ORIGINAL CONTRIBUTIONS





A Multi-institutional Study on the Mid-Term Outcomes of Single Anastomosis Duodeno-Ileal Bypass as a Surgical Revision Option After Sleeve Gastrectomy

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Abstract

Introduction Recently, a single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) has become increasingly popular for patients with BMI > 50 as a primary or staged surgery. Staging allows surgeons to do the sleeve gastrectomy (SG) first with the conversion only happening when a failure or technical challenge is identified.

Purpose We present the mid-term outcomes of SADI bypass surgery after SG.

Method A retrospective analysis was performed on a prospective database from four institutions. Ninety-six patients were identified from 2013 to 2018. Patients were divided into two groups: one had two-stage SADI because of insufficient weight loss, the second had planned two-stage SADI because of super obesity (BMI > 50 kg/m²). Incidence of complications was divided into < 30 days and > 30 days.

Result Of 96 patients, 3 patients were completely lost to follow-up. The mean age was 44.8 ± 11.3 years. There were no deaths or conversion to open surgery. The postoperative early complication and late complication rate was 5.3% and 6.4% respectively. At 24 months, group 2 had higher %weight loss (WL) and change in BMI units compared to group 1 with statistically significant difference. The average WL and change in BMI for entire patient's population at 24 months after 2nd stage SADI was 20.5% and 9.4 units respectively. The remission rate for DM was 93.7% with or without the use of medication.

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Conclusion The two-stage approach to SADI-S appears technically simpler than a single compromised operation. However, this approach needs more patients to understand its limitations.

Keywords Sleeve gastrectomy · SADI · SADI · SADI · S. Loop duodenal switch · Revision · Weight loss failure

Introduction

In 1991, Marceau introduced sleeve gastrectomy (SG) as a component of biliopancreatic diversion (BPD) [1]. Soon it gained popularity as a standalone bariatric surgery due to its relative operational simplicity, lack of foreign body implantation, and with an undisrupted gastrointestinal tract as seen with malabsorptive procedures [2]. Today, it is one of the most commonly performed restrictive procedures in the USA [3]. Its safety and effectiveness have been established in three international consensus summits [4–6].

There are many studies that have recognized SG with its promising weight loss and fewer complications [7-9]. However, weight maintenance over the long term has been an important concern. Alvarenga et al. published a paper on the outcomes of SG with long-term follow-up that showed excess weight loss (EWL) at 8 years was only 52% [10]. This means half of all SG patients meet standard definition of weight loss failure at most long-term follow-up. Similarly, a 5-year study on SG showed 55% EWL with 19.2% weight regain and 15.4% revision rate [2]. SG has also shown poor results in super morbidly obese patients and has a larger standard deviation for all patients in general [11], meaning that many patients do well with the sleeve but just as many do not. A SG study was done by using Spanish National Registry for bariatric surgery clearly showed that younger age, lower BMI $(< 50 \text{ kg/m}^2)$, and thinner bougie size were recommended for better long-term outcomes [12]. Similarly, several studies have predicted higher BMI results in lower weight loss with SG [13, 14]. Such sobering long-term data possesses a challenge for bariatric surgeons to come up with more acceptable approach for the patients who fail SG or who have weight regain.

The most common approach in the literature for SG failure is a conversion to Roux en Y Gastric Bypass (RYGB) [15]. However, this has resulted in 25% of the patients also failing to maintain their weight [16, 17]. Conversion to conventional duodenal switch (DS) is concerning because of high risk of malnutrition. The question remains for the practicing surgeon is what options are available that are easily reproducible with low complication rates?

Recently, a modification of DS, a single anastomosis, or loop construction has become increasingly popular as a primary or staged surgery. This modification is called as a single anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S) [18]. SADI-S eliminates the Roux limb in favor of a single anastomosis duodenal ileostomy, lengthens the common channel to 3 m, and does the sleeve over a 40 French bougie. This is easily a reproducible operation. Staging allows surgeons to do the SG first and conversion only happens when a failure or technical challenge is identified.

