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Is Laparoscopic Gastric Banding an Effective Treatment for Obesity in Adolescents and Adults as Measured by Physical Function?

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A SELECTIVE EVIDENCE BASED MEDICINE
REVIEW
In Partial Fulfillment of the Requirements For
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In
Health Sciences-Physician Assistant

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not “Is laparoscopic gastric banding an effective treatment for obesity in adolescents and adults as measured by physical functioning?”

STUDY DESIGN: Review of all English language primary studies from 2009, 2010, and 2011.

DATA SOURCES: Two randomized control trials and one cohort study were found using PubMed, Medline, and OVID

OUTCOMES MEASURED: There were multiple outcomes measured in the studies but the outcome of concern is quality of life post-operatively, specifically, physical functioning as measured by surveys including SF-36, Moorehead-Ardelt, BAROS, and CHQ CF-50.

RESULTS: In a randomized control trial (RCT) by Nguyen et al. they found using those patients that underwent gastric banding had an increase in physical function compared to pre-operative measurements using the SF-36 survey. The O’Brien et al. RCT also found that patients who underwent gastric banding had an increase in physical function compared to pre-operative data using the CHQ CF-50 survey. The Silberhumer et al. cohort study found the similar results as the two RCTs using the Moorehead-Ardelt and BAROS surveys to collect their information.

CONCLUSIONS: Both randomized control trials and the cohort study included in this selective review indicate that laparoscopic gastric banding is an effective treatment for obesity in adolescents and adults when looking at physical function

KEY WORDS: laparoscopic gastric banding, adolescents, adults, obesity, quality of life

Introduction

Obesity is becoming an increasing problem seen around the world. As obesity is becoming more prevalent, individuals are turning to surgical options to try to increase their ability to function as well as their quality of life. This paper evaluates two randomized controlled trials and one cohort study, looking at the change in the quality of life, specifically physical function, that laparoscopic gastric banding has provided in adolescents and adults.

More than one-third of the United States is obese, leading to secondary medical conditions such as type 2 diabetes, dyslipidemias, and hypertension. Obesity is an epidemic occurring nationwide, effecting every state and individuals daily. The prevalence by state varies, but no state has a prevalence under 20%, with the South being the highest prevalence at 29.5% of the population being obese.¹

Physician assistants and physicians see these patients' everyday and work to treat their obesity as well as their secondary medical conditions. Besides the fact that obesity can lead to secondary health issues, being obese is costly. According to the CDC, more than \$1,400 per year is additionally spent on health care for obese patients compared to those that have a normal BMI.¹ The CDC also states that in 2008 approximately \$147 billion dollars were spent on obese patients.¹ Even though there has not been a specific number found for the number of healthcare visits each year, it has been found that people who are obese spend more on health care, have more medications prescribed for them, and spend more time with practioners.²

When looking at what causes obesity, there are various etiologies. Some of these include having a higher caloric intake than the expenditure of calories and a sedentary lifestyle. Other medical and physiologic conditions include Cushing's syndrome, hypothyroidism, polycystic ovarian syndrome, and leptin receptor mutations.

A widely accepted value for a normal BMI ranges from 18.5-24.9 whereas 25.0-29.9 is considered overweight. The diagnosis of obesity can be made when a patient has a BMI greater than 30. From 30-34.5 is considered obesity class I, 35-39.9 is obesity class II, and greater than 40 is considered obesity class III or morbidly obese.³ Having an increased BMI is one factor included in the diagnosis of obesity. Other signs and symptoms an obese patient can demonstrate include: increased waist circumference (Men >40 inches, women >35inches), dermatologic issues such as acanthosis nigricans and hirsutism, sleep apnea, depression, fatigue, dyspnea on exertion, and joint pain.^{1,3} These patients could also have other comorbid diseases such as hypertension, diabetes mellitus, coronary artery disease, and congestive heart failure.

