ADVANCES IN CARDIAC ARRHYTHMIAS
and
GREAT INNOVATIONS IN CARDIOLOGY
XXVI Giornate Cardiologiche Torinesi

Turin
October 23-25, 2014
Galleria D'Arte Moderna
Centro Congressi Unione Industriale di Torino

Percutaneous treatment of functional and degenerative mitral regurgitation

DEGENERATIVE MITRAL REGURGITATION: EXPERIENCE AT CENTRO CARDIOLOGICO MONZINO

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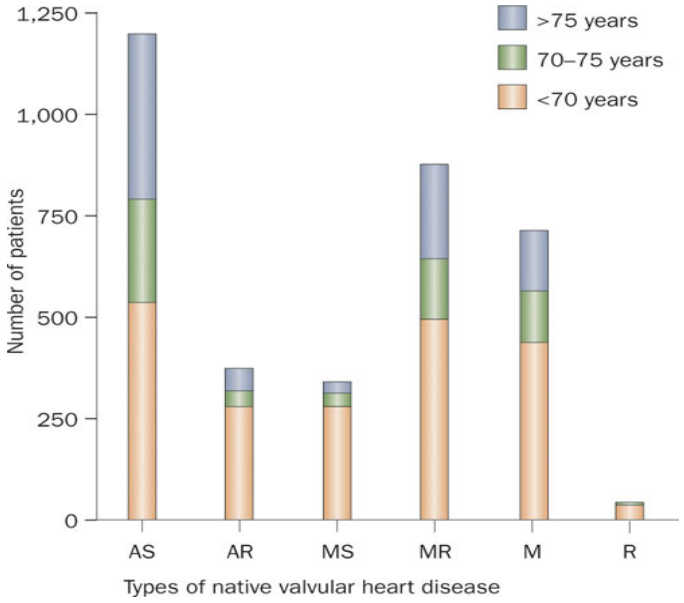
University of Milan

Centro Cardiologico Monzino

MITRAL REGURGITATION: EPIDEMIOLOGY

Distribution of the various types of native valvular heart disease in 3,547 patients in the Euro Heart Survey



Iung, B. & Vahanian, A. (2011) Epidemiology of valvular heart disease in the adult *Nat. Rev. Cardiol.* doi:10.1038/nrcardio.2010.202

nature REVIEWS CARDIOLOGY

MITRAL REGURGITATION: EPIDEMIOLOGY

- MR is the most common type of heart valve insufficiency in Europe and US, affecting millions of people worldwide

- There are more than 600,000 new diagnoses of significant MR each year in Europe and the US; however only 20 percent of these patients undergo surgery each year.

- Mitral valve surgery (repair or replacement) is the second leading valvular surgery performed in Europe and U.S. according to figures reported to the Society for Thoracic Surgeon Database through 2002

- Surgical reported etiologies of MR in patients who undergo surgery are degenerative disease (20-70%), ischemic heart disease (13-30%), rheumatic heart disease (3-40%) and endocarditic (10-12%)

PATIENTS NOT SUITABLE FOR OPEN MITRAL VALVE REPAIR

European Heart Journal (2007) 28, 1358–1365
doi:10.1093/eurheartj/ehm001

Clinical research
Valvular heart disease

What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery?

Mariana Mirabel[1], Bernard Iung[1]*, Gabriel Baron[2], David Messika-Zeitoun[1], Delphine Détaint[1], Jean-Louis Vanoverschelde[3], Eric G. Butchart[4], Philippe Ravaud[2], and Alec Vahanian[1]

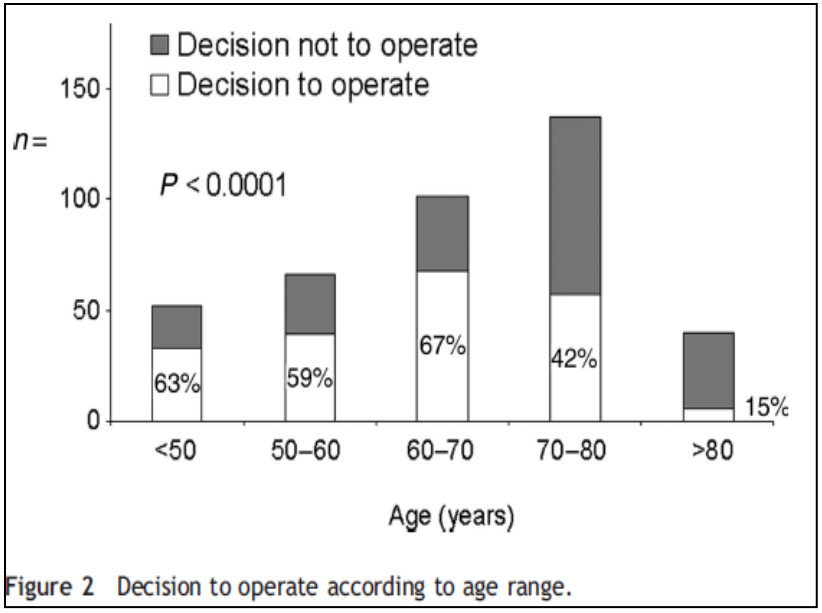


Figure 2 Decision to operate according to age range.

Table 3 Factors associated with a decision not to operate. Multivariable analysis

	P	Odds ratio	95% CI
LVEF (per 10% decrease)	0.0002	1.39	(1.17–1.66)
Aetiology	0.0006		
Ischaemic		1	
Non-ischaemic		4.44	(1.96–10.76)
Age (per 10-year increase)	0.001	1.40	(1.15–1.72)
Charlson comorbidity index (per 1 point increase)	0.004	1.38	(1.12–1.72)
Degree of MR	0.005		
Grade 4/4		1	
Grade 3/4		2.23	(1.28–3.29)

PATIENTS NOT SUITABLE FOR OPEN MITRAL VALVE REPAIR

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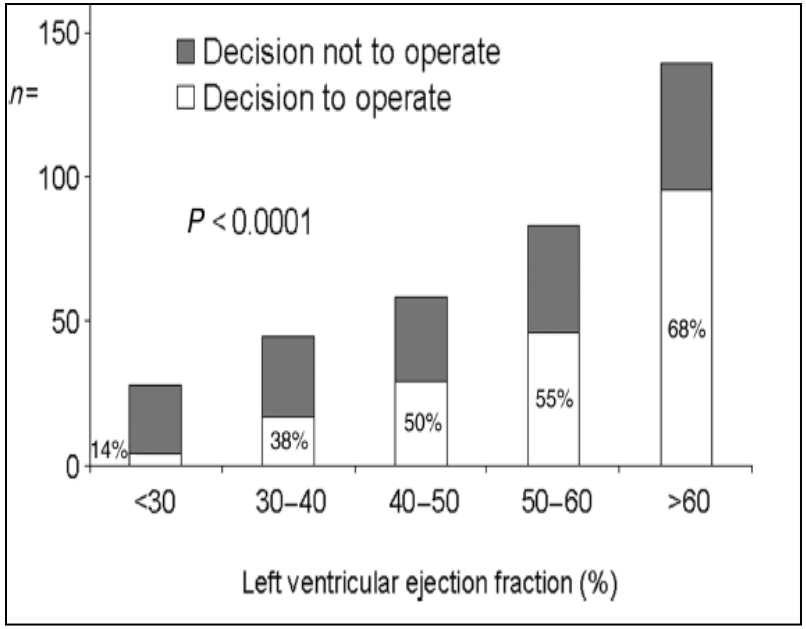


