Predictors of Reoperation and Failure to Rescue in Bariatric Surgery

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ABSTRACT

Background and Objectives: Morbidity and mortality have been shown to increase several-fold in patients who have undergone bariatric surgery and returned to the operating room after their initial procedures. Failure-to-rescue (FTR) analyses allow for an understanding of patient management and outcomes that is more distinguished than assessments of adverse occurrences and mortality rates alone. The objective of this study was to assess failure to rescue (FTR) and the characteristics and outcomes of patients undergoing reoperation after laparoscopic gastric bypass (LGBP) and laparoscopic sleeve gastrectomy (LSG).

Methods: The American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) participant data files were accessed to identify patients >18 years of age who underwent LGBP and LSG from 2011 through 2015. Patients were further classified into 3-day reoperation and nonreoperation cohorts. Patient demographics, comorbidities, and baseline health characteristics were collected. Pertinent outcomes, complications, and FTR were analyzed.

Results: A total of 96,538 patients were included. Of those, 1,850 (1.92%) returned to the operating room, and 94,688 (98.08%) did not. Patients who underwent reoperation had a greater likelihood of having any complication (72.20% vs. 51.29%; $P < .0001$) and had a higher overall mortality rate (1.46% vs. 0.10%, $P < .0001$). The FTR rates were 2.01% in the reoperation group and 0.14% in the nonreoperation group ($P < .0001$).

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Conclusion: Patients who undergo LGBP and LSG and have reoperations are at higher risk of developing complications with subsequent mortality.

Key Words: Bariatric surgery, Failure to rescue, Obesity, Reoperation.

INTRODUCTION

The obesity epidemic in the United States is a serious public health challenge, leading to major morbidity, mortality, and healthcare spending each year. Bariatric surgery is accepted as the best long-term treatment for obesity and its related comorbidities and is among the most common types of abdominal surgery performed in the United States today.[1–3] Trends in bariatric surgery have shown a recent shift from laparoscopic adjustable gastric banding (LAGB) to laparoscopic Roux-en-Y gastric bypass (LGBP) and laparoscopic sleeve gastrectomy (LSG).[1,4] LAGB has been associated with increased overall complications, when compared to LGBP and LSG, including pouch dilation, esophageal dilation, and stomach obstruction. Failure rates and revisional surgery rates have been reported to be as much as 44% and 30%, respectively, and LAGB has been associated with excess body weight loss of <50% compared to 60%–70% in LSG and LGBP.[3,5,6] Several randomized studies have demonstrated equivalent weight loss outcomes and comorbidity improvement between LSG and LGBP.[7–9]

As obesity rates continue to increase worldwide, it is important to understand the morbidity and mortality risks and the healthcare costs associated with bariatric surgery. Recent studies have characterized the incidence and outcomes after various bariatric surgery complications, including surgical site infections,[10] readmissions,[11] emergency department visits,[2] and reoperations.[12,13] Morbidity and mortality have been shown to increase severalfold in patients who undergo bariatric surgery and return to the operating room after their initial procedures.[12] Common reasons for reoperation after initial bariatric surgery include anastomotic or suture line leaks, postoperative hemorrhage, anastomotic strictures, intestinal obstruction, and adjacent organ injury.[12]

In 1992, Silber at al[14] introduced the concept of failure to rescue (FTR), defined as death after postoperative complication, which has become an important target for quality improvement efforts.[15] FTR analyses allow for an understanding of patient management and outcomes that is more distinguished than assessments of adverse occurrences and mortality rates alone.[14] The Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSA-QIP), a collaboration between the American College of Surgeons and the American Society for Metabolic and Bariatric Surgery, has established specific standards aimed at decreasing FTR in bariatric surgery cohorts.[16] Although overall mortality after bariatric surgery is relatively low, the obesity and related comorbidities associated with patients who undergo these operations put them at a considerably high risk,[4] which further increases upon reoperation. The purpose of this study was to compare characteristics, outcomes, and FTR rates in patients who undergo reoperation after LGBP and LSG.

