# Evaluation of single anastomosis sleeve ileal bypass in the treatment of morbidly obese patients with type 2 diabetes mellitus

**Original Article**

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## ABSTRACT

**Background:** Laparoscopic single anastomosis sleeve ileal (SASI) bypass has recently evolved as a novel approach to treating both obesity and its associated comorbidities. This study aims to evaluate the efficacy and feasibility of SASI bypass in patients with obesity and type 2 diabetes mellitus (T2DM).

**Patients and Methods:** We conducted a prospective study on 30 morbidly obese patients having T2DM between January 2021 to September 2022. All the patients underwent laparoscopic SASI bypass, and all were followed for 12 months after surgery in terms of T2DM remission. Other parameters were also recorded and analyzed. The percentage of mean excess weight loss (EWL%) was evaluated and noted at each follow-up.

**Results:** At 12 months, EWL% was 82%. All the patients evaluated had shown T2DM remission by 1 year (6.7% partial remission and 93.3% complete remission), with 77.8% remission of hypertension and 95.5% remission of dyslipidemia.

**Conclusion:** SASI offers an excellent EWL% reduction, T2DM remission, and comorbidities resolution, and it should be considered an effective way to treat obesity in T2DM.

**Key Words:** Bariatric surgery, laparoscopic single anastomosis sleeve ileal bypass, metabolic surgery.

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## INTRODUCTION

Confronted by the fact that 90% of all individuals having type 2 diabetes mellitus (T2DM) are overweight or obese, among all obesity-related comorbidities, the coexistence of T2DM and obesity has got the lion's share of researcher's concern. 'Diabesity,' is a medical term that was coined in 1973 to point out the pathophysiologic interconnection between T2DM and obesity, with up to a 4.5% increase in the risk of T2DM for every kilogram rise in bodyweight and a 10 times greater relative risk for T2DM in obese individuals as compared to their nonobese counterparts[1-3].

In September 2015, the Second Diabetes Surgery Summit was held with the contribution of outstanding diabetes organizations and international bariatric societies, including the International Federation for the Surgery of Obesity, to set guidelines for the appropriate selection for Bariatric Metabolic Surgery (BMS) among T2DM patients. Only four procedures were recognized by all these respectful organizations as standard surgical procedures, namely, laparoscopic adjustable gastric banding (LAGB), vertical sleeve gastrectomy (VSG), Roux-en-Y gastric bypass (RYGB), and biliopancreatic diversion (BPD) as the classic type or its duodenal switch variant[4].

The choice of surgical procedure treating both obesity and T2DM should be based on assessing the risk-to-benefit ratio in every patient by weighing the improvement in glycemic control and cardiovascular disease risk factors versus the long-term hazards of the selected procedure. To date, no operation can be pointed to as the gold standard operation for BMS as insufficient RCTs comparing different procedures head-to-head are available. Among the four accepted standard surgical procedures, evidence had demonstrated a gradient of efficacy as follows: LAGB<VSG<RYGB<BPD. The opposite gradient was reported for the safety of these procedures. Among these procedures, VSG and RYGB, have been the most performed and investigated constituting the bulk of evidence base for BMS in literature[4-6].

Although favorable results were reported by the simpler procedure VSG and with fewer postoperative complications, most of the literature with long-term follow-up periods has proven the superiority of gut-related procedures, even if added to the VSG itself, in maintaining weight loss, T2DM remission, and resolution of comorbidities[6-8]. VSG does not seem to be enough, and intestinal bypass with complete exclusion of bowel segments seems too much. One can imagine the ideal BMS as a VSG with added entero-endocrine effect or a bypass surgery with no residual stomach or completely excluded

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gut segment, an imagination that does not appear to be far from that of Santoro's when he introduced the VSG with transit bipartition (SG+TB) in 2012[5,6,9].

Since its introduction by Santoro, the efficacy and safety of SG+TB have been tested by several studies that suggested long-term results of SG+TB superior to VSG and comparable to that of BPD+DS and distal RYGB in terms of weight reduction and resolution of comorbidities (complete T2DM remission rated approaching 90%) but with much fewer complications especially nutritional deficiencies[5,6,10,11].

