Procedure-Related Morbidity in Bariatric Surgery: A Retrospective Short- and Mid-Term Follow-Up of a Single Institution of the American College of Surgeons Bariatric Surgery Centers of Excellence

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BACKGROUND: Our objective was to ascertain procedure-related morbidity among laparoscopic Roux-en-Y

gastric bypass (LRYGB), laparoscopic sleeve gastrectomy (LSG), and laparoscopic adjustable gastric banding (LAGB) patients. These are the 3 most common bariatric procedures performed worldwide. We reviewed our experience since the introduction of LSG and

compared the procedure-related morbidity among all 3 procedures.

STUDY DESIGN: We conducted a retrospective review of a prospectively collected database of all morbidly

obese patients who underwent bariatric surgery between the years 2005 and 2011. We identified and compared complications, mortality, readmissions, and reoperations in patients who

underwent LRYGB, LAGB, and LSG.

RESULTS: A total of 2,199 bariatric procedures were performed during this period of time. Of those

procedures, 1,327 were LRYGB, 619 were LSG, and 253 were LAGB. Perioperative mortality was not applicable for all 3 procedures. The leak rate was 0.5% for LRYGB and 0.3% for LSG, and was not applicable for LAGB. The average number of readmissions post-operatively was less than 2 times for all 3 procedures: LRYGB 1.96 times, LSG 1.49 times, and LAGB 1.54 times. The percentages of procedures requiring reoperations due to complications or failures were 14.6% in the LAGB group, 6.6% in the LRYGB group, and 1.8% in

the LSG group.

CONCLUSIONS: In short- and mid-term follow-up, LSG appears to have the lowest procedure-related

morbidity when compared with LRYGB and LAGB. (J Am Coll Surg 2013;217:

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Bariatric surgery has evolved dramatically from an open jejuno-ileal bypass, first described by Kremen and colleagues¹ in 1954, to several different laparoscopic procedures being performed in the modern era. The 3 most common procedures performed today are the laparoscopic Roux-en-Y gastric bypass (LRYGB), first described by Wittgrove and associates² in 1995; the

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laparoscopic adjustable gastric band (LAGB), first described by Belachew and coworkers³ in 1994; and the most recent, laparoscopic sleeve gastrectomy (LSG), first described by Hess and colleagues⁴ in 1998 as a component of biliopancreatic diversion and duodenal switch and later introduced in the laparoscopic era by Ren and coauthors⁵ initially as part of a staged procedure for super morbidly obese patients.

The LSG is rapidly gaining in popularity and consequently is also a frequent topic for discussion among experts. The LSG was initially described as the first step of a staged procedure for super morbidly obese patients followed by biliopancreatic diversion with duodenal switch or LRYGB. In a recent multi-institutional report from the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) by Hutter and associates, LSG was placed between LRYGB and the LAGB when comparing safety and effectiveness. 10,11

Abbreviations and Acronyms

BMI = body mass index

LAGB = laparoscopic adjustable gastric banding LRYGB = laparoscopic Roux-en-Y gastric bypass

LSG = laparoscopic sleeve gastrectomy

POD = postoperative day

Mortality and morbidity of bariatric surgery still draw significant attention in the current literature. Based on numerous recent sources, the mortality rate of laparoscopic bariatric procedures is extremely low. Multiple previous authors and several reports from our institution have reported the safety and efficacy of LSG, LRYGB, and LAGB. The aim of this study was to compare procedure-related morbidity of LRYGB, LSG, and LAGB following the standard technique of a single institution of the ACS Bariatric Surgery Centers of Excellence.

METHODS

After Institutional Review Board approval, we retrospectively reviewed a prospectively collected database of bariatric surgery patients entered into the ACS Bariatric Centers of Excellence (ACS BSCOE). We analyzed all the data from 2005 to 2011 collected at Cleveland Clinic Florida Bariatric and Metabolic Institute. All patients who underwent a primary bariatric procedure, including LRYGB, LSG, or LAGB, at our institution were included. All revisions and reoperations, and patients who had their operations at an outside institution were excluded. All of the operations were performed by 2 surgeons according to the National Institutes of Health (NIH) criteria for the management of morbid obesity and following a standard technique.

The main endpoints of the study were evidence of bleeding, leaks, readmissions, and reoperations. We compared these endpoints across the 3 procedures. Only procedure-related reoperations and readmissions were identified and reviewed. A 2-tailed *t*-test with a 95% confidence interval was used for statistical analysis.

