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1970

ABSTRACT

Crane, B.A., M.A., Dave, Masters of Public Health (Health Management and Policy), December, 2003, Bariatric Surgery and the Lap Band: An Analysis of Efficacy, 40 pages, 15 tables, references, 45 titles.

Obesity has quickly become both a national and global health issue. The evidence is increasingly consistent that obesity has a causal relationship with serious medical complications. The Lap Band, a surgical procedure for weight control, was approved by the Food and Drug Administration in June, 2001. The purpose of this study was to assess the efficacy of this procedure by reviewing existing literature and studying a patient population that had received Lap Band surgery. The retrospective review included information on 93 patients in the bariatric program at the University of North Texas Health Science Center at Fort Worth. The preliminary data in this study agrees with other studies, which show that the Lap Band is an effective intervention for morbidly obese patients.

BARIATRIC SURGERY AND THE

LAP BAND: AN ANALYSIS OF EFFICACY

Dave Crane, B.A., M.A.

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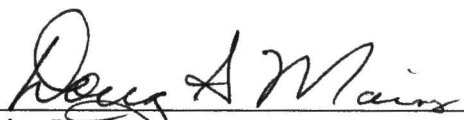

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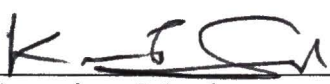

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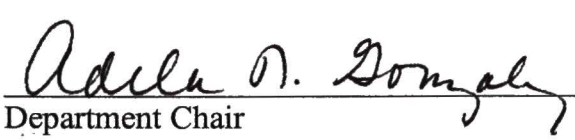

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ACKNOWLEDGMENTS

Any major undertaking such as a thesis is the end product of a network of people who have overlapping goals and an appreciation for research and accomplishment. The author wishes to thank Dr. Douglas Mains for his patience, support, and availability during the years that lead to the culmination of this paper. Thanks, also, to committee members Dr. Claudia Coggin and Dr. Karan Singh for their valuable feedback that helped in the evolution of this paper. Special thanks are due to Dr. Sam Buchanan in the Department of Surgery, for his many years of coaching, support, suggestions, and guidance.

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CHAPTER 1

INTRODUCTION TO THE STUDY

Statement of the Problem

Obesity is a complex, multifactorial condition. Current estimates are that 27% of adults are obese and an additional 34% are overweight. Although clearly genetics can play a role for some individuals, the recent increase in prevalence is attributed more to a "toxic environment" (Wadden, et al., 2002). Cultural factors have subtly encouraged higher consumption, while at the same time physical activity has decreased. The evidence is consistent that obesity has a causal relationship with medical complications such as diabetes, high blood pressure, hypertension, myocardial infarction, degenerative arthritis, and sleep apnea. Obesity is also associated with a decline in psychological health, having a negative effect on self-image and quality of life.

Typically, the goal of the obese patient seeking weight reduction is to return to his or her ideal body weight. The great majority of patients, however, return to their pre-treatment weight within three years (Cooper, et al, 2001). Note that while surgery is the modality of choice for the obese patient, a combination of approaches, including nutritional counseling, exercise, and cognitive restructuring, is optimal in treating obesity (Sarwer, et al, 1999).

Among surgical interventions, the adjustable band has become the procedure of choice (although this point is the subject of much debate in bariatric surgery societies)

because it is much less invasive, the band is removable, and recovery time is much shorter. Although issues about certain complications have been raised about the Lap Band, such as slippage (Zimmermann, et al, 2000), effect on esophageal motility (Weiss, et al, 2000), and pouch dilatation (Suter, et al, 2001), the early data on efficacy (reduced BMI, reduction of excess weight) are generally favorable (Zinzindohoue, et al, 2003). Note, however, that some studies question efficacy, especially for patients who have had placement of the band over a longer period of time (Kothari, et al, 2002).

History/Overview of Bariatric Procedures

In the last 40 years there have been more than 50 different bariatric surgeries developed for management of morbid obesity. The pioneering treatments that led to today's technology began in the 1950's, when it was discovered accidentally that cancer patients showed postoperative weight loss after portions of their stomach were removed. Current surgical treatments for obesity evolved from several procedures that have been refined for decades. The first was the jejunal-ileal bypass, in which the upper small intestine was joined to the lower part of the intestine. With this procedure, food passed through only 18 inches (rather than 20) of small intestine. The goal with this surgery was not to restrict the amount of food intake, but to actually create poor digestion so that food would pass through the digestive system before it had a chance to be absorbed. Not surprisingly, this procedure had a high complication rate due to malabsorption, and patients developed kidney and liver diseases due to the lack of nutrients. More importantly, there were patient deaths associated with this procedure, so it was abandoned.

The vertical banded gastroplasty procedure was developed in the 1960's, and it was with this procedure that the idea of restricting the size of the stomach as a means to reduce food intake was introduced. In this procedure, both a band and staples are used to create a gastric pouch in the upper part of the stomach. The small gastric pouch that was created by this procedure provided a feeling of satiety when filled, and the food would then pass through the rest of the digestive system. The vertical banded gastroplasty went through some modifications when it was found that the ideal gastric pouch size should be smaller, and when the staples in the stomach became weak after several months. There was still a high enough failure and complication rate, however, that this procedure was also abandoned in favor of vertical gastric stapling, a procedure that was introduced in 1980.

