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Characteristics of Bariatric Surgery Patients Lost to Follow-Up

Patrice Johnell
FLORIDA STATE UNIVERSITY
COLLEGE OF NURSING

CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS
LOST TO FOLLOW-UP

By

PATRICE JOHNELL

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The members of the committee approve the thesis of Patrice Johnell defended on July 9, 2009.

____________________________________
Laurie Grubbs
Professor Directing Thesis

____________________________________
Deborah Frank
Committee Member

____________________________________
Mary Beth Zeni
Committee Member

Approved:

____________________________________
Dianne Speake, Director, College of Nursing Graduate Program

____________________________________
Lisa Ann Plowfield, Dean, College of Nursing

The Graduate School has verified and approved the above-named committee members.
Dedicated to Mike
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ABSTRACT

Background: Patients who become lost to follow-up after bariatric surgery are “status unknown” and could be at risk for complications known to occur months and years after surgery. Bariatric programs stand to lose their designations as centers of excellence (COE) if patient follow-up does not meet COE requirements. Many programs are struggling to improve their follow-up rates, but little is known about the “lost” patient and what prompts them to terminate care. This research seeks to identify factors associated with patients who are lost to follow-up compared to patients who are not lost to follow-up.

Methods: The records of consecutive patients who underwent a laparoscopic Roux-en-Y gastric bypass (GBP) or an adjustable gastric banding procedure (AGB) in a single-surgeon practice, between 2004 and 2007 were reviewed. Patients were divided into LOST and NOT LOST subgroups. Patients were considered LOST if they had not had an office visit for at least 18 months or more, otherwise they were counted as NOT LOST. The convenience sample of 368 patients was stratified into surgery type, and a randomized sample was derived from the prohibitively large NOT LOST AGB cohort for the final analysis. For statistical purposes, the sample of observed cases (n=253) was weighted to account for the unobserved subjects. Surgery type, age, gender, marital status, children ≤12 years of age in the home, employment status, payment type, body mass index, goal weight, travel distance and mean quality of life score on a seven-question assessment tool were analyzed as possible predictors of LOST using logistical regression analysis.

Results: The observed study group was comprised of 253 subjects, 85 GBP patients and 168 AGB patients; 85.1% female and 14.9% male. Over a third of patients met criteria for LOST (36.1%). In the non-weighted logistic regression, statistically significant odds ratios were found for the dependent variable of LOST and coefficients of GBP (p=0.003), male gender (p=0.018), age group 45-54 (p=0.028) and lowest mean score on QOL assessment (p=0.039) (95% confidence level; p<0.05). In the weighted sample (n=368), the odds ratio for the coefficient GBP was 6.08 (p< 0.0001) with a 95% confidence interval (CI; 3.94, 9.37); for the coefficient of age 45-54 years the odds ratio was 2.19 (p=0.048) with a 95% confidence interval (CI; 1.01, 4.75).
Conclusion: Gastric bypass, male gender, middle age and low quality of life may be risk factors for lost to follow-up after bariatric surgery. Travel distance, payment type, marital status, employment status, children $\leq 12$ living in the home, preoperative BMI, and self-reported goal weight may not be risk factors associated with lost to follow-up.
CHAPTER 1

INTRODUCTION

Obesity is increasing in epidemic proportions throughout the world, affecting virtually all ages and economic groups. On a global basis, a disturbing rise in mortality and morbidity from obesity related diseases is attributed to the alarming growth rate within all levels of obesity. The condition of obesity, in addition to the condition of severe overweight, is a known risk factor for Type-2 diabetes, hyperlipidemia, hypertension, obstructive sleep apnea, heart disease, gastroesophageal reflux disease, degenerative arthritis, some types of cancer, depression, and other diseases. According to the World Health Organization, an estimated 400 million people are obese worldwide and by 2015 it is projected that 700 million people will be obese (World Health Organization, 2009). The International Association for the Study of Obesity is labeling obesity “The Millennium Disease” and is calling for urgent action to avoid severe health consequences globally (International Association for the Study of Obesity, 2009, para. 1).

The United States is the heaviest nation (Buchwald et al., 2004). An estimated 66% of adults living in the United States are overweight and among those adults, approximately 50% are obese. Since the 1976-1980 National Health and Nutrition Examination Survey (NHANES), the prevalence of obesity has risen dramatically for both adults and children (National Center for Health Statistics, 2008). Obesity is overtaking smoking as the leading cause of preventable premature death in America, with an estimated 365,000 to 400,000 deaths annually attributed to the disease (Christou et al., 2004; Mokdad, Marks, Stroup, & Gerberding, 2005).

In the U.S., the prevalence of obesity is described in terms of body mass index (BMI). BMI is expressed as a ratio of height and weight in the formula of weight in kilograms divided by height in meters squared. A BMI of 18.5-24.9 is normal, 25-29.9 is overweight, 30-39.9 is obese, and 40 or greater is morbidly obese (Centers for Disease Control, 2007). Individuals with a BMI of 35 to 40 comprise the level II obese category, which has doubled in prevalence since the NHANES survey from 15% to almost 33% in adults and more than tripling in children and adolescents ages 6 to 19 years (National Center for Health Statistics, 2008). The category of morbid obesity constitutes the subgroup experiencing the most rapid growth (Strum, 2007).

Public awareness of the importance of energy balance, good nutrition and increased physical activity is widespread, but not well practiced. Global, national, and local anti-obesity
programs are developing rapidly in response to this emerging threat to human health. Despite multiple calls for action at many levels the obesity epidemic is not abating (Wolfe & Morton, 2005). As was experienced with campaigns to reduce smoking, successful reversal of obesity is likely to take decades. The scope of the impact that growing obesity will have on our society is foreboding. For example, with obesity growing at alarming rates in children, diseases never before seen in children are becoming more prevalent (Apovian et al., 2005). Increasing numbers of children and adolescents are being diagnosed with adult diseases such as hypertension, Type-2 diabetes, sleep apnea and hyperlipidemia. Experts project that for the first time in history younger generations will have shorter life spans than preceding generations (Ludwig, 2007).

Obesity is more than a major health concern; it is also a growing social and economic problem. Severe overweight carries a strong social stigma of negative stereotyping, which causes obese individuals to internalize negative feelings and hold unfavorable attitudes toward others with obesity (Wang, Brownell, & Wadden, 2004). In our society, obesity is equated with failure, lack of self control, stupidity, social ineptness, poor hygiene, and worthlessness (Puhl & Brownell, 2001). Discrimination against the severely overweight begins in the earliest days of social interaction such as in preschool, and persists through adulthood (Buchwald, 2005). This prejudice is believed to contribute to depression, eating disorders, social isolation, body image disturbances, employment discrimination, decreased educational opportunities and other suffering. The total national economic burden in terms of healthcare costs and intangible costs is estimated to be in excess of $117 billion (Buchwald, 2005; Greenberg, Perna, Kaplan, & Sullivan, 2005). Medical economists warn that the U.S. health care system is not equipped to handle the growing cost of obesity in children and adults (Finkelstein, Fiebelkorn, & Wang, 2003).

Conventional treatments for obesity including diets, exercise, behavior modification, and pharmacotherapy, have been largely unsuccessful in producing sustainable weight loss in the obese population (Waseem et al., 2007). Accordingly, third party payers are less inclined to cover the cost of medically supervised weight loss programs, diet pills, and conservative treatments, thus creating a significant barrier to care (Frank, 2006). Despite an escalation in obesity research, very little is understood about the complex biochemical mechanisms that interplay between the brain and the gut, or the effects of excessive fat on the human body (Cummings, Overduin, Shannon, & Foster-Schubert, 2005; Waseem, Mogensen, Lautz,
Robinson, 2007). For this reason, development of a drug that can provide substantial, long-term weight loss with few side effects has been elusive. More effective pharmacological treatments for obesity are reported to be at least ten years away from the market (Sorli, 2008). Sustainable weight loss using conventional therapies is deemed to be impossible for severely overweight, morbidly obese individuals. The fact that conventional weight loss treatment is not effective in the morbidly obese population was verified in the 1991 National Institutes of Health (NIH) Consensus Conference Statement on gastrointestinal surgery for severe obesity. The statement conferred that gastrointestinal or obesity surgery is the only effective treatment for permanent weight loss in the morbidly obese population (NIH Consensus Development Conference Consensus Statement, 1991).

Surgical procedures to treat morbid obesity, collectively known as bariatric surgery, have been in use since the 1950s. Only recently have bariatric procedures gained wider acceptance in the medical establishment. Early procedures failed, namely the jejunoileal bypass (JIB), which resulted in widespread skepticism over the safety and efficacy of obesity surgery. The JIB caused serious, unforeseen late-term complications including liver failure, arthritis and even death, and has since been abandoned (American Society for Metabolic and Bariatric Surgery, 2005). Subsequent variations of weight loss procedures were also associated with high complication rates or poor weight loss, and for several decades bariatric surgery continued to be shunned by the medical community. Safer and more effective techniques evolved, and by the 1980s the open-incision gastric bypass and the vertical banded gastroplasty, commonly referred to as stomach stapling, became the procedures of choice. In 1993, the first laparoscopic gastric bypass was performed in the United States (Wittgrove Bariatric Center, 2004). In the years following, bariatric surgery experienced a huge surge in numbers.

A substantive body of research is showing favorable risk/benefit outcomes in contemporary bariatric surgery (Adams et al., 2007; Buchwald et al., 2004). Most studies show not only significant improvement or resolution of the most serious obesity comorbidities, but also major improvement in psychosocial disturbances, mobility, and quality of life (Sarwer, Wadden, & Fabricatore, 2005). Several studies are indicating a considerable healthcare cost benefit after surgery when compared to the long-term cost of medical treatment for diseases such as Type-2 diabetes, sleep apnea, hypertension and dyslipidemia (Jensen & Flum, 2005; Sampalis, Liberman, Auger, & Christou, 2004). Promising research is underway in the field of obesity.
endocrinology where research is showing “metabolic surgery” as the emerging primary treatment for progressive, chronic disease conditions such as insulin resistance and pancreatic beta cell destruction, Type-2 diabetes, metabolic syndrome, and polycystic ovarian disease and infertility (Cummings et al., 2005; Merhi, 2007; Pories et al., 1992). By 2006, the body of research in support of surgical treatment for morbid obesity was so compelling that it led to a landmark decision by the Centers for Medicare and Medicaid (CMS) to cover several types of bariatric procedures.

Bariatric surgery carries certain inherent risks. Permanent alterations in the digestive tract are required with some procedures, and implantation of a foreign body is the mechanism of weight loss for others. Some procedures are offered in the U.S. that are not recognized by the American Society for Metabolic and Bariatric Surgery (ASMBS), but have gained popularity among cash-paying patients despite little research to show their safety and effectiveness. All weight loss procedures are responsible for complications not ordinarily seen with most general abdominal surgeries. Serious complications unique to each type of procedure have been reported and some are well documented. Insidious disease processes such as foreign body-related tissue erosion, chronic anemia and osteoporosis are examples of complications known to occur many months and years after surgery. Moreover, many patients fail to lose weight after surgery or cannot psychologically adjust to life postoperatively (Elkins et al., 2005; Van Hout, Boekestein, Fortuin, Pelle, & Van Heck, 2006).

In lockstep with escalating obesity, the number of bariatric procedures performed in the U.S. grew from 13,365 in 1998 to an estimated 177,600 in 2006 (ASMBS, 2007; Santry, Gillen, & Lauderdale, 2005). Between 1998 and 2004 the rate of gastric bypass per 100,000 population grew from 5.3 to 37.1 (Shinogle, Owings, & Kozak, 2005). Today, at least ten variations of weight loss procedures are in use in the U.S., and some are considered to be experimental (ASMBS, 2005). The most common procedure performed nationally is the laparoscopic Roux-en-Y gastric bypass (GBP); however the GBP is steadily being eclipsed by the less invasive adjustable gastric banding procedure (AGB). Currently, the AGB is the most popular procedure in the rest of the world. The AGB was first introduced in the U.S. in 2001 with the LAP-BAND® manufactured by Allergan™. In 2007, the U.S. Food and Drug Administration approved a similar device, the REALIZE™ Band, from Ethicon Endo-Surgery, Inc., a division of Johnson & Johnson.
Guidelines for patient selection in bariatric surgery were set forth in the 1991 NIH Consensus Conference, and most third party payers including CMS, maintain requirements consistent with NIH guidelines. Bariatric surgery is reserved for patients who are in the level III obese category or morbidly obese (BMI \( \geq 40 \)), but surgery is also recommended for individuals who are in the level II obese category (BMI \( \geq 35 \) - 39) with at least one severe comorbidity such as Type-2 diabetes or hypertension. A BMI over 40 is equivalent to being approximately 100 pounds or more above “ideal body weight” as established by the Metropolitan Life Insurance Company (1999). Some centers have chosen to operate outside of the NIH guidelines and have extended treatment to patients with Type-2 diabetes and patients with BMIs as low as 30 (Dixon et al., 2008). Other centers have ventured beyond NIH guidelines by operating on children under the age of eighteen (Capella & Capella, 2003; Inge et al., 2004; Sugarman et al., 2002). In response to this trend, best practice guidelines in pediatric/adolescent weight loss surgery have been developed to augment the recommendations defined by the leading surgical societies (Apovian et al., 2005). Standards of care have been put forth by three major surgical societies: The American Society for Metabolic and Bariatric Surgery, the American College of Surgeons and the Society of American Gastrointestinal Endoscopic Surgeons.

Because of the known risks associated with bariatric surgery, long term patient follow-up is considered to be one of the most important elements of a comprehensive bariatric surgery program. Practice standards established by the leading surgical societies emphasize the importance of regular, long-term follow-up care. Unfortunately, maintaining long-term follow-up has been one of the biggest challenges for bariatric surgeons and programs. Most research reports indicate that a large percentage of patients lose contact with their surgeons and programs within a few years. Many programs do not require long term follow-up of their patients and others make no attempt to stay in contact with them. Mandatory follow-up standards are a major component of the quality-control measures for bariatric surgery programs receiving the industry’s highest distinction: bariatric surgery center of excellence (COE). This designation is awarded to surgeons and institutions by the ASMBS through the Surgical Review Corporation (SRC) and the by the American College of Surgeons (ACS) as “Bariatric Surgery Center Network”. Only programs that conform to the highest standards of care, including low morbidity and mortality, utilization of a multidisciplinary team, minimum case volumes, maintenance of a comprehensive database for reporting outcomes, beds and equipment with adequate size and...
weight capacity, and a number of other provisions, are eligible to receive and maintain COE designations. Centers of excellence must show proof of documented patient follow-up as a requirement of COE recertification.

**Statement of the Problem**

The number of bariatric procedures performed in the U.S. grows by the tens of thousands each year and for the foreseeable future bariatric surgery will remain an important treatment for morbid obesity and its related diseases (Wolfe & Morton, 2005). The pressure is mounting on institutions charged with the responsibility of protecting the public. Research in the field is still in its infancy and brand-new surgical techniques are being offered to patients on a cash-pay basis such as the sleeve gastrectomy and the mini-gastric bypass, despite limited research to support their use (ASMBS, 2007; Leslie, Kellogg & Ikramuddin, 2007). Longitudinal research is especially lacking for all of the current procedures. Courcoulas and Flum (2005) explain “…there is a gap between the proliferation of [bariatric] procedures and the evidence base needed to understand key components of their use” (p. 1957). The authors emphasize that the existing research is undermined because “Patients who do not participate in ongoing care (follow-up) may be different from those who do participate and this may limit the conclusions about [bariatric surgery’s] efficacy and safety” (p. 1958). Buchwald et al. (2004) notes that most of the studies are coming through case series of experienced surgeons focusing on selected outcomes.

Under ordinary circumstances, third-party payers play an important role in quality control by limiting the in-network care providers available to their clients for essentially non-elective treatments such as cardiac surgery, hysterectomy or chemotherapy. However, in the case of bariatric surgery, the treatment is often covered by insurance, but more closely resembles cosmetic surgery from the standpoint of quality control. Bariatric surgery is never emergent, is elective and can be paid for by cash, credit card or financing. In the U.S. today, hospitals and surgery centers offering bariatric surgery are not required to maintain a center of excellence, nor are they bound by the standards of care as recommended by the ASMBS or the ACS. Surgical societies have no regulatory authority outside of the COE designation process. Medicare and Medicaid both restrict clients to COE centers for their bariatric procedures, but most third-party payers have not adopted this practice. Inasmuch as general surgeons who perform bariatric
surgery are practicing within the domain of their specialty, general abdominal surgery, they are not required to obtain more than a few days of training for some procedures and “the degree of training varies, with some surgeons learning through observerships or week-end courses.” (Kaufman, McNelis, Slevin, & LaMarca, 2006, p. 1556).

