Laparoscopic Sleeve Gastrectomy in Patients With Preexisting Gastroesophageal Reflux Disease: A National Analysis

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The incidence of morbid obesity has been steadily increasing worldwide and is now commonly referred to as an epidemic. Morbid obesity has been associated with multiple adverse health effects, including mortality and morbidity from heart disease, diabetes mellitus, sleep apnea, osteoarthritis, and hypertension.1,2 An additional common weight-related comorbidity is gastroesophageal reflux disease (GERD), with an increase in both reflux symptoms (odds ratio, 1.94) and esophageal adenocarcinoma (odds ratio, 2.78) associated with a body mass index (BMI; calculated as weight in kilograms divided by height in meters squared) above 30.3,4 Attempts at medical management of morbid obesity, including severely restrictive and supervised inpatient weight loss programs, have universally been unsuccessful in achieving significant and sustained weight loss.

Bariatric surgery has emerged in the past 10 to 20 years as the only proven and effective treatment of morbid obesity and obesity-related complications.5 Although multiple surgical options have been proposed for achieving sustained weight loss, the Roux-en-Y gastric bypass (GB) has become the most widely used and accepted bariatric operation.6,7 Gastric bypass results in mean losses of 50% to 70% of excess body weight and control of obesity-related comorbidities, including GERD, in most bariatric patients.8 Another surgical option that has gained popularity in the past decade is the laparoscopic sleeve gastrectomy (LSG). This restrictive bariatric procedure was originally performed as the initial stage in a 2-step GB operation but has established popularity as a single, definitive procedure for weight loss based on its success, relative ease of operation, and low complication profile.9,10 Prior studies5,11,12 have

OBJECTIVES To analyze the effect of laparoscopic sleeve gastrectomy (LSG) on patients with gastroesophageal reflux disease (GERD) and to compare the results of LSG vs gastric bypass (GB) among patients with known GERD.

DESIGN, SETTING, AND PATIENTS We performed a retrospective review of the Bariatric Outcomes Longitudinal Database from January 1, 2007, through December 31, 2010, including inpatient and all outpatient follow-up data. We compared patients undergoing LSG with a concurrent cohort undergoing GB.

MAIN OUTCOMES AND MEASURES Rates of improvement or worsening of GERD symptoms, development of new-onset GERD, and weight loss and complications.

RESULTS A total of 4832 patients underwent LSG and 33,867 underwent GB, with preexisting GERD present in 44.5% of the LSG cohort and 50.4% of the GB cohort. Most LSG patients (84.1%) continued to have GERD symptoms postoperatively, with only 15.9% demonstrating GERD resolution. Of LSG patients who did not demonstrate preoperative GERD, 8.6% developed GERD postoperatively. In comparison, GB resolved GERD in most patients (62.8%) within 6 months postoperatively (P < .001). Among the LSG cohort, the presence of preoperative GERD was associated with increased postoperative complications (15.1% vs 10.6%), gastrointestinal adverse events (6.9% vs 3.6%), and increased need for revisional surgery (0.6% vs 0.3%) (all P < .05). The presence of GERD had no effect on weight loss for the GB cohort but was associated with decreased weight loss in the LSG group.

CONCLUSIONS AND RELEVANCE Laparoscopic sleeve gastrectomy did not reliably relieve or improve GERD symptoms and induced GERD in some previously asymptomatic patients. Preoperative GERD was associated with worse outcomes and decreased weight loss with LSG and may represent a relative contraindication.

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demonstrated that LSG is associated with significant weight loss and improvement of most comorbidities. However, the effect of LSG on GERD is unknown, and some small studies have suggested that anatomical changes associated with LSG may exacerbate GERD symptoms or induce GERD in previously asymptomatic patients. Available knowledge of the short-and-longer-term outcomes associated with LSG is limited by the scarce published data available defining the association of GERD and LSG. Most studies that examined the association between GERD and LSG have been small, single-center series and have examined LSG as only a secondary outcome measure. However, these series have raised significant concern and debate about the effect of LSG on GERD and whether GERD may even be a contraindication to LSG.

The purpose of our study was to analyze the demographics, outcomes, and complication rates among a large nationwide database of patients who underwent LSG for morbid obesity. Specifically, we evaluated the development, resolution, and persistence of GERD in bariatric patients who underwent LSG and compared these results with a control population undergoing standard Roux-en-Y GB.

