**ORIGINAL CONTRIBUTIONS** 





# An Analysis of Mid-Term Complications, Weight Loss, and Type 2 Diabetes Resolution of Stomach Intestinal Pylorus-Sparing Surgery (SIPS) Versus Roux-En-Y Gastric Bypass (RYGB) with Three-Year Follow-Up

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#### Abstract

**Background** For many years, the Roux-en-Y Gastric Bypass (RYGB) was considered a good balance of complications and weight loss. According to several short-term studies, single anastomosis duodenal switch or stomach intestinal pylorus sparing surgery (SIPS) offers similar weight loss to RYGB with fewer complications and better diabetes resolution. No one has substantiated mid-term complication and nutritional differences between these two procedures. This paper seeks to compare complication and nutritional outcomes between RYGB and SIPS.

**Methods** A retrospective analysis of 798 patients who either had SIPS or RYGB from 2010 to 2016. Complications were gathered for each patient. Nutritional outcomes were measured for each group at 1, 2, and 3 years. Regression analysis was applied to interpolate each patient's weight at 3, 6, 9, 12, 18, 24, and 36 months. These were then compared with *t* tests, Fisher's exact tests, and chi-squared tests.

**Results** RYGB and SIPS have statistically similar weight loss at 3, 6, 9, 12, and 36 months. They statistically differ at 18 and 24 months. At 36 months, there is a trend for weight loss difference. There were only statistical differences in nutritional outcomes between the two procedures with calcium at 1 and 3 years and vitamin D at 1 year. There were statistically significantly more long-term class IIIb-V complications, class I-IIIa complications, reoperations, ulcers, small bowel obstructions, nausea, and vomiting with the RYGB than the SIPS.

**Conclusion** With comparable weight loss and nutritional outcomes, SIPS has fewer short- and long-term complications than RYGB and better type 2 diabetes resolution rates.

 $\label{eq:second} \begin{array}{l} \mbox{Keywords} \ \mbox{Gastric Bypass} \cdot \mbox{RvGB} \cdot \mbox{SIPS} \cdot \mbox{Stomach Intestinal Pylorus Sparing Surgery} \cdot \mbox{SADI-S} \cdot \mbox{T2DM} \cdot \mbox{Diabetes Resolution} \cdot \mbox{Complication Comparisons} \cdot \mbox{Single Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy} \cdot \mbox{Bariatric Surgery} \end{array}$ 

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### Background

The Roux-en-Y gastric bypass (RYGB) has been around since 1967 with its introduction by Dr. Mason. While the RYGB has been around, there have been many different procedures that rise in popularity and fall like the vertical-banded gastroplasty and most recently the Lap-Band. It remained popular because it provided a unique combination of comorbidity resolution, sustained weight loss, and low surgical morbidity. Up until 2012, RYGB was the most commonly performed procedure in the USA and worldwide. However, as the sleeve gastrectomy (SG) has gained traction worldwide, it has displaced the RYGB as the most common bariatric operation [1]. This sudden switch over the course of just a few years implies that there were many problems that bariatric surgeons and future patients had with RYGB. So, when an alternative (the sleeve) became available, which promised to have comparable weight loss to RYGB patients and lower complication rates [2], surgeons quickly adopted the new procedure. However, as more data about the sleeve has become available, it is obvious that it does not work well for patients with higher BMIs and those with T2DM [3].

In 2007, Sanchez-Pernaute et al. started performing the single anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S) because of inconsistent sleeve results and problems with the creation of the Roux limb in RYGB and Duodenal Switch (DS) [4]. The group postulated that its weight loss would be comparable to RYGB. Through time, they have published papers which have shown short-term to mid-term weight loss results (less than 3 years) that are at least as good as the RYGB if not better [5-8]. Our group started performing a variant of SADI-S in 2013 called stomach intestinal pylorussparing surgery (SIPS). Through published studies comparing the weight loss results of SIPS and RYGB, we were able to see that SIPS and RYGB provide similar weight loss at 18 months [9, 10]. However, we were criticized for our inability to have nutritional outcomes or adequately compare complications. Other groups have published some of this data but in smaller bits and pieces [11–15]. This paper seeks to substantiate previous studies results and demonstrate comparisons of complication rates and nutritional outcomes in our own data set.

