Obesity Surgery (2018) 28:3062–3072
https://doi.org/10.1007/s11695-018-3358-x

ORIGINAL CONTRIBUTIONS

Mid-term 4-Year Outcomes with Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy Surgery at a Single US Center

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Published online: 16 June 2018

Abstract

Background Single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S) is a modification of Roux-en-Y duodenal switch (RYDS). Long-term data on this operation is lacking in the literature. We reviewed our mid-term data of this RYDS modification.

Purpose To analyze the outcomes with SADI-S at 4 years.

Methods Data from patients who underwent a primary SADI-S procedure performed by three surgeons at a single institution from June 2013 through February 2018 were retrospectively reviewed. All revision bariatric surgeries were excluded. Regression analyses were performed for all follow-up weight loss data.

Results There were 437 patients in our database. The pre-operative mean body mass index (BMI) was 49.8 ± 8.8 kg/m^2. The 30-day complication rate was 7.7%. The 30-day readmission, reoperation, and mortality rates were 1.8, 1.3, and 0.2%, respectively. The long-term complication rate was 10.9%. Seventy-nine patients were 4 years post SADI-S surgery and follow-up was possible for 44 patients (55.7%). At 4 years, patients had an average change in BMI of 18.1 ± 6 units with an excess weight loss (EWL) of 85.7 ± 27.3%. At 4 years, 97.6% patients were able to maintain HbA1c < 6% with or without the use of diabetic medication. There was a statistically significant difference between most of the pre-operative and post-operative nutritional data.

Conclusions SADI-S is a safe and effective procedure in both short- and mid-term data points. Diabetes resolution and weight loss appear similar to traditional RYDS and better than RYGB.

Keywords SADI-S · Single anastomosis duodeno-ileal bypass with sleeve gastrectomy · SIPS · Stomach intestinal pylorus-sparing surgery · Weight loss · Obesity · Outcomes · Long term · 4 years

Introduction

Roux-en-Y duodenal switch (RYDS) has proven to be the most efficacious form a weight loss treatment for the super morbidly obese and in the treatment of diabetes yet it forms a minority of the total bariatric cases [1, 2]. Modifications that can make the operation technically simpler and reduce the long-term risk of short bowel syndrome would benefit both the clinician and the patient. Our practice has attempted to simplify the procedure by eliminating the Roux limb in favor

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of a single anastomosis duodenal ileostomy and lengthening the common channel to 3 m while making the sleeve portion over a 40 French bougie. We call this modification as the "stomach intestinal pylorus-sparing surgery" (SIPS) or the "single anastomosis duodenal-ileal bypass with sleeve gastrectomy" (SADI-S).

The longer common channel length helps reduce the incidence of diarrhea and short bowel syndrome. The preservation of the pylorus provides control of solid emptying reducing the chances of dumping syndrome and assisting in maintaining a physiologically based rate of gastric emptying. The 40 French bougie is not so small that patients have difficulty eating. Using this configuration, we hoped to maintain the current excellent weight loss while eliminating the internal hernias and ulcers associated with RYDS and drastically reduce the incidence of diarrhea and vitamin deficiencies.

Retrospective analyses of our preliminary experience with SADI-S showed effective weight loss with morbidity comparable to other stapling procedures [3]. However, long-term follow-up was needed to evaluate SADI-S procedure further. In this study, we report our 4-year outcomes with SADI-S surgery.

Methods

This study has been approved by the Quorum institutional review board (IRB) (QR# 31353). This is retrospective analyses of data from all patients who underwent a primary SADI-S procedure performed by three surgeons, at a single private institute from June 2013 through February 2018. All the surgeries were performed at two private hospitals. All revisions of prior bariatric procedures were excluded. Patients chose SADI-S based on an extensive pre-operative education. Patients signed a consent form detailing the procedure that included all the potential benefits and risks associated with it.

Descriptive statistics were used to analyze pre-operative characteristics such as age, weight, height, and body mass index (BMI). Procedure time was gathered and started with the first incision and ended with the dressing.

Patients were followed in our multidisciplinary program with all follow-up data entered in our programmatic database. Nutritional counseling, support groups, and exercise training were available for all patients. All the patients are recommended to take ADEK multivitamins, calcium citrate 1800/2400 mg/day, iron 65 mg/day, and daily protein intake 60–80 g/day.

BMI and weight were measured at each follow-up visit. Also, the presence or absence of obstructive sleep apnea (OSA), type 2 diabetes mellitus (T2DM), hypertension (HTN), and hyperlipidemia were recorded.

A non-linear regression analysis was performed based on recorded weight loss values to obtain the 1-, 1.5-, 2-, 3-, and 4-year weight loss values. This is the most accurate way to assess weight loss at certain time points when patients do not follow up at regularly scheduled visits. This allows for greater accuracy regarding specific time points rather than the currently practiced bar sliding scales which count follow-up at even 10 months as a 6-month follow-up. Calculations were made to determine their percentage excess weight loss (%EWL) and change in BMI points.

Additionally, complications from each patient were also recorded. For analysis, they were divided into those that occurred with the first 30 days, and those that occurred subsequently. Also, nutritional values were collected for the patients who had completed 1, 2, 3, and 4 years.

