Outcomes Amongst Obesity Class I, II, and III Patients Undergoing Minimally Invasive Aortic Valve Replacement

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Abstract

Background: Minimally invasive heart valve surgery has previously been shown to be safe and feasible in obese patients. Within this population, we investigated the effect of obesity class on the patient outcomes of minimally invasive aortic valve replacement (mini-AVR). Methods: A single center retrospective cohort study of consecutive patients with obese body mass indices (BMIs) who underwent mini-AVR between 2012 and 2018. Patients were stratified into 3 groups according to Centers for Disease Control and Prevention adult obesity classifications: Class I (BMI 30.0 to < 35.0), Class II (BMI 35.0 to < 40.0), and Class III (BMI [?] 40.0). The primary outcomes were postoperative length of stay (LOS), 30-day mortality within, and cost. Results: Amongst 182 obese patients who underwent mini-AVR, LOS (Class I 4 [3-6] vs. Class II 4 [3-6] vs. Class III 5 [4-6] days; p=0.098) and costs (Class I $24,487 [$20,199-$27.480] vs. Class II $22,921 [$20,433-$27,740] vs. Class III $23,886 [$20,063-$33,800] USD; p=0.860) did not differ between obesity class cohorts. Postoperative 30-day mortality (Class I 2.83% [n=2] vs. Class II 0% [n=0] vs. Class III 0% [n=0]; p=0.763) was limited by an insufficient sample size relative to a low event rate but did not differ between patient cohorts. Conclusions: Mini-AVR is safe and feasible to perform for obese patients regardless of their obesity class. Patients with obesity should be afforded the option of minimally invasive aortic valve surgery regardless of their obesity class.

Introduction

First described in congestive heart failure and chronic kidney disease patients, reverse epidemiology and the obesity paradox suggest an unexpected protective effect of overweight and obese body mass indices (BMIs) on patient outcomes.[1,2] This paradoxical effect has been replicated in multiple studies since the early 2000's, notably by Mariscalco and colleagues who studied over 900,000 patients to find an association between obesity and lower postoperative risk after cardiac surgery.[3] Owing to the demonstration of the obesity paradox predominantly in observational studies, its value within clinical practice continues to be debated.

With the rise of minimally invasive heart valve surgery, both minithoracotomy and partial sternotomy have been demonstrated to be safe and feasible in patients with obesity.[4,5] Minimally invasive valve surgery offers these patients an enhanced recovery experience with fewer postoperative complications as compared to the conventional full sternotomy.[6,7]

It is as of yet unknown how the feasibility and outcomes of minimally invasive valve surgery vary across the range of obese BMIs.[6,7] The purpose of this study was to assess the outcomes of minimally invasive aortic valve replacement between patients of different obesity classes. We therein consider the operationalization of obesity class in operative planning, as a means of providing optimal, individualized patient care.

Materials and Methods

This is a retrospective cohort study of all adult patients ([?] 18 years of age) who underwent isolated minimally invasive aortic valve replacement at a single academic medical center between January 1, 2015 and June 5, 2020 (Robert Wood Johnson University Hospital, New Brunswick, New Jersey). This center has an average annual surgical volume of 15,000 cases performed out of twenty-two operating rooms; approximately 1,600 are cardiac surgical procedures, with 1,400 open cases and 200 transcatheter valves procedures per year. The data source for the study is the cardiac surgery database of the academic center, developed according to The Society of Thoracic Surgeons (STS) Adult Cardiac Database version 2.81 definitions. The database contains patient demographics, baseline clinical and perioperative characteristics, in-hospital outcomes, and 30-day outcomes. This study was approved by the Institutional Review Board at the academic center.

