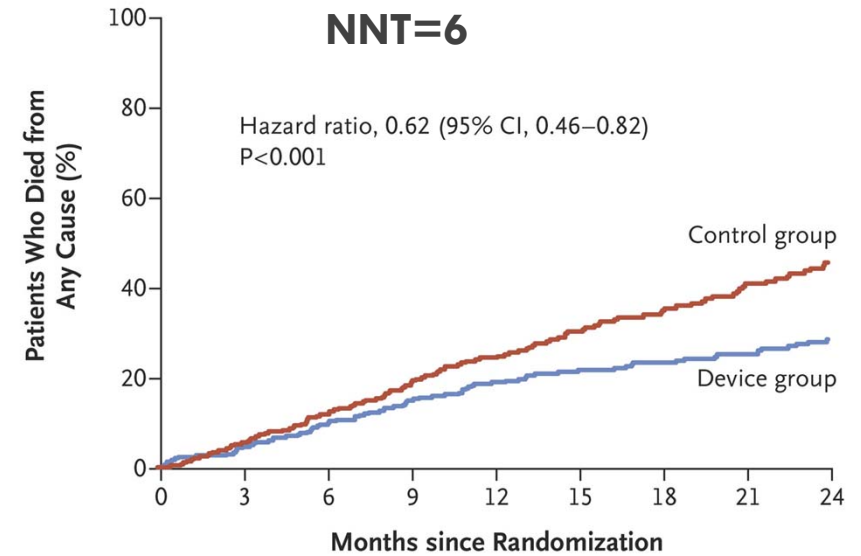
A Hospitalization for Heart Failure



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

C Death from Any Cause

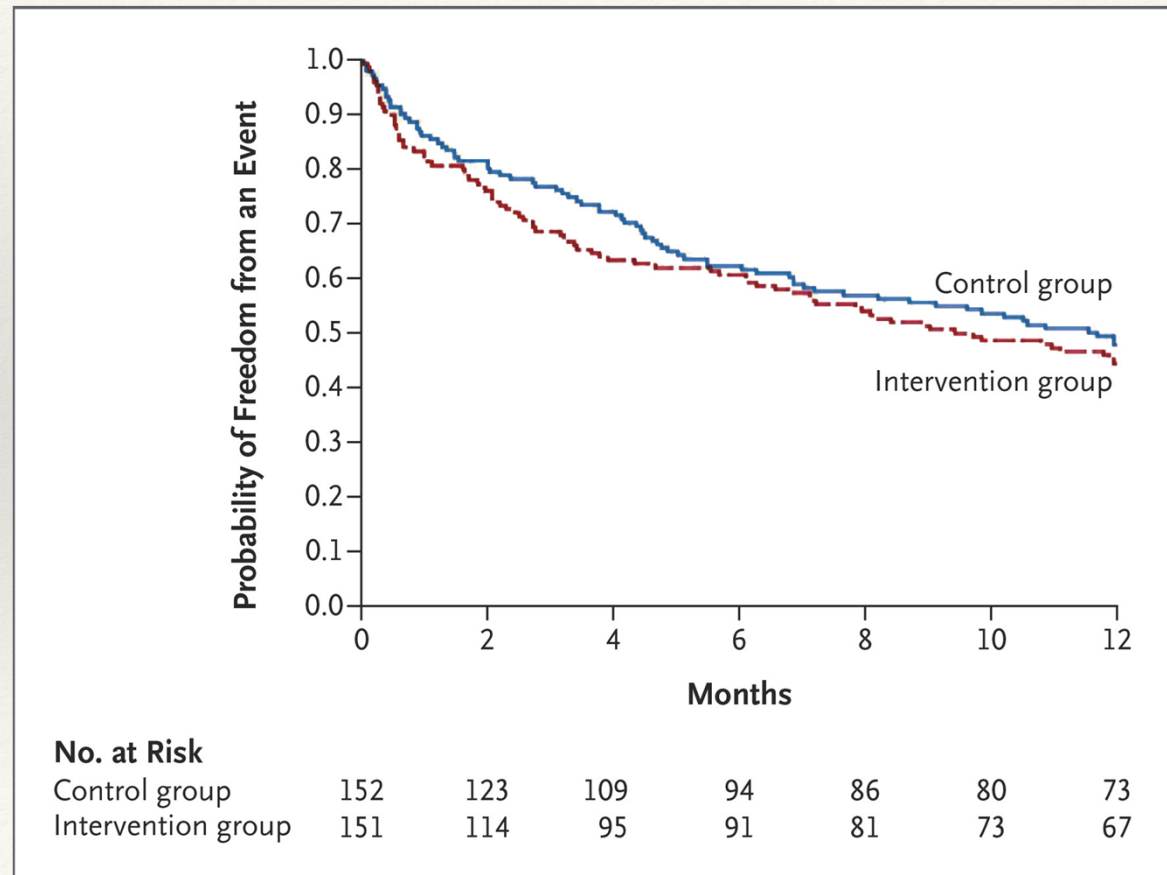


No. at Risk

Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

≠ PATIENT SELECTION ≠ RESULT

MITRA FR



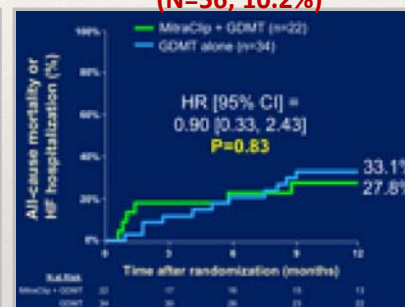
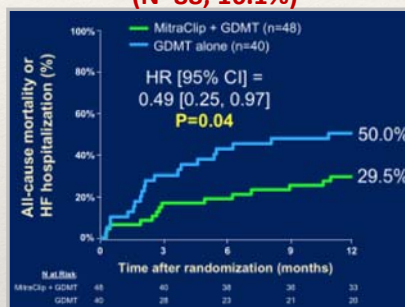
≠ PATIENT SELECTION ≠ RESULT

	MiTRA.FR	COAPT
	n=304	n=614
Severity FMR	ESC Guidelines - ERO >20 mm ² or - VR>30 mL/beat Mean ERO 31±10 mm ² Mean LVEDVI 135±35 mL/m ²	US Guidelines - ERO >30 mm ² or - VR>45 mL/beat Mean ERO 41±15 mm ² Mean LVEDVI 101±34 mL/m ²
GMDT at baseline and FU	Allowing adjustment in a 'real-world fashion'	Confirmed by CEC 'maximal tolerated GMDT'. Few changes FU
AP failure	9%	5%
Procedural complications	14.5%	8.5%
MR≤2+ 12 mo	17%	5%

