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# Objective Comparison of Complications Resulting from Laparoscopic Bariatric Procedures

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- BACKGROUND:** Several surgical treatment options for morbid obesity exist. Currently, there are no studies that objectively compare complication rates after laparoscopic bariatric operations performed at a single institution. We objectively classify and compare complications resulting from laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion (BPD) with duodenal switch (DS).
- STUDY DESIGN:** A retrospective review of a prospective database of all patients undergoing laparoscopic bariatric operation was performed. Complications were categorized according to severity score using a well-described classification system and compared between procedures.
- RESULTS:** From September 2000 to July 2003, 780 laparoscopic bariatric operations were performed: 480 LAGB, 235 RYGB, and 65 BPD±DS. There was one late death. Total complication rates were: 9% for LAGB, 23% for RYGB, and 25% for BPD±DS. Complications resulting in organ resection, irreversible deficits, and death (grades III and IV) occurred at rates of 0.2% for LAGB, 2% for RYGB, and 5% for BPD±DS. LAGB group had a statistically significant lower overall complication rate, both by incidence and severity, as compared with other groups ( $p < 0.001$ ). After controlling for differences of admission body mass index, gender, and race, the LAGB group had an almost three and a half times lower likelihood of a complication compared with the RYGB group (odds ratio, 3.4; 95% CI, 2.2–5.3,  $p < 0.001$ ) and had an over three and a half times lower likelihood of a complication compared with the BPD with DS group (odds ratio, 3.6; 95% CI, 1.8–7.1,  $p < 0.001$ ). There was no statistically significant difference between complication rates of RYGB and BPD±DS.
- CONCLUSIONS:** Bariatric operation complication rates range from 9% to 25%; very few complications are serious. Laparoscopic adjustable gastric banding is the safest operation in terms of complication rate and severity when compared with laparoscopic Roux-en-Y gastric bypass or laparoscopic malabsorptive operations. (J Am Coll Surg 2006;202:252–261. © 2006 by the American College of Surgeons)
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Bariatric operation is currently the only effective treatment for morbid obesity in terms of inducing and maintaining satisfactory weight loss and decreasing weight-related comorbidities. Laparoscopic access for bariatric operation has had a profoundly positive impact in terms of reducing recovery time and perioperative complica-

tions.<sup>1</sup> Concern remains about short- and longterm safety. In a previous study, we found that patient choice of bariatric operation was based on the safety and invasiveness of the operation.<sup>2</sup> Although laparoscopic Roux-en-Y gastric bypass (RYGB) is considered the gold standard in the United States, most European surgeons prefer a less invasive, reversible procedure, such as laparoscopic adjustable gastric band (LAGB). Malabsorptive procedures, such as laparoscopic biliopancreatic diversion with or without duodenal switch (BPD±DS), have also been offered as effective primary procedures for inducing and maintaining dramatic weight loss.

There are numerous cohort studies of the safety and efficacy of each individual type of bariatric procedure, but the bariatric surgical literature lacks a uniform study

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**Abbreviations and Acronyms**

|        |   |
|--------|---|
| BMI    | = body mass index   |
| BPD    | = biliopancreatic diversion                                 |
| BPD±DS | = biliopancreatic diversion with or without duodenal switch |
| DS     | = duodenal switch   |
| EWL    |   |
| LAGB   | = laparoscopic adjustable gastric band                      |
| RYGB   | = Roux-en-Y gastric bypass                                  |

that objectively compares the complications of various bariatric operations. To this end, we have reviewed the complications of three commonly performed laparoscopic bariatric procedures as treatment for morbid obesity, objectively classified, and then compared them. We acknowledge the lack of standardized reporting of complications and other negative outcomes in the bariatric surgical literature. This variability in reporting complications stems from disagreement about which events constitute complications and lack of a definition of “severity” of complications. We have used a classification system of complications of operations proposed by Clavien and colleagues<sup>3</sup> and applied this system to the complications of 780 bariatric procedures performed at our institution over a 35-month period.

**METHODS****Patients**

Operations were offered to patients who met the 1991 National Institutes of Health Consensus Development Conference criteria for bariatric operation.<sup>4</sup> These criteria include patients with a body mass index (BMI = weight [kilograms] / height [meters]<sup>2</sup>) > 40 kg/m<sup>2</sup> or less severely obese patients (BMI between 35 and 40 kg/m<sup>2</sup>) with high-risk obesity-related comorbid conditions. All patients had failed medical therapy for their obesity.

