Impact of Roux-en-Y gastric bypass and sleeve gastrectomy on three common co-morbidities in morbidly obese Egyptian patients: A randomized comparative study

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ABSTRACT

Objectives: *Several co-morbidities may be associated with obesity. The aim of this prospective, randomized, uncontrolled study is to compare between laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG) in terms of their impact on 3 common obesity-related co-morbidities: hypertension, diabetes mellitus (DM) and gastroesophageal reflux disease (GERD).* ***Methods:*** *Over a 20-month period, 50 morbidly obese patients were randomly allocated into one of two groups (A & B). Group A patients (n=25) underwent LRYGB, whereas group B patients (n=25) underwent LSG. Patients were followed up for 6 months. Primary endpoints included percentage of excess weight loss (%EWL) and impact on 3 obesity-related co-morbidities: hypertension, DM and GERD.* ***Results:*** *The %EWL was significantly higher in group A at 6 months postoperatively (61.1 ± 11.95 kg/m^2) compared to group B (57.17 ± 8.36 kg/m^2); P=0.007. The rates of remission of hypertension were higher in group A (60%) compared to group B (25%). Complete resolution or improvement of type 2 DM was achieved in both groups. Four / 5 patients with preoperative GERD symptoms in group A (80%) had complete relief of their symptoms at 6 months, compared to 3 / 6 patients in group B (50%).* ***Conclusion:*** *Both LRYGB and LSG are effective in terms of short-term weight loss. However, LRYGB provides better weight loss at 6 months after surgery. Both LRYGB and LSG are associated with excellent and comparable rates of type 2 DM resolution / improvement, but the rates of remission of hypertension and relief of GERD symptoms appear to be higher after LRYGB.*

Keywords: *Obesity; Roux-en-Y gastric bypass; sleeve gastrectomy; co-morbidities.*

INTRODUCTION

With the increasing prevalence of obesity worldwide, bariatric surgery has gained popularity as the treatment of choice for morbid obesity [1,2]. Although diet control, physical exercise, and medication can induce some weight loss, studies from Western countries have shown that bariatric surgery is the only treatment capable of providing substantial and sustainable weight loss in morbidly obese patients [2]. A wide range of procedures are now available in the ever-growing field of bariatric surgery, yet, there are still no clearly established criteria to aid patient selection for a specific procedure [3].

Laparoscopic Roux-en-Y gastric bypass (LRYGB) was first described several decades ago, and is currently viewed as the gold standard surgical treatment for morbid obesity, as it provides excellent long-term weight loss and high rates of remission of obesity related co-morbidities [4]. However, LRYGB is a technically challenging procedure, requiring great skills, especially in cases of super obesity (body mass index [BMI] > 50 kg/m²) and super-super obesity (BMI > 60 kg/m²). In such cases, the risk of major post-operative adverse events is higher than in patients with BMI < 50 kg/m2 [5]. On the other hand, sleeve gastrectomy (LSG), first performed laparoscopically by Ren and colleagues in 1999, was initially utilized as a first-stage operation of a 2-stage biliopancreatic diversion or RYGB in high-risk patients [6-8]. Later, LSG has been increasingly used as a stand-alone procedure because of its relative technical ease compared to other bariatric procedures, acceptable operative time, low complication rates, and substantial long-term weight loss with improvement of co-

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morbidities [9-11]. It has been reported that LSG has climbed from 0% to 37% of the total bariatric procedures performed between 2003 and 2013. Nowadays, in some regions of the world, LSG has become the most frequently performed bariatric procedure [12,13].

Several co-morbidities may be associated with obesity. These include diabetes mellitus (DM), hypertension, dyslipidemia, obstructive sleep apnea, asthma, gastroesophageal reflux disease (GERD), osteoarthritis, back pain, and depression [14]. The beneficial effect of weight loss surgery on glucose homeostasis in Type 2 diabetes mellitus (T2DM) deserves special mention. Pories et. al. were among the first to draw attention to the almost "magical" diabetes remission following bariatric surgery [15]. Interestingly, some studies have shown that the improvement in glucose homeostasis after bariatric procedures often occurs before significant weight loss [16]. Most studies have shown resolution or improvement of T2DM, hypertension and dyslipidemia in more than 60 % of patients undergoing LSG at 3–5-years follow up [17,18]. Meanwhile, Peluso and Vanek have demonstrated complete resolution or improvement of hypertension, DM and GERD in 80%-100% of patients who underwent gastric bypass surgery [14]. Data on whether LSG improves or worsens GERD, a common problem in morbidly obese patients, are still inconclusive. Following LSG, the prevalence of GERD symptoms have ranged from a relative decrease of 97% to an increase of 300% [19].

Researchers comparing LRYGB and LSG have reported conflicting results, and there are few studies from the middle east **[20-26]**. Which procedure is more suitable for Egyptian patients is still under investigation. Here, we report the early outcomes of both procedures in our institute.

The aim of this prospective, randomized, uncontrolled study was to compare between LRYGB and LSG in terms of their efficacy and safety in treatment of morbidly obese Egyptian patients, as well as their impact on 3 common obesity-related co-morbidities: hypertension, DM and GERD.

