

Effects of pre-existing co-morbidities in variable lifestyle modification programs on weight loss
and aerobic capacity in two types of bariatric surgery patients.

A Thesis Presented

by

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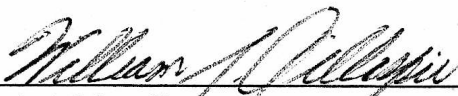
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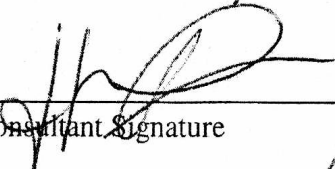
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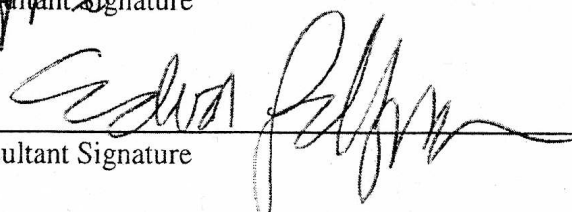
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ABSTRACT

Vogt, S.V. Effects of pre-existing co-morbidities in variable lifestyle modification programs on weight loss and aerobic capacity in two types of bariatric surgery patients. M.S. in Clinical Exercise Physiology, 2008; 58 pg. (Dr. W. Gillespie, Dr. H. Pino, and Dr. E. Saltzman).

Introduction: Bariatric surgery patients with pre existing co morbid conditions such as diabetes and hypertension are at increased cardiovascular risk. The relationship of exercise in promoting a more healthy body composition with bariatric surgery is not clearly defined.

Subjects: Bariatric surgery patients (n=223) at Tufts Medical Center in Boston, MA. were followed for changes in absolute and relative body weight over two years. Patients were stratified by surgical procedure, prevalence of baseline diabetes or hypertension, and participation in an exercise program or no exercise program at three semi-annual visits.

Results: Surgical groups were significantly different in absolute and relative body weight at baseline and over the two year follow up. There were no significant differences in body weight at baseline between the co morbidity groups or over the two year follow up. The exercise group was significantly different from non exercise group at the last follow up (18-24 months) for absolute body weight. Only seven participants qualified for fitness assessments of which these patients increased in estimated MET capacity without any significant relationship to change in body weight over the follow up period.

Conclusions: While surgical groups displayed significant differences in body weight across the two years there were no significant differences between the baseline co morbidity groups and differences only at 18-24 months between the exercise and non exercise groups. Participation in exercise programming possibly increased lean body mass for a corresponding increase in body weight possibly responsible for the increase in estimated MET capacity.

CHAPTER I

INTRODUCTION

The World Health Organization (WHO) currently estimates two billion people are either overweight or obese. By 2015, obesity is expected to affect 700 million (WHO, 2006) with the United States contributing significantly over the last 30 years with an approximate 20% rise settling at 34% of the U.S. population measuring a BMI over 40 kg/m² (Ogden, Carroll, McDowell, and Flegal, 2007). To battle the growing epidemic many initiatives in the U.S. have developed target goals to promote general health; sadly, the U.S. Centers for Disease Control (CDC) reported in 2006 only four states within the target goal of the *Healthy People 2010's* goal of $\leq 20\%$ obese (CDC, 2006). As obesity currently ranks second only behind smoking in the U.S. for preventable causes of death, this epidemic will leave its mark through its associations to chronic diseases referred to as “co morbidities” (Allison, Fontaine, Manson, Stevens, and VanItallie, 1999). Without effective and long lasting treatment of primary obesity, it is expected co morbidities such as hypertension, dislipidemia, diabetes, and cardiovascular disease will continue to increase health disparities in overweight patients (Wilson, D’Agostino, Sullivan, Parise, and Kannel, 2002).

Because obesity requires integrated management (behavior modification, diet, exercise, and pharmacotherapy), it has become difficult to provide interventions which deliver long lasting health benefits. Traditionally, nutritional therapies appeared to offer the ability to reduce body weight, but alone could not significantly improve cardiovascular health as programs which integrated physical activity. Treatment goals (weight loss, treatment of co morbidities, and

maintenance of reduced body weight) must be properly defined for individual patients. As patients with morbid obesity ($BMI \geq 40\text{kg/m}^2$) began turning to medical centers for assistance in weight loss, treatments became focused on a rapid reduction of overall cardiovascular disease capable only by bariatric surgery to induce significant (20-40% initial body weight) weight loss (Fontaine, Redden, Wang, Westfall, Allison, 2003). Surgical methods succeeded not only as an effective conventional therapy, but the only treatment methods with statistically significant improvements in body weight and co morbidities 10 years post procedure. These results yield improvements in both body weight, body mass index, and in co morbidities (Sjorstrom, et al., 2004) to continue validating the efficacy of weight loss surgery to give morbidly obese patients fresh opportunities to obtain an improved cardiovascular prognosis.

Statement of the problem

This study investigated how body weight was affected in two types of bariatric surgery patients (gastric bypass and gastric banding) by presence of baseline diabetes and hypertension as well as participation in guided exercise programming. The groups will be associated by:

- 1.) Surgical effect- gastric bypass or gastric banding.
- 2.) Prevalence of baseline co morbidities- assigned with a baseline diagnosis of Diabetes and/or Hypertension.
- 3.) Exercise participation- Participation in guided exercise counseling with two required fitness assessments to measure change in estimated aerobic capacity (MET's).

The program participants were a part of the comprehensive lifestyle modification and surgical weight loss program at the Obesity Consult Center (OCC) of Tufts Medical Center in Boston, Massachusetts. Only patients who chose to participate in the exercise programming

portion and set up initial and follow up exercise testing sessions were included in the exercise participation group.

Delimitations

This study examined 223 bariatric surgery patients, 68 gastric banding and 155 gastric bypass patients, at the OCC of Tufts Medical Center from January 1, 2000 to January 1, 2008. Only patients who completed pre-procedure, surgery, and follow-up visits throughout the two year period were included in the study. All patients qualified according to the National Institutes of Health (NIH) Bariatric Surgery Guidelines (Buchwald, 2005) as well as by the OCC guidelines to qualify for surgery (see Table 1; TMC, 2008).

Table 1: Criteria for bariatric surgery qualification at the Obesity Consult Center of TMC.

NIH Criterion for Surgery	OCC Guidelines
BMI \geq 40kg/m ²	1 year sobriety from dependencies.
BMI = 35-40kg/m ² + a life threatening CP disorder.	2 Nutritional Counseling Sessions.
BMI= 35-40 kg/m ² and 2+ co morbid conditions.	5 Behavior Modification Sessions.
Without serious psychological conditions.	*5-10% Excess Body Weight Loss.
*Between 18-65 yrs of age.	

*Criteria will be upheld at the discretion of the surgeon.

In pre-procedure screenings, co morbidities were evaluated for target weight loss goals. Co morbidities were identified including diseases such as osteoarthritis, degenerative joint disorders, coronary heart disease, diabetes, hypertension, hyperlipidemia, sleep apnea, and other disorders with only diabetes and hypertension used in data analysis. The lifestyle modification (non exercise) group participated in thorough psychological, nutritional and dietary counseling. The voluntary exercise group went through two phases of ACSM exercise counseling in addition to lifestyle modification to enhance weight loss and improve body composition. All participants who returned for evaluation at three visits (one at 6-12 months, one at 12-18 months, and one at

18-24 months) were included in the study. Weight loss was measured for both lowest achieved body weight and also by change in pre operative to post operative weight over the two years between various experimental groups. Documentation for follow ups were retrieved from medical tracking programs (Remedy-MD), patient medical records, and MD databases.

Limitations

As this is a retrospective study, guidelines for weight loss treatments were established on a clinical basis and not specifically controlled within the intervention groups. The weight lost between initial contact with the OCC and surgical date was not tracked and thus not included in this study, which could also result in variances in success experienced between patients. Patients on drugs with cardiovascular effects such as Beta Blockers also limited the ability to include many hypertensive patients in the fitness assessment portion of the data. Other weight loss strategies including private exercise training and pharmacologic interventions were not tracked or monitored and could have a significant effect on weight loss success.

