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Single anastomosis sleeve ileal (SASI) bypass versus sleeve gastrectomy: a case-matched multicenter study

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Abstract

Background The present study aimed to compare the outcome of single anastomosis sleeve ileal (SASI) bypass and sleeve gastrectomy (SG) in regards weight loss, improvement in comorbidities at 12 months of follow-up, and postoperative complications.

Methods This was a case-matched, multicenter analysis of the outcome of patients who underwent SG or SASI bypass. Patients who underwent SASI bypass were matched with an equal number of patients who underwent SG in terms of age, sex, BMI, and comorbidities. The main outcome measures were excess weight loss (EWL) at 6 and 12 months after surgery, improvement in medical comorbidities, and complications.

Results A total of 116 patients (97 female) of a mean age of 35.8 years were included. Fifty-eight patients underwent SASI bypass and an equal number underwent SG. %EWL at 6 months postoperatively was similar between the two groups. SASI bypass conferred significantly higher %EWL at 12 months than SG (72.6 Vs 60.4, $p < 0.0001$). Improvement in type 2 diabetes mellitus (T2DM) and gastroesophageal reflux disease (GERD) after SASI bypass was better than SG (95.8% Vs 70% and 85.7% Vs 18.2%, respectively). SASI bypass required longer operation time than SG (108.7 Vs 92.8 min, $p < 0.0001$). Complications occurred in 12 (20.7%) patients after SG and 4 (6.9%) patients after SASI bypass ($p = 0.056$).

Conclusion The %EWL at 12 months after SASI bypass was significantly higher than after SG. SASI bypass conferred better improvement in T2DM and GERD than SG. Both procedures had similar weight loss at 6 months postoperatively and comparable complication rates.

Keywords Single anastomosis · SASI · Sleeve gastrectomy · Case-matched · Bypass

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Bariatric surgery has been recognized as the most effective treatment of morbid obesity as compared to medical and conservative treatments [1]. Furthermore, bariatric surgery can achieve better resolution of type 2 diabetes mellitus (T2DM) than intensive medical therapy alone [2]. The beneficial effect of bariatric surgery extends to include improvement in or even resolution of several other obesity-related comorbidities such as hypertension, dyslipidemia, sleep apnea, and joint pain.

Bariatric procedures can be classified according to the mechanism of weight loss exerted. Whether employing restrictive, malabsorptive, or mixed weight loss mechanism, bariatric surgery continues to achieve satisfactory outcomes. While a recent meta-analysis [3] found roux-en-Y-gastric bypass (RYGB) and sleeve gastrectomy (SG) confer similar weight loss, both were superior to laparoscopic adjustable gastric banding.

SG has gained increasing popularity in the last few years owing to its good outcomes in regards weight loss and improvement in obesity-associated comorbidities [4]. However, despite the excellent overall results of SG in the literature, there remain a few issues to be considered. SG can be followed by a number of complications that include staple line leak and bleeding, persistent vomiting, gastroesophageal reflux disease (GERD), and nutritional deficiencies [5]. Furthermore, it has been demonstrated that while SG achieves the best outcome in patients with body mass index (BMI) less than 50 kg/m^2, its efficacy may be reduced in super obese patients with BMI exceeding 50 kg/m^2 [6].

Recently, Mahdy et al. [7] introduced a technical modification of SG by adding a single anastomosis between the gastric pouch and the ileum, the single anastomosis sleeve ileal (SASI) bypass. As the authors implied, after SASI bypass the patient stops eating earlier partly due to filling of the stomach and partly owing to early satiety sensation. The early satiety was presumed to be induced by the perception of nutrients in the ileum which tends to reduce proximal bowel activity and stimulate the secretion of satietogenic distal gut hormones that reduce gastric emptying [8].

The objective of adding the gastroileal bypass to SG was to induce neuroendocrine modulation that serves to achieve satisfactory and sustained weight loss and improvement in T2DM. The original series reported an excess weight loss of 90% at 12 months of follow-up and complete resolution of T2DM by three months postoperatively [7]. We conducted the present study to compare the outcome of SASI bypass with that of SG in regards weight loss, improvement in comorbidities at 12 months of follow-up, and postoperative complications.

Patients and methods

Study design

This is retrospective, case-matched study on patients with morbid obesity who completed 12 months of follow-up after SG or SASI bypass. Morbid obesity was defined as BMI >40 kg/m^2 or >35 kg/m^2 with at least one associated medical comorbidity.