All patients were educated and screened with preoperative psychological, nutritional, and medical evaluations. Education included a mandatory 2-hour information session given by the surgeon, comprehensive program Web site ([www.nyuweightloss.org](http://www.nyuweightloss.org)), standardized information booklets about all types of bariatric operations, and a preoperative quiz. Patients did not undergo formal screening for eating behaviors (ie, sweet-eaters versus volume-eaters), but were assessed for motivation and commitment to longterm followup. Patient

preference played a major role in determining the type of laparoscopic bariatric procedure performed. Insurance coverage dictated a minority of the bariatric operations that a patient would undergo. No formal algorithm was used to recommend a given procedure for a given patient. There was no upper BMI limit for a particular procedure. All patients were treated within a comprehensive bariatric program at a teaching institution. A fellowship-trained laparoscopic bariatric surgeon performed all operations with the assistance of either a clinical fellow or resident.

Data were entered prospectively into a database and the following information was extracted for analysis: age, admission BMI, gender, race, procedure performed, operative time, followup dates, and postoperative complications. Informed consent was obtained from all patients. The study was conducted after Institutional Review Board approval.

**Surgical technique**

Adjustable gastric banding (LAGB) was performed laparoscopically with five ports using the pars flaccida technique, as described in a previous publication by Ren and Fielding.<sup>5</sup> The Lap-Band (Inamed Health) was placed 1 to 2 cm below the gastroesophageal junction and secured anteriorly by plication of the fundus and cardia below the band to the stomach of the upper gastric pouch, with a running 2-0 Prolene suture. In addition, after the first 143 bands were placed, the perigastric fat pads were consistently removed to avoid the complication of stomal obstruction.<sup>6</sup> No saline was injected into the band at the time of operation. Hollow tubing connected the band to an access port, which was secured to the anterior rectus sheath in a midabdominal location. The 9.75-cm Lap-Band was used in women with BMI < 50 kg/m<sup>2</sup>; heavier women and all men received the 10-cm Lap-Band device.

RYGB was performed laparoscopically with six ports. A 3.5 linear stapler transected the stomach to create a 15-mL gastric pouch. An antecolic, antegastric end-to-side gastrojejunostomy was created with a 25-mm circular end-to-end stapler (US Surgical Corporation) through a modified nasogastric tube-anvil apparatus.<sup>7</sup> The remaining enterotomy was closed with a linear stapler. Orogastic methylene blue was used to test for anastomotic leak routinely. A Roux limb of 100 to 150 cm was measured and a stapled side-to-side jejunojunction was created. The remaining enterotomy

was closed with an intracorporeal single-layer continuous 3-0 absorbable suture. A 7Fr Jackson-Pratt drain was placed at the gastrojejunostomy. All port sites > 5 mm were closed under direct vision with full-thickness 0-vicryl sutures.

BPD±DS was performed laparoscopically with six ports. A 50-cm common channel (100-cm common channel for DS) was created through a side-to-side ileoenterostomy with a 45-mm linear stapler. The remaining enterotomy was closed with an intracorporeal single-layer continuous 2-0 suture. The duodenum was divided 3 cm distal to the pylorus using a 45-mm 2.5-mm linear stapler. A sleeve gastrectomy was created with sequential firings of 3.5-mm linear staplers, creating a 100- to 150-mL gastric pouch. If DS was performed, an antecolic side-to-side duodenoenterostomy was made with a 45-mm 2.5-mm linear stapler. If DS was not performed, an antecolic side-to-side gastroenterostomy was made using a 60-mm 3.5 mm linear stapler. The remaining enterotomy was closed with a running 3-0 suture. Orogastric methylene blue was used to test for anastomotic leak routinely. A 10Fr Jackson-Pratt drain was left near the duodenal stump and another was placed at the duodenoenterostomy (or gastroenterostomy). All port sites > 5 mm were closed under direct vision with 0-vicryl sutures.

