ORIGINAL CONTRIBUTIONS



A Matched Cohort Analysis of Sleeve Gastrectomy With and Without 300 cm Loop Duodenal Switch With 18-Month Follow-Up

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Abstract

Background In bariatric surgery, a significant question remains unanswered—What proportion of weight loss comes from each component and does this differ with time? Single anastomosis duodenal switch (LDS) combines a vertical sleeve gastrectomy (VSG) with a loop attachment of the duodenal stump. There are two major variables the sleeve, and the intestine that processes ingested food. A comparison of patients that had a VSG with those that have had a LDS approximates the contribution of each component.

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Methods A retrospective matched cohort analysis of VSG and LDS patients was obtained by matching every LDS patient to a VSG patient of the same sex and BMI. Excess weight lost percentage (%EWL) and the total weight loss percentage (%TWL) was analyzed. The data was compared through descriptive statistics and non-linear regression analysis.

Results Over 18 months, patients who received the LDS lost more %TWL and %EWL and the difference was statistically significant (p < 0.05). Additionally, with time, the difference became more profound. Weight loss stabilized at approximately 9–12 months and 15 to 18 for VSG and LDS patients', respectively. At 6 months post op, there was approximately 13 % difference in weight loss. This increased to 29 % difference at 18 months.

Conclusion LDS patients lose more weight than VSG. Preserving 3 m of intestinal length adds 30 % greater weight loss at 18 months. Early weight loss is similar between the two operations, while the intestinal component becomes more important with weight loss differentials increasing as time since surgery lengthens.

Keywords Loop duodenal switch \cdot Single anastomosis duodenal switch \cdot Sleeve gastrectomy \cdot Malabsoptive procedures

Introduction

Bariatric surgical procedures are the most efficacious treatment modality for morbid obesity. However, many important details including the mechanisms of action for the various procedures remain unclear. Classically, procedures have been divided into restrictive or malabsorptive. Restrictive procedures reduce the volume of the stomach. Malabsorptive procedure short-circuits the intestine. Popular theory is that restriction makes you eat less, and malabsorption makes some of what is eaten to be passed into the fecal stream. Recent research has demonstrated that bariatric procedures change gastrointestinal physiology far more than can be explained by these simplistic theories [1, 2]. Rapid passage from the stomach stimulates L cells in the distal intestine and increases the production of incretins. These incretins reduce gastric emptying, promote insulin production, and seem to change energy regulation [3, 4]. Despite an increased understanding of many of these factors, several simple and important questions remain unanswered. For example, how much weight loss comes from the stomach, and how much from the intestine in either Roux en Y gastric bypass [5] (RYGB) or duodenal switch (DS)? Recently, a modification of the DS, a single anastomosis or loop construction has become increasingly popular. The operation labeled LDS in the USA, involves creation of a vertical sleeve gastrectomy over a 40 to 44 bougie, division of the duodenum and attachment to the small intestine 3 m from the ileocecal valve. This simplified DS offers an excellent platform to examine how much weight loss comes from the gastric and intestinal components. As opposed to gastric bypass, the stomach component can be separately studied. Since there is only a single anastomosis, there are no separate alimentary, bilio-pancreatic, or common channels. This allows easier interpretation of the intestinal contribution.

The purpose of this study is to determine what percentage of weight loss comes from each component and how this changes with time. To answer, we performed a matched cohort analysis between patients that had a vertical sleeve gastrectomy (VSG) and those that had a loop duodenal switch (LDS).

Methods

Patients that had either VSG or LDS between 2011 and 2014 were analyzed for potential inclusion. Each patient signed consent to have their data analyzed in a blinded fashion. They also signed a specific consent to have the sleeve or

Fig. 1 Graph of percentage total weight loss (%TWL) over the course of 18 months between the two procedures

LDS. IRB approval for this study was obtained from the Quorum IRB study number 31353. Patients were included in the study if there was a match of both gender and BMI (within one point). This allowed for a matched cohort analysis between the two procedures. During this period there were 426 total VSG procedures, and 71 total LDS procedures. Following matching there were 106 patients available for comparison, 53 with each procedure. Only patients having primary procedures were considered for comparison. Patients having revision were excluded.