Consecutive patients who underwent SASI bypass in the period of January 2016 through July 2018 were matched with a similar number of patients who underwent SG within the same study period.

Patients who underwent SASI bypass (cases) were matched with patients who underwent SG (controls) in a 1:1 ratio. Matching of cases and controls was based on baseline characteristics including age, sex, weight, height, BMI, and medical comorbidities to reduce the effect of these confounding factors on the outcome of the procedures.

Setting

Data were collected prospectively in two academic centers; the General Surgery Department, Mansoura University Hospitals, Egypt and the Al Qassimi Hospital, Sharjah, UAE. Ethical approval for the study was obtained from the institutional review boards of the respective institutions.

Selection of the procedure

The selection of each procedure (SG versus SASI bypass) was made by shared decision making after detailed informed discussion between the patient and the surgeon with regards to the technical aspects, advantages, risks, and costs of each procedure.

Eligibility criteria

Patients of either gender aged between 16 and 70 years with primary morbid obesity with or without obesity-associated comorbidities were included.

The following patients were excluded:

- Patients with endocrine disorders other than T2DM
- Patients with major psychiatric disorders (according to the Diagnostic and Statistical Manual of Mental Disorders) that may compromise their volition and organization to an extent that affects perception of and compliance with the postoperative dietary regimen and instructions.
- Patients with ASA III and higher.
- Pregnant patients.
- Patients who underwent SG or SASI bypass as revisional surgery
- Patients who did not complete at least 12 months of follow-up.

Preoperative assessment

After taking detailed history regarding dietary habits, associated comorbidities, and previous investigations and treatments for morbid obesity, general and abdominal examination was performed. Patients' weight and height were recorded and BMI was calculated. Abdominal ultrasonography, ECG, chest X-ray, and pulmonary function tests were done for all patients prior to surgery. Patients with clinical symptoms of GERD were investigated with 24-h pH study using pH impedance catheter at baseline.

Patients received a subcutaneous injection of low-molecular weight heparin (Enoxaparin, 40 I.U) ten hours before the operation and were advised to wear an elastic compression stocking before and after the procedure. Informed written consents were taken from the patients after explanation of the nature and possible harms and benefits of each procedure.

Surgery

All procedures were performed under general anesthesia with endotracheal intubation in the French position by expert bariatric surgeons. Two grams of cefotaxime were administered on induction as prophylactic antibiotics.

Sleeve gastrectomy

After creation of pneumoperitoneum, a 10-mm visual trocar was inserted. Then under direct vision a 5-mm trocar (haptic retractor port) was placed under the xiphoid process and two 12-mm trocars were placed in the right and left midclavicular line.

Using harmonic ace scalpel ™, dissection of the greater curvature started 5 cm away from the pylorus up to the cardio-esophageal junction. Afterwards, a 36-Fr bougie was inserted into the stomach and the stomach was then resected using linear staplers starting 5 cm from the pylorus up to the angle of Hiss.

SASI bypass

Upon completion of SG and creation of the gastric tube, the patient's position was changed to trendelenburg position. 250 cm of ileum were measured starting from the ileocecal junction. Using 45-mm linear stapler, an antecolic side-to side anastomosis between the antrum of the stomach and the ileum was created. The anterior wall of gastroenterostomy was closed with a Vicryl or V-lock 2/0 continuous sutures. The resected stomach was removed through the left midclavicular port and a drain was placed and left for 24 h.

Follow-up

Patients were discharged home once considered stable and were scheduled for follow-up at the outpatient clinic once every week during the first month after the surgery then every month for three months, then every 3 months for one year.

During follow-up visits patients' weight was measured and BMI was calculated, port-site wounds were inspected, and complications were recorded. Body weight, BMI, percentage of excess weight loss (%EWL), and improvement of medical comorbidities at 6 and 12 months after surgery were recorded.

Endpoints of the study

The primary endpoint of the study was the %EWL at 12 months after each procedure. Secondary outcomes comprised operation time, change in BMI and improvement in comorbidities at 6 and 12 months postoperatively, and postoperative complications.