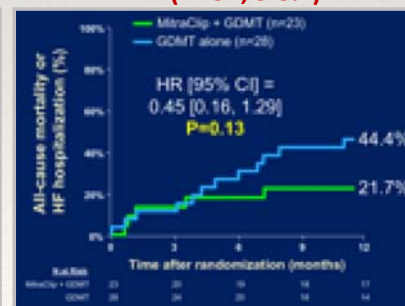
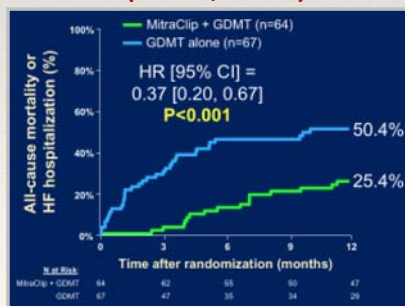
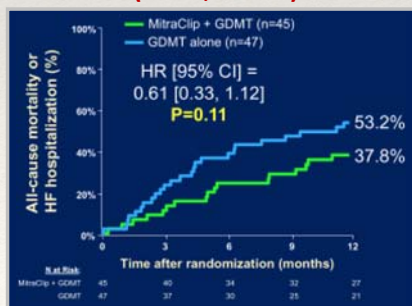
≠ PATIENT SELECTION ≠ RESULT

Impact of EROA and LVEDV: COAPT Sub-Analysis All-cause mortality or HF hospitalization through 12 months

EROA >40 mm², LVEDVI >96 ml/m² EROA >30-40 mm², LVEDVI >96 ml/m² EROA ≤30 mm², LVEDVI >96 ml/m²
(N=130; 23.7%) (N=88; 16.1%) (N=56; 10.2%)

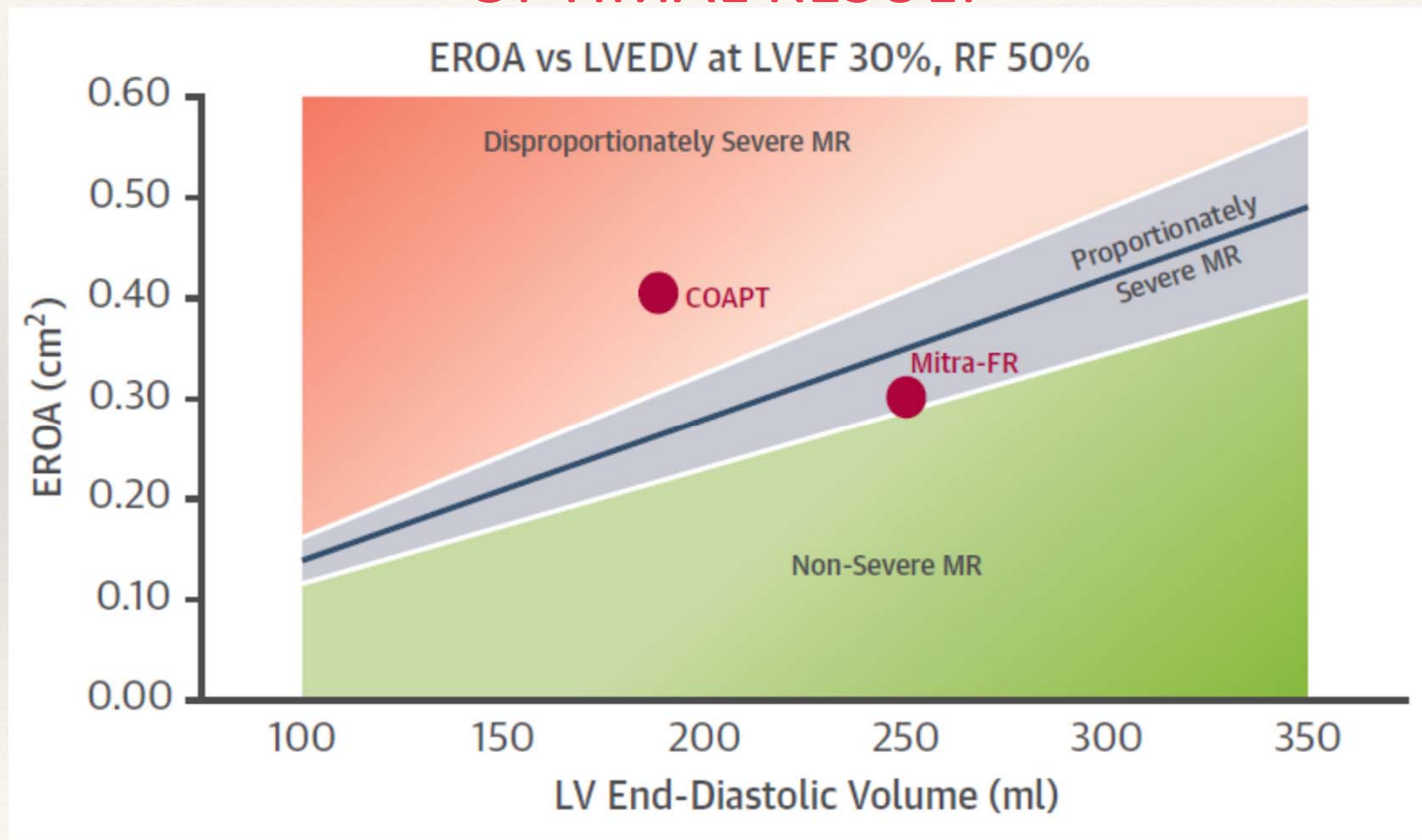


EROA >40mm², LVEDVI ≤96 ml/m² EROA >30-40mm², LVEDVI ≤96 ml/m² EROA ≤30 mm², LVEDVI ≤96 ml/m²
(N=92; 16.8%) (N=131; 23.9%) (N=51; 9.3%)



