

Contents lists available at ScienceDirect

IJC Heart & Vasculature



journal homepage: www.sciencedirect.com/journal/ijc-heart-and-vasculature

National outcomes of urgent vs. non-urgent percutaneous edge-to-edge transcatheter mitral valve repair

Yasser Al-khadra^{a,*}, Motaz Baibars^c, Wael Dakkak^b, Zurain Niaz^c, Radhika Deshpande^c, Basma Al-Bast^a, M. Chadi Alraies^d, Abdul Moiz Hafiz^a

^a Cardiovascular Division, Southern Illinois University School of Medicine, Springfield, IL, USA

^b Internal Medicine Division, Southern Illinois University Southern Illinois University School of Medicine, Springfield, IL, USA

^c Collaborative Inpatient Medicine Service, Howard County General Hospital – Johns Hopkins Medicine, Columbia, MD, USA

^d Cardiovascular Division, Detroit Medical Center, Detroit, MI, USA

ARTICLE INFO ABSTRACT Keywords: Background: The current data regarding outcomes of transcatheter edge-to-edge mitral valve repair with the Percutaneous mitral repair MitraClip system in the urgent setting has not been well described. Therefore, we sought to evaluate the out-MitraClip comes of urgent MitraClip procedures compared with non-urgent ones. Urgent Method: The Nationwide Inpatient Sample database years 2011-2017 was used to identify hospitalizations for MitraClip in the urgent setting. Propensity score matching was used to compare the patients who underwent MitraClip in urgent versus non-urgent settings. Results: A total of 15,993 patients underwent the MitraClip procedures from 2011 to 2017. 3,929 (24.6%) were urgent and 12,064 (75.4%) were non-urgent. Patients in the urgent group were younger (75.08 vs 77.46) and more likely to be African American (p < 0.001). The urgent group had a higher burden of comorbidities such as diabetes, atrial fibrillation, renal failure and pulmonary circulatory disorders. Using multivariable logistic regression, there was no statistically significant difference in mortality between urgent and non-urgent groups (4.2% vs 1.8%, OR 0.64; 95% CI 0.41–1.00, p = 0.051). Using propensity score matching, there was no statistically significant difference in the in-hospital mortality between urgent and non-urgent groups (4.4% vs 2.8%, OR: 1.60, 95% CI: 0.71–3.63, p = 0.254). The risks of acute kidney injury and discharge to an outside facility were higher in the urgent group (p < 0.001). Conclusion: No significant in-hospital mortality for patients who underwent urgent versus non-urgent MitraClip procedures. Therefore, urgent MitraClip procedure might be an acceptable option when indicated.

1. Introduction

Mitral valve regurgitation is a commonly seen valvular heart disease with an estimated prevalence of over two million patients in the United States [1–3]. Percutaneous mitral valve repair has emerged as a viable option for patients with severe mitral regurgitation who are not candidates for surgical repair [4].

MitraClip (Abbott Laboratories, Lake Park, IL) is the only percutaneous device approved for mitral valve repair by the United States Food and Drug Administration. Offering a percutaneous alternative to traditional mitral valve surgery for critically ill patients who may not be able to survive surgery seems an attractive option [5], but such patients have been excluded by clinical trials [6–8]. Attempts at offering MitraClip therapy have been made in such patients in extremis situations at a few centers, but the outcomes data in these patients is few and far between due to difficulty studying such a population in a clinical trial. Therefore, the only data on such patients comes from case reports or a few published single-center experience reports [9–13].

Larger studies are lacking for such patients. Further, prior registry analyses also have excluded such patients [14]. Using a large national database, we sought to evaluate the in-hospital outcome of percutaneous mitral valve repair using MitraClip in patients with mitral regurgitation in the urgent setting and compare these outcomes with those who underwent this procedure in a non-urgent setting.

https://doi.org/10.1016/j.ijcha.2022.101087

Received 9 June 2022; Accepted 9 July 2022

2352-9067/© 2022 Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

^{*} Corresponding author at: Southern Illinois University, Memorial Medical Center, N 1st St, Springfield, IL 62781, USA. *E-mail address:* yasseralkhadra@gmail.com (Y. Al-khadra).

2. Methods

The National Inpatient Sample is a publicly available and deidentified database of hospital discharges in the United States from approximately 8 million hospital stays that were selected by a complex probability sampling design and the weighting scheme recommended by the Agency for Healthcare Research and Quality [1]. Each record includes one primary diagnosis and up to 24 secondary diagnosis codes between 2011 and 2013, 29 secondary diagnosis codes between 2014 and 2015, and 39 secondary diagnosis codes between 2016 and 2017. We obtained national inpatient sample data from 2011 to 2017 and used the International Classification of Disease Ninth and Tenth Editions, Clinical Modification (ICD-9-CM) (ICD-10-CM) codes to identify all patients aged \geq 18 who underwent MitraClip using the codes 35.97 and 02UG3JZ. Patients with urgent procedures were identified and compared with non-urgent procedures.

