Laparoscopic Single Anastomosis Sleeve Ileal Bypass: Initial Results

Abou-Ashour H., MD, MRCS; Moutafa A, MD; Mohamed Nazeh Shaker Nassar
Department of General Surgery, Faculty of Medicine, Menoufia University, Egypt

Background: Bariatric surgery has become the most valuable approach in managing morbid obesity where it can achieve sustained great weight loss. The restrictive, malabsorptive and mixed procedures, have shown to achieve promising and good results in weight loss.

Patient and methods: It is a prospective observational study which was held in Menoufia University, general surgery department between September 2018 and October 2021. Eighty obese patients with their body mass index (BMI) between 35kg/m^2 and 60 kg/m^2, and their age ranging between 18 and 65 years were included. All of them underwent laparoscopic sleeve ileal bypass SASI bypass. We studied the impact of SASI bypass on weight loss and metabolic comorbidities.

Result: There were high statistically significant differences during the follow-up period as regards pre and post-operative BMI, type 2 diabetes mellitus, hyperlipidemia ($p<0.001$).

Conclusions: SASI bypass seemed to be safe and effective bariatric procedure that confers significant loss of weight and improvement of obesity related comorbidities.

Key words: Single anastomosis sleeve ileal bypass; Metabolic syndrome; Metabolic surgery Gastric bypass; SASI operation; Bariatric surgery.

Introduction

Bariatric surgery has been shown to be the most effective method for treatment of morbid obesity. Surgeries which have restrictive, malabsorptive, or mixed procedures, have shown to achieve effective and good results in weight loss. Medical follow up is usually required for long time with the supplementation of vitamins and nutrients for those who underwent gastric bypass. Restrictive procedures are frequently associated with vomiting, dysphagia as a result of anatomical restrictions.[1]

Researches and advances in bariatric surgical techniques have resulted in other techniques such as the single anastomosis sleeve ileal bypass (SASI), which emerged as a new bariatric and metabolic surgery based on Santoro's operation, where an ileal loop is anastomosed to the sleeve gastrectomy.[2]

The operation maintains the conventional pathway of food, permitting only a small amount of ingested food to be absorbed and most of food is bypassed directly into the ileum and induces the metabolic effect of the procedure. Additionally, it has the advantages of having minimal nutritional complications and liberal visualization of biliary system could be performed by endoscopy.[3]

The reduction of the gastric tube pressure after performing gastrojejunostomy significantly decreased gastroesophageal reflux disease (GERD), and leakage from sleeve gastrectomy.[4]

Despite there is little data in the literature, the laparoscopic SASI bypass seemed to be safe, effective, and simple procedure for the treatment of morbid obesity and its associated metabolic comorbidities. Moreover, it may lower the postoperative nutritional complications in comparison to other malabsorptive bariatric procedures.[5]

However, long-term follow-up period should be performed to evaluate postoperative weight loss, metabolic changes, and nutritional status of patients. In addition, radiological evaluation of the procedure is required to measure the actual amount of food that passes in each outlet from stomach to intestine.[6]

The primary end point of this study is to evaluate the short-term outcome of laparoscopic SASI bypass as regards weight loss, and its impact on metabolic comorbidities in the morbidly obese patients. The 2ndry study end point is the complication of this operation.

Patients and methods

This is a prospective observational study included 80 morbid obese patients. Their body mass index (BMI) varied between 35 kg/m^2 and 65 kg/m^2, and their age ranged between 18 and 65 years. All patients were operated for sleeve ileal bypass in Menoufia university hospital. The study was conducted between September 2018 and October 2021. All patients underwent full history taking and

thoroughly clinical examination, routine laboratory investigations, fasting, postprandial blood glucose, HbA1c and complete lipid profile.

- Pre-operative upper GI endoscopy was performed for patients.
- Echo cardiography were performed for all patients.

The study was approved from the institution review board and an informed written consent was taken from all participants. We included adult males and females' patients from 18-65 years, patients with BMI 35-65. All patients have been informed about surgical details and they were informed that the operation is still experimental.

We excluded patients who underwent previous bariatric operations, patients with type 1 diabetes mellitus, patients with endocrinal diseases e.g., hypothyroidism and Cushing's disease, patients suffering from gastritis, GERD, hiatus hernia, patients with inflammatory bowel diseases like Crohn's disease.

Surgery

Before surgery, patients were evaluated as regards the general condition, mental status and obesity associated comorbidities such as diabetes, hypertension, or cardiovascular diseases. A high protein diet was instructed to patients, and we encouraged them to perform regular exercises one week before the surgery. Participants were instructed to take clear fluids the day before surgery and to start fasting for 12 hours before surgery. Low molecular-weight heparin before surgery was given.

In the supine position, patients were intubated, and we established pneumoperitoneum through a 10-mm umbilical port. Under xiphoid process, we placed a 5-mm trocar for the liver retraction and 12- and 15-mm trocars were placed on the right and left-middle clavicular lines, respectively. On the left anterior axillary line another 5-mm trocar was placed for assistance. Then we inserted an oral Ryle's tube to deflate the stomach, and dissection was started along the greater curvature 5 cm from the pylorus up to the cardio-esophageal junction. After liberating the stomach from great curvature, a 36-French orogastric tube was put into the stomach and the duodenum. A linear staplers that were applied parallel to the lesser curve to resect the stomach, starting 3 to 5 cm from the pylorus up to the angle of Hiss.

