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ORIGINAL CONTRIBUTIONS

Bariatric Surgery Is Acceptably Safe in Obese Inflammatory Bowel Disease Patients: Analysis of the Nationwide Inpatient Sample

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Abstract
Background The prevalence of obesity in patients with inflammatory bowel disease (IBD) has increased over the past decades. Data to support the safety of bariatric surgery (BAR) in IBD remain scarce. Our aim was to evaluate the safety and early postoperative complications of BAR in IBD patients.
Methods We used the Nationwide Inpatient Sample (NIS) 2011, 2012, and 2013 to perform a cohort study. The study group was all hospitalized patients between ages 18–90 years who underwent BAR with a discharge diagnosis of IBD as per the Ninth International Classification of Diseases codes (ICD-9). Adults who underwent BAR without ICD-9 codes of IBD were identified as the comparison group. Complications were compared using multivariate logistic regression analysis.
Results We identified 314,864 adult patients who underwent BAR between 2011 and 2013. Mean age was 45.5 ± 0.11 years, and 79% were females. Seven hundred and ninety patients had underlying IBD; 459 had Crohn's disease and 331 had ulcerative colitis. The remaining patients formed the comparison group. Mean length of hospital stay (LOS) was longer in the IBD group by 1 day ($p = 0.01$). The IBD group had a significantly higher risk of perioperative small bowel obstruction (SBO) (adjusted odds ratio, 4.0; 95%, CI; 2.2–7.4). Other technical and systemic complications were similar between the two groups, with no mortality reported in the IBD group.
Conclusions BAR in IBD patients has an acceptable safety profile, with immeditae risk limited to perioperative SBO and an apparently low risk of mortality or other major immediate postoperative complications.

Keywords Bariatric surgery · Inflammatory bowel disease

Introduction

Obesity has reached pandemic levels, and in the United States (US), it is estimated that more than 35% of adults are obese [1]. Mirroring this rise in obesity is an increase in inflammatory bowel disease (IBD) incidence which is estimated to be 10.7 cases per 100,000 person-years for Crohn's disease (CD) and 12.2 cases per 100,000 person-years for ulcerative colitis (UC) [2]. These trends, and the fact that obesity may be a risk factor for IBD, explain the increasing prevalence of obese IBD patients. Importantly, both obesity and IBD are risk factors for increased cardiovascular morbidity. Bariatric surgery (BAR) is the most effective solution for obesity; additionally, BAR has been shown to decrease the risk of cardiovascular mortality [3]. Furthermore, recent advances resulting in a plethora of bariatric procedures and interventions have shown good efficacy in obese patients [4, 5].

Therefore, appropriate candidates should not be deprived of this important, potentially life-saving procedure, if the intervention is deemed acceptably safe. Conceptually, bariatric intervention is thought to be more challenging in IBD patients,

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considering the inflammatory state that may interfere with wound healing and recovery of normal bowel motility following the procedure, as well as the difficulty in reoperation if the patient has previously undergone an IBD-related abdominal surgery.

Prior studies that have attempted to address the feasibility and safety of BAR in IBD patients were limited by small numbers and did not specifically evaluate immediate in-hospital postoperative complications [6–13]. To examine these questions, we designed a retrospective cohort study to evaluate BAR for IBD patients, including patient characteristics, in-hospital complications, mortality, and length of hospitalization.

Methods

Data Source

We examined the Nationwide Inpatient Sample (NIS) from the Healthcare Cost and Utilization Project (HCUP) for the years 2011, 2012, and 2013 [14]. The NIS is the largest all-payer inpatient database in the US. Each year, it contains over 7 million inpatients and represents a 20% sample of inpatient hospital admissions excluding federal hospitals, rehabilitation, and long-term acute care hospitals. It covers all patients regardless of their insurance coverage. The year 2011 contained a 20% sample of the participating state's hospitals then included all discharges from the selected hospitals. However, the sampling design was changed in the year 2012 and after to contain all hospitals participating in HCUP from each state, but only took a 20% sample of discharges from each hospital. We applied the trend weights provided by the NIS to combine the datasets from 2011 through 2013. The NIS data includes demographic variables, primary and secondary diagnoses up to 25, primary and secondary procedures up to 15, hospital charges, length of stay, and hospital mortality. Since the NIS is publicly available and deidentified, the Mayo Clinic Institutional Review Board deemed this study exempt from full review.

