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ORIGINAL CONTRIBUTIONS

Revisional Laparoscopic SADI-S vs. Duodenal Switch Following Failed Primary Sleeve Gastrectomy: a Single-Center Comparison of 101 Consecutive Cases

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Abstract

Background Single-anastomosis duodeno-ileal bypass (SADI-S) is being proposed for obese patients with insufficient weight loss or weight regain after sleeve gastrectomy (SG), but limited information is available. The purpose of this study is to assess the safety and efficacy of SADI-S as a revisional surgery after SG, compared with standard duodenal switch (DS).

Methods Unicentric cohort study including all patients submitted to SADI-S and DS after failed SG in a high-volume institution, between 2008 and 2020.

Results Forty-six patients submitted to SADI-S and 55 to DS were included, 37.2 and 41.5 months after SG (p = 0.447), with initial BMI of 56.2 vs. 56.6 (p = 0.777) and 39.2 vs. 39.7 before revisional surgery (p = 0.675). All surgeries were laparoscopic. Clavien-Dindo > II complication rate was 6.5% for SADI-S and 10.9% for DS (p = 0.095), with no 90-day mortality. Follow-up at 2 years was available for 38 SADI-S' and 38 DS' patients, with total weight loss of 35.3% vs. 41.7% (p = 0.009), and excess weight loss 64.1% vs. 75.3% (p = 0.014). Comorbidities resolution for SADI-S and DS was: 44.4% vs. 76.9% for diabetes (p = 0.029) and 36.4% vs. 87.5% for hypertension (p = 0.006); with no differences for resolution of dyslipidemia (72.7% vs. 88.9%, p = 0.369) and obstructive sleep apnea (93.3% vs. 91.7%, p = 0.869). DS' patients required more extra nutritional supplementation. Three SADI-S patients needed conversion to DS, two for biliary reflux and one for weight regain.

Conclusion After a failed SG, revisional DS permits better weight control and diabetes and hypertension resolution than SADI-S, at the expense of higher supplementation needs.

Keywords Obesity · Revisional surgery · Weight regain · Duodenal switch · Duodeno-ileal bypass · SADI-S

Introduction

Although sleeve gastrectomy (SG) was initially conceived as a part of duodenal switch (DS), its simplicity and short-term good results have increased its popularity as a stand-alone bariatric surgery [1, 2]. However, approximately 50% of patients submitted to SG will present insufficient weight loss or weight regain in the long term, despite proper selection and perioperative management [3–5]. With the large number of SG being performed, bariatric surgeons face the challenge of an increasing number of patients requiring conversion into a more efficient procedure in the long term [4, 6, 7]. DS is the most effective revisional bariatric procedure following a failed SG, but many surgeons are concerned about its complex surgical technique and risk of postoperative complications [8, 9].

Key Points
- Duodenal switch is more effective than SADI-S after a failed sleeve gastrectomy.
- Both revisional procedures are safe in experienced hands.
- Duodenal switch is associated to more extra supplementation needs.

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The single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) was conceived as simplification of DS, intended to decrease its operating time and postoperative risks, while maintaining its principles and efficacy [10–12]. Although short- and mid-term results of primary SADI-S are known, information about its efficacy as a revisional procedure after failed SG remains scarce, limited to a few non-comparative cohort studies [13–15].

The purpose of this study is to compare the safety and efficacy of SADI-S and DS, as second-step surgeries after failed SG.

Material and Methods

Study Design and Patients

Cohort study includes all patients undergoing revisional DS and SADI-S due to SG failure in a high-volume center from May 2008 to December 2020. SG failure was considered when excess weight loss was < 50%, BMI remained stable ≥ 35 kg/m^2, and/or control of obesity-related comorbidities was not satisfactory. Revisional surgery was indicated on individualized basis in a multidisciplinary committee integrated by endocrinologists, nutritionists, psychologists, pneumologists, and surgeons. Since our initial experience with SADI-S in 2014, there were no different indication criteria for DS and SADI-S. Patients were informed about the various revisional options at an educational seminar. Then, they had a visit with the surgeon, with whom risks and potential benefits were discussed before they signed specific informed consent.

Preoperative Care Circuit

Prior to revisional surgery, patients were visited by each member of the team, and the anesthesiologist. Education seminars were done including dietary, psychological, and physical counseling support. Two weeks before surgery, they followed a high-protein liquid diet for extra weight loss.

