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The Prevalence and Impact of Obesity on the Outcomes of Patients Undergoing Transcatheter Mitral Valve Repair using MitraClip - A National Inpatient Sample Analysis 2016 to 2020.

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The Prevalence and Impact of Obesity on the Outcomes of Patients Undergoing Transcatheter Mitral Valve Repair using MitraClip - A National Inpatient Sample Analysis 2016 to 2020.

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Abstract

Background: Low Body Mass Index (BMI) is associated with poor outcomes in patients who undergo various cardiac interventions. Studies on patients with elevated BMI have produced mixed results. Our study aims to evaluate the impact of obesity on the in-hospital outcomes of patients undergoing transcatheter mitral valve repair using MitraClip in the United States.

Methods: The National Inpatient Sample (NIS) database (2016-2020) was analyzed to identify patients who underwent transcatheter mitral valve repair using MitraClip. Patients less than 18 years, with protein-energy malnutrition and rapid weight loss, were excluded. Our final study population was classified into Obese (BMI ≥ 30 Kg/m^2) and Non-obese (Normal/Overweight) (BMI 0f 18.5 -29.9 Kg/m^2) cohorts based on their Body Mass Index (BMI). The primary outcomes were the prevalence of obesity and in-hospital mortality. Secondary outcomes were the rate of periprocedural complications, including cardiogenic shock, cardiac arrest, myocardial infarction, and acute kidney injury.

Result: 40,950 patients underwent transcatheter mitral valve repair (MitraClip) during our study period. 7.8% were identified as obese. Obese patients were more likely to be female (50.6% vs. 43.9%, p

Conclusions: Our study suggests obesity does not influence short-term in-hospital outcomes in patients undergoing transcatheter mitral valve repair using MitraClip.

Keywords

Obesity, Body Mass Index, MitraClip, Transcatheter Mitral Valve Repair

Conflict of Interest Statement

The authors have no conflict of interest

Cover Page Footnote

None

OBSERVATIONAL STUDY

The Prevalence and Impact of Obesity on the Outcomes of Patients Undergoing Transcatheter Mitral Valve Repair Using MitraClip - A National Inpatient Sample Analysis 2016 to 2020

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Background: **Low Body Mass Index (BMI) is associated with poor outcomes in patients who undergo various cardiac interventions. Studies on patients with elevated BMI have produced mixed results. Our study aims to evaluate the impact of obesity on the in-hospital outcomes of patients undergoing transcatheter mitral valve repair using MitraClip in the United States.**

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Conclusions: **Our study suggests obesity does not influence short-term in-hospital outcomes in patients undergoing transcatheter mitral valve repair using MitraClip.**

Keywords: Obesity, Body mass index, MitraClip, Transcatheter mitral valve repair

1. Introduction

The established therapy for degenerative mitral valve regurgitation had long been open mitral valve surgery. Over the last decade, edge-to-edge repair with the MitraClip has allowed a percutaneous approach. Several clinical studies have demonstrated the feasibility, efficacy, and safety outcomes of MitraClip procedures compared to surgery with similar results in both high and low-risk surgical candidates.[1–4] However, despite the surge in percutaneous repair of the MV, certain patient characteristics have been shown to influence the success of the procedure, including Body Mass Index (BMI).[5–7] The impact of BMI on the outcomes of MitraClip procedures has been mixed in the literature. Some studies show a trend toward the significance of the obesity paradox with better

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results in certain hospital outcomes in obese patients compared to non-obese patients, while other studies suggest no demonstrable effect.[5,8]

Herein, we build on the prior works on this subject by examining the impact of BMI on MitraClip outcomes using the largest multicenter database in the USA. We specifically assess how the severity of obesity affects in-hospital outcomes following valve repair. Considering the size and diversity of our population, this study will provide a more nuanced insight for patient selection.

2. Methods

Data was sourced from the Nationwide Inpatient Sample (NIS) database from 2016 to 2020. The NIS is a hospital inpatient stay database derived from hospitals" billing data to statewide data organizations across the USA, covering more than 97% of the US population.[9] Each year approximates a 20% stratified sample of discharges from US community hospitals, excluding rehabilitation and long-term acute care hospitals.[10] This dataset is weighted to obtain national estimates. The 2016 to 2020 databases are coded using the International Classification of Diseases, Tenth Revision, Clinical Modification/Procedure Coding System (ICD-10-CM/PCS). In the NIS, diagnoses are divided into principal and secondary diagnoses. Procedures Performed during hospitalization are also obtained using ICD 10 PCS codes.