In the 1980's, gastric stapling became popular. In this procedure, the upper portion of the stomach was stapled off, but there was enough room left for food to pass through the rest of the digestive system. This allowed the patient to have a feeling of fullness with the benefits of proper nutrient absorption. Although effective in the first months, this procedure also was abandoned because patients eventually gained weight again because the opening in the stomach stretched, allowing for more food intake.

During the 1980's, another procedure, the Roux-en-Y (gastric bypass), was also developed. In this anatomy-altering procedure, the small gastric pouch is created and then rerouted and attached to the first part of the intestine. This procedure is still popular today. The Roux-en-Y combines restricted eating via a gastric pouch with dumping syndrome, which occurs when a patient eats too much fat or sugar. The last, and most recent procedure that is gaining popularity, is the Lap Band. Silicone banding has been

done in Europe for about a decade, and was approved for use in the USA in June, 2001.

Description, Development, and History of the Lap Band

The development of the Lap Band is described by its creator, Mitiku Belachew, MD, as "a dream that became a reality" (Belachew et al, 2001). The first human laparoscopic band procedure was performed on September 1, 1993 after extensive animal trials by Belachew and his team. During the early 1990's there was a laparoscopic explosion taking place, and laparoscopic adjustable silicone gastric banding (or LASGB, as it was called) introduced revolutionary advantages for the obese patient. Obese patients, because of their visceral fat and deep operative field, among other issues, are normally considered high-risk for bariatric surgery. The most important advantage was that the procedure was now minimally invasive, rather than open.

The band that was eventually developed was adjustable and could be removed if necessary. It was based on an earlier band that Lubomyr Kuzmak developed in the 1980's, which he implanted in patients using an open procedure. In the animal model, Belachew was able to resolve issues related to the band such as 1.) calibration of the band as it was fastened around the stomach; 2.) fixation of the band on itself; and 3.) ad hoc instrumentation (use of the laparoscopic tools during surgery.) Issues with the surgical technique itself were also addressed, such as retraction of the liver and omentum, and dissection of the stomach without perforation. The goals – and ultimate accomplishments – of the animal model were to develop a prototype band and to develop a standard surgical technique.

Today, the Lap Band is a product of the Inamed Health Corporation and is promoted to potential patients as a solution for long-term *sustained* weight loss. The band material is silicone, and it comes in two sizes: 9.75 centimeters and 10.0 centimeters. When the band is inserted laparoscopically, it is placed around the stomach so that a small gastric pouch is formed. The site where the band constricts the stomach is the stoma. The underlying principle is that the creation of the small pouch promotes early satiety when eating and also limits food intake because of its small size. It is recommended for patients with a BMI of at least 40 or a BMI of at least 35 with one or more severe cormorbid conditions. It is also recommended for patients who are 100 or more pounds over their ideal body weight according to the 1983 Metropolitan Life Insurance Tables (using medium-frame weight from the table for consistency). The band tubing holds saline solution that causes it to inflate and deflate. By varying the amount of the saline solution in the tubing, the pouch size and stoma diameter can be adjusted. The tubing is connected to an access port that is placed subcutaneously on or in the rectus muscle. Postoperatively, saline solution can then be injected in or removed from the tubing to adjust the pouch and stoma as needed. There are usually one to four adjustments needed per year for each patient.

Purpose

Currently, many third-party payors do not reimburse for this procedure. This can be for a number of reasons, but many payors have cited both a lack of U.S. data and concerns about efficacy of the Lap Band as their primary reasons for denial of the procedure. It is expected that as more studies are published in U.S. journals (with

favorable results assumed) that third-party payors will then be more likely to reimburse for this procedure. U.S. and European data will be reviewed in this study, as well as efficacy of the Lap Band. Efficacy in this study will be determined via a retrospective chart review of cases performed by the University of North Texas Health Science Center at Fort Worth surgeons since the inception of their program in January, 2002. The results of this study will add to the body of literature in which early results of weight loss after Lap Band surgery have been reported.

Research Question

The Lap Band was approved for use in the U.S. in June, 2001 and surgeons at the University of North Texas Health Science Center at Fort Worth Surgery Clinic were among the first to start performing the procedure (in January, 2002). Their program has multiple interventions: The primary intervention is the surgery itself, but patients are first screened by a group of psychologists as well as a nutritionist. The psychologists administer and score the Eating Inventory (EI) and the Minnesota Multiphasic Personality Inventory (MMPI) to assess patients' psychological status, and also provide postoperative therapy if needed. The psychological testing process is used to eliminate patients with significant psychopathology, but these tests are administered primarily to approve the surgery for those likely to succeed. The nutritionist provides both preoperative and postoperative counseling and instruction on proper nutrition. Generally the surgeons, psychologists, and nutritionist must all reach a consensus opinion that a patient is a good candidate for surgery. As patients return to the clinic for postoperative

followup visits, their weight is recorded. Efficacy of weight loss can be determined by subtracting the number of pounds lost from the patients' excess body weight.

The Lap Band is surrounded by problems. Although it is a safe, reversible, and less costly alternative to the Roux-en-Y procedure, there is continued debate in the bariatric community about its efficacy. The controversy dates back historically to early restrictive procedures in which patients eventually learned how to eat in a way that minimized the effectiveness of the intervention. It should be noted that patient compliance is extremely important in the followup phase after Lap Band surgery. The band can loosen, and patients who do not ask for a band adjustment can soon eat in quantities that will lead to weight gain.

