CALIFORNIA TECHNOLOGY ASSESSMENT FORUM℠

TITLE: LAPAROSCOPIC ADJUSTABLE SILICONE GASTRIC BANDING FOR OBESITY

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CALIFORNIA TECHNOLOGY ASSESSMENT FORUM℠

LAPAROSCOPIC ADJUSTABLE SILICONE GASTRIC BANDING FOR OBESITY

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum (CTAF) is requested to update its review of the scientific evidence for the use of laparoscopic adjustable silicone gastric banding (LAGB) surgical techniques for the treatment of morbid obesity. LAGB is promoted as a less invasive, potentially reversible alternative to Roux-en-Y gastric bypass (RYGB), the bariatric procedure that is most frequently performed in the United States. When last reviewed on February 28, 2007, the Forum concluded that there was insufficient evidence to conclude that the short term procedural benefits of LAGB outweigh the harms when compared with the long term benefits of RYGB. There was consensus that LAGB improved clinically important outcomes more than no treatment, but there was significant uncertainty about the relative risks and benefits relative to RYGB. Thus, the focus of this review will be on CTAF TA criterion 4. Additional information was requested on the impact of the procedures on metabolic parameters of energy balance and their hormonal control. Since the last review, investigators published many additional comparative studies and two randomized trials directly comparing the two procedures.

BACKGROUND

Obesity is a chronic disease that is increasing rapidly in the United States. The degree of obesity is usually described using body mass index (BMI). It is calculated as weight (in kilograms) divided by height (in meters) squared. Class 1 obesity is defined as a BMI ≥30 kg/m^2, class 2 obesity as BMI >35, and class 3 (severe, previously termed morbid) obesity as a BMI≥40 kg/m^2 or >35 with comorbidities. Patients with a BMI > 50 kg/m^2 are sometimes classified as super-obese. The percentage of obese men in the US nearly doubled between 1991 and 1998, and the percentage of obese women has increased by 50 percent. During this same period, the number of states in the United States in which more than 15 percent of the people were obese increased from eight percent to 79 percent.[1] The prevalence of obesity among U.S. adults was approximately 30 percent based upon data collected for the National Health and Nutrition Examination Survey (NHANES) between 1999 and 2002.[2, 3] In addition, the Center for Disease Control has reported that the prevalence of morbid obesity has increased from 0.78 percent in 1990 to 2.2 percent in 2000.[4] The prevalence of class 3 obesity was as high as 7.8% among women ages 40-59 in the most recent NHANES report.[3]

Obesity, weight loss, and health outcomes

Obesity is associated with premature death as well as an increased risk for diabetes, hypertension, hypercholesterolemia, heart disease, osteoarthritis, sleep apnea and gall bladder disease. Studies have demonstrated that weight loss is associated with a decreased risk for development of these diseases. The Nurses' Health Study, a cohort study of over 100,000 women aged 30 to 55 years, found that weight loss above 5 kg was associated with a graded decrease in the risk of diabetes mellitus [5]. A second cohort study of 28,388 overweight women aged 40 to 64 years found that intentional weight loss of more than 9.1 kg was associated with a 25 percent decrease in all-cause, cardiovascular and cancer mortality [6]. In addition, any amount of intentional weight loss was associated with a ten percent reduction in cardiovascular disease, a 20 percent reduction in all-cause mortality, a 30 to 40 percent reduction in mortality from diabetes, and a 40 to 50 percent reduction in mortality from cancers related to obesity among 15,069 women with co-morbid conditions such as heart disease or diabetes mellitus. Weight loss lowers blood pressure in more than one-half of treated subjects [7]. On average, the blood pressure falls 0.3 to 1.0 mmHg for every 1.0 kg of weight that is lost. Those who maintain weight loss maintain lower blood pressure than those who regain weight.[8] Weight loss also is associated with a decreased risk of osteoarthritis. In a study of 800 women, a decrease in BMI of 2 kg/m^2 or more during the previous ten years decreased the odds for developing osteoarthritis by over 50 percent.[9] This benefit extended to women with a high risk for osteoarthritis due to a high baseline BMI (25 kg/m^2). Finally, the social stigma associated with obesity leads to decreased quality of life. Weight loss has been shown to improve both social functioning and quality of life [10, 11].

Treating obesity

Behavior modification, diet, and exercise are the primary treatments for obesity. More aggressive therapy with medications (orlistat, sibutramine) may be indicated for patients who have medical complications of obesity, but drug therapy is limited by side effects. Regaining lost weight is a common problem in treating obesity. Of those subjects who lose weight during any treatment program, most do not maintain the weight loss. Identification of those subjects who will succeed in losing weight is difficult. Characteristics of patients who maintain weight loss include a weight loss of more than two kilograms in four weeks, frequent and regular attendance at a weight loss program, and the subject's belief that his or her weight can be controlled. Systematic reviews of behavioral and drug therapy report average long-term weight loss of between four and seven kilograms [12-15].

Gastrointestinal surgery for obesity

Surgery is another option for patients at high-risk of complications from obesity. A recent systematic review and meta-analysis concluded that patients achieved effective weight loss with surgery and that most patients had complete resolution or improvement of their diabetes, hypertension, hyperlipidemia, and obstructive sleep apnea.[16] Indeed, surgical interventions for obesity are increasingly popular in the United States. Between 1998 and 2004, the number of bariatric surgeries performed increased from about 13,000 annually to 121,000, a nine-fold increase.[17] Over the same period, inpatient mortality associated with bariatric surgery decreased from 0.89% to 0.19% and the average length of stay decreased from five to 3.1 days.[17] More recently, inpatient mortality has declined to less than 0.1%.[18] These improvements in outcomes over time illustrate why contemporary rather than historical controls must be used when comparing surgical treatments for obesity.

Surgical intervention has the advantage of being a long-term treatment for a chronic health problem. In addition, surgery leads to more substantial weight loss than the other treatment options.[19] However, surgery for morbid obesity is a major intervention with risks of significant early and late morbidity and of perioperative mortality. The National Institutes of Health consensus conference on obesity surgery recommends that surgery be considered only in the following populations [20]:

- Patients with a BMI >40 kg/m^2
- Patients with a BMI >35 kg/m^2 who also have serious medical problems, (diabetes, obstructive sleep apnea) that would improve with weight loss.

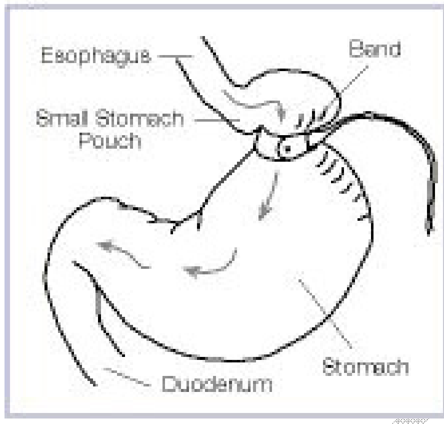
All patients must have failed sustained weight loss programs, have acceptable operative risk, and be committed to life-long follow-up. These remain the recommendations today, although there is increased interest in expanding the indications for surgery to less obese patients, particularly those with diabetes.[21-23]

Surgical procedures of the upper gastrointestinal tract that are designed to induce weight loss are collectively referred to as bariatric surgery. Bariatric surgery is either restrictive, malabsorptive, or a combination of both. Restrictive procedures reduce the size of the stomach leading to early satiety and decreased total caloric intake. Malabsorptive procedures create separate intestinal pathways (limbs) for food and biliary/pancreatic secretions. They eventually connect, but the length of small intestine that is common to both food and the secretions is short leading to decreased absorption of both calories and nutrients.

<u>Restrictive procedures</u>

Purely restrictive procedures reduce food intake, but do not disrupt normal digestion. Usually a small pouch is made in the stomach that holds only about one ounce of food and has a small outlet. Thus, patients are unable to eat large amounts of food at one sitting without significant discomfort and nausea. This requires significant changes in the patients eating habits.

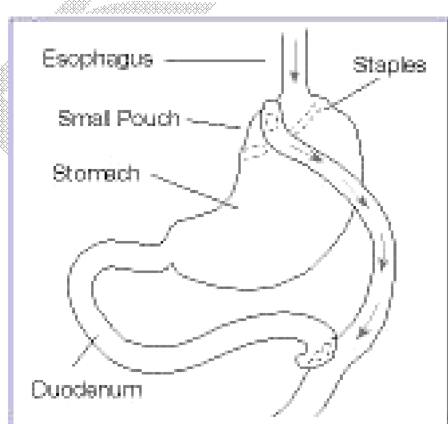
Figure 1: Adjustable gastric banding



Adjustable gastric banding (Figure 1)

Gastric banding limits food intake by placing a ring around the stomach just below the gastroesophageal junction. The band used includes an inflatable balloon that allows adjustment of the size of the outlet [24]. These procedures are now primarily performed laparoscopically. Adding or removing saline through a subcutaneous port changes the diameter of the outlet. Complications include splenic injury, esophageal injury, wound infection, band slippage and erosion, reservoir deflation/leak, persistent vomiting, failure to lose weight and acid reflux.

