

Original article

Perioperative outcomes of bariatric surgery in the setting of chronic steroid use: an MBSAQIP database analysis

Michael Mazzei, M.D., M.P.H., M.S.^a, Huaqing Zhao, Ph.D., M.S.^b,
Michael A. Edwards, M.D.^{a,*}

^aDepartment of Surgery, Division of Bariatric and Minimally Invasive Surgery, Temple University Hospital, Philadelphia, Pennsylvania

^bDepartment of Clinical Science, Lewis Katz School of Medicine at Temple University, Philadelphia, Pennsylvania

Received 5 December 2018; accepted 11 February 2019

Abstract

Background: Chronic steroids are a treatment option for many chronic diseases but predispose patients to both weight gain and surgical complications. They therefore represent a unique interface between obesity, chronic disease, and surgical risk. As the benefits of bariatric surgery for controlling metabolic disease become more apparent, patients with chronic illnesses on corticosteroids are increasingly being referred for surgery despite an unclear safety profile. The Metabolic and Bariatric Surgery Accreditation Quality Improvement Program database represents the largest bariatric-specific clinical data set for comparing outcomes in this complex patient population.

Objective: To compare perioperative outcomes following bariatric surgery in the setting of chronic steroid/immunosuppression.

Setting: University Hospital, United States.

Methods: Using the Metabolic and Bariatric Surgery Accreditation Quality Improvement Program MBSAQIP database, we identified patients on chronic corticosteroids who underwent laparoscopic sleeve gastrectomy or laparoscopic gastric bypass in 2015 or 2016. Unmatched as well as propensity-score and case-controlled matched cohort analyses were performed of patients on corticosteroid therapy compared with those without.

Results: Of the 302,140 patients who underwent sleeve gastrectomy or laparoscopic gastric bypass in 2015–2016, a total of 4947 (1.63%) were on chronic steroids/immunosuppressive drugs. Patients using steroids were older with significantly higher rates of co-morbid conditions. Hospital length of stay, intensive care unit admission, reoperation, readmission, bleeding, leak, and infectious complications were significantly higher in steroid users; however, in a propensity and case-control matched analysis of 8710 patients and 6598 patients, respectively, steroids were not found to be independent risk factors for poorer outcomes except for an increased rate of leak.

Conclusions: Generally, steroid use does not independently predict poorer outcomes among bariatric surgery patients except for an increased leak rate. With appropriate patient selection based on associated co-morbid factors, primary bariatric surgery is safe in patients using corticosteroids, with an acceptable 30-day postoperative risk profile. (Surg Obes Relat Dis 2019;15:926–934.) © 2019 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

Key words:

Bariatric surgery outcomes; Chronic steroid use; Immunosuppression; Propensity-score matching; Case-control matching

Our research was supported by the Department of Surgery at Temple University Hospital and the Lewis Katz School of Medicine at Temple University.

* Correspondence: Michael A. Edwards, M.D., F.A.C.S., F.A.S.M.B.S., Temple University Hospital, Division of Bariatric and Minimally Invasive Surgery, 3401 N Broad St, Philadelphia, PA 19140.
E-mail address: maeedw@gmail.com (M.A. Edwards).

The potent anti-inflammatory effects of steroids make them among the most frequently prescribed classes of drugs. Examples of their use include patients with a history of solid organ transplant and patients with autoimmune, pulmonary, or rheumatologic disease as well as those with endogenous deficiencies. While these medications represent a critical facet of the treatment algorithms for many different diseases, their prolonged use is known to promote a number of adverse effects, including gastrointestinal ulcers, osteoporosis, increased susceptibility to infection, and changes in mood. Chief among these adverse effects is significant weight gain.

Prolonged corticosteroid therapy commonly causes weight gain and redistribution of adipose tissue, resulting in Cushingoid features, including truncal obesity, facial adipose tissue (moon facies) and dorsocervical adipose tissue (buffalo hump) [1]. A recent survey of long-term glucocorticoid users identified weight gain to be the most common self-reported adverse effect, with over 70% reporting this effect. An analysis of prospective trials of chronic steroid use demonstrated a 4%–8% increase in mean weight associated with steroid use [2].

Laparoscopic bariatric surgery has been identified as providing substantial weight loss, control of metabolic disease, and a significant survival benefit with a low risk of complication or death [3]. In the setting of this favorable benefit-to-risk profile, patients with more severe chronic diseases are increasingly being referred for consideration of bariatric surgery. Because obesity is closely related to steroid use, many steroid users could potentially be considered candidates for weight loss surgery. However, bariatric surgery has an unclear safety profile in the setting of chronic steroids. They have long been suspected to confer a higher risk of surgical complications in general surgical patients [4], and recent data link steroid use to increased perioperative complications after bariatric surgery [5,6].

