PREOPERATIVE PATIENT CONTACTS AND POSTOPERATIVE WEIGHT LOSS AFTER BARIATRIC SURGERY: A RETROSPECTIVE STUDY

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ABSTRACT

Background: Obesity is a significant threat to the health of millions of Americans. The disease is strongly associated with a number of conditions that increase the risk of premature mortality, including type 2 diabetes, hypertension, obstructive sleep apnea, and certain cancers. Bariatric surgery, specifically Roux-en-Y gastric bypass (RYGB) and vertical sleeve gastrectomy (SG), produce significant and durable weight losses. Third-party payers require that patients complete a number of preoperative consultations, typically including a medical assessment and mental health evaluation, as well as medical weight management (MWM), which typically consists of 3-6 months of in-person visits with a primary care provider or registered dietitian (RD). The number of visits and duration of the preoperative consultation and MWM process is often dictated by the patient's third-party payer. Few studies have investigated if these contacts are associated with greater postoperative weight loss. Further, the relationship of these preoperative contacts to postoperative follow-up, which is associated with weight maintenance, is unknown.

Objective: To determine if the frequency of preoperative contacts, and the duration of the preoperative assessment period (and duration of MWM in particular), is associated with percent weight loss in the first two years following bariatric surgery. The relationship between preoperative contacts with postoperative attrition also was explored.

Methods: One thousand five hundred bariatric surgery cases from 2009-2014 from a single institution were analyzed. Preoperative contacts were abstracted from the electronic medical record and categorized by type. Weight was collected from postoperative visits with the surgical practice or primary care physician records.

Generalized linear mixed models were used to assess the relationship between the frequency of preoperative contacts and duration of preoperative care with the bariatric surgery team and weight loss in the first 24 months after surgery. Logistic regression models were used to assess the association between the number of preoperative contacts and the duration of the preoperative assessment period with completion of postoperative follow up visits.

Results: The frequency of preoperative contacts (including individual visits, education sessions, support groups, psychology visits, telephone calls, and electronic messages) and duration of preoperative care were not associated with postoperative percent weight loss. A greater number of individual visits with the bariatric surgery team was associated with 0.26% smaller postoperative weight loss (95% CI -0.47%, -0.05%; P = 0.02). Additional contacts with the psychologist also were associated with 1.46% smaller postoperative percent weight loss (95% CI -2.79%, -0.12%; P = 0.03). Number of preoperative contacts and duration of preoperative care were not associated with postoperative follow up.

Conclusion: The frequency of preoperative contacts with the bariatric surgery team, and the duration of preoperative care, were not associated with weight loss in the first two years after bariatric surgery. More individual visits with the bariatric team and additional visits with the psychologist prior to surgery were associated with smaller postoperative weight loss. These results suggest that the intensity and length of the preoperative assessment period, which is often mandated by third party payers, is unrelated to early postoperative weight loss. More extensive preoperative assessment by the multidisciplinary team, and mental health professional, however, may be identifying patients who are at risk for smaller postoperative weight losses. Further research should

attempt to determine an appropriate recommendation for MWM in respect to duration and frequency, while also considering the quality and content of these clinical visits.

DEDICATION

To my parents, Tom and Joan,

for teaching me the value of hard work

To my siblings, Tom, Kaitlyn, Patty, Ken, and Jack,

for fostering our lifelong drive to do good and make the world a little better

And to my husband, Rich,

for always challenging me to grow and improve, supporting all my endeavors, and being my greatest cheerleader

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CHAPTER 1

BACKGROUND

Obesity Prevalence and Impact

Obesity is one of the greatest public health challenges of the 21st century.[1,2] Body mass index (BMI) is the most common method of assessing obesity. While a less-than-ideal measure, it is relatively easy to assess and is strongly associated with morbidity and mortality.[3] The World Health Organization defines obesity as having a BMI of 30 kg/m^2 or greater.[4] Obesity can be subcategorized into three classes by BMI: Class I or mild (30-34.9 kg/m^2), Class II or moderate (35-39.9 kg/m^2), and Class III or severe ($\geq$40 kg/m^2). Within the United States, the prevalence of obesity among adults has nearly tripled since 1980 from 13.4% to 37.7% in 2014.[5,6] If this trajectory of growth continues, more than half of American adults will have obesity by 2030.[7] This projection, when considered in the context of weight-related medical comorbidities, represents a significant threat to the sustainability of our country's current health care model.

Obesity impacts Americans across gender, age, race, socioeconomic status, and education levels. Adult obesity is most prevalent in minority populations, with 42.5% of Hispanic adults and 48.1% of non-Hispanic black adults having obesity.[5] Women have a higher age-adjusted prevalence of obesity than men, 40.4% (95% CI 37.6%, 43.3%) vs 35.0% (95% CI 32.8%, 37.2%).[2] Obesity disproportionately impacts women with lower education levels and between 40-59 years of age.[2] The prevalence is concerning when considering that obesity is a risk factor for premature death and the development of multiple comorbidities. These include type 2 diabetes, sleep apnea, stroke, dyslipidemia,

hypertension, and certain cancers.[8] Worldwide, obesity is considered a leading cause of death, second only to smoking.[9] The Global BMI Mortality Collaboration calculated that 1 in 5 North American premature deaths of all-causes could be prevented if individuals with overweight or obesity had a normal BMI.[9]

The individual and societal costs of obesity are great and include significant psychosocial and financial burdens.[10] Persons with obesity report experiencing significantly lower quality of life than their normal-weight counterparts.[11] Adults with obesity miss more days of work than individuals of normal weight.[12] Personal expenditures such as fuel and clothing are greater for persons with obesity.[13] Obesity is also associated with lower wages, increasing the burden of the added costs of living for persons with the disease.[14] For employers, absenteeism related to obesity costs American businesses approximately $4.3 billion annually.[15] This impact is seen in presenteeism as well, where employees with obesity cost employers $506 more per employee annually.[16]

The individual and societal economic tolls of obesity are compounded when weight loss treatment and treatments for weight-related comorbidities are considered. Adults with obesity spend 42% more on direct healthcare costs compared to adults without the disease.[17] Total health care costs associated with obesity in the United States range from $147 billion to $210 billion annually and account for more than 20% of total healthcare spending.[17-19] Pharmaceutical costs for individuals with obesity are nearly twice as high compared to persons of a normal body weight.[20]

Obesity Causes and Risk Factors

Obesity is a complex, multifactorial disease that results from a combination of factors, including calorie intake, physical activity, environment, individual/societal influences, as well as genetic and physiological factors.[21] There is little debate that the overconsumption of calories contributes to obesity. Unsurprisingly, increased caloric intake of American adults over the past thirty years has been correlated with increased rates of obesity.[22] Increases in portion sizes of many foods, along with the regular consumption of sugar, are often seen as the major contributors to these increases in caloric intake.[23] Decreases in physical activity also are believed to contribute to the increasing rates of obesity.[24] In 2015, only 1 in 5 adults in the United States met physical activity recommendations of 150 minutes of moderate-intensity physical activity and muscle strengthening each week.[25]

Environmental factors influence both the increased caloric consumption and decreased activity levels witnessed over the past several decades.[26] Property values by zip code have been shown to be one of the strongest predictors of obesity.[27] Higher rates of obesity are seen in persons living on the far ends of the population density spectrum, both dense urban areas and remote rural areas have higher rates of obesity compared to suburban locations.[5,28,29] Proximity to calorically dense, less nutritious foods is also an issue; with increased access to fast food restaurants and convenience stores linked to higher rates of obesity.[30] At the same time, higher food prices are associated with higher rates of obesity.[31] Furthermore, social and family-level variables have been related to the development of obesity. For example, parental restrictive feeding practices and child nighttime sleep duration have been identified as modifiable risk factors for obesity in

adolescents.[32] However, the strongest risk factor for a child developing obesity is if he or she has a parent with obesity.[32,33] This is particularly true for mothers compared to fathers.[34] Additionally, weight gain in pregnancy has been associated with the child's BMI into adulthood.[35]

Genetics also plays a role in the development of obesity.[36,37] Approximately 40-70% of the variability in an individual's body weight is influenced by genetic factors.[38-41] The development and maintenance of obesity also is influenced by other physiological factors. Dietary intake is regulated by a number of appetite and satiety hormones.[42] These include peptide YY, pancreatic polypeptide, ghrelin, glucagon-like peptide-1, and cholecystokinin.[43] Stress has been shown to inhibit secretion of peptide YY in women with obesity.[44] Observed levels of glucagon-like peptide-1 are lower in persons with obesity.[45] Ghrelin, the stomach-derived peptide also known as the "hunger hormone," stimulates the desire to eat in humans.[46] Ghrelin levels decrease in a fed or obese state and, in turn, reduce the hormonal drive to eat in humans.[46,47] With weight loss or reduced caloric intake, ghrelin levels increase, stimulating hunger once again and contributing to the difficulty of sustaining a caloric deficit to achieve weight loss.

In summary, obesity is a significant public health issue, affecting more than 1 in 3 adults in the United States.[2] Its causes are multifactorial and consequences are vast. The complexity of these factors represent significant challenges to the successful treatment (and prevention) of the disease.

Obesity Treatment

The most common forms of treatment for obesity include lifestyle modification, pharmacotherapy, and bariatric surgery. The specific approach is typically determined by BMI and the presence of comorbid diagnoses. As BMI increases, treatments are recommended to be used in conjunction with each other, increasing the complexity and intensity of the intervention with the goal of promoting greater weight loss.

Current expert-based recommendations suggest that comprehensive lifestyle modification intervention (including caloric restriction, increased physical activity, and behavioral modification strategies) is the approach of choice for all individuals with a BMI of 25 kg/m^2 or greater.[48] Lifestyle interventions produce clinically meaningful weight losses of 5-7% of total body weight, with significant improvements in blood glucose, blood lipid levels, and blood pressure.[48,49] One of the most widely used examples of this approach is the Diabetes Prevention Program (DPP). The DPP is an intensive lifestyle intervention that was developed and tested in a randomized controlled trial examining the effects of lifestyle modification compared to metformin or placebo in more than 3,800 individuals at risk for the development of type 2 diabetes.[50,51] Design of the lifestyle modification intervention was influenced by social cognitive theory, and the intervention was delivered through in-person visits, group visits, and telephone encounters.[52] Study participants had a high frequency of contacts with interventionists, with a minimum of 3 contacts per week required via in-person visits, phone calls, and/or written communications.

