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# A Study of Clinical Outcomes Using Serum Albumin and Percentage of Weight Loss following Nutritional Intervention in Post-Operative Bariatric Patients.

Jennifer Michelle Angus
*East Tennessee State University*

# A Study of Clinical Outcomes Using Serum Albumin and Percentage of Weight Loss Following Nutritional Intervention in Post-Operative Bariatric Patients

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Jennifer Michelle Angus

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Elizabeth F. Lowe, Chair

Alison K. Schaefer

W. Andrew Clark, PhD

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ABSTRACT

A Study of Clinical Outcomes Using Serum Albumin and Percentage of Weight Loss Following Nutritional Intervention in Post-Operative Bariatric Patients

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The purpose of this study was to determine if post-operative serum albumin and percentage of weight loss improved in patients who received formalized pre-operative nutrition counseling. Nutrition intervention was measured quantitatively. A retrospective review of records was conducted on 77 RYGB patients (68 female subjects and 9 male subjects), ages 21-64, during January 2001 through January 2006.

The results indicated that patients who received pre-operative nutrition intervention had better clinical outcomes of serum albumin than those with no nutrition intervention from a registered dietitian. However, outcomes regarding percentage of weight loss varied. Both pre-operatively and at the 3 month post-operative visit the weight of subjects who received nutrition intervention seemed to be increasing by the 6 month post-operative visit the subjects with no nutrition intervention had lost more weight.

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# CHAPTER 1

# INTRODUCTION

Research has shown that about 97 million adults in the United States are considered overweight or obese [1, 2]. Due to the increasing incidence of obesity and lack of success from traditional weight loss programs, many people consider bariatric surgery for weight reduction. It has been estimated that approximately 140, 000 bariatric surgery procedures were performed in the United States in 2005 compared to 110,000 surgeries in 2003, which has been on the rise from 10,000-15,000 per year in the early 1990s [2,3]. The most popular types of bariatric procedures performed in the United States was the Roux-en-Y gastric bypass and the vertical gastric lap banding [2].

Faintuch et al. found that multiple complications are associated with Roux-en-Y gastric bypass (RYGB) including malnutrition, protein-calorie malnutrition, and weight loss failure [4]. Faintuch et al. stated that although research has shown that with standard RYGB surgery, protein-calorie malnutrition (PCM) appears to be exceedingly rare; when it has occurred, it has shown good response to nutrition therapy [4,5]. Serum albumin is a laboratory test used to determine adequacy of nutrition status, and it is a sensitive and cost-effective method of assessing the severity of malnutrition [6, 7]. Serum albumin alerts healthcare team members to the nutritional status of the patient. Brugler et al. found that early nutrition screening and intervention has been shown to help reduce malnutrition in bariatric surgery patients [6, 8]. Serum transferrin and prealbumin are additional biochemical indicators used in clinical settings to accurately assess nutritional status of hospitalized patients [8].

With bariatric patients, weight loss is a good indicator of success with their surgery. The greatest weight loss typically occurs within 18-24 months post-operatively, and some weight regain is common by 5 years post-operative [9, 10, 11]. Cresci found during his research that nutrition intervention has been shown to help improve patient compliance to ensure a more favorable surgical outcome [9]. Albumin and body weight are measured at frequent intervals on bariatric surgery patients during the pre-operative phase, at the time of admission for surgery, and during the post-operative period to determine adequacy of nutritional status. Serum albumin is used to help identify patients at risk for malnutrition, allowing for appropriate nutrition intervention from a registered dietitian. This information may be used as an indicator to help initiate more timely nutrition intervention and prevention of post-operative complications following bariatric surgery [4].

### *Problem Statement*

The prevalence of overweight and obesity has risen in the United States and 97 million adults were considered overweight or obese in 2004 [1, 2]. Cresci during his research has shown that non-surgical weight loss strategies have not been proven effective in maintaining long-term weight loss [9]. Surgical strategies may be more successful in long-term weight loss and were found to be safer and more effective than in the past due to improvements in technology [4]. Faintuch et al. found that integrated interdisciplinary approaches to pre-operative evaluation and education, as well as post-operative care for patients who underwent surgical interventions, greatly improved the long-term success and quality of life of those obese patients [4]. Long-term nutritional

considerations with RYGB included protein-calorie malnutrition, dehydration, vitamin and mineral deficiencies, anemia, weight loss failure, and dumping syndrome [11]. Parrish found during his research that pre-operative education has been shown to improve pre-operative and post-operative patient outcomes and to prevent nutritional complications associated with bariatric surgery [1, 2, 9].

Serum albumin is a biochemical indicator of nutritional status and can be used to determine outcomes following bariatric surgery as it correlates with malnutrition [6]. Albumin of 3.8 mg/dl or higher showed successful nutritional intervention [6]. Another indicator of success in RYGB surgery was percentage of weight loss post-operatively. A weight loss of 50% to 75% of excess body weight from ideal body weight within 18 months and remaining stable over time is expected with RYGB [2]. Most weight was lost in the first 6 months post-operatively and then rate of weight loss decreased and plateaus at about 18 months post-operatively [9]. A 10% to 15% weight regain has been shown after 5 years [9].

Faintuch et al. found noncompliance to instruction regarding nutritional intake is a problem with bariatric patients, which puts them at risk for nutritional complications associated with bariatric surgery, but with adequate screening complications can be reduced and/or prevented [4]. Medical nutrition therapy (MNT) has helped decrease the number of costly procedures related to complications and the number of hospital stays secondary to complications of bariatric surgery [2]. Nutrition screening, pre-operative and post-operative medical nutrition therapy plays an important role in the MNT process with bariatric surgery patients.

The purpose of the study was to determine if post-operative serum albumin and percentage of weight loss improved in patients who received at least 3 months of formalized pre-operative nutrition therapy. Nutrition screening, education, and intervention were used in the delivery of medical nutrition therapy to improve weight loss and prevent protein-calorie malnutrition in bariatric surgery subjects.

### *Hypothesis*

Bariatric surgery subjects who have formalized medical nutrition therapy will have a higher percentage of weight loss and higher levels of serum albumin post-operatively when compared to subjects who received no formalized medical nutrition therapy

### *Null Hypothesis*

There will be no significant difference in percentage of weight loss or serum albumin in post-operative bariatric subjects with formalized medical nutrition therapy when compared to subjects who have no formalized medical nutrition therapy.

### *Delimitations*

Deliminations of the study:

1. All subjects had undergone Roux-en-Y gastric bypass procedure, which impaired the ability to generalize results to other surgical procedures.
2. Subjects were restricted to those admitted to Skyline Medical Center between January 2001-January 2006 for the purpose of Roux-en-Y gastric bypass surgical procedure.

### *Limitations*

Limitations of the study:

1. Research data were obtained through a retrospective chart review of patients who had undergone Roux-en-Y gastric bypass surgery at Skyline Medical Center in Nashville, TN. Because this study is retrospective, nutrition intervention had already been conducted or not been conducted.
2. Serum albumin levels can be influenced by many conditions not associated with RYGB.

### *Assumptions*

The following assumptions were critical to the study:

1. The length of the study was adequate to obtain the data for analysis
2. Data related to the subject's physical status, medical history, and laboratory tests were analyzed and recorded accurately in the medical record
3. Patients followed nutritional and medical guidelines accurately during the pre-operative period and the post-operative period.

### *Definition of Terms*

1. **Obesity**: an abnormal increase of fat in the subcutaneous connective tissues. (12)
2. **Overweight**: excessive increase in adipose tissue or in muscle and skeletal tissue (muscular overweight). (13)
3. **Serum albumin**: a major protein of human blood plasma. (13)
4. **Protein-Calorie Malnutrition**: undernutrition resulting from inadequate intake, digestion, or absorption of protein or calories. (14)

5. **Body Mass Index (BMI):** a rough method of assessing nutritional status; correlates with risk of disease and death due to causes associated with obesity; because it does not distinguish excess adiposity from excess lean body mass, it is not useful in competitive athletes, body builders, pregnant women, or children. Measurement of relative percentage of fat and muscle mass in the human body in which weight in kilograms is divided by height in meters and the result is used as an index of obesity. (12)(15)

6. **Nutrition Assessment**: the process used to evaluate nutritional status, identify malnutrition, and determine which individuals need aggressive nutritional support. (12)

7. **Medical Nutrition Therapy**: involves the assessment of nutritional status of patients' condition, illness, or injury that puts them at risk. This includes review and analysis of medical and diet history, laboratory values, and anthropometric measurements. Based on the assessment of nutrition modalities most appropriate to manage the condition or treat the illness are chosen to include diet modification and counseling, specialized nutrition therapies. (12)

8. **Roux-en-Y gastric bypass (RYGB)**: high division of the stomach, anastomosis of the small upper pouch of the stomach to the jejunum, and closure of the distal part of the stomach that is retained; used for treatment of morbid obesity. (12)

9. **Dumping Syndrome**: a syndrome that occurs after eating, most often seen in patients with shunts of the upper alimentary canal; characterized by flushing, sweating, dizziness, weakness, and vasomotor collapse, occasionally with pain and

headache; results from rapid passage of large amounts of food into the small intestine, with an osmotic effect removing fluid from plasma and causing hypovolemia. [12]

10. **Postprandial**: occurring after dinner, or after a meal; postcibal. [13]
11. **Bariatric Surgery:** field of medicine encompassing the study of overweight, its causes prevention and treatment including surgery. [11]
12. **Co-Morbidities**: A concomitant but unrelated pathologic or disease process; usually used in epidemiology to indicate the coexistence of two or more disease processes. [12]

# CHAPTER 2

## REVIEW OF LITERATURE

Obesity has a significant impact on health, psychosocial well-being, longevity, and quality of life [15]. Numerous studies have demonstrated that obese persons experience significant impairments in the quality of life as a result of their obesity [16]. With the guidance and support of health care providers, psychologists, registered dietitians (RD), trainers, family members, and friends, obesity can be managed and quality of life can be improved [16]. The American Dietetic Association (ADA) notes that up to 50% of chronic disease mortality is attributable to lifestyle factors that can be changed, such as modifying diet and exercise [17].