All surgeries were done by the three surgeons at the Bariatric Medicine Institute at a single hospital in Salt Lake City with identical technique.

The VSG was created by stapling alongside a 40 French bougie placed on the lesser curvature. No patient in the study had their staple line over sewn or staple line reinforced. The staple line in all patients was started approximately 5 cm from the pylorus and ended at the angle of his. Each patient had a visual inspection of the hiatus to evaluate for hiatal hernia with simultaneous repair if defect was found.

The loop duodenal switch procedure began with an identical technique. A VSG created over a 40 bougie and identified hiatal hernias. Following this the gastroepiploic vessels are divided from the end of the sleeve staple line past the pylorus to the point where the perforating vessels from the pancreas enter the duodenum. This is 5 cm beyond the pylorus. A blunt instrument is passed behind the duodenum to create a passageway for the division of the duodenum. The duodenal bulb 3 cm from the pylorus is circumferentially dissected. The duodenum is divided with an Endo GIA stapler (Covidien). The terminal ileum is identified and 300 cm of small bowel are measured from this point. The anti-mesenteric border of the bowel at this point is attached to the end of the proximal duodenum staple line using an absorbable suture. The loop is set up so the efferent limb is descending on the patient's right, and the afferent limb is ascending coming up from the left. A duodenotomy and enterotomy are made that are approximately 2 cm. The enterotomy is closed with a running

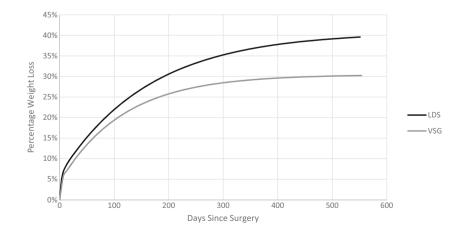


Table 1 Patient baseline demographic data

	VSG	LDS	P value
N	53	53	
Male/female	19/34	19/34	1
Weight	303.45 ± 64.53	290.03 ± 56.93	0.28
Age	45.15 ± 10.94	52.15 ± 12.81	0.005
BMI	46.11 ± 7.62	46.18 ± 7.56	0.96
Sleep apnea	20/53 (38 %)	30/53 (57 %)	0.08
Diabetes	8/53 (15 %)	30/53 (57 %)	< 0.001
GERD	14/53 (26 %)	28/53 (53 %)	0.01
Hypertension	22/53 (42 %)	30/53 (57 %)	0.174

Data expressed as mean \pm standard deviation or as proportion of patients with comorbidities

posterior layer and a running anterior layer. The anastomosis is tested intraoperatively for leaks (using methylene blue, endoscopy, or nasogastric tube). Figure 1 depicts the operation.

Patients were followed in our multidisciplinary program with all follow-up data entered in our programmatic database. Nutritional counseling, support groups, and exercise training were available for all patients and post operative instructions identical except for vitamin supplementation which was expanded for LDS patients. Followup interval was also identical. BMI and weight were measured at each follow-up visit. In addition, the presence or absence of sleep apnea, diabetes, GERD, and hypertension was recorded.

A non-linear regression analysis was performed based on recorded weight loss values to obtain the 3, 6, 9, 12, 15, and 18 month 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. *T* tests were used to compare the percentage excess weight loss (%EWL) and percentage total body weight loss (%TWL) and describe the

differences between the data. Calculations were made to determine their %TWL and %EWL.

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.

All statistics were run through SigmaPlot software.

Results

The average BMI, weight, height, and age in this study are recorded in Table 1. As mentioned in the methods, patients were matched for sex and BMI. When this was completed, there were some differences between the two cohorts. LDS patients, on average were older, and more likely to have diabetes, these differences were statistically significant. LDS patients were more likely to have sleep apnea, GERD, and hypertension, but these differences were not statistically significant.

According to the %TWL and %EWL, there was a statistically significant difference between the weight loss of the VSG and the LDS at 3, 6, 9, 12, 15, and 18 months (P < 0.05).

The %TWL of SG patients at 18 months is 30 %. The %TWL of LDS patients at 18 months is 40 %. The difference between the two is statistically significant (P < 0.05). This corresponds to an approximate 30 % difference at 18 months. Interestingly, the percent difference expands over each time period measured. Results are seen for this in Table 2 and Fig. 1.

