

# **Management of Patients with Mitral Regurgitation**

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# Disclosures

- Relationship with companies who manufacture products used in the treatment of the subjects under discussion

Relationship

Manufacturer(s)

Speaker's Honoraria

Edwards Lifesciences

Consultant (Advisory Board)

Abbott , Medtronic  
Saint Jude Medical ,Valtech

# Guidelines on the management of valvular heart disease (version 2012)

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

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# The « Heart Team »

Surgeons

Cardiologists

Anaesthesiologists

Treatment of Mitral Valve  
Disease

Other specialists:  
HF, EP,  
Geriatricians,...

Imaging specialists (Echo, CT, MRI)

# Patient Evaluation

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

[www.escardio.org/guidelines](http://www.escardio.org/guidelines)



# Essential questions in the evaluation of a patient for valvular intervention

- Is valvular heart disease severe?
- Does the patient have symptoms?
- Are symptoms related to valvular disease?
- What are patient life expectancy and expected quality of life?
- Do the expected benefits of intervention (versus spontaneous outcome) outweigh its risks?
- What are the patient's wishes?
- Are local resources optimal for planned intervention?

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).



# Echocardiographic criteria for the definition of severe valve regurgitation: *an integrative approach*

	Aortic regurgitation	Mitral regurgitation	Tricuspid regurgitation
<i>Qualitative</i>			
<b>Valve morphology</b>	Abnormal/flail/large coaptation defect	<b>Flail leaflet/ruptured papillary muscle/large coaptation defect</b>	Abnormal/flail/large coaptation defect
<b>Colour flow regurgitant jet</b>	Large in central jets, variable in eccentric jets	Very large central jet or eccentric jet adhering, swirling, and reaching the posterior wall of the left atrium	Very large central jet or eccentric wall impinging jet
<b>CW signal of regurgitant jet</b>	Dense	Dense/triangular	Dense/triangular with early peaking (peak vel < 2 m/s in massive TR)
<b>Other</b>	Holodiastolic flow reversal in descending aorta (EDV > 20 cm/s)	Large flow convergence zone	—

Adapted from Lancellotti, EAE Recommendations. *Eur J Echocardiogr.* 2010;11:223-244 and 307-332

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).



# Echocardiographic criteria for the definition of severe valve regurgitation: *an integrative approach*

	Aortic regurgitation	Mitral regurgitation		Tricuspid regurgitation
<b>Semiquantitative</b>				
Vena contracta width (mm)	> 6	≥ 7 (> 8 for biplane)		≥ 7
Upstream vein flow	–	<b>Systolic pulmonary vein flow reversal</b>		Systolic hepatic vein flow reversal
Inflow	–	<b>E-wave dominant ≥ 1.5 m/s</b>		E-wave dominant ≥ 1 m/s
Other	Pressure half-time < 200 ms	TVI mitral/TVI aortic > 1.4		PISA radius > 9 mm
<b>Quantitative</b>		<b>Primary</b>	<b>Secondary</b>	
EROA (mm <sup>2</sup> )	≥ 30	≥ 40	≥ 20	≥ 40
R Vol (ml/beat)	≥ 60	≥ 60	≥ 30	≥ 45
+ enlargement of cardiac chambers/ vessels	LV	LV, LA		RV, RA, inferior vena cava

Adapted from Lancellotti, EAE recommendations. *Eur J Echocardiogr*. 2010;11:228-244 and 307-332

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

# « Anatomy, Mechanisms, Function »

## « Pathophysiology Triad »

*Etiology* - cause of the disease

*Lesions*- results from the disease

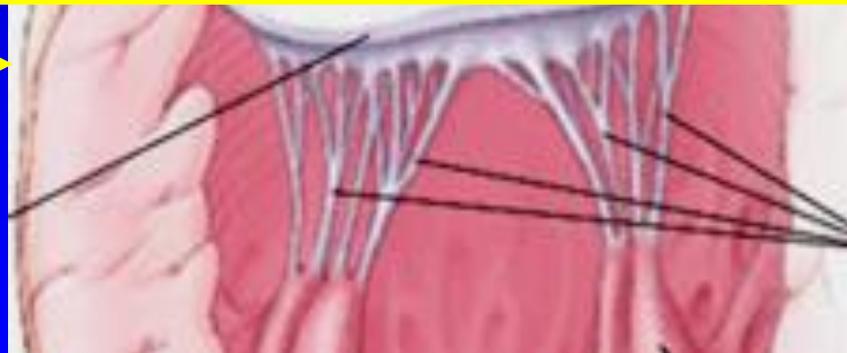
*Dysfunction*- results from the lesions

A. Carpentier

Ann

ssures

Leaflets →



Subvalvular apparatus

←  
Papillary  
muscles

Complex interaction

# Prediction of Repair

**Table 1** Probability of successful mitral valve repair in organic mitral regurgitation based on echo findings

Aetiology	Dysfunction	Calcification	Mitral annulus dilatation	Probability of repair
Degenerative	II: Localized prolapse (P2 and/or A2)	No/Localized	Mild/Moderate	Feasible
Ischaemic/Functional	I or IIIb	No	Moderate	Feasible
Barlow	II: Extensive prolapse ( $\geq 3$ scallops, posterior commissure)	Localized (annulus)	Moderate	Difficult
Rheumatic	IIIa but pliable anterior leaflet	Localized	Moderate	Difficult
Severe Barlow	II: Extensive prolapse ( $\geq 3$ scallops, anterior commissure)	Extensive (annulus + leaflets)	Severe	Unlikely
Endocarditis	II: Prolapse but destructive lesions	No	No/Mild	Unlikely
Rheumatic	IIIa but stiff anterior leaflet	Extensive (annulus + leaflets)	Moderate/Severe	Unlikely
Ischaemic/Functional	IIIb but severe valvular deformation	No	No or Severe	Unlikely

*(Lancellotti P. Eur J Echocardiogr 2010;11:307-332)*

# Treatment

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

[www.escardio.org/guidelines](http://www.escardio.org/guidelines)



# Medical Therapy

- Anticoagulation (INR 2-3) if paroxysmal or permanent AF
- Diuretics and vasodilators in acute MR
- Vasodilators only if heart failure in chronic MR

# Surgery in Mitral Regurgitation

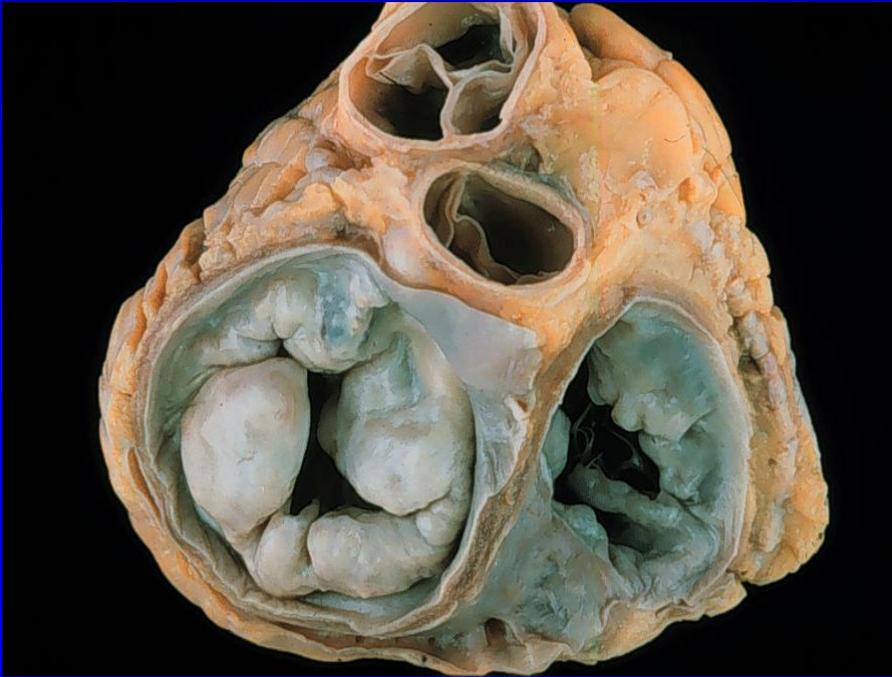
- In expert centres, in patients with primary MR, the repair rate is >90% and >90% of patients are alive and free from reoperation after 10-15 years.
- Surgery for secondary MR remains a challenge. Most studies failed to demonstrate improved long-term clinical outcome following surgical correction.

