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Long-term outcomes of laparoscopic adjustable gastric banding

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ABSTRACT

Background: Laparoscopic adjustable gastric banding (LAGB) is an option for the treatment of severe obesity. Few US studies have reported long-term outcomes. We aimed to present long-term outcomes with LAGB.
Methods: Retrospective study of patients who underwent LAGB at an academic medical center in the US from 1/2005 to 2/2012. Outcomes included weight loss, complications, re-operations, and LAGB failure.
Results: 208 patients underwent LAGB. Mean BMI was 45.4 ± 6.4 kg/m^2. Mean follow-up was 5.6 (0.5−10.7) years. Complete follow-up was available for 90% at one year (186/207), 80% at five years (136/171), and 71% at ten years (10/14). Percentage of excess weight loss at one, five, and ten years was 29.9, 30, and 16.9, respectively. Forty-eight patients (23.1%) required a reoperation. LAGB failure occurred in 118 (57%) and higher baseline BMI was the only independently associated factor (OR 1.1; 95%CI 1.0−1.1; p = 0.016).
Conclusion: LAGB was associated with poor short and long-term weight loss outcomes and a high failure rate. With the increased safety profile and greater efficacy of other surgical techniques, LAGB utilization should be discouraged.
Summary: Long-term outcomes of LAGB was studied in 208 patients. Complete follow-up was available for 90% at one year (186/207), 80% at five years (136/171), and 71% at ten years (10/14). Percentage of excess weight loss at one, five, and ten years was 29.9, 30, and 16.9, respectively. LAGB failure occurred in 118 (57%) and higher baseline BMI was the only independently associated factor (OR 1.1; 95%CI 1.0−1.1; p = 0.016).

1. Introduction

Laparoscopic adjustable gastric banding (LAGB) gained initial popularity in Europe, Australia and other parts of the world since it was first introduced in Belgium in 1993 by Belachew et al.[1] By 2008, it was estimated to be the second most commonly performed bariatric procedure worldwide after gastric bypass.[2] Successful long-term weight loss results with LAGB have been reported from centers in Australia and Europe with a percentage of excess weight loss (%EWL) between 41% and 59% and maintained for ten years or longer.[3–7] However, and despite these publications, LAGB utilization in Europe significantly decreased; from 43% of all bariatric procedures performed between 2008 to 15% in 2013[2] and a decreasing trend continues to be observed in other recent publications from individual European countries.[8,9]

After the FDA approval of LAGB for commercial use in the United States in 2001,[10] there was a significant increase in LAGB utilization in the US, with a 329% increase in academic medical centers between 2004 and 2007.[11] However, and despite the FDA expanding the indications for LAGB implantation in 2011,[12] this was followed by a large decline in utilization, with LAGB being offered as only 1% of the procedures in academic medical centers in 2014.[13,14]

This decline in utilization of LAGB is thought to be a consequence of the increased safety profile of other more efficacious bariatric surgical techniques [Laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic sleeve gastrectomy (LSG)][15–20] and a widespread, often unpublished, perception of high failure rates with LAGB.[6,7,21,22]

Notwithstanding, LAGB is still one of the surgical treatment

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options for severe obesity and in 2015 the American Society for Metabolic and Bariatric Surgery (ASMBS) reported that 11,172 LAGB were implanted in the US.[23]

We are unaware of any publication from a US center with long-term outcomes and high completeness of follow-up. Most studies have reported short-term and medium-term outcomes[17–20,24–27] with two single institution one-cohort studies reporting longer-term outcomes (>6 years). However, those had low rates of follow-up (<50%)[21] or a small number of patients at eight years (n = 2)[22]. We believe that higher quality data documenting the longer outcomes of LAGB is needed in the US to help inform patients and providers in the decision-making process when choosing a bariatric surgical technique.

The aims of our study were to evaluate the long-term outcomes of LAGB at a US academic medical center, determine success/failure rates, study factors associated with LAGB success/failure, and assess the outcomes of conversion procedures of failed LAGBs.

2. Material and methods

2.1. Study design and participants

We performed a retrospective one-cohort study of all the patients who underwent LAGB at the University of Wisconsin-Madison Bariatric Surgery Program between January 2005 and February 2012. The procedures were performed by four surgeons during the 7-years LAGB was implanted. Patients who had their primary LAGB operation at another center were excluded from this study. Patients were considered possible candidates for LAGB if they had a body mass index (BMI) $\geq$ 40 kg/m^2 or BMI $\geq$ 35 kg/m^2 with obesity-related comorbidities and had failed a medically supervised weight loss program. Preoperatively, all patients had comprehensive medical evaluations and underwent individual preoperative evaluation and counseling by a multidisciplinary team that included dieticians, a physician assistant, psychologists, and bariatric surgeons. The patients participated in pre-operative educational classes with a total of 7–10 h of educational sessions with the same multidisciplinary team.

