



Insufficienza Mitralica ischemica: MitraClip?

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AZIENDA ULSS 12 VENEZIANA – MESTRE E VENEZIA - ITALY



CLASSIFICAZIONE EZIOPATOGENETICA



IM primaria

- Degenerativa
- Reumatica
- Endocardite
- Congenita

Risultato di un difetto anatomico dei lembi valvolari o dell'apparato valvolare

IM secondaria

- Ischemica
- C. Dilatativa
- C. Ipertrofica

Risultato della dilatazione o disfunzione del ventricolo sinistro



CLASSIFICAZIONE EZIOPATOGENETICA



IM primaria



Prolasso



Valvola normale

IM secondaria

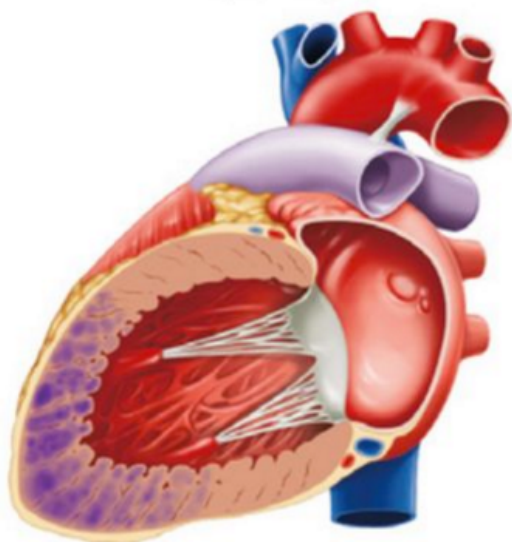


dilatazione Vsin ed anulectasia

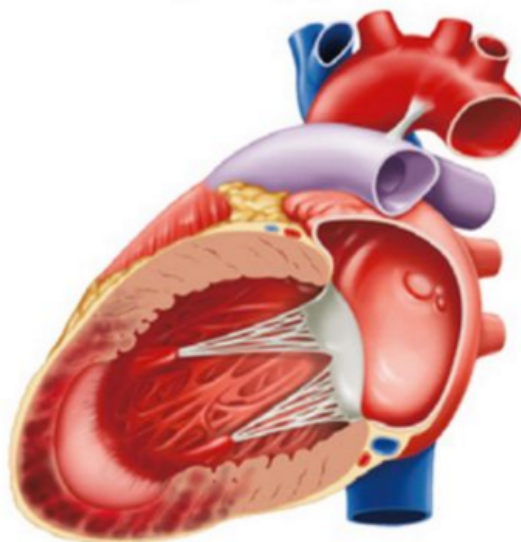
J Am Heart Assoc. 2012



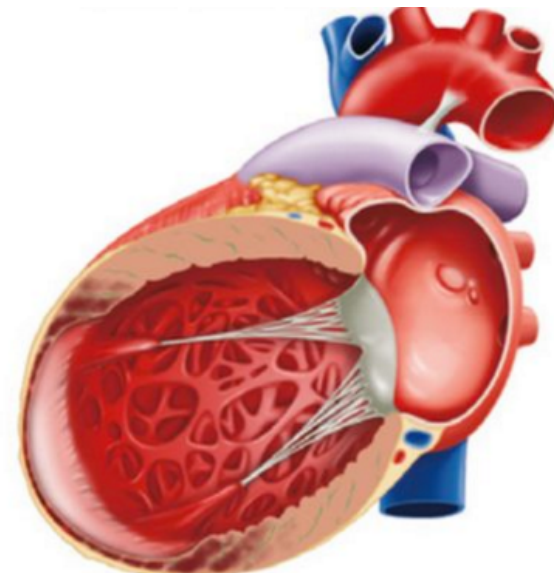
IM SECONDARIA ISCHEMICA



INFARTO



REMODELING



CARDIOPATIA DILATATIVA

ore

giorni

mesi / anni

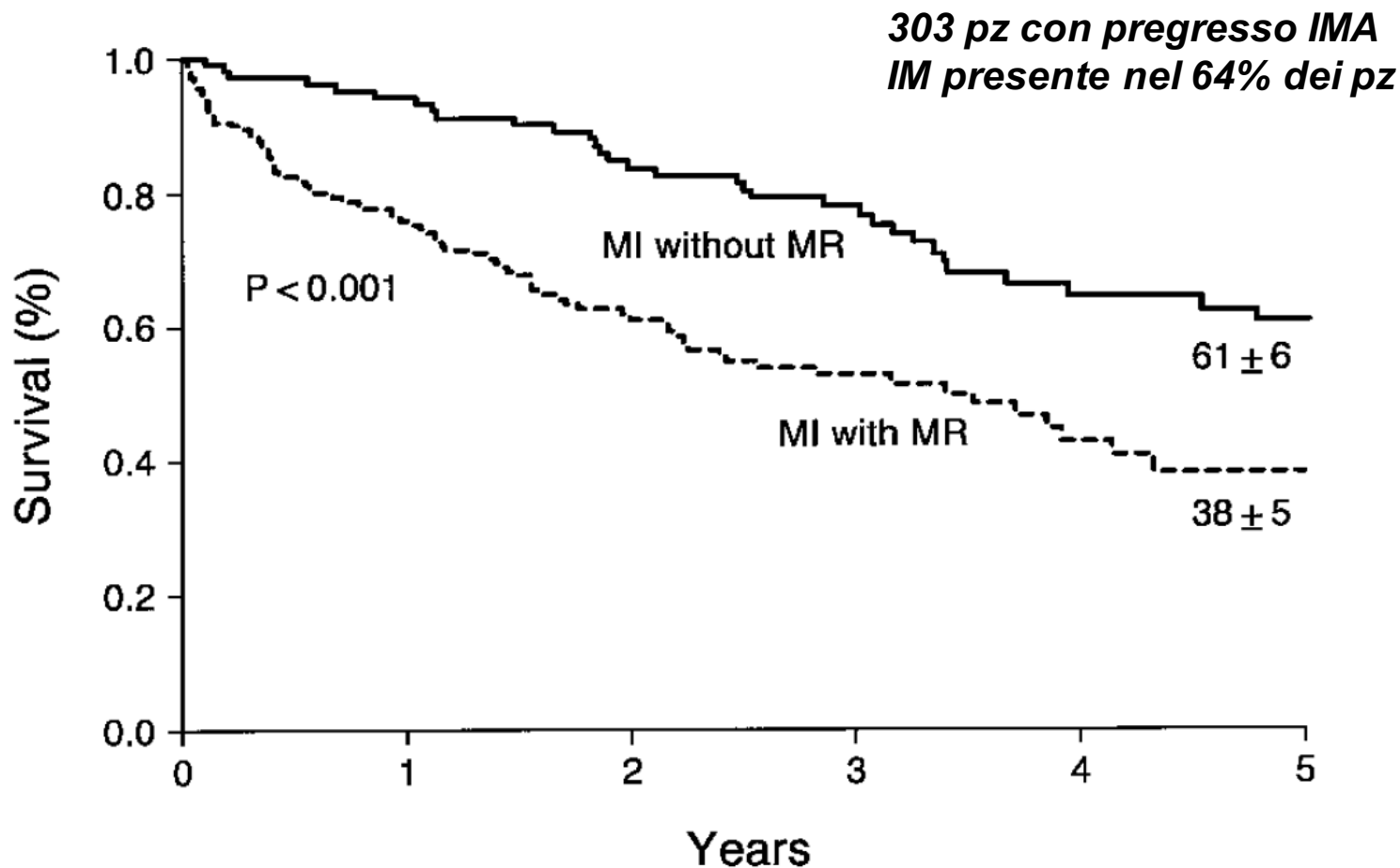
adapted from: J Am Heart Assoc. 2012



IM ISCHEMICA



Prevalenza e Significato prognostico



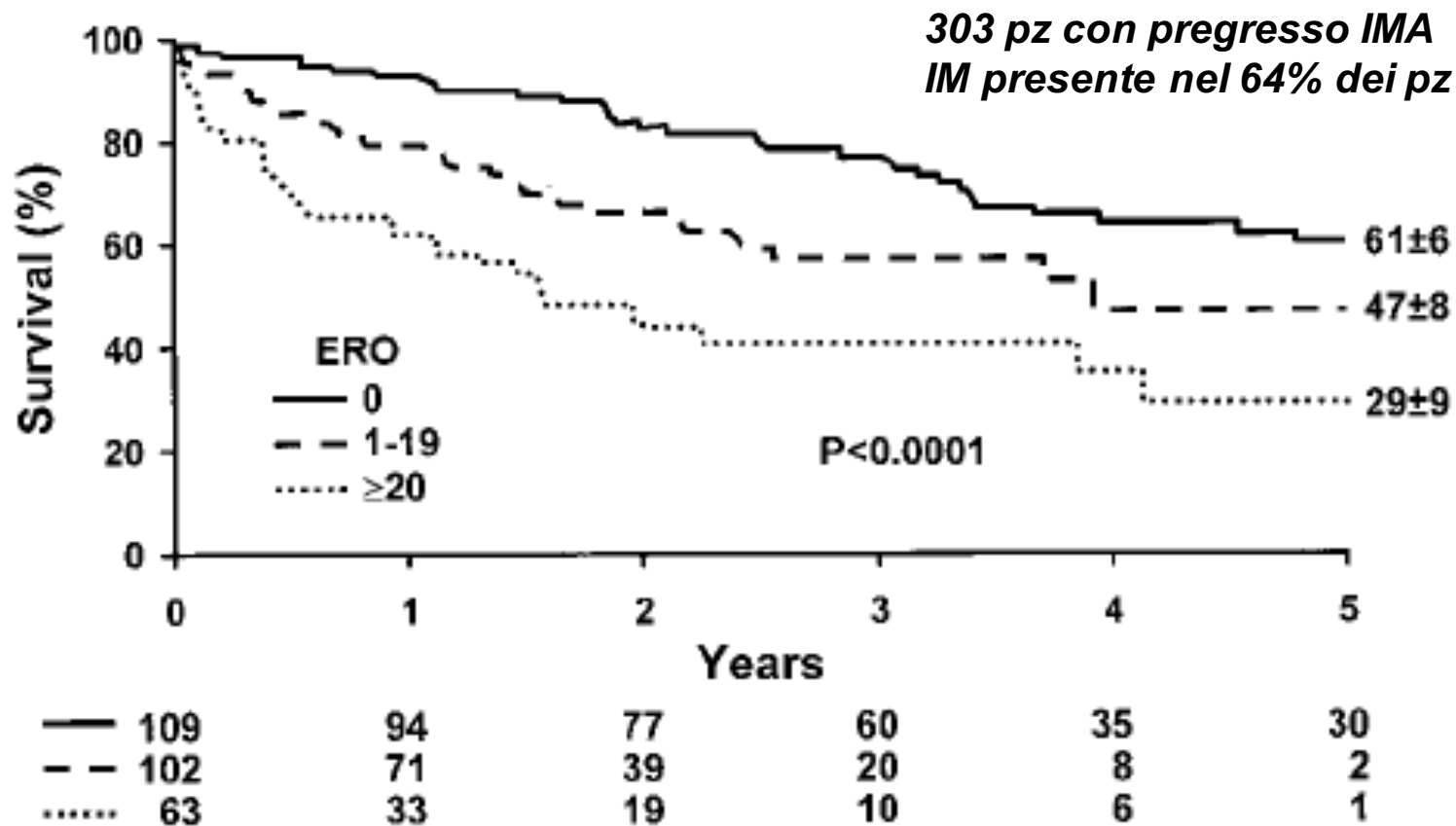
Grigioni et al. Circulation 2001;103:1759