Methods

Local institutional review board review and approval were obtained for this study. Informed consent was waived because the data were deidentified and contained within a retrospective database. This study was performed using data obtained from the Bariatric Outcomes Longitudinal Database (BOLD). This is a US national bariatric database established in 2007 and maintained by the Surgical Review Corporation as part of compliance efforts for administration of a bariatric center of excellence program. As a requirement for initial and continued certification as a bariatric center of excellence, all participating institutions are required to prospectively collect and submit data to the BOLD. The BOLD represents the largest and most comprehensive clinical bariatric surgery database, with more than 400,000 patients currently enrolled. A particular strength of the BOLD design is the inclusion of data from all phases of patient care, including preoperative, operative, and long-term postoperative follow-up. Data collection and entry for the BOLD are performed by a dedicated bariatric nurse or advanced care practitioner, and the database is subjected to routine quality assessment and data validation. A fully Health Insurance Portability and Accountability Act-compliant and deidentified BOLD data set was used for this study.

All adult patients (aged >17 years) who underwent either an LSG or a Roux-en-Y GB operation for the purpose of weight loss from January 1, 2007, through December 31, 2010, were included in this study. Preoperative data, including standard demographics, anthropometric measurements, and comorbidities, were recorded. The BOLD includes fields for recording the presence and scoring the severity of 33 separate comorbid conditions, including GERD. Symptoms of GERD were graded based on medical diagnosis of GERD and need for medication and/or antireflux surgery to treat symptoms. The preoperative and postoperative grading system for the presence of GERD in the BOLD is consistent among all the surgical centers and represents the most reliable data point in the BOLD when evaluating the presence of GERD. Patients with a preoperative GERD score of 0 were defined as having no GERD. The remainder of the cohort was categorized as having GERD and allowed for estimation of baseline disease prevalence among the study cohorts. The severity of GERD was scored from 1 (intermittent symptoms that required no medication) to 5 (severe symptoms not controlled with high-dose proton pump inhibitors). Patients with preexisting GERD were additionally dichotomized according to the presence or absence of severe GERD, which was defined as a score of 3 or greater. For patients with multiple preoperative visits recorded, the comorbidity assessment performed at the most recent visit before surgery was used.

Intraoperative and perioperative data, including the type of surgery, major complications, and hospital length of stay, were recorded. The total incidence of reported complications and the incidence of complications by body system (eg, pulmonary and gastrointestinal) were recorded. Postoperative data, including changes in height, weight, and BMI from subsequent follow-up visits, were recorded. The presence or absence of GERD, as well as the severity, was recorded at the last follow-up visit and compared with the preoperative GERD status. New-onset GERD was any postoperative GERD score greater than 0 among the preoperative GERD-negative cohort. The change in GERD status among the preoperative GERD-positive cohort was assessed as no change, improved (decreased GERD score), or worsened (increased GERD score). Weight loss was characterized by calculating the percentage change in BMI from the preoperative baseline in addition to the percentage of excess body weight lost. For comparison of bariatric success rates, success was defined as losing at least 50% of excess body weight. Outcome measures were analyzed and compared only among those patients with complete postoperative data recorded at the 6-month or greater time point.

Data were collected in a computerized spreadsheet and then imported into SPSS statistical software, version 18 (SPSS Inc) for statistical analysis. Simple descriptive analysis was performed to assess preoperatively and postoperatively the incidence of GERD and severe GERD among the cohorts. Categorical variables between groups were compared with the chi-square or Fisher exact test and continuous variables with the t test or Mann-Whitney test. Within-group comparisons of preoperative and postoperative data were performed with the McNe mar test (categorical) or a paired-sample t test (continuous). Statistical significance was set at P < .05.

Results

From the BOLD, 4832 patients who underwent LSG and 33,867 who underwent GB from January 1, 2007, through December 31, 2010, were identified. Table 1 presents the demographics and key preoperative variables among the 2 study cohorts. The 2 groups were similar for most variables analyzed, including age, sex, and BMI. The overall prevalence of diagnosed GERD.
among the study population was 49.7%, with severe GERD (GERD score ≥3) identified in 25.7%.

Table 2 presents the prevalence of GERD and severe GERD among the 2 study cohorts. Although the presence of GERD was relatively common among both cohorts, it was slightly more prevalent among patients undergoing GB (50.4%) vs LSG (44.5%).

