

**Advances in Cardiac Arrhythmias and Great Innovations in Cardiology -
Torino, 27/28 ottobre 2017**

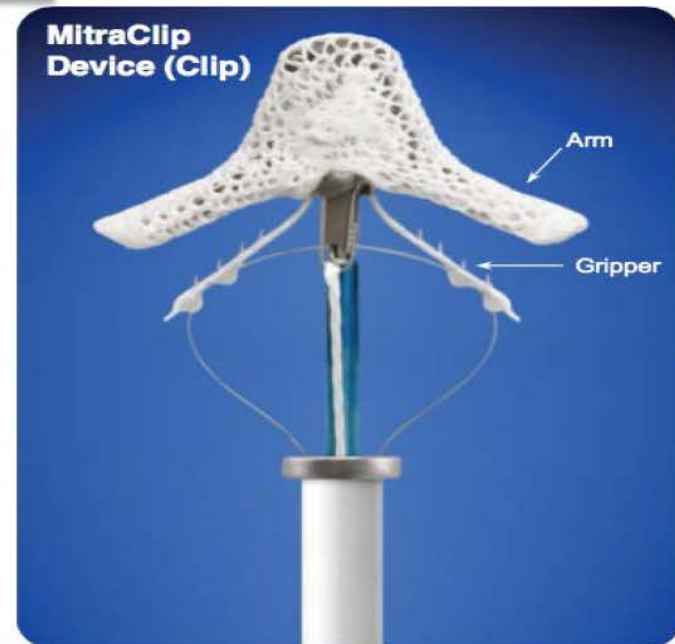
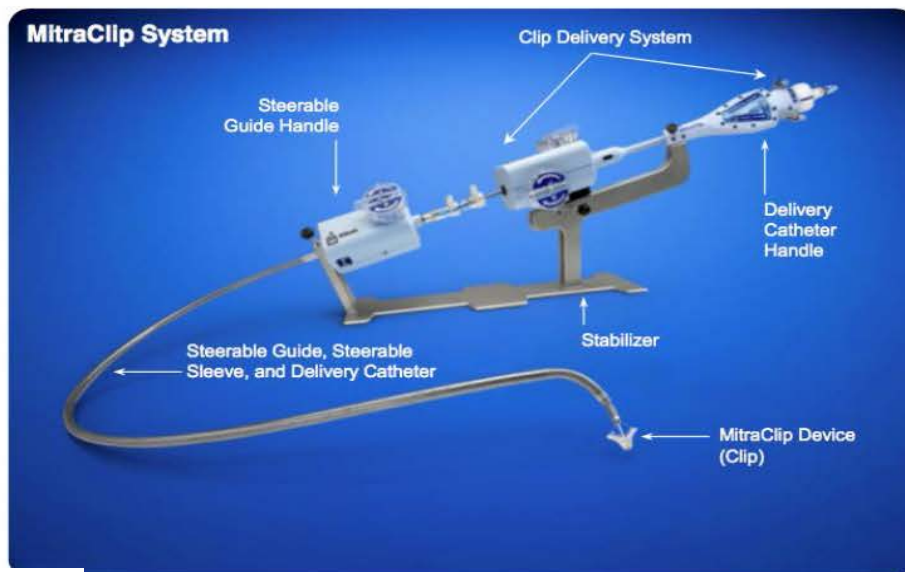
Mitraclip:

What do you know about long term results ?



**Claudio Moretti, MD, PhD
Division of Cardiology
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University of Turin**





Goar FG, et al. Endovascular edge-to-edge mitral valve repair: short-term results in a porcine model
Circulation 2003;108: 1990–3.

- **Coaptation of Leaflets**

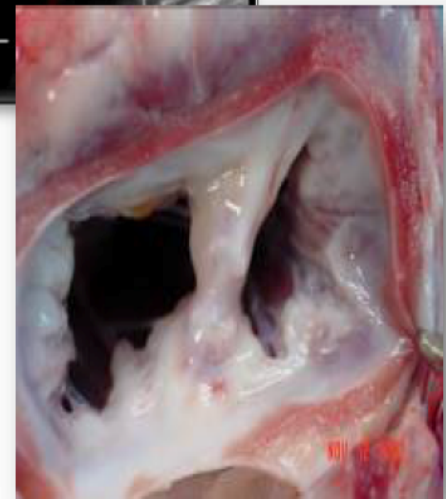
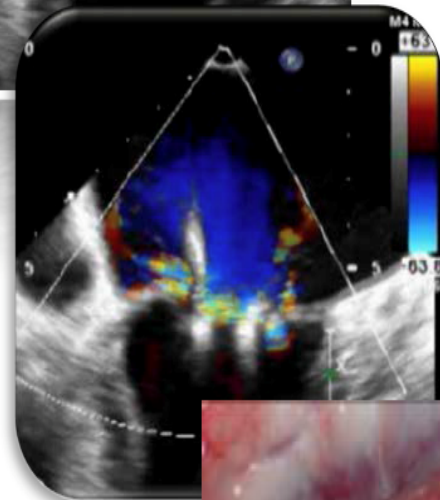
- Reduces MR

- **Creates tissue bridge**

- Limits dilatation of annulus
- Septal-lateral (A-P) dimension
- Supports durability of repair

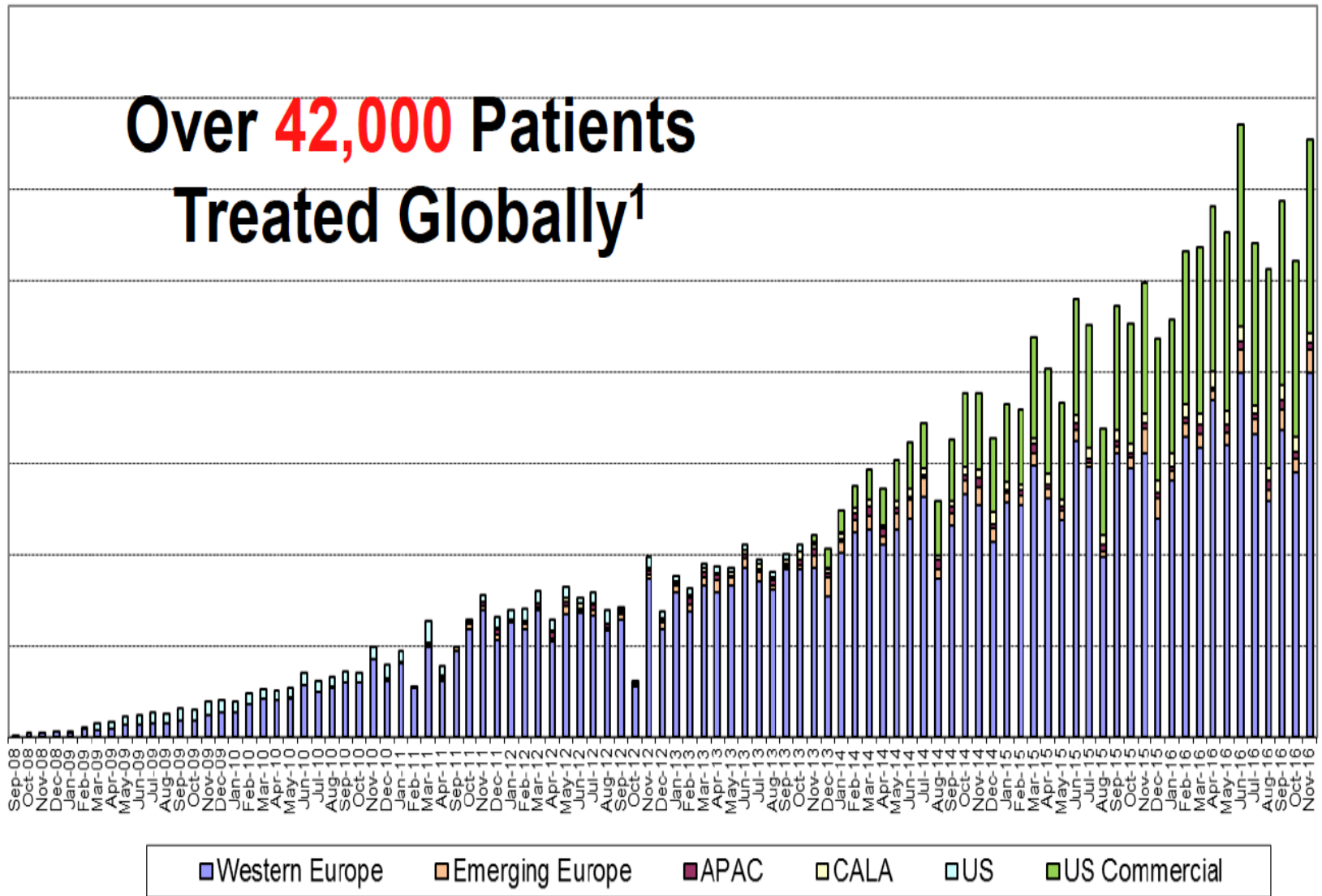
- **Restrains LV wall**

- Limits LV dilatation

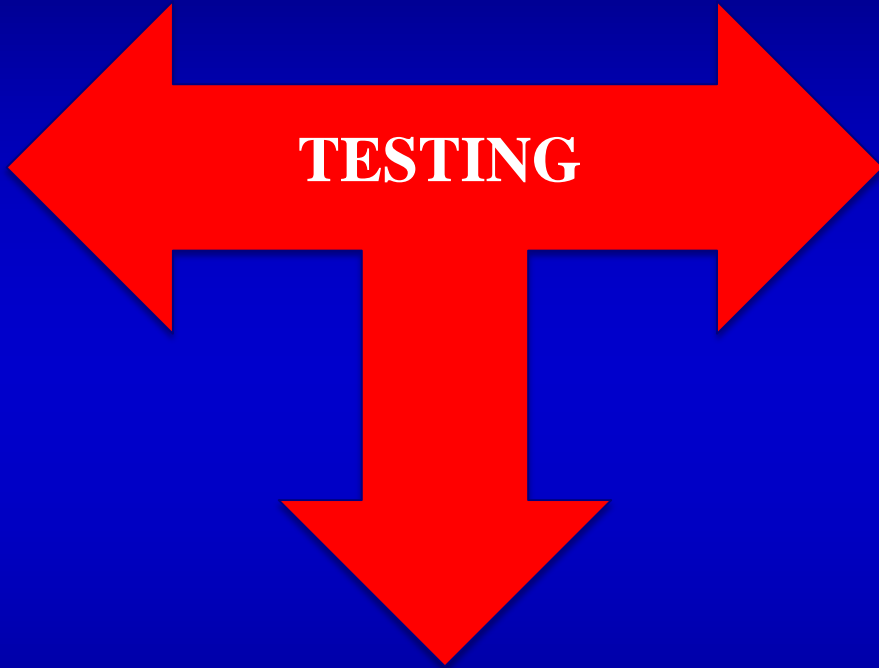


Over 42,000 Patients Treated Globally¹

Implantation Procedures



1. Includes clinical and commercial procedures as of 30/11/2016. Source: Data on file at Abbott Vascular



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812

APRIL 14, 2011

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Percutaneous Repair or Surgery for Mitral Regurgitation

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BACKGROUND

Mitral-valve repair can be accomplished with an investigational procedure that involves the percutaneous implantation of a clip that grasps and approximates the edges of the mitral leaflets at the origin of the regurgitant jet.

