



Real-world experience with MitraClip

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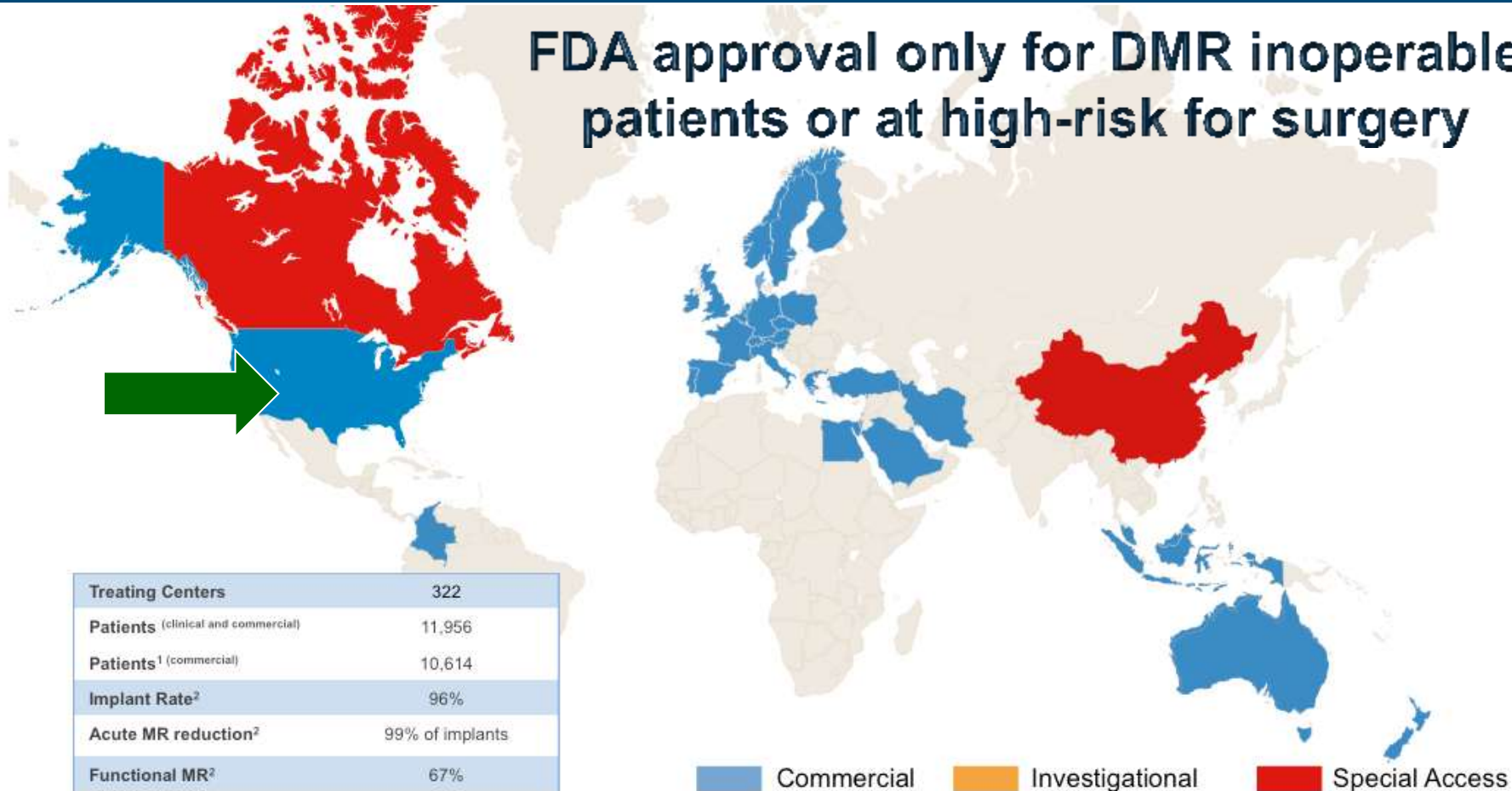


MitraClip Therapy

Current Global Adoption

31-Dec-2013 data

FDA approval only for DMR inoperable patients or at high-risk for surgery

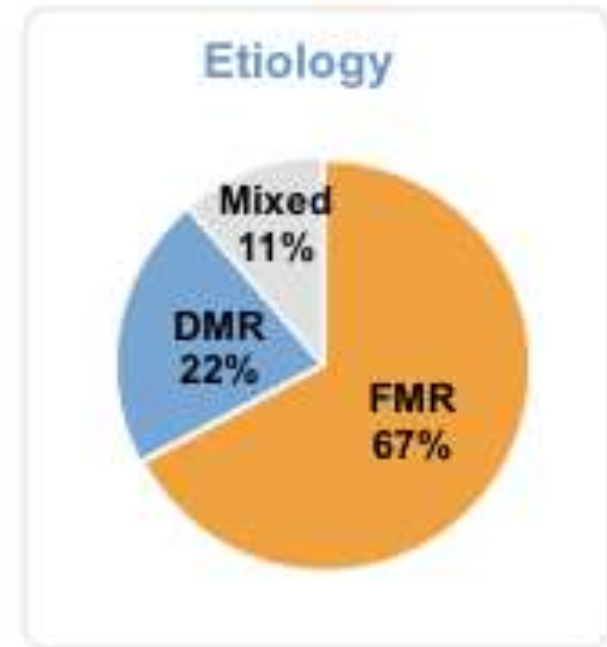


Treating Centers	322
Patients (clinical and commercial)	11,956
Patients ¹ (commercial)	10,614
Implant Rate ²	96%
Acute MR reduction ²	99% of implants
Functional MR ²	67%
Degenerative MR ²	22%
Mixed ²	11%



Commercial MitraClip Implant Experience

- Treating Centers: 289
- Patients¹: 10,614
- Implant Rate¹: 96%
- Acute MR reduction^{1,2}: 99% of implants
- Etiology
 - Functional MR 67%
 - Degenerative MR 22%
 - Mixed 11%



1. First-time procedures only.

2. Successful implants only.

Data as of 12/31/2013. Source: Abbott Vascular.



Percutaneous Mitral Valve Interventions in the Real World

Early and 1-Year Results From the ACCESS-EU, A Prospective, Multicenter, Nonrandomized Post-Approval Study of the MitraClip Therapy in Europe

Francesco Maisano, MD,* Olaf Franzen, MD,† Stephan Baldus, MD,‡ Ulrich Schäfer, MD,§ Jörg Hausleiter, MD,|| Christian Butter, MD,¶ Gian Paolo Ussia, MD,#** Horst Sievert, MD,†† Gert Richardt, MD,‡‡ Julian D. Widder, MD,§§ Tiziano Moccetti, MD,|||| Wolfgang Schillinger, MD¶¶

