Effectiveness of LAGB on Obese Diabetic Patients

Kathryn M. Mayhew

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Abstract
Background: Obesity, and therefore diabetes, is an ever growing problem in worldwide healthcare. As weight loss is critical in controlling blood sugar levels, more patients are turning to bariatric surgery after failing conventional weight loss methods. Gastric bypass, as the most commonly performed bariatric surgery, has been shown to be effective in glycemic control and even diabetes resolution. Laparoscopic adjustable gastric banding, however, is becoming more prevalent and its effects on diabetes and serum glucose levels have not been studied as extensively as gastric bypass.

Hypothesis: LAGB is an effective method of glycemic control in obese, diabetic patients. Study Design: Exhaustive search of available medical literature.

Methods: Literature search of Medline OVID, CINHAL, and WebScience using the keywords "gastric banding", "diabetes", "impaired glucose tolerance", and "glucose control".

Results: All studies confirmed LAGB is effective in weight loss and glycemic control with a majority of patients achieving diabetes resolution one year post surgery.

Conclusion: LAGB should be considered as a treatment for obese diabetic patients. Preliminary evidence suggests consideration for pre-diabetics and patients below the NIH recommended guidelines of BMI ≥40 or ≥ 35 with co-morbidities should also be considered as a preventative measure.
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The student authors attest that this work is completely their original authorship and that no material in this work has been plagiarized, fabricated or incorrectly attributed.
Effectiveness of LAGB on Obese Diabetic Patients

Kathryn M. Mayhew

A Clinical Graduate Project Submitted to the Faculty of the
School of Physician Assistant Studies
Pacific University
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For the Masters of Science Degree, August 15, 2009

Faculty Advisor: Judy Ortiz, PA-C
Clinical Graduate Project Coordinators: Rob Rosenow PharmD, OD & Annjanette Sommers MS, PAC
Biography

Kathryn Mayhew was born and raised in southern Oregon and attended college at George Fox University. She graduated with a B.S. in Biology and minor in Chemistry in 1998. Before deciding to become a Physician Assistant, she worked in research at Oregon Health & Science University studying hypoxic ischemia in ovine and murine models. Following this, she worked as an autopsy assistant and certified nursing assistant.
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**Keywords:** Laparoscopic adjustable gastric banding, diabetes, glycemic control.
Acknowledgements

To my husband Mike Mayhew. Your patience, love, and support have made this an exceedingly easier experience than it could have been. I owe you lots of back rubs and dish duty baby!

To my extended family, thank you for cheering me on. I hope to make you proud.

To my classmates. You inspired me and motivated me when I was ready to break equipment or scream.
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Table 1 : Changes in BMI, Fasting Blood Sugar levels, and HbA1c post LAGB

List of Abbreviations

%EWL: % Excess weight loss
BMI: Body mass index
FBS: Fasting blood sugar
FDA: Food and Drug Administration
HbA1c: Hemoglobin A1c
LAGB: Laparoscopic adjustable gastric banding
NIH: National Institute of Health
T2DM: Type 2 Diabetes Mellitus
Effectiveness of LAGB on Obese Diabetic Patients

Introduction

The World Health Organization estimates that by the year 2015 there will be 2.3 billion overweight and 700 million obese adults in the world\(^1\). As it is an independent risk factor for Type 2 Diabetes Mellitus (T2DM) and is associated with other comorbidities such as hypertension, osteoarthritis, GERD, and depression, obesity has become a major health problem in American society\(^2,3\). With over half of diabetics being obese and approximately 9% having a body mass index (BMI) of >40, or severely obese, this population requires special consideration\(^3,4\). In fact, according to Brancatisano et al., obesity combined with T2DM can increase mortality by 45-55% in a five year period\(^3\).

First line treatment is, of course, weight loss which has been shown to be highly effective in managing glucose levels and in increasing insulin sensitivity\(^5\). Newly diagnosed patients are counseled by clinicians on diet and in restricting caloric intake to reduce fasting blood sugars (FBS), thereby preventing complications. For most patients, this means drastic changes in eating and exercise habits. Observational experience and research trials have demonstrated that continued weight loss or long term maintenance of weight loss is extremely difficult outside a clinically structured program with patient accountability\(^6\) and even those have only modest success\(^7\). In many cases, patients are not only fighting physiological accommodations of chronic overeating but also psychologically compelling impetus.

