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Efficacy of Bariatric Surgery Compared to Non-Surgical Treatments for Morbid Obesity

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by

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Abstract

The purpose of this research is to show the efficacy of Roux-en-Y gastric bypass and sleeve gastrectomy as compared to traditional diet and exercise models. Morbid obesity is related to increased blood pressure, incidence of diabetes, high cholesterol, and incidence of obstructive sleep apnea, all of which contribute to increased incidence of myocardial infarction, stroke, and vascular compromise. Finding ways to combat morbid obesity has resulted in invasive surgical techniques because traditional diets and exercise work infrequently and often fail. Systematic reviews, meta-analysis, randomized controlled trials, and retrospective studies were found using the database of CINAHL, SportsDiscus, PsycInfo, Embase, and PubMed. All of the studies were published no later than 2014 and used human adult subjects ages 19-65. The studies reviewed show that bariatric surgery is a safe, effective obesity treatment with a low risk of post-operative complications and mortality related to surgery. The reviewed studies found that patients who undergo the Roux-en-Y gastric bypass can lose 80% or more of excess weight, and those who undergo sleeve gastrectomy can lose 60% or more of excess weight. The research also shows that the bariatric surgeries discussed here help people maintain weight loss for up to ten years.

*K*ey Words: *bariatric surgery, Roux-en-Y gastric bypass, sleeve gastrectomy, morbid obesity, weight reduction,* and *long term.*

Introduction

The incidence and prevalence of obesity among adults have steadily increased since 1975. The World Health Organization (WHO) estimated in 2016 that 1.9 billion adults were overweight, and 650 million people worldwide are considered obese. These numbers continue to increase each year. Obesity contributes to increased incidence of cardiovascular disease, diabetes mellitus type II, obstructive sleep apnea, and musculoskeletal problems. Bariatric surgery has become a popular treatment choice for people who are morbidly and super morbidly obese. Classification for being overweight are those with a body mass index of 25 – 29.9 kg/m^2, and an obese classification is a BMI of 30 kg/m^2 or higher. Subclasses of I, II, or III further describe obesity with respective BMI of 30-34.9 kg/m^2, 35-39.9 kg/m^2, and $\geq$ 40 kg/m^2 (WHO, 2018). Obesity class III is also referred to as morbid obesity in some references (Arterburn et al. 2018).

Data analyzed by Flegal, Kruszon-Moran, Carroll, Fryar, & Ogden (2016) from the National Health and Nutritional Examination Survey (NHANES) from 2005 to 2014 found that the prevalence of obesity and morbid obesity has statistically significantly increased in women but not for men over that period. In the 2005-2006 survey, 33.5% (CI 95% 29.5-37.7%) of men and 35.7% (CI 95% 33.0 – 38.5%) of women were considered obese. In the 2013-2014 survey 35.2% (CI 95% 33.1-37.3%; P = .02) of men and 40.5% (CI 95% 37.9 – 43.2%; P = .004) of women were considered obese. Furthermore, 5.5 % (95% CI 4.2-7.0%) of men and 9.7 (CI 95% 7.9-11.9%) of women were categorized as obesity class III or morbidly obese.

Bariatric surgery has become an acceptable and standard treatment for those with a BMI equal to or greater than 35 kg/m^2. According to DynaMed (2017), the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) gave bariatric surgery a Grade A, BEL 1 recommendation for those with a BMI of $\geq$ 40 kg/m^2 with no

related comorbidities or a BMI of ≥ 35 kg/m^2 with one comorbidity. For patients with a BMI ≤ 30 kg/m^2 to 34.9 kg/m^2, AACE/ACE gave bariatric surgery a Grade B, BEL 2 recommendation to improve the risk of cardiovascular disease-related to obesity. A Grade B, BEL 1 recommendation is given if the patients have diabetes mellitus type II and cardiovascular lab work not improved with medication therapy or lifestyle changes. In patients with a BMI ≤ 30 kg/m^2 to 34.9 kg/m^2 with diabetes mellitus type II ACCE/ACE gives a Grade C, BEL 3 recommendation if the patient is taking a medication to help with glycemic control and to help reduce risk of cardiovascular disease.

History of sleeve gastrectomy and Roux-en-Y gastric bypass

In 1952, the first article describing the use of surgery to treat obesity was published in Sweden by Dr. Viktor Henrickson. He wrote a case study featuring an obese patient who had failed to lose weight by traditional methods of diet and exercise. During this procedure, a 105 cm portion of the small bowel was resected. Unfortunately, this first attempt at bariatric surgery failed, and the patient inevitably did not lose any weight, but felt healthier and had more energy (Baker, 2011).

In the United States, the first gastric bypass surgery performed was in 1954. During this procedure, a portion of the jejunum was attached to the transverse colon. This procedure was called a jejunoileal bypass (JIB). Physicians found this process successful for weight loss but were fraught with adverse side effects, including diarrhea, dehydration, electrolyte imbalances, vitamin deficiencies, and blind loop syndrome which occurs when nutrients backed up into the defunctionalized limb of the bowel that was bypassed and allowed bacterial overgrowth.

In the 1970s, the first Roux-en-Y configuration of the gastric bypass was performed in Italy. During this procedure, the jejunum was divided, and the distal segment was brought up,

creating an anastomosis with the upper portion of the stomach. The proximal segment was attached to the ileum just before the ileocecal valve. This procedure solved the problem of blind loop syndrome seen in the JIB; however, because the duodenum is circumvented, patients often experience vitamin and mineral malabsorptive problems. By 1977, many versions of Roux-en-Y gastric bypass had been attempted. A physician by the name of Griffin created a version of gastric bypass where the body of the stomach was separated from the fundus creating a small pouch. The jejunum is divided with the distal end pulled up and anastomosed with the pouch on the greater curvature side while the proximal end is anastomosed with the ileum, as seen in the earlier version of the Roux-en-Y configuration. This smaller pouch allowed for a more restrictive component to the gastric bypass.

A version of the gastric sleeve was introduced in the 1980s and later modified in the 1990s. During this procedure, the stomach is divided vertically, separating the fundus and most of the body of the stomach, leaving a narrow "sleeve" for food and nutrients to pass. This portion of the stomach is excised, making this procedure irreversible. During this procedure, the pylorus remains intact, which helps prevent dumping syndrome often seen with the Roux-en-Y gastric bypass. The gastric sleeve proved to be much less technical than the gastric bypass since there are no anastomoses created (Baker, 2011).

Statement of the Problem

Weight loss is an essential part of reducing the risk of cardiovascular disease, resolving and controlling diabetes, reducing the risk for experiencing certain types of cancers, and reducing musculoskeletal problems (WHO, 2018). Both the Roux-en-Y gastric bypass and gastric sleeve are effective weight management procedures, but both carry inherent risks. Non-invasive diet and exercise programs can be useful in managing weight but can quickly fail, with

the weight regained. When encountering patients classified as morbidly obese, providers need to be able to discuss the risks and benefits of both invasive and non-invasive weight reduction options.

Research Question

In morbidly obese patients, does the Roux-en-Y gastric bypass or sleeve gastrectomy provide a more significant weight loss over a more extended period when compared to more traditional non-invasive weight reduction programs?

Literature Review

The literature reviewed shows studies on the effectiveness and both short and long-term efficacy for the Roux-en-Y gastric bypass, gastric sleeve, and non-invasive conventional weight loss methods. The literature reviewed considered adverse side effects and mortality. Most studies classify a person morbidly obese if they have a BMI greater than 40, and super morbidly obese classification varies between a BMI greater than 50 or 60, depending on the study. Weight loss success varies in each study, as well. Some research considers losing more than 30% of excess weight successful, while others feel greater than 50% excess weight loss is successful.

Methods

The articles in the following literature review were found by searching CINHAL, SportDiscus, PsycINFO, Embase, and PubMed using the keywords "*bariatric surgery*," *Roux-en-Y gastric bypass," sleeve gastrectomy," morbid obesity,"* "*weight reduction*," and "*long term*." The search was limited to adult human subjects and included both men and women between ages 19-64 years, published between 2014 and 2019. Systematic reviews, meta-analysis, randomized controlled trials, and retrospective studies containing weight loss data about Roux-en-Y gastric bypass and sleeve gastrectomy were included. Cochrane database was searched using the terms

"*Roux-en-Y*" and "*sleeve gastrectomy*" and resulted in one article that pertained to bariatric surgery in adults.

