#### **ORIGINAL CONTRIBUTIONS**





# A Matched Cohort Comparison of Long-term Outcomes of Roux-en-Y Gastric Bypass (RYGB) Versus Single-Anastomosis Duodeno-ileostomy with Sleeve Gastrectomy (SADI-S)

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Received: 2 October 2020 / Revised: 11 November 2020 / Accepted: 11 November 2020 © Springer Science+Business Media, LLC, part of Springer Nature 2020

## Abstract

**Background** The long-term effectiveness of Roux-en-Y gastric bypass (RYGB) and single-anastomosis duodeno-ileostomy with sleeve gastrectomy (SADI-S) is unknown.

Purpose Compare the long-term outcomes.

Setting Single private institute, USA.

**Materials and Methods** Data from 1254 patients who underwent primary RYGB or SADI-S were used for a retrospective matched cohort. Data were obtained by matching every RYGB patient to a SADI-S patient of the same sex, body mass index (BMI), and weight. Only patients out 5 years and had at least one > 5-year follow-up visit were included.

**Results** The matched cohort included 61 RYGB and 61 SADI-S patients. There was no statistical, demographic difference between the two groups. At 5 years, a 100% follow-up was available in each group. The intraoperative outcomes were significantly better with SADI-S. The 30-day readmission, reoperation, emergency department (ED) visits, and complication rates were statistically similar between the two groups. The long-term complication rates, Clavien-Dindo grade IIIb complications, and number of patients with more than one complication were significantly lower with SADI-S. Weight loss was significantly greater in the SADI-S group at 5 years. The long-term weight-loss failure rate was significantly higher in the RYGB group. The SADI-S procedure was associated with fewer reintervention through 6 years (14.7% patients vs. 39.3% patients, p = 0.001). Conversion or reversal of the procedure was required only in the RYGB group. There also was no significant difference in nutritional outcomes between the two procedures.

**Conclusions** This study showed that problems, including long-term complications, reinterventions, weight-loss failure, and conversion, were more often associated with RYGB than with SADI-S. The SADI-S may be considered one of the viable alternatives to RYGB.

Keywords Long term · Matched cohort · RYGB · SADI-S · Versus · Bariatrics

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<sup>1</sup> Bariatric Medicine Institute, 1046 East 100 South, Salt Lake City, UT 84102, USA Bariatric surgery procedures can treat morbid obesity and associated comorbid conditions. There are two mechanisms, restriction and malabsorption of food, by which a bariatric procedure can induce significant weight loss. A mixed type of bariatric procedure is a combination of a degree of restriction and malabsorption. Such procedures are usually used to treat patients with a higher body mass index (BMI). In this category of bariatric procedures, the RYGB has the longest history of any bariatric procedure worldwide [1]. According to a report by the American Society for Metabolic & Bariatric Surgery (ASMBS), the RYGB is the second most performed bariatric procedure in the USA [2]. When compared to the total number of other types of mixed or malabsorptive bariatric procedures, it is the most common bariatric procedure in the USA to date. In spite of being the most commonly performed mixed type of bariatric procedure and its overall benefits, the report by the ASMBS shows a continuous and rapid decline in the number of RYGB operations in recent years [3]. The numerous long-term complications associated with the procedure may have been the reason for its decreasing trend over time.

The single-anastomosis duodeno-ileostomy with sleeve gastrectomy (SADI-S) is a mixed type of bariatric procedure. The procedure was introduced as a potential alternative to RYGB or biliopancreatic diversion with duodenal switch (BPD-DS). Recently, there has been a slow rise in the number of SADI-S cases. The need for an alternative mixed bariatric procedure along with several favorable early-, medium-, and long-term outcome reports on the procedure has helped SADI-S gain popularity in the field [4-21]. Moreover, based on clinical knowledge, expert opinion, and published peerreviewed scientific evidence, the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) and the American Society for Metabolic & Bariatric Surgery (ASMBS) considered the SADI-S an established bariatric procedure [22, 23]. There have been only a few reports on the long-term outcomes of the primary SADI-S procedure [4, 5]. The long-term outcomes of this mixed type of bariatric procedure are promising [4, 5]. However, no study has compared its long-term effect with the other mixed type of established procedures in bariatric.

To address this gap in the literature, the present study aimed to evaluate and compare the long-term outcomes of laparoscopic primary RYGB and laparoscopic primary SADI-S in a matched group of individuals.

# Methods

This study has been approved by the Quorum institutional review board (IRB) (QR# 31353). The de-identified data of 1254 patients that had either laparoscopic primary RYGB or laparoscopic primary SADI-S from January 2012 through November 2019 by three surgeons at a single institute were retrospectively analyzed for potential inclusion. Although three surgeons participated in the study, they assisted each other. Moreover, their techniques and protocols were identical. During this period, 504 patients underwent laparoscopic primary RYGB procedure, and 750 patients underwent laparoscopic primary SADI-S procedure.

The study had three main inclusion criteria. One, the patients needed to be out 5 years following the surgery. Second, at least one follow-up visit was required past 5 years. After implementing the first two filters, every primary RYGB patient was matched to a primary SADI-S patient of the same sex and BMI (with one point). Patients that did not match were excluded from the study.