The purpose of this study is to determine if SADI-S is a safer and efficient option for patients who have failed SG. We had successfully presented the preliminary experience of SG failure to SADI-S surgery at the 1st international consensus conference on the duodenal switch [19]. Here, we present mid-term outcomes of SADI-S surgery for failed SG patients from four different centers.

Method

This is a multicenter retrospective study of prospectively collected database of patients who underwent revisional SADI-S surgery from failed SG between at four US centers chosen because of the relationships among the surgeons (center 1: Bariatric Medicine Institute in UT, performed by author), (center 2: Rex Bariatric Specialists in NC, performed by author), (center 3: WakeMed Bariatric Specialists of NC, performed by author), (center 4: Ventura Advanced Surgical Associates in CA performed by author). The data collection was standardized across three centers. All the surgeons have used a standardized approach in doing these surgeries. However, not all cases were done exactly the same as there is variability both within practices and between practices. Yet, each practice did a 300-cm common channel when choosing the limb length. This was consistent among all surgeons and practices.

Each center had a consent from their patients to have their de-identified data analyzed. Each patient signed a specific informed consent which details the risk of revision surgery as well as consent for their SADI-S surgery.

Patients were divided into two groups: one group had unplanned 2-stage SADI-S because of insufficient weight loss (defined as %EWL < 50%, progressive weight regain after an initial successful weight loss (defines as EWL > 50%)) and the second group had planned two-stage SADI-S because of super obesity (body mass index (BMI) > 50 kg/m²). Patient who had insufficient weight loss (group 1) underwent upper gastrointestinal series (UGI) to look for the evidence of dilation. They were given various revision surgery options and after detailed discussion with the surgeon, patient chose to undergo laparoscopic SADI-S surgery. The relevant information included demographic characteristics, time from the SG to SADI-S surgery, comorbidity data, operative data, length of stay, and weight loss data. Procedure time was gathered and started with the first incision and ended with the dressing. Comorbidities included were diabetes mellitus (DM), hypertension (HTN), and hyperlipidemia (HL). 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. Clavien–Dindo scale was used for the description of complications. All patients were advised to have monthly postoperative follow-up visits to assess weight loss, complications, and mortality.

A non-linear regression analysis was performed based on recorded 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 in regard to 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), percentage weight loss (%WL), and change in BMI points. All statistics were run through SigmaPlot software.

Operative Technique: First Center, Third Center, and Fourth Center (Hand-Sewn Technique)

LSG (first surgery): The LSG is created by stapling alongside a 40 Fr. bougie (Allergan Corporation) placed on the lesser curvature. The staple line in all patients is started approximately 5 cm from the pylorus and ended at the angle of his. There is no staple line over-sewing and no buttressing done.

SADI (second surgery): Our technique has been published previously [20]. Briefly, the terminal ileum is identified and then small bowel is traced retrograde to 300 cm and tacked to the gastrocolic omentum. The proximal duodenum dissected free from its surrounding attachments [21]. Then the duodenum is transected using an Endo GIA^{TN} (Covidien) stapling device. An anti-tension row is sewn between the proximal duodenal stump and the mesenteric border of the distal small bowel. A duodenotomy and enterotomy are made and are closed in a single posterior and anterior row.

Operative Technique: Second Center (Triple-Stapled Technique)

SADI (second technique): Triple-stapled technique has been published previously [22]. The first step is retroduodenal dissection, which begins with the dissection of inferior border of the duodenum to develop a plane behind the duodenal bulb. A stapler is introduced into this tunnel; positioning at the junction of the duodenal bulb and second part of the duodenum. The duodenum is transected. The loop is then approximated into the duodenal bulb. Retraction sutures are placed inferiorly on the bulb as well as on the ileum allowing for the positioning on to the stapler within matching enterotomies on to the duodenum and ileum. A stapler is introduced into the duodenal bulb and ileum respectively. This is placed along the anterior wall and rotated positioning into the duodenal bulb in an oblique fashion attempting to achieve at least 3 cm of staple line. Other sutures are placed along the inferior and superior staple line to align enteroenterostomy for closure. Central suture is also placed. With the assistance of these alignment sutures, 60-mm stapler is placed and remaining enteroenterostomy is closed. This completes the formation of three-row-stapled technique.