≠ PATIENT SELECTION ≠ RESULT

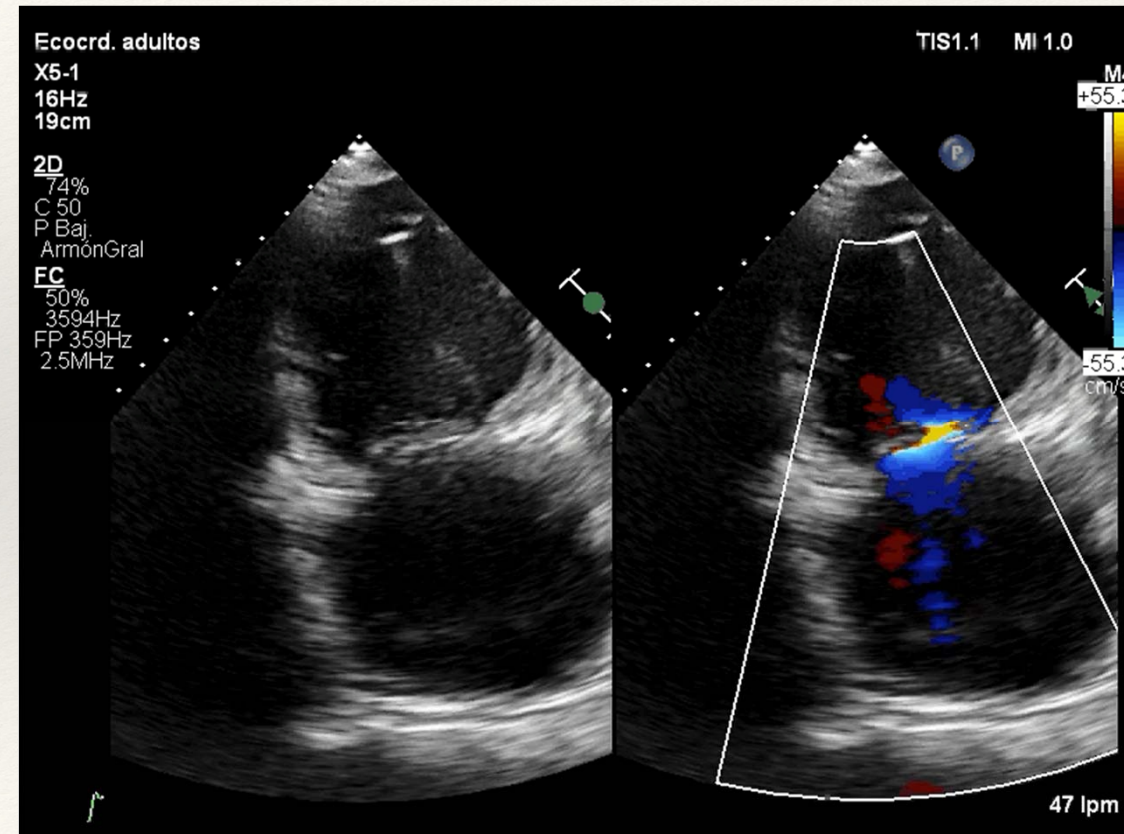
OPTIMAL RESULT



FUNCTIONAL MR. OPTIMAL PATIENT

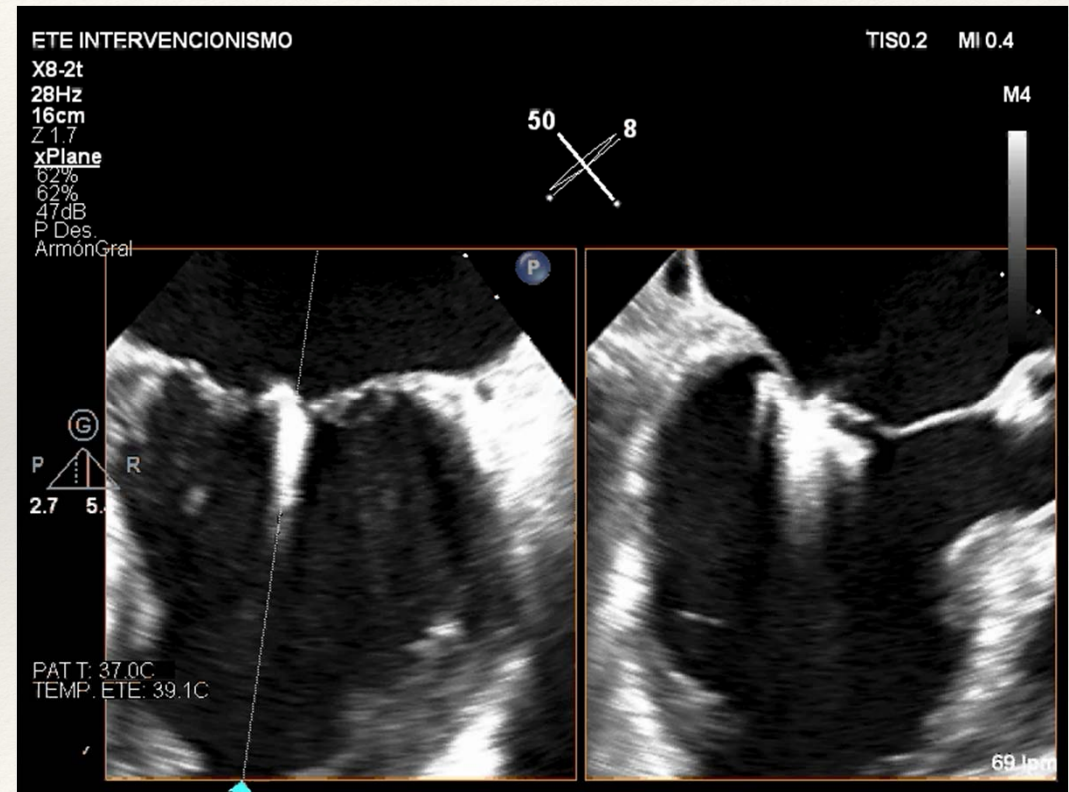
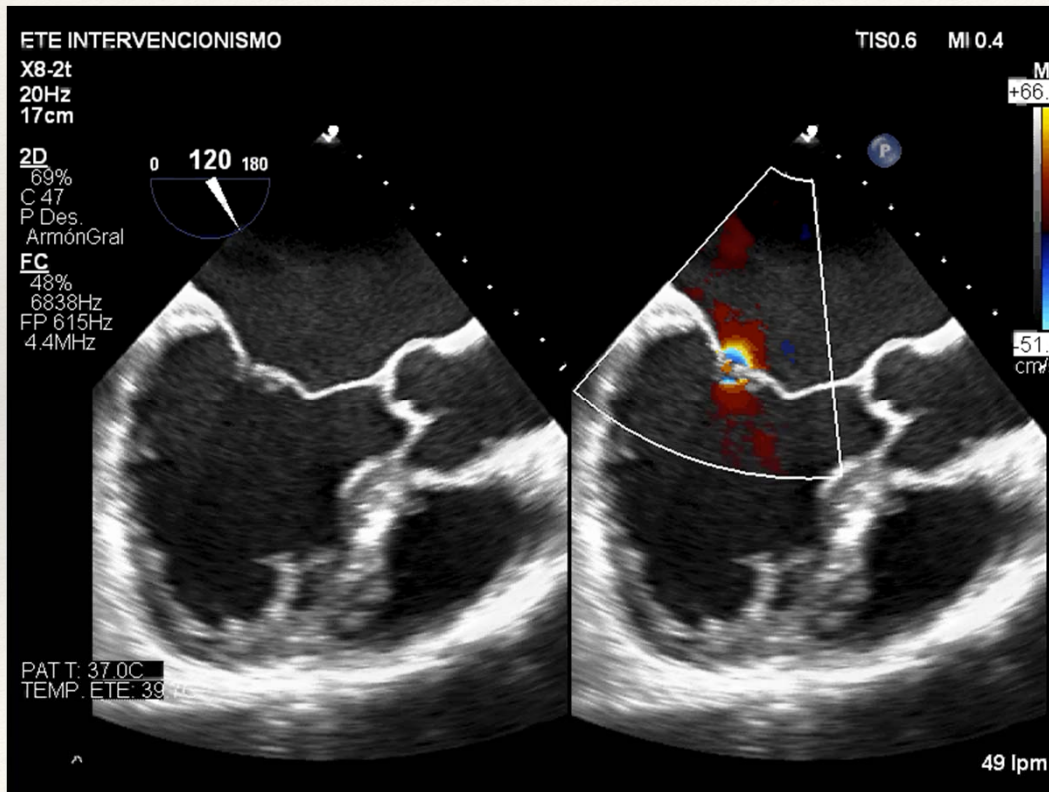
OPTIMAL RESULT

