Obesity

Laparoscopic Adjustable Gastric Banding and Other Devices for the Management of Obesity

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Obesity is a chronic relapsing disease associated with comorbidities, disability, psychosocial impairment, and reduced life expectancy. In most developed and developing countries, the prevalence of obesity and related diseases such as type 2 diabetes mellitus continues to rise. Today, about one third of US adults are obese, and although the prevalence has doubled over recent decades, the prevalence of the more severe forms of obesity has increased 5- to 10-fold. The determinants of the current epidemic are complex and very difficult to address at a population level. The World Health Organization recognizes obesity as a societal issue related to fundamental changes in behavior associated with industrialization, urbanization, and loss of traditional lifestyles. Genes and gene-environmental interaction are also critical. The explosion of interest in preconception, fetal, and early life nutrition has highlighted the potential importance of epigenetic and metabolic programming in setting the scene for an individual’s weight trajectory. Certainly, a weight problem during adolescence heralds a very high risk of a lifelong battle with weight. Obesity may more broadly be seen as a marker for, but not a necessary element of, the chronic disease driven by fundamental industrial and postindustrial changes in the environment and human behavior. Obesity prevention will be challenging and will require a multidimensional environmental and societal makeover. Unfortunately, as physicians and healthcare providers, our role in primary prevention will be limited.

Although primary prevention should be a global priority, we must also focus on effective therapy for those affected by obesity and its associated diseases. However, the chronic nature of obesity is often forgotten and displaced by a quick fix or quick cure mentality, which is just as illogical as short-term approaches to other chronic conditions such as type 2 diabetes mellitus, dyslipidemia, hypertension, or coronary artery disease. Weight management is often considered to be as simple as energy in, energy out, without consideration of the strong homeostatic responses to weight loss. A prescription for compliance and willpower does not usually solve the problem. Any achievement of weight loss provides the ideal conditions for weight regain. Physiological changes that impair an individual’s ability to sustain weight loss include reduced energy expenditure through loss of lean body mass, energy adaptation with reduced thyroid activity, reduced sympathetic nervous activity, and improved muscle efficiency. On the other hand, weight loss generates feelings of hunger, changes the perceptions of food intake, increases the attractiveness and taste of food, reduces cognitive restraint, and increases the hedonic response to food. This is the body’s understandable bias against energy restriction or starvation. Effective long-term therapy beyond lifestyle adjustment is needed for chronic disease management.

Pharmacotherapy has provided the logical addition to lifestyle therapy for attenuating and treating cardiometabolic risk and disease; however, drug therapy for long-term weight management has, to date, been frustrating. During 2010, 3 preparations were submitted to the US Food and Drug Administration for assessment, and none was approved. In addition, sibutramine was removed from the market by the manufacturer when long-term treatment was associated with an increased risk of nonfatal myocardial infarction and stroke in people with preexisting cardiovascular disease and diabetes mellitus. Currently, we have few medications available, and they are not generally used as long-term treatment, with only 2% of patients still using orlistat at 2 years. For a medication to be approved for weight loss, it needs to deliver proven efficacy and have an excellent safety profile, considering the population likely to be eligible. The future for developments in pharmacotherapy for weight management is quite exciting, with a large array of potential targets available. Therapy may broadly target reducing hunger and energy intake, increasing energy expenditure, or reducing absorption of nutrients. For example, gastrointestinal hormones such as glucagon like peptide-1 provide an incretin effect to enhance meal-stimulated insulin secretion and modest but useful weight loss. There is a range of novel oral preparations, individual and combination peptide hormones, injectable agonists, and designer peptides to target dual receptors.

Gastrointestinal manipulation through bariatric surgery has, to date, given us the only reliable method of producing and sustaining substantial weight loss for the majority of those with obesity. Examining the intricacies of surgically induced weight loss is a major research priority, with knowl-
The adjustable gastric band is placed at the gastric cardia immediately below the gastroesophageal junction. The adjustment reservoir is attached to the rectus sheath.

