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ORIGINAL CONTRIBUTIONS

Roux-en-Y Gastric Bypass with Long Biliopancreatic Limb Compared to Single Anastomosis Sleeve Ileal (SASI) Bypass in Treatment of Morbid Obesity

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Abstract

Purpose Bariatric surgery is the most effective treatment of morbid obesity. Bariatric procedures employ different mechanisms of action to induce weight loss. The present study aimed to compare single-anastomosis sleeve ileal (SASI) bypass and roux-en-Y gastric bypass RYGB with long biliopancreatic limb (BPL) in terms of weight loss, remission of comorbidities, complications, and nutritional status.

Methods This was a single-center cohort study on patients with morbid obesity who underwent RYGB with long BPL of 150 cm or SASI bypass. The main outcome measures were weight loss and improvement in comorbidities at 12 months, nutritional status, and complications.

Results The present study included 92 patients (59.8% females) of a mean age of 38.4 years and mean BMI of 42 kg/m^2. RYGB and SASI bypass were followed by a significant decrease in body mass index at 12 months and were comparable in terms of excess and total weight loss. Improvement in comorbidities after the two procedures was similar. The serum albumin levels showed a significant decline after RYGB, but not after SASI bypass. The postoperative serum iron levels were higher after SASI bypass than after RYGB. There was no significant difference in regard to complication rates (13% vs 4.3%, $p = 0.27$).

Conclusions RYGB with long BPL and SASI bypass achieved satisfactory weight loss and improvement in comorbidities that were comparable among the two groups. Long BPL RYGB was followed by a significant decrease in serum albumin and iron levels at one year, which was not observed after SASI bypass.

Keywords RYGB · SASI bypass · Single-anastomosis · Sleeve ileal · Long biliopancreatic limb · Morbid obesity

Key Points

- RYGB and SASI bypass were followed by a significant decrease in BMI and were comparable in terms of excess and total weight loss and improvement in comorbidities.
- The serum albumin levels showed a significant decline after RYGB, but not after SASI bypass.
- The postoperative serum iron levels were higher after SASI bypass than after RYGB.
- There was no significant difference in regards to complication rates.

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Background

Laparoscopic Roux-en-Y gastric bypass (RYGB) is considered one of the most effective procedures for the treatment of morbid obesity. Since its introduction, there have been many variations to RYGB to increase weight loss while having minimal nutritional complications. In malabsorptive or mixed bariatric procedures, such as RYGB, the bowel length determines the absorptive capacity for micronutrients. Subsequently, the outcome in terms of weight loss, improvement in comorbidities, and micronutrient deficiencies should be correlated with the length of the bowel bypassed [1–3]. To date, the best alimentary and biliopancreatic limb (BPL) lengths in the RYGB remain unclear.

While the absorptive capacity of the BPL is completely lost as there is no transit of nutrients through this bowel segment, the alimentary limb (AL) may still absorb some nutrients that do not require further digestion by biliopancreatic secretion [4]. Most studies have reported AL length of 100–150 cm and BPL length of 50–90 cm, whereas the common limb length was not usually recorded.

The understanding of digestive physiology is now changing, and the interacting neuroendocrine signals that control hunger, satiety, and energy expenditure are better understood. Bipartition is a surgical technique for obesity based on the concept of digestive adaptation [5]. Santoro et al. reported the long-term data regarding sleeve gastrectomy with transit bipartition (SG þ TB), which is a simple surgical procedure that aims to amplify the nutritive stimulation of the distal gut and simultaneously diminish the exposure of the proximal bowel to nutrients, without completely deactivating duodenum and jejunum.

SASI bypass was based on the principles of SG þ TB, yet it entails a single anastomosis rather than a roux-en-Y one. Recently, a number of studies reported promising short-term outcome of SASI bypass in terms of weight loss and remission of diabetes mellitus (DM), yet comparative studies assessing SASI bypass against other commonly performed procedures are still needed [6, 7].

In a recent study [8], we assessed the outcome of SASI against two standard procedures recognized by the major bariatric societies, the sleeve gastrectomy and one-anastomosis gastric bypass (OAGB). The study concluded that SASI bypass was associated with greater weight loss, better improvement in DM, and more long-term nutritional complications than the other two procedures.

