



**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)

## Indications for mitral valve intervention in chronic secondary mitral regurgitation<sup>a</sup>

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

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When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and have a low surgical risk.

**IIb**

**C**

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When revascularization is not indicated,

When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility.

**IIb**

**C**

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When revascularization is not indicated,

When revascularization is not indicated and

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 revascularization, the Heart Team may consider a percutaneous edge-to-edge procedure or valve surgery after careful evaluation for a ventricular assist device or heart transplant according to individual patient characteristics.

**IIb**

**C**

**2016 update to The American Association for Thoracic Surgery consensus guidelines: Ischemic mitral valve regurgitation**

- ... concern the **fundamental change in the level of evidence guiding the recommendation for LOE A to LOE B....**
  - ...our belief that several of the randomized trials and prospective series for the surgical treatment of IMR currently available are simply **not large enough to support LOE A** classification
- We have added to each Guideline that **surgical correction of IMR “is reasonable” and “may be considered” in patients “who remain symptomatic despite Guideline-directed medical and cardiac device therapy.”**

■ **IIA, LOE B**

- In **severe** ischemic MR MV **replacement is reasonable** in patients with severe IMR who remain **symptomatic despite** guideline directed medical and cardiac device therapy, and who have a basal aneurysm/dyskinesis, significant leaflet tethering, and/or severe LV dilation (EDD>6.5 cm).

■ **IIB, LOE B**

- MV **repair** with an undersized complete rigid annuloplasty ring may be considered in patient with **severe IMR who remain symptomatic** despite guideline directed medical and cardiac device therapy and who do not have a basal aneurysm/dyskinesis, significant leaflet tethering, or severe LV enlargement .
- In patients with **moderate IMR undergoing CABG**, MV repair with an undersized complete rigid annuloplasty ring may be considered

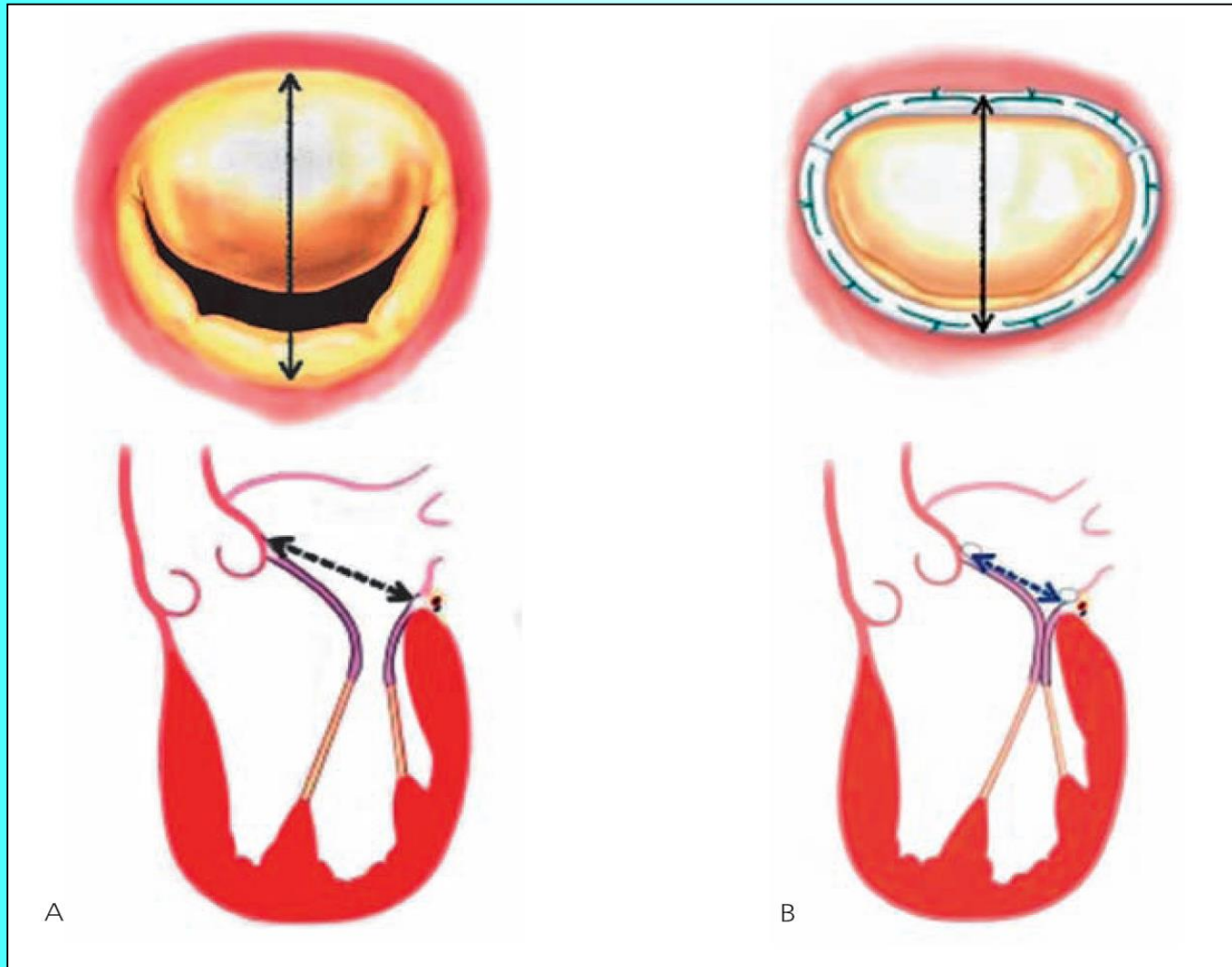
## Possible Scenarios:

- Patients with primary indication to revascularization
  - Severe MR
  - Moderate MR
  
- Patients with isolated severe secondary MR
  - LVEF > 0.30
  - LVEF < 0.30.



# Mitral repair

## Annuloplasty



# Mitral repair

## Annuloplasty



How  
we do  
it

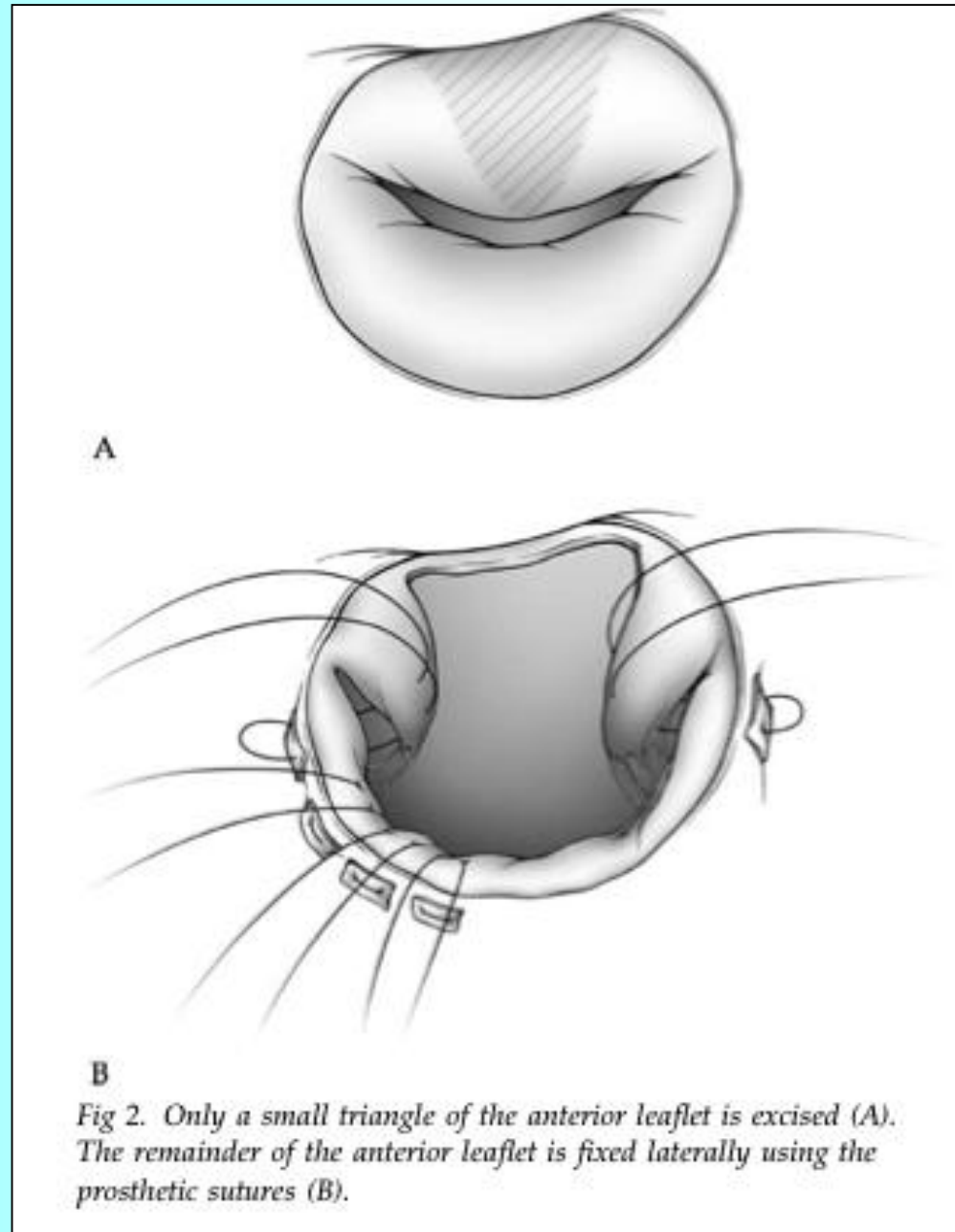
*In my opinion:*

- In FMR secondary to ischaemia or cardiomyopathy is better to use a **complete rigid ring**
- When end diastolic ventricular diameter exceeds 65 mm is probably better to add some other correction in the ventricle, or in the chordal apparatus as **alternative to mitral replacement**

# Mitral replacement

- MVR for FMR is performed with complete preservation of both anterior and posterior leaflet chords

Calafiore: Ann Thor Surg 71:1146, 2001.