Overall Study Population and Inclusion/Exclusion Criteria

We examined NIS data for all adults who underwent BAR between 2011 and 2013. We followed a previously used method in identifying patients who underwent bariatric surgery, wherein patients were included if they had a procedure code(s) for foregut surgery (43.0–44.99, 45.50–45.91) and a confirmatory diagnosis code for obesity (278.00–278.8) or a diagnosis related group code for obesity surgery (288), using codes from prior publications [15]. This strategy was used since the International Classification of Diseases, Ninth Revision (ICD-9), coding system does not capture all interventions currently offered for weight loss. We excluded patients with any diagnosis codes for gastrointestinal tract neoplasm (150.0–159.9) or a primary diagnosis code for inflammatory bowel disease (555.0–556.9).

Procedures codes were utilized to identify the following procedure categories: gastric bypass, gastroplasty (vertical banded gastroplasty and adjustable gastric banding), malabsorptive surgeries (duodenal switch, biliopancreatic diversion, and isolated intestinal bypass), gastrectomy (all types of partial gastrectomies), and other surgeries (nonspecified gastric procedures and gastric bubble insertion) (Supplemental Table 1).

Study and Comparison Groups

The study group consisted of patients with secondary diagnosis codes (Dx2-25) of IBD (UC [556.0-9] and CD [555.0-9]). A comparison group included all patients without secondary diagnosis codes of IBD and who underwent BAR (codes defined above).

Definition of Variables

We examined demographic information, including age, race, and gender. The burden of comorbid illness was assessed based on the Charlson comorbidity index (CCI) [16]. CCI scores range from 0 to 17, with higher numbers representing a greater comorbidity burden. The CCI has been previously utilized as a validated measure of comorbidity adjusting for disease burden in administrative databases [16].

Primary Outcome Measures

Similar to previous publications [15], we classified complications that occurred during admissions for BAR into two categories: technical and systemic. Technical complications were related to wound complications, bleeding, anastomotic complications, and GI obstruction (Supplemental Table 2). Systemic complications were respiratory (including acute bacterial pneumonia, acute respiratory failure, and need for tracheostomy), cardiac (acute myocardial infarction), neurological (acute cerebrovascular accident), renal (acute renal failure), thromboembolic (acute pulmonary embolism, acute deep venous thrombosis), and shock (Supplemental Table 3). Analysis of complications by the type of BAR was limited due to the classification (by code) of the majority of procedures as "undefined" in the database.

Secondary Outcome Measures

Inpatient mortality and length of hospital stay (in days) were evaluated as secondary outcomes.

