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ORIGINAL CONTRIBUTIONS

A Matched Cohort Analysis of Stomach Intestinal Pylorus Saving (SIPS) Surgery Versus Biliopancreatic Diversion with Duodenal Switch with Two-Year Follow-up

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Abstract

Background In bariatric surgery, the procedure with the highest average weight loss is the biliopancreatic diversion with duodenal switch (BPDDS). A new simplified duodenal switch called the stomach intestinal pylorus sparing (SIPS) surgery with less malabsorption and one fewer anastomosis claims to have similar outcomes when compared to the BPDDS.

Methods A retrospective matched cohort analysis of SIPS versus BPDDS patients in a single private practice was obtained by matching every BPDDS to a SIPS patient of the same gender and BMI. Excess weight loss percentage (EWL), BMI, and percentage total weight loss (%TWL) were compared. Additionally, comorbidity resolution, nutritional data, and complications were also compared. Data was analyzed using both descriptive and comparative statistics.

Results Over 2 years, there was no statistical difference in weight loss between BPDDS and SIPS. There also was no difference in nutritional data between the two procedures pre- and post-op. Complication rates were lower in SIPS however, due to the small sample sizes this is not statistically significant.

Conclusion Weight loss and nutritional results between SIPS and BPDDS are similar at 2 years. However, there are fewer complications with SIPS.

Keywords SIPS · BPDDS · Duodenal switch · Diabetes resolution · Loop duodenal switch · Single anastomosis duodenal switch · Bariatric surgery · Obesity

Background

In the setting of morbid obesity, the most efficacious treatment for it is surgery. Out of the procedures available the biliopancreatic diversion with duodenal switch (BPDDS) has the highest weight loss on average [1]. However, it is only performed by a small minority of surgeons due to its complexity and complications and accounts only for 2.1 % of bariatric

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Table 1 Pre-operative demographic statistics

	SIPS	BPDDS	*P* value
N	61	61	1
Male/female	23/38	23/38	1
Height	68″ ± 4”	67″ ± 4”	.17
Weight	330.8 ± 77.2	318.7 ± 60.7	.338
BMI	50.1 ± 8.6	50.2 ± 8.6	.949
Age	47 ± 14	52 ± 12	.036
Sleep apnea	32 (52 %)	45 (74 %)	.143
Hypertension	42 (69 %)	17 (28 %)	<.001
Diabetes	31 (51 %)	32 (52 %)	1
GERD	33 (54 %)	33 (54 %)	1

Data is presented as averages ± standard deviations or as the amount with a person with a comorbidity

surgeries in the USA [2]. So, most patients with the highest BMI's are not offered this as an option by their surgeons. Additionally, the sleeve gastrectomy (SG) (the first part of the duodenal switch) is not an effective operation for those with high BMI's [3] and these patients are often referred for Roux-en-Y gastric bypass (GBP). Despite the LRYGBP weight loss being better than the sleeve in the early and mid-term in the long-term, the data is equivocal and the complication rate is much higher.

In 2007, Sánchez-Pernaute and Torres in Spain started performing a single anastomosis duodenoileal bypass with a 250 cm common channel and performing the sleeve over a 54-French bougie. The main reason was to simplify the BPDDS and avoid the complications associated with Roux limb formation. With this, they postulated that weight loss would be slightly less than BPDDS and be more than the GBP. His first five papers showed great weight loss and lower complication rates when compared to traditional Roux-en-Y DS and Roux-en-Y bypass [4–9].