# Repair or replace?



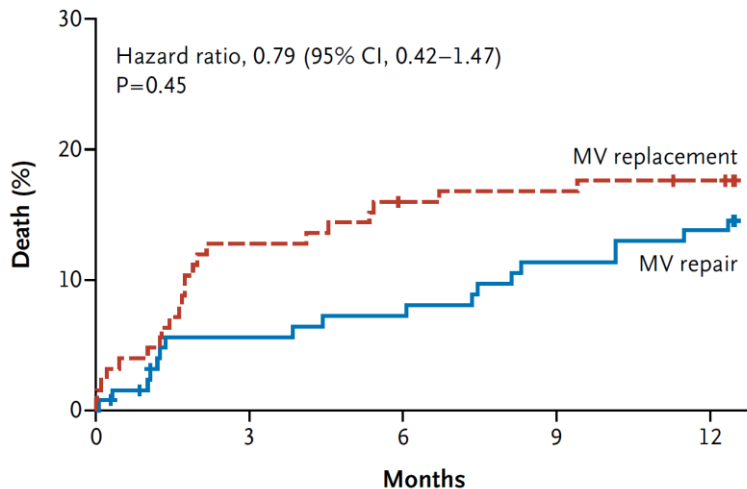
ORIGINAL ARTICLE

Mitral-Valve Repair versus Replacement for Severe Ischemic Mitral Regurgitation

Michael A. Acker, M.D., Michael K. Parides, Ph.D., Louis P. Perrault, M.D., Alan J. Moskowitz, M.D., Annetine C. Gelijns, Ph.D., Pierre Voisine, M.D., Peter K. Smith, M.D., Judy W. Hung, M.D., Eugene H. Blackstone, M.D., John D. Puskas, M.D., Michael Argenziano, M.D., James S. Gammie, M.D., Michael Mack, M.D., Deborah D. Ascheim, M.D., Emilia Bagiella, Ph.D., Ellen G. Moquete, R.N., T. Bruce Ferguson, M.D., Keith A. Horvath, M.D., Nancy L. Geller, Ph.D., Marissa A. Miller, D.V.M., Y. Joseph Woo, M.D., David A. D'Alessandro, M.D., Gorav Ailawadi, M.D., Francois Dagenais, M.D., Timothy J. Gardner, M.D., Patrick T. O'Gara, M.D., Robert E. Michler, M.D., and Irving L. Kron, M.D., for the CTSN\*

- We randomly assigned 251 patients with severe ischemic mitral regurgitation to undergo either mitral-valve repair or chordal-sparing replacement in order to evaluate efficacy and safety.

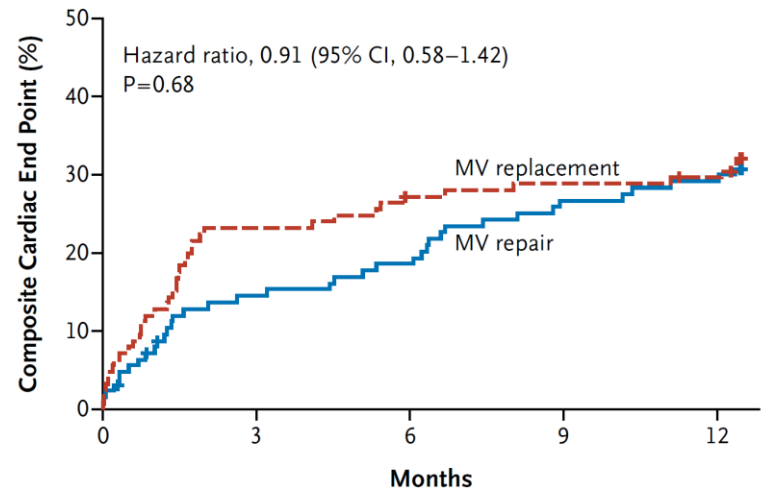
A Death



No. at Risk

MV repair	126	116	114	109	106
MV replacement	125	109	104	103	101

B Composite Cardiac End Point



No. at Risk

MV repair	126	105	100	90	87
MV replacement	125	96	90	88	86

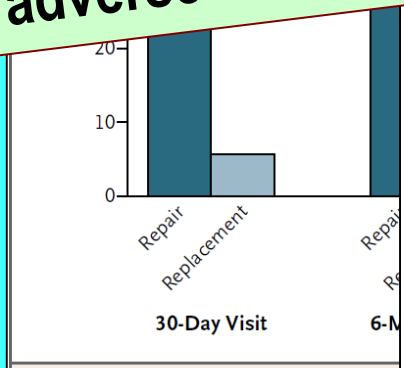
Figure 1. Rates of Death and the Composite Cardiac End Point.

ORIGINAL ARTICLE

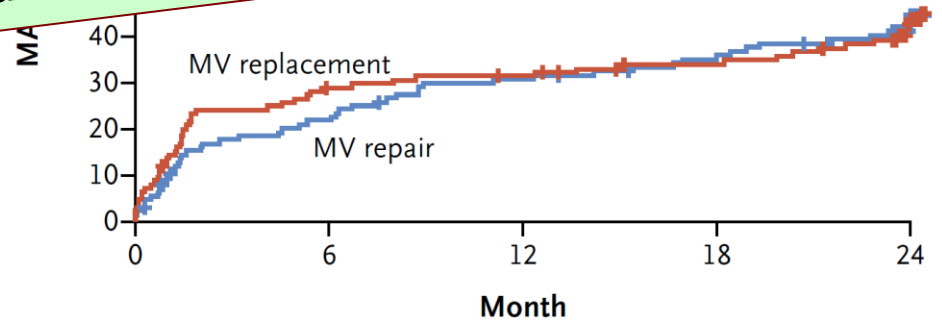
Two-Year Outcomes of Surgical Treatment of Severe Ischemic Mitral Regurgitation

D. Goldstein, A.J. Moskowitz, A.C. Gelijns, G. Ailawadi, M.K. Parides, L.P. Perrault, J.W. Hung, P. Voisine, F. Dagenais, A.M. Gillinov, V. Thourani, M. Argenziano, J.S. Gammie, M. Mack, P. Demers, P. Atluri, E.A. Rose, K. O'Sullivan, D.L. Williams, E. Bagiella, R.E. Michler, P.P. Tchao, N.L. Geller, W.C. Taddei, P. Pibarot

- There were no significant between-group differences with respect to left ventricular reverse remodeling or survival.
- However, the rate of recurrence of moderate or severe mitral regurgitation was significantly higher with mitral-valve repair, resulting in more heart-failure-related adverse events and cardiovascular admissions.



**Figure 2.** Cumulative Failure of Mitral Valve Intervention. Failure of the intervention was defined as moderate or severe mitral regurgitation on echocardiography, or mitral-valve repair or replacement.

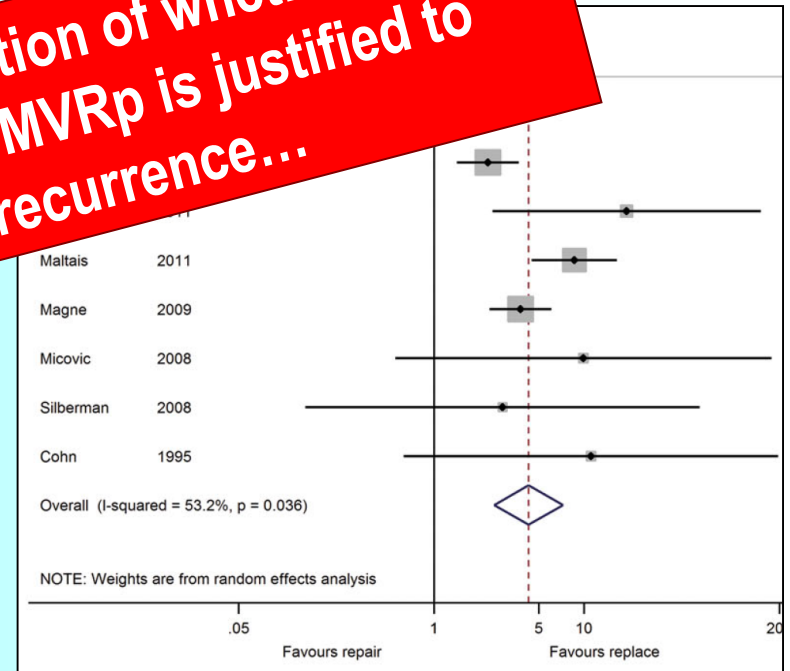
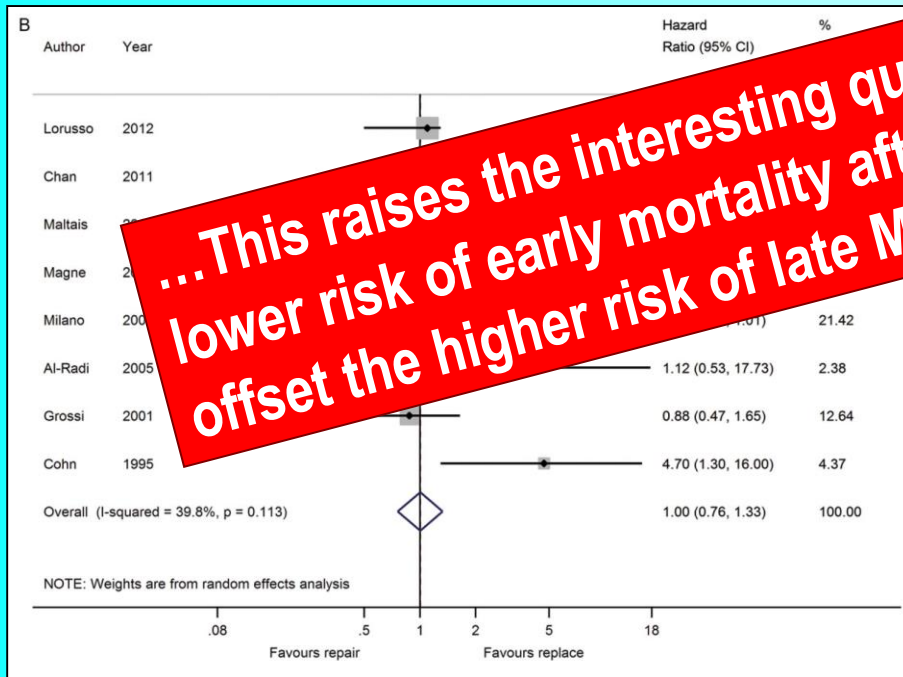


