Original Article

Single anastomosis sleeve jejunal bypass versus one anastomosis gastric bypass in treatment of obesity and metabolic diseases: A randomized controlled trial

Yehia K. S. M. Salem, Sameh A. A. Maaty, Karim S. Abdelsamee, Ahmed M. Farrag

Department of General Surgery, Faculty of Medicine, Ain Shams University, Cairo, Egypt.

ABSTRACT

Introduction: Bariatric surgeries are an effective treatment for morbid obesity and its associated co-morbidities including type 2 diabetes mellitus, hypertension (HTN), and dyslipidemia. Single anastomosis sleeve jejunal (SASJ) has not been well studied in the literature or compared with other bariatric surgeries. We aim to compare one anastomosis gastric bypass (OAGB) to SASJ in terms of reduction in BMI, resolution of co-morbidities, postoperative complications, and nutritional status.

Patients and Methods: A randomized clinical trial of patients undergoing either OAGB or SASJ at 1:1 ratio for treatment of morbid obesity. Participants were enrolled since April 2022 and were followed for at least 12 months at bariatric surgery department at Ain Shams University Hospital, a tertiary care center. Inclusion criteria for participant's enrollment were age between 18 and 60 years old and BMI greater than or equal to 40 or BMI 35–40 with obesity-related comorbidities. Patients were excluded if preoperative upper gastrointestinal endoscopy showed GERD class C or Barrett's esophagus, previous upper gastrointestinal tract surgery or liver cirrhosis, on oral steroid therapy, previous bariatric surgery, contraindications for abdominal insufflation as those with severe cardiovascular or severe restrictive respiratory diseases, Not fit for general anesthesia, significant abdominal ventral hernia, major psychiatric illness, and pregnant. Primary outcome involves weight loss, BMI loss, total weight loss %, and excess weight loss (EWL%). Secondary outcomes include resolution of comorbidities, biliary reflux, postoperative complications, readmissions, reoperations, and nutritional status.

Results: Since April 2022, 68 patients have been enrolled into the study. The mean age, weight, and BMI of the entire cohort are 38.32±10.08 years old, 124.72±18.75 kg, and 43.97±5.47 kg/m^2. A higher number of patients had DM and/or HTN in SASJ (38.2% DM, 47.1% HTN) compared with OAGB. Comparison between both groups showed no significant statistical difference in postoperative complications (*P=0.135*), readmissions (*P=1*), reoperations (*P=0.555*), and bile reflux (*P=0.09*). Both SASJ and OAGB groups had comparable postoperative weight loss, BMI, EWL % at 6 and 12 months of follow-up, however, OAGB had significantly higher total weight loss % at 6 months only. SASJ patients had a significantly higher rate of resolution from DM compared with OAGB patients (*P=0.012*). No significant difference between both groups in the resolution of HTN (*P=0.07*) and dyslipidemia (*P=0.03*). Patients who had OAGB had a higher rate of gallstones postoperatively compared with SASJ patients (*P=0.001*). None of the patients had anemia, hypoalbuminemia, or iron deficiency. Regarding vitamin D and calcium, no significant differences between both surgeries (SASJ and OAGB) were noted.

Conclusion: Remission rates of DM are higher in SASJ in comparison to OAGB. SASJ had similar weight loss, BMI loss, and EWL to OAGB. Both procedures have comparable results as regards postoperative complications, readmissions, and re-operations except development of gallstones which is significantly higher in OAGB group.

Key Words: Metabolic diseases, obesity, one anastomosis gastric bypass, single anastomosis sleeve jejunal bypass.

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Corresponding Author: Yehia Khaled, MSc, Department of General Surgery, Faculty of Medicine, Ain Shams University, Cairo, Egypt. **Tel.:** 01000949404, **E-mail:** yehia-khale@med.asu.edu.eg

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INTRODUCTION

Obesity is a pandemic health problem in both developed and developing countries and the costs of care continue to grow in parallel with the prevalence of the disease. This morbid condition leads to a high incidence of complications and a decrease in life expectancy, especially among younger adults. Young adults aged 20–30 years old with morbid obesity (BMI >45) had years of life lost (YLL) of 13 and eight in white men and women, respectively. For black young adults, years of life lost were 20 and five in men and women, respectively, for the same level of obesity[1].