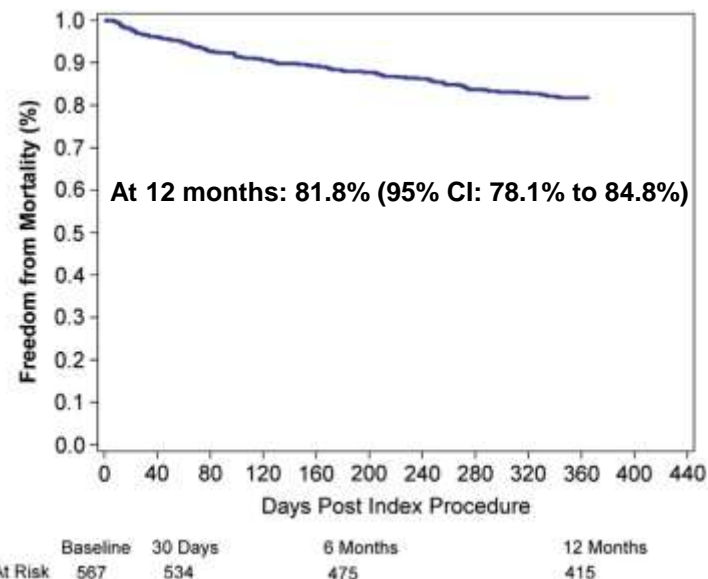


Table 3 Site-Reported Safety Outcomes at 30 Days and 12 Months

ACCESS-EU Phase I

Safety Outcomes	30 Days			12 Months		
	All Patients (N = 567)	FMR Patients (n = 393)	DMR Patients (n = 117)	All Patients (N = 567)	FMR Patients (n = 393)	DMR Patients (n = 117)
Death	3.4% (19/567)	2.8% (11/393)	6.0% (7/117)	17.3% (98/567)	17.0% (67/393)	17.1% (20/117)
Stroke	0.7% (4/567)	0.5% (2/393)	0.9% (1/117)	1.1% (6/567)	1.0% (4/393)	0.9% (1/117)
Myocardial infarction	0.7% (4/567)	0.8% (3/393)	0.9% (1/117)	1.4% (8/567)	1.8% (7/393)	0.9% (1/117)
Renal failure	4.8% (27/567)	5.1% (20/393)	2.6% (3/117)	8.6% (49/567)	9.4% (37/393)	6.0% (7/117)
Respiratory failure	0.7% (4/567)	1.0% (4/393)	0% (0/117)	0.9% (5/567)	1.0% (4/393)	0.0% (0/117)
Need for resuscitation	1.8% (10/567)	2.3% (9/393)	0.9% (1/117)	2.1% (12/567)	2.8% (11/393)	0.9% (1/117)
Cardiac tamponade	1.1% (6/567)	1.0% (4/393)	0.9% (1/117)	1.2% (7/567)	1.0% (4/393)	0.9% (1/117)
Bleeding complications	3.9% (22/567)	3.8% (15/393)	3.4% (4/117)	4.8% (27/567)	4.6% (18/393)	3.4% (4/117)

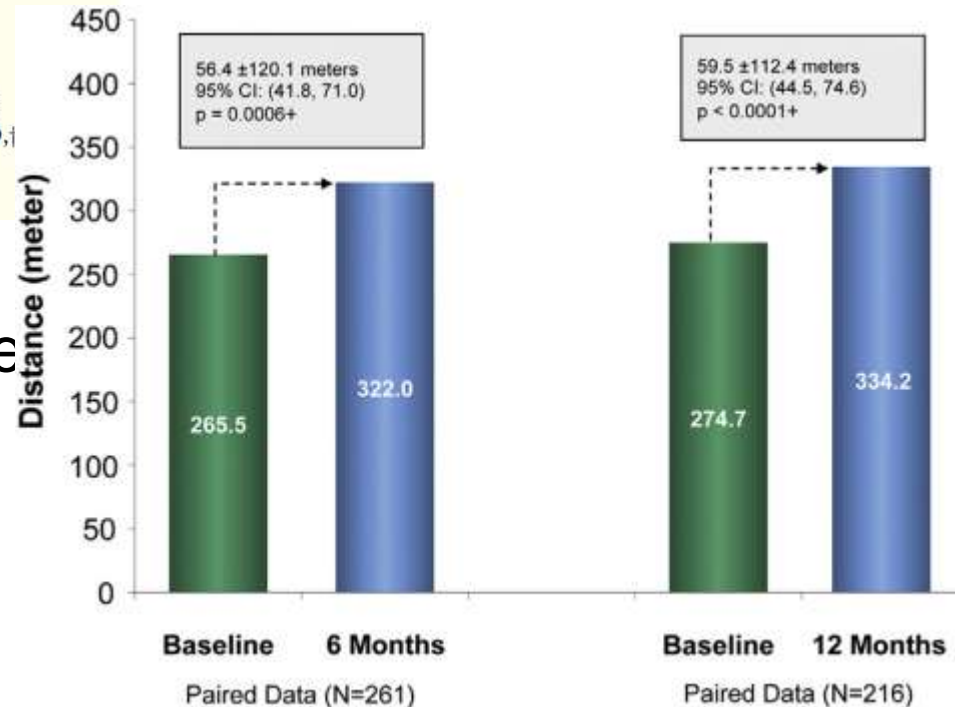


Percutaneous Mitral Valve Interventions in the Real World

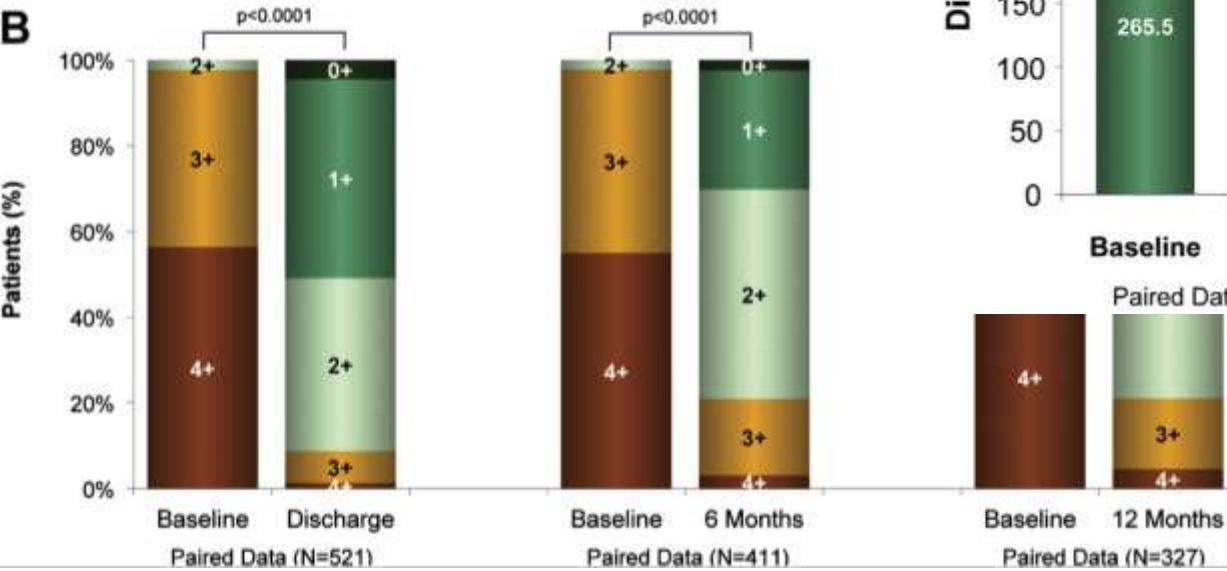
Early and 1-Year Results From the ACCESS-EU,
A Prospective, Multicenter, Nonrandomized Post-Approval
Study of the MitraClip Therapy in Europe

