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THE RELATIONSHIP OF EATING BEHAVIORS, HUNGER CONTROL, AND PHYSICAL
ACTIVITY TO WEIGHT LOSS AND QUALITY OF LIFE IN LAPAROSCOPIC
ADJUSTABLE GASTRIC BANDING PATIENTS

A dissertation submitted in partial fulfillment of the requirements for the Degree of Doctor of
Philosophy at Virginia Commonwealth University.

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Abstract

THE RELATIONSHIP OF EATING BEHAVIORS, HUNGER CONTROL AND PHYSICAL ACTIVITY TO WEIGHT LOSS AND QUALITY OF LIFE IN GASTRIC BANDING PATIENTS

By: Nancy Gott Baugh, RN

A dissertation submitted in partial fulfillment of the requirements for the degree of Doctor of Philosophy at Virginia Commonwealth University.

Virginia Commonwealth University, 2011

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Gastric banding as a weight loss surgery has increased in popularity in the United States since its approval by the Food and Drug Administration in 2001. Successful weight loss after weight loss surgery is most frequently defined as greater than 50% of excess weight loss (EWL). Systematic reviews show that the band is widely effective in achieving successful weight loss in most patients; however, individual studies show more inconsistent outcomes. Weight loss outcomes after gastric banding surgery at Virginia Commonwealth Health System were less than 50% EWL at 1 and 2 years. A retrospective, descriptive study sought to answer the following questions: (a) what is the relationship between physical activity, eating behaviors and hunger

control on weight loss and quality of life after gastric banding surgery, and (b) does successful weight loss at 1 year predict successful weight loss at 2 years?

Weight loss outcomes at 34.6% at 1 year and 39.7% at 2 years, were less than the established success rate of greater than 50% EWL. However, most patients lost some weight and demonstrated a significant improvement in most domains of health-related quality of life. Participation in physical activity increased between preoperative baseline to year 1 but decreased by 2 years. There was a significant relationship between participation in greater than 150 minutes per week of moderate or vigorous physical activity and adequate weight loss ($p = 0.025$) and participation in health enhancing physical activities and adequate weight loss ($p < 0.05$). There was no statistically significant relationship noted between eating behaviors and the percentage of EWL at 1 or 2 years. There was a significant relationship between degree of hunger reported by patients and successful weight loss at 1 year ($p < 0.05$). In addition, 1-year weight loss is a significant predictor for 2-year weight loss. Based on the findings of this study, it is recommended that gastric banding patients participate in at least 150 minutes per week of moderate to vigorous physical activity. Moreover, an increased focus on early reduction of hunger in the banding patient by development of band adjustment protocols may enhance weight loss.

CHAPTER ONE: INTRODUCTION

The two articles provided for the publication style dissertation option are derived from the research study “The Relationship of Eating Behaviors, Hunger Control, and Physical Activity to Weight Loss” and “Quality of Life in Laparoscopic Adjustable Banding Patients.” The primary aim of the study was to examine the impact of physical activity, eating behaviors, and hunger control on weight loss and quality of life in gastric banding patients. The secondary aim was to determine if successful weight loss at 1 year predicted weight loss at 2 years. The sample included 134 patients who had gastric banding surgery between 2004 and 2008. Institutional review board approval was obtained from the university to conduct a retrospective, descriptive study. Data were collected from the Bariatric Database at Virginia Commonwealth University.

Chapter Two provides a state of the science review of research about the obesity epidemic in the United States, social cognitive theory as the theoretical framework of the study and the evolution of gastric banding as an important tool to manage morbid obesity. A review of the literature includes information about outcomes that have been published since the gastric band was approved in 2001 by the Food and Drug Administration (FDA) and concludes that weight loss outcomes after gastric banding are inconsistent, ranging from 30% to 70% of percentage excess weight loss (EWL). Quality of life outcomes seem to be similar for gastric bypass and gastric banding patients although there are only several studies examining this relationship in gastric banding patients. There are few studies on the impact of physical activity

and eating behaviors on weight loss in gastric banding patients. There are very few studies examining hunger control after gastric banding although this is the proposed mechanism of action of the device. The conclusion of this article is that there is a clear need for research on factors that affect the weight loss outcomes and quality of life after gastric banding.

Chapter 3 focuses on the results of the study examining the impact of physical activity, eating behaviors, and hunger control on weight loss and quality of life in gastric banding patients. Weight loss outcomes were 34.6% at 1 year and 39.7% at 2 years, which was less than the internationally established success rate for bariatric surgeries of greater than 50% EWL; however, in this study, most patients lost some weight and demonstrated a significant improvement in most domains of health-related quality of life. Participation in physical activity increased from preoperatively to year 1 but decreased in year 2. Although participation in physical activities overall decreased from year 1 to year 2, there was a significant relationship between participation in greater than 150 minutes per week of moderate or vigorous physical activity and adequate weight loss ($p = 0.025$) and participation in health-enhancing physical activities and adequate weight loss ($p < 0.05$). There was no statistically significant relationship noted between any of these eating behaviors and the percentage of excess weight loss at 1 or 2 years. There was a significant relationship between degree of hunger reported by patients and successful weight loss at 1 year ($p < 0.05$). There is sufficient statistical evidence of a positive linear relationship between 2-year weight loss and 1-year weight loss ($p < 0.05$). That is, 1-year weight loss is a significant predictor for 2-year weight loss. Based on the results of this study, it is recommended that gastric banding patients participate in at least 150 minutes per week of moderate to vigorous physical activity. Additionally, clinicians should consider development of adjustment protocols that achieve early reduction of hunger in the band.

CHAPTER TWO: STATE OF THE SCIENCE ARTICLE

Relationships of Hunger Control, Eating Behaviors and Physical Activity

With Weight Loss and Quality of Life in Gastric Banding Patients

Introduction

Gastric banding has become one of the most commonly performed weight loss surgeries in the United States since its approval by the Food and Drug Administration in 2001. The procedure is increasing in popularity because of the perception of a relatively low rate of serious complications, short hospital stay, and shorter recovery period in comparison to gastric bypass surgery. These perceptions are mostly correct; however, weight loss outcomes after gastric banding are highly variable among patients, and overall these patients lose less excess weight than those undergoing gastric bypass (Nguyen, Slone, Nguyen, Hartman, & Hoyt, 2009). It is a common assumption among healthcare practitioners working with this patient population that successful weight loss is primarily a function of hunger control and physical activity and patient counseling is focused on patients' eating behaviors and exercise. The multidisciplinary team of the Bariatric Center of Excellence at Virginia Commonwealth University Health System (VCUHS) recommends that weight loss surgery patients exercise 60 minutes a day on most days of the week and counsel patients regarding their diets and eating behaviors at each follow-up visit. However, there is little evidence regarding the effect of the band on hunger and satiety and there is conflicting evidence on the relationship between physical activity and weight loss in the

general population and in banding patients. There is some evidence suggesting that physical activity may not be an effective method of weight control in some people. Additionally, there are cognitive, social and behavioral factors that play a major role in weight control and could explain part of the variability in weight outcomes.

The team at VCUHS has been performing gastric banding surgery since 2004 and tentative evaluation of outcomes in this patient population has shown an overall excess weight loss of less than 25%, which is much less than that reported in published studies to date. Most studies that report mean excess weight loss do not report a range among individual patients; therefore, it is difficult to assess what individual patients are experiencing. Initial data at VCUHS indicates that our patients have lost between 0 to 100 pounds with several patients actually gaining weight. It is important to identify behaviors that may predict success in these patients since most insurance companies will pay for only one bariatric procedure per lifetime. To assist in understanding the interrelationships among hunger control, eating behaviors, physical activity and weight loss, and quality of life in banding patients, a social cognitive and biobehavioral framework will be used.

Background of the Problem

Obesity has reached epidemic proportions in the United States with more than one-third of adults classified as obese (BMI > 30 kg/m²) and only one state (Colorado) having an obesity prevalence of less than 20% (Centers for Disease Control [CDC], 2008). Obesity is a complex, multivariate problem, which not only has a significant impact on morbidity and mortality, but also has a devastating effect on physical functioning, psychological well-being, and overall quality of life (Flegel, Graubard, Williamson, & Gail, 2005). Obesity is defined by body mass index (BMI) of equal to or greater than 30 kg/m² and morbid obesity by a BMI of equal to or

greater than 40kg/m^2 . The prevalence of morbid obesity is increasing at an alarming rate worldwide. Factors contributing to the obesity epidemic include genetic, environmental, physiologic, psychosocial, economic, and behavioral factors. Growth in technology and urbanization of populations in developing countries promotes a sedentary lifestyle while diets are increasingly higher in sugar and saturated fats (James, 2004). The increasing rate of obesity is of concern because of the causal link with a number of adverse consequences including, but not limited to, coronary heart disease, diabetes, hypertension, dyslipidemia, sleep apnea, stroke, and cancer.

Current weight loss therapies include a limited number of medications, surgical interventions, and behavioral/cognitive therapies; however, there is a high degree of variability of response among individuals to these interventions (Teixeira, Going, Sardinha, & Lohman, 2005). Adherence to behavioral therapy in particular is inconsistent, and high attrition is common in weight loss efforts and is impacted by environmental, psychosocial, and physiologic factors (National Institutes of Health [NIH], 1998). A meta-analysis of studies reviewing the effectiveness of weight loss programs in the United States revealed widespread failure with existing obesity treatments that are focused on diet and exercise (Anderson, Konz, Frederich, & Wood, 2001). Long-term weight maintenance, although possible for some, is notoriously difficult for many (Byrne, 2003).

Because of the failure of conventional weight loss therapies for morbid obesity, the NIH recommends surgical therapy as the only intervention associated with long-term success (NIH, 1998). Currently, the two most consistently performed bariatric surgeries in the United States are the Roux-en-Y (RNY) gastric bypass and gastric banding. These procedures produce weight loss primarily through gastric restriction and malabsorption (RNY) or by restriction only (banding).

The goal of both procedures is for patients to lose 50% of their excess weight. A systematic review of over 50 studies comparing the band with RNY found weight loss outcomes to be comparable at 4 years after surgery (Chapman et al., 2004). Two years later, a systematic review of published studies by O'Brien, McPhail, Chaston, and Dixon (2006) found similar weight loss for both procedures: excess weight loss (EWL) of 55% for banding and 58% for gastric bypass. In contrast, a more recent systematic review of 14 studies by Tice, Karliner, Walsh, Peterson, and Feldman (2008) comparing these two procedures found that there was greater weight loss for the RNY procedure (76% excess weight loss) as compared with gastric banding (48% excess weight loss). Additionally, this study found significantly greater resolution of sleep apnea, diabetes and hypertension with gastric bypass. Both surgeries are considered to be safe with overall mortality reported as 0.3% at high volume surgery centers (Longitudinal Assessment of Bariatric Surgery [LABS], 2009). A randomized study also published in 2009 by Nguyen et al. (2009) conducted over 5 years found no deaths at 90 days for either surgery and the 1 year mortality rate to be 0.9% for gastric bypass and no deaths in the banding patients.

Many patients chose the banding procedure because of a perceived higher complication rate of the RNY. However, the weight loss outcomes after banding are highly variable and seem to be dependent on careful assessment and screening of patients. Successful weight loss with the gastric band has been defined as weight loss at the end of the third year post procedure of greater than 50% of initial excess weight. Failure is defined as less than 20% of loss of the initial excess weight after 3 years (Snyder, Nguyen, Scarborough, Yu & Wilson, 2009). A meta-analysis of outcomes of 28,980 gastric banding patients found an average excess weight loss of 56%, with the most significant weight loss occurring in patients with a BMI of $> 40\text{kg/m}^2$ (Cunneen, 2008). All studies reporting co morbidities found significant resolution of sleep apnea ($> 85\%$),

diabetes, (> 60%), hypertension (> 43%) and dyslipidemia (70%) after gastric banding. A recent metaanalysis by Weichman et al. (2010) on 2,909 banding patients found the 3-year excess weight loss to be 52.9%. These studies report a significantly higher weight loss than previous comprehensive metaanalyses by O'Brien et al. (2006) who reported an excess weight loss of between 42 to 62%, and by Picot et al. (2008) who reported excess weight loss of 47.5%.

