The Key Questions in Mitral Valve Interventions

Where Are We in 2018?

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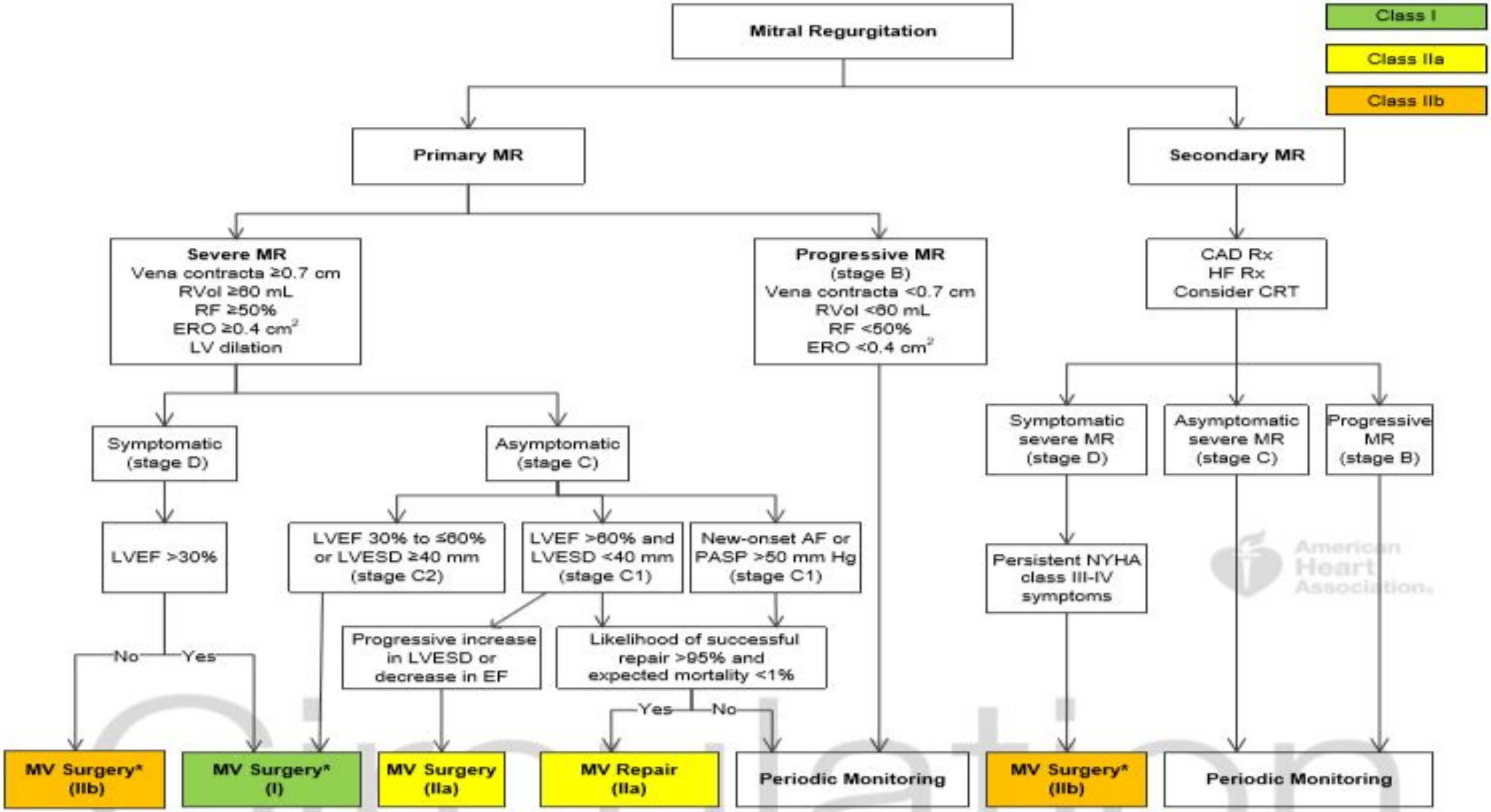
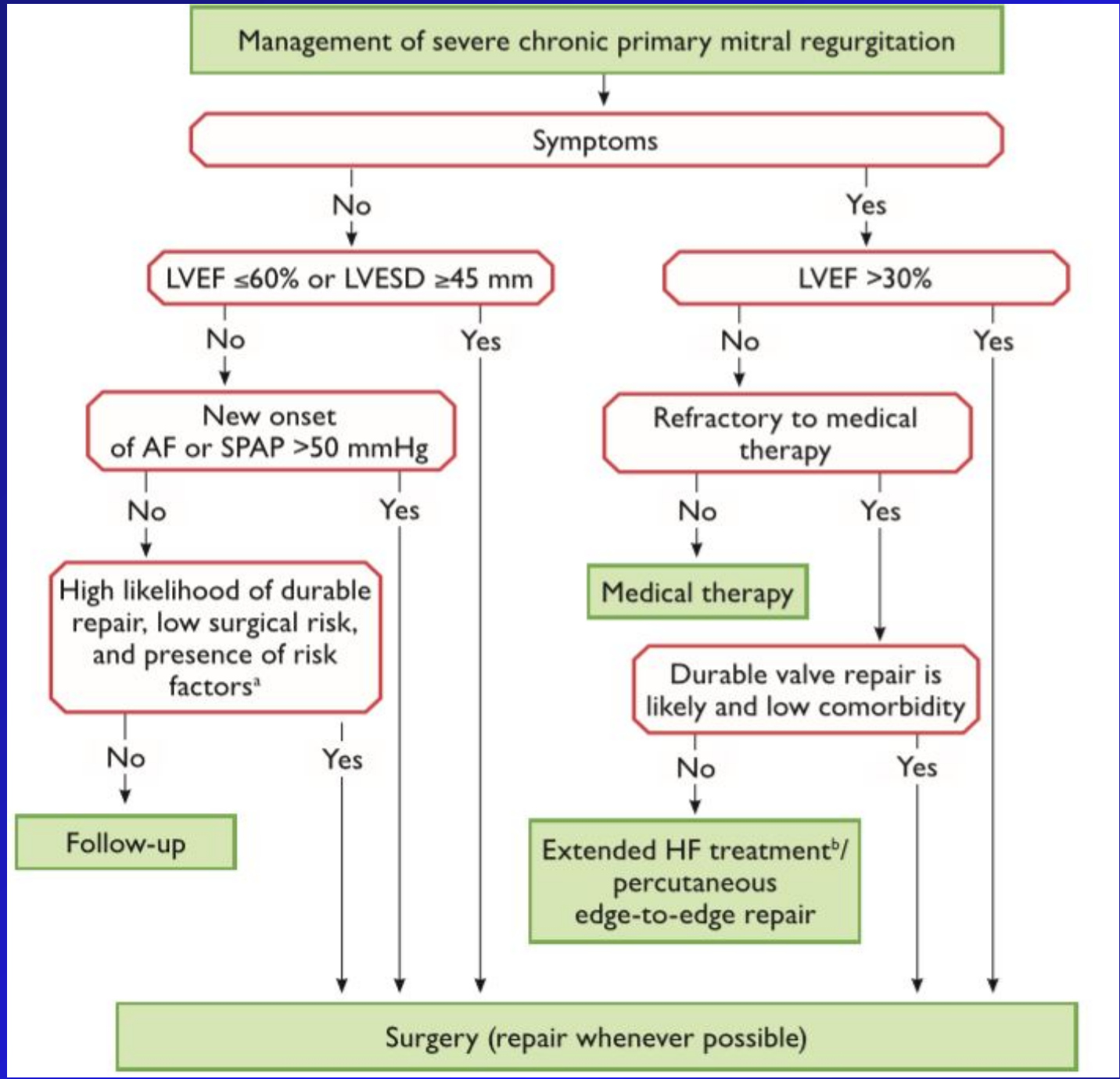
30° GIORNATE CARDIOLOGICHE TORINESI - OCT 2018

- Are guidelines matching reality?
- Is MR quantification reliable?
- Surgery : respect or resect?
- Minimal access vs Sternotomy?
- Surgery vs Percutaneous treatment ?

Are guidelines matching reality?


Mitral Regurgitation
Class I
Class IIa
Class IIb
Primary MR
Secondary MR
Severe MR
Vena contracta ≥0.7 cm
RVol ≥60 mL
RF ≥50%
ERO ≥0.4 cm²
LV dilation
Progressive MR
(stage B)
Vena contracta <0.7 cm
RVol <60 mL
RF <50%
ERO <0.4 cm²
CAD Rx
HF Rx
Consider CRT
Symptomatic
(stage D)
Asymptomatic
(stage C)
Symptomatic
severe MR
(stage D)
Asymptomatic
severe MR
(stage C)
Progressive
MR
(stage B)
LVEF >30%
LVEF 30% to ≤60%
or LVESD ≥40 mm
(stage C2)
LVEF >60% and
LVESD <40 mm
(stage C1)
New-onset AF or
PASP >50 mm Hg
(stage C1)
Persistent NYHA
class III-IV
symptoms
Progressive increase
in LVESD or
decrease in EF
Likelihood of successful
repair >95% and
expected mortality <1%
No
Yes
Yes
No
MV Surgery*
(IIb)
MV Surgery*
(I)
MV Surgery
(IIa)
MV Repair
(IIa)
Periodic Monitoring
MV Surgery*
(IIb)
Periodic Monitoring


Management of severe chronic primary mitral regurgitation
Symptoms
No
Yes
LVEF ≤60% or LVESD ≥45 mm
LVEF >30%
No
Yes
No
Yes
New onset of AF or SPAP >50 mmHg
Refractory to medical therapy
No
Yes
No
Yes
High likelihood of durable repair, low surgical risk, and presence of risk factors[a]
Medical therapy
Durable valve repair is likely and low comorbidity
No
Yes
No
Yes
Follow-up
Extended HF treatment[b]/ percutaneous edge-to-edge repair
Surgery (repair whenever possible)

Guidelines do not match real world

Asymptomatic patients

Centre of excellence (applicable in Europe?)

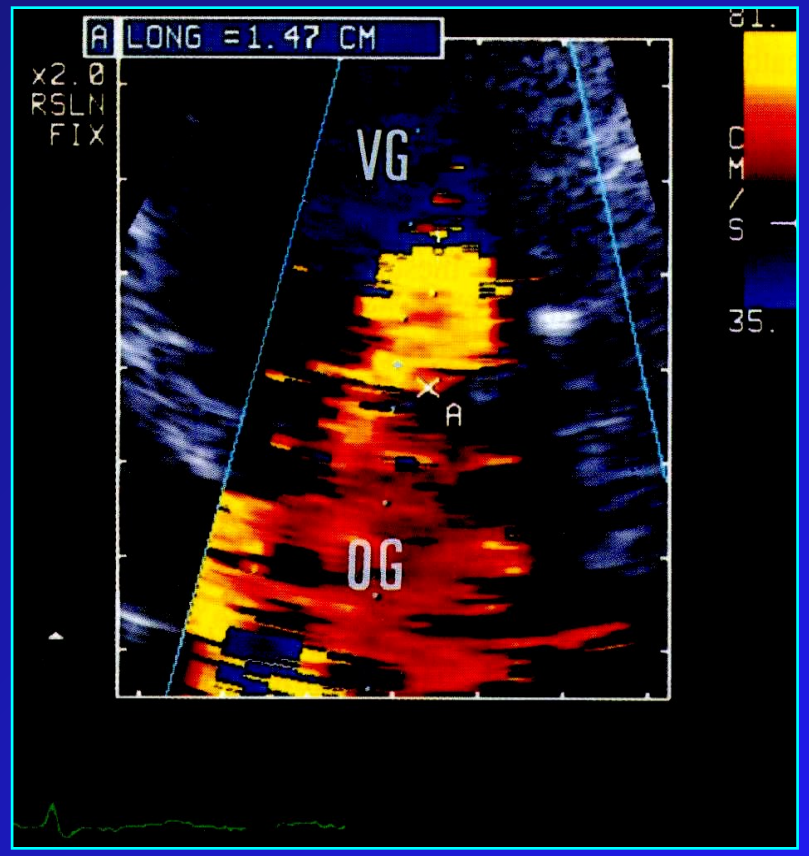
Asymptomatic have the biggest ventricles

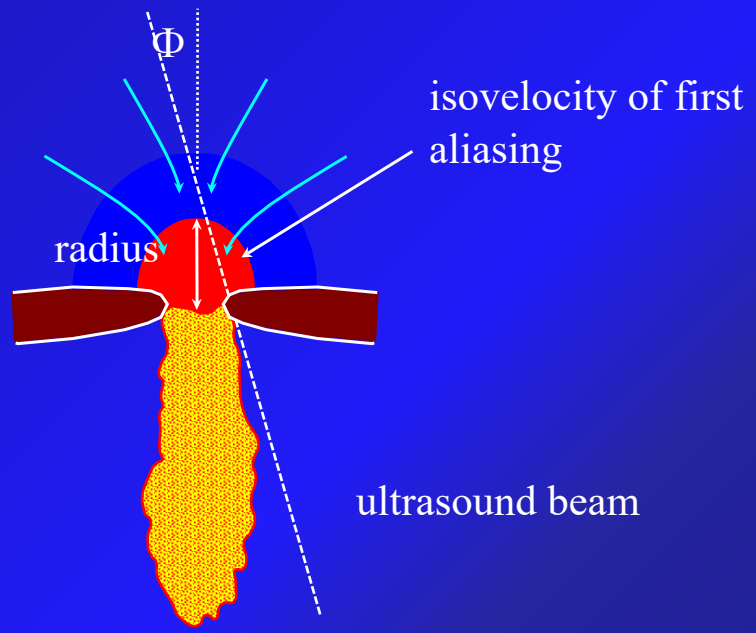
No reference to LA volume

LV Strain

Is MR quantification reliable?

Assessment of MR severity : Proximal Isovelocity Surface Area (PISA)





$$flow = \frac{SVi}{Sicosf/\ 2pr2}$$

Assessment of MR severity : Proximal Isovelocity Surface Area (PISA)

	Regurgitant volume	Effective orifice
grade 1	< 30 mL	< 20 mm^2
grade 2	30 - 44 mL	20 - 29 mm^2
grade 3	45 - 59 mL	30 - 39 mm^2
grade 4	≥ 60 mL	≥ 40 mm^2

But MR is not accurately quantified in excentric jets

- underestimates RV
- requires angle correction

Reason why grading still expressed in grade 1 to 4 +

Why not cross-check findings?

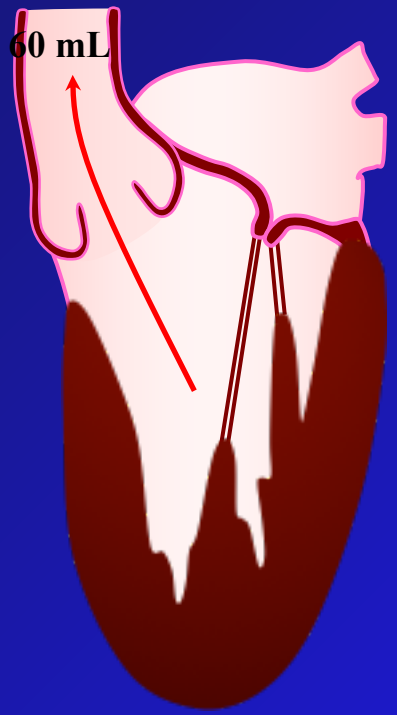
Cross-check PISA findings

LA volume ≥ 60 ml / m2
Longitudinal strain ≤ -15.9% to -22.1%
Exercise echo
Look at the LV

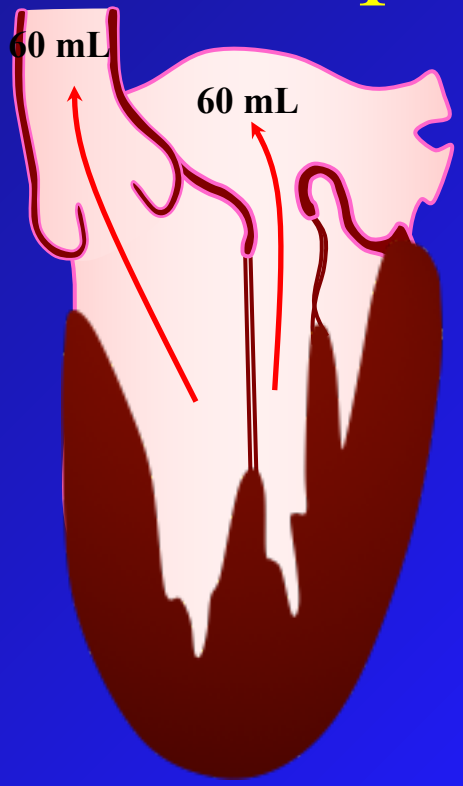
Look at the LV !