IM ISCHEMICA



Prevalenza e Significato prognostico



Grigioni et al. Circulation 2001;103:1759



IM ISCHEMICA

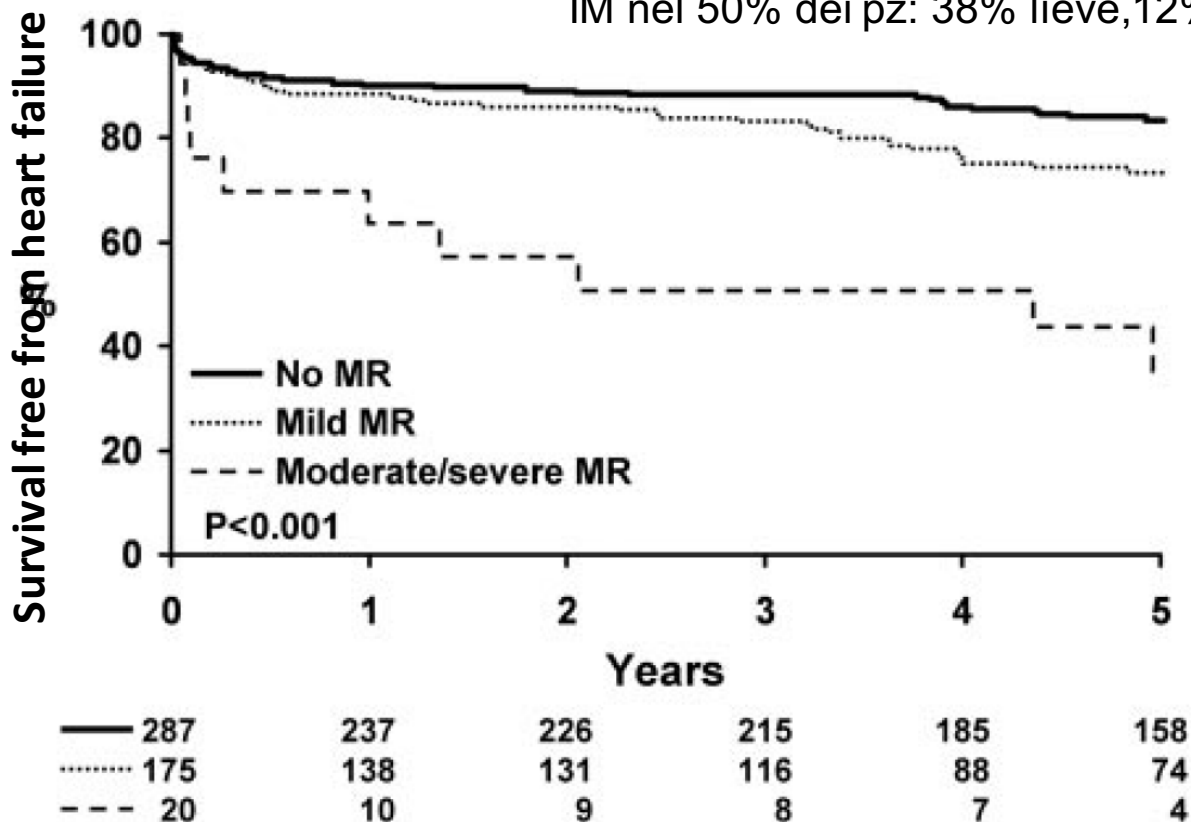


Prevalenza e Significato prognostico

773 pazienti

Ecocardiogramma entro 30 giorni dopo IMA

IM nel 50% dei pz: 38% lieve, 12% moderata/severa



Bursi et al *Circulation*. 2005;111:295-301



IM ISCHEMICA

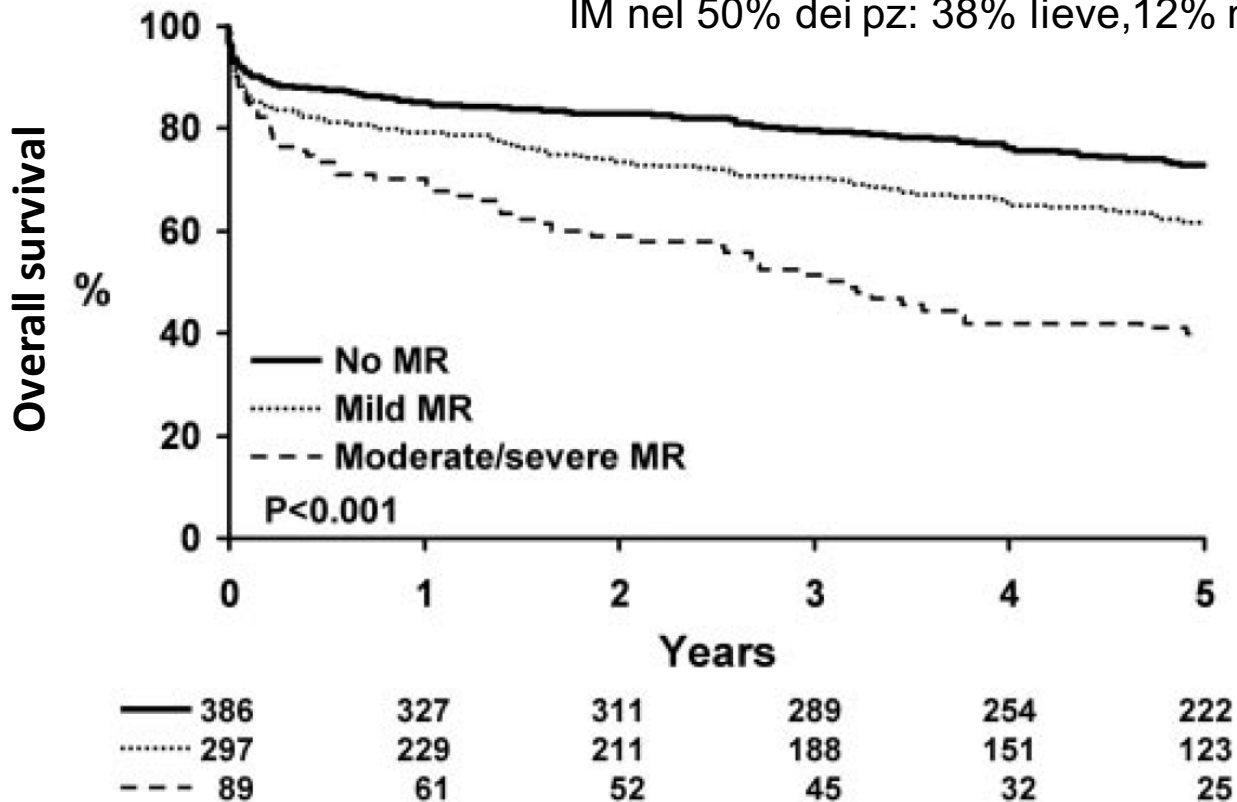


Prevalenza e Significato prognostico

773 pazienti

Ecocardiogramma entro 30 giorni dopo IMA

IM nel 50% dei pz: 38% lieve, 12% moderata/severa



Bursi et al Circulation. 2005;111:295-301



IM ISCHEMICA

Trattamento



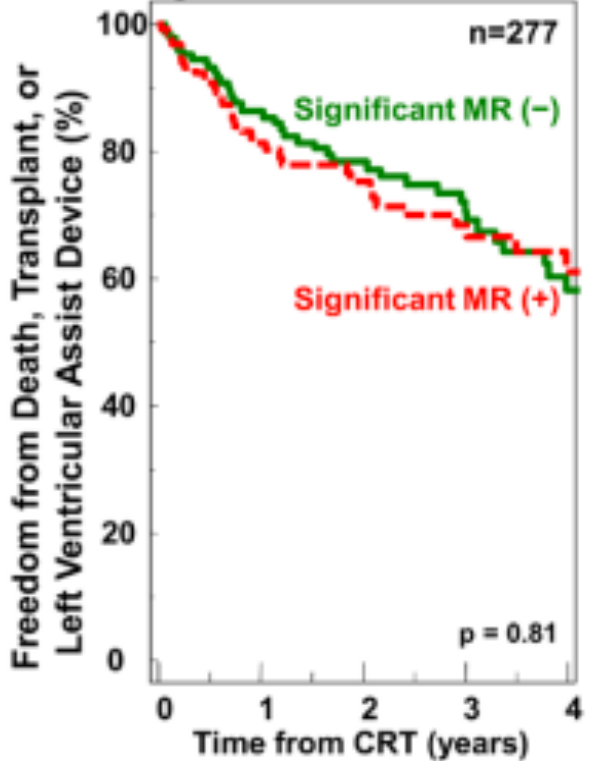
- **Terapia medica** (ACE-I, Bbloc, Diuretici, Nitrati, Anti-Aldost.)
- **Resincronizzazione** (CRT-D)
- **Rivascolarizzazione miocardica** (PCI/CABG)
- **Trattamento chirurgico della valvola**
(anuloplastica/valvuloplastica/ sostituzione)
- **Valvuloplastica percutanea** (MITRACLIP)



IM ISCHEMICA CRT

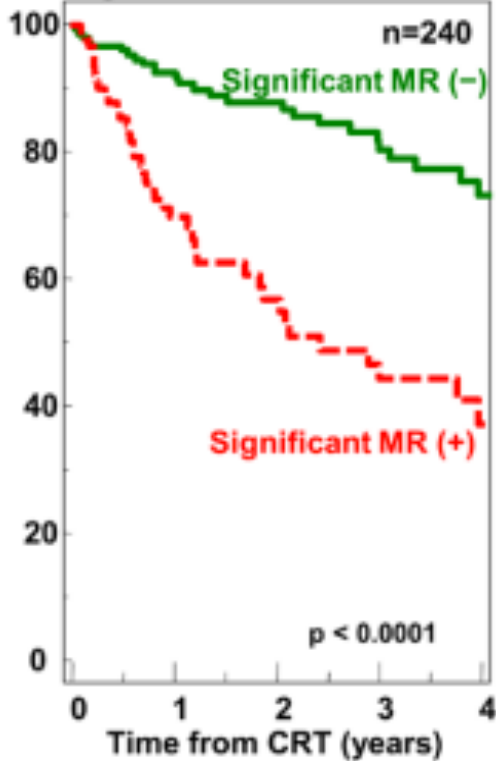


A Patients with and without Significant MR at Baseline



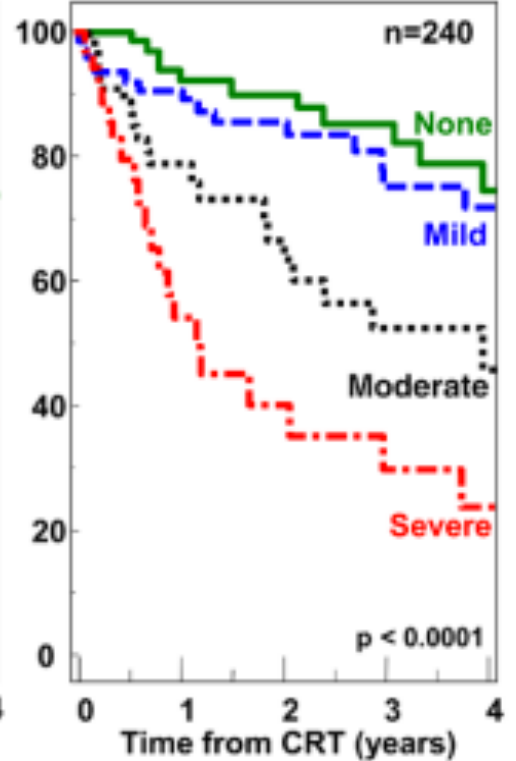
Significant MR (-)				
145	101	69	47	24
Significant MR (+)				
132	82	58	37	17

B Patients with and without Significant MR after CRT



Significant MR (-)				
150	116	82	56	32
Significant MR (+)				
90	45	29	19	8

C Patients Stratified by MR Grade after CRT



MR None				
73	56	41	29	16
MR Mild				
77	60	41	27	16
MR Moderate				
55	32	21	13	6
MR Severe				
35	13	8	6	2



IM ISCHEMICA

Chirurgia / Riparazione percutanea



European Heart Journal (2012) 33, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES



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

6.2.4 Percutaneous intervention

Experience from a limited number of patients in the EVEREST trials and from observational studies suggests that percutaneous edge-to-edge mitral valve repair is feasible—at low procedural risk—in patients with secondary MR in the absence of severe tethering and may provide short-term improvement in functional condition and LV function.^{136,137} These findings have to be confirmed in larger series with longer follow-up and with a randomized design. Data on coronary sinus annuloplasty are limited and most initial devices have been withdrawn.¹⁵⁸



IM ISCHEMICA

Chirurgia / Riparazione percutanea



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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

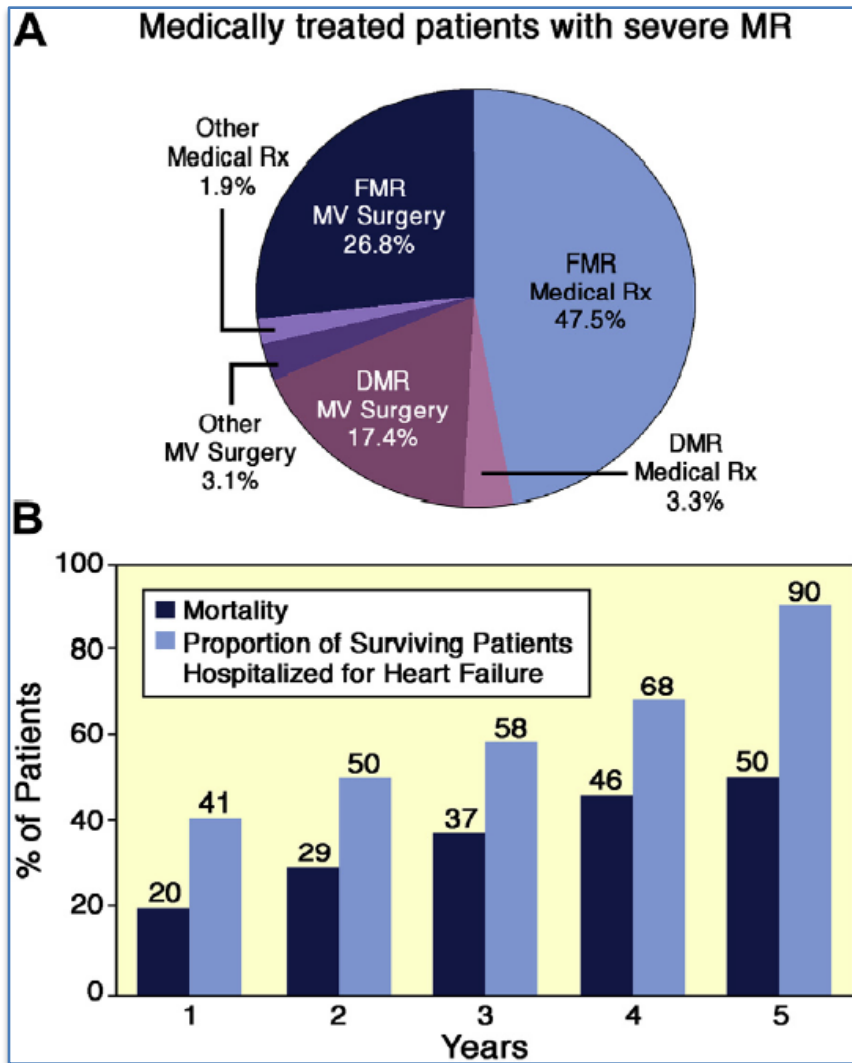
Cleveland Clinic database 2000-2008: **5.737 con MR ≥ 3**

