

Laparoscopic Adjustable Gastric Banding for Morbid Obesity



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Executive Summary

Background

Bariatric surgery leads to substantial amounts of weight loss in morbidly obese patients, and this weight loss leads to net improvement in health outcomes. Among different surgical procedures, gastric bypass is the most common procedure performed in the U.S., and offers the most favorable benefit/risk ratio among established procedures. Laparoscopic adjustable gastric banding (LAGB) is an alternative technique that has the potential advantages of being less invasive and reversible. Prior TEC Assessments have concluded that LAGB did not meet the TEC criteria.

Objective

To review the available evidence on whether LAGB results in similar improvements in health outcomes as does open or laparoscopic gastric bypass (GBY).

Search Strategy

MEDLINE search for the period of 1980 through September 2006, supplemented by hand search of bibliographies and search of Cochrane database.

Comparative studies of LAGB vs. GBY (open or laparoscopic) were included in the Assessment if they had at least 25 patients per treatment arm, reported on the outcomes of weight loss and/or adverse events, and had at least 1 year of follow-up (for weight loss outcomes). Single-arm studies with the same characteristics were included, except that the minimum number of enrolled patients was 100 or more. Single-arm studies that reported on longer term outcomes (i.e., 3 years or longer) and that had the most complete follow-up at 2 and 3 years were highlighted.

Main Results

Eight comparative trials of LAGB vs. GBY, enrolling 4,191 patients, and 57 single-arm series met the inclusion criteria for this Assessment. A total of 9 single-arm series met the additional follow-up criteria of at least 50% of enrolled patients available at 2 years' follow-up.

Substantial weight loss does occur following LAGB; however, the amount of weight loss at 1 year is less than that seen following GBY. The percent excess weight lost (%EWL) at 1 year is approximately 40%, compared to 60% or higher for GBY. At time points longer than 1 year, some of the comparative studies report that the difference in weight loss between LAGB and GBY lessens; however, other studies do not. Weight loss outcomes from the 9 single-arm series with the most complete follow-up do not support the hypothesis that weight loss continues to increase after 1–2 years of follow-up.



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These studies also confirm that short-term (perioperative) complications are very low with LAGB, and lower than either open or laparoscopic GBY. Death is extremely rare, and serious perioperative complications probably occur at rates of less than 1%.

The reported rates of long-term adverse events vary considerably. In the comparative trials, reoperations are reported in approximately 25% of patients, while in the single-arm studies the composite rate for reoperations is approximately half of this value (11.9%). The rates of other long-term complications are also highly variable; for example, the reported range of rates for band slippage is 1–36% and the range for port access problems is 2–20%.

Author's Conclusions and Comments

Conclusions regarding the comparative efficacy of different bariatric surgery techniques on weight loss are best made from comparative trials, particularly trials with concurrent control groups that demonstrate baseline comparability of groups on important clinical and demographic variables. This is best achieved through randomized, controlled trials, although other well-controlled designs may also be acceptable. The current body of literature lacks high-quality clinical trials that directly compare outcomes between LAGB and GBY. Therefore, the conclusions in this Assessment are derived from other types of evidence, primarily comparisons of clinical series, with or without matching.

Weight loss at 1 year is less for LAGB compared with GBY, and conclusions on the comparative weight loss at longer time periods are not possible from these data. Some studies report that the difference in weight loss between these procedures diminishes, or disappears, with longer follow-up. However, the present data are mixed and, overall, do not confirm this hypothesis. It appears more likely from the current data that attrition bias may account for the diminution of the difference in weight loss over time, particularly when patients who have their band removed or deflated are excluded from analysis.

The data on long-term complications remain suboptimal. The reporting of long-term complications in these trials is not systematic or consistent. As a result, highly variable rates of long-term outcomes are reported. It is not possible to determine the precise rates of long-term complications from these data, but it is likely that complications are under-reported in many studies due to incomplete follow-up and a lack of systematic surveillance. The high rates of long-term complications reported in some studies raise concern for the impact of these events on the overall benefit/risk ratio for LAGB.

In comparing LAGB with GBY, there is a tradeoff in terms of risks and benefits. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay, and earlier return to usual activities. However, the amount of weight loss will also be less for LAGB. The patterns of long-term complications also differ between the two procedures. For LAGB, longer term adverse events related to the presence of a foreign body in the abdomen will occur, and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

For patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either GBY or LAGB as the preferred procedure. Preoperative counseling should include education on the comparative risks and benefits of the two procedures in order to allow the optimal choice to be made based on patient and surgeon preferences.

Based on the available evidence, the Blue Cross and Blue Shield Medical Advisory Panel made the following judgments about whether laparoscopic adjustable gastric banding for morbid obesity meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

Bariatric surgery is a procedure and is not subject to U.S. Food and Drug Administration (FDA) regulations. However, certain devices that may be used as part of the procedure may be subject to FDA approval. The Lap-Band® system received premarket application (PMA) approval by the FDA in June 2001 for use in morbidly obese patients.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The evidence is sufficient to permit conclusions concerning the short-term safety and efficacy of LAGB in comparison with GBY. Weight loss at 1 year following LAGB is substantial, in the range of 40% EWL, although less than that seen following GBY. The short-term complications of LAGB are very low, with serious short-term complications being uncommon, and mortality exceedingly rare. Rates of short-term adverse events, including serious procedural complications and mortality, are lower for LAGB compared with GBY.

Conclusions concerning longer term weight loss following LAGB are less definitive. Some studies report that the difference in weight loss between LAGB and GBY diminishes over longer time periods; however, other studies do not. Studies that report longer term outcomes do not generally have complete follow-up, and therefore, it is not possible to determine whether continued increases in %EWL are due to further weight loss or attrition bias.

The evidence on the rates of long-term complications is also not robust. The precise rates of long-term complications cannot be determined from the data due to inadequacy of long-term follow-up in the available studies. However, the data do define a range of complications that permits decision-making on the overall benefit/risk ratio of this procedure. A considerable minority of patients who undergo LAGB may require reoperations for long-term complications, and/or removal of the band.

3. The technology must improve the net health outcome.

The amount of weight loss following LAGB is substantial, in the range of 40% EWL at 1 year. This amount of weight loss is equal to or greater than the amount of weight loss that has been associated with health outcome benefits, such as a reduction in the incidence of diabetes. There is a low rate of serious procedural complications, and therefore, the weight loss benefit outweighs the short-term risks. Longer term risks may be more frequent and are less well defined, but are unlikely to offset the benefits of the procedure. Longer term complications may result in reoperations and/or removal of the band. The reversibility of the procedure makes it unlikely that long-term complications will offset the benefits of this procedure.

4. The technology must be as beneficial as any established alternatives.

The main established alternative to LAGB is open or laparoscopic GBY. Both procedures are effective in producing weight loss; the comparison of LAGB with GBY offers a tradeoff in terms of safety and efficacy. LAGB is a safer procedure in the short term, and is reversible. However, LAGB results in lower amounts of weight loss at 1 year compared with GBY. The longer term complications of LAGB are more common than short-term complications, and are different than those seen with GBY.

While it is not possible to say with confidence whether LAGB or GBY is the “better” procedure, either one might be a reasonable choice for a patient considering bariatric surgery. Numerous factors may play a role in decision-making including baseline BMI, surgical risk, comorbidities, and tolerance for repeat procedures.

5. The improvement must be attainable outside the investigational settings.

Training on insertion of LAGB is widely available and expertise for inserting the devices is common among bariatric surgeons in the U.S. As a result, the use of LAGB has been widely disseminated among bariatric surgery centers, both in the academic and community settings.

Based on the above, laparoscopic adjustable gastric banding meets the TEC criteria when performed in appropriately selected patients, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up post-surgery.

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Assessment Objective

Morbid obesity, generally defined as a body-mass index (BMI) of 40 kg/m² or greater, is associated with excess mortality and a high burden of obesity-related morbidities. Nonsurgical treatments (i.e., lifestyle modifications, behavioral therapy, medications) are first-line therapies for obesity; however, the majority of morbidly obese patients do not achieve substantial weight loss with these approaches. Bariatric surgery is a therapeutic option for patients who have failed conservative treatment.

Gastric bypass with Roux-en-Y anastomosis (GBY) has been considered the bariatric surgery of choice in the U.S., and this is supported by a substantial body of literature. Comparative trials have shown gastric bypass with Roux-en-Y anastomosis to be superior to alternative procedures such as vertical-banded gastroplasty (9 studies, N=3,780), horizontal gastroplasty (2 studies, N=261), and open gastric banding (2 studies, N=283). Roux-en-Y gastric bypass achieves greater weight loss than these other procedures and can be performed with low rates of morbidity and mortality.

Laparoscopic adjustable gastric banding (LAGB) has been available in the U.S. since 2001. LAGB is a purely restrictive bariatric procedure, in which a saline-filled prosthetic band is used to partition the stomach. It is a less technically complex procedure compared to gastric bypass, and thus has the potential to reduce short-term complications. Laparoscopic adjustable gastric banding has the additional advantage of reversibility, which is unique among bariatric surgery procedures.

Prior TEC Assessments and Special Reports have addressed various aspects of bariatric surgery. Conclusions from these reports include:

- Bariatric surgery is efficacious in causing weight loss in morbidly obese patients who have failed diet and exercise.
- The reduction in weight loss from bariatric surgery is associated with improvements in health outcomes. The most marked improvements are in diabetes. Reductions in hypertension, depression and anxiety have also been reported, but less consistently.
- Laparoscopic gastric bypass achieves outcomes comparable to open gastric bypass.

- Comparative studies of gastric bypass vs. LAGB are lacking. The following limited conclusions can be made from the available evidence:
 - Weight loss at 1 year is less with LAGB compared to open or laparoscopic GBY. Differences in weight loss over later time periods may lessen, but inadequate long-term follow-up in the available studies limits the validity of this data.
 - The rates of long-term complications of LAGB are uncertain, thus making it difficult to determine the overall benefit/risk ratio of the procedure. Studies with more complete follow-up report higher rates of long-term complications, thus highlighting the importance of complete, long-term follow-up in determining these rates.

The present Assessment will build on these previous conclusions and evaluate new literature published since June 2005 to determine whether LAGB currently meets the TEC criteria. Particular attention will be placed on evidence that might address the uncertainties found in previous reports. This includes prospective studies that allow direct comparisons of LAGB with open or laparoscopic GBY, particularly in terms of long-term weight loss. It also will include clinical series or cohort studies that have relatively complete long-term follow-up, defined as 3 years or longer, in which rates of long-term complications can be derived.

Background

Obesity

Obesity is a growing problem worldwide; in the U.S., it is estimated that approximately 60 million individuals are obese (Balsiger et al. 2000). The current classification of obesity is based on the body-mass index (BMI), defined as the weight in kilograms divided by the square of the height in meters (kg/m²). Use of the BMI has achieved widespread acceptance for the classification of obesity because it correlates more closely with direct measurements of body fat in the laboratory than other measures using weight and height (Kral 2001). Table 1 shows the current guidelines for classifying patients by BMI.

Severe or morbid obesity is defined by a BMI of 40 kg/m² or greater, and has a prevalence in the U.S. of 6% for women and 2% for men (Balsiger et al. 2000). Patients with morbid

Table 1. Classification of Obesity*

	Obesity Class	BMI (kg/m ²)	Health Risk
Underweight	—	<18.5	Increased
Normal	—	18.5–24.9	Normal
Overweight	—	25.0–29.9	Increased
Obese – Mild	I	30.0–34.9	High
Moderate	II	35.0–39.9	Very high
Severe	III	≥40.0	Extremely high
(Super-Obese)**	IV	≥50.0	Extremely high

*Adapted from Klein 2001

**Not included in original classification

obesity are considered by most experts to represent a distinct class of obese patients, with special needs and challenges, who require different, more aggressive approaches to weight loss (Kral 2001). A morbidly obese white man at age 20 years can expect to live 13 years less than his counterpart with a normal BMI, which equates to a 22% reduction in life expectancy (Fontaine et al. 2003). Medical conditions associated with obesity increase in frequency and severity with increasing weight, and are, therefore, found with the highest prevalence in morbidly obese patients (National Heart, Lung, and Blood Institute, National Institutes of Health 1998).

