

Original article

## Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) for obese diabetic patients

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### Abstract

**Background:** Bariatric operations achieve a high remission rate of type 2 diabetes in patients with morbid obesity. Malabsorptive operations usually are followed by a higher rate of metabolic improvement, though complications and secondary effects of these operations are usually higher.

**Objectives:** Analyze the results of a simplified duodenal switch, the single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) on patients with obesity and type 2 diabetes mellitus (T2 DM).

**Setting:** University Hospital, Madrid, Spain.

**Methods:** Ninety-seven T2 DM patients with a mean body mass index (BMI) of 44.3 kg/m<sup>2</sup> were included. Mean preoperative glycated hemoglobin was 7.6%, and mean duration of the disease was 8.5 years. Forty patients were under insulin treatment. SADI-S was completed with a sleeve gastrectomy performed over a 54 French bougie and a 200 cm common limb in 28 cases and 250 cm in 69.

**Results:** Follow up was possible for 86 patients (95.5%) in the first postoperative year, 74 (92.5%) in the second, 66 (91.6%) in the third, 46 (86.7%) in the fourth and 25 out of 32 (78%) in the fifth postoperative year. Mean glycemia and glycated hemoglobin decreased immediately. Control of the disease, with HbA1c below 6%, was obtained in 70 to 84% in the long term, depending on the initial antidiabetic therapy. Most patients abandoned antidiabetic therapy after the operation. Absolute remission rate was higher for patients under oral therapy than for those under initial insulin therapy, 92.5% versus 47% in the first postoperative year, 96.4% versus 56% in the third and 75% versus 38.4% in the fifth. A short diabetes history and no need for insulin were related to a higher remission rate. Three patients had to be reoperated for recurrent hypoproteinemia.

**Conclusion:** SADI-S is an effective therapeutic option for obese patients with diabetes mellitus. (Surg Obes Relat Dis 2015;11:1092–1098.) © 2015 American Society for Metabolic and Bariatric Surgery. All rights reserved.

### Keywords:

SADI-S; Biliopancreatic diversion; Duodenal switch; One loop; Malabsorptive surgery; Diabetes; Metabolic surgery

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The race for metabolic surgery had its starting signal > 20 years ago, when Pories [1], following previous studies from Sugerman [2], suggested that obesity surgery could be a cure for diabetes, and this could happen independently from weight loss. Further studies from Rubino, Gagner and

others [3–5], confirmed this hypothesis, and set the bases for metabolic surgery as we know it today.

All bariatric operations induce a significant improvement of glycemia control in diabetics, in relation to a decrease in caloric intake. However, powerful mechanisms against diabetes progression are triggered by the anatomic gastrointestinal changes generated by the different techniques. Currently we know that the bypass of the duodeno-pancreas region, the anastomosis between the stomach or duodenum and the jejunum or the ileum, the changes produced in gastric emptying, the resection of the gastric fundus and the decrease in fat absorption by shortening of the absorptive channel, are all mechanisms implied by different reasons in the metabolic improvement of type 2 diabetics.

Single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) is a modified biliopancreatic diversion [6–8], which includes most of these antidiabetic mechanisms, and so it is supposed to improve diabetes as well as the original Scopinaro's procedure [9] or the variation introduced by Hess [10].

In the present work we analyze the evolution of obese patients with type 2 diabetes mellitus (T2DM) submitted to SADI-S. The study was approved by the Ethics Committee of our institution and results are part of the study NCT01463904 registered in ClinicalTrials.gov.

### Patients and methods

From May 2007, 168 patients have been consecutively submitted to SADI-S as a primary surgery or as a second step after a previous sleeve gastrectomy (21), as a revision of a gastric bypass (1) or a vertical banded gastroplasty (3). Ninety-seven of them had diagnosis of type 2 diabetes mellitus (T2DM) and constitute our group of study. The mean age of the series was 50 years (21–71). Fifty-two were women and 45 men. Mean preoperative weight was 119.5 kg, mean preoperative BMI 44.3 kg/m<sup>2</sup> (33–67) and mean excess weight 52.7 kg (26–99).