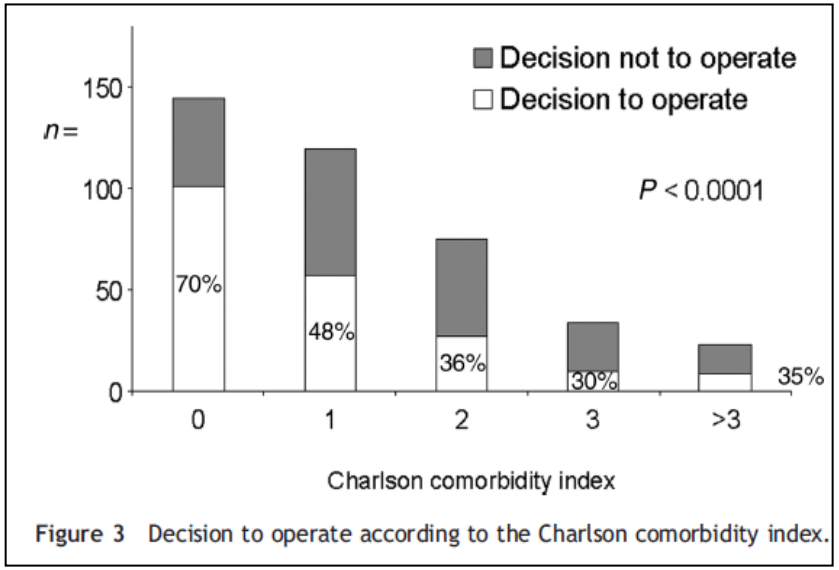
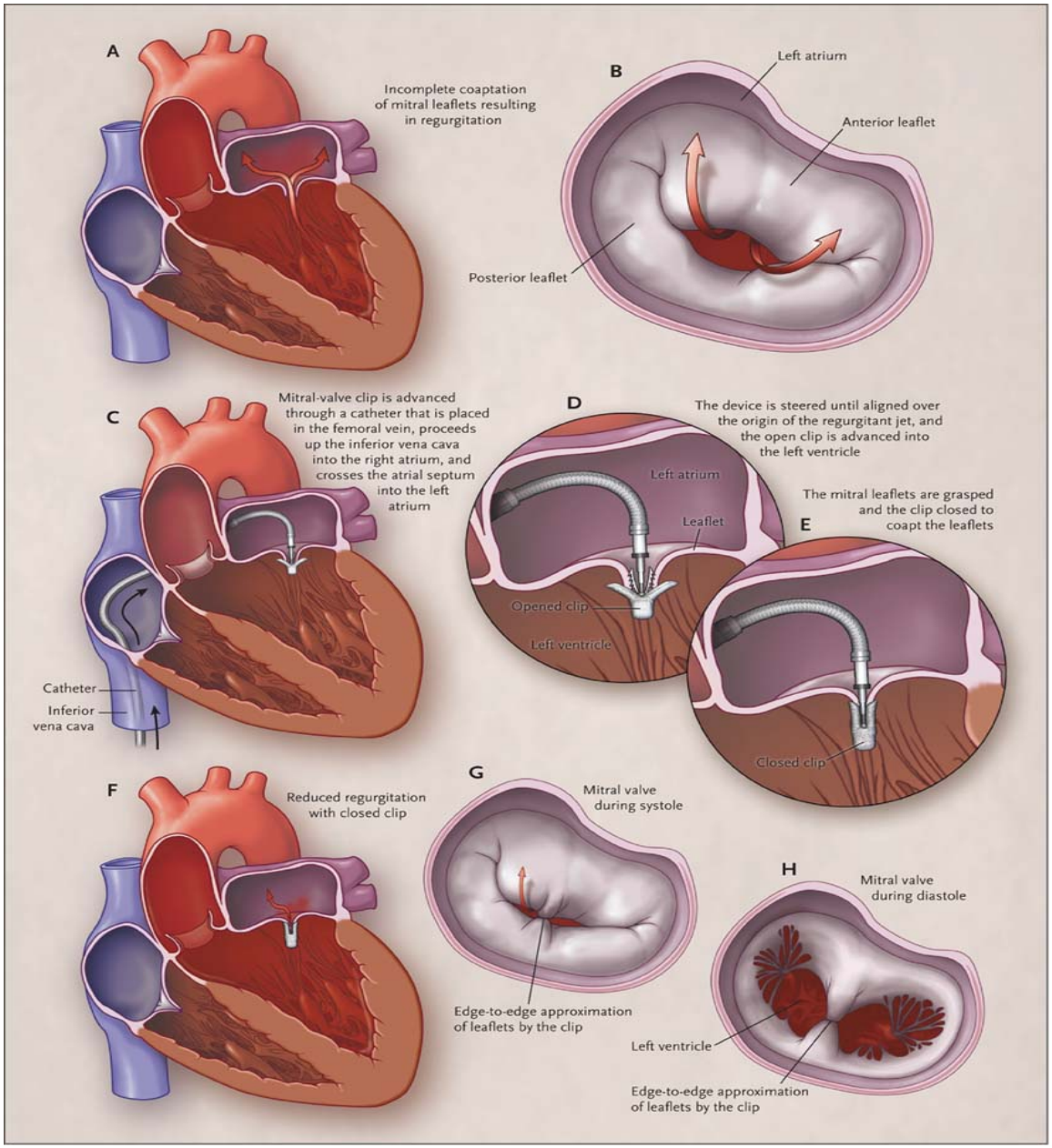
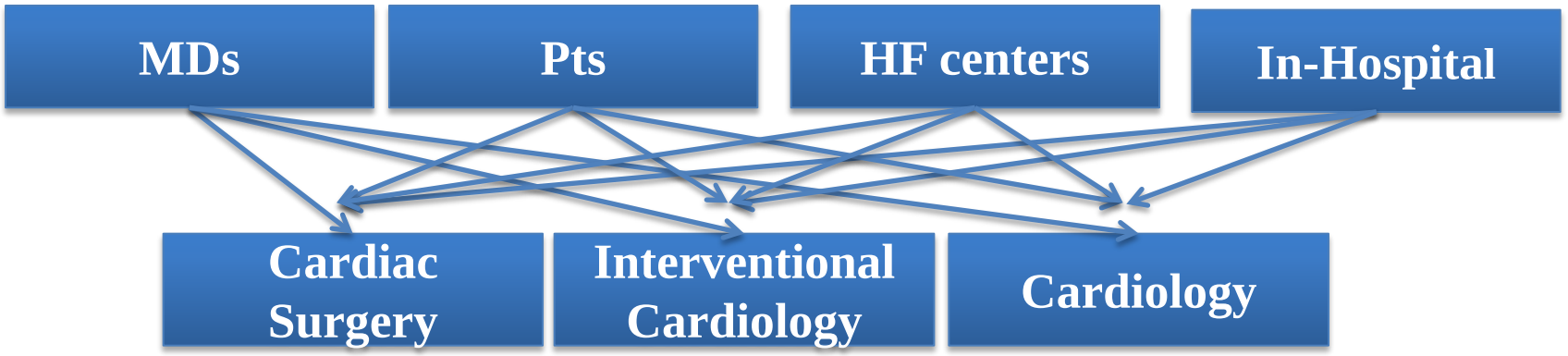


Figure 3 Decision to operate according to the Charlson comorbidity index.

MitraClip system is intended for insufficient mitral valve reconstruction through tissue approximation



REFERRAL PATHWAYS FOR MITRACLIP



Surgical risk evaluation (HEART TEAM)

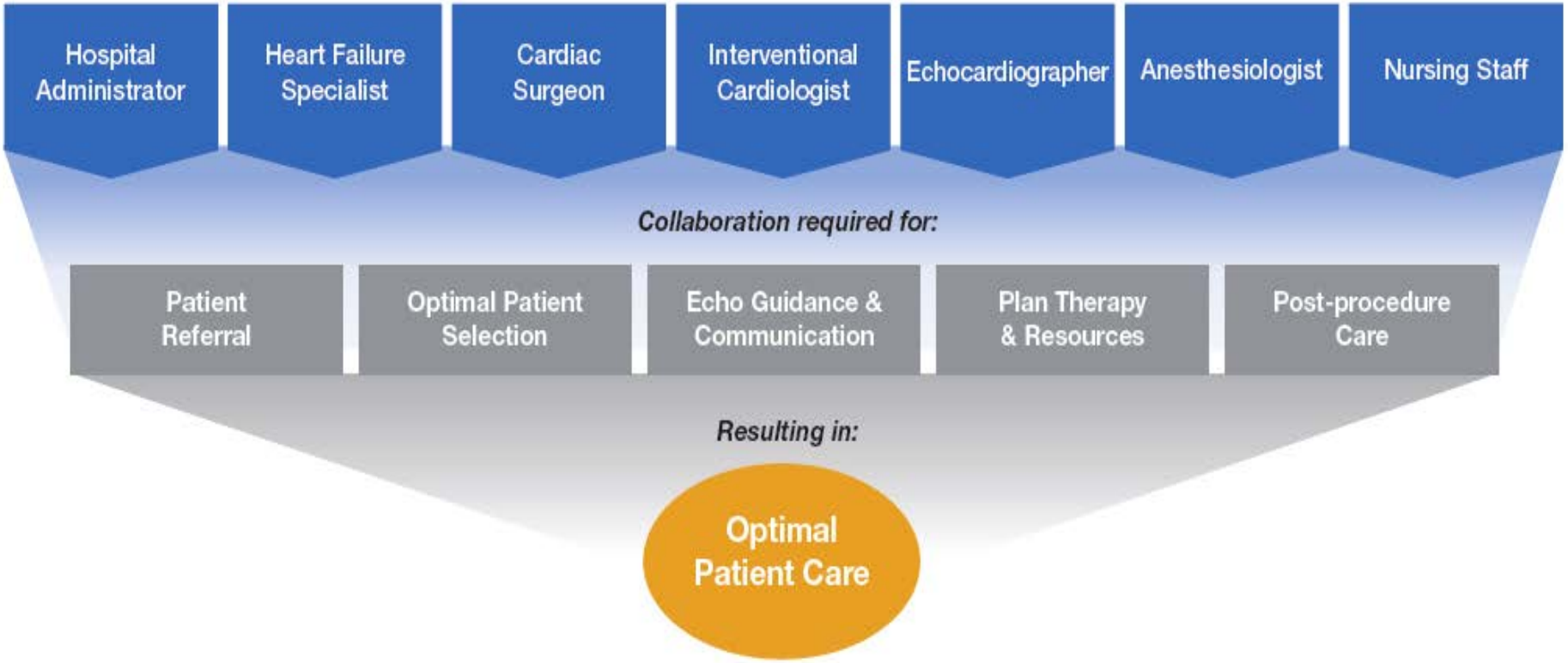
Anatomical eligibility

Procedure

Follow-up – Medical treatment

MULTIDISCIPLINARY TEAM

A multidisciplinary approach and collaboration across specialties is critical to MitraClip Therapy success.