PATIENTS AND METHODS

Fifty morbidly obese patients underwent either LRYGB or LSG between February 2015 and September 2016 at Kasr Al-Ainy Hospital, Faculty of Medicine, Cairo University. Before surgery, informed consent was obtained from all patients after explaining the proposed operative procedure, its benefits, possible risks/ complications *(including the risk of conversion to open surgery)*, as well as alternative treatment options. The study protocol was approved by the institutional Ethical Committee and conformed to the ethical guidelines of the Helsinki Declaration *(as revised in Seoul, Korea, October 2008)*.

Patients were selected on the basis of strict inclusion and exclusion criteria **(Table 1)**. Preoperative evaluation and preparation followed the local standard protocol. All patients were subjected to full history taking, clinical examination and psychological assessment. A liver shrinkage diet *(i.e. low calorie / low carbohydrate diet)* was commenced 2–4 weeks prior to surgery. Routine laboratory investigations, glycated hemoglobin (HbA1c), lipid profile and thyroid function tests were performed. Abdominal ultrasonography, chest X-ray and pulmonary function tests were routinely carried out in all patients. As regards co-morbidities, hypertension was defined as a blood pressure > 140 mmHg (systolic) and / or 90 mmHg (diastolic) or the use of antihypertensive medication(s), whereas DM was defined as a fasting plasma glucose level > 126 mg/dl on at least 2 different occasions and / or a HbA1C > 6.5 or the use of anti-diabetic medication(s). Upper GI endoscopy was performed only in patients with symptoms suggestive of GERD or peptic ulcer disease. All co-morbidities that increase peri-operative risk were controlled preoperatively as much as possible. Thromboembolic prophylaxis with subcutaneous low molecular weight heparin was initiated on the evening prior to surgery and continued daily postoperatively until proper ambulation (for a maximum of 14 days). A prophylactic intravenous antibiotic (3 gm of ampicillin-sulbactam) was given to all patients with induction of general anesthesia (GA).

Table 1: Inclusion and exclusion criteria used for patient selection in our study group

Inclusion criteria	Exclusion criteria
• BMI ≥ 40 or BMI ≥ 35 with a significant obesity-related co-morbidity. • Age between 14 and 60 years. • No endocrinal causes for obesity. • Failure of all appropriate non-surgical measures (diet, exercise and/or medication) to achieve or maintain adequate, clinically beneficial weight loss for at least six months. • Psychological stability. • Motivation & acceptance of surgical risks. • Fitness for surgery and anesthesia. • Compliance to treatment and long-term follow up.	• Patients with large ventral hernias. • Active alcohol or substance abuse. • Active gastric ulcer disease. • GERD with a large hiatal hernia. • Pregnancy or lactation. • Previous upper abdominal / bariatric surgery or other contraindication for laparoscopic surgery. • Mental illness, dementia, or other significant psychiatric disorder. • Any condition that would preclude compliance with the study e.g.: a) Inflammatory bowel disease within the previous 10 years. b) Congenital or acquired anomalies of the gastrointestinal tract (e.g., atresia, stenosis). c) Significant longstanding heart/lung disease or other severe systemic disease.

BMI = Body Mass Index; GERD = Gastro-esophageal Reflux Disease

The study patients were randomly allocated into one of two groups (A & B), each including 25 patients. Randomization was carried out using 50 sequentially-numbered, sealed, opaque envelopes that were randomly distributed inside a box and were disclosed to the patients on the night before surgery. Group A patients underwent LRYGB, whereas group B patients underwent LSG. In all patients, age, gender, height, body weight, BMI, as well as details regarding hypertension, DM and / or GERD -if present- were recorded before surgery.

All procedures were performed under GA with the patient in supine position and the surgeon standing between the patient's legs. The patient was firmly secured to the operating table to allow for placement in the anti-Trendelenburg position when required, while appling compression stockings to the patient's legs. In all cases, carbon dioxide insufflation was used to create pneumoperitoneum, using a Veress needle in the left hypochondrium, maintaining a 15 mmHg intra-abdominal pressure, and a flow rate of 2-2.5 L/min, to be increased up to 10 L/min after ports insertion. After creation of pneumoperitoneum, five ports were placed in a "diamond-shaped" pattern in the upper abdomen as follows: *"A 12-mm camera port just to the left of the midline approximately two handbreadths below the xiphisternum / a 12-mm port at or slightly lateral to the right midclavicular line (MCL), 2–3 fingerbreadths below the right costal margin "CM" (the surgeon's left hand working port) / a 12-mm midline port 2–3 fingerbreadths below the xiphisternum (for the liver retractor) / a 12-mm port at the left MCL, 2-3 fingerbreadths below the left CM (the surgeon's right hand working port) / a 5-mm assistant port at the left anterior axillary line, 2–3 fingerbreadths below the left CM"*.