The lifestyle intervention produced an average weight loss of 5.6 kg (6% of body weight) and was associated with significant reductions in fasting blood glucose,

triglycerides, blood pressure, use of hypertensive medications, and increases in HDL cholesterol within the first 6 months.[53,54] Six years after the onset of intervention, diabetes was reduced 58% compared to baseline.[55] A secondary analysis found that the lifestyle intervention significantly reduced the progression of metabolic syndrome compared to placebo among participants who did not already have the condition by 41% (95%CI 28%, 52%).[56] In addition, DPP was considered to be low in price with a high return on investment, costing approximately $750 per participant per year with continued savings of averted costs after 10-year follow up. Centers providing group interventions saw the greatest savings, costing one-third of the expense of individual sessions.[57,58]

For persons with a BMI $\geq$ 30 kg/m^2 and those with a BMI $\geq$ 27 kg/m^2 with at least one comorbidity, pharmacotherapy, along with lifestyle modification, is advised.[48] Currently, a number of weight loss medications have approval from the Food and Drug Administration. These medications include lipid malabsorption agents (orlistat), serotonin agonists (lorcaserin), appetite suppressants (phentermine and topiramate), and GLP-1 receptor agonists (liraglutide).[59-68] Orlistat inhibits the production of gastric and pancreatic lipases, enzymes necessary for fat digestion.[63] When this medication is taken with meals, fat is malabsorbed. While absorption of calories is reduced, patients can experience unpleasant side effects including steatorrhea and fecal incontinence with high fat intake. The drug produces a clinically significant weight loss, with the earliest trials showing a significantly greater weight loss compared to placebo (10.2% [10.3 kg] vs 6.1% [6.1 kg], P <0.001).[69] In another randomized controlled trial, Davidson and colleagues found similar results, with a significantly greater weight loss when compared to placebo (8.76 $\pm$ 0.37 kg vs 5.80 $\pm$ 0.70 kg, P <0.001).[64] Lorcaserin is believed to

activate specific neurons in the hypothalamus, reducing appetite and decreasing intake. The drug has shown greater weight losses after one year of treatment as compared to placebo (5.81% $\pm$ 0.16% vs 2.16% $\pm$ 0.14%; P <0.001).[61] A review of phentermine and topiramate trials found that the combination produces a mean weight loss of 10% of baseline over 2 years in over 50% of patients treated.[66] Liraglutide, a GLP-1 analog, increases the amount of insulin secreted, delays gastric emptying, and affects hormonal reward systems around food.[70] The daily injectable has been shown to produce minimally greater weight loss compared to placebo (5.8 kg, 95% CI 3.7, 8.0; vs 3.8 kg, 95% CI 1.6, 6.0).[68,71]

Although these medications typically produce weight losses greater to those seen with lifestyle modification alone, one of the greatest challenges to providers who prescribe these medications is insurance coverage.[72] Third party coverage for these medications is the exception rather than the rule in the United States. These medications are expensive, often costing hundreds of dollars each month, which makes them unaffordable for many persons with obesity. As a result, less than 1% of persons with obesity who could be treated with pharmacotherapy currently use this approach to treatment.[73]

Bariatric Surgery

For individuals with severe obesity, the 5-10% weight loss typically experienced with lifestyle modification and/or pharmacotherapy may have little impact on weight related health problems. Furthermore, the likelihood of a person with severe obesity achieving a normal BMI through just lifestyle modification is slim; estimates suggest that

as few as 1 in 1,290 persons are able to reduce their weight from severe obesity to a normal body weight.[74] Therefore, bariatric surgery is recommended for persons with severe obesity, or a BMI of $\geq$40 kg/m^2 or $\geq$35 kg/m^2 with significant weight-related comorbidity.[48] Despite the demonstrated safety and efficacy of bariatric surgery (detailed below) as the most sustainable and effective treatment for severe obesity, only 190,000 individuals--or approximately 1% of the clinically eligible population of approximately 16 million American adults with a BMI $\geq$ 40 kg/m^2--undergo surgery annually.[75-77]

The "gold standard" of bariatric procedures is the Roux-en-Y gastric bypass (RYGB).[76] In the procedure, the surgeon creates a small pouch, approximately 2 ounces in size, at the top portion of the stomach; disconnects the small intestine at the distal duodenum; connects the proximal jejunum to the gastric pouch (by creating a gastrojejunal anastomosis), and connects the distal duodenum to the jejunum with 100 - 150 cm Roux limb. This surgery is typically performed laparoscopically, utilizing only five small (< 2 cm) incisions, which is believed to minimize perioperative and postoperative risks while reducing recovery time and scarring. The theorized mechanisms of action of RYGB are believed to be restrictive, malabsorptive, and hormonal in nature.[76]

Vertical sleeve gastrectomy (SG) currently accounts for more than half of all bariatric surgeries being performed in the United States.[78] The procedure is performed by removing the majority, approximately 90%, of the fundus of the stomach.[76] Similar to RYGB, the majority of SG procedures are performed laparoscopically, significantly reducing surgical risk and improving the safety of the operation.

RYGB produces significant weight loss, with the majority of patients experiencing 25-35% total body weight loss within 12-18 months and maintaining 20-30% total body weight loss 10 years postoperatively.[79-84] The procedure also is associated with resolution or improvement of weight-related comorbidities, such as type 2 diabetes and hypertension, for the majority of patients.[85-89] Patients undergoing SG typically experience somewhat smaller weight losses of approximately 20-35% total body weight loss within 12-18 months postoperatively and 15-35% total body weight loss at five years.[90-92] At five years post-SG, resolution of diabetes, hypertension, and hyperlipidemia is 66%, 50%, and 100% respectively.[92,93]

With both procedures, approximately 5-10% of individuals experience a complication. Only 2.3% of patients experience serious complications, operationalized as a life-threatening medical issue such as a gastric leak or pulmonary embolism.[94] The Longitudinal Assessment of Bariatric Surgery (LABS) Consortium, a large, multicenter study of over 3,500 individuals who underwent bariatric surgery between 2005 and 2007, reported mortality rates within 30 days of surgery of 3 in 1000 cases.[95] This rate has continued to decline over the past decade. A recent analysis of elective surgical procedures found that bariatric surgery had lower 30-day postoperative mortality than the seven other surgeries assessed, including cholecystectomy, hysterectomy, knee arthroplasty, hip arthroplasty, colorectal resection, gastric resection, gastrectomy, and coronary artery bypass grafting.[96] Risk of 30-day mortality for individuals undergoing hip replacement surgery was more than 15 times higher when compared to bariatric surgery.[96] Thus, bariatric surgery, particularly when performed in high volume academic medical center settings, is one of the safest surgical procedures.

Despite these impressive outcomes, suboptimal weight loss and weight regain after bariatric surgery are significant concerns. Approximately half of all patients experience some weight regain within the first two years after surgery.[97,98] The mean weight regain within the first six years of surgery is 7%.[86] More substantial weight regain occurs in a large minority of patients. Lent and colleagues for example found that 17% of over 3,000 patients failed to maintain 20% of their initial weight loss at five years post-RYGB.[98] The Swedish Obese Subjects study, the largest and longest study of bariatric surgery in the world, observed a mean weight regain of 34% of initial weight lost by 10 years post-RYGB.[99] Adams et al. found that only 40% of patients maintained at least a 30% total body weight loss by 12 years post-RYGB.[100] Weight regain threatens the durability of the health benefits typically seen in the first few years after surgery. As the mean age of persons who undergo bariatric surgery is in the early 40s, weight regain may result in the return of obesity-related health problems for millions of Americans in the second half of their lives.

A number of factors likely contribute to postoperative weight regain. A systematic review of this literature suggested that these factors could be categorized into 4 groups: metabolic, psychiatric, physical inactivity, and dietary non-compliance.[101] Many of these are modifiable factors. For example, Odom et al. found that patients engaging in self-monitoring behaviors were less likely to experience weight regain.[102] In another study of patients a mean of seven years post-RYGB, there was a positive relationship between moderate-to-vigorous physical activity and weight maintenance.[103] In the LABS Surgery cohort, Mitchell et al. found three behaviors most closely linked to larger postoperative

weight loss at year 3: weekly self-weighing, stopping eating when feeling full, and not eating continuously throughout the day.[104]

In summary, bariatric surgery is the most effective treatment for severe obesity. The majority of patients experience substantial weight loss and improvements in weight-related comorbidities. However, a considerable minority, roughly 20%, experience smaller-than-expected weight losses or sizable, early weight regain. The reasons for these suboptimal outcomes are still being investigated, but likely result from a number of physiological and behavioral factors. Several of these factors are assessed and targeted for behavioral change as part of the preoperative assessment process.

Preoperative Assessment of Candidates for Bariatric Surgery

Convened in 1991, the Consensus Development Conference Panel on Gastrointestinal Surgery for Severe Obesity was tasked with establishing guidelines for both surgical and non-surgical treatment of severe obesity.[105] The panel recommended that patients being considered for surgery be evaluated by a "multidisciplinary team with access to medical, surgical, psychiatric, and nutritional expertise." As bariatric surgery grew in popularity in the 1990s and 2000s, evaluation by a multidisciplinary team became the standard of care.

In 1995, the National Institutes of Health Expert Panel on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults published treatment guidelines, updating the recommendations from the 1991 panel.[106] In 2007, and again in 2013, the American Association of Clinical Endocrinologists, The Obesity Society, and the American Society for Metabolic and Bariatric Surgery (ASMBS), provided further

guidelines for the pre- and perioperative management of bariatric surgery patients.[75,107] All three sets of guidelines essentially remained the same from the initial conference panel in 1991; the value of the more recent guidelines is that they provide an evidence base for the patient care recommendations.

In general, the guidelines recommend that individuals interested in bariatric surgery undergo preoperative assessments by clinicians from medicine, surgery, dietetics, and psychiatry/psychology. The medical assessment of candidates includes initial evaluation of weight status. The BMI guidelines indicate surgery for patients with a BMI of $\geq$40 kg/m^2 or BMI between 35 and 39.9 kg/m^2 with a weight-related comorbidity such as type-2 diabetes, hypertension, or obstructive sleep apnea.[75] Other comorbidities to be considered include nonalcoholic fatty liver disease, gastroesophageal reflux, pseudotumor cerebri, asthma, venous stasis, and urinary incontinence. Surgery should not be considered in patients with limited life expectancy due to irreversible end-organ failure or inoperable malignancies. Female patients who are pregnant or plan to become pregnant within 12 months should also not be considered for surgery until postpartum.

Surgical assessment includes a physical examination and possible imaging to determine the technical ability to perform bariatric surgery in individuals with multiple previous abdominal surgeries.[75] Patients with contraindications to general anesthesia or uncorrectable coagulopathy should not be considered for bariatric surgery. A preoperative upper gastrointestinal series or upper endoscopy are recommended to assess for any anatomical concerns related to surgery.

Preoperative nutritional assessment by a registered dietitian (RD) is an integral component of determining surgical candidacy.[75,107] The nutrition assessment is

comprehensive, including an evaluation of weight loss history, current dietary behaviors, and knowledge of postoperative dietary recommendations. Prospective patients are educated in the dietary and behavioral changes required of surgery and encouraged to begin to practice these behaviors in preparation of surgery. Nutrition assessment includes education on potential nutrient deficiencies associated with the altered anatomy and weight loss expectations.[108,109] Inability to demonstrate comprehensive understanding of basic nutrition and postoperative nutrition recommendations is a contraindication for surgery.[75]

The mental health evaluation of the bariatric surgery candidate is another central component of the preoperative process.[110] The evaluation includes an assessment of specific psychosocial characteristics such as motivations for, expectations about, and knowledge of bariatric surgery.[111] Current and past psychiatric status is evaluated. While presence of a current psychiatric diagnosis does not contraindicate surgery, patients with recent suicidal attempt or ideation, active or recent psychosis, or active or recent illicit drug or alcohol use disorder are recommended to delay surgery and engage in mental health treatment prior to surgery.[112,113] Comprehensive mental health evaluations also provide the patient with psychoeducation about the dietary and behavioral changes required with surgery.[75] Patients also are recommended to attend at least one bariatric support group prior to surgery.[75]

Medical Weight Management

Preoperative Medical Weight Management (MWM) is a period of medically supervised weight loss prior to bariatric surgery. It is recommended for most patients by

the clinical practice guidelines from the American Association of Clinical Endocrinologists, the Obesity Society, and the American Society for Metabolic and Bariatric Surgery.[75] Most third-party payers in the United States require some period of MWM prior to surgery.[114]

Even prior to these guidelines, MWM was common practice within bariatric programs. In the 1991 guidelines, the panel members concluded that individuals who were appropriate for bariatric surgery should be deemed by an experienced clinician to have a low probably of successful weight loss with nonsurgical weight loss methods.[105] This recommendation was interpreted in clinical practice to suggest that patients should have engaged in more conservative weight loss efforts, such as lifestyle modification and/or pharmacotherapy, prior to bariatric surgery. This interpretation inadvertently established MWM as a standard preoperative practice without an evidence base. In fact, evidence suggests that most candidates for bariatric surgery already had a lengthy history of efforts, and unfortunately failures, with more conservative weight loss treatments.[115]

By the early 2000s, MWM was being mandated by insurance companies as a prerequisite for preauthorization for surgery. The 2004 Consensus Conference of ASMBS published bariatric-specific guidelines which challenged the practice, concluding: "Bariatric surgery candidates should have attempted to lose weight by non-operative means…but should not be required to have completed formal non-operative obesity therapy as a precondition for the operation."[116] While this statement made efforts to de-emphasize mandated preoperative MWM, the practice was already well established in preoperative care.

