Acta Cardiol Sin 2021;37:286–295
Original Article
doi: 10.6515/ACS.202105_37(3).20201020A

Valvular Heart Disease

Outcomes after Transcatheter Mitral Valve Edge to Edge Repair; a Comparison of Two Pathologies

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Background: The clinical use of transcatheter mitral valve repairis growing. We aimed to compare the clinical and echocardiographic outcomes after transcatheter mitral valve repair using the edge-to-edge technique in patients with functional and degenerative mitral regurgitation (MR). Furthermore, we correlated the clinical and echocardiographic measurements.

Methods: The study included 111 patients who underwent the MitraClip procedure from 2012 to 2018. The patients were divided into two groups according to the etiology; functional mitral regurgitation (FMR) (n = 88; 79.28%) and degenerative mitral regurgitation (DMR) (n = 23; 20.72%).

Results: Advanced age (p = 0.002) and FMR (p = 0.001) increased coronary care unit stay, and history of heart failure hospitalization (p = 0.003). Advanced age (p = 0.022) and FMR (p < 0.001) also increased the duration of hospital stay. Severe renal impairment [hazard ratio (HR): 2.6; p < 0.001], female gender (HR: 3.9; p = 0.005), and history of stroke (HR: 5.6; p = 0.065) decreased survival, while post-procedure diuretics improved survival (HR: 0.3; p = 0.024). Moderate residual MR [sub-distribution hazard ratio (SHR): 4.1; p = 0.011], lower EuroSCORE (SHR: 0.9; p = 0.013), and lack of β-blockers (SHR: 0.2; p = 0.034) were predictors of MR recurrence. There were no significant correlations between NYHA class and pulmonary artery pressure (PASP) (p = 0.896), end-systolic (p = 0.856), and end-diastolic diameters (p = 0.965). There were significant improvements in left ventricular dimensions and PASP after MitraClip. However, these changes were not maintained over time. The grade of MR significantly improved after the procedure (p = 0.001), with no difference between groups (p = 0.89).

Conclusions: The MitraClip procedure showed positive results in terms of sustainable symptomatic relief, although this finding was not reflected in left ventricular dimensions. The technique is equally effective in FMR and DMR.

Key Words: Degenerative mitral regurgitation • Functional mitral regurgitation • MitraClip

INTRODUCTION

The management of severe mitral regurgitation (MR) in patients with a prohibitive surgical risk continues to be challenging. The maximum medical therapy is usually not sufficient, and several interventional options have been proposed with controversial outcomes. Transcatheter edge-to-edge repair using the MitraClip system (Abbott Laboratories, Abbott Park, IL, USA) has been introduced for the management of symptomatic MR.[1] MitraClip has been shown to improve symptoms and quality of life; therefore, it has been included in the American and European guidelines as a class IIB indication for patients with degenerative and functional MR with a prohibitive operative risk and a life expectancy > 1 year.[2,3]

Received: May 26, 2020 Accepted: October 20, 2020
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Studies comparing transcatheter mitral valve repair using the MitraClip device to guideline-directed medical therapy (GDMT) for the management of functional mitral regurgitation (FMR) have reported that MitraClip reduced 12-month mortality, and rate of hospital readmission.[1,4] The Endovascular Valve Edge-to-Edge Repair Study (EVEREST I) also demonstrated excellent results with regards to device safety and feasibility; however, there was a high rate of surgical re-intervention with MitraClip compared to surgery.[5]

The number of MitraClip implantations has increased recently; however, not all mitral valve pathologies have been well presented in the literature, and there is a paucity of data on the long-term outcomes after the MitraClip procedure.[6-8] In this study, we aimed to compare the clinical, echocardiographic, and survival outcomes after transcatheter mitral valve repair using the edge-to-edge technique in patients with functional and degenerative MR. Furthermore, we correlated the clinical and echocardiographic measurements in these patients.

METHODS

Study design and patients

This retrospective cohort study included 111 patients who had transcatheter mitral valve edge-to-edge repair using MitraClip from February 2012 to December 2018. The study was approved by the local Research Ethical Committee, which waived the requirement for informed consent. Data were retrieved from the MitraClip database, which is a prospectively maintained database for all patients undergoing MitraClip.