No. at Risk		0	6	12	18	24
MV repair	126	96	84	77	48	
MV replacement	125	87	83	76	50	

**Figure 3.** Time-to-Event Curves for Major Adverse Cardiac or Cerebrovascular Events (MACCE). The curves show that the rates of MACCE were similar between the repair and replacement groups over the 24-month period.

## Is valve repair preferable to valve replacement in ischaemic mitral regurgitation? A systematic review and meta-analysis<sup>†</sup>

Mohammad Yousef Salmasi<sup>a\*</sup>, Metesh Acharya<sup>b</sup>, Nada Humayun<sup>a</sup>, Dinnish Baskaran<sup>c</sup>,  
Stephanie Hubbard<sup>d</sup> and Hunaid Vohra<sup>a</sup>



long-term (5-year) survival

long-term (5-year) recurrence of mitral regurgitation

... This raises the interesting question of whether the lower risk of early mortality after MVRp is justified to offset the higher risk of late MR recurrence...

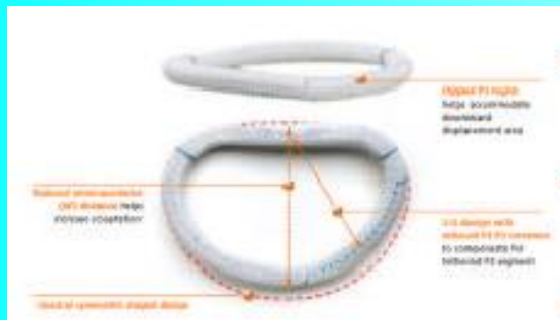
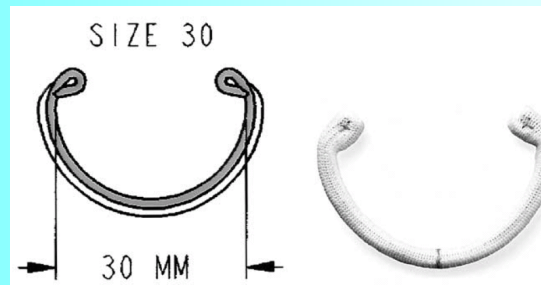


**Repair: ...can we do something more?**



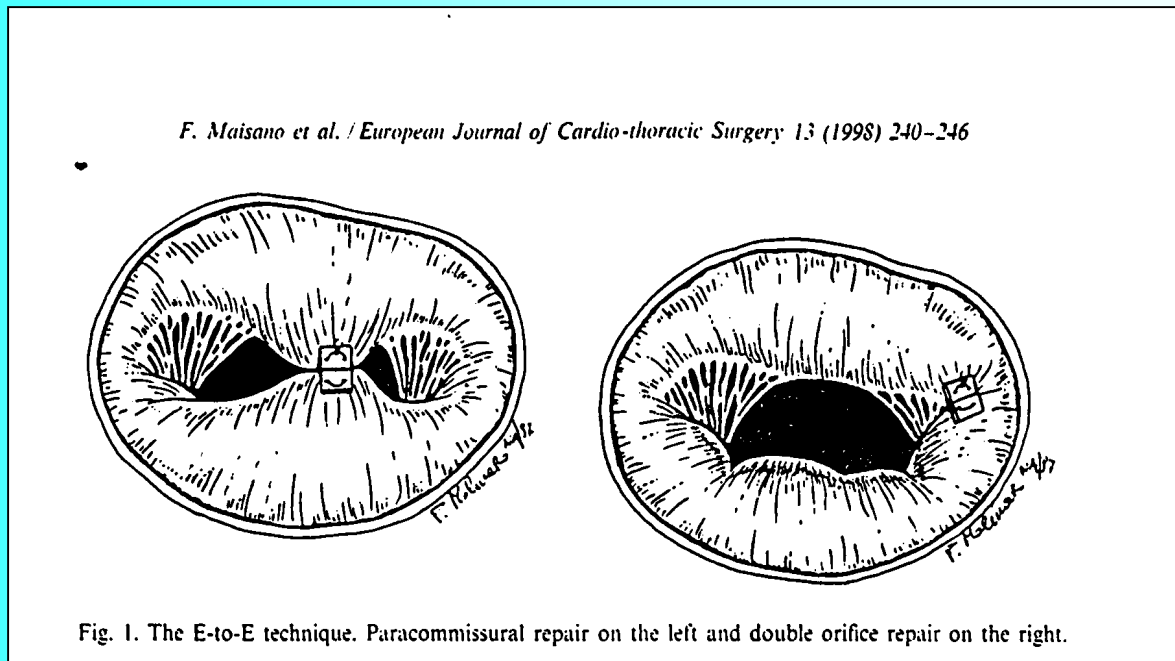
# The mitral valve annulus correction: ...change the ring

- The innovation in mitral valve ring annuloplasty design includes **special shaped** rings and adjustable rings, allowing adjustment of septo-lateral dimensions intra or postoperatively.



## Leaflets and chordae correction:

- **“Edge to edge” or Alfieri stitch**
  - attaches the anterior and posterior leaflets to correct incomplete leaflet coaptation.



## Long-term results of mitral repair in patients with severe left ventricular dysfunction and secondary mitral regurgitation: does the technique matter?<sup>†</sup>

Michele De Bonis<sup>a,\*</sup>, Elisabetta Lapenna<sup>a</sup>, Fabio Barili<sup>b</sup>, Teodora Nisi<sup>a</sup>, Mariachiara Calabrese<sup>a</sup>, Federico Pappalardo<sup>a</sup>, Giovanni La Canna<sup>a</sup>, Alberto Pozzoli<sup>a</sup>, Nicola Buzzatti<sup>a</sup>, Andrea Giacomini<sup>a</sup>, Emanuela Alati<sup>a</sup> and Ottavio Alfieri<sup>a</sup>

CIF OF CARDIAC DEATH

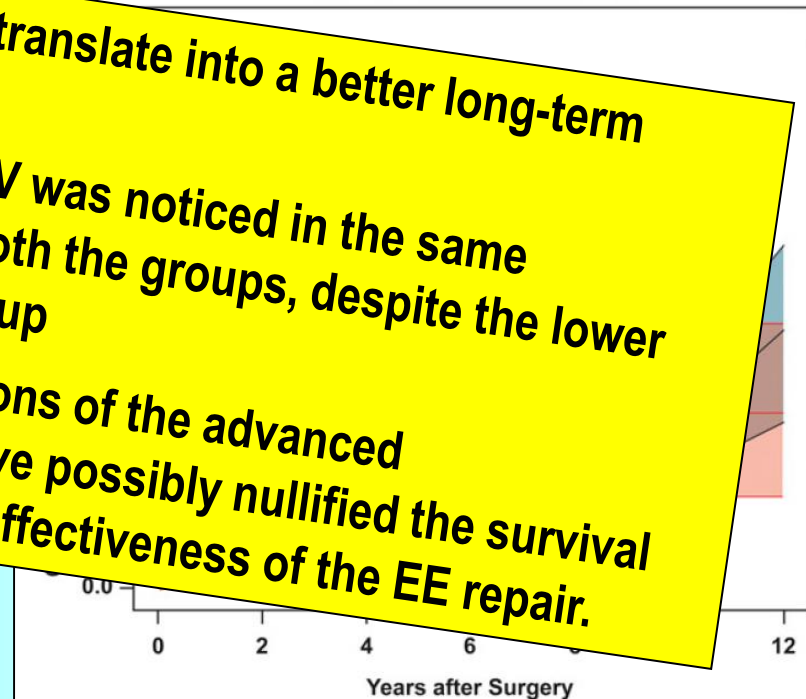


Figure 2: Cumulative incidence function of cardiac death in the two groups.