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Surgical treatment of morbid obesity results in significant sustained weight loss, which reduces obesity-related morbidity and increases survival compared with patients receiving optimal medical therapy. In a study by Sjöström *et al*. with an average of 10.9 years of follow-up, 4047 obese Swedish patients received either bariatric surgery or conventional medical therapy. Surgery group had a lower adjusted hazard ratio (0.71, *P=0.01*) compared with control group[2].

Bariatric surgery is currently considered the most effective treatment for morbidly obese patients (BMI >35 Kg/m^2) for weight loss[3,4]. Novel and conventional bariatric surgeries manage obesity-related comorbidities as remission of type 2 diabetes mellitus (type 2 DM) and improvement of other metabolic syndrome, such as hyperlipidemia and hypertension (HTN). Some previous studies demonstrated that these metabolic effects are not only due to weight loss and decreased caloric intake, but also to endocrinal changes from surgical manipulation of the gastrointestinal tract[5].

In 1997, Dr Robert Rutledge developed one anastomosis gastric bypass (OAGB) procedure to modify the standard Billroth II procedure. A pouch of the stomach along lesser curvature is made then a loop of small intestine is anastomosed to the gastric pouch at about 200 cm from the duodenojejunal junction (ligament of Treitz)[6].

On the other hand, in laparoscopic single anastomosis sleeve jejunal (SASJ) bypass, we shifted the anastomosis up to the jejunum to keep pass to the duodenum to decrease nutritional deficiency and to allow endoscopic management of obstructive jaundice. The effect of the SASJ procedure on nutritional deficiency was passed by Pazouki and found to have a safe nutritional outcomes[7–9].

Objective

The objective of this study is to compare the outcomes of SASJ bypass as a modified technique from SASI and OAGB as a treatment option for morbid obesity as regard weight loss and co-morbidities resolution.

PATIENTS AND METHODS:

Study time and setting

We conducted a randomized clinical trial (noninferiority trial) of patients undergoing either OAGB or SASJ for the treatment of morbid obesity.

Participants were enrolled since April 2022 and were followed-up for at least 12 months at bariatric surgery department at Ain Shams University Hospital, a tertiary care center. Decision of procedural choice was a shared decision between the multidisciplinary team and the patients.

Study outcomes

Primary outcome involves weight loss, BMI loss, total weight loss (TWL %), and excess weight loss (EWL %). Secondary outcomes include resolution of comorbidities (DM, HTN, and dyslipidemia), biliary reflux, postoperative complications, readmissions, reoperations, and nutritional status.

Eligibility criteria

Inclusion criteria for random enrollment of participants are age between 18 and 60 years old and BMI greater than or equal to 40 or BMI 35–40 with obesity related comorbidities (e.g. HTN, hyperlipidemia, type 2 DM, obstructive sleep apnea, nonalcoholic fatty liver disease, gastroesophageal reflux disease and severe arthritis).

Patients were excluded if preoperative upper gastrointestinal endoscopy showed GERD class C and Barrett's esophagus, previous upper gastrointestinal tract surgery or liver cirrhosis, on oral steroid therapy, previous bariatric surgery, contraindications for abdominal insufflation as those with severe cardiovascular or severe restrictive respiratory diseases, not fit for general anesthesia, significant abdominal ventral hernia, major psychiatric illness, and pregnant.

Sampling and randomization

Patients were allocated to wither OAGB or SASJ with 1:1 ratio. Patients who presented to bariatric clinic at Ain Shams University hospitals, fit eligibility criteria, and agreed to participate were enrolled.

Operative techniques

SASJ is a new operation for morbid obesity, we did sleeve gastrectomy using a bougie with the size of 36 Fr primarily. After that, the gastrojejunostomy anastomosis was made within 200 cm of the ligament of Treitz, and the selected loop was stapled side to side within 6 cm or more away from the pylorus.

The OAGB includes creation of long narrow gastric pouch about (80–100) cc volume, after that, the gastrojejunostomy anastomosis will be 200 cm from ligament of Treitz.

Follow up

Postoperatively, patients were followed-up at 1 week, 1, 6, and 12 months at the surgical clinic. In each clinic visit, patients were assessed for any postoperative complications, EWL, HTN and glycemic control, and diet plan. Every 6 months, patient's lipid profile was assessed.

Statistical analysis

Collected Data were revised, coded, and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges when parametric. Qualitative variables were presented as number (n) and percentages (%). The comparison between groups with qualitative data were done by using χ^2 test. The comparison between two groups with quantitative data and parametric distribution were done by using Independent t-test. The confidence interval was set to 95% and the margin of error accepted was set to 5%. The sample size was calculated using online power (sample size) calculators https://www.sealedenvelope.com/power/binary-noninferior.