METHODS

The American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) is a nationally validated, risk-adjusted database that collects preoperative, perioperative, and 30-day outcomes data in patients who undergo surgical procedures at participating hospitals. Institutional review board approval was obtained to access the ACS-NSQIP participant use data files and identify patients ≥18 years of age who underwent LGBP and LSG from 2011 through 2015. Patients with a primary Current Procedural Terminology (CPT) code of 43644 (laparoscopy, surgical, or gastric restrictive procedure; with gastric bypass and Roux-en-Y gastric bypass), 43645 (laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption), or 43775 (laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy [sleeve gastrectomy]) were included in the dataset. Patients were further classified into 30-day reoperation versus nonreoperation cohorts based on the ACS-NSQIP variable "return to operating room."

Patient demographics, baseline health characteristics, relevant comorbidities, and American Society of Anesthesiology (ASA) classification were also queried from the NSQIP database. Demographics included age, sex, race, ethnicity, and body mass index (BMI). Baseline health characteristics included recent weight loss and smoking within 1 year of the operation. Relevant comorbidities included diabetes mellitus, chronic obstruc-

tive pulmonary disease (COPD), congestive heart failure (CHF), dyspnea, hypertension, renal failure, dialysis, metastatic cancer, chemotherapy, and presurgical sepsis. ASA scores were grouped as ≤2 (no or mild systemic disease) or >2 (severe systemic disease, severe systemic disease that is a constant threat to life, or a person in moribund condition).

Thirty-day outcomes and complications were also collected from the ACS-NSQIP data files. Outcomes included mortality, ≥30 days in the hospital after surgery, discharge disposition, and readmission. Pertinent complications included wound and surgical site infections, pneumonia, reintubation, pulmonary embolism, failure to wean off the ventilator, renal insufficiency, cerebrovascular accident (CVA), neurological deficits, cardiac arrest requiring resuscitation, myocardial infarction, bleeding requiring a transfusion, urinary tract infection (UTI), and sepsis or septic shock. Patients were considered at risk for FTR if they had at least 1 in-hospital complication.

All statistical analyses were performed on Statistical Analysis Software v. 9.4 (SAS Institute, Cary, North Carolina, USA). Categorical variables were analyzed with χ^2 and Fisher's exact test when appropriate. Logistic regression was used to assess factors that independently predict return to operating room and FTR. Potential predictors were selected if they were statistically significant at $P < .05$, upon univariate analysis, and backward selection was used for multivariate analysis, with a significance level set at $P = .20$ for inclusion in the final model. Odds ratios (ORs) were evaluated and 95% confidence intervals (CIs) were constructed for group differences.

RESULTS

Return to Operating Room

Demographics and Preoperative Factors

There were 96,538 patients identified in the NSQIP database who underwent LGBP or LSG from 2011 through 2015. Of those, 1,850 (1.92%) underwent reoperation, whereas 94,688 (98.08%) did not. Patients who returned to the operating room versus those did not were more likely to be white non-Hispanic (64.03% vs 62.21%; $P = .01$), ≥65 years of age (5.95% vs 4.88%; $P = .03$), and male (22.92% vs 20.90%; $P = .03$); to have an ASA score >2 (70.70% vs 68.50%; $P = .04$); and to smoke cigarettes (11.95% vs 9.95%; $P = .0046$). Patients who had a reoperation had higher rates of COPD (3.41% vs 1.77%; $P < .0001$), CHF (0.81% vs 0.25%; $P < .0001$), and hyperten-

sion (55.19% vs 49.99%; $P <$ .0001) and were less likely to be functionally independent (98.27% vs 99.27%; $P <$ .0001). Patients who returned to the operating room also had higher rates of presurgical sepsis (0.70% vs 0.26%; $P =$ .0003) (**Table 1**).

After multivariate analysis, return to operating room was independently predicted by smoking at the time of surgery (OR 1.22, 95% CI 1.06–1.41), COPD (OR 1.57, 95% CI 1.21–2.04), CHF (OR 2.36, 95% CI 1.38–4.04), hypertension (OR 1.22, 95% CI 1.11–1.34), presurgical sepsis (OR 2.43, 95% CI 1.38–4.30), and the presence of any complication (OR 2.53, 95% CI 2.28–2.80) (**Table 2**).