There can’t be severe MR without LV dilatation !

Early ventricular remodeling after mitral repair



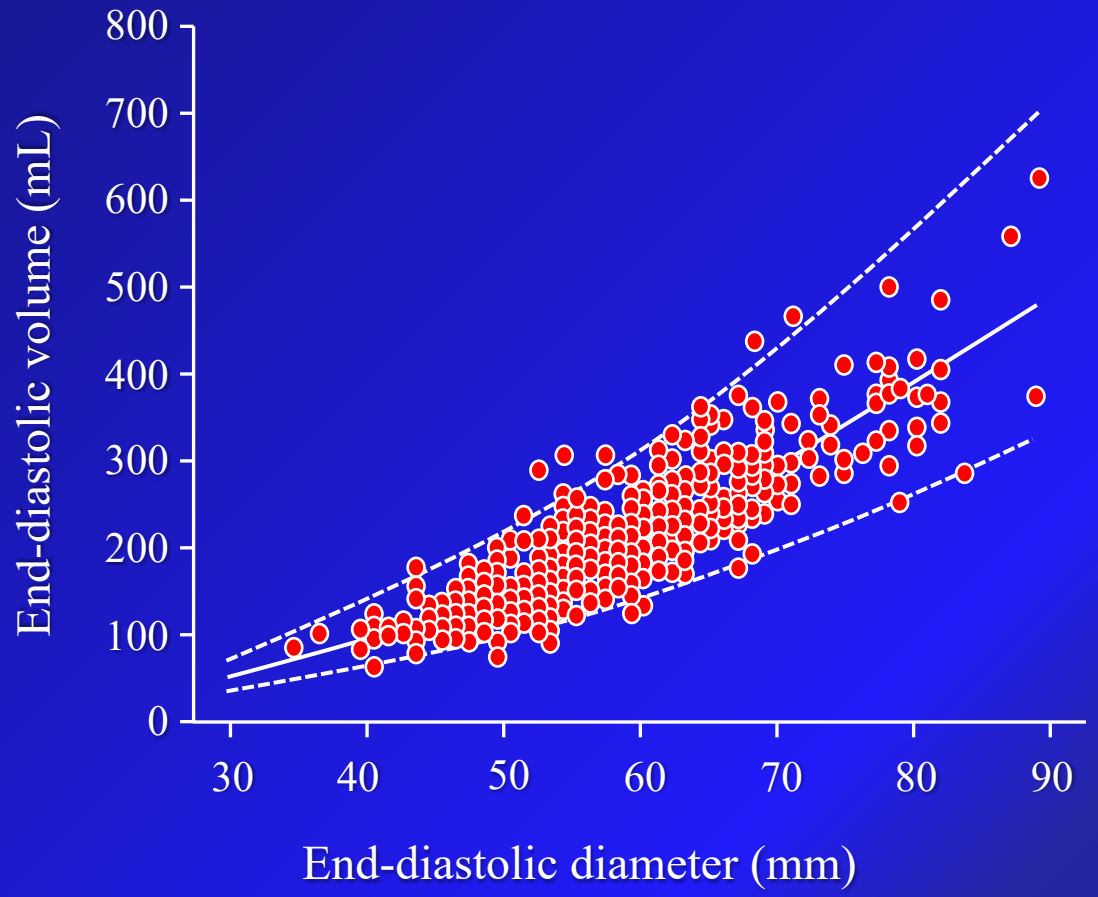
EDV: 100 mL
ESV: 40 mL
LVEF: 60%



EDV: 180 mL
ESV: 60 mL
LVEF: 66%

EDV: 120 mL
ESV: 60 mL
LVEF: 50%

Relation of LV internal dimensions to LV volumes



Dujardin K. et al., *J Am Coll Cardiol* (1997) 30:1534-1541

Surgery : respect or resect?

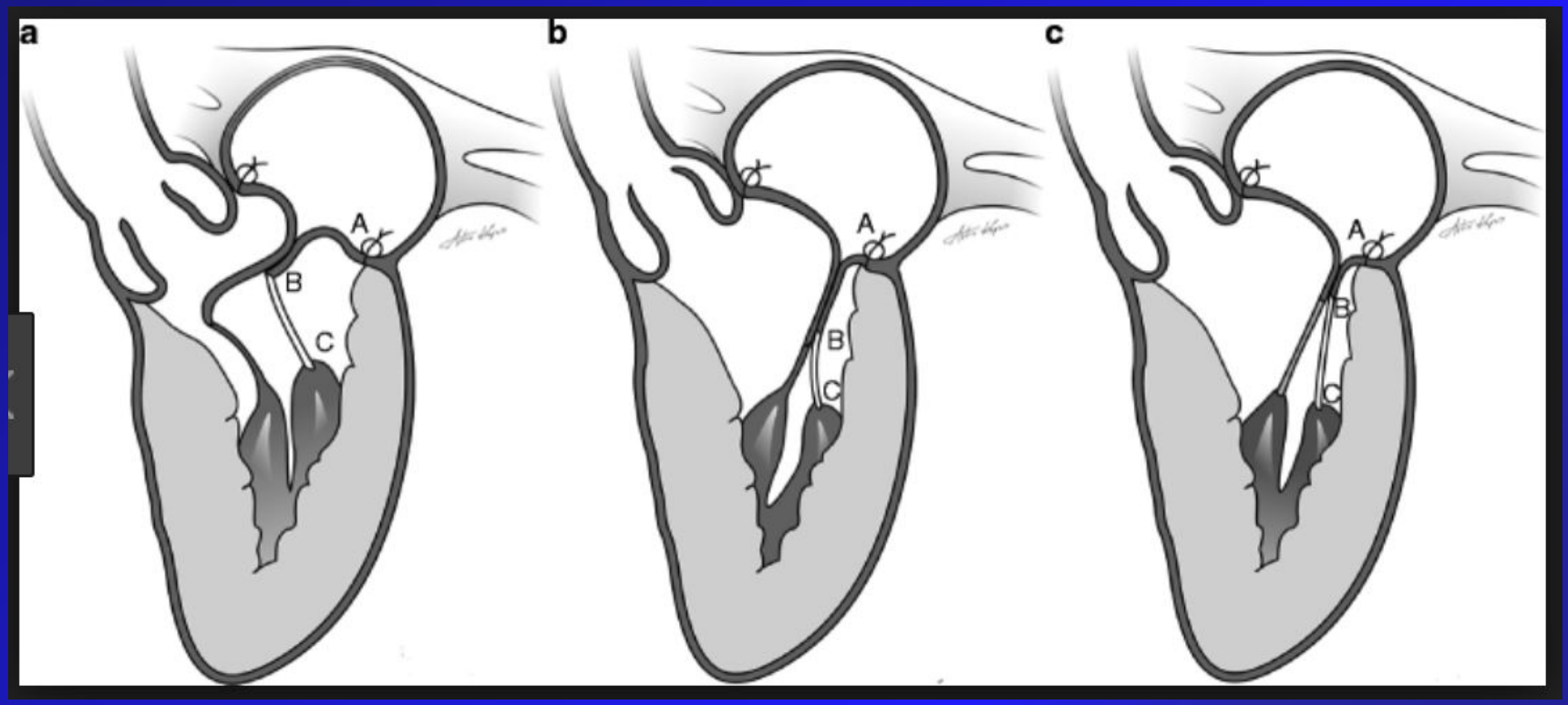
Basic Surgical Strategy

2 radically different approaches coexist

- Respect rather than resect
- Respect when you can **BUT**

RESECT WHEN YOU SHOULD

Respect rather than resect



Perier. Ann Thorac Surg 2008

Respect rather than Resect

(Perier - Ann Thorac Surg 2008)

Resects up to 35 % of cases in the first series

Currently tends to resect in 50%

This concept fits well with minimally invasive

needed or compromise?

Respect rather than Resect

(Perier - Ann Thorac Surg 2008)

Why is resection required?

Because of excess width

How can Gore Tex overcome this issue?

Adult: Mitral Valve: Editorial

Respectful resection to enhance the armamentarium of mitral valve repair: Is less really more?
Harold G. Roberts, J. Scott Rankin, Lawrence M. Wei, Chris C. Cook, Muhammad Salman, Vinay Badhwar

Adult: Mitral Valve

"Respect when you can, resect when you should": A realistic approach to posterior leaflet mitral valve repair
Gilles D. Dreyfus, Filip Dulguerov, Cecilia Marcacci, Shelley Rahman Haley, Antonia Gkouma, Carine Dommerc, Adelin Albert

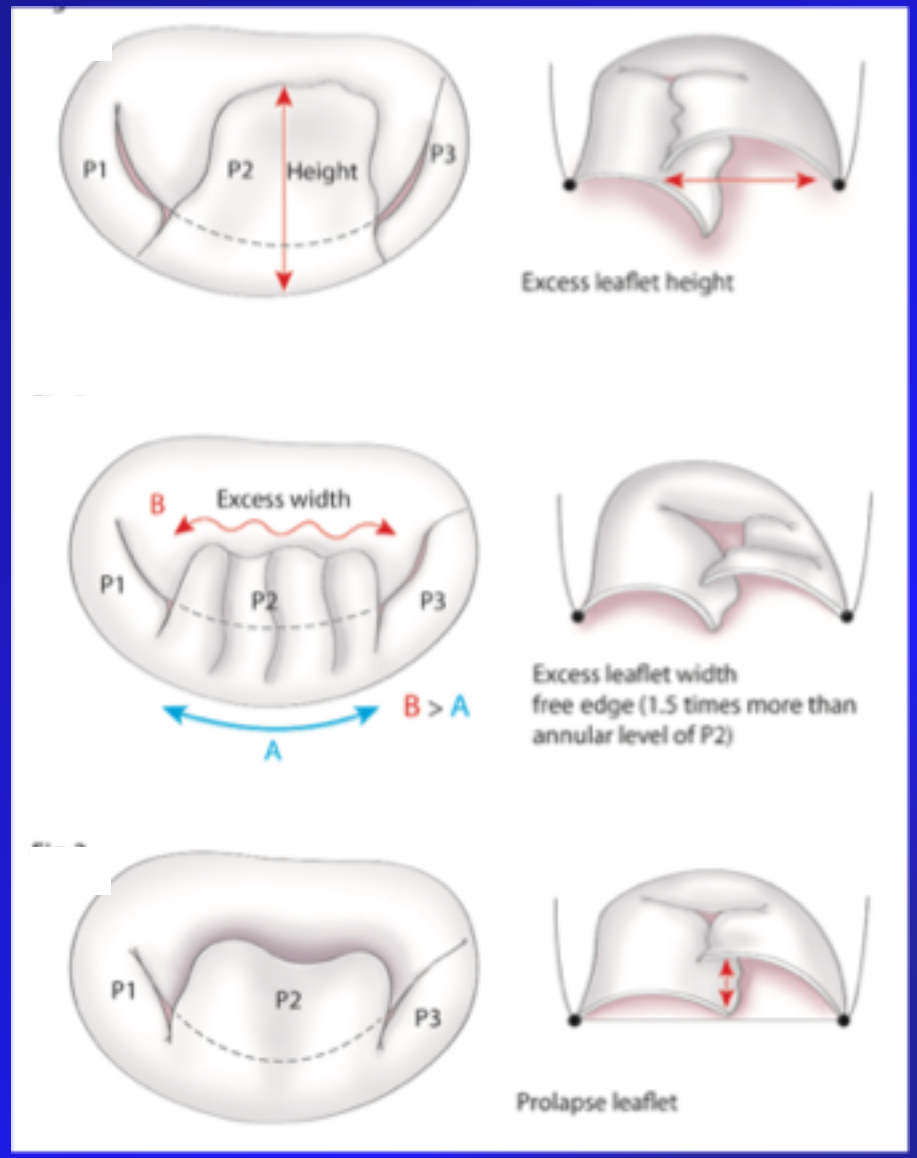
Discussion

Editorial Commentary

Posterior leaflet mitral valve prolapse: One repair does not fit all
Syed A. Sadeque, Clifford W. Barlow

What are the lesions in MV regurgitation?

3 lesions MUST be addressed



Excess height

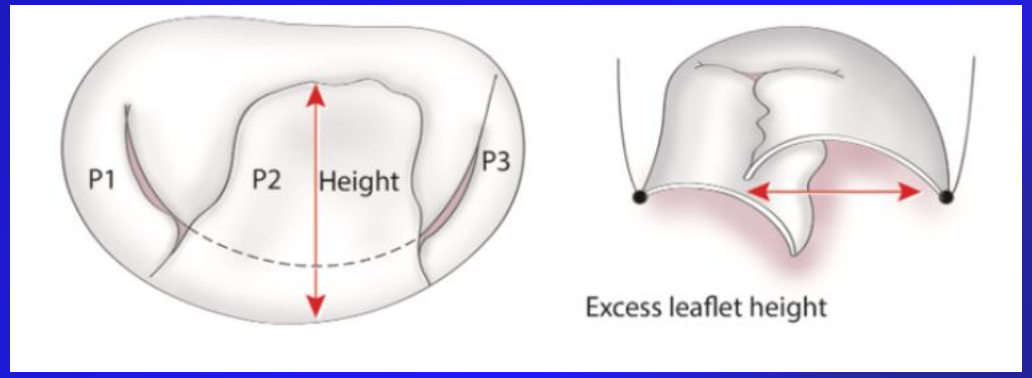
Excess width

Prolapse

Can such lesions be addressed without resection at all?

