Severe MR with Reduced LV function

ΠΗΝΕΛΟΠΗ Θ.ΓΙΑΝΝΑΚΟΠΟΥΛΟΥ
ΚΑΡΔΙΟΛΟΓΟΣ
ΕΠΙΜ.Β'
ΚΑΡΔΙΟΛΟΓΙΚΗ ΚΛΙΝΙΚΗ
Γ.Ν.Γ.ΠΑΠΑΝΙΚΟΛΑΟΥ

Causes of MR

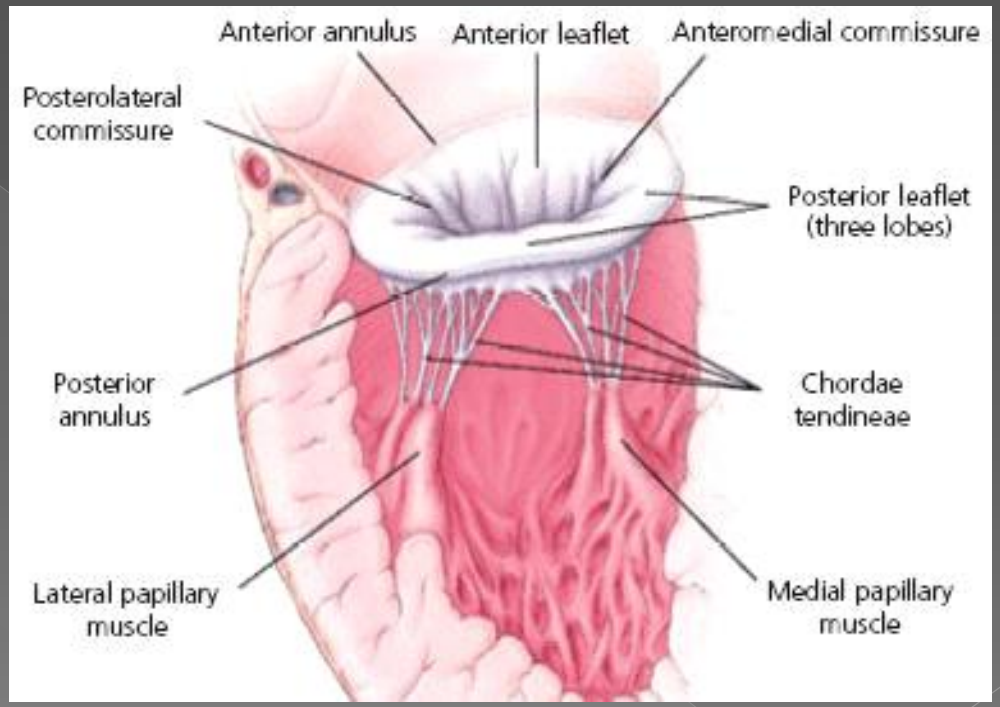
- **NON ISCHEMIC**

DEGENERATIVE

ENDOCARDITIS

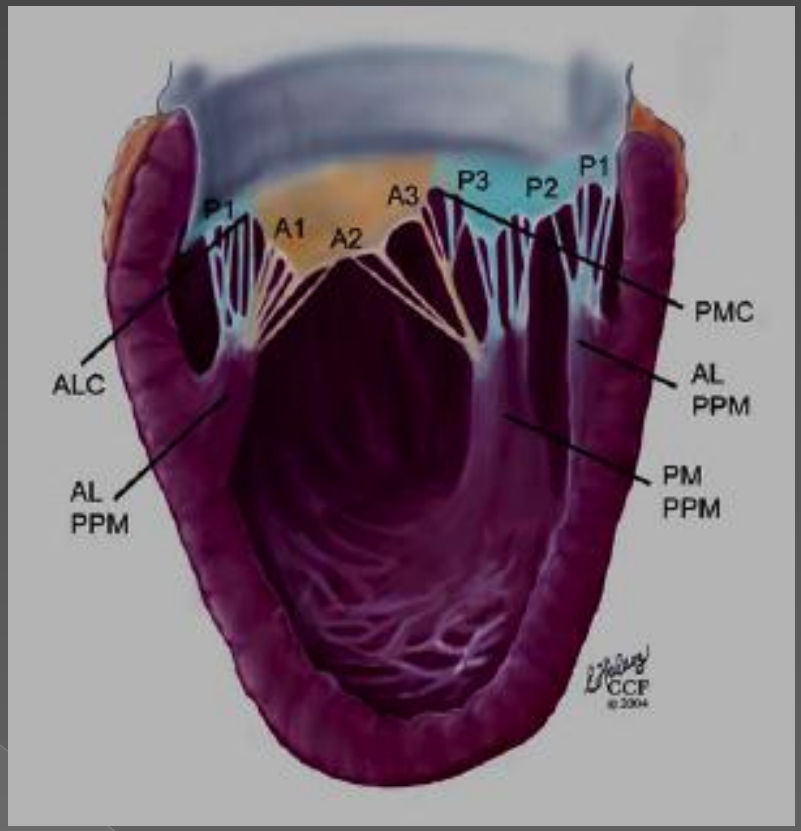
RHEUMATIC

MISCELLANEOUS
- CONGENITAL
- CARDIOMYOPATHY-RELATED
- INFLAMMATORY
- DRUG-INDUCED
- TRAUMATIC



- **ISCHEMIC**

Anatomy


P1
A1
A2
A3
P3
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P1
PMC
ALC
AL
PPM
AL
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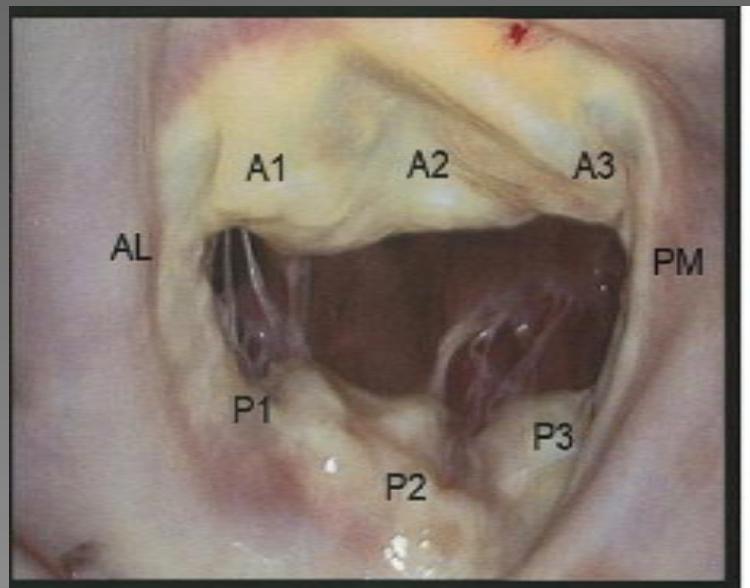
PM
PPM
CCF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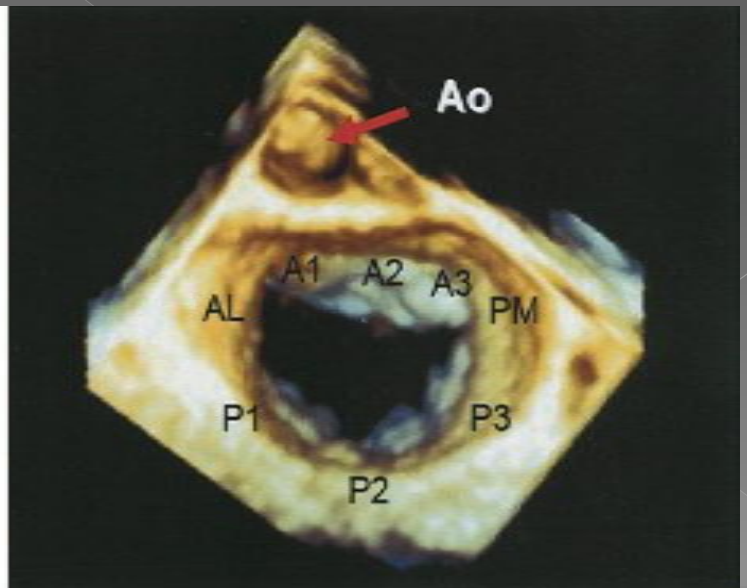
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Definition of severity of MR

PRACTICE GUIDELINE

2008 Focused Update Incorporated Into the ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1998 Guidelines for the Management of Patients With Valvular Heart Disease)

Endorsed by the Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons

	Mitral Regurgitation		
	Mild	Moderate	Severe
Qualitative			
Angiographic grade	1+	2+	3–4+
Color Doppler jet area	Small, central jet (less than 4 cm^2 or less than 20% LA area)	Signs of MR greater than mild present but no criteria for severe MR	Vena contracta width greater than 0.7 cm with large central MR jet (area greater than 40% of LA area) or with a wall-impinging jet of any size, swirling in LA
Doppler vena contracta width (cm)	Less than 0.3	0.3–0.69	Greater than or equal to 0.70
Quantitative (cath or echo)			
Regurgitant volume (ml per beat)	Less than 30	30–59	Greater than or equal to 60
Regurgitant fraction (%)	Less than 30	30–49	Greater than or equal to 50
Regurgitant orifice area (cm^2)	Less than 0.20	0.20–0.39	Greater than or equal to 0.40
Additional essential criteria			
Left atrial size			Enlarged
Left ventricular size			Enlarged

JACC Vol. 52, No. 13, 2008
September 23, 2008:e1–142

Definition of severity of MR

Table 1 Mitral Regurgitation Severity by Echocardiography

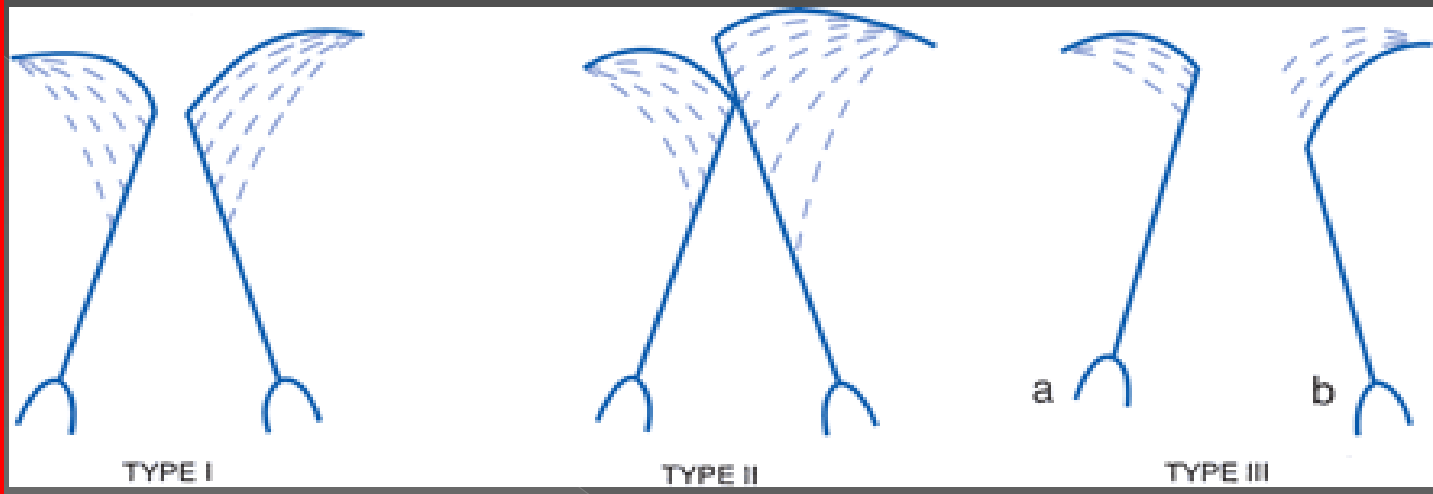
Echo Parameter	Mild	Moderate	Severe
Vena contracta width (cm)	<0.3	0.3–0.69	≥0.7
Regurgitant volume (ml/beat)	<30	30–59	≥60
Regurgitant fraction (%)	<30	30–49	≥50
Effective regurgitant orifice area (cm^2)	<0.2	0.2–0.39	≥0.40

JACC Vol. 55, No. 4, 2010
January 26, 2010:271–82

Carpentier's functional classification of MR

Acute IMR
type II
(pm
rupture)

Chronic IMR
type I
IIIb



-In type I, the leaflet motion is normal, and mitral regurgitation is a result of mitral annular dilatation.

-In type II, there is leaflet prolapse or excessive motion.

-In type III, there is leaflet restriction or tethering, and this type is subclassified further into IIIa (tethering during diastole) and IIIb (tethering during systole).