We conducted a retrospective cohort study of hospitalizations from 2016 through 2020 who underwent MitraClip repair procedures. We used ICD-10 PCS codes from a literature review of similar validated studies on MitraClip interventions.[8,11,12]

This manuscript is exempt from Rochester Regional Health Institutional Review Board approval as it involves data without patient identifiers. The data used in this study are readily available online at www.hcup-us.ahrq.gov. Ethical compliance with human/animal studies is not applicable as no animals were used in this study, and the study involves data without patient identifiers.

The study population included all hospital admissions for transcatheter mitral valve repair using MitraClip in the NIS database between 2016 and 2020. Patients under 18 years of age, those diagnosed with Protein Energy Malnutrition, and those experiencing Rapid Weight loss were excluded. We further stratified our sample Population into two cohorts based on their weight, Obese (BMI $\geq$30 kg/m^2) and Non- Obese (Normal/Overweight) (BMI 0f 18.5–29.9 kg/m^2) (Study flow chart in Fig. 1). From our cohorts, we assessed for the differences in baseline characteristics and comorbidities (Table 1). Study variables: sociodemographic characteristics (Age, Gender, Race, and hospital characteristics) are included as part of the HCUP database, while ICD-10 diagnostic codes were used to identify BMI and other comorbidities evaluated in our study. We also assessed the five-year trend of percutaneous mitral valve repair procedures within the study period (2016–2020).

The primary outcome compared inpatient mortality following MV repair in Obese vs. non-Obese patients. Secondary outcomes included rates of complications such as acute kidney injury (AKI), cardiogenic shock (CS), cardiac arrest (CA), Myocardial Infarction (MI), and Use of Temporary Mechanical circulatory support (Intra-aortic balloon pump and Impella devices). We also compared the mean length of stay (LOS) and the mean total hospital charges (THC) in both cohorts as surrogate marker for healthcare cost utilization. We analyzed the data using Stata® Version 17 software (StataCorp, Texas, USA). We analyzed all the weighted samples for national estimates following Healthcare Cost and Utilization Project (HCUP) regulations for using the NIS database.

A multivariate logistic regression model was used to calculate the adjusted odd ratios for our study outcomes, and covariates were obtained based on prior literature review of potential confounders.[5,8,11] The final model consisted of age, sex, race, Hospital size, location of Hospital, median Income based on Zip code, Insurance type, anemia, smoking, and Covariates in the Charlson Deyo comorbidity index; (Congestive Heart Failure, Myocardial infarction, Peripheral vascular disease, Dementia, Cerebrovascular accident, Connective tissue disease, Liver disease anemia, and Diabetes mellitus).[13,14] P-values considered significant in the multivariate analysis were two-sided, with 0.05 as the threshold for statistical significance.

3. Results

A total of 40,950 patients who underwent transcatheter mitral valve repair (MitraClip) in the United States between 2016 and 2020 were analyzed in this study. There was a threefold increase in the number of patients who underwent the procedure (Fig. 2). Among our study population, 3175 (7.8%) patients were identified as obese. When compared to patients with normal and overweight body mass index (BMI), they were more likely to be younger (mean age 70.7 $\pm$ 0.8 years vs. 76.5 $\pm$ 0.4 years, $p < 0.001$), female (50.6% vs. 43.9%, $p < 0.001$),