Definitions

The endpoints of the study were defined according to the standardized outcomes reporting in metabolic and bariatric surgery [9] as follows:

- %EWL: [(preoperative weight − weight at twelve months)/preoperative excess weight] × 100.
- Complete remission of T2DM: fasting plasma glucose level < 100 mg/dL or HbA1C level < 6% without the use of hypoglycemic medication at one year after surgery.
- A partial improvement in T2DM: reduction of at least 25% of the fasting plasma glucose level and of at least 1% in the hemoglobin A1c level with the use of hypoglycemic medications
- Remission of hypertension was considered if the disease was controlled and the patients was normotensive (BP < 120/80) off antihypertensive medication.
- Remission of dyslipidemia: normal lipid profile off medications.
- Remission of GERD: absence of symptoms, no medication use, and normal 24-h pH study conducted at 6 months postoperatively.
- Postoperative complications: an undesirable and unintended result of the operation affecting the patient that occurs as a direct result of the operation. Complications were classified as grade I–V according to Clavien–Dindo classification.

Data collection

The following data were collected by two authors: patients' age, sex, weight, height, BMI, medical comorbidities, type of surgery, operation time, complications, change in BMI at 6 and 12 months after surgery, %EWL at 6 and 12 months postoperatively, and improvement in comorbidities.

Sample size calculation

The sample size of this study was calculated by online sample size and study power software (https://clincalc.com/stats/samplesize.aspx) based on the primary endpoint of the study (%EWL at 12 months). In light of previous literature [4, 7] that reported %EWL at 12 months after SASI bypass and SG to be 90% and 67%, respectively, we assumed that a minimum of 112 patients equally divided on both groups was needed to achieve a study power of 85% with alpha set at 5%.

Data analysis

Data were coded in Excel spreadsheets and were analyzed using SPSS™ version 23 (IBM corp., Chicago, USA). Continuous data were expressed in the form of mean ± standard deviation (SD), or median and normal range and categorical data as number and proportions. Paired Student's t-test was used for analysis of quantitative data, Fisher's exact test or Chi square test were used to analyze categorical data. Multiple linear regression analysis was performed to determine the significant independent predictors for higher %EWL after SG and SASI bypass**.** P values less than 0.05 were considered significant.

Results

Patients' characteristics

Overall, the study included 116 patients of a mean age of 35.8 ± 9.4 years. Patients were 97 (83.6%) female and 19 (16.4%) male. The mean preoperative weight was 133.3 ± 56.8 kg and the mean height was 163.5 ± 7.8 cm. The mean preoperative BMI was 50.05 ± 22.5 kg/m^2. Forty-four (37.9%) patients had T2DM, 22 (18.9%) had hypertension, 17 (14.6%) had dyslipidemia, and 18 (15.5%) had GERD.

Fifty-eight patients who underwent SASI bypass were matched with a similar number of patients who underwent SG (Fig. 1). There were no statistically significant differences between the two groups in regards patients' demographics, BMI, and obesity-related comorbidities (Table 1).

