Title Page

Mid Term Outcomes of Gastric Bypass Weight Loss Failure to Duodenal Switch

Short Title: *Failed Roux-en-Y gastric bypass (RYGB) converted to laparoscopic duodenal switch (DS)*

ABSTRACT

Background The Roux-en-Y gastric bypass (RYGB) is a very effective treatment for obesity and its related co-morbidities. However, some patients fail to lose more than 50% of their excess weight loss (EWL) and others regain much of the weight that they lost.

Objective The purpose of this study was to analyze early outcomes following conversion of RYGB to Duodenal Switch (DS) in terms of weight loss, change in co-morbidities and complications.

Setting This is a retrospective analysis from one surgeon at a single private Institution.

Methods We analyzed data from 32 obese patients retrospectively, who underwent revision for failed RYGB. Nine patients underwent DS with Roux-en-Y reconstruction (RYDS) and 23 patients underwent single anastomosis DS (SADS) between October 2012 and December 2015. Regression analyses were performed for all follow-up weight loss data.

Results The patients experienced mean EWL of 16.2% over an average of 16 years (range: 0, 38) with their primary RYGB surgery. Of 32 patients who underwent revision DS, 22 patients are beyond 1 year post-operative mark (follow- up 81.8%) and 15 patients are beyond 2 years post-operative mark (follow- up 73.3%). One patient lost to follow-up. The patients experienced mean EWL of 31.2%, 45.1%, 51%, 54.2%, 56%, and 56.4% at 3, 6, 9, 12, 18, and 24 months following their revisional surgery. Mean total body weight loss (TWL) achieved at 12 and 24 months was 27.7% and 29.2% respectively. There was no statistical significant difference in mean %EWL at 12 months ($P = 0.468$) and 24 months ($P = 0.266$) between RYDS and SADS.

Conclusion A laparoscopic revision from RYGB to DS is an effective weight loss operation with midterm follow-up of 2 years. Though long-term follow-up is warranted to measure recidivism, the initial data seems favorable.

Keywords: Revision laparoscopic duodenal switch; failed Roux-en-Y gastric bypass; weight loss failure; weight regain; recurrent co-morbidity; Revision surgery.

Introduction

Bariatric surgery improves quality of life and obesity-related co-morbidity, leading to a reduction in long-term mortality in morbidly obese patients [1, 2]. The Roux-en-Y gastric bypass (RYGB) is the most studied bariatric procedure worldwide and is widely considered the gold standard in bariatric surgery [3]. However, despite the successful outcomes of RYGB, weight recidivism is becoming a significant issue. Long-term follow-up studies have shown high weight loss failure rates following this procedure [4].

The "duodenal switch" (DS) is a surgical weight loss procedure utilizing both restrictive and malabsorptive methods to achieve long term weight loss [5]. The first part is a Sleeve gastrectomy (SG) that permanently removes part of the stomach. Its outcomes are well known and characterized [6, 7]. Next a long section of small intestine is bypassed to limit absorption of food. Perhaps most importantly the pylorus is preserved to help maintain consistent blood sugars [8].

Weight loss failure, weight recidivism and recurrent co-morbidities after RYGB are challenging problems for bariatric surgeons today [9, 10]. We believe that weight regain is not necessarily the patient's fault; just as some people don't tolerate the lap band others can't lose and maintain weight loss without a pylorus. In these instances conversion to a DS is a safe operation for patients who have failed other bariatric operations [11-13].

Methods

This is a retrospective analysis from one surgeon at a single private institution. Each patient who enters the practice consents to have their de-identified data analyzed. Each patient

signed a specific informed consent which detailed the risks of revisional surgery as well as consent for their DS. In the case of the single anastomosis duodenal switch (SADS) and Roux-en-Y reconstruction duodenal switch (RYDS) there were separate consent forms with diagrams illustration. Each patient was encouraged to watch actual videos of the revisional procedure that we discussed.