Nonsurgical Treatments for Morbid Obesity

Nonsurgical treatments for patients with morbid obesity are recommended prior to considering surgery. Lifestyle modifications such as restricted calorie diet and regular exercise are recommended for all obese patients. Behavioral therapy is a resource-intensive intervention that includes a number of general principles: 1) self-monitoring of food intake; 2) avoidance of triggers to eating; 3) social and family support; and 4) cognitive restructuring (Klein 2001). Currently, two medications have received FDA approval for long-term use in the treatment of obesity: sibutramine (Meridia®, Abbott Laboratories) and orlistat (Xenical®, Roche).

Unfortunately, nonsurgical approaches to reducing weight seldom succeed over the long term for morbidly obese patients (National Heart, Lung, and Blood Institute, National Institutes of Health 1998). Only a few extremely obese individuals can reduce and control weight through diet and exercise, since the

majority of patients find it difficult to comply with these lifestyle modifications on a long-term basis. Behavioral therapy can achieve modest long-term weight loss, but a high rate of relapse and discontinuation of the programs occur by 1 year (Klein 2001). Some programs using intensive behavioral interventions and very-low-calorie diets have reported dramatic short-term weight loss, but this has not been maintained following completion of the intervention (National Heart, Lung, and Blood Institute, National Institutes of Health 1998).

There are no clinical trials of medications that focus on the morbidly obese population. In the general population of obese patients, these drugs are more effective than placebo in reducing weight, but the average amount of excess weight loss is relatively small (5.2 kg above placebo in one study; 1.8% body weight lost above placebo in another study) (Klein 2001). It is problematic to extrapolate the results of these drug trials to morbidly obese patients, since the impact of similar amounts of weight loss may differ between these 2 groups

Bariatric Surgery for Morbid Obesity

Bariatric surgery has been available as a treatment for obesity for several decades. The National Institutes of Health (NIH) guidelines for surgical treatment of obesity state that surgery should be considered for patients with a BMI greater than 40 kg/m² (or greater than 35 kg/m² with life-threatening comorbidity) who have failed conservative treatment, are motivated, and well informed (National Heart, Lung, and Blood Institute, National Institutes of Health 1998). These guidelines maintain that patients should undergo a thorough pre-operative workup that includes psychological

evaluation, and that follow-up after surgery should be lifelong.

A number of more recent guidelines parallel the NIH recommendations, with some minor modifications. The American College of Physicians guidelines for management of obesity (Snow et al. 2005) add that patients should be referred to high-volume centers with surgeons who are experienced in bariatric surgery. The American College of Surgeons outlines general recommendations for the training of surgeons and bariatric facility resources (American College of Surgeons 2000). The New York State Consensus guidelines (New York Health Plan Association Obesity Surgery Project 2004) include numerous “other considerations” for patient selection in addition to the minimum provided by National Heart, Lung, and Blood Institute. These include an ideal age of between 18 and 65 years, “long-standing” obesity, no history of substance abuse or tobacco products, and no contraindications to major abdominal surgery.

A 2003 TEC Special Report focused on whether bariatric surgery improved health outcomes, compared to nonsurgical treatment (Vol. 18, No. 9). This report described a lack of high-quality randomized controlled trials (RCTs) in this area. The Swedish Obese Subjects (SOS) Intervention Trial, an ongoing prospective, nonrandomized comparative trial, was the most rigorous trial included in that Report on the comparative efficacy of surgical and nonsurgical treatment in morbidly obese patients. In this trial, morbidly obese subjects were recruited from 480 primary care centers and offered bariatric surgery. Each patient agreeing to surgery was matched on 18 clinical variables with a patient who elected nonsurgical treatment. The study plans on enrolling 2,000 patients per group and following up outcomes for 10 to 20 years following surgery.

Results up to 8 years following surgery were available at the time of the 2003 TEC Special Report. At 2 years (Sjostrom et al. 2000), the surgery group had an incidence of diabetes that was 30-fold lower than usual care patients (0.2 vs. 6.3%, $p < 0.001$) and an incidence of hypertriglyceridemia 10-fold lower than usual care patients (0.8 vs. 7.7%, $p < 0.001$). The incidence of hypertension was reduced to a lesser degree, with a 2.5-fold reduction in incidence (5.4 vs. 13.6%, $p < 0.001$). At 8 years, Sjostrom et al. (2000) reported that a large difference in inci-

dence rates for diabetes between the surgery group and usual care group persisted (3.6% vs. 18.5%, $p = 0.0001$), while the difference in incidence of hypertension was no longer present (26.4% vs. 25.8%, $p = \text{NS}$).

Based on these data from the SOS study, along with smaller studies that offered corroborative results, the TEC Special Report concluded that the evidence was sufficient to determine that health outcomes were improved following bariatric surgery.

Since the 2003 TEC Special Report, additional evidence has reinforced this conclusion. Further data from the SOS study (Sjostrom et al. 2004) reported outcomes of major morbidities at 10 years, including hypertension and diabetes, for 1,268 patients. This article reported a continued reduction in the incidence of diabetes, with an odds ratio of 0.25 (95% CI: 0.17–0.38; $p < 0.001$) for surgical treatment compared to nonsurgical treatment. A smaller reduction in the incidence of hypertension, with an odds ratio of 0.75 (95% CI: 0.52–1.08; $p = 0.13$), did not reach statistical significance. This study also reported significantly better rates of recovery from diabetes and hypertension in the surgical group. Diabetic patients who underwent bariatric surgery were 8.42 times more likely to recover from diabetes at 10 years (95% CI: 5.68–12.5; $p < 0.001$), and patients with hypertension were 1.68 times more likely to recover at 10 years (95% CI: 1.09–2.58; $p < 0.02$).

At least 2 retrospective comparative cohort studies have been published since 2003 and suggest that mortality is improved with bariatric surgery. The first, performed in Quebec, Canada (Christou et al. 2004), compared outcomes from 1,035 bariatric surgery patients included in the McGill University bariatric surgery database with 5,746 nonsurgically treated patients included in the Quebec provincial health insurance database, matched for age and gender. Overall mortality in the surgical group was 0.68% compared to 6.2% in the nonsurgical group (relative risk reduction [RRR] 89%; 95% CI: 73–96%, $p < 0.001$). There were also significant reductions in the incidence of a wide range of medical comorbidities for the surgery cohort except for digestive disorders, which were increased by approximately 50%.

The second retrospective cohort study, from Washington State (Flum and Dellinger 2004), compared 3,328 patients who underwent bariat-

ric surgery with 62,781 morbidly obese patients who were hospitalized but did not undergo bariatric surgery. Over 15 years of follow-up, these authors reported a multivariate hazard ratio of 0.67 (95% CI: 0.54–0.85; $p=0.004$) for mortality in patients undergoing bariatric versus non-surgical treatment.

Bariatric Surgery Techniques

A number of different bariatric surgery procedures have been developed. The different procedures are often classified as restrictive or malabsorptive. Restrictive procedures reduce the size of the stomach reservoir, causing limitations in the amount of food ingested by mechanical means and early satiety. Malabsorptive techniques reduce the ability of the GI tract to absorb food through bypassing specific portions of the GI tract. Some operations, such as gastric bypass with Roux-en-Y, combine elements of restrictive surgery with malabsorptive surgery. These are sometimes classified as “complex” operations in comparison with “simple” restrictive operations that only partition the stomach.

Gastric Bypass with Roux-en-Y Anastomosis.

In this procedure, the majority of the stomach is resected (subtotal gastrectomy) and the gastric outlet is attached to the mid-portion of the jejunum. Alternatively, gastric partitioning by stapling may be used in place of gastric resection. The gastric partitioning reduces the amount of food that can be ingested, and the Roux-en-Y anastomosis allows food to bypass the duodenum and proximal jejunum (Balsiger et al. 2000), resulting in global malabsorption over the bypassed portion of the intestine.

Open gastric bypass is a major surgical procedure, with the attendant risks and recovery period expected with intraperitoneal surgery. Adverse effects of gastric bypass also include complications specific to the procedure, such as leaks or obstruction at the anastomotic sites. In addition, dietary modifications are necessary to achieve a successful outcome. For example, the “dumping syndrome,” defined as abdominal symptoms and diarrhea shortly after eating, is due to reduced transit time in the intestine, and patients must eat small meals to ameliorate these symptoms. Due to the altered passage of food, patients are also at risk for a number of metabolic complications, including iron deficiency anemia, vitamin B₁₂ deficiency, and hypocalcemia. These potential adverse effects are summarized in Table 2.

More recently, gastric bypass has been performed via the laparoscopic approach. Laparoscopic gastric bypass is a technically complex operation that requires a dedicated team and a relatively high degree of skill and experience in laparoscopic surgery. Five or 6 port access sites in the upper abdomen are used. Gastric partitioning and anastomoses of the proximal and Roux limb are performed with laparoscopic instruments, and with limited direct visualization of the surgical field. In addition to the usual patient selection criteria, some surgeons will require additional criteria to be met for patients to qualify for laparoscopic surgery. These may include: an absolute weight limit (e.g., BMI <50 kg/m²), no previous abdominal surgery, no evidence of hypoventilation syndrome, and no evidence of liver enlargement.

Table 2. Potential Adverse Effects Following Gastric Bypass

Short-term Adverse Events	Long-term Adverse Events	Dietary Modifications
<ul style="list-style-type: none"> – Intraoperative: <ul style="list-style-type: none"> – Bowel perforation – Bleeding – Splenic injury – Anastigmatic leaks – Early postoperative: <ul style="list-style-type: none"> – Death – Cardiopulmonary complications – Thromboembolic complications – Bowel obstruction – Wound infection 	<ul style="list-style-type: none"> – Reoperations – Readmission to hospital – Incisional hernia – Staple line failure – Anastomotic problems – Dilated pouch – Marginal ulcer – Gastritis – Cholecystitis – Dehydration/malnutrition – Depression – Vitamin/mineral deficiencies <ul style="list-style-type: none"> – Iron – Folate – B₁₂ 	<ul style="list-style-type: none"> – Small meals – Early satiety – Dumping syndrome – Avoid high calorie liquids or snacks – Daily vitamin supplementation

A substantial body of literature supports the superiority of gastric bypass with Roux-en-Y anastomosis over other bariatric surgery procedures (Schauer and Ikramuddin 2001). In these studies, gastric bypass consistently achieves greater amounts of weight loss compared to alternative procedures, without any demonstrable increases in morbidity or mortality. The most rigorous of these comparative trials, the Adelaide Study (Hall et al. 1990), randomized 310 morbidly obese patients to gastric bypass, vertical-banded gastroplasty, or horizontal gastroplasty. The percent of patients with greater than 50% excess weight loss at 3 years' follow-up was 67% for gastric bypass, 48% for vertical-banded gastroplasty, and 17% for horizontal gastroplasty ($p < 0.001$). No demonstrable differences in adverse events were noted among groups.

Laparoscopic Adjustable Gastric Banding.

Gastric banding is a restrictive procedure that works via a prosthetic device that is wrapped around a portion of the stomach. Adjustable gastric banding refers to bands in which the pressure can be varied without an invasive procedure. Gastric banding is less technically complex compared to other bariatric surgery procedures, since the band is entirely external to the stomach and can be adjusted without entering the gastric cavity. This procedure is entirely reversible by removal of the prosthetic band.

Gastric banding was originally performed via an open approach, but laparoscopic adjustable gastric banding has largely replaced open gastric banding. The literature includes reports of two types of adjustable gastric banding placed laparoscopically, the Lap-Band® adjustable gastric band, and the Swedish adjustable gastric band. Both of these gastric bands are saline-filled devices that can be inflated or deflated via a reservoir attached to the band and are accessed through a port without an additional invasive procedure. The band is placed after dissection of the proximal stomach from adjacent structures and sutured in place to the stomach.

Short-term complications of LAGB are expected to be low, but can occur. There is a risk of organ injury, bowel perforation and/or bleeding, pulmonary complications, and intra-abdominal infections. Similar to other restrictive procedures, longer term complications can occur. Nausea and vomiting can

result, especially if the band pressure is too high. Dilation of the pouch may occur, usually resulting in weight gain. Gastroesophageal reflux disease (GERD) may occur due to the increased pressure gradient introduced in the stomach. These complications may respond to adjustment of the band pressure. Other long-term complications can occur as a result of the prosthetic device. There may be slippage of the device and, over time, the device may erode through the gastric wall. Malnutrition and vitamin deficiencies may also occur as long-term complications.

