

Single-anastomosis Sleeve Jejunal Bypass: a Mid-term Follow-up Report of a New Surgical Technique

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- Single anastomosis sleeve ileal bypass (SASI) is a combined bariatric metabolic technique, in which few studies have shown its outcomes efficacy.
- However, this technique has a high risk of malnutrition due to long biliopancreatic limb.
- Single anastomosis sleeve jejunal bypass (SASJ) has a shorter limb.
- Therefore, it seems to have a lower risk of nutrient deficiency.
- Furthermore, this technique is relatively new, and little is known about the efficacy and safety of SASJ. We aim to report our mid-term follow-up of SASJ from a high-volume center for bariatric metabolic surgery in the Middle East region.

- For the current study, the 18-month follow-up data of 43 patients with severe obesity who underwent SASJ was collected.
- The primary outcome measures were demographic data, weight change variables according to ideal body mass index (BMI) of 25 kg/m² at 6, 12, and 18 months, laboratory assessments, remission of obesity-associated medical problems, and other potential bariatric metabolic complications after the surgery.

- Over time, BMS procedures developed into techniques with greater weight loss and fewer complications;
- SG is one of the most prevalent and well-known approaches, which is one of the first choices for most patients with severe obesity and bariatric surgeons around the world .
- Although SG is surgically a restrictive procedure by decreasing the volume of the stomach; however, with an effect on gut hormones (i.e., decrease Ghrelin, increase glucagon-like Peptide-1 (GLP-1), increase peptide YY), it has a malabsorptive effect too .

- However, to create a more sustainable and significant weight loss, anastomoses between the stomach and intestine or between two parts of the intestine can be created similar to another well-known procedure, RYGB.
- An example of anastomosis between two parts of the intestine besides SG is between the duodenum and ileum, which is called the single anastomosis duodenal-Ileal approach (SADI).
- Recently, surgeons used more developed techniques with single anastomosis between the sleeve and ileum, which is called SASI , or between the sleeve and jejunum, which is called SASJ.

- SASI bypass has several superiorities based on the previous study by Mahdi et al. ; in addition, SASJ and SASI unlike SADI are easily reversible techniques.
- However, SASJ is a kind of modification to SASI with a shorter biliopancreatic limb length; therefore, it seems SASJ has a lower risk of nutrient deficiency.
- The longer common limb length compared to SASI may avoid long-term nutritional complications; therefore, SASJ is safer theoretically than SASI in patients with extreme weight loss and baseline nutritional deficiencies and simpler due to its surgical steps.

- SASJ is a newer bariatric metabolic technique and the literature needs more investigation on its safety in all aspects and efficacy from around the world and in different ethnicities.
- Besides Sewefy et al. who reported their experience with SASJ in 2- and 6-year follow-ups on an acceptable number of populations, this procedure is neither a common approach for surgeons nor patients due to its unknown outcomes and complications.
- Therefore, in this study, we aim to report our mid-term follow-up of SASJ from a high-volume center for BMS in the Middle East region .

Methods and Material

- **Study Population**

- For this study, 43 patients with severe obesity who were a candidate for BMS and underwent SASJ for the first time in Al-Zahra university hospital (center of excellence for BMS) from January 2016 to April 2019 was collected.
- Due to being a new surgical approach and adhering to our local and national ethical considerations, a larger sample size was not feasible for this study.
- The 2016 IFSO Position Statements and 2012 Interdisciplinary European Guidelines on Metabolic and BMS and their later amendments were used as our surgical criteria

- Patients aged between 20 and 60 years old with body mass index (BMI) above 35 kg/m² with an obesity-related medical problem (e.g., hypertension (HTN) and/or T2D) or BMI above 40 kg/m² and patients' willingness to participate in the study were determined as the inclusion criteria.

- As long as this procedure is a new introduction to the BMS world, those who were not a candidate for other common techniques (i.e., RYGB, OAGB, or SADI/SASI) were selected for SASJ .