Data were retrieved retrospectively. Baseline patient-level characteristics included demographics (age, sex, race, primary expected payer, median household income for patient's zip code), Elixhauser (except for valvular disease) and other relevant comorbidities (hyperlipidemia, coronary artery disease, prior stroke/transient ischemic attack, atrial fibrillation, carotid artery disease). Hospital-level characteristics were census region, bed size, and teaching status. Using the Clinical Classification Software codes provided by the Healthcare Cost and Utilization Project and the Elixhauser Comorbidity Index, comorbidities were appointed via ICD-9 and ICD-10 codes. A list of ICD-9-CM and ICD-10-CM codes and Clinical Classification Software codes used to identify comorbidities is included in supplemental table 1.

The primary outcome was in-hospital mortality. Secondary outcomes studied were in-hospital complications including bleeding requiring transfusion, cardiac complications (iatrogenic cardiac complications, hemopericardium, cardiac tamponade, and pericardiocentesis), respiratory complications (acute postoperative pneumothorax, postoperative pulmonary edema, pulmonary collapse, prolonged mechanical ventilation >96 h and tracheostomy), acute kidney injury, as well as the length of stay and discharge to an outside facility. The list of ICD-9-CM and ICD-10-CM diagnosis codes used to identify in-hospital outcomes is included in supplemental table 1.

Continuous variables were expressed as weighted mean values \pm standard deviation (normal distribution) or median with interguartile range (non-normal distribution), and categorical variables were expressed in percentages. Independent t-tests were used for the comparison of continuous variables measurements, while the chi-square test for categorical variables. Weighted values of patient-level observations were generated to produce a nationally representative estimate of all US hospitalized patients. Univariate and multivariate logistic regression analysis were used to compare in-hospital mortality and complications between both groups. The regression model was adjusted for demographics (age, race and gender), patients' insurance, socioeconomic status, hospital characteristics and all comorbidities listed in Table 1. Adjusted odds ratios (aORs) and 95% confidence intervals (CIs) were used to report the results of regression models. Linear regression models were used to assess the length of stay and log transformation of length of stay was done to adjust for positively skewed data. For trend analysis, we utilized the Cochrane-Armitage method to identify the presence of a linear trend in the utilization of MitraClip in the urgent and non-urgent group.

To further explore the validity of our findings, we performed propensity score-matching analysis between urgent and non-urgent groups. All patients in both groups were matched for baseline characteristics, hospital characteristics, patients' socioeconomic status, and insurance. The urgency of the procedure was expressed in the 1:3 propensity score matching analysis using the nearest neighbor method. A P-value of<0.05 was considered statistically significant. SPSS version 25 software (IBM Corp, Armonk, NY) was used for all statistical analyses.

IJC Heart & Vasculature 41	(2022)	101087
----------------------------	--------	--------

Table 1

Baseline characteristics of patients with mitral regurgitation undergoing urgent	
mitraClip compared with non-urgent.	

