# Chapter 9
# Laparoscopic Adjustable Gastric Banding: Procedure and Outcomes

**Brandice Durkan and Monali Misra**

## History

The gastric band was originally designed as a nonadjustable device placed on the upper aspect of the stomach to allow restriction of intake of food, with the ultimate goal of early satiety and weight loss. Unfortunately, as patients lose weight, a loss of restriction was noted, which affected the end goal of weight loss. This prompted the need to develop a band with the ability to be adjusted to different levels of restriction as required by the patient. Fortunately in the mid 1980s, this device was created and performed with favorable results [1, 2]. In the early 1990s, the laparoscopic version of the adjustable gastric band was created, allowing a minimally invasive, safe option for significant, durable weight loss [3–5].

The gastric band was originally placed lower on the stomach, using a perigastric dissection. This choice for initial placement contributed to unacceptable rates of gastric herniation which is also referred to as slippage or prolapse (10–15 %) [6]. This can occur early or much later in the patient's surgical course. Early prolapse usually leads to severe obstructive symptoms while late prolapses can be either chronic or acute in presentation. When chronic, one finds progressive enlargement of the pouch, which leads to the appearance of chronically worsening obstructive symptoms of heartburn, reflux, and vomiting.

In order to lower the high gastric herniation rate, a new surgical method termed the pars flaccida technique was developed. This technique had been determined

M. Misra (✉) · B. Durkan
Department of Surgery, Cedars Sinai Medical Center,
Los Angeles, CA, USA
e-mail: drmonamisra@gmail.com

B. Durkan
e-mail: brandice.durkan@cshs.org



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to be as effective as the perigastric approach in generating substantial weight loss, improved health, and quality of life and has been shown to be significantly less associated with early and late prolapse [7].

## Technique

Typically, the adjustable gastric band is placed laparoscopically using 4–6 small incisions. The key points of the operation include creating a retrogastric tunnel extending from the lower medial aspect of the right crus of the diaphragm toward the angle of His. This is best created under direct visualization. Gentle and careful blind passage of a blunt instrument is also performed by some surgeons, but significant experience of the anatomy is needed. Great care must be taken to avoid injuring the posterior wall of the stomach with this maneuver. This is especially important in patients with preexisting hiatal hernias.

The band is then prepared with sterile saline and then placed into the abdomen via the 15 mm port. The end-tag of the band is then brought up to meet the now retrogastric grasper or specially designed band passer and is pulled through (Fig. 9.1a–c). The band tubing is then grasped and the band is retracted into appropriate position (Fig. 9.2). The band is then locked into position (Fig. 9.3a–c). Permanent suture is employed to secure the band in place by creating an anterior gastro-gastric fundoplication in order to prevent herniation of the stomach upward through the band (Figs. 9.4 and 9.5). The final position of the band should appear in a 2-to-8 angle for proper placement as referenced to the face of a clock.

The tubing is brought out through the abdominal wall. The distal end of the band tubing is then attached to the port. The port is fixed to the anterior fascia to allow it to remain flat against the fascia and prevent flipping of the port. The excess tubing is placed back into the abdomen.

Currently, there are two brands of adjustable gastric bands which are FDA approved for use in the USA. Both are equally safe and effective [8].

## Mechanism of Action

The LAGB has been clearly shown to reduce energy intake [9, 10]. The mechanism of action was originally attributed to restriction; however, several studies have shown minimal to no delayed gastric emptying. If weight loss were due to generating enhanced difficulty in attaining desired meal size alone, strong evolutionary mechanisms to maintain energy balance would likely produce shortened post-meal satiety and resultant grazing between meals. The negligible delay in gastric emptying and prolonged satiety noted by LAGB patients suggests stronger additional mechanisms at work. Greater early satiation and a longer period of satiety appear to be essential to the ability of the band to produce sustained weight loss. This was