Mechanism of Action: LAGB

Gastric bariatric procedures have in the past been referred to as restrictive. This generated the concept that you simply cannot move food easily through a barrier—akin to aversion therapy—with food sitting above a physical restriction and food feeding the individual as it enters gradually through an hourglass to slow the delivery process and inhibit further eating. However, numerous studies examining the rate of gastric emptying after gastric stapling procedures have consistently shown minimal or no delay in gastric emptying and that prolonged satiety after a small meal was not temporally related to any delay.19 If weight loss were induced by a forced reduction in meal size alone, then powerful physiological mechanisms to maintain energy balance would drive a shorter period of postmeal satiety and provide the impetus to graze between meals. The trivial delay in gastric emptying and discordance with satiety has been confirmed with LAGB.20 Not only is the delay with a correctly adjusted band slight, but negligible food is found above the band after a meal with the band either correctly adjusted or empty. Indeed, food transits the band during a meal, and the band should not physically limit meal size.21 Greater early satiation (conclusion of eating owing to meal satisfaction) with a small meal, followed by a prolonged period of satiety (between-meal satisfaction and lack of hunger), appears to be the critical element in the ability of the LAGB to reduce and sustain lower caloric intake. This has been shown in a double-blind randomized, controlled trial with the band either correctly adjusted or empty. When the band was correctly adjusted, the subjects were less hungry after a 12-hour fast and more satisfied by a small meal, and that meal satisfied for a longer period.22

A range of hormones associated with energy regulation and satiety were measured during this study, including insulin, leptin, ghrelin, pancreatic polypeptide, and peptide YY. Given that there were no differences in hormone levels in the activated band compared with the inactivated state, it would appear that these hormones do not play a significant role in LAGB function.22,23

It is hypothesized that the mechanical effects of the band influence central control of energy balance via a rich stream of vagal afferent signals arising from specialized mechano-receptors, including intramuscular arrays, which in rats are concentrated in a network and form a fovea in the gastric wall just distal to the gastroesophageal junction,24 and intraganglionic lamina endings situated in the capsule of the myenteric...
plexus, which respond to active and passive gastric movement. Signals from these receptors may be important in both meal termination and satisfaction and provide an important sense of well-being, although the functional roles of these receptors remain poorly understood.

That the LAGB is not restrictive-obstructive or aversive therapy and that the band allows a small meal to satisfy for a long time has very important management implications. Food passes the band throughout the meal, and any true holdup of food either during or after the meal is problematic. Patients with adjustable gastric bands need to understand the importance of early satiation and prolonged satiety in allowing a >50% reduction in daily energy intake and a 50% loss of excess weight at 12 months after surgery. Eating slowly, chewing carefully, and avoiding obstructive symptoms are important and underlie the use of the green zone in adjusting the band (Figure 2).

### Indications for LAGB Surgery

There are a number of national and international guidelines for prioritization or eligibility for bariatric surgery (Table 1). The most commonly used LAGB, the Lap-Band System, has recently been approved by the US Food and Drug Administration for those with a body mass index (BMI) down to 30 kg/m² with comorbidity. The guidelines also recommend that patients should have failed to lose weight and to sustain significant weight loss through nonsurgical weight management programs before being eligible. This approval recognizes the efficacy and safety profile of the device and acknowledges that people can have refractory obesity and weight-related comorbidity warranting intervention without having a BMI >35 kg/m².

The International Diabetes Federation has also recognized that people with diabetes mellitus should be eligible for bariatric surgery with a BMI between 30 and 35 kg/m² and in

### Table 1. National and International Guidelines for Eligibility for Bariatric Surgery in Adults

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Recommended BMI, kg/m²</td>
<td>NA</td>
<td>NA</td>
<td>&gt;50</td>
<td>NA</td>
</tr>
<tr>
<td>Eligible BMI based on BMI only, kg/m²</td>
<td>&gt;40</td>
<td>&gt;40</td>
<td>&gt;40</td>
<td>&gt;35</td>
</tr>
<tr>
<td>Eligible BMI based on BMI and comorbid conditions, kg/m²</td>
<td>35–40 with 1 serious weight-loss–responsive comorbidity</td>
<td>35–40 with 1 serious weight-loss–responsive comorbidity</td>
<td>35–40 with 1 serious weight-loss–responsive comorbidity</td>
<td>&gt;30 with diabetes mellitus and other comorbidity not controlled by optimal medical therapy</td>
</tr>
<tr>
<td>Comment</td>
<td>US Medicare National Coverage Determinations 2004 removed “serious” for BMI 35–40 kg/m²</td>
<td>Recognized use &lt; BMI 35 kg/m²</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

NIH indicates National Institutes of Health; NHMRC, National Health and Medical Research Council; NICE, National Institutes for Health and Clinical Excellence; IDF, International Diabetes Foundation; FDA, Food and Drug Administration; and BMI, body mass index. In all instances, patients should have failed to lose weight and sustain significant weight loss through nonsurgical weight management programs.

