Evolution of Laparoscopic Adjustable Gastric Banding

Corrigan L. McBride, MDa,*, Vishal Kothari, MD

In the United States, obesity continues to be a major health issue.1,2 The Centers for Disease Control and Prevention determined that more than 30% of Americans were obese in 2009.3,4 Young Americans today are possibly heading toward the first decrease in life expectancy in the era of modern health care.5 Obesity clearly is a chronic condition involving genetic, metabolic, and environmental factors.6–8 Surgeons today are working harder than ever to offer patients bariatric procedures as a therapeutic tool in the fight against obesity.9–11 Multiple studies have shown the efficacy of the laparoscopic Roux-en-Y gastric bypass (LRYGB) as the gold standard procedure in bariatric surgery.12 Patients still, however, express concerns about the short-term and long-term consequences of changes to their anatomy and the possible disastrous complications of an anastomotic leak.13 The creation of Bariatric Centers of Excellence was one way to combat these concerns by showing patients that higher-volume centers could perform these procedures with significantly less morbidity and mortality.14 Even so, Americans still desired an alternative solution to surgical weight loss.15 The introduction of laparoscopic adjustable banding in the last 2 decades became this new surgical tool, providing similar outcomes with limited morbidity and mortality.16 As younger and younger patients are becoming obese and morbidly obese at earlier ages, there may be a role for banding as a preventive tool as well.17,18 With the recent Food and Drug Administration (FDA) approval of the LAP-BAND in patients with a body mass index (BMI) greater than 30 (BMI is weight in kilograms divided by height in meters squared, ie, kg/m²), this article looks at the evolution of laparoscopic adjustable gastric banding (LAGB).
HISTORY OF GASTRIC BANDING

The FDA approved the first laparoscopic adjustable band in 2001.19 The LAP-BAND, as it was named by Allergan (Irvine, CA), was a purely restrictive weight-loss tool that provided patients a safe outpatient procedure to help with weight loss. Its origins began in the 1980s when Szinicz and colleagues20 discovered that creating restrictive pouches in dog and rabbit models created significant weight loss. This research eventually translated into the vertical banded gastroplasty (VBG) by Mason and colleagues in 1982.21,22 The VBG was a restrictive procedure using staple lines to create safe sustained weight reduction. These staple lines, however, eventually became disrupted, causing significant weight regain over time, or the bands eroded, causing obstruction. Open gastric banding tried to eliminate the use of staples by placing polyester or polypropylene mesh around the proximal stomach to create restriction.23 This attempt also failed, due to erosion and gastric outlet obstruction. Kuzmak and colleagues24 translated this into humans with the first open adjustable band placement in 1986.25 His contemporaries, Forsell and colleagues, began working on the Swedish Adjustable Gastric Band at this time as well.26,27 As the laparoscopic era of surgery flourished in the early 1990s, Belachew and colleagues28,29 solidified the LAGB with the first placement of a LAP-BAND in a human in September 1993. Subsequently, the LAP-BAND was approved internationally and became the most common surgery in European countries. The FDA initiated trials in the United States in 1995 and approved its use in 2001. Since that time, Ethicon EndoSurgery (Cincinnati, OH) has bought the Swedish Adjustable Band from the Swiss company Obtech Medical. Ethicon developed the REALIZE band, which became approved for use in the United States in 2008. As of February 2010, the FDA approved the LAP-BAND for use in patients with severe comorbidities and BMI of 30 to 35.18 Both bands are currently available to patients in the United States, providing a safe procedure with minimal morbidity, quick recovery, and the possibility of reversibility.