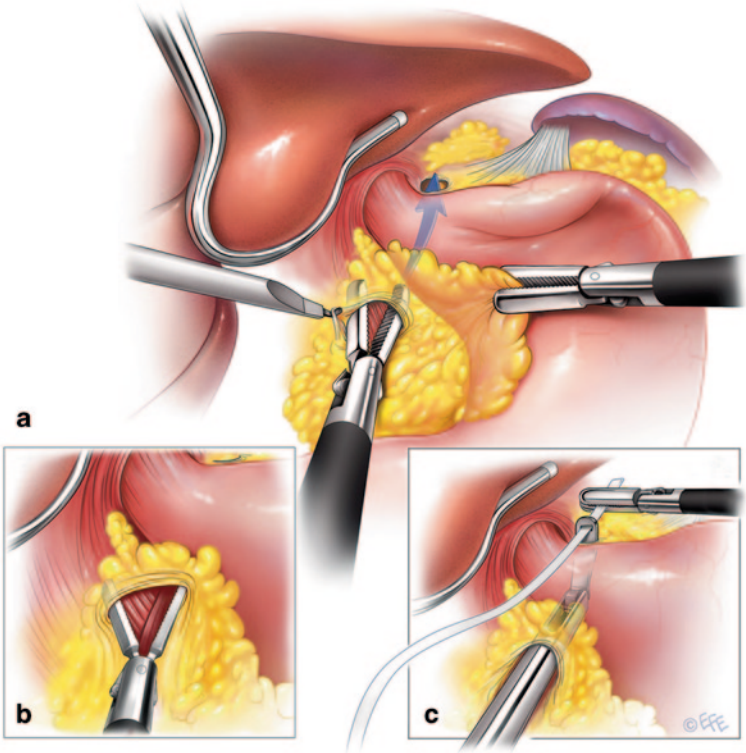


**Fig. 9.1** **a** The retrogastric tunnel extends from the lower medial aspect of the *right crus* of the diaphragm toward the angle of His. **b** The tunnel is best created under direct visualization or by careful blind passage of a blunt instrument by surgeons with significant experience of the anatomy. **c** The end-tag of the band is brought up to meet the retrogastric grasper or band passer and is pulled through

demonstrated by a double-blind randomized, controlled trial with the band either correctly adjusted or empty. When the band was correctly adjusted, subjects were less hungry after a 12-h fast and found a small meal more satisfying [11]. Glucose, insulin, ghrelin, and leptin levels in this study did not vary between optimal and decreased, suboptimal restriction.

Esophageal motility has been shown to be well preserved in LAGB patients with a successful outcome. One study showed that varying the volume between optimal, 20 % under, and empty produced few changes in esophageal motility [12]. The authors also noted repetitive esophageal contractions in 40 % of swallows in optimally adjusted LAGB patients. Repetitive contractions appear to be of functional importance as they reflect the esophageal response to decreased bolus transport across the band.

Postoperative management is affected by achieving appropriately adjusted bands, carefully avoiding either a lack of restriction or excessive restriction with obstructive symptoms.