*Outdated, of historic interest.
†Review in 3 years (ie, 2006) suggested.
Contraindications and Precautions

Contraindications for bariatric surgery include current drug or alcohol abuse, uncontrolled psychiatric illness, and lack of comprehension of the risks-benefits, expected outcomes, alternatives, and lifestyle changes required with bariatric surgery. In addition, general conditions such as recently diagnosed malignancy and multiple organ failure would contraindicate elective surgery, and specific conditions such as recent myocardial infarction and multiple organ failure would contraindicate elective surgery, and specific conditions such as recent myocardial infarction substantially increase the risk associated with surgery, later complications, or poor outcomes. Cardiac conditions, including ischemic heart disease and cardiac failure, need to be assessed on an individual basis, considering the likely benefits of weight loss. Local gastrointestinal contraindications or precautions include the presence or suspicion of esophageal or gastric malignancy, portal hypertension with varices, liver failure, and Crohn disease. These should be carefully assessed by the surgical team.

Efficacy: Weight Loss

The pattern of weight loss after LAGB surgery is not as rapid as that after the more disruptive surgical options such as Roux-Y-gastric bypass (RYGB) and sleeve gastrectomy but is progressive over 2 or even 3 years and then appears to be sustainable. At 5 years after surgery, the mean percentage excess weight loss is 50% to 55%, or 20% to 25% of total weight. We have extended a previous systematic review of the English literature searching for all weight-loss data from primary LAGB studies in articles measuring weight loss as percentage of excess weight loss and found 25 eligible studies. The results are displayed in Figure 3.

Surgical experience with the LAGB device outside the United States extends back to 1993, but it was not until 2001 that the first adjustable band was approved by the US Food and Drug Administration. The sustained weight loss achieved in European and Australian series has been reproduced in the US series. The longest published follow-up is in a very well-monitored group of patients from Padua, Italy, and details 1791 consecutive patients with a mean excess weight loss of 50% 12 years after LAGB. An interesting, probably unique, aspect of LAGB weight loss is that, although slower than that with more disruptive procedures to achieve maximal weight loss, the weight loss achieved is sustained at 50% of excess weight loss at 8 years. Procedures such as RYGB and sleeve gastrectomy have better early weight loss but a predictable partial weight regain between 2 and 5 years after surgery. A comparison of the 2 most commonly used procedures, RYGB and LAGB, is detailed in Table 2.

An author of this review (J.D.) has played a central role in 3 randomized controlled trials comparing LAGB surgery with conventional nonsurgical weight-loss programs that have demonstrated superior sustained weight loss at 2 years after surgery (Figure 4A through 4C). The first, in patients with a BMI 30 to 35 kg/m², compared LAGB surgery with an intensive medical therapy involving a very-low-energy diet, pharmacotherapy, and lifestyle modification. The second, in a group of participants in the BMI 30- to 40-kg/m² range with recently diagnosed type 2 diabetes mellitus, compared conventional diabetes management, which included an enhanced lifestyle weight-loss program, with the same comprehensive program and the addition of LAGB. In the third randomized controlled trial, severely obese adolescents (BMI ≥35 kg/m²) were treated with either an LAGB program or intensive dietary and behavioral therapy. These studies provide clear evidence of efficacy compared with nonsurgical therapy.

Health Outcomes

Comorbidity

Comorbidity of obesity can be defined as any condition with a plausible relationship with obesity and weight (fat) gain in which there is an increasing incidence or prevalence with increasing BMI and generally an improvement or remission in the condition with weight loss. Comorbidity can be complex, involving metabolic, mechanical, psychological, and socioeconomic conditions. Sustained weight loss through bariatric surgery has given us unparalleled insights into the nature of obesity-related comorbidities. Obesity, especially central obesity, and weight gain are associated with a metabolic and inflammatory cascade often referred to loosely as the metabolic syndrome, driving a broad range of disease. Although components of this metabolic-inflammatory milieu may not provide greater cardiovascular risk than the sum of the individual parts, the real value is in recognizing the common elements underlying the pathophysiology of all components. This recognition will allow a better assessment of the whole of patients’ associated comorbidities and a more widely accepted acknowledgement that lifestyle and therapeutic approaches may be invoked to treat all obesity-related comorbidities simultaneously. It is important to recognize that conditions such as nonalcoholic steatohepatitis, obstructive sleep apnea, and polycystic ovary syndrome...
are strongly associated with the more traditionally accepted components of the metabolic syndrome: central obesity, elevated blood pressure, impaired glucose tolerance or type 2 diabetes mellitus, and dyslipidemia, characterized in the obese by high triglyceride and low high-density lipoprotein cholesterol concentrations.

Understandably, there is no better treatment for obesity-related comorbidity than sustained weight loss, and there appear to be additional benefits in the weight-loss state that are greater than expected for the same BMI without weight loss.\(^\text{53}\) The ultimate aim is not a normal BMI of \(25 \text{ kg/m}^2\).