In the USA, we began in 2013 doing a slight variation of Sánchez-Pernaute and Torres' single-anastomosis duodenoileal bypass by making the common channel slightly longer at 300 cm and making the sleeve slightly smaller with a 40-French bougie. One of the reasons for our group to not perform SADI-S as described by Sánchez-Pernaute and Torres was due to malnutrition fears. In his papers [4–9], he observed about a 1 % incident of malnutrition, so we postulated that increasing it to 300 cm would diminish this even further. This variation we named SIPS as in stomach intestinal pylorus saving (SIPS) surgery. We started performing this after having done standard BPDDS since 2011. We were satisfied with weight loss of BPDDS, but unsatisfied with the frequency of diarrhea, smelly stools, flatulence, vitamin deficiencies, and the potential for internal hernias that was observed in our practice. SIPS, we believed, allowed us to keep the weight loss and diabetes resolution seen in the BPDDS, without as many problems. This retrospective matched cohort analysis at 2 years between BPDDS and SIPS will test that hypothesis.

Methods

All patients in this study had either SIPS or BPDDS at a single institution from 2011 to 2015. All SIPS and BPDDS surgeries were performed by one of two surgeons at the same institution. All revisional cases of any type were excluded from this study. IRB approval for this study was obtained from the Quorum IRB study number 31353. All patients gave written consent for their data to be used in this study.

Surgical technique for BPDDS begins by locating the ileocecal valve. The small bowel was traced retrograde to 150 cm and marked. Next, another 150 cm was counted retrograde and transected using a GIA stapler. The biliary limb was then anastomosed to the ileum at the 150 cm mark using a GIA stapler using a side-to-side anastomotic technique. The enterotomy was closed with a GIA stapler as well. The mesenteric defect was closed with silk suture. This created a 150 cm common channel and a 150 cm Roux limb.

At this point, we dissected into the lesser sac and then sequentially fired a GIA stapler 5 cm from the pylorus onto the stomach following the 40-French bougie up to the angle of HIS. We did not use any buttressing material nor was the

Table 2 Post-operatively weight loss results between the procedures

%EWL	3 months	6 months	9 months	12 months	18 months	24 months
SIPS	41.8 ± 14.6	58.3 ± 16.5	69.5 ± 17.8	78.7 ± 19.2	85 ± 16.5	83.7 ± 17.3
N	57/61 (93 %)	54/58 (93 %)	43/56 (77 %)	40/51 (78 %)	30/43 (70 %)	19/27 (70 %)
BPDDS	45.7 ± 17.4	63.7 ± 20.7	75 ± 22.7	82.7 ± 24.3	91 ± 23.8	95.3 ± 23
N	49/60 (82 %)	49/60 (82 %)	47/60 (78 %)	47/60 (78 %)	46/60 (77 %)	43/60 (72 %)
P value	.212	.145	.207	.403	.233	.054

Percentage excess weight loss (%EWL) data is presented as averages ± standard deviations. *N* values are expressed as the amount of patients that followed up at each time interval over the total number of patients that were that far out from surgery

Table 3 Post-operatively weight loss results between the procedures

BMI	3 months	6 months	9 months	12 months	18 months	24 months
SIPS	40.5 ± 8	36.2 ± 6.9	33.1 ± 6.4	30.8 ± 6.1	28.9 ± 4.4	29.1 ± 4.7
N	57/61 (93 %)	54/58 (93 %)	43/56 (77 %)	40/51 (78 %)	30/43 (70 %)	19/27 (70 %)
BPDDS	38.8 ± 6.8	34.7 ± 6.4	32 ± 6.1	30.1 ± 6.1	28 ± 5.5	26.8 ± 5.1
N	49/60 (82 %)	49/60 (82 %)	47/60 (78 %)	47/60 (78 %)	46/60 (77 %)	43/60 (72 %)
P value	.245	.257	.406	.595	.454	.099

Body mass index (BMI) data is presented as averages ± standard deviations. *N* values are expressed as the amount of patients that followed up at each time interval over the total number of patients that were that far out from surgery

staple line oversewn. We then dissected free the duodenal bulb 3 cm from the pylorus, circumferentially. It was transected using a GIA stapler. We then oversewed the duodenal stump using PDS suture. Next, we brought up the Roux limb and sewed it to the proximal duodenal stump using 2.0 polysorb. Enterotomies were made in both limbs and 3.0 polysorb was used to do another posterior row. An anterior row was also done using 3.0 polysorb.