SURGICAL TECHNIQUE OF LAGB PLACEMENT

Significant advances in the placement of the LAGB have occurred in the last 2 decades. Belachew’s original technique for LAP-BAND placement was called the perigastric technique.28,29 The band was placed 3 cm below the gastroesophageal junction. A tunnel was created from the lesser sac around the stomach to the greater curvature, creating a 25- to 30-cm pouch. The greater curvature was then plicated over the band. A gastrostenometer was used to inflate 1 to 2 mL of saline and determine proper pressure and position. Early international results of this technique found an extremely high prolapse rate of approximately 15% to 30% and erosion rate of 1% to 3%.30 It seemed that partially inflating the band at the time of surgery and the creation of a large pouch led to worsening nausea and vomiting, predisposing patients to prolapse, deserosalization, and erosion.31

Due to the significant complication rate, Forsell’s original technique for the Swedish Adjustable Gastric Band (SAGB), now the REALIZE Band, has become the standardized placement for LAGB.32 This technique, known as the pars flaccida technique, creates a 1-cm virtual pouch below the esophagogastrectomy junction. The gastrohepatic ligament is opened and a retrogastric tunnel is created above the omentalis bursa where the stomach is naturally fixed to its posterior attachments. The greater curve dissection is completed at the angle of His. A small retrogastric tunnel is created only large enough for the band to pass through. This action allows the stomach to stay fixated to the decussating fibers of the right and left diaphragmatic crura, keeping the band in a fixed position. Plication stitches are then placed anteriorly from the
greater curvature to above the band to hold the band in place. In addition, fluid is no longer recommended to fill the band during initial placement. Multiple studies comparing the two techniques have shown similar outcomes in weight loss and a dramatic decrease in prolapse and erosion rates with the pars flaccida technique, which is now standard practice for all LAGBs.

PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE CARE

Like all bariatric procedures, patients who wish to undergo LAGB require extensive preoperative preparation. The National Institutes of Health (NIH) requirements for bariatric surgery include a BMI greater than 40 without severe medical comorbidities, or BMI greater than 35 with severe medical comorbidities such as type 2 diabetes mellitus, hypertension, obstructive sleep apnea, and degenerative joint disease. Once these criteria are met, patients must undergo significant nutritional education, dietary counseling, and often psychological screening before surgery. Medical clearances may be obtained for patients who have significant cardiac and pulmonary risk factors.

Once the screening process is complete, the patient is taken to the operating room. Endotracheal intubation is required for LAGB. After this is completed, patients are positioned on a bariatric capacity operating table in supine position with a foot board to prevent patient sliding and lower extremity neuropathy. In general, 5 to 6 ports are placed in the upper abdomen to maintain adequate exposure during the procedure. One of the trocars is typically 15 mm in size, as this will accommodate introduction of the band. A Nathanson liver retractor or similar retracting device is placed in the epigastrium to lift the left lateral segment of the liver and expose the esophagus, hiatus, and stomach. Fatty attachments of the angle of His are dissected. Then the gastrohepatic ligament is opened and the base of the right crus is identified, and the peritoneum is incised. A grasper or band-passing device is passed through a retrogastric tunnel until it emerges behind the dissected angle of His. The band device is introduced through a 15-mm trocar into the abdomen. The end of the band is grasped, and the grasper or band-passing device is pulled back through the gastric tunnel until the entire band is around the stomach. Two graspers are used to fasten the buckle of the band. Two to 4 anterior plication stitches are placed from the greater curvature to the stomach above the band. The band is then rotated so there is no friction of the buckle against the plication. The tubing is pulled out of the 15-mm port. The tubing is connected to the subcutaneous reservoir. Air is removed from the band and the subcutaneous reservoir is fastened to the abdominal wall fascia with sutures or a stapling device.