Therefore, in extreme cases, additional methods must be used to acquire desired results. A treatment increasing in popularity for weight loss is bariatric surgery. Multiple studies on this topic have demonstrated positive effects on quality of life and diabetic
outcomes. However, there are two different procedural methods of bariatric surgery: malabsorptive, such as the Roux-en-Y gastric bypass, and restrictive, such as laparoscopic adjustable gastric banding. Most studies up to this point have looked at gastric bypass or bypass and banding combined, only a few have studied banding alone.

The Roux-en-Y procedure is the oldest FDA approved method and is currently the most commonly performed in the US. Here, the surgeon staples a portion of the stomach then reroutes the small intestine to bypass the first several centimeters. This reduces the size of the stomach, limiting the amount of possible food intake, and decreases absorption once the food is processed.

Laparoscopic adjustable gastric banding (LAGB) was approved in 2001 by the Food and Drug Administration (FDA), but was practiced in Europe several years earlier. In this procedure, the surgeon creates 3-6, 3cm incisions in the patient’s abdomen to insert laparoscopic equipment. An inflatable band is then placed around the proximal antrum of the stomach. The band can be inflated or deflated in a clinic setting, as desired, to restrict food intake.

Statistically, the Roux-en-Y is the most effective method of producing sustained weight loss. However, it carries a greater risk of morbidity and mortality than LAGB (2.6% vs. 0%) and is associated with serious nutritional deficiencies due to the decreased absorption. While it can be performed laparoscopically, the Roux-en-Y procedure is occasionally converted to an incisional surgery. LAGB, on the other hand, is rarely converted and is a reversible procedure. Logistics are also in favor of LAGB. Generally, gastric banding means a shorter time on the operating table as well as a quicker discharge. For these reasons, LAGB is the most commonly performed bariatric
surgery worldwide and is rapidly replacing gastric bypass as the favored surgery in the U.S\textsuperscript{13}. However, as far as this researcher could gather, there is no systematic review of LAGB alone and its effects on diabetes.

As FBS and Hemoglobin A\textsubscript{1c} (HbA\textsubscript{1c}) are the measures used in a clinic setting to diagnose or monitor T2DM, these will be used as the objective data to determine if LAGB is effective in controlling diabetes in obese patients. The results of this research could change personal recommendations and treatments to patients in primary care settings.

\textbf{Methods}

CINHAL, OVID and WebScience were searched using the keywords “gastric banding”, “diabetes”, “impaired glucose tolerance”, and “glucose control”. Some articles were also selected from the reference sections of key articles. Each article was critically appraised.

Inclusion criteria included: any primary article directly addressing the effects of laparoscopic adjustable gastric banding performed on obese or morbidly obese human patients with diabetes. As FBS and HbA\textsubscript{1c} are the primary measures of glycemic control, the articles were also required to have these numbers in the follow up data at least one year post operation in order to address long term effects. Exclusion criteria included: abstracts only, an article not being written in English, or being older than 10 years, or review articles. One article was excluded due to data being reported in graph form without clear numerical values assigned to data points. One article scored less than 3 out of 5 on the therapy analysis validation form and therefore was not used.

\textbf{Results}
Dixon and O’Brien studied 50 severely obese (BMI > 35) diabetic patients who had attempted other methods of weight reduction for at least 5 years before presenting to a surgeon for LAGB. One year later, BMI dropped from 48.2 to 38.7 with a % excess weight loss (%EWL) of 38%. Fasting plasma glucose decreased from 169.2 mg/dL to 111.6 mg/dL. HbA1c levels also declined from 7.8 to 6.2%. Dixon and O’Brien did not record numerical data for the number of patients able to discontinue their medications but did note a “major reduction” in oral hypoglycemic use.14

Six years later, Dixon et al. expounded on their findings from the previous study and created the only randomized control trial of obese, recently diagnosed (≤ 5 years), diabetic patients, contrasting LAGB with conventional therapy. Conventional therapy consisted of individually structured lifestyle modification programs (diet and exercise), medical therapies determined by an experienced diabetologist, and regular six week visits. All reported data was acquired two years post-operation. This group had the lowest preoperative average BMI of all six studies at 37 due to the inclusion of 13/60 patients with a BMI less than 35. These 13 were equally distributed between the surgical and control groups. The surgical arm of this study achieved an average of 62.5% EWL. HbA1c baseline average was 7.8%, two years later it was 6.0%. 80% of participants reached targeted HbA1c levels which was a statistically significant improvement from baseline. Plasma glucose decreased by 51.2 mg/dL from 156.7 mg/dL to 105.6 mg/dL (see Table 1). Metformin and insulin use also decreased in that same time period.15

Brancatisano et al. prospectively studied 78 obese diabetics who fit the NIH requirements for bariatric surgery. This study also reported significant decreases in BMI, HbA1c and glucose in the 12.5 months post surgery. T2DM patients demonstrated 38%
EWL and decreased BMI from 47 to 38. Average HbA1c went from 8.0 to 6.1%. Serum glucose fell from 172.8 to 102.6 mg/dL. Here too, a significant percentage of the population was able to discontinue or reduce oral hypoglycemic and insulin use³.