All statistics were run through SigmaPlot™ (Systate Software Inc., headquartered in San Jose, CA).

Surgical Technique

Our technique has been described previously [4, 5].

Results

The analyzed sample size of the study was 437. Of these 437 patients, 357 patients, 286 patients, 155 patients, and 79 patients were beyond the 1, 2, 3, and 4 years post-operative mark respectively. Follow-up was possible for 266 patients at 1 year (74.5%), 169 patients at 2 years (59.1%), 90 patients at 3 years (58.1%), and 44 patients at 4 years (55.7%). Three patients were lost to follow-up. They lived in a different state and requested to be seen by a bariatric surgeon in their respective state.

The pre-op characteristics, rates of comorbidities, and operative details of patients are shown in Table 1. No intraoperative complication was noted.

Weight Loss Analysis

The weight loss data were categorized into two sections as demonstrated in Table 2. At 4 years, patients had an average change in BMI of 18.1 ± 6 kg/m^2 with 85.7 ± 27.3% of EWL. There was a statistically significant difference in %EWL ($p < 0.001$) and change in BMI ($p < 0.011$) between 1 and 1.5 years; however, no difference seen between 1.5 and 2 years, 2 and 3 years, and 3 and 4 years. More importantly, 93.1% of patients lost > 50% EWL at 4 years with minimal weight regain (Fig. 1).

Table 1 Demographics

	SADI-S
N	437
Age (years)	46.6 ± 13.2
Male/female	161/276
Weight (lbs)	317.1 ± 68.5
BMI (kg/m^2)	49.8 ± 8.8
Hypertension	245 (56%)
Sleep apnea	197 (45%)
Diabetes	191 (43.7%)
Hyperlipidemia	168 (38.4%)
Operative details	
Operative time (mins)	67.9 ± 16.8
Length of stay (days)	1.6 ± 0.9

BMI body mass index, *SADI-S* single anastomosis duodenal-ileal bypass with sleeve gastrectomy

Complications

The overall early complication rate was 7.7% (Table 3), and late complication rate was 10.9% (Table 4) for the entire group. The Clavien-Dindo scale was used for the description of complications. Eight patients (1.8%) needed readmission within 30 days of the surgery. Six patients (1.3%) needed re-operation within 30 days of the surgery.

Early Complications

There were total 36 early complications (7.7%). The most common early complications were nausea ($n = 10$, 2.2%) and wound infection ($n = 10$, 2.2%). Of the 36 complications, 6 complications (1.3%) were grade I, 19 complications (4.2%) were grade II, 2 complications (0.4%) were grade IIIa, 6 complications (1.3%) were grade IIIb, and 1 complication (0.2%) was grade V. Grade V patient developed a leak from mishandled bowel that perforated into the mesentery without any signs of free air or contrast extravasation on computed tomography (CT) scan. Postoperatively, the patient developed acute renal failure (ARF) and acute respiratory distress syndrome (ARDS). Patient's health kept deteriorating and finally died on post-operative day 5. Portal vein thrombosis (PVT) was seen in 2 patients (0.4%) in the early phase of starting SADI-S surgery and has not recurred since the time we changed our deep vein thrombosis (DVT) protocol (our new protocol 2.5 mg apixaban PO, twice daily for 1 month post-op).

Late Complications

There were total 4 late complications (10.9%). The most common late complication was stricture ($n = 13$, 2.9%). However, all the strictures occurred in the early phase (first year) of starting SADI-S surgery and were part of the learning curve. This complication has not recurred since then. Of the 48 complications, 14 complications (3.2%) were grade I, 3 complications (0.6%) were grade II, 29 complications (6.6%) were grade IIIb, and 2 complications (0.4%) were grade V. Grade V complications were unrelated to surgery. The first patient died because of cardiac arrest of unknown etiology. The second patient had a history of severe OSA but never took treatment for the same. Post-operatively, the patient had severe hypoxia and respiratory acidosis. We explained the patient the risk of sudden death due to OSA and advised to get sleep apnea study done and use continuous positive airway pressure (CPAP). However, patient refused the treatment and also demanded an early discharge. One month later, the patient complained of sudden chest pain but refused to go to the emergency room (ER). The patient died the same night. Eight patients needed common channel lengthening (CCL), 7 needed due to severe diarrhea, and 1 needed due to hypoproteinemia. Of these 7 patients, 1 developed diarrhea because of the miscounted common channel of 160 cm from primary SADI-S surgery. Similarly, hypoproteinemia was due to miscounted common channel and not due to the procedure itself. Four patients were seen with retrograde filling of afferent limb and were treated surgically by tacking the afferent limb to the sleeve. Since 2015, we have made this as a standard procedure to tack the afferent limb to the sleeve, and since then, we have not encountered this complication.

