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Author manuscript

Surg Obes Relat Dis. Author manuscript; available in PMC 2018 January 01.

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Published in final edited form as:

Surg Obes Relat Dis. 2017 January ; 13(1): 35–40. doi:10.1016/j.soard.2015.10.086.

Expanded Indications for Bariatric Surgery: Should Patients on Chronic Steroids Be Offered Bariatric Procedures?

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Abstract

Background—Patients who take chronic corticosteroids are increasingly referred for bariatric surgery. Little is known about their clinical outcomes.

Objective—Determine whether chronic steroid use is associated with increased morbidity and mortality after stapled bariatric procedures.

Setting—American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) database.

Methods—We reviewed all patients who underwent laparoscopic sleeve gastrectomy (LSG) or laparoscopic Roux-en-Y gastric bypass (RYGB) and were reported to the ACS-NSQIP from 2011 to 2013. Patients were grouped based on type of surgery and history of chronic steroid use. Primary outcome measures were mortality and serious morbidity in the first 30 days. Regression analyses were used to determine predictors of outcome.

Results—Of 23,798 patients who underwent LSG and 38,184 who underwent RYGB, 385 (1.6%) and 430 (1.1%), respectively, were on chronic steroids. Patients on chronic steroids had a 3.4 times increased likelihood of dying within 30 days (95% CI 1.4–8.1, $p=0.007$), and two-fold increased odds of serious complications (95% CI 1.2–2.3, $p=0.008$), regardless of surgery type. In multivariate regression, steroid usage remained an independent predictor of mortality and serious complications.

Conclusions—In a large, nationally-representative patient database, steroid use independently predicted mortality and serious postoperative complications after stapled bariatric procedures. Surgeons should be cautious about offering stapled bariatric procedures to patients on chronic steroids.

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Jennifer Kaplan, Samuel Schecter, Matthew Lin, Stan Rogers, Voraboot Taweerutchan, Andrew Posselt, and Jonathan Carter declare no conflict of interest. Jennifer Kaplan is funded a National Institute of Health, National Institute of Diabetes and Digestive and Kidney Diseases T32 training grant (project# 5T32DK007573-25).

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Keywords

Bariatric surgery; steroids; outcomes; morbidity; mortality; predictors

Introduction

Over the past decade, laparoscopic bariatric surgery has provided obese patients substantial weight loss, control of metabolic disease, and survival benefit - all at a very low risk of complication or death⁽¹⁻³⁾. Because of this favorable benefit-to-risk profile, many bariatric centers have seen increasing referrals of patients with more severe chronic disease for consideration of bariatric surgery. Examples include patients with a history of solid organ transplant and patients with autoimmune, pulmonary, or rheumatologic disease. Management of these patients sometimes involves the chronic use of steroids⁽³⁾. Chronic steroids are known to confer a higher risk of surgical complications in general surgical patients, and new data links steroid use to post-discharge complications in the bariatric population^(4,5).

We hypothesized that chronic steroid use would be associated with increased mortality and serious complications within the first 30 days after stapled bariatric procedures. To investigate, we used the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) dataset to investigate the impact of chronic steroid use on 30-day outcomes after laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (RYGB).

Methods

Data collection

We retrospectively reviewed all LSGs and RYGBs reported in the ACS-NSQIP dataset from 2011 to 2013. The ACS-NSQIP is a validated, risk adjusted, prospective, outcomes-based program of hospitals in the United States. The database includes preoperative risk factors and 30-day morbidity and mortality, and has been described elsewhere⁽⁶⁾. This study was approved by the University of California San Francisco Institutional Review Board.

Study Population

We reviewed the clinical data of all adult patients (18 years of age or greater) who underwent either LSG or RYGB between January 2011 and December 2013. Only patients with a primary Current Procedure Terminology (CPT) code 43644, 43645 (RYGB), or 43775 (LSG) were included. Study groups were created based upon the type of procedure performed, and further stratified by a history of chronic steroid use. ACS-NSQIP defines chronic steroid use as a corticosteroid taken orally or intravenously for a chronic condition within 30 days of surgery and for a duration longer than 10 days⁽⁷⁾.

