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Laparoscopic Sleeve Gastrectomy with Roux en-Y Bypass (A Novel Modification) for Morbid Obesity: A Prospective Observational Study

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Abstract

Background: Recently, obesity witnessed a dramatic increase and its related comorbidities have grown. Bariatric surgeries were developed to reduce weight. However, all techniques had their advantages and shortages. In this work, we aimed to assess our new modification of combining sleeve gastrectomy with Roux en-y bypass for the management of obesity, hoping to gain benefits from both techniques to increase the excess bodyweight loss (EBW%).

Methods: The study was a prospective observational study on 23 Morbidly obese patients. The study was held from January 2020 to April 2022. The recruited patients were submitted to detailed clinical assessment and investigations to check fitness for surgery. Besides operative data, any intra- or post-operative complications were recorded. Each patient was followed up for at least one year. The follow-up visits were scheduled at regular intervals (one week, one month, six months, and twelve months).

Results: The mean operative time was 113.91 minutes (65-150). No intraoperative complications or conversion. There was intraluminal bleeding in one patient within 48 hours postoperatively with successful conservative management. There was a complete cure of diabetes mellitus (DM) for 5, 2, and 3 patients and antidiabetic drugs were reduced for 64.3%, 21.43%, and 7.14% at 1, 6, and 12 months follow up respectively. Hypertension was cured in 1,1,2 patients, and antihypertensives were reduced for 2,1,1 patient, at 1, 6, and 12 months follow up respectively. EWL% was 14.4%, 40.78%, and 73.74% at 1,6,12 months follow up respectively. Hemoglobin concentration and ionized calcium improved over time. Finally, serum albumin at 1, 6, and 12 months follow-up was 3.64, 3.58, 3.78 g/dL respectively.

Conclusion: New modifications of combining LSG and LRYGB have shown to be safe and effective procedures. In addition, it is associated with minimal postoperative nutritional complications and permits complete visualization of the biliary system using endoscopy.

Keywords: Laparoscopy, Bariatric Surgery, Roux en-Y, Obesity, Estimated weight loss

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Introduction

Obesity is a problem for the obese and all physicians, regardless of their field of medical practice, as it has a significant negative effect on each organ. It is used as a modern

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indicator of Westernization and challenge of developing countries. However, national health systems are not yet ready to deal with this challenge (1). Bariatric surgeries

↑What is "already known" in this topic:

Obesity has become an international epidemic. Many treatment options are available, from dietetic systems to surgical interventions. In addition, different surgeries are present with wide variations of direct and long-term results.

→What this article adds:

The current work introduces our initial experience with a modified surgery (combining sleeve gastrectomy with Roux en-y bypass) to gain the benefits of both approaches for obesity. This modification permits complete (better) visualization of the biliary system. The results indicated that the intervention is safe and effective and associated with minimal postoperative nutritional complications. However, the results need further validation in future studies.

provide a valuable treatment option and are associated with a significant reduction of obesity-associated morbidity and mortality when compared with conservative treatment (2, 3).

In sleeve gastrectomy (SG), the stomach is divided and stapled in a vertical manner, with removal of more than 85%. This changed the stomach to a tube or banana-shaped pouch, with significant limitation of consumed food amount. However, it had its own hazards (e.g., gastritis, heartburn, gastric ulcers, other organ injury during surgery, leak from the stapler line, poor nutrition, and stenosis that could lead to obstruction or vomiting (4).

Roux-en-Y gastric bypass (RYGB) become popular among bariatric procedures. The old supporters of RYGB, banding, and biliopancreatic diversion are losing the support in time, due to less efficacy or high surgery-related morbidities, primarily nutritional imbalances, and significant micronutrient deficiency (e.g., iron, vitamin B12, thiamine and folate) (5, 6).

In this study, we aimed to assess our new modification (combining SG and Roux en-Y gastric bypass for the management of obesity, hoping to gain the benefits of both techniques to increase EBW% loss and improve comorbidities of obesity.

Methods Study Design

This is an observational, prospective study with inclusion of 23 morbidly obese subjects from January 2020 to April 2022. They were selected from New Damietta University Hospital (Al-Azhar University), after permission consent from all patients and the institutional review and ethical approval.

The subject was included if they were aged 18-50 years, with body mass index (BMI) > 30 kg/m² with comorbidities or BMI > 35kg/m² without comorbidities. Both men and women were included provided that they were fit for surgery. However, subjects with uncompensated cardiovascular disease, hepato-renal insufficiency, pulmonary dysfunction, or uncontrolled endocrinal disease were excluded from the study.