In patients who underwent LRYGB (Group A patients), the lesser curvature of the stomach was exposed at the junction of the body and antrum. The stomach was initially stapler-divided at a right-angle to the lesser curvature, proximal to the incisura angularis *"i.e. proximal to the crow's foot"*. A 36-Fr bougie was then advanced orally by the anesthetist, and the stomach was again stapler-divided, but in an upward direction, parallel to the lesser curvature and lateral to the angle of His, thus creating a 30-50 cc vertical gastric pouch. The omentum was then retracted upwards to identify the duodeno-jejunal (DJ) flexure at the ligament of Treitz. In all cases, the biliopancreatic (BP) limb was divided at a point 50 cm distal to the DJ flexure using a linear stapler, and the mesentery was divided using a Harmonic Scalpel™ or a Ligasure™ device. A side-to-side jejunojejunostomy was then

performed using a linear stapler 150 cm distal to the distal stapled end, thus creating a 150-cm long alimentary (Roux) limb. The gastrojejunostomy was then created using a linear stapler with blue loads. The mesenteric and Peterson`s defects were closed. At the end of the procedure, methylene blue and air leak tests were performed to check for anastomotic leak. A 20-Fr silicone drain was placed and trocar sites were closed.

In patients who underwent LSG (Group B patients), the gastrosplenic ligament was divided from the greater curvature of the stomach close to the gastric wall, using a Harmonic Scalpel™ or a Ligasure™ device. The left crus was dissected and the angle of His delineated. Posterior adhesions to the pancreas were lysed. Posterior fundal vessels were clipped, if present. A 36-Fr bougie was advanced orally by the anesthetist and positioned in the first part of the duodenum. Gastric transection was started 3-4 cm proximal to the pylorus using an Endo-GIA linear stapler, in order to create the gastric sleeve. The stapler was first placed across the antrum and fired. Sequential stapler firings, in the direction of the gastro-esophageal junction (GEJ), were used to transect the stomach, 1-2 cm from its lesser curvature, up to the angle of His. The first one or two firings of the linear stapler were carried out using green or gold loads (depending on the gastric wall thickness), while blue loads were used for subsequent firings. A methylene blue test was performed to check for staple-line leak. The stomach specimen was removed , a 20-Fr silicone drain was placed, and trocar sites were closed.

In all patients, early mobilization was encouraged upon return to the surgical ward. On postoperative day (POD)1, after performing an upper gastrointestinal gastrografin study in selective cases to look for any leak or stenosis **(Fig. 1)**, clear oral fluids were allowed. Patients were discharged home once the following criteria were met: *"hemodynamically stable, afebrile patient / audible bowel sounds / well tolerated liquid diet / good pain control with the use of oral analgesia / no complications".* Patients were placed on a liquid-only diet for 1 month, then a semi-solid diet for 2 weeks, followed by mashed food for another 2 weeks. A regular healthy diet was then started. Twice daily multivitamin supplements, calcium, vitamin D, and monthly intramuscular vitamin B12 injections (1000 IU) were prescribed for all patients. Patients were instructed to come for follow up at 1 week, 1 month, 3 months and 6 months after surgery. Patients who did not regularly attend for follow up were excluded from the study.

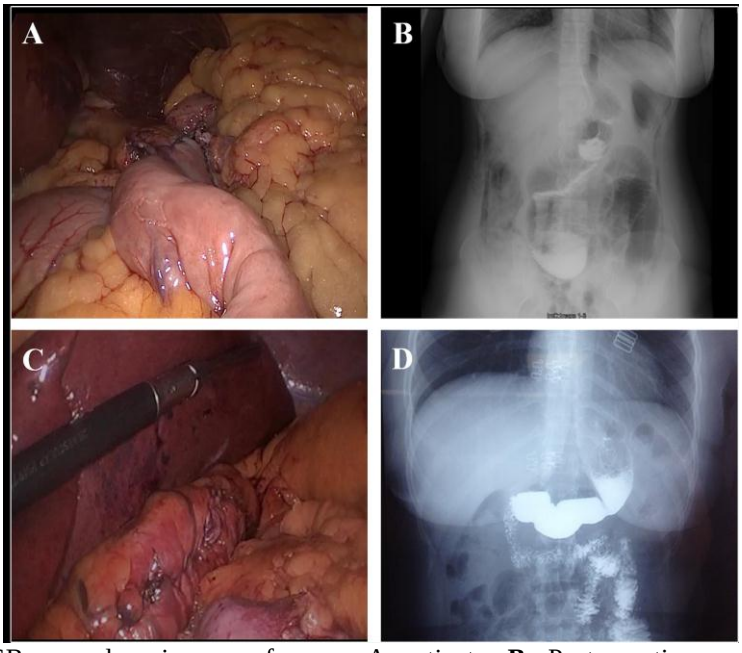

Fig. 1: A. LRYGB procedure in one of group A patients. **B.** Postoperative upper gastrointestinal gastrografin study after LRYGB. **C.** LSG procedure in one of group B patients. **D.** Postoperative upper gastrointestinal gastrografin study after LSG.