How to deal with
Excess height

Techniques



- Resection : reduces height
- Pulling free edge downwards
  (Gore tex neochordae) : buries leaflet into the LV

Results

- Brings P2 at the same level as P1-P3
- Leaflet restriction (Gore Tex neochordae)

Butterfly technique addresses at the same time excess height and width

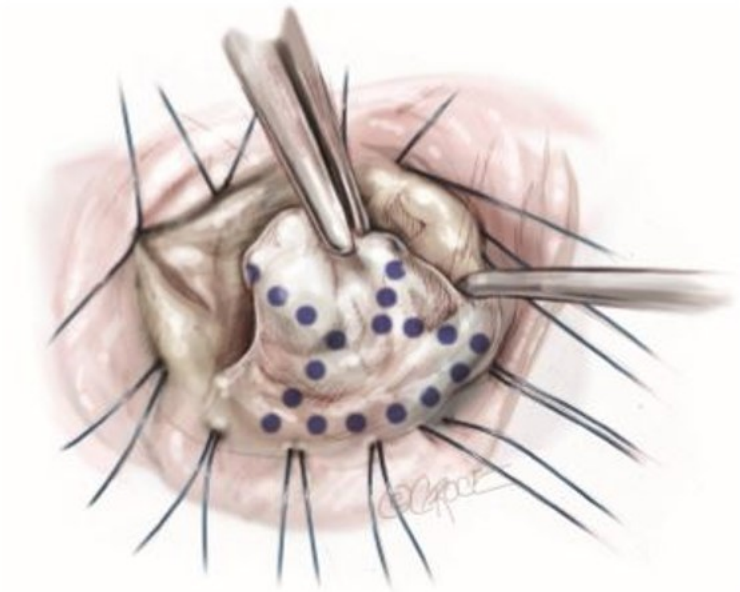
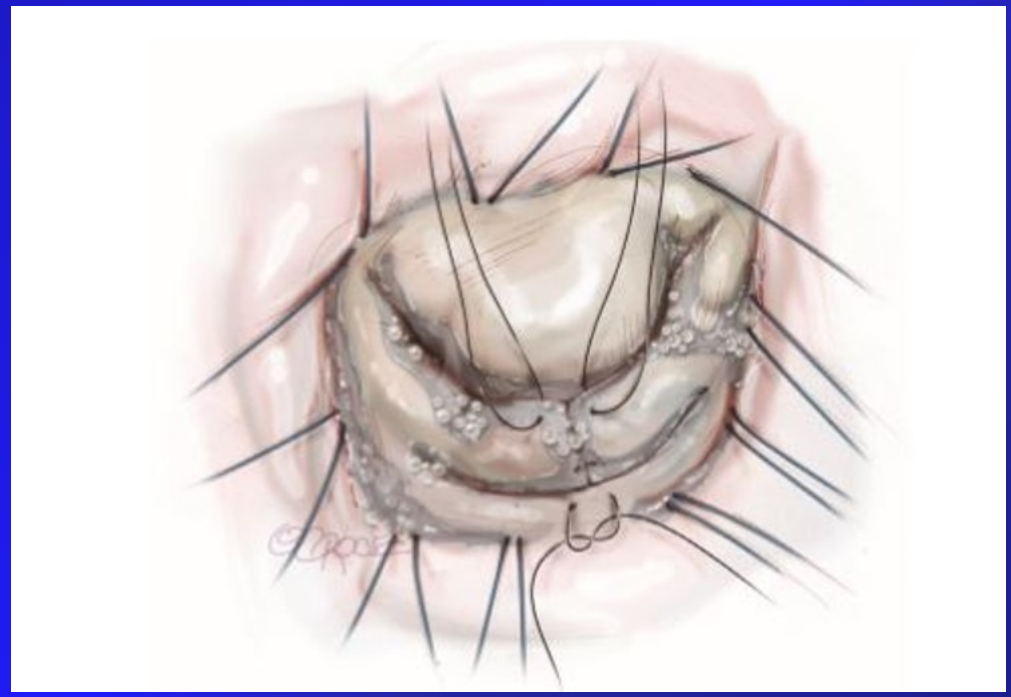


Figure 7 A butterfly design is completed to demonstrate as a shallow triangle at the free margin combined with a reverse triangle with its base at the annulus.

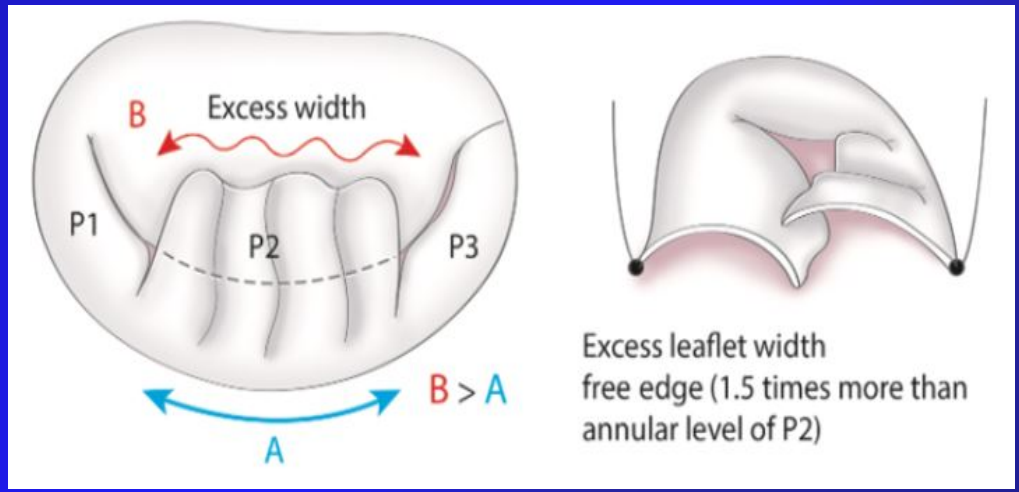


Tohru Asai, Ann Cardiothorac Surg 2015

How to deal with
Excess width

Techniques

- Triangular resection
- Ignore it

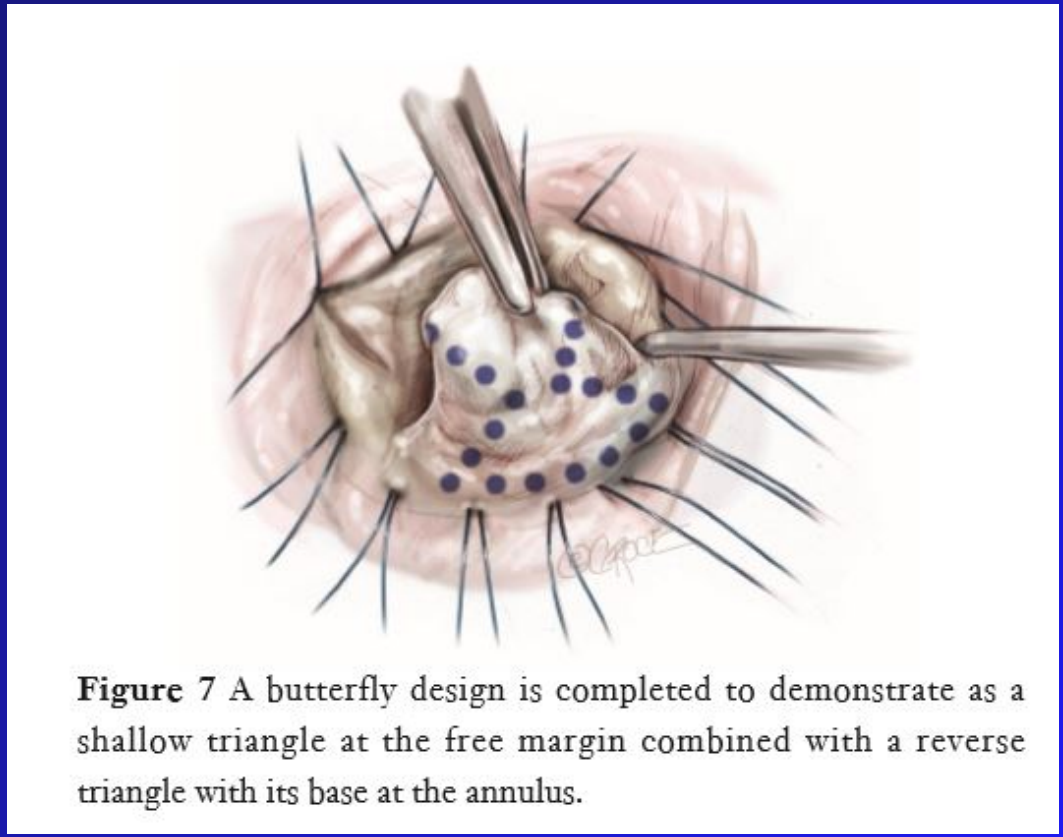


Results

Smooth coaptation surface

Rough and irregular coaptation surface

Butterfly technique addresses at the same time excess height and width



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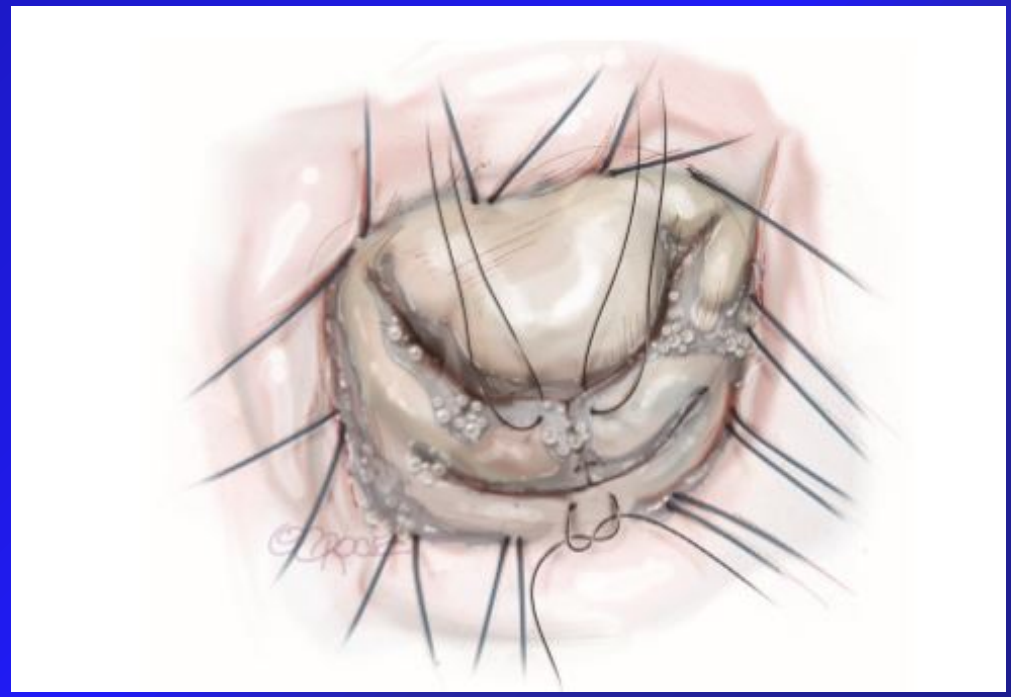
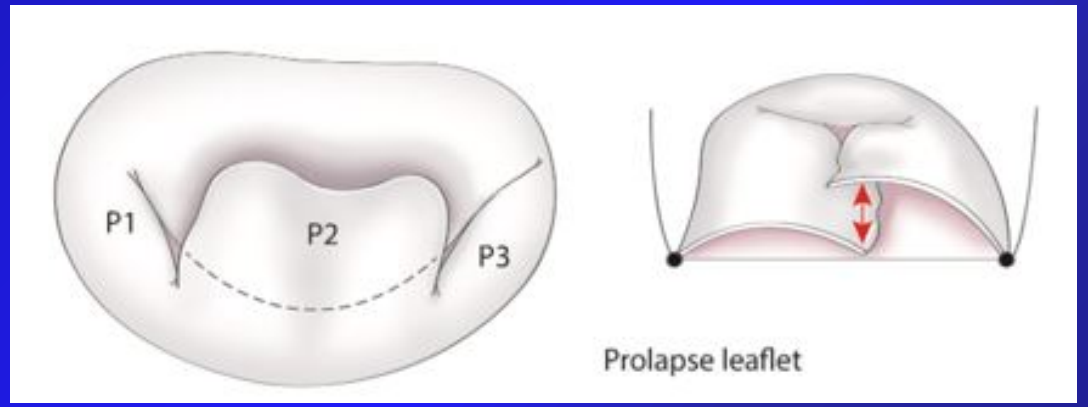