There are multiple methods available to help fight obesity. The first method of treatment is lifestyle modification. It is recommended that patients change the way that they eat with diet therapy, exercise, and behavior modification. This multidisciplinary approach can include working with a nutritionist as well as personal trainers and healthcare providers to achieve goals. Even though these methods are first line, people still struggle and look to continue to try and fight their obesity. When these steps have not helped, people look for other methods to cope with their condition. Patients may use a medication option such as Orlistat or over the counter Alli, which are used to help block fat absorption. Lorcaserin is another drug available that acts a serotonin receptor agonist, which causes a decrease in food intake.³ Phentermine, and Topiramate are two other drugs that can be used in medical management. Phentermine works to reduce appetite secondary to central nervous system effects, where as Topiramate works on appetite suppression and causes satiety enhancement.³ Other patients take a surgical route, and look to a surgical procedure to help them fight their condition. In bariatric surgery there are

three main types of surgeries that can be performed. These include gastric banding, Roux-en-Y gastric bypass, and a

gastric sleeve procedure. In individuals that undergo these surgical procedures, they have shown to have a decrease in weight, BMI, and have a decrease in comorbid conditions.

When lifestyle modifications are not working, individuals and practitioners look to surgical methods as a beneficial option to help the individual achieve the outcomes they want.

Laparoscopic gastric banding is an existing surgical treatment in adults, and is currently starting to be used in adolescents, which can provide greater outcomes, compared to lifestyle modification.

Objective

The objective of this selective EBM review is to determine whether or not “Is laparoscopic gastric banding an effective treatment for obesity in adolescents and adults as measured by physical functioning?”

Methods

This investigation looks at two randomized controlled trials and one cohort study. The population that was used included patients that ranged from fourteen to sixty years of age or, adolescents younger than fourteen but also suffering from one or more comorbidity. Other criteria included patients that failed to reduce and maintain weight loss after trying several methods. Patients also needed to have a BMI of 35 or greater. All studies included laparoscopic gastric banding as the intervention being used. In the cohort study, Silberhumer et al. examined pre-operative data compared to post-operative at three and five year intervals. In the Nguyen et al. trial, laparoscopic gastric banding was compared to gastric bypass surgery. Whereas in the O'Brien et al. randomized control trial, the groups that were being compared were laparoscopic

gastric banding to supervised lifestyle modifications. There were multiple outcomes measured in the studies but the outcome of concern for this paper is quality of life post-operatively, specifically, physical functioning as measured by surveys including SF-36, Moorehead-Ardelt, BAROS, and CHQ CF-50.

The author performed searches using the PubMed database, Medline database, and OVID database using the key words of laparoscopic gastric banding, adolescents, adults, obesity, and quality of life. All searches performed were set for English language. All articles searched were published in peer-reviewed journals and were selected based on relevance and importance of outcome to the patient. Inclusion criteria included randomized controlled trials (RCT), cohort studies, and studies that included patient oriented outcomes. Exclusion criteria included children under the age of fourteen that had no comorbid conditions, previous Cochrane reviews, and previous student published systematic reviews. All studies used similar statistics when evaluating quality of life, using a p-value. In all studies, $p \leq 0.05$ was considered statistically significant.

The demographics of the studies are included and outlined below in **Table 1**. Each study included a BMI of greater than thirty-five and failure of previous interventions of weight loss.

Table 1- Demographics and Characteristics of included studies

Study	Type	# pts	Age (yr)	Inclusion Criteria	Exclusion Criteria	W/D	Intervention
Nguyen ³ , 2009	RCT	250	18-60	Body mass index between 40 to 60; Or BMI of 35 with comorbidities; An acceptable operative risk; Between the ages of 18-60	Patients with a large ventral hernia; Hiatal hernia; Those who have had previous gastric or bariatric surgery	53	Laparoscopic adjustable gastric banding
O'Brien ⁴ , 2010	RCT	50	14-18	Age between 14 to 18 years; BMI greater than 35; Identifiable medical complications such as hypertension, metabolic syndrome, asthma, back pain; Physical limitations such as an inability to play a sport, difficulties with activities of daily living, or psychosocial difficulties such as isolation or low self-esteem, subject to bullying that stems from obesity and evidence of attempts to lose weight by lifestyle means for more than 3 years	Intellectual disability; Prader Willi Syndrome	8	Laparoscopic adjustable gastric banding
Silberhumer ⁵ , 2011	Cohort Study	50	9-19	Patients above the 99.5 th age- and gender- adjusted growing percentile Adolescents under 14 years old who had to suffer from at least one comorbidity; Patients that have failed to reduce and maintain weight loss through several methods such as diet camps, behavioral therapy, and drug therapy	N/A	5	Laparoscopic adjustable gastric banding

Outcomes Measured

Each trial and study used different tools to measure and record outcomes pre-and post-operatively. The Nguyen et al. used the SF-36 survey to measure quality of life outcomes preoperatively and post-operatively at one month and twelve months. The O'Brien et al. trial used the Child Health Questionnaire (CHQ CF-50) to measure quality of life pre-randomization and at two-year follow-up. The Silberhumer et al. used the Moorehead-Ardelt and BAROS questionnaires to measure quality of life preoperatively, one year, three years, and five years postoperatively.