Figure 2: Roux-en-Y gastric bypass



Roux-en-Y gastric bypass (Figure 2)

The RYGB is the most common form of bariatric surgery in the US (over 80% of all procedures recently).[25, 26] A recent meta-analysis estimated that patients lose between 62% and 70% of excess body weight following the procedure with good resolution of comorbidities.[16] For instance, diabetes resolved in approximately 77% of patients. Outcomes also correlate with both physician experience with the procedure and surgical volume.[27, 28] Clinical trials also suggest that performing RYGB laparoscopically may reduce length of stay and some long-term risks with equivalent outcomes.[29-32] The majority of RYGB procedures in the United States are now performed laparoscopically.[18, 33]

The RYGB is primarily a restrictive procedure with a variable amount of malabsorption. First a small stomach pouch (about 20 cc to 30 cc) is made to restrict food intake. Then a portion of the jejunum is attached to the pouch to allow food to bypass the distal stomach, duodenum, and proximal jejunum (Figure 2). Bypassing this segment of the small intestine reduces absorption of some nutrients. The length of the Roux limb (portion of the jejunum from the new stomach pouch the point where it joins up with the segment from the remainder of the stomach) is usually between 50 cm and 150 cm. The length of the common limb where absorption can occur) is usually more than 300 cm in length. Shorter common limbs may be associated with greater malabsorption, though comparative studies between short and long limb gastric bypasses have demonstrated equivalent weight loss.[34, 35] Complications associated with gastric bypass include failure of the gastric partition, leaks at the junction of the stomach and small intestine, marginal ulcers and strictures at the gastrojejunostomy and acute gastric dilatation either spontaneously or secondary to a blockage at the Y-shaped anastomosis. Other complications following surgery include vomiting, incisional hernias, obstruction, nutrient deficiencies (poor absorption of iron, vitamin B12, vitamin D, folate, and calcium) and the dumping syndrome. Rapid gastric emptying, or dumping syndrome, happens when the jejunum fills too quickly with undigested food from the stomach. Symptoms include nausea, vomiting, bloating, diarrhea, sweating, palpitations, and shortness of breath. This happens most commonly when the patient consumes refined carbohydrates and concentrated sweets. Thus, some surgeons consider this a desirable side effect as the symptoms reinforce compliance with a healthier diet. Patients with dumping syndrome can minimize symptoms by eating several small meals a day that are low in carbohydrates and drinking liquids between meals, not with them. The symptoms are thought to aid weight loss by conditioning the patient against eating sweets, though they can have a dramatic impact on a patient's quality of life.

Comparisons between procedures

Gastric bypass with Roux-en-Y anastomosis has been considered the surgery of choice in the US. Comparative trials (n = 13 studies, greater than 4000 participants) have demonstrated that this procedure leads to greater weight loss than vertical banded gastroplasty, horizontal gastroplasty, and open gastric banding with fewer re-operations and minimally higher morbidity. The comparative trials between surgical treatments demonstrate that all of the approaches result in substantial, prolonged weight loss averaging 17 to 65 kilograms over one to five years of follow-up [12-15]. This degree of weight loss is considerably higher than four to seven kilogram weight loss observed in clinical trials of behavioral interventions and drug therapy (orlistat, sibutramine).

The Swedish Obese Subjects (SOS) study is the largest prospective study on the effects of operative treatment for obesity. A total of 1000 patients were allocated to one of the three surgical procedures (gastric banding; vertical banded gastroplasty; or gastric bypass) and 1000 controls (matched for age, sex, BMI, clinical site, and co-morbidities) are being followed for ten years [36, 37]. Preliminary analyses at two years found that surgical patients had lost 28 kg and controls had lost 0.5 kg. The patients treated with gastric bypass lost significantly more weight (44 kg) than those who had either of the other two procedures (31 kg VBG; 26 kg gastric banding, not adjustable) [38]. The investigators have published ten year results with weight loss outcomes significantly greater for gastric bypass compared with banding at all time points.[39] The results for vertical banded gastroplasty consistently fell between gastric banding and gastric bypass. As compared with a control group of patients of similar weight at baseline, the two-year incidence rates of diabetes mellitus and hypertension were lower in the surgically treated patients, and they had less hyperinsulinemia and hypertriglyceridemia and higher serum high-density-lipoprotein (HDL) cholesterol concentrations [38]. Most importantly, after a median follow-up of 11 years with 99.9% complete follow-up, there was a statistically significant 29% reduction in all cause mortality for the patients in the surgical group compared with the control group. Other studies have reported reductions in total mortality ranging from 40% to 89%.[40-43]

Effects of bariatric surgery on endocrine control of energy, appetite, body weight, and diabetes

The control of energy balance and its effects on body weight, appetite, and blood sugar is complex and incompletely understood. There have been several recent detail reviews of the studies of the hormones involved and the impact of different bariatric procedures on these hormones.[44-47] Bariatric surgery, particularly forms that bypass some portion of the small intestine, have dramatic and almost immediate effects on glycemic control. In particular, investigators have observed that patients with type 2 diabetes have normal blood glucose levels without medication within days of RYGB, while it often takes months for patients treated with purely restrictive forms of bariatric surgery to obtain the same benefit. This has been taken as evidence that surgeries bypassing part of the small intestine immediately affect the balance of hormones involved in glucose homeostasis. I will briefly summarize the literature on several of the most commonly cited hormones below, but there are many others including undiscovered hormones that some investigators believe must exist.[47]

Leptin generated tremendous excitement when it was first discovered, but does not appear to be involved in the specific effects of bariatric surgery on weight, appetite, and glycemic control. It is a circulating hormone whose levels are proportional to fat mass and is thought to act at the level of the hypothalamus to decrease the intake of food and increase energy expenditure.

Ghrelin is a small peptide hormone secreted by the stomach and duodenum. Levels of ghrelin increase prior to each meal and decrease after the meal. It is thought to increase appetite and is inversely proportional to BMI. With weight loss, ghrelin levels increase and presumably hunger increases as well. When given to humans, it increases food intake and promotes weight gain. Some authors have argued that a decrease in ghrelin levels following RYGB is responsible for the reduction in appetite following surgery and thus some of the difference in weight loss observed between RYGB and other procedures. However, as Ashrafian and le Roux report,[44] among the 42 studies they reviewed, half (21) reported a decrease in ghrelin, eleven reported no change, and ten reported an increase in ghrelin following bypass procedures. Among the 22 studies measuring ghrelin levels following purely restrictive surgeries, only four reported a decrease in ghrelin, seven reported no change, and half (11) reported an increase in ghrelin following bypass procedures. Thus, the data from a large number of studies present an inconsistent picture, but suggest that ghrelin levels may play a role in the effectiveness of bariatric surgery.

Peptide tyrosine tyrosine (PYY) is secreted from enteroendocrine cells in the terminal ileum and colon. It induces a feeling of fullness when it is released after eating, delaying gastric emptying and decreasing acid secretion. It is secreted in two circulating forms: PPY_{1-36} and PYY_{3-36}. Injections of PYY_{3-36} have been demonstrated to lower the threshold for satiety in humans and decrease food intake over time. PYY is suppressed during fasting. More than 40 studies demonstrate an increase in PYY levels following bypass procedures.[44] There are only three studies measuring PYY after restrictive procedures: two showed no change and one showed an increase in PYY levels.

Glucose-dependant insulinotropic peptide or gastric inhibitory peptide (GIP) is another peptide hormone released by enteroendocrine cells of the duodenum. Like PYY, it peaks after a meal, but seems to play more of a role in stimulating pancreatic beta cells to release insulin and to replicate and resist apoptosis, thus increasing the number of functioning insulin-producing cells. Studies of bypass surgery suggest that GIP levels decrease both between and immediately after meals.[44] Purely restrictive procedures seem to have little effect on GIP.

Glucagon-like peptide-1 (GLP-1) is a peptide hormone secreted by the distal ileum. Blood levels increase after a meal, but it has a very short half-life. Like GIP, it potentiates insulin secretion and stimulates the growth of pancreatic beta-cells. Like PYY, it increases the sensation of satiety, reduces hunger, suppresses gastric acid secretion and slows gastric emptying. Injections of GLP-1 in humans induced weight loss within five days. Exenatide (Byetta), a GLP-1 agonist, is FDA approved for the treatment of diabetes. As was the case for PYY, more than 40 studies demonstrate an increase in GLP-1 levels measured post-prandially or between meals following bypass procedures.[44] There are only three studies measuring GLP-1 after restrictive procedures: two showed no change and one showed a decrease in GLP-1 levels.