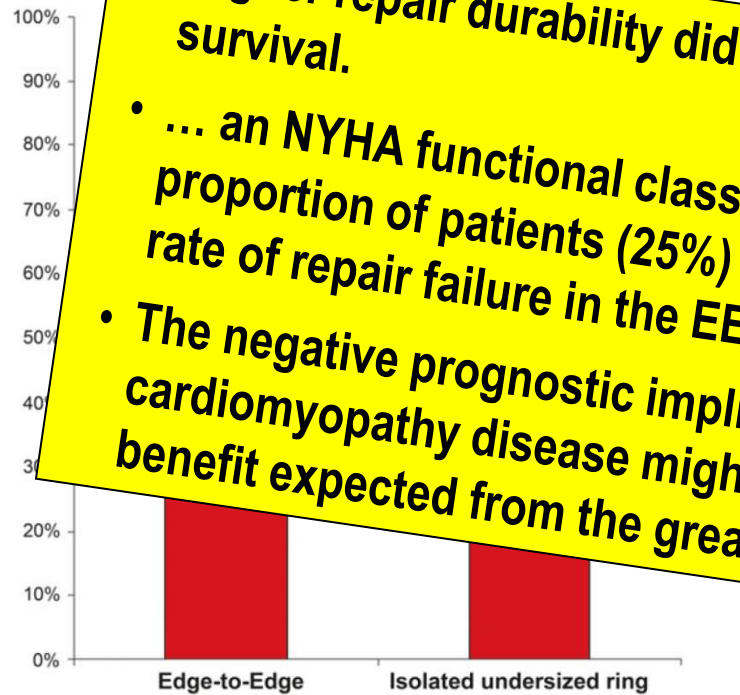


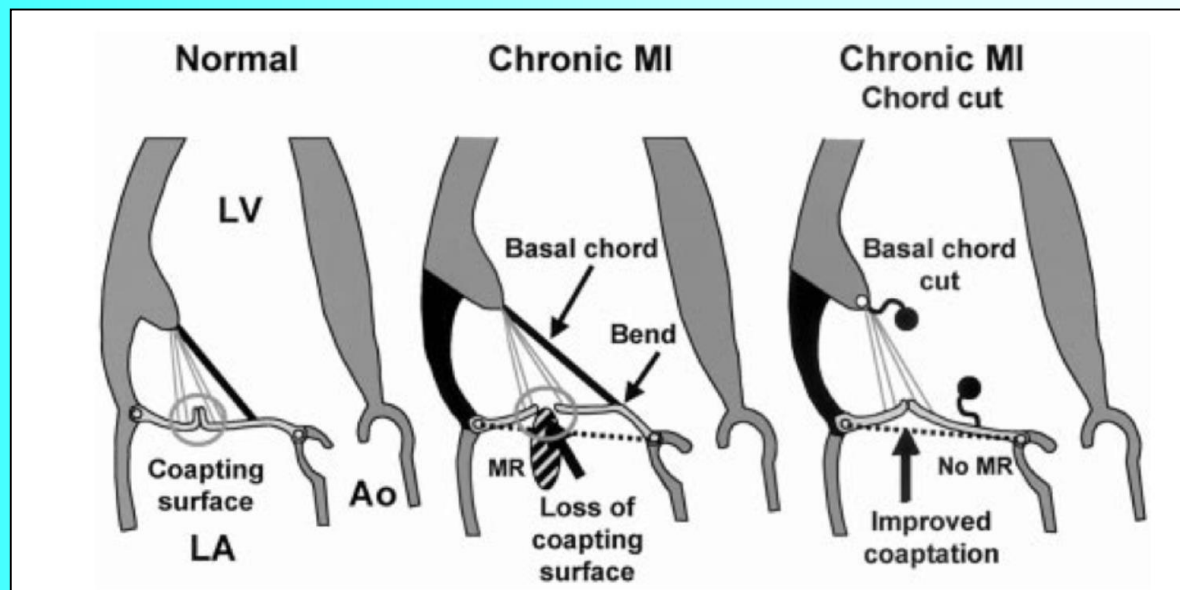
Figure 4: Grade of mitral regurgitation at the last echocardiographic assessment in the two groups.

- Higher repair durability did not translate into a better long-term survival.
- ... an NYHA functional class III–IV was noticed in the same proportion of patients (25%) in both the groups, despite the lower rate of repair failure in the EE group
- The negative prognostic implications of the advanced cardiomyopathy disease might have possibly nullified the survival benefit expected from the greater effectiveness of the EE repair.

## Leaflets and chordae correction:

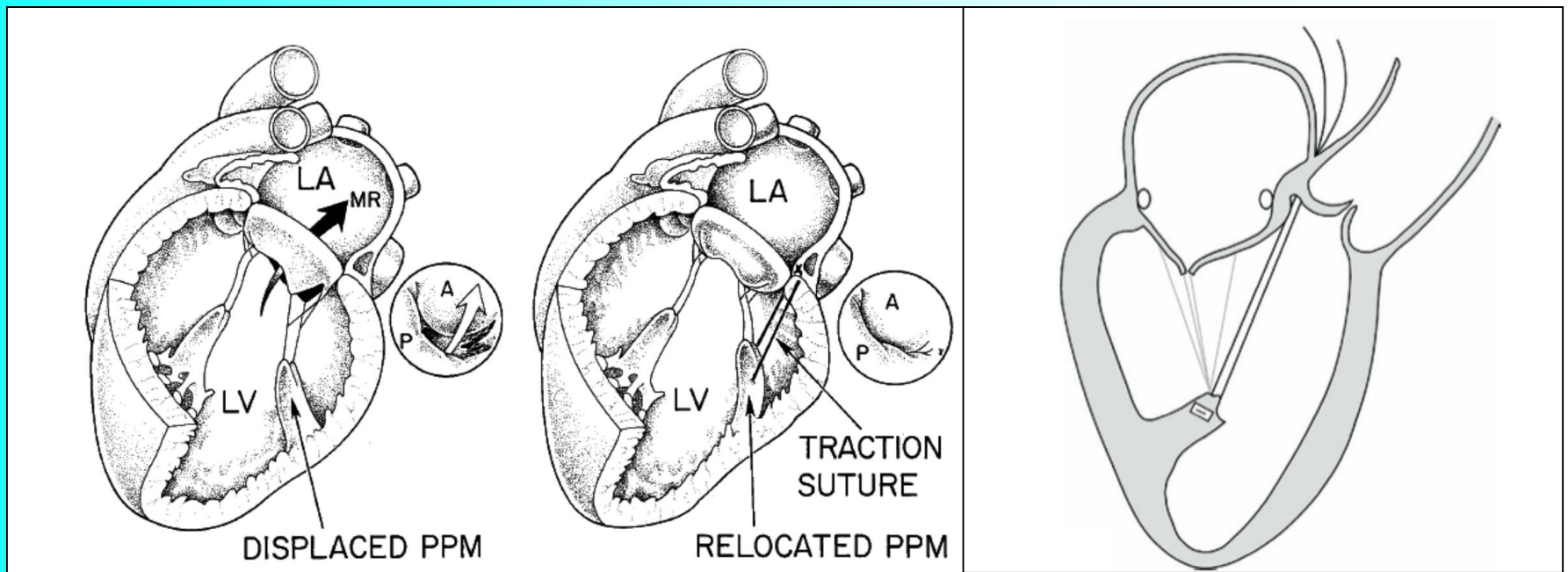
### ➤ Chordal cutting of the secondary “strut” chordae

- releases the anterior leaflet from the tethering due to papillary muscle displacement and improves mitral valve geometry.



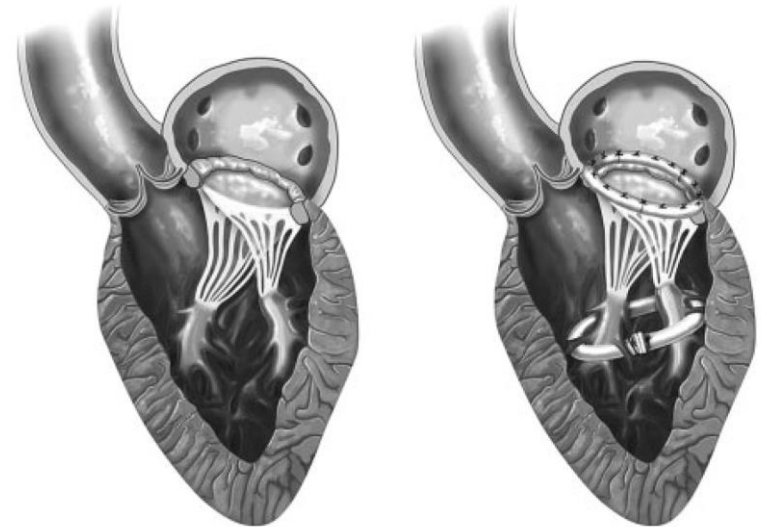
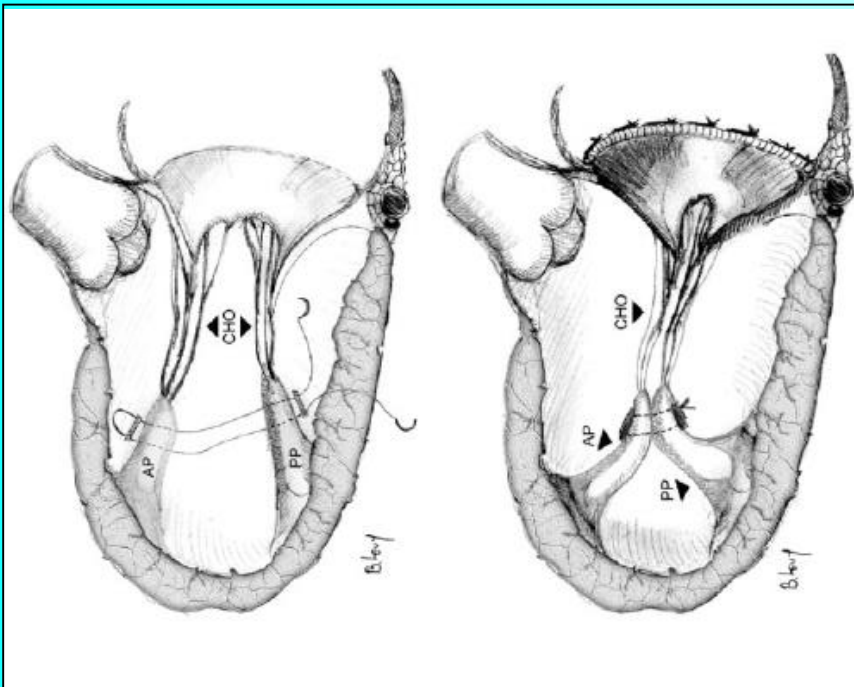
# The mitral subvalvular apparatus