Short Term (≤ 5 years) Efficacy Comparison of Roux-en-Y and Gastric Sleeve

Research from most studies identifies that both Roux-en-Y and gastric sleeve promote successful weight loss and weight maintenance for five years. Patients experience rapid weight loss with in the first year after surgery with slowing into the second year, then maintaining a steady weight state through the next three to five years.

Peterli et al. (2018) conducted a randomized controlled trial between January 2007 and November 2011 using data retrieved from a bariatric center in Switzerland. Participants in the study were included if they had a BMI ≥ 40 kg/m^2 or ≥ 35 kg/m^2 with one comorbidity, were between the ages of 18-65, and had failed with conservative treatment for at least two years. Patients were excluded if they had prior bariatric surgery, severe GERD (even with medication), hiatal hernias, dense adhesions in their small bowel, a need for endoscopic follow up or a history of IBS. Based on the inclusion and exclusion criteria, 225 people remained eligible to participate in the study. However, only 217 joined and were randomly assigned either to sleeve gastrectomy or Roux-en-Y gastric bypass. Both procedures were done laparoscopically. After the procedures, several participants were lost to follow up, and only 205 cases had enough statistical data to use in the follow-up study.

Patients followed up at six weeks post-surgery and then were seen at three-month intervals for the first year, at six-month intervals for the second year, then once a year for the next three years. This study used the percentage of excess BMI lost as the primary endpoint. This study found no statistical difference in the percent of excess BMI lost between sleeve gastrectomy and Roux-en-Y, unlike many other studies. At one year, sleeve gastrectomy(n=107)

had a 72.4% excess BMI loss while Roux-en-Y (n=110) had 76.7% loss. This is a difference of 4.22%, (95% CI = 9.96% to 1.51%: p-value = 0.30). During the second year, there was 71.9% excess BMI loss for sleeve gastrectomy and 77.4% loss for Roux-en-Y. The difference of 5.57% (95% CI = 11.84% to 0.71%; P value = 0.25). At three-years, sleeve gastrectomy saw a 69.5% decrease in percent BMI lost as compared to 73.9% loss for Roux-en-Y. The loss difference between the two of 4.32% (95% CI = -10.59% to 1.59%; P value = 0.30). Sleeve gastrectomy had a percent BMI loss of 64.1% and 61.1% in years four and five, respectively, while Roux-en - Y has a loss of 70.8% and 68.3% for those years. The difference of percent BMI loss was 6.73% (95% CI = 13.25% to 0.20%) and 7.18% (95% CI =14.30% to 0.06%) for years four and five respectively, with p-value = 0.22 for both years (Peterli et al., 2018).

Even though the sample size for each group was much smaller than other studies, it is one of the few randomized controlled studies where there were very few participants lost to follow up. The authors used the percentage of excess BMI lost as the primary endpoint, which is more difficult to compare to other studies. Other studies have found statistical significance between Roux-en-Y and sleeve gastrectomy weight loss, where this study did not.

In a systematic review conducted by Puzziferri, Roshek, Mayo, Gallagher, Belle & Livingston (2014), reports from 1946 to 2014 on the efficacy of bariatric surgery were reviewed. Only 29 of the 7,371 studies found met the author's inclusion criteria. To be included in the review, the study had to have a minimum of 20 participants, collected data for a minimum of two years, and had to have at least an 80% follow up. Many studies were excluded from this review due to the lack of follow up by the end of the study period. Each study was evaluated for reports of percent of excess weight loss (EWL), changes in BMI, and outcomes on comorbid conditions.

This review found eleven studies that included 3,544 patients that underwent gastric bypass surgery. Percentage EWL was reported in all studies at a 95% CI. The calculated weighted mean was 65.7% weight loss. The weighted mean for 115 sleeve gastrectomy patients was 64.5% EWL. Only two studies on sleeve gastrectomy were used in this analysis. Gastric bypass data at two vs. three years showed a weighted mean of percent EWL of 68.4% and 64.5% ($P<0.001$), respectively. Two vs. four-year weighted mean of percent EWL showed no difference from the sample weighted mean of 64.5%.

Even though only 29 studies were used in this review, the author collected data that was reliable based on the inclusion criteria 80% or better follow up. Based on the number of patients in the gastric bypass group, the percent of EWL is reliable and shows that the procedure is successful in treating obesity. In the sleeve gastrectomy group, the sample size is much smaller but still shows that the procedure is effective (Puzziferri et al., 2014).

Arterburn et al. (2018) conducted a retrospective cohort study that examined electronic patient records for the common bariatric surgery types: Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG). The authors used data from eleven different clinical networks that are collectively supported by the Patient-Centered Outcomes Research Institute. Data from 24,982 RYGB patients and 18,961 SG records were used for the analysis of total weight loss (TWL) percentage.

At one year following surgery, 14,929 patients who underwent SG had a TWL percentage of 25.2% (95% CI: 25.4% to 25.1%), while 19,029 patients who had RYGB showed TWL percentage of 31.2 % (95% CI: 31.3% to 31.1%). The difference in TWL between SG and RYGB was 5.9% (P-value <0.001). At three years following surgery, 5,304 SG records were compared to 9,225 RYGB records and found TWL percentages of 21.0% (95% CI: 21.3% to

20.7%) and 29.0% (95% CI: 29.2% to 28.8%, respectively, with a difference of 8.0% (p-value <0.001). At five years post-surgery, 1,088 SG records were compared to 3,676 RYGB records. This found TWL percentages of 18.8% (95% CI 19.6% to 18.0%) for SG and 25.5% (95% CI: 25.9% to 25.1%) for RYGB with a difference of 6.7% (p-value of <0.001).

The authors also report the proportions of patients who lost >5% TWL, >10% TWL, >20% TWL, and > 30% TWL in 1, 3, and 5 years. Almost all patients who had the RYGB and SG procedures had >10% TWL in the first year. Approximately 90% of patients who had RYGB achieved >20% TWL and 60% achieved >30% TWL in the first year. SG had slightly lower results, with roughly 70% achieving >20% TWL and 30% reaching >30% TWL. At five years post-surgery, the RYGB group had over 95% of patients maintain >5 TWL, 90% of patients who maintained >10% TWL, roughly 65% who maintained >20% TWL, and approximately 35% who maintained >30% TWL. The SG group had 90% of patients maintained > 5% TWL, 75% maintained >10% TWL, 40% maintained >20% TWL, and 20% maintained >30% TWL (Arterburn et al., 2018).

This study has merit because of the large group numbers and propensity score corrections that were done. The RYGB showed higher TWL percentages over the one, three, and five-year period than SG. Comparing the first-year weight loss percentage to the five-year weight loss percentage, RYGB only had a 5.7% TWL percentage decline from 31.2% to 25.5% while the SG had a 6.4% decline from 25.2% to 18.8%. This comparison shows that with both procedures, weight was lost quickly in the first-year post-surgery, but some weight was regained slowly over five years. When looking at the proportion data, it clearly shows that a more significant proportion of patients maintain higher weight losses with the RYGB than the SG.

Uno et al. (2017) conducted a retrospective study from Japan that looked at which bariatric procedure may be better for the super morbidly obese (SMO) and morbidly obese (MO). The study compared three different bariatric surgery types: laparoscopic Roux-en-Y gastric bypass (LRYGB), laparoscopic sleeve gastrectomy (LSG), and laparoscopic sleeve gastrectomy with duodenojejunal bypass (LSG/DJB).

The SMO classification is for a person with a BMI ≥50 kg/m^2, but ≤ 70 kg/m^2 and MO are classified as BMI between 35-50 kg/m^2. In this study, 248 patients who had prior bariatric surgery were divided between the three previously mentioned bariatric surgeries. Each patient classified was considered SMO or MO, based upon preoperative BMI. The SMO group had 28 patients who had the LSG procedure and 20 patients with LRYGB procedure. Mean BMI in the SMO was 57.1 ± 5.1 kg/m^2 for the LSG procedure and 55.7 ± 4.2 kg/m^2 for the LRYGB procedure. The MO group had 89 patients who had LSG and 47 who had LRYGB. Mean BMI was 41.0 ± 3.9 kg/m^2 and 31.4 ± 3.7 kg/m^2 for the LSG and LRYGB, respectively.

