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Gastric Bypass Reversal and Simultaneous Conversion to SADI-S for Weight Regain: Preliminary Results

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Abstract: ***Roux-en-Y gastric bypass (RYGB) is an effective operation to treat morbidly obese patients, but weight loss is not sustainable for most patients. Such as revision or conversion surgeries, an alternative has been a single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S). Thus, this study addresses the description, feasibility, and early results of converting RYGB to SADI-S for weight recovery. Twelve patients (92% female, 41 ± 9 years old) were followed for 6 to 38 months after conversion from RYGB to SADI-S. At 6 months, body mass index decreased from 41 ± 3.4 to 32 ± 4.3 Kg/m2, and excess body weight loss was 59 ± 20%. Six patients (50%) developed early complications (<30 days): transient gastroparesis, leak and intra-abdominal abscess resolved conservatively, pulmonary embolism and 1 hemoperitoneum. The common channel was 250 cm in the first 5 cases, of which 4 had late complications including severe diarrhea, reflux or weakness/malnutrition and a greater decline in albumin than 7 cases with 300 cm common channel. There were no reoperations or deaths. We believe that the detailed description of this method can help others bariatric surgeons choose it for their patients with primary RYGB failure without significant nutritional deficiencies.***

Keywords: Gastric bypass; reversal to normal anatomy, SADI-S; revisional surgery; weight regain

1. Introduction

Roux-en-Y gastric bypass (RYGB) is an effective operation to treat morbidly obese patients. A complex gut-brain-signaling mechanism, as well as gut microbiota, may play a role in weight maintenance after bariatric surgery[1,2]. However, good behavior is mandatory for lasting weight loss. Indeed, most patients with weight regain continue to be sedentary[3] and present eating behavior disorders[2] that lead to an excess of weight loss below 50% in 20 to 35% of patients after ten years following RYGB[4,5].

Pharmacological treatment may help patients with weight regain, but weight loss is not sustainable for most patients. Endoscopic procedures that narrow the gastrojejunostomy or the gastric pouch have been shown to provide additional weight loss due to an increase in fullness sensation[6], but no long-term outcomes have been reported. Currently, more than 10% of bariatric operations from Europe and North America are revisions. Out of those, 63% of revisions or conversions were done because of weight regain or comorbidities[7,8] which may include gastric pouch resizing[9,10] especially when it is dilated, biliopancreatic limb distalization[11,12], and application of an adjustable gastric band around the gastric pouch[13]. The outcomes of these revisional procedures are conflicting, and 20% of early complications and poor patient satisfaction have been described[14]. Some authors have reported good weight loss through the conversion of failed either sleeve gastrectomy or RYGB to a duodenal switch[15–17], but malnutrition may occur.

A single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) is an adaptation of the original duodenal switch which provides similar outcomes in

weight loss[18]. The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) position statement which analyzed data from many services worldwide consider primary SADI-S as investigational since there is no significant evidence on benefits over original duodenal switch[19]. However, recently, IFSO and ASMBS accepted the procedure[8,20]. On the other hand, in revisions for insufficient weight loss or weight regain after RYGB, the original duodenal switch has been done with acceptable results, but it is time-consuming[15,16]. Recently, conversion to SADI-S has been proposed as a safe but faster procedure than duodenal switch for weight loss after RYGB failure[21,22].This study addresses the feasibility, and early results of conversion of RYGB to SADI-S for weight regain.

2. Methodology

Patients

Between April 2016 and December 2018, patients with substantial weight regain (>50% of weight loss), or final body mass index (BMI) greater than 35 Kg/m^2 after RYGBwere referred to laparoscopic SADI-S. Patients with no significant gastric pouch dilation at computed tomography were considered for conversion. A multidisciplinary team followed them to assure that neither nutritional nor psychological disorders such as drugs and excessive alcohol consumption were in course. Only patients with primary RYGB failure without significant nutritional deficiencies were included. The study was approved by the local Ethical Committee (CAAE 31575620.8.0000.5342) in accordance with the Helsinki Declaration and informed consent was obtained from each patient.