Variable	Urgent Group	Non-Urgent Group	P- Value
Age yrs.	$\begin{array}{c} \textbf{75.08} \pm \\ \textbf{12.651} \end{array}$	$\begin{array}{c} 77.46 \pm \\ 11.142 \end{array}$	<0.001
Sov			
Female %	47.6	46.8	0.401
Race %			< 0.001
White	75.3	81.1	
Hispanic	8.9 9.1	6.2	
Asian or Pacific Islander	1.9	2.9	
Native American	0.8	0.3	
Other	3.9	2.7	
Primary expected payer %			< 0.001
Medicare	81.0	85.6	
Private Insurance	10.6	10.9	
Self-Pay	0.9	0.3	
No Charge	0.1	0.1	
Other	2.4	1.0	
Median Household Income %			< 0.001
0 to 25 percentile	24.0	22.1	
26 to 50 percentile	24.4 27.8	22.7	
76 to 100 percentile	23.8	27.5	
Bed Size %			< 0.001
Small	7.1	5.2	
Medium	17.9	16.9	
Large	75	77.9	
Location/Teaching Status %			0.002
Rural	0.1	0.4	
Urban Teaching	92.3	91.2	
Hospital Perion %			<0.001
Northeast	20.7	15.7	<0.001
Midwest	19.2	23.7	
South	34.7	34.3	
West	25.4	26.3	
Comorbidities			
Hypertension %	53.8	62.9 26.3	< 0.001
Diabetes mellitus, Complicated %	21.8	20.3 13.7	< 0.001
Dyslipidemia %	74.4	80.9	< 0.001
Atrial Fibrillation %	51.3	47.5	< 0.001
CAD %	82.8	83.6	0.324
Prior Stroke/TIA %	12.7	12.9	0.696
Acquired Immune Deficiency %	0.6	0.0	< 0.001
Alcohol Abuse %	2.0	1.5	0.063
Deficiency Anemia %	42.2	30.2	< 0.001
Rheumatoid Arthritis/Collagen Vascular Disease %	1.7	6.8	0.616
Chronic Blood loss Anemia %	2.2	1.3	0.001
Congestive heart failure %	5.3	3.4	< 0.001
Depression %	41.3 10.6	37.5 11.6	<0.001 0.176
Coagulopathy %	25.0	18.7	< 0.001
Drug Abuse %	1.4	0.89	0.007
Hypothyroidism	28.8	27.9	0.393
Liver Disease %	5.2	3.5	< 0.001
Lympnoma % Fluid and Electrolytes Disturbances %	0.8 46.5	2.3 23.3	<0.001
and Electory co Disturbulices /0			(0.001

(continued on next page)

Table 1 (continued)

Variable	Urgent Group	Non-Urgent Group	P- Value
Metastatic Cancer %	1.8	0.9	< 0.001
Solid Tumor Without Metastasis %	2.8	2.5	0.415
Other Neurological Disorders %	9.8	7.7	0.001
Obesity %	14.5	15.6	0.217
Paralysis %	4.6	2.4	< 0.001
Psychosis %	1.8	0.9	< 0.001
Renal Failure %	55.9	47.4	< 0.001
Peripheral vascular disease %	21.2	19.7	0.084
Pulmonary Circulation Disorders %	1.6	0.6	< 0.001
Peptic Ulcer Disease Excluding Bleeding %	1.8	0.6	< 0.001
Weight Loss	13.6	6.0	< 0.001

Values are expressed as mean \pm SD for continuous variables or percentages for categorical variables.

Abbreviations: MCS– mechanical circulatory support.; CAD - coronary artery disease; TIA – transient ischemic attack.

3. Results

A total of 15,993 patients underwent MitraClip procedure between 2011 and 2017. Out of 15,993 patients, 3,929 (24.6%) were urgent and 12,064 (75.4%) were non-urgent. Baseline characteristics for both groups are summarized in Table 1. Patients who underwent urgent procedures were younger (75.08 vs 77.46 years old; p < 0.001) and more likely to be African American (p < 0.001). The prevalence of complicated diabetes, liver disease, renal failure, coagulopathy, fluid and electrolytes disorders, acquired immune deficiency, chronic blood loss anemia, pulmonary circulatory disorders, weight loss, atrial fibrillation and deficiency anemia were all higher among patients in the urgent group. Congestive heart failure, peripheral vascular disease, coronary artery disease, history of stroke or transient ischemic attack, carotid artery disease, obesity, hypothyroidism, rheumatoid arthritis and collagen diseases, depression and solid tumors without metastasis were equally likely to be present in both groups. The urgent group were less likely to have private insurance, and more likely to have a median household income in the lowest quartile, compared with the non-urgent group (p < 0.001). Further, there was a statistically significant increase in trend in the utilization of MitraClip in urgent settings from 94 (27.7%) cases in 2011 to 1,330 (23.4%) in 2017 (Ptrend = 0.011) (Fig. 1).

After adjusting for patients' demographics, procedure urgency, comorbidities, insurance and socioeconomic status using multivariable regression mode, we found no statistically significant difference in the in-hospital mortality between the urgent versus the non-urgent group (4.2% vs 1.8%, aOR 0.64; 95% CI 0.41–1.00, p = 0.051). Risk-adjusted linear regression for LOS demonstrated a statistically significant longer

LOS in the urgent group (median LOS = 8 days; [IQR] (3–15)) when compared with those with the non-urgent group (median LOS = 2 days; Interquartile range [IQR] (1–4)) (p < 0.001) (Fig. 2).

