# CLIPADO MITRAL PERCUTÁNEO: COMO REALIZAR UM PROCEDIMENTO EXITOSO?


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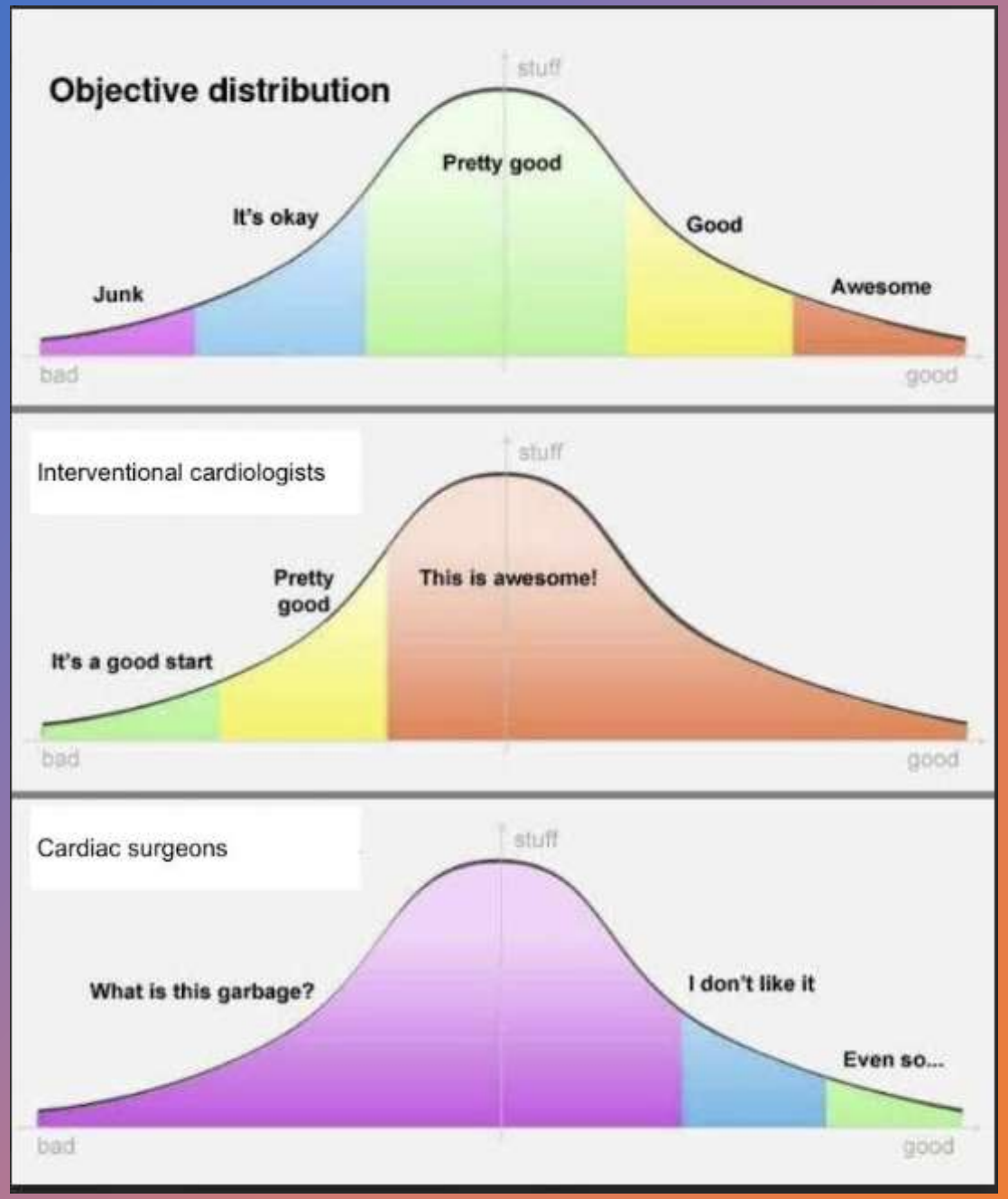
# CONFLITO DE INTERESSE

- PROCTOR ABBOTT




# INTERVENTIONAL

# X

# SURGEON

# A staging classification of right heart remodelling for patients undergoing transcatheter edge-to-edge mitral valve repair

**Jasmin Shamekhi**[1]*, MD; Atsushi Sugiura[1], MD; Maximilian Spieker[2], MD; Christos Iliadis[3], MD; Marcel Weber[1], MD; Can Öztürk[1], MD; Marc Ulrich Becher[1], MD; Vedat Tiyerili[1], MD; Sebastian Zimmer[1], MD; Patrick Horn[2], MD; Ralf Westenfeld[2], MD; Roman Pfister[3], MD; Victor Mauri[3], MD; Jan-Malte Sinning[4], MD; Malte Kelm[2], MD; Stephan Baldus[3], MD; Georg Nickenig[1], MD

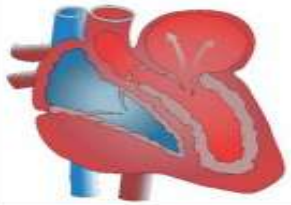
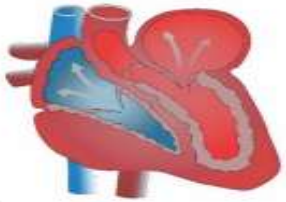
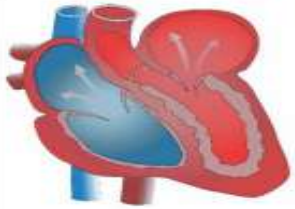
| | Criteria | Echocardiography |
|---|---|---|
|  Stage 0 | Severe MR without right heart damage | |
|  Stage 1 | Tricuspid damage | Moderate - to severe TR |
|  Stage 2 | Right ventricular damage | Right ventricular fractional area change <42% and TAPSE <17 mm or right atrial area >25 cm² and/or indexed right ventricular volume >30 ml/m² |

**Figure 2.** *Staging classification according to right heart remodelling in patients undergoing a MitraClip procedure due to severe MR. MR: mitral valve regurgitation; TAPSE: tricuspid annular plane systolic excursion; TR: tricuspid valve regurgitation*

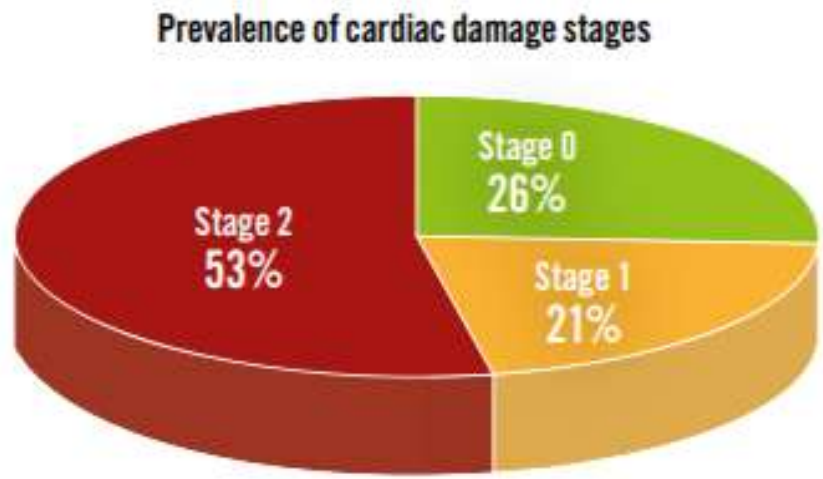
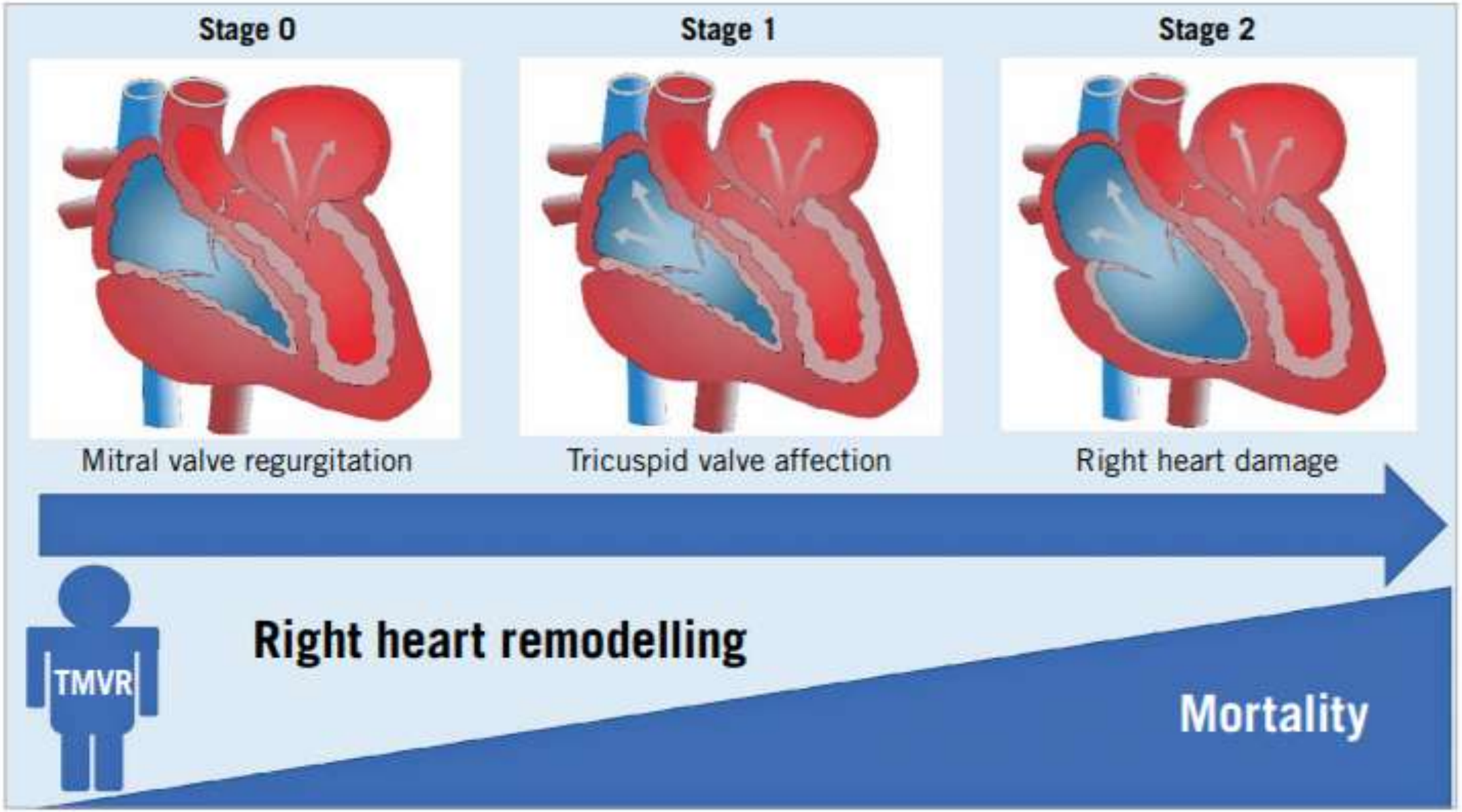
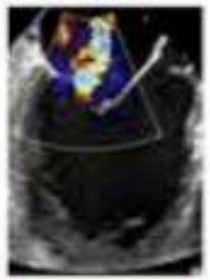
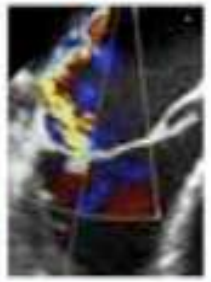
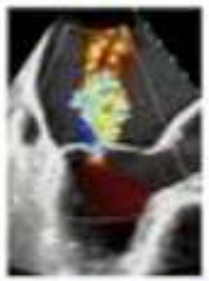



