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Original Article

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Transcatheter Edge-to-Edge Repair Versus Annuloplasty in Functional Mitral Valve Regurgitation: A Comparison of Cardiovascular Outcomes

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Abstract

Background: The EVEREST trials established the MitraClip as a viable alternative to surgery in treating functional mitral valve regurgitation (FMVR). The MitraClip G4 offers a less invasive way of managing severe FMVR. We sought to compare in-patient mortality and cardiovascular complications in patients with heart failure with reduced ejection fraction (HFrEF) who developed severe FMVR requiring treatment with MitraClip G4 versus annuloplasty. Comparisons of outcomes to previous iterations of the MitraClip were included in the analysis.

Methods: Using the National Inpatient Sample, we included adult patients with FMVR and HFrEF between 2016 and 2020 who underwent percutaneous repair or annuloplasty. MitraClip G4 use was assumed for MitraClip performed in the third quarter of 2019 and afterward. To avoid overlap between the G4 and previous iterations, MitraClip data from 2019 were excluded. Mortality, stroke, and other complications were assessed. Survey-weighted logistic regression was used to adjust for selection bias in the treatment received based on age and comorbidities. The weighted analysis included 19,500 patients receiving either MitraClip G4 or annuloplasty.

Results: The MitraClip group was associated with a decreased risk of in-hospital mortality (odds ratio (OR): 0.38, confidence interval (CI): 0.18 - 0.77), ischemic stroke (OR: 0.29, CI: 0.13 - 0.61), and myocardial infarction (OR: 0.15, CI: 0.08 - 0.28). The MitraClip G4 cohort did not outperform earlier clip versions in reducing complications.

Conclusions: The MitraClip G4 was associated with lower in-hospital mortality and cardiovascular complications than annuloplasty but had outcomes similar to earlier clip versions. Additional studies comparing percutaneous therapies and surgical interventions are necessary to determine optimal treatment strategies for patients with FMVR.

Keywords: MitraClip; Annuloplasty; Functional mitral valve regurgitation; Outcomes analysis

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Introduction

Functional mitral valve regurgitation (FMVR) refers to the retrograde blood flow from the left ventricle to the left atrium due to ischemic or non-ischemic cardiomyopathy [1]. In contrast with the more common degenerative mitral valve disease, the valve itself is not the culprit for the dysfunction. The pathophysiology involves papillary muscle displacement with global left ventricular (LV) remodeling or scarring [2, 3]. The result is incomplete mitral leaflet closure in the setting of structurally normal leaflets. This valvulopathy is projected to affect approximately four million Americans by 2030, per a population-based study by Nkomo et al [4]. Ischemia is the most common etiology, as LV remodeling and wall motion abnormalities following an acute coronary syndrome can lead to mitral valve tethering and reduced closing forces [5]. The Carpentier's echocardiography-based classification system divides mitral valve regurgitation into five groups according to leaflet motion. Class IIIb, or symmetric systolic restriction of the leaflets, is most commonly seen in ischemic FMVR [1]. Non-ischemic causes include idiopathic dilated cardiomyopathy and atrial fibrillation. Clinically significant left atrial enlargement in chronic atrial fibrillation can lead to mitral annular enlargement and reduced leaflet coaptation, further exacerbating regurgitant flow [6]. When left untreated, patients with FMVR are more likely to develop cardiovascular complications, including pulmonary hypertension, heart failure, and recurrent cardiac-related hospitalizations.

Until the development of minimally invasive percutaneous transcatheter therapies, the standard of care for FMVR involved medical management and surgical repair of the valve.

Beta-blockers and angiotensin-converting enzyme inhibitors reverse LV remodeling in patients with underlying ischemia [7]. Non-surgical candidates with New York Heart Association class II to IV symptoms on guideline-directed medical therapy and an ejection fraction less than 35% may benefit from cardiac resynchronization therapy (CRT) [8]. Surgical intervention via mitral valve annuloplasty effectively aligns the leaflets into a central line of coaptation. It is associated with a reduced rate of perioperative complications and mortality when compared with valve replacement [9]. Nevertheless, the growing popularity of minimally invasive percutaneous devices offers yet another alternative to patients hoping to avoid the operating room.