The recorded preoperative weight and BMI were the ones closest to the surgery. The ideal weight was defined by the weight corresponding to a BMI of 25 kg/ m<sup>2</sup>. Data points like weight, BMI, ideal body weight (IBW), and excess body weight (EBW) were used to calculate the change in BMI, percent of total weight loss (%TWL), percent excess body mass index (%EBMIL), and percent excess weight loss (%EWL). The short-term (< 30 days) and long-term (> 30 days) complications were reviewed and graded on the Clavien-Dindo scale [24]. Weight-loss failure was defined as not losing or not maintaining > 50% of the excess weight at or beyond 18 months postoperatively [9]. A high-risk patient was defined as any patient with >65 years of age, male patient with BMI >55 kg/m<sup>2</sup>, and female patient with BMI > 60 kg/m<sup>2</sup>. Comorbid conditions included were hypertension (HTN), type 2 diabetes (T2D), hyperlipidemia (HLD), gastroesophageal reflux disease (GERD), and obstructive sleep apnea (OSA). The presence of any of the comorbid conditions was based on medication use or a positive sleep study. For the RYGB patients, we recommended a multivitamin, calcium citrate (1500 mg/day), iron (if needed [65 mg/day]), vitamin  $B_{12}$  (1000 mcg/week), vitamin D (5000 IU per day), and probiotics (daily). For the SADI-S group, we recommended ADEK multivitamin, calcium citrate (1800-2400 mg/day), iron (65 mg/day), vitamin, and probiotics (daily).

Continuous variables were characterized using means and standard deviations. Categorical variables were characterized using frequencies and percentages. Demographic characteristics were compared using *t* tests. For all analyses that involved inferential statistics, a *p* value of < 0.05 was considered statistically significant. Non-linear regression analyses were performed to obtain weight-loss values. All statistical analyses were done using Sigma Plot statistical software (Systat Software, San Jose, CA, USA).

#### **Surgical Technique**

The RYGB Procedure Our surgical technique of laparoscopic RYGB has been described previously [25]. The surgical technique was 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 gastrointestinal anastomosis (GIA) 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 a 25-mm end-to-end anastomosis (EEA) technique. The biliopancreatic limb was 30 cm long, and the common channel was not counted in any patient.

**The SADI-S Procedure** Our surgical technique of SADI-S has been described previously [4, 8, 13]. Of note, we do not close the mesenteric space behind the loop when constructing the anastomosis.

## Results

Overall, 122 patients were identified for analysis. The matched cohort included 61 RYGB and 61 SADI-S patients. The follow-up was available on 100% of patients in each group.

The demographic statistics are shown in Table 1. There was no statistically significant difference in percent female, age, preoperative BMI, weight, IBW, and EBW, and baseline comorbid conditions like HTN, T2D, HLD, GERD, and OSA. However, the SADI-S group had a significantly higher number of high-risk patients (27 [44.2%] vs. 9 [14.7%], p < 0.001) (Table 1).

#### **Operative Outcomes**

The mean length of stay (LOS) was significantly shorter with the SADI-S procedure  $(2 \pm 1\text{-day vs. } 2.7 \pm .9\text{-day}, p < 0.001)$  (Table 1).

 Table 1
 Characteristics and operative outcomes of patients in the study groups

	RYGB	SADI-S	p value
Variable			
Subject (no.)	61	61	-
M/F (no.)	12/49	12/49	1.000
Age (year)*	$44.3\pm13.2$	$49.1\pm14.2$	0.056
Preoperative BMI (kg/m <sup>2</sup> )*	$48.1\pm8.5$	$47.8\pm8.1$	0.842
Preoperative weight (kg)*	$133.4\pm27.9$	$132.1\pm26.3$	0.790
IBW (kg)*	$61.5\pm9.5$	$62.3\pm10.3$	0.670
EBW (kg)*	$71.8\pm23.8$	$69.7\pm22.5$	0.620
High risk (no.)	9	27	< 0.001
Baseline obesity-related comor	bidity		
HTN (no.)	26	41	0.011
T2D (no.)	22	30	0.200
HLD (no.)	26	26	0.855
GERD (no.)	20	22	1.000
OSA (no.)	28	30	0.856
Operative outcomes			
Length of stay (day)*	$2.7\pm0.9$	$2\pm 1$	< 0.001

Values with italic emphasis are statistically significant

*RYGB*, Roux-en-Y gastric bypass; *SADI-S*, single-anastomosis duodenoileal bypass with sleeve gastrectomy; *no.*, number; *M*, male; *F*, female; *BMI*, body mass index; *IBW*, ideal body weight; *EBW*, excess body weight; *HTN*, hypertension; *T2DM*, type 2 diabetes; *HLD*, hyperlipidemia; *UA*, unavailable; *GERD*, gastroesophageal reflux disease; *OSA*, obstructive sleep apnea

\*Value expressed as mean ± standard deviation

#### 30-Day Readmission, Reoperation, and Emergency Room Visit

The 30-day readmission, reoperation, and emergency room (ER) visit rates are shown in Table 2. The 30-day readmission rate was 3.2% with both procedures. The 30-day reoperation rate was 3.2% with the RYGB procedure and 0% with the SADI-S procedure. The 30-day ER visit rate was 3.2% with the RYGB procedure and 1.6% with the SADI-S procedure. There were no statistically significant differences in the 30-day readmission, reoperation, and ER visit rates between the two groups.

#### Short-term Complication

The total number of patients that experienced short-term complications was statistically similar between the two groups (p = 1.000) (Table 2).