- 71 yo male
- CABG (AMI-LAD, SVG-M1, DP)
- Functional MR IV. EF 36%
- NYHA CF III
- TT: Furosemide, BB, Sacubitril-VST, EPN, Coumadin
- NT-proBNP 1600pg/mL
- STS 7%
- ETT: LVEDD 58mmHg, PAP 50mmHg, TAPSE 11mm



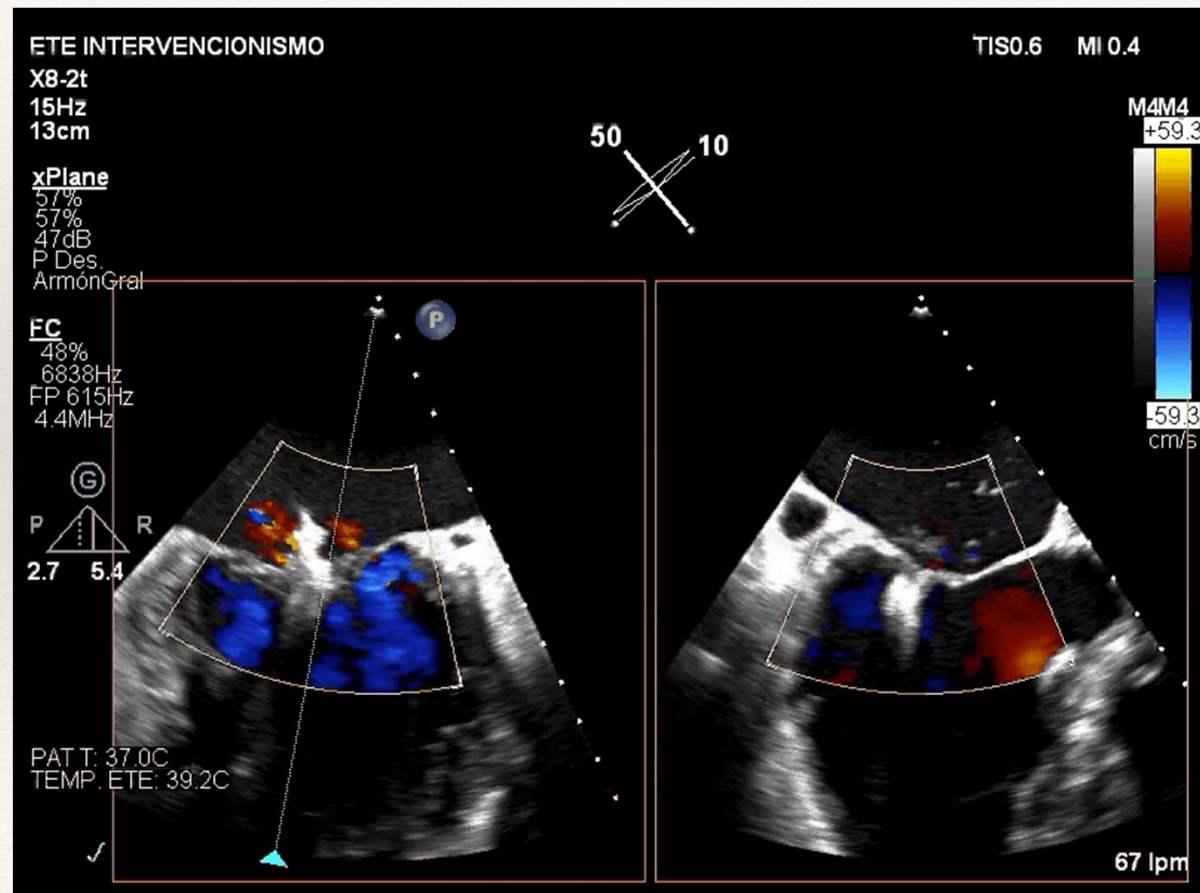
FUNCTIONAL MR. OPTIMAL PATIENT

OPTIMAL RESULT



FUNCTIONAL MR. OPTIMAL PATIENT

OPTIMAL RESULT



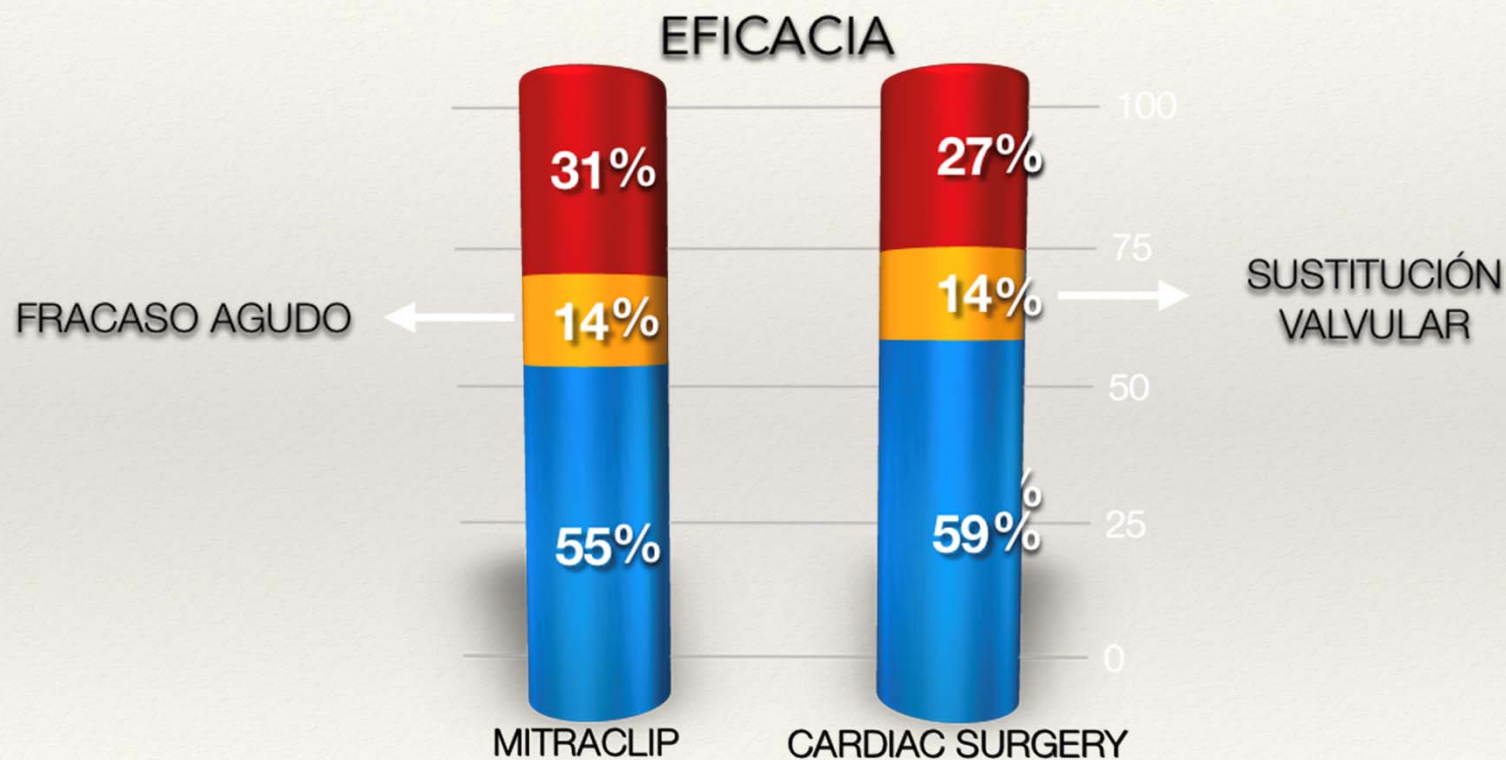


CLINICAL AND ANATOMICAL SELECTION FOR DEGENERATIVE MR

- PATIENT SELECTION FOR MITRACLIP: THE KEY TO SUCCESS

DEGENERATIVE MR. PATIENT SELECTION

EVEREST II RCT

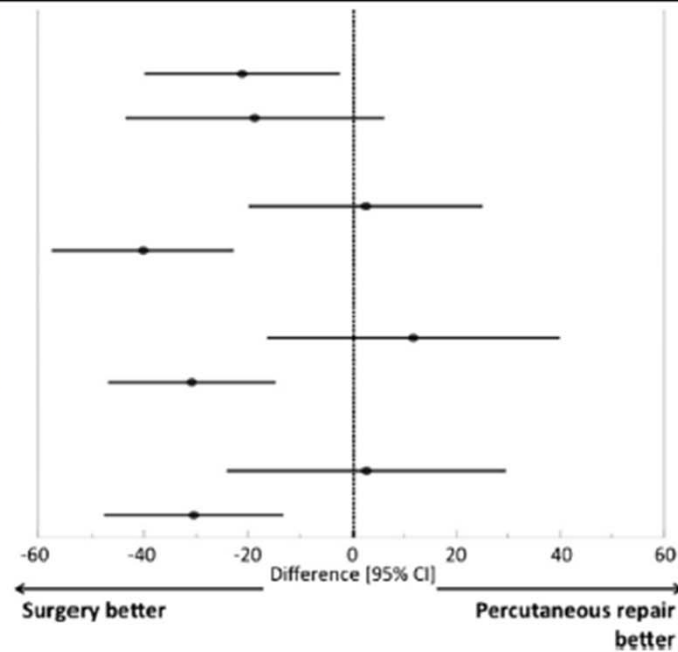


DEGENERATIVE MR. PATIENT SELECTION

EVEREST II RCT

TABLE 4 Subgroup Analyses for Freedom From Death, MV Surgery or Reoperation, and 3+ or 4+ MR at 5 Years

Subgroup	Percutaneous Repair	Surgery	Difference (95% CI)	p value	Interaction p value
Sex					
Male	42.9 (42/98)	63.9 (23/36)	-21.0% (-39.5% to -2.5%)	0.03	0.89
Female	46.4 (26/56)	65.0 (13/20)	-18.6% (-43.2% to 6.1%)	0.15	
Age					
Age ≥70 yrs	45.1 (32/71)	42.3 (11/26)	2.8% (-19.5% to 25.0%)	0.81	0.005