FDA Status. Bariatric surgery is a procedure and is not subject to U.S. Food and Drug Administration (FDA) regulations. However, certain devices that may be used as part of the procedure may be subject to FDA approval. The Lap-Band® system received premarket application (PMA) approval by the FDA in June 2001 for use in morbidly obese patients.

Health Outcomes in Obesity Research

The primary health outcomes that will be considered as part of this Assessment are weight loss and adverse events.

Weight loss is the most common outcome measure used in trials of obesity research, and can be expressed in a variety of ways (Table 3). Standardized measures of weight loss, such as the percent of excess weight loss, are more clinically meaningful than are absolute amounts of weight loss. For the purposes of this Assessment, all weight loss outcomes will be considered, but standardized measures that are commonly in use, particularly the percent excess weight loss (%EWL) and the decrease in BMI, will have the greatest utility in comparing results across studies.

In determining the comparative benefit of different surgical procedures, weight loss outcomes will be considered together with adverse effects for each procedure. These outcomes are sufficient for making judgments, since virtually all of the improvements in health outcomes following surgery are mediated through weight loss. The benefits of surgery in terms of weight loss will be balanced against the adverse effects of each procedure, both short-term (perioperative) and long-term (>30 days following surgery).

The impact of completeness of follow-up on the above health outcomes was demonstrated in the 2005 TEC Assessment (Vol. 20, No. 5).

Table 3. Variations in Reporting Weight Loss Outcomes

Outcome Measure	Definition	Clinical Significance
Decrease in weight	Absolute difference in weight pre- and post-treatment	Unclear relationship to outcomes, especially in morbidly obese
Decrease in BMI	Absolute difference in BMI pre- and post-treatment	May be clinically significant if change in BMI clearly leads to change in risk category
% excess weight lost (%EWL)	$\frac{\text{Amount of weight lost}}{\text{Excess body weight}}$	Has anchor to help frame clinical significance; unclear threshold for clinical significance
% pts losing >50% of excess body weight (EBW)	$\frac{\text{Number of patients losing >50\% BW}}{\text{Total patients}}$	Additional advantage of framing on per-patient basis. Threshold for significance (>50%) arbitrary
% ideal body weight (%IBL)	$\frac{\text{Final weight}}{\text{Ideal body weight}}$	Has anchor to help frame clinical significance; unclear threshold for clinical significance

Abbreviations Key in Appendix

Overall, the completeness of follow-up in single-arm studies of LAGB was poor (Table 4), with only approximately 60% of total patients available for follow-up at 1 year, approximately 25% at 3 years, and only 5% at 5 years.

Sensitivity analysis performed for this Assessment revealed that both reported weight loss and complication rates were sensitive to completeness of follow-up (Table 5). Weight loss reported at 3 years was markedly higher for those studies with less complete follow-up compared to studies with more complete follow-up (60.3 vs. 42.4 %EWL). For complications, the rates reported were 2–3 times lower in studies with less complete follow-up. These data suggest that attrition bias in studies of bariatric surgery leads to overestimation of weight loss and underestimation of long-term complication rates.

The importance of long-term, complete follow-up for late complications was also highlighted by data reported in Biertho et al. (2005). In this study, long-term complications were reported by year, thereby providing insight into the length of follow-up required to capture the majority of long-term complications. For a number of complications, the incidence of adverse events increased in years 2 through 5. For example, there were no cases of band slippage reported in year 1; in years 2 through 4 this rate increased 1.3–1.5% per year, and

in year 5, the rate decreased to 0.5%. Band removal and reoperations were most common in the third and fourth years. Overall, the complication rates were highest in years 2 and 3 (6.7% and 6.6% respectively), but even at year 5, there were substantial numbers of complications still being recorded (3.2%). Therefore, in studies that have follow-up less than several years, the rates of these complications will be underestimated.

Methods

Search Methods

The MEDLINE database was searched using the terms (all fields): “obesity” or “obese” or “morbid obesity.” These terms were cross-referenced with the terms (all fields): “surgery” or “gastric band” or “adjustable gastric band” or “laparoscopic gastric band.” Searches were performed on PubMed for the period of January 1980 through September 2006 and were limited to English-language articles reporting on human subjects. Initial search was supplemented with the “related articles” function for several key trials. Computerized searches were supplemented by manual reviews of bibliographies of selected references and pertinent Cochrane reviews. Citation abstracts were reviewed for relevance and all potentially relevant articles were reviewed in full.

Table 4. Overall Follow-up in Studies of LAGB that Report Follow-up Data

	Baseline	1 year	2 years	3 years	4 years	5 years
LAGB						
n (studies)	18	18	16	13	5	4
n (patients)	7,295	4,603	2,992	1,999	802	359
% total pts	100%	63%	41%	27%	11%	4.9%

Table 5. Sensitivity Analyses for Weight Loss and Long-term Complications in Single-arm Studies of LAGB

Variable	Definition (n studies)	% EWL	Δ BMI	Reoperation	Removal	Slip/Dilation	Erosion	Port
Completeness of follow-up at 1 year	$\geq 69\%$ (n=9)	40.2 \pm 4.4 (n=6)	8.8 \pm 0.9 (n=8)	16.0 \pm 16.2 (n=8)	10.2 \pm 11.1 (n=7)	12.0 \pm 7.5 (n=8)	3.1 \pm 3.7 (n=7)	11.7 \pm 10.2 (n=7)
	<69% (n=9)	47.6 \pm 5.7 (n=7)	11.1 \pm 2.1 (n=7)	7.4 \pm 3.1 (n=6)	2.7 \pm 1.9 (n=8)	4.8 \pm 2.7 (n=8)	0.6 \pm 0.7 (n=7)	4.8 \pm 2.8 (n=7)
Completeness of follow-up at 3 years	$\geq 39\%$	42.4 \pm 8.1 (n=5)	9.5 \pm 1.6 (n=6)	—	—	—	—	—
	<39%	60.3 \pm 5.0 (n=4)	12.3 \pm 2.7 (n=4)	—	—	—	—	—
Prospective data collection	Yes (n=8)	44.6 \pm 7.3 (n=5)	10.6 \pm 1.7 (n=7)	13.3 \pm 6.3 (n=7)	5.7 \pm 4.9 (n=7)	9.0 \pm 7.5 (n=8)	1.8 \pm 2.5 (n=8)	4.5 \pm 2.5 (n=7)
	No (n=28)	44.9 \pm 7.0 (n=15)	10.2 \pm 2.1 (n=18)	6.8 \pm 3.7 (n=20)	2.5 \pm 2.0 (n=18)	6.4 \pm 3.4 (n=22)	0.8 \pm 0.6 (n=17)	5.4 \pm 6.1 (n=19)
U.S. study	Yes (n=4)	39.8 \pm 4.7 (n=3)	10.3 \pm 2.7 (n=3)	16.6 \pm 10.5 (n=2)	5.9 \pm 7.9 (n=3)	8.0 \pm 10.7 (n=4)	0.6 \pm 0.4 (n=3)	6.0 \pm 2.6 (n=4)
	No (n=32)	45.7 \pm 6.9 (n=17)	10.3 \pm 1.9 (n=22)	9.6 \pm 9.7 (n=26)	4.5 \pm 6.7 (n=22)	7.6 \pm 4.5 (n=26)	1.6 \pm 2.3 (n=22)	5.7 \pm 6.4 (n=22)

Study Selection

Studies were selected for inclusion in this Assessment if they met the following criteria:

1. Full-length articles published in peer-reviewed journals in the English language between 1985 and September 2006
2. Patient population of adults with morbid obesity, as defined by:
 - a. BMI >40 kg/m²
 - b. BMI >35 kg/m² and at least one serious medical comorbidity, OR
 - c. Similar measure of defining morbid obesity (e.g., >100% above ideal body weight)
3. Patients treated with laparoscopic adjustable gastric banding.
4. At least 1-year follow-up (except for short-term adverse events, for which this criterion did not apply)
5. Reports on at least one relevant outcome:
 - a. Weight loss
 - b. Adverse effects of surgery (early morbidity/mortality of procedure, long-term adverse effects due to altered GI anatomy and physiology).
6. Study design is:
 - a. Comparative study of gastric bypass (open or laparoscopic) vs. laparoscopic adjustable gastric banding that includes at least 25 evaluable patients per treatment arm, OR:
 - b. Single-arm study that reports on outcomes of laparoscopic adjustable gastric banding AND includes at least 100 evaluable patients.

In cases of multiple publications from a single study, the article that was most recent or had the most complete reporting of results was used. Where different outcomes were reported in multiple publications, or when a subset of an overall population was reported in a separate publication, these outcomes were reported as part of the larger, overall study.

Study Quality Assessment

Study quality was formally assessed for comparative studies based on the quality assessment approach outlined by the U.S. Preventive Services Task Force (USPSTF; Harris et al. 2001). In this approach, 5 quality indicators are assessed as met or not met. These are:

- Initial assembly of comparable groups (adequacy of randomization, allocation

concealment, and equal distribution of confounders among groups);

- Maintenance of comparable groups (attrition, crossovers, contamination, non-adherence);
- Comparable performance of and clear definition of interventions with equivalent attention and quality of care;
- Comparable measurements: unbiased, reliable, and valid (includes masking of outcome assessment);
- Appropriate analysis of outcomes. Intent-to-treat analysis for randomized, controlled trials, consideration of confounding variables in nonrandomized studies. All important outcomes considered.

An overall level of quality of “good” (meets all criteria), “fair” (does not meet all criteria but no “fatal flaws”), or “poor” (has “fatal flaws”) is assigned based on these 5 parameters.

Medical Advisory Panel Review

Current Assessment. This Assessment was reviewed by the Blue Cross and Blue Shield Association Medical Advisory Panel (MAP) on November 2, 2006. In order to maintain the timeliness of the scientific information in this Assessment, literature search updates were performed subsequent to the Panel’s review (see “Search Methods”). These updated searches were confined to comparative studies, since the volume of single-arm studies published precludes performing rapid updates. If the search updates identified any additional studies that met the criteria for detailed review, the results of these studies were included in the tables and text where appropriate.

Previous Assessments. A TEC Assessment completed in 1991 concluded that open gastric bypass and vertical-banded gastroplasty (VBG) improved health outcomes to a greater degree than nonsurgical alternatives, and these procedures met the TEC criteria.

TEC Assessments completed in 2003 and 2005 (Vol. 18, No. 10, and Vol. 20, No. 5) determined that outcomes for open gastric bypass were superior to VBG and thus established open gastric bypass as the “gold-standard” bariatric procedure. Another TEC Assessment completed in 2005 (Vol. 20, No. 15) specifically addressed laparoscopic gastric bypass (LGBY) and found that this technique met TEC criteria. These Assessments also evaluated alternative

procedures (LAGB, biliopancreatic diversion, and long-limb gastric bypass) compared to open gastric bypass and determined that these other procedures did not meet the TEC criteria. There was a lack of high-quality trials at the time to directly compare weight loss and adverse events among these procedures. Single-arm series did not have sufficiently rigorous data to form conclusions, especially for adverse events.

Formulation of the Assessment

Patient Indications

Patients with a BMI of greater than 40 kg/m², or with a BMI of greater than 35 kg/m² and serious weight-related comorbidities, are candidates for bariatric surgery. In general, these patients will have failed conservative treatment, including lifestyle modifications and medications. However, because the expected success rate for these treatments in morbidly obese patients is low, most researchers do not consider this a necessary condition prior to attempting surgery.

Technologies to Be Compared

This Assessment will focus on gastric bypass vs. laparoscopic adjustable gastric banding (Lap-Band® or Swedish adjustable gastric band).

Health Outcomes

Weight loss is the most commonly reported outcome measure reported in trials of surgery for obesity, and is sufficient for comparing the relative efficacy of different procedures when combined with the adverse effects of surgery. For the purposes of this Assessment, all weight loss outcomes will be considered, but standardized measures that are commonly in use, particularly percent EWL and the decrease in BMI, will have the greatest utility in comparing results across studies.

Adverse effects of surgery include the short-term morbidity and mortality from the operation itself. Long-term adverse effects are related to symptoms caused by the altered passage of food through the GI tract following surgery, and often persist indefinitely.