In the RYGB group, there were a total of six (9.8%) shortterm complication events in five (8.1%) patients (Table 2). Of these five patients, in total, two Clavien-Dindo grade IIIb complications occurred in two (3.2%) patients.

In the SADI-S group, there were a total of six (9.8%) shortterm complication events in six (9.8%) patients (Table 2). There were no grade IIIb complications in this group.

There was no statistically significant difference in the total number of patients that experienced grade IIIb complications between the two groups (p = 0.476).

#### Long-term Complication

The total number of patients that experienced long-term complications was significantly higher in the RYGB group (38 [62.2%] vs. 12 [19.6%],  $p \le 0.001$ ) (Table 3).

In the RYGB group, there were 64 (104.9%) long-term complication events in 38 (62.2%) patients (Table 3). In this group, there were 40 (65.5%) long-term grade IIIb complications in 28 (45.9%) patients.

In the SADI-S group, there were 14 (22.9%) long-term complication events in 12 (19.6%) patients (Table 3). In total, there were five (8.1%) long-term grade III complications in five (8.1%) patients.

The total number of patients that experienced grade II and IIIb complications was significantly higher in the RYGB group (grade II [p = 0.016], grade IIIb [p < 0.001]).

#### Short- and Long-term Complication

The RYGB group had a significantly higher number of patients with more than one complication during follow-up (17 [27.8%] vs. 2 [3.2%], p < 0.001). In the RYGB group, in total, 42 (68.8%) patients experienced any type of complication, 
 Table 2
 30-day readmission, reoperation, and ER visit and short-term complications

30-day readmission, reoperation, a	nd E	R visit								
		RYG	B no. (%)	SADI-S no. (%)		<i>p</i> value				
30-day readmission (event)		2 (3.2	2)	2 (3.2)	2 (3.2)					
Cause		GJA	leak	Dysphagia						
		Abdo	minal pain	Dehydration						
30-day reoperation (event)		2 (3.2	2)	0				0.476		
Cause		Adhe	sions at the JJ	-						
		GJA	leak	-						
30-day ER visit (event)		2 (3.2	2)	1 (1.6)				1.00		
Cause		GJA	leak	Nausea and vomiting						
		Abdo	minal pain	-						
Short-term complication										
Complication (event)	RYGB			Complication (event)	SADI-S			<i>p</i> value		
	No.		%		No.		%	(RYGB vs. SADI-S [pt])		
Marginal ulcer	1		1.6	Dehydration	2		3.2	-		
Anastomotic leak	1		1.6	Wound infection	2		3.2	-		
Abdominal pain	1		1.6	Blood in JP drain	1		1.6	-		
Dysphagia	1		1.6	Nausea and vomiting	1		1.6	-		
Wound abscess	1		1.6					-		
Hypokalemia	1		1.6					-		
Total event	6		9.8	Total event (no.)	6		9.8	-		
Total patient (no. [%])	5 (8	.1%)		Total patient (no. [%])	6 (9	.8%)		1.000		
Clavien-Dindo classification grade	RYGB			Clavien-Dindo classification grade	SADI-S			<i>p</i> value		
	Eve		Patient		Eve		Patient	(RYGB vs. SADI-S [pt])		
	No.	%	No. (%)		No.		No. (%)			
Ι	3	4.9	2 (3.2%)	Ι	0	0	0	0.476		
II	1	1.6	1 (1.6%)	II	6	9.8	6 (9.8%)	0.119		
IIIa	1	1.6	1 (1.6%)	IIIa	0	0	0	1.000		
IIIb	2	3.2	2 (3.2%)	IIIb	0	0	0	0.476		
IV	0	0	0	IV	0	0	0			

ER, emergency room; RYGB, Roux-en-Y gastric bypass; SADI-S, single-anastomosis duodeno-ileostomy with sleeve gastrectomy; no., number; GJA, gastro-jejunal anastomosis; JJ, jejuno-jejunal anastomosis; JP, Jackson-Pratt; pt, patient

Clavien-Dindo classification grade: I, any deviation from the normal postoperative course; II, normal course altered; IIIa, complications that require an intervention performed under local anesthesia; IIIb, complications that require an intervention performed under general anesthesia; V, death

and in the SADI-S group, in total, 16 (26.2%) patients experienced any type of complication (p < 0.001).

## Long-term Reintervention

The total number of patients that required long-term reintervention was significantly higher in the RYGB group (24 [39.3%] vs. 9 [14.7%], p = 0.004) (Table 4).

In the RYGB group, in total, there were 60 long-term reinterventions in 24 (39.3%) patients (Table 4). Of these 60 long-term reinterventions, 46.6% (28/60) were esophagogastroduodenoscopies (EGD), 33.3% (20/60) were computed topography scans (CAT scan), 16.6% (10/60) were upper gastrointestinal series (UGI), 1.6% (1/60) were manometries, and 1.6% (1/60) were ultrasound scans (USG).

In the SADI-S group, in total, there were 14 long-term reinterventions in nine (14.7%) patients (Table 4). Of these 14 long-term reinterventions, 50% (7/14) were EGDs, and 50% were UGI series.

The total number of patients that required EGD or CAT scan was significantly higher in the RYGB group (EGD [p = 0.034], CAT scan [p < 0.001]) (Table 4).