EVEREST II:
ENDOVASCULAR VALVE EDGE TO EDGE REPAIR STUDY

The NEW ENGLAND JOURNAL of MEDICINE

Percutaneous Repair or Surgery for Mitral Regurgitation

Ted Feldman, M.D., Elyse Foster, M.D., Donald G. 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*

The NEW ENGLAND JOURNAL of MEDICINE

Feldman T et al. N Engl J Med 2011. DOI: 10.1056/NEJMoa1009355

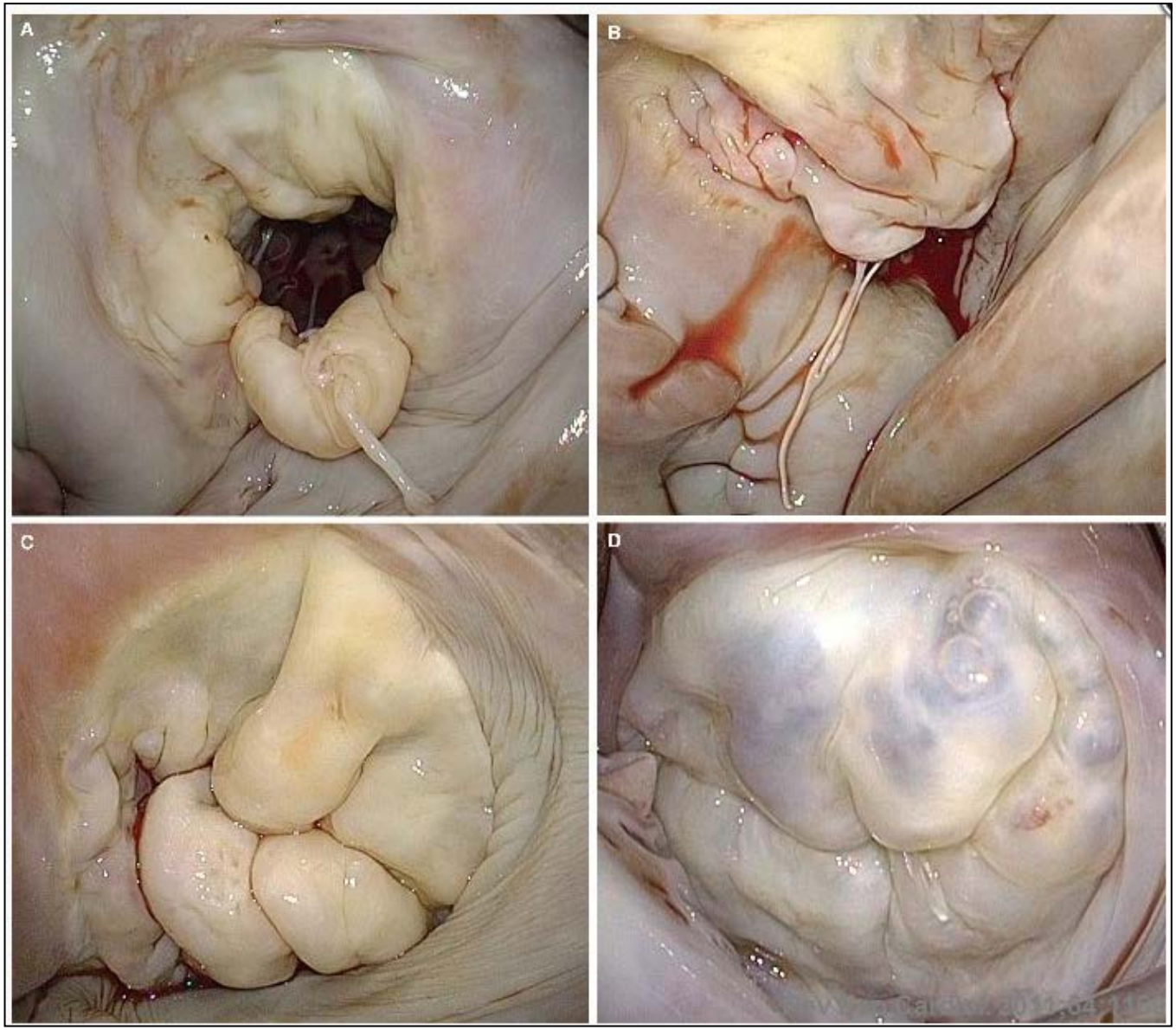
EVEREST II: CONCLUSIONS

- Although percutaneous treatment was effective at reducing mitral regurgitation, surgical treatment was more effective, as graded by an echocardiographic core laboratory
- Percutaneous treatment was associated with a reduction in the rate of major adverse events at 30 days and with sustained clinical improvement, as measured by quality of life, heart failure status, and left ventricular function
- Measures of efficacy remained durable through 24 months of follow-up, and 78% of patients remained free from mitral-valve surgery

EVEREST II: CONCLUSIONS

- Patients who underwent percutaneous repair had significantly reduced left ventricular end-diastolic volume and dimensions, improved NYHA functional class, and improved quality of life at 12 months, as compared with baseline measures
- A transient decrease in the physical component of the quality-of-life score in the surgery group at 30 days was probably related to the invasiveness of surgery
- Percutaneous treatment was associated with more frequent additional procedures for treatment of mitral regurgitation than was surgery

DEGENERATIVE MITRAL VALVE REGURIGITATION



MITRACLIP: PATIENTS SELECTION

- Clinically significant mitral valve regurgitation (3/4+) in patients not suitable for open mitral valve surgery
- The primary regurgitant jet originates from malcoaptation of the mitral valve in a location accessible with the MitraClip implant
- If a secondary jet exists, it should be considered clinically insignificant
- Trans-septal catheterization is determined to be feasible by the treating physician

MITRACLIP: ECOCARDIOGRAPHIC ASSESSMENT

- Key echocardiographic inclusion criteria

a primary regurgitant jet which originated from the A2/P2 scallops.

