

Chapter 1

Bariatric Surgery

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Physiology of Obesity

Bariatric (*Bar-iatric*) means weight (*bar*) treatment (*iatic*). Bariatric surgery refers to a number of commonly performed procedures that are executed for treatment of morbid obesity and the associated comorbidities; these surgical procedures are recommended for patients with morbid obesity. Morbid obesity is a diagnosis, based on body mass index, also known as BMI. The BMI is a value derived from an individual's height to their weight (kg/m^2). Other measurements, such as waist circumference and muscle mass, are all indexes that need to be carefully examined when evaluating a patient's overall health to be considered for weight loss surgery.

Obesity is a risk factor for many medical illnesses including: diabetes, cardiovascular disease, cancer and even in some cases, premature death. Sustained weight loss may protect and reduce the risk of these conditions. The Swedish Obese Subjects (SOS) study was one of the first long-term clinical trials documenting bariatric surgery efficacy and its influence on the frequency of obesity related comorbidities. Multiple studies have shown the benefits of surgery compared to non-surgical treatment for comorbidities associated with morbid obesity [1].

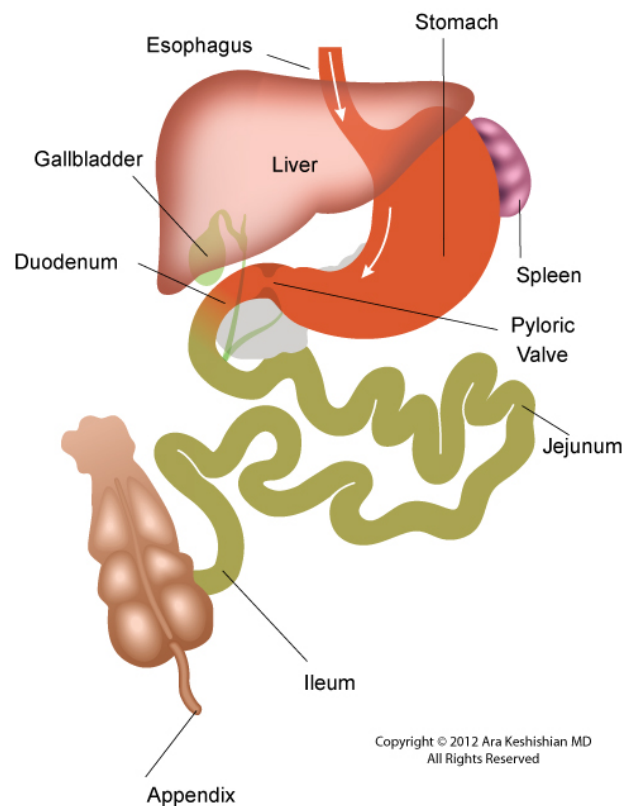


Figure 1: Normal Anatomy.

Evolution of Bariatric Surgery

The first reported cases of weight loss surgery in the United States were performed in the 1950's at the University of Minnesota through a procedure called Jejunoileal Bypass (JI Bypass). This involves connecting the proximal jejunum to the distal ileum, by passing 90% of the small bowel. Results of the procedure showed a decrease in the absorptive surface area, as well as creation of a blind limb. Although significant weight loss was achieved, many patients' developed substantial complications such as liver failure, believed to be caused by overgrown bacteria in the intestinal blind limb. Other complications included steatorrhea, arthritis, major protein and vitamin deficiencies and even dermatologic changes. The JI by pass fell in disfavor due to the high complication rate, which lead to the development of new surgical strategies [2,3].

Gastric Bypass - RNY

Gastric bypass, also known as the Roux-en-Y gastric bypass, made its debut in the 1960's after significant weight loss had been noted in patients who had partial gastrectomy for ulcers; this technique was adapted for obese patients by doctors Mason and Ito.

The initial operation by Dr. Mason included a loop bypass with a large stomach pouch. This procedure was noted to cause biliary reflux and inadequate weight loss. The procedure was then modified to include a Roux-en-y limb and small pouch of the stomach, which resolved the issue of bile reflux [4].