Patients with urgent procedures had a significantly higher incidence of bleeding requiring blood transfusion (3.9% vs 2.1%), respiratory complications (24.2% 15.4%), acute kidney injury (35.0% vs 9.3%), and discharge to an outside facility (24.5% vs 9.1%) (p < 0.001 for all). After multivariate risk adjustment, the risk of bleeding requiring blood transfusion (aOR: 1.37, [95% CI: 1.047–1.79], P = 0.022), respiratory complications (aOR: 1.50, [95% CI: 1.047–1.79], P = 0.001), acute kidney injury (aOR: 3.78, [95% CI: 3.18–4.51], P < 0.001), and discharge to an outside facility (aOR: 2.53 [95% CI: 2.13–3.01], P < 0.001) remained significantly higher in the urgent group; whereas cardiac complications showed no statistically significant difference between the both groups (aOR: 1.26 [95% CI: 0.97–1.64], P = 0.078) (Table 2).

After propensity-score matching, there were no significant differences in comorbidities between urgent and non-urgent groups (Table 3). There was no statistically significant difference in the in-hospital mortality between the urgent and non-urgent groups (4.4% vs 2.8%, OR: 1.60, 95% CI: 0.71–3.63, p = 0.254). Furthermore, the incidence of respiratory complications (13.1% vs 7.7%, OR: 1.79, 95% CI: 1.09–2.95, p = 0.021), acute kidney injury (33.6% vs 11.2%, OR: 4.00, 95% CI: 2.73–5.86, p < 0.001), and discharge to an outside facility (7.3% vs 7.4%, OR: 2.76, 95% CI: 1.83–4.14, p < 0.001) have remained higher in the urgent group compared with the non-urgent group (Table 4). In addition, there were no differences in the rates of bleeding requiring blood transfusion (9.6% vs 6.3%, P = 0.104) between the urgent and non-urgent groups before and after matching are shown in supplementary figure 1.

4. Discussion

Our study found a significant increase in the utilization of MitraClip procedures between 2011 and 2017 (Fig. 1) from a few hundred cases in 2011 to almost 6000 cases in 2017. Being the only FDA approved procedure for transcatheter mitral valve repair and perhaps increasing cumulative operator experience count could account for this. Interestingly our analysis shows a similar trend in urgent settings but to a lesser degree with less than a hundred cases in 2011 to about 1300 cases in 2017. This is understandable and perhaps reflects some more hesitancy in applying a relatively new invasive procedure in a sicker patient population [15,16].

Our results indicate there is no difference in mortality or cardiac complications between the two groups however there are ramifications with other adverse outcomes for urgent procedures. The question is if non-cardiac outcomes are worse, but latter outcomes no different,



Fig. 1. Utilization trend of MitraClip in the urgent setting over the study period.

IJC Heart & Vasculature 41 (2022) 101087



Fig. 2. Forest plot of the multivariable logistic regression analysis of the outcomes of urgent MitraClip procedures compared with non-urgent MitraClip Procedures.

Table 2

Multivariate logistic regression for the outcome of percutaneous mitral valve repair using MitraClip in patients who underwent urgent compared with non-urgent procedures.

Outcome	Urgent	Non- Urgent	UOR(95% CI) Urgent (when compared with Non-urgent)	aOR(95% CI) Urgent (when compared with Non-urgent)	Unadjusted P- Value	Adjusted P- Value
Overall (n) In-Hospital Mortality, % Length of Stay (IQR)	3,929 4.2 8 days (3–15 days)	12,070 1.8 2 days (1–4 days)	2.372(1.932-2.913)	0.647 (0.417–1.002)	<0.001	0.051 <0.001
Hemorrhage Requiring Transfusion, %	3.9	2.1	1.831 (1.482–2.264)	1.370 (1.047–1.792)	<0.001	0.022
Cardiac Complications, %	4.4	3.2	1.418 (1.181–1.702)	1.266 (0.974–1.646)	< 0.001	0.078
Respiratory Complications, %	24.2	15.4	1.761 (1.526–2.032)	1.500 (1.174–1.917)	<0.001	0.001
AKI, %	35.0	9.3	5.254 (4.803-5.748)	3.788 (3.181-4.510)	< 0.001	< 0.001
Discharge to Facility, %	24.5	9.1	3.236 (3.941–3.560)	2.538 (2.139–3.012)	<0.001	<0.001

Abbreviations: aOR - adjusted odds ratio; IQR - interquartile range; AKI - acute kidney injury. Unadjusted odds ratios are displayed given low event rate.

should an argument be made to offer MitraClip sooner to urgent patients or should it be more widely adopted for such patients or would perhaps equipoise be best achieved with more careful case selection? These questions would perhaps best be answered by a dedicated randomized control trial.

