Journal of
Obesity & Weight Loss Therapy
ISSN: 2165-7904

DOI: 10.4172/2165-7904.1000138

Research Article Open Access

The Effect of Laparoscopic Adjustable Gastric Banding on Osteoarthritis and other Obesity-Related Comorbidities

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Abstract

Objective: The purpose of this study is to utilize a standardized scoring system to objectively assess and quantitatively measure the effect of laparoscopic adjustable gastric banding (LAGB) on knee osteoarthritis (OA) and three other common obesity-related comorbidities: diabetes mellitus (DM), hypertension (HTN), and hyperlipidemia (HLD).

Methods: Data was retrospectively collected from an electronic registry, including patient demographics, preoperative and post-operative BMI, and obesity-related comorbidity (ORC) status. Knee OA, DM, HTN, and HLD were scored, preoperatively and postoperatively, from 0-5 according to severity using the Assessment of Obesity-Related Comorbidities (AORC) Scale. Improvement in ORC status was calculated based on the difference between preoperative and postoperative AORC scores. Resolution of disease was defined as having AORC>0 preoperatively and AORC=0 postoperatively. Paired t-tests were utilized to determine whether comorbidity score change was significant following surgery.

Results: We identified 192 patients with ORC who underwent LAGB between 2008 and 2010. At mean patient postoperative follow-up of 18.9 months, the percent of excess weight loss (%EWL) was 23.3%. Patients with OA, DM, HTN, and HLD had statistically significant AORC score change for each ORC ($p < .0001$), with mean AORC score improvement of 1.2, 1.1, 0.9, and 0.9 points, respectively. Postoperative percent resolution of pain from knee OA was 51%, while DM, HTN, and HLD resolution was 31%, 23%, and 34%, respectively.

Conclusion: LAGB had statistically significant AORC score improvements for OA, DM, HTN, and HLD. A substantial portion of our study population had ORC resolution following bariatric surgery, especially with respect to pain from knee OA. Our results encourage future high-quality randomized controlled trials to explore the effectiveness of bariatric surgery versus the current standard of care in the treatment of OA.

Abbreviations: AORC: Assessment of Obesity-Related Comorbidities; ORC: Obesity-Related Comorbidities; BOLD: Bariatric Outcomes Longitudinal Database; BMI: Body Mass Index; OA: Osteoarthritis; DM: Diabetes Mellitus; HTN: Hypertension; HLD: Hyperlipidemia; LAGB: Laparoscopic Adjustable Gastric Banding; %EWL: Percent of Excess Weight Loss; IBW: Ideal Body Weight

Introduction

In recent decades, the incidence of obesity has risen dramatically to become a life-threatening epidemic in the United States and other developed nations [1]. The World Health Organization's global estimated, from 2008 report that 1.5 billion adults were overweight and 500 million were considered obese [2]. By 2015, nearly 2.3 billion adults will be overweight and greater than 700 million will be obese [2,3] Obesity is intimately associated with many serious comorbidities, including osteoarthritis (OA), that have potentially devastating short and long-term consequences. OA is currently the leading cause of disability and chronic pain amongst adults, and the third leading cause of life-years lost secondary to disability [4] Obesity is the main modifiable risk factor in the development of OA [5-8] as numerous studies have shown increasing OA incidence and severity with increasing body mass index (BMI) [4,9-11]. Although the development of joint OA is believed to be secondary to elevated mechanical loads, the additional association of obesity and OA of non-weight bearing joints suggests a mechanism of systemic inflammation [12]. Other common obesity-related comorbidities (ORC) include diabetes mellitus (DM), hypertension (HTN), hyperlipidemia (HLD), and cardiovascular disease, amongst many other chronic diseases. Thus, treating obesity requires simultaneously monitoring and managing the various multidisciplinary comorbidities that accompany it. It is estimated that pharmacological and behavioral therapy, combined with conventional diet and exercise recommendations, produce sustained weight loss in less than 5% of morbidly obese patients [13]. Although most medical therapies for weight loss have limited success, bariatric surgery, has been proven to not only be the most effective therapy for weight loss, but also safe, reproducible, and capable of sustained weight reduction [14-16]. Although weight loss from bariatric surgery results in a significant qualitative improvement in obesity-related comorbidities, there is a paucity of research that quantitatively measures the effects of bariatric surgery on the severity of obesity-related comorbidities [16]. The purpose of our retrospective study was to objectively assess and quantitatively measure the clinical effects of LAGB, the procedure with the most benign safety profile, on knee OA and 3 other common ORCs: DM, HTN, and HLD. In order to maintain a uniform and consistent