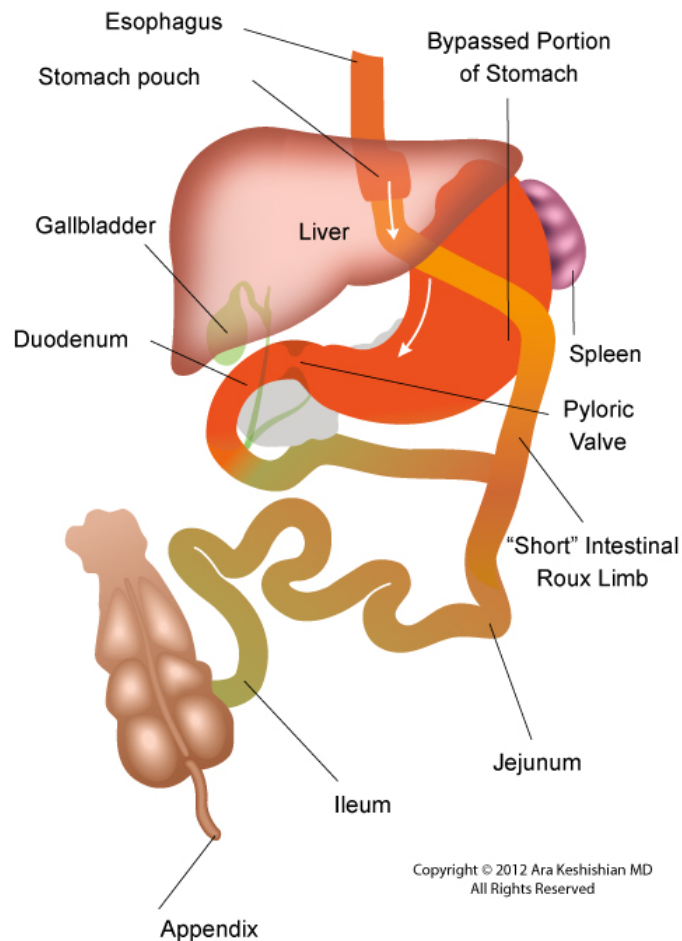


Figure 2: Gastric Bypass.

In a gastric bypass operation, a small gastric pouch, (2-3 ounces), is created just distal to the gastroesophageal junction. A short segment of Roux-en-Y limb, approximately 50 cm, is created by the proximal jejunum and brought up for creation of the gastrojejunostomy anastomosis. The optimal size of the gastrojejunostomy anastomosis has been studied to be approximately 1.5 cm. Since the pyloric valve is excluded, this may result in Dumping Syndrome. Dumping syndrome includes a series of symptoms that occur between minutes to hour(s) after certain types of meals have been consumed by gastric bypass patients. These symptoms may include nausea, vomiting, abdominal pain, high heart rate, dizziness and lightheadedness. In extreme cases some patients may actually experience confusion and syncope (fainting).

Dumping syndrome can be categorized from early to late dumping syndrome.

Inadequately processed and prepared food by the stomach into the small bowel is the underlying cause of dumping syndrome. The uncontrolled passage of food into the small bowel may lead to a rapid surge in blood sugar level, which can cause an equally rapid rise in blood insulin level. This results in very low blood sugar and the clinical sequela outlined above [5].

Numerous studies have shown that the procedure offers intermediate maintained weight loss and improved weight-related comorbidities. As the weight is lost, the patients experience associated illnesses such as Type II

diabetes hypertension, and hypercholesteremia. Other conditions such as arthritis, urinary incontinence, steatohepatitis, venous stasis disease, acid reflux, and obstructive sleep apnea may improve. On average, half of the weight loss a gastric bypass patient experiences is within first six months post-op, and usually peaks between 18-24 months. The weight loss and comorbidity alleviation results in significant improvements in the quality of life [6].

Even though short-term results of the gastric bypass operation may be acceptable when measured by excess weight loss, the long-term outcome of maintained weight loss, along with the associated complications of the surgery, make it a procedure that I personally do not recommend. The percentage of excess weight lost (EWL) is subject to change with the data of patients for length, quality and frequency of follow up, initial patient weight many other variables. As with all weight loss surgical procedures, gastric bypass patients require life-long follow-ups for the best possible outcome [7].

Until 2012, the gastric bypass was the most commonly performed operation in the United States. (Reference BOLD, ASC/MBSAQIP, National Inpatient Sample data and outpatient estimations).

