

# Evaluation of Laparoscopic Single Anastomosis Sleeve Ileal Bypass (SASI) as a Treatment Modality for Morbidly Obese Patients with Type 2 Diabetes Mellitus

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**Abstract:** *The single anastomosis sleeve ileal (SASI) bypass is a Novel Metabolic/Bariatric Surgery operation based on mini gastric bypass operation and Santoro's operation in which a sleeve gastrectomy is followed by a side to side gastro-ileal anastomosis. Amidst the current worldwide epidemic of type 2 diabetes mellitus (T2DM), the global diabetes health burden is projected to reach 522 million in 2030, with much of this increase occurring in developing countries. Aim of the work: to evaluate the role of single anastomosis sleeve ileal bypass (SASI) as a bariatric and metabolic procedure in control of type 2 diabetes in obese patients over one year post-operative. Patients and methods: This prospective cohort study included 40 obese adult patients with type 2 DM. Some of them have other associated comorbidities. They were recruited at department of surgery, Misr University for science and Technology and Al-Azhar University. The follow up was obtained during the first year post-operative. Results: In this study, complete remission of diabetes was achieved in 80% of the patients by the end of the study. This was beside marked weight reduction and improvement of lipid profile without causing micronutrients deficiencies during the study period. Conclusion: SASI bypass can be one of the most efficient metabolic procedures and could be associated with less risks. The procedure should be considered under investigations until enough long term data are available. Thus it is worth to be explored in research aiming for more data.*

**Keywords:** SASI bypass, Obesity, Type 2 diabetes

## 1. Introduction

Obesity has become a national and worldwide epidemic. It is not just a cosmetic consideration, it is a chronic medical disease that can lead to diabetes, hypertension, heart disease and other chronic illnesses. Although dietary and lifestyle modifications have traditionally been the mainstay of treatment of obesity, their lack of success at long-term weight reduction and the paucity of effective pharmacologic agents led to change the direction to the surgical management to find a perfect solutions to satisfy the patient and make his life more comfortable. [1]

Obesity is defined as, a body mass index (BMI) of 30 kg/m<sup>2</sup> or more. Morbid obesity is defined as a body mass index (BMI) of > 40 kg/m<sup>2</sup> or BMI > 35 kg/m<sup>2</sup> together with obesity-related disease. [2]

Diabetes is particularly common among the morbidly obese, and in some series as many as 30% of those referred for bariatric surgery had type 2 diabetes mellitus. In the morbidly obese, weight loss also has a powerful preventative effect on the development of diabetes. [3]

Bariatric surgery is known to be a highly effective and long lasting treatment achieving long-term weight loss for morbid

obesity and many related conditions, including type 2 diabetes mellitus. [4]

Single anastomosis sleeve ileal bypass (SASI) procedure appeared as a new metabolic and bariatric surgery, in which a sleeve gastrectomy is followed by a side-to-side gastroileal anastomosis. [5]

**Why SASI:** Because it combines between the advantages of both restrictive and malabsorptive procedures as it is more durable and overcomes the vitamins and mineral deficiency problems occurring in other malabsorptive surgeries as almost 30% of the food passes through its normal way so vitamins and minerals will be absorbed normally and the remaining 70% passes through the gastric bypass to the intestine directly to avoid absorbing a bigger quantity of fats and sugar which will result in weight loss and diabetic resolution. [6]

Moreover, some studies state that the incidence of leakage and gastroesophageal reflux disease (GERD) from sleeve gastrectomy was significantly decreased after performing gastro jejunostomy due to decrease in the stomach tube pressure. [7]

## 2. Aim of the Work

The aim of this thesis is to Study the short term effect of Laparoscopic Single anastomosis sleeve ileal bypass (SASI) on Obese Patients with Type 2 Diabetes Mellitus as regards control of plasma glucose level.

### Obesity and Type 2 Diabetes Mellitus

Obesity has reached epidemic proportions globally, and all evidence suggests that the situation is likely to get worse. In developed regions such as Europe, the USA, and Australia the prevalence is high and increasing but in some developing countries even more extreme situations exist. Coincident with the high rates of obesity, the prevalence of type 2 (non-insulin-dependent) diabetes mellitus is also escalating, and this increase is expected to continue, so that by the year 2030 it is predicted that a total of 216 million people worldwide will have type 2 diabetes. [8]

### *The 'DIABESITY' Epidemic & Magnitude of the problem*

The World Health Organization has termed the increased prevalence of obesity and diabetes as a '21st Century epidemic'. Obesity is the most frequently encountered metabolic disease worldwide. Moreover, its incidence and prevalence are rising rapidly. More than half of the world's population is considered to be overweight. [9]