Weight loss after LAGB surgery is accompanied by improvements in or normalization of insulin sensitivity and glycemia, obesity-related dyslipidemia, C-reactive protein and other proinflammatory cytokine levels, nonalcoholic fatty liver disease, sleep disturbance (including obstructive sleep apnea and daytime sleepiness), and ovulatory function and fertility in women with polycystic ovary syndrome.\(^\text{54,55}\) At 2 years after surgery, \(>50\%\) of those with type 2 diabetes mellitus will be off all antidiabetic treatments while achieving a euglycemic state in clinical remission.\(^\text{51,56}\) Remission rates are greater if the disease is treated early, ie, before irreparable \(\beta\)-cell damage has occurred.\(^\text{57}\)

Caution is advised with regard to the effect of weight loss on some cardiovascular risk factors and diseases. The effect of weight loss on blood pressure control is variable and may not be durable.\(^\text{58}\) Hypercholesterolemia is not a comorbidity of severe obesity. Total cholesterol and low-density lipoprotein cholesterol levels are actually lower with increasing BMI \(>35 \text{ kg/m}^2\), and weight loss alone has little effect on these levels.\(^\text{59,60}\) However, the dyslipidemia of obesity, characterized by high triglycerides and low high-density lipoprotein cholesterol, is reversed with sustained weight loss.\(^\text{60}\) Obstructive sleep apnea responds variably to weight loss, and in studies in which polysomnography has been repeated after weight loss, it is rarely resolved completely.\(^\text{61}\) These high-risk conditions need to be monitored, and medications should not be stopped inappropriately to avoid leaving the patient at risk.

The effect of obesity on cardiovascular risk is attenuated and possibly reduced in older populations\(^\text{62}\) and in those with established hypertension, cardiac failure, coronary artery disease, and other diseases.\(^\text{63,64}\) This obesity paradox raises practical clinical questions on selecting those who may benefit most from surgery, changes in surgical risk-benefit with aging and established disease, and the rate and extent of weight loss that provide benefit. These questions remain largely unanswered.

### Quality of Life, Body Image, Depression

Some of the most satisfying outcomes of weight-loss surgery are enhanced quality of life, alleviation of psychosocial issues, and increasing patient satisfaction.\(^\text{65}\) There are consistent improvements in health quality of life\(^\text{66}\) and body image,\(^\text{67}\) better control in those with binge eating disorder,\(^\text{68}\) and fewer symptoms of depression.\(^\text{69}\) One large prospective study evaluated quality of life after LAGB surgery with the Medical Outcome Study Short Form-36 health survey, which includes both physical and psychosocial dynamics.\(^\text{70}\) Among the 459 patients, it was clear that obese individuals were impaired in all aspects measured by the Short Form-36, and all of these areas significantly improved after surgery. The

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### Table 2. Summary of the Characteristics of Laparoscopic Adjustable Gastric Banding Compared With Roux-en-Y Gastric Bypass

<table>
<thead>
<tr>
<th>Feature</th>
<th>LAGB</th>
<th>RYGB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excess weight loss at 3–5 y,*(^\text{33,40-42}) %</td>
<td>50</td>
<td>60 (75 with banded RYGB)</td>
</tr>
<tr>
<td>Percentage mean weight loss, %</td>
<td>20–30</td>
<td>25–35</td>
</tr>
<tr>
<td>30-d postoperative mortality, (^\text{40,43}) %</td>
<td>0.05–0.1</td>
<td>0.3–0.5</td>
</tr>
<tr>
<td>Pattern of weight loss</td>
<td>Gradual; usually maximal at 2–3 y</td>
<td>Rapid; maximal at 1–2 y; some weight regain at 3–5 y</td>
</tr>
<tr>
<td>Long-term data available (ie, (&gt;10) y)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Evidence of reduced long-term mortality (^\text{44-47})</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nutritional concerns</td>
<td>Low (deficiencies in iron, vitamin B(_{12}), folate)</td>
<td>Moderate (deficiencies in iron, vitamin B(_{12}), folate, calcium, vitamin D, copper, zinc)</td>
</tr>
<tr>
<td>Follow-up requirements</td>
<td>Life-long (high in the first 12 mo)</td>
<td>Life-long (assessment and nutritional support)</td>
</tr>
<tr>
<td>Key complications</td>
<td>Gastric pouch dilatation, erosion of band into the stomach, leaks to the LAGB system, weight regain</td>
<td>Abdominal pain, staple line leak, stomach ulcer, intestinal obstruction, gallstones, nutritional deficiency, weight regain</td>
</tr>
<tr>
<td>Cost-effective (^\text{48})</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

LAGB indicates laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass. *Excess weight defined as the weight of an individual in excess of their weight at a body mass index of 25 kg/m\(^2\).
patients’ quality of life within 1 year of LAGB was closer to that of normal community values, and this finding was sustained throughout the 4 years of the study.