# Methods

All patients in this study had either the RYGB or SIPS performed at a single institution from 2010 to 2016. All RYGB and SIPS were performed by one of three surgeons at this institution. Revisional cases were not included in this study. IRB approval for this study was obtained from the Quorum IRB, study number 31353. All patients gave written consent to having their data used for this study.

The surgical technique for RYGB is done by first selecting a site for the pouch along the lesser curvature 5 cm distal to the angle of His and placing a staple line positioned perpendicular to the lesser curve. The pouch was then completed by 2–4 sequential firings of 45-mm staplers placed parallel to the lesser curve, with the division ending at the angle of His. The anvil was placed using an Orvil device (Medtronic Inc., USA). This was then attached to a 150-cm roux limb using 25-mm EEA technique. Our biliopancreatic limb is 30 cm long, and our common channel is uncounted.

Our surgical technique for SIPS has been published previously [11, 15]. Briefly, we first locate the terminal ileum and count out 300 cm of small bowel from the ileocecal valve. Next, we create a sleeve gastrectomy over a 40 French bougie. There is no over sewing or buttressing. Once this sleeve is completed, the gastroepiploic-perforating vessels are taken down from the end of the sleeve staple line past the pylorus to where the perforating vessels from the pancreas enter the duodenum. The duodenum is then divided with an Endo GIA stapler (Medtronic). Then, the previously marked ileum point is then located and the ant-mesenteric border of the bowel is attached to the end of the proximal duodenum staple line using absorbable suture. A duodenotomy and enterotomy are made that are 2 cm long and are closed with a single running posterior layer and a single running anterior layer. The afferent limb is then attached to the antrum of the stomach using a single suture to prevent bile reflux.

Patients were selected for surgery based upon their surgical preferences. Each patient was given materials educating them on each procedure. Education materials included extensive preoperative education from the institutional support staff and signing specific informed consent detailing each procedure with an included diagram.

Patient demographic data was gathered. Co-morbidities looked at were sleep apnea (SA), hypertension (HTN), type 2 diabetes mellitus (T2DM), and gastroesophageal reflux disease (GERD). Patients were only counted as having comorbidities if they were currently on medication or in the case of sleep apnea if they had a sleep study confirming or were currently on a CPAP machine. Demographic differences were then compared using *t* tests.

Patients' data were then gathered looking at nutritional parameters including glycated hemoglobin (HBA1C), fasting glucose levels, insulin, vitamins D, B1, and B12, ferritin, calcium, albumin, total proteins, cholesterol, and triglycerides. These nutritional parameters were then compared using chisquared tests and Fisher's exact tests.

Diabetes resolution rates were also looked at. Resolution rates were compared based upon differing levels of HBA1C of 5.7, 6, and 6.5%. Diabetes resolution was defined as keeping HBA1C levels below a certain percentage and the cessation of T2DM medications. Resolution rates were then compared based upon prior means of keeping their diabetes in check (insulin, oral medications, and diet). Resolution rates were then compared using Fisher's exact tests and chi-squared tests.

#### Table 1 Demographic characteristics

	SIPS	RGYB	P value
N	341	457	
M/F	123/218	92/365	< 0.001
Age	$47.2 \pm 13.6$	$44.5\pm12.8$	0.004
Weight	$316.3\pm70.9$	$299.3\pm68.9$	< 0.001
Height	$66.7'' \pm 4.1$	$65.6'' \pm 4.7$	< 0.001
BMI	$49.6\pm9$	$48.3\pm9.2$	0.047
Hypertension	56%	43%	< 0.001
GERD	30%	42%	< 0.001
Diabetes	41%	32%	0.015
Sleep apnea	46%	46%	0.963

Data is presented as averages  $\pm\, standard\,$  deviation or percentage with comorbidities

Body mass index (BMI); male/female (M/F); stomach intestinal pylorussparing surgery (SIPS); Roux-en-Y gastric bypass (RYGB)

Complications were then gathered for each patient. Complications were divided into classes I–IIIa and IIIb–V according to the Clavidien-Dindo classification of surgical complications. Complications were then further divided into operative (less than 30 days post-operatively) and long term (greater than 30 days). Complication rates were then compared using chi-squared tests.