Estimate of Bariatric Surgery Numbers, 2011-2014

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	2011	2012	2013	2014
Total	158,000	173,000	179,000	193,000
RNY	36.7%	37.5%	34.2%	26.8%
Band	35.4%	20.2%	14%	9.5%
Sleeve	17.8%	33%	42.1%	51.7%
BPD/DS	0.9%	1%	1%	0.4%
Revisions	6%	6%	6%	11.5%
Other	3.2%	2.3%	2.7%	0.1%

ASMBS total bariatric procedures numbers from 2011, 2012, 2013 and 2014 are based on the best estimation from available data (BOLD, ASC/MBSAQIP, National Inpatient Sample data and outpatient estimations).

Adjustable Gastric Banding

In 1978 Dr. Wilkinson wrapped a band of Marlex mesh just distal to the GE junction partitioning the stomach without stapling or dividing it.

In 1980, gastric segmentation procedures, described by Dr. Molina, featured Dacron vascular graft instead of the Marlex mesh. The gastric pouch created was smaller than previously with Wilkinson’s approach. Complication of the Dacron graft resulted in adhesion of the band to other anatomical sites, predominantly the liver, ensuing in its replacement with PTFE (Gortex®).

This procedure continuously evolved and in 1983 Kuzmak started using a 1 cm Silicone® band distal to the GE junction, creating an approximate 30-50 mL proximal stomach pouch and 13mm stoma. Later modifications to this band allow for its adjustability in diameter using an inflatable balloon, known as adjustable gastric banding. The new Silicone® band with the adjustable balloon

was connected to a small reservoir implanted under the skin of the abdomen allowing, adjustability of the band diameter. Filling of the balloon is done by injecting saline through the port, resulting in a tightened of the band and increased restriction. This was believed to support increased weight loss, whilst deflation expanded the inner-diameter of the band reducing weight loss [8,9] because of reduced restriction.

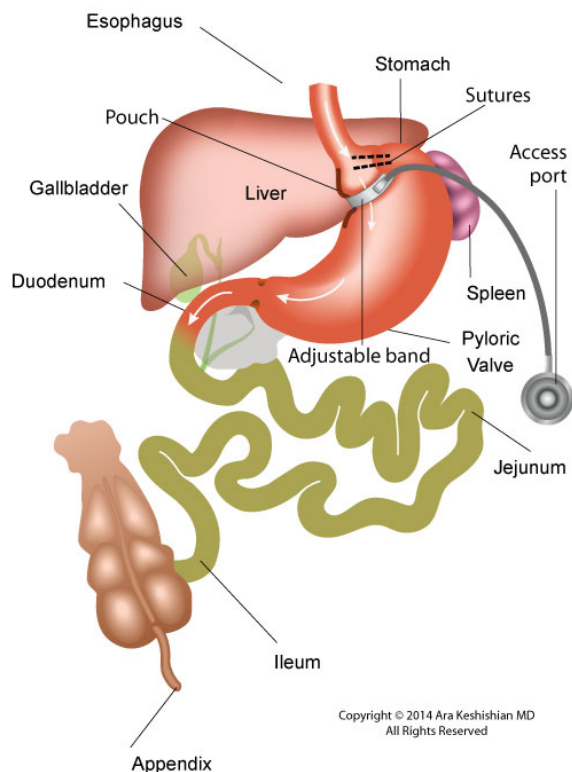


Figure 3: Gastric Banding.

There are currently several brands of adjustable bands available on the market with no significant differences reported between them. Band use has been decreasing over the last 5 years because its high, long-term complication and very poor weight loss profile.

Studies have reported a large amount of incidences regarding re-operation due to the long-term complications. The obstacles associated with adjustable gastric bands include: port complications, erosions band slippage,; inadequate weight loss or weight regain, esophageal dilation, motility disorders, and gastroesophageal reflux [10]. Revision surgery from an adjustable gastric band to a different bariatric procedure has been proven to be more difficult than it had been suggested [11].