The surgical technique for SIPS is similar to the single anastomosis duodenal switch (SADI-S) as published by Sánchez-Pernaute and Torres [9]. Although the anastomosis is the same, our common channel is 300 cm rather than 250 cm. The SG is over a 40-French bougie as opposed to a 54.

Patients were selected for each surgery based on when they came in. Those who came in between 2011 and 2013 had the option for BPDDS or gastric bypass and only those who chose the BPDDS received this treatment. From 2013 to 2016, BPDDS was no longer an option for patients in our practice. Patients could choose between SIPS and LRYGBP. Patients chose SIPS based on an extensive pre-operative educational experience and signed a specific informed consent detailing the SIPS procedure and how it differed from traditional BPDDS.

Data for each procedure was gathered retrospectively from a prospectively kept database. This study was a matched cohort based upon BMI and gender. Due to only having performed 61 BPDDS primary procedures, this left us with 61 BPDDS patients to be matched with SIPS patients. Matching was done in a blinded fashion free from long-term results by looking only at lists with randomly assigned ID numbers for each patient with each patient's gender and pre-operative BMI. Criteria for SIPS patients to be matched to BPDDS patients were BMI within 1 point and same gender. If there was no match for a patient, they were excluded from the study. 122 patients met the inclusion criteria for this study (61 for each procedure). All patients had at least 3 follow-up points after surgery.

Excess weight loss (EWL), body mass index (BMI), and percentage total weight loss (%TWL) were the data points used for weight loss in this study. Demographic data from both procedures was compared using *t* tests. Comorbidities included in this study were type 2 diabetes mellitus (T2DM), gastroesophageal reflux disease (GERD), hypertension (HTN), and sleep apnea. Presence of a comorbidity was based upon medication use. In the case of sleep apnea, it was only included if the patient was on a CPAP machine or had sleep study done.

Each patient had their weight loss modeled on a non-linear regression curve. Each patient then had their weight loss interpolated at 3,6,9,12,18, and 24 months. A patient data for each interpolated weight loss was only included if the individual regression had an r^2 value greater than .95 (simply, this means that at most 5 % of the weight loss cannot be explained by simply time since the operation, but by extraneous variables). At each time interval, weight loss was measured and

Table 4 Post-operatively weight loss results between the procedures

%TWL	3 months	6 months	9 months	12 months	18 months	24 onths
SIPS	19.5 ± 5	27.3 ± 6.1	32 ± 7.3	36 ± 8.5	39.1 ± 9	38.7 ± 9.3
N	57/61 (93 %)	54/58 (93 %)	43/56 (77 %)	40/51 (78 %)	30/43 (70 %)	19/27 (70 %)
BPDDS	20.9 ± 6.4	29.5 ± 7.6	34.8 ± 8.7	38.4 ± 9.6	42.4 ± 9.9	44.2 ± 11.7
N	49/60 (82 %)	49/60 (82 %)	47/60 (78 %)	47/60 (78 %)	46/60 (77 %)	43/60 (72 %)
P value	.209	.107	.103	.224	.145	.157

Percentage total weight loss (%TWL) data is presented as averages ± standard deviations. *N* values are expressed as the amount of patients that followed up at each time interval over the total number of patients that were that far out from surgery