The patients were divided into two groups according to the etiology of mitral valve disease; FMR (n = 88; 79.28%) and degenerative mitral regurgitation (DMR) (n = 23; 20.72%). The patients were involved in the procedure decision by actively participating in a heart team meeting, which included cardiac surgeons, invasive cardiologists, heart failure specialists, and echocardiographers. The patient was considered to be a candidate for transcatheter repair if they were symptomatic (NYHA class III or IV), had moderately severe (grade 3+) to severe (grade 4+) MR on baseline echocardiography, and had an intermediate to high surgical risk, as decided by the heart team. The latter was defined by a high risk of mortality (new EuroSCORE II 6-7 or higher) and/or additional surgical risk factors such as chest wall deformity, or when the patients declined the surgery.[9] The specific anatomic eligibility features of the EVEREST trial were used as a reference but without being absolute inclusion or exclusion criteria.[10] Therefore, a patient was considered for MitraClip when there were flail leaflets with a flail gap of < 10 mm and a flail width of < 15 mm. Additionally, patients were considered when the leaflet coaptation depth was < 11 mm in those with FMR or when the mitral valve orifice area was more than 4 cm^2. The patient had to be on GDMT for heart failure for at least three months and advised by a heart failure specialist before undergoing MitraClip.

Procedure

Transcatheter mitral valve repair was performed using the MitraClip system (Abbott Vascular, Menlo Park, California, USA) using a standard protocol. All MitraClip procedures were performed by two interventional cardiologists trained and licensed for the procedure. Access to the right atrium was established via the femoral vein, usually the right side. The transseptal puncture was done under transesophageal echocardiography (TEE) guidance. After the guiding catheter had been secured into the left atrium, the MitraClip system was introduced inside the guiding catheter into the left atrium. The recommended steps of straddling, clip perpendicularity, grasping, and clip deployment were done according to the manufacturer's guidelines. The whole procedure was done under general anesthesia and TEE guidance. Mitral valve function and severity of residual MR were then assessed by TEE. If a further reduction in MR was required, a second device might be placed. All procedures were done in the cardiac catheterization laboratory with a surgical team back-up. After the procedure, the patients were transferred to the coronary care unit (CCU) for one day, and then shifted to the ward thereafter. Generally, patients were discharged 3-5 days after the procedure.

Echocardiography assessment

All patients underwent clinical assessment and transthoracic echocardiography before and after the procedure. Echocardiography was performed according to the guidelines of the American Society of Echocardiogra-

phy.[11,12] MR severity was graded as none, mild (1+), moderate (2+), moderately severe (3+), and severe (4+). A DMR etiology was defined as the presence of thickening calcification of mitral valve leaflets and/or moderate to severe mitral annular calcification.[10] In contrast, an FMR etiology was defined as the presence of left ventricular dysfunction with the absence of morphological abnormalities of the mitral apparatus and dilated mitral valve annulus (more than 3.5 cm at the end-systole in the parasternal long-axis view).[13] Left ventricular ejection fraction was calculated using linear measurements. In our study, we opted to use linear measurements for better echo-image resolution. Pulmonary artery systolic pressure (PASP) was calculated using the maximum velocity of the tricuspid regurgitation signal with inferior vena cava collapsibility during the respiratory cycle. Pulmonary hypertension was defined as a peak pulmonary systolic pressure of more than 40 mmHg by echocardiography. The echocardiographic measurements were done at baseline, one day after the procedure, at one and six months, and then yearly.

Outcomes

A successful procedure was defined as a reduction of MR by two grades or more without complications necessitating cardiac surgery intervention and without stroke. Study outcomes included 30-day mortality, hospital complications, duration of CCU and hospital stays. Long-term outcomes included changes in MR severity and NYHA class, left ventricular dimensions, and PASP. Time to event outcomes included survival, recurrence of grade (3+) MR, and readmission for heart failure.

Statistical analysis

Categorical variables were presented as frequencies and percentages, and continuous variables as mean ± standard deviations or median and interquartile range. Normal distributions were assessed visually using histograms and the Shapiro-Wilk test. The Wilcoxon test was used to compare pre- and post-procedure data. Comparisons of categorical dependent variables were made using the McNemar test. Negative binomial regression analysis was used to identify predictors of CCU and hospital stays. Stepwise regression with the forward method was performed and a p-value of 0.1 was used as a criterion for the final model. Spearman correlation was used to assess correlations between echocardiographic measures and NYHA class.

Time to event variables (survival and freedom from grade 3+ MR) were plotted using the Kaplan Meier method. The log-rank test was used to compare survival distribution between groups. Cox regression analysis was used to identify predictors of mortality, and hazard ratios were reported. Death was considered to be a competing risk for recurrent MR, and competing risk regression was performed using the Fine-Gray method and subdistribution hazard ratios were reported. The cumulative incidence of MR in both groups was plotted.

Repeated measures were assessed with mixed-effect linear regression with the restricted maximum likelihood method. All statistical analyses were performed using Stata 16.1 (Stata Corp, College Station, Texas, USA), and a p-value of less than 0.05 was considered to be statistically significant.