Research has indicated that traditional methods of weight loss therapy have been somewhat successful, while surgical intervention has shown positive impact on the quality of life [18]. Patients undergoing gastric bypass should have a complete pre-operative workup from the healthcare team, including gastroenterologist, pulmonologist, psychologist, surgeon, and registered dietitian (RD) to help reduce and/or prevent post-operative complications [16]. Despite compelling evidence that malnutrition increases post-operative morbidity and mortality following major elective surgery, pre-operative nutrition counseling or management is often ignored and post-operative nutrition education is not instituted until after onset of complications [9].

Serum hepatic protein levels have been commonly used in clinical practice to determine and monitor nutritional status. Hepatic proteins that are commonly used in nutrition practice are albumin, prealbumin, and transferrin [19]. Despite recent literature indicating that serum hepatic proteins are impacted more significantly by factors other

than nutritional status, they continue to be used to evaluate nutritional status, including the presence of malnutrition [19]. In a study by David Seres, the incidence of malnutrition was high among hospitalized patients but still indicated significant doubt as to whether surrogate nutritional markers reflected the adequacy of nourishment [20]. These hepatic proteins were more often used to prove the value of MNT because the collection of outcome data was cumbersome and expensive [20]. It was difficult to obtain accurate records of incidence of complications, length of hospital stay, mortality, and cost of MNT; therefore, measuring serum albumin level seemed to be the most convenient and rapid way and is covered by insurance [20]. Serum albumin is a biochemical indicator of nutritional status and can be used to predict outcomes following bariatric surgery as it correlates with malnutrition [19, 20, 21]. Albumin of 3.8 mg/dl or higher showed successful nutritional intervention [6]. Brugler et al. showed routine albumin testing, as part of the medical screening process, helped identify concerns regarding malnutrition post-operatively [6]. Another indicator of success in RYBG surgery was percentage of weight loss post-operatively. A weight loss of 50% to 75% of excess body weight from ideal body weight was expected in an 18 month period [2]. Most weight was lost in the first 6 months post-operatively and then rate of weight loss decreased and plateaued at about 18 months post-operatively [2]. According to Sonnanstine et al., a 10% to 15% weight regain has been shown in patients undergoing RYGB after 5 years [2].

Noncompliance to nutritional intervention is a problem with bariatric patients, which puts them at risk for nutritional complications associated with bariatric surgery [4]. Adequate screening can help prevent nutritional complications with these patients. Medical nutrition therapy has helped decrease the number of costly procedures related to

complications and the number of hospital stays secondary to complications of bariatric surgery [6]. Nutrition screening, pre-operative and post-operative nutrition therapy plays an important role in the MNT process with bariatric surgery patients.

According to Robinson et al., the incidence of malnutrition in hospitals can exceed 50% [21]. Poorly nourished patients had a complication rate up to 20 times higher than their well-nourished counterparts as well as longer hospitalizations, increased healthcare costs, and a higher mortality rate [21].

Noncompliance with nutrition and medical therapy with bariatric surgery is still being studied. The association with noncompliance with protein-calorie malnutrition (PCM) and vitamin and mineral deficiency, as well as regain of body weight is ongoing and limited research is available. Using measures such as serum albumin, prealbumin, and weight loss have been effective as screening tools to evaluate nutrition risk in the hospital setting [19]. Albumin is a sensitive and cost-effective means of assessing the nutritional status of patients who are critically ill or who are not meeting visceral protein needs [19]. Assessing serum albumin and prealbumin levels upon admission and at regular intervals during hospitalization helps identify those patients at nutrition risk [6]. Serum albumin is the most cost-effective means of assessing nutritional status, but with a half-life of 14 days it may not be the best indicator of PCM or of other serum proteins [6]. Serum albumin was still a reliable outcome indicator of patient results if measured regularly and a thorough clinical and physical exam followed [6]. Weight loss with bariatric patients usually occurs within a specific period of time, and if too much weight is lost or not enough weight is lost it could be an indicator of PCM or noncompliance [2]. The greatest amount of weight loss should occur in the first year after surgery and then taper off

around 18 months [2]. Weight loss is dependent on diet compliance and amount of exercise.

Due to the increase in obesity and increased number of hospitalizations associated with obesity related co-morbidities, the number of patients seeking bariatric surgery was on the rise in the 1990s and increased from about 10-15,000 to 140,000 in 2005 [2,3]. Hospitals formed interdisciplinary teams that included psychologists, registered dietitians (RD), physicians, respiratory therapists, and nurses who specialized in bariatrics to develop treatment plans to prepare the patient for surgery and to help improve post-operative medical and nutritional outcomes [18]. MNT provided by the RD helped improve outcomes such as PCM and maintenance of weight lost by implementing and reinforcing the appropriate diet [2]. Early nutritional intervention can potentially reduce the number of patients who have PCM or other nutritional complications, including regaining weight that has been lost [2].

Traditional weight loss programs, such as diet and exercise programs, behavior modification, and/or pharmacological therapy have not been successful or effective in maintaining long-term weight loss for the morbidly obese [9]. With this as a concern, bariatric surgery has become increasingly popular as a way of losing excess weight and maintaining it long term [10]. Bariatric surgery does not come without medical or nutritional complications, so this is not always an appropriate step for weight loss. The National Institutes of Health/National Heart, Lung, and Blood Institute (NIH/NHLBI) established the first federal obesity clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults [10]. These guidelines were designed to help physicians and clinicians in their care of overweight and obese patients [10]. They

were developed using evidence based model and methodology and were based on the most extensive review of scientific evidence on overweight and obesity to date [10]. According to the guidelines, assessment of overweight involves evaluation of three key measures including BMI, waist circumference, and a patient's risk for disease and conditions associated with obesity [10]. In fact, a patient must meet criteria set by the panel of experts of a BMI ≥ 40 or BMI ≥ 35 with multiple obesity related co-morbidities [10].

Metabolic and nutrition complications of bariatric surgery include dumping syndrome, dehydration, PCM, vitamin and mineral deficiencies, weight loss failure, and anemia [11]. Vitamin and mineral deficiencies such as iron, vitamin $B_{12,}$ and folate were the most common deficiencies associated with Roux-en-Y gastric bypass (RYGB) [9]. PCM and abnormalities of calcium, thiamin, and fat-soluble vitamin status can also occur with bariatric surgery [11]. Very few studies have assessed the long-term metabolic and nutritional outcomes of patients undergoing RYGB, but those available reported that deficiencies typically occurred 1 to 2 years post-operatively [4]. PCM was rare in the uncomplicated RYGB, but it was more prevalent among those experiencing persistent vomiting and diarrhea associated with malabsorption [2]. PCM can also occur in patients with noncompliance with diet, especially those not consuming adequate calories and protein as instructed; symptoms of PCM include decreased serum albumin, hair loss, brittle nails, and losing weight too rapidly [4].

Faintuch et al. conducted a retrospective study using subjects who were treated for morbid obesity by RYGB during a 68 month period (January 1998 – August 2003) [4]. Medical records from 236 RGYB post-operative patients were retrospectively reviewed

for occurrence of severe post-operative malnutrition [4]. Of the 236 subjects, 11 were identified with severe malnutrition, including 10 females and 1 male aged 45.1 ± 10.6 years [4]. They had mean initial BMI of 54.6 ± 8.4 kg/m2 [3]. Inclusion criteria included negative history, nutrient deficits, organ failures, surgical discharge in good condition, and presence of at least three of five aberrations including hypoalbuminemia, anemia, edema, inability to walk, or difficulty performing simple tasks [4]. All subjects had a RYGB procedure following standard protocol for the hospital [4]. Each subject was placed on a multivitamin and mineral preparation and instructed to take it and to complete follow up visits for 2 years post-operatively [4].