Surgical Technique

Surgical team was composed by one proctor and one senior surgeon who performed procedures alternatively, aided by a resident. Primary SG was performed over a 42 Fr Bougie. DS and SADI-S included ligation of the right gastric artery, and hand-sewn duodeno-ileal anastomosis. Limbs were measured from the left side of the patient upwards from the ileo-caecal junction clapping the bowel with marked graspers every 5 cm. DS' common and alimentary limb lengths were 100 and 200 cm, while SADI-S' common limb length was 300 cm. Mesenteric and Petersen defects were systematically closed with a non-absorbable running suture, and a drain was placed in the duodenal stump [16].

Follow-Up

During hospitalization, patient education was reinforced by a nutritionist. After discharge, patients were followed at outpatient by surgeon, endocrinologists, and nutritionist for at least 6 years. Follow-up included at least two blood tests during the first year and then yearly, or more often if needed, in order to detect possible nutritional, vitamin, and micronutrient deficiencies. Whole nutritional supplementation included a multivitamin treatment with extra doses of vitamin D, calcium, and proteins.

Data Source and Study Outcomes

Data were obtained from a prospectively maintained database including sex, age, weight and BMI, obesity-related metabolic comorbidities, surgical approach, 30-day complications (type and Calvien-Dindo severity score), 90-day mortality, weight evolution after surgery at 3 and 6 months, 1 year, and then yearly, as well as comorbidity resolution, need of extra supplementation, and need for further revisional surgeries. Primary outcome was weight loss, expressed as a percentage of total weight loss (TWL) and excess weight lost (EWL) at 2 and 5 years. EWL was calculated taking as reference an ideal BMI of 25 kg/m^2. Secondary outcomes were postoperative complications; 90-day mortality; remission rates for type 2 diabetes, hypertension, dyslipidemia, and obstructive sleep apnea (OSA), and need of extra supplementation aside from the routinely given to treat nutritional deficiencies. Remission of diabetes was defined as maintenance of HbA1c below 6% without anti-diabetic medications; for the rest of comorbidities, as complete withdrawal of all specific treatment by the physician.

Statistical Analysis

Continuous variables were expressed as mean ± standard deviation. Differences between techniques were evaluated using parametric tests (χ^2 for categorical and t-Student test for continuous variables). No hypothesis testing was done, and therefore, no sample size calculated, as recommended in http://nature.com/articles/d41586-019-00857-9 for cohort comparative studies. Statistics were analyzed with IBM-SPSS Statistics Version 20 computer software. A p value < 0.05 was considered significant.

Results

There were 101 patients qualifying for the study, of whom 55 underwent conversion from SG to DS (54.5%) from April 2008 to November 2020, and 46 to SADI-S (45.5%) from May 2015 to March 2020.

Baseline Characteristics

Table 1 shows demographic and clinical data of the study population, comparing DS' and SADI-S' patients. Gender, age, initial BMI (56.6 vs. 56.2 kg/m^2), and BMI before revisional surgery (39.8 vs. 39.2 kg/m^2) were similar in both groups. No differences were found in percentages of obesity-related comorbidities, both before SG and second procedure. Time between SG and revisional DS and SADI-S was 41.5 and 37.2 months (p = 0.447).

Weight Loss Changes

Thirty-eight patients in each group were followed at 2 years of revisional surgery, and 26 DS and 11 SADI-S patients at 5 years. Table 1 presents antropometric changes at 2 years of DS and SADI-S: mean BMI was 32.5 vs. 35.8 kg/m^2 (p = 0.002); patients with BMI < 35 kg/m^2 were 76.9% vs. 44.7% (p = 0.025). Evolution of %TWL and %EWL are shown in Figs. 1 and 2: compared with DS, SADI-S patients presented a significant weight regain beginning in the second post-operative year (difference +11.2% EWL), and more evident at 5 years (difference +12.9% EWL). One SADI-S patient was converted to DS due to weight regain.

Evolution of Obesity-Related Comorbidities

Table 1 shows comorbidities' proportions prior to SG, before second intervention, and 2 years after. DS achieved higher remission rate of diabetes (76.9% vs. 44.4%, p = 0.029) and arterial hypertension (87.5% vs. 36.4%, p = 0.006) than SADI-S. There were no significant differences in dyslipidemia and OSA resolutions.