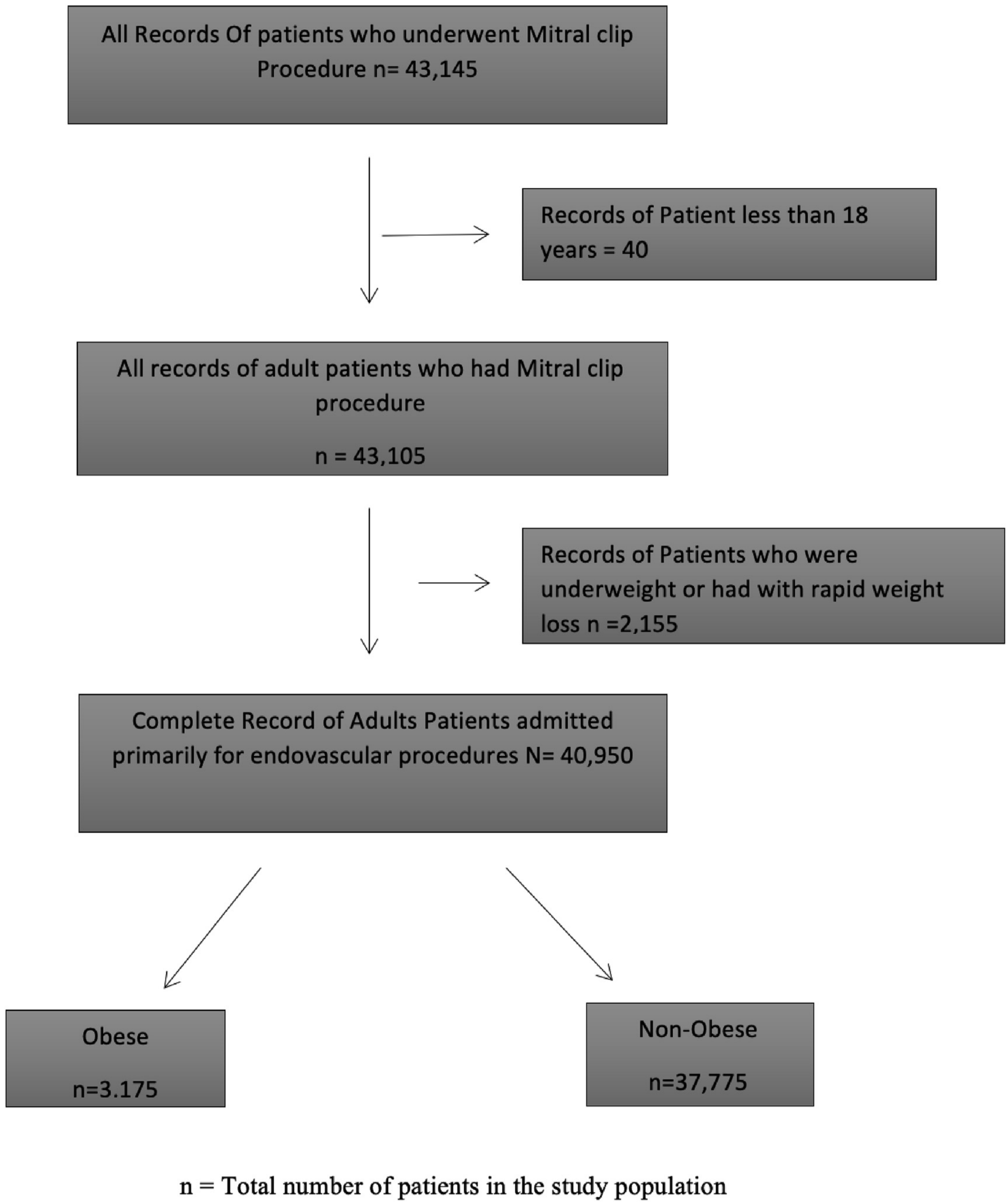

Fig. 1. Selection flow chart.

dyslipidemia (68.6% vs. 59.6%, $p < 0.001$), congestive heart failure (85.1% vs. 79.4%, $p < 0.001$) and more likely to be black (15.5% vs. 7.9%, $p < 0.001$). Obese patients were also more likely to have chronic obstructive pulmonary disease (27.5% vs. 20.3%, $p < 0.001$) as well as chronic kidney disease (44.5% vs. 36.5%, $p < 0.001$) and required more home oxygen (8.4% vs. 4.7%, $p < 0.001$) when compared to patients with normal and overweight BMI. Notably, obese patients were less likely to be Caucasian (72.8% vs. 80.8% $p < 0.001$).

In evaluating in-hospital outcomes, after adjusting for baseline characteristics and comorbidity using the Charlson Comorbidity Index, when compared to non-obese patients, obese patients had no significant difference in mortality, odds ratio [aOR 0.90 (95% CI, 0.45−1.82, $p = 0.771$)]. Additionally, no statistically significant differences in the odds of other periprocedural complications, including cardiac arrest [aOR 0.95 (95% CI, 0.25−3.58, $p = 0.941$)], cardiogenic shock [aOR 1.04 (95% CI, 0.68−1.62, $p = 0.834$)] and myocardial infarction [aOR 0.7 (95%

Table 1. Baseline characteristics and comorbidities.