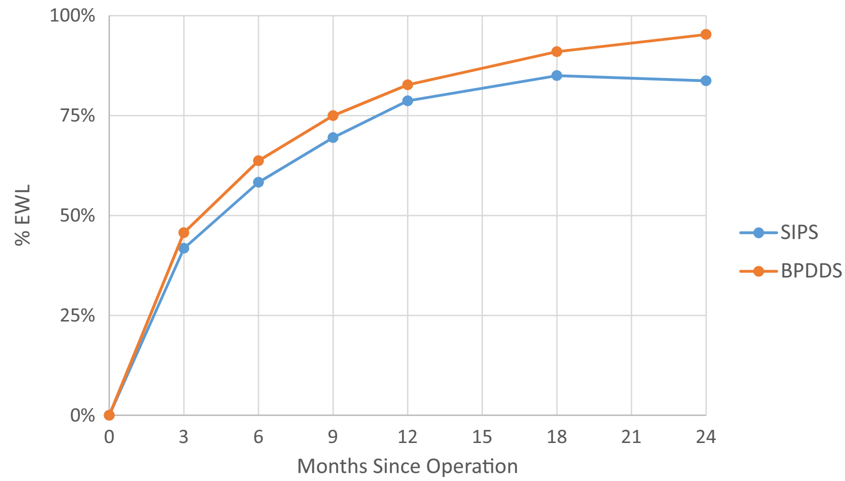

Fig. 1 Shows the difference in %EWL over the course of 2 years between SIPS and BPDDS. For values and standard deviations consult Table 2

then averages and standard deviations were calculated. Weight loss results were then compared using *t* tests.

Nutritional data and complications were gathered for each patient. Chi-squared tests, Fisher exact tests, and *z* tests were then run to compare the comorbidities and nutritional rates between the two procedures.

All statistical analyses were run through Sigma Plot statistical software.

Results

Pre-operative demographic statistics were gathered and presented on Table 1. The only categories that were statistically significantly different were age and hypertension rates. Post-operatively weight loss results between the procedures were similar for BMI, EWL, and %TWL at each time interval (Tables 2, 3, 4 and Figures 1, 2, 3).

Nutritional data is found on Table 5. There were no significant differences between SIPS and BPDDS patients in terms of percentages of patient with abnormal values. Diabetic patients returned to normal levels of hemoglobin A1C (HBA1C <6.0) in 86 % of SIPS patients and 87 % of BPDDS patients ($p = .701$).

Mean operative times were statistically significantly different (P value <0.001) with SIPS taking a mean of 70± 14 min and BPDDS a mean of 137± 36 min.

Short-term complication rates are presented on Table 6. Six people required reoperations in the BPDDS group in the short term; two people required operative abscesses drainage, two patients had leaks at the duodenoileostomy, one person had a small bowel obstruction, and another had a duodenal stump leak. In the SIPS group, only one person required reoperation from a sleeve stricture that was a result from scar tissue from a prior Nissen fundoplication and the ensuing dilation caused a small bowel perforation.

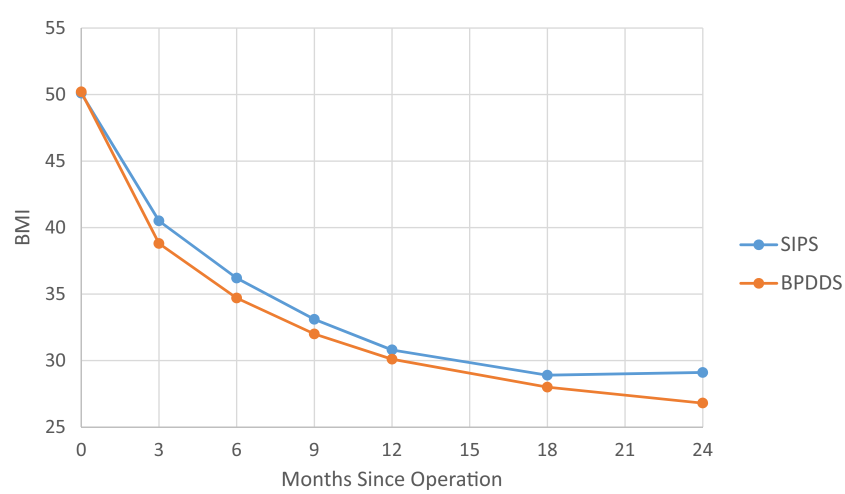

Fig. 2 Shows the difference in BMI over the course of 2 years between SIPS and BPDDS. For values and standard deviations consult Table 3