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Wolfgang Schillinger, MD,¶¶

6-min walk distance improvement

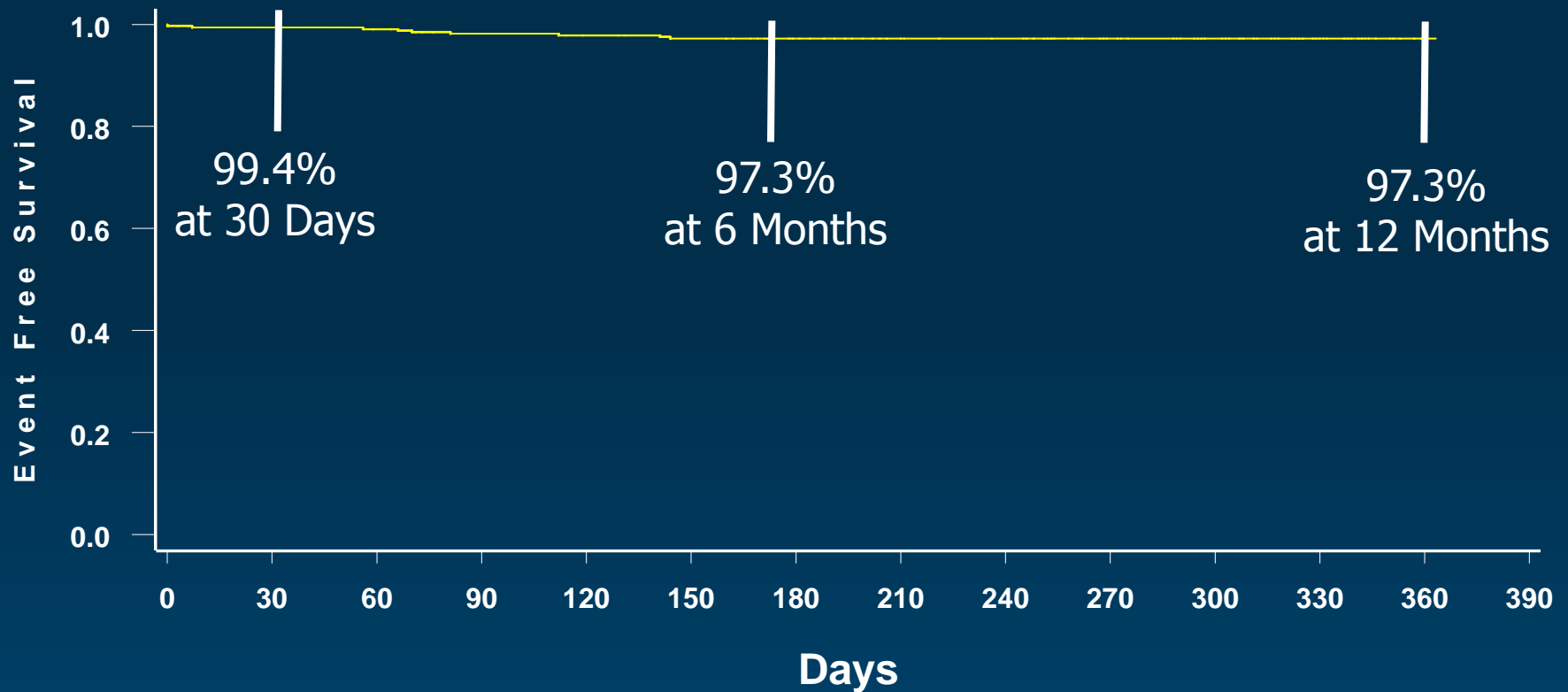


Mitral Regurgitation Improve



Kaplan-Meier Freedom from MV Surgery

ACCESS EU FMR Patients



At Risk	0 Days	30 Days	180 Days	365 Days
FMR N	355	335	298	194

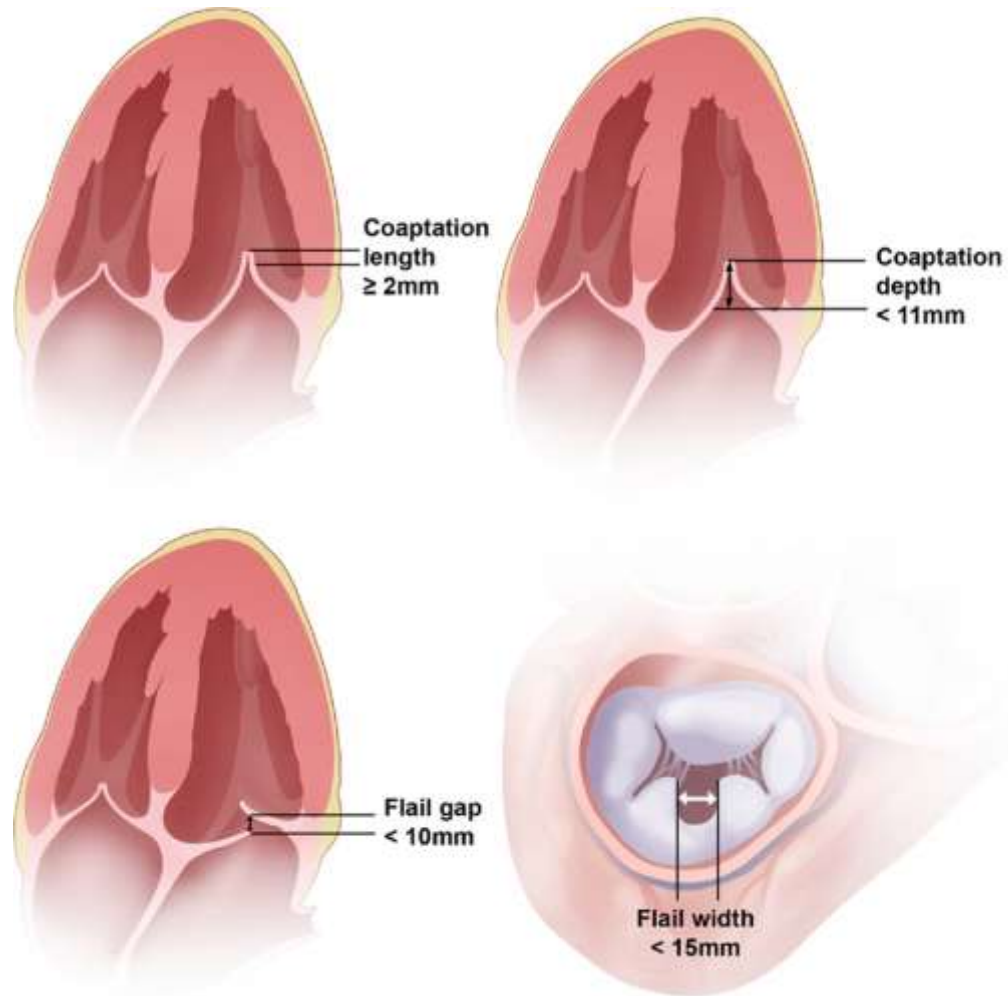


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EVEREST Anatomic Criteria

Are they really mandatory?



MitraClip[®] therapy in patients with end-stage systolic heart failure

Olaf Franzen^{1*}, Jan van der Heyden², Stephan Baldus¹, Michael Schlüter¹, Wolfgang Schillinger³, Christian Butter⁴, Rainer Hoffmann⁵, Roberto Corti⁶, Giovanni Pedrazzini⁷, Martin J. Swaans², Michael Neuss⁴, Volker Rudolph¹, Daniel Sürder⁷, Jürg Grünenfelder⁶, Christine Eulenburg⁸, Hermann Reichenspurner⁹, Thomas Meinertz¹, and Angelo Auricchio⁷

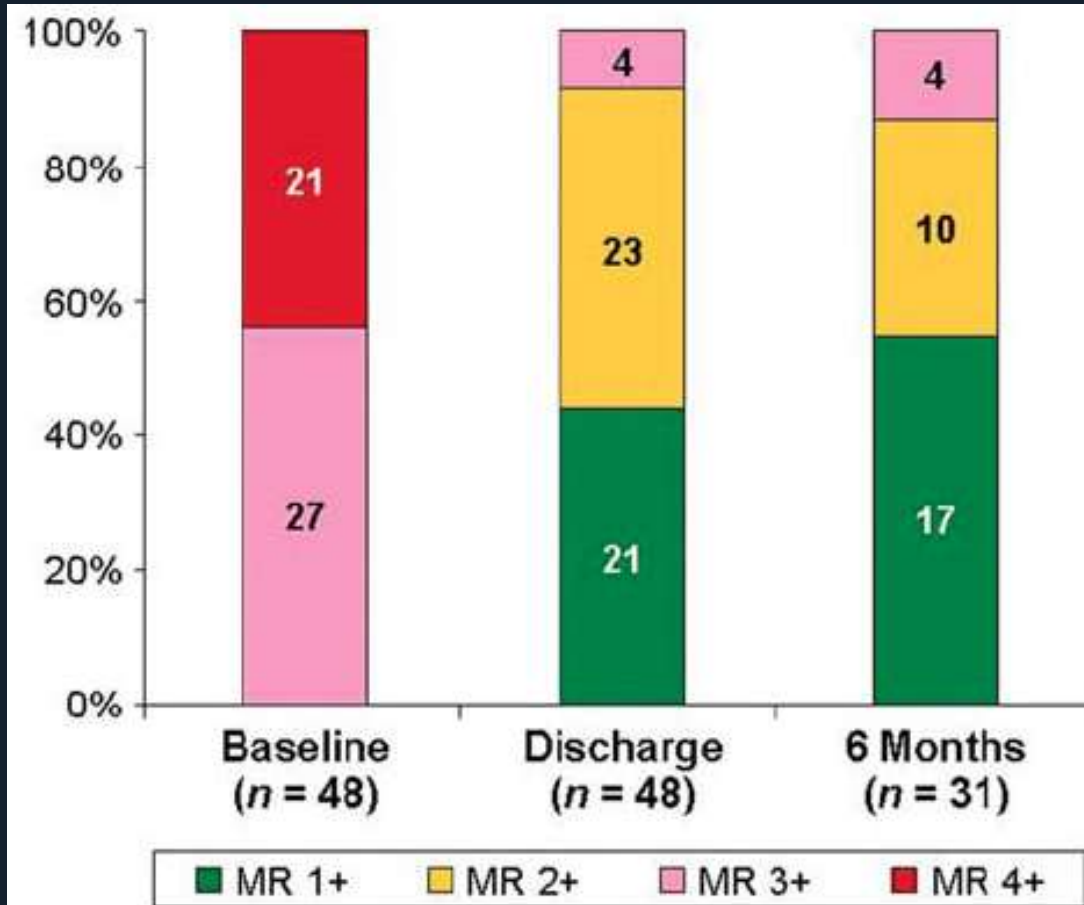
- ✓ *50 HF pts with LVEF ≤ 25%*
- ✓ *FMR ≥ 3+ in NYHA III-IV*
- ✓ *All patients were on optimal medical therapy*