In the present study, we chose to compare SASI bypass with RYGB with long BPL rather than the standard RYGB since the long BPL is associated with greater malabsorptive power, and our objective was to compare the bipartition mechanism of SASI with the malabsorption/diversion mechanism of RYGB. Therefore, the present study aimed to compare SASI bypass and RYGB bypass with long BPL of 150 cm in terms of weight loss, remission of type 2 DM (T2DM), and other medical comorbidities, nutrient deficiencies, and complications.

Patients and Methods

Study Design

Prospective data of patients with morbid obesity who underwent either RYGB with BPL of 150 cm and AL of 100 cm or SASI bypass were reviewed. Morbid obesity was defined as BMI >40 kg/m^2 or >35 kg/m^2 with at least one associated medical comorbidity. The study was conducted at Al Qassimi Hospital, Sharjah, United Arab Emirates in the period of January 2019 through January 2020. Ethical approval for the study was obtained from the Research Ethics Committee of the Ministry of Health and Population with reference number MOHAP/DXB-REC/SSS /No. 132/2020.

Selection Criteria

Patients of either sex aged 18–65 years with morbid obesity who underwent RYGB with BPL of 150 cm and AL of 100 cm or SASI bypass were included. All patients matched the MOHAP guidelines to have bariatric surgery.

We excluded patients with obesity secondary to endocrine disorders, those with history of previous bariatric surgery and those unwilling to comply with the diet regimen after surgery.

Preoperative Assessment and Preparation

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 body mass index (BMI) was calculated. Abdominal ultrasonography, ECG, and chest x-ray were done for all patients prior to surgery.

Patients received a subcutaneous injection of low-molecular weight heparin (Enoxaparin, 40 I.U), 10 h before the operation and were also 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.

Procedure Selection

The selection of the procedure for each patient was based on shared decision-making between the patient and a multidisciplinary team that included the operating surgeon, physician, dietitian, psychologist, and anesthetist. Patients were asked about their expectations and main concerns, and then the benefits and drawbacks of each procedure were explained to them. We explained to the patients that we expect similar outcomes after the two procedures in terms of weight loss and comorbidity improvement, yet we anticipated lower incidence of nutrient deficiency after SASI bypass since it entails bipartition rather than complete diversion of food, and thus part of food will pass through the normal pathway.

Surgery

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

SASI Bypass Using five-port technique, standard sleeve gastrectomy (SG) was performed. Devascularization of the greater curvature was done using a vessel sealing device, starting 5 cm away from the pylorus. Then, guided by a 36-Fr orogastric tube inserted into the stomach, the stomach was resected using a linear stapler starting 5 cm away from the pylorus and proceeding up to the angle of Hiss.

Upon completion of SG and creation of the gastric pouch, the patient's position was changed to Trendelenburg position. Three meters of ileum were measured starting from the ileocecal junction. Using 45-mm linear stapler, an antecolic side-to-side anastomosis between the antrum and the body 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.

RYGB with Long BPL The gastro-hepatic ligament was dissected 5 cm below the gastroesophageal junction. A gastric pouch was created by transecting the stomach transversely then vertically with a surgical stapler to construct a 50-ml gastric pouch. The stapler was guided by the insertion of a 36 Fr calibration tube.

A gastrotomy was made at the lowermost point of the gastric pouch posterior to the staple line using the harmonic scalpel. The greater omentum and transverse colon were retracted cranially and the proximal jejunum near the ligament of Treitz was identified. 150 cm of the proximal jejunum were measured; then an enterotomy was made at that point using the harmonic scalpel. An antecolic isoperistaltic gastrojejunostomy was created on the posterior wall of the gastric pouch using a 45-mm linear stapler. The calibration tube was introduced easily from the gastric pouch to the alimentary limb of the anastomosis. The anastomotic rent was closed in one layer using PDS 2/0 suture. The integrity of the staple line was tested by intragastric injection of methylene blue. One meter distal to the gastrojejunostomy, a side-to-side jejuno-jejunal anastomosis was constructed using a 45-mm stapler. The mesenteric defect and Peterson defect were closed using 2/0 silk suture.

Study Outcomes

The primary outcome of this study was weight loss measured by the percentage of excessive weight loss (%EWL) and total weight loss (%TWL) and the remission of T2DM, hypertension, hyperlipidemia, sleep apnea. Secondary outcomes of the study were postoperative complications and nutritional status.