Patients had a mean duration of their metabolic disease of 8.5 years before the operation (1–35). Thirteen patients were under diet control for diabetes, 44 were on oral antidiabetics and 40 were under insulin therapy. Mean preoperative glycemia was 167.6 mg/dL (88–408), and mean glycated hemoglobin (HbA<sub>1c</sub>) 7.6% (5.4–14). Eighty-six percent of the patients had HbA<sub>1c</sub> >6%, 65% >6.5%, and 52% >7%. Mean C-peptide was 2.95 ng/mL (0.4–9.2). Mean values of Quantitative Insulin Sensitivity Check Index (QUICKI) and Homeostasis Model Assessment (HOMA) for patients with no insulin treatment were .29 (0.24–.41) and 7.9 (0.6–34.8) respectively.

Mean preoperative microalbuminuria was 21.6 mg/L, and mean albumin to creatinine ratio was 27.2 mg/g creatinine, with 11% of the patients in the range of microalbuminuria and only 1 patient with preoperative criteria of diabetic nephropathy.

Seventy-four patients (76%) had diagnosis of dyslipidemia: 65% had hypertriglyceridemia, 29% had HDL <40 mg/dL, 46% had LDL >100 mg/dL and 30% had total cholesterol >200 mg/dL. Sixty-eight percent of the patients had hypertension under treatment.

The operation performed was a SADI-S with a 200 cm common channel in 28 cases and a 250 cm one in the other 69 patients. In brief, a sleeve gastrectomy over a 54F bougie was performed. Duodenal division was completed at the level of the gastroduodenal artery. The ileal loop was ascended antecolically and an end-to-side duodeno-ileal anastomosis was completed either hand-sewn or mechanically with a 30 mm linear stapler. A vacuum drain was systematically left. Patients started oral liquids on the first postoperative day, the drain was removed on the second day and they were discharged between the third and fourth postoperative day. Antidiabetic treatment was individually managed by the endocrinologist after surgery, based on previous antidiabetic therapy. Calcium, iron and multi-vitamin supplements were systematically prescribed. Post-operative visits were programmed every 3 months.

Statistical calculations were performed with IBM SPSS 20.0 for Macintosh. Continuous variables were presented as mean (range). Categorical variables were expressed as frequencies. Differences between groups were evaluated through t test and chi<sup>2</sup> as appropriate. Predictive value of significant variables was calculated by multivariable logistic regression analysis, and to determine the cut-off value for prognostic factors, a receiver operating characteristic (ROC) curve analysis was executed.

### Results

There was one anastomotic leak, one patient was reoperated for hemoperitoneum and one patient was reoperated for an incarcerated umbilical hernia. Follow up was possible for 86 of 90 patients completing the first post-operative year (95.5%), 74 patients after 2 years (92.5%), 66 after 3 years (91.6%), 46 after 4 years (86.7%) and 25 out of 32 patients 5 years after the operation (78%).

Excess weight loss (EWL) of the whole series was 73% at 6 months, 91% at first year, and 92%, 85%, 88% and 98% in the second to fifth postoperative years (Fig. 1). In the follow up, 6 patients failed to reach a 50% EWL (6.1%). Overall weight loss was 31% at 6 months from surgery, 39% at 1 year, 39% at 2 years, 35% at 3 years, 37% at 4 years and 38% at 5 years from the operation.

The mean number of daily bowel movements was 2.5. Three patients have been reoperated for recurrent hypoproteinemia. In 2 cases the revisional surgery was a conversion into a Roux-en-Y duodenal switch with a 200 cm common limb and a 350 cm alimentary limb, while in the other reoperation consisted on the division of the duodeno-ileal anastomosis and the performance of a new one 1 meter proximal. Two of the revised patients suffered another