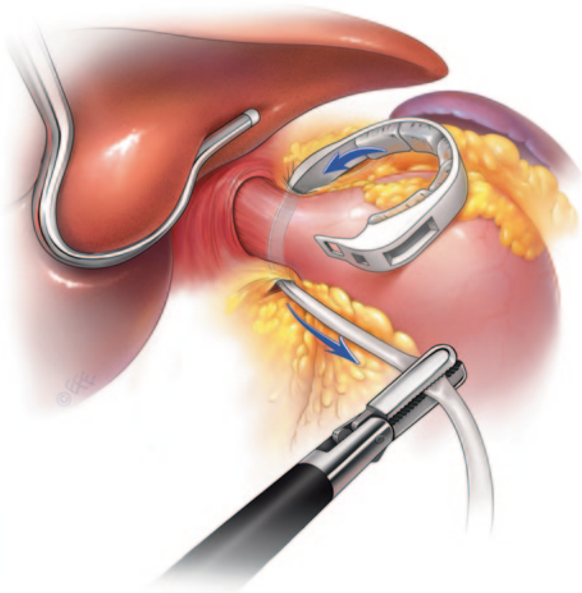

**Fig. 9.2** The band tubing is then grasped and the band is retracted into appropriate position

## Band Adjustments

Band adjustments are typically performed in the office with or without the aid of fluoroscopy. Prior to each band fill, a detailed history is required including current food choices, hunger between meals, portion sizes, symptoms of regurgitation, night cough, and any discomfort with eating should be noted. Patients need to comprehend the importance of early satiation and prolonged satiety in permitting 50 % reduction in daily energy intake [13]. This may be accomplished by eating slowly and increasing the time spent for chewing to avoid obstructive symptoms. One bite of food should be chewed almost 20 times until mushy. Once swallowed, at least 30 s to a minute should pass before another small bite is placed into their mouth. The standard portion size is approximately 1–1.5 decks of cards (or the palm of your hand) consumed slowly over approximately 20–30 min. Patients are recommended to consume 3–4 small meals a day.

The band should be adjusted to the "green zone" based on symptomatology (Fig. 9.6). If patients are hungry between meals and needing larger portions, they are likely in the yellow zone and an adjustment to add fluid into the band is needed. If they are having good portion control with feelings of satisfaction and lack of hunger, they are in the green zone and no adjustment is needed. Lastly, if they are experiencing symptoms of regurgitation, discomfort while eating, or night cough, they are in the red zone and will require an adjustment to remove fluid from the band. Red zone

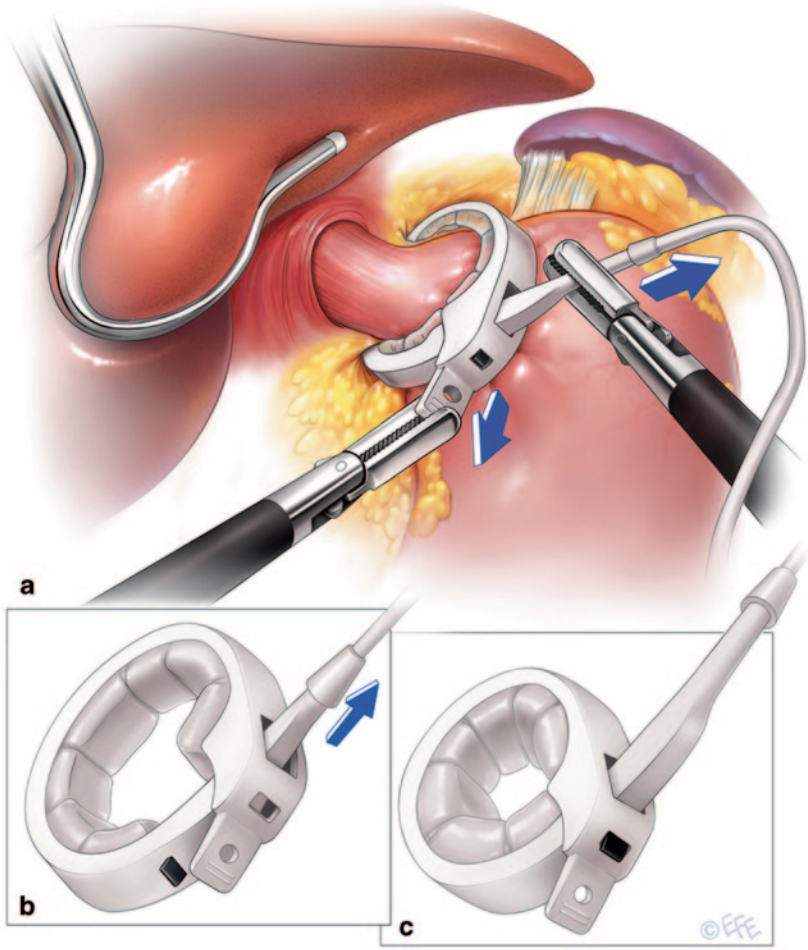


**Fig. 9.3** **a** The band is then locked into position through the use of counter tension applied by graspers in the direction of the *arrows*. **b** The band is in the unlocked position and the *arrow* illustrates the force vector required to lock the band in place. **c** The band is now in the locked position

patients typically have poor weight loss and make poor food choices such as high calorie liquids as they are too tight and unable to tolerate healthy optimal foods.