- Exclusion criteria were those with previous BMS, heart failure, pregnancy, malignancy, rheumatologic and immune system problems, uncontrolled psychological disorders, or drug abuse/addiction.

- Patients were treated by the same multidisciplinary team constituting of the same surgeons, dieticians, psychologists, gastroenterologists, and radiologists.
- Detailed information about the surgery with its latest updates, potential complications, and nutritional requirements was provided to all patients individually before registering for the preoperative evaluations.

Intervention

- In brief, routine SG was started with omentolysis using a vessel sealing LigaSure (Covidien) 2–3 cm from the pylorus to the angle of His. The stomach was cut from 4 cm before the pylorus to 1 cm before the esophagus with EndoGIA staplers (60 mm; Covidien) along a 36-F bougie. The entire stapler line was reinforced using a 2–0 PDS thread.
- For the gastrojejunal anastomosis, 200 cm from the Treitz ligament was measured; 40 times 5 cm by 5 cm by the fenestrated grasper. The intestinal loop was brought up to the gastric sleeve. A stapled side-to-side anastomosis was performed using a forty-five linear cutting stapler at the site of the antrum 4–6 cm from the pylorus sphincter posterior to the proximal part of the sleeve stapling facing to the gastric fundus.

- The entire stapler line was reinforced using a 2–0 PDS thread. The gastrojejunal anastomosis defect was closed with a two-layer running suture, and a methylene blue leak test was performed during the procedure to assess if there were any leaks .

Postoperative

- Early ambulation within 6 h from the end of the surgery was encouraged, and cold-water drinking was started within 1 day after the procedure if the assessments were negative for leakage.
- Postoperative thrombosis prophylaxis was done using heparin for 2 weeks twice a day and then was continued by leg compression for the next month.
- Patients were recommended to administer a liquid diet for 7–10 days, followed by a soft diet for a month after the surgery, and eventually, they were put on a high-protein, low-calorie diet.
- All candidates were followed up every 10 days during the first month, every 3 months in the first year, and every 6 months in the second year.