- **surgical ventricular restoration procedure**
- surgical techniques directly addressing the **papillary muscle displacement**
  - **Traction suture**



# The mitral subvalvular apparatus

- Combining a ring annuloplasty with a papillary muscle intervention supports a reduction in chordal tethering forces by restoring the anterolateral papillary muscle position closer to the mitral annulus



**Figure 1:** Illustration of the papillary muscle Sling. A 4-mm polytetrafluoroethylene graft is placed through the ventricular trabeculations, around the bases of each papillary muscle, and tightened to approximate the papillary muscles.

## ■ Papillary muscles sling

## Papillary Muscle Approximation Versus Restrictive Annuloplasty Alone for Severe Ischemic Mitral Regurgitation

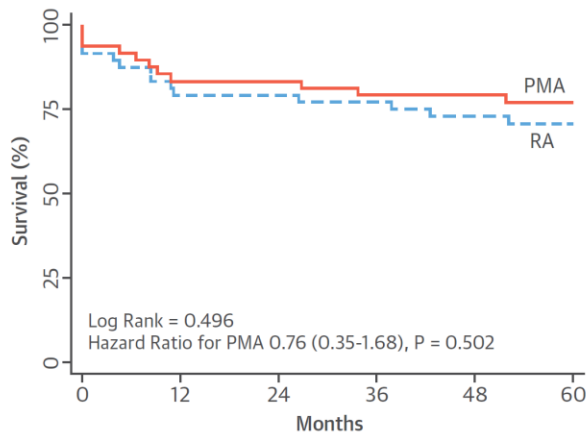


Francesco Nappi, MD,<sup>a,b</sup> Mario Lusini, MD, PhD,<sup>a</sup> Cristiano Spadaccio, MD, PhD,<sup>b,c</sup> Antonio Di Biase, MD,<sup>a</sup> Elvio Covino, MD,<sup>a</sup> Christophe Acar, MD, PhD,<sup>d</sup> Massimo Galiuto, MD, PhD,<sup>e</sup> and Giuseppe De Marco, MD, PhD,<sup>a</sup>

• these findings resulted in improved long-term cardiac outcomes, but did not produce differences in overall mortality and QOL

- Ninety patients were randomized to either restrictive mitral annuloplasty (RA) or papillary muscle approximation with undersizing restrictive mitral annuloplasty (PMA) associated with complete surgical myocardial revascularization.

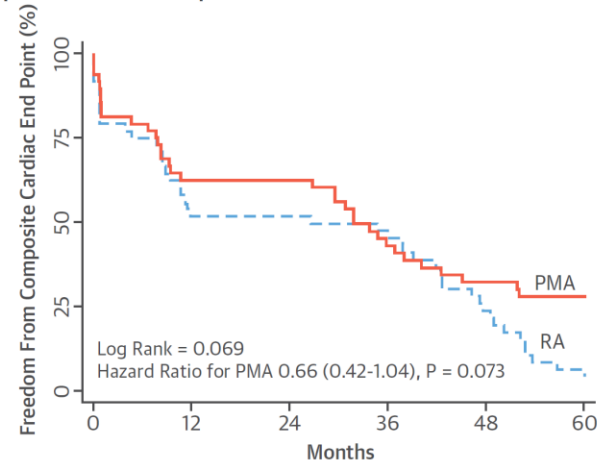
**A** Death



No. at risk

PMA	48	40	40	38	38	37
RA	48	38	38	37	35	34

**B** Composite cardiac end point



No. at risk

PMA	48	29	29	20	15	13
RA	48	24	24	21	11	3

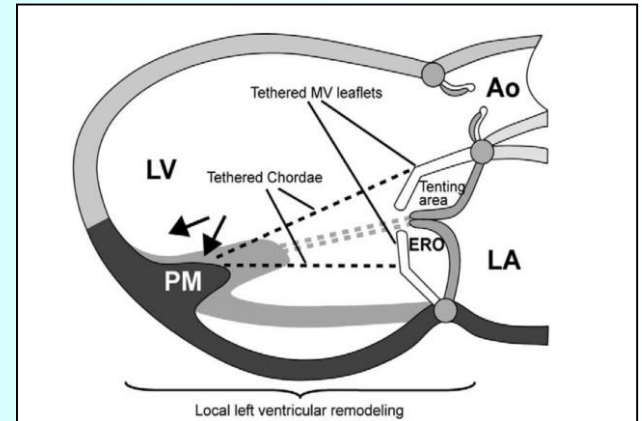
Value  
 in Delta\*

.001

.001

# Predictors of recurrent MR:

- Posterior leaflet angle  $> 45^\circ$
- Distal anterior leaflet angle  $> 25^\circ$
- Tenting height  $> 10$  mm
- Tenting area  $> 2.5$  cm<sup>2</sup>
- LVEDD  $> 65$  mm
- Severe scarring of posterolateral ventricular wall



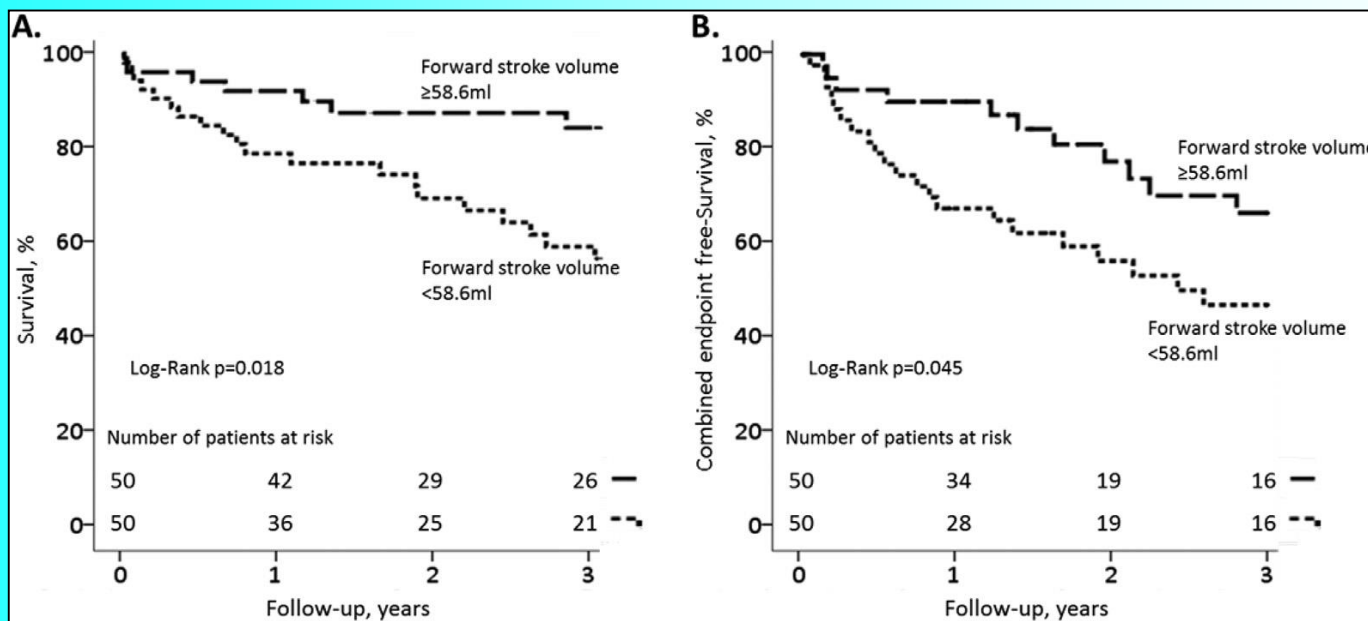
1. Ciarka A, Braun J, Delgado V, et al. Predictors of mitral regurgitation recurrence in patients with heart failure undergoing mitral valve annuloplasty. *Am J Cardiol* 2010; 106:395–401.
2. Magne J, Pibarot P, Dagenais F, et al. Preoperative posterior leaflet angle accurately predicts outcome after restrictive mitral valve annuloplasty for ischemic mitral regurgitation. *Circulation* 2007; 115:782–791.
3. Braun J, van de Veire NR, Klautz RJ, et al. Restrictive mitral annuloplasty cures ischemic mitral regurgitation and heart failure. *Ann Thorac Surg* 2008; 85:436–437.



