Title
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Journal
Journal of the American College of Surgeons, 227(1)

ISSN
1072-7515

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Publication Date
2018-07-01

DOI
10.1016/j.jamcollsurg.2018.03.030

Peer reviewed

Risk Factors for Gastrointestinal Leak after Bariatric Surgery: MBSAQIP Analysis

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Disclosure Information: Nothing to disclose.

Disclosures outside the scope of this work: Dr Stamos is a consultant and receives payment for lectures from Novadaq, Ethicon, and Olympus; owns stock in Novadaq; and receives royalties from Elsevier.

Presented at the Western Surgical Association 125th Scientific Session, Scottsdale, AZ, November 2017.

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Brief title: Leak in Laparoscopic Bariatric Surgery

ABSTRACT

BACKGROUND: Gastrointestinal leak remains one of the most dreaded complications in bariatric surgery. We aimed to evaluate risk factors and the impact of common perioperative interventions on the development of leak in patients underwent laparoscopic bariatric surgery.

STUDY DESIGN: Using the 2015 database of accredited centers, data were analyzed for patients underwent laparoscopic sleeve gastrectomy (LSG) or Roux-en-Y gastric bypass (LRYGB). Emergent, revisional, and converted cases were excluded. Multivariate logistic regression was used to analyze risk factors for leak including provocative testing of anastomosis, surgical drain placement, and use of postoperative swallow study.

RRSULTS: Data from 133,478 patients underwent LSG (N=92,495, 69.3%) and LRYGB (N=40,983, 30.7%) were analyzed. The overall leak rate was 0.7% (938/133,478). Factors associated with increased risk for leak were oxygen dependency (AOR, 1.97), hypoalbumenia (AOR, 1.66), sleep apnea (AOR, 1.52), hypertension (AOR, 1.36), and diabetes (AOR, 1.18). Compared to LRYGB, LSG was associated with a lower risk of leak (AOR 0.52; 95% CI 0.44-0.61; P<0.01). Intraoperative provocative test was performed in 81.9% of cases and the leak rate was higher in patients with vs. without a provocative test (0.8% vs. 0.4%, respectively, P<0.01). Surgical drain was placed in 24.5% of cases and the leak rate was higher in patients with vs. without a surgical drain placed (1.6% vs. 0.4%, respectively, P<0.01). Swallow study was performed in 41% of cases and the leak rate was similar between patients with vs. without swallow study (0.7% vs. 0.7%, P=0.50).

CONCLUSIONS: The overall rate of gastrointestinal leak in bariatric surgery is low. Certain preoperative factors, procedural type (LRYGB), and interventions (intraoperative provocative test and surgical drain placement) were associated with a higher risk for leaks.

KEYWORDS:

Laparoscopic bariatric surgery, laparoscopic Roux-en-Y gastric bypass, Laparoscopic sleeve gastrectomy, Gastrointestinal leak, Provocative test, Surgical drain, Swallow study

ABBREVIATIONS:

Laparoscopic sleeve gastrectomy (LSG); Laparoscopic Roux-en-Y gastric bypass (LRYGB); Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP); Body mass index (BMI); Adjusted odds ratio (AOR); Confidence interval (CI); Chronic obstructive pulmonary disease (COPD); Gastroesophageal reflux disease (GERD); Deep vein thrombosis (DVT); Pulmonary embolism (PE); Obstructive sleep apnea (OSA);

INTRODUCTION

Gastrointestinal leak remains one of the most dreaded postoperative complications in bariatric surgery. Gastrointestinal leak significantly increases health care utilization and cost.(1) Laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGB) are the most commonly performed bariatric procedures in the United States.(2-5) Published meta-analyses have reported a gastrointestinal leak rate ranging from 0% to 8% after LSG (6-9) and 0.1% to 8.3% after LRYGB (10-13). Although the occurrence of a postoperative gastrointestinal leak is low and has been steadily declining in recent years, it is still a complication that can lead to high morbidity and mortality.(14)

There are several interventions employed by surgeons in an effort to detect gastrointestinal leaks either intraoperatively or in the immediate postoperative period. An intraoperative test for leak can be performed utilizing either endoscopy with carbon dioxide insufflation, or placement of an orogastric tube with distention of the gastric pouch with air, or with methylene blue dye. The advantage of an intraoperative provocative test is the ability to intervene with suture closure of the staple line in the event a leak is identified. Other interventions that can facilitate early detection of gastrointestinal leak include intraoperative placement of a surgical drain or performance of a postoperative contrast swallow study. The current literature debates the utility and effectiveness of each of these methods in prevention or identification of gastrointestinal leak in patients undergoing LSG (15-18) or LRYGBP (10, 14, 19-21). The aim of this study was to evaluate risk factors for gastrointestinal leak and the impact of provocative testing, placement of a surgical drain, and performance of a postoperative swallow study on the development of gastrointestinal leaks in patients who underwent LSG and LRYGB.