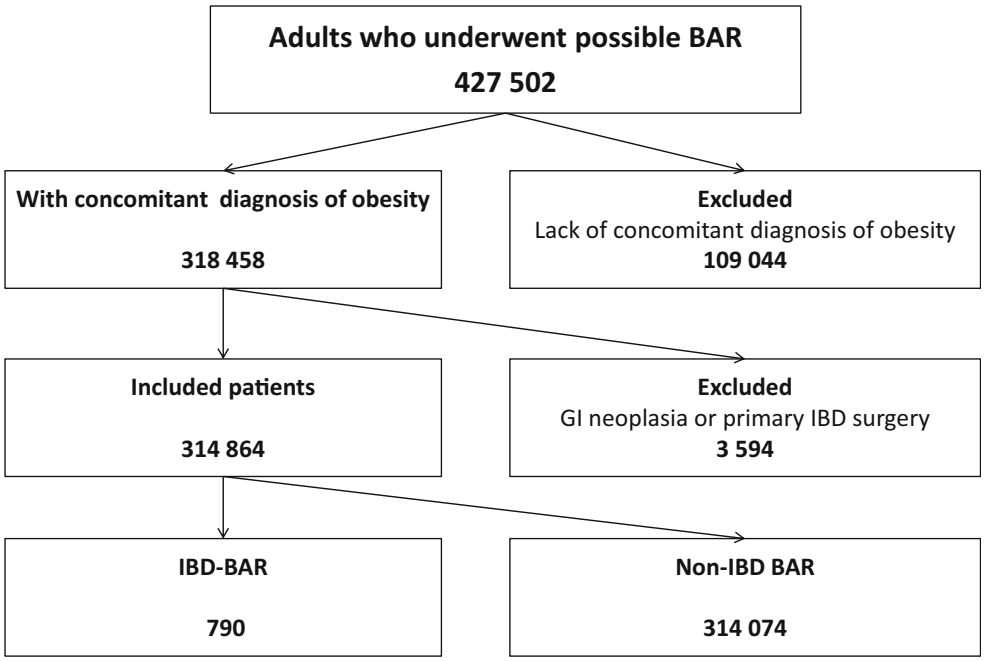

Fig. 1 Flow diagram of study population selection and study groups designation

Statistical Analysis

Prior studies have shown early bariatric surgery complications in about 3% of patients [15]. A sample size of 400 IBD patients and 400,000 controls would provide 80% power to measure a twofold difference in the rate of early complications among the IBD patients, using a two-sided test at the 0.05 level of significance. Baseline characteristics were compared using chi-square test for categorical variables and Student *t* test for continuous variables. We determined the frequency of each outcome. We compared complications using univariate and multivariate logistic regression analysis for dichotomous outcomes and linear regression for continuous outcomes. Odds ratios (OR) and mean differences were reported as crude and adjusted values controlling for baseline characteristics which included age, gender, race, and CCI.

Discharge-level sampling weights available in the database were applied to obtain national estimates representing discharges from all US community hospitals. A two-sided p value of less than 0.05 was considered statistically significant. All statistical analyses were performed using STATA 14.0 (StataCorp, College Station, Texas, USA).

Sensitivity Analysis

To assess the possibility of variation in complications based on the database year, we repeated the analysis for the primary and secondary outcome measures after excluding one-year dataset at a time. Furthermore, we repeated this analysis after excluding procedure codes that could be used for purposes other than bariatric interventions.

Results

Figure 1 shows a flow diagram depicting selection of study population, IBD, and non-IBD groups. Overall, 314,864 patients undergoing elective BAR were identified, with 790 having a secondary diagnosis of IBD and comprising the case group. Of these, 459 had CD and 331 had UC.

Characteristics of the Study Population

Table 1 highlights patient characteristics for the IBD and non-IBD groups. There was a statistically significant (and clinically insignificant) difference in age at time of BAR, as IBD patients were slightly older than non-IBD (48.2 ± 1 vs. 45.5 ± 0.1 years, $p = 0.009$). Furthermore, the IBD group had a greater proportion of Caucasians compared with the non-IBD group, which likely reflects the natural history of IBD (82.4 vs. 67.5%, $p < 0.05$). Lastly, there were no differences in the presence of comorbid conditions; the majority of CCI scores were 2 or less in both groups. Details regarding the type of BAR were limited as the majority of interventions were coded as "undefined." However, among those that were reported, there was a higher proportion of duodenal switch procedures performed in IBD patients compared to those without IBD (18.7 vs. 10%, $p = 0.01$).

Primary Outcomes

Figures 2a-c show the technical complications in a IBD patients compared with non-IBD patients. There was a significant increase in small bowel obstruction in the IBD group compared to those without IBD (7.2 vs. 1.85%; adjusted OR