Mortality
Bariatric surgery saves lives by providing weight loss in those with severe obesity, whose expected lifespan is reduced by ~5 to 20 years.\textsuperscript{71} Several studies have examined long-term mortality in patients undergoing bariatric surgery, including LAGB, and compared it with that of matched community control subjects. Studies vary considerably in their design but have shown consistent mortality advantage. Combining the data yields a reduction in medium-term mortality of \( \approx 50\%. \textsuperscript{72} \)

The landmark Swedish Obese Subjects study, in which >2000 people having bariatric surgery were compared with well-matched control subjects from the community, found a 24% reduction in mortality, with the most common causes of death, myocardial infarction and cancer, being reduced in the surgical group.\textsuperscript{46} A series comparing nearly 8000 RYGB surgery patients and matched control subjects reported a 38% fall in all-cause mortality, with reductions in coronary artery disease, diabetes, and cancer deaths of 56%, 92%, and 60%, respectively.\textsuperscript{47}

Compared with obese community control groups, weight loss after LAGB reduces mortality.\textsuperscript{44,45} An Australian group of 966 patients achieved a mean weight loss of 22.8% at 2 years after LAGB and, compared with a matched community cohort at a mean of 5 years’ follow-up, had an adjusted 72% lower risk (hazard ratio, 0.28%; 95% confidence interval, 0.1–0.85) of death.\textsuperscript{44} Similarly, an evaluation of 821 LAGB patients in Italy documented a stable excess weight loss of 40% and a 64% (hazard ratio, 0.28%; 95% confidence interval, 0.1–0.85) lower risk of death 5 years after LAGB.\textsuperscript{45}

It is interesting that none of the surgical studies to date has shown a greater mortality advantage associated with greater weight loss. Perhaps this finding is related to the health benefits of a sustained modest 10% weight loss, which the vast majority of surgical patients achieve but is rarely achieved and sustained with nonsurgical therapy.\textsuperscript{46,73}

Cost-Effectiveness
The direct health costs of overweight and obesity account for between 5% and 10% of health budgets.\textsuperscript{74,75} Indirect societal costs, including absenteeism, poor productivity, disability, and premature death associated with obesity, especially severe obesity, are also considerable and rising.\textsuperscript{76} A recent review by Southampton Health Technology Assessments Centre concluded that bariatric surgery appears to be a clinically effective and cost-effective intervention for moderately to severely obese people compared with nonsurgical interventions.\textsuperscript{48} A number of studies have demonstrated that over time LAGB surgery not only is cost-effective but also delivers direct health cost savings.\textsuperscript{77,78} Conservative extrapolation of the cost of managing type 2 diabetes mellitus from actual costs over 2 years in the Australian diabetes cohort randomized controlled trial\textsuperscript{51} demonstrated that for diabetes costs alone, there would be modest lifetime savings.\textsuperscript{78} In a recent study using US healthcare claims data from >7000 LAGB patients compared with a propensity score–matched control group with a BMI >35 kg/m\textsuperscript{2}, there were modest sustained savings in the LAGB group but continuing cost increases in the control group. The net costs of banding had been reduced to 0 in 4 years after band placement. In a subgroup with type 2 diabetes mellitus having LAGB surgery, net costs reduced to 0 in just over 2 years.\textsuperscript{79} Similar analyses in several European countries have also demonstrated cost savings after band placement.\textsuperscript{80} In a US study using multiple scenarios, LAGB was consistently more cost-effective than RYGB.\textsuperscript{81} This can represent an even greater return on investment when indirect societal costs savings accrue.\textsuperscript{82} It would be difficult to provide a more compelling economic argument for any therapy today.

Figure 4. A, Body mass index (BMI) of 30 to 35 kg/m\textsuperscript{2}: laparoscopic adjustable gastric banding (LAGB) vs intensive medical therapy.\textsuperscript{49} B, Type 2 diabetes patients with a BMI of 30 to 40 kg/m\textsuperscript{2}: LAGB and conventional diabetes therapy vs lifestyle and conventional diabetes therapy.\textsuperscript{51} C, Adolescents 14 to 18 years of age with BMI >35 kg/m\textsuperscript{2}: LAGB vs intensive diet and lifestyle.\textsuperscript{50}
Table 3. Recent US Studies Looking at Bariatric Surgical Morbidity and Mortality