The MitraClip gained FDA approval in 2013 and has since undergone multiple upgrades. Currently, transcatheter edge-to-edge repair (TEER) is a class IIa recommended therapy for severe FMVR in patients who do not require coronary revascularization and have appropriate hemodynamic and anatomic features [10]. On the contrary, surgery is a class IIb recommendation for the same patient population [10].

The EVEREST-II trial demonstrated that percutaneous repair of FMVR was associated with superior clinical outcomes and had a lower risk of post-procedural complications than conventional surgery [11]. As the MitraClip has undergone multiple iterations since its inception, an updated comparison of cardiovascular outcomes in the newest version, G4, versus those of annuloplasty is essential to gauge its continued standing relative to surgery. Furthermore, comparing the most updated version of the MitraClip to earlier clip versions and annuloplasty is critical for accurate preoperative risk stratification of this vulnerable patient class. Herein, we present a retrospective study assessing clinical outcomes in patients with FMVR treated with MitraClip G4 or annuloplasty, including comparisons to earlier iterations of the MitraClip.

Materials and Methods

Data source

Data were obtained from the Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS) files between 2016 and 2020. The NIS is a public database containing an extensive collection of all-payer inpatient care and discharge-level data provided by the states participating in HCUP. Criteria to aggregate hospital data included geographic region, rural or urban location, teaching status, patient volume, hospital bed size, primary payer, and patient median household income. Detailed information on the design of the NIS is available in literature [12].

This study was deemed non-human subjects research by the Southern Illinois University School of Medicine Institutional Review Board because the HCUP-NIS is a publicly available database and contains de-identified patient information.

Study population

We used the 10th edition of the International Classification of Diseases Clinical Modification (ICD-10-CM) diagnosis codes to identify procedural types and adults with FMVR diagnoses. Procedure code 02UG3JZ refers to a supplemental mitral valve with a synthetic substitute, the appropriate designation for TEER or MitraClip, per the manufacturer's website. The code 02QG0ZZ classifies surgical repair of the mitral valve using an open approach, referring to annuloplasty. FMVR was designated using I34.0 and I50.2, the codes for mitral valve regurgitation and systolic heart failure, respectively. Patients with a history of cardiogenic shock (R57.0) or those who underwent coronary artery bypass grafting (I25.810), percutaneous coronary intervention (PCI) (Z95.5), and surgical valve replacement (Z95.2, Z95.4) were excluded from the study. Since annuloplasty rings are often combined with other procedures, such as coronary revascularization or aortic valve replacement, excluding these concomitant surgeries was necessary to ensure a one-to-one comparison between TEER and annuloplasty.

Clip type was determined using the quarter the G4 was introduced (Q3 2019) as the threshold between the G4 (Q3 2019 and later) and earlier versions (Q2 2019 and before). To avoid overlap between the G4 and previous iterations, MitraClip data from 2019 were excluded. Numbers and comparisons incorporate the discharge weights provided in the NIS.

Baseline patient characteristics used included demographics (age, sex, primary payer, and median household income) and common comorbidities known to be risk factors for cardiovascular disease (CVD) (cerebrovascular disease, coronary artery disease, peripheral artery disease, obstructive sleep apnea, atrial fibrillation, obesity, hypertension, type 2 diabetes mellitus, chronic kidney disease (CKD), and tobacco use). A list of ICD-10-CM codes used to identify baseline comorbidities between MitraClip and annuloplasty is provided in Table 1.

Outcome measures

Our primary outcomes of interest included in-hospital mortality and cardiovascular complications such as pulmonary embolism, cardiac tamponade, ischemic stroke, and myocardial infarction. Secondary outcomes included cost of stay and other postprocedural complications such as gastrointestinal bleeding and postprocedural hemorrhage. ICD-10-CM codes for primary and secondary outcomes are listed in the first column of Table 2.