Ponce et al. excluded diabetics not on medications from their study in order to directly research effects of LAGB on medication use. BMI decreased from 48.7 to 38.2 at twelve months and to 38.4 at 24 months. %EWL measured 39% at 12 months and 52.6% at 24 months. HbA1c measured 7.25% then fell to 5.87% at one year and 5.58% at two years. Serum glucose levels were not reported. At the one year data point, 66% of the 53 T2DM patients were off all medications. By the second year, 80% had discontinued⁴.

In 2005, Pontiroli et al. published a study specifically oriented towards LAGB in the morbidly obese (BMI > 40) and its influence on diabetes remission. In it, they reported a BMI decrease from 48.3 to 41.9 at one year and 41.1 at two years with data continuing up to four years. HbA1c was reduced from 9.4% to 5.9% in the first year and by the fourth year it was down to 5.3%. Serum glucose levels and %EWL were not reported¹².

Singhal et al. had the largest study group with 122 obese diabetic subjects undergoing LAGB. Changes in BMI were not reported but %EWL at one year was 34.3%. FBS dropped from 163.8 to 124.2 mg/dL. HbA1c changed from 8.2 to 7.4% and all post surgical values were considered statistically significant. This article did report on the number of patients able to discontinue or decrease medications, however, the data was broken down into individual drug statistics. With patients on multiple therapies at one time, it is impossible to determine the total percentage of subjects discontinuing all
medications. However, each individual drug was decreased or discontinued to a statistically significant level\textsuperscript{16}.

\textbf{Discussion}

Only studies reporting data at least one year post surgery were included in this analysis. While there are undeniable benefits to short term glycemic improvements, diabetes is a chronic illness requiring constant monitoring. A treatment capable of controlling FBS on a long term basis is essential.

Lifestyle modifications, such as diet and exercise, are first line in prevention and control of T2DM. Barnard et al. contrasted an American Diabetes Association (ADA) recommended diet vs. a vegan diet for glycemic control and reported a 0.14\% and 0.34\% decrease in HbA1c respectively in a 74 week period\textsuperscript{17}. Other studies report decreased insulin use or even discontinuation in a majority of their diet therapy patients\textsuperscript{18}. Non medical, non surgical methods can work.

However, all diet studies required extreme changes in subjects’ eating habits and strict control of fiber, carbohydrate, and animal fat intake. The majority of studies consisted of regular interventional groups lead by physicians, dieticians, and/or cooking instructors\textsuperscript{17,19}. In many cases they included structured exercise plans as well. To expect the average person to follow such a rigorous regimen without support and accountability is unreasonable. In fact, Meneghini states that 95\% of patients not involved “in a prevention research study are unable to achieve and maintain any significant weight loss over time”\textsuperscript{10}.

When compared to surgical therapies, diet alone falls short of enabling patients to reach target BMIs and therefore FBS or HbA1c. In Dixon et al.’s study comparing
LAGB to diet therapy, not only did patients lose a significantly lower percentage of excess weight than their surgical counterparts (1.4% vs. 20%) but, as time passed, the patients were unable to maintain their weight loss\textsuperscript{15}. Pontiroli et al., in 2002 reported diet-treated patients as obtaining a lower BMI than LAGB patients at six and nine months but by month twelve, average BMI had returned almost to baseline for the dietary group while LAGB treated subjects continued to lose weight\textsuperscript{12}. Modest weight reduction is difficult to obtain with nonsurgical methods\textsuperscript{14}. Therefore, as glycemic control is directly linked with \%EWL\textsuperscript{3,11,15}, if unable to maintain weight loss, diabetic patients will never attain remission.