Because of this unique interface between obesity, chronic disease, and surgical risk, it is increasingly important to likewise understand the potential risks associated with operating on this complex population. To that end, in the present study we compare the 30-day outcomes in bariatric patients with chronic steroid therapy and immunosuppression compared with those without steroid therapy using the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) Participant Use Files (PUF). To our knowledge, this is the largest study to date specifically looking at the effects of chronic steroid use or immunosuppression on perioperative outcomes after bariatric surgery [7].

Methods

The MBSAQIP participant user file

We retrospectively analyzed data from the MBSAQIP PUF database to compare bariatric surgical outcomes between individuals who were immunosuppressed or on

chronic steroids with those who did not, from 2015 to 2016. The MBSAQIP is responsible for the accreditation of bariatric surgical facilities in the United States; among the requirements for certification, surgical facilities are required to report bariatric surgical outcomes to the MBSAQIP PUF, a Health Insurance Portability and Accountability Act-compliant data file registry containing prospectively entered, risk-adjusted, clinically rich data using standardized definitions for preoperative, intraoperative, and postoperative variables specific to metabolic and bariatric surgical care. Data points are abstracted at participating institutions by certified reviewers who are audited for accuracy of performance.

Inclusion criteria

For the purposes of this analysis, criteria for inclusion was limited to patients undergoing either laparoscopic Roux-en-Y gastric bypass or laparoscopic sleeve gastrectomy (primary or secondary current procedural terminology codes 43644, 43645, or 43775) as these procedures represent the preponderance of primary weight loss procedures offered in the United States at this time, accounting for 85.2% of all surgeries offered in the MBSAQIP database in 2015–2016 and 93.6% of all primary weight loss procedures offered during that time. Further exclusion criteria included patients younger than 18 years and patients undergoing revisional or conversational procedures. Cases in the resulting cohort ($n = 301,678$) were stratified by the preoperative co-morbid condition of steroid use or immunosuppression. A flow diagram of inclusion criteria is depicted in Fig. 1.

Data collection

Descriptive statistics were collected and compared between groups, including demographic factors such as age, sex, race, preoperative body mass index and weight, health summary status variables, including the American Society of Anesthesiologists' classification, and preoperative co-morbidities, such as history of myocardial infarction, hypertension requiring medication, hyperlipidemia, renal insufficiency, renal failure requiring dialysis, vein thrombosis requiring therapy, history of pulmonary embolism, diabetes, smoking history, renal disease, dialysis, obstructive sleep apnea, history of chronic obstructive pulmonary disease, and oxygen dependence. Operative choice was also noted.

Outcomes of interest primarily included 30-day overall mortality, 30-day reoperation rate, 30-day reintervention rate, and 30-day readmission rate as well as hospital length of stay, intensive care unit (ICU) days, and ventilator days. Secondary outcomes of interest included the rates of aggregate complications (defined in Appendix 1 and including leak, bleeding, cardiovascular, renal pulmonary, and infections). Univariate analyses were performed using Pearson χ^2 test for categorical variables and independent sample t tests for normally distributed continuous variables.