RESULTS

Baseline data

Patients with FMR were significantly younger and had more myocardial infarction (MI). Preoperative ejection fraction, left ventricular dimensions, and PASP were significantly different between groups (Table 1).

Procedural data

Five cases were aborted; 4 patients were aborted because of difficult septal puncture and one case because of the creation of significant mitral stenosis. MitraClip was deployed in 106 (95.5%) patients; one clip was deployed in 69 (62.2%) patients, two clips in 33 (29.7%) patients, and three clips in 4 (3.6%) patients. Among these patients, 2 (2.43%) needed emergency mitral valve surgery due to partial leaflet detachment.

Post-procedural complications were comparable between groups (Table 2), and there were no significant differences in the post-procedure medications between both groups apart from aldosterone antagonists, which were prescribed more frequently in the patients with FMR.

There were no significant differences in CCU and hospital stays between groups in univariable analysis. Multivariable analysis showed that advanced age and FMR increased CCU stay, a history of HF hospitalization

Table 1. Baseline demographic, clinical and echocardiographic data

	Functional MR (n = 88)	Degenerative MR (n = 23)	p value
Age (years)	67 (56.5-72.5)	78 (71-82)	< 0.001
Male	54 (61.36%)	10 (43.48%)	0.122
Body mass index (BMI)	27.79 (25.81-32.83)	31.25 (25.16-33.31)	0.618
Risk stratification			
NYHA Class III/IV (within 2 weeks)	85 (96.59%)	20 (86.96%)	0.069
EuroSCORE II	5.465 (3.14-8.43)	5.45 (2.61-8.2)	0.496
Rhythm			
Atrial fibrillation	17 (19.32%)	8 (34.78%)	0.114
Device implantation			
ICDs	21 (23.86%)	1 (3.35%)	0.041
Pacemaker	2 (2.27%)	1 (4.35%)	0.505
Previous history			
MI	57 (64.77%)	5 (21.74%)	< 0.001
CABG	18 (20.45%)	4 (17.39%)	> 0.99
PCI	44 (50%)	7 (30.43%)	0.094
HF hospitalization (last year)	55 (62.50%)	10 (43.48%)	0.099
Medical comorbidity			
Hypertension	74 (84.09%)	21 (91.30%)	0.381
Diabetes	57 (64.77%)	15 (65.22%)	0.968
COPD	16 (18.18%)	6 (26.09%)	0.397
Severe renal impairment	31 (35.23%)	11 (47.83%)	0.244
Old stroke	3 (3.41%)	2 (8.70%)	0.276
Laboratory findings			
Creatinine clearance (mL/min)	59.5 (44.5-80)	52 (34-68)	0.072
NT proBNP (pg/mL)	1940 (863-3342)	1102 (447-2809)	0.13
Pre-procedure ECHO			
Left ventricular ejection fraction (%)	27.5 (20-37.5)	45 (45-55)	< 0.001
EDD (mm)	59 (53-65)	51.5 (47-54)	< 0.001
ESD (mm)	48 (43-55)	38 (33-43)	< 0.001
PASP (mmHg)	55 (40-70)	45 (30-55)	0.021
Mean mitral valve gradient (mmHg)	3 (3.1-6)	4.5 (3.5-6.3)	0.265

Continuous data are presented as median (25^{th}-75^{th} percentiles) and categorical variables as number and percent.
CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; ECHO, electrocardiography; EDD, end-diastolic diameter; ESD, end-systolic diameter; HF; heart failure; ICD, implantable cardioverter-defibrillator; MI, myocardial infarction; MR, mitral regurgitation; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; PCI, percutaneous coronary intervention.

within 1 year, and the duration of hospital stay (Table 3).

Time to event outcomes

The median duration of follow-up was 22 (9-45) months, including 21 (8.5-47.5) months in the FMR patients and 22 (9-30) months in the DMR patients. Survival distributions for mortality and freedom from grade 3+ MR are shown in Figures 1A and B. Twenty-three patients died during the study period. The survival rates were 91.28% at 1 year, 86.39% at 2 years, and 70.8% at 3 years. Severe renal impairment, female gender, and history of stroke decreased survival, whereas discharge diuretics improved survival (Table 4).