SADI-S technique

SADI-S was performed through laparoscopic access in a similar technique, as reported by Heneghan et al.[22]. The surgeon started in the left-side of the patient, which was positioned in supine with the operating table in a Trendelenburg position. The ileum was measured and attached to the omentum with two temporary stitches for posterior omega duodenum-ileum anastomosis at 300 cm from the ileocecal valve. This anastomosis was performed either manually or with a linear stapler (white cartridge). Right after, the patient was positioned in a reverse Trendelenburg, and the surgeon changed to the right side of the patient. Adhesions were divided to allow complete exposure of the bypass anatomy. The gastrojejunostomy was excised after transecting the gastric pouch and the proximal alimentary limb near the gastrojejunostomy with a linear stapler. The bowel anatomy was reconstructed in two patients by resecting the alimentary limb in one and restoring the original anatomy in other. In the remaining 10 patients, the Roux limb was left intact. The remnant stomach was completely mobilized, starting at 6 cm from the pylorus towards the fundus. In patients with gastroesophageal reflux disease (GERD), the hiatal hernia was repaired when identified intra-operatively, with preservation of vagus nerve. The gastric pouch was then anastomosed by hand-sewn suture or with a linear stapler. Initially, we performed the gastro-gastrostomy (GGS) where the stomach was transected during the RYGB. After the first 5 surgeries, we moved the GGS down to the anterior antrum, starting between 4 and 6 cm from the pylorus. A loose sleeve was created by resecting the stomach from the proximal edge of the gastro-gastric anastomosis over a 32 Fr Bougie towards the greater curvature, 6 cm above the pylorus. The duodenum was divided with a white linear stapler which was placed at 3 cm distally to the pylorus with minimal posterior dissection to preserve blood supply. An omega 2 cm duodenoileal hand-sewn or stapled anastomosis was performed at 250 cm in the first 6 patients, and 300 cm in the others. The Petersen space was then closed with the mesentery at right and mesocolon at the left side of the patient with a running non-absorbable suture. No drains were routinely placed. An intraoperative upper endoscopy was performed to assure patency and impermeability of the anastomoses and to detect bleeding and possible ischemic tissues.

Venous thromboembolism prophylaxis

Patients were instructed to wear compression socks 2 hours before hospital admission. Subcutaneous heparin was administered 2 hours after surgery and was kept TID until hospital discharge for all 12 patients. Mobilization was started within 3 hours after conscious recovery. Patients were instructed to use subcutaneous enoxaparin 40 mg once a day for six days after leaving the hospital. After patient 11, protocol changed so that heparin started intraoperatively when surgery lasted longer than 3 hours.

Clinical evaluation

BMI was assessed before SADI-S and every 6 months postoperatively. An update evaluation was added during the conclusion of the study. Blood tests were performed every 6 months and upper endoscopy every 12 months after SADI-S.

Upper endoscopy

Endoscopy was performed after 8 hours of fasting, using a video endoscope (Olympus CV 150, Tokyo, Japan). Reflux esophagitis was described according to Los Angeles classification[23]. Proton pump inhibitor (PPI) was discontinued 7 days before the exams.

Statistical analysis

Quantitative data were presented as mean ± SD or when otherwise stated. Qualitative data were described with absolute and relative numbers. Comparisons of quantitative data were performed using the Student t-test. Analyzes were carried out using GraphPad Prism (version 8.1.1). A p-value lower than 0.05 was considered significant.

3. Results

Twelve patients [11 female (92%), 41 ± 9 years old, 41 ± 3.4 Kg/m^2 – **Table 1**] had a conversion to laparoscopic SADI-S 11 ± 4 years after RYGB. Regained BMI was 9 ± 3.5 Kg/m^2 in this period. After SADI-S patients were followed for 18 months on average, ranging 6 to 38 months.

Initial BMI before RYGB started close to 50 and achieved a 32 Kg/m^2 nadir. Before SADI-S, BMI was 41 and dropped to 32 Kg/m^2 after a mean follow-up of 18 months (70% excess weight reduction), similar to the lowest BMI after RYGB (**Figure 1**). Complications with early readmission occurred in 5 patients (**Table 1**). Two because of minor lung embolism treated with anticoagulation, one for GGS leak

and one for perigastric abscess, both treated with percutaneous drainages. One patient developed hemoperitoneum in the 2nd postoperative day due to hemorrhagic ovarian cyst. There was no conversion to open surgery, no ICU stay, and no death.