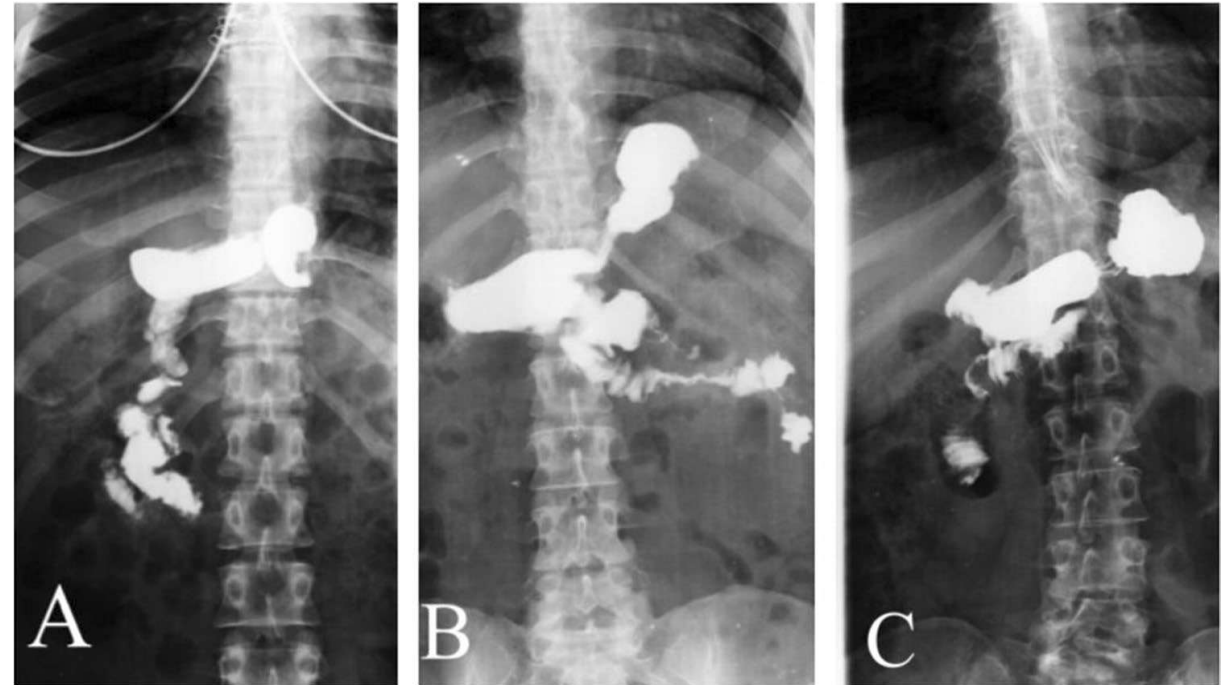
Assessments

- A checklist including demographic data, weight, BMI, blood sample test results, and the presence of obesity-associated medical problems or any other complications was obtained before and during postoperative follow-ups.
- Our primary outcome was the 18-month and the trend of %EWL and other weight-change-related variables

- The secondary outcomes were important factors of homeostasis and their levels in the blood plus the postoperative bariatric-related complications.
- To calculate the weight-change variables (%EWL and total weight loss percentage (%TWL)) in postoperative months 1, 3, 6, 12, and 18, the ideal body weight equivalent to BMI = 25 kg/m² was used.

- blood sample constituting hemoglobin (Hb, mg/dl), HbA1C (mmol/lit), and albumin (g/dl) was checked at the baseline and repeated at 6, 12, and 18 months postoperatively.
- Ferritin, folic acid, zinc, vitamin D (ng/ml), and B12 were checked at the baseline and repeated 12 and 18 months after surgery.

- All blood tests were conducted by the same team in our central laboratory with the routine standard protocols based on the provided kits.
- To assess the functionality of GJ anastomosis and to evaluate the amount of food passing the bipartition pathways of SASJ, upper GI with barium contrast was performed at 6 months after the surgery randomly on some participants (10 patients accepted to participate in a GI series study)



- American Diabetes Association 2015 report and its later amendments were used to diagnose, confirm, and define complete remission of T2D.
- The 2013 European Society of Hypertension and European Society of Cardiology report for HTN management and its later amendments were used to diagnose, confirm, manage, and define remission of HTN. Hyperlipidemia (HLP) was defined based on the Adult Treatment Panel III cholesterol guideline.

Results

- In the current study, 43 patients with severe obesity underwent SASJ with a mean age of 35.6 ± 8.3 years old and female gender predominance of 28:15 (65.1%:34.9%).
- The baseline height, weight, and BMI with the weight-change-related variables are in Table 1