In 2014, Mui tried to add more to the simplicity of SG+TB by constructing a gastro-ileal anastomosis as a simple loop instead of the Roux-en-Y pattern. Mahdy and colleagues later adjusted the simplified technique of Mui and colleagues and introduced the single anastomosis sleeve ileal (SASI) procedure[12-14]. The reported results of SASI resembled those of the Roux-en-Y bipartition with significant loss of weight and resolution of comorbidities.

The objective of this study was to assess the SASI bypass procedure as a viable option for managing patients suffering from severe obesity and T2DM, with a 1-year follow-up period. The study evaluated the efficacy of SASI bypass in controlling T2DM by analyzing glycemic control, insulin resistance improvement, and its impact on managing severe obesity. The study also assessed the operative time, intraoperative complications, length of hospital stay, early postoperative complications, and percentage of excess weight loss (EWL%) associated with SASI bypass.

## PATIENTS AND METHODS:

This research was performed at the Department of General Surgery, Alexandria University Hospitals. Ethical Committee approval and written, informed consent were obtained from all participants. The study was designed as a prospective study, and it aimed to examine the effects of SASI bypass in a sample of 30 morbidly obese patients with T2DM who were admitted to the Main Alexandria University Hospital. The study included only patients between the ages of 18 and 60, with a BMI between 35 and 50 (classes II and III obesity according to WHO classification[15]). T2DM was diagnosed by two fasting plasma glucose concentrations more than or equal to 126 mg/dl, HbA1c more than or equal to 6.5%, or treatment with oral hypoglycemic agents or insulin.

To ensure the validity of the results, patients with type 1 or any special type of diabetes, those with obesity related to a reversible endocrinal disorder or eating disorders, or with T2DM for more than 10 years were excluded from the study. Additionally, patients with drug abuse, alcohol addiction, or any other uncontrolled psychiatric disorders or who had undergone previous bariatric surgery or other upper abdominal surgeries other than cholecystectomy were excluded.

All patients underwent a thorough preoperative assessment, including a detailed medical history, clinical examination, and laboratory work that included glucose homeostasis parameters, blood lipid profile, and endocrine evaluation. Routine upper gastrointestinal endoscopy and abdominal ultrasonography were to exclude the presence of cholelithiasis and to detect the degree of fatty liver. All patients were kept on a low-calorie protein diet for 6 weeks, and deep vein thrombosis prophylaxis was given 12 h before surgery in the form of subcutaneous low molecular weight heparin.

### *Surgical technique*

Routine steps of sleeve gastrectomy were adopted for patients in the split-leg position. Following complete mobilization of the stomach from the greater omentum side, a 36 F bougie was inserted along the lesser curvature, and antral resection was started 6 cm from the pylorus and continued up to 0.5–1 cm from the angle of His[16].

Following the creation of the gastric sleeve, the table position was reversed to the horizontal position while tilting to the left. The surgeon then moved to the left side of the patient. The ileocecal junction was identified, and a loop measuring 300 cm was measured upwards. This measured loop was brought up and stapled side-to-side to the anterior wall of the gastric antrum in an isoperistaltic manner. The gastro-ileal anastomosis was performed 3 cm away from the pylorus using a linear stapler loaded with a 45 mm blue cartridge. The diameter of the ileo-antral anastomosis did not exceed 3 cm. The staple defect was closed in one layer using a barbed suture. The integrity of the staple line was tested by the methylene blue test, followed by the insertion of an abdominal drain.

### *Postoperative follow-up*

After the operation, patients were given oral clear fluids and encouraged to walk. They were also administered low molecular weight heparin for 2–3 weeks. Proton pump inhibitors were prescribed for 4 months postoperatively. Patients were monitored 1 week after the operation and then every month.

In the first postoperative month, patients were prescribed a protein-rich, low-calorie liquid diet. The dietitian supervised the addition of other elements. Multivitamins and vitamin D3 supplements were also prescribed. Patients underwent a complete laboratory work-up every 3 months, including HOM-IR and assessment of anthropometric measures and EWL%[17]. Upper endoscopy was conducted every 6 months.

