

## Very long-term outcomes of mitral transcatheter edge-to-edge repair

Marta Bargagna<sup>1\*</sup>, MD; Nicola Buzzatti<sup>1</sup>, MD; Paolo Denti<sup>1</sup>, MD; Alessandra Sala<sup>1</sup>, MD, PhD; Guido Ascione<sup>1</sup>, MD; Nicolò Azzola Guicciardi<sup>1</sup>, MD; Matteo Saccocci<sup>1</sup>, MD; Claudio Ruffo<sup>1</sup>, MD; Roberta Meneghin<sup>1</sup>, BS; Francesco Ancona<sup>2</sup>, MD; Cosmo Godino<sup>3</sup>, MD; Eustachio Agricola<sup>2</sup>, MD; Anna M. Scandroglio<sup>4</sup>, MD; Ottavio Alfieri<sup>1</sup>, MD; Michele De Bonis<sup>1</sup>, MD; Francesco Maisano<sup>1</sup>, MD

\*Corresponding author: Department of Cardiac Surgery, IRCCS San Raffaele Hospital, "Vita-Salute" San Raffaele University, Via Olgettina 60, 20132, Milan, Italy. E-mail: [bargagna.marta@hsr.it](mailto:bargagna.marta@hsr.it)

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**T**ranscatheter edge-to-edge repair (TEER) using the MitraClip device (Abbott) has been a significant advancement in the management of patients with severe mitral regurgitation (MR) who are considered high risk for conventional surgery<sup>1</sup>. Despite its widespread acceptance and growing application, the long-term benefits and patient selection criteria continue to be explored and debated within the clinical community<sup>2-4</sup>.

This single-centre retrospective study represents a comprehensive review of long-term outcomes with TEER using MitraClip, performed at the cardiac surgery department of San Raffaele University Hospital in Milan, Italy. It included a cohort of 150 consecutive patients with severe MR ( $\geq 3+$ ) on echocardiographic assessment, treated between October 2008 and January 2013 for both primary (PMR) and secondary MR (SMR) (**Supplementary Table 1**), who were followed for 10 years after the procedure. Before the intervention, all patients were evaluated by a dedicated Heart Team.

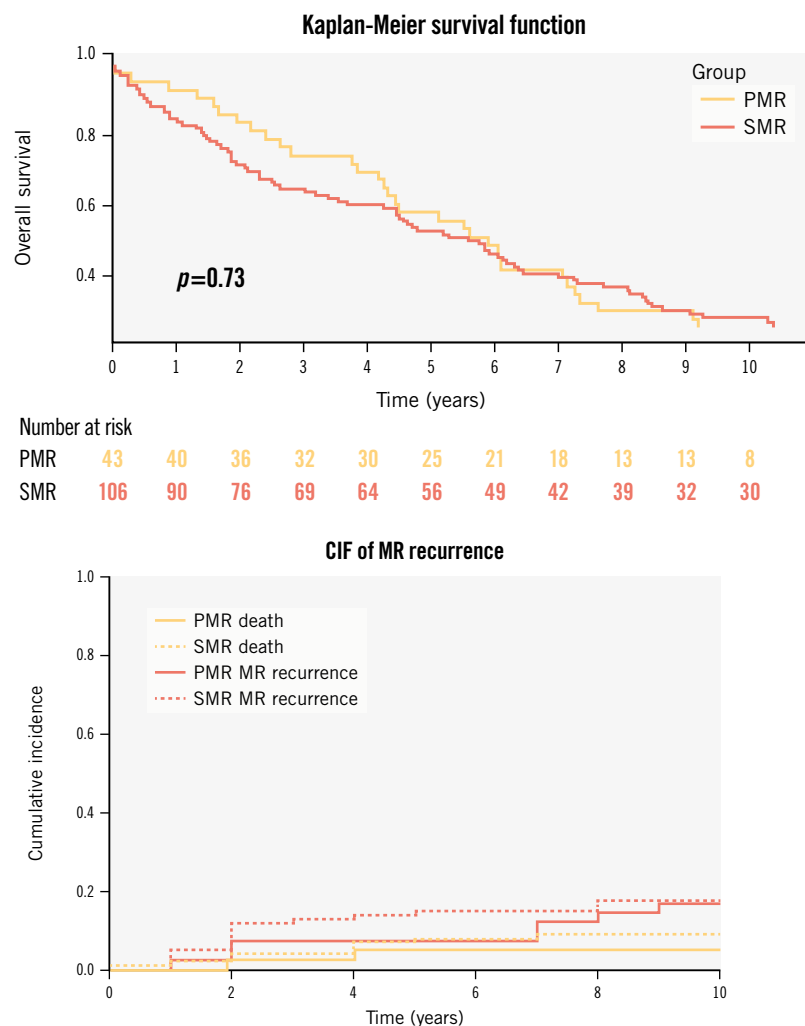
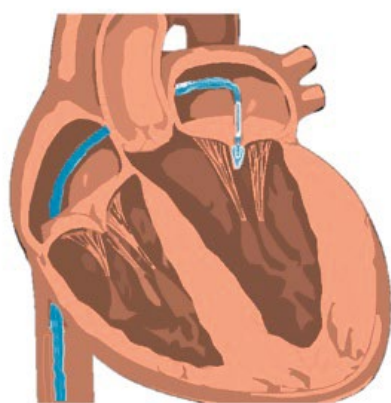
EVEREST eligibility criteria<sup>5</sup> were used as a reference, but patients outside them were also included. SMR patients were retrospectively assessed for COAPT eligibility<sup>6</sup>. All patients received first-generation MitraClip devices.