Mechanisms of MR

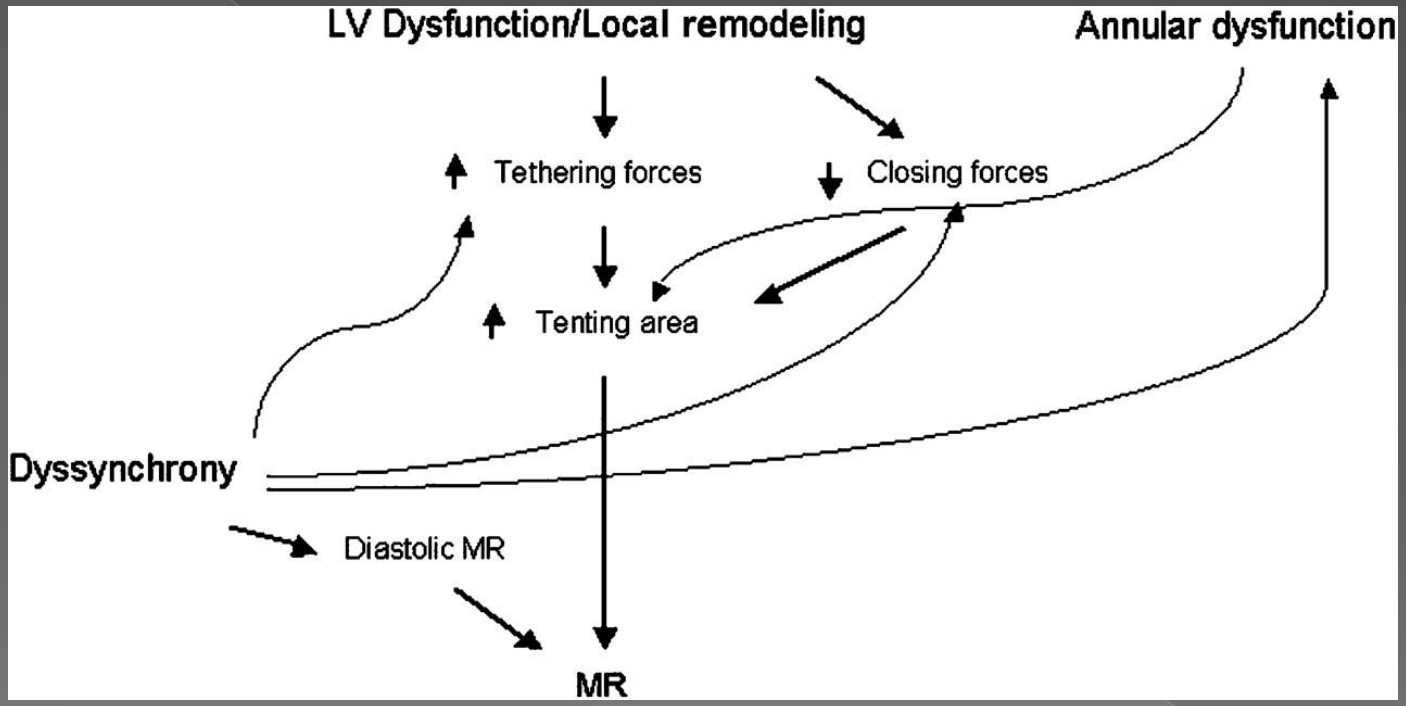
- **Functional**

  (**structurally normal valve**,
  annular dilatation associated with LV remodelling)

- **Organic**

  (flail
  prolapse
  restriction)

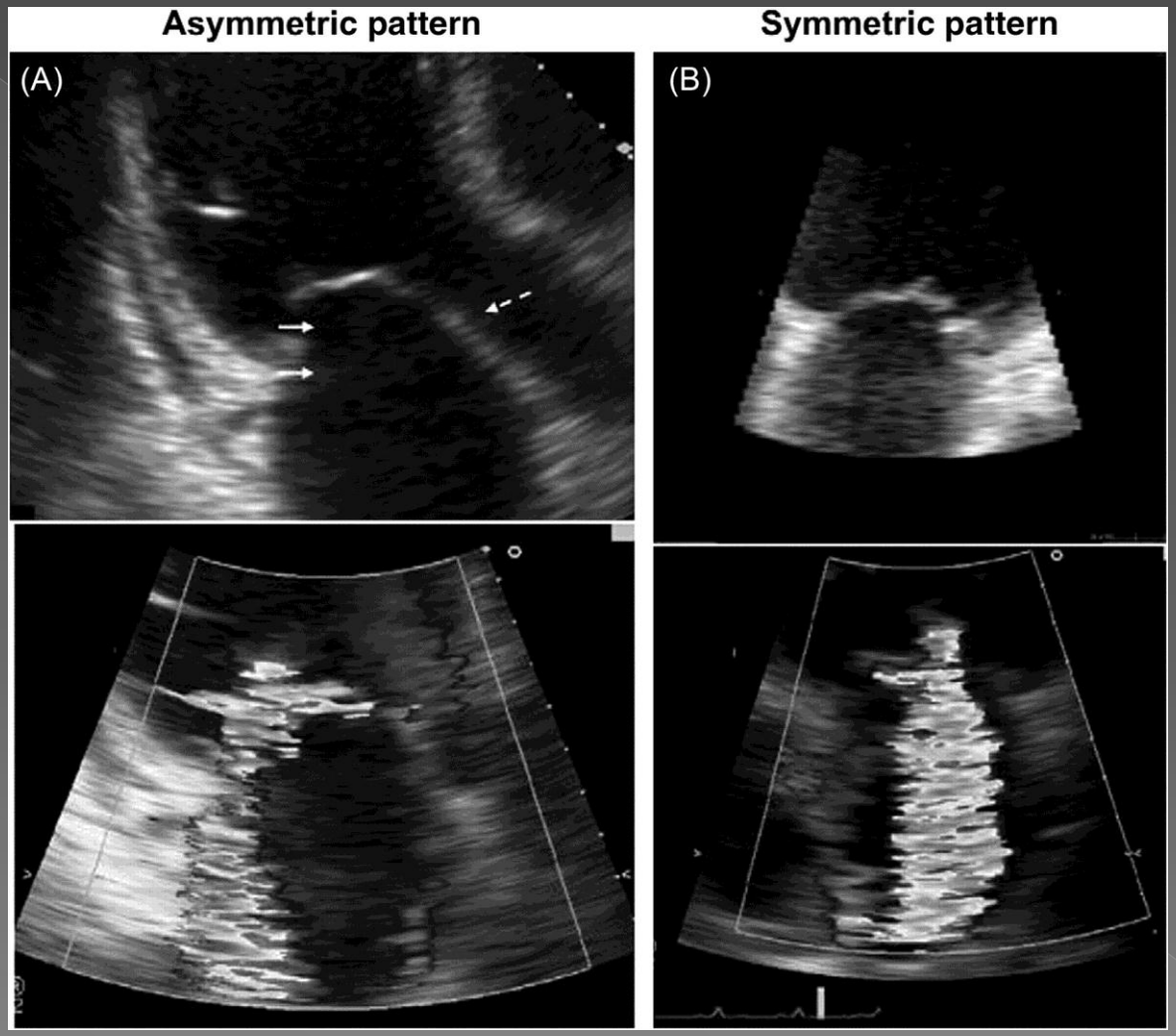
Pathophysiologic factors and their interactions in determining IMR



Agricola, E. et al. Eur J Echocardiogr 2008 9:207-221; doi:10.1016/j.euje.2007.03.034

European Journal of Echocardiography

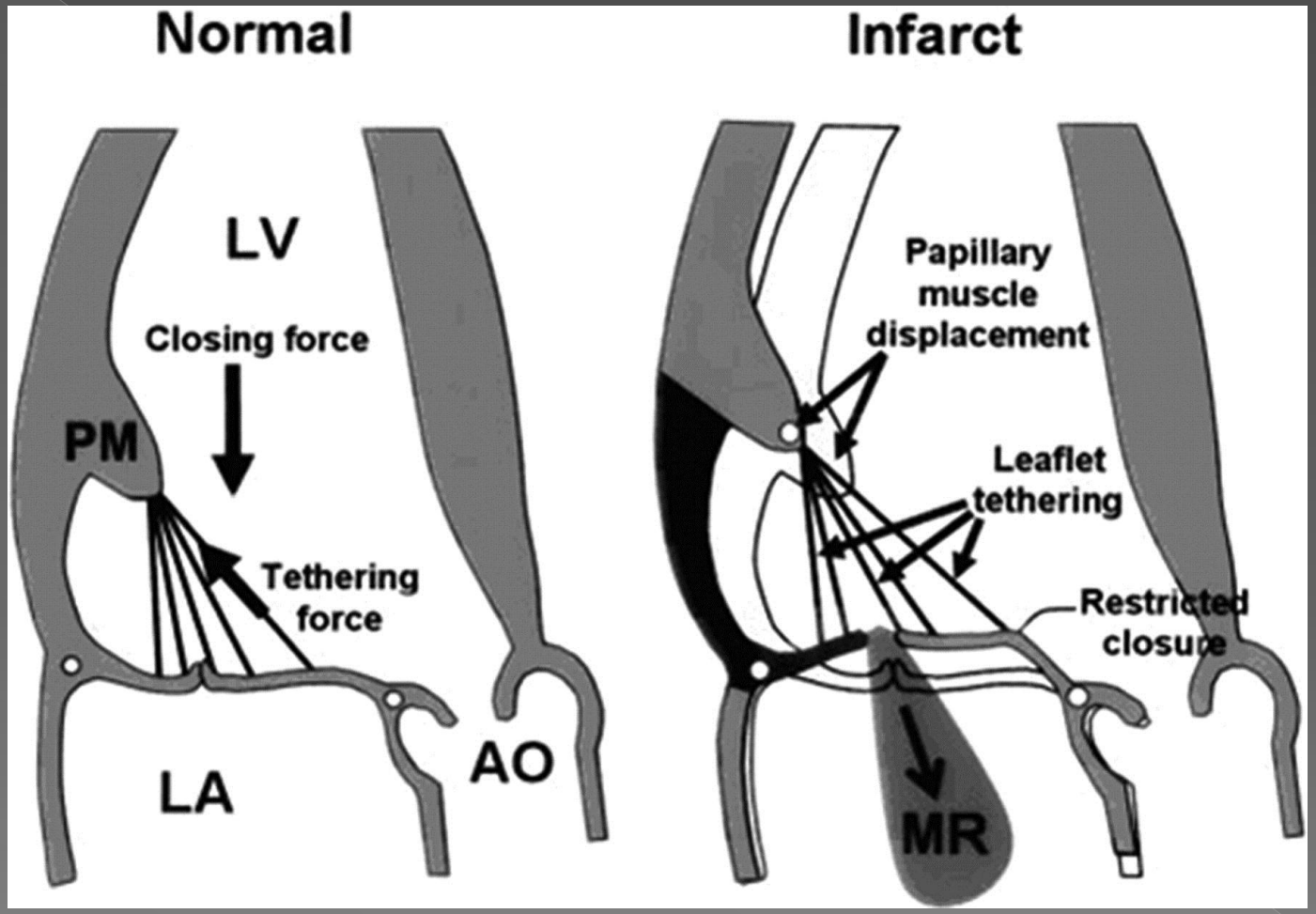
(A) Asymmetric tethering



Agricola, E. et al. Eur J Echocardiogr 2008 9:207-221; doi:10.1016/j.euje.2007.03.034

European Journal of Echocardiography

Mechanisms of MR



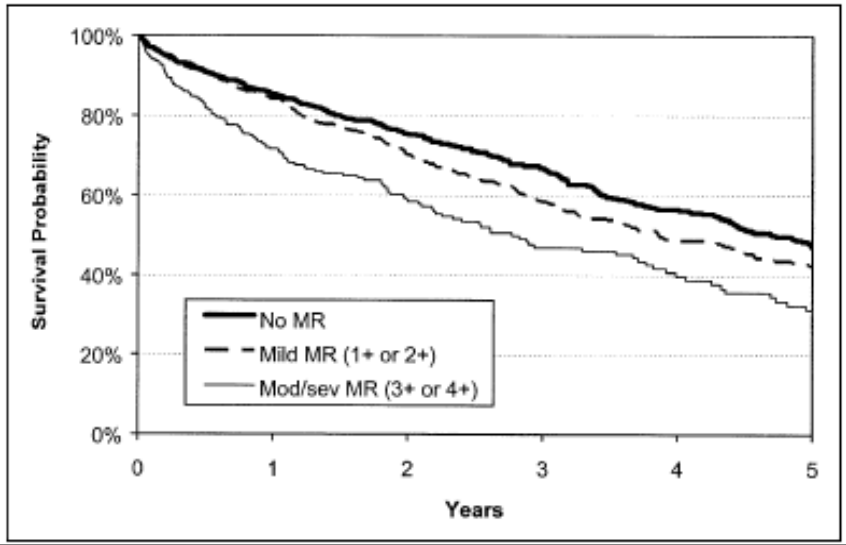
Di Salvo, T. G. et al. J Am Coll Cardiol 2010;55:271-282

JACC Journal of the American College of Cardiology

Relation of Frequency and Severity of Mitral Regurgitation to Survival Among Patients With Left Ventricular Systolic Dysfunction and Heart Failure

Benjamin H. Trichon, MD, G. Michael Felker, MD, Linda K. Shaw, MS, Christopher H. Cabell, MD, and Christopher M. O'Connor, MD

- 2057 pts **(30% severe MR)**
- **MR** independent ***predictor of survival***



THE AMERICAN JOURNAL OF CARDIOLOGY® VOL. 91 MARCH 1, 2003

The relationship between mitral regurgitation and ejection fraction as predictors for the prognosis of patients with heart failure

Redi Pecini[1]*, Jens Jakob Thune[2], Christian Torp-Pedersen[3], Christian Hassager[4], and Lars Køber[4]

[1]Department of Cardiology and Endocrinology, Frederiksberg Hospital, University of Copenhagen, Copenhagen, Denmark; [2]Department of Cardiology, Bispebjerg Hospital, University of Copenhagen, Copenhagen, Denmark; [3]Department of Cardiology, Gentofte Hospital, University of Copenhagen, Hellerup, Denmark; and [4]Department of Cardiology, Rigshospitalet, University of Copenhagen, Copenhagen, Denmark

- 3078 pts
- Follow-up 4.5 y
- Moderate +severe MR → ↑mortality rate in ↓↓EF

Conclusion

Moderate- and high-grade MR have a negative effect on prognosis of patients with HF. However, this effect is found only in patients with a severely reduced LVEF.