Third-party payors generally do not want to pay for the Lap Band, citing the lack of U.S. data to support reimbursement for the procedure. Also, as health insurance premiums steadily rise, many employers have eliminated benefits for weight control management to keep the cost of premiums down. For patients who do not have this benefit, as well as patients who are uninsured, the cost of bariatric surgery can be prohibitive. This study will analyze data from actual cases of some of the first patients to receive the Lap Band after its FDA approval in June, 2001 and will assess the efficacy of the surgery in the early stages of postoperative care.

Hypotheses

Hypothesis 1:

The University of North Texas Health Science Center at Fort Worth Surgery Clinic patients who have had Lap Band surgery will experience a weight loss 50% or more excess weight in a twelve month period postoperatively.

Successful weight loss with the Lap Band ("efficacy" of the band) is defined as 50% or greater excess weight loss with no need for reoperation. This is an arbitrary definition of "efficacy," but one that many bariatric surgeons consider a successful indicator (Doherty, et al, 2002).

Hypothesis 2:

The University of North Texas Health Science Center at Fort Worth Surgery Clinic patients who have had Lap Band surgery will experience an average weight loss of one to two pounds per week during the postoperative period.

An average weight loss of one to two pounds per week is recommended by the providers of the program as safe and effective during the postoperative phase. This is another measure of efficacy as defined by the providers of the program and the manufacturer of the Lap Band.

Hypothesis 2 was tested by determining Ideal Weight, Excess Weight, Percent Excess Weight Loss, and Percent BMI Loss.

Definitions of Terms

ASGB: Adjustable Silicone Gastric Banding. This was an open, rather than laparoscopic, placement of the band and predates LASGB.

Bariatric Surgery: Group of surgical procedures that have the specific goal of management of obesity and the comorbidities associated with obesity.

Body Mass Index (BMI): BMI is the medical standard used to determine the exact degree of excess weight and is calculated using the following formula: Weight (in kilograms) divided height (in meters) squared. The standards are the same for men and women, but there is some controversy in this measure because it does not account for varying degrees of muscle mass.

Comorbidities: An extensive range of illnesses and diseases that are contributed to or caused by morbid obesity. Examples include diabetes, degenerative joint disease, hypertension, sleep apnea, respiratory disease, and depression. Normally, the threshold for surgical treatment of obesity is a BMI of 40, but if significant comorbidities exist the threshold is lowered to a BMI of 35.

Dumping Syndrome: Occurs when food travels a much shorter path through the digestive system after certain types of bariatric surgery, such as a partial gastrectomy or gastric bypass. Typical symptoms are nausea, diarrhea, palpitation, sweating, and overall weakness. The symptoms occur because some nutrients are now not absorbed before they reach the bowel, and these nutrients release hormones in the bowel resulting in pooling of fluids.

Excess Weight Loss: The difference between the patient's weight before surgery and the medium-frame weight ("ideal weight") as recommended by the Metropolitan Life Insurance Company's 1983 height/weight tables.

Ideal Weight: Generally, a BMI in the normal range (see table below) that is derived

from insurance statistics. In the literature, generally ideal weight is the medium-frame weight found in the Metropolitan Life Insurance Company's 1983 height/weight tables. Ideal weight is associated with actuarial estimates of relative health and survival.

Laparoscopic Surgery: Also referred to as minimally invasive surgery. Laparoscopic procedures are done using only a few half-inch incisions. Ports are placed through the incisions, and a camera and fiber-optic instruments are used by the surgeon via the ports.

LASGB: Laparoscopic Adjustable Silicone Gastric Banding, in which the band is placed inside the patient using a laparoscopic, rather than open, procedure. Laparoscopic placement introduced advantages such as adjustability, reversibility, and minimal invasiveness.

Malabsorption: The inability to absorb nutrients from food due to the shorter path through the digestive system after some types of bariatric surgeries, such as the partial gastrectomy or the gastric bypass.

Morbid Obesity: Equivalent to at least 100 pounds overweight or a body mass index

TABLE 1

Obesity, BMI, and Disease Risk

Classification of Obesity	BMI	Obesity Class	Disease Risk (Relative to Normal Weight and Weight Circumference)	
			Men < 40 in. Women < 35 in.	Men > 40 in. Women > 35 in.
Underweight	<18.5			
Normal	18.5 – 24.9			
Overweight	25.0 – 29.9		Increased	High
Obesity	30.0 – 34.9	I	High	Very High
Obesity	35.0 – 39.9	II	Very High	Very High
Extreme Obesity	>40	III	Extremely High	Extremely High

(BMI) of 40 or greater. Morbid obesity correlates to "clinically severe" or Class III obesity on the BMI scale. Generally the excess weight results in some degree of impairment of health and can considerably reduce life expectancy. Table 10 provides a classification of the level of obesity based on Body Mass Index with associated disease risk.

Stomach Stapling: An outdated term that is no longer used by bariatric surgeons. Many current procedures now involve stapling of the stomach, so this term has become too vague and nonspecific.