#### **Conversion and Reversal**

A significantly higher number of patients in the RYGB group required a conversion (7 [11.4%] vs. 0%, p = 0.020) (Table 4). Three (4.9%) patients in the RYGB group were reversed to normal anatomy (Table 4). Of the four patients that were converted to SADI-S, the indications for conversions were

#### Table 3 Long-term complications

Complication (event)	RYC	βB		Complication (event)	SAD	I-S		<i>p</i> value
	No.		%		No.		%	(RYGB vs. SADI-S [pt])
Marginal ulcer	10		16.3	Stricture	4		6.5	-
				a. Upper $1/3$ of the sleeve				
				b. Incisura				
Dumping syndrome	7		11.4	Diarrhea	3		4.9	-
Small bowel obstruction	7		11.4	Constipation	2		3.2	-
Internal hernia	6		9.8	Internal hernia	1		1.6	-
Anastomotic stricture	5		8.1	Dehydration	1		1.6	-
Abdominal pain	3		4.9	GERD	1		1.6	-
Ventral hernia	3		4.9	Inadequate weight loss	1		1.6	-
Dehydration	3		4.9	Dilated fundus	1		1.6	-
Perforated marginal ulcer	3		4.9					-
Intraabdominal abscess	2		3.2					-
Abdominal wall abscess	2		3.2					-
Constipation	2		3.2					-
Gastric outlet obstruction	2		3.2					-
Fistula	2		3.2					-
a. Gastrocutaneous								
b. Gastroenteric								
Hiatal hernia	2		3.2					-
Diarrhea	1		1.6					-
Abdominal wall seroma	1		1.6					-
Chronic pancreatitis	1		1.6					-
Dilated fundus	1		1.6					-
Dysphagia	1		1.6					-
Total event	64		104.9	Total event (no.)	14		22.9	-
Total patient (no. [%])	38 (6	52.2%)		Total patient (no. [%])	12 (1	9.6%)		< 0.001
Clavien-Dindo classification grade	RYC	βB		Clavien-Dindo classification grade	SAD	I-S		<i>p</i> value
0	Ever	ıt	Patient	0	Ever	nt	Patient	(RYGB vs. SADI-S [pt])
	No.	%	No. (%)		No.	%	No. (%)	
Ι	2	3.2	2 (3.2%)	Ι	3	4.9	3 (4.9%)	1.000
II	13	21.3	13 (21.3%)	П	3	4.9	3 (4.9%)	0.016
IIIa	9	14.7	8 (13.1%)	IIIa	3	4.9	3 (4.9%)	0.206
IIIb	40	65.5	28 (45.9%)	IIIb	5	8.1	5 (8.1%)	< 0.001
IV	0	0	0	IV	0		0	-

Values with italic emphasis are statistically significant

RYGB, Roux-en-Y gastric bypass; SADI-S, single-anastomosis duodeno-ileostomy with sleeve gastrectomy; no., number; GERD, gastroesophageal reflux disease; pt, patient

Clavien-Dindo classification grade: I, any deviation from the normal postoperative course; II, normal course altered; IIIa, complications that require an intervention performed under local anesthesia; IIIb, complications that require an intervention performed under general anesthesia; V, death

inadequate weight loss (three patients [4.9%] and non-healing marginal ulcer (one patient [1.6%]). All the conversions were single step.

### Long-term Weight-Loss Outcomes

In this study, nine (14.7%) patients in the RYGB group and three (4.9%) of the patients in the SADI-S group required medication-assisted weight loss (p = 0.128) (Table 5).

At 5 years, the weight loss was significantly better with the SADI-S procedure (p < 0.001) (Table 5). The change in BMI was  $15.8 \pm 2.7$  with the RYGB procedure and  $18.1 \pm 3.1$  with the SADI-S procedure (p < 0.001). The %TWL was  $32.5 \pm 7.5$  with the RYGB procedure and  $37.8 \pm 4.9$  with the SADI-S procedure (p < 0.001). In both groups, RYGB and SADI-S, there was no statistically significant difference in weight loss between 5 and 6 years.

The long-term weight-loss failure rate was significantly higher in the RYGB group (22 [36%] vs. 13 [21.3%], p = 0.028) (Table 5).

#### Long-term Nutritional Outcomes

The nutritional outcomes are shown in Table 6.

The nutritional outcomes were compared using the total number of patients with abnormal lab values and mean values of the nutrients (Table 6). Nutrients like vitamins D, B<sub>1</sub>, and B<sub>12</sub>; insulin; fasting blood glucose; glycosylated hemoglobin (A1C); serum albumin; serum total protein; serum calcium; cholesterol; and triglyceride were compared between the two procedures at baseline and > 5 years. Nutrients like vitamins A, E, and K, and zinc, and copper were only available for the SADI-S patients.

