

Laparoscopic SADI-S versus OAGB as Revisional Procedures after Failed Sleeve Gastrectomy; Comparative Study after 2 Years of Follow up

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Background: Sleeve gastrectomy has taken the upper hand as a bariatric surgery. Unfortunately, the procedure has high rate of weight regain. Yet, the lack of standard revisional surgery is driving the bariatric surgery community to compare different procedures to help find the most convenient one.

Objectives: The present study aims to compare SADI-S and OAGB as redo surgeries after failed sleeve gastrectomy in morbidly obese patients as regard short term outcome including intra and early postoperative complications; and outcome at 2 years follow up including weight loss and maintenance, resolution of preoperative comorbidities and postoperative malnutrition.

Patients and methods: This is a prospective randomized study that started on January 2018 till June 2022. The study included fifty morbidly obese patients who had previously undergone successful sleeve gastrectomy followed by failure due to weight regain. Patients were randomly divided into 2 groups; group A that included 25 patients who underwent SADI-S and group B that included 25 patients who underwent OAGB. Patients were operated from 2018 to 2020 and followed up for at least 2 years.

Results: SADI-S has a significantly longer operative time than OAGB. Yet, both procedures have comparable results as regard weight loss, resolution of preoperative comorbidities and postoperative nutritional outcome.

Conclusion: Both SADI-S and OAGB are effective revisional procedures after failed sleeve gastrectomy on short-term and after 2 years follow up. Yet, multicenter studies with a large series of patients and long term follow up are needed for better assessment of both procedures.

Key words: Weight regain, one anastomosis gastric bypass, single anastomosis duodeno ileal bypass, revisional surgery.

Introduction

Laparoscopic sleeve gastrectomy (LSG) is considered the "Rising star" of bariatric surgery over the past 5 years being both technically simple as well as of a low complication rate when compared to other bariatric procedures.¹ It can be done as a solo procedure or as a first step for a second bariatric procedure.^{2,3} The rate of weight regain with LSG ranges from 5.7% at two years postoperative to 75.6% at six years,⁴ leading to an increase in the number of revisional surgeries significantly nowadays.^{5,6}

While no definite bariatric surgery can be considered the gold standard revisional procedure after LSG failure,⁷ RYGB is still the most feasible option. However other emerging options are now available as the mini gastric bypass, the duodenal switch, and the recently introduced single anastomosis duodeno-ileal bypass (SADI-S).⁸

The present study is conducted to compare 2 of the revisional surgeries available namely, the SADI-S and the OAGB.

SADI-S was introduced as a modification of BPD-DS with only a single anastomosis.⁹ Thanks to this modification, postoperative leaks and anastomotic strictures and intestinal herniation decreased with shortened operative time and less anesthetic

complications.¹⁰

On 2020, the American Society for Metabolic and Bariatric Surgery (ASMBS) endorsed the SADI-S as an appropriate metabolic procedure. They recommended continuous nutritional and metabolic support for bariatric patients, as the procedure still lacks evidence for optimal limb length as well as long term follow up regarding intestinal adaptation, nutritional status and weight loss or regain.¹¹

On 2021, the International Federation for the Surgery of obesity and Metabolic Disorders (IFSO) updated their statement to not considering SADI-S as an investigational procedure and admitted its safety and efficacy on maintaining significant weight loss and metabolic health on short term data recommending long term follow up for maintenance of as well as possibility of development of nutritional deficiencies.¹²

The one anastomosis gastric bypass/mini gastric bypass (OAGB-MGB) was reported as a well-tolerated and potent revisional option in the long term.¹³

Aim of the work

The study aims to compare SADI-S and OAGB as redo surgeries after failed sleeve gastrectomy

in morbidly obese patients as regard short term outcome including intra and early postoperative complications; and outcome at 2 years follow up including weight loss and maintenance, resolution of preoperative comorbidities and postoperative malnutrition.

Patients and methods

This is a prospective randomized study that started on January 2018 till June 2022. The study included fifty morbidly obese patients who had previously undergone successful sleeve gastrectomy followed by failure due to weight regain. Patients were randomly divided into 2 groups using closed envelope method. Group A included 25 patients who underwent SADI-S and group B included 25 patients who underwent OAGB. Patients were operated from 2018 to 2020 and followed up for at least 2 years

In general, we defined failure of sleeve gastrectomy as: failure to lose 50% of excess body weight or regain up to 20% of lost excess weight within one year or more from sleeve gastrectomy or metabolic failure in the form of relapse of diabetes mellitus after remission post sleeve gastrectomy.

Inclusion criteria

- Gender: either males or females.
- Patients to whom sleeve gastrectomy was the first bariatric procedure.
- Patients who regained $\geq 20\%$ of excess body weight after laparoscopic sleeve gastrectomy.
- Patients with normal volume sleeved stomach by CT volumetry.

Exclusion criteria

- Severe GERD and Barrett's oesophagus.
- Major hiatus hernia.
- Smoking.

Methodology

All the patients were assessed by a multi-disciplinary team (MDT) consisting of a psychiatrist, a clinical nutritionist, an anesthetist, and a bariatric surgeon.

