ORIGINAL ARTICLE

Morbidity of Anastomotic Leaks in Patients Undergoing Roux-en-Y Gastric Bypass

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Objective: To document the effect of anastomotic leaks on morbidity and mortality after Roux-en-Y gastric bypass (RYGB) for obesity.

Design: Prospectively collected data on 840 consecutive patients who underwent RYGB between 1998 and 2005. Multivariate logistic regression analysis was used to determine the effect of anastomotic leaks on postoperative morbidity independent of sex, age, preoperative body mass index, access (open vs laparoscopic), calendar year of RYGB, and comorbidities. $P<.05$ was considered significant.

Results: A total of 36 patients (4.3%) developed leaks after RYGB. Patients who developed anastomotic leaks had a significantly higher overall complication rate (61% vs 20%, $P<.001$), mortality (14% vs 4%, $P=.01$), and duration of hospital stay (24.5 vs 4.5 days, $P<.001$) compared with patients who did not develop leaks. In a multivariate logistic regression model, anastomotic leaks increased the likelihood of mortality (odds ratio [OR], 15; 95% confidence interval [CI], 3-80; $P=.002$) and overall complications (OR, 6; 95% CI, 3-13; $P<.001$), specifically sepsis (OR, 27; 95% CI, 2-472; $P=.02$), renal failure (OR, 16; 95% CI, 3-99; $P=.003$), small-bowel obstruction (OR, 11; 95% CI, 2-68; $P=.008$), internal hernia (OR, 10; 95% CI, 2-51; $P=.008$), thromboembolism (OR, 9; 95% CI, 3-27; $P<.001$), and incisional hernia (OR, 5; 95% CI, 2-13; $P=.001$).

Conclusions: Anastomotic leaks significantly increase the likelihood of developing additional life-threatening complications after RYGB. Close and aggressive monitoring is recommended for early detection and management of added complications, should they occur.

Arch Surg. 2007;142(10):954-957

ONE OF THE MOST SERIOUS complications of Roux-en-Y gastric bypass (RYGB) is an anastomotic leak, which is reported to occur in up to 5.6% of RYGB procedures.[1,2] A recently published study of laparoscopic RYGB and open RYGB identified older and heavier male patients with multiple comorbid conditions as being at increased risk for developing anastomotic leaks and subsequent mortality.[2]

Anastomotic leaks after RYGB are difficult to detect because the associated symptoms may be subtle and nonspecific[3] and because routine postoperative upper gastrointestinal series have a low yield[4] but may detect small leaks in otherwise asymptomatic patients.[5]

In addition to anastomotic leaks, patients undergoing RYGB (laparoscopic vs open RYGB, respectively) can develop a host of other systemic and life-threatening complications, such as pulmonary embolism (0.4% vs 0.8%), bowel obstruction (2.9% vs 2.1%), gastrointestinal bleeding (1.9% vs 0.6%), wound infection (2.9% vs 6.6%), stomal stenosis (4.7% vs 0.7%), ventral hernias (0.5% vs 8.6%), pneumonia (0.1% vs 0.3%), and death (0.2% vs 0.9%).[6] Given the gravity of these complications, and because of the ensuing systemic inflammatory response in patients with anastomotic leaks, we hypothesized that the likelihood of developing major complications is increased in patients with anastomotic leaks after RYGB.

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METHODS

This study was approved by the institutional review board of the University of South Florida College of Medicine. Prospectively collected data on all consecutive patients who underwent primary or revisional RYGB at Tampa General Hospital, Tampa, Florida, from 1998 to 2005 were analyzed. Patient demographics, comorbidities, hospital course, and outcomes were evaluated.