**Figure 3.** *Prevalence of right heart remodelling stages in the patient population. According to preprocedural echocardiography, 237 (26%) patients were in stage 0, 196 (21%) patients were in stage 1, and 496 (53%) patients were in stage 2.*




**Central illustration.** *Right heart remodelling and the extent of cardiac damage is associated with mortality in patients undergoing a MitraClip procedure to treat severe mitral valve regurgitation. TMVR: transcatheter mitral valve repair*

## CENTRAL ILLUSTRATION: Secondary Mitral Regurgitation Phenotypes in the Context of Transcatheter Mitral Valve Edge-To-Edge Repair

| | Proportionate vSMR | Disproportionate vSMR | aSMR |
|---|---|---|---|
| |   |   |   |
| Characteristics | • "MITRA-FR" phenotype<br>• MR severity proportionate to LV dilation<br>• "Global" LV dysfunction | • "COAPT" phenotype<br>• MR severity exceeds the degree of LV dilation<br>• "Additional" pathologies (asymmetric tethering, cardiac dyssynchrony) | • Normal LV function<br>• Normal LV dimensions<br>• Excessive LA dilation<br>• Isolated mitral annular dilation |
| Response to GDMT | ++ | + | ? |
| Response to TEER | + | ++ | ? |

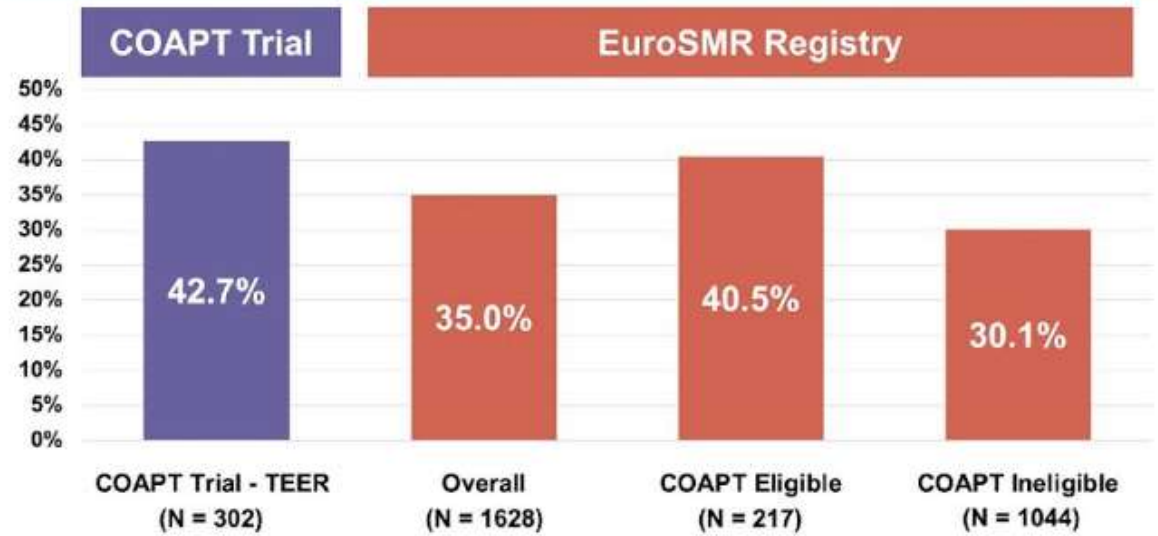
Stolz L, et al. J Am Coll Cardiol Img. 2024;10.1016/j.jcmg.2024.01.012

## TABLE 1 COAPT-Like Profile Definition

All the following criteria should be fulfilled:

- Left ventricular ejection fraction ≥20%
- Left ventricular end-systolic diameter ≤70 mm
- Systolic pulmonary artery pressure ≤70 mm Hg
- Absence of moderate or severe right ventricular dysfunction (TAPSE ≥15 mm and/or RV peak systolic velocity on TDI ≥8 cm/s)
- Absence of severe (4+) tricuspid regurgitation
- Absence of hemodynamic instability*

## 5-Year Survival after Mitral TEER




## Independent Predictors of 5-year Survival after M-TEER

**Age (per 1 year)**
Adj-HR 1.027 (1.016-1.039)

**eGFR (per 10 ml/min)**
Adj-HR 0.856 (0.815-0.899)

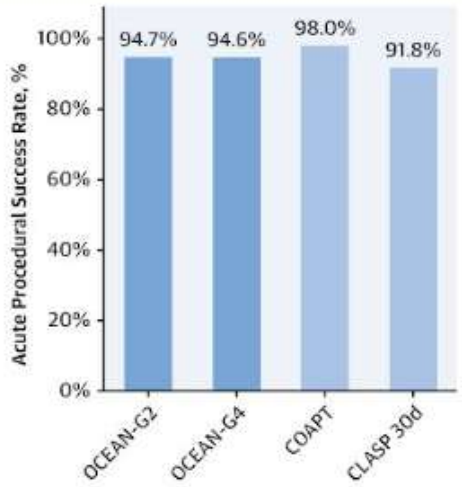
**MR post ≥3+**
Adj-HR 1.519 (1.153-2.001)

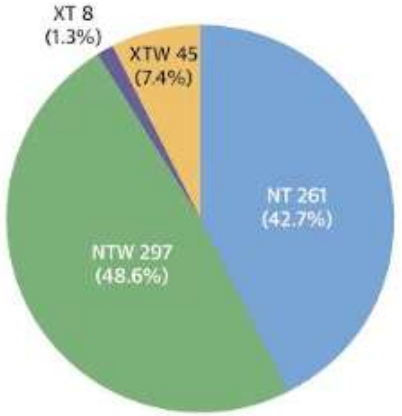
**NYHA IV**
Adj-HR 1.633 (1.153-1.975)

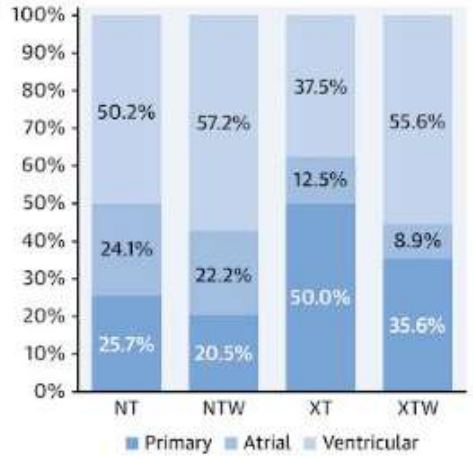
**LVEF (per 10%)**
Adj-HR 0.864 (0.803-0.930)