Reasons for these inconsistent outcomes after banding surgery seem to be similar to those for traditional weight loss programs and include physiological, psychosocial, and behavioral variables, particularly those related to eating and physical activity. Dixon and O'Brien (2002) found negative predictors of long-term weight loss included increasing age, higher BMIs, limited physical activity and poor general health. Snyder et al. (2009) also found associations between higher age and BMI and poor weight loss. Weichman et al. (2010) proposed that the number and frequency of follow-up visits have an impact on successful weight loss. They found that patients who had more than seven follow-up visits in the first year had a significantly higher mean excess weight loss than those who had less than seven visits in the first year. They concluded that more frequent visits result in earlier attainment of satiety that results from optimal band adjustment.

Psychological disorders such as depression and anxiety may affect eating behaviors and participation in physical activity (Byrne, 2002). Food is frequently used as a coping mechanism and many obese persons engage in a perpetual cycle of mood disorders, poor eating behaviors, and weight gain. The resulting guilt perpetuates the cycle and the person continues to gain weight (Elfhag & Rossner, 2005). Many engage in other disordered eating patterns such as bingeing, grazing, and nocturnal eating (Linde, Jeffrey, Levy, Sherwood, Utter, & Pronk, 2004). Such psychological and behavioral issues persist after gastric banding surgery and continue to play a significant role in weight loss (Ray, Nickels, Sayeed, & Sax, 2003).

Social Cognitive Theory

Predicting outcomes of behavioral and cognitive therapies is difficult due to the interactions of the many variables determined by personal, environmental, and social factors. Typically, changes in health behaviors are difficult and failure to maintain permanent change in behavior is a common phenomenon. Social cognitive theory can be a useful framework for understanding and predicting human behavior and adaptation and has its origins in social learning theory from the discipline of psychology. Alfred Bandura refined social learning theory to emphasize the role of cognition and psychosocial factors in learning new behaviors and subsequently renamed it “social cognitive theory” (SCT). Bandura (1977) defined SCT as “a triadic, dynamic, and reciprocal interaction of personal factors, environment, and behavior” (p. 254). Bandura’s theory has shown promise for identifying and developing methods that promote behavior change and is the basis for many interventions aimed at health promotion (Bandura, 2004). The relationship between SCT and behavior change has been examined in many studies in a variety of disciplines including medicine, nursing, psychology, sociology, nutrition, business and athletics.

The key constructs of SCT that have particular relevance to health promotion include reciprocal determinism, outcome expectations, and self-efficacy. Reciprocal determination explains human functioning as an interaction of the environment, personal factors and behavior which are constantly influenced by each other (Pajares, 1997). Personal factors are composed of cognitive, affective and biological structures that are influenced by the environment to shape behavior (Bandura, 1986). Environment refers to external factors that can affect a person’s behavior and includes socioeconomic status, education, and social structures. The environment provides models for behavior whereby the person learns through observing the actions and

outcomes of others' behaviors. The environment may also refer to a person's perception of outside influences that shape the person's personal standards, expectations and emotional state. In other words, behavior is largely shaped by the environment and in turn, our behaviors can affect the environment (Glanz, Rimer & Lewis, 2002).

Bandura (1986) suggested that a person's belief system about what he/she can and cannot do is cognitively generated and that behavior is determined more by personal beliefs than by results of previous performance. Hence, people are proactively involved in their own development and can set goals based on perceptions of their own capabilities. They are able to exercise a measure of control over their thoughts, feelings, and actions and change their behavior accordingly. Courses of action are then organized cognitively and goals are set based on the person's perceptions of his/her capabilities. Additionally, Bandura (1997) emphasized the role of self-regulation as being uniquely human and having a major impact on the ability to explore one's own cognitions and beliefs and make changes in behavior accordingly.

Strong emotions may lower performance for difficult tasks and people may allow their emotional state to affect judgments about their capabilities. Bandura (2004) described these affective processes as physiologic arousal that may occur when a person is asked to perform a difficult task or change a behavior. Anxiety and fear may result in feelings of incompetence and inadequate performance. Depression may result in situations in which goals were set too high and the person experiences failure.

Outcome expectations refer to individuals' beliefs about the consequences of their behavior and the assumption that a specific response will result from a specific behavior (Anderson, Winett & Wojcik, 2001). If a person doubts personal efforts will lead to a certain outcome, the behavior may not be attempted. In contrast, Bandura (1986) referred to an efficacy

expectation as a judgment of personal competence to successfully perform a behavior. Outcome expectations and efficacy expectations may not always be congruent. For example, individuals may agree that a 1,000 calorie per day diet will cause weight loss (outcome expectancy) but may not believe that they would be able to participate successfully in a 1,000 calorie per day diet (efficacy expectation).

Observational or vicarious learning is another important construct of social SCT that describes how a person may duplicate behaviors observed in others or refrain from certain behaviors based on the type of outcome the person being observed elicits (Pajares, 1997). This view differs from earlier behaviorist theories suggesting that learning occurs from performing the behavior and experiencing the effects of that behavior. Bandura (1986) noted that this form of learning is very powerful and a greater number of behaviors are learned by observation of others than by direct experience; in fact, he proposed that almost any behavior can be learned in this way. Except in early childhood, behavioral acquisition can be acquired by verbal description of the behavior alone. This type of verbal modeling of behavior greatly reduces the time and resources that would be required from direct experience. Vicarious learning also reduces the number of errors that may occur from direct experience.

Obesity is a heterogeneous condition and individual responses to interventions are highly variable. People generally have high outcome expectations for weight loss which may facilitate initial success; however, the majority of weight loss attempts are unsuccessful (Foster et al., 2003). There is growing interest in the cognitive, behavioral, and psychosocial factors related to successful weight loss and maintenance. Identifying variables that may impede or enhance weight loss and then applying appropriate cognitive behavioral interventions may increase overall response to treatment.

Maladaptive Eating Behaviors

Patients with presurgical eating disturbances such as grazing, sweets eating, or bingeing may have suboptimal weight loss after gastric banding. The incidence of maladaptive eating behaviors such as bingeing is high among candidates for weight loss surgery (deZwaan, Mitchell & Howell, 2003). Colles, Dixon and O'Brien (2008) showed that preoperative grazing predicted 19.5% of the variance in percentage of weight lost postoperatively. Saunders (2004) defined grazing as the frequent consumption of small amounts of food over an extended period and found grazing to be prevalent among obesity surgery patients. Additionally, he found that a preference for high caloric liquids is associated with poor weight loss after bariatric surgery. There is evidence to suggest that binge eating is highly prevalent among morbidly obese patients who seek bariatric surgery and tends to persist after the procedure, resulting in insufficient weight loss or weight regain (Hsu, Sullivan, & Benotti, 1997). Other researchers suggest that preoperative binge eaters may convert to grazers postoperatively (Busetto, Valente, & Pisent, 2005; Saunders, 2004). A study by Toussi, Fujioka, and Coleman (2008) examined the relationships among weight loss, patient characteristics, psychological factors, and behavioral issues and found that patients who lost the most weight 2 years after bariatric surgery were more likely to be non-White, have a lower socioeconomic status, and have a diagnosis of binge eating before surgery. It is speculated that with a restrictive procedure such as banding, binge eating should be more difficult because of physical restriction; however, two prospective studies on the relationship between preoperative bingeing and weight loss after surgery found no such relationship (Busetto, Segato, & DeLuca, 2005; Potoczna, Branson, & Kral, 2004).

The Nurses' Health Study II found an association between consumption of sugar-sweetened beverages, weight gain, and type 2 diabetes but no such relationships with

consumption of diet beverages (Schulze et al., 2004). It is speculated that high fructose corn syrup in soft drinks contributes to a high glycemic index and a fast and dramatic increase in both glucose and insulin concentrations in the blood (Janssen, Shapiro, & Deberley, 1999). Excessive consumption of sweetened beverages such as sodas and sweet tea is common in morbidly obese patients and seems to be associated with inferior weight outcomes after restrictive weight loss surgeries (Brolin, Robertson, & Kenler, 1994; Busetto et al., 1996). Himpens, Dapri, and Cadiere (2006) found sweets-eating behaviors to persist and to be a cause of failure after restrictive surgeries such as gastric banding. Patients may be classified as sweets eaters if they consume > 300 calories of sweet foods or beverages three times or more per average week (Herpertz, Kielmann, Wolf, Hebebrand, & Senf, 2004). Sugarman et al. (1992) proposed that after restrictive surgeries, sweets eaters do not lose as much weight as nonsweets eaters. However, Dixon and O'Brien (2001) found no such difference in their banding patients, and this finding was supported in a study by Hudson, Dixon, and O'Brien (2002) who found that a preference for sweets did not result in inferior weight loss in banding patients.

Hunger Control

The primary weight loss mechanism of the gastric band is to produce early and prolonged satiety, ultimately leading to reduced intake and weight loss. Appropriate fluid volume in the gastric band is a crucial factor in maintaining an increased sense of satiety and reduced hunger. Burgmer, Grigutsch, and Zipfel (2005) reported a marked reduction in reports of hunger in gastric banding patients. Typically, patients receive the first “fill” of their bands 6 weeks after surgery and then have “adjustments” approximately every month until it is determined they have an optimally filled band. The multidisciplinary team defines this as early and prolonged satiation, losing one to three pounds per week and no symptoms of obstruction, such as vomiting or reflux.

Whenever patients develop symptoms of obstruction, fluid is removed from the band which in most cases provides relief. If patients continue to have symptoms, the correct position of the band is evaluated with a contrast swallow study.

An optimally adjusted gastric band produces higher ratings of satiety, marked reductions in reports of hunger and superior weight loss compared with unrestricted bands and nonbanded control patients (Burgmer et al., 2005). Although the exact mechanism for the physiologic response of a decreased sensation of hunger is unclear, it is postulated that there may be two mechanisms involved. The first is a mechanical process where physical restriction of the gastro-esophageal junction results in delayed gastric emptying. A randomized control trial by Bergmann, Chassany, Petit, Triki, Caulin, and Segrast, 1992) found that an association between delayed gastric emptying and decreased appetite. The second mechanism seems to be related to less stimulation of the hunger center in the hypothalamus by the hormone, ghrelin, which is produced in the gastric mucosa (Schwartz, Woods, & Porte, 2000). There is very little data in the literature establishing the norms of satiety in banding patients and no guidelines exist to assist practitioners in making treatment decisions regarding optimal filling of the band. Burton et al. (2010) developed an instrument to assess satiety, adverse upper gastrointestinal symptoms and weight loss and found the tool to be helpful in determining optimal ranges of satiety in response to band adjustments while avoiding symptoms of obstruction. Another study on aspects of band adjustment found that greater subjective hunger was associated with decreased weight loss in gastric banding patients (Burgmer et al., 2005). A double blind randomized controlled trial by Dixon, Dixon and O'Brien (2005) demonstrated a highly significant increase in reported hunger after removal of all fluid from the gastric band.

Physical Activity

Physical activity is defined as any bodily movement that results in energy expenditure and has long been recognized for its contribution to weight loss and maintenance (Poirier & Despre, 2001). The strong inverse relationship between physical activity and obesity has been well documented (King, Fitzhugh, Bassett, McLaughlin, Strath, & Swartz, 2001; Schmitz, Jacobs, Leon, Schreiner, & Sternfeld, 2000). The American Dietetic Association maintains that successful weight management requires not only a healthy diet but also daily physical activity (Seagle, Strain, Makris, & Reeves, 2009). The Centers for Disease Control (CDC), the U.S. Department of Health and Human Services, and the U.S. Department of Agriculture (USDA) also recognize physical activity for its contribution to energy expenditure and weight maintenance (Poirier & Despre, 2001). These organizations vary in their specific recommendations for physical activity for weight management but range from 150 minutes of moderate aerobic exercise per week (USDA) to 60 to 90 minutes of moderate exercise on most days of the week (CDC). It is recognized that morbidly obese persons may have impaired ability to exercise due to physiologic problems such as abnormal gait and dyspnea and they tend to be more sedentary; however, even low intensity exercises such as walking can contribute to energy expenditure (Bond, Leahey, Vithianathan, & Ryder, 2009).