- Key echocardiographic exclusion criteria

flail segment width ≥ 15 mm

flail gap ≥ 10 mm

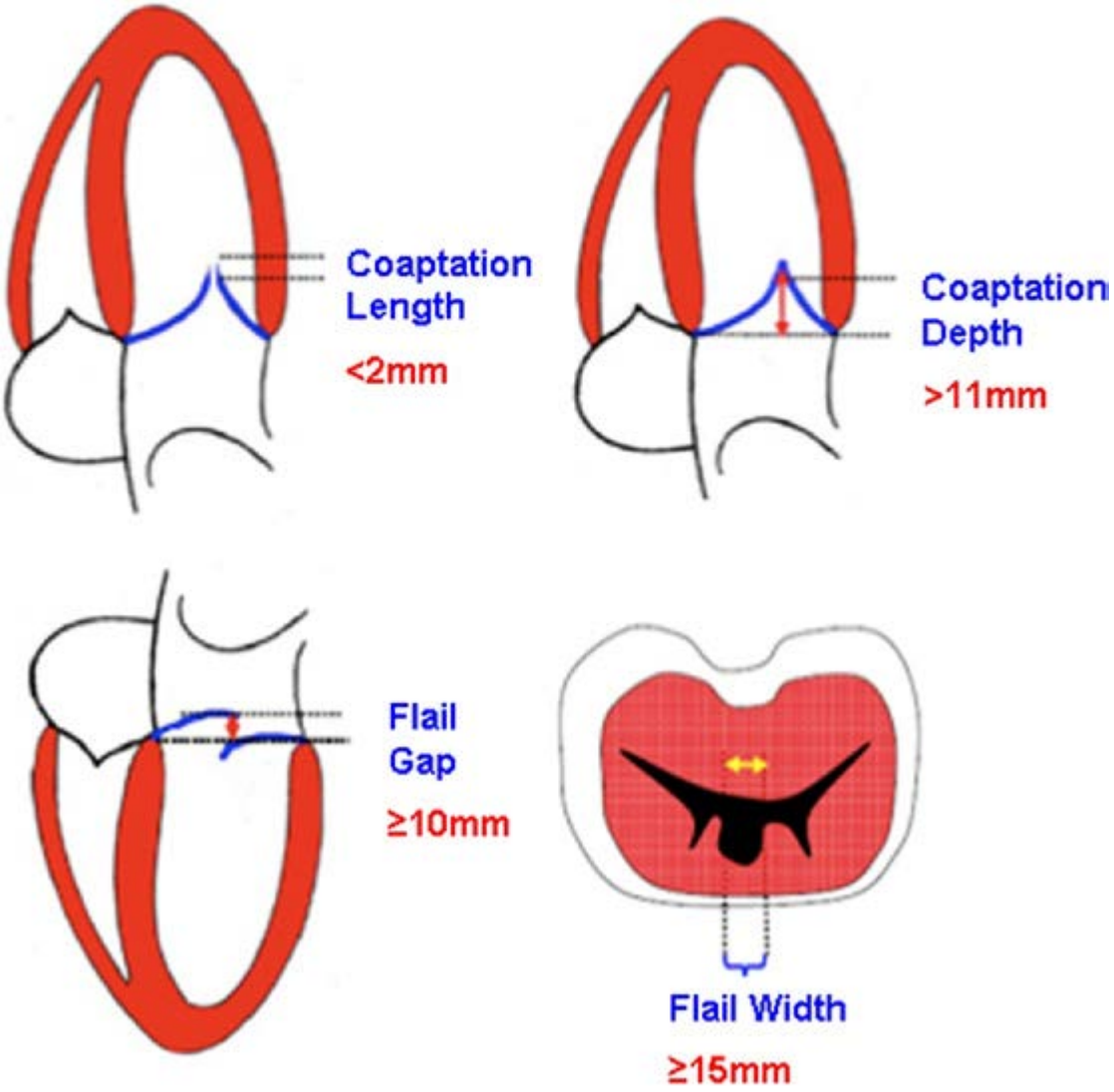
coaptation depth > 11 mm,

vertical coaptation length < 2 mm,

mitral valve area < 4.0 cm2,

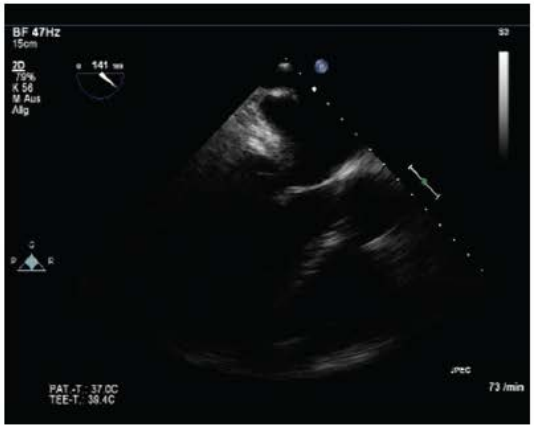
LVIDs > 55 mm

KEY ECHOCARDIOGRAPHIC EXCLUSION CRITERIA

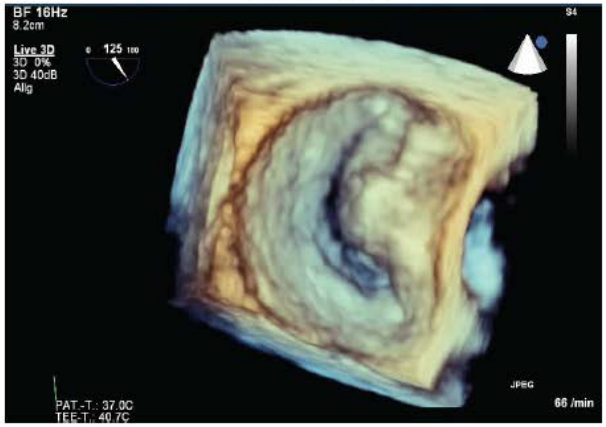


OTHER EXCLUSION CRITERIA

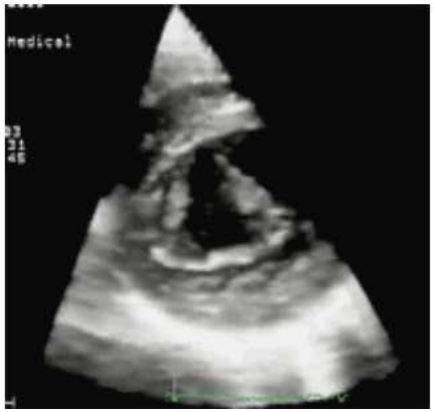
Insufficient echo windows



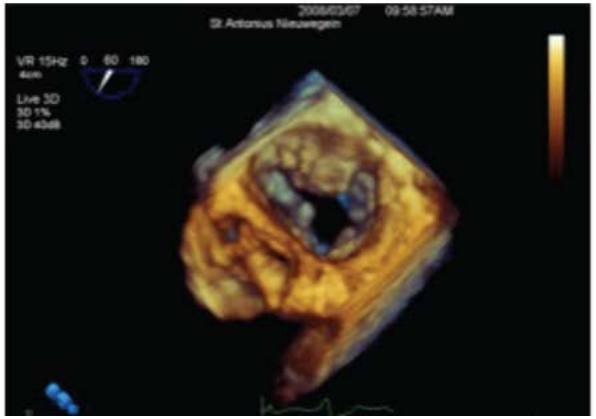
MVA < 4 cm^2 / Severely calcified leaflets



Cleft



Endocarditis



MITRACLIP: OTHER EXCLUSION CRITERIA

- Severe mitral annulus calcification
- Evidence of calcification or cleft of the grasping area
- Severe bileaflet flail or severe bileaflet prolapse
- Lack of both primary and secondary chordal support
- Emergency surgery
- Previous mitral valve repair
- Echocardiographic evidence of intracardiac mass / trombus /vegetations
- Infections that may require antiobiotics
- Presence of intracardiac pacing leads that may interfere with the mitraclip device
- Controindications to TEE (esophagus diverticula)
- Significant chest or spine deformity
- Acute endocarditis or rheumatic disease

OUR DECISION TREE FOR MITRACLIP IN DMR

- Severe MR with volume overload
- High EUROScore
- Frialty Index
- Symptomatic patients
- Heart Team: Operable?

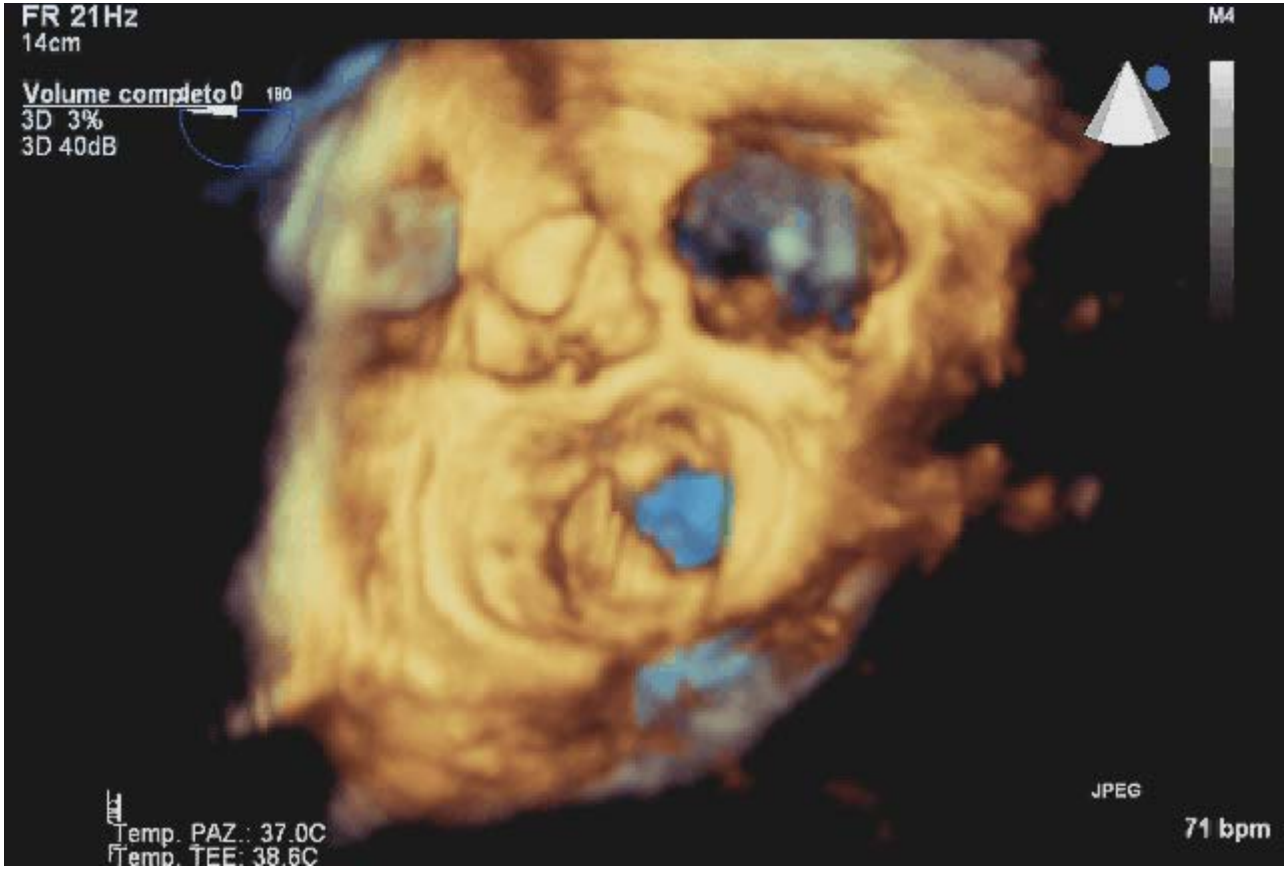
  - Yes → Surgery
  - Yes, but with high risk (EUROScore > 10)
  - No operable