Long-term reintervention	RYGB			SADI-S	5		<i>p</i> value
	Event No.	%	pt No. (%)	Event	%	pt	(RYGB vs. SADI-S [pt])
FGP@				No.		No. (%)	0.024
EGD <sup>@</sup>	28	46.6	16 (26.2%)	7	50	6 (9.8%)	0.034
UGI	10	16.6	9 (14.7%)	7	50	6 (9.8%)	0.581
CAT scan	20	33.3	14 (22.9%)	0	0	0	< 0.001
Manometry	1	1.6	1 (1.6%)	0	0	0	1.000
USG	1	1.6	1 (1.6%)	0	0	0	1.000
Total reintervention	60	98.3	-	14	0	-	-
Total patient (no. [%])*	24 (39.3	3%)		9 (14.7	%)		0.004
Median no. of reintervention*	2			1			-
Range (min, max) (no.)*	(1, 7)			(1, 4)			-
Conversion	RYGB			SADI-S	5		<i>p</i> value
Patient (no. [%])	7 (11.49	%)		0			0.020
Reversal	RYGB			SADI-S	5		<i>p</i> value
Patient (no. [%])	3 (4.9%	b)		0			0.248

Table 4 Long-term reintervention, conversion, and reversal

Values with italic emphasis are statistically significant

RYGB, Roux-en-Y gastric bypass; SADI-S, single-anastomosis duodeno-ileostomy with sleeve gastrectomy; no., number; EGD, esophagogastroduodenoscopy; UGI, upper gastrointestinal series; CAT scan, computed tomography; USG, ultrasonography

<sup>@</sup> Diagnostic or therapeutic

\*Values are only for patients that required any reintervention

The total number of patients with abnormal lab values at baseline and > 5 years was compared between the two procedures. There was no statistically significant difference between the two groups for nutritional data such as vitamins

-				
Medication-assis	ted weight loss	RYGB	SADI-S	p value
Patient (no. [%]	)	9 (14.7%)	3 (4.9%)	0.128
Weight-loss outc	omes			
5 years		RYGB	SADI-S	<i>p</i> value
Follow-up (%	)	100	100	-
1. BMI		$34.1\pm3.9$	$29.1\pm5.9$	< 0.001
2. Change ir	n BMI	$15.8\pm2.7$	$18.1\pm3.1$	< 0.001
3. %TWL		$32.5\pm7.5$	$37.8\pm 4.9$	< 0.001
4. %EWL		$62.4 \pm 12.3$	$73.5\pm9.7$	< 0.001
Long-term weig	nt-loss failure	RYGB	SADI-S	<i>p</i> value
Non-responder	<25%EWL	4 (6.5%)	3 (4.9%)	-
	25-50%EWL	18 (29.5%)	10 (16.3%)	-
Total (non-respo	nder patient)	22 (36%)	13 (21.3%)	0.028
Responder	50-75%EWL	27 (44.2%)	30 (49.1%)	-
	100–75%EWL	9 (14.7%)	12 (19.6%)	-
	>100%EWL	3 (4.9%)	6 (9.8%)	-

Non-responders indicate those not losing or not maintaining > 50% weight loss; Responders indicate those losing or maintaining > 50% weight loss. Values with italic emphasis are statistically significant

RYGB, Roux-en-Y gastric bypass; SADI-S, single-anastomosis duodenoileostomy with sleeve gastrectomy; *no.*, number; *BMI*, body mass index; %*TWL*, percent of total weight loss; %*EWL*, percent excess weight loss D, B<sub>1</sub>, and B<sub>12</sub>; insulin; fasting blood glucose; A1C; serum albumin; serum total protein; and triglyceride (Table 6). However, when the mean values of nutrients at baseline and > 5 years were compared between both groups, serum calcium and cholesterol levels were significantly better (calcium [p < 0.001], cholesterol [p < 0.001]) with the SADI-S procedure (Table 6).

# Discussion

This is the first study in the literature that compared the longterm outcomes of the two established bariatric procedures, the RYGB and the SADI-S, in a matched group of individuals. We found that the operative outcomes, long-term complication rates, weight loss, and weight-loss failure rates were significantly better with the SADI-S procedure.

The RYGB is a powerful bariatric procedure. Despite the overall benefits of RYGB, there are numerous long-term complications associated with it. A long-term report on RYGB by Higa et al. had 32–37% patients with long-term complications, and internal hernia was the most common complication (16%), followed by gastrojejunal stenosis and marginal ulcer [26]. In the present report, in the RYGB group, 62.2% of patients experienced long-term complications. Kothari et al., in their long-term outcome report, found that marginal ulcer (3.6%), small bowel obstruction (1.3%), and internal hernia (1.1%) were the common complications associated with RYGB [27]. In a report by Sugerman et al., anastomotic complications (15%) and