In the specialty of bariatric surgery, several forces are coming together that could prove to be dangerous and unethical. Much as the jejunoileal bypass surprised the medical community with unforeseen bad outcomes in the 1970s and 1980s, current bariatric procedures also could prove to be deleterious in the long term. In the present situation, a conflict of interest is being staged in an environment of sporadically enforced safeguards for lucrative surgical procedures (Mitka, 2003). The growing public demand for weight loss surgery is being met by the proliferation of centers (especially outpatient surgery centers) providing services. Some centers take cash only, but most centers have a cash-pay option and accept insurance. Price-war ads are prevalent on Internet websites such as ObesityHelp.com, and television commercials for the LAP-BAND®, the REALIZE™ band and the gastric bypass are prevalent but rarely include disclaimers for risks and complications typically seen with drug advertisements. Persuasive advertising may encourage some individuals to choose surgery in haste. At the present time, a potential for conflicts of interest exists within the context of weak regulation in bariatric patient care, inconclusive evidence for safety and efficacy of bariatric procedures, patient demand for resolution of obesity and related health problems, and commercial interests. The convergence of forces in contemporary bariatric surgery forecasts a perfect storm.

Significance of the Problem

Complications following bariatric surgery are not rare. Major complication rates after gastric banding procedures are reported to be as high as 20-24% (Ponce, Paynter, & Fromm, 2005; Tolonen, Victorzon, & Makela, 2008). Problems after band placement are often related to improper adjustment of the diameter of the gastric band. When the band is too restrictive, it disrupts the normal functioning of the esophagus, the esophageal sphincter, and the new stomach pouch. A band that is too tight causes mechanical obstruction, dysfunctional eating of soft or liquid calorie-dense foods, regurgitation of food, gastroesophageal reflux; and can progress to much more serious complications such as dysphagia, aspiration of food, gastric prolapse, total obstruction, and gastric ischemia (Allen, 2007; Suter, Calmes, Paroz, & Giuisti, 2007). A band
that is too loose results in insufficient weight loss, patient dissatisfaction, and failure of the procedure (Sannen, Himpens, & Leman, 2001). Device infections and erosion of the band into the stomach wall are other serious, late complications (Brethauer, Rogula, & Schauer, 2007; Holeczy, Novak, & Kralova, 2001). Long-term complications associated with the GBP include weight regain, food intolerance, vomiting, stomal stenosis, marginal ulcers, bowel obstruction, and nutritional deficiencies leading to severe microcytic and macrocytic anemias, metabolic bone disease, and neurological disorders (Brethauer et al., 2007; Kushner, 2005). Suicide, eating disorders, and addiction to drugs and alcohol have been reported for both procedures (Kalarchian et al., 2002; Omalu et al., 2005).

Another significant aspect of the problem concerns the specifics of COE requirements. The ACS Bariatric Surgery Center Network Accreditation Program requirement for long-term follow-up states the following: “Centers must document at least one year of personal contact with patients or document contact effort. An attempt to contact a patient should include two letters to the patient, one which should be certified, along with a phone call to the patient and a letter to the patient’s doctor.” (American College of Surgeons, 2007, p. 19). The American Society for Metabolic and Bariatric Surgery requires centers earning designation as Center of Excellence to show proof of infrastructure designed to maintain a minimum of 75% follow-up at five years postoperatively (SRC, 2005). Many programs are falling short of this requirement, due in large part to the cost of resources required to maintain regular contact with patients. Surgeons and programs may be ineligible for center of excellence (COE) designations or stand to lose their status as a COE, thus lose their eligibility for Medicare, Medicaid and other third-party payer reimbursement if follow-up compliance does not meet requirements. Loss of COE would have the effect of reducing case volumes thus compounding the risk of COE ineligibility based on minimum yearly case requirements. Programs servicing smaller communities are especially vulnerable to follow-up compliance standards.

Programs that do not strive for or do not meet criteria for COE have a duty to ensure optimal outcomes, however in a general surgeon’s office a long term follow-up model of care is extraordinary. Historically, surgeons’ offices have functioned on a model of acute symptom-driven care, and often are not set up to function as chronic care medical service providers (Funnell, Anderson & Ahroni, 2005). Nonetheless, surgeons and programs should strive for 100% follow-up or carefully refer patients to providers who are well-versed in bariatric surgery.
patient care. Inevitably, many patients will fall back on care from their primary care providers who are not always familiar with the various procedures and the established standards of care (Frank, 2006). A loss occurs on many levels when patients become lost to follow-up: Patients are exposed to more risk and do not receive the quality of care they should receive; programs are less able to maintain quality requirements and are at risk of losing their center of excellence designations; the industry loses valuable information about the long-term effects of bariatric surgery; and the public is deprived of some measure of protection that results from outcomes reporting and evidence-based practice.

Many programs are struggling to find ways to boost their patient follow-up rates. Yet, little is known about the “lost” patient and what prompts them to terminate care. Few papers address the issue of compliance to follow-up care in bariatric surgery, and few studies investigate strategies to minimize patient attrition. Patients and bariatric surgeons have a mutual responsibility to commit to regular, lifelong follow-up, and each patient lost to follow-up should, in fact, be considered a failure of the program. Patients who are lost to follow-up remain “status unknown”. More information is needed to determine why patients terminate their care. New strategies must be developed to improve patient follow-up.

**Statement of Purpose**

This research seeks to investigate the “silent” lost to follow-up patient. What factors, if any, are associated with patients who do not return for follow-up? How do patients who are lost to follow-up compare to patients who are not? Are there any preoperative factors that might help to predict follow-up behavior? Are there any postoperative factors that may be associated with patients’ failure to return for care?

One factor that is predicted to affect compliance is type of procedure since the AGB is dependent on follow-up visits for weight loss, but the GBP is not. Another factor that would reasonably be linked to follow-up compliance is travel distance. Other factors are not as clear cut such as age, gender, and payment type. If factors can be identified, interventions to improve patient follow-up may be initiated. Also, patient selection criteria may be revised if certain preoperative factors can be associated with poor compliance with follow-up.

The goal of this study is to document the scope of the problem, describe relationships between relevant variables, and provide a starting point for the development of experimental
interventions to increase bariatric patient follow-up. Relying solely on patients to be responsible for keeping up with their yearly visits without strong encouragement from the surgeon’s office, results in follow-up percentages below industry standards (Harper, Madan, Ternovits, & Tichensky, 2006).

Better follow-up would likely result in better health management, better weight loss, increased opportunity for the multi-disciplinary team to provide coaching, counseling, teaching, and emotional support, and greater patient satisfaction and quality of life. Improving follow-up would help to identify issues before they develop into problems, thereby preventing and/or lowering the incidence of complications, and reducing overall risk and harm to the patient. Optimal patient follow-up would allow for the accumulation of more reliable outcomes data, and result in successful compliance with COE requirements.

**Research Question**

The research question is: What factors, if any, are associated with bariatric surgery patients who are lost to follow-up compared to those not lost to follow-up? Factors include age, gender, marital status, employment status, children 12 years of age and under living in the home, type of bariatric procedure, travel distance, payment type, weight and BMI, excess weight, goal weight, and self-reported quality of life.

**Operational Definitions**

1. **Lost to follow-up**: No follow-up visit for at least 18 months or more.
2. **Not lost to follow-up**: Follow-up visits are current; no more than 17 months have elapsed since the last visit.
3. **Clinic or surgeon’s office**: The bariatric surgery program office(s) in a single surgeon practice, hospital-based program in north Colorado. There are three clinics in total.
4. **Follow-up visit**: A visit that occurs in the clinic at regular, prescheduled intervals and as needed to assess patient health and progress, provide treatment, provide education, guidance and support; and to perform band adjustments as needed for the AGB patients. Visits are conducted by the bariatric surgeon, or the family nurse practitioner, or the physician’s assistant, or a combination of these practitioners.
5. **Travel distance**: Distance in miles between the patient’s last known address and the closest clinic of three affiliated bariatric program clinics in north Colorado.

6. **Goal weight**: Self-reported desired weight provided by the patient at the initial consultation visit.

7. **Percent excess weight loss**: An industry standard; a calculation used to assess patients’ progress with weight loss after surgery, expressed as a percentage of excess weight in pounds. “Excess weight” is the difference between the patient’s weight (determined at the initial consult visit prior to surgery), and the “ideal body weight” as defined in the Metropolitan Life height and weight tables for “medium frame” (Metropolitan Life Insurance, 1999).

8. **Quality of life score**: The score obtained from a 7-question quality of life questionnaire (7QQoLQ) that has been used in the bariatric clinic for seven years (Appendix A). The instrument assesses a patient’s happiness and satisfaction with the physical, mental, emotional, and social aspects of their lives, and perception of general health (Shellenbarger, 2008).

**Conceptual Framework**

Nora Pender’s Health Promotion Model (HPM) is a middle-range theory that was used as the conceptual framework for the study of follow-up behavior among bariatric surgery patients. The model has been extensively used in nursing research and has been the theoretical framework supporting and guiding over 100 research studies (Pender, Murdaugh, & Parsons, 2006). The HPM focuses on explaining the biopsychosocial processes that motivate and influence individuals toward health promotion behaviors. Pender’s HPM was originally developed in the 1980s and later revised in 1996 (Pender, 1996). The theoretical model is rooted in several well-established theories of human behavior, one of the most prominent of which is Bandura’s Social Cognitive Theory (SCT), also known as Social Learning Theory. The SCT is a model that describes behavioral change and human agency for change as a give and take, multidimensional relationship among cognitive, affective and biologic interpersonal factors, and external factors (Bandura, 1977, 1986). In their review of health promotion models in adolescents and the HPM, Srof and Velsor-Friedrich (2006) explain: “The assumption that people have power to shape their own destiny and to control outcomes is a common thread in the SCT and HPM” (p. 367).
The HPM uses a wellness orientation and is focused on achievement of higher levels of well-being (Galloway, 2003). The model exemplifies a number of concepts, factors, relationships and other characteristics that contribute to an individual’s health promoting behaviors. The theoretical framework lends itself well to visualizing logical, practical nursing interventions that could be applied at various junctures within the model (Polit & Peck, 2008). The model’s clarity provides a road map for inserting health promoting strategies that can be operationalized in real-life settings. It provides a framework for discriminating which concepts are associated with specific health behaviors in the general areas of a) individual characteristics and experiences, b) behavior-specific cognitions and affects, and c) situational and interpersonal influences (Pender, 1996).

Health Promotion Model (Pender, 1996)

Pender asserts that prior behavior and perceived competence or self-efficacy influence the enactment of health promoting behavior. When individuals perceive that they are competent
and their efforts will be effective, they are more likely to commit to action and actual performance of the target behavior (Pender, 1996). These propositions are particularly germane to the study of bariatric surgery patients. As a criterion for patient selection, patients must show that they have failed multiple times to lose weight. By definition, their candidacy for surgical treatment is predicated on a lack of self-efficacy to lose weight. Prior eating behaviors and perceived lack of confidence to achieve success after surgery may be partially responsible for poor follow-up behavior.

In the realm of perceived barriers to action, Pender proposes that an inverse relationship exists between perceived barriers and perceived self-efficacy. Furthermore, situational influences in the external environment can increase or decrease commitment to and engagement in health-promoting behavior (Pender, 1996). Family support and modeling is an important component of the HPM and bariatric surgery patients are especially vulnerable to family influences. A patient’s family member may become a significant barrier to their success when the family member is resistant to making changes in their own eating habits and physical activity level. Long distances required to travel to the clinic are likely to be a perceived barrier to follow-up, including the potential cost of time away from work and the high cost of fuel. Inability to pay for services is another possible barrier that would affect health promotion behavior to follow-up.

Pender proposes that an individual’s positive affect toward a behavior increases perceived self-efficacy, further increasing positive effect, and increasing the probability of commitment and action toward the target behavior (Pender et al., 2006). An important component of this study is a patient’s perceived quality of life as a mediating factor in follow-up behavior. Quality of life ties into concepts of positive affect and self-efficacy and was explored in this study in the context of Pender’s propositions. The cognitive-perceptual elements of the HPM includes items such as an individual’s belief in the importance of health, personal definition of health, perceived health status, and perceived benefits to a health promotion behavior (Galloway, 2003). This study will look at perceived quality of life in patients before surgery. Possibly, a patient’s perception of low benefit of follow-up may correspond with poor perception of self or physical limitations preoperatively.

Of particular relevance to patient follow-up in Pender’s health promotion framework is the component of “cuing”. The influence of cues is difficult to measure because they are by nature complex and subtle (Galloway, 2003). Internal cues, such as sounder sleep and decreased
shortness of breath, are stimuli to promoting healthy behaviors in obese individuals; external cues such as health risk information in the media may also influence healthy behaviors. Patients who do not have strong internal cues may respond well with external cues such as the intervention by way of appointment reminder postcards, reminder telephone calls, and/or emails. The application of nursing interventions targeted at both internal and external cues may be an effective way to improve patient follow-up.

On the HPM pathway to follow-up adherence, the demographical and constitutional variables of gender, age, marital status, employment status, payment type, BMI, and quality of life would conceptually fit under “personal factors” in the realm of “characteristics and experiences”. Goal weight and perceived quality of life would be subsumed under “prior related behavior” of the first block and mediated by perceptions and possibly “interpersonal influences” under the second block of “behavior-specific cognitions and affect”. Situational influences in the second block may include aspects of the variables of marital status, employment status, and payment type.

**Assumptions & Limitations**

The assumptions in this study were that data entered into the patient records by clinic personnel were accurate; that patients were truthful and accurate in completing forms and surveys; that becoming lost to follow-up with bariatric surgeons and programs constitutes a negative outcome for patients who have undergone a bariatric procedure; and that patients were lost to follow-up if they had not come in for a visit to the clinic for 18 months or more, otherwise they were not lost to follow-up. The retrospective design of the study precluded determination of cause and effect relationships and the study sample may not have been generalizable to the target population.

**Summary**

In this chapter, the problem of obesity both globally and in the U.S. was described. Bariatric surgery, namely the GBP and the AGB, have been effective therapies to reduce or eliminate comorbidities of obesity in the morbidly obese population. The number of surgeries performed each year is growing rapidly. Prospective and longitudinal research is lacking, and
complications are known to occur in patients many months and years after surgery. Long term patient follow-up is essential but is difficult for bariatric programs to maintain. More research is needed to shed light on why patients terminate their care. Strategies to improve patient follow-up must be employed by programs experiencing patient attrition.

This study will investigate characteristics of patients who are lost to follow-up by reviewing patient medical records in a single surgeon, hospital-based bariatric surgery program. Pender’s Health Promotion Model will serve as the theoretical framework for the study.
CHAPTER 2

REVIEW OF LITERATURE

Introduction

Review of the literature is organized in four sections. First, literature focusing on theoretical concepts of health promotion in the bariatric surgery clinic setting will be reviewed, along with support for Pender’s Health Promotion Model as a conceptual framework for use in research and nursing practice. Second, the two types of bariatric surgical procedures performed at the participating facility will be described, including expected weight loss for each. Third, literature supporting bariatric surgery as a treatment for morbid obesity, related diseases, and improved quality of life will be followed by the a description of some of the most common late complications of the AGB and the GBP that are likely to be minimized by patients’ adherence to regular long-term follow-up care. Fourth, a review of relevant literature will be provided on various potential correlates of outcomes in bariatric surgery including preoperative predictors, adherence to follow-up, frequency of visits, quality of life, weight loss success, travel distance, financial status, basic demographics and other indicators.

Theoretical Literature

Nursing and conceptual frameworks from the social sciences with central constructs of patient empowerment and self-efficacy are very popular in the healthcare setting. These concepts are replacing older models of care that view patients as compliant or non-compliant “rule-followers”; recipients of advice and prescriptions for care from the “expert” healthcare professionals (Funnell et al., 2005; Poole et al., 2005). Patient empowerment models involve the patient’s active participation in all healthcare decisions, and patients are considered the experts of their own lives. Despite the shift to patient empowerment models of care, the onus is on the bariatric surgeons and the bariatric surgery programs to maintain long-term patient follow-up. Patient empowerment and self-efficacy are constructs central to the HPM, and also have been described as constructs within alternative theoretical models in papers applying theory to patient management in the bariatric surgery setting. A review of those papers will follow a discussion of relevant studies using Pender’s Health Promotion Model.
No articles were found that utilized the HPM in a bariatric surgery setting. Nonetheless, a review of the literature indicates that the HPM has been effectively tested as a conceptual framework for a variety of different types of health promoting behaviors in diverse populations. An application of the HPM was used to investigate determinants of physical activity among Taiwanese adolescents in a quasi-experimental design. Perceived self-efficacy was the most important predictor of physical activity. Interpersonal influences in relation to peers predicted physical activity, whereas influence from parents did not (Wu & Pender, 2002). After testing a proposed framework adapted from the revised HPM, the authors concluded that the model explained a modest portion of variance related to physical activity in their sample. They also concluded that future testing of the framework using a longitudinal research design would likely increase understanding of the best strategies to promote physical activity in this population. Wu & Pender’s study was included in an integrative review of HPM research and adolescent health promotion behaviors conducted by Srof and Velsor-Friedrich (2006). The authors concluded that existing research with teens supports the HPM as a framework for predicting health promoting behaviors, but question whether the linear nature of the model presents limitations in terms of understanding more circuitous and triangulated aspects of health promotion behaviors.

