Laparoscopic sleeve gastrectomy with loop bipartition versus laparoscopic sleeve gastrectomy in treating obese people with type II diabetes mellitus: a prospective randomized comparative study

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Introduction
Sleeve gastrectomy with loop bipartition is a new operation based on the modification of Santoro's operation by making sleeve gastrectomy followed by side-to-side gastro-ileal anastomosis. The aim of this study is to compare this novel operation with sleeve gastrectomy only as a therapeutic method for obese patient with diabetes type II.

Patients and methods
The trial was designed as a prospective randomized comparative study. The trial protocol was approved by the institutional ethics committee. A total of 51 patients between 18 and 60 years, with a BMI between 40 and 60 kg/m^2 and indication for bariatric surgery according to the national institutes of health criteria were randomized to receive either laparoscopic sleeve gastrectomy with loop bipartition (LSGB) (n=26) or laparoscopic sleeve gastrectomy (LSG) (n=25). The primary and secondary end points were assessed before surgery and afterward at discharge and at the time points 3, 6, and 12 months postoperatively.

Result
Both operations are effective in the treatment of obesity with a significant difference in operative time and blood loss. There was no significant difference between both groups regarding early and late complications. LSGB is more effective than LSG in the decrease of BMI, waist circumference, weight loss, lipids levels, blood glucose, and glycated hemoglobin than LSG group after 1 year of surgery.

Conclusion
LSGB is an effective easy procedure to treat morbidly obese patients with type II diabetes. This operation showed many advantages with little complications.

Keywords:
loop bipartition, obesity, sleeve gastrectomy, type II diabetes

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Introduction

There is a nearby relationship between obesity and type II diabetes. The probability and seriousness of type II diabetes are closely linked to BMI [1].

One of the major factors leading to diabetes is body fat distribution, but until now, it is not clear why not all obese people develop type II diabetes and why not all people with type II diabetes are obese [2,3].

Bariatric procedures fundamentally alter physiology, and in those with diabetes, bariatric surgery can affect insulin sensitivity and insulin secretion, resulting in remission of diabetes in many recipients [4].

The action of each procedure differs, and the mechanisms by which each procedure produces weight loss and alters physiological mechanisms, such as glucose homeostasis, are multiple and often integrated. The known mechanisms include gut hormone-mediated changes affecting appetite, insulin dynamics, food preferences, and energy expenditure [5]. Recently, the bariatric surgeons had designed new procedures that act by neuroendocrine changes instead of at mechanical restriction and malabsorption [6].

Sleeve gastrectomy with transient bipartition (SG+TB) was recently studied by Santoro and colleagues on a large series of patients regarding the long-term result. This technique is a modification of duodenal switch to avoid nutritional deficiency owing to exclusion of duodenum [7]. With this simple surgical step, the patient will benefit from nutritional absorption of

the distal gut as well as decrease food exposure to the proximal bowel without complete isolation of duodenum [8].