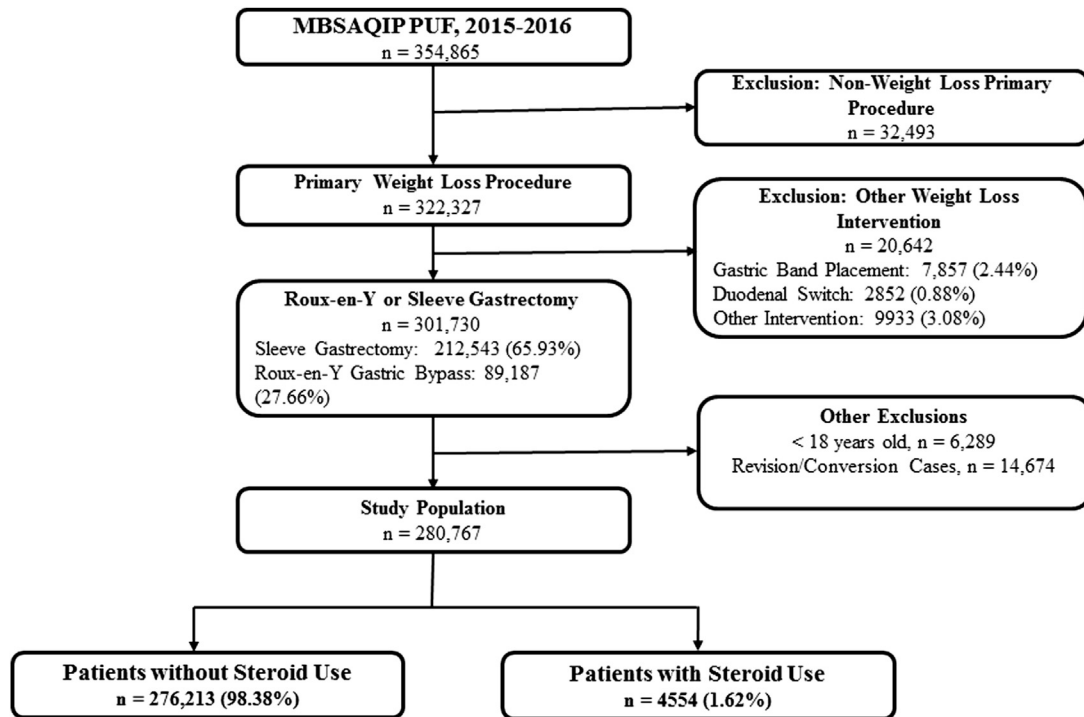


Fig. 1. Flow diagram of inclusion and exclusion criteria. MBSAQIP = Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program; PUF = participant use files.

Matched analysis

To determine the independent risk of chronic steroid use on bariatric outcomes while controlling for potentially confounding co-morbidities, 1:1 matching was performed on the steroid-using and steroid-free cohorts using both a propensity-score matching technique and a case-control matching technique. For propensity-score matching, a logistic regression was performed in which steroid use/immunosuppression status was regressed on baseline demographic characteristics presumed to serve as confounders; a propensity score from 0–1 was generated from this and assigned to each subject based on the probability of steroid use given other covariates. A 1:1 matching of case and control patients with propensity scores that fell within caliper distance of .005 was then used to generate new cohorts hypothesized to be balanced on important potentially confounding baseline characteristics. For propensity score calculation, candidate variables for regression consisted of all available demographic characteristics and preoperative co-morbidities as well as operation choice.

In addition, a second form of matched analysis known as case-control-matching was also performed. In this analysis, matching on a 1:1 basis by a number of physician-selected clinically relevant baseline variables was used to identify new cohorts with equal distributions of those variables. Successful matches between patients with and without chronic steroid use consisted of 100% conformity on all categorical

data points and proximity to within a specified caliper distance for continuous data points. Candidate variables included demographic factors, health summary status variables and co-morbidities; the advantage of this is a hypothesized tighter match of baseline characteristics at the expense of a smaller sample size.

In both matched cohorts, univariate analysis was repeated in a manner identical to the unmatched cohorts. All statistical analysis was performed with SPSS version 25 (IBM, Armonk, NY). A P value $< .05$ was considered statistically significant.

Results

Baseline characteristics

Of the 354,865 cases in the 2015 and 2016 MBSAQIP PUF, a total of 280,767 were ultimately included in our analysis. Patient demographic characteristics comparing those on chronic steroids with steroid-free patients are listed in Table 1. At baseline, patients in the steroid cohort were older (48.8 ± 11.1 years versus 44.6 ± 12.0 years, ratio of mean [RM] = 1.1, $P < .001$), were less likely to be male (18.8% versus 20.8%, RM = .9, $P = .001$), and had a higher perioperative risk based on the American Society of Anesthesiologists physical status classification ($2.9 \pm .4$ versus $2.8 \pm .5$, RM = 1.1, $P < .001$). They were equal in terms of body mass index (BMI) at both highest measured level (47.4 ± 8.3 kg/m² versus 47.3 ± 8.3 kg/m², RM = 1.0,

Table 1
Patient demographic characteristics of bariatric patients with and without preoperative chronic steroid use

	(–) Steroids (n = 275,820)	(+) Steroids (n = 4947)	RR/RM	P value
Demographic data				
Age, yr	44.6	48.8	1.1	<.001
Sex, male, %	20.8	18.8	.9	.001
Race, white, %	64.4	66.3	1.0	.009
Race, black, %	16.8	18.1	1.1	.02
Race, Hispanic, %	12.3	10.9	.9	.004
Race, Asian, %	.5	.5	1.0	.9
Patient data				
BMI, highest, kg/m ²	47.3	47.4	1.0	.2
BMI, OR closest, kg/m ²	45.5	45.4	1.0	.5
ASA class	2.8	2.9	1.1	<.001
Sleeve gastrectomy, %	71.1	74.8	1.1	<.001
Albumin, g/dL	4.1	4.0	.9	.3
Hematocrit, %	40.9	40.4	.9	.003
Co-morbid conditions, %				
GERD	31.1	45.0	1.5	<.001
Limit ambulation	1.8	4.8	2.7	<.001
History of MI	1.3	2.6	1.9	<.001
History of PCI	2.1	4.3	2.0	<.001
Cardiac surgery	1.1	2.8	2.4	<.001
Hypertension	48.8	63.0	1.3	<.001
Hyperlipidemia	24.5	34.5	1.4	<.001
VTE	1.6	3.7	2.4	<.001
Venous stasis	1.04	2.2	2.1	<.001
Dialysis	.3	1.1	3.9	<.001
CKD	.6	3.7	6.0	<.001
Anticoagulation	2.4	6.8	2.9	<.001
Diabetes	26.6	32.7	1.2	<.001
Insulin	8.8	14.3	1.6	<.001
Smoker	8.8	8.7	1.0	.9
Partial dependence	.7	2.0	3.1	<.001
Total dependence	.3	.5	1.4	.1
COPD	1.7	8.9	5.3	<.001
Home O ₂	.7	3.9	5.9	<.001
History of PE	1.1	2.6	2.4	<.001
OSA	37.8	47.9	1.3	<.001
IVC filter	.9	1.5	1.7	<.001

