

Stomach Intestinal Pylorus-Sparing Surgery for Morbid Obesity

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ABSTRACT

Background and Objective: The Roux-en-Y duodenal switch (RYDS) is one of the most efficient forms of bariatric surgery. However, diarrhea, malnutrition, ulcers, and internal hernias have hampered its widespread adoption. The stomach intestinal pylorus-sparing (SIPS) procedure was developed to alleviate these sequelae while retaining the same weight loss as the RYDS. In this study, we report our midterm experience with this novel technique.

Methods: Retrospective analysis was performed on data from 225 patients who underwent a primary SIPS procedure by 2 surgeons at a single center from October 2013 through December 2016.

Results: Two hundred twenty-five patients were identified for analysis. The mean preoperative body mass index (BMI) was 52.4 ± 9.1 kg/m². Forty-eight patients were beyond 2 years after surgery, with data available for 30 patients (62.5% follow-up). Three patients were lost to follow-up. At 2 years, the patients had an average change in BMI of 26.6 U (kg/m²) with an average of 88.7% of excess weight loss. Three deaths were related to the surgery. The most common short-term complication was a leak (2.2%), whereas the most common long-term complication was diarrhea (2.2%).

Conclusion: In conclusion, SIPS surgery is a safe procedure with favorable weight loss outcomes at 2 years.

Key Words: Morbid obesity, Single anastomosis loop duodenal switch, Stomach intestinal pylorus-sparing surgery, Weight loss outcomes.

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INTRODUCTION

The Roux-en-Y duodenal switch (RYDS) is one of the most efficient forms of bariatric surgical therapies available.¹ However, diarrhea, malnutrition, and internal hernias have hampered its widespread adoption.²⁻⁵ In 2007, Sánchez-Pernaute in Spain first performed a modification of the traditional duodenal switch (DS) using a single anastomosis instead of an Roux-en-Y reconstruction with the sleeve formed over a 56-French bougie.⁶ This modification was used to eliminate the internal hernias, diarrhea, and malnutrition associated with the RYDS. The technique was further modified by Mitzman et al⁷ when they created a smaller sleeve (40-French bougie sizing instead of 56) and combined this with less malabsorption (a 300-cm instead of a 250-cm common channel). This modification was named stomach intestinal pylorus-sparing (SIPS) surgery. The preservation of more intestine reduces the risk of malnutrition and diarrhea often associated with RYDS.^{1,8} The preservation of the pyloric valve prevents dumping syndrome associated with the Roux-en-Y gastric bypass (RYGB). The loop configuration maintains the contact between pancreatic enzymes, bile salts, and food, eliminating the ulcers and strictures related to both the RYDS and RYGB.

The SIPS surgery has created much interest in the bariatric community in recent years. The purpose of this study was to detail our experience with the SIPS procedure, especially regarding weight loss and complications. This was a retrospective analysis of procedures performed by 2 surgeons at a single private institution.

MATERIALS AND METHODS

Two hundred twenty-five patients with morbid obesity underwent a SIPS procedure from October 2013 through December 2016. All revision cases of any type were excluded from this study. All the patients were required to provide written informed consent specific to the SIPS procedure before undergoing surgery. Preoperative and postoperative outcome data (weight loss, comorbidity resolution, complications, and mortality) were obtained from a prospectively kept database.

All operations were performed laparoscopically by 2 surgeons, using standardized perioperative and postopera-

tive protocols. Their technique was standardized, and they always assisted each other. A multidisciplinary team that included a nutritionist, a psychologist, and a surgeon, according to a standardized protocol, routinely evaluated each patient after surgery.

Comorbidities included in this study were sleep apnea, type 2 diabetes mellitus (T2DM), hypertension (HTN), hyperlipidemia, and gastroesophageal reflux disease (GERD). The presence of comorbidities was based upon medication use. Sleep apnea was included only if the patient was on a continuous positive airway pressure (CPAP) machine or had a sleep study done. Comorbid conditions were assessed in each patient before the SIPS surgery and at selected follow-up visits.

All patients were required to attend follow-up consultations at our institute at 1 week and 1, 3, 6, and 12 months and then every year after the surgery.

The following parameters were recorded: weight (in pounds), body mass index (BMI) (in kg/m²), percentage of excess BMI lost (%EBMIL) with excess >25 kg/m².