The cohort primarily consisted of males (78%), and the median age was 73.2 years. A significant portion (107 patients, 71.3%) suffered from SMR due to left ventricular dysfunction, as indicated by a median left ventricular ejection fraction (LVEF) of 26% (about 30% of them had an LVEF  $< 20\%$ , and 16.5% of patients were COAPT-like). This subset of patients typically presents a more complex challenge due to the underlying cardiac pathology contributing to the MR.

The procedural success was measured by the degree of MR reduction achieved immediately post-implantation. Initial results were promising, with most patients experiencing a significant decrease in MR severity. However, residual MR greater than 3+ was still observed in 11.3% of the patients at the time of discharge (**Supplementary Table 2**). Over the course of follow-up, comprehensive echocardiographic data were acquired with a high retention rate (96% of patients, median time 4.6 [1.4-5.9] years). The median follow-up duration was 5.7 years, during which a substantial number of patients (119) passed away, with almost half of these deaths (48.7%) attributable to cardiovascular causes. Heart failure-related rehospitalisation was  $51.1 \pm 5.1\%$ , and 12 patients underwent further procedures during the follow-up period (**Supplementary Figure 1, Supplementary Figure 2, Supplementary Table 3, Central illustration**). The long-term durability of the repair was assessed, and the cumulative incidence function (CIF) of MR recurrence, with death as the competing risk, was  $49 \pm 21.5\%$  for SMR and  $23.8 \pm 23.8\%$  for PMR at 1 year, and  $21.5 \pm 4\%$  for SMR and  $19 \pm 6\%$  for PMR at the 10-year benchmark (**Supplementary Figure 3, Central illustration**).

Survival analysis showed that only 25.3% (38/150 patients) of the initial cohort were still alive after 10 years. Survivors, compared to non-survivors, tended to be younger (age:  $66.3 \pm 10.9$  years vs  $73.5 \pm 10.0$  years;  $p < 0.01$ ), had a lower incidence of atrial fibrillation (21.1% vs 46.4%;  $p < 0.01$ ), better kidney function (estimated glomerular filtration rate:  $58.7$  [37.3-100.7] ml/min vs  $46.1$  [34.4-65.7] ml/min;  $p = 0.01$ ), and lower predicted mortality rates according to the Seattle Heart Failure Model

# Ten-year outcomes of patients treated with 1<sup>st</sup>-generation MitraClip between 2008 and 2013 for primary and secondary MR.