Tohru Asai, Ann Cardiothorac Surg 2015.4(4):370-375

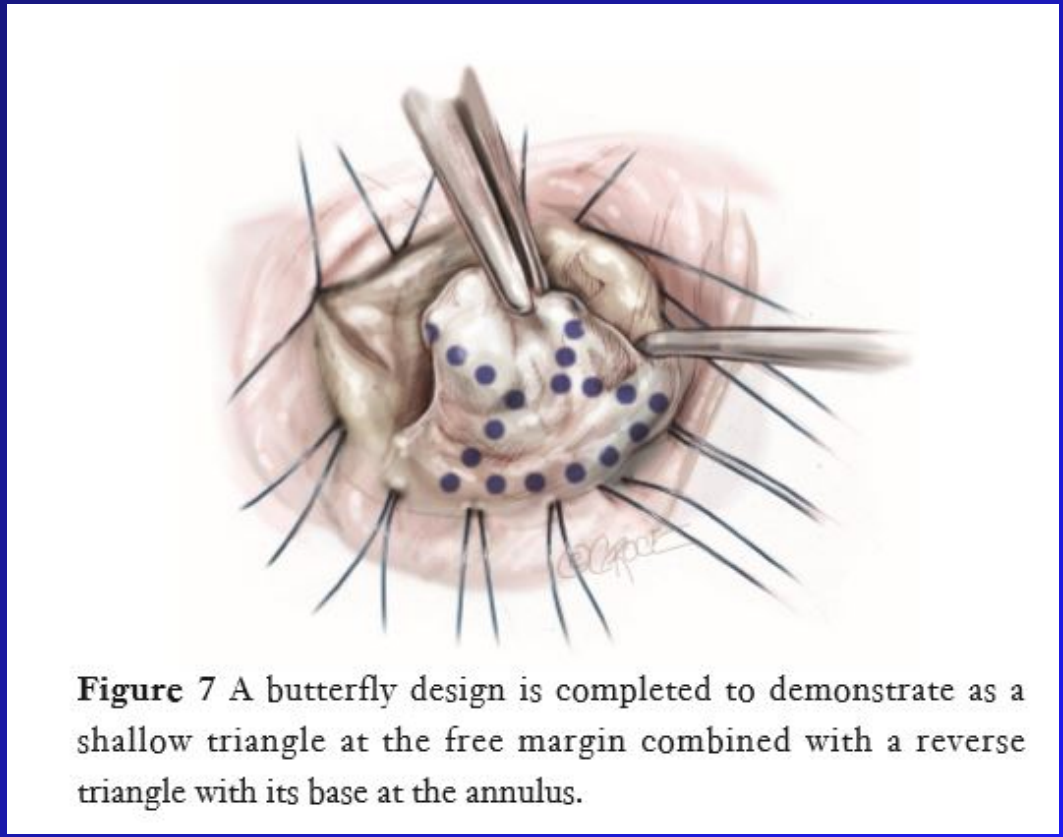
How to deal with
Prolapse

Techniques

- Native chord transfer
- Artificial neochordae



Butterfly technique addresses at the same time excess height and width



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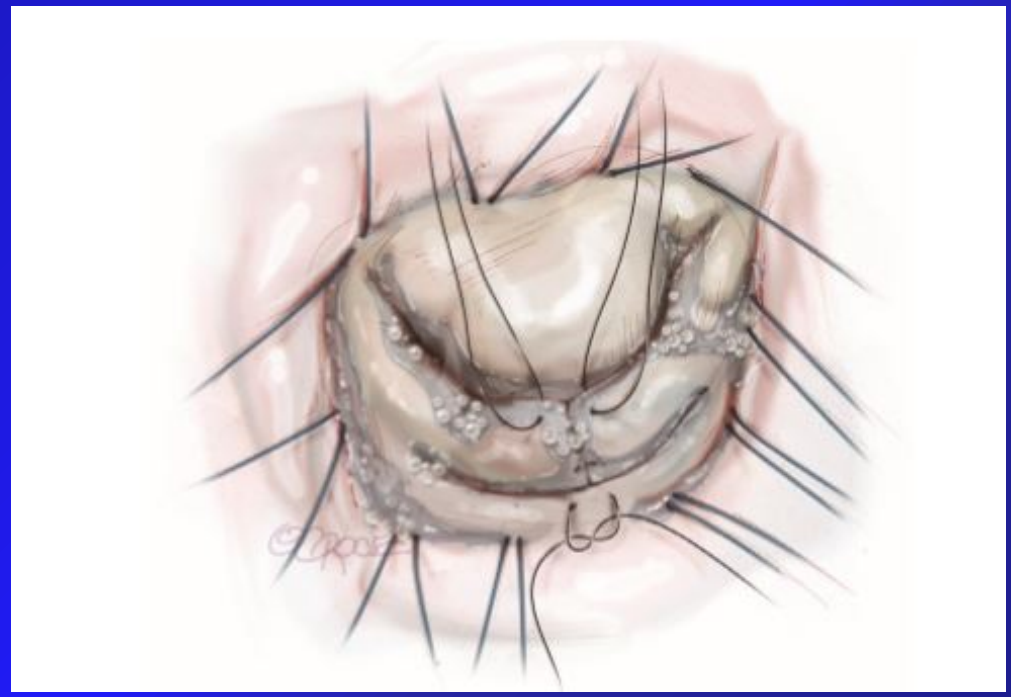
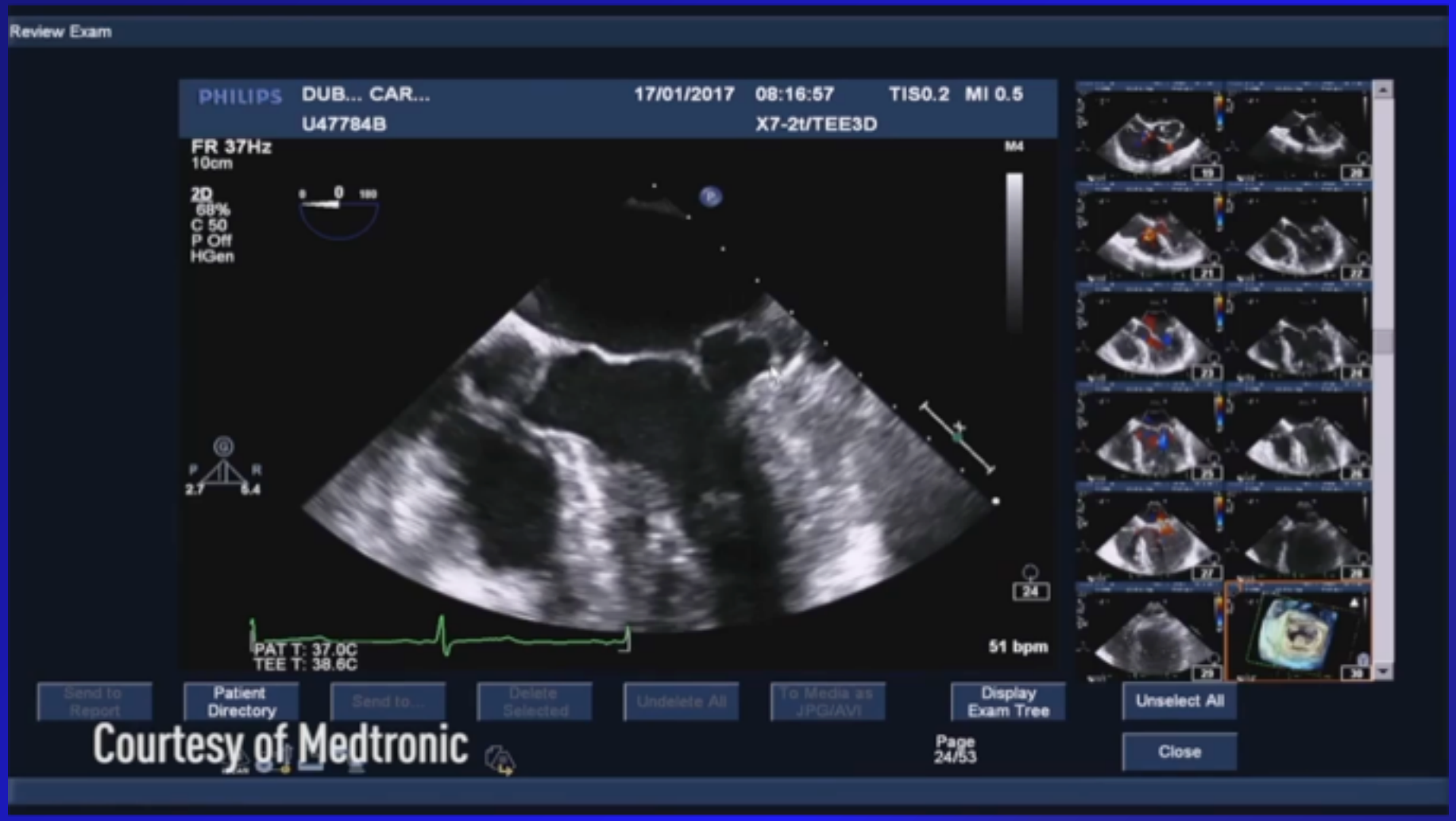
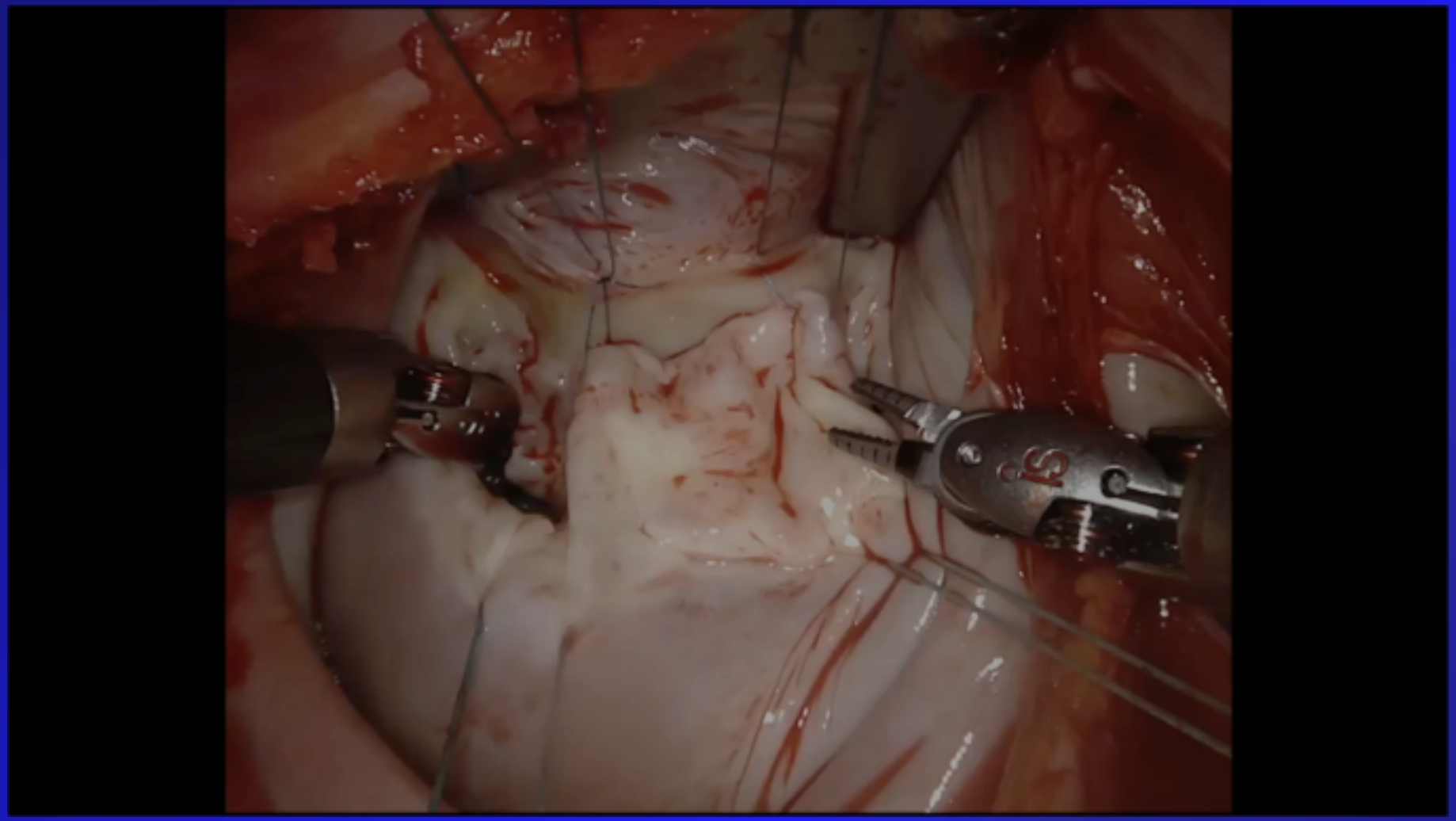


Tohru Asai, Ann Cardiothorac Surg 2015.4(4):370-375

Sternotomy: Height, Width, Prolapse Treatment



Robotic: Height, Width, Prolapse, PC Treatment



In our personal series, only 18% of PL prolapse were treated without any resection.

Surgery consisted only in resuspension of a localised prolapsed area

Sternotomy = endoscopy = robotic

Minimal access vs Sternotomy?

The Magnitude of the Problem

- Sternotomy looks old fashion
- Minimal access is not minimally invasive
- Minimal access attracts patients and might have attract cardiologists before the percutaneous era
- Only percutaneous techniques are minimally invasive

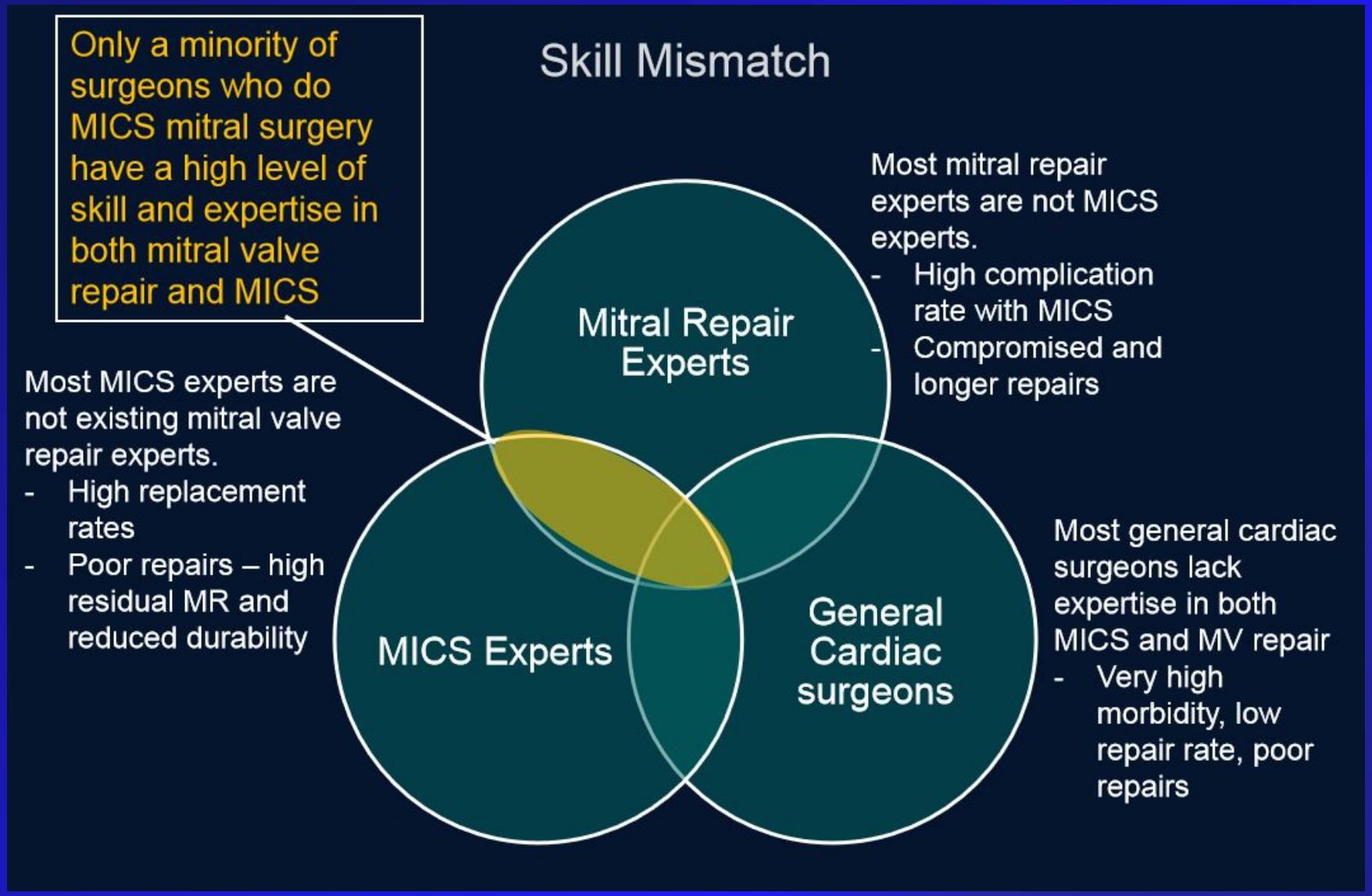
The Magnitude of the Problem

In my generation of heart surgeons:

1) Becoming an expert in MVr and in general cardiac surgery

and thereafter

2) Becoming an expert in minimal access surgery


Only a minority of surgeons who do MICS mitral surgery have a high level of skill and expertise in both mitral valve repair and MICS
Skill Mismatch
Most mitral repair experts are not MICS experts.
- High complication rate with MICS
- Compromised and longer repairs
Mitral Repair Experts
Most MICS experts are not existing mitral valve repair experts.
- High replacement rates
- Poor repairs – high residual MR and reduced durability
MICS Experts
General Cardiac surgeons
Most general cardiac surgeons lack expertise in both MICS and MV repair
- Very high morbidity, low repair rate, poor repairs

Learning curve in MVr

- If it takes 100 cases to become an expert in open MVr
- If it takes 100 cases to become an expert in minimal access MVr

200 cases in a short period of time to be efficient
in both procedures

→ 50 cases per year to maintain proficiency

Learning curve in minimal access surgery

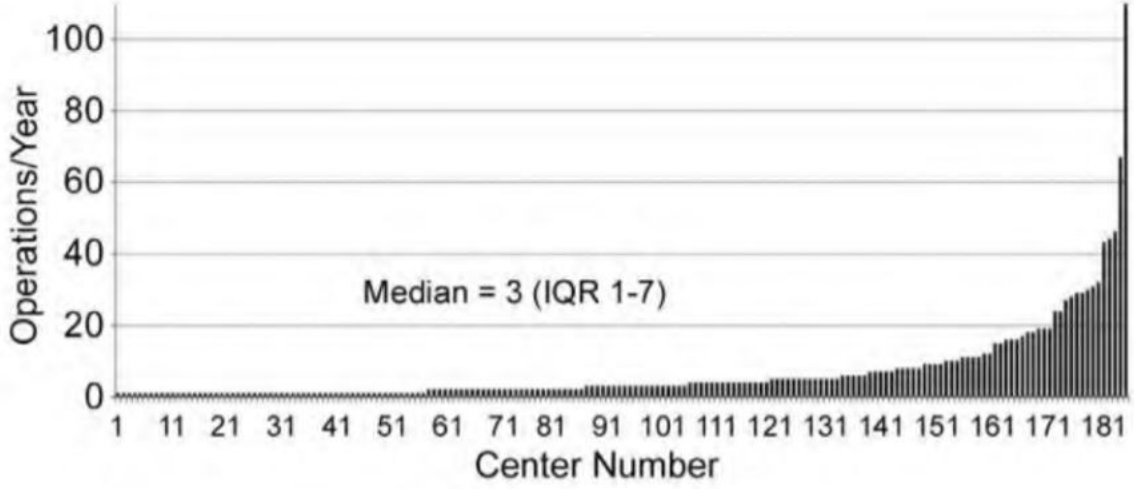


Fig 3. Distribution of less-invasive mitral valve operations among centers performing this operation. (IQR = interquartile range.)