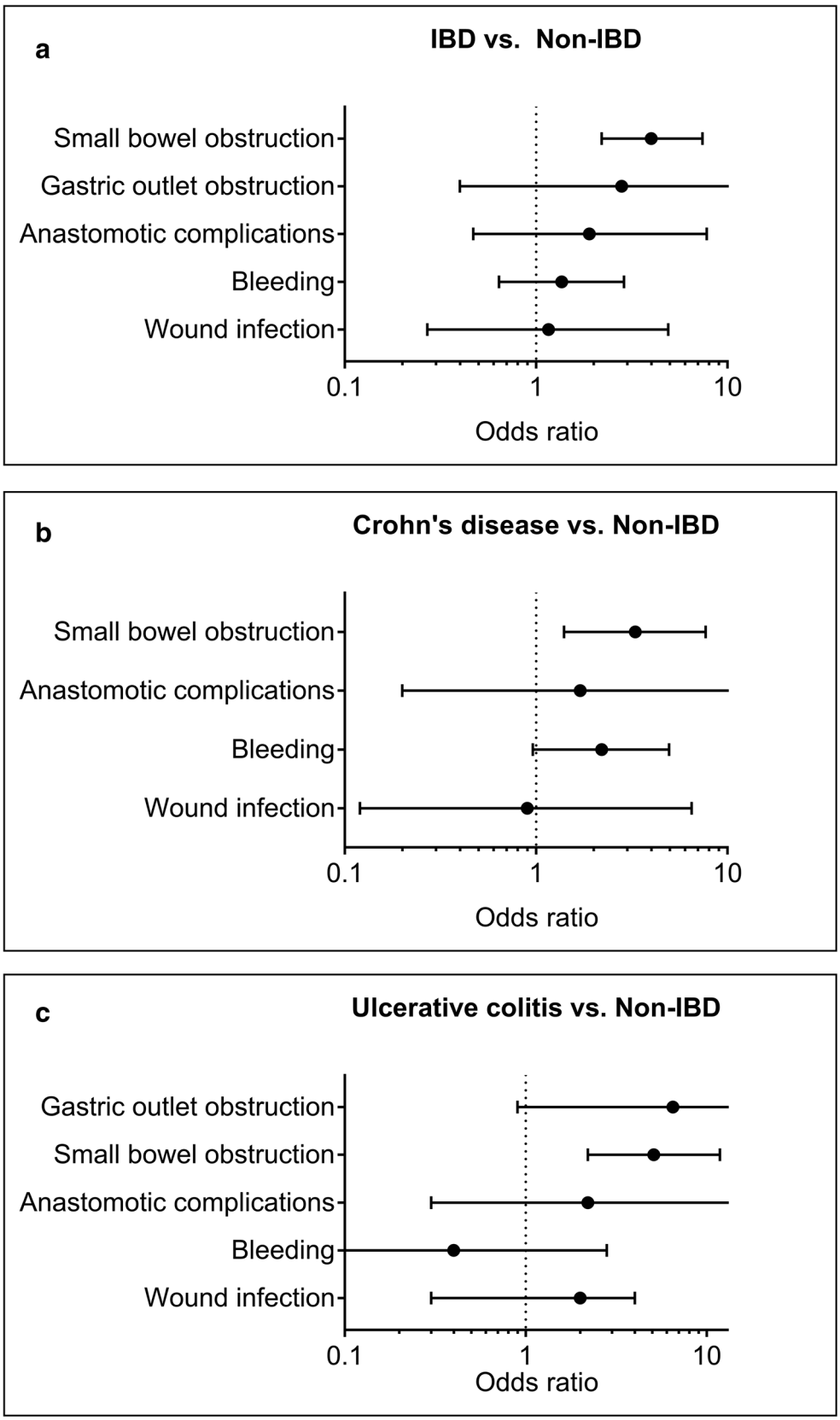

Fig. 2 Technical complications in **a** IBD patients compared with non-IBD patients, **b** Crohn's disease patients compared with non-IBD patients, and **c** ulcerative colitis patients compared with non-IBD patients

[AOR], 4.0; 95% CI, 2.2–7.4; $p < 0.001$). This difference persisted in CD patients (6%), as well as UC patients (9%). There was a trend for more gastric outlet obstruction (GOO) events ($N = 5$) in UC patients (1.5 vs. 0.23%; AOR, 5.1; 95% CI, 2.2–11.8; $p = 0.06$). No GOO events occurred in CD patients. The associations with anastomotic complications, including the occurrence of leaks, percutaneous abdominal drainage, and fistula formation, were similar between IBD and non-IBD patients (1.27 vs. 0.62%; AOR, 1.9; 95% CI, 0.47–7.8; $p = 0.4$). The association with anastomosis complications was similar between CD and UC patients (1.1 vs. 1.5, AOR, 1.3; 95% CI, 0.08–22.6, $p = 0.84$).

