The epidemic of obesity requires an intervention that is both effective and broadly acceptable. Conventional medical programs have been ineffective. Traditional surgical approaches, such as gastric bypass and biliopancreatic diversion, are accepted by less than 1% of the severely obese each year. Laparoscopic adjustable gastric banding (LAGB) has been in clinical use for 8 years and it is timely to look at the developments in technique and to look at the outcomes for safety, effectiveness, and acceptability. Data are based on our clinical experiences and research reports derived from 1145 patients treated to date by laparoscopic adjustable gastric banding. We have also drawn on the published literature and on a systematic review of the literature about LAGB published by the Australian Safety and Efficacy Register of New Interventionsal Procedures–Surgical. Generally reports that have included more than 100 patients and 3 or more years of follow-up have been selected. Laparoscopic adjustable gastric banding has proved to be a safe procedure, 7 to 10 times safer than gastric bypass in terms of mortality, and associated with few perioperative complications. Late events have been more frequent with prolapse of the stomach through the band occurring in 15% of our initial patients and erosion of the band into the stomach in 3.2% of our initial patients. Both complications are treatable laparoscopically and have become less common with modifications of technique. Weight loss is gradual but progressive over the first 2 years and has stabilized at about 50% of excess weight lost for the next 4 years. There are major associated improvements in the multiple comorbidities of obesity including type 2 diabetes mellitus (DM), asthma, hypertension, dyslipidemia, asthma, gastroesophageal reflux disease, sleep disordered breathing, comorbidities of pregnancy, and the quality of life (QOL). Laparoscopic adjustable gastric banding has several attributes that potentially will enable it to overcome the community’s resistance to bariatric surgery. It has proved to be safe. It is highly effective in achieving good weight loss, major improvements in health, and improved QOL. Because of the laparoscopic placement, adjustability, and the easy reversibility, LAGB can provide these benefits in a gentle and safe way.

The disease of obesity is the most common chronic health problem in the Western world, and its prevalence is increasing. In the United States, the most recent measurements by the National Health and Nutrition Survey, presented in 1999, indicated 27% of adults are obese (ie, body mass index [BMI] >30), which is an 80% increase over a 20-year period. A serious commitment to broad community programs for prevention has not yet occurred. No data are available to indicate success would be achieved. Optimal application of healthy eating practices and increased exercise and activity, supplemented by drug therapy and behavioral modification programs, can potentially achieve a modest weight loss, if main
The correct technique for LAGB and the correct care of the patient afterward are crucial to achieving an optimal outcome. Poor technique, inadequate skills, and the surgeon’s “learning curve” are likely to be important factors in the occurrence of bad results. The original techniques described by Belachew et al and Favretti et al have undergone substantial modification. It is important to highlight those aspects of our current technique that differ from these original descriptions. This process of evolution is certain to continue as data accumulate that better define the optimal methods. Table 1 lists many of the changes. Some key modifications deserve specific comment.

First, the recommended path for passage of the band has changed from the perigastric path to the pars flaccida path. With the perigastric path, a dissection was performed at the upper lesser curve along the surface of the gastric wall to enter or pass just above the lesser sac. This path creates a setting in which the smooth posterior aspect of the stomach can slip through the band and create a symptomatic prolapse. The pars flaccida path begins at the anterior aspect of the lowermost fibers of the right crus and exposes the left crus, and the dissection passes along the left crus to join an opening in the peritoneum at the angle of His. This path is almost always outside the lesser sac and posterior prolapse rarely occurs.

The band is placed at the apex of the stomach with no significant gastric pouch above. However, it is essential that the band overlie some stomach. The sense of satiety generated by this position is the primary mechanism for effectiveness and will not be achieved if the band is too high.

Anterior prolapse has been uncommon but represents technical failure of the anterior fixation and, therefore, is quite avoidable. The wrap should be loose. Erosion of the band into the stomach has been markedly reduced by not suturing the gastric wall to the crura of the diaphragm or pushing it on the buckle area of the band.