Hypotheses

For the purposes of this study, the following hypotheses are put forth:

1. There will be significant differences in absolute and relative weight loss between gastric bypass and gastric banding patients from pre surgery compared to lowest weight achieved during the two year follow up.
2. There will be significant differences in the absolute and relative weight loss for all bariatric surgery patients who had baseline co morbidities of diabetes and/or

hypertension than those without either condition at baseline, during the two year follow up.

3. There will be significant differences in the amount of absolute and relative weight loss for all bariatric surgery patients who completed the exercise program than those without the exercise program during the two year follow up.
4. There will be a significant relationship between change in MET capacity and change in body weight for all bariatric surgery patients who participated in the exercise program.

Definition of terms

1. **ACSM Guidelines:** Outlines specific goals for exercise testing and prescription (see Table 3) for Phase I and Phase II of the exercise intervention strategy published by the ACSM (Whaley, 2006) for obese individuals.
2. **Bariatric Surgery:** All surgeries including gastric banding and gastric bypass procedures which are performed with the intentions to provide clients with dramatic weight loss (20-40% body weight) and reduction in co morbid conditions to alleviate present health threats.
3. **Body Mass Index (BMI):** A weight to height ratio which is measured in kg/m^2 as the standardized measurement to determine overweight and obesity status.
4. **Gastric Banding:** A type of bariatric surgery which places a band around the uppermost part of the stomach to reduce the opening into the digestive system thus preventing the ability to overeat; often these procedures are equipped with adjustable bands (Lap-band) which can be adjusted to reduce or enlarge opening to the stomach without any further surgical procedures.
5. **Gastric Bypass:** A type of bariatric surgery which bypasses part of the small intestine and reduces the size of the stomach to reduce both the amount of food required till satiation and also the amount of nutrients absorbed; the most commonly performed type is Roux-en-Y procedure.
6. **Hypertension:** Defined as a resting blood pressure $\geq 140/90$ mmHg according by standards from the Joint National Counsel (JNC) VII on identification and treatment of hypertension (2003).
7. **METs:** Defined as the metabolic equivalents expressed as a ratio of the observed oxygen consumption to resting metabolism.
8. **Morbid Obesity:** Defined as persons with a BMI ≥ 40.0 kg/m^2 (Whaley, 2006).

9. **Obesity:** Defined as persons with a BMI over 30.0 kg/m^2 ; further broken down by ACSM (Whaley, 2006) into Class I (BMI= $30\text{-}34.9 \text{ kg/m}^2$), Class II (BMI= $35\text{-}39.9 \text{ kg/m}^2$), and Class III (BMI= $\geq 40 \text{ kg/m}^2$) (Whaley, 2006).
10. **Overweight:** Defined as persons with a BMI from $25.5\text{-}29.9 \text{ kg/m}^2$ (Whaley, 2006).
11. **Type II Diabetes Mellitus:** Standards set by the American Diabetics Association (ADA) Expert Panel on Diagnosis of Diabetes Mellitus for fasting blood glucose levels greater than 126 mg/dL (7.0 mmol/L) and is not insulin dependent in nature (ADA, 2003); also designated Idiopathic Non Insulin Dependent Diabetes Mellitus (INIDDM).
12. **Waist Circumference (WC):** Is a measurement of cardiac risk. Defined as the narrowest point of the torso between the umbilicus and the xiphoid process in centimeters (Whaley, 2006) to correlate the elevated risk of persons who exhibit android obesity body types with standards set separately for men and women.
13. **Waist to Hip Ratio (WHR):** The ratio of waist to hip measurements as a marker for stratifying types of obesity (Whaley, 2006) Waist is to be measured horizontally at the narrowest point of the torso. Hip is measured horizontally from the point of the greatest circumference of the buttocks and standards are set separately for men and women.

CHAPTER 2

REVIEW OF LITERATURE

Obesity is defined as a disease and carries the weight of a variety of physical, financial, emotional, and physiologic costs. As programs for obesity prevention cannot battle the current epidemic proportion in the United States, often secondary treatment options are utilized for both the treatment of co morbidities and to promote weight loss. With treatment in specifically obese populations, multi dimensional treatment programs can provide sufficient weight loss to reduce mortal events in both the short and long term pictures.

Physical dangers of obesity

Obesity itself has been correlated with increased risk of disability, disease, and premature death providing a strong reason to further develop treatment strategies. Disability of obesity is quantified through reduction in performance in activities of daily living (ADL's) in both a 1.97 risk ratio (RR) for mild and a 9.81 RR of severe ADL impairments (Houston, Stevens, Cai, and Morey, 2005). Secondary risks of obesity include development of diseases such as osteoarthritis, GERD, sleep apnea, hypertension, hyperlipidemia, diabetes, and cancer (NIH, 2000) and will affect patients until a healthier body weight has been achieved. When looking at increased body weight, obesity reduces life expectancy up to 20 years (Fontaine, et al, 2003) with 23-50% of various age/gender/ethnic groups (Headly et al, 2004).

Assessment of Obesity

It is important to classify patients with appropriately consider treatment options. Elevated body fat is correlated with reduced activity levels and with a poor cardiac risk profile yet body

fat is not used to define obesity in clinical practice. This is because there are few reliable and clinically appropriate methods to assess body fat or standards of body fat. Alternative measurements significantly correlated to excess body fat and to a variety of cardiac risks include: body mass index (BMI), circumference measurements (WC and WHR), and excess body weight (EBW) in the overweight populations (see Table 2; Whaley, 2006).

Table 2: ACSM Categories of obesity for elevated and high- risk overweight patients.

	Overweight (Elevated risk)		Obese (High Risk)	
	Men	Women	Men	Women
% Body Fat (age diff)	20-29%	32-41%	>25%	>39%
Body Mass Index	25.0-29.9kg/m ²		> 30kg/m ²	
Waist Circumference	100-120cm	90-109cm	>120 cm	>110cm
Waist to Hip Ratio	.9-.99	.8-.99	>1.0	
Excess Body Weight	>10% over ideal body weight		> 30% over ideal body weight	

While body size and composition assessments are important for obesity classification it is very important for treatment assignment to assess compounding conditions (co morbidities) with the effect these conditions effect mortality. Often treatment strategies will be determined as more urgent with the prevalence of one or two co morbid conditions (as seen in NIH criteria for bariatric surgery; Buchwald, 2005). As the only clinically valid body composition methods used for disease stratification are BMI and circumference measurements other techniques such as skin folds, density measurements, and bio electrical impedance are not recommended for medical weight loss patients.

Body weight to height ratio: Body Mass Index (BMI) is often used most often with overweight patients because other methods are not as clinically appropriate due to need for staff training and cost efficiency. BMI correlates strongly with both body composition and disease

risk; however, Poirer (2007) found while BMI does associate strongly to excessive body weight, it ranges with age and/or fitness and should be applied sparingly in medical weight loss patients. Surprisingly, body fat is a poor predictor of cardiovascular disease compared to BMI in clinical practice and further supports the use of BMI. More in-depth research reveals elevated BMI's (especially those $\geq 35 \text{ kg/m}^2$) have increased risk of: premature mortality (Flegal, Graubard, Williamson, and Gail, 2005), increased disability (Alley, and Chang, 2007), and increased co morbid disease prevalence (Wilson, et al., 2002). As BMI has relationships with a variety of morbid conditions, it is valid and useful in clinical practice for overweight patients.

Assessment of Co morbidities

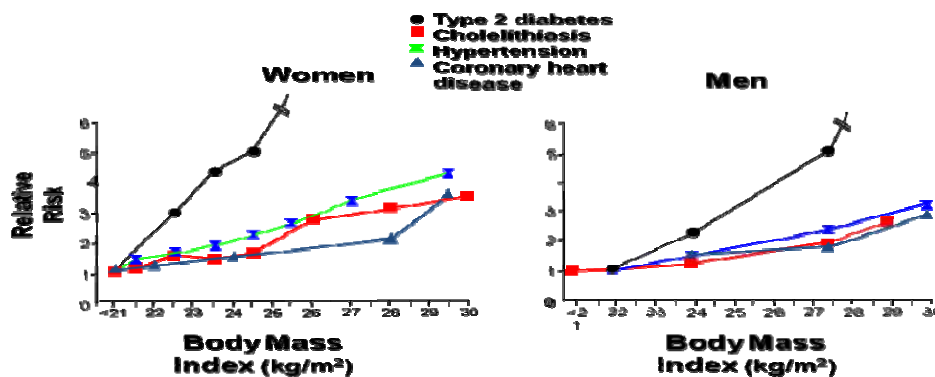
Current standards for assessment of individual co morbid conditions are set by the governing bodies with error discussed in each consensus statement. The most current hypertension guidelines set by the JNC 7, developed guidelines for hypertension treatment and management options. According to the JNC 7 hypertension should be diagnosed at BP= 140/90 mmHg with healthy (desired) levels at $\geq 120/80$ mmHg (JNC, 2003). Diabetes guidelines set by the American Diabetes Association (ADA) supports a Type 2 Diabetes diagnosis with two consecutive fasting blood glucose levels above 125 mg/dL or an oral glucose tolerance test at two hours of 200+ mg/dL (ADA, 2003). All of these disorders have been significantly related to cardiovascular disease risk and thus are important factors to consider in an appropriate weight management assessment and treatment and programs (Wilson, et al, 2002).