%EWL was calculated as follows: (preoperative weight — follow-up weight)/preoperative excess weight/100. Remission and improvement in comorbidities were defined in accordance to the standardized outcomes reporting in metabolic and bariatric surgery devised by the ASMBS [9].

Remission of T2DM was defined in this study as a fasting plasma glucose level < 110 mg/dL or HbA1C level < 6% without hypoglycemic medication at one year after surgery, whereas improvement was defined as a reduction of at least 25% in the fasting plasma glucose level and of at least 1% in the hemoglobinA1c level with hypoglycemic drug treatment. Remission of other comorbidities was considered if the disease was controlled without any medications.

Follow-Up

Patients were discharged in the third postoperative day and were scheduled for follow-up at the outpatient clinic once every week during the first month after the surgery then every month for the first 3 months, then every 3 months for 1 year. At each visit, weight was recorded and BMI was calculated. Improvement in comorbidities was assessed at 12 months after surgery. Complications and change in nutritional parameters as serum albumin and iron were collected and recorded

Data Collected

Baseline data included age, gender, initial weight, initial BMI, and medical comorbidities. Outcome data included %EWL, %TWL, BMI, early complications during the first month, and long-term complications. Biochemical parameters collected included fasting blood sugar, HbA1c, serum iron, serum hemoglobin, and serum albumin levels.

Sample Size Calculation

The sample size was calculated using an online sample size and study power software (https://clincalc.com/stats/samplesize.aspx). Based on the primary end point of the study (%TWL at 12 months) and in light of previous studies [6, 10] that reported TWL of 33% after RYGB with long BPL and 27% after SASI bypass, and considering a standard deviation of 10, it was assumed that a minimum of 88 patients, divided on the two groups equally, were required to achieve a study power of 80% with alpha set at 5%.

Statistical Analysis

Data were analyzed using IBM® SPSS® (version 21.0 for Windows). Unless stated otherwise, all data are expressed as the mean ± standard deviation (SD) or as percentages. Descriptive and inferential statistical analyzes were performed using both parametric and non-parametric procedures as appropriate. Comparisons of categorical/ordinal variables were performed using chi-square analysis for trends or Fisher exact test. Continuous variables were compared using an independent student test. All tests were two-tailed, and the results with $p < 0.05$ were considered statistically significant.

Results

Characteristics of the Entire Cohort

The present study included 92 patients of a mean age of 38.4 ± 9.5 years. Patients were 55 (59.8%) women and 37 (40.2%) men. The mean weight of patients was 113.8 ± 25.2 kg, and the mean preoperative BMI was 42 ± 6.5 kg/m^2. Regarding medical comorbidities, 48 (52.1%) patients had type 2 DM, 33 (35.9%) had hypertension, 17 (18.5%) had dyslipidemia, and 6 (6.5%) had obstructive sleep apnea.

Forty-six patients underwent SASI bypass and another 46 underwent RYGB with long BPL. There were no significant differences between the two groups in regards to age, sex, preoperative weight, BMI, and comorbidities except for dyslipidemia which was more common in the SASI group (28.2% vs 8.7%; $p = 0.03$) (Table 1).

Table 1 Patients' demographics in the two groups

Variable	SASI ($n = 46$)	RYGB ($n = 46$)	p value
Mean age in years	38.4± 9.2	38.3± 9.8	0.96
Male/female	23/23	14/32	0.08
Mean weight in kg	116± 24.6	111.5± 25.8	0.39
Mean height in cm	166.6± 10.4	162.2 ± 13.7	0.08
Mean BMI in kg/m^2	44.4± 9.8	41.1 ± 8.7	0.09
Diabetes mellitus (%)	29 (63)	19 (41.3)	0.06
Hypertension (%)	21 (45.6)	12 (26.1)	0.08
Dyslipidemia (%)	13 (28.3)	4 (8.7)	0.03
Sleep apnea (%)	5 (10.9)	1 (2.2)	0.2

**BMI* body mass index **SASI* single anastomosis sleeve ileal **RYGB* Roux-en-Y gastric bypass

Weight Loss

Both groups showed a significant decrease in body weight and BMI at 12 months postoperatively. The postoperative weight and BMI were significantly lower at 12 months after RYGB than after SASI bypass [(72.8± 14.5 vs 83.6±18.2; p= 0.002) and (27.7± 3.9 vs 32± 7.6; p=0.001)]. However, both groups were comparable in terms of %EWL (78.5± 29.4 vs 79.4± 26.8; p=0.88) and %TWL (30.4± 12.1 vs 33.4± 10.3; p=0.2) (Table 2).