Postoperative Factors

Patients who had reoperation after LGBP or LSG had a greater likelihood of having any complication (72.20% vs 51.29%; $P <$ .0001) and had a higher overall mortality rate (1.46% vs 0.10%; $P <$ .0001). In univariate analyses, the reoperation group had higher rates of several complications, all statistically significant at $P <$ .0001. Those complications with the greatest difference in magnitude across groups included organ/space surgical site infections (18.00% vs 0.21%), failure to wean off the ventilator (ventilator support >48 h) (8.54% vs 0.07%), blood transfusion (17.62% vs 0.92%), and postsurgical sepsis (10.54% vs 0.16%). Patients who did not have a reoperation after

Table 1.
Demographics and Preoperative Factors Associated with Return to the Operating Room

Variable	Return to Operating Room	Nonreturn to Operating Room	P
Occurrence of reoperation	1850 (1.92)	94,688 (98.08)	–
CPT 43644	1,205 (65.14)	44,223 (46.70)	–
CPT 43645	44 (2.38)	1,098 (1.16)	–
CPT 43775	601 (32.49)	49,367 (52.14)	–
Race and ethnicity			
White, non-Hispanic	1,203 (65.03)	58,901 (62.21)	.01
White, Hispanic	129 (6.97)	6,518 (6.88)	.88
Black, non-Hispanic	252 (13.62)	13,497 (14.25)	.44
Black, Hispanic	12 (0.65)	806 (0.85)	.35
Asian	19 (1.03)	743 (0.78)	.24
Unknown, non-Hispanic	24 (1.30)	1549 (1.64)	.25
Unknown, Hispanic	30 (1.62)	2094 (2.21)	.09
Age ≥65	110 (5.95)	4617 (4.88)	.03
Male	424 (22.92)	19,780 (20.90)	.03
ASA >2	1,308 (70.70)	64,866 (68.50)	.04
Diabetes	536 (28.97)	25,938 (27.39)	.13
Current smoker	221 (11.95)	9,422 (9.95)	.005
COPD	63 (3.41)	1,677 (1.77)	<.0001
CHF	15 (0.81)	232 (0.25)	<.0001
Hypertension	1,021 (55.19)	47,334 (49.99)	<.0001
Presurgical sepsis	13 (0.70)	248 (0.26)	.0003
Dyspnea	289 (15.62)	12,664 (13.37)	.005
Functionally independent	1,818 (98.27)	93,996 (99.27)	<.0001
Functionally partially dependent	17 (0.92)	385 (0.41)	.0007
Functionally totally dependent	3 (0.16)	20 (0.02)	<.009

N = 96,538. Data are number of patients (percentage of total patients in the subgroup). Categorical variables were analyzed with chi-square and Fisher's exact test when appropriate.

Table 2.
Multivariate Logistic Regression Analysis Assessing Demographic and Preoperative Factors Predicting Return to the Operating Room

Variable	OR	95% CI
Current smoker	1.22	1.06–1.41
COPD	1.57	1.21–2.04
CHF	2.36	1.38–4.04
Hypertension	1.22	1.11–1.34
Presurgical sepsis	2.43	1.38–4.30
Dyspnea	1.13	0.99–1.29
Any complication	2.53	2.28–2.80

Logistic regression was performed with potentially predictive variables in which $P < 0.05$ in univariate analysis.

Table 3.
Postoperative Complications and Outcomes Associated With Return to the Operating Room

Variable	Return to Operating Room	Nonreturn to Operating Room
Occurrence of reoperation	1850 (1.92)	94,688 (98.08)
Any complication	1,345 (72.20)	48,569 (51.29)
Mortality	27 (1.46)	92 (0.10)
Discharge home	1,732 (94.90)	94,226 (99.61)
Superficial surgical site infection	92 (4.97)	878 (0.93)
Wound infection	42 (2.27)	68 (0.07)
Organ space infection	333 (18.00)	196 (0.21)
Wound dehiscence	24 (1.30)	43 (0.05)
Pneumonia	105 (5.68)	252 (0.27)
Unplanned intubation	113 (6.11)	169 (0.18)
Pulmonary embolism	15 (0.81)	167 (0.18)
Ventilator >48 hours	158 (8.54)	64 (0.07)
Renal insufficiency	53 (2.86)	108 (0.11)
Acute renal failure	45 (2.43)	38 (0.04)
Urinary tract infection	58 (3.14)	590 (0.62)
Cardiac arrest	24 (1.30)	48 (0.05)
Myocardial infarction	14 (0.76)	62 (0.07)
Blood transfusion	326 (17.62)	869 (0.92)
Postsurgical sepsis	195 (10.54)	150 (0.16)
Septic shock	143 (7.73)	29 (0.03)

Data are number of patients (percentage of total patients in the subgroup). For all variables, $P < .0001$. Categorical variables were analyzed with chi-square and Fisher's exact test when appropriate.