Surgical technique

Laparoscopic Roux-en-Y gastric bypass

We performed this technique in an antecolic, antegastric fashion. The gastrojejunostomy was created using a linear stapler with a side-to-side anastomosis. The anterior layer was closed using 2-layer 2.0 vicryl running suture. 19

Laparoscopic sleeve gastrectomy

We began our dissection along the greater curvature approximately 5 cm proximal to the pylorus. The sleeve

was fashioned using a 38-French bougie and routine oversewing of the staple line with a running 2.0 vicryl suture.¹⁸

Laparoscopic adjustable gastric banding

We used the standard pars flaccid technique for band placement. The predominant band used in this series was the Ethicon Realize band; however, the Allergan Lap-band was used as well in isolated cases.¹⁹

Postoperative care

All of our patients were admitted to a monitored unit after the procedure. A routine gastrograffin upper gastrointestinal series was performed on postoperative day (POD) 1, as well as a lower extremity duplex to rule out clot formation. Diet was started with liquids after the upper gastrointestinal series was confirmed to be normal. Laparoscopic adjustable gastric banding patients were routinely discharged on POD 1, LSG patients on POD 2, and LRYGB patients on POD 3.

After discharge, patients were followed up at 2 weeks after surgery. Routine follow-up visits were at 2 months, 6 months, 9 months, and then yearly after the surgery. At all follow-up visits, the patients were seen by a certified bariatric nurse, a bariatric surgeon, and a bariatric nutritionist to review progress and appropriate diet.

RESULTS

A total of 2,199 bariatric procedures (excluding revisions, reversals, and conversions) were performed between the years 2005 and 2011. Of those procedures, 1,327 were RYGB (60.3%), 619 were LSG (28.1%), and 253 were LAGB (11.5%). The demographic data of the patients included in our analysis are shown in Table 1.

A mean body mass index (BMI) drop of 14.8 kg/m² (range 0 to 45.1 kg/m²) was observed in LRYGB patients, 11.2 kg/m² (range 2.5 to 39.9 kg/m²) in LSG patients, and 5.6 kg/m² (range 2.5 to 26.5 kg/m²) in LAGB patients, at a mean follow-up period of 17 months (range 1 to 79 months). The mean drop of BMI in LSG patients was significantly lower than that of LRYGB patients and significantly higher than that of LAGB patients, positioning itself in the middle in terms of weight loss (2-tailed test was used and in both comparisons p < 0.01).

The most common reasons for readmissions, in descending order of frequency, in all 3 procedures were nausea, vomiting, abdominal pain, and dysphagia. The number of readmissions was minimal in all 3 groups, RYGB being 1.96 times (range 1 to 12 times), LSG 1.49 times (range 1 to 6 times), and 1.54 times (range 1 to 3 times) for LAGB (Table 2). Readmission in our study is defined as any patient who was admitted either

Table 1. Patient Demographics

Procedure	LRYGB	LSG	LAGB
Mean age (range), y*,†	46.3 (16-75)	46.1 (12-79)	48.1 (19-76)
Sex, male ratio to 1 female [†]	0.4	0.5	0.4
Mean BMI (range), kg/m ^{2*,†}	48.1 (33-112)	44.2 (30-74)	42.2 (31-65)
Average no. of comorbidities (range)** [†]	2.3 (0-7)	1.8 (0-5)	1.9 (0-5)

^{*}At the time of operation.

as an inpatient or observed in the emergency room or on the surgical floor. Most readmissions for LAGB consisted mainly of removing fluid from the band to relieve intractable vomiting due to obstruction, and followed by a short hospital stay. However, LRYGB readmission tended to last longer, with more diagnostic interventions. Laparoscopic sleeve gastrectomy demonstrated a significantly lower average number of readmissions when compared with that of LRYGB (2-tailed t-test, p < 0.02). In addition, the number of readmissions in LRYGB demonstrated a broader range, with patients being readmitted up to 12 times after the initial procedure; LSG showed 6 readmissions at most. The average number of readmissions in LAGB was not significantly different from that of LSG.