Laparoscopic Sleeve Gastrectomy

Laparoscopic Sleeve Gastrectomy is part of the Duodenal Switch operation. It has gained acceptance as one of the primary weight loss surgical procedures, where a restrictive mechanism is considered sufficient for adequate and sustained weight loss. According to the published data this method has been the most common weight loss surgical procedure since 2013, surpassing gastric banding and gastric bypass procedures. The Laparoscopic Sleeve Gastrectomy reduces the size of stomach by 70-85%, which is accomplished by removing the “greater curvature” of the stomach (the size of the sleeve has been debated in literature). It is clear that when making the sleeve smaller, a 38 F bougie may result in more weight loss at a significantly

higher chance of reflux. This results in not only a greatly reduced volume of the stomach, but also reduced levels of Ghrelin. Ghrelin is a gastrointestinal hormone that plays a significant role in appetite regulation and control. Unlike the Gastric Bypass, which changes the way the stomach and small bowel interact, the only difference with the Laparoscopic Sleeve Gastrectomy is the reduced size of the stomach. This procedure avoids the frequent complications of the Gastric Bypass, such as dumping syndrome, marginal ulcers, intolerance of solids, iron deficiency, and weight regain [12,13].

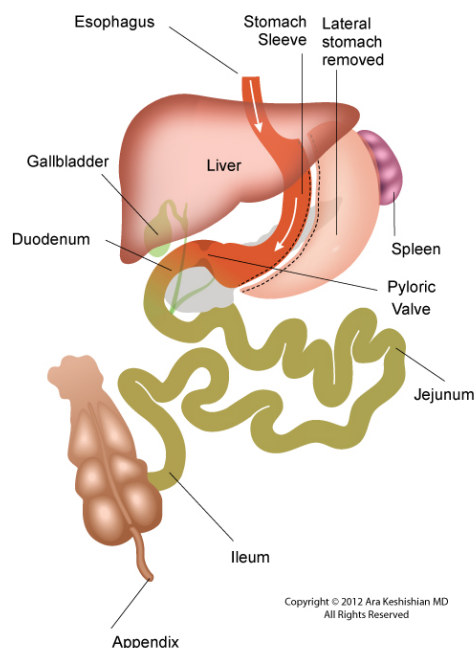


Figure 4: Sleeve Gastrectomy.

Duodenal Switch

The Duodenal Switch (DS) operation is a hybrid procedure with two components of the sleeve gastrectomy and Roux-en-Y small bowel bypass, which reduces both caloric intake and absorption. The procedure is modified from the BPD and designed to prevent ulcers and eliminate dumping syndrome, all while minimizing nutrient malnutrition frequently seen with BPD [14].

The sleeve gastrectomy component is created by dissecting along the greater curvature of the stomach, approximately 5 cm proximal to the pylorus to the GE junction. By using a 38-F bougie as a sizer, a tubular sleeve stomach is created by removing the greater curvature of the stomach. This removes a major segment of the stomach that produces acid and the Ghrelin hormone, hunger regulation.

The Duodenal Switch portion of the procedure itself involves 2 components. The first is the creation of a Roux-en-Y limb by dividing the bowel at a certain point proximal to the ileocecal valve. In my experience and opinion, it is recommended that the patient's small bowel be completely measured and 2 distinct points be marked, 10% and 40% of the total length proximal to the ileocecal valve. These measurements should be based on the patient's total bowel length, not patient weight. There is no scientific evidence that shows any correlation between the length of the bowel and severity of the obesity [15]. Additionally,

the percentages constructed by bowel lengths for the alimentary and common channels can be adjusted based on each patient's unique metabolic requirements. The small bowel should be divided at the 40% marking. The proximal end of the small bowel divided at this location should then be brought down for a side-to-side anastomosis at the 10% marking. The distal end of the divided small bowel at the 40% marking is then taken up in a retro colic plane to the right of the middle colic artery for anastomosis with the post pyloric transected duodenum. The second stage of the duodenal switch portion of the procedure is the duodeno-ileostomy anastomosis. This is accomplished by first dividing the duodenum. The duodenum is transected approximately 4-5 cm distal to the pyloric valve, proximal to the Ampulla of Vater. This is a 4-5 cm segment of the duodenum, as with the rest of the small bowel is crucial in absorption of nutrients and minerals.

The small intestine is then attached at the end of the post pyloric transected duodenum, which remains continuous with the reduced stomach. The distal duodenum carries bile and pancreatic secretions into the small bowel to meet with digesting foods forming, the common channel at the site of the distal anastomosis [16].