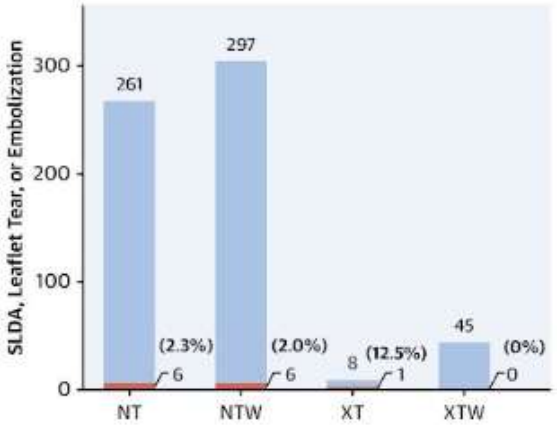

**COAPT Eligibility**
Adj-HR 0.780 (0.646-0.942)

**CENTRAL ILLUSTRATION: TEER Outcomes in G4 System in OCEAN-Mitral Registry**

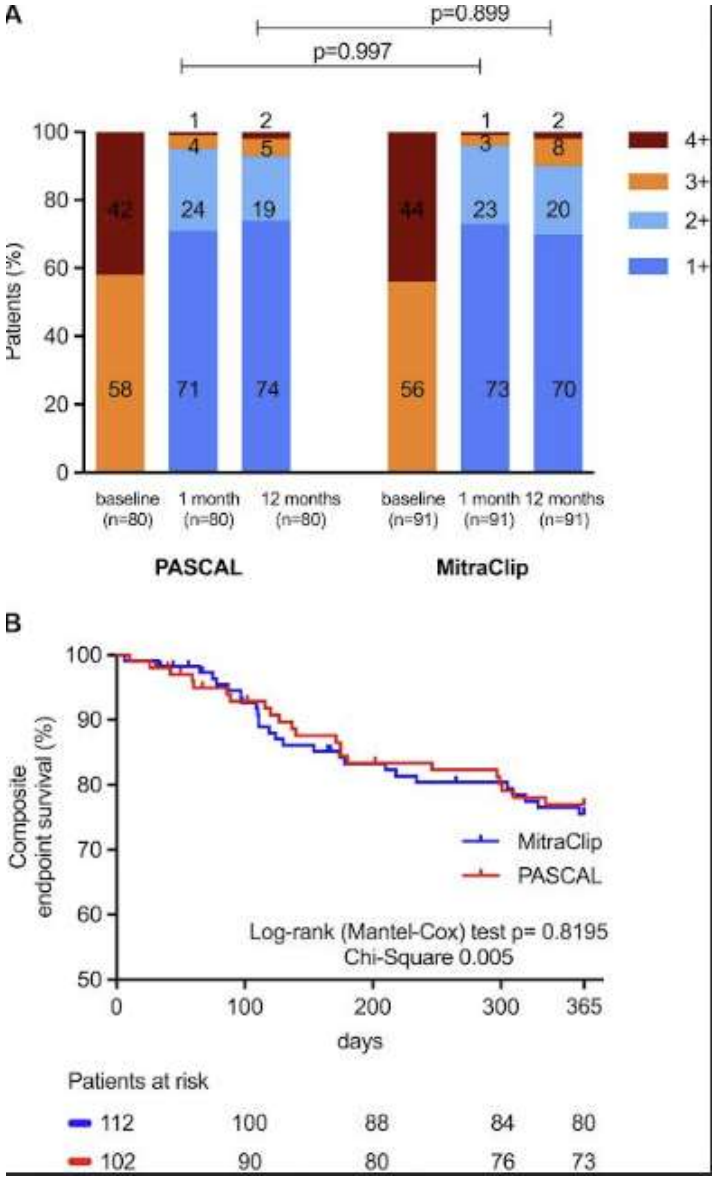


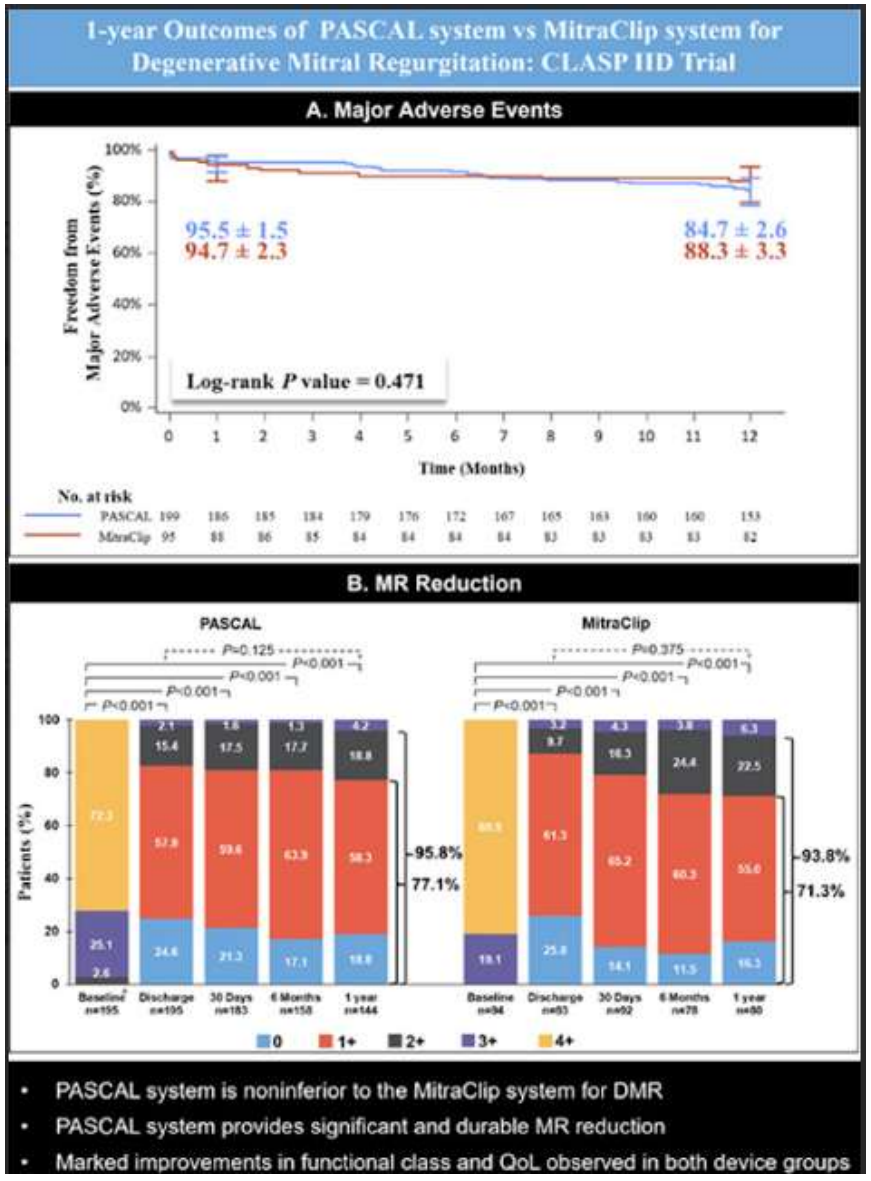



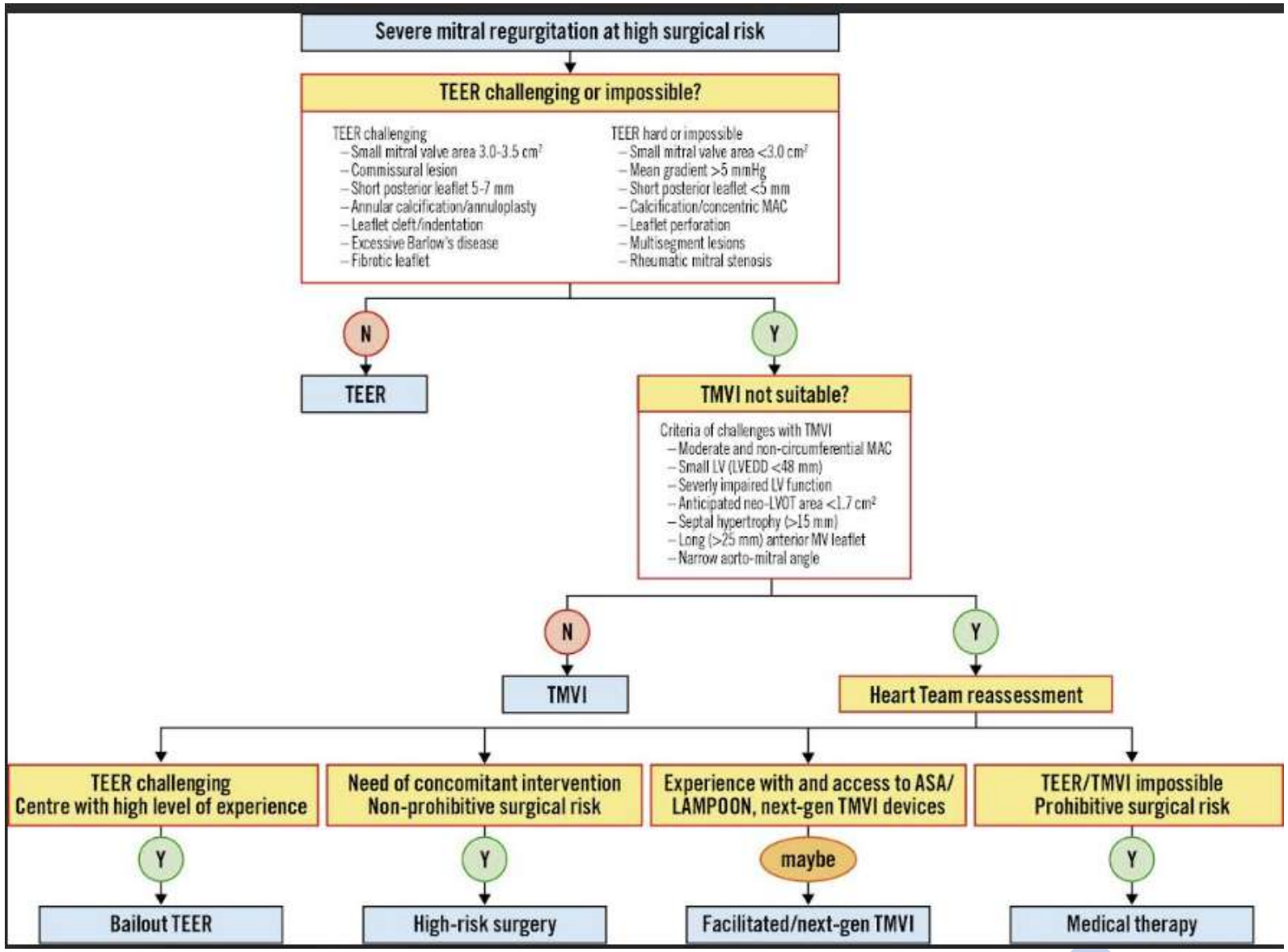




Saji M, et al. JACC: Asia. 2023;3(5):766-773.


A
p=0.899
p=0.997
Patients (%)
baseline (n=80)
1 month (n=80)
12 months (n=80)
baseline (n=91)
1 month (n=91)
12 months (n=91)
PASCAL
MitraClip
4+
3+
2+
1+
B
Composite endpoint survival (%)
MitraClip
PASCAL
Log-rank (Mantel-Cox) test p= 0.8195
Chi-Square 0.005
days
Patients at risk
112 100 88 84 80
102 90 80 76 73


1-year Outcomes of PASCAL system vs MitraClip system for Degenerative Mitral Regurgitation: CLASP HD Trial
A. Major Adverse Events
Freedom from Major Adverse Events (%)
95.5 ± 1.5
94.7 ± 2.3
84.7 ± 2.6
88.3 ± 3.3
Log-rank P value = 0.471
Time (Months)
No. at risk
PASCAL 199 186 185 184 179 176 172 167 165 163 160 160 153
MitraClip 95 88 86 85 84 84 84 84 83 83 83 83 82
B. MR Reduction
PASCAL
MitraClip
P=0.125
P<0.001
P<0.001
P<0.001
P<0.001
P=0.375
P<0.001
P<0.001
P<0.001
P<0.001
Patients (%)
95.8%
77.1%
93.8%
71.3%
Baseline n=155
Discharge n=105
30 Days n=183
6 Months n=158
1 year n=144
Baseline n=94
Discharge n=93
30 Days n=92
6 Months n=78
1 year n=80
0
1+
2+
3+
4+
• PASCAL system is noninferior to the MitraClip system for DMR
• PASCAL system provides significant and durable MR reduction
• Marked improvements in functional class and QoL observed in both device groups