Results were recorded at one and two-year intervals. The success of the procedure is defined as ≥ 50% of excess weight loss. In the first year, the SMO group had 27 of 28 participants follow up in the LSG group. Mean BMI dropped to 39.1 ± 8.5 kg/m^2, which is 57.7 ± 21.4 % excess weight loss. At two years post-surgery, there were 23 of 28 participants who followed up with a BMI down to 36.0 ± 7.8 kg/$m^{2,}$ which resulted in 65.1 ± 23.4% excess weight loss. In the LRYGB group, one year following surgery, 19 of 20 participants had follow-up data. Mean BMI dropped to 33.9 ± 4.9 kg/m^2, which is 73.4 ± 16.1% excess weight loss. At two years, LRYGB had 15 of 20 participants follow up with a mean BMI down 32.8 ± 6.8 kg/m^2, and excess weight loss of 73.7 ± 22.0%. When comparing the two procedures, there was statistical

significance in the first year with a p-value = 0.01 for BMI and the percentage of excess weight loss. In the second year, the comparison of LSG to LRYGB had p-value = 0.217 for BMI.

In the MO group, all 89 patients who had the LSG procedure followed up in the first year. Mean BMI dropped to 27.0 ± 4.1 kg/m^2, and the percent of excess weight loss was 90.1 ± 25.0%. Two years' post-surgery, 77 of 89 LSG patients followed up. Mean BMI was 27.5 ± 4.4, which is 88.4 ± 34.7% excess weight loss. This group lost a large amount of weight very quickly in the first year and gained some of the weight back in the second year. BMI did remain in the overweight category, however, and did not return to the obese category. Forty-one of the 47 participants in the LRYGB group have a mean BMI dropped to 25.7 ± 3.0 kg/m^2 and percent of excess weight loss at 96.3 ± 19.0% in the first year follow up. In the second year, only 28 of the 47 participants followed up. Mean BMI was 25.8 ± 3.0 kg/m^2, with 95.4 ± 18.7% excess weight loss. Statistical comparison of the LSG to LRYGB has a p-value of 0.08 and 0.06 for the first- and second-year BMI data, respectively, neither of which were considered statistically significant in this study. Percent of excess weight loss has a p = 0.26 and 0.31 in the first and second years, respectively, which was also not considered statistically significant (Uno et al., 2017).

The data shows a slightly lower BMI for patients who had LRYGB as compared to LSG, but not enough to be considered significant. Based on the data, either procedure would be successful in the MO. LRYGB was statistically more successful in the SMO group showing that it may be a better procedure in this type of group. The statistics of the study are also limited by small sample numbers, especially in the SMO group. Another limitation of the study is the lack of break down of patient race. The study was conducted in Japan; therefore, we need to assume

that the majority of the patients are of Asian descent. This study has better follow up than many studies.

Long Term (≥ 5 years) Efficacy Comparison of Roux-en-Y and Gastric Sleeve

Long term efficacy of bariatric surgery is one factor to take into consideration when a patient is contemplating if a surgical option is right for them. However, there are not many studies that collect data past five years for the Roux-en-y gastric bypass and even fewer for the sleeve gastrectomy procedure. Only one meta-analysis and one retrospective study were found with good follow up data.

Golzarand, Toolabi, & Farid (2017) conducted a meta-analysis of data using 23 studies that reported long term (≥5 -10 years) and very long-term (≥ 10 years) percent excess weight loss and BMI changes for LRYGB. The studies had a total of 1,671 participants. The mean starting weight was 134.7 ± 15.6 kg, and BMI was 47.2 ± 15.6 kg/m^2. Only three of the studies contained very long-term data past ten years. Percent of excess weight lost ≥ five years was 62.85% (95% CI 58.33-66.82; p = <0.001). Percent of excess weight lost ≥ ten years was 63.52% (95% CI 54.07- 72.97; p< 0.001). BMI decreased by 14.75 kg/m^2. The study shows that weight loss not only was maintained but continued longer than ten years.

For LSG, the author found 20 studies that reported data longer than five years, but no studies had data for longer than ten years. Data from 1,114 patients who had LSG procedure had a mean starting weight of 126.2 ± 16.7 kg and a BMI of 47.3 ± 7.1 kg/m^2. Percent of excess weight loss from 16 studies showed a loss of 53.25% (95% CI 50.27-56.18; p < 0.001). BMI decreased by 11.32 kg/m^2 (95% CI -12.87 to -9.77, p <0.001) (Golzarand, Toolabi, & Farid, 2017).

The very long-term outcome is helpful when looking at the efficacy of the procedures. Unfortunately, because of missing data, a comparison of LRYGB to LSG cannot be conducted over a ten-year period. Both methods did show a significant percent excess weight loss and reduction of BMI greater than five years, which will be reassuring to people considering bariatric surgery for treatment of morbid obesity.

Maciejewski et al., (2016) conducted a retrospective cohort study that looked at data for Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and adjustable gastric band (AGB) surgeries. For ten years, data were collected on the RYGB, and four years of data were collected on SG. Sleeve gastrectomy is a newer procedure and does not have the extensive follow-up data the other studies have. This study also matched surgical patients with similar non-surgical patients for comparison of surgical vs. non-surgical success.

This study was performed through the Veterans Administration (VA) Hospital and used only male patients. Data were collected from January 2000 to September 2011. At seven years past their surgery date, patients who underwent the RYGB procedure had lost 22.2% (95% CI 16.0%-28.5%) of the baseline weight, and by year ten, these patients had maintained a 21.3% (95% CI 19.5% - 37.6%) weight loss. The data is quite significant as the non-surgical counterparts only lost 7.3% (95% CI 1.4% - 13.3%) of excess weight.

Of the patients who had RYGB procedure, 564 out of 573 patients had a follow-up at ten years. Patients in this group lost a mean of 41.3 kg, which is approximately 56.4% of excess body weight lost. During the same time frame, 1,247 patients in the non-surgical group had a weight loss of 6.3 kg or 7.7% of excess body weight lost. Four hundred five people of 564 (71.8%) managed to maintain a weight loss of ≥ 20% after ten years, and 224 of the 564 (39.7%)

managed to maintain ≥30% excess weight loss. Only 19 of the 564 (3.4%) participants were within 5% of their baseline weight at ten years past surgery (Maciejewski et al., 2016).

The larger sample size in this study makes the statistics more reliable. However, all of the patients in this study were male, so it may be challenging to apply this statistical data to women and maintain accuracy. The study did not explore whether the non-surgical group participated in any weight loss program.

Efficacy of Non-Surgical Obesity Treatments

Even with the ability to perform bariatric surgery to treat obesity, an invasive procedure is not the choice for everyone. Some people are surgical candidates based on comorbidities and cardiovascular risk, and others may feel that the risks of surgery outweigh the benefits. Some people may also be resistant to the permanent lifestyle changes that accompany bariatric surgery.

Burguera et al. (2015) conducted a randomized controlled trial in Spain to evaluate the effectiveness of Intensive Lifestyle Intervention (ILI) compared to Conventional Obesity Therapy (COT) and bariatric surgery. One hundred six patients were randomly assigned to either the ILI group (n = 60) or the COT group (n=46). Both groups had weight checks weekly for the first three months, then twice weekly in the ILI group for the next 21 months. The COT group had weight checks every three months.

In the ILI group, patients had weekly group meetings for the first 12 weeks, which then increased to twice-weekly meetings from weeks 13-52. During the 90-minute meetings, there was a focus on dietary habits, food choices, energy intake, and consumption. This group also had a daily exercise routine created by a physiotherapist. Some participants also used weight loss medications such as Orlistat if they were eligible; however, the number of patients who used weight loss medications was not reported. In the COT group, each participant received standard

dietary information and followed up every three months with an endocrinologist or a dietician. In the COT group, 15% of the patients received weight-loss medications.

The division into the ILI group and the COT group was randomized; however, there was anticipation that the ILI group would see 50% of the participants drop out of the trial before its completion, so the ILI group participation number was increased to compensate. Baseline BMI for the COT and ILI group was 47.2 ± 5.4 kg/m^2 and 45.8 ± 5.5 kg/m^2, respectively. At the end of the first year, 21.7% of the COT group had dropped out. The percentage of weight loss for this group was 0.6% and BMI of 46.37 ± 4.83 kg/m^2. In the ILI group, 41.7% of the group dropped out by the end of the first year. The percentage of weight loss was 10.5%, and BMI reduced to 40.15 ± 5.33 kg/m^2. By the end of the trial, 36.9% of the original 46 participants in the COT group had dropped out. Of those left in the group, there was a 3.3% weight loss and BMI reduction to 46.2 ± 5.4 kg/m^2. The ILI group saw a 70% dropout rate from the original 60 participants leaving only 14 participants. They had an 11.3 % weight loss and 40.6 ± 6.9 kg/m^2 BMI change. In the ILI group, 21.6% of the participants started with a BMI of >50 kg/m^2, classifying them as super morbidly obese, while 78.3% had a BMI between 40 and 50 kg/m^2 classifying them as morbidly obese. Of those that completed the two-year trial, 11.1% had reduced their BMI to < 30 kg/m^2, placing them in the overweight category (Burguera et al., 2015).