1095 pz. con IM severa ed HF

(814 Funzionale, 226 Degenerativa)

Principali criteri di esclusione da CCH:

- Severa disfunzione Vsin (LVEF <30%)
- Comorbidità /STS score elevato
- Età Avanzata





IM ISCHEMICA



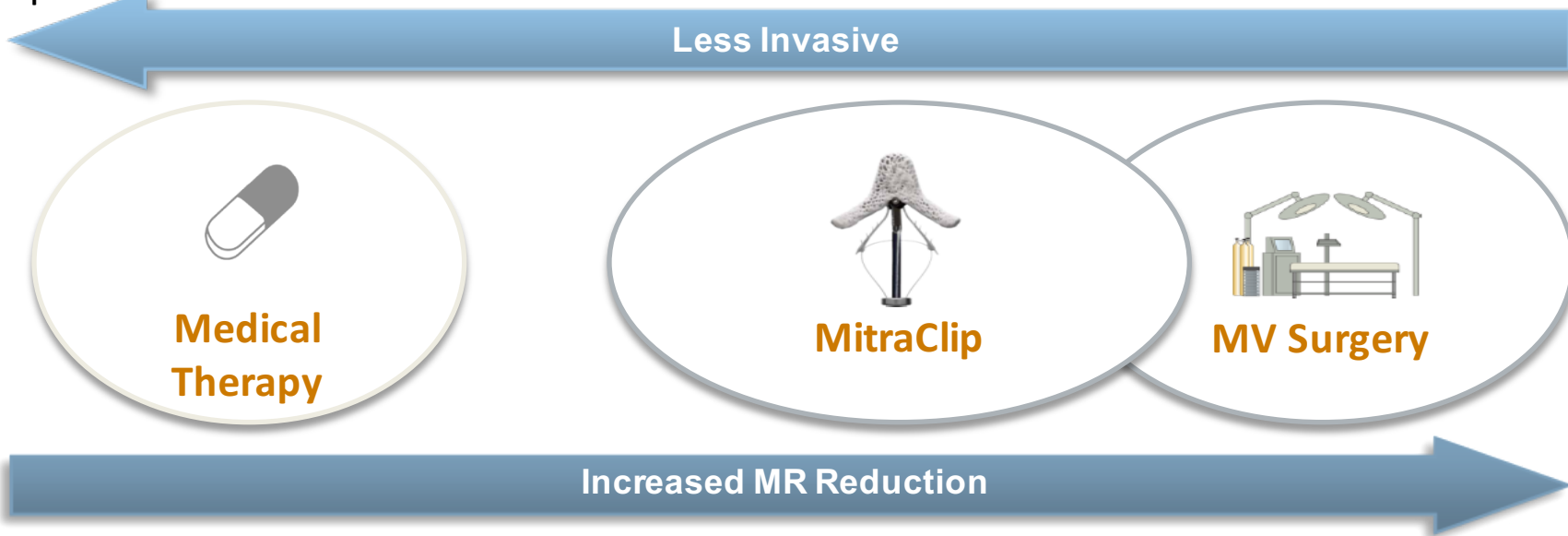
Riparazione percutanea con MitraClip

Medical therapy is limited to symptom management

MV surgery has been the only option that reliably reduces MR

A significant gap exists between patients who receive medical and surgical options, based on risk-benefit profile

MitraClip therapy is a first-in-class, minimally invasive catheter-based technology option to reduce MR

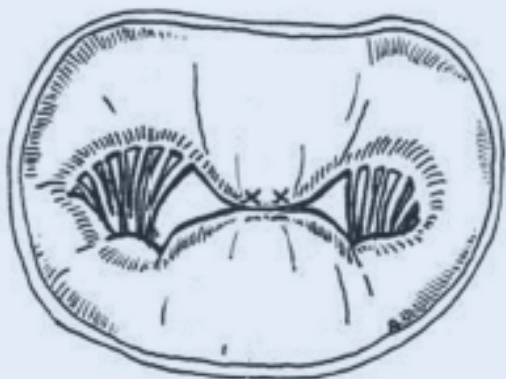




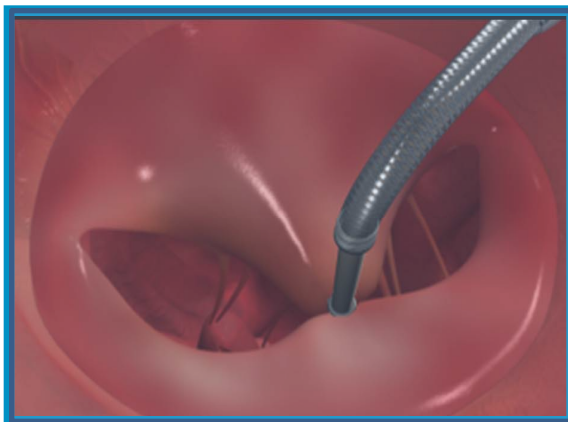
IM ISCHEMICA



Riparazione percutanea con MitraClip



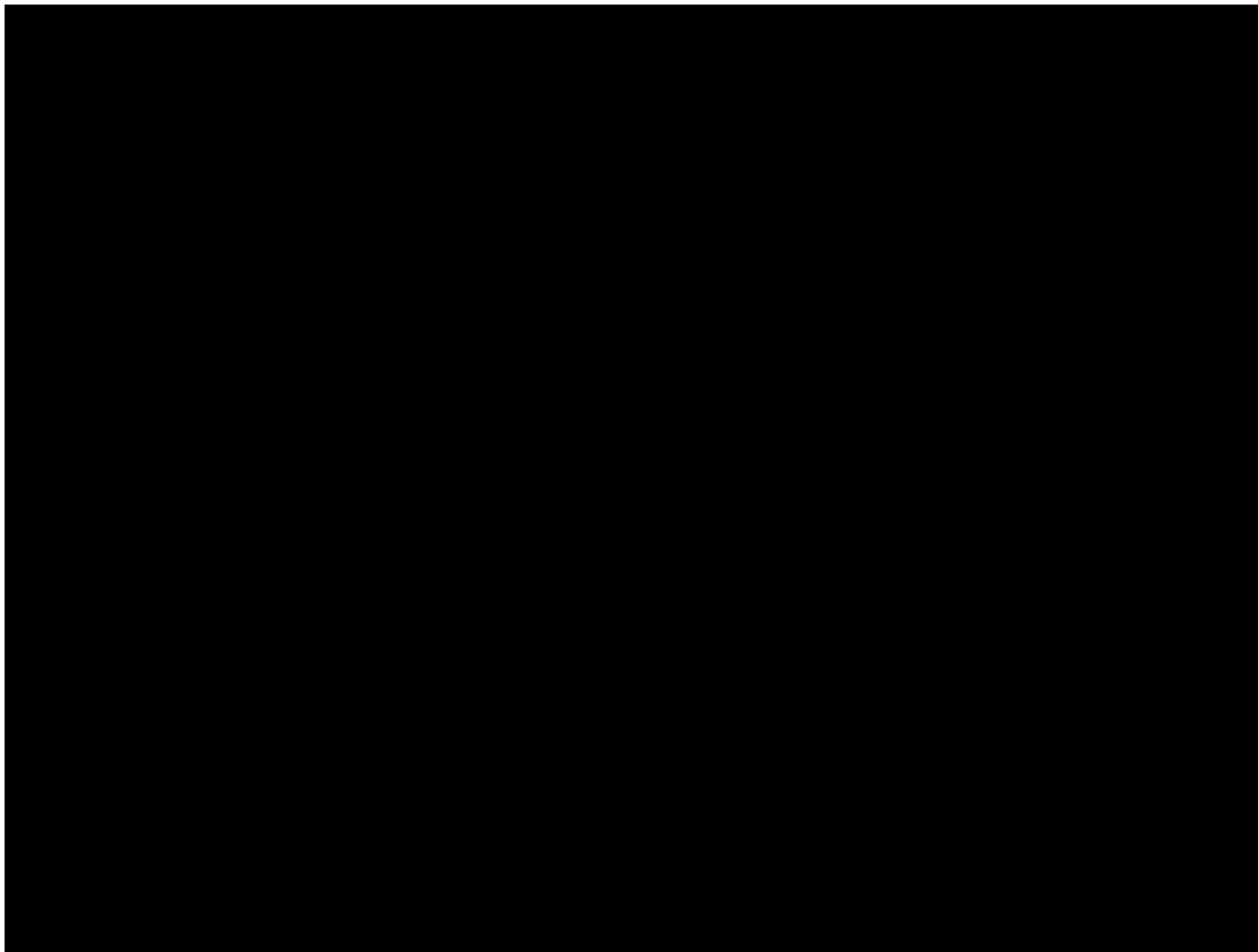
- Double-orifice suture technique developed by Prof. Ottavio Alfieri
- First published results in 1998 illustrated proven benefit
- Suggested procedure best suited for minimally invasive approach





MitraClip

La procedura



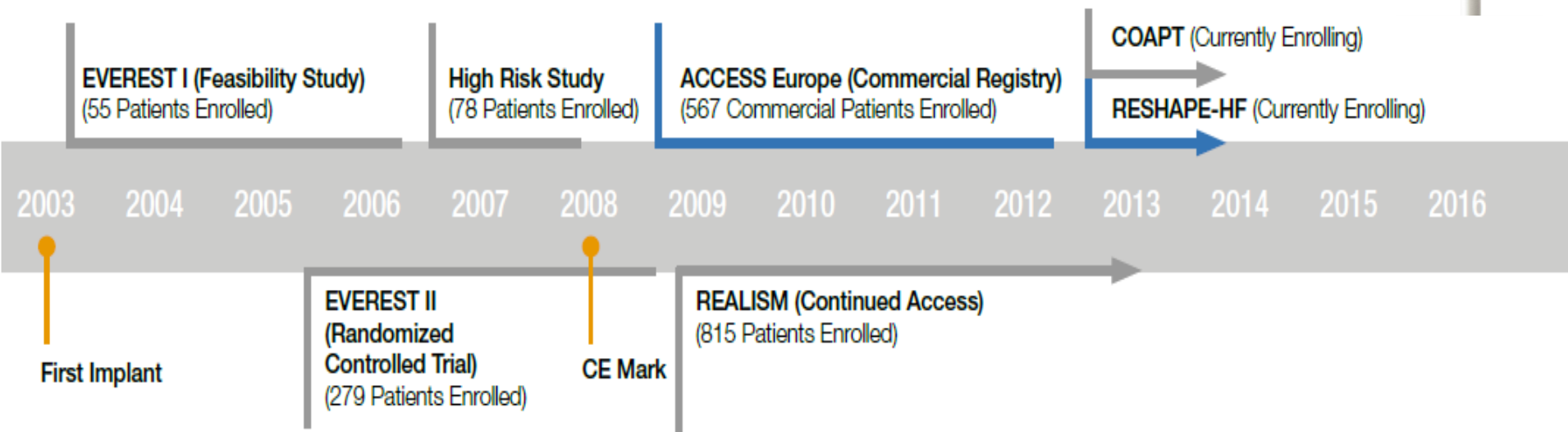
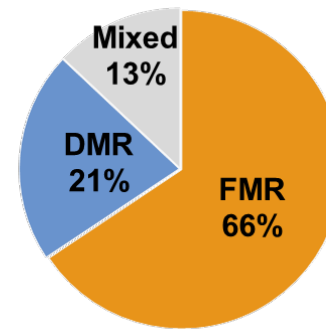


Worldwide Clinical Experience



- Over 30,000 patients have been treated with the MitraClip Therapy worldwide.¹

- 75% are considered high risk* for mitral valve surgery
- 66% have functional mitral regurgitation (MR), 21% DMR.
- 96% Implant Rate



1. Data as of 30/01/2014. Source: Abbott Vascular.

* Determination of high surgical risk based on: logistic EuroSCORE $\geq 20\%$, or STS calculated mortality $\geq 12\%$, or pre-specified high surgical risk co-morbidities specified in EVEREST II High Risk Study protocol.