To determine the effectiveness of glycemic control, improvement was measured based on a 25% reduction in fasting plasma glucose level and a 1% decrease in the HbA1c level with hypoglycemic drug treatment. Partial remission of diabetes was defined as an HbA1c level below 6.5% and fasting glucose between 100 and 125 mg/dl for at least 1 year without pharmacological therapy. Complete remission of type 2 diabetes was defined as a plasma glucose level below 100 mg/dl and an HbA1c level below 6.0% without drug therapy for at least 1 year[17-19].

The American Society of Metabolic and Bariatric Surgery defines partial or complete remission of hypertension. Complete remission was defined as blood pressure below 120/80 mmHg without anti-hypertensive medications. Partial remission of hypertension was defined as blood pressure between 120 and 140/80-90 mmHg. Remission of dyslipidemia was defined as a normal lipid profile without pharmacological therapy.

### *Statistical analysis of data*

In this study, we used IBM SPSS Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0. Armonk, NY: IBM Corp. We checked the normality of the distribution of variables using the Shapiro–Wilk test. For normally distributed quantitative variables, we used analysis of variance with repeated measures followed by the Bonferroni adjustment for multiple comparisons between different periods. For non-normally distributed quantitative variables, we used the Friedman test followed by the Bonferroni adjustment for multiple comparisons between different periods. The significance level for the results was set at 5%.

## RESULTS:

Our study was conducted on 30 morbidly obese patients with T2DM between January 2021 and September 2022, with an age range of 25–56 years and a mean age of 39.07±8.37 years. Out of these, 25 were females, and five were males, with a male-to-female ratio of 1 : 5. The duration of T2DM ranged from 0.5 to 9 years with a mean of 3.94±2.6 years. The patients' BMI ranged from 35.7 to 50 kg/m$^2$, with a mean of 44.71±4.1 kg/m$^2$ and a median of 45.551 kg/m$^2$.

Of the 30 cases, 21 (70%) patients were on oral hypoglycemic drugs while nine (30%) patients used insulin to control T2DM. Additionally, 22 (73.3%) patients had dyslipidemia, 18 (60%) patients had hypertension, and six (20%) patients had gastroesophageal reflux disease. Joint problems were recorded in six (20%) patients, obstructive sleep apnea in three (10%) patients, and asthma in three (10%) patients. Polycystic ovaries were found in three (10%) patients, with one infertile patient among those three patients. Two (6.7%) patients had depression, and psychological consultation validated both to be psychologically stable to go for surgery.

The mean operative time was 91.4±15.3 min (range: 70–125 min). Two (6.7%) patients were found to have gallstones in preoperative abdominal sonography, and laparoscopic cholecystectomy was added. In another patient (3.3%), a small sliding hiatal hernia was detected in gastroscopy, and hiatal exploration and cruroplasty followed by pouch fixation to the left crus of the diaphragm were added to the SASI bypass.

Intraoperative complications were encountered in two patients. In one (3.3%) patient, serosal bowel injury happened during adhesiolysis that was controlled by interrupted seromuscular sutures. In another patient (3.3%), an intraoperative leak of methylene blue dye during testing of the anastomosis was observed, which was managed by interrupted sutures at the site of the leak and retesting of the anastomosis. The length of patients' hospital stays ranged from 1 to 4 days with a mean of 1.10±0.55 days. One (3.3%) patient had dark bloody diarrhea on the first postoperative day that was thought to be due to intraluminal bleeding and was managed by conservative measures.

The percentage of EWL 1 year following surgery was 58.7–96.6% with a mean of 82.0±9.22% which was statistically significant. Preoperative and postoperative recorded values of glucose homeostatic parameters are demonstrated in (Fig. 1). All the recorded parameters showed statistically significant reduction at 1-year intervals. Preoperative and postoperative nutritional parameters (serum hemoglobin, albumin, iron, calcium, vitamin D3, and vitamin B12) are shown in (Fig. 2). None of the nutritional parameters showed a postoperative reduction, with vitamin D3 and vitamin B12 showing statistically significant increases at 1-year intervals.

