

Clinical Outcomes of Percutaneous Mitral Valve Repair with Mitraclip®: A Longitudinal Observational Study (The Mitra-Angio-CDO Study)

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Background: The MitraClip device is used as an endovascular therapy for mitral valve repair in patients with severe mitral insufficiency and high surgical risk. This therapy was used for the first time in Colombia in 2013, after its authorization by the National Institute of Drug and Food Surveillance.

Materials and Methods: A quantitative, observational, descriptive, longitudinal study was conducted, with an analytical component stratified by age, in adults who underwent mitral valve repair with MitraClip from March 2013 to June 2022 to determine the clinical outcomes associated with hospitalization, mortality, complications, and health-related quality of life.

Results: A total of 94 patients with a mean age of 70.3±10.3 years were evaluated, most of whom were male (65%), hypertensive (80%), and had New York Heart Association class III–IV classification (90.4%) and functional mitral insufficiency (93.6%) classified as severe (74.5%). The recurrence of all-cause hospitalization was 39.4%, of which 88% corresponded to heart failure. The immediate success of the procedure, determined as mitral insufficiency classified as ≤moderate after implantation, was 93.6% ($p < 0.001$). In-hospital mortality was 2.1%, mortality at 6 months was 12.8% (≤70 years 11.6% vs >70 years 13.7%, $p = 0.007$), mortality at 1 year was 16%, and mortality at 2 years was 20.2%. The incidence of complications was low, the most frequent one being *de novo* atrial fibrillation (7.4%), followed by major bleeding requiring transfusion (4.3%). The Kansas City Cardiomyopathy Questionnaire scale was used, with a mean score of 69.9±19.3.

Conclusion: Percutaneous mitral valve repair with MitraClip is a safe technique that directly affects survival and quality of life. There was a low incidence of complications related to the procedure and the patient's preoperative condition, with results comparable to those of studies carried out in Europe and the United States.

Keywords: heart failure, severe mitral insufficiency, percutaneous mitral valve repair, survival, quality of life. (source: MeSH)

Introduction

Mitral insufficiency (MI) is a heart disease in which the mitral valve does not close properly, resulting in backflow of blood or regurgitation from the left ventricle into the left atrium during ventricular contraction.¹ Mitral regurgitation (MR) leads to volume overload in the atrium, which can cause symptoms such as respiratory distress, fatigue, and impaired cardiac function.² MI affects approximately 2% of the global population³ and is considered the most common valve abnormality in the United States and the second most common in Europe, with its prevalence increasing progressively with age.⁴ The RECOLFACA study determined that 13.1% of the causes of heart failure in Colombia are associated with the valve.⁵

MitraClip is a percutaneous device designed for the treatment of MI,⁵ and consists of a clamp system that is placed on the mitral valve, allowing for partial closure of the valve leaflets and thus reducing blood regurgitation.^{6,7} Transcatheter edge-to-edge repair (TEER) therapy for MR was developed in the late 1990s, mimicking the surgical Alfieri technique. Following extensive clinical trials demonstrating its safety and efficacy (such as EVEREST), the MitraClip system has evolved through several generations to enhance procedural success even in challenging anatomies. The latest generation, the MitraClip G4 system, offers a more tailored approach by featuring four clip sizes (NT, XT, NTW, and XTW), based on two different arm lengths and two widths. This advanced design enables the independent grasping of the anterior and posterior mitral leaflets, a feature intended to increase the success rate. Furthermore, the G4 system is equipped with a fluid-filled pressure monitoring system in the steerable guide catheter to measure real-time hemodynamics during the procedure, facilitating an easier and safer approach for treating both degenerative MR (DMR) and functional MR (FMR).⁸

The use of MitraClip has been extensively described and studied in randomized clinical trials^{9–11} and several multicenter observational registries.^{12–18} These investigations have demonstrated the benefits, efficacy, and safety of this procedure in patients with severe MI, as well as significant improvements in their symptoms, quality of life, and cardiac function.^{12,15,19–21} In addition, decreased hospitalization rates for heart failure and increased long-term survival rates have been observed.^{9,12,15,21,22} In Latin America²³ and Colombia,⁷ there is some clinical data on the use of MitraClip, but studies in this region are still limited.

The literature supporting the MitraClip procedure is predominantly derived from Western cohorts through randomized trials and multinational registries,^{1–4} establishing robust standards for safety and efficacy.^{5,6} However, the optimal application and outcomes of this therapy in the Colombian and broader Latin American population are not yet fully defined, given potential regional differences in patient demographics, underlying heart failure etiologies, and comorbidity patterns.⁷ For instance, local epidemiological data from the RECOLFACA study highlighted that 13.1% of heart failure cases in Colombia are attributable to valvular disease,^{8,9} a finding that suggests unique local disease characteristics that may influence treatment responses compared to the patient profiles included in major international trials.¹⁰ Therefore, validating the long-term safety, complications, and effectiveness of percutaneous mitral valve repair with MitraClip in a significant cohort of Colombian patients is essential to ensure appropriate implementation aligned with local healthcare needs.^{7,11}

Therefore, this study aimed to evaluate the clinical outcomes of hospitalization, mortality, complications, and health-related quality of life in patients who underwent percutaneous mitral valve repair with MitraClip in a high-complexity institution in Santiago de Cali, Colombia.

Materials and Methods

This quantitative, observational, descriptive, longitudinal study, with an analytical component stratified by age, included patients who underwent MitraClip surgery at Angiografía de Occidente and Clínica de Occidente in Cali, Colombia. The data were collected from 95 individuals between March 1, 2013, and June 30, 2022; only 1 individual was excluded due to incomplete data.

Patients' medical records (medical history and laboratory and echocardiographic reports) were reviewed, and the data were recorded according to the established research variables. Each individual was assigned an identification code to maintain confidentiality, which was entered into a Microsoft Excel[®] sheet designed for this purpose. Kaplan–Meyer curves were built with Real Statistics[®] 8.7 software to evaluate survival after 6 months, 1 year, and 2 years, comparing by age in order to generate a robust comparative analysis of outcomes among older adults, left ventricular ejection fraction (LVEF) calculated by 2D biplane Simpson's method and intervention group. Outcomes associated with hospitalization and all-cause mortality 2 years after the procedure were analyzed, as well as the associated complications.

In addition, the Kansas City Cardiomyopathy Questionnaire (KCCQ),²⁴ validated in Spain²⁵ and Mexico,²⁶ was applied 6 months after the procedure in the surviving population ($n = 55/58.5\%$).