Faintuch et al. noted that age, gender distribution, and presence of comorbidities in the 11 subjects did not differ [4]. In the 11 subjects the derangement was diagnosed 17.9 ± 15.8 months after RYGB [4]. Mean BMI was 31.4 ± 8.6 kg/m2 (42.5 ± 9.9% total reduction, or 2.4 ± 2.1 % decrease in 1 month) and serum albumin and hemoglobin were 24.0 ± 8.2 g/L and 97.0 ± 23.0 g/L respectively. The 11 patients showed depleted albumin and hemoglobin that were used as indicators of PCM in this study. In this study, edema was found to be present in 45.4% (5/11) of the subjects with hospitalization required in 54.5% (6/11) and 18.2 % (2/11) subjects eventually died [4]. All 11 subjects were severely affected by malnutrition. Hemoglobin was almost universally depressed and only three patients presented with serum albumin close to or above 3.5 mg/dl [4]. Edema was found to be very common in this study group. Serum iron and vitamin $B_{12}$ were not routinely measured and could not be included [4]. The initial approach in most subjects, either at home or in the hospital, was a high- nitrogen oral diet with good initial response, but with more variable long-term results [4]. Even though there was a good

initial response with oral diet, some of the subjects required enteral or parenteral nutrition support. Further surgery was needed for four of the subjects. Two of the subjects died due to recalcitrant malnutrition, one late after surgical correction of gastric outlet stenosis, along with a second one displaying anorexia nervosa [(4)].

The popularity of RYGB, which may offer the best benefit/complication ratio in bariatric surgery, has only infrequently been jeopardized by unfavorable nutrient outcome [(2)]. Improvements in surgical technique, nutritional care, vitamin supplementation, and long-term follow up contributed substantially to improvement in prevention of post-operative management [(2)]. As observed in the study by Faintuch et al., serious PCM was unusual but not rare and could be prevented or lessened by pre-operative and adequate post-operative follow up to lessen noncompliance [(3)].

# CHAPTER 3

# RESEARCH METHODOLOGY

## *Participants*

A retrospective chart review was conducted to evaluate the effectiveness of pre-operative nutrition intervention for bariatric patients as a preventative measure against post-operative complications. The study was conducted on medical records of patients who had been admitted to the bariatric program at Skyline Medical Center in Nashville, Tennessee, where they underwent elective Roux-en-Y gastric bypass surgery. Records of 77 Roux-en-Y bariatric patients admitted during January 2001 through January 2006 were evaluated by the principle investigator. Subjects included 9 male subjects and 68 female subjects; range in age of subjects was 40-58 years. Pre-operatively subjects were classified as having depleted albumin levels < 3.5 g/dl, low to low/normal albumin levels 3.5-3.8 g/dl, and/or normal albumin levels > 3.8 g/dl. Subjects were also classified by percentage of body mass index (BMI) loss pre-operatively and post-operatively. Albumin levels were obtained as needed at physician discretion which included at least pre-operatively, peri-operatively, and post-operatively to accurately assess visceral protein status. Subjects were weighed routinely to determine success with weight loss pre-operatively and post-operatively.

## *Development of Instrumentation*

A data sheet was designed to obtain relevant information for the study at both the initial visit (appendix A) and follow up appointments (appendix B). Information obtained from charts included age, sex, albumin (mg/dl), weight, primary diagnosis,

secondary diagnosis, medical nutrition therapy (if applicable), and anthropometric data. The independent variables were albumin and weight. Dependent variables included the number of pre-operative nutrition counseling visits. Albumin was measured according to standard protocol as defined by Skyline Medical Center during hospital stay. Albumin levels were obtained pre-operatively and post-operatively according to standard practice as ordered by the primary physicians. Body weight was recorded using bed scales at time of admission. Body weight in the patients receiving nutrition intervention was recorded at time of nutrition counseling sessions by the principle investigator using the same electronic scale each visit. Patients who received no medical nutrition therapy were weighed at the physician's office during routine visits (Appendix C). BMI was completed at each visit based on current weight and initial height (Appendix D). Reliability of albumin levels was determined by standard laboratory analysis with instrumentation routinely calibrated in accordance with established laboratory protocol.

### *Procedure*

The initial research proposal was approved by the graduate committee in the Department of Family and Consumer Sciences at East Tennessee State University. The research proposal was also submitted to the Institutional Review Board (IRB) at ETSU for approval. The study was eligible for exempt review by the IRB because the existing data were recorded in a manner that human subjects could not be identified. An informed consent was not required due to the retrospective nature of the study using a closed record review. The research proposal, as well as the IRB approval letter, was also submitted to the education department at Skyline Medical Center, and a letter of confidentiality was signed before research data were collected. Implementation of the

study began after exemption from the IRB and approval from Skyline Medical Center were obtained. The study population included both subjects who had been referred to the registered dietitian (RD) by the bariatric surgery office during pre-operative visits and also subjects who were not required by their insurance or the physician to complete medical nutrition therapy. Prior to the study the facility did not have a registered dietitian who worked in the bariatric field, so education was performed by the nurse at the bariatric clinic. All subjects who were seen by a RD for more than 3 months were included in the study, as well as all subjects admitted to the program between January 2001 through January 2006 who did not receive any formalized medical nutrition therapy. Subjects counseled by the dietitian received education according to standard protocol for pre-operative weight loss, as well as post-operative nutrition education (Appendix E).

Subjects were encouraged to lose 10% weight loss prior to surgery to prevent hepatic stenosis and also to prevent post-op complications. On initial visit subjects were asked a series of questions (Appendix A) to assess readiness for weight loss and surgery and also to assess current diet to determine if subject is a good candidate for bariatric surgery. Follow-up assessments were also completed using a standard form to assess subjects meeting pre-operative and post-operative goals (Appendix B). Subjects were counseled according to National Health, Lung, and Blood Institute approved guidelines regarding evidenced-based guidelines for weight management (Appendix E). Subjects were weighed at the registered dietitians' office using a standard scale. Subjects were weighed without shoes, and clothing was recorded at each visit and subjects were told to wear similar clothes at each visit. Subjects were counseled monthly for weight loss and

adequate preparation of nutritional considerations for Roux-en-Y gastric bypass. Practice guidelines developed at Skyline Medical Center and based upon American Dietetic Association guidelines were used to determine readiness during assessment of nutritional status and also for standardized pre-operative and post-operative medical nutrition therapy (Appendix E).

Subjects were classified into two groups, those who had nutrition counseling and those who did not receive nutrition counseling intervention from a registered dietitian prior to surgery. Subjects who did not receive nutrition counseling intervention were admitted to the program prior to initiation of RD in the bariatric surgical center. Serum albumin levels and percentage of weight loss were measured during pre-operative visits and post-operative visits. These laboratory values and anthropometric measures were obtained on admission to hospital, 3 months post-operatively and 6 months post-operatively on subjects who followed up with appointments as recommended. All other variables (age, BMI, sex, and race) were collected to determine if those variables might have impacted surgical and nutritional outcomes.

A data collection sheet was developed to obtain relevant data needed for the study (Appendix C). The subjects' medical record numbers were used to obtain medical records from the bariatric surgeon's office and from the dietitian's office. The medical record numbers were coded for the data collection sheet to protect the privacy of subjects and to maintain the confidentiality of data. Data were collected on 77 patients who were admitted for RYGB surgery between January 2001 and January 2006. The data were then entered into a statistical software packet for analysis.

*Data Analysis*

Data for each group being studied were collected and organized for entry into a statistical format using statistical software packet for analysis (SPSS). A Non-parametric test procedure (Mann-Whitney test) was used to determine the effects of medical nutrition therapy on albumin and weight percentages. Mann-Whitney tests are used to test for differences between two independent groups on a continuous measure. This test is the non-parametric alternative to the t-test for independent samples. The Mann-Whitney test actually compares medians. It converts the scores on the continuous variable to ranks across the two groups and then evaluates whether the two groups differ significantly. Non-parametric statistics were used due to the small sample size involved in the study.