Statistical analysis

Individual admissions were weighted per recommendations from the NIS [13]. Applying discharge weights allows for a nationally representative sample, which reduces bias in inferences made to the overall US population [14].

Univariate comparisons of patient characteristics between those undergoing percutaneous repair with MitraClip or surgery with annuloplasty were done using survey-weighted *t*-tests for continuous variables (e.g., age) and survey-weighted Chi-squared tests for binary variables (e.g., comorbidities). Un-

Table 1. Patient Characteristics for Those Receiving MitraClip G4 Versus Annuloplasty and Previous Clip Versions

	MitraClip G4 (N = 7,270)	Annuloplasty (N = 12,230)	P-value	Earlier MitraClip (N = 12,205)	P-value
Age, years, mean (SD)	76.4 (10.7)	57.4 (19.8)	< 0.001	78.3 (10.1)	< 0.001
Female, n (%)	3,470 (47.8)	4,545 (37.2)	< 0.001	6,190 (50.7)	0.07
Race, n (%)			< 0.001		0.01
White	5,485 (75.4)	9,195 (75.2)		9,320 (76.4)	
Black	770 (10.6)	875 (7.2)		940 (7.7)	
Hispanic	410 (5.6)	730 (6.0)		760 (6.2)	
Others	605 (8.3)	1,430 (11.7)		1,185 (9.7)	
Hospital region, n (%)			< 0.001		0.35
Northeast	1,240 (17.1)	2,315 (18.9)		1,980 (16.2)	
Midwest	1,285 (17.7)	3,295 (26.9)		2,415 (19.8)	
South	2,810 (38.7)	3,830 (31.3)		4,510 (37.0)	
West	1,935 (26.6)	2,790 (22.8)		3,300 (27.0)	
Primary payer, n (%)			< 0.001		0.89
Medicare	6,105 (84.0)	4,955 (40.6)		10,645 (87.3)	
Medicaid	265 (3.6)	1,220 (9.9)		255 (2.1)	
Private insurance	705 (9.7)	5,470 (44.8)		1,115 (9.1)	
Others/self-pay	190 (2.6)	575 (4.7)		175 (1.4)	
Median household income (quartile), n (%)			< 0.001		0.20
0 - 25th percentile	1,665 (23.3)	2,465 (20.5)		2,705 (22.6)	
25 - 50th percentile	1,895 (26.5)	2,720 (22.6)		2,880 (24.0)	
50 - 75th percentile	1,865 (26.1)	3,205 (26.7)		3,240 (27.0)	
75 - 100th percentile	1,725 (24.1)	3,625 (30.2)		3,170 (26.4)	
Comorbidities, n (%)					
Cerebrovascular disease I6X	405 (5.6)	670 (5.5)	0.90	680 (5.6)	1.00
Coronary artery disease I25	3,985 (54.8)	4,360 (35.7)	< 0.001	6,705 (54.9)	0.94
Peripheral artery disease I73.9	280 (3.9)	255 (2.1)	0.001	785 (6.4)	0.001
Obstructive sleep apnea G47.33	1,015 (15.4)	1,295 (10.6)	0.002	1,425 (11.7)	0.04
Atrial fibrillation I48	4,430 (60.9)	6,100 (49.9)	< 0.001	7,560 (61.9)	0.53
Obesity E66	915 (12.6)	1,740 (14.2)	0.15	1,225 (10.0)	0.01
Hypertension I10	640 (8.8)	4,305 (35.2)	< 0.001	2,535 (20.8)	< 0.001
Type 2 diabetes mellitus E11.9	675 (9.3)	770 (6.3)	0.001	1,470 (12.0)	0.008
Chronic kidney disease, any stage N18.9	1,880 (25.9)	905 (7.4)	< 0.001	2,940 (24.1)	0.33
CKD stage 1 N18.1	15 (0.2)	15 (0.1)	0.52	15 (0.1)	0.52
CKD stage 2 N18.2	140 (1.9)	250 (2.0)	0.80	155 (1.3)	0.11
CKD stage 3 N18.3	1,290 (17.7)	560 (4.6)	< 0.001	2,000 (16.4)	0.27
CKD stage 4 N18.4	435 (6.0)	80 (0.7)	< 0.001	720 (5.9)	0.91
CKD stage 5 N18.5	-[a]	0 (0)	0.07	50 (0.4)	0.14
Tobacco use F17	435 (6.0)	1,160 (9.5)	< 0.001	555 (4.5)	0.05
COPD J44.9	1,330 (18.3)	860 (7.0)	< 0.001	2,520 (20.6)	0.07
Hospital bed-size, n (%)			0.01		0.14
Small	570 (7.8)	1,265 (10.3)		820 (6.7)	
Medium	1,440 (19.8)	2,590 (21.2)		2,210 (18.1)	
Large	5,260 (72.3)	8,375 (68.5)		9,175 (75.2)	
Hospital location and teaching status, n (%)			0.84		0.002
Rural	40 (1.2)	130 (1.1)		90 (0.3)	
Urban non-teaching	565 (7.8)	985 (8.1)		1,060 (8.7)	
Urban teaching	6,615 (91.0)	11,115 (90.9)		11,105 (91.0)	