Adjustments are performed using sterile technique. Often a small amount of lidocaine is used to numb the skin above the port. A Huber needle is always used to adjust the band as it has a beveled tip to prevent coring of the port with repeated adjustments. Saline fluid is either added or removed as needed. Patients are usually asked to drink a couple of glasses of water prior to leaving the office to ensure they are not too tight. Patients are typically asked to return for an adjustment when they are no longer in the green zone.

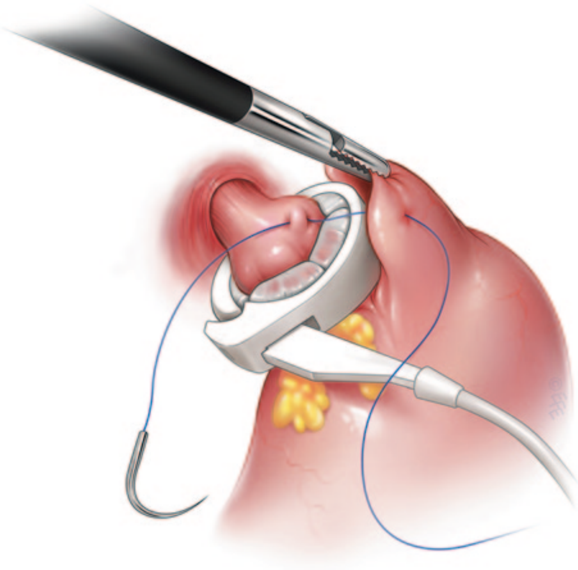

**Fig. 9.4** An anterior gastro-gastric fundoplication is made in order to prevent herniation of the stomach through the band. Permanent suture is used to secure the band in place