Age <70 yrs	43.4 (36/83)	83.3 (25/30)	-40.0% (-57.0% to -22.9%)	<0.001	
Type of MR					
Functional MR	40.5 (17/42)	28.6 (4/14)	11.9% (-16.0% to 39.8%)	0.43	0.02
Degenerative MR	45.5 (51/112)	76.2 (32/42)	-30.7% (-46.5% to -14.8%)	<0.001	
LVEF					
LVEF <60%	44.1 (26/59)	41.2 (7/17)	2.9% (-23.7% to 29.5%)	0.83	0.04
LVEF ≥60%	44.1 (41/93)	74.4 (29/39)	-30.3% (-47.3% to -13.3%)	0.001	



Values are % (n/N) unless otherwise indicated.
Abbreviations as in Table 1.

DEGENERATIVE MR. PATIENT SELECTION



DEGENERATIVE MR. PATIENT SELECTION

SURGICAL RISK SCORES

STS Adult Cardiac Surgery Database Version 2.9

RISK SCORES

Procedure: Isolated AVR

CALCULATE

Risk of Mortality: 6.124%

Renal Failure: 2.293%

Permanent Stroke: 3.478%

Prolonged Ventilation: 10.560%

DSW Infection: 0.045%

Reoperation: 4.108%

Morbidity or Mortality: 17.285%

Short Length of Stay: 13.784%

Long Length of Stay: 9.992%

PRINT CLEAR

Details of Selected Field:
Height Cm

Indicate the height of the patient in centimeters.