RESULTS:

Since April 2022, 68 patients were enrolled into the study. Mean age, weight, and BMI of entire cohort are 38.32±10.08 years old, 124.72±18.75 kg, and 43.97±5.47 kg/m2. Patients were divided equally into SASJ group (n=34) or OAGB group (n=34). Significantly higher number of patients had DM and/or HTN in SASJ (38.2% DM, 47.1% HTN) compared with OAGB. All other baseline characteristics were comparable between both groups as shown in (Table 1). No significant difference between both groups in hospital stay, but four patients in SASJ group had intraoperative hiatal hernia repair (Table 2).

Table 1 Baseline characteristics of included participants

	Single anastomosis sleeve jejunal group (N=34) [n (%)]	One anastomosis gastric bypass group (N=34) [n (%)]	Test-value	*P value*	Significance
Age (y)					
Mean±SD	39.38±7.9	37.26±11.9	0.865•	0.390	NS
Range	21–53	19–60			
Sex					
Female	20 (58.8)	20 (58.8)	0.000*	1.000	NS
Male	14 (41.2)	14 (41.2)			
Weight					
Mean±SD	122.91±18.40	126.53±19.20	−0.792•	0.431	NS
Range	92.01–160.12	102.2–160.95			
Height					
Mean±SD	1.68±0.09	1.7±0.12	−0.847•	0.400	NS
Range	1.5–1.86	1.5–1.94			
BMI					
Mean±SD	44.06±5.33	43.88±5.69	0.132•	0.895	NS
Range	35.94–53.5	35.11–53.3			
Smoking					
No	31 (91.2)	28 (82.4)	1.153*	0.283	NS
Yes	3 (8.8)	6 (17.6)			
DM					
No	21 (61.8)	30 (88.2)	6.353*	0.012	S
Yes	13 (38.2)	4 (11.8)			
HTN					
No	18 (52.9)	26 (76.5)	4.121*	0.042	S
Yes	16 (47.1)	8 (23.5)			
Abnormal lipid profile					
No	30 (88.2)	32 (94.1)	0.731*	0.393	NS
Yes	4 (11.8)	2 (5.9)			
Previous surgery					
No	17 (50)	13 (38.2)	0.954*	0.329	NS
yes	17 (50)	21 (61.8)			

Table 2: Hospital stay and intraoperative events between one anastomosis gastric bypass and single anastomosis sleeve jejunal groups

	Single anastomosis sleeve jejunal group (*N*=34) [n (%)]	One anastomosis gastric bypass group (*N*=34) [n (%)]	Test-value	*P* value	Significance
Hospital stay (day)					
Mean±SD	1.06±0.34	1.00±0.00	1.000•	0.321	NS
Range	1–3	1–1			
Intra-operative events					
No	30 (88.2)	34 (100)	4.250*	0.039	S
Yes (HH repair)	4 (11.8)	0			

Comparison between both groups showed no significant statistical difference in postoperative complications (*P=0.135*), readmissions (*P=1*), reoperations (*P=0.555*), and bile reflux (*P=0.09*), (Table 3). Both SASJ and OAGB groups had comparable postoperative weight loss, BMI, EWL % at 6 and 12 months of follow-up, however, OAGB had significantly higher TWL % at 6 months only, (Table 4).

Table 3: Postoperative complications, readmissions, reoperations, and bile reflux between single anastomosis sleeve jejunal and one anastomosis gastric bypass groups

	Single anastomosis sleeve jejunal group (*N*=34) [n (%)]	One anastomosis gastric bypass group (*N*=34) [n (%)]	Test-value	*P* value	Significance
Postoperative complications					
No	32 (94.1)	32 (94.1)	4.000*	0.135	NS
Bleeding	0	2 (5.9)			
Reflux and gastritis	2 (5.9)	0			
Readmissions					
No	32 (94.1)	32 (94.1)	0.000*	1.000	NS
Yes	2 (5.9)	2 (5.9)			
Re-operations					
No	33 (97.1)	32 (94.1)	0.349*	0.555	NS
Yes	1 (2.9)	2 (5.9)			
Bile Reflux					
No	22 (64.7)	28 (82.4)	2.720*	0.099	NS
Yes	12 (35.3%)	6 (17.6%)			