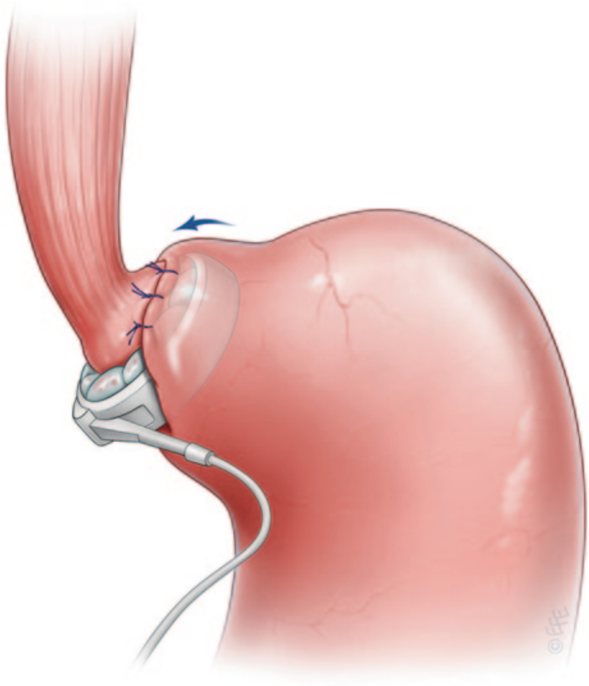

**Fig. 9.5** The final position of the band should be from the 2 o'clock to 8 o'clock angle for proper placement

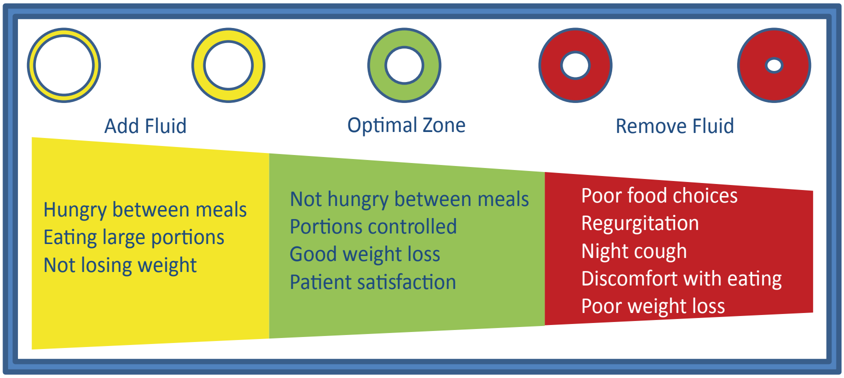


**Fig. 9.6** The *green* zone chart allows patients to understand what a correctly adjusted band should feel like

## Indications and Contraindications

Criteria for patient selection for weight loss surgery are based on guidelines of the National Institute of Health and national surgical societies. The American College of Surgeons, Society of Gastrointestinal Endoscopic Surgeons (SAGES) and The American Society of Bariatric Surgeons have all offered guidelines for patient selection.

The National Heart, Lung, and Blood Institute in cooperation with The National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health (NIH) compiled recommendations on patient selection for bariatric surgery in 1998. This report updated the NIH Consensus Development Conference Statement of 1991. The 1998 recommendations were published as the Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: The Evidence Report [14]. The NIH made the recommendation that weight loss surgery is an option for carefully selected patients with clinically severe obesity (Body Mass Index > 40 or > 35 with comorbid conditions). This is after less invasive weight loss methods have failed and the patient remains at a high risk for obesity-related morbidity or mortality. The report also summarized available data regarding weight reduction after the age of 65. The potential benefits of weight reduction for daily functioning, decreased risk of future cardiovascular events, and the patient's motivation for weight reduction should be thoroughly evaluated. Any weight reduction program should minimize the likelihood of adverse effects on bone health and overall nutritional status in the older adult.

The America College of Surgeons published recommendations for "Recommendations for Facilities Performing Bariatric Surgery" (ST-34) [15]. They point out that bariatric surgical procedures are not for cosmesis, but for prevention of negative health consequences of morbid obesity. Patients must be committed to both the appropriate preoperative evaluation and the long-term postoperative medical management. Patients must have a full understanding of the potential complications of the procedure.

The American Society of Gastrointestinal Endoscopic Surgeons (SAGES) issued "The SAGES Guidelines for Laparoscopic and Conventional Surgical Treatment of Morbid Obesity." The specific criteria for surgical therapy are for people with a body mass index (BMI) of greater than 40 kg/m$^2$ or a BMI greater than 35 kg/m$^2$ with significant comorbidities, with evidence that dietary attempts at weight control have been ineffective.

The American Society of Bariatric Surgeons (ASBS) emphasize that surgical treatment should be offered to patients who are severely obese, well informed, motivated, and have acceptable operative risks. Anyone with psychopathology that jeopardizes an informed consent and cooperation with long-term follow-up may be poor surgical candidates. Central obesity and obesity-associated functional impairments such as musculoskeletal or neurologic or body size problems precluding or severely interfering with employment, family function, and ambulation may be best served by surgical treatment.

There are six categories defined by the NIH recommendations that assist in determining appropriateness for surgical weight loss: Age, BMI, family history of significant comorbid medical conditions related to morbid obesity, the development of significant comorbid health conditions related to morbid obesity, failure of established weight control programs to achieve sustained weight loss, and mental competence to give informed consent to participate in long-term follow-up programs.