CT gastric volumetry was ordered for every single patient to evaluate the presence of hiatus hernia, and the size, kink and anatomy of the sleeved stomach. Patients with normal volume were only included in this study.

The patients were fully informed about the benefits, alternatives, risks of the operations including (Wound infection, anastomotic leak, gastrointestinal tract hemorrhage, bowel obstruction, stomal stenosis, pulmonary embolism, conversion to open Surgery

and incisional hernia).

An informed written consent was taken from all patients regarding both the procedure with its complications as well as our research.

Operative Details

Both procedures were done under general anesthesia.

In an anti-Trendelenburg position, a standard laparoscopic approach was performed with four-five ports, with the surgeon standing between the patient's legs.

Diagnostic laparoscopy is first performed.

A. Single anastomosis duodeno ileal bypass (SADI-S):

After a complete evaluation of the abdomen, the distal end of the previous sleeve is identified, and with the stomach held upwards, dissection of the greater curvature is completed through the first segment of the duodenum, 2- or 3-cm distal to the pylorus.

The duodenum is totally mobilized posteriorly until the gastroduodenal artery is exposed. The duodenal dissection is completed by opening the peritoneum over the hepatoduodenal ligament; the duodenum is then encircled from behind taking care not to damage the right gastric artery. The duodenum is divided with a 60-mm blue cartridge linear stapler.

The ileocecal junction is located, and 300 cm is measured proximally. The selected ileal loop is ascended to antecolic position and anastomosed to the proximal duodenal stump with interrupted 3-0 absorbable suture material. A methylene blue leak test is performed, and a tube drain is placed.

B. One anastomosis gastric bypass (OAGB):

After a complete evaluation of the abdomen, adhesiolysis between sleeve and liver is done followed by dissection of omentum, which is often found adherent to the greater curvature of the sleeve.

The lesser omentum is then dissected using either below the level of the crow's foot, and the antrum is divided using endo-GIA stapler, usually 45-mm gold/green is engaged across the antrum of the stomach at right angles to its axis

If the fundus is significantly dilated, it is possible to reshape the pouch with a 2-3 fires of linear stapler green loads vertically, always calibrating on a 36f bougie.

The jejunum is then identified at the ligament of treitz. The level of the bypass is performed at 180

cm of jejunum.

A stapled gastrojejunostomy is done and the inside of the anastomosis is checked; in case of bleeding, intraluminal titanium endoclips or soft electrocautery can be applied.

The anastomosis is closed with 2-0 vicryl or barbed sutures (v-loc™). Then methylene blue leak test is performed a tube drain is inserted along the stable line of gastric pouch and gastro jejunostomy.

Post-operative

A Gastrograffin meal study is done on 1st post-operative day. Oral fluids are allowed provided that the gastrograffin study is free and the patient is vitally stable. The discharge is scheduled 24-48 h after the surgical procedure as long as there are no clinical complications or post-operative biochemical and imaging abnormality.

A standard post-operative protocol for bariatric patients is used at discharge. The patients are advised to follow a strict dietary regimen of 3 progressive phases (Liquid, semisolid, and solid diet), each one lasting at least 2–3 weeks. High protein diet (60-80gm/day) with multivitamins (Vitamin B complex, vitamin b12 and fat-soluble vitamins ADEK) and minerals supplementation are prescribed for all patients.

All the patients received prophylactic dose anticoagulation for 2 weeks and proton-pump inhibitor for at least 6 months.

All patients are advised to follow up with a clinical nutritionist in our team.

Primary outcome includes the postoperative BMI, percentage of excess body weight loss (%EBWL) and percentage of total body weight loss (%TBWL) in both groups at 6 months, 1 year and 2 years.

Secondary outcome parameters includes the efficacy of two procedures regarding comorbidities resolution and nutritional deficiencies.

Statistical methods

Data was summarized using mean, standard deviation, minimum and maximum in quantitative data and using frequency (Count) and relative frequency (Percentage) for categorical data.

Comparisons between groups were done using unpaired t test in normally distributed quantitative variables and Chi square test and Fisher Exact test in categorical data. P-values less than 0.05 were considered as statistically significant.

Results

Fifty patients were identified eligible for this study. They were divided into 2 groups, each of 25 patients

depending on the type of revisional surgery done. The SADI-S group and the OAGB group.

Preoperative data

The demographic and anthropometric data are summarized in **(Table 1)**. There was no statistically significant difference between both groups in terms of age and gender. The weight, BMI, ideal body weight and excess body weight before revisional surgery were statistically insignificant between both groups.

Preoperative comorbidities associated with morbid obesity included hypertension, hyperlipidemia, type 2 diabetes, impaired glucose tolerance, and obstructive sleep apnea syndrome. Preoperative comorbidities were comparable in both groups **(Table 2)**.