# CHAPTER 4

## RESULTS

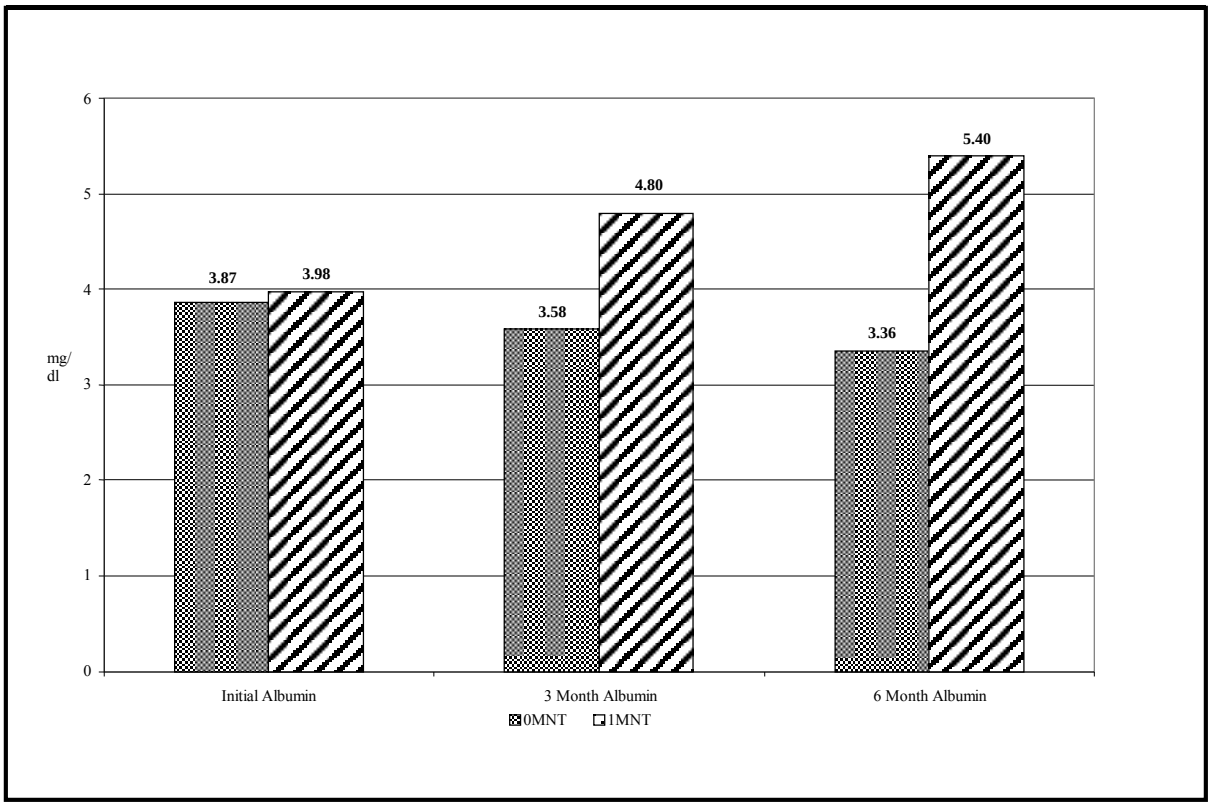
This study was conducted to determine if there was a significant difference in percentage of weight loss and serum albumin between RYGB subjects who received pre-operative nutrition intervention provided by a RD and those who had no nutrition intervention. RYGB subjects were separated into two groups based upon nutrition intervention. Nutrition assessments and education were conducted on subjects as required by insurance and physician's order to have medical nutrition therapy by a RD.

Medical records of 77 subjects were included in the study, and all subjects had undergone RYGB surgery. The age range of the subjects was 21 to 64 years with a mean age of 40.58 years, and the sample was comprised of 88.3% (n = 68) females and 11.7% (n = 9) males. Seventy-six percent (n =59) of the subjects were Caucasian and 23.4% (n = 18) of the subjects were of another race.

Serum albumin and percentage of weight loss were evaluated using non-parametric tests to determine if pre-operative nutritional intervention affected serum albumin levels and percentage of weight loss in subjects post-operatively. Of the 77 subjects in the study, 57 did not receive pre-operative nutrition intervention and 20 subjects received nutrition intervention and education by a registered dietitian. A registered dietitian was added to the bariatric surgery clinic in December 2004, so only the subjects admitted after December 2004 were counseled by a dietitian; therefore, all subjects prior to December 2004 were not counseled by a RD. Because of the short time frame there was a limited number of subjects counseled by a RD in this study. According to the data regarding serum albumin levels, the subjects seen by the registered dietitian had a mean

pre-operative albumin of 3.98 mg/dl and 57 subjects without nutrition intervention had a mean pre-operative serum albumin of 3.87 mg/dl. Analysis indicated that there was not a significant difference ($p > 0.86$) in pre-operative albumin levels between the two groups. At the 3 month post-operative visits subjects receiving nutrition intervention had a post-operative serum albumin mean of 4.8 mg/dl, whereas the group without nutrition intervention ($n= 57$) had a mean post-operative serum albumin of 3.58 mg/dl ($p< 0.038$). Although both groups were within normal limits, there did appear to be a positive trend between pre-operative nutrition intervention and serum albumin levels as apparent in the substantially higher serum albumin with nutrition intervention. Also in correlation to the rise in serum albumin with nutritional intervention, there was a significant difference ($p< 0.001$) between the groups 6 months after the RYGB surgery. The mean serum albumin in the group receiving nutrition intervention was 5.4 mg/dl and the mean serum albumin in the group without nutrition intervention was 3.36 mg/dl. This indicated that the group with no nutrition intervention had mild albumin depletion 6 months post-operatively, which could be related to poor nutritional intake, noncompliance with medical and nutritional therapy, or possibly related to other complications or illness. (Figure 1)

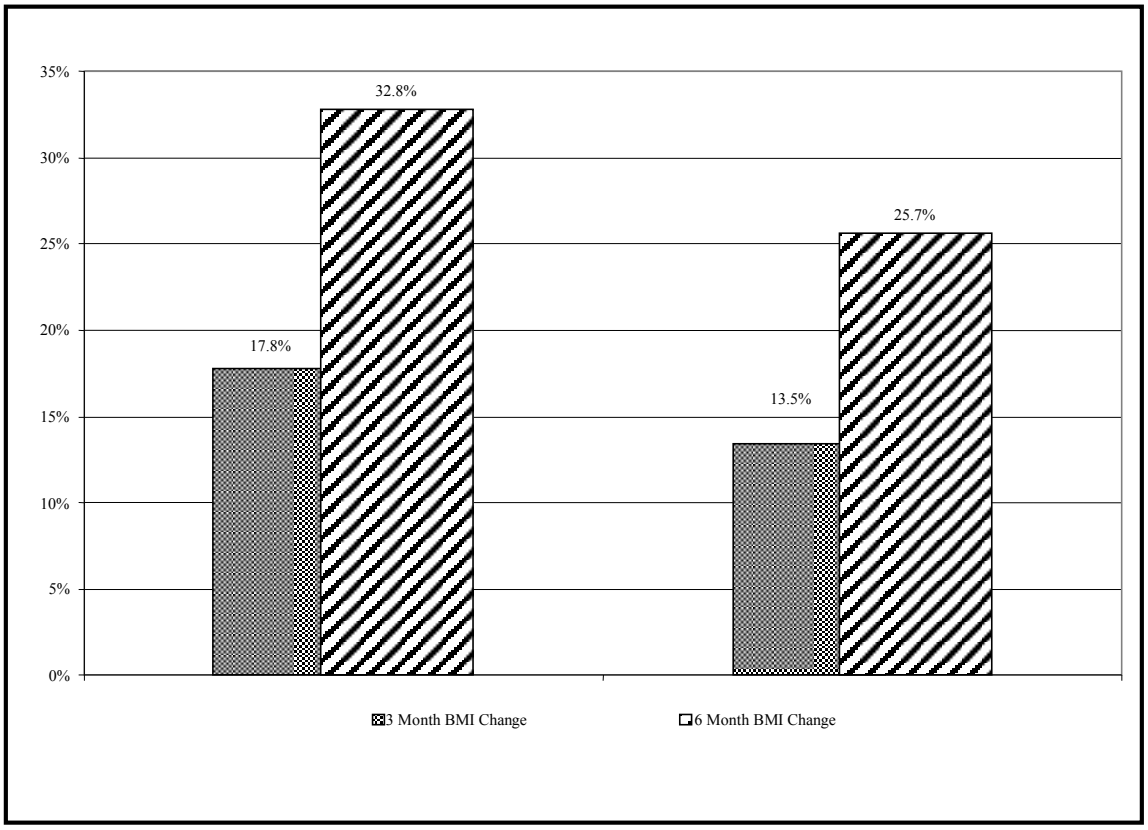
**Figure1:** Medical Nutrition Therapy Effect on Albumin Gain in Pre-Operative and in Three and Six Months Post-Operative Visits




The same subjects were used to determine the effect of nutrition intervention on percentage of weight loss. There was not a significant difference in pre-operative weight loss ($p>0.68$) in patients with or without nutrition intervention. According to the data, no significant difference was seen at either 3 month ($p<0.187$) or 6 month ($p<0.412$) post-operative visits. The 20 subjects counseled by a registered dietitian had a mean loss of 40.78 % when compared to 57 subjects without nutrition intervention with a mean of 38.38 % lost in post-operative visits. At 3 month post-operative visits a mean loss of 44.68% was seen in subjects with nutrition intervention and a mean loss of 37.01% in subjects without intervention. At 6 months

post-operatively there was not a significant difference ($p<0.1$), but the patient without nutrition intervention had a higher mean loss of 40.24% when compared to the group with nutrition intervention who had a mean loss of 35.48%. (Figure 2)

**Figure 2.** Medical Nutrition Therapy Effect on Average Percent BMI Loss at Three and Six Months Post-Operatively




With percentage of BMI loss in patients 3 months post-operatively there was not a significant difference ($p< 0.627$) in those who did or did not receive medical nutrition therapy, whereas at 6 month visit a significant difference ($p > 0.013$) was noted.

