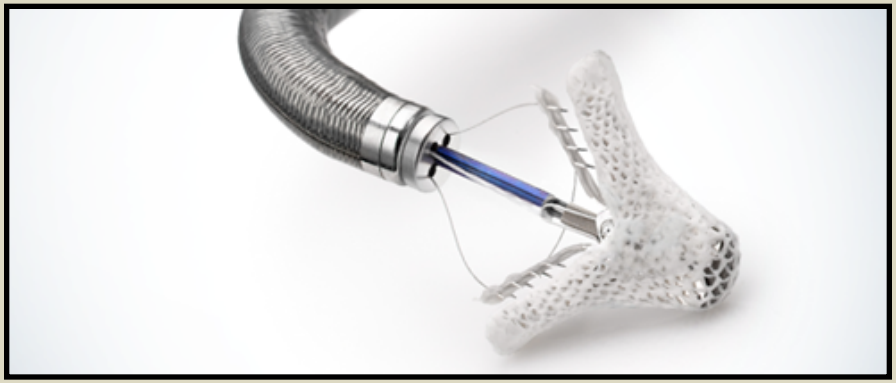
La Riparazione con MitraClip

Indicazioni Attuali e Tecnica di Una Procedura in Forte Espansione



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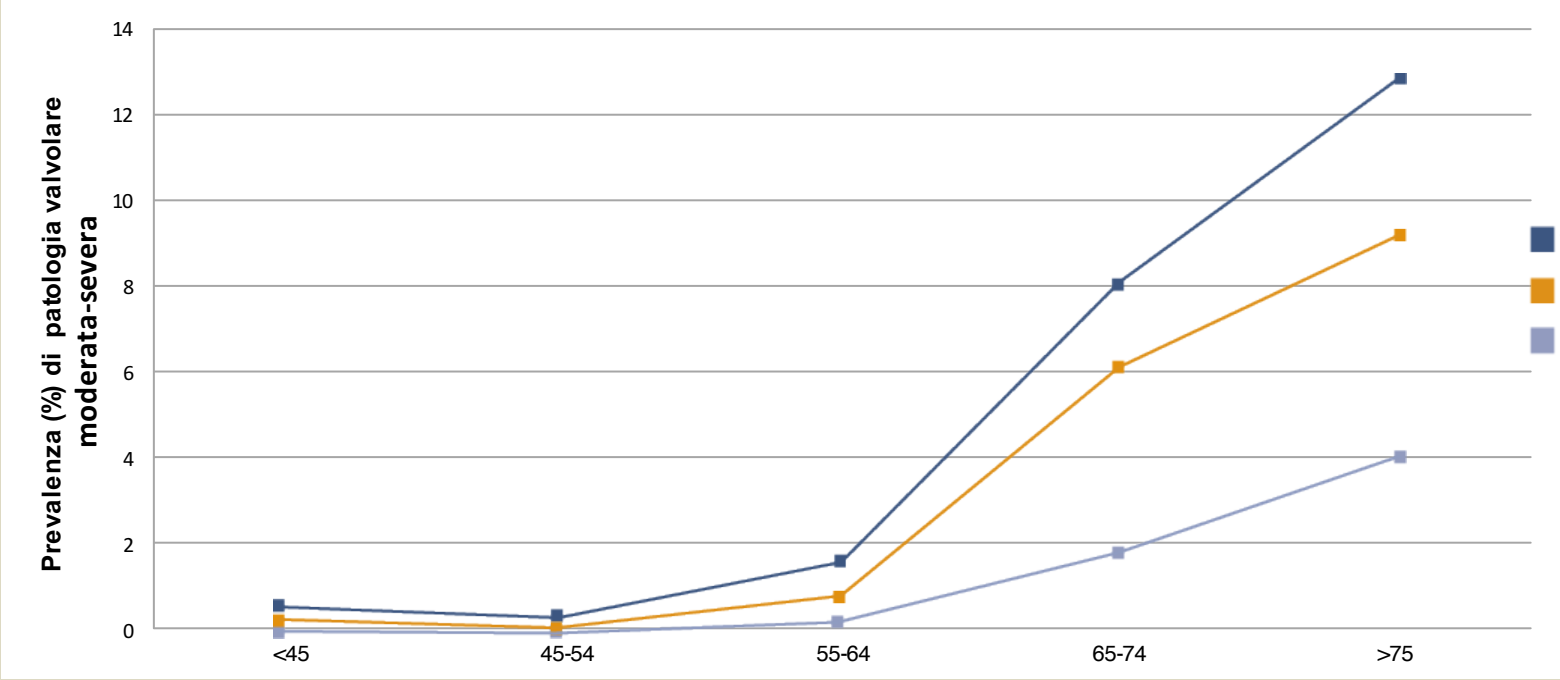
ECOCARDIOCHIRURGIA 2016
Direttori: Antonio Mantero & Giuseppe Tarelli

Prevalenza dell'IM: una patologia che aumenta con l'Età[1,2]

Quasi 1 persona su 10 con 75 anni di età o più è affetta da IM ≥2+



[1] Heart Disease and Stroke Statistics 2010 Update: A Report From the American Heart Association. *Circulation* 2010;121:e46-e215

[2] Nkomo et al. Burden of Valvular Heart Diseases: A Population-based Study. *Lancet* 2006;368:1005-11

Funtional MR Severity as a Predictor of Mortality

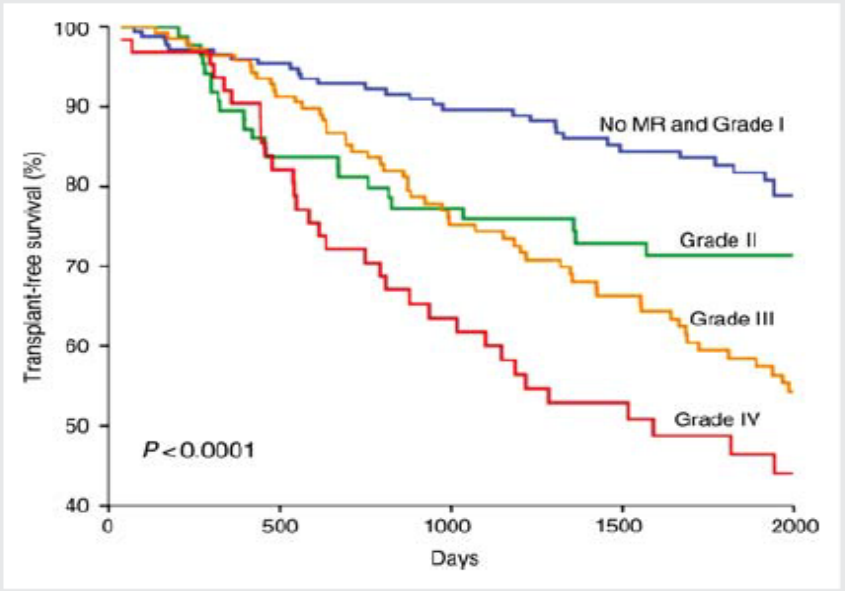


Figure 1 Event-free survival according to the presence and degree of functional mitral regurgitation. Blue line indicates patients without functional mitral regurgitation or Grade I functional mitral regurgitation, green line indicates patients with Grade II functional mitral regurgitation, yellow line indicates patients with Grade III functional mitral regurgitation, and red line indicates patients with Grade IV functional mitral regurgitation.

- ❑ 469 CHF patients with FMR
- ❑ Five-year clinical follow-up
- ❑ FMR classified as:
  - Absent-Grade I
  - Grade II
  - Grade III
  - Grade IV
- ❑ FMR is an independent determinant of death and heart transplantation only in less severe CHF and in patients with a lower risk profile
- ❑ This finding indicates that FMR plays a major role in the early phase of CHF, suggesting that this should be the focus of strategies attempting to reduce it

Bursi F et al. Prognostic implications of functional mitral regurgitation according to the severity of the underlying chronic heart failure: a long-term outcome study. Eur J Heart Fail 2010;12:382-388.

MR Severity as a Predictor of Mortality and Cardiac Events

456 patients with asymptomatic organic MR

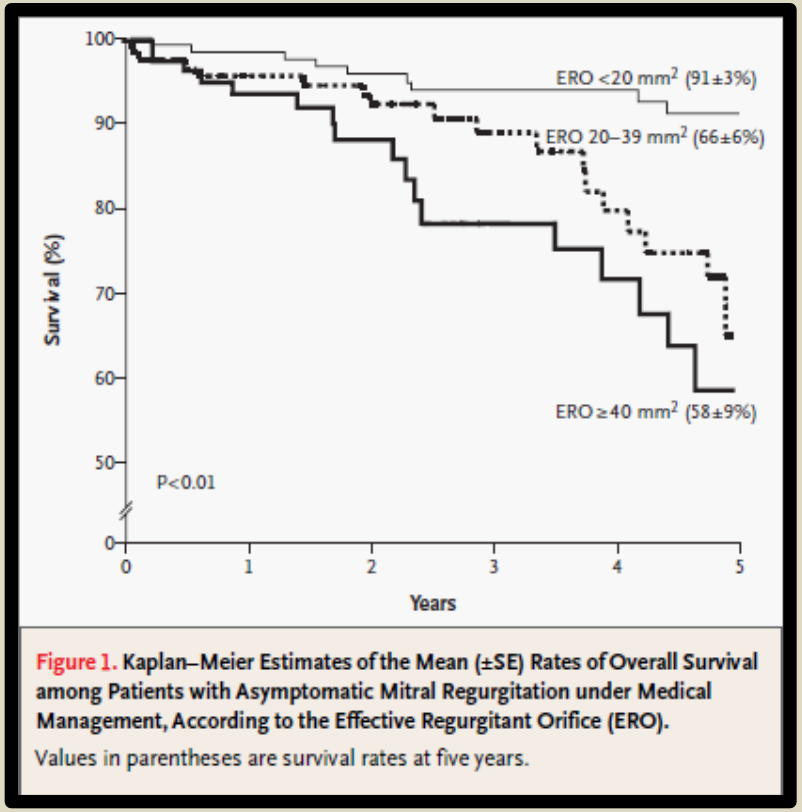


Figure 1. Kaplan–Meier Estimates of the Mean (±SE) Rates of Overall Survival among Patients with Asymptomatic Mitral Regurgitation under Medical Management, According to the Effective Regurgitant Orifice (ERO).

Values in parentheses are survival rates at five years.

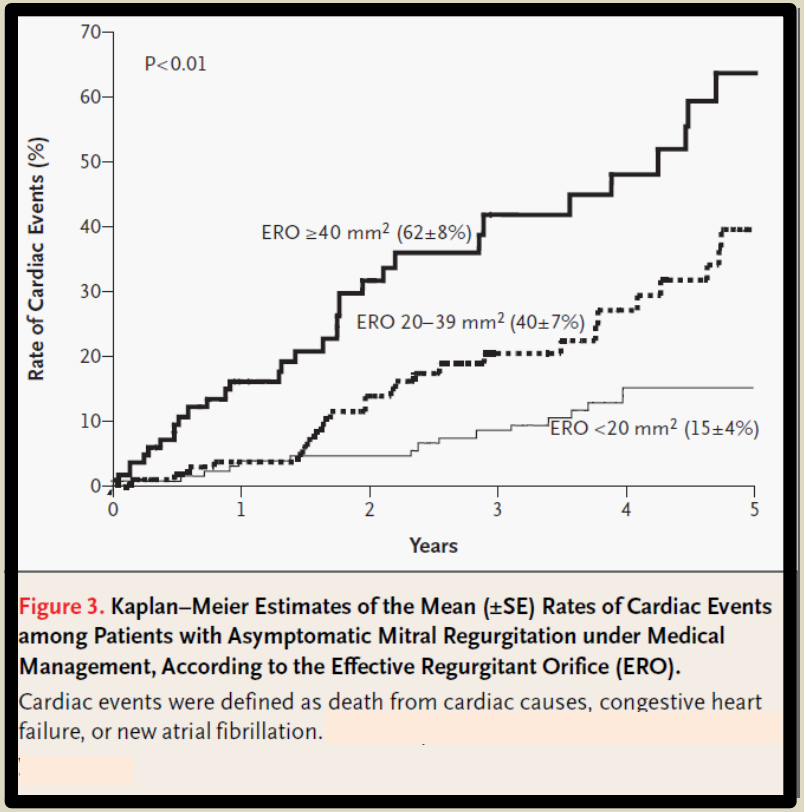


Figure 3. Kaplan–Meier Estimates of the Mean (±SE) Rates of Cardiac Events among Patients with Asymptomatic Mitral Regurgitation under Medical Management, According to the Effective Regurgitant Orifice (ERO).

Cardiac events were defined as death from cardiac causes, congestive heart failure, or new atrial fibrillation.

Patients with Effective Regurgitant Orifice (ERO) ≥40 mm² have a significantly increased risk of death and cardiac events and should promptly be considered for valve repair

Enriquez-Sarano M et al. Quantitative Determinants of the Outcome of Asymptomatic Mitral Regurgitation N Engl J Med 2005; 352:875-883.