The non-bariatric surgical history included a total of 8 patients in each group with insignificant statistical difference **(Table 2)**. The SADI-S group included open procedures in 5 patients; 2 patients underwent 2 caesarean section, 2 patients underwent appendectomy and 1 patient underwent caesarean section together with appendectomy. Three patients in the SADI-S group underwent laparoscopic cholecystectomy; all were done in the same setting during the previous sleeve gastrectomy. The OAGB group included open surgical procedure in 4 patients; 3 patients underwent appendectomy, and 1 patient underwent appendectomy and caesarean section. Four patients underwent laparoscopic procedures; 3 patients had laparoscopic cholecystectomy in the same setting of the previous sleeve gastrectomy and 1 patient underwent laparoscopic appendectomy.

Intraoperative data

The operative time in our study was calculated from skin to skin. The mean operative time was much higher in the SADI-S group being 141.28 ± 17.58 minutes while 110.4 ± 14.64 minutes in the OAGB group; this result is statistically highly significant **(Table 3)**.

Twelve patients underwent intraoperative laparoscopic cholecystectomy, 5 in the SADI-S group and 7 in the OAGB group. There were no intraoperative complications in either group, no intraoperative bleeding or leak. There were no cases of intraoperative mortality **(Table 3)**.

In the present study, the hospital stay was statistically insignificant between both groups. **(Table 4)**.

During the postoperative 30 days follow up, we didn't encounter any early general or specific postoperative complications including bleeding (Endoluminal or intraperitoneal), leakage from gastro-jejunostomy or duodeno-ileostomy, duodenal stump blowout, trocar site herniation and small bowel obstruction in

either group. There were no cases of readmission or reoperation.

Late complications were encountered in both groups in the form of chronic diarrhea, malnutrition, marginal ulcer and bile reflux. These results showed no statistically significant difference between both groups (**Table 5**).

Postoperative weight loss during 6months, 1 year and 2 years follow up are summarized in Tables 6-8. Parameters to assess weight loss postoperatively included the postoperative weight, BMI, EWL% and TWL%. None of these parameters showed any statistical difference between both groups.

Results of weight loss with each procedure are summarized in (**Tables 9,10**). Both procedures showed highly statistically significant weight loss as revisional bariatric surgeries when comparing preoperative and the 2 years postoperative weight loss parameters.

Remission of comorbidities

Remission of preoperative comorbidities associated

with obesity was obvious at 2 years follow up showing resolution and improvement in 50-100% of different comorbidities in both groups with comparable results (**Table 11**).

Nutritional and metabolic outcome

Follow up laboratory investigations to assess postoperative nutritional status at 2 years follow up are shown in Table 12. There was no statistically significant difference between both groups. The mean hemoglobin level decreased postoperatively with development of mild anemia in both groups. The mean levels of total proteins and serum albumin generally decreased in both groups, yet the postoperative levels are still within the normal range. The mean level of parathyroid hormone was abnormally high preoperative while it decreased to normal range postoperatively in both groups. The level of calcium decreased with increase in the level of vitamin D postoperative, yet both are still within the normal range. The mean level of vitamin A, E and K decreased in both groups while still within the normal range.

Table 1: The demographic and anthropometric data

| | SADI-S | OAGB | P value |
|--|----------------|----------------|---------|
| Age (years) | 34.24 ± 5.24 | 35.24 ± 5.83 | 0.74 |
| Mean ± SD (range) | (25-44) | (25-49) | |
| Gender (M:F) | 3:22 | 4:21 | 0.68 |
| Height (meter) | 1.6 ± 0.08 | 1.63 ± 0.1 | 0.21 |
| Mean ± SD (range) | (1.53-1.81) | (1.53-1.88) | |
| Weight before sleeve gastrectomy (kg) | 127.8 ± 15.12 | 126.64 ± 19.81 | 0.82 |
| Mean ± SD (range) | (107-180) | (100-195) | |
| BMI before sleeve gastrectomy (kg/m ²) | 49.88 ± 4.83 | 47.25 ± 4.01 | 0.04 |
| Mean ± SD (range) | (42.45-61.14) | (41.09-55.17) | |
| Weight before revisional surgery (kg) | 114.08 ± 12.13 | 115.12 ± 17.07 | 0.8 |
| Mean ± SD (range) | (97-145) | (95-175) | |
| BMI before revisional surgery (kg/m ²) | 44.32 ± 2.86 | 42.97 ± 3.35 | 0.13 |
| Mean ± SD (range) | (40.35-49.53) | (40.03-49.51) | |
| Ideal body weight (kg) | 64.51 ± 7.41 | 67.04 ± 8.68 | 0.27 |
| Mean ± SD (range) | (58.52-88.36) | (57-88.36) | |
| Excess body weight (kg) | 49.57 ± 7.34 | 48.08 ± 10.81 | 0.57 |
| Mean ± SD (range) | (38.48-64.9) | (35.71-86.64) | |

BMI: body mass index.

Preoperative comorbidities associated with morbid obesity included hypertension, hyperlipidemia, type.