Patient-level demographics included age, gender, height and weight, functional status, and American Society of Anesthesiologists (ASA) class, and comorbidities. Body mass index (BMI) was calculated from height and weight when available. The following comorbidities

and characteristics were included: diabetes, hypertension, history of chronic obstructive pulmonary disease (COPD), dyspnea, congestive heart failure (CHF), and steroid use. Functional status was categorized into independent and dependent. Laboratory values included white blood cell count, hematocrit, serum albumin and creatinine. For the purposes of analysis, laboratory values were dichotomized at the following cutoff points: white blood cell count at $10 \times 10^9/\text{L}$, serum albumin at 3.5 g/dL, hematocrit at 35%, and serum creatinine at 1.1 mg/dL.

Primary Outcome Measures

The primary outcome measures were serious complications and 30-day mortality. Serious morbid complications were defined as return to the operating room, cardiovascular event (postoperative myocardial infarction, need for cardiopulmonary resuscitation, or cardiac arrest), septic shock, stroke, re-intubation, or prolonged ventilation over 48 hours. Secondary outcome measures included length of stay, readmission, and other complications. Other complications included infection (superficial or deep surgical site infection), pneumonia, urinary tract infection, venous thromboembolism, bleeding requiring transfusion, or renal complication (postoperative progressive renal insufficiency or acute renal failure).

Statistical Analysis

Demographics, clinical characteristics, and postoperative outcomes were compared within surgery subgroups between patients who had a history of chronic steroid use and those who did not using the chi-squared test or Fischer's exact for proportions and the Wilcoxon rank-sum test for non-normally distributed continuous variables. Predictors of serious morbidity and 30-day mortality were identified in univariate logistic regression. A test of collinearity was performed to ensure each variable in the model was unique. Multivariate predictors were identified using backwards-stepwise logistic regression with a cutoff of $p < 0.05$. Statistical significance was set at $p < 0.05$. All statistical analysis and data management were conducted using STATA version 13.1 (StataCorp LP, College Station, TX).

Results

Patient characteristics

Patient demographics and clinical characteristics are listed in Table 1. From 2011 to 2013, 61,982 patients underwent minimally invasive bariatric surgery and were reported to ACS-NSQIP, with 23,798 undergoing LSG and 38,184 undergoing RYGB. Chronic steroid use was identified in 385 (1.6%) of LSG patients and 430 (1.1%) of RYGB. In both surgical groups, patients taking steroids were 4–5 years older and were more likely to have medical comorbidities such as hypertension, dyspnea, or COPD ($p < 0.001$). Overall, patients taking steroids were four times more likely to be functionally dependent (OR 4, 95% CI 2.4–7.1, $p < 0.001$). Additionally, patients taking steroids were more likely to have hypoalbuminemia (LSG $p = 0.01$, RYGB $p = 0.02$) and leukocytosis ($p < 0.001$). Finally, the ASA class distribution of patients taking steroids was more heavily weighted towards severe systemic disease ($p < 0.001$).

Unadjusted Outcomes

Unadjusted outcomes are listed in Table 2. For both LSG and RYGB groups, patients who took steroids had a five-fold higher 30-day mortality rate (LSG $p=0.004$, RYGB $p<0.001$). The rate of serious complications was double in patients taking steroids, regardless of type of surgery performed (LSG $p=0.01$, RYGB $p=0.001$). The median length of stay in patients taking steroids was one day longer in the LSG group ($p<0.001$). For both bariatric procedures, patients who took steroids had a 30-day readmission rate almost double that of those who did not ($p<0.001$).

Predictors of serious complications and morbidity

To ascertain whether steroid usage was an independent predictor of mortality within 30 days, we constructed a multivariate logistic regression model (Table 3). This model had an area under the receiver-operating curve of 0.83. After adjustment, steroid use was associated with 3.4 times increased risk of mortality (95% CI 1.4–8.1, $p=0.007$). Other independent predictors of mortality were COPD, low serum albumin, RYGB (as opposed to LSG), and ASA class. Protective factors included female gender and leukocytosis.

We repeated the multivariate logistic regression, this time to determine independent predictors of serious complications (Table 4). For this model, the area under the ROC was 0.62. After adjustment, steroid use was associated with 1.7 increased odds of serious morbidity (95% CI 1.2–2.3, $p=0.008$). Other independent predictors of serious complications were dependent functional status, RYGB procedure (as opposed to LSG), low serum albumin, and ASA class. Again, female gender was protective, with 20% lower odds of serious complications.

