

# Mid-Term Results and Responsiveness Predictors After Two-Step Single-Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy

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## Abstract

**Background** In patients with insufficient weight loss after sleeve gastrectomy (SG) or in super obese individuals, among many surgical options available, a single-anastomosis duodeno-ileal bypass (SADI) after SG (SADI-S) could be considered. Due to the limited information available about the use of SADI as a second-step procedure, the objective of this study was to evaluate the mid-term results and responsiveness of SADI after sleeve gastrectomy.

**Methods** We present prospective data from 30 consecutive patients with a mean BMI of 40.1 kg/m<sup>2</sup>, a mean excess weight of 44.7 kg, and a mean excess weight loss (EWL) of 37.5%, who were submitted to a SADI as a second-step revisional procedure.

**Results** There were no intraoperative complications. Four early complications (13.34%) occurred within the first

24 postoperative hours. Six, 12, and 24-month follow-up number of patients available was 30 (100%), 22 (73.3%), and 16 (53.34%), respectively. Percent total weight loss (%WL) was 28.1 at the time of revision and 46.26% 24 months after SADI. Global %EWL was 78.93 ± 35.5. The complete remission rate after SG was 50% for diabetes, 33.3% for dyslipidemia, and 25% for hypertension, and 71.4%, 31.2%, and 27.7%, respectively, after SADI. Three (10%) patients required revisional surgery due to hypoalbuminemia.

**Conclusions** SADI as a second-step strategy in super obese patients or after failed SG offers a more than satisfactory ponderal weight loss and an acceptable comorbidities resolution. However, the risk of severe malnutrition after distal SADI-S makes necessary a careful patient selection.

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**Keywords** Obesity · Sleeve gastrectomy · Duodeno-ileal bypass · Weight loss · SADI-S

## Introduction

Sleeve gastrectomy (SG) provides excellent mid- and long-term results for both weight loss and comorbidity as a stand-alone procedure for the vast majority of morbidly obese patients [1]. However, long-term results indicate that up to 64 and 70% of patient present insufficient weight loss and weight regain, respectively, despite proper preoperative management and selection [2]. Moreover, SG is often performed in high-risk [3, 4], extreme age [5, 6] patients, or it is included in a two-step sequential strategies in super obese individuals [7]. Despite the fact that there is no conclusive data in the literature to support them in terms of perioperative risk and long-term outcomes, two-step malabsorptive procedures can be considered for both, insufficient weight loss after SG and super obesity, in the absence of anatomical disturbances or compliance issues. They provide not only optimal weight loss but also less perioperative risk, giving the chance of selecting those patients with better outcome in order to avoid unnecessary procedures [8]. Despite the fact that two-step duodenal switch (DS) has been considered a solid and effective alternative, other biliopancreatic diversion procedures (BPDs), such as single-anastomosis duodeno-ileal bypass after SG (SADI-S), have been proposed [9, 10].

Although one-step short- and mid-term SADI-S results are well known [11], its results as a secondary procedure after failed SG or as a sequential procedure in super obese patients remain scarce [12]. Moreover, the impact of each surgical step in the final clinical outcome has not been evaluated yet, and there are not clinical indicators of which patient could present a better responsiveness to the malabsorptive step after SG.

Hence, our main aims were to evaluate the mid-term results of this two-step surgical approach, to analyze the impact of each step separately, and to identify those factors that could be related to worse weight loss.

## Patients and Methods

Between 2010 and 2014, 406 SG were performed, 172 (42.3%) of them as a first step in super obese (SO) patients. Thirty patients (8 male, 22 female) underwent SADI as a second-step revisional procedure from February 2012 to September 2015. Indication for SADI was based upon one or more of these three criteria after, at least, 12-month follow-up: %EWL < 50, post-SG BMI >35 kg/m<sup>2</sup>, or weight regain. Twenty-eight patients were submitted to SADI as a planned two-stage from the start. In the remaining two SADI patients, in which their initial BMI was <50 kg/m<sup>2</sup>, SG was

performed as a standard-alone procedure and showed weight regain during follow-up in the absence of any anatomical alteration (i.e., dilatation).

The mean time between SG and SADI was 30.27 months (13–84). The mean age of SADI patients was 47.83 years (30–59). Prior to first-step procedure, mean initial weight was 132.4 kg (90–189), mean body mass index (BMI) was 51.9 kg/m<sup>2</sup> (38.5–71), and mean of excess of weight was 76 kg (33–98). When SADI was performed, the mean weight was 104.4 kg (82–139), the mean BMI was 40.1 (35–51), with a mean excess of weight of 44.7 kg (24–91), and a mean excess weight loss of 37.5% (–5.2–59.4).