# Rationale for Percutaneous Valve Intervention in MR

- MR is frequent and carries a poor prognosis
- Patients are often elderly with several comorbidities
- Surgery may be high risk or even contraindicated
- In practice, many patients are denied surgery

# Primary MR

Barlow's Disease



Fibroelastic Deficiency





## ***Carpentier's principles of a reconstructive valve operation:***

- **Preserve or restore full leaflet motion**
- **Create a large surface of coaptation**
- **Remodel and stabilise the entire annulus**



# Operative mortality after surgery for MR

	<b>EACTS</b>	<b>STS</b>	<b>UK</b>	<b>Germany</b>
	<b>(2010)</b>	<b>(2010)</b>	<b>(2004-2008)</b>	<b>(2009)</b>
Mitral valve repair, no CABG (%)	2.1 (3231)	1.6 (7293)	2 (3283)	2 (3335)
Mitral valve replacement, no CABG (%)	4.3 (6838)	6.0 (5448)	6.1 (3614)	7.8 (1855)
Mitral valve repair/replacement +CABG (%)	6.8/11.4 (2515/1612)	4.6/11.1 (4721/2427)	8.3/11.1 (2021/1337)	6.5/14.5 (1785/837)

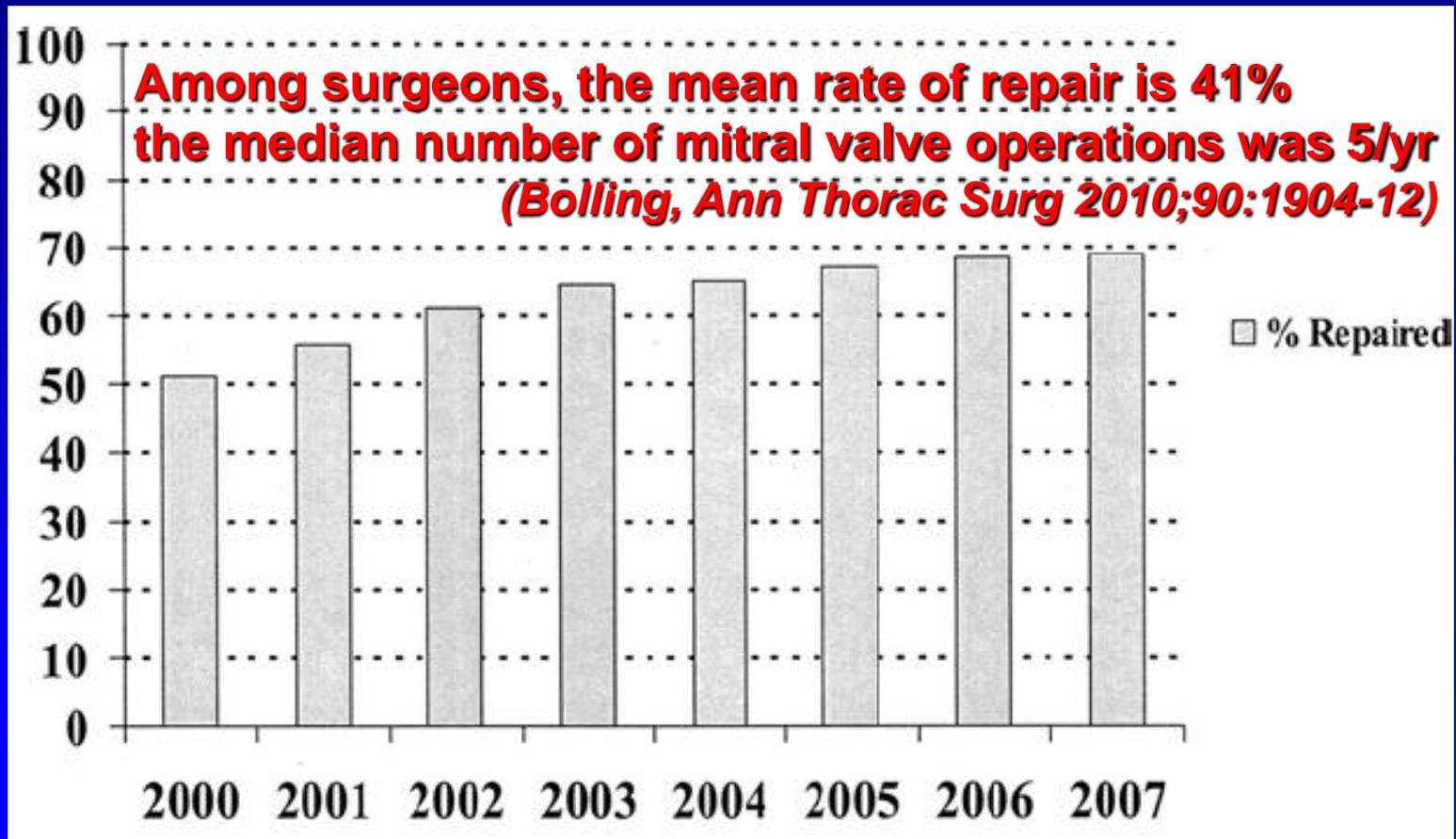
( ) = number of patients.

CABG = coronary artery bypass grafting; EACTS = European Association for Cardiothoracic Surgery (32); STS = Society of Thoracic Surgeons (USA). Mortality for STS includes first and redo interventions (33); UK=United Kingdom (34); Germany (35).



# Trends in Mitral Valve Surgery

910 US Hospitals - 47,126 pts with MR – STS database



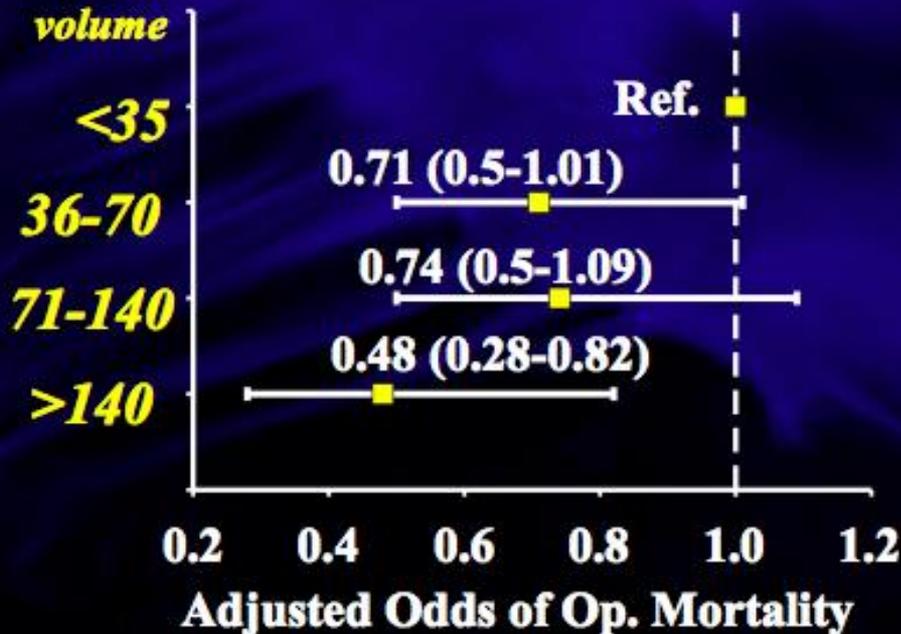
*(Gammie JS et al. Ann Thorac Surg 2009;87:1431-9)*