The recruited subjects were submitted to detailed clinical assessment and different investigations. Laboratory tests included complete blood count (CBC), coagulation profile, hepatic and renal function tests, thyroid profile, diurnal cortisol level, fasting and postprandial blood glucose, calcium, albumin, and folate), electrocardiogram, abdominopelvic ultrasonography, X-ray chest, respiratory functions tests, and upper gastrointestinal (GIT) endoscope.

Operative details

The night before the operation, patients received low molecular weight heparin, and one dose of third-generation cephalosporin were administered on the operative table. Then the patient was intubated in the supine position. The pneumoperitoneum was established through a 10-mm supraumbilical visual port. Under the xiphoid process, a 5-mm trocar was placed for the insertion of the liver retractor. 12- and 15-mm trocars were positioned on the right and

left-middle clavicular lines, respectively, for surgeon instruments. Another 5-mm trocar was placed on the left anterior axillary line for the assistant. The stomach deflation was achieved by the insertion of an oral Ryle's tube.

Dissection with a vessel sealing device started on the middle part of greater curvature and directed upwards to the cardio-esophageal junction until total gastric fundus mobilization and delineation of left crus (Figure 1), then downwards to 5 cm from the pylorus. After devascularization of greater curvature, a 38-French bougie tube was inserted into the stomach. The stomach resection was completed by linear staplers that were applied parallel to the lesser curve starting 5 cm from the pylorus up to the angle of Hiss (Figure 2).

The transverse mesocolon was retracted toward the patient's head and divided from its middle with a vessel-sealing device to facilitate the elevation of the jejunum (Figure 3). The gastric sleeve was anastomosed side-to-side antecolic to the jejunum after it had been divided with a linear stapler 50–75 cm distal to the ligament of Treitz (Figure 4). The gastro-entrotomy was closed with polyglactin 2/0 continuous stitches (Figure 5). This distal part was brought up as a 'Roux-limb'. The excluded biliary limb was connected to the jejunum 150 cm distal to gastrojejunostomy with a linear stapler (Figure 6). Then, the enterotomy was closed

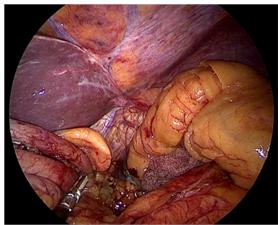


Figure 1. Delineation of left crus

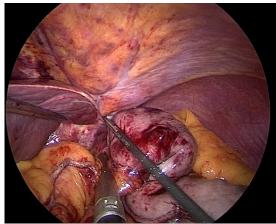


Figure 2. The stomach was resected using linear staplers up to the angle of Hiss



Figure 3. The transverse mesocolon was retracted upwards and divided from its middle with vessel sealing device

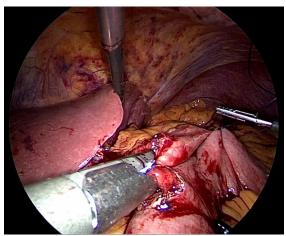


Figure 4. The gastric sleeve is anastomosed side to side antecolic to the jejunum

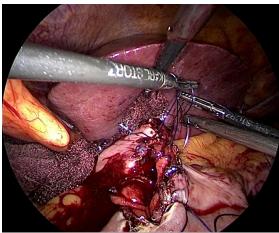


Figure 5. Gastroentrotomy was closed with polyglactin 2/0 continuous stitches

with polyglactin 2/0 continuous stitches (Figure 7). A leak test was performed with methylene blue, and the resected stomach was then removed through the left mid-clavicular port. Closure of the mesenteric defect was a routine and drains were left in the operative bed for 24 to 72 hr.

Any intra- or post-operative complications were documented besides operative data.

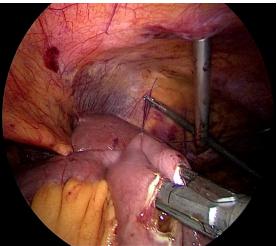


Figure 6. Side to side jejunojejunostomy about 150cm from gastrojejunostomy

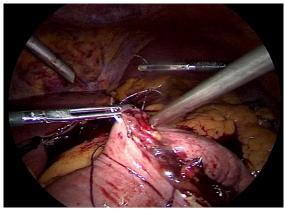


Figure 7. Enterotomy was closed with polyglactin 2/0 continuous stitches.

The total duration of follow-up period was set for one year, at least for all patients. The visits were scheduled at regular intervals: one week, one month, six months, and twelve months.