The «unmet need»

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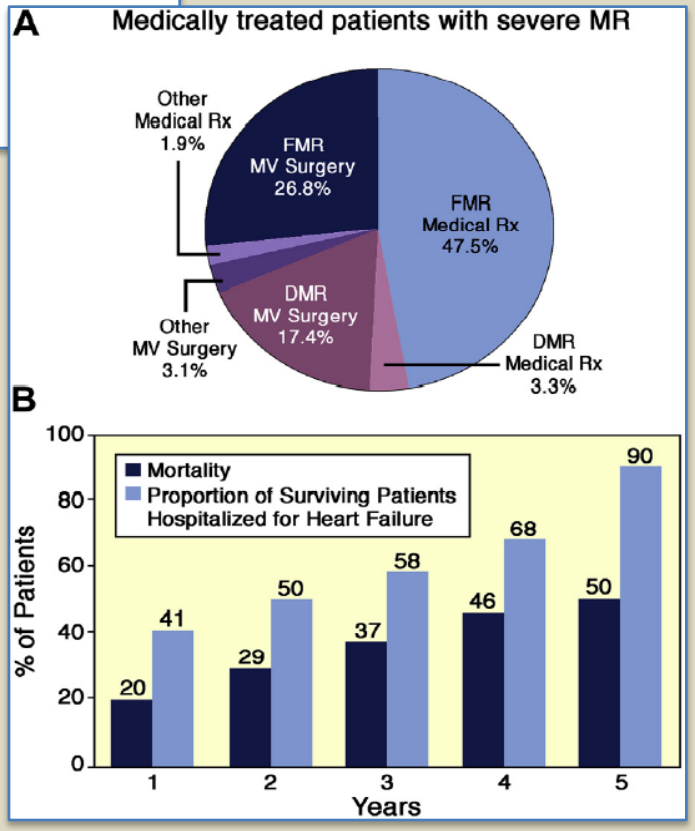
CORRESPONDENCE

Research Correspondence

Prevalence and Outcomes of Unoperated Patients With Severe Symptomatic Mitral Regurgitation and Heart Failure

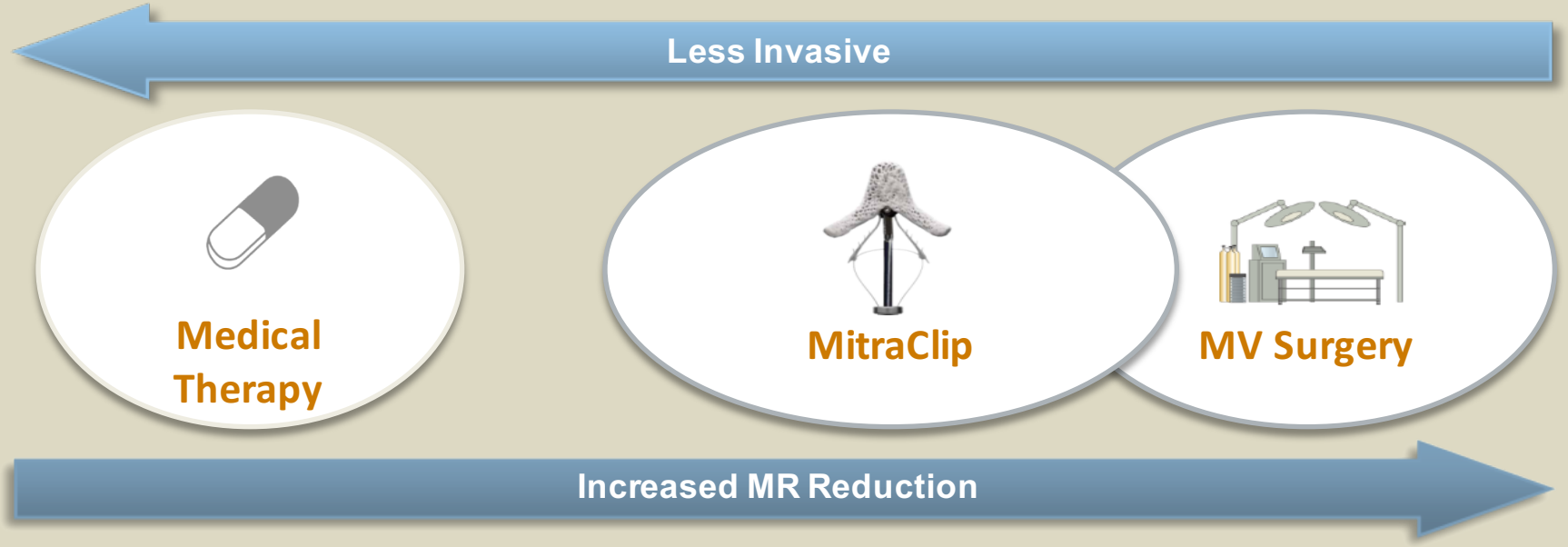
Comprehensive Analysis to Determine the Potential Role of MitraClip for This Unmet Need

- **2000-2008: identificati 5,737 con MR ≥3+**
- **1,095 pz con IM severa ed HF (814 FMR, 226 DMR)**
- **518 operati (~47.3%), 577 non operati (~52%)**
- **577 pz NON operati (~52%), Follow-up a 5 anni:**
  - **- mortalità → 50%**
  - **- ospedalizzazioni → 90%**



MitraClip Therapy: Filling a Treatment Gap

- Medical therapy addresses symptom management only
- MV surgery has been the only option that reliably reduces MR
- **A significant gap exists between patients who receive medical therapy and those undergoing MV surgery, which is based on risk-benefit profile**
- **MitraClip** therapy is a **first-in-class**, **minimally invasive, catheter-based** procedure to reduce MR



Linee Guida ESC/EACTS 2012 sulla gestione delle patologie valvolari

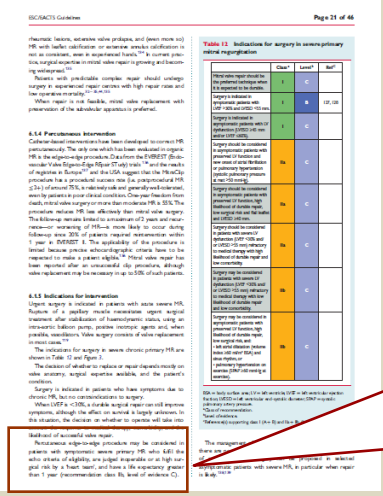
European Heart Journal
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

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

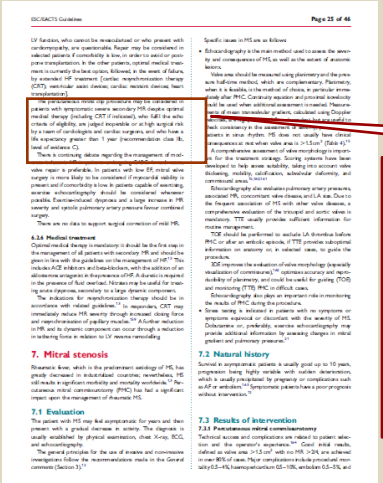
The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France)*, Ottavio Alfieri (Chairperson)* (Italy), Felicita Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volkmar Falk (Switzerland), Bernard Iung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schuler (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)



Indicazioni per IM Degenerativa

*" **La procedura percutanea edge-to-edge può essere presa in considerazione in pazienti sintomatici con severe insufficienza mitralica primaria che rispondono ai criteri di eleggibilità, sono giudicati inoperabili o ad alto rischio chirurgico** da un "heart team", e hanno un'aspettativa di vita maggiore di 1 anno (**classe di raccomandazione IIb, livello di evidenza C**)"*



Indicazioni per IM Funzionale

*"**La procedura percutanea MitraClip può essere presa in considerazione in pazienti sintomatici con severe insufficienza mitralica secondaria nonostante ottima terapia medica (incluso la CRT se indicato)**, che rispondono ai criteri di eleggibilità, sono giudicati inoperabili o ad alto rischio chirurgico da un team di cardiologi e cardiochirurghi", e hanno un'aspettativa di vita maggiore di 1 anno (**classe di raccomandazione IIb, livello di evidenza C**)"*

Source: http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/valvular-heart-disease.aspx

Percutaneous edge-to-edge repair as treatment option for high-risk surgical patients in ESC Heart Failure 2012 guidelines

European Heart Journal
doi:10.1093/eurheartj/ehs104

ESC GUIDELINES

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC

Authors/Task Force Members: John J. V. McMurray (Chairperson) (UK)*, Stamatis Adamopoulos (Greece), Stefan D. Anker (Germany), Angelo Auricchio (Switzerland), Michael Böhm (Germany), Kenneth Dickstein (Norway), Volkmar Falk (Switzerland), Gerasimos Filippatos (Greece), Cândida Fonseca (Portugal), Miguel Angel Gomez Sanchez (Spain), Tiny Jaarsma (Sweden), Lars Kober (Denmark), Gregory Y. H. Lip (UK), Aldo Pietro Maggioni (Italy), Alexander Parkhomenko (Ukraine), Burkert M. Pieske (Austria), Bogdan A. Popescu (Romania), Per K. Rønnevik (Norway), Frans H. Rutten (The Netherlands), Juerg Schwitter (Switzerland), Petar Seferovic (Serbia), Janina Stepinska (Poland), Pedro T. Trindade (Switzerland), Adriaan A. Voors (The Netherlands), Faiez Zannad (France), Andreas Zeiher (Germany).

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Other ESC entities having participated in the development of this document:

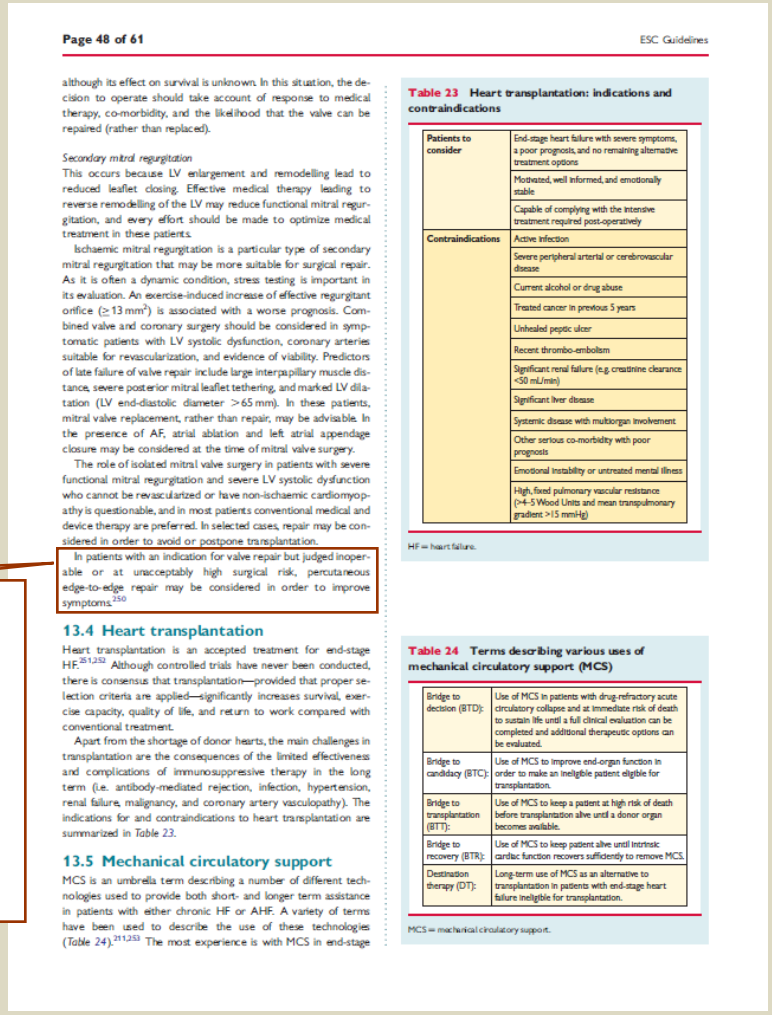
Associations: European Association for Cardiovascular Prevention & Rehabilitation (EACPR), European Association of Echocardiography (EAE), European Heart Rhythm Association (EHRA), European Association of Percutaneous Cardiovascular Interventions (EAPCI)

Working Groups: Acute Cardiac Care, Cardiovascular Pharmacology and Drug Therapy, Cardiovascular Surgery, Grown-up Congenital Heart Disease, Hypertension and the Heart, Myocardial and Pericardial Diseases, Pulmonary Circulation and Right Ventricular Function, Thrombosis, Valvular Heart Disease

Councils: Cardiovascular Imaging, Cardiovascular Nursing and Allied Professions, Cardiology Practice, Cardiovascular Primary Care

Disclaimer. The ESC Guidelines represent the views of the ESC and were arrived at after careful consideration of the available evidence at the time they were written. Health professionals are encouraged to take them fully into account when exercising their clinical judgement. The guidelines do not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patients, in consultation with that patient, and where appropriate and necessary the patient's guardian or carer. It is also the health professional's responsibility to verify the rules and regulations applicable to drugs and devices at the time of prescription.

…"**In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered** in order to improve symptoms."…..



although its effect on survival is unknown. In this situation, the decision to operate should take account of response to medical therapy, co-morbidity, and the likelihood that the valve can be repaired (rather than replaced).

Secondary mitral regurgitation

This occurs because LV enlargement and remodelling lead to reduced leaflet closing. Effective medical therapy leading to reverse remodelling of the LV may reduce functional mitral regurgitation, and every effort should be made to optimize medical treatment in these patients.

Ischaemic mitral regurgitation is a particular type of secondary mitral regurgitation that may be more suitable for surgical repair. As it is often a dynamic condition, stress testing is important in its evaluation. An exercise-induced increase of effective regurgitant orifice ($\geq 13\ mm^2$) is associated with a worse prognosis. Combined valve and coronary surgery should be considered in symptomatic patients with LV systolic dysfunction, coronary arteries suitable for revascularization, and evidence of viability. Predictors of late failure of valve repair include large interpapillary muscle distance, severe posterior mitral leaflet tethering, and marked LV dilatation (LV end-diastolic diameter >65 mm). In these patients, mitral valve replacement, rather than repair, may be advisable. In the presence of AF, atrial ablation and left atrial appendage closure may be considered at the time of mitral valve surgery.

The role of isolated mitral valve surgery in patients with severe functional mitral regurgitation and severe LV systolic dysfunction who cannot be revascularized or have non-ischaemic cardiomyopathy is questionable, and in most patients conventional medical and device therapy are preferred. In selected cases, repair may be considered in order to avoid or postpone transplantation.

In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms.[250]

13.4 Heart transplantation

Heart transplantation is an accepted treatment for end-stage HF.[251,252] Although controlled trials have never been conducted, there is consensus that transplantation—provided that proper selection criteria are applied—significantly increases survival, exercise capacity, quality of life, and return to work compared with conventional treatment.

Apart from the shortage of donor hearts, the main challenges in transplantation are the consequences of the limited effectiveness and complications of immunosuppressive therapy in the long term (i.e. antibody-mediated rejection, infection, hypertension, renal failure, malignancy, and coronary artery vasculopathy). The indications for and contraindications to heart transplantation are summarized in *Table 23*.

13.5 Mechanical circulatory support

MCS is an umbrella term describing a number of different technologies used to provide both short- and longer term assistance in patients with either chronic HF or AHF. A variety of terms have been used to describe the use of these technologies (*Table 24*).[211,253] The most experience is with MCS in end-stage

Table 23 Heart transplantation: indications and contraindications

Patients to consider	End-stage heart failure with severe symptoms, a poor prognosis, and no remaining alternative treatment options
	Motivated, well informed, and emotionally stable
	Capable of complying with the intensive treatment required post-operatively
Contraindications	Active infection
	Severe peripheral arterial or cerebrovascular disease
	Current alcohol or drug abuse
	Treated cancer in previous 5 years
	Unhealed peptic ulcer
	Recent thrombo-embolism
	Significant renal failure (e.g. creatinine clearance <50 mL/min)
	Significant liver disease
	Systemic disease with multiorgan involvement
	Other serious co-morbidity with poor prognosis
	Emotional instability or untreated mental illness
	High, fixed pulmonary vascular resistance (>4–5 Wood Units and mean transpulmonary gradient >15 mmHg)

HF = heart failure.