Minimally invasive aortic valve replacement (mini-AVR) patients included those who underwent aortic valve replacement through partial sternotomy or right minithoracotomy. Patients were selected for minimally invasive valve surgery versus conventional full sternotomy based upon shared decision-making between the surgeon and the patient. The study population was stratified into three cohorts by patient BMI according to the Centers for Disease Control and Prevention adult obesity classifications: Class I (BMI 30.0 to $<$ 35.0 kg/m^2), Class II (BMI 35.0 to $<$ 40.0 kg/m^2), and Class III (BMI [?] 40.0 kg/m^2). Patients with a non-obese BMI ($<$ 30 kg/m^2) and those who underwent additional concomitant procedures (*e.g.* , double valve replacement) were excluded from the study.

Baseline patient demographic, clinical, and perioperative characteristics were recorded and compared between cohorts. Primary outcomes of postoperative length of stay, mortality within 30 days after surgery, and total direct costs were evaluated. To contextualize 30-day mortality, in-hospital mortality and 30-day readmission were analyzed as secondary outcomes. Postoperative complications of atrial fibrillation, acute renal failure, bleeding requiring transfusion, delayed extubation, circulatory support with intra-aortic balloon pump, and stroke were assessed as tertiary outcomes.

Continuous and categorical variables are presented as median and interquartile range (IQR: 25th to 75th percentiles) and frequencies and percentages, respectively, and compared using the Kruskal–Wallis one-way analysis of variance test or Fishers exact test with the Freeman-Halton extension.[8] Statistical significance was accepted at ap value of less than 0.05.

Results

During the study period, 404 patients underwent isolated mini-AVR. There were 222 patients with a non-obese BMI who were excluded from the study. The final study population included 182 patients: 106 (58.2%) with Class I obesity, 42 (23.1%) with Class II obesity, and 34 (18.7%) with Class III obesity. The total study population had a median (IQR) BMI of 34.0 (31.7-37.4) kg/m^2.

Baseline demographic and clinical characteristics amongst patient cohorts are described in Table 1. The prevalence of diabetes mellitus correlates with obesity class, with the proportion of diabetic patients increasing from Class I to Class II and from Class II to Class III (Class I 33.0% [n=35] vs. Class II 33.3% [n=14] vs. Class III 55.9% [n=19]; p=0.049). The Society of Thoracic Surgeons (STS) predictive risk of mortality (PROM) score also increases with increasing obesity class (Class I 1.03% [0.70-1.92%] vs. Class II 1.39% [0.96-2.22%] vs. Class III 1.86% [1.22-2.41%]; p=0.028). The proportion of patients with hypertension does not differ between cohorts (p=0.687). Most patients were of Caucasian race, with all African American and Asian patients falling into the Class I obesity cohort. Patient race was not statistically different between obesity classes (p=0.327).

Table 2 presents perioperative characteristics of the population stratified by patient cohort. There was no difference amongst cohorts in bypass or cross-clamp time (p=0.332 and p=0.784, respectively), ICU length of stay (p=0.180), or intraoperative or postoperative transfusion of blood products. Patients with Class II obesity demonstrated a less frequent requirement for postoperative packed red blood cell transfusions (Class I 12.3% [n=13] vs. Class II 0.0% [n=0] vs. Class III 14.7% [n=5]; p=0.018), but with no different rates of postoperative bleeding (Class I 0.94% [n=1] vs. Class II 0.0% [n=0] vs. Class III 5.88% [n=2]; p=0.131).

The postoperative length of stay (Class I 4.0 [3.0-6.0] days vs. Class II 4.5 [3.0-6.0] days vs. Class III 5.0 [4.0-6.0] days; p=0.098) and total direct costs (Class I $24,487 [$20,199-$27.480] vs. Class II $22,921 [$20,433-$27,740] vs. Class III $23,886 [$20,063-$33,800]; p=0.860) did not differ between obesity class cohorts (Figure 1). Postoperative 30-day mortality (Class I 2.83% [n=2] vs. Class II 0% [n=0] vs. Class III 0% [n=0]; p=0.763) did not differ between patient cohorts and was contextualized by in-hospital mortality and 30-day readmission rates that also failed to show between-cohort differences. Aside from postoperative atrial fibrillation, which was observed much more frequently in patients with Class II and III obesity (p<0.001), postoperative complication rates were comparable between cohorts (Figure 2).

