Laparoscopic adjustable gastric band
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Since Belachew [1] first performed the procedure in 1993, laparoscopic adjustable gastric banding (LAGB) has gained in popularity around the world as a first-choice surgical therapy for severely obese patients. LAGB is a purely restrictive operation that relies on decreased amount of intake as the mechanism for weight loss, and has less risk of malnutrition than with diversionary or bypass procedures. Adjustable gastric banding involves the surgical implantation of an inflatable silicone band around the uppermost part of the stomach, which is tightened in the office based on individual weight loss and appetite. Band tightening or adjustments are performed by percutaneously accessing a subcutaneous reservoir port that is connected to the band, and injecting fluid into the system. Band adjustments are required approximately five or six times in the first year and two or three times in the second year. Weight loss is gradual, averaging 1 to 2 lb per week during the first 2 years after surgery. The LAP-BAND System (Inamed Health, Santa Barbara, California) was the first device approved by the Federal Drug Administration (FDA) in 2001, and is presently the only adjustable gastric band available in the United States. Other versions exist internationally, one of which is in the approval process for use in the United States.

If one were asked to define a good minimally invasive bariatric procedure, there are some features that might be considered. Above all else, the procedure should be safe. There should be a reasonably quick operating room time and a low rate of conversion to open surgery. Hospital stay should be short, with minimal postoperative complications, especially related to wound and pulmonary difficulties, and patients should be able to return to work and normal activities as soon as they can. Ideally, there should be few long-term risks once the procedure is completed. The weight loss should be effective and lasting, and the symptomatic consequences of the procedure should be well tolerated by the majority of patients. If the
patient cannot tolerate the procedure, it should be able to be converted to an alternate procedure, or completely reversed. Finally, it should be a procedure that is reproducible and teachable on a broad front to surgeons in training, and to any surgeon who is committed to the principles of bariatric surgery.

This article on LAGB for morbid obesity aims to address the issues raised in the preface to this edition concerning the effectiveness of the band as a minimally invasive procedure by assessing the above features as presented in recent literature.

**Safety, conversion to open, and early complications**

Virtually all published series of primary LAGB insertions have a conversion rate around 1%. This is usually due to hepatomegaly, or occasionally to adhesions. There are few comparative laparoscopic versus open data for LAGB. De Luca et al [2] compared 4-year results in 69 patients who underwent LAGB procedure by laparotomy or laparoscopy. Four open patients were reoperated to remove the band, and in 9 patients a ventral hernia appeared (5 patients repaired). In the laparoscopic cases there were 4 intraoperative gastric perforations, but all were repaired and the band placed at the same time (three conversions to open), causing an increased postoperative hospital stay. This is evidence of the learning curve. De Wit and colleagues [3] performed a prospective randomized trial comparing open and laparoscopic adjustable silicone gastric banding (LASGB) in 50 patients. The total number of readmissions (6 versus 15) and overall hospital stay in the first year (7.8 versus 11.8 days) were both lower after LASGB ($P < 0.05$). Weight and body mass index (BMI) were reduced significantly in both groups, but there was no difference between the groups. The laparoscopic procedure was associated with a shorter initial hospital stay and fewer readmissions during follow-up, and is therefore the preferred treatment.

There are some data comparing LAGB with other procedures that assess perioperative complications. Suter and associates [4] compared the early results of laparoscopic gastric banding and open vertical-banded gastropasty (VGB) in 197 patients. Mortality was similar, but the postoperative morbidity was higher in the VBG group (23.8% versus 8.0%, $P < 0.005$). The hospital stay was much shorter in the LAGB group; weight loss was less after 6 and 12 months, but was similar after 18 months in both groups.

LAGB is the safest bariatric operation available, with 0.05% mortality [5], 5% 30-day morbidity, and a delayed complication (gastric prolapse, erosion, port/tubing disconnection) rate of 12% [6–15]. O’Brien and Dixon [16] reviewed 1120 laparoscopic bands, and at 6 years have found no mortality. Weiner and coauthors [17] have 8-year data on 984 patients with zero mortality. A combined series [18] from Europe of 5827 patients has 0.2% mortality. Fielding and Duncombe [19] have 2110 bands at 7 years with 0.05% mortality. A combined Italian series [20] of 1265 patients with
BMI 44 has 0.5% mortality. The dominant theme of these longer-term follow-ups is that the laparoscopic band is very safe.

The Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S), a government body whose role is to assess the safety and effectiveness of new procedures, evaluated the LAGB against open VBG and open Roux-en Y gastric bypass (RYGB) in terms of safety and efficacy. Their literature review (121 studies) [5] found LAGB to be safer than VBG and RYGB, and to be effective up to 4 years after surgery. Their conclusions were that in published literature, the laparoscopic band has mortality of 0.05%, compared with 0.5% for the gastric bypass. At 4 years, weight loss was the same, after an initial advantage to the RYGB. The median complication rate for LAGB was 11.3%, with very few studies reporting overall morbidity rates above 20% [5]. The frequency of complications is inversely related to surgeon experience with the procedure.

The ASERNIP-S review illustrated the relationship between the number of patients in the series and the incidence of complications. This underscores the learning curve associated with LAGB surgery, and may explain some of the early US center outcomes [21]. More importantly, the severity of complications after LAGB is significantly lower compared with gastrointestinal bypass operations.

When complications from LAGB, laparoscopic RYGB, and laparoscopic biliopancreatic diversion with duodenal switch (BPDDS) are compared according to severity (grade 1–4) and time of occurrence (early versus late), LAGB is the safest operation. A recent review of over 3000 patients with RYGB from one center over a 20+ years period of time [22] showed 1.5% mortality and 3.2% leak. Flum and Dellinger [23] recently reported a 1.9%, 30-day mortality in 3328 patients from Washington state undergoing RYGB. As ASERNIP-S recently reported, mortality was directly related to experience.

These data have recently been further supported by Laker et al [24], who compared risk of bad outcomes among LAGB, RYGB, and biliopancreatic diversion (BPD), all done laparoscopically, in a major teaching hospital in New York. In a study of 780 bariatric operations (480 LAGB, 235 RYGB, and 65 BPD) there was one late death after RYGB. Total complication rates were 9% for LAGB, 23% for RYGB, and 25% for BPD with or without duodenal switch (BPD ± DS). Complications resulting in organ resection, irreversible deficits, and death (Grades III and IV) occurred at rates of 0.2% for LAGB, 2% for RYGB, and 5% for BPD ± DS. The LAGB group had a statistically significant lower overall and severe complication rate compared with other groups ($P < 0.001$). After controlling for differences between the groups on age, admission BMI, gender, and race, LAGB patients had almost three and a half times lower likelihood of a complication compared with the RYGB group (OR = 3.4, 95% CI = 2.2–5.3, $P < 0.0001$). The odds ratio for developing complications after LAGB is 3.5 times lower than laparoscopic RYGB and laparoscopic malabsorptive operations.
Retrospective data from Biertho and colleagues [25] comparing LAGB to RYGB found a significantly lower postoperative major complication rate after LAGB (1.7%) compared with RYGB (4.2%). Fisher [26] recently showed that, in his hands, LAGB patients were discharged significantly quicker than after laparoscopic RYGB, and that LAGBs were able to resume normal activity at 7 days, compared with 18 days for laparoscopic RYGB ($P = 0.0002$). Dolan and coworkers [27] compared BPD and LAGB in 46 superobese (BMI $>50$) patients. Median excess weight loss at 24 months was 15% greater with BPD than with LAGB, but hospital stay and complication rates were also considerably greater with BPD. Rates of resolution of obstructive sleep apnea, hypertension, and diabetes mellitus following LAGB were similar to those of BPD. The researchers felt that the significant complication rate associated with BPD in superobesity outweighs any potential benefits of the extra weight loss gained over LAGB.