Table 24 Terms describing various uses of mechanical circulatory support (MCS)

Bridge to decision (BTD):	Use of MCS in patients with drug-refractory acute circulatory collapse and at immediate risk of death to sustain life until a full clinical evaluation can be completed and additional therapeutic options can be evaluated.
Bridge to candidacy (BTC):	Use of MCS to improve end-organ function in order to make an ineligible patient eligible for transplantation.
Bridge to transplantation (BTT):	Use of MCS to keep a patient at high risk of death before transplantation alive until a donor organ becomes available.
Bridge to recovery (BTR):	Use of MCS to keep patient alive until intrinsic cardiac function recovers sufficiently to remove MCS.
Destination therapy (DT):	Long-term use of MCS as an alternative to transplantation in patients with end-stage heart failure ineligible for transplantation.

MCS = mechanical circulatory support.

Source: ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012 published on ESC web-site: http://www.escardio.org/guidelines-surveys/esc-guidelines/Pages/acute-chronic-heart-failure.aspx?hit=dontmiss

WHO refer to PMVR

MitraClip in Specific Patient Groups

MR patient groups in which significant clinical benefits have been reported:

- High surgical risk for excessive comorbidities (advanced COPD, CKD, etc.)
- Patients with previous cardiac surgery at high risk for re-do operation
- Severe heart failure, despite optimal medical therapy[1]
- CRT non-responders[2]
- Degenerative MR, declined for surgery (experienced Heart Team!)[3]
- Bivalvular disease: severe aortic stenosis and MR in high-risk patients[4]
- Severe LV dysfunction (IDCM, ischemic CM) refractory to medical therapy[5]
- Bridge to transplant??

The following parameters should be taken into consideration by the Heart Team[6]:

- Moderate to severe or severe MR
- Echocardiographic criteria for eligibility
- Level of surgical risk
- Greater than one year life expectancy

1. Franzen et al. MitraClip Therapy In Patients With End-Stage Systolic Heart Failure. Eur J Heart Failure. 2011; 13: 569-576.
2. Auricchio et al. Correction of Mitral Regurgitation in Nonresponders To Cardiac Resynchronization Therapy By MitraClip Improves Symptoms And Promotes Reverse Remodeling. JACC 2011; 58: 2183-2189.
3. Reichenspurner, H. et al. Clinical Outcomes through 12 months in patients with Degenerative Mitral Regurgitation treated with the MitraClip device in the ACCESS-Europe Phase I trial. Eur J Cardiothoracic Surgery. 2013: July 17. [Epub ahead of print]
4. Rudolph V, Schirmer J, Franzen O, Schlüter M, Seiffert M, Treede H, Reichenspurner H, Blankenberg S, Baldus S. Bivalvular transcatheter treatment of high-surgical-risk patients with coexisting severe aortic stenosis and significant mitral regurgitation. Int J Cardiol. 2013; 167(3):716-2
5. Franzen O, Baldus S, Rudolph V, et al. Acute outcomes of MitraClip therapy for mitral regurgitation in high-surgical-risk patients: Emphasis on adverse valve morphology and severe left ventricular dysfunction. Eur Heart J. 2010; 31:1373-1381
6. ESC/EACTS 2012 Guidelines on the management of valvular heart disease. Eur Heart J (2012) 33, 2451–2496

WHO refer to PMVR: Patient Selection*

- Moderate-to-Severe or Severe MR (3+ or 4+)
- Symptomatic
- Level of surgical risk
- Echocardiographic and anatomic criteria for eligibility

*Greater than one year life expectancy

Ecocardiographic Evaluation of MR Severity

	Aortic regurgitation	Mitral regurgitation		Tricuspid regurgitation
Qualitative				
Valve morphology	Abnormal/flail/large coaptation defect	Flail leaflet/ruptured papillary muscle/ large coaptation defect		Abnormal/flail/large coaptation defect
Colour flow regurgitant jet	Large in central jets, variable in eccentric jets[a]	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[a]
CW signal of regurgitant jet	Dense	Dense/triangular		Dense/triangular with early peaking (peak <2 m/s in massive TR)
Other	Holodiastolic flow reversal in descending aorta (EDV >20 cm/s)	Large flow convergence zone[a]		–
Semiquantitative				
Vena contracta width (mm)	>6	≥7 (>8 for biplane)[b]		≥7[a]
Upstream vein flow[c]	–	Systolic pulmonary vein flow reversal		Systolic hepatic vein flow reversal
Inflow	–	E-wave dominant ≥1.5 m/s[d]		E-wave dominant ≥1 m/s[e]
Other	Pressure half-time <200 ms[f]	TVI mitral/TVI aortic >1.4		PISA radius >9 mm[g]
Quantitative		Primary	Secondary[h]	
EROA (mm^2)	≥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

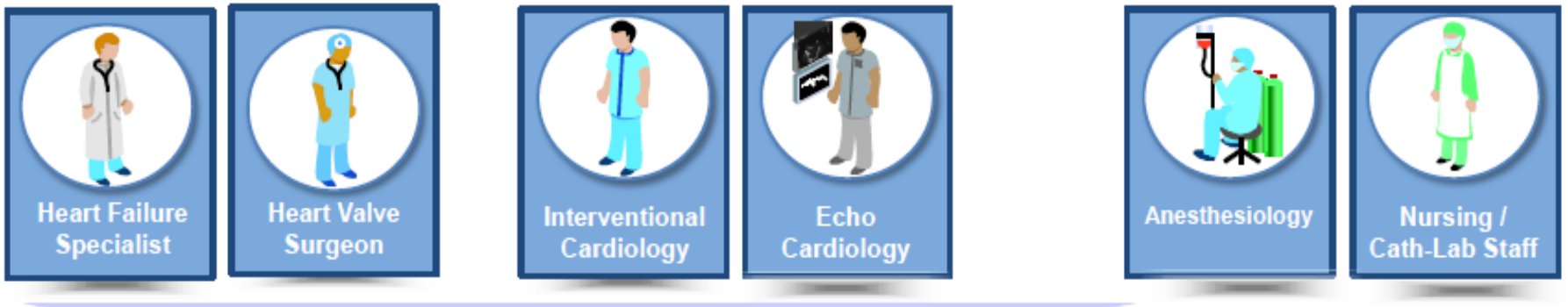
ESC/EACTS Guidelines on the management of valvular heart disease. *European Heart Journal* (***2012***) *33, 2451–2496 doi:10.1093/eurheartj/ehs109*

Echocardiographic and Anatomic Criteria for Eligibility

- **Etiology:** Degenerative, Functional or Mixed
- **Focus on MV and leaflets** (flail, prolapse, restriction, cleft, etc)
- **Left ventrcicle:** EF and dimension
- **Left atrium:** dimension, annulus, atrial fibrillation
- **Subvalvular apparatus** (chordal relationships, papillary muscles)
- **Jet origin**
- **Atrial septum:** ASD, PFO, fossa size, aneurysm, etc
- **Other:** thrombus in LAA, vegetation, calcium etc.
- **Required anatomical measurements:**
  - Mitral Valve Area (≥ 4 cm^2)
  - Fossa/Coaptation ratio (≥ 4 cm)
  - Leaflets length (≥ 10 mm), leaflets thickness (≤ 5 mm)
  - No calcification in the grasping area
- **Degenerative Mitral Regurgitation (DMR)**
  - Flail Gap (≤ 10 mm)
  - Flail Width (≤ 15 mm)
- **Functional Mitral Regurgitation (FMR)**
  - Vertical Coaptation Length (≥ 2 mm)

Multidisciplinary Team

MitraClip therapy success is skills and communication of a trained team

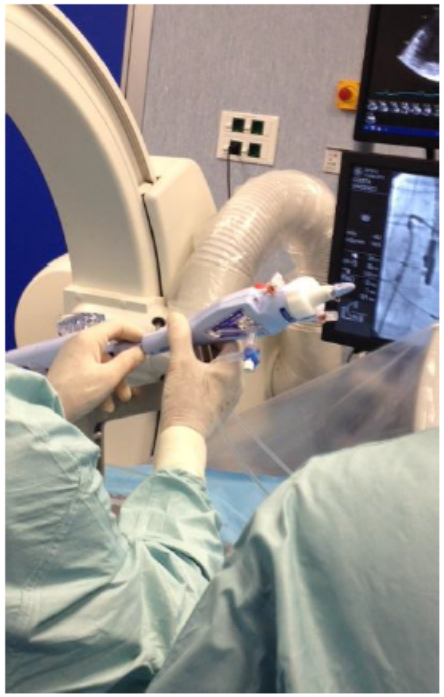


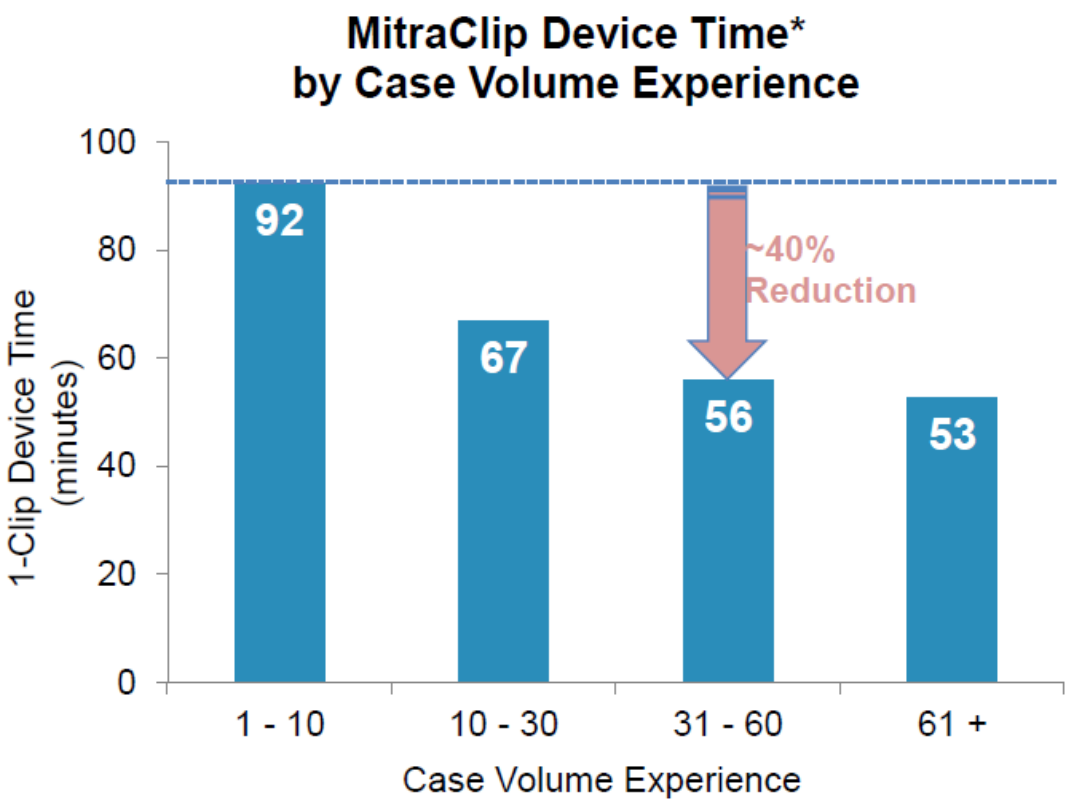
Patient selection and optimal Therapy pathway

Teamwork and training: Optimal Interventional result

Learning Curve

- ❑ At least 20 cases to **«understand what you are doing»**
- ❑ At lest 50 cases to achieve optical outcomes
- ❑ At leat 2 cases/month to maintain procedural expertise

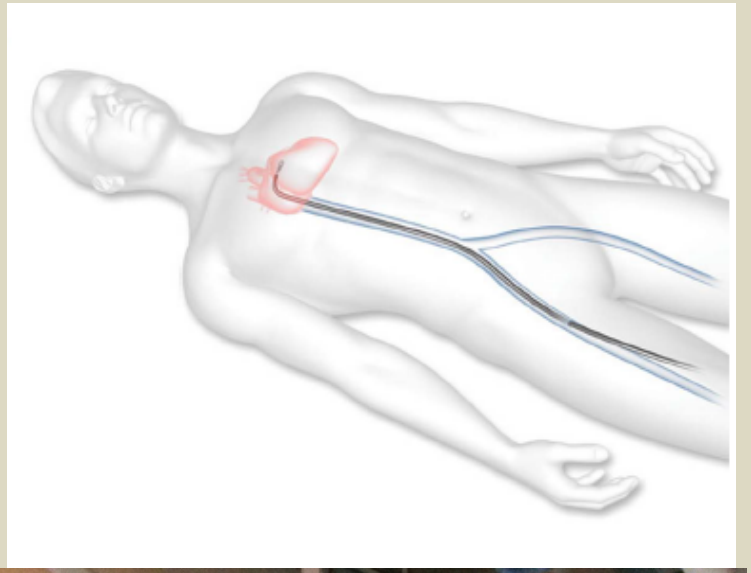


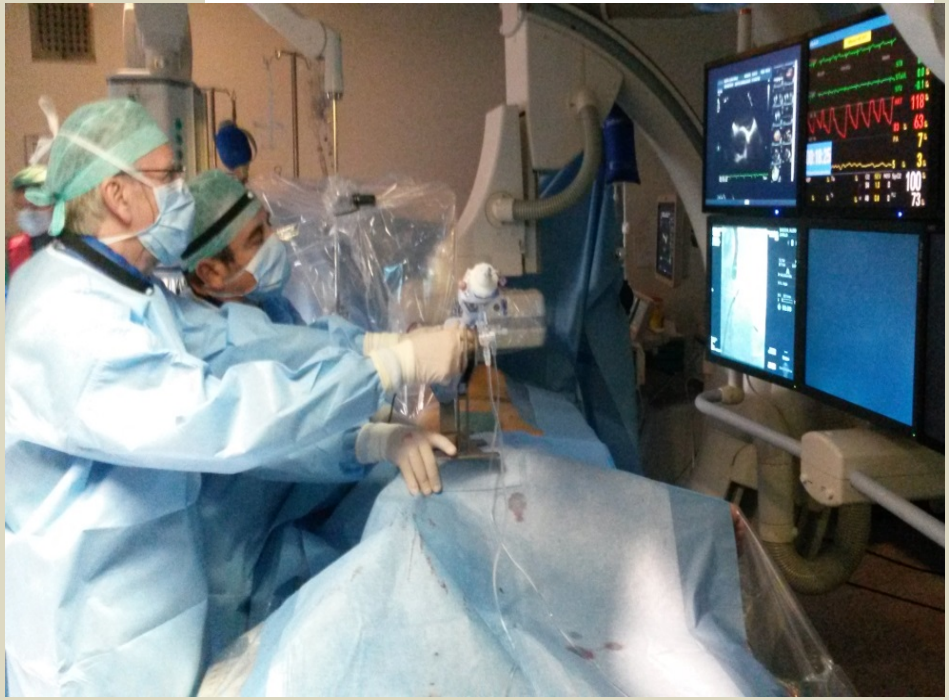


Data courtesy of Abbott Vascular - 246 hospital commercial experience in 1-Clip device times from Sept. 2008 to Sept. 2013