Bleeding complications included the occurrence of intraoperative hemorrhage, postoperative hematoma formation, need for blood transfusion, and occurrence of a gastrointestinal bleed. Overall bleeding complications were not significantly different between IBD and non-IBD patients (5.4 vs. 3.34%; AOR, 1.4; 95% CI, $p = 0.43$). However, there was a trend towards more bleeding events in CD patients relative to non-IBD (7.1 vs. 3.34%; AOR, 2.2; 95% CI, 0.96–4.95; $p = 0.06$). This trend was not present in UC group, and rates were similar to non-IBD patients (3 vs. 3.4%; AOR, 0.4; 95% CI, 0.05–2.8; $p = 0.35$). Wound complications included wound infection, seroma formation, and dehiscence or reoperation for wound dehiscence. Association with these complications was similar between IBD and non-IBD patients (1 vs. 0.68%; AOR, 1.2; 95% CI, 0.3–4.9, $p = 0.84$), and they were similar between CD and UC patients (0.7 vs. 1.5%, respectively, AOR, 1.9; 95% CI 0.03–115.4, $p = 0.76$) (Table 2).

Systemic complications (Table 3) included respiratory, renal, cardiac, thromboembolic and neurological events, or systemic shock. The rates of respiratory and renal complications were similar between IBD and non-IBD patients, respectively (2.4 vs. 1.2%, AOR: 1.2; 95% CI, 0.35–4.2; $p = 0.75$ and 3.7 vs. 1.9%, AOR: 1.3; 95% CI, 0.4–4.2; $p = 0.7$). In addition, no IBD patients experienced cardiac, thromboembolic, neurologic events, or systemic shock.

Secondary Outcomes

IBD patients had a longer length of hospital stay compared with non-IBD patients (3.4 ± 0.4 vs. 2.5 ± 0.03 days; mean difference, 1.1 days; 95% CI, 0.2–1.6; $p = 0.01$). IBD patients had no mortality events during hospitalizations, and the mortality rate for non-IBD patients was 0.25%.

Sensitivity Analysis:

We performed a sensitivity analysis to examine the effect of the calendar year of database on our results. We excluded each year's dataset (2011 or 2012 or 2013) one at a time and analyzed the data again including the other 2 years only (Supplementary Table 4). We could not estimate the odd ratio for anastomosis complications when we excluded the year 2013 or gastric outlet obstruction when we excluded 2012 because of the absence of events in the IBD group. Otherwise, the magnitude and significance of our results did not change by excluding any of the years.

Although we identified our cohort using previously published and validated method [15], we opted to repeat the analysis after excluding surgery codes that could be used for purposes other than bariatric interventions (45.50, 45.51, 45.90, 45.91, 43.7, 43.5, and 43.6), to provide an additional layer of sensitivity analysis. We identified 106 patients in the IBD group and 36,449 patients in the non-IBD group who underwent bariatric procedures. The results for wound

Table 1 Baseline characteristics of the study population comparing IBD to Non-IBD

	IBD, $N = 790$	Non-IBD, $N = 314{,}864$	p value
Age, mean years ± SE	48.15 ± 1	45.5 ± 0.11	0.009
Female, N (%)	625 (79%)	245,837 (78.3%)	0.8
Length of hospitalization, mean days ± SE	3.4 ± 0.4	2.5 ± 0.03	0.01
Race, N (%)			
White	599 (82.4%)	197,952 (67.56%)	0.05
Black	58 (8%)	45,611 (15.57%)	
Hispanic	40 (5.4%)	36,292 (12.4%)	
Asian	0	2162 (0.7%)	
Native American	5 (0.7%)	1264 (0.4%)	
Other	25 (3.4%)	9703 (3.3%)	
Charlson comorbidity index (CCI), N (%)			
0	313 (39.6%)	145,507 (46.3%)	0.26
1	301 (38.1%)	110,834 (35.3%)	
2	110 (14%)	39,450 (12.6%)	
> 2	66 (8.3%)	18,284 (5.8%)	

Table 2 Technical complications in IBD, Crohn's disease patients, and ulcerative colitis patients, compared with non-IBD patients. AOR, adjusted odds ratio (for age, gender, race, and comorbidities)