### Postoperative care

For the LAGB, contrast esophagrams were routinely obtained on the first postoperative day to evaluate for perforation or obstruction and to document band position and pouch size. Patients were then discharged on a liquid diet for 2 weeks and then advanced to puree and then solids over the next 6 weeks. Patients were seen every 1 to 2 months during the first year after operation to monitor weight loss, appetite, and food restriction. Followup was then decreased to every 3 months. Band adjustments were performed in the office, based on progression of weight loss, food restriction, and hunger. Band adjustments involved percutaneously accessing the midabdominal port with a noncoring needle and injection or removal of sterile saline. Symptoms of increased appetite, less-than-anticipated weight loss, and minimal intake restriction were cues to inflate the band. Symptoms of dysphagia or food intolerance resulted in band deflation. Radiographic and endoscopic studies were performed for symptoms of dysphagia, reflux, or suspected device failure. Postoperative annual esophagrams were

performed routinely to check for band position and subclinical esophageal dilatation.

For RYGP and the BPD±DS, routine postoperative upper gastrointestinal radiologic studies were not performed unless there was doubt about the integrity of the proximal anastomosis or there were technical problems during the procedure. An upper gastrointestinal radiologic study was ordered if the patient was febrile or experienced tachycardia (> 120 beats per minute) postoperatively. Otherwise, the patient was given clears on the first operative day and then advanced to a pureed diet on the second postoperative day. Patients were seen postoperatively at 2 weeks and then every 3 months for the first year and annually thereafter.

### Classification/calculations of complications

All surgical complications were included in the analysis. For the purposes of this article, we defined *complication* as “a documented deviation from the ideal postoperative course”—ranging from fever and atelectasis to mesenteric infarction and death. We defined the median length of stay to be 1 day for LAGB, 3 days for RYGB, and 4 days for BPD±DS, as supported by our results after data evaluation. We categorized the complications of the three procedures into grades based on the 1992 classification system proposed by Clavien and colleagues;<sup>3</sup> we also subdivided the complications into early (within the first 30 postoperative days) and late (after 30 postoperative days; see Table 1).

Because one patient could have multiple unrelated complications, the complication with the highest grade was used to calculate the percentage of patients who had incurred a complication. Unrelated complications were included in the total number of complications. A complication that required repeated interventions for the same complication (eg, stomal stenosis requiring repeated endoscopic dilation) was counted as a single complication. If a complication of a lower grade evolved into a higher-grade complication, only the highest grade was used for analysis.

Complications were distinguished from sequelae. Diarrhea, bloating, and gallstone formation were considered sequelae of the primary operations. Postsurgical biliary colic requiring cholecystectomy was not considered a complication. Nutritional complications were not included.

**Table 1.** Classification of Complications from Bariatric Operations

| Grade | Definition  | Examples   |   |  |
|-------|---|--|---|--|
|       |   | LAGB   | RYGB  | BPD±DS   |
| I     | Events carrying "minor risks"<br>1. Not life-threatening<br>2. Not requiring use of drugs other than analgesics, antireflux agents, antipyretics, antiemetics, antidiarrheals, or drugs required for urinary retention or low urinary tract infections<br>3. Requiring only interventions that can be performed at the bedside<br>4. Never associated with hospital stay greater than twice the median stay for the procedure | 1. Hospital admissions for intravenous hydration<br>2. Prolonged postoperative stay (< 2 d) secondary to ileus or nausea/vomiting  | 1. Hospital admissions for intravenous hydration<br>2. Prolonged postoperative stay (< 6 d) secondary to ileus or nausea/vomiting   | 1. Hospital admissions for intravenous hydration<br>2. Prolonged postoperative stay (< 8 d) secondary to ileus or nausea/vomiting  |
| IIa   | Events requiring use of drug therapy, TPN or blood transfusions, or events requiring hospital stay greater than twice the median stay   | 1. Prolonged postoperative stay (> 2 d) secondary to ileus or nausea/vomiting<br>2. Wound infection requiring IV Abx<br>3. Prolonged LOS for postoperative edema at band site<br>4. Postoperative bleeding requiring blood transfusion | 1. Prolonged postoperative stay (> 6 d) secondary to ileus or nausea/vomiting<br>2. Wound infection requiring IV Abx<br>3. Rhabdomyolysis requiring IV fluids, no operation<br>4. Leak managed with TPN only<br>5. Pulmonary embolism<br>6. Bleeding requiring blood transfusions | 1. Prolonged postoperative stay (> 8 d) secondary to ileus or nausea/vomiting<br>2. Wound infection requiring IV Abx<br>3. Pancreatitis<br>4. Delayed gastric emptying requiring TPN               |
| IIb   | Events requiring therapeutic imaging procedures, therapeutic endoscopy, or reoperation (not requiring organ resection or anastomotic revision)  | 1. Reoperation for bleeding<br>2. Exploratory laparoscopy<br>3. Band revision/removal<br>4. Port revision  | 1. Reoperation for bleeding<br>2. Repair of internal hernia without SB resection<br>3. Endoscopic dilation for stomal stenosis<br>4. Exploratory laparoscopy<br>5. Repair of leak without revision  | 1. Reoperation for bleeding<br>2. Repair of internal hernia without SB resection<br>3. Endoscopic dilation for stomal stenosis<br>4. Exploratory laparoscopy<br>5. Repair of leak without revision |
| III   | Events with residual and lasting disability and/or requiring organ resection  | 1. Rhabdomyolysis requiring debridement<br>2. Sigmoid esophagus  | 1. Revision of anastomosis<br>2. Resection of bowel   | 1. Revision of anastomosis<br>2. Resection of bowel  |
| IV    | Death as a result of any complication   | 1. Death   | 1. Death  | 1. Death   |