Gammie et al. Ann Thorac Surg 2010; 90: 1401-10

Learning curve in minimal access surgery

Learning Minimally Invasive Mitral Valve Surgery

A Cumulative Sum Sequential Probability Analysis of 3895 Operations From a Single High-Volume Center

David M. Holzhey, MD, PhD; Joerg Seeburger, MD; Martin Misfeld, MD, PhD; Michael A. Borger, MD, PhD; Friedrich W. Mohr, MD, PhD

Background—Learning curves are vigorously discussed and viewed as a negative aspect of adopting new procedures. However, very few publications have methodically examined learning curves in cardiac surgery, which could lead to a better understanding and a more meaningful discussion of their consequences. The purpose of this study was to assess the learning process involved in the performance of minimally invasive surgery of the mitral valve using data from a large, single-center experience.

Methods and Results—All mitral (including tricuspid, or atrial fibrillation ablation) operations performed over a 17-year period through a right lateral mini-thoracotomy with peripheral cannulation for cardiopulmonary bypass (n=3907) were analyzed. Data were obtained from a prospective database. Individual learning curves for operation time and complication rates (using sequential probability cumulative sum failure analysis) and average results were calculated. A total of 3895 operations by 17 surgeons performing their first minimally invasive surgery of the mitral valve operation at our institution could be evaluated. The typical number of operations to overcome the learning curve was between 75 and 125. Furthermore, >1 such operation per week was necessary to maintain good results. Individual learning curves varied markedly, proving the need for good monitoring or mentoring in the initial phase.

Conclusions—A true learning curve exists for minimally invasive surgery of the mitral valve. Although the number of operations required to overcome the learning curve is substantial, marked variation exists between individual surgeons. Such information could be very helpful in structuring future training and maintenance of competence programs for this kind of surgery. (***Circulation*. 2013;128:483–491.**)

Is minimal access surgery suitable for all cases?

Simple cases

What is a simple case?

- **One lesion : excess width or excess height with elongated and/or ruptured chordae**
- **Sternotomy = Robotic = Endoscopic**

Is minimal access surgery suitable for all cases?

Complexe cases

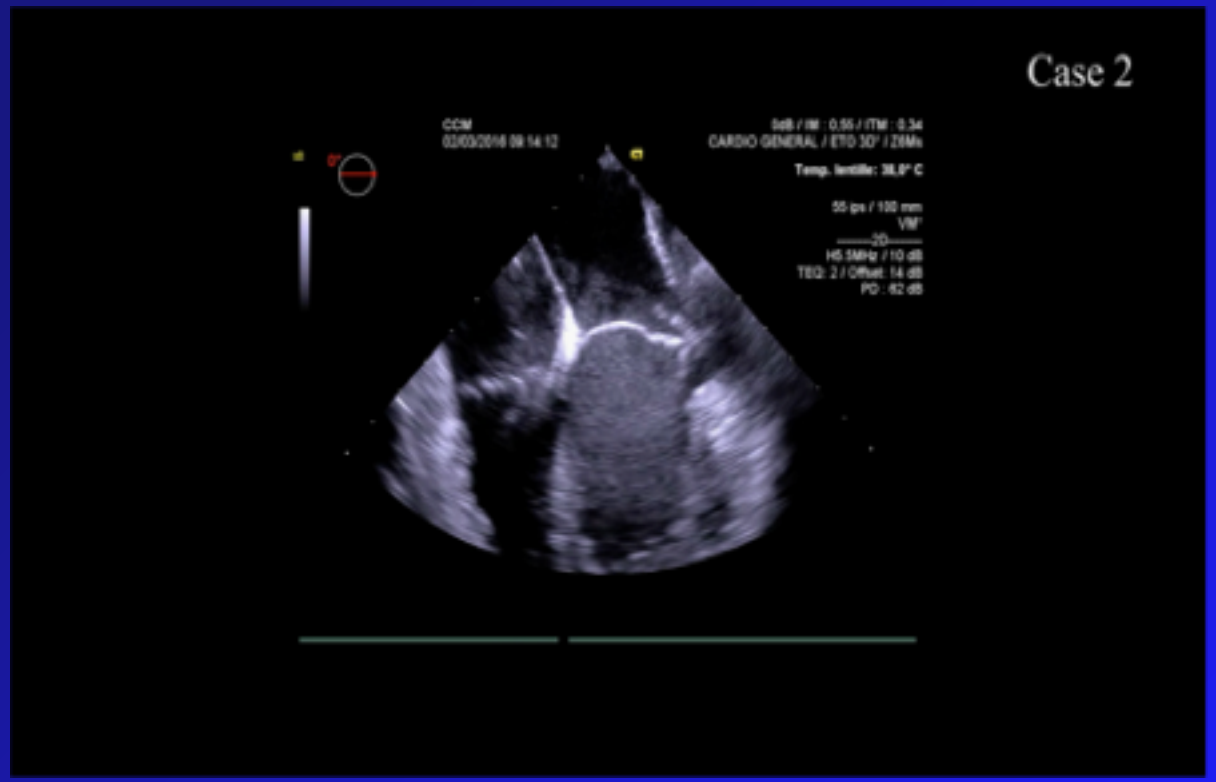
What is a complex case?

- Depends on surgical interpretation and expertise
- Multiple PL lesions
- Commissural prolapse
- Pathological indentations
- « Hyper Barlows »
- Annular calcifications