The MitraClip System: an Italian Consensus Statement

Journal of Cardiovascular Medicine, 15 (3) p.173-188, 2014

Journal of Cardiovascular Medicine

Reprinted from ■ Volume 15 ■ Issue 3 ■ pp. 173–188

www.jcardiovascularmedicine.com

Clinical guidelines and position paper

Transcatheter treatment of chronic mitral regurgitation with the MitraClip system: an Italian consensus statement

Francesco Maisano^a, Francesco Alamanni^b, Ottavio Alfieri^a, Antonio Bartorelli^b, Francesco Bedogni^c, Francesco M. Bovenzi^d, Giuseppe Bruschi^e, Antonio Colombo^a, Alberto Cremonesi^f, Paolo Denti^a, Federica Etori^g, Silvio Klugmann^e, Giovanni La Canna^a, Luigi Martinelli^e, Lorenzo Menicanti^h, Marco Metra^g, Fabrizio Oliva^e, Luigi Padelettiⁱ, Alessandro Parolari^b, Francesco Santini^j, Michele Senni^k, Corrado Tamburino^l, Gian P. Ussia^m, Francesco Romeo^m, on behalf of the Italian Federation of Cardiology (FIC), Italian Society of Cardiology, (SIC), Italian Association of Hospital Cardiologists (ANMCO), Italian Society of Interventional Cardiology (GISE), Italian Society for Cardiac Surgery (SICCH), Italian Society of Arrhythmias and Electrophysiology (AIAC)



«...Le recenti Linee Guida della Società Europea di Cardiologia e della Associazione Europea di Chirurgia Cardio-Toracica, considerano la MitraClip come una potenziale opzione terapeutica in pazienti selezionati affetti da rigurgito mitralico severo sintomatico con alto rischio chirurgico o inoperabili⁵²...»

«...Il processo di selezione per l'impianto di MitraClip deve essere riservato ad un centro.. che includa i cardiologi interventisti, i cardiocirurghi, gli ecocardiografisti, gli anestesisti, e gli specialisti dello scompenso cardiaco (Heart Team)...»

«...In candidati selezionati, la procedura MitraClip appare associata ad un miglioramento della qualità di vita, ad una possibilità di rimodellamento inverso del ventricolo sinistro, ad un aumento della capacità funzionale, e a una riduzione di ospedalizzazioni. Pertanto, la terapia MitraClip può giocare un ruolo significativo nel campo della terapia non farmacologica dello scompenso cardiaco e della malattia della valvola mitrale...»

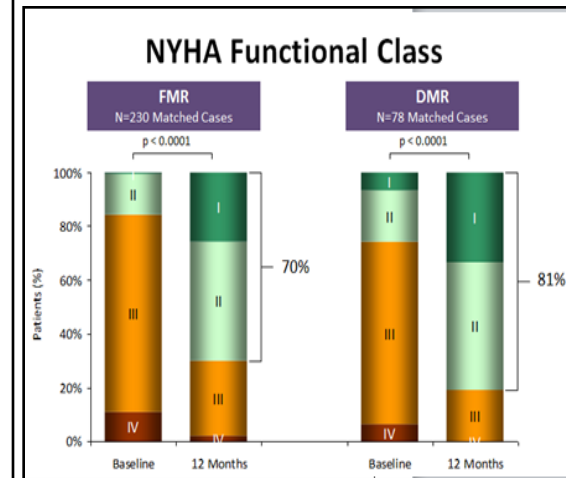
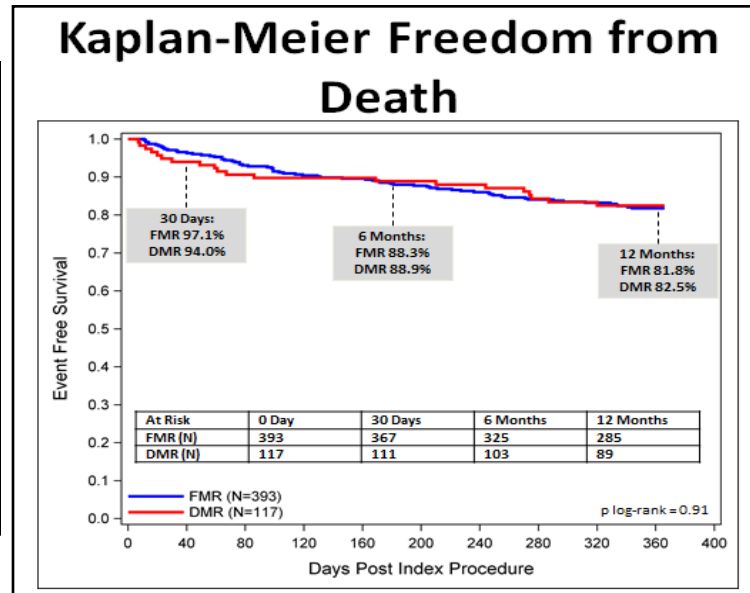
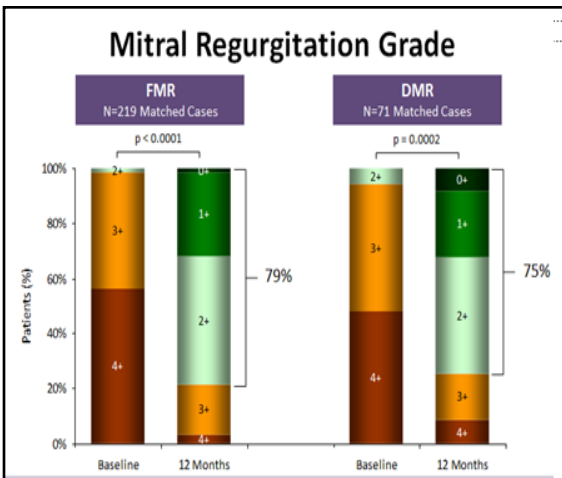
52 Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease (version 2012): the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J* 2012; 33:2451–2496.



Effects of MitraClip on FMR



- Data from **ACCESS-EU Study** on functional MR
- 393 pts
- **66% EF <40%; 44% EF < 30%**
- MR ≥ 3
- NYHA III-IV 87%
- Mean Logistic Euroscore 25%





TRAMI Registry II: 1064 Patients Analysis



Acute outcomes after MitraClip® therapy in highly aged patients: results from the German TRAnscatheter Mitral valve Interventions (TRAMI) Registry

Wolfgang Schillinger^{1*}, MD; Mark Hünlich¹, MD; Stephan Baldus², MD; Taoufik Ouarrak³, PhD; Peter Boekstegers⁴, MD; Ulrich Hink⁵, MD; Christian Butter⁶, MD; Raffi Bekerredjian⁷, PhD; Björn Plicht⁸, MD; Horst Sievert⁹, MD; Joachim Schofer¹⁰, MD; Jochen Senges³, MD; Thomas Meinertz², MD; Gerd Hasenfuß¹, MD; for the German TRAMI Registry Investigators

Baseline characteristics stratified by age

P<0.0001

Baseline characteristics stratified by age	Age <76 years n=539	Age ≥76 years n=525
Log. EuroSCORE, (%)	18	25
Log. EuroSCORE ≥20%, (%)	47.7	63.8
NYHA III-IV (%)	86.8	86.8
LVEF<30% (%)	43.6	21.7
LVEF 30-50%, (%)	34.6	38.2
FMR etiology (%)	76.6	64.2
MR severe (%)	94.6	95.1

Post-discharge outcomes relative to median follow-up time.

	Age <76 years n=539	Age ≥76 years n=525	P value
Patient with MACCE (death, MI, stroke) (%)	9	15	<0.05
Death, (%)	9	15	<0.05
Hospitalisation because of heart failure (%)	11.5	12.7	0.66
NYHA class I-II (%)	69.6	61.4	

- Acute outcomes after MitraClip in highly aged patients: 1064 patients
- Elderly and younger patients have similar benefits from MitraClip therapy
- Age was the most frequent cause for denying surgery



GRASP IT Registry

One- and Twelve-Month Safety and Efficacy Outcomes of Patients Undergoing Edge-to-Edge Percutaneous Mitral Valve Repair (from the GRASP Registry)

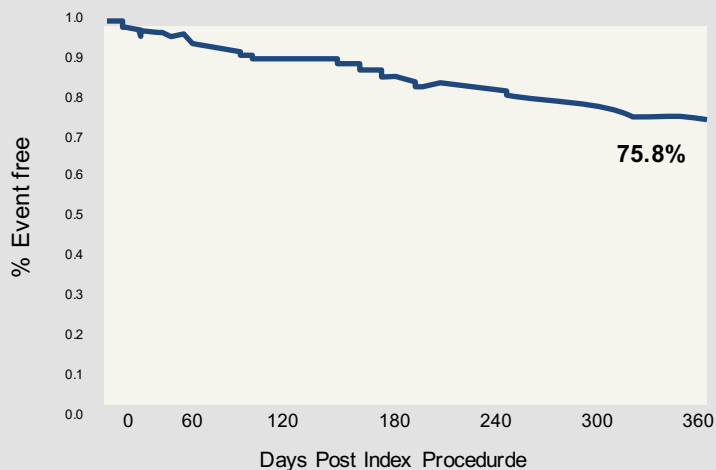
Carmelo Grasso, MD^a, Davide Capodanno, MD, PhD^{a,b,*}, Salvatore Scandura, MD^a, Stefano Cannata, MD^a, Sebastiano Immè, MD^a, Sarah Mangiafico, MD^a, Anna Pistritto, MD^a, Margherita Ministeri, MD^a, Marco Barbanti, MD^a, Anna Caggegi, MD^a, Marta Chiarandà, MD^a,

- ★ Investigator-initiated, retrospective registry of 304 consecutive patients undergoing Mitraclip therapy between October 2008 and October 2013 at four Italian centers
- ★ 79% FMR; 21% DMR
- ★ Median follow-up of 366 days (IQR 150 to 691)

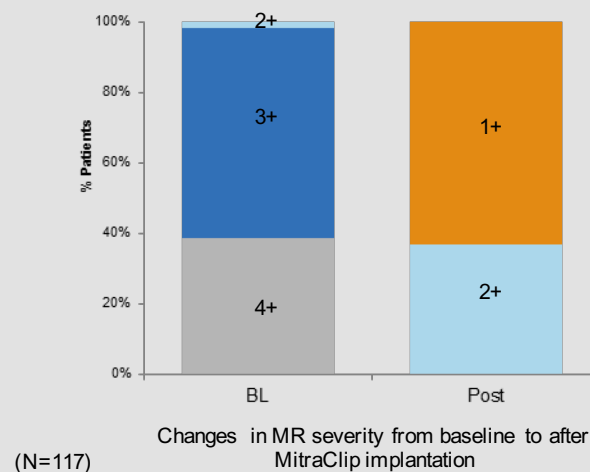
MR ≥ 3+ elderly patients at high risk for surgery

Baseline characteristics	
Age	72 ± 10
FMR etiology (%)	76
LVEF (%)	38 ± 13
NYHA III-IV (%)	80%
Logistic EuroSCORE (%)	12 ± 14
Coronary Artery Disease (%)	49%