After finishing sleeve gastrectomy, the position was changed to Trendelenburg position. Then we retracted the transverse mesocolon cephalad and performing longitudinal omentotomy till the transverse colon to reduce tension of the ilio-gastric anastomosis. We calculate the whole length of the small intestine, then 300 cm was measured from the ileocecal junction and we put a stitch as a mark. Then a small window in the mesenteric border was done by Harmonic ace ®. And we hanged the ileum with a tape through this window to avoid serosal tearing. **(Figure 1)** Then position was adjusted again to anti Trendelenburg position. An anchoring stitch were then made between the stomach and the ileum. Then a side-to-side an antecolic gastro-ileostomy by 3cm stoma using a 45-mm blue linear stapler **(Figure 2)**. The rest of gastro-ileostomy stapler opening was closed with a V- lock, PDS or Vicryl 2/0 continuous sutures. **(Figure 4).** A naso-gastric tube was placed in the gastric pouch and the leak test was performed using 100 ML methylene blue and a drain were left for 72 hrs.

- Surgical steps are illustrated in **(Figsures 1- 4).**
- The patients were given thromboembolic prophylaxis in the form of low-molecular-weight heparin for 15 days. Antibiotic injection (Cefoperazone & sulbactam 1500 mg IV /12 hrs) for 72 hours then oral antibiotics were prescribed for one week (Amoxicillin + clavulanic acid [Augmentin powder ®], 1 gm/12 hr). A proton pump inhibitor (PPI) was prescribed for 3 months. Patients were discharged 3 days after surgery after an oral contrast study is free of leak.

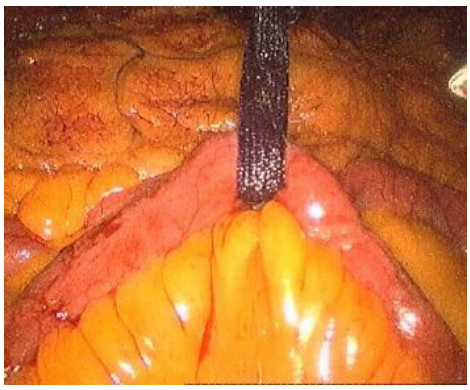

Fig 1: Hanging the ileal loop to the sleeved stomach by a tape.

Fig 2: Establishing a gastrocolic ansastmosis using stapler.

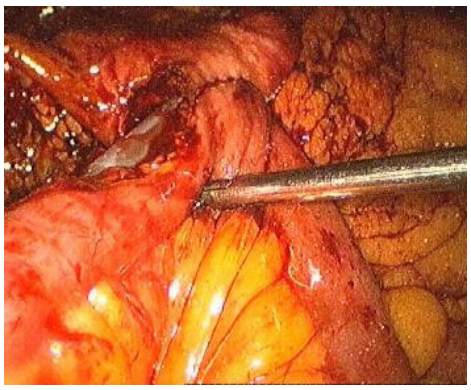

Fig 3: Passing the bougie to the ileal loop to facilitate anastomosis.

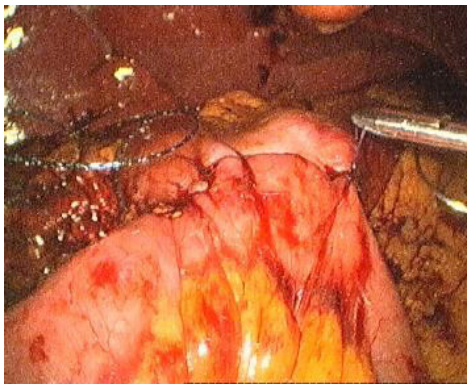

Fig 4: Completion of the sleeve ieal anastomosis using V- Lock®.

During the 1st 48 hrs. patients were on "nil by mouth" then a low-caloric clear liquids were allowed for two weeks followed by a low-caloric semisolid food for –two to four weeks. Regular diet was subsequently allowed. Patients were followed up once weekly on the first month for early detection of any postoperative complications such as bleeding, collection, fever, or leakage and for assessing the level of blood glucose.

- Then assessment was performed every 2 months for a year. The statistical analysis was performed after one year of follow up to assess the degree of weight loss, BMI, %EWL, fasting blood sugar, HbA1, blood lipid profile, new onset GERD, or occurrence of complications.

Statistical analysis

Data were collected, revised, coded and entered to the statistical package for social science (SPSS) version 23. Qualitative data were presented as number and percentages while quantitative data were presented as mean, standard deviations and ranges when their distribution found parametric. The comparison between pre and post operative qualitative data were done by using Chi-square test and Fisher exact test was used instead of Chi-square when the expected count in any cell found less than 5.