Data regarding complications were based on physician observation or patient self-reporting and were confirmed with appropriate imaging studies and laboratory tests. The early (within 30 days after surgery) and late (after 30 days) complication rates were analyzed.

Statistical Methods

All statistical analysis was conducted with Sigma Plot statistical software (Systat Software, San Jose, California, USA).

Operative Technique

We have been using a standardized surgical technique for the SIPS surgery since 2013. The laparoscopic SIPS surgery was performed with a standard 5-port technique. Initial access was obtained by means of an optical trocar just to the left of the umbilicus. A pneumoperitoneum was established to a pressure of 15 mm Hg with CO₂ gas. A 5-mm 30° laparoscopic camera was used. A liver retractor was placed through the mid epigastrium.

The surgeon (standing on the right side of the patient) operated through the right upper abdominal port and right anterior subcostal port. The assistant surgeon (standing on the left side) operated through the 2 left subcostal ports. After the patient was positioned and the ports placed, the abdomen was inspected, and adhesions were lysed with an EnSeal device (Ethicon, Cincinnati, Ohio,

USA). The standard approach was to split the omentum down to the colon. The first step was to locate the ileocecal valve. We then moved 300 cm proximal to the ileocecal valve. The antimesenteric border of the bowel at this point was attached to the omentum just below the pyloric valve.

At this point, we freed the greater curvature of the stomach in a fashion similar to the technique used in a sleeve gastrectomy, with the EnSeal device (Ethicon), to seal vessels and for blunt dissection. The dissection was then carried medially to the second and third portions of the duodenum. Retrogastric and retroduodenal adhesions were taken down.⁹ The Band Passer (gold tip) (Ethicon) was then used to dissect circumferentially around the duodenum. The duodenum was then transected with a stapler blue load (Ethicon), and an adequate visualization of the biliary tree was attained. The sleeve gastrectomy was then completed after positioning a 40-French ViSiGi 3D orogastric tube (Boehringer Laboratories, Phoenixville, Pennsylvania, USA). The sleeve begins 6–8 cm from the pylorus and ends 1 cm off the angle of His with no buttress or oversewing. The first stapler firing was a green load for women and a black load for men. The next firing was gold, followed by blue loads until completion.

We then created an end-to-side (duodenum-to-ileum) anastomosis by first creating a back row between the 2 structures. The added row was 2-0 silk sutures on an Endo Stitch (Medtronic, Minneapolis, Minnesota, USA) placed interrupted (4–5 sutures) and secured with a Ti-Knot device (LSI Solutions, Inc., Victor New York, USA). Enterotomies were made on both structures with regular electrocautery. An anastomosis was created with a stapler blue load (60-mm), using ~30 mm of the stapler. The common defect was then closed using 3-0 Vicryl suture on the Endo Stitch (Medtronic) in a running, continuous fashion, starting at each corner. The anastomosis was then oversewn with an additional layer of 2-0 silk, this time on a free needle, in an interrupted fashion (**Figure 1**).

The patients were discharged when oral intake was adequate and the pain was well controlled. All patients attended a follow-up visit with the operating surgeon at 10–14 days after surgery.

RESULTS

Two hundred twenty-five patients were identified for analysis. Three patients were lost to follow-up.

The mean preoperative BMI and weight were 52.4 ± 9.1 kg/m² and 324.4 ± 71.7 lb, respectively (**Table 1**). The

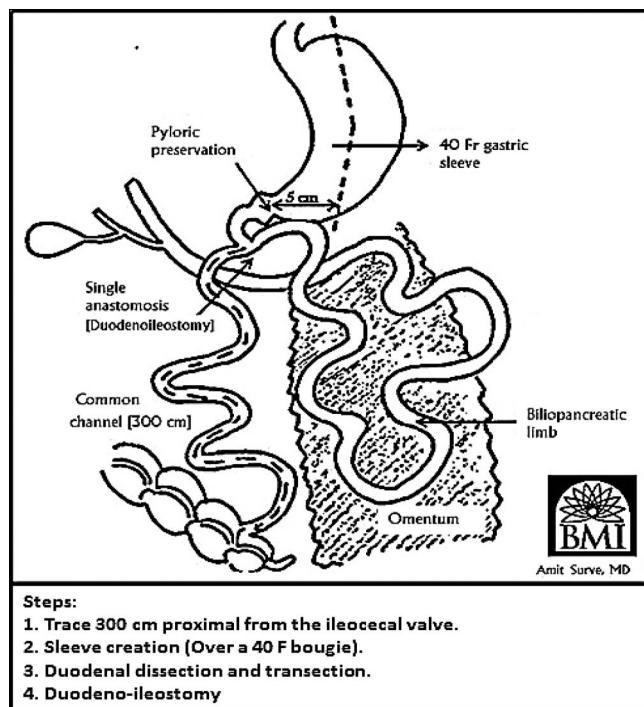


Figure 1. Hand-drawn sketch of SIPS surgery.