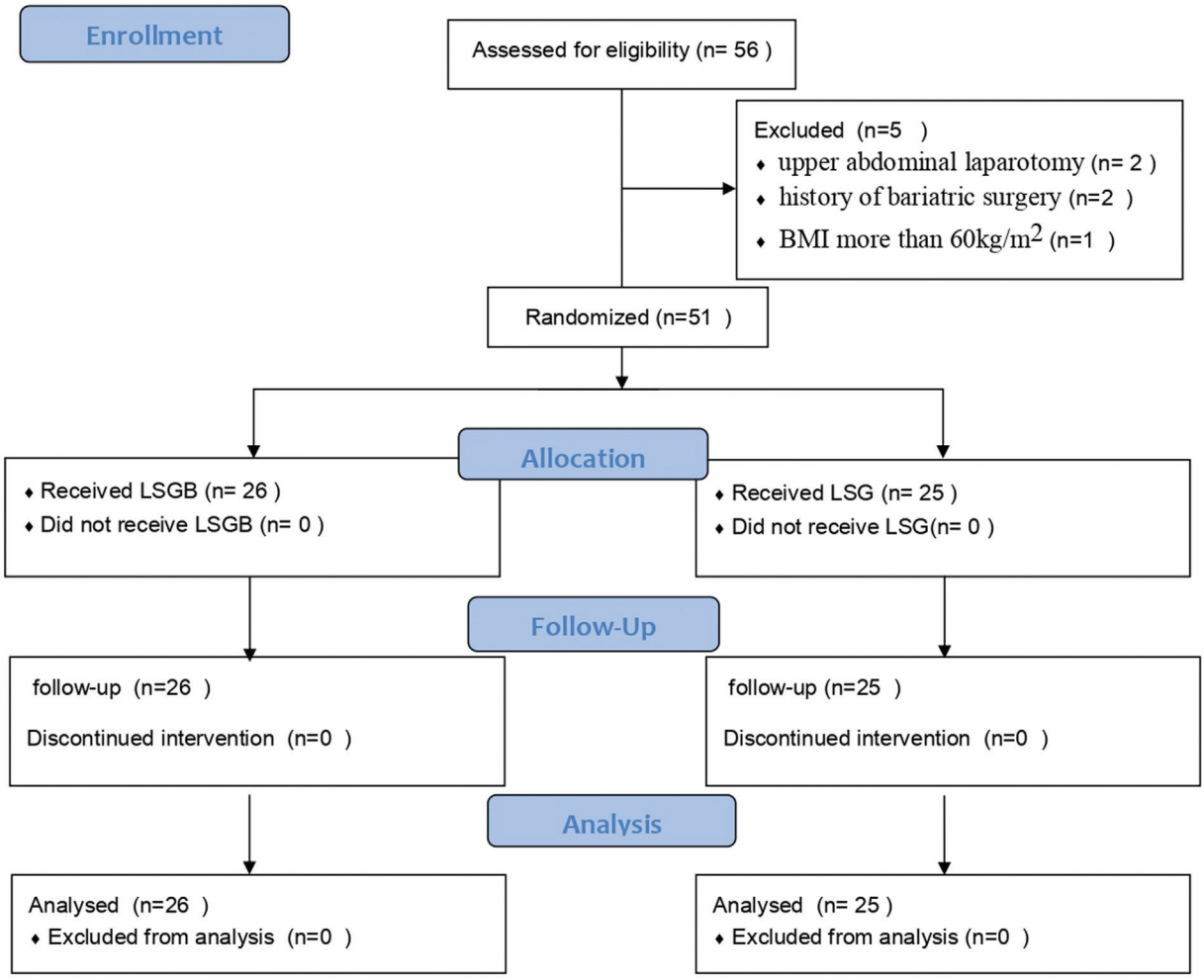
A recent modification of the SG+TB was done by a loop rather than Roux-en-Y bipartition reconstruction in Santoro's technique, and the purpose of this study was to compare this operation with ordinary sleeve gastrectomy regarding efficacy, adverse effect, and the therapeutic role for obese patients with type II diabetes mellitus (T2DM).

Patients and methods

The study was conducted in the GIT Unit of the General Surgery Department of Zagazig University Hospital in the period from April 2016 to August 2018. The hospital Institutional Review Board approved the study protocol, and its identifying number is the research registry number IR-16869-2. Informed consent was obtained from all individual participants included in the study after full explanation of operative, postoperative details, and expected complications. According to the National Institute of Health criteria, 56 patients were fit for the study and were randomly divided into two groups by block randomization method. The first group (n=26) underwent laparoscopic sleeve gastrectomy with loop bipartition (LSGB) (Fig. 1), whereas laparoscopic sleeve gastrectomy (LSG) was done in the second group (n=25). The researchers excluded five patients with BMI more than 60 kg/m^2, history of bariatric surgery, or upper abdominal laparotomy (Fig. 2).

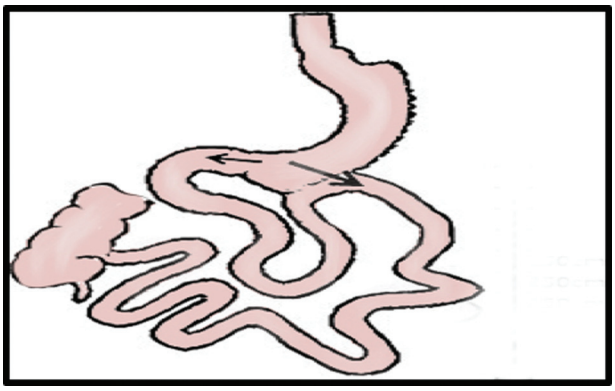
Perioperative evaluation of all patients was done by a team consisting of bariatric surgeons, anesthesiologist, cardiologist, nutritionist, endocrinologist, and psychologist. Usual perioperative investigations like a full blood test, radiography chest, and ECG were done. Thyroid and adrenal hormones were evaluated to exclude hormonal causes of obesity. All patients gave