VBG: Vertical banded gastroplasty, in which both a band and staples are used to create a small stomach pouch in the upper stomach. Introduced the idea of restricting the size of the stomach as a means of reducing food intake.

CHAPTER 2

REVIEW OF THE LITERATURE

There are many third-party payors who will not reimburse for laparoscopic banding due to the current lack of long-term, U.S. data. There is a large body of data that has originated in Europe, where the band has been in use for the past ten years. Much of the review of the literature will include this data. There are "competing bands" in Europe, such as the Swedish adjustable gastric band (SAGB), and Mason vertical band, but only studies involving the Lap Band are included. The studies tend to review complication rates, comorbidities, and resulting weight loss after placement of the band. The common monitoring tool for efficacy of LASGB is weight loss. Weight loss is measured both as reduction in the patient's BMI and/or reduction of excess weight. Screening programs also tend to be very much alike, consisting of a multidisciplinary team of doctors and other professionals who evaluate the physical, psychological, and nutritional capacities of each patient.

The second U.S. FDA-approved clinical trial took place during March, 1999 to June, 2001. In this study by Rubenstein (2002), 63 morbidly obese patients received the Lap Band in a multidisciplinary program with frequent follow-ups. Table 2 summarizes the results from this trial:

TABLE 2

Summary of Percent Excess Weight Loss, Rubenstein (2002)

Months Post-op	% Excess Weight Loss	Range (pounds)
6	27.2	1-68
12	38.3	10-77
24	46.6	16-89
36	53.6	21-94

The number of subjects that completed the trial was 51. Band removal for 12 patients was necessary due to complications after laparoscopic placement of the band. Rubenstein concluded that LAGB was safe, and that sustainable weight loss could be maintained but that patient selection, surgical expertise, and long-term patient management after band placement were important factors that determined success of any program.

An important study by Doherty, et al (2002) found long-term studies on efficacy lacking, and subsequently did a prospective study (from March, 1992 to January, 1997) with 22 patients. Their study showed initial weight loss after placement of the band, but over a six-year period patients gradually regained most of their weight. They reported that although the procedure was "safe", over a period of several years the procedure was unsuccessful for treatment of morbid obesity. Problems they cited were: frequent reoperations needed to correct for complications, frequent vomiting, reflux esophagitis, limited solid food choices, herniation of the band, and pouch enlargements. Table 3 summarizes the resulting percent excess weight loss of the Lap band cohort:

TABLE 3

Summary of Postoperative BMI and Percent Excess Weight Loss Doherty et al., (2002)

Years Postop	0	1	2	3	4	5	6
Mean BMI	47	40	41	41	44	47	43
% Excess Weight Loss	0	27	28	25	17	21	15

These results are in sharp contrast to the many studies that found more significant weight loss over a shorter period of time after LAGB surgery.

A study by Forestieri et al., (1998) enthusiastically recommended the Lap Band as the "first choice" for gastric restriction procedures. The researchers do point out, however, that further follow-up is necessary for a complete assessment of such issues as reoperation, sustained weight loss, and long-term effects of the band, such as erosion. Their group consisted of 62 patients who underwent surgery between October 1994 and December 1996. Patients were subjected to the usual screening criteria (history and physical, specialty consult, nutritional consult, and psychological profile). Table 4 summarizes the relevant weight loss information for the patient group followed in this study:

TABLE 4

Summary of Mean and Percent Excess Weight Loss, Forestieri et al., (1998)

	3 mos.	6 mos.	12 mos.	18 mos.	24 mos.
Mean Weight Loss (lbs)	45.5	56.6	78.7	99.0	136.1
% Excess Weight Loss	29.6	36.8	51.2	64.4	88.5

In their study Belachew et al., (2002) report results gathered restropectively from three major bariatric centers in Belgium that used the Lap Band from 1993 to 1997. These researchers describe the Lap Band as a "breakthrough" because of the often-cited advantages of reversibility, adjustability, and minimally invasive surgical technique (all very important since morbidly obese patients are usually considered high-risk). They also stressed the need for long-term data as a rationale to support efficacy of this method of bariatric surgery, and they gathered data from three major centers in Belgium. Results in this study are based on a group of 763 patients who had a minimum 90% follow-up rate over a four year period. Weight loss was found to be effective and acceptable, but less than that experienced by patients who had malabsorptive procedures. Relevant statistics are summarized in Table 5:

TABLE 5

Summary of Mean BMI and Mean Excess Weight Loss, Belachew et al., (2002)

	Pre-Op	6 mos.	12 mos.	24 mos.	48 mos.
Mean BMI	42	35	32	30	30
Mean Excess Weight Loss	0	30	40	50	50-60

Zinzindohoue et al (2003) also found efficacy in the Lap Band procedure in a long-term prospective study. Their study took place between April 1997 and June 2001 and had a large group of subjects (N = 500). As with other studies, a multidisciplinary team assessed patients for physical and psychological health. Knowledge about nutrition was assessed and counseling began for this intervention. The decision to operate was reached by consensus of this group. Relevant statistics about the weight loss of this

group are summarized in Table 6. The researchers also cited other advantages of this surgery as compared to other more invasive surgeries: short hospital stay, an earlier return to work, the ability to remove the band if necessary, and fewer wound complications. Long-term management and multidisciplinary care are important for continued, sustained successful weight-loss.

