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Original article

Long-term outcomes of primary single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S)

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Abstract

Background: The long-term outcomes of primary single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) have never been reported in the literature.

Objectives: The study aimed to evaluate the long-term outcomes after primary laparoscopic SADI-S (LSADI-S).

Setting: Single, private institute, United States.

Methods: Data from 750 patients who underwent a primary LSADI-S from June 2013 through November 2019 by 3 surgeons were retrospectively analyzed.

Results: Seven hundred fifty patients were included in the study. The mean age and preoperative body mass index were 49.3 ± 13.1 years and 50 ± 12.6 kg/m^2, respectively. Follow-up was available on 109 patients (61%) at 5 years and on 87 patients (53%) at 6 years. Six patients did not have any follow-up. The average operative time and length of stay were 67.6 ± 27.4 minutes and 1.5 ± .8 days, respectively. The intraoperative, short-term, and long-term complication rates were 0%, 7.8%, 11.7%, respectively. The 30-day emergency room visit, readmission, and reoperation rates were .4%, 1.1%, and 1.1%, respectively. In total, there were 15 (2%) grade IIIb long-term complications unique to LSADI-S. Complete remission of type 2 diabetes was seen in 77% of the diabetic population. At 5 and 6 years, the mean change in body mass index was 17.5 ± 6.9 and 17.6 ± 6.4 kg/m^2, respectively. The mortality rate was .5%.

Conclusions: LSADI-S is effective in this retrospective review in achieving good initial weight loss and weight maintenance. Although our data show acceptable nutritional complications, questions still remain because of the retrospective nature of the study. (Surg Obes Relat Dis 2020;16:1638–1646.)

Key words: SADI-S; SIPS; Long-term outcomes; Diabetes; Bariatric; Loop duodenal switch

The traditional duodenal switch (DS) is the most effective weight loss operation. However, utilization of this bariatric surgical procedure is limited compared with Roux-en-Y gastric bypass (RYGB), one-anastomosis gastric bypass, and sleeve gastrectomy (SG) because of its technical complexity, nutritional deficiencies, and complications.

The single-anastomosis duodeno-ileal bypass with sleeve gastrectomy using (SADI-S) is a modification of the traditional Roux-en-Y DS (RYDS). The loop configuration offers the opportunity to minimize the risk of ulcers and internal hernias while simplifying the operation [1]. Our group first used this approach in 2013 with a 300-cm common channel to reduce nutritional problems associated with the RYDS.

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Several short- and mid-term studies on SADI-S have been published recently [1–23]. These studies have shown that SADI-S has been effective in treating morbid obesity. Compared with other recognized procedures, in the short term, the weight loss was better than SG and RYGB; however, similar to RYDS [4,7,16]. Also, SADI-S can be used as a revision surgery after failed adjustable gastric banding and RYGB [12,14]. Moreover, SADI can also be used as a revision surgery after failed SG or as a planned second-stage surgery after SG [24].

These advantages of SADI-S surgery have been reported in several studies [1–23]. Although there is ample short- and mid-term evidence about the benefits and risks of SADI-S surgery, there is a paucity of long-term data to confirm the efficacy. The question is if SADI-S retains most of its advantages in the long term. So far, there has been only a single report on long-term outcomes of SADI-S; however, this was studied only in a diabetic population with very small numbers, which included revisional cases as well [25].

This is the first article and the largest series in the literature to report the long-term outcomes of primary laparoscopic SADI-S surgery (LSADI-S) and did not limit the population to diabetics.

Methods

This study has been approved by the Quorum institutional review board (QR# 31353). 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. This is a retrospective analysis of data from 750 consecutive patients who had undergone a primary LSADI-S procedure performed by 3 surgeons at a single, private institute from June 2013 through November 2019. Although 3 surgeons participated in the study, the technique and protocols were identical. Exclusion criteria were pregnant female or actively breastfeeding; patients considered being part of a vulnerable population, revision bariatric surgery, and patients with an estimated life expectancy of <6 months. All patients were required to attend an educational seminar. During the seminar, the patients were informed about the various surgical procedures for weight loss and their co-existing conditions. After this, the patients had an individual evaluation in the clinic. Each patient signed an informed consent detailing the surgery, risks, and potential benefits as well as to participate in our de-identified database. All potential surgery patients were evaluated using a multidisciplinary team approach.