At the sixth postoperative month, three (10%) patients included in the study were found to have asymptomatic antral biliary gastritis that was managed conservatively by medical treatment. One year following the SASI bypass, only one (3.3%) patient, who was not one of the three patients detected in the sixth postoperative month, was found to have asymptomatic antral biliary gastritis. None of the patients included in the study had marginal ulceration on routine postoperative endoscopy. One year following the SASI bypass, 28 (93.3%) patients had complete T2DM remission, and two (6.7%) patients had partial remission. Out of the 18 hypertensive patients, 14 (77.8%) patients experienced resolution, and 95.5% of the patients with dyslipidemia (21 out of 22) experienced normalization of their serum lipid parameters.

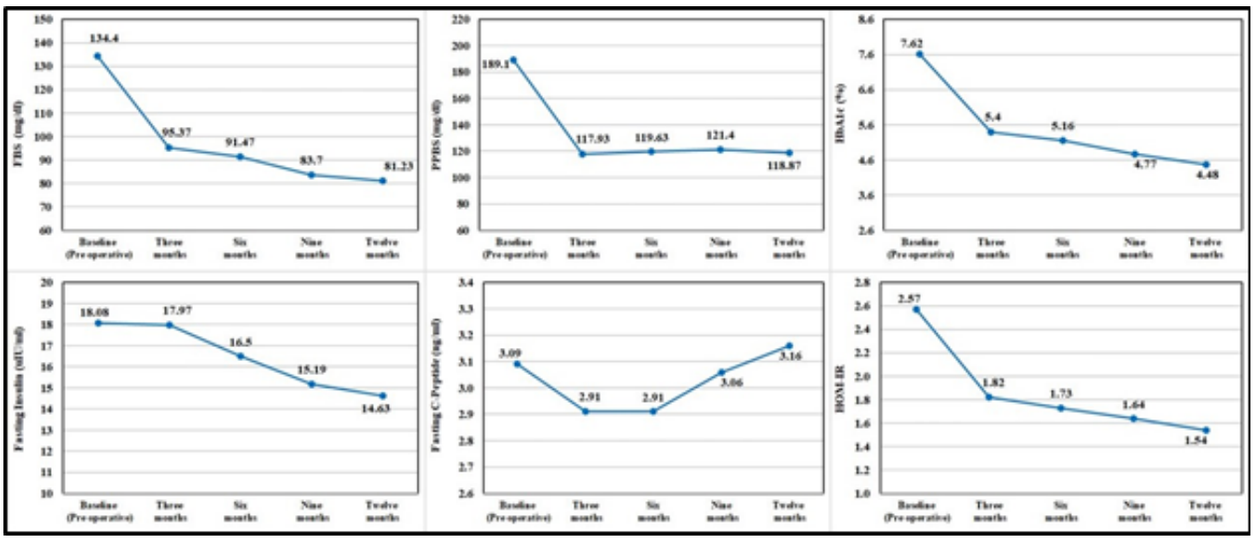


**Fig. 1:** Baseline and postoperative glucose homeostatic parameters.

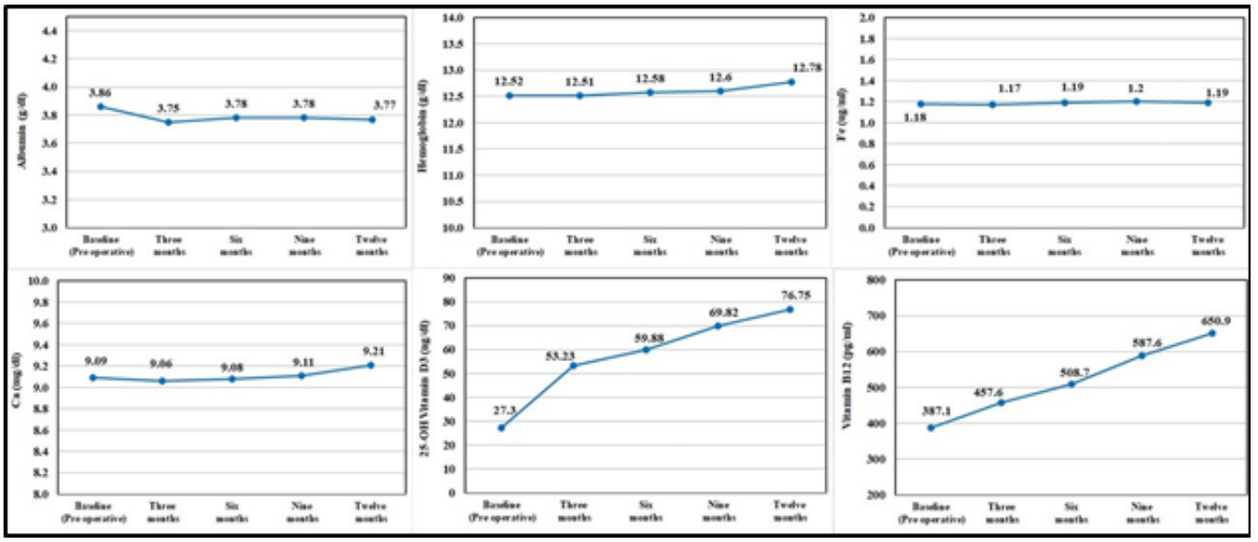


**Fig. 2:** Baseline and postoperative nutritional parameters.

## DISCUSSION

The development decision to perform a surgical procedure to treat both obesity and T2DM should be based on a careful evaluation of the risks and benefits for each patient, taking into account factors such as improvement in glycemic control and cardiovascular disease risk factors and the potential long-term hazards of the chosen procedure. There is no one 'gold standard' operation for BMS, as there is a lack of randomized controlled trials comparing different procedures. However, evidence has shown a gradient of efficacy among the four standard surgical procedures, with LAGB being the least effective and BPD being the most effective. Conversely, the safety of these procedures follows the opposite gradient. The most commonly performed and studied procedures are VSG and RYGB, which constitute the majority of the evidence base for BMS in the research literature of metabolic surgery, new trends in surgeries have evolved, and this rise of new surgeries is consistent with increased knowledge of gastrointestinal physiology. There has not been a single, efficient surgery to be done for all cases, as every surgery comes with its pitfalls. Metabolic surgeries have proved their superiority over medical treatment in glycemic control and reduction of cardiovascular risks. However, further research is still needed to determine the best metabolic surgery that would efficiently improve glycemic control and decrease cardiovascular risks, and yet is modifiable, carries low or no risks of malnutrition, and is an efficient weight loss surgery[20].