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Received May 29, 2012; **Accepted** June 20, 2012; **Published** June 24, 2012

Citation: Liu JX, Samuels J, Abramson SB, Saunders JK, Parikh M (2012) The Effect of Laparoscopic Adjustable Gastric Banding on Osteoarthritis and other Obesity-Related Comorbidities. J Obes Wt Loss Ther 2:138. doi:10.4172/2165-7904.1000138

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method of assessing comorbidity severity, we utilized a comorbidity severity scale created by Ali et al. [15], known as the Assessment of Obesity-Related Comorbidities (AORC) Scale. The AORC Scale is a 6-point scoring system that assigns a numerical value (0-5) to each ORC according to the comorbidity's magnitude of severity (Table 1). The AORC scale is the basis of comorbidity assessment in the Bariatric Outcomes Longitudinal Database (BOLD), the world's largest prospective repository of clinical bariatric surgery patient information, with data for over 400,000 patients. By utilizing this scale, the improvement in the clinical severity and resolution of knee pain from OA, and other ORCs following LAGB can be quantitatively measured and interpreted. This data will allow clinicians to objectively assess the overall effectiveness of bariatric surgery-induced weight loss in treating the symptoms of osteoarthritis and other complications associated with obesity.

Patients and Methods

Patient information

From an institutional review board-approved electronic registry, we retrospectively identified 192 patients who had laparoscopic adjustable gastric banding between January 2008 and March 2010 at a large, urban safety-net hospital. All patients met the National Institutes of Health consensus conference guidelines on gastrointestinal surgery for severe obesity [17]. Each patient underwent thorough evaluation by a surgeon, internist, nutritionist, and psychologist or psychiatrist, prior to bariatric surgery.

Surgical technique and postoperative protocol

The laparoscopic adjustable gastric band (Lap-Band AP-system; Allergan Health, Irvine CA) entails positioning a silicone band around the superior-most portion of the stomach, approximately 2cm below the esophagus. The band is locked and secured anteriorly with a running permanent suture for gastro-gastric placation, creating a 15-20cc gastric pouch. The access port is sutured to the rectus sheath with permanent sutures. All fluid is removed from the band at surgery. All patients underwent esophagram on the first postoperative day prior to resuming a clear diet. Patients were usually discharged by the 1st - 3rd postoperative day, depending on procedure-specific postoperative protocols. Postoperative dietary guidelines were based on the ASMBS Allied Health Nutritional Guidelines for the surgical weight loss patient [18]. Patients were usually maintained on clears for 48 hours postoperatively, then advanced to full liquid diet (including low-fat, low sugar, protein-rich shakes) for 2 weeks, followed by pureed diet for 2 weeks, then transitioned to regular diet. Band adjustments were done percutaneously in the clinic according to a commonly used algorithm based on hunger and weight loss [19]. Patients were closely followed with several clinic visits after the bariatric surgery procedure. After the initial postoperative assessment, the clinician sets the schedule for patient follow-up.

Assessment of Obesity Related Comorbidities (AORC) Scale

During the initial preoperative consultation, and for every patient encounter following the date of the bariatric surgical procedure, all patients were systematically documented and methodically screened using the Assessment of Obesity-Related Comorbidities scheme, shown in (Table 1) [15]. Recording of the diagnoses of osteoarthritis, specifically knee OA, and other ORCs were made based on chart review, patient history, physical exam, radiographs or laboratory results at the time of each visit. Using this scale, a score from 0-5, according to comorbidity severity, was given to each of the four comorbidities. The AORC scale was originally developed to score the severity of 17 major obesity-related comorbidities that affect the bariatric population, and to accurately and quantitatively assess the response of ORCs following weight-reduction surgery. The AORC scale's criteria for severity were created as a result of input from a multidisciplinary group of clinical experts representing endocrinology, orthopedics, cardiology, psychiatry, gastroenterology, and bariatrics. The scale focuses on physiologic as well as treatment-based criteria to grade the severity of disease, and was designed to be a standardized, global assessment of a patient's comorbidity status at any given time. A modified version of the scheme is widely used by bariatric surgeons nationwide via the Bariatric Outcomes Longitudinal Database to uniformly document comorbidity severity. Utilization of BOLD is a requirement for institutional accreditation as a Bariatric Surgery Center of Excellence [20].