The most common causes for reoperations were small bowel obstruction (20.5%) in LRYGB, stenosis (36.4%) in LSG, and band slippage (63.9%) in LAGB (Table 3). The most common reoperations performed were internal hernia repair (28.4%) in LRYGB patients, conversion to LRYGB (45.5%) in LSG patients, and removal of the band (52.8%) in LAGB patients (Table 4). Patients with LAGB had the highest rate of reoperations (10.9%) when compared with that of patients with LRYGB (5.9%) and LSG (1.8%). There was no perioperative mortality in this series.

Follow-up for our series was 51.3% at more than 1 postoperative year and 32% at more than 2 postoperative years; follow-up of more than 3 years was 21.6%. Perprocedure follow-up of 3 years or more was highest for LAGB at 41.3%, with 20.8% for LRYGB and 13.2% for LSG. For patients who underwent LAGB, the average time from operation to readmission was 16.4 months (median 15.5 months), for LSG patients the average

time to readmission was 5.7 months (median 26.5 days), and for LRYGB patients the average time to readmission was 4.2 months (median 5.2 months). For the time to reoperation, the average for the LAGB patients was 17.8 months (median 18.5 months), for LSG patients the average was 32.3 months (median 42 months), and for the LRYGB group the average time was 17.2 months (median 28.5 months).

DISCUSSION

Bariatric surgery has evolved into a safe and effective mode of treatment for morbid obesity.²⁰ The LSG is one of the fastest growing bariatric procedures in the world, and its short- and mid-term effectiveness and safety have been studied and reported worldwide.^{18,21} Although LSG's effectiveness has been reported in many studies, the short- and mid-term morbidity is still being under-reported compared with the other well established procedures.²²

One of the most attractive aspects of LSG is the "simplicity" of the procedure. It offers an immediate restriction without need for adjustments, there is no foreign body implanted, and there is no rerouting of the small bowel, which results in dumping syndrome, micronutrient malnutrition, internal hernias, and related complications.²³ The exact metabolic mechanism of action of LSG is still not well understood, but there is likely a physiologic or hormonal aspect in addition to the restrictive component.²³⁻²⁷

The other 2 widely performed procedures are LAGB and LRYGB.¹⁶ Both have been performed for a significantly longer period of time when compared with LSG, which was introduced as a primary bariatric

Table 2. Readmissions and Reoperations

Procedure	Rate of leaks among readmissions, n (%)	Average no. of readmissions (range)	Reoperations, %
LRYGB	7 (0.5)	1.96 (1-12)	5.9
LSG	2 (0.3)	1.49 (1-6)	1.8
LAGB	N/A	1.54 (1-3)	10.9

LAGB, laparoscopic adjustable gastric banding; LRYGB, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy.

[†]The differences in mean age, male-to-female ratio, mean BMI, and average number of comorbidities in each group were not statistically significant (p > 0.05).

BMI, body mass index; LAGB, laparoscopic adjustable gastric banding; LRYGB, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy.

Table 3. Causes of Reoperation

Table 3. Causes of Reoperation	
Operation	n
LRYGB	88
SBO	18
Lysis of adhesions due to abdominal pain	16
GJ anastomosis stricture/obstruction	13
Internal herniation	10
Marginal ulceration	10
Weight regain	6
JJ anastomotic stricture	3
Peritonitis	2
Gastrogastric fistula	2
Perforated GJ anastomosis	2 2 2
Trocar site hernia	2
Alimentary limb malrotation	1
Intussusception	1
Kinking at the JJ anastomosis	1
Hematoma	1
LSG	11
Stenosis	4
GERD/hiatal hernia	3 3
Weight regain	3
Leak	1
LAGB	36
Band slippage	23
GERD/Barrett's esophagus	4
Failure of weight loss	4
Band erosion	3 2
Dysphagia	2

EGD, esophagogastroduodenoscopy; GJ, gastrojejunal; JJ, jejuno-jejunal; LAGB, laparoscopic adjustable gastric banding; LRYGB, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy; SBO, small bowel obstruction.

procedure only in the early 2000s.^{3,28} Recently, Higa and colleagues²⁹ published their long-term follow-up for the LRYGB patients with excellent outcomes; however, the loss to follow-up at 10 years was close to 90%. Despite RYGB's efficacy, there is still great variation in how a gastric bypass can be performed, resulting in a high incidence of short-, mid-, and long-term complications. Strictures, marginal ulcerations, internal hernias or small bowel obstructions, gastrogastric fistulas, and micronutrient malabsorption are some of those complications.²⁹ The LAGB has also been in use for many years, and although one would expect excellent results in a reversible procedure, the long-term effectiveness and safety of this procedure are debatable.30 Numerous recent articles have shown poor long-term results and a high percentage of long-term complications associated with this procedure that result in reoperations, explantations, and conversions.³⁰⁻³² Very few long-term data are available,