Improvement in Comorbidities

Remission or improvement in DM was recorded in 24/29 (82.7%) patients after SASI bypass versus 14/19 (73.7%) patients after RYGB ($p = 0.69$). There were no significant differences between the two groups in terms of improvement in hypertension (57.1% vs 58.3%, $p = 0.95$), dyslipidemia (76.9% vs 100%, $p = 0.54$), and sleep apnea (20% vs 0%, $p = 0.99$) (Table 3).

Change in Biochemical Parameters

Both procedures were followed by a significant reduction in the fasting blood glucose and HbA1c levels, and this reduction was comparable between the two groups. The postoperative serum hemoglobin levels were significantly lower after RYGB as compared to SASI bypass. The serum albumin levels showed a significant decline at 12 months after RYGB whereas no significant change was observed after SASI bypass. The serum iron levels showed a significant increase after SASI bypass and a slight, non-significant decrease after RYGB. Overall, the postoperative serum iron levels were higher after SASI bypass than after RYGB (Table 4).

Complications

Six complications were recorded after SASI bypass, five of which were procedure-related [bowel obstruction ($n = 1$), GERD ($n = 2$), bleeding and hematoma ($n = 1$), and persistent vomiting ($n = 1$)] and one was patient-related [pulmonary embolism ($n = 1$)].

One female patient aged 58 years with BMI of 38 kg/m^2 developed increasing chest pain, cough, and dyspnea within 48 h after SASI bypass. Chest CT scanning revealed signs of pulmonary embolism which was promptly treated with intravenous hydration and systemic anticoagulation therapy (subcutaneous enoxaparin, 80 IU twice per day for 10 days). The patient was improved on treatment, and the embolism was resolved without residual lung damage.

Table 2 Weight loss at 12 months postoperatively in the two groups

Variable	SASI (n = 46)	RYGB (n = 46)	p value
Mean preoperative weight in kg	116 ± 24.6	111.5 ± 25.8	0.39
Mean postoperative weight in kg	83.6 ± 18.2	72.8 ± 14.5	0.002
p value	< 0.0001	< 0.0001	
Mean preoperative BMI in kg/m2	44.4 ± 9.8	41.1 ± 8.7	0.09
Mean postoperative BMI in kg/m2	32 ± 7.6	27.7 ± 3.9	0.001
p value	< 0.0001	< 0.0001	
Mean %EWL at 12 months	78.5 ± 29.4	79.4 ± 26.8	0.88
Mean %TWL at 12 months	30.4 ± 12.1	33.4 ± 10.3	0.2

*_BMI_ body mass index *_EWL_ excess weight loss *_TWL_ total weight loss

*_SASI_ single anastomosis sleeve ileal *_RYGB_ Roux-en-Y gastric bypass

Another 36-year-old female patient with BMI of 36.8 kg/m^2 developed bowel obstruction after SASI bypass. The obstruction did not resolve by conservative treatment and required laparoscopic exploration. A twisted gastroileal anastomosis was found and was revised laparoscopically.

Two patients had staple line bleeding, one of whom responded well to conservative treatment while the other had unstable hemodynamic status and required laparoscopic exploration with evacuation of a big hematoma and clipping of the bleeding points in the staple line.

Finally, a 50-year-old female patient experienced persistent vomiting after SASI bypass that did not resolve with conservative measures. Upper gastrointestinal endoscopy revealed stenosis of the gastroileal anastomosis, and laparoscopic revision of the anastomosis was performed.

Therefore, reoperation was required in three patients after SASI bypass: one had revision of SASI bypass for persistent vomiting, another had staple line bleeding and hematoma that required laparoscopic exploration and hemostasis, and finally one patient required laparoscopic exploration for bowel obstruction.

Two procedure-related complications were recorded after RYGB, both patients had reactionary hemorrhage that was controlled with conservative measures and did not warrant surgical intervention. There was no significant difference between the two procedures in regard to overall complication rates (13% vs 4.3%, $p = 0.27$).