Table 2: Preoperative comorbidities and surgical history

| | SADI-S | OAGB | P value |
|--|---------------|-------------|----------------|
| HBP | 10 (40%) | 8 (32%) | 0.56 |
| HLP | 7 (28%) | 5 (20%) | 0.51 |
| IGT | 2 (8%) | 2 (8%) | 1 |
| DMT2 | 10 (40%) | 13 (32.5%) | 0.39 |
| OSAS | 4 (16%) | 3 (12%) | 0.68 |
| Previous non bariatric abdominal surgery | 8 (32%) | 8 (32%) | 1 |
| Open | 5 (20%) | 4 (16%) | 0.71 |
| Laparoscopic | 3 (12%) | 4 (16%) | 0.68 |

HBP: High blood pressure, HLP: Hyperlipidemia, IGT: Impaired glucose tolerance, DMT2: Diabetes mellitus type 2, OSAS: Obstructive sleep apnea syndrome.

Table 3: Operative data

| | SADI-S | OAGB | P value |
|---|---------------|-------------|--------------------|
| Operative time (minutes) | 154.6 ± 16.47 | 88 ± 18.03 | <0 .01 |
| Mean ± SD (range) | (120-200) | (50-120) | Highly significant |
| Intraoperative laparoscopic cholecystectomy | 5 (20%) | 7 (28%) | 0.51 |
| Intraoperative complications | 0 | 0 | |

Table 4: Early postoperative period

| | SADI-S | OAGB | P value |
|------------------------------------|---------------|-------------|----------------|
| Postoperative hospital stay (Days) | 3.4 ± 1.12 | 3.16 ± 0.99 | 0.42 |
| Mean ± SD (range) | (2-5) | (2-5) | |

Table 5: Late complications at 2 years follow up

| | SADI-S | OAGB | P value |
|------------------|---------------|-------------|----------------|
| Chronic diarrhea | 1 | 0 | 1 |
| Malnutrition | 2 | 2 | 1 |
| Marginal ulcer | 0 | 1 | 1 |
| Bile reflux | 0 | 2 | 0.49 |

Table 6: Summary of weight loss at 6 months follow up

| Follow up at 6 months | SADI-S | OAGB | P value |
|------------------------------|---------------|---------------|----------------|
| Weight (kg) | 85.92 ± 9.41 | 89.6 ± 11.51 | 0.22 |
| Mean ± SD (range) | (69-106) | (72-130) | |
| BMI (kg/m ²) | 33.52 ± 2.99 | 33.61 ± 3.57 | 0.93 |
| Mean ± SD (range) | (28.39-39.35) | (26.54-41.14) | |
| EWL% | 56.84 ± 14.38 | 53.04 ± 15.34 | 0.37 |
| Mean ± SD (range) | (25.3-91.51) | (12.82-90.38) | |
| TWL% | 28.16 ± 8.28 | 21.79 ± 5.81 | 0.29 |
| Mean ± SD (range) | (11- 50) | (5.45-35.34) | |

BMI: Body mass index, EWL%: Percentage of excess weight loss, TWL%: Percentage of total weight loss.

Table 7: Summary of weight loss at 1 year follow up

| Follow up at 1 year | SADI-S | OAGB | P value |
|--------------------------|----------------|----------------|---------|
| Weight (kg) | 69.48 ± 10.17 | 73.68 ± 10.39 | 0.19 |
| Mean ± SD (range) | (56-95) | (54-95) | |
| BMI (kg/m ²) | 27.13 ± 2.15 | 27.56 ± 2.93 | 0.55 |
| Mean ± SD (range) | (23.15-32.47) | (21.91-34.41) | |
| EWL% | 89.82 ± 11.47 | 85.53 ± 15.99 | 0.28 |
| | (63.24-111.95) | (49.15-113.06) | |
| TWL% | 38.84 ± 5.02 | 35.53 ± 7.91 | 0.08 |
| | (24.19-49.17) | (20.91-55) | |

BMI: Body mass index, EWL%: Percentage of excess weight loss, TWL%: Percentage of total weight loss.

Table 8: Summary of weight loss at 2 years follow up

| Follow up at 2 years | SADI-S | OAGB | P value |
|--------------------------|---------------|---------------|---------|
| Weight (kg) | 65 ± 8.46 | 68.96 ± 10.36 | 0.15 |
| Mean ± SD (range) | (54-87) | (55-97) | |
| BMI (kg/m ²) | 25.28 ± 1.72 | 25.74 ± 2.31 | 0.42 |
| Mean ± SD (range) | (22.41-29.97) | (22.31-30.85) | |
| EWL% | 99.25 ± 8.72 | 96.05 ± 12.56 | 0.3 |
| | (79.75-113.6) | (68.38-115.3) | |
| TWL% | 42.97 ± 4.67 | 39.81 ± 6.36 | 0.051 |
| | (34.51-51.79) | (29.09-54.17) | |

BMI: Body mass index, EWL%: Percentage of excess weight loss, TWL%: Percentage of total weight loss.