Table 2 Weight loss analysis

	3 months	6 months	9 months	1 year	1.5 years	2 years	3 years	4 years
N	348	302	270	266	187	169	90	44
Change in BMI (kg/m^2)*	9.36 ± 2.79	13.55 ± 3.77	15.99 ± 4.66	17.92 ± 5.48	19.61 ± 6.29	19.51 ± 6.77	19.2 ± 7.13	18.16 ± 6.01
%EWL**	40.2 ± 13.67	58.1 ± 17.44	68.94 ± 19.66	77.69 ± 20.92	85.3 ± 23.56	85.96 ± 24.29	83.09 ± 25.54	85.79 ± 27.38

EWL excess weight loss, *BMI* body mass index

*Significant difference between 1 and 1.5 years ($p < 0.011$), no difference between 1.5 and 2 years, 2 and 3 years, and 3 and 4 years

**Significant difference between 1 and 1.5 years ($p < 0.001$), no difference between 1.5 and 2 years, 2 and 3 years, and 3 and 4 years

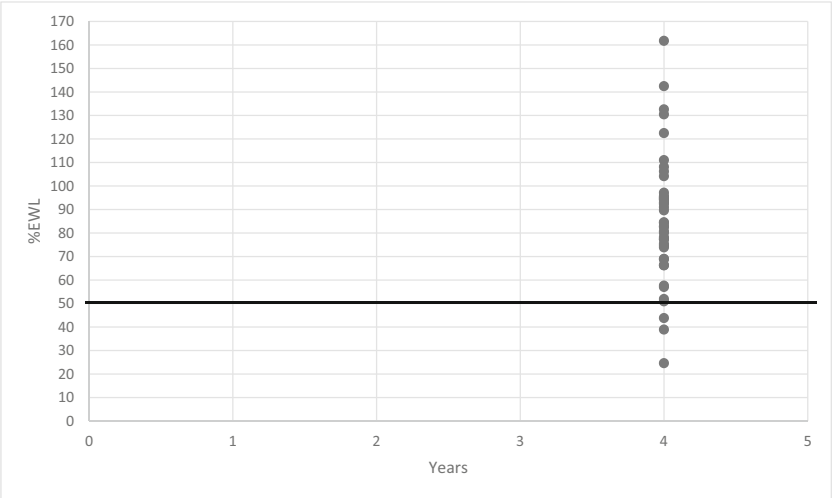

Fig. 1 %EWL over 4-year follow-up. Data are displayed as the %EWL achieved by each patient at the 4-year follow-up visit. A bold line indicates the %EWL of 50: 93.1% of patients had %EWL > 50% at 4 years (6.8% had %EWL < 50)

Nutritional Outcomes

We compared the nutritional outcomes (no. of patients with abnormal values) between baseline and 1, 2, 3, and 4 years (Table 5). The number of patients with the abnormal pre-operative diabetic panel (glycosylated hemoglobin (HbA1c), fasting glucose, and insulin), lipid panel (cholesterol and triglyceride), and vitamin D levels significantly reduced at each follow-up ($p < 0.001$). Additionally, the number of patients with abnormal pre-operative vitamin B12 and B1 levels also decreased at each follow-up; however, the difference was not statistically significant.

More patients had abnormal post-operative values for ferritin, calcium, and vitamin A compared to their pre-operative value, but the difference was not statistically significant. The number of patients with abnormal albumin level ($p = 0.10$) and total protein levels ($p < 0.001$) increased over the years compared to pre-operative value with the statistically significant difference. While the number of patient with abnormal PTH (hyperparathyroidism) value increased over the years, the statistical difference was only seen at 4 years ($p = 0.06$).

We did not collect copper and zinc pre-operatively, so we do not have pre-operative value for comparison. However, there was no difference in the number of patients with abnormal values between each follow-up. Similarly, at our center, we started collecting vitamin E and K1 after January 2017, and thus, we do not have the data for the patients who were 2–4 years out from the surgery.

Resolution of Comorbidities

Complete remission of T2DM was considered when HbA1c was maintained below 6% without anti-diabetic medications. Overall remission rates were 78.6, 77.8, 81.3, and 81.3% after 1, 2, 3, and 4 years, respectively. In our study, improvement of T2DM was considered when HbA1c was < 6% being on the same medication dose or dose was decreased. Most post-operative levels of HbA1c were normalized from the first post-operative year. In our study, 16.2% of the patients achieved HbA1c < 6% with the use of medication. That means, 97.6% of patient were able to maintain HbA1c < 6% with or without the use of medication (remission = 35, improvement = 7, total = 42/43) at 4 years. This also correlates to the HbA1c value in the nutritional table (Table 5), where 52/55 number of patients reached normal HbA1c < 6% at 4 years (94.5%).

Lipid profile improved significantly. Remission was considered when the patient had normal lipid panel without anti-lipidemic medications. Overall remission rates were 72.4, 70.3, 64.4, and 70.5% after 1, 2, 3, and 4 years respectively. In our study, the improvement was considered when lipid levels reached normal value being on the same medications or decreased medication. One hundred percent patients were able to maintain normal lipid levels at 4 years with or without the use of medication (remission = 24, improvement = 10, total = 34/34). This also correlates with the cholesterol levels at 4 years (Table 5), where 37/39 patients reached normal cholesterol levels by 4 years (95%).