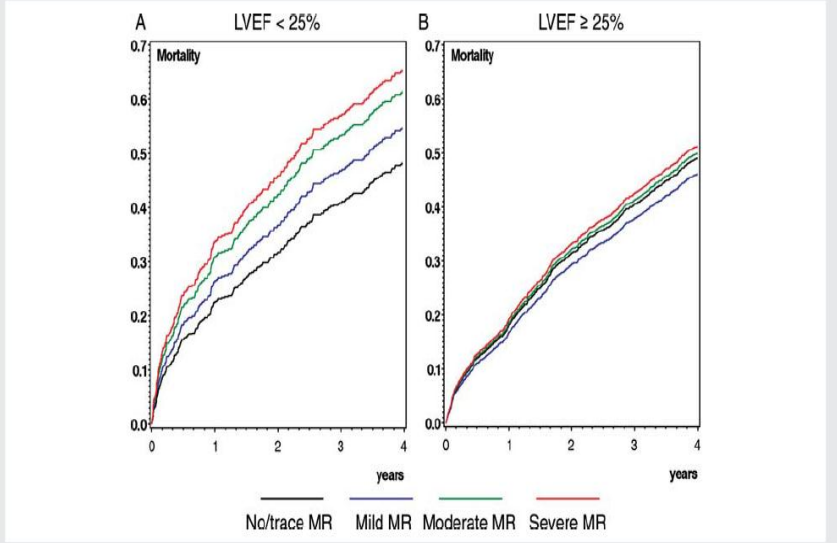


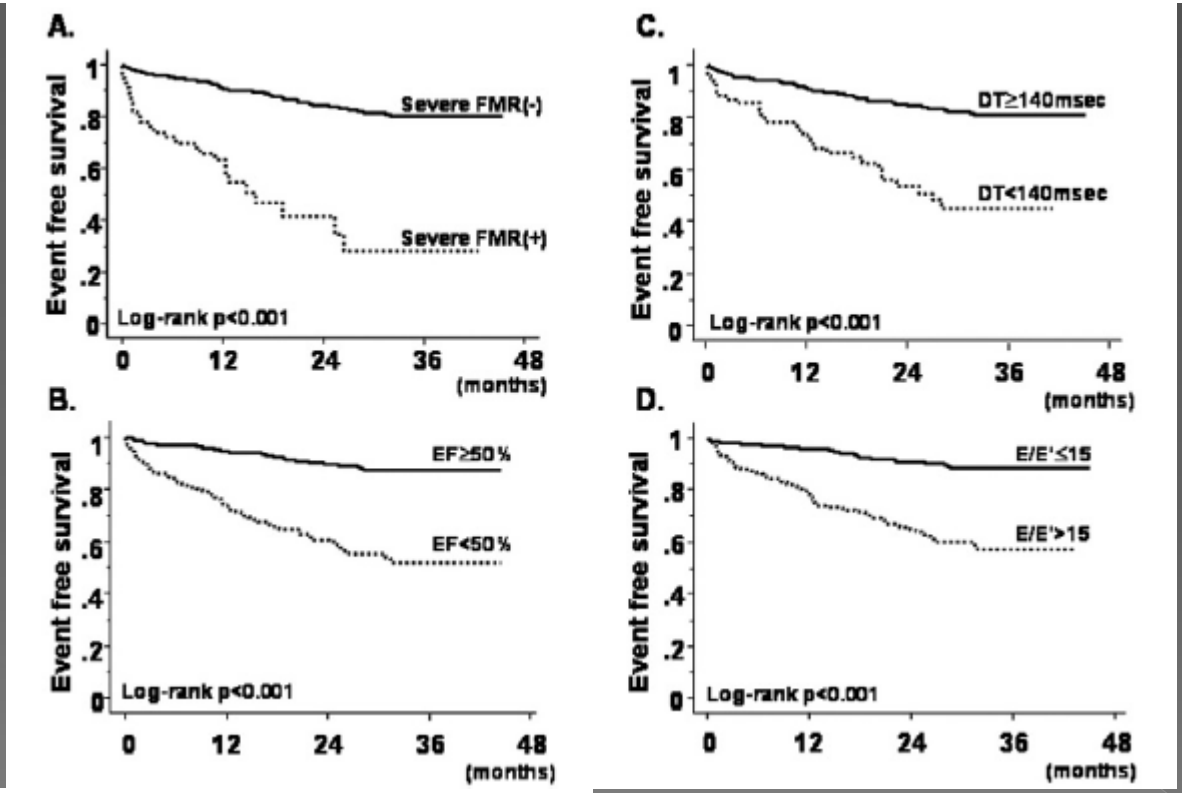
Figure 2 Adjusted mortality rates for patients with left ventricular ejection fraction <25% (left) and left ventricular ejection fraction ≥25% (right).

EUROPEAN SOCIETY OF CARDIOLOGY®

European Journal of Heart Failure (2011) **13**, 1121–1125
doi:10.1093/eurjhf/hfr114

Functional Mitral Regurgitation Predicts Prognosis Independent of Left Ventricular Systolic and Diastolic Indices in Patients with Ischemic Heart Disease

Hiroyuki Okura, MD, Yuko Takada, Tomoichiro Kubo, MD, Koichiro Asawa, MD, Haruyuki Taguchi, MD, Iku Toda, MD, Minoru Yoshiyama, MD, Junichi Yoshikawa, MD, and Kiyoshi Yoshida, MD, *Sakai, Osaka, and Kurashiki, Japan*

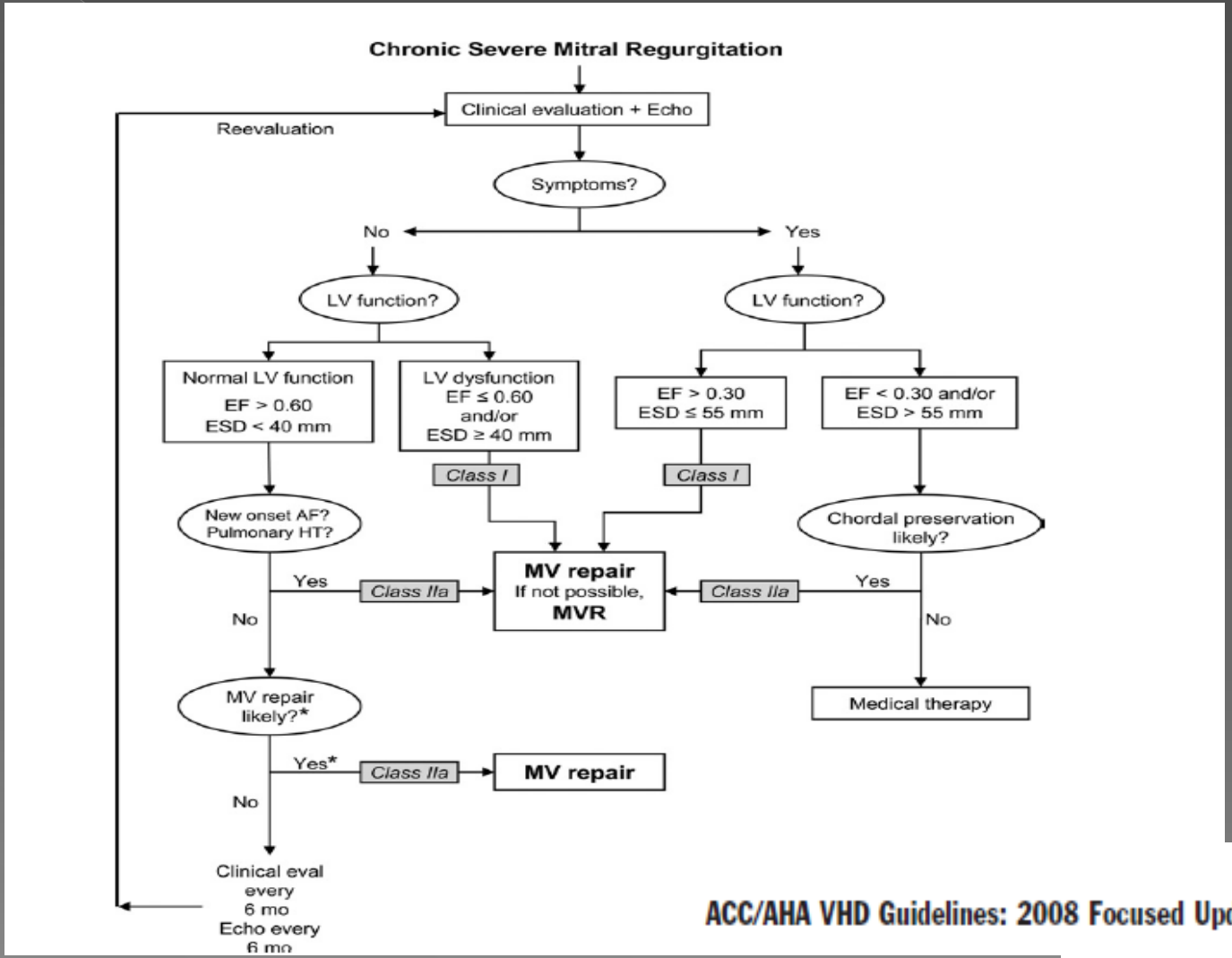


CONCLUSION

Severe FMR and E/E', and left ventricular EF are strong and independent echocardiographic predictors of mortality and morbidity in patients with ischemic heart disease.

Journal of the American Society of Echocardiography
April 2008

Management of severe MR



Bonow *et al.*

ACC/AHA VHD Guidelines: 2008 Focused Update Incorporated

JACC Vol. 52, No. 13, 2008
September 23, 2008:e1–142

Guidelines on the management of valvular heart disease

The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology

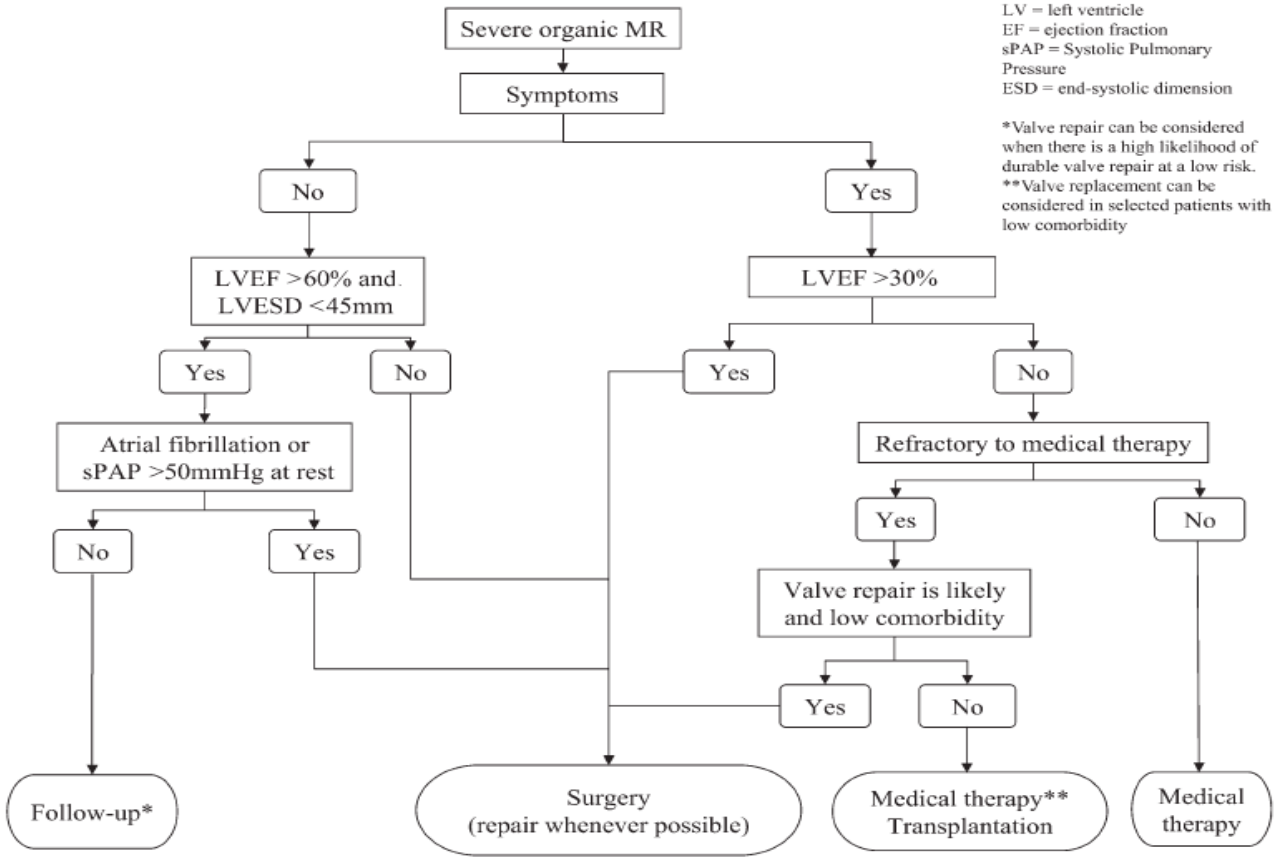


Figure 3 Management of severe chronic organic mitral regurgitation.