METHODS

Data source

We performed a retrospective cohort study using the 2015 Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database. The MBSAQIP database was created in 2012 by the American College of Surgeons (ACS) and the American Society for Metabolic and Bariatric Surgery (ASMBS). To date, there are over 790 accredited centers that have submitted data on more than 90% of bariatric procedures performed annually in the United States.(22) The MBSAQIP is a rigorous dataset including capture of 100% of all bariatric cases at each participating institution, clear definitions of data parameters, and collection of data by a certified clinical reviewers.

Study design and population

Clinical data on patients who underwent LSG or LRYGB were analyzed based on the Current Procedural Terminology (CPT) codes: LSG (43775) and LRYGB (43644, 43645). Emergent, revisional, and converted cases were excluded. Patients were categorized into two groups, those with or those without gastrointestinal leak. Postoperative leak was defined according to MBSAQIP original variables as 30-day leak outcomes, drain present >30 days, organ space surgical site infection, leak-related 30-day readmission, leak-related 30-day reoperation, or leak-related 30-day intervention. Preoperative characteristics and comorbidities were analyzed to determine factors predictive of gastrointestinal leaks. Also, utilization of intraoperative provocative testing, placement of a surgical drain, and performance of a postoperative swallow study were examined. Intraoperative provocative testing was defined according to MBSAQIP as insufflation of air through an endoscope or nasogastric tube with the anastomosis submerged under saline to look for bubbles, or the installation of methylene blue (or other liquid) under

pressure while looking for blue dye leak with the Roux limb clamped distal to the anastomosis. Surgical drain placement was defined according to MBSAQIP as a drain inserted during the time of the initial bariatric or metabolic surgical procedure that exits the body from an intra-abdominal area. Postoperative swallow study was defined according to MBSAQIP as an x-ray study used to evaluate the anatomy and function of the esophagus, stomach, and small intestine. Oral contrast is given during this study and the contrast is followed as it goes from the mouth to the small intestine. Approval for the use of the MBSAQIP patient-level data in this study was obtained from the Institutional Review Board at the University of California, Irvine Medical Center and the MBSAQIP.

Statistical analysis

Statistical analyses were performed using SPSS software, Version 23 (SPSS Inc., Chicago, IL). Patient characteristics were reported as proportions for categorical variables and means ± standard deviations for continuous variables. A multivariate logistic regression model was used to analyze the risk factors for gastrointestinal leak, as well as the independent association between various intraoperative and postoperative interventions with the development of gastrointestinal leak. Variables used in the multivariate analyses included demographic data (age, gender, race, and body mass index [BMI]), preoperative comorbidities, procedural type, and various intraoperative and postoperative interventions. For each variable, the adjusted odds ratio (AOR) with a 95% confidence interval (CI) was calculated. Statistical significance was set at $P < .05$.

RESULTS

Data on 133,478 patients who underwent LSG or LRYGB were analyzed. Most patients were

female (79%) and White (74.5%). Cases included 69.3% (N=92,495) LSG and 30.7% (N=40,983) LRYGB procedures. The overall rate of gastrointestinal leak was 0.7% (938/133,478). Table 1 summarizes the characteristics and comorbidities of patients with versus without gastrointestinal leak. Compared to patients without gastrointestinal leak, patients with gastrointestinal leak had longer mean operative time (98 ± 57 versus 87 ± 46 min, respectively, P<0.01) and longer mean length of hospital stay (4 ± 5 versus 1.8 ± 2 days, respectively, P<0.01).