The incidence of anastomotic leaks was analyzed by demographic factors (sex, age, and preoperative body mass index [BMI; calculated as weight in kilograms divided by height in me-

Table 1. Comorbidities Evaluated as Potential Predictors of Added Morbidity After Roux-en-Y Gastric Bypass

- Cardiac
  - Congestive heart failure
  - Coronary artery disease/myocardial infarction
  - Cardiomyopathy
  - Arrhythmia
  - Hypercholesterolemia/hyperlipidemia/hypertriglyceridemia
  - Tobacco abuse
  - Hypertension
  - Lower extremity edema
- Respiratory
  - Obstructive sleep apnea
  - Asthma/chronic obstructive pulmonary disease
  - History of pneumonia
  - Shortness of breath
- Gastrointestinal/hepatic
  - Alcohol abuse
  - Gall bladder disease
  - Peptic ulcer disease
  - Gastroesophageal reflux/pyrosis
  - Hiatal hernia
  - Hepatitis
  - Cirrhosis
  - Nonalcoholic fatty liver disease
- Endocrine
  - Diabetes
  - Hypothyroidism
- Hematologic
  - History of thromboembolism
  - Anemia
- Vascular
  - Varicose veins
  - Peripheral vascular disease

ters squared]) using the χ^2 test. The incidence of added morbidity and mortality, such as small-bowel obstruction, internal hernia, stricture, gastrogastric fistula, enterocutaneous fistula, surgical site infection, incisional hernia, sepsis, bleeding, anastomotic ulcer, thromboembolism, pneumonia, liver failure, respiratory failure, renal failure, nephrolithiasis, and myocardial infarction was compared in patients with and without anastomotic leaks using the Fisher exact test.

The effect of an anastomotic leak on additional morbidity and mortality was evaluated using multivariate logistic regression, controlling for other potential predictors. Evaluated variables included presence of anastomotic leak, age, sex, preoperative BMI, calendar year of RYGB, access (open vs laparoscopic), and individual comorbidities, as listed in **Table 1**. Forward stepwise variable selection using the likelihood ratio test was completed using 0.05 as the entry criterion and 0.10 as the removal criterion. Statistical analyses were conducted using SPSS (SPSS Inc, Chicago, Illinois).

RESULTS

PATIENT CHARACTERISTICS

Eight hundred forty patients (85% women) underwent open (n=442) or laparoscopic (n=398) RYGB. Median age was 45 years (range, 19-70), preoperative weight was 137 kg (range, 50-301), and preoperative BMI was 49 (range, 17-103). Follow-up was complete and up to date in 68% patients; 45% of these patients were in the 6- to 12-month postoperative period. Median follow-up was 11 months (range, 1-75).

Table 2. Incidence of Additional Morbidity and Mortality in Patients Who Did and Did Not Develop Anastomotic Leaks

Added Morbidity/Mortality	No. of Patients (%)		*P* Value[a]
	Leak (n = 36)	No Leak (n = 804)	
Death	5 (14)	30 (4)	.01
Overall complications other than leak	22 (61)	164 (20)	< .001
Infection (surgical site)	8 (22)	44 (6)	.001
Incisional hernia	7 (19)	42 (5)	.003
Gastrogastric fistula	6 (17)	3 (0.4)	< .001
Sepsis	5 (14)	6 (0.7)	< .001
Venous thromboembolism (PE/DVT)	5 (14)	17 (2)	.002
Small-bowel obstruction	5 (14)	23 (3)	.005
Gastrointestinal bleeding	3 (8)	23 (3)	NS
Internal hernia	2 (6)	5 (0.6)	.03
Renal failure	2 (6)	3 (0.4)	.02
Respiratory failure	2 (6)	6 (0.7)	.04
Pneumonia	1 (3)	6 (0.7)	NS
Enterocutaneous fistula	1 (3)	1 (0.1)	NS
Liver failure	1 (3)	2 (0.2)	NS
Myocardial infarction	0 (0)	1 (0.1)	NS
Anastomotic stricture	2 (6)	20 (2)	NS
Anastomotic ulcer	0	11 (1)	NS
Kidney stones	0	8 (1)	NS

Abbreviations: DVT, deep venous thrombosis; NS, not significant; PE, pulmonary embolus.
[a] $P < .05$ was significant by the Fischer exact test.

INCIDENCE OF ANASTOMOTIC LEAKS

Thirty-six patients (4.3%) developed anastomotic leaks. Mean duration of hospital stay in patients with an anastomotic leak was 24.5 days (95% confidence interval [CI], 15.7-33.4) vs 4.5 days (95% CI, 4.2-4.8) in those patients without an anastomotic leak ($P<.001$). There was no difference in the incidence of anastomotic leaks among men vs women (6 of 127 vs 30 of 713, $P=.81$), among patients younger than 45 years vs patients 45 years or older (14 of 417 vs 22 of 423, $P=.23$), among patients with preoperative BMIs less than 50 vs patients with preoperative BMIs of 50 or greater (18 or 439 vs 18 of 397, $P=.87$), or among patients who underwent open vs laparoscopic RYGB ($P>.05$).