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CIF: cumulative incidence function; MR: mitral regurgitation; PMR: primary MR; SMR: secondary MR

(SHFM). Notably, these patients also demonstrated a higher procedural success rate, with a significant reduction in MR observed immediately post-procedure (residual MR 0-1: 89.5% vs 59.8%;  $p=0.004$ ). There were no differences in secondary MR aetiology distribution (78.9% vs 68.8%;  $p=0.23$ ), LVEF ( $32\pm 14$  vs  $38\pm 18$ ;  $p=0.06$ ), or EVEREST-like patients (50.0% vs 44.6%;  $p=0.57$ ) (**Supplementary Table 4**, **Supplementary Table 5**).

A logistic regression analysis was performed to identify factors independently associated with increased mortality risk. Age (odds ratio [OR] 1.07, 95% confidence interval [CI]: 1.02-1.13;  $p=0.006$ ) and the presence of significant residual MR  $\geq 2+$  (OR 8.72, 95% CI: 2.08-36.61;  $p=0.003$ ) were the most potent predictors of poor outcomes, highlighting the importance of achieving optimal MR

reduction during the initial procedure (**Supplementary Table 6**). Residual MR 2+ was confirmed to be associated with 10-year mortality after removing patients with acute residual MR 3+ and 4+ (OR 17, 95% CI: 2.3-131.4;  $p=0.006$  for 2+ vs 0/1+). A COAPT-like profile was not associated with survival benefit in the SMR subgroup. In the SMR subgroup, predicted 5-year SHFM versus observed mortality was 49.5% versus 29.9%;  $p<0.001$ . At 10 years post-MitraClip, 79% of living patients were in New York Heart Association Class I-II.

This study provides valuable insights into the long-term outcomes with TEER using MitraClip, marking it, to the best of our knowledge, as the longest follow-up reported to date<sup>2,4</sup>. The findings underscore the effectiveness of the procedure in a select group of patients while also emphasising

the critical nature of patient selection and procedural success in determining long-term survival and quality of life<sup>7</sup>.

The major limitations of the study are its retrospective single-centre nature, the small number of high-risk patients treated and eligible for 10-year follow-up, and the first experience of our operators in using the first-generation MitraClip device, which is now outdated.

In conclusion, TEER with MitraClip offers a treatment option for patients with severe MR who are not candidates for surgery. While the procedure has shown promising results, the ongoing challenge remains in refining patient selection and improving techniques to ensure the best possible outcomes. As technology advances and more data become available, these insights will continue to shape the future of MR management, ensuring that patients receive the most effective and personalised care possible.

### Authors' affiliations

1. Department of Cardiac Surgery, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; 2. Echocardiography Laboratory, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; 3. Department of Cardiology, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy; 4. Department of Anesthesiology, IRCCS San Raffaele Hospital, Vita-Salute San Raffaele University, Milan, Italy

### Conflict of interest statement

F. Maisano received grants and/or institutional research support from Abbott, Medtronic, Edwards Lifesciences, Biotronik, Boston Scientific, NVT, Terumo, Venus Medtech, and Pie Medical Imaging; he received consulting fees, personal and institutional honoraria from Abbott, Medtronic, Edwards Lifesciences, Xeltis, Venus Medtech, Occlufit, Simulands, Mtex, and Squadra; he has received royalty income/IP rights from Edwards Lifesciences; and he received stock from Magenta Medical, Transseptal Solutions, and 4Tech. P. Denti received speaker honoraria from Abbott and Edwards Lifesciences; has been a consultant for HVR, Approxima, InnovHeart, and Pi-Cardia. N. Buzzatti has been a consultant for InnovHeart. F. Ancona received speaker honoraria from Abbott. M. De Bonis received speaker honoraria from Medtronic and Edwards Lifesciences; and is co-founder and CMO of Startric. The other authors have no conflicts of interest to declare.

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### Supplementary data

- Supplementary Table 1.** Baseline and echocardiographic characteristics.
- Supplementary Table 2.** Intraoperative and postoperative characteristics.
- Supplementary Table 3.** Follow-up outcomes.
- Supplementary Table 4.** Major baseline features of 10-year survivors and non-survivors.
- Supplementary Table 5.** Baseline characteristics and in-hospital outcomes of 10-year survivors.
- Supplementary Table 6.** Logistic regression model for predictors of 10-year mortality.
- Supplementary Figure 1.** Kaplan-Meier freedom from all-cause death.
- Supplementary Figure 2.** Kaplan-Meier freedom from all-cause death in primary MR versus secondary MR.
- Supplementary Figure 3.** Cumulative incidence function of MR recurrence (MR  $\geq 3$ ), with death as the competing risk.