The comparison between the pre and postoperative quantitative data and parametric distribution were done by using Paired t-test while the comparison between more than two paired groups with quantitative data and parametric distribution were done by using Repeated Measures ANOVA followed by post hoc analysis using Bonferroni test.

The confidence interval was set to 95% and the margin of error accepted set to 5%. So, the p-value was considered significant as the following:

P > 0.05: Non significant.

P < 0.05: Significant.

P < 0.01: Highly significant.

Results

Among the studied cases there were 28 (35%) males and 52 (65%) females, according to smoking status there were 3 (4%) ex-smokers and 10 (12.5%) current smokers, all the studied cases had attempted to lose weight by lifestyle modification, the mean age of the studied cases was 38.66 (±12.64 SD).

The mean preoperative BMI was 42.07 (±7.49 SD). After 12 months the mean postoperative BMI was 26.53 (±7.29 SD), the mean weight loss was 43±15.87 SD kg and the EWL% was 91.1 (± 4.7 SD).

There were high statistically significant differences between pre and post operative results as regards BMI (p<0.001).

Prior to surgery there were 50 patients (62.5%) with type 2 diabetes mellitus, 40 (50%) with hypertension, 32 (40%) with hyperlipidemia, and 12 (15%) with sleep apnea syndrome.

There was high statistically significant difference in remissions as regard type 2 diabetes mellitus, hypertension, hyperlipidemia and sleep apnea syndrome (p < 0.001).

Hemoglobin level, Vitamin D, total protein and serum albumin were recorded retrospectively at the third month, then undergo follow up untill the end of the study. Hemoglobin level declined in 16% of patients. Serum albumin and total protein declined in 28% of patients. Vitamin D levels were declined in 40% of patients.

As regards complications, one patient (1.25%) had fever, tachycardia in the 2nd operative day, gastro-graphine study showed anastomotic leak. Laparoscopic exploration was done, and leak was found at the angle of anastomosis. Direct repair was performed and an omental patch was used to cover

the repaired leak **(Fig. 5)**. One patient (1.25 %) diarrhea which improved spontaneously after two attacks during the first operative month.

Two patients 2.5% had postoperative fever due to chest infection and port site infection.

One patient 1% had portside hernia. Results are shown in **(Tables. 1-4)** and **(Figs. 8-17).**

Fig 5: Repair of early leak, covered by omental patch.

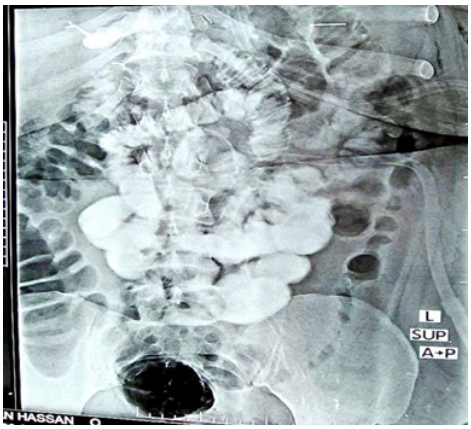

Fig 6: Passage of dye to the ileum.

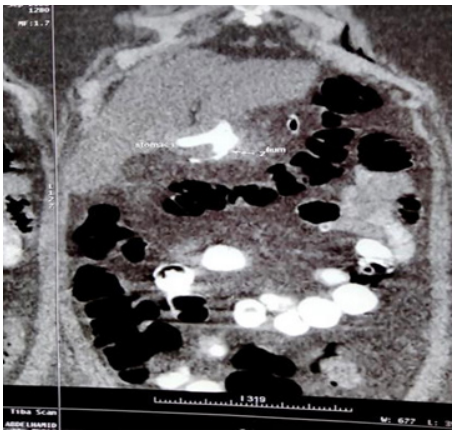

Fig 7: Gastroileal anastmosis (the white dye in the upper abdomen).

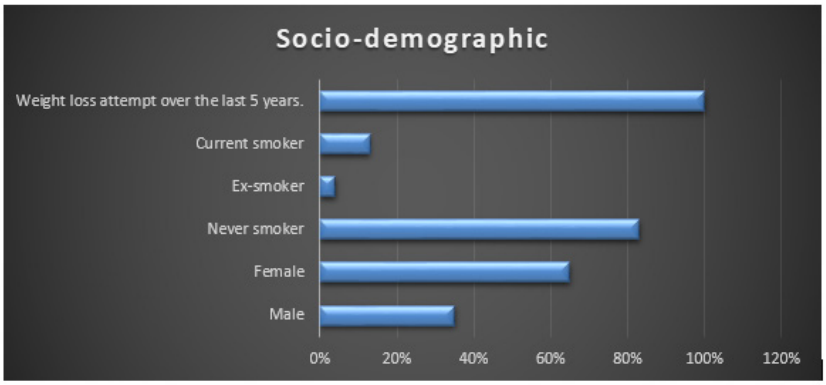

Fig 8: Shows socio-demographics of the patients.

Fig 9: Shows socio-demographics data.