In a study of factors influencing use of hearing protection among farmers, constructs of the HPM were tested and utilized. Researchers found that in a group of 139 subjects, interpersonal support, barriers, and situational influences were statistically significant predictors of this health behavior; predicting 78% of the cases. The overall chi-square for the three variable model was 67.39 ($df=3$, $p<0.0001$) (McCullagh, Lusk, & Ronis, 2002). Another study looked at the HPM as a causal model of construction workers’ use of hearing protection (Lusk, Ronis, & Hogan, 1997). Benefits, barriers, self efficacy and perceived health were important predictors of use of hearing protection. The authors indicate that there is considerable consistency in research tests of the HPM, and emphasize the value of applying the HPM to specific health promotion behaviors: “The HPM could be expected to predict specific behaviors better than general health habits. Likewise, those components of the HPM measuring specific behaviors are the ones that have been the best predictors” (p. 193).

Few articles focusing on theory-guided care of the bariatric surgery patient were found in the literature. Two articles promoted models of care that embraced concepts of patient empowerment and self-efficacy. Funnell et al. (2005) assert that models of care endorsing the
concept that health professionals know what is best for the patient do not work well in the bariatric surgery patient population, and that for patients to succeed, a plan of care has to “...fit patients’ goals, priorities, lifestyle as well as facilitate their weight loss” (p. 418). They propose a model in which “Professionals need to give up feeling responsible for their patients and become responsible to them” (p. 418). Some of the concepts outlined in their empowerment model include reframing dialogue such as initiating visits not with weight measurements and diet questions, but a focus on the patient’s feelings, psychological well-being and their expertise. They advocate having care providers explain their role to the patient as one of “coach” and/or “partner”; conducting visits that focus on the patient as a whole rather than a product of their surgery; and providing many opportunities for patients to self-manage their care through ongoing education and support programs, and referrals.

The Transtheoretical Model of behavior change (TTM) was used as a conceptual application to design and implement a successful surgical weight loss program in one paper by Bond et al. (2004). The researchers recommend that patients be encouraged to view surgery as a “new lease on life” and permanent weight loss success is dependent on patients taking ownership of their own health. The authors posit that theory should drive behavior change interventions designed to promote new healthy behaviors while strengthening resilience against old unhealthy behaviors, and such interventions should be provided before and after surgery as an integral part of the multidisciplinary treatment program. The TTM was proposed as a fitting model for bariatric surgical patients because a main assumption of the model is that behavior change is not an event but a process that unfolds over time; requiring different interventions through stages of change that may be cyclical (progressive and regressive), and are characterized by differing stages and degrees of readiness to change. As stated in the article, “The potential for regressions is particularly evident among morbid obesity surgery candidates who have often made numerous unsuccessful attempts at weight loss” (p. 853). In their paper, Bond et al. (2004) offer an example of stage-matched interventions to promote post-surgical physical activity among patients based on the model. For example, in the earlier stages of change, interventions included the provision of educational materials, discussions of perceived benefits of regular exercise and offering feedback regarding individual patient’s fitness levels and anthropometric measurements. Utilizing core assumptions of the later stages of change within the TTM framework, concepts of “counterconditioning” interventions were employed; for example, having patients substitute
specific sedentary behaviors such as watching TV with specific physical activity related behaviors such as walking around the park. Also, “stimulus control” measures such as having patients keep a daily planner for exercise were interventions designed by the authors for utilization in the later stages of the model.

Another qualitative study investigated the postoperative psychosocial changes in the lives of individuals who had undergone gastric bypass surgery (Bocchieri, Meana, & Fisher, 2002). This study is included here because it investigated patients long-term postoperatively, which parallels the intent of the current research. Bocchieri et al. used Grounded Theory as the underlying framework for their study. Grounded Theory has a basic premise that theory must emerge from the data. This theory was utilized to capture emergent themes and their interrelationships. Using unstructured and semi-structured interviews and focus groups, 31 patients were questioned about how surgery had affected their lives. The researchers concluded that tension-generating changes, such as those revealed in the areas of feelings about the self, interpersonal relationships, and acquisition of new skills, may be major factors determining long-term outcomes of weight loss and psychosocial adjustment of gastric bypass patients.

**Bariatric Procedures**

The current research investigates patients from one center who have undergone either a laparoscopic Roux-en-Y gastric bypass (GBP) or a laparoscopic LAP-BAND© adjustable gastric banding procedure (AGB) for the treatment of morbid obesity. Both procedures are performed using minimally invasive surgical techniques, including use of the da Vinci® System surgical robot (Intuitive Surgical® Sunnyvale, CA). Patients receive 5-6 small abdominal incisions in surgery. The following description of the anatomical changes that take place during the procedures will help to provide a better understanding of the later complications that occur, the weight loss that can be expected, and why life-long surveillance is so important.

**The Adjustable Gastric Band**

The AGB is considered the safest, least invasive weight loss surgery option, with a mortality rate of 0.05%, and a 3.5 times lower rate of complications when compared to the laparoscopic GBP (Fielding & Ren, 2005). It is a purely restrictive procedure that induces weight loss by decreasing hunger and reducing the quantity of food that can be eaten at a meal. It involves implantation of an inflatable silicone band around the uppermost part of the stomach,
which is tightened in the surgeon’s office by infusing saline into a port (band adjustment) connected to the band by a silastic tube. The port is usually placed lateral to the umbilicus, and is sutured into place against the abdominal wall, under the skin and fat of the abdomen. Weight loss is gradual, averaging 1-2 pounds per week during the first two years after surgery. To maintain consistent weight loss, patients require 6-10 band adjustments during the first post-operative year; with several more adjustments required the second year. Without adjustments, the AGB will not result in weight loss.

*The Laparoscopic Roux-en-Y Gastric Bypass*

More invasive than the AGB is the laparoscopic gastric bypass, which involves dividing, stapling and rerouting of the stomach and small bowel. It is a combined restrictive and malabsorptive procedure. A small pouch is created using the uppermost part of the stomach, and the remnant stomach is completely divided leaving the duodenum intact. Approximately 100 centimeters of small bowel is bypassed and the distal jejunum is brought up and connected to the new stomach pouch. The proximal jejunum and the entire duodenum (which still remains intact with the remnant stomach) are reconnected back into the small bowel forming a “Y” to allow bile and pancreatic secretions to flow back into the small bowel.

**Positive and Negative Outcomes of Bariatric Surgery**

*Weight Loss, Improvement in Obesity, Comorbidity & Mortality*

AGB patients can be expected to lose 38% or more (average 44.7%) of their excess body weight one year after surgery and lose 47% or more (average 54.9%) at two years; 53% or more (average 57.5%) at three years and maintain or improve weight loss up to years four and five (Fielding & Ren, 2005). GBP patients can be expected to lose between 60-80% of their excess body weight at one year, maintain or improve weight loss during year two, and plateau or regain up to 20 pounds thereafter (Buchwald, 2005).

Comorbidity improvement after bariatric surgery has been the focus of a major portion of scientific literature in the field. In general, outcomes are outstandingly favorable with respect to improvement in or resolution of Type-2 diabetes, sleep apnea, hypercholesterolemia, hypertriglyceridemia, hypertension, gastroesophageal reflux disease, urinary stress incontinence, joint and back pain, immobility, and many other conditions. The literature strongly supports bariatric surgery for improvement in psychological and emotional problems, socialization, self-
esteem, interpersonal relationships and other parameters of quality of life. Quality of life improvement is arguably the most important benefit for patients overall.

A significant barrier to accumulating thorough bariatric surgery outcomes research is the ethical dilemma of withholding surgery in randomized trials (Courcoulas & Flum, 2005). Longitudinal, observational studies with large patient samples comprise the bulk of the most compelling research in the field, and several recent landmark papers have helped to solidify the base of knowledge in support of bariatric surgical therapies. The largest investigation of outcomes in bariatric surgery has been undertaken by the prospective, controlled Swedish Obese Subjects (SOS) study involving 4047 obese subjects. The study is ongoing. Of the subjects, 2010 underwent bariatric surgery and 2037 received conventional treatment (matched control group). Subjects were recruited over a 13.4 year period, from September 1, 1987 to January 31, 2001, and they consented to participate in follow-up examinations at 15 and 20 years. In the most recent analysis, the follow-up period ranged from 4 years, 9 months to 18 years, 2 months, with a mean (±SD) of 10.9±3.5 years. The study has a follow-up rate of 99.9%. Of the 2010 subjects, 376 underwent adjustable or non-adjustable gastric banding, 1369 underwent vertical banded gastroplasty (VBG), and 265 underwent gastric bypass. Subjects in the surgery group had a mortality hazard ratio of 0.76, as compared with the control group (95% confidence interval, 0.59 to 0.99; \( p=0.04 \)). During the follow-up period, 129 subjects (6.3%) from the control group died; 101 (5.0%) in the surgery group died. In the control group, the average change in weight remained ±2% of total body weight. In the surgery group, the mean (±SD) weight loss after 10 years was 25±11% for gastric bypass, 16±11% for the VBG group, and 14±14% for the banding group. Researchers concluded that bariatric surgery for severe obesity is associated with long-term weight loss and decreased overall mortality (Sjostrom et al., 2007).

A systematic review and meta-analysis was conducted by Buchwald et al. (2004) to determine the impact of bariatric surgery on weight loss, operative mortality outcome, and four major obesity comorbidities. One hundred and thirty six studies consisting of 22,094 patients were extracted from key databases such as MEDLINE. The mean percentage of excess body weight loss for gastric bypass patients was 68.2%; gastric banding was 61.6%. Type-2 diabetes was completely resolved in 76.8% of patients, and resolved or improved in 86%. Hyperlipidemia improved in 70% or more of patients; hypertension was resolved in 61.7% of patients and resolved or improved in 78.5%. Obstructive sleep apnea was resolved in 85.7% of patients and
was resolved or improved in 83.6% of patients. Operative mortality (≤30 days) for the procedures investigated: 1) purely restrictive procedures (banding and gastric stapling); 2) gastric bypass; and 3) biliopancreatic diversion or duodenal switch, was 0.1%, 0.5%, and 1.1%, respectively.

Another important study by Busetto et al. (2007) analyzed mortality in two groups of morbidly obese patients over 20 years. One group underwent AGB surgery and the other group was observed. The AGB group of 821 consecutively treated patients was compared to a matched cohort selected from a group of patients seeking medical treatment (n=4681). The AGB patients had a 5-year 60% lower risk of death than comparable morbidly obese patients. The survival rate was significantly greater in the surgical group (p=0.0004).

A similar study comparing matched cohorts of bariatric surgical patients versus nonsurgical patients in a 5-year observational design was undertaken by Christou et al. (2004). The treatment cohort (n=1035) was matched to the non-treatment cohort (n=5746) and analyzed for morbidity and mortality. The bariatric surgery group consisted largely of gastric bypass patients, and surgery resulted in a significant reduction in mean percent excess weight loss (67.1%, p<0.001). The mortality rate in the bariatric surgery group was 0.68% compared with 6.17% for the controls (relative risk 0.11; 95% CI 0.04-0.27). The treatment group had a significantly lower mortality rate (p<0.001) and an 89% reduction in the relative risk of death. The most notable risk reduction in terms of morbidity was in incidence of malignancies; cardiovascular and circulatory conditions, including hypertension; endocrinologic conditions, including Type-2 diabetes; infectious diseases; and respiratory conditions. On average, the total direct health care costs for the controls were 45% higher in the non-treatment cohort as compared with the bariatric patients.

In a retrospective cohort study of 7925 gastric bypass patients, with a comparison, matched cohort of 7925 severely obese patients and a mean follow-up of 7.1 years, long-term mortality after gastric bypass surgery was significantly reduced (p<0.001), particularly deaths from Type-2 diabetes (p<0.005), heart disease (p<0.006) and cancer (p<0.001) (Adams et al., 2007).

The first randomized controlled trial in the medical literature demonstrating superior efficacy of bariatric surgery (AGB patients) compared to conventional medical therapy for the treatment of early Type-2 diabetes (n=55) was conducted from December 2002 to December
Remission of Type-2 diabetes in the medically treated group was 73% versus 13% in the AGB group \(p<0.001\) (Dixon, O’Brien, Playfair, Chapman, & Schachter, 2008).

Schauer et al. (2003) evaluated pre and postoperative data collected during a 5-year period on 1160 patients who underwent a laparoscopic gastric bypass procedure. Their results showed an 83% resolution of Type-2 diabetes with an average excess body weight loss of 60%. The group of patients with the shortest duration and mildest form of Type-2 diabetes had a higher rate of resolution after surgery, suggesting that early surgical intervention is warranted in these patients.

**Improvement in Psychosocial & Quality of Life Domains**

Positive outcomes in psychological, social and general quality of life domains after bariatric surgery are well-documented in the literature (Arcila et al., 2002; Boan, Kolotkin, Westman, McMahon, & Grant, 2004; Bouldin et al., 2006; Buddeberg-Fischer, Klaghofer, Sigrist, & Buddeberg, 2004; Dixon, Dixon, & O’Brien, 2001; Dixon & O’Brien 2002; Hell, Miller, Moorehead, & Samuels 2000; Herpertz et al., 2003; Hrabosky et al., 2006; Kent, 2007; Mitchell et al., 2001; Schok et al., 2000; Tolonen, Victorzon, & Makela, 2004; Van Hout, Verschure, & Van Heck, 2005).

Patients’ report of a “rebirth” or “transformation” was the core process identified in the unique and important qualitative study by Bocchieri et al. (2002). Gastric bypass patients, averaging 28 months past surgery, were interviewed for their perceptions of what life is like after surgery. The authors reported that most changes were unequivocally positive, with improvement in physical activities and physical abilities being the most prevalent benefit cited by patients.

Psychosocial outcome of bariatric surgery was investigated by Herpertz et al. (2003) in a systematic review of all prospective and retrospective (non-) controlled trials of the previous two decades. The authors focused on outcomes in psychiatric comorbidity, psychopathology, psychosocial functioning, econometric data, and general QOL. Sixty three studies were reviewed. They concluded that “Mental health and psychosocial status including social relations and employment opportunities improve for the majority of people after bariatric surgery” (p. 1300).

Livingston and Fink (2003) reviewed 11 clinical trials conducted between 1990 and 2002 that examined the effect of bariatric surgery on QOL. They concluded that there is enough evidence in the literature to suggest that QOL is greatly reduced by obesity, and weight loss
surgery greatly improves QOL. However, the authors stated that there is a pressing need for long-term trials to assess the durability of these results.

**Long-term Complications of Bariatric Surgery**

To the extent that the current study focuses on characteristics of patients lost to long-term follow-up, negative outcomes more commonly occurring in the perioperative or early postoperative period will not be reviewed here. This review will cite literature on the common problems patients encounter in the later term; problems that could potentially be avoided with patient adherence to regular long-term follow-up care.

Complications after AGB include food intolerance, regurgitation of food, nausea and vomiting, nutritional deficiencies, gastric prolapse or “slipped band”, gastric ischemia, infection of the band and/or the port site, peritonitis, obstruction of the outlet of the pouch, malfunction of the device, erosion of the band into the stomach wall, esophageal dysmotility, esophageal dilatation, gastroesophageal reflux, hiatal hernia, over-tightening of the band, and under-tightening of the band.

In the AGB patient, the most common long-term problems after surgery are ineffective band adjustments and gastric prolapse. The two conditions are likely to be minimized by adequate patient follow-up for assessment and adjustments to the tightness of the band (Allen, 2007). Ineffective or infrequent band adjustments result in poor weight loss. Weight loss has been shown to be better in patients who have a greater frequency of visits within the first two to six years after surgery (O'Brien et al., 2002; Shen et al., 2004). Bands that are adjusted too tight may result in gastric prolapse, and if left untreated, can lead to dysphagia, total obstruction, gastric ischemia, emergency surgery, gastrectomy and possible death (Kriwanek, Schermann, Abdullah, & Roka, 2005; Landen, Majerus, & Delugeau (2005). Regular long-term follow-up would theoretically identify patients with early symptoms of tight bands and/or prolapse. Case studies cited above indicate that some patients with eventual gastric necrosis had mild symptoms for up to 8 days before presenting to the emergency department.