Abx, antibiotics; BPD±DS, biliopancreatic diversion with or without duodenal switch; IV, intravenous; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass; SB, small bowel; TPN, total parenteral nutrition.

**Table 2.** Preoperative Characteristics

| Characteristic   | Group          |                |                 | p Value |
|------------------|----------------|----------------|-----------------|---------|
|                  | LAGB (n = 480) | RYGB (n = 235) | BPD±DS (n = 65) |         |
| Age (y)          |                |                |                 |         |
| Mean ± SD        | 41.79 ± 10.90  | 41.22 ± 9.86   | 41.08 ± 8.11    |         |
| Median           | 42             | 41             | 42              |         |
| Range            | 17–70          | 19–66          | 23–60           | 0.73    |
| Admission BMI    |                |                |                 |         |
| Mean ± SD        | 46.13 ± 7.06   | 47.45 ± 6.99   | 52.56 ± 8.74    |         |
| Median           | 44.6           | 46.5           | 51.6            |         |
| Range            | 35.0–78.8      | 35.0–69.7      | 37.7–75.3       | < 0.001 |
| Gender, n (%)    |                |                |                 |         |
| Male             | 144 (30)       | 41 (17.5)      | 9 (13.9)        |         |
| Female           | 336 (70)       | 194 (82.6)     | 56 (86.2)       | < 0.001 |
| Race, n (%)      |                |                |                 |         |
| Caucasian        | 405 (84.4)     | 180 (76.6)     | 59 (90.8)       |         |
| African American | 37 (7.7)       | 30 (12.8)      | 4 (6.2)         |         |
| Hispanic         | 34 (7.1)       | 21 (8.9)       | 1 (1.5)         |         |
| Other            | 3 (0.6)        | 4 (1.7)        | 1 (1.5)         |         |
| Unknown          | 1 (0.2)        | 0              | 0               | 0.04    |

BPD±DS group had a higher BMI versus LAGB and RYGB groups (ANOVA). LAGB group had fewer women than the RYGB and BPD±DS groups (chi-square). RYGB group had more African Americans than LAGB and BPD±DS groups (chi-square). BMI, body mass index; BPD, biliopancreatic diversion; BPD±DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.

### Data analysis

Preoperative data and perioperative complications were compared using ANOVA for age and BMI and chi-square tests for gender and race. BPD groups with and without DS were pooled together. Complications were compared using Fisher's exact test or chi-square test, as appropriate. For purposes of statistical analysis, the patient was used as the unit of observation (as opposed to the complication) to maintain the assumption of independent observations for standard statistical hypothesis testing methods. Because group comparisons of patient characteristics revealed significant differences between the groups in terms of admission BMI, gender, and race, these factors were incorporated into a logistic regression model for analysis and then a chi-square test was used to compare the groups. Differences observed were considered statistically significant at  $p < 0.05$ .

### RESULTS

A total of 480 LAGB, 235 RYGB, and 65 BPD±DS were performed over the 35-month period. Preoperative characteristics are shown in Table 2. Mean ages were comparable (41 to 42 years). BPD±DS group had a significantly higher admission BMI than the other groups ( $p < 0.001$ ). The difference between LAGB and

RYGB admission BMI was not significant. LAGB group had significantly fewer women and the RYGB group had significantly more African Americans. All operations were primary except for one, which was a revision of an LAGB to biliopancreatic diversion. Mean operative times in minutes were  $61 \pm 24$ ,  $138 \pm 41$ , and  $270 \pm 93$  for LAGB, RYGB, and BPD ± DS, respectively. There were no conversions to open in the LAGB group, 2 (0.9%) conversions in the RYGB group, and 3 (4.6%) conversions in the BPD ± DS group. Median length of stay was 1 day for LAGB, 3 days for RYGB, and 4 days for BPD ± DS. Mean followup in months was 12.5 (range 1 to 31 months), 12.4 (range 0.5 to 39 months), and 14.5 (range 0.1 to 31 months) for LAGB, RYGB, and BPD±DS, respectively.