Although there are relatively few studies on the role of physical activity on weight loss outcomes after obesity surgery, several recent studies suggest that participation in regular activity after RNY surgery results in better weight loss and maintenance at 2 years postoperatively (Bond et al., 2004; Evans et al., 2007; Silver, Torquati, Jensen, & Richards, 2006). Evans (2009) recommended that weight loss surgery patients participate in at least 150

minutes of moderate or higher intensity exercise per week progressing to 200 to 300 minutes per week for optimum weight loss and maintenance.

There are even fewer studies on the relationship between physical activity and weight loss in gastric banding patients. In one study, Colles et al. (2008) found regular walking was associated with better weight outcomes 1 year after gastric banding procedures. In a nationwide study in France, researchers found that change in eating habits and regular participation in physical activity predicted success of weight loss in banding patients (Chevallier, Paita, Rodde-Dunet, Nogoies, Slim, & Basdevant, 2007). Those who exercised lost 2.3 times more weight than those who did not. A study by Bueter et al, (2007) found no correlation between engagement in physical activity and weight loss in gastric banding patients.

In contrast to the many studies showing a positive relationship between exercise and weight loss, a study by King, Hopkins, Caudwell, Stubbs, and Blundell (2008) found that individuals who exerted 2,500 kcal of energy per week through physical activity did not lose the predicted amount of weight because of increased caloric intake. Supporting these findings, a study by Caudwell, Hopkins, King, Stubbs, and Blundell (2009) found large variability in weight loss (including weight gain) among obese men and women who exercised and associated this finding with increased food intake after exercise in participants. Although there has been a long assumed association between exercise dose and amount of weight loss, a recent randomized controlled trial by Church, Martin, Thompson, Earnest, Mikus, and Blair (2009) found less weight loss among postmenopausal women assigned to 194 minutes of supervised exercise per week compared with those who engaged in 72 or 136 minutes per week suggesting there may an optimal balance between energy intake and expenditure.

The idea that the body may make compensatory adjustments to energy expended during exercise and actually prevent weight loss was highlighted by Epstein and Wing (1980) over 20 years ago. They suggested that exercise may stimulate appetite causing the person to eat more food and not lose weight. Subsequent studies supported this correlation between energy expenditure and increased food intake (Blundell & King, 1998; Blundell, Stubbs, Hughes, Whybrow, & King, 2003; King et al, 2001). Other studies have found an association between physical activity and subsequent selection of inappropriate high fat and high calorie snacks and it is speculated that some people may reward for themselves in this way for their hard work or may believe exercise has counterbalanced the calories in their snacks (Davis & Woodside, 2002; Tremblay, Almeras, Boer, Kranenberg & Despres, 1994).

A better understanding of the relationship between physical activity and weight loss after gastric banding surgery clearly has implications for planning individualized treatment strategies to improve weight loss for each patient. Engagement in physical activity may be an effective adjunct to changes in eating behaviors and hunger control in some banding patients. However, the current recommendations of 60 minutes of moderate intensity exercise per day for optimal weight loss and maintenance may be daunting for some individuals and may result in more sedentary behavior or increased food intake. More research is needed on the effectiveness of physical activity on weight loss in gastric banding patients and how much exercise is needed.

Quality of Life

Excessive weight may affect a person's quality of life (QOL) because of the adverse effects on overall physical health and psychological and emotional consequences. Both generic and obesity specific tools have been used to measure quality of life in the obese population. The most frequently used tool is the Medical Outcomes Study Short Form 36 (SF-36). This tool has

been used in many different patient populations and age groups to evaluate the relative burden of disease and to assess response to interventions. It has been widely used to measure QOL among morbidly obese patients after gastric bypass surgery and gastric banding surgery. The scale consists of two major components of health-related QOL. The physical component includes physical function, role activity, bodily pain, and general health perceptions. The mental component includes vitality, social functions, role-emotion, and mental health. Each domain score is ranged from 0 to 100 with higher numbers reflecting higher functioning and quality. The SF-36 has been shown to have high internal consistency and test retest reliability (Ware, Kosinski, Turner-Bowkin, Gandek, & Marsh, 2007).

Several studies of weight and health-related quality of life indicate that obesity has an adverse effect on quality of life. Fine et al. (1999) used the SF-36 to examine the association between QOL and weight among 40,098 women participating in the Nurses' Health Study. They found that weight gain is associated with decreased physical functioning, vitality, and overall QOL and increased bodily pain. Researchers in Sweden investigated the impact of weight on QOL in 5,633 male and female adults using the SF-36. They found that the level of obesity had a significant impact on QOL and that obese women rated their QOL as worse when compared with obese men. A more recent study by Lynch et al. (2010) found that obesity negatively affected QOL in postmenopausal women of diverse ethnic backgrounds who were enrolled in the Women's Health Initiative.

The primary goals of weight loss surgeries are to improve overall health status and quality of life (QOL) through significant and sustained weight loss. At VCUHS, practitioners have noted that with significant weight loss there is dramatic improvement or resolution of medical co morbidities including metabolic syndrome, hypertension, sleep apnea, dyslipidemia

and gastroesophageal reflux. Additionally, weight loss is also associated with improved ovarian function and fertility. Patients also report general improvements in physical and psychological functioning and improved body image. Most research studies looking at the correlation between weight loss and quality of life after weight loss surgery attribute the improvement in QOL to the weight loss and resolution of co morbidities.

A number of studies have reported improved quality of life after gastric banding surgery. Schok, Geenen, van Antwerpen, de Witt, Brand, and van Ramshort (2000) utilized the SF-36 tool to evaluate QOL in 74 gastric banding patients at 1 and 3 years after surgery and found significant improvement in psychological and social quality of life, although their perceived physical quality of life was below that of the normal population. Dixon et al. (2001) studied 459 gastric banding patients using the SF-36 tool and found that those who reported their health-related quality of life as poor prior to surgery experienced significant and sustained improvement postoperatively. Mathis-Vliegme and de Witt (2007) used an obesity specific QOL instrument, the Impact of Weight on Quality of Life tool to examine outcomes of gastric banding. They found that after 5 years, gastric banding patients had a significantly improved sense of well-being, perceived attractiveness, and self-worth. They also found that the patients engaged in significantly more physical activity but did not correlate this with QOL. A study by Freys, Tigges, Heimbucher, Fuchs, Fein, and Thiede (2001) reported a significant improvement in QOL using a tool called the Gastrointestinal Quality of Life tool in 73 banding patients but reported a high number of complications (38%) that resulted in reoperation. A more recent study by Clough, Layin, Shah, Wheatley and Taylor (2010) of 113 gastric banding patients reported marked improvement in physical, mental, emotional and social QOL in gastric banding patients over the age of 60 although they experienced less excess weight loss than their younger cohorts.

Holterman et al. (2010) reviewed outcomes of gastric banding surgery in 26 adolescents and found significantly improved QOL using the PEDSQL that measures health-related QOL in the pediatric population. There was a significant improvement in co morbidities and decreased medication use in this group and they reported reduced depression, improved self-esteem and less bodily pain. Several recent European studies have found improved QOL after gastric banding using the Ardelet-Moorehead Quality of Life questionnaire (Kinzl, Schrattecker, Trawyer, Aigne, Fioloa, & Bieble, 2007; Muller, Wenger, Scheiss, Clavian, & Weber, 2008; Titi, Jenkins, Modak & Galloway, 2007). In contrast, Horchner, Tuinebreijer, and Kelder (2001) found that at 2 years postoperatively banding patients experienced less bodily pain after gastric banding but no significant improvement in overall quality of life scores.

There is consistent evidence that participation in physical activity has a dramatic effect on improving QOL in the general population (Brown, Moriarity, Ford, Giles, & Mokdad, 2003; Brown et al., 2004; LaForge, Rossi, & Prochaska, 1999); however, this relationship has not been studied in gastric banding patients.

Conclusion

Weight loss surgeries such as gastric banding can produce significant weight loss in some morbidly obese patients. Unfortunately, many gastric banding patients do not achieve adequate weight loss and others experience considerable weight regain. Weight loss outcomes at VCUHS Bariatric Center of Excellence have been suboptimal and there are few resources available to guide the care of these patients. There are research studies available on postoperative gastric bypass patients suggesting that inconsistent weight outcomes can be attributed to maladaptive eating and sedentary activity, however, this type of data is lacking in the banding population. An important consideration in gastric banding patients that has been minimally explored is

achievement of hunger control and satiation through optimal band adjustment. Research in this area is needed to establish guidelines for achieving early satiation through optimal adjustments. Additionally, there have been few studies examining maladaptive eating behaviors in this population and how these may affect outcomes.

There have been few studies examining the relationship between physical activity and weight loss in gastric banding patients and the limited research results have been inconsistent. Additionally, there have been few studies on the relationship between weight loss and quality of life in gastric banding patients. There have been no reported studies examining the relationship between physical activity and quality of life in gastric banding patients.

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CHAPTER THREE. STUDY FINDINGS ARTICLE

1. Introduction

The prevalence of morbid obesity is increasing at an alarming rate worldwide and is becoming a major public health problem in the United States. Because of the failure of conventional weight loss therapies for morbid obesity, the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) recommends surgical therapy as the only intervention associated with long-term success (NIH, 1998). Laparoscopic adjustable gastric banding (LAGB) has been steadily increasing in popularity since approval by the FDA in 2001. Successful weight loss with the LAGB is defined as greater than 50% of excess weight loss (EWL). The percentage of EWL is the preferred means of reporting weight loss after bariatric surgery and is calculated as: $(\text{preoperative weight} - \text{postoperative weight}) / (\text{preoperative weight} - \text{ideal weight}) \times 100$. Early studies on the effectiveness of the LAGB were encouraging, with most studies reporting the average percentage of EWL over 50% and a low incidence of complications. A systematic review of 4594 studies published worldwide involving 28,980 gastric banding patients found an average EWL of 56 % with the most significant weight loss occurring in patients with a BMI of $> 40\text{kg}/\text{mm}^2$ (Cunneen, 2008). A recently published retrospective analysis of 2,090 banding patients found a mean EWL of 52.9% at 5 years postoperatively (Weichman et al., 2010). However, a review of individual studies show more inconsistent outcomes, with percentages of EWL ranging from less than 30% to as much as 70 % (Ahron, Montgomery, & Watkins, 2005; Demaria et al., 2001; Ren, 2004;

Two recently published studies found the majority of patients failed to achieve the benchmark of 50 % of EWL at 2 and 3 years postoperatively (Boza et al., 2010; Kasza et al., 2010).

A number of studies have reported improved quality of life (QOL) after gastric banding surgery (Ahron, Montgomery, & Watkins, 2005; Dixon, Dixon & O'Brien 2001; Horchner, Tuinebreijer, & Kelder, 2001; Schok, Geenen, & van Antwerpen, 2000; Weiner, Datz, Wagner, & Bockhorn, 1999). A study by Freys et al. (2001) reported a significant improvement in QOL in 73 banding patients but reported a high number of complications (38%) that resulted in reoperation. A more recent study by Clough, Layin, Shah, Wheatley and Taylor (2010) reported marked improvement in physical, mental, emotional and social QOL in gastric banding patients over the age of 60 years although they experienced less EWL than their younger cohorts. In contrast, researchers from Brussels recently published findings from the first study to look at outcomes past the 10-year mark that presented less favorable outcomes (Himpens, Cadiere, Bazi, Vouche, Cadiere, & Dupri, 2011). Weight loss outcomes in this group averaged 43%. However, the reoperation rate for band complications was 60%.

The primary weight loss mechanism of the gastric band is to produce early and prolonged satiety ultimately leading to reduced intake and weight loss. Appropriate fluid volume in the gastric band is a crucial factor in maintaining an increased sense of satiety and reduced hunger. Although the exact mechanism for this physiologic response is unclear, it is postulated to be related to physical restriction at the gastro-esophageal junction resulting in delayed gastric emptying (Ren, Weiner, & Allen, 2004). There are very few studies examining the relationship between hunger control and weight loss and very few guidelines in the literature to assist the bariatric team in achieving early satiety in this patient population. Dixon et al. (2005) investigated the relationship ghrelin, the hormone that induces hunger and achievement of satiety

in banding patients, and found that ghrelin levels increased postoperatively. Recent studies by Bennet et al. (2010) and Burton et al. (2008) suggest there is a relationship between weight loss and achieving appetite suppression.