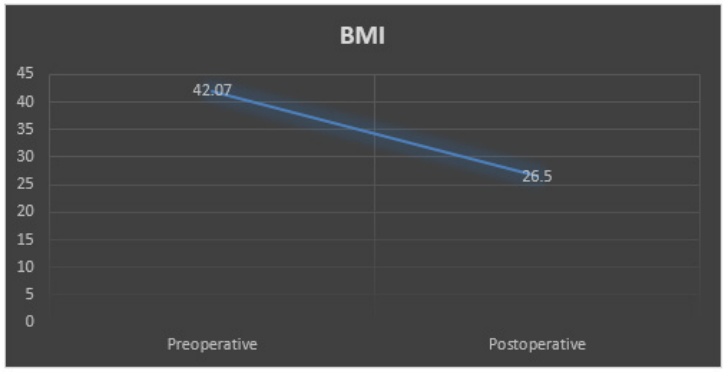

Fig 10: Shows curve of difference of Pre- and Post-operative BMI.

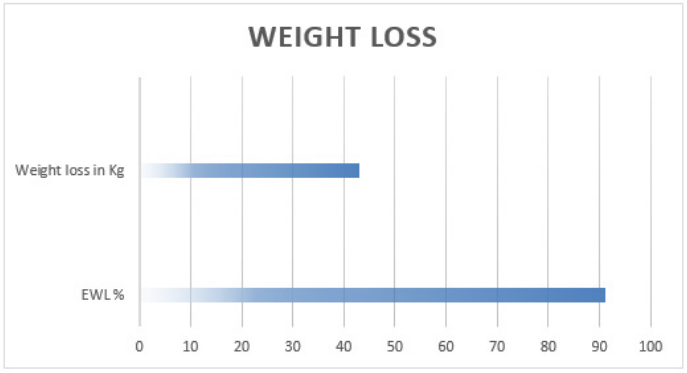

Fig 11: Shows weight loss in SASI group.

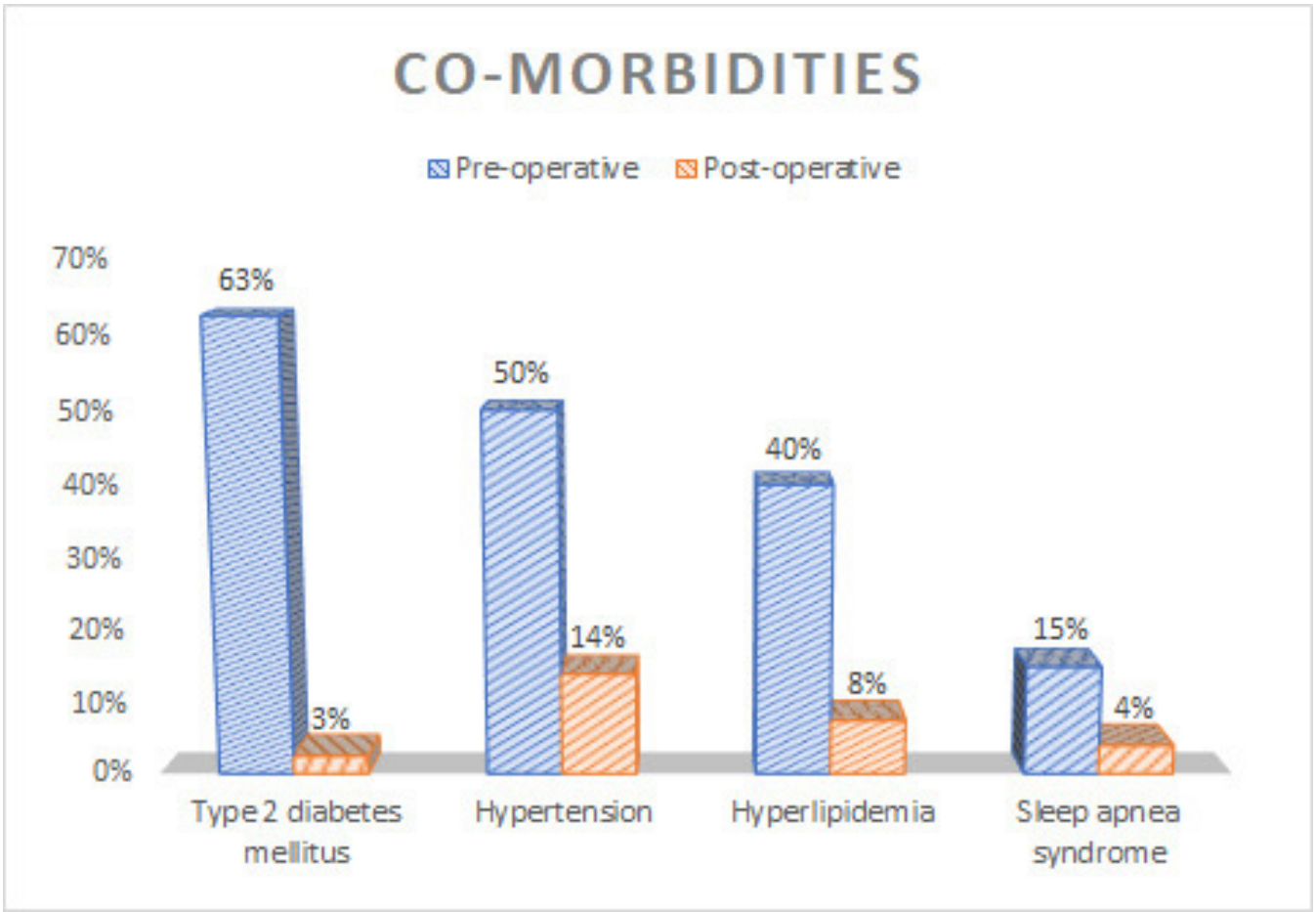

Fig 12: Shows co-morbidities pre- and post-operative.