Death was a competing risk for recurrent MR. Competing risk regression was done to identify the predictors of grade 3+ MR in the presence of death as a competing factor. Recurrent grade 3+ MR occurred in 35 patients. Moderate residual MR and lower EuroSCORE were predictors of grade 3 MR. Post-procedural beta-blockers protected against recurrent MR (Table 5). The cumulative incidence of recurrent MR is shown in Supplementary Figure 1, and the stacked cumulative incidence of

Table 2. Procedural and postprocedural data

	Functional MR (n = 88)	Degenerative MR (n = 23)	p value
Deployment of two or three clips	28 (32.94%)	9 (42.86%)	0.393
Early post-procedure adverse events			
Aborted procedure	3 (3.4%)	2 (6.7%)	0.276
Tamponade	6 (6.82%)	0	0.341
Stroke	1 (1.14%)	0	> 0.99
New dialysis	3 (3.41%)	1 (4.34%)	> 0.99
30-day mortality	6 (6.82%)	0 (0.0%)	0.341
Residual moderately severe MR	12 (14.6%)	2 (8.7%)	0.730
Early clip detachment (partial)	6 (6.82%)	0	0.341
Discharge medications			
ACE or ARB	67 (76.14%)	13 (56.52%)	0.062
Warfarin	8 (9.09%)	5 (21.74%)	0.138
NOAC	11 (12.50%)	2 (8.70%)	> 0.99
Aspirin alone	21 (23.86%)	6 (26.09%)	0.791
Aspirin dual platelet therapy	59 (67.05%)	12 (52.17%)	0.186
Beta blockers	80 (90.91%)	18 (78.26%)	0.093
Aldosterone antagonist diuretics	48 (54.55%)	3 (13.04%)	< 0.001
Diuretics	78 (88.64%)	17 (73.91 %)	0.073
Length of stay (days)			
Number of days in CCU	2 (1-4)	1 (1-3)	0.136
Post procedure hospital stay	5 (3-6)	4 (2-6)	0.336
Late complications			
Late MVR	2 (2.27%)	1 (4.34%)	0.505
Late Mitral Clip	1 (1.15%)	2 (6.7%)	0.108
Late ICD	9 (10.23%)	0	0.20
Late clip detachment	2 (2.27%)	1 (4.34%)	0.505

Continuous data are presented as median (25^{th}-75^{th} percentiles) and categorical variables as number and percent.
ACE, angiotensin-converting enzyme; ARBs, angiotensin II receptor blockers; CCU, coronary care unit; ICD, implantable cardioverter-defibrillator; MR, mitral regurgitation.

Table 3. Multivariable analysis of predictors of coronary care unit and hospital stay

CCU stay	Coef.	p value	[95% conf.	Interval]
Age	0.028	0.002	0.011	0.046
DMR	-0.954	0.001	-1.505	-0.402
History of MI	-0.343	0.079	-0.726	0.040
Hospital stay				
HF hospitalization	0.441	0.003	0.154	0.728
Preprocedure AF	0.277	0.079	-0.032	0.586
DMR	-0.904	< 0.001	-1.324	-0.483
Age	0.016	0.022	0.002	0.030
Preprocedure EF	0.014	0.064	-0.001	0.029
PASP	-0.006	0.086	-0.013	0.001

AF, atrial fibrillation; CCU, coronary care unit; DMR, degenerative mitral regurgitation; EF, ejection fraction; HF; heart failure; MI, myocardial infarction; PASP, pulmonary artery systolic pressure.

death and recurrent MR is shown in Supplementary Figure 2. The cumulative incidence of MR was lower in the patients with DMR, but without reaching a significant level. The cumulative incidence rates of recurrent grade 3+ MR were 23.11% at 1 year, 34.06% at 2 years, and 41.33% at 3 years.

There was no difference in readmission for heart failure in both groups (log-rank p = 0.59) (Supplementary Figure 3). Thirty patients had readmission for heart failure, and the freedom from readmission for heart failure was 82% at 1 year, 73.1% at 2 years and 67.8% at 3 years.

Correlations between clinical and echocardiographic outcomes

NYHA class improved in the FMR patients (< 0.001) and in the DMR patients (0.001) at last follow-up compared to the baseline value. Twenty-eight (32.94%) patients, including 21 (32.31%) with FMR and 7 (35%) with DMR were in class III/IV at follow-up (Supplementary Figure 4). There were no correlations between NYHA class and PASP (p = 0.896), end-systolic diameter (p =

0.856), and end-diastolic diameter (p = 0.965).

Long-term remodeling

There were significant improvements in left ventricular dimensions, degree of mitral regurgitation, and PASP after MitraClip. However, these changes were not maintained over time (Table 6 and Supplementary Figure 5-7). The changes were not significant in both groups. The grade of MR significantly improved after the procedure (p = 0.001), and there was no significant difference between groups (p = 0.89) (Figure 2).

Table 4. Multivariable predictors of factors affecting survival after MitraClip

Time to death	HR	p value	[95% Conf.	Interval]
Severe renal impairment	2.562	< 0.001	1.564	4.197
Discharge diuretics	0.310	0.024	0.112	0.859
Gender	3.916	0.005	1.503	10.202
History of stroke	5.601	0.029	1.188	26.415
Previous PCI	2.542	0.065	0.945	6.836
Previous CABG	2.060	0.138	0.792	5.362

CABG, coronary artery bypass grafting; HR, hazard ratio; PCI, percutaneous coronary intervention.