From our database 32 patients were seen for weight recidivism or weight loss failure following RYGB in the last 4 years. Failure of RYGB was defined as not losing or not maintaining > 50% weight loss at 18 months postoperatively. Patients who met the criteria for RYGB failure were given various revision surgery options and after detailed discussion with the surgeon, 32 patients chose to undergo laparoscopic revisional DS.

All patients underwent revisional DS surgery between October 2012 and December 2015. Pre-operative data and post-operative outcome data (weight loss, comorbidity resolution, complications, and mortality) were obtained from a prospectively kept data base. Co-morbidities included were sleep apnea, diabetes, hypertension and gastroesophageal reflux disease (GERD). An upper gastrointestinal endoscopy (EGD) or upper gastrointestinal series (UGI) was performed on all patients pre-operatively to evaluate the appropriateness for the revision. Of the 32 patients, 9 underwent laparoscopic RYDS with a 150cm common channel and a 150cm Roux limb, while 23 patients underwent laparoscopic SADS with a 300cm common channel. All our patients were seen by a registered dietitian at each visit who offered behavioral modification suggestion and vitamins and mineral supplements made by Bariatric Advantage designed especially for the DS that includes fat soluble vitamins, water soluble vitamins, iron, zinc,

copper, and calcium citrate. However, we have no idea on compliance of the patients using our prescribed regimen.

We stopped performing the RYDS in 2013 and performed only SADS thereafter. In the US we began doing the SADS in 2013 after having done RYDS since 2011. We were satisfied with the weight loss of the RYDS but unsatisfied with the frequency of diarrhea, smelly stools, flatulence, and vitamin deficiencies of copper and zinc seen in our practice.

Statistical Methods

Post-operative weight loss data were analyzed using non-linear regressions. All statistical analysis was run through Sigma Plot statistical software.

Operative Technique

All our procedures were done as a single time point. We have not done staged procedures for RYGB to RYDS or SADS. The surgery begins with placement of five trocars under direct vision. Adhesions were taken down. Then the Roux limb was resected off the gastric pouch (figure 1b: step 1 and 2) and the pouch was checked endoscopically for viability. If the patients have a Roux limb longer than 50cm, we excise it back to 15cm from the jejunojunostomy. If it is 50cm or less, we leave the Roux limb alone. The resected small bowel was then removed out of the abdominal cavity (figure 1b: step 3).

The gastric remnant was mobilized and the fundus resected (figure 1b: step 4). The remnant was attached to the gastric pouch using one of three methods: a totally hand sewn methods, a partially hand sewn method and an EEA method (figure 1b: step 5). These methods

are all similar to gastric bypass gastrojejunal anastomosis techniques [14]. This was checked with endoscopy for patency, viability and to perform an air leak test.

Once this was accomplished and the ileocecal valve was located, there was a creation of either a 150cm common channel and 150cm Roux or a 300cm common channel.(figure 1b: step 6).

At this point, dissection began and the sleeve gastrectomy was done over a 40 french bougie without staple line reinforcement or over sewing (figure 1b: step 7). This was done away from the gastrogastrostomy (G-G). If the stomach was already very narrow as was often seen from longtime disuse then minimal resection was done of the body and antrum in order to maintain viable blood supply. The stomach was then taken out of the abdominal cavity.

The duodenal bulb was dissected 3cm from the pylorus circumferentially and transected using a GIA stapler (figure 1b: step 8) [15]. The duodenal stump was over sewed using PDS suture. Next, the limb was brought up sewed it to the duodenal stump using 2.0 polysorb (figure 1b: step 9). Enterotomies were made in both limbs and 3.0 polysorb was used to do another posterior row. An anterior row was also done using 3.0 polysorb. The bowel was inspected for bleeding and bowel damage. 2 large drains were placed. The skin was closed with staples. Drains were sewn into place.

Results

Thirty-two patients were identified for analysis.

Revision DS: The pre-operative characteristics and operative details are shown in table 1. Twenty-two patients are beyond 1 year post-operative mark, 18 of which have data (81.8%). 15

patients are beyond 2 years post-operative mark, 11 of which have data (73.3%). One patient lost to follow-up.

