Laparoscopic Single Anastomosis Sleeve-Jejunal Bypass (SASJ) versus Laparoscopic One-Anastomosis Gastric Bypass (OAGB) in obese patients: A Prospective non randomized controlled study

Ahmed M. Farrag, MD; Mohamed Gamal Fouly, MD; Kareem Ahmed Kamel, MD
Department Of General Surgery, Faculty of Medicine, Ain Shams University, Egypt

Background: Many restrictive and mal-absorptive procedures were known for obesity management. One of them is single anastomosis sleeve jejunal bypass (SASJ). Few studies had compared SASJ to other bariatric surgeries. We aimed to compare OAGB to SASJ in weight-loss, reduction in BMI, remission of co-morbidities and operative time.

Methodology: We conducted a prospective non-randomized controlled trial comparing OAGB or SASJ for obesity management. The decision of procedural choice was a shared decision between multidisciplinary team and the patients. Throughout 2019 (January-December) patients were operated and followed for 2 years.

Results: OAGB had a statistically highly significant BMI difference compared to SASJ at 12 months and 24 months p<0.001. However, regarding 3 months BMI difference, no statistical significance was detected between both surgeries, p=0.172. Mean operative time was significantly lesser in OAGB p<0.001 which was statistically highly significant. (79.5%) in OAGB group and (64.7%) in SASJ group had remission of co-morbidities. (20.5%) in OAGB group and (35.3%) in SASJ group had improvement of comorbidities yet, no significant difference between both in remission or improvement of co-morbidities p value=0.250. No statistically significant difference between both groups in post-operative complications.

Conclusion: OAGB and SASJ achieved satisfactory results regarding BMI loss and remission of co-morbidities. OAGB had less operative time compared to SASJ. OAGB had higher BMI loss at 12 and 24 months but not at 3 months of follow-up. More studies with larger sample size are needed with prolonged follow up to compare SASJ to other bariatric surgeries.

Key words: Remission, SASJ, DM, comorbidities.

Introduction

Morbid obesity and its associated co-morbidities; type 2 DM, hypertension , and dyslipidemia, are effectively managed by bariatric surgeries.[1] The WHO reported a three times increase, between 1975 and 2016 in the prevalence of obesity globally.[2] According to the 2018 IFSO global registry report, sleeve gastrectomy is the most popular bariatric operation, it resembles 46% of all bariatric procedures.[3]

Laparoscopic sleeve gastrectomy, a restrictive surgery, achieves satisfactory weight loss and improvement of co-morbidities when BMI is <50. On the other hand, malabsorptive and restrictive procedures as One anastomosis-gastric bypass (OAGB), Single Anastomosis Sleeve Jejunal bypass (SASJ), Single Anastomosis Sleeve Ileal (SASI) and single anastomosis duodeno-ileal bypass (SADI), are effective in patients with BMI>50.[4]

Single Anastomosis Sleeve Jejunal (SASJ) bypass is a sleeve gastrectomy combined with single loop jejunal anastomosis, thus, it preserves endoscopic access to the duodenum and may be associated with less anastomotic complications compared to Roux en Y gastric bypass (RYGB). SASI and SASJ are modifications of Sleeve gastrectomy with transit bipartition described by Santoro et al. Santoro proposed that morbid obese patients have increased absorption in proximal small intestine and low absorption in distal loops thus low blood levels of satiety neuroendocrine hormones (GLP-1; Glucagon like peptide-1) and PYY (peptide YY)) and high levels of ghrelin hormone.[5-7]

Many studies had compared OAGB to RYGB and OAGB to SASI. OAGB had comparable results to RYGB regarding weight loss and remission of co-morbidities.[8–11] Very Few studies had compared SASJ to other bariatric surgeries.[12–14]

In a recent meta-analysis, Sameh et al. reported that SASI bypass is associated with satisfactory short term outcomes regarding weight loss and remission of co-morbidities mainly DM.[15] SASJ, which has shorter biliopancreatic limb compared to SASI, has less nutritional deficiencies and satisfactory weight loss(16).SASJ short and long term outcomes are not well studied yet. Our study aims to compare OAGB to SASJ regarding reduction in BMI, remission of co-morbidities, and operative time.