Overall Freedom from death, surgery or MR ≥ 3+ at 1 year was 75.8%



100% of patients achieved MR ≤ 2+ post procedure

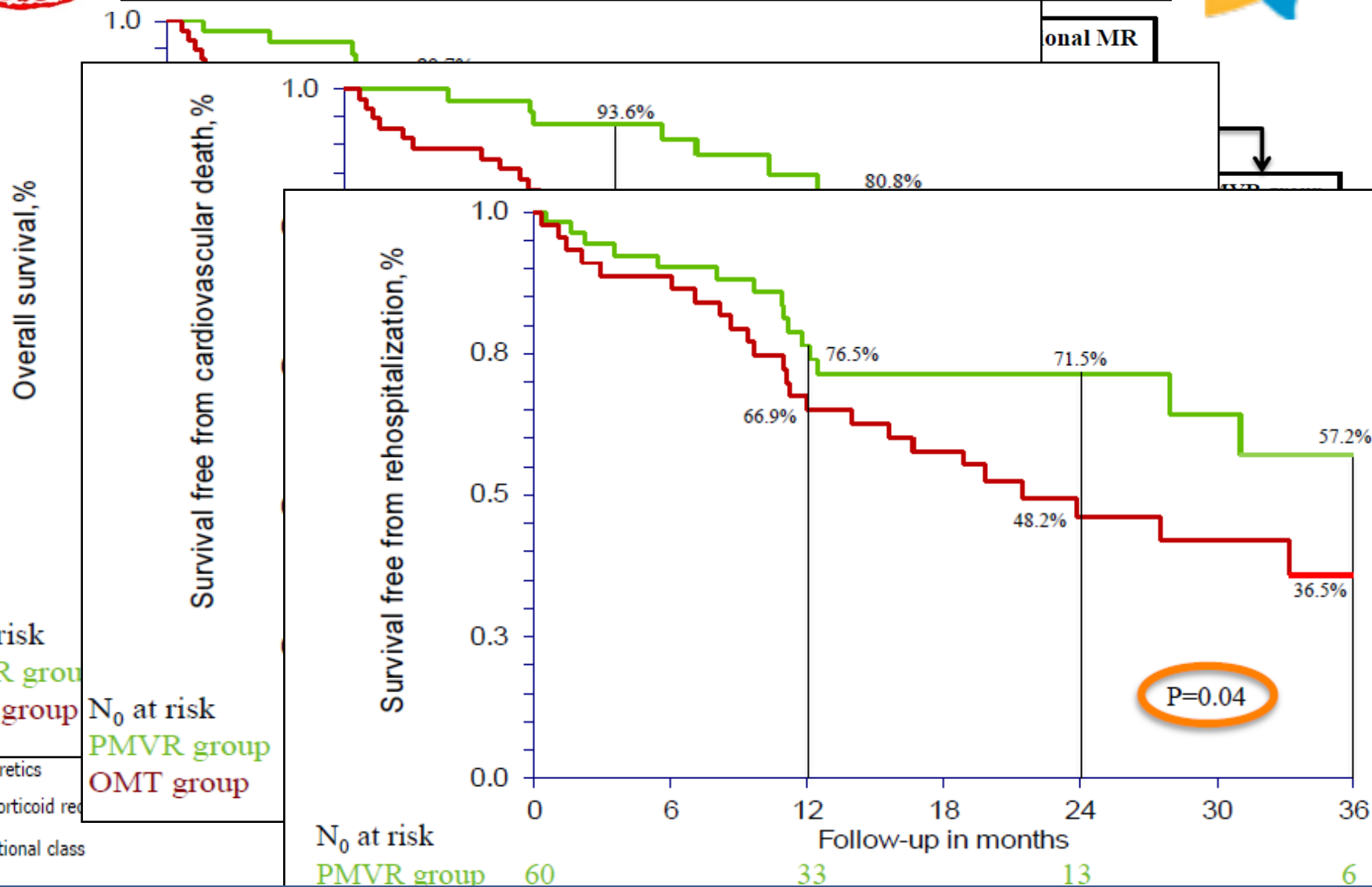


“..PMVR with the MitraClip technique was shown to be safe and reasonably effective in 117 patients from a real-world setting..”



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

Cristina Giannini, MD, PhD¹, Francesca Fiorelli, MD¹, Marco De Carlo¹, MD, PhD, Fabio





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).

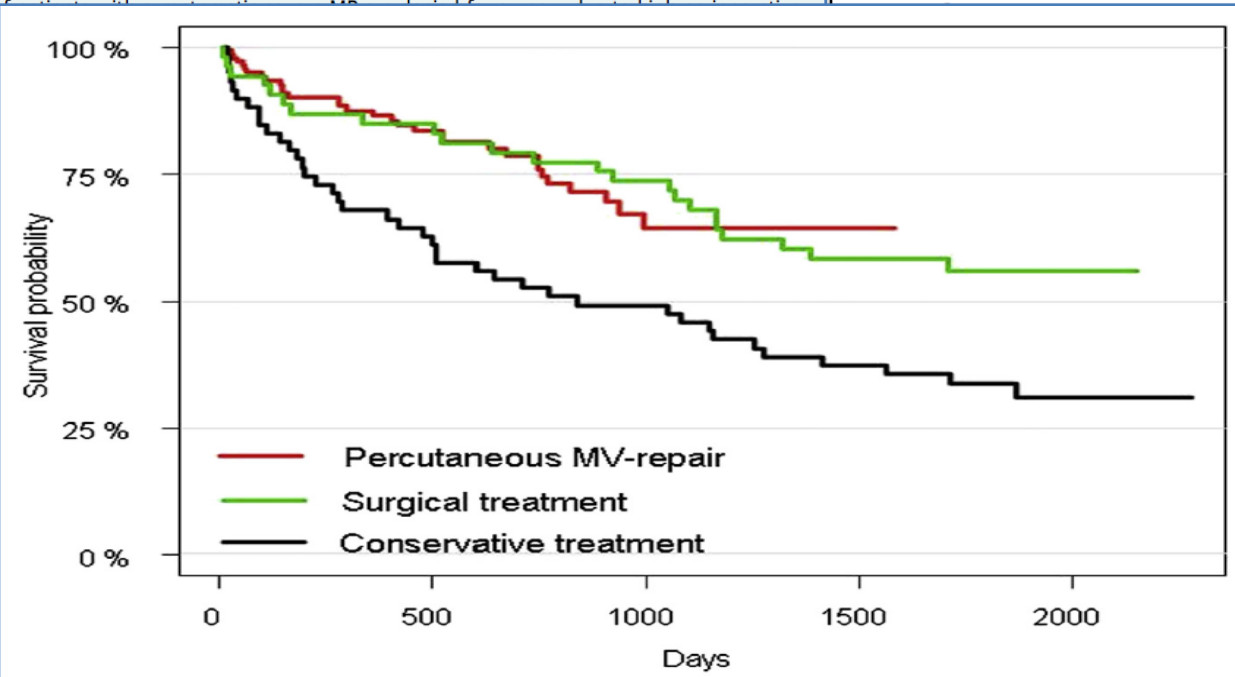
BACKGROUND Up to 50% of patients with severe MR are at high surgical risk. Transcatheter MV repair may be an alternative for high-risk patients.

METHODS Consecutive patients with severe MR were treated with MitraClip (n = 53) or conservatively (n = 59) according to the logistic EuroSCORE for cardiac surgery as judged by the heart team.

RESULTS The log EuroSCORE was higher in surgical patients (43.9 ± 14.4) and conservatively treated (34.5 ± 16.5) than in percutaneous MV-repair patients (14.2 ± 8.9%). Survival was similar in all groups. The same trend was observed when controlling for risk factors, both for surgical vs conservative treatment (HR 0.78, p = 0.006) and surgical vs percutaneous MV-repair (HR 2.16, p = 0.430).

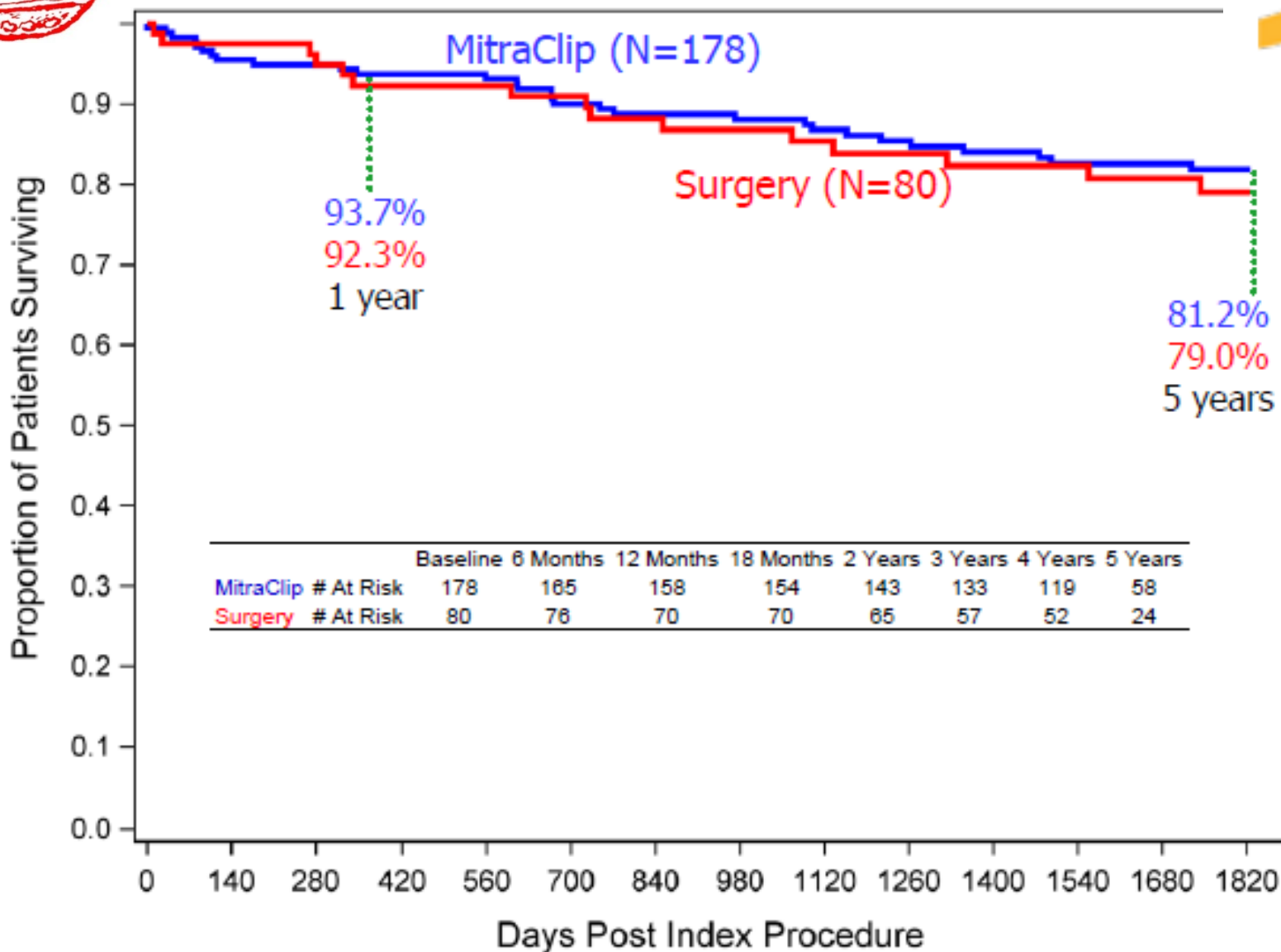
CONCLUSIONS Despite a higher log EuroSCORE, high-surgical-risk patients with symptomatic severe MR treated with transcatheter MV repair show similar survival rates compared with surgically treated patients, with both displaying survival benefit compared with conservative treatment. (J Am Coll Cardiol 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)
		91 (65.5)	38 (71.7)
		32 (23.0)	9 (17.0)
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)