Of the total 780 patients, 112 experienced 140 complications (Tables 3 and 4), for a total complication rate of 14.4%. Ninety-one patients had a single complication, 14 had 2 complications, and 7 had 3 complications. Total complication rates for LAGB, RYGB, and BPD±DS were 9%, 23%, and 25%, respectively. LAGB had a significantly lower complication rate compared with other groups (RYGB and BPD±DS,  $p < 0.001$ ).

Complications for each operation were graded by se-

**Table 3.** Distribution of 112 Patients Who Experienced a Complication

| Complication | LAGB |      | RYGB |    | BPD±DS |      | Total |      | p Value |
|--------------|------|------|------|----|--------|------|-------|------|---------|
|              | n    | %    | n    | %  | n      | %    | n     | %    |         |
| No           | 438  | 91.3 | 181  | 77 | 49     | 75.4 | 668   | 85.6 | —       |
| Yes          | 42   | 8.8  | 54   | 23 | 16     | 24.6 | 112   | 14.4 | <0.001  |
| Total        | 480  |      | 235  |    | 65     |      | 780   |      |         |

LAGB group had a lower complication rate versus RYGB and BPD±DS (Fisher's exact).

BPD, biliopancreatic diversion; BPD±DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.

verity and compared (Table 5). Complications that resulted in organ resection or death (grades III, IV) were separated from the lower-grade complications (grades I, IIa, IIb). There was one grade III/IV complication in the LAGB group, five in the RYGB group, and three in the BPD±DS group. There was one grade IV complication: a death in the RYGB group 6 months after operation, directly related to postoperative mesenteric venous thrombosis, for an overall mortality rate of 0.1%. The LAGB group had a significantly lower incidence of organ resection/longterm disability and death (grades III/IV) as compared with the other groups (0.2%, 2.1%, and 4.6%, respectively, for the LAGB, RYGB, and BPD±DS groups;  $p < 0.001$ ). This was true as well for the lower-grade complications (grades I/II). When divided into early and late complications (Table 5), the LAGB group continued to have statistically significantly lower early (3.3%, 9.4%, and 12.3% for LAGB, RYGB, and BPD±DS, respectively;  $p < 0.001$ ) and late (5.4%, 13.6%, and 12.3% for LAGB, RYGB, and BPD±DS, respectively;  $p < 0.001$ ) complication rates compared with the other groups. Details of grades III/IV complications are provided in Table 6.

After adjusting for the significant differences between the groups preoperatively (ie, gender, race, and admission BMI), an odds ratio was calculated to predict the likelihood of complications (Table 7) based on procedure alone. After controlling for gender, race, and ad-

mission BMI, patients undergoing an LAGB had an almost three and a half times lower likelihood of developing a complication as compared with patients undergoing RYGB (odds ratio, 3.4; 95% CI, 2.2–5.3;  $p < 0.001$ ) and an over three and a half times lower likelihood of a complication compared with patients undergoing BPD±DS (odds ratio, 3.6; 95% CI, 1.8–7.1;  $p < 0.001$ ). There was no significant difference between the RYGB and BPD±DS groups. None of the preoperative characteristics (age, BMI, gender, race) predicted risk for developing a complication.

## DISCUSSION

Patient concern over bariatric operations has been based primarily on safety. In a questionnaire distributed to 470 consecutive patients undergoing bariatric operation in 2 major centers in 2 different countries, 85% chose LAGB, with 49% claiming “safety” as the reason over RYGB and BPD with DS.<sup>2</sup> With these findings, we compared outcomes of three different laparoscopic bariatric operations in terms of surgical morbidity categorized by severity.