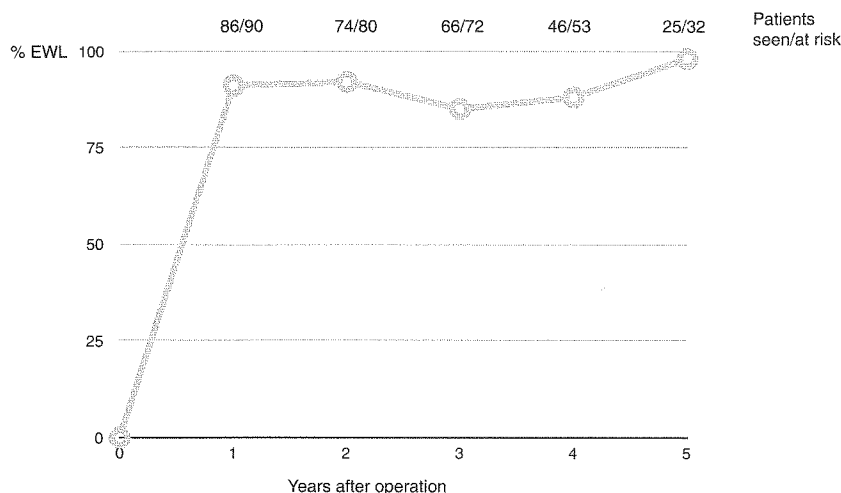


Fig. 1. Percentage of excess weight loss of the whole series.

episode of hypoproteinemia due to food rejection in fear of weight regain, and subsequently never recurred; the other patient did well.

Mean postoperative levels of glycemia and HbA<sub>1c</sub> normalized from the first postoperative year, as did insulin resistance and sensitivity indices (Table 1). Control of the disease was considered when normal levels of HbA<sub>1c</sub> (<6%) were achieved, independently of antidiabetic therapy. Insulin-dependent patients achieved this control in 82% of the cases in the first postoperative year, and in 78%, 67%, 69% and 70% in the following years. Patients on oral antidiabetic treatment reduced HbA<sub>1c</sub> <6% in 100% of the cases in the first postoperative year, and in 97%, 96%, 91%, and 84% in the following years.

Postoperative antidiabetic treatment was maintained upon decision of the endocrinologist, based on current ADA criteria. Forty patients had preoperative insulin therapy. After the first postoperative year only 3 maintained insulin, 14 had oral therapy and the rest were off-medication. These numbers remained quite stable during all the follow-up (Fig. 2). Forty-four patients were initially with oral

antidiabetics. After the first postoperative year, 7% maintained this therapy, 3% in the second and third year, 14% in the fourth and 25% in the fifth postoperative year (2 out of 8) (Fig. 2).

Diabetes remission was considered when HbA<sub>1c</sub> was maintained below 6% without antidiabetic medication for > 1 year. Overall remission rate was 71.6% after the first postoperative year, 92.5% for patients initially under oral antidiabetic treatment and 47% for those under insulin therapy. After the second, third, fourth, and fifth postoperative years these numbers were 77% (97% and 54% respectively), 75.8% (96.4% and 56%), 63.3% (85.7% and 47.3%) and 52% (75% and 38.4%) (Fig. 3). Most patients who achieved remission (89%) acquired it in the first postoperative year. After an initial remission only 4 patients recurred in the first 5 years (in 308 patient-years follow up).

In the univariable analysis, older age, higher preoperative glycemia, higher preoperative HbA<sub>1c</sub>, lower C-peptide, longer diabetes duration and the preoperative need for insulin therapy were all significantly related to a lower diabetes remission rate. In the multivariable analysis both diabetes duration and the need of preoperative insulin therapy maintained statistical significance. Receiver operating characteristic (ROC) curve indicated that > 7 years of diabetes duration before surgery was strongly correlated with nonremission of the disease, with a sensitivity of 85%, a specificity of 74% and an area under the curve of .882 (Fig. 4).

Lipidic profile improved significantly. In the first postoperative year, 89% of the patients had normal triglycerides, 65% had normal HDL, 79% normal LDL, and 96% normal total cholesterol values; follow up mean values are represented in Table 1.

Hypertension remitted in 52% of the patients, and improved in 44%.

