



Laparoscopic Single Anastomosis Sleeve Ileal Bypass with Follow-up of Weight Loss and Metabolic Impact

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Abstract

BACKGROUND: Bariatric surgery has been an effective safe management for severe obesity. The newly developed single-anastomosis sleeve ileal (SASI) bypass has shown efficacy as a functional as well as mechanical restrictive bariatric procedure, with a neuroendocrine modulation effect. SASI bypass is still an investigational procedure; hence, more evidence is needed till it is declared as a standard bariatric procedure by the IFSO.

AIM: The current work aimed to describe our experience regarding the technical steps, the efficacy and the short-term outcome of SASI bypass procedure in patients with severe obesity.

PATIENTS AND METHODS: Forty-seven patients with severe obesity underwent SASI bypass procedure. They were followed till 1 year postoperatively. The weight loss, comorbidities, and laboratory changes were assessed.

RESULTS: Patients evaluation at the 1-year post-operative follow-up revealed a mean percentage of total body weight loss (%TWL) of 37.55 ± 6.17 and a mean percentage excess body weight loss (%EBWL) of 76.21 ± 9.8 . The remission rates of type 2 diabetes mellitus, hyperlipidemia, and hypertension were 85.7%, 94.7%, and 89.66%, respectively, with statistically high significant differences between the pre-operative and 1-year post-operative comorbidities rate. Stepwise regression analysis demonstrated that only the pre-operative HbA1C remained in the model predicting the %TWL, and the pre-operative BMI was the remaining factor in the model predicting the %EBWL in the study patients.

CONCLUSION: The present study adds a new evidence to the promising outcome of the newly introduced SASI bypass procedure. After 1 year, the study patients showed excellent weight loss and comorbidities remission together with acceptable major complication rates.

Edited by: Ksenija Bogoeva-Kostovska
Citation: Abdalaziz A, Sarhan MD, Abou-Eisha HA, Abdelsalam A, Saqr A, Fathy E. Laparoscopic Single Anastomosis Sleeve Ileal Bypass with Follow-up of Weight Loss and Metabolic Impact. Open Access Maced J Med Sci. 2022 Apr 12; 10(B):1325-1331. <https://doi.org/10.3889/oamjms.2022.8989>
Keywords: Obesity; Bariatric surgery; Single-anastomosis sleeve ileal bypass; Weight loss; Comorbidities
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Received: 13-Feb-2022
Revised: 23-Mar-2022
Accepted: 02-Apr-2022
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Funding: This research did not receive any financial support
Competing Interests: The authors have declared that no competing interests exist
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Introduction

Obesity has been evidenced to be an insidious enemy impacting the human health at several aspects [1]. Bariatric surgery has been an effective safe management for severe obesity. It is mainly based on restricting the gastric volume and/or inducing malabsorption with intestinal bypass [2]. However, inspired by the advances in digestive physiology knowledge regarding the satiety and hunger control, a novel bariatric procedure initiating neuroendocrine alterations rather than just performing mechanical restriction and/or mal-absorption should be objected [3], [4].

Sleeve gastrectomy (SG) has displayed a promising outcome that was revealed in the clinical practice and the ongoing research [5], [6]. However, the success of SG in induction satisfactory weight loss in patients suffering from super obesity and super super-obesity is still a matter of debate [7], [8].

The Roux-en-Y gastric bypass (RYGB) is one of the earliest bariatric surgeries [9]. Despite its overall well described benefits [10], [11], it was reported that

the RYGB operations rate has rapidly and continuously declined in the recent years [12]. This was attributed to the frequent long-term associated complications [13].

In 2012, Santoro *et al.* presented their experience in performing SG with transit bipartition (SG + TB) [14]. They entailed SG and RYGB with a common limb, yet without exclusion of the duodenum. This procedure implies the augmentation of distal bowel nutritive stimulation and the diminution of the proximal gut exposure to nutrients [14].