Optimal age range for surgical intervention is between 18- and 65-years-old. Younger patients may be considered if they require rapid weight reduction for resolution of obesity-related life-threatening comorbid health conditions. For patients who are older than 65 years, the expectation of improved life expectancy or quality of life should outweigh the risk of surgery. Patients should have a body mass index $>40$ kg/m$^2$ or a body mass index $>35$ and $<40$ kg/m$^2$ with the presence of significant comorbid conditions related to morbid obesity.

According to the NIH, weight loss surgery is indicated for people with a high risk for obesity-associated morbidity or mortality. As such, surgery may be indicated in for a person with a strong family history of obesity-related health conditions. For patients who have already developed significant medical conditions related to morbid obesity, weight loss surgery may cure or significantly improve comorbid diseases and prevent their associated morbidity and mortality. Examples of significant medical conditions include diabetes mellitus, sleep apnea, high cholesterol, the metabolic syndrome, or infertility.

Surgical treatment of morbid obesity is appropriate only in patients in whom success with established weight loss programs seems unlikely. In order to qualify, patients must have made sustained efforts in organized weight loss programs over a substantial time period. Appropriate programs include a variety of commercial weight loss programs, caloric restriction diets directed by nutritionists, dieticians, or diabetes centers, or intense exercise programs directed by an exercise therapist or other qualified professional.

Patients must be mentally competent to give informed consent. Patients with a significant psychosis may not be able to adhere to the prolonged follow-up programs.

In 2011, the FDA approved the use of the lap band in patients with BMIs of 30–34.9 with one significant obesity-related comorbidity, or patients with BMIs of 35–39.9 with no comorbidities. This decision was made after review of studies showing the safety and efficacy of the lap band in lower BMI patients, providing durable weight loss and significant comorbidity improvement or resolution [16, 17]. Although currently insurance companies follow the original guidelines and have not adopted coverage of the lap band procedure at this lowered BMI, it is an option for patients requiring sustainable weight loss for comorbidity resolution or improvement, and will significantly impact comorbidity prevention.

## Weight Loss Outcomes

Although weight loss after LAGB surgery is not as rapid as seen with Roux-Y-gastric bypass or sleeve gastrectomy, weight loss with the band is progressive over approximately 2 years and appears durable. One study demonstrated that after reaching peak weight loss at 2 years, there is a high degree of stability of the weight loss status through the next 13 years [18]. Randomized controlled trials have demonstrated LAGB to be superior to conventional nonsurgical weight-loss programs for sustained weight loss and diabetes management [19–21].

The first adjustable band was approved by the US Food and Drug Administration in 2001. As the LAGB has been available for use outside the USA since 1993, there are much longer follow-up durations. An Italian series has the longest follow-up and details of 1791 consecutive patients with a mean excess weight loss of 50 % 12 years after LAGB [19]. Procedures such as RYGB and sleeve gastrectomy have better early weight loss but usual partial weight regain 2–5 years after surgery [22, 23].Although LAGB weight loss takes a longer course to reach a maximum, at 5 years LAGB patients achieve the comparable weight loss results of 55 % of excess weight loss versus 58 % with Gastric Bypass. [22].

## Health Outcomes

### *Diabetes*

The risk of developing type 2 diabetes increases with the degree and duration of obesity and is more common with a central weight distribution. The associated decrease in insulin sensitivity seen with central obesity correlates with impaired glucose tolerance, dyslipidemia, and systemic hypertension and increased cardiovascular risk. The beneficial effect of weight reduction on control of type 2 diabetes has been known for some time and studies have shown benefit even from modest weight reduction [24, 25].

At 2 years after placement of the lap band, 50 % of those with type 2 diabetes mellitus will no longer require diabetic therapy [21, 26]. The sooner the intervention to time of diabetic onset, the higher the remission rate, likely due to the maintained β-cell function [27]. The improvement in insulin sensitivity is correlated with weight loss, but improvement in β-cell function is not. The percentage of excess weight lost also affects the likelihood of remission of type 2 diabetes.

A randomized controlled study published by Dixon in 2008 clearly demonstrated the effectiveness of Lap band versus conventional medical therapy for diabetes resolution with 73 % versus 13 % resolution seen in the surgical group at 2 years [21].