Severe mitral regurgitation at high surgical risk
TEER challenging or impossible?
TEER challenging
– Small mitral valve area 3.0-3.5 cm²
– Commissural lesion
– Short posterior leaflet 5-7 mm
– Annular calcification/annuloplasty
– Leaflet cleft/indentation
– Excessive Barlow's disease
– Fibrotic leaflet
TEER hard or impossible
– Small mitral valve area <3.0 cm²
– Mean gradient >5 mmHg
– Short posterior leaflet <5 mm
– Calcification/concentric MAC
– Leaflet perforation
– Multisegment lesions
– Rheumatic mitral stenosis
N
TEER
Y
TMVI not suitable?
Criteria of challenges with TMVI
– Moderate and non-circumferential MAC
– Small LV (LVEDD <48 mm)
– Severly impaired LV function
– Anticipated neo-LVOT area <1.7 cm²
– Septal hypertrophy (>15 mm)
– Long (>25 mm) anterior MV leaflet
– Narrow aorto-mitral angle
N
TMVI
Y
Heart Team reassessment
TEER challenging
Centre with high level of experience
Need of concomitant intervention
Non-prohibitive surgical risk
Experience with and access to ASA/
LAMPOON, next-gen TMVI devices
TEER/TMVI impossible
Prohibitive surgical risk
Y
Bailout TEER
Y
High-risk surgery
maybe
Facilitated/next-gen TMVI
Y
Medical therapy

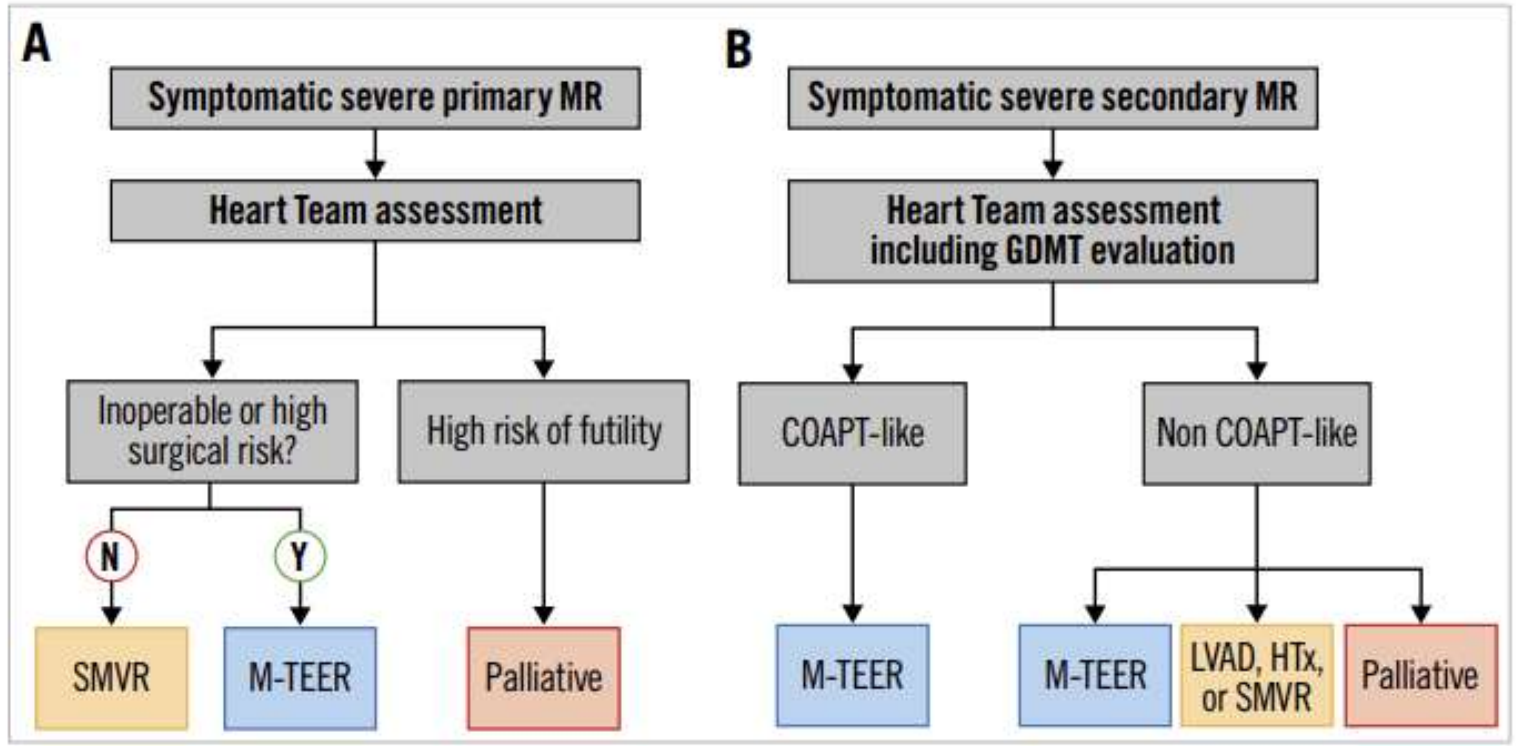



**Figure 1.** *Patient stratification and simplified guideline recommendation. Therapeutic strategies for patients with (A) symptomatic severe primary mitral regurgitation (MR) or (B) symptomatic severe secondary MR. COAPT: Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation; GDMT: guideline-directed medical therapy; HTx: heart transplantation; LVAD: left ventricular assist device; M-TEER: mitral valve transcatheter edge-to-edge repair; N: no; SMVR: surgical mitral valve repair or replacement; Y: yes*

## Mitral valve transcatheter edge-to-edge repair

**Jörg Hausleiter**[1*], MD; Thomas J. Stocker[1], MD; Marianna Adamo[2], MD; Nicole Karam[3], MD, PhD; Martin J. Swaans[4], MD, PhD; Fabien Praz[5], MD

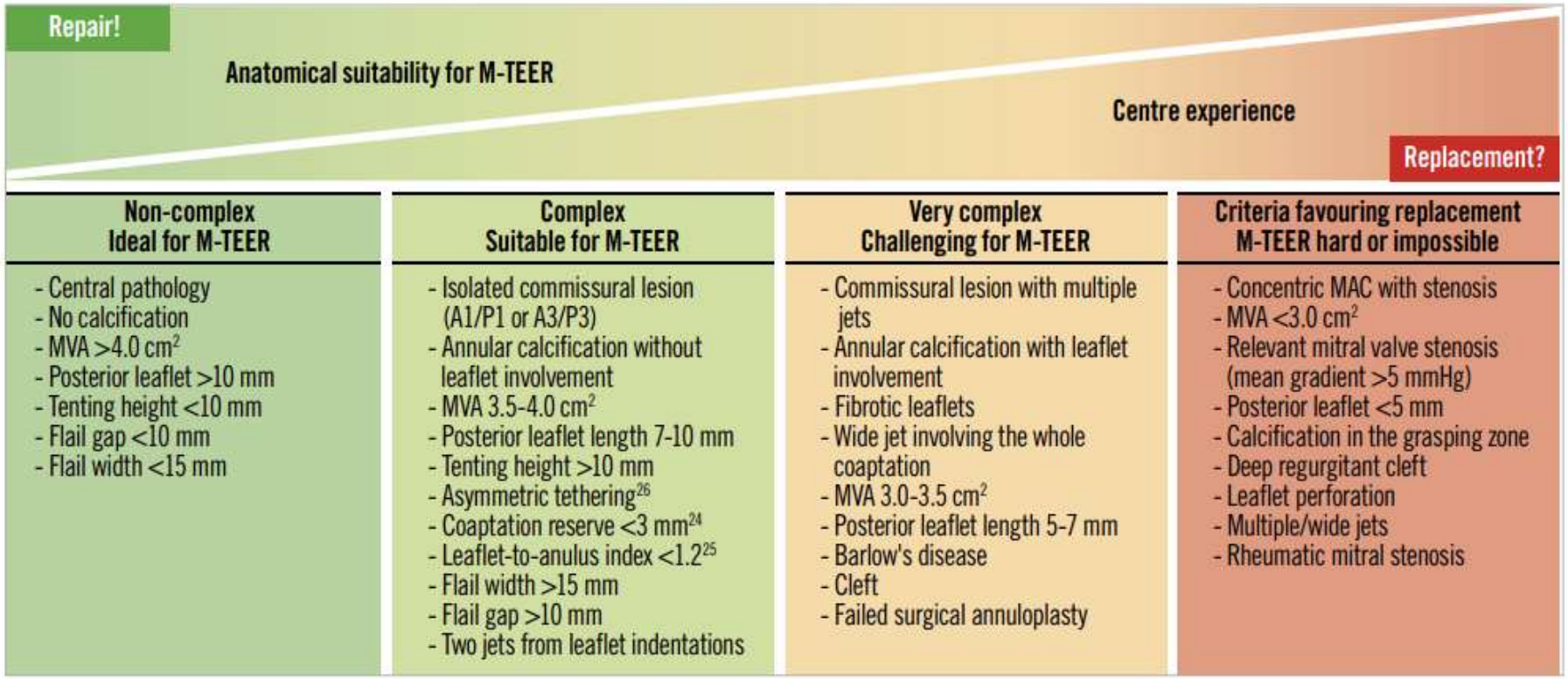



**Figure 4.** *Complexity of valve morphology and centre experience as criteria for mitral valve transcatheter edge-to-edge repair. A1/P1: lateral segments of anterior (A1) and posterior (P3) mitral valve leaflet; A3/P3: medial segments of anterior (A3) and posterior (P3) mitral valve leaflet; MAC: mitral annular calcification; M-TEER: mitral valve transcatheter edge-to-edge repair; MVA: mitral valve area*