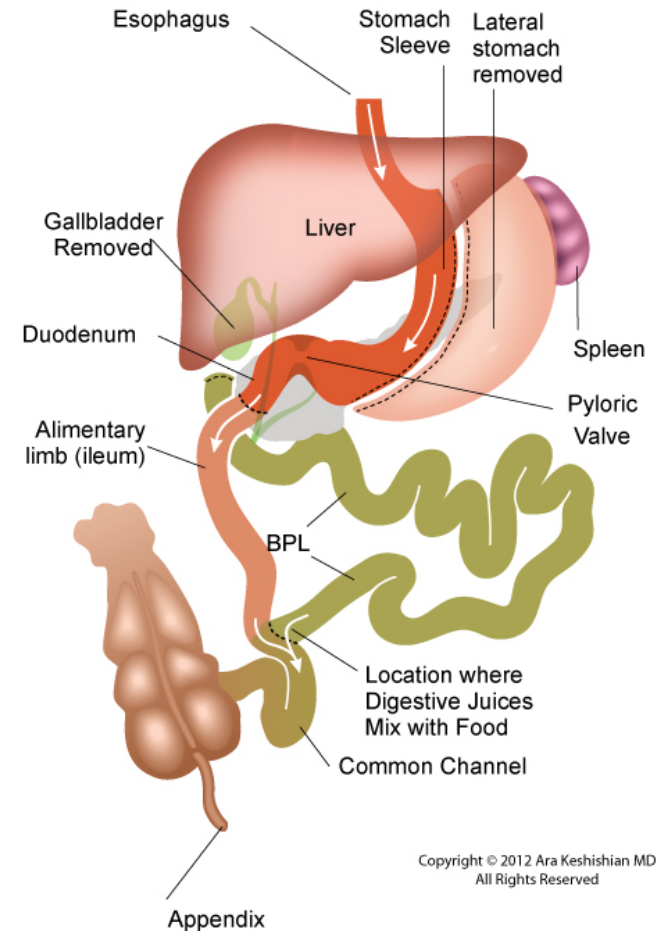


Figure 5: Duodenal Switch.

The DS procedure is one of the most complex operations in bariatric surgery, but it is reported to have the

highest weight loss among patients in long-term studies. As with all weight loss surgical procedures, the benefits of the weight loss come with the risk of nutritional deficiencies. These may be more pronounced with DS in patient's who are unable or unwilling to follow physician recommendations. It is critical that with any weight loss surgery, a patient assesses the risk of long-term nutritional and metabolic outcomes against the benefits of the surgery. Patients who have done DS may experience foul smelling loose stools and flatulence after significant dietary indiscretion with fat and carbohydrates. However, those who are offering alternative procedures over exaggerate the "bathroom issues" of DS patients.

DS is performed laparoscopically. However, due to its complexity, the procedure requires well-trained surgeons.

SADI- SIPS

Single Anastomosis Duodeno-Ileostomy (SADI) and Stomach Intestinal Pylorus-Sparing (SIPS) surgeries are NOT the same as the Duodenal Switch (DS) operations. Any suggestions that the SADI or the SIPS procedures are the same as DS is misleading and inaccurate. SADI and SIPS procedures have evolved recently primarily in response to the high failure rate of all other weight loss surgical procedures. An easier alternative to DS was sought and SIPS-SADI was born; now this procedure has been misrepresented to be the same as the DS. The only similarity anatomically is the presence of the pyloric valve as

a functional part of the post-surgical anatomy. The small bowel portion of the SIPS-SADI is unlike that of the DS. In DS operations, the absorption of the fat is primarily limited to the common channel, which is usually 10% of the total length (if the surgeon performing the duodenal switch bases the common and alimentary limb lengths as a percentage of the total length). This number is much closer to 40-50% in the SIPS-SADI procedure. Additionally, bile reflux, internal hernia, inadequate weight loss and even weight regain, are all possible complications much more likely than that with DS. The revision of the SADI-SIPS is possible, but not as simple as some suggest. The length of the small bowel, location of the anastomosis in relation to the colonic mesentery, length of the duodenal, are all factors in dictating how easy or difficult the revision of the SADI-SIPS to DS will be [17,18].

It is critical that patients are very well informed (informed consent) as to the exact operation that is being performed on them. As stated above, Duodenal Switch operation is not the same as SADI or SIPS. The notion that they can be interchangeable is anatomically, and medically inaccurate.