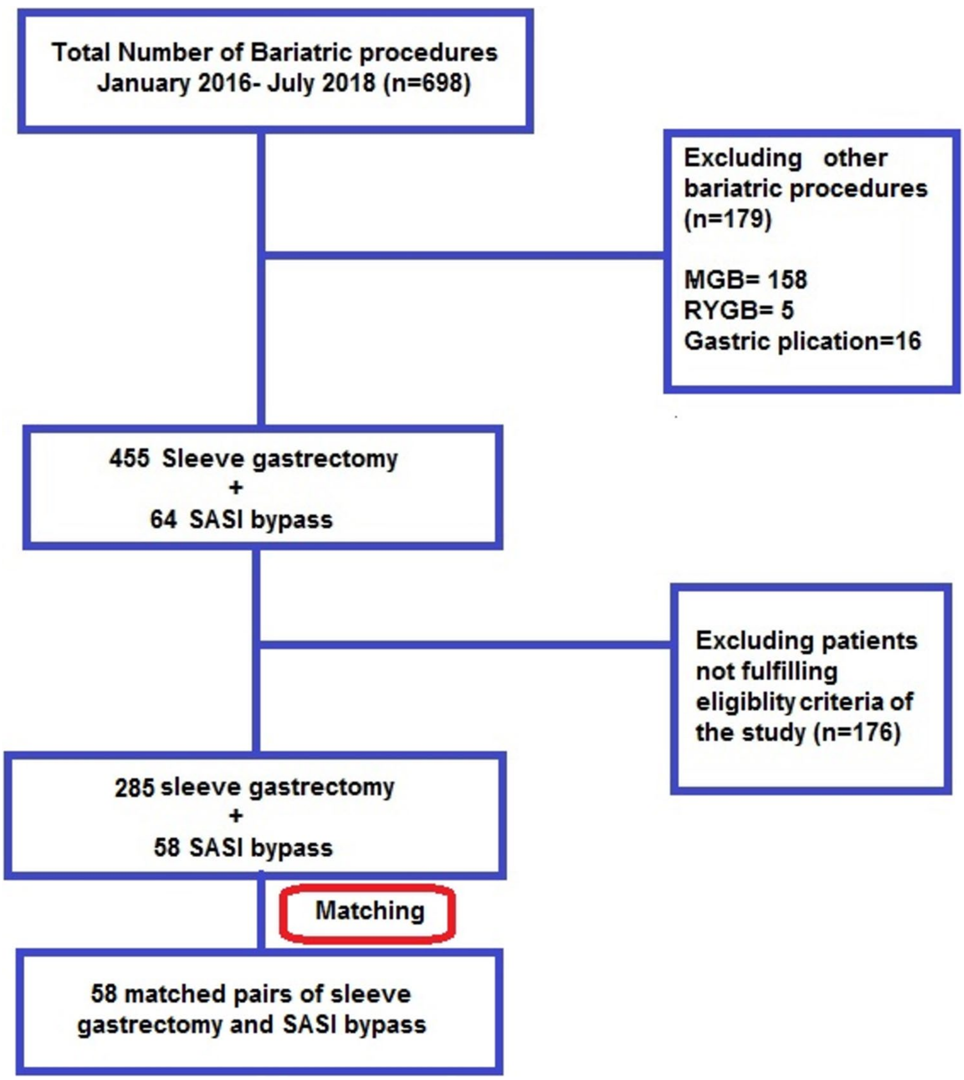


Fig. 1 Diagram illustrating the process of patient selection, exclusion, and matching

Table 1 Patients' demographics in the two groups

Variable	SASI (*n* = 58)	Sleeve gastrectomy (*n* = 58)	*p* value
Mean age in years	37.9 ± 8.5	36.9 ± 9.8	0.55
Male/female	13/45	6/52	0.13
Mean weight in kg	131.3 ± 46.7	135.8 ± 63.9	0.66
Mean height in cm	163.7 ± 7.8	163.4 ± 7.9	0.84
Mean BMI in kg/m^2	48.9 ± 16.9	51.5 ± 25.9	0.52
Diabetes mellitus (%)	24	20	0.56
Hypertension (%)	14	8	0.23
Dyslipidemia (%)	8	9	0.79
GERD (%)	7	11	0.44

Table 2 Weight loss at 6 months postoperatively in the two groups

Variable	SASI (*n* = 58)	Sleeve gastrectomy (*n* = 58)	*p* value
Mean preoperative weight in kg	131.3 ± 46.7	135.8 ± 63.9	0.66
Mean weight at 6 months in kg	97.5 ± 19.1	102.1 ± 15.1	0.15
p value	**< 0.0001**	**0.0002**	–
Mean preoperative BMI in kg/m^2	48.9 ± 16.9	51.6 ± 25.9	0.52
Mean BMI at 6 months in kg/m^2	36.5 ± 6.7	38.3 ± 6.2	0.13
p value	**< 0.0001**	**0.0002**	–
%EWL at 6 months	46.2 ± 14.3	43.4 ± 11.2	0.18

Bold values are statistically significant ($p < 0.05$)

Weight loss

Both groups showed a significant decrease in body weight and BMI at 6 and 12 months postoperatively. There no were no significant differences between SG and SASI bypass in weight loss at 6 months after surgery. However, the differences between the two groups in body weight and BMI at 12 months were statistically significant.

Similarly, while the %EWL at 6 months postoperatively was similar between SG and SASI bypass, SASI bypass conferred significantly higher %EWL at 12 months as compared to SG (72.6 ± 14.03 Vs 60.4 ± 12.5, $p < 0.0001$) (Tables 2 and 3).

Improvement in comorbidities at 12 months

SASI bypass achieved significantly higher improvement in T2DM and GERD than SG (95.8% Vs 70% and 85.7% Vs 18.2%, respectively). The improvement in hypertension and dyslipidemia was comparable between the two procedures (Table 4).