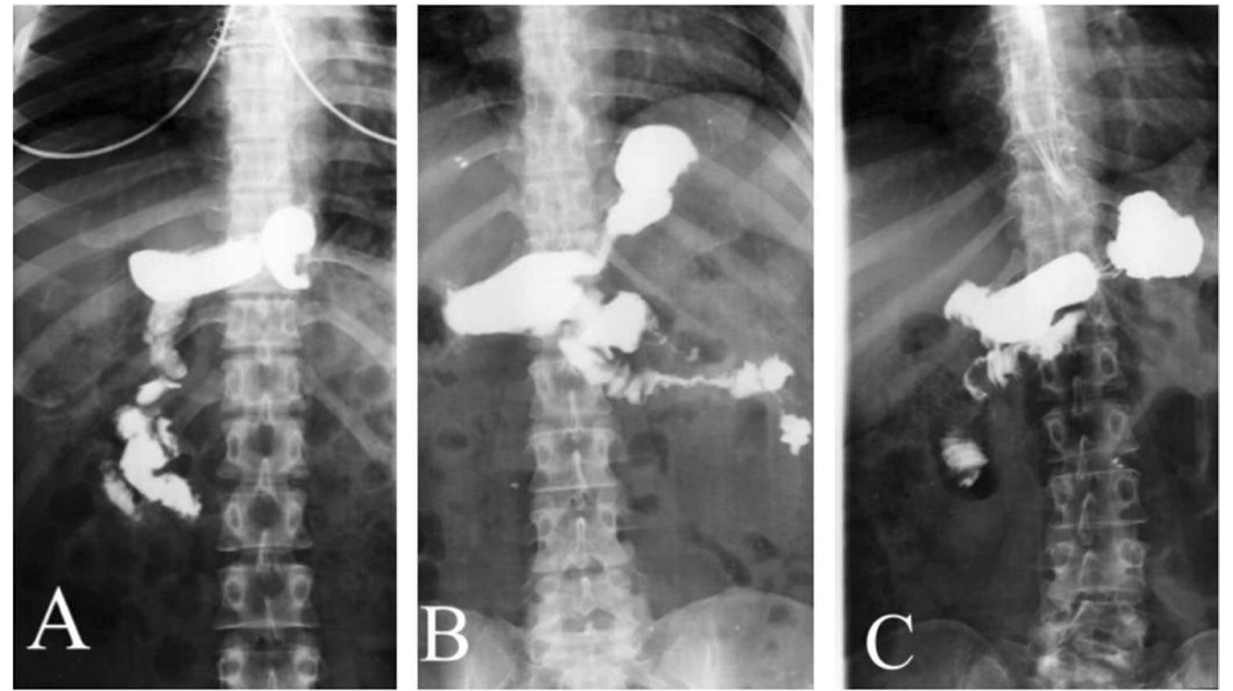
Table 1 Trends of weight and weight-related variable after SASJ during 18-month follow-up (all results are presented as mean \pm standard deviation and the range of variables present in parentheses)

	Baseline	1 mo	3 mo	6 mo	12 mo	18 mo
Weight (kg)	118.3 \pm 14.3 (87–150)	104.7 \pm 14.5 (73–138)	93 \pm 14.1 (69–122)	84.4 \pm 13 (65–119)	77.2 \pm 11.2 (59–111)	74.8 \pm 8.6 (57–92)
BMI (kg/m ²)	44.9 \pm 4.7 (38–59.6)	39.8 \pm 4.7 (33–54)	35.3 \pm 4.6 (28.2–48.2)	32.1 \pm 4.7 (25.4–45.2)	29.5 \pm 4.5 (22.3–41)	28.6 \pm 3.8 (22–36)
EWL (%)	-	21.9 \pm 6.1	40.5 \pm 9.6	54 \pm 12.8	64.8 \pm 15.1	68 \pm 14.2
TWL (%)	-	11.6 \pm 2.9	21.6 \pm 4.5	28.7 \pm 5.8	34.5 \pm 6.9	36.3 \pm 6.9

The repeated measure was used for statistical analysis, and all *p*-value analyses are significant with a < 0.001 level

BMI, body mass index; *EWL*, excess weight loss; *TWL*, total weight loss

- None of the patients represented major BMS complications, including bleeding, leak, or pulmonary embolism.
- No patient was lost due to follow-up.
- Upper GI series revealed that the same amount of food passed both the antrum and the GJ anastomosis in 6 out of 10 samples; however, in 2 of them, most of the foods passed the antrum-pylorus-duodenum pathway and the remaining 2 samples showed the GJ anastomosis passed the higher amount of received food.





- The repeated measure ANOVA revealed a significant weight loss ($p < 0.001$), decrease in BMI ($p < 0.001$), and %EWL ($p < 0.001$) within 18 months of follow-up.
- Further evaluations revealed statistically significant improvement in the number of patients with T2D (100%), HTN (86%), HLP (69%), and gastroesophageal reflux disease (GERD) (86%)

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Table 2 SASJ and comorbidities after surgery