Data collection and analysis

All patients were routinely followed with regular, scheduled clinic visits following their bariatric surgery procedure. During each visit, bariatric surgeons, along with the clinicians treating the patient for specific comorbidities, reassess the presence of the patient's comorbidities, as well ORC severity, according to the AORC scale. Data retrospectively collected for each encounter included patient age, gender, height, as well preoperative and postoperative weight, BMI, and comorbidity severity using the AORC scheme. For each patient, the AORC data obtained at the most recent follow-up visit were collected for data analysis. To evaluate comorbidity improvement following bariatric surgery, the change in ORC status was calculated based on the difference between preoperative AORC score and postoperative AORC score. We also assessed comorbidity resolution,

Musculoskeletal-joint disease	Diabetes mellitus	Hypertension	Dyslipidemia
0) Not present	0) Not present	0) Not present	0) Not present
1) Pain with community ambulation	1) Hyperinsulinemia without hyperglycemia	1) Borderline/intermittent/diagnosis not confirmed	1) Borderline
2) Symptoms requiring nonnarcotic analgesia	2) Diabetes diagnosed, controlled by diet and exercise	2) Controlled by diet and exercise	2) Controlled by lifestyle changes: step 1, step 2 diet
3) Pain with household ambulation	3) Controlled by oral medications	3) Treatment with single medication	3) Controlled by low-dose medication
4) Surgical intervention required other than joint replacement	4) Controlled by insulin	4) Treatment with multiple medications	4) Controlled by high-dose medication
5) Awaiting or undergone joint replacement	5) Poorly controlled or severe complications	5) Poorly controlled or severe complications	5) Not controlled by medication

Table1: Assessment of Obesity-Related Comorbidities Scale [15].

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defined as having AORC>0 prior to surgery, and AORC=0 following surgery. Percent of excess weight loss (%EWL), the preferred and most commonly used outcome in the bariatric surgical literature to evaluate weight loss [21], was calculated based on ideal body weight (IBW), using the Robinson formula for IBW [22]. Comorbidity scores were collected and aggregated in a database for statistical analysis. Paired t- tests were utilized to determine whether AORC score change was significant following bariatric surgery. Statistical significance was defined at p = 0.05.

Results

Out of the 192 patients identified in the registry, the majority (92%) of our patient population were female. At the time of surgery, the mean age was 43.2, and the mean BMI was 43.7 (Table 2). OA, present in 80% of all patients, was the most common obesity-related comorbidity in our study (Table 3). The preoperative AORC score for OA, DM, HTN, and HLD was 2.4, 3.2, 3.4, and 2.8, respectively. Overall mean percent of excess weight loss (%EWL) was 23.3% (SD 12.0%) following LAGB, at a mean postoperative follow-up time of 18.9 months (Table 4). There were statistically significant decreases in AORC scores for all comorbidities following LAGB (p<0.0001). Patients with OA had a mean AORC score improvement of 1.2, while DM, HTN, and HLD had AORC score improvements of 1.1, 0.9, and 0.9 points, respectively (Figure 1). The percent of patients with resolution of each comorbidity following LAGB is summarized in (Figure 2). Of all the patients with documented knee pain prior to surgery, 51% of these patients reported complete resolution of all the patients with documented knee pain prior to surgery, 51% of these patients reported complete resolution of pain after LAGB. A higher %EWL was correlated with a larger change in AORC score for OA (correlation=-0.341, 95% CI=[-0.454, -.215], p<0.0001).

Total Patients		192
Gender **Female, N (%)**	**Male, N (%)**	15 (8%) 177 (92%)
Age **Median [range]**	**Mean (SD)**	43.2 (11.5) 44 [18, 68]
Height (cm) **Median [range]**	**Mean (SD)**	62.6 (3.5) 62 [49, 75]
Weight (lb) **Median [range]**	**Mean (SD)**	244 (41) 241 [156, 382]
BMI (kg/m2) **Median [range]**	**Mean (SD)**	43.7 (5.4) 43.3 [35.0, 61.6]

Table 2: Descriptive summary of study population at time of surgery.