Variable	MitraClip Procedure n = 40,950		P-value
	Non- Obese	Obesity	
Number, n (%)	n = 37,775 (92.2)	n = 3175 (7.8)	
Patient Characteristics			
Age, years, mean ± SE[a]	76.5 ± 0.4	70.7 ± 0.8	<0.001
Sex (%)			<0.001
Male	56.1	49.4	
Female	43.9	50.6	
Race (%)			<0.001
White	80.8	72.8	
Black	7.9	15.5	
Hispanic	5.8	7.5	
Asian	2.8	1.7	
Native American	0.4	0.1	
Others	2.2	2.3	
Comorbidities (%)			
Dyslipidemia	59.6	68.6	<0.001
Chronic heart failure	79.4	85.1	<0.001
History of MI[a]	14.7	16.5	0.126
History of PCI[a]	2.9	2.1	0.197
Coronary Artery Disease	2.8	2.7	0.909
History of Stroke	1.9	1.4	0.102
Hypertension	15.1	13.3	0.145
Peripheral Vascular Disease	2.4	3.8	0.002
COPD[a]	20.3	27.5	<0.001
Chronic Kidney Disease	36.5	44.5	<0.001
Smoking	33.2	33.8	0.725
Electrolytes abnormalities	14.9	17.5	0.037
Oxygen Dependance	4.7	8.4	<0.001
Anemia	29.5	33.5	0.008
Charlson Comorbidity Index Score			<0.001
0	8.9	4.7	
1	21.9	15.2	
2	18.7	16.8	
≥3	50.6	63.4	

[a] SE: Standard Error, MI: Myocardial Infarction, PCI: Percutaneous Coronary Intervention, COPD: Chronic Obstructive Pulmonary Disease.

CI, 0.31–1.60, p = 0.402)]. Notably, obese patients were observed to have higher odds of acute kidney injury [aOR 1.29 (95% CI, 1.02–1.65, p = 0.034)] (Table 2). In further sub-analysis of patients with and without underlying Chronic Kidney Disease (CKD), we found no significant differences in AKI incidence, respectively. When sub-analysis of the risk of AKI was performed by Obesity class, only patients with Obesity class III had significant results. [aOR 2.10 (95% CI, 1.30–3.40, p = 0.002)] (Tables 3 and 4). No significant differences were observed in the length of stay and total hospital cost in both patient cohorts.

4. Discussion

This study retrospectively compared in-hospital outcomes among obese and non-obese patients who underwent transcatheter mitral valve repair using MitraClip. Our key findings include: (I) The total number of individuals who underwent the procedure progressively increased threefold during our study period. (II) Among the 40,950 patient cohort identified as those who underwent the procedure using the 2016–2020 NIS data, 7.8% of patients were classified as obese using their Body Mass Index. (III) Obese patients undergoing transcatheter mitral valve repair using MitraClip are more likely to develop acute kidney injury when compared to non-obese patients. (IV) Comparing in-hospital mortality, there is no significant difference between obese and non-obese patients in our study population. (V) In evaluating other periprocedural complications, there was no significant difference in cardiac arrest, cardiogenic shock, myocardial infarction, and the use of mechanical circulatory support devices (intra-aortic balloon pump, impella pumps, and veno-arterial extracorporeal membrane oxygenation) between obese and non-obese patients" cohorts. (VI) No significant differences were observed in