Intraoperative provocative testing was performed in 81.9% of patients (N=104,868). The rate of gastrointestinal leak was significantly higher in patients with versus without a provocative test (0.8% vs. 0.4%, respectively, P<0.01). We do not have data regarding the specific type of intraoperative provocative testing such as endoscopy vs. air insufflation or methylene blue dye injection using a nasogastric tube. Surgical drains were placed in 24.5% of cases (N=32,650). The rate of gastrointestinal leak was significantly higher in patients with versus without placement of a surgical drain (1.6% vs. 0.4%, respectively, P<0.01). A postoperative swallow study was performed in 41% of patients (N=54,800). The rate of gastrointestinal leak was similar between patients who had a swallow study and patients who did not (0.7% vs. 0.7%, P=0.50). Table 2 summarizes the multivariate logistic regression analyses for postoperative gastrointestinal leak. Patient characteristics including age, race, sex, and BMI did not impact the gastrointestinal leak rate. Preoperative comorbidities associated with increased risk for gastrointestinal leak were history of oxygen dependency (AOR, 1.97), hypoalbumenia (AOR, 1.66), sleep apnea (AOR, 1.52), hypertension (AOR, 1.36) and diabetes mellitus (AOR, 1.18). There was no effect of preoperative renal insufficiency, chronic steroid use, venous stasis, and gastroesophageal reflux disease on development of gastrointestinal leak. With respect to

procedure type, LSG was associated with lower risk of gastrointestinal leak compared to LRYGB (AOR 0.52; 95% CI 0.44-0.61; P<0.01). Performance of a provocative test and placement of a surgical drain were associated with higher leak rate (AOR of 1.41 and 3.46, respectively) whereas there was no effect of postoperative swallow study on the leak rate.

DISCUSSION

Gastrointestinal leak is a major complication after bariatric surgery. Using the MBSAQIP database, we found the overall leak rate after LSG and LRYGB to be low at 0.7% with a higher leak rate with LRYGB compared to LSG. This finding is consistent with other large published studies and intuitive as LRYGB is an anastomotic/reconstructive procedure and the LSG is not. (6-9) There is a difference in the pathophysiology of a gastrointestinal leak between LSG and LRYGB. The most commonly reported location for leak after LRYGB was at the gastrojejunal anastomosis, whereas most leaks after LSG occurred at the proximal third of the long gastric staple line. (23) It has been postulated that the causes of leaks are multiple factorial including preoperative, intraoperative, and postoperative factors. In this study, we found that preoperative history of oxygen dependency, hypoalbumenia, sleep apnea, hypertension, and diabetes mellitus were factors predictive of gastrointestinal leak. Additionally, the use of intraoperative provocative testing and placement of a surgical drain were associated with a higher leak rate, whereas postoperative performance of a swallow study had no impact on the rate of leak.

Patient comorbidities and the surgeon's experience may influence the rate of gastrointestinal leak after LSG and LRYGB.(24, 25) Similar to our findings, hypertension and diabetes have been reported as independent risk factors for anastomotic leakage following intestinal surgeries,

possibly due to chronic microvascular damage, which is correlated with an increased risk for anastomotic dehiscence.(26, 27). Additionally, studies have shown that continuous positive airway pressure (CPAP) and anemia (low oxygenation) are risk factors for leaks after bariatric surgery, and their correction plays a role in decreasing the overall leak rate (28-30). Therefore, it is imperative to screen patients with a potential diagnosis of obstructive sleep apnea in the preoperative setting and their condition evaluate and optimize prior to surgical intervention. Currently, there are three main interventions performed to detect gastrointestinal leak in bariatric surgery. These include the use of intraoperative provocative testing, placement of a surgical abdominal drain, and performance of a postoperative swallow study. An intraoperative provocative test is commonly performed to assess the integrity of the staple line following LSG and LRYGB. There are 2 distinct methods, either placement of an orogastric tube with injection of methylene blue dye or air, versus intraoperative endoscopy with carbon dioxide insufflation while submerging the staple line in saline and observing for air leak. In this study, we found that the use of intraoperative provocative testing was associated with a higher leak rate. Based on the senior author's experience, we believe that this association may be related to the specific technique in performance of the provocative testing. Many surgeons perform the leak test using the orogastric tube method, which by the nature of its blind insertion can cause trauma to a freshly constructed staple line. We hypothesize that this technique may explain the higher rate of postoperative leak. In the authors' opinion, the preferred intraoperative provocative test would be to use an endoscope, examining the staple line for bleeding and testing the integrity of the anastomosis using an air leak test. This test is safe with minimal trauma as it is performed under direct visualization. Unfortunately, the MBSAQIP database does not report the specific technique used in intraoperative provocative testing. The higher leak rate with intraoperative

provocative testing may be a reflection of the specific technique used in testing rather than the overall concept of provocative testing. In a study examining the role of intraoperative provocative testing following colorectal surgery using a sigmoidoscope, Kwon et al. reported a benefit of provocative testing with a reduction in the composite adverse event rate with routine testing of left-sided colorectal anastomoses.(31)