Procedure Setting

- Standard cath-lab or hybrid room
- Fast-track general anesthesia with orotracheal intubation in majority of cases
- Radial artery line for AP monitoring and jugular vein catheterization for CVP monitoring
- TEE (2D-3D) probe in place for the entire duration of the procedure
- Right femoral vein access with 24Fr sheath





MitraClip Key Procedural Steps

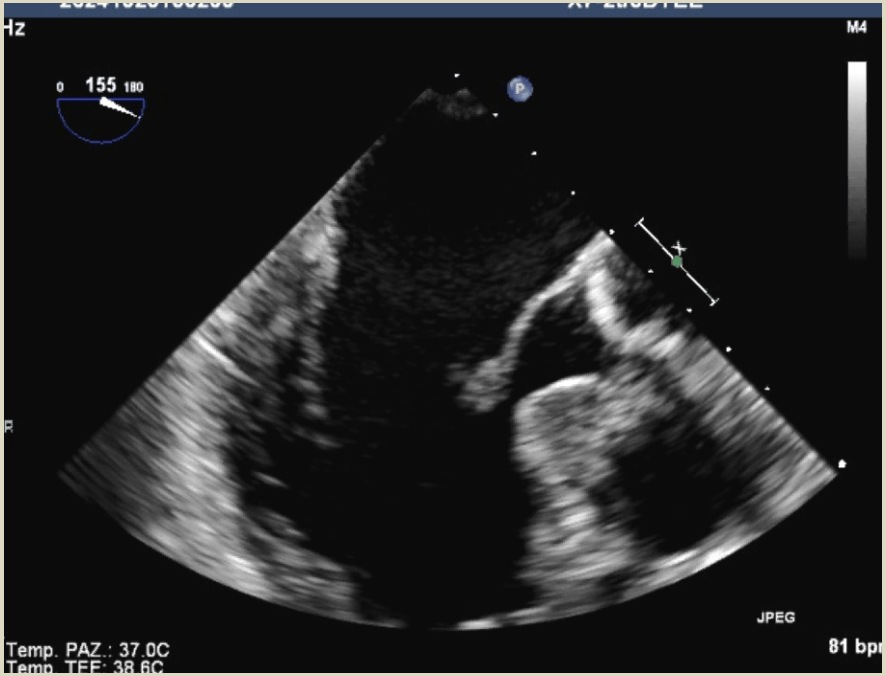
1. Transeptal Puncture & Guide Wire Insertion
2. 24Fr Sheath Insertion
3. CDS Insertion & Positioning
4. Clip Orientation & Grasping
5. Deployment & System Removal

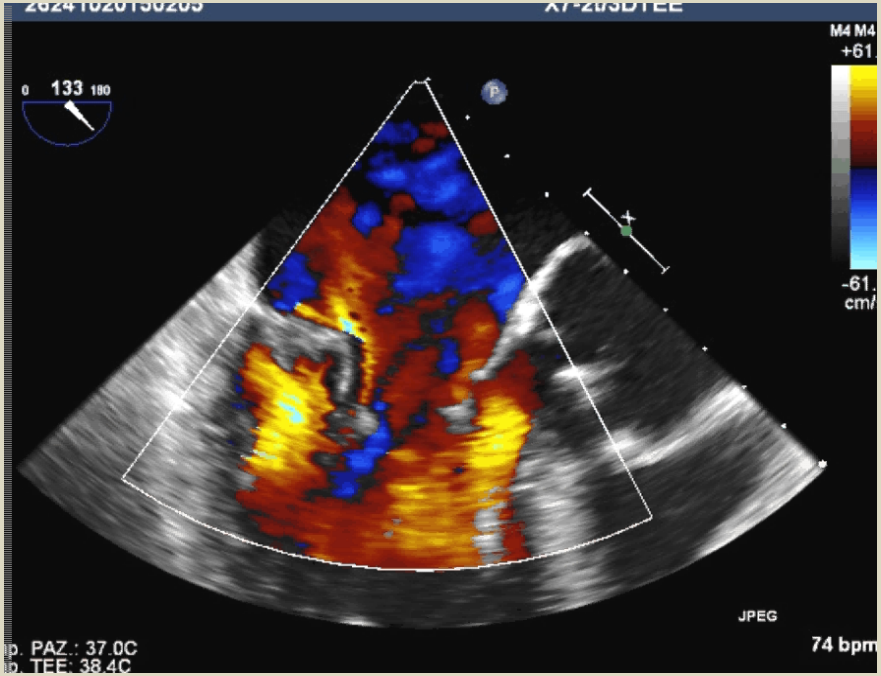
The Five Key Points For MitraClip Success

- Superb Imaging (2D-3D Echo)
- Optimal transseptal puncture
- Correct trajectory
- Arms perpendicular to the line of coaptation
- Well-positioned and reliable grasp

Age & Gender:	83-year-old male, 75 Kg, 175 cm
Relevant clinical history:	**Risk factors / Comorbidities:** Advanced age, hypertension and moderate pulmonary hypertension **01/2014:** Admission for HF and left basal pneumonia **03/2014:** During a FU visit, a holosystolic murmur was found. TTE showed severe MR due to bi-leaflet prolapse **03/2014 - 12/2014:** progressive asthenia and dyspnea for mild efforts **01/2015:** Hospitalization for recurrent HF (NYHA class III-IV). TTE showed mitral annulus and left atrium dilation with initial left ventricle systolic dysfunction (EF= 55%, biplane diastolic volume= 61ml/m^2), and evidence of chordal ruptures of the anterior (A3) and posterior (P2) of the mitral valve (MV) leaflets resulting in bi-leaflet flail and massive MR. Moderate TR and pulmonary hypertension (44 mmHg). Coronary angiography excluded significant CAD.

Basal TEE

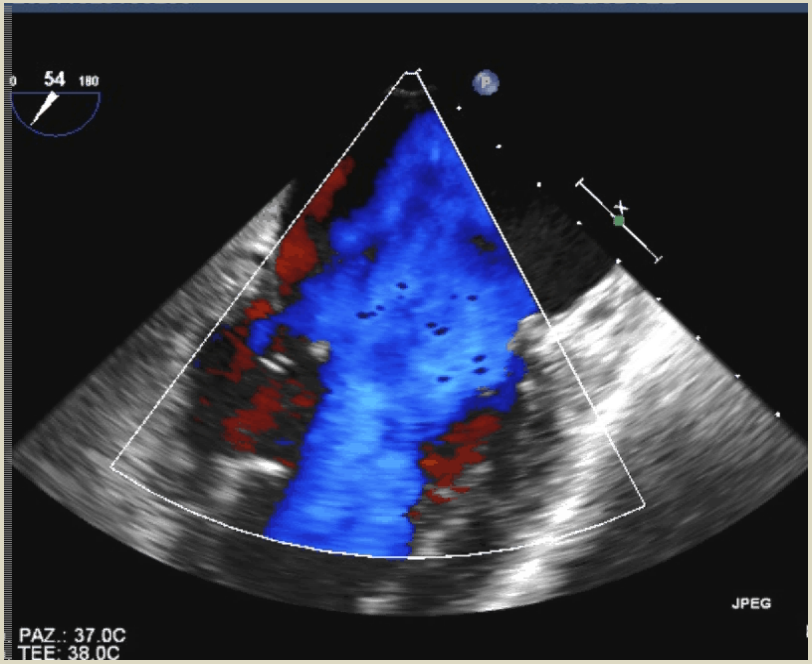




LVOT views showing bi-leaflet prolapse with chordal rupture of the anterior mitral valve leaflet resulting in severe MR (EROA= 0.5).

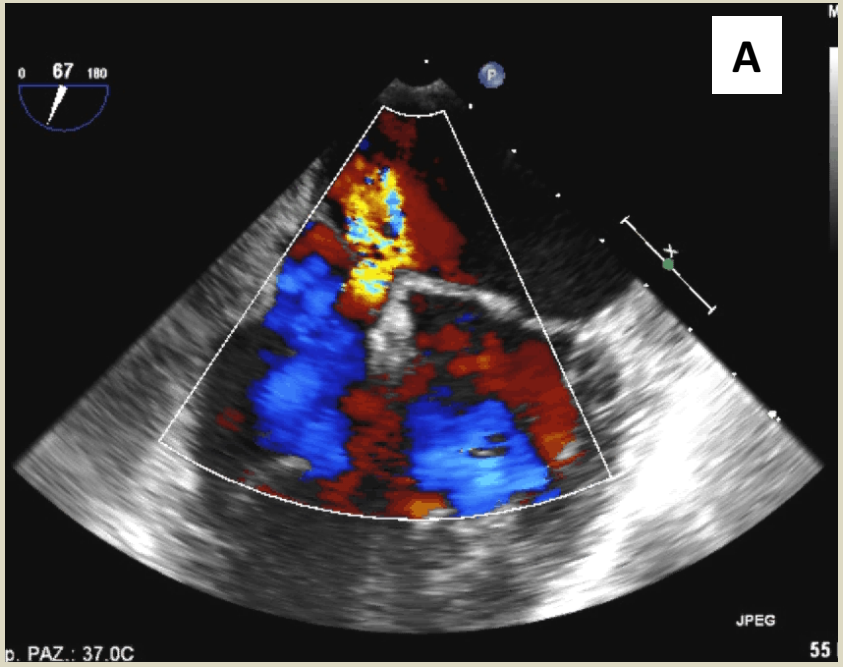
Basal TEE

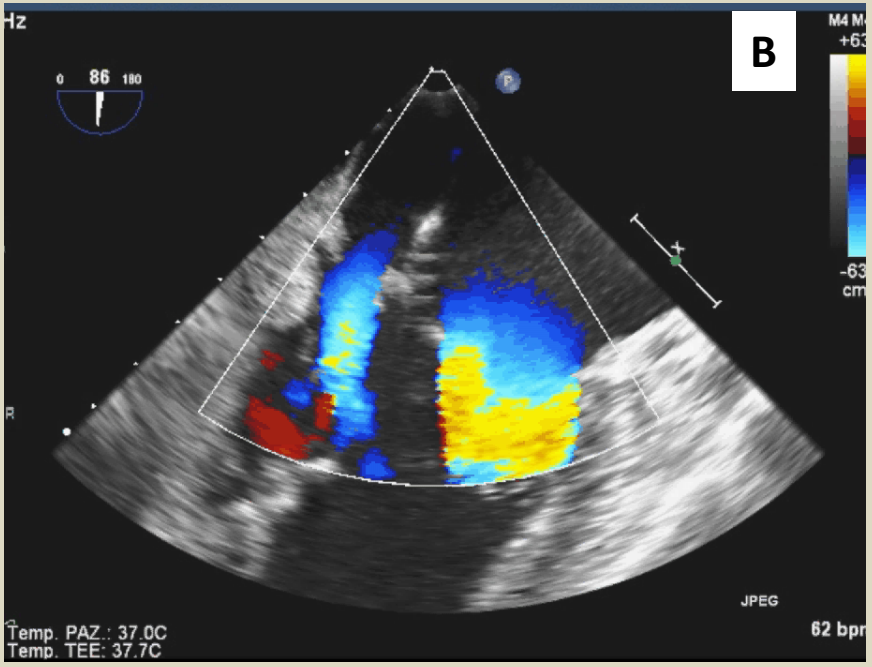
Inter-commisural view showing regurgitant jet between A2-P2 and A3-P3 scallops.



3-D acquisition showing prolapse and thickening of both leaflets with two chordal ruptures (red arrows) of anterior (A3) and posterior (P2) MV leaflets.

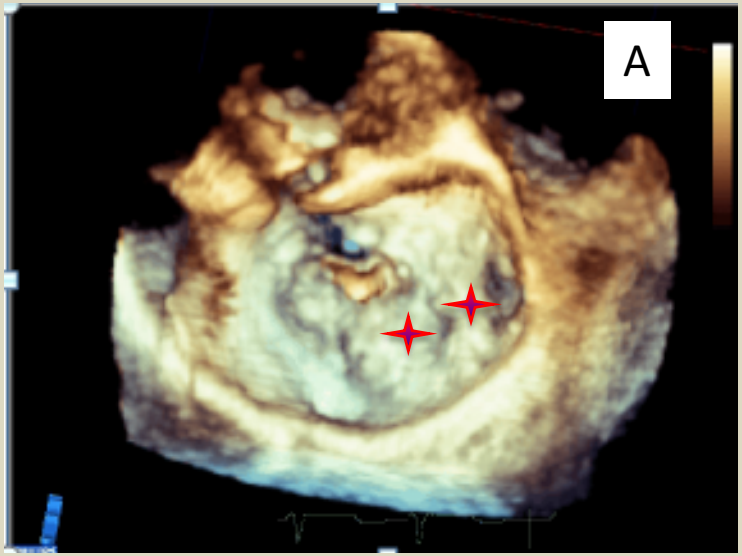
Intraprocedural TEE (1)

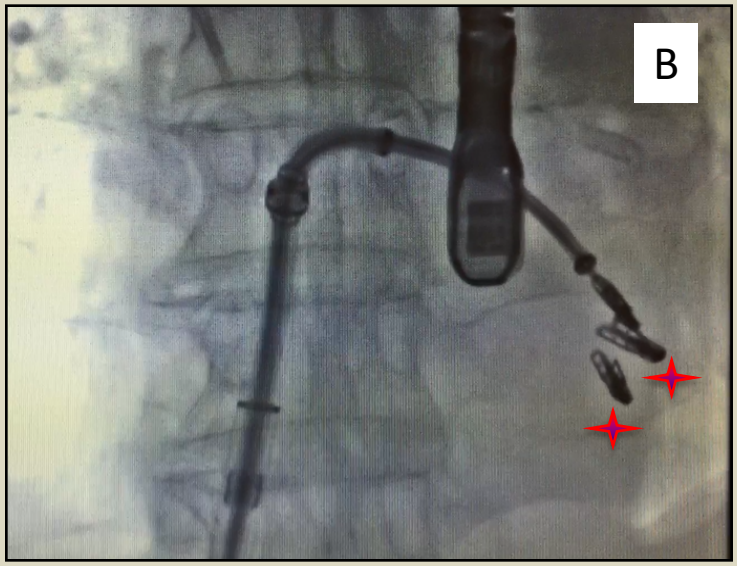




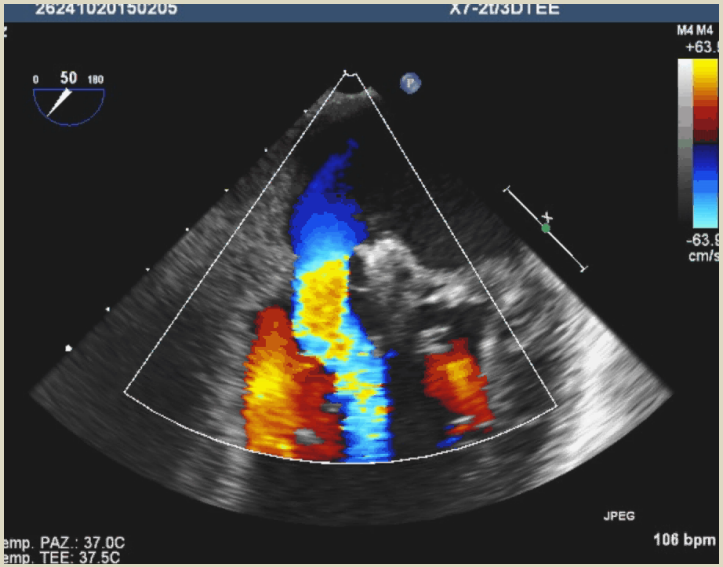
Inter-commisural views showing implantation of the 1st clip in the medial part of A2-P2 scallops in order to approximate the leaflets (A) and of the 2nd clip in the A3-P3 scallops in order to capture the flail (B). Note that medial MR is completely abolished, whereas a residual jet is still present in the central portion of the MV.