The descriptive analysis was conducted with age stratification (≤ 70 years and > 70 years). For the qualitative variables, absolute and percentage frequencies were calculated, while mean and standard deviation values were calculated for the quantitative variables. In addition, an analysis of the intervention group (the first 50 patients who underwent the intervention and a second group of patients) was conducted to assess the experience curve, spanning the four generations of devices.

The presence of statistically significant differences between the exposure prevalence of qualitative variables was evaluated using the Chi² test.

Statistical Analysis

The study employed specific statistical methods to evaluate clinical outcomes, complementing its quantitative, observational, descriptive, and longitudinal design with an analytical component stratified by age.

Kaplan–Meyer curves were constructed to assess patient survival at 6 months, 1 year, and 2 years following the MitraClip procedure. This evaluation specifically included comparisons stratified by age, LVEF, and intervention group.

For assessing statistically significant differences between the exposure prevalence of qualitative variables, the Chi² test was utilized. Comparisons of mean values between groups were determined using the Student's *t* test.

To estimate the effect of the MitraClip intervention in terms of reducing the severity of MI, Cohen's *d* was applied. The effect size interpretation for Cohen's *d* was predefined using cut-off values: small effect (0.20), medium effect (0.50), and large effect (0.80).

The analysis employed JASP statistical software, while other statistical analyses were performed using STATA 17.0[®] software. Statistical significance for all tests was established when the *p*-value was less than 0.05 (*p* < 0.05).

Our study was approved by the technical scientific committee of the clinical institution and the Ethics and Bioethics Committee of the School of Health of Universidad Santiago de Cali (Record No. 04–2023), considering it a risk-free investigation. In addition, the ethical principles established by the Declaration of Helsinki and the principles of confidentiality were followed. According to Colombian Ministry of Health Resolution 8430 of 1993, non-risk research collecting data from clinical records does not require informed consent.

Results

During the observation period, 94 percutaneous mitral valve repairs were performed with MitraClip. Table 1 shows the sociodemographic characteristics of the patients with an analytical approach stratified by age. The mean age was 70.3 ± 10.3 years; about 65% were men, and their main comorbidities were arterial hypertension (HBP) (79.8%), atrial fibrillation (AF) (35.1%), and heart failure (60.6%). We found that the younger group presented significantly more cases of heart failure (≤ 70 years 74.4% vs > 70 years 57%, *p* = 0.012).

Table 1 Sociodemographic Characteristics of Patients Undergoing Mitraclip Implantation

Characteristics	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total		P value
	n	%	n	%	n	%	
Gender							0.695
Female	16	37.2	17	33.3	33	35.1	
Male	27	62.8	34	66.7	61	64.9	
Affiliation system							0.570
Contributive	38	88.4	43	84.3	81	86.2	
Subsidized	4	9.3	1	2	5	5.3	
Other	1	2.3	7	13.7	8	8.5	0.048
Socioeconomic stratum							0.511
Stratum 1	3	7	2	3.9	5	5.3	
Stratum 2	14	32.5	5	9.8	19	20.2	
Stratum 3	11	25.6	20	39.2	31	33	
Stratum 4	11	25.6	10	19.6	21	22.3	
Stratum 5	4	9.3	10	19.6	14	14.9	
Stratum 6	0	0	4	7.9	4	4.3	–

(Continued)

Table 1 (Continued).

Characteristics	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total		P value
	n	%	n	%	n	%	
Comorbidities							
Arterial hypertension	33	76.7	42	82.4	75	79.8	0.500
Heart failure	32	74.4	25	49	57	60.6	0.012
Atrial fibrillation	13	30.2	20	39.2	33	35.1	0.363
Ischemic heart disease	9	20.9	19	37.3	28	29.8	0.085
Hypothyroidism	12	27.9	9	17.6	21	22.3	0.234
Dyslipidemia	8	18.6	10	19.6	18	19.1	0.902
Chronic kidney disease	8	18.6	13	25.5	21	22.3	0.425
Type II diabetes mellitus	6	14	15	29.4	21	22.3	0.073
Other	8	18.6	20	39.2	28	29.8	0.073
Cardiovascular surgical history							
Stent angioplasty	13	30.2	24	47.1	37	39.4	0.096
Arteriogram coronary	14	32.6	10	19.6	24	25.5	0.151
Myocardial revascularization	3	7	15	29.4	18	19.1	0.006
Pacemaker	7	16.3	8	15.7	15	16	0.938
ICD–CRT	7	16.3	3	5.9	10	10.6	0.232
Valve replacement	1	2.3	5	9.8	6	6.4	0.140
None	7	16.3	5	9.8	12	12.8	0.349

Abbreviations: ICD, Implantable cardioverter–defibrillator; CRT, Cardiac resynchronization therapy.

Moreover, 58.5% of subjects had previous ischemic heart disease, 39.4% had undergone endovascular management, and 19.1% had undergone myocardial revascularization surgery (MRS). When comparing by age, older patients had a higher prevalence of surgical management (≤ 70 years 7% vs > 70 years 29.4%, $p = 0.006$). In addition, 26.6% had an implanted electrical stimulation device (pacemaker 16%, cardioverter–defibrillator 10.6%).

Table 2 shows patients' cardiovascular and laboratory characteristics. More than 90% of individuals had MI of functional etiology, 69 of which were considered severe (73.4%). When comparing MI severity in the 2 groups, we found that the number of severe MI cases was higher in individuals under 70 years of age compared to the older ones, and this difference was statistically significant (≤ 70 years 83.7% vs > 70 years 64.7%, $p = 0.038$).

Table 2 Cardiovascular and Laboratory Clinical Characteristics of Patients Undergoing Mitraclip Implantation

Characteristics	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total		P value
	n	%	n	%	n	%	
Cardiovascular parameters							
NYHA							
I	1	2.3	0	0	1	1.1	—
II	4	9.3	4	7.8	8	8.5	0.801
III	23	53.5	39	76.5	62	66	0.019
IV	15	34.9	8	15.7	23	24.4	0.031
LVEF							
≤40%	40	93	38	74.5	78	83	0.026
41–49%	1	2.3	10	19.6	11	11.7	0.009
≥50%	2	4.7	3	5.9	5	5.3	0.877
Mean (SD)	25% (10%)		34% (11%)		30% (12%)		0.000

(Continued)

Table 2 (Continued).