Being overweight constitutes a health risk as it is associated with several comorbidities including type 2 diabetes mellitus (T2DM), cardiovascular diseases, hypertension, dyslipidaemia, hyperuricaemia, respiratory diseases, osteoarthritis and depression. [10]

The vertiginous rise in obesity triggers a parallel upward swing in diabetes mellitus statistics. According to Ford et al., for every kilogram of weight gain, the risk of diabetes increases 4.5 %. [11]

Obesity and T2DM frequently occur together, and statistics show that 60-90% of all patients with T2DM are or have been obese. Obesity is generally considered to be a strong risk for the later development of T2DM. Studying this problem over time, the question arises whether obesity is not only a risk factor but also a cause of T2DM. [12]

Morbid obesity can lead to affecting nearly every organ system. Because of their impact on the patients' quality of life, life expectancy, and health care finances, obesity and its related co-morbidities constitute a significant health problem worldwide. [13]

### Pathogenesis of T2DM

The pathophysiology of glucose intolerance in T2DM is complex and involves both genetic and acquired factors. Among the acquired factors, weight gain and physical inactivity are of paramount importance. In diabetic individuals with overt fasting hyperglycemia, the triumvirate of 1) impaired insulin secretion by the pancreatic  $\beta$ -cells, 2) muscle insulin resistance, and 3) hepatic insulin resistance all play central roles in the development and progression of glucose intolerance. [14]

### Surgery to treat morbid obesity may be contraindicated if candidates have shown any of the following:

- Peri-operative risk of cardiac complications.
- Poor myocardial reserve.
- Significant chronic obstructive airways disease or respiratory dysfunction.
- Non-compliance with medical treatment.
- Psychological disorders of a significant degree that would be considered by a psychologist or psychiatrist to worsen or interfere with the long-term management of the patient after the operation.
- A serious eating disorder.
- Severe hiatus hernia /gastroesophageal reflux. [15]

### Single Anastomosis Sleeve Ileal Bypass

Such a procedure maintains the normal pathway of food, allowing only a small percentage of ingested food to be absorbed, while the majority of food is bypassed directly into the ileum and induces the metabolic effect of the procedure. In addition, it has the advantages of being associated with minimal postoperative nutritional complications and allows the complete visualization of biliary system using endoscopy. [16]

### Anesthesia:

General endotracheal anesthesia with muscle relaxant was used for all patients.

## 3. Surgical Technique

### 3.1 Sleeve gastrectomy

The patient is positioned in 30° anti-Trendelenburg position with legs abducted. The surgeon stands between the patient's legs, the first assistance, holding the camera, is on the left side of the patient aside the scrub nurse, a second assistant is placed on the right side. Pneumoperitoneum is generally created using Veress needle placed in the left subcostal margin (Palmer's point). After obtaining a pneumoperitoneum pressure of 15 mmHg, the Veress needle is withdrawn and replaced by a 12-mm optical trocar to allocate the camera. Four additional trocars are placed in the upper abdominal quadrants under direct vision. The procedure starts with the identification of the pylorus. Using a marked grasper and stretching the gastric wall, a distance of 4-6 cm along the greater gastric curvature is measured and marked. [17]

The first maneuver of the procedure is skeletonization of the greater curvature. Radiofrequency or ultrasound energy instruments are used. The skeletonization is completed toward the pylorus until the 4-6 cm mark is reached and then it proceeds upward to the angle of His. The complete mobilization of the fundus is of primary importance to achieve a correct fundectomy.

Once the stomach is completely mobilized, an oro-gastric tube (Bougie) is inserted by the anesthesiologist in order to calibrate the resection. A 38-French bougie is pushed down possibly through the pylorus and placed against the lesser

curvature. Gastric resection is performed using a linear stapler. The stapler is applied alongside the calibrating bougie. Because of the decreasing thickness of the gastric wall from the antrum to the corpus and fundus, the cartridges must be chosen accordingly. The staple height used is 4.4 or 4.1 mm near the antrum and 3.8 or 3.5 mm on corpus and fundus. [18]

Before closing and firing the staplers, the anterior and posterior gastric walls are fully stretched by two graspers positioned on the greater curve and moved along it. At the incisura angularis, the stretching is somewhat loosened to avoid a functional stricture that may occur at this level. The last cartridge is fired 1-2 cm away from the angle of His so that the staple line does not fall in the "critical area". At the end of the procedure, the staple line is meticulously checked and bleeding spots are treated by hemostatic clips or stitches. A nasogastric tube is positioned in the gastric remnant and a methylene blue dye test is routinely performed to check the sealing of the staple line and to evaluate the residual gastric capacity, usually 60-80 ml. [17]