Complete remission of HTN was considered when systolic/diastolic blood pressure was below 120/80 without anti-hypertensive drugs. HTN remission rates were 66.4, 68.3, 64.4, and 70.7% after 1, 2, 3, and 4 years respectively. The improvement was considered when there was normalization of systolic or diastolic blood pressure being on same medications or medications itself were decreased. Ninety-eight percent of the patients were able to keep the blood pressure to normal with or without the use of medication (remission = 36, improvement = 14, total 50/51) at 4 years.

Although we did not do a sleep study on all our patients with OSA pre-operatively or post-operatively, remission was considered when CPAP was stopped for the patients by their primary care physicians, and improvement was considered

Table 3 Early complication

Complication	*N*	Grade I	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade IVb	Grade V
Nausea[1]	10	6	4					
Wound infection	10		10					
Post-operative bleed operative management	4				4			
Post-operative bleed non-operative management[2]	2		2					
Intra-abdominal abscess[3]	2			1	1			
PVT[4]	2		1	1				
DKA[5]	1		1					
Leak (DI anastomosis)[6]	1				1			
Dehydration with readmission[7]	1		1					
Death (SB injury)[8]	1							1
Total	34 (7.7%)	6 (1.3%)	19 (4.2%)	2 (0.4%)	6 (1.3%)			1 (0.2%)

N number of patients, *PVT* portal vein thrombosis, *DKA* diabetic keto-acidosis, *DI* duodeno-ileostomy, *SB* small bowel

[1] Of 10 patients with nausea, 6 patients were treated with anti-emetics and 4 patients needed IV hydration

[2] Post-operative bleed non-operative managements—of 2 patients, 1 needed blood transfusion and 1 needed PRN

[3] Of 2 patients with intra-abdominal abscess, 1 patient got percutaneous drainage of abscess with the help of a drainage catheter and was discharged home on antibiotics. Since percutaneous drainage was not possible for the second patient, so the peritoneal lavage was done in the operating room

[4] Of 2 patients diagnosed with PVT, 1 patient had non-occlusive PVT that was treated only with anti-coagulant. The second patient had occlusive PVT and was treated with SMA-catheter directed TPA along with anti-coagulant. This complication has not recurred after we changed our DVT protocol (2.5 mg apixaban PO, twice daily for 1 month)

[5] This patient had a history of insulin dependent diabetes mellitus (IDDM). Post-operatively, patient ignored orders to discontinue diuretics and alter diabetic management. This put patient into DKA. The patient was treated IV fluids and insulin

[6] This patient was on chronic anti-coagulation for the bleeding disorder. Post-operatively, patient developed obstructing blood clot at the duodeno-ileostomy (DI)

[7] This patient had severe dehydration that needed readmission for IV therapy (This was before we began our IV fluid clinic)

[8] The patient developed leak from mishandled bowel that perforated into the mesentery without any signs of free air or contrast extravasation on computed tomography (CT) scan. Post-operatively, patient developed acute renal failure and acute respiratory distress syndrome. Patient's health kept deteriorating and finally died on post-operative day 5

when patients reported improvement of the symptoms or titration of CPAP dose. Remission rates were 56.9, 58.5, 60, and 63.8% after 1, 2, 3, and 4 years, respectively.

Table 6 summarizes the comorbidity resolution rate.

Discussion

Biliopancreatic diversion (BPD) was modified to RYDS by Hess et al. [1] and Marceau et al. [6]. They proposed a sleeve gastrectomy (SG) over 40–60 French Bougie. Marceua et al. proposed common channel of 100 cm, while Hess et al. used a formula to calculate common channel, which was generally 10% of entire small bowel length. The proposed SG allowed preservation of gastric antrum and pylorus, thus maintaining acid secretion and intrinsic factor. This allowed less malabsorption of vitamin B12, calcium, iron, and protein after RYDS with adequate weight loss. RYDS was modified by Juan Antonio Torres and Anders Sanchez in 2007 to an operation called SADI-S [7].

SIPS is very similar in design to SADI-S. The only difference between the two is the latter uses 54 French bougie (vs. 42 French) and intestinal length of 2 m originally and increased to 2.5 m later (vs. 3 m). By creating a longer bowel length, we expect to reduce short bowel syndrome, which is a risk for patients who have an intestinal length of less than 2 m [8]. The intestinal length of 2.5-m is adequate for the majority of the patients. However, by keeping it 3 m, we provide a margin if the bowel is inaccurately measured. As per the new recommendation of the IFSO, we prefer calling this modification as SADI-S only [9].