Characteristics	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total		P value
	n	%	n	%	n	%	
Mitral insufficiency etiology							
Functional	42	97.7	46	90.2	88	93.6	0.140
Degenerative	1	2.3	5	9.8	6	6.4	
Cause of heart disease							
Ischemic	10	23.3	20	39.2	30	31.9	0.098
No Ischemic							
Valve-related	22	51.1	23	45.1	45	47.9	0.558
Hypertensive	8	18.6	3	5.9	11	11.7	
Tachycardia-induced cardiomyopathy	3	7	5	9.8	8	8.5	0.625
Mitral insufficiency severity							
Mild	0	0	1	2	1	1.1	-
Moderate	0	0	2	3.9	2	2.1	-
Moderate to severe	7	16.3	15	29.4	22	23.4	0.134
Severe	36	83.7	33	64.7	69	73.4	0.038
Laboratory tests	Mean	SD	Mean	SD	Mean	SD	
Before surgery							
Hemoglobin, g/dL	12.9	1.9	12.2	1.6	12.5	1.77	0.059
Platelets, 10 ³ /mm ³	219	120	228	85	224	102	0.681
Sodium, mEq/L	139	3.9	140.2	3.5	139.7	3.7	0.123
Potassium, mEq/L	4.07	0.57	4.01	0.46	4.04	0.51	0.581
Creatinine, mg/dL	1.44	1.54	1.23	0.44	1.32	1.09	0.391
TSH (n = 28/30), mU/L	2.65	5.70	1.13	2.51	1.83	4.32	0.202
TPT (n = 38/50), seconds	28.9	13.9	34.6	17.2	32	16	0.089
TP, seconds	12.9	7.9	13.6	4.3	13.3	6.2	0.624
INR	1.12	0.6	1.18	0.3	1.15	0.4	0.574
After surgery							
Lactate (n = 41/50), mmol/L	1.69	1.01	1.55	0.75	1.62	0.88	0.464
Acid-base disorders (n = 41/50)	n	%	n	%	n	%	
Metabolic acidosis	11	26.8	14	28	25	27.5	0.901
Respiratory alkalosis	15	36.6	20	40	35	38.5	0.739
Mixed disorder	5	12.2	6	12	11	12	0.977
Normal	10	24.4	10	20	20	22	0.615
Oxygenation disorders							
Mild	8	19.5	17	34	25	27.5	0.123
Moderate	1	2.4	2	4	3	3.3	0.678
Normal	32	78.1	31	62	63	69.2	0.099

Abbreviations: NYHA, New York Heart Association; LVEF, Left ventricular ejection fraction; SD, Standard deviation; TSH, Thyroid stimulating hormone; TPT, Thromboplastin partial time; TP, Prothrombin time; INR, International normalized ratio.

In terms of heart failure stage, 66% were classified as New York Heart Association (NYHA) class III and 24% as NYHA class IV. Considering age stratification, NYHA class III accounted for 53.5% of cases in individuals younger than 70, whereas it accounted for 76.5% in individuals older than 70 years ($p = 0.019$). In addition, NYHA class IV was 34.9% vs 15.7% ($p = 0.031$) for both age groups, respectively. Left ventricular function was mildly reduced (LVEF $<50\%$) in 95.7% of patients, and 83.9% exhibited reduced LVEF ($\leq 40\%$). When comparing both groups, the percentage corresponding to the younger population was 93% as opposed to 76% in those older than 70 years ($p = 0.026$). Slightly decreased LVEF was observed in 11.8% of patients (≤ 70 years 2.3% vs >70 years 20%, $p = 0.009$), and the mean LVEF was lower in the younger group (25%) than in the older group (34%) ($p = 0.000$).

A sub analysis of patients aged ≤ 70 years was conducted. Of the 43 individuals, we found that 18 (41.9%) were between 65 and 70 years old, and their most frequent condition was dilated cardiomyopathy and depressed LVEF (with an average of 27%). At the same time, 14 patients (77.8%) required LVEF $\leq 30\%$ and were classified with severe MI, which clarifies the aforementioned data.

All-cause hospitalization (Table 3) was 39.4% (≤ 70 years 46.5% vs >70 years 33.3%, $p = 0.193$). Based on this percentage, the hospitalization rate associated with cardiovascular conditions was 67.6% (≤ 70 years 30.2% vs >70 years 23.5%, $p = 0.717$), of which hospitalization due to heart failure was 88% (≤ 70 years 84.6% vs >70 years 91.7%, $p = 0.588$).

Figure 1 shows the degree of severity of MI before and after the procedure. When determining the decrease in severity after the procedure, we found that of the 73.5% of patients classified as severe, 71% were reclassified as mild, and 20.3% as moderate. Similarly, of the 23.4% of individuals who had moderate to severe MI prior to implantation, 86.4% were reclassified as mild and 13.6% as moderate after the procedure. Based on these results, the effectiveness of the procedure was 93.6%. Regarding the mean difference analysis conducted before (3.69 standard deviation [SD] ± 0.56) and after (1.35 SD ± 0.69) the procedure, the effect of the intervention was classified as medium (Cohen's $d = 2.79$; 95% confidence interval: 2.34–3.24; $p < 0.001$).

In-hospital all-cause mortality was 2.1%, and mortality at 30 days was 3.2%. Likewise, all-cause mortality was 12.8% at 6 months, 16% after 1 year, and 20.2% after 2 years (Figure 2). Age-stratified mortality (Figure 3) after 6 months was 11.6% in the younger group and 13.7% in the older group ($p = 0.007$). Mortality at 1 year was 14% in the younger group and 18% in the older group ($p = 0.083$), while mortality at 2 years was very similar in both groups: 20.9% and 19.6% ($p = 0.837$).

A subgroup analysis was performed according to the intervention date to evaluate mortality and its association with the experience curve (Figure 4). The cohort was thus divided into 2 groups: the first 50 patients to undergo the intervention (group A), and the remaining 44 patients intervened up to June 30, 2022 (group B). It is worth clarifying that during the observation period, the four generations of MitraClip devices developed by the parent company (Abbott) were used and that more advanced equipment was used with the second group of patients. As a consequence, mortality was lower in group B after 6 months (A: 14% vs B: 11.6%, $p = 0.125$), after 1 year (A: 18% vs B: 13.6%, $p = 0.729$), and after 2 years (A: 24% vs B: 18.2%, $p = 0.475$).

Complications related to the procedure and implantation were analyzed, as described in Table 4, and were stratified by age. *De novo* AF was evidenced in the first 7 days in 7.4% of cases, major bleeding requiring transfusion occurred in 4.3% of patients, and soft tissue hematomas were also evidenced in 4.3% of cases, all of them in the first group to receive the intervention since percutaneous closure was not performed in the venotomy. Decompensated heart failure occurred in 2.1% of patients (acute pulmonary edema) in the immediate postoperative period. No cases of acute myocardial infarction, cardiac tamponade, displacement of pacemaker leads, or endocarditis were reported.