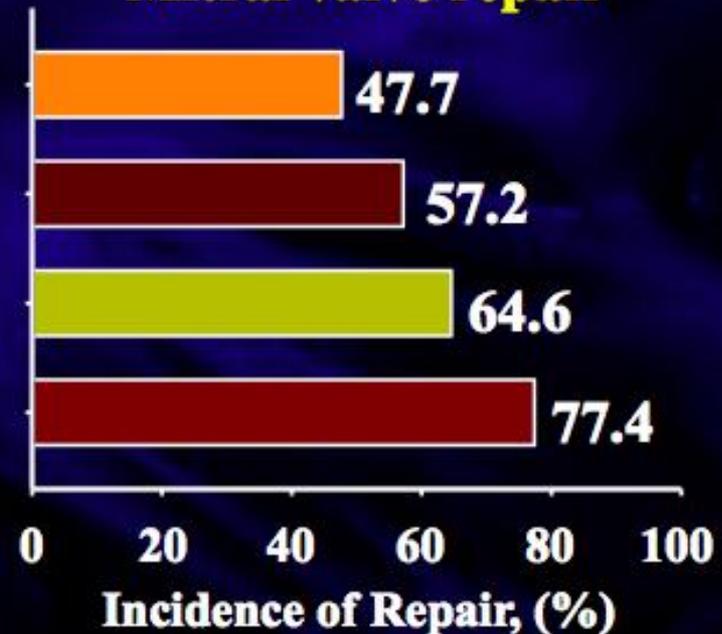
# Volume rates and in Mitral Valve Repair

Hospital procedural volume influences both surgical mortality and the likelihood of repair vs. replacement

Annual hosp.  
volume



Mitral valve repair



STS Database: *Gammie et al., Circ, 2007; Gammie et al., ATS, 2005.*



# **‘Mitral Repair: We Must Do Better’**

- Most surgeons do not routinely repair mitral valves
- Non repair surgeons do not routinely cross refer
- Patients with predictable complex repair should undergo surgery in experienced repair centres with high repair rates and low operative mortality
- Cardiologists should be conscious of the lack of consistency in surgical repair in complex mitral valve morphology: rheumatic lesions, extensive valve prolapse, MR with leaflet calcification or extensive annulus calcification

***Dedicated “MR teams” appear able to change practice***

# Indications for surgery in symptomatic severe primary MR

	Class	Level
<i>Mitral valve repair should be the preferred technique when it is expected to be durable.</i>	I	C
Surgery is indicated in symptomatic patients with LVEF > 30% and LVESD < 55 mm.	I	B
Surgery should be considered in patients with severe LV dysfunction (LVEF < 30% and/or LVESD > 55 mm) refractory to medical therapy with high likelihood of durable repair and low comorbidity.	IIa	C
Surgery may be considered in patients with severe LV dysfunction (LVEF < 30% and/or LVESD > 55 mm) refractory to medical therapy with low likelihood of durable repair and low comorbidity.	IIb	C

« Early surgery is recommended for mitral regurgitation »

*(M Enriquez-Sarano. Circulation 2010;121;804-812)*

« The case for watchful waiting in asymptomatic severe degenerative mitral regurgitation »

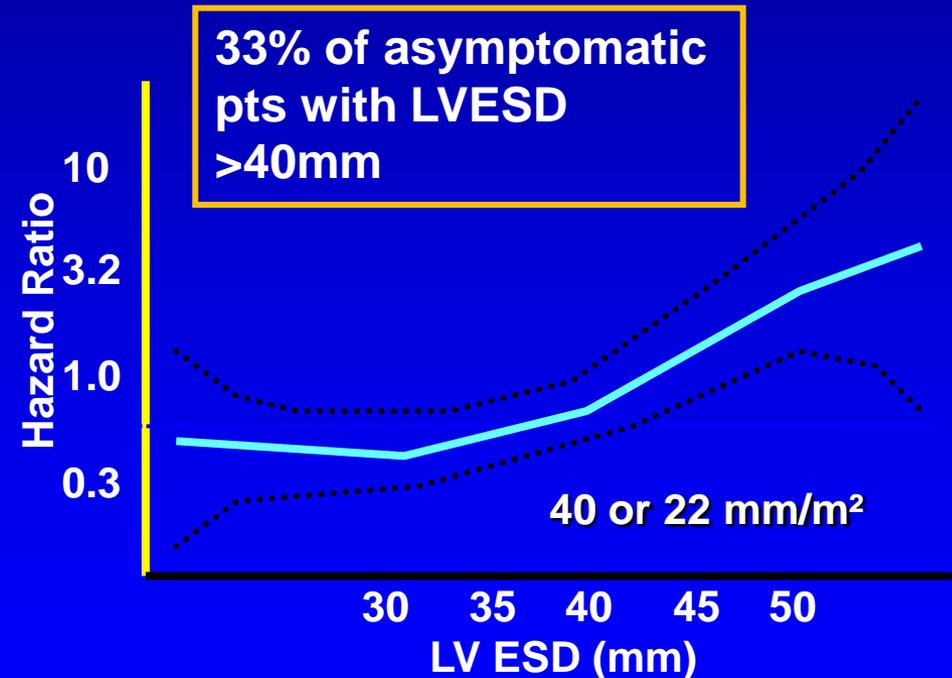
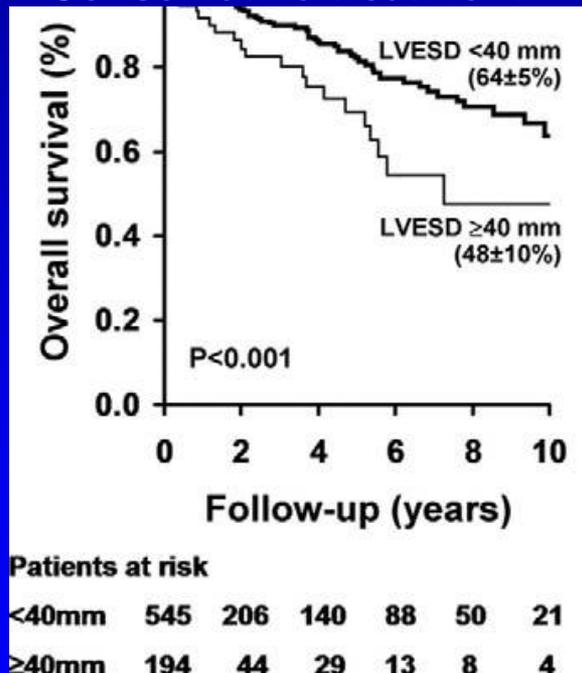
*( L Gillam. Circulation 2010;121;812-821)*