Discussion

The mechanisms by which different bariatric procedures achieve weight loss and improvement in obesity-related comorbidities have been thoroughly investigated and better understood in the recent years [11–13]. RYGB and SASI bypass employ two different mechanisms of action as the former entails exclusion of an intestinal segment and complete diversion of the ingested meal, whereas the latter adopts the principle of bipartition with switching rather than complete exclusion. To the best of our knowledge, there are no former studies that compared RYGB with long BPL and SASI bypass in treatment of morbid obesity. Therefore, we conducted this study to assess the outcome of the two procedures in terms of weight loss, improvement of comorbidities, and nutritional outcomes.

Although the present study was a retrospective analysis of prospective data, there were no significant differences between the two procedures with regard to the baseline patients' characteristics which can serve to minimize the risk of selection bias. Overall, RYGB with long BPL achieved satisfactory weight loss at 12 months postoperatively, and both were comparable in regard to EWL, TWL, improvement in DM, and other comorbidities. However; nutrient deficiencies, namely, albumin and iron deficiency, were more common after RYGB.

We chose to perform RYGB with long BPL to assess the bariatric and metabolic outcome of this modification. It is known that RYGB depends on a combination of both

Table 3 Improvement in comorbidities in the two groups

Variable	SASI (n = 46)	RYGB (n = 46)	p value
Remission or improvement in diabetes mellitus	24/29 (82.7)	14/19 (73.7%)	0.69
Remission or improvement in hypertension	12/21 (57.1%)	7/12 (58.3%)	0.95
Improvement in dyslipidemia	10/13 (76.9%)	4/4 (100%)	0.54
Improvement in sleep apnea	1/5 (20%)	0/1 (0)	0.99

*_SASI_ single anastomosis sleeve ileal *_RYGB_ Roux-en-Y gastric bypass

Table 4 Change in the laboratory parameters in the two groups

Variable	SASI (*n* = 46)	RYGB (*n* = 46)	*p* value
Mean preoperative fasting blood sugar	8 ± 4.2	6.5 ± 3.5	0.06
Mean postoperative fasting blood sugar	5.7 ± 1.9	5.1 ± 2.7	0.22
p value	0.001	0.03	
Mean preoperative HbA1C	7.1 ± 2.4	6.7 ± 2.8	0.46
Mean postoperative HbA1C	5.8 ± 2.7	5.4 ± 1.5	0.38
p value	< 0.0001	0.006	
Mean preoperative serum hemoglobin	12.9 ± 1.9	12.2 ± 1.3	0.04
Mean postoperative serum hemoglobin	12.8 ± 1.66	11.8 ± 1.6	0.004
p value	0.94	0.19	
Mean preoperative serum albumin	3.39 ± 0.28	4.3 ± 0.5	< 0.0001
Mean postoperative serum albumin	3.38 ± 0.66	3.6 ± 1.3	0.3
p value	0.92	0.001	
Mean preoperative serum iron	9.5 ± 5.7	8 ± 4.6	0.17
Mean postoperative serum iron	12.4 ± 6.5	7.7 ± 5.2	0.0002
p value	0.02	0.77	

**SASI* single anastomosis sleeve ileal **RYGB* Roux-en-Y gastric bypass

malabsorptive and restrictive elements [14]. Despite this combined mechanism of action, up to 15% of patients fail to achieve satisfactory weight loss after RYGB [15]. Therefore, modifications of this procedure, including change in the size of gastric pouch, stoma size, or limb lengths, were devised to improve the results [10, 16].

To date, the exact mechanism by which BPL elongation affects weight loss remains unclear. Theoretically, a long BPL is associated with an exaggerated hind gut effect, as the food bolus is rapidly delivered to the hind gut leading to secretion of glucagon like peptide-1 (GLP-1) and incretin. These hormones induce nausea and ileal brake which eventually lead to weight loss [17, 18].

A recent study conducted by Moon et al. [19] reported that long BPL RYGB managed to achieve %TWL of 32.3% at 12 months postoperatively. This was close to the 12-month TWL recorded after RYGB in our study (33.4%) and to what was documented by Homan et al. [10] who reported EWL of 81% and TWL of 33% at 1 year after long-limb RYGB.