The recent meta-analytic review of the two most commonly used LAGBs revealed a 60 % resolution of diabetes, and significant improvements of the other parameters of the metabolic syndrome, clearly demonstrating the effectiveness of this device in comorbidity resolution as well as weight loss [8].

## *Asthma/Sleep Apnea*

Morbidly obese adults have a high rate of asthma, and major reductions in asthma severity occur after weight loss. This is likely due in part to the prevention of gastroesophageal reflux. One study examining the effect of LAGB on asthma symptoms found significant improvements in all aspects of asthma assessed. These included severity, daily impact, medications needed, hospitalization, sleep, and exercise [28].

Obesity-related sleep disorders improve markedly after weight loss. Waist circumference was the best clinical measure predicting observed sleep apnea [29]. Following the expected excess weight loss with band placement, there is a statistically significant improvement in habitual snoring, observed sleep, abnormal daytime sleepiness, and poor sleep quality.

A 93 % resolution of sleep apnea was shown in a study published in 2001, clearly demonstrating the continued benefits of comorbidity resolution of this safe, effective device [29].

## *Hypertension*

Weight loss also modifies other significant cardiovascular risk factors. Hypertension is better controlled and fewer patients require antihypertensive medications following band placement [27]. Resolution of hypertension, defined as no longer requiring medications to remain normotensive, has been found in 68–74 % of lap band patients [27, 30].

These findings were once again demonstrated in the meta-analysis by Cunneen et al. revealing an average of 46–63 % resolution of hypertension with LAGB [8].

## *Gastroesophageal Reflux*

The relationship between morbid obesity and gastroesophageal reflux disease (GERD) before and after LAGB placement remains controversial. It is commonly thought that obesity is an important factor for the development of GERD. Perhaps the chronic elevation in intra-abdominal pressure favors reflux [31]. Other studies have not found any correlation between obesity and gastroesophageal reflux symptoms and esophageal dysmotility [32]. At this time, most surgeons recommend and studies demonstrate an aggressive approach to hiatal hernia repair at the same time as LAGB placement. They believe that this significantly reduces the risk of development of GERD and improvement in GERD symptoms postoperatively. Dixon's paper clearly shows a 76% resolution and 14% improvement in GERD symptoms 2 years postop [33].

## Complications

LAGB, as a surgery for obesity, carries lower procedural risks and is a shorter, less invasive operation when compared to RNYGB or sleeve gastrectomy. There is evidence to support that band placement may even be safely performed in an ambulatory care surgical center [34, 35]. LAGB surgery generally has a very low risk of mortality and morbidity. Mortality rates are in the range of 0.05% [36]. Despite the rarity of operative and early postoperative mortality, deaths attributed to pulmonary thromboembolism, vascular injury and resultant blood loss, and bowel perforation leading to sepsis have been reported. Data from the American College of Surgeons Bariatric Surgery Center Network (Table 9.1) shows the LAGB procedure to compare favorably to the gastric bypass and sleeve gastrectomy procedures in short- and medium-term follow-up.

Over the course of the laparoscopic adjustable band's history, there have been several changes that have led to a significant decrease in the need for revisional surgery. These may be mostly attributed to technical changes in the bands and adjustment systems, and better teaching of placement technique. Currently, the most common complication is dilatation of the proximal gastric pouch [36]. This is most likely due to overly tightening the LABG in attempts to achieve greater weight loss and poor follow-up. This eventually leads to either a portion of the stomach herniating above the band or a progressive stretching of the gastric wall. Both are associated with dysphagia and regurgitation, gastroesophageal reflux, obstruction, night cough, and poor eating behavior. Once the symptoms are identified and diagnosis