Baseline patient characteristics

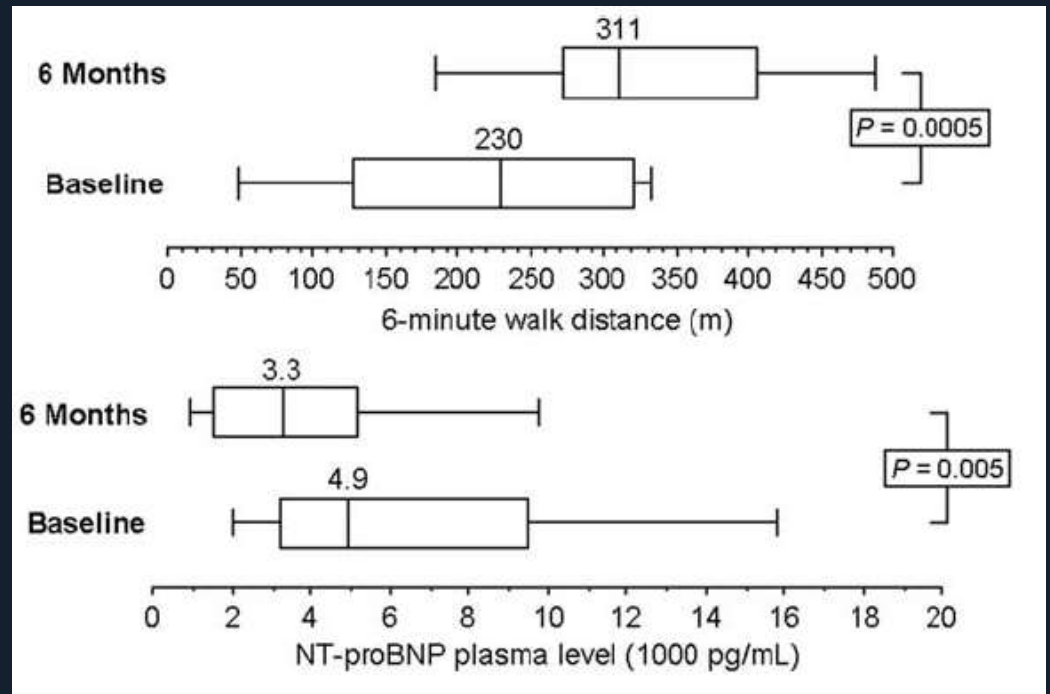
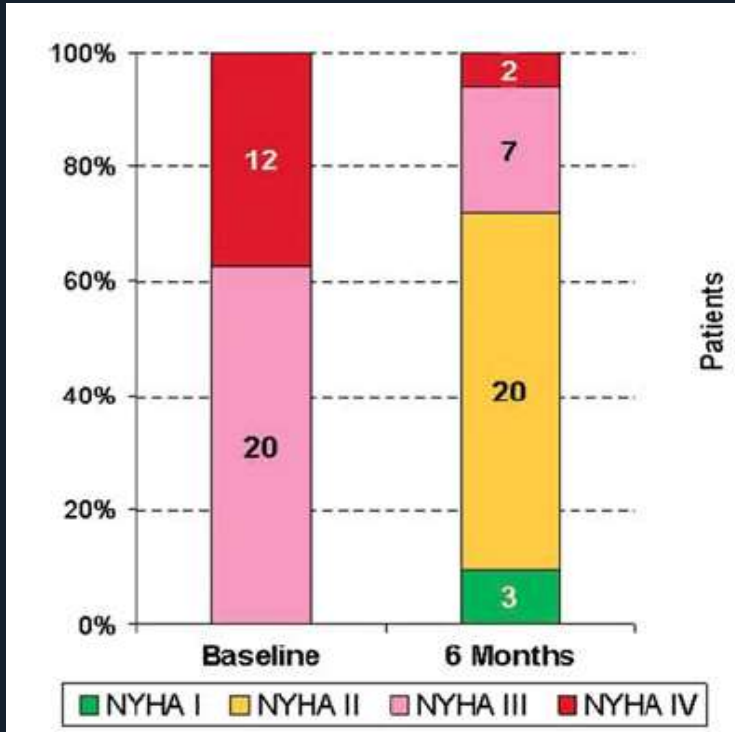
	n = 50
Age (year \pm SD)	70 \pm 11
Male gender, n (%)	38 (76)
Logistic EuroSCORE (% \pm SD)	34 \pm 21
Cardiomyopathy, n (%)	
Ischaemic	28 (56)
Non-ischaemic	22 (44)
MR aetiology, n (%)	
Functional	49 (98)
Functional with degenerative aspect	1 (2)
MR severity, n (%)	
3+ (moderate-to-severe)	27 (54)
4+ (severe)	23 (46)
NYHA functional class, n (%)	
III	27 (54)
IV	23 (46)
LV ejection fraction (% \pm SD)	19 \pm 5
LV end-diastolic diameter (mm \pm SD)	70 \pm 9
LV end-systolic diameter (mm \pm SD)	62 \pm 9
LV end-systolic diameter >55 mm, n (%)	39 (78)
LV end-diastolic volume (mL \pm SD)	252 \pm 88



MR Severity



Functional Results



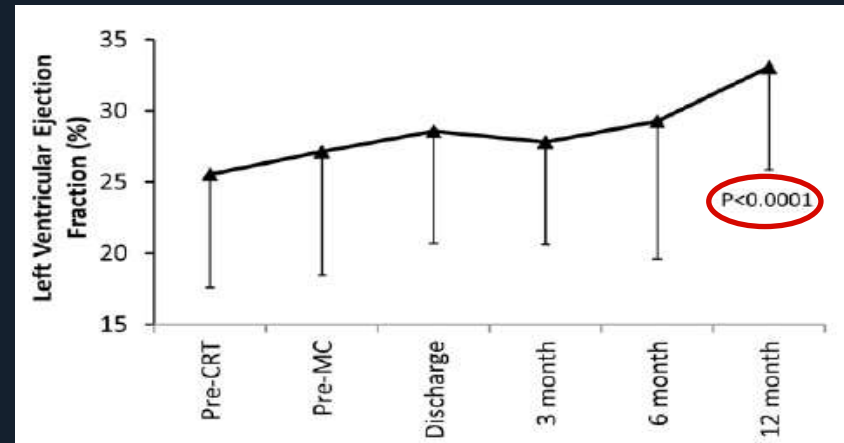
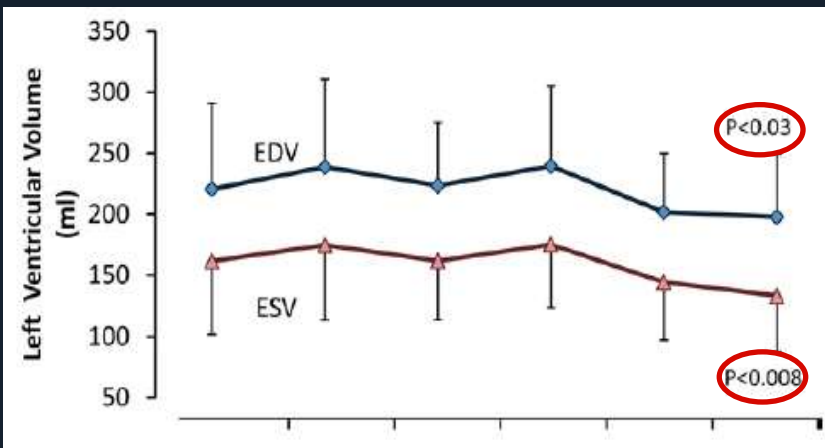
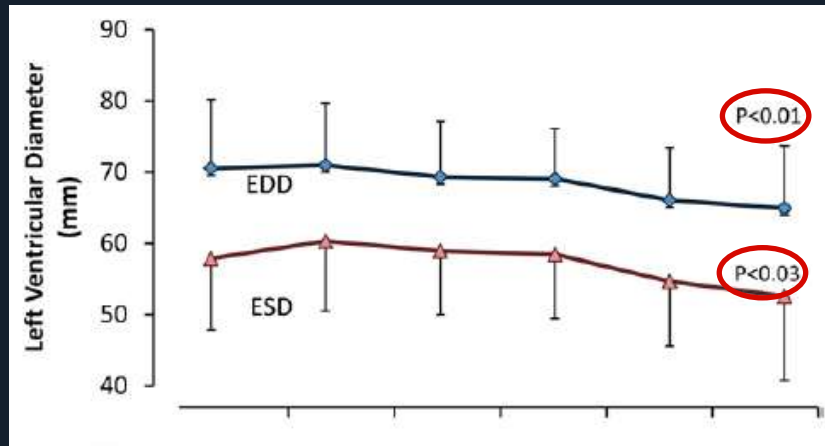
Correction of Mitral Regurgitation in Nonresponders to Cardiac Resynchronization Therapy by MitraClip Improves Symptoms and Promotes Reverse Remodeling