This study shows that weight loss can be achieved without having bariatric surgery and that the intense lifestyle interventions, which were far more rigorous than the conventional obesity therapy, was more effective. The problem with both of the non-surgical treatments is the high rate of drop out, leaving a minimal sample size. The small groups make the statistics more

unreliable than the more extensive group studies. The dropout rate also speaks to the difficulty of overcoming obesity with non-invasive measures.

Another study completed by Dandanell et al. (2017) used 80 participants from a previous study that involved intensive lifestyle intervention (ILI) treatment for obesity to see if the ILI treatment had any effect on cardiometabolic health. The 80 subjects were divided into three groups based on previous weight loss. The first group has a previous weight loss of > 10%; this is the clinical weight loss (CWL) group. The second group lost from 1-10%, this is the moderate weight loss (MWL) group, and the third group had weight regain (WR).

Participants were a part of an 11-12 week ILI that consisted of physical training and discussion of healthy eating and lifestyle habits. At the end of the ILI period, participants re-evaluated their weight and body composition. The CWL group (n= 34) had a baseline BMI of 40 ± 2 kg/m^2 before ILI and BMI of 34.1 ± 1 kg/m^2 after the intervention. Bodyweight changed from 120 ± 5 kg to 104 ± 5 kg, and excess body fat changed from 53 ± 3 kg to 40 ± 3 kg following the lifestyle intervention. The MWL group (n = 23) saw a BMI change from 35 ± 1 kg/m^2 to 31 ± 1 kg/m^2, bodyweight change from 107 ± 4 kg to 94 ± 3 kg, and body fat change from 42 ± 3 kg to 32 ± 3 kg following a lifestyle intervention. The WR group (n= 22) had BMI change from 39 ± 1 kg/m^2 to 35 ± 1 kg/m^2, bodyweight change from 118 ± 4 kg to 105 ± 4 kg, and body fat change from 47 ± 3 kg to 38 ± 3 kg following the intervention. All values had p-value < 0.001.

Follow up for the CWL, MWL, and WR group was done 4.5 ± 1, 4.8 ± 1, and 7.2 ± 1 year later, respectively, for each treatment group. At follow up, the CWL group lost an additional 12 ± 2 kg ($p < 0.001$) while the MWL group gained 7 ± 1 kg ($p < 0.001$) and the WR group gained 24 ± 3 kg ($p < 0.001$) (Dandanell et al., 2017).

This study shows that all groups experienced weight loss with ILI, but without much support, the MWL and WR group gained the weight back, and only the group who had lost the most, in the beginning, maintained and even continued their weight loss. Further exploration would have to be done to explain why this group continued to lose weight, and the others did not.

Neilsen et al. (2016) compared an intense weight loss program to bariatric surgery. In this study, patients participated in the Rééducation Nutritionnelle et Psycho-Comportementale (RNCP®) program. This program consisted of a weight loss phase and a weight maintenance phase. During the weight loss phase, patients meet with weight loss specialists, dieticians, and the patient's physician to create a weight loss goal and follow up. Patients met with a nutritionist every two weeks for weight and circumference measurements along with monitored blood work. Once the patient has reached their weight goal, they entered a 5-stage weight stabilization phase. This phase length was personalized for each patient based upon the amount of weight loss in the first phase. For every 1 kg of weight loss, the patient spent that amount of time in the stabilization phase. During this phase, there was a focus on maintaining weight loss by balancing energy intake with energy expenditure.

Through the RNCP program, 663 female patients chose to participate in the study. Following the first phase of the program, 189 participants were found to have a successful weight loss of ≥ 60 % excess weight loss (EWL), while 179 participants had ≤ 30% EWL, which was considered less successful. The remainder of the study focused on these two groups. This study did not address the values of the other 295 participants that were in between the 30-60% weight loss.

The baseline median bodyweight of the group was 111.7 kg, BMI of 40.1 kg/m^2, average waist circumference measurement of 124 ± 11 cm, and percent of fat mass 43.9 ± 4.4% or 48.8

kg. Baseline body weight in the successful weight loss group (≥ 60%) had a median of 110.9 kg, and BMI of 39.6 kg/m^2, a waist circumference of 124 ± 11 cm, percent of fat mass of 43.9 ± 4.2%, and weight of the fat mass of 48.9 kg. In the less successful group, the baseline median body weight was 114.6 kg, BMI of 41.0 kg/m^2, a waist circumference of 125 ± 12 cm, the fat mass percentage of 44.3 ± 4.8%, and weight of the fat mass of 50.0 kg. Measurements were retaken after approximately 18 months.

In the successful weight loss group, patient mean weight with the standard error of the mean (mean ± SEM) was 113.1 ± 1.2 kg. After the weight loss period the weight was 80.7 ± 1.2 kg, a difference of -32.5 kg (95% CI of -34.2, -30.8; P < 0.001). Patients in this group lost 0.48 kg/week. Waist circumference went from 123.6 ± 0.9 cm to 94.7 ± 0.9 cm, a difference of -29.0 cm (95% CI -30.4, -27.5; p < 0.001). Percent of fat mass started at 43.9 ± 0.4% and decreased to 36.5 ± 0.4%. A difference of -7.4% (95% CI -8.0, -6.8; p < 0.001).

In the less successful weight loss group, the patient mean weight with the standard error of the mean (mean ± SEM) was 116.0 ± 1.2 kg. After the weight loss period the weight was 106.6 ± 1.2 kg; a difference of -9.2 kg (95% CI -10.9, -7.4; P < 0.0010. Patients in this group lost -0.13 ± 0.01 kg/week. Waist circumference changed from 124.9 ± 1.0 cm to 114.5 ± 1.0 cm, a difference of -10.4 cm (95% CI -11.9, -8.9; P < 0.001). Percent of fat mass started at 44.6 ± 0.5% and decreased to 43.0 ± 0.5%, a difference of -1.6% (95% CI -2.2, -1.0; P < 0.001) (Nielsen et al., 2019).

This study shows that with the right type of program, patients can lose weight and maintain weight loss. The changes in body weight, waist circumference, and percentage of fat mass were all statistically significant, with p-values of 0.001. The study divided the original group into a successful weight loss group and a less successful weight loss group but failed to

explain the importance of this division, nor did it address why one group was more successful than the other group. The authors also fail to mention anything about the group in the middle. The results of this study are hard to apply to men because the sample was only women. There was also a 35% dropout rate and lack of comment as to why people dropped out of the study. The authors also failed to comment on why one group was more successful than another.

Shadid, S., Jakob, R., & Jensen, M. (2015), completed a case-controlled study that compared a multidisciplinary lifestyle intervention treatment to a control group receiving traditional care. All subjects in this trial were candidates for bariatric surgery. Patients included in this study were referred by physicians. To be included in the study, the patient had to be over 18 years old, could not have untreated thyroid dysfunction, growth hormone deficiency, Cushing syndrome, or active malignancies. Patients were screened for the ability to be able to participate in group therapies and their motivation to participate. Patients who remained eligible after screening participated in a six-week pretreatment phase, which involved consulting with a dietitian, attend all medical appointments, and submitting to blood work, keeping a food log and making changes in dietary and physical exercise habits.

Those who completed the pretreatment phase were invited to participate in the formal study, of which 98 patients chose to participate. Each participant was given an individualized exercise plan, participated in group sessions, and face-to-face counseling sessions. All sessions were aimed at teaching lifestyle changes and good eating habits. At the end of the two-year trial, this group was compared to a control group that consisted of 148 patient records with similar patient demographics.