Table 4: Comparison between single anastomosis sleeve jejunal and one anastomosis gastric bypass regarding weight loss, BMI, excess weight loss, and total weight loss

After 6 months	Single anastomosis sleeve jejunal group No.=34	One anastomosis gastric bypass group No.=34	Test-value•	*P* value	Significance
Weight					
Mean±SD	96.01±15.81	97.32±17.17	−0.327	0.745	NS
Range	66.56–128.69	75.31–126.74			
BMI					
Mean±SD	34.47±5.19	33.76±5.37	0.551	0.583	NS
Range	26–43	27–43			
EWL					
Mean±SD	54.26±15.38	58.18±16.26	−1.023	0.310	NS
Range	36.84–90.86	36.4–84.25			
TWL					
Mean±SD	22.03±2.60	23.33±2.60	−2.047	0.045	S
Range	18.65–27.66	19.32–28.38			

After 12 months					
Weight					
Mean±SD	79.19±14.31	76.02±14.20	0.915	0.363	NS
Range	53.76–110.74	56.48–104.04			
BMI					
Mean±SD	28.47±5.00	26.44±4.89	1.691	0.096	NS
Range	21–37	21–36			
EWL					
Mean±SD	88.00±23.79	98.86±24.76	−1.844	0.070	NS
Range	57.89–136.56	61.13–131.5			
TWL					
Mean±SD	35.80±3.78	39.96±5.37	−3.700	0.000	HS
Range	30.56–41.57	32.46–54.72			

Both SASJ and OAGB patients were evaluated for resolution of obesity-related comorbidities including DM, HTN and dyslipidemia, and presence of gallstones. SASJ patients had significantly higher rate of resolution from DM compared with OAGB patients (*P=0.012*). No significant difference between both groups in resolution of HTN (*P=0.07*) and dyslipidemia (*P=0.03*). Patients who had OAGB had higher rate of gallstones postoperatively compared with SASJ patients (*P=0.001*), (Table 5).

Nutritional status of patients was assessed through hemoglobin level, iron, albumin, vitamin D, and calcium serum level. None of the patients had anemia, hypoalbuminemia, or iron deficiency. Regarding vitamin D and calcium, no significant difference between both surgeries (SASJ and OAGB) were noted, (Table 6).

Table 5: Resolution of comorbidities and presence of gallstones between both groups

	Single anastomosis sleeve jejunal group (*N*=34) [n (%)]	One anastomosis gastric bypass group (*N*=34) [n (%)]	Test-value	*P* value	Significance
DM Resolution					
No	8 (61.5)	3 (75)	6.353*	0.012	S
Complete resolution	5 (38.4)	1 (25)			
HTN Resolution					
No	18 (52.9)	26 (76.5)	5.091*	0.078	NS
Complete resolution	14 (41.2)	8 (23.5)			
Partial resolution	2 (5.9)	0			
Hyperlipidemia					
No	30 (88.2)	32 (94.1)	0.731*	0.393	NS
Complete resolution	4 (11.8)	2 (5.9)			
Gallstones					
No	33 (97.1)	22 (64.7)	11.508*	0.001	HS
Yes	1 (2.9)	12 (35.3)			

Table 6: Postoperative Nutritional status according to surgery performed

	Single anastomosis sleeve jejunal group (*N*=34) [n (%)]	One anastomosis gastric bypass group (*N*=34) [n (%)]	Test-value	*P* value	Significance
Anemia					
No	34 (100)	34 (100)	NA	NA	NA
Iron					
No	34 (100)	34 (100)	NA	NA	NA
Albumin					
No	34 (100)	34 (100)	NA	NA	NA

VitD					
No	34 (100)	33 (97.1)	1.015*	0.314	NS
Yes	0	1 (2.9)			
Calcium					
No	34 (100)	32 (94.1)	2.061*	0.151	NS
Yes	0	2 (5.9)			

DISCUSSION

SASJ bypass, a novel restrictive and malabsorptive surgery, modulates glucagon like peptide-1 and PYY neuroendocrine hormones through stimulation of distal bowel[8,10]. SASJ has an advantage over Roux-enY gastric bypass (RYGB) and OAGB in accessibility to biliary tree using ERCP (Retrograde Cholangiopancreatography) and revision or conversion to other procedures[10,11].

In single-blinded randomized controlled trial of 160 patients, Hany *et al*. compared RYGB to OAGB as revisional surgeries for weight regain after LSG. Both RYGB and OAGB achieved comparable BMI and excess BMI loss percent with no difference in rate of complications and improvement or resolution of comorbidities after 2 years of follow-up. However, RYGB and OAGB hinder accessibility to biliary tree using ERCP[12].