Complications and Side Effects

All primary and revisional interventions were done by laparoscopy, without any conversion to laparotomy or intraoperative complications. Table 2 summarizes short- and long-term postoperative complications and

Table 1 Patients' basal and evolutive characteristics

Variable		Basal (pre-sleeve)			Pre-revisional surgery			2 years after revisional surgery		
		DS n = 55	SADI-S n = 46	p	DS n = 55	SADI-S n = 46	p	DS n = 38	SADI-S n = 38	p
Age (years) m ± SD		44.9 ± 11.5	45.3 ± 10.6	0.871	48.4 ± 11.9	48.4 ± 11.3	0.999	50.5 ± 11.5	50.2 ± 11.3	0.999
Time from sleeve gastrectomy (months) m ± SD					41.5 ± 30.1	37.2 ± 26.1	0.447			
Sex n (%)	Male	18 (32.7)	13 (28.3)	0.564						
	Female	36 (65.5)	33 (71.7)							
Height (meters) m ± SD		1.66 ± 0.11	1.64 ± 0.10	0.344						
Weight (kg) m ± SD		155.96 ± 31.1	150.98 ± 28.8	0.344	108.06 ± 16.4	105.72 ± 19.6	0.573	87.80 ± 13.4	96.43 ± 16.6	0.015
BMI (kg/m^2) m ± SD		56.64 ± 8.5	56.15 ± 8.5	0.777	39.75 ± 4.4	39.20 ± 6.2	0.594	32.52 ± 4.1	35.83 ± 4.8	0.002
BMI < 35 kg/m^2 n (%)		0	0	-	9 (16.4)	9 (16.9)	0.675	26 (76.9)	17 (44.7)	0.025
BMI < 30 kg/m^2 n (%)		0	0	-	0	0	-	16 (43.2)	5 (13.5)	0.005
Type 2 DM n (%)	Present	21 (38.2)	17 (37.2)	0.899	19 (34.5)	11 (23.9)	0.244	3 (7.9)	4 (10.8)	0.664
	Resolved				2/21 (9.5)	6/17 (35.3)	0.053	10/13 (76.9)	4/9 (44.4)	0.029
HT n (%)	Present	25 (45.4)	18 (39.1)	0.522	21 (38.2)	15 (32.6)	0.560	2 (5.3)	7 (18.9)	0.062
	Resolved				4/25 (16)	3/18 (16.7)	0.953	14/16 (87.5)	4/11 (36.4)	0.006
DL n (%)	Present	13 (23.6)	17 (37.0)	0.145	13 (23.6)	13 (28.3)	0.597	1 (2.6)	3 (8.1)	0.291
	Resolved				0/13 (0)	4/17 (23.5)	0.060	8/9 (88.9)	8/11 (72.7)	0.369
OSA n (%)	Present	28 (50.9)	17(37.0)	0.221	19 (34.5)	17 (37.0)	0.801	1 (2.6)	1 (2.6)	0.985
	Resolved				9/28(32.1)	12/29(41.4)	0.470	11/12(91.7)	14/15 (93.3)	0.869