In the control group, baseline BMI was 43.1 ± 0.4 kg/m^2, mean weight was 122.4 ± 1.8 kg, excess weight of 51.4 ± 1.3 kg, and percent of excess weight of $72 \pm 2\%$. In the treatment

group, baseline BMI was 44.2 ± 0.6 kg/m^2, mean weight was 128.5 ± 2.4 kg, excess weight of 55.9 ± 2.0 kg, and percent of excess weight of 76 ± 2%. After two years, the control group BMI was 43.2 ± 0.5 kg/m^2, mean weight was 123.0 ± 1.7 kg, excess weight 51.9 ± 1.5 kg, and percent of excess weight of 73 ± 2%, which is a slight increase from two years prior. In the treatment group, two years later, 63 of the 98 participants completed the program. BMI decreased to 37.4 ± 0.7 kg/m^2, mean weight was 108.5 ± 2.3 kg, excess weight 35.9 ± 2.0 kg, percent excess weight 50 ± 3%, all with P-value <0.001 BMI decreased by 6.8 kg/m^2, mean weight decrease of 20 kg, =excess weight decreases of 20 kg, and decrease percent excess weight of 26%.

The initial study ended at two years, but some participants were able to continue with follow up at three and four years. For these groups, it was found that at three years, they had lost 20.2 ± 2.3 kg, and 15 ± 1% of initial body weight. At four years, there was a loss of 21.4 ± 2.8 kg and 16 ± 1% initial body weight (Shadid, Jakob, & Jensen, 2015).

This study demonstrates that lifestyle intervention is a feasible way to treat obesity, and weight loss can be maintained over a more extended period. However, at the conclusion of this study, after two years, the mean BMI was still classified as Class 2 obesity. It is important to note that the treatment group had many multifactorial supports. These may prove to be an essential part of the success of helping those seeking obesity treatment.

The authors, Zenténius, E., Andersson-Assarsson, J., Carlsson, L., Svensson, P., & Larsson, I. (2018), used the control group from the Swedish Obesity Study to determine what self-reported methods of weight loss have long term positive effects. The group consisted of 2032 participants at the start of the study. Follow up was done at six months, 1, 2, 3, 4, 6, 8, and 10 years. Patients were surveyed about their method of weight loss attempts during follow-up appointments. The responses were categorized into seven different groups: no attempt, own

regimen, health care support, commercial program, exercise, antiobesity medication, and a low-calorie diet.

At the start of the study, there were 1,446 women and 590 men. Starting BMI was 40.1 ± 4.7 kg/m^2, and starting weight was 114.7 ± 16.5 kg. Weight change, from baseline, was calculated at each follow-up appointment at the previously mentioned intervals. Based on the weight change, patients were classified into the following categories: < 5.0%, ≥ 5.0%, ≥ 10.0%, and ≥ 15% weight change that could be either loss or gain. At 10 years, 26.1% of participants has lost ≥ 5.0%, 12.5% has lost, ≥ 10.0%, and 6.4% has lost ≥ 15% body weight. Unfortunately, 36.3% gained ≥ 5.0%, 22.3% gained ≥ 10.0%, and 11.7% gained ≥ 15% body weight.

When looking at specific weight loss attempts, 82.7% (95% CI 81.3%-84.1%) of the group had made some sort of weight loss attempt. Over half (50.7%, 95% CI 48.1 – 53.2%) of the group reported using their own regime while 42.3% (95% CI = 39.1 – 45.0%) reported using exercise as a technique for weight loss at some time during the 10-year study. Those reporting health care support were 25.6% (95% CI 22.8-28.5%) and 12.5% (95% CI 10.3-14.8%) reported using commercial programs; while 8.7% (95% CI 6.7-10.7%) reported antiobesity medication, and 5.3% (95% CI 4.9-5.6%) reported very low-calorie diet. Over the ten years, 22% (95% CI 22.2-23.6%) reported no attempt at weight loss. In a comparison of the 145 participants who lost ≥ 10% of body weight to the 258 participants who gained ≥ 10% of body weight, the only reported difference was more exercise in the group that lost weight (Zentenius et al., 2018).

This study is interesting because it takes into consideration the weight loss attempts tried by many people. It does not analyze the actual weight loss from each type of attempt, which would be very interesting. There is no data reported from each follow-up interval either, which would be interesting to see if there was more weight loss early in the study compared to later.

The study design makes finding which method works the best for weight loss difficult because participants within the study could change methods throughout the study if they choose. The group size was large, making the statistics more reliable, but there were too many variables to conclude that one weight-loss method is better than another. The best conclusion to be made is that about half of those who make weight loss attempts will succeed.

Outcome Comparison of Roux-en-Y and Gastric Sleeve vs. Non-Invasive Obesity Treatment

Beaulac & Sandre (2017) composed a summary of systematic and non-systematic reviews on how to treat obesity using surgical and non-surgical procedures: Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), supervised meal replacement and behavioral or lifestyle interventions. The data was broken out into result summaries for six months, one year, 3-5 years, and ten years.

At six months, RYGB was found to have 55-62% excess weight loss (EWL) compared to 35-60% for SG. A low-calorie diet saw a 5-9% decrease in initial weight loss (IWL), and a very low-calorie diet (VLCD) saw a reduction of 16 % IWL. At one year, RYGB had 51-76% EWL, while SG had 63% EWL. A VLCD saw an estimated 10% IWL and using meal replacement kept weight loss around 7-8%. No data is reported for the low-calorie diet. At 3-5 years, RYGB shows 53-94% EWL, and the SG has 61-81% EWL. The VLCD shows 3-6% IWL maintained at 4-5 years. No data is reported for the low-calorie diets. At ten years, RYGB maintains 52% EWL. No other data is given for SG or dietary treatments at ten years. Behavior modifications, in conjunction with a weight management plan, seems to create the most success.

The purpose of the article is to provide a tool to assist people in deciding how they may wish to treat obesity. There is an excellent break down of the possible weight loss outcomes for RYGB, SG, VLCD, and low-calorie diets. The article does not provide any statistical analysis of

the different studies used. This article is concise about the data but is not as helpful with statistical analysis (Beaulac & Sandre, 2017).

Reges et al. (2018) conducted a retrospective cohort study using data from Clalit Health Services in Israel. The authors took 8,385 surgical patients and matched each one with three non-surgical obese patients, making a total of 25,155 non-surgical matches. Each match was based on age, sex, race, and comorbidities. The surgical group used 3635 patients who underwent gastric banding, 1,388 patients who underwent Roux-en-Y gastric bypass, and 3,362 patients who underwent sleeve gastrectomy. The gastric bypass group had a baseline median BMI of 40.6 kg/m^2 while the non-surgical counterpart had a baseline BMI of 40.5 kg/m^2. Both groups consisted of 67.7% women and 32.3% men. In the gastric bypass surgical group, 78.7% were of Jewish descent and 21.3% of non-Jewish descent. In the gastric bypass matched non-surgical group, 66.4% were of Jewish descent, while 33.6% were of non-Jewish descent. In the sleeve gastrectomy group, the median BMI was 40.6 kg/m^2, and the non-surgical matched group was 40.5 kg/m^2. Both groups consisted of 65.5 % women and 34.5% men. In the sleeve gastrectomy surgical group, 80.8% of the patients were of Jewish descent, while 19.2% were of non-Jewish descent. In the sleeve gastrectomy non-surgical group, 66.8% were of Jewish descent, while 33.2% were of non-Jewish descent.

The primary outcome for Reges et al. (2018) was all-cause mortality; however, they reported for the gastric bypass the median follow-up period was 5.5 years for all 1388 surgical participants and 4.8 years for the 4164 non-surgical matches. During that period, the median BMI was 30.9 kg/m^2 (IQR 27.3-35.5) for the surgical group, which was a drop of 9.4 (SD 5.6) BMI points, and 60.9% of the group achieved a $\geq$ 20% BMI reduction. In the comparative non-surgical group, the median BMI was 39.3 kg/m^2 (IQR 35.4-43.4), which was a loss of 1.4 (SD

6.3) BMI points and only 7.3% of the group achieving ≥ 20% BMI reduction. In the sleeve gastrectomy group, the median time of follow up for the surgical group was 3.2 years for all 3362 patients, and the non-surgical group median follow up was 3.0 years for 10,086 patients. The surgical group had a median BMI of 29.8 kg/m^2 (IQR 26.6-33.3), a loss of 10.6 (SD 4.9) BMI points, and 70.8 achieved ≥ 20% BMI reduction. In the non-surgical group, the median BMI was 39.3 kg/m^2 (IQR 35.6-43.1), a loss of 1.3 (SD 5.8) BMI points, and 7.1% of this group had ≥ 20% BMI reduction.