Result

Ninety-six patients were identified for analysis (center 1: 69 patients, center 2: 15 patients, center 3: 9 patients, and center 4: 3 patients). Three patients were lost to follow-up. These patients lived in a different state and requested to be seen by a bariatric surgeon in the respective states.

The mean age was 44.8 ± 11.3 years. There was no statistically significant difference in age between group 1 and group 2. The mean interval between the two procedures was 34.1 ± 27.8 months. The mean BMI before the SADI was 42.8 ± 9.2 kg/m². Off course, group 2 had a shorter interval (8.9 months vs 46 months) between two procedures and were heavier than group 1 (48.6 kg/m² vs 40.1 kg/m², since these were the patients who had planned two-stage SADI-S due to super-obesity.

None of the patients from group 1 had dilation of sleeve seen on their UGI series.

The mean operative time and hospital stay for SADI were 98.7 ± 60.9 min and 1.2 ± 1.2 days respectively. There was no statistically significant difference between group 1 and group 2 in terms of operative time. However, group 2 had a longer length of stay compared to group 1 and this difference was statistically significant (p < 0.05). There were no deaths or conversion to open surgery. They were no intraoperative complications.

Weight Loss

First Stage SG

The mean preoperative BMI before SG was 50.5 ± 13.2 kg/m². At 33.4 ± 27.4 months, patients who underwent SG had an average 24.9 ± 17.2 %EWL and 14.5 ± 9 %WL of respectively (Table 1).

 Table 1
 Weight loss from primary sleeve gastrectomy/first stage of SADI

	Group 1 $(n = 64)$	Group 2 ($n = 29$)
Pre-sleeve weight (lbs.)	282.2 ± 99	387.7 ± 100.4
Pre-sleeve BMI (kg/m ²)	46 ± 9.7	59.6 ± 14.3
Lowest weight after SG (lbs.)	227 ± 65	312.4 ± 75.2
Final weight after SG (lbs.)	255 ± 56.5	315.7 ± 75.9
Weight regain (lbs.)	29.9 ± 21	3.2 ± 6
Total weight loss (%)	12.8 ± 9.3	17.8 ± 7.3
Excess weight loss (%)	23 ± 19.4	29 ± 10.6
Total F/U (months)	45.9 ± 28.9	8.9 ± 4.9

*Values are expressed as mean \pm standard deviation

n number of patients, *SG* sleeve gastrectomy, *SADI* single anastomosis duodeno-ileal bypass, *BMI* body mass index, *F/U* follow-up

Second Stage SADI

Of 93 patients (since 3 patients were lost to follow-up out of 96 patients), group 1 had 64 patients (center 1: 42 patients, center 2: 11 patients, center 3: 9 patients, center 4: 2 patients), and group 2 had 29 patients (center 1: 24 patients, center 2: 4 patients, center 4: 1 patients). Of 93 patients, 72 patients, 56 patients, and 51 patients were beyond 12, 18, and 24 months respectively. The rates of visit completion according to follow-up time points were 56.9%, 53.5%, and 52.9% at 12, 18, and 24 months respectively.