The access port should be accessible. By placing it on the surface of the anterior rectus sheath, adjustment is easily performed in the surgeon’s office. This saves time and costs, thereby encouraging frequent adjustments to the tightness of the band. This modification has been the single most important change in achieving good weight loss without causing symptoms of vomiting and heartburn.

OUTCOMES AFTER LAGB

Early Complications and Deaths

Perhaps the most attractive feature of LAGB is its safety. There have been no deaths in the perioperative period...
in our series of 1065 patients treated by laparoscopic placement of the BioEnterics Lap-Band System. We have a total follow-up of about 3500 patient-years; there have been no disease-related deaths so far in this group of patients. There has been 1 death in a motor vehicle accident. A recent systematic review of the literature about LAGB reported 3 (0.05%) deaths in 5827 patients making it about 10 times safer than gastric stapling procedures.  

Complications in the perioperative period have also been low. We have identified 17 events (1.5%) that delayed hospital discharge or caused readmission. The most common complication has been infection at the site of the access port (10 patients). Others include delayed emptying due to excessive tightness (4 patients) and deep vein thrombosis (1 patient). No serious complications have occurred in the laparoscopic group. In contrast, the open procedure, which has usually been in association with reversal of a failed gastric stapling procedure, had significant complications (25 [41%] of 61 patients).  

Late Complications

The significant adverse events of prolapse (also called “slippage”), erosions, and tubing leaks have been common as late events after LAGB. Prolapse of the stomach through the band leads to an excessive amount of stomach above the band, asymmetrically placed and emptying poorly. Patients note the onset of heartburn, reflux of fluid into the mouth especially at night, and dysphagia. Prolapse of the posterior wall of the stomach is a feature of the perigastric approach, especially if the band is passed across the apex of the lesser sac rather than through the tissues above the lesser sac. We have had no episodes of posterior prolapse when using the pars flaccida path. The problem has lead to revision of the band placement in 172 patients (15%). It is usually managed laparoscopically by removal of the band from the perigastric path and placement of a new band along the pars flaccida path. Anterior prolapse represents a failure of anterior fixation, either by leaving the fundus at the greater curve unfixed or by suture failure. Anterior prolapse has occurred in 8 patients. It is usually treated by laparoscopic reduction and refixation. The incidence of prolapse is decreasing with improvements in technique. We have had 123 prolapses (31%) in the first 400 patients, 46 (12%) in the second 400, and 11 (3%) in the last 350 patients treated. The mean time from LAGB to treatment of prolapse has been 18.1 months.

Erosion of the band into the stomach has been an infrequent and manageable event. Overall published incidence has ranged between 0% to 3.5%. To date, 34 (3.2%) of our 1150 patients have had erosions. These all occurred in the first 500 patients treated. There have been no erosions in the last 650 patients. The most common presentation is of loss of the sense of satiety and increase in weight. No patient has had acute abdominal pain. We have explored different treatment options. Our present approach is for laparoscopic removal of the eroded band, repair of the stomach, and placement of a new band at a single operation. We have used this approach in 12 patients without resulting complications.

WEIGHT LOSS

The Figure shows the pattern and the extent of weight loss that has occurred in our patients who have been followed up for up to 6 years. Important features of this curve are the gradual loss over a 2-year period followed by a stable level of around 50% of excess weight lost at up to 6 years of follow-up. The gentle weight loss during the first 2 years is a key feature of the adjustable band, reflecting the ability to achieve and maintain a slow, steady weight loss without undue symptoms by graded adjustments of the degree of gastric restriction.