European Heart Journal (2007) **28**, 230–268
doi:10.1093/eurheartj/ehl428

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INDICATIONS FOR SURGERY IN CHRONIC ORGANIC MR

Class I.

- *Symptomatic* pts with LVEF >30% and ESD <55mm (IB).

- *Asymptomatic* pts with LV dysfunction (ESD >45mm and/or LVEF <=60%) (1C)

INDICATIONS FOR SURGERY IN CHRONIC ORGANIC MR

Class IIA

- *Asymptomatic pts with preserved LV function and atrial fibrillation or pulmonary hypertension (SPAP >50mmHg at rest).* ***IIaC***
- *Pts with* ***severe LV dysfunction*** *(LVEF <30% and/or ESD >55mm) refractory to medical therapy with high likelihood of durable repair,and low comorbidity.* ***IIaC***
- Asymptomatic pts with preserved LV function,high likelihood of durable repair,and low risk for surgery.***IIbB***
- Pts with ***severe LV dysfunction*** (LVEF <30% and/or ESD >55mm) refractory to medical therapy with low likelihood of durable repair,and low comorbidity. ***IIbC***

Mitral valve surgery in patients with severe left ventricular dysfunction ☆

Ehab S. Bishay[a], Patrick M. McCarthy[a,b,*], Delos M. Cosgrove[a], Katherine J. Hoercher[a,b], Nicholas G. Smedira[a,b], Debabrata Mukherjee[b,c], Jennifer White[d], Eugene H. Blackstone[a,d]

[a]*Department of Thoracic and Cardiovascular Surgery, The Cleveland Clinic Foundation, 9500 Euclid Avenue, Cleveland, OH 44195, USA*

44 pts
40% valvular MR-30% ischemic
Follow-up: 5 years

Table 4
Changes in left ventricular echocardiographic dimensions[a]

	Preoperative	Postoperative
End-diastolic diameter (mm)	65 (56,75)	57 (46,70)
End-systolic diameter (mm)	50 (43,57)	46 (34,49)
End-diastolic volume (ml)	166 (124,221)	137 (81,230)
End-systolic volume (ml)	118 (88,158)	81 (41,160)
Sphericity index (D/L)	0.83 (0.8,0.9)	0.76 (0.7,0.9)
Mitral regurgitation	3.8 (3.4,4)	1 (0,2)
Stroke volume (ml)	47 (34,66)	52 (32,84)
Ejection fraction (%)	28 (24,34)	36 (26,52)

Conclusions: Mitral valve surgery offers symptomatic improvement and survival benefit in patients with severe LV dysfunction and mitral regurgitation. More liberal use of this surgery for cardiomyopathy patients is warranted.

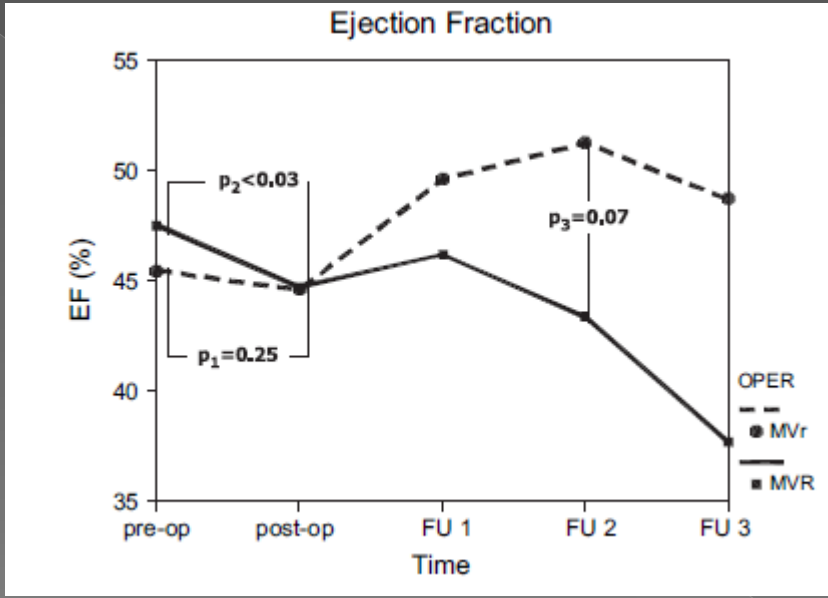
European Journal of Cardio-thoracic Surgery 17 (2000) 213–221

Mitral valve repair versus replacement for isolated non-ischemic mitral regurgitation in patients with preoperative left ventricular dysfunction. A long-term follow-up echocardiography study

Nikos Kouris [a,*], Ignatios Ikonomidis [b], Dimitra Kontogianni [a], Peter Smith [b], Petros Nihoyannopoulos [b]

[a] *Western Attica General Hospital, Athens, Greece*
[b] *Hammersmith Hospital, Imperial College, London, UK*

45 pts
Non-ischemic MR
Follow-up:6 yrs



Conclusion: MVr in pts with non-ischemic MR and preoperative LV dysfunction achieves better preservation of LV systolic indices than MVR, probably due to preservation of the subvalvular apparatus and LV geometry.

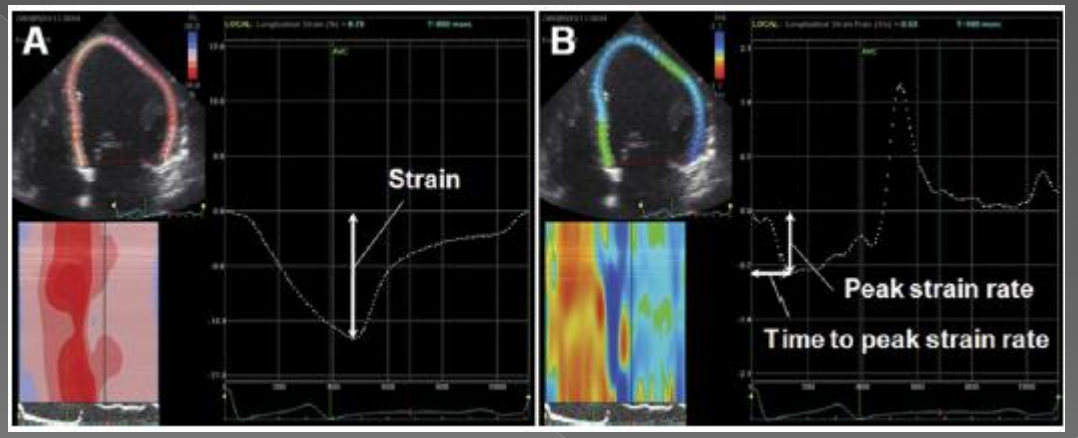
Eur J Echocardiography (2005) **6**, 435–442

Conventional ECHO parameters OR NEW

Echocardiographic Predictors of Left Ventricular Function and Clinical Outcomes After Successful Mitral Valve Repair: Conventional Two-Dimensional Versus Speckle-Tracking Parameters

Jong-Min Song, MD, PhD, Se Hun Kang, MD, Eun-Jeong Lee, RDCS, Min-Jung Shin, RDCS, Jae Won Lee, MD, PhD, Cheol Hyun Chung, MD, PhD, Dae-Hee Kim, MD, PhD, Duk-Hyun Kang, MD, PhD, and Jae-Kwan Song, MD, PhD

147 pts
Severe MR-non ischemic



In conclusion, preoperative LV remodeling parameters, such as LV end-systolic dimension and volume, are superior to speckle tracking imaging-derived deformation indices in predicting LV dysfunction and clinical events after successful MV repair in patients with severe MR.

(Ann Thorac Surg 2011;91:1816–23)

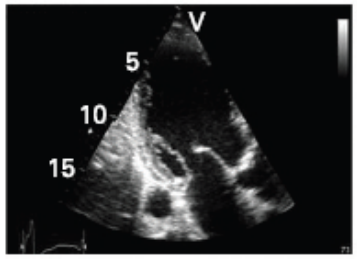
How to manage ischaemic mitral regurgitation

Patrizio Lancellotti,[1] Thomas Marwick,[2] Luc A Pierard[3]

Clinical: HF symptoms, decompensated HF, medical treatment (ACE inhibitor, β-blocker, spironolactone), comorbidities

Echo: ERO ⩾ 20 mm^2, dynamic FIMR (ΔERO > 13 mm^2 at exercise)
LV remodelling and sphericity, mitral valve deformation
viability ± ischaemia, LV dyssynchrony

Tethering force



CABG/PCI
MV repair
LV reshape
CRT ± ICD
medical only

Closing force

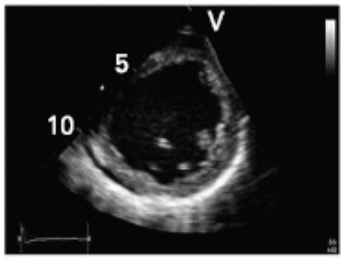


Figure 1 Global management of functional ischaemic mitral regurgitation. ACE, angiotensin converting enzyme; CABG, coronary artery bypass grafting; CRT, cardiac resynchronisation therapy; ERO, effective regurgitant orifice; FIMR, functional ischaemic mitral regurgitation; HF, heart failure; ICD, implantable cardioverter-defibrillator; LV, left ventricle; MV, mitral valve; PCI, percutaneous coronary intervention.

Heart 2008;**94**:1497–1502.

VALVULAR HEART DISEASE

How to manage ischaemic mitral regurgitation

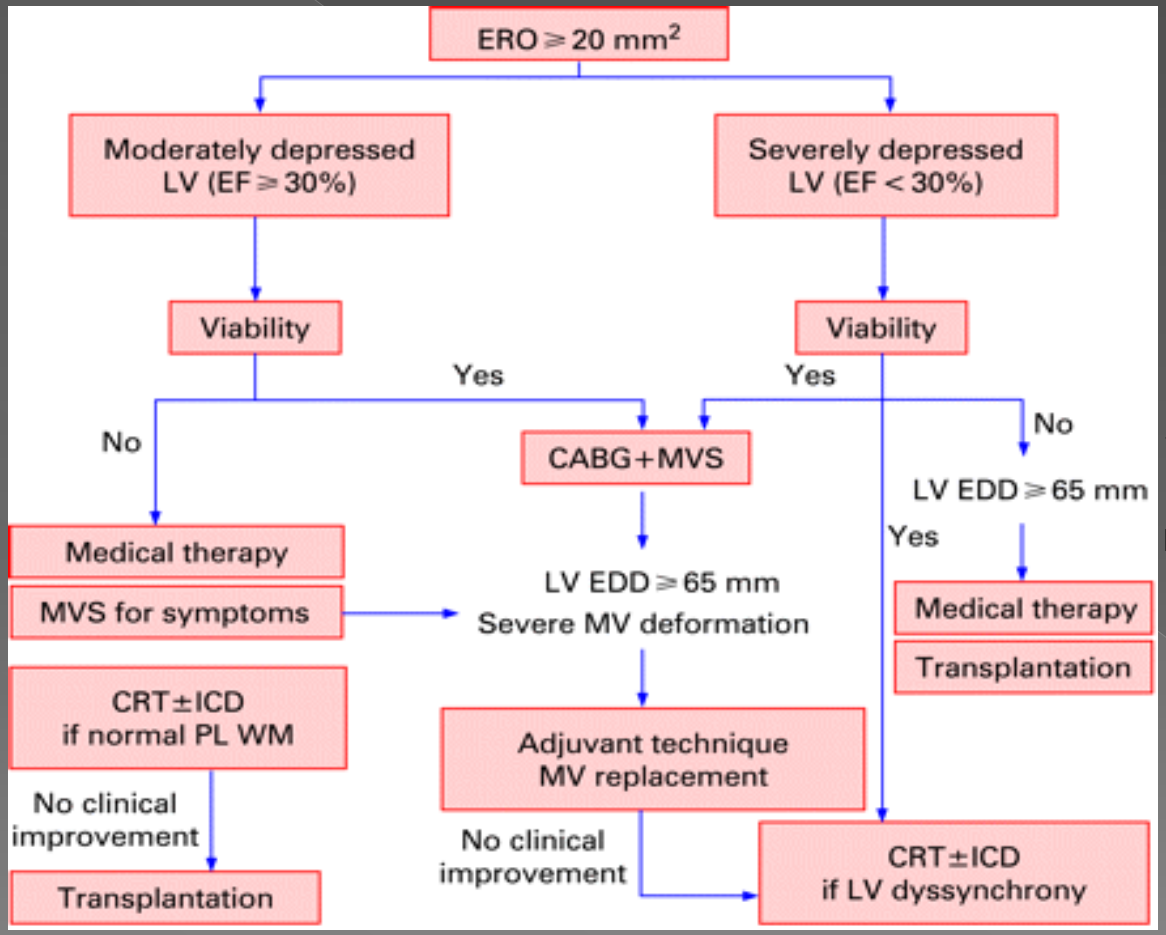
Patrizio Lancellotti,[1] Thomas Marwick,[2] Luc A Pierard[3]