Hypoalbuminemia was detected in 12% of the cases, low vitamin A levels in 53% and high parathormone levels in

Table 1  
Preoperative and postoperative glycemic and lipidic profiles

	Preoperative	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
<b>Patients seen/at risk</b>	97/97	86/90	74/80	66/72	46/53	25/32
Glycemia (mg/dL)	167.6	93	93.8	103.9	97.3	101.6
HbA <sub>1c</sub> (%)	7.6	5.1	5.07	5.25	5.43	5.52
HOMA	7.9	.96	1.45	.87	—	—
QUICKI	.29	.41	.4	.4	—	—
Triglycerides (mg/dL)	205	103	96	104	105	105
HDL (mg/dL)	46.6	45.7	48.3	47.3	45.3	57.4
LDL (mg/dL)	98.7	73.9	73.2	74.5	74.4	81.3
Cholesterol (mg/dL)	185	138	142	140	139	160

HDL = high-density lipoprotein; HOMA = Homeostasis Model Assessment; LDL = low-density lipoprotein; QUICKI = Quantitative Insulin Sensitivity Check Index.

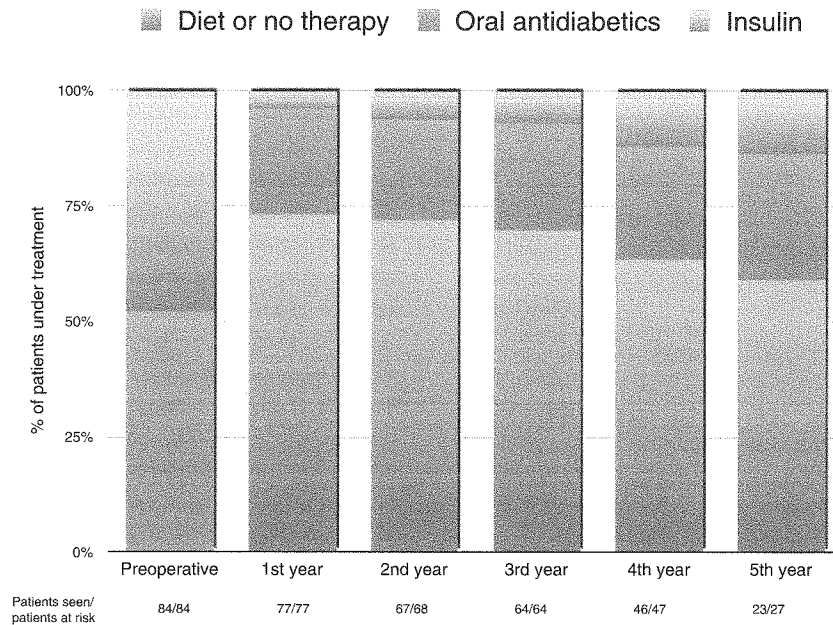


Fig. 2. Percentage of patients receiving treatment for type 2 diabetes pre- and postoperatively. Patients with diet therapy or no antidiabetic treatment have been discarded.

54% of the cases in the third postoperative year. Analytical data are represented in Table 2.

### Discussion

We herein present the results of SADI-S, a simplified duodenal switch, on diabetes mellitus, in patients submitted to surgery for severe or morbid obesity. Our study found

that patients with oral antidiabetic agents or insulin achieve an initial remission rate of 70%–77%; remission rates for patients under oral therapy are almost 100%, whereas for patients under insulin therapy these numbers go down to 50%. Remission occurs rapidly after surgery, with most patients attaining it in the first postoperative year. In the long term, a slight reduction in the remission rate is