Table 1: Demographic data, weight changes and perioperative complications

Case	Age (years)	Sex (female/ male)	Time window (years)	Initial BMI (Kg/m^2)	Nadir BMI after RYGB	BMI before SADI-S*	BMI after SADI-S (follow-up**)	Excess weight loss (%)	Common limb length (cm)	Early complications (< 30 days)
1	38	F	12	56	30	39	22 (38)	119	250	No
2	32	F	6	47	33	37	25 (35)	104	250	Hemoperitoneum#
3	53	F	15	49	32	38	28 (27)	77	250	Abdominal abscess
4	40	F	7	45	32	41	33 (23)	49	250	No
5	53	F	14	46	29	38	22 (19)	120	250	No
6	48	F	16	53	28	45	30 (15)	77	300	No
7	33	F	7	47	30	43	34 (12)	50	300	Gastroparesis
8	38	F	14	49	33	40	33 (10)	47	300	Pulmonary embolism
9	26	F	8	67	40	48	42 (10)	27	300	No
10	40	M	11	53	37	43	30 (9)	73	300	Pulmonary embolism
11	52	F	12	46	32	40	32 (8)	51	300	No
12	36	F	4	50	25	37	32 (6)	43	300	No
Sum/Mean	41	F=11 M= 1	11	51	32	41	30 (18)	70		

*Single-anastomosis duodenoileal bypass with sleeve gastrectomy; **In months; #Hemorrhagic ovarian cyst.

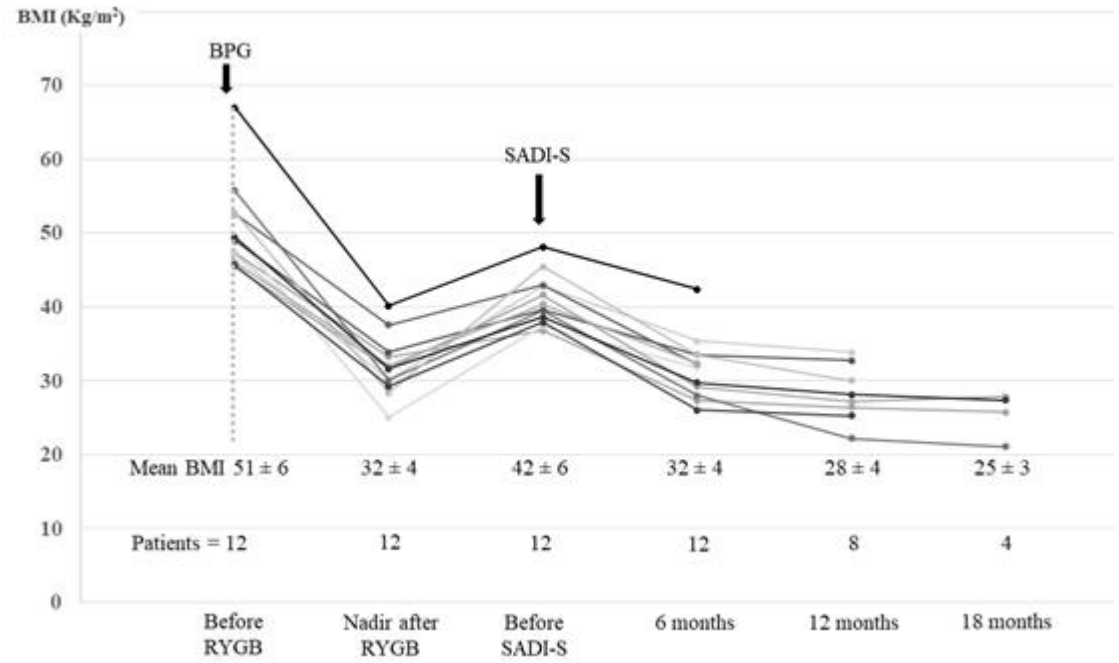

Figure 1: Body mass index (BMI) changes during the follow-up before RYGB (gastric bypass) and after SADI-S (Gastric bypass conversion to single-anastomosis duodenoileal bypass with sleeve gastrectomy) in 12 patients.