The main primary endpoint of our study was the percentage of excess weight loss (%EWL). This was assessed in all patients *(at the initial screening visit, then at 1 month, 3 months, and 6 months after surgery)* as *100 x [weight loss / baseline excess weight]*. Weight loss (in kg) was defined as *[weight at baseline – weight at follow-up]*. Baseline excess weight (kg) was calculated, according to the theoretical weight *(based on 1983 Metropolitan Life Insurance tables)* [26], as *[weight at baseline – theoretical weight]*. Successful weight loss in our study was defined as a %EWL > 50% at 6 months postoperatively, based on Reinhold criteria [27]. Other primary endpoints included the impact on 3 obesity-related co-morbidities: hypertension and DM *(at 1, 3 and 6 months after surgery)* as well as GERD *(at 6 months after surgery)*. Remission of hypertension was defined as *"normalization of the baseline characteristics with discontinuation of anti-hypertensive medication(s)"*. Remission of DM was defined as *"a fasting plasma glucose level ≤ 125 mg/dl (6.9 mmol/l) and a HbA1c < 6.5% with discontinuation of anti-diabetic medication(s)"*. Improvements in hypertension and / or DM were defined as *"improvement of the corresponding baseline characteristics, while continuing to use the same or lower doses of anti-diabetic and / or anti-hypertensive medication(s), respectively"*. The *GERD- Health-Related Quality of Life (GERD-HRQL) Questionnaire*, which was developed and validated to measure the changes of typical GERD symptoms in response to treatment [28], was conducted in all patients at 6 months postoperatively. The *GERD-HRQL* comprised 15 questions, for each of which a score of 0-5 was given according to symptom severity. The total score was calculated by summing the individual scores, with a lowest possible score (no symptoms) of 0, and a highest possible score (worst symptoms) of 75. Secondary study endpoints included operative time; length of hospital stay; intra-operative and postoperative complications (excluding nutritional deficiencies).

Values in our study were expressed as means and standard deviations (mean ± SD) or as numbers (%). Continuous variables were compared using the Student *t* test, whereas categorical variables were compared using the Chi-square test. Groups were compared using one-way analysis of variance (ANOVA) and Chi-square test, or Fisher's exact test where appropriate. For all statistical tests, a P value < 0.05 was considered statistically significant. Data were analyzed using the Statistical Package of Social Science for Windows version 21.0 *(SPSS Inc. IBM, U.S.A.)*.

RESULTS

Patients ranged in age from 18 to 58 years (mean, 36.06 years) with a male to female ratio of 7 : 43 (14% : 86%). The mean age was 35.5 ± 9.7 years in LRYGB patients (Group A) and 36.6 ± 10.7 years in LSG patients (Group B), whereas the mean BMI was 47.0 ± 6.2 kg/m2 in group A and 50.0 ± 6.5 kg/m2 in group B **(Table 2, Fig. 2).** In the LRYGB group, 4 patients (16%) had Type 2 diabetes mellitus (T2DM), 5 (20%) had hypertension, and 5 (20%) had preoperative GERD symptoms. In the LSG group, 3 patients (12%) had T2DM, 4 (16%) had hypertension, 6 (24%) had preoperative GERD symptoms **(Table 3)**. All 50 patients managed to complete a 6-months follow up and none was excluded from our study.

Table 2: Age, body weight and body mass index (BMI) in the study groups.

	LRYGB Group				LSG Group				P value
	Mean	**SD**	**Mini.**	**Maxi.**	**Mean**	**SD**	**Mini.**	**Maxi.**	
Age	35.52	9.713	18.00	56.00	36.60	10.75	18.00	58.00	0.09
Weight	132.7	25.6	110.00	204.00	136.7	22.54	101.00	185.00	0.061
BMI	47.04	6.24	38	60	50.00	6.58	40	69	0.08

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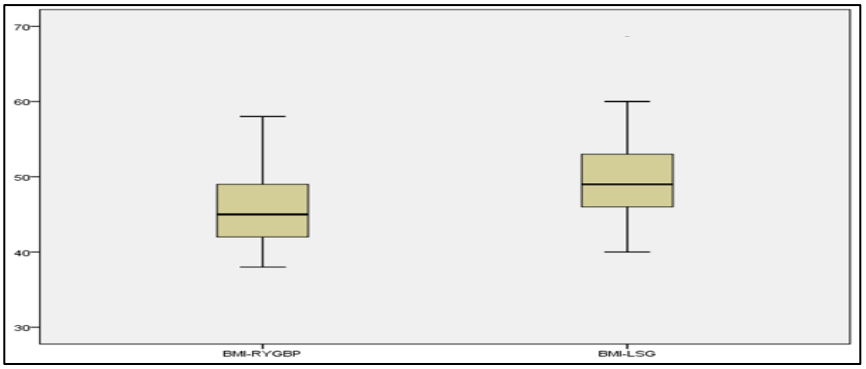

Fig. 2: Box plot chart comparing BMI in the study groups.

Table 3: Prevalence of diabetes and hypertension in the study groups.