Long-term complications associated with the GBP are weight regain, food intolerance, vomiting, stenosis of the stoma (the connection between the pouch and the small bowel), marginal ulcers (ulcers that occur in the stomach and small bowel at the anastomoses) staple line disruption, fistula, internal hernias, bowel obstruction, and nutritional deficiencies resulting in severe micro and macrocytic anemias, metabolic bone disease, and neurological disorders.
Of these adverse outcomes, one of the most insidious and potentially dangerous long-term adverse effects is nutritional deficiency, especially iron deficiency in menstruating women. Not often seen after AGB, deficiencies are very common after GBP, and frequently worsen over time as stores of vitamins and minerals are slowly depleted. Life-long supplementation is imperative (Kushner, 2005). Due to the bypass of stomach and a portion of small bowel, GBP patients are at risk for protein, iron, calcium, vitamin D, thiamine, folate, and vitamin B12 and other deficiencies. A review of the most commonly deficient vitamins and minerals following bariatric surgery was conducted by Bloomberg, Fleishman, Nalle, Herron, and Kini (2005). Iron deficiency rates were anywhere from 39% to 52% two years to four years after gastric bypass. Reports of B12 deficiency were 33% to 37% in several studies spanning two to four years post surgery. Vitamin D and calcium deficiencies were also noted to be high in the gastric bypass group with some patients developing metabolic bone disease. Severe iron-deficiency anemia requiring iron infusions has been reported, and pernicious anemia and elevated homocysteine levels (a risk factor for cardiac disease) are a direct consequence of B12 and/or folate depletion (Kushner, 2005). Faintuch et al. (2004) analyzed 236 consecutive gastric bypass patients and found 4.7% (11) of the patients became severely protein malnourished 17.9 ± 15.8 months after surgery; five patients had edema and six patients required hospitalization. Gastric stoma stenosis (narrowing of the pouch outlet) and vomiting were listed as co-factors; two patients died.

Stomal stenosis and recurrent vomiting are potential causes of “Bariatric Beriberi” a thiamine deficiency disease that has been reported in some case studies after gastric bypass and AGB (Gollobin & Marcus, 2002). Temporary neurological deficits have been reported such as confusion, ataxia, diplopia, nystagmus, fatigue, poor memory, anorexia, nausea, vomiting, polyneuritis of the lower extremities including parasthesias, burning of the feet, muscle cramps in the calves, muscle weakness, and other symptoms resulting from the deficiency, also known as Wernicke’s Syndrome or Wenicke’s Encephalopathy (WE) (Kushner, 2005; Salas-Salvado et al., 2000; Sola et al., 2003). Permanent disability such as nystagmus and cognitive impairments such as memory loss have been reported. Acute WE secondary to thiamine depletion after GBP is usually associated with persistent vomiting, but is often misdiagnosed which delays treatment. Patients have been misdiagnosed with conditions such as acute stroke, and seizure disorder. Since thiamine is critical to carbohydrate metabolism, in-hospital intravenous fluid-dextrose...
resuscitation may exacerbate ongoing brain cytotoxicity when thiamine is not administered before glucose (Choi & Scarborough, 2004; Loh et al., 2004).

Another insidious long-term complication of gastric bypass is “marginal ulcer”. Marginal ulcers form at the margins of the anastomoses between the stomach pouch and the jejunum. They are readily treatable if caught early, but if left untreated can result in pain, blood loss, anemia, fistula between the pouch and the remnant stomach, rupture, peritonitis, hemorrhage, emergency surgery and death. GBP patients are warned against the use of all non-steroidal anti-inflammatory drugs including COX-2 inhibitors, and aspirin due to the high potential for ulcers to form (Fujioka, 2005; Buchwald, 2005).

**Correlates, Predictors, Outcomes and Follow-up**

Researchers have had limited success in identifying consistent behavioral predictors or demographic predictors of unfavorable outcomes (i.e., suboptimal weight loss; complications) after bariatric surgery (Dixon et al., 2001; Van Hout et al., 2005; Wadden & Sarwer, 2006). Wadden & Sarwer, in a systematic literature search, identified relevant variables that may have predictive value for success after bariatric surgery. The researchers concluded that greater success occurred in patients who, among other characteristics, are young, female, have a high self-esteem, have good mental health, and were obese prior to age 18. Larsen et al. (2004) looked at personality characteristics that may be associated with short and long-term weight loss. They found that none of the personality variables were associated with weight outcome at short-term follow-up; six of seven personality variables did not predict long-term weight outcome; “egoism” was associated with less weight loss, but was not statistically significant (n=168; \( p=0.034; \) \( p \)-values were set to the conservative Bonferroni criterion of \( p=0.007 \)). They also found that a higher baseline BMI, female gender, and lower educational level were associated with larger weight loss.

**Motivation for Surgery**

Libeton, Dixon, Laurie, and O’Brien (2004) found that health issues dominated the motivation for seeking surgery, and weight outcomes did not appear to be affected by the patients’ primary motivating factor in AGB patients (n=208) at least one year post-surgery. Buddeberg-Fischer et al. (2004) had similar findings in a 2-year follow-up investigation of the impact of psychological stress before surgery, and outcomes (n=131); motivation for surgical
treatment was primarily driven by factors relating to physical and psychological health. Subjects under great stress preoperatively (n=48) had the same positive physical and psychological well-being as subjects with little or no pre-operative stress (n=69). Psychologically stressed patients who did not undergo surgery had the worst outcome (n=38).

**Predictors of Weight Loss**

Dixon et al. (2001) studied a number of preoperative factors for their predictive value on weight loss after AGB (n=440). Factors that were statistically significant at one year for lower percent excess weight loss were increasing age (R= -0.13; \( p \leq 0.01 \)), insulin resistance (R=0.22; \( p < 0.001 \)), poor physical ability (R=0.25; \( p < 0.005 \)), pain and poor general health responses on the SF-36 Health Survey (R=0.25; \( p < 0.005 \)). Factors that had no influence were gender, history of mental illness, and measures of mental illness.

In Averbukh et al. (2003), predictors of weight loss at one year post gastric bypass (n=145) were investigated. Gender, ethnicity, family histories of obesity, diagnosis of diabetes or hypothyroidism, or psychiatric medication use were not significant predictors of weight loss. Pre-surgical severity of depression (higher score) was a statistically significant predictor of increased weight loss (\( p = 0.027 \)). In Boan et al. (2004), researchers concluded that Roux-en-Y gastric bypass (n=40) resulted in significant improvements in disordered eating (\( p < 0.001 \)), weight-related QOL (\( p < 0.0001 \)), and physical activity (\( p < 0.0001 \) on 8 out of 9 measures of physical activity) in addition to weight loss (\( p < 0.0001 \)).

**Quality of Life**

Measures of QOL after bariatric surgery have been investigated in a number of studies. No studies investigating QOL and adherence to follow-up visits were found. Several studies will be described here as they relate to other correlates of outcome in the post-operative bariatric population. Van Hout et al. (2006), in a systematic review of outcomes, reported that most patients experience improvements in psychosocial functioning after surgery. However, the authors note that “…studies show great variation in outcome, suggesting that post-operative improvements may lag behind the psychosocial functioning of norm groups or may show a decline over the years.” (p. 792). They conclude that “a significant minority of patients do not benefit psychologically from the surgery.” (p. 787).

Tolonen et al. (2004) studied parameters of health-related QOL in patients 12 and 28 months after AGB surgery. They suggested that there may be a decline in health-related QOL
after 12 months related to dimensions of eating and possibly to unsatisfactory weight loss. Schok et al. (2000) surveyed patients after AGB surgery on indicators of QOL pre and 12-38 months postoperatively (n=74). Using normal functioning on the RAND-36 Health Survey as evaluation criteria, they concluded that one to three years after surgery, the physical dimension of QOL was still below normality. Dixon and O’Brien (2002) found that improvement in QOL using the SF-36 was greater in AGB patients with preoperative disability, and the extent of weight loss was not a good predictor of QOL. Mean scores of QOL returned to community norms by one year after surgery.

**Payment Type, Desired Weight and Preoperative Weight Loss**

Durkin, Bloomston, Murr, and Rosemurgy (1999) compared three groups: commercially insured (traditional indemnity insurance), patients with entitlement programs (Medicare), and medically indigent patients (Medicaid or no funding) and determined that patients (n=131) lost weight following a vertical banded gastroplasty (a purely restrictive procedure) independent of their insurance status.

Weight goals and previous weight loss attempts were investigated in two studies. In White, Masheb, Rothschild, Burke-Martindale and Grilo, (2007) the coauthors sought to determine if unrealistic weight goals would change after gastric bypass surgery and whether they would have a negative or positive impact on weight loss and associated behavioral and psychological benefits (n=139). The authors concluded that unrealistic weight loss goals do not appear to have negative prognostic significance on outcomes postoperatively. Gibbons et al. (2006) found that the great majority of candidates for bariatric surgery (n=177) had made multiple efforts to lose weight using conventional methods prior to surgery.

**Follow-up**

Few papers have specifically investigated the subject of follow-up after bariatric surgery. Only three papers were found that investigated predictors of patient adherence to follow-up care after bariatric surgery. Wheeler, Prettyman, Lenhard, & Tran (2007) used the database of an outpatient bariatric program containing cross sectional data collected retrospectively over a one year period to investigate variables associated with patient adherence to follow-up care. Adherence was defined as having one post-surgical appointment within 90 days of having surgery. A block entry logistic regression analysis was done from a database of patients who underwent an AGB or GBP (n=375). The researchers found significance for positive adherence
on three variables; increasing age (\(p=0.031\)), single marital status (\(p=0.001\)), and employment (\(p=0.014\)); and significance for negative adherence on two variables; increasing BMI (\(p=0.000\)), and self pay (\(p=0.023\)); with no significance on gender or Beck Depression Inventory score.

In Lara et al. (2005), travel distance from the clinic did not significantly affect compliance at the initial follow-up, 3-month, and 12-month appointments (\(p \geq 0.05\)) in GBP patients (\(n=150\)). Distance did tend to affect compliance at the 6-month appointment and significantly affected compliance at the 9-month appointment (\(p=0.035\)). Males were more likely to be compliant at the 12-month follow-up visit (\(p=0.040\)). Age was not predictive of compliance (\(p=0.827\)).

A study by Harper et al. (2006), found a difference in patients’ weight loss when they investigated the differences between patients who do not automatically return for their annual visits and those that do return without being prompted. Of 105 consecutive patients, 48 (40%) did not automatically come in for their annual follow-up. At the 14-month mark, patients were called; six patients could not be located. They found no difference in pre-operative BMI between the two groups. Percent excess body weight loss was significantly greater in the group that did not require prompting for their appointments (76% vs. 65%; \(p < 0.003\)).

Typical follow-up rates for GBP patients are in the range of 60% to 80% and according to Fielding and Ren (2005), GBP patients are more difficult to follow than AGB patients. This is due in part to the fact that without regular adjustments to the AGB, patients will not lose weight; whereas the GBP patient’s pouch size cannot be adjusted to induce better weight loss. Two important papers looked at the influence of patient follow-up on weight loss. Shen et al. (2004) compared the impact of follow-up appointments on weight loss between groups of GBP patients (\(n=115\)) and AGB patients (\(n=186\)). They found that over the first two years after surgery, weight loss was significantly better in AGB patients who returned for over 6 visits versus AGB patients who returned for 6 or fewer visits (\(p=0.005\)). In the GBP subgroups, patients who returned 3 or less times had similar weight loss to GBP patients who returned for visits more than 3 times (\(p=NS\)). They concluded that patient follow-up plays a significant role in the amount of weight loss after AGB, but not after GBP.

Maintaining high levels of follow-up many years after surgery has been achieved by some programs, but is not the norm. Pories et al. (1995), in a landmark paper, documented that with excellent long-term follow-up, GBP induces sustainable control for obesity and Type-2 diabetes. Over a 14–year period, only 17 out of a total of 608 patients were lost to follow-up.
Five hundred and fifty three of 574 living patients maintained contact over that time period, a follow-up rate of 96.3%. Another excellent rate of follow-up was found in a study investigating outcomes after AGB placement. This program maintained a 98.6% follow-up over a six year period on a total of 706 patients (O'Brien et al., 2002). One report by Mitchell et al. (2001) investigated outcomes on a cohort of 100 patients who were interviewed by telephone 13-15 years after gastric bypass surgery. Ultimately they achieved a 78% follow-up in this group, but not without great incentives. Patients were offered $15.00 to participate in the interview. When 16 patients refused, they were offered $100.00 each, and eight of the sixteen patients agreed to participate. Investigative research focusing on correlates of patient adherence to follow-up care after bariatric surgery is scant. Ethical and institutional mandates for bariatric surgery programs to ensure thorough patient follow-up care are equivocal. Many factors may influence a patient’s non-compliance with expected adherence to follow-up visits.

**Summary**

Literature on the relative benefits and risks of bariatric surgery indicates that positive outcomes outweigh negative outcomes, however long term complications can occur, and many patients terminate follow-up care with their surgeons. Longitudinal studies of patient outcomes after bariatric surgery are needed, and studies to date are often biased by significant patient attrition. Research on predictors and other correlates of bariatric patient adherence to follow-up care are sorely lacking. Although some predictors of patient adherence have emerged from the research such as age, type of insurance coverage, distance from the surgeon’s office, weight loss, and others, results are inconsistent and inconclusive. Also missing in the literature is investigative research looking into the effectiveness of interventions and other strategies to control attrition. Despite the establishment of standards of care recommending long-term patient follow-up, little research is available to help understand why patients terminate contact with their surgeons and programs, and “drop out”.

CHAPTER 3
METHODOLOGY

Introduction

This chapter will include all elements of the research method including the research design, the variables, the setting of the study, the population and sample, power analysis of the sample size, sampling method with inclusion and exclusion criteria, protection of human subjects, instruments, procedure for collecting and recording data, data analysis with supporting evidence, and assumptions.

Design

This study has a quantitative non-experimental, descriptive research design and is correlational, retrospective and case-controlled. The dependent variable was “lost to follow-up” status: any postoperative bariatric surgery patient who had not returned to the clinic for a follow-up visit for at least 18 months or more. The independent variables were: age, gender, marital status, income status, bariatric procedure type, preoperative weight and BMI, preoperative self-reported goal weight, QOL before surgery, travel distance to nearest program clinic, payment type. The control group consisted of patients who had a status of not lost to follow-up.

Setting

The setting for the study was a single-surgeon practice office also known as the bariatric surgery program clinic, in a suburban, north Colorado city. The bariatric program is located within, and is owned and operated by a 398-bed, fully accredited, private, not-for-profit, level II-trauma medical center. The medical center, bariatric program, and bariatric surgeon are collectively designated as an American Society for Metabolic and Bariatric Surgery Center of Excellence.

Sample

The target population was all patients in the U.S. who have undergone a laparoscopic gastric bypass or adjustable gastric banding procedure. The accessible population consisted of a
convenience sample of all patients who underwent an elective bariatric procedure at a single medical center, by a single bariatric surgeon. The sampling frame was the patient medical records retained by the bariatric clinic. The sample consisted of all consecutive patients who had a bariatric procedure (AGB or GBP) between August 1, 2004 and August 31, 2007 (inclusive). Subjects were excluded from the study if they had surgical revisions to their original procedures or if they were no longer returning to the clinic for known reasons including surgical reversal of their bariatric procedure, those who had complications requiring major revision of the original procedure, those who gave formal notice that they moved out of the area, and/or those patients who informed us that they would be establishing postoperative care with another health care provider. The sample was stratified into two subgroups: “Lost to follow-up” (LOST) and “Not lost to follow-up” (NOT LOST).

Protection of Human Subjects

Full permission to proceed with the study was granted by the Florida State University Institutional Review Board (IRB) (Appendix B), the IRB of the participating hospital (Appendix C) and the participating clinic (Appendix D), prior to extracting data from patient records. No research assistants were utilized. Data were collected from the patient records and immediately de-identified by assigning each subject an arbitrary identification number. Codes for patient identity were stored on a flash drive and kept in a locked drawer in the researcher's clinic office until all data analysis was completed. The linking codes were destroyed on May 12, 2009. The de-identified data was stored on a flash drive, and kept in a locked drawer in the researcher's home for a period of three years. After three years, the data will be destroyed. Ethical considerations of research were maintained at all times to protect and respect the human dignity and privacy of the subjects.

Instruments

One independent variable investigated in the study was quality of life. Patients’ responses to questions on a recently validated QOL assessment tool (Shellenbarger, 2008) were extracted from their medical records and included in the analysis. These data were used to determine if there was any association between QOL responses preoperatively, and ultimate status of LOST post-operatively. This assessment tool, The Seven-Question Quality of Life Questionnaire...
(7QoLQ) (Appendix A), had been used in the clinic since 2002 as a quick way to assess changes in patient’s level of functioning at each visit. It surveys six domains of quality of life; social functioning, mental health and vitality, body image, general health, role limitation due to physical health, and physical functioning.

Items on the 7QoLQ were derived from the Medical Outcomes Study Short-Form Health Survey (SF-36) (Ware & Sherbourne, 1992) and the Medical Outcomes Study Short-Form Health Survey (SF-12) (Ware, 2008). Validity and reliability of the 7QoLQ was tested in a research project conducted by the bariatric clinic’s family nurse practitioner as partial requirement for a doctorate in nursing practice through the University of Colorado, Boulder (Shellenbarger, 2008). Shellenbarger established test-retest reliability for each item on the 7QoLQ by administering the questionnaire to the same participants two weeks apart (n=38). Spearman’s Rho correlations ranged from .708 to .945, all significant at the p<0.01 level. Concurrent validity of the 7QoLQ was tested using the SF-12. Significant correlation was found between the Physical Health items on the SF-12 and the 7QoLQ (R=.466-.808; p<0.01) (n=52) and the Mental Health items (R=.354-.494; p<0.01) (n=52). Construct validity was determined by measuring the difference in individual item responses between a group of patients who were waiting for surgery (n=25) and a group of patients who had received the intervention of surgery and were at least six months post-operative from their bariatric procedures (n=39). The postoperative group showed significantly higher scores on all of the items, with p-values ranging from <.000 to <.002.