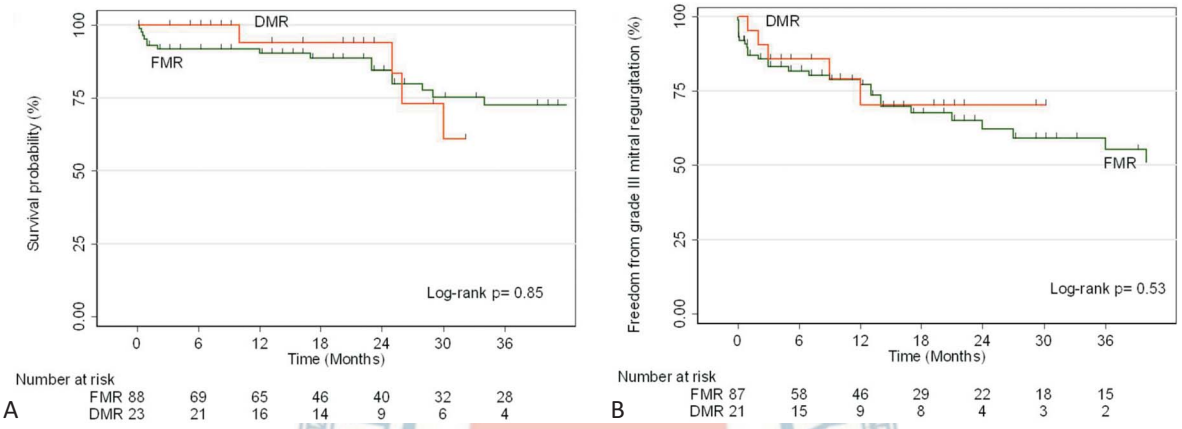

Figure 1. *(A) Survival distribution in patients with functional and degenerative mitral regurgitation after MitraClip. (B) Freedom from grade 3+ mitral regurgitation after MitraClip in both groups. DMR, degenerative mitral regurgitation; FMR, functional mitral regurgitation.*

Table 5. Competing-risks regression of predictors of recurrent mitral regurgitation in the presence of death as a competing risk factor

Time to grade 3+ MR	SHR	p value	[95% conf	Interval]
DMR	0.522	0.376	0.124	2.202
Moderate MR postprocedural	4.116	0.011	1.374	12.330
ES II	0.871	0.013	0.780	0.971
Discharge beta blocker	0.158	0.018	0.034	0.733
Discharge ACEi/ARBs	1.236	0.754	0.330	4.635
Discharge diuretics	1.825	0.520	0.292	11.392
Discharge aldosterone	0.929	0.897	0.303	2.849

ACEi, angiotensin-converting enzyme inhibitors; ARBs, angiotensin receptor blockers; DMR, degenerative mitral regurgitation; ES, EuroSCORE; MR, mitral regurgitation; SHR, sub-distribution hazard ratio.

Table 6. Changes in end-diastolic, end-systolic diameters, and pulmonary artery systolic pressure in both groups during a 2-year follow-up

	Pre-discharge	6 months	1 year	2 years	p value
FMR-EDD (mm)	56.02 ± 8.03	57.73 ± 7.85	58.32 ± 9.91	58.04 ± 9.09	0.68
DMR-EDD (mm)	50.38 ± 8.27	50.29 ± 7.36	52.25 ± 5.97	48.42 ± 5.06	0.34
FMR-ESD (mm)	46.68 ± 9.17	46.18 ± 8.99	46.62 ± 11.91	47.56 ± 10.54	0.33
DMR-ESD (mm)	35 ± 8.53	33.86 ± 7.81	36.11 ± 6.95	36 ± 1.83	0.66
FMR-PASP (mmHg)	45.49 ± 12.88	45.85 ± 15.02	46.52 ± 18.14	51.3 ± 18.78	0.36
DMR-PASP (mmHg)	42.06 ± 11.05	51.25 ± 19.71	56.11 ± 19.97	46.88 ± 19.63	0.13

DMR, degenerative mitral regurgitation; EDD, end-diastolic diameter; ESD, end-systolic diameter; FMR, functional mitral regurgitation; PASP, pulmonary artery systolic pressure.