At 18 months the average sleeve patient will have a %EWL of 70 %. An average LDS patient however will have a %EWL of 90 % at 18 months. This difference is statistically significant (P < 0.05). Results are seen for this in Table 3 and Fig. 2.

The VSG stops losing statistically significant amounts of weight at 12–15 months (P=0.321). The LDS stops losing statistically significant amounts of weight at 15–18 months (P=0.223).

Table 2Patients' percentagetotal weight loss (%TWL) at 3, 6,9, 12, 15, and 18 monthsfollowing surgery found throughnon-linear regression

%TWL	3 months	6 months	9 months	12 months	15 months	18 months	
LDS	20.7	29.2	34.1	37.1	38.7	39.6	
Ν	52/53	50/53	46/53	46/53	44/53	36/44	
CI	(19.8, 21.6)	(28.1, 30.3)	(33.1, 35.1)	(36.2, 37.9)	(37.8, 39.7)	(38.5, 40.7)	
VSG	18.5	25	27.9	29.3	30	30.2	
Ν	53/53	52/53	46/53	43/53	37/53	36/53	
CI	(17.5, 19.5)	(24.3, 26.3)	(27, 28.7)	(28.4, 30.3)	(28.9, 31.2)	(29, 31.5)	
P Value	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05	

All values are expressed as percentage points

CI 95 % confidence intervals

Table 3Patient's percentageexcess weight loss (%EWL) at 3,6, 9, 12, 15, and 18 monthsfollowing surgery found throughour non-linear regression analysis

%EWL	3 months	6 months	9 months	12 months	15 months	18 months
LDS	49	71.4	81.6	86.5	88.5	89.5
Ν	52/53	50/53	46/53	46/53	44/53	36/44
CI	(45.9, 52.1)	(68.7, 74.1)	(79.3, 83.9)	(83.9, 89.1)	(85.5, 91.5)	(86.2, 92.3)
VSG	44.9	60.5	66.4	68.5	69.2	69.5
Ν	53/53	52/53	46/53	43/53	37/53	36/53
CI	(41.8, 48.1)	(58.1, 62.8)	(63.7, 69)	(65.4, 71.6)	(65.9, 72.7)	(66, 73)
P value	>0.05	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05

All values are expressed as percentage points

CI 95 % confidence intervals

Complication rates are found on Tables 4 and 5. The majority of complications were related to the sleeve aspect of the procedure. Nausea rates were the only similar complication between the two procedures and they had similar complication rates (11 vs 9 % for the VSG and LDS, respectively). The single bleed in the LDS group was in the area of the VSG component. The only bowel-related complaints were three patients that reported diarrhea. Two of these episodes were self-limited, and normalized with dietary modification. A single LDS patient required reoperation 5 months after the original procedure for bowel lengthening due to high amounts of diarrhea. On exploration, it was found that the anastomosis was only 160 cm from the ileocecal valve.

Discussion

The purpose of our study is to determine what the impact is of adding an intestinal component to a sleeve gastrectomy. To determine this, we matched LDS patients to VSG patients based on sex and BMI. Following the development of these matched cohorts, we analyzed to see if there were any major differences that could influence outcomes. Interestingly, the LDS group was older and more likely to have diabetes. Both of these factors have been reported to reduce average weight loss [6-10]. As a result, our data, if anything underestimates the contribution of the intestinal component.

Early weight loss, is similar between each operation, demonstrating that early weight loss is predominantly caused by the gastric component. At 9 to 12 months, the VSG patients weight loss stabilizes, while patients with LDS continue to lose weight. As a result, the difference in weight loss increases. At 6 months, the difference was 13 %. At 18 months, this increased to 29 %.

This data is consistent with data achieved by Marceau and Biron. They studied patients that had a VSG and patients that only had the intestinal component of a duodenal switch without gastric reduction. In the first year, the sleeve only patients lost significantly more weight. At 5 years, the data reversed. The intestinal only group had lasting weight loss, and the sleeve only group had nominal weight loss [11]. Thus, it seems that early weight loss is gastric and later weight loss is secondary to the intestinal aspects of the procedure. Overall, at 18 months, LDS patients lost approximately 30 % more weight because of this.