Specific Assessment Question

Are outcomes of laparoscopic adjustable gastric banding (Lap-Band® and/or Swedish adjustable gastric band) as good as outcomes of gastric

bypass (open or laparoscopic) for patients with morbid obesity, as judged by:

- amount of weight loss
- adverse events

Review of Evidence

Methodologic Considerations

Conclusions regarding the comparative efficacy of different bariatric surgery techniques on weight loss are best made from comparative trials, particularly trials with concurrent control groups that demonstrate baseline comparability of groups on important clinical and demographic variables. This is best achieved through randomized, controlled trials, although other well-controlled designs may also be acceptable. Despite the large quantity of literature published on outcomes of various bariatric surgical procedures, this body of literature lacks high-quality clinical trials that directly compare outcomes between LAGB and GBY.

Single-arm series often have the advantage of larger numbers of patients than are included in comparative trials. The larger numbers offer the potential to better define the rates of uncommon events, particularly for complications. In addition, clinical series may better reflect results obtained in actual practice, as opposed to the highly controlled conditions present in prospective clinical trials. Because of these factors, data from large clinical series may be able to corroborate the effectiveness of bariatric surgery in achieving weight loss in actual practice, and may help in defining complication rates more precisely.

However, there are a number of difficulties that arise in attempting to determine the comparative efficacy using data from single-arm series. Surgical procedures are inherently prone to variability between individual surgeons, especially for procedures that are technically complex. Variability in skill, expertise, and training of individual surgeons for a particular procedure may affect both the beneficial and harmful outcomes of surgery. In addition, outcomes of a surgical procedure may vary between hospitals independent of the individual surgeon(s), due to the quality of the nursing and ancillary staff, the resources available, and the volume of procedures performed. Lack of standardization in reporting outcomes also hinders the ability to compare outcomes between single-arm series. While reporting

of weight-loss outcomes following bariatric surgery is fairly well standardized, the reporting of adverse events shows wide variability among the studies included in this Assessment. Systematic reporting of adverse events is unusual in this literature. Authors tend to classify adverse events in different ways, thus reporting different sets of adverse events at different points in time. The intensity of surveillance for adverse events may differ considerably, and systematic surveillance at regularly planned intervals is generally not done. For this Assessment, a set of the most important complications was defined for each procedure, divided into short-term (i.e., perioperative) and long-term adverse events. Data from each study on adverse events were then fit into these categories, to the extent possible.

Numerous other sources of variability also have the potential to have an impact on outcomes. Patient clinical characteristics may vary (demographics, average BMI, comorbidities), especially in situations where patient selection criteria differ, for example between open and laparoscopic gastric bypass. Psychological factors such as expectations from treatment may also differ between patient populations, and these factors may play a large role in outcomes of bariatric surgery. Secular trends in the field of surgery are also a consideration when studies are compared from different time periods and may further bias comparisons among single-arm studies. Improvements in technology and/or systems of care over time cannot easily be accounted for in these comparisons.

Are outcomes of laparoscopic adjustable gastric banding (Lap-Band® and/or Swedish adjustable gastric band) as good as outcomes of open gastric bypass for patients with morbid obesity, as judged by:

- Amount of weight loss
- Adverse events

For the 2005 Assessment, there were 4 comparative trials of LAGB vs. GBY, and 46 single-arm studies included. At that time, the lack of high-quality comparative trials limited the conclusions that could be made for laparoscopic adjustable gastric banding. Weight loss outcomes at 1 year were probably less than those seen for gastric bypass, and weight loss outcomes beyond 1 year could not be determined. Complication rates were poorly reported, but were probably low in the short term. Long-term complications were limited by poor reporting

and large losses to follow-up. Particularly for complications that were expected to occur after 1 year, such as band slippage, the data were inadequate to form conclusions.

For the current update, an additional 4 comparative trials and 11 single-arm series were included. The single-arm series consisted of 10 studies evaluating LAGB (Lap-Band®) and one study evaluating the Swedish adjustable gastric band (SAGB). Thus, a total of 7 comparative trials, enrolling 4,191 patients, and 57 single-arm series are included in this Assessment. A total of 9 single-arm series met the additional follow-up criteria of at least 50% of enrolled patients available at 2 years' follow-up. These 9 single-arm series are considered to provide the most accurate information on longer term weight loss and adverse events outcomes for LAGB.

In addition to the included studies, there was one randomized, controlled trial of LAGB published recently (O'Brien et al. 2006) that did not meet the inclusion criteria for this Assessment for several reasons. This study included 80 patients with BMI between 30 and 35 who were randomized to LAGB or intensive medical therapy. The population included in this study is different from that addressed by other studies of bariatric surgery and as defined in the TEC Assessments, both of which refer to patients with morbid obesity. According to widely followed guidelines published by the National Institutes of Health (National Heart, Lung, and Blood Institute, National Institutes of Health, 1998), patients with a BMI of less than 35 do not meet indications for bariatric surgery.

Furthermore, the comparison in this RCT of LAGB with nonsurgical therapy, while an important one, does not provide any relevant evidence that addresses the specific question for this Assessment, i.e., whether outcomes from LAGB are comparable to those obtained with gastric bypass. Finally, due to the small numbers in this trial, it is not powered to provide information on rates of adverse events, and therefore does not contain relevant information on complications of LAGB.

Comparative Trials. A total of 8 comparative trials met the inclusion criteria; these are summarized in Table 6. There were 3 comparative trials of LAGB vs. LGBY that matched patients on key clinical characteristics (Cottam et al. 2006; Hell et al. 2000; Weber et al. 2004). These trials provide the most direct evidence on the

comparative benefits and risks of the two procedures.

Cottam et al. (2006) was the largest of these matched comparative studies, with 181 patients in each arm. Patients who underwent LAGB were matched on BMI and date of surgery with patients who had undergone LGBY. This study also provided the longest follow-up, with weight loss outcomes reported out to 3 years.

The trials by Hell et al. (2000) and Weber et al. (2004) matched patients on age, gender and BMI. Hell et al. (2000) was a small study that compared 30 patients in each group undergoing one of 3 types of bariatric surgery (i.e., gastric bypass, vertical-banded gastroplasty, or laparoscopic adjustable gastric banding). Weber et al. (2004) identified 103 patients undergoing laparoscopic gastric bypass and matched these with 103 patients who had undergone laparoscopic gastric banding at the same institution. These 3 trials were rated as “fair” by quality rating, since they did not meet all the quality criteria, but did not contain any fatal flaws (Appendix Table A).

In all 3 of these matched trials, weight loss at 1 year was greater for the gastric bypass groups as compared to the LAGB groups (Table 6). Cottam et al. (2006) reported that the %EWL was 76% in the LGBY group compared to 48% in the LAGB group ($p < 0.001$). Hell et al. (2000) reported that approximately twice as many patients undergoing GBY had at least 50% EWL at 1 year of follow-up (93% v 54%, p NR). Weber et al. (2004) reported that both the %EWL (55% vs. 35%, $p < 0.05$) and the decrease in BMI (14.8 vs. 9.0, $p < 0.02$) was significantly greater in the LGBY group.

Only one of these 3 matched trials (Cottam et al. 2006) reported weight loss at longer time points. Cottam et al. (2006) reported %EWL and change in BMI at 2 years and 3 years (Table 6). The difference between the groups was maintained at these longer time points, with only a slight difference in the magnitude of difference at 2 years (80% vs. 55%, $p < 0.001$) and at 3 years (74% vs. 51%, $p < 0.001$). None of these trials reported on weight loss outcomes at time points longer than 3 years.

The remaining 4 comparative trials represent comparisons of outcomes from separate clinical series of patients who had LAGB or LGBY. In 4 of these studies (Kim et al. 2006; Rosenthal

et al. 2006; Parikh et al. 2005; Bowne et al. 2006) patients from one institution who had undergone either procedure were compared. The final comparative trial, Biertho et al. (2005) compared 805 patients who underwent SAGB from one institution in Switzerland with 456 patients who underwent LAGB in the U.S. Three of these studies were rated “fair” quality (Appendix Table A) as they did not meet all quality criteria but did not contain any fatal flaws. The remaining 2 studies (Rosenthal et al. 2006; Biertho et al. 2005) had evidence of substantial differences in the clinical and demographic characteristics of the two groups, and were thus rated “poor” quality.

Weight loss at 1 year was significantly greater for the LGBY group for each of these studies, with differences in %EWL ranging from 19.4–34.0%. Changes in BMI at 1 year was reported by one of these studies (Bowne et al. 2006), with a significantly larger decrease reported for the LGBY group (16 vs. 11, $p < 0.001$). Weight loss at longer time periods was reported by 2 of the studies (Kim et al. 2006; Parikh et al. 2005). Kim et al. (2006) reported that the difference in %EWL between groups at 2 years was smaller than at 1 year (33.6% vs. 19.5%) and was no longer statistically significant. Parikh et al. (2005) reported the %EWL at 2 years and 3 years. The difference in %EWL between groups was less at 2 years (8.9%) and at 3 years (7.3%), although comparisons at these later time points remained statistically significant at $p < 0.05$.

Complications were inconsistently reported by these comparative trials (Tables 7 and 8). The rates of short-term adverse events were very low for LAGB, and lower than for LGBY. There were no deaths reported in 1,658 patients undergoing LAGB. The most common short-term adverse event was wound infection, reported in 1.0% of patients. The remainder of the short-term adverse event rates were less than 1%.

Long-term adverse events were more common, but less consistently reported in these studies. There was a high pooled percentage for reoperations (23.6%), but this complication was only reported in 3 studies with 344 patients. The rate of slippage/dilation was 5.0%, and the rate of other complications, including band erosion, obstruction, port problems, and/or hernia were less than 5.0%.

Table 6. Laparoscopic Adjustable Gastric Banding: Comparative Studies – Study Characteristics and Weight Loss Outcomes

Study/Yr Patients	Group	n	Mean Age	Mean BMI	F/U mos.	Wt loss (1 yr)		Wt loss (2 yr)		Wt loss (3 yr)	
						%EWL	↓ BMI	%EWL	↓ BMI	%EWL	↓ BMI
Kim et al. 2006											
– Pts identified from prospective bariatric surgery database	LGBY	232	38.5	47.2	24	68%		68%			
– All pts undergoing either LGBY or LAGB at one institution between 2/01-7/04	LAGB	160	41.7	47.1		34.4%		48.5%			
	p value					<0.05		NS			
Rosenthal et al. 2006											
– Pts identified from prospective bariatric surgery database	LGBY	849	47	55.6	12	73.4%					
– 1,001 consecutive pts undergoing laparoscopic bariatric surgery between 6/200-12/03	LAGB	152	54	40.2		54%					
– Pts recommended for LGBY if DM or >3 comorbidities; recommended for LAGB if BMI <40 or <20 yo	p value					NR					
Bowne et al. 2006											
– Pts identified from prospective bariatric surgery database	LGBY	46	42.8	56.7	13.0 (med)	52% ¹	16 ¹				
– 106 consecutive pts with super obesity (BMI>50) who underwent LGBY or LAGB during a 3-yr period	LAGB	60	41.9	55.4	17.7 (med)	32% ¹	11 ¹				
	p value					<0.001	<0.001				
Cottam et al. 2006											
– Matched-pair cohort analysis	LGBY	181	43	47.2	36	76%	16	80%	20	74%	22
– Pts from prospective database of bariatric surgery pts	LAGB	181	42	47.2		48%	11	55%	15	51%	16
– 208 consecutive pts undergoing lap GBY, 181/208 matched with:	p value					<0.001	<0.05	<0.001	<0.05	<0.001	<0.05
– 181 pts treated with LAGB											
– Matched on BMI and date of surgery											

¹ %EWL and BMI results at last follow-up (median f/u 13.0 months for LGBY; 17.7 months for LAGB)

Table 6. Laparoscopic Adjustable Gastric Banding: Comparative Studies – Study Characteristics and Weight Loss Outcomes (cont'd)