Patient related factors	
Age ¹ (years)	90
Gender	male
Renal impairment ² <i>See calculator below for creatinine clearance</i>	normal (CC >85ml/min)
Extracardiac arteriopathy ³	yes
Poor mobility ⁴	yes
Previous cardiac surgery	yes
Chronic lung disease ⁵	yes
Active endocarditis ⁶	yes
Critical preoperative state ⁷	no
Diabetes on insulin	no
EuroSCORE II	EuroSCORE II 59.98 %
<p>Note: This is the 2011 EuroSCORE II</p> <p>Calculate Clear</p>	

DEGENERATIVE MR. PATIENT SELECTION

FRAILTY SCORES

➤ Comorbidity:

- Charlson index(life-expectancy)

➤ Functional assessment:

- Basic: Barthel index
- Instrumentals: Lawton index

➤ Cognitive assessment:

- Pfeiffer test

➤ Execution tests

- Speed of march

- Handgrip

➤ Bioimpedance

- Phase angle

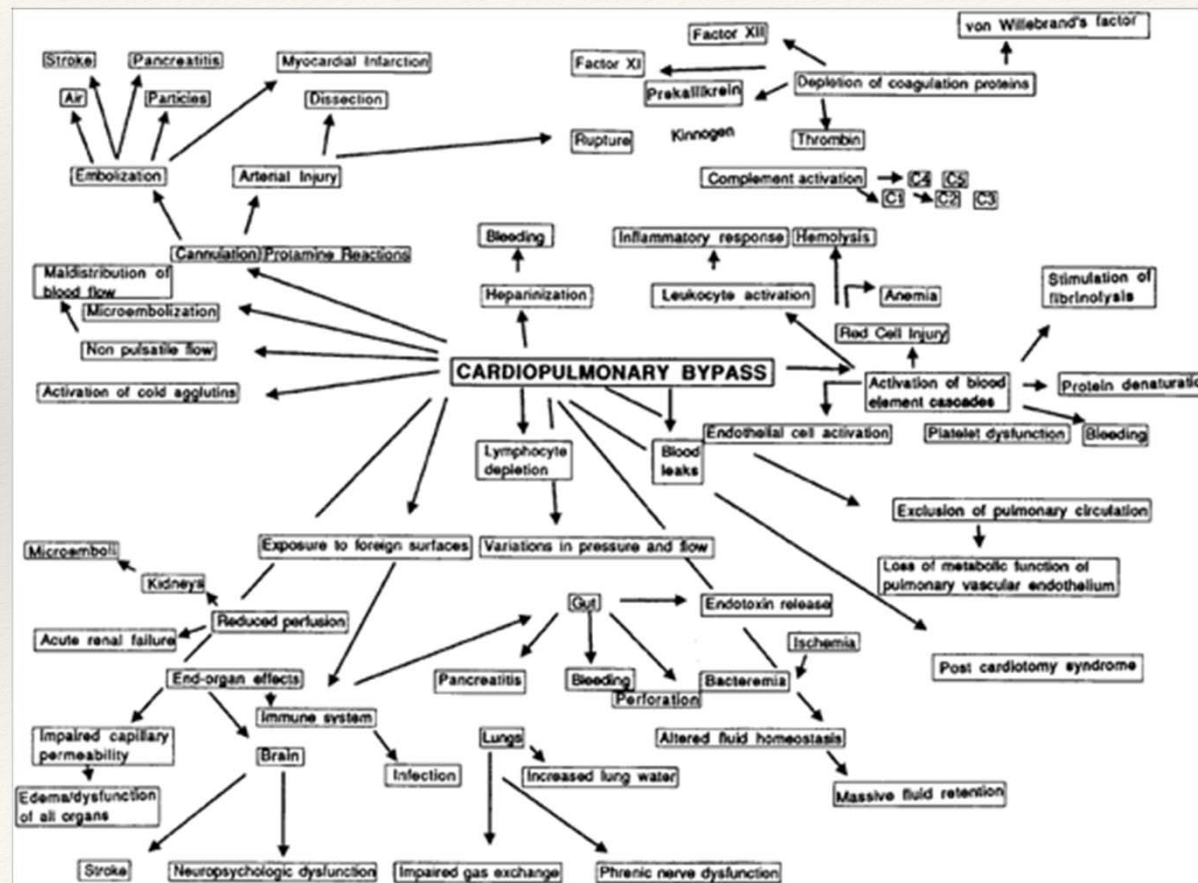
- Skeletal mass index

- Excess of extracellular H₂O

- Excess body fat

DEGENERATIVE MR. PATIENT SELECTION

AVOID CPB



DEGENERATIVE MR. ANATOMICAL SELECTION

IDEAL

- Central pathology in segment 2
- No leaflet calcification
- Mitral valve opening area > 4cm²
- Mobile length of the posterior leaflet ≥ 10mm
- Coaptation depth < 11mm
- Normal leaflet strength and mobility

RECONSIDER

- Pathology in segment 1 or 3
- Mild calcification outside the grip zone of the clip system, ring calcification, post-annuloplasty
- Mitral valve opening area > 3cm² with good residual mobility
- Mobile length of the posterior leaflet 7-10mm
- Coaptation depth ≥ 11mm
- Leaflet restriction in systole (Carpentier III B)
- Flail width > 15mm only with a large ring width and the option for multiple clips

AVOID

- Perforate mitral valve leaflet or cleft.
- Severe calcification in the grip zone
- Hemodynamically significant stenosis (gradient ≥ 5mmHg or MVA < 3cm²)
- Mobile length of the posterior leaflet < 7mm
- Rheumatic leaflet thickening and restriction in systole and diastole.
- Barlow's syndrome with multisegment flail leaflets.