Table 4. Reoperations per Procedure

Table 4. Reoperations per Procedure	
Procedure	n
LRYGB	88
Internal hernia repair and/or closure of	
mesenteric/JJ defect	25
Revision of GJ anastomosis	22
Lysis of adhesions	16
Revision of JJ anastomosis	7
Gastrostomy placement	4
Diagnostic laparoscopy	3
Pouch trimming	2
Trocar site hernia repair	2 2
Dilation of anastomotic stricture	2
GJ leak repair	1
Evacuation of hematoma	1
Hiatal hernia repair	1
Reversal of LRYGB	1
LSG	11
Conversion to LRYGB	5
Myotomy for stenosis	2
Diagnostic laparoscopy	2
Hiatal hernia repair	1
LAGB	36
Removal of the band	19
Conversion to LRYGB/sleeve	10
Repositioning of the band	4
Replacement/repositioning of the port	2
EGD and exploration of the port	1

EGD, esophagogastroduodenoscopy; GJ, gastrojejunal; JJ, jejuno-jejunal; LAGB, laparoscopic adjustable gastric banding; LRYGB, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy.

however, when looking at LSG, the newest bariatric procedure.

Laparoscopic sleeve gastrectomy has been reported in many studies as an excellent procedure for weight loss and resolution of comorbidities. 17,18 Some studies put its effectiveness between that of LRYGB and LAGB;9,32 other publications show it to be as effective as the LRYGB.³³ Despite LSG being a novel procedure when compared with LAGB and LRYGB, the short- and mid-term procedure-related morbidity shown in our series is striking. In previously reported long-term follow-up studies presented from our group and others, the long-term morbidity described for this procedure showed the most prevalent, severe gastroesophageal reflux disease, to be as high as 23%.²⁰ In this retrospective single institution review, LSG is placed below the LRYGB and LAGB when looking at short- and mid-term procedurerelated morbidity.

A common conclusion of most publications regarding LSG is the patient's excellent quality of life after the

procedure. D'Hondt and colleagues²³ reported LSG as a safe and effective procedure, with 92.5% of postoperative patients achieving excellent food tolerance. Kehagias and associates³⁴ showed fewer postoperative metabolic derangements than with the LRYGB, with equal safety and effectiveness. Additional evidence further supporting the safety and efficacy of this procedure is the recent endorsement by Centers for Medicare and Medicaid Services (CMS) of LSG to treat the morbidly obese in the elderly population.

In our study, the rate of reoperation was lowest for the LSG when compared with the other procedures. The most common reasons for reoperation were severe reflux, weight regain, and stenosis, which is consistent with other reports in the literature. The leak rate in our series was low for both the LRYGB and LSG; the 1 leak reported in this series occurred after LSG during our initial experience and there have been no leaks since 2005. The leak rate was also lower in our series than in some of those reported in the literature.³⁵ The readmission rate after all procedures was low; however, LSG had a statistically lower rate than LRYGB.

The average time to readmission varied with each procedure, with the LAGB patients having the longest time between procedure and readmission (16.4 months); however, the time when readmissions occurred is the same as when most reoperations took place. Average amount of time to readmission for LRYGB was about 4 months, and reoperations were closer to 2 years postoperatively. The LRYGB was the only procedure that required reoperation during the hospital stay for the initial procedure. Readmissions after LSG had a couple of outliers that increased the average time to 5.7 months. Aside from the extreme outliers, the readmissions happened within 30 days, as evidenced by the median number. The average time to reoperation was significantly longer for the LSG patients (almost 3 years); this perhaps is part of the evidence of the low mid-term morbidity of the LSG.

Unique patient populations for the LRYGB patients are those with abdominal pain and those undergoing diagnostic laparoscopy. Abdominal pain is a known symptom after LRYGB and could represent a sign of adhesive small bowel obstruction or internal herniation. We believe that observation and implementation of diagnostic laparoscopy is a common diagnostic and potentially therapeutic modality for abdominal pain in a patient with a history of gastric bypass. The main reason for operating on abdominal pain is to rule out internal hernia, which can be present despite normal radiologic findings. The need to operate on patients with abdominal pain and negative radiologic findings is necessary only in

LRYGB patients, as was seen in our study, with diagnostic laparoscopy necessary only in the LRYGB group.