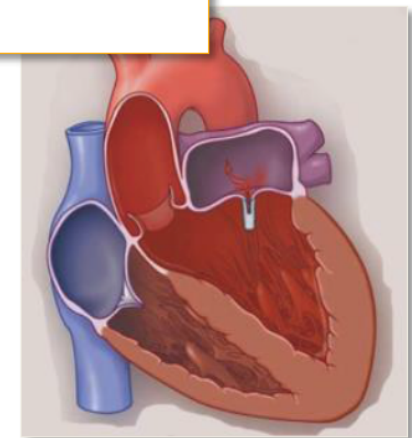
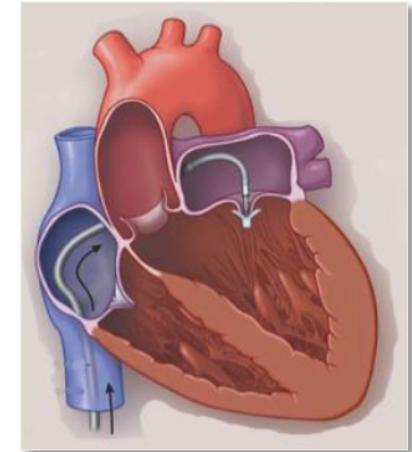
CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

...percutaneous repair group and 75% in the surgery group ($P=0.007$). The respective rates of the components of the primary end point were as follows: death, 6% in each group; surgery for mitral-valve dysfunction, 20% versus 2%; and grade 3+ or 4+ mitral regurgitation, 21% versus 20%. Major adverse events occurred in 15% of patients in the percutaneous-repair group and 48% of patients in the surgery group at 30 days ($P<0.001$). At 12 months, both groups had improved left ventricular size, New York Heart Association functional class, and quality-of-life measures, as compared with baseline.

CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes. (Funded by Abbott Vascular; EVEREST II ClinicalTrials.gov number, NCT00209274.)



New Engl J Med 364:1395-1406, 2011

Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation



5-Year Results of EVEREST II

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Paul A. Grayburn, MD,||| Michael J. Mack, MD,¶¶ D. Scott Lim, MD,## Gorav Ailawadi, MD,***
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Andrew Wang, MD,||| Donald D. Glower, MD,¶¶¶ Laura Mauri, MD,§§§§ for the EVEREST II Investigators

Treatment of MR with MitraClip® showed superior safety compared with surgery, but **less effective reduction in MR at 1 year**

OBJECTIVES: To evaluate the final 5-year clinical outcomes and durability of percutaneous MV repair with the MitraClip® device compared with conventional MV surgery

METHODS: Patients with grade 3 or 4 MR were randomly assigned to MitraClip® or conventional MV surgery in a 2:1 ratio (178:80). Patients prospectively consented to 5 years of follow-up

Feldman T, et al. Randomized comparison of percutaneous repair and surgery for mitral regurgitation: 5-year results of EVEREST II. J Am Coll Cardiol. 2015;66:2844–54.

TABLE 1 Baseline Characteristics: All-Treated Cohort

	Percutaneous Repair	Surgery
Age, yrs	67.0 ± 12.7 (178)	64.7 ± 12.6 (80)
Female	36.5 (65/178)	33.8 (27/80)
LVEF, %	59.9 ± 10.1 (176)	61.3 ± 10.7 (80)
NYHA functional class		
I	9.6 (17/178)	17.5 (14/80)
II	40.4 (72/178)	32.5 (26/80)
III	43.8 (78/178)	45.0 (36/80)
IV	6.2 (11/178)	5.0 (4/80)
MR etiology		
Functional	27.0 (48/178)	22.5 (18/80)
Degenerative	73.0 (130/178)	77.5 (62/80)
Degenerative with anterior/bileaflet flail/prolapse	32.6 (58/178)	27.5 (22/80)
Degenerative with posterior flail/prolapse	37.6 (67/178)	47.5 (38/80)
Degenerative with neither flail nor prolapse	2.8 (5/178)	2.5 (2/80)

Feldman T, et al. Randomized comparison of percutaneous repair and surgery for mitral regurgitation: 5-year results of EVEREST II. J Am Coll Cardiol. 2015;66:2844–54.

All-Treated Cohort: Efficacy Endpoint and Components at 5 years

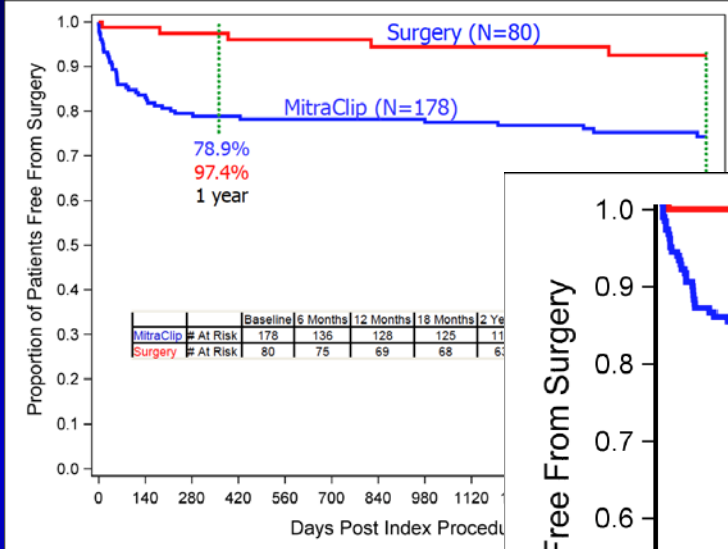
	5 Years			5 Years if Event-Free at 1 Year		
	Percutaneous Repair (n = 154)	Surgery (n = 56)	p Value	Percutaneous Repair (n = 87)	Surgery (n = 48)	p Value
Freedom from death, MV surgery, or reoperation, and 3+ or 4+ MR	44.2 (68)	64.3 (36)	0.01	69.0 (60)	75.0 (36)	0.55
Death	20.8 (32)	26.8 (15)	0.36	16.1 (14)	16.7 (8)	>0.99
MV surgery or reoperation	27.9 (43)	8.9 (5)	0.003	5.7 (5)	6.3 (3)	>0.99
3+ or 4+ MR	12.3 (19)	1.8 (1)	0.02	11.5 (10)	2.1 (1)	0.10

Values are % (n). *Includes patients that completed the 5-year visit and had MR grade available or died or had MV surgery before withdrawal from the study.

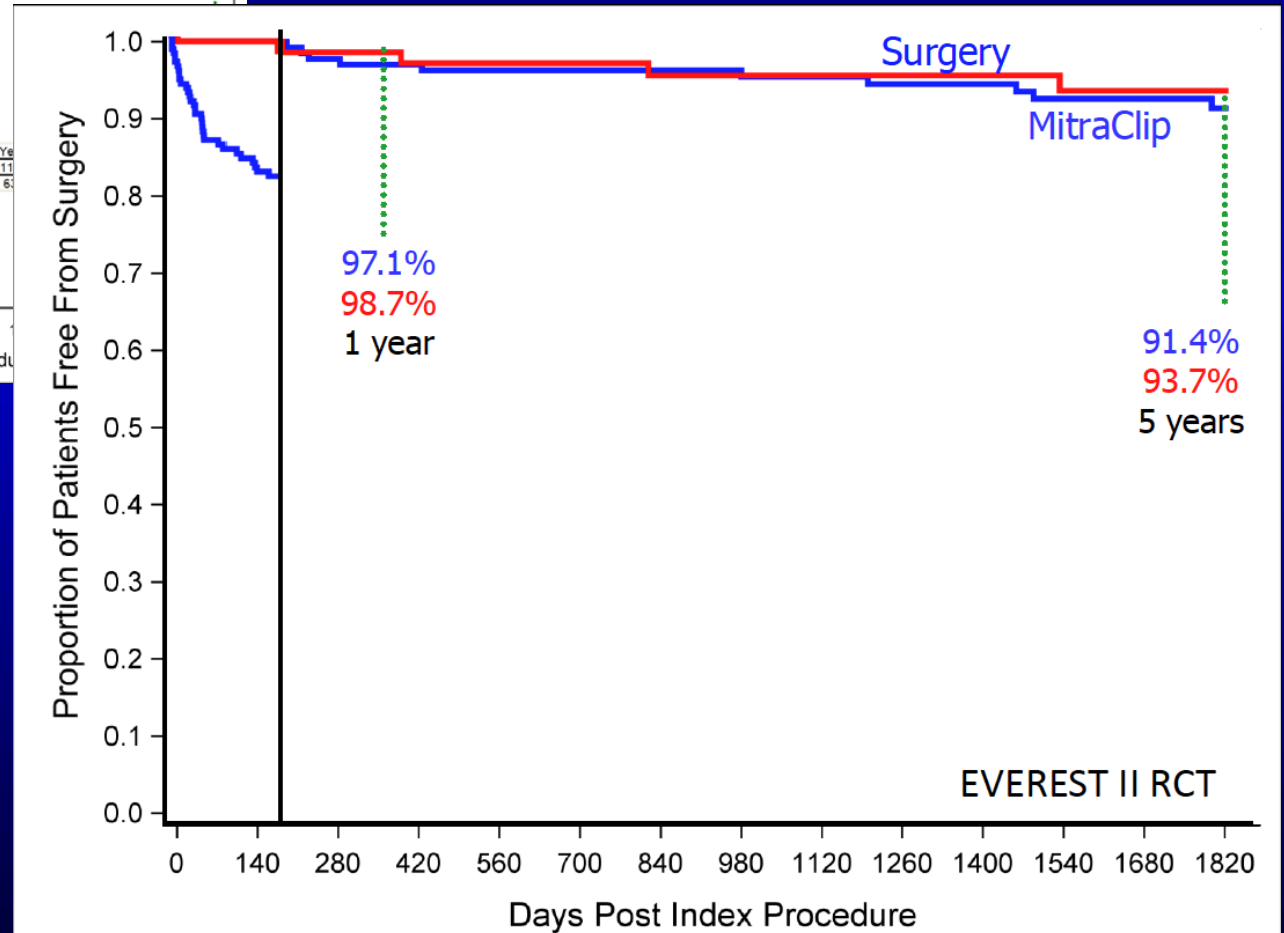
MR = mitral regurgitation; MV = mitral valve.

Feldman T, et al. Randomized comparison of percutaneous repair and surgery for mitral regurgitation: 5-year results of EVEREST II. J Am Coll Cardiol. 2015;66:2844–54.