Intraprocedural TEE and fluoroscopy (2)



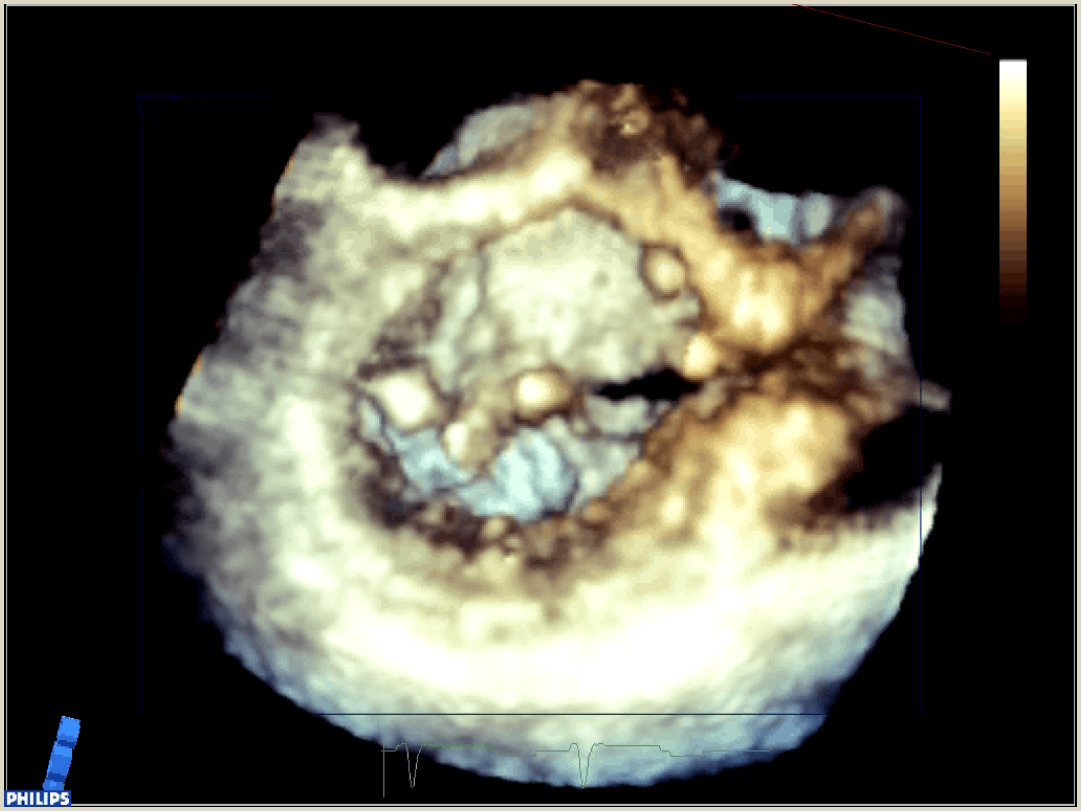


3-D view showing the two implanted clips (red stars) (A) and fluoroscopic image (B) showing implantation of the 3rd clip in the central part of the MV in order to achieve stabilization of the other clips (red stars) and optimization of the final result.



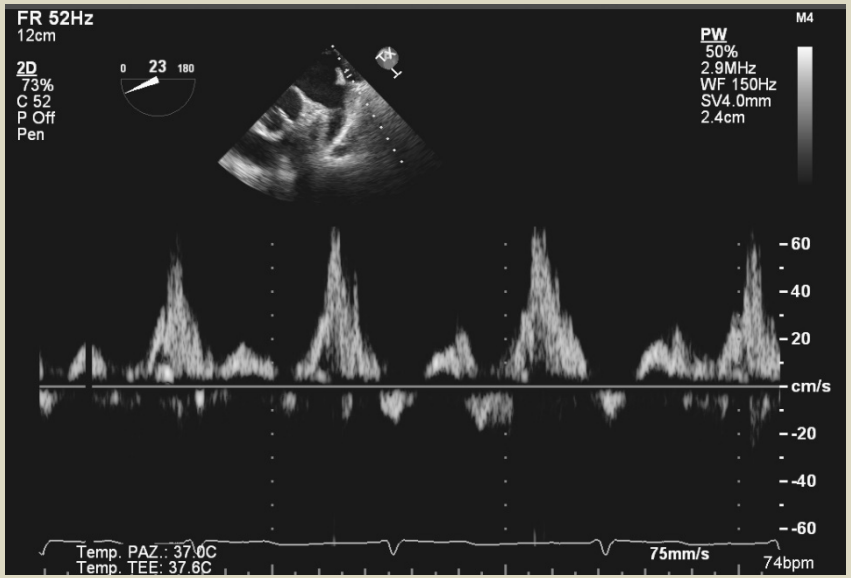
Inter-commisural view showing the final result after implantation of 3 clips. Note the trivial residual jet.

Intraprocedural TEE (3)



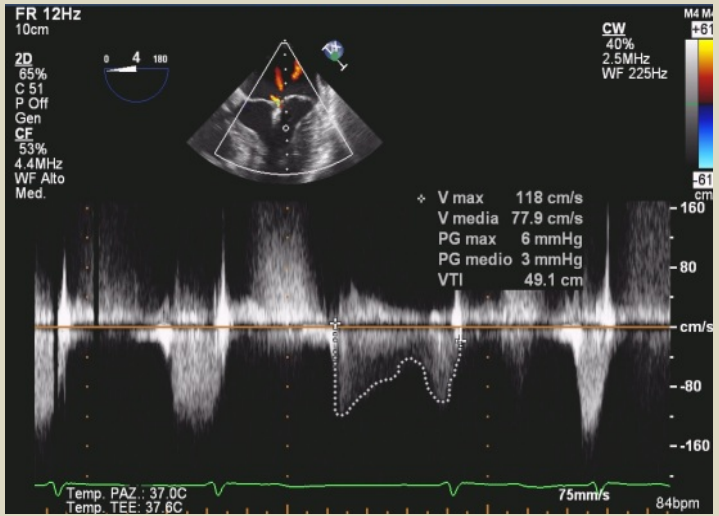
3-D view from the left ventricle showing the 3 implanted clips.

Intraprocedural TEE (4)



Basal PW-Doppler showing prevalence of pathological diastolic component of the pulmonary vein flow.

Final PW-Doppler showing restoration of physiological systolic vein flow.



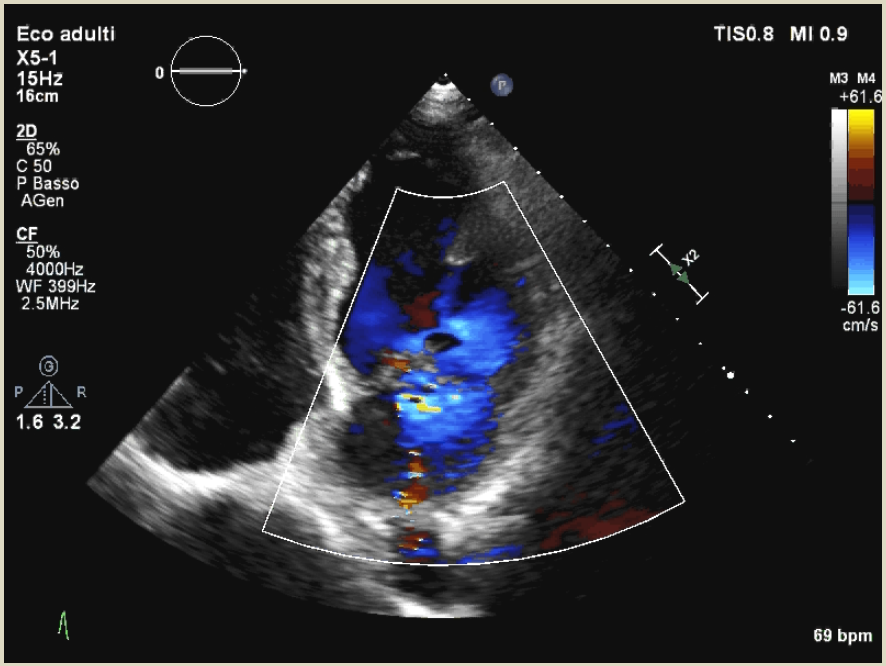
Final CW-Doppler assessment confirming the absence of a significant gradient (mean= 3 mmHg).

Follow-up:

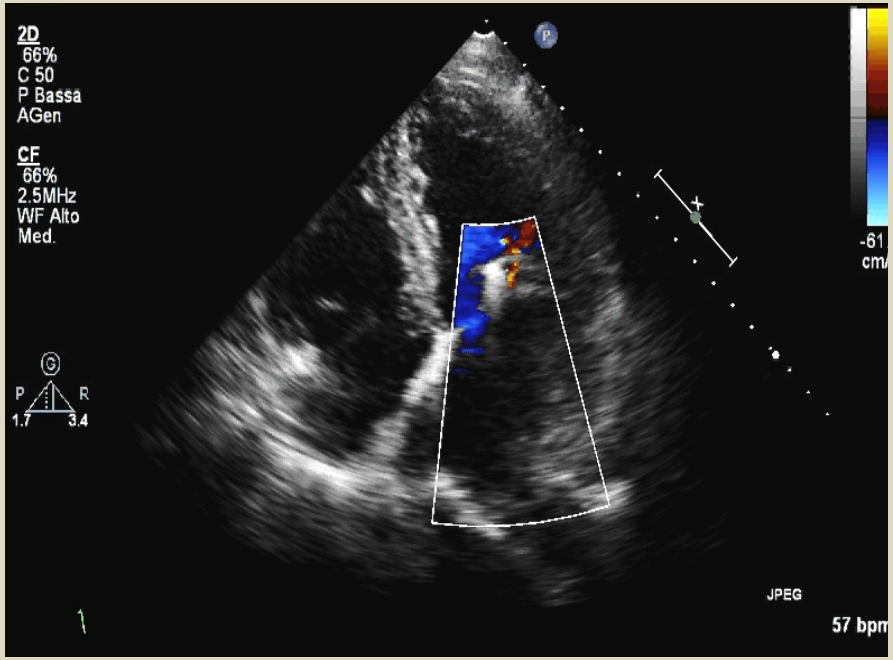
6-month ecochardiography and clinical follow-up:

- TTE confirmed mild residual MR and a mean gradient of 2 mmHg
- Left ventricle biplane diastolic volume: 98 ml (pre-procedure: 116 ml)
- Left ventricle diastolic diameter 55 mm (pre-procedure: 62 mm)
- EF 59% (pre-procedure: 55%)
- Mild tricuspid regurgitation (pre-procedure: moderate)
- Patient asymptomatic (NYHA Class I). No hospital re-admissions