# Impact of LV Dilatation on Survival

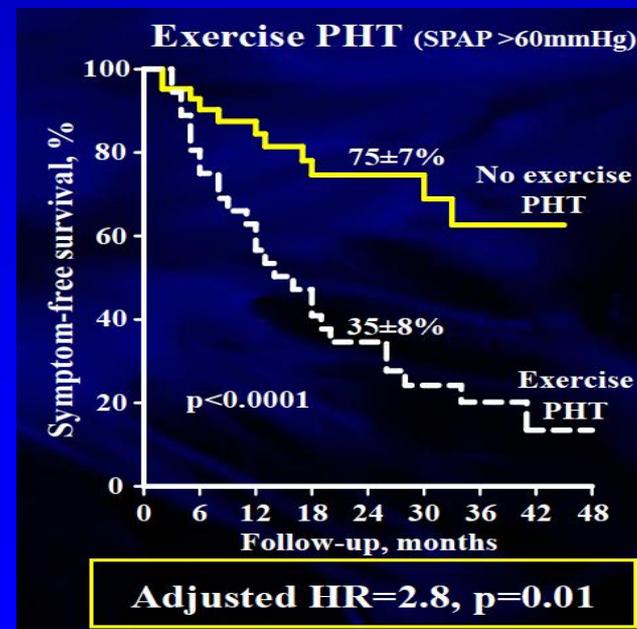
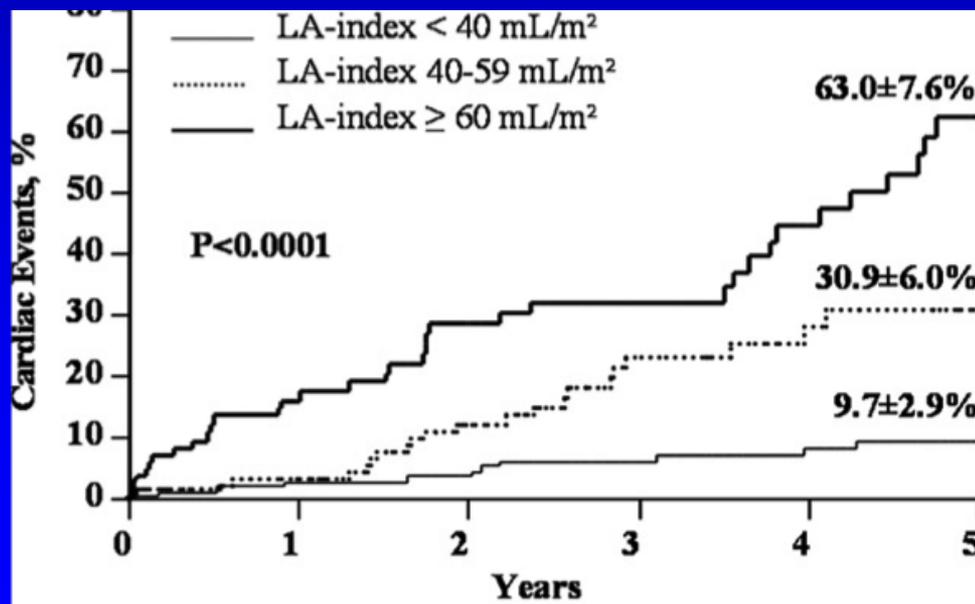
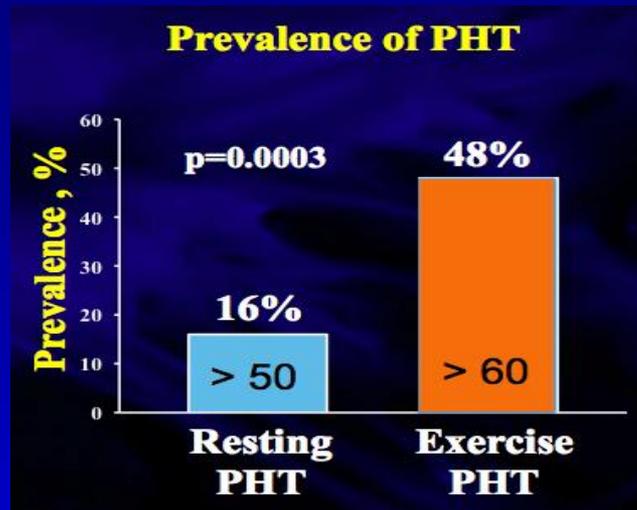
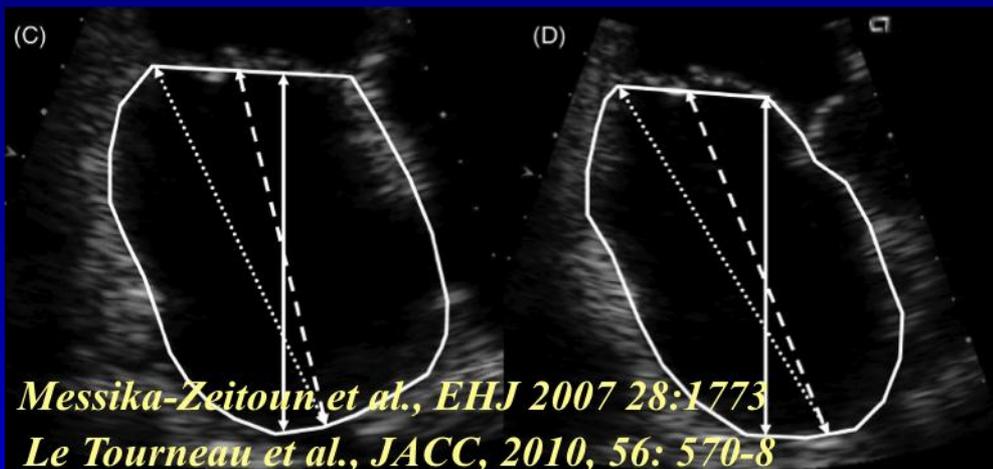
## MIDA registry