} MITRACLIP

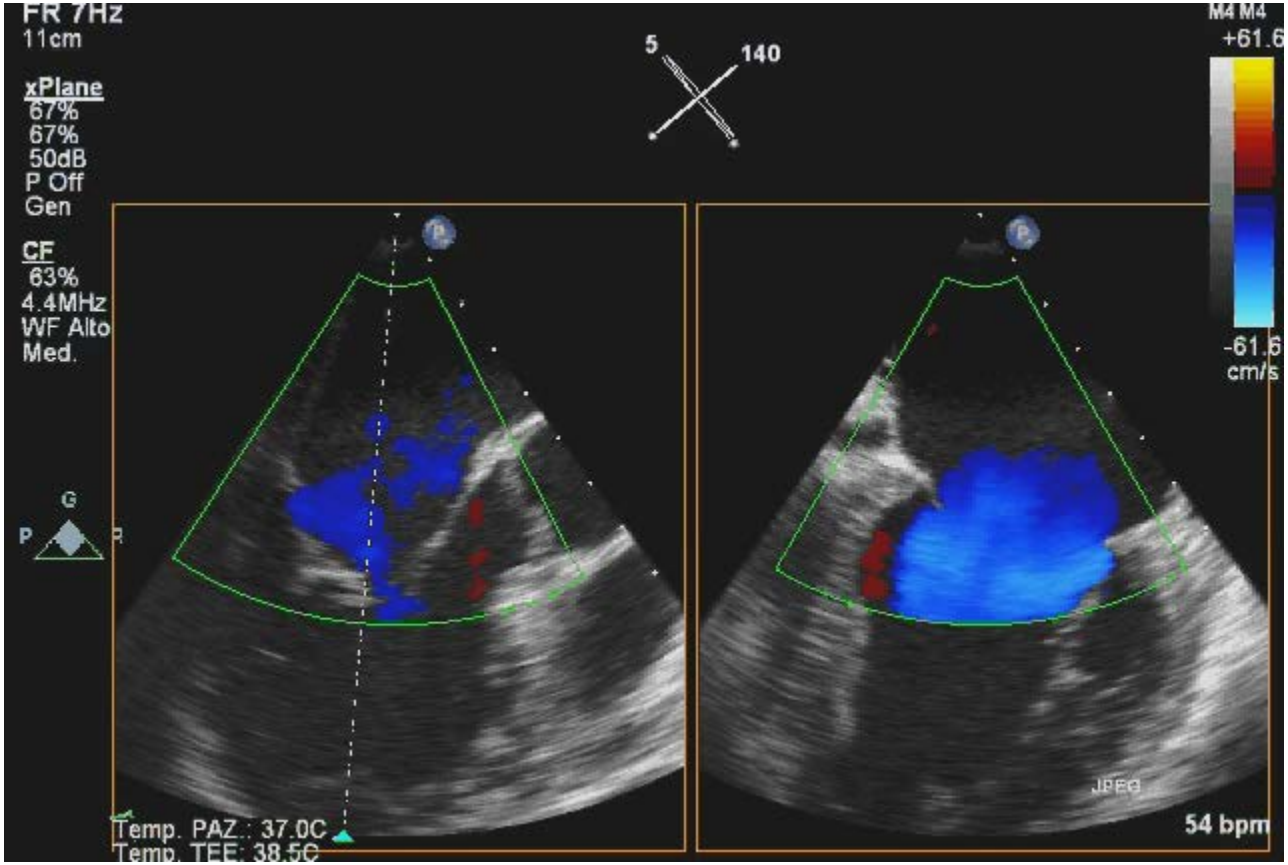
CLINICAL CASE I

- Female, 80 yrs, Frialty ++
- Dilatation of the LA
- Mild annulus dilation
- Thickened mitral valve with prolapse of the posterior leaflet associated with chordal rupture and flail at level of P2-P3 (flail gap 4-5 mm, flail width 14 mm)
- Mild dilation of the LV, normal EF

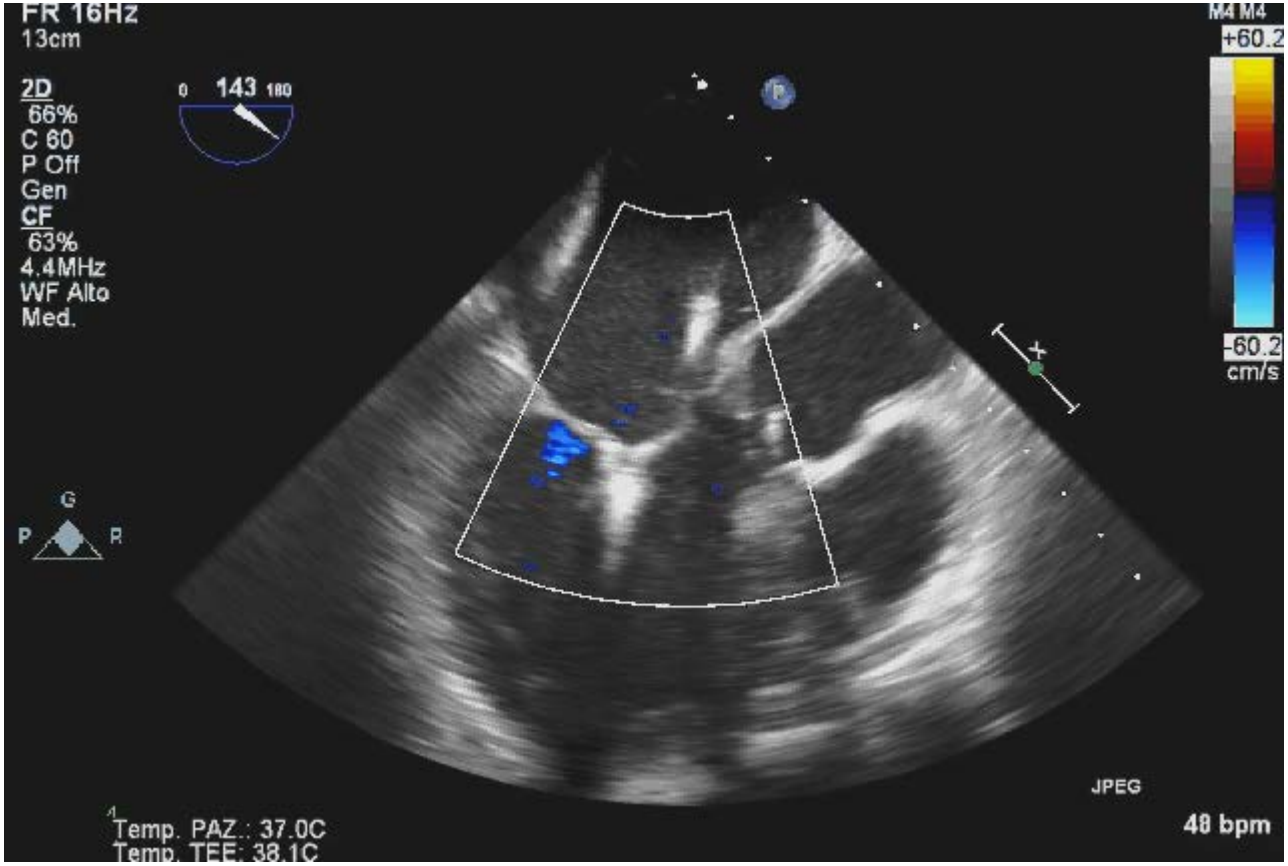
DMR: PRE IMPLANTATION



DMR: PRE COLOR DOPPLER



DMR: IMPLANTATION OF CLIP



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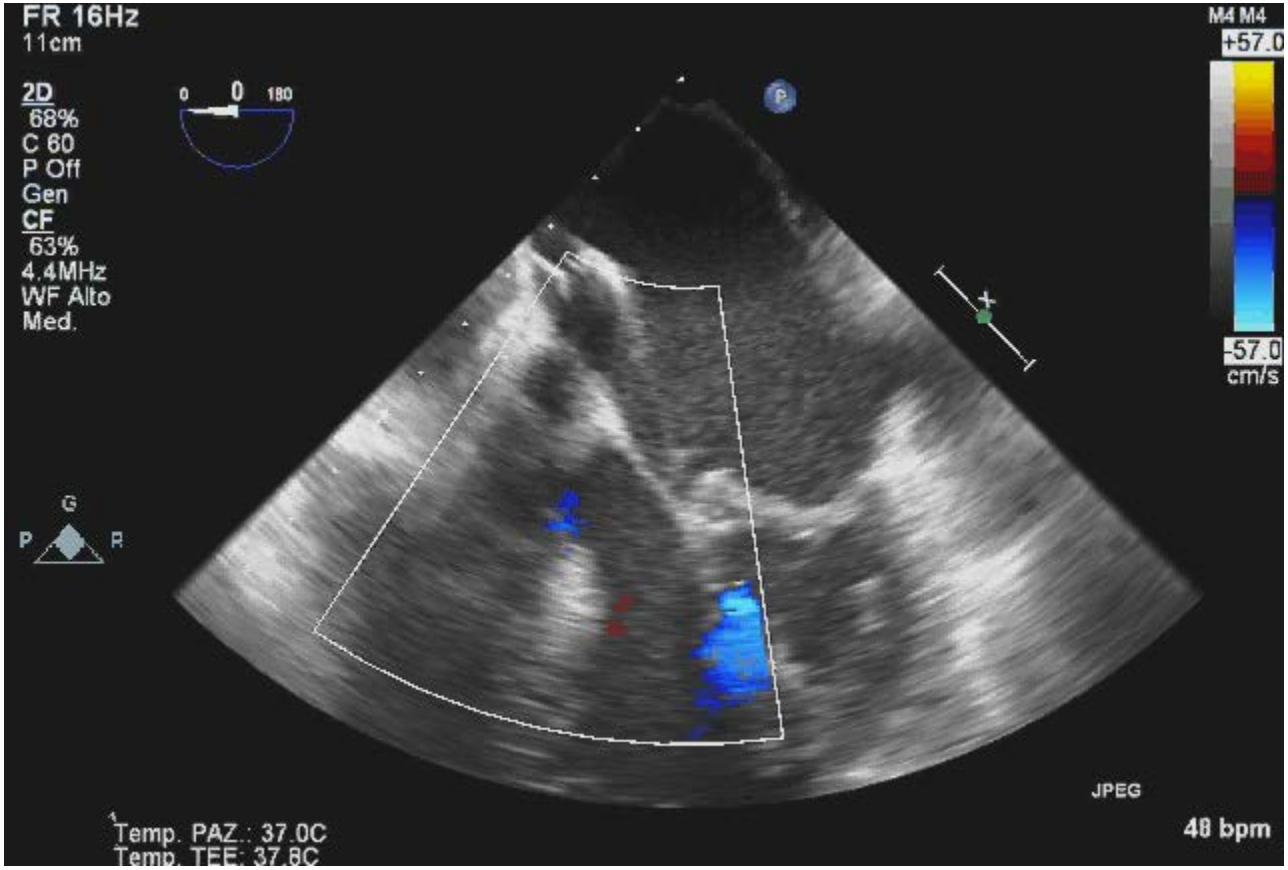
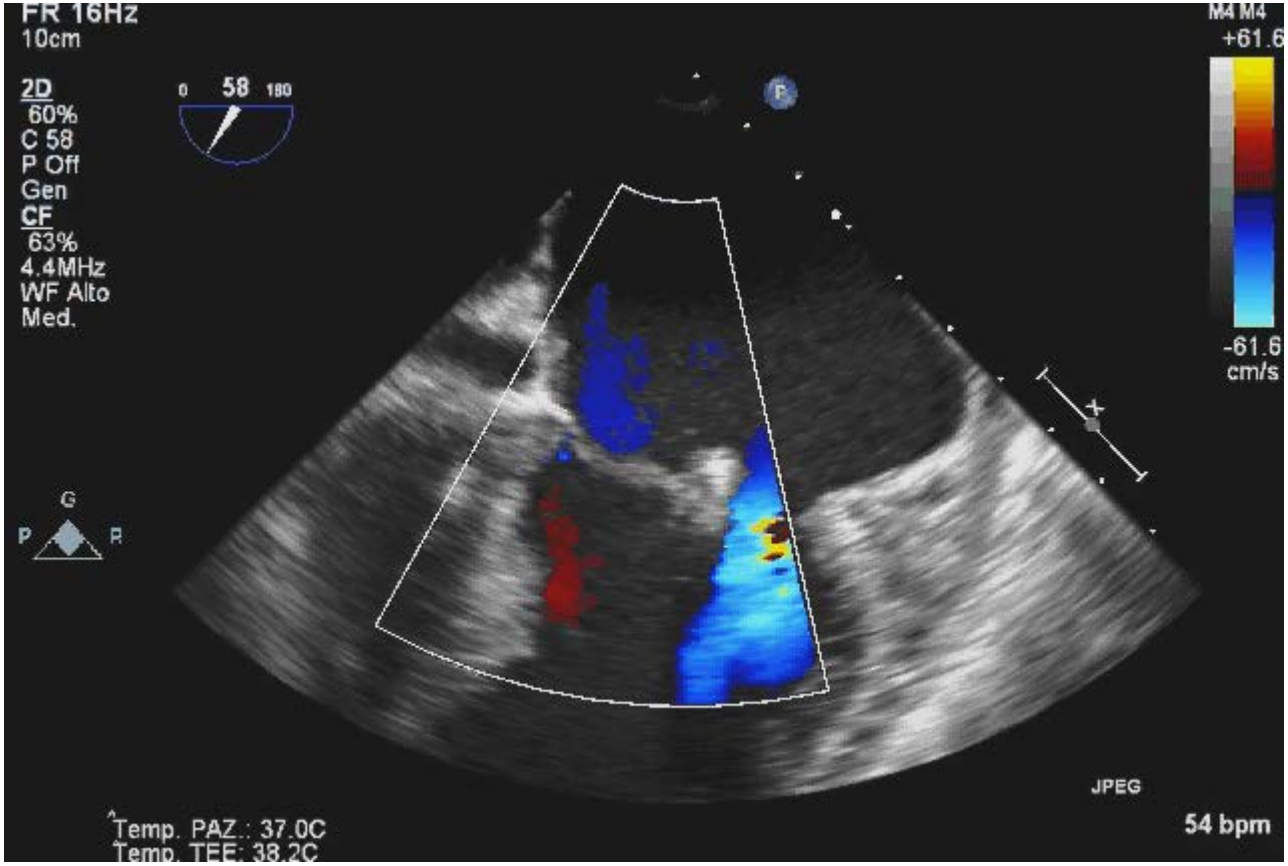