Our results show that all three types of laparoscopic bariatric operations are safe. Published mortality rates for LAGB, RYGB, and BPD±DS range from 0% to 2%.<sup>8–11</sup> There were no 30-day mortalities in our series. Our early (0%) and late (0.1%) mortality rates are extremely low, particularly when compared with the fact

**Table 4.** Distribution of 140 Complications among Each Bariatric Group

| Grade | LAGB (n = 480) |     | RYGB (n = 235) |      | BPD ± DS (n = 65) |       | Total (n = 780) |
|-------|----------------|-----|----------------|------|-------------------|-------|-----------------|
|       | n              | %   | n              | %    | n                 | %     |                 |
| I     | 7              | 1.5 | 12             | 5.1  | 4                 | 6.2   | 23              |
| IIa   | 4              | 0.8 | 19             | 8.1  |                   | 710.8 | 30              |
| IIb   | 37             | 7.7 | 34             | 14.5 |                   | 710.8 | 78              |
| III   | 1              | 0.2 | 4              | 1.7  | 3                 | 4.6   | 8               |
| IV    | 0              |     | 1              | 0.4  | 0                 |       | 1               |
| Total | 49             |     | 70             |      | 21                |       | 140             |

Majority of complications (94%) were grades I to II.

BPD, biliopancreatic diversion; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.

**Table 5.** Distribution of Complications by Grade and Time (Early Versus Late)

|           | LAGB (n = 480) |     | RYGB (n = 235) |      | BPD±DS (n = 65) |      | Total (n = 780) |     | p Value |
|-----------|----------------|-----|----------------|------|-----------------|------|-----------------|-----|---------|
|           | n              | %   | n              | %    | n               | %    | n               | %   |         |
| Grade*    |                |     |                |      |                 |      |                 |     |         |
| I/IIa/IIb | 41             | 8.5 | 49             | 20.9 | 13              | 20   | 103             | 13  | < 0.001 |
| III/IV    | 1              | 0.2 | 5              | 2.1  | 3               | 4.6  | 9               | 1.1 | 0.001†  |
| Total     | 42             |     | 54             |      | 16              |      | 112             |     | —       |
| Time‡     |                |     |                |      |                 |      |                 |     |         |
| Early     | 16             | 3.3 | 22             | 9.4  | 22              | 9.4  | 46              |     | < 0.001 |
| Late      | 26             | 5.4 | 32             | 13.6 | 32              | 13.6 | 66              |     | < 0.001 |
| Total     | 42             |     | 54             |      | 54              |      | 112             |     | —       |

\*LAGB had a lower grade III/IV complication rate versus RYGB and BPD±DS (chi-square).

†Fisher's exact test used.

‡LAGB had lower early and late complication rates versus RYGB and BPD±DS (chi-square).

BPD, biliopancreatic diversion; BPD±DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.

that partial gastrectomies and colectomies can have mortality rates of up to 7.6% and 5.4%, respectively.<sup>12,13</sup> The majority (94%) of our complications were grades I and II. Our total complication rate for all laparoscopic operations is comparable with, if not better than, the 24% complication rate of major foregut operations for non-malignant disease.<sup>14,15</sup> This is of particular importance, given the higher surgical risk of morbidly obese patients. This supports the fact that laparoscopic bariatric operations can be performed safely, and can be influenced by skill level of the surgeon, the facility, and program. This study can objectively compare all three of these laparoscopic operations quite accurately because the surgeon, the program, and the bariatric team were standard. Each patient underwent the same nutritional and psychological evaluation, with the same philosophy of care post-operatively by the same bariatric team.

Published complication rates of LAGB, RYGB, and BPD±DS vary depending on the institution and how the surgeon diagnoses and defines a particular complication.<sup>16-19</sup> An objective classification system focuses

on the diagnostic tests and therapeutic procedures required to treat a complication rather than the complication itself; such an approach tends to eliminate subjective interpretation of severity (eg, "minor versus major") and surgeons' natural tendency to down-rate complications. For example, the published leak rate after RYGB ranges from 0.9% to 5.5%. Presumably, this variability is related to routine use of early postoperative radiographic evaluation; ie, detection of "subclinical" leaks. In an objective complication system, a leak would be classified based on its therapeutic procedure: a subclinical leak requiring prolonged hospitalization would be graded IIa; a leak requiring stitches at the anastomosis would be graded IIb; and a leak requiring complete revision of the anastomosis would be graded III. Use of such a classification system is also advantageous in retrospective reviews, where details of complications might not be available but documentation of tests and treatments are usually adequate. Perhaps the biggest advantage of a standardized complication system that uses uniform reporting and grading of surgical complications is