The 2 operations were found to have markedly different effects on GERD as shown in Figure 1. Most LSG patients (84.1%) continued to have GERD symptoms postoperatively, with only 15.9% demonstrating GERD resolution in addition, 9.0% of LSG patients had worsening of their GERD symptoms postoperatively. In comparison, GB was associated with complete resolution of GERD symptoms in most patients (62.8%), stabilization of symptoms in 17.6%, and worsening of symptoms in 22.2% (all P < .05 vs LSG). Comparison of the effect of surgery on GERD was also performed for the subgroup of patients who presented with severe GERD symptoms preoperatively (GERD score ≥3). With LSG, 84.1% had no improvement in GERD postoperatively and 15.9% reported some improvement of symptoms. A markedly different effect was seen in the GB cohort (Figure 2), with most patients demonstrating improvement or resolution of GERD symptoms postoperatively (all P < .05). An additional finding was that LSG was also associated with the development of GERD symptoms in 8.6% of patients who had no identified GERD preoperatively.

Analysis of postoperative complications and outcomes was performed for patients with at least 6 months of follow-up data available. Baseline demographics, comorbidities, and preoperative BMI were similar between the 2 groups. There was an increased overall complication rate noted among patients with GERD, from 10.6% in the GERD-negative patients to 15.1% in those with GERD and 16.3% in those with severe GERD (P = .007). The increased complication rates were primarily seen in the category of adverse gastrointestinal events, increasing from 3.6% in those without GERD to 6.9% and 7.5% in those with GERD and severe GERD, respectively (P = .01). There was also a small but statistically significant increase in the need for revisional surgery between LSG patients with and without preoperative GERD symptoms (0.6% vs 0.3%, P = .03). No significant difference was found in complication profiles or revisional surgery among GB patients with or without GERD.

The failure to lose at least 50% of excess body weight was then compared between cohorts. The presence of GERD preoperatively had no effect on weight loss among the GB cohort. However, the incidence of weight loss failure increased from 28.0% among LSG patients without preoperative GERD to 34.0% among those with preoperative severe GERD (P = .017). Evaluation of resolution of comorbid conditions was...
performed for the LSG cohort, comparing the preoperative GERD-negative with the preoperative GERD-positive subgroups. The percentage of patients who experienced resolution of comorbidities, including diabetes, obstructive sleep apnea, hypertension, and hyperlipidemia, was decreased in the LSG patients who had preoperative GERD compared with patients who did not report preoperative GERD (Figure 3).

Discussion

With the rapidly increasing rates of obesity and obesity-related metabolic disease, bariatric surgery has matured as a defined specialty with an increasing number of surgical procedures available. One of the most rapidly increasing procedures being performed for morbid obesity is the LSG. This procedure offers many attractive advantages to both patients and surgeons, including the relative technical simplicity and avoidance of intestinal manipulation compared with the GB. The LSG has demonstrated an overall low complication profile and short- to mid-term results with weight loss and comorbidity control that are similar to other accepted bariatric procedures. The favorable results and safety profile have resulted in a recent position statement from the American Society of Metabolic and Bariatric Surgery accepting LSG as a stand-alone bariatric procedure.

Gastroesophageal reflux disease is a common comorbid condition seen in all patient populations but appears to be increased in incidence and severity among the obese and morbidly obese. This finding has been attributed to a wide array of factors, including increased abdominal pressure, decreased lower esophageal sphincter pressures, esophageal motility disorders, and an increase in anatomical abnormalities, such as hiatal hernia. Previous studies have also defined GERD as a common comorbidity in up to 70% of bariatric surgical patients. Our study results confirm the high prevalence of GERD symptoms among morbidly obese patients undergoing bariatric surgery, with approximately half of all patients having some symptoms of GERD and one-quarter having severe GERD. This finding also highlights the importance of routine assessment for the presence and severity of GERD by the bariatric surgeon during the preoperative evaluation process and selection of the appropriate surgical procedure.