Sanchez-Pernaute et al. reported EWL of 94.7% at 1 year after SADI-S, and then the weight is maintained unchanged over the second and third year [10]. Although our %EWL was little lesser than Sanchez-Pernaute's paper, the weight loss pattern was very similar to the ones reported from their study. EWL approximates 80% after the first post-operative year; it is increased to 85% by 1.5 years and is unchanged and maintained over 85% by second to fourth post-operative year. Neichoy et al. also reported 88% EWL at 2 years [11] similar to our weight loss. Our study used non-linear regressions to get the best possible weight loss. The use of non-linear regression allowed our line of best fit to have a higher correlation coefficient when compared with linear regression. Another important thing to

Table 4 Long-term complications

Complication	*N*	Grade I	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade IVb	Grade V
Stricture[1]	13				13			
Nausea and vomiting[2]	12	10	2					
Diarrhea[3]	9	2			7			
Retrograde filling of afferent limb[4]	4				4			
Constipation	1	1						
Non-healing wound infection	1		1					
Malnutrition[5]	1				1			
Hypoproteinemia[6]	1				1			
Dilated fundus[7]	2	1			1			
Reversed loop[8]	1				1			
Abdominal pain of unknown etiology[9]	1				1			
Death[10]	2							2
Total	48 (10.9%)	14 (3.2%)	3 (0.6%)		29 (6.6%)			2 (0.4%)

N number of patients

[1] Of 13 patients with sleeve stricture, 8 needed esophagogastroduodenoscopy (EGD) with dilation and 5 needed partial gastrectomy. All the strictures occurred in the first year of starting SADI-S surgery and have not seen any since then (part of the learning curve)

[2] Of 12 patients with nausea and vomiting, 8 were treated with only anti-emetics, 2 denied any intervention or treatment, and 2 had severe nausea and vomiting that caused dehydration needing IV hydration

[3] Of 9 patients with diarrhea, 1 patient was only treated with anti-diarrheals and 1 patient was put on low fat diet. Seven patients needed common channel lengthening to treat severe diarrhea. Of these 7 patients, 1 patient developed diarrhea because of miscounted common channel of 160 cm from primary SADI-S surgery. Common channel was lengthened to 450 cm

[4] These patients complained of chronic nausea and upper gastrointestinal series (UGI) showed flow of contrast in afferent limb. They underwent exploratory laparotomy and afferent limb was tacked to sleeve 4 cm proximal to pylorus. The technique has been previously discussed (37). Because of these patients, we have now made this as a standard procedure to tack the afferent limb to the sleeve. And since then, we have not seen any of this complication

[5] This patient suffered malnutrition because of severe depression. This patient underwent common channel lengthening to 470 cm

[6] This patient had miscounted common channel length of 185 cm. Malnutrition was a result of miscounted common channel and not due to procedure itself. The patient had difficulty keeping his pre-albumin up with excess weight loss. Feeding tube was placed but did not resolve the issue, finally patient underwent common channel lengthening to 385 cm

[7] Both this patients had severe abdominal pain. UGI series showed dilated fundus. Of 2 patients, one underwent partial gastrectomy while the other patient refused to seek any intervention

[8] This patient had persistent nausea and vomiting that did not resolve with dietary chnages, and anti-emetics. Patient underwent UGI series that showed reversed loop that was causing the symptoms. Patient underwent small bowel reconstruction with a Roux-en-Y anatomy. This complication was part of the learning curve

[9] This patient had chronic abdominal pain that did not resolve with pain medications. UGI was normal. Patient underwent exploratory laparotomy with severe adhesiolysis. However, no other cause was found for her abdominal pain. Post-operatively, patient continued complaining about pain. She underwent multiple diagnostic interventions but no abnormality was found. She even took nerve injections for pain but with no relief. Since we could not find any abnormality related to her complains, we transferred her to University hospital for further evaluation

[10] Both of these patients had death unrelated to surgery. First patient died because of cardiac arrest of unknown etiology. Second patient had a history of severe obstructive sleep apnea (OSA) but never took treatment for the same. Post-operatively, patient had severe hypoxia and respiratory acidosis. We explained the patient the risk of sudden death due to OSA and advised to get sleep apnea study done and use CPAP. However, patient refused the treatment and also demanded an early discharge. One month later, patient complained of sudden chest pain but refused to go to ER. The patient died the same night

note is that we only had 6.8% of the patients who failed to reach 50% EWL at 4 years. Sanchez-Pernaute study had 6.1% of the patients who also failed to reach 50% EWL at 5 years [12]. Some might argue that if 25% of the patients at 4 years have EWL > 100%, they might be considered outliers and might falsely elevate the mean; however, to overcome this, we removed the median for the patients at 4 years, and it was 83.5%. This value is closer to the mean 85.7% (Table 4). The median is more accurate in depicting results not skewed by outliers. With the mean being very close to the median, these outliers do not seem to have the impact we normally would think. Secondly, our standard excess weight is anything above a BMI > 25 kg/m^2. Thus, EWL > 100% is not excessive unless they present with the complication like malnutrition.