The supplementary data are published online at:  
<https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-24-00392>



## Supplementary data

**Supplementary Table 1. Baseline and echocardiographic characteristics.**

	N=150	Secondary MR (N=107)	Primary MR (N=43)
Age, years (median;IQR)	73.2 (66.2-79)	71.2 (65.1-75.3)	80.8 (74.7-85.6)
Male (n,%)	117 (78)	91 (85)	26 (60.5)
Ischemic MR (n,%)	79 (52.6)	79 (73.8)	-
Coronary artery disease (n,%)	100 (66.6)	81 (75.7)	19 (44.2)
Atrial fibrillation (n,%)	60 (40)	42 (39.2)	18 (41.8)
eGFR mL/min (median;IQR)	48.1 (36.1-70.6)	48.5 (35.7-72.9)	47.7 (36.5-64.5)
Diabetes (n,%)	26 (17.3)	23 (21.5)	3 (7)
Previous cardiac surgery (n,%)	45 (30)	35 (32.7)	10 (23.2)
Furosemide, mg (median;IQR)	75 (50-125)	100 (50-200)	25 (25-50)
NYHA $\geq$ III (n,%)	118 (78.6)	89 (83.2)	29 (67.4)
NT-proBNP pg/mL (median;IQR)	2229 (1202-3789.5)	2971.5 (1554.5-5550)	1026 (388.5-1978.5)
Pacemaker (n,%)	61 (40.6)	56 (52.3)	5 (11.6)
CRT (n,%)	36 (24)	34 (32.1)	2 (4.6)
LVEF, % (median;IQR)	30 (24.2-52)	26 (20-30)	60 (54.5-66)
LVEF $\leq$ 20% (n,%)	32 (21.3)	32 (30)	-
End Diastolic Diameter, mm (median;IQR)	66 (59-72)	68 (63.2-75)	56 (50-62)
End Diastolic Volume, mL (median;IQR)	168 (128-231.5)	191 (154.5-253)	103.5 (80.7-128)
Mitral valve area, cmq (median;IQR)	5 (4.2-5.4)	5 (4.2-5.4)	5 (4.3-6.5)
PAPs, mmHg (median;IQR)	46 (35-60)	45 (37.2-60)	46 (35-55)
sTDI, cm/sec (median;IQR)	10 (9-12)	10 (8-12)	12 (11-12)
Tricuspid regurgitation $\geq$ 3 (n,%)	34 (22.6)	26 (24.3)	8 (18.6)
EVEREST-like (n,%)	69 (46)	38 (35.5)	31 (72.1)
COAPT-like (n,%)	16 (10.6)	16 (16.5)	-
Logistic EuroSCORE, % (median;IQR)	17.8 (9.5-27.6)	19.2 (11-29)	12.3 (6.4-21.6)
STS-PROM mortality score, % (median;IQR)	5.2 (2.8-11.9)	7.3 (2.8-13.3)	4.4 (2.8-6.4)
SHFM 5-year mortality, % (median;IQR)	44 (29-6)	49.5 (30.7-73.7)	33 (27-50)
SHFM Life Expectancy, years (median;IQR)	6.4 (4.2-9)	5.8 (3.5-8.5)	8.1 (5.7-9.7)

COAPT: Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation; CRT: cardiac resynchronization therapy; eGFR: estimated

Glomerular Filtration Rate; EuroSCORE: European System for Cardiac Operative Risk Evaluation; EVEREST: Endovascular Valve Edge-to-Edge Repair Study; LVEF: left ventricle ejection fraction NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PAPs: Pulmonary Artery systolic Pressure sTDI: spectral Tissue Doppler Imaging; SHFM: Seattle Heart Failure Model; STS-PROM: Society of Thoracic Surgeon Predicted Risk of Mortality.