Table 9: Postoperative weight loss in the SADI-S group

| | Preoperative | 2 years postoperative | P value |
|--------------------------|----------------|-----------------------|--------------------|
| Weight (kg) | 114.08 ± 12.13 | 65 ± 8.46 | <0.01 |
| Mean ± SD (range) | (97-145) | (54-87) | Highly significant |
| BMI (kg/m ²) | 44.32 ± 2.86 | 25.28 ± 1.72 | Highly significant |
| Mean ± SD (range) | (40.35-49.53) | (22.41-29.97) | |

Table 11: Remission of comorbidities at 2 years follow up

| Comorbidities | SADI-S | OAGB | P value |
|---------------------|----------|------------|---------|
| HBP (preoperative) | 10 (40%) | 8 (32%) | 0.39 |
| • Complete response | 3 (30%) | 4 (50%) | |
| • Partial response | 7 (70%) | 4 (50%) | |
| HLP (preoperative) | 7 (28%) | 5 (20%) | 0.41 |
| • Complete response | 4 (57%) | 4 (80%) | |
| • Partial response | 3 (43%) | 1 (20%) | |
| IGT (preoperative) | 2 (8%) | 2 (8%) | 1 |
| • Complete response | 2 (100%) | 2 (100%) | |
| DMT2 (preoperative) | 10 (40%) | 13 (32.5%) | 0.51 |
| • Complete response | 4 (40%) | 7 (54%) | |
| • Partial response | 6 (60%) | 6 (46%) | |
| OSAS (preoperative) | 4 (16%) | 3 (12%) | 1 |
| • Complete response | 4 (100%) | 3 (100%) | |

Nutritional and metabolic outcome.

Table 12: Nutritional and metabolic outcome in both groups

| | SADI-S | OAGB | P value |
|---|--------------------------------|--------------------------------|----------------|
| Preoperative Hemoglobin (N=12-15g/dl) | 12.4 ± 10.07 (10.6-15) | 12.37 ± 1.7 (10.6-15.2) | 0.91 |
| 2y postoperative Hemoglobin (N=12-15g/dl) | 11.19 ± 1.05 (9.4-13.8) | 11.58 ± 0.94 (10.2-13.87) | 0.17 |
| Preoperative Total serum protein (N=6-8.5g/dl) | 7.32 ± 0.55 (6.4-8.4) | 7.22 ± 0.58 (6.1-8.2) | 0.53 |
| 2y postoperative Total serum protein (N=6-8.5g/dl) | 6.44 ± 0.59 (5.5-7.8) | 6.15 ± 0.62 (5-7.6) | 0.09 |
| Preoperative Albumin (N=3.5-5g/dl) | 3.88 ± 0.24 (3.4-4.3) | 3.89 ± 0.22 (3.5-4.3) | 0.86 |
| 2y postoperative Albumin (N=3.5-5g/dl) | 3.3 ± 0.29 (2.7-3.8) | 3.44 ± 0.24 (3.1-3.8) | 0.06 |
| Preoperative Parathyroid hormone (10-65pg/ml) | 73.92 ± 17.2 (45-110) | 71.76 ± 14.72 (46-100) | 0.64 |
| 2y postoperative Parathyroid hormone (10-65pg/ml) | 52.92 ± 17.2 (24-89) | 51.08 ± 14.56 (25-79) | 0.69 |
| Preoperative Calcium (N=8.5-1.5mg/dl) | 9.37 ± 0.37 (8.9-10.5) | 9.28 ± 0.4 (8.4-10) | 0.39 |
| 2y postoperative Calcium (N=8.5-1.5mg/dl) | 9.04 ± 0.4 (8.2-10.2) | 8.94 ± 0.33 (8.1-9.7) | 0.45 |
| Preoperative Vitamin B12 (N=211-911pg/ml) | 504.6 ± 158.79 (203-803) | 426.28 ± 146.23 (204-684) | 0.08 |
| 2y postoperative Vitamin B12 (N=211-911pg/ml) | 536.72 ± 185.08 (208-874) | 500.08 ± 160.17 (250-824) | 0.46 |
| Preoperative Vitamin A (N=20-65ug/dl) | 43.44 ± 11.49 (22.67-64.78) | 44.18 ± 11.32 (22.57-64.33) | 0.82 |
| 2y postoperative Vitamin A (N=20-65ug/dl) | 32.84 ± 8.44 (17-48.58) | 34.79 ± 7.94 (17.08-51.23) | 0.4 |
| Preoperative Vitamin D (N=32-100ng/ml) | 27.43 ± 8.1 (10-46.18) | 31.91 ± 8.65 (13.56-49.06) | 0.06 |
| 2y postoperative Vitamin D (N=32-100ng/ml) | 42.63 ± 14.63 (20.4 - 68.4) | 35.85 ± 13.49 (14.1-70.3) | 0.49 |
| Preoperative Vitamin E (N=5.5-18mg/l) | 10.86 ± 3.37 (6.25-17.1) | 10.21 ± 3.04 (6.68-17.58) | 0.48 |
| 2y postoperative Vitamin E (N=5.5-18mg/l) | 6.96 ± 1.54 (3.42-9.72) | 7.5 ± 1.69 (4.02-11.34) | 0.24 |
| Preoperative Vitamin K (N=0.13-1.8ng/ml) | 1.18 ± 0.36 (0.32-1.74) | 1.24 ± 0.4 (0.18-1.71) | 0.56 |
| 2y postoperative Vitamin K (N=0.13-1.8ng/ml) | 0.7 ± 0.27 (0.16-1.24) | 0.81 ± 0.35 (0.1-1.46) | 0.23 |

Discussion

Bariatric surgery has widely spread all over the world.^{2,3} Weight loss and maintenance of this weight loss together with resolution or improvement of comorbidities associated with obesity is the marker of success of a bariatric procedure.¹⁴

We conducted this prospective randomized study on 50 morbidly obese patients who underwent sleeve gastrectomy as their primary bariatric surgery. Then patients regained $\geq 20\%$ of their lost weight. Patients were randomly classified into 2 groups according to the type of revisional surgery; the SADI-S group and the OAGB group. Each group included 25 patients. Patients were followed up for at least 2 years.