Published results from series with more than 100 patients treated and a follow-up of at least 3 years are given in Table 2. For comparison, equivalent studies for Roux-en-Y gastric bypass are also given. Both sets of data are derived from the systematic review by Australian Safety and Efficacy Register of New Interventionsal Procedures—Surgical with the addition of 3 studies published after completion of the review. In common with all other bariatric procedures, there are few reports with more than 5 years of follow-up to provide clear data on long-term effectiveness. These data indicate that the percent of excess weight loss for the 2 procedures is not different at 5 years.
IMPROVEMENTS IN HEALTH AND QOL

Weight loss is the most powerful medical therapy available because it provides major improvements in a range of common and serious diseases. The most important outcomes from LAGB have been the marked improvements in health and QOL. The following is an overview of some of the changes we have measured in a selection of comorbidities of obesity.

Type 2 DM

Type 2 DM is the paradigm of an obesity-related disease. In most cases, it exists because of the obesity and, in most cases, it will disappear with weight loss. It is common, it generates multiple serious complications, and it is lethal.

We have studied the effect of weight loss at 1-year following LAGB placement in 50 subjects with type 2 DM.12 Fifty patients (17 males and 33 females) with type 2 DM were derived from 500 consecutive patients and were studied preoperatively and again 1 year after surgery. The preoperative mean (SD) weight and BMI were 137 (30) kg and 48.2 (8), respectively, and at 1 year 110 (24) kg and 38.7 (6), respectively.

There was significant improvement in all measures of glucose metabolism with remission of type 2 DM in 32 patients (64%), major improvement of control in 13 patients (26%), and no change in 5 patients (10%). Mean (SD) preoperative glycosylated hemoglobin A1c level was 7.8% (3.2%) and was 6.2% (2.7%) at 1 year (P<0.001). Remission of type 2 DM was predicted by greater weight loss and a shorter history of DM (pseudo-r²=0.44, P<.001). The improvement in type 2 DM was related to increased insulin sensitivity and improved β-cell function. Delay in achieving weight loss after diagnosis of type 2 DM permits irreversible beta-cell damage to occur, especially if the DM is poorly controlled. Early treatment of obesity is an important part in the management of a person who has newly diagnosed DM. In association with weight loss, there were significant improvements in the fasting triglyceride level, high-density lipoprotein cholesterol level (HDL-C), hypertension, sleep, depression, appearance evaluation, and health-related QOL in this group of patients.

Weight loss seems to be strongly protective against the development of DM. With about 3500 patient-years of follow-up, none of our patients has presented with the onset of type 2 DM following LAGB. The fasting blood glucose level continues to decrease during a 4-year follow-up period and the major initial reductions of glycosylated hemoglobin A1c and serum insulin are maintained during this period (Table 3).

Hypertension

Hypertension is another disease that is strongly, but not totally, driven by obesity. The prevalence of hypertension in our overall patient group has been 33%. The community norm (CN) for age- and sex-matched controls is 14.6%, confirming the increased risk of hypertension in association with severe obesity.

We have studied the outcome of 88 consecutive patients who have hypertension at 12 months after band placement. Preoperatively, only 10 of these patients had a blood pressure level within the normal range; all were receiving therapy for hypertension. Hypertension was present in 78 patients preoperatively although 53 patients were taking antihypertensive medications. The remaining 25 patients were not receiving therapy for hypertension.

At review at 12 months after band placement, 75 patients had normal blood pressure levels, 13 remained hypertensive, and only 27 were taking any antihypertensive medication. From these data we found that 52 patients (59%) had resolution of the problem (a normal blood pressure level and taking no antihypertensive therapy), 29 patients (33%) had improved (taking less antihypertensive medications and easier control), and 7 patients (8%) were unchanged.