Complications post laparoscopic revision DS are shown in table 2. There were 5 (15.6%) re-admissions with 30 days of discharge. Early complication rate was 25%. There was no 30- day mortality in any patient and 1 death was noted over a year, not related to surgery.

Success was defined as weight loss equal to or greater than 50 percent of excess body weight and failure as less than 50 percent of excess body weight, after one year of surgery [16 - 18]. Based on this definition, of the 18 patients who had their last available follow-up more than 1 year post op, 14 (77.7%) were successful in terms of weight loss and co-morbidities resolution both (table 3).

Post- operative nutritional data such as vitamins A, B-1, B-12, D, serum calcium and albumin were also analyzed. The labs were available for total of 14 (63.6%) patients. Overall mean values for the nutritional data were close to normal (refer to table 4).

Weight loss analysis

Primary surgery (RYGB): The patients lost a mean excess weight of 16.2% over an average of 16 years (range: 0, 38). See figure 2.

Revision DS: Patients had experienced mean losses of 31.2%, 45.1%, 51%, 54.2%, 56%, and 56.4% of their excess weight at 3, 6, 9, 12, 18, and 24 months, respectively. (table 5)

RYDS: 9 patients who underwent RYDS lost 64.6% of their mean excess weight at 12 months (follow-up: 62.5%) and 67.5% at 24 months (follow-up: 57.1%).

SADS: 23 patients who underwent SADS lost 52.8% of their mean excess weight at 12 months (follow-up: 92.8%) and 54.5% at 24 months (follow-up: 87.5%).

There was no statistical significant difference in mean percent excess weight loss (%EWL) at 12 months ($P = 0.468$) and 24 months ($P = 0.266$) between RYDS (9 patients) and SADS (23 patients).

Discussion

The RYGB is the one of the most successful bariatric procedures. It provides durable weight loss for years. However, up to 25% of patients fail to maintain their weight loss [19-22]. These failure rates have remained consistent over time [23-25].

The question remains for the surgical practitioner what options are available for the 25% who have failed to maintain their weight loss after RYGB. Various surgeons have tried revising the stoma, the pouch size or lengthening the Roux limb to create a distal bypass (none of these have experienced short term or long term success) [26, 27].

The question for those who don't perform the DS is why this should work when a distal bypass doesn't. We believe this is all related to the pylorus. When RYGB patients come to clinic following weight loss failure they almost always are eating small frequent high carbohydrate meals. We believe this is a physiologic response to vacillating blood sugar amounts [8]. Huang et al. [24] present their experience with a patient who had inadequate weight loss and dumping syndrome after RYGB and underwent surgical revision to modified DS with immediate resolution of the dumping syndrome. This proves the essential role that the pylorus plays in the maintenance of consistent blood glucose levels. We believe that with

consistent blood sugar levels there will be more satiety. Almost certainly there are additional factors at work but this forms the core around which we have based our operative selection.

Our study of this population mirrors the only other similar but much smaller study reported by Gagner in 2007, where 12 patients who failed RYGB were converted to Biliopancreatic diversion with duodenal switch (BPD/DS) [13]. In their study they achieved 63 percent EWL at 11 months postoperatively with resolution of all the co-morbidities in their patients. Our study had similar weight loss at 11 months but we had 2 year follow up with 56.4 percent EWL. In this study the two year follow up is important since the nadir of weight loss following DS is at 18 months statistically thus we are reporting the maximum weight loss a revisional DS patient can experience following this surgery. However, a vital point of this paper is the fact that this procedure has very good weight loss but in no way approaches the weight loss seen when SADS or RYDS are done as a primary procedure [29-33].