Discussion

To the authors' knowledge, the herein presented study is the first to scrutinize differences in outcomes after minimally invasive valve surgery according to patient obesity class. Our results demonstrate mini-AVR to be feasible and safe in obese patients irrespective of obesity class, thus supporting a nondiscriminatory approach to operative planning for patients with valvular disease. The postoperative lengths of stay averaged four to five days and total direct costs $22,000-25,000, both outcomes comparable between patients of any obesity class. Thirty-day postoperative mortality affected two patients in the study population, and they were of Class I obesity, notably the largest patient cohort. Consequently, patients with comorbid obesity and aortic valve disease should be considered for minimally invasive surgery without concern for a disproportionately complicated course of recovery.

Performing minimally invasive valve surgery for obese patients has often been a point of contention due to concerns of adequate surgical field exposure, single lung ventilation, and the greater frequency of additional chronic medical conditions in this population. Nevertheless, studies comparing the outcomes of patients with normal (18.5-25 kg/m^2), overweight (25-30 kg/m^2), and obese ($>$ 30 kg/m^2) BMI have shown that experienced centers see comparable rates of postoperative mortality, reoperation, blood transfusion, wound infection, stroke, pacemaker implantation, and length of stay after minimally invasive valve surgery.[9] Aljanadi *et al.* found that five-year survival between obese and non-obese patients undergoing minimally invasive mitral valve surgery was similar (95.8% vs 95.5%, p=0.83).[10] In consideration of the patient with obesity, Santana *et al.* demonstrated minimally invasive approaches to be superior to full sternotomy with fewer postoperative complications (23.5% vs 51.0%, p=0.034) and lower in-hospital mortality (0% vs 8.3%, p=0.04).[4]

However, to date, these observations have not been scrutinized between obesity classes, raising question of the broad application of these findings across the continuum of higher BMIs. Our study thus builds on previous work to share multiple important findings. First, we demonstrated that mini-AVR is feasible in patients of Class I, II, and III obesity. Second, mini-AVR is safe despite baseline STS PROM scores that positively correlate with obesity class: patients amongst obesity classes experience no different lengths of stay, short-term mortality, hospital readmission rates, or perioperative complications (with the exception of atrial fibrillation). Third, the cost of performance of minimally invasive AVR (*i.e.* , via partial sternotomy or minithoracotomy) does not differ between patient obesity classes. Collectively, these observations support the equitable provision of minimally invasive options to obese patients regardless of obesity class – options that may in turn minimize perioperative pain, expedite recovery, and reduce resource utilization without compromising clinical outcomes.

Additional observations were made regarding the relationships between select baseline patient characteristics and obesity classes. Common to the current literature, we observed an association between obesity class and metabolic comorbidities, namely, diabetes mellitus;[11] while our study found no difference in the frequency of diabetes between patients with Class I versus Class II obesity, diabetes was significantly more common amongst patients in the Class III obesity cohort. The STS PROM score also demonstrated a stepwise relationship with obesity class. In line with this finding, Ghanta and colleagues have shown that STS PROM tends toward lower risk scoring for obese patients (spanning Class I and II BMIs) versus normal weight, overweight, and morbidly obese (Class III) patients.[12] In contrast to the current literature that correlates hypertension and obesity class, however, our study found no such association.[12,13] This is due to an exceedingly high prevalence of hypertension across our study population (affecting 90-95% of patients on average), which would have required a large study population to differentiate minute differences amongst obesity cohorts.