K-M Freedom from surgery



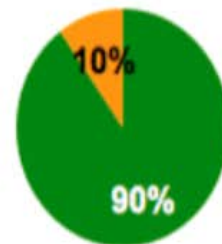
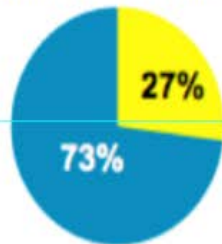
K-M Freedom from surgery 6-Month Landmark Analysis



UTILIZATION of MITRACLIP

EVEREST II

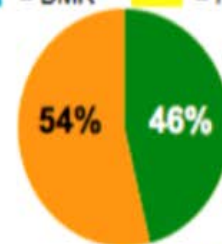
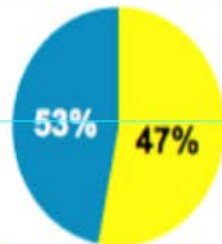
(Randomized Controlled Trial)



- 178 patients
- Implant rate – 89%

REALISM

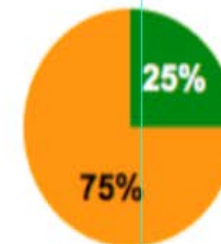
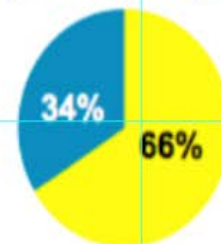
(Continued Access Registry)



- 571 patients
- Implant rate – 94%

Commercial

(Europe, Canada, Asia, Australia)



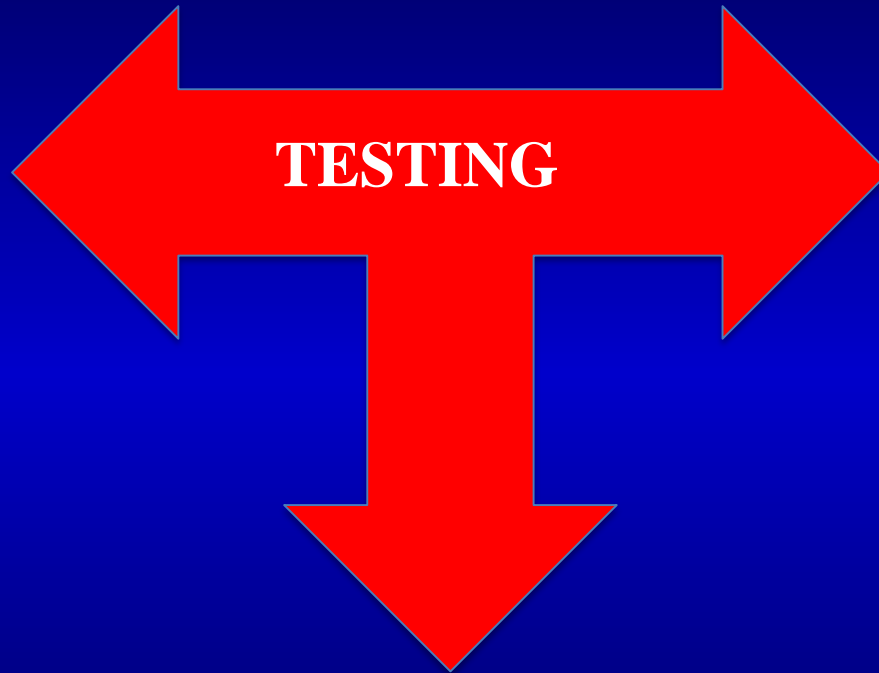
- 2,472 patients
- Implant rate – 95%

■ = DMR¹ ■ = FMR¹

■ = Standard Risk² ■ = High Risk²



DEVICE



TESTING



**HIGH
RISK**

Table 1 Baseline characteristics of patients undergoing MitraClip implantation in different registries and trials

	EVEREST II (n = 184)	ACCESS-EU (n = 567)	Transcatheter Valve Treatment Sentinel Pilot Registry (n = 628)	TRAMI (prospective cohort) (n = 749)
Age (years)	67.3 ± 12.8 ^a	73.7 ± 9.6	74.2 ± 9.7	76.0 [71.0–81.0] ^b
Female gender, n (%)	69/184 (37.5%)	205/567 (36.2%)	232/628 (36.9%)	289/749 (38.6%)
NYHA functional class III/IV, n (%)	94/184 (51.1%)	466/549 (84.9%)	537/628 (85.5%)	646/726 (89.0%)
Left ventricular ejection fraction				
LVEF (%)	60.0 ± 10.1 ^a	NA	42.6 ± 15.9	NA
LVEF, <30%, n (%)	NA	193/562 (34.3%)	206/628 (32.8%)	236/700 (33.7%)
LVEF, 30–50%, n (%)	NA	NA	NA	247/700 (35.3%)
LVEF >50%, n (%)	NA	NA	NA	217/700 (31.0%)
Aetiology of MR, n (%)				
Secondary	49/184 (26.6%)	393/510 (77.1%)	452/628 (72.0%)	478/670 (71.3%) ^c
Primary	135/184 (73.4%)	117/510 (22.9%)	176/628 (28.0%)	172/618 (27.8%) ^c
Severity of MR, n (%)				
3+/4+ (1+, 2+, 3+, 4+)	176/184 (95.7%)	554/567 (97.7%)	NA	NA
Severe (mild, moderate, severe)	NA	NA	541/368 (86.1%)	660/704 (93.8%)
Comorbidities, n (%)				
Coronary artery disease	86/183 (47.0%)	354/565 (62.7%)	194/628 (30.9%)	424/543 (78.1%)
Previous myocardial infarction	40/183 (21.9%)	175/547 (32.0%)	196/628 (31.2%)	201/721 (27.9%)
Previous stroke	NA	73/566 (12.9%)	90/628 (14.4%)	76/718 (10.6%)
Atrial fibrillation	59/175 (33.7%)	356/526 (67.7%)	199/628 (31.7%)	319/724 (44.1%)
Diabetes mellitus	14/184 (7.6%)	168/567 (29.6%)	175/628 (27.9%)	226/719 (31.4%)
COPD	27/183 (14.8%)	107/562 (19.0%)	121/628 (19.3%)	160/718 (22.3%)
Renal failure	6/184 (3.3%)	236/567 (41.6%)	192/628 (30.5%)	468/714 (65.5%)
Previous CABG	38/184 (20.7%)	164/567 (28.9%)	203/628 (32.3%)	186/724 (25.7%)
Previous AVR or TAVR	NA	NA	NA	66/724 (9.1%)
Previous MV surgery or intervention	0	NA	NA	14/726 (1.9%)
Previous valve surgery	NA	NA	65/628 (10.4%)	NA
Estimated surgical risk				
Log. EuroSCORE (%)	NA	23.0 ± 18.3	20.4 ± 16.7	20.0 [12.0–31.0]
STS score (%)	5.0 ± 4.0	NA	NA	6.0 [4.0–11.0]

Table 2 In-hospital/30 days outcomes after MitraClip implantation in different registries and trials

	EVEREST II (n = 184)	ACCESS-EU (n = 567)	Transcatheter Valve Treatment Sentinel Pilot Registry (n = 628)	TRAMI (prospective cohort) (n = 749)
Hospital stay (days)	NA	7.7 ± 8.2 (median: 6.0)	5.0 [3.0–7.0]	9.0 [6.0–15.0]
Procedural success (Clip implanted + MR ≤2+/not severe)	137/178 (77.0%)	516/567 (91.0%)	599/628 (95.4%)	719/741 (97.0%)
Mitral regurgitation at discharge, n (%)				
None/mild	NA	NA	268/368 (72.8%)	631/741 (85.2%)
Moderate	NA	NA	93/368 (25.3%)	93/741 (12.6%)
Severe	NA	NA	7/368 (1.9%)	17/741 (2.3%)
0–1+	NA	50.9%	NA	NA
2+	NA	40.3%	NA	NA
3+/4+	41/178 (23%)	8.8%	NA	NA
Adverse events	All events until day 30	All events until day 30	In-hospital events	In-hospital events
MACCE (death, MI, and stroke)	NA	NA	NA	22/712 (3.1%)
In-hospital mortality	NA	11/563 (2.0%)	18/628 (2.9%)	18/749 (2.4%)
30-day mortality	2/184 (1%)	19/567 (3.4%)	NA	34/749 (4.5%)
Myocardial infarction	0/184 (0%)	4/567 (0.7%)	0/628 (0%)	0/711 (0.0%)
Stroke	2/184 (1%)	4/567 (0.7%)	1/628 (0.2%)	6/712 (0.8%)
Non-MACCE				
TIA	NA	NA	NA	6/712 (0.8%)
Respirat. failure (re-intubation)	NA	4/567 (0.7%)	NA	16/711 (2.3%)
Severe bleeding, transfusion	24/184 (13%)	22/567 (3.9%)	70/628 (11.2%)	50/711 (7.0%)
Low cardiac output	NA	NA	NA	9/710 (1.3%)
Pericardial tamponade	3/184 (1.6%)	6/567 (1.1%)	7/628 (1.1%)	12/710 (1.7%)
Clip embolization	0/184 (0%)	0/567 (0%)	4/628 (0.7%)	0/710 (0.0%)
Partial clip detachment	9/184 (4.9%)	27/567 (4.8%)	NA	5/749 (0.7%)
Additional MV procedure, n (%)	28/184 (15.2%)	16/567 (2.8%)	NA	11/710 (1.5%)
Surgical	28/184 (15.2%)	6/567 (1.1%)	NA	6/710 (0.8%)
Percutaneous	0	10/567 (1.7%)	NA	5/710 (0.7%)



Table 3 One-year outcomes after MitraClip implantation in different registries and trials

	EVEREST II (<i>n</i> = 184)	ACCESS-EU (<i>n</i> = 567)	Transcatheter Valve Treatment Sentinel Pilot Registry European Sentinel Pilot Registry (<i>n</i> = 552/628)	TRAMI (prospective cohort) (<i>n</i> = 749)
Mitral regurgitation at 1 year, <i>n</i> (%)				
None/mild	NA	NA	216/368 (58.6%)	NA
Moderate	NA	NA	130/368 (35.4%)	NA
Severe	NA	NA	22/368 (6.0%)	NA
0+/1+	84/153 (54.9%)	100/327 (30.6%)	NA	NA
2+	41/153 (26.8%)	158/327 (48.3%)	NA	NA
3+/4+	28/153 (18.3%)	69/327 (21.1%)	NA	NA
NYHA class at 1 year, <i>n</i> (%)				
I–II	180/184 (97.8%)	245/343 (71.4%)	265/357 (74.2%)	305/482 (63.3%)
III–IV	4/184 (2.2%)	98/343 (28.6%)	92/357 (25.8%)	177/482 (36.7%)
Quality of life				
EQ-5D-3L (compared with baseline)	NA	NA	NA	
Mobility	NA	NA	NA	0.58
Self-care	NA	NA	NA	<0.001
Usual activities	NA	NA	NA	0.89
Pain/discomfort	NA	NA	NA	0.21
Anxiety/depression	NA	NA	NA	<0.0001

Table 3 One-year outcomes after MitraClip implantation in different registries and trials







	EVEREST II (n = 184)	ACCESS-EU (n = 567)	Transcatheter Valve Treatment Sentinel Pilot Registry European Sentinel Pilot Registry (n = 552/628)	TRAMI (prospective cohort) (n = 749)
Adverse events				
MACCE (death, MI, and stroke)				
Death	11/181 (6.1%)	98/567 (17.3%)	15.3% (Kaplan–Meier curve)	152/749 (20.3%)
Myocardial infarction	1/184 (0.5%)	8/567 (1.4%)	NA	4/425 (0.9%)
Stroke	2/184 (1.1%)	6/567 (1.1%)	NA	9/423 (2.1%)
Non-MACCE				
TIA	1/184 (0.5%)	NA	NA	16/426 (3.8%)
Bleeding complications	5/184 (2.7%)	27/567 (4.8%)	NA	56/443 (12.6%)
Need for resuscitation	2/184 (1.1%)	12/567 (2.1%)	NA	9/426 (2.1%)
Rehospitalizations, n (%)				
Cardiac decompensation	NA	NA	NA	364/566 (64.3%)
Other cardiac reason	NA	NA	22.8% (Kaplan–Meier curve)	80/566 (14.1%)
Non-cardiac reason	NA	NA	NA	101/566 (17.8%)
Additional MV procedure, n (%)				
Surgical	37/181 (21%)	55/567 (9.7%)	17/444 (3.8%)	37/436 (8.5%)
Percutaneous	37/181 (21%)	36/567 (6.3%)	4/444 (0.9%)	10/436 (2.3%)
	0/181 (0%)	19/567 (3.4%)	13/444 (2.9%)	23/436 (5.2%)

Predictors for long-term survival after transcatheter edge-to-edge mitral valve repair