	Preoperative	18 months
T2D, <i>n</i> (%)	10 (23.25)	0 (0)*
HTN, <i>n</i> (%)	7 (16.27)	1 (2.32)*
HLP, <i>n</i> (%)	13 (34.88)	4 (9.30)*
GERD, <i>n</i> (%)	14 (32.54)	2 (4.64)*
Ferritin deficiency (< 40 µg/L)	9 (20.93)	5 (11.62)†
Vitamin D deficiency (< 30 ng/ml)	26 (60.46)	15 (34.88)*

*All *p*-values were significant (<0.05) with the Chi-square test expect for the mentioned comparison

†This *p*-value is not significant

T2D, type 2 diabetes; *HTN*, hypertension; *HLP*, hyperlipidemia; *GERD*, gastro esophageal reflux disease

- Figure 2 depicts the trend of weight loss and %EWL and Fig. 3 shows the %TWL and BMI trends, during the follow-up period for better interpretation

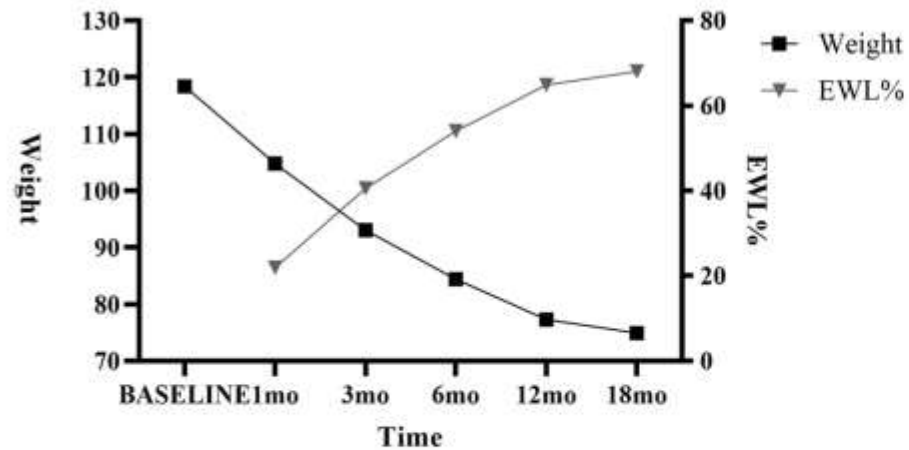


Fig.2 The trajectory of weight and %EWL after SASJ within 18-month follow-up

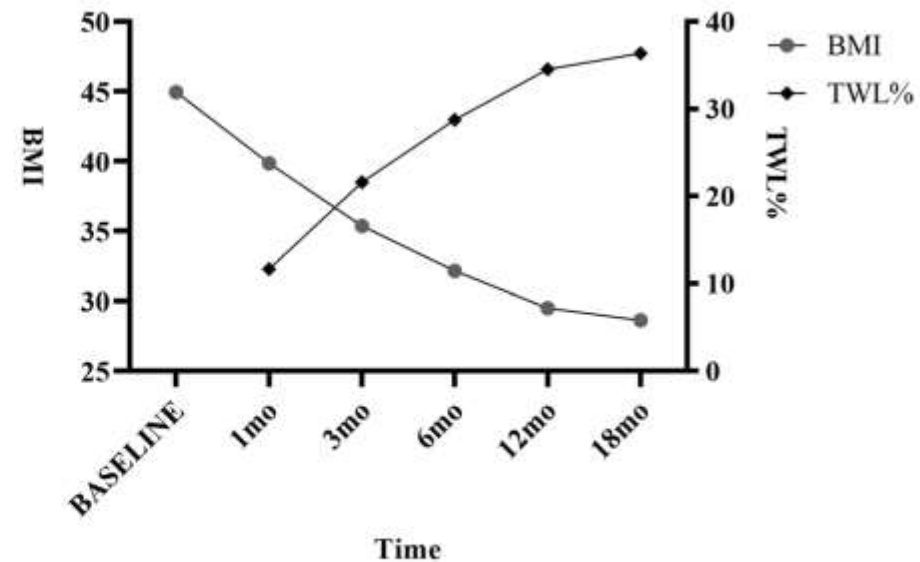


Fig.3 The trajectory of BMI and %TWL after SASJ within 18-month follow-up

Results

- Some of the nutritional markers in the blood changed significantly and some of them didn't.
- No adverse effect was seen in 61.5% of the patients. Nevertheless, hair loss, hemorrhoid, and chronic nausea were the most significant complaints in 12 (27.90%), 1 (2.32%), and 2 (4.65%) of the patients, respectively.