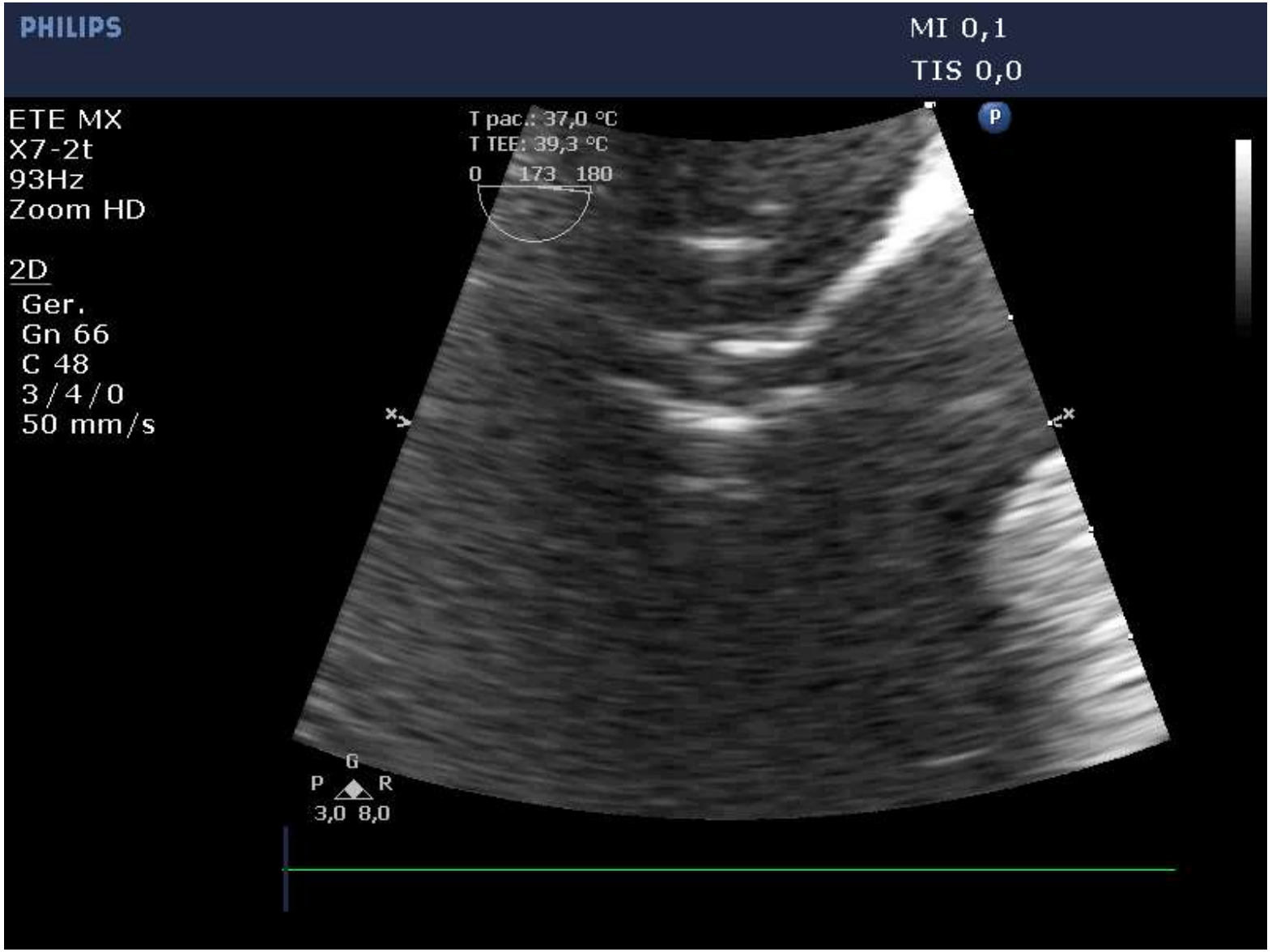
# Mitral valve transcatheter edge-to-edge repair

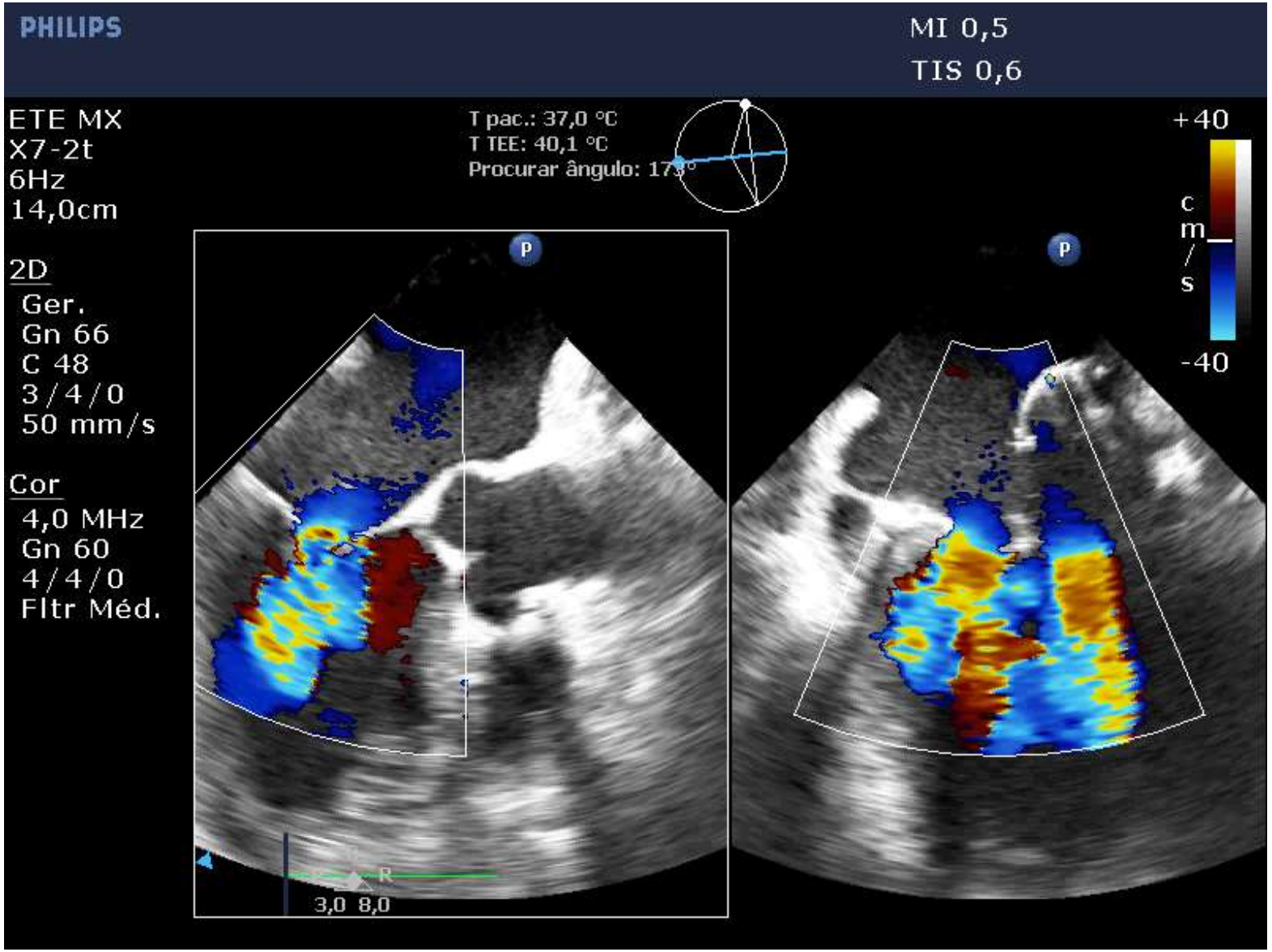
**Jörg Hausleiter**[1*], MD; Thomas J. Stocker[1], MD; Marianna Adamo[2], MD; Nicole Karam[3], MD, PhD; Martin J. Swaans[4], MD, PhD; Fabien Praz[5], MD

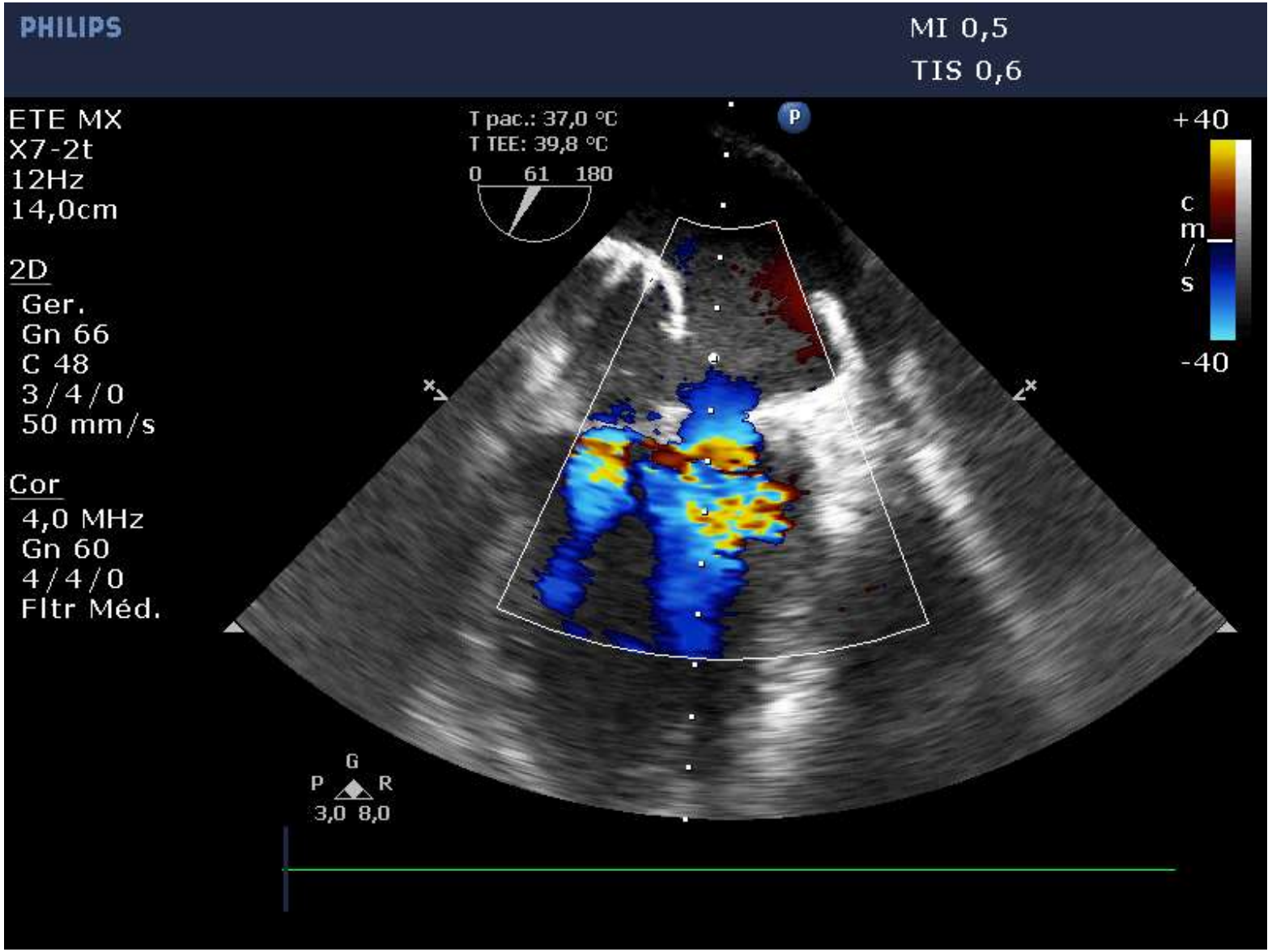
# MitraClip Planning

| Optimal/Ideal | Challenging/Less Ideal | Advanced/Unsuitable |
|---|---|---|
| Beginner/Initial cases | Intermediate/Multiple cases | Expert/High volume center |
| Central A2/P2 | Zones 1 or 3 | Cleft or Perforation |
| No Calcification | None in grasping zone | Grasping zone $Ca^{2+}$ |
| MVA > 4 $cm^2$ | MVA >3 $cm^2$, mobile | MVA <3 $cm^2$ |
| Post Leaflet >10 mm | Post Leaflet 7 - 10 mm | Post Leaflet <7 mm |
| Tenting Height <10 mm | Tenting Height >10 mm | |
| Normal leaflets & mobility | Carpentier IIIB | Carpentier IIIA, Rheumatic |
| Gap < 10mm, Width < 15mm | Width >15mm (Large valve) | Multiple segments, Barlows |