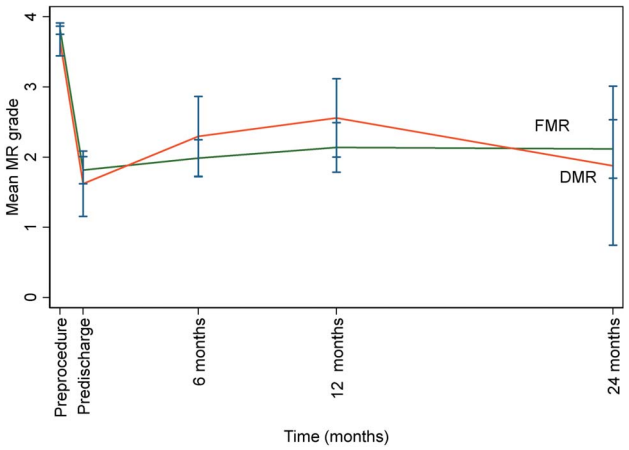

Figure 2. *Changes in the degree of mitral regurgitation after MitraClip. DMR, degenerative mitral regurgitation; FMR, functional mitral regurgitation; MR, mitral regurgitation.*

DISCUSSION

Evidence of the MitraClip procedure and its safety and efficacy in treating severe MR is growing.[14] In this study, we reported the early and late outcomes after transcatheter mitral valve edge-to-edge repair using MitraClip in patients with prohibitive surgical risk and those who deferred surgery. There were marked post-procedural improvements in the degree of MR and NYHA class in a large proportion of the patients. The median EuroSCORE II in both groups was 5.5, which was relatively lower than that reported in several other studies.[7]

The ACCESS-EU[15] registry and SENTINEL[16] study reported the outcomes of MitraClip in patients with FMR. The ACCESS-EU registry (ACCESS-Europe A Two-Phase Observational Study of the MitraClip® System in Europe) enrolled 567 patients, most of whom had FMR and a logistic EuroSCORE of 24.8% with 30-day and 1-year mortality rates of 2.8% and 17%, respectively. At discharge, a reduction of MR to ≤ 2+ was achieved in more than 90% of the patients. The SENTINEL study was conducted across 8 European countries at 25 centers involving 628 patients (72% with FMR) who were treated with MitraClip and reported a procedural mortality rate of 2.9% with an estimated 1-year mortality rate of 15.3%.

The strikingly different findings of the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) trial[17] and MITRA-FR[18] studies raised major questions about the role of MitraClip. Both studies investigated MitraClip plus GDMT versus GDMT alone in patients with FMR. The COAPT study found an overwhelming benefit in the reduction in HF hospitalization and mortality, whereas the MITRA-FR study found no difference between the treatment groups. It was pointed out that the subset of patients enrolled in the COAPT study had more severe MR and less advanced left ventricular disease (dilation/dysfunction) compared with the MITRA-FR study.[19,20]

These findings emphasize the notion that not all FMR is the same, which could explain the discordant results. Differences in selection and timing of enrollment were also present; where the COAPT study only enrolled patients after maximizing GDMT, the MITRA-FR study included patients who continued to undergo changes in medication after enrollment.[1] These findings reinforce the importance of appropriately identifying patients for this procedure and the optimal timing of the intervention, and suggest that further studies are needed to elucidate these factors.

Most previous studies on MitraClip have included patients with FMR only. The EVEREST trial[21] included patients with FMR and DMR and reported significant left ventricular remodeling after 12 months, especially in patients with FMR. In our study, 111 patients were recruited, of whom 79% were diagnosed with FMR and the other 21% with DMR. Most of the FMR patients had a history of myocardial infarction compared to the DMR patients (64.77% vs. 21.74%, respectively). Morbidity and complications after the procedure were comparable between groups. The recurrence of grade 3+ MR was higher in the functional group but did not reach statistical significance; moreover, moderate residual MR post-procedure was found to be an independent risk for future MR reoccurrence. These findings are consistent with previously published data[5,6] and highlight that more than mild residual MR is not satisfactory after MitraClip. Interestingly, beta-blockers at discharge were shown to reduce the recurrence of MR, which, in our opinion, needs further testing. The patients with a lower EuroSCORE had more recurrence of MR, which may be related to better clinical outcomes in the patients with longer survival. This highlights the importance of proper patient selection, since patients with expected better survival will suffer from recurrent MR.

Angiotensin converting enzyme inhibitors/angiotensin II receptors blockers (ACEI/ARBS) were used in

72% of the patients and aldosterone antagonists in 45% post-procedure because of the high incidence of moderate and severe renal impairment in our cohort (n = 88; 79.3%). Keeping in mind the mandatory need for these medications in this group of patients and their effects on left ventricular remodeling,[22-24] the lack of these drugs in this cohort could explain the pattern of the changes in left ventricular dimensions during follow-up.