## Surgical Technique

A standard laparoscopic SG was performed in all patients as a primary procedure. Gastric section was initiated 5 cm proximal to the pylorus employing a 32-French bougie as calibrator and a 2/0 polypropylene running suture as staple-line reinforcement. When laparoscopic duodeno-ileal bypass was performed (two were robotically assisted), patients were in supine position with the surgeon standing between patient's legs. After pylorus was identified, the inferior side of the antrum was dissected and retracted upwards until the gastroduodenal artery was identified. Dissection progressed through the first 4 cm of the duodenum preserving the right gastric artery. The duodenum was then transected with a 60-mm blue cartridge linear stapler (Echelon Flex®, Ethicon Endo Surgery Inc., Cincinnati, OH, USA). After identification of ileocecal junction, ileum was measured proximally up to 200 ( $n = 2$ ), 250 ( $n = 17$ ), or 300 ( $n = 11$ ) cm and ascended antecolically. Isoperistaltic terminal-lateral duodeno-ileal anastomosis was performed with manual two-layer running suture.

## Statistical Analysis

A descriptive analysis has been carried out at basal level and at 6, 12, 18, and 24 months after surgery. Frequency and percentages have been calculated for qualitative variables and mean, median, and interquartile range, for quantitative variables. To test variations in trend, Skillings-Mack test has been performed. Weight box-plots have been used to describe evolution along time. Final (*after SG and SADI*) BMI under 35 kg/m<sup>2</sup> and >50%EWS were the criteria employed to identify those individuals with an optimal response to surgery (SG, SADI, or both). Relation of response has been analyzed by means of chi-square (exact Fisher's tests) test for qualitative and Kruskal-Wallis/Mann-Whitney or *t* test/ANOVA for quantitative variables. A 95% confidence level was considered significant. All analysis has been done using STATA 13.1.

The study protocol was approved by our Institution's Ethics Committee. Accordingly, all clinical and demographical data

were prospectively collected in an encrypted database after obtaining informed consent from all patients.

## Results

The mean operative time was 123 min (55–160), and no intraoperative complications were observed. There was not perioperative mortality. However, four (13.3%) patients suffered from the following early postoperative complications: pulmonary atelectasis (1), rectus muscle sheath hematoma (1), successfully managed by percutaneous embolization, and two anastomotic leaks reoperated within the first 24 postoperative hours. In both patients, early resuture of anastomotic defect was effective, and they were discharged with no further complications. The mean postoperative stay was 3.46 days (2–23).

During the first three postoperative weeks, all patients received hypocaloric/hyperproteic diet before solid alimentation was progressively introduced. Vitamin B<sub>12</sub> (1000 µg monthly; Optovite®; Normon), multivitamin complex (90 mg daily; Supradyn®; Bayern), and vitamin D<sub>3</sub> (15.960 UI/2 weeks; Hidroferol®; Faes-Farma) were initially prescribed to every patient. During follow-up, iron, vitamin A, vitamin E, folic acid, or lipase supplementations were prescribed based upon both clinical and analytical findings.

Patients were evaluated every 3 months after surgery during the first year and every 6 months during the second and third year. The median follow-up time was 22 months (9–36). Six, 12, and 24-month follow-up number of patients available was 30 (100%), 22 (73.3%), and 16 (53.34%), respectively. Table 1 shows postoperative ponderal evolution. Mean global post-SG + SADI %EWL was 63.37 ± 17.11, 73.1 ± 22.45, and 78.93 ± 35.5 at 6, 12, and 24 after surgery. The mean BMI after second-step surgery was 33.2 ± 4.9, 31.46 ± 7.12, and 28.64 ± 5.58 after 6, 12, and 24 months, respectively. When postoperative weight loss trends after SG and SADI were compared as separated operations (Fig. 1), significant differences between both procedures were found. Weight loss after SADI not only reaches its nadir later than SG (19 vs.

12 months) but also shows a sharper decrease that persists significantly longer (*p* value for interaction test = 0.002).

