

# Five Year Follow up after Surgical Treatment of Type 2 Diabetes with Laparoscopic Sleeve Gastrectomy Associated with a Duodenal Ileal Interposition

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## Abstract

**Introduction:** Type 2 diabetes mellitus (T2D) is a chronic disease, primarily caused by a combination of defective insulin secretion and the inability of insulin-sensitive tissues to respond to insulin. Laparoscopic sleeve gastrectomy associated with duodenal ileal interposition (SGDII) has been shown to be a feasible treatment option for patients with T2D, as it provides improvement and control of glycemia, dyslipidemia and arterial hypertension. The aim of this study was to evaluate the mid and long-term results of SGDII for the treatment of diabetic patients, considering diabetic remission, weight loss and postoperative complications. **Materials and Methods:** Retrospective study with 96 patients with T2D submitted to SGDII, between 2010 and 2016. The glycated hemoglobin (HbA1c) value < 6.5%, without the use of hypoglycemic agents, was considered as remission of T2D. The research was approved by the Ethics and Research Committee of Hospital São José do Avaí and The National Research Ethics Commission (CONEP)—CAEE 0023.0.316.000-10. Written informed consent was obtained from all subjects prior to their inclusion in the study, in accordance with the Declaration of Helsinki. **Results:** Sixty-one patients (62.8%) were male, and 36 patients (37.2%) were female. The average age was 50.9 years. Median BMI was 33.43 kg/m<sup>2</sup>. The incidence of major postoperative complications in the first 30 days was 2.1%, with no mortality. Dyslipidemia control was sustained, after five years, in 62% of the patients. The five years follow-up demonstrated that 80% of patients had T2D remission at one year, 74.5% at three years and 61.8% at five years. Univariate analysis demonstrated that preoperative values of HbA1c and BMI, preopera-

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tive use of insulin, gender, and 30-day complication were not predictors of remission at all study intervals. The average duration of the disease was nine years and the mean glycated hemoglobin before surgery was 8.95%. **Conclusion:** SGDII resulted in good glycemic control at 5-years follow-up and represents a valid alternative for the treatment of T2D.

## Keywords

Diabetes, Surgery, Metabolic Syndrome, Dyslipidemia, Ileal Interposition, Metabolic Surgery, Bariatric Surgery, Obesity

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## 1. Introduction

Type 2 diabetes mellitus (T2D) is a highly prevalent disease, with increasing incidence in recent decades. Numbers from the International Diabetes Federation (IDF), show that there are 351 million people with diabetes, with a projection that, by 2045, 783 million adults will be living with diabetes—or one in ten adults [1].

Numerous trials show that surgery controls diabetes in patients with obesity better and longer than clinical treatment, represented by diet, pharmacological approach with medications such as metformin or other agents, including combination therapy and insulin [2] [3] [4]. The largest cohort of randomized patients demonstrated, in a prospective observational study with a three-year follow-up, found diabetes remission (1 - 3 years) in 37.5% of patients following surgery (Gastric banding (AGB), Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG)) and in 2.6% of the cases after medical/lifestyle intervention [5]. Bariatric surgery is still superior in reaching reduction in body mass index (BMI) in patients with BMI < 30 kg/m<sup>2</sup>, but glycemic control, especially in patients who cannot manage the disease with clinical treatment, is limited and inferior [6] [7].

Glucose improvement after metabolic surgery occurs because of weight loss and weight-independent factors such as bile acid metabolism, incretin hormone secretion, neuronal signaling, and gut microbiota [8].

The aim of this study was to evaluate the medium and long-term results of SGDII in T2D patients with overweight and obesity.

## 2. Methods

The research was approved by the Ethics and Research Committee of Hospital São José do Avai in 2009 and The National Research Ethics Commission (CONEP) in 2010 (CAEE 0023.0.316.000-10). Informed written consent was obtained from all subjects prior to their inclusion in the study, in accordance with the Declaration of Helsinki.