Prevalence of Co morbidities in Overweight Patients

NHANES III data states 65% of persons with a BMI $\geq 27 \text{ kg/m}^2$ have co morbidities such as diabetes or hypertension (CDC, 2006). These problems associated with overweight patients

have been measured for elevated risk of hypertension (RR=2.2), diabetes (RR=1.85), hyperlipidemia (RR=1.06), and total CHD events (RR=1.56). Risk for prevalence of any co morbid conditions increases risk ratio for overweight men (1.23) and women (1.48) which increased in obese men (1.77) and women (1.51) compared to those below the overweight BMI cut off (Wilson, et al, 2002). Ledoux et al, (1997) found patients with elevation or one standard deviation from the group average of BMI and WHR the odds ratio increased for many cardiovascular disease risk factors with elevated WHR (1.93) and BMI (1.23).

Figure 1: Relative risk for various co morbid conditions relative to BMI (kg/m^2) by Wilson et al. (2002).



Sugarman, Wolfe, Sica, and Clore (2002) found diabetes (15%) and hypertension (51%) were present in many of gastric bypass patients and without any significant differences in BMI values for those who had co morbidities and those who without suggesting other contributing factors such as genetic component. Though treatment may not completely resolve the problems associated with these chronic disorders it is important to realize a modest drop in body weight (5-10%) will result in a significant improvement in disease (Wilson, et al., 2002).

Assessment of Treatment Options:

Obesity increases risk for many health problems that manifest chronically and acutely. Some effects of obesity include: reduced mobility, increased stress, decreased health, and

increased disability. As weight increase, sedentary behavior increases thus promoting weight gain, reduced vessel compliance, reduced cardiac function, a poor lipid profile, and reduced glucose tolerance. Without interruption of this progression these issues will eventually develop into diseases such as hypertension, cardiovascular disease, dislipidemia, and diabetes (RR=1.78) (Wilson, et al 2002). As the results of poor diet and exercise can influence the development of these co morbid conditions, the weight gain itself still has an independent impact on morbidity rates thus management strategies should revolve around both the treatment of co morbid conditions and also the ability to improve body composition by considering relative and absolute body weight in each patient.

Diet: Based upon the idea of reducing intake to create a negative caloric balance, dietary therapies have been studied for weight loss and weight loss management. A variety of proposed dietary therapies including very low calorie diets (VLCD), low calorie diets (LCD), Atkins (low carbohydrate), Ornish (low fat), Zone (high protein), reduced portions, and liquid diets (Gardner, et al., 2007) provide individual successes but after the first year no superiority of any specific diet type for weight management (Jakicic, et al., 2001) is seen. Diet alone leads to a decrease in body weight on average 5-10% of initial body weight and does have impact on cardiovascular risk profile for effects on low density lipoprotein (LDL) cholesterol and diabetes management (Hensrud, 2001). Diets alone do not maintain lean muscle mass, have limited ability to improve cardiovascular function, and also have a variable influence on improvements of high density lipoproteins (HDL) cholesterol, triglycerides (TG), and total cardiovascular events.

Exercise: For co morbidity improvements and body composition, exercise prescriptions are beneficial but require a unique understanding in the treatment goals for duration, frequency, intensity, and type. Programs which integrate exercise for overweight patients have statistically

significant ($p \leq .01$) improvements in body weight, fat mass, and VO₂max (Donnelly, et al, 2003) as well as significant improvements in several chronic diseases like hypertension, dislipidemia, diabetes, sleep apnea, and GERD (NHLBI, 2007). While exercise has not been the most effective weight loss therapy, it maintains reduced weight regain after one year (Lesser, Yanovski, and Yanovski, 2002 and Andersen and Jakicic, 2003) and thus should be utilized to develop a successful weight loss program. As surgical protocol determines the timing for treatment introductions (including diet, exercise progression, and additional lifestyle modification strategies), exercise should be recommended not only after surgery, but before because of effect on quality of life and fitness benefits related to faster recovery time post op (Bond, et al 2006). With appropriate integration and prescription type, exercise can promote lifestyle changes and cardiovascular improvements for increases in life expectancy and reduced the prevalence of many chronic disorders.

To see health related benefits (cardiovascular improvements) of exercise, the ACSM (Whaley, 2006) and the Surgeon General recommend about 30 minutes per day on most (5) days of the week at a moderate intensity for healthy persons not applied to persons seeking weight loss. For weight loss, the advised duration varies from 45-90'/day (ACSM, IASO, and Institute of Medicine) (Jakicic, Marcus, Gallagher, Napolitano, and Lang, 2003 & Saris, Blair, and van Baak, 2003) and can be incorporated as either structured exercise or general increases in daily activity. As structured exercise programs often are developed in fitness facilities, research has shown self reported activity and home based programs are also effective at reducing both BMI and excess weight for bariatric surgery patients (Bond et al., 2004 and Dunn, et al., 1999) and thus serve the purpose to provide significant improvements in both the cardiovascular and musculoskeletal systems. After 24 weeks of varying intensities, the amount of reduced body

weight was similar in all groups as higher intensities decreased mortality (.80 to sedentary participants) in physically active persons and decreased risk for chronic disease (Jakicic, Marcus, et al., 2003 and Katzmarzyk, Janssen, and Ardern, 2003). As other treatment options do not have significant effects on cardiovascular disease profile, it is recommended exercise prescriptions be utilized in both treatment areas for co morbid improvements as well as for impact on relative weight improvements in bariatric surgery patients.

Behavior Modification: Current strategies for behavior modification have proven to be useful and effective therapies to augment diet change of social eating habits, binge eating disorders, body image perceptions, self image management, and exercise habits. As described in the Transtheoretical Model of Change recommendations are based on the patients' readiness to change diet, exercise, and other behaviors (Prochaska, and DiClemente, 1982). Patients progress is dependent on develop effective strategies for controlling portion sizes, eating frequency, binge habits, emotional eating, and understanding nutritional priorities (Wadden, Butryn, and Byrne, 2004). The application of this therapy is not effective without other diet and exercise plans, but can make a significant impact on the ability for each individual to maintain lost weight.

Surgical Procedures: While bariatric surgery is the highest risk therapy modality, it is also the most effective therapy at providing the three largest components to a successful weight loss program: significant absolute weight loss, improvements in cardiovascular risk, and the ability to sustain these benefits long term. As surgical procedures have been developed to reduce surgical risk and expand to provide the most beneficial outcomes, the various types of surgery (two most common now are currently gastric banding and gastric bypass) work by either reducing intake (banding) or by reducing total absorption (bypass). The Swedish Obesity Study (SOS) has presented the benefits and health gains from various bariatric surgery procedures for

641 bariatric patients and 627 obese matched controls' for 10 years and watched for weight loss and co morbid changes. Weight is reduced 38% in gastric bypass 26% in iliopancreatic diversion, and 21% of the gastric banding patients and had increased .1% in the control group after two years. Other variables significantly improved at 10 years post procedure include BMI, WC, DBP, pulse pressure, glucose, insulin, uric acid, TG, HDL, TC, and energy intake (Sjostrom, et al., 2004). Sugarman, Wolfe, Sica, and Clore (2002) found co morbidities related to obesity after bypass surgery were resolved in 66% (HTN) and 86% (DM) of diagnosed patients while eliminating all pharmacotherapy in the patients who used diabetes meds before surgery. With significant reductions in body weight and improvements in cardiovascular risk factors, cardiovascular disease risk changes by reducing all cause mortality (3.8%), cardiovascular death (4.4%), and cardiovascular events (20.4%) compared with non surgical body weight matched controls (Batsis et al, 2007). Studies done recently exceed the traditional 10 year follow up, but leaving bariatric surgery as the only treatment providing statistically significant weight loss at the 10 year mark and beyond.