Complex Case

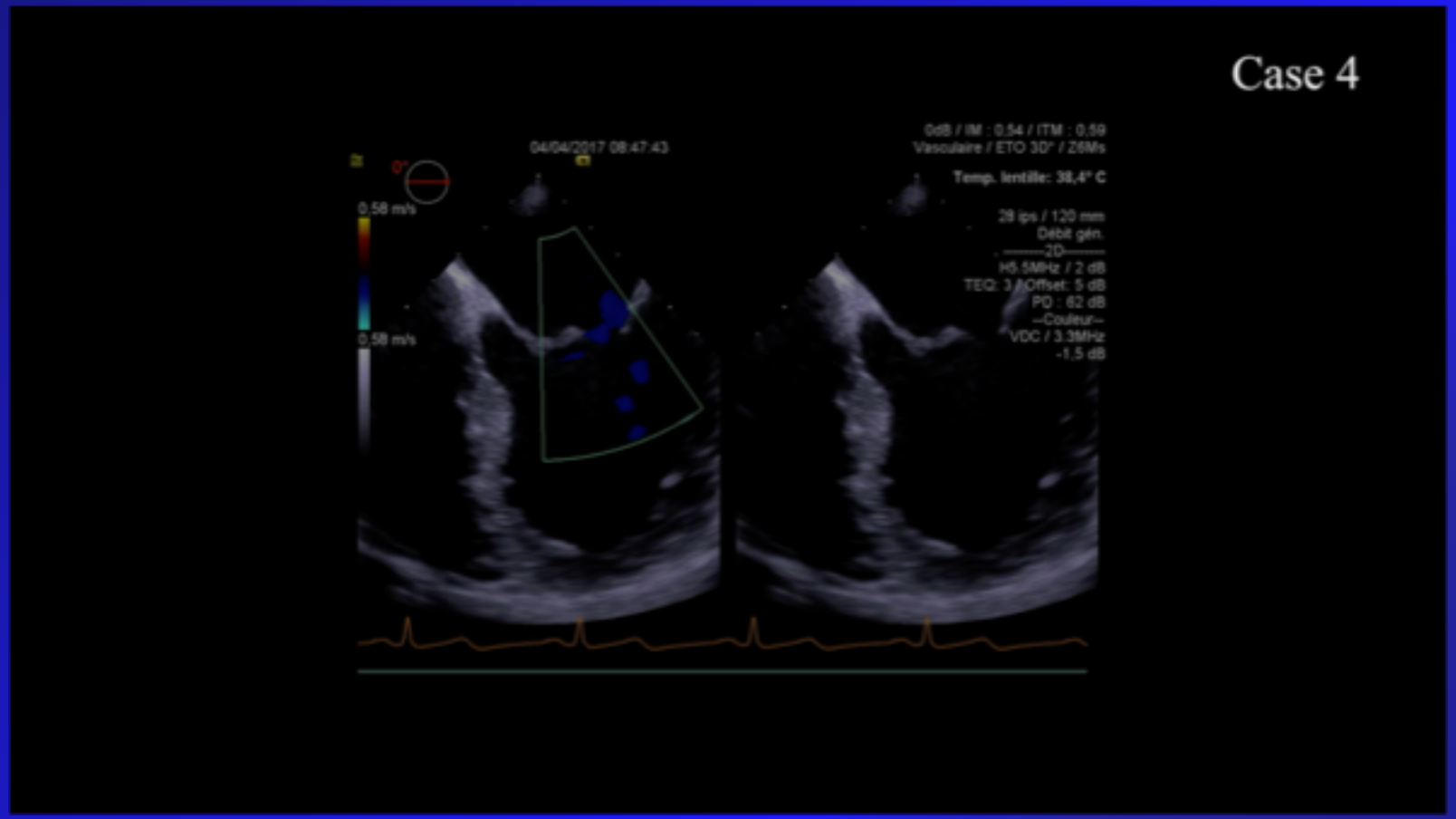
Multiple Lesion

Minimally invasive approch should not allow incomplete repair



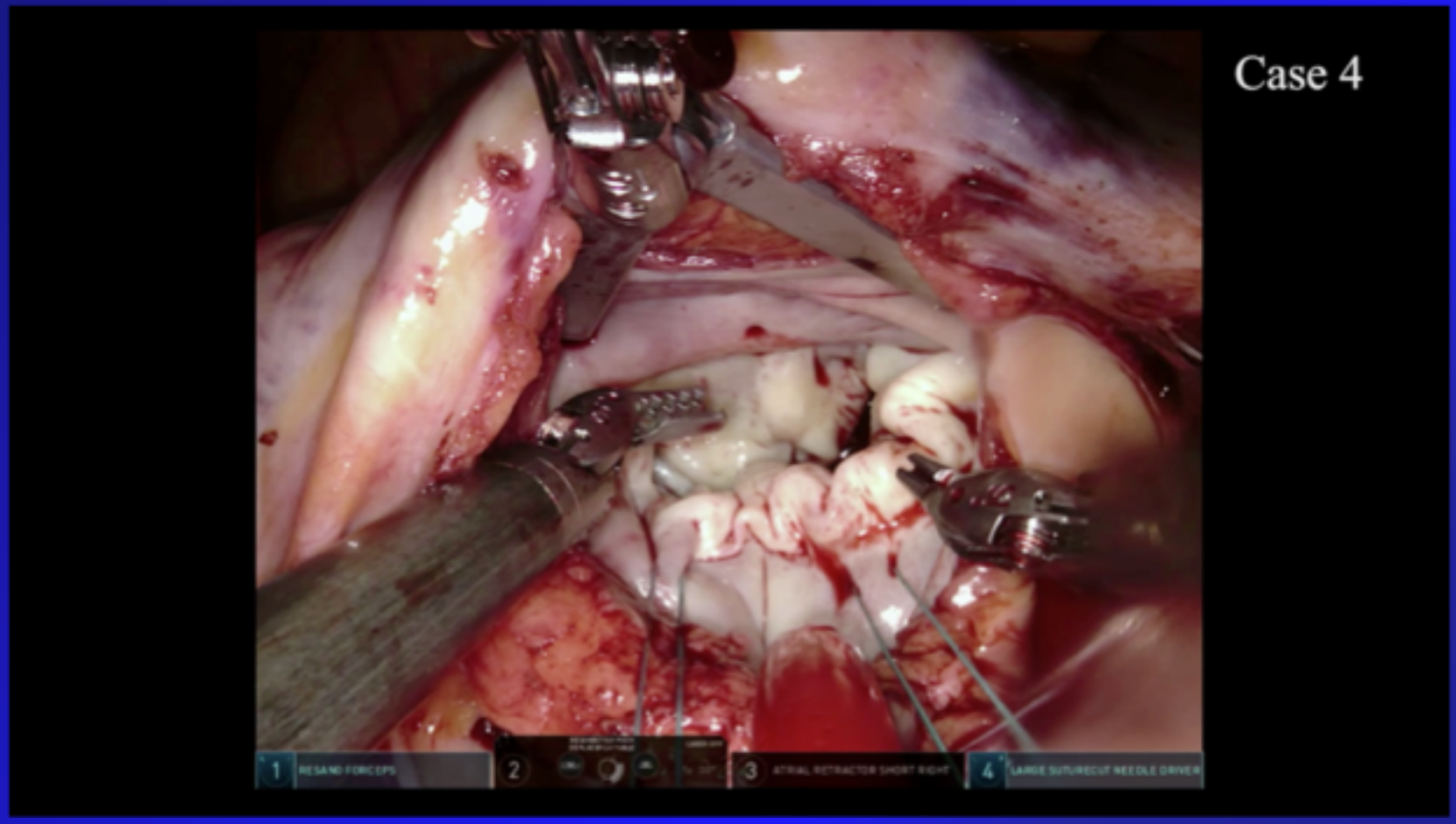
Complex Case - Hyper Barlow

Preop echo



Complex Cases - Hyper Barlow

Surgery



Sternotomy = Endoscopy = Robotic

IF and only if

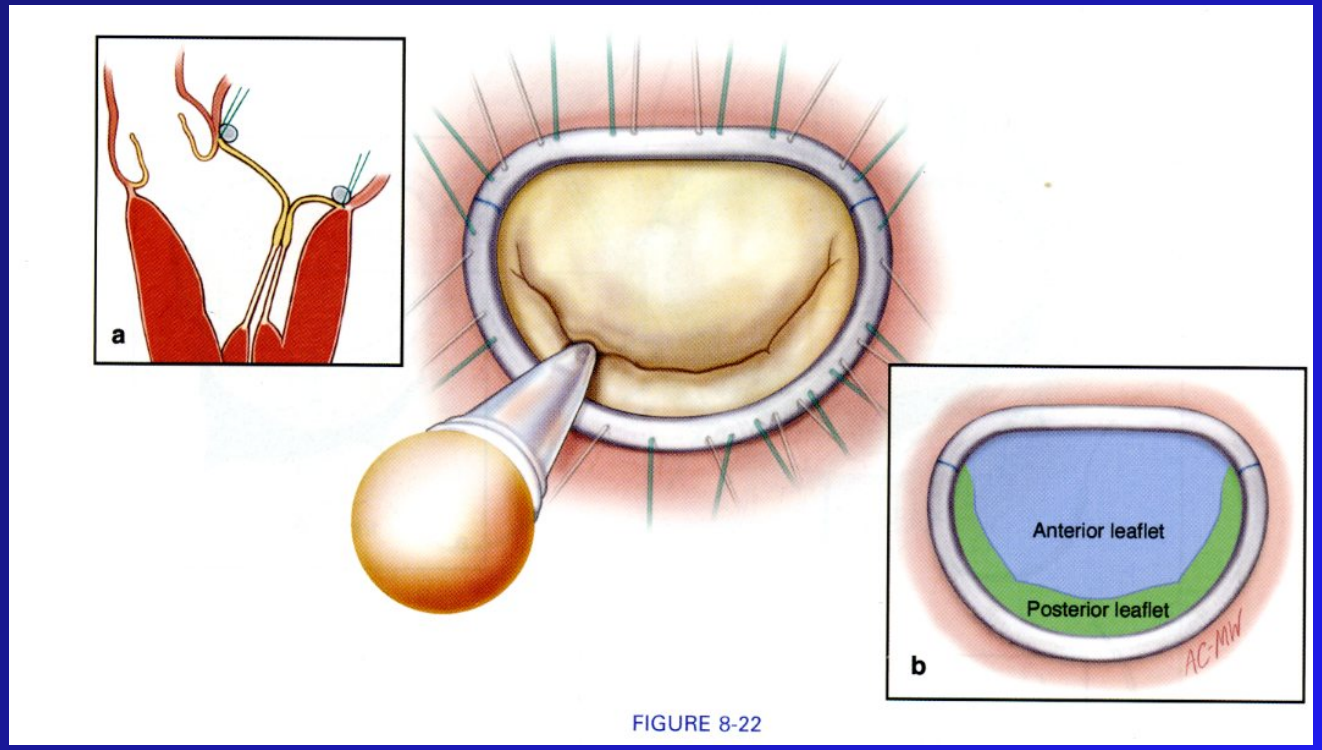


FIGURE 8-22

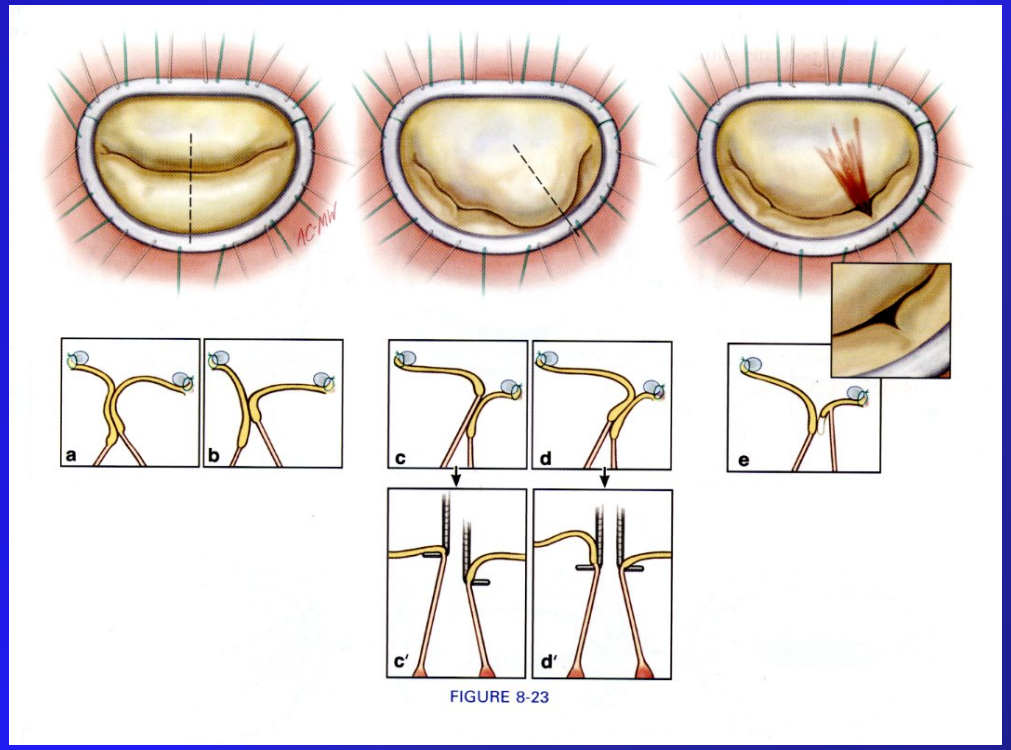


FIGURE 8-23

Carpentier's Reconstructive valve surgery, 2010

Surgery vs Percutaneous treatment ?

Edge-to-Edge is not efficient without Annuloplasty

Long-Term Results (≤18 Years) of the Edge-to-Edge Mitral Valve Repair Without Annuloplasty in Degenerative Mitral Regurgitation

Implications for the Percutaneous Approach

Michele De Bonis, MD; Elisabetta Lapenna, MD; Francesco Maisano, MD;
Fabio Barili, MD, PhD; Giovanni La Canna, MD; Nicola Buzzatti, MD;

Conclusions—In degenerative MR, the overall long-term results of the surgical edge-to-edge technique without annuloplasty are not satisfactory. Early optimal competence (residual MR ≤1+) was associated with higher freedom from recurrent severe regurgitation. (***Circulation***. **2014;130[suppl 1]:S19-S24.**)

suture without any annuloplasty. Annuloplasty was omitted in 36 patients because of heavy annular calcification and in 25 for limited annular dilatation. A double-orifice repair was performed in 53 patients and a commissural edge-to-edge in 8. Hospital mortality was 1.6%. Follow-up was 100% complete (mean length, 9.2±4.21 years; median, 9.7; longest, 18.1). Survival at 12 years was 51.3±7.75%. At the last echocardiographic examination, MR ≥3+ was demonstrated in 33 patients (55%). At 12 years, freedom from reoperation was 57.8±7.21% and freedom from recurrence of MR ≥3+ was 43±7.6%. Residual MR >1+ at hospital discharge was identified as a risk factor for recurrence of MR ≥3+ (hazard ratio, 3.8; 95% confidence interval, 1.7–8.2; P=0.001). In patients with residual MR ≤1+ immediately after surgery, freedom from MR ≥3+ at 5 and 10 years was 80±6% and 64±7.58%, respectively.

Conclusions—In degenerative MR, the overall long-term results of the surgical edge-to-edge technique without annuloplasty are not satisfactory. Early optimal competence (residual MR ≤1+) was associated with higher freedom from recurrent severe regurgitation. (***Circulation***. **2014;130[suppl 1]:S19-S24.**)

EVEREST II

4-Year Results of a Randomized Controlled Trial of Percutaneous Repair Versus Surgery for Mitral Regurgitation

Laura Mauri, MD,*† Elyse Foster, MD,‡ Donald D. Glower, MD,§ Patricia Apruzzese, MS,† Joseph M. Massaro, PhD,†‖ Howard C. Herrmann, MD,¶ James Hermiller, MD,# William Gray, MD,** Andrew Wang, MD,‡ Wesley R. Pedersen, MD,†† Tanvir Bajwa, MD,‡‡ John Lasala, MD, PhD,§§ Reginald Low, MD,‖‖ Paul Grayburn, MD,¶¶ Ted Feldman, MD,## for the EVEREST II Investigators

Boston, Massachusetts; San Francisco and Davis, California; Durham, North Carolina; Philadelphia, Pennsylvania; Indianapolis, Indiana; New York, New York; Minneapolis, Minnesota; Milwaukee, Wisconsin; St. Louis, Missouri; Dallas, Texas; and Evanston, Illinois

Objectives This study sought to evaluate 4-year outcomes of percutaneous repair versus surgery for mitral regurgitation.

Conclusions Patients treated with percutaneous repair of the mitral valve more commonly required surgery to treat residual MR; however, after the first year of follow-up, there were few surgeries required after either percutaneous or surgical treatment and no difference in the prevalence of moderate-severe and severe MR or mortality at 4 years.

to 5 years of follow-up.

Results At 4 years, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ MR in the intention-to-treat population was 39.8% versus 53.4% in the percutaneous repair group and surgical groups, respectively ($p = 0.070$). Rates of death were 17.4% versus 17.8% ($p = 0.914$), and 3+ or 4+ MR was present in 21.7% versus 24.7% ($p = 0.745$) at 4 years of follow-up, respectively. Surgery for mitral valve dysfunction, however, occurred in 20.4% versus 2.2% ($p < 0.001$) at 1 year and 24.8% versus 5.5% ($p < 0.001$) at 4 years.

Conclusions Patients treated with percutaneous repair of the mitral valve more commonly required surgery to treat residual MR; however, after the first year of follow-up, there were few surgeries required after either percutaneous or surgical treatment and no difference in the prevalence of moderate-severe and severe MR or mortality at 4 years. (Endovascular Valve Edge-to-Edge Repair Study [EVEREST II]; NCT00209274) (J Am Coll Cardiol 2013;62:317–28)

4-Year Results of a Randomized Controlled Trial of Percutaneous Repair Versus Surgery for Mitral Regurgitation

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Methods Patients with grade 3+ or 4+ MR were randomly assigned to percutaneous repair with the MitraClip (Abbott, Menlo Park, California) device or conventional mitral valve surgery in a 2:1 ratio (184:95). Patients prospectively consented to 5 years of follow-up.

Results At 4 years, the rate of the composite endpoint of freedom from death, surgery, or 3+ or 4+ MR in the intention-to-treat population was 39.8% versus 53.4% in the percutaneous repair group and surgical groups, respectively ($p = 0.070$). Rates of death were 17.4% versus 17.8% ($p = 0.914$), and 3+ or 4+ MR was present in 21.7% versus 24.7% ($p = 0.745$) at 4 years of follow-up, respectively. Surgery for mitral valve dysfunction, however, occurred in 20.4% versus 2.2% ($p < 0.001$) at 1 year and 24.8% versus 5.5% ($p < 0.001$) at 4 years.

Conclusions Patients treated with percutaneous repair of the mitral valve more commonly required surgery to treat residual MR; however, after the first year of follow-up, there were few surgeries required after either percutaneous or surgical treatment and no difference in the prevalence of moderate-severe and severe MR or mortality at 4 years. (Endovascular Valve Edge-to-Edge Repair Study [EVEREST II]; NCT00209274) (J Am Coll Cardiol 2013;62:317–28)

Everest II Trial

Table 1 Baseline Characteristics

Characteristic*	Percutaneous Repair Group (n = 184)	Surgical Group (n = 95)
Age, yrs, mean ± SD (n)	67.3 ± 12.8 (184)	65.7 ± 12.9 (95)
Sex		
Male	62.5% (115/184)	66.3% (63/95)
Female	37.5% (69/184)	33.7% (32/95)
Comorbidities		
Congestive heart failure	90.8% (167/184)	77.9% (74/95)
Atrial fibrillation	33.7% (59/175)	39.3% (35/89)
Coronary artery disease	47.0% (86/183)	46.3% (44/95)
Prior myocardial infarction	21.9% (40/183)	21.3% (20/94)
Previous CABG	20.7% (38/184)	18.9% (18/95)
Previous percutaneous intervention	24.0% (44/183)	15.8% (15/95)
Hypercholesterolemia	61.0% (111/182)	62.8% (59/94)
Hypertension	72.3% (133/184)	78.9% (75/95)
Diabetes mellitus	7.6% (14/184)	10.5% (10/95)
Chronic pulmonary disease	14.8% (27/183)	14.8% (14/95)
LVEF, %	60.0 ± 10.1 (182)	60.6 ± 11.0 (95)
NYHA functional class, % (n/N)		
I	9.2% (17/184)	20.0% (19/95)
II	39.7% (73/184)	32.6% (31/95)
III	44.6% (82/184)	43.2% (41/95)
IV	6.5% (12/184)	4.2% (4/95)
MR, % (n/N)		
1+ to 2+, mild-to-moderate	0.0% (0/184)	1.1% (1/95)
2+, moderate	4.3% (8/184)	6.3% (6/95)
3+, moderate-to-severe	70.7% (130/184)	70.5% (67/95)
4+, severe	25.0% (46/184)	22.1% (21/95)
Regurgitant volume, ml/beat	42.0 ± 23.3 (174)	45.2 ± 26.6 (88)
Regurgitant orifice area, cm^2	0.56 ± 0.38 (171)	0.59 ± 0.35 (87)
MR etiology, % (n/N)		
Functional	26.6% (49/184)	27.4% (26/95)
Degenerative		
With anterior or bileaflet flail, or prolapse	31.5% (58/184)	26.3% (25/95)
With posterior flail or prolapse	39.1% (72/184)	44.2% (42/95)
? With neither flail nor prolapse?	2.7% (5/184)	2.1% (2/95)

Mauri et al., *J Am Coll Cardiol*. 2013 Jul 23;62(4):317-28

Eur J Cardiothorac Surg. 2016 Mar 23. pii: ezw093. [Epub ahead of print]

Optimal results immediately after MitraClip therapy or surgical edge-to-edge repair for functional mitral regurgitation: are they really stable at 4 years?

De Bonis M[1], Lapenna E[2], Buzzatti N[2], La Canna G[2], Denti P[2], Pappalardo F[2], Schiavi D[2], Pozzoli A[2], Cioni M[2], Di Giannuario G[2], Alfieri O[2].

Table 1: Clinical and echocardiographic preoperative data in the 'MitraClip' and 'Surgical edge-to-edge' groups

	MitraClip group $n = 85$	Surgical EE group $n = 58$	*P*-value
Male gender (*n*, %)	70 (82)	40 (69)	0.06
Age (years)	69 ± 9.4	62 ± 10.1	0.0001
Ischaemic DCM (*n*, %)	62 (73)	36 (62)	0.1
NYHA class (*n*, %)			0.9
II	13 (15)	9 (15)	
III	57 (67)	36 (62)	
IV	15 (17)	13 (22)	
Atrial fibrillation (*n*, %)	24 (28)	12 (20)	0.3
Log EuroSCORE	19 ± 15.9	11.4 ± 3.2	0.04
LVEF (%)	28 ± 9.7	28 ± 6.5	
LVEDD (mm)	67 ± 7.8	69 ± 5.8	0.1
LVESD (mm)	54 ± 9.1	52 ± 7.9	0.3
LVEDV (ml)	188 ± 66.2	203 ± 58.02	0.1
SPAP (mmHg)	47 ± 14.2	48 ± 13.2	0.5
SPAP > 40 mmHg (*n*, %)	46 (54)	33 (56)	0.1
TR 3+ or 4+ (*n*, %)	17 (20)	11 (19)	0.8
Coaptation depth (cm)	1.2 ± 0.34	1.2 ± 0.46	0.5
Tented area (cm^2)	2.8 ± 0.99	2.8 ± 0.88	0.6

LVEF: left ventricular ejection fraction; LVEDD: left ventricular end-diastolic diameter; LVESD: left ventricular end-systolic diameter; LVEDV: left ventricular end-diastolic volume; SPAP: systolic pulmonary artery pressure; TR: tricuspid regurgitation; EE: edge-to-edge; NYHA: New York Heart Association; DCM: dilated cardiomyopathy.

Everest II

60.0 ± 10.1 (182) 60.6 ± 11.0 (95)

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Author information

Abstract

OBJECTIVES: Recurrent mitral regurgitation (MR) is common after surgical and percutaneous (MitraClip) treatment of functional MR (FMR). However, the Everest II trial suggested that, in patients with secondary MR and initially successful MitraClip therapy, the **results** were sustained at 4 years and were comparable with surgery in terms of late efficacy. The aim of this study was to assess whether both those findings were confirmed by our own experience.

pendent predictor of both recurrent MR ≥ 3 and MR ≥ 2+. The absence of a concomitant annuloplasty is one of the most likely explanation of the higher recurrence rate of MR in the percutaneous approach despite the initial restoration of valve competence [16, 17]. We already reported that, in secondary MR, MitraClip is

Afterwards, patients with an echocardiographic follow-up at 2 years (60 patients), 3 years (40 patients) and 4 years (21 patients) showed a significant increase in the severity of MR compared with the corresponding 1 year grade (all P < 0.01). Freedom from MR ≥ 3+ at 4 years was 75 ± 7.6% in the MitraClip group and 94 ± 3.3% in the surgical one (P = 0.04). Freedom from MR ≥ 2+ at 4 years was 37 ± 7.2 vs 82 ± 5.2%, respectively (P = 0.0001). Cox regression analysis identified the use of MitraClip as a predictor of recurrence of MR ≥ 2+ [hazard ratio (HR) 5.2, 95% confidence interval (CI) 2.5-10.8, P = 0.0001] as well as of MR ≥ 3 (HR 3.5, 95% CI 0.9-13.1, P = 0.05).

CONCLUSIONS: In patients with FMR and **optimal** mitral competence after MitraClip implantation, the recurrence of significant MR at 4 years is not uncommon. This study does not confirm previous observations reported in the Everest II randomized controlled trial indicating that, if the MitraClip therapy was initially successful, the **results** were sustained at 4 years. When compared with the surgical EE combined with annuloplasty, MitraClip therapy provides lower efficacy at 4 years.