This was a retrospective cohort study, with consecutive medium and long-term analysis of 96 patients with T2D who underwent SGDII, between 2010 and

2016, in a single hospital, with a high volume (>300 procedures/year) of bariatric surgeries. Data were collected from electronic medical records from the hospital and outpatient units. All patients received care from a specialized multidisciplinary team, corroborating the surgical indication. The time of this study was relatively long, necessary to have a follow-up of 5 years to observe the resolutions of diabetes and comorbidities.

Adults were eligible for enrollment if they were 18 to 70 of age, with at least three years of diagnosis of DM2, according to the American Diabetes Association (ADA) criteria, namely: fasting blood glucose  $\geq 126$  mg/dL, 2-hour oral glucose tolerance test (OGTT)  $75 \geq 200$  mg/dl, glycosylated hemoglobin (HbA1c)  $\geq 6.5\%$  and random plasma glucose  $\geq 200$  mg/dl; patients using oral hypoglycemic agents and/or insulin with evidence of stable treatment for a period of more than 12 months; stable weight, defined as no change (>3.0%) in the last three months before inclusion; serum C-peptide values  $> 0.5$  ng/ml. Patients were excluded for prior weight loss surgery, impaired mental status, alcohol or other drug addiction, pregnancy, type 1 diabetes mellitus, glomerular filtration rate  $< 30$  ml/h, and cancer under treatment. Follow up visits were schedule to one, three and six months, and then annually. As it was a retrospective study, patients who met the inclusion and exclusion criteria were included.

The variables used were HbA1c, LDL, triglycerides, BMI, diabetes time, insulin, sex, age and complications within 30 days. The software MD\_L60, Version: eMD Central 7\_DB: 83 was used.

The procedure included the following surgical steps.

- Laparoscopic access through 07 ports.
- Sleeve gastrectomy with a linear stapler, followed by staple line reinforcement. A 36 F calibration bougie was used: Gastric section with linear stapler (Medtronic™), six loads, 60mm, starting at the antral-body transition, approximately 5.0 to 10.0 cm from the pylorus, according to the patient's BMI. In patients with BMI  $< 30$  kg/m<sup>2</sup>, the first gastric section was started 10 cm from the pylorus in the cranial direction. In patients with BMI  $> 30$  kg/m<sup>2</sup>, 5.0 cm from the pylorus. Complementation of the gastric section with a 45 mm or 60 mm long cutting linear endostapler (Medtronic™) and 3.5 mm high staples, until the angle of His. Continuous suturing along the entire staple line, using 3-0 polypropylene.
- Section of the first duodenal portion, two centimeters from the pylorus with a linear stapler 60 mm (Medtronic™);
- Dissection and opening of the transverse mesocolon, placing the sectioned duodenum into the inframesocolic space;
- Ileal section 30 cm from the ileocecal valve, linear stapler 45 mm (Medtronic™);
- Measurement of 170 cm of ileum proximally and ileal transection (segment that will be interposed);
- Ileo-ileal anastomosis between the ileal stumps remaining from the interposition; linear stapler 45 mm (Medtronic™);

- A manual end-to-side anastomosis in the proximal duodenum to the interposed proximal ileum, inframesocolic;
- Side to side anastomosis between the distal ileum and the proximal jejunum, 50 centimeters after the Treitz angle; linear stapler 45 mm (Medtronic™);
- Closure of all mesenteric defects with interrupt stitches on mesenteric borders directly after each anastomosis. The transmesocolic space was neared, and the body of the stomach was fixed with a continuous suture towards the root of the mesentery, performing a gastropexy (Final appearance: **Figure 1**).

Oral hypoglycemic agents were discontinued after surgery, and the daily glycaemic levels were tabulated, with a regular insulin regimen, as needed, for 30 days.

The definition of T2D remission followed the latest *American Diabetes Association* glycaemic control protocol as a reference, with a target of HbA1c < 6.5% for at least one year. The control of dyslipidemia in five years was also evaluated, having as criteria, LDL < 100 mg/dL and Triglycerides < 150 mg/dL. Postoperative complications up to 30 days were described by the Clavien-Dindo classification [9].