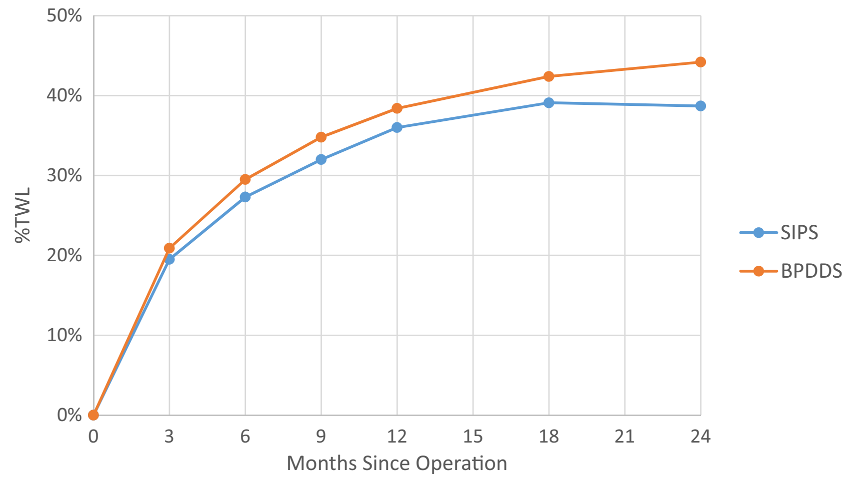

Fig. 3 Shows the difference in %TWL over the course of 2 years between SIPS and BPDDS. For values and standard deviations consult Table 4

Long-term complication rates are presented on Table 7. Three people needed reoperations in the BPDDS group. One person had liver failure requiring the DS to be reversed to a SG. One person had malnutrition that could not be treated with vitamins and supplements and required a common channel lengthening from 150 to 280 cm. One person had severe vomiting that was found to be a small bowel obstruction. In the SIPS group, only one person required reoperation. This person had diarrhea with malnutrition. Once, the patient was operated on, the patient was diagnosed with a short common channel of 160 cm common channel instead of the 300 cm standard. The common channel was lengthened to 450 cm and the problem was gone on the first operative day.

Discussion

There are several methods available to determine the effectiveness of a procedure. The matched cohort allows one to start out with similar patients and see the end results. We were able to perform this cohort analysis since our practice only performed 61 traditional BPDDS. This gave us ample opportunity to match each BPDDS patient with a SIPS patient. We did this in a blinded fashion in order to not skew the results with a bias towards one procedure or the other. Patients were also given the same training and regimen pre- and post-operatively. This eliminated practice variability as a cause of differences between the groups.

Table 5 Significant differences between SIPS and BPDDS patients in terms of percentages of patient with abnormal values

	SIPS				BPDDS				Statistical difference	
	Pre op		1 year post-op		Pre-op		1 year post-op		*P* value	
	Abnormal	Total	Abnormal	Total	Abnormal	Total	Abnormal	Total	Pre	Post
HBA1C	35	54	7	36	42	57	4	34	.420	.515
Glucose	27	59	8	39	32	60	6	36	.521	.771
Insulin	37	55	1	19	30	59	0	25	.112	.432
Vit D	30	53	15	37	40	58	20	34	.250	.157
Vit B1	15	52	5	32	17	56	5	29	.969	1
Vit B12	3	54	14	37	4	59	7	35	.904	.123
Ferritin	8	50	7	37	5	61	5	34	.329	.756
Ca	4	58	2	39	2	60	4	34	.644	.408
Alb	1	30	3	39	0	22	5	36	1	.469
TP	1	29	4	39	0	22	5	36	1	.730
Cholesterol	20	58	1	20	28	59	0	28	.215	1
TG	31	58	3	20	32	59	2	28	.920	.636