Intraabdominal surgical drain placement is used by some surgeons after gastrointestinal surgery to detect the presence of gastrointestinal leaks in the postoperative period. Unlike the commonly used intraoperative provocative testing, less than 25% of the patients had a surgical drain placed, which could mean that surgical drain is being placed on a selective rather than routine basis as there have been study demonstrating that measurement of drain amylase helps to detect leaks after gastric bypass surgery.(32) We found that the use of surgical drain was associated with a higher rate of leak. This finding could be related to selection bias whereby a surgical drain is placed in more technically complex cases as determined by the surgeon. These intraoperative factors noting the complexity of the operation and the decision of the surgeon to place a drain are not available in the database. Despite this limitation, our results are consistent with recent prospective randomized clinical trials reporting the lack of benefit of surgical drain placement in patients undergoing gastrectomy for cancer.(33, 34) Furthermore, an expanded retrospective study showed that routine drains likely have no benefit after LRYGB.(19) In a recent systematic review, Messager and colleagues also reported that there was no evidence to favor intra-abdominal drainage after gastrectomy with respect to morbidity and mortality, nor was it helpful in the detection or management of leaks.(35) With regard to the swallow study performance, our investigation found no impact of this study on leak development following LSG or LRYGB. Our

finding is consistent with previously published studies showing minimal benefit of a postoperative swallow study.(36, 37)

There are several limitations to this study. The MBSAQIP database only extends follow-up to 30 days postoperatively, and therefore the true rate of gastrointestinal leak may be underestimated. As with any national database, there are limitations regarding the accuracy of coding and data input. The database does not provide information on whether an intervention was performed routinely or performed selectively. This information is important as selective intervention is usually based on a surgeon's knowledge regarding the complexity of the operation and the likelihood for development of leaks. As previously stated, the MBSAQIP database does not include details regarding the specific method of intraoperative provocative testing. The higher leak rate associated with provocative testing might be related to the technique used (blind insertion of an orogastric tube versus endoscopy) rather than the actual testing of an anastomosis. It is therefore important to interpret our findings with caution. Our results only showed an association between the use of provocative testing and surgical drain placement with a higher leak rate. The MBSAQIP database does not have enough specificity to determine any causal relationship. Despite these limitations, this study provides a large sample size to examine the preoperative risk factors for leak and the impact of various intraoperative and postoperative interventions on the development of gastrointestinal leak after laparoscopic bariatric surgery.

CONCLUSION

The overall rate of gastrointestinal leak following LSG and LRYGB is low at 0.7%, with sleeve gastrectomy having a significantly lower leak rate compared to gastric bypass. Hypertension,

diabetes mellitus, sleep apnea, oxygen dependency, and hypoalbumenia were found to be independent risk factors for gastrointestinal leak. The use of intraoperative provocative testing and placement of a surgical drain were associated with a higher leak rate, but performance of a postoperative swallow evaluation had no impact on the leak rate.

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Table 1. Patient Characteristics, Comorbidities, and Interventions in Patients With vs Without Gastrointestinal Leak