Study/Yr Patients	Group	n	Mean Age	Mean BMI	F/U mos.	Wt loss (1 yr)		Wt loss (2 yr)		Wt loss (3 yr)	
						%EWL	↓ BMI	%EWL	↓ BMI	%EWL	↓ BMI
Parikh et al. 2005											
– Pts identified from prospective bariatric surgery database	LGBY	97	42	54.8	36	57.7%		54.7%		56.8%	
– All pts who underwent laparoscopic bariatric surgery from 10/00-6/04 with super obesity (BMI>50)	LAGB	197	43	55.3		35.3%		45.8%		49.5%	
	p value					<0.05		<0.05		<0.05	
Weber et al. 2004											
– Pts from prospective database of bariatric surgery pts	LGBY	103	40.1	47.8	24	54.8	14.8				
– 103 consecutive pts undergoing lap GBY, matched with	LAGB	103	39.6	48.0		35.1	9.0				
– 103 pts treated with LAGB	p value					<0.05	<0.02				
– Matched on age, sex, and BMI											
Biertho et al. 2003											
– 805 pts receiving SAGB at one institution, compared with	LGBY	456	40.2	49.4		67					
– 456 pts from a second institution undergoing lap GBY	LSAGB	805	41.7	42.2		33					
	p value					<0.0001					
Hell et al. 2000											
– Prospective clinical series with concurrent comparison group(s)	GBY	30	37.6	46.3	39 mos. (mean)	% >50% EWL					
– Consecutive pts undergoing one of three types of bariatric surgery.	VBGP	30				93					
– Matched on sex, age, and BMI	LAGB	30				57					
						54					

Table 7. Laparoscopic Adjustable Gastric Banding: Comparative Studies – Short-term Adverse Outcomes

n Studies	n Pts	Group	Measure	Perioperative Complications						
				Death	Perf	Conv	Thromb	Card	Bleed	Wound
7	2,533	LGBY	Pooled percentage	0.3%	1.6%	1.1%	0.8%	0.5%	1.7%	2.6%
				2/2,533	29/1,783	17/1,551	13/1,551	9/1,680	27/1,551	47/1,783
			Median	0	1.9%	1.0%	0.9%	1.0%	1.9%	2.5%
			Range	0-0.4%	0.9–2.9%	0–2.1%	0–1.0%	0.1–2.2%	0–2.5%	0–8.0%
7	1,658	LAGB	Pooled percentage	0	0.2%	1.9%	0.2%	0.7%	0.3%	1.4%
				0/1,658	3/1,477	25/1,317	2/1,317	10/1,374	4/1,317	21/1,477
			Median	0	0.1%	0.5%	0	0.5%	0.2%	1.0
			Range	0	0–1.2%	0–3.0%	0–0.2%	0–1.7%	0–1.0%	0–16%

Table 8. Laparoscopic Adjustable Gastric Banding: Comparative Studies – Long-term Adverse Outcomes

n Studies	n Pts	Group	Measure	Long-term Complications								
				Reop	Removal	Slip/Dil	Erosion	Esoph	Obstr	Port	Hern	GERD
7	2,533	LGBY	Pooled percentage	16.4%	NR	NA	NA	NA	5.2%	NA	0.4%	NR
				54/330					76/1,454		7/1,640	
			Median	14.6%	—	—	—	—	4.9%	—	0.2%	—
			Range	6.5–19.9%	NR	NA	NA	NA	1.1–8.7%	NA	0.04–2.9%	NR
7	1,658	LAGB	Pooled percentage	23.8%	NR	5.0%	0.8%	3.7%	0	3.8%	0.2%	3.3%
				82/344		56/1,120	8/1,060	34/908	0/1,120	43/1,128	3/1,220	2/60
			Median	25.0%	—	4.5%	1.3%	—	0	2.9%	0	—
			Range	22.7–25.2%	NR	1.4–36%	0.5–1.9%	2.8–24.3%	0	1.9–20%	0–0.4%	3.3%

A comparative analysis of complications of LAGB vs. LGBY was published by Parikh et al. (2005), but reported in different format. Complication rates were not reported by type, but were classified by severity and timing. The results of this study are summarized in Table 9. Serious short-term complications (grade III/IV) were very uncommon with LAGB, occurring at a rate of 0.2%. Long-term complications were more frequent, occurring in 5.4% of patients. The rates for LGBY were higher than for LAGB in every category. The total complication rate for LAGB (8.7%) was almost 3 times lower than that reported for LGBY (23.0%).

Single-arm Series. There were a total of 57 single-arm trials that met the inclusion criteria for this review, 44 reporting on the use of the LAGB (Lap-Band®) and 13 reporting on the Swedish adjustable gastric band (SAGB); these are summarized in the Appendix tables. The quality of these data is limited. The trials varied considerably on the numbers of patients enrolled, the length and completeness of follow-up, and the quality of reporting outcomes. In general, there was a lack of systematic reporting on the entire range of potential complications, and poor follow-up in terms of length and completeness. However, the large number of patients enrolled in these trials does offer the possibility of estimating rates of uncommon events, especially serious adverse events.

The single-arm studies with the most complete follow-up (>50% of enrolled patients available at 2 years) were identified, in an attempt to minimize the effect of attrition bias that limited the ability to form conclusions in previous Assessments. The nine single-arm studies that met this additional criterion are shown in Table 10.

These single-arm trials had a mean %EWL at 1 year of 39.4%, which increased somewhat in year 2 to 45.4% (Table 11). In subsequent years, the %EWL did not increase further, and in fact returned to approximately the same level at year 1, with the mean %EWL being 41.6, 44.3, and 36.0 at years 3, 4, and 5, respectively.

Suter et al. (2006) reported weight loss both by intent-to-treat and by treatment received (patients who remained available for follow-up and did not have the band removed). The comparison of these 2 analyses is shown in Table 11, and gives some insight into the potential impact of attrition bias. By year 3,

the difference between the intent-to-treat and treatment-received analysis becomes apparent, and by years 4 and 5, there is a substantial difference in the amount of weight loss reported, suggesting that attrition bias can substantially impact weight loss outcomes leading to overestimation of weight loss at longer time periods.

Adverse events from these single-arm trials are summarized in Table 12. The rates of short-term adverse events are low, similar to those seen in the comparative trials. Mortality in these studies was rare, with a pooled average of 0.1%. The most frequent short-term adverse events were conversions to open procedures (2.1%), cardiopulmonary complications (4.7%), and wound/port site infections (5.8%). The remainder of complications occurred with a frequency of less than 1%. The rates reported in these studies for long-term adverse events are on average higher than the short-term complications, and there is considerable variability in the range of reported rates.

Discussion

The available evidence on the comparative efficacy of LAGB vs. GBY consists primarily of comparisons of clinical series of patients undergoing each procedure. Some of these studies match patients on key clinical and demographic features, thus partially addressing the numerous potential sources of variability and confounding that make comparisons of these case series difficult. The non-matched comparative studies are prone to additional selection bias, limiting the validity of their conclusions.

Results of the current Assessment reinforce the conclusion of the 2005 Assessment that LAGB results in less weight loss at 1 year compared to GBY. Weight loss in the range of 40% EWL at 1 year is likely to be a reasonably accurate measure of this outcome. This is compared to 60–70% EWL that is generally reported with GBY.

There continues to be uncertainty regarding the evolution of weight loss past 1 year following LAGB. While some studies do show a trend for continued increase in the %EWL and a continued decrease in BMI at later time points, it is not possible to determine to what degree this represents continued weight loss vs. attrition bias. In the largest matched study with the longest follow-up (Cottam et al. 2006), the

Table 9. Summary of Complications as Reported by Parikh et al. (2006)

Complication	LAGB (n=480)		LGBY (n=235)		p Value
	n	%	n	%	
Grade					
I/IIa/IIb	41	8.5%	49	20.9%	<0.001
III/IV	1	0.2%	5	2.1%	0.001
Total	42	8.7%	54	23.0%	
Timing					
Early	16	3.3%	22	9.4%	<0.001
Late	26	5.4%	32	13.6%	<0.001
Total	42	8.7%	54	23.0%	

Table 10. Single-arm Studies with Most Complete Follow-up (>50% of enrolled patients retained at 2 years' follow-up)

Study/Yr	Mean Age	Mean BMI	% Male	F/up (mos)	n enr/eval	n at f/u (yrs)					Pro	Con	U.S.	Preop W/U	Comments
						1	2	3 (% available)	4	5					
Lap-Band™															
Champault 2006	38.4	44.3	22	34 (mean)	152	—	139	—	—	—	X	X		X	
Suter 2006	38.5	43.5	15	74 (mean)	317	311	304	294	261	210	X	X		X	
Martikainen 2004	44	49	31	55 (mean)	123	120	108	91	86	63		X		X	
Frigg 2004	41	45	21	44 (mean)	295	243	200	155	98			X			
Busetto 2002	37.6	46.6	28	36	260	252	247	250				X		X	
Favretti 2002	37.9	46.4	22	84	830	660	479	305	185	74		X		X	
Pontiroli 2002	42.9	44.9	19	36	143	143	94	56						X	
Silecchia 2001	36.3	44.2	20	32 (mean)	148	103	75	32			X	X			
FDA data 2000	38.8	47.4	15	36	299	233	189	178			X	X	X	X	
Swedish Adjustable Gastric Band															
Branson 2005	42	42.1	21	48	410	—	—	—	404		X	X		X	

Table 11. Weight Loss Outcomes in Single-arm Studies with the Most Complete Follow-up

Study/Year	n enrolled	% EWL (yrs)					Preop BMI	Reduction in BMI (yrs)				
		1	2	3	4	5		1	2	3	4	5
Lap-Band™												
Champault 2006	152	40.5	56				44.3	14.7	15.6			
Suter 2006 ¹	317	45	51	49	48	41	43.5	9	11	10	9	8
	317	45	53	53	54	56	43.5	9	12	11	12	13
Martikainen 2004	123	36	36	33	31	31	49	8.1	8.7	7.5		
Frigg 2004	295	40	46	47	54		45	8	10	10	11	
Busetto 2002	260	40		43			46.6	8.6	9.6	9.6		
Favretti 2002	830						46.4	9.1	10.0	9.6	9.8	10.0
Pontiroli 2002	143						44.9	8.0	8.2	7.9		
FDA data 2000	299	35	38	36			47.5	8.5	9.4	9.8		
Total – mean (SD)	2,419	39.4 (3.6)	45.4 (8.5)	41.6 (6.9)	44.3 (11.9)	36.0 (7.1)	45.6 (1.9)	8.2 (3.7)	9.2 (4.1)	9.2 (1.0)	9.9 (1.0)	9.0 (1.4)
Swedish Adjustable Gastric Band												
Branson 2005	410	—	—	—	—	—	42.1	—	—	—	11.5	

¹ Analysis by intent-to-treat (top line) and by treatment received, defined as pts available for f/u without removal of LAGB (bottom line)

Table 12. Adverse Events in Single-arm Studies with the Most Complete Follow-up

Study/Yr	n	Perioperative Complications							Long-term Complications								
		Death	Perf	Conv	Throm	Card	Bleed	Wound	Reop	Rem	Sl/Dil	Eros	Esoph	Obstr	Port	Hern	GERD
Lap-Band™																	
Champault 2006	152	0		0		2.0		2.6		5.0	11.2	3.3		3.3	7.8		
Suter 2006	317	0.3	0.6					0.3	0.3	21.7	7.6	6.3	9.5	3.2		20.2	6.9
Martikainen 2004	123		3.3		2.4	8.1	0.8	4.1	52	32.5	21.1	8.9	3.3		18.7		29.3
Busetto 2002	260	0	0.8	4.2	—			4.6	4.2	1.9	12	0.8	—	—	29	—	—
Favretti 2002	830	0	0.1	2.7	—	—	—	—	3.9	1.7	10	0.5	—	—	—	—	—
Pontiroli 2002	143	—	—	2.8	—	—	—	—	5.6	—	5.6	—	—	—	2.8	—	—
Silecchia 2001	148	0.8	0.8	3.4	0.8	—	0.8	—	9.2	9.2	1.7	7.6	—	—	—	—	—
FDA data 2000	299	0	0.7	0.7	0.3	—	—	14	24	15	24	1.0	10	14	8.7	5.4	34
Total – pooled %	2,272	0.1	0.6	2.1	0.9	4.7	1.8	5.8	11.9	6.6	10.7	2.9	6.0	10.4	14.2	5.4	21.7
Swedish Adjustable Gastric Band																	
Branson 2005	410	0	0.2		0.2	2.0	0.5	0.5	16.3	9.8	3.4	1.5			6.4		

difference between LGBY and LAGB remains relatively constant up to 3 years of follow-up. However, in the 2 other matched studies that report weight loss past 1 year, there was a diminution in the magnitude of the difference in %EWL over time.