The rationale for using QOL data was that such data are completely subjective and are strong in realism. This variable added dimension to the study because it was different than the other independent variables which were objective in nature with one exception, the self-reported goal weight. The use of QOL measurements pre and postoperatively on bariatric patients is strongly supported in the literature (Boan et al., 2004; Chen et al., 2007; Fabricatore, Wadden, Sarwer, & Faith, 2005; Van Hout et al., 2005).

Procedure

After obtaining permission from the Florida State University Institutional Review Board (IRB), the IRB of the participating hospital, and the clinic director, patient records were accessed from the medical records room of the bariatric clinic. Between March 10, 2009 and March 18,
In 2009, data was extracted from the patient medical records, de-identified and recorded onto collection sheets developed by the researcher for this purpose. Subsequently, the data was entered into an Excel spreadsheet and retained for analysis. Prior to collecting data the decision was made by this researcher that all charts of the LOST patients would be reviewed. This group constituted the dependent variable in the study, embodied the essence of the research question and was expected to be a manageable group of subject records to review. Early in the data collection process it was determined that the cohort of AGB patients in the NOT LOST subgroup was much larger than the other three subgroups and too large to use in its entirety (n=224). A randomized sample of 100 patients was obtained from this group, of which 93 patients met inclusion criteria (7.0%). The entire sample of 224 NOT LOST AGB subjects was subsequently reduced by 7% (n=208) and factored in for statistical analysis through the process of “weighting”. Each observed subject (n=93) carried a weight of 2.237 persons to represent the entire NOT LOST AGB subgroup in the final calculations. The remaining three subgroups were small enough to use in their entirety; AGB-LOST (n=75), GBP-NOT LOST (n=27), and GBP-LOST (n=58). Therefore, some of the calculations consisted of a total of 368 patients, however only 253 subjects were actually observed. An adjunct faculty member statistician from the Florida State University College of Nursing was retained for assistance in the statistical data analysis.

**Data Analysis**

Descriptive statistics were calculated using the Statistical Package for the Social Sciences (SPSS) and the R Statistical Package (R) and were used to organize, synthesize, and describe the study sample, and to direct further analysis of the research question. When meaningful, the sample was stratified into LOST, NOT LOST, AGB, GBP, AGB NOT LOST, AGB LOST, GBP NOT LOST, and GBP LOST subgroups. Measures of central tendency and dispersion were calculated for continuous variables such as age, weight, height, BMI, travel distance, and QOL scores. Frequency tables, percentages and cumulative percentages were used to evaluate subject characteristics for discrete variables such as gender, marital status, employment status, payment type, etc. The 93 randomized sample subjects in the AGB-NOT LOST subgroup were weighted as described above, for the descriptive statistics.
The research question sought to identify associations between the dependent variable of LOST and multiple independent variables. Therefore, multivariate statistical analysis was applied to examine the relationships. Multivariate logistic regression was used in this case because it lends itself well to studies with a retrospective design and works by modeling the probability of an outcome rather than predicting group membership (Polit & Peck, 2008). Logistic regression produces estimates of odds ratios that are “adjusted” to control for the influence of other independent variables. Odds ratios provided an estimate that allowed for determining confidence intervals of relative odds (e.g., the odds of being lost to follow-up given a certain age group versus the odds of being lost given a different age group). Unadjusted odds ratios were calculated as an extra measure to determine the reliability of the logistic regression and were found to be consistent.

Logistic regression requires that all non-discrete variables be converted into categorical “dummy” variables. In this study, continuous variables were divided into four or five scaled categories, and discrete variables were consolidated into two categories where possible. Effort was made to weight the categories equally. Variables that were redundant or were found to be the least significant were eliminated from the regression; children ≤12, excess weight, ideal weight and goal weight, and others. Reference variables were selected based on prior knowledge of the sample population, and were selected if they were expected to represent the least likely group to be lost-to-follow-up. For example, the reference group used for the travel distance variable was the group of subjects who lived within 10 miles of the nearest clinic. The QOL categories were derived from the raw scores of the 7QQoLQ. Raw scores ranging from a possible lowest score of 7 to a highest score of 35 were converted to a scale of 1.0-5.0 to produce four categories for the regression. Regressions were calculated using SPSS for the non-weighted regressions and Statistical Analysis Software (SAS) for the weighted regressions. Significance was set at the <.05 level.

**Summary**

This chapter described the study design, the setting, the population and sample, the protection of human subjects, the instrumentation, the procedure used for collecting and recording data and the statistical methods used for analysis.
CHAPTER 4

RESULTS

The purpose of this study was to examine retrospectively, characteristics of patients who fail to return for follow-up visits after bariatric surgery. This chapter will present the statistical findings of the study which answered the research inquiry of what factors, if any, were associated with patients who were lost to follow-up compared to patients who were not lost to follow-up.

Demographic and other characteristics of the study sample (n=368; weighted) were computed for continuous variables (Table 1) and discrete variables (Table 2). Results show that 85.1% (n=313) of subjects were female and 14.9% (n=55) were male. Mean age was 44.4 (±11.7), and mean BMI was 46.1 (±6.8) kg/m². The average excess weight was 152.3 (±44.9) lbs. over an ideal weight average of 128.6 (±13.8) lbs. Means for subjects’ self-reported goal weights and QOL scores were 154 (±25.6) lbs. and 2.93 (±0.58), respectively. Travel distance to the nearest of three bariatric program clinics averaged 86.7 (±165.5) miles although the majority of patients lived within 21 miles of the nearest clinic (median, 20.4 miles), with a few patients living over 1000 miles away.

Table 1 Sample Characteristics – Continuous Variables

<table>
<thead>
<tr>
<th></th>
<th>ALL</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>368*</td>
</tr>
<tr>
<td>PERCENTAGE</td>
<td>100%</td>
</tr>
<tr>
<td><strong>Means &amp; Standard Deviations</strong></td>
<td></td>
</tr>
<tr>
<td>AGE (yrs)</td>
<td>44.4 (± 11.7)</td>
</tr>
<tr>
<td>BMI (wtkg/htm²)</td>
<td>46.1 (± 6.8)</td>
</tr>
<tr>
<td>HEIGHT (in)</td>
<td>65.4 (± 3.1)</td>
</tr>
<tr>
<td>INITIALWEIGHT (lbs)</td>
<td>280.9 (± 52.5)</td>
</tr>
<tr>
<td>EXCESS WT (lbs)</td>
<td>152.3 (± 44.9)</td>
</tr>
<tr>
<td>IDEAL WT (lbs)</td>
<td>128.6 (± 13.8)</td>
</tr>
<tr>
<td>GOAL WT (lbs)</td>
<td>154.3 (± 25.6)</td>
</tr>
<tr>
<td>MEAN QOL SCORE (1.0-4.99)</td>
<td>2.93</td>
</tr>
<tr>
<td>TRAVEL DISTANCE (miles)</td>
<td>86.7 (± 165.5)</td>
</tr>
</tbody>
</table>

*weighted
Table 2 Sample Characteristics – Discrete Variables

<table>
<thead>
<tr>
<th>ALL</th>
<th>100% (368*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
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</tr>
<tr>
<td>Female</td>
<td>85.1% (313)</td>
</tr>
<tr>
<td>Male</td>
<td>14.9% (55)</td>
</tr>
<tr>
<td>Marital Status</td>
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</tr>
<tr>
<td>Married</td>
<td>72.1 (265)</td>
</tr>
<tr>
<td>Divorced</td>
<td>11.4% (42)</td>
</tr>
<tr>
<td>Single</td>
<td>9.9% (37)</td>
</tr>
<tr>
<td>Live-in Partner</td>
<td>4.2% (15)</td>
</tr>
<tr>
<td>Widowed</td>
<td>2.1% (8)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.3% (1)</td>
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<tr>
<td>Payment Type</td>
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</tr>
<tr>
<td>Private Ins.</td>
<td>69.8% (257)</td>
</tr>
<tr>
<td>Cash Pay</td>
<td>17.0% (62)</td>
</tr>
<tr>
<td>Medicare</td>
<td>13.0% (48)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.2% (1)</td>
</tr>
<tr>
<td>Occupation</td>
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<tr>
<td>Employed</td>
<td>79.0% (291)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>9.3% (34)</td>
</tr>
<tr>
<td>Retired</td>
<td>7.9% (29)</td>
</tr>
<tr>
<td>Student</td>
<td>3.0% (11)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.8% (3)</td>
</tr>
<tr>
<td>Children ≤ 12 yrs.</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>67.4% (248)</td>
</tr>
<tr>
<td>Yes</td>
<td>31.8% (117)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.8% (3)</td>
</tr>
</tbody>
</table>

*weighted

Over one third of patients were found to be lost to follow-up. The NOT LOST (63.9%) and LOST (36.1%) subgroups were similar across the majority of variables (Table 3). A higher percentage of males were in the LOST group (20.3%) vs. the NOT LOST group (11.8%) (Table 4). A higher percentage of married subjects were in the LOST group (78.9% vs. 68.3%) and accordingly, a lower percentage of single subjects were in the LOST group (6.8% vs. 11.7%).
Table 3  Sample Comparison of NOT LOST vs. LOST – Continuous Variables

<table>
<thead>
<tr>
<th></th>
<th>NOT LOST</th>
<th>LOST</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>235*</td>
<td>133</td>
</tr>
<tr>
<td>PERCENTAGE</td>
<td>63.9%</td>
<td>36.1%</td>
</tr>
<tr>
<td><strong>Means &amp; Standard Deviations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGE (yrs)</td>
<td>43.9 (± 12.2)</td>
<td>45.3 (± 10.6)</td>
</tr>
<tr>
<td>BMI (wtkg/htm²)</td>
<td>46.0 (± 7.0)</td>
<td>46.2 (± 6.5)</td>
</tr>
<tr>
<td>HEIGHT (in)</td>
<td>65.3 (± 3.1)</td>
<td>65.6 (± 3.1)</td>
</tr>
<tr>
<td>initial WEIGHT (lbs)</td>
<td>279.9 (± 54.1)</td>
<td>282.7 (± 49.7)</td>
</tr>
<tr>
<td>EXCESS WT (lbs)</td>
<td>152.1 (± 46.4)</td>
<td>152.6 (± 42.5)</td>
</tr>
<tr>
<td>IDEAL WT (lbs)</td>
<td>127.8 (± 13.5)</td>
<td>130.0 (± 14.3)</td>
</tr>
<tr>
<td>GOAL WT (lbs)</td>
<td>154.4 (± 24.8)</td>
<td>154.1 (± 27.0)</td>
</tr>
<tr>
<td>MEAN QOL SCORE (1.0-4.99)</td>
<td>2.96</td>
<td>2.86</td>
</tr>
<tr>
<td>TRAVEL DISTANCE (miles)</td>
<td>79.0 (± 142.6)</td>
<td>100.2 (± 199.7)</td>
</tr>
</tbody>
</table>

*weighted

Payment-type mix differed between the LOST and NOT LOST groups with a much larger percentage of NOT LOST subjects paying cash for their surgeries (21.9% vs. 8.3%). This finding is biased by the fact that the study institution offers a cash-pay option for gastric banding only, and a greater number of AGB patients were in the NOT LOST subgroup.

Table 5 shows the tabulation of AGB vs. GBP patients for continuous variables in the study sample. As expected, most of the demographic and biometric variables were similar across surgery types. The most notable exceptions were a higher percentage of married subjects in the GBP subgroup (83.5% vs. 68.7%), and a higher number of employed subjects (91.9% vs. 75.1%) in this subgroup (Table 6) compared to the AGB subgroup. Again, payment-type mix was skewed by the zero-percent cash-pay result in the GBP subgroup. A higher percentage of patients with children ≤12 were found in the AGB subgroup (70%) as compared to the GBP subgroup (58.8%).
Table 4        Sample Comparison of NOT LOST vs. LOST – Discrete Variables

<table>
<thead>
<tr>
<th></th>
<th>ALL NOT LOST (63.9%) (n=235*)</th>
<th>ALL LOST (36.1%) (n=133)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GBP</td>
<td>11.5% (27)</td>
<td>42% (58)</td>
</tr>
<tr>
<td>AGB</td>
<td>88.5% (208)</td>
<td>58% (75)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>88.2% (207)</td>
<td>79.7% (106)</td>
</tr>
<tr>
<td>Male</td>
<td>11.8% (28)</td>
<td>20.3% (27)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>68.3% (160)</td>
<td>78.9% (105)</td>
</tr>
<tr>
<td>Divorced</td>
<td>11.4% (27)</td>
<td>11.3% (15)</td>
</tr>
<tr>
<td>Single</td>
<td>11.7% (28)</td>
<td>6.8% (9)</td>
</tr>
<tr>
<td>Live-in Partner</td>
<td>5.7% (13)</td>
<td>1.5% (2)</td>
</tr>
<tr>
<td>Widowed</td>
<td>2.9% (7)</td>
<td>0.8% (1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.8% (1)</td>
<td></td>
</tr>
<tr>
<td>Payment type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private Ins.</td>
<td>62.9% (148)</td>
<td>81.9% (109)</td>
</tr>
<tr>
<td>Cash Pay</td>
<td>21.9% (51)</td>
<td>8.3% (11)</td>
</tr>
<tr>
<td>Medicare</td>
<td>15.2% (36)</td>
<td>9.2% (12)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.8% (1)</td>
<td></td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>77.3% (182)</td>
<td>82.0% (109)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>9.9% (23)</td>
<td>8.3% (11)</td>
</tr>
<tr>
<td>Retired</td>
<td>8.6% (20)</td>
<td>6.8% (9)</td>
</tr>
<tr>
<td>Student</td>
<td>4.2% (10)</td>
<td>0.8% (1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>2.1% (3)</td>
<td></td>
</tr>
<tr>
<td>Child(ren) ≤ 12 yrs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>67.3% (158)</td>
<td>67.7% (90)</td>
</tr>
<tr>
<td>Yes</td>
<td>31.7% (75)</td>
<td>31.6% (42)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1.0% (2)</td>
<td>0.8% (1)</td>
</tr>
</tbody>
</table>

*weighted

Due to the differences between the AGB and the GBP, a cross tabulation was created to further stratify subjects by AGB NOT LOST, AGB LOST, GBP-NOT LOST, and GBP-LOST subgroups and evaluated for Ns and measures of central tendency and dispersion (Table 7).
Table 5  Sample Comparison of Surgery Types – Continuous Variables

<table>
<thead>
<tr>
<th></th>
<th>ALL</th>
<th>AGB</th>
<th>GBP</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>368*</td>
<td>283*</td>
<td>85</td>
</tr>
<tr>
<td>PERCENTAGE</td>
<td>100%</td>
<td>76.9%</td>
<td>23.1%</td>
</tr>
<tr>
<td><strong>Means &amp; Standard Deviations</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AGE (yrs)</td>
<td>44.4 (± 11.7)</td>
<td>45.5 (± 12.0)</td>
<td>40.8 (± 1.0)</td>
</tr>
<tr>
<td>BMI (wtkg/htm²)</td>
<td>46.1 (± 6.8)</td>
<td>45.7 (± 7.1)</td>
<td>47.5 (± 5.5)</td>
</tr>
<tr>
<td>HEIGHT (in)</td>
<td>65.4 (± 3.1)</td>
<td>65.4 (± 3.1)</td>
<td>65.4 (±3.0)</td>
</tr>
<tr>
<td>initial WEIGHT (lbs)</td>
<td>280.9 (± 52.5)</td>
<td>278.7 (± 55.0)</td>
<td>288.4 (± 42.5)</td>
</tr>
<tr>
<td>EXCESS WT (lbs)</td>
<td>152.3 (± 44.9)</td>
<td>149.9 (± 47.1)</td>
<td>159.9 (± 35.9)</td>
</tr>
<tr>
<td>IDEAL WT (lbs)</td>
<td>128.6 (± 13.8)</td>
<td>128.7 (± 14.0)</td>
<td>128.5 (± 13.4)</td>
</tr>
<tr>
<td>GOAL WT (lbs)</td>
<td>154.3 (± 25.6)</td>
<td>154.6 (± 26.1)</td>
<td>153.4 (± 24.0)</td>
</tr>
<tr>
<td>QOL SCORE (1.0-4.99)</td>
<td>2.93 (± 0.58)</td>
<td>2.96 (± 0.57)</td>
<td>2.80 (± 0.62)</td>
</tr>
<tr>
<td>TRAVEL DISTANCE (miles)</td>
<td>86.7 (± 165.5)</td>
<td>148.6 (± 82.0)</td>
<td>102.3 (± 212.8)</td>
</tr>
</tbody>
</table>

*weighted

Table 7 shows that 26% (n=75) of the total number of AGB patients (n=283) were lost to follow-up. In comparison, 68% (n=58) of the GBP patients (n=85) were lost to follow-up. Therefore, in terms of percentages, there were over twice as many patients lost to follow-up in the GBP group compared to the AGB group. Overall, LOST GBP patients comprised 43.6% (n=58) of the total number of LOST patients (n=133).