This study shows that both surgical groups lost more weight than the non-surgical counterparts. However, this study shows that the sleeve gastrectomy had slightly better results than the Roux-en-Y gastric bypass. The study design was robust with reasonable inclusion and exclusion criteria for participation in the study. The greatest strength of this study is the 100% follow up. Many comparative studies have a loss of follow up, making the data questionable (Reges et al., 2018).

The RNCP® study conducted by Nielsen, M., Sjödin, A., Fabre, O., Legrand, R., Astrup, A., & Hjorth, M. (2019) found when comparing non-invasive weight management to bariatric surgery, 75% of the bariatric surgery group had lost ≥ 60% of excess body weight during 18 months. In contrast, only 29% of the RNCP program lost this amount of access weight. Of the participants who lost < 30% of excess weight, only 1.6 % were in the bariatric surgery group compared to 27% from the RNCP program.

In the surgical group, 80% of the participants were female, and 20% were male. The mean BMI for this group was 45.2 ± 5.9 kg/m^2. The mean age was 40.4 ± 9.6 years. This data is the only baseline data provided for this group. Separate data for RYGB and SG was also not provided.

Douglas, Bhaskaran, Batterham, & Smeeth (2015) conducted a retrospective study using patient records, from the Clinical Practice Research Datalink(CPRD) in the United Kingdom, who had bariatric surgery on or before December 31, 2014, compared to patients who did not have bariatric surgery. In the study, 3,882 bariatric surgery patients were matched with a non-surgical bariatric patient of the same gender, age, general practice, calendar period, and closest propensity score. To be included in the surgical group, patients had to participate in the CPRD for one year before the study, had to have had prior bariatric surgery and could not have a bariatric reversal surgery. The non-surgical groups included those with a BMI ≥ of 40 kg/m^2 who were acceptable candidates for bariatric surgery but chose not to have the bariatric procedure.

Of the participants, 1,421(36.6%) patients had gastric bypass, and 613 (15.8%) had a sleeve gastrectomy. At 1-4 months following surgery, gastric bypass participants had a 6.56 kg/month weight loss and a decrease in BMI by 2.36% per month as compared to a 6.29 kg/month weight loss and 2.21% BMI reduction per month for sleeve gastrectomy. At 5-12 months, gastric bypass weight changed by 1.50 kg/month, and BMI changes of 0.55% were recorded. The sleeve gastrectomy had a 0.97 kg/month weight loss and a 0.35% BMI change. During the 13-48 month period, gastric bypass had a 0.02 kg/month weight gain and a 0.01% increase in BMI, while the sleeve gastrectomy had a 0.05 kg/month weight gain and a 0.03% BMI increase for the same period. The non-surgical group experienced no notable change in weight or BMI over the four-year measurement period.

Of the individuals who underwent bariatric surgery, a hazard ratio and 95% CI were calculated for possible clinical outcomes of developing certain co-morbid conditions: diabetes mellitus type II onset (HR = 0.68, 95% CI = 0.55-0.83), hypertension onset (HR = 0.35 95% CI

= 0.27- 0.45), MI onset (HR = 0.28 95% CI = 0.10-0.74), and, obstructive sleep apnea onset (HR = 0.55, 95% CI 0.37-0.82). Resolution of diabetes mellitus type II and hypertension were notably increased in the gastric bypass and sleeve gastrectomy group.

Douglas et al. (2015) show that both the gastric bypass and sleeve gastrectomy cause significant decreases in weight and BMI. The study does show the sustainability of weight loss, the decreased onset of T2DM, hypertension, MI, and OSA over the four-year study period. In some cases, there was a resolution of T2DM and hypertension in patients who those conditions before surgery. This study is a good comparison study of gastric surgery compared to non-surgical treatment of obesity. Overall, the research shows that gastric surgery is a valid treatment option for morbid obesity. There were stronger associations of resolution of co-morbid conditions with the gastric bypass and sleeve gastrectomy than other types of bariatric surgeries.

In a retrospective cohort study conducted by Maciejewski et al. (2016), through the Veterans Administration (VA) Hospital, outcome data comparing a non-surgical group to those who had the Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and adjustable gastric band (AGB) surgeries. During the study period, 1787 patients had the RYGB procedure. Each surgical participant was matched with three similar non-surgical patients based on gender, age, race, and which geographic region of residence. Patient records in which the patient died within one year of surgery or patients that exhibited a lack of follow up were excluded. This study looked at the percentage of weight loss compared to the baseline weight.

At the beginning of the study, RYGB patients compared to non-surgical patients had a baseline BMI of 47.7 and 47.1, respectively. After the first year, 31.0% (95% CI = 30.4%-31.6%) of baseline weight was lost for RYGB patients. Non-surgical patients only lost 1.1%, making the 29.9% difference between the two groups clinically significant. The difference

between the two groups at three years was 29.9% and at five years was 22.2%. When comparing RYGB to SG, there is a 7.9% difference in weight loss in favor of RYGB. At four years, RYGB still had a more significant weight loss at 27.5% as compared to SG that only had 17.8%. Over four years, the proportion of patients who had RYGB maintained a ≥ 20% weight loss as compared to SG. RYGB groups also had the lowest percentage of people regain their weight compared to SG.

The study did show that both procedures caused significant weight loss; however, patients who had the RYGB procedure lost more weight and kept the weight off longer than the other group. This study also shows that bariatric surgery is far more effective for weight loss than doing nothing at all.

Post-Surgical Complications and Mortality of Roux-en-Y and Gastric Sleeve

Bhatti, J., Nathens, A., Thiruchelvam, D., & Redelmeier, D. (2016) conducted a self-matched longitudinal cohort study that assessed whether emergency department visits increased for patients after undergoing bariatric surgery. The data was collected in Ontario, Canada, between April of 2006 and March of 2011. The study included patients between 18-64 years, of age who had undergone bariatric surgery. Each patient who was involved had records reviewed three years before bariatric surgery (baseline) with records three years after surgery (subsequent period) focusing only on emergency room visits. Three months before surgery and three months' post-surgery (perioperative period) were exempt from the study.

There were 8,815 subjects in this study, and almost all patients had undergone gastric bypass surgery vs. sleeve gastrectomy. Of the group, 1,417 patients had one emergency room visit in the baseline period, and 1,661 had one emergency room visit in the postoperative period ($p < 0.001$). Emergency room visits were 17% higher after surgery than before surgery (CI 15-

19%; $p < 0.001$). These visits are an increase from 882 per 1,000 patient-years to 1,000 per 1,000 patient-years, a rate ratio (RR) of 1.17 (95% CI 1.13-1.21; $p \leq 0.001$). The study found that before surgery, complaints were mainly related to cardiovascular, respiratory, ears, and dermatology. These complaints decreased after surgery, and complaints related to gastrointestinal, genitourinary, psychiatric, substance abuse and trauma increased. Ambulance transports also increased for patients after surgery as compared to before surgery (RR 1.82; 95% CI 1.68-1.99). After surgery, emergencies also had more hospitalizations as compared to before surgery (RR 1.82; 95% CI 1.69-1.98). Less than 1 in 1,000 patients died after surgery.

There are abundant sample sizes and statistically significant data showing that there is indeed an increase in emergency room visits after surgery for at least three years based on coding by emergency room physicians. The authors feel that this may be related to patients not understanding the changes in metabolism and absorption of substances after surgery. However, when the emergency room visit is coded, it does not necessarily state if the diagnosis is directly related to bariatric surgery. It would be interesting to compare the group to non-surgical candidates to see if bariatric surgery is the cause is for increasing emergency room visits or if there is a societal trend to increasing visits to the emergency room (Bhatti, Nathens, Thiruchelvam, & Redelmeier, 2016).

Bruschi Kelles, S.M., Diniz, M., Machado, C., & Barreto, S. (2014) conducted an asynchronous prospective cohort study that attempted to determine the 10-year mortality rate of patients who underwent open Roux-en-Y gastric bypass surgery in Brazil. Patients were under a private HMO and had surgery between January 2001 and December 2010. Patient records for 4344 people were followed until their death or ten years has passed, whichever event occurred first. If a patient died during the ten-year follow-up period, the death was classified as either

related to bariatric surgery or not associated with bariatric surgery and as either a natural death or a death from violence. The data was collected from the Brazilian National Information System on Mortality.