The impact of attrition bias was evaluated in 1 of the single-arm studies (Suter et al. 2006), in which results of analyses by intent-to-treat and treatment received were compared. In this study, like most others, patients who had their band removed, in addition to those lost to follow-up, were not included in the treatment-received analysis. Results showed that by years 3–5, the weight loss curves for the 2 analyses diverged considerably, suggesting that attrition bias is important in evaluating long-term weight loss for patients undergoing LAGB. Therefore, the current analysis does not support the hypothesis that the difference in weight loss between GBY and LAGB lessens at time points longer than 1 year. It is possible that the trends in longer term weight loss are caused by attrition bias, particularly if patients who have their bands deflated or removed are excluded from analysis.

The present analysis also confirms prior conclusions concerning the rate of short-term complications following LAGB. Serious short-term adverse events are very uncommon, and occur less frequently with LAGB compared to LGBY. Death is extremely uncommon, and serious adverse events occur at rates less than 1.0%.

The data on long-term complications is less robust, and as a result, there is still some uncertainty concerning the rates of long-term complications. For LAGB, the frequency of long-term complications is higher than short-term complications, but there is a wide range of reported values and a great deal of uncertainty concerning the summary values reported in this Assessment. This uncertainty derives from the lack of systematic surveillance and reporting of long-term adverse events, and from the incomplete follow-up that is seen in most of these trials. The comparative studies do not follow patients long enough to determine accurate rates of these events. Some of the single-arm studies do provide longer term follow-up, but the inconsistent classification and reporting of adverse events makes a rigor-

ous analysis impossible. Long-term prospective trials that have adequate follow-up and report systematically on complications for at least 3 to 5 years are needed to remediate these important deficiencies in the current evidence base.

It is difficult to directly compare LAGB with GBY, since the profile of benefits and risks differs between the two procedures, and each has its advantages and disadvantages. LAGB offers a less-invasive procedure that is associated with fewer procedural complications, a decreased hospital stay and earlier return to usual activities. However, the average amount of weight loss will be less following LAGB compared to GBY. The patterns of long-term complications also differ. For LAGB, longer term adverse events related to the presence of a foreign body in the abdomen will occur, and will result in reoperations and removal of the band in a minority of patients. Patients who have their bands removed can later be offered an alternative bariatric surgery procedure, such as gastric bypass.

For patients considering bariatric surgery, there is sufficient evidence to allow an informed choice to be made between gastric bypass and LAGB. An informed patient may reasonably choose either GBY or LAGB as the preferred procedure. For example, a patient who is risk-averse and has a relatively low BMI, e.g., 40–45, might be inclined to choose LAGB. A patient with a much higher BMI, e.g., greater than 50, whose primary goal is to maximize weight loss might be more inclined to choose gastric bypass. Preoperative counseling should include education on the comparative risks and benefits of the two procedures in order to allow the optimal choice to be made based on patient and surgeon preferences.

Summary of Application of the Technology Evaluation Criteria

Based on the available evidence, the Blue Cross and Blue Shield Medical Advisory Panel made the following judgments about whether laparoscopic adjustable gastric banding (LAGB) meets the Blue Cross and Blue Shield Association Technology Evaluation Center (TEC) criteria.

1. The technology must have final approval from the appropriate governmental regulatory bodies.

Bariatric surgery is a procedure and is not subject to U.S. Food and Drug Administration (FDA) regulations. However, certain devices that may be used as part of the procedure may be subject to FDA approval. The Lap-Band® system received premarket application (PMA) approval by the FDA in June 2001 for use in morbidly obese patients.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The evidence is sufficient to permit conclusions concerning the short-term safety and efficacy of LAGB in comparison with GBY. Weight loss at 1 year following LAGB is substantial, in the range of 40% EWL, although less than that seen following GBY. The short-term complications of LAGB are very low, with serious short-term complications being uncommon, and mortality exceedingly rare. Rates of short-term adverse events, including serious procedural complications and mortality, are lower for LAGB compared with GBY.

Conclusions concerning longer term weight loss following LAGB are less definitive. Some studies report that the difference in weight loss between LAGB and GBY diminishes over longer time periods; however, other studies do not. Studies that report longer term outcomes do not generally have complete follow-up, and therefore it is not possible to determine whether continued increases in %EWL are due to further weight loss or attrition bias.

The evidence on the rates of long-term complications is also not robust. The precise rates of long-term complications cannot be determined from the data due to inadequacy of long-term follow-up in the available studies. However, the data do define a range of complications that permits decision-making on the overall benefit/risk ratio of this procedure. A considerable minority of patients who undergo LAGB may require reoperations for long-term complications, and/or removal of the band.

3. The technology must improve the net health outcome.

The amount of weight loss following LAGB is substantial, in the range of 40% EWL at 1 year. This amount of weight loss is equal to or greater than the amount of weight loss that has been associated with health outcome benefits, such as a reduction in the incidence of diabetes. There is a low rate of serious procedural complications, and therefore, the weight loss benefit outweighs the short-term risks. Longer term risks may be more frequent and are less well defined, but are unlikely to offset the benefits of the procedure. Longer term complications may result in reoperations and/or removal of the band. The reversibility of the procedure makes it unlikely that long-term complications will offset the benefits of this procedure.

4. The technology must be as beneficial as any established alternatives.

The main established alternative to LAGB is open or laparoscopic GBY. Both procedures are effective in producing weight loss; the comparison of LAGB with GBY offers a tradeoff in terms of safety and efficacy. LAGB is a safer procedure in the short term, and is reversible. However, LAGB results in lower amounts of weight loss at 1 year compared with GBY. The longer term complications of LAGB are more common than short-term complications, and are different than those seen with GBY.

While it is not possible to say with confidence whether LAGB or GBY is the “better” procedure, either one might be a reasonable choice for a patient considering bariatric surgery. Numerous factors may play a role in decision-making including baseline BMI, surgical risk, comorbidities, and tolerance for repeat procedures.

5. The improvement must be attainable outside the investigational settings.

Training on insertion of LAGB is widely available and expertise for inserting the devices is common among bariatric surgeons in the U.S. As a result, the use of LAGB has been widely disseminated among bariatric surgery centers, both in the academic and community settings.

Based on the above, laparoscopic adjustable gastric banding meets the TEC criteria when performed in appropriately selected patients, by surgeons who are adequately trained and experienced in the specific techniques used, and in institutions that support a comprehensive bariatric surgery program, including long-term monitoring and follow-up post-surgery.

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Appendix

Abbreviations Key

Δ	change
AGB	adjustable gastric banding
ADV	adverse events
BAROS	bariatric surgery analysis and reporting outcome system
BMI	body mass index
BW	body weight
CON	consecutive series of patients
CVD	cardiovascular disease
DBP	diastolic blood pressure
DM	diabetes mellitus
EWL	excess weight loss
GBA	gastric banding
GBY	gastric bypass with Roux-en-Y
HGP	horizontal gastroplasty
IBW	ideal body weight
LAGB	laparoscopic gastric bypass
MOR	morbidity
NR	not reported
NS	non-significant
PHY	physiologic outcome measure
PRO	prospective data collection
PSY	psychosocial
QOL	quality of life
SRGP	Silastic ring gastroplasty
SAGB	Swedish adjustable gastric band
SBP	systolic blood pressure
TBW	total body weight
U.S.	study performed in the United States
VBGP	vertical banded gastroplasty
WTL	weight loss

Complications

Anas	complication at the anastomotic site(s), e.g., stenosis/stricture, leak, or staple-line failure
Bleed	bleeding complications
Cardio	cardiopulmonary complications, e.g. MI, CHF, pneumonia, respiratory failure
Conv	conversion from laparoscopic to open procedure
Death	death within 30 d of operation
Eros	erosion of adjustable band through esophageal/stomach wall or into other visceral organ
Esoph	esophageal abnormalities
Hern	abdominal wall hernia at incision or port site
Infect	Infection resulting from device, other than wound infection(s)
N/V	chronic nausea and/or vomiting, moderate or severe
Nutr	nutritional deficiencies, including vitamin deficiencies
Obstr	bowel obstruction resulting from procedure
Perf	perforation of bowel and/or visceral organ, including splenic injury
Port	complications at the port access site, including infection, dysfunction, and/or revisions
Reop	reoperation resulting from a complication of the original procedure
Sl/Dil	slippage of adjustable band or dilation of proximal GI tract
Throm	thromboembolic complication
Ulcer	mucosal ulceration occurring at or near site of procedure
Wound	wound complications, including infection and dehiscence

Table A. Assessment of Study Quality for Comparative Studies of LAGB vs. GBY– USPSTF Framework

Study/yr	1 Initial Assembly of Comparable Groups	2 Maintenance of Comparable Groups	3 Comparable Intervention(s)	4 Comparable Measurements	5 Appropriate Analysis of Outcomes	OVERALL QUALITY LEVEL
Gastric Bypass vs. Laparoscopic Gastric Banding						
Kim et al. 2006	Yes	NR Follow-up information not reported	No/NR Details of post-op care and follow-up not reported	Yes	No Wt loss outcomes only No intent-to-treat analysis	FAIR Did not meet all quality criteria but no ‘fatal flaws’
Rosenthal et al. 2006	No Baseline differences demonstrated on age, BMI	NR Follow-up information not reported	No/NR Details of post-op care and follow-up not reported	Yes	No Wt loss outcomes only No intent-to-treat analysis	POOR Lack of comparability, poor reporting of f/u are ‘fatal flaws’
Bowne et al. 2006	Yes	NR Follow-up information not reported	No/NR Details of post-op care and follow-up not reported	Yes	No Wt loss outcomes only No intent-to-treat analysis	FAIR Did not meet all quality criteria but no ‘fatal flaws’
Cottam et al. 2006	Yes Pts matched for major clinical characteristics	NR Follow-up information not reported	No/NR Details of post-op care and follow-up not reported	Yes	No Wt loss outcomes only No intent-to-treat analysis	FAIR Did not meet all quality criteria but no ‘fatal flaws’
Parikh et al. 2005	Yes		No/NR Details of post-op care and follow-up not reported	Yes	No Wt loss outcomes only No intent-to-treat analysis	FAIR Did not meet all quality criteria but no ‘fatal flaws’
Weber et al. 2004	Yes Pts matched for major clinical characteristics	NR Follow-up information not reported	Yes	Yes	No Wt loss outcomes only No intent-to-treat analysis	FAIR Did not meet all quality criteria but no ‘fatal flaws’

Table A. Assessment of Study Quality for Comparative Studies of LAGB vs. GBY– USPSTF Framework (cont'd)

Study/yr	1 Initial Assembly of Comparable Groups	2 Maintenance of Comparable Groups	3 Comparable Intervention(s)	4 Comparable Measurements	5 Appropriate Analysis of Outcomes	OVERALL QUALITY LEVEL
Gastric Bypass vs. Laparoscopic Gastric Banding						
Biertho et al. 2003	No Patients from two different institutions from two different countries	NR Follow-up information not reported	No/NR Details of post-op care and follow-up not reported	Yes	No Wt loss outcomes only No intent-to-treat analysis	POOR Lack of comparability, poor reporting of f/u are 'fatal flaws'
Hell et al. 2000	No Non-randomized study	Yes No loss to f/u	Yes	Yes	No Wt loss and QOL outcomes, no morbidity outcomes No intent-to-treat analysis	FAIR Did not meet all quality criteria but no 'fatal flaws'