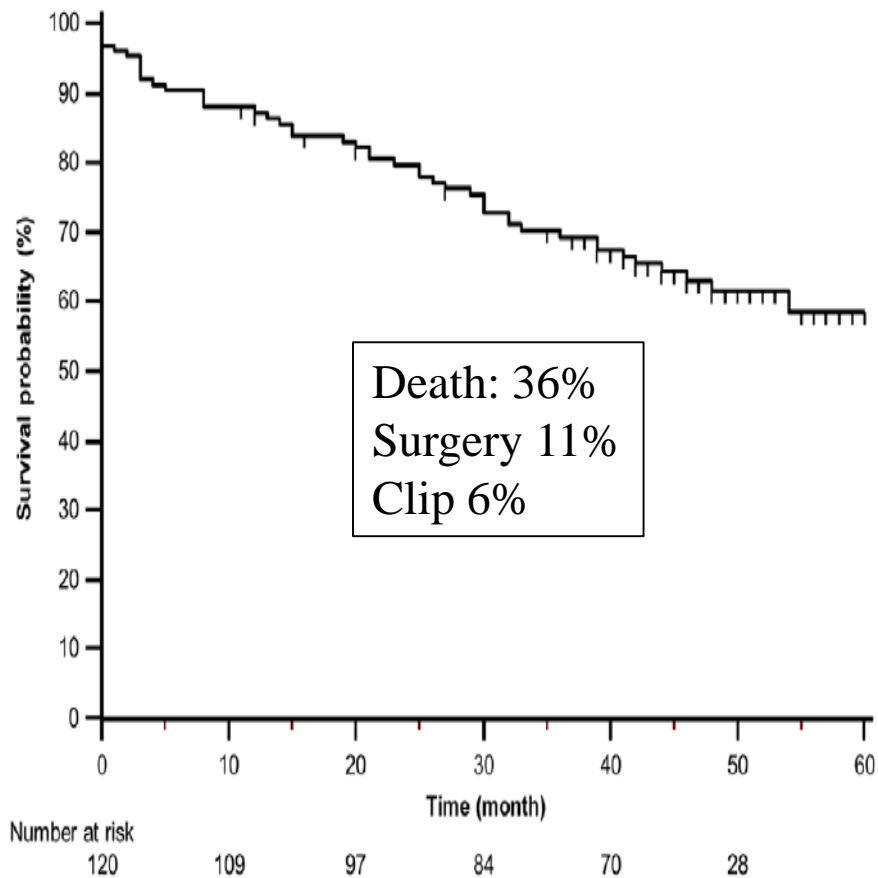
Mathias Orban^{1,2}  | Martin Orban^{1,2}  | Hasema Lesevic² | Daniel Braun^{1,2} |
Simon Deseive^{1,2} | Carolin Sonne² | Lisa Hutterer¹ | Christian Grebmer² |
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- ❑ Dual-center observational analysis / Munich
- ❑ 126 consecutive inoperable pts with degenerative/functional MR
- ❑ Failure to put at least 1 clip: exclusion criteria

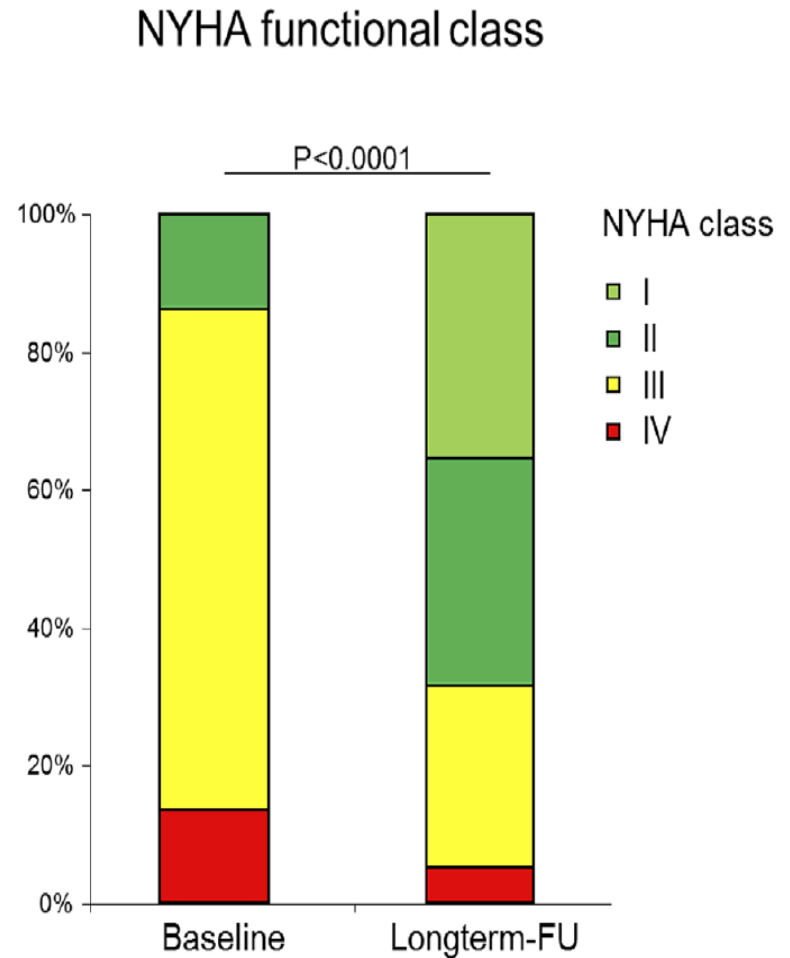
TABLE 1 Baseline characteristics

Parameter	All n = 126	Primary MR n = 75	Secondary MR n = 51	P-value*
Age, year \pm SD	 72.6 \pm 10.6	73.0 \pm 11.6	71.9 \pm 9.1	0.557
Male gender, n (%)	79 (62.7)	40 (53.3)	39 (76.5)	0.27
Body mass index, mean \pm SD	25.2 \pm 3.9	25.2 \pm 3.8	25.2 \pm 4.0	0.912
Logistic EuroSCORE, mean \pm SD	 19.1 \pm 20.0	13.9 \pm 17.5	26.6 \pm 21.0	<0.001
STS-score, mean \pm SD	14.0 \pm 15.5	11.1 \pm 14.1	18.2 \pm 16.5	0.01
Mitral regurgitation, aetiology, n (%) secondary	51 (40.5)	n. a.	n. a.	
MR, severity, n (%)				0.138
2+	2 (1.6)	0 (0)	2 (3.9)	
3+	59 (46.8)	33 (44)	26 (51)	
4+	65 (51.6)	42 (56)	23 (45.1)	
NYHA functional class, n (%)				0.366
II	13 (10.3)	10 (13.3)	3 (5.9)	
III	 87 (69.0)	51 (68)	36 (70.6)	
IV	26 (20.6)	14 (18.7)	12 (23.5)	
MR, post-procedural severity, n (%)				0.247
1+	70 (55.6)	45 (60.0)	25 (49.0)	
2+	 46 (36.5)	25 (33.3)	21 (41.2)	
3+	8 (6.3)	3 (4)	5 (9.8)	
4+	2 (1.6)	2 (2.7)	0 (0)	
LV-EF, mean % \pm SD	 48.4 \pm 15.6	57.2 \pm 9.9	35.4 \pm 13.3	<0.001
RVTG, mean mmHg \pm SD	40.1 \pm 12.9	39.0 \pm 12.8	41.4 \pm 13.0	0.352
Right ventricular function, n (%)				<0.001
normal	88 (69.8)	64 (85.3)	24 (47.1)	
depressed	 38 (30.2)	11 (14.7)	27 (52.9)	

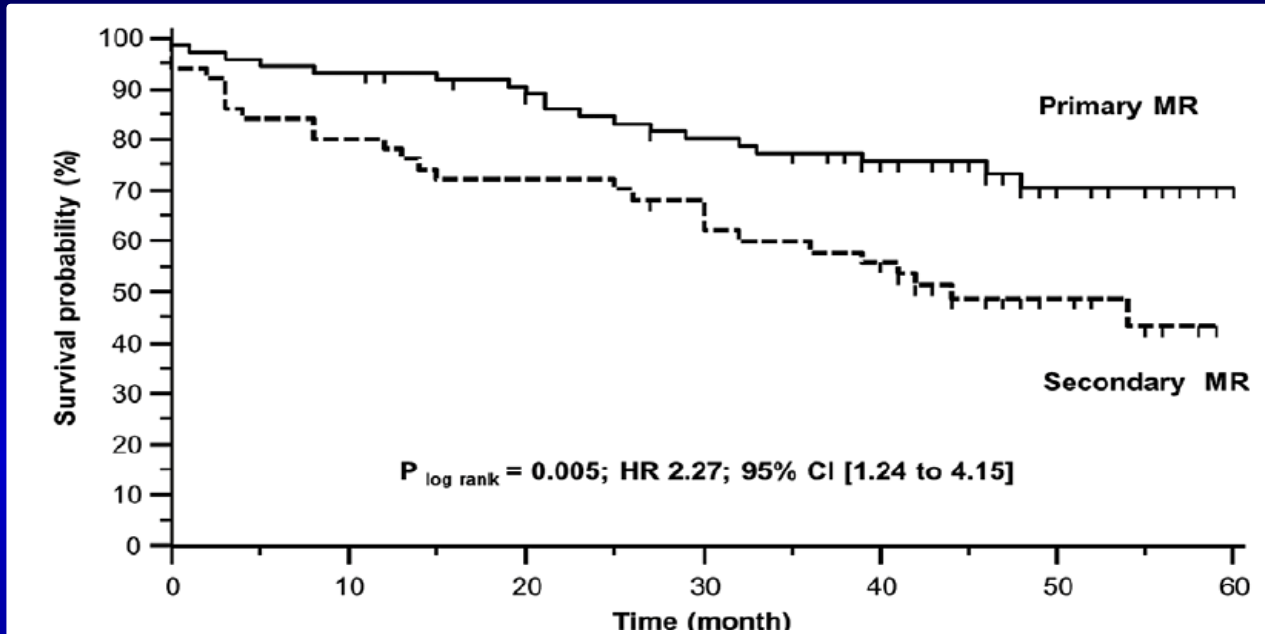
K-M long term survival



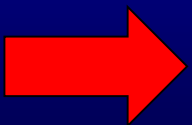
Clinical follow up > 3 yrs



K-M LONG TERM SURVIVAL

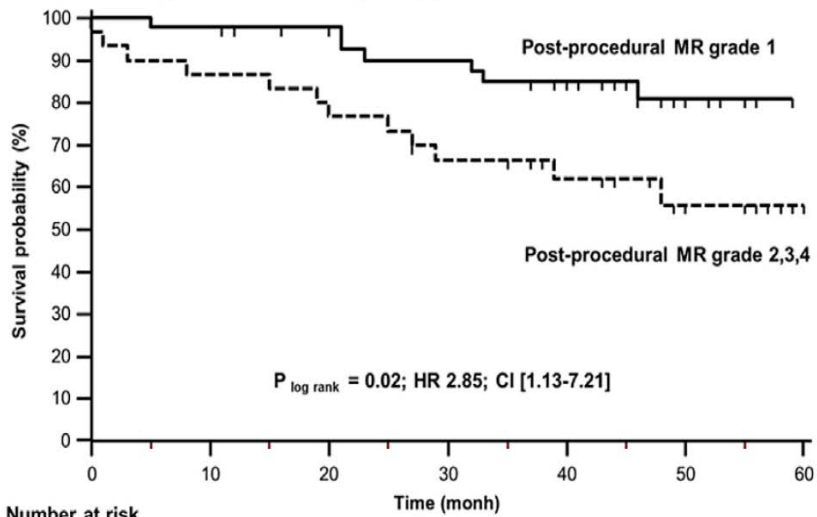


Variable	Hazard ratio (95%CI)	P-value
Left-ventricular ejection fraction ^a	0.58 (0.35-0.95)	0.031
Tricuspid regurgitation, severity ^b	1.26 (0.91-1.76)	0.167
Glomerular filtration rate ^a	0.33 (0.18-0.61)	0.0004
Mitral regurgitation, post-procedural severity ^b	1.55 (1.03-2.32)	0.035