Statistical analysis

Collected data were compiled and analyzed using SPSS version 23 (SPSS Inc., Chicago, IL) with statistical significance established at $P \le 0.05$. Continuous variables are presented as means (\pm standard deviation (SD)), and categorical variables were presented using relative frequency distributions and percentages. Continuous variables were compared using an independent samples t-test. Categorical data were analyzed using the chi-square test or Fisher's exact test. Statistical significance was established at $P \le 0.05$.

Results

There were 16 women (69.56%) and 7 men (30.43%). Their age ranged from 18 to 50 years, with a mean age of 33.87 years. BMI ranged 30 kg\m² to 57 kg\m², with a mean BMI of 46.43 kg\m². Considering the comorbidities, there were 14 diabetic patients (60.87%), 8 hypertensive patients (34.78%), 2 patients with sleep apnea syndrome (8.69%), 4 patients complaining of arthritis (17.39%), 6 patients with Hill-II hiatus hernia (26.1%) (Table 1). Laboratory values

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Table 1. Demographic characteristics

| Variable Number of patients | | % | | |
|-----------------------------|-------------------------|-------|--|--|
| Age | 18-50 y (mean 33.87y) | | | |
| Sex | 16 Females | 69.56 | | |
| | 7 males | 30.43 | | |
| BMI | 30-57 kg\m² (mean 46.43 | | | |
| | kg\m²) | | | |
| DM | 14 patients | 60.87 | | |
| Hypertension | 8 patients 34.7 | | | |
| SAS | 2 patients | 8.69 | | |
| Arthritis | 4 patients | 17.39 | | |
| Hiatus hernia | 6 patients 26.1 | | | |

of hemoglobin, ionized calcium, serum albumin, and Folic acid were normal.

Operative time ranged 65-150 minutes, with a mean time of 113.91 minutes. No intraoperative complications had occurred or conversion. There was intraluminal bleeding in one patient (4.35%) within 48 hours postoperatively and managed successfully with conservative measures (Ryle tube, blood transfusion, intravenous fluids, antihemorrhagic drugs and good monitoring). No leakage was observed. ICU admission for 24 hours was indicated for one patient (4.35%), who developed postoperative dyspnea and then discharged without complications. Two patients developed postoperative paralytic ileus for 5 days due to electrolyte disturbances and passed smoothly with conservative treatment. No mortality could be documented in the follow-up period.

There was a complete cure of DM for 5,2,3 patients, 35.7%, 14.28%, and 21.43% at 1, 6, and 12 months follow-up respectively. Also antidiabetic drugs were decreased for 9,3,1 patients, 64.3%, 21.43%, 7.14%, at 1, 6, 12 months follow up respectively. Regarding hypertension, there was a cure of 1,1,2 patients, 12.5%, 12.5%, and 25%, at 1, 6, and 12 months followup, respectively. Antihypertensives were decreased for 2,1,1 patient, 25%, 12.5%, 12.5%, at 1, 6, 12 months follow up respectively.

SAS improved completely for one patient after one month and the other after 6 months. Arthritis symptoms were improved after 6 months for 4 patients. As regards improvement of hiatus hernia symptoms, it occurred for 2 patients after one month 4 patients after 6 months.

EWL% was 14.4%, 40.78%, and 73.74% at 1,6,12

months follow-up, respectively. Female hemoglobin was 10.6, 10.51, 12.13 g\dL at 1,6,12 months follow up respectively, Considering male hemoglobin, it was 10.68, 11.2, 13,23 g\dL at 1,6,12 months follow up respectively. Ionized calcium was 3.67, 4.26, and 4.43 mg/dL at 1,6,12 months follow up respectively. As regards serum albumin at 1,6,12 months follow-up, it revealed 3.64, 3.58, and 3.78 g/dL respectively. Postoperative follow-up data were presented in Table 2.

Discussion

In recent years, with the increasing prevalence of obesity among the world population, the incidence of comorbidities has grown (7, 8). Current guidelines based on published results recommend bariatric surgery as the only treatment that can offer sustainable weight loss over a long time (9, 10). Bariatric surgery has undergone many revolutions in recent decades, from open surgery to well-defined laparoscopic techniques (11).

Laparoscopic sleeve gastrectomy (LSG) was initially developed by Gagner et al. and constituted the first stage of bariatric surgery for superobese or high-risk patients (12). LSG is a relatively simple surgical procedure with lower drawback rates and without major influence on the normal path of digestion and absorption (13).