The 2011 ASMBS Position Statement on Preoperative Supervised Weight Loss Requirements further challenged the necessity of preoperative MWM and concluded that: "Policies such as these [prolonged preoperative diet efforts prior to insurance carrier approval of bariatric surgery] that delay, impede, or otherwise interfere with life-saving and cost-effective treatment, which has been proved to be true for bariatric surgery to treat morbid obesity, are unacceptable without supporting evidence."[117] Despite the more recent position statements in opposition of MWM, the practice remains a standard element of most insurance policies determining requirements for preauthorization.[118]

Preoperative Medical Weight Management and Postoperative Outcomes

Prior to the publication of the 1998 surgical guidelines, only two studies had investigated the relationship between preoperative MWM and surgical outcomes.[88,119] Martin and colleagues instructed 70 patients undergoing RYGB to consume a liquid diet comprised of 420 Calories and 70 grams of protein daily for at least one month prior to surgery. These individuals experienced no difference in postoperative morbidity as compared to patients who were not instructed to use the very low calorie diet prior to surgery.[119] In addition, Van de Weijert and colleagues, in a sample of 200 patients, found greater total weight loss in those who made efforts to lose weight prior to surgery.[88] Thus, there was not a particularly strong evidence base to support the 1998 recommendation for preoperative MWM. Over the past two decades, a number of studies have since investigated the relationship between preoperative MWM and postoperative weight loss. These studies can be categorized into those who have focused on the amount of

preoperative weight loss and those that have focused on the completion of preoperative MWM.

Preoperative Weight Loss and Postoperative Weight Loss

Since the 1998 recommendations, this literature has grown and a number of reviews in the past several years have summarized the studies that have focused on the relationship between preoperative weight loss size and postoperative outcomes.[120-122] A meta-analysis by Livhits and colleagues of six studies on the issue and published in 2009 found that preoperative weight loss resulted in a mean of 5% overall greater excess weight loss (95% CI 2.7%, 7.3%).[120] Subsequently, Ochner and colleagues conducted a review focusing on the effectiveness of preoperative weight loss and postoperative weight loss outcomes of 13 studies.[121] The majority of the studies assessed reported mixed findings, with one retrospective study finding an inverse relationship between preoperative weight loss and postoperative weight loss at three months.[123] The authors concluded that while preoperative weight loss may lead to some improvements in postoperative outcomes, the preoperative requirements, as implemented in clinical practice, were ineffective at producing a meaningful weight loss in many patients.

Gerber and colleagues summarized the literature on preoperative weight loss in 2015. With no additional studies provided compared to the other reviews noted above, the authors deduced that it is not entirely clear whether preoperative weight loss predisposes persons undergoing bariatric surgery to better postoperative weight loss outcomes.[124] The authors also suggested those who are successful at achieving weight loss prior to surgery may create a selection bias "by being more motivated to take

responsibility for their new lifestyle, and thus, being more successful in achieving and sustaining satisfactory weight loss over time."

The largest study of the issue, an evaluation of over 20,000 RYGB patients in the Scandinavian Obesity Registry was published in 2016.[125] The authors found preoperative weight loss of 4.8% was associated with increased weight loss at one year postoperatively, with the greatest effect seen in persons with a BMI > 45.7 kg/m^2 (OR 2.39; 95% CI 2.10, 2.72). In another recent study, Krimpuri and colleagues found preoperative weight loss was independently predictive of one year postoperative BMI change; however, that effect was lost when controlling for age, race and sex.[126]

Duration of Preoperative MWM and Postoperative Weight Loss

A number of studies have looked at the effect of the completion of the preoperative MWM program with varying duration, rather than the amount of weight lost during MWM, on postoperative weight loss. Jamal and colleagues found that patients who underwent insurance-mandated preoperative dietary counseling for 13 weeks prior to RYGB experienced significantly smaller percent excess weight loss than patients who had no such requirement (60% vs 67%, P < 0.0001).[127] Kuwada and colleagues found that patients required to complete at least six months of insurance-mandated MWM experienced no significant differences in percentage of excess body weight loss preoperatively and at 6- and 12-months postoperatively compared to patients without the requirement.[128] A review by Liu and colleagues of eight studies that assessed the effects of behavioral interventions on postoperative weight loss concluded that five of the eight studies found a greater postoperative weight loss compared to a control or comparison group.[129] However, only two of the studies included long-term weight loss outcomes of

greater than one year post-surgery, when patients typically reach their maximum weight loss.[130,131] In another review of completion of MWM, Cassie and colleagues reported that only nine of 24 studies found that preoperative MWM was associated with improved postoperative outcomes and concluded that there was insufficient data to support the recommendation of MWM.[122] The most recent study evaluating insurance-mandated MWM found no difference in postoperative weight loss between mandated MWM and no MWM at both one and two years postoperatively.[132]

Tewksbury and colleagues published the most recent review of MWM, including both preoperative weight loss and completion in relation to postoperative weight loss.[133] The authors note the lack of consensus on a standardized approach to MWM, as most MWM is informed by third-party payer policy rather than empirical evidence. Additionally, there are a number of methodological concerns with previous investigations that have left the field without clarity on the value of the clinical practice in light of the changes in the types of surgical procedures now in practice. For example, the measurement of MWM has varied greatly from just reporting completion of MWM, reporting duration, or only reporting preoperative weight loss. Little consideration has been given to the frequency of contacts with a provider or total duration of preoperative care. Additionally, the most recent statistics show that SG now accounts for more than half of all bariatric surgeries being performed.[78,134] This trend calls into question the generalizability of previous studies' findings, considering the majority of the literature on MWM consists of primarily vertical banded gastroplasty, adjustable gastric banding, and RYGB.[88,107,135-141]

Preoperative Medical Weight Management and Social Cognitive Theory

Preoperative MWM, similar to lifestyle modification interventions for weight loss more generally, is based on social cognitive theory, first described by Bandura in 1977.[142] According to the theory, undesirable behavior can be replaced with new patterns of actions through direct experience or by observing the conduct of others.[143] The interaction between personal, behavioral, and environmental factors is known as triadic reciprocal determinism and is the primary foundational aspect of the theory.[144] Core constructs and assumptions of social cognitive theory include self-efficacy, behavioral capability, observational learning, incentive motivation, outcome expectations, and self-regulation.

The preoperative evaluation, education, and management of a bariatric surgery patients can be seen as a real-world application of the theory. Recommendations for counseling with an RD revolve around self-monitoring of relevant behaviors with the goal of improving self-efficacy. Education sessions including the initial information session and the preoperative education class set outcome expectations. These sessions emphasize the importance of patient-provider contact in identifying maladaptive behaviors and replacing them with more adaptive approaches to eating and physical activity. Further, patients are required to attend a bariatric support group, where they can experience observational learning by discussing common challenges with others who are currently in the preoperative process or who have undergone surgery in the past. Preoperative care additionally provides a mechanism by which to foster engagement and communication between the surgery office and the patient. Ideally, this established line of

communication would translate into completion of long-term follow up visits with the surgical team.

Postoperative Follow Up and Postoperative Weight Loss

After bariatric surgery, patients are recommended to follow up with the bariatric program for the rest of their lives. Frequency, however, varies by program. The 2013 Clinical Guidelines state, "The frequency of follow up depends on the bariatric procedure performed and the severity of co-morbidities."[75] A number of studies have investigated the relationship between postoperative follow up and weight loss.[97,145-147] A meta-analysis of these studies found that compliance with program-recommended follow up visits was associated with greater excess weight loss in the first year after RYGB.[147] Attendance at visits with an RD postoperatively has also been found to be associated with greater weight loss.[97,146]

While there is evidence to suggest that postoperative follow up is associated with greater weight loss, overall, postoperative follow up rates are poor. Approximately three quarters of patients miss postoperative appointments in the first 24 months and only 41% attend a 24-month follow up visit.[148,149] Higa and colleagues recently found that only 33% of RYGB patients completed a 24-month follow up visit and only 7% completed a follow up visit at 10 years, even with efforts to contact the patients to return for these visits.[83] Thus, despite the apparent relationship between postoperative contacts and weight loss, postoperative follow up is suboptimal.

Prior to 2012, two agencies provided accreditation for bariatric surgery centers in the United States: American Society for Metabolic and Bariatric Surgery and the

American College of Surgeons. From 2012 to 2014, the two organizations combined to create one accrediting group, the Metabolic and Bariatric Surgery Accreditation Program (MBSAQIP).[150] Accreditation from this program is required by most private payers and is based on established quality standards. These standards include comprehensive preoperative assessment, continuous quality metrics reporting, adequate bariatric specific resources and equipment, required team trainings, and continuous quality improvement. Adherence to these standards is assessed through annual reporting and a site visit every three years.

MBSAQIP standards mandate lifelong follow up for bariatric surgery patients, requesting that accredited centers attempt to contact a patient multiple times using both telephone and written communication to encourage patients to complete follow up visits.[150] More specifically, MBSAQIP requires accredited programs to attempt to complete follow up visits, at minimum, within 30 days of surgery, 6-months, 12-months, and annually thereafter. These requirements have great potential to improve postoperative outcomes; it remains to be seen if the goal of life-long follow up, will be realized.

Summary of the Literature

Obesity is one of our country's most significant public health issues, affecting approximately one-third of American adults at present. Lifestyle modification interventions for weight loss produce clinically significant weight losses in the short-term, but weight regain within a few years is common. For severe obesity, bariatric surgery is the most effective and durable treatment. However, not all patients experience optimal weight loss or sustained weight maintenance, and follow up is poor.

The preoperative assessment and management of candidates for bariatric surgery has long been considered a critical part of postoperative success. However, the evidence to support the value of this process, and MWM in particular, is mixed. Some studies have suggested that preoperative weight loss is associated with greater postoperative weight loss; others have not found this relationship. Some studies have suggested that the duration of MWM has no relationship with postoperative weight losses, despite theories suggesting more time to practice behaviors being associated with favorable outcomes. Still other studies have suggested that the completion of postoperative follow up visits is associated with greater weight loss in the first few postoperative years. However, there have been no studies on the relationship between preoperative patient contacts and subsequent postoperative contacts. The present study was designed to address these issues. Based on social cognitive theory, it could be behaviorally hypothesized that increased frequency of contacts and duration of care with the bariatric surgery team would be associated with larger postoperative percent weight loss and improved follow up. However, little evidence exists supporting this premise, suggesting a non-directional assessment and statistical hypothesis.

The study has 3 specific aims:

1. Assess the relationship between the <u>frequency</u> of preoperative patient contacts with the bariatric team and postoperative percent weight loss.
    a. It is hypothesized that patients with varying frequency of preoperative contacts with the bariatric surgery team will experience differences in postoperative percent weight loss over the first 24 months.

b. Patients with varying number of contacts dedicated with MWM (i.e. contacts with an RD) preoperatively will experience differences in postoperative percent weight loss over the first 24 months.

2. Assess the relationship between the duration of the preoperative assessment process and postoperative percent weight loss.
    a. It is hypothesized that patients with varying number of days of preoperative care with the bariatric surgery team will experience differences in postoperative percent weight loss over the first 24 months.
3. Explore the relationship between the frequency and duration of preoperative contacts with the bariatric surgery team and postoperative contacts over the first 24 postoperative months.
    a. It is hypothesized that the frequency of preoperative contacts with the bariatric surgery team will be associated with retention at 6-, 12-, and 24-month postoperative visits (as required by MBSAQIP).
    b. It is hypothesized that the duration of preoperative care with the bariatric surgery team will be associated with postoperative retention at 6-, 12-, and 24-months.