Comparison between basal and 6-month TTE assessment

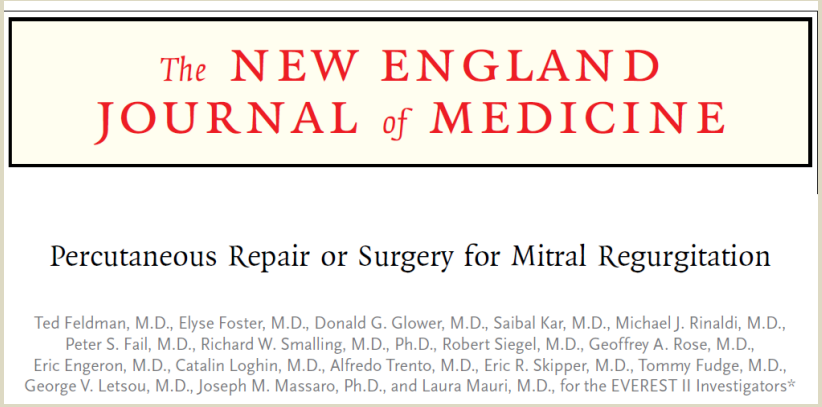


Basal TTE apical 4-chamber view showing severe MR



TTE at six-month FU: Apical 4-chamber view shows mild MR

EVEREST II - Endovascular Valve Edge-to-Edge REpair STudy

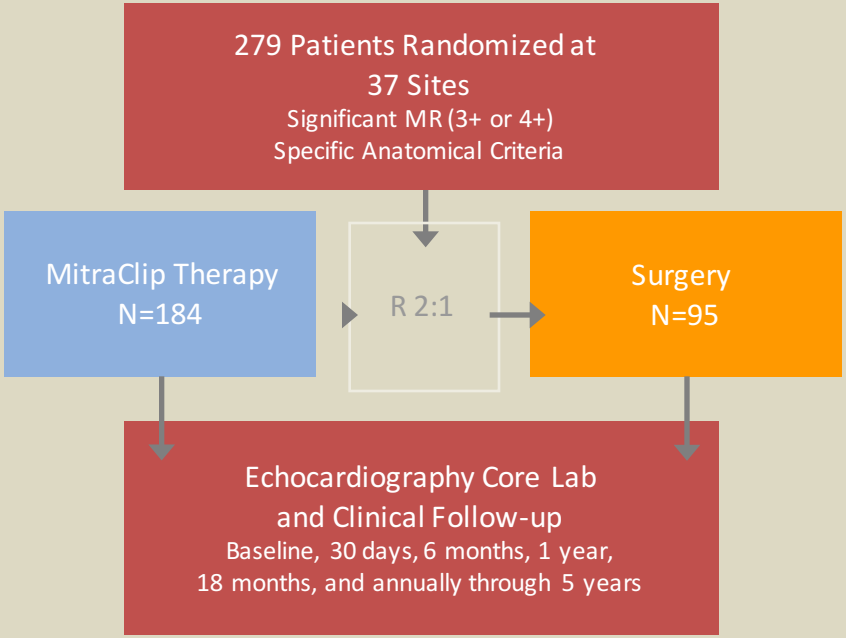


The NEW ENGLAND JOURNAL of MEDICINE

Percutaneous Repair or Surgery for Mitral Regurgitation

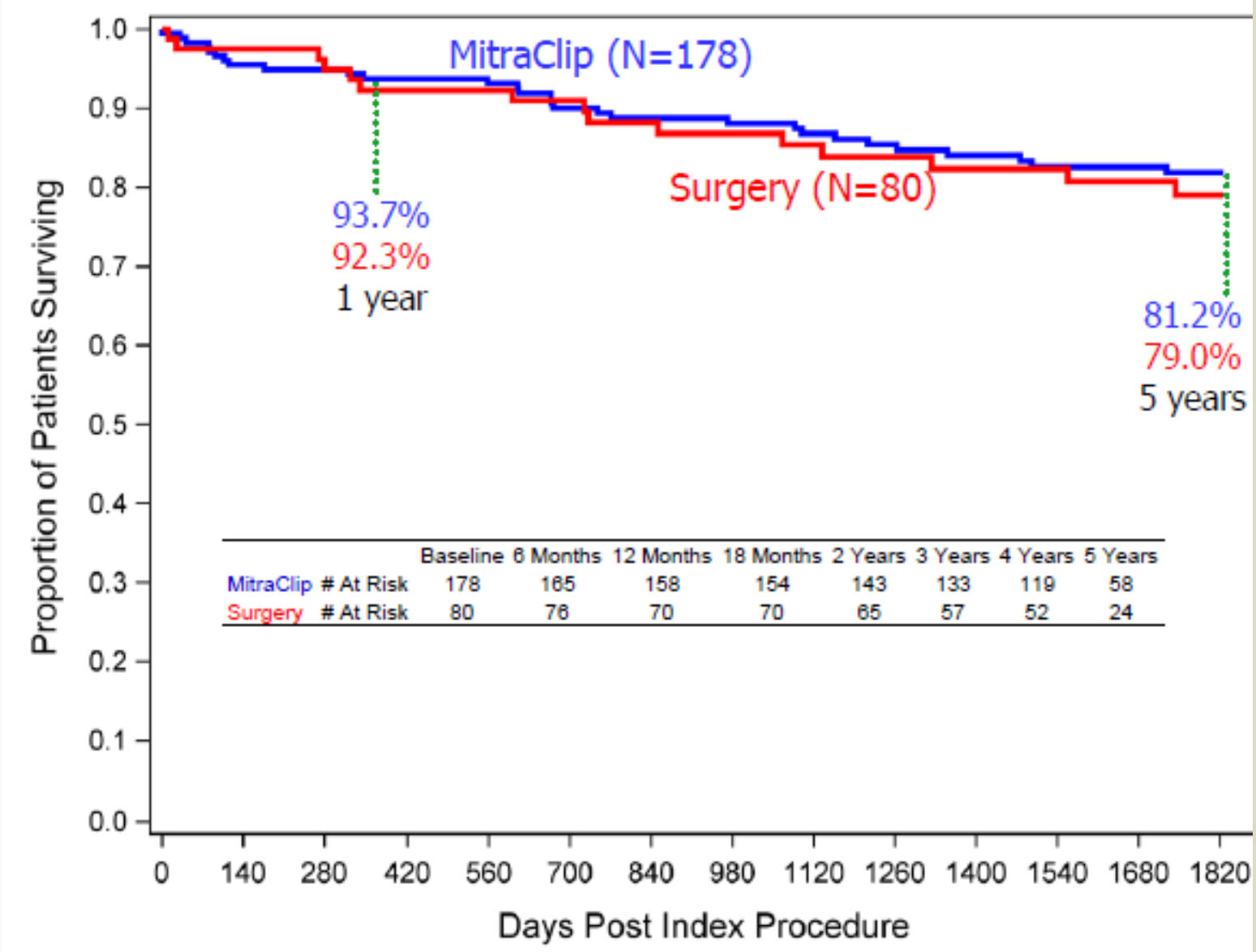
Ted Feldman, M.D., Elyse Foster, M.D., Donald G. Glower, M.D., Saibal Kar, M.D., Michael J. Rinaldi, M.D., Peter S. Fail, M.D., Richard W. Smalling, M.D., Ph.D., Robert Siegel, M.D., Geoffrey A. Rose, M.D., Eric Engeron, M.D., Catalin Loghin, M.D., Alfredo Trento, M.D., Eric R. Skipper, M.D., Tommy Fudge,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

The EVEREST II RCT was a prospective, multi-center trial designed to compare the safety and effectiveness of the MitraClip System with mitral valve surgery in the treatment of patients with significant (≥3+) mitral regurgitation



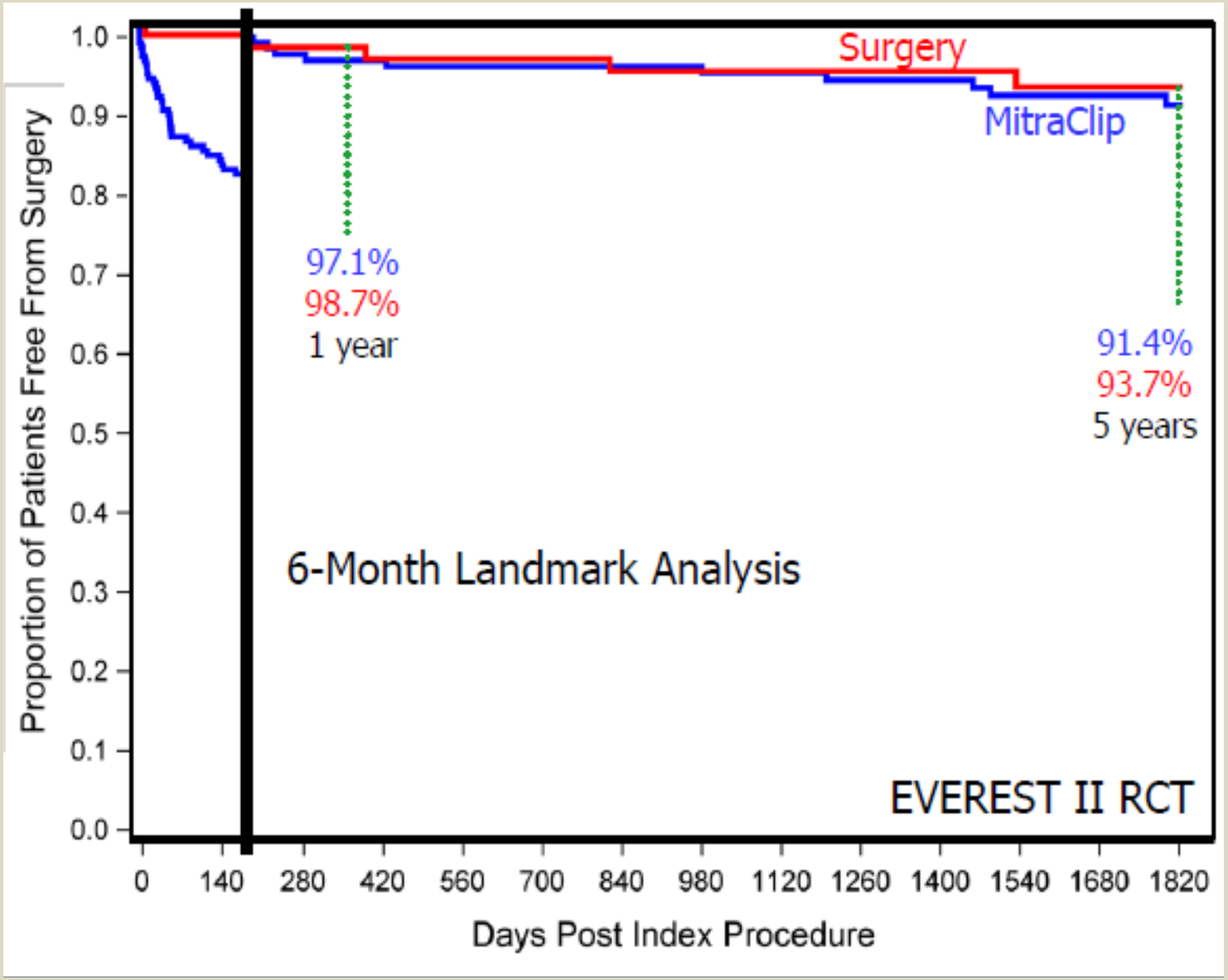
Patient Demographics	MitraClip Therapy (n=184)	Surgery (n=95)	P-value
Age (mean)	67 years	66 years	0.32
Male	63%	66%	0.60
History of CHF	91%	78%	0.005
Degenerative MR Etiology	74%	73%	0.81
Functional MR Etiology	26%	27%	0.81
Mean Ejection Fraction	60%	61%	0.65
Previous Coronary Artery Bypass Grafting (CBAG)	21%	19%	0.54
NYHA Functional Class III/IV	51%	48%	0.61
Atrial Fibrillation	34%	39%	0.42

Kaplan-Meier Freedom From Mortality



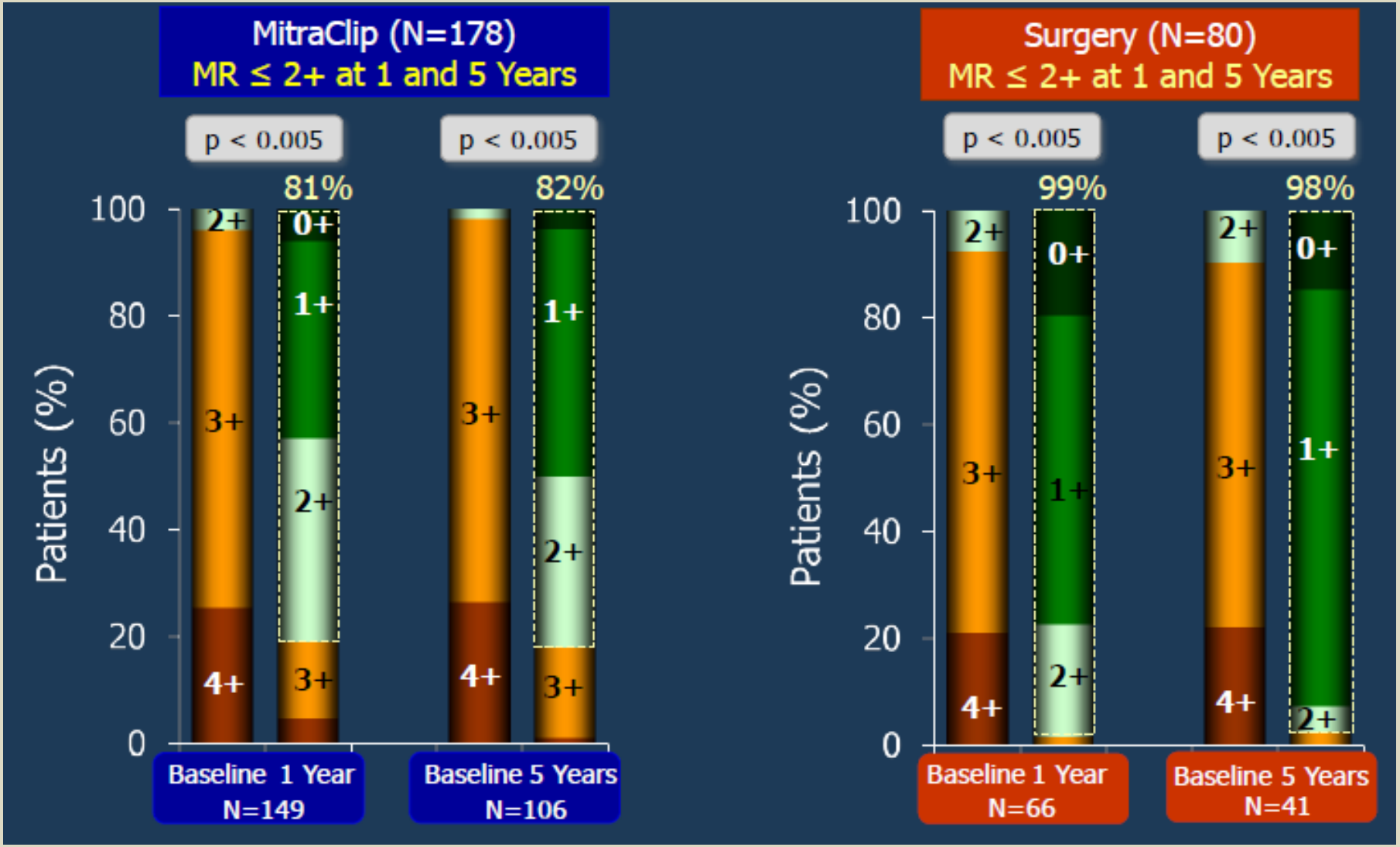
	Baseline	6 Months	12 Months	18 Months	2 Years	3 Years	4 Years	5 Years
MitraClip # At Risk	178	165	158	154	143	133	119	58
Surgery # At Risk	80	76	70	70	65	57	52	24