Discussion

Although chronic steroid use in the severely-obese population undergoing bariatric surgery has been associated with increased readmission rates⁽⁸⁾, the effect on major morbidity and mortality in the early postoperative period is incompletely understood. In one small cohort study of 31 patients with systemic lupus erythematosus who underwent LSG or RYGB, three-fourths of whom were immunosuppressed at the time of surgery, early complications occurred in 13%, but by three years, almost half saw a reduction in their immunosuppression needs or were off of immunosuppressive medications altogether⁽⁹⁾. In an ACS-NSQIP analysis of all bariatric procedures, steroid use was associated with 1.4 times the odds of post-discharge complications⁽⁵⁾. Given that many centers are being referred increasing numbers of patients on chronic steroids referred for bariatric surgery, we sought to characterize the perioperative risks in this group.

Our analysis of over 60,000 patients who underwent LSG or RYGB in a recent 3-year period confirmed our hypothesis that chronic steroids were associated with more serious complications and mortality. In fact, steroid use was one of the strongest predictors of morbidity and mortality when compared to all the other variables contained in ACS-NSQIP and included in the analysis. The risk associated with steroid use was independent of patient comorbidities, functional status, and ASA class, procedure type, BMI, age, and gender.

Our study is limited by the 30-day data collection model of ACS-NSQIP, which may have missed serious complications that occurred later (for example, a leak after LSG from steroid-induced failure-to-heal that manifested 6 weeks after surgery). Second, there may be other important predictors that either co-varied with steroid use, or predicted outcome, that were not captured in the ACS-NSQIP database. Potential examples would include surgeon experience, hospital volume, accreditation status, actual duration of steroid use, duration of diabetes and other comorbidities, and dose of steroid medications⁽¹⁰⁾. Third, there is a strong selection bias in the data set. ACS-NSQIP only reports outcomes of patients on steroids who actually received bariatric surgery. These patients were likely to be more surgically fit than a generalized obese population on chronic steroids. As a result, we may be underestimating steroid-attributable morbidity and mortality. Fourth, our study does not address long-term weight and metabolic outcomes – it is impossible to know whether the anorexic effect of bariatric surgery counters the orexigenic effect of systemic steroids, and so the degree of long term weight loss in this population remains unknown. Finally, our study is based on hospital participation in ACS-NSQIP. Patients who had bariatric surgery in non-NSQIP hospitals may have a different risk profile and outcomes.

Conclusions

In conclusion, chronic steroid usage is an independent and strong predictor of morbidity and mortality after stapled bariatric procedures. Patients taking these medications should be appropriately counseled regarding the risks and benefits so that they may make an informed decision regarding bariatric surgery.

Acknowledgments

The authors thank Pamela Derish from the UCSF Department of Surgery for editing this manuscript.