Characteristics of the 4,344 subjects include: 79.3% (n=3443) were female; 39.7% (n=1,723) with hypertension; 12.2% (n=529) with diabetes mellitus type II; 13.9% (n=603) with arthropathy; and 6.4% (277) with obstructive sleep apnea. Baseline BMI had a median of 42 kg/m^2. The median follow-up period was 4.1 years. During the first 30 days post-surgery, there were 24 deaths (0.55%), and a total of 82 deaths (1.9%) for the entire follow up period. Of the 82 deaths in the follow-up period, 45 (54%) were related to bariatric surgery. Sepsis accounted for 42.7% (n=35) of the natural deaths and was the most common cause of mortality due to surgery. Thromboembolism was the next most common surgery-related cause of death at 24.3% (n=20). Of the deaths classified as violent deaths, suicide accounted for 9.8% (n=8). Researchers did find that the risk of mortality from bariatric surgery may increase if the patient has a BMI ≥ 50 (HR 5.14; 95% CI 2.82-9.38; $p < 0.01$), age is > 50 years old (HR 3.68; 95% CI 1.99-6.80; $p < 0.01$), has hypertension (HR 2.41, 95% CI 1.31-4.42; $p < 0.01$) and the surgeon is less experienced (HR 2.19, 95% CI 1.21-3.96; $p = 0.01$) (Bruschi Kelles et al., 2014).

Further investigation is needed to examine the safety of laparoscopic surgery vs. the open procedure used in this study. The authors do mention that the 9.8% suicide rate may be addressed with increased psychologic counseling before and after surgery. The experience of the surgeon was also a variable factor that could be modified with increased training requirements

Nocca et al. (2017) conducted a retrospective study reviewing patient records of those who underwent laparoscopic sleeve gastrectomy (LSG) between 2005 and 2011. This study was conducted in France, where LSG is the most common bariatric procedure performed there.

During the study period, there were 1,050 who opted for the LSG procedure. Laparoscopic procedures were performed in 998 patients, while 52 patients had open laparotomy due to previous abdominal surgeries.

During the surgery, 1.6% of patients experienced complications. Minor liver lesions represented 1% of the complications, failure of the staple line represented 0.3%, small splenic injuries represented 0.2%, and stapling of the nasogastric tube represented 0.1%. The death occurred in 0.1% of the surgeries performed.

Post-surgical complications resulting in secondary surgical or endoscopic procedures occurred in 6.8% of the cases. The most common cause was due to the formation of a gastric fistula, which occurred 3.8% of the time, hemorrhage, which occurred 3.4% of the time, 0.2% had gastric stenosis, and 0.4% had trocar hernias. Other postoperative complications not resulting in a second surgical procedure included gastroesophageal reflux disease (GERD) 39.1% of the time, biliary pain occurred 3.6% of the time, acute pancreatitis 0.3% of the time, portal vein thrombosis 0.3% of the time, bile reflux 0.2% of the time and significant depression 0.01% of the time. GERD was the most commonly reported five-year complication in 15-35% of the people.

The authors of the study only report complications of one type of bariatric surgery. The study lays out the post-operative and intra-operative complications, but it does not indicate any long-term complications other than GERD. The follow-up data looks impressive, but the study states, "from a total of 175 patients that had completed five years of surgery, 144 (82.3%) were available for follow up." The statement is unclear about 175 patients. The numbers appear as if there was great follow up, but if only 144 of the original 1050 followed up in five years, that is only 13.7%. The follow-up data for the percentage of excess BMI loss appears to be out of the

larger group with 1050 participants. According to the data presented there, patients at three, four, and five years had over 60% excess BMI loss. When comparing the complications to the potential for weight loss, LSG may be a very viable option for obesity with few complications (Nocca et al., 2017).

Sanni A. et al. (2014) utilized the ASC-NSQIP database to obtain information about preoperative risk factors, laboratory values, and 30-day bariatric surgery postoperative complications. The study had 11,617 patients that underwent laparoscopic Roux-en-Y gastric bypass (LGBP), and 3,069 patients underwent laparoscopic sleeve gastrectomy (LSG).

Baseline data and ASA surgical fitness scores in the LGBP group consisted of the following: mean age 43.8 ± 11.5 years, mean BMI 46.6 ± 7.8 kg/m^2, ASA class 1 0.4% (n=51), ASA class 2 was 35.3% (n=4,097), ASA class three was 62.1% (n=7,199), and ASA class four was 2.1 % (247). In the LSG group, mean age was 43.7 ± 11.2 years, mean BMI was 46.7 ± 8.4 kg/m^2, ASA class one was 0.4% (n=12), ASA class two was 34.2% (n=1,048), ASA class three was 62.8% (1,924), and ASA class four was 2.6% (n=81). Baseline data for both groups was very comparable.

Post-operative complications resulted in 5.1% (n= 589) of LGBP patients and in 1.4% (n= 98) of LSG patients (P<0.0001). Mortality resulted in 0.2% (n=19) LGBP patients and in 0.1% (n=3) of LSG patients (P=0.1401). Post-surgical complications resulting in a secondary surgical procedure occurred 2.2% (n=255) of the time with LGBP and 1.6% (n=48) of the time with LSG (p-value <0.0001).

Specific post-operative complications that were statistically significant included: bleeding as the most common in 153 (1.32%) of LGBP and 15 (0.49%) of LSG (p-value < 0.0001), and UTI was the second most common problem in 82 (0.71%) of LGBP and is the most common for

LSG patients with 19 (0.62%) reports (p-value = 0.0124). Other significant complications were pneumonia (p-value = 0.0166), re-intubation (p-value = 0.0011), pulmonary embolism (p-value = 0.0095), failure to wean the patient off of the ventilator (p-value = 0.0121), renal insufficiency (p-value = 0.0011) and DVT (p-value = 0.0005).

The authors used a logistic regression model to assess the risk of co-morbid factors that may increase the risk of postoperative outcomes. They found that diabetes, hypertension, chronic obstructive pulmonary disease, and shortness of breath increased complications following surgery by 1% for each comorbidity the patient had (OR 1.01, 95% CI 1.006-1.02). They also found that for each point of increased BMI a patient had, the postoperative complication risk increased by 2% (OR 1.02, 95% CI 1.01-1.027). In the LGBP group, of the patients that had diabetes, 37.7% (n=222) had complications, in those with pre-existing shortness of breath, 24.3% (n=143) had complications, those with COPD only 3.4% (n=20) had complications, and those with hypertension 63.0 (n=371) had complications. In the LSG group 31.6% (n=31) of those with diabetes had complications, those with shortness of breath had a 26.3% (n=30) complication rate, 2.6% (n=3) with COPD had complications and 62.3% (n=71) with hypertension had complications (Sanni et al., 2014).

This study was a very comprehensive study that used many patient records to determine if the surgical complication risk is worth the benefit of bariatric surgery. They also have some percentages of how the procedure would reduce mortality by 35-89% by decreasing many of the co-morbidities that accompany obesity(Sanni et al., 2014). They did not, however, have any specific statistics in this study to support that particular percentage. This study was beneficial for this research because it has large group sizes with patient demographics that are very comparable for each treatment group that helps make the statistical analysis much more reliable. Most of the

p-values are of statistical significance except for mortality. Overall, the statistics are reliable, and even though there is some risk with bariatric surgery, the potential to lose up to 70% of excess weight may outweigh the chance for some people.

Discussion

All the studies reviewed showed that bariatric surgery is an effective way to treat morbid obesity and the comorbidities that follow. Each study showed that the participants lost a significant amount of weight. Both Peterli et al. (2018) and Reges et al. (2018) found that participants in the studies lost a significant amount of weight but found no significant difference in weight loss between the sleeve gastrectomy and the Roux-en-Y gastric bypass. Reges et al. (2018) found that the sleeve gastrectomy was more effective than the Roux-en-Y gastric bypass.

Peterli et al. (2018) found that the Roux-en-Y gastric bypass lost slightly more weight than the sleeve gastrectomy but not enough to be statistically significant. This lack of statistical significance was attributed to the randomized treatments for each patient. In all other studies, the patient and surgeon still chose which procedure would create the best outcome for the patients. The lack of statistical significance between procedure with randomization may speak for the importance of choosing the right procedure for each patient.

In the systematic review conducted by Puzziferri et al. (2014), they also found significant weight loss for the patients undergoing bariatric surgery. This study started with over 7,000 studies, of which only 29 of those studies had enough follow up data to be included. The data shows that gastric bypass had slightly increased weight loss percentage; however, there were only two studies included with data for sleeve gastrectomy, and neither of those studies included data for longer than two years. Puzziferri et al. (2014) makes a point in the discussion that most of the studies do not have statistics for failure rate and proposes that this may be due to the lack

of follow-up due to procedural failure. Further study would have to be conducted to understand why the follow-up percentages are so low.