**Supplementary Table 2. Intraoperative and postoperative characteristics.**

	N=150	Secondary MR (N=107)	Primary MR (N=43)
Procedural success (measured at 30 days) (n,%)	128 (85.3)	91 (85)	37 (86)
Numbers of clips (n,%)			
1	48 (32)	33 (30.8)	15 (34.8)
2	96 (64)	69 (64.4)	27 (62.7)
3	6 (4)	5 (4.6)	1 (2.3)
Conversion to surgery (n,%)	1 (0.6)	-	1 (2.3)
Residual MR (n,%)			
0	13 (8.6)	5 (4.6)	8 (18.6)
1	86 (57.3)	66 (61.7)	18 (41.8)
2	34 (22.6)	21 (19.6)	13 (30.2)
3	14 (9.3)	12 (11.2)	2 (4.6)
4	3 (2)	1 (0.9)	2 (4.6)
Residual valve area, cmq (median;IQR)	2.7 (2.5-3)	2.7 (2.4-3)	3 (2.6-3)
Post-procedural sPAP, mmHg (median;IQR)	38 (30-48)	40 (30-47.5)	37.5 (30-46)
In-hospital mortality (n,%)	3 (2)	2 (1.8)	1 (2.3)
Home discharge (n,%)	92 (61.3)	63 (58.8)	29 (67.4)

MR: mitral regurgitation; PAPs: Pulmonary Artery systolic Pressure.

**Supplementary Table 3. Follow-up outcomes.**

	N=150	Secondary MR (N=107)	Primary MR (N=43)
Follow-up time, years (median;IQR)	5.7 (2.0-9.6)	5.6 (1.8-9.9)	5.9 (3.3-9.2)
Echocardiographic follow-up time, years (median;IQR)	4.6 (1.4-5.9)	4.4 (1.2-5.8)	4.8 (2.7-6.0)
All-cause death (n,%)	119 (79.3)	83 (77.5)	36 (83.7)
Cardiac Death (n,%)	58 (38.6)	49 (45.8)	9 (28.1)
Hospitalization for HF (n,%)	56 (37.3)	47 (46.5)	9 (20.9)
Mitral valve surgery (n,%)	6 (4)	3 (2.9)	3 (6.9)
RE-Mitraclip (n,%)	3 (2)	2 (1.9)	1 (2.3)
LVAD implantation (n,%)	1 (0.6)	1 (0.9)	-
Heart transplantation (n,%)	2 (1.3)	2 (1.8)	-
ICD/CRT implantation (n,%)	19 (12.6)	19 (18.4)	-
NYHA $\geq$ III (n,%)	34 (22.6)	31 (31.3)	3 (7.5)
Single leaflet attachment (n,%)	7 (4.6)	2 (2)	5 (11.6)
Residual MR $\geq$ 3+ (n,%)	32 (21.3)	21 (21.2)	11 (27.5)
LVEF, % (median;IQR)	34.5 (24.2-47.2)	29 (20-35.5)	55 (49.7-60)
End Diastolic Diameter, mm (median;IQR)	62 (55-71)	65 (58-72.5)	51 (48.5-56.5)
PAPs, mmHg (median;IQR)	40 (35-50)	40 (36-51)	40 (35-45)
Tricuspid regurgitation $\geq$ 3+ (n,%)	16 (4)	13 (13.1)	3 (7.5)

ICD/CRT: implantable cardioverter defibrillator/cardiac resynchronization therapy; LVEF: left ventricle ejection fraction; LVAD: Left Ventricle Assist Device MR: mitral regurgitation; MR: mitral regurgitation; NYHA: New York Heart Association; PAPs: Pulmonary Artery systolic Pressure.