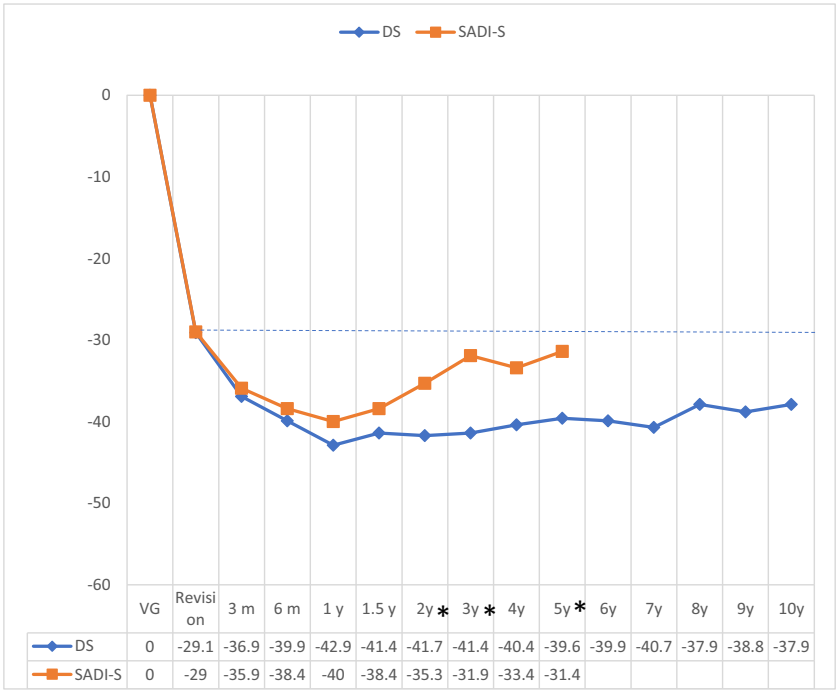

Fig. 1 Total weight loss evolution. *p < 0.05

* p < 0,05

requirement of nutritional supplementations aside from standard treatment. In the whole cohort, 18 subjects presented some type of short-term complication (17.8%), most of them staged as Clavien-Dindo I and II. Compared to SADI-S, DS was associated to a non-significantly higher percentage of complications (20% vs. 10.9%) and severe complications (10.9% vs. 6.5%). Hemoperitoneum was the most frequent, occurring in 3 DS cases (5.6%). There was one duodenal stump leak and one abdominal abscess in the DS group. Hospital

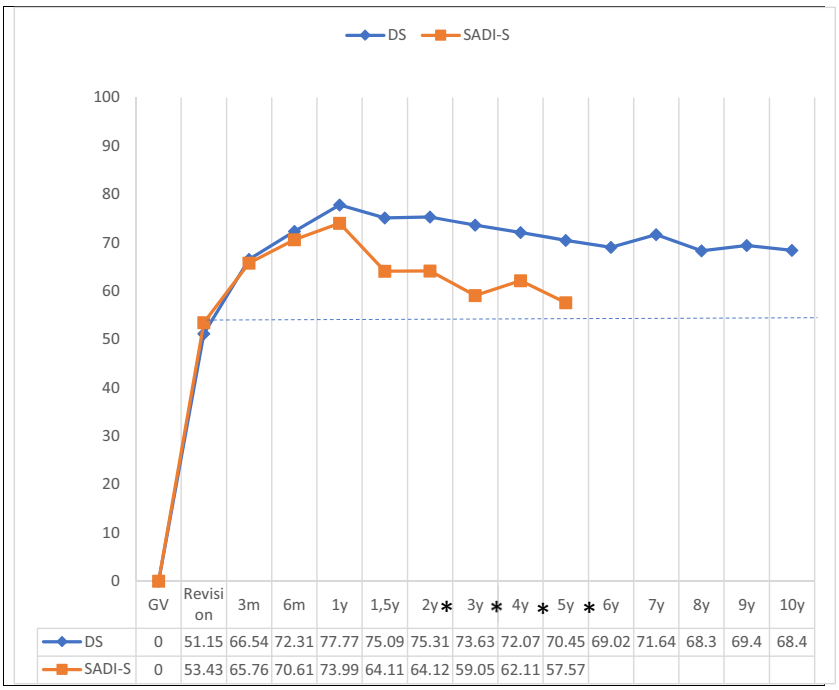

Fig. 2 Excess weight loss evolution. *p < 0.05

* p < 0,05

Table 2 Complications and extra supplementation needs

Variables		DS n = 55	SADI-S n = 46	p
Intraoperative complications				
Conversion to laparotomy		0	0	-
Intraoperative complication		0	0	-
Shot-term evolution (≤ 30 days from surgery)				
Overall complications n (%)		11 (20)	5 (10.9)	0.095
Severe complications (Clavien-Dindo > II) n (%)		6 (10.9)	3 (6.5)	0.441
Complication type n (%)	Duodenal stump leak	1 (1.9)	0	
	Abdominal access	1 (1.9)	0	
	Hemoperitoneum	3 (5.6)	0	
	Intraluminal bleeding	2 (3.7)	0	
	Pancreatitis	0	1 (2.2)	
	Hernia incarceration	1 (1.9)	1 (2.2)	
	Wound infection	1 (1.9)	0	
	Pulmonary embolism	0	1 (2.2)	
	Respiratory complication	0	2 (2.2)	
Length of postoperative stay (days) m ± SD		4.67 ± 5.7	2.24 ± 1.2	0.006
30-day mortality		0	0	-
Long-term evolution (> 30 days from surgery) n (%)				
Overall complications n (%)		4 (7.3)	3 (6.5)	0.882
Complication type n (%)	Incisional hernia	2 (3.8)	1 (2.2)	
	Internal hernia	1 (1.9)	0	
	Adherence bowel obstruction	1 (1.9)	0	
	Biliary reflux	0	2 (4.4)	
	Hypoalbuminemia	0	0	
90-day mortality		0	0	-
Extra supplementation n (%)		36 (65.5)	17 (36.9)	< 0.001
Supplementation type	Vitamin A	20 (36.4)	5 (10.9)	
	Vitamin B	4 (7.3)	1 (2.2)	
	Vitamin K	1 (1.8)	0	
	Vitamin E	2 (3.6)	0	
	Vitamin D	30 (54.5)	16 (34.8)	
	Calcium	18 (32.7)	5 (10.9)	
	Iron	23 (41.8)	7 (15.2)	
	Cooper	3 (5.5)	1 (2.2)	
	Zinc	5 (9.1)	1 (2.2)	
	Folic acid	6 (10.9)	7 (15.2)	