**Table 6.** Grades III/IV Complications and Treatment by Procedure

| Procedure | n | Complication                           | Timing | Treatment   |
|-----------|---|--|--------|---|
| LAGB      | 1 | Malignant hyperthermia/ rhabdomyolysis | Early  | ICU/mechanical ventilation/gluteal rhabdomyolysis/debridement     |
| RYGB      | 1 | Obstruction of jejunojejunostomy       | Early  | Surgical revision of anastomosis                                  |
|           | 1 | Afferent limb obstruction              | Early  | Surgical revision of anastomosis                                  |
|           | 2 | Incarcerated internal hernia           | Late   | Resection of small bowel  |
|           | 1 | Mesenteric venous thrombosis           | Late   | Multiple bowel resections/ sepsis/multisystem organ failure/death |
| BPD±DS    | 1 | Duodenal stump leak                    | Early  | Staple line repair/duodenostomy tube                              |
|           | 1 | Incarcerated internal hernia           | Late   | Resection of small bowel  |
|           | 1 | Perforation after anastomotic dilation | Late   | Surgical revision of anastomosis                                  |

BPD±DS, biliopancreatic diversion with or without duodenal switch; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.

**Table 7.** Logistic Regression Model (Correcting for Preoperative Differences)

| Parameter        | Estimate | Standard error | Wald chi-square | p Value  | Odds ratio | 95% CI      |
|------------------|----------|----------------|-----------------|----------|------------|-------------|
| RYGB versus LAGB | 0.6085   | 0.1153         | 27.8539         | < 0.0001 | 3.377      | 2.149–5.307 |
| BPD versus LAGB  | 0.6392   | 0.1743         | 13.4447         | 0.0002   | 3.591      | 1.813–7.111 |
| BPD versus RYGB  | 0.0306   | 0.1691         | 0.0328          | 0.8564   | —          | —           |

Controlling for preoperative differences in terms of admission body mass index, gender, and race, patients undergoing an LAGB have 3.4× lower likelihood of developing a complication versus RYGB and 3.6× lower likelihood of having a complication versus BPD with or without duodenal switch. BPD, biliopancreatic diversion; LAGB, laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass.

the ability to make more meaningful comparisons among different bariatric centers and bariatric surgical techniques. This would be most applicable to the bariatric centers of excellence that are currently being organized by academic societies and insurance carriers.

Patient referral patterns accounted for the disparity between the numbers of patients in each surgical group. Specifically, because of the reputation of New York University as an experienced center for LAGB operations, many patients came to our program seeking this operation. There is no one treatment algorithm that has been scientifically proved to be the most optimal, only anecdotal opinion. This classification system might possibly be the model used to substantiate the optimal treatment algorithm in the future. For this reason, we did not distinguish between sweet-eaters and volume-eaters, and we did not have an upper BMI limit for a particular procedure. There was no randomization for this study, but purely a prospective observation of outcomes where patients selected a certain operation. A selection bias is inevitable: in our patient population, patients with lower BMI opted for LAGB and higher-BMI patients preferred BPD ± DS. Even after statistically controlling for these fundamental differences in admission BMI, the difference in complication rates between the LAGB and BPD ± DS group persisted.

In our series, LAGB is the safest of all three bariatric operations, even after statistically correcting for preoperative demographic disparities. Clearly, LAGB is the least invasive of the three procedures, with no stapling or dividing of native tissue required. This is reflected in the data not only in terms of total complication rate but, more importantly, in severity of the complications. There have been technical improvements in the procedure, such as use of pars flaccida approach, delayed initiation of adjustments, and smaller volume or greater frequency of adjustments, which have led to marked improvements in reoperation.<sup>20</sup> In our series, LAGB had a 0.2% grades III/IV complication rate as compared with 2% after RYGB and 5% after BPD ± DS. These are