As regards GERD, in the SASI group (*n* = 58), seven (12%) patients had preoperative GERD and six (85.7%) of whom showed improvement after SASI bypass, whereas none of the remaining 51 (88%) patients developed clinical symptoms of GERD after SASI bypass. In the SG group (*n* = 58), 11 (19%) patients had preoperative GERD and only two showed postoperative improvement in symptoms, whereas nine remained the same after SG. Among

Table 3 Weight loss at 12 months postoperatively in the two groups

Variable	SASI (*n* = 58)	Sleeve gastrectomy (*n* = 58)	*p* value
Mean preoperative weight in kg	131.3 ± 46.7	135.8 ± 63.9	0.66
Mean weight at 12 months in kg	81.7 ± 19.5	90.5 ± 12.5	**0.004**
p value	**< 0.0001**	**< 0.0001**	–
Mean preoperative BMI in kg/m^2	48.9 ± 16.9	51.6 ± 25.9	0.52
Mean BMI at 12 months in kg/m^2	30.6 ± 5.5	34 ± 4.9	**0.0006**
p value	**< 0.0001**	**< 0.0001**	–
%EWL at 12 months	72.6 ± 14.03	60.4 ± 12.5	**< 0.0001**

Bold values are statistically significant ($p < 0.05$)

Table 4 Improvement in comorbidities in the two groups

Variable	SASI (*n* = 58)	Sleeve gastrectomy (*n* = 58)	*p* value
Remission or improvement in diabetes mellitus	23/24 (95.8%)	14/20 (70%)	**0.03**
Remission or improvement in hypertension	8/14 (57.1%)	5/8 (62.5%)	0.99
Improvement in dyslipidemia	7/8 (87.5%)	6/9 (66.7%)	0.57
Improvement in gastroesophageal reflux disease	6/7 (85.7%)	2/11 (18.2%)	**0.01**

Bold values are statistically significant ($p < 0.05$)

the remaining 47 (81%) patients who underwent SG with no preoperative GERD symptoms, seven (14.8%) developed de-novo GERD symptoms (Fig. 2).

Operation time and complications

SASI bypass required longer operation time than did SG (108.7 ± 14.7 Vs 92.8 ± 14.6 min, $p < 0.0001$). There was no conversion to open surgery in both groups.

Twelve (20.7%) complications were recorded after SG and four (6.9%) complications after SASI bypass ($p = 0.056$). Complications of SG included de-novo GERD ($n = 7$), staple line leak ($n = 1$), persistent vomiting ($n = 2$), bleeding ($n = 1$), post site hematoma ($n = 1$). Complications of SASI bypass included bleeding ($n = 1$), bowel obstruction ($n = 1$), and pneumonia ($n = 2$) (Table 5). There were no mortalities in this study.

Predictors of %EWL at 12 months

Multiple regression analysis of the %EWL at 12 months revealed that the predictive factors of higher %EWL were:

- Female gender (coefficient = − 7.66, SE = 3.6, $p = 0.035$)
- Lower preoperative BMI (coefficient = − 0.58, SE = 0.15, $p = 0.0001$)
- SASI bypass (coefficient = 12.22, SE = 2.46, $p = 0.0001$).

On the other hand, age (coefficient = − 0.042, SE = 0.14, $p = 0.77$), lower body weight (coefficient = − 0.11, SE = 0.06, $p = 0.055$), and greater height (coefficient = 0.45, SE = 0.16, $p = 0.09$) were not associated with higher %EWL.

Table 5 Complications in both groups according to Clavien–Dindo classification

Variable	SASI ($n = 58$)	Sleeve gastrectomy ($n = 58$)	p value
Clavien–Dindo I (%)	0	3 (5.2)	0.44
Clavien–Dindo II (%)	2 (3.4)	7 (12.1)	
Clavien–Dindo III (%)	2 (3.4)	2 (3.4)	
Clavien–Dindo IV (%)	0	0	