Predictors of Weight Loss Success

The treatment modality is the most significant predictor of weight loss as surgical means are 2-3 times greater than other observed non surgical treatments (Christiansen, Bruun, Madsen, and Richelesen, 2007). This is easily explained by the relative amount of weight which could be lost in morbidly obese patients compared to overweight patients. Surgical and non surgical patients are assumed to be similar for other areas including initial body weight, complexity of management strategy, rate of weight loss, and physiologic barriers to weight loss (ex: orthopedic issues) to effect the ability to lose weight before and after surgery. In general little is known

about behavioral or other predictors of long term success after surgery, thus the role of exercise will continue to become important.

Risk factors associated with poor surgical outcomes are identified within the pre op screening period before entering the surgical phase. Recommended screening for weight loss surgery patients include diseases of the cardiovascular, pulmonary, gastrointestinal, endocrine systems, cessation of smoking, pre operative weight loss, pre operative education and counseling (behavioral, exercise, and nutritional), and a clear understanding of the surgical procedures as the largest success with both operative outcomes and long term surgical success are obtained from a thorough understanding of an informed multi disciplinary team (Saltzman et al, 2005 and Perugini et al, 2003). In an appropriate pre op evaluation risk factors such as binge eating habits, previous weight loss attempts, excess body weight, nutritional deficiencies, and desires of lifestyle flexibility (especially for women who wish to become pregnant) can be identified to stratify the type of surgery would be best appropriate. As prevalence of many co morbidities will complicate surgical procedures and healing processes, it is important to have a patient correctly diagnosed and treated (Chamberlain, Siegel, and Saltzman, 2004) especially as diabetes may have an impact on the ability for patients to lose weight (Perugini, et al., 2003). Postponing surgeries till later on it life may also have less an effect as older patients often lose less weight (Valera-Mora et al, 2005). Granted a successful operation, many variables in initial post op protocol have an impact on long term sustainability which these surgeries will provide safe weight loss including diet adherence, frequency of follow ups, adjustments in equipment (adjustable banding), and additional nutritional supplementation (especially for bypass patients). From a careful screening and appropriate follow up the optimal success can be seen in surgical

weight loss patients to provide adequate weight loss and treatment of co morbidities sustained long term.

Long Term Assessment of Treatment Options:

Obesity has been studied under many management strategies. As obesity is related to many factors, isolated treatment strategies have not been extremely effective in either initial weight loss in maintenance of a reduced body weight. Development of lifestyle modification models with gradual approaches have improved success in long term weight loss (often defined as a 10% reduction in initial body weight) but few persons can sustain long term weight loss. Weight loss by lifestyle choices delivers limited impact (only 28% sustained >10% BW) (Christiansen et al., 2006) with only 3-5% requiring revision (Brolin, 2002) surgical options can provide an estimated 35% reduction in body weight. Because of all these benefits, bariatric surgery has become the leading treatment to lose initial body weight, treat co morbidities and maintain reduced body weight in many morbidly obese patients.

Co morbidities are reduced in patients who integrate diet and exercise more than just diet alone (Kukkonen-Harjula, Borg, Nenonen, and Fogelholm, 2005). In gastric bypass patients Class II and Class III obese patients were significantly ($P < .001$) decrease systolic blood pressure, diastolic blood pressure, total cholesterol, HDL, LDL, TG, fasting blood glucose, and BMI values compared to non operative control's. Other findings of this study determined a 3.8-4.6% decrease in all cause mortality in the gastric bypass group with only a .2% decrease in the non operative group while total cardiovascular events decreased (18.8-20.4%). Surgery prevented deaths and cardiovascular events in the population (Batsis, et al., 2007).

The majority of research agrees even the most comprehensive non surgical treatments rarely result in long term maintenance of weight loss and reduction in weight regain (McMahon, et al., 2006). This is likely in part due to the pervasive link between obesity and alternative methods of coping, socializing, choice decisions, biological mechanisms and lifestyle management. While non surgical treatment is not preferred for morbidly obese patients, Leser, et al. (2002) found long term treatment for obese women maintained weight loss for longer periods (3 and 5 years post diet/exercise program) of time when diet (encourage 30% and lower daily fat intake) and regular physical activity (high activity levels) habits were integrated into a daily routine with those not utilizing both for preventative weight regain. While combination therapy includes opportunities to educate, practice, and develop life style habits to promote weight loss (15%) the effect often tapers off at two (6.8%) and four (4.6%) years with only 28.9% able to maintain greater than 10% of the weight lost (Christiansen, Bruun, Madsen, and Richelsen, 2007).

Conclusion

As obesity continues to effect individuals on along a wide spectrum of health concerns, a comprehensive and validated treatment plan is important. Treatment strategies become the most effective with multi faceted teams who each work within and across focus areas including behavioral, nutritional, physical activity, and medical counseling. With multi faceted programs patients will be able to increase overall health by decreasing body weight, improving body composition, decreasing co morbidities, and reduce total cardiac events not only within the first year of treatment but sustained over the long term under the consistent treatment outcomes related to bariatric surgery.

CHAPTER 3

METHODS AND PROCEDURES

This chapter includes methods and procedures related to subject selection, test procedures, intervention procedures, and the statistical measures used in this retrospective study.

Subjects

The Obesity Consult Center (OCC) at Tufts Medical Center obtains the majority of patients through medical referrals. Most patients in the program have elevated risk factors (diseases such as diabetes, hypertension, hyperlipidemia, and cardiovascular disease) secondary to obesity and are entered into a medical weight loss program. Most in the OCC attempted weight loss with little success and were referred for either medically supervised weight loss or bariatric surgery.

All patients when entering the OCC bariatric surgery program were assessed according to cardiovascular disease risk, behavioral characteristics, nutritional habits, and lifestyle habits. Patients qualified for bariatric surgery according to NIH criteria: BMI ≥ 40 kg/m² or BMI 35-40 kg/m² and one or more co morbidities (Buchwald, 2005) as well as to the OCC guidelines (refer to Table 1 and Appendix D). Baseline measurements of co morbidities including diabetes (fasting blood glucose > 125 mg/dL) and hypertension (systolic >140 mmHg and diastolic >90 mmHg) were also used in patient stratification.

Test Procedures

Patients who had bariatric surgery between January 1, 2000 and January 1, 2008 were given behavior modification therapy and nutritional counseling. IRB approval for patient data

usage was obtained through the Tufts Medical Center as well as through Northeastern University (See Appendix A and B). At every visit patients were measured using an electronic floor scale (Detectoscale 758C) designed for morbidly obese persons. Patients who entered the exercise intervention program were assessed for estimated sub maximal functional capacity using Rockport 1 Mile or Balke-Ware treadmill tests. The clinical exercise physiologist administered both tests at the local community health center near the OCC with pre measured distances for the Rockport test and pre entered programs for designated treadmills. Patients were monitored for weight for a minimum of two years post procedure.

A Microsoft Excel database was developed for all primary visit information including body weight and co morbidities. All statistics were performed with SPSS (SPSS Inc.) 16.0 software.

Intervention Program

Behavior modification and nutritional counseling. Pre surgical treatments included individual weight loss (10% Expected Weight Loss), nutritional counseling, and behavioral counseling. If patients fulfilled pre surgical requirements they were directed to the surgeon for discussion of surgical options. In the initial contact with the surgeon, considerations for choice of surgical procedure included baseline co morbidities, excess body weight, behavioral profile, and lifestyle. Post op patients were encouraged to return for post op visits with each team member at intervals varying on procedure type and using predictive values. All patients were encouraged to return at least twice annually following surgery where body weight was recorded.