ASA = American Society of Anesthesiologist; BMI = body mass index; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; GERD = gastroesophageal reflux; IVC = inferior vena cava; MI = myocardial infarction; O₂ = oxygen; OR = operation; OSA = obstructive sleep apnea; PCI = percutaneous coronary intervention; PE = pulmonary emboli; RM = ratio of means; RR = relative risk; VTE = venous thromboembolic events.

$P = .2$) and closest to surgery (45.4 ± 8.0 kg/m² versus 45.5 ± 8.0 kg/m², RM = 1.0, $P = .5$). They had a significantly higher preponderance of most co-morbidities, including history of myocardial infarction (2.6% versus 1.3%, relative risk [RR] = 2.0, $P < .001$), venous thromboembolic event (3.7% versus 1.6%, RR = 2.4, $P < .001$), diabetes mellitus (32.7% versus 26.6%, RR = 1.2, $P < .001$), and chronic obstructive pulmonary disease (8.9% versus 1.7%, RR = 5.3, $P < .001$). They had a significantly higher need for medical intervention for chronic co-morbidities, including the use of home oxygen (3.9% versus .7%, RR = 5.9, $P < .001$), insulin (14.3% versus 8.8%, RR = 1.6, $P < .001$), and systemic anticoagulation (6.8% versus 2.4%, RR = 2.9, $P < .001$) (Table 1).

Perioperative outcomes

Perioperative outcomes between unmatched cohorts are described in Table 2. Mean operative length was 1 minute longer in the steroid cohort (88.2 versus 87.2 minutes, RR = 1.0). Patients using steroids were found to be at greater risk of nearly all adverse perioperative outcomes. These patients were more likely to require unplanned ICU transfer (1.2% versus .7%, RR = 1.8, $P < .001$), transfusion (1.0% versus .7%, RR = 1.5, $P = .004$), and reintubation (.4% versus .2%, RR = 2.5, $P < .001$). The 30-day adverse outcomes were likewise increased in patients on chronic steroid therapy, including rates of readmission (6.0% versus 4.0%, RR = 1.5, $P < .001$), reintervention (2.3% versus 1.4%, RR = 1.6, $P < .001$), and

Table 2
Outcomes in unmatched cohorts of bariatric patients with and without preoperative chronic steroid use

	(-) Steroids (n = 275,820)	(+) Steroids (n = 4947)	RR/RM	P value
Hospital outcomes				
OR length, min	87.2	88.2	1.0	.004
Postop LOS, d	1.8	2.0	1.1	<.001
Total LOS, d	1.8	2.0	1.1	<.001
ICU admission, %	.7	1.2	1.8	<.001
Transfusion required, %	.7	1.9	2.9	<.001
Intubation, %	.7	1.1	1.7	<.001
30-day outcomes, %				
Mortality	.1	.2	1.8	.09
Reoperation	1.3	1.7	1.4	.007
Readmission	4.0	6.0	1.5	<.001
Intervention	1.4	2.3	1.6	<.001
Aggregate complications, %				
Leak	.3	.6	2.1	<.001
Bleed	.4	.7	1.6	.003
Cardiac	.1	.1	1.0	>.99
Pulmonary	.5	1.0	2.1	<.001
Renal	.2	.6	4.2	<.001
VTE	.6	.9	1.5	.008
Wound infection	.8	1.4	1.8	<.001
Other infection	.8	1.5	1.9	<.001
Total infection	1.4	2.5	1.8	<.001
Total morbidity, %				
Morbidity	5.4	8.2	1.5	<.001

ICU = intensive care unit; LOS = length of stay; OR = operation; RM = ratio of means; RR = relative risk; VTE = venous thromboembolic event.

reoperation (1.7% versus 1.3%, RR = 1.4, $P = .007$). Overall, individuals on steroid therapy had a total perioperative morbidity (defined as mortality, readmission, reoperation or reintervention, or unplanned ICU admission) of 8.2% compared with a rate of 5.4% among patients without chronic steroid therapy (8.2% versus 5.4%, RR = 1.5, $P < .001$). This corresponds to an absolute risk increase of 2.8% and a number needed to harm of 36.1 patients among patients on chronic steroid therapy compared with those not on therapy.