Figure 1



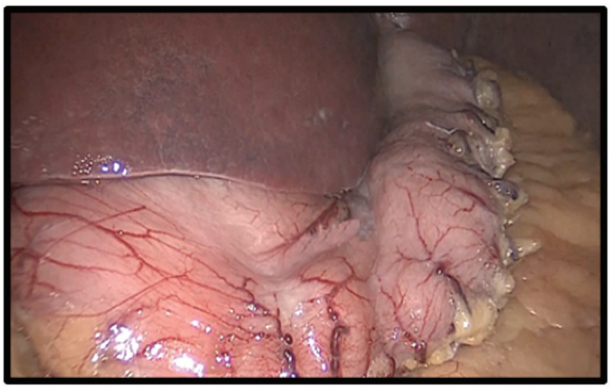
Study groups randomization, follow-up, and analysis.

Figure 2



Sleeve with loop bipartition.

Figure 3



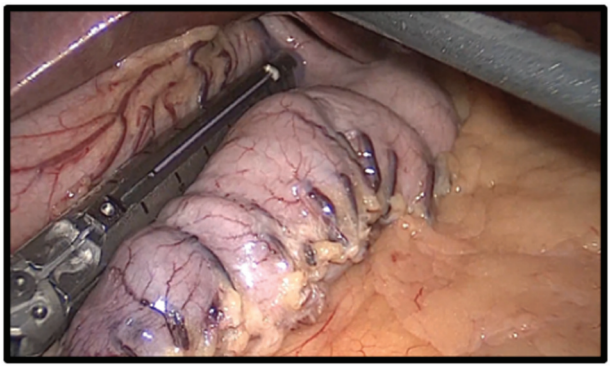
Devascularization of the greater curvature.

a history of type II diabetes based on investigations and medical treatment. All patients were well controlled before surgery. We used insulin injection in some cases before and after the operation according to the needs of the patient to grantee good postoperative healing and recovery. Gastroscopy was done as a routine procedure to exclude any gastric problems as well as an abdominal ultrasound to evaluate abdominal organs. All patients were kept on low-caloric protein diet at least for 6 weeks. Third-generation cephalosporin was given as prophylactic antibiotic 1 h before operation. Low-molecular-weight heparin was given for all patients 12 h before the operation as deep venous thrombosis prophylaxis.

Under general anesthesia, patients were in the French position. After pneumoperitoneum induction, five trocars were placed as follow: first one 12-mm camera trocar above and slightly to the left of umbilicus; second 12-mm trocar on the upper right quadrant; third 12-mm trocar was placed 5 cm under left costal margin; fourth (5 or 10 mm) trocar on left anterior axillary line 4–5 cm below costal margin; and fifth 10-mm trocar below the xiphoid process for retraction of liver.

For both groups, sleeve gastrectomy was similarly performed. The procedure started by devascularization of the greater curvature of the stomach (Fig. 3) starting from the antrum (6–7 cm from the pylorus) toward angel of His and left crus of the diaphragm. The harmonic scalpel was used for dissection of the omentum, gastro-epiploic ligament, short gastric vessels, and adhesion between the fundus and the diaphragm. Endo-GIA stapler was used to make the sleeve over a 36-Fr bougie (Fig. 4). Under-running sutures were done after finishing stapling. In the first group (LSGB), the table is changed to the horizontal position to prepare patients to the second step (bipartition loop). Ileal loop 250 cm from the ileocecal junction (Fig. 5) was ascended without division of the greater omentum to make isoperistaltic side-to-side gastroileostomy (Fig. 6) at the dependent part of the antrum about 3 cm away from the pylorus using a linear stapler. The anastomosis was not exceeding 3 cm in diameter