The major difference between the RYDS, Roux-en-Y gastric bypass (RYGB), and SADI-S is the presence of distal

Table 5 Compares nutritional outcomes at 12, 24, 36, and 48 months

	Pre-op ($N = 437$)		1 year ($N = 357$)		2 years ($N = 286$)		3 years ($N = 155$)		4 years ($N = 79$)		P value
	Abn	Total	Abn	Total	Abn	Total	Abn	Total	Abn	Total	
HbA_{1c}	210	391	12	209	9	174	6	105	3	55	< .001
Glucose	214	417	27	229	23	194	12	115	6	60	< .001
Insulin	225	367	6	120	5	106	4	70	1	34	< .001
Ca	15	411	19	227	14	191	7	114	6	59	.073
PTH	22	77	54	148	41	116	28	60	25	41	.006
Albumin	3	308	13	223	10	187	6	111	5	57	.010
TP	4	305	20	223	16	187	8	111	6	57	< .001
Cholesterol	113	405	11	146	9	128	7	76	2	39	< .001
TG	205	405	19	146	17	128	11	76	4	39	< .001
Ferritin	17	373	12	209	11	179	8	105	5	51	.528
Vit B12	8	376	1	207	0	178	0	103	0	52	.064
Vit B1	21	339	7	192	5	162	3	98	2	51	.427
Vit A	0	72	3	84	2	65	3	47	3	40	.232
Vit D	181	375	49	213	43	183	25	108	13	56	< .001
Vit E	0	73	0	17	–	–	–	–	–	–	1
Vit K1	0	71	1	17	–	–	–	–	–	–	1
Copper	–	–	21	198	16	167	13	102	8	53	.667
Zinc	–	–	26	197	21	166	10	102	5	53	.769

Abn abnormal, *TP* total protein, *TG* triglyceride, *HbA1c* glycosylated hemoglobin, *Ca* calcium, *PTH* parathyroid hormone

$P < 0.001$ is considered as statistically significant difference

anastomosis which is associated with small bowel obstructions secondary to internal hernias. This has been a source of major morbidity and mortality. A multicenter study by Surve et al. on 1328 patients over 9 centers who underwent SADI-S showed no incidence of internal hernias or volvulus [13]. Sethi et al. published long-term outcomes of RYDS where they showed EWL of 65.1% at 2 years, 8% internal hernias, 7% small bowel obstructions due to adhesions, and 4% malnutrition rate [14]. The reported incidence of internal hernias after RYDS varies from 0.4 to 18% [13–15]. High rates of internal hernias are also seen after RYGB. Obeid et al. reported the 12.8% incidence rate of an internal hernia with 10–13 years of follow-up [16]. However, with the avoidance of distal anastomosis, we have not had any readmission for small bowel obstructions secondary to internal hernias or volvulus, nor it has been ever reported in the literature after primary SADI-S surgery. Additionally, elimination of one anastomosis has further benefited; a reduction in the postoperative leak. We experienced a very low rate of the postoperative leak (0.2%), which was possibly due to a patient taking an anti-coagulant for the bleeding disorder. This led to the development of blood clot at the duodeno-ileostomy (DI). It is postulated that anastomotic leaks are very low in experienced hands [17] and one should find even lower rate with 1 anastomosis compared to 2. The other interesting complication that occurred in 13 patients at long-term was sleeve stricture. The strictures were caused by technical difficulties in the early phase of starting the SADI-S surgery and could be attributed to the part of the learning curve. However, since then, we have not seen any strictures.

However, with the arrival of the SG, many studies have recognized that it promises weight loss similar to RYGB with far fewer complications. The important question to answer is that if one can achieve satisfactory weight loss with SG, then why to add a malabsorptive component to it and increase the risk of vitamin and micronutrient deficiencies. Marceau and Biron published a study comparing the weight loss between patients who had undergone SG and patients who got intestinal component of DS without gastric reduction [18]. Initially, patients with SG had higher weight loss; however, at 5 years, patients with intestinal component had lasting weight loss compared to SG patients who had nominal weight loss. The similar results were seen in a matched cohort published between SG and SIPS by our institution that showed early weight loss was similar between the two operations, while the intestinal component becomes more important with weight loss differentials increasing as time since surgery lengthens [19]. This shows that early weight loss is from gastric component but adding intestinal component prolongs the weight loss.

We have seen many weight loss failures with RYGB. Our approach has been to convert them to SADI-S [20]. Most of the patients who have failed RYGB are eating small frequent carbohydrate meals. This is a physiological response to

Table 6 Resolution of comorbidities

		1 year ($N = 357$)	2 years ($N = 286$)	3 years ($N = 155$)	4 years ($N = 79$)
Diabetes	*N*	117/156	104/125	75/77	43/44
	Remission	*92 (78.6%)*	*81 (77.8%)*	*61 (81.3%)*	*35 (81.3%)*
	Improvement	23 (19.6%)	21 (20.1%)	13 (17.3%)	7 (16.2%)
	Worsened	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Unchanged	2 (1.7%)	2 (1.9%)	1 (1.3%)	1 (2.3%)
Hyperlipidemia	*N*	87/133	81/114	59/61	34/34
	Remission	*63 (72.4%)*	*57 (70.3%)*	*38 (64.4%)*	*24 (70.5%)*
	Improvement	22 (25.2%)	22 (27.1%)	19 (32.2%)	10 (29.4%)
	Worsened	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Unchanged	2 (2.2%)	2 (2.4%)	2 (3.3%)	0 (0%)
Hypertension	*N*	131/202	120/161	90/97	51/51
	Remission	*87 (66.4%)*	*82 (68.3%)*	*58 (64.4%)*	*36 (70.5%)*
	Improvement	42 (32%)	36 (30%)	31 (34.4%)	14 (27.4%)
	Worsened	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Unchanged	2 (1.5%)	2 (1.6%)	1 (1.1%)	1 (1.9%)
Obstructive sleep apnea	*N*	86/161	82/128	60/74	36/42
	Remission	*49 (56.9%)*	*48 (58.5%)*	*36 (60%)*	*23 (63.8%)*
	Improvement	25 (29%)	23 (28%)	22 (36.6%)	11 (30.5%)
	Worsened	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Unchanged	12 (13.9%)	11 (13.4%)	6 (16.6%)	3 (8.3%)