Aggregate complications representing the rates of certain systems-based complications associated with the bariatric surgery leading to readmission, reintervention, or reoperation are also listed. While the rates of individual complications were generally low, patients on steroids had higher rates of nearly all categories of aggregate complications. The rates of postoperative bleeding were increased (.7% versus .4%, RR = 1.7, $P = .003$) as were pulmonary complications (1.0% versus .5%, RR = 2.1, $P < .001$) and postoperative infections (2.5% versus 1.4%, RR = 1.8, $P < .001$). Of particular note was the risk of anastomotic leak, which was significantly elevated among patients on chronic immunosuppression (.6% versus .3%, RR = 2.1, $P < .001$).

Matched analysis

The extent of the matching success and the resulting cohort demographic characteristics for both matching styles

are shown in Table 3. Propensity score matching resulted in matched cohorts consisting of 8710 patients (4355 in each group) who had statistically equal distributions of preoperative BMI and most co-morbid conditions, although several co-morbid characteristics were not equally matched because of their small contribution to the probability of steroid use given other covariates during propensity matching (Table 3). Case-control matching resulted in matched cohorts consisting of 6598 patients (3296 in each group) who had identical distributions of sex, race, operation type, and co-morbidities and were statistically equal in terms of age and preoperative BMI (Table 3).

Perioperative and 30-day outcomes of the matched cohorts are listed in Table 4. After propensity matching, operation length was significantly shorter in the chronic steroid cohort (87.9 versus 104.3 minutes, RR = .8, $P = .003$). Sleeve gastrectomy rate was 6.5% higher in this cohort ($P < .001$). After propensity matching, steroid use was no longer associated with higher rates of reoperation (1.7% versus 1.5%, RR = 1.1, $P = .5$), readmission (5.9% versus 5.3%, RR = 1.1, $P = .2$) or intervention (2.3% versus 2.0%, RR = 1.1, $P = .5$). Mortality continued to show no significant difference between groups (.2% versus .1%, RR = 2, $P = .2$). Hospital lengths of stay were longer for the cohort using steroids (2.7 versus 2.4 days, ROM = 1.2, $P = .001$). The rates of unexpected ICU admission were likewise equal between groups (1.1% versus 1.2%, RR = .9, $P = .7$) as were rates of

Table 3
Propensity-score and case-control matching covariates

	1:1 Propensity matched (n = 8710)				1:1 Case-control matched (n = 6598)			
	(–) Steroid	(+) Steroid	RR/RM	P value	(–) Steroid	(+) Steroid	RR/RM	P value
Demographic data								
Age, yr	47.9	48.5	1.0	<.001	47.7	47.8	1.0	.9
Sex, male, %	8.8	18.6	2.1	<.001	14.3	14.3	1.0	>.99
Race, white, %	63.2	66.2	1.1	.003	69.1	69.1	1.0	>.99
Race, black, %	20.3	18.1	.9	.009	16.8	16.8	1.0	>.99
Race, Hispanic, %	11.9	11.0	.9	.1	10.4	10.4	1.0	>.99
Race, Asian, %	.6	.5	.7	.3	.2	.2	1.0	>.99
Patient data								
BMI, highest, kg/m ²	47.3	47.2	1.0	.5	46.4	46.5	1.0	.7
BMI, OR closest, kg/m ²	45.4	45.3	1.0	.4	44.5	44.6	1.0	.7
Sleeve gastrectomy, %	68.2%	74.7	1.1	<.001	77.4	77.4	1.0	>.99
Co-morbid conditions, %								
GERD	46.3	43.7	.9	.02	41.0	41.0	1.0	>.99
Limited ambulation	3.8	3.9	1.0	.9	1.1	1.1	1.0	>.99
History of MI	2.0	2.5	1.2	.1	.4	.4	1.0	>.99
History of PCI	3.0	3.7	1.2	.07	1.0	1.0	1.0	>.99
Cardiac surgery	1.6	2.2	1.4	.04	.4	.4	1.0	>.99
Hypertension	56.6	61.8	1.1	<.001	58.4	58.4	1.0	>.99
Hyperlipidemia	30.5	33.2	1.1	.006	28.1%	28.1%	1.0	>.99
VTE	3.6	3.2	.9	.2	.4	.4	1.0	>.99
Venous stasis	1.8	2.0	1.1	.5	.2	.2	1.0	>.99
Dialysis	.7	.7	1.1	.8	.03	.03	1.0	>.99
CKD	1.4	2.5	1.7	<.001	.2	.2	1.0	>.99
Anticoagulation	4.7	5.6	1.2	.07	1.5	1.5	1.0	>.99
Diabetes	30.9	31.5	1.0	.6	27.0	27.0	1.0	>.99
Insulin	12.3	13.0	1.1	.3	9.5	9.5	1.0	>.99
Smoker	8.0	8.6	1.1	.4	6.7	6.7	1.0	>.99
COPD	5.6	6.1	1.1	.3	2.2	2.2	1.0	>.99
Partial dependence	1.4	1.7	1.2	.2	.1	.1	1.0	>.99
Total dependence	.2	.4	2.4	.03	.1	.1	1.0	>.99
Home O ₂	1.0	2.3	1.2	.2	.3	.3	1.0	>.99
History of PE	1.91	2.3	1.2	.2	.3	.3	1.0	>.99
OSA	44.0	46.5	1.1	.02	42.1	42.1	1.0	>.99
IVC filter	1.2	1.2	1.1	.8	.03	.03	1.0	>.99