Severe renal impairment, female gender, and history of stroke negatively affected survival in our cohort. In a multicenter study, the predictors of in-hospital mortality after MitraClip were heart failure, blood transfusion, stroke, endocarditis, pulmonary embolism, pericardial tamponade, and effusion.[7] Immediately post-procedure, the echocardiographic outcomes, end-systolic diameter, and end-diastolic diameter were statistically significantly reduced as well as the PASP, however this significant reduction was not sustained over the follow-up period. About 31% of the patients in our cohort had residual or recurrent grade 3+ MR. This relatively high recurrent rate can explain the non-sustained effect of the MitraClip procedure on the left ventricular negative remodeling dimensions. Interestingly, these negative findings were not reflected in the symptomatic clinical improvement (67% remained in NYHA class I-II).

The success of MitraClip has prompted the development of newer percutaneous therapies such as the CardioBand[25] and Carillion Mitral Contour systems[26] with the hopes of improving management and health outcomes of these complex patients with limited current treatment options.

Study limitations

Despite our technical success, limitations of the study include its retrospective nature and limited sample size. Although it would be interesting to compare our MitraClip patients with medically or surgically managed patients, we did not have access to relevant data. Additionally, the study reported the experience from a single center, and further studies are warranted before generalization of the results.

CONCLUSIONS

The MitraClip procedure was positive in terms of sustainable symptomatic relief. However, this finding was not reflected completely in left ventricular dimensions over long-term follow-up. The technique was equally effective in patients with both functional and degenerative mitral valve regurgitation.

CONFLICT OF INTEREST

All the authors declare no conflict of interest.

FUNDING

None.

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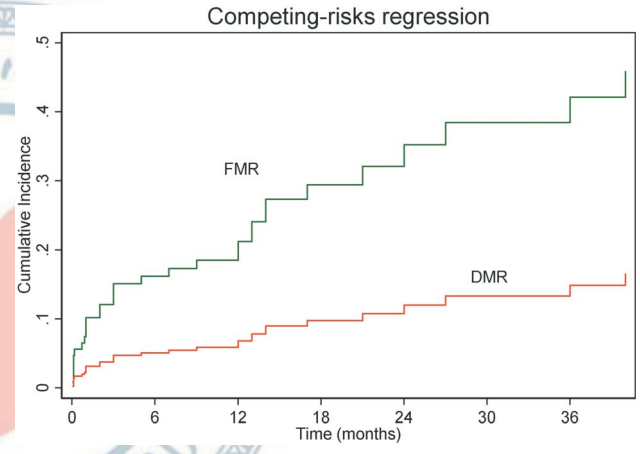
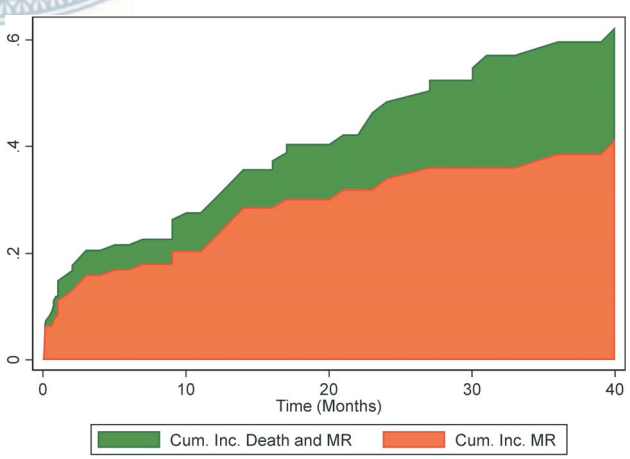
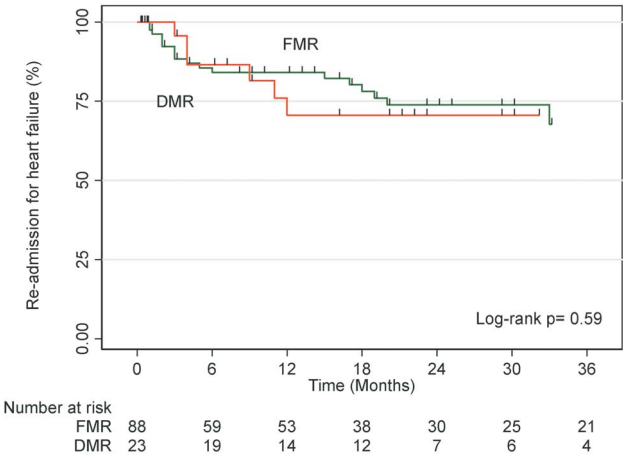
SUPPLEMENT