The incidence of diagnostic laparoscopies in the LRYGB group of patients was high in this series as a result of the authors' choice to not close potential hernia defects and always remain suspicious of a possible internal herniation. Another factor responsible for the higher number of diagnostic laparoscopies is that 60% of the authors' patient population for bariatric surgery has a previous history of abdominal procedures, which might result in adhesive partial small bowel obstruction. The factors that might influence occurrence of an internal hernia are the route of the alimentary limb (antecolic vs retrocolic), division or not of the small bowel mesentery, and weight loss. Although our incidence of reoperation for small bowel obstruction/internal hernias after LRYGB appears to make up a large percentage of reoperations and complications, our overall rate of internal hernia that has been published in the past shows numbers comparable to those in the rest of the published literature.³⁶

To our knowledge, this study is one of the first to report long-term procedure-related morbidity comparing 3 bariatric procedures. The strengths of this study include a single institution, a standard technique, a large patient population, and a prospectively collected long-term database entered to the ACS Bariatric Centers of Excellence. Although our technique follows the recommendations of the international consensus paper recently published, there is still a lot of variation in surgical technique for LSG worldwide, which is likely why outcomes are not as good as those reported in this series.

The weaknesses of this study are that it is nonrandomized and retrospective in nature. There is obviously a patient selection bias because LRYGB is indicated for higher BMI, while LSG and LAGB are recommended for those with BMI less than 50 kg/m². That can be used to rationalize why LSG has better outcomes than LRYGB; however, it still is not acceptable that LAGB is promoted as the safest and most reversible procedure yet has worse outcomes than LSG. Some other biases were that patients with diabetes and high insulin use were more likely to seek out LRYGB over LAGB or LSG when we first started performing LSG. However, in recent years, patients have been more likely to also choose LSG over LAGB. Patients with severe gastroesophageal reflux disease or gastric/esophageal dysmotility were more likely to seek out LRYGB as well.

Another weakness of this study is that the rate of follow-up after 12 months started dropping dramatically and went as low as 21% follow-up at 3 years after surgery. There are a few potential reasons for this, one being that

Fridman et al

patients lose insurance and are unable to afford a visit, or they move out of state looking for employment. Another reason is that our institution is privileged to see a large number of international patients who can't always travel for a follow-up visit and are difficult to reach once they return home. Finally, perhaps when patients see good results, they don't think they need to follow up any longer, which is potentially illustrated by LSG having the lowest follow-up rate of all 3 procedures. However, 2 articles, by Harper and colleagues³⁷ and Shen and associates,³⁸ each reported the importance of follow-up in bariatric surgery patients.

The outcomes of the 3 procedures at our institution are comparable to the national data, as we have previously published. The immediate postoperative complications are comparable to the numbers published in the literature as well. Some of the potential reasons for our medium- and long-term outcomes can be related to the uniformity with which each procedure was performed between the 2 surgeons day in and day out. Perhaps the reason that our data are different from the ACS data is due to large heterogeneity of technique and pre- and postoperative care used by many surgeons in the country that are included in the ACS NSQIP database. If there were more consistent guidelines used by the bariatric surgeons, the outcomes could be different.

Strictures and leaks are the 2 most feared complications after LSG. Although why they occur is not yet clearly understood, we believe that they might be related, to some degree. The use of a bougie size of 38 F, oversewing the staple line, and avoiding application of the staple gun medial to the gastroesophageal junction fat pad are, in our experience, factors that might result in a significant reduction of complications in patients undergoing LSG. A potential reason for our high rate of reoperation for band patients could be the high percentage of patients we lose to follow-up (our fluoroscopic-guided band adjustments could be a potential factor) because band patients especially need very close and more frequent physician care.

CONCLUSIONS

The LSG appears to have the lowest short- and mid-term procedure-related morbidity when compared with LAGB and LRYGB at our institution. We believe it is a safe and effective procedure that has the least potential for short- and mid-term complications with appropriate follow-up and when performed in accordance with the recommendations of the international consensus statement. More prospective data with a longer follow-up are needed to further solidify our conclusion.

Author Contributions

Study conception and design: Fridman, Lo Menzo, Szomstein, Rosenthal

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