### 3.2 Sleeve-ileal anastomosis

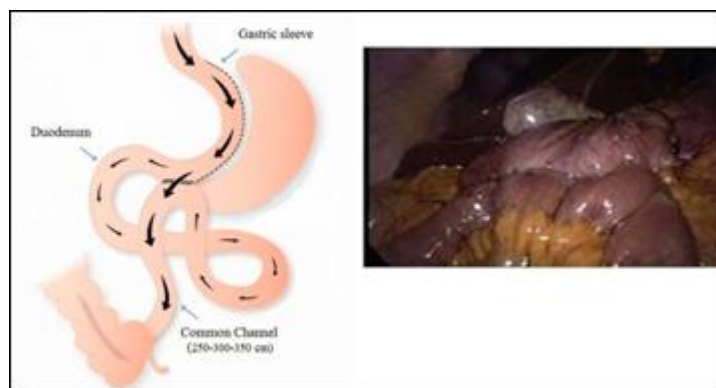
After creation of the sleeved gastric tube, Identification of the caecum and ileo-caecal junction with great caution during manipulation. Standardizing the measurement process is crucial because a common channel shorter than 250 cm would inevitably result in mal absorption and malnutrition. Finally, it is imperative that the gastroileal anastomosis be constructed at least 2-3 cm away from the pylorus in order to avoid disturbing the pyloric sphincter function which may then lead to complete diversion of food

through the anastomosis. Moreover, the anastomosis should be done with the anterior gastric wall because a posterior anastomosis would be more dependent and may lead to complete diversion instead of bipartition. The size of the gastroileal anastomosis should not exceed 3 cm, otherwise more food will favorably go through the wider anastomosis. [19]

Using the Harmonic scalpel, a small gastrotomy was done at the infero-lateral end of the sleeve, and a small enterotomy was done adjacent to it. A 45mm articulating green cartridge was introduced through the surgeon's right hand side was used to perform a side to side sleeve-ileal anastomosis in an isoperistaltic horizontal direction. The 2 limbs of the stapling cartridge were introduced in the way that the anastomosis didn't exceed 3cm. [20]

The staple defect was then closed with a one layer running 3/0 Vicryl sutures. A hypnotic stitch was taken between the afferent ileal loop and the sleeve to decrease tension on suture line. With boujie in place and control of both afferent and efferent ileal loops. A methylene blue test was done to test water tightness.

The transected stomach was then removed through the 15mm trocar site. An intra-abdominal tube drain was inserted alongside the sleeve and the anastomosis before the liver retractor was removed. Gradual abdominal deflation, removal of trocars under vision and skin closure with subcuticular monofilament absorbable sutures were the last steps. [21]



### 3.3 Postoperative care:

- 1) Patients received nothing by mouth post operatively till gastrografen contrast study was performed on the third post operative day.
- 2) Patients received an anticoagulant therapy; elastic stocking and subcutaneous low molecular weight heparin as prophylactic measures against postoperative pulmonary embolism.
- 3) Patients received intravenous broad spectrum antibiotic together with intravenous analgesia (drip method) to provide more consistent pain relief than intermittent injections
- 4) The patients received proton pump inhibitors to avoid stress ulcers.

- 5) Nasogastric tube was commonly removed if present in the second post operative day after the contrast study.
- 6) After removal of the nasogastric tube the patients were instructed to start clear oral fluids.
- 7) Patients were usually discharged in the third post operative day.
- 8) Patients were instructed to follow up five stages diet regimen under supervision of the nutritionists.

### 4. Follow-up

The follow up period was carried out on an outpatient basis: Weekly visit for one month after discharge from the hospital then follow-up is obtained at 3, 6, 9 and 12 months and then yearly by:

BMI, FBG, PPG, HbA1c, Dose and discontinuation of anti-diabetic medications, Dose and discontinuation of anti-hypertensive medications, Blood pressure, Lipid profile.

## 5. Patients & Methods

### Patients

This study was carried out in Al-Azhar University Hospitals, and Misr University Hospital, during the period starting from November 2019, till from November 2021. This study was designed as a one-armed clinical trial (prospective interventional) study, to evaluate the effect of Laparoscopic Single anastomosis sleeve ileal bypass (SASI) on obese patients with type 2 diabetes mellitus. Fourty patients were included in this study.