For every advantage, there is a cost. The cost of intestinal manipulation is the increased risk of vitamin and

100% 90% 80% ^oercentage Excess Weight Loss 70% 60% 50% -IDS 40% VSG 30% 20% 10% 0% 100 200 300 400 500 600 **Days Since Surgery**

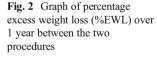


Table 4Complication rates for the two procedures with operativebeing less than 30 days and long term being more than 30 days

VSG minor complications		LDS minor complications			
Operative Nausea-2	Long term Nausea-4 GERD-4	Operative Nausea-1 Post-operative bleed-1 Incision infection-1	Long term Nausea-4 Dilated fundus-1 Diarrhea-3 Constipation-2 Abdominal Pain-1		

EGD esophagogastroduodenoscopy

micronutrient deficiency. This is true for every malabsorption procedure. However, when viewing out nutritional data at 1 year, there were not real differences between the two groups primarily because our study with current follow-up is not adequately powered to prove a statistical difference. If a surgeon really felt that 300 cm of intestinal length was too much, this anastomosis could always moved as proximal as they wanted. Indeed Huang has done just that and demonstrated good weight loss and low nutritional problems [12].

Additionally, some may state that the LDS is a far riskier operation. Table 4 reports the complications from each procedure. While there were several more complications in the LDS group, only a single patient required an additional procedure. Again, whether the benefits of the LDS exceed the increased risk cannot be answered by this study and must be made in conjunction with the patient.

Many would believe that the higher weight loss percentages in LDS patients are secondary to malabsorption. Yet, we have aimed to maintain 3 m of intestine. Several patients in our series reported constipation and the majority had one to three bowel movements daily. As a result,

 Table 5
 Major complications for the two procedures

VSG major complications	LDS major complications
Nausea-1	Abdominal pain-1
Stricture-1	Sleeve strictures-2
	Dilated fundus-1
	Miscounted bowel-1

For VSG patients: One patient with nausea was given an EGD. The other patient with the stricture had it dilated using an achalasia balloon

For LDS patients: One patient with abdominal pain and had a negative EGD. The patient symptoms resolved without further intervention. Two patients had sleeve strictures which were were dilated with achalasia balloons and symptoms resolved. One patient with a dilated fundus had it resected with resolution of symptoms. One patient which unrelenting diarrhea was found to have a common channel of 160 cm on reoperation 5 months from the original surgery. The symptoms resolved immediately when the bowel was lengthened to 400 cm

an important component to the increased weight loss may be activation of entero-hormones in the hind gut. It has been also speculated that while the stomach is important for hunger, the intestine is primarily responsible for satiety and energy regulation.

Weight loss percentages in our study are comparable to the duodenal switch weight loss percentages in other studies. Weight loss results between the regular duodenal switch and the VSG have already been shown to be significantly different [13, 14]. This again seems to indicate that stimulation of the distal intestine is more important than fat malabsorption caused by a short common channel. Only fecal stool studies that carefully monitor intake and measure calories in defecation samples can definitively answer this question.

Our use of non-linear regressions allowed our comparisons to be more accurate and to get the best comparison possible. There have been some studies that state the need for changing how we do statistics in order to be more accurate [15]. Compared with a linear regression or simple calculations of the mean our correlation of our data, our R value was significantly higher. Thus, our correlation between the data is higher and allows us to more accurately report results. This use of statistical analysis allows our study to compare the data without having to exclude patient data that does not fit exactly into the 3, 6, 9, 12, 15, and 18 month follow-up points.

Some may criticize the lack of there not being standard deviations with our data. This is the norm, but our study strived to find a more accurate way to represent the data. Our use of confidence intervals was a simple use of trying to show where the true mean of our patient population lies. We are 95 % sure that our populations lie in these intervals at individual points. One disadvantage being is most readers do not have familiarity with confidence intervals and R values. R values and confidence intervals show what standard deviations shows, the variability and the correlation in the data. Since we didn't exclude any follow up points, our measures of correlation to our data comes with our R values and confidence interval size. The R values of the LDS vs SG for %TWL and EWL were (0.95 vs 0.9) and (0.91 vs 0.85), respectively. Conversely, our confidence intervals increase overtime in both procedures although not as much in the LDS. This shows that our data for the LDS is much more closely correlated with our mean than the VSG since a higher R value denotes a closer correlation and that LDS weight loss is not as variable.