Methodology

We conducted a prospective non-randomized controlled trial for morbid obese patients comparing OAGB or SASJ for treatment of obesity. The decision of procedural choice was a shared decision between multidisciplinary team and the patients. Throughout 2019 (January-December) patients were operated then patients were followed for 2 years. All surgeries

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were done by the same surgical team. We included all patients above 18 years old, BMI > 35 or BMI > 30 with comorbidities and we excluded patients below 18 years or over 60 years, had previous bariatric or GIT surgery, psychiatric disorders that bariatric surgeries were contraindicated with them, pregnancy, and medical conditions contraindicated a laparoscopy. Patients were followed for 2 years at outpatient clinics. BMI difference is calculated as preoperative BMI - postoperative BMI at intervals for either procedure.

Pre-operatively, a multidisciplinary (MDT) team assessed the patient medical, nutritional, psychiatric conditions and BMI and co-morbidities including, Diabetes mellitus (DM), Hypertension (HTN), and Obstructive sleep apnea. Each patient was counseled about either procedure and offered all knowledge about each. Procedure choice was a shared decision between MDT and the patient Patients were also assessed for BMI and co-morbidities including, Diabetes mellitus (DM), Hypertension (HTN), and Obstructive sleep apnea. Informed consent was obtained from all patients accepted to participate in the study. Risks, complications and alternative procedures were explained to the patient. Confidentiality was assured of the personal data and medical information of all patients. Ethical approval was taken from Ain Shams University, faculty of medicine, general surgery department ethical committee.

Postoperatively, Patients were followed for 2 years at 3, 12, 24 months intervals for postoperative reduction in BMI, remission of co-morbidities, and operative time.

Study outcomes

The primary outcome was BMI difference pre and post operatively during follow up period and intervals. Secondary outcomes included either remission or improvement of comorbidities, operative time, intra and post-operative complications.

Definition of outcomes: BMI loss, we calculated the difference between pre-operative BMI and post-operative BMI in each group at intervals (3-12-24) months. Hypertension remission was defined as blood pressure ≤ 130/85 mmHg without any medications. Type 2 DM remission was defined as HbA1C < 6.5% without any medications. Obstructive sleep apnea remission was defined as the cessation of CPAP mask use. Hypertension and DM Improvement was defined as decrease in dosage and/or frequency of medications to control.

Technique

Laparoscopic OAGB:

Patient is positioned in anti-Trendelenburg position and five ports were inserted. A 36- Fr. bougae calibrated long gastric pouch was fashioned. Anastomosis was fashioned between the gastric pouch and a jejunal loop at 2 m. distance from Ligament of Trietz **(Figure 1).**

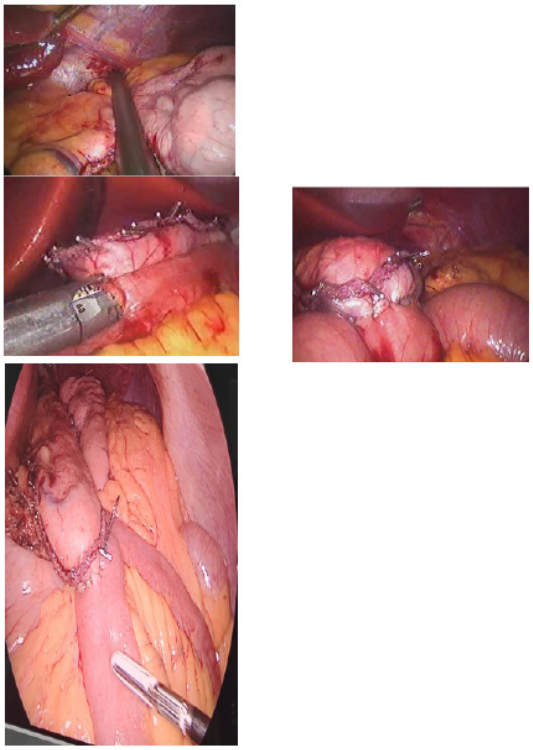

Fig 1: Gastro-jejunal anastomosis done with a Endo GI stapler (A), One anastomosis Gastric Bypass bypass (B): gastric pouch with jejunal loop.