stay was longer for DS (difference +2.4 days, p = 0.006). No mortality was observed at 90 days of surgery in either group.

In the long term, 7.3% DS' and 3 6.5% SADI-S' patients presented some complication (p = 0.882). One DS patient was operated on for mesenteric hernia and 2 SADI-S patients were converted to DS for symptomatic documented biliary reflux. DS patients required more extra supplementation (especially iron and vitamins B and D), with no case of persistent diarrhea or hypoalbuminemia.

Discussion

In this single-institution cohort study including 101 patients with insufficient weight loss or weight regain after SG, we

found that revisional DS was associated to a sustained weight loss at mid-term, together with remarkable diabetes, hypertension, dyslipidemia, and OSA remission rates. In contrast, revisional SADI-S obtained a poorer weight control at 2 and 5 years, and lower remission rates for diabetes and hypertension. Vitamin and micronutrient supplementation needs were greater in DS than in SADI-S. To our knowledge, this is the largest series reporting clinical data from patients submitted to a revisional procedures after SG, and the first study comparing the effectiveness and safety of SADI-S and DS in this setting.

Effectiveness

The most frequent cause of weight recidivism after SG is inadequate patient selection. In most of the patients of the present study, initial BMI made failure of SG predictable [17, 18]. Even though we recommend hypoabsortive surgery in grade IV obesity, SG was planned as definitive procedure in all cases of this study, due to surgeon's preference or patient's demand.

Selecting the most effective treatment after a failed SG is a challenge. Assessment of alimentary habits has not proven efficacy. Re-sleeve is only potentially useful when a gastric pouch dilatation is proven, and, even in these rare cases, 2 years EWL is only 44% [6]. Results of Roux-en-Y gastric bypass (RYGBP) are not satisfactory either, as reported by several small series with EWL ranging from 61 to 65% and comorbidities resolution under 50% at an average of 18 months from surgery [6, 19–21].

DS permits a better weight control than RYGBP [22] and is the most natural revisional surgical option after a failed SG, as SG was originally introduced as a component of DS [1, 23, 24]. In patients undergoing conversion to DS in this study, global EWL at 2 years was 75.3%, comparable to the 73.7% reported by Dapri et al. [25] and the 80% reported by Carmeli et al. [26]. Recently, there has been an increasing interest in SADI-S as a simplification of DS with potentially similar results. In this study, patients submitted to revisional SADI-S had EWL 64.1% at 2 years, which is similar to the 65.2% reported by Zaveri et al. [15] and the 68.6% by Sanchez-Pernaute et al. [7]. Balibrea et al. reported a 2-year EWL of 79% for second-stage SADI-S, but parting one tiers of patients from BMI under 50 kg/m^2 and including a heterogeneity of common afferent limbs measures [13]. It must be noted that SADI-S was initially described with a common limb of 200 cm, being afterward adjusted to 250 cm and finally to 300 cm in order to prevent malnutrition, at the expense of poorer weight control [11, 13].

According to our results, revisional DS is superior to SADI-S with 300 cm common length in weight control and diabetes and hypertension resolution at 2 and 5 years; these findings had not been described previously, due to the lack of comparative studies. We have previously proved that primary one-step SADI-S' results are inferior to DS' in patients with BMI ≥ 55 kg/m^2 [16], as the mean initial BMI in the present study. It may be recommendable that the choice of the revisional procedure is done considering the BMI before SG and the fact that failure of a previous surgery selects patients with poorer compliance.