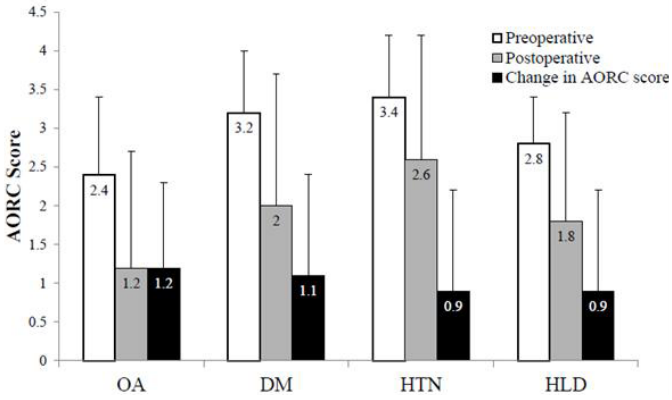
Comorbidity	Number of patients with comorbidity	% of Patients with Comorbidity	Preoperative AORC Score Mean (SD)
Osteoarthritis	154	80%	2.4 (1.0)
Diabetes mellitus	64	33%	3.2 (0.8)
Hypertension	97	51%	3.4 (0.8)
Hyperlipidemia	77	40%	2.8 (0.6)

Table 3: Percent of subjects with each comorbidity prior to surgery (AORC score >0) and the preoperative AORC scores.

Parameter	Mean (SD)
Months since surgery	18.9 (8.0)
Weight (lb)	203.3 (41.1)
Change in Weight (lb)	40.7 (36.3)
BMI (kg/m2)	36.0 (5.9)
%EWL, Mean (SD)	23.3% (12.0%)

%EWL = (Weight loss/Baseline excess weight) x 100

Table 4: Study population characteristics after laparoscopic adjustable gastric banding Baseline excess weight = Baseline weight - Ideal body weight (IBW) IBW calculated based on Robinson Formula [22].



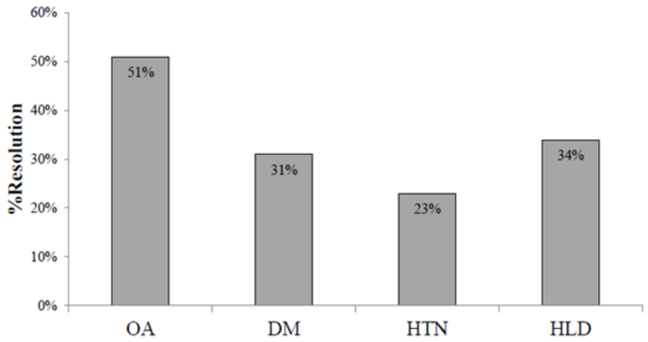
Average 18.9 month follow-up. Paired t-tests between preoperative and postoperative AORC scores were statistically significant for all 4 ORCs (p < 0.0001)
AORC: Assessment of OBESITY-Related Comorbidities
LAGB: Laparoscopic Adjustable Gastric Banding
OA: Osteoarthritis
DM: Diabetes Mellitus
HTN: Hypertension
HLD: Hyperlipidemia

Figure 1: Comparison of preoperative, postoperative and change in AORC score LAGB.

Discussion

Although obesity is the most important modifiable risk factor for the development of OA, there is a paucity of evidence assessing the quantitative effectiveness of bariatric surgery-induced weight loss on OA. The purpose of our study was to objectively assess the improvement of OA and other obesity-related comorbidities after bariatric surgery. We evaluated 192 bariatric surgery patients that have undergone LAGB and monitored the clinical outcomes of OA, DM, HTN, and HLD for a mean of 18.9 months following the time of surgery. We used the AORC scale created by Ali et al. [15] to objectively and quantitatively grade the severity of each ORC preoperatively and postoperatively, and to longitudinally follow the outcomes of each comorbidity. Overall, LAGB led to a significant improvement in AORC scores of all ORCs following surgery, especially OA.

Our data contributes to the few, but growing number of studies that uses a validated, quantitative scale to uniformly assess the response of OA symptoms following bariatric surgery. Gill et al. [16], recently conducted a systematic review which initially identified 400 articles that involved bariatric surgery in obese patients with assessment of hip or knee OA [16]. After the articles were screened for randomized



Average 18.9 month follow-up. Values of each ORC are % of patients with preoperative AORC score > 0 and postoperative AORC score = 0
AORC: Assessment of OBESITY-Related Comorbidities
LAGB: Laparoscopic Adjustable Gastric Banding
OA: Osteoarthritis
DM: Diabetes Mellitus
HTN: Hypertension
HLD: Hyperlipidemia

Figure 2: % Resolution of ORCs following LAGB.

or non-randomized controlled trials, case-controlled studies, or case series that assessed the primary outcome of hip or knee joint pain following bariatric surgery, only 6 studies remained (5 case series and 1 case-controlled study) that reported the appropriate outcome data [16]. Although the 6 studies used different primary outcome measures and methods to assess joint function and pain following surgery, such as the Knee society score, Harris hip score, Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain score, joint space width measurement, and various scales to assess pain, a general trend was identified that indicated marked improvement of hip and knee OA that was secondary to weight loss produced by bariatric surgery [16].