Laparoscopic SASJ:

Patient is positioned in anti-trendelenburg position, and five ports were inserted. After dissection of the omentum along the greater curvature till the left crus of diaphragm, a 36- Fr. bougae calibrated long gastric tube was fashioned starting 4 to 5 cm from the pylorus. Then 45 mm stapled side-to side anastomosis between antrum of stomach and jejnum 2 m. distance from Ligament of Trietz was fashioned **(Figure 2).**

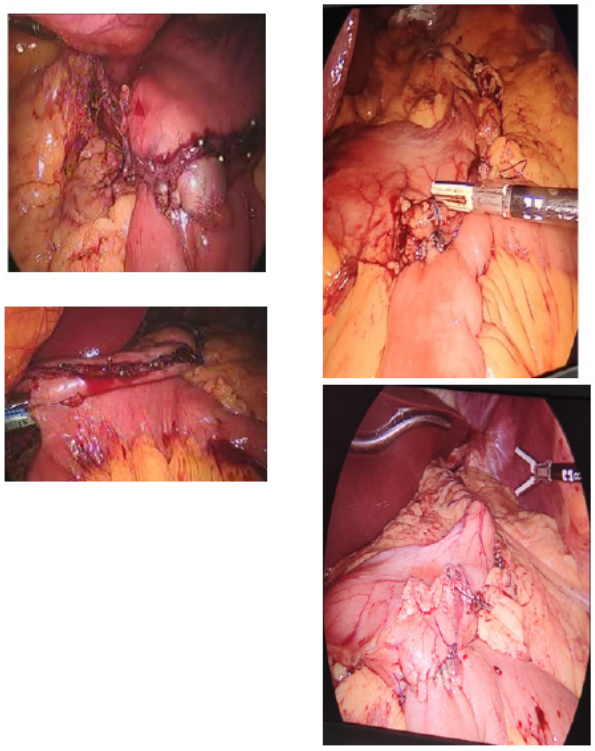

Fig 2: Creating Sleeve gastrectomy using linear stapler (A), Gastro jejunal anastomosis (Middle), Single anastomosis sleeve jejunal bypass (Right).

Results

A total of 100 patients were included in our study with mean age of (39.84±5 among group 1 and 41.17±5.3 among group 2) and mean pre-operative BMI of (40.7±7.05 among group 1 and 38.9±6.03 among group 2). Females accounted for 70% of group 1 and 62% among group 2. 73% of patients had at least one pre-operative comorbidity. Patients' baseline characteristics are shown in **(Table 1).**

Regarding BMI loss, we calculated the difference between pre-operative BMI and post-operative BMI according to each type of surgery at 3, 12, 24 months intervals. OAGB had a statistically highly significant BMI difference compared to SASJ at 12 months (OAGB 16±1.4 vs SASJ 11.9±2.36, p<0.001) and 24 months (OAGB 22.5±3.26 vs SASJ 16.1±1.83, p<0.001), respectively. However, regarding 3 months BMI difference, no statistical significance is detected between both surgeries, p=0.172 as shown in **(Table 2).**

There was no statistically significant difference between groups' %EWL at 3 months (18.05±5.02 in OAGB vs. 20.06±6.01 in SASJ) with (p>0.05). While, the mean %EWL (75.23±12.04 in OAGB vs. 66.20±8.02 in SASJ) (91.27±14.04 in OAGB vs. 80.24±9.03 in SASJ) at 12 and 24 months respectively. This were significantly greater in OAGB group than SASJ group, with p-value (p<0.001) as shown in **Table 3, Figure 3.**