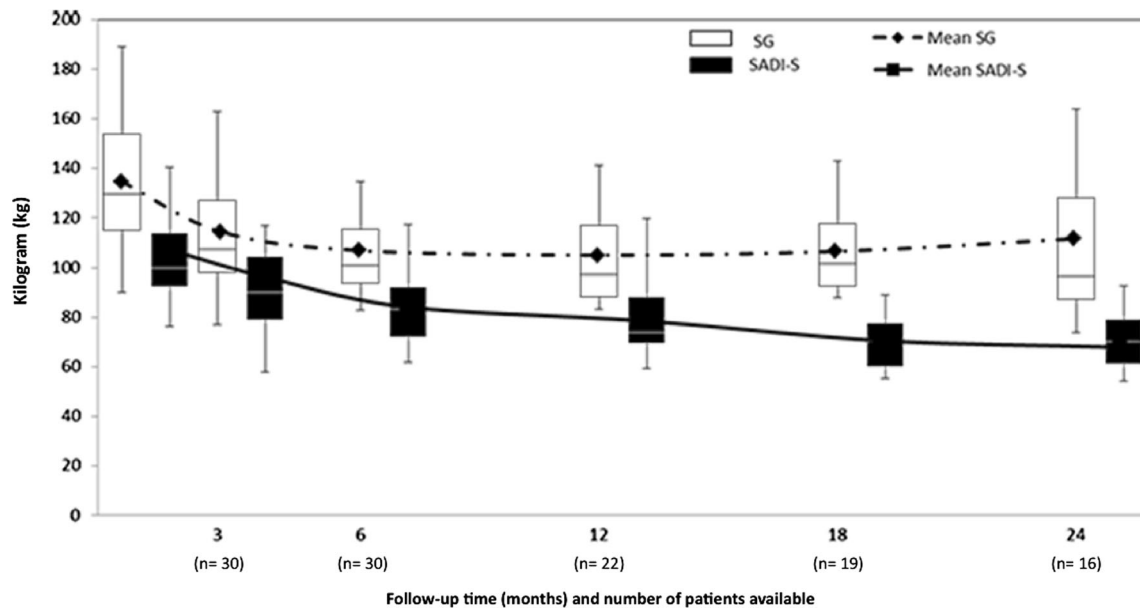
After univariate analysis, no consistent relationship between gender, time between procedures or previous comorbidities, and weight loss was found. As expected, a common channel length shorter than 250 cm was correlated with higher global %EWL after SADI and SG + SADI. Although initial weight was not correlated with a different ponderal evolution, patients with higher initial BMI presented worse BMI loss results after SG and lower %EWL rates. Nevertheless, no relationship between %EWL after SG, SADI, or SADI-S evolution was found. Finally, younger patients (39.18 ± 6.7 vs. 53.4 ± 6.9 years) showed higher %EWL after SG and SADI-S.

During follow-up, three patients developed severe hypoalbuminemia that required prolonged total parenteral nutrition. Their anastomosis was redone at 150 cm from the angle of Treitz and subsequently converted to single-anastomosis duodeno-jejunal bypass. Two of these SADI anastomoses were performed at 200 cm from the ileocecal valve, and the other one was initially performed at 250 cm. However, during revisional surgery, it was observed that duodeno-ileostomy was at 175 cm from the ileocecal valve. Other late complications were pneumonia (1), acute hepatitis (1), severe iron-deficiency anemia (7), and dumping (3). Dumping diagnosis was clinical and based on a Sigstad's score > 7 and was successfully managed with dietary modifications. The mean number of daily bowel movements was 4.2 (2–9), and four (13.3%) patients presented severe steatorrhea that required pancreatic enzyme supplementation. Table 2 resumes analytical data at 12 and 24 months after SG and SADI, and Table 3 summarizes oral supplements taken after SG and during post-SADI follow-up. No other late postoperative complications were observed. Before SG, 14 patients were diabetic (46.7%; 50% received insulin therapy), 18 had hypertension (60%), and 16 suffered dyslipidemia (53%). Complete remission rate (*revised ADA criteria for DM2 and absence of treatment for hypertension and dyslipidemia*) after gastrectomy was 50, 33.3, and 25%, respectively. After SADI, five (71.4%) patients showed complete remission of DM2, all patients presented normal blood glucose, and glycated hemoglobin levels and two received a daily dose of metformin.