**Figure 1.** Final appearance of the surgery.

### 3. Statistical Analysis

Categorical variables were expressed in terms of frequency and percentage, and numerical variables that did not show normal Gaussian distribution were expressed in terms of medians, first and third quartiles. Those with normal Gaussian distribution were expressed in terms of average and standard deviation. The normality of the distribution of the numerical variables was checked by the Shapiro Wilk test. To compare the percentages of remission at one, three and five years after surgery, the proportion comparison test was applied. In the comparison of averages between the variables in the pre and postoperative moments, the paired t-student test was applied. All analyzes were performed using SPSS™ version 23 software and at a significance level of 0.05. In the multivariate analysis stage, binary logistic regression models were adjusted for each remission outcome at one, three and five years after surgery. The significant variables in the univariate stage were all inserted into the model, and then removed one by one, starting with those with the highest p-value, until only variables with  $p < 0.05$  remained in the model.

### 4. Results

Ninety-six patients were included in this study and 91 (94.8%) were followed for at least 1 year, 61 (63.5%) for at least 3 years, and 55 (57.3%) for at least 5 years. **Table 1** shows the results for HbA1c values, remission of T2D, complications up to 30 days, duration of T2DM, and weight and body mass index (BMI) before and five years after surgery. Sixty-one patients (62.8%) were male, and 36 patients (37.2%) were female. The average age was 50.9 years. Initial BMI ranged from 22.4 to 52.1 kg/m<sup>2</sup>, with an average of 33.43 kg/m<sup>2</sup>. The average duration of T2D was 9.0 years. The average preoperative HbA1c was 8.95% ± 1.96%.

There were no serious intraoperative complications and no conversion to laparotomy. The average surgery time was 223.5 minutes with no mortality. Fourteen early postoperative complications (14.5%) were observed, including four episodes of digestive bleeding (4.1%), two episodes of pneumonia (2.1%), four episodes of paralytic ileus (4.1%), two cases of enteric fistula (2.1%), both in the duodenum distal stump, and two cases of cardiac arrhythmia (2.1%), as shown in **Table 2**. The duodenum complications were successfully treated by laparoscopy. All these complications are described in **Table 3**, according to the Clavien-Dindo Classification. Nutritional deficiencies were not the goal of this study, but it can be inferred that changes resulting from SG, such as changes in gastric pH, and duodenal bypass, may be present.

From the 91 patients followed for one year, T2D remission rate was 80%. The remission rate at three years was 70.5% and 61.8% for five years (**Figure 2**).

Regarding diabetes control and preoperative BMI, patients with a BMI < 30 kg/m<sup>2</sup> had a T2D remission rate of 53% in five years. The remission rate for patients with a BMI < 40 kg/m<sup>2</sup> was 64% and for patients with a BMI > 40 kg/m<sup>2</sup> was 67%.

**Table 1.** Clinical and epidemiological data.

Variable	Description
<b>Preoperative HbA1c</b>	96
<6.5%	11 (11.5)
>6.5%	85 (88.5)
<b>HbA1c after one year</b>	91
<6.5%	65 (71.4)
>6.5%	26 (28.6)
<b>HbA1c after three years</b>	61
<6.5%	48 (78.7)
>6.5%	13 (21.3)
<b>HbA1c after five years</b>	55
<6.5%	41 (74.5)
>6.5%	14 (25.5)
<b>Preoperative OAD</b>	96
No	9 (9.4)
Yes	87 (90.6)
<b>OAD after one year</b>	91
No	72 (79.1)
Yes	19 (20.9)
<b>OAD after three years</b>	61
No	47 (77.0)
Yes	14 (23.0)
<b>OAD after five years</b>	55
No	35 (63.6)
Yes	20 (36.4)
<b>Remission one year</b>	91
No	33 (36.3)
Yes	58 (63.7)
<b>Remission three years</b>	61
No	18 (29.5)
Yes	43 (70.5)
<b>Remission five years</b>	55
No	21 (38.2)
Yes	34 (61.8)
<b>T2Dduration</b>	9.00 (5.00 - 16.00)
<b>Preoperative HbA1c</b>	8.95 ( $\pm$ 1.96)
<b>Preoperative weight</b>	94.34 ( $\pm$ 19.22)
<b>Preoperative BMI (kg/m<sup>2</sup>)</b>	33.43 ( $\pm$ 5.73)
<b>5 years postoperative weight</b>	73.71 ( $\pm$ 15.59)
<b>5 years postoperative BMI (kg/m<sup>2</sup>)</b>	26.17 ( $\pm$ 4.39)