Figure 4

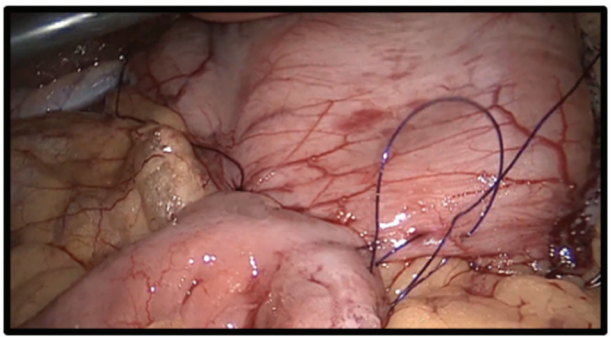


Endo-GIA stapler is making sleeve.

Figure 5

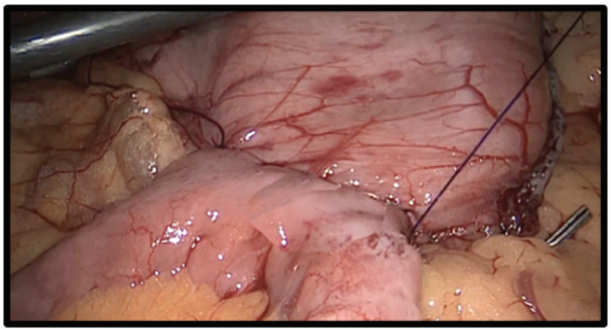
Choice of ileal loop 250 cm from ileocecal junction.

Figure 6



Side-to-side gastroileostomy.

Figure 7



3-cm diameter gastroileostomy.

(Fig. 7). The opening of the stapler was closed with two layers of sutures using 3/0 PDS. All patients were tested for leakage with a methylene blue test. The transected part of the stomach was retrieved through the 12-mm trocar at left midclavicular line. Tube drain 20 Fr was placed intraabdominally and removed 24 h after the operation.

Regarding intraoperative complication, we had two cases of mesenteric injury and bleeding, which were managed by sutures, and a third patient's GE junction blew up because the balloon was inflated while doing the leak test and also was sutured.

Although all patients were advised for early ambulation postoperatively, prophylactic subcutaneous micronized heparin 40 mg was given at least for 10 days. All patients started clear oral fluids sips at night of operative day. Oral contrast study with gastrografin was done as a routine procedure before patient discharge to exclude any leakage. Home medicine included proton pump inhibitor for 3 months. Diet modification was done by the dietitian. For 1 month, patients were kept on a low-caloric protein diet. Multivitamins were given for all patients for 6 months. Most patients tolerated solid foods after 4–6 weeks without complications. Postoperative follow-up of the patients was scheduled as following 1 week, 1 month, 3 months, 6 months, and 12 months. Regular laboratory tests (complete blood count, serum iron, vitamin B, creatinine, blood calcium, and liver enzymes) were done. Postoperative upper endoscopy was done in some cases owing to epigastric pain, heartburn, and repeated vomiting.

Both groups of patients were compared regarding diabetes relief, comorbidities, and excess weight loss, which were considered as primary study outcomes. The secondary outcomes were postoperative complications and nutritional status. Preoperative data included demographics, weight, BMI, comorbidity, medications, medical history, and social history. Operative data included duration and intraoperative complications. Postoperative data included hospital admission duration, early postoperative complications (vomiting, fever, leak, collection, and chest problems). After 1 month, late complications were recorded like reflux, vomiting, stricture, obstruction, and nutritional problems (iron-deficiency anemia, hypoalbuminemia, calcium deficiency, and vitamins D and vitamin B_{12} deficiency).

IBM SPSS, 21.0 (IBM Armonk, NY) was used for data analysis. The normality of continuous variables was presented as mean±SD or median where applicable. The percentages were used for categorical variables. The independent samples *t* test was used for differences between groups in normally distributed continuous variables. However, the χ^2 and the Fisher's exact tests were used to compare categorical variables. The effect of operation time on each group was tested using repeated-measure analyses of variance. The adjusted odds ratios and 95% confidence intervals of excess weight loss were identified using multivariate logistic regression methods.

Results

Details of demography, anthropometry, comorbidities, and biochemistry at the time of surgery in the study population are represented in Table 1.