Data were collected at baseline and each follow-up visit after surgery. Data for each patient were gathered retrospectively from a prospectively kept database. The preoperative assessment was performed within 30 days before the scheduled surgical procedure. The preoperative assessment included patient demographic characteristics, height, weight, body mass index (BMI), co-morbidity assessment, labs, surgical history, gastroesophageal reflux disease (GERD)–health-related quality-of-life questionnaire, and preoperative dietary restrictions. The operative assessment included weight, BMI, American Society of Anesthesiology grade, skin-to-skin time, anesthesia start and stop time, estimated blood loss, intraoperative complications, surgical technique, and if any patient was converted to open. All surgeries were performed laparoscopically using standardized perioperative and postoperative protocols. The discharge assessment included length of stay and surgical site infection assessment. The patients were required to follow-up at 2 weeks, at 1, 3, 6, 12, and 18 months, and then once annually after the surgery. Attempts were made to contact patients who were noncompliant. E-mails and telephones were used to contact patients. At least 2 phone calls were made to the patients, and each attempt was documented in the database. In addition, attempts were made to reach out to the general practitioner to determine the status of the patients. After this, after a period of 2 weeks, the patients were considered lost to follow-up.

The short- ($\leq$30 d) and long-term ($>$30 d) complications were reviewed and graded on the Clavien-Dindo scale [26]. The following weight-related parameters were recorded: weight (in pounds), BMI (in kg/m^2), and percentage of excess BMI lost with excess $>$25 kg/m^2, and percent total weight loss (%TWL). Weight loss failure was defined as not losing or not maintaining $>$50% weight loss at 18 months postoperatively [14]. Nutritional values were collected pre- and postoperatively. For each patient, labs were assessed every 3 months (if needed) in the first postoperative year and then annually. Postoperatively, the patients were recommended to take ADEK multivitamins (Bariatric Advantage, Aliso Viejo, CA, U.S.A.) by our facility. The patients were asked to take 2 tablets a day of Advanced EA Multivitamin by Bariatric Advantage (Bariatric Advantage, Aliso Viejo, CA, U.S.A.). In addition, they were also recommended protein intake of 60 to 80 g/d. Co-existing conditions included were type 2 diabetes (T2D), hyperlipidemia (HLD), hypertension (HTN), GERD, and obstructive sleep apnea (OSA). The presence of any of the co-existing conditions was based on medication use or a positive sleep study. The resolution or improvement of the co-existing conditions was defined according to the American Society for Metabolic and Bariatric Surgery guidelines [27].

Continuous variables were characterized using means and standard deviations. Categoric variables were characterized using frequencies and percentages. For nutritional data, Fisher's exact tests were used. All statistical analyses were done using R: A language and environment for statistical computing [28].

Operative technique

Our surgical technique of SADI-S has been described previously [4,15]. We do not close the mesenteric space behind the loop when constructing the anastomosis.

Results

Seven hundred fifty consecutive patients were identified for the study. Of 750 patients, 601, 464, 356, 319, 179, and 87 patients were beyond the 1, 2, 3, 4, 5, and 6 years' postoperative mark, respectively. Follow-up was possible for 442 patients at 1 year (74%), 268 patients at 2 years (58%), 177 patients at 3 years (50%), 146 patients at 4 years (46%), 109 patients at 5 years (61%), and 46 patients at 6 years (53%). The 30-day follow-up was 94% (≥23-day data at least). Six patients did not have any follow-up (.8%).

The mean age of the patients was 49.3 ± 13.1 years (Table 1). The study had 37% male and 63% female patient population. The mean BMI and weight were 50 ± 12.6 kg/m^2 and 314.3 ± 68 lbs, respectively. At baseline, 50.2%, 46.2%, 40%, 35%, and 29.3% of patients had HTN, OSA, T2D, HLD, and GERD, respectively. Of the available data, the study had 273 high-risk patients (36.4%). Sixty-nine patients (9.2%) were tobacco users.