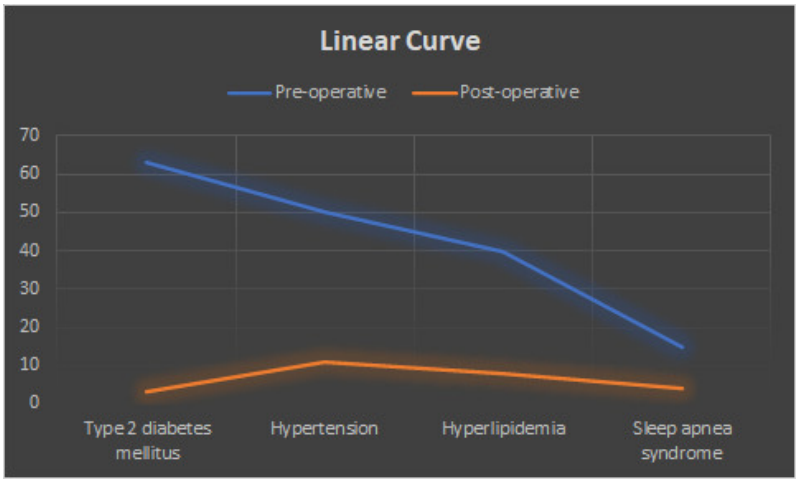

Fig 13: Shows linear curve of co-morbidities pre- and post-operative.

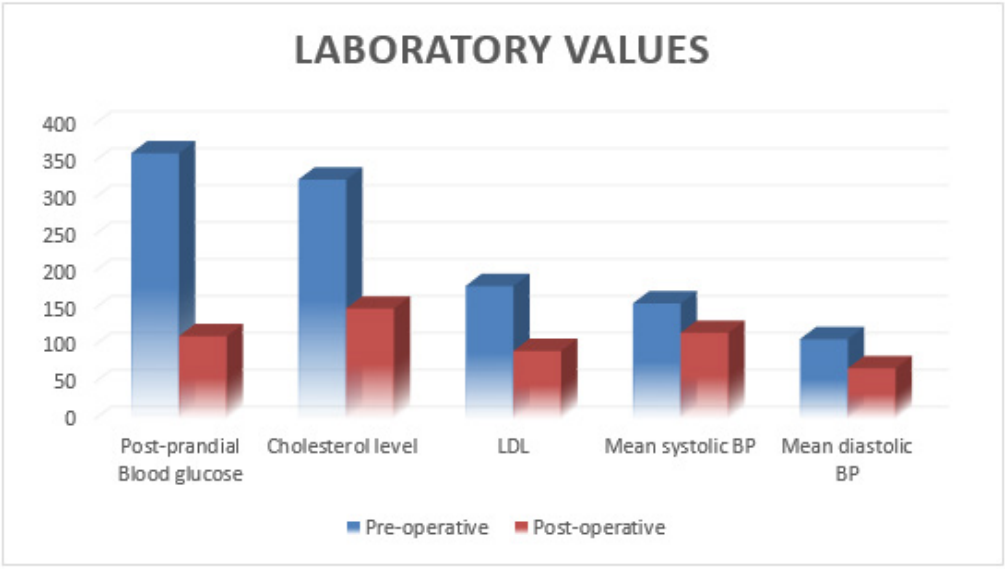

Fig 14: Shows Laboratory values pre- and post-operative.