N number of patients with comorbidity at given point of a time (patient seen/at risk)

$P < 0.001$ is considered as statistically significant difference

vacillating blood sugar levels. This leads to the dumping syndrome. This is one of the most common complains seen after RYGB, as reported in up to 70% [21]. The pylorus's job is to maintain consistent blood sugar levels and thus maintain satiety. We had previously hypothesized that preservation of pyloric valve would reduce the chances of dumping syndrome [3]. Neichoy B et al. also did not find any patients who experienced dumping syndrome with SADI-S at 2-year follow-up [11]. Similar results were seen with Sanchez-Pernaute at 5-year follow-up [12]. With 4-year data and 437 sample size, we did not find a single case of dumping syndrome which emphasizes the importance of pyloric sparing surgery.

Most surgeons who perform RYGB choose not to do BPD-DS due to a fear of malnutrition. We extensively studied this retrospectively. Patients were followed at regular interval till 1 year with blood work and then at least once at 2–4 years. Eight percent of the patients had abnormal albumin levels, and 10.5% had abnormal total protein level at 4 years. And this difference was statistically significant compared to baseline. However, the mean pre-operative and post-operative albumin (pre-operative 4.2 ± 0.37 vs post-operative 3.9 ± 0.5) and total protein levels (pre-operative 7.3 ± 0.5 vs post-operative 6.6 ± 0.5) were normal at 4 years. Beside this, clinical malnutrition was seen in 2 patients, 1 patient (0.2%) who had malnutrition due to severe depression and 1 patient (0.2%) who had severe hypoproteinemia due to miscounted common channel and both were treated with CCL. None of this clinical malnutrition can be attributed to the primary surgery itself. Similar rates of malnutrition were seen by Sancher-Pernaute et al. at 3 years [10]. Many times patient tends to be non-compliant about the diet regime that must include 90-g protein per day, and malnutrition can be secondary to non-compliance. Although our patients underwent the corrective procedure (CCL) to treat malnutrition, none of them needed reversal procedure for malnutrition.

Frequent loose stools can potentially be a side effect of malabsorptive procedures. In this study, of the 437 patients, 9 (2%) patients complained of persistent diarrhea. Of the 9 patients, 2 patients had mild diarrhea and were treated symptomatically, while 7 patients had severe diarrhea and underwent common channel lengthening to a 450- and 500-cm common channel. Diarrhea stopped after this corrective surgery. Additionally, of these 7 patients, 1 patient had diarrhea because of the miscounted common channel of 160-cm and not because of the primary standard SADI-S procedure. Practically, only 6 patients (1.3%) had severe persistent diarrhea because of SADI-S procedure at 4 years. However, our rate of diarrhea and rate of readmissions were low at even 4 years.

All patients were encouraged to follow-up with our dietician at regular interval and were given identical vitamin and mineral supplements as RYDS. The major concern with these

primary procedures is lack of compliance with supplements. We did not find the statistical difference in vitamin values measured between all 4 years. Surprisingly, there was a statistical difference between pre- and post-operative vitamin D levels with fewer patients having abnormal values post-operatively. Our major concern was calcium deficiency; however, there was no statistically significant difference between the baseline and follow-up at each month. All the patients with malabsorptive procedure need a higher daily recommendation for calcium due to body's limited ability to absorb calcium. The goal is to reach D3 levels over 30 ng/ml and parathormone under 100 pg/ml. However, this has also been seen for RYGB [22] and BPD-DS [23]. Dolan et al. [24] compared the nutritional side effects of BPD alone vs. BPD-DS, by performing a nutritional screen at a median follow-up of 28 months. One quarter of the patients were hypocalcemic despite more than 80% taking vitamin supplements. There was no significant difference between the BPD and BPD-DS, suggesting that DS does not lessen the nutritional side effects of BPD. Recently, a paper published by Abd-Elatif et al. on the nutritional markers after SADI-S showed that SADI-S is not associated with broad nutritional deficiencies [25]. Compared to BPD-DS, the SADI-S with its 300-cm common channel had less malnutrition and malabsorption [14].