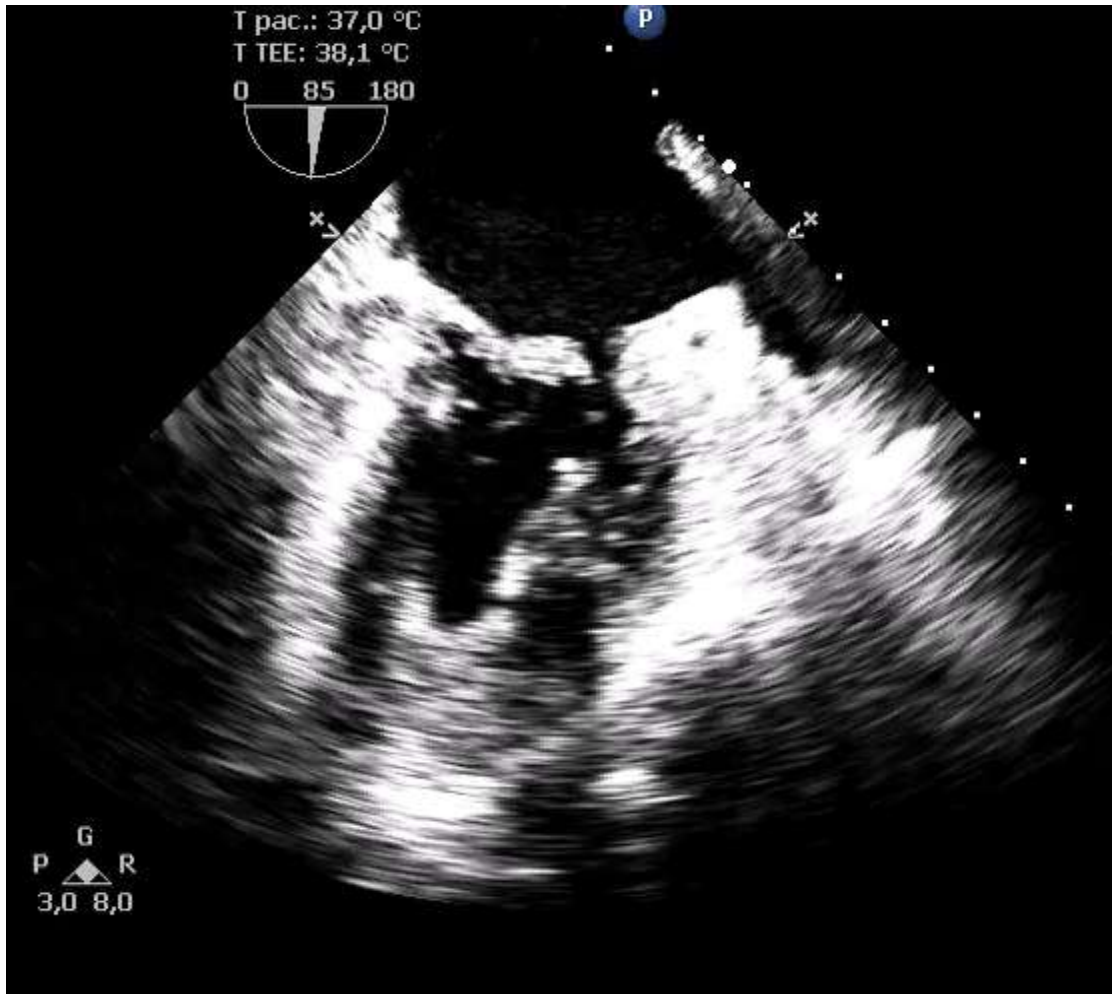
Clin Res Cardiol 2014;103(2):85-96

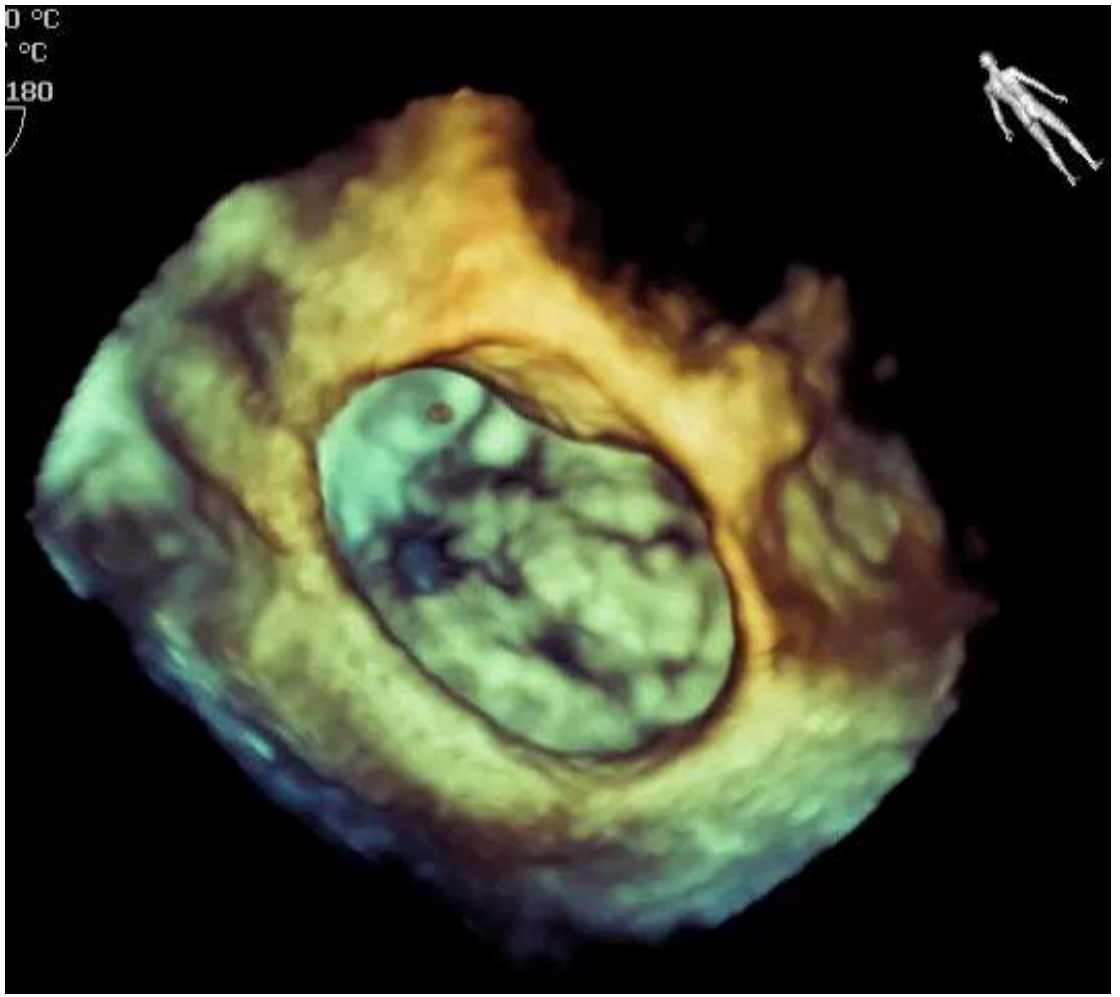

PHILIPS
MI 0,1
TIS 0,0
ETE MX
X7-2t
93Hz
Zoom HD
2D
Ger.
Gn 66
C 48
3/4/0
50 mm/s
T pac.: 37,0 °C
T TEE: 39,3 °C
0 173 180
P
G
P R
3,0 8,0


PHILIPS
MI 0,5
TIS 0,6
ETE MX
X7-2t
6Hz
14,0cm
T pac.: 37,0 °C
T TEE: 40,1 °C
Procurar ângulo: 173°
+40
cm/s
-40
2D
Ger.
Gn 66
C 48
3/4/0
50 mm/s
Cor
4,0 MHz
Gn 60
4/4/0
Fltr Méd.
P
P
R
3,0 8,0