Sociodemographic characteristics demonstrated that while Caucasian patients dominated both urgent and non-urgent MitraClip recipients, they were higher in the non-urgent vs. urgent group, 81.1 vs. 75.3 %, respectively; Black and hispanic patients had a higher representation in the urgent group compared to the non-urgent group; 8.9 vs. 9.1 %, compared to 6.8 vs. 6.2 %; respectively; p < 0.001 (Table 1). This discrepancy could possibly be explained by the fact that MitraClip is usually an elective procedure and requires preprocedural arrangements, and thus a higher number of insured patients with a higher annual income are present in the non-urgent group than the urgent one (Table 1). As a corollary, when a patient needs an urgent MitraClip, it is likely in acute hemodynamic instability due to severe mitral regurgitation when failing or suboptimally managed by vasopressors in a setting of severe mitral regurgitation causing an acute decompensated heart failure in circulatory shock - more likely in uninsured and lower annual income patients - as demonstrated in our analysis. Consistent with these findings would be a higher rate of comorbidities such as complicated diabetes, drug and alcohol abuse, renal failure, and pulmonary circulatory disorders in the urgent group compared to the non-urgent group (Table 1), which reflects a poor baseline health over all. An urgent procedure is likely to occur during significant cardiac presentation and hence a higher rate of heart failure, renal failure, pulmonary circulatory compromise, atrial fibrillation, electrolytes imbalance, and coagulopathy (Table 1) were found in our analysis for such patients.

On the other hand, it is not likely that patients who were candidates

for elective MitraClip had successfully been managed for mitral regurgitation over time until patients became symptomatic despite optimal medical therapy - based on labelling for the procedure. Therefore, it is foreseeable to have a higher rate of "stable" comorbidities such as hypertension, hyperlipidemia, and uncomplicated diabetes in this group (Table 1). Interestingly, prior coronary artery disease and carotid artery disease rates were relatively similar in both groups without significant differences, unlike peripheral vascular disease that was higher in the urgent group (Table 1). Such findings may reflect the silent and slowly progressive nature of the atherosclerotic coronary disease versus the easier to diagnose that may be overlooked in both groups, versus the more symptomatic atherosclerotic disease in the peripheries with probably a higher prevalence [17-19]. When propensity score was applied to all baseline characteristics, the only statistically significant difference was found in the electrolytes imbalance where it was significantly worse in the urgent group (Table 3).

In the SHOCK trial, presence of at least moderate mitral regurgitation with shock had roughly three times higher odds of 1-year mortality and provided the greatest discrimination between survivors and non-survivors [20,21]. Higher mortality in the urgent MitraClip recipients would be a natural expectation given their burden of co-morbidities as described above pre MitraClip. When analyzing the outcomes of the 15,999 MitraClip recipients in both urgent and non-urgent groups, the mortality rate was found to be 4.2% in the urgent group compared to 1.8% in the non-urgent group (p < 0.001), presenting more than two folds rate increase; however, such a difference became insignificant after adjusting for demographics, procedure urgency, comorbidities, insurance and socioeconomic status using multivariable regression model - adjusted p-value (p 0.051) (Table 2). This outcome can be explained by the fact that if a patient's critical illness is due to mitral valve

Table 3

Baseline characteristics of the propensity score matched cohort with mitral regurgitation undergoing urgent MitraClip compared with non-urgent.

Variable	Urgent Group	Non-urgent Group	P- Value
Age vrs.	72.14 +	73.80 +	0.135
1.80 9101	15.168	13.605	01100
Sex			
Female %	45.4	46.9	0.910
Page %			0.885
White	73.8	77.0	0.005
Black	7.9	6.6	
Hispanic	9.6	9.0	
Asian or Pacific Islander	3.5	2.4	
Native American	0.4	0.2	
Other	4.8	4.8	
Primary expected payer %	75.1	70.0	0.837
Medicaid	75.1 65	78.3 4.6	
Private Insurance	14.8	14.5	
Self-Pay	1.3	1.1	
No Charge	0.4	0.2	
Other	1.7	1.3	
Median Household Income %			0.929
0 to 25 percentile	22.3	23.8	
26 to 50 percentile	22.3	21.4	
51 to 75 percentile	28.4	26.7	
76 to 100 percentile	27.1	20.2	
Bed Size %	2.0	4.4	0.812
Medium	3.9 18 3	4.4 16.6	
Large	77.7	79.0	
0			
Location/Teaching Status %			0.984
Rural	0.4	0.4	01901
Urban Nonteaching	12.5	12.5	
Urban Teaching	87.3	87.1	
Hospital Region %			0.521
Northeast	24.5	20.1	
Midwest	19.7	20.8	
South West	35.8	35.9	
West	20.1	23.2	
Comorbidities	68.6	70.7	0 550
Diabetes mellitus Uncomplicated %	21.0	21.4	0.330
Diabetes mellitus, Complicated %	4.8	3.5	0.392
Dyslipidemia %	48.0	52.5	0.258
Atrial Fibrillation %	56.8	56.5	0.953
CAD %	61.1	62.1	0.809
Prior Stroke/TIA %	12.7	12.3	0.901
Alcohol Abuse %	2.0	1.8	0.488
Deficiency Anemia %	27.9	23.0	0.146
Rheumatoid Arthritis/Collagen	5.2	5.3	0.955
Vascular Disease %			
Chronic Blood loss Anemia %	1.3	0.9	0.626
Congestive heart failure %	3.1	1.5	0.145
Chronic Pulmonary Disease %	∠ờ.ờ 6.1	28.0 5.9	0.815
Coagulopathy %	16.2	14.0	0.438
Drug Abuse %	1.3	1.1	0.808
Hypothyroidism	17.0	17.7	0.828
Liver Disease %	3.5	2.0	0.229
Lymphoma %	0.4	0.7	0.635
FILLI AND Electrolytes Disturbances % Metastatic Cancer %	31.9 0.0	20.8 0.2	0.001