Nine patients had a conversion from open RYGB to SADIS-S, and 3 from laparoscopic RYGB (**Table 2**). Surgeries lasted 3 hours and 27 min on average, with a median hospital stay of 2 days (ranging 1 to 5). Hiatal hernia was repaired in two patients. In one patient (patient number 3), the alimentary limb was resected, and in other (patient number 1) the Roux-limb was restored to normal anatomy. Two anastomoses were performed, a gastro-gastric, and a duodeno-ileostomy, which were done either with a linear stapler or hand-sewn fashion way (**Table 2**). The first 5 patients had a GGS done at the gastric remnant lesser curvature, while the remaining 7 patients had the GGS placed in the antrum. Common limb length was 250 cm in the first 5 patients and 300 cm in the last 7 patients.

Table 2: Operative details of RYGBP conversion to laparoscopic SADI-S

Case	RYGB access	Operative time (min)	Hospital stay (days)	Hiatal hernia repair	Gastro gastrostomy details	Common limb Length (cm)
1#	Open	180	1	No	HS##/ LC*	250
2	Open	190	1	No	LS**/ LC	250
3	Open	220	2	No	HS/ LC	250
4	Open	230	2	Yes	HS/ LC	250
5	Open	240	3	No	HS/ LC	250
6	Open	250	3	No	LS/ Antrum	300
7	Laparoscopic	240	5	No	LS/ Antrum	300
8	Open	180	2	Yes	LS/ Antrum	300
9	Open	180	2	No	LS/ Antrum	300
10	Open	220	2	No	LS/ Antrum	300
11	Laparoscopic	180	3	No	LS/ Antrum	300
12	Laparoscopic	180	1	No	LS/ Antrum	300
Sum/Mean	Open = 9 Laparoscopic = 3	207	2.2	2	LC = 5 Antrum = 7	

#Patient with two stages operation: conversion to sleeve and then SADI-S; ##Hand-sewn; *Lesser curvature; **Linear stapler.

Reduction in BMI (%) at 6 months after SADI-S (**Figure 2**) was significantly higher in patients with 250 vs 300 cm, median 30 (IQR 24.4-38.7) vs. 17.5 (IQR 15-24.9) with P=0.012, respectively, while albumin level was higher in patients with 300 compared to 250 cm (4.3 vs. 3.6 g/L; P = 0.048).

Late readmission occurred in 5 patients (**Table 3**). Two of them had GGS stenosis treated by endoscopic dilations. A patient (number 1) was readmitted because of severe diarrhea, and other 2 patients for causes unrelated to SADI-S.

Other late complications included diarrhea, weakness, and severe malnutrition with anasarca (patient number 5). This case needed readmission for enteral feeding. Six patients with heartburn were successfully treated with continuous PPI. Out of two patients who had a hiatal hernia repaired, one had one-year postoperative endoscopy showing grade C reflux esophagitis without symptoms, needing regular treatment with PPIs, while the other had no GERD symptom after 8 months follow-up.

Four of 5 patients with 250 cm common channel had late complications, including severe diarrhea, reflux, or weakness/malnutrition (**Table 3**). Patients with 300 cm common channel had no late complications.

Laboratory data, including hemoglobin, ferritin, albumin, vitamin D and B12, PTH and calcium showed that ferritin increased, and calcium decreased after SADI-S (**Table 4**).