CHAPTER 3

METHODS

Study Setting and Design

The University of Pennsylvania Health System Metabolic and Bariatric Surgery Program (Penn Bariatrics) is the largest and most experienced bariatric surgery program in the Philadelphia area. The program encompasses three hospitals and six outpatient locations. The clinical team is comprised of professionals from multiple disciplines including surgery, nursing, nutrition, and psychology. Annually, the program performs more than 700 operations, completes more than 10,000 outpatient contacts, and welcomes more than 1,000 patients to its support groups. The Hospital of the University of Pennsylvania earned Bariatric Surgery Center of Excellence (BSCOE) accreditation in 2006 and transitioned to an MBSAQIP-Comprehensive Center with Adolescent Privileges in 2014. Pennsylvania Hospital also secured BSCOE status in 2008 and transitioned to MBSAQIP-Comprehensive Center in 2014. Penn Presbyterian Hospital earned MBSAQIP-Comprehensive Center accreditation in 2015. The program has a rich history of conducting research and has received funding from the National Institutes of Health since 2002 to support this work.

Individuals interested in bariatric surgery at Penn Bariatrics first attend an information session led by a member of the treatment team. The session provides an overview of the program and surgical procedures offered. Persons who then intend to pursue surgery schedule an initial consultation with a bariatric surgeon, nurse practitioner, and RD who evaluate their appropriateness for surgery. Patients also

undergo additional preoperative testing and evaluation recommended by ASMBS. After the initial evaluation with the program, patients complete 3-6 months of monthly preoperative MWM sessions with bariatric clinicians including an RD, with the exact frequency and duration determined by a third-party payer or the clinician. Visits consist of individual counseling by an RD on self-monitoring of dietary intake, exercise, and weight along with behavior modification in preparation for the dietary and behavioral changes required of surgery. Other providers further assess and manage relevant preoperative risk factors (i.e. smoking cessation, euglycemia, CPAP compliance) as needed. Patients also are required to complete a psychological evaluation prior to surgery and attend at least one support group. Individual visits are documented by the clinicians in the electronic medical record (EMR). Telephone encounters, both incoming and outgoing are also documented in the EMR.

The study sample included persons who underwent SG or RYGB from January 1, 2009 through December 31, 2014 at the Hospital of the University of Pennsylvania, the main hospital of Penn Bariatrics. Cases at the remaining hospitals were not included due to variations in preoperative documentation of visits and lack of continuous BSCOE or MBSAQIP accreditation. Cases of individuals under the age of 18 years old at the time of the operation, adjustable gastric banding procedures, open procedures, and revision procedures were excluded due to low volume of cases.

Measures

Demographic Variables

Demographics contained in the EMR used in the analysis included gender, age at time of surgery, race, and payer. Payer was defined as Medicaid, Medicare, private, or Veterans Administration. Smoking status was included in the analysis. Comorbidities documented in the EMR at the time of the operation included type 2 diabetes, hypertension, hyperlipidemia, gastroesophageal reflux disease, obstructive sleep apnea, chronic obstructive pulmonary disease, and chronic kidney disease. These comorbidities are aligned with the major comorbidity data collected by MBSAQIP.[150] Number of comorbidities was defined as a count of previously listed conditions.

Anthropometrics

Height and weight measurements were collected in the EMR in accordance with MBSAQIP definitions. Height was measured by the clinical staff using a calibrated stadiometer. The last measured height prior to surgery was used in the analysis. Weight was measured at each clinical visit by staff using a calibrated scale. Last recorded weight prior to surgery was used as baseline.

Frequency of Preoperative Contacts

Preoperative contacts were defined as any contacts with a member of the team, including physicians, nurse practitioners, nurses, RDs, and psychologists prior to surgery. This included individual visits, support group, and education sessions of initial information session and preoperative education class. Phone encounters or electronic messages through the EMR with the bariatric surgery team were also included. Contacts with an RD were defined as any preoperative contacts that included documentation by an

RD. These were considered MWM visits as well as counted in the total number of contacts. Each type of contact was coded separately in the EMR. All contacts were summed to calculate the frequency of patient-provider contacts during the preoperative assessment process.

Duration of Preoperative Contacts

Preoperative duration was defined as number of days from initial in-person contact (operationalized as attendance at the initial information session or initial individual visit if the patient did not attend a session) to the date of surgery.

Postoperative Weight

Postoperative weight was collected from either the postoperative visit with the surgical team or if missing, from the available primary care provider visit. Visit windows for these weights followed MBSAQIP data collection guidelines and were defined as 6 months (31-273 days postoperatively), 12 months (274-547 days postoperatively), and 24 months (548-912 days postoperatively). If multiple weights were available from a time period, the weight closest to the point of measurement (6, 12 or 24 months) was used.

Postoperative Retention

Postoperative missing follow up was defined as a patient not completing an in-person visit or patient-initiated contact within the projected window. This included in-clinic visits and support group attendance. Telephone calls and EMR messaging were excluded. Visit windows followed MBSAQIP data collection guidelines and were defined as 6 months (31-273 days postoperatively), 12 months (274-547 days postoperatively), and 24 months (548-912 days postoperatively).

Analytic Plan

Data Management

SAS 9.4 was used for data management and analysis. The raw data were abstracted from the EMR by the Penn Data Analytics Center. The data were de-identified by removing any private health information including name, date of birth, and medical record number. Patients were then assigned a random identification code. All character variables were converted to numeric variables with a corresponding data dictionary. String text diagnoses were converted to binary (yes/no) variables for comorbidities of interest (type 2 diabetes, hypertension, obstructive sleep apnea, chronic kidney disease, chronic obstructive pulmonary disease, hyperlipidemia, gastroesophageal reflux disease).

Frequency was calculated as total number of preoperative contacts prior to surgery, including in-person visits, education sessions, support groups, telephone calls, electronic messages, as well as visits with the psychologist, and labeled as total number of preoperative contacts. This was then repeated to create separate variables of number of preoperative visits with an RD and by each type of contact (i.e. individual visit, education session, support group, telephone, electronic messaging). Frequency was also measured in an annualized form to account for time and intensity of treatment. Annualized rate of preoperative contacts was calculated as $(\text{NumberOfContacts}/\text{Duration}_{\text{days}})*365_{\text{days}}$. The variable of duration of preoperative care was calculated using the date of initial contact and date of surgery and calculated as $\text{Surgery}_{\text{date}} - \text{InitialContact}_{\text{date}}$ and measured in days. BMI was calculated using weight at baseline, 6 months, 12 months, and 24 months postoperatively (and baseline height) with the standard equation of $\text{Weight}_{\text{kg}} / \text{Height}_{\text{m}}^2$. Percent weight loss was the primary outcome variable. This was calculated as

$Weight_{Baseline}$ -- $Weight_{xMonth}$ / $Weight_{Baseline}$ at 6 months, 12 months, and 24 months postoperatively. Percent excess weight loss was also described and calculated as ($Weight_{Baseline}$ -- $Weight_{xMonth}$) / [$Weight_{Baseline}$ – (25*$Height_m^2$)]. Dummy variables for missing follow up and percent weight loss less than 20% were also created for each time period.

Preliminary Analysis

Descriptive statistics were performed to assess the sample characteristics. The majority of missing data was expected to be postoperative weight data. Univariate generalized linear mixed models of each demographic variable and missing postoperative weight based on alpha = 0.1 were used to identify variables to be included in a secondary multivariate analysis. The results of the subsequent multivariable analysis were then included as covariates in the primary analysis. Means and frequency of continuous and categorical values were used to provide insight to any areas of largely missing data, incorrectly recoded variables, or implausible data possibly due to error. Continuous variables were assessed to identify any outliers. Sensitivity analysis examining the association between postoperative percent weight loss and missing weight data was used to assess the missing at random assumption.

Primary Aim

To test hypothesis 1a, a multivariate generalized linear mixed model controlling for covariates determined in the preliminary analysis assessed the association between the frequency of preoperative contacts and postoperative total percent weight loss over the first 24 months postoperatively. Due to the limited missing data for predictor variables, PROC GLIMMIX SAS function was used to handle missing outcome data by maximum

likelihood.[151] In addition to variables identified in the preliminary analysis, the model controlled for age, sex, race, procedure, baseline BMI, and insurance, secondary to varying preoperative requirements.[141,152] Another mixed model was used to examine hypothesis 1b--the relationship between number of preoperative contacts with the RD (MWM) and postoperative percent weight loss, controlling for the same factors. As the statistical hypothesis was non-directional, two-tailed test based on alpha = 0.05 was used for both models. ANOVA was used to identify any relationship between baseline characteristics and number of preoperative contacts. An additional logistic regression was used to assess the relationship between baseline variables and percent weight loss of less than 20%, the lower end of the expected weight loss in the first two postoperative years.[79-84,90-92]

Secondary Aim

To test hypothesis 2a, a multivariable generalized linear mixed model analysis, including the same covariates as the primary analysis, assessed the relationship between duration of preoperative care with the surgical team and postoperative percent weight loss over the first 24 months. Since the statistical hypothesis did not predict a directional outcome, a two-tailed test based on alpha = 0.05 was conducted.

Tertiary Aim

The third aim of exploring the relationship between the frequency and duration of preoperative visits on the completion of postoperative follow up visits was assessed by generalized logistic regression at each visit point. As there was not compelling information from the literature to make a directional prediction about the relationship, a two-tailed test based on alpha = 0.05 was used.

CHAPTER 3

RESULTS

Characteristics of the Study Sample

Demographic characteristics of participants are reported in Table 1. Approximately 75% of the sample was female and just over half identified as white (N = 770, 51.3%). The mean age at time of surgery was 44.1 years (SD = 11.8). With respect to insurance coverage at time of surgery, approximately half were insured with a private plan (N = 790, 52.7%), 302 (15.5%) had Medicaid, and 232 (20.1%) had Medicare. Four individuals had a Veteran's Administration plan and the remaining (N = 172, 11%) were missing or unknown.

Table 1. Baseline Demographics of Adults Prior to Bariatric Surgery (N=1500)

Variable		Count	Percent
Sex			
	Female	1126	75.1
	Male	374	24.9
Age, y			
	Mean (SD)	44.1	11.8
	Range	18 – 78	
Race			
	White	770	51.3
	Non-White	730	48.7
Insurance			
	Private	790	52.7
	Medicaid	302	20.1
	Medicare	232	15.5
	Veterans Administration	4	0.3
	Missing/Unknown	172	11.5

Table 2 summarizes the baseline clinical characteristics of the sample. Mean weight prior to surgery was 136.6 kg (SD = 29.5) and BMI was 48.0 kg/m^2 (SD = 8.5). The type of surgical procedure was nearly evenly split between RYGB (N = 775, 51.7%) and SG (N = 725, 48.3%). The majority of the sample reported that they never smoked (N = 885, 57%); remaining reported being a former or current smoker (N = 615, 43%). Most had a diagnosis of hypertension (N = 901, 60.1%) and/or a diagnosis of obstructive sleep apnea (N = 804, 53.6%). Forty-three percent had a diagnosis of gastroesophageal reflux disease and a third had type 2 diabetes and/or hyperlipidemia. Of the seven comorbidities assessed, the mean number of diagnoses per patient was 2.3 (SD = 1.5).