[a]Value censored due to low cell size (< 10). Numbers and comparisons incorporate the discharge weights provided in the NIS. Data are from 2016 to 2020. To avoid overlap between G4 and prior iterations, MitraClip data from 2019 were excluded. P-values are comparisons to MitraClip G4. CKD: chronic kidney disease; COPD: chronic obstructive pulmonary disease; SD: standard deviation.

Table 2. Unadjusted Outcomes of the MitraClip G4 vs. Annuloplasty and Previous Iterations of MitraClip

Outcomes	MitraClip G4 (N = 7,270)	Annuloplasty (N = 12,230)	P-value	Earlier MitraClip (N = 12,205)	P-value
In-hospital mortality R99, n (%)	90 (1.2)	195 (1.6)	0.37	165 (1.4)	0.76
Length of stay, days, median (IQR)	1 (1, 3)	6 (5, 9)	< 0.001	2 (1 - 4)	< 0.001
Cost of stay, thousands of dollars, median (IQR)	173.8 (128.5 - 261.0)	167.3 (119.6 - 262.2)	0.06	174.6 (121.2 - 254.5)	0.05
Pulmonary embolism I26, n (%)	40 (0.6)	60 (0.5)	0.80	25 (0.2)	0.07
Acute ischemic stroke I63, n (%)	50 (0.7)	220 (1.8)	0.004	105 (0.9)	0.56
Myocardial infarction I21, n (%)	95 (1.3)	515 (4.2)	< 0.001	125 (1.0)	0.42
Gastrointestinal bleed K92.2, n (%)	40 (0.6)	55 (0.4)	0.66	35 (0.3)	0.20
Non-traumatic intracerebral hemorrhage I61.9, n (%)	0 (0)	0 (0)	-	0 (0)	-
Postprocedural hemorrhage of skin and subcutaneous tissue L76.2, n (%)	0 (0)	-[a]	0.44	20 (0.2)	0.12
Pericardial effusion I31.3, n (%)	25 (0.3)	75 (0.6)	0.25	50 (0.4)	0.75
Tamponade I31.4, n (%)	230 (3.2)	320 (2.6)	0.32	270 (2.2)	0.07

[a]Value censored due to low cell size (< 10). Numbers, odds ratios, and comparisons account for discharge weights only. P-values are for comparisons to MitraClip G4. IQR: interquartile range.

adjusted comparisons of outcomes were made using weighted logistic and linear regressions for binary and continuous outcomes, respectively. The only variable included in unadjusted models was treatment type, with annuloplasty as the reference group. Adjusted comparisons were made using multivariate weighted logistic and linear regressions as in unadjusted models. Adjusted models further accounted for discharge characteristics found to be significantly different between groups (i.e., age, gender, primary payer, household income, hospital size, hospital location, CVD, obstructive sleep apnea, obesity, hypertension, diabetes, CKD, and tobacco use).