Mean operative time was significantly shorter in OAGB compared to SASJ which was statistically highly significant (51.1±8.4 vs. 72.6±10.6±, p<0.001), as shown in **(Table 3).**

Regarding pre-operative comorbidities, no statistically significant difference between both groups was found. 24patients (48%) among OAGB group had type 2 DM in contrast to 19 patients (38%) among SASJ group. DM completely remitted in 17 patients (70.8%) and improved in 7 patients (29.2%) among OAGB, in contrast to that DM completely remitted

in 9 patients (47.4%) and improved in 10 patients (52.6%) among SASJ group. These results about remission of type 2 DM either complete remission or improvement were statistically insignificant between both groups. 13 patients (26%) among OAGB group had hypertension in contrast to 15 patients (30%) among SASJ group. hypertension completely remitted in 12 patients (92.3%) and improved in 1 patient (7.7%) among OAGB, in contrast to that hypertension completely remitted in 13 patients (86.7%) and improved in 2 patients (13.3%) among SASJ group. These results about remission of hypertension either complete remission or improvement were statistically insignificant between both groups. 2 patients (4%) in OAGB group had obstructive sleep apnea which was remitted after surgery in contrast to no cases in SASJ group.

Fifty-three patients had complete remission of their co-morbidities (31/39 in OAGB group and 22/34 in SASJ group) and 20 patients had improvement in their comorbidities (8/39 in OAGB group and 12/34 in SASJ group) yet, no statistically significant difference between both surgeries in remission or improvement of co-morbidities p value=0.250. **(Table 5, Figure 4).**