Exercise counseling group. The exercise counseling group received all of the same treatments as the behavior modification and nutritional counseling group with the addition of

individualized exercise counseling and prescriptions. This program utilized a biphasic approach by first (Phase I) integrating previously sedentary individuals through a gradual exercise adaptation (starting at initial Surgeon assessment) and then a secondary (Phase II) maintenance phase (at 10 wks follow up). For the initial exercise adaptation prescription, a full physical activity history was taken as well as a cardiovascular disease risk assessment. All patients then completed a supervised Rockport 1 Mile or Balke Ware treadmill test (see Appendix C). For exercise prescription target heart rate zones were given from American College of Sports Medicine (ACSM) guidelines (see Table 3; Whaley, 2006) for both activity integration and maintenance long term.

Table 3. ACSM guidelines for exercise testing and prescription for overweight and obese patients.

Exercise Testing	Exercise Prescription
<ul style="list-style-type: none"> Initial 2-3 MET workloads with reduced increment increases. 	<ul style="list-style-type: none"> Emphasize large muscle group aerobic activities.
<ul style="list-style-type: none"> Adapted to co morbidity specifics. 	<ul style="list-style-type: none"> Initial intensity= 40-60% Vo₂R with emphasis on duration over intensity.
<ul style="list-style-type: none"> Medications kept regular. 	<ul style="list-style-type: none"> Progression intensity= 50-75% (moderate).
<ul style="list-style-type: none"> Adaptation of equipment including machinery and BP cuff size. 	<ul style="list-style-type: none"> Frequency= 5-7d/wk.
	<ul style="list-style-type: none"> Duration= 45-60'/day ≈ 150'/wk.

Pictures and diagrams with descriptions for all resistance training programs were also provided to ensure patients were engaging in a major muscle group resistance group of low intensity. Phase 1 focused on integrating the daily required activity (30'/day at 5d/wk) while Phase 2 was more for maintenance and progression of physical activity. At 10 weeks post op patients were re evaluated for program progression and prescribed to the next progression of intensity or duration with any other follow ups on a voluntary basis. Follow up fitness assessments were done for patients according to progression by another Rockport 1 Mile Test or

a Balke-Ware Treadmill test. Only patients who have completed the pre and post fitness assessments were assessed for change in estimated MET and aerobic capacities.

Statistical Analysis

All of the data were entered into an Excel database and were organized according to surgical procedure, co morbidity, and exercise status. Data were reported for the patients on pre surgery and follow up body weight over two years and evaluated for body weight at 6-12, 12-18, and 18-24 months post op. Co morbidities (diabetes and hypertension) of each patient were extracted from physician databases. Body weight loss was evaluated at three various intervals of 6-12, 12-18, and 18-24 months post op for both absolute and relative weight loss during the two year period. Absolute weight loss was reported in total pounds lost and relative as a percentage of initial body weight maintained. The data were analyzed using Analysis of Variance (ANOVA) to determine statistical differences in weight loss between surgical groups, co morbidity groups, and exercise groups. A probability of $<.05$ was considered statistically significant.

The following will test for values associated to the hypothesis:

1. There will be significant differences in absolute and relative weight loss between gastric bypass and gastric banding patients from pre surgery compared to lowest weight achieved during the two year follow up.
2. There will be significant differences in the absolute and relative weight loss for all bariatric surgery patients who had baseline co morbidities of diabetes and/or hypertension than those without either condition at baseline, during the two year follow up.

3. There will be significant differences in the amount of absolute and relative weight loss for all bariatric surgery patients who completed the exercise program than those without the exercise program during the two year follow up.
4. There will be a significant relationship between change in MET capacity and change in body weight for all bariatric surgery patients who participated in the exercise program.

CHAPTER IV

PRESENTATION AND DISCUSSION OF RESULTS

The purpose of this chapter is to present and interpret the results of the study. The chapter also includes a discussion of the results and comparison with previous studies.

Results

Table 4 Characteristics of patients at baseline by surgical, co morbidity and exercise groups.

	N	Gender		Age (Yrs.)	Initial Wt (LBS.)	Initial BMI (Kg/m ²)
		M	F			
All Patients	223	32	191	41.62	278.42	45.84
GBP	155	18	137*	41.70	283.80*	46.93*
GBD	68	14	54	41.46	266.15	43.36
No DM and/or HTN	55	6	49	38.98*	273.47	45.49
DM and /or HTN	168	26	142	42.49	280.04	45.96
Exercise	30	7	23	41.16	276.66	45.56
No Exercise	193	25	168	44.60	289.70	47.64

GBP = gastric bypass; GBD = gastric banding; DM = diabetes mellitus; HTN = hypertension

*Significant for P < .05.

Description of Subjects

Table 4 presents the characteristics of all patients at baseline by surgical group, co morbidity group, and exercise group. Data were collected on 223 patients, from the surgical weight loss program at the Obesity Consult Center of Tufts Medical Center in Boston, Massachusetts between January 1, 2000 and January 1, 2008. There were 32 (14.3%) males and 191 (85.7%) females with the average age 41.6 years. Initial body weight was 278.4 lbs. and initial BMI was 45.8 kg/m². There were 155 gastric bypass patients (18 males and 137 females) and 68 gastric banding patients (14 males and 54 females) in the program. There were 55 patients (6 males and 49 females) without diagnosed diabetes mellitus or hypertension and 168

patients (26 males and 142 females) were positive for having diabetes, hypertension, or both.

The majority of these patients with baseline co morbidities had only hypertension (N=127) while only a few (N=3) were diagnosed with diabetes alone and 38 had been diagnosed with both hypertension and diabetes (See Figure 2).

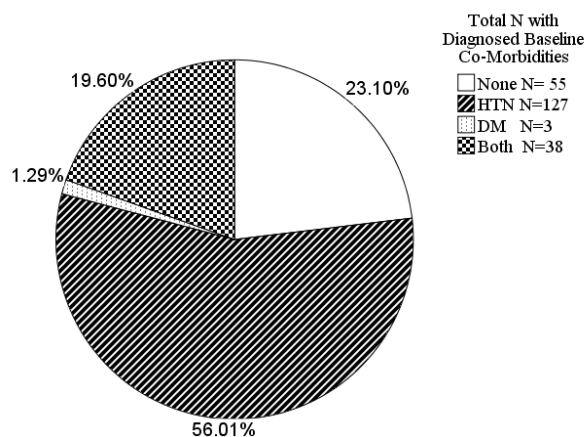


Figure 2: Prevalence of baseline co morbidities (N=223).

There were 30 subjects (7 males and 23 females) with qualified pre and post surgery fitness evaluations and 193 (25 males and 168 females) without the required fitness assessments. As the Rockport 1 mile test was designed for middle aged patients and is required to be performed at a vigorous pace all patients with a heart rate below 120 bpm were eliminated. This left only 7 patients with two valid aerobic fitness tests. Patients with documented use of Beta blockers were not included. All of the fitness assessments were calculated as estimated VO₂ (ml/kg/min) and then converted into MET (VO₂/3.5) for a peak MET capacity.

Baseline differences

There were significant differences ($P < .05$) between the two surgical groups for gender, initial weight, and initial BMI (See Table 4). The gastric bypass group was 11% male and 89% female ($P < .05$). The gastric banding group was 21% male and 79% female ($P < .05$). The gastric

bypass group was 283.9 lbs compared to the gastric banding group 266.1 lbs ($P < .05$). The gastric bypass group had elevated BMI's (46.9 kg/m^2) compared to the gastric banding group (43.36 kg/m^2) ($P < .05$). The co morbid groups were significantly different ($P < .05$) at baseline for age alone, where the group without co morbidities was 38.9 yrs and the group with diagnosed co morbidities was older at 42.4 yrs. The baseline co morbidity group was significantly influenced by patients with either or both baseline diabetes and/or hypertension as 75% displayed either one of the two diseases (See Figure 2). The exercise groups were not significantly different for baseline characteristics in age, gender, or body weight (See Table 4).

Follow up differences

Table 5: Comparison of initial body weight to changes in body weight over the two year follow up.

	N	IBW (LBS.)	LBW (LBS.)	Δ BW (LBS.)	PWC (%)
All Patients	223	278.42	187.60	90.82	32.48
GBP	155	283.80*	175.83*	107.97*	38.16*
GBD	68	266.15	214.44	51.71	19.54
No DM &/or HTN	55	273.47	186.58	86.89	31.45
DM &/or HTN	168	280.04	187.93	92.10	32.82
Exercise Group	30	276.66	186.13	90.53	32.63
No Exercise	193	289.70	197.07	92.63	31.49

GBP = gastric bypass; GBD = gastric banding; DM = diabetes mellitus; HTN = hypertension

*Significant for $P < .05$.