Indications for surgery in ischaemic mitral regurgitation (IMR)

Clinical situation	Mitral valve surgery (ESC guidelines 2007)
Patients with severe IMR (ERO ⩾20 mm²)	
Ruptured papillary muscle due to acute MI	Immediate
LV ejection fraction ⩾30% undergoing CABG	Recommended (IC)
LV ejection fraction <30% and option for CABG	Reasonable if symptomatic (IIaC)
LV ejection fraction ⩾30%, no option for CABG	To consider if symptomatic and low morbidity (IIbC)
Patients with moderate IMR (ERO <20 mm²)	
Undergoing CABG	Reasonable if repair is feasible (IIaC)
No option for CABG or undergoing PCI	Uncertain ("a priori not")
Patients with trace IMR	
Undergoing CABG	Not recommended

Heart 2008;**94**:1497–1502.

Figure 2 Management of patients with severe functional ischaemic mitral regurgitation.



Comorbidity

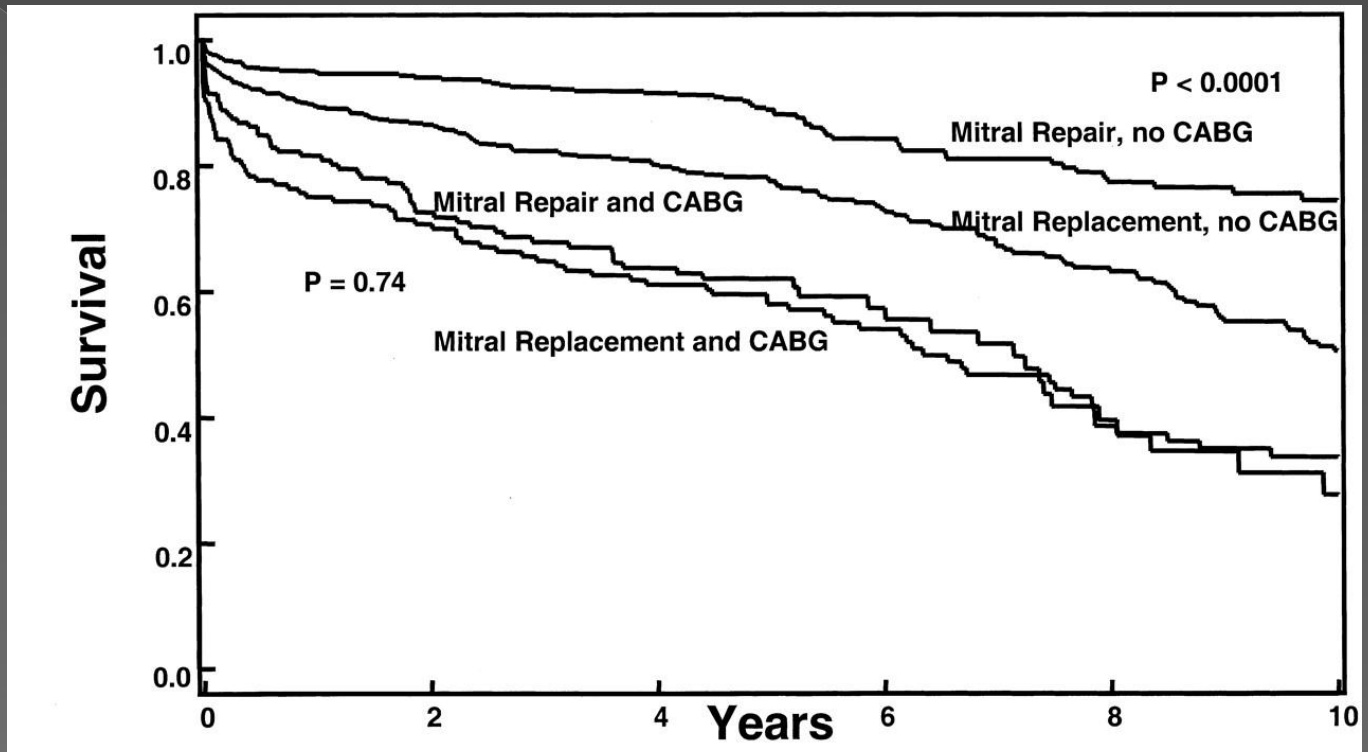
↑FIMR during exercice

LV not severely remodelled

Revascularisation almost complete

Lancellotti, P. et al. Heart 2008;94:1497-1502

Figure 3. Survival, mitral valve repair versus replacement, with and without CABG.



Repair, No CABG	1	0.95	0.94	0.92	0.91	0.89	0.84	0.81	0.77	0.76	0.74
At Risk	429	386	308	294	281	252	135	121	101	79	63
Replace, No CABG	1	0.89	0.86	0.82	0.8	0.77	0.73	0.67	0.63	0.55	0.51
At Risk	448	396	316	282	250	223	146	120	109	85	77
Repair, Yes CABG	1	0.82	0.72	0.68	0.64	0.62	0.55	0.5	0.37	0.31	0.28
At Risk	152	121	93	85	76	69	31	26	16	10	6
Replace, Yes CABG	1	0.75	0.7	0.64	0.61	0.58	0.53	0.47	0.37	0.35	0.34
At Risk	152	114	97	87	81	72	52	43	33	29	24

Thourani V H et al. Circulation 2003;108:298-304

IMPACT OF CORONARY ARTERY BYPASS SURGERY ON ISCHEMIC MITRAL REGURGITATION

J. Mustonen[1], H. Suurmunne[1], J. Kouri[2], O. Pitkänen[2], T. Hakala[1]

[1] Departments of Internal Medicine and Surgery, North Karelia Hospital, Joensuu, Finland;
[2] Departments of Surgery and Anaesthesiology, Kuopio University Hospital, Kuopio, Finland

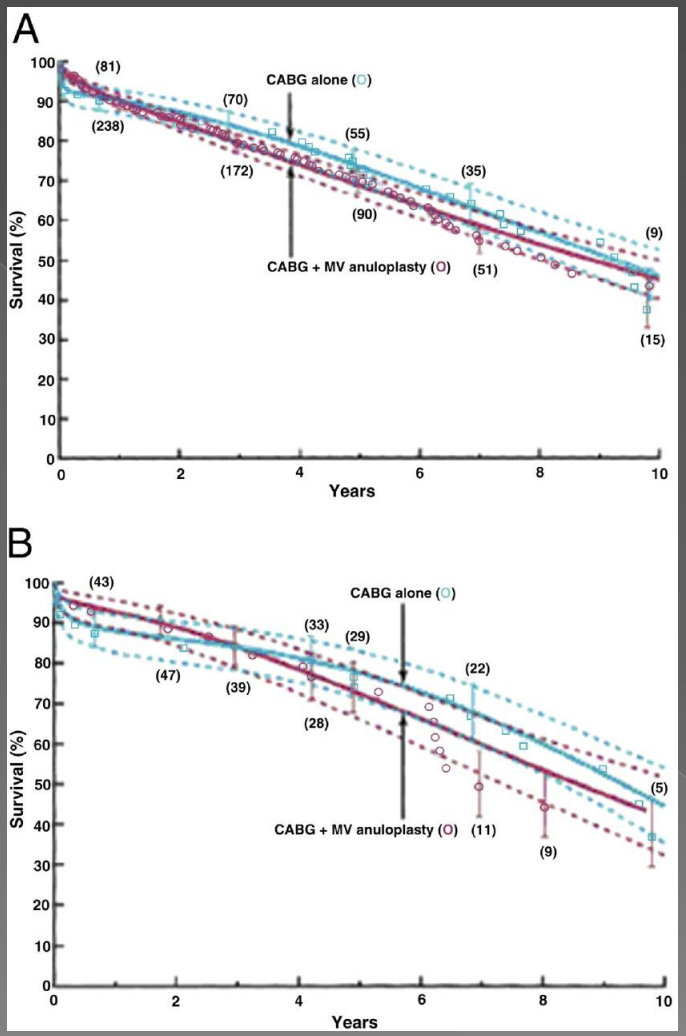
Only 4 pts with severe MR
Mainly in good LVEF

Methods: Between 1992–2005, 1995 patients underwent CABG and 170 of them had IMR. Data of 131 patients were retrospectively analyzed and living patients (n = 112) had a clinical follow-up visit. The mean follow-up time was 6.5 years.

Conclusion: Half of the patients, who have IMR at the time of CABG, have no IMR or only mild IMR postoperatively. Good LVEF adds to the probability that CABG only can reduce IMR.

Scandinavian Journal of Surgery 100: 114–119, 2011

Survival After CABG Plus MV Annuloplasty Versus CABG Alone



Di Salvo, T. G. et al. J Am Coll Cardiol 2010;55:271-282

JACC Journal of the American College of Cardiology

MR

- However, after MV repair surgery, published data show a *rate of recurrence* of grade 3 or 4 MR of 17-20% at 5 yrs

Figure 4 Echocardiographic assessment of mitral valve deformation

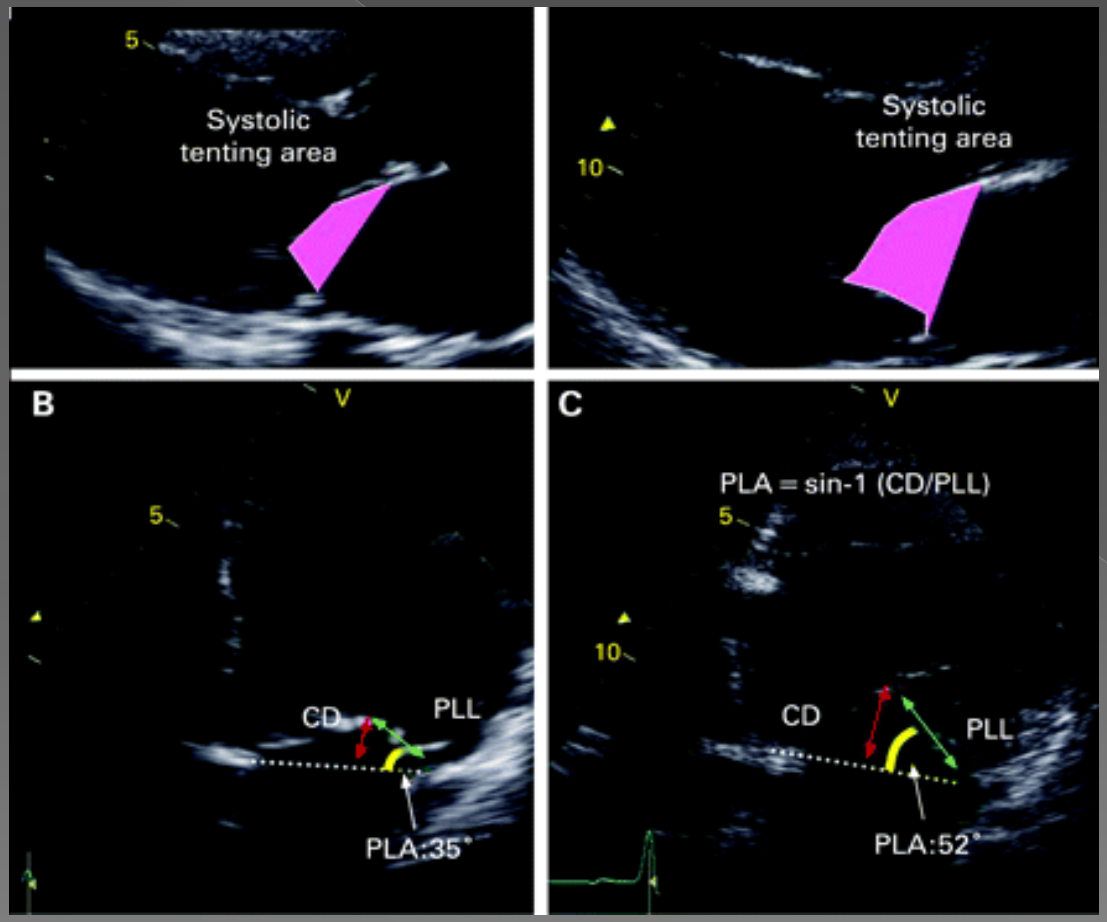


Table 3 Preoperative predictors of mitral valve repair failure (transthoracic echocardiography)