Table 1
Demographic characteristics and operative outcomes

Variable	Value
Subject, n	750
Age, yr*	49.3 ± 13.1
M/F, %	37/63
Preoperative weight data	
Weight, lbs*	314.3 ± 68
BMI, kg/m^2*	50 ± 12.6
IBW, lbs*	142.9 ± 22.2
Preoperative obesity-related co-morbidity, n (%)	
HTN	377 (50.2)
OSA	347 (46.2)
T2D	300 (40)
HLD	263 (35)
GERD	220 (29.3)
High-risk patient, n (%)	
BMI ≥55 kg/m^2	172 (22.9)
Age ≥65 yr	101 (13.4)
Total	273 (36.4)
Operative outcomes	
Operative time (skin-to-skin), min*	67.6 ± 27.4
Length of stay, d*	1.5 ± .8

M = male; F = female; BMI = body mass index; IBW = ideal weight; EBW = excess weight; HTN = hypertension; OSA = obstructive sleep apnea; T2D = type 2 diabetes; HLD = hyperlipidemia; UA = unavailable; GERD = gastroesophageal reflux disease.

* Value expressed as mean ± standard deviation.

Operative outcomes

The mean skin-to-skin operative time was 67.6 ± 27.5 minutes. And the mean length of stay was 1.5 ± .8 days. No intraoperative complications were noted.

Short- and long-term complications

The short-term complication rate was 7.8% (Table 2). The most common short-term complications that occurred were nausea and vomiting and wound infection. During the first 30 days, 7 patients (.9%) experienced grade IIIb complications (Table 2). The short-term mortality rate was .1%.

During the first 30 days, 3 patients (.4%) required emergency room visits. The most common reason for the emergency room visit was nausea and vomiting. The 30-day readmission and reoperation rate were 1.1% and 1.1%, respectively. The most common reason for 30-day readmission and reoperation was nausea and vomiting, and intraabdominal hematoma, respectively.

The long-term complication rate was 11.7% (Table 3). The most common causes that were identifiable were stricture (sleeve, hiatal hernia repair, and incisura) and nausea. Thirty-three patients (4.4%) experienced grade III b complications. Of 33 grade-IIIb complications that occurred, 15 complications (2%) were unique to SADI-S. The long-term mortality rate was .4%. In total, 4 deaths (.5%) were noted.

Weight loss outcomes

At 5 years, the mean BMI was 32.1 + 7.5 kg/m^2 (Table 4). The mean change in BMI was 17.5 + 6.9 kg/m^2. The mean percentage excess weight loss (%EWL) and %TWL were 75.1 + 26.5 (median: 77.1) and 34.9 + 10.9 (median: 34.9), respectively.

At 6 years, the mean BMI and change in BMI was 30.5 ± 6.7 and 17.6 ± 6.4 kg/m^2, respectively. The mean %EWL and %TWL was 80.7 ± 27.9 (median: 83.9) and 36.2 ± 10.8 (median: 37.8), respectively.

At 5 and 6 years, the weight loss failure was seen in 17.4% and 13% of patients, respectively.

At 5 years, of the eligible patients, 9.1% of patients were able to maintain >100%EWL, 24.7% of patients had >75% to 100%EWL, 48.6% of patients had >50% to 75%EWL, 14.6% of the patients had >25% to 50%EWL, and 2.7% of patients had <25%EWL. At 6 years, of the eligible patients, 10.8% of patients were able to maintain >100%EWL, 34.7% of patients had >75% to 100%EWL, 41.3% of patients had >50% to 75%EWL, and 10.8% of patients had >25% to 50%EWL, and 2.1% of patients had <25%EWL.

Nutritional outcomes

Compared with baseline, at 5 years, the diabetic panel, cholesterol, triglyceride, ferritin, and vitamins B1 and D improved significantly (Table 5). Calcium, parathyroid

Table 2
Short-term complication

Complication	n	Clavien-Dindo classification grade				
		I, n	II, n	IIIa, n	IIIb, n	V, n
Nausea/nausea and vomiting	17	12	5			
Wound infection	10	10				
Diarrhea	9	9				
Constipation	7	7				
Postoperative bleed	3		1		2	
Intraabdominal hematoma	3				3	
PVT	2		1	1		
Leak at the DI	1				1	
DKA	1		1			
Hematemesis and hematochezia	1			1		
Intraabdominal abscess	1				1	
Hepatic abscess	1			1		
Dehydration	1		1			
Blood in JP drain	1		1			
Death*	1					1
Total, n (%)	59 (7.8)	38 (5)	10 (1.3)	3 (.4)	7 (.9)	1 (.1)

PVT = portal vein thrombosis; DKA = diabetic ketoacidosis; JP = Jackson-Pratt.