Medications are second line for T2DM treatment. However, as with all chronic diseases, there is physical deterioration over time. In diabetics, pancreatic function gradually fails and glycemic control becomes more difficult\textsuperscript{14}. In a study published in 1999, Turner et al. showed that oral hypoglycemic medication, when used as monotherapy, would improve the HbA1c of diabetic patients 2-3 times better than diet alone. After three years, only 50% of these patients could sustain a HbA1c in normal range (<7.0%) on monotherapy and by nine years, only 25% could maintain a normal HbA1c. As the disease progresses, multiple therapies become critical to achieving target levels. Eventually, a patient can be taking several oral hypoglycemics and insulin but remains hyperglycemic\textsuperscript{20}.

With that in mind, LAGB proves itself to be a highly effective method of long term diabetes control. The studies analyzed here demonstrate substantial decrease and long term maintenance of fasting serum glucose levels and HbA1c at several years post LAGB surgery. The Swedish Obese Subjects Study has shown bariatric surgery,
including LAGB, to be effective in weight reduction for at least ten years\textsuperscript{21}. Theoretically, the sequelae of this weight loss continue to be effective as well.

Diabetes remission in three of the five articles was defined as exceptional glycemic control with HbA1c below 6.0\% and cessation of all medications\textsuperscript{3,4,15}. Dixon et al.’s 2008 study had a 76\% remission rate at two years\textsuperscript{15}. Ponce et al. reported remission increasing with time- 66\% at one year, 80\% at two years and, of the 3 patients who continued follow up to three years, 100\% were in remission\textsuperscript{4}. Brancatisano et al. reported a 43\% complete remission of diabetes after 12.5 months\textsuperscript{3}. Dixon and O’Brien’s initial 2002 study defined remission as exceptional glycemic control but omitted the discontinuation of medication criterion. This study reported a 64\% remission rate at one year\textsuperscript{14}. Pontiroli and associates did not define remission but reported it at 45\%, again at one year\textsuperscript{22}. Singhal et al. did not mention remission specifically but did report 93\% of patients significantly reducing FBS and 75\% improving HbA1c at the end of one year\textsuperscript{16}.

If reporting the number of patients able to decrease their medications plus the number of patients who discontinued completely, the percentages go up significantly. In some cases, it doubles\textsuperscript{3,22}. Even studies not directly measuring FBS or HbA1c support these findings by reporting a decrease in oral hypoglycemic use, with a significant percentage of patients discontinuing medications entirely\textsuperscript{23-26}.

With bariatric surgery being the only effective, long term treatment for diabetes in a majority of patients, it should be considered more often by primary care clinicians for obese diabetics. Several investigators have noted diabetics tend to lose less weight than non diabetics\textsuperscript{3,4,14}, making their ability to control FBS without surgical intervention even
less likely. Therefore, LAGB, as the preferred method of bariatric surgery, is a logical treatment option for these patients.

One interesting incidental finding noted in several studies is that the time from diagnosis to treatment seems to make a difference in patients’ remission rates. Brancatisano et al. reported a direct correlation linking the interval between T2DM diagnosis and surgical treatment to the likelihood of remission. 73% of LAGB patients who had been diagnosed less than five years had resolution compared to 27% of patients who had had T2DM for more than five years. According to this, if treated within five years of diagnosis, a patient is 6.5 times more likely to go into remission. Ponce et al. in 2004 and Dixon and O’Brien in 2002 support this finding, creating a strong argument for prompt surgical intervention in morbidly obese T2DM patients.

Preliminary studies indicate that not only is LAGB capable of causing remission in diabetics but it also prevents the development of diabetes in obese patients. Therefore, as LAGB seems to provide effective preventative treatment, clinicians may want to consider this therapy earlier than guidelines recommend. Current NIH guidelines for bariatric surgery are patients with a BMI $\geq 40$ or a BMI $\geq 35$ with obesity related co-morbidities, including diabetes. In order to challenge these recommendations, O’Brien et al. created a randomized control study on diabetic patients with a BMI of 30-35 kg/m$^2$. Once again, LAGB patients demonstrated a significant decrease in excess weight and superior glycemic control over medically managed patients.

If LAGB can prevent a chronic disease and improve overall quality of life, the topic of when bariatric surgery is performed should be readdressed. Although NIH criteria for bariatric surgery are set based on a risk to benefit ratio, with LAGB
decreasing the mortality rate established by gastric bypass and the obvious preventative and curative benefits of bariatric surgery in obese diabetic patients with co-morbidities, these criteria should be reconsidered in select patients.

**Conclusion**

LAGB is an effective method of long term diabetic control. With the strong evidence towards remission and prevention of diabetes, primary care clinicians should consider LAGB during treatment of obese patients.
References


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<td>Dixon and O’Brien</td>
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<td>Ponce, J</td>
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