In 2016, Mahdy *et al.* declared that they had adjusted the SG + TB procedure by conducting a loop instead of a Roux-en-Y bipartition that would limit the incidence of postoperative leakage, considering the single anastomosis site, and they evaluated this single-anastomosis sleeve ileal (SASI) bypass efficacy as a functional as well as mechanical restrictive procedure, with a neuroendocrine modulation effect, in patients with obesity and type 2 diabetes mellitus (T2DM), and they found excellent promising outcomes [15].

SASI bypass procedure has shown satisfactory weight loss and metabolic comorbidities remission in other studies [16], [17]. It is hypothesized that SASI bypass procedure involves the appetite reduction by two devices;

SG related ghrelin decline and distal bowel stimulation by the fast passage of food [15], [18], [19]. The distal bowel stimulation decreases the activity of the proximal gut and delays gastric emptying, namely, the ileal break mechanism. In addition, distal bowel hormones such as GLP-1 enhance the central satiety center [20].

Considering the aforementioned hopeful research results of the SASI bypass procedure, the current work aimed to describe our experience regarding the technical steps, the efficacy and the short-term outcome of SASI bypass procedure in patients with severe obesity.

Patients and Methods

This is a prospective study that was conducted on patients with severe obesity those were assigned for bariatric surgery in our institution, during the period from February 2018 to the first of September 2019. This study was commenced after getting the approval of the regional research ethics committee and it was in accordance with the Helsinki Declaration.

Patients were eligible for bariatric surgery in our institution if they had a BMI ≥ 40 kg/m² or ≥ 35 kg/m² with comorbidities, aged between 16 and 65 years, and generally fit for surgery. Consecutive patients having a BMI ≥ 40 kg/m², and those with a poor dietary lifestyle, such as excess sweets and frequent snacks taking, were candidates for the present study. Patients who were heavy smokers or alcoholics, patients with the previous gastric or duodenal surgery, endocrine disorders, apart from T2DM, psychiatric illness, or a recent diagnosis of malignancy were excluded from the study.

The preliminarily included patients were interviewed and offered a thorough detailed explanation of the surgery procedure. They were informed about the novelty and the experimental nature of the SASI bypass procedure, and that the risks and outcome were comparable with the standardized surgical procedures, however, with a potentiality of less complications and better metabolic outcome especially for T2DM. Patients were ensured that their acceptance or decline to participate in the study would not affect the quality of the offered health service. The patients who accepted to be involved in the study were finally included.

Pre-operative preparation

The patients of the study had their routine assessment and workup including social and dietary history, medical history, proper physical examination, laboratory evaluation, abdominal ultrasonography, and other specialties consultation if needed.

Operative technique

After induction of general anesthesia, the SG was performed through 5-port technique, while the operating table in the anti-trendelenburg position, the surgeon situated between the patients' legs, and devascularization of the stomach greater curvature was done using the bipolar LigaSure. The stomach was then tabularized over a suitable sized oral bougie (36 French), using a linear stapler, commencing 5-6 cm from the pylorus, where gastrostomy was formed for further anastomosis.

Afterward, for the SASI bypass, the table was positioned horizontally and the surgeon stood to the left of the patient. The ileocecal junction was defined and after 300 cm proximally, without division of the greater omentum, this loop underwent 3-cm anastomosing and stapling in an iso-peristaltic side to side manner with the previously formed gastrostomy, about 3 cm proximal to the pylorus, with the use of a linear stapler (Echelon-45, Ethicon Endosurgery Inc., Johnson and Johnson).

The anastomosis defect was sewn with 3/0 polydioxanone (PDS, Ethicon Inc., Johnson and Johnson) in a two-layer running suture. The excised stomach was removed through the left mid-clavicular port. The leak test was performed along the staple line.

Immediate post-operative follow-up

Patients encouraged for early ambulation few hours after surgery. Oral fluids were allowed 4 h after complete recovery as tolerated by the patients. Patients underwent barium meal X-ray study on the 2nd post-operative day. Operative events and the early post-operative complications were recorded. The hospital stay length was recorded for each patient.