Table 2. Baseline Clinical Characteristics of Adults Prior to Bariatric Surgery (N=1500)			
Variable		Count/Mean	Percent/SD
Weight, kg		136.6	29.5
	Range	77.6 - 300.1	
BMI, kg/m^2		48.0	8.5
	Range	32.5 - 84.0	
Surgical Procedure			
	Roux-en-Y Gastric Bypass	775	51.7
	Vertical Sleeve Gastrectomy	725	48.3
Smoking Status			
	Never	885	57.0
	Former/Current	615	43.0
Comorbidity			
	Hypertension	901	60.1
	Obstructive Sleep Apnea	804	53.6
	Gastroesophageal Reflux Disease	645	43.0
	Diabetes	506	33.7
	Hyperlipidemia	465	31.0
	Chronic Obstructive Pulmonary Disease	69	4.6
	Chronic Kidney Disease	42	2.8
Number of Comorbidities			
	Mean (SD)	2.3	1.5
	Range	0-7	

The frequency of patient-provider preoperative contacts and days from the initial contact with the surgical team to the day of surgery are shown in Table 3. Patients had a median of nine preoperative total contacts (IQR = 7, 11). The mean annualized rate of contacts was 16 (IQR = 9, 24). The greatest number of contacts were in-person, individual visits (Median = 4, IQR = 2, 26). Median education session, support group, and contacts with the psychologist were all one contact each. Median number of contacts with an RD for MWM prior to surgery was 4 (IQR = 2, 6). Median days from initial contact to surgery was 196 (IQR = 132, 374).

Table 3. Frequency of Contacts Prior to Bariatric Surgery and Days from Initial Preoperative Contact to Surgery

		Median	IQR
Preoperative Contacts		9	7, 11
	Range	4 – 74	
Annualized Rate of Contacts		16	9, 24
	Range	1-95	
Contacts by Type			
	Individual	4	2, 26
	Telephone	2	0, 38
	Support Group	1	1, 8
	Education	1	0, 5
	Electronic	0	0, 6
	Psychology	1	1, 5
Contacts with RD		4	2, 6
	Range	1 – 19	
Preoperative Duration, days		196	132, 374
	Range	27-3721	

IQR = Interquartile Range

Table 4 and Figure 1 describe the observed weight changes for the sample at 6, 12, and 24 months postoperatively. At 6 months and 12 months, mean percent weight loss was 21.7% $\pm$ 6.0% and 27.3% $\pm$ 9.1%, respectively. Mean percent weight loss at 24 months was 27.0% $\pm$ 11.2. Mean weight loss at 6 months was 29.6 kg $\pm$ 10.4 and 12 months was 37.1 kg $\pm$ 14.7. At 24 months post-bariatric surgery, mean weight loss was 36.3 kg $\pm$ 17.1.

Table 4. Weight, Body Mass Index, Percent Body Weight Change, and Percent Excess Weight Loss after Bariatric Surgery; Observed Data

	Mean (SD)							
	Baseline		6 months		12 months		24 months	
	n=1500		n=1090		n=783		n=570	
	M	SD	M	SD	M	SD	M	SD
Weight, kg	136.6	29.6	107.0	24.9	98.7	24.5	98.4	26.4
BMI, kg/m^2	48.0	8.5	37.7	7.6	34.9	7.7	34.8	8.3
Weight Loss, kg	--		29.6	10.4	37.1	14.7	36.3	17.1
Excess Weight Loss, %	--		48.4	16.4	60.7	22.4	60.1	26.3
Weight Change, %	--		21.7	6.0	27.3	9.1	27.0	11.2

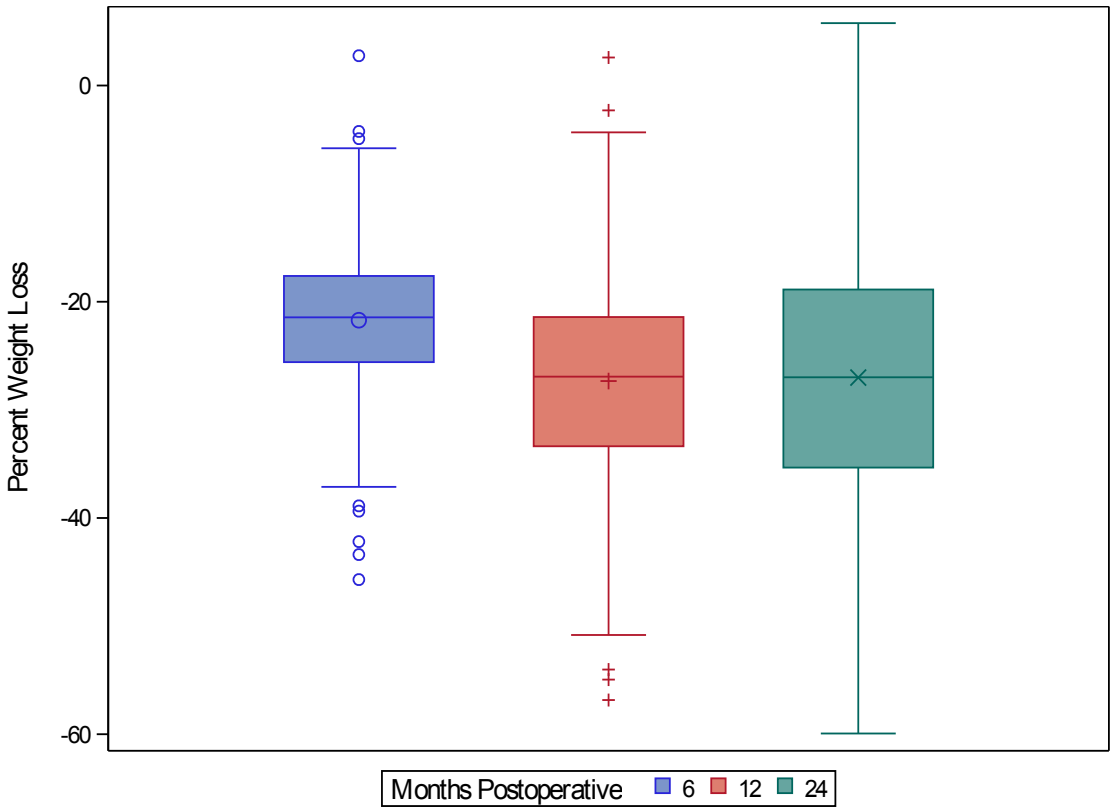

Figure 1. Weight, Body Mass Index, Percent Body Weight Change, and Percent Excess Weight Loss after Bariatric Surgery; Observed Data

Preliminary Analysis

The median duration of the preoperative assessment period in the sample was 196 days (IQR 132, 374). The period ranged from 27 days to 3721 days, greater than 10 years. The size of this range warranted assessment for outliers. Figure 2 presents a histogram of the distribution of preoperative duration. Approximately 1% of the sample (21 cases) had an observed preoperative duration greater than five years (1825 days). This was more than five times the longest mean duration of preoperative care published (344 days).[153] Therefore, these 21 cases were considered clinical outliers and excluded from the final analyses. Four individuals with Veterans Administration insurance were excluded due the relative infrequency of this insurance type in the sample. An additional 172 cases were excluded secondary to missing insurance data. A final sample of 1303 cases were included in the analyses below.

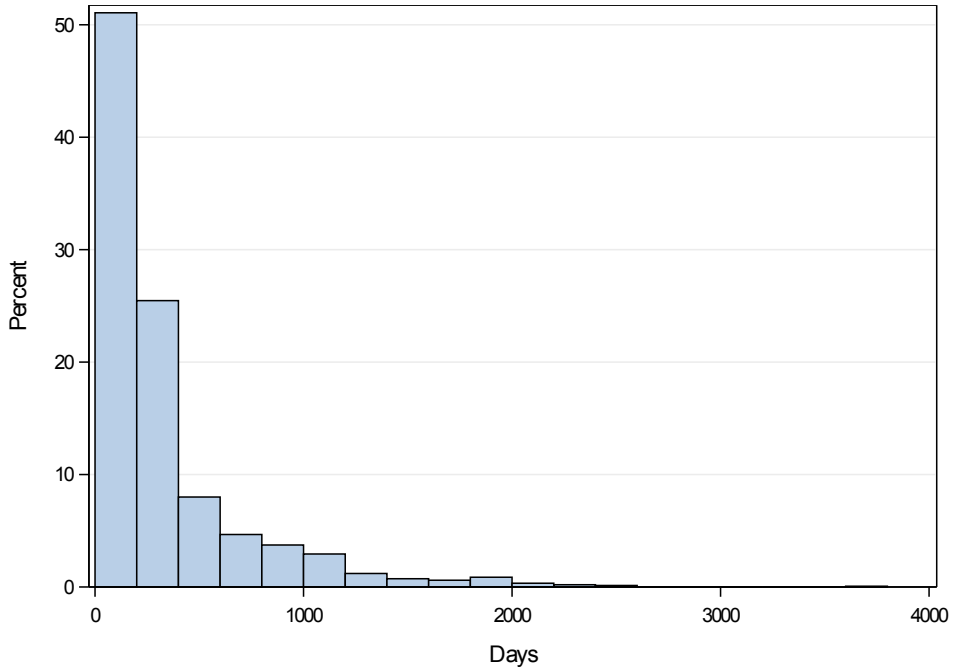

Figure 2. Histogram of Preoperative Duration Distribution

Table 5 presents the relationship between relevant baseline variables and missing postoperative data, to assess for the need to consider these variables as covariates in subsequent analyses. The relationship of age at time of surgery, sex, race, smoking status, BMI, procedure, insurance, and number of comorbidities to missing postoperative weight over the first 24 months postoperatively were each evaluated using a univariate generalized linear mixed model. Using a significance value of alpha = 0.1, age, sex, insurance, and number of comorbidities were included in the multivariable analysis. Surgical procedure (P = 0.01), insurance coverage (P = 0.0003) and number of comorbidities (P < 0.0001) were associated with missing follow up variables. As a result, these factors were identified and used as covariates for the primary analysis. Age, race, sex, and baseline BMI also were included in the analyses due to varying preoperative requirements and previous studies finding differences in postoperative weight loss.[141,152]

Table 5. Analysis to Identify Baseline Variables Associated with Missing Follow up Weights in the Analysis Sample (N=1303)	
Baseline Variable	P
Age	<0.0001
Sex	0.34
Race	0.25
Smoking Status	0.22
BMI	0.80
Surgical Procedure	0.009
Insurance	<0.0001
Number of Comorbidities	<0.0001
Multivariable Analysis	
Age	0.56
Surgical Procedure	0.01
Insurance	0.0003
Number of Comorbidities	<0.0001

Table 6 displays the sensitivity analysis performed to assess the robustness of the results in regards to the missing at random assumption. When controlling for age, sex, race, procedure, smoking status, baseline BMI, insurance, and number of comorbidities, and using a significance value of alpha = 0.05, no association was found between missing postoperative weights and percent weight loss at any time point. This indicates that overall missing follow up data were likely not related to the outcome, and therefore should not bias the results.

Table 6. Mean Postoperative Percent Body Weight Loss by Whether Weight was Missing at Each Follow Up Assessment																
	6 months				12 months				24 months				Any Visit			
	Observed		Missing		Observed		Missing		Observed		Missing		Observed		Missing	
	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
6 months	-		-		22.0	5.9	21.2	6.0	22.1	6.0	21.4	5.9	21.4	5.9	22.2	5.9
12 months	27.1	9.1	28.0	9.2	-		-		27.3	9.2	27.0	8.9	27.1	9.2	27.3	9.0
24 months	27.0	11.0	27.5	12.0	27.3	11.1	26.0	10.8	-		-		26.6	11.1	27.3	11.1
	P = 0.94				P = 0.50				P = 0.49				P = 0.66			

Note. P values based on mixed models, adjusted for age, sex, race, smoking status, BMI, surgical procedure, insurance, number of comorbidities.

Note. 172 cases excluded due to missing insurance data.

Note. 4 cases excluded to due low volume of Veteran's Administration insurance.

Note. 21 cases excluded due to preoperative duration of >5 years.

Aim 1 – The Relationship between the Frequency of Preoperative Patient Contacts with the Bariatric Team and Postoperative Weight Loss

The relationship between the frequency of preoperative contacts and postoperative weight loss is presented in Table 7 and Table 8. For annualized rate of preoperative contacts shown in Table 7, no association was found between annualized rate and postoperative weight loss (P = 0.12). As seen in Table 8, each additional preoperative contact (not accounting for period of time between them) was not associated with postoperative weight loss (P =0.42).