A strong inverse relationship between physical activity and obesity has been well documented (King, Fitzhugh, Bassett, McLaughlin, Strath, & Swartz, 2001; Schmitz, Jacobs, Leon, Schreiner, & Sternfeld, 2000). The American Dietetic Association maintains that successful weight management requires not only a healthy diet but also daily physical activity (Seagle, Strain, Makris, & Reeves, 2009). The (CDC) and the U.S. Department of Agriculture (USDA) also recognize physical activity for its contribution to energy expenditure and weight maintenance (Poirier & Despre, 2001). These organizations vary in their specific recommendations for physical activity for weight management, ranging from 150 minutes of moderate aerobic exercise per week (Department of Health and Human Services) to 60 to 90 minutes of moderate exercise on most days of the week (CDC, USDA). Although there are relatively few studies on the role of physical activity on weight loss outcomes after obesity surgery, several recent studies suggest that participation in regular activity after gastric bypass surgery results in better weight loss and maintenance (Bond et al., 2009; Evans et al., 2007; Hatoum, Stein, & Merrifield, 2008). There are even fewer studies on the relationship between physical activity and weight loss in gastric banding patients. In one study, Colles, Dixon, and O'Brien (2008) found regular walking was associated with better weight loss outcomes after 1 year in gastric banding patients. Chevallier et al. (2007) conducted a nationwide study in France to determine what factors predicted success of weight loss in banding patients. Factors associated with success in that study included change in eating habits and regular participation in physical activity. Those who exercised lost 2.3 times more weight than those who did not. A recent study

by Thalheimer et al. (2009) found sedentary behavior to be a significant ($p = 0.045$) predictor of failure to lose weight in 85 gastric banding patients. A better understanding of the relationship between physical activity and weight loss after gastric banding surgery has implications for planning treatment strategies to improve weight loss for each patient.

Patients with presurgical eating behavior disturbances such as grazing, sweets eating, and bingeing may have suboptimal weight loss after gastric banding. Excessive consumption of sweetened beverages such as sodas and sweet tea is common in morbidly obese patients and has been associated with inferior weight outcomes after restrictive weight loss surgeries (Brolin, Robertson, & Kenler, 1994; Busetto, Valente & Pisente, 1996). Himpens, Dapri, and Cadiere (2006) found sweets eating behaviors to persist and to be a cause of failure after restrictive surgeries such as gastric banding. Sugarman et al. (1992) proposed that after restrictive surgeries, sweets eaters experienced less weight loss compared to nonsweets eaters; however, Dixon and O'Brien (2001) found no difference in their LAGB patients. This finding was supported in a study by Hudson, Dixon, and O'Brien (2002), who found that a preference for sweets did not result in inferior weight loss in banding patients.

Colles et al. (2008) found that uncontrolled eating after gastric banding was associated with poor weight loss. However, a recent systematic review suggests that although uncontrolled eating behaviors may persist in some patients after surgery, in the majority of banding patients, overeating behaviors were reduced. It is speculated that reduction in overeating is related to the restrictive nature of the band (Dodsworth, Warren-Forward, & Baines, 2010).

The current study explores the association of eating behaviors, hunger control and physical activity with weight loss and quality of life in LAGB patients. The majority of studies exploring factors that impact success after bariatric surgery have focused on gastric bypass

patients. There are few studies addressing behavioral factors such as physical activity or maladaptive eating behaviors and how they affect outcomes in LAGB patients. Additionally, there are very few studies addressing hunger control and achievement of early satiety. This article reports the findings of a study exploring the association of eating behaviors, hunger control and physical activity with weight loss and quality of life in LAGB patients. The results of this study may provide insight into LAGB patient behaviors and contribute to development of effective treatment strategies to optimize successful weight loss and maintenance.

2. Methods

2.1 Design/Aims

The primary aim of this retrospective, descriptive study was to examine the impact of eating behaviors, hunger control and physical activity on weight loss and quality of life in LAGB patients. The independent variables were physical activity, eating behaviors and hunger control. The dependent variables were percentage of excess weight loss and quality of life at one and two years postoperatively. The secondary aim of the study was to determine whether successful weight loss at 1 year predicted successful weight loss at 2 years.

2.2 Sample

Participants in the study were 134 patients aged 15-70 years old who underwent LAGB at a university healthcare system between December 2004 and December 2008. To be eligible for surgery patients required a BMI greater than 40 kg /m² or greater than 35 kg /m² with associated comorbidity (e.g. diabetes, hypertension, obstructive sleep apnea, hyperlipidemia) and failed previous, significant attempts to lose weight.

2.3 Procedures

Institutional review board approval was obtained from the university to conduct a retrospective study on patients who received gastric banding from 2004 to 2008. At the initial consultation, data regarding demographics, weight, BMI, EWL, comorbidities, and eating behaviors were collected. Patients completed study questionnaires about quality of life and physical activity at the initial visit and at each postoperative visit. Patients rated their level of hunger and satiety at each postoperative visit using a Likert-type scale.

2.4 Measures

Anthropometric: Percentage of EWL is the preferred means of reporting weight loss in morbidly obese patients after bariatric surgery and is based on the patients' ideal body weight. Percentage of EWL is calculated as $(\text{weight loss})/(\text{excess weight}) \times 100$, with excess weight defined as weight above ideal body weight.

Physical Activity: The International Physical Activity Questionnaire short form (IPAQ-short) has been used extensively to measure health related physical activity in adults. The form is a self-report measure that assesses physical activity undertaken across a comprehensive set of domains. Questions are asked regarding the duration and intensity spent in physical activities at work, as part of house and yard work, and in spare time for recreation, exercise and sports in the previous 7 days. The metabolic equivalent of each task (MET) can be calculated to provide information about the volume of activity. The subjects were categorized as "sufficiently active" or "insufficiently active" to maintain health. "Sufficiently active" is defined as (a) vigorous activity 3 or more days per week for at least 20 minutes per day, or (b) moderate activity and/or walking 5 or more days per week for at least 30 minutes a day or, (c) any activity on 5 or more days per week with a total of 600 or more MET minutes/week. In a revised version of the IPAQ

(2004) the category of participation in health enhancing physical activity (“HEPA active”) was added and is defined as (a) vigorous activity on 3 or more days a week with a total of 1500 vigorous MET minutes/week, or (b) any activity on 5 or more days per week totaling 3000 or more MET minutes/week. The HEPA score exceeds the current CDC and FDA public health recommendations for physical activity (Craig et al., 2003).

The IPAQ short form has demonstrated good reliability and acceptable validity properties when compared with other established self-reports of physical activity. Craig et al. (2003) found the tool correlated well with pedometer readings ($r = 0.30$). A recent study by Papanthasiou, Georoudis, Georgakopoulos, Katsouras, Kalfakakou, and Evanglou (2010) found acceptable correlations ($r = 0.37-0.47$) between the IPAQ and exercise capacity on a treadmill.

Quality of Life: The SF-36 is one of the most widely used tools for self-reported health-related quality of life. It is a generic health survey geared to adults aged 18 years or older and consists of 36 questions yielding eight domains of functional health and well-being. The physical functioning, role limitations and vitality dimensions assess the extent to which the respondents perceive that their quality of life is influenced by their physical condition. The extent to which bodily pain hinders their ability to perform activities of daily living is also assessed. The mental component includes social functioning, role limitations due to emotional problems and general mental health. A Likert-type scale of rating produces domain raw scores, which are transformed into a 0 to 100 scale, with higher numbers reflecting higher functioning and quality. The scores are calibrated so that 50 is the average score or norm with a standard deviation of 10. The SF-36 has demonstrated sound psychometric properties in a number of studies (Elliott, Renier, & Palchu, 2003; McHorney, Ware, Rogers, Raczek, & Lu, 1992). Ware et al. (2007) found the tool

to have high internal consistency and test-retest reliability. Fallide and Ramos (2000) found the SF-36 to have high internal consistency, reporting Cronbach's alphas of 0.72 to 0.94).

Eating Behaviors: Eating behaviors were assessed at the initial consultation by a registered dietician. Using food diaries and patient self-report the dieticians determined the extent to which patients engaged in the following behaviors: sweets eating, drinking sugar sweetened beverages, eating junk food, volume eating, alcohol use and history of other eating disorders defined as follows:

Sweets eater: Someone who consumes over 300 calories of sweet foods (e.g., candy, cookies, cakes, pies, ice cream, etc.) at least three times per week.

Sweetened beverage drinker: Someone who routinely chooses to drink regular sweetened beverages (e.g., sodas, tea, Kool-Aid®) rather than dietetic versions.

Junk food eater: Someone who routinely consumes over 300 calories of nonsweet junk foods (e.g., chips, pretzels, high fat microwave popcorn, pre-packages cheese crackers, etc.) at least three times a week.

Volume eater: Someone who reports they consume larger than normal portions or who goes back for seconds on a routine basis.

Alcohol overuse: Intake of greater than one standard alcoholic beverage per day for females and greater than two standard alcoholic drinks per day for males.

Hunger: At each follow-up visit the patients were assessed by the bariatric team for their level of hunger using a 4-point frequency scale: 0 = none, 1 rarely, 2 = occasionally, 3 = frequently.

2.5 Data Analysis

Data were entered into an Excel spreadsheet and imported into the Statistical Package for the Social Sciences (17th version) for analysis. Descriptive statistics were used to analyze demographics. Chi square tests of independence were used to relationship between physical activity behaviors, eating behaviors, hunger scores and percentage of EWL. For each chi square analysis, patients were grouped by weight loss categories of less than or equal to 24.9%, 25-49.9%, and greater than or equal to 50% EWL. One-way analysis of variance was performed to assess the change in health-related quality of life in LAGB patients from preoperatively to 2 years postoperatively. Linear regression was performed to determine if successful weight loss at 1 year predicted successful weight loss at two years at $\alpha = 0.05$.

3. Results

A demographic profile of the study participants is presented in Table 1. Most of the participants were female (84%). Caucasians accounted for the majority (59%) of the group African Americans comprised 38%, Hispanics 2 % and 1 % was classified as “other.”

Weight Loss

Weight loss outcomes for years 1 and 2 are summarized in Tables 2 and 3. The mean EWL for both years is less than 50%. The mean preoperative BMI was 44.1 ± 5.1 ; the mean BMI at year 1 was 36.7 ± 5.1 and the mean BMI for year 2 was 35.9 ± 6.7 . At year 1, 30 patients (23%) achieved a weight loss of $>50\%$ EWL 40 (29%) patients achieved a weight loss of between 25 and 49.9% EWL; and the remaining 64 patients (48%) achieved an EWL of less than 25%. Of the 64 patients with data at 2 years postoperatively, 23 (34%)

Table 1

Demographic Characteristics of Sample (N=134)

Age	Mean= 46.6 years Range= 15-70 years Median= 42 years
Gender	
Female	113 (84%)
Male	21 (16%)
Ethnicity	
Caucasian	79 (59%)
African American	51 (38%)
Hispanic	3 (2%)
Other	1 (<1%)
BMI kg/m ²	44.1 ± 5.1 Range=24.8-48.7
Weight (lbs)	272.6 ± 41

Table 2

Weight Loss at 1 Year (N=134)

	Mean	Median	SD	Minimum	Maximum
Weight	226.5	224.8	37.7	151	345
BMI	36.7	36.2	5.1	24.8	48.7
Pounds lost	46.1	39.8	24.4	2.4	135
% EWL	34.6	31.8	16.7	1.9	82.2

Table 3

Weight Loss at 2 Years (N=64)

	Mean	Median	SD	Minimum	Maximum
Weight	223	219.7	46.8	121.7	334
BMI	35.9	35.8	6.7	20.3	50.9
Pounds lost	51.3	47	30.4	-8.0	120
% EWL	39.7	38.6	25	-8.5	114.1

experienced a greater than 50% EWL patients (32%) achieved a weight loss of between 25 and 49.9% EWL and the remaining 21 patients (34%) achieved less than 25% EWL at 2 years.

Interestingly, 23 patients gained weight between years 1 and 2. Of those gaining weight, 12 (52%) had lost less than 25% EWL in year 1, 7 patients (30%) had lost between 25 and 49.9% EWL, and 4 (17%) had lost greater than 50% EWL in year 1.