K-M LONG TERM SURVIVAL – post proc MR

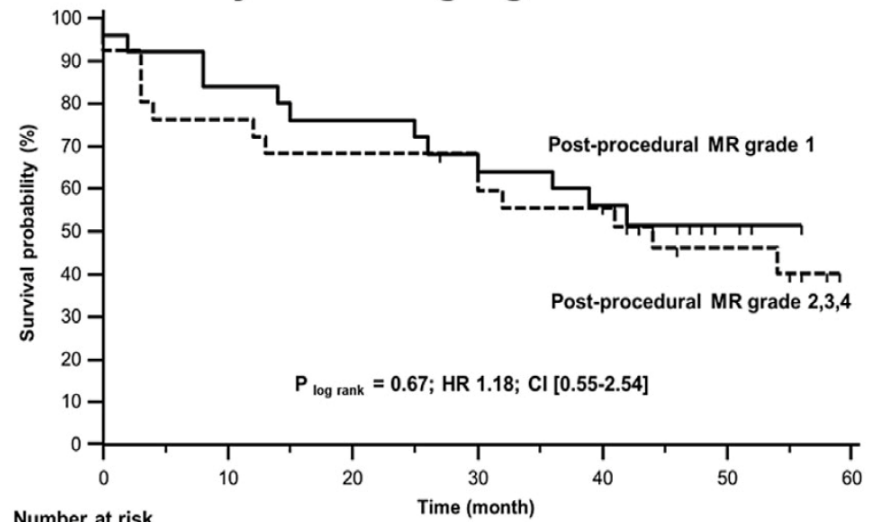
A Primary mitral regurgitation



Number at risk

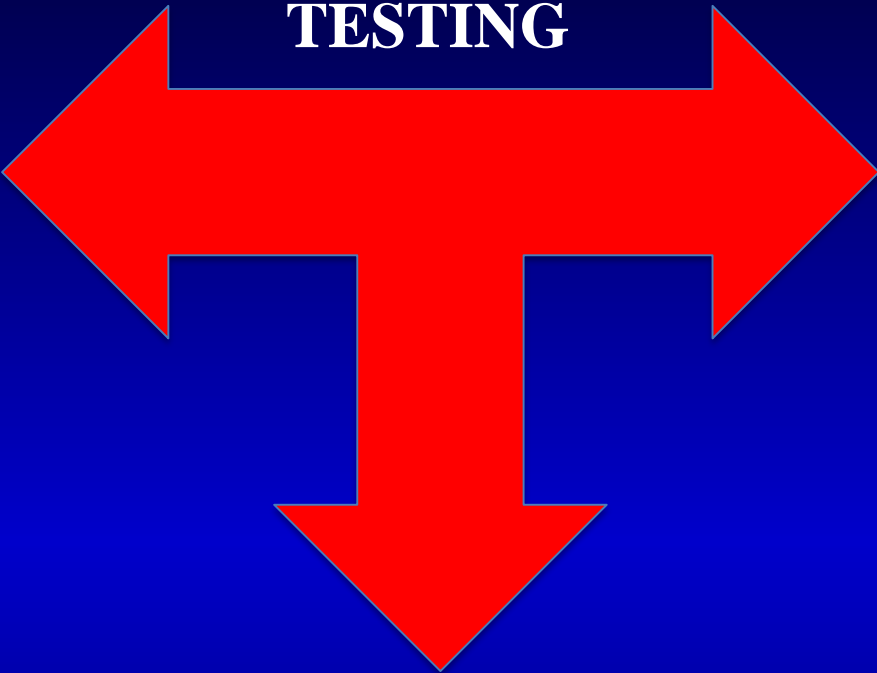
MR grade 1	44	43	38	35	30	9
MR grade ≥ 2	29	26	23	19	14	7

B Secondary mitral regurgitation



Number at risk

MR grade 1	24	21	19	16	13	4
MR grade ≥ 2	23	19	17	14	13	8



Selezione dei pazienti: quali criteri?

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

In patients with HF with moderate-severe, secondary mitral regurgitation who are judged inoperable or at high surgical risk, percutaneous mitral valve intervention (percutaneous edge-to-edge repair) may be considered in order to improve symptoms and quality of life, although no RCT evidence of improvement has been published, only registry studies.^{504–506}

- IM moderato - severa
- Pazienti sintomatici
- Alto rischio chirurgico

Classe IIb

Quello che le linee guida NON riportano...

Criteria ASPECIFICI, di scarso aiuto nella pratica clinica

Nei pazienti con Scompenso Cardiaco avanzato (principali candidati alla MitraClip) la risposta clinica è altamente variabile

Selezione dei pazienti

... la realtà clinica

N.A., 74 anni

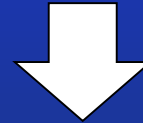
- CMP ipocinetico-dilatativa ad eziologia ischemica nota dal 2003
- FE 25%
- NYHA III
- IM severa 4+
- 2015: plurimi ricoveri per SC
- 01/2016: **MitraClip**



Oggi NYHA II, non più ricoveri per recidive di SC

P.G., 68 anni

- CMP ipocinetico-dilatativa idiopatica nota dal 1994
- FE 20%
- NYHA III
- IM severa 4+
- 2014: plurimi ricoveri per SC
- 06/2014: **MitraClip**

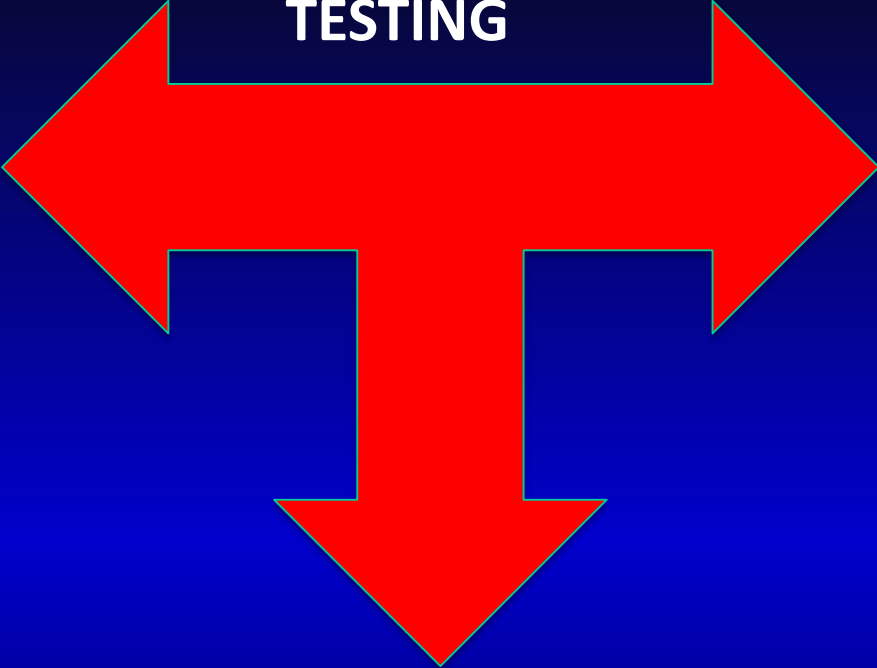


7 ricoveri per SC nei 18 mesi successivi. Decesso 02/2016.



DEVICE

TESTING



HIGH RISK



SCOMPENSO C.
AVANZATO



TURIN'S
STRATEGY

Obiettivi ed Endpoint dello studio

Nei pazienti con scompenso cardiaco avanzato e IM funzionale:

- ✓ Individuare i predittori di *buona risposta clinica*
- ✓ Individuare i predittori di *eventi cardiaci avversi*

Endpoint

- I. Remissione dal grado avanzato di scompenso cardiaco
 - NYHA ≤ 2
 - Non più ospedalizzazioni per SC nel follow-up
- II. Morte cardiaca o recidive di scompenso cardiaco (futilità)

Follow-up 12 mesi



DISEGNO DELLO STUDIO

Studio clinico *prospettico* e *multicentrico*:

- Cardiologia U della Città della Salute e della Scienza di **Torino**
- University Heart Centre di **Zurigo**
- Cardiologia del Policlinico San Matteo di **Pavia**

Criteri di inclusione

Pre-impianto

- ✓ FE \leq 35%
- ✓ NYHA 3-4 in OMT
- ✓ Ospedalizzazione per SC nei 12 mesi precedenti
- ✓ IM funzionale severa
- ✓ Elevato rischio chirurgico
- ✓ Eleggibilità anatomica alla procedura

Post-impianto

- ✓ IM residua lieve 1-2 +

192 pazienti MitraClip valutati



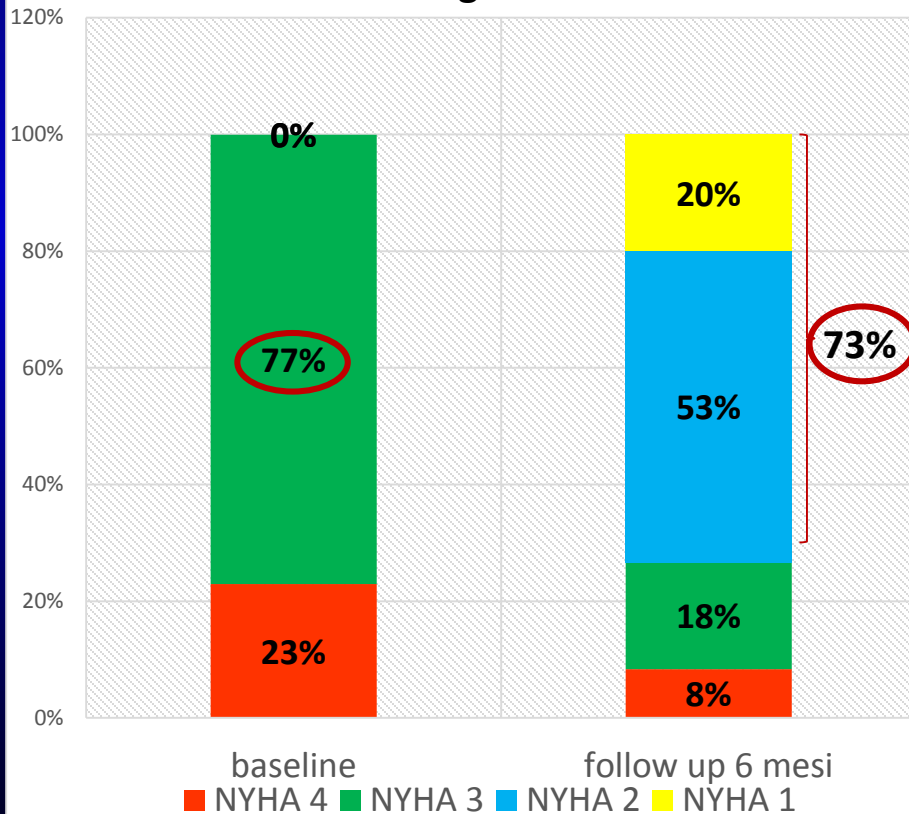
60 pazienti avanzati
selezionati per lo studio