**Table 1** Postoperative ponderal evolution

	12 months after SG (n = 30)	Reoperation (n = 30)	6 months after SADI (n = 30; 100%)	12 months after SADI (n = 22; 73.34%)	24 months after SADI (n = 16; 53.34%)
Total weight loss(kg)	28.2 (7.94)	28.06 (8.45)	45.31 (10.74)	49.72 (16.72)	53.16 (12.3)
% Total weight loss	23.12 (6.83)	21.16 (7.42)	36.1 (12.2)	41.15 (11.7)	46.26 (13.2)
Global %EWL	39.62 (14.02)	37.25 (18.02)	63.57 (17.11)	73.1 (22.45)	78.93 (35.50)
%EWL after SADI	N/A	N/A	45.49 (20.94)	60.87 (23.85)	44.25 (34.97)
BMI (kg/m <sup>2</sup> )	N/A	N/A	33.20 (4.98)	31.46 (7.12)	28.64 (5.58)
%EBMIL	43.05 (23.78)	N/A	28.37 (15.88)	36.16 (18.54)	49.72 (19.90)

<sup>a</sup> Results are expressed as mean ± SD



**Fig. 1** Weight evolution after SG and SADI-S

However, 24 months after SADI, two patients had elevated insulin and HOMA index values without clinical consequences. Dyslipidemia remitted in five (31.2%) patients and improved in four (25%). Hypertension complete remission and improvement rates were 27.7 and 22.2%, respectively.

## Discussion

Our work describes mid-term results after SADI in both failed SG and two-step strategy super obese patients. To our knowledge, this is the largest series reporting clinical data from patients following a second-step procedure after SG. Our experience indicates that it is possible to obtain an optimal weight loss during the first 24 months, with a relative %EWL from SG to SG + SADI of 44% and a 79% of global EWL. These results are comparable to those previously reported employing SADI as a second-step operation [12] and are obtained in a cohort of 64% patients with an initial BMI superior to 50 kg/m<sup>2</sup>. Although there is no consensus about which technique should be performed after SG as a second-step procedure, BPD, Roux-en-Y Gastric Bypass (RYGBP), and re-sleeve are commonly considered. Our weight loss results are comparable, or slightly better, to those obtained 1 and 2 years after re-sleeve (57 and 44%EWL, respectively) or RYGBP (61 and 48%EWL, respectively) [13, 14]. In addition, similar outcomes (55%EWL after 12 months) have been reported when RYGBP is performed in super obese patients in a two-step strategy [15], or when indicated in poor comorbidity control, or even in severe gastroesophageal reflux (61.7%EWL after 16 months) [16]. Moreover, when BPD-DS is performed as a two-step procedure after SG, mid-term results are also superior to those obtained after RYGBP (80 vs. 65.5%EWL) but comparable to two-step

SADI-S's (72%EWL) [17, 12]. These results are quite positive, especially taking into account that our series includes both super obese and SG failed patients that could be considered as poor responders to bariatric surgery. This particular observation could explain better results observed when SADI-S is performed as a single-stage procedure [11].

SADI was initially proposed as simpler procedure due to its lower perioperative complication rates and to its hypothetically favorable impact on nutritional status [9, 11]. Nevertheless, complications like anastomotic leaks, occurred in the first 10 cases and within the first 24 h, should also be considered as technical and taken into account, especially during the learning curve process.

The main concern about adding a malabsorptive technique after SG is achieving an acceptable weight loss without provoking denutrition. In our series, there is a relationship between efferent loop length and risk of malnutrition. Indeed, based in our results, if the duodeno-ileostomy is performed closer than 250 cm to the ileocecal valve, the high risk of hypoalbuminemia and vitamin and/or micronutrients deficiency should be taken into account before indicating any malabsorptive procedure. However, due to our small sample size, these results should be taken into account very carefully, especially when no data on single-stage SADI-S are included. When SADI was performed, specific common channel measures were selected based basically in two criteria: clinical observation of the initial nutritional status of our own patients and sequential technical modifications introduced by the group that described the procedure after mid-term results analysis (10, 11). Therefore, although in our series relationship between common channel length and nutritional disturbances could seem to be clear, there is a number of factor that could have influenced that observation.