The reader of our study will notice a few things that make our performance of this procedure unique. The first is our performance of a fundectomy during the surgery. This is to eliminate most of the receptive relaxation that the stomach experiences after a meal. We also do the surgery loosely over a 40 french bougie. While that is a small bougie size we don't come close to the bougie at all. Thus our gastric remnant volume reduction comes primarily from fundectomy and not the SG. Another important technical aspect of the procedure is the preservation of the gastroepiploic perforators to the stomach. Normally we take these down when doing a DS [15]. However, when performing this procedure due to the variable lesser curve anatomy and blood supply we choose to preserve at least three perforating vessels rather than trust that the left gastric has not been divided. The reader will also note that we employed

three techniques when performing the gastrogastrostomy. While this is important to tell the reader we don't believe this portion of the procedure has any effect on the long term weight loss or weight maintenance of the surgery. The performance of this procedure is much easier when it can be done with an EEA technique. However, this is not always possible and any surgeon who undertakes this surgery should be facile at multiple ways of performing gastro-gastrostomies.

Another potential limitation of the study relates to the performance of the DS. In 9 patients we did a RYDS and the other we performed a SADS. Despite the fact they were similar in terms of weight loss it was easier and less time consuming to perform the SADS. This analysis must be tempered as there were very few patients in the RYDS groups to make firm conclusions on differences especially long term ones.

Although limited nutritional data was one of the major limitations of our study, it was not intended to answer any realistic concerns, post DS. The mean albumin for our patient's ≥12 months was 3.6 which are normal. Range for this subset was 1.7 - 4.6. This includes three patients, two of which had borderline albumin levels of 3, and the other patient had an albumin level of 1.7 because of heart failure, that was not related to the surgery. Nutritional data were also not reported in Gagner paper. However, Torres et al. from Spain reported his series of SADS patients and showed with a 250 cm common channel that his nutritional outcomes did not differ from his gastric bypass patients [29]. In the nine patients who had a RYDS, their nutritional outcomes were less than those experienced by Marceau group in Quebec since our Roux limb and common channel are longer [34].What we can say is that no patient that we were able to contact for this study has experienced protein calorie malnutrition with 300 cm intestinal length.

Lastly we attempted to be exhaustive in our presentation of complications because the complication rate is so high (25%). Surgeons should be wary of doing this procedure without adequate institutional support. These patients require more of everyone on the team from the work up to the aftercare.

Conclusion

A laparoscopic revision from RYGB to DS is an effective weight loss operation with midterm follow-up of 2 years. Complication rate is significant when compared to primary procedures. Long-term follow-up is warranted to measure weight recidivism.

Conflicts of Interest

None of the authors have any conflicts of interest to declare

Statement of Human and Animal Rights

I certify that the manuscript did not involve the use of animal or human subjects.

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

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Figure Legends

330 Figure 1 Hand drawn sketches of a) Roux-en-Y gastric bypass (RYGB), b) RYGB conversion to single anastomosis duodenal switch (SADS) (steps) and c) RYGB converted to SADS.

Figure 2 Graphical representation of weight loss with primary surgery (RYGB) and revision surgery (DS).

335 **Table 1** Characteristics and operative details of patients undergoing revision DS surgery from 2012-2015.

Characteristic	Value
Subjects (n)	32
Male/Female (n)	2/30
Primary RYGB	
Pre RYGB weight (lbs)	315.5 ± 106.14
Pre RYGB BMI (kg/m^2)	51.21 ± 14.33
Time to reoperation (year) *	16.4 ± 9.3
Revision DS	
Age (year)*	49.6 ± 9.4
Follow-up (mo)*	15 ± 11.1
Preoperative weight (lbs.) *	281.2 ± 73.8
Preoperative BMI (kg/m^2) *	45.6 ± 10.7
Ideal body weight (lbs.) *	128.2 ± 13.5
Excess body weight (lbs.) *	153 ± 70.4
Operative Details (Revision DS)	
No of patients undergoing laparoscopic RYDS	9
No of patients undergoing laparoscopic SADS	23
Operating time (min) *	155.5 ± 38.6
Blood loss (cc) *	40.5 ± 22.7
Length of stay (day) *	3.4 ± 1.8

Abbreviations: BMI = body mass index, DS = duodenal switch, n = number of patients, RYDS: Roux-en-Y reconstruction duodenal switch, SADS: Single anastomosis duodenal switch, DS: duodenal switch.