**Supplementary Table 4. Major baseline features of 10-year survivors and non-survivors.**

	Survivors=38	Non-survivors=112	P value
Age, years (mean±SD)	66.3 ± 10.9	73.5 ± 10.0	<0.01
Male (n,%)	28 (73.7)	89 (79.5)	0.46
Secondary MR (n,%)	30 (78.9)	77 (68.8)	0.23
Atrial fibrillation (n,%)	8 (21.1)	52 (46.4)	<0.01
Coronary artery disease (n,%)	26 (68.4)	74 (66.1)	0.79
NYHA (n,%)			
2	12 (31.6)	20 (17.9)	0.20
3	21 (55.3)	74 (66.1)	
4	5 (13.2)	18 (16.1)	
eGFR, ml/min (median;IQR)	58.7 (37.3-100.7)	46.1 (34.4-65.7)	0.01
End Diastolic Diameter, mm (median;IQR)	65 (60.7-72.2)	66 (59-71.2)	0.67
End diastolic volume (mean±SD)	170 ± 58	188 ± 74	0.62
LVEF (mean±SD)	32 ± 14	38 ± 18	0.06
LVEF <20% (n,%)	7 (18.4)	18 (16.1)	0.74
sPAP, mmHg (mean±SD)	46 ± 14	49 ± 16	0.28
Tricuspid regurgitation ≥3+ (n,%)	5 (13.2)	29 (25.9)	0.10
NT-ProBNP, pg/ml (median;IQR)	1330 (1289-3320)	2253.5 (1254.7-4316)	0.28
EVEREST-like (n,%)	19 (50.0)	50 (44.6)	0.57
STS-PROM, % (median;IQR)	4.2 (2.5-8.2)	5.9 (2.9-12.1)	0.09
SHFM Life Expectancy, years (median;IQR)	8.3 (6.7-10.3)	5.9 (4-8.7)	0.02
SHFM 5-year mortality, % (mean±SD)	37 ± 18	53 ± 26	<0.01
Residual MR (n,%)			0.004
0-1	34 (89.5)	67 (59.8)	
2	2 (5.3)	33 (29.5)	
3	2 (5.3)	7 (6.3)	
4	0 (0)	5 (4.5)	

eGFR: estimated Glomerular Filtration Rate EVEREST: Endovascular Valve Edge-to-Edge Repair Study; LVEF: left ventricle ejection fraction; MR: mitral regurgitation; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PAPs: Pulmonary Artery systolic Pressure SHFM: Seattle Heart Failure Model; STS-PROM: Society of Thoracic Surgeon Predicted Risk of Mortality.