BMI = body mass index; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; GERD = gastroesophageal reflux disease; IVC = inferior vena cava; MI = myocardial infarction; O₂ = oxygen; OR = operation; OSA = obstructive sleep apnea; PCI = percutaneous coronary intervention; PE = pulmonary emboli; RM = ratio of means; RR = relative risk; VTE = venous thromboembolic event.

transfusion (.9% versus .9%, RR = 1.0, *P* = .9) and intubation (.4% versus .4%, RR = 1, *P* > .99). Overall, the rates of significant morbidity for patients using steroids were not significantly different from patients who were steroid-free (7.9% versus 7.2%, RR = 1.1, *P* = .2) following propensity-score matching (Table 4). This corresponds to an absolute risk increase of .71% and a number needed to harm of 140.8 patients for steroid use as an independent perioperative risk factor. The exception to this was the rate of anastomotic leak, which remained significantly higher in the chronic steroid use cohort (.6% versus .3%, RR = 2.2, *P* = .03).

Some findings were preserved following case-control matched analysis (Table 4). Mean operative duration remained lower in the chronic steroid cohort (84.7 versus 96 minutes, RR = .9, *P* < .001), even though sleeve gastrectomy rates were similar between cohorts (*P* > .99). There was no difference in mortality across the 2 groups (.2% versus .1%, RR = 2.5,

P = .3). In this matched cohort analysis, readmission (5% versus 3.8%, RR = 1.3, *P* = .02) and reintervention (1.9% versus 1.2%, RR 1.6, *P* = .03) were significantly higher in the steroid use cohort. Reoperation was nonsignificantly higher in this cohort as well (1.9% versus 1.2%, RR = 1.6, *P* = .06). This corresponded to a total morbidity of 6.7% versus 5.3% (RR = 1.3, *P* = .01) or an absolute risk increase of 1.4% associated with preoperative chronic steroid use and a number needed to harm of 70.9. The only factor that seemed to contribute in a statistically significant fashion to the slightly higher morbidity seen in this matched analysis was again the anastomotic leak rate (.5% versus .2%, RR = 3, *P* = .03).

Discussion

This study to our knowledge represents the first matched analyses of the MBSAQIP PUF database specifically

Table 4
Outcomes of propensity-score and case-control matched analysis

	1:1 Propensity matched (n = 8710)				1:1 Case-control matched (n = 6598)			
	(–) Steroid	(+) Steroid	RR/RM	P value	(–) Steroid	(+) Steroid	RR/RM	P value
Hospital outcomes								
OR length, min	104.3	87.9	.8	.003	96.0	84.7	.9	<.001
Postop LOS, d	2.1	2.0	1.0	.005	1.9	1.9	.9	.2
Total LOS, d	2.1	2.0	1.0	.008	1.9	1.9	.9	.3
ICU admission, %	1.2	1.1	.9	.7	.6	.7	1.2	.6
Transfusion required, %	.9	.9	1.0	.9	.4	.7	1.7	.1
Intubation, %	.4	.4	1.0	>.99	.2	.2	1.2	.8
30-day outcomes, %								
Mortality	.1	.2	2.0	.2	.1	.2	2.5	.3
Reoperation	1.5	1.7	1.1	.5	1.0	1.5	1.5	.06
Readmission	5.3	5.9	1.1	.2	3.8	5.0	1.3	.02
Intervention	2.0	2.3	1.1	.5	1.2	1.9	1.6	.03
Aggregate complications, %								
Leak	.3	.6	2.2	.03	.2	.5	3.0	.03
Bleed	.5	.7	1.4	.3	.3	.6	1.8	.06
Cardiac	.1	.1	.8	.7	.1	.1	1.5	.7
Pulmonary	.8	.9	1.2	.5	.5	.7	1.5	.2
Renal	.4	.6	1.3	.4	.2	.3	1.4	.5
VTE	.8	1.0	1.2	.5	.4	.7	1.9	.06
Wound infection	1.4	1.3	.9	.6	.9	1.0	1.2	.4
Other infection	1.4	1.4	1.0	>.99	.9	1.2	1.2	.4
Total infection	2.5	2.4	1.0	.8	1.7	2.0	1.2	.3
Total morbidity, %								
Morbidity	7.2	7.9	1.1	.2	5.3	6.7	1.3	.01