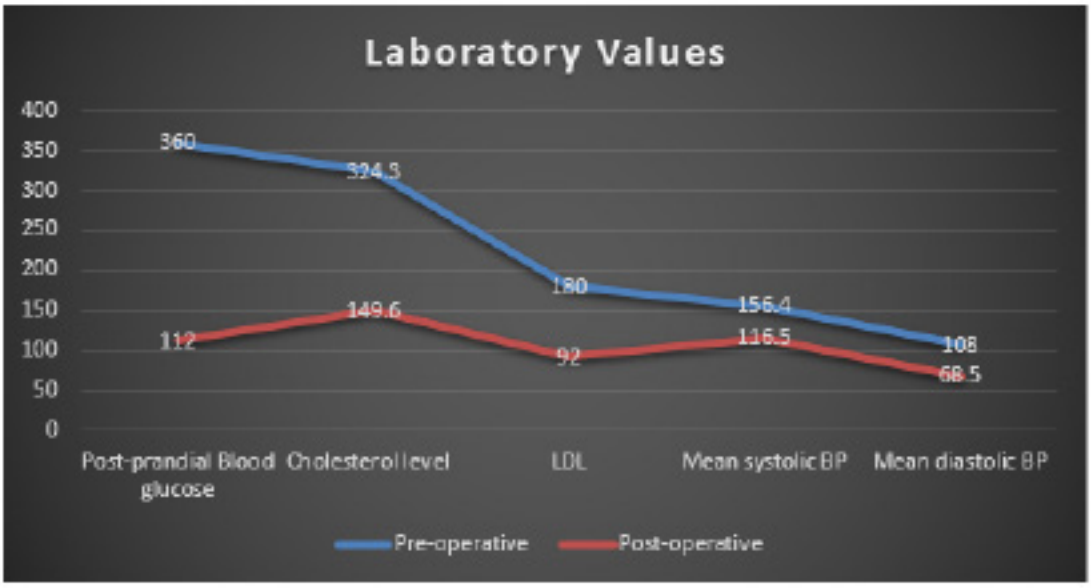

Fig 15: Shows linear curve of laboratory values pre- and post-operative.

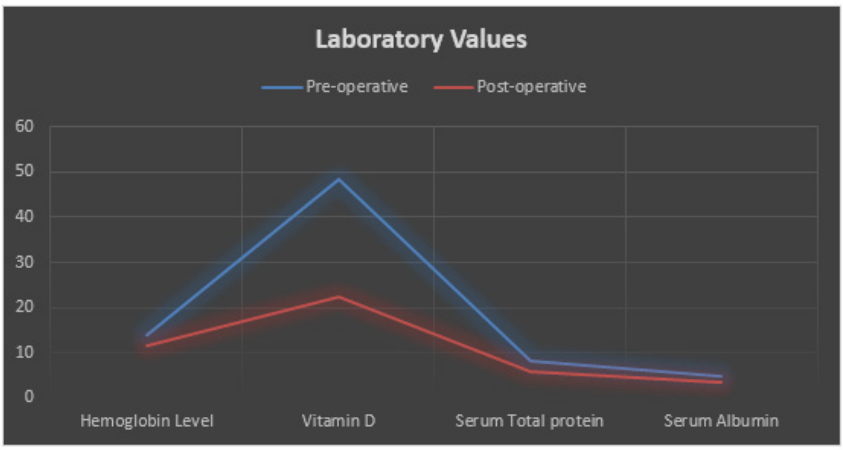

Fig 16: Shows Linear curve Laboratory values pre- and post-operative.

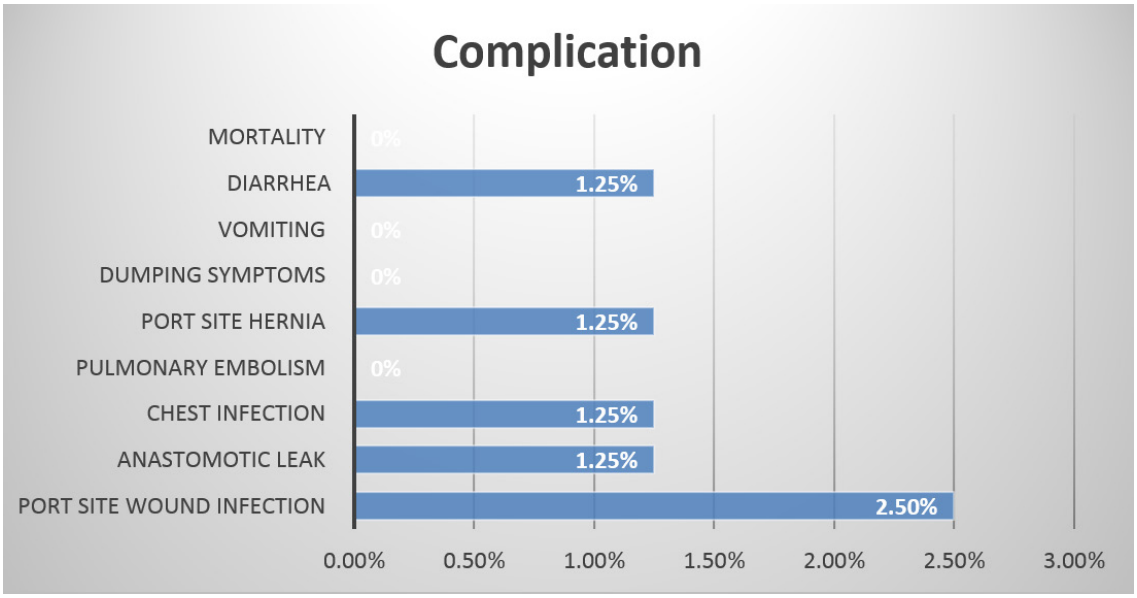

Fig 17: Shows Complication.