Table 3 (continued)

Variable	Urgent Group	Non-urgent Group	P- Value
Solid Tumor Without Metastasis %	2.2	2.0	0.888
Other Neurological Disorders %	2.6	2.9	0.803
Obesity %	8.3	7.6	0.724
Paralysis %	0.9	0.9	0.949
Psychosis %	1.3	0.9	0.626
Renal Failure %	37.6	35.4	0.562
Peripheral vascular disease %	10.9	10.5	0.863
Pulmonary Circulation Disorders %	2.2	1.1	0.248
Weight Loss	4.4	3.3	0.475

Values are expressed as mean \pm SD for continuous variables or percentages for categorical variables.

Abbreviations: MCS- mechanical circulatory support.; CAD - coronary artery disease; TIA - transient ischemic attack.

Table 4

Propensity score matching outcomes between urgent and non-urgent groups in patients undergoing percutaneous mitral valve repair using MitraClip.

Outcome	Urgent	Non- Urgent	OR (95% CI) Urgent (when compared with Non-urgent)	P- Value
Overall (n)	229	543		
In-Hospital Mortality, %	4.4	2.8	1.607 (0.711–3.633)	0.254
Hemorrhage Requiring Transfusion, %	9.6	6.3	1.591 (0.909–2.786)	0.364
Cardiac Complications, %	8.3	6.1	1.398 (0.778–2.515)	0.263
Respiratory Complications, %	13.1	7.7	1.798 (1.095–2.954)	0.021
AKI, %	33.6	11.2	4.003 (2.731-5.866)	< 0.001
Discharge to Facility, %	24.5	10.5	2.760 (1.836–4.149)	< 0.001

Abbreviations; UOR - unadjusted odds ratio; AKI - acute kidney injury.

regurgitation, then MitraClip or any procedure to correct it with least risk should be therapeutic [21].

As expected, bleeding requiring transfusion was significantly higher in the urgent MitraClip recipients given the non-elective nature of such a procedure in these patients (Tables 1 and 2). Furthermore, acute renal failure was almost four fold in the urgent MitraClip recipients (35% vs. 9.3%, p < 0.001) (Table 2), which is not surprisingly given a higher prevalence of cardiogenic shock in the urgent group [22–24].

Respiratory complications were 24.2% in the urgent group versus 15,4% in the non-urgent group (p < 0.001) (Table 2), probably due to higher incidence of circulatory failure observed in the urgent group recipients [25–27]. Patients in the urgent group were discharged to the rehab facility more than 2.5-fold more than the non-urgent group after a lengthier hospital stay (average of eight days versus two days in the nonurgent group) (Table 2). All of the outcomes examined remained statistically significant after adjusting the p-value except for the in-hospital mortality; hence, it is presumably fair to indicate that despite the significant higher illness severity, when urgent MitraClip is indicated, performing the procedure is an acceptable approach without an accompanying mortality rise (Table 2). Further, applying the propensity score to all our outcomes of interest, the in-hospital mortality rate related to urgent MitraClip became insignificantly different from the MitraClip performance in the non-urgent group (Table 4). There was a statistically significant higher acute kidney injury and percentage of patients discharged to the facility from the urgent MitraClip group after propensity score matching (Table 4).