340 *Values expressed as mean ± SD

Table 2 Short-term and long-term complications with revision DS.

Short-term			**Long-term**		
Complications	RYDS (n=4/9, 44.4%)	SADS (n=4/23, 17.3%)	**Complications**	RYDS (n=2/9, 22.2%)	SADS (n=3/23, 13%)
Abdominal abscess: 2*	1	1	Gastric ulcer: 1*	0	1
Peritonitis: 3**	2	1	Internal hernia: 1**	0	1
Acute blood loss anemia: 1	1	0	Stricture: 1***	1	0
Gastric leak: 1***	0	1	Small bowel obstruction: 1****	0	1
Gastric outlet obstruction: 1****	0	1	Sepsis: 1	1	0

Abbreviation: DS: duodenal switch, RYDS: Roux-en-Y reconstruction duodenal switch, SADS: Single anastomosis duodenal switch, n= number of patients, (%).

Short-term complication

*Both the patients with abdominal abscess needed re-admission within 30 days of discharge. Both underwent exploratory laparotomy with gastric lavage.

** Two patients had peritonitis on post-operative day 2. Both patients had leak from small bowel, needing repair of small bowel enterotomy. One patient was re-admitted within 30 days of discharge with gastro-gastric anastomotic leak causing peritonitis, needing repair.

*** This patient was also re-admitted within 30 days of discharge with gastric leak.

****Patient experienced severe abdominal pain within 30 days of discharge and was diagnosed with gastric outlet obstruction caused by adhesion near pylorus. Adhesiolysis was performed for this patient.

Long-term complication

*Patient had recurrent ulcers and strictures needing esophagogastroduodenoscopy (EGD) with dilation.

**Patient presented 3 months post revision SADS with abdominal pain. Exploratory laparotomy was performed with reduction of small bowel and closure of internal hernia.

***Patient had stricture of the sleeve due to external scar tissue, therefore no dilation was needed. Only adhesiolysis was performed.

****Two year post-DS, patient presented with severe abdominal pain. CT- scan revealed intussusception. Exploratory laparotomy was performed and dilation of jejunojejunostomy from old RYGB was found as one of the causes. Resection of roux limb was carried out with side-to-

side isoperistaltic entero-enterostomy between biliopancreatic limb and afferent limb. A kink at loop duodenal ileostomy on the afferent side was also found as the other cause of small bowel obstruction. A side-to-side entero-enterostomy was performed.

Table 3 Highlights outcomes in patients post revision DS (last available follow up >1 year).

Pt no	Pre RYGB BMI (kg/m^2)	No of years after RYGB	Last available f/u since revision DS (month)	Pre revision DS BMI (kg/m^2)	Current BMI (kg/m^2)	% Excess Body Weight Loss post revision DS	Outcomes
1	44.5	-	16	44.6	27	70.8	Successful
2	48	-	21	47.7	30.6	63.8	Successful
3	72.8	17	24	66.5	32.1	75.8	Successful
4	-	19	24	32.2	22.6	77.1	Successful
5	-	30	21	49.8	24.9	84.9	Successful
6	41.6	31	24	41.7	38.4	23.7	*Failure*
7	48.2	24	25	40.3	27.1	67.3	Successful
8	56.5	25	13	51	43	43.5	*Failure*
9	47.8	25	13	48.6	40.7	27.9	*Failure*
10	46.9	19	39	45.6	32.8	52	Successful
11	51.6	20	21	43	26.5	76.5	Successful
12	-	31	26	55	55	0	*Failure*
13	36.6	20	32	33.8	22.8	82.8	Successful
14	-	13	12	39.4	27.7	64.4	Successful
15	48.2	24	25	40.3	27.1	67.3	Successful
16	-	12	25	66	33.3	70.7	Successful
17	56.4	2	25	35.7	24.3	75.7	Successful
18	35.9	7	31	38.1	26.5	69.2	Successful

Abbreviations: DS: Duodenal switch, RYGB: Roux-en-Y gastric bypass, BMI: body mass index, According to the definition of success, of 18 patients who had their last available follow-up more than 1 year post op, 14 (77.7%) were successful in terms of weight loss.