SASJ has not been well studied in the literature. In this study, we compared the outcomes of SASJ surgery with those of OAGB. In our study which enrolled 68 patients who had either SASJ or OAGB, both procedures had comparable weight loss, BMI loss, EWL throughout 1 year of follow-up. TWL at 6 months was higher in OAGB group compared with SASJ but not at 1 year of follow-up.

Both procedures had no difference in postoperative complications, readmissions, reoperations, and bile reflux. Regarding the resolution of obesity-related comorbidities, SASJ patients had a significantly higher rate of resolution from DM compared with OAGB patients. No significant difference between both groups in resolution of HTN and dyslipidemia. Higher rate of gall stones was in OAGB group.

In a prospective study of 49 obese patients (BMI <35 Kg/m^2) with type 2 DM by Alamo and colleagues 81.6% of patients managed to have complete remission of type 2 DM after SASJ[13]. In our study, 38.4% of patients with type 2 DM had complete remission after SASJ, but remission of type 2 DM after OAGB was 25%, so SASJ is more effective in management of type 2 DM. Our results are comparable with Alamo *et al*. yet such discrepancy of remission rates may be attributed to our small sample size.

Both procedures, SASJ and OAGB, have good response regarding remission of HTN as 14 patients had complete remission in SASJ group and two patients had partial remission (still on medical treatment but dose is lowered), but eight patients in OAGB group had complete remission of HTN.

Also, the authors (Alamo *et al*.) reported that SASJ had sufficiently excess weight loss (EWL %) of 31.9, 56.9, 76.1, and 81.5% at 1, 3, 6, and 12 months after the surgery, respectively[13]. In our study, patients who had SASJ had EWL% of 54.26% and 88% at 6 and 12 months, respectively.

Recently, a nonrandomized clinical trial comparing SASJ to OAGB with a 2-year follow-up reported no difference between both surgeries in gallstone development. Two patients developed gallbladder stones after OAGB while one patient had gallbladder stones after SASJ. Our results were contrary to their findings: the OAGB group (35.5%) had a significantly higher incidence of gallstones development compared with SASJ (2.9%)[14].

In a recent nonrandomized clinical trial on 100 patients, patients had either RYGB, OAGB, sleeve gastrectomy, or SASJ. Patients were followed-up for 6 months for EWL, BMI, hemoglobin A1C, and albumin level. Their results were consistent with our findings after 6 months of follow-up, all four procedures had comparable EWL, BMI, and improvement of type 2 DM[15].

In another study of 150 patients undergone SASJ, Sewefy *et al*. followed patients' outcomes including BMI, postoperative complications, nutritional status, and comorbidities for 24 months. Authors reported EWL% of 85% in 1 year, complete remission of DM in 23.2%, and 89% remission of HTN. Two patients had postoperative bleeding and five patients had biliary reflux[16].

In our study, both groups had comparable results as regards postoperative laboratory assessment as regards anemia, iron deficiency, albumin, vitamin D, and calcium. Our results were consistent with that of Sewefy *et al*. in which none of SASJ patients had nutritional deficiency after 2 years of follow-up[16].

Fast food products are absorbed rapidly in proximal part of small bowel with less function for distal bowel for absorption leading to decrease production of glucagon like peptide-1 and PYY (peptide YY) neuroendocrine hormones. Bariatric surgery has an effective role in reducing morbid obesity and its related morbidity and mortality, including cardiovascular, endocrinal, musculoskeletal, and psychological problems[8,10,11,17].

RYGB and OAGB are effective not only as primary surgeries for management of obesity and its related comorbidities but also as revisional surgeries after failed bariatric surgeries. For example, Laparoscopic sleeve gastrectomy is one of the most performed bariatric procedures, but weight regain, De novo GERD, and postoperative complications might require a revisional surgery[18].

Remission rates of DM are higher in SASJ in comparison to OAGB. SASJ had similar weight loss, BMI loss, and EWL to OAGB. Both procedures have comparable results as regards postoperative complications, readmissions, and re-operations except development of gallstones which is significantly higher in OAGB group. Our study had several limitations. Small number of patients and short follow-up period. We did not include weight regain and failure of weight loss due to short follow-up period.

CONFLICT OF INTEREST

There are no conflicts of interest.

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