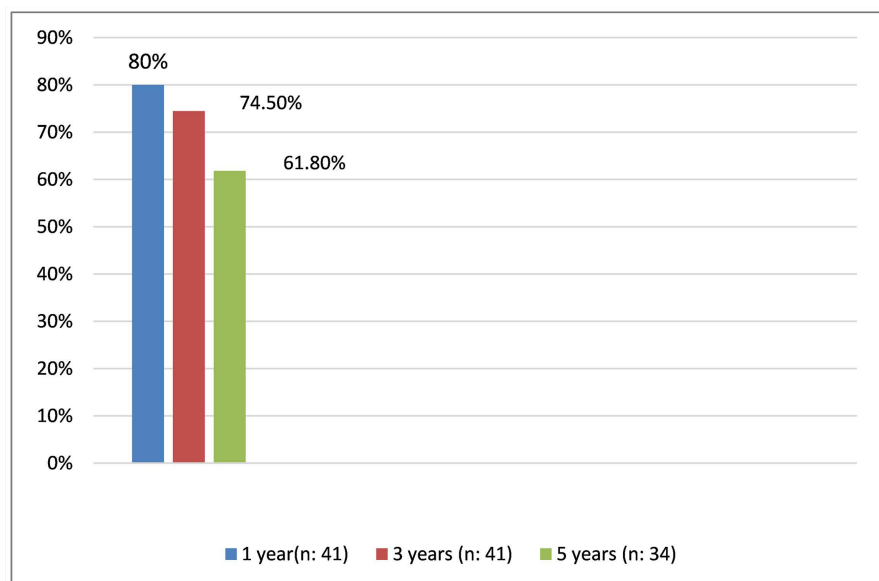
OAD—oral antidiabetics. Frequency (%); Median (1° Quartile - 3° Quartile); Average ( $\pm$  standard deviation).

**Table 2.** Postoperative complications up to 30 days.

Complications	<i>n</i>	%
Digestive bleeding	4	4.1
Pneumonia	2	2.1
Postoperative ileus	4	4.1
Enteric fistula	2	2.1
Cardiac arrhythmia	2	2.1
Total	14	14.5

**Table 3.** Postoperative complications up to 30 days—Clavien-Dindo Classification.

Grades	<i>n</i>	%
Grade I	2	2.1
Grade II	10	10.3
Grade IIIb	2	2.1
Total	14	14.5

**Figure 2.** Percentage of remission for those who were followed up for at least five years, at one, three and five years postoperatively.  $p = 0.092$ . Source: own authorship.

Dyslipidemia control, defined by LDL cholesterol  $< 100$  mg/dL and triglycerides  $< 150$  mg/dL, after five years, was found in 62% of the patients.

The average preoperative BMI was  $33.43 \text{ Kg/m}^2$  with a postoperative BMI of  $26.16 \text{ Kg/m}^2$ .

**Table 1** shows a univariate association between the variables HbA1c, weight, BMI and pre-operative use of insulin, in addition to gender and the presence of complications within 30 days, with the outcome being remission within 1 year. It was demonstrated that only the variables weight ( $p = 0.034$ ) and pre-operative BMI ( $p = 0.062$ ) were eligible for the binary logistic regression analysis stage, as

they presented a significant p-value ( $p < 0.20$ ). Adjusting the binary logistic regression model for the outcome remission in one year, no variable remained significant in the final model ( $p < 0.05$ ), with no evidence of significant predictors for diabetes remission in one year among those evaluated in this study. The same observation was found after three and five years.

## 5. Discussion

Current guidelines are supportive of bariatric surgery for those with obesity and T2D [10]. When considering the possibility of a surgical treatment for a disease that traditionally has a clinical approach, its pathophysiology must be considered, including genetic background and ethnicity. The median BMI of a T2D patient in this country is 29 kg/m<sup>2</sup>. The BMI cutoff point for increased risk of T2DM is also much lower among groups of Asian individuals [11] [12].