Data is presented as abnormal amounts of people with totals at pre-op and 1 year post-op for both procedures

Table 6 Short-term complication rates

Short-term complications			
SIPS		BPDDS	
Nausea	8	Intra-abdominal abscess	2
Vomiting	3	Anastomotic leak	2
Small bowel perforation	1	Sepsis	2
Sleeve stricture	1	Postoperative bleed	2
Post-operative bleed	1	Mild renal failure	2
Low oxygen saturation	2	Duodenal stump leak	1
Ileus	2	Stricture	1
		Nausea	1
		Vomiting	1
		Peritonitis	1
		Small bowel obstruction	1

Data is presented as the number of patients with the specific complication

Many comparative studies have differing amounts of males and females. This has shown to have variable results [10–13]. The matched cohort based upon gender helped eliminate this is as a factor in differences in results. The most consistent preoperative predictor of weight loss is preoperative BMI [14–17]. In matching these two groups in this way, there was an elimination of the common variability that can show up in comparing the totals from both groups.

While these groups were matched for BMI and gender they were not matched up for T2DM. This has shown to sometimes to be a factor in weight loss results [18–20]. However, the BPDDS group only had one more patient with diabetes than the SIPS group. So, this was eliminated as a factor that could affect weight loss results.

However, one of our demographic characteristics, age, was shown to be significantly different with the BPDDS patients being statistically significantly older than the SIPS patients. Age has conflicting evidence for it to be a predictor of weight loss results [17, 18, 20, 21]. It is impossible to say if this skewed our results in our study.

With our comorbidities' make-up between the two procedural groups, only HTN was found to be significantly different. HTN has not been shown to be a factor in poor results in weight loss surgery [22, 23].

The weight loss results presented in this work are not currently outside of the currently published values [4–8, 24–26]. This shows that SIPS weight loss results are reproducible across differing practices and times. Our weight loss results are also in line with BPDDS results recently published [27, 28]. This strengthens our study comparison of these two malabsorption procedures.

Many of the complications in both groups were the result of sleeve part of the DS and SIPS procedure. These would not change regardless of SIPS or DS and these are not expected to change going forward [29]. However, in general, with only 61 patients in each group and a generally low overall complication rate, it is impossible to draw statistical conclusions rates about complications between the two groups. Additionally, the higher overall rate of complications of the BPDDS could be attributable to the learning curve. The complications presented as part of the study are only for completeness.

One of the common fears of the BPDDS is malnutrition rates being too high for the small amount of extra weight loss and no change in patient satisfaction [30]. SIPS procedures in this study were shown to not have any incidences of uncontrolled malnutrition when done correctly. The one found there was due to a miscounted common channel, but once rectified went away. This is especially significant since two of the five patients with malnutrition had to have their BPDDS revised and their bowel limb lengths were correct.

Another way this difference in malabsorption pitfalls shows up is in high diarrhea rates [31]. In the BPDDS group there was a 12 % rate of chronic diarrhea. However, in the

Table 7 Long-term complication rates

Long-term complications			
SIPS		BPDDS	
Diarrhea	1	Diarrhea	7
Common channel lengthening	1	Common channel lengthening	1
Abdominal pain	3	Abdominal pain	1
GERD	6	GERD	4
Malnutrition	1	Malnutrition	5
Nausea/vomiting	4	Nausea/vomiting	3
Failure to lose 50 % EWL at 2 years	1	Failure to lose 50 % EWL at 2 years	1
Constipation	2	Small bowel obstruction	1
Gastric stenosis	1	Hiatal hernia	3
		Liver failure	1

Data is presented as the number of patients with complication

SIPS group, there were more cases of constipation than diarrhea. For all the fear and precautions involved in post-operative prevention of diarrhea, the results of diarrhea were truly surprising. This may also show that the malnutrition fears of SIPS while valid may be exaggerated.