A series of logistic regressions was calculated for the non-weighted sample of 253 subjects using SPSS and combinations of the dummy variables. Ideal body weight, goal weight, excess weight and children ≤ age 12 were found to be the most insignificant in relation to LOST and eliminated from the final regression to give more strength to the remaining variables. The final regression analysis (Table 8) showed statistically significant odds ratios (OR) for four variables. The relative odds that a subject would fall in the LOST patient subgroups were significantly greater for subjects who had gastric bypass surgery (p=0.003); were male (p=0.018); were between 45 and 54 years of age (p=0.028; and had the lowest mean scores for QOL at the initial consult visit (p=0.039).
### Table 6  Sample Comparison of Surgery Type – Discrete Variables

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>AGB</th>
<th>GBP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>368*</td>
<td>283*</td>
<td>85</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>85.1% (313)</td>
<td>84.5% (239)</td>
<td>87.1% (74)</td>
</tr>
<tr>
<td>Male</td>
<td>14.9% (55)</td>
<td>15.5% (44)</td>
<td>12.9% (11)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>72.1% (265)</td>
<td>68.7% (194)</td>
<td>83.5% (71)</td>
</tr>
<tr>
<td>Divorced</td>
<td>11.4% (42)</td>
<td>13.7% (39)</td>
<td>3.5% (3)</td>
</tr>
<tr>
<td>Single</td>
<td>9.9% (37)</td>
<td>10.1% (29)</td>
<td>9.4% (8)</td>
</tr>
<tr>
<td>Live-in Partner</td>
<td>4.2% (15)</td>
<td>4.7% (13)</td>
<td>2.4% (2)</td>
</tr>
<tr>
<td>Widowed</td>
<td>2.1% (8)</td>
<td>2.4% (7)</td>
<td>1.2% (1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.3% (1)</td>
<td>0.4% (1)</td>
<td></td>
</tr>
<tr>
<td>Payment Type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private Ins.</td>
<td>69.8% (257)</td>
<td>61.4% (174)</td>
<td>97.6% (83)</td>
</tr>
<tr>
<td>Cash Pay</td>
<td>17.0% (62)</td>
<td>22.1% (62)</td>
<td>0% (0)</td>
</tr>
<tr>
<td>Medicare</td>
<td>13.0% (48)</td>
<td>16.5% (47)</td>
<td>1.2% (1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.2% (1)</td>
<td></td>
<td>1.2% (1)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>79.0% (291)</td>
<td>75.1% (213)</td>
<td>91.8% (78)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>9.3% (34)</td>
<td>11.1% (31)</td>
<td>3.5% (3)</td>
</tr>
<tr>
<td>Retired</td>
<td>7.9% (29)</td>
<td>9.6% (27)</td>
<td>2.4% (2)</td>
</tr>
<tr>
<td>Student</td>
<td>3.0% (11)</td>
<td>3.5% (10)</td>
<td>1.2% (1)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.8% (3)</td>
<td>0.7% (2)</td>
<td>1.2% (1)</td>
</tr>
<tr>
<td>Child(ren) ≤ 12 yrs.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>67.4% (248)</td>
<td>70.0% (198)</td>
<td>58.8% (50)</td>
</tr>
<tr>
<td>Yes</td>
<td>31.8% (117)</td>
<td>28.9% (82)</td>
<td>41.2% (35)</td>
</tr>
<tr>
<td>Unknown</td>
<td>0.8% (3)</td>
<td>1.1% (3)</td>
<td></td>
</tr>
</tbody>
</table>

*weighted
ORs listed in column Exp (B) of Table 8, show the odds of being lost to follow-up across all of the variables. The OR for the gastric bypass is consistent with the descriptive statistical findings suggesting that subjects with this surgery type may have a greater chance of being LOST, and in this regression it is 2.7 times the odds for AGB. The OR for age 45-54 years is also high at 2.3, as are the ORs for male gender (2.5), and for lowest QOL score (2.0). Travel distance, degree of obesity (BMI), marital status, employment status, and insurance coverage vs. cash pay were not significantly associated with being LOST.

Table 7  Sample Comparisons of GBP vs. AGB for LOST & NOT LOST

<table>
<thead>
<tr>
<th></th>
<th>AGB NOT LOST</th>
<th>AGB LOST</th>
<th>GBP NOT LOST</th>
<th>GBP LOST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total N</td>
<td>283* (100%)</td>
<td>85 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>208* (74%)</td>
<td>75 (26%)</td>
<td>27 (32%)</td>
<td>58 (68%)</td>
</tr>
<tr>
<td>AGE (yrs)</td>
<td>44.3 (± 12.5)</td>
<td>48.7 (± 10.3)</td>
<td>40.6 (± 10.1)</td>
<td>40.9 (± 9.5)</td>
</tr>
<tr>
<td>BMI (wtkg/htm²)</td>
<td>46.0 (± 7.2)</td>
<td>44.8 (± 6.8)</td>
<td>46.3 (± 5.6)</td>
<td>48.0 (± 5.6)</td>
</tr>
<tr>
<td>HEIGHT (in)</td>
<td>65.3 (± 3.2)</td>
<td>65.7 (± 2.9)</td>
<td>65.3 (± 2.1)</td>
<td>65.4 (± 3.3)</td>
</tr>
<tr>
<td>initial WEIGHT (lbs)</td>
<td>279.9 (± 56.3)</td>
<td>275.2 (± 51.8)</td>
<td>280.0 (± 35.0)</td>
<td>292.3 (± 45.4)</td>
</tr>
<tr>
<td>EXCESS WT (lbs)</td>
<td>151.9 (± 48.0)</td>
<td>144.6 (± 44.7)</td>
<td>153.6 (± 31.9)</td>
<td>162.8 (±37.5)</td>
</tr>
<tr>
<td>IDEAL WT (lbs)</td>
<td>128.0 (± 14.0)</td>
<td>130.0 (± 13.9)</td>
<td>126.3 (± 8.8)</td>
<td>129.5 (± 15.0)</td>
</tr>
<tr>
<td>GOAL WT (lbs)</td>
<td>154.9 (± 25.6)</td>
<td>153.7 (± 27.7)</td>
<td>150.6 (± 18.1)</td>
<td>154.7 (± 26.5)</td>
</tr>
<tr>
<td>QOL SCORE (1.0-4.99)</td>
<td>2.99 (± 0.56)</td>
<td>2.88 (± 0.58)</td>
<td>2.77 (± 0.60)</td>
<td>2.83 (± 0.63)</td>
</tr>
<tr>
<td>TRAVEL DISTANCE (miles)</td>
<td>76.6 (± 142.3)</td>
<td>96.9 (± 163.1)</td>
<td>97.6 (± 140.3)</td>
<td>104.5 (±240.4)</td>
</tr>
</tbody>
</table>

*weighted

Two of the four variables that were found to have statistically significant correlation to LOST in the non-weighted sample, were also found to have statistically significant correlation to LOST in the weighted sample. The variables were gastric bypass and age 45-54 years. The other two variables, male gender and lowest mean QOL score, almost reached level of significance but had lower-limit confidence intervals of slightly below 1.0. The weighted sample resulted in a much larger OR of 6.08 in the gastric bypass cohort (CI; 3.94, 9.37; \( p < 0.0001 \)), and an OR of 2.18 for the age 45-54 cohort (CI; 1.008, 4.744; \( p = 0.048 \)).
Table 8  Logistic Regression for Dependent Variable: LOST (non-weighted)

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp (B)</th>
<th>5% CI for Exp (B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=253</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastric bypass (GBP)</td>
<td>1.005</td>
<td>0.340</td>
<td>8.733</td>
<td>1</td>
<td>0.003**</td>
<td>2.732</td>
<td>1.403, 5.321</td>
</tr>
<tr>
<td>Travel distance 11-20 mi.</td>
<td>0.152</td>
<td>0.405</td>
<td>0.140</td>
<td>1</td>
<td>0.706</td>
<td>1.164</td>
<td>0.526, 2.573</td>
</tr>
<tr>
<td>Travel distance 21-99 mi.</td>
<td>0.009</td>
<td>0.384</td>
<td>0.001</td>
<td>1</td>
<td>0.980</td>
<td>1.010</td>
<td>0.476, 2.140</td>
</tr>
<tr>
<td>Travel distance 100-199 mi.</td>
<td>0.360</td>
<td>0.445</td>
<td>0.661</td>
<td>1</td>
<td>0.416</td>
<td>1.436</td>
<td>0.600, 3.434</td>
</tr>
<tr>
<td>Travel distance &gt;200 mi.</td>
<td>0.107</td>
<td>0.456</td>
<td>0.055</td>
<td>1</td>
<td>0.815</td>
<td>1.112</td>
<td>0.455, 2.717</td>
</tr>
<tr>
<td>BMI 40-49 wtkg/htm²</td>
<td>-0.339</td>
<td>0.402</td>
<td>0.712</td>
<td>1</td>
<td>0.399</td>
<td>0.712</td>
<td>0.324, 1.566</td>
</tr>
<tr>
<td>BMI 50-59 wtkg/htm²</td>
<td>-0.22</td>
<td>0.477</td>
<td>0.220</td>
<td>1</td>
<td>0.639</td>
<td>0.799</td>
<td>0.314, 2.037</td>
</tr>
<tr>
<td>BMI 60-69 wtkg/htm²</td>
<td>-0.198</td>
<td>0.743</td>
<td>0.071</td>
<td>1</td>
<td>0.790</td>
<td>0.821</td>
<td>0.191, 3.517</td>
</tr>
<tr>
<td>Age 35-44 yrs.</td>
<td>0.267</td>
<td>0.402</td>
<td>0.440</td>
<td>1</td>
<td>0.507</td>
<td>1.306</td>
<td>0.594, 2.873</td>
</tr>
<tr>
<td>Age 45-54 yrs.</td>
<td>0.843</td>
<td>0.385</td>
<td>4.808</td>
<td>1</td>
<td>0.028*</td>
<td>2.324</td>
<td>1.094, 4.938</td>
</tr>
<tr>
<td>Age &gt;55 yrs.</td>
<td>0.432</td>
<td>0.431</td>
<td>1.001</td>
<td>1</td>
<td>0.317</td>
<td>1.54</td>
<td>0.661, 2.400</td>
</tr>
<tr>
<td>Male gender</td>
<td>0.929</td>
<td>0.394</td>
<td>5.550</td>
<td>1</td>
<td>0.018*</td>
<td>2.532</td>
<td>1.169, 5.483</td>
</tr>
<tr>
<td>Married</td>
<td>0.232</td>
<td>0.329</td>
<td>0.497</td>
<td>1</td>
<td>0.481</td>
<td>1.261</td>
<td>0.662, 2.400</td>
</tr>
<tr>
<td>Unemp. retired or student</td>
<td>-0.05</td>
<td>0.431</td>
<td>0.013</td>
<td>1</td>
<td>0.911</td>
<td>0.953</td>
<td>0.409, 2.217</td>
</tr>
<tr>
<td>Lowest mean QOL score</td>
<td>0.68</td>
<td>0.329</td>
<td>4.270</td>
<td>1</td>
<td>0.039*</td>
<td>1.973</td>
<td>1.036, 3.76</td>
</tr>
<tr>
<td>Low mean QOL score</td>
<td>0.518</td>
<td>0.352</td>
<td>2.167</td>
<td>1</td>
<td>0.141</td>
<td>1.679</td>
<td>0.842, 3.349</td>
</tr>
<tr>
<td>Cash pay</td>
<td>-0.48</td>
<td>0.442</td>
<td>1.197</td>
<td>1</td>
<td>0.240</td>
<td>0.617</td>
<td>0.842, 3.349</td>
</tr>
<tr>
<td>Constant</td>
<td>-1.03</td>
<td>0.589</td>
<td>3.043</td>
<td>1</td>
<td>0.081</td>
<td>0.358</td>
<td></td>
</tr>
</tbody>
</table>

Reference groups=Lap-Band (AGB), travel distance 0-10 mi.; BMI 35-39; age 18-34, female; unmarried; employed; highest mean QOL score; insured.  *p<0.05; **p<0.01

Logistic regression analysis was conducted using the weighted sample of subjects (n=368) using SAS. Similar trends were observed in this regression. Table 9 depicts the ORs and confidence limits for the weighted sample.
### Table 9  
**Odds Ratios for Dependent Variable: LOST (weighted)**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Estimate</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric bypass</td>
<td>6.077***</td>
<td>3.941</td>
<td>9.370</td>
</tr>
<tr>
<td>Travel distance 11-20 mi.</td>
<td>1.042</td>
<td>0.452</td>
<td>2.398</td>
</tr>
<tr>
<td>Travel distance 21-99 mi.</td>
<td>0.992</td>
<td>0.444</td>
<td>2.214</td>
</tr>
<tr>
<td>Travel distance 100-199 mi.</td>
<td>1.428</td>
<td>0.554</td>
<td>3.681</td>
</tr>
<tr>
<td>Travel distance &gt;200 mi.</td>
<td>1.113</td>
<td>0.415</td>
<td>2.981</td>
</tr>
<tr>
<td>BMI 40-49</td>
<td>0.749</td>
<td>0.329</td>
<td>1.702</td>
</tr>
<tr>
<td>BMI 50-59</td>
<td>0.753</td>
<td>0.282</td>
<td>2.009</td>
</tr>
<tr>
<td>BMI 60-69</td>
<td>0.767</td>
<td>0.178</td>
<td>3.300</td>
</tr>
<tr>
<td>Age 35-44 yrs.</td>
<td>1.261</td>
<td>0.550</td>
<td>2.889</td>
</tr>
<tr>
<td>Age 45-54</td>
<td>2.187*</td>
<td>1.008</td>
<td>4.744</td>
</tr>
<tr>
<td>Age &gt;55</td>
<td>1.530</td>
<td>0.608</td>
<td>3.850</td>
</tr>
<tr>
<td>Male gender</td>
<td>2.248</td>
<td>0.985</td>
<td>5.127</td>
</tr>
<tr>
<td>Married</td>
<td>1.307</td>
<td>0.671</td>
<td>2.545</td>
</tr>
<tr>
<td>Unemployed</td>
<td>0.973</td>
<td>0.399</td>
<td>2.371</td>
</tr>
<tr>
<td>Lowest QOL score</td>
<td>1.946</td>
<td>0.956</td>
<td>3.965</td>
</tr>
<tr>
<td>Low QOL score</td>
<td>1.639</td>
<td>0.814</td>
<td>3.302</td>
</tr>
<tr>
<td>Cash pay</td>
<td>0.673</td>
<td>0.283</td>
<td>1.598</td>
</tr>
</tbody>
</table>

Reference groups=Lap-Band (AGB), travel distance 0-10 mi.; BMI 35-39; age 18-34, female; unmarried; employed; highest mean QOL score; insured.  
*\( p<0.05; **p<0.01 ***p<0.001 \)

### Conclusions

1. GBP patients were more likely to become lost to follow-up than AGB patients.
2. Males were more likely to become lost to follow-up than females.
3. Middle aged patients (45-54) were more likely to become lost to follow-up than other age groups.
4. Patients with the lowest mean QOL scores at initial visit were more likely to become lost to follow-up than higher scoring individuals.
5. Travel distance to the nearest clinic was not a significant factor associated with lost to follow-up.
6. Level of obesity (BMI) was not a significant factor for being lost to follow-up.
7. Marital status was not a significant factor associated with lost to follow-up.
8. Employment status was not a significant factor associated with lost to follow-up.
9. Child(ren) ≤12 living in the home was a not significant factor associated with lost to follow-up.
10. Payment type insured vs. cash-pay was not significantly correlated to lost to follow-up.
11. Goal weight was not significantly correlated to lost to follow-up.

Summary

This study indicates that gastric bypass patients have a much greater chance of becoming lost to follow-up than Lap-Band patients. Males were more than twice as likely to drop out; patients in the middle years of life are associated with poorer adherence to follow-up; and patients with the lowest level of functioning as measured on the QOL tool may be at a higher risk of becoming lost. Travel distance was not a significant risk factor for LOST in the weighted and non-weighted regressions. Demographic characteristics that did not appear to have a bearing on lost status were marital status, employment/income status, payment type, children age twelve and under living in the home, BMI, and goal weight.
CHAPTER 5
DISCUSSION

This study used a convenience sample to compare bariatric surgery patients who were lost to follow-up with those who were not lost to follow-up across a number of variables. This chapter discusses the findings of the study, trends, and possible meaning behind factors found to be associated with or not associated with lost to follow-up. Findings are discussed in relationship to the current literature. This chapter also discusses findings in the context of Pender’s Health Promotion Model, which was the conceptual framework used to guide the research. Limitations and assumptions are reviewed and implications for nursing practice, advanced nursing practice, nurse administration and nursing education are explored, as well as recommendations for future research.