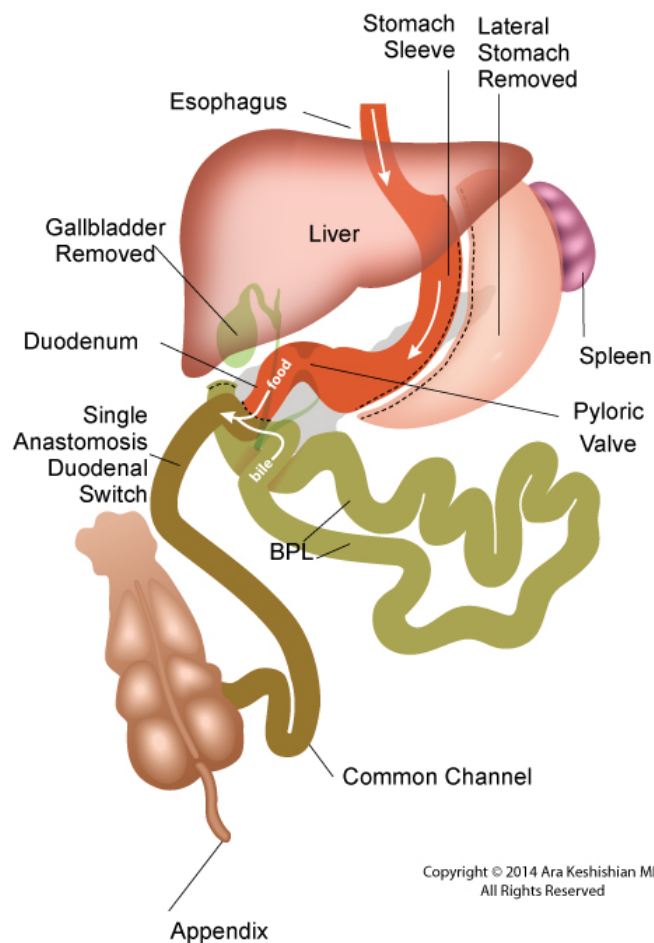


Figure 6: SADI- SIPS.

Gastric Balloon

FDA approved the Orbera™ gastric balloon in 2015 for use and placement in the United States. In this procedure, the surgeon performs an upper endoscopy and a balloon is placed in the stomach. It is then filled to the appropriate volume, which can range from 400-700 ml. The balloon has to be removed in 6 months. The short-term outcome of balloon placement/removal is outlined by the manufacturer in the table below. There is no long-term data available.

Table 1: Weight loss at key Time points using %EWL and %TBWL (mlTT with LOCF).

Weight Loss Measure	Group ^a	Month 6		Month 9		Month 12	
		Mean (SD) Range	P-value ^b	Mean (SD) Range	P-value ^b	Mean (SD) Range	P-value ^b
%EWL (based on BMI of 25)	ORBERA™	38.4 (27.61) -28.9 – 133.3	<0.001	34.6 (28.4) -42.1 – 138.3	<0.001	29.0 (30.70) -43.2 – 150.1	<0.001
	Control	12.1 (18.58) -20.4 – 68.8		12.3 (19.33) -19.8 – 65.9		11.1 (20.67) -25.6 – 66.7	
%EWL (based on MetLife)	ORBERA™	29.6 (20.18) -23.4 – 85.9	<0.001	26.5 (20.70) -34.2 – 86.3	<0.001	22.1 (22.47) -35.0 – 93.7	<0.001
	Control	9.5 (14.4) -15.8 – 56.3		9.7 (15.11) -16.1 – 54.7		8.7 (16.43) -20.8 – 55.0	
%TBWL	ORBERA™	-10.2 (6.56) -29.2 – 9.6	<0.001	-9.1 (6.86) -28.0 – 14.0	<0.001	-7.6 (7.48) -32.3 – 14.3	<0.001
	Control	-3.3 (5.02) -19.0 – 5.4		-3.4 (5.33) -19.8 – 5.7		-3.1 (5.90) -22.1 – 8.6	
Weight Loss (lbs)	ORBERA™	-21.8 (14.56) -69.0 – 22.2	<0.001	-19.4 (15.56) -82.7 – 32.4	<0.001	-16.2 (17.05) -95.3 – 33.2	<0.001
	Control	-7.0 (10.63) -36.0 – 10.9		-7.1 (1.32) -42.4 – 13.6		-6.3 (12.48) -47.4 – 20.7	

^aAll randomized subjects were used in these analyses, 125 Orbera and 130 Control subjects.