Since its description by Mahdy *et al*.[17], the SASI bypass has gained considerable acceptance in the literature. Many surgeons have directed their interest towards its efficacy. SASI was found to have a great impact on T2DM, hyperlipidemia, hypertension, and obstructive sleep apnea[9,21,22].

A systematic review conducted by Emile *et al*.[22], analyzed 10 articles with 914 patients who had undergone SASI. Their results favored SASI, for T2DM and other metabolic disorders and showed great results. In our study, EWL, after the first year, ranged from 58.70 to 96.60 kg with a median of 80.6 kg. These findings were congruent with Kermansaravi *et al*.[23] and agreed with most of the studies considered by Emile and colleagues proving the efficacy of SASI bypass in weight reduction in morbid obese patients with T2DM.

SASI bypass demonstrated marvelous resolution rates of obesity-associated comorbidities, especially T2DM, with remission rates of 100% or approaching 100% in most of the published studies, including the current study. Even the studies reporting lower rates of T2DM remission than those published by Mahdy *et al*.[24] (82.7%), Hosseini *et al*.[21] (87.5%), and Kermansaravi *et al*.[23] (88.9%), the percentage of the studied cohort not achieving remission reported improvement in T2DM. Studies with longer duration of follow-up have reported different rates of T2DM after the first postoperative year. Aghajani *et al*.[25] have reported an almost steady rate of T2DM remission throughout the 4 years of follow-up. Dowgiatto *et al*.[26] have reported a 92.3% complete remission of T2DM at 2 years follow-up. In the study of Khalaf *et al*.[9], the rate of postoperative T2DM remission only declined from 98.2% at 1 year following SASI bypass to 97.9% at 2 years follow-up. On the other hand, Hosseini *et al*.[21] reported a T2DM remission rate declining from 87.5% in the first year to 84.3% in the second year down to 65% in the third year following SASI bypass.