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 local anesthesia; V = death.

* The patient developed a leak from mishandled bowel that perforated into the mesentery without any signs of free air or contrast extravasation on a computed tomography scan. Postoperatively, the patient developed acute renal failure and acute respiratory distress syndrome. The patient's health kept deteriorating and died on postoperative day 5.

hormone, albumin, total protein, and vitamin E worsened significantly. Vitamin B12 improved, and vitamin A and K worsened; however, there was no statistically significant difference.

Co-existing conditions

Over the 6 years, complete remission of T2D, HLD, HTN, GERD, and OSA was seen in 77%, 66.4%, 53.7%, and 52.9%, respectively (Table 6). Improvement of T2 D, HLD, HTN, GERD, and OSA was seen in 19.3%, 25%, 31%, 22.6%, and 20.5%, respectively.

Discussion

In our study, we examined the records of patients who had undergone primary LSADI-S surgery to determine the long-term outcomes. This series is the largest and longest cohort of patients to date undergoing primary LSADI-S. The LSADI-S results in significant, sustained weight loss, and durable improvement and remission of obesity-related co-existing conditions.

One of the main advantages of LSADI-S is a single anastomosis. It has been shown that the incidence of anastomotic complications seen with LSADI-S was lower than the reported incidence of anastomotic complications seen with RYGB and RYDS [1]. It has been suggested that the single anastomosis and a common channel of 300 cm allow the reduction of gastrointestinal symptoms and decrease the possibility of intestinal vascular obstruction and short bowel syndrome associated with traditional RYDS [4]. Another potential advantage of LSADI-S is that it does not cause an abrupt rise and fall of blood glucose, which we feel promotes satiety (many surgeons feel that the rise and fall of blood glucose promote long-term weight loss) [29]. Also, the preservation of pylorus controls the emptying of solids, suggesting that it also plays a role in reducing the chances of dumping syndrome [2]. In addition, it has been reported that there is minimal risk of bile reflux gastritis with the pylorus present in LSADI-S [1]. We believe the loop configuration maintains the contact between pancreatic enzymes, bile salts, and food, thus reducing the incidence of ulcers and strictures related to both traditional RYDS and RYGB [2].

The LSADI-S is a safe procedure with low postoperative morbidity and mortality rates. In the present study, the starting mean BMI was 50 kg/m^2, and the ending mean BMI was 30.5 kg/m^2. Among all the co-existing conditions, the T2D and HLD resolution rates were highest.

Risstad et al. [30], in their 5-year outcome article on traditional RYDS, reported a change in BMI of 22.1 kg/m^2. With LSADI-S, at 6 years, our patients lost 17.6 to 24 BMI points. However, in the Risstad et al. [30] study, only patients with a preoperative BMI of 50 to 60 were included. In a long-term study by Sethi et al. [31], combined results of biliopancreatic diversion and traditional RYDS were reported. In their study, at 5 years, the TWL was 35.9 ± 12.1%. At 6 years, with LSADI-S, the TWL was 36.2 ± 10.8%. The long-term weight loss after the traditional RYDS procedure

Table 3
Long-term complication

Complication	n	Clavien-Dindo classification grade				
		I, n	II, n	III, n	IIIb, n	V, n
Diarrhea	22	16			6	
Nausea and vomiting	13	11	1	1		
Stricture	12			8	4	
1. Upper one third of the sleeve						
2. Hiatal hernia repair a. Incisura						
Constipation	9	9				
Cholelithiasis	6				6	
GERD	5		4		1	
Retrograde filling of the afferent limb	4				4	
Death*	3					3
Malnutrition	2				2	
Dilated fundus	2	1			1	
Gastric outlet obstruction	2				2	
Hiatal and ventral hernia	2				2	
Hypoproteinemia	1				1	
Reversed loop	1				1	
Abdominal pain of unknown etiology	1				1	
Dehydration	1		1			
Internal hernia	1				1	
Inadequate weight loss	1				1	
Total, n (%)	88 (11.7)	37 (4.9)	6 (.8)	9 (1.2)	33 (4.4)	3 (.4)

GERD = gastroesophageal reflux disease.