Parameters	Threshold
Coaptation distance	⩾1 cm
Systolic tenting area	>2.5–3 cm^2
Posterolateral angle	⩾45°
Lateral wall motion abnormality	Scar
Central regurgitant jet	–
Complex regurgitant jets	Multiple
Left ventricular end-diastolic diameter	⩾65 mm
Left ventricular end-systolic diameter	⩾51 mm

Lancellotti, P. et al. Heart 2008;94:1497-1502

HEART

Echocardiographically based treatment of chronic ischemic mitral regurgitation

Antonio M. Calafiore, MD,[a] Angela L. Iacò, MD,[a] Antonio Bivona, MD,[b] Egidio Varone, MD,[b] Salvo Scandura, MD,[b] Patrizia Greco, MD,[b] Antonella Romeo, MD,[b] and Michele Di Mauro, MD[c]

147 pts (137 repair)
< 10% MVR
Mechanism of MR +LV

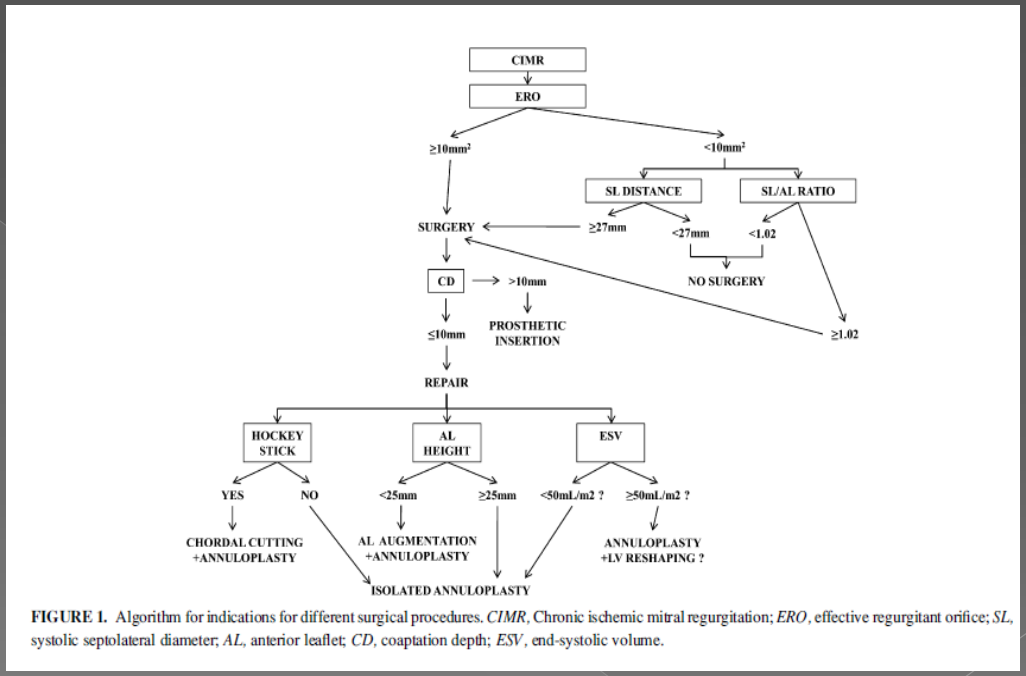


FIGURE 1. Algorithm for indications for different surgical procedures. *CIMR*, Chronic ischemic mitral regurgitation; *ERO*, effective regurgitant orifice; *SL*, systolic septolateral diameter; *AL*, anterior leaflet; *CD*, coaptation depth; *ESV*, end-systolic volume.

Conclusions: Echocardiographically based strategy contributed to reduced postoperative mitral regurgitation persistence (effective regurgitant orifice $\geq 10\ mm^2$ in 7.7% of cases, with no patients showing effective regurgitant orifice $\geq 20\ mm^2$). All patients remained in New York Heart Association functional class I or II, but more than mitral annuloplasty was performed in close to 40%. (J Thorac Cardiovasc Surg 2011;141:1150-6)

The Journal of Thoracic and Cardiovascular Surgery • May 2011

Outcomes of coronary artery bypass grafting and reduction annuloplasty for functional ischemic mitral regurgitation: A prospective multicenter study (Randomized Evaluation of a Surgical Treatment for Off-Pump Repair of the Mitral Valve)

Eugene A. Grossi, MD,[a] Y. Joseph Woo, MD,[b] Nirav Patel, MD,[c] Judith D. Goldberg, ScD,[a] Charles F. Schwartz, MD,[a] Valavanur A. Subramanian, MD,[c] Christopher Genco, MD,[d] Scott M. Goldman, MD,[e] Marco A. Zenati, MD,[f] J. Alan Wolfe, MD,[g] Yugal K. Mishra, MD,[h] and Naresh Trehan, MD[i]

75 pts
Moderate-severe MR
EF> 25%
LVEDD<7.0 cm

APPENDIX 3. Details of patients with recurrent mitral insufficiency (n = 12)

Mean ejection fraction	37.4%
Mean LVEDD (cm)	6.1 cm
Soft annuloplasty device used	1 (8.3%)
Annuloplasty device > 28 mm	7 (58.3%)

LVEDD, Left ventricular end-diastolic diameter.

Conclusions: Coronary artery bypass grafting + reduction annuloplasty for functional ischemic mitral regurgitation predictably reduces mitral regurgitation and relieves symptoms. This treatment of moderate to severe mitral regurgitation is associated with improved indices of ventricular function, improved New York Heart Association class, and excellent freedom from recurrent mitral insufficiency. Although long-term prognosis remains guarded, this multicenter study delineates the intermediate-term benefits of such an approach. (J Thorac Cardiovasc Surg 2011;141:91-7)

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Mitral Valve Surgery in Advanced Heart Failure

Thomas G. Di Salvo, MD, MPH, MBA,* Michael A. Acker, MD,† G. William Dec, MD,‡ John G. Byrne, MD*

Nashville, Tennessee; Philadelphia, Pennsylvania; and Boston, Massachusetts

Table 3 Abbreviated Criteria for Selection of Appropriate Operative Candidates

Favorable surgical considerations
Coronary artery disease and concurrent revascularization
Ventricular reconstruction (e.g., Dor)
Reversible pulmonary hypertension
No prior operations
Favorable medical considerations
NSR (or likelihood of restoration)
"Tolerance" of reasonable doses of vasodilators and beta-blockers
Preservation of renal function
Absence of hyponatremia
Absence of refractory right heart failure
Absence of cachexia
Favorable LV reverse remodeling viability
Absence of severe ventricular dilation (LVEDD >80 mm)
Lower sphericity index
Preservation of LV torsion
Presence of contractile reserve
Beneficial response to cardiac resynchronization

JACC Vol. 55, No. 4, 2010
January 26, 2010:271–82

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Table 5 Current and Evolving Options for Mitral Valve Surgery in Advanced Heart Failure

1. Mitral repair
   - Annulus (annuloplasty)
     - Ring (rigid, flexible; undersized)
     - Asymmetrical
     - Percutaneous techniques
   - Leaflets
     - Edge-to-edge leaflet (Alfieri)
     - Leaflet lengthening
   - Chordae
     - Basal chordae resection
   - Papillary muscle
     - Scar excision with papillary muscle "reimplantation"
     - Internal slings
     - Surgical "buckles"
     - External bands
     - Mesh patches
   - Ventricular "reshaping" (with annuloplasty)
     - Infarct plication
     - Infarct excision and patching (e.g., Dor)
     - Localized infarct patch with epicardial balloon
     - External restraint (e.g., Acorn CorCap)
2. Mitral replacement with chordal sparing

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Table 4 Suggested Approach to the Management of Severe MR in Advanced Heart Failure

1. Optimize medical therapy
Angiotensin-converting enzyme inhibitor/angiotensin receptor-blocker, beta-blockers, aldosterone antagonists, flexible sliding-scale diuretic program, hydralazine-isosorbide dinitrate
Define adequacy of medical therapy by cardiac catheterization in selected instances
Ensure compliance with medical therapy and lifestyle accommodations
2. Evaluate for revascularization in patients with coronary artery disease
3. Provide CRT
Indications: LV ejection fraction <35%, QRS interval >120 ms, New York Heart Association functional class III to IV
Reassess clinical response and MR severity
4. Reconfirm the severity of MR
"Definitive" imaging modality after optimizing medical therapy, revascularization, and CRT with cardiac magnetic resonance imaging or echocardiography
5. For patients who remain intolerably symptomatic, define perioperative risk and surgical options
Ideally, perioperative risk should be ≤2% on the basis of composite medical and surgical factors
Ideal candidates will have heart failure duration <5 years, resting heart rate <100 beats/min, systolic blood pressure >80 mm Hg with normal proportional pulse pressure, serum sodium >135 mmol/dl, blood urea nitrogen >100 mg/dl, creatinine >2.5 mg/dl, normal total bilirubin, LV end-diastolic diameter <80 mm, peak VO_2 >14 $mg \cdot kg^{-1} \cdot min^{-1}$, 6-min walk test >350 m, no cachexia, no prior cardiac surgery, reversible pulmonary hypertension, no refractory right heart failure
6. Estimate LV reverse remodeling viability on the basis of aggregate clinical data
7. Discuss mitral valve surgery frankly with the patient and family
Issues to discuss: 1) perioperative risk; 2) durability of planned correction; and 3) clinical outcomes on the basis of available data: functional capacity, long-term LV remodeling and function, and mortality.

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January 26, 2010:271–82

Mitral regurgitation surgery in patients with ischemic cardiomyopathy and ischemic mitral regurgitation: Factors that influence survival

Simon Maltais, MD, PhD,[a] Hartzell V. Schaff, MD,[a] Richard C. Daly, MD,[a] Rakesh M. Suri, MD, PhD,[a] Joseph A. Dearani, MD,[a] Thoralf M. Sundt III, MD,[a] Maurice Enriquez-Sarano, MD,[b] Yan Topilsky, MD,[b] and Soon J. Park, MD, MSc[a]

Retrospective analysis 431 pts
78% MVr *vs* 22% MVR
LVEF <45%

Predictors of Early (1-Year) and Late (Constant) Mortality

	Early (1-y) hazard	Late (constant hazard)
Risk factors	HR (*P* value)	HR (*P* value)
Previous CABG surgery	3.39 (<.001)	
Emergency/urgent status	2.08 (.007)	
LVEF (per 10% decrease)	1.31 (.02)	
Age	1.50 (.026)	1.58 (<.001)
Renal insufficiency		1.72 (.025)
Diabetes		2.50 (<.001)

Conclusions: Survival after combined coronary artery bypass grafting and mitral valve surgery in patients with ischemic cardiomyopathy (left ventricular ejection fraction $\leq 45\%$) and mitral regurgitation is compromised and mostly influenced by factors related to the patient's condition at the time of surgery. The specifics of mitral valve repair versus replacement did not seem to affect survival. (J Thorac Cardiovasc Surg 2011;142:995-1001)

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New Horizons:

MitraClip: a novel percutaneous approach to mitral valve repair

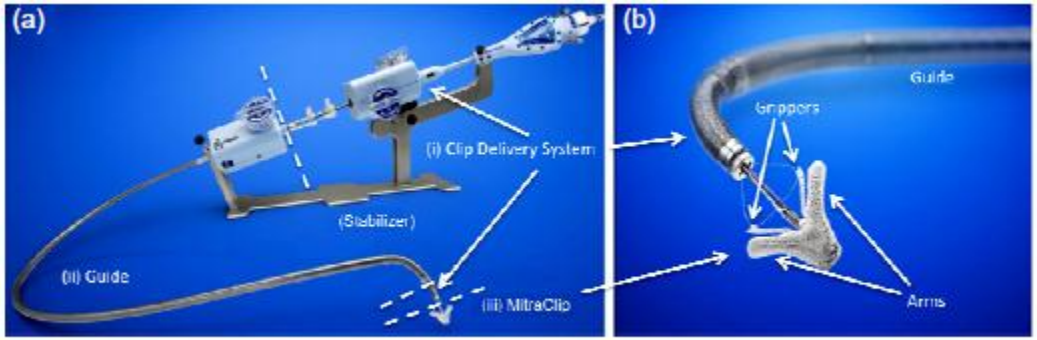

Fig. 1 Evalve MitraClip system (a) and MitraClip device (b)