739 patients with flail leaflet, follow-up:  $6.1 \pm 3.7$  years

### Conservative treatment



# LA Volume/Exercise PHT and Outcome

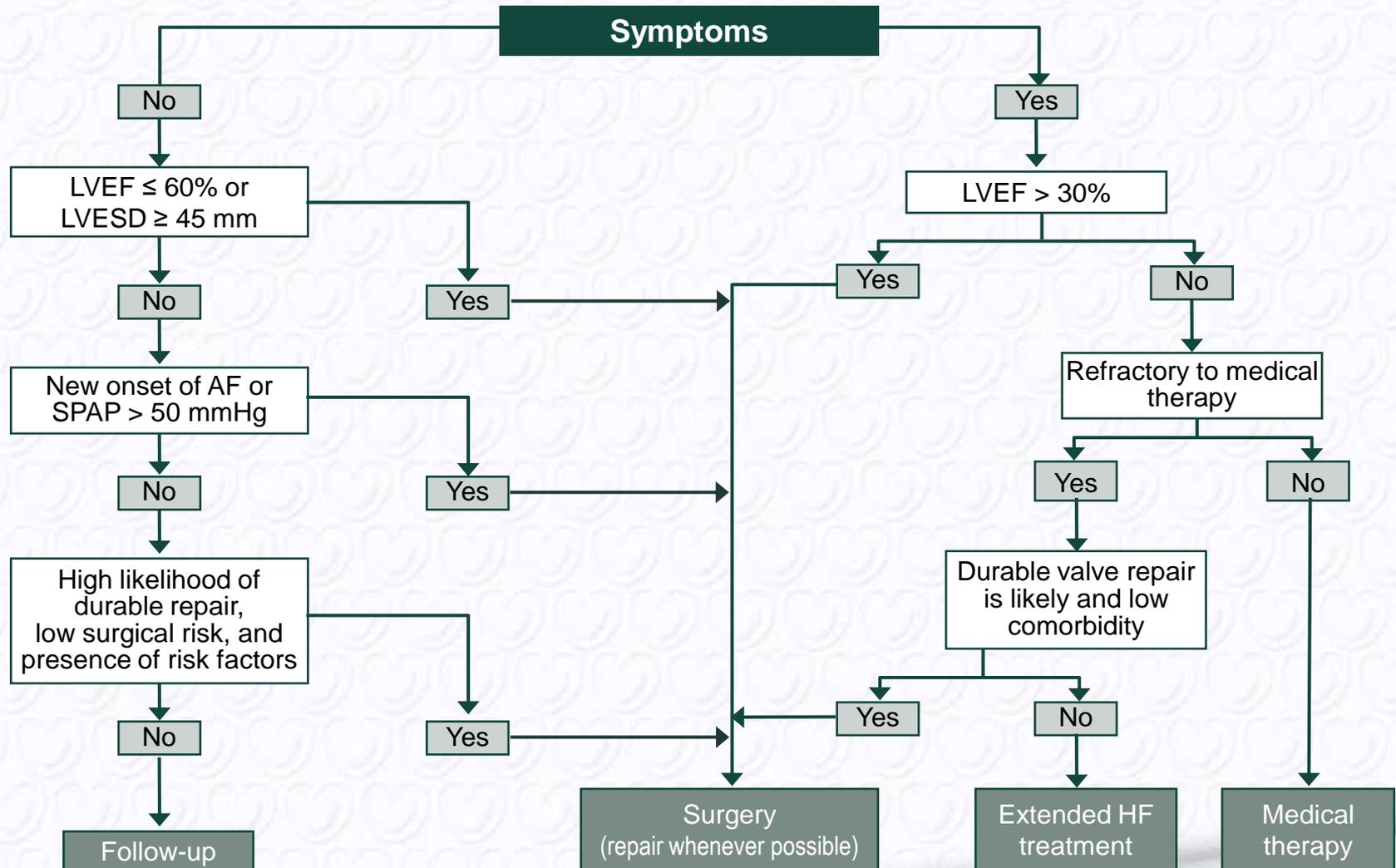


*Magne J, Lancellotti P, Piérard LA. Circulation, 2010.*

# Indications for surgery in asymptomatic severe primary MR

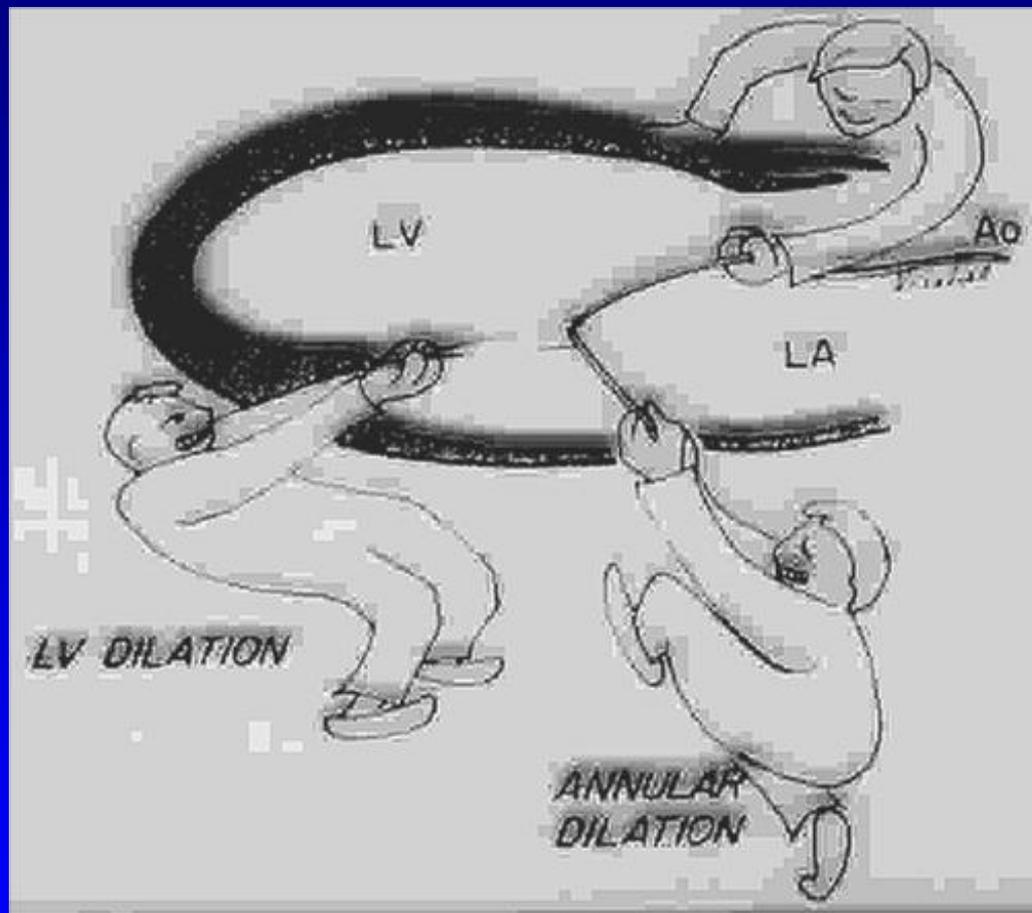
	Class	Level
Surgery is indicated in asymptomatic patients with LV dysfunction (LVESD $\geq$ 45 mm and/or LVEF $\leq$ 60%).	I	C
Surgery should be considered in asymptomatic patients with preserved LV function and new onset of atrial fibrillation or pulmonary hypertension (systolic pulmonary pressure at rest $>$ 50 mmHg).	IIa	C
<b><i>Surgery should be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk and flail leaflet and LVESD <math>\geq</math> 40 mm.</i></b>	IIa	C
<b><i>Surgery may be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, low surgical risk, and:</i></b> <ul style="list-style-type: none"> <li><b><i>• left atrial dilatation (volume index <math>\geq</math> 60 ml/m<sup>2</sup> BSA) and sinus rhythm,</i></b> or</li> <li><b><i>• pulmonary hypertension on exercise (SPAP <math>\geq</math> 60 mmHg at exercise).</i></b></li> </ul>	IIb	C

# Management of severe chronic primary mitral regurgitation



European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
 European Journal of Cardio-Thoracic Surgery 2012 -  
 doi:10.1093/ejcts/ezs455).

# Secondary MR



« Who is the egg ,who is the chicken? »

(Courtesy of A Berrebi)

# Background in the Management of (Moderate-Severe) Secondary MR

1. Operative mortality is higher than in primary MR
2. Long-term prognosis is worse (comorbidities)
3. No evidence that surgery prolongs life (5-yrs death 50%)
  1. CABG alone does not correct MR in most patients
  2. Untreated MR is associated with recurrent HF and death
  3. Functional improvement uniformly reported after surgery
4. Persistence and high recurrence rate of MR after MV repair