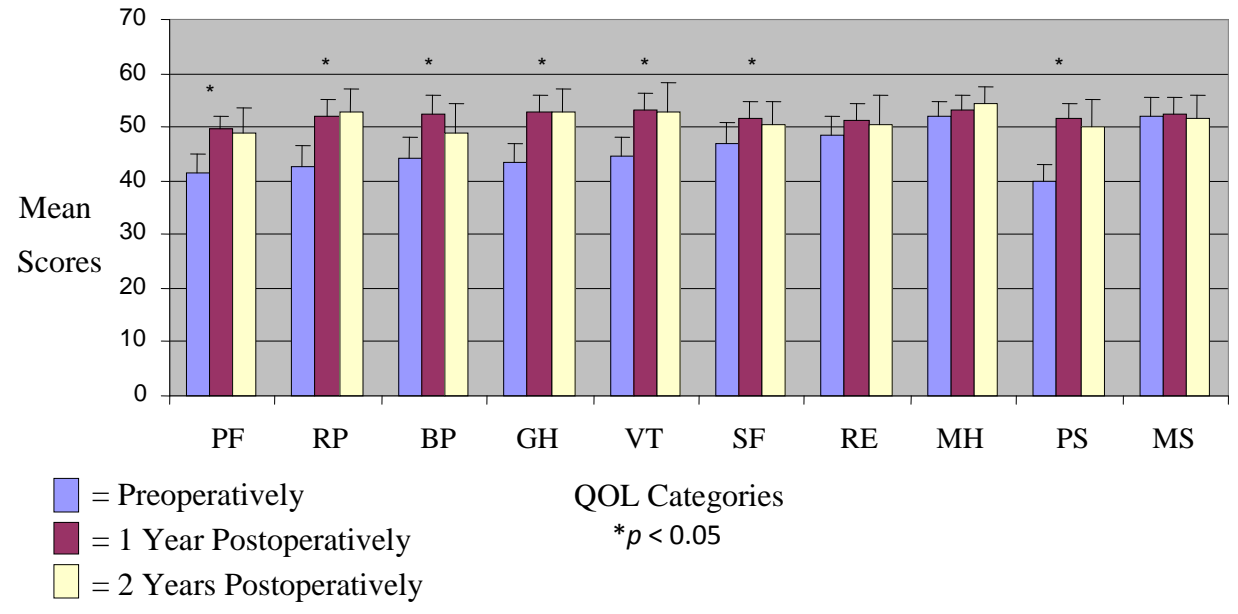
Quality of Life

As shown in Figure 1 mean scores for the domains of physical functioning, physical role limitations, general health perceptions, vitality, social functioning, and overall physical health improved significantly between preoperatively and year 1 ($p < 0.05$). Additionally, the mean scores for the domains of physical functioning, physical role limitations, general health perceptions, vitality, social functioning, and overall physical health improved significantly between preoperative baseline and year 2 ($p < 0.05$). Reports of bodily pain decreased significantly from preoperative baseline to year 1 and year 2 ($p < 0.05$). There was no significant improvement in emotional functioning or overall mental health from preoperative baseline to year 1 or year 2.

Physical Activity

The average time spent sitting per day, walking per week and participating in total physical activity per week preoperatively and at 1 and 2 years was calculated. The average minutes spent sitting per day was determined to be 432 minutes preoperatively (range = 210-1,180 min/day). This number decreased to an average of 324 minutes per day at one year (range = 0-900 min/day) but increased to 363 minutes per day at 2 years (range = 30-1080 min/day). At

Figure 1: Quality of Life Scores in Gastric Banding Patients



QOL Categories: PF= physical functioning, RP= physical role, BP= bodily pain, GH= general health, VT= vitality, SF= social functioning, RE= emotional role, MH= mental health, PS = physical summary, MS= mental summary

year 1, there was no association between the minutes spent sitting per day and the percentage of EWL. There were insufficient data to analyze the association between sitting and weight loss at year 2.

Preoperatively, the patients in this sample walked an average of 178 minutes per week (range = 0-1,680 min/week). The average time spent walking per week increased to 387 min/week (range 0-1,680 min/week) at 1 year but decreased to 307 min/week at 2 years (range 0-1,680 min/week). There was no association between the number of minutes walked per week and the percentage of EWL at years 1 or 2

The average total minutes of physical activity in MET minutes/week was determined to be 1,053 MET minutes/week preoperatively (range = 0-9,144). The average at 1 year increased to 3,317 MET minutes/week at one year (range = 0-21, 546) but decreased to 2,686 MET minutes/week at 2 years (range = 0 -14,746). There was no evidence to support an association between total minutes of physical activity in MET minutes/week and percentage of EWL ($\chi^2 = 6.21, p = 0.184$) at year 1. However, a significant association between total physical activity in MET minutes/week and percentage EWL was found at year 2 ($\chi^2 = 16.263, p = 0.003$).

At year 1, 33.3% of the patients were participating in health enhancing physical activity (HEPA) and by year 2 this had decreased to 28.3%. There was a significant positive ($\chi^2 = 5.985, p < 0.05$) relationship between HEPA participation and percentage of EWL at 1 year, however there was no relationship at year 2 ($\chi^2 = 1.948, p = 0.378$). At year 1, 57.5 % of patients could be described as participating in sufficient activity. Although sufficient activity increased to 71.4% by year 2, there was no significant relationship between participation in sufficient activity and percentage of EWL at 1 year or 2 years.

By year 1, 37.9% of patients were participating in greater than 150 minutes of moderate or vigorous physical activity per week. There was a significant positive association between participation in greater than 150 minutes per week in moderate or vigorous activity and percentage of EWL at 1 year. ($\chi^2 = 7.356$, $p = 0.025$). The percentage of patients participating in this activity increased to 44.8% by year 1; however the association with EWL was not significant at year 2.

Eating Behaviors

Table 4 shows the percentage of EWL at 1 and 2 years for each identified eating category: sweets eaters, sweetened beverage drinkers, junk food eaters, volume eaters and alcohol users. The relationship between sweets eating and drinking sweetened beverages and percentage of EWL was not significant at year 1 or year 2. There was not a significant relationship between eating junk food regularly and amount of weight loss at year 1 and year 2. Additionally, there was not a significant relationship between being a volume eater and weight loss at year 1 and year 2. Regular use of alcohol was low in this cohort at 20%, which is less than the United States average of 64 % for adults (Gallup, 2009). There was no relationship between regular alcohol use and the percentage of EWL at year 1 and year 2.

Hunger

At year 1, 76 % of patients who experienced adequate weight loss (> 50 % EWL) reported feeling occasionally hungry or not hungry at all for most of the day. For those patients losing less than 24 % EWL, 67% reported feeling constantly or often hungry throughout the day. There was a significant positive relationship between degree of hunger reported by patients and successful weight loss at 1 year ($\chi^2 = 27.92$, $p < 0.05$). At 2 years, 42% of patients with successful weight loss reported feeling occasionally or not hungry, whereas among those with

Table 4

Eating Behaviors and Percentage of Excess Weight Loss (EWL) at 1 Year (N=134) and 2 Years (N= 64)

	< 24.9% EWL	25-49.9% EWL	>50% EWL
	1 Year/ 2 Year	1 Year/ 2 Year	1 Year/ 2 Year
Sweets eaters	28%/ 27%	30%/ 31%	19%/ 19%
Sweetened beverage eaters	22%/ 22 %	25%/ 25%	15%/ 15%
Junk food eaters	22%/ 23%	27%/ 27%	18%/ 17%
Volume eaters	24%/ 22%	28%/ 29%	22%/ 21%
Alcohol users	5%/ 5%	8%/ 9%	7%/ 6%

less than 24% EWL, 52% were often or constantly hungry. There was not a significant relationship between degree of hunger and weight loss at year 2.

One-Year Weight Loss as a Predictor of Two-Year Weight Loss

There was statistical evidence of a positive linear relationship between 2-year and 1-year weight loss ($R^2 = 58.2, p < 0.05$). Successful weight loss during the first year after gastric banding predicts weight loss in year 2.

4. Discussion

Patients in this sample demonstrated high variability in weight loss outcomes after gastric banding surgery, and the percentage of EWL was not as dramatic for this cohort as compared with literature reports of patients who had gastric banding at other institutions worldwide. Weight loss outcomes for patients in this study were 34.6% at one year and 39.7% at 2 years, which is less than the widely accepted definition of success as 50% EWL. This study sheds light on issues impacting successful weight loss outcomes after LABG. Further research is needed to explore biobehavioral factors that may impact successful weight loss. Development of postoperative treatment protocols that address gastric band adjustment, physical activity recommendations and psychosocial support are crucial.

Few studies have been published examining weight loss outcomes beyond 10 years and these show mixed results (Biagini & Karam, 2008; Favretti, Ashton, Busetto, Segato, & DeLuce, 2009; Himpens et al., 2011; Stroh, Hohmann, Schramm, Meyer, & Manger, 2011). Long-term success of gastric banding is dependent on frequent follow-up and aggressive adjustments of the band. However, there are few guidelines and very little data available in the literature to assist practitioners in developing a standardized approach to frequency of follow-up visits and adjustment technique. Many programs have developed their own protocols through “trial and

error” and patient feedback. In the protocol developed by this team the first adjustment is done at the 6-week follow-up visit. Based on the amount of weight loss or gain since the previous visit, hunger score, reported eating behaviors and lack of symptoms of esophageal obstruction, the clinician added 0.5 to 1 ml of normal saline to the band. The patient was seen every month thereafter until it was determined that the patient was “optimally” adjusted. Optimal adjustment was defined as losing one to two pounds per week, reporting feeling “not hungry” for most of the day, and no reports of symptoms that would indicate mechanical obstruction of the esophagus. It would be very helpful for other bariatric teams to conduct research and publish the effectiveness of their adjustment protocols with the goal of standardizing approaches worldwide.

This study is one of the first to assess the relationship between hunger scores and weight loss in gastric banding patients. It had been assumed by the bariatric team involved in this study that a reduction in hunger was partially responsible for weight loss in gastric banding patients. This assumption was indeed supported by the findings of this study in that there was a significant inverse relationship between patient reports of decreased hunger and successful weight loss at year 1. The results indicate that achieving reports of “no hunger” to “occasional hunger” for most of the day are associated with greater percentage of EWL. Based on the findings of this study, clinicians should consider development of adjustment protocols that achieve early reduction of hunger in the banding patient with the expectation that this will result in earlier and superior weight loss.

Although reduction of hunger is the purported mechanism of action of the band, there are few studies examining the relationship between the placement of a gastric band and its effect on the gut-brain axis. A study by Dixon et al. (2005) found profound suppression of ghrelin, the hormone that stimulates appetite, after gastric bypass surgery. In contrast, Korner et al. (2009)

found ghrelin levels increased significantly 1 year after gastric banding, which could partially explain the weight regain that occurred 2 years after surgery in this cohort. More studies are needed to increase understanding of the mode of action and effect of neuromodulating interventions, such as gastric banding, on the gut-brain axis. Another recommended direction for future research is a biobehavioral approach to investigating the interactions of biological markers, such as ghrelin, leptin and other hormones that affect the gut-brain axis, on hunger and satiety while exploring correlations with behavioral and psychosocial factors that may affect long-term weight loss and maintenance.

There is a small body of literature examining the impact of weight loss on quality of life in gastric banding patients. Results of this study are consistent with the cited studies finding decreased pain, increased energy, improvement in physical activity in general, ability to accomplish tasks, and participation in social activities. In contrast to the cited studies, this cohort did not exhibit an improvement in emotional and mental health. Although psychological screening was performed preoperatively, there was not a mechanism in place for ongoing psychosocial support of gastric banding patients at this institution. Further research examining emotional and psychosocial variables that impact success in this patient population is clearly warranted. In the meantime, bariatric programs should consider interventions that provide postoperative psychosocial support to promote adherence to behavioral changes needed to ensure weight loss success and perhaps enhance quality of life.

The results of this study support recommendations of previous studies (Evans et al, 2007; Evans, 2010) for at least 150 minutes per week of moderate to vigorous physical activity to achieve and maintain weight loss after bariatric surgery. Further exploration of factors that may contribute to a decrease in physical activity between postoperative years 1 and 2 should be

explored. Interventions need to be developed and tested to assist patients in enhancing and maintaining participation in sufficient activity.