Table 4 Highlights nutritional outcomes in patients post revision DS.

		Albumin	Calcium	Vitamin-B1	Vitamin-B12	Vitamin-A	Vitamin-D
Pre revision DS	Value*	3.9 ± 0.4	9.3 ± 0.5	128.3 ± 54.4	405.8 ± 285	40.5 ± 14.8	23.9 ± 13.5
	Range	3 - 4.5	8.4 - 10.5	32.6 - 251.4	148 - 1589	30 - 51	5.3 - 60
	Abnormal Labs (n)	3/32	1/32	3/32	3/32	1/32	14/32
≥6 months (n: 17/27)	Value*	3.8 ± 0.8	9 ± 0.6	146.4 ± 49.7	716.4 ± 721.5	39.3 ± 15.4	45.7 ± 27.7
	Range	2 - 4.3	7.8 - 9.9	81.3 - 208.4	281 - 2000	25 - 57	18.9 - 96
	Abnormal Labs (n)	2/17	1/17	0/17	0/17	0/17	3/17
≥12 months (n: 14/22)	Value*	3.6 ± 0.9	8.9 ± 0.8	100.9 ± 34.6	742.5 ± 425	36 ± 12.9	45.1 ± 27.7
	Range	1.7 - 4.6	7.8 - 10.3	50 - 147.2	384 - 1459	24 - 57	11 - 96
	Abnormal Labs (n)	3/22	5/22	1/22	2/22	0/22	2/22
	Normal Range	**3.5 - 5.5 g/dL**	**8.5 - 10.2 mg/dL**	**74 - 222 nmol/L**	**200 - 1100 pg/mL**	**24 - 90 ug/dL**	**25 - 80 ng/mL**

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*Values are expressed as mean ± standard deviation

DS= Duodenal Switch, n= number of patients

Table 5 Highlights weight loss outcomes at 3, 6, 9, 12, 18, and 24 months, post revision DS (RYDS and SADS)

	Value					
Month after revision DS	3	6	9	12	18	24
Subjects (n), (%)	25/28, (89.2%)	23/27, (85.1%)	20/24, (83.3%)	18/22, (81.8%)	14/19, (73.6%)	11/15, (73.3%)
%EWL*	31.2 (26, 36.5)	45.1 (40.8, 49.5)	51 (47.4, 54.7)	54.2 (50.3, 57.9)	56 (51.3, 60.7)	56.4 (51.3, 61.5)
%TWL*	15.2 (12.6, 17.7)	22.2 (19.9, 24.5)	25.8 (23.9, 27.6)	27.7 (25.8, 29.5)	28.9 (26.5,31.2)	29.2 (26.6, 31.8)
Change in BMI* (kg/m^2)	7.1 (5.6, 8.6)	10.5 (9.1, 11.9)	12.3 (11.2, 13.4)	13.3 (12.2, 14.4)	14 (12.6, 15.4)	14.2 (12.6, 15.8)
BMI * (Kg/m^2)	42 (40.2, 43.9)	40.1 (38.4, 41.8)	38.3 (36.5, 40)	36.3 (34.3, 38.4)	33 (30.4, 35.9)	29.9 (26.5, 33.4)
%EBMIL*	41 (33.3, 48.6)	58.3 (51.9, 64.8)	66.3 (61, 71.5)	70.2 (64.6,75.7)	72.4 (65.6, 79.2)	72.9 (65.5, 80.2)

*Values are expressed as means (95% Confidence Interval)

Abbreviation: %EWL = percent excess weight loss, %TWL = percent total weight loss, BMI= body mass index, %EBMIL = percent excess BMI lost, RYDS = Roux-en-Y reconstruction duodenal switch, SADS= Single anastomosis duodenal switch, DS = duodenal switch.