Initial body weight (IBW) was compared to the lowest body weight (LBW) achieved over the two year follow up. Absolute body weight and percent body weight change (PWC) were analyzed for significant differences between the two surgical groups, the two co morbidity groups and the two exercise groups (See Table 5). The mean lowest body weight achieved for all patients was 187.6 lbs from an initial mean body weight of 278.4 lbs. which represented a mean weight loss of 90.8 lbs. or 32.4% of initial body weight over the two year follow up period.

There were significant differences between the surgical groups for differences in initial body weight, change in absolute body weight, and percent body weight ($P < .05$). The initial body weight for the gastric bypass group was 283.8 lbs, while the lowest weight was 175.8 lbs for a change of 107.9 lbs or 38.1%. For the gastric banding group, the initial body weight was 266.1 lbs and the lowest weight achieved dropped to 214.4 lbs for a change of 51.7 lbs or 19.5%. These changes were significantly different with the gastric bypass group with a greater drop in both absolute and relative weight loss. There were no significant differences between the co morbidity or exercise groups for initial body weight, lowest body weight, change in absolute body weight or percent of body weight.

Table 6: Comparison of absolute and relative body weights for the experimental groups over the two year follow up period.

	Avg. LBS 6-12 Mos.	Avg. LBS 12-18 Mos.	Avg. LBS 18-24 Mos.	Avg. % of IBW 6-12 Mos.	Avg. % of IBW 12-18 Mos.	Avg. % of IBW 18-24 Mos.
All Patients	208.82	194.73	194.39	78.0%	74.2%	74.8%
GBP	199.18*	181.36*	181.33*	69.9%*	64.1%*	64.7%*
GBD	230.67*	225.00*	223.94*	86.0%*	84.4%*	84.9%*
No DM &/or HTN	205.25	192.87	195.76	78.1%	74.8%	75.5%
DM &/or HTN	210.00	195.34	193.93	77.8%	73.6%	74.0%
Exercise Group	217.86	205.34	209.92*	78.3%	74.1%	74.2%
No Exercise	207.41	193.07	191.96*	77.7%	74.3%	75.3%

GBP = gastric bypass; GBD = gastric banding; DM = diabetes mellitus; HTN = hypertension

*Significant for $P < .05$.

ANOVA tests were performed to compare the initial body weight (IBW) with average body weight (absolute and relative) at the post operation measurement periods: 6-12 months, 12-18 months, and 18-24 months (See Table 6 and Figures 3, 4, and 5). There were significant differences between surgical groups for absolute and relative weight loss at each of the three measurement periods. There were no differences in absolute or relative weight loss for the co

morbidity groups at any of the three measurement periods. Absolute weight was significantly different between the exercise groups at only the 18-24 month measurement period.

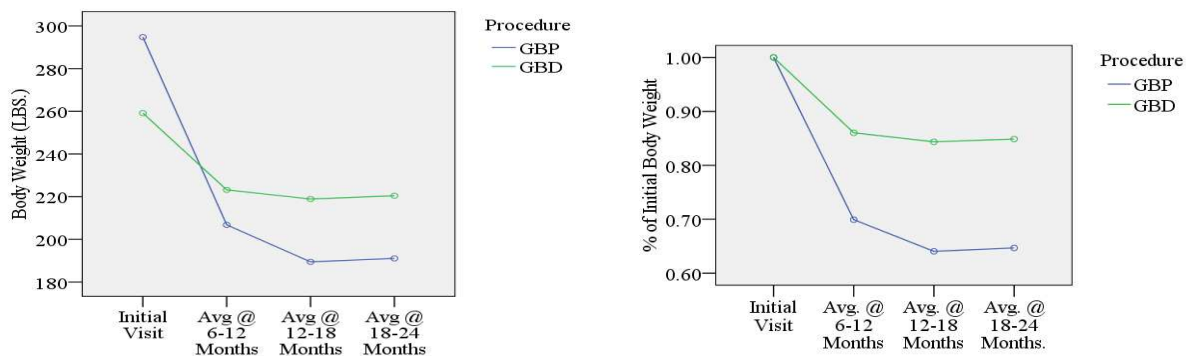


Figure 3: Changes in absolute and relative weight loss for two surgical treatment groups.

Figure 3 shows the changes in both absolute and relative weight loss between the gastric bypass and gastric banding groups over the two year follow up. The gastric bypass group had the most significant changes ($P < .05$) in both absolute and relative body weight, starting out heavier and achieved a significantly lower absolute body weight than the gastric banding group.

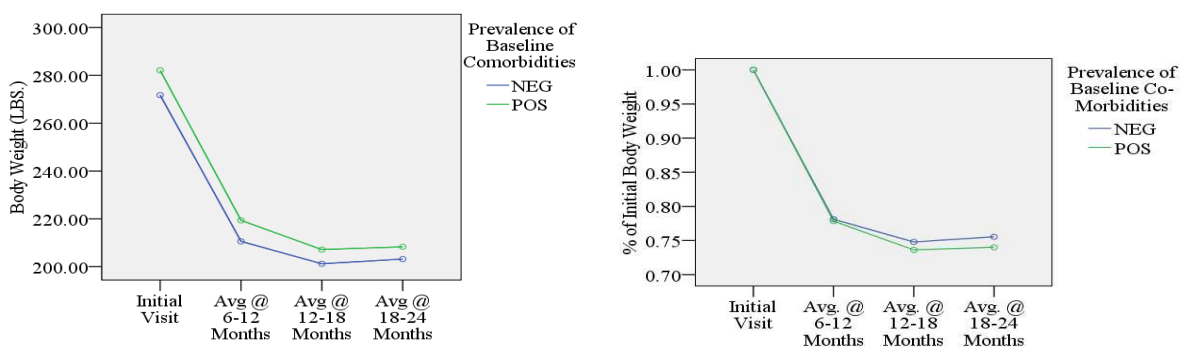


Figure 4: Changes in absolute and relative weight loss for the two co morbidity groups.

Figure 4 shows the changes in absolute and relative body weight throughout the two year follow up period for the group with co morbidities versus the group with none. While both

groups lost a significant amount of body weight throughout the study there were no statistical differences in either absolute or relative weight loss between the two groups.

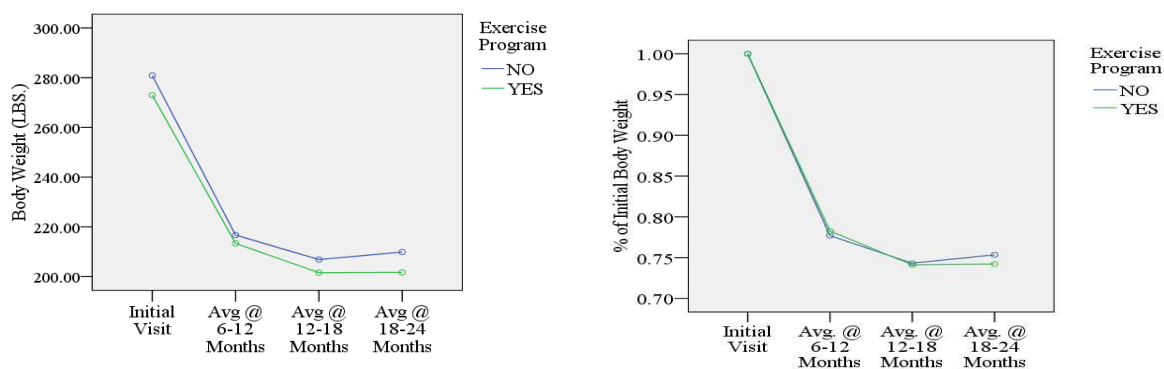


Figure 5: Changes in absolute and relative weight loss for the exercise group versus the non exercise group.

The exercise group was significantly different from the non exercise group at only at the 18-24 Month follow up in absolute weight only (Figure 5). The relative weight changes were not significantly different from one another at any of the follow up periods between the exercise group and the non exercise group.

Changes in Fitness

Table 7: Comparison of the pre and post fitness tests (n=7).