Nutrient	RYGB				SADI-S						
	-	Preoperative (27/61, 44.2%)		> 5-year postoperative (21/61, 34.4%)		Preoperative (59/61, 96.7%)		> 5-year postoperative (11/61, 18%)		<i>p</i> value	
	Abn (no.)	Total (no.)	Abn (no.)	Total (no.)	Abn (no.)	Total (no.)	Abn (no.)	Total (no.)	Preoperative	> 5-year postoperativ	
Vitamin D											
pt	15	27	10	17	29	53	5	11	0.868	0.761	
$Mean \pm SD$	$32\pm13.8$		$31.5 \pm 16.6$	5	$31.9\pm19$		$33.8\pm7.9$		0.981	0.673	
Normal range Vitamin B <sub>1</sub>	32–100 ng	g/mL							-	-	
pt	1	17	1	14	7	52	1	11	0.669	1.000	
Mean $\pm$ SD	$152 \pm 79$		$165.8 \pm 12$	7.2	$169.8 \pm 19$	4	$164.4 \pm 54$	.5	0.715	0.973	
Normal range Vitamin B <sub>12</sub>	66.5–200	nmol/L							-	-	
pt	1	27	1	17	1	54	0	10	1.000	1.000	
-	$1778.4 \pm 13$		$1056.6 \pm 1$		$596.5 \pm 24$		$1329.8 \pm 6$		0.338	0.457	
Normal range			1020.0 - 1	020.0	570.5 - 24		1527.0±0		-	-	
Insulin	211-911	ε/IIIL							-	-	
pt	11	23	0	13	26	53	1	10	0.880	0.435	
Mean $\pm$ SD	$39.2 \pm 13.3$		$8.2 \pm 4.5$	15	$34.9 \pm 36.3$		$9 \pm 7.2$	10	0.584	0.747	
Normal range			0.2 ± 4.5		$34.9 \pm 30.2$	5	9 - 1.2		-	-	
Fasting blood gl		L							-	-	
pt	5	10	3	9	20	26	2	3	0.224	1.000	
	$127.5 \pm 70$		$109.2 \pm 55$		$151 \pm 106.$		$129.3 \pm 27$		0.525	0.569	
Normal range			109.2 ± 55		$151 \pm 100.$	. /	129.3 - 21	.0	-	-	
A1C*	05-100 III	g/uL							-	-	
pt	4	7	4	7	22	27	3	3	0.315	0.475	
Mean $\pm$ SD	4 7.1 ± 1.9	/	$4 6.7 \pm 1.7$	/	$8 \pm 2.8$	21	$6.7 \pm .8$	5	0.430	1.000	
Normal range			$0.7 \pm 1.7$		0 - 2.0		$0.7 \pm .0$		-	-	
Albumin	4-070								-	-	
pt	0	13	1	20	1	32	1	10	1.000	1.000	
Mean $\pm$ SD	0 4.1±.4	15	$3.8 \pm .5$	20	$4.2 \pm .3$	32	$3.9 \pm .4$	10	0.363	0.587	
Normal range		at.	$5.6 \pm .5$		4.2 ± .3		J.7 ± .4		-	-	
Total protein	5.2–4.8 g/	uL							-	-	
-	0	12	2	20	5	30	0	11	0.201	0.527	
pt Mean ± SD	0 7.2±.5	13	2 6.6±.6	20	5 7.2±.5	30	$0 \\ 6.8 \pm .4$	11	0.301 1.000	0.527 0.332	
Normal range			$0.0 \pm .0$		1.2 ± .5		$0.0 \pm .4$		-	-	
-	0–6.4 g/ui	_							-	-	
Calcium	1	27	2	20	0	50	2	10	0.214	0.594	
pt Mean ± SD	1	27	2 6.6±.6	20	0	59	2	10	0.314	0.584	
Mean $\pm$ SD Normal range	9.6±.5	ma/dI	$0. \pm 0.0$		$9.5 \pm .4$		$9.1 \pm .4$		0.324	< 0.001	
Cholesterol		-								-	
pt	7	26		17	15	58	1	10	0.868	1.000	
Mean $\pm$ SD	$177.3 \pm 38$		$151.9 \pm 35$	.9	$184.1 \pm 44$	.2	$79.5 \pm 36.3$	3	0.500	< 0.001	
Normal range Triglyceride	100–199 r	ng/dL							-	-	
pt	13	26	4	17	31	58	1	10	0.955	0.621	
$Mean \pm SD$	$181.5\pm90$	.9	$121.5\pm68$	.9	$232.4\pm28$	9.4	$79.5 \pm 36.3$	3	0.384	0.088	

 Table 6 (continued)

Nutrient	RYGB				SADI-S					
(27/6	Preoperative (27/61, 44.2%)		> 5-year postoperative (21/61, 34.4%)		1		> 5-year postoperative (11/61, 18%)		<i>p</i> value	
	Abn (no.)	Total (no.)	Abn (no.)	Total (no.)	Abn (no.)	Total (no.)	Abn (no.)	Total (no.)	Preoperative	> 5-year postoperative
Normal range	40–150 m	g/dL							-	-
Vitamin A										
pt	N/A	N/A	N/A	N/A	N/A	N/A	3	11	-	-
$Mean \pm SD$	N/A		N/A		N/A		$48.9 \pm 13.4$ .4 ± .1	1	-	-
Normal range	20–65 µg/	dL or .5–2 µ	umol/L						-	-
Vitamin E										
pt	N/A	N/A	N/A	N/A	N/A	N/A	0	10	-	-
$Mean \pm SD$	N/A		N/A		N/A		$10.9\pm2.7$		-	-
Normal range	5.5–18 mg	g/L							-	-
Vitamin K										
pt	N/A	N/A	N/A	N/A	N/A	N/A	0	10	-	-
$Mean \pm SD$	N/A		N/A		N/A		$.4 \pm .4$		-	-
Normal range	0.13–1.8 n	ıg/mL							-	-
Zinc										
pt	N/A	N/A	N/A	N/A	N/A	N/A	1	9	-	-
$Mean \pm SD$	N/A		N/A		N/A		$75\pm11.8$		-	-
Normal range	56–134 μ <u>ε</u>	g/dL							-	-
Copper										
pt	N/A	N/A	N/A	N/A	N/A	N/A	0	9	-	-
$Mean \pm SD$	N/A		N/A		N/A		$258.7\pm41$	6.8	-	-
Normal range	72–166 µş	g/dL							-	-