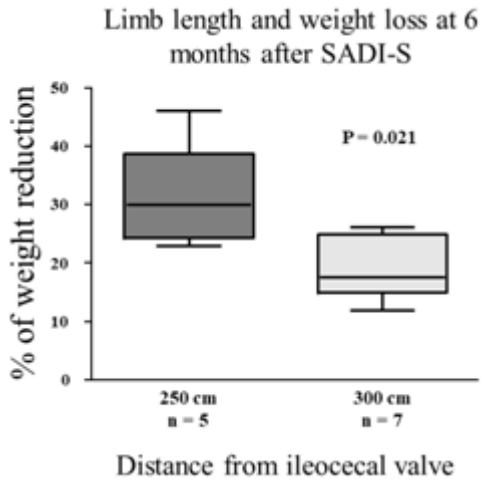

Figure 2: Limb length (250 vs 300 cm) and weight loss

Table 3: Weight loss after SADI-S and late complications

Case	Follow-up in months	Late readmission	GGS* stenosis	Diarrhea (daily episodes)	Reflux esophagitis	On PPI**	Other late complications (> 30 days)
1	38	1	0	2-4	No	No	Weakness/severe diarrhea
2	35	1	1	No	No	No	No
3	27	1	0	No	Grade D##	Yes	Weakness
4	23	0	0	2-3	Grade C†	Yes	No
5	19	2	1	3-6	No	Yes	Anasarca/enteral feeding
6	15	0	0	No	No	Yes	No
7	12	0	0	No	Na#	No	No
8	10	0	0	No	Na†	No	No
9	10	0	0	No	Na	Yes	No
10	9	1	0	No	Na	No	No
11	8	0	0	No	Na	No	No
12	6	0	0	No	Na	Yes	No
Sum/Median	18	6 readmission in 5 patients	2	3 patients	2 out of 6 patients	6 patients	

*Gastrogastrostomy; **Proton pump inhibitors; #Not available; ##Los Angeles classification. †Patients with repaired hiatal hernia.

Table 4: Laboratory changes before and after SADI-S

Case	M*	Hemoglobin		Ferritin		Albumin		Vitamin D		Vitamin B12		PTH		Calcium	
		Before SADI-S ǁ After**													
1	38	13	11.4	112	303	4.1	3.6	30	19	860	408	25	57	11	8.5
2	35	12.9	11.7	6	7	4.2	3.2	24	33	135	487	33	92	#	10.3
3	27	12	12.3	30	85	4	4.1	36	13	353	1500	125	47		9.3
4	23	10	12.1		84	4.4	4.6	29	23	193	303		106	9.8	8.7
5	19	14.3	11.4	9	150	4.4	2.9	17	35	230	352	48	50	9.9	8.3
6	15	11	11.4	10	14	4.4	4.3	20	34	148	533	70	114	9.2	8.3
7	12	10.7	12.1	8	59	4.2	4.4	12	18	340	742	77	81		9.6
8	10	10.2	12.2	58	23		4.2	32	47	182	266	45	47		9.3
9	10	14.3	13.2	42	36	4.3	4.1	12	22	359	519		58	9.7	8.8
10	9	16.4	16.3	59	89	3.9	4.3		32		243		59		
11	8	11.9	12.5	12	140	4.3	4.3		31		2000	93	53		10
12	6	13	12.2	8	16	3.8	4.2	16	35	506	636	56	102		
Median	14	12.4	12.2	12	59	4.2	4.2	22	28	285	503	56	57	9.8	8.9
P##		0.969		0.032		0.609		0.277		0.085		0.342		0.009	

*Months of follow-up; **Laboratory tests after SADI-S were performed in the last month of follow-up; #Empty spaces means not available data; Hemoglobin in g/dl, ferritin and vitamin D in ng/ml, albumin in g/L, vitamin B12 and PTH in pg/ml, calcium in mg/dl; ##Paired t-test for available data.

4. Discussion

Weight regain after gastric bypass is not unusual, and it has been challenging to promote weight loss despite any nonsurgical or surgical procedure[24]. Food urges, excess calorie intake, sedentarism, excessive alcohol consumption, and drug abuse are related to weight regain after bariatric procedures. In our series, before surgical recommendation, patients had a multidisciplinary evaluation that assisted them in quitting alcohol and in adhering nutritional prescriptions at least 6 months before conversion to SADI-S.

Malnourishment counterbalances the satisfactory results of the original duodenal switch in weight loss. Despite promising outcomes have been reported after conversion to duodenal switch[15,16], most surgeons do not perform duodenal switch routinely because of the risk of vitamin and protein deficiencies. SADI-S is a variation of the conventional duodenal switch that appears to provide similar weight loss with improvement in nutritional disorders[25]. However, in this series, RYGB conversion was destined to patients with more severe disease that were refractory to anatomical and metabolic changes caused by the primary operation. Therefore, a more efficient operation is demanded. Indeed, SADI-S was performed as the last available therapy to these patients.