LGBP or LSG were more likely to be discharged home (99.61% vs 94.90%; $P < .0001$) (**Table 3**).

Failure to Rescue

The FTR rates, defined as the percentage of patients who died among those who experienced postoperative complications, were 2.01% in the reoperation group and 0.14% in the group with no reoperation ($P < .0001$). Multivariate analyses evaluated patient demographics and preoperative factors associated with FTR in this bariatric surgery cohort. FTR was independently predicted by return to the operating room (OR 12.11, CI 7.67–19.11), male gender (OR 2.81, CI 1.86–4.24), age ≥65 years (OR 2.49, CI 1.45–4.28), hypertension (OR 3.01, CI 1.78–5.09), presurgical sepsis (OR 10.64, CI 3.68–30.73), and dyspnea (OR 1.92, CI 1.21–3.06) (**Table 4**).

DISCUSSION

Obesity is second only to smoking as the leading cause of preventable death in the United States, and it is expected to surpass smoking in the near future.[17] By 2030, it is estimated that >80% of adults and 30% of adolescents in the United States will be overweight or obese, and 1 in 6 health care dollars spent will be attributable to associated problems.[18] Bariatric surgery has revolutionized the way that obesity is managed. It has consistently been shown to surpass dietary modification, behavioral therapy, increased physical activity, and other nonoperative approaches with respect to improvements in mortality, BMI, comorbid conditions, quality of life, and occupational outcomes.[3,10,19] Despite generally low morbidity and mortality rates, it is essential for surgeons to understand asso-

Table 4.
Multivariate Logistic Regression Analysis Assessing Demographic and Preoperative Factors Predicting FTR

Variable	OR	95% CI
Reoperation (Return to Operating Room)	12.10	7.67–19.11
Male	2.81	1.86–4.24
Age ≥65	2.49	1.45–4.28
ASA >2	0.67	0.43–1.05
Hypertension	3.01	1.78–5.09
Presurgical sepsis	10.64	3.68–30.73
Dyspnea	1.91	1.21–3.06

Logistic regression was performed with potentially predictive variables in which $P < 0.05$ in univariate analysis.

ciated risks and complications, as the use of bariatric surgery as a management approach continues to trend upward. The present study provides additional analysis of FTR as it relates to readmission in a national cohort of patients who have undergone bariatric surgery.

Among the patients at the highest risk for poor medical and surgical outcomes are those who return to the operating room after their primary bariatric procedure. Nandipati et al[12] assessed factors predicting increased risk for reoperation in patients who had undergone LGBP or LAGB procedures; however, LSG has become an increasingly preferred operative method since this publication. The present study found a 1.92% 30-day reoperation rate for patients who underwent LSG and LGBP from 2011 through 2015, which is comparable to findings in prior investigations. Hutter et al[20] reported 5.02% and 2.97% 30-day reoperation rates in 14,491 LGBP and 944 LSG cases, respectively, Young et al[7] found reoperation rates of 2.46% and 1.6% after LGBP and LSG, respectively, and Sanni et al[3] found reoperation rates of 2.2% and 1.6% in LGBP and LSG, respectively. Qin et al,[21] in an assessment of the 2005–2012 NSQIP database, found no statistically significant difference in 30-day reoperation rates between cases managed with LGBP and LSG.

We found older patients (≥65 years) to be at a higher risk for reoperation, which is consistent with bariatric surgery studies reporting higher frequency of complications with increased age.[3,4] Qin et al[21] found that patients >65 years of age are at greater risk for medical and overall complications, but not for surgical complications specifically. Currently, 35% of patients >60 years of age are obese.[21] As the population ages, further research is warranted to evaluate the specific risks and outcomes for bariatric surgery in older patient cohorts.[21]

The presence of COPD, CHF, and hypertension were independent predictors of reoperation upon multivariate analysis. In the analysis by Nandipati et al[12] of patients who underwent LGBP or LAGB, hypertension was associated with return to the operating room in univariate analysis, but in multivariate analysis, patients were at increased risk of return to the operating room if they had low preoperative serum albumin, had a history of bleeding disorders, or were on dialysis. Coblijn et al[4] found that COPD is an independent risk factor for postoperative complications in bariatric surgery. Although the NSQIP database did not allow us to assess the management or extent of these comorbidities, bariatric surgeons should ensure that patients with COPD, CHF, and hypertension

have their conditions adequately managed before undergoing bariatric surgery.