Table 3 SASJ and nutritional status after surgery (all results are presented as mean \pm standard deviation)

	Baseline	6 months	12 months	18 months
Hemoglobin (mg/dl)	12.5 \pm 1.4	12.6 \pm 1.3	12.8 \pm 1.2	12.8 \pm 1.2*
Vitamin D (ng/ml)	28.4 \pm 10.5	-	49 \pm 24.2	50.4 \pm 21.4*
HbA ₁ C (mmol/mol, %)	6.1 \pm 0.5	5.89 \pm 0.2	5.8 \pm 0.2	5.7 \pm 0.2*
Albumin (g/dl)	4 \pm 0.1	4.04 \pm 0.1	4.1 \pm 0.1	4.1 \pm 0.1*
Ferritin (μ g/l)	76.8 \pm 33.4	-	78.5 \pm 35.6	83.1 \pm 34.1†
Vitamin B ₁₂ (pg/ml)	502.2 \pm 225.6	-	503.3 \pm 232.8	508.4 \pm 223.5†
Folic acid (ng/ml)	6.9 \pm 0.8	-	6.9 \pm 0.7	7.1 \pm 0.7†
Zinc (ng/dl)	12.5 \pm 2.4	-	12.6 \pm 2.2	13.4 \pm 2.2‡

*The repeated measure was used for statistical analysis, and these *p*-values were significant with a <0.001 level

†These *p*-values are not significant

‡The *p*-value of this variable was 0.025 according to the repeated measure analysis

dl, deciliter; *g*, gram; *l*, liter; *mg*, milligram; *ml*, milliliter; *mmol*, milimole; *ng*, nano gram; *pg*, pico gram; μ g, micro gram

- Chronic nausea was presented by two patients who experienced epigastric pain and bilious vomiting, which was terminated within a month in one person and 3 months in the latter with conservative management by proton pump inhibitors and domperidone. In addition, the incisional or internal hernia was not found in any of the patients during our observations.

By assuming the effect size (f) ≥ 0.17 , the calculated power of the study was $\geq 80\%$.

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Discussion

- SASJ, as one of the new bariatric metabolic approaches, has some similarities and differences with other bariatric metabolic operations.
- As long as we need a better and faster way to lose weight without imposing additional complications, intestinal bypass becomes inevitable; however, malnutrition is a potential risk in these scenarios .

- During the era of changing and modifying bariatric metabolic approaches, SG can have a single anastomosis for a better outcome, similar to the combined approaches.
- This anastomosis has been made between the stomach and ileum in SASI or stomach and jejunum is SASJ.
- According to the advantages of SASI reported before, we expect to observe them in SASJ as well .

- According to our findings, SASJ within an 18-month follow-up has a promising effect on weight loss, remitting obesity-related medical problems, and not imposing a higher risk of malnutrition or other major complications for patients.

- According to our experience and review of literature, SASJ can be performed for patients with some criteria such as a history of gastric cancer in their family, *Helicobacter pylori* recurrent infections, intestinal metaplasia in gastroesophageal junction, peptic ulcer disease, diagnosed T2D, and abundant sweet eating or petite eating.
- Unlike RYGB, OAGB, SADI, and SASI, which have some absolute and relative indications and contraindications, SASJ is new and has no clear indication in any patient due to a lack of evidence and systematic reviews.
- SASJ vs. RYGB/OAGB has superiority in their shorter surgery time and accessibility to the gastrointestinal tract by upper endoscope and vs. SADI and SASI it may have a lower risk of nutrient deficiency and also is a simpler procedure.