In summary, after RYGB both PYY and GLP-1 levels consistently increase and GIP levels increase. This should result in improved insulin responsiveness, decreased appetite, and improved satiety and may explain the rapid resolution of Type 2 diabetes in patients undergoing RYGB. Ghrelin levels may also decrease, but the data are less consistent. There are fewer studies of LAGB, but in general they suggest it has minimal impact on levels of these four hormones in humans. Several small studies in humans comparing levels of ghrelin, PYY, GLP-1, GIP, insulin and insulin resistance in patients treated with RYGB to similar patients treated with LAGB suggest that the effects described above are correct.[48-53]

Adjustable gastric banding

Adjustable gastric banding for treatment of morbid obesity placed by laparotomy was developed by Kuzmak in 1983.[54] Several different adjustable gastric bands are available for use in the United States. Laparoscopic placement is intended to reduce postoperative complications and the length of hospital stay.[24] This procedure is becoming increasingly popular in the United States. At academic centers, there was a 329% increase in laparoscopic adjustable banding procedures from 2004 to 2007.[18]

The adjustable gastric banding system is designed to induce weight loss by limiting food consumption. The band is placed laparoscopically around the upper stomach, allowing the formation of a small gastric pouch and stoma. There is no resection or stapling of the stomach itself, and no gastric or intestinal bypass. The initial pouch size is established through the use of a calibration balloon. The inner surface of the band is inflatable and connected by tubing to an access port placed on or in the rectus abdominus muscles or fixed in an accessible subcutaneous location. Postoperatively, the surgeon may adjust the stoma size percutaneously by injecting or aspirating saline from the access port with a needle (LAP-BAND® Product Information, 2004).

The laparoscopic technique[55, 56] involves placing the band using a four or five-port laparoscopic technique. The gastric dissection is undertaken high on the lesser curvature of the stomach. A balloon catheter inserted through the mouth and advanced into the stomach is inflated with saline and pulled back to lodge at the gastroesophageal junction in order to size the proximal pouch. The band device is closed over a pressure-sensitive location on the calibration tube to determine correct positioning and to avoid too much tissue within the band. Saline is then injected into the band to determine the maximal fill volume. Three or four anterior sutures between the pouch and distal stomach are placed to prevent anterior band slippage. The saline in the band is then withdrawn and the band left empty for one month after surgery in an attempt to decrease band slippage.[57] Improvements in technique (the pars flaccida approach) and surgeon experience have dramatically reduced the incidence of band slippage. For example, in one center, the change in technique decreased their slippage rate from 24% (91/378) to 2% (13/622).[58]

Advantages of laparoscopic gastric banding compared with open gastric banding or RYGB include possible reductions in wound complications, incisional hernias, respiratory complications because of improved post-operative ventilation and earlier mobilization, shorter recovery time, and shorter hospital stay.[24, 59] Other advantages of LAGB include the maintenance of gastric integrity, thus, the possibility of total reversibility of the operation and the potential for readjustment of the band to address either persistent postoperative vomiting or failed weight loss if needed.[56] In some instances, the procedure can also be used for revision of failed RYGP or vertical banded gastroplasty.[60, 61]

Potential disadvantages to laparoscopic LAGB include the occurrence of significant complications and adverse events, sometimes necessitating removal of the device.[24, 56] The common late complications include erosion of the band into the stomach, band slippage with pouch dilation, and problems with the port and tubing used to inject saline for band adjustments. Additionally, patients must come back to the clinic regularly to have their band adjusted, usually under fluoroscopic guidance. In one report, the surgeon indicated that patients in his clinic returned on average nine times per year for band adjustment.[62]

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

Two gastric banding devices currently have FDA premarket approval (PMA) clearance for marketing. They are, the REALIZE™ Band (Ethicon Endo-Surgery, Inc, Cincinnati, OH), which received FDA PMA clearance on September 28, 2007. This was the original Swedish Band. The other band, the LAP-BAND® Adjustable Gastric Banding (LAGB®) System (BioEnterics Corporation, Carpinteria, CA) received FDA PMA clearance on June 19, 2000. The LAP-BAND is now marketed by Allergan, Santa Barbara, CA.

TA Criterion 1 is met

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database, and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words adjustable silicone gastric band, LapBand, and Swedish Band. The search was updated for the period from January 2007 through September 2009. The bibliographies of systematic reviews and key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full. For this updated review, case series were excluded; only comparative trials were evaluated.

Ideally, the primary outcomes evaluated in clinical trials of bariatric procedures would be long-term mortality and the resolution of obesity-associated co-morbidities such as diabetes, hypertension, dyslipidemias, sleep apnea, arthritis, and gastroesophageal reflux disease. Long-term patient satisfaction and quality of life are also key outcome measures. The most important harms would include 30-day morbidity and mortality following the procedure and long-term complications, particularly those requiring additional surgical interventions or causing significant patient morbidity.

Outcomes in the published trials include technical success of the procedure; weight loss as judged by changes in body weight and BMI (weight divided by height-squared (kg/m^2), percentage of excess body weight lost (EBWL); resolution of obesity-related comorbidities; and both short and long-term complications. Excess body weight loss is the weight loss measure that appears to be most useful when comparing across studies with differences in baseline characteristics at baseline such as BMI. To calculate EBWL, start with the patient's excess weight: the difference between their weight prior to surgery and their ideal weight. Excess body weight loss during follow-up is the patient's weight loss from baseline divided by their excess weight. Inadequate follow-up is a significant issue when evaluating the weight loss results from the case series and comparative trials. Many of the frequently quoted results summarizing long-term weight loss come from very large case series, but represent data from less than ten percent of the original study population.

According to Reinhold's criteria (1982), the weight loss result following bariatric surgery is "excellent" if the percentage of excess weight lost is > 75%; "good" if between 50% and 75%; "fair" from 25% and 50%; and "poor" below 25%. Using the final BMI, the result is "excellent" if the BMI is <30 kg/m^2, "good" between 30 and 35 kg/m^2, "fair" from 35 to 40 kg/m^2, and "poor" if >40 kg/m^2. While resolution of pre-existing comorbidities associated with severe obesity is the most important outcome variable to assess in clinical trials, most investigators (and patients) primarily focus on reductions in excess weight as the primary outcome.

The updated literature search identified 15 new trials with at least 50 subjects that compare LAGB to RYGB. In addition, the search identified two randomized trials comparing the two procedures.[63, 64] Summaries of the case-series data can be found in the February 2007 CTAF review of laparoscopic adjustable gastric banding. The data extracted from the twelve comparative studies[59, 65-75] evaluated in the 2007 CTAF review were retained in the Tables to help place the new studies in the context. The 2007 assessment is available at: http://www.ctaf.org/content/assessment/detail/685

TA criterion 2 is met.

Levels of Evidence: 2-5

TABLE 1: Characteristics of the Studies Comparing LAGB to RYGB

Study	Design	Arm	N	Age, years	BMI, kg/m²	Follow-up, months	Quality	Comments
Hell	Retrospective, no matching.	LAGB	30	36	47	40	Poor	Comparison in different countries
2000		RYGB	30	41	45	60		
Biertho	Retrospective, no matching	LAGB	805	42	42	NR	Poor	Comparison in different countries
2003		RYGB	456	40	49			
Weber	Matched on age, sex, BMI	LAGB	103	40	48	42	Fair	
2004		RYGB	103	40	48	18		
Jan	Retrospective, no matching	LAGB	154	46	51	NR, <24	Poor	
2005		RYGB	219	42	50			
Parikh	Retrospective, no matching, BMI>50	LAGB	197	43	55	NR, <24	Poor	
2005		RYGB	97	42	55			
Bowne	Retrospective, no matching, BMI>50	LAGB	60	42	55	18	Poor	
2006		RYGB	46	43	57	13		
Cottam	Matched on age, sex, BMI, date of surgery	LAGB	181	42	47	NR, 23% at 36+ months	Fair	
2006		RYGB	181	43	47			
Galvani	Retrospective, no matching	LAGB	470	41	47	NR	Poor	
2006		RYGB	120	41	46			
Kim	Retrospective, no matching	LAGB	160	42	47	NR	Poor	
2006		RYGB	232	39	47			
Parikh	Retrospective, no matching	LAGB	480	425	46	12	Poor	
2006		RYGB	235	41	47	12		
Rosenthal	Retrospective, no matching	LAGB	152	54	40	77% with "complete" FU	Poor	
2006		RYGB	849	47	56			
Jan	Retrospective, no matching	LAGB	406	47	51	~12	Poor	
2007		RYGB	492	44	49	~16		