Although our study aimed to measure the efficacy of SASI bypass on T2DM, other improvements were observed that would add to the increased value of SASI bypass toward decreasing cardiovascular risks, including hypertension and dyslipidemia. A 77.8% (14/18 patients) of the patients who suffered from hypertension before surgery experienced complete resolution. Our findings were similar to the findings of Mohamed *et al*.[27] (78.5%), slightly higher, than those published by Emile *et al*.[12] (57.1%), and slightly lower than those published by Kermansaravi *et al*.[23] (85.7%), Madyan *et al*.[28] (100%), Mahdy *et al*.[29] (99.2%), Vennapusa *et al*.[30] (90.2%), and Mahdy *et al*.[17] (86.6%). Dyslipidemia was a common finding among our patients (73.3%), triggering our interest in discovering the impact of SASI bypass on serum lipid derangements. Out of the 22 patients, 95.5% (21/22) experienced normal serum lipid parameters after the surgery. This improvement was also observed by Kermansaravi *et al*.[23] (100%), Emile *et al*.[12] (87.5%), Mohamed *et al*.[27] (76.9%), Mahdy *et al*.[29] (65%), and Mahdy *et al*.[17] (97.1%).

Although previous studies claimed a significant decrease in the albumin level after SASI[23,29,31], the effect of SASI on albumin levels and other nutritional parameters in our study did not show a significant decrease throughout our 1-year follow-up. This finding corresponds to the first published study by Mahdy *et al*.[17]. Furthermore, Khalil *et al*.[32] compared SASI bypass with VSG, and they did not detect a significant difference in the incidence of hypoalbuminemia between the two operations (11 and 8%, respectively). This variability among reported results in the literature may be due to nonstandardization of the technique.

In 2019, a consensus meeting for standardization of BMS procedures suggested a standard technique for SASI bypass by adopting the following: the width of the residual gastric pouch should be 3 cm and its volume should range from 150 to 250 ml, the gastro-ileal anastomosis should be 2–3 cm away from the pylorus, and its diameter should be less than or equal to 3 cm and the common limb length should be 300 cm to avoid side effects such as marked weight loss and protein malnutrition[22]. Performing a regular sleeve gastrectomy of 150-250 ml is advised as a tight sleeve was found to be associated with higher intraluminal pressure and thus a higher rate of vomiting that if persisted may end up in malnutrition[33].

When constructing the gastro-ileal anastomosis, it is crucial to position it at least 2-3 cm away from the pylorus to avoid complete food diversion through the anastomosis. Furthermore, it is recommended to perform the anastomosis with the anterior wall of the stomach as posterior anastomosis is more dependent and may cause food to completely divert from the pylorus. To prevent food from passing through the wider anastomosis, the size of the gastro-ileal anastomosis should be less than or equal to 3 cm in diameter[22,33].

Our study has certain limitations. The number of patients we studied was low, and we followed them up for only 1 year. Additionally, our study was conducted in a single center, and we did not have any comparative groups to test the effectiveness of SASI bypass against other procedures.

## CONCLUSION

SASI bypass seems to prove itself to be an extremely promising procedure among other BMSs because it maintains an almost optimal balance between physiologic changes of the gut entero-hormonal axis and malabsorption. SASI bypass offered a very attractive option for obese patients, especially those suffering from obesity-associated comorbidities, yet these promising outcomes were over short periods of follow-up (3 months–4 years) and with few studies including a large number of patients and even fewer reviews. So, the SASI bypass is viewed as an investigational procedure still being tested to see if it would maintain its luster over time with longer follow-up periods and larger cohorts.

## CONFLICT OF INTEREST

There are no conflicts of interest.

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