Weight loss data was gathered for BMI and percentage excess weight loss (%EWL). Excess weight was defined as any weight above a BMI of 25. Each patient had their weight loss modeled on a non-linear regression curve. Using this curve, patient's weight was interpolated at 3, 6, 9, 12, 18, 24, and 36 months if they did not come in within 30 days of those exact follow-up dates. A patient's interpolated weight loss data was

only includ ed if the individual regression had an  $r^2$  value greater than 0.95 (simply, this means that at most, 5% of the weight loss cannot be explained by time since surgery, but by extraneous variables). At each time interval, weight loss was measured, and then averages and standard deviations were calculated. Weight loss results were then compared using *t* tests.

All statistical analyses were run through SigmaPlot statistical software.

# Results

Demographic data was gathered and presented on Table 1. All demographic data gathered was statistically different except for sleep apnea, with SIPS patients having higher percentage of males, higher percentage of HTN, and T2DM, a lower percentage of GERD, and being older, heavier, and taller.

Follow-up was 71%, 57%, 47%, 41%, 26%, 19%, and 13% of RYGB patients at 3, 6, 9, 12, 18, 24, and 36 months, respectively. Follow-up was 85%, 75%, 64%, 56%, 43%, 39%, and 53% of SIPS patients at 3, 6, 9, 12, 18, 24, and 36 months, respectively.

Nutritional data is presented on Table 2. On average, most patients followed up only about at 1 year post-operatively with labs drawn; however, some followed up beyond 1 year and their data is included. Post-operatively, there were only statistical differences in calcium, vitamin D, and total protein levels at 1 year post-operatively. Only calcium was different at one and three years post-operatively. Pre-operatively, only HBA1C, fasting glucose, insulin, and ferritin levels were statistically different with SIPS having more abnormal values than RYGB.

Diabetes resolution rates at differing levels of HBA1C are presented on Table 3. At each level of measurement of

Table 2Nutritional variables

	SIPS								RYG	В							P value			
	Pre-0	Ор	1 Yea	ar	2 Yea	ars	3 Yea	ars	Pre-0	Op	1 Yea	ar	2 Yea	ars	3 Yea	ars				
	Abn	Total	Pre-Op	1	2	3														
HBA1C	209	307	34	194	2	29	3	9	130	271	26	141	4	23	10	30	< 0.001	0.943	0.387	1
Glucose	166	327	42	214	4	31	1	9	116	310	26	168	3	25	10	37	< 0.001	0.359	1	0.421
Insulin	172	287	5	101	0	27	0	8	117	259	1	66	1	18	0	24	< 0.001	0.459	0.4	1
Vitamin D	173	288	88	198	11	28	6	9	177	289	37	150	7	22	13	29	0.838	< 0.001	0.768	0.447
Vitamin B1	40	265	17	179	4	26	2	9	28	211	18	132	2	18	3	23	0.665	0.337	1	0.604
Vitamin B12	24	290	71	196	10	29	3	7	27	290	40	148	6	25	7	30	0.769	0.091	0.522	0.360
Ferritin	36	290	34	197	8	28	1	8	18	286	17	162	4	25	6	32	0.017	0.094	0.337	1
Calcium	15	322	18	211	2	31	4	9	11	306	2	169	2	25	3	38	0.082	0.003	1	0.018
Albumin	6	224	18	208	2	30	1	9	7	117	13	167	0	24	1	35	0.224	0.908	0.497	0.371
Total protein	8	223	21	208	3	30	1	9	3	117	5	167	1	24	2	35	0.854	0.013	0.620	0.506
Cholesterol	84	315	7	128	3	29	0	9	87	303	8	82	2	24	2	31	0.632	0.367	1	1
Triglycerides	153	315	15	128	2	29	0	9	136	303	13	84	1	23	3	31	0.402	0.560	1	1

Data is presented as number of abnormal followed by total number of people who had that lab at the follow-up point

Glycosylated hemoglobin (HBA1C); abnormal (Abn); single anastomosis pylorus-sparing surgery (SIPS); Roux-en-Y gastric bypass (RYGB)

Table 3 HBA1C levels (%) RYGB (%) SIPS (%) P value < 5.7 62 81 0.008 < 6.0 69 90 0.003 93 < 6.5 69 0.004

HBA1C levels, SIPS had statistically higher amounts of diabetic resolution than RYGB.