MORBIDITY AND MORTALITY OF ANASTOMOTIC LEAKS

The overall incidence of major complications was significantly higher in patients who developed anastomotic leaks compared with those who did not (61% vs 20%, $P<.001$). Additionally, the overall mortality was 14% in patients who developed anastomotic leaks compared with 4% in patients who did not develop anastomotic leaks ($P=.01$).

Table 2 lists added morbidity in patients who developed anastomotic leaks. The incidence of surgical site infection, gastrogastric fistulae, sepsis, venous thrombo-

Table 3. Multivariate Logistic Regression of Anastomotic Leak on Added Morbidity and Mortality After Roux-en-Y Gastric Bypass

Added Morbidity/Mortality	Odds Ratio (95% Confidence Interval)	*P* Value
Death	15 (3-80)	.002
Overall complications other than leak	6 (3-13)	< .001
Sepsis	27 (2-472)	.02
Renal failure	16 (3-99)	.003
Small-bowel obstruction	11 (2-68)	.008
Internal hernia	10 (2-51)	.008
Venous thromboembolism	3 (3-27)	< .001
Incisional hernia	5 (2-13)	.001

embolic events, internal hernias, small-bowel obstruction, respiratory failure, and renal failure significantly increased in patients who developed anastomotic leaks vs patients who did not (all, $P < .05$).

ANASTOMOTIC LEAKS AS PREDICTORS OF ADDED MORBIDITY

The effect of an anastomotic leak on additional morbidity and mortality was assessed using multivariate logistic regression. When adjusted for comorbidities, an anastomotic leak significantly increased the likelihood of mortality (odds ratio [OR], 15; 95% CI, 3-80; $P = .002$) and other complications (OR, 6; 95% CI, 3 -13; $P < .001$). Anastomotic leaks were specifically associated with an increased risk of sepsis (OR, 27; 95% CI, 2-473; $P = .02$), renal failure (OR, 16; 95% CI, 3-99; $P = .003$), small-bowel obstruction (OR, 11; 95% CI, 2-68; $P = .008$), internal hernia (OR, 10; 95% CI, 2-51; $P = .008$), venous thromboembolism (OR, 9; 95% CI, 3-27; $P < .001$), and incisional hernia (OR, 5; 95% CI, 2-13; $P = .001$) compared with patients who did not develop anastomotic leaks (**Table 3**). In this multivariate analysis, the likelihood of anastomotic stricture, gastrogastric fistula, surgical site infection, enterocutaneous fistula, gastrointestinal bleeding, anastomotic ulcer, liver failure, pneumonia, respiratory failure, and myocardial infarction was not increased in patients with an anastomotic leak compared with those without.

COMMENT

Anastomotic leaks are one of the most dreaded complications of RYGB because of the difficulty in diagnosis, the nonspecificity of clinical presentation, and body weight limitations of radiological diagnostic equipment. The etiology of anastomotic leaks is probably multifactorial. Ischemia, tension, and surgeon's experience are implicated in the pathogenesis of anastomotic leaks after RYGB.[1,7-11]

In our study, we identify a greater risk of added morbidity and mortality in patients who develop anastomotic leaks after bariatric operations. We found that patients with anastomotic leaks had significantly increased mortality, surgical site infection, incisional hernia, gastrogastric fistula, sepsis, venous thrombosis and/or pulmonary embolism, small-bowel obstruction, internal hernia, renal failure, and respiratory failure compared with patients who did not develop leaks.