Kaplan-Meier Freedom From MV Surgery or Re-operation



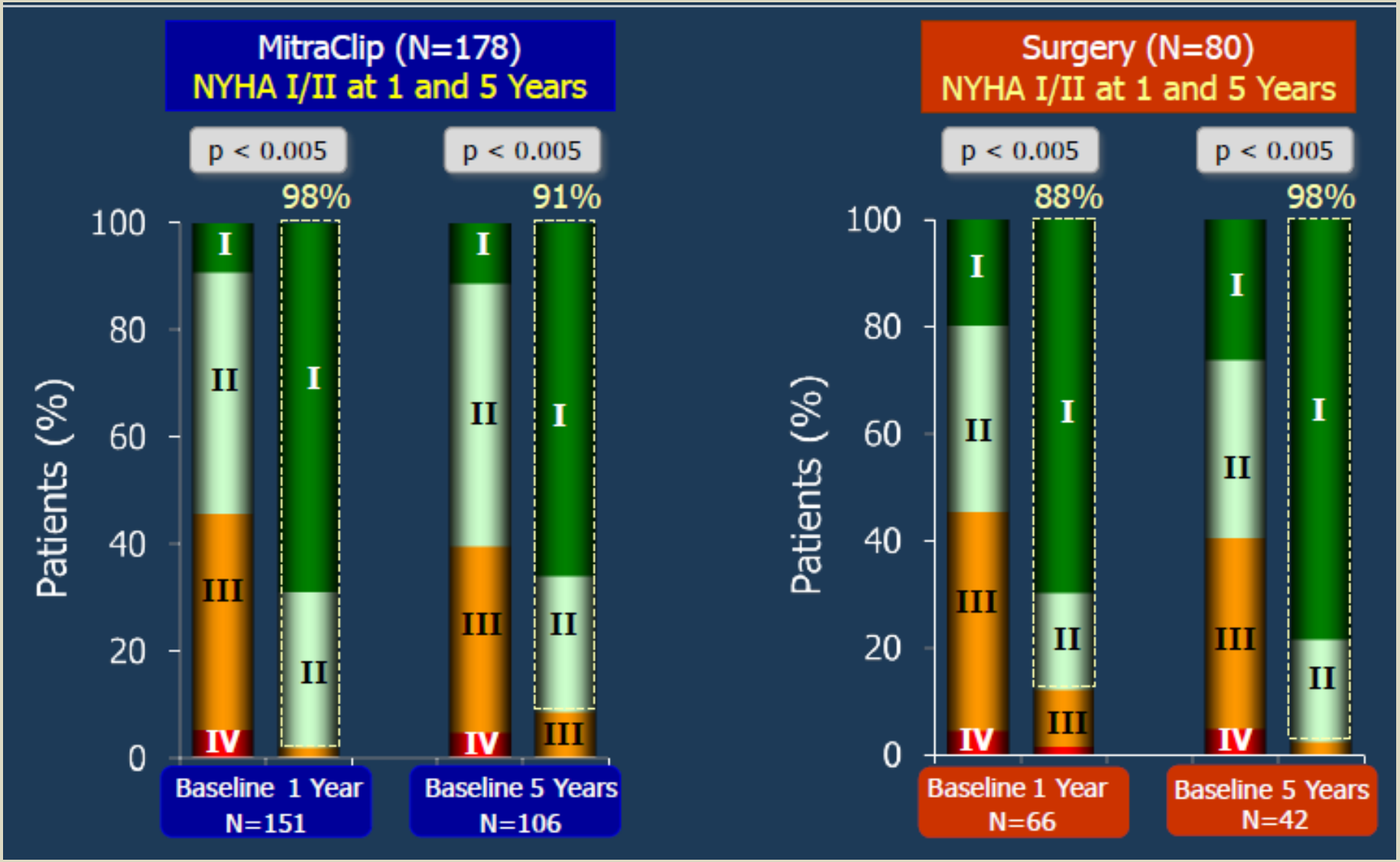
Mitral Regurgitation Grade

Everest II RCT all treated patients (n=258)

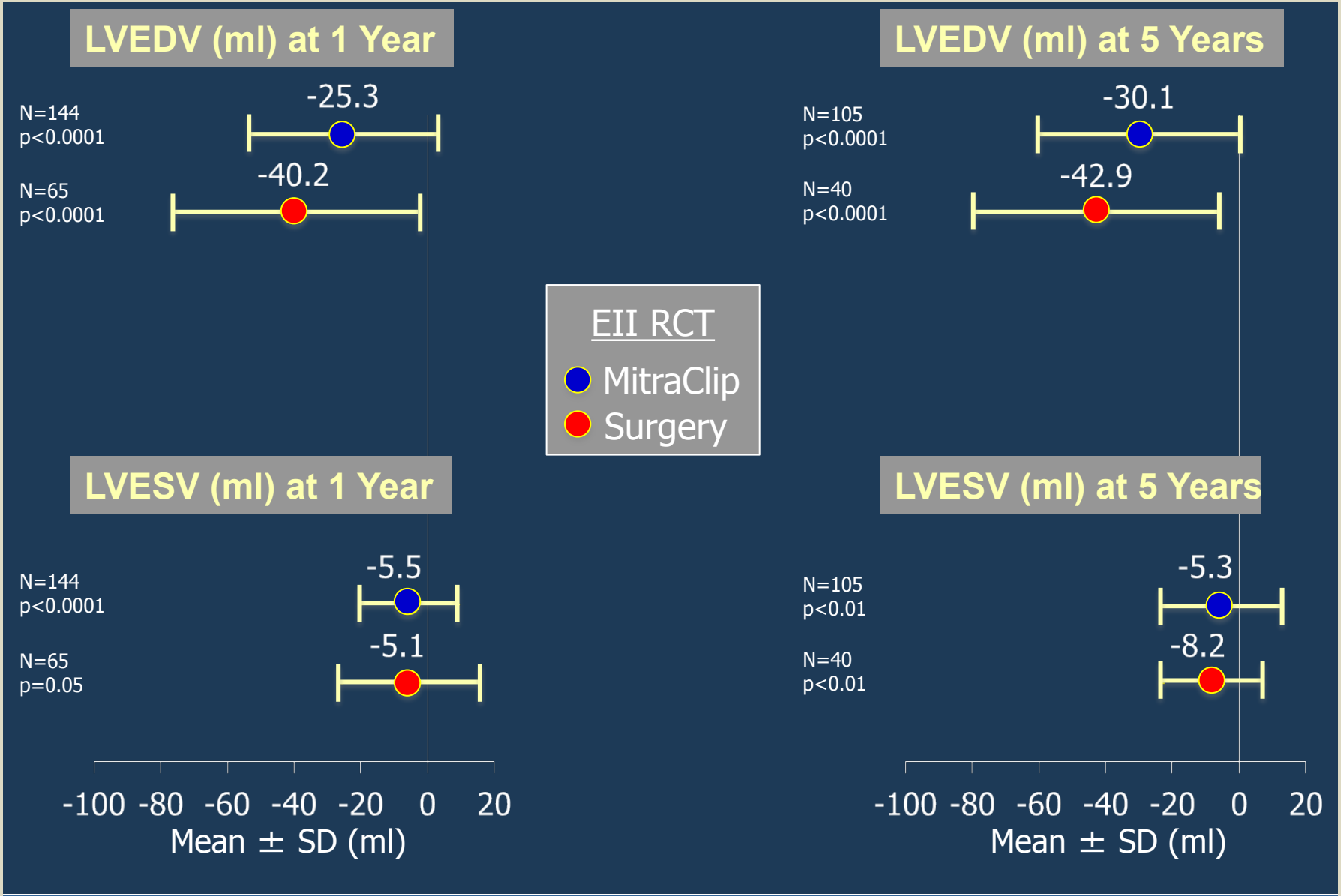


NYHA Funtional Class

Everest II RCT all treated patients (n=258)

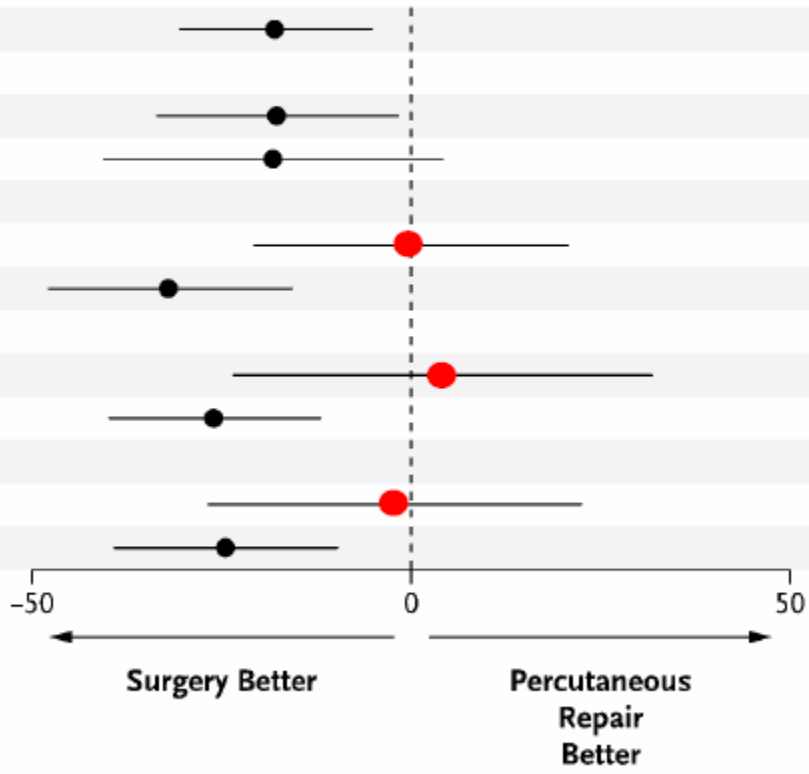


Reduction in LV Volumes at 1 and 5 years



Subgroup Analyses of Efficacy End Point at 5 Years

Subgroup	Percutaneous Repair	Surgery	P Value for Interaction
	no. of events/total no. (%)		
All patients	100/181 (55)	65/89 (73)	
Sex			0.97
Male	63/114 (55)	43/59 (73)	
Female	37/67 (55)	22/30 (73)	
Age			0.009
≥70 yr	52/86 (60)	23/38 (61)	
<70 yr	48/95 (51)	42/51 (82)	
MR			
Functional	26/48 (54)	12/24 (50)	0.02
Degenerative	74/133 (56)	53/65 (82)	
LVEF			0.06
<60%	35/68 (51)	15/28 (54)	
≥60%	64/111 (58)	50/61 (82)	



Survival of Transcatheter Mitral Valve Repair Compared With Surgical and Conservative Treatment in High-Surgical-Risk Patients

Martin J. Swaans, MD,* Annelies L. M. Bakker, MD,* Arash Alipour, MD, PhD,* Martijn C. Post, MD, PhD,*

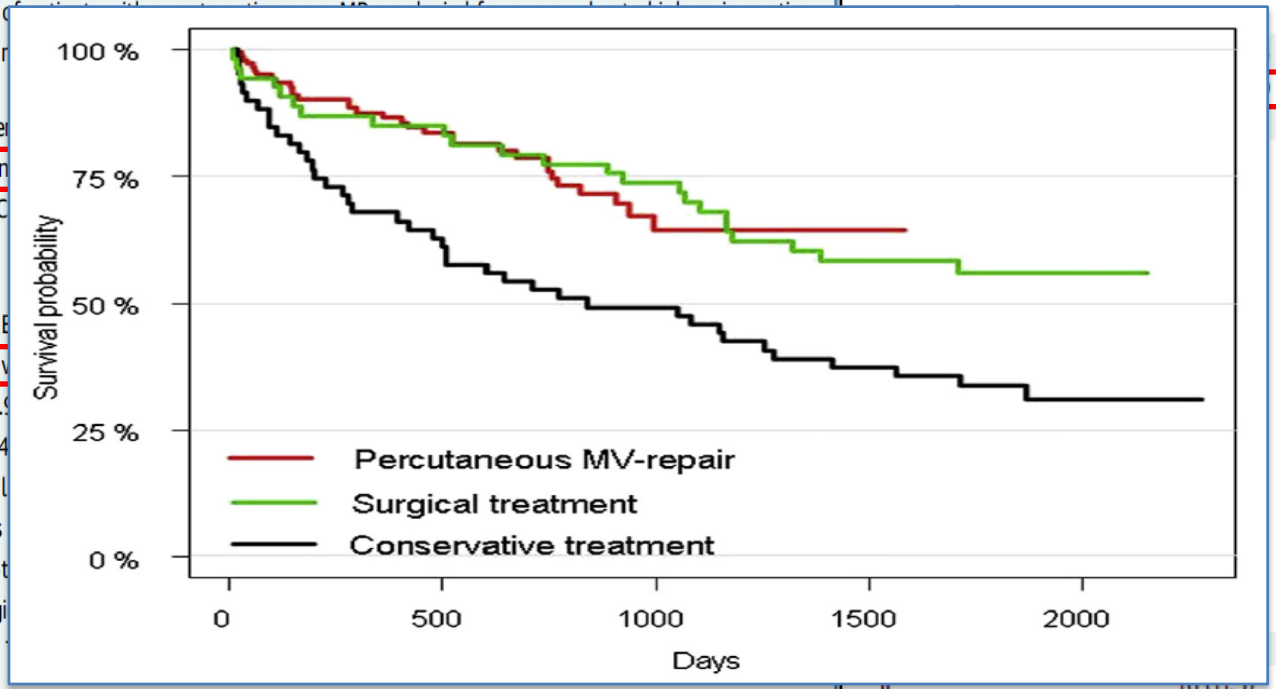
OBJECTIVES The goal of this study was to compare survival between transcatheter mitral valve (MV) repair using MitraClip system (Abbott Vascular, Santa Clara, California), MV-surgery, and conservative treatment in high-surgical-risk patients symptomatic with severe mitral valve regurgitation (MR).

BACKGROUND Up to 50% o
risk. Transcatheter MV repair r

METHODS Consecutive patie
(n = 53) and conservatively (n
logistic European System for C
as judged by the heart team.

RESULTS The log EuroSCORE
(14.2 ± 8.9%) and conservativ
higher in surgical patients (43.9
and conservatively treated (34
groups showed similar survival
survived. The same trend was
controlling for risk factors, bot
to 0.78, p = 0.006) and surgi
conservatively treated group.
2.16, p = 0.430).

CONCLUSIONS Despite a higher log EuroSCORE, high-surgical-risk patients with symptomatic severe MR treated with transcatheter MV repair show similar survival rates compared with surgically treated patients, with both displaying survival benefit compared with conservative treatment. (J Am Coll Cardiol Intv 2014;7:875-81) © 2014 by the American College of Cardiology Foundation.