Table 3 Clinical Outcomes 2 Years After Mitraclip Implantation

Characteristics	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total (n = 94)		P value
	n	%	n	%	n	%	
All-cause hospitalization	20	46.5	17	33.3	37	39.4	0.193
Cardiovascular cause	13	30.2	12	23.5	25	67.6	0.717
- Associated with heart failure	11	84.6	11	91.7	22	88	0.588
- Not associated with heart failure	2	15.4	1	8.3	3	12	
Non-cardiovascular cause	7	16.3	5	9.8	12	32.4	
All-cause mortality	9	20.9	10	19.6	19	20.2	0.874
Cardiovascular cause	6	14	4	7.8	10	56.6	0.245
Associated with heart failure	5	83.3	1	25	6	60	0.065
Not associated with heart failure	1	16.7	3	75	4	40	
Non-cardiovascular cause	3	6.9	6	11.8	9	47.4	

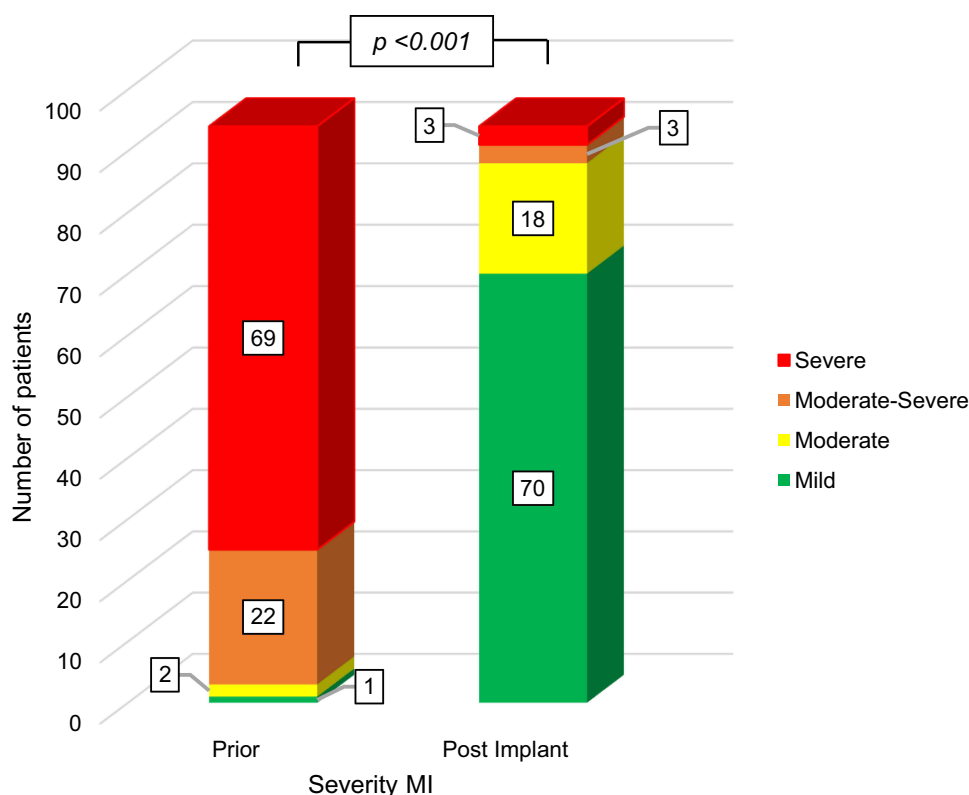


Figure 1 Mitral regurgitation severity before vs after mitralclip implantation. This bar chart shows the number of patients classified by severity of mitral regurgitation (Mild, Moderate, Moderate to Severe, Severe) before and after MitraClip implantation, including a p-value indicating the statistical significance of the change in MR severity.

When assessing the complications related to implantation, there were two cases of unsuccessful procedures: a partial tear of the leaflets and relevant residual mitral stenosis, both of them being predominantly found in the older group. There was one case of single leaflet device attachment, which was corrected immediately. There were no MitraClip embolizations or need for cardiac surgery during the first 30 days.

Furthermore, 2 cases of in-hospital mortality before 30 days were reported: one case was due to late partial tearing of the valve leaflets after successful implantation, which required a second intervention, thus increasing the degree of tearing when a second clip was placed. As a result, the patient developed acute pulmonary edema and died in the intensive care unit (ICU) 24 hours after surgery. In the second case, the procedure was performed successfully, and warfarin was administered as an anticoagulant because the patient had AF. As a result, the patient developed over-anticoagulation with warfarin and a subsequent massive retroperitoneal hematoma, resulting in multiple organ dysfunction and death due to severe anemia.

To correct mitral regurgitation, 57.5% of the patients required the implantation of one clip, 40.4% required 2 clips, and only 2 cases required 3 clips (2.1%), with an average use of 1.4 clips (Table 5). The average ICU stay was 2.24 ± 1.67 days, the average number of days requiring vasoactive support was 1.11 ± 1.77 days, and the vasoactive drugs most frequently used were norepinephrine (50%), milrinone (43.5%), and nitroglycerin (28.2%), with no statistical significance being observed in the comparison groups.

The quality-of-life analysis performed with the KCCQ scale 6 months after the procedure was applied to 55 patients (58.5%), with an overall score of 69.9 ± 19.3 , suggesting a good quality of life. Figure 5 outlines the data of the different domains of the questionnaire.

Discussion

This observational study is one of the first of its kind in Colombia and South America and includes 9 years of experience in mitral valve repair with MitraClip in patients with severe MI. A total of 94 complete records of individuals who underwent the intervention between March 2013 and June 2022 were included.