Unlike previously cited studies that found association between eating behavior disturbances and suboptimal weight loss after gastric banding surgery, this study found these behaviors to be fairly well distributed among the weight loss categories. For example, although it was anticipated that a higher percentage of patients who lost less than 24% of EWL would be sweets eaters, sweetened beverage drinkers, junk food eaters and volume eaters, this was not the case. In fact, there were higher percentages of sweets eaters, sweetened beverage drinkers and junk food eaters among those who lost between 25 and 49.9 % EWL. Examination of changes in eating patterns after gastric banding may help identify whether changes in these patterns are associated with positive or negative weight loss outcomes.

Although 23 (36%) patients in this sample gained weight by year 2, there was a significant positive relationship between weight loss postoperative years 1 and 2 such that successful weight loss at 1 year predicted continued weight loss at 2 years. The majority of patients lost an average of 5.1% more weight between years 1 and 2. Therefore, future studies examining how patients can achieve successful weight loss in the first year after gastric banding are important.

Limitations of this study included the subjective nature of questionnaires used for data collection, and the results were limited to 1 and 2 year data. Measures of hunger also were a limitation in this study. The achievement of satiety may be a preferable measure for future LAGB studies, given that lack of hunger and achievement of satiety are not the same thing, particularly in the obese patient who may have disordered physiological and psychological perceptions of these feelings. Objective measures of physical activity such as pedometers should

be considered for future studies. Longitudinal studies are needed that focus on biobehavioral and environmental influences on weight outcomes in gastric banding patients. Despite these limitations, this study has addressed several gaps in the literature and added to the body of knowledge addressing outcomes after gastric banding.

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Appendix A: IRB Approval Form

Category 1: Educational strategies, curricula, or classroom management methods [§46.101(b)(1)]. This research is only being conducted in established or commonly accepted educational settings and the research involves only normal educational practices. Will Identifiers be retained? No Yes* If yes, specify what identifiers and what protections will be utilized to protect the identity and the research data in the research plan. Check here if this research project qualifies for exemption under Category 1.

Category 2: Educational tests, surveys, interviews, or observations of public behavior [§46.101(b)(2)]. This category of research cannot include children unless it is observation of public behavior where the research staff does not participate in the activity being observed. Will research participant identifiers be retained?

Yes: Human subjects will be identified but disclosure of the information obtained outside the research will not place the subject at risk of criminal or civil liability or be damaging to the subjects financial standing, employment or reputation. Specify what identifiers will be utilized and how the data will be recorded and protected in the research plan.
or

No: The information will be obtained and recorded in such a manner that human subjects cannot be identified.

Does this research include the use of educational tests? No Yes - Confirm that: Educational tests are only being conducted in established or commonly accepted educational settings and the research involves only normal educational practices: Yes Children are excluded from the research: Yes

List any standardized educational tests utilized in this research within the research plan.

Does this research involve surveys or interviews?

No Yes - Provide a copy of each survey/interview instrument and confirm that: No information is included regarding: sexual activity or sexual abuse; past or present illicit drug use; illegal activities; child or elder abuse; or suicide or homicidal thoughts or activities. No questions are included that are reasonably expected to provoke psychological anxiety. No identifiers are requested for individuals (e.g., health information) who have not specifically provided consent (e.g., relatives, teachers, etc.). No questions could possibly make the individual vulnerable or otherwise subject them to financial, employment, psychological or medical risk.

Check here if this research project qualifies for exemption under Category 2.

Category 3: Educational tests, surveys, interviews, or observations of public behavior (not approvable under Category 2) [§46.101(b)(3)]. This study involves elected or appointed public officials or candidates for public office and the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Note: How the identifiable information will be maintained must be clear in the research plan.

Check here if this research project qualifies for exemption under Category 3.

Category 4: Existing data, documents, records, specimens - secondary data analysis [§46.101(b)(4)]. All data must be pre-existing at the start of this research project (retrospective data only). In your research plan, identify inclusion dates (a start date is not mandatory, but the end date must be earlier than the date this protocol is submitted for review). Check one:

Data is publicly available (identifiers may be retained and the research plan notes how they will be protected).

or

Data will be recorded in such a way that individuals can not be identified directly or indirectly through identifiers linked to the subject at any time during the study (NO identifiers within the research data files, NO medical record number, identifiers with a key, or student numbers).

Check here if this research project qualifies for exemption under Category 4.

Category 5: Federal department or agency research and demonstration projects for evaluation of public benefit/service programs [§46.101(b)(5)]. For this research project there is no statutory requirement that IRB approval be obtained. The project will not involve significant physical invasions or intrusions upon the privacy of participants. OHRP (or the applicable federal agency) has authorized or concurred with this exemption determination. Check applicable features of the program being studied:

Public Federal benefit program.

Procedures for obtaining benefits or services under these programs.

Possible changes or alternatives to those programs or procedures.

Possible changes in methods or levels of payments for benefits for services under those programs.

This research project qualifies for exemption under Category 5.

Category 6: Taste and food quality/consumer acceptance studies (no additives or safety questions) [§46.101(b)(6)].

Identify the food type from the following:

Wholesome food without additives

Food with additives (Note: Contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

Is this study subject to FDA regulation? Yes No

Will research participant identifiers be retained?

No

Yes: Human subjects may be identified if disclosure of the information obtained outside the research will not place the subject at risk of criminal or civil liability or be damaging to the subjects financial standing, employment or reputation. (Note: The research plan must specify what identifiers will be utilized and how the data will be recorded and protected).

Check here if this research project qualifies for exemption under Category 6.

Final Category Certification:

I certify that all portions of my research project are covered by one or more of the above exempt categories. Note: If this is not correct then you should stop and submit your protocol as expedited or Full board using that form.

Section IV: Sponsor Data

1. Does the research project involve a Direct Federal Award made to VCU (or a research funding proposal for such)? No Yes

2. Have you submitted a related research funding proposal(s) to the VCU Office of Sponsored Programs (OSP) that requires approval of congruence with this study?

No

Yes: You must provide the PT/PD # for each related funding proposal (regardless of funding source):

Is approval of grant congruence required for this protocol?

No

Yes: You must submit the entire grant proposal for review, including the OSP Internal Approval Form.

Section V: Project Detail

Cancer:

(a) Does this study involve cancer patients, their families, or their health care providers? No Yes*

(b) Is this a Cancer Prevention Study? No Yes*

* If YES, the research project must be reviewed and approved by the Massey Cancer Center Protocol Review and Monitoring System before IRB Review, and a copy of the approval letter provided. For information, see <http://www.massey.vcu.edu/research/?pid=2013> or call the PRMS Coordinator at 628-1924.

GCRC: Will this project be conducted in the General Clinical Research Center (GCRC)? No Yes*

* If YES, review information for investigators available at <http://www.vcuhealth.org/crc/>

VCUHS: Will this project be conducted in a VCUHS patient care area or involve VCUHS patients?

No Yes

Where is this study going to take place (check all that apply) ?

At VCU

At non- VCU sites, follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm>

At foreign Sites follow guidance at <http://www.research.vcu.edu/irb/wpp/flash/XVII-11.htm>

Section VI: Research Participant Information

Children: Does this study involve the inclusion of data on research participants who are children? No Yes

(Note: In Virginia, children are those under the age of 18 and not emancipated.)

Subject Enrollment Plan: Anticipated total # of subjects under this IRB approval? 200

Is this a Multi-Center Project? No Yes

Total number of sites:

Total number of expected Participants (at all sites):

Section VII: Principal Investigator Statement of Compliance

I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including myself, sub/co-investigators, research coordinators, trainees, and students have completed the VCU required training on human subjects protection. I agree to a continuing exchange of information with the VCU IRB including the requirements to (i) obtain IRB approval before making changes to the study that either add an additional category of exemption,

change risk level, or for surveys change the content areas covered by the survey (see category 2 above) (ii) provide progress reports to the VCU IRB at their request (at least every 3 years) and at study closure, and (iii) report promptly to the IRB all unanticipated problems and serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the IRB).

I have instructed any students or trainees working on this project that they may not proceed with the research without first receiving a formal written letter of approval from the VCU IRB. I certify that all key personnel on this project have completed the required VCU training on human subjects protection.

I have informed my Department/Division Chair or Dean about this research protocol.

Signature of Investigator:

Date:

Section VIII: Research Plan

Hypothesis and/or Specific Aims AND/OR Goals: Briefly describe. Including background information that the reviewer will need to understand risk/benefits and scientific need for this study.

The primary aim of this study is to examine the impact of physical activity, eating behaviors and hunger control on weight loss and quality of life in gastric banding patients who had surgery at VCU Health System since 2004. The secondary aim of the study is to determine variables at year 1 that may be predictive of outcomes at 2 years.

Obesity is a complex, multivariate problem which not only has a significant impact on morbidity and mortality but has a devastating effect on physical functioning, psychological well-being and overall quality of life (Flegel, 2005). Obesity is defined as a body mass index (BMI) of equal to or greater than 30 kg/m² and morbid obesity as a BMI of equal to or greater than 40kg/m². The prevalence of morbid obesity is increasing at an alarming rate worldwide. Factors contributing to this epidemic include genetic, environmental, physiologic, psychosocial, economic and behavioral. Growth in technology and urbanization of populations in developing countries may promote a sedentary lifestyle while diets are increasingly higher in sugar and saturated fats (James, 2004). The increasing rate of obesity is of concern because of the causal link with a number of adverse consequences including, but not limited to, coronary heart disease, diabetes, hypertension, dyslipidemia, sleep apnea, stroke and cancer.

Obesity is a heterogeneous condition and individual responses to interventions are highly variable. Current weight loss therapies include a limited number of medications, surgical interventions and behavioral/cognitive therapies; however, there is a high degree of variability of response among individuals to these interventions (Teixeira, Going, Sardinha & Lohman, 2005; Toussi, Fujioka & Coleman, 2008). Adherence to behavioral therapy in particular is inconsistent and high attrition is well known in weight loss efforts and is impacted by environmental, psychosocial and behavioral factors (NIH, 1998). A meta-analysis of studies reviewing the

effectiveness of weight loss programs in the United States revealed widespread failure with existing obesity treatments that are focused on diet and exercise (Anderson, Konz, Frederick & Wood, 2001). Long-term weight maintenance, although possible for some is also notoriously difficult (Byrne, 2002; Ray, Nickels, Sajeed & Sax, 2003).

Because of the high failure rate of conventional weight loss therapies for morbid obesity, the NIH recommends surgical therapy as the only intervention associated with long-term success (NIH, 1998). Currently, the two most consistently performed bariatric surgeries in the United States are the Roux-en-Y (RNY) gastric bypass and gastric banding. These procedures produce weight loss primarily through gastric restriction and malabsorption (RNY) or by restriction only (banding). The goal of either surgery is for the patient to lose 50 per cent of their excess weight. A systematic review of 14 studies by Tice, Karline, Walsh, Peterson and Feldman (2008) comparing these two procedures found that there was greater weight loss for the RNY procedure (76% excess weight loss) as compared with gastric banding (48% excess weight loss). The mortality rate for the two procedures was similar although the band had a lower morbidity rate (5%) compared with RNY (9%). An earlier systematic review of over 50 studies comparing the band with RNY found weight loss outcomes to be comparable at 4 years after surgery. (Chapman, et al., 2004).

Gastric banding has increased dramatically in the U.S since the FDA approved the procedure in 2001. Many patients choose the banding procedure because of the perceived higher complication rate with the RNY. Weight loss outcomes after banding are highly variable and seem to be dependent on careful assessment and screening of patients (Kral, 2001). Additionally, maintenance of weight loss after banding requires long-term dietary modification and/or exercise to be effective and patient compliance is crucial.