**Complications**

After Belechew [1] published his work in 1994, LAGB became popular in Europe, Australia, and Mexico. The technique has evolved considerably since then [28]. The first major change was evolution of the pars-flaccida approach to the esophagogastric angle, such that the band is placed out of the lesser sac. This has greatly reduced the incidence of gastric herniation through the band, the so-called “slip.” The incidence of this complication has fallen from 12% in early series to 1% to 2% in current practice [18]. The second change was to leave the band uninflated at surgery, so that it remained loose while the gastro-gastric sutures healed. This has further reduced the chance of slip by eliminating vomiting in the early postoperative period. The adjustments to the band are done slowly and regularly, usually at 6- to 8-week intervals. This encourages regular attendance at follow-up and ensures a steady rate of weight loss. Finally, the adjustments are performed in the surgeon’s office, based on the patients’ hunger, rate of weight loss, and the volume of food they can eat. This has greatly simplified the adjustment schedule, and virtually eliminated the need for radiographs. These changes have led to high levels of patient tolerance of the laparoscopic band, and to sustainable weight loss.

Gastric prolapse, also known as band slippage, consists of herniation of the stomach up through the band cephalad, resulting in an enlarged gastric pouch, band malposition, and partial or complete gastric occlusion that typically presents as nocturnal vomiting. It occurs at a rate of 1.8% to 5% [29,30]. Band erosion occurs rarely (0%–7%), and appears to be associated with surgical technique, either from sewing the stomach over the band buckle or from microperforation of the stomach during surgery. Port and tubing problems include port migration, port infection, tubing disconnection, tubing kink, and port leak. These mechanical problems require surgical repair to maintain a functional device for weight loss.
Esophageal dilation may be an indication for band removal in patients who cannot tolerate restriction. DeMaria and associates [21] raised concerns about the possible long-term deleterious effects of long-term dilatation. In response to this, Fielding et al [31] have assessed follow-up results for complication, band removal, weight loss, and comorbidity reduction in patients with LAGB performed in 1998 by perigastric technique, and in 2000 by pars-flaccida technique, offering patients in 1998 a barium esophagram to assess dilatation. One hundred and twenty-three patients who had mean BMI 44.5 kg/m$^2$ had LAGB in 1998, and 162 who had mean BMI 44 had LAGB in 2000. Patient follow-up at mean 67 months was 88% for 1998 and 94% at 34 months for 2000. Mean excess weight loss (EWL) for 1998 was 51.2%, with mean BMI 31.9. Slip occurred in 9.5% of patients in 1998, compared with 4.3% in 2000 ($P < 0.01$). Only 1 of 34 patients had esophageal dilatation on barium esophagram. This dilatation completely resolved after band deflation.

Weight loss

There have now been more than 120,000 LAGBs placed, and there are numerous favorable early results published with 2- and 3-year follow-up. The one prospective randomized trial between LAGB and VBG [32], with 30 patients in each group, showed 6-month weight loss to be 50% EWL versus 87% EWL respectively, although 6-month data are meaningless. There are no long-term data from prospectively controlled studies. Early reports at 2 and 3 years suggested weight loss of 55% to 60% EWL (Table 1). Weight loss after LAGB is gradual and steady for up to 3 years, after which a steady plateau of 51% to 56% EWL is maintained out to 5 years. The purely restrictive nature of the operation results in daily caloric intake between 800 and 1200 for women and 1200 to 1500 for men, and thus a 1 to 2 lb per day weight loss is achieved. Average weight losses at years 1, 2, 3, 5 and 6 are 44.7%, 54.9%, 57.5%, 53%, and 57%, respectively (see Table 1).

Table 1

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This has been further supported by more recent data at 5, 6, 7, and 8 years (Table 2). O’Brien and Dixon [16] have data on 1120 laparoscopic band patients at 6 years, with BMI falling from 46 to 30 kg/m², and 54% EWL. Weiner and coworkers [17] have 8-year data on 984 patients who had BMI 47, showing 57% EWL. Fielding and Duncombe [19] have 2110 bands, BMI 47, with 50% EWL at 6 years. A combined series from Europe [18] of 5827 patients who had a BMI of 46 has BMI 31 at 5 years. Steffen and coauthors [33] prospectively followed 824 patients after LAGB to 5 years (97% follow-up) and found that 83% achieved and maintained greater than 50% EWL. The second dominant theme of these longer-term follow-ups is that the laparoscopic band is effective.

Early experience in the United States was less satisfactory. In contrast to these positive international data, a small US series based around patients in the early FDA trial reported very high rates of band removal, correlating this with significant incidence of esophageal dilatation. DeMaria et al [30] reported high band-failure rates and band removal, in a series of perigastric bands that were infrequently adjusted. This obviously raised concerns about the long-term safety and efficacy of the LAGB in the US population, and had a profound effect on the perception of LAGB in the United States.