**Supplementary Table 5. Baseline characteristics and in-hospital outcomes of 10-year survivors.**

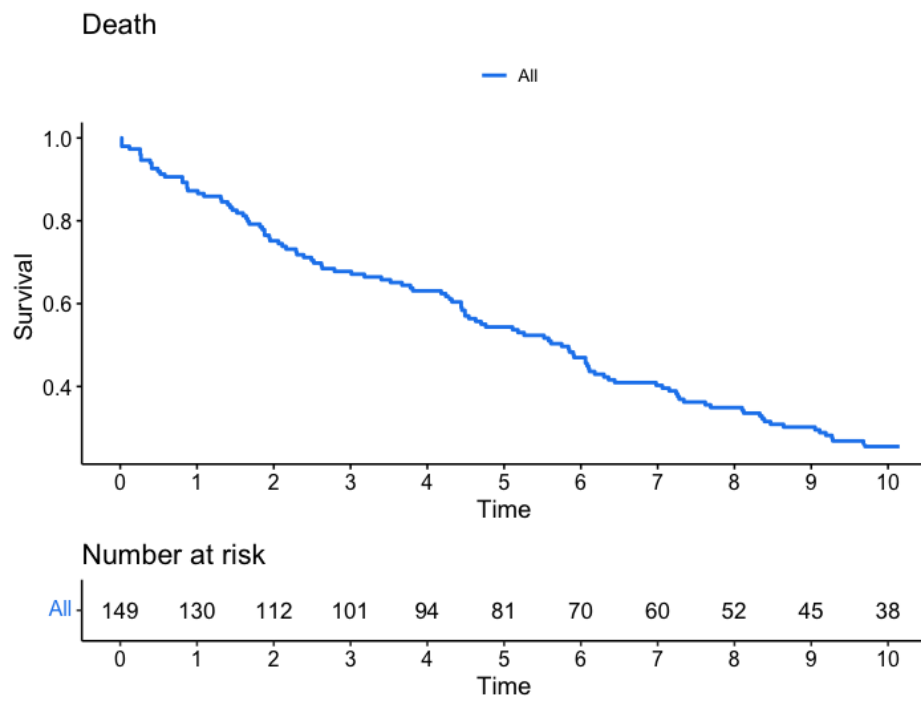
	Survivors=38	Secondary MR=30	Primary MR=8
Age, years (mean±SD)	66.3 ± 10.9	64.5 ± 10.1	72.9 ± 12.1
Male (n,%)	28 (73.7)	25 (83.3)	3 (37.5)
Secondary MR (n,%)	30 (78.9)	30 (100)	-
Atrial fibrillation (n,%)	8 (21.1)	7 (23.3)	1 (12.5)
Coronary artery disease (n,%)	26 (68.4)	22 (73.3)	4 (50)
NYHA (n,%)			
2	12 (31.6)	8 (26.6)	4 (50)
3	21 (55.3)	17 (56.6)	4 (50)
4	5 (13.2)	5 (16.6)	-
eGFR, ml/min (median;IQR)	58.7 (37.3-100.7)	62.1 (40.9-97.6)	55.3 (41.2-68.7)
End Diastolic Diameter, mm (median;IQR)	65 (60.7-72.2)	68 (62-74)	52 (49-62.7)
End diastolic volume (mean±SD)	170 ± 58	166.5 (147.5-211.7)	93.5 ± 23.0
LVEF (mean±SD)	32 ± 14	26.7 ± 9.2	49.2 ± 14.2
LVEF <20% (n,%)	7 (18.4)	7 (23.3)	-
sPAP, mmHg (mean±SD)	46 ± 14	45.3 ± 14.8	48.2 ± 9.1
Tricuspid regurgitation ≥3+ (n,%)	5 (13.2)	3 (10)	2 (25)
NT-ProBNP, pg/ml (median;IQR)	1330 (1289-3320)	2330.5 (1264-3516.2)	968 (424-1798.5)
EVEREST-like (n,%)	19 (50.0)	14 (46.6)	5 (62.5)
COAPT-like (n,%)	6 (16.8)	6 (20)	-
STS-PROM (median;IQR)	4.2 (2.5-8.2)	4.2 (2.4-8.8)	4.4 (2.9-6.5)
SHFM Life Expectancy (median;IQR)	8.3 (6.7-10.3)	7.7 (5.7-9.7)	8.8 (7.8-10.3)
SHFM 5-year mortality (mean±SD)	37 ± 18	38.8 ± 20.2	31.4 ± 11
Residual MR at discharge (n,%)			
0-1	33 (86.8)	28 (93.3)	5 (62.5)
2	3 (7.9)	1 (3.3)	2 (25)
3	1 (2.6)	1 (3.3)	-
4	1 (2.6)	-	1 (12.5)

COAPT: Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation eGFR: estimated Glomerular Filtration Rate EVEREST: Endovascular Valve Edge-to-Edge Repair Study; LVEF: left ventricle ejection fraction; MR: mitral regurgitation; NT-proBNP: N-terminal pro-brain natriuretic peptide; NYHA: New York Heart Association; PAPs: Pulmonary Artery systolic Pressure SHFM: Seattle Heart Failure Model; STS-PROM: Society of Thoracic Surgeon Predicted Risk of Mortality.