Data were presented as the number of patients with abnormal labs, preoperative and postoperative as well as mean  $\pm$  SD. Values with italic emphasis are statistically significant

*RYGB*, Roux-en-Y gastric bypass; *SADI-S*, single-anastomosis duodeno-ileal bypass with sleeve gastrectomy; *no.*, number of patients; *Abn*, abnormal; *SD*, standard deviation; *A1c*, glycated hemoglobin

\*Patients with preoperative T2D

marginal ulcers (9%) were the most common complications following RYGB [28]. Similar results were found in a study by Obeid et al. In their study, internal hernia (12.8%) and small bowel obstruction (6.1%) were the most common complications that occurred [29]. In most long-term outcome studies on RYGB, internal hernia, small bowel obstruction, and marginal ulcer were the long-term concerns. The reported incidence of internal hernia following RYGB ranges from .5 to 16% [7]. The reported internal hernia rate with SADI-S has always been low and ranges from 0 to .1% [4, 7]. In the present study, the RYGB group had 9.8% of patients who experienced internal hernia. However, with SADI-S, this percent (1.6%) was far lesser than RYGB. In SADI-S, the chances of internal hernia are low as the mesentery is not closed but wide open. We believe that there will be some incidence of volvulus in the long term, but very few incidences of vascular compromise, as the space is large. The biggest problem with this hypothesis is that it rests on comparatively few patients. Early on, many prominent surgeons said internal herniation after RYGB was not a problem, and they turned out to be very wrong. It was only with thousands of patients and numerous papers that this came to light. It is entirely possible that this same scenario could happen with SADI-S.

The reported incidence of marginal ulcer following RYGB ranges from .6 to 25% [7]. The present study had 16.3% of patients with a marginal ulcer in the RYGB group. The reported incidence of marginal ulcer with SADI-S is .1% [4, 7]. The present study had no ulcers in any of the SADI-S patients. Collectively, the studies on the long-term outcomes of RYGB indicate that the most commonly occurring long-term complications like internal hernia, marginal ulcers, and strictures are lesser with SADI-S than any other Roux-based procedure [4, 7, 26–29].

Another major problem associated with RYGB is the long-term grade III complications requiring surgical interventions. The reported rate of reoperation with RYGB ranges from 3 to 28% [30]. Angrisani et al. reported a 28.6% reoperation rate in RYGB patients [30]. In the present study, there were around 46% of patients that required reoperation in the RYGB group. Compared to RYGB, only 8.1% of patients required reoperation in the SADI-S group.

The long-term risks of reintervention following any type of mixed bariatric procedure are usually high. RA et al. studied the long-term risks of reintervention in 19,954 patients who underwent the RYGB procedure [25]. The reintervention rate at 5 years was 28.3%. In the present study, around 39% of the patients in the RYGB group and 14% of the patients in the SADI-S group required long-term reintervention. In both groups, the most common reintervention was EGD for any reason (diagnostic or therapeutic). Following EGD, the most common reintervention in the RYGB group was the CAT scan.

At first glance, experienced RYGB surgeons will question these findings since the short-term complication rates are similar. This reflects the fact that most surgeons can learn to do procedures safely in the short term. This is also true when comparing 30-day complication rates between RYGB and sleeve gastrectomy (SG) as well. However, most of the longterm complications do not come back to the surgeon of record, leaving the surgeon with a mistaken impression that the complication rate is lower than it is. However, when comparing the RYGB with SADI-S, the lack of Roux limb–specific complications is what drives the differences in complication rates. This is almost certainly not related to the skill of the surgeon, but solely on the choice of which procedure to perform.

The reported long-term weight loss with the RYGB procedure ranges from 49 to 68%EWL and from 22 to 31%TWL in the literature [31]. However, these all were >5-15 years of follow-up studies. Obeid et al., in their study, reported a weight loss of 61%EWL, specifically at 5 years in 68 RYGB patients [29]. Kothari et al. also reported similar weight-loss results at 5 years [27]. In their study, the weight loss was around 60%EWL at 5 years. Angrisani et al. had 24 patients with 66%EWL at 5 years [30]. Higa et al. had 43 patients with 68%EWL at 5 years [26]. We found similar results at 5 years. In the present study, the RYGB patients lost 62%EWL (32%TWL) at 5 years. So far, there have been only two long-term reports on the outcomes of SADI-S [4, 5]. Sanchez-Pernaute et al. reported the long-term outcomes in one of their reports on SADI-S [5]. However, this was studied only in a diabetic population, which also included revisional cases. In their study, the SADI-S procedures were performed using a 200-250-cm common channel. They had 25 patients at 5 years, and the reported EWL was 98% with a 200-250-cm common channel. In the present study, a common channel of 300 cm was used, and the weight loss at 5 years was 73.5% EWL and 37.8% TWL. Prospective studies on different lengths of the common channel in primary SADI-S are required to see the difference in the number of cases of diarrhea, malnutrition, and weight-loss outcomes. A similar problem, like different limb lengths, exists with RYGB as well. Nergaard et al. reported better weight loss with a 2-m biliopancreatic (BP) limb than with a 60-cm BP limb and a 150-cm alimentary limb [32]. However, Christou et al. found that the limb length did not impact the long-term weight loss in RYGB patients [33]. In our study, in the RYGB group, the BP limb was 50 cm and the Roux limb was 150 cm long.