Although there was no significant difference between the two groups regarding sex distribution, yet the LSG grouphad a higher proportion of women compared with the LSGB group (92 vs. 73%). Overall, among the common obesity-related comorbidities, diabetes was seen in 100% of all patients, followed by hypertension (19.6%) and hyperlipidemia (13.7%).

Table 1 Characteristics of the study groups

	LSGB (*N*=26)	LSG (*N*=25)	*P* value
Age (years)	38.6±13.2	38±13.8	1
Sex			
Male	7 (27)	2 (8)	0.76
Female	19 (73)	23 (92)	
Weight	118.9±23.1	115±18.7	0.5
BMI	45.5±7.1	45.1±6.2	0.8
Diabetes	26 (100)	25 (100)	1.0
Hypertension	6 (23)	4 (16)	0.5
Dyslipidemia	2 (7.6)	5 (20)	0.2
Sleep apnea	2 (7.6)	1 (4)	0.5

Values are represented as mean±SD and *n* (%). LSG, laparoscopic sleeve gastrectomy; LSGB, laparoscopic sleeve gastrectomy with loop bipartition.

Surgical outcomes according to the surgical procedures are presented in Table 2.

The mean operative times were significantly shorter in the LSG group compared with the LSGB group ($P<0.0019$). Blood loss was significantly less in the LSG group in comparison with the LSGB group ($P<0.004$). Table 2 shows no significant difference between the two groups regarding postoperative complications and hospital stay. Only two patients with an internal hernia required reoperation. Other patients underwent endoscopic and conservative treatments for other postoperative complications.

There was weight loss after surgery in both groups in the first 3 months, but there was no significant difference between them. The LSGB group showed better weight loss at 6 and 12 months after operation (Fig. 8).

Diabetes resolution was better in LSGB group than LSG group (92 vs. 48%; $P=0.03$). The LSGB group had significantly lower fasting blood glucose and glycated hemoglobin (HbA1c) levels than LSG group in 1 month, 3 months, 6 months, and 12 months postoperatively (Fig. 9). One-year postoperatively, the mean reduction of HbA1c of LSGB group was 4.5 versus 3.5% in the LSG group. In the first 3 months, there was no significant difference between the two groups regarding diabetes resolution, but it changed to be significant during the last 6 months of postoperative follow-up.

After 1 year, all patients showed a marked reduction in body weight, waist circumference, blood pressure, and insulin, C-peptide, and blood lipid levels (Table 3).

Table 2 Operative and postoperative outcomes (early and late complications)

	LGSB	LGS	*P* value
Operation time	90.5±35.1	64.5±18.7	0.0019*
Blood loss	60.8±10.9	50.4±8.2	0.004*
Hospital stay	4.2±2.6	3.2±2.5	0.16
Intraoperative complication	2	1	0.5
Early postoperative complication			
Leakage	2	1	0.5
Bleeding	1	0	1.0
Ulcer	2	0	0.4
Stricture	2	2	0.9
Pneumonia	1	3	0.2
Pulmonary embolism	0	1	0.4
Late postoperative complications			
Internal hernia	2	0	0.4
Nausea and vomiting	0	3	0.1
Stenosis	0	2	0.2
Urinary tract infection	1	1	0.9
Anemia	0	2	0.2
Hypovitaminosis	4	2	0.4
Hypoalbuminemia	3	2	0.6
Reflux	2	1	0.5
Dump syndrome	4	0	0.1

For comparison between the two groups, we used Student *t* test, Fisher's exact test, or χ^2 test based on variable type. *Significant difference between two groups.

LSGB group had a significant decrease in BMI, waist circumference, weight loss, lipids levels, blood glucose, and HbA1c than LSG group after 1 year of surgery. This means that LSGB patients showed improvement of the metabolic condition in comparison with LSG patients.