EVEREST II TRIAL

Table 3 Effectiveness Endpoint and Components at 4 Years

	1 Year			4 Years		
	Percutaneous Repair	Surgical	p Value	Percutaneous Repair	Surgical	p Value
Freedom from death, MV surgery or reoperation, and MR 3+ or 4+	55.2% (100/181)	73.0% (65/89)	0.007	39.8% (64/161)	53.4% (39/73)	0.070
Death	6.1% (11/181)	5.6% (5/89)	1.000	17.4% (28/161)	17.8% (13/73)	0.914
MV surgery or reoperation	20.4% (37/181)	2.2% (2/89)	<0.001	24.8% (40/161)	5.5% (4/73)	<0.001
MR 3+ or 4+ at follow-up	21.0% (38/181)	20.2% (18/89)	1.000	21.7% (35/161)	24.7% (18/73)	0.745

Mauri et al., *J Am Coll Cardiol*. 2013 Jul 23;62(4):317-28

ALFIERI STITCH

MITRACLIP

Eur J Cardiothorac Surg. 2016 Mar 23. pii: ezw093. [Epub ahead of print]

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(*P* = 0.0001). Finally, a decrease in the LVEDD was documented for surgery (from 69 ± 5.5 to 62 ± 9.5 mm, *P* = 0.0001) but not for MitraClip (from 67 ± 7.8 to 66 ± 10.3 mm, *P* = 0.1).

Freedom from cardiac death at 4 years (81 ± 5.2 vs 84 ± 4.6%, P = 0.5) was similar in the surgical and MitraClip group. The initial **optimal** MitraClip **results** did not remain stable. At 1 year, 32.5% of the patients had developed MR ≥ 2+ (P = 0.0001 compared with discharge). Afterwards, patients with an echocardiographic follow-up at 2 years (60 patients), 3 years (40 patients) and 4 years (21 patients) showed a significant increase in the severity of MR compared with the corresponding 1 year grade (all P < 0.01). Freedom from MR ≥ 3+ at 4 years was 75 ± 7.6% in the MitraClip group and 94 ± 3.3% in the surgical one (P = 0.04). Freedom from MR ≥ 2+ at 4 years was 37 ± 7.2 vs 82 ± 5.2%, respectively (P = 0.0001). Cox regression analysis identified the use of MitraClip as a predictor of recurrence of MR ≥ 2+ [hazard ratio (HR) 5.2, 95% confidence interval (CI) 2.5-10.8, P = 0.0001] as well as of MR ≥ 3 (HR 3.5, 95% CI 0.9-13.1, P = 0.05).

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patients) and 4 years (21 patients) showed a significant increase in the severity of MR compared with the corresponding 1 year grade (all $P < 0.01$). Freedom from MR ≥ 3+ at 4 years was 75 ± 7.6% in the MitraClip group and 94 ± 3.3% in the surgical one ($P = 0.04$). Freedom from MR ≥ 2+ at 4 years was 37 ± 7.2 vs 82 ± 5.2%, respectively ($P = 0.0001$). Cox regression analysis identified the use of MitraClip as a predictor of recurrence of MR ≥ 2+ [hazard ratio (HR) 5.2, 95% confidence interval (CI) 2.5-10.8, $P = 0.0001$] as well as of MR ≥ 3 (HR 3.5, 95% CI 0.9-13.1, $P = 0.05$).

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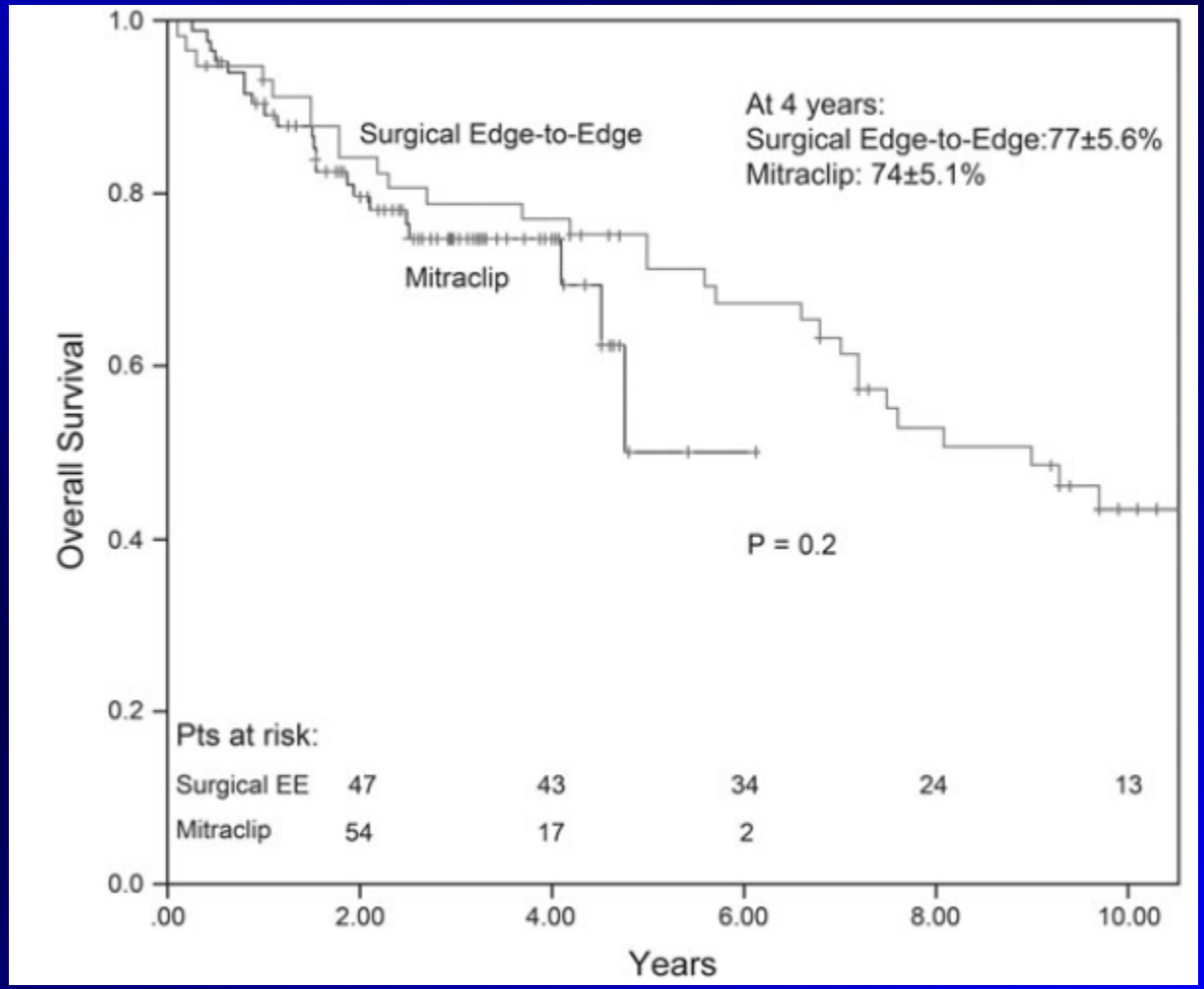
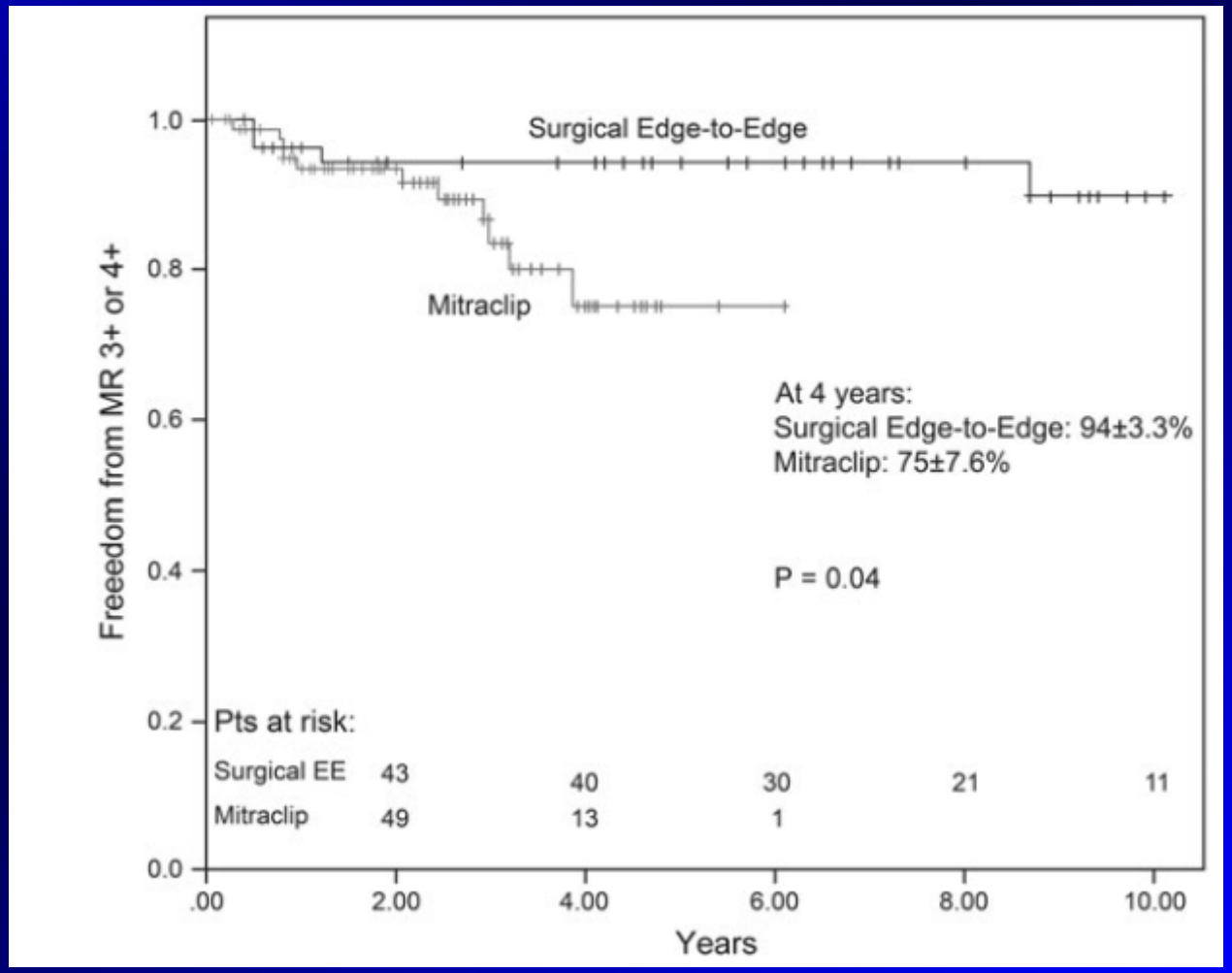
OVERALL SURVIVAL



De Bonis et al., *Eur J Cardiothorac Surg*. 2016 March;50(3):488-94

FREEDOM FROM MR 3+ OR 4+



De Bonis et al., *Eur J Cardiothorac Surg*. 2016 March;50(3):488-94

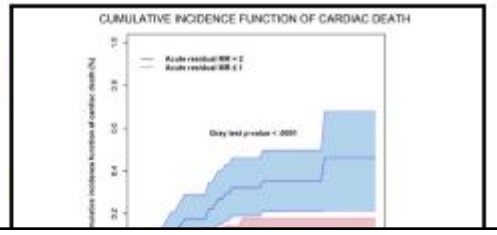
What is a "good" result after transcatheter mitral repair? Impact of 2+ residual mitral regurgitation

Nicola Buzzatti, MD,[a] Michele De Bonis, MD,[a] Paolo Denti, MD,[a] Fabio Barili, MD,[b] Davide Schiavi, BS,[a] Giovanna Di Giannuario, MD,[a] Giovanni La Canna, MD,[a] and Ottavio Alfieri, MD[a]

ABSTRACT

Objective: The study objective was to assess the impact on follow-up outcomes of residual mitral regurgitation 2+ in comparison with ≤1+ after MitraClip (Abbott Vascular Inc, Santa Clara, Calif) repair.

Methods: We compared the outcomes of mitral regurgitation 2+ and mitral regurgitation <1+ groups among a population of 223 consecutive patients with



Conclusions: Residual 2+ mitral regurgitation after MitraClip implantation was associated with worse follow-up outcomes compared with <1+ mitral regurgitation, including survival, symptom relief, and mitral regurgitation recurrence. Better efficacy should be pursued by transcatheter mitral repair technologies. (J Thorac Cardiovasc Surg 2016;151:88-96)

15.3% ± 3.8% and 43.2% ± 6.8%, respectively (Gray test $P < .001$). Multivariate model showed that mitral regurgitation 2+ was the only factor associated with the development of mitral regurgitation ≥3+ at follow-up (adjusted hazard ratio, 6.71; 95% confidence interval, 3.48-12.90; $P < .001$). Mitral regurgitation cause was not associated with cardiac death and recurrence of mitral regurgitation ≥3+ at follow-up. No relationship between New York Heart Association class and follow-up time after MitraClip implant was found (odds ratio, 1.07; 95% confidence interval, 0.98-1.15; $P = .11$), and factors related to postoperative New York Heart Association also included residual mitral regurgitation 2+ ($P = .07$).

Conclusions: Residual 2+ mitral regurgitation after MitraClip implantation was associated with worse follow-up outcomes compared with ≤1+ mitral regurgitation, including survival, symptom relief, and mitral regurgitation recurrence. Better efficacy should be pursued by transcatheter mitral repair technologies. (J Thorac Cardiovasc Surg 2016;151:88-96)

Perspective

Residual 2+ MR is frequent after MitraClip (Abbott Vascular Inc, Santa Clara, Calif) implantation. In our series, it was associated with worse survival, symptom relief, and MR recurrence compared with the ≤1+ MR group. Better efficacy should be pursued by transcatheter mitral repair technologies, especially before expanding indications to lower-risk patients.

See Editorial Commentary page 97.

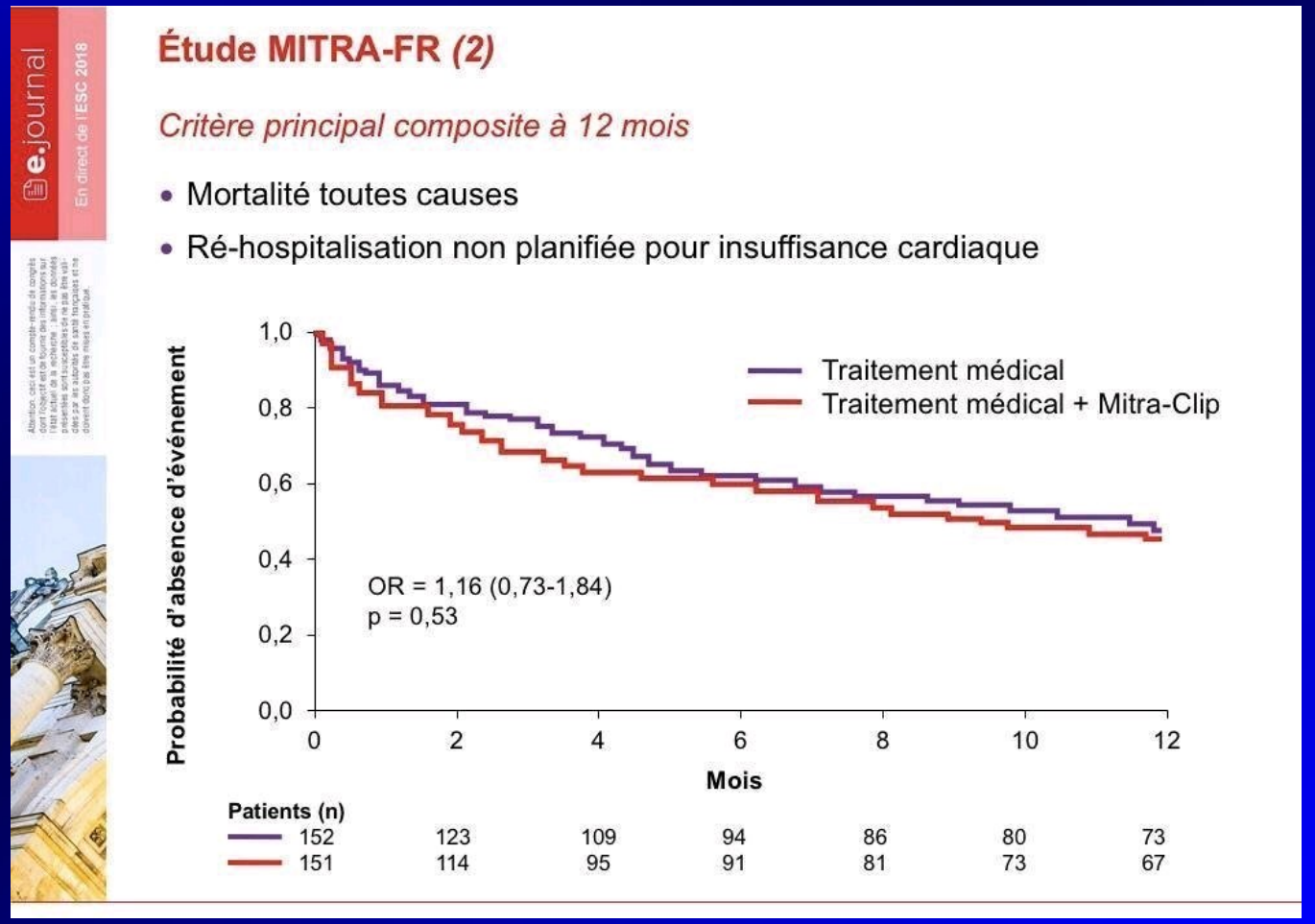
See Editorial page 7.