DMR: FINAL COLOR-DOPPLER



CRITERIA OF EFFECTIVENESS OF THE MITRACLIP

- Mitral regurgitation decrease
- No mitral stenosis
- No reversal of flow at the level of the pulmonary a.
- PISA decrease

CLINICAL CASE II

- Female, 88 yrs, Frialty Index ++

- Left atrial enlargement and ring (36 mm)

- Calcification of the ring from the posteromedial commissure to the central portion slight calcification at the base of posterior leaflet

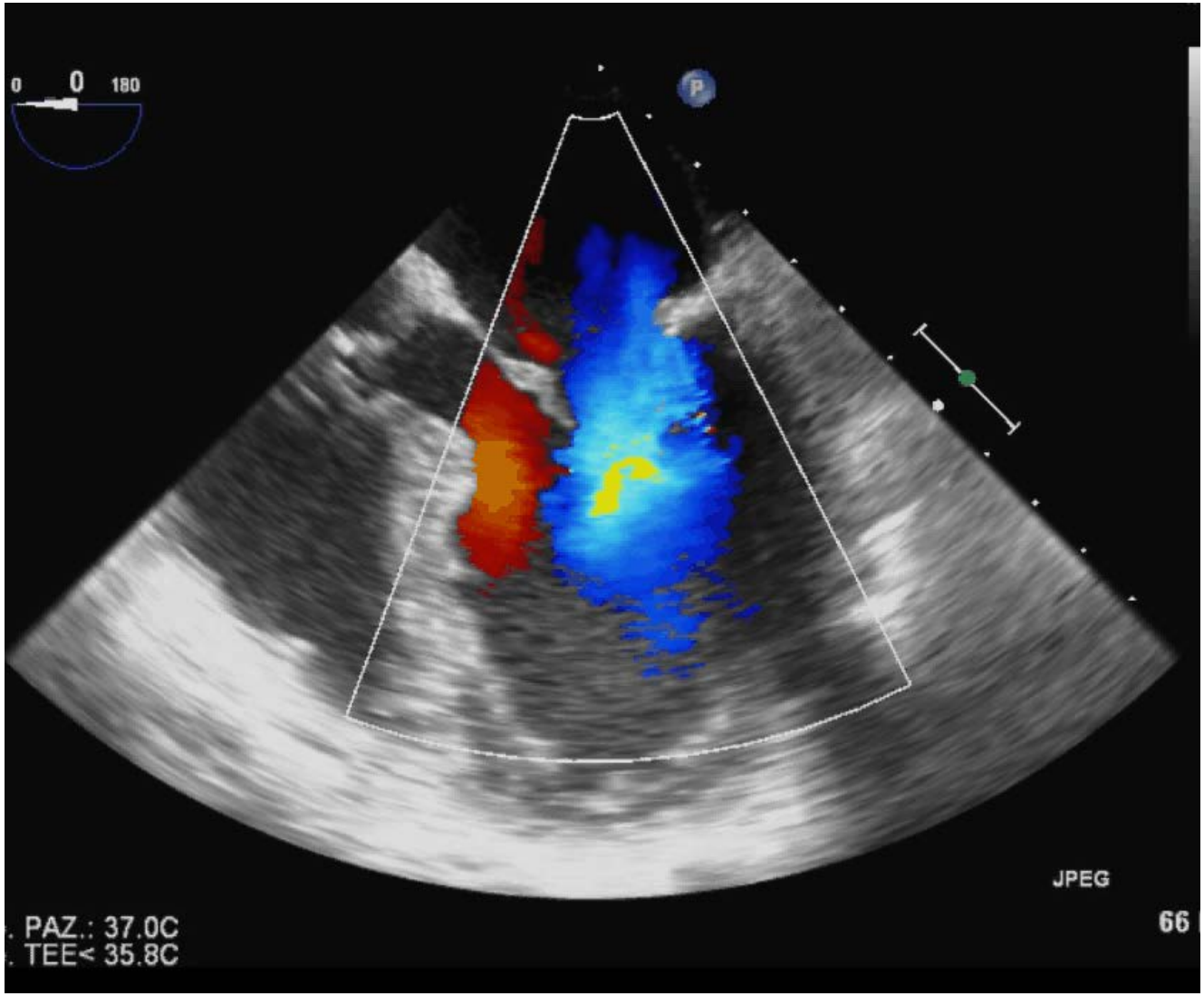
- Thickened mitral valve leaflet prolapse and flail of posterior leaflet (P2 to P3) associated with chordae rupture and partial eversion (5 mm) of P2 conditioning severe insufficiency