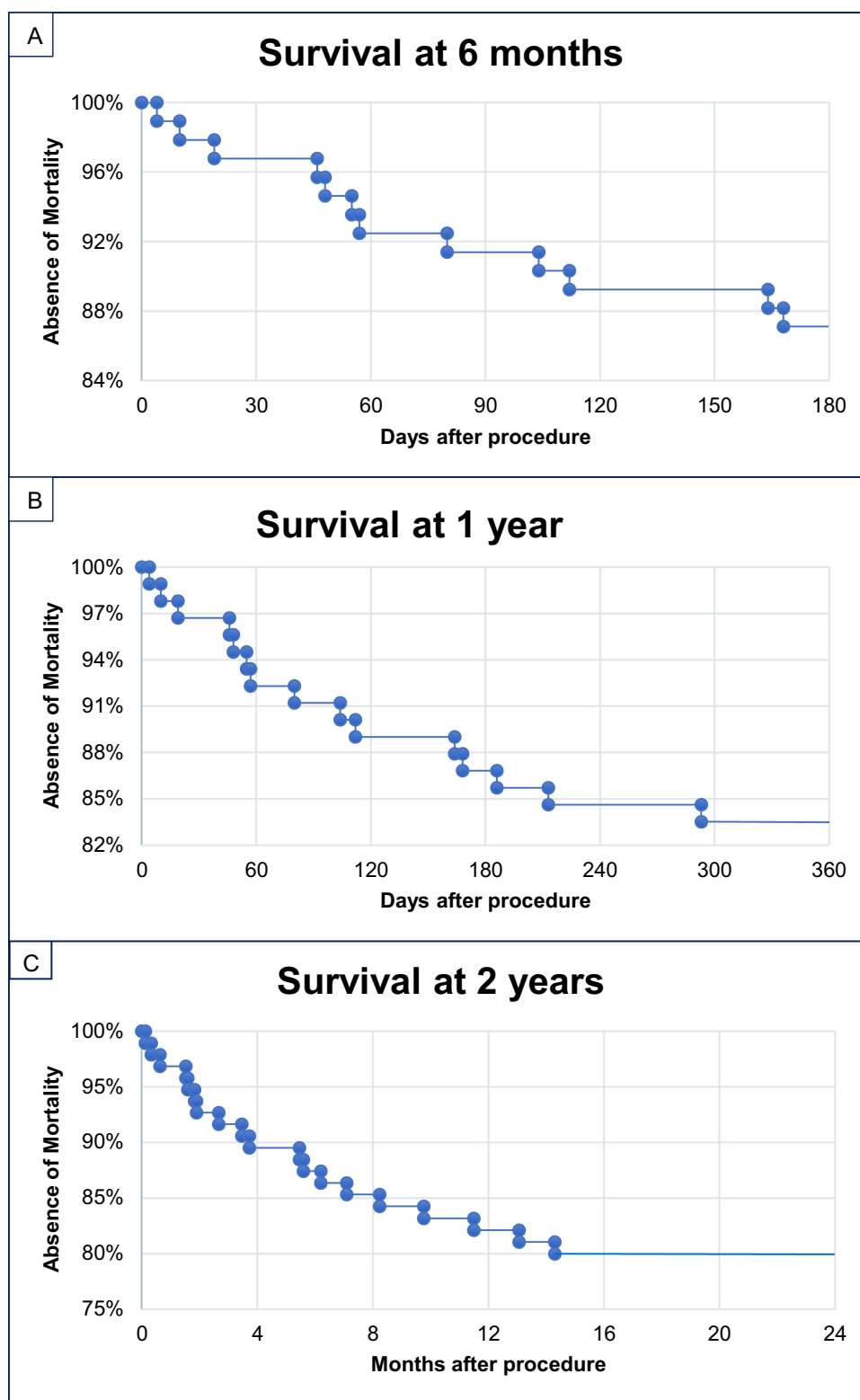


Figure 2 Survival at 6 months, 1 year, and 2 years. This figure shows the overall survival curves of patients following the MitraClip procedure at 6 months (**A**) 1 year (**B**) and 2 years (**C**).

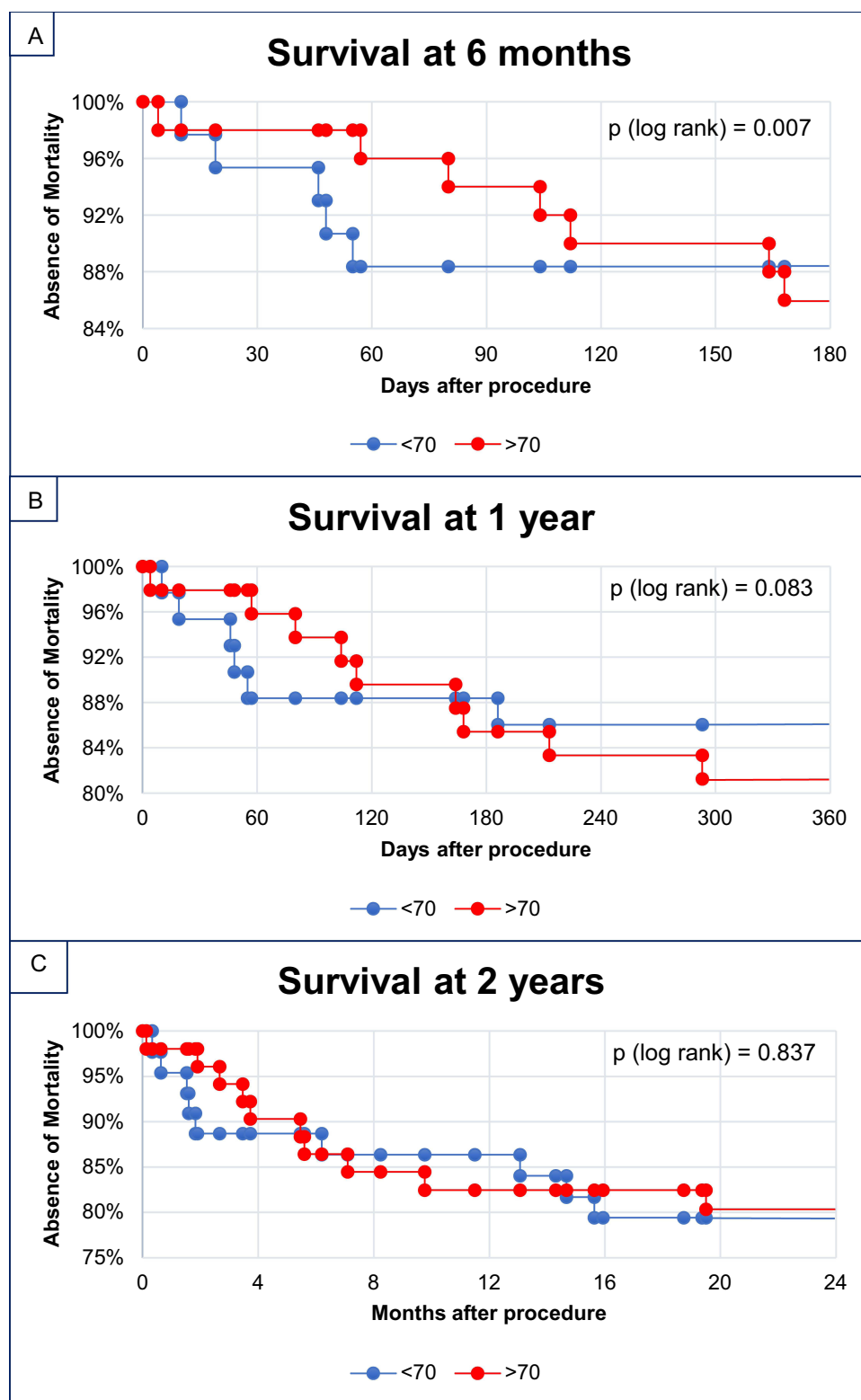


Figure 3 Survival at 6 months, 1 year, and 2 years by age. This figure presents survival curves stratified by age (<70 years and >70 years) at 6 months (A) 1 year (B) and 2 years (C) after MitraClip implantation, along with p-values (Log rank test) indicating the statistical significance of differences between age groups at each time point.