Findings

The average patient receiving bariatric surgery at the study institution was a 44 year old female with a BMI of 46, married, employed, with no children age ≤12, who used private insurance and lived within 21 miles of the nearest clinic. The overall findings of this study indicated that differences occurred between bariatric surgery patients who were LOST and those who were NOT LOST. Over 36% of patients met criteria for LOST. Gastric bypass patients, males, patients aged 45-54, and patients scoring lowest on the QOL tool were more likely to be LOST. Travel distance was not a risk factor for LOST, nor was young children living in the home, marital status, employment status, payment type, degree of overweight (BMI, weight, ideal weight, excess weight), or goal weight.

According to the present study, most GBP patients can be expected to become lost to follow-up within the first few years after surgery. GBP patients were almost three times more likely to be LOST than AGB patients. The best explanation for this finding is that GBP patients will lose weight regardless of follow-up visits at least for the first year after surgery (Shen et al., 2004). The relative odds were 2:1 that men would be LOST. Men tend to use fewer healthcare services than women, and this finding is consistent with gender differences in healthcare seeking behaviors in family practice settings. According to the American Academy of Family Physicians,
cultural norms and gaps in education can create apprehension and result in avoidance among men to seek preventative healthcare (American Academy of Family Physicians, 2008). Preventative health is reinforced for women through structured screening guidelines for yearly women’s health checkups. No parallel process exists for men, and the lack of screening guidelines for males affects men’s attitudes about preventive healthcare.

The finding that age group 45-54 years had a 2:1 chance of being LOST may be related to increasing demands of family. The 45-54 year age group is the so called “sandwich generation” in which middle-aged individuals may be caring for their own children while simultaneously caring for aging parents. The sandwich generation phenomenon is said to be receiving greater attention in recent years due to the large population of individuals born during the post-World War II baby-boom within the 45-54 year age group. Several other demographic trends may be contributing to the sandwich generation effect. As people live longer, middle-aged individuals tend to have parents who are still alive, and these parents have fewer children, resulting in fewer siblings to share the burden of elder care (Pierret, 2006). Also, women are having children at later ages so their parents are older, but their children are still young, and support for children may be lasting longer than in previous generations.

Lowest mean score on quality of life at the consult visit was associated with LOST. The logistic regression showed an inverse relationship on this variable: the lower the level of functioning, the more likely the patient would be LOST. The finding that lower functioning may predict lost status suggests that lower functioning individuals in the preoperative period may not achieve as much improvement in quality of life as higher functioning individuals, despite their weight loss in the post-operative period. Mean QOL scores were inversely related to level of attrition suggesting the need for better collaboration between the surgeon, nurse and psychologist in the preoperative phase of care.

Travel distance was not predictive of LOST and was an unexpected finding and a positive result for the bariatric program. The bariatric program tries to accommodate patients living at a distance because patients tend to have strong feelings about the surgeons and programs they select and are willing to drive or fly the distance. Also, patients may be required by their health insurance carriers to receive services from the surgeon and facility and/or may require services from a COE, but a COE is not available locally. Approximately 45% of the clinic’s referrals
come from current patients, patients’ families and friends and repeat referring physicians many of whom are from distant regions. Long distance referrals are often clustered and come from communities and cities such as Grand Junction, Colorado; Casper, Wyoming; and Albuquerque, New Mexico, where information about the surgeon and program is spread by word of mouth. The finding that travel distance is not affecting patient follow-up provides evidence to support the current practice of accepting patients from other regions and states.

**Relationship to Literature**

In this study a mean BMI of 46.1 was obtained and was consistent with the BMI of 46.9 obtained in a multinational meta-analysis that included over 22,000 bariatric surgery patients (Buchwald et al., 2004). Compared to the present study, Buchwald et al. showed a higher percentage of males in the gender mix: 72.6% female and 19.4% male and showed a lower mean age of 39 years compared to the current study with 85.1% females, 14.9% males, and a mean age of 44 years.

The clinic’s experience with GBP patients is consistent with Shen et al. (2004), which compared weight loss with number of postoperative visits within the first year across cohorts of AGB and GBP patients. The majority of GBP patients lose most of their weight within the first year after surgery. Their results indicated that weight loss in GBP patients is independent of postoperative visits, whereas weight loss after gastric banding had a positive correlation with number of visits. The mechanism of weight loss is different for each procedure; the AGB is adjusted during office visits over many months to produce weight loss, whereas the GBP is not adjustable and produces weight loss rapidly after surgery. “Since [GBP] patients lose weight regardless of seeing their surgeons, much less incentive exists for patients to return to their surgeon. This may explain why the follow-up in most [AGB] series in the literature is much higher” (Shen et al., 2004, p. 518).

Wheeler et al. (2007), had a similar research objective and research design to the present study but had different results on key variables such as gender (no difference in adherence between the sexes); age (increase in age positively associated with adherence); BMI (higher BMI negatively associated with adherence); marital status (single status positively associated with adherence), employment status (positive for adherence), and payment type (cash pay negatively
associated with adherence). The comparability of the Wheeler et al. study and the present study is limited by the difference in days since surgery (90 days for Wheeler et al. vs. 540 days for the current study). Also, Wheeler et al. explained that they did not factor in all postoperative visits with the surgeon, which may have had the effect of counting a patient non-adherent when they were actually adherent.

Lara et al. (2004) investigated travel distance, age, and gender as factors related to compliance with follow-up visits. The researchers found no correlation between non-compliance and age. Males were more compliant at the one year postoperative visit, and overall, travel distance was a predictor of non-compliance. The findings in Lara et al. are opposite from the findings in the present study across all three variables.

In Harper et al. (2006) a significant difference was found between follow-up compliant and follow-up non-compliant patients with regard to weight loss at 12-14 months postoperatively (p<0.02) suggesting that non-compliance is related to less success with weight loss. If patients are less compliant with follow-up because their weight loss is inferior, then the assertion that GBP patients are disinclined to adhere to follow-up because they have superior weight loss is a false premise. Harper et al. found no difference between the two groups on gender, a finding that was not consistent with this researcher’s findings. However, comparable findings between the present study and Harper et al. were those of no statistically significant relationship between preoperative BMI or payment type and compliance with follow-up visits.

One explanation for the discrepancies in study findings of this researcher and study findings of Wheeler et al. (2007), Lara et al. (2005), and Harper et al. (2006), is the use of multiple variables. Different methodologies may have been a factor in divergent results, as they each used different study designs. Time frame was an issue in attempting to compare results, as was the differing definitions of “visit”, “follow-up”, “compliance”, and “adherence”. Also, each study had a different ratio of surgery types: for example, in Harper et al. and Lara et al., all subjects were GBP patients, whereas in this study and the other referenced studies, ratios of AGB patients to GBP patients were dissimilar.
Theoretical Framework

Pender’s Health Promotion Model provided the conceptual framework for the study. The HPM proved very useful in identifying the multiplicity of factors that may influence health promoting behaviors in bariatric surgery patients. GBP patients were more likely to be LOST defined as absence of the health promoting behavior of yearly check-ups. This phenomenon is assumed to be related to superior first year weight loss and ties into “behavior-specific cognitions” and the theoretical proposition that persons commit to engaging in behaviors from which they expect to derive personally valued benefits (Pender et al., 2006). GBP patients are likely to perceive less benefit from follow-up, or find “no purpose” in such visits. They may not be motivated to come in for a “well-adult” check-up, and return only if they are having a problem. With weight loss already achieved, and health problems resolved, the GBP patient’s motivation to return for follow-up must come from some other perceived benefit. On the other hand, they may have less success with weight loss and be embarrassed to come to the clinic. If return for follow-up is related to less success with weight loss and as Harper et al. (2006) found in their study, lack of success with weight loss predicts non-compliance. On the HPM model, barriers related to self-efficacy with roots in prior related behaviors of failure to lose weight may influence commitment to follow-up with the program.

What motivates the patients who do engage in health promoting behaviors of keeping appointments? Why are they more committed? According to Pender, greater perceived self-efficacy results in fewer perceived barriers to a specific behavior. One factor that may be influencing committed patients to adhere to follow-up is that of knowledge base. Committed patients may have a better understanding of the potential dangers of surgery, or they may have better retention of the information they received in preoperative classes and clinic visits. If true, they would be more inclined to place higher value on routine visits where they learn details of their progress and obtain evaluation of their laboratory tests. If this assumption is correct, a critical analysis of patient education is necessary. New strategies for patient education could be employed to test the effectiveness of the learning experience and the commitment to follow-up in the clinic. Implementation of research-based teaching methods could be tested, such as patient-empowerment models of learning that have been effective in diabetic teaching (Piper & Brown, 1998).
When positive emotions are associated with a behavior, the probability of commitment to action is increased (Pender et al., 2006). Committed patients may perceive benefit in gaining psychological support and reassurance from the staff, and perhaps they associate visits with positive emotions. If these assumptions are true, patient adherence to follow-up may be enhanced by developing ways to maximize the patient experience in the office, such as providing computers or televisions in the waiting area and treatment rooms; providing educational videos for health promotion; healthy snacks and beverages; and giving patients gift certificates or items such as travel mugs as a reward for “doing the right thing for their health”. Men have socio-cultural barriers to health-promoting care. Targeting techniques to motivate men to return for follow-up may include calling them at work for reminders, or connecting with their spouse or significant other. According to Pender, family members are an important source of “interpersonal influence” that can increase commitment to and engagement in health-promoting behavior (Pender et al., 2006). Giving men a separate waiting area where sports television can be viewed and providing reading materials that are more gender-specific may increase perceived benefit to follow-up. The middle-aged patient may be more vulnerable to barriers related to negative “interpersonal influences” such as competing demands of spouse, children and parents simultaneously. Improved access to care is likely to be an especially important factor for this age group, and extended clinic hours as well as improving access to satellite clinics or incorporating a home health model of care would be ways to try to improve follow-up in this patient population.

Patients who score in the lowest quartile on the quality of life questionnaire would fit within the basic element of the HPM: individual characteristics and experiences. Personal factors of depression, poor self-image, and avoidance of socialization are strong obstacles to health promotional behavior. Lower functioning individuals would presumably be more inclined to perceive barriers associated with traveling to and being in the doctor’s office (energy level, logistics of travel, anxiety about program staff’s perception of their progress, etc.). The finding that low QOL score is related to LOST suggests that lower self-image, poor self esteem, social isolation and physical limitations would have a stronger effect on follow-up compliance than the belief that a visit would improve weight loss or improve health. Low functioning may negatively influence a patient’s belief that a routine check-up would provide support and encouragement or
would be a positive experience. Placing phone calls to these patients between scheduled visits may be helpful.

The HPM provided an excellent framework for this study. The framework was flexible and allowed for all of the independent variables to be conceptualized on the continuum to health promoting behavior. Although the potential factors influencing bariatric surgery patients’ adherence to follow-up are virtually limitless, the model allowed for focus on individual characteristics and revealed entities that may be influencing follow-up behavior. The identification of factors that may be influencing follow-up compliance led to a systematic conceptualization of interventions to reduce patient attrition which could be tested in future prospective, case-controlled research studies.

**Assumptions and Limitations**

The assumptions that records were kept accurately and patients were truthful in their responses and reports were neither supported nor unsupported. The assumptions that patients were in fact lost to follow-up after 18 months of no visits or not lost to follow-up if they had a visit within 17 months were neither supported nor unsupported. Also, the assumption that becoming lost to follow-up after bariatric surgery constitutes a negative outcome for patients was neither supported nor unsupported.

Conclusions about cause and effect relationships are not possible with a retrospective study design; therefore, this study could not determine if the independent variables resulted in LOST status and could only indicate an increased probability that the effect would occur. The convenience sample was a limitation because it may have been atypical and not generalizable to the target population. The study had several limitations in addition to those described in Chapter 1. Sampling bias may have occurred. The decision was made by this researcher to divide the sample into strata in order to capture the greatest number of subjects with the dependent variable of LOST. The sample was subsequently stratified into surgery type, GBP and AGB, which resulted in a prohibitively large subgroup of AGB NOT LOST subjects. A randomized sample of the AGB NOT LOST subgroup was later obtained which may not have been a representative sample of the subgroup. To correct potential errors in sampling and ensure a more adequate representation, the randomized group was weighted in the descriptive statistics and in some of
the inferential statistics. In retrospect, a research design that simply took a random sample of 253 patients from the entire sample of 368 consecutive patients within the study time frame may have been a better choice.

Another limitation was related to the passage of time and the possibility of a “cohort effect”. Sample characteristics may have changed due to factors such as community changes, different market share demographics, and trends in patients’ selection of procedure type. A limitation of the methodology was the fact that number of days since surgery was not included as an independent variable in the logistic regression. Most programs experience increasing patient attrition over time, therefore the results may have been skewed by the fact that more patients chose the AGB over the GBP as time passed. Comparisons in surgery types on the dependent variable could have been biased by time. The participating clinic was not collecting data on several demographic data points during the time frame of the study; ethnicity, race, income level, and level of education, which brought into question the generalizability of the sample. Finally, this research is a pilot study for the screening tool, the 7QoLQ. Its use as a meaningful measure of quality of life is yet to be fully established.

**Implications for Nursing Practice**

The main implication for nursing this paper brings to light is related to the importance of identifying patients at risk after bariatric surgery and ensuring that they are receiving appropriate and preventive care. Whether patients return to their bariatric surgeons or go back to their primary care providers, they require monitoring for life. The extent to which patients are at risk is not fully known because long term data is scant and inconclusive, but also because disease processes in bariatric surgery patients are hidden and frequently discovered in the course of a well-adult check-up. For example, iron deficiency is common among menstruating female GBP patients, especially if they have stopped taking iron supplements, and may result in anemia. Other anecdotal evidence indicates significant risk related to bone density. Repeat bone scans in premenopausal GBP patients frequently show early signs of bone demineralization despite calcium and vitamin D supplementation. Also, AGB patients often live with reflux esophagitis for many months (a known risk factor for Barrett’s esophagus) due to over-adjustment of their bands. Nurses will encounter bariatric surgery patients in increasing numbers and have a large
role to play in helping patients avert long term problems. A greater likelihood that bariatric patients are lacking in their preventative care exists based on the high levels of patient attrition experienced in programs today.

**Advanced Practice Nurse**

The advanced practice nurse (APN) is a vital member of the bariatric multispecialty team, and is in the best position to take a leading role as nurse researcher. Research designed for the purpose of reducing patient attrition in bariatric surgery programs would have the added benefit of improving the quality of outcomes research. Groups identified as more vulnerable to attrition could be targeted by APN researchers for intervention as early as the consult visit.

Surveys developed by the APN could be used to identify factors and predictors influencing follow-up compliance. A four-way approach to collecting information at key time intervals would capture greater details about patients’ behavior. First, surveys would be initiated before the patient had surgery with questions designed to obtain information about patient motivation for follow-up and perceived barriers to follow-up. Secondly, a focus on patients’ perceptions and feelings at the actual visit encounter would serve as a critical opportunity to gather information and may reveal current life experiences and motivations to return for appointments. Thirdly, collecting responses from patients during telephone interviews conducted immediately following a missed appointment would provide needed information about barriers to care. And finally, collecting patient responses (if they are able to be contacted) during telephone interviews conducted after patients are lost to follow-up would likely provide information about enduring barriers to follow-up.

An example of a preoperative survey question would be: “What is the single most effective thing we could do to improve the likelihood that you will return for your postoperative appointments?”; an example of a well-adult yearly visit survey question would be “What was the primary motivating factor that prompted you to come in for your annual visit today?”; and a lost to follow-up patient could be asked “What can we do to make your experience in the clinic better or easier?” Comparing survey responses over time may help determine common trends in patients’ experiences, attitudes and behavior (i.e., problems with a particular staff member; long waiting times; disappointment with weight loss) or persistent barriers to care (i.e., loss of employment and/or insurance, lack of family support; marital problems).
Another important task for the APN working in a bariatric surgery clinic is that of conducting periodic assessments of the preoperative and postoperative patient education curriculum and implementing improvements based on current theory and research. More effective patient education may lead to improvement in follow-up compliance (Denmark, 2004; White et al., 2002). Inservice education is another vital role for the APN in a bariatric surgery practice. The Surgical Review Corporation, the organization that manages COE designations for hospitals and outpatient surgery centers for the American Society of Metabolic and Bariatric Surgery, has established ten requirements for provisional COE designation. Requirement number eight reads as follows: “The applicant utilizes designated nurse or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients” (SRC, 2009, Webpage, item 8).