# Restrictive Mitral Valve Annuloplasty: Prognostic Implications of Left Ventricular



- Surgical repair is associated with LV hemodynamic improvement at discharge.
- LV forward flow is independently associated with survival and combined endpoint free survival,
- Conventional variables of LV systolic function such as LV ejection fraction were not.



(A) Survival

(B) Combined  
endpoint free  
survival

## Possible Scenarios:

- **Patients with primary indication to revascularization**
  - Severe MR
  - **Moderate Mitral Regurgitation**
- Patients with isolated severe secondary MR
  - LVEF > 0.30
  - LVEF < 0.30.

## Surgical Treatment of Moderate Ischemic Mitral Regurgitation

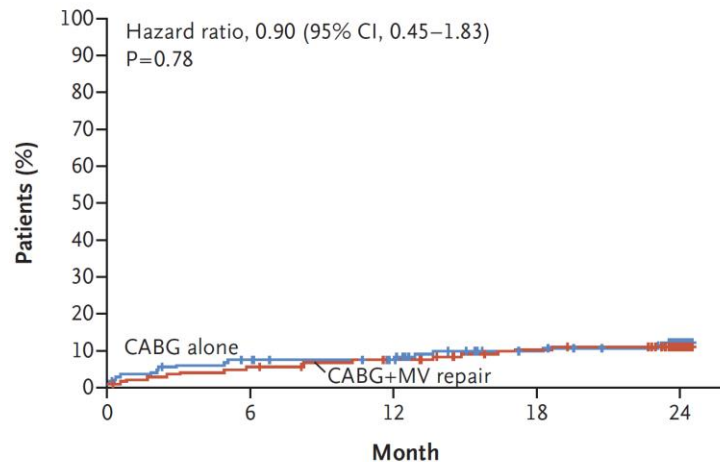
P.K. Smith, J.D. Puskas, D.D. Ascheim, P. Voisine, A.C. Gelijns, A.J. Moskowitz, J.W. Hung, M.K. Parides, G. Ailawadi, L.P. Perrault, M.A. Acker, M. Argenziano, V. Thourani, J.S. Gammie, M.A. Miller, P. Pagé, J.R. Overbey, E. Bagiella, F. Dagenais, E.H. Blackstone, I.L. Kron, D.J., E.A. Rose, E.G. Moquete, N. Jeffries, T.J. Gardner, P.T. O'Gara, J.H. Alexander, and R.E. Michler, for the Cardiothoracic Surgical Trials Network Investigators\*

- "STICH" trial: Subgroup analysis in the moderate-severe FIMR patients revealed, that CABG combined with mitral valve surgery showed a **clear trend towards improved long term survival compared with both CABG alone, and medical therapy alone.**
- However, probably due to the relatively small number of patients in the moderate-severe FIMR subgroup (n = 91), this difference did not reach statistical significance

- The addition of mitral-valve repair to CABG had no incremental effect on reverse left ventricular remodeling at 2 years.
- However, patients who underwent CABG alone had a higher prevalence of postoperative moderate or severe mitral regurgitation, although this difference did not translate into higher rates of death or MACCE

- We randomly assigned 301 patients with moderate ischemic mitral regurgitation to CABG alone or CABG plus mitral-valve repair (combined procedure).