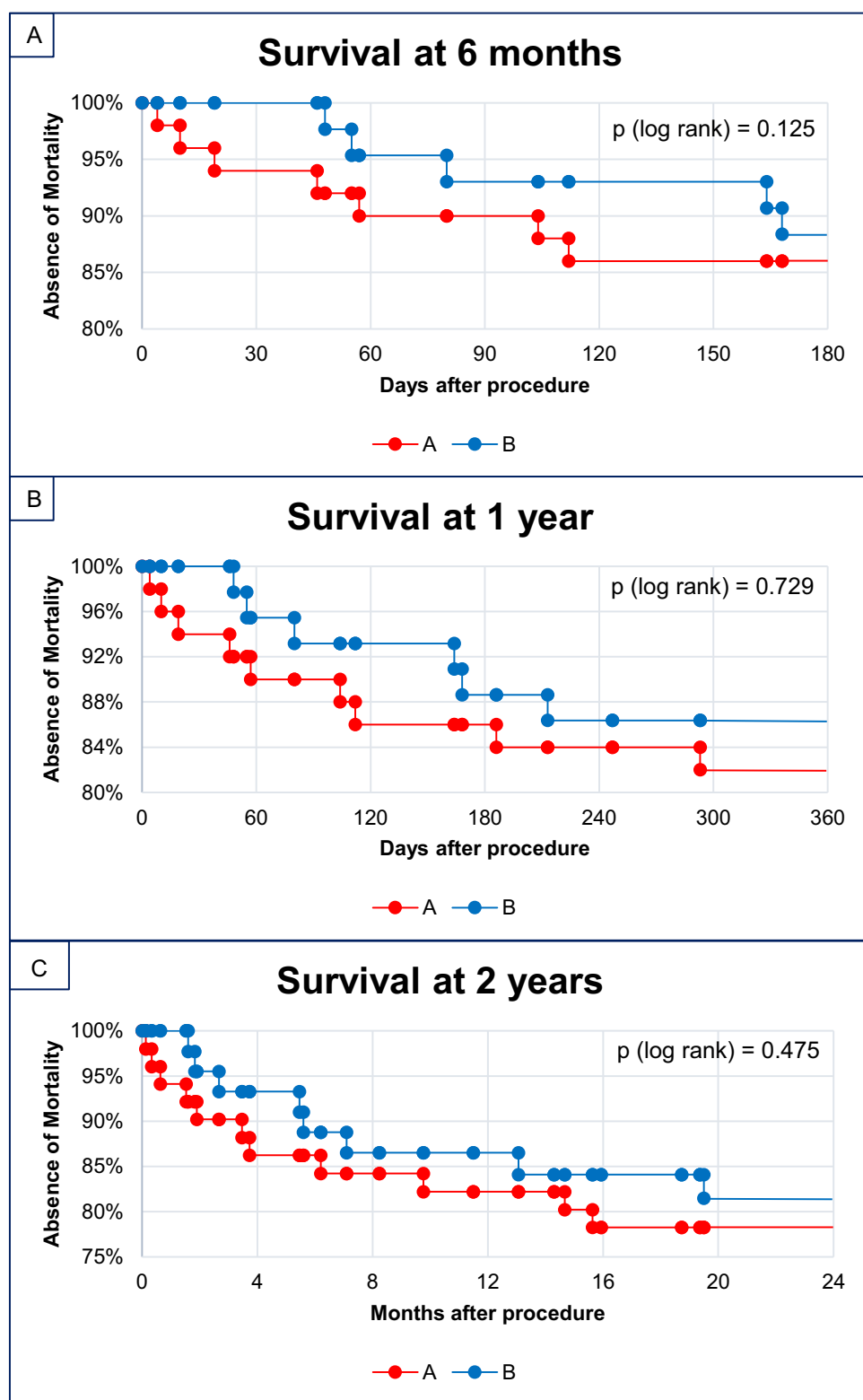


Figure 4 Survival at 6 months, 1 year, and 2 years by intervention group. This figure compares survival curves at 6 months (A) 1 year (B) and 2 years (C) between the two intervention groups (the first 50 patients and the subsequent 44 patients treated up to June 2022), also showing p-values (Log rank test) for each period.

Table 4 Complications Associated with Mitraclip Implantation

Complication	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total (n = 94)		P value
	n	%	n	%	n	%	
In-hospital death at 30 days	1	2.3	1	2	2	2.1	0.903
Cardiopulmonary resuscitation	1	2.3	0	0	1	1.1	-
De novo atrial fibrillation	1	2.3	6	11.8	7	7.4	0.082
Acute kidney injury	1	2.3	1	2	2	2.1	0.903
Major bleed requiring blood transfusion	1	2.3	3	5.9	4	4.3	0.395
Major vascular complication	1	2.3	1	2	2	2.1	0.903
Pulmonary embolism	1	2.3	0	0	1	1.1	-
Cerebrovascular accident	0	0	1	2	1	1.1	-
Other	3	7	6	11.8	9	9.6	0.432

Table 5 Number of Implanted Clips and Intensive Care Unit (ICU) Stay

Number of Implanted Clips	Age ≤ 70 Years (n = 43)		Age > 70 Years (n = 51)		Total (n = 94)		P value
	n	%	n	%	n	%	
One	25	58.1	29	56.9	54	57.5	0.901
Two	18	41.9	20	39.2	38	40.4	0.795
Three	0	0	2	3.9	2	2.1	-
ICU stay	Mean	SD	Mean	SD	Mean	SD	
Stay (days)	1.98	1.15	2.45	1.77	2.24	1.67	0.125
Days on vasoactive drugs	0.84	1.27	1.33	2.09	1.11	1.77	0.161
Drug administered	n (19)	%	n (27)	%	n (46)	%	
Norepinephrine	7	36.8	16	59.3	23	50	0.134
Vasopressin	1	5.3	3	11.1	4	8.7	0.488
Milrinone	8	42.1	12	44.4	20	43.5	0.875
Levosimendan	2	10.5	2	7.4	4	8.7	0.712
Dobutamine	1	5.3	2	7.4	3	6.5	0.772
Nitroglycerin	6	31.6	7	25.9	13	28.2	0.675
Nitroprusside	3	15.8	1	3.7	4	8.7	0.152
Amiodarone	1	5.3	3	11.1	4	8.7	0.488

The average age of our study population was 70.3 ± 10.3 years, which was similar to the average age in the COAPT and MITRA FR studies,^{9,10} as was the predominant gender (65% male). Although patients' history of HBP (79.8%) and AF (35.1%) was similar to the one reported in several analyses,^{9,11,13,16–18} with some exceptions, patients' history of coronary artery disease (29.8%), MRS (19.1%), and heart failure (60.6%) were strikingly inconsistent with the values reported up to the present time. Reports of coronary disease range from 47% to 78.5%,^{10,11,13,15,18} while our findings are similar to those of the Sentinel study, which reported 30.9%. Regarding MVR surgery, the literature also reports higher values, ranging from 28.9% to 46.7%,^{9,10,12,15–17} while our records are similar to those of Grasso (19%), Sünder (20.4%), and Withlow (20.7%).^{11,13,18} Regarding heart failure, the ACCESS EU and EVEREST II trials reported 70.1% and 90.8%, respectively.