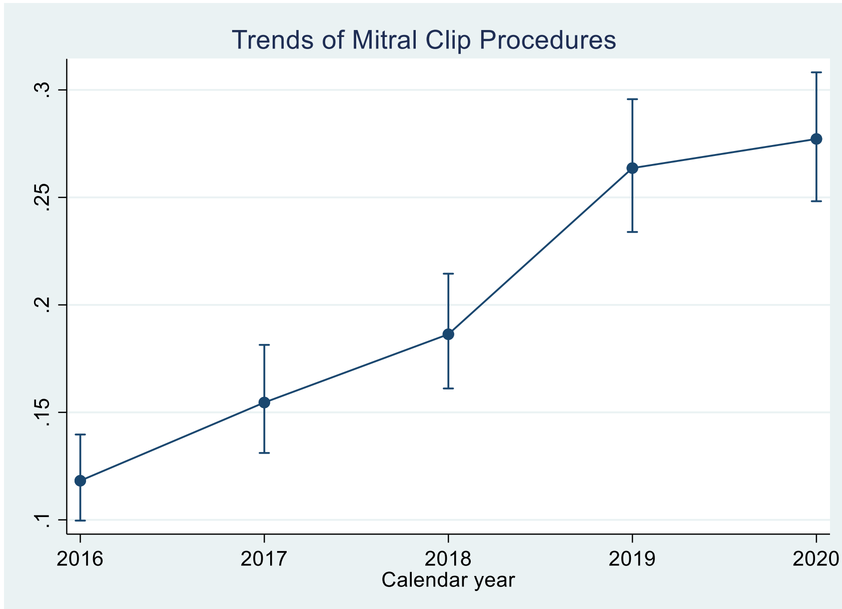

Fig. 2. Trends in transcatheter mitral valve repair using MitraClip.

Table 2. Comparison of in-hospital outcomes between normal weight and obese patients undergoing transcatheter mitral valve repair using MitraClip.

Outcomes	Normal (%)	Obesity (%)	Adjusted OR[a]	Confidence Interval[a]	P-value
Mortality	1.6	1.7	0.90	0.45−1.82	0.771
Cardiac arrest	0.4	0.7	0.95	0.25−3.58	0.941
Cardiogenic Shock	3.7	4.9	1.04	0.68−1.62	0.834
Myocardial Infarction	1.3	1.6	0.70	0.31−1.60	0.402
Temporary MCS[a]	1.8	2.7	1.12	0.60−2.11	0.719
Acute Kidney Injury	12.9	18.0	1.29	1.02−1.65	0.034

[a] OR: Odds ratio,95% CI: Confidence Interval, MCS: Mechanical Circulatory Support (Intra-aortic balloon pump, Impeller pumps, Veno-Arterial Extracorporeal Membrane Oxygen).

Table 3. Sub-analysis of the association between Obesity class and Acute Kidney Injury.

Non-Obese (reference)	Adjusted OR[a]	Lower limit of CI[a]	Upper limit of CI[a]	P-value
Class I (30.0−34.9)	1.02	0.64	1.62	0.956
Class II (35.0−39.9)	1.25	0.78	2.00	0.349
Class III (≥40)	2.10	1.30	3.40	0.002

[a] OR: Odds ratio,95% CI: Confidence Interval.

Table 4. Sub-analysis of the association between Obesity class and Acute Kidney Injury among Patients with Chronic Kidney Disease.

Variables	Adjusted OR[a]	Lower limit of CI[a]	Upper limit of CI[a]	P-value
Chronic Kidney Disease	1.15	0.81	1.64	0.422
No Chronic Kidney Disease	1.33	0.79	2.81	0.281

[a] OR: Odds ratio, 95% CI: Confidence Interval.

comparing total hospitalization cost and length of stay among obese and non-obese patients.

Obesity is a complex multifactorial disease with significant cardiovascular comorbid burdens such as hypertension, diabetes, dyslipidemia, and obstructive sleep apnea.[15−17] According to the World Health Organization, the prevalence of obesity has tripled since 1975, with over 650 million obese persons globally and obesity ranks number two as a leading cause of preventable deaths after tobacco use.[18,19] The overwhelming evidence supports poor outcomes among patients with low BMI undergoing percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), and transcatheter aortic valve replacement (TAVR).[20–23] However, the relationship between elevated BMI and cardiac interventions is more complex; most studies suggest a relatively neutral to favorable impact of obesity on clinical outcomes. Studies evaluating short and long-term outcomes of PCI on mortality among obese patients revealed a positive correlation, a concept termed "the obesity paradox,[24,25] which has also been described in multiple other studies.[26–29] The pathophysiology behind this concept is not clearly understood but there are several hypotheses including the cardioprotective effects of some adipokines (e.g apelin, adiponectin) produced by adipose tissues. It has also been postulated that the increased mobilization of endothelial progenitor cells in patients with obesity may have some protective effects against atherogenesis through enhancing the regeneration of damaged myocardium and through angiogenesis-reducing apoptosis and fibrosis of the myocardium.[30,31] Similarly, lower in-hospital mortality rates and a neutral impact on the risk of myocardial infarction were observed in patients undergoing CABG and PCI.[23,32] *Xiao-Feng Tan* et al., in a systematic review and meta-analysis of twelve studies and 91,582 patients undergoing percutaneous coronary intervention suggest the higher dosage and intensive use of medications such as beta blockers, statins, angiotensin converting enzyme inhibitors/ angiotensin receptor blocker and antiplatelet agents which were more prominent in overweight and obese patients post-intervention may play a positive role in improving short-term (30 days) mortality when compared to normal weight patients.[33] However, the impact of this phenomenon is mainly observed amongst overweight and class I obese patients.[34]