Angelo Auricchio, MD, PhD,* Wolfgang Schillinger, MD,† Sven Meyer, MD,‡
Francesco Maisano, MD,§ Rainer Hoffmann, MD,|| Gian Paolo Ussia, MD,¶
Giovanni B. Pedrazzini, MD,* Jan van der Heyden, MD,# Simona Fratini, MD, PhD,**
Catherine Klersy, MD, MSc,†† Jan Komtebedde, DVM,* Olaf Franzen, MD,‡
on behalf of the PERMIT-CARE Investigators

*Lugano, Switzerland; Göttingen, Hamburg, and Aachen, Germany;
Milan, Catania, L'Aquila, and Pavia, Italy; and Nieuwegein, the Netherlands*



Reverse Remodeling in CRT Non-Responder Patients treated with MitraClip



GRASP registry

The
American Journal
of
Cardiology

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, Fabio Dipasqua, MD^a, Sandra Giaquinta, MD^a, Michele Occhipinti, MD^a, Gianpaolo Ussia, MD^a, and Corrado Tamburino, MD, PhD^{a,b}



Baseline clinical characteristics

	Overall (n = 117)	Degenetative (n = 28)	Functional (n = 89)	p value
Age, years±SD	72 ± 10	73 ± 9	72 ± 11	0.50
Men, n (%)	78 (67 %)	19 (68 %)	59 (66 %)	0.88
NYHA ≥ 3 n (%)	93 (80%)	23(82%)	70 (79%)	0.69
Diabetes mellitus, n (%)	40 (34 %)	5 (18 %)	35 (39 %)	0.04
Hypertension, n (%)	92 (79 %)	18 (64 %)	74 (83 %)	0.03
Chronic Kidney disease, n (%)	44 (38 %)	8 (29 %)	36 (40 %)	0.33
Coronary artery disease, n (%)	57 (49 %)	7 (25 %)	50 (56 %)	0.004
Prior CABG, n (%)	22 (19 %)	2 (7 %)	20 (23 %)	0.07
Atrial Fibrillation, n (%)	47(40%)	11 (39%)	36 (40 %)	0.91
COPD, n (%)	24 (21%)	3 (11 %)	21 (24 %)	0.26
Left ventricular EF%	38 ± 13	55 ± 7	33 ± 10	< 0.001
Logistic Euroscore, %±SD	12±14	11±16	13±13	0.46

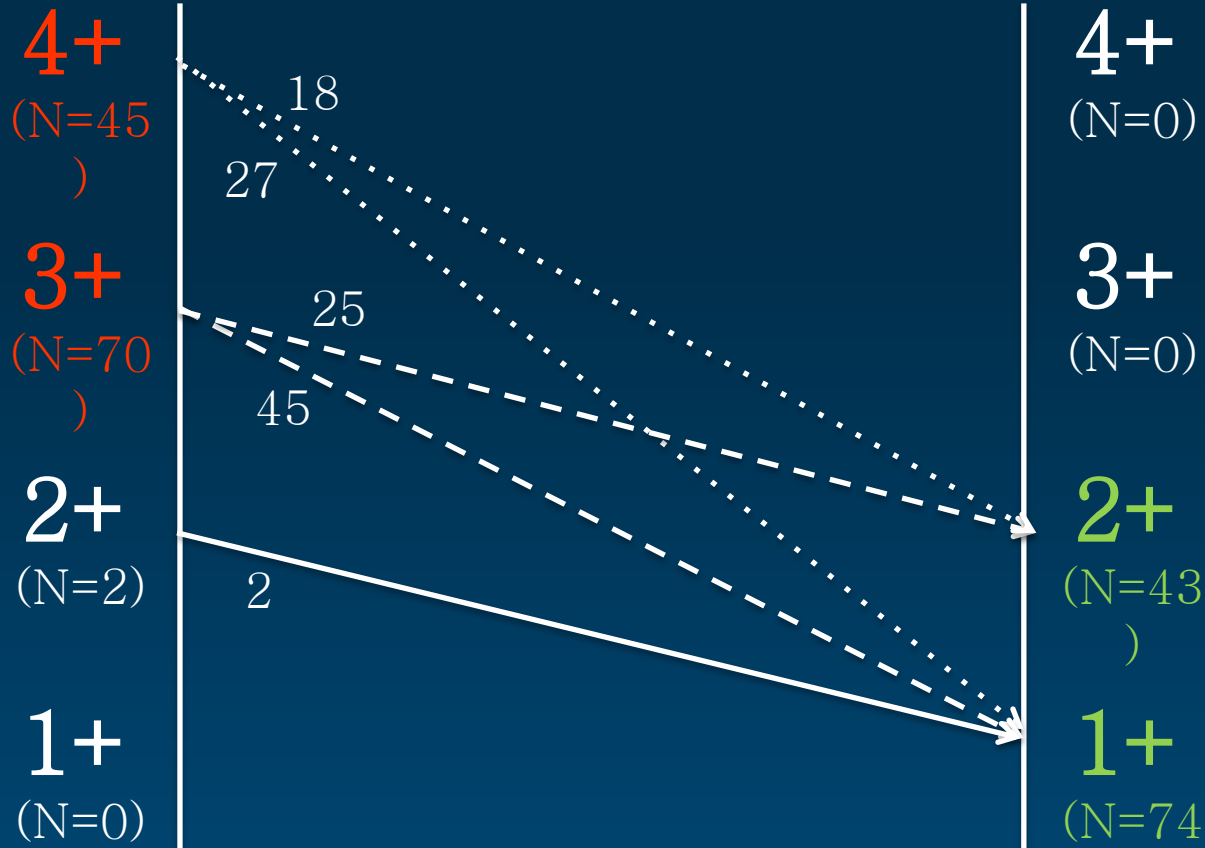


GRASP registry

Acute Procedural Success 100%

Baseline MR severity
(N=117)

Postprocedural MR severity
(N=117)



Catania Experience

Oct-2008 Feb-2014
GRASP Registry



Ferrarotto Hospital
University of Catania

Tamburino, personal data



Baseline clinical characteristics

	Overall (n = 180)	Degenerative (n = 38)	Functional (n = 142)	p value
Age, years \pm SD	72 \pm 10	73 \pm 13.5	71 \pm 8,7	0.39
Men, n (%)	111 (62%)	19 (50%)	92 (65%)	0.68
NYHA \geq 3 n (%)	145 (80%)	21 (55%)	114 (80%)	0.65
Diabetes mellitus, n (%)	63 (35 %)	8 (21%)	55 (39%)	0.04
Hypertension, n (%)	136 (75%)	23(60%)	113 (79%)	0.01
Chronic Kidney disease, n (%)	87 (48%)	16 (42%)	71 (50%)	0.34
Coronary artery disease, n (%)	100 (55%)	10 (26%)	90 (63%)	< 0.001
Prior coronary a. bypass graft, n (%)	37 (20%)	4 (10%)	33 (23%)	0.09
Atrial Fibrillation n (%)	70 (39%)	15 (39%)	55 (39%)	0.95
Chronic obstructive pulmonary, n (%)	39 (22%)	4 (10%)	35 (25 %)	0.06
Left ventricular ejection fraction %	37 \pm 13	52 \pm 12	33 \pm 11	< 0.001
Logistic EuroScore, % \pm SD	13 \pm 12	10 \pm 9	14 \pm 12	0.47