Study	Design	Arm	N	Age, years	BMI, kg/m²	Follow-up, months	Quality	Comments
New Studies								
Mognol 2005	Retrospective, no matching	LAGB LRYGB	179 111	40 40	54 59	Unclear	Poor	All with BMI≥50
Bessler 2008	Retrospective, no matching	LAGB RYGB	138 403	43 42	47 51	≥ 12	Poor	Patients with surgical revision excluded
Lancaster 2008	Administrative data 2006 National Surgical Quality Improvement Program	LAGB LRYGB	1,176 3,580	46 44	45 48	1	Poor	No propensity score analysis.
Lee 2008	Retrospective, no matching	LAGB LRYGB	116 544	32 31	42 41	30	Poor	Overly simplistic analysis
Lee, Kim 2008	Retrospective, no matching	LAGB LRYGB	51 25	33 29	40 41	Unclear	Poor	Early experience
Muller 2008	Matched on age, sex, BMI	LAGB LRYGB	52 52	41 40	45 46	71 30	Poor	Large difference in time since surgery when outcomes assessed.
Puzziferri 2008	Prospective cohort	LAGB RYGB	631 1102	45 43	49 51	24 24	Poor	12% missing data, mixed open and lap, 6% revising VBG to RYGB.
Te Riele 2008	Matched on age, race, sex, weight	LAGB RYGB	53 53	38 40	51 51	18 23	Fair	Primarily open RYGB
Ballantyne 2009	Prospective, no matching	LAGB LRYGB	111 104	46 41	45 47	5 5	Poor	
Hinojosa 2009	Administrative data 2004-2007: University Health System Consortium	LAGB LRYGB	4,226 20,543	-	-	1 1	Poor	Useful for short term complications in real world

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Study	Design	Arm	N	Age, years	BMI, kg/m²	Follow-up, months	Quality	Comments
Lee 2009	Prospective, no matching	LAGB LRYGB	140 660	-	-	-	Poor	Minimal reporting of outcomes
Lindsey 2009	Administrative data 2006: New York State	LAGB LRYGB	2,492 3,912	43.3 41.8	-	1	Poor	
LABS Consortium 2009	Prospective cohort	LAGB LRYGB	1,198 2,975	46 44	44 47	1	Poor	No adjusted analyses for key outcomes
Sasse 2009	Retrospective cohort	LAGB LRYGB	210 38	46 46	44 45	12 12	Poor	
Wong 2009	Retrospective cohort	LAGB LRYGB	57 7	41 39	40 43	24 24	Poor	
RCTs								
Angrisani 2007	Randomized trial	LAGB LRYGB	30 (27) 29 (24)	33 35	43 44	60 60	Fair	First RCT. Small study.
Nguyen 2009	Randomized trial	LAGB LRYGB	125 (86) 125 (111)	45.8 41.4 p<.01	45.5 47.5 p=.01	43 50	Fair	High procedure refusal rate after randomization (31% in LAGB group). Thus, significant baseline imbalances in age and BMI.

LRYGB	Laparoscpic Roux En Y Gastric Bypass
VBG	Vertical banded gastroplasty
RCT	Randomized controlled trial

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TABLE 2: Percentage Excess Body Weight Lost in the Studies Comparing LAGB to RYGB

Study	Arm	N	Year 1		Year 2		Year 3		Comments
			EBWL, %	*FU, %*	*EBWL, %*	*FU, %*	*EBWL, %*	*FU, %*	
Hell 2000	LAGB	30	-	-	-	-	60	100	
	RYGB	30					60	100	
Biertho 2003	LAGB	805	33	82	-	-	-	-	
	RYGB	456	67	31					
Weber 2004	LAGB	103	35	NR	42	<50%	-	-	
	RYGB	103	55		54				
Jan 2005	LAGB	154	34	60	-	<20%	-	-	
	RYGB	219	64						
Parikh 2005	LAGB	197	35	80	46	43	50	16	
	RYGB	97	58	74	55	24	57	22	
Bowne 2006	LAGB	60	31	92	-	-	-	-	
	RYGB	46	52	85					
Cottam 2006	LAGB	181	48	-	55	-	51	19	
	RYGB	181	76		80		74	15	
Galvani 2006	LAGB	470	39	-	45	-	55	-	
	RYGB	120	65		67		63		
Kim 2006	LAGB	160	34	-	48	-	-	-	
	RYGB	232	64		68				
Parikh 2006	LAGB	480	-	-	-	-	-	-	
	RYGB	235							
Rosenthal 2006	LAGB	152	54	-	-	-	-	-	
	RYGB	849	73						
Jan 2007	LAGB	406	34	65	39	25	35	9	
	RYGB	492	65	48	67	21	47	10	

Study	Arm	N	Year 1		Year 2		Year 3		Comments
			EBWL, %	*FU, %*	*EBWL, %*	*FU, %*	*EBWL, %*	*FU, %*	
New Studies									
Mognol	LAGB	179	41	NR	46	? 65	-	-	Limited reporting
2005	LRYGB	111	63		73	? 17			
Bessler	LAGB	138	33	88	41	34	39	24	
2008	RYGB	403	60	83	60	29	57	29	
Lancaster	LAGB	1176	-	-	-	-	-	-	-
2008	LRYGB	3580							
Lee	LAGB	116	35	-	43	-	42	-	Median FU 30 months
2008	LRYGB	544	71		74		71		
Lee, Kim	LAGB	51	47	-	55	-	63	-	
2008	LRYGB	25	77		80		86		
Muller	LAGB	52	-	-	-	-	-	-	Different lengths of follow-up
2008	LRYGB	52							
Puzziferri	LAGB	631	37	64	44	32	-	-	
2008	RYGB	1102	70	59	75	24			
Te Riele	LAGB	53	34	89	43	47	-	-	40% vs. 76% success rate, p=.03
2008	RYGB	53	62	85	60	32			
Ballantyne	LAGB	111	-	-					Follow-up too short: 5 months
2009	LRYGB	104							
Hinohosa	LAGB	4,226	-	-	-	-	-	-	-
2009	LRYGB	20,543							
Lee	LAGB	140	LRYGB greater and faster	-		-		-	No data given
2009	LRYGB	660							
Lindsey	LAGB	2,492	-	-	-	-	-	-	
2009	LRYGB	3,912							
LABS Consortium	LAGB	1,198	-	-	-	-	-	-	Study focused on adverse events
2009	LRYGB	2,975							

Study	Arm	N	Year 1		Year 2		Year 3		Comments
			EBWL, %	*FU, %*	*EBWL, %*	*FU, %*	*EBWL, %*	*FU, %*	
Sasse	LAGB	210	32	52	-	-	-	-	Only 63% of patients due for 12 month FU
2009	LRYGB	38	69	39					
Wong	LAGB	57	31	84	34	47	-	-	
2009	LRYGB	7	70	86	61	71			
RCTs									
Angrisani	LAGB	27	35	96-100	-	-	67	96-100	1 patient in LAGB group lost to FU
2007	LRYGB	24	51	100			47	100	
Nguyen	LAGB	86	36.5	NR	42	92	41.5	72	
2009	LRYGB	111	64.3	NR	69	85	67.5	73	

FU Follow up

TABLE 3: Resolution of Comorbidities among Patients entering Study with the Condition in the Studies Comparing LAGB to RYGB*

Study	Arm	N	DM2	HTN	Dyslipidemia	OSA	GERD	Arthritis	Asthma
Hell	LAGB	30	-	-	-	-	-	-	-
2000	RYGB	30							
Biertho	LAGB	805	-	-	-	-	-	-	-
2003	RYGB	456							
Weber	LAGB	103	59	70	0	-	-	-	-
2004	RYGB	103	84	75	50				
Jan	LAGB	154	-	-	-	-	-	-	-
2005	RYGB	219							
Parikh	LAGB	197	-	-	-	-	-	-	-
2005	RYGB	97							
Bowne	LAGB	60	40	27	40	34	-	14	12
2006	RYGB	46	100	63	43	88		29	73
Cottam	LAGB	181	50	56	46	-	-	-	-
2006	RYGB	181	78	81	81				
Galvani	LAGB	470	68	59	-	55	56	60	-
2006	RYGB	120	75	61		63	75	69	
Kim	LAGB	160	77	56	37	-	88	84	-
2006	RYGB	232	72	66	48		84	75	
Parikh	LAGB	480	-	-	-	-	-	-	-
2006	RYGB	235							
Rosenthal	LAGB	152	-	-	-	-	-	-	-
2006	RYGB	849							
Jan	LAGB	406	-	-	-	-	-	-	-
2007	RYGB	492							

Study	Arm	N	DM2	HTN	Dyslipidemia	OSA	GERD	Arthritis	Asthma
New Studies									
Mognol 2005	LAGB LRYGB	179 111	-	-	-	-	-	-	-
Bessler 2008	LAGB RYGB	138 403	-	-	-	-	-	-	-
Lancaster 2008	LAGB LRYGB	1176 3580	-	-	-	-	-	-	-
Lee 2008	LAGB LRYGB	116 544	HI 1.4 HI 0.9	140/87 121/72	Total Chol 189 Total Chol 151	-	-	-	-
Lee, Kim 2008	LAGB LRYGB	51 25	LRYGB "more likely to improve"		LRYGB "more likely to improve"	LRYGB "more likely to improve"		LRYGB "more likely to improve"	
Muller 2008	LAGB LRYGB	52 52	57 100	-	-	-	-	-	-
Puzziferri 2008	LAGB RYGB	631 1102	-	-	-	-	-	-	-
Te Riele 2008	LAGB RYGB	53 53	-	-	-	-	-	-	-
Ballantyne 2009	LAGB LRYGB	111 104	HI improvement greater with LRYGB (p<.05)	-	-	-	-	-	-
Hinohosa 2009	LAGB LRYGB	4,226 20,543	-	-	-	-	-	-	-
Lee 2009	LAGB LRYGB	140 660	74 93	-	-	-	-	-	-
Lindsey 2009	LAGB LRYGB	2,492 3,912	-	-	-	-	-	-	-