<table>
<thead>
<tr>
<th>Complication</th>
<th>LAGB</th>
<th>RYGB</th>
<th>BPD</th>
<th>SG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite events</td>
<td>1</td>
<td>L, 4.8; O, 7.8</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Mortality</td>
<td>0</td>
<td>L, 0.2; O, 2.1</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>ACS-NQIP86 (30 d)</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Major complication, %</td>
<td>1</td>
<td>3.3</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Any complication, %</td>
<td>2.6</td>
<td>6.7</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>OR return, %</td>
<td>0.94</td>
<td>3.6</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Post-op hospital stay, d</td>
<td>1</td>
<td>2</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>BOLD at 1 y,87 %</td>
<td>4.6</td>
<td>14.9</td>
<td>25.6</td>
<td>10.9</td>
</tr>
<tr>
<td>Mortality</td>
<td>0</td>
<td>L, 0.2; O, 2.1</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>Any complication</td>
<td>9</td>
<td>23</td>
<td>25</td>
<td></td>
</tr>
<tr>
<td>Grade 3 or 4 event</td>
<td>0.2</td>
<td>2</td>
<td>5</td>
<td>...</td>
</tr>
</tbody>
</table>

LAGB indicates laparoscopic adjustable gastric band; RYGB, Roux-en-Y gastric bypass; BPD, biliopancreatic diversion; SG, sleeve gastrectomy; LABS, longitudinal assessment of bariatric surgery; L, laparoscopic; O, open; ACS-NQIP, American College of Surgeons National Quality Improvement Program; OR, operating room; BOLD, Bariatric Outcomes Longitudinal Database (Centers of Excellence registry); and NYU, New York University. Grade 3 and 4 complications include long-term disability, organ resection, or death.

Safety

Early to 1 Year

The reversible, less disruptive nature of LAGB lends itself to low procedural risks, shorter operations,38 and surgery performed in a day-stay ambulatory surgical center.33,84 LAGB surgery generally has a low risk of mortality and morbidity.40 Mortality rates are on the order of 1:1000 to 3000, which is comparable to or lower than that of common abdominal procedures such as appendectomy and cholecystectomy.40,43,85 A range of recent large US studies clearly demonstrate that LAGB is safer than other common bariatric procedures in the early postoperative period and first year after surgery (Table 3).13,86,88 Although operative and early postoperative deaths are unusual, mortality reported has been related to pulmonary thromboembolism, bleeding related to vascular injury at the time of surgery, and sepsis related to gastric or esophageal perforation. This evidence of better first-year morbidity, mortality, and hospital readmissions needs to be carefully considered in the evaluation of risk and benefit, especially in patients considered to have high operative and postoperative risk.89

Medium to Late

Late problems after band placement have varied greatly in incidence since the introduction of LAGB in 1993. Generally, there has been a major reduction in the incidence of the common reasons for revisional LAGB surgery related to improvements in the placement technique, technical changes in the bands and adjustment systems, and less aggressive use of restriction. The most common complication is enlargement of the very small gastric pouch proximal to the adjustable band. Enlargement of the pouch can be caused by the stomach sliding up above the band or local stretching of the stomach wall and results in symptoms of gastroesophageal reflux, regurgitation, dysphagia, obstruction, night cough, and the development of poor eating behaviors.90 Symptoms are easily recognized; the problem is diagnosed with x-rays with upper gastrointestinal series; and treatment generally involves laparoscopic reposition of the band to its correct position.90 A recent systematic review of proximal pouch enlargement looking at cohorts of >500 patients at baseline and followed up at least 2 years found a 5% reoperation rate.91 A potentially life-threatening band complication is large acute pouch dilatation associated with total obstruction and abdominal pain.92,93 Patients with upper gastrointestinal obstruction need to be seen urgently by a surgeon familiar with LAGB surgery. Erosion or migration of the band into the lumen of the stomach has an incidence of 1.5% as reported in a recent meta-analysis of almost 16 000 patients, with lower rates found with increased surgical experience.94 Erosions usually present with loss of action of the band, with patients reporting hunger and weight regain. There may be some upper abdominal pain, but patients rarely present as an urgent surgical problem such as peritonitis. Most erosions can be suspected on the basis of symptoms or diagnosed with upper gastrointestinal endoscopy and are treated with band system removal, followed by delayed replacement.94

Other issues with the band include leaks from the adjustable system. Leaks usually occur in the region of the adjustment port, present as loss of efficacy and weight gain, and are treated by replacement of the adjustment port and adjacent tubing. When LAGB surgical revisions are required, the reason typically is a problem with pouch enlargement, erosion, a leaking system, or intolerance to the band itself. Such complications require reoperation in 10% to 15% of patients, and permanent removal of the band is infrequent, occurring in ~5% of situations.95 Higher revision and explantation rates were described in early series before band placement and adjustment techniques had been refined.96,97

Ultimately, all materials age, and although silicone has very durable properties, replacement with time may be needed. Early devices placed in the late 1980s are performing satisfactorily to date, but younger patients should not expect that they will keep a particular gastric band for life.