2.2. Type of LAGB and surgical technique

The type of LAGB used evolved during the years based on surgeon's preferences and the introduction of the newer generation of commercially available products. Between 2005 and 2007, the Lap Band 10-cm (n = 59) or Vanguard (n = 26) band (Allergan, Inc., Irvine, California) was used. From October of 2007, the Lap-Band AP Standard (n = 18), AP Large (n = 6) (Allergan, Inc., Irvine, California) or Realize adjustable band (Realize; Ethicon Endo-Surgery, Inc., Cincinnati, OH) system (n = 99) was used.

All procedures were completed laparoscopically. The band was inserted using the pars flaccid technique according to the manufacturer's guidelines. In brief, the operation consisted of adequately exposing the His angle by removal of the covering fat pad while retracting the gastric fundus inferiorly. Dissection was continued until the left crus of the diaphragm was completely exposed. A small incision in the avascular aspect of the gastrohepatic ligament was created, and care was taken to identify and preserve the hepatic branch of the vagus nerve. Blunt dissection was used to create a space between the base of the right crus and its overlying peritoneum. A long grasper was then gently passed above the right crus, underneath the gastroesophageal junction, toward the His angle. The band was passed around the gastroesophageal junction, and a 30-mL gastric pouch was estimated or measured by a balloon introduced through the patient's mouth. The band was snapped in place and secured with 4 or 5 gastrogastric stitches, with the initial throw of each gastric stitch in a position as far as needed in the outer aspect of the anterior gastric fundus to prevent a tight tunnel. The band reservoir was not filled until the sixth postoperative week.

2.3. Perioperative care

Patients were given clear liquids on the first postoperative day and then advanced to a full-liquid diet on the same day or second postoperative day. Patients were seen 2 and six weeks postoperatively, then at 3, 6, 12, 18 and 24 months and annually after that. Adjustments to LAGB were performed according to manufacturer guidelines. More frequent clinic visits were arranged if needed. After the operation, patients received prenatal vitamins, calcium supplements, cholecalciferol (vitamin D), and acid suppression medication. Nutritional supplements were prescribed as needed for documented deficiencies. Weight was documented at each of the follow-up visits.

2.4. Data and study outcomes

This study was approved by the UW Institutional Review Board. A bariatric surgery database that is prospectively maintained was used to obtain the patient's demographics and pre-operative characteristics. Outcome data were obtained from the database records, and by reviewing the patients' electronic charts including all bariatric and non-bariatric provider's clinical notes. All follow-up data originated from an in-person clinic visit with a medical provider within the UW Medical Center. Patients were also contacted via phone and regular mail letters to invite them to return to the clinic. The percentage of data collected from visits at the bariatric clinic visits versus visits to other providers clinics and review of electronic charts varied over the years: data was collected from bariatric clinic visits in 100% of subjects during the first 3 years and then fell to about 80% (with little variation) from bariatric clinic visits in years 4–10.

Data collected included patient's baseline demographics (age, gender, weight, and BMI), the pre-operative presence of obesity-related comorbidities (type-2 diabetes mellitus, hypertension, obstructive sleep apnea, and hyperlipidemia) and perioperative and long-term outcomes. Perioperative outcomes included any complication that occurred within 30 days post-operatively whereas long-term outcomes included complications that occurred after 30 days. The number of LAGB adjustments, reoperations, and conversion to other bariatric procedures were also collected. Excess weight (EW) was calculated as the weight in pounds above the weight of a BMI of 25 kg/m^2. %EWL was calculated as the weight lost from baseline divided by EW and multiplied by 100. Percentage of total body weight loss (TBWL) was calculated as the weight lost divided by the baseline body weight multiplied by 100. We defined LAGB failure as %EWL<25 and/or LAGB removal with or without conversion to another bariatric procedure.[10,19] Weight loss measures and rates of LAGB failure were calculated at six months and one year and 1-year intervals after that. Time of follow-up was defined as the time (in years) between LAGB placement and January of 2016. The percentage of completeness of follow-up at each year after surgery was calculated.

2.5. Statistical analyses

Data was analyzed using IBM SPSS Statistics version 23.0 (Armonk, NY). Numerical variables were presented as mean ($\pm$standard deviation) and compared using Student's t-test whereas categorical data were compared using the $\chi 2$ test. Multivariate logistic regression with a backward selection procedure was

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