	1 st Test	2 nd Test	Differences
HR (bpm)	150.43	126.29	-24.14 bpm
Est. MET Cap	4.53	5.77	1.24 MET
Est Vo2 (ml/kg/min)	15.85	20.20	4.35 ml/kg/min

With only 30 subjects with pre and post surgery assessments the strength of relationship between changes in fitness were best assessed according to estimated peak MET capacity. Patients with qualified fitness assessments were all female (n=7) with an initial mean body weight (IBW) of 279.0 lbs and a mean age of 40.4 yrs. Most of the patients were GBP (n=5) and had baseline co morbidities (n=6). These patients lost on average 99.4 lbs over the two year

follow up period and increased MET capacity (1.24 METS), increased estimated VO₂ (4.35 ml/kg/min), and reduced test HR responses (-24.1 bpm) (see Table 7). The only significant relationship ($P < .05$) was between baseline co morbidities and lowest weight achieved within the qualified fitness assessments and not by age or surgical procedure nor estimated MET capacity or change in MET capacity. Figure 6 shows the results of a regression analysis of the change in METS with the change in weight over the two year follow up. There was no significant relationship between these variables.

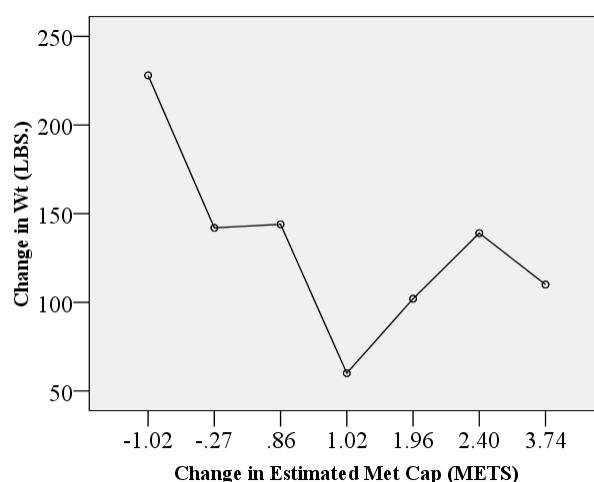


Figure 6: Correlation of changes in MET capacity with changes in body weight (LBS).

Discussion

There were significant differences ($P < .05$) between the two surgical groups for change in absolute and relative weight loss. There were no significant differences between the group with co morbidities and the group with none for either absolute or relative weight loss. There were significant differences between the exercise versus non exercise groups in absolute weight loss and no differences in relative weight loss.

Many studies have significant differences in weight loss between gastric bypass and gastric banding. The largest and most cited study is the Swedish Obesity Study (SOS) with significant weight loss in patients between surgical groups compared with weight matched

participants (Sjostrom et al, 2004). The SOS study followed 641 patients for up to 10 years subsequent to operation. Surgical patients who completed up to two years of the follow up had an average age of 47.4 years and were 29% male. The mean weight was 120.6 kg, and BMI was 42.3 kg/m². At two years the results for the control and experimental groups for hypertension were 29% non surgical and 24% of the surgical patients with diabetes in 8% of the non surgical compared to 1% of the surgical groups. Compared to several other studies this prevalence of co morbid conditions is extremely low. Maximum weight loss was seen at one year for the gastric bypass group with a 38% drop in body weight compared to the gastric banding group which had reduced 21% of body weight. The present study was smaller, with a greater number of gastric bypass patients to influence the group averages. There was a greater proportion of patients with baseline diabetes and hypertension (70%) than the control group of the SOS study reported at baseline and at the two year follow up. This present study averaged weight loss of 32% from initial measurements and greater weight loss compared to the SOS study, but is explained by different numbers of gastric bypass and gastric banding patients.

Sugarman et al (2002) studied the effect of baseline diabetes and hypertension specifically as it impacted weight loss in 1,025 gastric bypass surgery patients. Twenty two percent were of this study were males with an average age of 39 years and a BMI of 51 kg/m². A larger number (n=559) patients had either hypertension (>150/90mmHg) or diabetes (>150mg/dL) and 115 exhibited both characteristics. With a significant difference at baseline in age between those with either hypertension or diabetes and those without, over a two year follow up period patients reduced body weight by 35%. The subjects in the present study were slightly older at 41.6 yrs, included both surgical types, and had a lower BMI of 45.84 kg/m² at entrance. The present study failed for significant differences in weight loss between the group with

hypertension and diabetes compared to those with neither this could be purely related to the lack of detailed tracking of the diseases throughout the two year follow up.

Bond et al (2004) studied the effects of physical activity in 1,585 gastric bypass patients over a two year period with self-reported physical activity based on a rolling 1-4 scale of 106 sedentary to 1,479 physically active patients. Physically active patients were slightly older (40 yrs.) than the sedentary patients (44 yrs.) with equivalent baseline BMI's at of 49.8 kg/m² for the physical activity patients and 49.6 kg/m² of the sedentary patients. Post surgical changes were 18.3 kg/m² for the physical activity group and 16.6 kg/m² in the sedentary patients. Patients were also separated according to initial BMI: 35-49 kg/m² (Group 1) and 50-70 kg/m² (Group 2) to identify discrepancies for weight loss among the wide array of GBP patients. In both groups there were significant differences ($P < .05$) for age and post surgical BMI loss between the physically active and sedentary patients. No measure of physical activity intensity, level, or other measurements of aerobic capacity were mentioned in the findings. In the present study the weight groups were not stratified but these groups were considerably different. The two studies were noticeably different in the percentage of active: non active ratios with the present study returning a low participation of the activity group whereas Bond et al had a very large participation in the activity group.

Notarius, Rhode, MacLean, and Magder (1998) studied the effect of exercise capacity in 20 female gastric bypass patients. This study was stratified by four groups with 5 patients in each divided by pre-procedure and post procedure status and measured for absolute VO₂ and total daily energy expenditure. The 5 patients successfully lost weight and increased exercise endurance compared to 5 patients who were not able to sustain or achieve weight loss. Peak VO₂ dropped in the successful group and was attributed to loss in lean muscle mass, which is strongly

associated to changes in absolute VO_2 values. The present study noted 7 qualified fitness assessments during the follow up but average weight loss of 99.4 LBS matched with a 1.24 increases in MET capacity and a 5 ml/kg/min increase in absolute estimated VO_2 . When comparing the exercise group to the non exercise group there was a significant change in body weight at the 18-24 month measurement period as the exercise group increased in body weight and the non exercise group maintained body weight from the prior 12-18 month measurement. This may be due to the effect of exercise and conditioning to maintaining and increasing lean muscle mass thus preserving and improving overall aerobic capacity with a noted increase in absolute body weight.

Though most of the previous studies detailed the individual effects of surgical, disease, and physical activity intervention it is important to understand how these treatments interact between one another. Previous studies have not specifically examined the differences between the two surgical groups for effect of baseline co morbidities and/ or exercise participation on weight loss and the relationship between these factors could play a significant role for application of treatment strategy. The surgical groups were different in body weight at baseline and continued to maintain this relationship throughout the two years. The co morbidity group was significantly different at baseline age and this relationship is documented in previous research. The exercise group significantly changed in body weight from the non exercise group as body weight increased slightly from the 12-18 month measurement and a previously un documented increase in estimated MET capacity and this may indicate an interaction between fitness programming and baseline co morbidities. Previous authors reporting decreases in absolute VO_2 values did not include exercise programming thus this study is necessary. Because

this study was not a randomized, controlled, trial further research is necessary to confirm the value of exercise programming in post op weight loss with exercise programming.