Although laparoscopic surgical antireflux procedures have been demonstrated to be highly successful in improving or relieving severe GERD, they have a significantly increased failure and complication rate among the morbidly obese population. An increasingly supported alternative is to consider a bariatric procedure that can achieve both sustained weight reduction and control or elimination of GERD symptoms. A prospective study by Braghetto et al compared 3 operations among obese patients with GERD and Barrett esophagus and found that GB
was the most effective in reducing symptoms, decreasing histologic changes, and producing significant weight loss. Multiple other series\textsuperscript{23-25} have demonstrated the efficacy of GB in relieving GERD or in continuing to control GERD among patients undergoing conversion from a fundoplication to a GB. Our study results concur with these previous series, demonstrating that most patients undergoing GB have either improvement or resolution of GERD symptoms and that de novo development of GERD after GB is extremely uncommon. However, some post–Roux-en-Y GB patients continue to have GERD after surgery. Some studies\textsuperscript{26-28} have suggested that GERD may not necessarily be adequately controlled with Roux-en-Y GB in all patients. One study\textsuperscript{29} reported that up to 22% of patients who undergo successful Roux-en-y GB continue to report symptoms of GERD postoperatively. From their experience, Chen et al\textsuperscript{30} report that despite extensive evaluations for pathologic factors to explain persistent GERD symptoms, some patients require antireflux surgery post-Roux-en-Y GB to address medically refractory GERD. In this subset of patients requiring post-Roux-en-y GB antireflux surgery, symptoms of GERD resolved, supporting the assumption that the patients actually had GERD and not another condition that caused their symptoms.

In contrast, few published data were initially available regarding the effect of LSG on reflux and GERD. With the rapid growth of LSG as a stand-alone bariatric procedure during the past decade, an increasing number of reports described the development or worsening of GERD symptoms postoperatively. In a 2006 prospective randomized trial of adjustable gastric banding vs LSG, there was a 22% incidence of de novo GERD at 1 year in the LSG cohort.\textsuperscript{31} A number of other single-center experiences reported cases of esophageal dysmotility, worsening of GERD, or de novo development of GERD after LSG.\textsuperscript{32-34} A 2011 systematic review\textsuperscript{35} of this topic identified 15 relevant series, but only 2 reported GERD as a primary outcome measure. Widely disparate results were found, with some series reporting increases in GERD and others reporting a decreased prevalence after LSG. A recent series by Tai et al\textsuperscript{36} demonstrated significant increases in GERD (47%), erosive esophagitis (67%), and hiatal hernia (27%) after LSG. One of the primary purposes of the current study was to analyze a large, multicenter, and nationally representative sample to establish baseline preoperative and postoperative prevalence estimates for GERD after LSG. We have demonstrated that the prevalence of GERD symptoms preoperatively among patients undergoing LSG is 45%, with approximately 1 in 4 patients having severe GERD. This highlights the concern that there is a large population at risk of potential adverse outcomes after LSG if the procedure is associated with anatomical or physiologic changes that increase the risk of postoperative GERD.

Multiple anatomical or physiologic factors have been proposed and identified that could contribute to the worsening of reflux or the de novo development of GERD after LSG. Several studies\textsuperscript{37-39} have suggested that the increased incidence of GERD in relation to LSG may be due to a significant decrease in lower esophageal sphincter resting tone and pressures after surgery. Klaus and Weiss\textsuperscript{40} analyzed their experience and the available literature and suggest that preoperative manometry should be routinely performed and that patients with a lower esophageal sphincter pressure should not undergo LSG. The size and configuration of the gastric sleeve may also have a significant effect on the risk for postoperative GERD. An excessively large or dilated sleeve may retain increased acid production capacity, leading to reflux, and an overly narrowed orstricted sleeve may result in reflux and decreased esophageal acid clearance.\textsuperscript{36,39-41} Disruption of the antropyloric pump mechanism or pyloric narrowing has also been implicated.\textsuperscript{39} Finally, the presence of a hiatal hernia that is not recognized or that develops over time may result in the development of significant reflux symptoms.\textsuperscript{33,42,43} The importance of these anatomical factors in determining the risk of GERD after LSG is highlighted by several series that describe technical details of the procedure that can reduce the incidence of postoperative GERD. These details include attention to the sleeve size and volume, avoidance of narrowing the gastric body or pylorus, and identification and repair of all associated hiatal hernias.\textsuperscript{36,39,40,43-46} One series demonstrated that attention to crucial repair during LSG resulted in GERD remission in 73% and a decrease in the development of de novo GERD from 23% to 0%.\textsuperscript{43} These series suggest that technical modification may have a major role in reducing the risk of postoperative GERD with LSG but require larger samples and longer follow-up periods.