Weight loss surgeries such as gastric banding can produce significant weight loss in some morbidly obese patients. Unfortunately, many gastric banding patients do not achieve adequate weight loss and others experience considerable weight regain. Weight loss outcomes following gastric banding at VCUHS bariatric Center of Excellence have been suboptimal and there are few resources available to guide the care of these patients. There are research studies available on postoperative gastric bypass patients suggesting that inconsistent weight outcomes can be attributed to maladaptive eating and sedentary activity, however, this type of data is lacking in the banding population. An important consideration in gastric banding patients that has been minimally explored is achievement of hunger control and satiation through optimal band adjustment. Research in this area is needed to establish guidelines for achieving early satiation through optimal adjustments. Additionally, there have been few studies examining maladaptive eating behaviors in this population and how these may affect outcomes. There also have been few studies examining the relationship between physical activity and weight loss in gastric banding patients and the limited research results have been inconsistent. Additionally, there have been few studies on the relationship between weight loss and quality of life in gastric banding patients. There have been no reported studies examining the relationship between physical activity and quality of life in gastric banding patients. Thus, the proposed study is designed to provide new information related to factors potentially associated with successful outcomes following gastric banding using existing data collected and stored by VCUHS Center of Excellence, one of the largest databases on gastric banding patients.

Preliminary 3-year outcome data indicate that gastric banding patients at VCUHS have lost approximately 37% of their excess weight. This number is below that reported in the literature.

Reports published since the FDA approved the procedure in 2001 report anywhere from 42 to 62% excess weight lost. Two recent systematic reviews reported mean excess weight loss of 48% (Picot et al, 2008) and 53% (Weichman et al, 2010). Most studies do not report a range of individual weight loss, therefore it is difficult to determine the experiences of individual patients. Initial data at VCUHS indicates patients have lost between 0 and 100 pounds. The bariatric team speculates that the reasons for these inconsistent outcomes are related to physiological, psychosocial and behavioral variables; however, studies in the literature are overwhelmingly devoted to gastric bypass patients. Thus, causes of inconsistent weight loss outcomes in gastric banding patients has been minimally explored. Research is badly needed to establish guidelines for achieving optimal outcomes in this patient population. In particular, there are only several studies addressing the issue of hunger control and early satiety through optimal band adjustments, which is surprising given that this is the physiological mechanism by which the band reportedly works. There are few studies addressing the effects of behavioral issues such as maladaptive eating and physical activity and their effects on weight loss in banding patients. Additionally, while there are many studies looking at the effect of weight loss on quality of life in gastric bypass patients, there are very few addressing this issue in gastric banding patients. Because most insurance companies will pay for only one bariatric procedure per lifetime, it is crucial that we identify factors that impact patient success and develop interventions that optimize individual outcomes for gastric banding vs. bypass patients.

Impact of Physical Activity on Weight Loss in Gastric Banding Patients: The American Dietetic Association maintains that successful weight management requires not only a healthy diet but daily physical activity (Seagle, Strain, Makris & Reeves, 2009). Many organizations such as the Centers for Disease Control (CDC) and the US Department of Health and Human Services and the United States Department of Agriculture (USDA) also recognize physical activity for its contribution to energy expenditure and weight maintenance (Poirier & Despre, 2001). These organizations vary in their specific recommendations for physical activity for weight management but range from 150 minutes of moderate aerobic exercise per week (USDA) to 60 to 90 minutes of moderate exercise on most days of the week (CDC). It is recognized that the morbidly obese person may have impaired ability to exercise due to physiologic problems such as abnormal gait and dyspnea and tends to be more sedentary; however, even low intensity exercises such as walking can contribute to energy expenditure (Bond, Leahey, Vithianathan & Ryder, 2009). Although there are few studies on the role of physical activity on weight loss outcomes after obesity surgery, several recent studies suggest that participation in regular activity after RNY surgery results in better weight loss and maintenance at 2 years post operatively (Silver, Torquati, Jensen & Richards, 2006; Evans et al., 2007). Colles, Dixon and O'Brien (2008) found regular walking was associated with better weight outcomes after one year in gastric banding patients. A study of predictors of success including participation in physical activity in gastric banding patients showed similar results at 2 years (Chevallier, et al., 2007). Chambliss (2005) found that the duration of exercise was more important than intensity in promoting weight loss in sedentary overweight women. A recent randomized control trial by Church et al (2009) found no significant effect in weight loss in postmenopausal women assigned to different doses of exercise although a significant reduction in waist circumference was noted. Caudwell, Hopkins, King, Stubbs, and Blundell (2009) found large variability in weight loss among obese men and women who exercised and correlated it with increased food intake after exercise in some participants. Evans (2009) recommends that weight loss surgery

patients should participate in 150 minutes per week of moderate or higher intensity exercise and progress to 200 to 300 minutes per week for long-term weight maintenance.

Impact of Eating Behaviors on Weight Loss in Gastric Banding Patients: Patients with presurgical eating disturbances such as grazing, sweets eating, and bingeing may have suboptimal weight loss after gastric banding. The incidence of maladaptive eating behaviors such as bingeing is high among candidates for weight loss surgery (deZwaan, Mitchell, & Howell, 2003). Colles, Dixon and O'Brien (2008) showed that preoperative grazing predicted 19.5 percent of the variance in percent of weight lost postoperatively. Saunders (2004) defined grazing as the frequent consumption of small amounts of food over an extended period and found grazing to be prevalent among obesity surgery patients. Additionally, he found that a preference for high caloric liquids is associated with poor weight loss after bariatric surgery. There is evidence to suggest that binge eating is highly prevalent among morbidly obese patients who seek bariatric surgery which tends to persist after the procedure, resulting in insufficient weight loss or weight regain (Hsu, Sullivan & Benotti, 1997). Other researchers suggest that preoperative binge eaters may convert to grazers postoperatively (Busetto, Valente & Pisente, 2005; Saunders, 2004). A study by Toussi, Fujioka and Coleman (2008) examined the relationships between weight loss, patient characteristics, psychological factors and behavioral issues and found that patients who lost the most weight two years after bariatric surgery were more likely to be non-white, have a lower socioeconomic status and have a diagnosis of binge eating before surgery. It is speculated that with a restrictive procedure such as banding, binge eating should be more difficult because of physical restriction; however, two prospective studies on the relationship between preoperative bingeing and weight loss after surgery found no relationship (Potoczna, Branson & Kral, 2004; Busetto, Segato & DeLuca, 2005).

The Nurses' Health Study II found an association between consumption of sugar sweetened beverages, but not diet beverages, with weight gain and type 2 diabetes. (Schulze et al, 2004) It is speculated that high fructose corn syrup in soft drinks contributes to a high glycemic index and a fast and dramatic increase in both glucose and insulin concentrations in the blood (Janssen, Shapiro & Deberley, 1999). Excessive consumption of sweetened beverages such as sodas and sweet tea is common in morbidly obese patients and seems to be associated with inferior weight outcomes after restrictive weight loss surgeries (Brolin, Robertson & Kenler, 1994; Busetto, Valente & Pisente, 1996). Himpens, Dapri and Cadiere (2006) found sweets eating behaviors to persist and to be a cause of failure after restrictive surgeries such as gastric banding. Patients may be classified as sweets eaters if they consume > 300 calories of sweet foods or beverages three times or more in one average week (Herpertz, Kielmann, Wolf, Hebebrand & Senf, 2004). Sugarman et al, 1992) proposed that after restrictive surgeries, sweets eaters do not lose as much weight as non sweets eaters, however, Dixon and O'Brien (2001) and Hudson, Dixon and O'Brien (2002) found no relationship between a preference for sweets and inferior weight loss in banding patients.

Impact of Hunger Control on Weight Loss in Gastric Banding Patients: The primary weight loss mechanism of the gastric band is to produce early and prolonged satiety ultimately leading to reduced intake and weight loss. This is accomplished by injecting an appropriate fluid volume into the gastric band. The silicone gastric band is surgically placed around the upper part of the stomach creating a stomach pouch with an approximately one-inch wide outlet. Tubing runs from the gastric band to an injection port that is placed under the skin. Sterile normal saline is injected into the port to make the band tighter. An average of five to seven adjustments are made until the patient reports little to no hunger. Typically, patients receive the first "fill" of their

bands six weeks after surgery and then have adjustments approximately every month until it is determined they have an optimally filled band. The multidisciplinary healthcare team defines this as early and prolonged satiation, losing one to three pounds per week, and having no symptoms of obstruction, such as vomiting or reflux. Whenever patients develop symptoms of obstruction, fluid is removed from the band which in most cases provides relief. If patients continue to have symptoms, the correct position of the band is evaluated with a contrast swallow study.

An optimally adjusted gastric band produces higher ratings of satiety, marked reductions in reports of hunger and superior weight loss compared with unrestricted bands and non-banded control patients (Burgmer, Grigutsch & Zipfel, 2005). Although the exact mechanism for the physiologic response of a decreased sensation of hunger is unclear, it is postulated that there may be two mechanisms involved. The first is a mechanical process in which physical restriction of the gastro-esophageal junction results in delayed gastric emptying. An early randomized controlled trial by Bergmann, Chassany, Petit, Triki, Caulin, and Segrast (1992) documented an association between delayed gastric emptying and decreased appetite.

The second mechanism seems to be related to less stimulation of the hunger center in the hypothalamus by the hormone ghrelin which is produced in the gastric mucosa (Schwartz, Woods & Porte, 2000). There is very little data in the literature establishing the norms of satiety in banding patients and no guidelines exist to assist practitioners in making treatment decisions regarding optimal filling of the band. Burton et al. (2010) developed an instrument to assess satiety, adverse upper gastrointestinal symptoms and weight loss and found the tool to be helpful in determining optimal ranges of satiety in response to band adjustments while avoiding symptoms of obstruction. Another study on aspects of band adjustment found that greater subjective hunger was associated with decreased weight loss in gastric banding patients (Burgmer, Grigutsch & Zipfel, 2005). A double blind randomized controlled trial by Dixon, Dixon and O'Brien (2005) demonstrated a highly significant increase in reported hunger after removal of all fluid from the gastric band.

Quality of Life: Excessive weight may affect a person's quality of life (QOL) because of the adverse effects on overall physical health and psychological and emotional consequences. Both generic and obesity specific tools have been used to measure quality of life in the obese population. The most frequently used tool is the Medical Outcomes Study Short Form 36 (SF-36). This tool has been used in many different patient populations and age groups to evaluate the relative burden of disease and to assess response to interventions. It has been widely used to measure QOL among morbidly obese patients after gastric bypass surgery and gastric banding surgery. The scale consists of 2 major components of health related QOL. The physical component includes physical function, role activity, bodily pain and general health perceptions. The mental component includes vitality, social functions, role-emotion and mental health. Each domain score is ranged from 0 to 100 with higher numbers reflecting higher functioning and quality. The SF-36 has been shown to have high internal consistency and test retest reliability (Ware et al., 2007).

Several studies of weight and health-related quality of life indicate that obesity has an adverse effect on quality of life. Fine et al. (1999) used the SF-36 to examine the association between QOL and weight among 40,098 women participating in the Nurses' Health Study. They found that weight gain is associated with decreased physical functioning, vitality, and overall QOL and increased bodily pain. Researchers in Sweden investigated the impact of weight on QOL in 5633 male and female adults using the SF-36. They found that the level of obesity had a significant

impact on QOL and that obese women rated their QOL as worse when compared with obese men. A more recent study by Lynch et al (2010) found that obesity negatively affected QOL in post menopausal women of diverse ethnic backgrounds who were enrolled in the Women's Health Initiative.

The primary goals of weight loss surgeries are to improve overall health status and quality of life (QOL) through significant and sustained weight loss. At VCUHS, practitioners have noted that with significant weight loss there is dramatic improvement or resolution of medical comorbidities including metabolic syndrome, hypertension, sleep apnea, dyslipidemia and gastroesophageal reflux. Additionally, weight loss is also associated with improved ovarian function and fertility. Patients also report general improvements in physical and psychological functioning and improved body image. Most research studies looking at the correlation between weight loss and quality of life after weight loss surgery attribute the improvement in QOL to the weight loss and resolution of comorbidities.