TABLE 6

Summary of Mean Excess Weight Loss and Mean BMI, Zinzindohoue et al., (2003)

	Pre-Op	Year 1	Year 2	Year 3
Mean Excess Weight Loss	N/A	42.8	52.0	54.8
Mean BMI	44.3	34.2	32.8	31.9

Miller and Hell (1999) performed procedures on 102 patients between July, 1994 and August, 1998. In their study, they focused more on potential long-term complications during follow-up compared to other types of surgeries, but their results also included weight loss for this group. The authors consider the procedure the method of choice, and classified this surgery as low-risk for morbidities and effective for weight loss. Like all researchers in bariatric surgery, they emphasized that surgery was only one intervention and that other professionals, such as a psychologist and nutritionist, should be part of the program. The median BMI for their group dropped from 44 to 34 after 12 months, to 30 after 24 months, and 28 after 36 months.

Abu-Abeid and Szold (1999) studied the efficacy and safety of LASGB with a group of 391 patients. They reviewed the complications after surgery, such as band slippage, resistant port infection, longstanding pain, port migration, band repositioning,

bleeding port site and local relocation of the port, but found that rates of occurrence were acceptable. Reoperation rate after LASGB has been someone controversial, with some researchers (Doherty, et al, 2002) citing unacceptably high numbers. Abu-Abeid and Szold, however, had a rate of 6.6% reoperations which was considered acceptable. Both early and late complication rates are lower than those reported for other bariatric procedures. Table 7 summarizes weight loss for their patient group over an 18 month period:

TABLE 7

Summary of 18-Month Weight Loss, Abu-Abeid and Szold (1999)

Months	0	1	3	6	12	18
BMI	43.1	37.6	34.9	33.5	31.9	29.8

Holeczy et al (1999) report excellent preliminary results with a small group of patients (14) in Slovakia who received the Lap Band during 1997 to 1998. Although this study involves a small, early sample, it is significant because up to the time of this study bariatric surgery had not been done in Slovakia. Holeczy and his team prepared for two years for this procedure, and recruited a sample of patients with a mean age of 43 and a mean BMI of 46.2. Weight loss in the first month following surgery ranged from 19.9 to 33.2 pounds. Monthly weight losses following this averaged 6.6 to 8.8 pounds per month, and weight loss at one year after the operation averaged 60% of excess weight.

Two studies by Doldi et al., (1997, 2000) found favorable results for patients receiving LASGB. In the 1997 study, Doldi compared weight loss results over a 20 year period for five different bariatric surgeries. Mortality and morbidity issues were less

frequent for LASGB, although weight loss occurred more slowly. Still, his research group considered LASGB the procedure that was the most versatile and least traumatic for patients to accept since there is no anatomical consequence. In the second study, Doldi and his group placed Lap Bands in a group of 172 patients over a five-year period. Although this study does center more on complications related to the surgery, results showed an effective and acceptable weight loss in these patients with a mean weight loss of 30.2% three years after surgery. For the same period, the percent excess weight loss for this group was 62.5% and BMI decreased 29.5%. Overall, 97.8% of the patients in the group experienced a satisfactory, or significant, weight loss.

Meucci et al (1997) found gastric banding to be the first bariatric procedure choice for patients for a number of reasons, including the effective weight loss results. Their 62-patient sample underwent surgery from October 1994 to December, 1996 and had a postoperative evaluation at 1, 2, 3, 6, 12, and 24 months with a 100% follow-up rate. Table 8 summarizes mean weight loss for their group of patients over a period of 24 months:

TABLE 8

Summary of Mean Weight Loss and Mean Percent Excess Weight Loss, Meucci et al., (1997)

Months	3	6	12	18	24
Mean Weight Loss (pounds)	45.5	56.6	78.7	99.0	136.1
Mean % Excess Weight Loss	29.6%	36.8%	51.2%	64.4%	88.5%

Two studies (Heindorff et al, 1997; Miller and Hell, 1997) deserve inclusion since, unlike most studies on the Lap Band, a traditional experimental method

(randomized study with pre and post test comparisons) was used. Heindorff et al compared two groups of obese patients. Eight were randomly assigned to operative treatment with the Lap Band, and another group of eight was randomly assigned to a dietary group. At the end of 40 weeks, the Lap Band patients had lost an average of 57.5 pounds, while the dietary group gained a small amount of weight (an average of 2.21 pounds). In the Miller and Hell study, the Lap Band was compared to the Swedish Adjustable Gastric Band (SAGB) in a prospective ramdomized study. A group of 15 morbidly obese patients received the Lap Band, and a second group of 12 received the SAGB. Although, admittedly, the experimental groups were small, the study found both bands to be effective with essentially the same results in weight loss and complication rates.

Dargent & Zimmerman (1998) answer an important question in their study that compares postoperative results for morbidly obese and superobese (BMI above 50). Their study evaluated 716 patients who received the Lap Band from April 1996 to November 1997. 640 in this group were morbidly obese and 76 were superobese. After 18 months of followup the morbidly obese group had an average excess weight loss of 64% and the superobese group had an average excess weight loss of 68%.