Long-Term Management

Obesity and its related comorbidity are chronic conditions, and long-term management plans are required. Follow-up is the key to success with LAGB and ultimately all bariatric surgery. Band adjustments enhance weight loss by keeping patients in the “green zone” and avoiding excessive hunger or obstructive symptoms (Figure 2). Adjustments are also made as target weight loss changes and as nutritional needs during pregnancy or illness change.98 With past nonsurgical weight loss methods, patients have probably experienced weight regain, followed by disappointment, frustration, and a sense of hopelessness, which may lead to a despondent approach to lifestyle alteration. Surgery, by generating satiety and control, provides the opportunity to make real changes in food choices, eating behaviors, and physical activity.26

Although there is a lower risk of nutritional deficiency with LAGB than with other bariatric procedures, the nutritional...
status of the patient is of ongoing concern because obese people are often malnourished and because, after surgery, energy intake reduces from \(\approx 10,000 \text{kJ/d (2400 cal/d)}\) to \(4500 \text{kJ/d (1000 cal/d)}\), so dietary composition is important and should focus on adequate protein and micronutrient intake.\(^{26}\) A once-a-day multivitamin containing daily requirements of folic acid, vitamin B\(_1\), and vitamin B\(_{12}\) is recommended. In addition, other supplements, including calcium, vitamin D, and iron, may be added for at-risk groups or if the diet is assessed as problematic.\(^{32,99}\)

As for all bariatric surgery, long-term follow-up with access to a multidisciplinary team is critical to successful, safe, and sustained weight loss with a focus on minimizing risks and complications. Specifically, the LAGB requires adjustment, an attribute we consider to be very important, and this adjustment requires durable access to experienced, well-trained band adjusters and a multidisciplinary team. An adjustable band is like a cardiac pacemaker; it is an effective tool if placed carefully, adjusted to suit the patient, and maintained appropriately over the longer term. Band adjustments can be readily performed at during an office visit, and patients who attend regular office visits lose significantly more weight.\(^{26}\) Patients generally require 4 to 10 adjustments in the first year and 1 to 3 each year thereafter. The band can be adjusted for many circumstances, including pregnancy, illness, and remote travel, but primarily to keep it in the green zone, ie, the zone of early satiation and prolonged satiety after a small meal (Figure 2).

### Choice of Procedure

The choice of bariatric procedure is complex, requiring a careful risk-benefit analysis and acceptance of variation in regional practice and expertise (see Table 4). The decision should be made by severely obese patients in consultation with their bariatric surgical multidisciplinary team.\(^{30}\)

LAGB surgery may be considered to have favorable attributes for younger people and women planning families, and it may also be a preferred option in the older and sicker patient when the risks of more complex surgery are greater and slower, more controlled weight loss is preferable.\(^{62,89}\) The recent approval by the Food and Drug Administration of the Lap-Band for the BMI range of 30 to 35 kg/m\(^2\) with obesity-related comorbidity is an important consideration. On the other hand, the more rapid and greater weight loss achieved with RYGB may be considered favorable for bigger people with a body mass index of \(>50\) or \(60 \text{ kg/m}^2\) or for those with long-standing type 2 diabetes mellitus who may benefit from the better immediate glycemic control and early non-weight-loss benefits of diversionary surgery.\(^{41,56}\)

It is important to recognize that all conventional surgical procedures vary in their risks and benefits, and to date, there are few hard data that can be used to match patients to procedures. Ultimately, it is a matter of informed patient choice.

### Other Gastrointestinal Devices for the Management of Obesity

Multiple devices are being explored for altering energy balance and for non-weight-loss effects on glucose tolerance as seen with RYGB and other gastrointestinal diversionary procedures. In general, these techniques can be divided by mode of placement into those that are upper gastrointestinal endoscopic or laparoscopic; some techniques combine both approaches. Today, few devices are available on the market, and we have extensive clinical experience only with the IGB.