For all analyses, statistical significance was set at $P < 0.05$. All analyses were performed using R statistical software's "survey" package [15, 16].

Results

Patient and hospital characteristics

The final discharge-weighted analysis included 7,270 and 12,230 adult patients in the MitraClip and annuloplasty groups, respectively. As for device comparison, 7,270 received the MitraClip G4, while 12,205 had an earlier clip version. Individuals receiving MitraClipG4 tended to be older, female, have lower incomes, and be on Medicare. They were also more likely to have significant comorbidities, including coronary artery disease, obstructive sleep apnea, atrial fibrillation, fibrillation, advanced CKD, and chronic obstructive pulmonary disease. Analysis of MitraClip G4 versus annuloplasty with patient and hospital demographics is displayed in Table 1. Individuals receiving MitraClip tended to be older, white, and female with lower incomes and Medicare as their insurance. They were also more likely to have coronary artery disease, atrial fibrillation, and advanced CKD. Those receiving the MitraClip G4 were slightly younger, more likely to be African-American, and had lower rates of peripheral artery disease, hypertension, and diabetes than those receiving earlier clip versions.

In-hospital outcomes

Unadjusted outcomes of all treatment groups MitraClip versus annuloplasty are displayed in Table 2. Notably, the MitraClip G4 cohort had a statistically significant lower risk of acute ischemic stroke and myocardial infarction. Median length of stay was shorter in the MitraClip group by a factor of 6. No cases of non-traumatic intracerebral hemorrhage were reported in either group. Other outcomes were similar between groups.

Adjusted outcomes of patients are expressed in Table 3. In contrast with the unadjusted data, a statistically significant decrease in in-hospital mortality was observed in the MitraClip G4 group. Furthermore, the risk of ischemic stroke, myocardial infarction, and cardiac tamponade were lower in the percutaneous repair cohort. The hospital length of stay was still significantly shorter after adjustment. Other outcomes were similar between groups after adjustment.

Unadjusted outcomes of the MitraClip G4 compared to

Table 3. Adjusted Outcomes of Patients Receiving the MitraClip G4 vs. Annuloplasty and Earlier Clip Versions

Outcomes	MitraClip G4 vs. annuloplasty		MitraClip G4 vs. earlier versions	
	OR/mean difference (95% CI)	P-value	OR/mean difference (95% CI)	P-value
In-hospital mortality	0.38 (0.18 - 0.77)	0.007	0.86 (0.48 - 1.54)	0.62
Length of stay, days	-5.51 (-6.32 to -4.70)	< 0.001	-1.23 (-1.75 to -0.71)	< 0.001
Cost of stay, thousands	-17.00 (-35.09 to 1.09)	0.07	5.00 (-5.12 to 15.14)	0.33
Pulmonary embolism	1.61 (0.51 - 5.03)	0.42	3.00 (0.95 - 9.47)	0.06
Acute ischemic stroke	0.29 (0.13 - 0.61)	0.001	0.74 (0.36 - 1.53)	0.42
Myocardial infarction	0.15 (0.08 - 0.28)	< 0.001	1.15 (0.63 - 2.11)	0.65
Gastrointestinal bleed	0.54 (0.17 - 1.70)	0.29	1.81 (0.66 - 4.94)	0.25
Pericardial effusion	0.49 (0.16 - 1.55)	0.23	0.84 (0.30 - 2.38)	0.75
Tamponade	1.73 (1.08 - 2.78)	0.02	1.35 (0.90 - 2.01)	0.15

Because treatments are non-randomly assigned, survey regressions (linear or logistic) account for discharge weights and discharge characteristics found to be significantly different between groups. Non-traumatic intracerebral hemorrhage and postprocedural hemorrhage of skin and subcutaneous tissue were not considered due to an insufficient number of events. CI: confidence interval; OR: odds ratio.

earlier iterations were all similar. After adjustment, the only outcome found to be different between the MitraClip G4 and earlier versions was the length of stay, with the G4 having a median length of stay 1 day shorter than that of the previous clip versions.