Because of the limited size of the data set no definite conclusions could be made regarding this trend. With this data, the null hypothesis could not be rejected ($p<0.05$).

# CHAPTER 5

## DISCUSSION AND CONCLUSION

With the tremendous increase in bariatric surgery, healthcare providers are challenged to provide a continuum of care and to help control complications associated with this weight loss surgery [2]. Identifying malnutrition and other nutrition complications associated with surgery can help prevent hospitalizations [7]. By providing interdisciplinary patient education including nutrition and psychological services, healthcare providers are noticing a decrease in hospital admissions, costly procedures, and length of stay [7]. Providing nutrition assessment and education for patients undergoing bariatric surgery has been shown to reduce complications associated with malnutrition [11]. Malnutrition was rare in bariatric patients and was usually related to inadequate protein and calorie intake, illness, and noncompliance issues [11]. Early detection of malnutrition enables prompt and aggressive intervention to prevent and/or correct protein-calorie malnutrition and vitamin and mineral deficiencies [4]. According to previous studies, initial screening of patients undergoing bariatric surgery, as well as post-operative follow-up visits can help identify those patients at risk for protein-calorie malnutrition [2]. Appropriate MNT may lead to improved health outcomes resulting in improved quality of life and prevention of other obesity-related problems [7].

The results of this study showed no significant difference in serum albumin or percentage of weight loss between the two study groups in the pre-operative phase. Subjects who had received nutrition intervention showed a substantial improvement 3 months post-operatively in both serum albumin and percentage of weight loss. In the 6 month post-operative results, the serum albumin trend was continuing to be higher in

subjects with nutrition intervention, but the weight loss in those with nutritional intervention was significantly lower. Fifty-seven subjects in the study had not received medical nutrition therapy during their pre-operative, peri-operative, and post-operative visits which could result in a lack of compliance with the post-operative bariatric diet because these subjects were not provided standard guidelines to follow pre-operatively or post-operatively. The higher weight loss at the 6-month period could be related to these subjects weighing more prior to the surgery and/or possibly due to incidence of protein-calorie malnutrition. Subjects receiving medical nutrition therapy were recommended to lose 10% of initial body weight prior to surgery to help prevent hepatic stenosis, improve post-operative complications, as well as help decrease fat percentage prior to surgery for a more favorable weight loss outcome. Rapid weight loss with bariatric subjects can also be an indicator of protein-calorie malnutrition which most likely is related to non-compliance to diet restrictions with high protein, low calorie diet leading to dumping syndrome, nausea/vomiting, obstructions, etc.

Commitment to long-term follow up and compliance is essential to success of weight loss in these subjects. They must take responsibility in their care to ensure a favorable outcome. Subjects at the 6 month post-operative period may have already started to follow a regular diet. Those who have not changed their lifestyles and made the appropriate changes at this time can see a lapse in the amount of weight loss that occurs. Therefore, with adequate follow–up, including an interdisciplinary team approach, prevention or minimization of dietary intolerances and manifestations of nutrient deficiencies will be improved.

Albumin levels were rising due to the maintenance or improvement of nutritional status after surgery; patients who comply with medical and nutritional intervention had improved surgical outcomes. Thus it may be concluded that post-operative serum albumin was positively influenced by nutrition intervention prior to RYGB surgery.

Noncompliance with treatment was a normal occurrence that could indicate a correlation between malnutrition and surgical outcomes in a bariatric patient. After completion of the study, it was concluded that subjects who were compliant with their medical and nutritional intervention had improved outcomes.

Expansion of this study would be worthwhile to strengthen the data and validity of the research. Further research could be conducted on compliance with care and instruction from the interdisciplinary team prior to undergoing RYGB surgery. Due to the noncompliance in bariatric patients and the resulting issues such as malnutrition, the study should be expanded to evaluate a larger study group once a larger data set is available.

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APPENDICES

APPENDIX A

***Outpatient Initial RYGB Questionnaire***

Name: Date of Visit:

Referring Physician:

Insurance Company:

Anthropometrics:

Height ___ ft ___in
Current weight ___ # ___ kg
UBW ___ # ___ kg
BMI ___
WNL overweight (mild moderate severe super) obesity
IBW ___ # ___kg
GBW ___# ___kg

Medical Background:

Pertinent Medications:

Supplements/Vitamins and Minerals:

Doctor/Dietitian Supervised Weight Loss Programs:

Other Weight Loss Programs:

Successes/Failures with programs:

Labs:

Current Exercise: Any physical ailments limiting exercise?

Smoke/Drink:

Work schedule:

Support system:

Typical Day Meal Plan

Patient Goals:

APPENDIX B

***Pre-Operative and Post-Operative Follow-Up Appointments***

Visit 1 2 3 4 5

Current weight:

Current amount of weight loss: % wt loss

Current BMI:

Typical Day Meal Plan:

Current Exercise:

Food/Exercise Log:

Vitamins/Minerals:

Patients Goals:

# APPENDIX C

## *Data Set*

| name | sex | race | height | BMI | pre wt | post wt | ppost wt | pre alb | post alb | ppost alb | nutrition | age |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 1 | 0 | 5 | 56 | 285 | 246 | 195 | 3.7 | 4.2 | n/a | 0 | 48 |
| 2 | 1 | 0 | 5.66 | 38 | 285 | 196 | 173 | 4.1 | 4.1 | 4.2 | 0 | 44 |
| 3 | 1 | 0 | 5.17 | 74 | 402 | 347 | 253 | 3.9 | 3.8 | 3.7 | 0 | 41 |
| 4 | 1 | 0 | 5.75 | 56 | 380 | 310 | 196 | 3.5 | 4.1 | 4.1 | 0 | 44 |
| 5 | 1 | 0 | 5.58 | 61 | 391 | 326 | 168 | 4.4 | 4 | 3.8 | 0 | 43 |
| 6 | 0 | 0 | 6.25 | 60 | 481 | 404 | 332 | 3.7 | 3.4 | n/a | 1 | 47 |
| 7 | 1 | 1 | 5.33 | 47 | 273 | 218 | 179 | 4 | 4.7 | 4.4 | 0 | 46 |
| 8 | 1 | 0 | 5.5 | 74 | 461 | 370 | 230 | 3.8 | 3.6 | 3.5 | 0 | 30 |
| 9 | 1 | 0 | 5.5 | 49 | 304 | 275 | 244 | 4.3 | 4.4 | 4.7 | 0 | 41 |
| 10 | 0 | 0 | 5.66 | 53 | 348 | 244 | 198 | 4.1 | 4.3 | 5 | 0 | 42 |
| 11 | 1 | 0 | 5.33 | 50 | 292 | 237 | 186 | 4 | 4.2 | 4.2 | 0 | 41 |
| 12 | 0 | 0 | 6 | 61 | 449 | 363 | 289 | 4 | n/a | 4.3 | 0 | 40 |
| 13 | 1 | 0 | 5 | 50 | 258 | 216 | 190 | 4.4 | 4.2 | n/a | 0 | 40 |
| 14 | 1 | 0 | 5.42 | 62 | 374 | 313 | 159 | 3.9 | 4.2 | 3.4 | 0 | 45 |
| 15 | 1 | 0 | 5 | 38 | 197 | 176 | n/a | 3.9 | n/a | n/a | 1 | 52 |
| 16 | 1 | 0 | 5.58 | 43 | 276 | 224 | 175 | 3.6 | 3.8 | 3.9 | 0 | 27 |
| 17 | 1 | 0 | 5.42 | 47 | 286 | 233 | 183 | 3.6 | 3.7 | 3.2 | 0 | 33 |
| 18 | 1 | 0 | 5.66 | 41 | 240 | 197 | 173 | 4 | 3.7 | n/a | 0 | 39 |
| 19 | 1 | 0 | 5.66 | 54 | 312 | 252 | 190 | 4 | 4.5 | 4.6 | 0 | 35 |
| 20 | 0 | 0 | 5.5 | 48 | 300 | 259 | n/a | 3.9 | 4.4 | n/a | 1 | 60 |
| 21 | 1 | 0 | 5.42 | 51 | 309 | 268 | n/a | 4 | n/a | n/a | 1 | 47 |
| 22 | 1 | 0 | 5.75 | 49 | 328 | 284 | 234 | 4 | n/a | 3.9 | 1 | 47 |
| 23 | 0 | 1 | 6.17 | 46 | 363 | 294 | 272 | 4.7 | 4.4 | n/a | 1 | 43 |
| 24 | 1 | 1 | 5.5 | 50 | 313 | 235 | 168 | 3.1 | 3.9 | 4 | 0 | 30 |
| 25 | 1 | 0 | 5.33 | 55 | 318 | 285 | 245 | 3.5 | 3.5 | 3.6 | 1 | 42 |
| 26 | 1 | 1 | 5.58 | 36 | 228 | 175 | n/a | 4.1 | 3.9 | n/a | 1 | 25 |
| 27 | 1 | 1 | 5.58 | 62 | 398 | 316 | n/a | 3.6 | n/a | n/a | 1 | 29 |
| 28 | 1 | 0 | 5 | 47 | 243 | 178 | 164 | 3.7 | n/a | 3.9 | 1 | 55 |
| 29 | 1 | 0 | 5.42 | 46 | 278 | 213 | 192 | 4.3 | 3.9 | n/a | 1 | 40 |
| 30 | 0 | 1 | 5.75 | 63 | 426 | 347 | 294 | 4 | n/a | n/a | 1 | 26 |
| 31 | 1 | 1 | 6.17 | 54 | 422 | 382 | 299 | 3.7 | 4.3 | 4 | 0 | 46 |
| 32 | 1 | 1 | 5.42 | 42 | 262 | 205 | 211 | 3.7 | 3.7 | 3.7 | 0 | 41 |
| 33 | 1 | 1 | 5.33 | 41 | 239 | 175 | 119 | 4.1 | 2.9 | 3.5 | 0 | 54 |
| 34 | 1 | 0 | 5.92 | 66 | 476 | 398 | 305 | 4.1 | 3.6 | 4.4 | 0 | 21 |
| 35 | 1 | 0 | 5.08 | 44 | 233 | 194 | 149 | 4.1 | 3.9 | 3.8 | 0 | 33 |
| 36 | 1 | 0 | 5.58 | 56 | 359 | 293 | 244 | 4.5 | 4.6 | 4.5 | 0 | 31 |
| 37 | 1 | 0 | 5.25 | 46 | 261 | 210 | 151 | 3.3 | 3.4 | 4.4 | 1 | 38 |
| 38 | 1 | 0 | 5.25 | 47 | 268 | 243 | 231 | 4 | n/a | n/a | 1 | 51 |
| 39 | 1 | 0 | 5.17 | 54 | 297 | 220 | 186 | 3.5 | 3.8 | 4.2 | 0 | 49 |
| 40 | 1 | 0 | 5.08 | 51 | 268 | 174 | 159 | 3.4 | 3.2 | 3.8 | 0 | 33 |
| 41 | 1 | 0 | 5.08 | 42 | 227 | 189 | 154 | 4.4 | 4.2 | 4.3 | 0 | 48 |
| 42 | 1 | 0 | 4.83 | 60 | 285 | 244 | 143 | 3.8 | 3.8 | 4 | 0 | 42 |
| 43 | 1 | 1 | 5.58 | 51 | 327 | 279 | 265 | 4 | n/a | 3.9 | 0 | 40 |
| 44 | 1 | 0 | 5.33 | 57 | 330 | 262 | 187 | 4.1 | 4.1 | n/a | 0 | 21 |
| 45 | 0 | 0 | 5.92 | 72 | 515 | 414 | 283 | 4.3 | 5.2 | 3.1 | 0 | 49 |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 46 | 1 | 1 | 5.66 | 63 | 367 | 337 | n/a | 3.2 | n/a | n/a | 1 | 50 |
| 47 | 1 | 0 | 4.1 | 45 | 229 | 180 | 156 | 3.4 | n/a | 4.4 | 0 | 64 |
| 48 | 1 | 1 | 5.58 | 53 | 335 | 302 | 254 | 4.3 | 3.9 | n/a | 1 | 34 |
| 49 | 1 | 1 | 5.17 | 57 | 312 | 283 | 250 | 3.6 | 4.2 | n/a | 1 | 52 |
| 50 | 1 | 0 | 5.25 | 48 | 273 | 229 | 199 | 4.5 | n/a | n/a | 0 | 54 |
| 51 | 1 | 1 | 5.33 | 55 | 318 | 244 | 235 | 3.3 | 3.9 | n/a | 0 | 44 |
| 52 | 1 | 0 | 5.25 | 42 | 237 | 188 | 182 | 3.9 | 4.1 | 4.2 | 0 | 50 |
| 53 | 1 | 0 | 5.25 | 40 | 228 | 199 | n/a | 4.1 | n/a | n/a | 1 | 52 |
| 54 | 1 | 0 | 5.17 | 44 | 243 | 205 | 175 | 4.4 | 4.3 | 4.3 | 0 | 39 |
| 55 | 1 | 1 | 5.58 | 50 | 320 | 243 | 236 | 4 | 3.8 | n/a | 0 | 31 |
| 56 | 0 | 0 | 5.83 | 66 | 459 | 266 | n/a | 3.8 | 4.1 | n/a | 0 | 33 |
| 57 | 1 | 0 | 5.75 | 41 | 278 | 237 | 249 | 4 | 3 | n/a | 0 | 38 |
| 58 | 1 | 0 | 5.08 | 43 | 230 | 189 | 112 | 4 | 3.8 | 3.9 | 0 | 31 |
| 59 | 1 | 0 | 5.58 | 50 | 320 | 238 | 220 | 3.9 | 3.9 | 3.9 | 0 | 47 |
| 60 | 1 | 0 | 5.5 | 44 | 275 | 248 | 157 | 4.1 | 4.3 | n/a | 0 | 31 |
| 61 | 1 | 0 | 5.75 | 42 | 286 | 226 | 252 | 4 | 3.8 | n/a | 0 | 28 |
| 62 | 1 | 1 | 5.33 | 62 | 363 | 343 | 238 | 3.4 | 3.5 | n/a | 0 | 45 |
| 63 | 1 | 0 | 5.42 | 64 | 385 | 328 | 294 | 3.9 | 4.2 | 4.3 | 0 | 46 |
| 64 | 1 | 0 | 4.92 | 52 | 259 | 220 | 175 | 4.1 | 3.8 | 4.1 | 0 | 53 |
| 65 | 1 | 0 | 5.75 | 44 | 294 | 196 | 149 | 4.1 | 4.3 | n/a | 0 | 30 |
| 66 | 1 | 0 | 4.83 | 48 | 228 | 162 | 117 | 4 | 3.7 | 3 | 0 | 45 |
| 67 | 1 | 0 | 5.42 | 42 | 256 | 216 | 197 | 4.3 | 4.4 | 3.6 | 0 | 32 |
| 68 | 1 | 0 | 5.33 | 50 | 289 | 236 | n/a | 3.9 | 3.1 | 3.1 | 0 | 23 |
| 69 | 1 | 0 | 5.25 | 40 | 224 | 186 | 159 | 3.1 | 3.1 | 3.6 | 0 | 53 |
| 70 | 1 | 0 | 5.25 | 41 | 230 | 181 | 127 | 4 | n/a | 4 | 0 | 30 |
| 71 | 1 | 0 | 5.33 | 44 | 258 | 209 | 204 | 3.8 | 3.7 | 4.1 | 0 | 59 |
| 72 | 1 | 0 | 5.42 | 62 | 374 | 290 | 287 | 3.2 | 3.5 | 3.7 | 0 | 44 |
| 73 | 1 | 1 | 5.58 | 43 | 276 | 201 | 200 | 4.1 | 4.1 | n/a | 0 | 25 |
| 74 | 1 | 0 | 5.83 | 44 | 305 | 265 | n/a | 3.6 | n/a | n/a | 0 | 22 |
| 75 | 1 | 1 | 5.5 | 50 | 310 | 249 | 205 | 3.7 | 3.8 | n/a | 0 | 30 |
| 76 | 1 | 0 | 5.25 | 45 | 252 | 197 | 168 | 4 | 3.8 | 4.1 | 1 | 39 |
| 77 | 0 | 0 | 6 | 49 | 363 | 313 | | 3.7 | 4 | n/a | 1 | 52 |