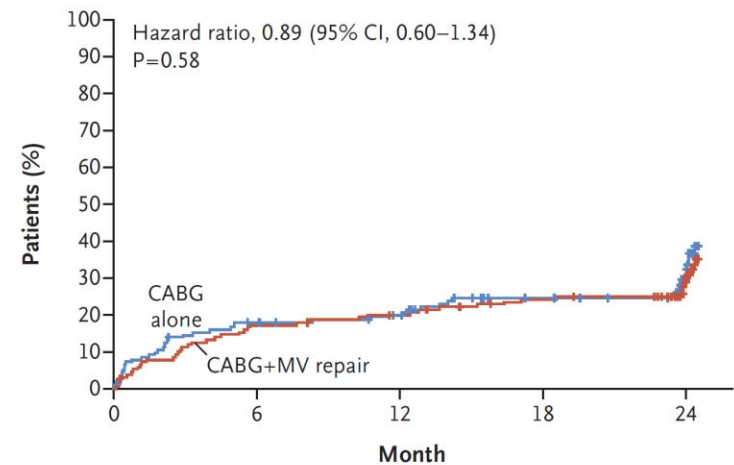
**A Death**



**No. at Risk**

	0	6	12	18	24
CABG alone	151	138	132	117	66
CABG+MV repair	150	142	136	126	80

**B Major Adverse Cardiac or Cerebrovascular Event**

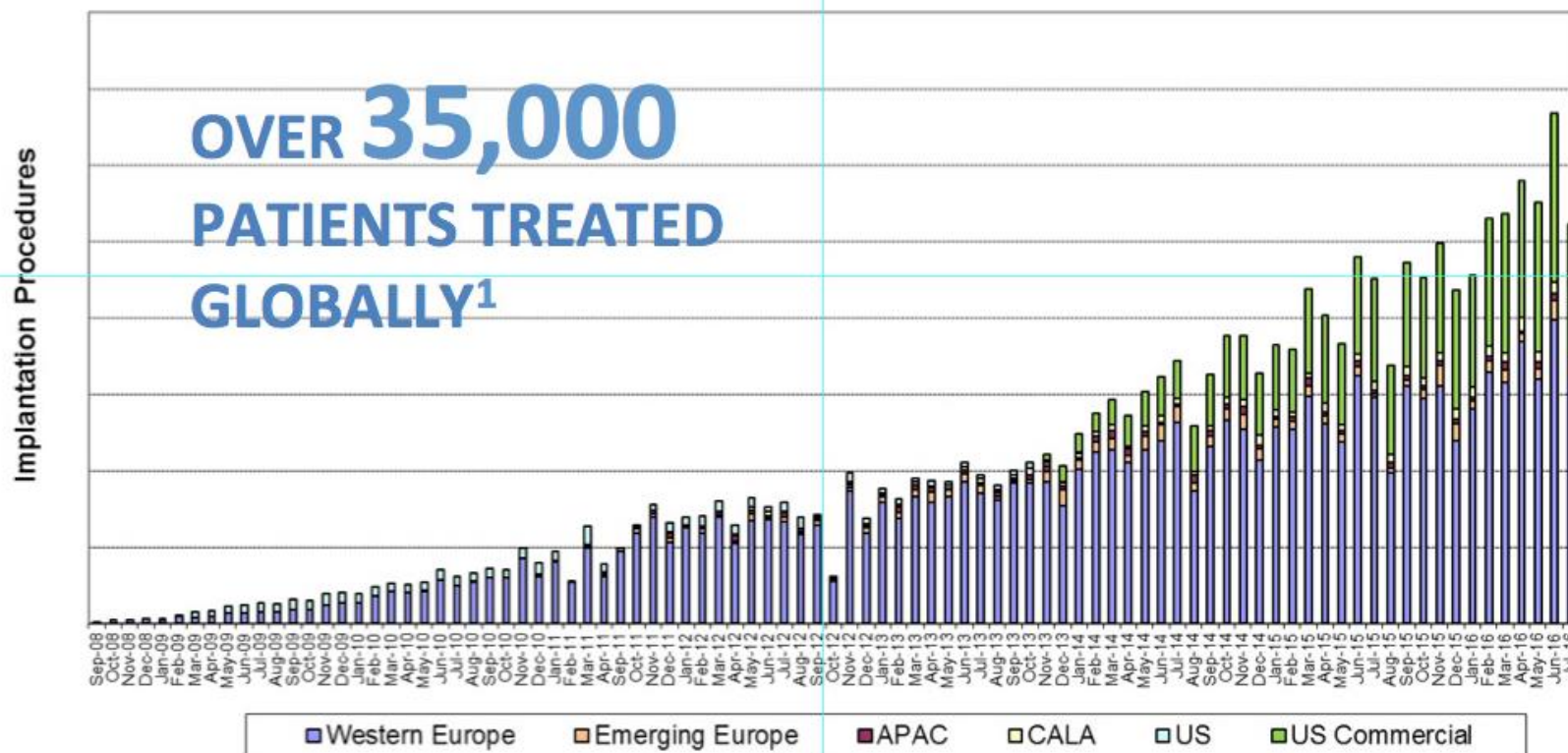


**No. at Risk**

	0	6	12	18	24
CABG alone	151	121	113	96	53
CABG+MV repair	150	123	117	106	64

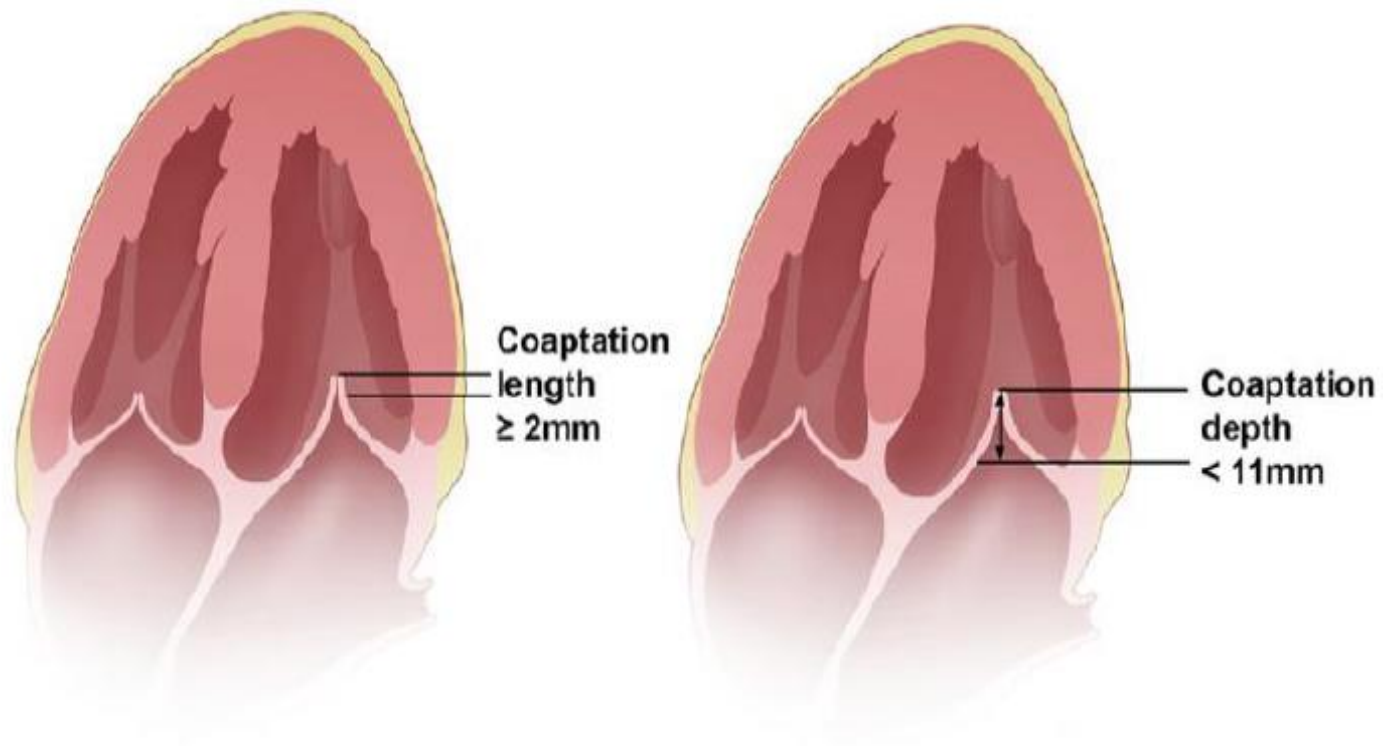
# GLOBAL MITRACLIP EXPERIENCE

## Global MitraClip Experience



1. Includes clinical and commercial procedures as of 31/07/2016. Source: Data on file at Abbott Vascular

# Mitraclip feasibility in Functional MR



# Secondary Mitral Regurgitation in Heart Failure

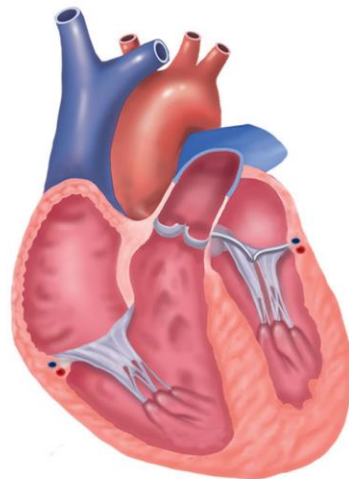
Pathophysiology, Prognosis, and Therapeutic Considerations

Anita W. Asgar, MD,\* Michael J. Mack, MD,† Gregg W. Stone, MD‡

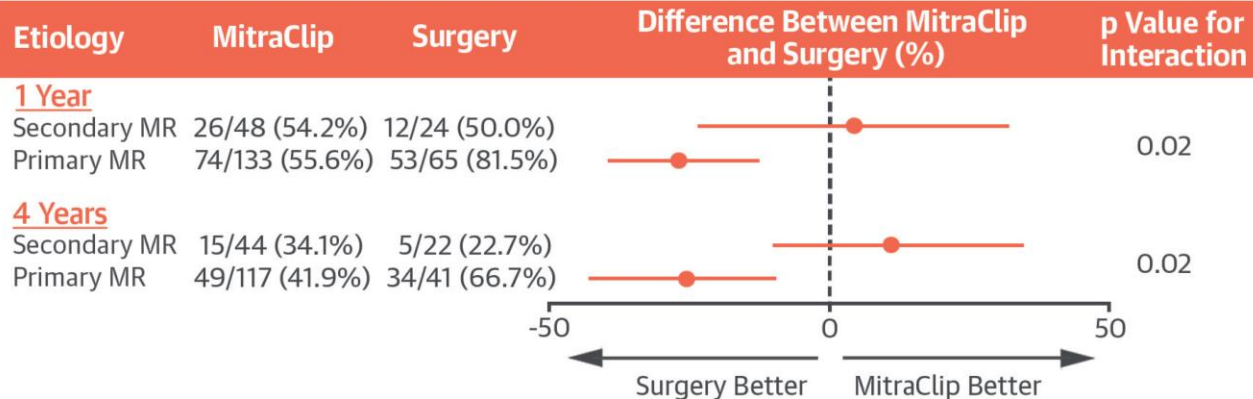
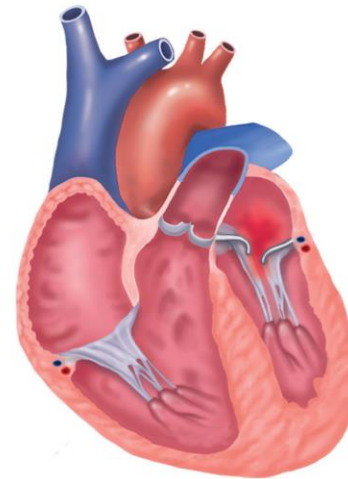
JACC VOL. 65, NO. 12, 2015

MARCH 31, 2015:1231-48

Normal

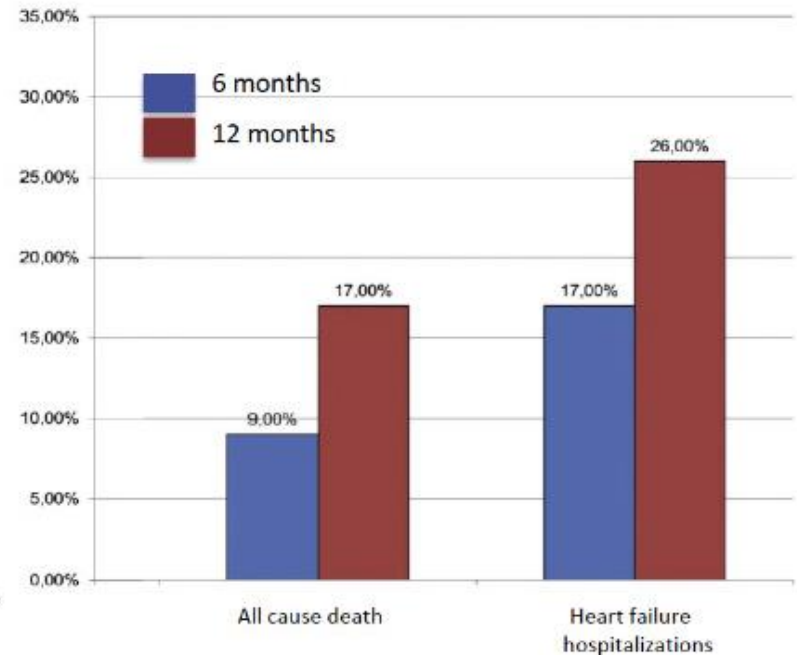
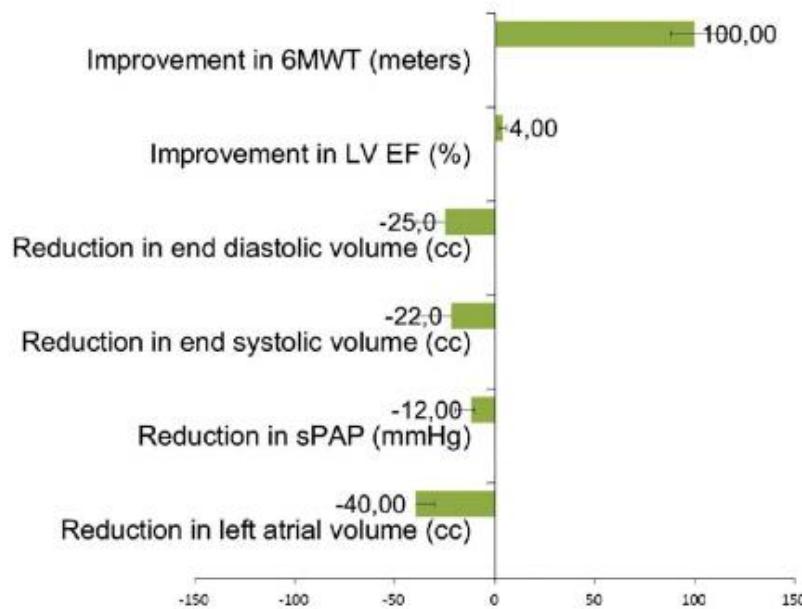