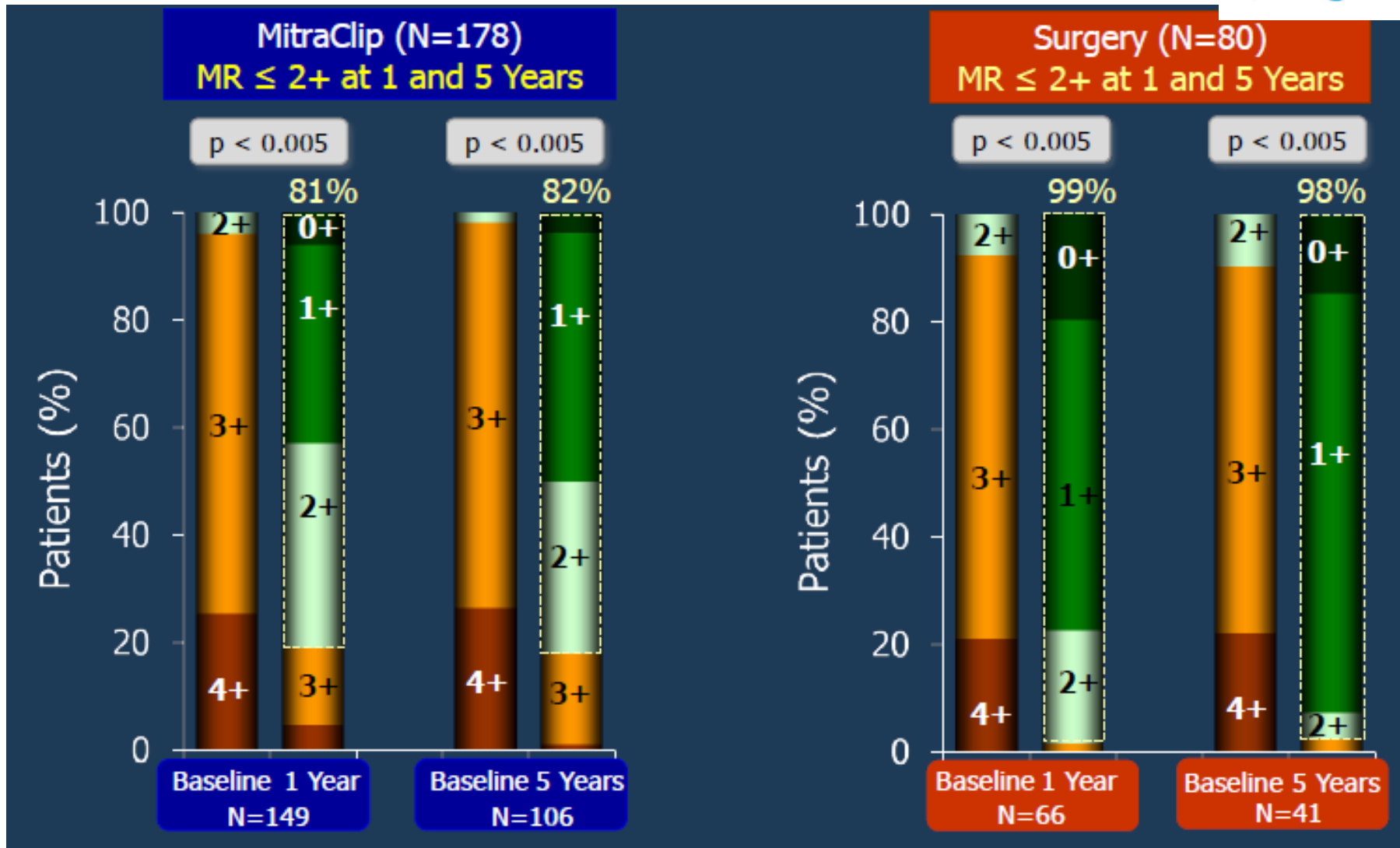
5-Years FU mortality in EVEREST II





Mitral Regurgitation Grade

Everest II RCT all treated patients 258





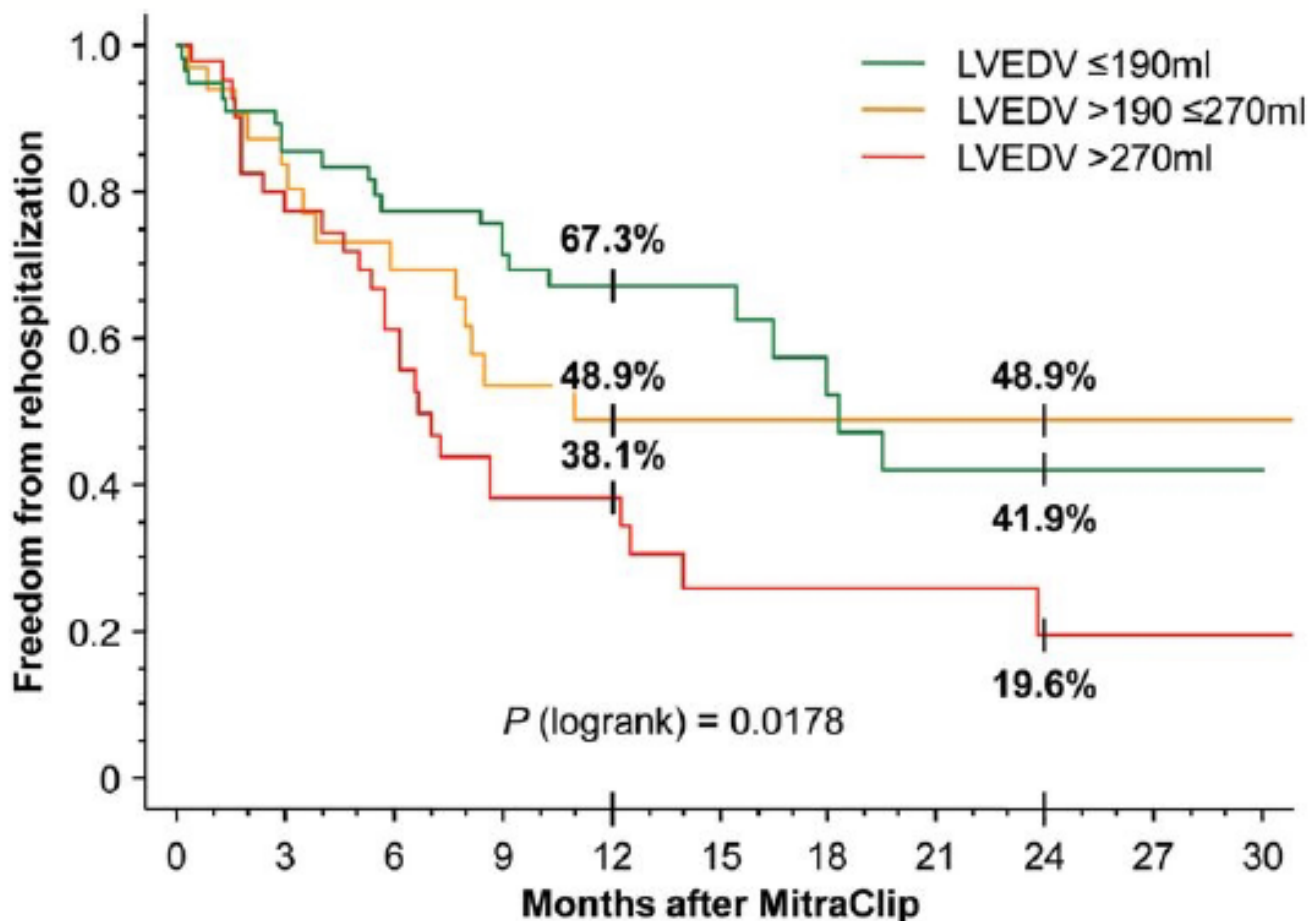
NYHA Functional Class

Everest II RCT all treated patients 258





Timing of Intervention is Key



Rudolf V et al Eur J Heart Failure 2013; 15:796-807



L'ESPERIENZA DEL CENTRO DI MESTRE.



- Primo caso febbraio 2010
- Ad oggi 108 procedure effettuate
- 63 casi di IM Funzionale; 10 Casi di IM ad eziologia mista
- Nelle IM funzionali 1 clip in 33 casi, 2 clip in 30 casi, 3 clip in 7 casi
- Successo procedurale (IM residua ≤ 2) 92% dei casi.



MitraClip Database

CASO CLINICO #78



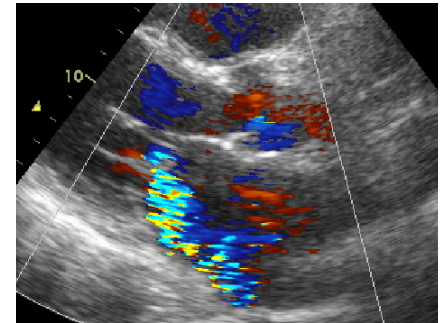


Female 81 yo

Arterial hypertension

COPD with pulmonary arterial hypertension; Multifactorial anemia.
Past breast cancer (right mastectomy + chemotherapy + radiotherapy).
Follow up: negative

April 20th 2014 anterolateral and inferior STEMI
Pain to balloon (4h).

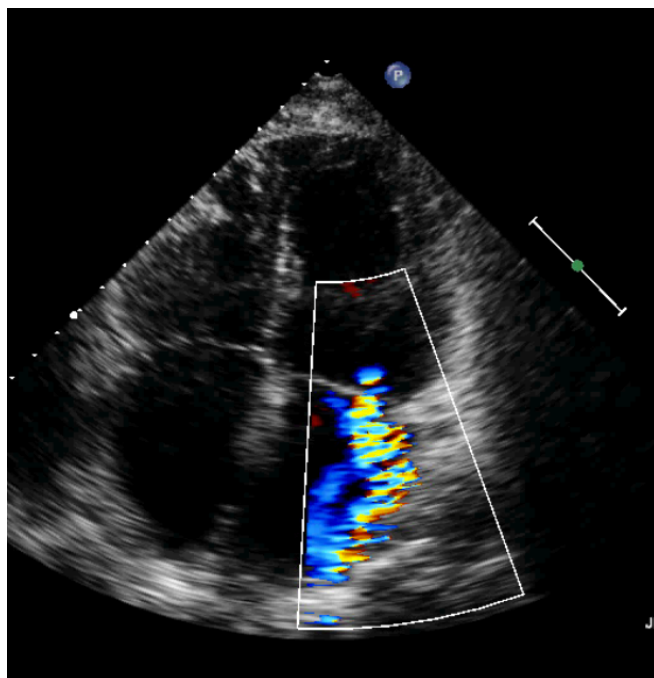


TTE after one month of refractory heart failure: EF 45%, MR 3-4/4 meeting criteria for PMVR.