Non randomized observational trials for most

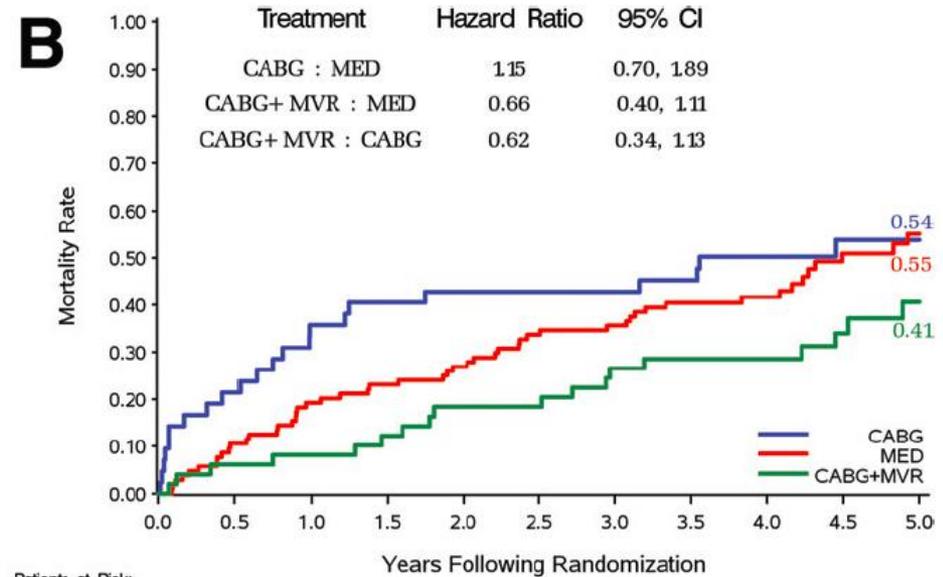
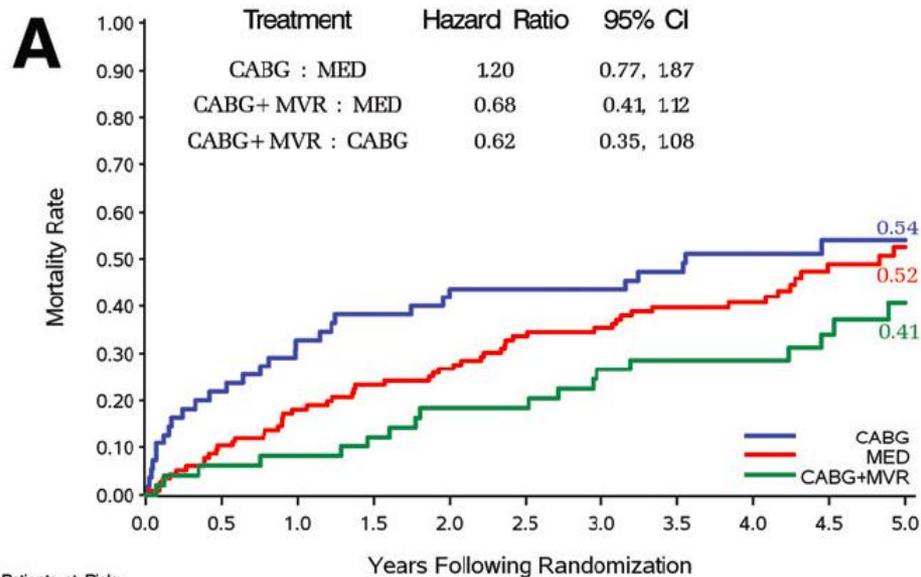
Retrospective trials

One randomized study not powered to evaluate the outcome has compared CABG with CABG/ MVRepair in moderate ischemic MR

→ Improvement in NYHA class/LV function

# Combined Surgery in Secondary MR

1212 randomized patients in the STICH trial (Ventricular Reconstruction) with LV EF < 35%, 435 (36%) had none/trace MR, 554 (46%) had mild MR, 181 (15%) had moderate MR, and 39 (3%) had severe MR



Patients at Risk:

	0.0	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0
CABG	55	37	31	31	24	9					
MED	116	95	85	75	50	22					
CABG+MVR	49	45	40	36	28	15					

Patients at Risk:

	0.0	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0
CABG	42	27	24	24	19	7					
MED	104	84	76	67	43	19					
CABG+ MVR	49	45	40	36	28	15					

Observational data.

The decision to treat the mitral valve during CABG was left to the surgeon.

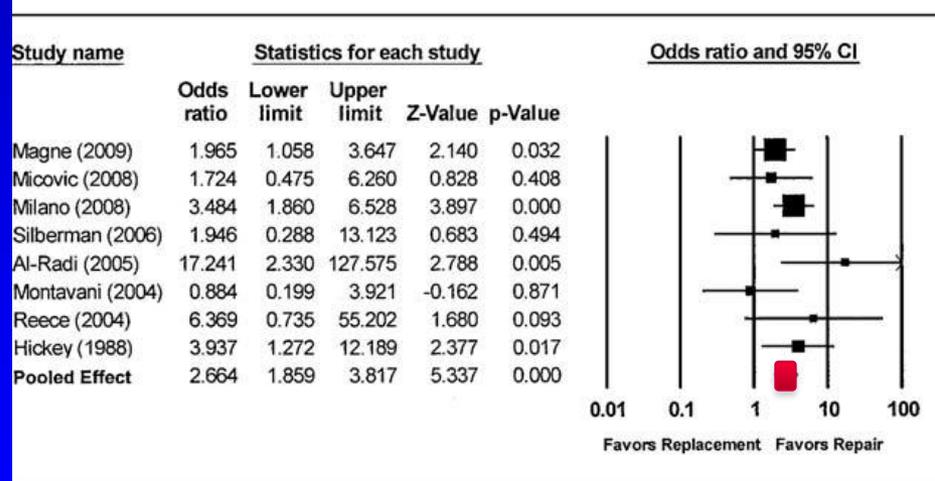
*Deja et al. Circulation. 2012*

# Surgical techniques in secondary MR

When surgery is indicated there is a trend favouring valve repair using only an undersized rigid ring annuloplasty which confers a low operative risk, although it carries a high risk of MR recurrence (up to 30-50% at 3 years)

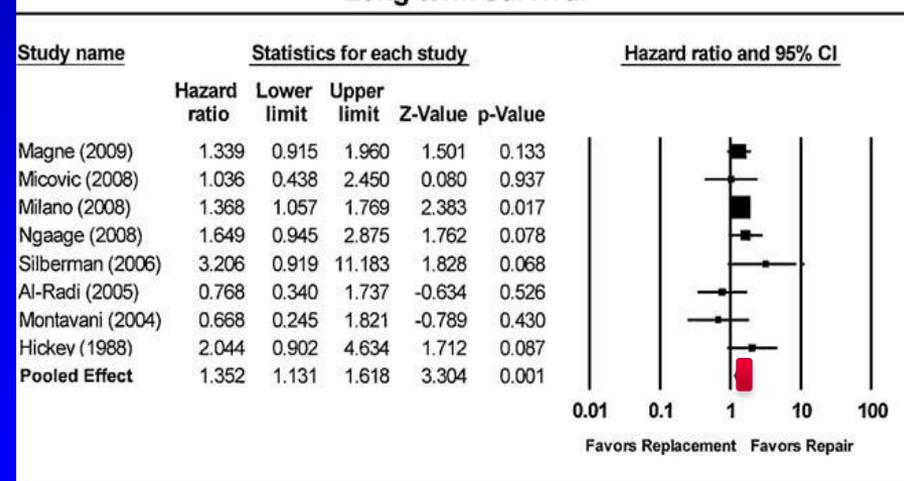
Meta-analysis of short-term and long-term survival following repair versus replacement for ischemic MR

## Short-term Survival



Significantly increased likelihood of short-term mortality associated with mitral valve replacement