More specific relationships were identified among the covariates and presented in Table 7. Non-white participants experienced 1.78% smaller weight loss compared to their white counterparts (95% CI -2.73%, -0.84%, P = 0.0002). Each additional year in age was associated with a 0.13% smaller postoperative weight loss (95% CI -0.07%, 0.03%; P < 0.0001). Each additional comorbidity was associated with a 0.60% smaller percent weight loss (95% CI -0.93%, -0.27%; P = 0.0003). Patients who underwent RYGB experienced 4.35% greater percent weight loss compared to SG patients (95% CI 3.49%, 5.21%; P <0.0001). No associations were found between sex, baseline BMI, or insurance and postoperative percent weight loss.

Table 7. Association between Annualized Rate of Preoperative Contacts and Postoperative Percent Weight Loss						
	Estimate	SE	t Value	95% CI		P
Variable				Lower	Upper	
Annualized Rate of Contacts	0.03	0.02	1.55	-0.008	0.07	0.12
Female (vs. Male)	0.04	0.54	0.08	-1.01	1.09	0.93
Non-White (vs. White)	-1.78	0.48	-3.70	-2.73	-0.84	0.0002
Age	-0.13	0.02	-5.62	-0.17	-0.06	< 0.0001
RYGB (vs. SG)	4.35	0.44	9.93	3.49	5.21	< 0.0001
BMI	-0.02	0.03	-0.65	-0.07	0.03	0.51
Number of Comorbidities	-0.60	0.17	-3.60	-0.93	-0.27	0.0003
Insurance						0.05
Medicaid (vs. Private)	-1.19	0.61	-1.97	-2.38	-0.01	0.05
Medicare (vs. Private)	-1.24	0.64	-1.94	-2.50	0.02	0.05

Table 8. Association between Number of Preoperative Contacts and Postoperative Percent Weight Loss						
	Estimate	SE	t Value	95% CI		P
Variable				Lower	Upper	
Preoperative Contacts	-0.05	0.06	-0.81	-0.16	0.07	0.42
Female (vs. Male)	0.009	0.54	0.002	-1.04	1.06	0.99
Non-White (vs. White)	-1.85	0.48	-3.85	-2.79	-0.91	0.001
Age	-0.13	0.02	-5.86	-0.17	-0.08	< 0.0001
RYGB (vs. SG)	4.21	0.46	9.16	3.31	5.11	< 0.0001
BMI	-0.02	0.03	-0.72	-0.07	0.03	0.47
Number of Comorbidities	-0.63	0.17	-3.79	-0.95	-0.30	0.0002
Insurance						0.11
Medicaid (vs. Private)	-1.02	0.61	-1.69	-2.21	0.17	0.09
Medicare (vs. Private)	-1.07	0.65	-1.65	-2.35	0.20	0.10

Table 9 displays the univariate analyses which assessed the relationship between preoperative contacts with any member of the team, the RD (representing MWM), and the psychologist, and postoperative weight loss, controlling for sex, race, age, procedure, baseline BMI, number of comorbidities, and insurance. No association was found between number of visits with an RD and postoperative weight loss (-0.12%, 95% CI -0.30%, 0.05%; P = 0.16). Each additional contact with a psychologist prior to surgery was associated with a 1.46% smaller postoperative weight loss (95% CI -2.79%, -0.12%; P = 0.03). Each additional individual visit contact with a member of the bariatric surgery team, excluding psychology, was associated with a 0.26% smaller percent weight loss (95% CI -0.47%, -0.05%; P = 0.02). No association was found between education, support group, telephone, or electronic contacts and postoperative weight loss.

Table 9. Association between Preoperative Contacts with a Registered Dietitian, Psychologist, and Contact Type and Postoperative Percent Weight Loss

	Estimate	SE	t Value	95% CI		P
Variable				Lower	Upper	
Contacts with RD	-0.12	0.09	-1.41	-0.30	0.05	0.16
Education Contacts	0.11	0.27	0.41	-0.43	0.65	0.68
Individual Contacts	-0.26	0.12	-2.44	-0.47	-0.05	0.02
Support Group Contacts	-0.04	0.45	-0.10	-0.92	0.84	0.92
Telephone Contacts	0.15	0.53	1.29	-0.08	0.37	0.20
Electronic Contacts	-0.18	0.41	-0.44	-0.98	0.62	0.66
Psychology Contacts	-1.46	0.68	-2.15	-2.79	-0.12	0.03

Note. Univariate analyses adjusted for age, sex, race, smoking status, BMI, surgical procedure, insurance, number of comorbidities.

The relationship between annualized frequency of preoperative contacts and baseline variables also was explored. Table 10 displays a sub-analysis examining the differences in annualized preoperative contacts by demographic and clinical variables. Younger patients completed more annualized preoperative contacts (P = 0.001). White patients completed more annualized preoperative contacts than non-white (18.92 $\pm$ 11.40 vs 17.02 $\pm$ 10.61; P = 0.002). Medicaid recipients completed the most number of contacts, followed by Medicare, and private insurance recipients (P = 0.03). Increased number of comorbidities was associated with a smaller number of annualized preoperative contacts (P < 0.0001). No association was found between annualized number of preoperative contacts and sex, surgical procedure, or BMI.

Table 10. Annualized Frequency of Preoperative Contacts by Demographic and Clinical Variables				
Variable		M	SD	P
Age, y				0.001
	18-34	20.23	11.67	
	35-44	17.48	11.44	
	45-53	17.61	11.28	
	≥54	16.83	9.38	
Sex				0.53
	Male	18.31	10.60	
	Female	17.87	11.20	
Race				0.002
	White	18.92	11.40	
	Non-White	17.02	10.61	
Surgical Procedure				0.14
	RYGB	15.52	10.79	
	SG	18.42	11.28	
BMI				0.07
	<40	17.64	10.24	
	40-44.9	19.26	11.62	
	45-49.9	17.35	11.53	
	≥50	17.49	10.52	
Number of Comorbidities				< 0.0001
	0-1	20.42	12.70	
	2-3	17.56	10.04	
	4-5	15.84	10.02	
	6-7	12.76	10.18	
Insurance				0.03
	Private	17.64	11.11	
	Medicare	17.25	10.68	
	Medicaid	17.64	11.11	

A sensitivity analysis was performed to explore the relationship between the baseline variables of interest and weight loss. Table 11 describes the results of an analysis to identify variables associated with patient's experiencing a < 20% weight loss. A logistic regression model was used to determine overall association. Older age (P <0.0001), SG (P < 0.0001), greater BMI (P < 0.05), and greater number of comorbidities (P = 0.0003) were associated with the likelihood of postoperative weight losses of < 20% at the end of the second postoperative year.

Table 11. Analysis to Identify Baseline Variables Associated with < 20% Weight Loss

Variable	P
Sex	0.74
Age	< 0.0001
Race	0.07
Insurance	0.12
Surgical Procedure	< 0.0001
BMI	0.03
Number of Comorbidities	0.0004
Smoking Status	0.53
Preoperative Contacts	0.72
Preoperative Duration	0.39

Aim 2 - The Relationship between the Duration of Preoperative Patient Contacts with the Bariatric Team and Postoperative Weight Loss

Table 12 displays the association between the duration of the preoperative evaluation period (days from initial contact to surgery) and postoperative weight loss. Duration of the period was not associated with postoperative percent weight loss (P = 0.40). Covariate assessment results were consistent with the analyses of Aim 1, with no association found between sex, age, procedure, baseline BMI, number of comorbidities, or insurance and postoperative percent weight loss. Non-white, older, and SG patients and patients with a greater number of comorbidities experienced a smaller postoperative percent weight loss.

Table 12. Association between Duration of the Preoperative Assessment Period and Postoperative Percent Weight Loss

Variable	Estimate	SE	t Value	95% CI		P
				Lower	Upper	
Preoperative Duration	-0.0005	0.0006	-0.84	-0.002	-0.0007	0.40
Female (vs. Male)	0.04	0.54	0.07	-1.01	1.09	0.94
Non-White (vs. White)	-1.82	0.48	-3.77	-2.77	-0.87	0.0002
Age	-0.13	0.02	-5.68	-0.17	-0.08	< 0.0001
RYGB (vs. SG)	4.25	0.45	9.52	3.78	5.13	< 0.0001
Baseline BMI	-0.02	0.03	-0.73	-0.07	0.03	0.47
Number of Comorbidities	-0.62	0.17	-3.68	-0.95	0.29	0.0002
Insurance						0.07
Medicaid (vs. Private)	-1.10	0.60	-1.83	-2.29	0.08	0.07
Medicare (vs. Private)	-1.15	0.64	-1.81	-2.41	0.10	0.07

Aim 3 - The Relationship between the Frequency and Duration of Preoperative Contacts with the Bariatric Surgery Team and Postoperative Contacts over the First 24 Postoperative Months

Tables 13-16 display the association between baseline characteristics and missing follow up at 6, 12, and 24 months. No association was found between the duration of the preoperative process, frequency of preoperative contacts and attendance at all recommended visits in the first two postoperative years. When assessing specific time points, no association was found between frequency or duration of preoperative contacts and participants missing a follow up visit at each of the individual recommended follow up time points (6, 12, or 24 months postoperatively).

Examining the covariates, being female was associated with failure to complete the 12 month visit (OR 1.42, 95% CI 1.08, 1.88; P = 0.01); however this was not seen at any other time point. Increased age was associated failure to complete the 6-month contact (OR 1.02, 95% CI 1.00, 1.04; P = 0.04); however this effect was lost at 12- and 24-months. Patients with Medicare coverage when compared with private payers were less likely to not complete the 6-month appointment (OR 0.39, 95% CI 0.22, 0.67; P = 0.01), however this effect was also lost at 12- and 24- months. Patients with Medicaid coverage were less likely to not complete all the follow up visits (OR 0.55, 0.36, 0.82; P = 0.003), specifically the 6- and 12-month visits. Patients who underwent RYGB were less likely to complete all recommended contacts as compared to those who underwent SG (OR 1.62, 95% CI 1.22, 2.15; P = 0.0009), specifically at 12-months and 24-months. Increased number of comorbidities was also associated with failure to complete all

recommended contacts, the 12-month contact, and the 24-month contact (P < 0.0001, P = 0.01, P = 0.004).