- EROA 0.78, VR 81mm

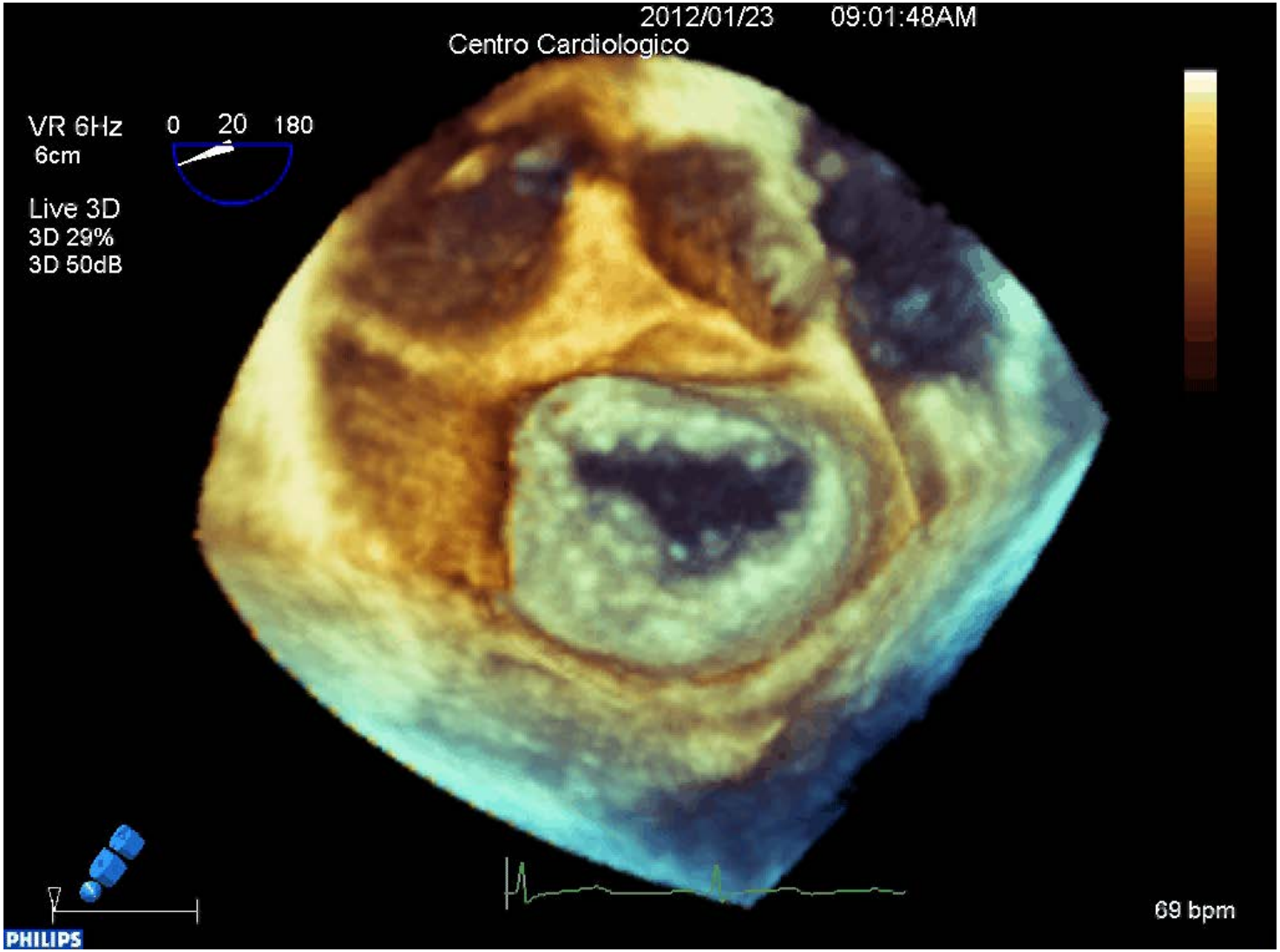
- Coanda effect throughout the atrial septum

- MVA 5.3 cmq

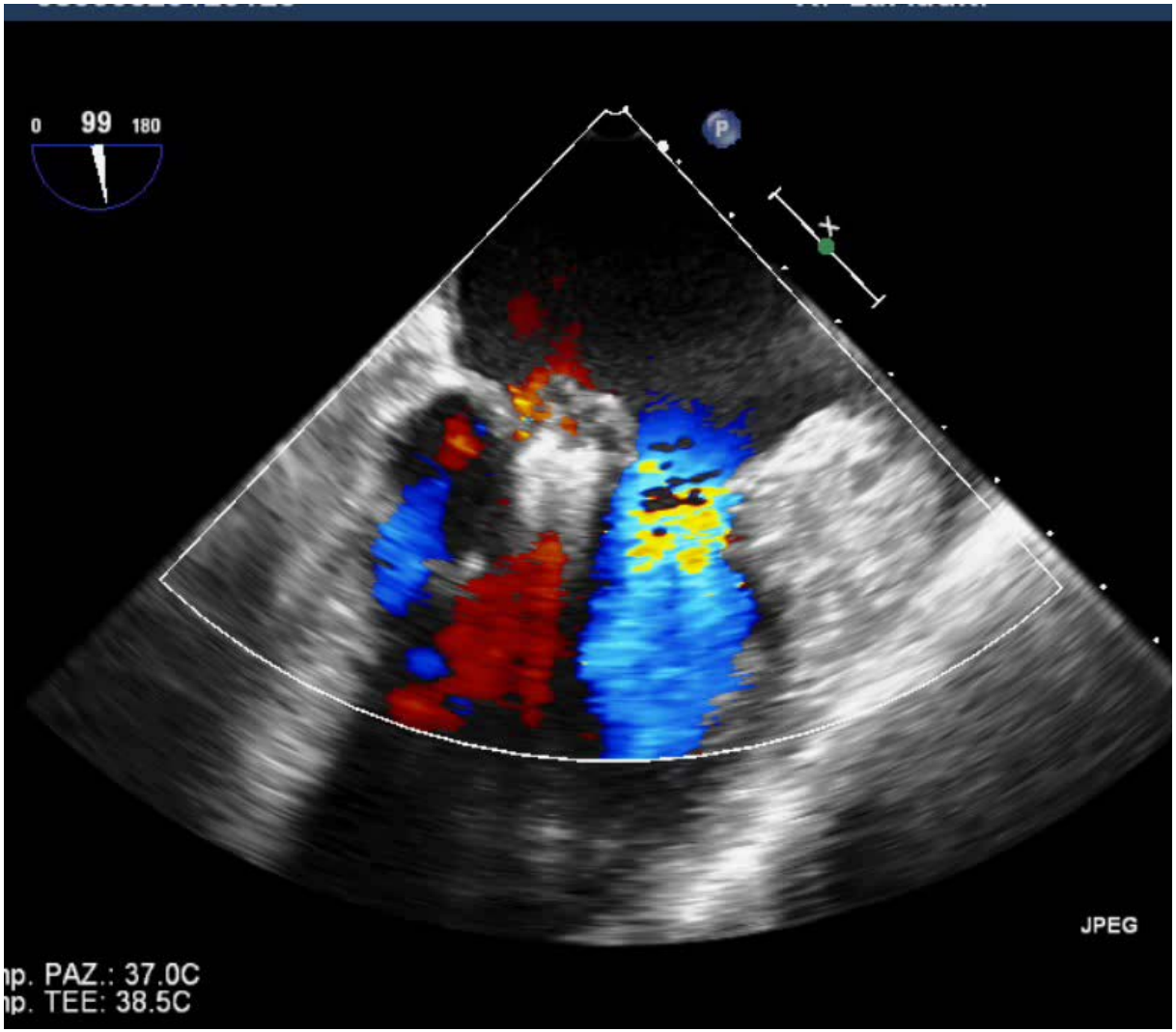
CC II: COLOR-DOPPLER PRE



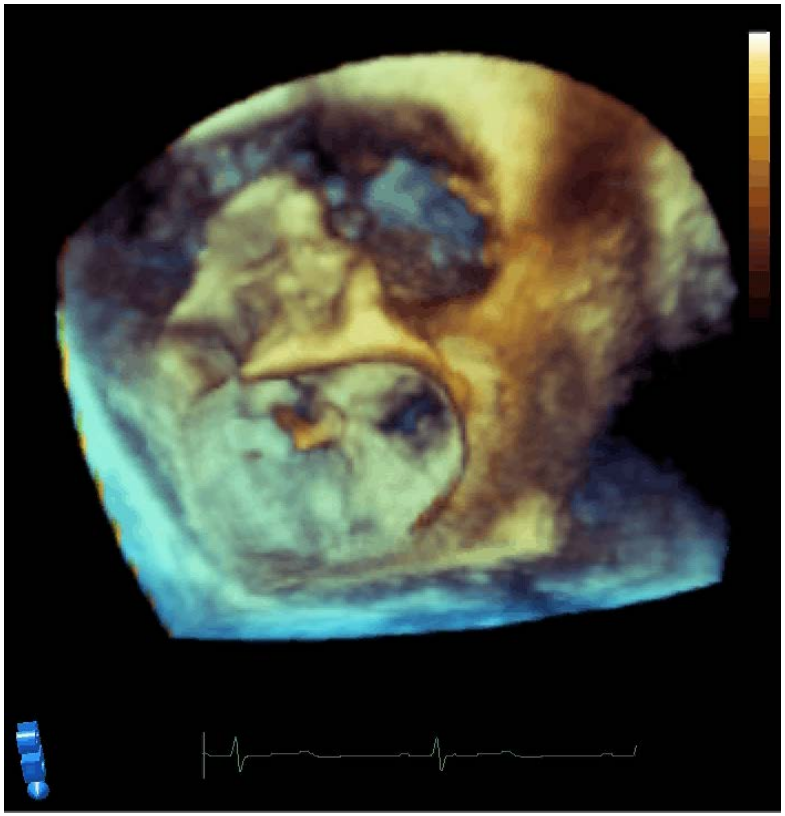
CC II: 3D-PRE

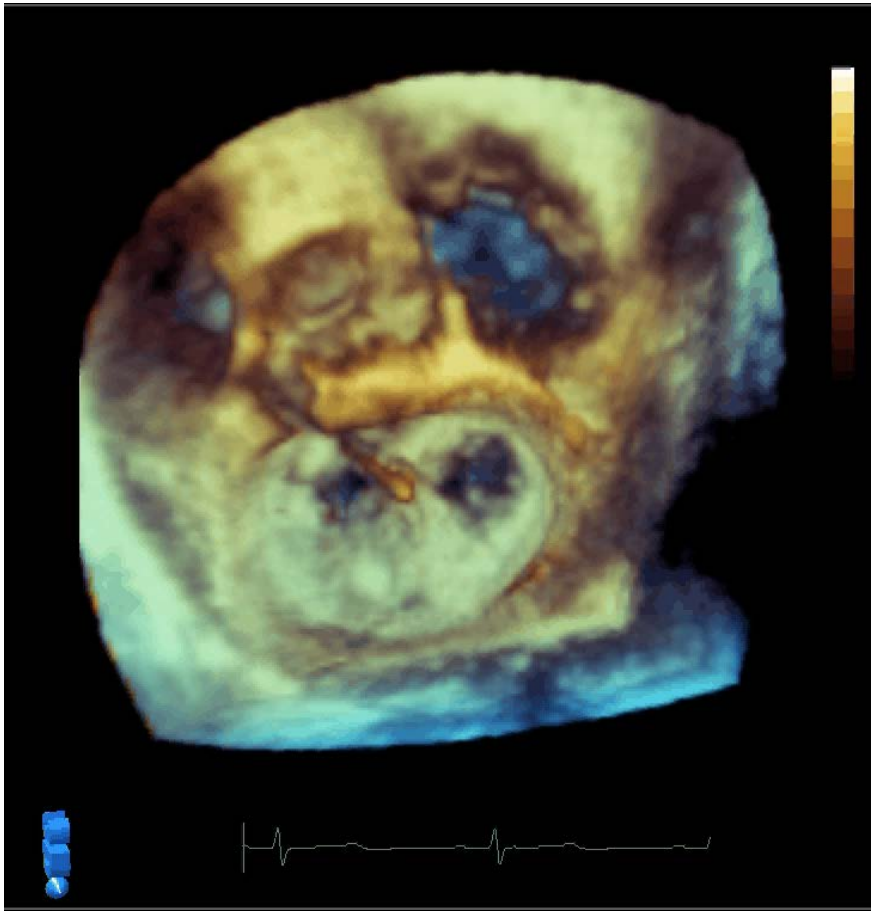

2012/01/23 09:01:48AM
Centro Cardiologico
VR 6Hz
6cm
0 20 180
Live 3D
3D 29%
3D 50dB
69 bpm
PHILIPS