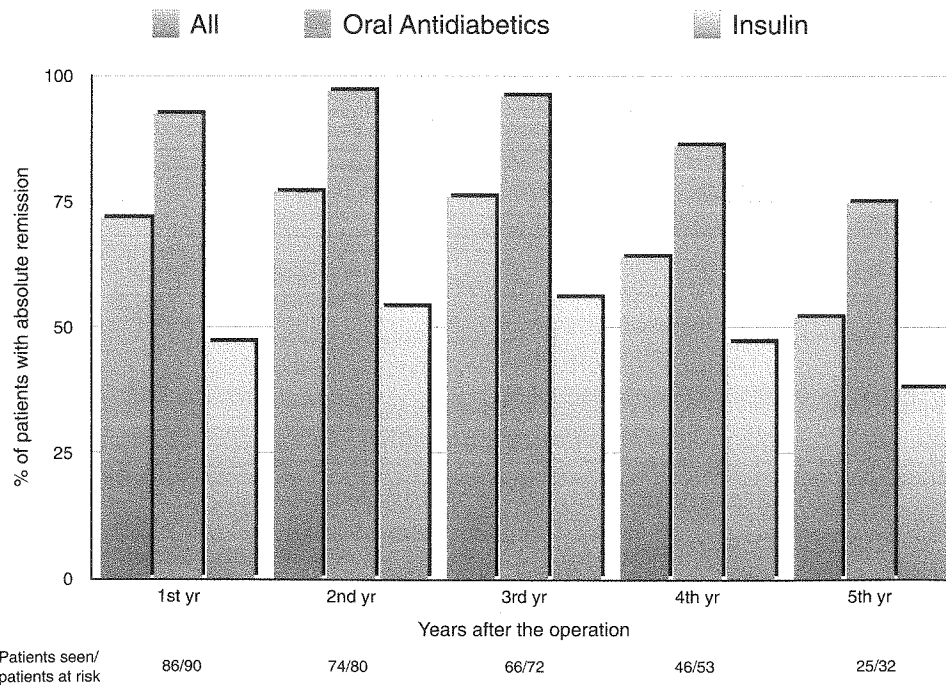


Fig. 3. Rates of absolute remission after the operation. Columns in blue represent the overall remission rate. Columns in green represent remission rate between patients with initial oral antidiabetic therapy, and columns in yellow include only patients with initial insulin therapy.

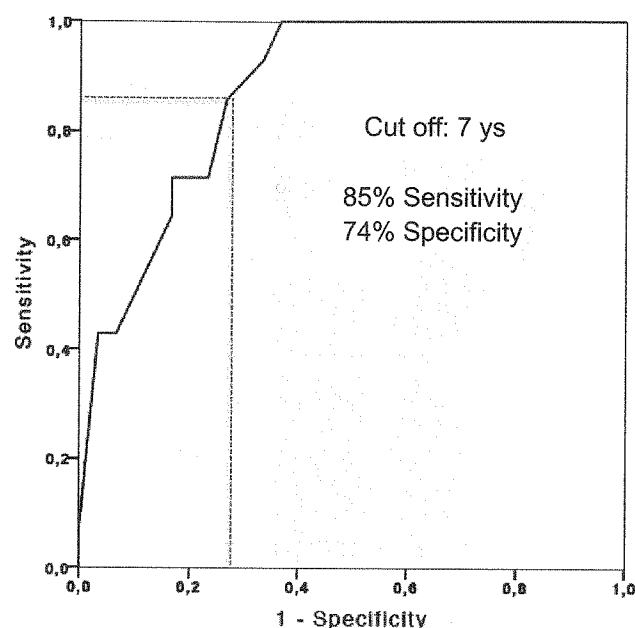


Fig. 4. Receiver operating curve correlating years of diabetes with absolute remission probability.

observed, with an 8% recurrence rate in the first 5 years. As in other studies, circumstances negatively correlated to metabolic remission are the duration of diabetic history and the need for preoperative insulin, both related to a higher beta-cell dysfunction.

Surgery has been found to be a good adjunct to standard therapy to improve glucose homeostasis in patients with T2DM, and sometimes, mostly in short-term moderate diabetics, to be able to induce a long-term remission of the disease. Initial reports were somewhat optimistic; Buchwald reported a 76.8% complete resolution rate,

98.9% for biliopancreatic diversion or duodenal switch, and 83.7% for gastric bypass [11]. A slight decrease in these numbers was observed in the second meta-analysis published by the author in 2009 [12], even more when results were evaluated at  $\text{tan} > 2$  years from surgery.