There was no significant difference between both groups as regard the demographic and preoperative data. The mean age was 34.24 ± 5.24 (25-44) in the SADI-S group and 35.24 ± 5.83 (25-49) in the OAGB group. Female prevalence was obvious in both groups.

The BMI before revisional surgery

The mean BMI before revisional surgery was 44.32 ± 2.86 (40.35-49.53) kg/m^2 in the SADI-S group and 42.97 ± 3.35 (40.03-49.51) kg/m^2 in the OAGB group with no statistical difference between the 2 groups (P value=0.13). These results are comparable to other studies.

Regarding SADI-S as a revisional surgery, Sánchez-Pernaute et al¹⁵ had 16 patients with mean BMI 44kg/m^2 (35.5–55.8) and Dijkhorst et al¹⁶ had 66 patients with mean BMI for these patients was $45.6 (\pm 6.9) \text{kg/m}^2$.

Regarding OAGB as a revisional surgery, Musella et al.¹⁷ reported mean BMI before OAGB (kg/m^2) 41.4 in 104 patients.

Operative time

In the present study, the mean operative time was 154.6 ± 16.47 minutes (120-200) in the SADI-S group and 88 ± 18.03 minutes (50–120) in the OAGB group. This result was highly significant (P value < 0.01). The SADI-S group took more operative time. We can relate this to the recent introduction of the SADI-S technique to the bariatric procedures together with the high learning curve of the procedure due to the quite difficulty of duodenal dissection that takes some more time to avoid injury of the duodenum, the gastroduodenal artery or even the common bile duct.

Regarding studies done on SADI-S post failed sleeve gastrectomy, the mean operative time was 114 minutes (45–160) in Sánchez-Pernaute et al,¹⁵ 105.5 ± 12.2 minutes in Wu et al,¹⁸ and 67.2 minutes

for 750 procedures performed by 3 surgeons in Surve et al study.¹⁹ These results are much lesser than our operative time. Those studies related their shorter operative time to the increase in their learning curve.^{15,18,19}

Regarding OAGB, the mean operative time in our study was comparable to Musella et al,¹⁷ who reported a mean operative time of 95.5 ± 3.5 minutes.

Bashah et al,²⁰ reported no significant difference in the mean operative time between both procedures referring this to the improvement of their learning curve in the SADI-S procedure.

Intraoperative and early post-operative complications:

In the present study we didn't encounter any intraoperative complication, no intraoperative mortality, intraoperative bleeding, methylene blue extravasation or unplanned need for postoperative ICU admission. We didn't report any case of conversion to open technique.

Also, early general, and specific postoperative complications including bleeding (Endoluminal or intraperitoneal), leakage from gastro-jejunosomy or duodeno-ileostomy, duodenal stump blowout, trocar site herniation and small bowel obstruction were not encountered in either group. These results were comparable to other studies; Sánchez-Pernaute et al,¹⁵ Ceha et al,²¹ and Bashah et al.²⁰

Post-operative hospital stay

The mean post-operative hospital stay in our study was 3.4 ± 1.12 (2-5) days in the SADI-S group and 3.16 ± 0.99 (2-5) days in the OAGB group. This was a statistically insignificant result.

Late complications

In the present study we encountered 2 cases of bile reflux and a case of marginal ulcer in the OAGB group. All patients were treated conservatively. Bashah et al results showed that patient who underwent OAGB-MGB had more complications with a rate of 27% when compared to the 19% complication rate for patients underwent SADI-S procedure. Most of these complications were short term and reversible. The main OAGB-MGB postoperative complications were related to exacerbating the upper gastrointestinal symptoms and possibly creating GERD, anastomotic ulcer, and bile reflux.

In this study, postoperative chronic diarrhea was reported in 1 case in the SADI-S group for 3 months and was managed conservatively. This is comparable to other studies where Pennestri et al,²² Surve et al,¹⁹ and Bashah et al,²⁰ reported chronic diarrhea in 2.5% (3 patients), 2.9% (22 patients) and 14%

(6patients) respectively. One patient in Pennestri et al study was converted to Reux En Y gastric bypass to treat chronic diarrhea. The 22 patients in Surve et al study required common channel lengthening. In Bashah et al, this complication was temporary and totally resolved within 3 to 6 months in all patients.

None of the patients in the OAGB group had chronic diarrhea. This was comparable to Bashah et al.²⁰

In this study, we reported 4 cases of malnutrition; 2 cases in the SADI-S group and 2 cases in the OAGB group. Those 4 patients required hospital admission and conservative management with no need for reoperation. In Surve et al,¹⁹ 2 patients (0.2%) suffered from malnutrition, and both required common channel lengthening.