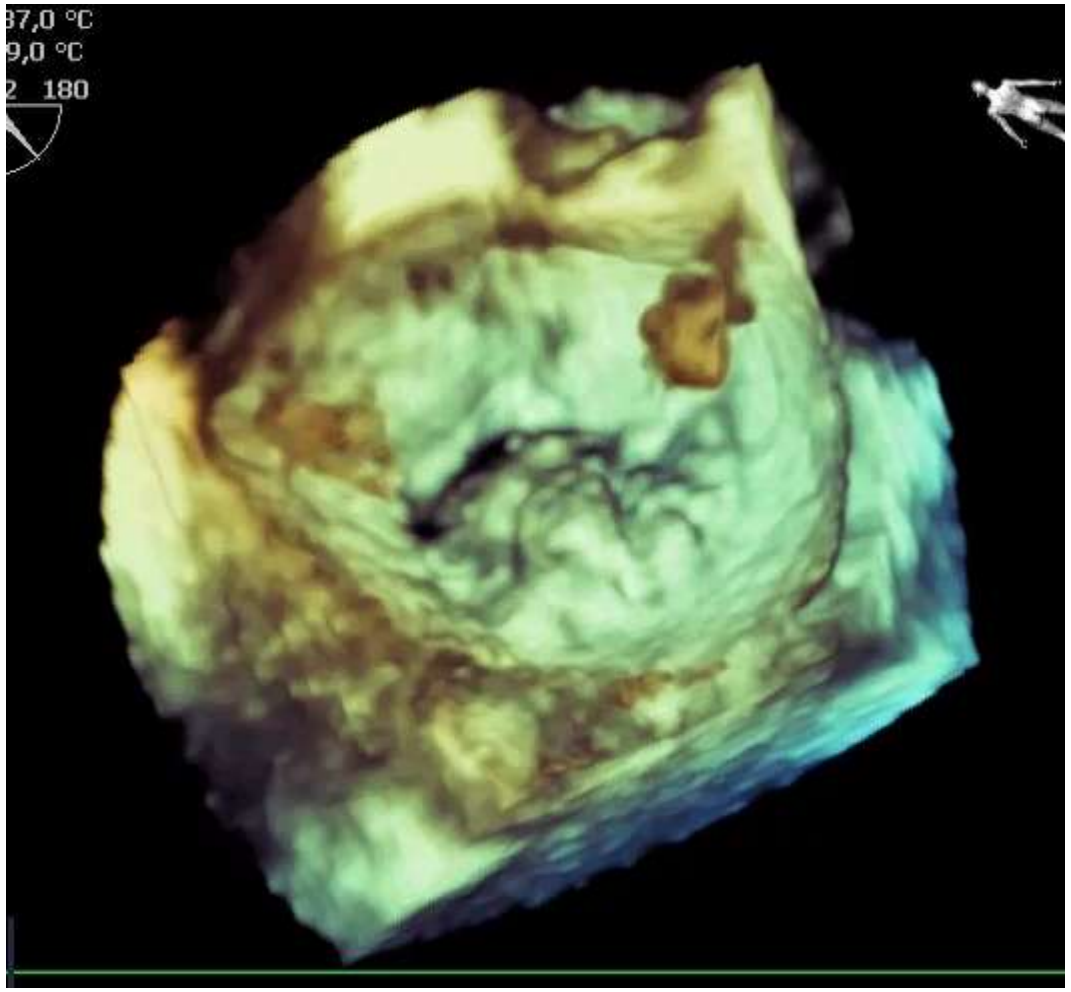

PHILIPS
MI 0,5
TIS 0,6
ETE MX
X7-2t
12Hz
14,0cm
2D
Ger.
Gn 66
C 48
3/4/0
50 mm/s
Cor
4,0 MHz
Gn 60
4/4/0
Fltr Méd.
T pac.: 37,0 °C
T TEE: 39,8 °C
0 61 180
P
+40
cm/s
-40
G
P R
3,0 8,0

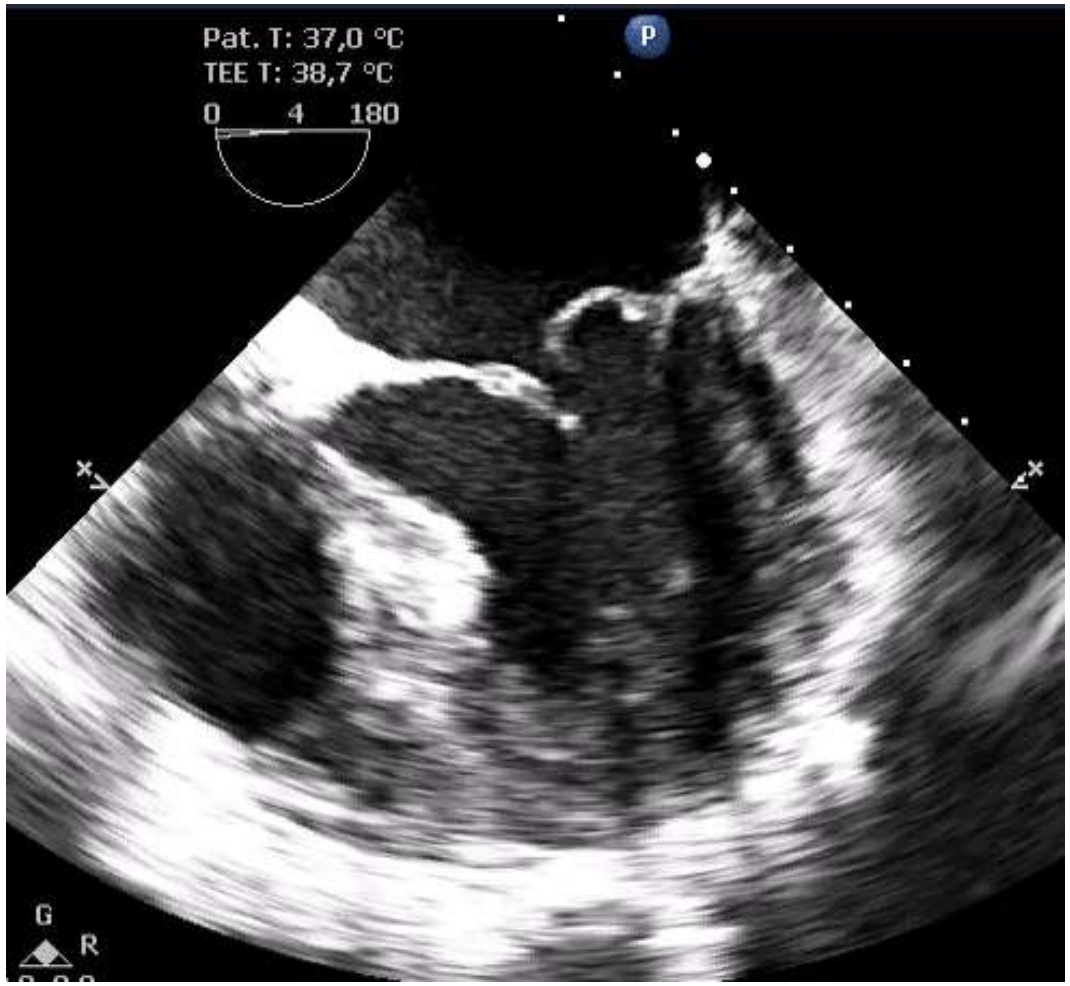
# BAD CASE



# BAD CASE



# PARA UN PROCEDIMENTO EXITOSO

## POSITIVO

- Valvula Funcional
- Falla de coaptacion central A2-P2
- Comprimento de P2 >7mm para R e >11mm para X
- Area valvar > 4,0cm² por planimetria
- Diametro intercomissural >40mm
- Distancia (ancho) del defecto < 15mm
- Separacion < 10mm
- Sin gradiente basal.

## NEGATIVO

- Válvula mixomatosa.
- Calcificacion area de captura
- Area <3,0cm²
- Diametro intercomissural <30mm
- Distancia (ancho) del defecto > 15mm
- Separacion > 10mm
- Gradiente médio basal >5mmHg.

For every complex problem there is an answer that is clear, simple, and wrong

[H.L. Mencken]


MUCHAS GRACIAS
POR SÚ ATENCIÓN!