Jennifer Kaplan is supported by NIDDK T32 5T32DK007573-23

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Table 1

Demographics and clinical characteristics

Sleeve Gastrectomy

	Steroids N = 385 (1.6%)	No Steroids N = 23,413 (98.4%)	P value	Steroids N = 430 (1.1%)	No Steroids N = 37,754 (98.9%)	P Value
Age, years *	49 (42–57)	44 (36–53)	<0.001	49 (40–56)	45 (36–54)	<0.001
Female	314 (81.6%)	18,311 (78.3%)	0.12	352 (81.9%)	29,928 (79.4%)	0.20
BMI, kg/m ² *	43.9 (39.9–48.9)	43.9 (40.0–49.6)	0.58	45.3 (41.1–52.1)	44.9 (40.8–50.4)	0.09
Comorbidities						
Diabetes	117 (30.4%)	5,290 (22.6%)	<0.001	153 (35.6%)	11,903 (31.5%)	0.07
Hypertension	256 (66.5%)	11,378 (48.6%)	<0.001	289 (67.2%)	20,157 (53.4%)	<0.001
Dyspnea	80 (20.8%)	2,835 (12.1%)	<0.001	96 (22.3%)	5,990 (15.9%)	<0.001
COPD	15 (3.9%)	282 (1.2%)	<0.001	27 (6.3%)	719 (1.9%)	<0.001
Congestive heart failure	2 (0.5%)	41 (0.2%)	0.15	7 (1.6%)	77 (0.2%)	<0.001
Smoking	36 (9.4%)	2,293 (9.8%)	0.77	43 (10.0%)	4,007 (10.6%)	0.68
Dependent Functional Status	7 (1.8%)	88 (0.4%)	<0.001	7 (1.6%)	180 (0.5%)	<0.001
Laboratory values						
WBC > 10×10 ⁹ /L	137 (35.6%)	6,200 (26.5%)	<0.001	168 (39.1%)	11,497 (30.5%)	<0.001
Creatinine > 1.1 mg/dL	121 (31.4%)	5,407 (23.1%)	<0.001	134 (31.2%)	8,451 (22.4%)	<0.001
Hematocrit < 35	35 (9.1%)	1,231 (5.3%)	0.001	34 (7.9%)	1,907 (5.1%)	0.007
Albumin < 3.5 g/dL	22 (5.7%)	779 (3.3%)	0.01	23 (5.4%)	1,226 (3.3%)	0.02
ASA Class			<0.001			<0.001
No/mild disturbance	69 (17.9%)	7,809 (33.4%)		49 (11.4%)	11,418 (30.3%)	
Severe disturbance	295 (76.6%)	15,067 (64.4%)		340 (79.3%)	25,238 (67.0%)	
Life threatening	21 (5.5%)	504 (2.2%)		40 (9.3%)	1,030 (2.7%)	

* Median (IQR)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; WBC, white blood cell count

Outcomes

Table 2

Sleeve Gastrectomy

	Steroid N = 385 (1.6%)	No Steroid N = 23,413 (98.4%)	P value	Steroid N = 430 (1.1%)	No Steroid N = 37,754 (98.9%)	P Value
Length of stay, days*	2 (2-2)	1 (1-2)	<0.001	2 (2-3)	2 (2-2)	<0.001
30-day mortality	2 (0.5%)	19 (0.1%)	0.004	4 (0.9%)	57 (0.2%)	<0.001
Return to the OR	8 (2.1%)	316 (1.4%)	0.22	18 (4.2%)	955 (2.6%)	0.03
30-day readmission	29 (7.5%)	875 (3.7%)	<0.001	47 (10.9%)	2,279 (6.0%)	<0.001
Any complication	30 (7.8%)	975 (4.2%)	<0.001	43 (10%)	2,670 (7.1%)	0.02
Wound infection	6 (1.6%)	191 (0.8%)	0.11	8 (1.9%)	645 (1.7%)	0.81
Pneumonia	1 (0.3%)	66 (0.3%)	0.94	2 (0.5%)	184 (0.5%)	0.95
Urinary tract infection	4 (1.0%)	128 (0.6%)	0.20	8 (1.9%)	332 (0.9%)	0.03
Venous thromboembolism	4 (1.0%)	103 (0.4%)	0.08	4 (0.9%)	165 (0.4%)	0.13
Cardiac complication	1 (0.3%)	16 (0.1%)	0.16	2 (0.5%)	62 (0.2%)	0.13
Sepsis or Shock	5 (1.3%)	90 (0.4%)	0.005	5 (1.2%)	275 (0.7%)	0.29
Unplanned reintubation	1 (0.3%)	62 (0.2%)	0.99	4 (0.9%)	162 (0.4%)	0.12
On ventilator > 48 hours	0 (0)	49 (0.2%)	0.37	3 (0.7%)	110 (0.3%)	0.12
Stroke	0 (0)	5 (0.02%)	0.77	0 (0)	4 (0.01%)	0.83
Bleed requiring transfusion	7 (1.8%)	227 (1.0%)	0.09	8 (1.9%)	669 (1.8%)	0.89
Renal complication	1 (0.3%)	62 (0.3%)	0.99	4 (1.0%)	102 (0.3%)	0.01
Serious complication	14 (3.6%)	430 (1.8%)	0.01	26 (6.1%)	1,229 (3.3%)	0.001

* Median (IQR)

Cardiac complication: postoperative myocardial infarction or cardiac arrest

Renal complication: postoperative renal insufficiency or postoperative acute renal failure

Serious complication: return to the OR, cardiac complication, renal complication, sepsis or shock, reintubation, stroke, or on ventilator > 48 hours