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 local anesthesia; V = death.

* Patient 1: cardiac arrest; Patient 2: obstructive sleep apnea; Patient 3: malnutrition. Patients 1 and 2 patients had death unrelated to surgery. The first patient died of cardiac arrest. The second patient had a history of severe obstructive sleep apnea; however, they never took any treatment. Postoperatively, the patient had severe hypoxia and respiratory acidosis. The risk of sudden death due to obstructive sleep apnea was explained to the patient. Also, the patient was advised to get a sleep study done and use a continuous positive airway pressure machine. However, the 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. The patient died the same night. Patient 3 was a 73-year-old male patient who had lost >100 lbs with single-anastomosis duodeno-ileal bypass with sleeve gastrectomy. The patient had a history of major depressive disorder and experienced severe malnutrition because he refused to eat; thus, he required total parenteral nutrition. At the time of common channel lengthening, his body mass index was 17 kg/m^2. The surgery was uneventful, and the patient was discharged home. He was seen at 30 days and was eating by the report and was gaining weight. However, he died before 90 days of unknown causes.

Of the 33 IIIb complications that occurred, 15 complications (2%) were unique to single-anastomosis duodeno-ileal bypass with sleeve gastrectomy.

Table 4
Weight loss outcomes

	Baseline	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr
Eligible patient, n	750	601	464	356	319	179	87
Data available, n	750	442	268	177	146	109	46
F/U, %	100	74	58	50	46	61	53
BMI, kg/m^2*	50 ± 12.6 (49.4)	32.6 + 6.7 (31.7)	29.9 + 6.5 (28.3)	31.1 + 7.9 (29.4)	31.5 + 7.6 (30.1)	32.1 + 7.5 (30.4)	30.5 + 6.7 (28.9)
Change in BMI, kg/m^2*	-	17.8 + 5.3 (17.4)	19.7 + 7.1 (18.4)	18.4 + 8.1 (17.7)	18 + 7.2 (17.4)	17.5 + 6.9 (17.7)	17.6 + 6.4 (17.4)
%EWL*	-	74.5 + 21.6 (72.4)	84.5 + 25.3 (84.7)	79 + 28.1 (79)	77.6 + 25.6 (78.2)	75.1 + 26.5 (77.1)	80.7 + 27.9 (83.9)
%TWL*	-	35.2 + 7.7 (35.6)	39.2 + 10.1 (39.1)	36.6 + 12.3 (37.6)	36 + 11.1 (35.4)	34.9 + 10.9 (34.9)	36.2 + 10.8 (37.8)

F/U = follow-up; BMI = body mass index; %EWL = percent excess weight loss; %TWL = percent total weight loss.

* Value expressed as mean ± standard deviation (median).