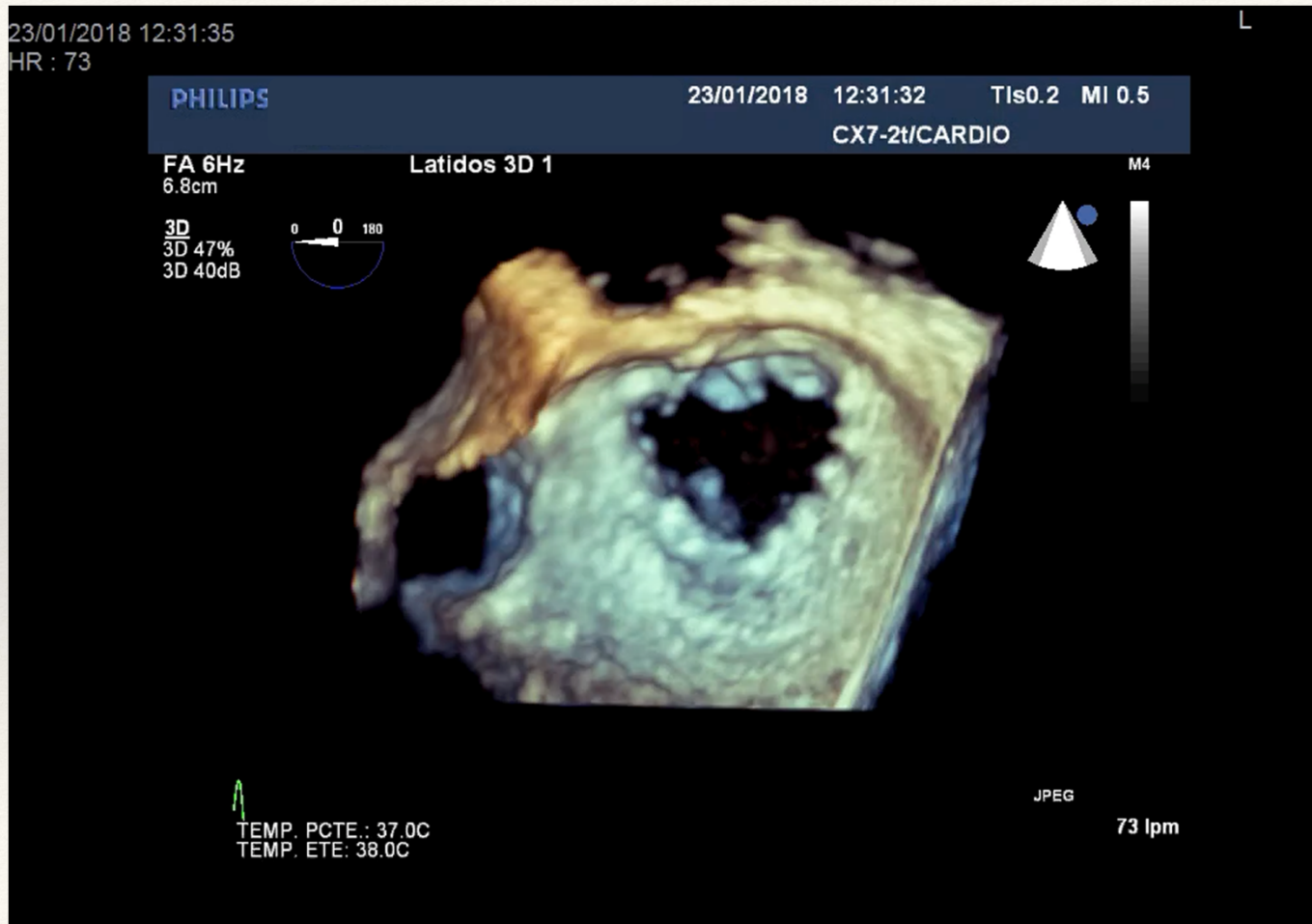
DMR. OPTIMAL PATIENT

OPTIMAL RESULT

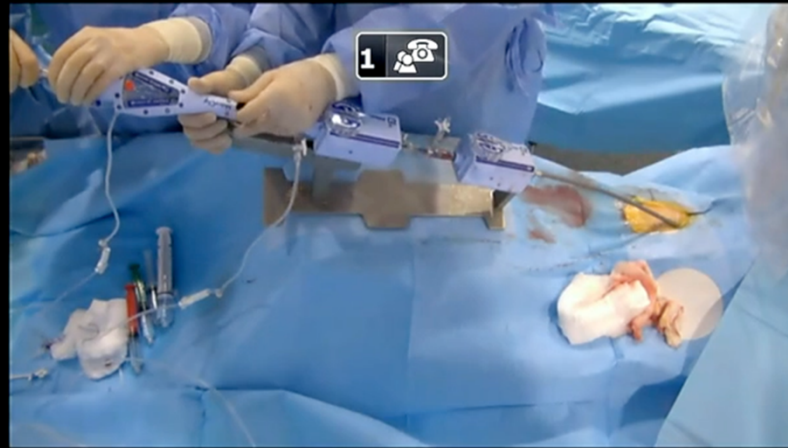
- 82 yo female
- AVR
- Afib
- CKF
- DMR IV. EF 60%
- NYHA CF III
- TT: Furosemide, Coumadin
- STS 8%
- Mild Frailty. No sarcopenia.