### Inclusion criteria:

- 1) Age: adult  $\geq 18$ -year-old.
- 2) Gender: both males and females.
- 3) BMI:  $\geq 35$  kg/m<sup>2</sup>, associated with obesity-related comorbidities, (including type 2 diabetes mellitus).  
Where diabetes mellitus is diagnosed when:
  - Symptoms of diabetes and a random blood sugar of 200 mg / dl (11.1 mmol / L) or higher, or
  - A fasting blood sugar level of 126 mg / dl (7.0 mmol / L) or higher, or
  - An Hb A1c of 6.5 percent or higher.
- 4) Failure of  $\geq 6$  months of organized non-surgical weight loss attempts.
- 5) Commitment to comprehensive medical and psychologic evaluations before and after surgery.
- 6) Commitment to medical and nutritional requirements postoperatively.
- 7) Ability to provide consent for surgical treatment.

### Exclusion criteria:

- 1) History previous gastric or bariatric surgery.
- 2) History of upper laparotomy.
- 3) Pregnancy or lactation.
- 4) Drug or alcohol addiction.
- 5) History of psychological instability.
- 6) Medically correctable cause for obesity.

### Pre-operative workup

All patients included in this study were subjected to **Verbal and written consent, complete history taking**, including (Co-morbid conditions including diabetes mellitus, hypertension, dyslipidaemia, and cerebro-vascular strokes, Previous surgeries, Dietary habits, Alcohol or drug intake). And full **clinical examination**, including (Conscious level, Complexions, Vital data, including blood pressure, Abdominal examination, BMI assessment). **Investigations**, including: Complete blood count. Liver function tests. Kidney function tests, Coagulation profile. Blood sugar, (fasting and postprandial), Glycosylated hemoglobin A1c, Serumcortisol. Lipid profile, Thyroid function tests, Chest X-ray, Abdomino-pelvic ultrasonography.

### Outcomes Assessment:

Weight loss depending on the change in BMI which was measured at the initial screening on the day of surgery, 1

week at stitch removal and at 1, 3, 6, and 12 months after surgery.

Intra- operative and post operative complications (early or late) were recorded for each operation.

- D. M control by measurement of HbA1c at 3, 6 and 12 months and FBS at 1, 3, 6 and 12 months with follow up of changes in dose or discontinuation of anti-diabetic medications.
- Hypertension control by measurement of Blood pressure at 1, 3, 6 and 12 months with follow up of changes or discontinuation of Anti-hypertensive medications.
- Hyperlipidemia control by lipid profile at 1, 3, 6 and 12 months.

## 6. Results

All of the forty patients included in this study, underwent laparoscopic single anastomosis sleeve ileal bypass (SASI). SASI was performed according to National Institutes of Health criteria for bariatric surgery indications. The surgical operation was applied as the previously described technique.

The mean operative time was  $125.2 \pm 15.6$  mins (range 90 – 150), being the maximum in highest BMI patients and in those who had intra-operative difficulties, and minimum in lower BMI patients and those with uneventful operations.

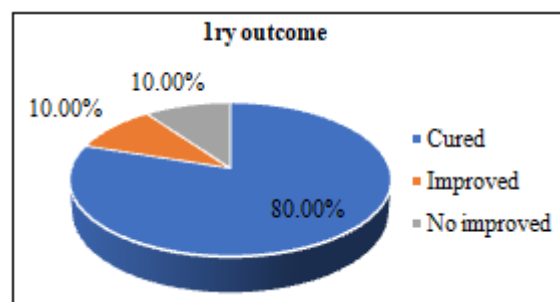


Chart 1: Primary Outcome

### Comparison between baseline and at different months follow-up weight

There was a highly significant difference between weight at baseline and at 1, 3, 6, and 12 months after operation, (p value 0.001). Also, there was a highly significant difference between weight at 3 months and at 6 months after operation, (p value 0.001). Similarly, there was a highly significant difference between weight at 6 months and at 12 months after operation, (p value 0.001).

Table 1: Comparison between baseline and at different months follow-up weight repeated measures ANOVA

	Mean	SD	P value compared to baseline
Weight baseline (kg)	127.1	10.2	---
Weight after 1 month	117.67	8.81	<0.001
Weight after 3 months	108	7.95	<0.001
Weight after 6 months	101.37	7.73	<0.001
Weight after 9 months	97.78	6.8	<0.001
Weight after 12 months	94.33	6.55	<0.001