Initially, the efficiency of the procedure was credited exclusively to gastric volume reduction through longitudinal gastric resection, the surgical intervention being classified as only a restrictive technique. Subsequent studies have shown the more composite mechanisms of action of LSG (14, 15).

Compared to LRYGB, LSG has several advantages. LSG is relatively easier to accomplish, conserves pylorus and antrum, resulting in less Dumping syndrome, avoids the risk of internal hernia and complications due to gastro-jejunostomy or jejuno-jejunostomy, decreases the risk of nutritional deficiencies and provides accessibility of the residue stomach via endoscopy, which is important (16).

In our study, operative time ranged 65-150 minutes with a mean of 113.91 minutes. The longer operative time was due to gastrojejunostomy and jejuno-jejunal anastomosis and closure of the mesenteric defect between the small bowel mesentery and the transverse mesocolon. Ibrahim et

Table 2. Postoperative follow-up data

| Variab | le | One month | 6 months | 12 months |
|------------------------------|-----------------------------|----------------|-----------------|-----------------|
| DM | | | | |
| 1) | Cured | 5 (35.7%) | 2 (14.28%) | 3 (21.43%) |
| 2) | Decrease antidiabetic drugs | 2 (14.28%) | 2 (14.28%) | |
| Hyper | tension | | | |
| 1. Cured | | 1 (12.5%) | 1 (12.5%) | 2 (25%) |
| 2. Decrease antihypertensive | | 2 (25%) | 1 (12.5%) | 1 (12.5%) |
| SAS improved completely | | 1 (50%) | 1 (50%) | |
| Hiatus hernia | | 2 (33.33%) | 4 (66.6%) | |
| EWL% | | 5-30% (14.47%) | 17-65% (40.78%) | 42-98% (73.74%) |
| Hemo | globin (g\dL) | | | |
| > | Male (Normal=13.2-16.6) | 9-13 (10.68) | 9.2-13.2(11.2) | 11.5-15 (13.23) |
| \triangleright | Male (Normal=13.2-16.6) | 9-13 (10.68) | 9.2-13.2(11.2) | 11.5-15 (13.23) |
| Calcium (ionized) | | 2.7-4.8 (3.67) | 2.9-5.2 (4.26) | 3.8-5.2 (4.43) |
| N=4.4 | -5.2 mg/dL | | | |
| Albumin | | 2.8-4.9 (3.64) | 2.7-4.8(3.58) | 2.9-5.1(3.78) |
| N=3.5 | -5.5 g/dL | | | |

al. documented that the mean operative time was 140 ± 56 minutes for the LRYGB group, significantly (P = 0.046) longer than the LSG group (98 ± 50) and this correlates with all other studies comparing these two operations (17).

Our study showed that there was a cure of DM for 71.42% and 14.28% decreased antidiabetic drugs, 50% of patients cured from hypertension and 50% decreased antihypertensive doses, and 100% of SAS and Hiatus hernia had improved within 6 months. Zhigang et al. revealed complete remission of T2DM for 28.2% of the BMI < 30 kg/m² group and 57.9% of the BMI > 30 kg/m² group (P = 0.029) (18). Boza et al. concluded that, twelve months after surgery, remission was observed in 25 of 30 patients (83.3%). After 2 years, remission was achieved in 13 of 20 patients (65%), and hemoglobin A1c decreased from $8.1 \pm 1.8\%$ to $5.9 \pm 1.1\%$ (19).

The mechanism of diabetes improvement after RYGB is complex. In addition to the amount of weight lost, endocrine factors are also accompanying, such as impaired ghrelin secretion, more stimulation of incretin secretion, enhanced hepatic sensitivity to insulin, and a subsequent improved peripheral resistance to insulin (20). The rapid remission of DM occurring shortly after the surgery, i.e., before the significant weight loss, proposes that the surgery alone has effects on glucose regulation regardless of weight loss, demonstrating that changes in dietary patterns and in nutrient absorption after RYGB also play a vital role in the control of the disease (21).

One of the largest studies comparing the evolution of GERD symptoms after LSG and laparoscopic Roux-en-Y gastric bypass (LRYGBP), showed that after LSG, 84.1 % of patients continued to have GERD symptoms postoperatively, and only 15.9 % demonstrated GERD resolution. Of LSG patients who did not present preoperative GERD, 8.6 % developed de novo GERD postoperatively. On the other hand, the LRYGBP was associated with complete resolution of GERD symptoms in 62.8 % of cases while symptoms continued unchanged in 17.6 % and get worse in 2.2 % (22).