mean operative time was 83 ± 15.4 minutes. The mean blood loss and length of stay was 25 ± 5 mL and 1.3 ± 0.7 days, respectively. Two hundred twenty-four cases were successfully completed with the laparoscopic approach. One case was converted to an open procedure. Of 225 patients, 10 underwent linear stapled duodenoileostomy (DI), and 215 had a hand-sewn one.

Complications after the SIPS surgery can be seen in **Tables 2** and **3**. The overall short- and long-term complication rates were 4.4% and 8%, respectively. The most common short-term complication was a leak (2.2%), whereas the most common long-term complication was diarrhea (2.2%). The 90-day readmission and reoperation rates were 4.5% and 3.5%, respectively. The mortality rate was 1.3%.

Weight Loss Analysis

Follow-up data were obtained for all patients. Patients experienced mean losses of 36.7, 50.6, 60.4, 71.3, 81.1, and 88.7% of their excess weight at 3, 6, 9, 12, 18, and 24 months, respectively (**Table 4**). At 24 months, the patients lost an average BMI of 26.6 ± 7.1 points.

Comorbidity resolution rates can be seen in **Table 5**. Remission of comorbidities was defined as normalization of the corresponding baseline characteristics without any

Table 1. Characteristics and Operative Details of Patients Who Underwent SIPS Surgery Between From October 2013 through March 2016

	Value
Characteristic	
Subject (n)	225
Male/female (n)	50/175
Age (year)	49.3 ± 11.3
Follow-up (mo)	9.9 ± 8.1
Preoperative weight (lb)	324.4 ± 71.7
Preoperative BMI (kg/m^2)	52.4 ± 9.1
Ideal body weight (lb)	154 ± 19.1
Excess body weight (lb)	171 ± 62.4
Operative Details	
Operating time (min)	83 ± 15.4
Blood loss (mL)	25 ± 5
Length of stay (day)	$1.3 \pm .7$

Unless otherwise stated, data are expressed as the mean \pm SD.

drugs or use of a continuous positive-pressure airway machine. Also, we have presented only a resolution and not changes in the degree of severity of the comorbidities. These results, therefore, represent an underreporting of the patients' improvement.

DISCUSSION

In the present study, we observed patients with obesity who underwent a SIPS procedure at our center. The results confirm that SIPS surgery is effective in promoting weight loss. The weight loss was impressive at 2 years, but requires further and more detailed study. Analyses of our results suggest that, on average, a patient will lose >26 BMI points at 2 years after surgery.

Advances in the surgical techniques in bariatric procedures have matched the exponential rise in obesity. Traditionally, bariatric procedures have been divided into restrictive procedures, malabsorptive procedures, or a combination of both.

Malabsorptive surgery has been shown to provide excellent weight loss and good rates of remission of coexisting conditions. However, there are some concerns about post-operative and malnutrition risks associated with this procedure, and consequently, the RYGB is still the most commonly performed procedure and is widely considered the

Table 2.

Short-Term Complications With SIPS Surgery

Complication	n	Revision (n: Procedure)
Leak from the DI	5*	1/5: RYDS
Stricture at the DI	3**	0
Small bowel injury	1	0
Death related to surgery	2	

*Five patients experienced a leak from the DI (2.2%). Of those 5 patients, 2 experienced a leak in the first 24 hours and were taken back to the operating room (OR). In those patients, we oversewed the DI with 2 additional 2-0 silk sutures in one patient and recreated the loop DI in the second patient (open case). The third patient experienced a leak 2 weeks after surgery. This patient had an abscess around the DI. Percutaneous abscess drainage was performed. The fourth patient needed a percutaneous drain, and no other intervention was needed. The fifth patient developed sepsis, at the third postoperative week. A computed tomography (CT) scan revealed a leak from the DI. This patient was revised to RYDS. The patient continued to leak from the DI (drains in place) and developed 3 small bowel leaks secondary to an open abdomen. The patient was operated on once more in an attempt to control the leak with no success and was then transferred to long-term care with only 1 active leak. Nine months after RYDS, this patient underwent revision to RYGB with significant lysis of adhesions. The patient was minimally improved but then opted for hospice care and expired.