Weight loss

In the present study, we the postoperative BMI, TBWL% and EWL% after 6 months, 1 year and 2 years follow up was statistically insignificant between SADI-S and OAGB. Bashah et al,²⁰ demonstrated no significant difference in EWL% between SADI-S and OAGB-MGB as revisional surgery ($p > 0.05$).

In the SADI-S group, we reported BMI of 33.52 ± 2.99 , 27.13 ± 2.15 and 25.28 ± 1.72 kg/m² at 6months, 1year and 2 years. We reported an EWL% of 56.84 ± 14.38 , 89.82 ± 11.47 and $99.25 \pm 8.72\%$ at 6months, 1year and 2 years. We reported TWL% 28.16 ± 8.28 , 38.84 ± 5.02 and $42.97 \pm 4.67\%$ at 6months, 1 year and 2 years.

In the OAGB group, patients achieved a BMI of 33.61 ± 3.57 , 27.56 ± 2.93 and 25.74 ± 2.31 kg/m² at 6 months, 1year and 2 years. They achieved an EWL% of 53.04 ± 15.34 , 85.53 ± 15.99 and 96.05 ± 12.56 % at 6 months, 1 year and 2 years. They achieved a TWL% of 21.79 ± 5.81 , 35.53 ± 7.91 and 39.81 ± 6.36 % at 6 months, 1 year and 2 years.

These results are comparable to other studies where Wu et al,¹⁸ had %EWL 63.52% and 70.72% at 6 and 12 months follow up after the SADI-S as a revisional surgery for 22 patients. And this is close to our results regarding the 6 months follow up but much lower regarding the 12 months follow up. Musella et al,¹⁷ reported %TWL of 28.5 and 31.1 at 6 and 12 months follow up after OAGB as revisional surgery post sleeve gastrectomy.

Sánchez-Pernaute et al,¹⁵ reported 68.6% mean EWL% and Dijkhorst et al,¹⁶ reported 16.5% (± 5.8) %TBWL at 6 months and 21.5% (± 8.1) %TBWL at 12 months. These results are much lower than our results.

Debs et al,²³ reported mean % EWL 80.2, mean %TWL of 74 at 12-month follow-up and mean %EWL 84.1, %TWL 79 in 66 patients who underwent SADI-S as revisional procedure post sleeve gastrectomy

and these results are near to our results regarding %EWL but much lower regarding %TBWL.

Remission of comorbidities

Regarding hypertension, 30% and 50% of patients had complete resolution and stopped anti-hypertensive medications while 70% and 50% showed improvement of their high blood pressure being controllable and stable by medications in the SADI-S group and OAGB group respectively. Hyperlipidemia showed complete resolution with normal blood test in 57% and 80% in the SADI-S and OAGB groups respectively. Partial resolution of hyperlipidemia in the form of normal laboratory test with medications occurred in 43% and 20% of patients in the SADI-S group and OAGB group respectively. All patients (100%) with impaired glucose tolerance in both groups had normal blood glucose at 2 years follow up. Regarding type 2 diabetes mellites 40% and 54% patients had complete resolution and stopped hypoglycemic drugs while 60% and 46% had their blood glucose level controlled by oral hypoglycemic drugs in the SADI-S and OAGB groups respectively. Regarding OSAS, all patients (100%) in both groups showed complete resolution of their symptoms at 2 years follow up.

Remission of comorbidities was statistically insignificant in both groups. This was comparable to other studies. Bashah et al,²⁰ demonstrated an equivalent positive effect of both SADI-S and OAGB on improving the comorbidities (T2D, hypertension, or lipid profile) over 1 year.

Sanchez-Pernaute et al,²⁴ reported a 52% remission rate of T2D over a 5-year follow-up, whereas Zaveri et al. reported an 81% remission rate over 4-year follow-up post SADI-S.²⁵ Musellu et al,¹⁷ reported remission rates from hypertension, diabetes, gastroesophageal reflux, and dyslipidemia were 40%, 62.5%, 58.7% and 52%, respectively after OAGB.

In the present study, we didn't report any case of weight regain in either group.

Bashah et al,²⁰ reported weight regain was in 2 patients (4%) in the OAGB group and no patients with weight regain in the SADI-S group in their 1 year follow up. Noun et al. study on OAGB reported 13% weight regain after 18-months follow-up.²⁶

Jamal et al. suggested that alterations in weight post OAGB-MGB might be connected to the study group's culture, eating habits, and genetic variability.²⁷

This weight regain could be reduced by diet modification, increasing the length of bypassed jejunum, or reducing the size of gastric pouch in intractable cases.²⁷⁻²⁹

Micronutrient follow up

In our study, we assessed patients for preoperative and postoperative levels of hemoglobin, total serum proteins, serum albumin, parathyroid hormone, calcium, vitamin B12 and fat soluble vitamins; A, D, E and K.