**Table 2** Analytical values 12 months after SG and 24 months after SADI

	Normal values	Post-sleeve gastrectomy ( <i>n</i> = 30)			12 months after SADI ( <i>n</i> = 22)			24 months after SADI ( <i>n</i> = 16)			<i>P</i> value
		Mean(SD)	Range	% Abnormal	Mean(SD)	Range	% Abnormal	Mean(SD)	Range	% Abnormal	
		Glucose (mg/dl)	74–110	101.27 (41.34)	1.99;196	26.67%	85.00 (11.52)	65.00;109	10.00%	85.15 (8.23)	
Insulin (mU/L)	3–25	13.87 (9.47)	1.20;37.2	18.18%	7.83 (3.64)	1.94;12.59	8.33%	11.88 (15.45)	2.50;49.11	25.00%	–
HbA1c (%)	4.7–6.4	6.33 (1.60)	4.80;10.4	33.33%	5.07 (0.50)	4.20;5.6	23.08%	4.92 (0.53)	4.00;5.7	27.27%	0.0970
C_Peptide(ng/mL)	0.81–3.85	1.97 (0.79)	0.93;3.45	0.00%	1.32 (0.42)	0.77;1.93	9.09%	1.25 (0.92)	0.73;3.33	25.00%	–
Homa index	2.6	4.03 (4.79)	0.22;18	36.36%	1.64 (0.78)	0.33;3.14	91.67%	2.51 (3.32)	0.62;10.55	87.50%	–
Proteins (g/dL)	6.6–8.3	6.98 (0.48)	6.05;7.87	27.59%	6.37 (0.71)	4.20;7.6	70.00%	6.11 (1.16)	3.40;7.19	58.33%	0.0169
Albumin (g/dL)	3.5–5.2	4.09 (0.36)	2.94;4.63	6.67%	3.71 (0.55)	2.22;4.5	21.05%	3.69 (0.66)	2.19;4.3	23.08%	0.0592
Cholesterol (mg/dL)	132–240	211.52 (46.64)	127.00;341	27.59%	146.15 (28.03)	98.00;195	35.00%	141.67 (41.89)	82.00;211	41.67%	0.1289
HDL (mg/dL)	40–100	51.11 (9.66)	33.40;75	10.34%	41.47 (7.34)	31.70;59	42.11%	47.04 (10.77)	32.70;62	33.33%	0.1434
LDL (mg/dL)	0–130	131.86 (36.17)	72.20;204.1	48.28%	84.21 (26.55)	47.30;129.8	0.00%	77.08 (32.10)	34.10;132.4	8.33%	0.2381
Triglycerides (mg/dL)	43–200	142.10 (92.98)	34.00;544	17.24%	96.63 (39.56)	46.00;172	0.00%	87.67 (43.42)	44.00;184	0.00%	0.1552
Hemoglobin (g/dL)	13.1–16.3	13.82 (1.62)	10.30;18.3	40.00%	13.04 (1.54)	10.70;16	50.00%	12.67 (2.01)	8.70;17.1	69.23%	0.0247
Iron (µg/dL)	50–150	87.41 (30.61)	41.00;173	6.90%	65.58 (24.86)	33.00;143	21.05%	70.08 (25.25)	14.00;100	8.33%	0.1744
Ferritin(ng/mL)	25–400	95.45 (149.09)	17.00;720	27.59%	156.47 (209.79)	4.00;878	31.58%	102.58 (121.61)	18.00;428	41.67%	0.0239
Vitamin B <sub>12</sub> (pg/mL)	211–911	612.83 (291.91)	267.00;1414	6.90%	837.16 (338.69)	460.00;1858	31.58%	679.00 (512.01)	111.00;1967	33.33%	0.0928
Folic acid (ng/mL)	3.4–24	5.60 (1.95)	3.00;10.9	13.79%	5.39 (3.29)	1.30;14.6	23.53%	6.13 (4.57)	2.80;15.5	18.18%	0.1854
Calcium (mg/dL)	8.8–10.6	9.26 (0.32)	8.70;10	10.34%	8.93 (0.54)	8.10;10	36.84%	8.81 (0.54)	7.90;9.8	45.45%	0.0254
Parathormone (pg/mL)	14.5–87.1	68.43 (25.85)	33.20;133	27.59%	91.18 (45.11)	38.80;217	44.44%	137.79 (152.24)	23.10;594	66.67%	0.1824
Vitamin D (ng/mL)	30–200	30.06 (28.84)	7.00;115	75.86%	21.88 (21.63)	7.30;100	82.35%	37.81 (39.69)	8.20;122	55.56%	0.0823
Zinc (µ/dL)	50–150	73.74 (12.45)	45.00;100.1	3.45%	48.58 (10.46)	31.00;67.8	53.33%	57.39 (10.50)	46.60;77	40.00%	0.4518