The mean preoperative BMI before second stage SADI was 42.8 ± 9.2 kg/m². At 12 months, patients who underwent revision SADI for weight loss failure (group 1) had an average WL of 19% and change in BMI of 7.8 units and patients who had planned two-stage SADI (group 2) had an average WL of 21.9% and change in BMI of 12 units. At 12 months, group 2 had higher WL% as wells as change in BMI units compared to group 1 with statistically significant difference. The average WL and change in BMI for entire patient's population at 12 months after second stage SADI was 20% and 9.3 units respectively. Similarly, at 24 months, patients from group 1 had WL and change in BMI of 19.3% and 7.9 units respectively and patients from group 2 had WL and change in BMI of 23.1% and 12.2 units respectively. At 24 months, once again, group 2 had higher WL% and change in BMI units compared to group 1 with statistically significant difference. The average WL and change in BMI for the entire patient's population at 24 months after second stage SADI was 20.5% and 9.4 units respectively (Tables 2 and 3).

The EWL of the SADI including the first stage SG at 12 months and 24 months was 64.1% and 64.9% respectively (Fig. 1). Although, group 2 had higher %EWL compared to group 1, there was no statistically significant difference between two at any given time point.

Complications

The postoperative early complication rate was 5.3% (n = 5/93, group 1—4/64, 6.25%, and group 2—1/29, 3.4%). Most common early complication was wound infection (3.2%). One patient had sepsis from a MRSA wound infection, 1 had cellulitis from a wound infection, and 1 patient had a minor wound infection treated with antibiotics. All three patients were readmitted (3.2%), and 1 patient with sepsis needed reoperation (1%) within 30 days of the surgery.

The postoperative late complication rate was 6.4% (n = 6/93, group 1—4/64, 6.25%, group 2—2/29, 6.8%). The most common long-term complication was diarrhea (4.3%). One patient in group 2 had the retrograde filling of the afferent limb that required the afferent limb to be tacked to sleeve 4 cm proximal to the pylorus. The technique has been previously discussed [23]. We have now made this as a routine procedure to tack the afferent limb to the sleeve (Table 4).

Resolution of Comorbidities

Complete remission of T2DM was considered when HbA1c was maintained below 6% without anti-diabetic medications [24]. Overall remission rate for the entire patient population was 81.2% at 1 year. In our study, improvement of T2DM was considered when HbA1c was < 6% being on the same medication dose or dose was decreased. In our study, 12.5% of the patients achieved HbA1c < 6% with the use of medication. That means, 93.7% of patient were able to maintain HbA1c < 6% with or without the use of medication (remission = 13, improvement = 2, total = 15/16). This also correlates to the HbA1c value in the nutritional table (Table 6), where 35/37 number of patients reached normal HbA1c < 6% at 1 year (94.5%).

Lipid profile improved significantly. Remission was considered when the patient had normal lipid panel without antilipidemic medications [24]. Overall remission rate was 45.4% at 1 year. In our study, the improvement was considered when lipid levels reached normal value being on the same medications or decreased medication. 63.5% patients were able to maintain normal lipid levels at 1 year with or without the use of medication (remission = 5, improvement = 2, total = 7/11).

Complete remission of HTN was considered when systolic/ diastolic blood pressure was below 120/80 without antihypertensive drugs [24]. HTN remission rate was 55.5% after 1 year. The improvement was considered when there was normalization of systolic or diastolic blood pressure being on same medications or medications itself were decreased. 85.1% of the patients were able to keep the blood pressure to normal with or without the use of medication (remission = 15, improvement = 8, total 23/27) at 1 year.

Table 5 summarizes the comorbidity resolution rate.

Table 2% weight loss aftersecond stage of SADI (not incl.SG)