Research findings could lead to the development of strategies that have been used effectively in other health care settings. Examples include sending appointment reminders and guidelines using text messaging, email, and Web-based applications in family and dental practices (Din, Tao, Malhotra, Zimmerman & Kakafka, 2005; Leong et al., 2006); entering into provider-patient partnership agreements in diabetic care (Denmark, 2004); conducting motivational interviews using computer administered self-interview in achieving compliance with visits and medications for treatment of human immunodeficiency virus (Dilorio et al., 2005); incorporating patient-centered approaches that target selected patient characteristics such as beliefs, attitudes and goals (Lauver et al., 2002), and providing greater access to care with walk-in options and open appointment times (Din et al., 2005). Advanced practice nurses working directly with bariatric surgery patients have the greatest potential to provide leadership in research and to influence lifestyle change and health promotion in bariatric surgery patients.

Finally, one of the most important roles for the APN is frontline in primary care settings, where they should have a current understanding of the anatomy and physiology of the various procedures, knowledge of the typical and atypical presentations for common problems and the best diagnostics for each, and knowledge of the latest recommendations for routine screening. Providers need to be ever vigilant in ruling out nutritional deficiencies in these patients. Thiamine, homocysteine, vitamin B-12, parathyroid hormone, vitamin D, ferritin and transferrin are examples of some of the serum chemistries recommended for yearly check-ups, but not
routinely done. Patients may be more compliant if they are encouraged by providers to return to the bariatric program for follow-up, support groups and postoperative education.

Administration

Nurse administrators must take a leading role in meeting the needs of bariatric surgery patients. They have a tremendous duty to be key participants in establishing practice standards and clinical pathways for bariatric surgery patients. Inservice education including obesity sensitivity training should be mandatory at all facilities for all employees, physicians and mid-level providers, until the knowledge gap closes. Patients should be identified at intake to avoid potentially harmful clinical procedures. Examples include radiology departments where patients may be mistakenly directed to drink prohibitive quantities of gastrografin; emergency departments where nasogastric tubes are inadvertently placed without the proper fluoroscopic guidance and x-rays are often misread; hospital admission departments where patients are placed on diets that are inappropriate; urgent care facilities where an AGB that is too tight prompts a hospital admission when a simple adjustment to the band would solve the problem; outpatient surgery centers where an AGB patient aspirates because the band was over-adjusted the day before surgery; long term healthcare facilities where patients may need extra work-up beyond the routine testing; and primary care offices where a patient with a history of vomiting and weakness is mistakenly sent home with a critical thiamine deficiency resulting in permanent neurological deficits. Nurse administrators have a duty to assume a pivotal role in developing research-based practices and protocols that support the bariatric patient population.

Education

Nurse educators must also assume a leading role in incorporating bariatric surgery content into nursing curricula. At the present time, providing such content may be difficult to accomplish because educational materials are limited and most materials are written for the layperson. One leading medical/surgical nursing textbook reviewed by this researcher contains incorrect information about bariatric surgery throughout the section. In the section, bariatric procedures are grouped together such as a listing for dietary guidelines that are designed for Lap-Band patients only (as noted in the footnote), but are placed under the general heading of patient education/dietary guidelines for patients after all types of bariatric surgery. The dietary guidelines recommend large intake of fluids which is appropriate advice for most Lap-Band
patients, but is not appropriate advice for gastric bypass patients or patients with a biliopancreatic diversion. In the textbook, the only long term complications listed for bariatric procedures, as a group, were gallstones, nutritional deficiencies and weight regain.

Prejudice against obese and morbidly obese individuals has been studied in nurses, and a recent meta-analysis concluded that negative attitudes toward obese adults persist among nurses (Brown, 2006). Nurse educators can help meet the increasing need for nursing knowledge in morbid obesity and bariatric surgery by incorporating teaching models that would help to dispel myths and stereotyping of obese individuals. Innovative educational models that allow nurses to gain exposure to the lived experience of morbid obesity, and the triumphs and joys of weight loss, health improvement, better appearance and overall quality of life in this patient group would serve to generate greater enthusiasm and interest in working with obese patients and bariatric surgery patients.

Nurse educators may find benefit in forging new relationships with community bariatric surgeons and program coordinators to help develop learning opportunities for nurses. Many programs have bariatric patient spokespersons that are adept at giving presentations about their personal experiences before and after surgery and could provide brief presentations in the classroom setting. The current study’s participating bariatric clinic provides proctoring for senior class nursing students from the University of Northern Colorado who are interested in individualized clinical training in bariatrics. The learning opportunity has generated much enthusiasm among nursing school faculty and nursing students. Students have completed projects such as assisting with obesity sensitivity training for hospital employees, co-facilitating support groups, and developing patient educational materials. After completing the rotation, students expressed great excitement about bariatric surgery and the life-changing transformations in patients they encountered every day.

Continuing education for nurses is especially necessary because most nurses will encounter bariatric surgery patients often. General knowledge about bariatric surgery is lacking in the medical community and nurses may not be able to depend on the physician to be knowledgeable about bariatric surgery (Leslie, Kellogg, & Ikrammudin, 2007). As longitudinal research exposes unforeseen side effects of bariatric procedures; the need for education becomes increasingly important. A case in point is the recent news release on the Mayo Clinic Website of a
retrospective study spanning 21 years that showed a higher incidence of fractures in patients after bariatric surgery; especially fractures of the hands and feet (Mayo Clinic, 2009, para. 3).

**Recommendations for Future Research**

Duplicate research is needed to determine if male patients, gastric bypass patients, patients who are middle-aged and patients who have low scores on quality of life indicators are more likely to become lost to follow-up over the long term (18 months or more past the last appointment). Of interest to this researcher is the continuation of the present study to determine if current findings remain consistent over time. It is possible that patients who were grouped as LOST may subsequently return to the clinic. Collecting data on patients formerly considered to be lost to follow-up would provide valuable information regarding the reasons patients miss appointments for extended periods (e.g., illness, job change, lack of income or insurance, divorce, or pregnancy), and also provide information about factors that motivate patients to return (e.g., weight regain, complications of bariatric surgery, or primary care provider referral).

The few papers available on factors influencing follow-up in bariatric surgery have inconsistent findings. Standardizing studies in terms of the postoperative time-frame would be helpful in comparing multivariate studies. Short term studies looking at visit compliance could focus on obtaining direct information from patients before they are lost to follow-up or before their contact information is obsolete. Also, patients who do not follow-up within the early postoperative time period may be more amenable to encouragement to follow-up, as was found in Harper et al. (2006).

This study investigated preoperative predictors of compliance, but future studies also need to include examination of postoperative predictors of compliance such as trends in weight loss, quality of life, incidence of depression, and comorbidity improvement over time (Elkins, et al, 2005). Case-controlled, interventional studies are especially necessary for programs attempting to maintain center of excellence designations. Programs may want to institute a number of interventions simultaneously to boost follow-up and later survey patients to investigate what motivated them to stay current with follow-up. One example of a relatively simple interventional, case-controlled study would be to institute reminders and other friendly communications with patients using text messaging, emails and/or social networks (such as
Facebook and Twitter) and compare their adherence to follow-up to controls with no reminders or controls using conventional voice-message reminders. As described previously, the greatest effect on patient follow-up percentages may be achieved by focusing interventional research on the most vulnerable groups, such as changing the clinic waiting area to enhance the environment for men; targeting the needs of the time-constrained middle-aged patient by improving access to care; increasing collaboration with psychologists and other team members in the preoperative period so that patients with especially low QOL scores can be identified and treated before surgery; revising education models in the patient education curriculum, and expanding between-visit communication with all patients, but especially gastric bypass patients, who appear to be most at risk.

**Summary**

A comparison of bariatric surgery patients who were lost to follow-up and bariatric surgery patients who were not lost to follow-up in a convenience sample from a single bariatric surgery practice revealed that GBP patients, patients 45-54 years of age, men, and patients scoring lowest on a QOL assessment were more likely to be lost to follow-up. Poor adherence to follow-up renders patients at risk because bariatric surgery is a relatively new treatment for morbid obesity that has known and unknown long-term complications. The numbers of bariatric procedures is growing rapidly, yet is not extensively researched. Nurses and primary care providers are typically not well-versed in the care of patients who have undergone these metabolic weight loss procedures. Advanced practice nurses, nurse researchers, nurse administrators, and nurse educators must take the lead in ensuring that this expanding population of bariatric patients is receiving the care they need.
APPENDIX A

SEVEN QUESTION QUALITY OF LIFE QUESTIONNAIRE
Please circle the most appropriate answer to the following questions:

Q1. Which Statement best fits how you feel on social occasions?
   A  I feel so uncomfortable socially I rarely go out.
   B  I always feel uncomfortable and avoid some social situations
   C  I often feel uncomfortable in social situations
   D  In social situations I feel comfortable most of the time
   E  When out socially I feel totally confident and comfortable in myself

Q2. How do you feel about yourself?
   A  I strongly dislike myself
   B  I have more negative thoughts than positive thoughts about myself
   C  I don’t really have positive or negative views about myself
   D  Most of the time I feel positive about myself
   E  I feel that I am a positive and worthwhile person “I like myself”

Q3. How do you feel about your appearance?
   A  I hate the way I look
   B  I’m often unhappy in the way I look
   C  I have mixed feelings about the way I look
   D  Most of the time I like the way I look
   E  I am happy in the way I look
Q4. Which of the statements best fits how you have felt over the last month?

A  I feel hopeless, sad and down all of the time
B  I feel sad and down most of the time
C  I am often sad and down
D  I rarely have times of negative thoughts when I am sad and down
E  I am never sad or down

Q5. In general my health over the last month has been:

A  Very Poor       B   Poor     C   Fair  D   Good       E  Excellent

Q6. During a normal day, which of these statements best fits your energy level?

A  I have no energy and I am very limited with work and other activities
B  I have little energy and I am limited with work and other activity
C  I have limited energy and I am not able to work and be as active as I would like to be
D  I have adequate energy and have no limitations on my work or other activities
E  I have plenty of energy and have no limitations on my work or other activities

Q7. Which statement best describes your physical ability

A  I have major physical disability that restricts most activities of everyday living
B  My limited physical ability restricts many activities of everyday living
C Some everyday activities are limited by my physical condition

D With my physical ability I am able to perform all but vigorous physical activity

E I am able to participate in vigorous physical activity
APPENDIX B

HUMAN SUBJECTS COMMITTEE APPROVAL
Office of the Vice President For Research  
Human Subjects Committee  
Tallahassee, Florida 32306-2742  
(850) 644-9673  FAX (850) 644-4392

APPROVAL MEMORANDUM

Date: 5/28/2008

To: Patrice Johnell

Address: 2360 44th Avenue, Greeley, CO 80634  
Dept.: NURSING

From: Thomas L. Jacobson, Chair

Re: Use of Human Subjects in Research  
Characteristics of Bariatric Surgery Patients Lost to Follow-up

The application that you submitted to this office in regard to the use of human subjects in the proposal referenced above have been reviewed by the Secretary, the Chair, and two members of the Human Subjects Committee. Your project is determined to be Expedited per 45 CFR § 46.110(7) and has been approved by an expedited review process.

The Human Subjects Committee has not evaluated your proposal for scientific merit, except to weigh the risk to the human participants and the aspects of the proposal related to potential risk and benefit. This approval does not replace any departmental or other approvals, which may be required.

If you submitted a proposed consent form with your application, the approved stamped consent form is attached to this approval notice. Only the stamped version of the consent form may be used in recruiting research subjects.

If the project has not been completed by 5/27/2009 you must request a renewal of approval for continuation of the project. As a courtesy, a renewal notice will be sent to you prior to your expiration date; however, it is your responsibility as the Principal Investigator to timely request renewal of your approval from the Committee.

You are advised that any change in protocol for this project must be reviewed and approved by the Committee prior to implementation of the proposed change in the protocol. A protocol change/amendment form is required to be submitted for approval by the Committee. In addition, federal regulations require that the Principal Investigator promptly report, in writing any unanticipated problems or adverse events involving risks to research subjects or others.

By copy of this memorandum, the Chair of your department and/or your major professor is reminded that he/she is responsible for being informed concerning research projects involving human subjects in the department, and should review protocols as often as needed to insure that the project is being conducted in compliance with our institution and with DHHS regulations.

This institution has an Assurance on file with the Office for Human Research Protection. The Assurance
Number is IR800000446

Cc: Laune Grubbs, Advisor
HSC No. 2008.1328
APPENDIX C

PARTICIPATING INSTITUTION RESEARCH APPROVAL
RE: BHRI # 11-08-0032
CHARACTERISTICS OF BARIATRIC SURGERY PATIENTS LOST TO FOLLOW-UP
IRIS Reference #: 005696
IRB Expedited Approval – New Protocol, Waiver of Informed Consent and Authorization to Use or Disclose PHI in Research

Dear Ms. Johnell:

This letter serves to notify you that the above referenced Protocol, request for waiver of Informed Consent, and waiver of Authorization to Use or Disclose PHI in Research received expedited review and approval by John Breen, MD, Chair of the Banner Health Institutional Review Board (NCMC Panel) on June 05, 2008 for conduct at North Colorado Medical Center. This expedited review was performed in accordance with 21 CFR 50.110(b) and 45 CFR 46.110(b). This study has received approval for one year. The FDA requires that all studies be reviewed at least annually. It was determined that all the specified criteria for a waiver of Authorization to Use or Disclose PHI in Research was met. It is recognized that the request meets the following requirements for waiver of authorization:

- Use and disclosure involves no more than minimal risk to the patients
- The research could not practically be conducted without the waiver
- The research could not be conducted without the use of the PHI
- The privacy risks are reasonable in relation to the anticipated benefits

The Board’s approval to conduct your study will expire on 04/2009. The IRB requests that you submit a Continuing Review report one month prior to the May 2009 IRB meeting. This allows time for processing and review prior to the IRB expiration date of the study. A closing report is required upon completion of the project. The occurrence of adverse reactions/events must be reported to the Board in writing within 3 days of the occurrence. Any changes in the study protocol, unusual events, results of the study or any additional information relative to the study must be submitted to the Board. In the event the study results are published, please send a copy to the Banner Health Research Institute so it may be included in the file. A copy of this letter will be placed in the study file.

The Board appreciates your participation in research. If you have any questions, please contact Michelle Faber, CRM, IRB Coordinator, at 970-546-3722.

Sincerely,

Signature applied by John Breen MD on 06/11/2008 08:36:44 AM GMT-07:00
John F. Breen, M.D.
Chair, Banner Health IRB (NMC Panel)

JB/nf
cc: Study File
    Facility Research Director
March 30, 2008

Vice President for Research
109 Wilescon Building
Florida State University,
Tallahassee, FL 32306-1330

Dear Sir or Madam:

Patrice Joinell RN has permission to use our clinic data for her project.

Sincerely,

Edward Amend RRT, MBS
Product Line Director for Bariatric Surgery Services
REFERENCES


http://www.aafp.org/online/etc/medialib/aafp_org/documents/about/rap/curriculum/mens
health.Par.0001.File.tmp/Reprint257.pdf


BIOGRAPHICAL SKETCH

Patrice Johnell
Birthplace: Los Angeles, California

EDUCATION:

1994-1998 Florida State University
2006-2009 Tallahassee, Florida
   Master of Science Nursing

1996-1998 Florida State University
   Panama City, Florida
   Master of Science Psychology Program

1976-1979 San Francisco State University
   San Francisco, California
   Bachelor of Science Nursing

1974-1976 Santa Barbara City College
   Santa Barbara, California
   Pre-Nursing Curriculum

CERTIFICATION:

May 1978 Registered Nurse Licensure California
May 1979 Public Health Nursing California
August 1979 Registered Nurse Licensure Hawaii
August 1981 Registered Nurse Licensure New Jersey
July 1984 Registered Nurse Licensure Missouri
July 1985 Registered Nurse Licensure Florida
June 2001 Registered Nurse Licensure Colorado
July 2006 Registered Nurse Licensure Florida

EMPLOYMENT:

2004-Present North Colorado Medical Center
   Greeley, Colorado
   Program Coordinator Bariatric Surgery
   Web Coordinator Bariatric Surgery

2001-2004 North Colorado Center for Bariatric Surgery
   Greeley Medical Clinic
   Greeley, Colorado
   Program Coordinator Bariatric Surgery
1996-2001  Northwest Florida Surgery Center  
            Panama City, Florida  
            Staff Nurse PACU

1988-1998  Self-Employed  
            Personal Fitness Trainer

1987-1989  Gulf Coast Community Hospital  
            Panama City, Florida  
            Staff Nurse ICU

1985-1988  Bay Medical Center  
            Panama City, Florida  
            Staff Nurse Acute Dialysis

1984-1985  St. Peter’s Medical Center  
            St. Louis, Missouri  
            Staff Nurse CCU

1981-1983  St. Peter’s Hospital  
            New Brunswick, New Jersey  
            Staff Nurse ER, ICU, CCU

1982-1984  Middlesex Hospital  
            New Brunswick, New Jersey  
            Staff Nurse Surgical ICU/Open Heart Recovery

1980-1982  Veterans Administration Hospital  
            New York, New York  
            Staff Nurse Surgical ICU/Open Heart Recovery

1979-1980  The Queen’s Medical Center  
            Honolulu, Hawaii  
            Staff Nurse Four Surgical ICU/Open Heart Recovery