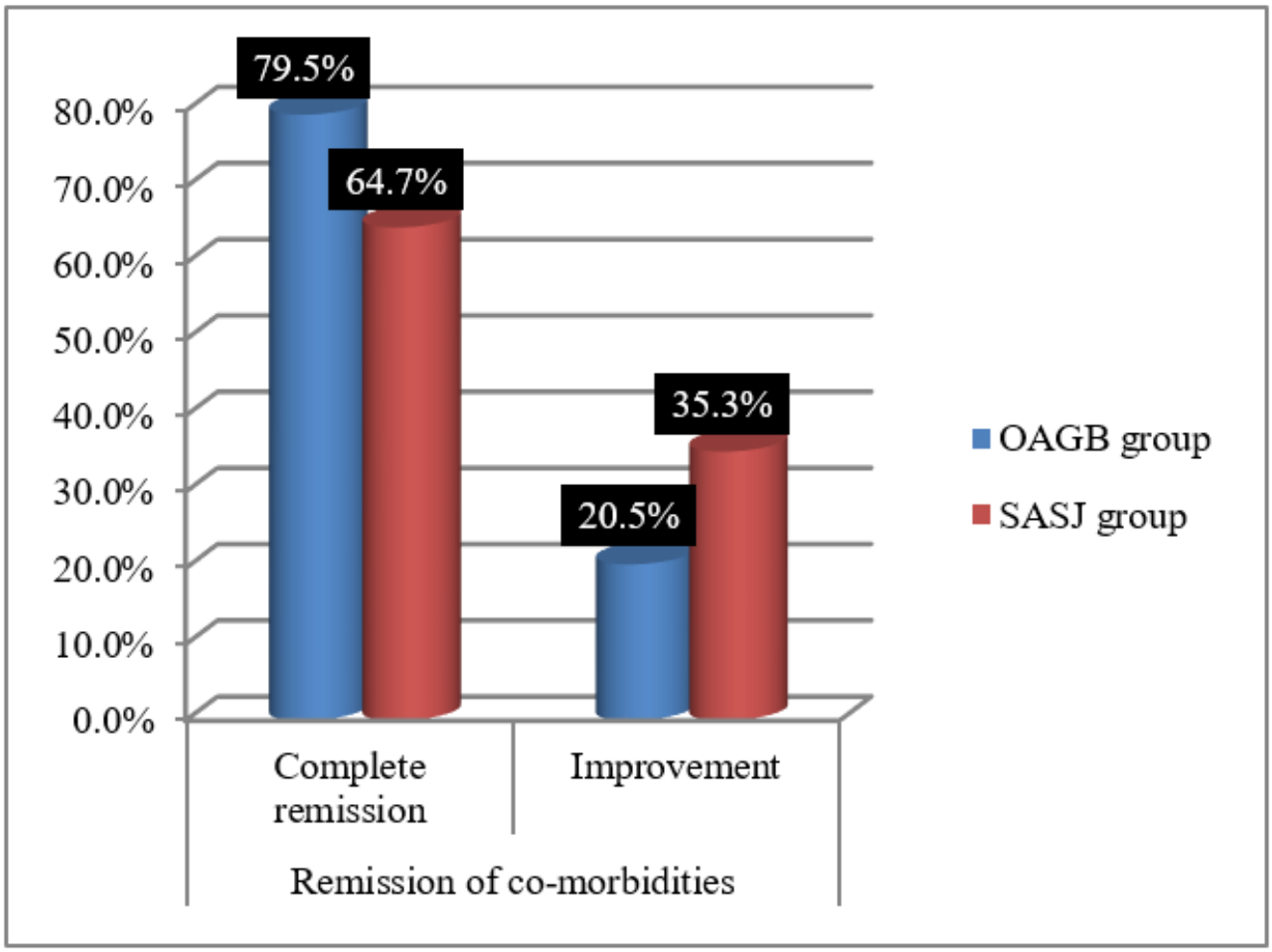

Fig 3: Chart showed post-operative remission of co-morbidities among both groups.

No statistically significant difference between both groups as regard post-operative complications.5 patients developed post-operative complications in SASJ group. Two patients had suture line bleeding. One patient suffered marginal ulcer. One patient had reflux esophagitis. 1 case developed gall stones with calcular obstructive jaundice. In the OAGB group, 6 patients suffered post-operative complications. Two patients had biliary reflux. One patient suffered hematemsis while the other had marginal ulcer **(Table 5, Figure 5).**

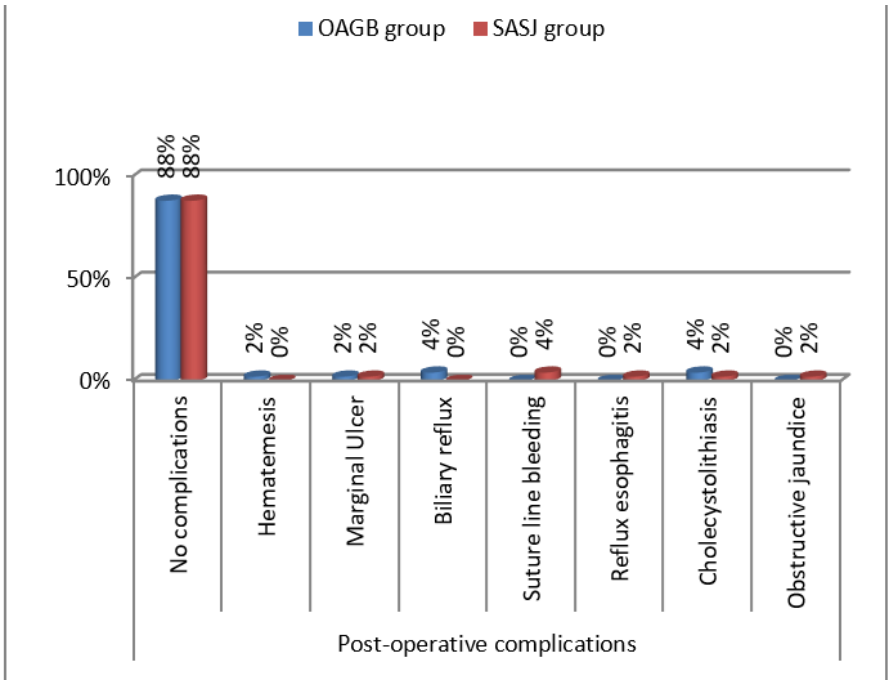

Fig 4: Chart showed post-operative complications in both groups.