Upon observation of the primary study outcomes, we found patient obesity class to have no effect on post-operative length of stay or direct cost of mini-AVR. Whilst Mariscalco *et al.* 's obesity paradox in cardiac surgery continues to be debated, single center studies have shown that patients with higher BMI experience longer lengths of stay and more expensive costs of care after cardiac surgery.[12,14] At our academic medical center, appropriate operative planning, intraoperative patient positioning, and, over the study period, a gradual implementation of typical Enhanced Recovery After Surgery (ERAS) protocol elements (*e.g.* , preoperative conditioning, early extubation) have perhaps prevented BMI from dictating operative room time and costly resource utilization. With a multidisciplinary team of cardiac surgery anesthesiologists and physician assistants, critical care physicians, and nurse practitioners providing comprehensive perioperative care, our patients are optimized for discharge within four to five days of their operation, as demonstrated in this study. Our study also failed to reveal a difference in 30-day mortality after mini-AVR amongst obesity classes, complementary to the meta-analysis conducted by Mariscalco *et al.* [3] Not only might obese patients experience paradoxically lower risks of mortality after cardiac surgery, but this risk may be comparable across all classes of obesity at least in the population of patient who undergo minimally invasive valve surgery.

Postoperative complications were generally experienced no differently by patients of any obesity classes. Only new atrial fibrillation was less frequently encountered by patients of Class I versus those of Class II and III obesity. With the incidence of onset of this arrhythmia as high as 20-50% after cardiac surgery, coupled with obesity as a known independent risk factor for atrial fibrillation, our finding should not preclude patients with Class II and II obesity from receiving minimally invasive valve surgery.[15,16]

There are several limitations to this study. First, bias can be attributed to its retrospective, observational design due to the lack of randomization, a control group, and *a priori* data field selection. Second, while our results demonstrated no difference in 30-day mortality amongst obesity classes, two patients in the study population did not survive the duration of the postoperative follow-up period. While we expect that these deaths occurred in the Class I obesity population by random chance consistent with its largest cohort size (total study population: Class I n=106 vs. Class II n=42 vs. Class III n=34), our study is under-powered to detect significant differences between such small event rates and thus to arrive at a sound conclusion regarding 30-day mortality amongst obesity classes. To better elucidate mortality differences amongst obese patients undergoing mini-AVR, a large database or multi-center study should be conducted.

Conclusions

In conclusion, at our academic medical center, patients with aortic valve disease and comorbid obesity who underwent aortic valve replacement experienced no different perioperative outcomes regardless of obesity class. When the obesity paradox was first discovered in the field of cardiac surgery, surprise was born from the assumption that patients with the medical comorbidity of an obese BMI would fare worse after a serious surgical intervention, as is cardiac surgery. Concertedly is the assumption that increasing obesity class may correlate with increasing perioperative risk, length of hospital stay, cost of care, and even postoperative mortality rate. In harmony with the obesity paradox, our findings again contradict such an assumption. Obese patients with higher BMIs faced no worse outcomes than those with lower BMIs after minimally invasive aortic valve replacement. Thus, the same discussions to be had with any patient considering a surgical intervention for heart valve disease, inclusive of shared decision-making of the operative approach – minimally invasive or conventional full sternotomy – should be afforded to obese patients regardless of obesity class.

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Tables

Table 1 Baseline demographics, clinical, and perioperative characteristics stratified by patient obesity class.