Results

Two of the three articles were presented as randomized controlled trial (RCT) while the third was a cohort study. In the Nguyen et al. RCT, 250 patients were used to compare laparoscopic gastric banding to gastric bypass. Patients were recruited to participate in the trial and needed to have a BMI between 40-60 or 35 with comorbidities to qualify. Age was another qualifying factor, with patients having to have an age between the ages of 18-60 years old. 53 patients were excluded due to the exclusion criteria of having a ventral hernia, hiatal hernia, or have had previous gastric or bariatric surgery. After exclusion factors, 111 people underwent gastric bypass and 86 underwent laparoscopic gastric banding. The trial took place over five years with postoperative follow up surveys conducted at one month and one year. The SF-36 survey used compared the two groups to US norms looking at various measurements. The score assigned to the US norm for physical function was 80. A summary of results can be seen in

Table 2.

Table 2- Physical Function Scores of Nguyen et al

	Pre-Operatively	1 Month Post-Op	1 year Post-Op
US Norm	80	80	80
Gastric Banding	41	48	98

To analyze the data, unpaired T-tests were used and a p-value of <0.05 was considered statistically significant. This study demonstrates that patients one year post-operatively with gastric banding have shown improvements in their quality of life when looking specifically at physical functioning. This demonstrates the efficacy of gastric banding when looking at physical functioning as an outcomes measure.

O'Brien et al performed an RCT examining adolescents comparing laparoscopic gastric banding to lifestyle modification. The study originally prescreened 163 adolescents for the study, of those, 84 underwent clinical assessment, and only 50 of those were included in the trial. Exclusion criteria included not meeting the BMI requirements, not wanting to attend seminars, lack of support, geographically remote, refusing randomization, and medical problems such as intellectual disability, and Prader Willi Syndrome. 50 patients were included in the study, meeting the inclusion criteria of being between ages 14-18 years of age and having a BMI of greater than 35. Other inclusion criteria included having identifiable medical complications such as hypertension, metabolic syndrome, asthma, and back pain. Also, physical limitations such as an inability to play a sport, difficulties with activities of daily living, or psychosocial difficulties such as isolation or low self-esteem, subject to bullying that stems from obesity and evidence of attempts to lose weight by lifestyle means for more than 3 years. Of the 50 that were randomized and included in the primary analysis, 8 withdrew before the end of the study. This study was performed over a three year period with two years of post-operative follow up. Data was collected using the CHQ survey and analyzed using a t-test with a 2-tailed p-value of less than 0.05 being considered statistically significant. A summary of results of looking at physical functioning can be seen in **Table 3**.

Table 3- O'Brien et al Physical Function Results

	Initial	Final	P-Value
LAGB	73.1	94.4	<0.001
Lifestyle Modification	80.04	78.1	0.79
US Norm	94.8	94.8	

An additional p value was calculated looking at the change in LAGB compared to lifestyle and found to be 0.002. This study shows that there was statistical evidence that patients who underwent gastric banding had an improved quality of life, specifically, had an increase in physical functioning, as compared to the lifestyle intervention group.

Silberhumer et al used a cohort study to examine laparoscopic adjustable banding in adolescents. Inclusion criteria for patients were that they needed to be above the 99.5th age- and gender- adjusted growing percentile, adolescents under 14 years old who had to suffer from one or more comorbidity, and that they have failed to reduce and maintain weight loss through several methods such as diet camps, behavioral therapy, and drug therapy. 50 patients were selected with a loss of 5 patients. This study took place over six years and included post-operative follow up, five years post-operatively. Surveys were conducted using Moorehead-Ardelt quality of life questionnaire and were extended with the addition of the Bariatric Analysis and Reporting Outcome System (BAROS). The data was analyzed using a paired sample student's t-test with the Moorehead- Ardelt having a p-value of <0.05 being statistically significant and BAROS having a p-value of <0.01 being statistically significant. **Table 4** summarizes results found.