In our vitamin and nutritional analysis, we were able to not find any statistical significant difference between the two procedures. This is quite remarkable due to the level of malabsorption already being acceptable to most surgeons that perform the BPDDS and the wider bariatric surgical community. Showing that these two procedures are similar should allow SIPS to not be looked at with as much trepidation as many surgeons see it right now.

Additionally, our data conclusively shows that you can replete nutritional stores while the patients are actively losing when looking at Vit D, B1, and B12. Iron, on the other hand, is very difficult. We found that if a patient was deficient pre-op they will also be post-operatively for both procedures.

Additionally, when we compare our nutritional data with Higa et al. and his long-term follow-up after gastric bypass [32], we find in our practice that we have lower rates of abnormal values for B12 (81 % for GBP v 20 % for SIPS), Ca (12.5 % for GBP v 5 % for SIPS), and albumin (30.8 % for GBP v 8 % for SIPS) by quite a lot for both the SIPS and BPDDS. We do not have a physiologic reason to explain these results. Perhaps our clinic does a better job of pre-operative education or there are additional factors involving the gastric bypass that we currently do not understand.

Another area of significance is the diabetes remission rates. BPDDS has been reported by Marceau as having a 93 % 20-year diabetes resolution rate [27]. Torres reported a slightly smaller remission rate than Marceau, but Torres had more insulin-dependent diabetic and stricter resolution criteria [7]. Our cohort did not have many insulin dependent patients as Torres so our rate of 86 for SIPS and 87 for BPDDS was higher. This lends credence that SIPS should retain the excellent diabetes resolution rates that BPDDS does.

A common concern of SIPS may come from the question of if the BPDDS is already a well-accepted procedure of why the SIPS even need to be around. The answer may come in helping more patients have higher amounts of weight loss since SIPS is a much easier operation to perform as demonstrated by average operative times being about half that of a BPDDS.

Another common concern of SIPS is the potential for bile reflux. Due to the loop configuration the reasoning goes that this procedure is unacceptable because of the potential for this problem. However, the loop gastric bypass has a loop configuration and rates of bile reflux are less than 1 % in long-term follow-up in socialized medicine countries that can track re-operation [33–35]. We did not see any patients with this problem in our cohort. This has been our experience for all SIPS cases in our practice to date.

There are potential problems with SIPS which include abnormal filling of the afferent limb, and volvulus around the single anastomosis but these are very rare and were not encountered in this study [36, 37].

One weakness of this study may be in the learning curve of the BPDDS procedure. This may have skewed the mean operative time. However, there was also a learning curve with the SIPS procedure and the operative times were still lower than the BPDDS. This is mostly due to having to avoid a second anastomosis and less overall anatomical reconstruction. However, there most certainly was refining of technique over time since the primary surgeon had performed about 190 SIPS procedures by the end of the study period. This may have influenced surgical times as well.

Another weakness of this study is it being retrospective in nature. There is no doubt that a randomized prospective trial would have been far superior.

Conclusion

SIPS offers comparable weight loss, nutritional data, and diabetes resolution when compared to BPDDS. SIPS as a procedure has less anatomical reconstructions to perform than traditional BPDDS and achieves similar results.

Compliance with Ethical Standards

Statement of Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Inform Consent Since this is a retrospective study formal consent is not required for this type of study.

Conflict of Interest Austin Cottam has no conflicts of interest to declare.

Daniel Cottam the corresponding author reports personal fees and other from Medtronic, outside the submitted work.

Dana Portenier has no conflicts of interest to declare.

Hinali Zaveri has no conflicts of interest to declare.

Amit Surve has no conflicts of interest to declare.

Samuel Cottam has no conflicts of interest to declare.

Legrand Belnap has no conflicts of interest to declare.

Walter Medlin has no conflicts of interest to declare.

Christina Richards has no conflicts of interest to declare.

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