With any mixed type of bariatric procedure, around 5-10% of patients will lose more than their ideal body weight. Higa et al. had 5.3% of patients who lost more than their IBW [26]. Similar results were found in the present study; both groups had a statistically similar number of patients that lost more than their IBW (RYGB = 4.9\% and SADI-S = 9.8\%).

Long-term weight-loss failure can be seen with any bariatric procedure. The reported long-term weight-loss failure rate with the RYGB procedure ranges from 14.6 to 35% [4]. It has been suggested that most patients who undergo the RYGB procedure are able to lose a significant amount of weight; however, these patients fail to maintain weight loss over time [33]. Higa et al. reported a 33.2% weight-loss failure rate [26]. Edholm et al. reported a 30% weight-loss failure rate (< 50%EBMIL) [34]. Christou et al. reported a failure rate of 18% within the first 5 years of follow-up [33]. Their results after > 10 years showed a weight-loss failure rate of 35% [33]. Suter et al. reported a weight-loss failure rate of 25% after 5 years [35]. In the present study, in the RYGB group, long-term weight-loss failure was noted in 36% of the patients. Of the 36% of patients who either failed to lose or maintain > 50%EWL in the long term, 13.6% of patients were converted to SADI-S.

Failed primary bariatric procedures are usually converted to other bariatric procedures or reversed to their normal anatomy, depending on the cause. In the long term, the most common reason for conversion to other bariatric procedures in RYGB patients is a weight-loss failure and not associated complications [36, 37]. Multiple treatment options for RYGB failure exist, including endoscopic therapies, adding an adjustable gastric band, revising the gastrojejunostomy, limb distalization, and conversion to BPD-DS or SADI-S. In the present report, in total, 6.5% of patients in the RYGB group were converted to SADI-S for any reason. The most common reason for conversion was insufficient weight loss. Similarly, the reason for failing the surgery in the SADI-S group was insufficient weight loss or regain. Both groups had a similar percentage of patients who achieved <25%EWL; however, the RYGB group had a higher percentage of patients in the 25-50%EWL category. The percentage of RYGB patients were double the percentage of patients in the SADI-S group in this category. Yet, this begs the question of what do you do with SADI-S patients that fail to achieve adequate weight loss, and at the present time, we have no adequate answer.

The long-term results of SADI-S were superior in most categories studied when compared with RYGB. However, one comparative report on the long-term outcomes of these two procedures cannot decide if SADI-S is the best alternative. In our opinion, with 7 years of experience with the SADI-S procedure and years of experience with the RYGB procedure, we can suggest that in our hands, the SADI-S is safer. More such type of long-term comparison reports with comorbidity and nutritional outcomes are required to make a definite conclusion.

The study had several limitations: first, the small sample size of the cohort. The study had 61 patients in each group, with a 100% follow-up at 5 years. In the majority of bariatric practices, only 20-25% of the patient population follow up after 5 years. Moreover, getting labs after 5 years is even more difficult. We were still able to compare our results with other long-term outcome studies in the literature because most studies on the long-term outcome of RYGB had less than 200 patients, specifically at 5 years [4, 5, 26, 27, 29, 30, 33]. Second is the lack of long-term comorbidity outcomes. We had sufficient long-term comorbidity data for one of the two procedures. However, since this was a comparative study, we decided not to present them. Third, the number of available labs was insufficient to make any definite conclusion on the nutritional outcomes. Surgeons will rightly be skeptical of this paper showing SADI-S with fewer nutritional complications than RYGB (especially calcium). Fourth is the retrospective nature of the study. Fifth is the learning curve of the SADI-S procedures. Our practice began to perform the SADI-S procedure in 2013. Around 55% of the SADI-S patients that have been included in the study had been operated in the first 2 years. Apart from these limitations, the study had some strengths. One of the strengths of the study was matching patients' demographics. Male sex and higher BMI have been identified as a risk factor for adverse events. In the present study, we were able to match both categories, allowing a fair comparison of like to like patients. Moreover, the matched cohorts are simpler to understand. Another strength of the study was the inclusion criteria. We were able to achieve a 100% follow-up in each group because of the strict inclusion criteria. The study only included patients out 5 years and had at least one > 5-year follow-up visit. And the last but most important strength of the study was that it adds to the knowledge on the long-term comparative outcomes of the two procedures as there is no such report in the literature.

# Conclusion

In this matched cohort comparison of long-term outcomes, the SADI-S procedure was superior to the RYGB procedure with regard to operative outcomes, lethal long-term complications, number of patients with more than one complication, reintervention rates, weight loss, weight-loss failure rates, and conversion rates. More such studies with a larger sample size are encouraged.

Author Contribution Amit Surve: conceived and designed the analysis, collected the data, performed the analysis, and wrote and revised the manuscript.

Daniel Cottam: primary operating surgery and reviewed the manuscript.

Christina Richards: primary or assisting surgeon.

Walter Medlin: assisting surgeon.

Legrand Belnap: assisting surgeon.

#### **Compliance with Ethical Standards**

**Conflict of Interest** Daniel Cottam, the corresponding author of this report, is part of the speaker bureau for Medtronic and has been awarded a research grant by Medtronic for the study of duodenal switch and reports personal fees and other from Medtronic and GI Windows, outside the submitted work. All other authors have no conflicts of interest to declare.

Ethical Approval For this type of study, formal consent is not required.

Informed Consent Does not apply.

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