**Table 9.1** Morbidity and mortality associated with LRYGB, LSG, and LAGB from the ACS-BSCN dataset. (Data from [37])

| – | LRYGB | LSG | LAGB |
|---|---|---|---|
| 30-day mortality (%) | 0.14 | 0.11 | 0.05 |
| 1 year mortality (%) | 0.34 | 0.21 | 0.08 |
| 30-day morbidity (%) | 5.91 | 5.61 | 1.44 |
| 30-day readmission (%) | 6.47 | 5.40 | 1.71 |
| 30-day reoperation/intervention (%) | 5.02 | 2.97 | 0.92 |

*LRYGB* laparoscopic Roux-en-Y gastric bypass, *LSG* laparoscopic sleeve gastrectomy, *LAGB* laparoscopic adjustable gastric band confirmed on upper gastrointestinal imaging series, treatment involves laparoscopic repositioning or removal of the band. Findings of complete obstruction may become life threatening, and patients with such symptoms must be seen urgently by a bariatric surgeon [38]. Unfortunately, the recent reports of high degrees of long-term failure may be directly attributed to this poor follow-up.

Band erosion into the lumen of the stomach is a rare but potentially devastating complication of LAGB placement. Band erosion has an incidence of approximately 1.5 % and is lower in the hands of experienced surgeons [39]. The mean time from initial band placement to erosion is 12 months. Erosions usually do not present as surgical emergencies but as loss of action of the band.

Complications requiring reoperation are reported in 10–15 % of patients, and permanent removal of the band is infrequent; less than 5 % [40, 41]. These numbers have been decreasing since the advent of the band given improvements in band materials and adjustment techniques. Given that the band is made of synthetic material, band replacement due to material wear remains a possibility even for a correctly placed and maintained band system.

## Postoperative Management

The success with LAGB begins prior to surgery. It is imperative that the patient understand that obesity is a chronic condition, and a commitment to follow-up is integral to successful postsurgical outcomes. At the completion of the surgical placement, no additional saline should be added. The initial addition of fluid most commonly occurs at the 4–6-week postoperative patient visit. Timely band adjustments support weight loss by helping patients avoid feeling symptoms associated with under or over filling. Band adjustments may be performed within an office visit. The use of fluoroscopy is helpful, especially in difficult patients. Patients generally require 4–10 adjustments in the first year and 1–3 during subsequent years [42]. Clear dietary recommendations are important immediately postoperative and in the long term. Only liquid intake is encouraged within the first 2 weeks after band placement. The anticipated intake during this time is approximated to be 800–1000 cal. Over the following 2–4 weeks, there is a transition phase from liquids to soft foods to solid food. A once-a-day multivitamin containing daily requirements of folic acid, vitamin B1, and vitamin B12 is recommended. In addition, other supplements, including calcium, vitamin D, and iron, may be added.

The LAGB allows for a sense of satiety and compliance with the following recommendations. Patients are typically encouraged to eat three to four small meals per day of high protein or complex carbohydrate, solid foods. Many patients experience difficulty with breads and red meat. Occasionally, there may be some difficulty with dry chicken, rice, and some types of vegetables. Patients are advised to eat slowly, stop when comfortable, and not snack between meals. There are to be no liquids with the meals, and most liquids should be calorie-free. Analysis of food intake with these specified rules indicated a daily consumption of between 800 and 1200 cal [42].

Generally, it is recommended that the LAGB patient be seen every 4–6 weeks during the first postoperative year and every 3–6 months for 2 additional years. After this period, yearly visits suffice depending on the need for adjustment. Associated comorbidities such as diabetes, hypertension, sleep apnea, and asthma should be monitored and therapy modified as needed. Plasma glucose, lipid profile, liver function tests, iron, vitamin B1, vitamin B12, and folate levels should be monitored. Communication with the patient's primary care provider is essential to managing these comorbid conditions. Postoperative care is continued for as long as the LAGB is in place and may represent a lifelong commitment.

It is clear that LAGB is a safe, effective solution to significant, sustainable weight loss as well as comorbidity resolution. It is also clear that patients receive long-term postoperative care to ensure the best outcomes.

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