Finally, two recent studies address a concern by critics of adjustable laparoscopic banding. Oria (2002) found in a systematic review of the literature on adjustable laparoscopic banding that the enthusium of the bariatric community about the Lap Band and other adjustable bands is based on inadequate information. Oria recommended larger patient samples (greater than 200) and longer follow-up time before any definitive

conclusions could be made about efficacy of adjustable gastric banding. Belachew et al (2002) summarized results for 763 patients who received the Lap Band in three different surgical centers in Belgium. The minimum follow-up time for this group was four years, and follow-up rate was 90%. The average preoperative BMI was 42, and four years after surgery mean BMI was 30. Weiner et al (2003), in their analysis of eight years of data (note that the median follow-up time for the group was 55.5 months, with the first 100 cases having a follow-up time of 98.9 months) mean excess weight loss was 59.3%. Overall, BMI decreased from 46.8 to 32.3.

The total number of patients involved in the studies by these researchers totals 8,677 as summarized in Table 9. Overlap of data on patients has been kept to a minimum (a few studies, such as those by O'Brien below, include results from previous studies.) Note that often, in theshort-term studies, the researchers noted that long-term followup was needed in order to make a valid assessment of the efficacy of the Lap Band.

TABLE 9

Summary of Review of Literature

Researcher	Year	Sample Size	Timeline	Country	Results
Abu-Abeid, et al	1999	391	Intermediate	Israel	Effective
Alvarez-Cordero, et al	1998	170	Short-Term	Mexico	Effective
Angrisani, et al	2000	1061	Intermediate	Italy	Effective
Belachew, et al	2002	763	Long-Term	Belgium	Effective
Castillo, et al	1997	50	Short-Term	Mexico	Effective
Chevallier, et al	1999	150	Short-Term	France	Effective
Coskun, et al	2003	70	Intermediate	Turkey	Effective
Dargent et al	1998	716	Short-Term	France	Effective
De Luca, et al	2000	69	Intermediate	Italy	Effective
De Jonge, et al	1999	56	Short-Term	Netherlands	Effective
Doldi, et al	2000	172	Long-Term	Italy	Effective
Doherty, et al	2002	62	Long-Term	U.S.	Not Effective
Favretti, et al	1999	509	Long-Term	Belgium	Effective
Fielding	2000	620	Intermediate	Australia	Effective
Forestieri, et al	1998	62	Short-Term	Italy	Effective
Holeczy, et al	1999	14	Short-Term	Slovakia	Effective
Heindorff, et al	1997	8	Short-Term	Denmark	Effective
Mazarguil, et al	1997	60	Intermediate	France	Effective
Mazarguil, et al	1998	250	Short-Term	France	Effective
Meucci, et al	1997	62	Short-Term	Italy	Effective
Miller, et al	1997	15	Short-Term	Austria	Effective
Miller, et al	1999	102	Long-Term	Austria	Effective
O'Brien, et al	1998	350	Intermediate	Australia	Effective
O'Brien et al	2002	709	Long-term	Australia	Effective
Natalini, et al	1997	204	Short-Term	Italy	Effective
Nowara	2001	108	Short-Term	Egypt	Effective
Paganini, et al	1998	37	Intermediate	Italy	Effective
Paganelli, et al	2000	156	Intermediate	Italy	Effective
Rubenstein, et al	2002	63	Short-Term	U.S.	Effective
Suter, et al	1998	76	Short-Term	Switzerland	Effective
Turicchia, et al	1999	58	Intermediate	Italy	Effective
Weiner, et al	2003	952	Long-Term	Germany	Effective
Zinzindohoue, et al	2003	500	Long-Term	France	Effective

Short-Term = < two years, Intermediate = 2 – 4 years, Long-Term = > 4 years.

CHAPTER 3

RESEARCH DESIGN AND MATERIALS

Data Sources

Lap Band surgery has been offered to patients at the University of North Texas Health Science Center at Fort Worth Surgery Clinic since January, 2002. Cases began as early as December 2001, however, because the surgeons in the program began doing cases at that time so they could be proctored for the procedure. By September, 2003, 93 patients had elective surgery for the Lap Band in the program. The medical charts for these 93 patients comprise the database for this study.

Protection of Human Subjects

The Institutional Review Board of the University of North Texas Health Science Center at Fort Worth granted exempt status for this study. The data for the study come from a secondary source (patient medical records) and did not require a consent form. Disclosure of patient information is extremely minimal because of the control exercised by the researchers during data collection and analysis.

Measurement/Instrumentation

Data gathered from the medical records for the patients in the program was entered into Excel for analysis. Information was de-identified to protect the confidentiality of each patient. Information will be analyzed and reported in aggregate form, also to protect the identities of the patients.

Inclusion and Exclusion Criteria

The subjects are male and female, 18 years and older. If a medical record could be located for any of the 93 patients who had surgery during the period of December 2001 to September 2003, the data was recorded for the study. Lap Band surgery is not offered to patients under the age of 18, so there are no results for children in the study.

All 93 charts were located and the information was recorded during the data collection phase. Information from all 93 patients was used for purposes of reporting demographic data and data on comorbidities. Inclusion for data analysis to determine efficacy of the Lap Band, however, was limited to patients who had entered the program on or before November 30, 2002. This would allow a sufficient amount of time (a minimum of 11 months) to trend the percent of excess weight loss and percent of excess BMI loss.