Table B. Primary Evidence Tables for Laparoscopic Adjustable Gastric Banding

Study/Yr Patients	Treatments Compared	n	Mean Age	Mean BMI	F/U mos.	Outcomes				
						WTL	MOR	QOL	PSY	ADV
Kim et al. 2006 – Pts identified from prospective bariatric surgery database – All pts undergoing either LGBY or LAGB at one institution between 2/01-7/04	Lap gastric bypass	232	38.5	47.2	24	1				
	Lap adj gastric band	160	41.7	47.1						
Rosenthal et al. 2006 – Pts identified from prospective bariatric surgery database – 1,001 consecutive pts undergoing laparoscopic bariatric surgery between 6/00-12/03 – Pts recommended for LGBY if DM or >3 comorbidities – Pts recommended for LAGB if BMI<40 or <20 yo	Lap gastric bypass	849	47	55.6	12	1				2
	Lap adj gastric band	152	54	40.2						
Parikh et al. 2005 – Pts identified from prospective bariatric surgery database – All pts who underwent laparoscopic bariatric surgery from 10/00-6/04 with super obesity (BMI>50) – Decision on type of surgery made by patient and surgeon	Lap gastric bypass	97	42	54.8	36	1				2
	Lap adj gastric band	197	43	55.3						
Bowne et al. 2006 – Pts identified from prospective bariatric surgery database – 106 consecutive pts with super obesity (BMI>50) who underwent LGBY or LAGB during a 3-yr period	Lap gastric bypass	46	42.8	56.7	13.0 (med)	1	2			3
	Lap adj gastric band	60	41.9	55.4	17.7 (med)					

Table B. Primary Evidence Tables for Laparoscopic Adjustable Gastric Banding

Study/Yr Patients	Treatments Compared	n	Mean Age	Mean BMI	F/U mos.	Outcomes				
						WTL	MOR	QOL	PSY	ADV
Cottam et al. 2006	Lap gastric bypass	181	43	47.2	36	1	2			3
– Matched-pair cohort analysis										
– Pts from prospective database of bariatric surgery pts	Lap adj gastric band	181	42	47.2						
– 208 consecutive pts undergoing lap GBY, 181/208 matched with:										
– 181 pts treated with LAGB										
– Matched on BMI and date of surgery										
Weber et al. 2004	Lap gastric bypass	103	40.1	47.8	24	1				2
– Pts from prospective database of bariatric surgery pts	Lap adj gastric band	103	39.6	48.0						
– 103 consecutive pts undergoing lap GBY, matched with										
– 103 pts treated with LAGB										
– Matched on age, sex, and BMI										
Biertho et al. 2003	Lap gastric bypass	456	40.2	49.4	39.6 (mean)	1				2
– 805 pts receiving SAGB at one institution, compared with	Lap Swed adj gastric band	805	41.7	42.2						
– 456 pts from a second institution undergoing lap GBY										
Morino et al. 2003	Vertical banded gastroplasty	51	38.2	44.2	33.1 (mean)	1				2
– Randomized, controlled trial										
– Patients scheduled for bariatric surgery at one institution	Lap Swed adj gastric band	49	37.2	44.7						
– BMI 40–50										
Hell et al. 2000	Gastric bypass	30	37.6	46.3	39 (mean)					
– Prospective clinical series with concurrent comparison group(s)	Vert band gastroplasty	30								1. % Excess weight lost
– Consecutive pts undergoing one of three types of bariatric surgery.	Lap adj gastric band	30								2. BAROS (Bariatric Analysis and reporting outcome system) score
– Matched on sex, age, and BMI										

Table C. Weight Loss Outcomes: Comparative Studies

Study/Yr	Treatment Groups	n (enr/eval)	Weight Loss Outcomes							
			1 year	p value	2 year	p value	3 year	p value	≥5 year	p value
Kim et al. 2006	Lap gastric bypass		%EWL 63.5%	<0.05	%EWL 68%	NS				
	Lap adj gastric band		34.4%		48.5%					
Rosenthal et al. 2006	Lap gastric bypass	849	%EWL* 73.4%	NR						
	Lap adj gastric band	152	54%							
Parikh et al. 2005	Lap gastric bypass	97	%EWL* 57.7%	<0.05	%EWL* 54.7%	<0.05	%EWL* 56.8%	<0.05		
	Lap adj gastric band	197	35.3%		45.8%		49.5%			
Bowne et al. 2006	Lap gastric bypass	46	%EWL* 52%	<0.001	* %EWL at last follow-up (median f/u 13.0 months for LGBY; 17.7 months for LAGB)					
	Lap adj gastric band	60	32%							
	Lap gastric bypass		Δ BMI* -16	<0.001	* BMI at last follow-up (median f/u 13.0 months for LGBY; 17.7 months for LAGB)					
	Lap adj gastric band		-11							

Table C. Weight Loss Outcomes: Comparative Studies (cont'd)

Study/Yr	Treatment Groups	n (enr/eval)	Weight Loss Outcomes							
			1 year	p value	2 year	p value	3 year	p value	≥5 year	p value
Cottam et al. 2006			%EWL		%EWL		%EWL			
	Lap gastric bypass	181	76%	<0.001	80%	<0.001	74%	<0.001		
	Lap adj gastric band	181	48%		55%		51%			
				Δ BMI		Δ BMI		Δ BMI		
	Lap gastric bypass	181	-16	<0.05	-20	0.05	-22	<0.05		
	Lap adj gastric band	181	-11		-15		-16			
Weber et al. 2004			%EWL		%EWL					
	Lap gastric bypass	103/	54.8%	<0.05	54%	<0.05				
	Lap adj gastric band	103/	35.1%		42.1%					
				Δ BMI		Δ BMI				
	Lap Gastric bypass	103/	-14.8	<0.02	-15.9	<0.02				
	Lap Adj gastric band	103/	-9.0		-11					
Biertho et al. 2003			%EWL							
	Lap gastric bypass	456/140	67%	<0.0001						
	Lap adj gastric band	805/664	33.3%							

Table C. Weight Loss Outcomes: Comparative Studies (cont'd)

Study/Yr	Treatment Groups	n (enr/eval)	Weight Loss Outcomes							
			1 year	p value	2 year	p value	3 year	p value	≥5 year	p value
Morino et al. 2003			%EWL		%EWL		%EWL			
	VBGP	51	62.3%	<0.05	63.5	NS	58.9	NS		
	Lap Swed adj gastric band	49	39.2		41.4		39.0			
				Δ BMI		Δ BMI		Δ BMI		
	VBGP	51	14.1	<0.05	14.5	NS	13.5	NS		
	Lap Swed adj gastric band	49	9.2		9.9		9.0			
Hell et al. 2000					%>50%EWL					
	GBY	30/30			93					
	VBGP	30/30			57					
	Lap adj gastric band	30/30			54					

Table D. Adverse Outcomes: Comparative Studies

Study/Yr	Group	n	Perioperative Complications							Long-term Complications							
			Death	Perf*	Conv	Throm	Card	Bleed	Wound	Reop	Rem	Sl/Dil**	Eros	Esoph	Obstr	Port	Hern
Kim et al. 2006	LGBY	232	0	0.9				2.2		1.7							0.04
	LAGB	160	0							0.6						3.8	
Rosenthal et al. 2006	LGBY	849	0	1.9	0.6	0.8	0.1	2.5	3.7			6.3	0		1.4		0.2
	LAGB	152	0	1.2	0	0	0	0	0			4.5	1.3		0		0
Parikh et al. 2005	LGBY	97	0	1.0	2.1	0.5	0.5	0	2.5								
	LAGB	197	0	0	0.5	0	0.5	0.5	1.0								
Bowne et al. 2006	LGBY	46	0	2.2	0	0	2.2	2.2	0	6.5		0			8.0	0	0
	LAGB	60	0	0	1.7	0	1.7	0	1.7	25.0		2.0			0	20	4.0
Cottam et al. 2006	LGBY	181	0							19.9							
	LAGB	181	0							22.7							
Weber et al. 2004	LGBY	103	0	2.9	1.0	1.0		1.9	7.8	14.6					4.9		2.9
	LAGB	103	0	0	0	0		1.0	15.5	25.2		35.9	1.9	24.3	0	1.9	0
Biertho et al. 2003	LGBY	456	0.4	1.3	2.0	0.9	0.2	0.7							1.1		0.2
	LAGB	805	0	0.1	3.0	0.2	1.0	0.2	0.1			1.4	0.5	2.8		2.9	0.4

* includes leaks for LGBY

** slippage/dilation for LAGB; strictures for LGBY

Table E. Study Characteristics: Single-Arm Studies

Study/Yr	Mean Age	Mean BMI	% Male	F/up (mos)	n Enrolled	n at f/u (yrs)					Pro	Con	U.S.	Preop W/U
						1	2	3 (% available)	4	5				
Lap-Band™														
Sarker 2006	42	50.6	21	14 (mean)	409	362	186	81	20		X	X	X	
Ganesh 2006	36	41.9	36	15 (mean)	256	161	—	—	—	—		X		X
Champault 2006	38.4	44.3	22	34 (mean)	152	—	139	—	—	—	X	X		X
Jenkins 2006	44	49	14	34 (mean)	125	—	—	—	—	—	X	X		X
Lee 2006	31.4	41.3	45	30 (med)	107	—	—	—	—	—	X	X		X
Suter 2006	38.5	43.5	15	74 (mean)	317	311	304	294	261	210	X	X		X
Ponce 2005	42.3	47.7	18	48 (max)	1,014	668	240	68	12			X	X	
Lyass 2005	—	—	—	18 (mean)	270	—	—	—	—	—		X	X	
Ahroni 2005	43.8	45.8	17	12	195	179					X	X	X	X
Watkins 2005	43.5	44.5	11		343	91	—	—			X	X	X	
Keider 2005	38	44.1	22	37 (mean)	2,134	NR	NR	NR	NR	NR		X		X
Sarker 2004	42	50.2	24	6.4 (mean)	154							X	X	
Ren 2004	42	49.6	23.1	12 (max)	445	99					X	X	X	X
Martikainen 2004	44	49	30.9	55 (mean)	123	120	108	91	86	63		X		X
Korenkov 2004	40.6	48.1	27.4	44.6 (mean)	106							X		
Frigg 2004	41	45	21	44 (mean)	295	243	200	155	98			X		
Dargent 2004	39.5	43.3	15.4	108 (max)	1,180	696	573	434	321	190		X		
Chevallier 2004	40.4	44.3	10.4	84 (max)	1,111							X		

Table E. Study Characteristics: Single-Arm Studies (cont'd)

Study/Yr	Mean Age	Mean BMI	% Male	F/up (mos)	n Enrolled	n at f/u (yrs)					Pro	Con	U.S.	Preop W/U
						1	2	3 (% available)	4	5				
Lap-Band™ (cont'd)														
Holloway 2004	NR	49	18	36 (max)	504	311	122	40				X		X
Spivak 2004	40	45.3	13	24 (max)	271	72	21					X	X	
Angrisani 2003	37.8	43.7	19.0	72 (max)	1,893	NR	NR	NR	NR	NR		X		
Weiner 2003	37.9	46.8	22	NR	984	NR	NR	NR	NR	NR		X		
Zinzindohoue 2003	40.4	44.3	14	13 (mean)	500	343	185	45				X		X
Busetto 2002	37.6	46.6	28	36	260	252	247	250				X		X
Chevallier 2002	40.2	43.8	12	24	400	168	33				X	X		X
Favretti 2002	37.9	46.4	22	84	830	660	479	305	185	74		X		X
Vertruyen 2002	41	44	10	36 (mean)	543	NR	NR	NR	NR	NR		X		X
O'Brien 2002	41	45	15	72	709	492	336	273	112	32	X	X		X
Belachew 2002	34	42	22	48 (min)	763	NR	NR	NR	NR	NR				
Pontiroli 2002	42.9	44.9	19	36	143	143	94	56						X
Angrisani 2001	38	44.1	20	48	1,265	NR	NR	NR	NR					
Szold 2002	38.1	43.7	24	17 (mean)	715	NR	181	121			X	X		
Frigg 2001	39	45	16	17 (mean)	148							X		
Silecchia 2001	36.3	44.2	20	32 (mean)	148	103	75	32			X	X		
Niville 2001	38	42.5	24	39 (mean)	306							X		
FDA data 2000	38.8	47.4	15	36	299	233	189	178			X	X	X	X

Table E. Study Characteristics: Single-Arm Studies (cont'd)

Study/Yr	Mean Age	Mean BMI	% Male	F/up (mos)	n Enrolled	n at f/u (yrs)					Pro	Con	U.S.	Preop W/U
						1	2	3 (% available)	4	5				
Lap-Band™ (cont'd)														
Cadiere 2000	40	45	24	24	652	NR	NR					X		
Paganelli 2000	40.3	43.7	21	12	156	NR						X	X	
Suter 2000	37.5	44.6	13	17 (mean)	150	NR	NR	NR		X			X	
Fielding 1999	41	46.7	15	12	335	125						X	X	
Miller 1999	36	44	10	28 (mean)	166/156	NR	NR	NR		X	X			
Dargent 1999	39.4	43	16	36	500	270	96	19				X		
Weiner 1999	35.2	47.8	11	24	184	112	53							
Furbetta 1999	43.3	43.3	22	12	169	50								
Kasalicky 1999	NR	NR	12	12	487							X		
Belachew 1998	35.5	42.9	21	36	350	NR	NR	NR				X		