#### Intragastric Balloons

IBGs (Figure 5A) that were air filled and had irregular shape were used during the 1980s but were abandoned because they were found to be ineffective and potentially dangerous.\(^{100}\) In 1987, a comprehensive reevaluation of IGB was performed, and recommendations were made for future development.\(^{101}\) A small range of IGBs are currently available (outside the United States). Most of the current literature pertains to the Bioenterics IGB, also called Orbera (now manufactured by Allergan Inc). A systematic review of the Bioenterics IGB examined 18 studies of varying quality, included 4877 patients, and reported a mean 17-kg weight loss and weight-loss–related changes in comorbidity and quality of life. Complication reporting in studies was variable, with 2% to 7% of balloons removed early because of intolerance. Serious complications such as gastric perforation and intestinal obstruction were uncommon.\(^{102}\) Balloons are placed temporarily (usually for 6 months) and are reported to induce 10% to 15% weight loss during the period of placement. Patients eligible for this therapy usually have a BMI \(>30 \text{ kg/m}^2\) or \(>27 \text{ kg/m}^2\).
with obesity-related comorbidity. Durability of the weight loss after removal of the balloon device is poorly reported, and, as with any therapy that is withdrawn, considerable weight regain is expected with removal. Maintaining weight loss is challenging once the IGB is removed. In addition to behavioral changes, meal replacement and appetite suppressant medications may be helpful and another IGB may be reinserted if needed. IGB technology is progressing. An air-filled balloon has been introduced, and some very early results with an adjustable-volume gastric balloon system have been reported.

**Novel Devices Under Development**

A range of novel devices that are placed in the stomach to mimic “restriction” or volume reduction or placed in the transpyloric area to delay or regulate gastric emptying are under development. Some endoscopically placed devices sit freely within the gastrointestinal tract; others are physically fixed to the upper gastrointestinal tract to mimic the proximal gastric restriction of the LAGB. Some use endoluminal impervious sleeves to bypass the gastroduodenal upper jejunal area to mimic the RYGB or bypass the duodenum and proximal jejunum to mimic the duodenal-jejunal bypass.

Of these, an endoscopically placed duodenal-jejunal bypass liner, the EndoBarrier (GI Dynamics Inc, Lexington, MA), was approved in 2010 for use in Europe (Figure 5B). The device is fixed to the proximal duodenum for 12 months. In a small US randomized sham-controlled study, 27 participants were randomized to the duodenal-jejunal bypass liner. Only 13 (48%) completed the 12-week study, and an analysis of the completers demonstrated a modest 6.2 kg (5.8%) weight loss. There were 7 device-related removals for bleeding and intolerance.105 In a small European multicenter randomized controlled trial with 30 patients randomized to the duodenal-jejunal bypass liner and 11 control subjects, 4 patients could not be implanted, and 4 had early explantations for device malfunction or pain. Adverse events were usual, with abdominal pain and nausea in the first week. The study demonstrated weight loss and improved glycemic control in those with diabetes mellitus. Larger longer-term studies are being conducted.

Endoscopic endoluminal surgical techniques, including suturing, stapling, and fixation devices, are also being examined to revise bariatric surgery or to mimic the surgical procedures of gastric banding, gastroplasty, or duodenal-jejunal bypass. In addition, laparoscopic procedures to place novel electronic gastric or gastroduodenal motility stimulators and vagal nerve blocking devices are also under investigation. These are considered less invasive than most conventional bariatric surgical procedures; however, some early promising results have been followed by disappointing data from randomized controlled trials. Testing of new electronic devices and modified existing technology will, we hope, lead to success in this area.

**Conclusions**

There is no doubt that there is a pressing need for effective long-term therapy for obesity and its related conditions. As for other chronic disease management, weight management will need to be long term and sustainable and is likely to require a combination of therapies and strategies in the majority of people to achieve and maintain satisfactory control. Therapy will build on lifestyle modification, including alterations in eating behaviors, food choices, psychosocial factors, and physical activity, but pharmacotherapy, devices, and surgery will form part of the treatment programs. Treating patients with severe complex obesity is no different from treating patients with complex diabetes mellitus or cardiovascular disease. There are no simple 1-stop solution, and the discipline of bariatric medicine, in conjunction with a multidisciplinary team approach that includes, when needed, surgeons and gastroenterologists, appears to be the most logical step forward.

LAGB has emerged as the first widely used and broadly applicable device for the long-term treatment of obesity. Safety and ease of reversibility are attributes that place this therapy between nonsurgical therapy and more disruptive surgery; however, adjustability is its most impressive attribute, allowing the device to be adapted to the needs of the individual patient at any time. There is little doubt that as we learn more about the secrets of the gastrointestinal tract in relation to energy balance and metabolic disease, further advances in surgery, devices, and pharmacotherapy will eventuate.

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**Disclosures**

Dr Dixon is a consultant for Allergan Inc, Metagenics Inc (Bariatric Advantage), and formerly Scientific Intake. He is also on the medical advisory board for Optifast, Nestle Australia. Dr Schlaich serves on scientific advisory boards for Abbott (formerly Solvay) Pharmaceuticals and Novartis Pharmaceuticals. The other authors report no conflicts.

**References**


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