A standardized supplementation regimen was prescribed for each patient. This regimen included a daily proton pump inhibitor for 3 months, in addition to the multivitamins and minerals pills containing the post bariatric surgery recommended doses for life-long.

Patients were constructed to seek medical advice in case of any complications or adverse events. Follow-up visits were arranged to be twice in the 1st month, then every 3 months postoperatively till 1 year.

Post-operative 1-year follow-up

The patients underwent complete medical and physical examination. The percentage of total body weight loss (%TWL) and excess body weight loss (%EBWL) was calculated, laboratory assessment regarding HbA1C and lipid profile was performed simultaneously.

The medications as oral hypoglycemic drugs, anti-hypertensive drugs, and anti-lipidemic drugs were assessed and recorded as follow-up of the improvement of the associated comorbidities of the

obesity, as the decrease of the doses or cessation of such drugs was considered as sign of improvement of the comorbidities such as the hypertension, type 2 diabetes and hyperlipidemia.

The %TWL was calculated as the weight loss at the 1-year follow-up divided by baseline weight, and then multiplied by 100. The EBW was calculated as the ideal body weight subtracted from the baseline weight. The %EBWL was calculated as follows; $[(\text{baseline weight} - \text{actual weight})/\text{EBW}] \times 100$.

The study outcomes

The primary outcome of the study was the effect of surgery on weight loss as interpreted by %TWL and the %EBWL of the patients at 1-year follow-up, and the secondary outcome was the potential changes in the metabolic disorders of the patients.

Statistical methods

Data were analyzed with the use of the statistical software SPSS[®], version 22 for windows (IBM Corp., Armonk, NY, USA). Evaluation of the study outcomes was performed using paired t-test, Fishers' exact, and Chi-square tests. Multivariate stepwise regression analysis was performed to assess the predictors of post-operative weight loss. The statistical significance was considered if $p < 0.05$.

Results

The total number of patients those was initially enrolled in the study was 51. One-year postoperatively, four patients dropped out and did not complete the follow-up examination. Finally, 47 patients were analyzed in this study.

Baseline data of the study patients

The age of the patients ranged from 22 to 57 years, with a mean of 38.47 ± 11.29 . Females constituted 70.2%

Table 1: Baseline data of the study patients

Item	Median	Range	Mean ± SD
Age (years)	38	22–57	38.47 ± 11.29
Weight (kg)	124	100–160	126.15 ± 13.52
BMI (kg/m ²)	50	43–60	50.23 ± 4.77
HbA1C level (%)	10	4.8–13	9.68 ± 2.17
Total cholesterol (mg/dL)	250	201–352	250.2 ± 56.7
Triglycerides (mg/dL)	187	133–280	194.74 ± 46.03
Serum albumin (mg/dL)	4	3.1–5.5	4.09 ± 0.59
Item	Count		Percentage
Gender			
Female	33		70.2
Male	14		39.8
Comorbidities			
T2DM	42		89.4
Hyperlipidemia	38		80.9
Hypertension	29		61.7

SD: Standard deviation, HbA1C: Hemoglobin A1c, BMI: Body mass index, T2DM: Type 2 diabetes mellitus.

of the study patients. The patients' weight ranged from 100 to 160, with a mean of 126.15 ± 13.52 , and the BMI ranged from 43 to 60 kg/m², with a mean of 50.23 ± 4.77 . Out of the 47 included patients, comorbidities in terms of T2DM, hypertension, and hyperlipidemia were found in 42 (89.4%), 29 (61.7%), and 38 (80.9%) patients, respectively (Table 1). Baseline HbA1C, serum albumin, and lipid profile are presented in Table 1.

Operative data

The surgery time ranged from 113 to 159 minutes, with a mean of 139.79 ± 23.12 . The hospital stay length ranged from 2 to 4 days, with a mean of 2.71 ± 0.59 (Table 2). Three patients underwent associated hiatus hernia repair (6.38%).