Table E. Study Characteristics: Single-Arm Studies (cont'd)

Study/Yr	Mean Age	Mean BMI	% Male	F/up (mos)	n Enrolled	n at f/u (yrs)					Pro	Con	U.S.	Preop W/U
						1	2	3 (% available)	4	5				
Swedish Adjustable Gastric Band														
Branson 2005	42	42.1	21	48	410	—	—	—	404		X	X		X
Biertho 2005	43	42.4	22.8	39.6 (mean)	824	821	744	593	380	184	X	X		
Greenslade 2004	40.1	42.9	14	48 (max)	215	NR	NR	NR	NR		X	X		X
Ceelen 2003	36	40	20	19.5 (med)	625	NR	NR	NR				X		X
Mittermair 2002	38	46.7	16	—	454						X			
Mortele 2001	NR	NR	20	—	218							X		
Nowara 2001	32.3	48.9	16	24	108	NR	NR							
Nehoda 2001	38.3	46.7	20	12	250							X		X
Hauri 2000	43	42.5	22	12	207	207					X			
Forsell 1999	40	NR	24	28 (mean)	326		289					X		
Chelala 1997	38	43	19	—	185							X		

Table F. Weight Loss Outcomes: Single-Arm Studies

Study/Year	n enrolled	% EWL (yrs)					Preop BMI	Reduction in BMI (yrs)				
		1	2	3	4	5		1	2	3	4	5
Lap-Band™												
Sarker 2006	409	44.3	48.0	53.3			50.6	10.7	11.5	15.2		
Ganesh 2006	256	51.7					41.9					
Champault 2006	152	40.5	56				44.3	14.7	15.6			
Jenkins 2006	125	45	58	58	70	74	49	11.7	15.0	16.1	18.5	21.7
Lee 2006	107	44.7	44.8				41.3	7.3	8.2			
Suter 2006 ¹	317	45	51	49	48	41	43.5	9	11	10	9	8
	317	45	53	53	54	56	43.5	9	12	11	12	13
Ponce 2005	1,014	40.5	52.9	62.0	64.3		47.7	10.5	13.8	16.1	16.0	
Ahroni 2005	195	45.7					45.8	13.5				
Watkins 2005	343	45.4					44.5	9.2				
Ren 2004	445	44.3					52.7	13.4				
Martikainen 2004	123	36	36	33	31	31	49	8.1	8.7	7.5		
Korenkov 2004	106				52.1		48.1				11.7	
Frigg 2004	295	40	46	47	54		45	8	10	10	11	
Dargent 2004	1,180	49	56	57	57	54						
Holloway 2004	504	50	61	65			49	13.0	16.0	16.0		
Spivak 2004	271	40	43				45.3	9.0	10.6			
Angrisani 2003	1,893						43.7	10.0	8.9	9.6	11.0	8.9
Weiner 2003	984	NR	NR	NR	NR	54	46.8	12.8				

¹ Intent-to-treat analysis. analysis by patients who retained band on second line

Table F. Weight Loss Outcomes: Single-Arm Studies (cont'd)

Study/Year	n enrolled	% EWL (yrs)					Preop BMI	Reduction in BMI (yrs)				
		1	2	3	4	5		1	2	3	4	5
Lap-Band™ (cont'd)												
Zinzindohoue 2003	500	43	52	55			44.3	10.1	11.5	12.4		
Busetto 2002	260	40		43			46.6	8.6	9.6	9.6		
Chevallier 2002	400	42	53				43.8	9.5	11.1			
Favretti 2002	830						46.4	9.1	10.0	9.6	9.8	10.0
Vertruyen 2002	543	38	61	62	58	53	44.0	10.8	12.7	13.9	12.6	12.8
O'Brien 2002	709	47	53	53	52	54	45	10	12	12	13	13
Belachew 2002	763	40	50	60	52	66	42	10	12			12
Pontioli 2002	143						44.9	8.0	8.2	7.9		
Angrisani 2001	1,265						44.1	9.0	13.9	12.0	12.6	
Szold 2002	715						43.3	10.2	10.3	11.2		
FDA data 2000	299	35	38	36			47.5	8.5	9.4	9.8		
Cadiere 2000	652	38	62				45	10	12			
Paganelli 2000	156	43										
Suter 2000	150	55	56				44.6	12.6	12.6			
Fielding 1999	335	52					46.7	12.0				
Miller 1999	166						44	10	14	16		
Dargent 1999	500	56	65	64								
Weiner 1999	184	58	87				47.8	15.8	19.2			
Furbetta 1999	169						43.3	8.3				
Belachew 1998	350	50	58	77			42.9	10.9	11.9	16.9		

Table F. Weight Loss Outcomes: Single-Arm Studies (cont'd)

Study/Year	n enrolled	% EWL (yrs)					Preop BMI	Reduction in BMI (yrs)				
		1	2	3	4	5		1	2	3	4	5
Swedish Adjustable Gastric Banding												
Branson 2005	410	—	—	—	—	—	42.1	—	—	—	11.5	
Biertho 2005	824	30.1	41.5	47.6	52.0	54.8						
Greenslade 2004	215	45	58	55	50	44	42.9	9.9	10.9	11.4	11.9	
Nowara 2001	108						48.9	11.7	14.6			
Nehoda 2001	250	71					46.7	18.7				
Hauri 2000	207	43					42.5	7.9				

Table G. Adverse Events: Single-Arm Studies

Study/Yr	n	Perioperative Complications							Long-term Complications								
		Death	Perf	Conv	Throm	Card	Bleed	Wound	Reop	Rem	Sl/Dil	Eros	Esoph	Obstr	Port	Hern	GERD
Lap-Band™																	
Sarker 2006	409	0.2			1.0	0.2		0.2	12.2	4.0	5.4			0.2		4.2	
Ganesh 2006	256	0.3		1.2		0.3		0.3	7.8	1.9	2.3	1.2				3.9	
Champault 2006	152	0		0		2.0		2.6		5.0	11.2	3.3		3.3		7.8	
Jenkins 2006	125	0		3.2					12.2	4.7						4.0	
Lee 2006	107	0		0					3.7	0.9				0.9			
Suter 2006	317	0.3	0.6				0.3	0.3	21.7	7.6	6.3	9.5	3.2			20.2	6.9
Ponce 2005	1,014	0	0.4	0.1			0.1	0.6	4.8	0.8	2.2	0.2		0.3	0.4		0.5
Ahroni 2005	195	0.5								0.5	1.5			4.1	2.1		
Watkins 2005	343		0.3	0	0			0.3		0.3	0	0		1.5	0.9	0	
Lyass 2005	270								13.0	5.0	3.0			1.5	5.0		
Keider 2005	1,272															7.1	
Sarker 2004	154	0.6			0.6	0.6			9.1	1.9	3.2	0.6				5.2	
Ren 2004	445	0.2			0	0				0.8	3.1	0.2		2.7	2.8		
Martikainen 2004	123		3.3		2.4	8.1	0.8	4.1	52	32.5	21.1	8.9	3.3		18.7		29.3
Korenkov 2004	106	0	0.9	4.4					-	-	-	-	-	-	-	-	-
Dargent 2004	1,180	0.2	0.5	0.4	0.2	0.5		0.2	12.7	5.6	8.8	1.9	2.0				
Chevallier 2004	1,000	0	0.4		0.2	0.2			11.1		10.1		0.5		5.7	0.4	

Table G. Adverse Events: Single-Arm Studies (cont'd)

Study/Yr	n	Perioperative Complications							Long-term Complications								
		Death	Perf	Conv	Throm	Card	Bleed	Wound	Reop	Rem	SI/Dil	Eros	Esoph	Obstr	Port	Hern	GERD
Lap-Band™ (cont'd)																	
Holloway 2004	504	0.2	1.8	0.2		0.2				2.6	5.6	0.4			8.5		
Spivak 2004	271			1.1	0.4	0.7	0.4				1.8		6.6	1.8	7.3		
Angrisani 2003	1,893	0.3		3.1								1.1	4.8		4.1		
Weiner 2003	984	0	0.1	0						1.3	4.5				2.2		
Zinzindohoue 2003	500	0	0.8	2.4	–	1.4	2.6	–	10	9.4	8.6	0	–	–	7.2	0.6	–
Busetto 2002	260	0	0.8	4.2	–		4.6		4.2	1.9	12	0.8	–	–	29	–	–
Chevallier 2002	400	0	1	3	0	1.8	–	–	8.8	5.8	8.5	0	–	–	7.5	0.5	–
Favretti 2002	830	0	0.1	2.7	–	–	–	–	3.9	1.7	10	0.5	–	–	–	–	–
Vertruyen 2002	543	–	1.3	1.1	0.2	0.4	0.2	–	5.9	2.6	4.6	0.9	–	–	2.8	–	–
O'Brien 2002	709	0	0.3	1.0	0.3	0.7	–	3.4	19	1.7	13	2.8	–	–	3.6	–	–
Belachew 2002	763	0.1	0.6	1.3	–	–	0.1	0.1	11	3.1	8.0	0.9	–	–	2.5	0	–
Pontiroli 2002	143	–	–	2.8	–	–	–	–	5.6	–	5.6	–	–	–	2.8	–	–
Angrisani 2001	1,265						44.1	9.0	13.9	12.0	12.6						
Szold 2001	715						43.3	10.2	10.3	11.2					8.5		
FDA data 2000	299	35	38	36			47.5	8.5	9.4	9.8			6.6	1.8	7.3		
Cadiere 2000	652	38	62				45	10	12				4.8		4.1		
Paganelli 2000	156	43													2.2		
Suter 2000	150	55	56				44.6	12.6	12.6				–	–	7.2	0.6	–

Table G. Adverse Events: Single-Arm Studies (cont'd)

Study/Yr	n	Perioperative Complications							Long-term Complications								
		Death	Perf	Conv	Throm	Card	Bleed	Wound	Reop	Rem	Sl/Dil	Eros	Esoph	Obstr	Port	Hern	GERD
Lap-Band™ (cont'd)																	
Fielding 1999	335	52					46.7	12.0					–	–	29	–	–
Miller 1999	166						44	10	14	16			–	–	7.5	0.5	–
Dargent 1999	500	56	65	64									–	–	–	–	–
Weiner 1999	184	58	87				47.8	15.8	19.2				–	–	2.8	–	–
Furbetta 1999	169						43.3	8.3					–	–	3.6	–	–
Belachew 1998	350	50	58	77			42.9	10.9	11.9	16.9			–	–	2.5	0	–
Swedish Adjustable Gastric Banding																	
Branson 2005	410	0	0.2		0.2	2.0	0.5	0.5	16.3	9.8	3.4	1.5					6.4
Biertho 2005	824	0.1	0.1	8.3					14.7		4.2		7.5				6.7
Greenslade 2004	215	–	–	–	–	–	–	–	–	1.9	0	1.4					7.5
Ceelen 2003	625	0	0.2	0.3	–	–	1.1	2.2	8.2	–	5.6	0	1.1	0.5	2.6	0.8	2.4
Mittermair 2002	454	–	–	–	–	–	–	–	–	–	–	3.1	–	–	–	–	–
Mortele 2001	218	–	–	–	–	–	–	–	6.4	–	11.5	–	–	1.8	2.3	–	5.0
Nowara 2001 (both)	108	0	1.9	1.9	–	–	0.9	–	4.6	3.7	2.7	–	–	–	5.6	–	–
Nehoda 2001	250	0	–	0.8	–	0.8	–	–	4.4	1.6	–	1.6	–	–	6.0	–	–
Hauri 2000	207	–	0	–	–	–	–	4.3	6.3	–	–	0.5	–	–	2.9	–	–
Forsell 1999	326	0	0.6	–	–	0.3	–	1.2	7.4	–	–	4.6	0.6	–	3.4	0.6	4.7
Chelala 1997	185	0.5	1.1	4.3	–	0.5	0.5	–	4.9	1.6	3.2	–	–	–	2.2	–	3.8



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