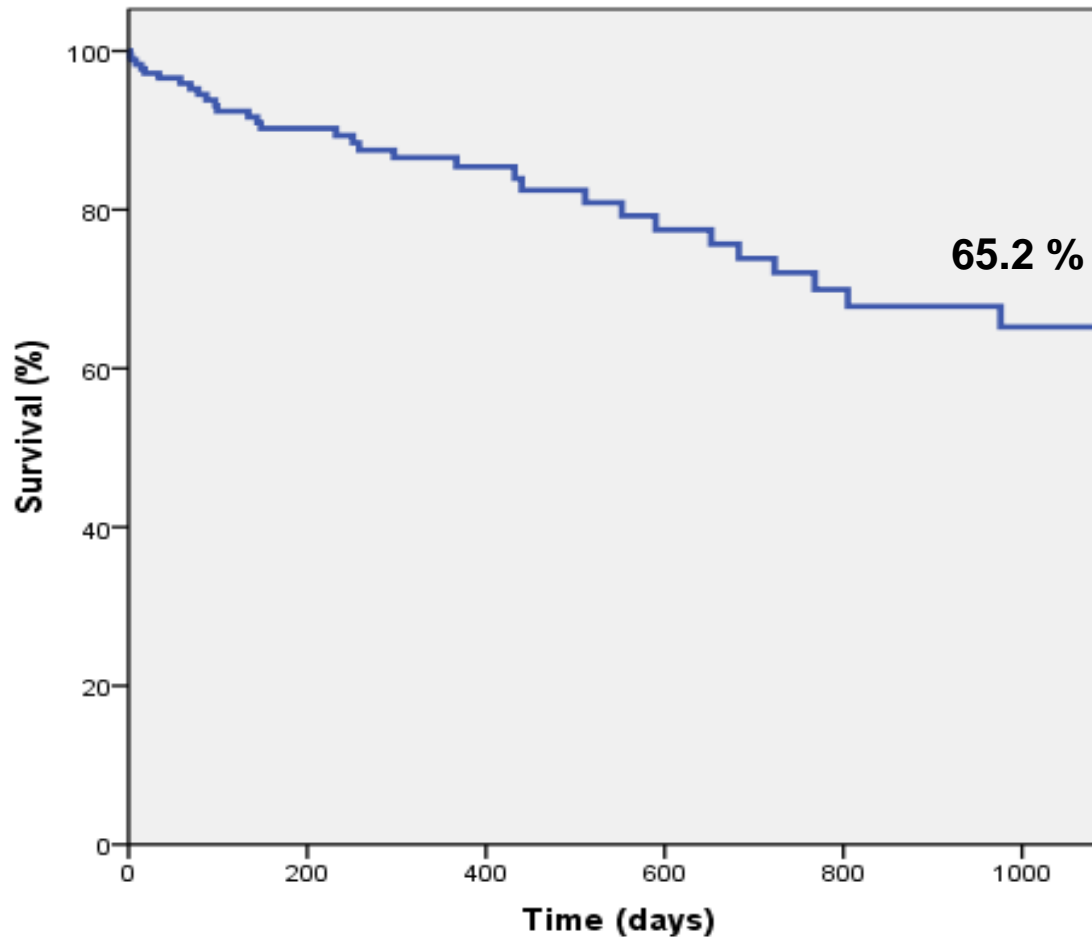


MAEs at 30-days

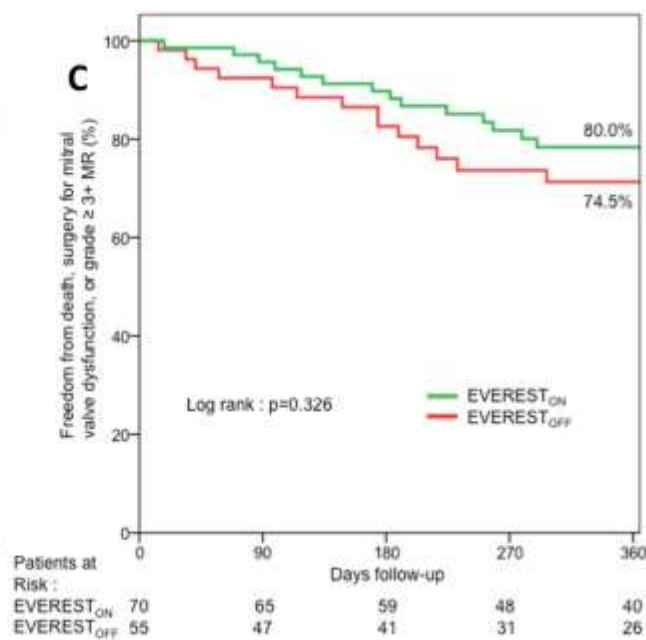
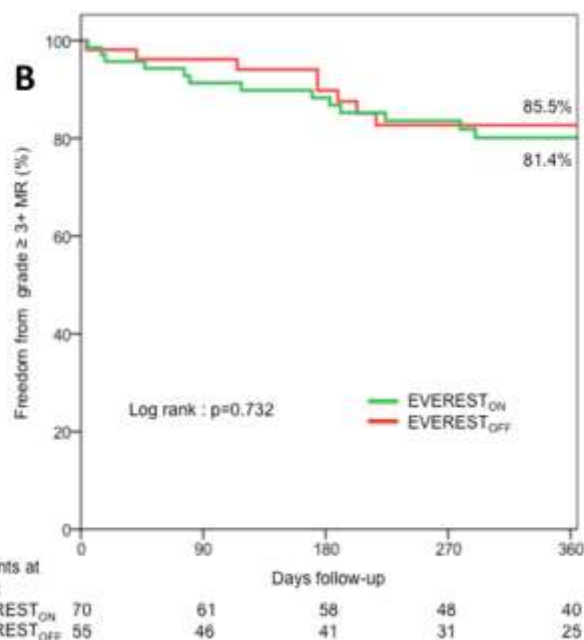
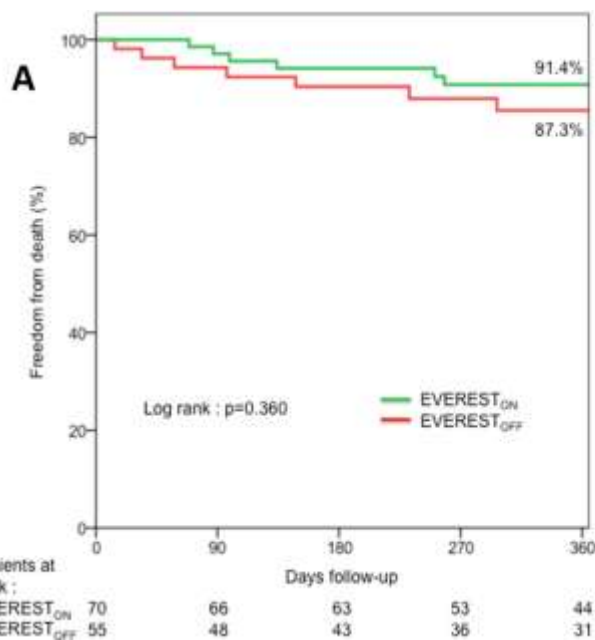
	Overall (N = 180)	Degenerative (N =38)	Functional (N=142)
Any major adverse event	8 (4.5%)	0	8 (5.6%)
Death	5 (2.7%)	0	5(3.5%)
Myocardial infarction	0	0	0
Reoperation for failed surgical repair or replacement	0	0	0
Urgent or emergency cardiovascular surgery for adverse event	0	0	0
Major stroke	1 (0.6%)	0	1 (0.7%)
Deep wound infection	0	0	0
Mechanical ventilation for >48 hours	0	0	0
Gastrointestinal complications requiring surgery	0	0	0
Septicemia	0	0	0
New onset of permanent atrial fibrillation	1 (0.6)	0	1 (0.7%)
Transfusion of ≥2 units of blood	1 (0.6)	0	1 (0.7%)



Kaplan-Meier freedom from death 3-years (overall)



Extended Use of Percutaneous Edge-to-Edge Mitral Valve Repair Beyond EVEREST Criteria: Thirty-Day and Twelve-Month Clinical and Echocardiographic Outcomes From the GRASP Registry



Percutaneous mitral valve repair with the MitraClip system for severe mitral regurgitation in patients with surgical mitral valve failure

Grasso C, Ohno Y, Attizzani GF, Cannata S, Immè S, Barbanti M, Pistritto AM, Ministeri M, Caggegi A, Chiarandà M, Dipasqua F, Ronsivalle G, Mangiafico S, Scandura S, Capranzano P, Capodanno D, Tamburino C.