Dyslipidemia

Dyslipidemia is an important comorbidity of obesity associated with a high incidence of coronary and vascular events.13 We have studied the lipid profile of 572 obese patients prior to LAGB.14 We confirmed that an increased total cholesterol level is not a comorbidity of obesity. There was no difference in the level of mean total cholesterol in our patients (3.1 mg/dL [5.52 mmol/L]) when compared with the CNs, matched for age and sex (3.0 mg/dL [5.47 mmol/L]). In fact, the mean total cholesterol level decreased slightly but significantly with an increasing BMI. Fasting triglyceride levels were markedly elevated at 0.02 mg/dL (1.96 mmol/L) (CN=0.01 mg/dL [1.12 mmol/L]) but did not change with increasing BMI. High-density lipoprotein cholesterol levels were lower at 0.03 mg/dL (1.21 mmol/L) (CN=0.04 mg/dL [1.44 mmol/L]) and decreased with an increasing BMI. Low-density lipoprotein cholesterol levels were marginally lower in men at 0.09 mg/dL (3.65 mmol/L) (CN=0.12 mg/dL [4.17 mmol/L]) but were not different in women, who made up 85% of our study group. The levels of low-density lipoprotein cholesterol decreased with an increasing BMI.

We have measured the changes in dyslipidemia in 515 severely obese patients before and up to 4 years after LAGB.15 In subgroups of these patients, we have collected more extensive data to identify predictors of change in lipid levels. Favorable changes in the levels of

Table 3. Changes in Markers of Insulin With Time After Laparoscopic Adjustable Gastric Banding

<table>
<thead>
<tr>
<th>Time, y</th>
<th>Total No. of Patients</th>
<th>Glucose Level, mg/dL</th>
<th>Glycosylated Hemoglobin A1c Level, %</th>
<th>Insulin Level, µU/mL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperative</td>
<td>717</td>
<td>3.1</td>
<td>5.77</td>
<td>20.9</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>451</td>
<td>2.8</td>
<td>5.37</td>
<td>10.9</td>
</tr>
<tr>
<td>2</td>
<td>251</td>
<td>2.8</td>
<td>5.28</td>
<td>11.4</td>
</tr>
<tr>
<td>3</td>
<td>137</td>
<td>2.8</td>
<td>5.21</td>
<td>9.6</td>
</tr>
<tr>
<td>4</td>
<td>73</td>
<td>2.7</td>
<td>5.20</td>
<td>9.4</td>
</tr>
<tr>
<td>5+</td>
<td>28</td>
<td>2.6</td>
<td>5.06</td>
<td>9.7</td>
</tr>
</tbody>
</table>

SI conversion factor: To convert glucose values to millimoles per liter multiply values by 0.05551.
fasting triglycerides, HDL-C, and total cholesterol: HDL-C ratio are seen at 1 year and there are further improvements in the level of HDL-C and total cholesterol: HDL-C ratio in the second year. All improvements were maintained to 4 years when BMI and weight were stable.

Asthma

We have studied the prevalence of asthma in obesity and the effects of weight loss on asthma in a group of patients having LAGB. Asthma was assessed preoperatively in all patients presenting for bariatric surgery. A consecutive sample of 32 patients who have asthma were followed up clinically and by a standard questionnaire at least 12 months after LAGB. Any change in asthma was recorded.

The prevalence of asthma was 24.6% (73 of 296 consecutive patients). This was significantly higher than the prevalence in a matched group in the Australian community (12%-13%; P < .001).

The 32 patients who were followed up had a mean body weight of 125.2 kg (BMI = 45.7) prior to operation and a weight of 89.3 kg (BMI = 32.9) at the 12-month follow-up visit. All 32 patients had a major clinical improvement in their asthma. The mean (SD) preoperative scaled asthma severity score of 44.5 (16) was reduced at follow-up to 14.3 (11) (P < .001). There were significant improvements in all aspects of asthma assessed. These included severity, daily influence, medications needed, hospitalization, sleep, and exercise. During the year preceding LAGB, 9 of these 32 patients had 1 or more admissions to the hospital for acute asthma. No admissions were required during the 12 months of follow-up. Mechanisms other than direct weight loss appear to play a part in this improvement and prevention of gastroesophageal reflux may be an important factor.