Table 2: Operative data of the study patients

Item	Median (range)	Mean ± SD
Surgery time (min)	130 (113–159)	139.79 ± 23.12
Hospital stay length (days)	3 (2–4)	2.71 ± 0.59

SD: Standard deviation.

Post-operative complications were encountered in four patients (8.51%); two patients (4.26%) experienced postoperative bilious vomiting that was managed conservatively with bowel rest, anti-emetics and prokinetics, one patient (2.13%) had wound infection with abscess formation that was incised 10 days postoperatively, and one patient had post-operative staple line bleeding that did not respond to conservative management and underwent exploration, where a hematoma was evacuated and the bleeding points of the staple line were clipped, denoting reoperation rate of 2.13%.

One-year post-operative data of the study patients

Patients' evaluation at the 1-year post-operative follow-up revealed that the weight and BMI decreased significantly with mean difference of 47.21 ± 6.17 and 18.17 ± 3.43 , respectively. The %TWL mean was 37.55 ± 6.17 and the mean %EBWL was 76.21 ± 9.8 . There were statistically high significant differences in the HbA1C, total cholesterol and triglycerides levels compared to the baseline measures, while no

Table 3: Data of the study patients at 1 year post-operative, and the differences between pre- and post-operative data

Item	Mean ± SD		t	p	
	1 year post-operative values	Paired differences			
Weight (kg)	86.12 ± 13.72	47.21 ± 6.17	52.42	<0.001**	
BMI (kg/m ²)	32.2 ± 3.87	18.17 ± 3.43	36.34	<0.001**	
EBWL (%)	76.21 ± 9.8	-	-	-	
TWL (%)	37.55 ± 6.17	-	-	-	
HbA1C level (%)	6.04 ± 0.82	3.65 ± 1.71	14.61	<0.001**	
Total-cholesterol (mg/dL)	145.75 ± 17.27	100.94 ± 53.11	13.03	<0.001**	
Triglycerides (mg/dL)	125.68 ± 23.92	69.06 ± 45.7	52.42	<0.001**	
Serum albumin (mg/dL)	4.04 ± 0.59	0.055 ± 0.81	0.47	0.64	
Comorbidities	Pre-operative		1-year post-operative		
	Count	Percentage	Count	Percentage	
T2DM	42	89.4	6	12.8	<0.001**
Hyperlipidemia	38	80.9	2	4.3	<0.001**
Hypertension	29	61.7	3	6.4	<0.001**

*McNemar test P value, **Statistically high significant. t: Paired t-test, BMI: Body mass index, TWL: Total body weight loss, EBWL: Excess body weight loss, HbA1C: Hemoglobin A1c, SD: Standard deviation, T2DM: Type 2 diabetes mellitus.

significant difference was noted in the serum albumin levels. The remission rates of T2DM, hyperlipidemia, and hypertension were 85.7%, 94.7%, and 89.66%, respectively, with statistically high significant differences between the pre-operative and 1-year post-operative comorbidities rate (Table 3).

Stepwise regression analysis models including age, pre-operative weight, pre-operative BMI, pre-operative HbA1C, pre-operative total cholesterol, and pre-operative triglycerides revealed that only the pre-operative HbA1C remained in the model predicting the %TWL, and the pre-operative BMI values were also the remaining factor in the model predicting the %EBWL in the study patients (Table 4).

Table 4: Stepwise linear regression analysis for independent factors predicting % total body weight loss and % excess body weight loss

Item	B	SE	p	95% CI for EXP (B)	
				Lower	Upper
Model 1 for prediction of % TWL					
Constant	46.327	2.598	<0.001**	41.095	51.559
Pre-operative HbA1C	-0.906	0.262	0.001**	-1.433	-0.379
Model 2 for prediction of % EBWL					
Constant	129.49	13.24	<0.001**	102.81	156.16
Pre-operative BMI	-1.06	0.262	0.001**0	-1.589	-0.532

**Statistically significant. The excluded variables for model 1 were age, pre-operative weight, pre-operative BMI, pre-operative total cholesterol, and pre-operative triglycerides. The excluded variables for model 2 were age, pre-operative weight, pre-operative HbA1C, pre-operative total cholesterol, and pre-operative triglycerides. HbA1C: Hemoglobin A1c, BMI: Body mass index, TWL: Total body weight loss, EBWL: Excess body weight loss, CI: Confidence interval.