Breakdown of diabetes treatments preoperatively and their corresponding diabetes resolution rates are found on Table 4. Of those RYGB patients that were only on oral medications that did not return to normal HBA1C levels, only one is currently taking meds. Of those RYGB patients that were on a mix of insulin therapy and oral medications that did not return to normal HBA1C levels, 78% improved to only taking oral medications and 22% remained on insulin without any sort of improvement. Of those SIPS patients that were only on oral medications that did not return to normal HBA1C levels, none are currently taking meds. Of those SIPS patients that were on oral medications and insulin therapy that did not return to normal HBA1C levels, 64% improved to only being on oral medications, 18% remained on insulin but on lower dosages, and 18% used diet to control their HBA1C levels.

Short-term complications are presented on Table 5. Short-term complications were defined as complications that occurred at most 30 post-operatively. Short-term nausea and vomiting were statistically different with RYGB patients having higher percentages of both complications. Class I-IIIa complication levels were statistically lower among SIPS patients than RYGB patients. Class IIIb-V complications were statistically similar between the two procedures.

Long-term complications are presented on Table 6. Long-term complications were defined as complications that occurred past 30 days post-operatively. Long-term nausea, vomiting, strictures, abdominal pain, ulcers, small bowel obstructions, internal hernias, diagnostic EGDs, and EGDs with dilation had statistically higher rates among RYGB patients over SIPS patients. Malnutrition, diarrhea, constipation, EGDs with stent placement, and revisions were statistically similar. Class I-IIIa and class IIIb-V complications were statistically different with RYGB having more complications than SIPS.

Weight loss results are found on Table 7. Both procedures provided statistically similar weight loss at 3, 6, 9, 24, and 36 months. Only in %EWL was 24 months statistically significantly different, but 18 months was statistically significantly different among BMI and %EWL. SIPS patients stopped losing statistically significant amounts of weight after 18 months. RYGB patients stopped losing statistically significant amounts of weight after 12 months.

# Discussion

There are several methods for determining efficacy of a procedure. We decided to use the entirety of our experience with both procedures to compare their efficacy. Since both procedures have been done by the same surgeons, we used this to minimize any problems due to surgeon to surgeon differences.

One problem with using a total patient population is the lack of similarity between the two groups. Out of all gathered demographic characteristics, SA was the only one to be shown to be statistically significantly similar. This meant that our SIPS patients were older, heavier, had more cases of HTN and T2DM, and had less cases of GERD. Despite these differences, SIPS had on average, statistically similar and sometimes better weight loss than RYGB. According to the literature, these factors generally would mean that SIPS should lose less weight than RYGB [16–21]. Additionally, this would have led to SIPS having higher risk for patients with complications. However, this risk jump did not result in higher complications or worse weight loss. It had the same weight loss and lower complications. This shows that the SIPS is a safer procedure for compared to RYGB, even when RYGB patients are healthier.

When Dr. Mason developed the gastric bypass back in the 60s, one of the things that it tried to fix was the malnutrition associated with the jejunoileal bypass. Dr. Mason's modern surgical operation, the RYGB, is not associated with high rates of malnutrition as long as distal bypass is not created [22]. Our

Table	4
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Diabetes remission at one year	5.7%		6.0%		6.5%	
	RYGB (%)	SIPS (%)	RYGB (%)	SIPS (%)	RYGB (%)	SIPS (%)
Dietary controlled	58	88	75	100	100	100
Oral medication	76	87	82	91	91	96
Insulin and oral medication	35	55	47	79	59	91