Another major concern is an afferent loop syndrome (ALS). To date, we have encountered 4 patients with the complains similar to ALS except they did not have bilious vomiting. When an upper gastrointestinal series (UGI) was performed in all the cases, filling of an afferent limb with contrast suggested a widely patent anastomosis, and the need to revise the DI was eliminated. Eventually, in all cases, the contrast emptied into the efferent limb without refluxing back to the stomach. Simply by bringing down the scar tissue and tacking the afferent limb above the DI resolved the retrograde filling of an afferent limb. Since then, we have made this as a standard practice, to tack the afferent limb to the sleeve 4 cm proximal to the pylorus [26]. We have not seen any of this complication since then. We believe this complication could also have been a part of our learning curve. Importantly with 5 years of experience, Dr. Sanchez and Dr. Torres et al. did not report a single incidence of ALS or major complications related to loop reconstruction [10, 12].

Although this is not a randomized prospective trial, we believe that these are very important findings. Fair criticism is that the SADI-S is still considered experimental procedure in the USA (while it is not by IFSO). The corresponding author is one of the first adopters of the SADI-S procedure in the USA. As a result, experience and learning curve cannot be completely dismissed when viewing post-operative complications. This is especially true for some of our long-term complications, such as stricture, retrograde filling of afferent limb, reversed loop, and miscounted common channel. These complications happened in the first 2 years of our experience and have not occurred in the last two. Additionally, many complications were unrelated to surgery such as malnutrition due to depression, 2 deaths due to cardiac arrest or OSA, and diabetic keto-acidosis (DKA) due to patient's negligence to continue diuretics or diabetic medications. Even the complication like PVT has not occurred since the time we have changed our DVT protocol nor have we seen any patients with dehydration after we started our intravenous (IV) fluid clinic. For simplification, if we were to eliminate these complications, our actual early and long-term complication rates would have been 6.8 and 5.7%, respectively, lower than the actual complication rates (7.7 and 10.9%) mentioned in the result section. However, we wanted to be as accurate and as transparent as possible while reporting our results and that is why we did not exclude these complications from our result section.

The other important hallmark of this study was the resolution of comorbidities. Four-year effect of SADI-S on T2DM remission was maintained in 81.3% of patients with no recurrence. Similarly, our HbA1c rate < 6% was maintained for 94.5–97.6% of our patients with or without the use of medication at 4 years. However, we believe the remission rate for diabetes might decrease over the long-term depending on the duration of the disease and use of insulin therapy. Sanchez-Pernaute et al. had also reported 72% remission rate at 12 years. At 5 years, they reported 52 and 8%, remission and recurrence rates, respectively [12]. Although they had low recurrence rate, they also had significantly lower remission rate compared to early post-operative results. But this trend has also been observed with RYGB and SG but with higher recurrence rate and lower remission rate [27–31]. Furthermore, for those with profound insulin resistance, RYGB may not be the best metabolic procedure as we discussed before. Five-year outcomes of the diabetes resolution rate with STAMPEDE trial found that 29% patients with RYGB and 23% patients with SG achieved HbA1c < 6% or less with or without medication [32]. This is far less than the remission rate we found in our study. Roslin et al. state that DS is the best option for T2DM remission and other metabolic syndromes [33]. Over 20 years of follow-up, DS has 93% T2DM resolution rate [34]. Our results are comparable to the ones seen after DS. SADI-S is a technical modification of DS and preserves all the anti-diabetic potential of the operation: moderate gastric restriction that causes moderate reduction in calorie intake, a bypass of the duodeno-pancreas, a rapid entrance of undigested chyme into the distal intestine, selective fat malabsorption, and maintenance of weight loss all very well explains the high diabetes remission rate. The same mechanisms explain the improvement of lipid profile [35].

As with any retrospective analysis, limitations exist. Patients follow-up at different intervals and also miss appointments. That being stated, weight loss has been impressive at 4 years. The other limitation is the sample size and only small percent of total sample size available at 4 years. Although the sample size is 437, it could always be more and we always strive for greater follow-

up but 55.7% at 4 years was all we could achieve despite years of letters, phone calls, and emails. Given that, it is important to note that there is very limited data on SADI-S and this study is the first comprehensive long-term report on the procedure. With longer common channel, eliminating the Roux limb and a smaller sleeve, SADI-S has shown better or similar weight loss with less malabsorptive deficiencies compared to RYDS or RYGB.

Conclusion

Analysis of our 4-year data showed that compared to RYDS, SADI-S is technically easier to perform, retains the majority of its efficacy, and reduces the likelihood of nutritional deficiencies. Similarly, compared to RYGB, SADI-S with reduced intestinal anastomosis has less post-operative ulcer, leak, operative time, and better weight loss. Modification of RYDS to SADI-S had an effective weight loss at mid-term follow-up and will require further long-term outcome studies with larger sample size.

Compliance with Ethical Standards

Statement of Human and Animal Rights I certify that the manuscript did not involve the use of animal or human subjects.

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

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

Hinali Zaveri has no conflict of interest to declare.
Amit Surve has no conflict of interest to declare.
Austin Cottam has no conflict of interest to declare.
Walter Medlin has no conflict of interest to declare.
Christina Richards has no conflict of interest to declare.
LeGrand Belnap has no conflict of interest to declare.
Samuel Cottam has no conflict of interest to declare.
Benjamin Horsley has no conflict of interest to declare.

All other authors have no commercial associations that might be a conflict of interest in relation to this article.

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