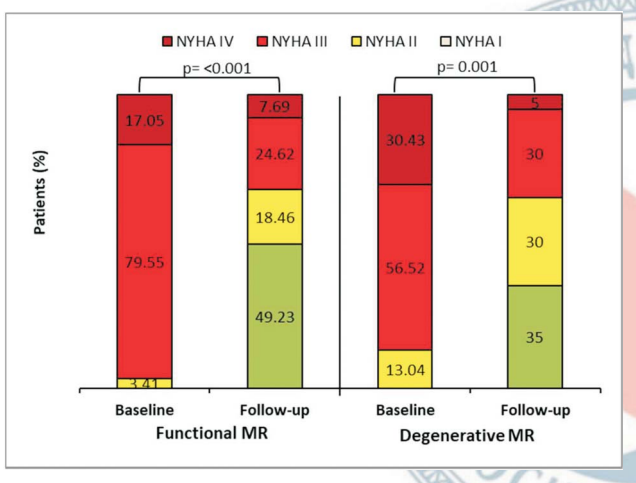
Supplementary Figure 1. *Cumulative incidence of recurrent mitral regurgitation in patients with functional and degenerative mitral regurgitation. DMR, degenerative mitral regurgitation; FMR, functional mitral regurgitation.*



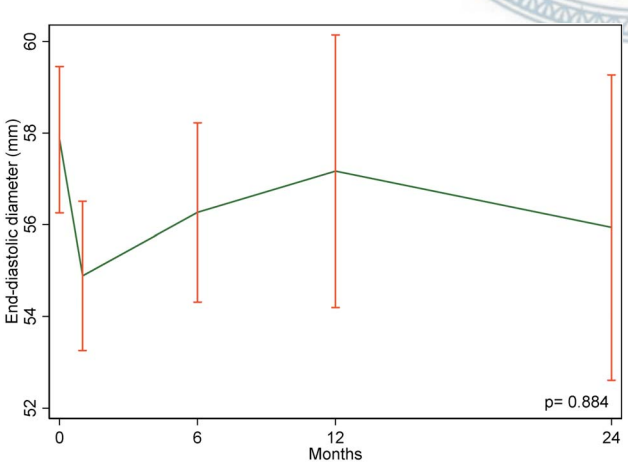
Supplementary Figure 2. *Stacked cumulative incidence of death and recurrent mitral regurgitation (MR) in all patients.*



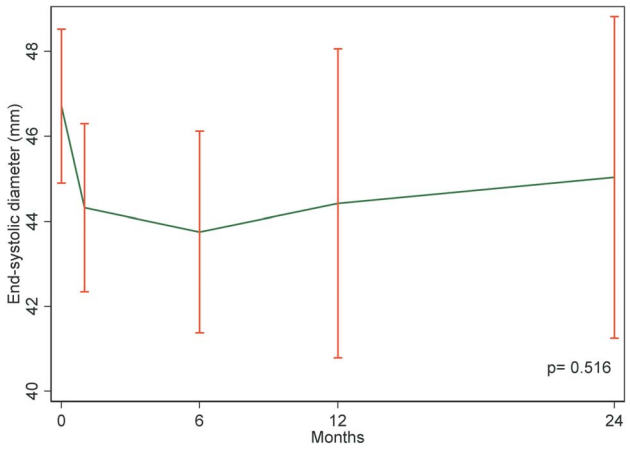
Supplementary Figure 3. *Kaplan Meier curve for readmission for heart failure in patients with functional and degenerative mitral regurgitation. DMR, degenerative mitral regurgitation; FMR, functional mitral regurgitation.*



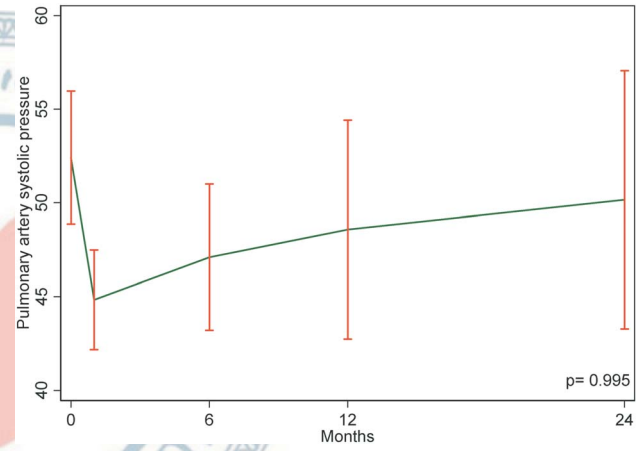
Supplementary Figure 4. *The changes in NYHA functional class at the last follow-up in both groups.*



Supplementary Figure 5. *Changes in end-diastolic dimensions in all patients during a 2-year follow-up.*



Supplementary Figure 6. *Changes in end-systolic dimensions in all patients during a 2-year follow-up.*



Supplementary Figure 7. *Changes in pulmonary artery systolic pressure in all patients during a 2-year follow-up.*