Short-term complications							
RYGB				SdIS			
Class I-IIIa complications		Class IIIb-V complications		Class I-IIIa complications		Class IIIb-V complications	
Class I nausea	87	Class IIIb abdominal pain	10	Class I nausea	26	Class IIIb abdominal pain	2
Class IIIa nausea	23	Class IIIb abscess	5	Class II nausea	1	Class IIIb abscess	2
Class I vomiting	49	Class IIIb small bowel obstruction	4	Class I vomiting	4	Class IIIb gastric perforation	1
Class IIIa vomiting	22	Class IIIb incisional hernia	2	Class I abdominal pain	3	Class IIIb leak	2
Class I abdominal pain	18	Class IIIb intra-abdominal hemato-	2	Class I constipation	1	Class IIIb bowel obstruction	1
Class IIIa abdominal pain	3	ma Class IIIb intra-abdominal hemor- rhace	2	Class I diarrhea	1	Class IIIb small bowel perforation	1
Class I constipation	16	Class IIIb ulcer	2	Class I hypotension	1	Class IIIb cholecystitis	1
Class I diarrhea	15	Class IIIb internal hernia	1	Class I dizziness	2	Reoperations	8
Class I esophageal pain	1	Class IIIb incarcerated hernia	1	Class I bradycardia	1		
Class I ulcer	2	Class IIIb gastric outlet obstruction	1	Class I ketoacidosis	1		
Class IIIa ulcer	3	Class IIIb ileus	1	Class I ileus	4		
Class II wound infection	3	Class IIIb anastomotic leak	1	Class II portal vein thrombosis	2		
Class II renal failure	б	Class IIIb small bowel intussusception	1	Class II deep vein thrombosis	1		
Class II dumping syndrome	3	Class IIIb small bowel perforation	1	Class II JP drain bleed	2		
Class IIIa gastric leak	1	Reoperations	22	Class II abdominal hematoma	3		
Class IIIa stricture	12	Multiple reoperations	3	Class II wound infection	8		
Class IIIa dysphagia	1						
Class IIIa gastrointestinal bleed	1						
EGD with stent	3						
EGD with dilation	13						
Diagnostic EGD	14						
Overall patients with class I-IIIa complications	141 (31%)	Overall patients with class IIIb-V complications	22 (5%)	Overall patients with class I-IIIa complications	58 (17%)	Overall patients with class IIIb–V complications	9 (3%)
Complications are presented as number of patients with the complication	mber of patients	s with the complication					

 Table 5
 Total short-term complications

Long-term complications							
RYGB				SIPS			
Class I-IIIa complications		Class IIIb-V complications		Class I-IIIa complications		Class IIIb-V complications	
Class I nansea	37	Class IIIb abdominal nain	37	Class I nausea	<i>cc</i>	Class IIIb abdominal nain	4
	10		1 1		l v	Class III diamban	- 6
	00		<u>,</u>		nc		<i>ר</i> ע
Class I vomung	87	Suruction	17	Class I vomiting	y	Class IIIb mainutrition	0
Class IIIa vomiting	90	nternal hernia	14	Class IIIa vomiting	4	Class IIIb cholecystitis	2
Class I abdominal pain	17	Class IIIb ventral hernia	8	Class IIIa stricture	11	Class IIIb dilated fundus	2
Class IIIa abdominal pain	16	Class IIIb hiatal hernia	4	Class I abdominal pain	4	Class IIIb afferent loop syndrome	1
Class I ulcer	5	Class IIIb gastric fistula	2	Class I constipation	4	Class IIIb afferent limb kink	1
Class IIIa ulcer	30	istula	2	Class I diarrhea	7	Class IIIb GI dysmotility	1
Class I constipation	11		3	Class I cholelithiasis	б	Class IIIb GERD	2
		intussusception					
Class IIIa constipation	1	Class IIIb candy cane Roux limb	2	Class I hepatic steatosis	-	Class IIIb vomiting	2
Class I diarrhea	7	Class IIIb malnutrition	2	Class I dilated fundus	1	Class IIIb gastric outlet	3
						obstruction	
Class IIIa diarrhea	3	Class IIIb gastric perforation	7	EGD with stent	1	Class IIIb small bowel perforation	2
Class I epigastric pain	4		2	Diagnostic EGDs	5	Class IIIb stricture	2
Class Illa epigastric pain	4	Class IIIb stricture	-	EGD with dilation	10	Class IIIb gastric stenosis	1
Class I GERD	1	Class IIIb leak	1	Multiple dilations	4	Class IIIb pelvic abscess	1
Class IIIa GERD	7	Class IIIb blocked bile duct	1	4		Common channel lengthening	4
Class II dumping syndrome	9	Class IIIb pancreatitis	1			Common channel shortening	1
Class II renal failure	1	Class IIIb intra-abdominal hemor-	1			Reoperations	19
		rhage				4	
Class IIIa stricture	39	Class IIIb deep vein thrombosis	1			Multiple reoperations	4
Class IIIa dysphagia	9	Class IIIb weight loss failure	1				
Class IIIa leak	1	Class IIIb gastroparesis	1				
Class IIIa upper gastrointestinal	1	Class IIIb abscess	1				
bleed							
Class IIIa bloody stool	1	Class IIIb chronic stenosis	1				
EGD with stent	2	Class IIIb outlet obstruction	1				
EGD with dilation	49	Class IIIb esophageal spasms	1				
Multiple dilations	14		8				
Diagnostic EGDs	87	Reoperations	62				
Multiple diagnostic EGDs	14	Multiple reoperations	21				
Overall patients with class I-IIIa	205 (45%)	Overall patients with class IIIb-V	62 (14%)	Overall patients with class I-IIIa	51	Overall patients with class IIIb–V 19 (6%)	19~(6%)
complications		complications		complications	(15- %)	complications	
					(~		