**Three patients had a stricture at the DI. Of the 225 patients, 10 received a hand-sewn DI. Of those, 3 patients (30%) experienced a stricture. An esophagogastroduodenoscopy (EGD) with balloon dilation was performed on all 3 patients with resolution of their symptoms (none required an additional dilation). There was 1 death resulting from a massive pulmonary embolism. The case was reviewed, and the patient had adhered to all postoperative instructions created to decrease the risk of pulmonary embolism.

gold standard in bariatric surgery. Weight loss failure, weight recidivism, and recurrent comorbidities after the RYGB are challenging problems for bariatric surgeons.¹⁰⁻¹² Currently, there is no clear concurrence about what is the best bariatric procedure to be performed.

The procedure with the highest average weight loss is the biliopancreatic diversion with duodenal switch (BPD-DS). However, a matched cohort revealed that the weight loss and nutritional outcomes between the BPD-DS and the SIPS procedure were statistically similar at 2 years. Also, complications were fewer with the SIPS surgery than with the BPD-DS.¹³ The SIPS surgery is a combination of both restriction and malabsorption which has been successful in achieving significant weight loss in the superobese population (BMI > 50 kg/m²).¹³

A recent study by Cottam et al⁸ compared the outcome of the SIPS surgery to that of RYGB. The SIPS surgery had

Table 3.

Long-Term Complications with SIPS Surgery

Complication	n	Revision (n: Procedure)
Stricture at the DI	1	
Edema*	3	1/3: CCL
Diarrhea**	5	4/5: CCL
Malnutrition***	3	1/3: CCL 1/3: Feeding tube 1/3: J tube
Dysphagia****	2	2/2: RYGB
SMVT	1	–
Liver abscess	1	–
Death related to surgery *****	2	

CCL, common channel lengthening; SMVT, superior mesenteric venous thrombosis. *Three of the patients experienced peripheral edema. Of those, 1 needed CCL achieved by taking down the anastomosis, creating a formal side-to-side ileal anastomosis, and then recreating the surgery with 100- to 200-cm more absorption. The other two resolved with dietary coaching. The onset of edema was as early as 6 months. **Five patients experienced chronic diarrhea, usually starting within the first 3 months. Of the 5 patients, 1 patient's complaints resolved over time, but the other 4 patients had to undergo CCL. All cases were in our first 25 patients, and the length of the common channel on all patients was less than 175 cm. The measuring technique was changed to marked graspers with 5- and 10-cm marks. We have not had problem with this since that time. ***Three patients experienced malnutrition. Of which, one needed a feeding tube. The cause of malnutrition was a sleeve stricture. ****Of these 3 patients, 2 were revised to RYGB. These patients had an angle of incisura narrowing (hour glass stricture of the sleeve). Attempts were made to correct the problem by esophagogastroduodenoscopy (EGD) with dilation, gastric stents, EGD with dilation using an achalasia balloon (105 French), with no resolution. A decision was then made to bypass above the problem area. *****Death was recorded in 6 of the 225 patients. Of those, 2 deaths were related to surgery and have been discussed in detail above. Two deaths were attributed to suicide and were both over 2 years after surgery. One death was attributed to liver failure in a patient who had stage III cirrhosis at the time of surgery (optimized). This death was >18 months after surgery. The cause of the last death was unknown (no autopsy performed) and occurred almost 24 months after surgery.

better diabetes resolution than the RYGB, but the 2 operations had similar weight loss. A comparison between the SIPS procedure and the sleeve gastrectomy (SG) also revealed that the SIPS surgery led to 30% greater weight loss than the SG at 2 years and superior comorbidity resolution.¹⁴ When the SIPS procedure was compared to traditional DS at 2 years, there was no difference in weight loss, and the comorbidity resolution rate was the same.¹³ However, although it cannot be said that this technique