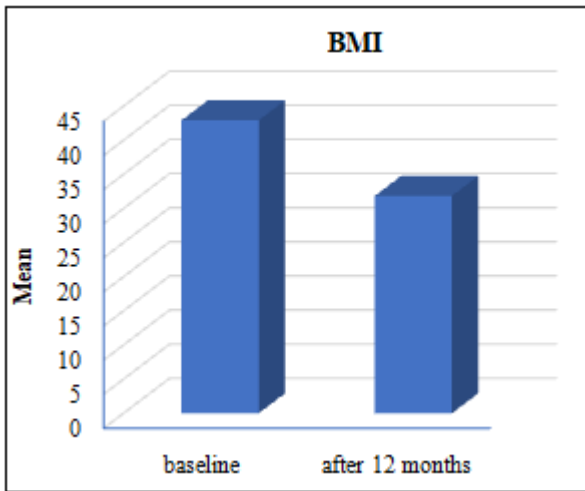
**Comparison between baseline and 12 month follow-up BMI**

There was a highly significant difference between BMI at baseline and at 12 months after operation, (p value 0.001).

**Table 2:** Comparison between baseline and 12 month follow-up BMI

	Mean	SD	P value compared to baseline
BMI baseline	42.92	2.49	
BMI after 12 months	31.84	1.03	<0.001

\*Paired t test



**Chart 2:** BMI at baseline and 12 months.

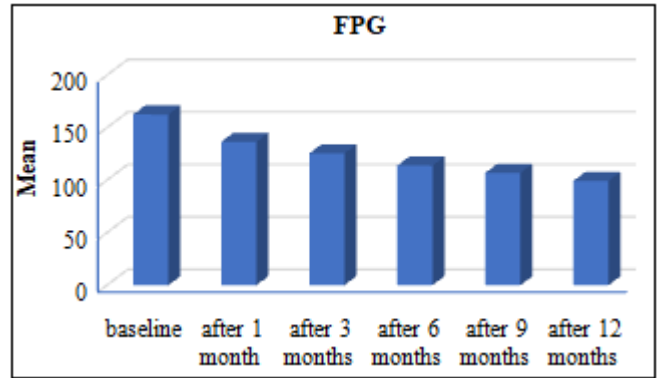
**Comparison between baseline and follow-up fasting plasma glucose level**

There was a highly significant difference between FFG at baseline and at 1, 3, 6, and 12 months after operation, (p value 0.001). Also, there was a highly significant difference between FFG at 3 months and at 6 months after operation, (p value 0.001). Similarly, there was a highly significant difference between FFG at 6 months and at 12 months after operation, (p value 0.001).

**Table 3:** Comparison between baseline and follow-up fasting plasma glucose level

	Mean	SD	P value compared to baseline
FPG baseline	162.63	15.99	---
FPG after 1 month	136.57	19.16	<0.001
FPG after 3 months	125.53	15.92	<0.001
FPG after 6 months	113.93	16.70	<0.001
FPG after 9 months	106.98	18.40	<0.001
FPG after 12 months	99.20	23.42	<0.001

\*Paired t test



**Chart 3:** FPG at baseline, 1, 3, 6, and 12 months.

**Comparison between baseline and follow-up postprandial plasma glucose level**

There was a highly significant difference between PPG at baseline and at 1, 3, 6, and 12 months after operation, (p value 0.001). Also, there was a highly significant difference between PPG at 3 months and at 6 months after operation, (p value 0.001). Similarly, there was a highly significant difference between PPG at 6 months and at 12 months after operation, (p value 0.001).

**Table 4:** Comparison between baseline and follow-up postprandial plasma glucose level

	Mean	SD	P value compared to baseline
PPG baseline	233.70	19.91	---
PPG after 1 month	190.02	21.85	<0.001
PPG after 3 months	177.55	24.29	<0.001
PPG after 6 months	163.85	22.90	<0.001
PPG after 9 months	152.17	26.98	<0.001
PPG after 12 months	146.53	32.64	<0.001

\*Paired t test

**Comparison between baseline and at different months follow-up Hb A1c level**

There was a highly significant difference between HB A1c at baseline and at 3, 6, and 12 months after operation, (p value 0.001). Also, there was a highly significant difference between HB A1c at 3 months and at 6 months after operation, (p value 0.001). Similarly, there was a highly significant difference between HB A1c at 6 months and at 12 months after operation, (p value 0.001).