APPENDIX D

***Percent loss BMI***

| Patient | NV | Initial BMI | 3 Month BMI | 3 Month BMI Change from Initial | 6 Month BMI | 6 Month BMI Change from Initial |
|---|---|---|---|---|---|---|
| 1 | 0 | 56 | 48 | 14% | 38 | 32% |
| 2 | 0 | 38 | 31 | 18% | 27 | 29% |
| 3 | 0 | 74 | 64 | 14% | 46 | 38% |
| 4 | 0 | 56 | 47 | 16% | 27 | 52% |
| 5 | 0 | 61 | 52 | 15% | 42 | 31% |
| 6 | 1 | 60 | 51 | 15% | 42 | 30% |
| 7 | 0 | 47 | 39 | 17% | 32 | 32% |
| 8 | 0 | 74 | 61 | 18% | 38 | 49% |
| 9 | 0 | 49 | 46 | 6% | 41 | 16% |
| 10 | 0 | 53 | 38 | 28% | 31 | 42% |
| 11 | 0 | 50 | 42 | 16% | 33 | 34% |
| 12 | 0 | 61 | 49 | 20% | 39 | 36% |
| 13 | 0 | 50 | 42 | 16% | 37 | 26% |
| 14 | 0 | 62 | 54 | 13% | 27 | 56% |
| 15 | 1 | 38 | 34 | 11% | na | |
| 16 | 0 | 43 | 36 | 16% | 28 | 35% |
| 17 | 0 | 47 | 40 | 15% | 31 | 34% |
| 18 | 0 | 41 | 31 | 24% | 27 | 34% |
| 19 | 0 | 54 | 40 | 26% | 30 | 44% |
| 20 | 1 | 48 | 43 | 10% | na | |
| 21 | 1 | 51 | 46 | 10% | na | |
| 22 | 1 | 42 | 43 | -2% | 36 | 14% |
| 23 | 1 | 46 | 38 | 17% | 35 | 24% |
| 24 | 0 | 50 | 39 | 22% | 28 | 44% |
| 25 | 1 | 55 | 50 | 9% | 43 | 22% |
| 26 | 1 | 36 | 28 | 22% | na | |
| 27 | 1 | 62 | 51 | 18% | na | |
| 28 | 1 | 47 | 35 | 26% | 32 | 32% |
| 29 | 1 | 46 | 37 | 20% | 33 | 28% |
| 30 | 1 | 63 | 53 | 16% | 45 | 29% |
| 31 | 0 | 54 | 49 | 9% | 45 | 17% |
| 32 | 0 | 42 | 35 | 17% | 36 | 14% |
| 33 | 0 | 41 | 31 | 24% | 21 | 49% |
| 34 | 0 | 66 | 56 | 15% | 43 | 35% |
| 35 | 0 | 44 | 37 | 16% | 27 | 39% |
| 36 | 0 | 56 | 47 | 16% | 39 | 30% |
| 37 | 1 | 46 | 37 | 20% | 27 | 41% |
| 38 | 1 | 47 | 43 | 9% | 41 | 13% |
| 39 | 0 | 54 | 40 | 26% | 34 | 37% |
| 40 | 0 | 51 | 33 | 35% | 31 | 39% |
| 41 | 0 | 42 | 35 | 17% | 29 | 31% |
| 42 | 0 | 60 | 53 | 12% | 31 | 48% |
| 43 | 0 | 51 | 45 | 12% | 43 | 16% |

| | | | | | | |
|---|---|---|---|---|---|---|
| 44 | 0 | 57 | 46 | 19% | 33 | 42% |
| 45 | 0 | 72 | 59 | 18% | 40 | 44% |
| 46 | 1 | 63 | 53 | 16% | na | |
| 47 | 0 | 45 | 38 | 16% | 33 | 27% |
| 48 | 1 | 53 | 49 | 8% | 41 | 23% |
| 49 | 1 | 57 | 57 | 0% | 46 | 19% |
| 50 | 0 | 48 | 41 | 15% | 35 | 27% |
| 51 | 0 | 55 | 43 | 22% | 42 | 24% |
| 52 | 0 | 42 | 33 | 21% | 32 | 24% |
| 53 | 1 | 40 | 35 | 13% | na | |
| 54 | 0 | 44 | 38 | 14% | 32 | 27% |
| 55 | 0 | 50 | 39 | 22% | 38 | 24% |
| 56 | 0 | 66 | 39 | 41% | na | |
| 57 | 0 | 41 | 36 | 12% | 38 | 7% |
| 58 | 0 | 43 | 36 | 16% | 21 | 51% |
| 59 | 0 | 50 | 38 | 24% | na | |
| 60 | 0 | 44 | 41 | 7% | 26 | 41% |
| 61 | 0 | 42 | 34 | 19% | 38 | 10% |
| 62 | 0 | 62 | 61 | 2% | 42 | 32% |
| 63 | 0 | 64 | 56 | 13% | 51 | 20% |
| 64 | 0 | 52 | 46 | 12% | 37 | 29% |
| 65 | 0 | 44 | 33 | 25% | 23 | 48% |
| 66 | 0 | 48 | 35 | 27% | 25 | 48% |
| 67 | 0 | 42 | 37 | 12% | 34 | 19% |
| 68 | 0 | 50 | 42 | 16% | na | |
| 69 | 0 | 40 | 33 | 18% | 28 | 30% |
| 70 | 0 | 41 | 32 | 22% | 22 | 46% |
| 71 | 0 | 44 | 37 | 16% | 35 | 20% |
| 72 | 0 | 62 | 49 | 21% | 49 | 21% |
| 73 | 0 | 43 | 32 | 26% | 32 | 26% |
| 74 | 0 | 44 | 39 | 11% | na | |
| 75 | 0 | 50 | 41 | 18% | 34 | 32% |
| 76 | 1 | 45 | 35 | 22% | 30 | 33% |
| 77 | 1 | 49 | 43 | 12% | na | |

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APPENDIX E

***Clinical Nutrition Services***
***Skyline Medical Center***
***Practice Guidelines—Roux-en-Y surgery***

1. **Definitions**:
    a. Morbid Obesity—Clinically severe obesity at which point serious medical conditions occur as a direct result of the obesity
        i. Defined as > 200% IBW, > 100# overweight, or BMI ≥ 40

    b. Roux-en-Y—Malabsorptive and restrictive surgery bypassing distal stomach, duodenum and proximal jejunum

**2. Obesity Related Co-morbidities**
    a. Diabetes
    b. HTN
    c. Hyperlipidemia
    d. Cardiac disease
    e. Respiratory disease
        i. Sleep apnea
    f. Depression
    g. Arthritis
    h. Stress Incontinence
    i. Menstrual Irregularity

**3. Medical Co-morbidities Resolved**
    a. Diabetes
    b. HTN
    c. Hyperlipidemia
    d. Cardiac disease
    e. Respiratory disease
        i. Sleep apnea
    f. Arthritis
    g. Stress Incontinence

**4. Long Term Considerations with RYGB**
    a. Nutritional
        i. Malnutrition
        ii. Dehydration
        iii. Vitamin/mineral deficiencies
        iv. Anemia
        v. Weight loss failure
        vi. Dumping Syndrome

    b. Gastrointestinal Issues

i. Nausea
ii. Vomiting
iii. Constipation
iv. Diarrhea
v. Abdominal pain
vi. Gallstones
vii. Marginal ulcers
viii. Gastritis
ix. Incisional hernia
x. Intestinal obstruction

**5. NIH Criteria 1991**

a. BMI ≥ 40 without comorbidities
b. BMI > 35 with significant comorbidities
c. Documented dietary attempts ineffective

**6. Macronutrient Needs**

**a. Protein**

i. Functions

1. To allow for growth, maintenance of body tissue
2. To repair and rebuild body tissues—healing
3. To provide energy
4. To preserve muscle mass (diet post-op is hypo caloric and may enhance the breakdown of muscle mass for fuel)

ii. Requirements

1. Post-surgery: 1.5 g/kg IBW
2. Minimal goal is 60 g protein daily
3. Eat protein foods first—HBV protein

**b. Hydration**

i. Signs of Dehydration

1. Dry skin/dry mouth/dry tongue
2. Dark urine
3. Decreased urine output
4. Diarrhea/vomiting put patient at risk

ii. Stay hydrated

1. Drink 64 oz water daily
2. Drink ½ cup fluids per ½ hr
3. Always carry water

**7. Micronutrient Needs**

**a. Vitamin $B_{12}$**

i. Function: needed for normal production of RBC's and healthy function of nervous system

ii. Preferential absorption sites: duodenum and proximal jejunum
iii. Decreased contact with gastric intrinsic factor
iv. At risk for developing: pernicious anemia
v. Recommendation: 500-1000 mcg sublingual or monthly injection

**b. Calcium/Vitamin D**

i. Function: needed for strong bones and teeth
ii. Preferential absorption sites: duodenum and proximal jejunum
iii. At risk for developing: osteoporosis or metabolic bone disease
iv. Recommendation
    1. Calcium citrate is best—does not need HCL to dissolve
    2. 1000-1500 mg w/ 400 IU Vitamin D daily

**c. Multivitamin**

i. Function: to insure adequate daily nutrient intake
    1. Begin with 1 children MVI for 4-6 weeks
    2. Advance to MVI with Iron and Folate
    3. Prenatal vitamin often prescribed

**d. Iron**

i. Function: helps build RBC's and carries Oxygen to cells
ii. Preferential absorption site: duodenum
iii. At risk for developing: iron deficiency anemia
iv. Recommendations: 18-27 mg elemental iron daily
    1. Include iron rich foods into daily diet: clams, oysters, liver, red meat, poultry, and dried fruits