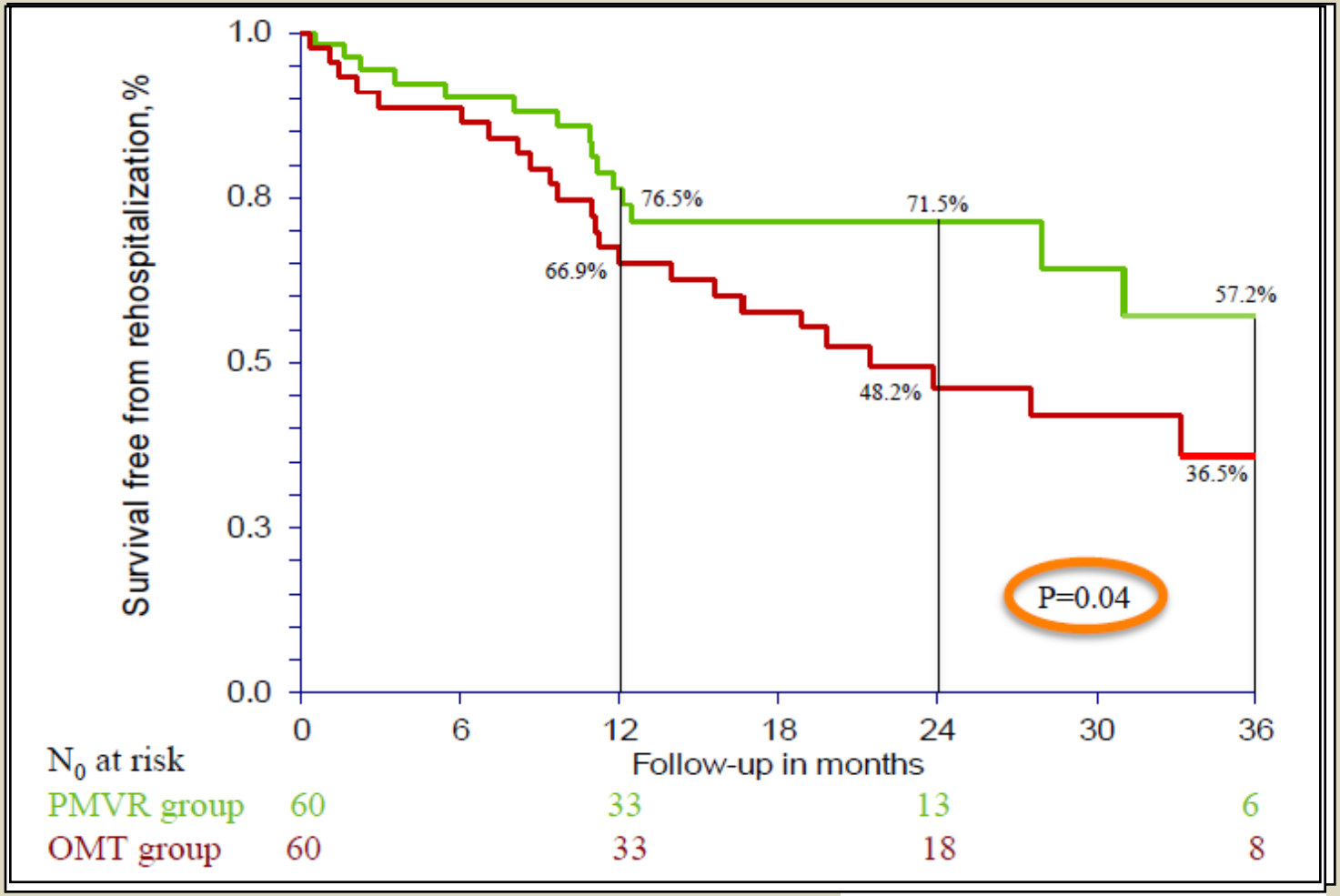


Characteristic	MitraClip	High-Risk Surgery	Conservative Treatment
No.	139	53	59
Age, yrs	74.6 ± 9.4	70.2 ± 9.5	71.7 ± 9.6
Male, %	94 (67.6)	27 (50.9)	32 (54.2)
		26.7 ± 5.3	26.5 ± 4.5
		43.9 ± 14.4	34.5 ± 16.5
		14.2 ± 8.9	18.7 ± 13.2
		28 (52.8)	25 (42.4)
		10 (18.9)	17 (28.8)
		27 (50.9)	24 (40.7)
		15 (28.3)	19 (32.2)
		28 (52.8)	45 (76.3)
		13 (24.5)	25 (42.4)
		5 (9.4)	9 (15.3)
		9 (17.0)	11 (18.6)
		1 (1.9)	2 (3.4)
		9 (17.0)	18 (30.5)
		11 (20.8)	14 (23.7)
		28 (52.8)	26 (44.1)
		14 (26.4)	19 (32.2)
			6 (11.3)	8 (13.6)
III	91 (65.5)	38 (71.7)	35 (59.3)
IV	32 (23.0)	9 (17.0)	16 (27.1)
Etiology			
FMR	107 (77.0)	31 (58.5)	48 (81.3)
DMR	25 (18.0)	17 (32.1)	4 (6.8)
Mixed	7 (5.0)	5 (9.4)	7 (11.9)

Comparison of Percutaneous Mitral Valve Repair Versus Conservative Treatment in Severe Functional Mitral Regurgitation

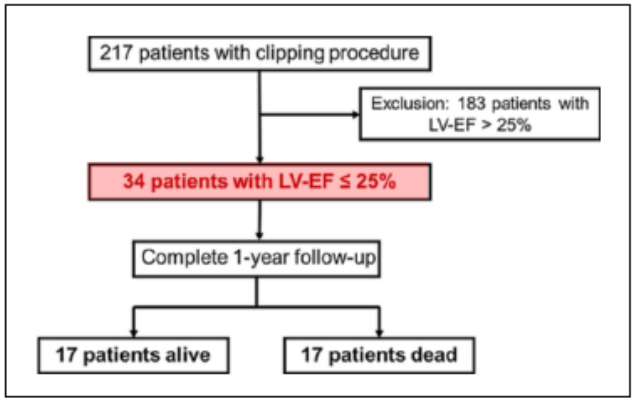
Cristina Giannini, MD, PhD[1], Francesca Fiorelli, MD[1], Marco De Carlo[1], MD, PhD, Fabio Guarracino, MD[2], Michela Faggioni, MD[1], Paolo Giordano, MD[1], Paolo Spontoni, MD[1], Andrea Pieroni, MD[1], Anna Sonia Petronio, MD[1].

The American Journal of Cardiology , Accepted on October 2015

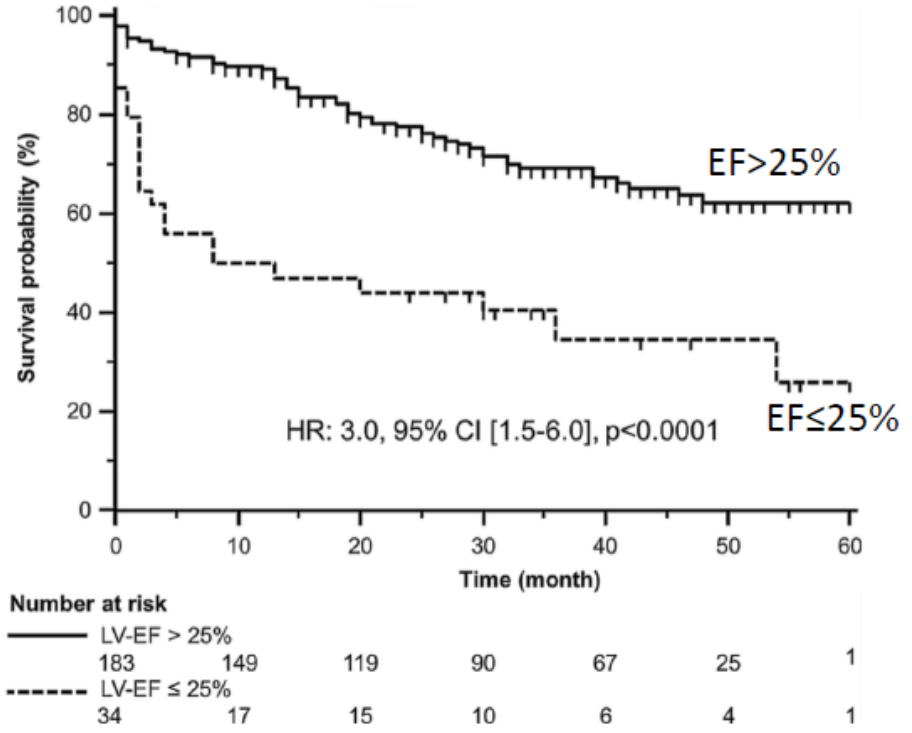


Long-Term Outcome of Patients with Severe Biventricular Heart Failure after MitraClip

Predictive value of LVEF



None of the patients met the inclusion criteria of EVEREST II

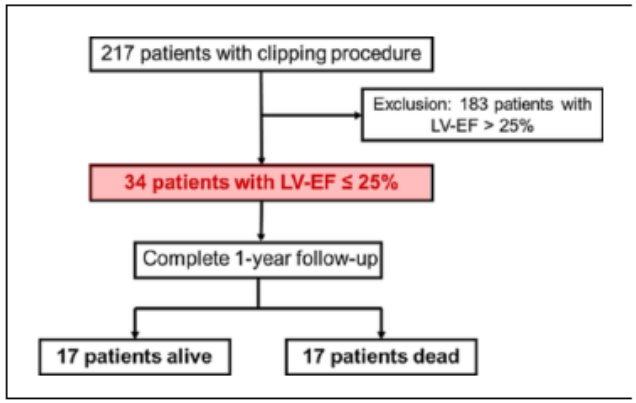


J Interven Cardiol 2015;28:164–171

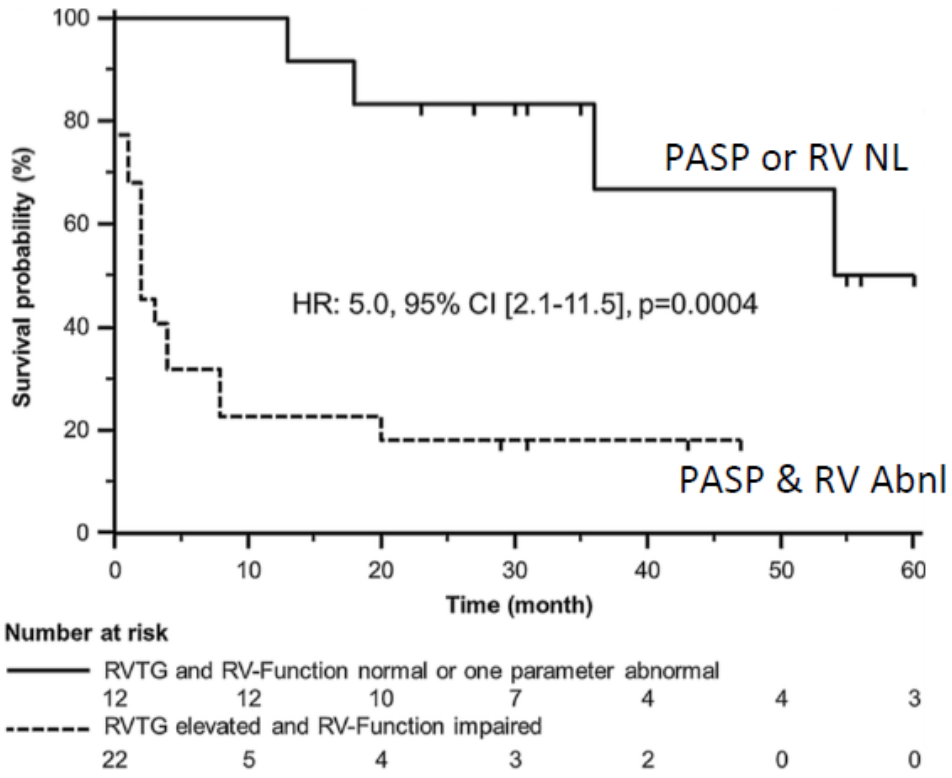
Long-Term Outcome of Patients with Severe Biventricular Heart Failure after MitraClip

Predictive value of PASP + RV function

One-year mortality of patients with pulmonary hypertension and depressed RV-function (n = 22) was very high (77%) compared to the remaining patients (n = 12, mortality rate of 0%, P = 0.0001).



None of the patients met the inclusion criteria of EVEREST II

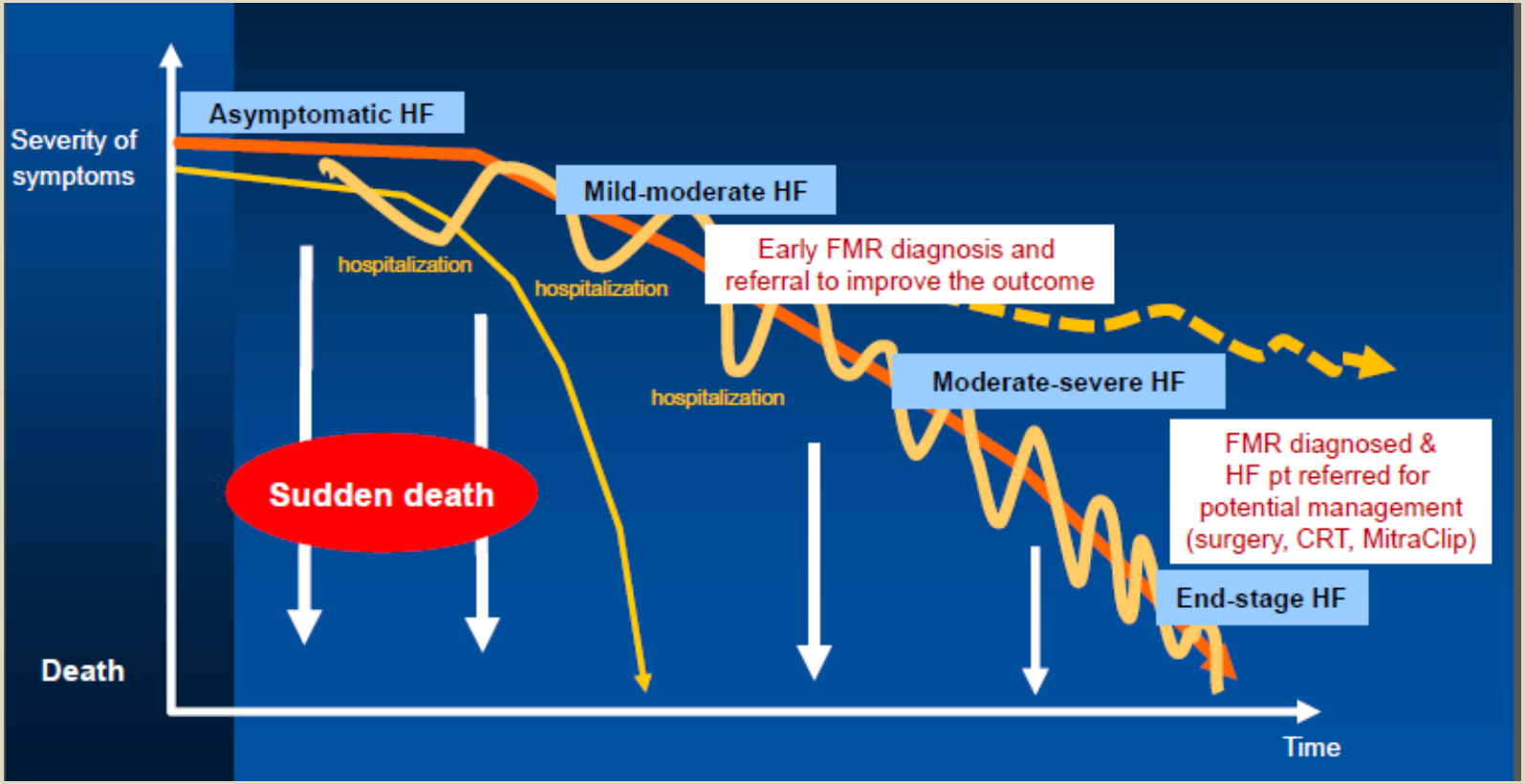


RVTG: right ventricular tricuspid pressure gradient

J Interven Cardiol 2015;28:164–171

WHEN refer a HF patient to PMVR: Timing is crucial

A proper timing is crucial for MitraClip therapy, because the observed risk factors for failure are index of advanced LV remodeling



Piotr Ponikowski, MD, PhD, FESC

Medical University, Centre for Heart Disease Clinical Military Hospital

HFA Athens 2014

PMVR: percutaneous mitral valve repair