Characteristic	**Obesity Class**	**Obesity Class**	**Obesity Class**	***p* value [?] = 0.05**
	Class I (n = 106)	**Class II (n = 42)**	**Class III (n = 34)**	
Baseline Demographics				
Age (y) median (IQR)	67 (58-72.75)	67.5 (60-71.75)	67.5 (64-73.75)	0.214
Male n (%)	64 (60.4%)	23 (54.8%)	14 (41.2%)	0.148
Race n (%)				0.327
Caucasian	86 (81.1%)	36 (85.7%)	32 (94.1%)	
African American	6 (5.7%)	0 (0.0%)	0 (0.0%)	
Asian Other (*e.g.*, Hispanic ethnicity)	2 (1.9%) 12 (11.3%)	0 (0.0) 6 (14.3%)	0 (0.0%) 2 (5.9%)	
Clinical Characteristics				
Atrial fibrillation n (%)	20 (18.9%)	12 (28.6%)	8 (23.5%)	0.411
Aortic gradient (mmHg) median (IQR)	46.0 (38.0-59.8)	45.0 (41.3-60.3)	45.0 (40.3-49.5)	0.553
Aortic insufficiency[a] n (%)				0.211
< Moderate	74 (69.8%)	30 (71.4%)	29 (85.3%)	
[?] Moderate	32 (30.2%)	12 (28.6%)	5 (14.7%)	
Body mass index median (IQR) Congestive heart failure n (%)	32.5 (30.9-33.5) 28 (26.4%)	36.7 (35.7-37.4) 11 (23.2%)	42.7 (40.9-46.8) 15 (44.1%)	<0.001 0.134

Characteristic	Obesity Class	Obesity Class	Obesity Class	p value [?] = 0.05
Prior CVA n (%)	5 (4.7%)	4 (9.5%)	2 (5.9%)	0.473
Cerebrovascular disease n (%)	8 (7.5%)	4 (9.5%)	4 (11.8%)	0.673
Chronic renal failure n (%)	2 (1.9%)	2 (4.8%)	2 (5.9%)	0.310
Cigarette smoking n (%)				
History	65 (61.3%)	27 (64.3%)	16 (47.1%)	0.256
Current at time of surgery	8 (7.5%)	2 (4.8%)	2 (5.9%)	0.913
Diabetes mellitus n (%)	35 (33.0%)	14 (33.3%)	19 (55.9%)	0.049
Ejection fraction (%) median (IQR)	60.0 (55.0-63.5)	58.0 (55.0-60.0)	61.5 (58.0-65.0)	0.402
Hypertension n (%)	96 (90.6%)	40 (95.2%)	32 (94.1%)	0.687
Hypercholesterolemia n (%)	91 (85.8%)	40 (95.2%)	30 (88.2%)	0.191
STS PROM score (%) median (IQR)	1.03 (0.70-1.92)	1.39 (0.96-2.22)	1.86 (1.22-2.41)	0.028

Abbreviations: *CVA cerebrovascular accident, IQR interquartile range, STS PROM Society of Thoracic Surgeons predictive risk of mortality, y years*

[a] Aortic insufficiency graded ordinally as none, trace, mild, moderate, or severe according to Doppler echocardiography.

Table 2 Perioperative characteristics stratified by patient obesity class.

Characteristic	Obesity Class	Obesity Class	Obesity Class	p value [?] = 0.05
	Class I (n = 106)	**Class II (n = 42)**	**Class III (n = 34)**	
Perioperative Bypass time (m) median (IQR) Cross-clamp time (m) median (IQR) ICU LOS (h) median (IQR)	70.0 (57.0-106.5) 52.5 (42.3-78.0) 12.3 (7.3-21.7)	64.5 (58.8-77.0) 47.0 (41.0-54.8) 9.1 (7.7-25.4)	72.5 (60.0-86.3) 54.0 (44.0-60.3) 16.9 (9.7-25.0)	0.332 0.784 0.180