Study	Arm	N	DM2	HTN	Dyslipidemia	OSA	GERD	Arthritis	Asthma
LABS Consortium 2009	LAGB	1,198	-	-	-	-	-	-	-
	LRYGB	2,975							
Sasse 2009	LAGB	210	-	-	-	-	-	-	-
	LRYGB	38							
Wong 2009	LAGB	57	-	-	-	-	-	-	-
	LRYGB	7							
RCTs									
Angrisani 2007	LAGB	27	-	0	-	100	-	-	-
	LRYGB	24	100	0	100	-			
Nguyen 2009	LAGB	86	NR, but 23% with DM2 at baseline	NR, but 43% with HTN at baseline	-	-	-	-	-
	LRYGB	111							

*Percentages of patients with comorbidity prior to surgery who have complete resolution following the bariatric procedure.

N	Number
DM2	Diabetes mellitus, type 2
HTN	Hypertension
OSA	Obstructive sleep apnea
GERD	Gastroesophageal reflux disease
HI	Homeostatic model assessment (HOMA) index=glucose x insulin

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TABLE 4: Percentage of Patients with Short-term Complications (30-day) in the Studies Comparing LAGB to RYGB

Study	Arm	N	Total	Death	Perforation	Conversion	VTE	Bleed	Infxn	Leak	Other
Hell	LAGB	30	-	-	-	-	-	-	-	-	-
2000	RYGB	30									
Biertho*	LAGB	805	1.7	0	0.1	3.0	0.2	1.2	1.2	0	0.1
2003	RYGB	456	4.2*	0.4	0	2.0	0.9	0.9	0.2	2.0	1.8
Weber	LAGB	103	18	0	1.0	0	0	1.0	16	0	3.9
2004	RYGB	103	21	0	1.0	1.0	1.0	1.0	7.8	1.9	5.8
Jan	LAGB	154	3.9	0.6	1.9	0.6	0.6	1.3	1.3	0	0
2005	RYGB	219	5.0	0.5	0.5	0.5	0	1.8	4.1	0.9	0
Parikh	LAGB	197	4.7	0	0	0.5	0	0.5	1.0	0	0
2005	RYGB	97	11	0	0	2.1	1.0	0	5.2	1.0	0
Bowne	LAGB	60	18	0	0	1.7	-	1.7	1.7	0	15
2006	RYGB	46	17	0	0	0	-	2.2	2.2	2.2	11
Cottam	LAGB	181	-	0	0	-	-	-	-	-	-
2006	RYGB	181		0	0						
Galvani	LAGB	470	3.6	0	0.2	0.2	0.2	0	0	0	3.2
2006	RYGB	120	6.6	0.8	0	2.5	0	0.8	0.8	0.8	1.7
Kim	LAGB	160	0.6	0	0	0	0	0	0.6	0	0
2006	RYGB	232	5.2	0	0	0	0	0	2.6	0.9	2.2
Parikh	LAGB	480	3.3	0	-	0	-	-	-	-	-
2006	RYGB	235	9.4	0		0.9					
Rosenthal	LAGB	152	4.6†	0	1.3	-	-	-	-	-	-
2006	RYGB	849	4.4	0	0	0.6	0.8	0.5	3.7	1.9	13
Jan	LAGB	406	7.9	0.2	0.5	-	0.5	0.5	2.5	0	-
2007	RYGB	492	15	0.2	0.6	-	0.6	2.2	4.7	0.8	-

Study	Arm	N	Total	Death	Perforation	Conversion	VTE	Bleed	Infxn	Leak	Other
New Studies											
Mognol	LAGB	179	2.8	0.6	0	0	0	0	2.2	0	0
2005	LRYGB	111	10	0.9	0	3.6	0	3.6	3.6	0.9	1.8
Bessler	LAGB	138	-	-	-	-	-	-	-	-	-
2008	RYGB	403									
Lancaster	LAGB	1176	2.6	0.09	-	-	0.2	0	1.6	-	-
2008	LRYGB	3580	6.7	0.14			0.8	0.4	3.0		
Lee	LAGB	116	0	0	-	-	-	-	-	-	-
2008	LRYGB	544	2.6	0							
Lee, Kim	LAGB	51	14	0	0	0	0	0	4	0	10
2008	LRYGB	25	32	0	0	0	0	4	0	8	20
Muller	LAGB	52	-	-	-	-	-	-	-	-	-
2008	LRYGB	52									
Puzziferri	LAGB	631	-	-	-	-	-	-	-	-	-
2008	RYGB	1102									
Te Riele	LAGB	53	0	0	0	-	0	0	0	0	
2008	RYGB	53	11.3	0	0		0	0	5.7	5.7	
Ballantyne	LAGB	111	-	-	-	-	-	-	-	-	-
2009	LRYGB	104									
Hinohosa	LAGB	4,226	2.8	0.02	0.8	-	0.2	0.3	0.03	0.2	0.8
2009	LRYGB	20,543	7.5	0.08	1.3		0.3	1.8	0.4	0.2	3.4
Lee	LAGB	140	0	0	-	-	-	-	-	-	-
2009	LRYGB	660	2.5	0.3							
Lindsey	LAGB	2,492	3.1	0.04	-	-	-	-	-	-	-
2009	LRYGB	3,912	8.6	0.03							
LABS Consortium	LAGB	1,198	1.0	0	-	-	0.3	-	-	-	0.7
2009	LRYGB	2,975	4.8	0.2			0.4				4.2

Study	Arm	N	Total	Death	Perforation	Conversion	VTE	Bleed	Infxn	Leak	Other
Sasse	LAGB	210	1.9	0	0	0	0	0	0.5	0	1.4
2009	LRYGB	38	2.6	0	0	0	0	0	0	0	2.6
Wong	LAGB	57	1.7	0	0	0	0	0	1.7	0	
2009	LRYGB	7	14	0	0	0	0	0	0	14	
RCTs											
Angrisani	LAGB	27	0	0	0	0	0	0	0	0	0
2007	LRYGB	24	8.3	0	4.2	4.2	0	0	0	4.2	0
Nguyen	LAGB	86	2.3	0	0	0	0	0	0	0	2.3
2009	LRYGB	111	6.3	0	0	0	0	1.8	0	0	4.5

* Major complications in first post-operative week rather than 30 days
† Major complications for RYGB and complications that required surgical correction for the LAGB group.

VTE	Venous thromboembolic disease
Bleed	Bleeding
Infxn	Infection

TABLE 5: Percentage of Patients with Long-term Complications (>30 days post-procedure) in the Studies Comparing LAGB to RYGB

Study	Arm	N	Total	Death	Reop	Slip/Dil	Erosion	Obst	Port	M. ulcer	IH	GB
Hell	LAGB	30	-	-	-	-	-	-	-	-	-	-
2000	RYGB	30										
Biertho*	LAGB	805	9.1	0	-	2.5	0	0.2	2.9	0	0.4	0
2003	RYGB	456	8.1	0	1.3	0	0	3.3	0	0	0.2	0
Weber	LAGB	103	45	0	27	36	5.8	0	1.0	0	0	0
2004	RYGB	103	14	0	11	1.0	1.9	11	0	2.9	1.0	0
Jan	LAGB	154	1.9	0	20	16	0	0	6.5	0	1.9	0
2005	RYGB	219	2.3	0.2	9.6	0	0	4.6	0	1.4	3.2	0
Parikh	LAGB	197	-	-	-	-	-	-	-	-	-	-
2005	RYGB	97										
Bowne	LAGB	60	78	0	25	1.7	0	3.3	18	0	0	0
2006	RYGB	46	28	0	6.5	0	0	11	0	4.3	0	0
Cottam	LAGB	181	-	0	24	7.2	0	0	9.4	0	0	0
2006	RYGB	181		0	19	0	0	1.7	0	0	0	0
Galvani	LAGB	470	17	0	8.1	14	0.2	0	2.8	0	0	0
2006	RYGB	120	14	0	8.3	0	0	5.8	0	0	0	0.8
Kim	LAGB	160	3.8	0	0	0	0	0	3.8	0	0.6	0
2006	RYGB	232	0.4	0	0	0	0	0	0	0	0	0
Parikh	LAGB	480	5.4	0	-	-	-	-	-	-	-	-
2006	RYGB	235	14	0.4								
Rosenthal	LAGB	152	9.2	0	14	1.3	1.3	2.6	-	0	0	0
2006	RYGB	849	7.7	0	0	0	0	1.4		1.4	0.2	0
Jan	LAGB	406	19	0.2	17	8.1	0.7	0.7	4.9	0	0.2	1.7
2007	RYGB	492	23	0.6	17	0	0	1.6	0	2.4	2.2	2.0