A number of studies have reported improved QOL after gastric banding surgery. Shok, Geenen, and van Antwerpen, (2000) utilized the SF-36 tool to evaluate QOL in 74 gastric banding patients at one and three years after surgery and found significant improvement in psychological and social quality of life, although their perceived physical quality of life was below that of the normal population. Dixon, Dixon and O'Brien (2001) studied 459 gastric banding patients using the SF-36 tool and found that those who reported their health related quality of life as poor prior to surgery experienced significant and sustained improvement postoperatively. Mathis-Vliegme and de Witt (2007) used an obesity specific QOL instrument: the Impact of Weight on Quality of Life tool to examine outcomes of gastric banding. They found that after 5 years, gastric banding patients had a significantly improved sense of well being, perceived attractiveness and self worth. They also found that the patients engaged in significantly more physical activity but did not correlate this with QOL. A study by Freys et al. (2001) reported a significant improvement in QOL using a tool called the Gastrointestinal Quality of Life tool in 73 banding patients but reported a high number of complications (38%) that resulted in reoperation. A more recent study by Clough, Layin, Shah, Wheatley and Taylor (2010) of 113 gastric banding patients reported marked improvement in physical, mental, emotional and social QOL in gastric banding patients over the age of 60 although they experienced less excess weight loss than their younger cohorts. Holterman et al (2010) reviewed outcomes of gastric banding surgery in 26 adolescents and found significantly improved QOL using the PEDSQL that measures health related QOL in the pediatric population. There was a significant improvement in comorbidities and decreased medication use in this group and they reported reduced depression, improved self-esteem and less bodily pain. Several recent European studies have found improved QOL after gastric banding using the Ardelt-Moorehead Quality of Life questionnaire. (Kinzel et al., 2007; Titi, Jenkins, Modak & Galloway, 2007; Muller, Wenger, Scheiss, Clavian & Weber, 2008). In contrast, Horchner, Tuinebreijer and Kelder (2001) found that at 2 years postoperatively banding patients experienced less bodily pain after gastric banding but no significant improvement in overall quality of life scores.

In addition to the effects of weight loss on QOL, there is consistent evidence that participation in physical activity has a dramatic effect on improving QOL in the general population (Brown et al., 2003; Brown et al., 2004; LaForge, Rossi, & Prochaska, 1999). This relationship has not been studied in gastric banding patients.

Research Method and Design: Provide a brief description of the project design including the setting in which the research will be conducted and procedures. If existing records are being reviewed please list what records will be accessed and how you have access to those records. The VCUHS Division of General Surgery has been performing bariatric procedures for weight loss since 1980 and has an extensive database that includes over 4200 patients. This database has been utilized as an important source of information for the analysis of the results of surgery for morbid obesity. In addition to providing quality assurance information, the data have been analyzed for a number of studies that have been published in peer-reviewed journals and presented at national conferences. As an American Society of Metabolic and Bariatric Surgery (ASMBS) Center of Excellence, data are required to be shared for national studies of mid- and long-term outcomes for bariatric surgery patients. The database consists of information gathered at the initial consultation and all follow-up visits. This information includes age gender, marital status, comorbidities, previous surgeries, surgery date, surgical complications, follow-up visit dates, weight, BMI, trajectory of excess weight loss, gastric band volume, hunger score, all component scores of the SF-36 and all information regarding participation in activity from the International Physical Activity Questionnaire short form (IPAQ-short). The student investigator will query the existing database for factors related to physical activity and hunger control that may impact weight loss and quality of life in gastric banding patients. Information about eating behaviors will be obtained from the initial evaluation data recorded by the registered dietitians on the bariatric team.

Evaluation of physical activity is multidimensional and should include consideration of type of activity, duration, frequency and intensity. The IPAQ-short has been used extensively to measure health-related physical activity in adults. The form is a self-report measure that asks questions about time spent in physical activities at work, as part of house and yard work, and for recreation, exercise and sports in the previous seven days. Frequency, duration and intensity of these activities are assessed. Intensity may be described as vigorous, which refers to activities that require hard physical effort and cause the person to breathe much harder than normal. Moderate activity is described as activities that take moderate physical effort and require the person to breathe somewhat harder than normal. The results provide separate scores on each activity type as well as a combined score of total activity over seven days. Metabolic equivalent scores can be calculated to provide information about the volume of activity. Studies have shown the IPAQ short-form to be valid and reliable in collecting physical activity data in healthy middle-aged adults (Craig et al., 2010).

The SF-36 will be used to assess quality of life and is a generic health survey that consists of 36 questions yielding scores on eight domains of functional health and well-being. The tool has been used in many different patient populations and age groups to evaluate the relative burden of disease and to assess response to interventions. It has been used to measure QOL among morbidly obese patients after gastric bypass surgery and gastric banding surgery. The scale consists of two major components of health related QOL: The physical component includes physical function, role activity, bodily pain and general health perceptions; the mental component includes vitality, social functions, role-emotion and mental health. Each domain score ranges from 0 to 100 with higher numbers reflecting higher functioning and QOL. The SF-36 has been shown to have high internal consistency and test-retest reliability (Ware et al., 2007). Information about eating behaviors is obtained at the initial consultation and at each follow-up visit by the dietitians on the bariatric team. Using food diaries and patient self-report the dietitians determine whether patients engage in the following behaviors: sweets eating, drinking

sugar-sweetened beverages, eating junk food, volume eating, alcohol use and history of other eating disorders. These eating behaviors are defined as follows:

Sweets eater: Someone who consumes over 300 calories of sweet foods (e.g., candy, cookies, cakes, pies, ice cream, etc.) at least 3 times per week.

Sweetened beverage drinker: Someone who routinely chooses to drink regular sweetened beverage. (e.g., sodas, tea, Kool-aid, etc.) over dietetic versions.

Junk food eater: Someone who routinely consumes over 300 calories of nonsweet junk foods (e.g. chips, pretzels, high fat microwave popcorn, pre-packages cheese crackers, etc.) at least 3 times a week.

Volume eater: Someone who perceives they consume larger than normal portions or who goes back for seconds on a routine basis.

Alcohol overuse: greater than one standard alcoholic beverage per day for females and greater than 2 standard alcoholic drinks per day for males.

Hunger: At each follow-up visit the patients are assessed for their level of hunger by dieticians: 0=none, 1=rarely, 2= occasionally, 3= frequently. The number of band adjustments and their time intervals will be recorded as a study covariate.

Data Analysis:

The primary aim of this study is to examine the impact of physical activity, eating behaviors and hunger control on weight loss and quality of life in gastric banding patients who had surgery at VCU Health System since 2004. The secondary aim of the study is to determine variables at one year that may be predictive of outcomes at 2 years.

The primary aim will be analyzed using multivariate regression to determine the relationship between multiple independent variables: physical activity, eating behaviors and hunger and the dependent variables: the percentage of excess weight loss and QOL after gastric banding surgery. The secondary aim will be analyzed using multiple regression to determine variables at one year that may predict two year weight loss.

Limitations of the Study:

A number of critical variables are not being measured in this study, including such biological factors as genetics and hormonal effects as well as sociobehavioral factors such as socioeconomic status, social support, family constellations, and the important variable of adherence. Use of an existing database includes inherent limitations in the availability of valid and reliable indicators.

Conflict of Interest: Disclose if there is any way in which the investigators might benefit by an individual participating in this project or completion of the project in general. Do not describe (1) academic recognition, such as publications or (2) grant/contract-based support of VCU salary commensurate with the professional effort required for the conduct of the project.

The investigators will not benefit in anyway by completion of this project.

IV. **Human Subjects Instructions:** ALL sections of the Human Subjects Instructions must be completed.

Description: Describe the subject population in terms of sex, race, ethnicity, age, etc., and the involvement of special cases of subjects, such as children, pregnant women, human fetuses, neonates, or others who are likely to be vulnerable. Please provide information on how individuals with limited English proficiency will be accommodated.

All patients who received gastric banding surgery at VCU health System since 2004 and are between 21 and 60 years of age. To be eligible for surgery, patients are required to have a BMI > 40 kg/m² or greater then 35kg/m² with significant health co morbidities. Exclusions: - weight

change caused by medical or psychiatric condition or use of medication known to affect weight, weight change as a result of pregnancy.

Research Material: Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.

Research will involve gathering and analyzing data about all gastric banding patients that has been entered into the Bariatric Surgery Database.

Recruitment Plan: Describe your plans for the recruitment of subjects including: (1) how potential subjects will be identified (e.g., school personnel, health care professionals, etc), (2) how you will inform potential participants about the study (e.g., information sheet, information section before a survey, or a verbal description) (3) how you will get the names and contact information for potential subjects, and (4) who will make initial contact with these individuals (if relevant) and how that contact will be made. If you plan to involve vulnerable persons (i.e., children, pregnant women, human fetuses, neonates, or others who are likely to be vulnerable), describe any special recruitment procedures for these populations.

Research will involve gathering and analyzing data about all gastric banding patients that has been entered into the Bariatric Surgery Database. The information in the database is on all patients who received gastric banding surgery at VCU health System since 2004 and are between 21 and 60 years of age. To be eligible for surgery, patients are required to have a BMI > 40 kg/m² or greater than 35kg/m² with significant health co morbidities. Exclusions include weight change caused by medical or psychiatric condition or use of medication known to affect weight and weight change as a result of pregnancy. Patients have been informed prior to surgery that they will need to be followed for the rest of their lives for outcomes resolution of comorbidities and any complication of the surgery.

D. Confidentiality and Privacy: Describe how the privacy of data collected as part of this project will be protected and confidentiality maintained. If identifiers are kept describe how they will be protected and their relationship to the data (for example, unique identifiers or identifiers separated from the data).

DATA HAVE BEEN ENTERED INTO AN ELECTRONIC DATABASE SINCE 2004 THAT IS LOCATED IN THE DIVISION OF GENERAL SURGERY IN A LOCKED ROOM AND IS PASSWORD PROTECTED. AFTER THE DATA ARE ENTERED, THE HARD COPIES OF THE QUESTIONNAIRES ARE DESTROYED BY SHREDDING. DATA ARE NOT DE-IDENTIFIED FOR THE GENERAL SURGERY DATABASE BECAUSE THE INFORMATION IS USED FOR PATIENT MONITORING AND COUNSELING. ACCESS TO THE DATA FOR THIS STUDY WILL BE RESTRICTED TO THE RESEARCHER, STATISTICIAN, AND A TRAINED RESEARCH ASSISTANT. FOR THIS STUDY, ALL DATA WILL BE DE-IDENTIFIED AT THE TIME THE DATABASE SUBSET FOR THIS RESEARCH IS CREATED. ARBITRARY SUBJECT CODE NUMBERS WILL BE USED FOR ALL DATA ENTRY.

Compensation Plan: Compensation for subjects (if applicable) should be described, including possible total compensation, any proposed bonus, and any proposed reductions or penalties for not completing the project. NOTE: Outside of the IRB, VCU has a gift card and monetary compensation policy which may apply to your procedures for payment of research participants. There will not be any compensation to subjects involved in this study.

Section IX: Submission Checklist - EXEMPT

The following elements are reminders of steps and documentation that must be included with your submission packet. Note: If required documents are missing or multi-page documents are not stapled, your review will be delayed.

Please check all that you are including with this submission

Enclosed N/A

VCU IRB Exempt Review Submission Form

Advertisements and Subject Recruitment Materials (if applicable)

(Any materials submitted must include a version number or date)

Information Sheet or Consent Information (if applicable)

Measures/Instruments (if applicable)

(e.g., surveys, interview or focus group guides, educational tests - materials submitted must include a version number or date)

Massey Cancer Center PRMS Approval Enclosed (if required)

(see Section V-1 of this form)

Conflict of Interest Disclosure Statement Enclosed

Research Funding Proposal and

OSP Internal Approval Form Enclosed (if applicable)

(See Section IV-4 of this form - Certain sponsors may require your proposal to be reviewed for congruence with your funding source. In this case, the entire proposal, excluding appendices, must be submitted).

Other (if applicable)

(Any materials submitted must include a version number or date)

Identify enclosure:

Number of Copies Required

Submit 3 copies of this checklist and all applicable documents
(including version number and date on each document submitted)

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Vita

Nancy Gott Baugh was born in Roanoke, Virginia on June 17, 1957, and is an American citizen. She graduated from Patrick Henry High School in 1975 in Roanoke, Virginia. She received her Bachelor of Science in Nursing in 1979 from Atlantic Christian College, Wilson, North Carolina in 1979. She received a Master of Science in Nursing from Virginia Commonwealth University in 1984, and a post-master's certificate as an adult nurse practitioner in 2004 from Virginia Commonwealth University. She taught nursing at Bon Secours Memorial School of Nursing from 1984 to 2004. She is currently a faculty at the University of Southern Maine College of Nursing.