Table 3

Predictors of mortality

	Univariate		Multivariate	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Steroid use	6.0 (2.6–13.7)	<0.001	3.4 (1.4–8.1)	0.007
Age, 10 years	1.5 (1.2–1.8)	<0.001		
BMI, 5 kg/m ²	1.1 (1.0–1.2)	0.07		
Female	0.2 (0.1–0.3)	<0.001	0.3 (0.2–0.5)	<0.001
Diabetes	2.0 (1.3–3.1)	0.002		
Hypertension	3.3 (2.0–5.6)	<0.001	1.8 (1.0–3.1)	0.04
Dyspnea	1.4 (0.8–2.5)	0.20		
COPD	8.2 (4.2–15.9)	<0.001	3.7 (1.8–7.5)	<0.001
Smoking	0.8 (0.4–1.8)	0.60		
<u>Surgery type</u>				
LSG	1.0 (Reference)		1.0 (Reference)	
RYGB	1.8 (1.1–3.0)	0.02	1.7 (1.0–2.8)	0.03
Dependent functional status	5.7 (1.4–23.3)	0.02		
WBC > 10×10 ⁹ /L	0.5 (0.3–0.9)	0.02	0.4 (0.2–0.8)	0.005
Creatinine > 1.1 mg/dL	2.2 (1.4–3.4)	0.001	1.6 (1.0–2.6)	0.05
Hematocrit < 35	1.4 (0.6–3.3)	0.38		
Albumin < 3.5 g/dL	3.6 (1.8–7.2)	<0.001	3.1 (1.5–6.3)	0.002
<u>ASA Class</u>				
No/mild disturbance	1.0 (Reference)		1.0 (Reference)	
Severe disturbance	3.9 (1.8–8.4)	0.001	2.6 (1.2–5.8)	0.02
Life threatening	31.5 (13.2–75.6)	<0.001	12.2 (4.8–30.7)	<0.001

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; LSG, laparoscopic sleeve gastrectomy; RYGB, laparoscopic Roux-en-Y gastric bypass; WBC, white blood cell count.

Table 4

Predictors of serious complications

	Univariate		Multivariate	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Steroid use	1.9 (1.3–2.6)	<0.001	1.7 (1.2–2.3)	0.008
Age, 10 years	1.2 (1.1–1.2)	<0.001	1.1 (1.0–1.1)	0.003
BMI, 5 kg/m ²	1.0 (1.0–1.1)	0.008		
Female	0.7 (0.7–0.8)	<0.001	0.8 (0.7–0.9)	<0.001
Diabetes	1.3 (1.2–1.4)	<0.001		
Hypertension	1.6 (1.4–1.7)	<0.001	1.3 (1.2–1.5)	<0.001
Dyspnea	1.3 (1.2–1.5)	<0.001	1.1 (1.0–1.3)	0.05
COPD	2.2 (1.7–2.8)	<0.001	1.5 (1.1–2.0)	0.005
Smoking	1.3 (1.1–1.5)	0.001	1.3 (1.1–1.5)	<0.001
<u>Surgery type</u>				
LSG	1.0 (Reference)		1.0 (Reference)	
RYGB	1.8 (1.6–2.0)	<0.001	1.7 (1.6–2.0)	<0.001
Dependent functional status	5.7 (4.0–8.1)	<0.001	4.3 (3.0–6.2)	<0.001
WBC > 10×10 ⁹ /L	1.0 (0.9–1.1)	0.57		
Creatinine > 1.1 mg/dL	1.2 (1.1–1.3)	0.002		
Hematocrit < 35	1.3 (1.1–1.6)	0.01	1.2 (1.0–1.5)	0.046
Albumin < 3.5 g/dL	1.8 (1.5–2.3)	<0.001	1.7 (1.4–2.1)	<0.001
<u>ASA Class</u>				
No/mild disturbance	1.0 (Reference)		1.0 (Reference)	
Severe disturbance	1.5 (1.3–1.7)	<0.001	1.3 (1.1–1.4)	<0.001
Life threatening	2.7 (2.1–3.4)	<0.001	1.8 (1.4–2.3)	<0.001

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; COPD, chronic obstructive pulmonary disease; LSG, laparoscopic sleeve gastrectomy; RYGB, laparoscopic Roux-en-Y gastric bypass; WBC, white blood cell count.