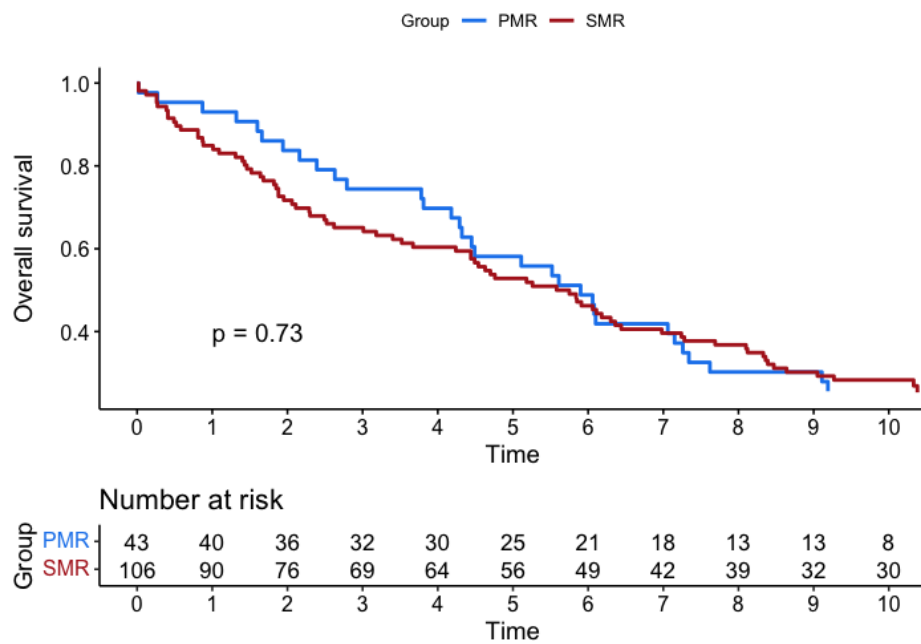
**Supplementary Table 6. Logistic regression model for predictors of 10-year mortality.**

	Univariable			Multivariable		
	OR	CI	p	OR	CI	p
Age	1.06	1.03-1.10	0.001	1.07	1.02-1.13	0.006
Atrial Fibrillation	3.25	1.37-7.71	0.007	2.25	0.86-5.86	0.097
eGFR	0.99	0.97-1.00	0.018	1.00	0.99-1.01	0.91
Furosemide	1.005	1.000-1.01	0.031	1.01	1.00-1.01	0.064
Residual MR $\geq 2+$	7.84	2.27-27.03	0.001	8.72	2.08-36.61	0.003

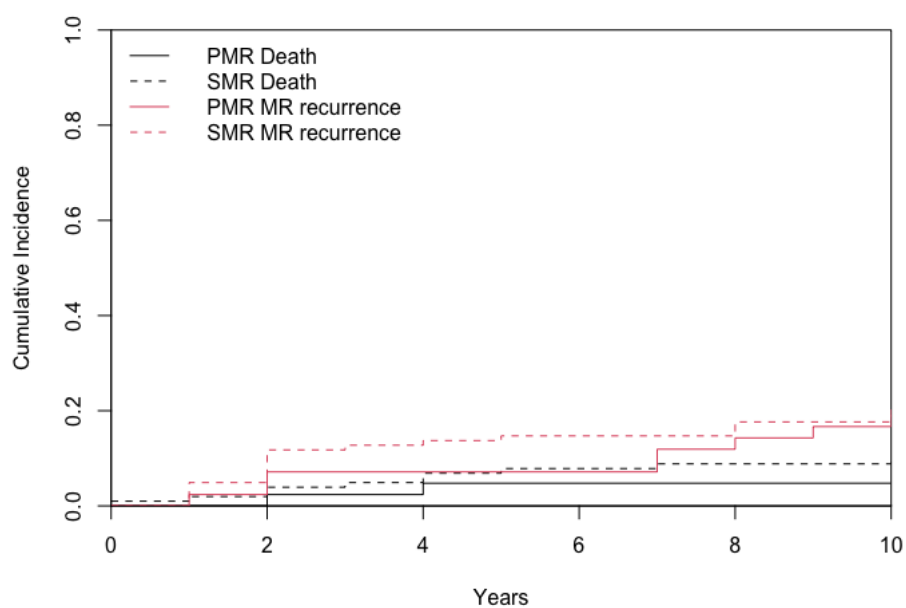
eGFR: estimated Glomerular Filtration Rate; MR: mitral regurgitation.



**Supplementary Figure 1.** Kaplan-Meier freedom from all-cause death.



**Supplementary Figure 2.** Kaplan-Meier freedom from all-cause death in primary MR versus secondary MR.



**Supplementary Figure 3.** Cumulative incidence function of MR recurrence (MR  $\geq 3$ ), with death as the competing risk.

MR: mitral regurgitation, PMR: primary MR, SMR: secondary MR.