Patients characteristics, comorbidities, and other factors	**With gastrointestinal leak (n=938)**	**Without gastrointestinal leak (n=132,540)**	**p Value**
Age, y, mean ± SD	45 ± 12	44 ± 12	0.67
Male, vs female, n (%)	220 (23.5)	27,871 (21)	0.24
Race, n (%)			
White	575 (84.4)	98,919 (80.4)	0.31
African American	138 (14.7)	22,623 (18.4)	0.12
Asian	1 (0.1)	623 (0.5)	0.05
Other ethnicities	1 (0.1)*	894 (0.7)†	NA
BMI, kg/m^2, mean ± SD	45.7 ± 9.5	45.4±9	0.9
Hypertension, n (%)	531 (56.6)	66,198 (49.9)	<0.01
Hyperlipidemia, n (%)	201 (21.4)	33,796 (25.5)	<0.01
Smoking, n (%)	76 (8.1)	12,127 (9.1)	0.29
Gastroesophageal reflux disease, n (%)	292 (31.1)	41,867 (31.6)	0.06
COPD, n (%)	19 (2)	2,459 (1.9)	0.79
Diabetes mellitus , n (%)	299 (31.9)	35,759 (27)	0.02
Dialysis, n (%)	4 (0.4)	332 (0.3)	0.03
Chronic steroid use, n (%)	13 (1.4)	1,715 (1.6)	0.92
Renal insufficiency, n (%)	3 (0.3)	861 (0.6)	0.24
History of deep vein thrombosis, n (%)	27 (2.9)	2,201 (1.7)	0.06
History of pulmonary embolism , n (%)	21 (2.2)	1,501 (1.1)	0.05
Venous stasis, n (%)	10 (1.1)	1,618 (1.2)	0.31
Obstructive sleep apnea, n (%)	461 (49.1)	50,159 (37.8)	<0.01

Oxygen dependent, n (%)	14 (1.5)	963 (0.7)	0.01
Hypoalbuminemia, n (%)‡	56 (6)	6,110 (4.6)	0.02
Mean operative duration, min ± SD	98 ± 57	87 ± 46	<0.01
Mean length of stay, d ± SD	4 ± 5	1.8 ± 2	<0.01
LSG (N=92,495), n (%)	454 (0.5)	92,041 (99.5)	NA
LRYGB (N=40,983), n (%)	484 (1.2)	40,499 (98.8)	NA
With provocative test (N=104,868), n (%)	826 (0.8)	104,042 (99.2)	NA
Without provocative test (N=23,230), n (%)	84 (0.4)	23,146 (99.6)	NA
With surgical drain (N=32,650), n (%)	516 (1.6)	32,134 (98.4)	NA
Without surgical drain (N=100,828) n (%)	422 (0.4)	100,406 (99.6)	NA
With swallow study (N=54,800), n (%)	361 (0.7)	54,439 (99.3)	NA
Without swallow study (N=78,678), n (%)	577 (0.7)	78,101 (99.3)	NA

*41 Missing.

†9,481 Missing

‡Serum albumin level lower than 3.5 g/dL.

LSG, laparoscopic sleeve gastrectomy; LRYGB, laparoscopic Roux-en-Y gastric bypass; NA, not applicable.

Table 2**.** Risk-Adjusted Analysis of Predictors of Gastrointestinal Leak after Laparoscopic Bariatric Surgery

	AOR	**95% CI**	**p Value**
Demographics			
Age	1.00	0.99-1.01	0.85
Male vs female (reference)	1.12	0.95-1.32	0.16
African American vs white race (reference)	0.22	0.03-1.59	0.13
Asian vs white race (reference)	0.14	0.02-1.04	0.05
Preoperative comorbidities (reference, no comorbidities)			
Hypertension	1.36	1.16-1.59	<0.01
Hyperlipidemia	0.58	0.48-0.70	<0.01
Diabetes mellitus	1.18	1.0-1.38	0.04
Renal insufficiency	0.51	0.16-1.61	0.25
Sleep apnea	1.52	1.31-1.75	<0.01
Chronic steroid use	0.96	0.55-1.68	0.89
Oxygen dependency	1.97	1.11-3.50	0.02
Hypoalbumenia	1.66	1.08-2.57	<0.01
Procedural type			
LSG vs LRYGB (reference)	0.52	0.44-0.61	<0.01
Intraoperative and postoperative interventions			
With vs without (reference) a provocative test	1.41	1.14-1.76	0.02
With vs without (reference) surgical drain	3.46	3.01-3.98	<0.01
With vs without (reference) swallow study	0.75	0.58-1.06	0.50

AOR, adjusted odds ratio; LSG, laparoscopic sleeve gastrectomy; LRYGB, laparoscopic Roux-en-Y gastric bypass

Precis

The overall rate of gastrointestinal leak in bariatric surgery is low. Certain preoperative factors, procedural type (laparoscopic sleeve gastrectomy), and interventions (intraoperative provocative test and surgical drain placement) predispose patients to higher risk for leaks.