As Schauer remarks [13] it is difficult to compare different studies because there is a huge variation in the severity of the populations included, and different criteria are used to define improvement or remission [14]. In the present report we base on glycated hemoglobin and on the need for medical treatment, to define remission and control of the disease;  $\text{HbA}_{1c}$  is the best way to determine diabetes control [15] and our group recently found that a simpler approach to evaluate remission, based on  $\text{HbA}_{1c}$  and the absence of medication, has the same value as more complex criteria [16]. We, along with others, consider remission with  $\text{HbA}_{1c}$  values below 6% [17], which is the currently the most frequently used level. Blackstone et al. [18] analyze different models for defining remission, and define the most strict criteria with  $\text{HbA}_{1c} < 5.7\%$ , which is the level for patients in risk for developing diabetes and microangiopathy [19]. They find a 46.9% remission rate for patients off medication with  $\text{HbA}_{1c} < 5.7\%$ , and 55.6% when 6% is the cutoff value.

In second place, to completely understand the effect of the operation, it is very important to correctly classify the patients included: insulin-resistance patients or prediabetics, patients under oral therapy and patients under insulin treatment. It is widely accepted [1,20] that prediabetics and those patients with only diet control of their disease are going to progress well, and will avoid the development of the metabolic disease in approximately 80%–90% of the cases independently on the type of surgery performed, as long as the operation is successful especially in maintaining the weight loss. With a thorough classification of patients

Table 2

First and third postoperative year nutritional parameters (in brackets, number of patients seen/at risk)

	First postoperative yr (n = 86/90)			Third postoperative yr (n = 66/72)			
	Mean (STM)	Range	% Abnormal	Mean (STM)	Range	% Abnormal	Normal values
Albumin (g/dL)	3.9 (.05)	2.4 – 5	13.7	4.01 (.06)	2.7 – 4.8	12	3.5 – 5
Proteins (g/dL)	6.5 (.05)	5.2 – 7.6	34	6.5 (.08)	5.5 – 7.7	29	6.5 – 8.5
Vitamin A (mg/L)	.3 (.01)	.15 – .57	44	.61 (.3)	.07 – 9	53	0.3 – .8
Vitamin E (mg/L)	9.7 (.5)	5 – 17	0	7.9 (.3)	4.4 – 13	7	5 – 18
Vitamin D (ng/mL)	20.5 (2)	4 – 113	15 – Deficiency 35 – Insufficiency	21.9 (2.6)	4 – 94.7	23 Deficiency 23 Insufficiency	0 – 10 Deficiency 10 – 20 Insufficiency
Parathormone (pg/mL)	76.3 (5.5)	17.7 – 275	24	107 (9.6)	42.2 – 289	54	16 – 87
Folic acid (ng/mL)	6 (.5)	1.4 – 25.2	8	5.8 (.4)	2.1 – 11.9	3	2.3 – 20
Vitamin B <sub>12</sub> (pg/mL)	345 (27)	108 – 1500	8	403 (44)	120 – 1521	8	180 – 914
Selenium (μg/L)	66.1 (2.5)	26 – 99	29	65.4 (2.9 – 21)	21 – 92	28	60 – 120
Copper (μg/L)	95.1 (3.6)	37 – 138	13	90.2 (3)	56 – 111	11	70 – 140
Zinc (μg/L)	68.5 (2.4)	24 – 120	17	66.1 (2.6)	39 – 115	33	60 – 150



based on preoperative drug usage and years of diabetic duration before surgery, Schauer reported a 100% resolution rate for impaired fasting glucose-patients, 97% for diet-controlled patients, 87% for those under oral therapy, and 62% for patients under insulin treatment (13).