Statistical Analysis

Excel was used to analyze the data to provide demographic information and descriptive statistics. In the data collection phase, the following information was recorded for each patient:

- Gender
- Age
- Race
- Marital status
- Height (height was recorded by clinic staff in feet/inches, and this was converted to meters for assessment of BMI)

- Weight – both the patient's pre-operative weight and each successive recorded post-operative weight. The associated dates of these measurements were also recorded. Weight was recorded by clinic staff in pounds, and this was also converted to kilograms to assess the patient's BMI.
- BMI (both pre-operative and post-operative)
- Comorbidities

The following were determined based on the information recorded in the data collection phase:

- Ideal Weight
  - Source: The 1983 Metropolitan Insurance height and weight tables. Ideal weight in the table is associated with height and is expressed as a range. The midpoint weight was selected as the ideal weight.
- Excess Weight
  - Formula: Actual Weight – Ideal Weight
- Percent Excess Weight Loss (%EWL)
  - Formula:

    [(Operative Weight – Follow-up Weight) / Operative Excess Weight] x 100
- Percent BMI Loss
  - Formula:

    [(Operative BMI – Follow-up BMI) / Operative BMI] x 100

Hypotheses

Hypothesis 1:

The University of North Texas Health Science Center at Fort Worth Surgery Clinic patients who have had Lap Band surgery will experience a weight loss 50% or more excess weight in a twelve month period postoperatively.

Successful weight loss with the Lap Band ("efficacy" of the band) is defined as 50% or greater excess weight loss with no need for reoperation. This is an arbitrary definition of "efficacy," but one that many bariatric surgeons consider a successful indicator (Doherty et al., 2002).

Hypothesis 2:

The University of North Texas Health Science Center at Fort Worth Surgery Clinic patients who have had Lap Band surgery will experience an average weight loss of one to two pounds per week during the postoperative period.

An average weight loss of one to two pounds per week is recommended by the providers of the program as safe and effective during the postoperative phase. This is another measure of efficacy as defined by the providers of the program and the manufacturer of the Lap Band.

Hypothesis 2 was tested by determining Ideal Weight, Excess Weight, Percent Excess Weight Loss, and Percent BMI Loss.

CHAPTER 4

RESULTS

Description of the Sample

Information was recorded on 93 patients during the data collection phase. All demographic data have been included in Table 10, although there are a few

TABLE 10

Summary of Demographic Information (All Patients)

Gender, N = 93	Male 15	Female 78			
Age, N = 93	Range 23-68	Mean 43.9	Median 44		
Race, N = 91	Caucasian 80	Black 5	Hispanic 5	Asian 1	
Marital Status, N = 93	Married 59	Divorced 17	Single 12	Widowed 3	Separated 2

exceptions, such as when a patient did not complete "Race" or "Marital Status" on the patient information form.) All patients are included so that a higher N can be used to establish a profile of the typical patient seeking bariatric surgery. Of the total sample, data for 20 patients have been included for analysis of efficacy of the Lap Band. The rationale for this is that the minimum time to establish efficacy is 10 to 12 months. There

were 31 patients who in this group, but 11 were lost to follow-up (defined as zero visits in the six months prior to the cut off date) resulting in the group of 20 patients.

The patient sample is predominantly white (86%), female (84%), and married (63%). The mean age for this group of patients is 43.9, although there is a wide range (23 years old to 68 years old). Minority groups are underrepresented (5.3%, 5.3%, and 1.0% for Blacks, Hispanics, and Asians, respectively). As in other bariatric studies, men represent a minority of patients seeking surgery (16%).

TABLE 11

Height, Weight, and BMI (Pre-operative)

N = 93	Men-Mean	Women-Mean	All Subjects-Mean
Height	5 feet, 11 inches	5 feet, 3.9 inches	N/A
Weight	345.3 pounds	279.1 pounds	N/A
BMI	47.1	46.6	46.7

As can be seen in Table 11, the average preoperative male patients typically weigh more than the average female patients (345.3 pounds compared to 279.1 pounds), but the mean BMI for male and female patients is essentially equivalent (47.1 for men compared to 46.6 for women).

The patient sample is predominantly white (90%), female (80%), and married (65%). The mean age for this group of patients is 46.8, although there is a wide range (26 years old to 66 years old). Minority groups are underrepresented (only 10% for Hispanics. Blacks and Asians are not represented). As in other bariatric studies, men represent a minority of patients seeking surgery (20%). (See Table 12 for a summary of these results).

TABLE 12

Summary of Demographic Information (Efficacy Group)

Gender, N = 20		Male 4		Female 16	
Age, N = 20	Range 26-66		Mean 46.8	Median 47	
Race, N = 20	Caucasian 18	Black 0	Hispanic 2	Asian 0	
Marital Status, N = 20	Married 13	Divorced 3	Single 3	Widowed 0	Separated 1

TABLE 13

Height, Weight, and BMI (Pre-operative)

N = 20	Men-Mean	Women-Mean	All Subjects-Mean
Height	5 feet, 11.3 inches	5 feet, 6.1 inches	N/A
Weight	319.5 pounds	271.1 pounds	N/A
BMI	43.9	42.7	43.4

Preoperatively, the average male patients typically weigh more than the average female patients (319.5 pounds compared to 271.1 pounds), but there is only a small difference between the mean BMI for male and female patients (43.9 for men compared to 42.7 for women).