Of the individuals in our registry, 90.4% had NYHA class III and IV, which is consistent with the results of the TRAMI study, which reported 93%.¹⁵ Other relevant studies reported values between 51.1% and 85.5% for NYHA class III and IV, respectively.^{9–13,16–18} Furthermore, 89% of our study individuals had LVEF $\leq 50\%$, whereas this percentage was 71% and 35.4% in the studies conducted by Eggebrecht and Sorajja, respectively. These results could be somewhat correlated with the symptoms and severity of MI observed in the patients from the MITRA-ANGIO-CDO study.

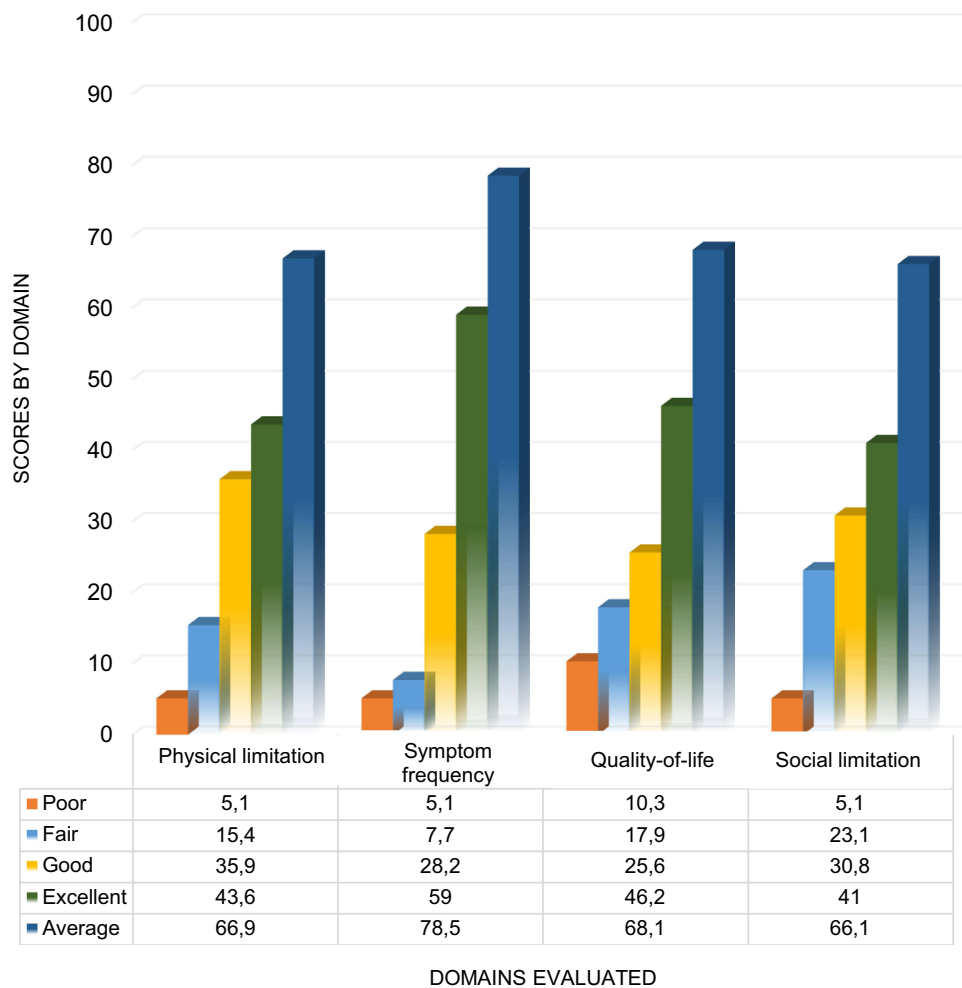


Figure 5 Stratification by quality of life score based on the KCCQ. This bar chart presents the stratification of quality of life scores obtained through the Kansas City Cardiomyopathy Questionnaire (KCCQ) across various domains (Physical Limitation, Symptom Frequency, Quality of Life, Social Limitation), showing the percentage of patients in different quality-of-life categories (Poor, Fair, Good, Excellent) and the mean score for each domain.

In-hospital all-cause mortality was 2.1%, whereas in other studies^{15–18} it ranged from 2.5% to 4%. Mortality after 30 days was 3.2%, which was lower than the values reported by several published registries,^{12,14–16} including data from the ACCESS EU (3.4%), TRAMI (4.7%), and REALISM (4.8%) studies. However, registries such as COAPT,⁹ MitraSwiss,¹⁸ and GRASP¹³ reported even lower mortality rates of 2.3%, 2.9%, and 0.9%, respectively.

In our study, mortality after 6 months was 12.8%; this value is not commonly reported in other studies, although it was reported in the study by Sorajja et al¹⁶ as 16.1%.

Regarding mortality after 1 year, our study reported a rate of 16%, which is consistent with that found in randomized clinical trials (COAPT = 18.8%, MITRA FR = 24.3%) and observational studies (TRAMI = 19.7%, ACCESS EU = 17.3%, STS = 25.8%, Sentinel = 15.3%).^{9,10,12–17}

Mortality after 2 years was 20.2% in our study, whereas the COAPT⁹ and TRAMI studies¹⁵ reported values of 29.3% and 31.9%, respectively. When comparing these values, it can be inferred that all-cause mortality over different periods was within an acceptable range in our study and highly consistent with international registries.

Immediate device success was defined as residual MI ≤moderate after clip insertion. Our study reported an effectiveness of 93.6%, of which 74.5% was ≤mild. In this regard, experimental studies such as EVEREST II (55%) and MITRA FR (91.9%) and observational studies such as MitraSwiss (85%), REALISM (86%), ACCESS EU (91.2%), and STS (91.8%) reported lower values. Conversely, data from the COAPT (94.8%), Sentinel (95.4%), and TRAMI (96.5) studies are slightly

higher. Our findings, like those cited above, show similar success rates, and the results obtained in our study are quite encouraging and show the importance of an experienced surgical team in the success of the procedure.