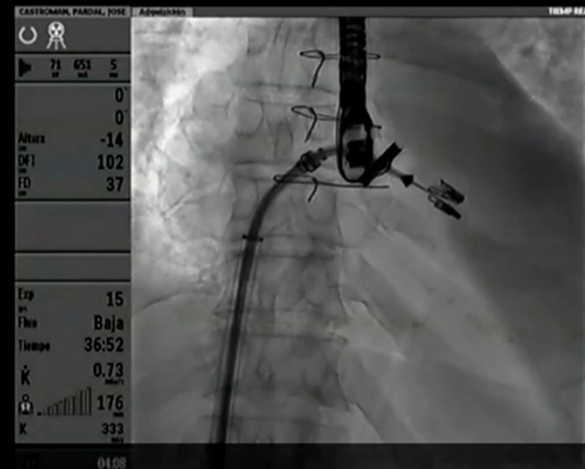
DMR. EXPERIENCED OF THE OPERATORS



DMR. EXPERIENCED OF THE OPERATORS



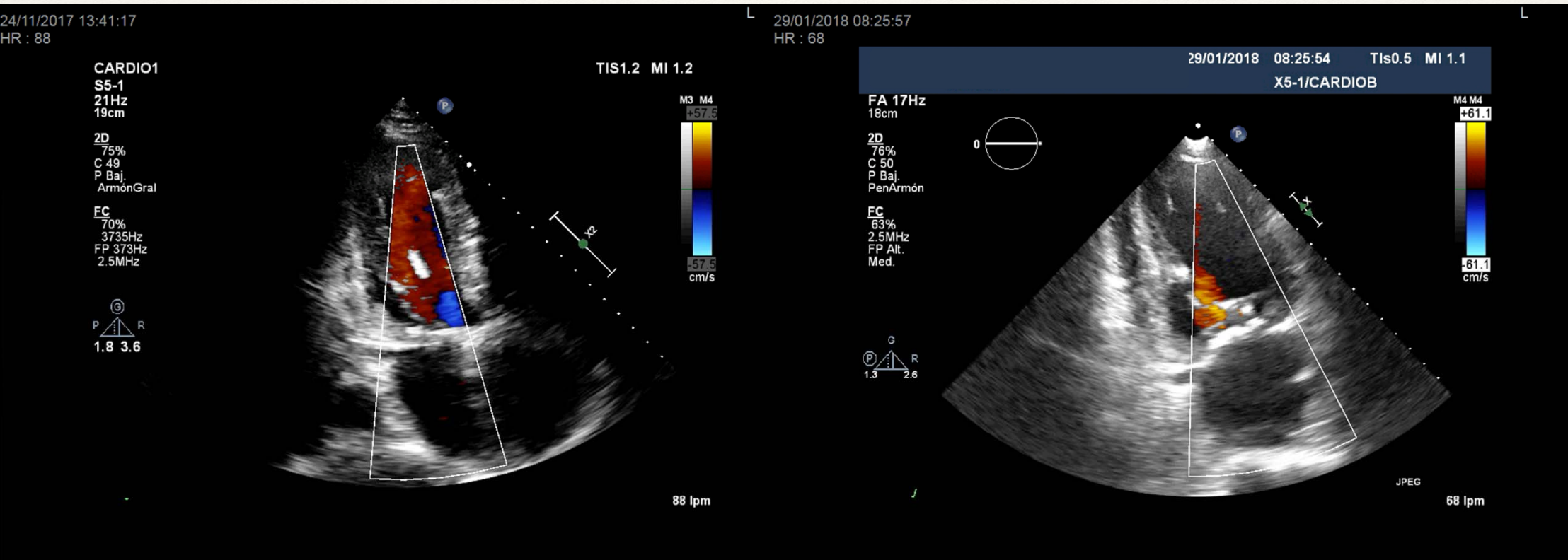
Hemodinamica-CHUS



DMR. EXPERIENCED OF THE OPERATORS

TTE PRE

TTE POST



OTROS DISPOSITIVOS DE
TÉCNICA EDGE-TO EDGE:
PASCAL

PACAL. DEVICE DESCRIPTION

Optimised leaflet capture

- Manoeuvring in three planes
- Independent leaflet capture



Empowering

Effective MR reduction

- Broad paddles maximise leaflet coaptation
- Spacer fills regurgitant orifice area



Effective

Excellent safety profile

- Spacer and contoured paddles reduce stress on leaflets
- Elongation promotes safe subvalvular manoeuvring

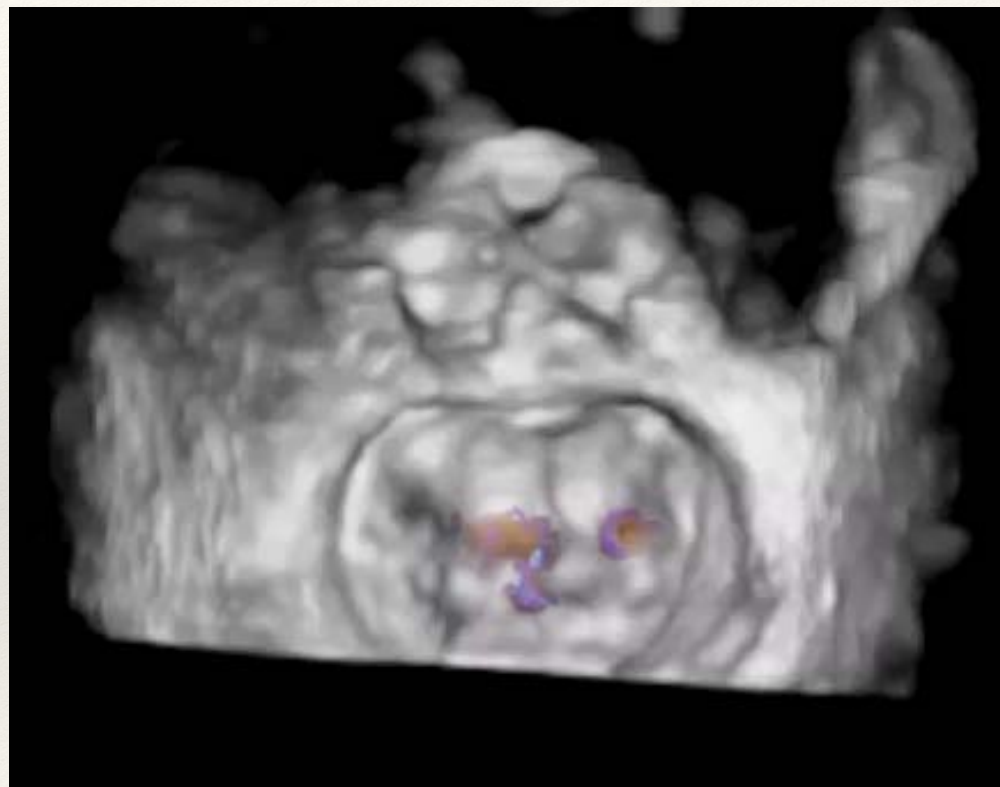
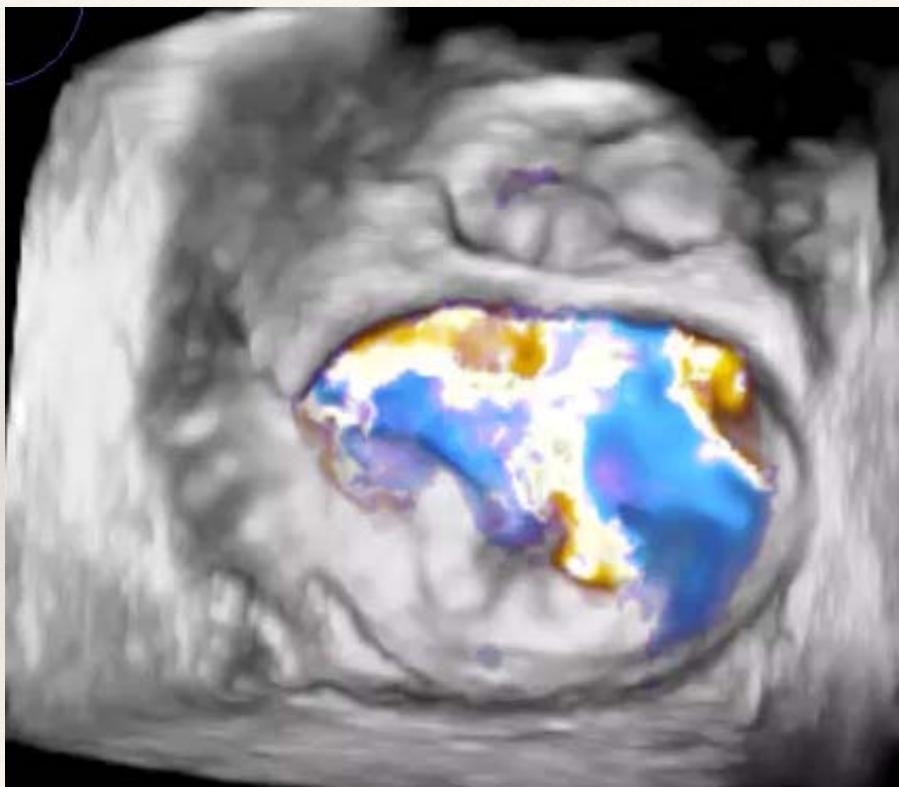


Safe

PACAL. PROCEDURE



PACAL. PROCEDURE



CONCLUSIONES

Developing a Mitraclip program is worthy: >50% of DMR and >90% FMR no surgery

➤ **FMR:**

- ❖ Mitraclip has shown a reduction in mortality (17%) compared to OMT
- ❖ Predictors of bad prognosis: CF IV, NT-ProBNP >10000
- ❖ Predictor of good result: disproportionately severe MR

➤ **DMR:**

- ❖ High-risk patients (surgical and frailty)
- ❖ Good anatomy (A2-P2, no large flail)