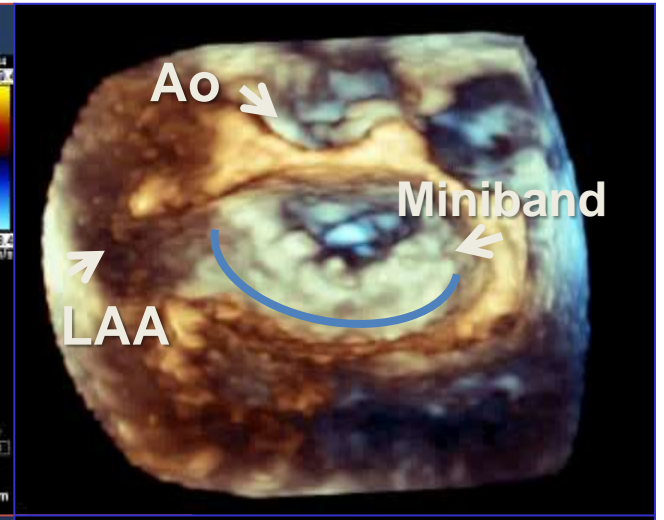
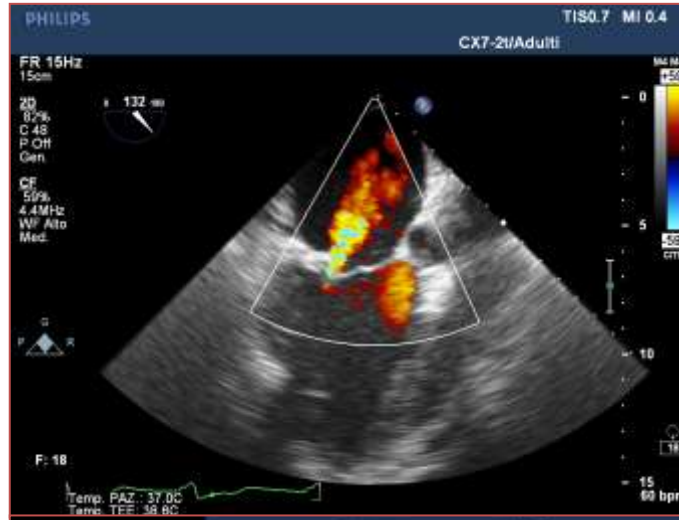
Representative Case

77 yrs
NICM, NYHA III
CRT (+)

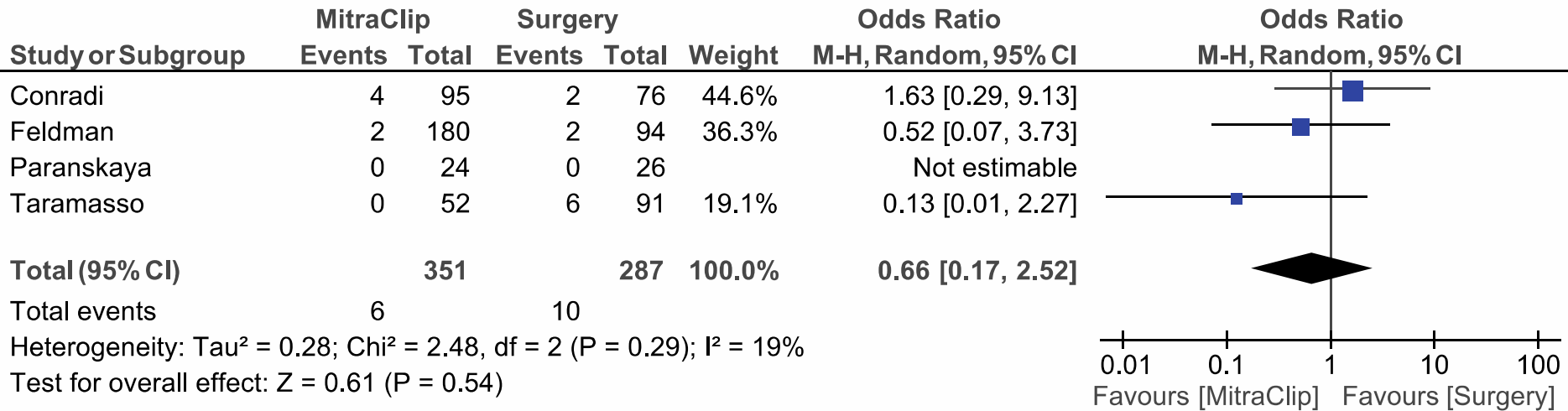
Dec. 2006
MV annuloplasty
+
TV annuloplasty