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Table 6Total long-term complications

2899

#### Table 7 Weight loss comparisons

		3 Months	6 Months	9 Months	12 Months	18 Months	24 Months	36 Months
SIPS	Ν	289/341 (85%)	256/341 (75%)	203/318 (64%)	161/287 (56%)	92/216 (43%)	57/148 (39%)	40/76 (53%)
	BMI	$40.4\pm7.8$	$36\pm7.1$	$33.6\pm6.7$	$31.4 \pm 6.3$	$29.8\pm6.5$	$29.2\pm7.2$	$29.3\pm8$
	%EWL	$40.9\pm14.1$	$59.2\pm17.7$	$69.2\pm19.8$	$78.3\pm\!21$	$84.9\pm22.6$	$86.7\pm24.5$	$86.1\pm27.5$
RYGB	Ν	325/457 (71%)	261/457 (57%)	213/457 (47%)	185/455 (41%)	115/443 (26%)	81/428 (19%)	51/387 (13%)
	BMI	$39.3\pm8.6$	$35.7\pm8.1$	$33.8 \pm 7.8$	$32.4\pm7.8$	$32\pm8.4$	$31.6\pm7.9$	$31.6\pm7.8$
	%EWL	$42.2\pm14.9$	$58.9 \pm 18.4$	$67.6\pm20.8$	$73.9\pm22.4$	$76.6\pm25.2$	$77.5\pm26.3$	$79.9 \pm 25.1$
P values	BMI	.099	.655	.780	.195	.040	.071	.171
	%EWL	.269	.850	.423	.061	.015	.039	.265

Data is presented as averages  $\pm$  standard deviations

Body mass index (BMI); Roux-en-Y gastric bypass (RYGB); stomach intestinal pylorus-sparing surgery (SIPS)

paper does show that there are minor increased levels of malabsorption compared to RYGB. At one year post-operatively, 44%, 9%, and 10% of SIPS patients are abnormal in their vitamin D, calcium, and total protein levels, respectively, compared to only 25%, 1%, and 3%, respectively, with RYGB. While there are differences in 1 year postoperatively nutritional parameters, there is no statistical difference in malnutrition rates that require readmission and surgery. This means that whatever malabsorptive problems that may arise with SIPS can be corrected with diet and vitamin supplements.

One area of significance to counter minor differences in nutritional parameters is T2DM resolution rates. RYGB has been shown to be effective for those with diabetes with longterm resolution rates as high as 50% by Dr. Schauer et al. in 2003 [23]. He then followed this study up with a landmark study in 2017 showing five-year T2DM resolution (in patients with a pre-op HBA1C of 9.3%), defined as HBA1C level less than 6% with or without medications, for RYGB at 29%. Among those patients who could achieve below 6% HBA1C without diabetes medication, the resolution rate was only 23% [24]. Diabetes resolution has been shown to not just a function of weight loss. When comparing similar weight loss patients between the Lap-Band and RYGB, the RYGB achieved 72% T2DM resolution vs 17% for the Lap-Band at two years [25]. Additionally, when more small intestine is bypassed, statistically higher rates of T2DM resolution result [26].

That being said, it should not be surprising that at any level of measurement for diabetic resolution, SIPS is significantly better than RYGB. We can only postulate on the reasons for this, but greater glycemic control for DS when compared to RYGB has been seen previously [27, 28]. Additionally, Marceau's group showed that their long-term diabetes remission rate at 20 years was 93% using HBAIC of 6.5% [29].