CC II: COLOR-DOPPLER POST



CC II: 3D POST





European Journal of Cardio-Thoracic Surgery 44 (2013) e280–e288
doi:10.1093/ejcts/ezt321 Advance Access publication 17 July 2013

ORIGINAL ARTICLE

Clinical outcomes through 12 months in patients with degenerative mitral regurgitation treated with the MitraClip® device in the ACCESS-EUrope Phase I trial†

Hermann Reichenspurner[a,*], Wolfgang Schillinger[b], Stephan Baldus[c], Jörg Hausleiter[d], Christian Butter[e], Ulrich Schäefer[f], Giovanni Pedrazzini[g] and Francesco Maisano[h] on behalf of the ACCESS-EU Phase I Investigators

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ORIGINAL ARTICLE

Clinical outcomes through 12 months in patients with degenerative mitral regurgitation treated with the MitraClip® device in the ACCESS-EUrope Phase I trial†

METHODS: The MitraClip Therapy Economic and Clinical Outcomes Study Europe (ACCESS-EU) Study has completed the enrolment of 567 patients as of April 2011, 117 of whom were DMR. Baseline demographics, procedural and acute safety results at 30 days and survival at 12 months were evaluated in the DMR subset. Effectiveness results, defined by a reduction in MR, and improvement in clinical outcomes based on changes in New York Heart Association (NYHA) functional Class, 6-min walk test (6MWT) and quality-of-life data were also assessed. Furthermore, DMR patients were stratified into high- and low-risk subgroups (logistic European System of Cardiac Operative Risk Evaluation I (logEuroSCORE I ≥20% or <20%, respectively) and differentially evaluated.

RESULTS: One hundred and seventeen DMR patients underwent the MitraClip procedure with a 94.9% rate (111 of 117) of successful clip implantation. Baseline characteristics and comorbidities included NYHA Class III/IV (74%), left ventricular ejection fraction (LVEF) <40% (9%), prior cardiac surgery (24%) and prior myocardial infarction (MI) (22%). Mean logEuroSCORE I was 15.5 ± 13.3%. Mortalities at 30 days and 12 months were 6.0 and 17.1%, respectively. At 12 months, 74.6% (53 of 71) of patients in follow-up achieved MR ≤grade 2+ and 80.8% (63 of 78) were in NYHA functional class I/II. Both Minnesota Living with Heart Failure questionnaire (MLHFQ) scores and 6MWT distance improved significantly at 12 months compared with baseline ($P = 0.03$ and $P < 0.0001$, respectively).

Table 3: 30-day site-reported safety outcomes

30-day site-reported safety outcomes	DMR patients (*n* = 117)	High-risk DMR patients (*N* = 33)	Low-risk DMR patients (*N* = 84)
Death	6.0% (7/117)	9.1% (3/33)	4.8% (4/84)
Stroke	0.9% (1/117)	0%	1.2% (1/84)
Myocardial infarction	0.9% (1/117)	3.0% (1/33)	0%
Renal failure	2.6% (3/117)	3.0% (1/33)	2.4% (2/84)
Need for resuscitation	0.9% (1/117)	3.0% (1/33)	0%
Cardiac tamponade	0.9% (1/117)	3.0% (1/33)	0%
Bleeding complications	3.4% (4/117)	6.1% (2/33)	2.4% (2/84)
Repeat MitraClip	0.9% (1/117)	0%	1.2% (1/84)
Mitral valve surgery	1.7% (2/117)	0%	2.4% (2/84)
Total adverse events	17.9% (21/117)	27.3% (9/33)	14.3% (12/84)

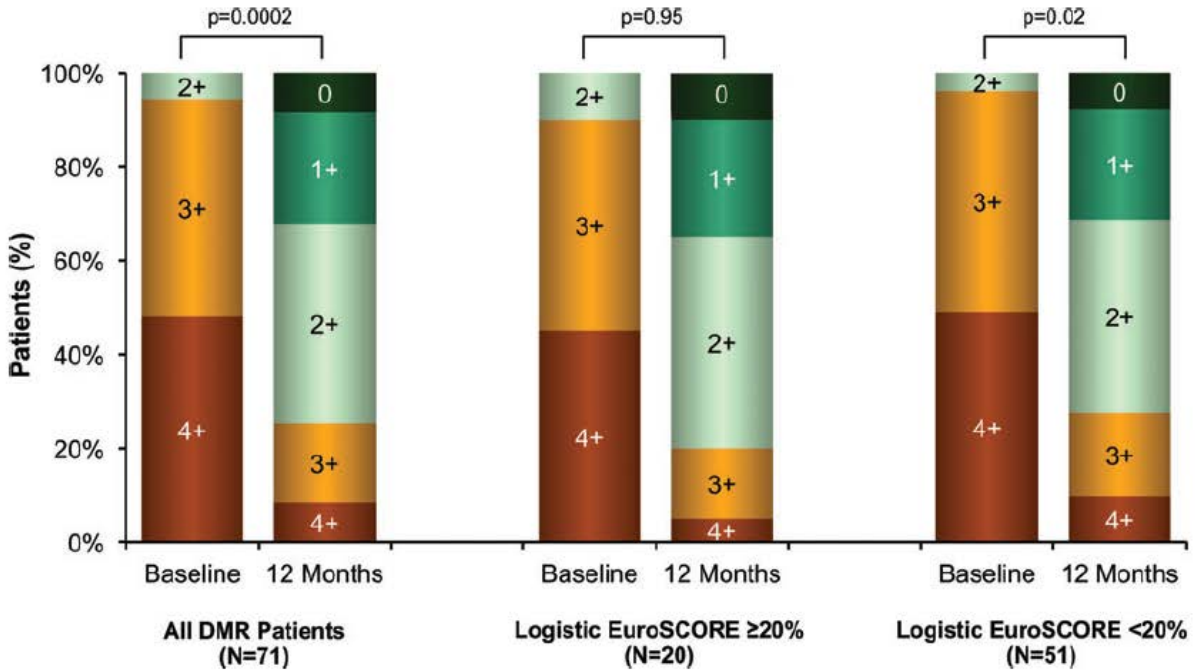

Figure 1: Mitral regurgitation at baseline and 12 months (paired data).

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MITRACLIP: CCFM EXPERIENCE

- October 2010 - October 2014: 49 patients
- Mean Age 76 ± 8 yr (20 female – 29 male)
- Severe MR not suitable for cardiac surgery
- log EUROScore: 22 ±16
- NYHA class IV: 29%
- Mechanism of regurgitation:

  23 functional

  26 degenerative

MITRACLIP: CCFM EXPERIENCE

BASELINE ECHO DATA

MR	EF	iEDV	iESV	PAPs
3.76 ±0.42	50 ± 16	122.5 ± 45.6	65.78 ± 39.38	46.4 ± 11.4

POST IMPLANT ECHO DATA

MR	EF	iEDV	iESV	PAPs
1.5 ±0.98	46.95 ± 14.93	109.63 ± 50.6	62 ± 42.7	39 ± 8.9

MITRACLIP: CCFM EXPERIENCE

- 1 procedure aborted for severe scoliosis
- 1 perioperatory groin arterial bleeding, treated with PTA
- 1 groin bleeding associated to NSTEMI (blood transfusion + PCI)
- 1 early clip detachment treated with second stage clip deployment
- 1 mid term failure (6 months), enlisted for a new procedure
  - 1 clip was implanted in 24 cases
  - 2 clips in 21
  - 3 clips in 4 pts

MITRACLIP: CCFM EXPERIENCE

- In-hospital mortality: 4% (2/49)

  1 pt died for sepsis and

  1 for cardiogenic schok
- Mean lenght-of-stay in ICU: 1 dy
- At discharge: 89% pts da MR <2+
- At 6 months f-up: 1 pt had MR >3
- At last f-up most of pts were in NHYA-class I-II

KEY MESSAGES

- MitraClip is a robotic endovascular device replicating the surgical double orifice technique
- Outcomes are very promising
- Enviroment requirements are similar to TAVI
- With experience, the procedure is faster, safer and more effective
- Skills required for a successful procedure are multiple, specific training is needed
- The intervention can be done by a surgeon with results at least comparable (maybe better) to those of an interventional cardiologist
- Best solution being togheter in the OR