Results from more recent US experience more closely match those from abroad, however. Rubenstein [34] has reported on patients after having 54% EWL at 3 years follow-up. Subsequently, Ren et al [35] first showed that application of techniques used in Australia delivered comparable results. More recently, Ren, Weiner and Allen [36] reviewed their experience from May 2001 to December 2002 with 445 patients having a BMI 49.6 kg/m² (35–92). These patients had been treated as described above, with pars-flaccida technique, a loose band, and with slow steady adjustments performed in the office. There was one death (0.2%). At 1-year follow up, this cohort of patients had 44% EWL.

Patient attitudes

There can be little doubt that LAGB offers effective early weight loss, and that it is a safe procedure for morbidly obese individuals. This makes it very

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attractive to many obese patients who would otherwise not come forward for surgery. Given the safety advantage and its effectiveness as a weight-loss tool, the LAGB is an attractive proposition for obese patients and their physicians. Two recent surveys have looked at why patients come forward for laparoscopic band surgery. The first [37], from Australia, showed that the dominant reason for surgery was ill health and fear of deteriorating future health, well in excess of concerns for appearance and fitness. Another combined study of 485 patients from New York and Australia [38] found that in both countries safety was the dominant reason people had come forward for LAGB.

**Comorbidity resolution**

The health benefits attendant on the weight loss that follows bariatric surgery are well known. They are the platform upon which the National Institutes of Health (NIH) guidelines for bariatric surgery have been created [39]. Reduction in multiple comorbidities has been well documented after LAGB surgery. O’Brien and coworkers [40] observed that after LAGB, patients experienced 74% improvement or resolution of dyslipidemia, 94% resolution of obstructive sleep apnea, 55% resolution of hypertension [41,42], 100% improvement of asthma, and 76% resolution with 14% improvement in gastroesophageal reflux [43–45]. In a study of 295 patients, Frigg et al [46] found that at 4 years, LAGB resulted in 54% EWL and 58% resolution of hypertension, 75% resolution of diabetes, and 79% resolution of reflux. There are no studies at this time that prospectively compare the outcomes of LAGB to nonsurgical medical management.

The role of LAGB surgery in the elimination of diabetes has recently been described. Dixon and O’Brien [47,48] reviewed 254 patients at surgery and 1 year. Thirty-nine patients were diabetics on medication. At 1 year, BMI fell from 46 to 36 kg/m², and weight fell from 128 kg to 101 kg, representing 44% EWL. The study showed a 50% increase in insulin sensitivity, from 16% to 25%, and a recovery of beta cell function. This was particularly beneficial in younger patients who had been diabetic for less than 5 years. Dolan and colleagues [48,49] reviewed 88 diabetic laparoscopic band patients, including 11 on insulin, with a 2-year follow-up. At 2 years, there was 51% EWL, and BMI fell from 47 to 34 kg/m². Seventy-four percent of patients on oral hypoglycaemic agents and 55% of patients on insulin were off all treatment by 6 months. The best predictor of cessation of therapy was 30% EWL.

Weight loss following LAGB surgery has a major impact on Type II diabetes mellitus, with resolution or improvement of diabetes in 80.8% of patients, as reflected by meta-analysis. In Buchwald and coauthors’ meta-analysis [50], the control of diabetes with LAGB was 47.9% (95% confidence, 29.1–66.7), in contrast to that following RYGB, which was 83.7% (77.3–90.1); this was associated with a higher percentage EWL in the
RYGB group 68.2% (56.7–74.8) in contrast to the LAGB patients 47.5% (40.7–50.2). It has been suggested that the gastric bypass may provide control of diabetes through the early entry of food into the small intestine.

Follow-up

In their landmark 1995 paper, Pories and coworkers [51] showed that, with high levels of follow-up, good weight loss after RYGB is maintainable, and there is marked elimination of diabetes. Their degree of follow-up has not been widely replicated with gastric bypass, due perhaps to the transient nature of the modern population, with patients traveling great distances to the surgeon of their choice, and to the fact that there is little that can actually be modified by follow-up except discussion of eating habits and maintenance of nutrition. This group is much more difficult to follow, and follow-up rates of 60% to 80% are more typical. A recent report of 240 diabetics in a series of 1160 gastric bypasses from a dedicated bariatric service [52] described follow-up of 80% at mean follow-up of only 19.7 months (6–54 months).