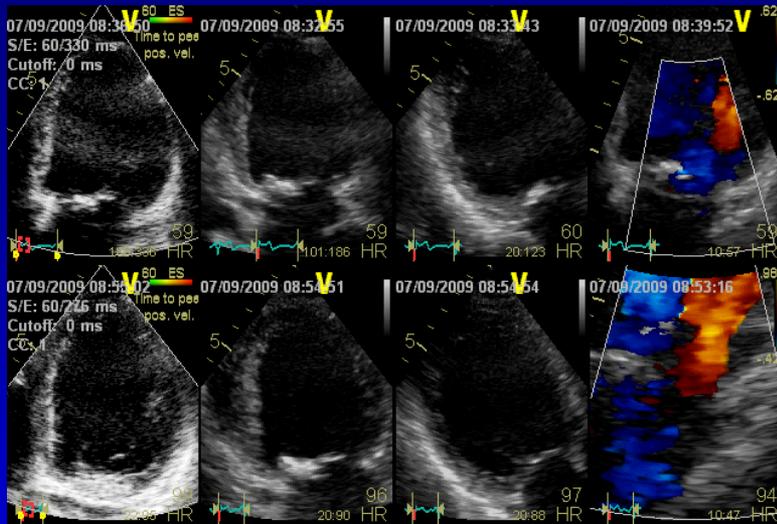
## Long-term Survival



Significantly increased likelihood of long-term mortality associated with mitral valve replacement

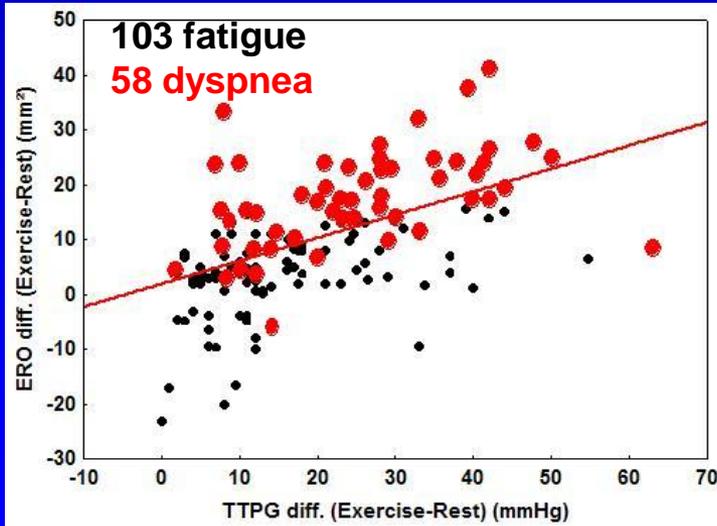
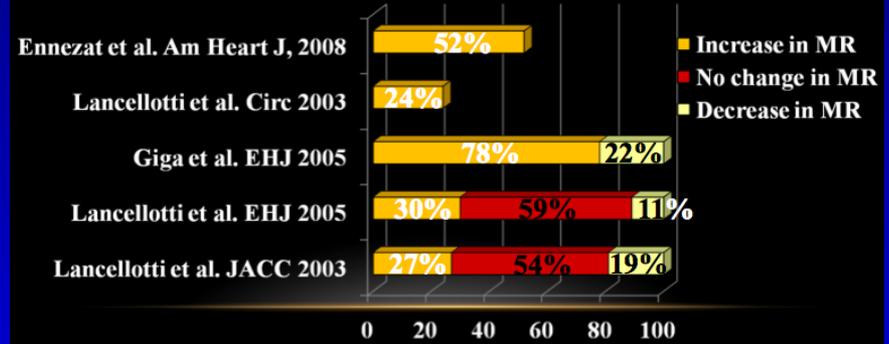
# Dynamic MR on Exercise

## Relationship with symptoms and outcome

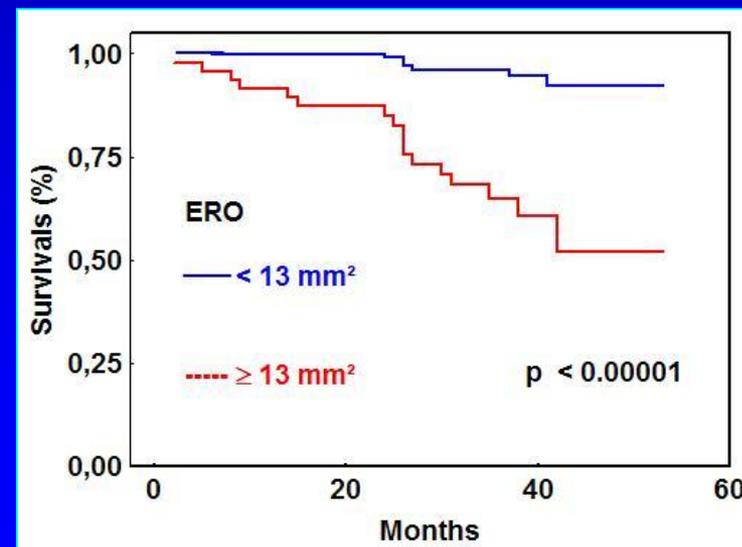


**Systolic heart failure and functional MR:**  
**exercise-induced increase in MR in ≈30% of patients.**

*Levine RA et Swammenthal E al. Circulation, 2005*



*Piérard et Lancellotti NEJM,*  
*2004 and 2006*



*Lancellotti et al Circulation 2003*  
*Lancellotti et al Eur Heart J 2005*

# Indications for mitral valve surgery in secondary mitral regurgitation

	Class	Level
Surgery is indicated in patients with severe MR undergoing CABG, and LVEF > 30%.	I	C
Surgery should be considered in patients with moderate MR undergoing CABG.	IIa	C
<i>Surgery should be considered in symptomatic patients with severe MR, LVEF &lt; 30%, option for revascularization, and evidence of viability.</i>	IIa	C
<i>Surgery may be considered in patients with severe MR, LVEF &gt; 30%, who remain symptomatic despite optimal medical management (including CRT if indicated) and have low comorbidity, when revascularization is not indicated.</i>	IIb	C

# What is Needed to Improve the Evidence on Usefulness of MVR in Ischemic MR?

- Dedicated RCT (CABG vs CABG/MVR → The CT Surgical Trials Network)
- Improvement of pre-operative evaluation (quantification of MR at rest and during stress, evaluation of Myocardial viability)
- Evaluation of Techniques
  - Annuloplasty, including dynamic components
  - LV « remodeling »

# Choice of the aortic/mitral prosthesis: in favour of a bioprosthesis

	Class	Level
A bioprosthesis is recommended according to the desire of the informed patient.	I	C
A bioprosthesis is recommended when good quality anticoagulation is unlikely (compliance problems, not readily available) or contraindicated because of high bleeding risk (prior major bleed, comorbidities, unwillingness, compliance problems, lifestyle, occupation).	I	C
A bioprosthesis is recommended for reoperation for mechanical valve thrombosis despite good long-term anticoagulant control.	I	C
A bioprosthesis should be considered in patients for whom future redo valve surgery would be at low risk.	Ila	C
A bioprosthesis should be considered in young women contemplating pregnancy.	Ila	C
A bioprosthesis should be considered in patients aged > 65 years for prosthesis in aortic position or <b>&gt; 70 years in mitral position</b> , or those with life expectancy lower than the presumed durability of the bioprosthesis.	Ila	C

# Indications for antithrombotic therapy after valvular surgery

	Class	Level
Oral anticoagulation is recommended lifelong for all patients with a mechanical prosthesis.	I	B
Oral anticoagulation is recommended lifelong for patients with bioprostheses who have other indications for anticoagulation.	I	C
The addition of low-dose aspirin should be considered in patients with a mechanical prosthesis and concomitant atherosclerotic disease.	IIa	C
The addition of low-dose aspirin should be considered in patients with a mechanical prosthesis after thromboembolism despite adequate INR.	IIa	C
<b>Oral anticoagulation should be considered for the first 3 months after implantation of a mitral or tricuspid bioprosthesis.</b>	IIa	C
<b>Oral anticoagulation should be considered for the first 3 months after mitral valve repair.</b>	IIa	C
Low-dose aspirin should be considered for the first 3 months after implantation of an aortic bioprosthesis.	IIa	C
Oral anticoagulation may be considered for the first 3 months after implantation of an aortic bioprosthesis.	IIb	C