We found overall mortality rates of 1.46% in the reoperation group compared to 0.10% in the nonreoperation group. These low mortality rates in bariatric surgery are well documented.[3,7,16,20] Over the past several decades, in general surgery in particular, FTR has been considered a superior quality indicator when compared to mortality rate alone.[16] In this study, patients were at risk of FTR if they experienced one or more complications after their primary bariatric procedure. Return to operating room, although indicative of a complication, was not independently considered a complication and, taken alone, did not place a patient in the cohort of patients at risk of FTR. The present study found an FTR rate of 2.01% in the reoperation group and 0.14% in the nonreoperation group. The difference in these rates is reasonable, as patients who require reoperations are more medically or surgically complex or have complications that are more severe than do patients without reoperations. In a 2015 review, Johnston et al[22] found FTR rates of 8.0%–16.9% in surgical patients overall. Our lower FTR rates are expected, given the relatively low risks and complications associated with bariatric surgery, although few studies have evaluated FTR in bariatric surgery cohorts specifically.[16,23] The timing of escalation of care has been cited as an important factor that predicts FTR.[22,24] Postoperative complications that require return to the operating room are among the most severe. Prompt recognition and surgical remediation are necessary. Although we were unable to examine specific timing of care in our cohort, it may have influenced the FTR rates in the present study.

In our analysis of 96,538 patients across hundreds of U.S. hospitals, the rate of reoperation was an independent predictor of FTR, which provides further insight into the importance of understanding risk factors for reoperations and escalating the care of patients with complications to a higher level when warranted.[25] We also found that FTR was independently associated with male sex; age ≥65 years; and preoperative hypertension, dyspnea, and sepsis. In a cohort of 7763 general, vascular, and surgical subspecialty cases from a NSQIP database, Chiulli et al[26] found that preoperative CHF, renal failure, and ascites were associated with FTR. Kim et al[27] found that patients undergoing hepatic resection with borderline operability, defined as age ≥75 years, dependent function, lung disease, ascites/varices, myocardial infarction, stroke, steroid use, weight loss >10%, or sepsis, had a mortality rate triple that of nonborderline patients.[27] In the present study, we identified the demographics and comorbidities

associated with patients after weight loss surgery. In line with the recommendations from other FTR studies, we encourage optimization and careful management of medical comorbidities before bariatric surgery as well as rapid attention to postoperative complications and escalation of care when appropriate.

There are several limitations to consider in the present study. We were unable to assess disease severity for comorbidities and complications, which may further distinguish the baseline characteristics and outcomes of our cohort. For example, a patient with recently diagnosed, well-managed COPD differs clinically from a patient who experiences frequent COPD exacerbations; however, we were unable to assess these nuances. We were also unable to determine which specific complications precipitate reoperations. A prior analysis demonstrated a 2.9-fold variation in reoperation rates after gastric band surgery.[13] It is plausible that there is geographic variation in reoperation rates in the LGBP and LSG populations—a factor that we were unable to evaluate. In addition, we could not assess hospital- and case-specific factors that have been shown to be significantly associated with FTR, including hospital volume, nurse staffing levels, hospital-specific mortality rates, and timing of escalation of care.[22,24]

Patients who undergo bariatric surgery patients are a medically complex group at risk of postoperative complications. This study reports factors influencing FTR in a bariatric surgery cohort. It also contributes to the growing body of knowledge on LGBP and LSG and more specifically the risks and outcomes of patients with reoperations. As bariatric surgery rates continue to rise, surgeons must remain vigilant in identifying those at risk for reoperation, complication, and FTR, escalating care to a higher level care when appropriate.

CONCLUSIONS

Of 96,538 patients who underwent LGBP or LSG from 2011 through 2015, 1.92% had a reoperation within 30 days. Return to the operating room was independently predicted by smoking, COPD, CHF, hypertension, weight loss >10% within 6 months, presurgical sepsis, and the presence of any complication. FTR rates were 2.01% in the reoperation group and 0.14% in the group that did not undergo a reoperation. Operating room return, male sex, age >65, hypertension, presurgical sepsis, and dyspnea were independent predictors of FTR.

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