**Table 5:** Comparison between baseline and at different months follow-up HbA1c level

	Mean	SD	P value compared to baseline
Hb A1c baseline	8.97	1.48	---
Hb A1c after 3 months	7.62	1.45	<0.001
Hb A1c after 6 months	6.32	1.5	<0.001
Hb A1c after 9 months	6.25	1.54	<0.001
Hb A1c after 12 months	5.78	0.86	<0.001

\*Paired t test

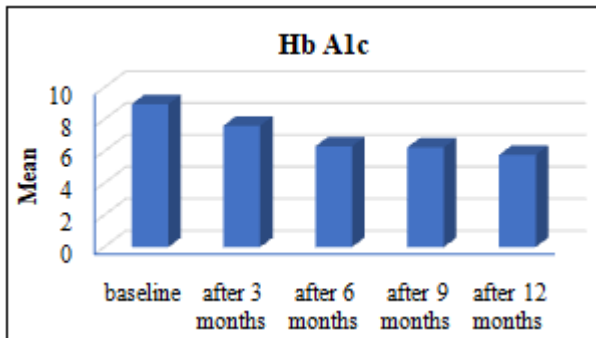


Chart 4: HbA1c at baseline, 3, 6, and 12 months.

Table 6: Secondary Outcome.

		Count	%
2ry outcome	Cured	22	55.00%
	Improved	7	17.50%
	No improved	11	27.50%

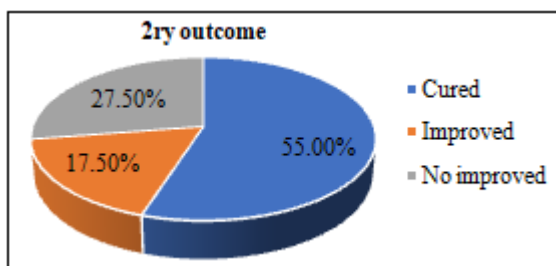


Chart 5: Secondary Outcome.

**Incidence of complications**

Out of 40 patients, 87.5 % (n= 35) had no complications. In the complication group, 5 % (n= 2) were affected by bilious vomiting and dehydration, 2.5 % (n= 1) were affected by stomal ulcers and stenosis and 2.5 % (n= 1) were affected by anastomotic intraluminal bleeding. Also 2.5 % (n= 1) were affected by surgical site infection.

Table 7: Incidence of complications

		Count	%
complications	vmt&deh	2	5%
	Stenosis	1	2.50%
	SSI	1	2.50%
	Bleeding	1	2.50%
	No	35	87.50%
ttt of complication	Hosp	2	40%
	Endoscopy	1	20%
	Antibiotic	1	20%
	Hosp & BI trans	1	20%
synch	Chole	2	5.00%
	No	38	95.00%

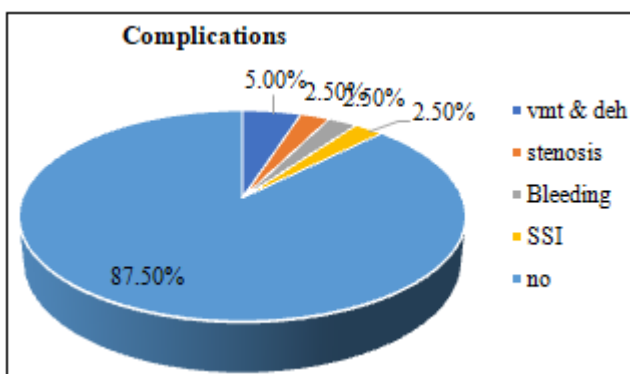


Chart (6): Complications

**7. Discussion**

Sleeve gastrectomy has become the most common bariatric procedure due to its excellent results. But a number of drawbacks of this procedure have been recognized such as a high incidence of postoperative GERD, weight regain on long-term follow-up and being less effective in super obese patients [(Elbanna et al., 2016), (Yeung et al., 2019) ]. SASI is a new surgical procedure; it is a modification of the sleeve gastrectomy by adding a single anastomosis between the gastric antrum and the ileum. This study is reporting clinical review of the efficacy of SASI bypass.

**Primary outcomes**

In literature, Almost studies have assessed the efficacy and safety of SASI bypass and reported excellent results with %EWL. the rate of loss of excess weight with one year follow up, a mean value of 94.33% as reported by (Vennapusa et al., 2017), 93.2% (Khalil et al., 2019), 63.9% (Mahdy et al., 2020), 86.2% (Kermansaravi et al., 2020), 86.9% (Khalaf and Hamed, 2020), 65.2% (Madyan et al., 2020), 85.6% (Romero and Rey Jesus, 2021), 87.6% (Mahdy et al., 2021) and 72.6% as reported by (Emile et al., 2020). The mean EWL % in our study is 61.38 + 1.08 at 12 months. Similarly, the mean BMI also reduced substantially (31.84 kg/m<sup>2</sup>) in accordance with the earlier studies, 25.39 kg/m<sup>2</sup> as reported by (Vennapusa et al., 2017), 22.6 kg/m<sup>2</sup> (Khalil et al., 2019), 31.2 kg/m<sup>2</sup> (Mahdy et al., 2020), 28.1 kg/m<sup>2</sup> (Kermansaravi et al., 2020), 33.6 kg/m<sup>2</sup> (Madyan et al., 2020), 32.1 kg/m<sup>2</sup> (Salama et al., 2020), 33.8 kg/m<sup>2</sup> (MohamedAbdulla et al., 2020), 28.2 kg/m<sup>2</sup> (Romero and Rey Jesus, 2021), 26.6 kg/m<sup>2</sup> (Mahdy et al., 2021)) and 30.6 kg/m<sup>2</sup> as reported by (Emile et al., 2020). Previous literature showed that SASI bypass has significantly higher %EWL at 12 months than other bariatric procedures [(Buchwald et al., 2004), (Alobaid et al., 2015) ] such as SG (72.6 Vs 60.4, p < 0.0001) [(Emile et al., 2020), (Emile et al., 2017), (Mahdy et al., 2016) ], bilio-pancreatic diversion (BPD) and the duodenal switch procedure.