RISULTATI

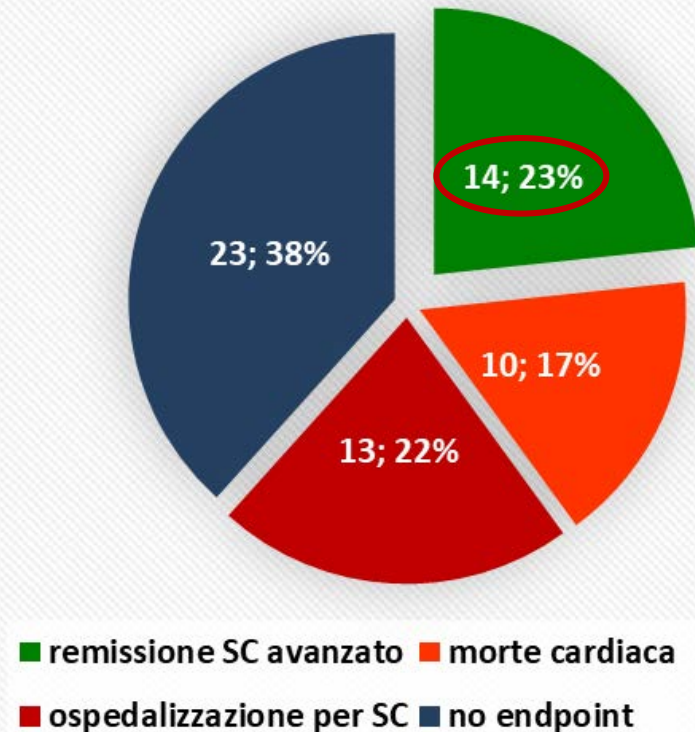
Significativo miglioramento della classe NYHA

RISULTATI a 12 mesi di follow up
(1 decesso peri-procedurale)

Classe NYHA in seguito a MITRACLIP



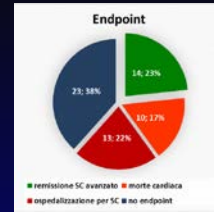
Endpoint



Totale = 60 pazienti

RISULTATI

Remissione da scompenso cardiaco avanzato

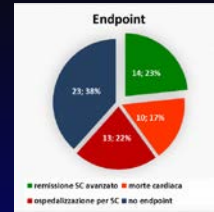


Caratteristica	Totale (n=60)	Non Remissione (n=46)	Remissione (n=14)	p-value
ACE/ARB	44 (73%)	37 (80%)	8 (57%)	0.10
Wedge Pressure	23.4 ± 1.9	23.0 ± 8.4	22.8 ± 8.3	0.94
mRAP >10 mmHg	11 (18%)	11 (24%)	0 (0%)	0.001
mPAP (mmHg)	33.9 ± 11.6	31.9 ± 10.6	33.5 ± 12.5	0.64
Indice Cardiaco	1.92 ± 0.58	1.92 ± 0.56	2.23 ± 0.80	0.18
PAPi	4.08 ± 2.02	4.10 ± 2.07	4.14 ± 1.58	0.95
RVSWI ≤0,4	6 (10%)	6 (13%)	0 (0%)	0.01
Frazione d'eiezione (%)	25.43 ± 5.07	24 ± 5	26 ± 5	0.14
TAPSE (mm)	16.3 ± 3.39	16 ± 4	16 ± 3	0.98

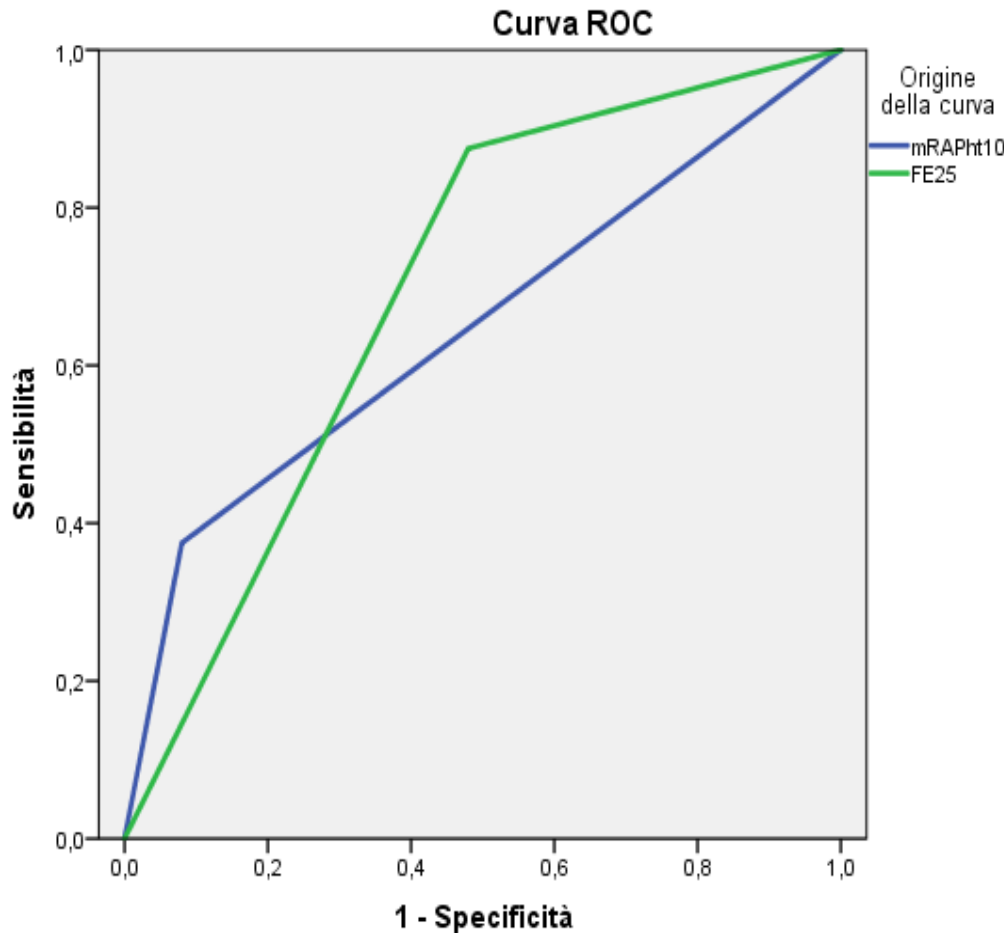
Nessun paziente andato incontro a remissione presentava una disfunzione **severa** del **ventricolo destro** valutata al cateterismo cardiaco

RISULTATI

Riospedalizzazione per SC o morte cardiaca



Riospedalizzati o morti (n=23)	p-value
23	0,97



Elevata specificità di mRAP (>90%)

↓

Utilità nell'esclusione dei pazienti con più probabilità di eventi avversi

	p-value
1	0,040
3	0,088

RISULTATI

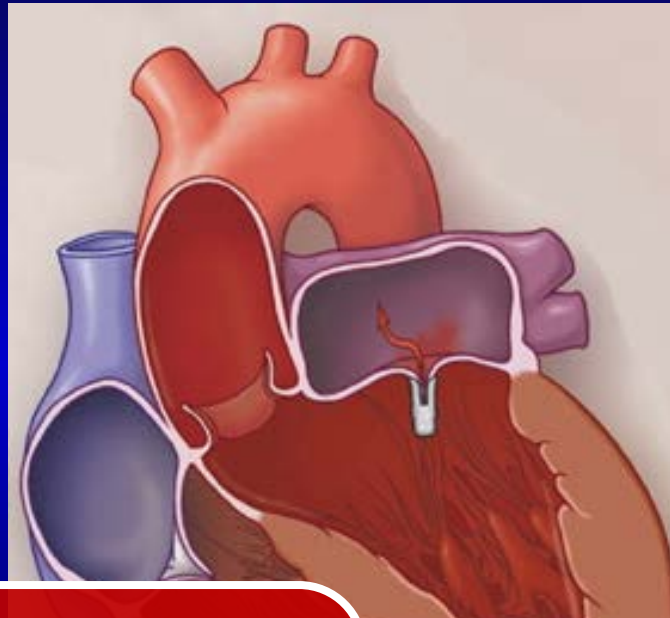
Analisi dei potenziali predittori di outcome clinico

Ventricolo DESTRO

NESSUN responder presentava disfunzione ventricolare destra alla valutazione emodinamica

La **mRAP elevata** si associa ad un rischio **5** volte maggiore di evento cardiaco avverso

La **valutazione emodinamica** ma non ecocardiografica della funzione ventricolare destra è il **cardine** sia per individuare i pazienti responder sia per predire gli eventi avversi



Ventricolo SINISTRO

FE \leq 25% determina un rischio **6** volte maggiore di ospedalizzazione o morte per Scopenso Cardiaco

Il peso prognostico della miopatia **supera** il beneficio derivante dalla correzione dell'insufficienza mitralica

CONCLUSIONI

La MitraClip ha un ruolo nella terapia dello SC avanzato:

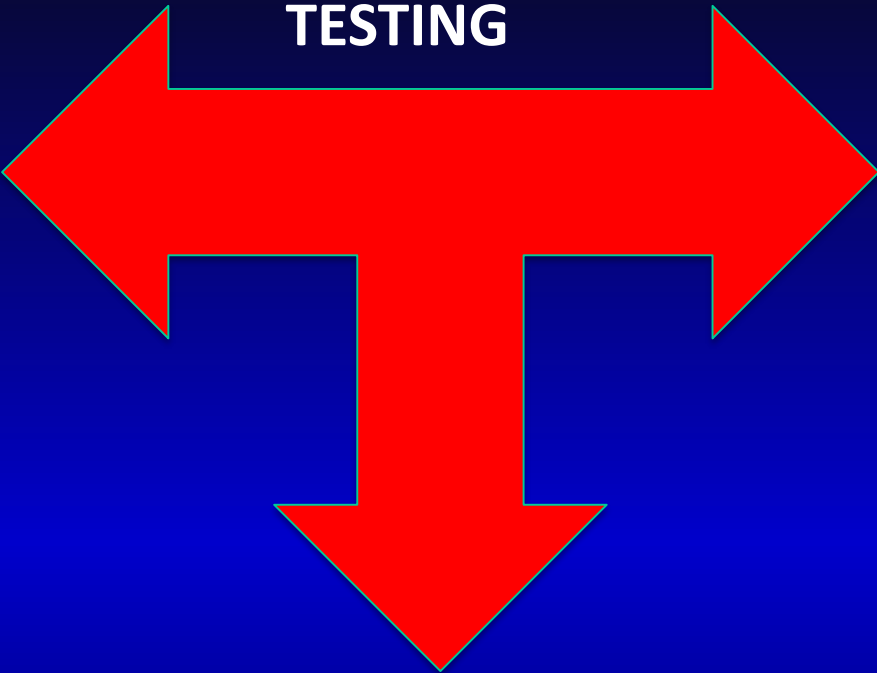
procedura a **basso rischio**, con **beneficio** in termini di miglioramento della classe funzionale e riduzione delle ospedalizzazioni nella maggior parte dei pazienti

Una **remissione dal grado avanzato** di scompenso cardiaco è possibile, ma solo nei pazienti **senza disfunzione del ventricolo destro e senza FE estremamente compromessa**

La **valutazione emodinamica** a paziente **ricompensato** è un **esame cardine** nel processo decisionale di cura del paziente e attualmente non può essere sostituita da quella ecocardiografica