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Figure(s)

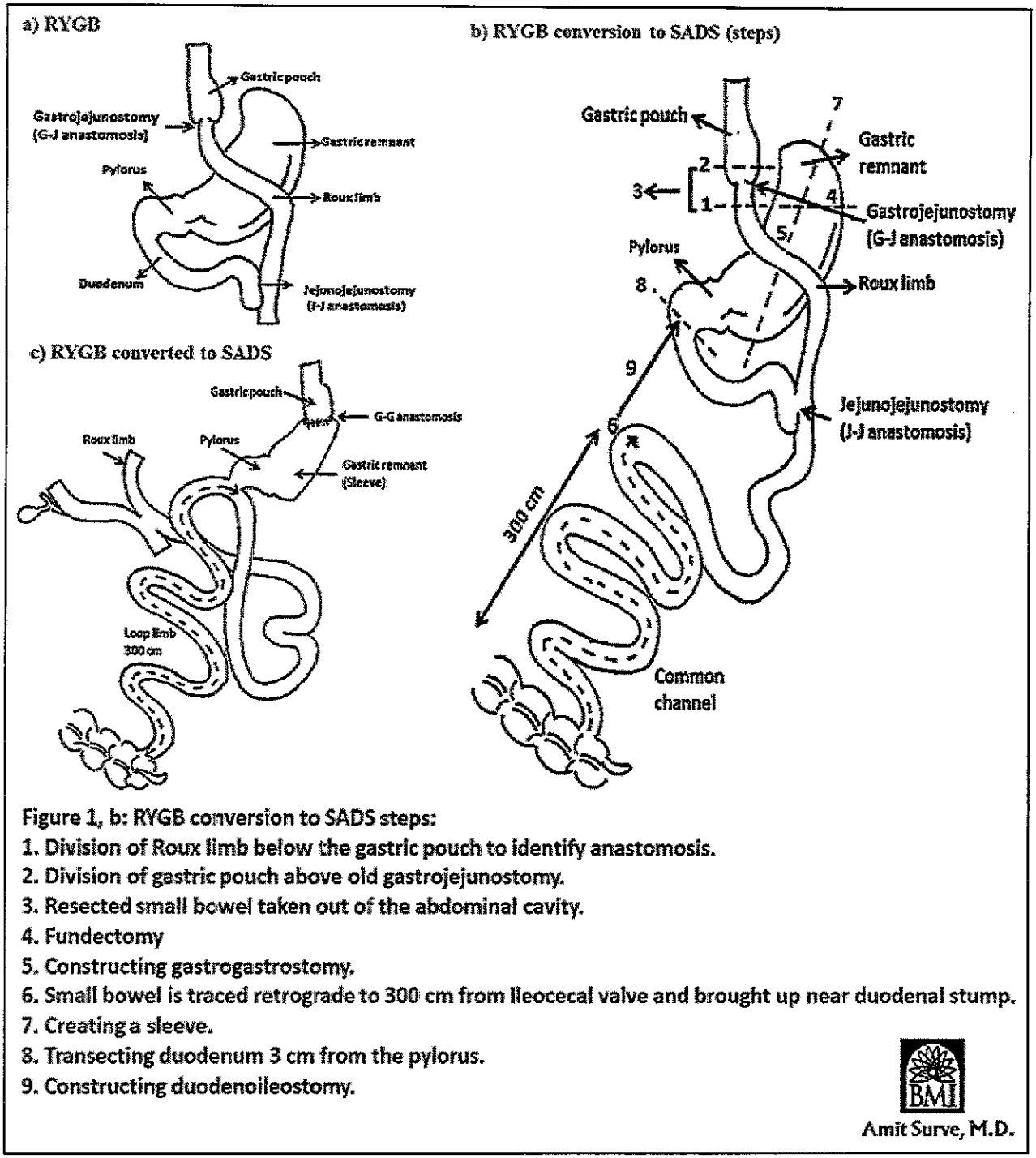
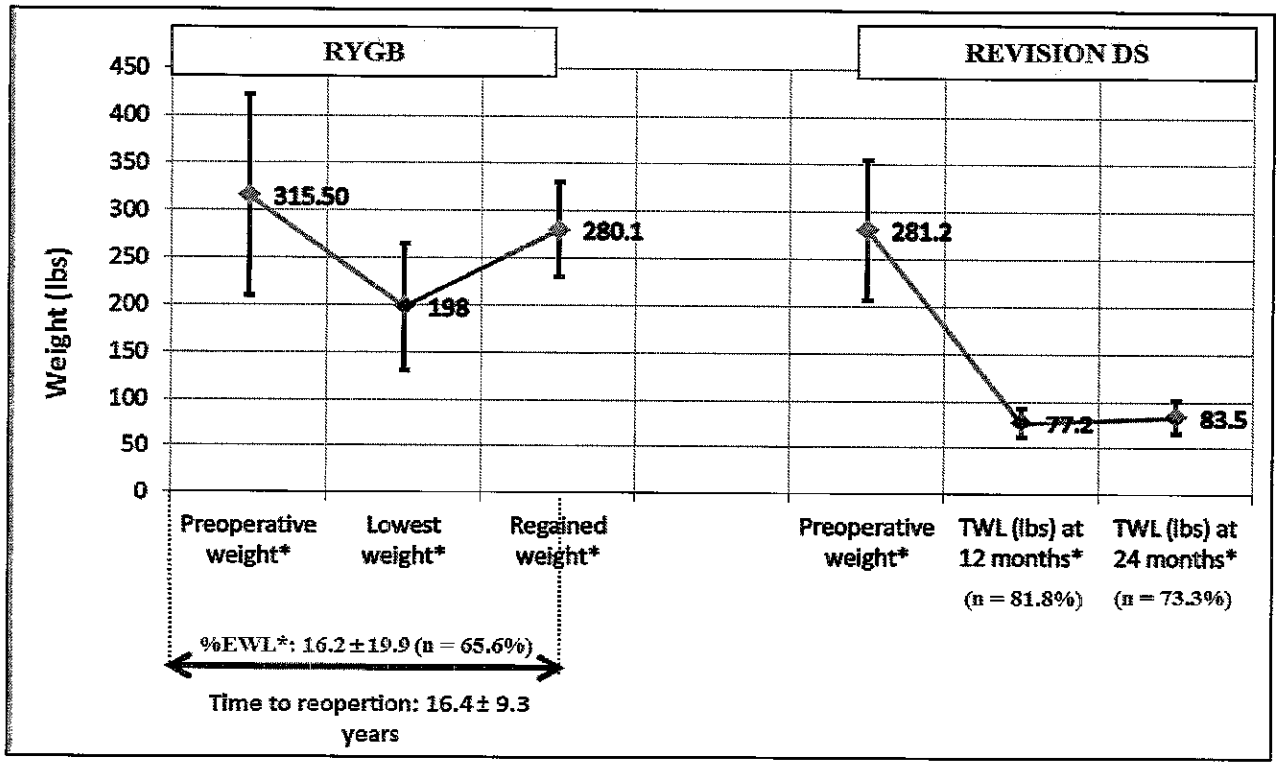


Figure 1 Hand drawn sketches of a) Roux-en-Y gastric bypass (RYGB), b) RYGB conversion to single anastomosis duodenal switch (SADS) (steps) and c) RYGB converted to SADS.



* Values are expressed as mean ± standard deviation.

Abbreviations: RYGB: Roux-en-Y gastric bypass, DS: duodenal switch, EWL: excess weight loss, TWL: total weight loss, n: follow-up percentage.

Figure 2 Graphical representation of weight loss with primary surgery (RYGB) and revision surgery (DS).