**e. Folate**

i. Function: produce growth and maintenance of cells, prevent heart disease, prevent neural tube defects in women of childbearing age
ii. Preferential absorption sites: duodenum and proximal jejunum
iii. At risk for developing: megaloblastic anemia
iv. Recommendation: 800-1000 mg daily

**8. Nutrition Assessment**

**a. Good Candidate for Surgery**

i. Meets NIH criteria
ii. No endocrine cause of obesity
iii. Acceptable operative risk
iv. Understands surgery and risks
v. Absence of drug or alcohol problem
vi. No uncontrolled psychological conditions
vii. Consensus after bariatric team evaluation
    1. Psychologist, internist, dietitian
viii. Dedicated to life-style change and follow-up

**b. Assess Diet**

i. Barriers to weight loss/triggers to eating
ii. Eating patterns/style
iii. Balanced diet/food choice skills
iv. Food intolerance/food allergies
v. Hunger and fullness cues
vi. Supplements and/or herbals
vii. Binge/purge/anorexia/bulimia (must be under control for 1 year)
viii. Activity level

**c. Pre-operative Nutrition Guidelines**

i. Food/exercise Journal
ii. Start exercise program
iii. Begin Multivitamin with iron, calcium citrate
iv. Identify hunger/fullness signals
v. Prepare and eat 3 meals per day
vi. Begin low fat, NCS diet
vii. Measure and monitor portion sizes
viii. Reduce caffeine and carbonated beverages in diet
ix. Avoid drinking fluids with meals
x. Increase water intake and sip fluids throughout the day
xi. Stop using straws
xii. Stop chewing gum
xiii. Understand post-operative bariatric diet
xiv. Slow weight loss goal of 10% pre-operatively

**d. Post-Operative Diet**

i. Stage I (day 1)
    1. 30 ml water every hour from 7a-10p
ii. Stage II (day 2)
    1. Includes water, bouillon, and flat diet ginger ale or diet sprite
    2. 90 cc bouillon
    3. 3 fl oz fluids taken between meals
    4. Diet provided from 7a-10p
iii. Stage III (day 3 to 2-3 weeks post-op)
    1. Includes 8 oz diet CIB with skim milk TID sipped slowly over 1 hour
    2. Non-caloric sugar free clear liquids provided between meals and no more than 8 fl oz provided per hour
    3. No acidic juices
    4. Yogurt ordered separately by MD
iv. Stage IV (2-3 weeks to at least 8 weeks after surgery)
    1. 3 fl oz (6 TBSP) HBV protein TID
        a. You can substitute 1 oz (2 TBSP) of meat with fruit or vegetable

2. 8 fl oz of diet CIB w/ skim milk or skim milk daily
3. 8 fl oz of non-caloric sugar free liquids between meals per hour

v. Stage V (begins 8 weeks after surgery)
1. Includes low fat, low sugar solid foods

**9. Post-operative RYGB Diet tips**

a. Do not overeat
b. Do not drink or eat at same time
c. Drink at least 64 oz water daily
d. Chew foods to consistency of pureed foods (10 minutes per oz)
e. Continue to focus on adequate protein
f. Stop eating when full
g. Stay hydrated
h. Do not skip meals
i. Avoid calorie-dense foods
j. Eat a balanced diet
k. Avoid or limit alcohol
l. Eat slowly
m. Contact physician, dietitian, or psychologist if you have a difficult time controlling your eating
n. Continue to avoid high fat, sugary foods

APPENDIX F

***Evidenced-Based Guidelines***

1. Clinical Guidelines
    a. Assessment
        i. BMI
            1. Underweight $< 18.5$ kg/m$^2$
            2. Normal 18.5-24.9 kg/m$^2$
            3. Overweight 25.0-29.9 kg/m$^2$
            4. Obesity
                a. I 30.0-34.9 kg/m$^2$
                b. II 35-39.9 kg/m$^2$
                c. III $\geq$40 kg/m$^2$
        ii. Waist Circumference

            1. Men > 102 cm ( > 40 in)
            2. Women > 88 cm (> 35 in)

        iii. Overall risk status
            1. Disease conditions
                a. CHD
                b. Atherosclerotic diseases
                c. Type II diabetes
                d. Sleep apnea

            2. Obesity-associated diseases
                a. Gynecological abnormalities,
                b. Osteoarthritis
                c. Gallstones
                d. Stress incontinence

            3. Cardiovascular risk factors
                a. Cigarette smoking
                b. HTN (systolic BP $\geq$ 140 mm Hg or diastolic BP $\geq$ 90 mm Hg, or patient is taking antihypertensive agents
                c. High risk LDL cholesterol ($\geq$160 mg/dl)
                d. Low HDL cholesterol (< 35 mg/dl)
                e. Impaired fasting glucose (110-125 mg/dl)
                f. Family history of premature CHD
                g. Age (men $\geq$45 years and women $\geq$55 years or postmenopausal)

            4. Other risk factors
                a. Physical inactivity

b. High serum triglycerides ( > 200 mg/dl)

5. Patient Motivation
    a. Reasons and motivation for weight reduction
    b. Previous history of successful and unsuccessful weight loss attempts
    c. Family, friends and work-site support
    d. Patient's understanding of the causes of obesity and how obesity contributes to several diseases
    e. Attitude toward physical activity
    f. Capacity to engage in physical activity
    g. Time availability for weight loss intervention
    h. Financial considerations

b. Evaluation and Treatment
    i. Goals of weight loss and management
        1. Prevent further weight gain
        2. Reduce body weight
        3. Maintain lower body weight over long term
            a. Initial goal: reduce body weight by 10% from baseline
            b. Reasonable time line for 10% reduction in body weight is 6 months of therapy
            c. BMI of 27-35, a decrease of 300-500 kcal/day will result in weight losses of about ½ to 1 lb/wk and a 10% loss in 6 months
            d. BMI > 35, a decrease of 500-1000 kcal/day will result in weight losses of about 1-2 lb/wk and 10% loss in 6 months
            e. At 6 months weight loss decreases and platueaus
            f. To maintain weight loss a program consisting of dietary therapy, physical activity and behavior therapy must be continued indefinitely
            g. At 6 months of treatment, efforts to maintain weight loss should be started. If more weight loss is needed, another attempt at weight loss can be made

    ii. Strategies for Weight Loss and Weight Maintenance
        1. Dietary therapy
            a. LCD recommended should be consistent with the NCEP's Step I or Step II diet
            b. Reduce both dietary fat and calories for deficit of 500-1000 kcal/day
            c. Diet should be individualized

        2. Physical activity

a. Decreases abdominal fat
b. Modestly contributes to weight loss in overweight and obese patients
c. Increases cardiorespiratory fitness
d. Maintenance of weight loss
e. Should set long-term goal to accumulate at least 30 minutes or more of moderate-intensity physical activity on most or all days of the week

3. Behavior therapy
    a. Assess motivation
    b. Assess readiness
    c. Set realistic, specific goals
    d. Self-monitoring
    e. Reward success
    f. Satiety sensation

4. Combined therapy
    a. LCD and physical activity is recommended since it produces weight loss that may also result in decreases in abdominal fat and increases in cardiorespiratory fitness

5. Pharmacotherapy
    a. Can be used in patients with a BMI ≥30 with no concomitant obesity-related risk factors or diseases
    b. Can be used in patients with a BMI ≥27 with concomitant obesity related risk factors
    c. Should never be used without concomitant lifestyle modifications
    d. Continuous assessment of drug therapy for efficacy and safety is necessary
    e. Drug safety and efficacy beyond 1 year of total treatment has not been established

6. Weight loss surgery
    a. BMI ≥ 40
    b. BMI ≥35 with obesity related comorbidities
    c. Failed less invasive weight loss methods

iii. Special Treatment Groups
1. Smokers
    a. All smokers should quit smoking

2. Older adults

    a. Care must be taken to ensure that any weight reduction program minimizes the likelihood of adverse effects on bone health or other aspects of nutritional status

3. Diverse patient populations
    a. Possibility that a standard approach to weight loss will work differently in diverse patient populations must be considered when setting expectations about treatment outcomes

# VITA

## JENNIFER MICHELLE ANGUS

Personal Data: Date of Birth: September 21, 1976
Place of Birth: Sumter, South Carolina
Marital Status: Single

Education: Public Schools, Columbia, Tennessee
Spring Hill, Tennessee
Middle Tennessee State University, Murfreesboro, Tennessee, Food and Nutrition Sciences, B.S., 1998
East Tennessee State University, Johnson City, Tennessee, Clinical Nutrition, M.S., 2007

Professional Experience: Renal Dietitian, Fresenius Medical Center; Bristol, TN 2003
Clinical Dietitian, Bristol Regional Medical Center; Bristol, TN 2003
Clinical Dietitian, Skyline Medical Center; Nashville, TN 2003-2007
Clinical Dietitian, Vanderbilt Medical University Center; Nashville, TN 2007