		LRYGB Group		LSG Group		P value
		n	%	n	%	
Diabetes	Yes	4	16 %	3	12 %	0.65
	No	21	84 %	22	88 %	
Hypertension	Yes	5	20 %	4	16 %	0.33
	No	20	80 %	21	84 %	

The percentages of excess weight loss (%EWL) following both LRYGB and LSG were higher than 50% at 6 months postoperatively (61.1 ± 11.95 kg/m^2 in the LRYGB group versus 57.17 ± 8.36 kg/m^2 in the LSG group) *i.e. overall successful weight loss in both groups*. There was no significant difference between the study groups in terms of %EWL at 1 month and 3 months postoperatively (P = 0.2 and 0.7 respectively). However, patients in the LRYGB group demonstrated a significantly higher %EWL at 6 months postoperatively (P = 0.007) **(Fig. 3)**. The operative time was significantly longer in the LRYGB group (120.44 ± 26.4 minutes), compared to the LSG group (108.8 ± 17.97 minutes); P = 0.001. Similarly, the length of hospital stay was significantly longer in the LRYGB group (4.36 ± 1.22 days) compared to the LSG group (2.76 ± 1.01 days); P = 0.001 **(Fig. 4)**.

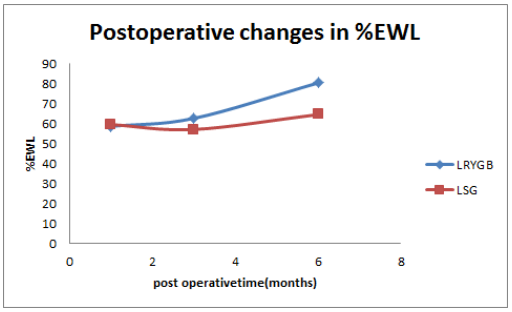

Fig. 3: Post-operative changes in the percentage of excess weight loss (%EWL) in the study groups.

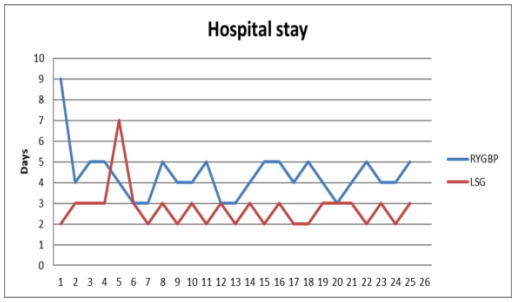

Figure 4. Length of hospital stay (days) in the study groups.

In the LSG group, intra-operative bleeding was encountered in 2 out of 25 cases (8%). In one case, bleeding was due to a iatrogenic splenic injury, and open conversion with splenectomy was carried out to control the bleeding. In the other case, bleeding originated from the posterior fundal vessels and was successfully controlled laparoscopically. The rate of intra-operative complications was relatively higher in the LSG group [2 cases (8%)], compared to the LRYGB group (0%), but the difference was not statistically significant *(P=0.56).* Major postoperative complications were reported in 3 cases in our study [2 cases (8%) in the LRYGB group (intestinal leak, intestinal obstruction); 1 case (4%) in the LSG group (staple-line leak)]. In the LRYGB group, one patient had an intestinal leak for which a laparotomy was carried out on POD3. This revealed a small perforation in the alimentary limb which was attributed, possibly, to the use of a traumatic grasper at the primary procedure while creating the gastrojejunostomy. Primary repair of the bowel perforation, after trimming of its edges, using interrupted vicryl sutures, was performed. Another patient in the same group presented on POD10 with severe colicky abdominal pain, jaundice and low-grade pyrexia. Blood tests revealed leucocytosis and elevated bilirubin levels; and a CT scan of the abdomen and pelvis with oral contrast showed markedly dilated proximal small bowel loops, with the contrast seen filling the rest of the non-dilated small bowel. This called for an urgent laparotomy on POD10 which revealed a mechanical stapler-induced obstruction of the biliopancreatic limb. A new hand-sewn jejuno-jejunal anastomosis was created **(Fig. 5)**. Both patients had a good recovery after relaparotomy and were discharged home few days later. In the LSG group, one patient had an early gastric leak - detected by gastrografin study on POD 1- for which a re-laparoscopy was carried out on POD 2. This revealed a staple-line leak at the incisura angularis. The leaking staple-line was oversewn laparoscopically using 4 interrupted vicryl sutures. The patient had a good recovery after re-laparoscopy and was discharged home few days later **(Fig. 6) (Table 4)**. The overall mortality rate in our study was 0%.