PRE - PROCEDURAL IMAGING

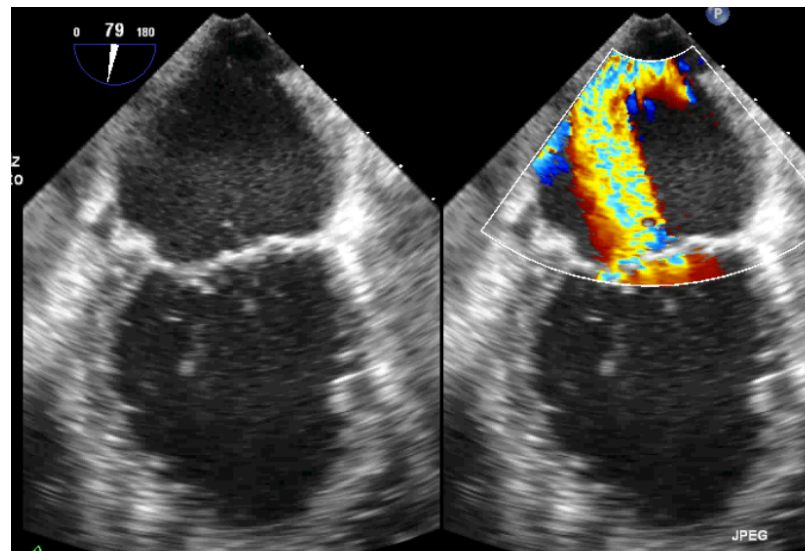
Baseline TTE

4 - CHAMBERS VIEW

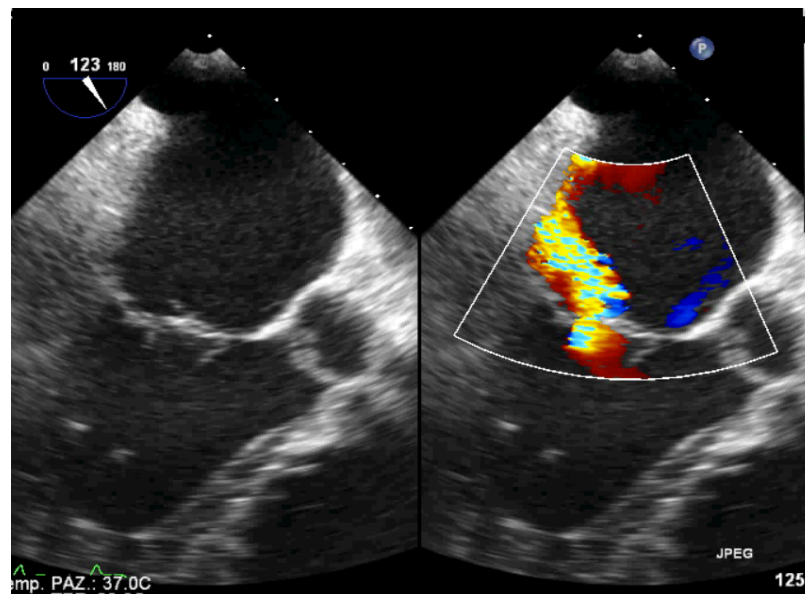


Baseline TEE

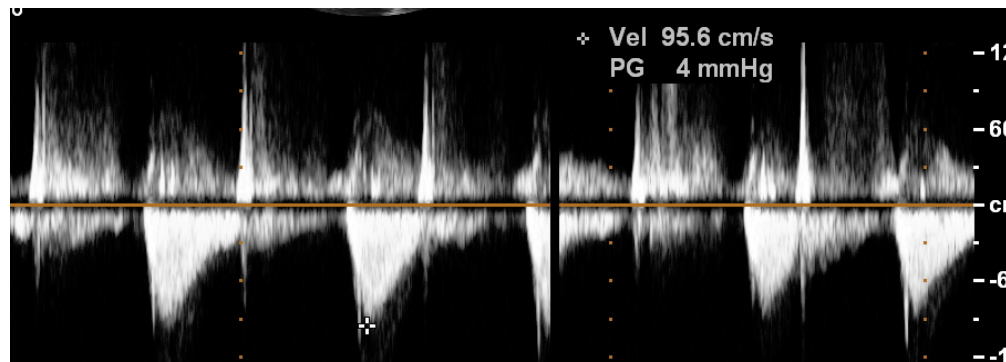
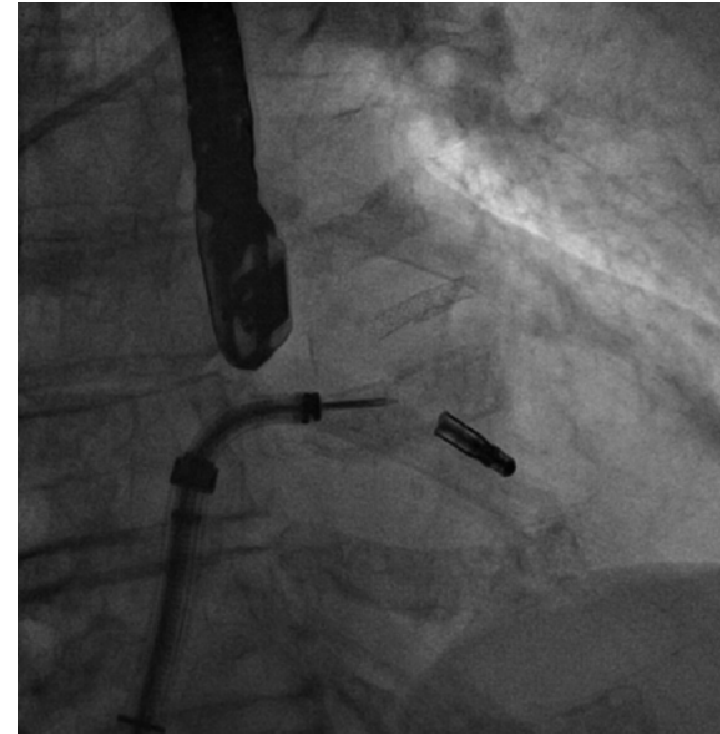
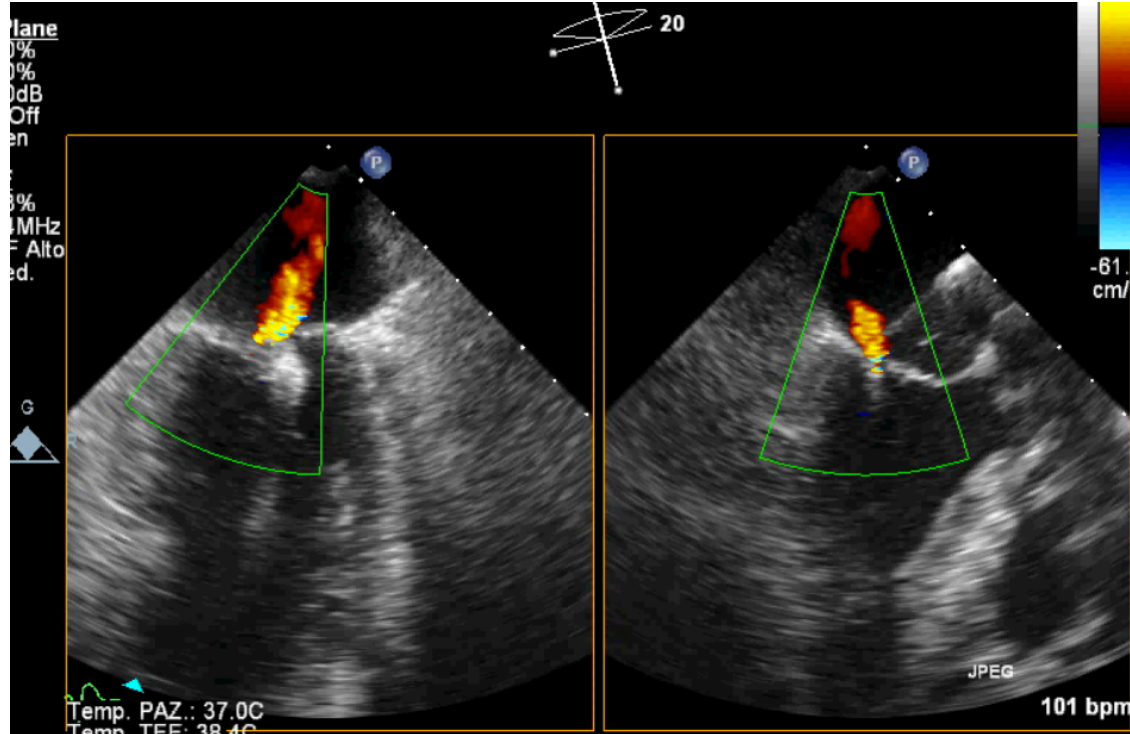
INTERCOMMISSURAL



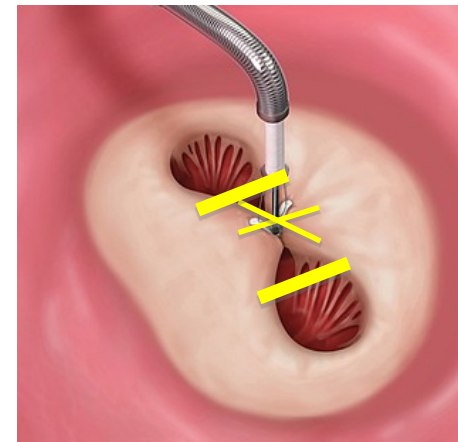
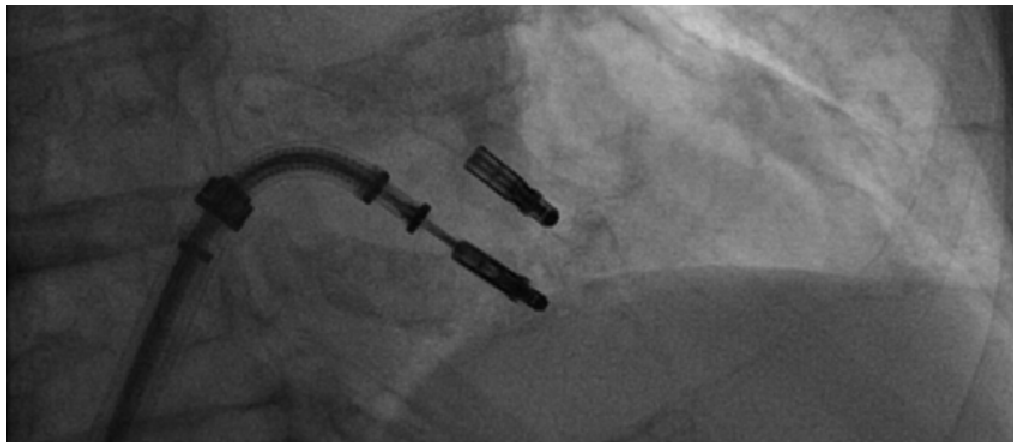
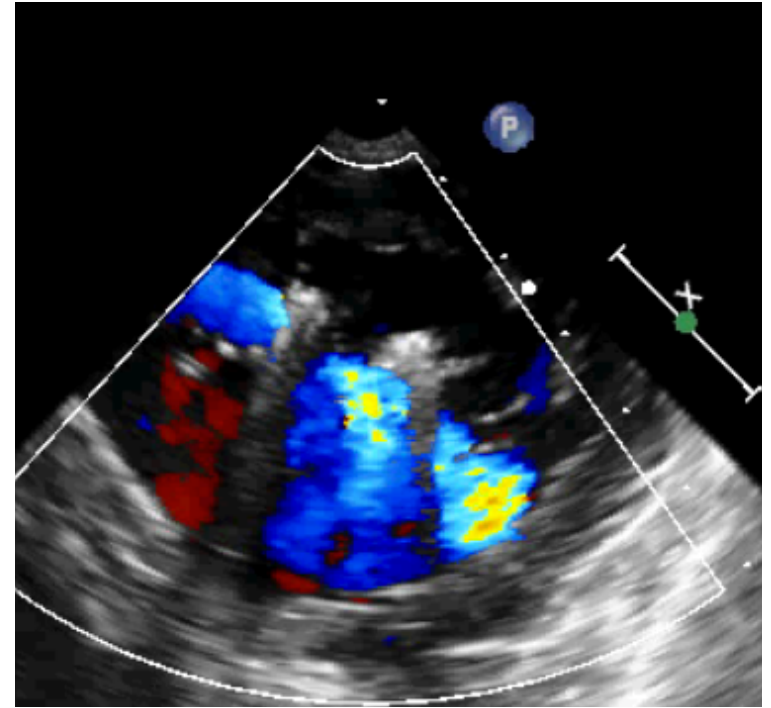
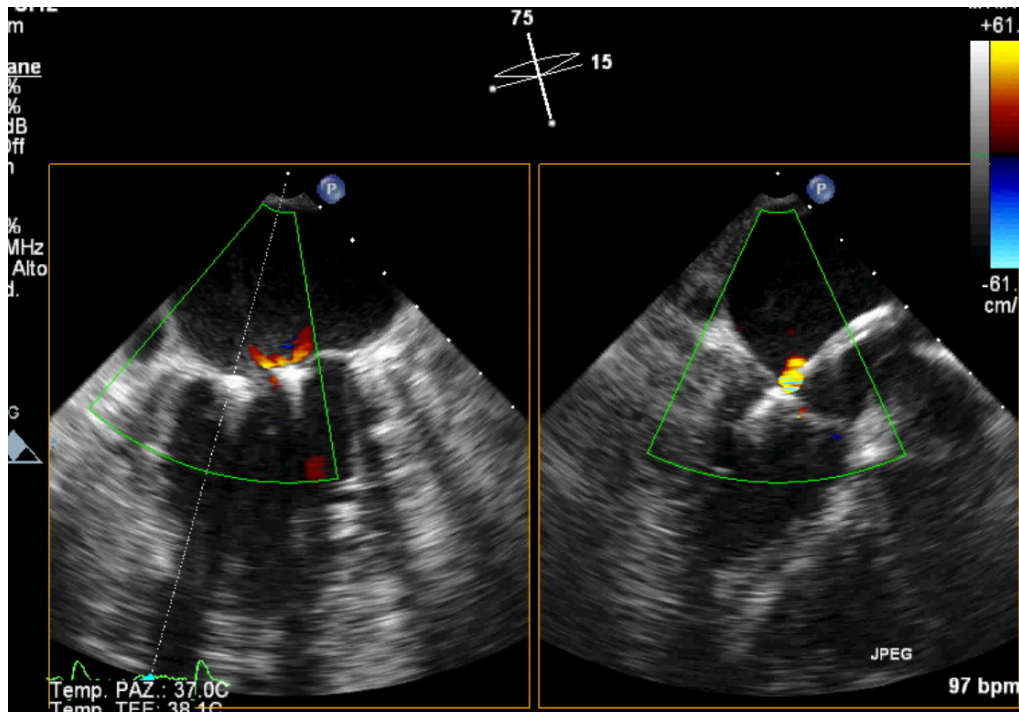
LVOT



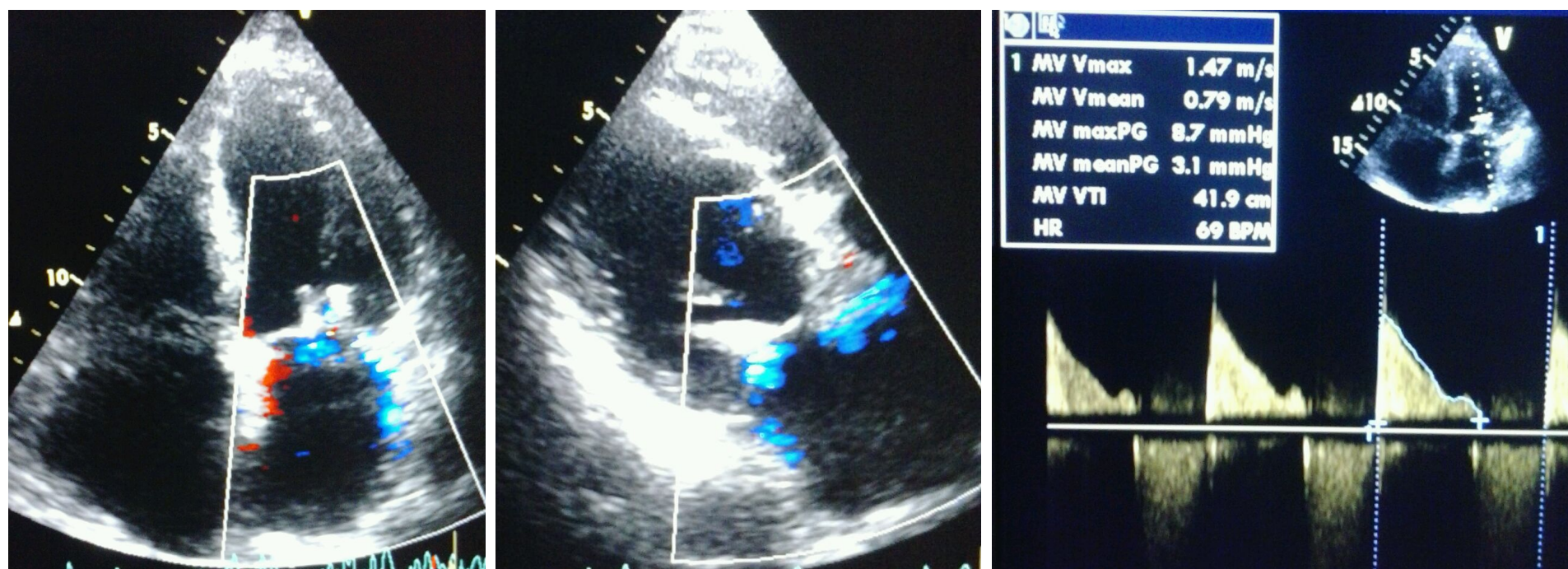
MITRACLIP DEPLOYMENT



SECOND MITRACLIP DEPLOYMENT



FOLLOW UP 6 months



Residual mild MR

Clinical improvement with NYHA I-II



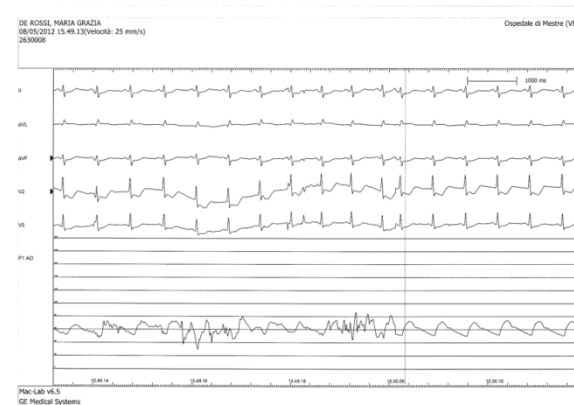
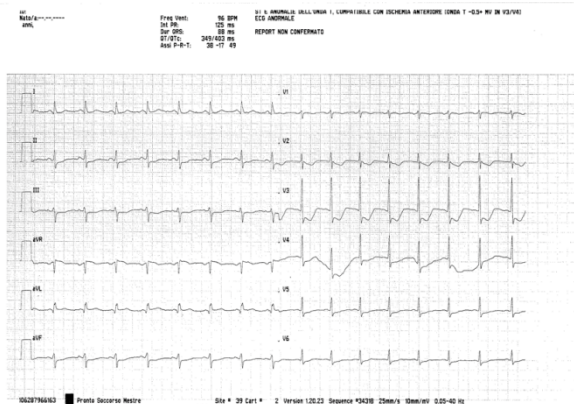
MitraClip Database