Technical complications		IBD vs. non-IBD			CD vs. non-IBD			UC vs. non-IBD		
	Non-IBD, $N = 314,074$	IBD, $N = 790$	AOR (95% CI)	p value	Crohn's disease, $N = 459$	AOR (95% CI)	p value	UC, $N = 331$	AOR (95% CI)	p value
Small bowel obstruction	5805 (1.85%)	57 (7.2%)	4 (2.2–7.4)	< 0.001	27 (6%)	3.3 (1.4–7.7)	0.005	30 (9%)	5.1 (2.2–11.8)	< 0.001
Gastric outlet obstruction	712 (0.23%)	5 (0.63%)	2.8 (0.4–20)	0.3	0	NA	NA	5 (1.5%)	6.5 (0.9–47.6)	0.06
Anastomotic complications	1960 (0.62%)	10 (1.27%)	1.9 (0.47–7.8)	0.37	5 (1.1%)	1.7 (0.2–12.4)	0.6	5 (1.5%)	2.2 (0.3–15.6)	0.42
Bleeding complications	10,498 (3.34%)	43 (5.4%)	1.36 (0.64–2.88)	0.43	33 (7.1%)	2.2 (0.96–4.95)	0.06	10 (3%)	0.4 (0.05–2.8)	0.35
Wound complications	2158 (0.68%)	8 (1%)	1.16 (0.27–4.9)	0.84	3 (0.7%)	0.9 (0.12–6.5)	0.92	5 (1.5%)	2 (0.3–4)	0.5

complications AOR 2.68 (95% CI: 0.38–19.1, $p = 0.23$), bleeding AOR 1.91 (95% CI: 0.44–8.36, $p = 0.38$), and anastomosis complications AOR 2.77(95% CI: 0.39–19.86, $p = 0.3$) remained the same. The association with small bowel obstruction became insignificant AOR 3.13 (95% CI: 0.74–13.25, $p = 0.12$), which might be explained by the decrease in the sample size. We could not estimate gastric outlet obstruction because of lack of events in the IBD group.

Discussion

In this study, we showed that BAR in IBD patients has an acceptable safety profile. While there was a modest increase in the length of hospital stay (LOS) and risk of small bowel obstruction (SBO), the risk of mortality or other major postoperative complications was low. The evaluation of the safety of BAR safety in an IBD cohort is important, considering the rise in obesity among IBD patients in clinical practice, with up to 40% of IBD patients being obese and an additional 30% being overweight [17–19].

Furthermore, these patients are at increased risk for cardiovascular disease due to their obesity as well as the IBD condition. A recent meta-analysis included 123,907 patients with IBD has shown that IBD is associated with 18% increased risk of cardiovascular morbidity, especially in females. The authors concluded that these patients should undergo aggressive risk factor modification to prevent fatal outcomes [20]. Another French cohort study assessing the risk of arterial events among 210,162 patients with IBD has shown increased risk for arterial events with IBD including ischemic heart diseases, cerebrovascular diseases, and peripheral artery diseases [21].

It is generally accepted that bariatric surgery is the most effective therapy for morbid obesity [22] and has clearly shown to decrease CV mortality in obese and metabolically unhealthy patients [23, 24]. As such, careful assessment of outcomes in the vulnerable obese-IBD cohort is warranted, as to not deprive these patients from this potentially life-preserving intervention.

The overall hospital mortality in our study was similar to that reported in other NIS-based studies previously (0.25 vs. 0.12%) [25], and there was no statistically significant difference in the IBD group. In fact, these patients did not experience mortality events during the index hospitalization. Although data examining the issue of BAR safety in the context of IBD are scarce, there are signals that bariatric intervention may be appropriately undertaken as a surgical intervention in this cohort. Shoar et al. [6] performed a well-conducted systematic review of all published literature and found that 43 IBD patients underwent BAR with a crude rate of 0.5% of all patients undergoing bariatric intervention in the respective cohorts of included studies in that review (Supplemental Table 5). This should be taken in the context of cross-sectional studies that showed 15–40% of adults with IBD

Table 3 Systemic complications in IBD compared with non-IBD patients. AOR, adjusted odds ratio (for age, gender, race, and comorbidities)