**Table 3** Oral supplementation after sleeve gastrectomy and SADI

Supplements	After sleeve gastrectomy ( <i>n</i> = 30)	After SADI 200 cm ( <i>n</i> = 2)	After SADI 250 cm ( <i>n</i> = 17)	After SADI 300 cm ( <i>n</i> = 11)
Vitamin B <sub>12</sub>	80%	100%	100%	100%
Vitamin D <sub>3</sub>	73%	100%	70%	36%
Calcium	56%	100%	88%	36%
Iron (oral)	3%	50%	64%	18%
Iron (parenteral)	0%	50%	29%	0%
Folic acid	3%	50%	58%	27%
Thiamine	3%	50%	17%	9%
Vitamin A	0%	50%	23%	9%
Vitamin E	0%	50%	6%	9%
Pancreatic lipase	0%	50%	18%	9%
Multivitamins	60%	100%	100%	100%

In contrast with previously reported results with SADI after SG, our global nutritional deficiency rate was considerably high [12]. However, it has to be taken into account that initially prescribed supplementation (especially Vitamin D) could be considered as lower than recommended after BPD-DS [18, 19]. Nevertheless, no severe nutritional abnormalities were observed if a 300-cm common channel was created. Therefore, patient selection and meticulous bowel length measurement must be warranted, since a 20% error can occur. Our patient selection after the first step SG was designed to perform SADI in those compliant patients that showed <50%EWL and/or >35 residual BMI. Therefore, there could be a selection bias in terms that the most compliant patients could be more predisposed to suffer malabsorption side effects. However, in our series, those four patients that developed malnutrition did not show any distinctive feature in terms of compliance.

Both ponderal and nutritional results after 300-cm SADI-S could be compared to those observed after duodeno-jejunal bypass with sleeve gastrectomy (DJB-SG). Interestingly, 12 months after, DJB-SG reported EWL was near to 80% and total weight loss near to 33%, which were better than those observed with RYGBP or mini-gastric bypass (MGBP). Moreover, nutritional status after DJB-SG was comparable to RYGBP [20]. Nevertheless, results of DJB as a second-step procedure after SG remain scant.

In our series, impact of SADI on type 2 diabetes resolution rates was satisfactory and similar to that observed after one-step SADI-S [10]; final metabolic outcomes after SG + SADI were acceptable; however, less hypertension and dyslipidemia improvement was observed compared with results achieved after SG in our own series or previously described after DS [19, 21]. After SG + SADI, only two patients did not show complete remission of type-2 diabetes. Both patients were receiving both insulin and oral antidiabetic drugs, and the duration of their diabetes prior to SG was 132 and 276 months. Hence, these two particular circumstances could have been influential

enough in the final outcome. Moreover, all the patients with hypertension and dyslipidemia with poor response to SG and/or second-step SADI were receiving more than two different drugs before the first-stage procedure was performed.

Differences in weight loss trend between SG and SADI were found: after SADI, a sharper weight loss slope was observed, and nadir was reached at 18 months after diversion even in patients with unsatisfactory results after SG. Hence, in our experience, SADI after SG contributes to improve ponderal results even in theoretically poor weight loss responders. Moreover, we tried to identify those patients in which the second-step SADI could be more beneficial, and aside from common channel length, our data suggests that a better weight loss after SG + SADI could be observed in younger patients, especially if weight loss after SG was optimal. Therefore, taking into account the risk of malabsorptive disturbances and those proposed responsiveness marker indication of SADI after SD should be made cautiously.

As a main limitation of our study, it has to be mentioned that these results show our clinical outcome within the very first 30 patients that underwent SADI as a second-stage procedure. Therefore, they include our learning curve and a substantial variation in the common channel length that could have influenced the clinical outcome. Other important limitations are the observational nature of the study, small sample size, and length of follow-up. Long-term follow-up is required to determine if results are maintained and complications do not damage weight loss results. Moreover, comparison with other techniques is necessary to draw conclusions.

## Conclusions

SADI after SG, either as a secondary procedure after failed SG or as a sequential procedure in super obese patients, offers a satisfactory weight loss and an acceptable control of

comorbidities. However, taking into account the impact on nutrition and better results in younger patients, carefully patient selection, accurate common channel measurement, and meticulous follow-up must be warranted.

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**Compliance with Ethical Standards** The study protocol was approved by our Institution's Ethics Committee. Accordingly, all clinical and demographical data were prospectively collected in an encrypted database after obtaining informed consent from all patients.

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