# The Evolution of Mitral Interventions

OPEN CHEST - OPEN HEART

Conventional

MINIMAL ACCESS - OPEN HEART

Endoscopic

CLOSED CHEST - OPEN HEART

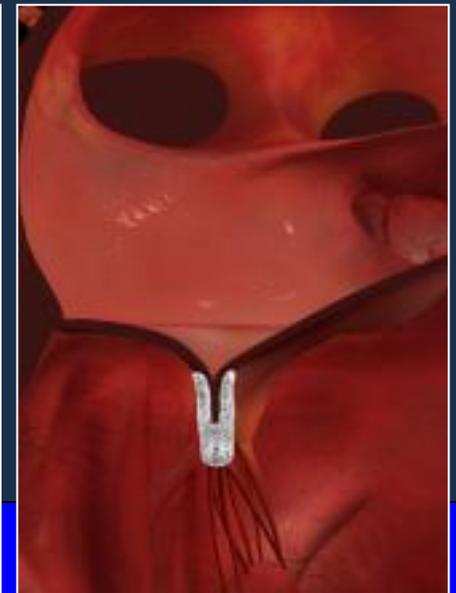
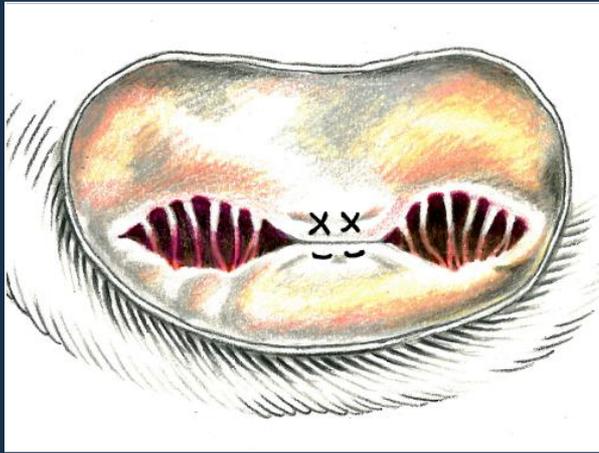
Robotic

***CLOSED CHEST - BEATING HEART***

***Transcatheter***

# Percutaneous Mitral Valve Repair

## Edge-to-Edge Technique



# Worldwide Experience (October 2012)

Study	Population	N*
EVEREST I (Feasibility)	Feasibility patients	55
EVEREST II (Pivotal)	Pre-randomized patients	60
EVEREST II (Pivotal)	Non-randomized patients (High Risk Study)	78
<b><i>EVEREST II (Pivotal)</i></b>	<b><i>Randomized patients</i></b>	<b>279</b> <b>184 Clip</b>
REALISM (Continued Access)	Non-randomized patients	758
Compassionate/Emergency Use	Non-randomized patients	60
ACCESS Europe Phase I	Non-randomized patients	567
ACCESS Europe Phase II	Non-randomized patients	279
Commercial Use	Commercial patients	4,798
<b><u>Total</u></b>		<b><u>6,839</u></b>

# ESC/ EACTS Guidelines for the Management of Valvular Heart Disease

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« The percutaneous Mitraclip procedure may be considered in symptomatic patients with severe primary or secondary MR despite optimal medical therapy, who fulfil the echo criteria of eligibility, are judged inoperable or at high risk for surgery by a heart team, and who have a life expectancy greater than one year »

(Recommendation class IIb, level of Evidence C)

« The current findings have to be confirmed in larger series with longer follow-up and with a randomized design »

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

# The Trial we Need in Secondary MR

HF patients with Severe MR and Low EF

**RESHAPE, COAPT will start soon**

Symptoms despite Optimal Medical  
Management

**Mitral VARC will be published in 2013**

Edge to Edge

Medical therapy

# Indications for surgery in tricuspid disease

	Class	Level
Surgery is indicated in symptomatic patients with severe TS.	I	C
Surgery is indicated in patients with severe TS undergoing left-sided valve intervention.	I	C
<b><i>Surgery is indicated in patients with severe primary, or secondary, TR undergoing left-sided valve surgery.</i></b>	I	C
Surgery is indicated in symptomatic patients with severe isolated primary TR without severe right ventricular dysfunction.	I	C
Surgery should be considered in patients with moderate primary TR undergoing left-sided valve surgery.	Ila	C
<b><i>Surgery should be considered in patients with mild or moderate secondary TR with dilated annulus (<math>\geq 40</math> mm or <math>&gt; 21</math> mm/m<sup>2</sup>) undergoing left-sided valve surgery.</i></b>	Ila	C
Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary TR and progressive right ventricular dilation or deterioration of right ventricular function.	Ila	C
<b><i>After left-sided valve surgery, surgery should be considered in patients with severe TR who are symptomatic or have progressive right ventricular dilatation/dysfunction, in the absence of left-sided valve dysfunction, severe right or left ventricular dysfunction, and severe pulmonary vascular disease.</i></b>	Ila	C

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

# Conclusions

- Evaluation of MR relies mainly on
  - ✓ Clinical assessment
  - ✓ Comprehensive echocardiographic examination
- Valve repair should be preferred whenever possible
- Surgery is indicated in cases of severe, symptomatic organic regurgitation
- Surgery is indicated in asymptomatic patients with severe organic MR and beginning impairment of left ventricular function.
- Early interventions can be considered in asymptomatic patients with preserved LV function, high likelihood of durable repair, and low risk for surgery

# Conclusions

- The results obtained with Edge to Edge technique suggest that it may be useful in selected high risk patients.

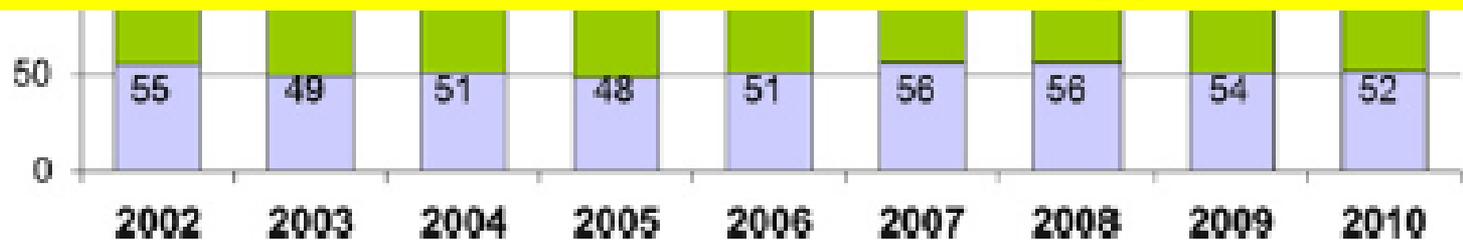
Do not forget the tricuspid valve !

- *In the future* improvement can be expected from :
  - ✓ Increased rate of durable surgical valve repair
  - ✓ Evaluation of percutaneous valve repair/replacement
  - ✓ Early detection of LV dysfunction
  - ✓ New trials enabling for better evidence.....

# The Future of the Treatment of Mitral Regurgitation



**A larger number of patients with mitral valve disease will be treated by safer/ less invasive surgery or, interventional cardiology**



**FIGURE 7.** Volume of surgical and percutaneous mitral valve treatment at the University Heart Center Hamburg 2002–2010.