Table 13. Association between Baseline Characteristics and Missing 6 Month Follow Up Visit (N Missing/Complete = 124/1179)				
	OR	95% CI		P
Variable		Lower	Upper	
Preoperative Contacts	0.99	0.94	1.04	0.65
Preoperative Duration	1.00	1.00	1.01	0.18
Age	1.02	1.00	1.04	0.04
Female (vs. Male)	1.44	0.90	2.30	0.13
Non-White (vs. White)	0.68	0.44	1.05	0.08
BMI	1.00	0.98	1.02	0.49
RYGB (vs. SG)	1.40	0.96	2.07	0.09
Number of Comorbidities	1.10	0.96	1.28	0.18
Insurance				0.001
Medicaid (vs. Private)	0.52	0.32	0.84	0.01
Medicare (vs. Private)	0.39	0.22	0.67	0.001

Table 14. Association between baseline characteristics and missing 12 month follow up visit (N Missing/Complete = 648/655)				
	OR	95% CI		P
Variable		Lower	Upper	
Preoperative Contacts	1.02	0.98	1.05	0.34
Preoperative Duration	1.00	1.00	1.00	0.52
Age	1.00	0.99	1.01	0.71
Female (vs. Male)	1.42	1.08	1.88	0.01
Non-White (vs. White)	0.85	0.66	1.09	0.19
BMI	1.01	1.00	1.02	0.14
RYGB (vs. SG)	1.48	1.16	1.87	0.001
Number of Comorbidities	1.26	1.15	1.38	< 0.0001
Insurance				0.0004
Medicaid (vs. Private)	0.54	0.40	0.74	< 0.0001
Medicare (vs. Private)	0.92	0.66	1.29	0.63

Table 15. Association between Baseline Characteristics and Missing 24 Month Follow Up Visit (N Missing/Complete = 924/379)				
	OR	95% CI		P
Variable		Lower	Upper	
Preoperative Contacts	1.02	0.99	1.06	0.28
Preoperative Duration	1.00	1.00	1.00	0.52
Age	1.00	0.99	1.01	0.76
Female (vs. Male)	1.15	0.86	1.55	0.34
Non-White (vs. White)	0.75	0.57	0.98	0.03
BMI	1.00	0.99	1.02	0.80
RYGB (vs. SG)	1.39	1.03	1.24	0.01
Number of Comorbidities	1.13	1.03	1.24	0.01
Insurance				0.42
Medicaid (vs. Private)	0.83	0.59	1.16	0.27
Medicare (vs. Private)	1.08	0.76	1.54	0.66

Table 16. Association between Baseline Characteristics and Missing Any Follow Up Visits (N Missing/Complete = 1007/296)				
	OR	95% CI		P
Variable		Lower	Upper	
Preoperative Contacts	1.03	1.00	1.07	0.08
Preoperative Duration	1.00	1.00	1.00	0.41
Age	1.01	0.99	1.02	0.35
Female (vs. Male)	1.11	0.81	1.52	0.53
Non-White (vs. White)	0.73	0.54	0.98	0.04
BMI	1.00	0.99	1.02	0.66
RYGB (vs. SG)	1.62	1.22	2.15	0.0009
Number of Comorbidities	1.16	1.05	1.29	0.004
Insurance				0.01
Medicaid (vs. Private)	0.55	0.36	0.82	0.003
Medicare (vs. Private)	1.02	0.70	1.48	0.92

CHAPTER 4

DISCUSSION

Summary

The present study aimed to determine whether the frequency of preoperative contacts with the bariatric surgery team and duration of preoperative care were associated with postoperative weight loss. The relationship between these two preoperative variables and attrition from postoperative care also was explored. The findings do not support the two primary hypotheses that preoperative frequency and duration of care is associated with postoperative weight loss. The number of contacts with an RD prior to surgery, representing participation in preoperative MWM, was not associated with postoperative weight loss. However, additional individual visits with the bariatric surgery team was associated with a 0.26% smaller weight loss. These individual visits were completed by any clinician on the surgical team (surgeon, nurse practitioner, nurse, or RD) and excluded telephone, electronic messaging, support group, education sessions, or visits with the psychologist. Each additional visits with the psychologist, beyond the one required by both the program and third party payers, was associated with 1.39% smaller percent weight loss. Race, age, procedure, and number of comorbidities were associated with postoperative weight loss as well. Neither number of preoperative contacts nor duration were associated with missing postoperative visits over the first two postoperative years.

These major findings, along with some secondary results, are discussed in detail below.

Aim 1 - Preoperative Contacts and Postoperative Weight Loss

Participants were found to have a median of 9 preoperative contacts with the bariatric surgery program over a period of approximately 28 weeks between their initial information session and surgical procedure. The number of contacts was not associated with postoperative percent weight loss. This is in contrast to the theoretical hypothesis, based on social cognitive theory, that preoperative contacts would provide the clinicians opportunities to provide counseling on self-regulation strategies as well as the dietary and behavioral requirements of bariatric surgery that would promote greater weight loss. When annualizing the frequency of contacts (to control for variability in the duration of the preoperative evaluation process), the frequency of contacts remained unassociated with weight losses, suggesting that the "intensity" of the preoperative counseling period is also unrelated to postoperative weight loss.

The number of preoperative contacts with the RD, representing preoperative MWM, was not associated with postoperative weight loss. National guidelines suggest that an indication for surgery is the ability to demonstrate understanding of postoperative dietary recommendations.[75,111] This often is operationalized as a nutrition assessment by an RD prior to surgery in addition to, and separate from, MWM, which is required of most third-party payers prior to authorization for surgery. Demonstrating adequate understanding of postoperative nutrition requirements is an integral part of the preoperative evaluation process.[75] However, the present study, as well as other investigations, have found that a behavioral nutrition intervention in the form of MWM may not be solely effective at improving postoperative weight loss. For example, Jamal and colleagues randomized RYGB patients to 13 weeks of weekly nutritional counseling

or no counseling and found that patients who underwent counseling experienced smaller weight losses at 12 months postoperatively.[127] While surprising, Jamal and colleagues suggested that the nutrition counseling was perceived by patients as a barrier to surgical treatment, rather than an intervention to improve outcomes, as the dropout rate was twice as high as in the group not required to complete the nutrition counseling. Studies following patients for up to two years have found similar results.[132,141] The most recent studies evaluating insurance-mandated MWM also have found no difference in weight loss between mandated MWM and no MWM at both 1 and 2 years postoperatively.[132,154] The findings of the present study add to the growing body of literature calling into question the relevance of preoperative MWM, suggesting nutrition intervention may not be impacting early postoperative weight loss as previously thought. However, it is important to note that there is great variability to the approach of MWM. While the theoretical tenants of the approach are consistent with social cognitive theory, and specific behavioral instruction borrows from state-of-the-art intensive lifestyle modification programs for weight loss, there has yet to be a large, controlled study of the preoperative delivery of robust lifestyle modification interventions available.

Although MWM is viewed by many in the field as a period of preparation prior to surgery to address maladaptive dietary behaviors and practice specific postoperative dietary recommendations, the findings imply that those interventions may not translate into additional postoperative weight loss. Unlike in preoperative MWM, adherence to postoperative dietary recommendations has been found to be associated with weight loss at more than seven years post-RYGB, and dietary intake at 6 months post-RYGB has shown to be predictive of weight up to 10 years postoperatively.[155,156] Patient perceptions

of postoperative nutrition interventions have been shown to be favorable as well, with patients previously reporting that postoperative nutrition interventions would be beneficial, however they cited lack of insurance coverage as the primary barrier to these services.[157,158] With the current study's findings, it may be that nutrition intervention may be more beneficial in the postoperative period.

While the frequency of visits with the RD prior to surgery was unrelated to postoperative weight loss, each additional individual visit with the bariatric team was associated with a 0.26% smaller percent weight loss (P = 0.02). This is also at odds with the theoretical hypothesis suggesting that increased contacts would be associated with larger postoperative weight losses. Instead, it may be that these additional contacts are a reflection of the clinical judgement of the treatment team. During the regularly scheduled sessions, treatment providers may be observing behaviors such as difficulty understanding or adhering to clinical recommendations that are leading them to schedule additional visits in an effort to mitigate these issues. While these additional individual visits are associated with smaller postoperative weight losses, it may be that these outcomes would be even less positive without this additional preoperative attention.

Additional visits with the psychologist also were associated with smaller weight loss. Bariatric care guidelines recommend that individuals thought to have relevant psychiatric comorbidities undergo a mental health evaluation prior to surgery.[48,159] In the United States, most third party payers mandate this evaluation as a pre-requisite to surgery. In the present study, additional psychological contacts were associated with a 1.46% smaller weight loss postoperatively. A number of studies have shown that individuals who present for bariatric surgery have higher rates of significant

psychopathology as compared to the general population.[160,161] Severe, untreated psychopathology is widely considered a contraindication to bariatric surgery.[110,162] Studies have suggested that between 10-20% of patients receive a recommendation from the mental health professional to enter into mental health treatment, or engage in adjunctive treatments (such as individual psychotherapy or attendance in the bariatric surgery program's support group) prior to surgery.[163,164] In these cases, patients are typically recommended to return for a follow up evaluation for clearance for surgery. Results from this study indicate that patients who ultimately have two or more contacts with the psychologist prior to surgery (5% of patients in the present study) experience smaller weight losses.

This observation indicates that these evaluations likely are identifying relevant psychosocial, behavioral, or environmental issue that may contribute to postoperative outcomes. This is in contrast to a recent opinion paper arguing that preoperative psychological evaluation may not be necessary for all surgical candidates.[162] The findings of this study may serve as a signal to the clinical team that patients with increased contacts with the psychology bariatric team members may be more likely to experience smaller weight losses postoperatively and may need additional assistance postoperatively to experience optimal outcomes.

Aim 2 - Preoperative Duration and Postoperative Weight Loss

The preoperative assessment process was observed to be longer, a median of 196 days from initial contact until surgery, compared to several other studies. Kuwada and colleagues' reported a preoperative assessment period of 105 days; Schneider and colleagues' reported 164 days.[128,147] Comparatively, Hayes and colleagues reported

approximately 334 days from initial contact to surgery in their sample.[153] Anecdotally, the authors of Hayes' study attributed the large variance in preoperative assessment days to internal program differences in their bariatric center's processes that lengthen the overall assessment period. The amount of time from initial contact to surgery is not commonly reported, despite it being an integral part of the bariatric surgery process. Most insurers require 3-6 months of MWM. How long that requirement actually translates to in office care is not well documented or often reported in the literature.

When taking into account both number of contacts and duration, by calculating the annualized rate of contacts, no relationship between preoperative contacts and postoperative weight loss was found. As noted above, the established recommendation of demonstrating adequate understanding of postoperative dietary requirements without additional counseling may be sufficient, with greater impact being feasible in the postoperative period.

Aim 3 - Preoperative Care and Postoperative Follow Up

The study found no association between the preoperative duration or frequency of contacts and completion of postoperative visits in the first two postoperative years. These findings also do not support the hypothesis that greater preoperative contacts may provide additional opportunity to build rapport with the clinical team that promotes continued follow up postoperatively. The results of this study suggest that preoperative contacts may not be an appropriate area for intervention to reduce postoperative attrition.

A number of demographic and descriptive variables were associated with postoperative follow-up. Older patients, as well those with Medicare, were more likely to miss the recommended 6-month postoperative visit. Women were more likely than men

to miss the recommended 12-month postoperative visit. While interesting, these findings are difficult to interpret without an examination of theoretically relevant behavioral and psychosocial variables that were not included in this study. These include self-efficacy, depression, and motivation/readiness. Patients with more medical comorbidities prior to surgery were less likely to return for postoperative visits. This result can be interpreted in several ways. First, it may be that these individuals face other physical or medical barriers that limit their ability to engage with recommended follow up. Second, patients with complex medical histories often have psychological or behavioral issues which contribute to their overall health and ability to engage in health care.[164] Unfortunately, this relationship was unable to be investigated in depth in the present study.