DEVICE



TESTING



HIGH RISK



**SCOMPENSO C.
AVANZATO**

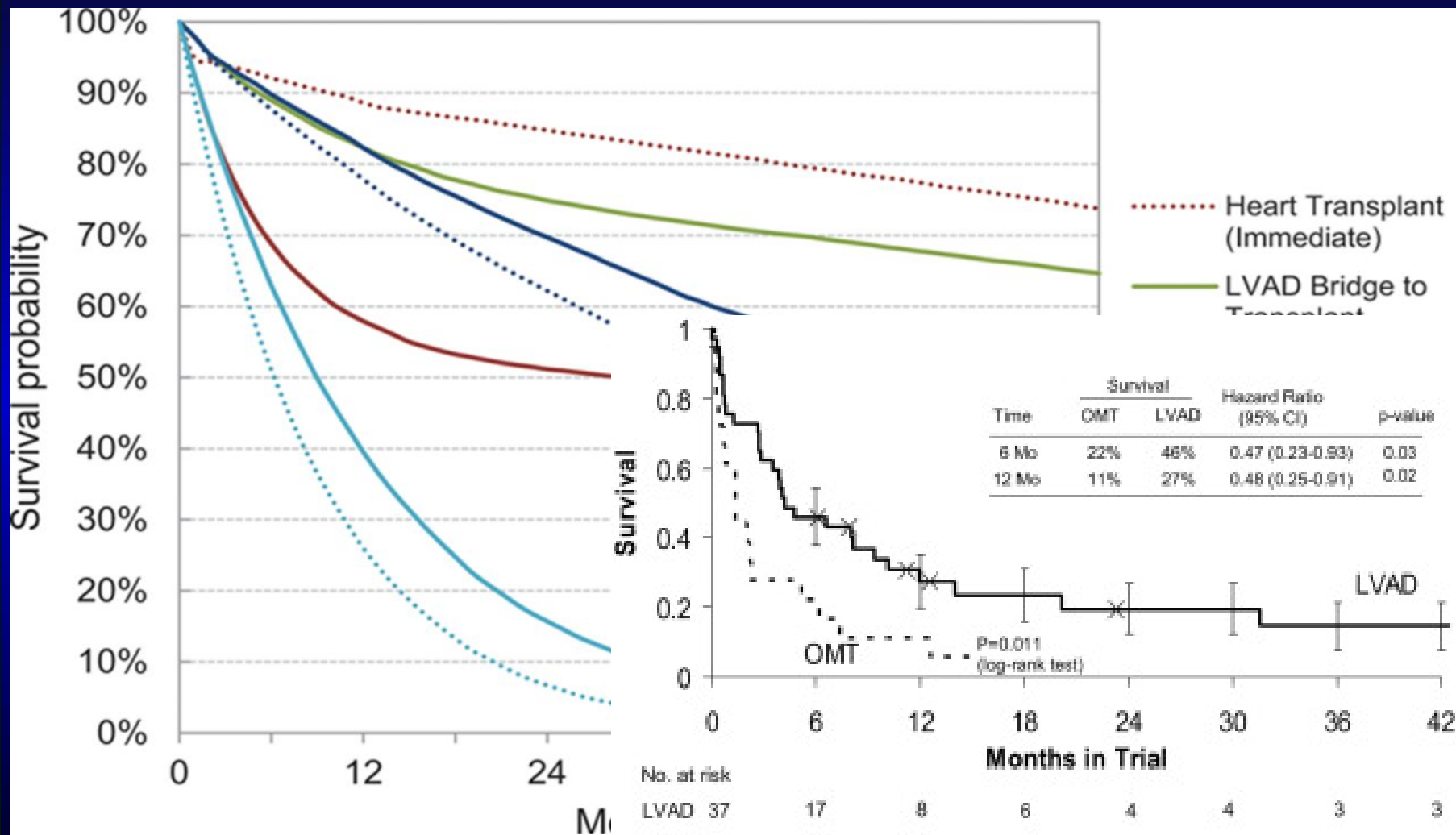


**TURIN'S
STRATEGY**



**SCOMPENSO C.
AVANZATO
ALTO RISCHIO**

La prognosi dello SCC avanzato



Long EF. *Circ Heart Fail.* 2014;7(3):470-478

Rogers JG. *J Am Coll Cardiol.* 2007 Aug 21;50(8):741-7

Obiettivo dello studio

- Valutare l'outcome di una serie consecutiva di pazienti con scompenso cardiaco avanzato ad alto rischio (classe INTERMACS ≤ 4) dopo impianto di MitraClip

Popolazione

Criteri di inclusione:

- persistenza di segni e sintomi di HF nonostante terapia medica ottimale (compresa CRT quando indicata)
- storia di HF avanzato cronico¹
- presenza di insufficienza mitralica funzionale (o prevalentemente funzionale) di grado moderato o severo
- classe funzionale NYHA IV al momento del ricovero (profilo INTERMACS ≤ 4)
- frazione di eiezione cronicamente $\leq 30\%$.

Criteri di esclusione:

- stenosi mitralica associata, presenza di severe calcificazioni dell'annulus mitralico, caratteristiche anatomiche sfavorevoli²
- device a livello del SIA tali da impedire la puntura transettale

¹ Meta-Morponi *Journal of Heart Failure* (2012) 18:104-111

² Meta-Morponi *Journal of Heart Failure* (2012) 18:104-111

Endpoint

Endpoint primario: mortalità per tutte le cause a 12 mesi.

Endpoints secondari:

- mortalità per causa cardiaca a 12 mesi;
- composito di morte cardiaca, trapianto cardiaco, impianto LVAD a 12 mesi;
- re-ospedalizzazione a 6 mesi;
- miglioramento del profilo INTERMACS a 12 mesi;
- tolleranza emodinamica ad ACE/ARB dopo la procedura

Popolazione (n = 17)

Età (anni)	67 ± 8
Sesso maschile	15 (88,2%)
Etiologia ischemica	10 (58,8%)
INTERMACS ≤ 3	4 (23,5%)
Cold profile	12 (70,6%)
SHFS (mortalità stimata ad un anno, %)	72 ± 16
PAS (mmHg)	100 ± 11
FC (bpm)	74 ± 25
Betabloccante	15 (88,2%)
ACEI/ARB	2 (11,8%)
Spironolattone	8 (47%)
Furosemide, dose (mg)	112 ± 98
Levosimendan	12 (70,6%)
CRT	5 (29,4%)
Frazione di eiezione (%)	25 ± 4
DTD VS (mm)	69,5 ± 7,3
Deceleration time (ms)	122,8 ± 20,1

Rapporto E/E' settale	16,4 ± 6,4
TAPSE (mm)	17,6 ± 4
Gradiente VA dx (mmHg)	39,3 ± 12,1
PVC (mmHg)	10,3 ± 5
PAPs (mmHg)	49,5 ± 14,2
RVCPI (mm·mmHg)	680,4 ± 354,9
Creatinina (mg/dl)	1,59 ± 0,46
GFR secondo MDRD (ml/min/1,73mq)	40,2 ± 13,6
Sodiemia (mEq/L)	137 ± 4
Bilirubina totale (mg/dl)	1,28 ± 0,69
Troponina T ad alta sensibilità (ng/ml)	0,06 ± 0,07
NT pro BNP (pg/ml)	8583 ± 7935
Indice cardiaco (l/min/mq)	2,04 ± 0,61
Wedge Pressure (mmHg)	21,3 ± 8,9
PAPm (mmHg)	29,4 ± 8,2
Resistenze vascolari polmonari (UW)	2,83 ± 2,11

Risultati

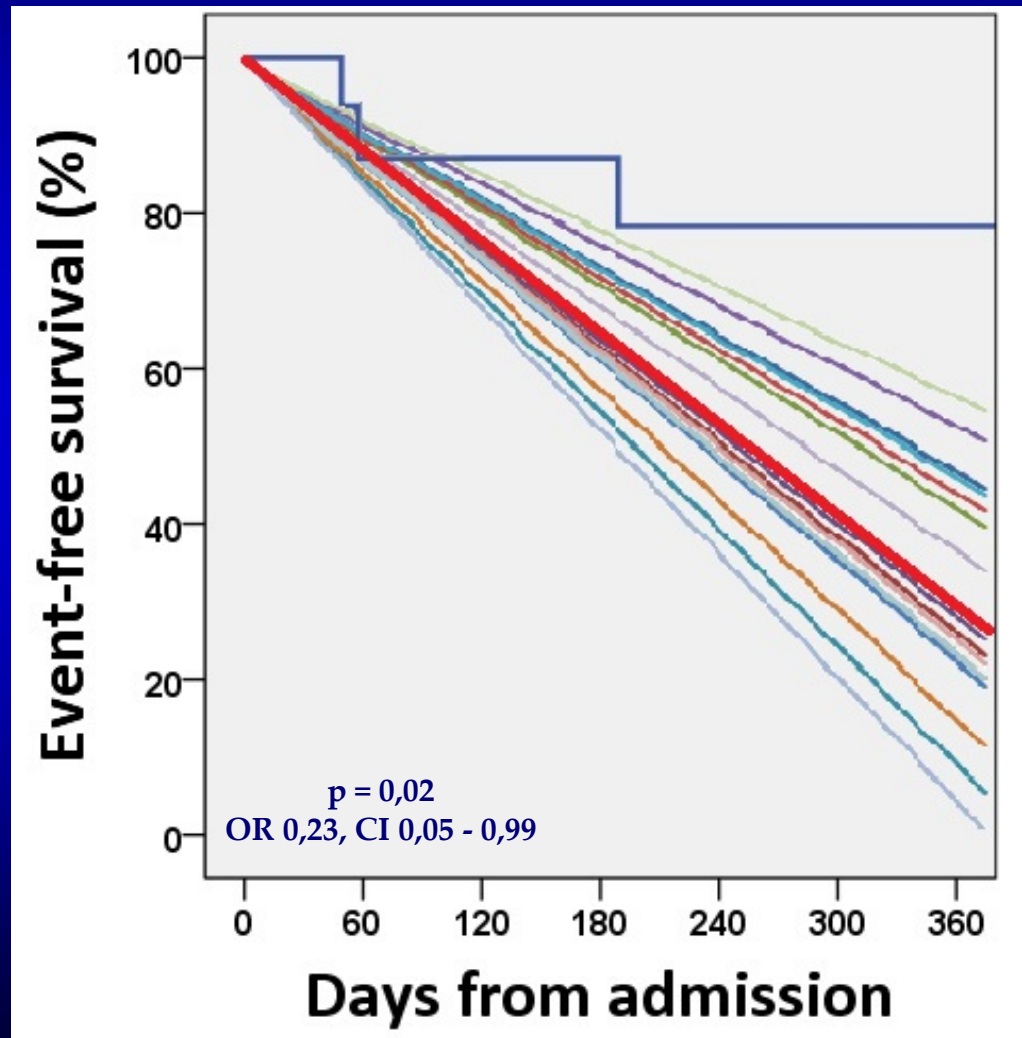
Endpoint primario

Morte per tutte le cause a 12 mesi	3 (17,6%)
Di cui INTERMACS 4 (n = 13)	1 (7,7%)
INTERMACS 3 (n = 4)	2 (50%)