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	Group 1 $(n = 64)$	Group 2 $(n = 29)$	Total $(n = 93)$	P value (group 1 vs group 2)
3 months	12.7 (11.3, 14.1)	11.6 (9.5, 13.7)	12.3 (11.1, 13.5)	0.378
n (%)	45/58 [77.5%]	23/28 [82.1%]	68/86 [79%]	
6 months	17 (15.9, 18.1)	17.4 (15.4, 19.4)	17.2 (16.2, 18.2)	0.721
n (%)	40/53 [75.4%]	19/27 [70.3%]	59/80 [73.7%]	
12 months	19 (17.6, 20.5)	21.9 (19.7, 24)	20 (18.8, 21.3)	0.028
n (%)	27/47 [57.4%]	14/25 [56%]	41/72 [56.9%]	
18 months	19.3 (17.6, 20.9)	22.9 (20.1, 25.6)	20.5 (19, 21.9)	0.036
n (%)	22/39 [56.4%]	8/16 [50%]	30/56 [53.5%]	
24 months	19.3 (17.6, 21)	23.1 (20.1, 26.2)	20.5 (19, 22.1)	0.032
n (%)	19/34 [55.8%]	8/15 [53.3%]	27/51 [52.9%]	

All the values are expressed as mean (95% confidence interval)

n number of patients available at given time point [% follow up available at given time point], SG sleeve gastrectomy, SADI single anastomosis duodeno-ileal bypass

Nutritional Outcomes

We compared the nutritional outcomes (no. of patients with abnormal values) between baseline and 12 months (Table 6). The number of patients with the abnormal preoperative diabetic panel (glycosylated hemoglobin (HbA1c) and fasting glucose) and lipid panel (cholesterol and triglyceride) significantly reduced at each follow-up (p < 0.001). Additionally, the number of patients with abnormal preoperative insulin, albumin, ferritin, vitamin B12, A, E, and B1 levels also decreased at each follow-up; however, the difference was not statistically significant.

More patients had abnormal postoperative values for calcium, total protein, and vitamin D compared to their preoperative value, but the difference was not statistically significant. The number of patients with abnormal vitamin K1 level (p = 0.001), zinc (p = 0.044), and PTH (hyperparathyroidism) (p = 0.035) increased over the years compared to preoperative value with the statistically significant difference.

Discussion

Weight regain after bariatric surgery is concerning for bariatric surgeons and patients [25, 26]. While SG is a technically simpler procedure than both RYGB and DS, it has seen an increased number of patients who are now failing this surgery. So, the question remains, why do SG fail? And what role can surgeons play in reversing recidivism?

The most common cause of weight recidivism is poor patient selection. Many surgeons perform only SG regardless of the preoperative BMI or the comorbid conditions. This results in lots of patient failures and these results are predictable [27]. Gastric pouch dilation is another frequent pattern reported by various studies for SG failure [26, 28]. However, the cause of this is unknown and this problem seems to be resolved with re-sleeving the patient [29]. Yet pouch dilation is relatively rare and this leaves the vast majority of patients with recidivism untreated. In our study, no patient suffered from dilation of their sleeve.

Table 3 Change in BMI aftersecond stage of SADI (not incl.SG)

	Group 1 ($n = 64$)	Group 2 (<i>n</i> = 29)	Total $(n = 93)$	P value (group 1 vs group 2)
3 months	5.5 (4.8, 6.3)	7.7 (5.3, 10.1)	6.4 (5.4, 7.4)	0.029
<i>n</i> (%)	45/58 [77.5%]	23/28 [82.1%]	68/86 [79%]	< 0.001
6 months	7.2 (6.6, 7.8)	10.6 (8.6, 12.5)	8.4 (7.7, 9.2)	
n (%)	40/53 [75.4%]	19/27 [70.3%]	59/80 [73.7%]	< 0.001
12 months	7.8 (7, 8.7)	12 (9.6, 14.5)	9.3 (8.2, 10.4)	
n (%)	27/47 [57.4%]	14/25 [56%]	41/72 [56.9%]	< 0.001
18 months	7.9 (7, 8.8)	12.2 (9.4, 15)	9.4 (8.2, 10.6)	
n (%)	22/39 [56.4%]	8/16 [50%]	30/56 [53.5%]	< 0.001
24 months	7.9 (7, 8.8)	12.2 (9.4, 15.1)	9.4 (8.2, 10.6)	
n (%)	19/34 [55.8%]	8/15 [53.3%]	27/51 [52.9%]	

All the values are expressed as mean (95% confidence interval)

n number of patients available at given time point [% follow-up available at given time point], SG sleeve gastrectomy, SADI single anastomosis duodeno-ileal bypass

Fig. 1 %EWL of SADI-S including SG over 24-month follow-up. There was no statistically significant difference between two groups



Frequently, surgeons advocate a thorough assessment of the patient's alimentary habits. However, there is not a single study which shows that this intervention makes any difference in future weight loss. Yes, a rare patient may have a maladaptive eating disorder but again the vast majority of patients are still left untreated.