The overall prevalence of obesity among patients who underwent transcatheter mitral valve repair during our study period was 7.8% which is comparable to 7.5% in a similar study conducted by *Karsten Keller* et al. using the database of the German national inpatient sample.[5] Our study's strength is a bigger sample size of approximately three times (40,950 patients vs. 13,563 patients); obese patients were significantly younger and more likely to be male in both studies. While this may contradict multiple studies[35,36] that have reported a higher incidence of obesity in females compared to their male counterparts, the overall prevalence of cardiovascular disease is higher in men and may explain the higher proportion of males in our study.

In our study, no significant differences were observed in in-hospital mortality, cardiac arrest, cardiogenic shock, myocardial infarction, or the use of mechanical circulatory support devices. Similar studies have comparable outcomes in terms of in-hospital mortality, cardiac arrest, and myocardial infarction. However, using a combined endpoint of cardiopulmonary resuscitation (CPR), mechanical ventilation, and death confirmed obesity paradox with 2.4% fewer occurrences in obese patients.[5] While short-term outcomes did not display obesity paradox, long-term outcomes may differ. *Robert M.A* et al. evaluated the effect of body mass index on short- and long-term outcomes of transcatheter aortic valve implantation and showed obesity was associated with a lower 30-day mortality risk emphasizing the obesity paradox.

Obesity is an independent risk factor for acute kidney injury in post-operative patients.[37] It can alter fluid hemodynamics with significant implications on renal perfusion and glomerular filtration rate.[38,39] This may explain the higher incidence of acute kidney injury in obese patients. Additionally, multiple other comorbid conditions, such as pulmonary hypertension, sleep apnea associated with venous congestion, and sodium dependence, can increase the risk of renal failure.[40] CKD at baseline, presence of albuminuria, diabetes, recent AKI, and inflammation all increase the risk of AKI. Multiple studies, including a paper by *Armijo G* et al., showed that in-hospital AKI does influence long-term outcomes including the risk of myocardial infarction and death, but this study does not have the long-term follow-up data to support this hypothesis.[41,42] Our study highlights the need to consider the role of morbid obesity (BMI $\geq$40) as an independent risk factor for acute kidney injury in the preprocedural evaluation of patients undergoing transcatheter mitral valve repair with MitraClip. Further measures may be taken to mitigate this risk, such as stopping nephrotoxic medications and avoidance of contrast for imaging among these high-risk populations.

Our studies have several limitations; this is a retrospective analysis with potential bias from unadjusted and unmeasured confounders. We utilized the National Inpatient Sample Database 2016–2020 for our study. Variables analyzed were extracted using ICD 10 coding. The use of ICD may be prone to subject to coding errors. Additionally, due to the design of the database, long-term outcomes cannot be assessed. Obesity was analyzed as one variable; perhaps the analysis of the various classes of obesity may reveal different outcomes. It is also important to consider the variable nature of BMI and understand that each 1 (one) standard deviation (SD) increase is associated with a higher risk of coronary, and cardiovascular events, and death.[43] Our study used a single point BMI measurement, which could also be considered a limitation.

In conclusion, this study which evaluated short-term outcomes did not demonstrate the obesity paradox and revealed no significant differences in in-hospital mortality, cardiogenic shock, cardiac arrest, myocardial infarction, total hospital charges, length of stay, and the use of mechanic circulatory support devices among obese and non-obese patients undergoing transcatheter mitral valve repair using MitraClip. However, our findings suggest morbid obesity (BMI $\geq$40) is an independent risk factor for acute kidney injury among these patients cohort. Further studies are needed to evaluate long-term outcomes.

Conflict of interest

The authors do not have any conflict of interest.

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