Discussion

In our retrospective study, we observed that adult patients with FMVR treated with MitraClip had a lower risk of cardiovascular complications than those who underwent surgical repair with annuloplasty. This pattern was borne out in the adjusted outcomes analysis as well, with the MitraClip G4 group developing fewer cases of ischemic stroke and myocardial infarction. Other in-hospital outcomes, such as mortality and length of stay, favored the minimally invasive percutaneous approach. Furthermore, the data posited that the current version of the MitraClip was only associated with shortening hospital stays by 1 day compared to previous device iterations. It was similar, however, in reducing cardiovascular and other complications compared to earlier models.

Prior investigations have also reported favorable in-hospital and post-discharge outcomes for percutaneous repair of FMVR. A meta-analysis of 7,498 patients with MitraClip implantation by Verma et al observed a cumulative all-cause mortality of 2.40% and 4.31% for inpatient and 30-day mortality [17]. The majority of deaths were from cardiac causes; however, the mechanism by which these patients decompensated was not apparent [17]. Comparison trials between percutaneous repair and pharmacotherapy have also demonstrated significant benefits for the former. Marmagkiolis et al conducted a meta-analysis of 2,189 patients receiving MitraClip or medical therapy over 10 years [18]. The MitraClip group had a significantly lower 12-month mortality of 18.4% versus 25.9% in the medical therapy group and reduced 1-year readmission rates [18]. Following the publication of the landmark EVEREST-II trial, additional studies were performed that corroborated the safety and efficacy of the MitraClip. Ailawadi et al enrolled 616 patients with moderate-severe FMVR from the EVEREST-II study and evaluated clinical and echocardiographic outcomes after 1 year [19]. With further stratification into non-high and high surgical risk groups, Kaplan-Meier survival at 1 year was more than 74% in both groups. Both saw comparable reductions in regurgitant flow [19]. Patients with concomitant FMVR and left ventricular desynchrony refractory to CRT have also been shown to benefit from MitraClip implantation. A retrospective analysis of 42 subjects with CRT and FMVR had a 2-year all-cause mortality rate of 25% [20]. Improved changes in biomarkers and hemodynamics, such as N-terminal pro B-type natriuretic peptide (NT-proBNP), tricuspid regurgitation peak gradient, and left ventricular end-diastolic volume, were also observed following MitraClip implantation [20].

As we demonstrated with our retrospective analysis, the safety of percutaneous repair of FMVR is at least comparable, if not better, to the surgical alternative. Other analyses with smaller study populations have also reported similar trends in quality metrics. A meta-analysis of nine studies involving 1,171 patients between 1997 and 2014 could not identify significant differences in short and long-term mortality in patients undergoing MitraClip implantation or mitral valve surgery [21]. However, the MitraClip group had higher rates of cardiovascular hospital readmissions and mitral regurgitation post-operatively, while the surgical group saw more immediate procedural complications [21]. These mortality trends were corroborated in an updated meta-analysis of nine studies following 1,873 patients between 2012 and 2019 [22]. Residual moderate-severe regurgitation was more frequent in MitraClip at discharge, and there was a greater need for mitral valve reoperation [22]. However, overall mortality was similar in transcatheter repair and mitral valve replacement [22]. A retrospective analysis comparing MitraClip to the Cardioband direct annuloplasty conveyed improved outcomes following surgery over percutaneous repair [23]. Annuloplasty reduced heart failure symptoms, all-cause readmission, and 12-month mortality more than MitraClip [23]. These results are in stark contrast to our NIS retrospective analysis. A randomized clinical trial comparing the safety and cardiovascular outcomes of the most updated MitraClip and annuloplasty ring would be beneficial in determining optimal therapy for patients differentiated by hemodynamic parameters and comorbidity burden.