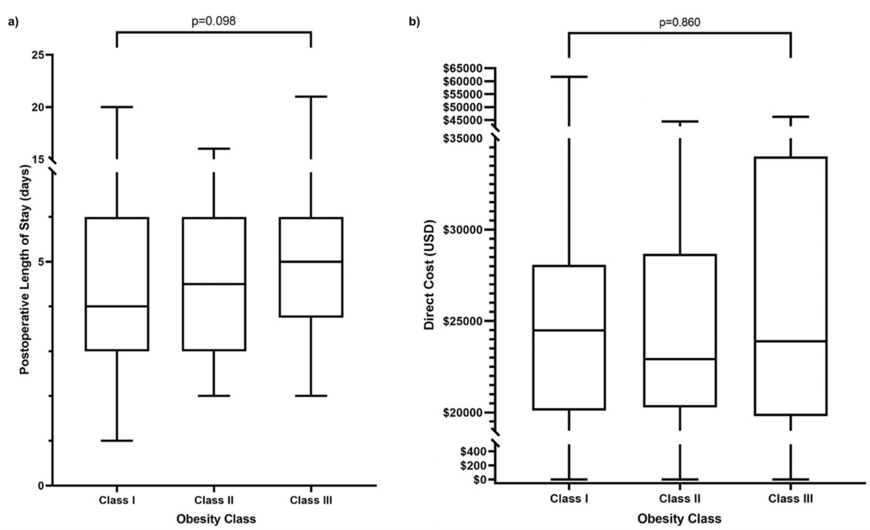
Characteristic	Obesity Class	Obesity Class	Obesity Class	p value [?] = 0.05
Blood products	5 (4.7%) 5 (4.7%)	4 (9.5%) 2 (4.8%)	0 (0.0%) 0 (0.0%)	0.174 0.571 0.086
[a] n (%)	0 (0.0%) 9 (8.5%)	2 (4.8%) 6	0 (0.0%) 5	0.411 0.018 0.272
Intraoperative	13 (12.3%) 5	(14.3%) 0 (0.0%)	(14.7%) 5 (14.7%)	0.131 0.071
Packed RBCs	(4.7%) 1 (0.9%) 7	0 (0.0%) 0 (0.0%)	2 (5.9%) 2 (5.9%)	
Fresh frozen	(6.6%)	0 (0.0%)	4 (11.8%)	
plasma				
Cryoprecipitate				
Platelets				
Postoperative				
Packed RBCs				
Fresh frozen				
plasma				
Cryoprecipitate				
Platelets				

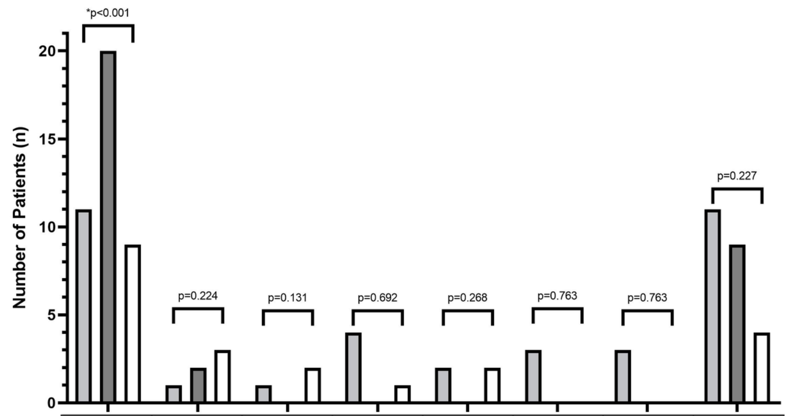
Abbreviations:*, h hours, ICU LOS intensive care unit length of stay, m minutes, RBCs red blood cells.* [a] Reported if patients received [?] 2 Units

Figure Legends

Figure 1 Comparison of **(a)** postoperative length of stay and **(b)** total direct costs for minimally invasive aortic valve replacement patients amongst Class I, Class II, and Class III obesity cohorts.

Figure 2 Postoperative complications, mortality, and readmission after minimally invasive aortic valve replacement in obese patients, stratified by Class I, Class II, and Class III obesity cohorts.





	Atrial Fibrillation	Acute Renal Failure	Bleeding Requiring Transfusion	Delayed Extubation	Stroke	In-Hospital Mortality	30-Day Mortality	30-Day Readmission
Class I	10.38%	0.94%	0.94%	3.77%	1.89%	2.83%	2.83%	10.58%
Class II	47.62%	4.76%	0.00%	0.00%	0.00%	0.00%	0.00%	21.43%
Class III	26.47%	0.00%	5.88%	2.94%	5.88%	0.00%	0.00%	11.76%