We have adjusted for underlying comorbidities and potential predictors of adverse outcomes, such as age and male sex, using multivariate logistic regression analysis to determine the effect of an anastomotic leak on additional morbidity or mortality. Although our analysis can suggest a potential etiology for the added morbidity, it does not imply causality. For example, while we found that anastomotic leaks are associated with a significantly increased risk of small-bowel obstruction and internal hernia, it is possible that this association is because of anastomotic leaks that were a consequence of internal hernias and small-bowel obstruction in the immediate postoperative period. Nevertheless, these findings are similar to those of a previous study in which we found that anastomotic leaks significantly increased the likelihood of venous thromboembolism.[12]

Although a recent study identified older and heavier patients with multiple comorbid conditions to be at increased risk of developing anastomotic leaks,[2] our study did not confirm these findings. We did not find either male sex or preoperative BMI to be associated with a greater incidence of anastomotic leaks and, additionally, we did not identify any difference in the rates of anastomotic leaks between open and laparoscopic RYGB.

Increased morbidity and mortality as well as reduced survival from anastomotic leaks have been reported in other disease processes. Rizk et al[13] studied the effect of anastomotic leaks after esophagogastrectomy for cancer on mortality and medical complications. Anastomotic leaks or technical complications, such as a paralyzed vocal cord or chylothorax, reduced the 3-year survival (31% vs 48%), increased medium duration of hospital stay (23 vs 11 days), increased in-hospital mortality (12% vs 4%), and increased medical complications (78% vs 47%) compared with patients without anastomotic leaks or technical complications. Atkins et al,[14] however, reported that an anastomotic leak, though associated with increased risk of mortality after esophagectomy, was not an independent predictor of mortality by multivariate analysis.

Similar results have been reported for anastomotic leaks after colorectal surgery. Higher 30-day mortality (18% vs 4%) and local recurrence rates (19% vs 10%) were reported in patients with anastomotic leaks after a colorectal operation.[15-17] To our knowledge, our study represents the first report of an increased risk of added morbidity and mortality after anastomotic leaks in patients undergoing RYGB.

One of the limitations of this study, given the multiple hypotheses we tested, is the likelihood that we will find a statistically significant association that has modest clinical significance. Nonetheless, our study highlights the significant adverse implications of an anastomotic leak after bariatric surgery. Additionally, this study does not assess the effect of modality of treatment (operative vs nonoperative) or delay in diagnosis of anastomotic leaks on added morbidity and mortality.

Additional and long-term follow-up data may uncover long-term sequelae of anastomotic leaks, such as

additional incisional hernias and anastomotic strictures. Notwithstanding the limitations of this study, these data clearly document the increased likelihood of developing life-threatening complications after RYGB. Hence, these patients should be monitored and treated aggressively, preferably in an intensive care setting.

Specifically, we recommend prophylactic use of inferior vena cava filters in patients who develop anastomotic leaks and end organ failure, which predicts a long intensive care unit stay and immobility. Similarly, we recommend aggressive treatment and resuscitation to avoid prolonged oliguria and renal failure. Incisional hernias are a consequence of sepsis and surgical site infection. We recommend drainage of all infected sites, expeditious application of closed vacuum pumps, and early application of skin grafting to open wounds. Although this study did not find a significant association between anastomotic leaks, strictures, or ulcers, we used upper gastrointestinal contrast studies and endoscopy to investigate mild symptoms of nausea and epigastric pain and inability to tolerate liquid intake in patients who had anastomotic leaks.

CONCLUSIONS

Anastomotic leaks are an adverse complication of bariatric surgery because of their added morbidity and mortality. Anastomotic leaks increase the likelihood of life-threatening complications independent of underlying comorbidities. Aggressive and close monitoring is recommended for early detection and management of added complications should they occur.

Accepted for Publication: December 22, 2006.
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Author Contributions: *Study concept and design:* Gonzalez and Murr. *Acquisition of data:* Gonzalez, Nelson, and Haines. *Analysis and interpretation of data:* Almahmeed, Nelson, Gallagher, and Murr. *Drafting of the manuscript:* Almahmeed and Gonzalez. *Critical revision of the manuscript for important intellectual content:* Nelson, Haines, Gallagher, and Murr. *Statistical analysis:* Almahmeed. *Administrative, technical, and material support:* Murr. *Study supervision:* Gallagher and Murr.

Financial Disclosure: None reported.
Previous Presentations: This study was presented as a poster at the 22nd Annual Meeting of the American Society of Bariatric Surgery; June 26–July 1, 2005; Orlando, Florida.

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