Table 1: Patient characteristics regarding type of operation One-Anastomosis gastric Bypass (OAGB) vs (SASJ)

	OAGB	SASJ	p-value
Number of patients	50(50%)	50(50%)	NA
Age (mean±SD)	39.84±5.1	41.17±5.3	0.204
Gender			
Male	15 (30%)	19 (38%)	0.527
Female	35 (70%)	31 (62%)	
Pre-operative BMI (mean±SD)	40.7±7.05	38.9±6.03	0.173
Pre-operative Co-morbidities			
No co-morbidity	11 (22%)	16 (32%)	0.302
DM	24 (48%)	19 (38%)	
HTN	13 (26%)	15 (30%)	
Obstructive sleep apnea	2 (4%)	0 (0%)	
Mortality			
No	50 (100%)	50 (100%)	NA
Yes	0 (0%)	0 (0%)	

Using: t-Independent Sample t-test for mean & SD; x2: Chi-square test for number & percentage%.

p-value >0.05 is insignificant.

NA: not applicable.

Table 2: Comparison between One-anastomosis gastric bypass (OAGB) and Single-anastomosis sleeve jejunal bypass (SASJ) regarding BMI difference 3, 12, 24 months of follow-up

	OAGB (n=50)	SASJ (n=50)	p-value
Pre-operative BMI (mean±SD)	40.7±7.05	38.9±6.03	0.173
BMI difference at 3 months	5.9±1.2	5.6±0.92	0.172
BMI differenceat 12 months	16±1.4	11.9±2.36	<0.001**
BMI differenceat 24 months	22.5±3.26	16.1±1.83	<0.001**

Using: t-Independent Sample t-test.

p-value >0.05 is insignificant; **p-value <0.001 is highly significant.

Table 3: Comparison between SASJ and OAGB group according to excess body weight loss (%EWL) %

Excess body weight loss (%EWL)%	SASJ (n=50)	OAGB (n=50)	t-test	p-value
%EWL% at 3 months	20.06±6.01	18.05±5.02	1.815	0.073
%EWL% at 12 months	66.20±8.02	75.23±12.04	4.414	<0.001**
%EWL% at 24 months	80.24±9.03	91.27±14.04	4.672	<0.001**

Using: Independent Sample t-test.

p-value >0.05 NS; **p-value <0.001 highly significant.

Table 4: Difference in operative time between One- anastomosis gastric bypass (OAGB) and Single-anastomosis sleeve jejunal bypass (SASJ)

	OAGB (n=50)	SASJ (n=50)	p-value
Operative Time (min.) (mean±SD)	51.1±8.4	72.6±10.6	<0.001**

Using: t-Independent Sample t-test;

**p-value <0.001 is highly significant

Table 5: Comparison between groups according to remission of co-morbidities and post-operative complications

		OAGB (n=50)		SASJ (n=50)		p-value
		No.	%	No.	%	
Remission of co-morbidities						
DM	Complete	17/24	70.8	9/19	47.4	0.212#
	Improvement	7/24	29.2	10/19	52.6	
HTN	Complete	12/13	92.3	13/15	86.7	0.896
	Improvement	1/13	7.7	2/15	13.3	
Obstructive sleep apnea	Complete	2/2	100	0/0	0	NA
	Improvement	0/0	0	0/0	0	
Overall	Complete	31/39	79.5	22/34	64.7	0.250#
	Improvement	8/39	20.5	12/34	35.3	
Post-operative complications						
No morbidities		44	88.0%	44	88.0%	1.000#
Hematemesis		1	2.0%	0	0.0%	0.317
Marginal Ulcer		1	2.0%	1	2.0%	1.000
Biliary reflux		2	4.0%	0	0.0%	0.155
Suture line bleeding		0	0.0%	2	4.0%	0.155
Reflux esophagitis		0	0.0%	1	2.0%	0.317
Cholecystolithiasis		2	4.0%	1	2.0%	0.560
Obstructive jaundice		0	0.0%	1	2.0%	0.317