The national inpatient sample database used in this analysis has been validated multiple times for accuracy. Nevertheless, as with all studies that use routinely collected electronic healthcare data, there are many limitations to our study. Given the retrospective design, there is a possibility that unmeasured confounders are present due to a lack of randomization. Due to the relatively large number of outcomes studied, we adjusted for all potential covariates available in the database and used propensity score matching as a sensitivity analysis to correct for differences in baseline characteristics between groups. Further, given the nature of this database, some variables could not be obtained, e.g., we were unable to obtain information regarding the amount of contrast used during the procedure, echocardiography data, or medication utilized periprocedurally, all of which could have affected some of the outcomes. Similarly, we did not have information related to hemodynamic parameters during the course of or details of hemodynamics after the t procedure, which may have provided valuable information about efficacy. Finally, outcome analysis was limited to in-hospital outcomes.

In conclusion, using a large nationwide database, there was no statistically significant difference in in-hospital mortality between urgent percutaneous mitral valve repair using MitraClip procedures compared with those in the non-urgent setting. Furthermore, no statistical difference was found in cardiac complications and hemorrhage requiring transfusion between urgent and nonurgent procedures, except higher incidence of non-cardiac events such as respiratory complications, acute kidney injury, and discharge to a care facility. This hypothesisgenerating analysis suggests mitral valve repair using MitraClip may be considered as a viable option in properly selected patients needing this procedure in a non-elective setting. This data is overall encouraging and may help design dedicated studies to study this high-risk population.

5. Authorship declaration

I certify that all authors listed above meet the authorship criteria and all authors participated and in agreement with the manuscript

Disclosure

Nothing to disclose.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2022.101087.

References

- M. Enriquez-Sarano, C.W. Akins, A. Vahanian, Mitral regurgitation, Lancet 373 (9672) (2009) 1382–1394.
- [2] B. Iung, A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease, Eur. Heart. J. 24 (13) (2003) 1231–1243.
- [3] V.T. Nkomo, J.M. Gardin, T.N. Skelton, J.S. Gottdiener, C.G. Scott, M. Enriquez-Sarano, Burden of valvular heart diseases: a population-based study, Lancet 368 (9540) (2006) 1005–1011.
- [4] T. Feldman, E. Foster, D.D. Glower, S. Kar, M.J. Rinaldi, P.S. Fail, R.W. Smalling, R. Siegel, G.A. Rose, E. Engeron, C. Loghin, A. Trento, E.R. Skipper, T. Fudge, G. V. Letsou, J.M. Massaro, L. Mauri, Percutaneous repair or surgery for mitral regurgitation, N. Engl. J. Med. 364 (15) (2011) 1395–1406.