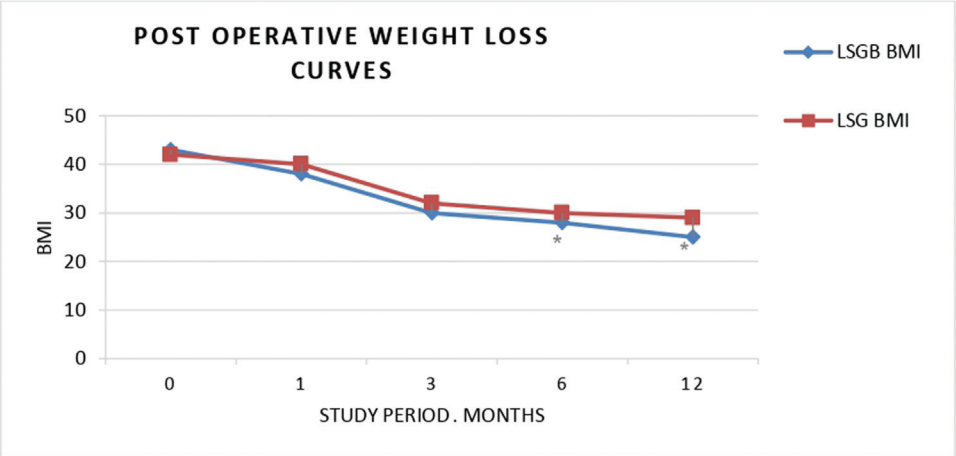
Discussion

Bariatric surgery proved to be effective in the treatment of T2DM [9]. All successful operations significantly improve insulin resistance and diabetes, but those based on mal-absorptive principles get higher resolution rates [10].

This new surgical procedure (sleeve gastrectomy with loop bipartition; SG+LB) was evolved and derived from the combined concepts of sleeve gastrectomy with transit bipartition (SG+TB) [11,12], single anastomosis duodenal-ileostomy, [12] mini-gastric bypass [13,14], and duodenal–jejunal bypass [15,16] that we have learned from the past years.

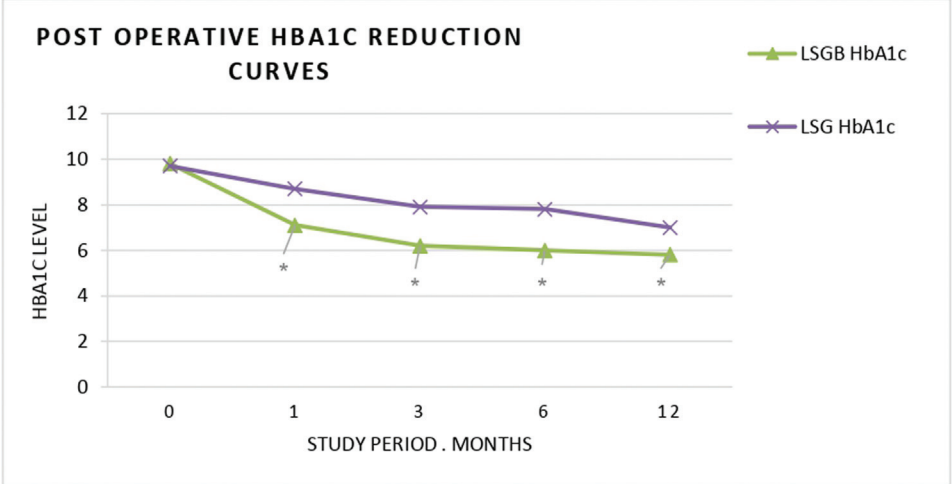
In this study, there was a significant difference in operative duration and blood loss between the two groups. However, the operative and postoperative complications rates were the same in both groups. Mahdy *et al.* [8] reported the same duration and postoperative complication in their study group.

Figure 8



Weight reduction curves of both groups.

Figure 9



Postoperative HbA1c of both groups. HbA1c, glycated hemoglobin.

As gasteoileostomy anastomosis was done at the dependent area of the antrum, the leakage in the LSGB group was very low with no significant difference with the other LSG group. These results were supported by an initial study done by Mui *et al.* [17] for evaluation of this novel technique.

We recorded only two (7.6%) cases of internal herniation owing to loss of sutures of the Petersen defect in the LSGB group versus no cases in the LSG group which was not significant. In another study [18], the rate of internal herniation after a Roux-en-Y operation was 1–16% within 1 year. This does not match with a previous study by Mahdy *et al.* [8] on gastric bipartition, as they did not have any case of an internal herniation in the same duration of postoperative follow-up.