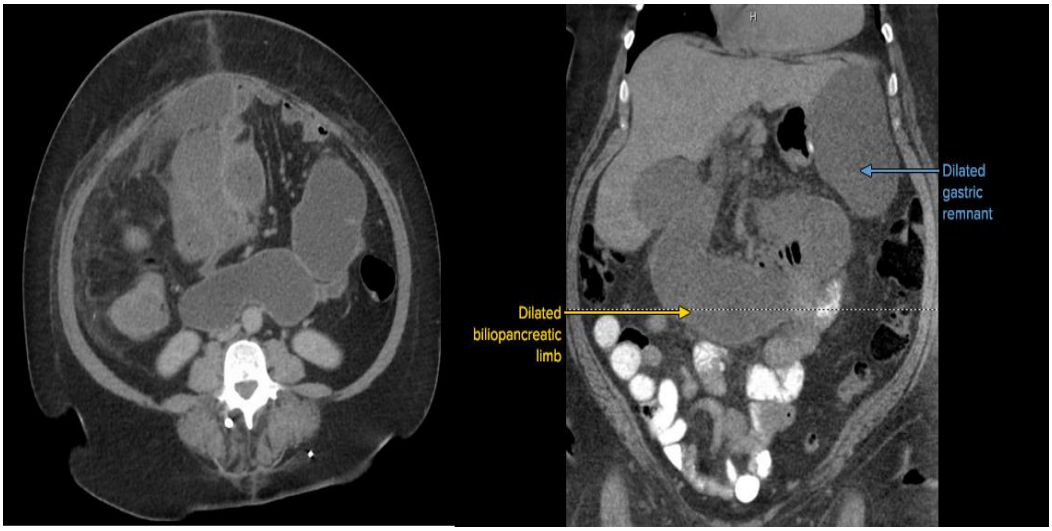

Fig. 5: A CT scan showing obstruction of the biliopancreatic limb in one of group A patients 10 days after LRYGB

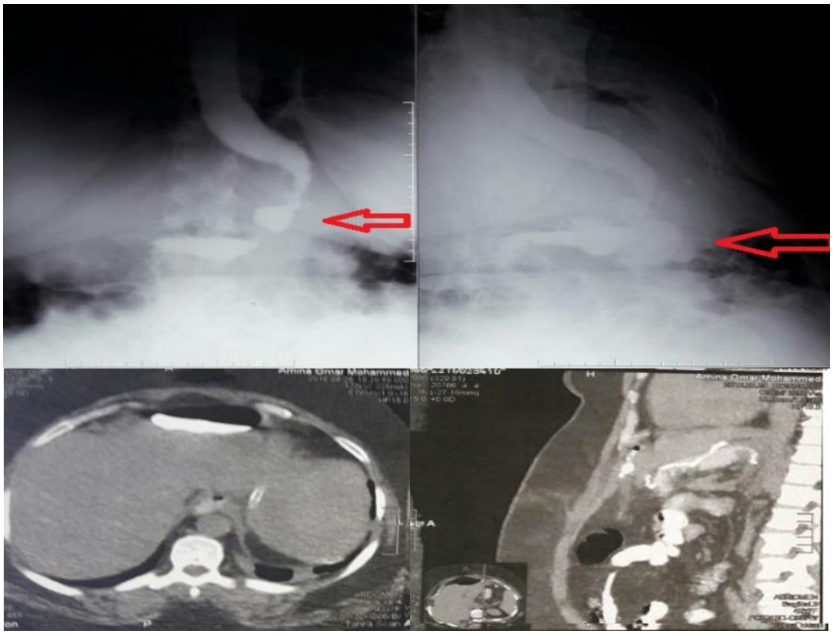

Fig. 6: Staple-line leak after LSG detected by gastrografin study and CT scan on POD 1 in one of group B patients

Table 4: Intra-operative and post-operative complications in the study groups.

Complications	**LRYGB group**		**LSG group**		**P Value**
	N	*%*	N	*%*	
Intra-operative bleeding	0	*0*	2	*8 %*	0.56
Minor post-operative bleeding	0	*0*	1	*4%*	0.87
Leak	1	*4 %*	1	*4 %*	0.54
Gastritis	1	*4 %*	3	*12 %*	0.25
Dumping	5	*20 %*	0	*0*	0.12
Intestinal Obstruction	1	*4 %*	0	*0*	0.902
Port site/ Incisional Hernia	2	*8 %*	0	*0*	0.92

In the LRYGB group, 3 out of 5 hypertensive patients (60%) showed clinical improvement with discontinuation of anti-hypertensive medications (P = 0.08), whereas 4 out of 4 diabetic patients (100%) showed complete remission of T2DM and excellent glycemic control with discontinuation of anti-diabetic medications. On the other hand, in the LSG group, 1 out of 4 hypertensive patients (25%) in the LSG group showed clinical improvement with discontinuation of anti-hypertensive medications (P = 0.88). Meanwhile, 2 out of 3 diabetic patients (66.7%) showed complete remission of T2DM with discontinuation of anti-diabetic medications, and 1 patient (33%) showed clinical improvement with conversion from insulin to oral hypoglycemic drugs. Hence, the rates of remission of hypertension were higher in the LRYGB group (60% for LRYGB versus 25% for LSG), whereas complete resolution or improvement of T2DM was achieved in both study groups. **(Fig. 7)**.