Historically, SG was originally the first step in a scheduled two-step operation, to either DS or RYGB [30], it is easier to revise patients with SG failure to the second unscheduled bariatric procedure. Adding malabsorption to the already restrictive SG has been proven to be an effective means for weight loss [31]. However, most of the surgeons are afraid to perform malabsorptive surgeries for failed SG due to high complication rates. To ensure patient safety and procedural success, a careful selection of revisional surgeries should be performed by experienced bariatric surgeons.

One of the revisional options available after failed SG has been RYGB. To date, there have been 12 single site small series papers with a total of 250 patients [25, 32–42]. The %EWL seen after conversion varies between 61 and 65% at an average of 18 months; the complication varies between 6 and 17% without any standardized complication reporting [25, 37]. Additionally, a RYGB after a SG places the patient

Table 4	Complications
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Complication	п	Grade I	Grade II	Grade IIIa	Grade IIIb	Grade IVa	Grade IVb	Grade V
Early complications								
Nausea	2	1	1					
Wound infection ¹	3		2		1			
Total	5 (5.3%)	1 (1%)	3 (3.2%)		1 (1%)			
Late Complications								
Diarrhea	4	4						
Retrograde filling of Afferent limb ²	1				1			
Vomiting needing EGD with dilation ³	1			1				
Total	6 (6.4%)	4 (4.3%)		1 (1%)	1 (1%)			

¹ Of 3 patients with wound infection, 1 had sepsis from a MRSA wound infection, 1 had cellulitis from a wound infection, and 1 had wound infection treated with antibiotics alone

² Patient with retrograde filling of afferent limb required reoperation to tack the afferent limb to sleeve 4 cm proximal to pylorus. We have now made this as a routine procedure to tack the afferent limb to the sleeve. This complication has not been since then

³ Patient with vomiting had anastomoses very close to the pylorus and needed EGD with dilation to alleviate the symptom

n number of patients, EGD esophagogastroduodenoscopy

Table 5	Resolution	of comorbidities	at 1	year
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A	
Available data	16/24
Remission	13 (81.2%)
Improvement	2 (12.5%)
Worsened	0
Unchanged	1 (6.2%)
Available data	11/20
Remission	5 (45.4%)
Improvement	2 (18.1%)
Worsened	0
Unchanged	4 (36.3%)
Available data	27/45
Remission	15 (55.5%)
Improvement	8 (29.6%)
Worsened	0
Unchanged	4 (14.8%)
	Remission Improvement Worsened Unchanged Available data Remission Improvement Worsened Unchanged Available data Remission Improvement Worsened

n number of patients with comorbidity at given point of a time

at high risk for internal hernia and ulcers [43] and leaves patients unable to take NSAIDS [44].

BPD-DS is another feasible malabsorptive surgical revision option for failed SG. Weight loss is better with BPD-DS compared to RYGB. Sovik et al. observed a 26% failure rate after RYGB versus 0% after BPD-DS [45]. However, the technical difficulty, postoperative complications, and