ORIGINAL ARTICLE

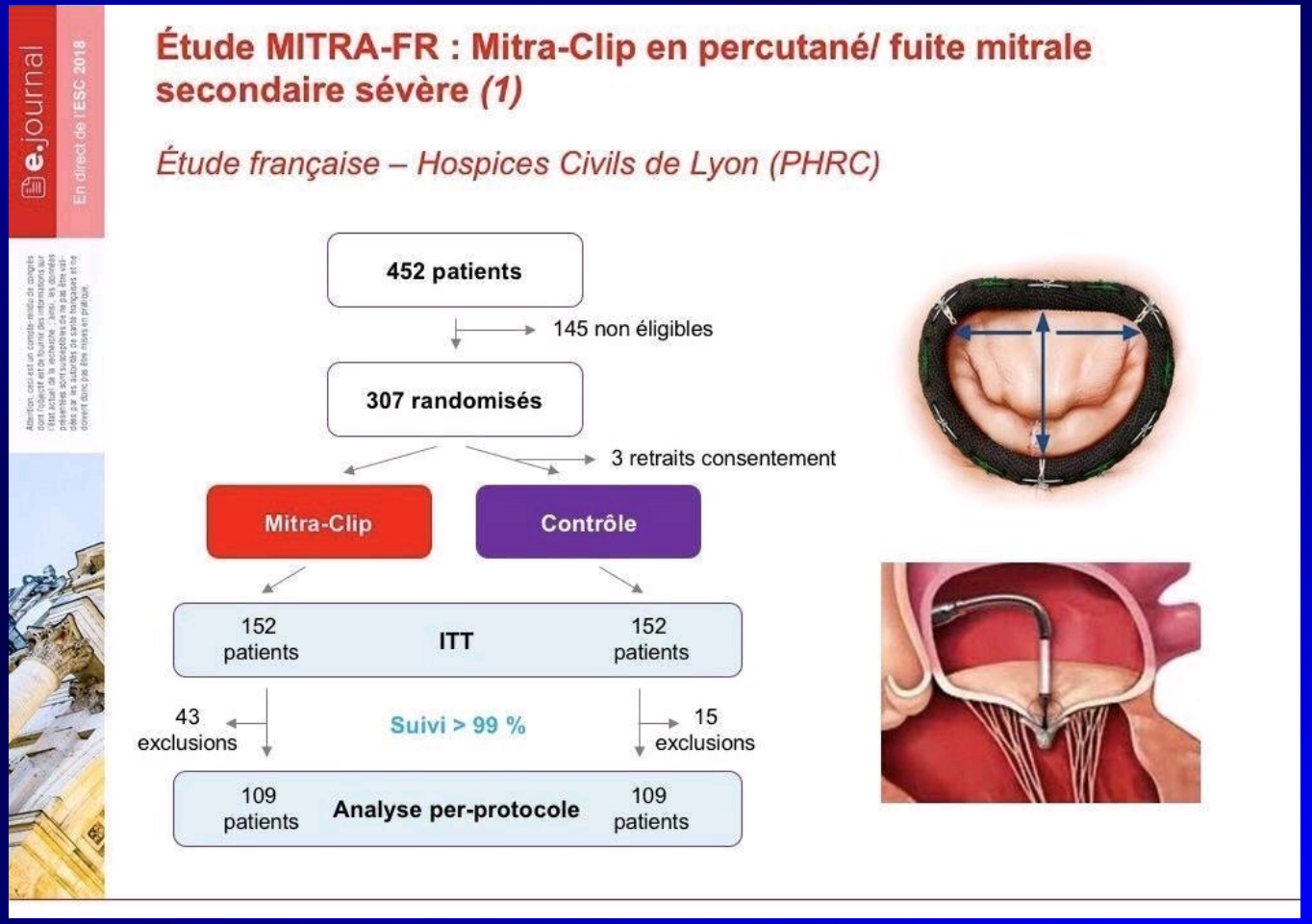
Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

MITRA-FR


e.journal
En direct de l'ESC 2018
Étude MITRA-FR (2)
Critère principal composite à 12 mois
• Mortalité toutes causes
• Ré-hospitalisation non planifiée pour insuffisance cardiaque
Probabilité d'absence d'événement
1,0
0,8
0,6
0,4
0,2
0,0
Traitement médical
Traitement médical + Mitra-Clip
OR = 1,16 (0,73-1,84)
p = 0,53
0
2
4
6
8
10
12
Mois
Patients (n)
152 123 109 94 86 80 73
151 114 95 91 81 73 67

MITRA-FR


e.journal
En direct de l'ESC 2018
Étude MITRA-FR : Mitra-Clip en percutané/ fuite mitrale secondaire sévère (1)
Étude française – Hospices Civils de Lyon (PHRC)
452 patients
145 non éligibles
307 randomisés
3 retraits consentement
Mitra-Clip
Contrôle
152 patients
ITT
152 patients
43 exclusions
Suivi > 99 %
15 exclusions
109 patients
Analyse per-protocole
109 patients

COAPT-Trial

ORIGINAL ARTICLE

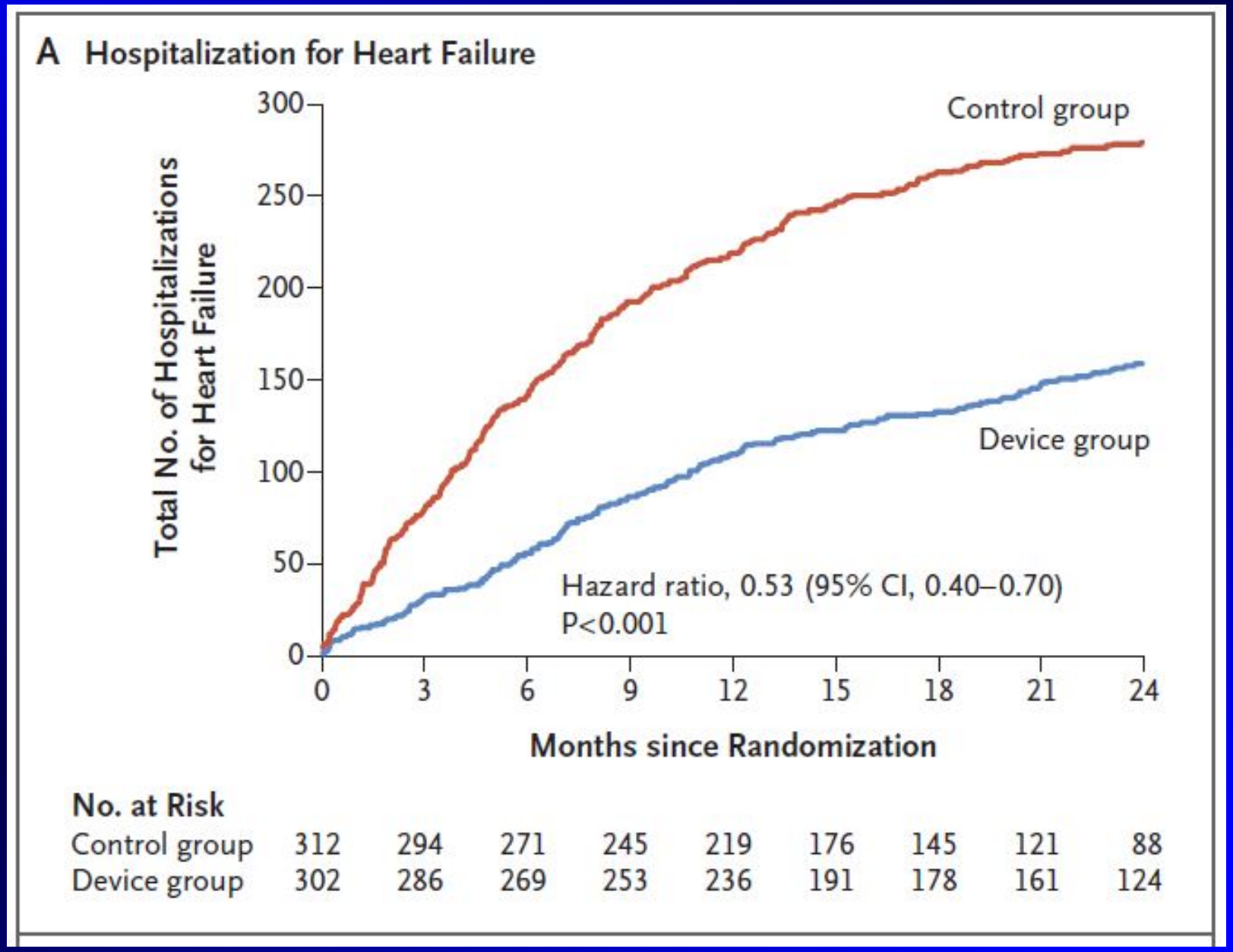
Transcatheter Mitral-Valve Repair in Patients with Heart Failure

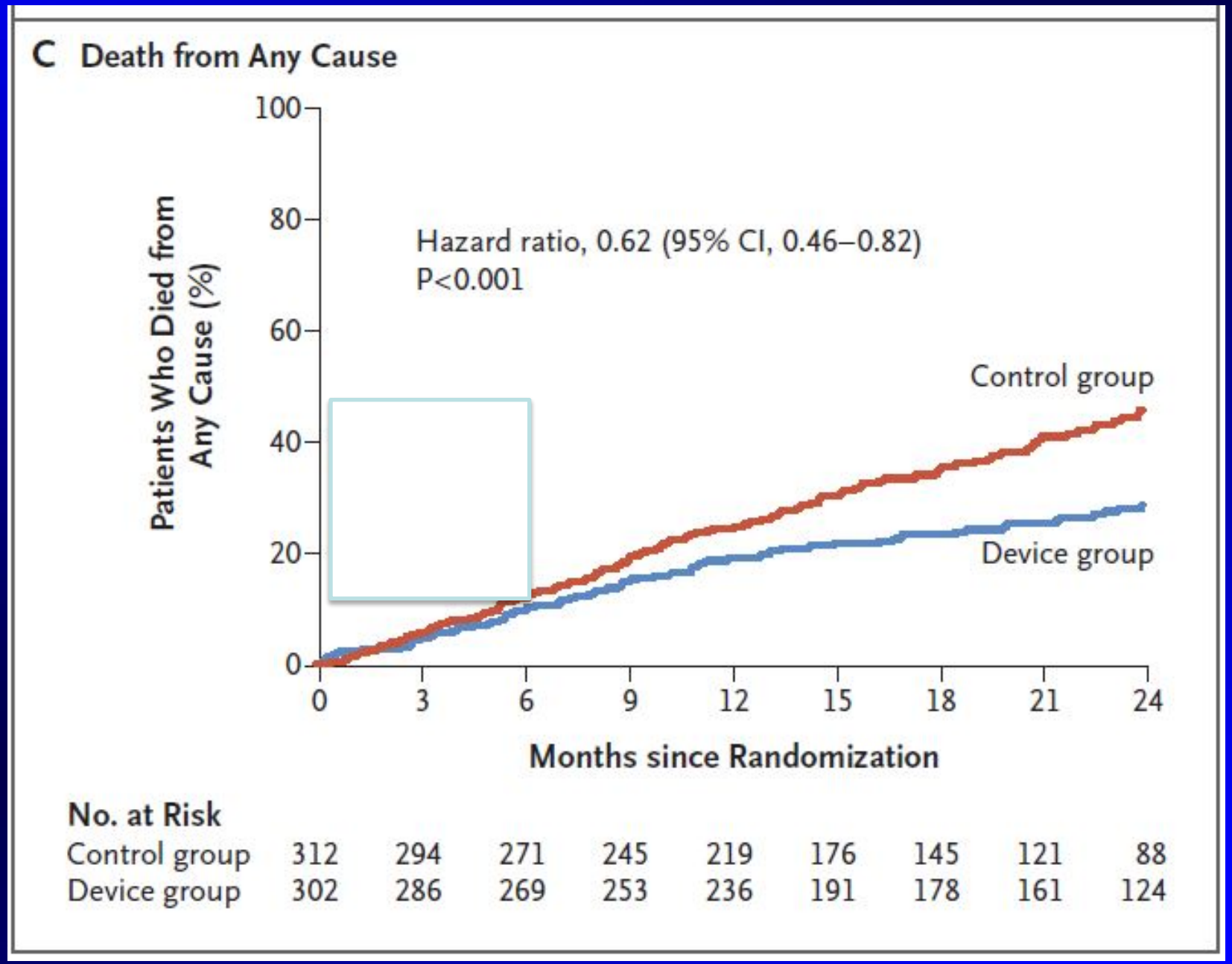
G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

COAPT-Trial

Table 1. (Continued.)

Characteristic	Device Group (N=302)	Control Group (N=312)
Effective regurgitant orifice area — cm^2	0.41±0.15	0.40±0.15
Left ventricular end-systolic dimension — cm	5.3±0.9	5.3±0.9
Left ventricular end-diastolic dimension — cm	6.2±0.7	6.2±0.8
Left ventricular end-systolic volume — ml	135.5±56.1	134.3±60.3
Left ventricular end-diastolic volume — ml	194.4±69.2	191.0±72.9
Left ventricular ejection fraction		
Mean — %	31.3±9.1	31.3±9.6
≤40% — no./total no. (%)	231/281 (82.2)	241/294 (82.0)
Right ventricular systolic pressure — mm Hg	44.0±13.4 (253)	44.6±14.0 (275)


A Hospitalization for Heart Failure
Total No. of Hospitalizations for Heart Failure
300
250
200
150
100
50
0
Control group
Device group
Hazard ratio, 0.53 (95% CI, 0.40–0.70)
P<0.001
0
3
6
9
12
15
18
21
24
Months since Randomization
No. at Risk
Control group 312 294 271 245 219 176 145 121 88
Device group 302 286 269 253 236 191 178 161 124


C Death from Any Cause
Patients Who Died from Any Cause (%)
100
80
60
40
20
0
Hazard ratio, 0.62 (95% CI, 0.46–0.82)
P<0.001
Control group
Device group
0
3
6
9
12
15
18
21
24
Months since Randomization
No. at Risk
Control group 312 294 271 245 219 176 145 121 88
Device group 302 286 269 253 236 191 178 161 124

There are still issues not sorted out

- Does annuloplasty create functional mitral valve stenosis?
- Should MVr receive anticoagulants and how?
- Impact on outcome of high volume centers
- Impact of LA volume on postoperative outcome
- Do semi rigid rings or flexible bands make any difference?