Postoperatively, patients are placed on a sugar-free liquid diet for approximately 2 weeks supplemented with protein drinks. Patients are usually discharged the same day as surgery or kept overnight for an extended 23-hour observation. Patients are then seen at a 2-week postoperative visit when their diets are advanced to soft puréed foods. Two to 4 weeks after this visit, the patients are scheduled for their first LAGB adjustment. Whether in the office or fluoroscopy suite, reservoirs are filled with 3 to 4 mL of fluid and patients are asked to test restriction by drinking fluids afterwards. Patients are instructed to remain on liquid diets for 24 to 48 hours to allow any edema to subside. Patients are asked to return every 4 to 6 weeks to assess restriction, and may require multiple visits in the first year until adequate restriction or “the sweet spot” is obtained. At each visit, patients are asked about rapid loss of satiety, increased meal volume, and hunger between meals to assess the need for addition or subtraction of fluid. Recent studies have shown that a more vigorous adjustment schedule results in better weight loss, better patient accountability, and decreases
in complications including prolapse, obstruction, and/or erosion.\textsuperscript{34} Ideal weight loss is gradual, at about 0.5 to 1 kg per week.

**OUTCOMES OF LAGB, SHORT TERM AND LONG TERM**

Safety is the major perioperative advantage of LAGB. LAGB is considerably safer than gastric bypass, with reported morbidity and mortality rates of 11.3% and 0.05%,\textsuperscript{41,42} 10 times lower than the mortality rate of gastric bypass at approximately 0.5%.\textsuperscript{41,43}

Multiple studies have reported minimal complications with LAGB in properly trained hands.\textsuperscript{44–46}

O’Brien and Dixon\textsuperscript{30} reported a 1.5% perioperative complication rate that resulted in delayed discharge or readmission.\textsuperscript{41} These complications included port site infections at 0.9%, acute gastric outlet obstruction at 0.4%, and deep venous thrombosis (DVT) at 0.09%.\textsuperscript{30} Fielding and colleagues\textsuperscript{45} reported a series of 335 LAGB patients with only 2 reoperations for malpositioning of the band, 1 subphrenic abscess, and 4 wound infections requiring antibiotics. Similar results have been published by Chevallier and colleagues\textsuperscript{47} in a series of 1000 LAGB patients. Their results included a 0.4% gastric perforation rate, early prolapse rate of 0.3%, pulmonary embolism in 0.2%, and acute respiratory distress syndrome in 0.2%.\textsuperscript{47}

Gastric perforation is the most detrimental complication, and rates are reported from 0.1% to 0.4% in multiple studies.\textsuperscript{48} To decrease the likelihood of gastric perforation, both major companies, Allergan and Ethicon, require proctoring before surgeons can place bands in the operating room. A proctor is a skilled surgeon who is trained in the insertion of the LAGB. This individual must observe a surgeon place bands in 2 different patients. Once they feel these individuals can safely place the LAGB, the company allows the sale of the device to the hospital.

Successful LAGB placement does not eliminate the potential for reoperation in the patient’s lifetime. Bueter and colleagues\textsuperscript{49} showed a 23% reoperation rate in a series of 172 patients over a 56-month median follow-up. These reoperations included band replacements, repositions, and conversions to other bariatric procedures, due to failure of weight loss. The pars flaccida technique has significantly reduced some of these reoperation rates. Dargent\textsuperscript{50} showed a significant decrease in prolapse rates, from 6.2% to 0.6%, using the pars flaccida technique. Erosion rates have also significantly decreased from 3% to 0.3%.\textsuperscript{51,52} While improvements in technique have improved overall outcomes, there is still a significant reoperation rate that patients need to consider when choosing the LAGB as an option for bariatric surgery.\textsuperscript{53,54}

**WEIGHT LOSS OUTCOMES**

Numerous studies have been performed to evaluate weight loss from LAGB. Using LRYGB as the gold standard, many of these studies showed that whereas early weight loss may be significantly less than for LRYGB in the first 6 months to a year, excess weight loss (EWL) does start to reach approximately 50% to 65% in 2 to 3 years,\textsuperscript{41,55–57} then slowly approaches the 65% to 70% EWL seen in LRYGB.\textsuperscript{12} This weight loss is gradual, and is dependent on adequate adjustments and more frequent follow-up.\textsuperscript{58} A study by Shen and Ren\textsuperscript{59} showed that patients with 6 or more visits at 1 year had an EWL of 50% compared with only 42% EWL for those patients with fewer than 6 visits. Belachew and Zimmermann\textsuperscript{91} reported percent EWL to be 40% at 1 year and 50% at 2 years, with a range of 50% to 60% at 48 months in a large trial of 763 patients.