Overweight and lean patients with diabetes may have an accelerated loss of pancreatic beta-cells, and there are studies demonstrating that patients with a higher BMI had lower HbA1c [13]. The importance of whether beta cell functioning is improved after surgery, not dependently of weight loss, may point to the risk of relapse with weight regain, by removing the effect of a better insulin sensitivity [14]. RYGB causes profound changes in insulin sensitivity, improved in proportion to the weight loss [15]. Targeting pancreatic  $\beta$  cells functioning would be of extreme importance for indication of surgical treatment of patients with DM2 and lower BMI [16]. Therefore, it is not clear to what extent the obesity model corresponds to the pathophysiology of T2D occurring in overweight or in non-obese patient [14].

The meta-analysis of Yu *et al.* included 17 eligible studies and reported initial remission rate of 63.0% with relapse in 30.0% of T2D patients with obesity, after RYGB. They also concluded that the risk of recurrence of T2D was lower after RYGB than after sleeve gastrectomy [17].

Likewise, Scopinaro *et al.* did not support RYGB weight loss-independent effect on beta-cell function in the T2D patients with obesity class I [7]. In T2D patients with BMI of 25 - 35, remission was achieved in 26.5% at 5 years. The authors concluded that a positive metabolic outcome would be less frequent in overweight and patients with obesity class I [18]. The French National Authority for Health (HAS) sponsored a study to assess the benefit-risk balance of metabolic surgery in patients with overweight or with class 1 obesity, and T2D. The authors demonstrated that remissions were observed, at three years, in 30% to 40% of cases. Surgical techniques included laparoscopic adjustable gastric banding (LAGB), SG and RYGB, with no evidence making it possible to favor one over the others [19]. Almost the same remission rate (40%) was found after biliopancreatic diversion (BPD), in nonobese patients with T2D [20].

Ke *et al.* studied 70 uncontrolled T2D patients who underwent laparoscopic RYGB, followed up above six months. The authors compared the remission rate according to the BMI and found that complete remission was 28.2% of the BMI



< 30 kg/m<sup>2</sup> group and 57.9% of the BMI > 30 kg/m<sup>2</sup> group [18].

In 2006, DePaula *et al.* described a new technique of sleeve gastrectomy associated with a jejunal ileal interposition, to treat obesity and its comorbidities, in 19 patients. After dividing the jejunum 50 cm from the ligament of Treitz, a 100-cm ileal segment was created, 50 cm proximal to the ileocecal valve, interposing it peristaltically in the proximal jejunum [21]. Although ileal interposition was described in 1982, the association with SG was debuting [22]. The rationale for adding a gastric resection was based upon the ileal brake phenomenon, considering that the elevation of ileal hormones after contact with undigested food would increase gastric emptying time [23]. Thus, it could be inferred that ileal procedures that aim to treat obesity and/or diabetes must be associated with gastric manipulation, under the risk of promoting gastroparesis [24].

The same authors, in 2010, demonstrated that if the ileal segment was interposed into the proximal duodenum, diabetes remission was higher [25]. In this paper, the authors did not completely discuss their findings, but in 2008, after finding that the AUC for total gastric inhibitory peptide (GIP) was greater compared with preoperative evaluation, they postulated that the reduction of the stimulus of the duodenum or even complete bypass of food transit would be able to reduce the characteristic GIP-resistant state of T2D. The explanation could be possible found by looking closely at the duodenum as an important organ in metabolic signaling, and its mucosal changes before and after the onset of T2D [26] [27].

Tinoco *et al.*, in 2011, with an 18-month follow up, found remission of T2D in 80% of the patients after SGDII [28].

De Paula *et al.* demonstrated, in 94 patients, the efficacy of SGDII in patients with a BMI < 35 Kg/m<sup>2</sup>. The authors found that insulin sensitivity was restored, and total insulin output increased  $\beta$ -cell glucose sensitivity doubled, with a lower baseline insulin sensitivity as the only predictor of remission [29].