Discussion

At present, the advances gotten in the bariatric surgery field have brought out new procedures that targeted balancing among safety, effectiveness, and feasibility. SASI bypass has recently developed as a modification in the previously implemented SG with transit bipartition (SG + TB) [5], in which SG is performed, and then followed by side-to-side gastro-ileal-anastomosis [15]. Accordingly, the current work aimed to describe our experience regarding the technical steps, the efficacy and the short-term outcome of SASI bypass procedure in patients with severe obesity.

In the present study, 47 patients with severe obesity underwent SASI bypass procedure, and followed up till 1 year postoperatively. The patients of the study were mainly females, with a mean age of 38.47 ± 11.29 , a mean BMI of 50.23 ± 4.77 , and high rates of comorbidities.

In regard to the primary outcome of this study, at the 1-year post-operative follow-up, the %TWL mean was 37.55 ± 6.17 , and the mean %EBWL was 76.21 ± 9.8 . This percentage of weight loss is considered satisfactory according to the previously published classification [21] despite longer efferent bowel length. Widely varied %EBWL values after SASI bypass procedure have been reported during the last few years. This, however, was expected in view

of the lack of the procedure standardization and the surgeons' variable levels of experience in performing such new procedure. The differences in the studies populations also could be a contributing factor. Our figures are within the range of the previously disclosed reports. The %EBWL at 1-year follow-up after SASI was found to be 86.9% in the study of Khalaf and Hamed [22], 86.2% in the study of Kermansaravi *et al.* [17], 72.6% in the study of Emile *et al.* [18], and 65.2% in the study of Madyan *et al.* [23]. Mahdy *et al.* found that % EBWL after 1 year of SASI bypass was 90%, 64%, and 78.5%, in three different consequent studies [6], [15], [20]. These data emphasize the wide variation of results, and, on the other side, the high effectiveness of SASI bypass procedure in achievement satisfactory weight loss.

Concerning the metabolic state of the study patients, after 1 year, there was statistically high significant reduction in the HbA1C, total cholesterol and triglycerides levels, and in the rates of different comorbidities, compared to the baseline measures, while no significant difference was noted in the serum albumin levels. The remission rates of T2DM, hyperlipidemia and hypertension were 85.7%, 94.7%, and 89.66%, respectively. However, improvement in these comorbidities was observed in all the cases (100%).

There was unanimous agreement among the studies investigating the SASI bypass procedure about its effect on T2DM remission. The improvement and remission rates ranged from 85% to 100% [6], [15], [17], [18], [20], [22], [23], [24].

A dedicated presentation of the possible theories elucidating the excellent metabolic effect of the SASI bypass procedure was reported by Romero *et al.* [16]. They described that the bipartition technique preserves the normal food pathway and permits a little amount of the taken food to be absorbed in the proximal part of the gut. This elicits the GLP-1 and incretin secretion, which then induce the described ileal break mechanism with a positive metabolic impact. Moreover, the bipartition technique seems to be associated with less nutritional impact. Being combined SG, this results in reduction of ghrelin, and also permitting the fast tracking of the food through the anastomosis, which contributes to the metabolic effect of distal bowel.

Out of the 47 patients, who were all having hyperlipidemia, 45 patients showed complete remission to the normal values, with the remaining two patients were found having familial hyperlipidemia. Nevertheless, both showed significant improvement in their lipid profile values. Similarly, Kermansaravi *et al.* [17] and Mahdy *et al.* [6] reported complete remission of hyperlipidemia patients.