Using: #Chi-square test; Fisher's exact.

p-value >0.0.05 is insignificant.

Discussion

In our current society, urbanization, technological improvements, and sedentary lifestyles have all led to fast food consumption, which is characterized by a high calorie diet and low fiber content. These foods are absorbed in the proximal small intestine, with reduced function in the distal colon, resulting in lower synthesis of the neuroendocrine hormones GLP-1 (Glucagon like peptide-1) and PYY (peptide YY). The purpose of bariatric surgery in the treatment of morbid obesity is to minimize morbidity and mortality associated with obesity, including cardiovascular, endocrine, musculoskeletal, and psychological issues.

SASJ bypass surgery is a unique procedure that not only combines restrictive and mal-absorptive effects, but also modifies GLP-1 and PYY neuroendocrine hormones via distal bowel stimulation.[16,17] Although

laparoscopic sleeve gastrectomy (LSG) is one of the most often done bariatric surgeries today, weight regain, the occurrence of denovo GERD, and postoperative severe complications such as gastric leakage and twist remain a challenge. SASJ offers an advantage over RYGB and OAGB in terms of ERCP access to the biliary tree and revision or conversion to other procedures.[4,17] SASJ has received little attention in the literature.

In our study, we compared the outcomes of SASJ procedure with those of OAGB in the management of obesity and its associated comorbidities.

At 3 months, there was no statistically significant difference in the %EWL between the groups ($p>0.05$). At 12 and 24 months, the mean %EWL of the OAGB group was higher than that of the SASJ group, with a p-value of ($p<0.001$).

Our results were matched with Sewefy et al results as they reported that the mean %EWL reached 76.5% for all included patients after 1 year of SASJ procedure. In 27 patients who completed 2 years of follow-up, the %EWL reached 77.6%.[18]

In our study regarding BMI reduction, we calculated the difference between pre-operative BMI and post-operative BMI according to each type of surgery at 3, 12, 24 months intervals. However, regarding 3 months BMI difference, no statistical significance is detected between both surgeries, $p=0.172$. Actually OAGB had a statistically highly significant BMI difference compared to SASJ at 12 months (OAGB 16±1.4 vs SASJ 11.9±2.36, $p<0.001$) and 24 months (OAGB 22.5±3.26 vs. SASJ 16.1±1.83, $p<0.001$), respectively.

This is supported with Sayadishahraki et al. study who conducted a study to compare between SASJ, OAGB, RYGB, and Sleeve Gastrectomy. The excess weight loss was assessed for 1 month, 3 months, and 6 months after the surgical procedure. SASJ group's excess weight loss was significantly higher at 3-months (P value = 0.011). BMI difference between the different surgical procedures was not significant at any time interval which is limited mainly due to short follow up period. SASJ, OAGB, RNYGB and Sleeve gastrectomy had improved type 2 DM.[12]

No statistically significant difference was found between both groups as regard post-operative complications. In our study we found that in SASJ group, 5 patients developed post-operative complications. Two patients had suture line bleeding that was managed conservatively. One patient suffered marginal ulcer that was managed by medical treatment. One patient had reflux esophagitis which was managed medically. 1 case developed gall stones with calcular obstructive jaundice which was managed with ERCP and laparoscopic cholecystectomy. In contrast to that In the OAGB group, 6 patients suffered post-operative complications. Two patients had biliary reflux that was managed by medical treatment. One patient suffered hematemesis while the other had marginal ulcer. Both were managed conservatively with medical treatment. Two patients had cholecystolithiasis after (1-1.5) year respectively which was accidently discovered during follow up which was managed with elective cholecystectomy.