Jilaihawi et al. / J Zhejiang Univ-Sci B (Biomed & Biotechnol) 2011 12(8):633-637

The NEW ENGLAND JOURNAL of MEDICINE

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Percutaneous Repair or Surgery for Mitral Regurgitation

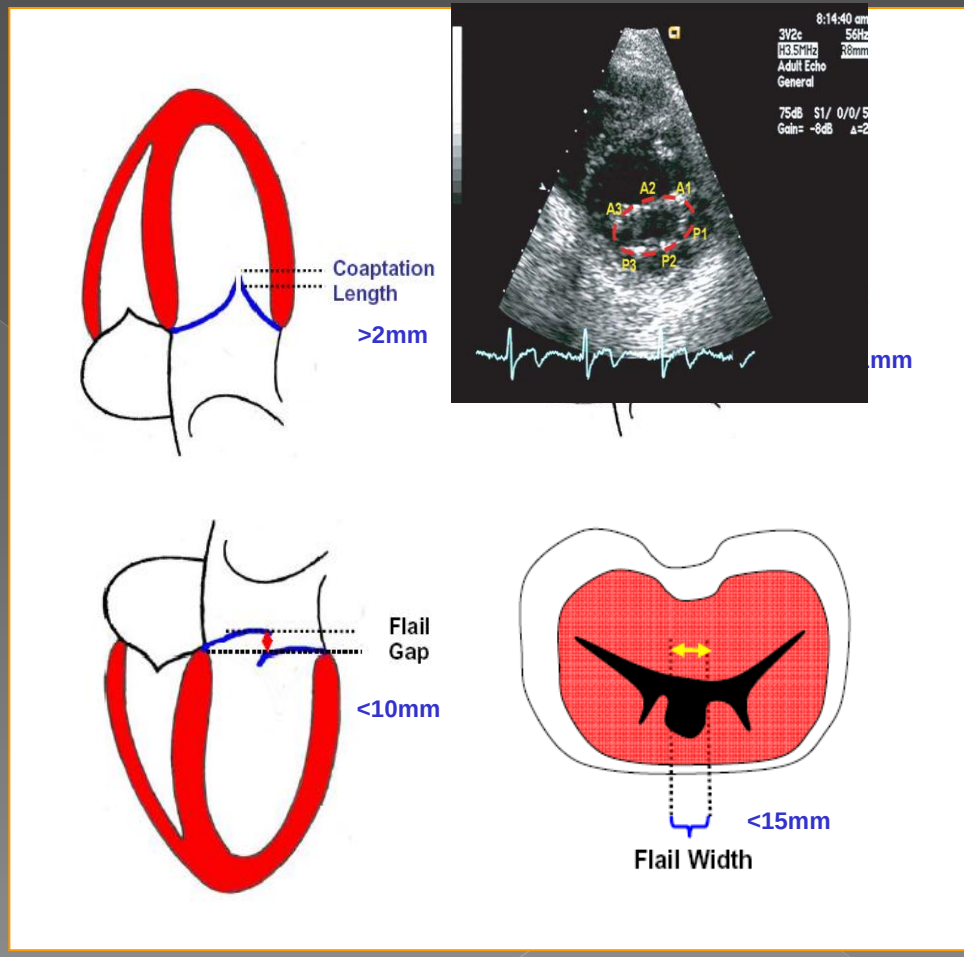
Ted Feldman, M.D., Elyse Foster, M.D., Donald D. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge, M.D., George V. Letsou, M.D., Joseph M. Massaro, Ph.D., and Laura Mauri, M.D., for the EVEREST II Investigators*

CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)

Anatomic Suitability
Leaflet mal-coaptation resulting in MR

- Sufficient leaflet tissue for mechanical coaptation
- Non-rheumatic/endocarditic valve morphology
- Anatomic considerations
  - Flail gap <10mm
  - Flail width <15mm
  - Mitral Area ≥ 4.0cm²
  - Coaptation length > 2mm



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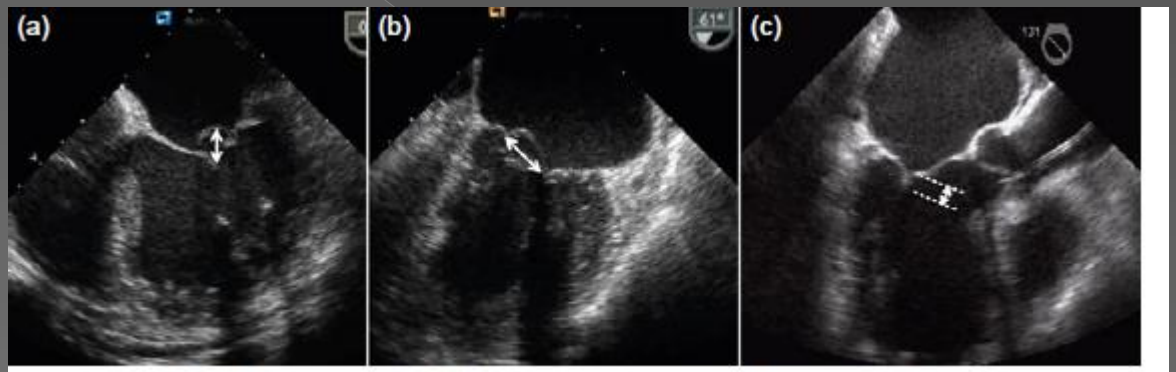
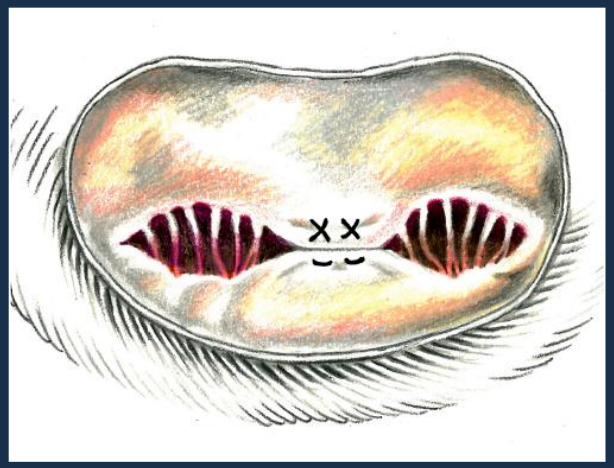


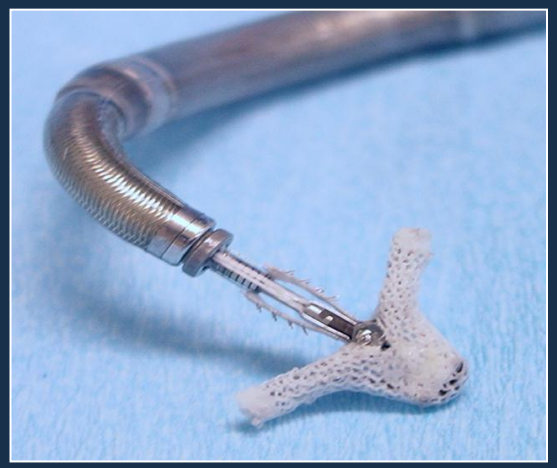
Fig. 2 Anatomical inclusion criteria for the MitraClip device

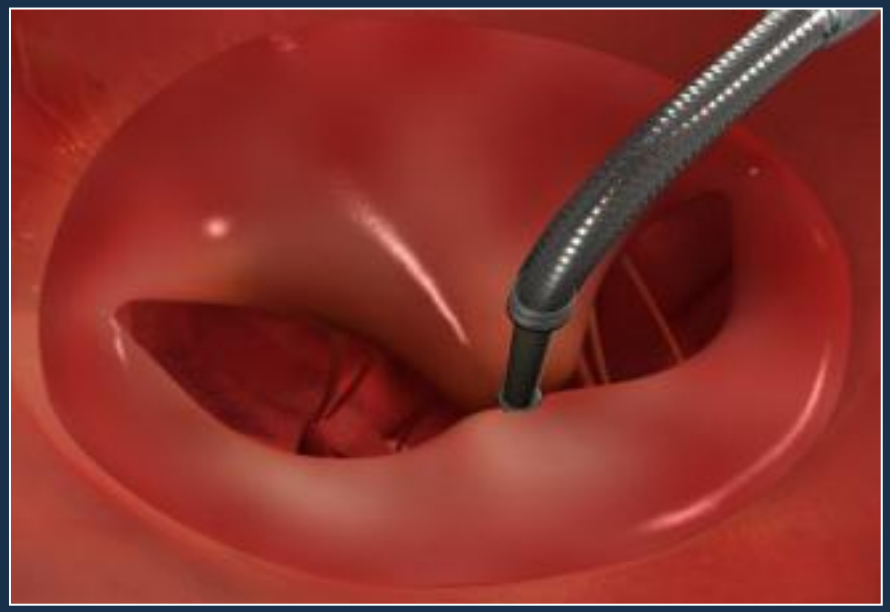
Jilaihawi et al. / J Zhejiang Univ-Sci B (Biomed & Biotechnol) 2011 12(8):633-637

Catheter-Based Mitral Valve Repair

MitraClip® System







Evanston Hospital NorthShore University HealthSystem

Investigational Device only in the US; Not available for sale in the US

Clinical Experience

Study	Population	n
EVEREST I (Feasibility)*	Non-randomized	55
EVEREST II*	Pre-randomization	60
EVEREST II	High Risk Registry	78
EVEREST II (Pivotal)	Randomized patients (2:1 MitraClip to Surgery)	279 184 MitraClip 95 Surgery
REALISM (Continued Access)	High Risk & Non High Risk	266
European Experience		472
	Total	1,115 MitraClip

*Percutaneous Mitral Valve Repair Using the Edge-to-Edge Repair: Six months Results of the EVEREST Phase I Clinical trial, JACC 2005;46:2134-2140. Percutaneous Mitral Repair with the MitraClip System: Safety and Midterm Durability in the Initial EVEREST Cohort, JACC 2009; 54:686-694.

Evanston Hospital NorthShore University HealthSystem

Data as of 2/15/2010.

EVEREST II Randomized Clinical Trial

Study Design

279 Patients enrolled at 37 sites

Significant MR (3+-4+)
Specific Anatomical Criteria

↓

Randomized 2:1

Device Group
MitraClip System
N=184

Control Group
Surgical Repair or Replacement
N=95

Echocardiography Core Lab and Clinical Follow-Up:
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years

Evanston Hospital NorthShore University HealthSystem

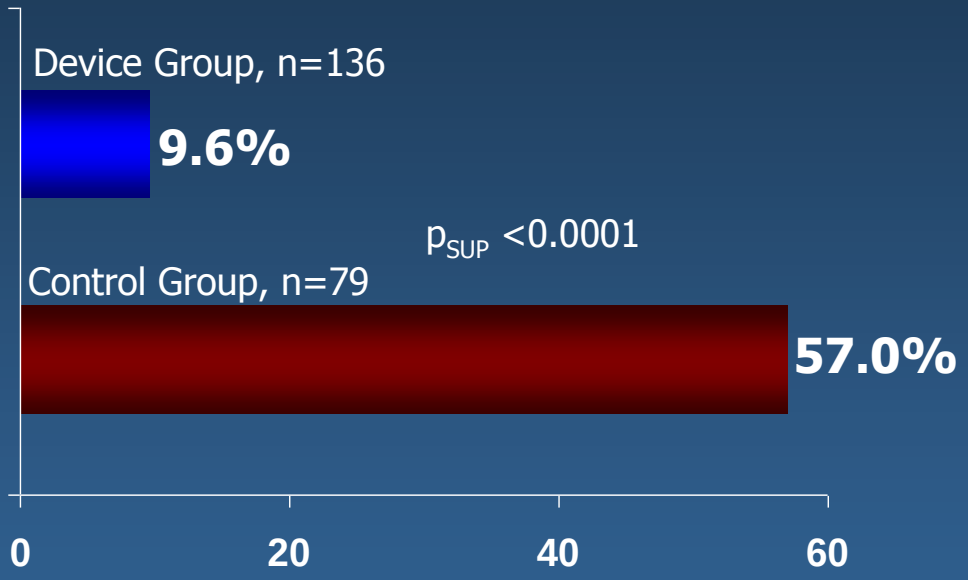
EVEREST II RCT: Primary Endpoints

Per Protocol Cohort

Safety

Major Adverse Events

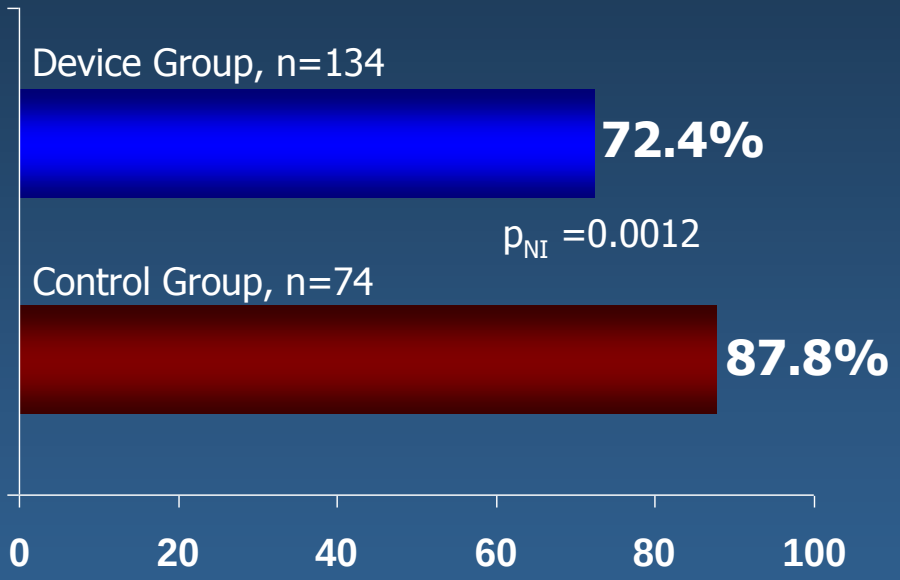
30 days



Effectiveness

Clinical Success Rate*

12 months



Met superiority hypothesis

- Pre-specified margin = 6%
- Observed difference = **47.4%**
- 97.5% LCB = 34.4%