Table 4- Silberhumer et al physical function results analysis

	~3 years post-op	5 years post-op
Moorehead-Ardelt	2.11+/- 0.8 points	2.13 +/- 0.8 points
BAROS	5.5+/-1.9	6.3+/- 2.2

The outcomes of the surveys showed patients seemed to have an increased quality of life at three years post surgery and up to five years postoperatively. These increases were shown with significant improvement in the patients' body image combined with an increased agility in patients with a functional band. An increased quality of life, as well as the specific population, is what is being assessed, which makes it clinically significant and applicable.

Each study found that there were some adverse effects of using a gastric band. In the Nguyen et al. trial, early complications included: postoperative obstruction requiring a replacement band, renal insufficiency, dehydration that required readmission, urinary tract infection, clinically significant atelectasis, and *Clostridium difficile* infection. Late complications included port revisions, band erosions/slippage/obstruction, and failure of weight loss requiring revisional surgery. In the O'Brien et al. trial, adverse events included proximal gastric enlargements, surgical revision procedures, replacement of access port, needle stick injury to tubing, cholecystectomy, and hospital admission for depression. In the Silberhumer et al. study, port rotation, port dislocation, band dislocation, and band leakage were adverse effects patients suffered from. Six patients from the study decided to have the band removed and switched to laparoscopic gastric bypass surgery.

Discussion

These three articles showed that even though mainly adults have undergone laparoscopic gastric banding and have found it effective, both the O'Brien et al trial and Silberhumer et al

study have found gastric banding as a suitable option for adolescents. As bariatric surgery is becoming more popular in the United States, individuals have to consider the cost of getting the procedure as a factor. Most health care plans cover bariatric surgery, but it varies from plan to plan how much will be covered. According to the Realize website, a brand of gastric lap-bands, both Medicare and most Medicaid plans cover bariatric surgery.⁷ According to Bariatric Surgery Resource, “the average cost for any type of gastric banding procedure is going to be just about \$19,000.⁸ Costs typically are higher in large metropolitan areas and tend to be more expensive on the east and west coast.⁸

As stated previously, others might take a more conservative approach and choose to use medication management by trying Orlistat, Lorcaserin, Phentermine, or Topiramate. Even though gastric banding has shown to be effective, some surgeons choose not perform this type of bariatric surgery. There have been improved outcomes while using other types of surgery including the gastric sleeve as well as the Roux-en-Y bypass surgery. Various studies have shown that using gastric bypass shows the largest change in BMI. With this piece of information, one might infer that because more weight is lost, there could be more of an improvement in quality of life, including physical function.

Limitations of searching for studies were due to the fact that there are limited RCTs available for surgical procedures due to the need for consent. Also, there had been a fairly recent Cochrane systematic review on laparoscopic gastric banding, which excluded previous studies for this selective EBM. Since more dramatic weight loss is being seen using the two other procedures, gastric banding is not being used as often, which can also be a cause of limitations. Gastric banding research is not being as actively performed compared to gastric bypass procedure. The Nguyen et al RCT states that their limitations include that the baseline BMI was

higher and age lower in the bypass group compared to the banding group. Other limitations they encountered include loss due to follow-up. The O'Brien et al randomized controlled trial limitations include recruitment methods and possibly the length of the study.

Conclusion

From the three studies, evidence suggests that laparoscopic gastric banding is an effective treatment for obesity in adolescents and adults when measuring quality of life, specifically at physical function. The studies followed the patients for an appropriate amount of time and it seems there were precautions made in order to avoid flaws or bias. The Nguyen et al. trial could have followed their patients past one year post-operative, but the other two studies used for this article shows that the results would have been similar.

There are current studies being done involving the benefits of using gastric banding in adolescents as well as adults. Currently there is an ongoing cohort study called LAP-BAND AP® EXperience (APEX) trial. From the data that has been collected so far, they have found the LBAP to be safe and effective in weight loss and improvement in quality of life.⁹

In the future more research can be done using larger study groups but it is difficult to conduct a randomized control trial for elective surgical procedures. Future studies can be done following patients more in to the future, looking at long term physical function, with the three main types of bariatric surgeries. Overall, evidence shows that laparoscopic gastric banding is an effective treatment when looking at physical function, but the future is looking to other surgical procedures over the banding procedure.

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