ICU = intensive care unit; LOS = length of stay; OR = operation; RM = ratio of mean; RR = relative risk; VTE = venous thromboembolic event.

looking at outcomes related to the presence of steroids in bariatric surgery. We conclude that while patients on chronic steroids therapy have a clinically significant higher risk of morbidity, mortality, and complications, this is mostly because of the underlying co-morbid conditions for which steroids or other immunosuppressive medication are prescribed. When controlling for these co-morbidities, much of the excess morbidity seen in the chronic steroid/immunosuppression group is removed. With matching, the number needed to harm for the matched cohorts fell between 70 and 140 patients, which speaks to the overall small additional risk of steroid therapy. With that in mind, patients on chronic steroid therapy would most likely benefit from the weight loss and concomitant improvement in co-morbid conditions that bariatric surgery offers.

These findings contrast to some extent with previous large database studies that have highlighted a significant independent risk conferred by steroids among bariatric patients. For example, a recent analysis of patients in the American College of Surgeons National Surgical Quality Improvement Program identified steroid use as independently predictive of mortality and serious postoperative complications after stapled bariatric procedures. In that study, the rate of serious complications was double in patients taking steroids, regardless of type of surgery performed. The median length of stay in patients taking steroids was 1 day longer in the

leak group, and for both bariatric procedures, patients who took steroids had a 30-day readmission rate almost double that of those who did not. The authors ultimately concluded that surgeons should be cautious about offering stapled bariatric procedures to patients on chronic steroids [8]. While we agree that the patient with chronic steroids represents a complex patient population, our study suggests that in appropriately selected patients based on associated co-morbid factors, primary bariatric surgery is safe in the setting of corticosteroids, with an acceptable 30-day postoperative risk profile.

It is important to note the exception to this rule: in all matched and unmatched analyses conducted here, the anastomotic leak was significantly higher for patients on chronic steroid therapy. While leak is a rare occurrence, the leak rate is increased between 2- and 3-fold in the setting of steroids. A number of large database studies have been conducted recently that identify steroids as a risk factor for leak after colorectal surgery [9–11]; it appears that this holds true for bariatric surgery as well. It is imperative, therefore, that patients on chronic steroids be counseled that their rate of anastomotic leak is significantly higher than average should they choose to undergo any bariatric operation. In our study, patients were designated as being on chronic steroids/immunosuppressant if they required oral or parenteral corticosteroids or other immunosuppressant medications within 30 days before their

bariatric procedure or at the time they were being considered as a candidate for bariatric surgery. The MBSAQIP does not distinguish between patients on corticosteroids versus other immunosuppressive agents. We assume that a sample of our chronic steroid cohort was likely on other immunosuppressant medication; therefore, patients on both chronic corticosteroids and other immunosuppressant medication should be counseled about the higher risk of anastomotic or staple line leak following bariatric surgery.

Before attempting weight loss surgery on patients on chronic steroids/immunosuppressants, potential benefits should be carefully weighed against the increased risks on a case-by-case basis. This should take into consideration the potential procedure type and surgical approach recommended to patients, which may ultimately impact outcome. In both our propensity and case-control matched cohort analysis, we found that operative duration was significantly shorter in the steroid cohorts. Several factors may have accounted for this observation, including the trend toward a smaller percentage of cases performed with robotic assistance in the steroid cohort following propensity matched (6.3% versus 7.3%, $RR = .86$, $P = .06$) and case-control match (6.6% versus 7.6%, $RR = .88$, $P = .1$) analysis. Once the decision is made to perform a bariatric surgery procedure on a patient on chronic steroids, special attention should be placed on the preoperative amelioration of modifiable risk factors. These surgeries should be preferentially conducted in high-volume bariatric centers with experience in dealing with high-risk patients. Clinical pathways may be put in place to facilitate multidisciplinary coordination of care. A team approach consisting of pulmonology, rheumatology, and hematology/immunology may be necessary depending on the underlying conditions to provide appropriate perioperative care for this challenging population.

There are several limitations to our study. First, steroid use represented a binary variable in the data set. This did not take into account the length of time that patients had been on chronic steroid therapy nor did it allow for consideration of the steroid dosage. Because of the limited granularity of this variable, the risk associated with steroid use in bariatric surgery can only be assessed in the broadest sense. The data point used to denote steroid use holds within in all patients who are immunosuppressed; a subset of these patients may be immunosuppressed for other reasons. Because this research identifies that co-morbid conditions are just as, if not more, contributory to adverse outcomes than the steroids themselves, subset analysis based on the underlying reason for steroid administration might identify particularly high-risk groups. However, this is not possible in the current data set.