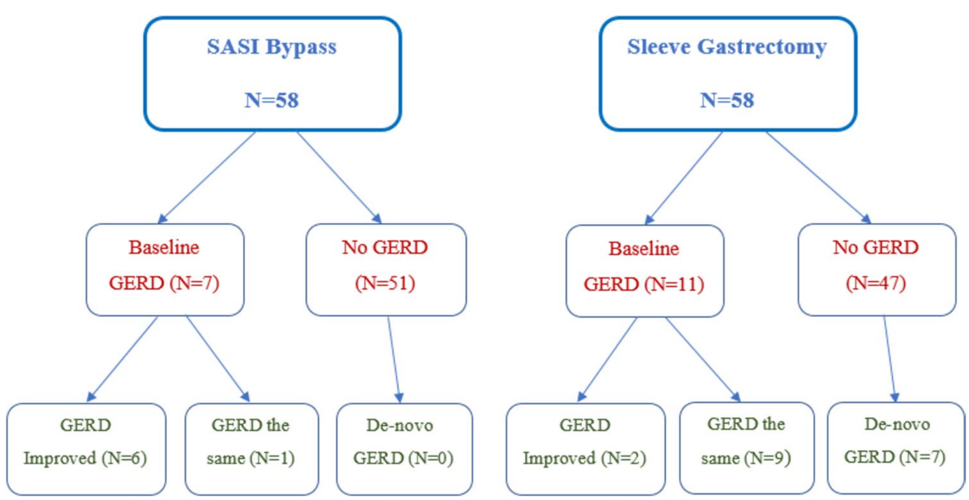
Discussion

SASI has been introduced as a novel bariatric procedure that employs the concept of bipartition instead of the traditional bypass mechanism employed in RYGB. SASI bypass is basically a technical modification of another procedure, the sleeve gastrectomy with transit bipartition, devised by Santoro et al. in 2012 [10]. While SASI bypass entails a single gastroileal anastomosis, the original bipartition procedure involved a roux-en-Y gastroileal anastomosis. Practically, both procedures are based on SG and the addition of gastroileal anastomosis has been described to induce early satiety and enhance remission of T2DM through neuroendocrine modulation [7].

A few reports [11, 12] have assessed the efficacy and safety of SASI bypass since the original report by Mahdy et al. [7] was published. The studies reported excellent results with %EWL reaching up to 94% at 12 months of follow-up. Moreover, remission and improvement in medical comorbidities was remarkable as one study [12] reported complete resolution of T2DM in almost 95% of patients, close to the figure (100%) reported by the original report [7].

Since SASI bypass is a technical modification of SG by adding a single gastroileal anastomosis, we thought that its

Fig. 2 The outcome of gastroesophageal reflux disease in both groups



outcome is best assessed in comparison with the original procedure. Hence, we conducted this case-matched study to compare the efficacy and safety of SASI bypass and SG in terms of weight loss, improvement in comorbidities, and complications.

Both groups had similar patient demographics, BMI, and number of comorbidities which may reflect the successful matching of both groups. This may help reduce the risk of selection bias that is inherent in retrospective studies as the present study. The selection of each procedure was based on an informed discussion between the patient and the physician and therefore the results of this study may actually represent the real-world data of both procedures. Only patients who completed 12 months of follow-up were included to the study to ensure inclusion of patients with the minimum accepted follow-up duration [13].

While previous evidence [6] demonstrated that the efficacy of SG may be reduced in patients with BMI greater than 50 kg/m^2, the average BMI of patients who underwent SG was 51.5 kg/m^2. This observation may be explained that the selection of the bariatric procedure was based upon shared decision making between the surgeon and the patient. Patients with BMI greater than 50 kg/m^2 were advised that SG might not be their optimal option. However, some patients still chose to undergo SG owing to the popularity and feasibility of the procedure that is associated with no enteric anastomoses and with minimal alterations in the nutritional status as compared to bypass and bipartition procedures.

Both SG and SASI bypass conferred significant weight loss and reduction in BMI at 6 and 12 months after surgery. While the difference between the two procedures in postoperative weight and BMI at 6 months was not statistically significant, the reduction in body weight and BMI at 12 months after SASI bypass was significantly higher than after SG.

We may explain the similar weight loss between the two procedures within the first six months after surgery that both procedures rely mainly on the restrictive effect of SG during this initial period, then the effect of hormonal changes, including Ghrelin and GLP-1, starts to become more pronounced after the initial phase of weight loss [14, 15]. The neuroendocrine modulatory effect [7] exerted by the single gastroileal anastomosis of SASI bypass may be an additional mechanism that contributes to more effective and sustained weight loss after SASI bypass as compared to SG, which may explain the greater weight loss at 12 months after SASI bypass.