^bP-values represent treatment group comparisons calculated using a mixed effects model using treatment group, study week, and the respective interaction term assuming random intercepts.

Note that the results are only compared to diet and exercise. In that case, at 12 months out (no long term studies are available in US) this has been described as it relates to diet and exercise as the base line. The patient who had

the balloon placed, had initially lost 21.8 lbs. compared to 7.0 lbs. with diet and exercise at 6 months from the time of placement (when the balloon was removed). Leaving the balloon in for longer than 6 months, significantly increases the chance of deflation and bowel obstruction. It is required that the balloons be removed 6 months after placement. At 9 months, the patient with the balloon removed had experienced weight gain while the diet and exercise group maintained the weight loss. This trend continued for 12 months. At 12 months, the balloon group had gained 26% of their weight loss $((21.8-16.2)/21.8=0.26, \%26)$, where as the diet and exercise group had only gained 10% $((7.0-6.3)/7.0=0.1, \%10)$. This means that at the 12 month follow up, the balloon group gained back 3 times more weight than the diet and exercise group. It is to be noted that the initial weight loss for the balloon group was more than that of the diet and exercise group [19,20].

Summary

To summarize a few of the surgical procedures and compare them side by side to help with better understanding, first is Duodenal Switch and Gastric Bypass, RNY. By having the DS surgery, approximately 75% of the patient's stomach had been removed, which is irreversible; Gastric Bypass, RNY, a small pouch of the stomach is connected to a segment of the small bowel and none of the stomach has been removed. Looking further into the pros and cons of these procedures it is noted that with DS, the small bowel is rerouted to limit fat and protein absorption;

while Gastric Bypass allows full absorption of fat, protein, and carbohydrates.

Summary: Comparison chart analyzing few of the surgical procedures previously discussed in this chapter.

		Duodenal Switch	Sleeve Gastrectomy	Adjustable Gastric Banding	Gastric Bypass	Gastric Balloon
Excess weight loss		76% [21]	66% [22]	41[3]-44% [23]	50% [24]	<10% [20]
Change in BMI Kg/m ²		-17.99[25]	-10.8[26]	-7.14 [23]	-16.70 [26]	N/A
Resolution/Improvement	Type II Diabetes	98.9% [26]	81% [25]	59% [27]	78% [28]	2.4% [20]
	Hyperlipidemia	99.5% [26]	67% [29]	36% [30]	61% [31]	19.2% [20]
	Sleep Apnea	98% [21]	80% [27]	45% [29]	76% [29]	N/A
	Hypertension	91.8% [26]	78% [21]	56% [29]	66% [29]	8.8% [20]
Reversal-revision for failure (Band removal)		0.7 [32] -5.7% [33]	1.5% [34]	22 [35]-24% [23]	20-30% [36]	N/A

*As noted in the SADI-SIPS section, there have been no long-term studies on this procedure.

AGB has proven to be an inferior option with high risks associated with it. Not only does it have negative long-term effects, it is also a very weight loss solution. As

stated earlier, many patients have required re-operation due to issues such as: port issues, erosions, slippage, inadequate weight loss or weight regain. This information was even present in the literature provided to the patient by the manufacturer. There has also been motility disorders contributing to the AGB and the complications associated with it. The AGB procedures are inferior to the alternatives available. Adjustable gastric banding should be considered as a last resort, if at all, as a surgical procedure for treatment of morbid obesity and its associated comorbidities. Other complications that continue to plague adjustable gastric banding include slipped band, erosion, esophageal dilatation, and the required need for frequent adjustments.

The last of the comparisons is based off of the little data that has been recovered from this study thus far. SADI and DS have some similarities when it comes to the percentage of the stomach that is being removed, 75% which is irreversible, the small bowel being rerouted to limit the absorption of fat, protein, and carbohydrates, and the removal of the gallbladder. These are the only commonalities these surgical procedures share. Unlike DS, the SADI procedure makes it so the small bowel is maintained in one loop, while DS has the small bowel in two parallel channels. In SADI, unlike DS, the bile reflux is present. The last and most important fact would be: SADI has no studies showing the long-term effects. With regards to the Gastric balloon, its benefits are marginal, short term, and may only benefit those patients with minimal weight loss.

It is important to make sure that patients contemplating the gastric balloons appreciate that it needs to be removed in 6 months, and that the risks of the procedure may not outweigh its benefits.

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