In the long term it seems to be a decrease of the effectiveness of surgery. We have found a low recurrence rate, but if we analyze our 5-year results, remission rates are significantly lower than early postoperative results, 52% versus 72%. Brethauer et al, from the Cleveland Clinic, reported recently a long-term follow-up study in which they reported this decline in the effectiveness of surgery with time, with an overall remission rate, complete and partial, of 50% after gastric bypass [21]. In the longest follow up study, Sjöström reports an initial remission rate of 72.3% which came down to 30.4% at 15 years [22]. DiGiorgi [23] et al. find a significant recurrence and even worsening rate after initial good results, which are related to a lower initial BMI; also the authors found a higher rate of weight regain in the group of patients with metabolic recurrence. We have a low recurrence rate, and we cannot relate it with weight loss failure, as the percentage of patients with weight loss failure is too low.

In the present series, negative prognostic factors for diabetic remission were duration of the disease and the need of preoperative insulin therapy. These factors are both related to a low beta cell reserve. Our group found previous relation of no-remission with other factors, as was the postoperative weight loss [24], but this was considering different surgical techniques which could be related with different effectiveness on weight loss. In the present work only one type of operation is included, SADI-S a novel type of biliopancreatic diversion, which has technical modifications from the duodenal switch, but preserves all the presumed antidiabetic potentials of the operation. Our results are comparable to those observed after duodenal switch, which usually exceed those obtained by less aggressive techniques, as gastric bypass or sleeve gastrectomy [25–27].

Biliopancreatic diversions create a moderate gastric restriction, which reduces caloric intake, make a bypass of the duodeno-pancreatic region, with its incretin effect, accelerate gastric emptying thanks to the sleeve resection, change the stomach or duodenal emptying into the distal bowel with is pro-incretin effect, and reduce fat absorption to the minimum. SADI-S has an added value, as it simplifies the operation with a reduction in the number of the anastomosis and avoiding of mesenteric opening and closing, and as we report in the present paper, maintains the good effects of malabsorptive surgery. It is true, however, that a mesocolic window is created, but it is probably too huge to generate obstructive problems related to internal herniation. Other similar operations have been proposed in recent years, as it is the duodeno-jejunal bypass presented by Lee et al. [28], in which a 1-loop duodenojejunal bypass is performed; though their follow up is yet short, results on weight loss and diabetes seem to be parallel to those

obtained after gastric bypass. Duodenojejunal bypass is not a malabsorptive operation; it is closer to gastric bypass with a metabolic modification, in which the length of the biliary limb is known but the common limb remains unknown. SADI-S has a greater effect on diabetes because it makes a constant reduction in the absorptive surface of the small bowel.

However, an absolute remission should not be the real aim of metabolic surgery [29]. In our study, 70% of insulin dependent patients get HbA<sub>1c</sub> levels <6%, and only 4 patients maintain insulin therapy – at reduced doses – in the long term. This means that most patients on insulin therapy get an appropriate control of the disease after bariatric surgery and are able to sustain this control in the long term. As this control is what apparently relates to the progression or not of diabetic complications, this should be in our opinion the real aim of metabolic surgery.

The main limitation of the present study is the non-randomization of the patients, which is necessary to compare current results with those obtained with standard techniques as gastric bypass or sleeve gastrectomy. A comparison to duodenal switch is also necessary, although our nutritional results (Table 2) are similar to those reported after the original technique [26]; in spite of this, a multi-institutional prospective randomized trial comparing SADI-S with duodenal switch is going to be started this year in Spain and Portugal. The main outcome measures of the study will be the effectiveness in weight loss and diabetic remission, and the reduction in postoperative and long-term complications. In this way we hope to obtain a definitive answer about the presumed benefit of the elimination of one anastomosis.

Also the number of patients is still low, and this could affect long-term results, as the missing of one or 2 patients can induce great variations in the final results.

## Conclusion

SADI-S has a beneficial effect on diabetic patients with morbid or severe obesity. It keeps the good results obtained after traditional malabsorptive operations with the addition of the decrease in technical difficulty and postoperative complications after the reduction to one anastomosis. Long-term comparison with gastric bypass and the so-called metabolic gastric bypass are necessary.

## Disclosures

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