We used the same AORC scheme to quantitatively assess the severity of HTN, DM, and HLD following bariatric surgery. Our data supports numerous studies that examine the effectiveness of weight loss and improvement of these ORCs following weight-reduction surgery [1,12,15,23-32]. The long-term %EWL of different bariatric surgery procedures have been reported to be as high as 47-70% [24]. In a recent study by Richette et al. [12], bariatric surgery patients followed for 6 months postoperatively had a mean 10.3 point drop in BMI and a significant reduction ($p<0.0001$) in WOMAC pain, stiffness, and function scores, as well as significant reductions in plasma total cholesterol, triglycerides, and glucose [12]. In the Swedish Obese Subjects study, patients with a mean age of 48 years and mean BMI of 41 underwent bariatric surgery, and were followed up at for at least 2 years (4047 patients) and 10 years (1703 patients). Following surgery, rates of recovery from DM, hypertriglyceridemia, HTN, and hyperuricemia were higher in the surgery group versus the control group [33]. Sugerman et al. [31], treated 1,025 patients with gastric banding surgery. A 1 year follow-up produced a mean 66% EWL, and complete resolution of HTN and DM of 69% and 83%, respectively [31].

Although there is strong evidence to support bariatric surgery and weight loss in obese patients with osteoarthritis, to date, there have been no prior randomized controlled trials conducted to assess the impact of weight-reduction surgery and weight loss on OA patients. Given that OA is the leading cause of pain and disability amongst adults [4] and is estimated to raise annual medical care expenditures by more than $180 billion annually [34], these studies are long overdue. Future high-quality, randomized studies with appropriate controls should be performed to evaluate the effect of bariatric surgery on the objective clinical, radiographic, and biochemical features that are present in OA, and furthermore, to describe how these features respond over time following surgery.

Furthermore, since the FDA recently lowered the indication for laparoscopic adjustable gastric banding to individuals with BMI 30-35 with severe obesity-related comorbidities [35], such studies are urgently needed in this population, as it is estimated that nearly 20% of adults with BMI of 30-35 have knee and hip OA [34]. Therefore, randomized clinical trials comparing the effectiveness of LAGB versus medical therapy for OA patients with BMI<35 should be implemented for future studies of OA therapy.

There are several limitations to our study. We opted to use the AORC scale since, although rudimentary, it is a consistent scale used across bariatric centers of excellence nationwide. The AORC scheme was designed to be a standardized, global assessment of obesity-related comorbidity status that is capable of assessing entire bariatric surgery patient populations at any given time. During preoperative or post-operative evaluation, the prevalence and severity of multiple ORCs can be easily accessed and graded. Given the broad scope of the AORC scheme for multiple ORCs, the scale does not provide the level of detailed information that OA-specific classification systems are capable of providing, such as the Kellgren and Lawrence system, the Outerbridge classification system, and the WOMAC pain score. The AORC scale used to assess OA is primarily based on joint pain and function. Because of these limitations, our preliminary data strongly support more rigorous future studies that identify the detailed clinical, radiographic, and biochemical effects of bariatric surgery-induced weight loss on OA. Ideally, thorough assessment of OA, or any other ORC, requires objective, disease-specific measurements and physiological staging of disease, which the AORC scheme is not designed to provide. Despite these limitations, the AORC scheme is an excellent tool for its original purpose: to describe the comorbidity status of an individual or entire bariatric surgery patient population, and to longitudinally and uniformly assess the severity of ORCs in response to bariatric surgery using a standardized and quantitative scale [15]. If outcome reporting of OA and other ORCs became standardized, it may lead to improved integration of future studies.

In conclusion, LAGB significantly reduced the symptomatic severity of OA and other obesity- related comorbidities, including DM, HTN and HLD. Using a standardized scoring system, our study shows LAGB significantly improved the status of all 4 documented ORCs, and furthermore, resulted in the resolution of comorbidities in a substantial portion of our study population, especially pain from knee OA. These results underscore the urgent need to clarify the role of bariatric surgery in the management of OA.

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