Demographic Variables and Postoperative Weight Loss

Men and women did not differ in postoperative weight loss. Several studies have found that men experience greater weight loss after bariatric surgery.[165,166] By contrast, in a study of over 20,000 bariatric surgery patients (58% RYGB and 40% SG) women were found to have greater weight losses at both 12 and 24 months postoperatively.[167] Other studies examining gender differences have found that males seeking bariatric surgery are more likely to have a greater number of comorbidities when compared to females.[168-170] For example, Stroh and colleagues found that male bariatric surgery candidates were more likely than females to have hypertension, insulin dependent and non-insulin dependent diabetes, and obstructive sleep apnea when compared to their female counterparts.[169] Males in the current study had a greater mean number of comorbidities compared to females (2.8 vs. 2.2); the number of comorbidities was associated with smaller postoperative weight losses in the present study. This observation

may explain the lack of gender difference. Several studies of this issues have not controlled for number of comorbidities when assessing postoperative weight loss differences.[165,166,171]

Caucasians lost 1.78% more weight over the first two years after surgery as compared to non-white participants. This also replicates other findings in the obesity literature.[165,172] Baseline BMI was not associated with postoperative weight loss. This is in contrast with previous studies that have found increased BMI to be associated with smaller postoperative weight loss.[165,173] As noted above, greater comorbidities prior to surgery was associated with smaller postoperative weight loss. The number of preoperative comorbidities may be considered a proxy measure of the level of clinical complexity of bariatric surgery patients in general. This is consistent with previous findings that greater number of comorbidities is associated with smaller weight losses after surgery.[168-170]

Approximately 40% of the participants included in the study were recipients of government-funded insurance. This is a larger percentage than seen in many other studies in the literature, where roughly one-third of individuals had Medicaid or Medicare.[153,154,174] Medicare and Medicaid recipients experienced smaller percent weight loss at the end of the second postoperative year compared to those patients with private insurance; however this did not reach statistical significance ($P > 0.05$). To qualify for Medicare or Medicaid, an individual would need to be over 65 years old, disabled, or of low socioeconomic status. Each of these factors have been associated with smaller weight loss outcomes in previous studies.[101,175] However, other studies have not found differences in weight loss based on insurance status.[153,176] A recent meta-analysis found

that Medicaid recipients and participants with a private payer had similar weight losses at both 12 and 24 months postoperatively.[176] Studies in the meta-analysis included both single-center and large database samples, comprising of both rural and suburban centers. The current patient sample was from an academic medical center in an urban location and approximately 40% had Medicare or Medicaid coverage. There are more Medicare and Medicaid beneficiaries in urban areas because of population density compared to rural areas, however the percent of the population with Medicare or Medicaid coverage in rural areas is greater.[177,178] In the present study, no significant difference was found between each on the government-funded insurances and private insurance with respect to percent weight loss.

Vertical Sleeve Gastrectomy vs. Roux-en-Y Gastric Bypass

The study sample was comprised of an almost equal split between SG and RYGB procedures. This reflects the shifting trends in surgical procedures over the past decade. In 2011, RYGB and adjustable gastric banding were the procedures of choice, representing 75% of all bariatric surgeries performed in the United States.[134] Currently, almost 60% of procedures performed in the United States are SG.[89] In the present study, RYGB patients experienced 4.35% larger percent weight loss over the first two postoperative years. These observations are consistent with several studies which have found that RYGB typically produces larger weight losses than SG over the first two years.[48,76,154] For example, the Michigan Surgery Collaborative (MSC) found that RYGB was associated with an excess weight loss of 70% and SG of 60% two years postoperatively.[179] [75]

Attrition has long been a challenge of postoperative care.[83] Anecdotally, postoperative follow up is believed to be of greater importance to RYGB patients, secondary to concerns about dietary restrictions and the risk of malnutrition if the postoperative dietary recommendations are not followed. In the present study, participants who underwent SG were more likely to complete recommended follow up visits than those who underwent RYGB. With SG increasing in popularity and utilization, this finding may be an indicator of future trends of improved postoperative visit compliance. However, this may also be a reflection of the smaller weight losses seen in SG patients. These patients may be more likely to return to the bariatric surgery program for postoperative appointments for additional support to experience greater weight loss.

Clinical and Policy Implications

Several of the findings from the study have clinical or policy implications. The study supports the most recent position statement by the ASMBS critical of the mandate from third party payers to extended MWM in order to receive authorization for surgery.[118] Increased annualized preoperative contacts, total preoperative contacts, and preoperative duration were not associated with postoperative weight loss. Extended preoperative assessment may be a deterrent to bariatric surgery for many individuals and may contribute to the observation that only approximately 1% of patients eligible for bariatric surgery undergo it.[127,141] A prolonged period of preoperative assessment prior to surgery is seen in solid organ transplantation, but few other areas of surgery.[180] Results from this study raise questions about the value of the current length of preoperative bariatric care, which is approximately 6 months in duration.

Additional individual visits were associated with a smaller percent weight loss. An extended preoperative assessment may be a result of the medical and psychological complexity of patients, as judged by the multidisciplinary team. Penn Bariatrics is the largest provider of bariatric care in the region. The program has a national reputation and may attract, or be referred, patients with more complex histories and/or current medical and psychological issues. Anecdotal experience has indicated that other programs in the region will send more complex cases to Penn Bariatrics. In the present study, patients with greater number of comorbidities completed more preoperative contacts and had a longer duration of preoperative care, which resulted in a smaller annualized rate of contacts. The clinical team at Penn Bariatrics has a great wealth of clinical experience and, as such, may be particularly adept at identifying clinical complexity that may be associated with poor postoperative outcomes. As a result, these clinicians may be recommending additional preoperative assessment individual visits, which may be increasing the duration of preoperative care (but decreasing the annualize rate of contacts calculated in the analyses described above), in an effort to mitigate variables that may contribute to suboptimal outcomes. More simply put, it may be that some patients with greater medical or psychosocial complexity would experience even smaller postoperative weight losses in the absence of additional preoperative assessment and care.

An extended preoperative assessment also may be patient-driven. The assessment period includes multiple visits with different providers. This requires a level of compliance from patients to coordinate and complete these visits in a timely manner. Some patients, after starting the preoperative assessment process, may determine that they are not ready to commit to surgery, halt the process, and subsequently return to the

program when they feel more prepared to complete the preoperative requirements. For patients for whom the clinical team has recommended additional visits, there may be additional barriers to completing these visits, such as scheduling or transportation issues. Each of these would, in turn, also reduce the annualized rate of frequency of visits. This may account for the smaller annualized rate seen with greater number of comorbidities, despite greater number of comorbidities being associated with greater number of preoperative contacts and longer duration of preoperative care.

Findings from this study indicate that patients who have more contacts and a longer preoperative assessment period experience no significant difference in weight loss after surgery. Little is known about each of the factors determining frequency of contacts and duration of preoperative assessment (insurance requirements, additional provider recommendations, and patient-driven reasons) in relation to postoperative weight loss. However, younger patients, males, white patients, and government-funded insurance recipients had a greater number of annualized preoperative contacts. This could be driven by any of the three factors affecting number of preoperative contacts, however these specific relationships were unable to be examined in depth in the present study.

Observations from the study suggest that program retention during the first two postoperative years is suboptimal and not consistent with MBSAQIP guidelines. Approximately 77% of patients missed at least one recommended follow-up visit at 6, 12, or 24 months. Women, patients with more comorbidities, and those who underwent RYGB were more likely to be non-adherent to the recommended follow up visit schedule. The recommendations for follow-up are communicated to patients verbally throughout the preoperative process and also found in the written materials provided to

patients. Unfortunately, these reminders did not appear to be sufficient to promote greater engagement. MBSAQIP guidelines, established in 2014, require the use of postoperative phone calls and letters to patients to promote postoperative follow-up. These strategies were not in place when the majority of patients in this sample underwent bariatric surgery. Thus, it is unclear if these recommendations will promote greater adherence to follow-up, or if additional strategies, such as the use of patient-provider contact via websites or smart phone applications, will be effective in maximizing follow-up and, ideally, promoting optimal outcomes for the largest number of patients.[181]

Strengths and Limitations

There are a number of strengths of this study. These include the large sample size, diversity of the sample (particularly with respect to type of insurance coverage and distribution of surgical procedures), and breadth of clinical data available in the EMR. Payer mix of the participant sample included a larger proportion of Medicare and Medicaid recipients than typically seen in bariatric surgery studies, accounting for approximately 40% of the study sample. Additionally, this is the largest investigation of the duration of the preoperative assessment process and postoperative weight loss.[154] The sample included an almost even split between RYGB and SG and more closely aligned with recent surgical trends.

This study is one of the first to evaluate the relationship between the frequency of preoperative contacts and postoperative weight loss. Regular patient-provider contact is a tenant of social cognitive theory.[142] These contacts allow for multiple opportunities to intervene promptly on personal, behavioral, and environmental factors that influence

behavior. Contacts prior to surgery are opportunities to foster self-efficacy and provide patients with situations for observational learning. Assessing the preoperative care process using frequency of these contacts helps capture this component of care and is a strength of this study.

Additionally, this is one of the first studies to assess preoperative care, including MWM frequency and duration, in relation to postoperative attrition. Several studies have examined the relationship between selected characteristics and postoperative weight loss. As found by Compher and colleagues, loss to follow up is associated with smaller postoperative weight losses.[145] Although it is important to assess the link between baseline characteristics and weight loss, a more beneficial approach may be to assess and develop interventions to improve postoperative follow up.

The study also has a number of limitations. While use of EMR data can be seen as a strength, the extracted data fields frequently did not include more granularity which would allow for a more detailed examination of patient-level variables. For example, categorization of whether a visit or contact was provider initiated, patient-driven, or insurance mandated is difficult to discern without a detailed chart review. The inability to assess the quality of the patient-provider contacts is another limitation of the study. There are no quality measures from the patient, including patient satisfaction or additional patient-reported outcomes, such as self-efficacy, knowledge, or readiness for surgery. This information is not routinely collected in the EMR at present.

Missing baseline characteristics were minimal, with the only significant missing data being from payer. This missing data can likely be attributed to inappropriate deletion of previous payer by registration staff when updating new coverage rather than just

updating or simply that the patients did not have coverage and paid out of pocket for their care. In this study, due to the inability to discern between self-pay and registration error along with the limitation of missing covariates in a mixed model, these cases were excluded from much of the analysis.

Future Directions

The results of this study provide valuable insight into the relationship between preoperative bariatric surgery care and postoperative outcomes and follow up. The results suggest that the frequency of preoperative contacts and duration of the preoperative assessment period was not associated with postoperative weight losses. These findings add to the growing literature that does not support mandatory lengthy and cumbersome preoperative processes for all patients seeking bariatric surgery. Since extension of the preoperative assessment period can be due to insurance requirement, clinician recommendation, or patient-driven factors (visit noncompliance, lack of readiness, scheduling conflicts, etc.), assessing the reason for extended preoperative assessment will be necessary in future studies to further understanding of its role on postoperative weight loss.

Prospective data collection of patient quality outcomes around frequency of visits and duration of preoperative care would be a likely next step to assessing the potential benefit or detriment of MWM. Additionally, prospective collection of reported self-efficacy throughout MWM and its relationship with postoperative weight loss and follow up would also be an important assessment of MWM. Future studies of this nature will

influence the future opinion of MWM and possibly the third-party payer requirements around it.

As noted above, the frequency of contacts cannot measure the quality of these contacts. Future studies can inset these preoperative frequencies with retrospective quality data, such as Press Ganey scores through which the patient rates his or her satisfaction with the visit on 5-point Likert scale for ten aspects of care. The reports from Press Ganey could be assessed to identify any trends between frequency of preoperative visits during that time period and patient satisfaction scores.

Conclusion

This large, comprehensive study found that frequency of contacts and duration of the preoperative assessment period was not associated with postoperative weight losses in adults who underwent bariatric surgery. Annualized contacts, accounting for the intensity of the preoperative assessment period, also were not associated with percent weight loss. The number of contacts with an RD, representing MWM, was not associated with postoperative percent weight loss, calling into question the value of extended MWM prior to surgery. More than one visit prior to surgery dedicated to psychological care was associated with smaller postoperative percent weight loss. Each additional individual visit prior to surgery was also associated with smaller postoperative percent weight loss. Non-white patients experienced smaller postoperative weight losses. The frequency and duration of the preoperative assessment period was unrelated to postoperative follow up.

The tenants of social cognitive theory would suggest that greater contact prior to surgery would promote greater success and patient-provider contact after surgery. This

was not found in the present study. Neither frequency of contacts, nor duration of preoperative care, were associated with postoperative percent weight loss. More specifically, additional individual visits and psychology visits were associated with smaller, not larger, percent weight loss. Rather, it may be that the additional individual visits and psychology visits are signaling greater complexity among patients and, without this additional preoperative assessment and care, these individuals would experience even smaller weight losses after bariatric surgery. Lengthy preoperative assessment, and MWM specifically, may not be necessary for all patients who pursue bariatric surgery.

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