CHAPTER V

SUMMARY, COMCLUSIONS, AND RECOMMENDATIONS

Summary

Morbid obesity is a serious chronic disease, which should be aggressively treated. The options to manage weight loss for the extremely obese patients have been vastly improved with bariatric surgery. To provide the best outcomes and appropriate treatment strategies for integrative care it must be understood how common variances in baseline characteristics would affect the results. This study compared the differences between two surgical groups, a group with co morbid conditions versus a group with none, and an exercise group compared to a non exercising group. A total of 223 bariatric surgery patients at the Obesity Consult Center at Tufts Medical Center in Boston, Massachusetts were retrospectively reviewed over a two year follow up period. The mean age of the group was 41.62 yrs with 32 males and 191 females. Patients were mostly gastric bypass (69.5%) and were significantly ($P < .05$) different in gender, age, and initial body weight from the gastric banding group (30.5%). Most of the patients (75.3%) had a baseline diagnosis of the co morbidities hypertension, diabetes, or both. Thirty of the 223 patients participated in regular exercise program. However, only 7 of the 30 had valid fitness tests to be included in data analysis and there were no significant differences at baseline for gender, age, and initial body weight between the exercise and non exercise groups. Changes in body weight were most significant between the surgical groups in terms of absolute body weight at the measurement periods 6-12, 12-18, and 18-24 months. At 18-24 months the exercise group also was statistically different from the non exercise group in absolute weight loss. Patients who completed valid fitness assessments had an increase in estimated MET and VO₂ capacities

between two fitness assessments, unlike previous research which has stated for GBP patients without structured exercise intervention. There were no significant relationships between change in METS and change in weight loss.

Conclusions

Based on the results of this study the following conclusions are warranted:

- 1.) There were statistically significant differences for change in absolute and relative body weight between the gastric bypass and gastric banding surgical groups during the two year follow up period; therefore hypothesis one is accepted.
- 2.) There were no statistically significant differences for change in absolute and relative body weight between the group with co morbidities (hypertension and diabetes) compared to the group with no co morbidities during the two year follow up period; therefore hypothesis two is rejected.
- 3.) There were statistically significant differences for change in absolute body weight at 18-24 months and no significant differences in change in relative body weight between the exercise group and the non exercise group during the two year follow up period; therefore hypothesis three is partially accepted.
- 4.) There were no statistically significant relationships between the change body weight and change in estimated MET capacity; therefore hypothesis four is rejected.

Recommendations for future research

This study was efficient at evaluating the differences in weight loss between two groups of bariatric surgery patients. As is preferred in all research, to develop a clearer understanding of

exercise programming and weight loss in bariatric surgery patients a randomized trial would be necessary. Other measurements which would provide a more in depth understanding of the body composition changes include valuable body composition assessments such as DEXA or hydrostatic weighing. A larger population group with more balanced subject groups would possibly increase and validate the interaction between surgery, baseline co morbidities, and exercise programming. A recommendation for a further study is to examine additional co morbidities and evaluate the weight loss and effect on disease state including sleep apnea, degenerative joint disease, and GERD. While the effect on weight loss between various co morbid groups will have an effect on long term weight loss, it is also important to identify whether absolute or relative weight changes will deliver the most significant effect on co morbid conditions to better direct the focus for expected weight loss. Because compliance within the exercise program was poor it would be important to require more closely supervised exercise programming to more clearly validate the changes in body weight when included into a physical activity regimen. As clinical exercise prescriptions are difficult to monitor and structure, more defined daily activity logs and use of pedometers as well as absolute aerobic measurements would clarify the relationships between bariatric surgery patients with and without co morbidities to continue losing weight and evaluate the best possible weight loss management strategy for more specifically defined co morbid diseased patients often seen in weight loss centers.

Appendix A:
Tufts IRB Approval

FEB-08-2008 14:28

TUFTS NEMC

P.02/02

Tufts-New England Medical Center

1796 Boston Dispensary
 1894 Floating Hospital for Infants and Children
 1938 Pratt Diagnostic Clinic
 1949 New England Medical Center Hospital
 1959 Rehabilitation Institute



Tufts University

1899 School of Medicine
 1899 School of Dental Medicine
 1879 School of Veterinary Medicine
 1980 Sackler School of Graduate
 Biomedical Sciences

NOTICE OF IRB APPROVAL - CONTINUING REVIEW

Shikora, Scott MD
 3008
 H-SURGERY
 Tufts-NEMC

IRB #: 6636
 Title: Bariatric Surgery Database
 Date of IRB Review: 3/28/2007
 Date of IRB Approval: 3/28/2007

Protocol approved: undated version received 08 March 2007

- as submitted

X

The above referenced-research was reviewed and approved using expedited review procedures in accordance with 45 CFR 46.110(b)(5)

Informed Consent Form(s): N/A

Human Protection Form for Funding Agency:

- not required

X

Regulations regarding your research protocol:

1. The approval is valid for one (1) year from the date of review (unless otherwise stipulated by the IRB).
2. Unanticipated or serious adverse reactions/side effects encountered in this study must be promptly reported to the IRB within five (5) days. *Deaths are reportable immediately.*
3. Any changes or modifications in the study protocol or consent form must be reviewed and approved by the IRB prior to implementation.
4. You may not use the ICF or any other study document until it has been approved and validated by the IRB.
5. If you are subject to HIPAA, the Security Rule applies to your research. If you create, store, or transmit electronic PHI you must meet institutional Security Rule standards. For more information, please contact your HIPAA Privacy Officer for Research.

THIS NOTICE MUST BE RETAINED WITH YOUR RESEARCH FILES.

3/30/07
 Date

[Signature]
 Signature of Chair/Vice-Chair
 Institutional Review Board (IRB)

TOTAL P.02

Appendix B:

Northeastern University IRB Approval



Division of Research Integrity
413 Lake Hall
Northeastern University
360 Huntington Avenue
Boston, Massachusetts 02115-5000

Phone: 617.373.7570
Fax: 617.373.4595

http://www.research.neu.edu/research_integrity/

NOTIFICATION OF IRB ACTION

Date: February 29, 2008 IRB #: 08-02-12

Principal Investigator(s): William Gillespie
Suzanne Vogt

Department: Health Sciences

Address: 316 Robinson Hall
Northeastern University

Title of Project: Effects of Pre-Existing Co-morbidities in Variable Lifestyle
Modification Programs on Weight Loss and Aerobic Capacity in Two
Types of Bariatric Surgery Patients

Participating Sites: Tufts- New England Medical Center – approval letter from IRB

Informed Consent: N/A – database use only

DHHS Review Category: Expedited #5

Monitoring Interval: 12 months

APPROVAL EXPIRATION DATE: FEBRUARY 28, 2009

Investigator's Responsibilities:

1. Informed consent form bearing the IRB approval stamp must be used when recruiting participants into the study.
2. The investigator must notify IRB **immediately** of unexpected adverse reactions, or new information that may alter our perception of the benefit-risk ratio.
3. Study procedures and files are subject to audit any time.
4. Any modifications of the protocol or the informed consent as the study progresses must be reviewed and approved by this committee **prior to being instituted**.
5. Continuing Review Approval for the proposal should be requested at least one month prior to the expiration date above.
6. This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

Matthew O. Hunt, Ph.D., Chair
Northeastern University Institutional Review Board

Nan C. Regina
Director, Research Integrity

Appendix C:

Test Protocols

6 Minute Walk Test

Instructions:

Determine an area where you can walk 50 feet. Walk the 50 feet route for 6 minutes keeping track of how many laps you have done. You want to go at your own pace trying to cover as much distance as you can. If you need to rest that is fine, but the clock keeps going until 6 minutes.

What to Report:

At the end of the 6 minutes record the total distance you covered by multiplying the number of times you completed the route by 50 feet and record your heart rate. For heart rate you can count your pulse for 10 seconds and multiply by 6.

Distance (feet): _____

Heart Rate: _____

RPE - Ratings of Perceived Exertion

6	No exertion at all
7	Extremely light
8	-----
9	Very light
10	-----
11	Light
12	-----
13	Somewhat hard
14	-----
15	Hard
16	-----
17	Very hard
18	-----
19	Extremely hard
20	Maximal exertion

Appendix D:
Bariatric Surgery Guidelines

Eligibility Criteria

The Obesity Consult Center uses the same indicators as the National Institutes of Health.

You may be a candidate for surgery if:

1. You have tried and failed with dieting in other organized programs
2. Your Body Mass Index (BMI) is 40 or greater (More on this below).
3. Your BMI is between 35 and 40 and you have some of the following health problems:
 - High blood pressure
 - Diabetes
 - Heart disease
 - Sleep apnea
 - High cholesterol
4. If you are more than 100 lbs over "ideal" weight.
5. If you are between 18 and 65 years of age.
6. If you have an absence of severe emotional or medical illness which would make surgery unnecessarily risky.
7. If you have been drug or alcohol dependent, you must be well into an effective treatment program with at least one year of sobriety

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