Study	Arm	N	Total	Death	Reop	Slip/Dil	Erosion	Obst	Port	M. ulcer	IH	GB
New Studies												
Mognol	LAGB	179	25	0	25	20	0.6	0	3.4	0	0	0
2005	LRYGB	111	16	0	4.5	0	0	10	0	3.6	0.9	0
Bessler	LAGB	138	-	-	-	-	-	-	-	-	-	-
2008	RYGB	403										
Lancaster	LAGB	1176	-	-	-	-	-	-	-	-	-	-
2008	LRYGB	3580										
Lee	LAGB	116	-	-	-	-	-	-	-	-	-	-
2008	LRYGB	544										
Lee, Kim	LAGB	51			4							
2008	LRYGB	25			16							
Muller	LAGB	52		0	11	11	-	0	-	-	0	-
2008	LRYGB	52		0	10	0		8			2	
Puzziferri	LAGB	631	-	-	-	-	-	-	-	-	-	-
2008	RYGB	1102										
Te Riele	LAGB	53	1.9	0	3.8	1.9	0	0	1.9	0	0	0
2008	RYGB	53	5.7	0	18.9	0	0	0	0	0	5.7	0
Ballantyne	LAGB	111	-	-	-	-	-	-	-	-	-	-
2009	LRYGB	104										
Hinohosa	LAGB	4,226	-	-	-	-	-	-	-	-	-	-
2009	LRYGB	20,543										
Lee	LAGB	140	-	-	-	-	-	-	-	-	-	-
2009	LRYGB	660										
Lindsey	LAGB	2,492	-	-	-	-	-	-	-	-	-	-
2009	LRYGB	3,912										
LABS Consortium	LAGB	1,198	-	-	-	-	-	-	-	-	-	-
2009	LRYGB	2,975										

Study	Arm	N	Total	Death	Reop	Slip/Dil	Erosion	Obst	Port	M. ulcer	IH	GB
Sasse	LAGB	210	-	-	-	-	-	-	-	-	-	-
2009	LRYGB	38										
Wong	LAGB	57	9	0	5.3	3.5	0	0	3.5	0		
2009	LRYGB	7	43	0	43	0	0	29	0	14		
RCTs												
Angrisani	LAGB	27	7.6	0	7.6	7.6	0	0	0	0	0	0
2007	LRYGB	24	4.2	0	0	0	0	4.2	0	0	0	0
Nguyen‡	LAGB	86	11.6	0	-	2.3	1.2	2.3	3.5	0	0	0
2009	LRYGB	111	26.1	0.9		0		19	0	1.8	2.7	0

* Major complications after the first post-operative week rather than 30 days
† Major complications for RYGB and complications that required surgical correction for the LAGB group.
‡ Mean follow-up 3.6 years for LAGB and 4.2 years for RYB. Death was from alcohol/drug abuse

Reop	Reoperation
Slip/Dil	Slippage/Dilation
Obst	Obstruction
Port	Port problems (leaks)
M. ulcers	Marginal ulcers
IH	Incisional hernia
GB	Gallbladder

TA Criterion 3: The technology must improve the net health outcomes.

The primary health measure driving the demand for surgical intervention is weight loss. This is usually reported as the percentage of excess body weight lost (%EBWL), but absolute weight loss, change in BMI, and post-surgical BMI are also commonly reported. Ideally, changes in obesity related conditions such as diabetes, hypertension, sleep apnea, joint pain, and hyperlipidemia would also be reported. There should also be demonstrable improvements in the patients' quality of life. These benefits must be balanced against the risks of peri-operative mortality; such as, short-term morbidity from wound infections, pulmonary emboli, bleeding, bowel obstruction, splenic injury and anastomotic leaks; and long-term morbidity from re-operations, incisional hernias, marginal ulcers, structure formation, device malfunction, malnutrition, and vitamin deficiency.

Patient Benefits

Initial results of laparoscopic LAGB were quite discouraging due to the high rate of complications requiring removal of the band and/or conversion to an open or alternate procedure.[54, 76-79] This led to a series of modifications of the surgical technique and better outcomes.[56, 80-84] As detailed in the prior CTAF review, current approaches to LAGB leads to significant weight loss in patients with class 2 or 3 obesity. The degree of weight loss and the resolution of co-morbidities are much greater than that achievable with diet therapy and current weight loss medications. There is good evidence for improvement or resolution of obesity related co-morbidities such as diabetes, HTN, and sleep apnea with the procedure, although long-term follow-up data are lacking. Peri-operative mortality rates are remarkably low in centers performing large numbers of the procedure. One study raised concerns about long-term outcomes such as band erosion into the stomach and band slippage, with re-operation rates due to band complications averaging five percent per year over the first five years of follow-up. Given appropriate informed consent regarding the need for frequent office visits for band adjustment and the long-term risks of band complications, the overall clinical benefits compared to no surgery appear to outweigh the risks when the surgery is performed at a high-volume center with experienced surgeons and a comprehensive pre- and post-operative weight management program.

TA Criterion 3 is met.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

Conclusions about the comparative efficacy of different procedures are best made from comparative trials using concurrent, ideally randomized controls. Surgical procedures are prone to variability between surgeons, surgical centers, and technical improvements over time. The quality of nursing staff, ancillary services, and the volume of procedures performed all can have substantial impact on outcomes. Thus, large, multicenter randomized trials are needed to have confidence that the results are due to the surgical technique and not a particular surgeon or surgical center. Additionally, bariatric surgical mortality has consistently been shown to be related to the age, sex, pre-operative BMI, and co-morbidities of the patient.[85, 86] Thus, at a minimum, non-randomized comparative studies should match on these characteristics as well as the surgical site and date of surgery.

Alternatives to LAGB surgery include low-calorie (800-1200) and very-low (400-800) calorie diets, behavioral modification, exercise and pharmacologic agents; and other bariatric procedures such as vertical banded gastroplasty, sleeve gastrectomy, RYGB, or biliopancreatic diversion surgeries. The National Institute of Health (NIH) Consensus Conference[20] concluded that, "diets alone cannot be considered a reasonable option for achieving weight loss in severely obese patients." In the 1980s, Bennett conducted an extensive review of the literature and concluded that dietary treatments of obesity resulted in weight loss of <15% of starting weight and that weight reductions decayed to zero at five years.[87] Waddell reviewed 60 controlled trials of behavioral therapy for weight loss and reported that average weight loss at last follow-up was <5 kg. In morbidly obese patients, there is no evidence that conservative (nonsurgical) interventions result in significant, sustained weight reduction.[88] The failure of conservative and dietary treatment to control morbid obesity has led to the development of surgical methods of control.[89]

RYGB is the bariatric procedure of choice in the United States. It has been shown to produce better weight loss than alternative procedures in multiple clinical trials and has acceptable morbidity and mortality. The laparoscopic approach to RYGB has become the standard because of lower perioperative morbidity and mortality.[18, 31-33, 90] Given the promising data for LAGB discussed above, ideally investigators would perform large, multicenter randomized trials comparing laparoscopic adjustable gastric banding to laparoscopic RYGB. Key outcomes to assess would be surgical and long-term mortality, surgical complications, weight loss, change in co-morbidities, quality of life and long-term complications. To date, two small, single site, randomized trials have been published.[63, 64]

Non-randomized comparative trials of laparoscopic adjustable silicone gastric banding to Roux-en-Y gastric bypass

Tables 1 to 5 summarize the 28 published trials that directly compare LAGB to RYGB and report weight loss outcomes and/or complications. In general, the quality of the trials was poor. Only two small studies randomized patients and both had serious methodological issues. These two studies will be discussed in detail below. In the non-randomized trials, the two groups in most of the studies are far from comparable. For example, two of the twelve studies reviewed in 2007 compared patients treated with LAGB in Europe to patients receiving RYGB in the United States.[59, 65] Similarly, two of the studies had age differences at the time of surgery of four to five years[59, 70] and two other studies had differences in baseline BMI that ranged from seven to 15 kg/m2.[65, 74] Only two studies matched patients by age, sex, and BMI,[67, 75] and only one study matched additionally by date of surgery.[67] Two of the new studies also matched patients by age, sex, and BMI,[91, 92] but not by date of surgery, so follow-up times were markedly different in the two groups in each of the studies and some of the differences between groups may be due to biases introduced by cohort effects. Three of the new studies analyze large administrative data sets[18, 93, 94] that allow calculation of reasonably precise estimates for peri-operative mortality and short-term major complications, but are limited by the lack of detailed individual patient information and longer term outcome data.