- Regarding the efficacy of SASJ on weight loss, our patients reached a %EWL of 54%, 65%, and 68% in 6, 12, and 18 months, respectively. Sayadi et al. and Hosseini et al. reported their 6 and 12 months %EWL to be 55% and 77%, respectively . A longer study by Sewefy et al. reported an 85% for 2-year %EWL.
- These results are near to our findings with a little discrepancy, which can be explained by patient baseline BMI or differences in surgical technique such as length of common and biliopancreatic limbs, size, and attaching technique of gastrojejunal anastomosis.

- The steep slope of weight loss in the first year may explain by the cumulative effects of restrictive and malabsorptive parts that both limit the amount of food intake, increase the excretion of undigested food, and reduce the total calorie absorbed.
- Moreover, this phenomenon is orchestrated by gut hormones such as Ghrelin and GLP-1.
- These findings have been found in other combined procedures for example the 1-year %EWL after RYGB, OAGB, and SASI was 56–72%, 60–84%, and 68–90%, respectively.
- These findings are indicating that SASJ has acceptable weight loss during the most crucial postoperative time, the first year, and its %EWL is within the other valid procedures.

- An important aspect of weight loss after SASJ and other combined procedures is that the trend will dramatically decrease after the first postoperative year, which is evident in our diagrams and has been demonstrated in Sewefy et al.'s and other bariatric metabolic operations.
- This event might be due to the ratio of the bypassed intestine, the size of the anastomosis, and intestinal adaptation to the bariatric metabolic procedure.
- The latter has been observed previously in RYGB and OAGB in which weight plateaus after the first year. However, it should be considered that SASJ as well as RYGB [25] can act as the salvage procedure for weight regain after SG in which patients may face insufficient weight loss or early weight regain after surgery.

- In our study, the significant weight loss was related to a similar improvement in obesity-related medical problems (i.e., T2D, HTN, HLP, and GERD). The rate of T2D remission was 100%, which is similar to other studies; Sayadi et al. reported that T2D remission was met in 100% of patients within 6 months, this rate 1 year after surgery was 83.3% in Hosseini et al.'s, and finally, 100% in the 2-year study by Sewefy et al.
- However, another study with a larger sample size and longer follow-up duration revealed that this remission rate is near 98%, which is near the 1-year T2D remission rate after SASI, and 83% after RYGB, 94% for OAGB, and 72–82% after SG alone.
- This achievement is explained by the weight loss, which leads to decreased adiposity and insulin resistance, and increased secretion of gut hormones (e.g., incretins (e.g. GLP-1) and peptide YY) .

- HTN remission was 86% during our 18-month evaluation, which is higher than what has been reported for the 1-year HTN remission rate in the Hosseini et al. report, which could be due to the complicated mechanism of HTN in our body and confounding cardiovascular risk factors such as smoking, physical activity, dietary plan, or family history.
- However, our result is similar to 2- and 6-year follow-up studies by Sewefy et al. in which HTN remission was 89% and 93%, respectively.
- Reports on RYGB, OAGB, SASI, and SG alone demonstrated that HTN remission is 70.3%, 94%, 51%, and 62.5%, respectively

- HLP improved in 69% of patients, which is similar to the 70% of Hosseini et al. report and is less than the 2- and 6-year follow-up study by Sewefy et al. in which their patients reached a remission rate of 100% and 96.8%, respectively.

- The association of obesity, GERD, and its resolution with BMS is complicated.

Previous studies have shown that GERD may improve, get worse, or not change after SG. However, combined procedures due to their gastrointestinal anastomosis have a higher risk of bile acid reflux, which may put patients at higher risk for GERD, Barrett's esophagus, and esophageal adenocarcinoma.

- The remission of GERD was 86%, which is consistent with all similar studies on this subject with different postoperative periods; 87%, 87%, and 89% in 1-, 2-, and 6-year evaluations, respectively.