The gold standard for all symptomatic reflux patients with morbid obesity is yet to be recognized. Therefore, it makes sense to combine hiatus hernia repair with bariatric surgery, preferably LRYGB, since this is considered the gold standard for bariatric surgery and has proven to be effective in controlling GERD in obese patients (23).

In our study, EWL% was 14.47%, 40.78%, and 73.74% at one, 6, and 12 months respectively. Hemoglobin and calcium levels had decreased at one and 6 months but returned to normal at 12 months. Albumin level was at lower normal at one and 6 months but started to increase at 12 months.

Regarding long-term outcomes, Rondelli et al. revealed that mean EWL at 1 year was higher in patients receiving LRYGB (62%) compared to those receiving LSG (49%) (P = 0.001). No differences in mean EWL were observed between LRYGB and LSG groups at 2 years (61% vs 61%; P = 0.84) and at 3 years (62% vs 61%; P = 0.79), respectively (24).

A study conducted by Moon et al. reported that the percentage of excess weight loss was 38.5 and 62.4% after 6 and 12 months after bypass respectively (25).

Jammu and Sharma (26) found that in all cases of MGB where the length of the bypass was 200 cm, no hypoalbuminemia resulted except in one case with diabetic nephropathy. Severe hypoalbuminemia was maximum in the MGB group, seen in longer bypasses, i.e., >250 cm, which caused increased protein malabsorption. With RYGB, DeFilipp et al. (27) found that longer bypasses led to more macronutrient deficiency.

We documented in our study that there was intraluminal bleeding in one patient (4.35%) within 48 hours postoperatively and managed successfully with conservative measures. No conversion, leakage, or mortality was documented in our study. The main early perioperative morbidities for Bypass were bleeding leakage, and wound infection. Carbajo et al. recorded 2 bleeding events within 24 hours after surgery and mini-laparotomy was used for hemostasis (28). Wang et al. noted 7 anastomosis bleeding cases, of which 5 were treated with proton pump inhibitors (PPIs) and transfusion while 2 needed reoperation (29). Noun et al. reported 15 bleeding cases, of which 12 might be staple-line-related bleeding (30). Musella et al. reported 25 (2.5%) abdominal bleeding cases (31).

The EWL% at 12 months after a Single Anastomosis Sleeve Ileal bypass was approximately 64%. This was higher than the average EWL% after sleeve gastrectomy (56%) but less than the average EWL% after RYGB (68%) in the study conducted by Fischer et al. (32).

A combination of both LSG and LRYGB has been shown to be a safe and effective bariatric procedure resulting in significant weight loss and favorable reduction of obesity comorbidities. Also they have the advantages of being associated with minimal postoperative complications and allow complete visualization of the biliary system using endoscopy.

The gastrojejunostomy anastomosis was made in a dependent part of the gastric antrum which imparts greater safety due to its minimal tension and minimal incidence of leakage or serious morbidity. Roux en-y gastrojejunostomy anastomosis is better than a simple loop in SASI to prevent biliary reflux to the stomach. Also, nutritional impairment is less than SASI, as it bypasses 150cm only from the jejunum

Obese patients who are complaining of hiatus hernia can benefit from our modification, as it decreases tension inside the gastric sleeve. If serious morbidity occurs, reversibility is feasible and safe. This could be attributed primarily to gastric sleeve, as reported by Kandel et al. (6) ISG is a more effective procedure than greater curvature plication. However, the rate of vomiting is higher after the procedure, that was reduced by the combination of LRYGB in the current work.

Conclusion

New modification of a combination of both LSG and LRYGB has shown to be a safe and effective bariatric procedure. It also has the advantage of being associated with minimal postoperative nutritional complications and allows complete visualization of the biliary system using endoscopy. Obese patients with hiatus hernia can benefit from our modification, as it decreases tension inside the gastric

sleeve. If serious morbidity occurs, reversibility is feasible and safe. However, the small number of included cases and short duration of follow-up are the main two limiting steps of the current work and must be considered when considering globalization of results.

Acknowledgments

None.

Authors Contribution

All authors conceived and designed the study, collected and analyzed the data, and wrote, read, refined and approved the final version of the manuscript.

Ethical Approvals

The article protocol was reviewed and approved by the institutional review board of Damietta Faculty of Medicine, Al-Azhar University, Damietta, Egypt (Registration number: DFM-IRB 0001267-20-01-020).

Conflict of Interests

The authors declare that they have no competing interests.

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