Within the same context, it was stated that weight loss is a mainstay in the treatment of obesity

related hyperlipidemia. Loss of weight results in marked reduction in triglycerides concentrations that are attributed to a lipoprotein lipase (LPL) activity enhancement, with a simultaneous decrease in the apolipoprotein C-III levels, decrease in cholesterol-ester-transfer-protein (CETP) activity, and elevated triglycerides-rich lipoproteins catabolism [25]. Besides, it is expected to observe an LDL-C reduction on weight loss that can be attributed to stimulation of LDL receptors. It was reported that a reduction in weight of 4–10 kg led to an LDL-C reduction rate of 12% [26].

Complete remission of hypertension occurred in 89.66% of the study patients at 1-year postoperative follow-up. This is in congruence with the previously reported remission rates of 85.7% [17] and 86% [6]. This effect is likely multifactorial, with at least contributions are conveyed by the decreased load encountered on patient's cardiac muscle after weight reduction, and the improved hyperlipidemia state.

The non-significant changes in the serum albumin levels after the SASI bypass was also observed by Mahdy *et al.* [15], [20], despite contradictory findings were reported by Kermansaravi *et al.* [17].

In the current work, post-operative complications rate was 8.51% (4 patients), of them, 6.38% (3 patients) were Clavien-Dindo Grade I (2 cases had post-operative bilious vomiting, and 1 case had wound infection), and 2.13% (1 patient) was Clavien-Dindo Grade III (staple line bleeding) that needed re-exploration.

Bile reflux is likely to occur in patients with an anastomosis between the intestine and the gastric pouch. This was reported to follow SASI bypass [20] and RYGB [27].

Stepwise regression analysis models including age, pre-operative weight, pre-operative BMI, preoperative HbA1C, pre-operative total cholesterol, and pre-operative triglycerides revealed that a model containing pre-operative HbA1C levels was the only predictor for %TWL and another model containing pre-operative BMI was the only predictor for %EBWL in the study patients.

Accordingly, Mahdy *et al.* [20] reported that lower pre-operative BMI was predictors for higher %EBWL following the SASI bypass procedure. Likewise, it was stated that higher pre-operative BMIs have been associated with lower %EWL after SG [22].

Our findings are in line with the recent evidence imported from the study of Ortega *et al.* [29]. The authors found that pre-operative HbA1c was a statistically significant predictor of post-operative weight loss. This raises concerns about the tight glycemic control that should be offered to patients and may contribute better outcomes of weight loss after bariatric surgery.

Strength and limitations

The study is limited by the effect COVID-19 epidemic, the short-term follow-up, the small sample, and the absence of other groups for comparison. Nevertheless, the findings of the study are strengthened by its design, being a prospective longitudinal one, and by assessing patients with severe obesity and high comorbidity rates that ensure the excellent promising outcome of the novel experimental procedure. Moreover, conducting the surgeries by a single surgery team granted homogeneity to the results.

Conclusion

The current work adds new evidence to the promising outcome of the newly introduced SASI bypass procedure. After 1 year, the study patients showed excellent weight loss and comorbidities remission together with acceptable major complication rates. Pre-operative tight glycemic control should be considered to achieve better weight loss outcomes. Further multi-centric studies, with large sample sizes, and long periods of follow-up are recommended.

Statement for informed consent

Informed consent was obtained from all individual participants included in the study.

- Statement for conflict of interest: The authors declare that they have no conflict of interest
- Ethical approval: This study has been approved by the appropriate institutional research ethics committee.

Key points

1. Obesity has been evidenced to be an insidious enemy impacting the human health at several aspects
2. Bariatric surgery has been an effective safe management for severe obesity
3. The newly developed single-anastomosis sleeve ileal (SASI) bypass has shown efficacy as a functional as well as mechanical restrictive bariatric procedure, with a neuroendocrine modulation effect
4. SASI bypass is still an investigational procedure; hence, more evidence is needed till it is declared as a standard bariatric procedure by the IFSO.

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