Mitral Valve Regurgitation



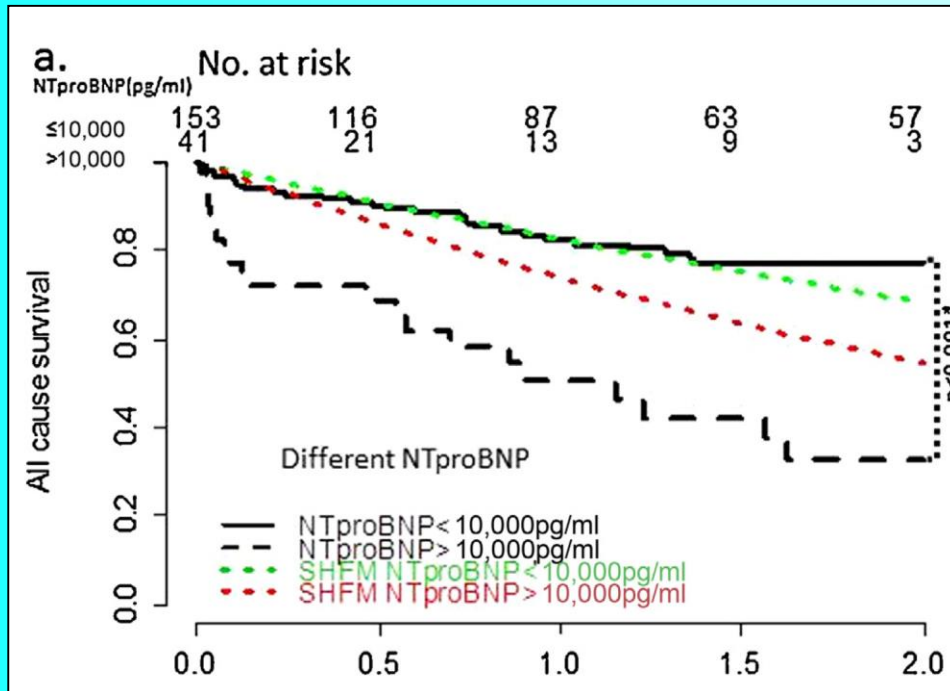
# Meta-Analysis of Mitraclip in Functional MR

9 studies, 875 patients, STS median 12%,



significant improvement in functional class and remodeling, even with severely dilated hearts, although efficacy limited in atrial fibrillation





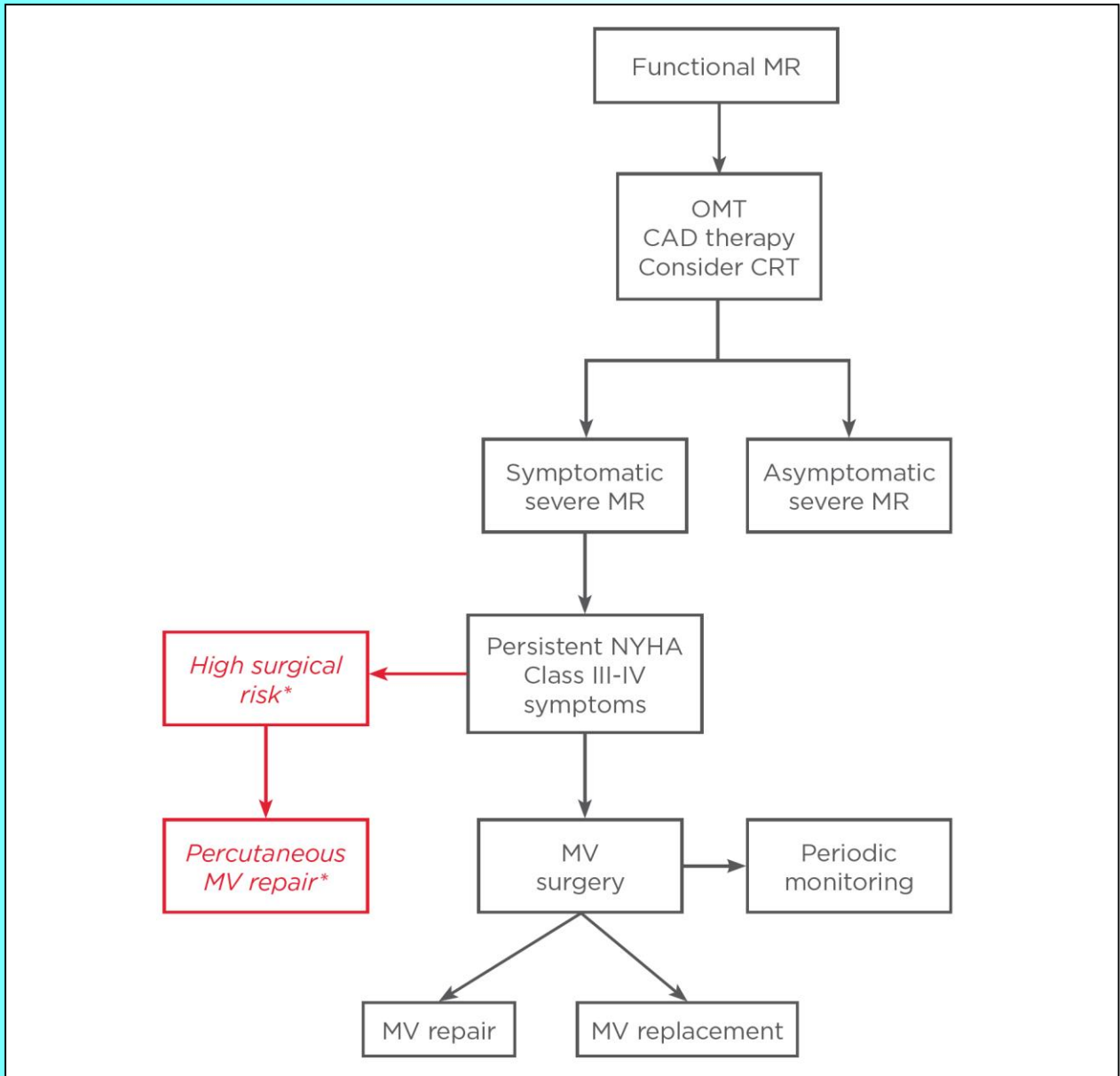
- Rates of mortality in a group of patients following successful treatment with a MitraClip was indistinguishable from that predicted by SHFM at 2 years.
- Especially end-stage heart failure patients with NTproBNP value >10,000 pg/ml do not appear to benefit from the MitraClip therapy, mainly due to a high 30-day mortality

**TABLE 5 Comparison of Ongoing Randomized Trials of the MitraClip in Patients With Heart Failure and Secondary Mitral Regurgitation**

	<b>COAPT</b>	<b>RESHAPE-HF</b>	<b>MITRA-FR</b>
Number of patients and sites	430 patients at 75 U.S. and Canadian sites	800 patients at 50 E.U. sites	288 patients at 18 French sites
Secondary MR grade (core laboratory verified)	≥3+ (EROA ≥30 mm <sup>2</sup> and/or Rvol >45 ml)	≥3+ (EROA ≥30 mm <sup>2</sup> and/or Rvol >45 ml)	Severe (EROA >20 mm <sup>2</sup> + Rvol >30 ml)
NYHA functional class	II, III, or ambulatory IV	III or ambulatory IV	II-IV
LVEF	≥20% to ≤50%	≥15% to ≤40%	≥15% to ≤40%
Surgical criteria	Not appropriate for mitral valve surgery (heart team)	None	None
Left ventricular volume entry criterion	LV end-systolic dimension ≤70 mm	LV end-diastolic dimension ≥55 mm	None
Control arm	Guideline-directed medical therapy (+CRT, if indicated)	Guideline-directed medical therapy (+CRT, if indicated)	Guideline-directed medical therapy (+CRT, if indicated)
Primary efficacy endpoint (superiority)	Heart failure rehospitalizations at 1 yr	Death or heart failure hospitalization at 1 yr	Death or recurrent heart failure hospitalization at 1 yr
Primary safety endpoint (noninferiority)	The composite of: SLDA; device embolization; endocarditis requiring surgery; echocardiography core laboratory-confirmed mitral stenosis requiring surgery; LVAD implant; heart transplant; or any device-related complications requiring nonelective cardiovascular surgery at 12 months	None	None
Health economics	Assessed	Assessed	None
Follow-up, yrs	5	2	2

COAPT = Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation; EROA = effective regurgitant orifice area; LV = left ventricular; LVAD = left ventricular assist device; MITRA-FR = Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation; Rvol = regurgitant volume; RESHAPE-HF = Randomized Study of the MitraClip Device in Heart Failure Patients With Clinically Significant Functional Mitral Regurgitation; SLDA = single leaflet device attachment; other abbreviations as in [Table 4](#).

# Conclusions:



➤ **When medical therapy**

- Always
- CRT if possible
- If remain symptomatic evaluation of other therapies

➤ **When surgery could be better?**

- Surgical risk not too high
  - Possibility of addressing multiple factors: Tricuspid Reg., A.F, other disease with advantage of surgical correction

➤ **When mitraclip could be better?**

- Surgical risk too high
- Ventricular reshaping unpredictable