Weight loss outcomes consistently favored RYGB by large amounts (Table 2). The median absolute difference in EBWL between the two groups across the 22 studies reporting weight loss outcomes at one year was 28%, a large and clinically significant difference. For example, in one of the studies that matched on age, sex, race, and weight, patients treated with LAGB had lost 34% of their excess weight at one year while patients treated with RYGB had lost 62% of their excess weight.[92] In several of the studies, these differences tended to narrow over time, though in others the differences remain stable for at least five years. In the most recent publications, the differences have tended to be even greater than 28%. These results were mirrored in the data on resolution of comorbidities (Table 3). The results for the two studies that matched patients[67, 75] strongly favored the RYGB group with absolute differences in resolution of comorbidities greater than or equal to 25% (number needed to treat equal to 4). Even larger differences were reported by Bowne et al in their study of patients with BMI's greater than 50 kg/m2.[66] For instance 100% of patients with diabetes who were treated with RYGB in this study had normalization of their blood sugars without medication compared with only 40% of diabetic patients treated with LAGB. However, two other large studies reported that the improvements in comorbidities were similar between the two groups, even though weight loss outcomes were much better for patients treated with RYGB.[68, 71] Few of the studies published since the 2007 CTAF review reported on resolution of comorbidities. Among those that did, results always favored RYGB with the magnitude of the difference similar to that reported in the earlier studies.[91, 95-98]

Short-term complication rates consistently favored LAGB. The three large studies using administrative data[18, 93, 94] and the prospective Longitudinal Assessment of Bariatric Surgery Consortium study[99] allow for precise estimates of the short term complication rates. When pooled, these four studies provide complication rates for 9,092 patients receiving LAGB and 31,010 patients receiving RYGB. There were fewer deaths in the LAGB group (0.03% vs. 0.09%), though mortality was very low in both groups (less than one in one thousand patients). There were also fewer major complications in the LAGB group (2.6% vs. 7.3%). Rates of conversion to open procedures, perforation, bleeding, and anastomotic leaks were very low in both groups.

Long-term complications were more common in the LAGB group and several studies reported large differences in the rates of long-term complications. For instance, in the first trial with matching,[67] early complications occurred in 21 patients in the RYGB group and 18 patients in the LAGB group with those in the RYGB requiring reintervention with endoscopic dilation or reoperation in 11 patients compared with only one patient in the LAGB groups. However, the opposite was true for complications occurring after 30 days. There were 14 significant complications, with 11 requiring reoperation in the RYGB group compared with 45 major complications and 27 reoperations in the LAGB group. The length of follow-up was greater in the LAGB group, which may partially explain the difference in the number of major complications. However, the reoperation rates were also higher in the LAGB group in the other trial with participants matched not only on patient characteristics, but also date of surgery (24% LAGB group vs. 19% RYGB group).[67] Long-term reoperation rates were also much higher in the LAGB group than the RYGB group in four of the nine other comparative trials reporting reoperations.[66, 70, 74, 100] A mixture of port problems and band slippage with pouch dilation were the most common reason for reoperation for patients receiving LAGB, while bowel obstruction was the most common problem for patients receiving RYGB. Band erosion, gall bladder problems, and incisional hernias were relatively uncommon late complications. Unfortunately, the new comparative studies added almost no data on long term complications. None of the studies adequately document the incidence of vitamin and mineral deficiencies associated with RYGB or their impact on patients (symptomatic anemia, osteoporosis, need for treatment, quality of life). Some of the excess in late complications seen with LABG has been eliminated with better technique. However, comparative long-term complication rates remains an area of great uncertainty and an important determinant of the overall balance of benefits and harms between the two procedures.

The complication rates for each procedure differ markedly from study to study. This likely reflects different lengths of follow-up and different definitions for significant complications across studies. Most of the studies reported the prevalence of complications rather than the annual rate of complications over time. It is unclear whether complications associated with LAGB are very common in the first one to two years after surgery and then decrease or whether the opposite is true as the port continues to be accessed and the materials age. Similar concerns apply to complications following RYGB.

Patient satisfaction and quality of life

Only two of the studies directly comparing LAGB to RYGB reported data on patient satisfaction.[66, 91] In the first study, nearly 80% of patients in the RYGB group reported being very satisfied with the procedure and none of the patients in this group were unsatisfied or regretted having the procedure.[66] This compares with 46% of the patients in the LAGB group being very satisfied with the procedure and 19% of the patients in the LAGB group reported being unsatisfied or regretted having had the procedure (p=0.006 between the two groups). In the second study, 97% of patients in the RYGB group reported being quite satisfied or very satisfied compared with 83% of patients in the LAGB group (p = 0.145). The second study also measured quality of life 3.1 years after RYGB and 5.9 years after LAGB – there were no measurable differences at that time on the SF-36 or on the Moorehead-Ardelt quality of life questionnaires.

Randomized trials comparing LAGB to RYGB

Two randomized trials have been published. The first, by Angrisani et al, was a small trial at a single site in Italy.[63] The surgeons had performed over 150 LAGB surgeries, but only five laparoscopic RYGB surgeries prior to the trial. They recruited patients between the ages of 16 and 50 years old with a BMI between 35 and 50 kg/m^2 who had not had prior abdominal surgery. Of the 59 patients randomized, eight (14%, 5 LRYGB, 3 LAGB) refused the operation to which they were randomized and were excluded from the trial. This left 27 patients in the LAGB group and 24 patients in the LRYGB group. This large, immediate drop-out after surgery, decreases the value of randomization and significantly downgrades the quality of the trial. The patients who remained in the trial were on average 24 years old with a BMI of 44 kg/m^2. The majority (82%) were female. The distribution of demographics and risk factors were similar between the two groups.

There were no deaths, but one patient in the LRYGB group had a 40 day stay in the intensive care unit (ICU) and a six month hospitalization for complications following jejunal perforation. Another patient in the LRYGB group had an anastomotic leak found intraoperatively that was repaired after conversion to an open procedure. No other open conversions or major complications occurred within 30 days in either group.

Patients were followed for five years with only one patient lost to follow-up in the LAGB group. Late complications included two gastric pouch dilations requiring band removed in the LAGB group and one internal hernia with bowel ischemia requiring resection in the RYGB group.

At five years, patients in the LAGB group had lost significantly less excess weight (47.5% vs. 66.6%, p<0.001) and had a higher average BMI (34.9 vs. 29.8 kg/m^2, p<0.001). Weight loss failure, defined by the investigators as a BMI> 35 kg/m^2, occurred more often in the LAGB group (34.6% vs. 4.2%, p<0.001). In the LAGB group, the patient with sleep apnea was cured. In the RYGB group, the patient with diabetes and the patient with hyperlipidemia were cured. None of the patients with hypertension in either group were medication free.

The second randomized trial was done at a single site in the United States and just published this month.[64] The patient group was somewhat different: eligible patients had a BMI between 40 and 60 kg/m2 or 35 kg/m^2 with comorbidities. Patients with ventral or hiatal hernias, prior bariatric surgery, or high operative risk were excluded. This trial also suffered from a large number of patients refusing the surgical group to which they were randomized (39 (31%) in the LAGB group and 14 (11%, p=0.0001 for differential refusal rate) in the RYGB group). The high differential dropout at randomization severely compromises the quality of the trial. Perhaps due to the high differential dropout, patients in the LAGB group were older (45.8 vs. 41.4 years, p<0.01) and had a lower BMI (45.5 vs. 46.5 kg/m^2, p=0.01) prior to surgery. Three-fourths of the patients were female in both groups.

Consistent with the prior literature, the operative time was significantly shorter in the LAGB group (68 vs. 137 minutes, p<0.01) as was the length of the hospital stay (1.5 vs. 3.1 days, p<0.01). Both the 30 day reoperation rate (1.2% vs. 5.4%, NS) and readmission rates (0% vs. 5.4%, p=0.04) were lower after LAGB. There was a trend towards fewer major complications (2.3% vs. 6.3%, p NS) and significantly fewer minor complications (4.7% vs. 15.3%, p=0.02) following LAGB. No single complication predominated following LAGB. The most common complications following RYGB were gastrointestinal obstruction and wound infections. Complications beyond 30 days also were lower in the LAGB group. Both major (11.6% vs. 26.1%) and minor complications (0% vs. 13.5%, p<0.01) were less common after LAGB. This was primarily due to anastomotic strictures (59% of major complications) and marginal ulcers (60% of minor complications) in the RYGB group. In the commentary following the article, one of the discussants noted that the rate of strictures (14%) was much higher than the 5% to 8% usually reported in the literature. Similarly, the rate of marginal ulcers (8%) was higher than the 3% reported in the literature. The investigators reported that during the trial, they changed technique and the rate of strictures dropped from 24% to 8%. They also noted that they had a low threshold for endoscopy and thus discover more marginal ulcers than other surgical groups. The only death reported was a patient in the RYGB group who died from drug and alcohol abuse eight months after the surgery. The mean and median follow-up are not reported in the publication, though it appears that at least 70% of the patients who were treated had follow-up data on weight at three years.