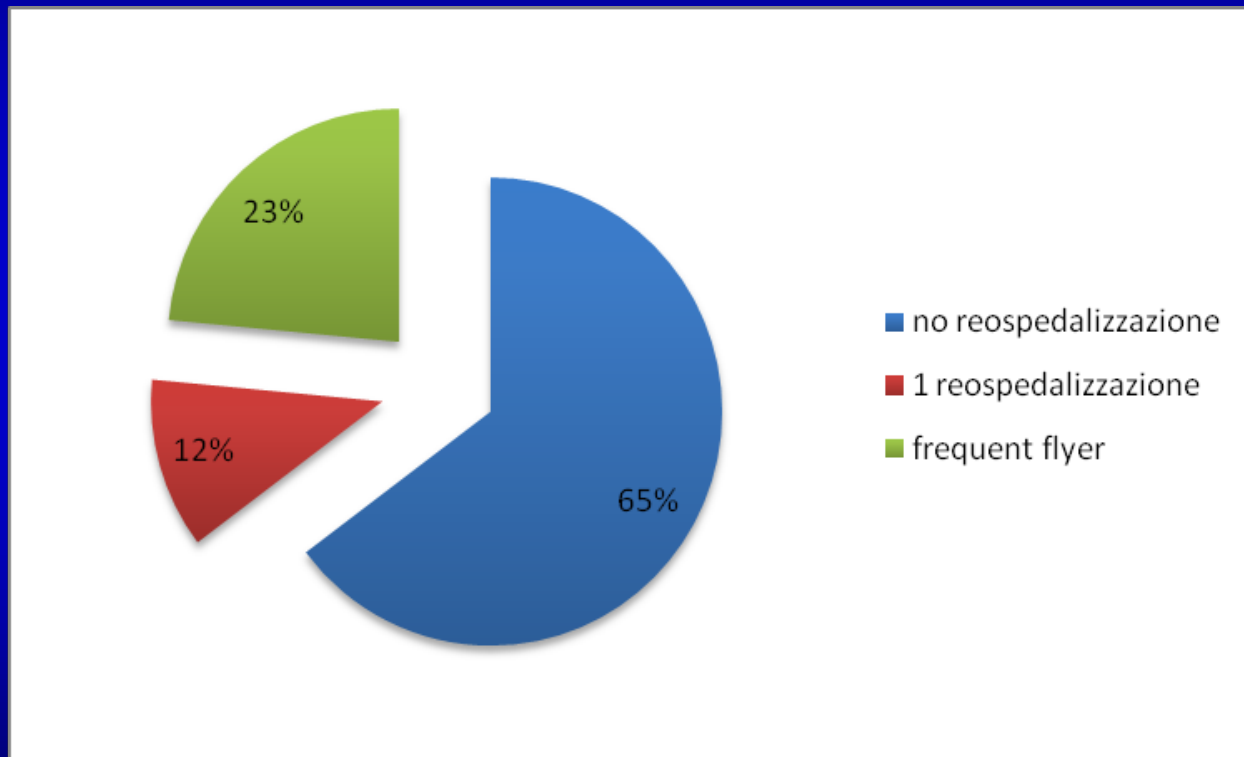
Endpoints secondari

Morte cardiaca a 12 mesi	2 (11,8%)
Di cui INTERMACS 4 (n = 13)	1 (7,7%)
INTERMACS 3 (n = 4)	1 (25%)
Composito di morte cardiaca, trapianto cardiaco, LVAD a 12 mesi	4 (23,5%)
Di cui INTERMACS 4 (n = 13)	3 (23,1%)
INTERMACS 3 (n = 4)	1 (25%)
Re-ospedalizzazione a 6 mesi	7 (41,2%)
Di cui INTERMACS 4 (n = 13)	5 (38,4%)
INTERMACS 3 (n = 4)	2 (50%)
Miglioramento profilo INTERMACS a 12 mesi	13 (76,5%)
Tolleranza emodinamica all'ACEI/ARB	10 (58,8%)
Di cui precedentemente intolleranti (n = 15)	8 (53,3%)

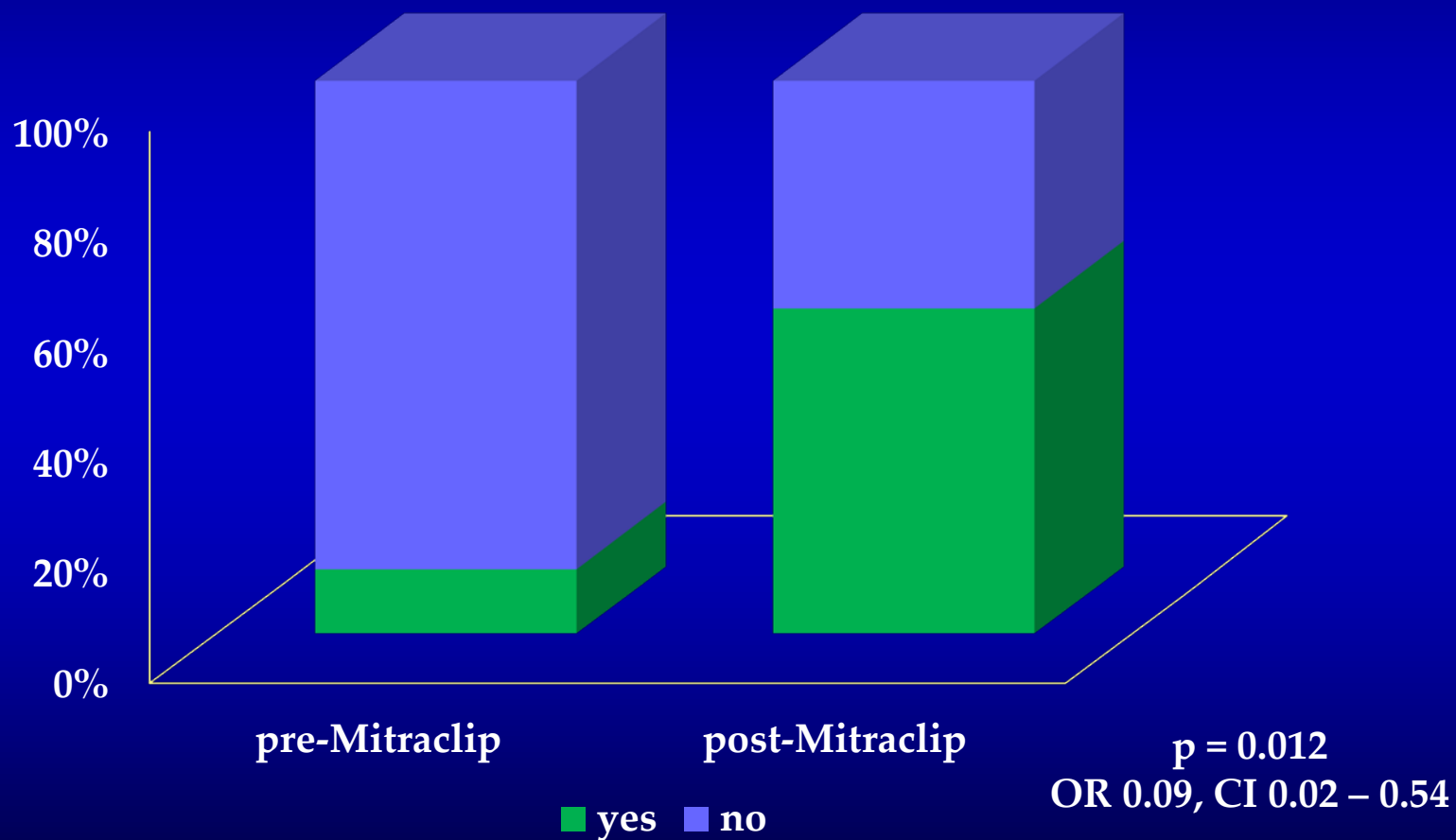
Risultati: confronto tra sopravvivenza stimata e osservata



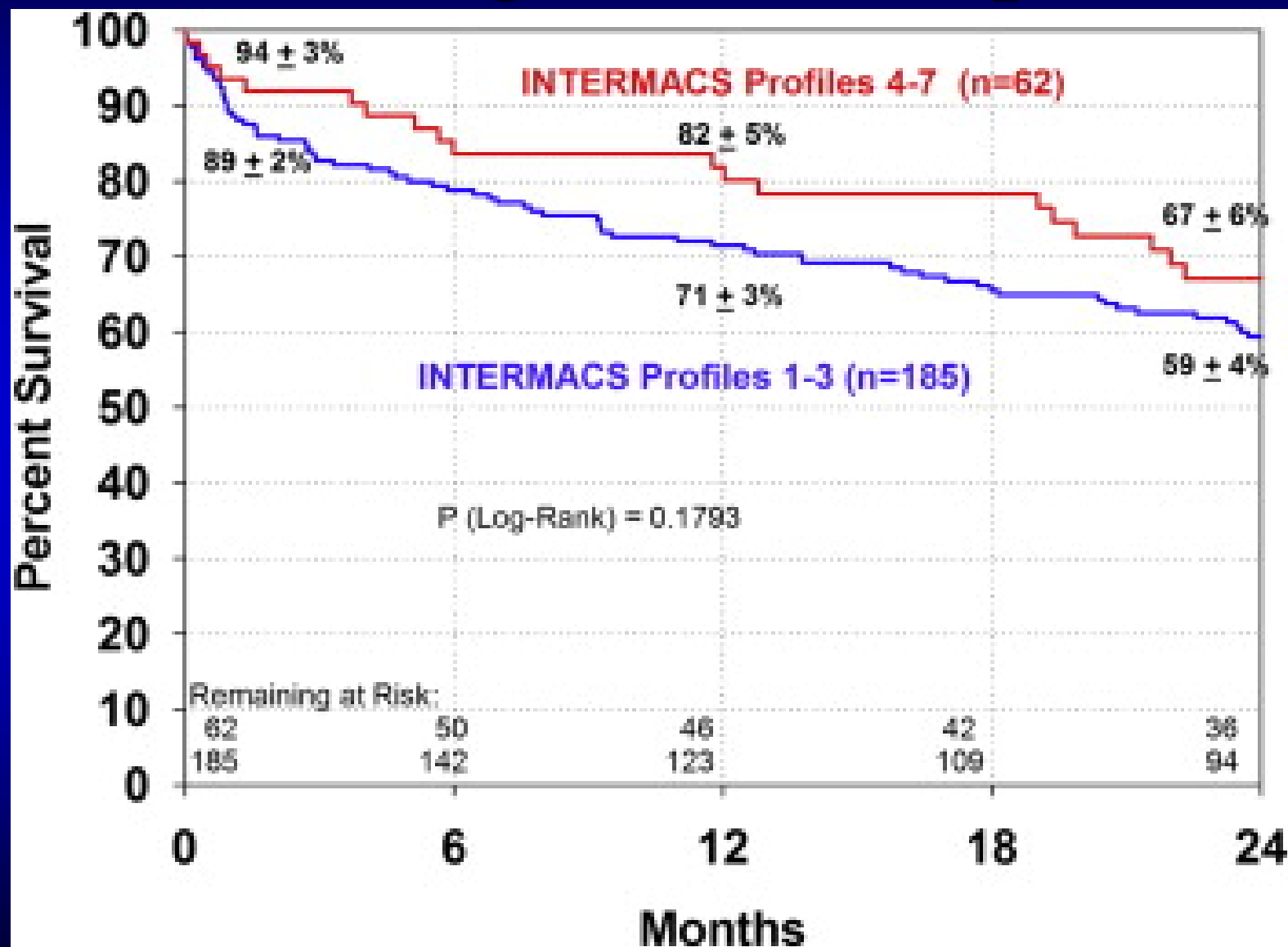
Risultati: riduzione delle re-ospedalizzazioni per HF



Risultati: tolleranza all'ACEI



Risultati: miglioramento profilo



CONCLUSIONI

L'impianto di MitraClip rappresenta una strategia terapeutica **a basso rischio** nell'ambito dello scompenso cardiaco avanzato ad alto rischio:

- ✓ il **miglioramento della prognosi e classe funzionale** ne fa un'arma per la destination therapy di pazienti non candidabili a LVAD o a trapianto cardiaco, offrendo una strategia alternativa o aggiuntiva al levosimendan ciclico o agli inotropi in infusione continua domiciliare.
- ✓ il **miglioramento del profilo emodinamico** del paziente ne consente l'utilizzo nell'ambito di **strategia bridge** a trapianto cardiaco o ad impianto di assistenza ventricolare sinistra.

Here we are...

