- [5] M. Akodad, G. Schurtz, J. Adda, F. Leclercq, F. Roubille, Management of valvulopathies with acute severe heart failure and cardiogenic shock, Arch. Cardiovasc. Dis. 112 (12) (2019) 773–780.
- [6] L. Mauri, E. Foster, D.D. Glower, P. Apruzzese, J.M. Massaro, H.C. Herrmann, J. Hermiller, W. Gray, A. Wang, W.R. Pedersen, T. Bajwa, J. Lasala, R. Low, P. Grayburn, T. Feldman, 4-year results of a randomized controlled trial of percutaneous repair versus surgery for mitral regurgitation, J. Am. Coll. Cardiol. 62 (4) (2013) 317–328.
- [7] G.W. Stone, JoAnn Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I. J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, M.J. Mack, Transcatheter Mitral-Valve Repair in Patients with Heart Failure, N. Engl. J. Med. 379 (24) (2018) 2307–2318.
- [8] J.-F. Obadia, D. Messika-Zeitoun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, D. Carrié, M. Nejjari, P. Ohlmann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, M. Gilard, E. Donal, J.-N. Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, G. Samson, P. Guerin, A. Vahanian, N. Mewton, Percutaneous Repair or medical treatment for secondary mitral regurgitation, N. Engl. J. Med. 379 (24) (2018) 2297–2306.
- [9] C.P. Kovach, S. Bell, A. Kataruka, M. Reisman, C. Don, Outcomes of urgent/ emergent transcatheter mitral valve repair (MitraClip): A single center experience. Catheter Cardiovasc Interv, (2020).
- [10] S.T. Pleger, E. Chorianopoulos, U. Krumsdorf, H.A. Katus, R. Bekeredjian, Percutaneous edge-to-edge repair of mitral regurgitation as a bail-out strategy in critically ill patients, J. Invasive. Cardiol. 25 (2013) 69–72.
- [11] S. Garcia, et al., Percutaneous mitral valve repair with MitraClip in inoperable patients with severe mitral regurgitation complicated by cardiogenic shock, J. Invasive. Cardiol. 32 (2020) 228–231.
- [12] M. Hernández-Enríquez, et al., MitraClip® repair in cardiogenic shock due to acute mitral regurgitation: from near-death to walking, J. Heart. Valve. Dis. 27 (2018) 114–116.
- [13] C.S. Zuern, J. Schreieck, H.J. Weig, M. Gawaz, A.E. May, Percutaneous mitral valve repair using the MitraClip in acute cardiogenic shock, Clin. Res. Cardiol. 100 (8) (2011) 719–721.
- [14] A.K. Chhatriwalla, S. Vemulapalli, D.R. Holmes, D. Dai, Z. Li, G. Ailawadi, D. Glower, S. Kar, M.J. Mack, J. Rymer, A.S. Kosinski, P. Sorajja, Institutional Experience With Transcatheter Miral Valve Repair and Clinical Outcomes: Insights From the TVT Registry, JACC Cardiovasc. Interv. 12 (14) (2019) 1342–1352.
- [15] T.G. Mesana, MitraClip real-world data: what is missing and looking into the future, Cardiovasc. Revasc. Med. 21 (9) (2020) 1063–1064.
- [16] J.L. Manghelli, D.I. Carter, A.J. Khiabani, H.S. Maniar, R.J. Damiano, M.A. Sintek, J.M. Lasala, A. Zajarias, S.J. Melby, Outcomes after the MitraClip procedure in patients at very high risk for conventional mitral valve surgery, Innovations (Phila) 13 (6) (2018) 433–437.
- [17] J. Shu, G. Santulli, Update on peripheral artery disease: Epidemiology and evidence-based facts, Atherosclerosis 275 (2018) 379–381.
- [18] M.H. Criqui, J.O. Denenberg, The generalized nature of atherosclerosis: how peripheral arterial disease may predict adverse events from coronary artery disease, Vasc. Med. 3 (3) (1998) 241–245.
- [19] R. Bauersachs, U. Zeymer, J.-B. Brière, C. Marre, K. Bowrin, M. Huelsebeck, Burden of coronary artery disease and peripheral artery disease: a literature review, Cardiovasc. Ther. 2019 (2019) 1–9.
- [20] M.H. Picard, R. Davidoff, L.A. Sleeper, L.A. Mendes, C.R. Thompson, V. Dzavik, R. Steingart, K. Gin, H.D. White, J.S. Hochman, Echocardiographic predictors of survival and response to early revascularization in cardiogenic shock, Circulation 107 (2) (2003) 279–284.
- [21] K. Flint, A. Brieke, D. Wiktor, J. Carroll, Percutaneous edge-to-edge mitral valve repair may rescue select patients in cardiogenic shock: Findings from a single center case series, Catheter. Cardiovasc. Interv. 94 (2019) E82–E87.
- [22] O. Adegbala, C. Inampudi, A. Adejumo, G. Otuonye, E. Akintoye, R. Elsayed, K. Williams, P. Alvarez, L. Afonso, A. Briasoulis, Characteristics and outcomes of patients with cardiogenic shock utilizing hemodialysis for acute kidney injury, Am. J. Cardiol. 123 (11) (2019) 1816–1821.
- [23] E. Roman-Pognuz, J. Elmer, J.C. Rittenberger, F.X. Guyette, G. Berlot, S. De Rosa, A. Peratoner, B.M.L. de Arroyabe, U. Lucangelo, C.W. Callaway, Markers of cardiogenic shock predict persistent acute kidney injury after out of hospital cardiac arrest, Heart. Lung 48 (2) (2019) 126–130.
- [24] S. Vallabhajosyula, L. Ya'Qoub, S.M. Dunlay, S. Vallabhajosyula, S. Vallabhajosyula, P.R. Sundaragiri, A.S. Jaffe, B.J. Gersh, K. Kashani, Sex disparities in acute kidney injury complicating acute myocardial infarction with cardiogenic shock, ESC Heart. Fail. 6 (4) (2019) 874–877.
- [25] N.A. Mokadam, K.K. Stout, E.D. Verrier, Management of acute regurgitation in leftsided cardiac valves, Tex. Heart. Inst. J. 38 (2011) 9–19.
- [26] J.H. Kim, A. Sunkara, S. Varnado, Management of cardiogenic shock in a cardiac intensive care unit, Methodist. Debakey. Cardiovasc. J. 16 (2020) 36–42.
- [27] M. Leitman, et al., Assessment and management of acute severe mitral regurgitation in the intensive care unit, J. Heart. Valve. Dis. 26 (2017) 161–168.