Table 4.
Weight Loss Outcomes After SIPS Surgery

	3 Months (n, % = 187/213, 87.7%)	6 Months (n, % = 148/181, 81.7%)	9 Months (n, % = 114/152, 75%)	12 Months (n, % = 93/133, 69.9%)	18 Months (n, % = 59/89, 66.2%)	24 Months (n, % = 30/48, 62.5%)
Change in BMI (kg/m ²)	9.5 ± 3.5	14.2 ± 5	17.2 ± 5.8	20 ± 6.2	22.4 ± 7.1	26.6 ± 7.1
%EBMIL	36.8 ± 10.8	50.8 ± 14.4	60.5 ± 17.1	71.5 ± 20.1	81.1 ± 23.3	88.8 ± 20.2
%TWL	18.6 ± 5	26 ± 6.9	31.5 ± 8.3	37 ± 9.4	41.8 ± 11.3	47.8 ± 10.4
%EWL	36.7 ± 10.9	50.6 ± 14.6	60.4 ± 17.3	71.3 ± 20.4	81.1 ± 23.7	88.7 ± 20.3
TWL (lb)	61.5 ± 23.4	87.7 ± 34.6	108.6 ± 42.7	125.1 ± 44.2	142 ± 50.5	167.7 ± 51.8

Data are expressed as the mean ± SD. %TWL, percentage of total weight loss.

Table 5.

Comorbidity Rates Before and at 12 Months After SIPS Surgery

Comorbidity	Before Surgery (n)	After Surgery	
		Available Data n (%)	Resolved n (%)
Sleep apnea	137	90 (65.5)	85 (94.4)
T2DM	103	63 (61.1)	25 (88.8)
HTN	158	92 (58.2)	63 (68.4)
Hyperlipidemia	74	47 (63.5)	37 (78.7)
GERD	78	50 (64.1)	16 (86)

will have different weight loss outcomes or comorbidity resolution at 5 years, certainly the 2-year data for the SIPS surgery has better weight loss outcomes and comorbidity resolution when compared to the SG. Based on the data from both Cottam et al^{8,14} and Sanchez et al,¹⁵ the diabetes resolution at 2 years is better for the SIPS procedure than both the SG and the RYGB.

Mitzman et al⁷ published the initial experience with the SIPS surgery. At 12 months (62% follow-up), the excess weight loss (%EWL) was reported to be 72%. In our study, at 12 months (69.9% follow-up), the %EWL was 0.7% less than that observed by Mitzman et al.

Dumping syndrome is a common complication after RYGB, as reported in up to 70% of patients.¹⁶ When performing the SIPS procedure, the pyloric valve and duodenum are left functioning. The pylorus controls the solid emptying, reduces the chance of dumping syndrome, and assists in maintaining a physiologically based rate of gastric emptying. None of our patients experienced dumping syndrome.

Another interesting and rare complication that occurred in 3 patients within 30 days of surgery was a stricture at the DI. The strictures were caused by technical difficulties, and because our technique has changed from linear to hand sewn, no further strictures or leaks have occurred. These strictures were subsequently dilated in a stepwise fashion starting with an 8-mm balloon and finishing with an 18-mm balloon.

Another area of significance is the diabetes mellitus (DM) remission rates. Marceau has reported the BPD-DS as having a 93%, 20-year diabetes resolution rate.¹⁷ A recent publication by Roslin et al¹⁸ states that the DS is the best option for T2DM remission and metabolic syndromes. In our study, the T2DM remission rate was 88.8%.

At present, data on the SIPS surgery are limited. This study is one of the few reports on the procedure. Our study had some limitations too. The current study was a retrospective instead of a prospective analysis. One of the limitations of the study was the relatively small sample size. Consistent follow-up visits after weight loss surgery are known to be challenging. The further limitation of this study includes the lack of long-term follow-up. As mentioned earlier, the SIPS surgery is a combination of both restriction and malabsorption, and malabsorptive procedures are associated with more nutritional deficiencies.^{19,20} Our report lacks nutritional data. Although nutritional data were not collected, clinical markers of malabsorption were recorded.

The results of the present study should be confirmed in similarly designed studies with greater sample sizes and involving the measurement of all nutritional parameters.

CONCLUSIONS

The SIPS surgery is safe and efficacious. At 2 years, our study model showed that the SIPS surgery had effective weight loss results. However, the use of this bariatric procedure is limited compared with other surgical options.

Additional long-term follow-up and larger study populations are necessary to evaluate the outcomes of this novel technique further and assess long-term complications. Also, more research is needed to ensure that weight loss continues long term.

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