Our study results concur with the results of several smaller and single-center series and raise concerns about the effect of LSG on patients with preexisting GERD.\textsuperscript{33,34,44,47} Overall, we found that in the LSG cohort, 70% of patients who had preoperative GERD had no resolution of symptoms postoperatively. Nineteen percent actually had a worsening of their symptoms postoperatively that persisted for 6 months or longer. In addition, 11% had worsening of their preexisting GERD postoperatively. In comparison, the GB cohort had resolution or stabilization of GERD in 95% of patients postoperatively, with just 5% of patients reporting worsening of symptoms. These data raise significant concerns about the effect of LSG on the obesity-related comorbidity of GERD and suggest that most patients with preexisting GERD will have either no improvement or possibly worsening of their symptoms after LSG. However, the frequency and severity of these symptoms may vary widely depending on how they are measured, the preoperative severity, the use of antiacid medications, and the resultant weight loss after surgery. Interestingly, we found that 8.6% of patients who had no symptoms of GERD preoperatively actually developed significant GERD postoperatively that was present at follow-up at 6 months or later after LSG. Similarly, Carter et al\textsuperscript{41} found that the risk of previously asymptomatic patients developing symptoms of GERD postoperatively ranged from 30% to 51%. Other series\textsuperscript{33,37,38} have also confirmed the de novo development of GERD, erosive esophagitis, and hiatal hernia after LSG. With the widespread use of proton pump inhibitors after bariatric surgery, the actual incidence of postoperative GERD may be even higher than reported in these series, and patients should be counseled regarding the potential for developing GERD after LSG.
An additional interesting finding of the current study was the possible effect of preexisting GERD on the longer-term bariatric outcomes of weight loss, comorbidity resolution, and the need for revisional surgery. Multiple series\textsuperscript{13,48,49} have confirmed that LSG results in significant weight loss and comorbidity reduction, although there is some disagreement about whether these results are equivalent to GB. However, this study demonstrates that patients who develop gastrointestinal complications, such as stricture, marginal ulcer, or significant GERD, often have suboptimal weight loss after bariatric surgery. This is likely due to alterations in dietary intake, such as substituting higher calorie and carbohydrate liquid foods for higher protein solid foods, and decreasing activity level due to pain and reflux symptoms. We hypothesized that the presence of preoperative GERD may adversely affect these outcome measures if not adequately controlled by the bariatric procedure. We found that the presence of preoperative GERD was associated with a 40% to 50% increase in complications and a significant increase in the risk of weight loss failure after LSG and that these risks were further increased among patients with severe GERD. In contrast, no such effect was found for preoperative GERD among patients undergoing GB. In addition, we found a small but statistically significant increase in the need for bariatric revisional surgery among GERD patients undergoing LSG. Although the exact indication for revisional surgery is unknown from the BOLD database, several series\textsuperscript{50-52} of revisional surgery after LSG have identified weight gain or severe GERD as the two most common reasons for the surgery. Langer and colleagues\textsuperscript{53} found that 11% of LSG in their series required revisional surgery, with all patients demonstrating weight loss and relief of GERD after conversion to GB. We hypothesize that our findings are similarly due to the increased weight loss failure rate and the prevalence of postoperative GERD symptoms among patients with preoperative GERD undergoing LSG.

This study has several significant limitations. Although the BOLD data are prospectively collected, this is a retrospective analysis and subject to the inherent limitations. A primary limitation of this study is the difficulty in accurately identifying and classifying GERD. The BOLD database uses a standardized 5-point scale based on symptoms and medication use, and no results of objective testing, such as endoscopy or pH monitoring, were used. It is likely that some patients were misdiagnosed as having GERD, which would affect the absolute rates and incidences. However, the size and nature of the data set should minimize the statistical effect of these errors, particularly because they can be reasonably assumed to be uniformly distributed among study groups. This highlights the need for better prospectively designed studies that include both subjective and objective measures to identify and characterize GERD and the response to surgery.

Conclusions

On the basis of these results and a review of the currently available literature, we believe that all patients should be evaluated for the presence and severity of GERD and counseled regarding the relative efficacy of LSG vs GB or other bariatric operations before surgery. Although there is no definitive evidence to support the listing of GERD as an absolute contraindication to LSG, the available data suggest that the presence of preexisting severe GERD or esophageal dysmotility may be considered a relative contraindication. This information should be taken into consideration during patient counseling and selection of the optimal bariatric procedure. This approach may better tailor the surgical procedure to the goals and expectations of the patient and surgeon and result in improved postoperative outcomes and satisfaction. Further study is clearly indicated to clarify the role of preoperative GERD in the selection of bariatric procedures, to evaluate the effect of LSG on reflux potential and GERD, and to identify technical factors that may minimize the risks of persistent or de novo GERD after LSG.