To our knowledge, no other analyses have been conducted comparing MitraClip G4 against annuloplasty. As the device continues to be upgraded, it has the potential to reduce rates of reoperation and significantly decrease the severity of FMVR. The advances in percutaneous transcatheter therapy follow a trend toward minimally invasive therapy in combating valvulopathies. A similar pattern is observed in the treatment of acute coronary syndromes as PCIs are non-inferior to coronary artery bypass grafting when assessing early mortality [24]. However, surgical revascularization remains superior in preventing significant adverse cardiovascular events in the long term compared to PCI [24]. Significant advancements in minimally invasive mitral valve repair coincide with improvements in therapies targeting aortic stenosis. Transcatheter aortic valve replacement is currently a class I indication for low-risk to inoperable patients based on the results of multiple landmark trials [25]. Furthermore, the selection of suitable candidates for TEER could be aided by exercise stress echocardiography [26]. Increases in stroke volume and mitral regurgitation during preprocedural stress echocardiography were associated with clinical benefit following percutaneous mitral valve repair [26]. Additional investigations comparing updated transcatheter valve repair options to surgical intervention are crucial to establishing the optimal treatment modalities for FMVR.

Study limitations

Our study has certain limitations. Data obtained from publicly available databases are at risk from errors in procedure coding or incorrect diagnostic labeling. Even though in-hospital mortality was able to be measured, other causes of death could not be appropriately differentiated. The exclusion criteria were utilized to eliminate sources of confounding; however, this list was not comprehensive, and other factors, such as illicit drug use, may have skewed the data. Since we excluded cardiogenic shock, we are unable to determine if patients were in shock on admission or if it occurred as a post-procedural complication. Our methodology for dividing the MitraClip G4 from earlier versions was based on the FDA approval date for the former. However, we cannot definitively state that MitraClip G4 was utilized in all adult patients with FMVR after the third quarter of 2019. The NIS cannot quantify residual mitral regurgitation grade or change in left ventricular ejection fraction after completion of each procedure. Therefore, we cannot comment on the efficacy of either treatment method. Other complications that could not be analyzed due to a lack of available codes included single leaflet detachment, clip embolization, and chordal rupture. Lastly, our analysis of outcomes was limited to in-hospital events. Thus, we were unable to comment on follow-up data.

Conclusions

In our retrospective study, we observed adult patients with FMVR treated using MitraClip G4 had a statistically significant decreased risk of in-hospital mortality, myocardial infarction, and acute ischemic stroke compared to annuloplasty. The MitraClip G4 did not outperform previous clip iterations in our analysis of cardiovascular outcomes post-procedurally.

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Conflict of Interest

The authors have no conflict of interest to report.

Informed Consent

Informed consent was not required as data were obtained from the National Inpatient Sample, and the identities of the patients in question cannot be ascertained.

Author Contributions

Andrew Sagalov: conceptualization, methodology, writing - original draft, writing - review and editing; Muhammad Adil Sheikh: supervision; Zurain Niaz: supervision; Michael Buhnerkempe: data curation and formal analysis; Steve Scaife: data curation; Abhishek Kulkarni: supervision and validation; Shruti Hegde: supervision and validation; Abdul Hafiz: supervision and validation; Ahmad Al-Turk: writing - review and editing, supervision, and validation.

Data Availability

The authors declare that data supporting the findings of this study are available within the article.

Abbreviations

CRT: cardiac resynchronization therapy; FMVR: functional mitral valve regurgitation; HCUP: Healthcare Cost and Utilization Project; HFrEF: heart failure with reduced ejection fraction; ICD: International Classification of Diseases; LV: left ventricular; NIS: National Inpatient Sample; TEER: transcatheter edge-to-edge repair

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