It is expected that the loss of excess weight may be even more if patients follow the nutritional guidelines strictly, which is high-protein low-calorie diet and regular exercise. [22]

Significant improvement of plasma glucose level control, and / or resolution of type 2 diabetes mellitus (as evident by diabetic markers like fasting as well as post prandial plasma glucose levels, and HbA1c), is commonly observed after SASI bypass. After 12 months, a remission of type 2 diabetes mellitus after SASI was 100 % as reported by (Mahdy et al., 2016), 83.9 % as reported by (Mahdy et al., 2020), 78.6 % as reported by (MohamedAbdulla et al., 2020), 95.8 % as reported by (Emile et al., 2020). In our study, resolution of type 2 diabetes mellitus occurred in 80 % of patients (n= 32), and improvement occurred in 10 % of patients (n= 4).

HbA1c followed a similar pattern to that of both FPG. A significant reduction was observed from baseline (9.9) to 6 months (5.7) and continued to decrease throughout the follow-up period until stabilizing at the 12 months (5.1), as reported by Mohamed Abdulla et al., 2020. Romero and Rey

Jesus, 2021 reported a mean HbA1c 9.7 at baseline and 5.6 at 12 months postoperative. Also Mahdy et al., 2020 reported a mean HbA1c 8.1 at baseline and 5.3 at 12 months postoperative. Similarly, in our study, HbA1c, demonstrated a significant reduction from 8.97 at baseline, to 7.62 at 3 months and continued to decrease to 5.78 at 12 months postoperatively.

### Secondary outcome

The most commonly resolution criteria for hypertension is systolic blood pressure < 140 mmHg and diastolic blood pressure < 90 mmHg, without antihypertensive agents. The most commonly resolution criterion for dyslipidemia is normal plasma lipid without drug. In our series, the mean baseline SBP and DBP of the study cases was 130.5 mm Hg and 83.5 mm Hg respectively. After 12 months, the mean SBP and DBP was 123 mm Hg and 80 mm Hg respectively.

Ten series reported the evolution of preoperative Hypertension. Remission or improvement of HTN after one year has varied between 75% and 94, 44% in seven series [(18), (Vennapusa et al., 2017), (Mohamed Abdulla et al., 2020), (Kermansaravi et al., 2020), (Madyan et al., 2020), (Mahdy et al., 2021), (Romero and Rey Jesus, 2021) ] and between 23, 2% and 57.1% in only three series [(Mahdy et al., 2020), (Khalaf and Hamed, 2020), (Emile et al., 2020) ].

Remission of dyslipidemia was defined as a normal lipid profile off-medications. The improvement of this pathology was observed, after one year, in 65%–100% of patients in most studies, (Mahdy et al., 2020), (Mohamed Abdulla et al., 2020), (Kermansaravi et al., 2020), (Emile et al., 2020), (Mahdy et al., 2021), (Romero and Rey Jesus, 2021), (Mohamed et al., 2020) ]. However, Vennapusa et al. have reported in a serie of 113 patients that remission of DL was obtained for only 26, 55%. In our study, A highly significant improvement of lipid profile ensued, resolution of dyslipidemia occurred in 55 % of patients (n= 22), and improvement occurred in 17.5 % of patients (n= 7).

The overall complication rates following SASI ranges from 10 % to 26 %. No early or late mortality was reported in our group of patients. In literature, the 0.3% postoperative mortality were reported only in one study. [23]

In our study group, all procedures were successfully completed laparoscopically, without need to conversion to open. Simultaneous procedures included cholecystectomy in 5 % of cases, (n= 3).