the complications that not only lead to death, but to reoperation for organ resection, significantly prolonged hospitalization, or residual disability. Patients undergoing LAGB had an approximately 3.5 times lower likelihood of experiencing a postoperative complication as compared with patients undergoing RYGB or BPD ± DS, which had no significant difference in complication rate between them. The majority of LAGB reoperations can be performed laparoscopically and require only brief hospitalization. In contrast, many RYGB reoperations need a laparotomy. Jan and colleagues<sup>21</sup> recently described an experience comparing LAGB and RYGB with 3-year followup. Reoperation occurred in 21 patients (10%) after laparoscopic RYGB and 31 (20%) patients after LAGB ( $p < 0.01$ ). Of the patients undergoing reoperation, 8 (38%) laparoscopic RYGB patients and 1 (3%) LAGB patient required open laparotomy.<sup>21</sup> These are also the complications that lead to increased health-care costs and likelihood of liability. We similarly found a markedly lower rate of grade IIb complications in the LAGB group (7.7%) as compared with RYGB (14.5%) and BPD ± DS (10.8%) groups. These are complications that require therapeutic imaging procedures, therapeutic endoscopy, or reoperation not requiring organ resection or anastomotic revision. Surgical revision for gastric prolapse (band slip) and port/tubing problems would be included in this category, and endoscopic dilation for stomal stricture or reexploration/drainage for anastomotic leak.

One could also argue that because we did not start offering LAGB until July 2001 (ie, until it was FDA approved), we had a learning curve with RYGB and BPD ± DS before beginning LAGB. We compared the complication rates of LAGB, RYGB, and BPD ± DS after removing the first 100 operations for each procedure offered. The significant difference in complications remained: 8.1%, 17.8%, and 18.4% for LAGB, RYGB, and BPD ± DS, respectively ( $p < 0.001$ ).

For the purposes of statistical analysis, multiple, clinically distinct complications from the same patient were

not considered independent, ie, the patient was used as the unit of observation rather than the complication. We calculated patient complication rates rather than total complication rates. Also, if a patient had a complication that required multiple interventions (eg, repeated endoscopic dilations for stomal stenosis), this patient was counted only once and the true morbidity was underestimated. This might have led to underreporting of complications if they were unrelated and multiple. This applied equally to all surgical groups.

In addition, mean followup of 12.4 to 14 months after operation might not have captured all the delayed complications that can arise after bariatric operations. Examples might include gastric prolapse/band slip, internal hernias, and nutritional deficiencies. Despite routine annual esophagrams, we have not yet encountered irreversible esophageal dilation, one of the reported potential longterm complications of LAGB.<sup>22</sup> Continued data collection will provide additional insight into delayed complication rates for LAGB, RYGB, and malabsorptive operations.

What is one to do with this information? That depends on how the surgeon and the patient view the comparative outcomes after the operations and the risks and complications we have described. Recent data would suggest that at least at 3 years, outcomes are very similar for LAGB and the RYGB. Vertruyen<sup>23</sup> has described a 52% EWL at nearly 7 years after LAGB;<sup>23</sup> likewise, Fielding and Duncombe<sup>24</sup> reported 51% EWL at 6 years after LAGB. The recent series from Jan and colleagues<sup>21</sup> compared 154 LAGB and 219 RYGB adult patients from 1 institution in Portland, Oregon. At 3 years followup, weight loss was almost identical: 57% after LAGB and 60% after RYGB ( $p = \text{NS}$ ). Parikh and colleagues<sup>25</sup> recently reviewed the New York University experience with 331 superobese (mean BMI of 55.3 kg/m<sup>2</sup>) patients. Mean %EWL ( $\pm$  SD) for LAGB was 35.3  $\pm$  12.6, 45.8  $\pm$  19.4, and 49.5  $\pm$  18.6 with followup of 87%, 76%, and 72% at 1, 2, and 3 years, respectively. Mean %EWL for RYGB was 57.7  $\pm$  15.4, 54.7  $\pm$  21.2, and 56.8  $\pm$  21.1 with followup of 76%, 33%, and 54% at 1, 2, and 3 years, respectively. There was no significant difference in %EWL between LAGB and RYGB at 2 and 3 years. Given that weight loss is very similar between LAGB and RYGB, and that there is a significant difference in complication rates, patient preference for the safest operation seems reasonable.

In conclusion, laparoscopic bariatric surgery is safe.

Using minimally invasive techniques to perform adjustable gastric banding, RYGB, and malabsorptive procedures is safe in the morbidly obese population. LAGB is the safest bariatric operation in terms of both complication rate and severity and might well be the preferred bariatric procedure for the great majority of our patients, given recent data suggesting equitable outcomes.

#### Author contributions

Study conception and design: Ren

Acquisition of data: Parikh, Laker, Weiner

Analysis and interpretation of data: Parikh

Drafting of manuscript: Parikh, Laker

Critical revision: Ren

Statistical expertise: Hajiseyedjavadi

Obtaining funding: Ren

Supervision: Ren

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