Table 5
Nutritional outcomes with SADI-S at 5 years

Nutrient	Baseline (n = 724)			Normal range	5 yr (n = 163)			*P* value (pre- versus post-abn.)
	Mean ± SD	Abn. n (%)	Total n (%)		Mean ± SD	Abn. n (%)	Total n (%)	
HbA1C	6.8 ± 4.8	307 (49.1)	624	4%–6%	5.2 ± .8	11 (10.5)	104	<.001
Glucose	118 ± 56	345 (51.2)	673	65–100 mg/dL	93.8 ± 33.4	26 (21.8)	119	<.001
Insulin	38.3 ± 70.6	311 (53)	586	2–23 mU/L	12.5 ± 32	3 (4.3)	69	<.001
Ca	9.2 ± .6	55 (8.2)	668	8.7–10.4 mg/dL	9.1 ± .4	18 (15.2)	118	<.05
PTH	57.2 ± 36.5	95 (32.4)	293	10–65 pg/mL	79.7 ± 86.3	30 (46.1)	65	.03
Albumin	4.2 ± 3.2	10 (1.7)	557	3.2–4.8 g/dL	4 ± .4	8 (6.9)	115	<.05
TP	7.2 ± .6	7 (1.2)	554	6–8.4 g/dL	6.7 ± .5	10 (8.6)	115	<.001
Cholesterol	179.2 ± 40	186 (28.4)	653	100–199 mg/dL	146 ± 43.6	8 (10.6)	75	<.05
TG	170.9 ± 126.9	295 (45.3)	651	40–150 mg/dL	97.4 ± 39.2	10 (13.3)	75	<.001
Ferritin*	137.5 ± 162.4	25 (4.1)	599	12–150/300 ng/mL	147.1 ± 157.1	11 (10)	109	<.05
Vit B12	585. ± 445.2	15 (2.5)	600	211–911 pg/mL	1122.1± 1060.9	0 (0)	106	.14
Vit B1	147.9 ± 75.6	36 (6.4)	555	66.5–200 nmol/L	153.1 ± 39.9	1 (.9)	101	<.05
Vit A	34.1 ± 29.4	9 (3.2)	281	20–65 ug/dL	45.6 ± 23	3 (5.1)	58	.45
Vit D	26.9 ± 15.1	331 (53.7)	616	32–100 ng/mL	31.9 ± 13.4	30 (27.5)	109	<.001
Vit E	10.5 ± 4.1	7 (2.4)	281	5.5–18 mg/L	10 ± 3.4	2 (10.5)	19	<.05
Vit K1	.8 ± .6	3 (1.2)	249	.13–1.8 ng/mL	.4 ± .3	1 (5.8)	17	.12
Copper	-	0	0	72–166 ug/dL	116.7 ± 63.5	3 (2.8)	105	-
Zinc	-	0	0	56–134 ug/dL	79.6 ± 57.2	19 (18.4)	103	-

Abn. = number of patients with abnormal labs; SADI-S = single-anastomosis duodeno-ileal bypass with sleeve gastrectomy; HBA1C = hemoglobin A1C; Ca = calcium; PTH = parathyroid hormone; TP = total protein; TG = triglyceride; Vit = vitamin.

* For males and females, we considered the serum ferritin value of 12–300 and 12–150 ng/mL, respectively.

ranges from 61% to 78% EWL [32]. With a common channel of 300 cm, the long-term weight loss results were comparable to traditional RYDS. Sánchez-Pernaute et al. [25] reported the long-term outcomes of SADI-S surgery; however, only the diabetic patient population was included. With a common of 200 to 250 cm, the patients achieved 98% EWL at 5 years. The overall total weight loss was 38%.

A report on our cohort of patients was previously published with a 4-year follow-up and approximately half the total number of patients that are reported in the present study [19]. The reported short- and long-term complication rates were 7.7% and 10.9%, respectively. In the present study, the short- and long-term complication rates were similar to those that had been reported in our 4-year study [19].

One of the unique complications of the surgery is the retrograde filling of the afferent limb [11]. Patients with retrograde filling of the afferent limb usually present with new-onset nausea, and abdominal fullness and pain. This is usually detected on an upper gastrointestinal series and requires surgical treatment [11]. Our previous study reported 4 patients that experienced the abnormal filling of the afferent limb; however, since then, we have not seen any patient with this complication [19]. We believe this is because of a change in our technique where we tack the afferent limb using a single suture up on to the sleeve. Thus, raising the afferent limb higher than the efferent limb. However, many surgeons never do this and have not seen this complication.

Table 6
Remission of co-existing conditions through 6 years

Obesity-related co-existing condition	Preoperative, %	Postoperative			
		R, %	I, %	N, %	W, %
T2D*	40	77	19.3	3.2	0
HLD	35	66.4	25	7.8	0
HTN	50.2	60	31	9	0
GERD	29.3	53.7	22.6	15	8.4
OSA	46.2	52.9	20.5	25.7	.7

R = resolved; I = improved; N = neutral; W = worsened; T2D = type 2 diabetes; HLD = hyperlipidemia; HTN = hypertension; GERD = gastroesophageal reflux disease; OSA = obstructive sleep apnea.

* T2D resolution was defined as normal measures of glucose metabolism in the absence antidiabetic medications and improvement was defined as reduction in hemoglobin A1C and fasting blood glucose not meeting criteria for remission or decrease in antidiabetic medications.