In this study, there is no significant difference between both groups regarding anemia, vitamins deficiency, and hypoalbuminemia, and these were still low in comparison with other bariatric bypass operations owing to the elimination of two ways of food passage. The postoperative undernutrition program makes patient malnutrition evaluation difficult [19]. In LSGB group there were four patients who developed hypovitaminosis and three patients developed hypoalbuminemia owing to very low intake of proteins and vitamins, as they were afraid of weight to regain. These patients were guided to correct diet and given supplementations. The incidence of malnutrition in other bariatric operations is high owing to patients' intolerance for prescribed diet, which must include a minimal intake of 90 g of protein per day [20].

Table 3 One-year postoperative remission of comorbidity, weight reduction, glycemia, and lipid profile

Outcome	LSGB group (*N*=26)	LSG group (*N*=25)	*P* value
Resolution of DM (HbA1c<6.5)	24 (92)	12 (48)	0.0006*
BMI	22.6±2.3	24.3±2.5	0.0147*
Waist circumference (cm)	78.6±6.4	84.2±4.6	0.0008*
Weight (kg)	60.6±9.1	65.7±6.8	0.023*
Excess weight loss (%)	93.2±32.4	76.3±37.8	0.09
Blood glucose (mg/dl)	100.2±19.5	140±52.1	0.0007*
HbA1c (%)	5.6±0.4	7.1±1.4	0.0001*
C-peptide (ng/ml)	1.7±1.2	1.6±1.2	0.7
Systolic blood pressure (mmHg)	120.4±18.2	122.5±12.6	0.6
Diastolic blood pressure (mmHg)	78.5±11.4	79.7±9.5	0.6
Total cholesterol (mg/dl)	163.5±27.3	206.5±57.2	0.001*
Triglycerides (mg/dl)	105.8±52	143.7±58.6	0.018*
HDL-C (mg/dl)	48.4±7.6	46.4±7.8	0.3
LDL-C (mg/dl)	98.7±22.5	137.5±39.7	0.0001*

For comparison between the two groups, we used Student *t* test, Fisher's exact test, or χ^2 test based on variable type. DM, diabetes mellitus; HbA1c, glycated hemoglobin; HDL-C, high-density lipoprotein-cholesterol; LDL-C, low-density lipoprotein-cholesterol; LSG, laparoscopic sleeve gastrectomy; LSGB, laparoscopic sleeve gastrectomy with loop bipartition. *Significant difference between the two groups.

According to our knowledge, this is the first comparative study between LSGB and LSG in the treatment of morbid obesity (BMI 40–60 kg/m^2) with uncontrolled T2DM. Both techniques were effective in the treatment of metabolic comorbidity of obesity in whom current medical treatment had failed.

In the LSGB group, diabetes improvement is related to restrictive action leading to a reduction of caloric intake and a rapid entrance of undigested chime into terminal ileum causing stimulation of the distal intestine. At the same time, a small amount of food passes through the duodenum causing diminished stimulation of the proximal intestine but not reducing it completely. This mechanism maintains weight loss and easily explains why 92% of patients of this group had completely resolved diabetes after 1 year with a normal level of glycosylated hemoglobin. These results were superior to LGS (48%), which depends on restrictive action only, and on matching previous studies, it could be seen that LSGB achieves 90–100% resolution of diabetes, whereas pure LGS procedure may achieve a rate of ~50% [8,19].Besides weight loss, the LSGB group also achieved lower blood lipid level and waist circumference significantly in comparison with the LSG group. That is why the LSGB group had a higher metabolic syndrome resolution rate than the LSG Group. This matches the new standard treatment of obesity and diabetes in Hong Kong as intestinal bypass added to SG, primary or staged, which is only reserved and offered to those with extreme obesity and poorly controlled DM [21].

In LSGB group, the majority of nutrients and food mainly pass through gastroileostomy rather than physiological pathway, and this observation is functionally similar to single anastomosis duodenal-ileostomy and duodenal–jejunal bypass, with less nutritional and surgical complications [22].

Conclusion

According to the results of this study, LSGB can be considered as a good choice for the morbidly obese diabetic patient. LSGB procedure is a novel hopeful operation, depending on keeping physiological principles of the digestive system, easier performance than Santoro's operation, and good results as bypass surgery without drawbacks. In this procedure, weight loss and diabetic control are associated with easy endoscopic access and absence of excluded segment.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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