Safety

Concern with technical difficulty, postoperative complications and malnutrition have historically prevented many surgeons against DS. In this study, DS was associated to a 10.9% of short-term complications graded as Clavien-Dindo > 2, most of them abdominal or digestive bleeding, with no mortality. There was one case of duodenal stump leak (1.9%), but no leaks in the duodeno-ileal or ileo-ileal anastomosis. We observed a non-significant lower incidence of complications and a significant shorter hospitalization time in SADI-S. However, surgical learning curve must be taken into account, as some DS cases were operated on earlier. Therefore, in experienced hands, revisional SADI-S and DS seem to be reasonably safe techniques in the short term. Re-SG seems to be more problematic revisional surgery, having an incidence of postoperative leak as high as 14%, a complication that is difficult to treat [25, 27].

Long-term complication rate was similar among DS and SADI-S patients (7.3 vs. 6.5%), but the nature of complications was different: one DS patient was submitted to urgent surgery due to a mesenteric hernia, while in 2 SADI-S cases, conversion to DS was needed because of biliary reflux. These findings are in accordance with previous reports of primary surgery: DS is associated with rates of internal hernia as high as 8% in the long term [28], while after SADI-S, in which mesentery is not divided, this complication only occurs in the Petersen space and has been rarely reported [16, 29]. As for biliary reflux, even though SADI-S technique preserves the pyloric barrier, this is logically more frequent after a Billroth II-like reconstruction than after the DS' Y-en Roux. It is therefore reasonable to include clinical and endoscopic monitoring of biliary reflux in the follow-up of one-anastomosis bariatric surgeries, as bile gastritis and esophagitis are potentially pre-malignant [30, 31].

Patients in the DS group in this study presented higher need of supplementation with fat-soluble vitamins (A, D, E, and K), as well as with other micronutrients, such as calcium, iron, copper, and folic acid. This finding is in concordance with previous studies [32, 33] and is attributable to the shorter common channel of the Roux configuration of DS. However, we found no cases of hypoalbuminemia or hypoglycemia. A series of 1243 patients submitted to primary DS with long follow-up reported a 1.5% incidence of severe hypoalbuminemia or intractable diarrhea [34]. In SADI-S' patients, this complication has been described when a 200- or

250-cm afferent limb was performed [11, 13] but not since this limb was standardized at 300 cm, as all SADI-S patients in the present study.

Limitations

The limitations of this study include its retrospective nature. Even though data were entered prospectively into our database, some mild complications might have been missed. In addition, only 11 SADI-S' patients had 5-year and none 10-year data. As some of DS cases were operated on earlier than SADI-S', surgical experience must be considered, especially when comparing short-term complications. Even though patients of this cohort followed strict analytic controls for at least 5 years, biochemical parameters were not included in the database. Instead, we recorded the need of extra vitamin and micronutrient supplementation, as a simplified reflection of the effort done to artificially maintain these parameters into the normality ranges. Patient-reported outcomes were not prospectively recorded during most of the study period either. Being patient comfort and satisfaction following bariatric surgery of great interest, we are currently determining number of bowel movements, its consistency (Bristol scale), gastroesophageal reflux symptoms (GERDQ questionnaire), and quality of life (SF-12 score) of all our patients, and we aim to report it soon. Finally, the high initial BMI of the patients of this study could limit the applicability of our findings in patients with pre-SG grade III obesity, in which SADI-S could play a more determinant role as a second-step procedure.

Conclusions

This single-institution cohort study including 101 patients submitted to revisional surgery due to a failed SG shows that DS permits better weight control and diabetes and hypertension resolution than SADI-S at 2 and 5 years, at the expense of more extra supplementation to compensate vitamin and micronutrient deficiencies. We therefore recommend DS in case of insufficient weight loss or weight regain after SG, especially in patients initially affected of grade IV obesity or persistent diabetes or hypertension with good follow-up compliance. Longer follow-up and prospective comparison are needed to confirm the real potential indication of SADI-S and DS as revisional procedures.

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Declarations

Ethics Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Consent to Participate Due to the retrospective nature of this study, formal consent was not required.

Conflict of Interest Dr. Osorio and Dr. Pujol-Gebelli report personal fees from Ethicon Endo Surgery Inc., outside the submitted work. The rest of authors have no conflict of interest.

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