It has been suggested that the SADI-S may result in fewer complications than the traditional RYDS. The reported incidence of internal hernia after traditional RYDS ranges from .4% to 16% [1]. Sethi et al. [31] reported 8% internal hernia. 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. As of now, there has been only a single case of internal hernia that has been reported after primary LSADI-S [22]. The present series had 1 (.1%) internal hernia [22]. The patient had bile reflux and required reoperation. It was found that the sleeve had twisted 180° from an internal hernia at the Petersen's defect space [22]. The patient also had a kink on the efferent limb.

Longer common channel length may be the explanation for the lower incidence of diarrhea and malabsorptive issues seen in the present study. With a common channel of 300 cm, a total of 22 patients (2.9%) experienced chronic diarrhea. Of 22 patients, 6 (.8%) required common channel lengthening (CCL). In a long-term outcome study by Topart et al. [33], 6.2% of patients required CCL procedure for diarrhea after traditional RYDS. The LSADI-S is an improvement over the traditional RYDS procedure, but for surgeons interested in this procedure, time should be spent, learning how to treat diarrhea with dietary, pharmacologic, and surgical management [3].

At 5 years, the total number of patients with abnormal levels of serum calcium, parathyroid hormone, albumin, total protein, and vitamin E were statistically higher than at baseline. However, in spite of the abnormal levels, very few patients presented with symptomatic deficiencies. None of the patients with abnormal levels of calcium and parathyroid hormone experienced osteopenia, causing a fracture. None of the patients with abnormal levels of vitamins A, E, and K presented with symptomatic deficiencies. This may be because most of the insufficiencies or deficiencies were corrected with oral supplementation. With regard to low albumin or total protein levels, only 1 patient experienced hypoproteinemia. However, the cause of hypoproteinemia, in this case, was miscounted common channel. The issue was resolved after a CCL procedure. One patient, with an organ transplant, was provided an intravenous total parenteral nutrition solution by other institution for malnutrition. A CCL procedure was performed by us because the total parenteral nutrition could not resolve the issue. There were 2 patients that required a feeding tube because of malnutrition; however, in 1 patient, a feeding tube was required during the first 30 days of the surgery because of dehydration caused by vomiting.

Sethi et al. [31] had 4.1% of patients that required reoperation due to severe malnutrition. In their study, 1 mortality was from severe malnutrition. In the present study, 2 patients (.2%) had malnutrition and required reoperation. One of those patients had major depressive disorder and refused to eat. He died between 30 and 90 days from the operation of unknown causes. The patient was seen at follow-up at 30 days after surgery and tolerated his diet, and by the report was eating. We were alerted to his death before 90 days after the operation, so we included him as a death in our study. Similar results were seen in the study by Marceau et al. [34], which showed the need for revision for malnutrition was rare (.7%).

The long-term reoperation rate after traditional RYDS ranges from 3% to 43% [32]. Hess et al. [35] reported a revision rate of 3.7%, and Topart et al. [33] reported a revision rate of 8.7%. The reoperation rate was high (37%) in Sethi et al. [31] study. In Sánchez-Pernaute et al. [25] study, 6 patients (6.1%) patients required reoperation. In the present series, in total, 5.3% of patients required reoperation.

There are a few studies on long-term mortality rates after bariatric surgery. The long-term mortality rate ranges from .6% to 11.8% after bariatric surgery [36]. The present study had a long-term mortality of .5%. We believe the long-term mortality rate with SADI-S is low or comparable with traditional RYDS. Marceau et al. [34] reported a long-term mortality rate of 1.1% [34]. Skogar and Sundbom [37], in their recent study, reported long-term mortality of 2.1%. The long-term mortality rates are higher, with RYGB than SADI-S and RYDS. Adams et al. [38] reported a long-term mortality of 2.7% after RYGB. Zhang et al. [39] and Christou et al. [40] reported 3.5% and 6.2% long-term mortality rates, respectively.

A small percentage of patients undergoing bariatric surgery will eventually fail to maintain <50%EWL. Failure rates are usually higher with restrictive procedures. The adjustable gastric banding is associated with high long-term failure rates ranging from 23.5% to 59.6% [41]. The long-term failure rates are highest with adjustable gastric banding, followed by SG, RYGB, and SADI-S (Fig. 1). The exact long-term failure rate of traditional DS is still unknown. The long-term failure rates with SG and RYGB are 30.4% to 51.4% and 14.6% to 35%, respectively (Fig. 1) [14,42,43]. With SADI-S, the long-term failure rate is 13% to 17% (Fig. 1).