 Table 6
 Nutritional outcomes between baseline and 12 months

	Preop (n = 93)	12 mont	ths $(n = 72)$) P value	
	Abn	Total	Abn	Total		
HbA _{1c}	14	67	2	37	0.036	
Glucose	23	77	3	40	0.005	
Insulin	12	40	2	13	0.299	
Ca	9	77	9	39	0.109	
PTH	15	43	19	32	0.035	
Albumin	2	71	0	40	0.456	
ТР	0	71	1	39	0.519	
Cholesterol	15	57	1	34	0.004	
TG	23	57	4	34	0.003	
Ferritin	13	64	5	36	0.422	
Vit B12	4	69	0	36	0.457	
Vit B1	6	63	2	34	0.533	
Vit A	1	39	0	31	0.904	
Vit D	42	68	22	35	0.913	
Vit E	2	37	0	31	0.624	
Vit K1	1	34	10	29	0.001	
Copper	0	30	0	32	0.965	
Zinc	1	31	6	31	0.044	

n number of patients

malnutrition have stopped many surgeons from performing this procedure. Iannelli et al. [46] performed staged BPD-DS on 25 patients after failed LSG. He observed an EWL of 59% at 30 months (100 cm common channel and 150 cm Roux limb); however, 82% of the patients were diagnosed with vitamin or mineral deficiency.

To address the concerns of BPD-DS, we have focused on the SADI-S for revisions from SG. The SADI-S is technically easier to perform than a BPD-DS, retains its efficacy, and reduces the postoperative complications [20]. Our data expands on Sanchez Pernaute et al. small series where they performed SADI-S as a second step revisional procedure for 16 patients with insufficient weight loss after SG [47]. The mean EWL at 1 year, 18 months, and 2 years was 68.6%, 73%, and 72% respectively. More importantly, there were no reported complications of ulcers, small bowel obstructions, or internal hernias. Our weight loss pattern was similar to the one reported by the study and we did not have any patients with a complication of small bowel obstruction or internal hernia.

One of the main problems with any intestinal bypass is malabsorption. We have published extensively on differences between SADI-S, BPD-DS, and RYGB. Our results showed nutritional complications were statistically similar between RYGB and SADI-S, while reports of malnutrition were less with SADI-S when compared with BPD-DS [20, 48]. While the highest postoperative complication rate was found with RYGB [49].

Another hallmark of this study is the resolution of comorbidities. Our revisional rate of comorbid resolution mirrors our primary rate [50] and is similar to Sanchez Pernaute et al. [47]. This is especially true for our diabetic data (Table 5).

Surgical approaches for a patient with super obesity has always been challenging. In this study, most patients with BMI > 50 kg/m² underwent SG as the first stage operation and within 1 year, they underwent 2nd stage SADI-S as this is the time when weight loss after SG stalls. Although this management exposes the patients to two general anesthetics and two laparoscopic surgeries, we have not found it to be unsafe. This approach also offers weight loss similar to that of primary SADI-S regardless of when the second stage operation is performed (see Fig. 1) [51]. This fact surprised us and has altered the way we practice medicine. We now know that "sleeve failure" can now be viewed as an integral part of a staged surgical protocol that does not affect long-term weight outcomes.

A weakness of this study is its retrospective nature. Another limitation is that not all cases were done exactly the same as there is variability both within practices and between practices. Yet, each practice did a 300-cm common channel when choosing the limb length. This was consistent among all surgeons and practices. Another limitation is 50% follow-up at 2 years. While not ideal, there is limited data on two-stage SADI-S procedure and with an increasing number of sleeve failures, any data is important. We tried to address the issue by making this study multi-institutional to eliminate the bias of any surgeon or practice.

Conclusion

Staged SADI-S is an effective weight loss option for SG weight loss failure and for patient who is not able to have a primary SADI-S at the initial operation. Weight loss and comorbidity resolution mirror primary surgery and have low complication profiles. However, these encouraging results need more patients and longer follow-up to understand its limitations.

Compliance with Ethical Standards

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

- Peter C. Ng has an active consulting agreement with Medtronic and Johnson & Johnson as proctor/lecturer.
- Paul Enochs reports personal fees and other from Medtronic, outside the submitted work.

All other authors have no conflicts of interests to declare.

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

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

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