	IBD, *N* = 790	Non-IBD, *N* = 314,074	AOR (95% CI)	*p* value
Respiratory, *N* (%)	19 (2.4%)	3700 (1.2%)	1.2 (0.35–4.2)	0.75
Acute myocardial infarction *N* (%)	–	367 (0.12%)	–	–
Acute cerebrovascular accident *N* (%)	–	350 (0.11%)	–	–
Acute renal failure *N* (%)	29 (3.7%)	5830 (1.9%)	1.3 (0.4–4.2)	0.7
Thromboembolic event *N* (%)	–	365 (0.11%)	–	–
Shock *N* (%)	–	65 (0.2%)	–	–

are also obese. Shoar and colleagues did not specifically evaluate in-hospital complications following BAR, in the immediate postoperative period. Our study is complementary to their work, and we found that overall immediate perioperative complications were not increased, with the exception of increased rate of SBO following surgery compared with non-IBD patients. This increase may necessitate special monitoring and interventions, such as longer duration of nasogastric tube placement for IBD patient should they undergo elective BAR, correction of electrolytes, and minimizing the use of narcotic analgesia in the postoperative period. Importantly, mortality and serious systemic postoperative adverse events were not noted in this large cohort of IBD patients, which is reassuring from a procedural safety and feasibility aspect. Although duration of hospital stay was statistically longer in the IBD cohort by 1 day compared to the non-IBD patients, this is unlikely to be of significant clinical relevance.

Obesity may increase certain postoperative complications. A recent NIS-based study showed that obese patients tend to have more wound complications, shock, and pulmonary embolism events when undergoing surgery for IBD indications, compared with non-obese peers [26]. Furthermore, an increase in the perioperative morbidity of IBD surgery with increasing body mass index (BMI) has also been shown in other studies [27]. In our current study, we did not examine the effect of various obesity categories on postoperative outcomes, and these observations were not reproduced in our analysis. Although this could be related to the lack of granularity in BMI categories, it may also be related to different clinical profiles of obese IBD patient needing surgery for an acute IBD complication in the context of robust inflammation, compared with bariatric surgery that might have been conducted in an elective fashion when the disease was quiescent.

Our study has several potential limitations. Firstly, the NIS database is limited to in-hospital stay and would not capture complications that occurred after discharge. Therefore, our analysis may underestimate short-term postoperative complications. Though this database does not have data on BMI, a critical predictive factor for increased complications [28], we were able to measure similar CCI between groups. The low CCI scores (< 2) seen in the majority of patients may limit the applicability of these findings to all IBD patients and may reflect a selection bias based on physician assessment of surgical fitness for the intended BAR procedure. We were unable to analyze trends for the type of BAR procedure in IBD patients, as most interventions were captured as "undefined" in the database. We were also unable to determine the influence of previous surgery that IBD patients might have undergone or if there was a difference in the use of narcotic pain medications; both factors may have influenced the occurrence of immediate postoperative small bowel obstruction. Though we carefully examined previous published literature to develop a detailed list of relevant and comprehensive ICD-9 codes for the intended analyses, all data in this study are dependent on the accuracy of coding procedures in the NIS. However, we feel that there is reasonable confidence in the results after the multi-layered sensitivity analysis that showed consistency in data and outcomes results over time.

In summary, we have attempted to provide practical information regarding immediate safety and feasibility of BAR in IBD patients. Our data show that it is reasonable to carefully proceed with bariatric interventions in obese IBD patients, especially those who are at higher risk of cardiovascular (CV) mortality and drastic need for weight reduction, to accrue benefits of weight loss. As a consequence of the increasing trend in obesity, bariatric surgeons may face augmented demand to treat IBD patients. Furthermore, obesity puts IBD patients at an important disadvantage in terms of technical feasibility of future IBD surgeries, considering that certain surgeries (e.g., ileal pouch-anal anastomoses) are more challenging in the context of increased BMI and it would be advantageous to address the body habitus should the need for IBD intervention arise in the future [29]. Further studies are certainly needed to examine long-term outcomes of bariatric surgery on IBD and to determine whether cardiovascular mortality is reduced from these interventions in this susceptible cohort of obese IBD patients.

Compliance with Ethical Standards Informed consent was not required since patients were unidentifiable in the Nationwide Inpatient Sample and the data is publically available.

The study is IRB exempted under category 4 (publically available data).

Conflict of Interest The authors declare that they have no conflict of interest.

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