Our study's weight loss percentages for the VSG were within the range of previously published studies [16–19]. Studies with LDS are much more limited. However, our results for its weight loss were comparable to the small number of studies already published which had 250 cm common

Table 6 Diabetic parameters

	Sleeve gastrectomy				Loop duodenal switch			
	Pre op		1 year post op		Pre op		1 year post op	
	Abnormal	Total	Abnormal	Total	Abnormal	Total	Abnormal	Total
PHBA1C	18	33	5	16	40	51	6	34
Glucose	19	47	6	19	29	52	8	39
Insulin	15	38	1	14	30	47	0	18

channels and more than those which counted 150 cm from the ligament of Trietz [8, 12, 20–22].

There are many limitation of the paper one of these would be the lack of information of HTN, GERD, and sleep apnea resolution. We were able to capture retrospective information on T2DM and its resolution rates (Table 6); however, this retrospective cohort study design is not accurately powered to detect such differences between the VSG and the LDS. Another limitation is the short follow-up of 18 months. If follow-up was longer, there may or may not have been incidents of malnutrition and weight regain in both groups not captured at this time point. Since LDS is a malabsorptive procedure this must be followed closely. However, 18 months is adequate to catch both procedures at their weight loss peaks since the sleeve peaks at 9 months and the LDS peaks at 15 to 18 months.

Another, whole set of unique complications could potentially occur as a result of the loop configuration when added to the sleeve which include afferent loop dilation syndrome, volvulus around the common anastomosis [23, 24], and bile reflux (this has never been reported yet in the literature but in theory it is a possibility). Small matched cohorts such as this one are poor at evaluating

Table	7	Vitamin	parameters
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outcomes that are rare. Larger cohorts and longer times frames are needed to establish rates of these unique complications and this study was not designed to address these issues.

Another significant issue relates to the vitamin deficiencies found in Table 7. Again while very informative with our current sample size of 52, there just were not enough patients to see differences between the groups. This fact completely surprised us at one year the one year mark and it bears further studies into the future.

Conclusion

Our cohort analysis reveals that early weight loss is predominantly from the gastric component. Adding an intestinal component to a VSG extends the period of weight loss from 9 months to 15 to 18 months. This corresponds to almost 30 % more weight loss. Early complications are more often related to the sleeve component. Nutritional data does not significantly differ in this small sample size between the groups at 1 year. Further studies will be conducted to determine whether the increased weight loss is

	Sleeve gastrectomy				Loop duoder	Loop duodenal switch			
	Pre op		1 year post op		Pre op		1 year post op		P value
	Abnormal	Total	Abnormal	Total	Abnormal	Total	Abnormal	Total	
Vit D	30	46	5	18	23	52	12	35	1
Vit B1	5	41	3	14	12	51	5	32	0.70
Vit B12	0	43	3	15	5	52	10	34	0.74
Ferritin	1	46	0	18	6	52	6	35	0.16
Ca	1	46	2	18	2	52	2	38	0.60
Alb	3	25	0	19	0	24	4	37	0.30
TP	1	26	0	19	1	22	3	37	0.54
Cholesterol	14	47	6	16	16	52	14	24	0.57
TG	15	47	1	15	34	52	5	24	0.40

more advantageous than potential long-term issues and if vitamin deficiencies remain similar through time.

Compliance with Ethical Standards

Conflict of Interest Austin Cottam has no conflicts of interest to declare.

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

Mitchell Roslin reports personal fees and other from Medtronic, outside the submitted work.

Samuel Cottam has no conflicts of interest to declare.

Walter Medlin has no conflicts of interest to declare.

Christina Richards has no conflicts of interest to declare.

Amit Surve has no conflicts of interest to declare.

Hinali Zaveri has no conflicts of interest to declare.

Statement of Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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

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