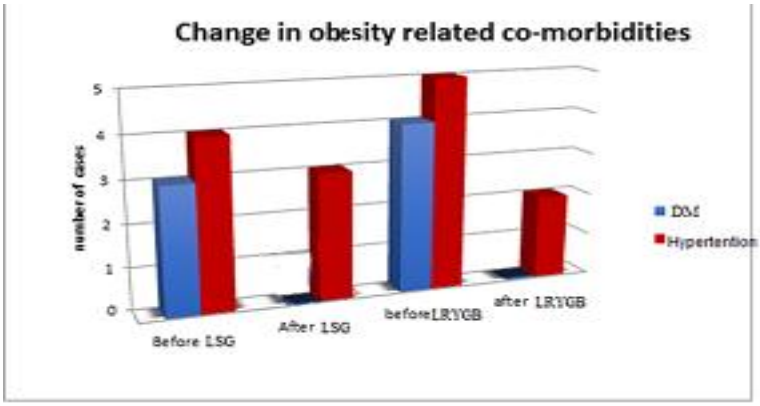

Figure 7. Changes in diabetes mellitus (DM) and hypertension at 6-months follow up.

In the LRYGB group, 4 out of 5 patients with preoperative GERD symptoms (80%) had complete relief of their symptoms at 6 months postoperatively, whereas only 1 patient (20%) had persistent GERD symptoms**.** In the LSG group, 3 out of 6 patients with preoperative GERD symptoms (50%) had complete relief of their symptoms at 6 months postoperatively, whereas 3 patients (50%) had persistent GERD symptoms **(Fig. 8)**. It is worth nothing, however, that one of the patients who did not have preoperative GERD symptoms started to develop reflux symptoms 3 weeks after LSG *(i.e. new-onset GERD)*.

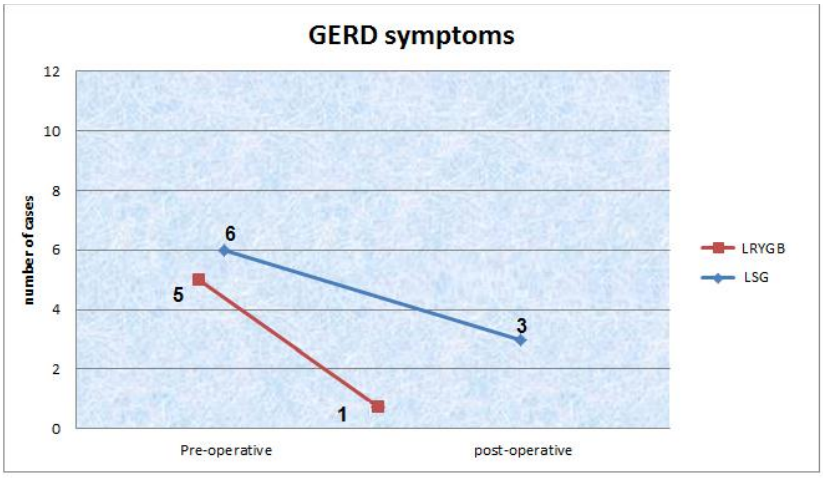

Figure 8. Changes in GERD symptoms in the study groups at 6-months follow up.

DISCUSSION

Bariatric surgery is a rapidly evolving field with continuous attempts by its surgeons to offer their patients procedures that can achieve their needs and objectives. Laparoscopic Roux-en-Y gastric bypass is currently recognized as the gold standard bariatric procedure. However, it is a technically challenging procedure that carries the risk of serious complications. On the other hand, LSG has gradually gained popularity in the recent years as an effective independent procedure [29]. Compared to LRYGB, LSG is less technically demanding, less costly, and requires less operative time [30].

Since LRYGB is still, more or less, an emerging surgical procedure in Egypt, its comparison with LSG is quite important to provide guidance for evidence-based bariatric surgery decisions. Hence, we conducted this prospective randomized study in order to compare between LRYGB and LSG in terms of their safety and efficacy in the treatment of morbid obesity. The study design (1:1 parallel randomized study) aimed to reflect the real effects of both bariatric procedures, while largely eliminating the influence of confounding factors such as age, gender and preoperative BMI.

Previous studies from different regions of the world have reported conflicting results with respect to the efficacy of the LRYGB and LSG procedures [20-25]. Most of those studies have shown that both procedures had similar effects on weight loss and DM. Hence, so far, there was no consensus on whether those two procedures were comparable in efficacy or one was superior to the other. However, Zhang et al. [21] have reported that weight loss at 3 years after surgery was better after LRYGB. A recent meta-analysis that included 21 studies has also shown that after a 1½-year follow up, LRYGB achieved a significantly higher % EWL than LSG [31]. This is somehow consistent with our study which showed that, although both LRYGB and LSG were highly effective in terms of short-term weight loss at 1 month and 3 months postoperatively, the mean %EWL in the LRYGB group was significantly higher than that in the LSG group at 6 months follow-up (61.1 ± 11.6% vs. 57.2 ± 8.4%; P = 0.007).