- Micronutrient deficiency and its related problems are the most significant concern for SASJ and SASJ-like approaches such as SASI and SADI.
- According to our experience, potential perioperative complications are thromboembolism, leak, and bleeding; none of them had higher rates in SASJ compared to routine procedures.
- Postoperative complications including malnutrition and reflux have lower risk than other procedures, which can be explained by its bipartition characteristic; GJ anastomosis works as a safety valve, which moves the acidic contents of the stomach to the jejunum and does not let the intraluminal pressure to rise.

- Regarding the effects of SASJ on malnutrition and decreasing important elements in blood, we did not observe any significant problems in any of the patients.
- This could be due to the creation of two open distinct pathways for food (i.e., classic pylorus-antrum-duodenum and the newly created anastomosis-jejenum pathway), leaving sufficient common limb length for absorption, frequent postoperative visits, multivitamin administration, and patients' awareness about the consequences of not adhering to our postoperative protocols.

- Our surgical technique was different from Hossein et al. and Pazouki et al. [20, 32] in how the anastomosis was attached to the stomach. The GJ anastomosis was created 4–5 cm from the pylorus and the stapler was directed to the fundus. This maneuver creates sufficient gastric length for the antrum and permits foods to pass either way randomly.
- Moreover, in this technique remaining antrum length leads the food to pass the antrum-duodenal pathway more than the procedures with shorter antrum length by the aid of gravity and it may influence the amount of nutrient absorption in comparison to other similar approaches.

- Albumin as one of the main determinants of nutritional status, decreased by the first 6 months; however, it improved by the end of the study. It should be noted that none of the albumin levels decreased below the lower normal limits.
- The hemoglobin levels generally improved during the study, as well as vitamin D. Low levels of vitamin D in over 34% of the patients, even by the end of the follow-up, may be attributed to the endemicity of vitamin D deficiency in our community, which can be noted at the study initiation when 60% of the patients were vitamin D deficient.

- Comparing SASJ to RYGB, OAGB, SASI, or SADI revealed the relative Obesity Surgery superiority of SASJ over the other techniques in this aspect, which is attributed to combining a safe procedure, SG, with a GJ anastomosis at a safe intestinal length.
- We did not evaluate the severity and frequency of dumping syndrome by a validated questionnaire and at a specific time; therefore, its incidence is possible after SASJ; however, none of our patients reported a combination of its routine symptoms including nausea/vomiting, palpitation, and flushing (the rest of the symptoms were not asked).

- Although our data should not be considered conclusive and further investigations are required in this area, the current article is strengthened in a way that is one of the first ongoing studies about SASJ in the world, which occurred in the Middle East region and a center of excellence for bariatric surgery with experienced surgeons.
- The long-term follow-up update will be reported in the near future

- For future single-group studies on SASJ and based on the G*Power software, we recommend a sample size of more than 60 patients to achieve a high power based on desired effect size and the number of postoperative follow-up measurements.
- Furthermore, it must be compared to other validated procedures with randomized controlled trials. Finally, the indications for SASJ are not clearly defined due to lacking systematic reviews for this subject.

- Our take-home messages are as follows:
- SASJ has significant and sustainable weight loss after surgery and can cut down the BMI from severe obesity range to near normal, resolute obesity-related medical problems, and therefore, bring a better life to patients with severe obesity. Indeed, there are some problems like any other surgery, which should be noted by both surgeon and patient.

Conclusion

- SASJ bariatric metabolic procedure has noticeable excessive weight loss, helps remission of obesity-associated medical problems, and imposes little or no major complications, which all of them are similar to other well-known bariatric approaches. However, more investigations are needed on this subject in other parts of the world with longer and larger sample sizes

Declarations

- **A Statement of Human Rights** The study has been approved by the Isfahan University of Medical Sciences Ethics Committee according to registered code “IR.MUI.MED.REC.1397.089” and has been performed in accordance with the ethical standards presented in the Declaration of Helsinki and its later amendments.
Consent to Participate Informed consent was obtained from all individual participants included in the study.
Conflict of Interest The authors declare no competing interests.