**GDMT**
- ACEi/ARB/ARNI
- Beta-blocker
- Aldosterone antagonist
- CRT
- Revascularization

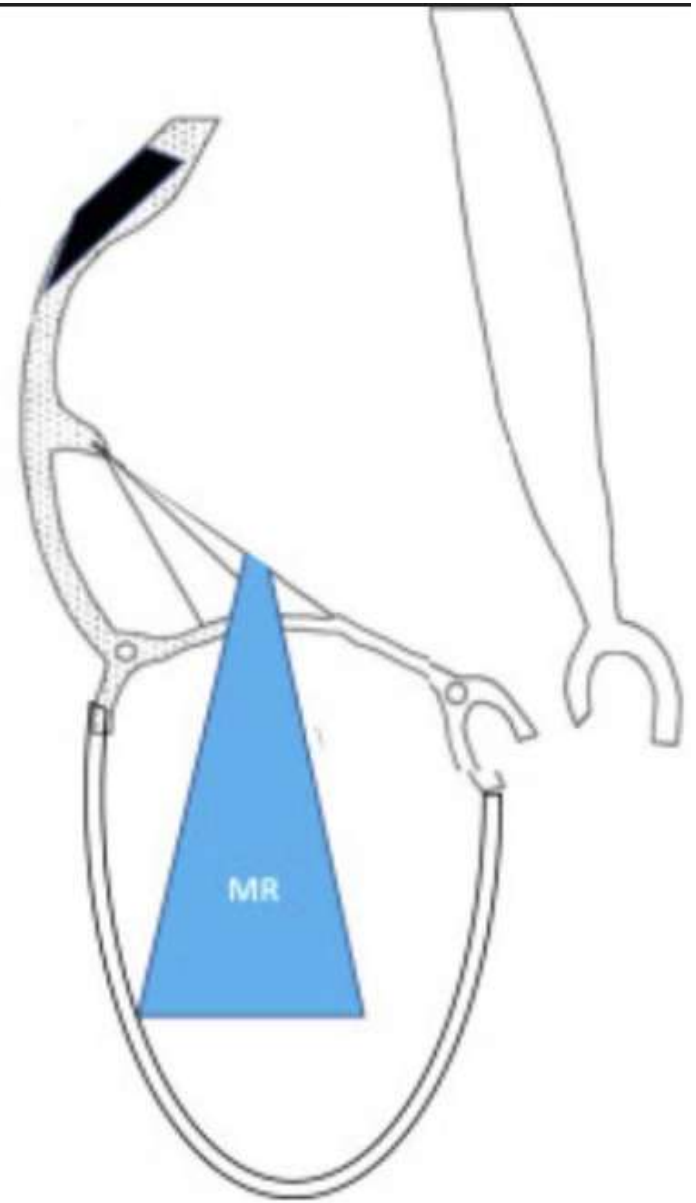
→ **LV Dilation and Remodeling**

→ **Leaflet Tethering**

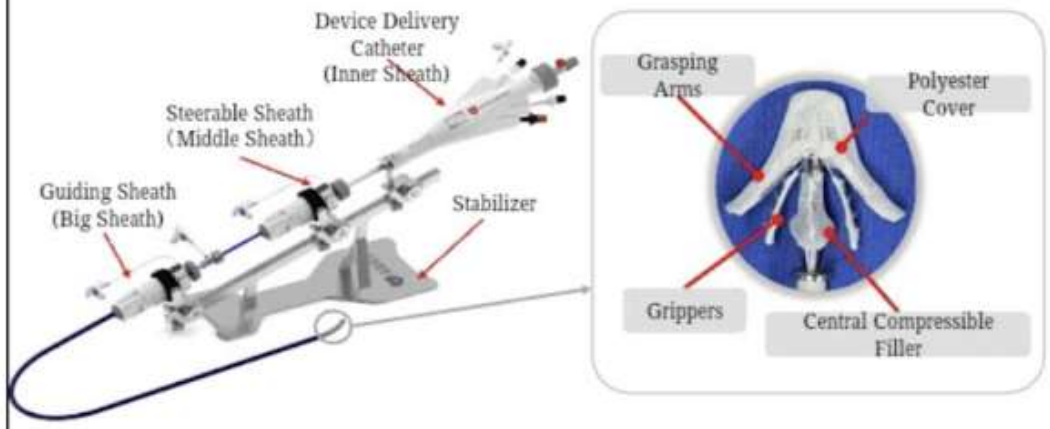
**TEER** → **Leaflet Mal-coaptation**

**Surgical Annuloplasty**
**AF Ablation** → **Annular and LA Dilation**

**Surgical MVR**



## Dragonfly Mitral and Tricuspid TEER System

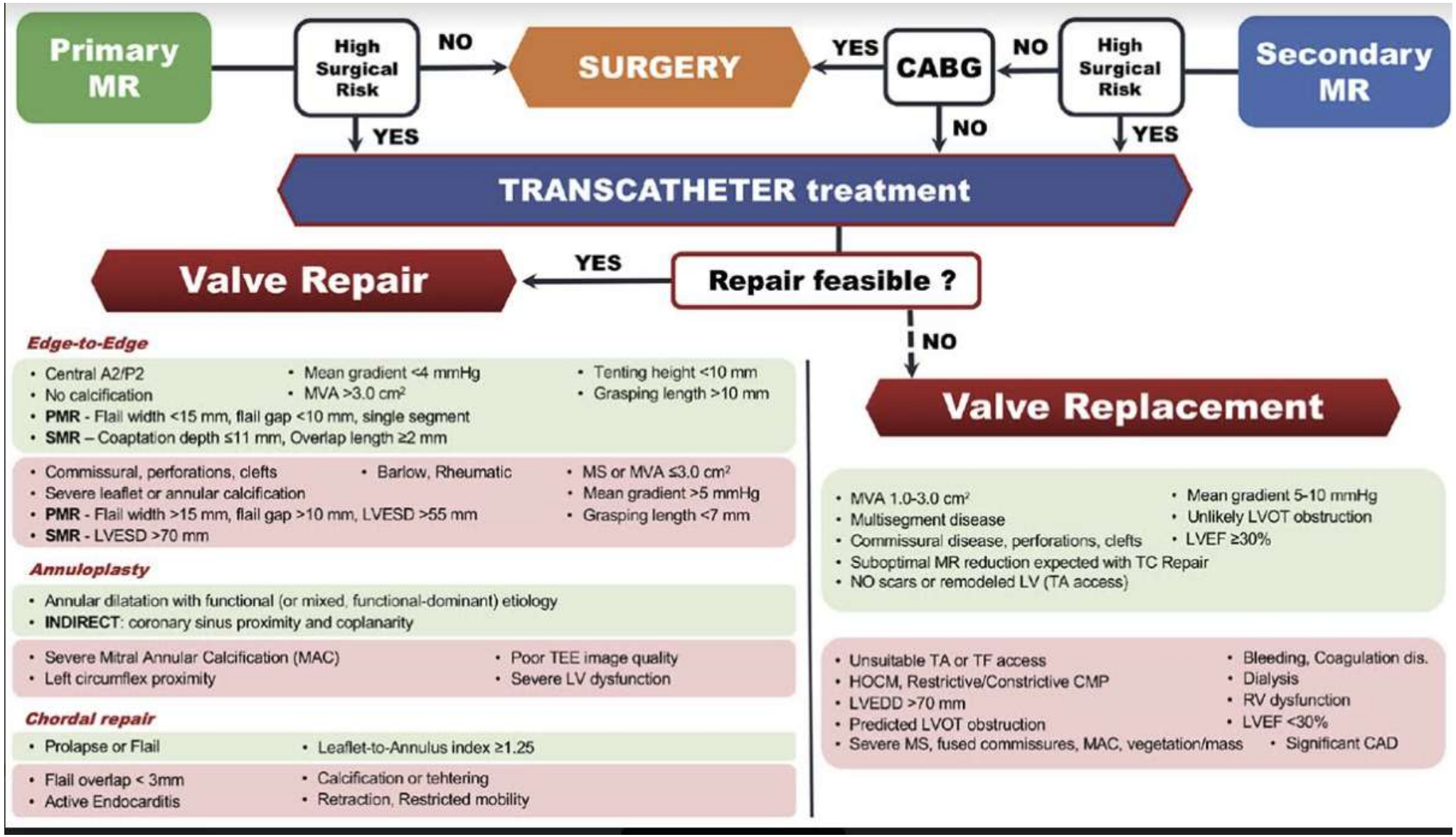



## Design features: Adjustable closing arms together with central filler




**Adjustable closing angle arms + Central filler spacer**

The filler is compressed, and distends on either side of the arms, blocking the regurgitant orifice.


Primary MR
High Surgical Risk
NO
SURGERY
YES
CABG
NO
High Surgical Risk
Secondary MR
YES
NO
YES
TRANSCATHETER treatment
Valve Repair
YES
Repair feasible ?
NO
Valve Replacement
Edge-to-Edge
• Central A2/P2
• No calcification
• PMR - Flail width <15 mm, flail gap <10 mm, single segment
• SMR – Coaptation depth ≤11 mm, Overlap length ≥2 mm
• Mean gradient <4 mmHg
• MVA >3.0 cm²
• Tenting height <10 mm
• Grasping length >10 mm
• Commissural, perforations, clefts
• Severe leaflet or annular calcification
• PMR - Flail width >15 mm, flail gap >10 mm, LVESD >55 mm
• SMR - LVESD >70 mm
• Barlow, Rheumatic
• MS or MVA ≤3.0 cm²
• Mean gradient >5 mmHg
• Grasping length <7 mm
Annuloplasty
• Annular dilatation with functional (or mixed, functional-dominant) etiology
• INDIRECT: coronary sinus proximity and coplanarity
• Severe Mitral Annular Calcification (MAC)
• Left circumflex proximity
• Poor TEE image quality
• Severe LV dysfunction
Chordal repair
• Prolapse or Flail
• Leaflet-to-Annulus index ≥1.25
• Flail overlap < 3mm
• Active Endocarditis
• Calcification or tehtering
• Retraction, Restricted mobility
• MVA 1.0-3.0 cm²
• Multisegment disease
• Commissural disease, perforations, clefts
• Suboptimal MR reduction expected with TC Repair
• NO scars or remodeled LV (TA access)
• Mean gradient 5-10 mmHg
• Unlikely LVOT obstruction
• LVEF ≥30%
• Unsuitable TA or TF access
• HOCM, Restrictive/Constrictive CMP
• LVEDD >70 mm
• Predicted LVOT obstruction
• Severe MS, fused commissures, MAC, vegetation/mass
• Bleeding, Coagulation dis.
• Dialysis
• RV dysfunction
• LVEF <30%
• Significant CAD

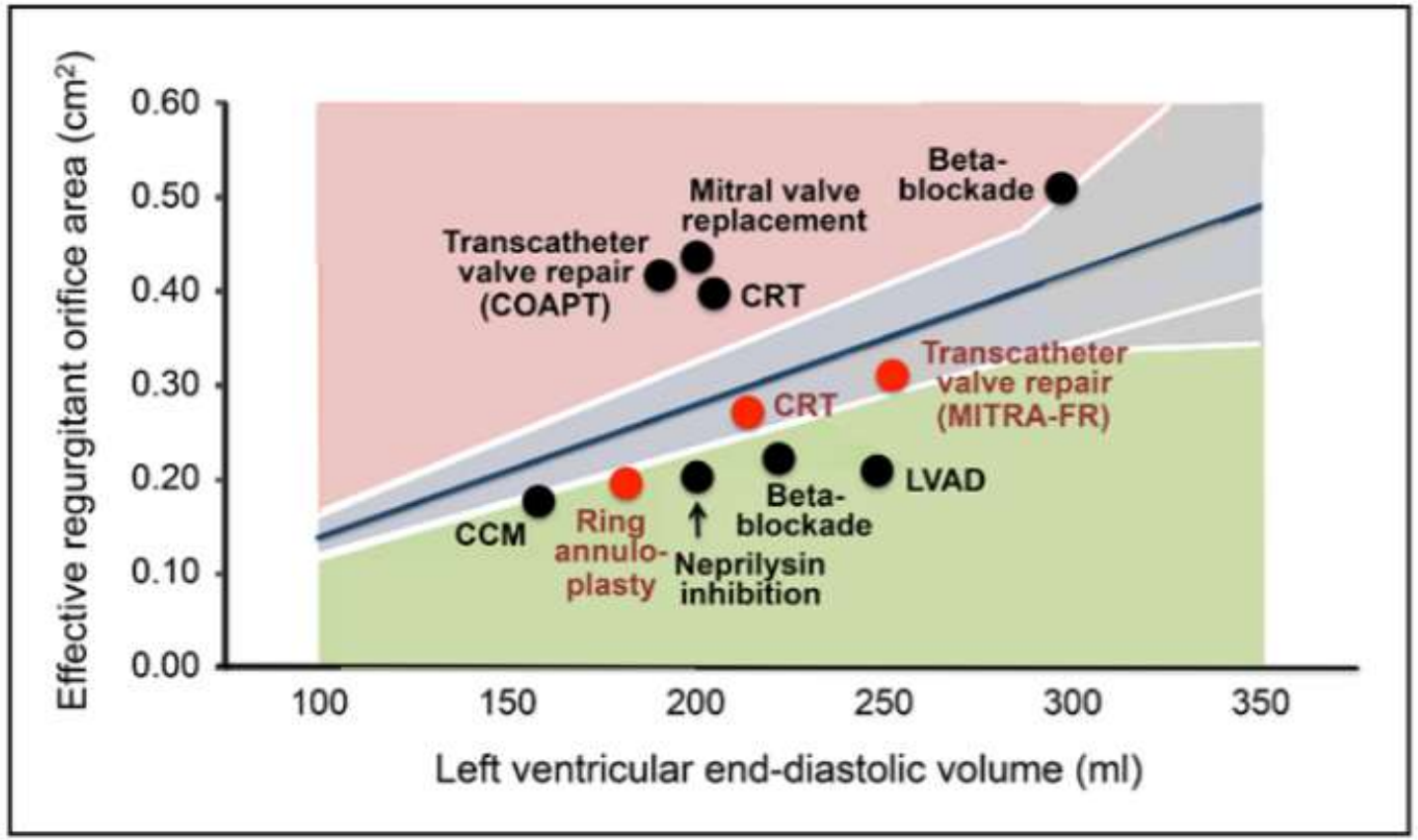



**Figure 3. Effect of pharmacological treatments and procedural interventions in proportionate and disproportionate mitral regurgitation (MR).**

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