Second, this data set is a retrospective cohort, and while it is inclusive of all bariatric surgeries performed at

accredited centers over 2 years, it provides an incomplete look at surgical decision-making in the perioperative period. For example, the database provides no insight into patient selection and the characteristics of those patients who were deemed to be too high-risk for bariatric surgery. It also does not account for differences in surgeon experience or case volume, which has been shown to have a considerable effect on outcomes. It also does not provide insight into perioperative technical decision-making, such as choice of operation. Patient care decisions are likewise not captured in the database; for example, it is not clear what underlying pathologies were present to require steroid therapy in these patients and the degree of control over the underlying disease in the preoperative period. Furthermore, the study is subject to the potential biases that are associated with any retrospective analysis of a multi-institutional clinical database. For most variables, missingness is low in this data set and did not appear to be a major issue; however, as with all database studies, results are limited by the timeliness and completeness of data entry by Bariatric Clinical Nurse Reviewers. While the MBSAQIP program offers training and oversight including auditing to ensure accuracy, variations in coding between institutions cannot be fully excluded as a source of bias. Lastly, this study was limited to perioperative outcomes data only, with the intention of determining the general risk that steroid use confers upon bariatric patients. As a result, outcomes related to long-term complications could not be assessed.

Conclusion

Through unmatched and matched analyses of the MBSAQIP PUF, we demonstrate that steroid use increases the risk of perioperative complications during or after bariatric surgery. However, after controlling for co-morbidities between groups, for most morbidities, steroids are not an independent risk factor. The exception to this is anastomotic leak, the risk of which is in all cases significantly and independently increased by the presence of steroids. Overall, the safe operation on patients on chronic steroid therapy depends on appropriate patient selection based on associated co-morbid factors. If co-morbid conditions are appropriately managed, primary bariatric surgery is safe in patients using corticosteroids, with an acceptable 30-day postoperative risk profile. Further research should be conducted to develop strategies for the reduction of perioperative risk in this challenging patient population.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

Appendix 1

Aggregate Variable	Composite Variables
Leak	Reoperation with Suspected Reason: Leak Readmission with Suspected Reason: Leak Intervention with Suspected Reason: Leak Drain present over 30 days Complication: Organ space SSI
Bleeding	Reoperation with Suspected Reason: Bleeding Readmission with Suspected Reason: Bleeding Intervention with Suspected Reason: Bleeding
Cardiac/CVA	Reoperation with Suspected Reason: Cardiac NOS, CVA, or MI Readmission with Suspected Reason: Cardiac NOS, CVA, or MI Intervention with Suspected Reason: Cardiac NOS, CVA, or MI Complication of CVA Complication of MI
Pulmonary	Reoperation with Suspected Reason: Shortness of Breath, Pneumonia, or Other Respiratory Failure Readmission with Suspected Reason: Shortness of Breath, Pneumonia, or Other Respiratory Failure Intervention with Suspected Reason: Shortness of Breath, Pneumonia, or Other Respiratory Failure Complication: On Ventilator > 48 hours Complication: Unplanned Intubation Complication: Pneumonia
Renal	Reoperation with Suspected Reason: Renal Insufficiency Readmission with Suspected Reason: Renal Insufficiency Intervention with Suspected Reason: Renal Insufficiency Complication: Progressive Renal Insufficiency Complication: Acute Renal Failure
DVT or PE	Reoperation with Suspected Reason: Vein Thrombosis Requiring Therapy or Pulmonary Embolism Readmission with Suspected Reason: Vein Thrombosis Requiring Therapy or Pulmonary Embolism Intervention with Suspected Reason: Vein Thrombosis Requiring Therapy or Pulmonary Embolism Complication: Vein Thrombosis Requiring Therapy Complication: Pulmonary Embolism Complication: Anticoagulation initiated of presumed/confirmed vein thrombosis/PE
Wound infection	Reoperation with Suspected Reason: Wound Infection or Other Abdominal Sepsis Readmission with Suspected Reason: Wound Infection or Other Abdominal Sepsis Intervention with Suspected Reason: Wound Infection or Other Abdominal Sepsis Complication: Post-Op Superficial Incisional SSI occurrence Complication: Post-Op Deep Incisional SSI occurrence

(continued on next column)

(continued)

Aggregate Variable	Composite Variables
Other Infection	Reoperation with Suspected Reason: Infection/Fever Readmission with Suspected Reason: Infection/Fever, Intervention with Suspected Reason: Infection/Fever Complication: Post-Op Sepsis Occurrence Complication: Post-Op Septic Shock Occurrence Complication: Post-Op Pneumonia occurrence Complication: Post-Op Urinary Tract Infection occurrence
Total Infection	Wound Infection, as above Other Infection, as above
Total Morbidity	Mortality within 30 Days Need for Intervention within 30 Days Need for Readmission within 30 Days Need for Reoperation within 30 Days Unplanned ICU Transfer within 30 Days

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