The presence of severe symptomatic MI entails poor prognosis, with a higher risk of heart failure and reduced survival rates, associated with an increase in the number of hospitalizations. In our study, the percentage of patients with all-cause hospitalization 24 months after the procedure was 39.4%, which is consistent with the values reported by Glower,¹⁴ Obadia,¹⁰ and Eggebrecht,¹⁵ which were 41%, 48.7%, and 48%, respectively. However, the latter value is only equivalent to 12 months. In contrast, hospitalization rates reported by Stone,⁹ Vanderheyden,¹⁷ and Sorajja¹⁶ were 35.7%, 22.8%, and 20.2%, respectively, with the same 12-month caveat for the latter data.

Regarding the procedure, the most common adverse event was *de novo* AF with 7.4%; Sorajja reported 11.7% in the Sentinel study.¹⁶ In our trial, 4.3% of individuals presented major bleeding requiring blood transfusion, similar to what Maisano noted in the ACCESS EU study, which was 4.8%.¹² In the TRAMI study,¹⁵ major bleeding occurred in 7.5% of cases, and transfusion was required in 10.4% of cases. After the implementation of ProGlide for venotomy closure, minor vascular complications decreased dramatically, as reported by Yeo et al,²⁷ which could motivate further analysis in this regard.

The observed clinical outcomes are intrinsically linked to the institutional learning curve and the simultaneous transition through different generations of the MitraClip device. Our study period encompassed the use of all four generations of the device developed by the parent company (Abbott). The later phase of the study (Group B, n=44) benefited from both accumulated expertise and the use of more advanced equipment compared to the initial phase (Group A, n=50). The impact of this combined effect is reflected in the survival data: mortality rates were consistently lower in Group B at all follow-up intervals compared to Group A (6 months: 11.6% vs 14%; 1 year: 13.6% vs 18%; 2 years: 18.2% vs 24%). Newer systems, like the MitraClip G4, incorporate features such as independent gripper control and four different clip sizes (NT, XT, NTW, XTW), which are specifically intended to increase procedural success and allow a tailored approach, even in challenging anatomies. This technological evolution, combined with the decreased incidence of complications noted over time (reflecting the professional team's learning process), supports the enhanced procedural safety and efficacy and correlates with the decreased mortality observed in the later cohort.

In terms of complications associated with the implantation, our data are consistent with those found in the literature. Similarly to several reports,^{9,12,13,15,16} no cases of clip embolization, veil separation, clip thrombosis, or need for open surgery were reported. The incidence of complications was low, and their onset decreased with time, reflecting the learning process of the professional team who performed the procedure.

The high procedural success achieved (93.6% residual MI $\leq$ moderate) was driven by adherence to selection criteria targeting symptomatic, high-risk patients with advanced M). Specifically, 96.8% of the cohort presented with severe (73.4%) or moderate to severe (23.4%) MI before implantation. The small fraction of patients with purely moderate or mild pre-procedural MI (3.2% total) likely reflects interventions performed early in the program's learning curve (starting in 2013) or complex scenarios where symptomatic severity drove the decision. Regarding baseline differences, the higher prevalence of prior surgical management (29.4%) in the older group compared to the younger group (7%) specifically denotes a history of major prior cardiac interventions such as MRS or valve replacement, reflecting accumulated cardiac comorbidity. Furthermore, the statistically lower LVEF observed in the younger group (mean 25% vs 34% in the older group, $p=0.000$) correlates directly with a higher disease burden in this subgroup, evidenced by a greater incidence of heart failure (74.4% vs 57%, $p=0.012$) and severe NYHA Class IV symptoms (34.9% vs 15.7%, $p=0.031$). Subanalysis indicated that the younger patients often presented with dilated cardiomyopathy, suggesting intervention was required due to highly advanced FMR associated with severe left ventricular remodeling, similar to the patient profile described in the MITRA-FR trial.^{10,22}

Finally, with regard to the analysis of health-related quality of life, we applied the KCCQ scale in the same way as the COAPT study, and the overall result was 69.9 ± 19.3 , suggesting a good quality of life. The Stone trial⁹ reported 66.4 ± 28.6 . Further research could assess quality of life over extended periods than our study's, even before the intervention.

Study Strengths

The MITRA-ANGIO-CDO study is one of the first observational studies on the use of the MitraClip device conducted in the field of interventional cardiology in Colombia and South America. Our study included a relevant cohort of patients

and assessed survival rates, complications, and health-related quality of life, which can be considered a starting point for further research and follow-up over longer periods.

Our study is relevant since it is the first investigation to record the results of percutaneous mitral repair in a considerable cohort of 94 patients from the Colombian population, collecting 9 years of experience.

Study Limitations

Our study has some limitations. Firstly, it is a single-center retrospective study, so data were limited to a single institution's experience and full details of several laboratory studies and complete echocardiographic study descriptions were unavailable. In addition, although the results are similar to those found in various publications, they should not be extrapolated arbitrarily, given their low external validity. It is also relevant to mention that a recall bias may be present in the patients who answered the quality-of-life survey.

Conclusion

Percutaneous mitral valve repair with MitraClip is a safe technique that directly affects survival and quality of life. There was a low incidence of complications, most of which were related to the procedure and patients' preoperative conditions, and the clinical outcomes of the procedure were comparable to those of developed countries.

Abbreviations

AF, Atrial fibrillation; DMR, Degenerative mitral regurgitation; FMR, Functional mitral regurgitation; HBP, Arterial hypertension; ICU, Intensive care unit; KCCQ, Kansas City Cardiomyopathy Questionnaire; LVEF, Left ventricular ejection fraction; MI, Mitral insufficiency; MR, Mitral regurgitation; MRS, Myocardial revascularization surgery; NYHA, New York Heart Association.

Acknowledgments

This research has been funded by Dirección General de Investigaciones of Universidad Santiago de Cali under call No. DGI-01-2025. We would like to thank Universidad Santiago de Cali for its constant support during the research process, as well as Angiografía de Occidente and Clínica de Occidente for allowing us to use the data from the study population. In addition, we would like to thank medical interns Natalia Díaz and Valentina Olaya for their collaboration in data collection, To Dr. Bonilla for her valuable contributions to the study and Dr. Carlos Nader Robles (RIP) for his extensive experience and collaboration in developing the technique.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This research has been funded by Dirección General de Investigaciones of Universidad Santiago de Cali under call No. DGI-01-2025.

Disclosure

The authors report no conflicts of interest in this work.

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