The preoperative and 2 years postoperative mean hemoglobin level were insignificant in both groups. Yet, the mean preoperative level was within the normal range (12-15gm/dl) in both groups while patients developed mild anemia during the 2 years follow up. Although all patients were on iron supplementation yet, the mean 2 years postoperative hemoglobin level was 11.19 ± 1.05 gm/dl in the SADI-S group and 11.58 ± 0.94 gm/dl in the OAGB group with a P value of 0.17.

While the preoperative mean albumin level in both groups was within the normal range, patients developed postoperative mild hypoalbuminemia. Although statistically insignificant (P value=0.06), albumin level was lower in the SADI-S group (3.3 ± 0.29 (2.7-3.8)) than the OAGB group (3.44 ± 0.24 (3.1-3.8)) at 2 years follow up. This can be explained by the longer length of common channel in the OAGB technique.

Regarding the preoperative levels of calcium, vitamin D and the parathyroid hormone, both groups showed normal calcium level (8.5-10.5mg/dl), lower than normal level of vitamin D (Normal=32-100ng/ml) and higher than normal level of parathyroid hormone (Normal=10-65pg/ml) with statistically insignificant difference between both groups.

The mean preoperative calcium level was 9.37 ± 0.37 mg/dl and 9.28 ± 0.4 mg/dl in SADI-S and OAGB groups respectively, with a P value of 0.39.

The mean preoperative vitamin D level was 27.43 ± 8.1 ng/ml and 31.91 ± 8.65 ng/ml in SADI-S and OAGB groups respectively, with a P value of 0.06.

The mean parathyroid level was 73.92 ± 17.2 (45-110) pg/ml and 71.76 ± 14.72 (46-100) pg/ml in SADI-S and OAGB groups respectively, with a P value of 0.64.

The 2 years postoperative levels of calcium, vitamin D and the parathyroid hormone were normal in both groups with no statistically significant difference.

The mean calcium level decreased at 2 years follow up, being 9.04 ± 0.4 mg/dl in the SADI-S and 8.94 ± 0.33 mg/dl in the OAGB with a P value of 0.45, yet it was within the normal level.

The level of vitamin D increased at 2 years postoperative in both groups to reach the normal level (32-100ng/ml). It was 42.63 ± 14.63 ng/ml in SADI and 35.85 ± 13.49 ng/dl in OAGB with P value

of 0.49.

The 2 years postoperative parathyroid level decreased to a normal level (10-65pg/ml) being 52.92 ± 17.2 pg/ml in SADI and 51.08 ± 14.56 pg/ml in OAGB with a P value of 0.69.

The mean preoperative and 2 years postoperative levels of vitamin B12 were within the normal range in both groups. The mean preoperative vitamin B12 was 504.6 ± 158.79 pg/ml and 426.28 ± 146.23 pg/ml in the SADI and OAGB respectively, with a P value of 0.08. The mean 2 years postoperative vitamin B12 was 536.72 ± 185.08 pg/ml and 500.08 ± 160.17 pg/ml in the SADI and OAGB respectively, with a P value of 0.46.

The mean preoperative and 2 years postoperative fat soluble vitamins other than vitamin d (A,E,K) were within the normal range in both groups with no statistically significant difference, although their levels are lower in the postoperative period compared to their preoperative levels.

The mean preoperative vitamin A was 43.44 ± 11.49 ug/ml and 44.18 ± 11.32 ug/ml in the SADI and OAGB respectively, with a P value of 0.82. The mean 2 years postoperative vitamin A was 32.84 ± 8.44 ug/ml and 34.79 ± 7.94 ug/ml in the SADI and OAGB respectively, with a P value of 0.4.

The mean preoperative vitamin E was 10.86 ± 3.37 mg/l and 10.21 ± 3.04 mg/l in the SADI and OAGB respectively, with a P value of 0.48. The mean 2 years postoperative vitamin E was 6.96 ± 1.54 mg/l and 7.5 ± 1.69 mg/l in the SADI and OAGB respectively, with a P value of 0.24.

The mean preoperative vitamin K was 1.18 ± 0.36 ng/ml and 1.24 ± 0.4 ng/ml in the SADI and OAGB respectively, with a P value of 0.56. The mean 2 years postoperative vitamin K was 0.7 ± 0.27 ng/ml and 0.81 ± 0.35 ng/ml in the SADI and OAGB respectively, with a P value of 0.23.

The same results were reported by Bashah et al after 1 year follow up.²⁰ Those results are comparable to other studies except the level of vitamin D which increased in the postoperative follow up than its preoperative level. Patients were found to experience a drop of vitamin D in the SADI-S group and anemia in the OAGB-MGB group.^{16,24,27,30-32} Creation of bypass anastomosis causes malabsorption of fat-soluble vitamins due to poor mixing with bile salts, thus creating a further reduction in vitamin D.³³

Limitations

The follow up period of this study is only 2 years. Long term follow-up with larger study group is needed for better assessment and comparison of the efficacy and nutritional deficiencies of both procedures as revisional surgeries.

Conclusions

SADI-S and OAGB, when performed as revisional procedures after failed LSG due to weight regain, are both effective with comparable outcome as regard weight loss and maintenance, remission of comorbidities and micronutrient deficiencies after 2 years of follow up.

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