In March 2017, the prospective randomized *Swiss Multicenter Bypass Or Sleeve Study (SM-BOSS)* was published [32]. In this study, 217 patients were randomized to receive either LSG or LRYGB (LSG, n = 107; LRYGB, n = 110) at 4 bariatric centers in Switzerland. The mean BMI of all patients was 44 kg/m^2 and the minimum follow-up was 3 years with a compliance rate of 97%. Both groups were compared in terms of weight loss, co-morbidities, quality of life, and complications. Excessive BMI loss was similar in the LSG and LRYGB groups at each time point [*1 year:* 72.3 ± 21.9% vs. 76.6 ± 20.9%, P = 0.139; *2 years:* 74.7 ± 29.8% vs. 77.7 ± 30%, P = 0.513; *3 years:* 70.9 ± 23.8% vs. 73.8 ± 23.3%, P = 0.316). At this 3-year time point, co-morbidities were significantly reduced and were comparable after both procedures except for GERD and dyslipidemia, which were more successfully treated by LRYGB. Quality of life improved significantly in both groups at 1, 2, and 3 years post-surgery. There was no statistically significant difference between the study groups in the number of complications treated by reoperation (LSG, n = 9; LRYGB, n = 16, P = 0.15) or the number of complications treated conservatively.

If a difference in the weight loss effect between LRYGB and LSG really exists, as our study and some other studies have demonstrated, that could be due to several reasons. First, LRYGB is a hybrid procedure that reduces both the stomach capacity and the absorption of nutrients. On the other hand, LSG, as a partial gastrectomy, is only a restrictive procedure that does not have any mal-absorptive effects. Second, a variety of hormones are known to play key roles in weight loss and remission of co-morbidities. Of those, some anorexigenic hormones [e.g. glucagon-like peptide-1 (GLP-1) and peptide YY] have been shown to increase significantly after LRYGB [33]. Meanwhile, fasting and post-prandial levels of ghrelin, an appetite-stimulating hormone, have been shown to remarkably decrease after LSG. This decrease in ghrelin secretion has not been observed following LRYGB [34]. Therefore, the mechanisms by which these two procedures bring about weight loss might be totally different. Third, although LSG may be as effective as LRYGB in terms of short-term weight loss, as some studies including ours have revealed, it might be inferior to LRYGB in terms of mid-term or long-term weight loss. As LSG is a purely restrictive procedure (with no influence on nutrient absorption), poor postoperative compliance with diet control may lead to gradual expansion of the gastric sleeve, thus offsetting the early restrictive effect of the procedure. Last, differences in study designs can also contribute to the discrepancies seen in the literature. Thereby, a prospective, multicenter, randomized clinical trial with long-term follow-up is necessary to elucidate the differences between LRYGB and LSG.

Data on the safety of LRYGB and LSG still presents wide divergence. In our study, we found no significant difference between the LRYGB and LSG groups in the rates of intra-operative and major postoperative complications, which were relatively acceptable in both groups. This is

consistent with the results of Zhang et al [31] and with the findings of a recent meta-analysis [35]. However, in studies from Switzerland and New Zealand, complications were significantly higher in LRYGB patients [23,25]. On the other hand, two secondary outcomes in our study were clearly in favor of the LSG procedure. These are the operative time and the length of hospital stay, which were both significantly shorter in the LSG group, compared to the LRYGB group (P = 0.001 and 0.001 respectively).

In our study, we found noteworthy rates of resolution / improvement of hypertension and T2DM in both LRYGB and LSG groups, confirming the beneficial metabolic effects of both procedures. The rates of T2DM resolution or improvement at 6 months after surgery were excellent and comparable in both study groups. However, LRYGB was associated with higher rates of remission of hypertension. Other studies have reported similar outcomes [22-24]. A recent meta-analysis of 62 studies has demonstrated that, although LSG is equivalent to LRYGB with regard to improvement in T2DM and sleep apnea, it is inferior to LRYGB with regard to remission of hypertension, dyslipidemia, GERD, and arthritis **[36]**. This is consistent with our study results so far. Many studies, however, were in favor of LRYGB regarding resolution of T2DM. In the bariatric surgery literature, although the remission rates of obesity-related co-morbidities are generally satisfactory after both LRYGB and LSG, there are large variations in the results from different cohorts and from different countries. Differences in the indications for surgery as well as variations in sample sizes and study designs might be responsible for such disparity.

At the end, it is important to emphasize that our study was not without limitations. In fact, being a single-center uncontrolled study is the main drawback. Other limitations include the relatively small sample size, the short follow-up, as well as the presence of confounding variables such as patients' compliance to follow-up and to postoperative instructions, especially with regard to diet control and lifestyle modifications.

In conclusion, both LRYGB and LSG are effective in terms of short-term weight loss. However, LRYGB provides better weight loss at 6 months after surgery. Both LRYGB and LSG are also associated with excellent and comparable rates of T2DM resolution or improvement, but the rates of remission of hypertension and relief of GERD symptoms appear to be higher after LRYGB. Regarding operative time and length of hospital stay, both are in favor of the LSG procedure. After all, both procedures are relatively safe with comparable and relatively acceptable intra-operative / major postoperative complication rates. Finally, and in view of the considerable variations in the bariatric literature, further randomized comparative studies with larger sample sizes and longer follow up are still needed in order to clearly elucidate the differences between LRYGB and LSG, thereby paving the way for the continuing development of evidence-based bariatric surgery guidelines.

Conflict of Interest Statement:

The authors of this manuscript have no conflicts of interest to disclose. Neither the authors nor participants had any financial interest in the subject, materials, or equipment discussed or in competing materials. There were no sources of funding for this work other than departmental resources.

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