Early studies in the United States reported poor weight loss and high complication rates.\textsuperscript{60,61} However, this was likely attributable to the perigastric technique of band placement and inadequate adjustment protocols. Ren and colleagues\textsuperscript{62} formulated
a multi-institutional study and reported a 44.3% EWL in 99 patients with mean preoperative BMI of 52. An American trial from Jan and colleagues\(^6\) compared 154 LAGB patients with 219 LRYGB patients from October 2000 to November 2003. EWL was 36% for LAGB versus 64% for LRYGB after the first year, 45% for LAGB versus 70% for LRYGB after the second year, and then 60% for LAGB versus 57% for LRYGB at the third year. As seen in previous studies, whereas early weight loss was less when compared with LRYGB, 3-year EWL correlates well with that for LRYGB. Therefore, it seems from these results as well that Americans can succeed with LAGB surgery.

**RESOLUTION OF COMORBIDITIES**

The real benefit of weight loss surgery is the resolution of the significant comorbidities related to morbid obesity. LRYGB has clearly shown that significant weight loss can improve type 2 diabetes, hypertension, gastroesophageal reflux (GERD), hyperlipidemia, sleep apnea, asthma, polycystic ovarian syndromes, depression, arthritis, stress incontinence, and overall quality of life.\(^3\)\(^0\),\(^6\)\(^3\) LAGB has been shown to improve these comorbidities as well.\(^5\)\(^4\)

Dixon and O’Brien\(^2\)\(^0\),\(^6\)\(^5\),\(^6\)\(^6\) have completed multiple studies showing improvements in diabetes after LAGB. These investigators reported significant normalization of glucose, hemoglobin A1c, and insulin resistance in 64% of type 2 diabetics and improvements in 26% after LAGB, and also noted resolution or improvements in hypertension with 92% of patients after LAGB. There were some reports of increasing rates of GERD after LAGB.\(^6\)\(^7\) This phenomenon was thought to correlate with the presence of hiatal hernias that were not concomitantly repaired during the time of surgery, as well as adjustment difficulties such as overtightening of the band.\(^6\)\(^8\) The pars flaccida technique and the adoption of the principle that all hiatal hernias should be repaired during LAGB changed these early outcomes.\(^4\)\(^6\),\(^6\)\(^9\) Dixon and O’Brien found that 89% of patients had resolution of GERD after LAGB, 5% had improvement in symptoms, 2.5% had no change in symptoms, and 2.5% had worsening of symptoms.

**SUMMARY**

A systematic review from October 2007 put it best:

*LAGB has been shown to produce a significant loss of excess weight while maintaining low rates of short-term complications and reducing obesity-related comorbidities. LAGB may not result in the most weight loss but it may be an option for bariatric patients who prefer or who are better suited to undergo less invasive and reversible surgery with lower perioperative complication rates. One caution with LAGB is the uncertainty about whether the low complication rate extends past three years, given a possibility of increased band-related complications (eg, erosion, slippage) requiring re-operation.*\(^7\)\(^0\)

It is clear that there is a role for LAGB in bariatric surgery. LAGB has evolved through the decades to become an effective option for patients fighting the disease of obesity. Patients can receive a less invasive bariatric procedure and have similar weight loss to LRYGB patients as well as resolution of their comorbidities,\(^7\)\(^1\)–\(^7\)\(^3\) although it comes with the risk of possible reoperation rate for band slippage, erosion, port flips, and foreign-body infections.\(^7\)\(^4\) Understanding these risks, patients can still make quality choices on bariatric procedures and still choose LAGB as an option. With recent FDA approval of the LAP-BAND for a BMI greater than 30, the next frontier will begin
for LAGB. LABG may play a crucial role in primary prevention of obesity and morbid obesity for Americans in the near future.

REFERENCES