Others reported that SASJ bypass is effective procedure with less nutritional deficiency in comparison to other mal-absorptive operations, and easy screening of the upper GIT and biliary tree which resembles one of the great unique advantages of SASJ over OAGB.[18]

In our study 1 case in SASJ group developed gall stones with calcular obstructive jaundice which was managed with ERCP and laparoscopic cholecystectomy. Actually this possibility to endoscopic access to the upper GIT and biliary tree in SASJ is greatly affected the outcome and morbidities with less complexity of the operation.

Our results were comparable to results in another study of 150 patients undergone SASJ, authors followed patients' outcomes for 24 months. Sewefy et al reported EWL% of 85% in 1 year and complete remission of DM present in 23.2% of the study sample. Two patients had postoperative bleeding and 5 patients had biliary reflux.[13]

In our study (79.5%) in OAGB group and (64.7%) in SASJ group) had complete remission of their co-morbidities. (20.5%) in OAGB group and (35.3%) in SASJ group) had improvement yet, no statistically significant difference between both surgeries in remission or improvement of co-morbidities p value=0.250.

We noticed in our study that although more patients had complete remission of their comorbidities in OAGB group than SASJ group but actually this was statistically insignificant between both groups. So in our study we found that effect of SASJ on obesity associated pre-operative comorbidities is comparable to OAGB.

In our study we found that DM completely remitted in (70.8%) and improved in (29.2%) among OAGB, in contrast to that DM completely remitted in (47.4%) and improved in (52.6%) among SASJ group. This was statistically insignificant.

Also we found that hypertension completely remitted in (92.3%) and improved in (7.7%) among OAGB, in contrast to that hypertension completely remitted in (86.7%) and improved in (13.3%) among SASJ group. This was statistically insignificant between both groups.

This is supported with Alamo et al study. Who conducted their research to assess the effect of SASJ on excess weight loss (EWL %) and type 2 DM control. They reported excess weight loss of 31.9%, 56.9%, 76.1%, and 81.5% at 3, 6, 12, and 18 months after the surgery, respectively. Forty patients (81.6%) achieved complete remission of type 2DM, but the authors studied patients with BMI <35Kg/m2.[14]

Our results were supported with Sewefy et al results who reported that Normalization of blood glucose occurred after SASJ in all diabetics. Hypertension remission occurred in 89% of all hypertensive patients.[18]

Sewefy et al reported that In 27 patients who were followed for 2 years after SASJ, the 77.6%, of EWL was achieved. Remission occurred within three months in all diabetic patients, hypertension remission occurred in 80% of patients, hyperlipidemia were remitted in 83.3% of patients, and obstructive sleep apnea were remitted in all cases. GERD symptoms were improved in 86.7% of patients.[19]

In our study, mean operative time was significantly shorter in OAGB compared to SASJ (51.1±8.4 vs. 72.6±10.6±, p<0.001) and this was statistically highly significant between both groups.

One of the strong points of our research that to our knowledge there were little studies that compare SASJ to OAGB. Our study had several limitations. Small number of patients and short follow up period. We did not include dysplidemia during testing for remission of co-morbidities of each surgery as well as nutritional deficiency and vitamin and mineral deficiency and supplement therapy for both procedures. We did not include weight regain and failure of weight loss due to short follow up period.

Conclusion

OAGB and SASJ achieved satisfactory results regarding BMI loss and remission of co-morbidities. OAGB had less operative time compared to SASJ. OAGB had higher BMI loss at 12 and 24 months but not at 3 months of follow-up. More studies with larger sample size are needed with prolonged follow up to compare SASJ to other bariatric surgeries.

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