It was notable that the %EWL at 6 and 12 months after SASI bypass in our study was much less than that reported by Mahdy et al. [7] (46% Vs 75%) and (72.6% Vs 90%), respectively. Another study [12] also documented %EWL to be 67.8 and 94.3 at six and twelve months after SASI bypass. These variations in weight loss after SASI bypass may be attributed to either different patients' characteristics or different technical aspects of the procedure among the studies. Technical variations in SASI bypass may involve the length of the common channel which may range from 250 cm up to 350 cm as Vennapusa and colleagues [12] demonstrated. In addition, the size of the gastroileal anastomosis can also factor in the wide variation of weight loss after SASI bypass.

While both procedures achieved similar improvement in hypertension and hyperlipidemia, SASI bypass showed to be have superior results to SG in terms of remission and improvement in T2DM and GERD. As Mahdy and colleagues [7] elaborated, SASI Bypass serves to confer significant improvement in T2DM through a number of mechanisms that include function restriction that results in remarkable reduction in the caloric intake, and the bipartition mechanism that allows rapid entrance of undigested chyme to amplify the nutritive stimulation of the distal gut and passage of a smaller part of the meal through the duodenum to diminish the nutritive overstimulation of the proximal gut. This may explain the impressive rates of remission/improvement in T2DM in the original series [7] and the subsequent studies [11, 12], including our study, which ranged from 90 to 100%. On the other hand, SG achieved remission or improvement in T2DM in 70% of patients, close to the figure (64%) presented by the STAMPEDE trial that compared SG, gastric bypass, and intensive medical treatment of T2DM [16].

As we enter the era of specialized metabolic surgery [17], SASI bypass may represent a valid option for patients with morbid obesity and T2DM; however, it should be compared with gastric bypass surgery in regards remission of T2DM to draw more solid conclusions. The excellent improvement in T2DM after various bariatric procedures, including SG, has impelled that bariatric surgery be considered as metabolic surgery and to be used exclusively in patients with T2DM including those with BMI less than 35 kg/m^2 [18].

The relation between SG and GERD seems to be contentious with some studies reporting worsening of GERD after SG and others reporting improvement in symptoms after SG [19, 20]. SASI bypass has conferred significant improvement in GERD symptoms in more than 85% of patients of our series. Improvement in GERD symptoms after SASI bypass may be attributed to the effect of adding an anastomosis between the distal gastric sleeve and the ileum which may reduce the intra-gastric pressure and help drainage of gastric acidity, thus contributes to the relief of the GERD symptoms. Revising SG to SASI bypass may have an advantage for patients who develop GERD after SG, which accounts for up to 23% of patients [21, 22].

The complication rates of SASI bypass and SG were comparable, implying that the addition of the gastroileal anastomosis did not incur further morbidities. The operation time of SASI bypass was about 15 min longer than SG which accounts for the time consumed for constructing the gastroileal anastomosis. Although no formal costs calculations have been performed in the present study, we may assume that SASI bypass costs more than SG if we added the expense of the additional cartridge used for creation of the gastroileal anastomosis.

Limitations of the present study include its retrospective nature which may be associated with selection bias. However, in order to overcome this limitation we performed case-matching between the two groups to ensure similar baseline characteristics of patients. The results of this report represent the short-term outcome of SG and SASI bypass, longer follow-up is needed to ascertain the results of this study and to assess the long-term nutritional changes after each procedure. A large multicenter randomized trial comparing SG and SASI bypass is needed to substantiate the findings of this retrospective study.

Conclusion

The %EWL at 12 months after SASI bypass was significantly higher than after SG. SASI bypass conferred better remission and improvement in T2DM and GERD and had longer operation time than SG. Both procedures had similar weight loss at 6 months postoperatively and comparable complication rates.

Author contributions SE and HE designed the study. SE, AM, MAR, and TM contributed to data collection, data analysis, writing and revising the manuscript. HE, SE, AE, and MAR, AM, and TM performed the procedures and contributed to data interpretation and critical revision of the manuscript. Mohamed Abdel-Razik supervised data collection, and critically revised the manuscript.

Compliance with ethical standards

Conflict of interests Sameh Emile, Amr Madyan, Tarek Mahdy, Ayman Elshobaky, Hosam Elbanna, and Mohamed Abdel-Razik had no conflicts of interests to disclose.

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