Arterburn et al. (2018) and Uno et al. (2017) both conducted retrospective studies comparing Roux-en-Y gastric bypass and sleeve gastrectomy. Both studies found that significant weight loss was achieved with each procedure, but more weight loss was experienced with the gastric bypass than the sleeve gastrectomy. Arterburn et al. (2018) had large sample sizes and gave proportion data for each procedure at one, three, and five years. This data clearly shows that weight loss is sustainable for five years, but as time passed, the proportion of patients that maintained the weight loss dwindled. The study also had significant loss of patient numbers as time progressed, leaving smaller and smaller sample sizes. Follow-up is a problem in many of the studies, and unfortunately, none of them explain why there is a loss of numbers for follow up.

Uno et al. (2017) analyzed data with the super morbidly obese (BMI $\geq$ 50 kg/m^2) group. Although they had smaller sample sizes, the follow up was higher than many other studies. This study showed more significant weight loss with the gastric bypass in the super morbidly obese group compared to sleeve gastrectomy, indicating that the Roux-en-Y gastric bypass may be a better procedure in patients with a BMI of 50 kg/m^2 or higher.

There is not a lot of long-term data out there about the efficacy of bariatric surgery. Golzarand, Toolabi & Farid (2016) showed through a meta-analysis that Roux-en-Y gastric bypass is an effective weight loss treatment for those who are morbidly obese. The data on sleeve gastrectomy shows that it is an effective procedure for up to five years, but it is a newer procedure and only became more common in 2010. Therefore, there has not been enough time passed to make conclusions about the efficacy of that procedure past ten years. More long-term studies will have to be conducted on the efficacy of sleeve gastrectomy.

Maciejewski et al. (2016) found similar results when comparing the efficacy of the Roux-en-Y over ten years to the sleeve gastrectomy. Both treatments were very effective for weight loss when compared to a similar population with no treatment at all. Authors also found that Roux-en-Y gastric bypass has data to support long term durability over ten years, while gastric bypass has data to support efficacy over five years.

Five studies looked at the efficacy of non-invasive weight loss programs. Burguera et al. (2015) conducted a two-year randomized controlled study that had patients divided into either an intensive lifestyle intervention (ILI) group or a conventional obesity therapy (COT) group. The ILI group had more participants in the beginning, as researchers expected a greater than 50% participation loss before the conclusion of the trial. They found that both groups had significant dropout rates; however, those that remained in the trial for the duration were successful in losing weight. Nielsen et al. (2019) and Shadid et al. (2015) conducted similar studies where participants were a part of an intensive lifestyle intervention group compared to a conventional group and found similar results to Burguera et al. (2015). There was a large percentage of participants who dropped out, but those who remained lost significant amounts of weight throughout the trial. All three studies showed that for those who are motivated and compliant, intensive lifestyle intervention was more efficacious than a conventional weight loss group. Dandanell et al. (2107) and Zentenius et al. (2018) contributed retrospective studies that used data from other obesity studies. Zentenius et al. (2018) looked specifically at what kinds of weight loss plans people are using to lose weight, and Dendanell et al. (2017) looked at weight loss data and cardiometabolic health of people who had participated in an ILI program. Zentenius et al. (2018) found that many programs will suffice for weight loss, but those who lost the most weight has a more substantial exercise component than just diet alone. The study by

Dandanell et al. (2017) showed the group with the most significant weight loss continued to lose weight over a long period, while the other two groups of minimal weight loss and weight regain did not maintain weight loss and experienced weight regain. This lack of maintenance may be related to the role of gratification found by losing weight. Those with more significant weight loss are more motivated to continue proper eating habits and exercise plans provided to them during the ILI. Those with very slow and very little weight loss have more difficulty maintaining the motivation to continue with recommended eating and exercise habits.

Comparing surgical and non-surgical options are important factors when a patient is deciding how to manage their obesity. The systematic review conducted by Beaulac & Sandre (2017) shows that bariatric surgery was far more efficacious for weight loss and weight loss maintenance than low calorie and very low-calorie diets. Both the Roux-en-Y gastric bypass and sleeve gastrectomy had an excess weight loss of over 50% after the first year, whereas calorie-restrictive diets resulted in a 10% weight loss. Douglas et al. (2015) not only showed the increased amount of weight loss achieved through bariatric surgery, but also showed that the weight loss was related to the resolution of hypertension, diabetes, and obstructive sleep apnea.

Nielson et al. (2019), Marciejewski et al. (2016), and Reges et al. (2018) all completed studies comparing surgical groups to non-surgical groups and found results showing that bariatric surgery was again more efficacious and maintainable than non-surgical treatments. However, two studies demonstrate gender bias: Nielson et al. (2019) only conducted their research on females, and Marciejewski et al. (2016) conducted research with a majority of male patients, making the results of each study challenging to translate to the other gender. The study conducted by Reges et al. (2018) shows that bariatric surgery was far more efficacious than non-surgical options in both men and women.

All surgical interventions come with the risk of an unintended outcome, and bariatric surgery is no exception. Bhatti et al. (2016) conducted a study looking to see if patients who had bariatric surgery had increased emergency room visits. The authors found that patients had increased emergency room visits presenting with complaints related to gastrointestinal, alcohol, and psychological issues. Bariatric surgery requires a person to make substantial lifestyle changes that are often difficult to maintain. Nocca et al. (2017) found that less than 2% of the patients who underwent the sleeve gastrectomy procedure has post-surgical complications, of which the most common experience (40%) was GERD. GERD was also reported in 15-35% of patients at five years post-surgery.

Bruschi Kelles et al. (2014) found that the Roux-en-Y gastric bypass is a relatively safe procedure with < 1% of patients with postoperative complications that resulted in death within 30 days of surgery. Of these deaths, 24% were related to sepsis. Only 1.9% of patients died within ten years of the procedure. Sanni et al. (2014) found that 5.1% of laparoscopic Roux-en-Y had post-surgical complications as compared to 1.4% of laparoscopic sleeve gastrectomy patients. The authors also found mortality rates of 0.2% of laparoscopic Roux-en-Y patients compared to 0.1% of laparoscopic sleeve gastrectomy patients.

Overall, Roux-en-Y gastric bypass and sleeve gastrectomy are very effective treatments for morbid obesity—patients who underwent the procedures lost anywhere from 50-80% of excess weight. The procedures showed to be effective over long periods, however, many factors not discussed here may contribute to the short term and long-term success of each procedure. Both procedures are relatively safe, with < 2% mortality. The Roux-en-Y is found to have a slightly increased risk of postoperative complications over the sleeve gastrectomy. It was also found that bariatric surgery patients lost a more significant amount of excess weight more

quickly, and the surgery is more efficacious than traditional diet and exercise plans. Traditional diet and exercise works for some people but most of the studies had significant dropout rates. The significant dropout rates may contribute to the idea of how difficult it is for many patients to follow a strict diet and exercise regimens. Further studies need to be conducted to examine the long-term efficacy of the sleeve gastrectomy as it is a newer procedure. A majority of these studies also have increased dropout rates, thus a need for more studies with better follow-up.

Applicability to Clinical Practice

In 2014 it was estimated that every year there are nearly 300,000 deaths due to co-morbidities related to obesity (Sanni et al. 2014). Obesity has been shown to contribute to increased blood pressure, cholesterol, and the incidence of diabetes mellitus type II. These co-morbidities are also known to contribute to increased risk for heart attack, stroke, and vascular disease. As health care providers, we are continually educating patients about the prevention of these lifelong, potentially debilitating diseases.

The saying "easier said than done," is particularly true when it comes to weight loss and weight maintenance. The amount of weight a patient would need to lose to change their BMI classification from morbidly obese to normal or overweight is often very daunting, and patients are often unsure where to start with a diet and/or exercise plan. Even with all the right foods and the appropriate amounts of exercise, it is challenging to reset the body's metabolic set point, which is why weight loss is so difficult, and long-term weight maintenance is even more challenging.

Bariatric surgery has shown to be an effective, long term treatment for those patients who are considered morbidly obese. Surgery has also shown to be relatively safe, with a low incidence of post-surgical complications and mortality. Along with successful weight loss, many

patients also find that co-morbid conditions associated with obesity are often put into remission. As health care providers, we have to educate patients about the disease of obesity, the possible co-morbidities, and all the available treatment options.

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