Table 1: Patient's demographics

Items	**Mean/SD. Number/%**	
Age (years)	38.66 ± 12.64	
Gender	**No.**	**%**
Male	28	35
Female	52	65
Weight (kg)	117.92 ± 23.21	
Height (m)	167.24 ± 5.72	
BMI (kg/m^2)	42.07 ± 7.49	
Smoking status	**No.**	**%**
Never	67	83.0
Ex-smoker	3	4.0
Current smoker	10	13.0
Weight loss attempt over the last 5 years	80	100.0

Table 2: Pre and postoperative BMI

	Preoperative	Postoperative	p value
BMI	42.07 ± 7.49	26.53 ± 7.29	<0.001*
EWL %		91.1± 4.7 % (71-100%)	<0.001*
Weight loss in Kg	----	43±15.78 (Rage 34- 83)	<0.001*

Table 3: Associated comorbidities

	Preoperative		Postoperative		p value
	No.	%	No.	Resolution	
Type 2 diabetes mellitus	50	62.5	2	96%	<0.001*
Hypertension	40	50	11	72.5.%	<0.001*
Hyperlipidemia	32	40	6	81.25%	<0.001*
Sleep apnea syndrome	12	15	3	75%	<0.001*
Post-prandial Blood glucose	360± 15		112± 18		<0.001*
Cholesterol level	324.3± 19.5		149.6± 15.5		<0.001*
LDL	180± 17.5		92± 6.6		<0.001*
Mean systolic BP	156.4± 12		116.5± 9		<0.001*
Mean diastolic BP	108± 7		68.5± 8		<0.001*
Hemoglobin level	13.8± 1.4		11.4± .8		<0.05*
Vitamin D level	48.6± 2.8		22.5± 1.2		<0.001*
Plazma protein level	8.2± .4		5.9± .2		<0.05*
Serum Albumin level	4.6± .4		3.4± .2		<0.05*

Table 4: Complications

	Number	%
Port site Wound infection	2	2.5%
Anastomotic leak	1	1.25%
Chest infection	1	1.25%
Pulmonary embolism	0	0%
Port site hernia	1	1.25%
Dumping symptoms	0	0%
Vomiting	0	0%
Diarrhea	1	1.25%
Mortality	0	0%

Discussion

Bariatric procedures can be subdivided into 3 basic categories based on their physiological mechanism: restrictive procedures, malabsorptive procedures, and combined procedures. Sleeve gastrectomy (SG) is considered one of the most popular bariatric procedures as it achieves satisfactory weight loss and improvement in comorbidities with acceptable low morbidity rate.[7]

Dyaczyński et al.[8] believed that SG tends to achieve the best outcome regarding weight loss and metabolic improvement when body mass index (BMI) is 50, defined as super obesity, represent a particular challenge to the health care system as those patients are more likely to have complex health issues and increased surgical risks.

The association between higher BMI and lower chances of successful weight loss and a higher risk of morbidity and mortality after bariatric surgery have been consistently shown.[9]

In patients with higher BMI, SG is usually combined with a malabsorptive procedure as the case with one-anastomosis gastric bypass (OAGB), single anastomosis duodeno-ileal bypass SADI, and single anastomosis sleeve ileal bypass (SASI). SASI has emerged as a novel bariatric and metabolic surgery in which SG is performed in conjunction with a single gastro-ileal loop anastomosis.[10]

Bhandari et al.,[11] reported that the main privilege of SASI bypass is that it maintains the normal pathway of food, allowing only a portion of ingested food to be absorbed, whereas the other portion is being bypassed directly into the ileum exerting the metabolic effect of the procedure. In addition, SASI is associated with minimal nutritional complications and allows complete endoscopic evaluation of the biliary system.

In the current study we reported that the mean postoperative BMI at 12 months was 26.53 (±7.29 SD) compared to 42.07 (±7.49 SD) preoperatively. The participants achieved a mean % EWL of 91.1± 4.7 % (range 71-100%). Matching our results with other authors results,[10,12,13] %EWL was higher in the present study, may be due to strict follow up. **(Tables 1,2 & Figures 9-11).**

Also, we illustrated that there was high statistically significant difference during the follow-up as regards type 2 diabetes which showed remission in 96% at 12 months after surgery p<0.001. Additionally, we reported that 80% of patients no longer required insulin by the 8th week after surgery. There was also high statistically significant difference between the other preoperative comorbidities as regards hypertension, hyperlipidemia and sleep apnea syndrome. (p<0.001).

(Table 3, Figures 12-15). In the present study we reported that patients could early tolerate larger amount of water without vomiting that could occur with restrictive surgeries. Reduced gastric pressure in turn addressed better hydration.

In the current study we reported some complications where minimal leak was reported in one patient and it was managed by laparoscopic exploration and direct repair, omental patch **(Figures 5).** Diarrhea was reported in one patient 1% during the 1st month after surgery and showed spontaneous resolution and it was not reported later on in any of the participants through the follow up.

Vit D3, Hb and plasma proteins level wasn't included prospectively in the study. However during routine unplanned checkup we found that hemoglobin level, Vitamin D, total plasma proteins and serum albumin were low at the 6th month of surgery. Hemoglobin level declined in 16% of patients. Serum albumin and total protein declined in 28% of patients. Vitamin D levels were declined in 40% of patients. **(Table 3, Figure 16).**

So, we started therapeutic doses of Vit D3, iron supplementation and encouraged higher protein intake and addition of protein powder to meals. These nutritional findings require further prospective studies in future.