In our series, one case (2.5 %) suffered bleeding, which was managed conservatively, requiring blood and plasma transfusion.

In our study, wound related complications in the form of surgical site infection and localized abscess formation in the abdominal wall, occurred in one case (2.5 %), which was treated by drainage under local anesthetic and antibiotics.

In our study, one patient (2.5 %) suffered stenosis, by the 6<sup>th</sup> postoperative week, and was managed by repeated endoscopic dilatation.

Two (5 %) of our patients experienced intractable vomiting leading to dehydration, by the 2<sup>nd</sup> week, who were hospitalized, and kept NPO, with IV fluids, and antiemetics.

In the literature, Anastomotic intraluminal bleeding was the most common cause of major early post operative complications (76.9%) (Khalaf and Hamed, 2020). This is in accordance with the complication pattern after one-anastomosis gastric bypass (OAGB) due to preserved blood supply to the gastric tube along the lesser curvature. In our study, Anastomotic intraluminal bleeding occurred in one case (2.5 %), which was managed conservatively, requiring blood and plasma transfusion.

This procedure has also a very important advantage, if any adverse events encountered in follow-up process we can easily and safely, in a short time, returns to sleeve gastrectomy.

The result of this review prompt us to prefer SASI bypass more than other bariatric bypass operations but we should be careful of complications since these results concerned patient followed mostly for one year after surgery and long follow up seems to be mandatory to better evaluate this technical surgery.

## 8. Summary and Conclusion

SASI by passisa promising operation that offers excellent weight loss and diabetic resolution, based on digestive adaptation physiologic principles, easier to perform than the Santoro's operation and BPD modifications, and with very good results as duodenal switch operation in the short run without mal-absorption morbidity.

The elimination of two ways for passage of food and one anastomosis decrease nutritional deficiency and the possibility of surgically related complications.

This is a one-armed clinical trial (Prospective interventional) study, done to evaluate the effect of Laparoscopic Single anastomosis sleeve ileal bypass on obese patients with type 2 diabetes mellitus. Fourty patients were included in this study, which was carried out in Al Azhar University Hospitals, and Misr University Hospital, during the period starting from November 2019, till November 2021.

All of the fourty patients included in this study, underwent laparoscopic Single anastomosis sleeve ileal bypass. SASI was performed according to National Institutes of Health criteria for bariatric surgery indications, for morbidly obese patients with type 2 diabetes mellitus, who failed  $\geq 6$  months of organized non-surgical weight loss attempts, and who agreed to be committed to medical and nutritional requirements postoperatively, and were subjected to comprehensive medical and psychologic evaluations before and after surgery.

Patients included in this study were subjected to verbal and written consent, history taking, including co-morbid conditions as diabetes mellitus, hypertension, dyslipidaemia, and cerebro-vascular strokes, as well as dietary habits, clinical examination, including abdominal examination and

BMI assessment, and investigations, including blood sugar, (fasting and postprandial), glycosylated hemoglobin A1c, and lipid profile.

The primary outcome was the assessment of percentage of excess weight loss (% of EWL), and the improvement of plasma glucose level control, and / or resolution of diabetes mellitus, and the secondary outcome was the assessment of mortality, perioperative complications, amelioration of other co-morbidities.

There was a highly significant difference between BMI at baseline and at 12 months after operation, resolution of type 2 diabetes mellitus occurred in 80 % of patients, and improvement occurred in 10 % of patients.

The overall complication rates following SASI ranged from 10 % to 26 %, with no reported mortality. No significant difference could be found between baseline and 12 months blood pressure measurements. However, a highly significant improvement of lipid profile ensued, resolution of dyslipidemia occurred in 55 % of patients, and improvement occurred in 17.5 % of patients.

Therefore, the results of this study demonstrated significant effect of laparoscopic single anastomosis sleeve ileal bypass on morbidly obese patients with type 2 diabetes mellitus, improving both obesity and obesity related co-morbidities.

In our opinion, the most important criteria in the selection of abariatric procedure remain the safety and efficacy in achieving both weight loss and remission of the metabolic consequences of obesity.

In conclusion, Laparoscopic single anastomosis sleeve ileal bypass is simple, effective and safe surgical procedure to achieve a significant weight loss and control of type 2 diabetes mellitus which starts in the early postoperative period, as well as improvement of obesity-related co-morbidity. There is significant reduction in the diabetes medications hence the cost of diabetes treatment and improvement of the quality of life. Moreover, it results in minimal post-operative nutritional complications in comparison to other bariatric procedures.

However, long-term follow-up period should be performed to better evaluate this technical surgery, postoperative weight loss, metabolic changes, and nutritional status of patients.

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