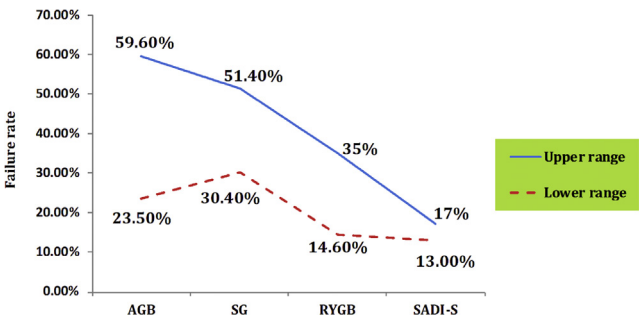

Fig. 1. Long-term failure rates with AGB, SG, RYGB, and SADI-S. Abbreviation: AGB = adjustable gastric banding; SG = sleeve gastrectomy; RYGB = Roux-en-Y gastric bypass; SADI-S = single-anastomosis duodeno-ileal bypass with sleeve gastrectomy.

Perhaps, the main reason, surgeons have hesitated in adopting the LSADI-S into their practice relates to long-term sequelae. While we have tried to be open about our data and have included our learning curve, it should be mentioned that nutritional deficiencies can develop long after 5 years (if osteopenia is real after this procedure, this is when we would expect to see it). We have attempted to have labs drawn yearly after the first year, and have orientated our entire practice from the surgeons to the front desk people to emphasize this fact. Still, with all that being said, we only saw 61% at 5 years. Also, our office has emphasized the idea that with LSADI-S, a malabsorptive, bariatric-specific vitamin should be taken and not just any over-the-counter vitamin. We have chosen one brand for our office, but there are many manufacturers of these types of bariatric-specific supplements that provide essential nutrients. Patients are encouraged to take any one of these supplements and follow-up in the clinic.

In addition, while this procedure in our hands has resulted in a vast reduction in the rate of ulcers and internal hernias compared with RYGB, and allowed nonsteroidal anti-inflammatory drugs users and smokers to have malabsorptive procedures. The procedure has not eliminated these complications entirely, and in fact, vigilance remains important for any patient who presents with postoperative complaints suggestive of ulcers, internal hernias, and obstructions.

The study's main limitation is the follow-up percentage. Our follow-up rate long term was 61% at 5 years. Because there are no long-term outcomes article in the literature, and the midterm data are limited, we believe it is crucial to report the long-term outcomes even with what we would consider a limited patient follow-up. However, there were enough patients past 5 years, so that the probability of our weight loss data changing would be minimal with the acquisition of more patients. There also were enough patient-years that any common long-term complication should have been seen. Also, as this is our total experience with this procedure, it includes our learning curve. Our complication rate has fallen as we have become more skilled at performing this procedure. This article is not and should not be the final word on SADI-S. There are many issues unresolved. For example, what is the optimal SG size and what is the optimal CCL for BMI or co-existing conditions. The question has not been answered by this article, and they deserve to be. In addition, what is the optimal length of the common channel to avoid diarrhea postoperatively, and what level of postoperative revisions for diarrhea is acceptable. We simply do not know. For this reason, further long-term studies are required to confirm the efficacy and safety of this procedure.

Conclusions

The long-term results suggest that LSADI-S offers good results for the treatment of both morbid obesity and its co-existing conditions. However, further long-term outcome studies with better follow-up rates are required to confirm the long-term nutritional results of LSADI-S.

Disclosures

Dr. Cottom reports personal fees and other from Medtronic and GI Windows, outside the submitted work. The other authors have no commercial associations that might be a conflict of interest in relation to this article.

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Editorial comment

Comments on: Long-Term Outcomes of Primary Single-Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)

Dear editorial team,

I have enjoyed reading the article by Surve et al. on Long-term Outcomes of Primary Single-Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S) [1]. I congratulate the team for their pioneering efforts at a time when very minute societal encouragement was given. This is timely because the ASMBS has finally sanctioned the procedure in the United States [2].

A total of 750 patients were studied, with a mean preoperative body mass index (BMI) of 49.3 kg/m^2, and