Our choice for surgical treatment of obesity is RYGB (75%) and sleeve gastrectomy (25%), with 5144 procedures done, since 2000. For surgical treatment of T2D we have been using SGDII since 2011. The name bariatric was changed to metabolic surgery in 2007. The finding of improved glucose homeostasis, as well as lipid profile, in patients with obesity and diabetes, facilitated the extrapolation of the bariatric model for the surgical treatment of diabetes. With follow-up, recurrence of the disease was observed in many cases, and a worst surgery performance was related to a lower BMI. It is known that for diabetes to occur, at least insulin resistance and beta cell dysfunction are necessary. Being overweight or obese will impact insulin sensitivity, but diabetes will develop only when insulin secretion fails to match the degree of insulin resistance. In this way, the direct application of the bariatric model to diabetes, considering the high prevalence of obesity in diabetes, did not reach the diabetes prevalence in obesity. In the USA, 15.5% of T2D patients have a BMI of 40.0 kg/m<sup>2</sup> or higher [30].

In the present study, 80% of patients had T2D remission after one year, 74.5% after three years, and 61.8% after five years. The rate of T2D remission after

SGDII is higher than after RYGB (29%) with a five year follow up. Folschi *et al.*, comparing SGDII to medical treatment in T2D obese patients (BMI > 30), found, after five years, remission in 68% of the cases [31].

Parikh *et al.*, on a systematic review with meta-analysis of diabetes remission among patients with a BMI < 35 kg/m<sup>2</sup>, found an overall rate of diabetes remission at 12 months of 54.7% of the cases, the highest one after ileal interposition (80.5% - 95% CI, 59.4 - 92.3%) [32].

Soggia *et al.* demonstrated, in randomly assigned 42 patients with class I obesity and poorly controlled T2D to SGDII, RYGB or clinical diabetes treatment. With an average HbA1c level of 9.3%, the authors showed that 100% of patients who underwent SGDII achieved glycemic control, compared with 46% of those who underwent RYGB and 8% of those treated clinically for diabetes after 1 year of treatment [33].

The feasibility and safety of the procedure were analyzed according to the following criteria: operative time, need for conversion to laparotomy, early post-operative complications, and procedure-related mortality. SGDII can be considered a complex laparoscopic surgery, and reproducibility evaluation is critical. Possibly, this would be the most used argument limiting its use, despite the better results, regarding T2D remission, than those observed after consigned bariatric surgical techniques which had their indication extended to the surgical treatment of T2D. Another matter of debate would be the number of the mesenteric defects to be closed and the risk of internal hernias, complication not found on our series. There is a unique feature on this operation. It was laparoscopically performed since its beginning. This was not observed with other challenging operations. All of them, laparoscopic gastrectomy, laparoscopic Whipple procedure or laparoscopic esophagectomy, all performed in our institution, were standard open procedures.

Postoperative complications (30 days) required surgical approach in 2.08% of the patients. As mentioned, two enteric fistulas, both in the duodenal stump, had a favorable outcome during the same hospital stay. We used an invaginating staple line to the sectioned duodenum, with 3-0 monofilament absorbable suture (Polydioxanone). Duodenal stump leaks have been reported in the surgical literature with a rate of approximately 1% - 6% [32]. The best comparison here would be with the duodenal switch operation, which carries a risk of 1.14% vs. 1.12% for RYGB [34].

Added to the challenge of approaching the duodenum, the presence of atherosclerosis, extensive in long lasting T2D, is associated with anastomotic leakage after abdominal surgery as well as other postoperative complications [35].

Postoperative bleeding occurred in four patients. All patients were treated conservatively with replacement of blood products and clinical support, with improvement of general symptoms. Bleeding rate (4.1%) was considered acceptable, especially when compared to RYGB, where most authors reported rates ranging from 1.5% to 4.1%. Once again, the severity of T2D should be considered, with many cases not suitable of discontinuing the prevention of athe-

rothrombotic events [36].

## 6. Conclusion

In the positive scenario demonstrated by the surgical treatment of T2D, SGDI should be considered and used as a potential therapeutic method, with a high chance of disease remission.

## Conflicts of Interest

The authors declare no competing interests.

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