July 2012
MitraClip

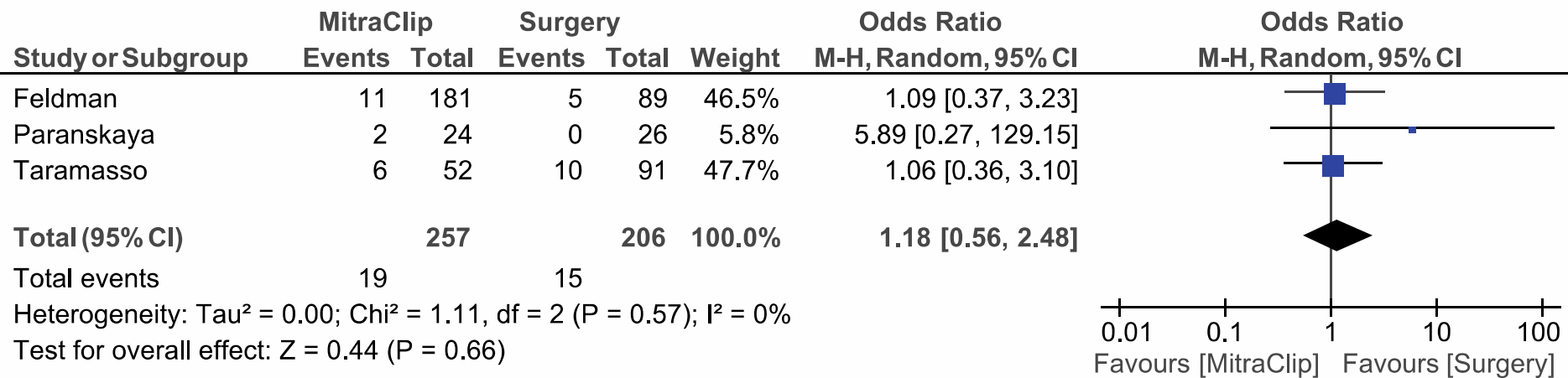
July 2013
NYHA I



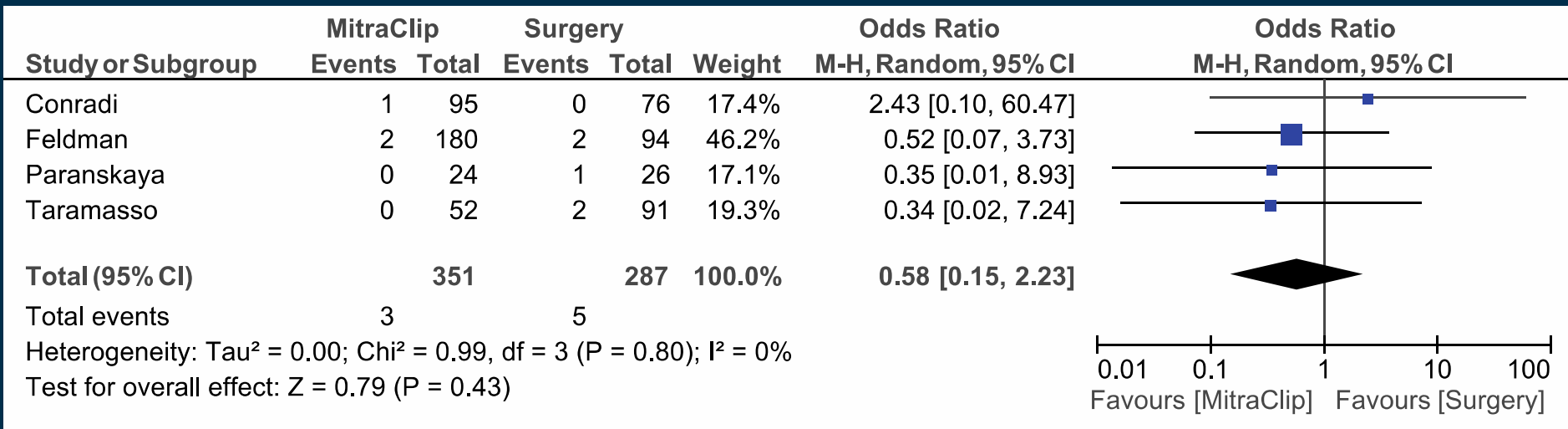
30d mortality



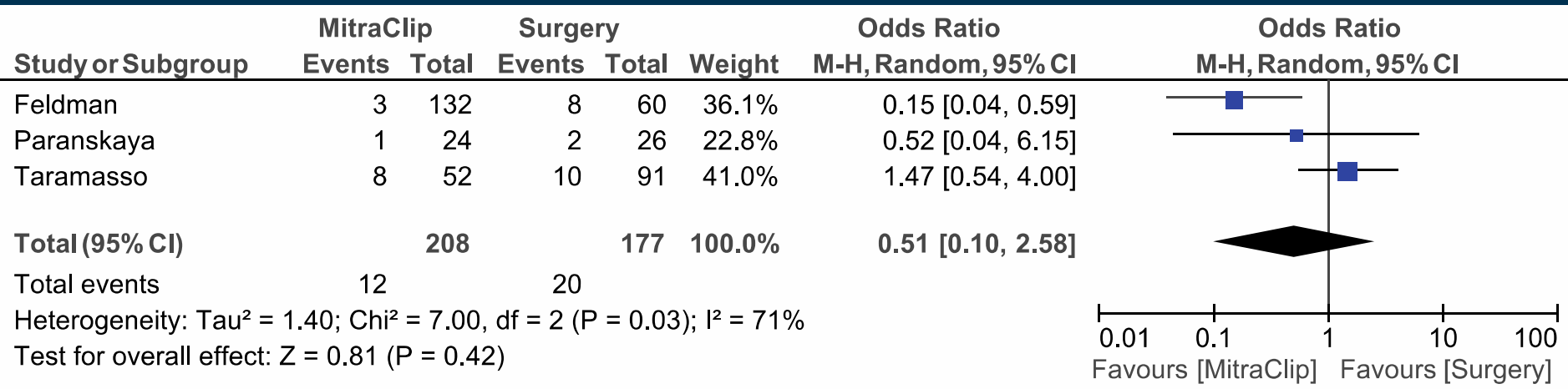
1y survival



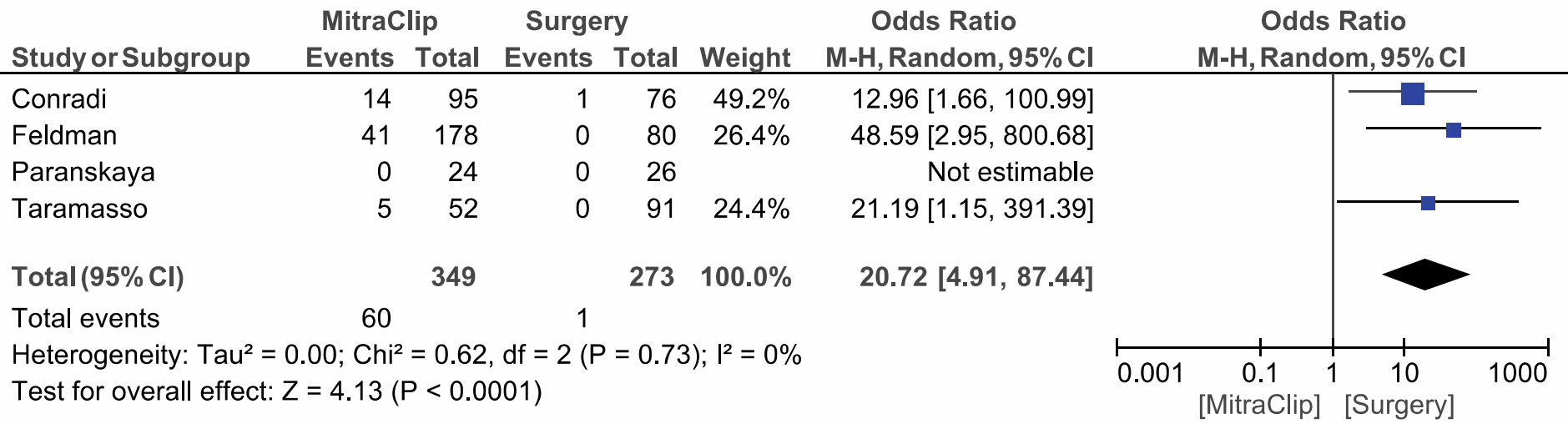
post-clip neurological events



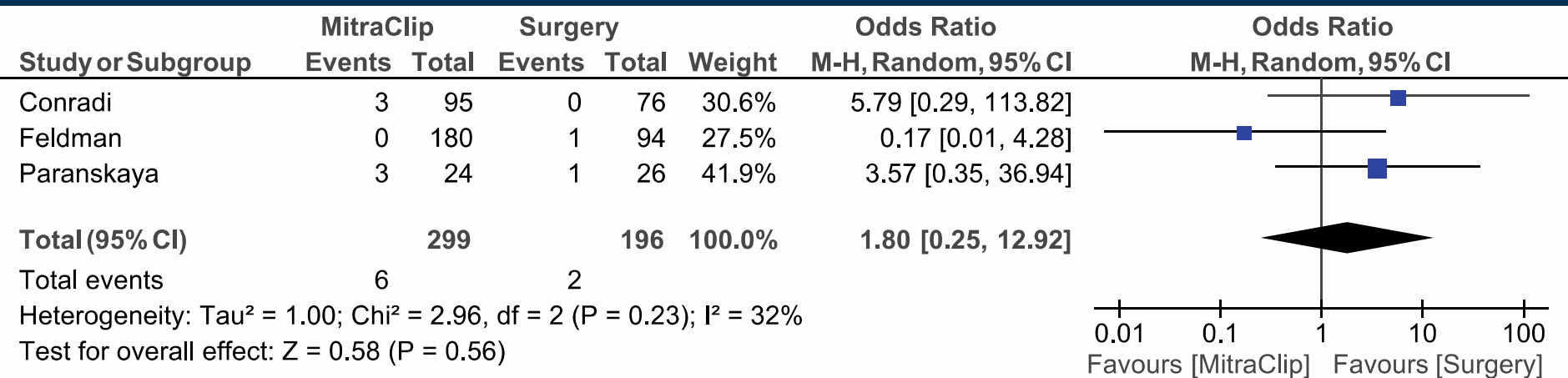
12m NYHA III/IV



Early Residual MR >2+



12m reoperation



Take home messages

- ✓ MitraClip procedure is safe and effective in patients from real-world and Everest -
- ✓ Provides significant clinical benefits, including symptomatic and functional improvement in both FMR and DMR patients
- ✓ Deterioration of post-procedural is more common in those with degenerative MR
- ✓ Survival benefit will be assessed by ongoing trials: RESHAPE-HF and COAPT