Met non-inferiority hypothesis

- Pre-specified margin = 31%
- Observed difference = **15.4%**
- 95% UCB = 25.4%

LCB = lower confidence bound
UCB = upper confidence bound

* Freedom from the combined outcome of death, MV surgery or re-operation for MV dysfunction, MR >2+ at 12 months

Evanston Hospital NorthShore University HealthSystem

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EVEREST II RCT: Summary

- Safety & effectiveness endpoints met
  - Safety: MAE rate at 30 days
    - MitraClip device patients: 9.6%
    - MV surgery patients: 57%
  - Effectiveness: Clinical Success Rate at 12 months
    - MitraClip device patients: 72%
    - MV Surgery patients: 88%
- Clinical benefit demonstrated for MitraClip System and MV surgery patients through 12 months
    - Improved LV function
    - Improved NYHA Functional Class
    - Improved Quality of Life
- Surgery remains an option after the MitraClip procedure

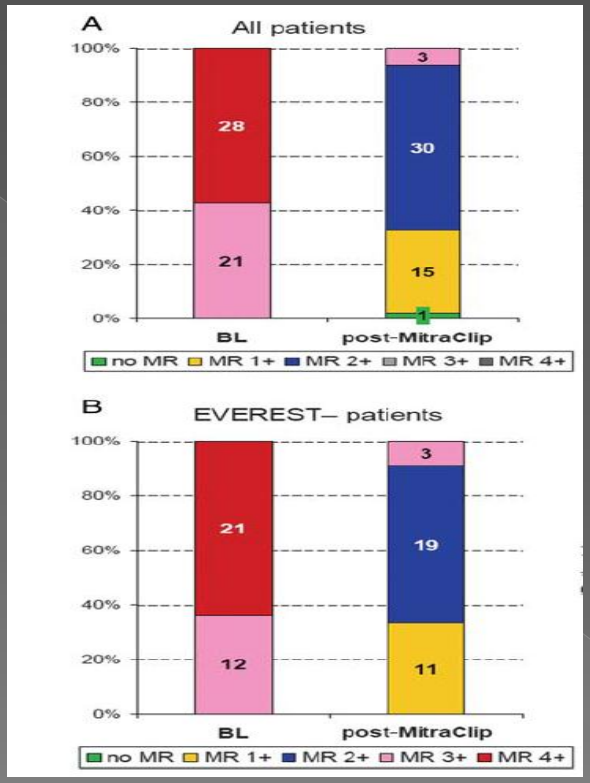
EVEREST II RCT: Conclusion

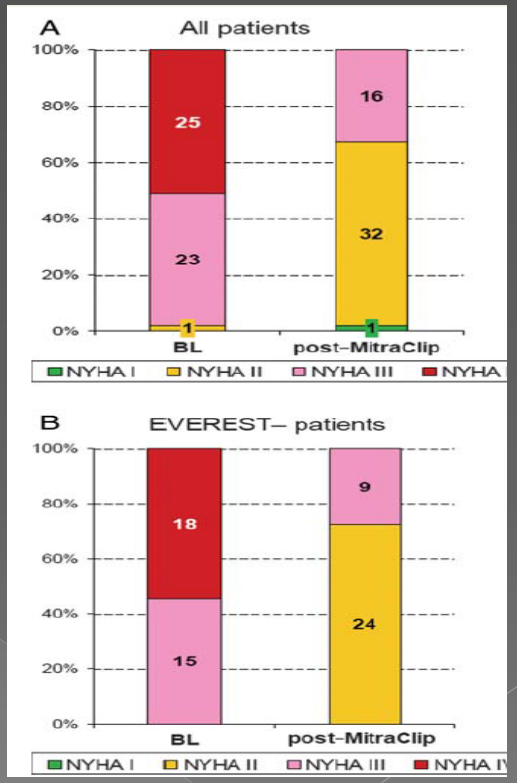
The MitraClip procedure is an important therapeutic option for selected patients with significant mitral regurgitation given the demonstrated safety, effectiveness and clinical benefit.

Acute outcomes of MitraClip therapy for mitral regurgitation in high-surgical-risk patients: emphasis on adverse valve morphology and severe left ventricular dysfunction

Olaf Franzen[1*], Stephan Baldus[1], Volker Rudolph[1], Sven Meyer[1], Malgorzata Knap[1], Dietmar Koschyk[1], Hendrik Treede[2], Achim Barmeyer[1], Joachim Schofer[3], Angelika Costard-Jäckle[1], Michael Schlüter[1], Hermann Reichenspurner[2], and Thomas Meinertz[1]

51 pts-high risk
LVEF <35%
73 yrs
At discharge 2/3 pts NYHA II or less

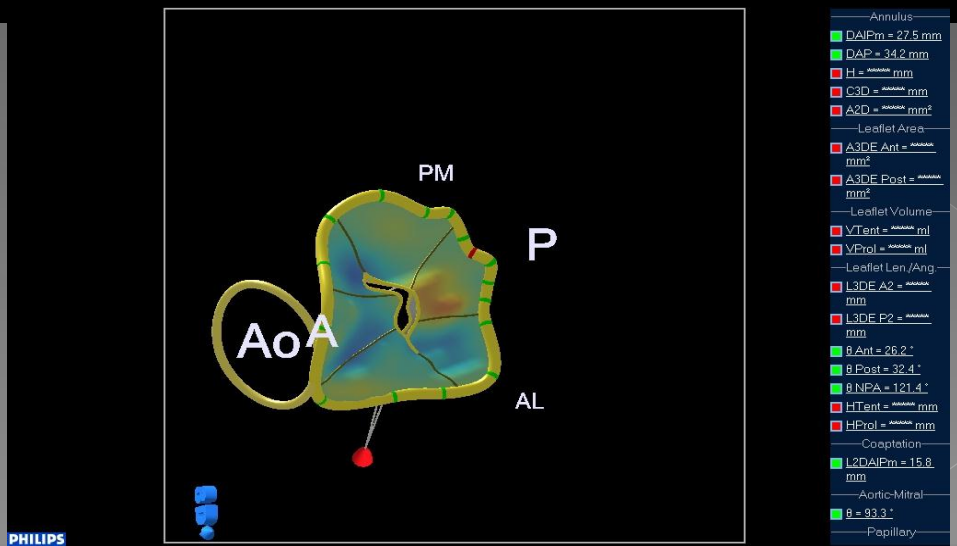




Conclusion Mitral valve repair using the MitraClip system was shown to be feasible in patients at high surgical risk primarily determined by an adverse mitral valve morphology and/or severe LV dysfunction.

European Heart Journal (2010) **31**, 1373–1381
doi:10.1093/eurheartj/ehq050


PHILIPS
TIS0.5 MI 0.7
X7-2t/Adult
FR 11Hz
9.3cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0 55 180
AoV
P2 prolapse
JPEG
PAT T: 37.0C
TEE T: 40.5C
57 bpm


PHILIPS
PM
P
AoA
AL
Annulus
DAIPm = 27.5 mm
DAP = 34.2 mm
H = ***** mm
C3D = ***** mm
A2D = ***** mm²
Leaflet Area
A3DE Ant = ***** mm²
A3DE Post = ***** mm²
Leaflet Volume
VTent = ***** ml
VProl = ***** ml
Leaflet Len./Ang.
L3DE A2 = ***** mm
L3DE P2 = ***** mm
θ Ant = 26.2 °
θ Post = 32.4 °
θ NPA = 121.4 °
HTent = ***** mm
HProl = ***** mm
Coaptation
L2DAIPm = 15.8 mm
Aortic-Mitral
θ = 93.3 °
Papillary

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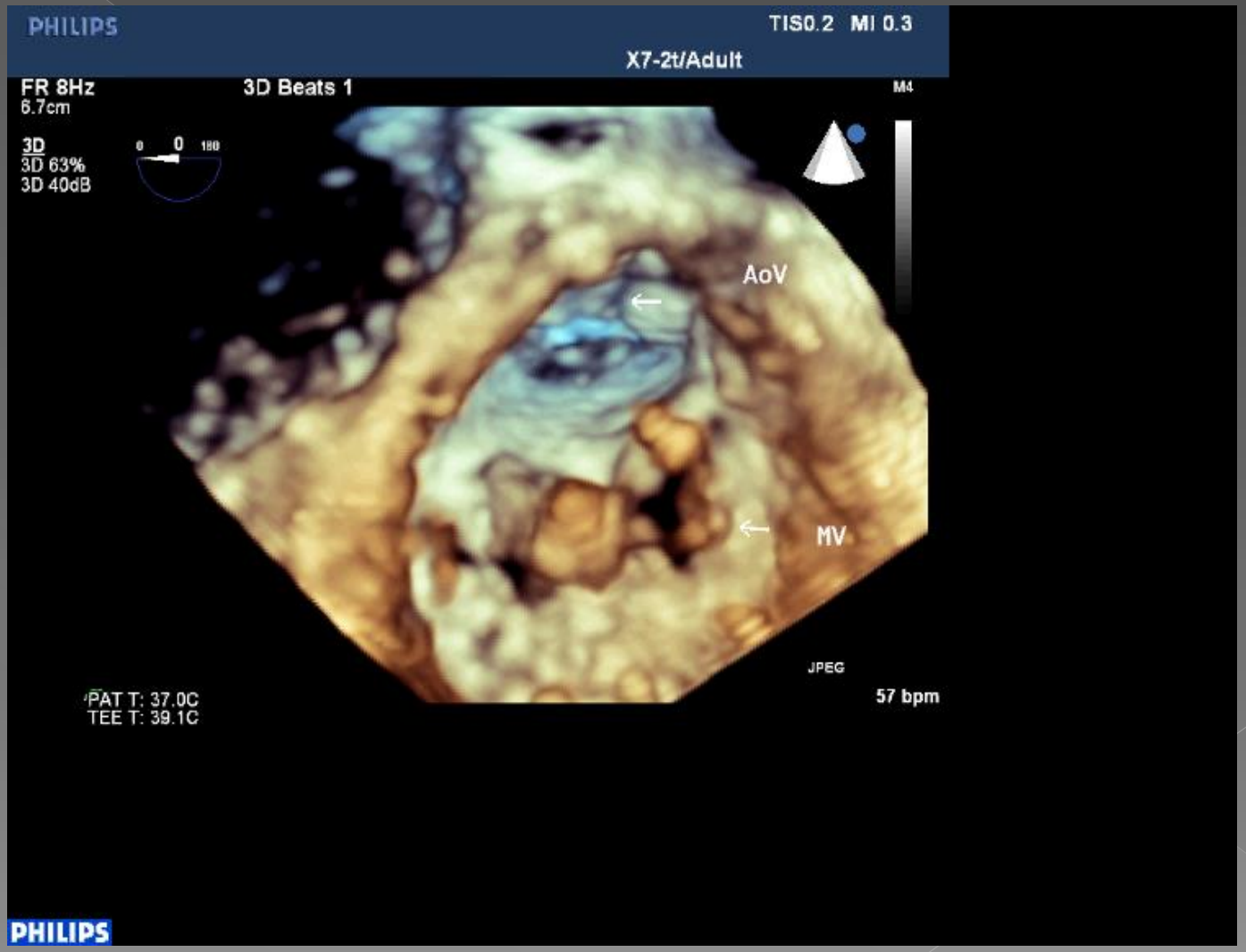

Ευχαριστω