On the other hand, SASI bypass was designed as a simple modification of sleeve gastrectomy with transient bipartition described by Santoro et al. The aim of the bipartition is to induce neuroendocrine effects to enhance the metabolic effect of the operation [4, 5]. We recorded an EWL of 78% at 12 months after SASI bypass, which was within the range of EWL reported by the first study on the procedure [20] (90%) and other studies [7] that reported an %EWL of 72.6%.

Both procedures conferred similar improvement in medical comorbidities. RYGB with long BPL achieved remission or improvement in 73% of patients with DM which concords with a previous meta-analysis that concluded a remission/improvement in DM after RYGB equal to 80% [21]. The rate of improvement in hypertension in our study (58%) was lower than that reported by other authors (83.4%) [22]. It was notable that the rate of improvement in DM after SASI bypass in our study was less than 85%, and this was lower than that reported in previous studies [7, 20, 23] that exceeded 95%. This can possibly be explained by the fact that most diabetic patients in our study had a long history of DM which may be associated with less response to metabolic surgery

Despite the similar effectiveness of the two procedures, there were differences in terms of nutritional status at 1 year postoperatively. A significant decline in serum albumin levels was observed after RYGB with long BPL whereas SASI bypass was not followed by a similar change. This may imply that despite the advantage gained from BPL elongation on weight loss, this elongation may affect the length of the common channel leading to an increased risk of postoperative malnutrition, namely, hypoalbuminemia [10]. Indeed, a previous study [24] found hypoalbuminemia to occur in up to 56% of patients after RYGB.

Furthermore, vitamin and mineral deficiencies are also common after RYGB and increasing the BPL length may perhaps worsen these deficiencies via bypassing the duodenum which is the major site of iron absorption. Previous studies showed that iron deficiency can be encountered in 20–49% of patients after RYGB [25, 26]. In agreement with the former studies, the present study found postoperative serum iron levels to be significantly lower after RYGB than SASI bypass.

On the other hand, SASI bypass was not followed by a significant reduction in albumin and iron levels. This was in line with a previous study [20] that reported a significant improvement in serum albumin and iron levels at 12 months after SASI as compared to their baseline levels. Conversely, another study [23] reported that albumin levels decreased down to 3.9 g/dl at 1 year after surgery; however, the postoperative albumin levels were within the normal range.

Although there was no statistically significant difference between the two procedures in terms of postoperative complications, there might be a clinically relevant difference. Almost all complications recorded in the study were procedure-related; however, complications after SASI bypass warranted reoperation in three patients whereas the complications recorded after RYGB were managed conservatively.

In summary, on comparing RYGB with long BPL and SASI bypass, we found both operations to be associated with comparable weight loss and comorbidity improvement, yet the risk of iron and albumin deficiency was more likely after long limb RYGB. The decreased incidence of nutrient deficiency after SASI bypass may be attributed to the fact that the normal food pathway was partly maintained which can help in the absorption of some essential nutrients and may be better than other bariatric procedures that involve bypass of the duodenum [27].

The present study has some limitations including the single-center and retrospective nature of the study which may be associated with inherent risk of bias. Although both procedures seem effective and associated with satisfactory outcomes, we should remember that these results reflect the short-term follow-up of 1 year, and thus more studies with longer follow-up are needed to draw more solid conclusions. Therefore, more studies including more patients from different bariatric centers with longer follow-up are recommended to ascertain the preliminary findings of this study.

Conclusion

RYGB with long BPL and SASI bypass achieved satisfactory weight loss and improvement in comorbidities that was comparable among the two groups. Long BPL RYGB was followed by a significant decrease in serum albumin and iron levels at 1 year, which was not observed after SASI bypass.

Author contribution Tarek Mahdy and Sameh Emile designed the study, participated in data collection and analysis, writing and revision of the manuscript. Abdulwahid Alwahedi, Waleed Gado and Carl Schou contributed to data interpretation, drafting, and critical revision of the final manuscript. Amr Madyan shared in data analysis and writing of the manuscript.

Declarations

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Ethics approval for the study was obtained from the Research Ethics Committee.

Informed consent Informed consent does not apply as for this type of study formal consent is not required.

Conflict of interest The authors declare no competing interests.

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