Gastroesophageal Reflux Disease

Gastroesophageal reflux is a common problem with an estimated prevalence in the community of around 20%. Obesity is regarded as an important contributing factor to the disease. Study of the frequency of gastroesophageal reflux symptoms in the obese indicates a prevalence in this group of between 37% and 72%. We have studied 450 consecutive preoperative patients looking for evidence of gastroesophageal reflux disease. Some disease was present in 52% of the patients, well above the CN of 20%. The prevalence of moderate disease (defined as daily symptoms requiring therapy) and severe disease (defined as requiring proton pump inhibitors with or without other therapy) was 9.3% and 12.7%, respectively, giving a total prevalence for these groups of 22%, 3 times the CN of 7%.

We have previously reported the outcome of 48 patients with gastroesophageal reflux disease. A total of 82 patients who had moderate or severe disease before the operation have been followed up at 1 year after LAGB. The median age was 39 years (age range, 23-58 years) and the male-female ratio was 5:4. Total resolution of all gastroesophageal reflux disease (no symptoms, no treatment) occurred in 73 patients (89%), improvement in 4% (5%), no change in 2 (2.5%), and aggravation of symptoms in 2 (2.5%). Patients with severe and moderate symptoms had similar improvement. Resolution or improvement occurred soon after surgery and before substantial weight loss.

Sleep Disordered Breathing

Sleep disordered breathing, particularly in the form of obstructive sleep apnea, occurs in about 4% of men and 2% of women in the general population. Obesity, especially upper body obesity, is considered a major risk factor for obstructive sleep apnea and clinical assessments and sleep studies indicate a prevalence of obstructive sleep apnea in morbid obesity to be 42% to 48% in men and 8% to 38% in women.

We have studied 313 consecutive patients with severe obesity (BMI > 35) who have completed a preoperative sleep questionnaire and a clinical assessment as a part of the preoperative evaluation prior to LAGB. A 12-month postoperative study has been completed on 123 of these patients. The characteristics of sleep disturbance and changes in responses to weight loss have been assessed.

There was a high prevalence of significantly disturbed sleep in both men (59%) and women (45%), with women less likely to have had their sleep disturbance investigated. Observed sleep apnea was more common in men, but day sleepiness was not affected by sex. Neck circumference has been the best clinical measure predicting obstructive sleep apnea.

The group lost an average of 48% of excess weight by 12 months. There was a significant improvement in the responses to all questions at follow-up with habitual snoring reduced to 14% (preoperatively 82%), observed sleep apnea to 2% (preoperatively 33%), abnormal day sleepiness to 4% (preoperatively 39%), and poor sleep quality to 2% (preoperatively 39%). The sleep quality score changed markedly. Prior to surgery, 29% had poor quality sleep and 28% had good quality sleep. These scores changed to 2% and 76%, respectively, at 1 year after operation.

Pregnancy

Pregnancy in severely obese women is associated with increased risks and costs. These women suffer an increased incidence of complications during pregnancy including hypertension, preeclampsia, late fetal death, and gestational DM. There is a higher risk of induction of labor, primary cesarean section, and peripartum morbidity. Their infants are more likely to have fetal growth abnormalities, macrosomia, and intrapartum growth retardation, and are more likely to require admission to a neonatal intensive care unit. They may also be at greater risk of developmental abnormalities including neural tube defects. Duration of hospital stay and overall cost is strongly related to maternal weight.

From a group of 650 patients who have had placement of the LAGB, we have followed up all women hav-
ing a pregnancy. In addition, obstetric histories have been taken from severely obese women presenting for LAGB and their incidence of obstetric complications is compared with the group who have completed pregnancy after LAGB placement.

We have followed up the pregnancy outcomes of 20 women who have completed 22 pregnancies with a band in situ. Eight of the 20 women had suffered infertility prior to weight loss. All 22 pregnancies were singleton, with no primary cesarean sections (3 for recurring indications). The mean maternal weight gain was 8.3 kg compared with 15.2 kg for the 15 previous pregnancies of the women in this group ($P<.05$). There was no difference in birth weights. Obstetric complications were minimal. There were no premature or low-birth-weight infants. Eleven of 15 subjects with active management of the band achieved a maternal weight gain within the advised range compared with only 2 of 7 prior to this. Cesarean section rate decreased from 31% to 15%. Gestational DM occurred in only 1 patient after LAGB compared with 9.4% of the obese controls. The gestational hypertension rate decreased from 37% to 5%.