One surprising finding of our analysis is the drastically different T2DM resolution rates seen in Tables 3 and 4 when

using different HBA1C standards. On every single standard of measurement, SIPS is always better than RYGB in resolving T2DM. Patients that want to have T2DM resolution should have SIPS done more often than RYGB. Including different standards allows comparisons of T2DM resolution rates between papers.

Additionally, it was important to note the type of resolution with regard to type of T2DM with patients. Insulin-dependent patients will do worse in overall resolution. Improvement happened for every SIPS patient, but not for every RYGB patient.

The reason for differing resolution rates is mostly due to the anatomical and physiologic differences in between the two procedures. Roslin et al. best demonstrated why RYGB has worse T2DM resolution. They showed the lack of a pylorus leads to hypo- and hyperglycemia throughout the post-surgery process, and this leads to hunger and weight gain [28]. Our study confirms what Roslin et al. had shown.

One surprising finding of our study relates to the overall complication rate between the procedures. Our overall long-term class IIIb-V complication rate of 14% for RYGB is not unusual and has been substantiated by a number of studies including meta-analysis [30, 31]. Yet, our SIPS had a class IIIb-V complication rate of only 6%. This is statistically different, and it is not due to learning curve with bypass. Conversely, it includes our sips learning curve. We expect our overall learning rate to go down over time. Many of the complications that drove the RYGB complication rate higher than the SIPS complication rate (ulcers, small bowel obstructions, internal hernias) are unlikely to change regardless of the numbers of patients since these complications are unique to Roux-en-Y construction.

The substantial difference in ulceration rates is quite remarkable. The ulceration rate of 10% for RYGB is well within established studies [32]. SIPS construction makes the possibility of an ulcer statistically irrelevant. This ultimately allows patients to have a greater quality of life, since they do not need as many medications, readmissions, have as much nausea and vomiting, or have as many potential EGDs [33].

One potentially fatal complication that can result from RYGB is internal herniation. If patients are not referred to bariatric care when they come in with these symptoms, it can easily be misdiagnosed and result in death. Internal hernias can present themselves at any point after a procedure. So, trying to rid patients of this risk is paramount. Our internal herniation rate with RYGB which was 3% was within standard studies [30, 31, 34], and there were no internal hernias with SIPS. There have not been any documented cases of internal hernia with SIPS in a primary case; the only reported case of internal herniation is a revisional procedure [35].

One potential complication that is commonly said about SIPS is bile reflux due to the loop configuration. However, with the mini/loop gastric bypass, rates of bile reflux are less than 1% in long-term follow-up studies [36, 37]. We postulated that it would be less due to the inclusion of the pylorus. To date, our practice has not seen a patient with bile reflux. The only study with that found bile reflux with SIPS found a bile reflux rate of 0.1% [38]. This is remarkably low and is even lower than any mini-gastric bypass and should not discourage SIPS from being a well-adopted procedure.

A weakness of this study was the lack of high amounts of nutritional data beyond one year. We included patient nutritional information for patients that did come in beyond their one-year appointments. While low, other papers have drawn conclusions on nutritional information from similarly low follow-up [30].

Another weakness of this study is its retrospective nature. There is no doubt of a prospective randomized trial would have been superior.

The lack of good follow-up beyond 6 months with the RYGB is definitely cause for concern. This weakness was addressed by trying to call patients and scouring hospital records. However, the RYGB with its low follow-up percentage had a high number of patients with follow-up at three years. A total of 51 patients allow a small 13% follow-up to be a statistically representative sample of the larger RYGB patient population. Additionally, patients lost to follow-up and patients that follow-up have statistically similar outcomes [39]. Therefore, we believe that even though our sample does not have a high follow-up percentage, it is statistically representative of the overall population.

# Conclusion

SIPS surgery offers comparable weight loss and nutritional data to RYGB. SIPS surgery is safer for patients and allows for better T2DM resolution.

#### **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.

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

**Conflicts 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.

Hinali Zaveri has no conflicts of interest to declare. Samuel Cottam has no conflicts of interest to declare.

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Walter Medlin has no conflicts of interest to declare.

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