TABLE 14

Weight and BMI (Post-operative)

N = 20	Men-Mean	Women-Mean	All Subjects-Mean
Weight	259.0 pounds	215.2 pounds	N/A
Average pounds lost	60.6	55.9	56.9
Pounds lost per week	1.2	1.13	1.15
BMI	37.5	35.8	36.1
%BMI Lost	14.6	17.2	16.7

Note that in Table 14 although men lost slightly more weight (an average of 60.6 pounds compared to 55.9 for women), women outperformed men on the BMI. This is expressed another way in Table 15:

TABLE 15

Percent Excess Weight Loss

N=20	Men-Mean	Women-Mean	All Subjects-Mean
Excess Weight	158.3 pounds	132.5 pounds	137.6 pounds
% Excess Weight Loss	38.3%	42.2%	41.3%

Although overall there was a weight loss between one and two pounds per week, there were seven cases where weight loss was less than one pound per week. Six of these patients were female, and one was male. There were seven cases where patients lost more than 50% of their excess weight. In this group, six patients were female and one was female.

CHAPTER 5

DISCUSSION

Conclusion

Much of the demographic information for this sample is congruent with that of other programs. For example, bariatric programs:

- Have more female than male patients
- Are underrepresented by Black, Hispanic, and Asian patients
- Have a patient population with a mean age in the upper-thirties to the mid-forties

Also, the mean BMI for the present sample, at 46.7, was also similar to that of other programs where the mean BMI tends to be in the mid-forties.

The decrease in pounds lost and the decrease in BMI for both male and female patients indicate dramatic weight loss for those patients in the program who remained compliant. Hypothesis 1 (The UNT Health Science Center Surgery Clinic patients who have had Lap Band surgery will experience a weight loss 50% or more excess weight in a twelve month period postoperatively) is supported by seven cases in 20 in which the patient did lose more than 50% excess weight before the end of the first year with the Lap Band. Other patients in this group were approaching this goal. Hypothesis 2 (The UNT Health Science Center Surgery Clinic patients who have had Lap Band surgery will experience an average weight loss of one to two pounds per week during the

postoperative period) is supported by 14 cases in 20 in which patients lost more than one pound per week. This is a 70% success rate and this amount of weight loss is also the stated goal of the program.

Criticisms of the BMI and 1983 Metropolitan Table Measurements

In their recent review of these measurements, Deitel & Green (2003) found both strengths and weaknesses. The Ideal Weight measurements are actuarial estimates of mortality based on height and weight. The information is derived from the pooled data of 4.2 million individuals from various life insurance companies in the U.S. and Canada. Metropolitan's table actually originated with the 1979 Build Study, which was a mortality study with an 18-year history of life expectancy associated with ideal weight. In the last 20 years there have been a number of criticisms that have accumulated about the Metropolitan Tables:

- The tables are based on a population that purchases insurance, and minorities are underrepresented in this population
- 10% of the data on weights in the table were self-reported by respondents in the study
- Socioeconomically, the tables are skewed because the population studied has a higher socioeconomic status that the general population
- Weights reported for the table included clothing, which could have led to Inaccuracies
- Respondents who had a major disease were excluded from the study

These criticisms are valid and substantial, but the greatest strength of the study is its large

subject pool of 4.2 million that has not been equaled in the last 20 years. For that reason the Metropolitan Table is still widely used. BMI is considered an accurate measure of relative "fatness" but studies using the BMI historically have had patient populations of 30,000 or less. Also, BMI can be an inaccurate measure for individuals with muscle mass that is higher than normal. Bodybuilders and others in sports that build muscle mass can be very healthy, but the BMI classifies them as morbidly obese. This is seen as a flaw in the BMI measurement system.

Limitations

Long-term follow-up of obese patient groups can be difficult (Denoel, et al, 1998) due to the immediate short-term results of significant weight loss. After the initial success following surgery, many patients become noncompliant and do not return for followup. Weight loss tends to be rapid in the first few months following surgery, and then stabilizes up until about two years after surgery, depending on the initial weight of the patient. In the sample from this retrospective study, there was a noncompliance rate of 35%. (There were 11 patients out of a possible 31 who did not follow-up for more than six months). This probably occurred, however, because this group of patients was not part of a formal study in which they were either paid or were aware that the results of their progress might be evaluated for a study. The resulting sample size is somewhat small (20 patients) and only four of these are male. The small sample size may not provide significance of efficacy in the statistical sense but can provide insight into the relative success of the program.

Recommendations

The noncompliance rate in this bariatric surgery program appears to be excessive, and it could be beneficial for the providers or clinic management to contact these patients to find out why they dropped out of the program. This information could improve patient care if patients report issues related to providers, or it could indicate problems with the administration of the program if patients report problems with access or insurance issues. A contract with each patient that explicitly states expectations about follow-up after surgery may also reinforce compliance.

Information about the success rate of this program should be sent to area insurance plans that have a history of poor or no reimbursement for this procedure. There are obvious mutual benefits for both the patient and the insurance plan when the patient is able to successfully lose weight for an extended period of time. This study, and most other studies, provide preliminary and/or intermediate data. It will be important for researchers to continue to follow the progress of laparoscopic adjustable gastric banding surgery for the long term to establish that the benefit of this procedure is permanent, rather than temporary.

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