Many endoscopic procedures may help patients with weight regain by fixing surgical abnormalities such as repairing proximal gastric pouch or gastro-jejunal stoma when dilations are identified[26]. However, in these patients, surgical anatomies were adequate. One option to deal with weight regain in patients with normal RYGB anatomy could be RYGB distalization. Although RYGB is predominantly a metabolic/hormonal operation, it causes some restrictions on food intake. Therefore, by shortening the common limb, absorption can be markedly reduced, leading to protein deficiencies. In fact, in a series of 29 patients submitted to a distal RYGB, the authors report 6 cases needing total parenteral nutrition and, because of that, one patient needed to have the common limb enlarged[11]. Fat and carbohydrates absorption may also be partially preserved, promoting unpredictable weight loss[27]. Indeed, selective malnourishment was observed in a patient from our series with restriction due to gastric stenosis causing meat intolerance. This patient developed a severe albumin deficiency leading to anasarca. Since then, we do not hesitate to proceed with early dilation of any anastomotic stenosis and assure adequate protein intake as soon as surgical condition permits.

There were no intraoperative complications in our initial experience with SADI-S. On the other hand, the development of leaks, abscesses, and stenosis after 15 days suggests ischemia of gastric anastomosis as previously reported[28]. We changed the technique by distalizing the anastomosis to the anterior wall of the antrum, followed by no further gastro-gastrostomy complication. We did not observe complications at the duodenoileal anastomosis, which may be explained by the reduced number of procedures. However, it can also be prevented by avoiding posterior dissection from the pancreas, which maintains blood supply.

In these patients, we must also be concerned about GERD.Either heartburn or PPI usage was observed in half of our patients, which are in accordance with preliminary findings reported by others in primary duodenal switch[29]. The conversion to normal anatomy and the newer GGS, with concomitant sleeve gastrectomy, could induce a narrow passage in a non-primary sleeve leading to GERD. As a result, the hiatal hernia repair must be considered.

Our patients lost 70% of excess body weight after 18 months follow-up, which is very similar to that reported in one patient at two years follow-up of conversion from RYGB to SADI-S[30], or in primary SADI-S as well[31]. This pronounced weight loss may be intensified by diarrhea and associated weakness. Indeed, these are the most important late complaints of SADI-S. After case 5, we moved the ileum anastomosis, initially placed at 250 cm, up to 300 cm from the ileocecal valve. We observed an increased weight loss with the shorter compared to the longer common limb length, at the expense of lower albumin levels and diarrhea in some patients with 250 cm. In previous SADI-S descriptions, the rate of malnutrition decreased from 8% to

2% when considering a common channel from 250 to 300 cm. However, specific tailoring should be done in each patient[32]. Fortunately, these patients, except one, have no current nutritional problems.

Although patients had intra and immediate postoperative intermittent venous compression, early hospital discharge, subcutaneous heparin at the end of the operation and walking started 3 hours after the end of the surgery, SADI-S are very complex and prolonged operations, particularly after open RYGB. Our current mean operative time is approximately 4 hours, which may explain the two pulmonary embolisms we observed. Therefore, it seems advisable to consider the immediate use of antithrombotic agents.

We recognize study limitations. This is a retrospective analysis of a small number of patients. Only half of the cases have over 12 months of follow-up. Hence, the purpose of this study is to show preliminary results concerning technical aspects, feasibility, and safety of SADI-S. Although ferritin and calcium levels changed after SADI-S, our limited number of participants and short follow-up precluded conclusions about nutritional impact.

5. Conclusion

We present preliminary data supporting that SADI-S might be an option to provide good weight loss after weight regain following RYGB. However, nutritional, as well as clinical support, is strictly necessary. It seems reasonable to perform the gastro-gastrostomy at the anterior antrum wall, and any stenosis needs to be promptly dilated. The common channel of 300 cm might prevent late complications. Gastroesophageal reflux disease was a common complication. Deep venous thrombosis and pulmonary embolism need special attention. Long term follow-up is awaited.

Disclosure

Conflict of interest: The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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