CHANGE IN QOL

Clearly, the outcome from bariatric surgery should not be measured by weight loss alone. Broader outcome measures are important and the effect of surgery on the patients' medical comorbidity and physical and psychosocial health needs to be assessed. From the patients' perspective, the QOL is arguably the most important outcome measure from a weight-reducing procedure.

The Medical Outcomes Study Short Form-36 Health Survey provides a validated instrument for measuring QOL. Population norms are well established. Subjects with a range of medical conditions have been surveyed and the Medical Outcomes Study Short Form-36 Health Survey is an instrument that has been used to study QOL changes with increasing BMI.26,27 Over a 3-year period all patients attending for preoperative assessment (n=459) or annual review after surgery (n=641) completed the Medical Outcomes Study Short Form-36 Health Survey. The 8 domain scores and physical and mental component summary scores were calculated. Scores were analyzed in groups based on time following surgery and compared with CN values.

The preoperative scores were all markedly lower than the CN values for all 8 domains and all had lower scores than those in the community with severe medical conditions.29 All scores improved significantly after LAGB and remained similar to CN values for 4 years after operation. Of the physical and mental summary scores, the preoperative impairment was greatest in the physical summary score (mean [SD], 36.8 [9.5] vs CN 51.3 [8.3], $P<.001$) and improved the most with weight loss (52.4 at 1 year; 49.2 at 4 years).

Severely obese subjects have poor health-related QOL as measured by the Medical Outcomes Study Short Form-36 Health Survey. Laparoscopic adjustable gastric bypass has provided a dramatic and sustained improvement in all measures of the Medical Outcomes Study Short Form-36 Health Survey for this group. Improvement is greater in those with greater preoperative disability and the extent of weight loss is not a good predictor of improved QOL.

ATTRIBUTES OF THE LAGB

Laparoscopic adjustable gastric banding has several particular attributes that potentially will enable it to overcome the community's resistance to bariatric surgery. First, it is safe. It has proved to be remarkably safe for a major surgical procedure in a high-risk population. Second, it is effective. It is effective in achieving good weight loss, effective in leading to major improvements in health, and effective in restoring QOL. Third, it achieves these effects in a gentle way. The operation, being laparoscopic and brief, does not generate major pain or disability. Day patient treatment or overnight stay is becoming routine. It is gentle in the follow-up phase because of the adjustability. Adjustability is the key to long-term effectiveness. There is no need to create excess tightness and excessive weight loss early as the adjustability permits smooth progression toward the weight goals. Fluid can be removed as well as added, enabling removal of restriction, if desired, as with pregnancy, major illness or operation, or remote travel. The ability to provide further adjustments years after operation should provide a durability of weight loss that has not been available with the gastric stapling procedures. Fourth, it is easily reversible. There is no intention of reversing the procedure but it is highly probable that, within 15 to 20 years, better options for weight reduction will be available. Especially for the young and middle-aged, the ability to be able to turn to a new approach is potentially important and attractive.

THE CHALLENGE

The existing data show the procedure of LAGB to be safe, effective, and gentle. It still remains to be established whether it will have an influence on the current epidemic of obesity. There are 3 challenges that must be overcome to achieve this. First, we need enough surgeons with good laparoscopic skills. The workload is immense and optimal results will not occur with suboptimal technique. Second, we must have a system in place for good patient support and care to undertake the assessments and advice before operation and, most importantly, to provide the ongoing care, with adjustments and support, permanently after operation. Third, we must continue to measure effectiveness of and to seek further improvements in techniques. The optimal techniques for LAGB and patient care after placement are still evolving. The sooner we can identify these and incorporate them into our clinical practice, the more the LAGB will be broadly accepted and the more the benefits of weight loss will be achieved across the community.

Accepted for publication December 17, 2002.

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