Follow-up is a key ingredient for the success of LAGB surgery. There has been little in the literature actually defining outcome dependant on follow-up. Shen and coauthors [53] have recently produced data on differential rates of follow-up assessing outcome after LAGB. At their institution, in the first year of follow-up, band surgery patients were followed every 4 weeks and RYGB patients every 3 months. The number of follow-up visits for each patient was calculated, and 50% compliance on follow-up and weight loss was compared. Between October 2000 and December 2002, 216 LAGBs and 139 RYGBs were performed. Of these patients, 186 LAGBs were available for 1-year follow-up (86%). At 1 year, EWL for LAGB was 44.5%. Seventy percent returned six or fewer times, and achieved 42% EWL. Fifty-six patients returned more than 6 times and had 50% EWL ($P = 0.005$).

This early experience with LAGB in New York at 1 year confirms, for the first time, the importance of follow-up in maximizing outcome. Fielding and Duncombe [31] recently confirmed the importance of effective follow-up in a series of 197 bands performed in a closed community in Cairns, Australia. They had follow-up of 97% at a mean of 27 months, with a mean 57% EWL, maintained out to 6 years, with an average of five visits per year. There was almost complete resolution of comorbidity at 2 years in this community.

Band removal

All bariatric procedures carry the possibility of failure or patient intolerance. LAGBs are typically removed due to failed weight loss, band erosion, or uncontrolled symptoms of reflux esophagitis or dysphagia. This
seems to occur at a rate of 3% to 6% in most large series. The LAGB has a real advantage in its ability to be easily removed by laparoscopy, and easy conversion to alternate procedures. Patients tend to be converted to either RYGB or BPD. Several authors have described RYGB to salvage failed LAGB [54–57]. None of these relatively small series describes any particular difficulty in performing the conversion. Dolan and Fielding [58] examined the failure rate with LAGB and results of band removal with BPDS ± DS for insufficient weight loss or a complication. The band was removed in 85 (5.9%) of 1439 patients, most commonly for persistent dysphagia and recurrent slippage. The removal rate and slippage rate decreased from 10.8% and 14.2% to 2.8% and 1.3%, respectively, following introduction of the pars-flaccida technique. Mean percentage EWLs 12 months following open BPD, laparoscopic BPD, open BPDDS and laparoscopic BPDDS were 44%, 37%, 35%, and 18%, respectively. The authors found that removal of the band with synchronous BPD or BPDDS can be performed laparoscopically. Favretti first described addition of the distal BPD-style bypass to a band for failed weight loss, leaving the band to control hunger. Himpens et al [59] described adding a band to a failed gastric bypass. Slater and Fielding [60] found identical results, showing that addition of a band to a failed BPD or a bypass to a failed band delivers excellent weight loss.

The advent of the 11-cm Vanguard (Inamed Health, Santa Barbara, California) band has expanded the possibilities in management of failed bands due to dysphagia. These bands are primarily indicated for hugely obese men, but have a place in this setting, and also in banding failed RYGB or BPD. Dargent [61] was the first to delineate the different possibilities. In a series of 1180 LAGBs performed since 1995, 67 (5.6%) were removed, and only 5 were converted to a different procedure. The remainder were repositioned, replaced for mechanical failure or erosion, or replaced with an 11-cm band.

Summary

Only a fraction of morbidly obese patients have come forward for bariatric surgery. This article confirms that LAGB is a safe, effective primary weight-loss operation for morbidly obese patients. The LAGB offers a simple, genuinely minimally invasive approach, with the potential to be attractive to many more patients. The key questions are whether it is effective in the long term and whether it is safe. The midterm data confirm that the laparoscopic band is an effective tool. LAGB surgery is safe, and the change to the pars-flaccida approach will lead to even higher patient satisfaction and lower incidence of band removal. So far, LAGB is living up to its early promise as an effective, minimally invasive bariatric procedure.
References