Again, one patient developed fever, tachycardia and leukocytosis the 2nd day after surgery and was diagnosed to have chest infection where he improved on medical treatment. Another patient had fever due to port site infection with gm +ve cocci which was managed conservatively. The rate of surgical complications in the present study were low and easy to control.

Matching our results with other studies, Madyan et al.[10] showed that twenty patients were included to their study. Their mean baseline BMI was 53.7 ± 5.9 kg/m^2 (Range, 50.8 to 64 kg/m^2). They reported significant decrease in BMI at 6 months after SASI bypass, (From 53.7± 5.9 preoperatively to 39.9± 5.2 kg/m2; P < 0.0001). Body weight also significantly decreased (144.3± 18 to 105.3± 14.6 kg; P<0.0001). in. The mean %EWL at 6 months was 44.3± 7.8 (Range, 21.5 to 58.3) and 65.2±12.6 at 12 months.

In a study conducted by Mahdy et al.[12] on three hundred ninety patients, their mean preoperative BMI was 43.2 ± 12.5 (Range, 35–80) kg/m^2 and their mean preoperative weight was 119.3 ± 37.9 (Range, 73.6–234) kg. Twelve months after surgery they reported that % EWL was 63.9 ± 29.5 (Range, 24.5–98.8). Additionally, after the SASI bypass, a significant decrease in BMI was observed (From 43.2 ± 12.5 to 31.2 ± 9.7 kg/m^2; p < 0.0001).

Salama et al.[13] reported that twenty-eight patients with an average BMI of 45.6 kg/m^2 ranging between 40.5 kg/m^2 and 58.4 kg/m^2. Patients of their study underwent revisional laparoscopic SASI after failed LSG. The mean interval time from the primary operation was 24.2 months (Range 18-40 months). They illustrated that their mean BMI decreased from 45.6 kg/m^2 preoperatively to 32.1 kg/m^2 postoperatively (Ranging from 24.8 kg/m^2 to 41.5kg/m^2) at 12 months.

Authors,[14,15] reported that sleeve gastrectomy may require revisional surgery after few years and may need conversion to RYGB due to failure to maintain successful weight loss. GERD also represents a serious challenge for the purely restrictive bariatric procedures such as the sleeve gastrectomy which has possible consequences of Barrett's esophagus Naik et al.[16]

A recent meta-analysis by Emile et al.,[17] concluded that sleeve gastrectomy may expose the distal esophagus to severe reflux, with an incidence of de novo reflux seen in up to 23% of patients.

In the present study we agreed with the concept that adding an anastomosis between the distal gastric sleeve and the ileum could reduce the intragastric pressure. Moreover, we believed that the valveless stoma between the ileum and the stomach can deflate potential high gastric pressure into the two ileal limbs thus contribute to the amelioration of 2ndry GERD.

Again Madyan et al.[10] showed that at 12 months after SASI bypass, 4 patients with type 2 DM showed complete resolution and one patient showed improvement in the diabetic state. Two patients with hypertension showed complete resolution, one showed improvement and the other one did not show improvement. Both patients with GERD and the patient with osteoarthritis reported marked improvement in their symptoms. They also reported that a female patient with primary infertility got pregnant at 7 months after SASI bypass.

Additionally, Mahdy et al.[12] also reported Among 279 patients with T2DM, complete remission was recorded in 234 (83.9%) patients and partial improvement in 43 (15.4%) patients. They added that 277 (99.3%) patients showed either complete remission or partial improvement in their glycemic state after SASI bypass. Patients who developed complete remission of T2DM showed a significant decrease in fasting blood glucose and a significant decrease in HbA1c. Eighty-six (36.1%) of 238 patients with hypertension, 104 (65%) of 160 patients with hyperlipidemia, 37 (57.8%) of 64 patients with (Obstructive sleep apnea syndrome) OSAS, and 70 (92.1%) of 76 patients with GERD showed remission after having the SASI bypass.

In the present study, laparoscopic single anastomosis sleeve ileal bypass had positive impact on weight loss. It showed highly significant disease resolution as regards type 2 diabetes, hypertension and hyperlipidemia. The procedure is technically simple which provide short learning curve. However its initial negative impact on vitamin D and plasma proteins level should be studied in details in further studies. Although the procedure seemed efficient but there is little data in literature and more studies and long term follow up is required to build solid evidence of its safety and efficiency.

Conclusions

SASI bypass seems to be an effective bariatric procedure that confers significant loss of weight and is efficient in controlling diabetes mellitus, hypertension and hyperlipidemia however its nutritional effects are still not clear and needs future studies to confirm whether post operative nutritional support and/or supplementations are required or not.

Study limitations

The number of studied patients is not large and detailed nutritional assessment needs future and longer follow up.

Consent to participate in the study

Patients informed consent was taken from all participants.

Competing interest

The authors declare that they have no competing interest

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