CASO CLINICO #47



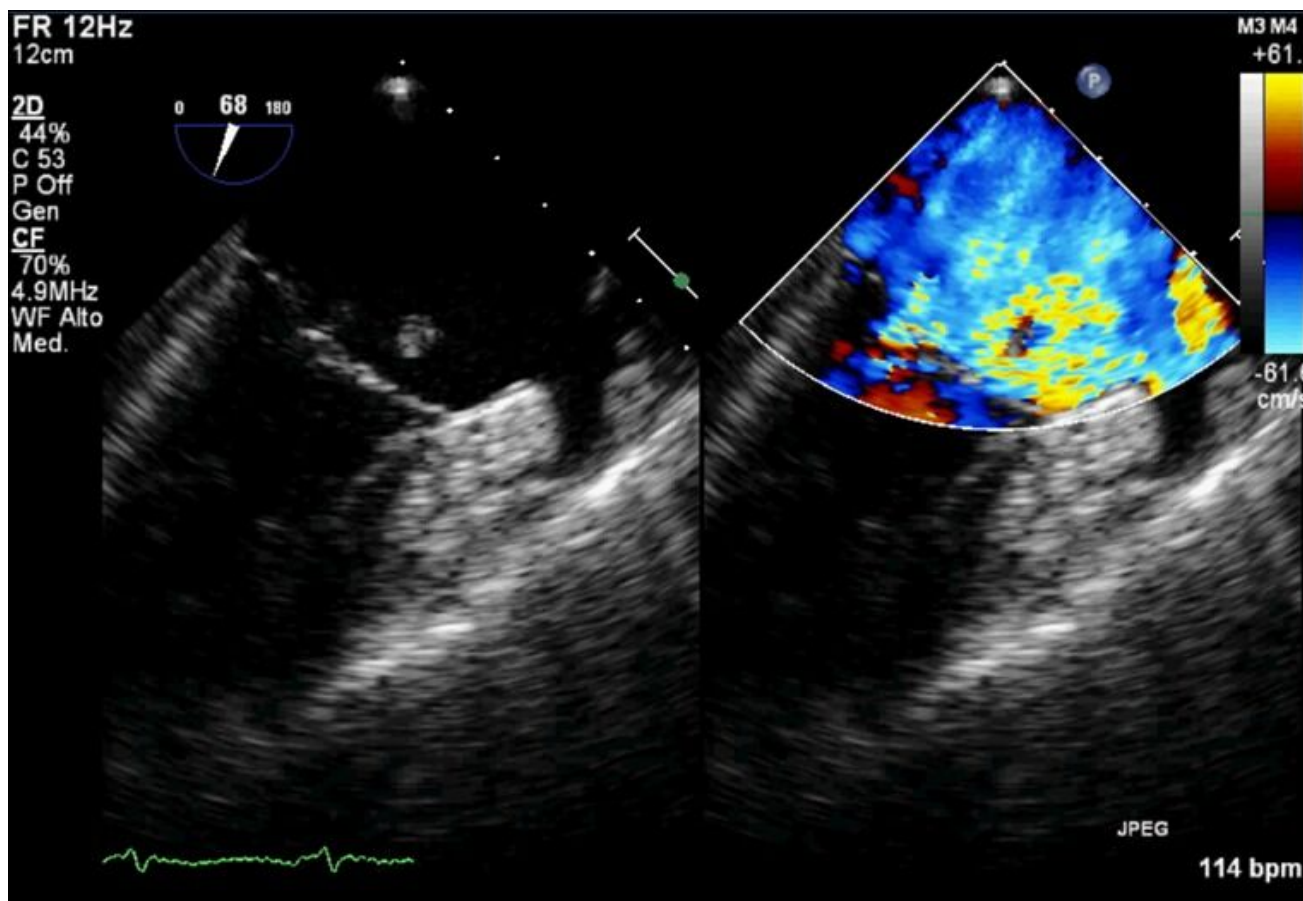


- 67 yrs old female
- no known cardiovascular risk factors, no past medical history
- ER admission after 2 hours from symptoms onset (chest pain, first episode)
- Inferior and posterior STEMI
- Primary PCI With DES on OM

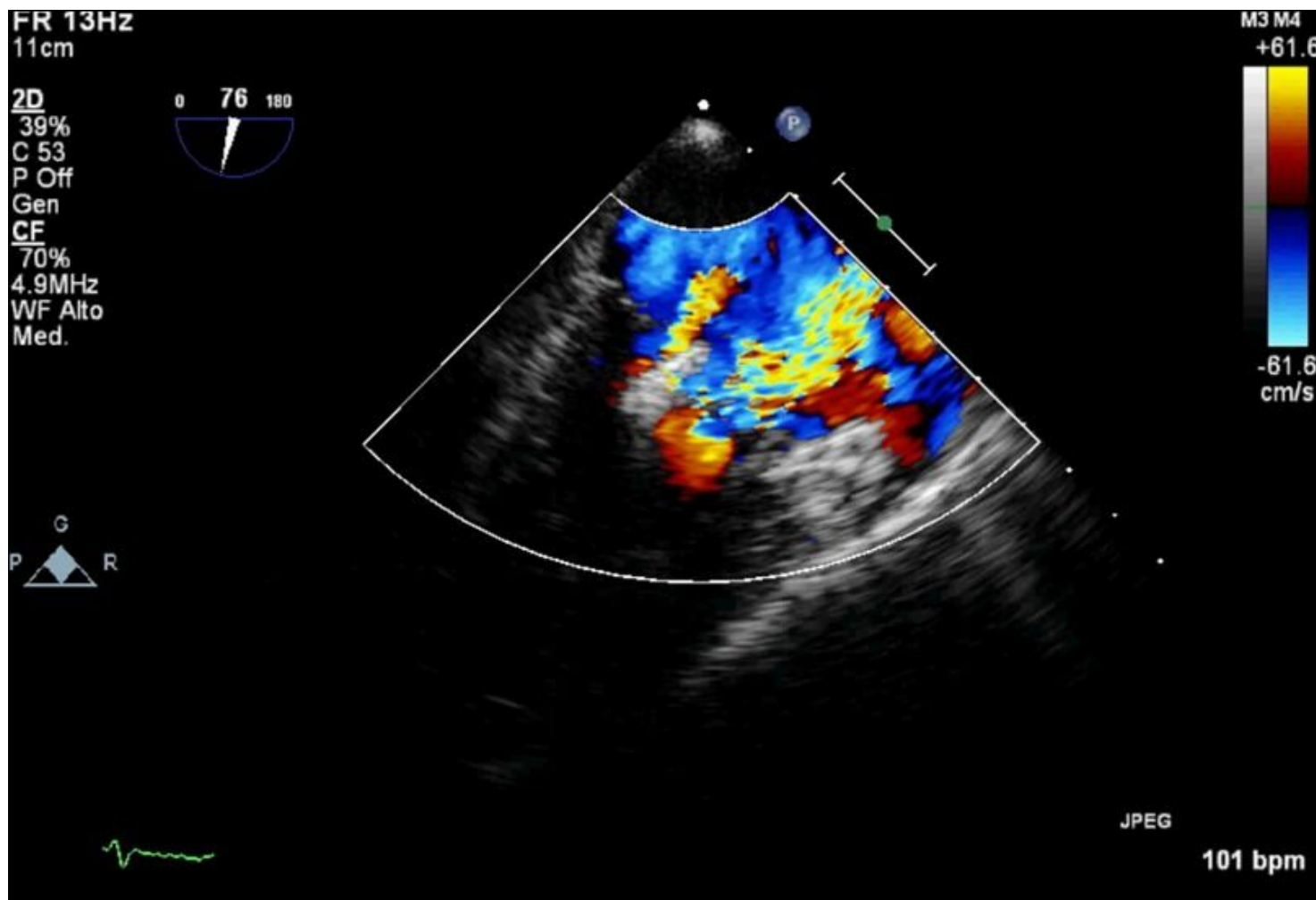


PRE – PROCEDURAL IMAGING

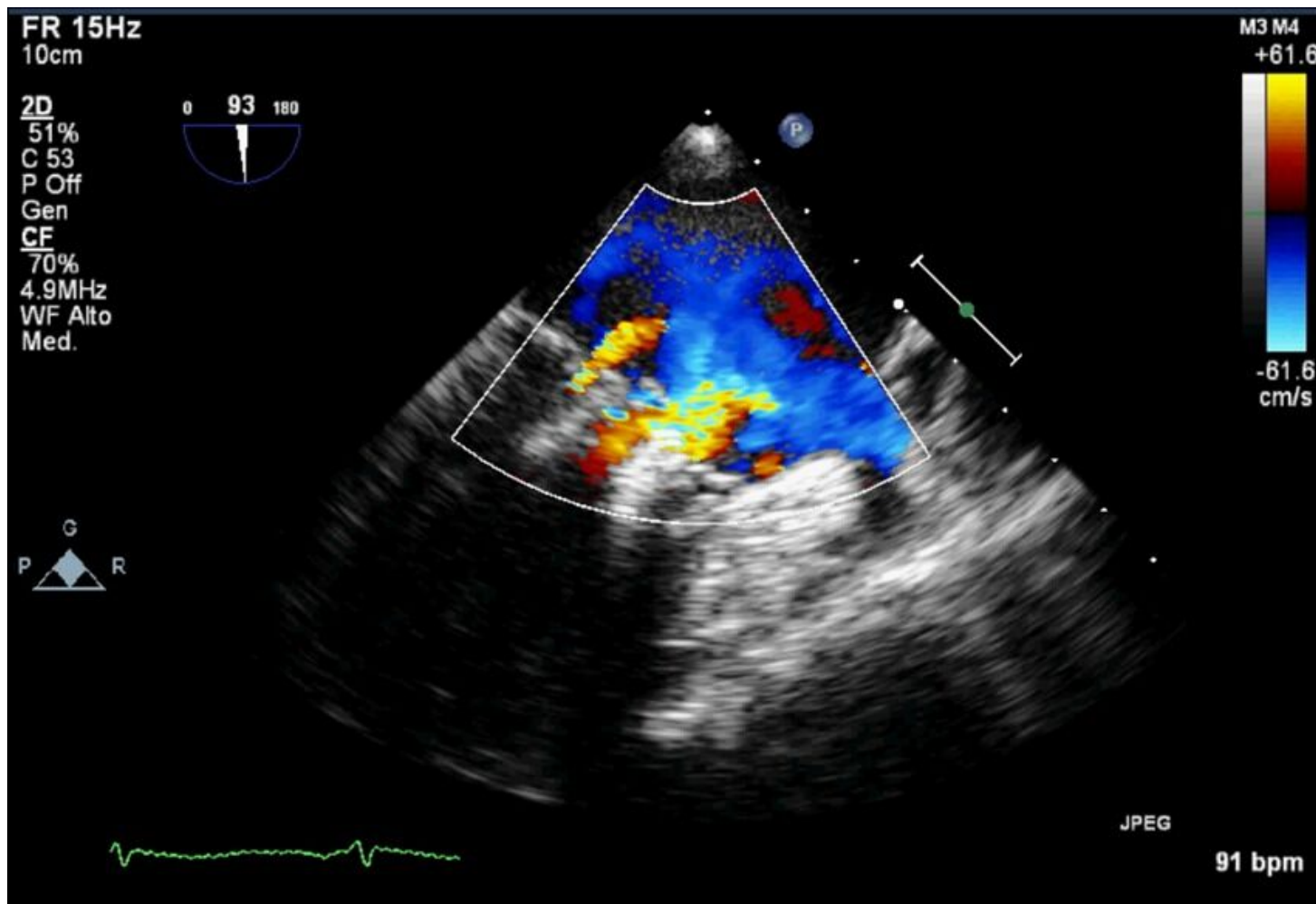
Baseline TEE



MITRACLIP DEPLOYMENT



SECOND MITRACLIP DEPLOYMENT





CONCLUSIONI

-LA PROCEDURA DI PLASTICA PERCUTANEA DELLA MITRALE E':

- SICURA

-EFFICACE

-VALIDA ALTERNATIVA ALLA CHIRURGIA NEI PAZIENTI AD ELEVATO RISCHIO



GRAZIE PER L'ATTENZIONE!