Excess weight loss was significantly less for LAGB at all time points including one year (36.5% vs. 64.3%, $p<0.05$) and four years (45.4% vs. 68.4%, $p<0.05$). At four years, patients in the LAGB group also had a higher average BMI (35.7 vs. 30.5 kg/m^2, $p<0.05$). Differences in excess weight loss and BMI were stable after the first year. Weight loss failure, defined by the investigators excess weight loss less than 20%, occurred more often in the LAGB group (16.7% vs. 0%, p not reported but less than 0.001 by my calculation). Weight loss was excellent or exceptional (more than 60% of excess weight lost) for 15% of the patients in the LAGB group and 64% of the RYGB group (p not reported, but less than 0.001 by my calculation). Even though more than 20% of the patients in both groups had diabetes and HTN, the investigators did not report on improvement or resolution of those comorbidities. At one month after surgery, quality of life had improved on one of the eight domains of the Short form-36 (SF-36) (general health) for the LAGB group, but had improved for five of the eight domains (general health, physical functioning, vitality, social functioning, bodily pain) for the RYGB group despite the higher rate of minor and major complications. By one year there were no differences between the groups.

Both of the randomized trials are only of fair quality because of the large number of patients who dropped out before receiving their assigned treatment. The value of randomization was lost. Thus the quality is only about as good as the higher quality observational trials. The trials support the general conclusions drawn from the observational trials: mortality is very low with both procedures, perioperative and 30 day outcomes strongly favor LAGB, but weight loss outcomes, overall success rates, and resolution of obesity associated co-morbidities strongly favor RYGB.

Comparison of different types of adjustable gastric bands

The Swedish Adjustable Gastric Band (Realize band, Ethicon in the United States) is an alternative to LAGB that is approved for use in Europe. It was designed to have greater compliance than LAGB, thus exerting less pressure in order to decrease late complications. One small, non-randomized study in Hungary compared LAGB to SB.[101] Fifty-four patients underwent laparoscopic surgery for morbid obesity using either LAGB or SB. There were 33 men and 21 women, with median age 42 (range 20-64), and a preoperative BMI of 50 kg/m(2) (range 41-66). Twenty patients received LAGB and thirty-two patients received the SB. EBWL at one year was 62% for LAGB and 67% for SB. There were no intraoperative or early complications in either group. Late complications were slightly more common in the LAGB group (5% vs. 3% slippage of band, 20% vs. 13% port problems).

A small RCT compared a third type of band, Heliogast, to LAGB.[102] From January to May 2001, 60 patients were randomized to LAGB (n=30) or the Heliogast band (Helioscopie). Follow-up of all patients was a minimum of 12 months. There were no differences in operating-time, intra-operative complications, or weight loss during the first four weeks after surgery. However, with increasing time, more complications with the Heliogast band and differences in weight loss favoring the Lap-Band became significant. The EBWL at one year was 42% for LAGB, but only 28% for Heliogast ($p<0.001$). The only late complications with LAGB were port problems (3%). In contrast, patients receiving the Heliogast band had more band erosions (3%), port problems (27%), and stoma problems (87%). The authors conclude that LAGB was clearly superior and that any new techniques or devices should be evaluated with RCTs to demonstrate safety and efficacy.

Recent systematic reviews

A number of systematic reviews of the topic have been published in the past two years.[103-111] All agree that bariatric surgery is relatively safe when performed at centers of excellence and that it is more effective than medical therapy at achieving long term weight loss and resolution of comorbidities in patients with class 3 obesity. One review focused specifically on weight loss and concluded that laparoscopic RYGB achieves significantly greater weight loss than LAGB at one, two and three or more years after the surgery.[110] A second focused on both weight loss outcomes and the resolution of type 2 diabetes.[111] Their summary estimates for EBWL were 46.2% for LAGB and 59.7% for RYGB. Diabetes resolved for 56.7% of patients receiving LAGB and 80.3% of patients receiving RYGB. The 2009 update of the Cochrane review on surgery for obesity[103] concurs with these overall conclusions, but notes that they should be interpreted cautiously because of the poor quality of the trials overall and the small number of trials comparing each procedure. They single out the data on the comparative safety of the procedures as particularly weak.

Summary

LAGB techniques have evolved over time with a concomitant decrease in early and late complications. The same is true for RYGB, particularly when performed laparoscopically. For example, in the RCT of Nguyen et al[64], the rate of anastomotic stricture dropped from 25% to 8% when the surgeons used a new circular stapler. Thus, we must look to data from either randomized clinical trials or carefully controlled studies of patients matched for date of surgery as well as predictors of poor surgical outcome (age, sex, pre-operative BMI). The comparative trials and the matched trials in particular demonstrate significantly greater weight loss and greater improvement in comorbidities for patients treated with RYGB compared to those treated with LAGB. However, early complications reflected in greater lengths of stay during the initial hospitalization and greater early reoperation rates are more common in the RYGB group. Long-term complication rates are more common in the LAGB group in some studies, but there is a relative dearth of high quality, multicenter data prospectively collecting long-term complication data in a consistent way for both procedures in the one to ten year follow-up period. It is not clear that the decrease in early complications with LAGB balances the lower weight loss and comorbidity resolution. The comparative data suggests that for every four patients with diabetes treated with LAGB instead of RYGB, one patient who would have been cured, will still meet criteria for diabetes. Additionally, as noted in the background, enterohormonal changes that follow RYGB, but not LAGB, may enhance appetite and glucose control beyond the effects due to greater weight loss. Furthermore, when asked, patients receiving RYGB are consistently more satisfied than patients receiving LAGB. Some investigators have decided not to offer LAGB to patients with very high BMI's (50 kg/m^2 and above) or diabetes because of these observations. It is not clear that there is any subgroup of patients currently eligible for bariatric surgery in whom the short term benefits of LAGB outweigh the long term advantages of laparoscopic RYGB.

TA Criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside the investigational settings.

The large number of reports from a variety of settings in Europe and the United States suggests that both open and laparoscopic LAGB can be performed with satisfactory surgical results under conditions of usual medical practice. These procedures are technically demanding and patients must be carefully selected. Major prerequisites for satisfactory performance of this surgery are prior laparoscopic experience and specific training in implantation and management of the device.[112] Recommendations from the manufacturer of the Lap-band system include:

- Surgeon completed at least 25 Nissen fundoplication procedures
- Surgeon completed at least 25 bariatric procedures
- Surgeon trained in technique at an authorized workshop
- Training in adjustment of device with cooperation of local Radiology Department
- Comprehensive patient support program in place (nutrition and exercise counseling; hospital facilities; psychological, general medicine, and radiology personnel)
- At least 25 procedures performed per year

Nonetheless, provided that physicians are experienced with the technique, results similar to those in the published trials summarized above should be attainable when used to treat individuals with morbid obesity in the community setting under conditions of a comprehensive bariatric surgery program. Similar concerns apply to surgeons performing RYGB, particularly LRYGB.

Recommendations For Facilities And Physicians Performing Bariatric Surgery

Facility Requirements

Health care facilities that perform bariatric surgery should maintain adequate facilities and equipment, as well as a properly trained bariatric surgery staff. The American College of Surgeons (ACS) recommends the facility set minimal standards in these areas, and that those standards be maintained under the direction of a qualified surgeon in charge of bariatric surgery management team. According to ACS, the surgery management team should include surgeons, skilled nurses, nutritionists, anesthesiologists, cardiologists, pulmonologists and rehabilitation therapists. ACS recommends the operating room be equipped with special operating tables and ancillary equipment available to accommodate patients weighing up to 750 pounds. In addition, the facility should have appropriate bariatric retractors, staplers, and appropriately long surgical instruments necessary to perform gastrointestinal surgery on severely obese patients.

Pre-operative assessment of patients with Class 3 obesity may require special radiology equipment, as well as special beds, chairs and commodes. ACS recommends that nursing personnel who care for the patient during the pre-operative period have training in respiratory care, assisting with ambulation, and recognizing cardiac, diabetic and vascular problems. ACS stresses that anesthesia for bariatric surgical procedures should be performed only by individuals with specialty training in this area. In addition, ACS recommends the staff of the recovery room and intensive care units have expertise in the post-operative care of morbidly obese patients. In particular, the recovery room staff should be familiar with the potential need for ventilatory support. Facilities performing bariatric surgery should also have long-term care follow-up facilities which provide rehabilitation therapy, psychiatric care, nutritional counseling and support groups. Finally, ACS notes that accreditation of a bariatric facility by an accrediting agency, such as the Joint Commission on Accreditation of Health Care Organizations, provides an indicia of competency.

The American Society for Metabolic and Bariatric Surgeons (ASMBS) and ACS are currently preparing guidelines to define criteria for Centers of Excellence in Bariatric Surgery.

Physician Qualifications

The ASMBS has established guidelines that define the minimally acceptable credentials for general surgeons to be eligible for hospital privileges to perform bariatric surgery. As a threshold requirement, the applicant-surgeon should meet the following "Global Credentialing Requirements":

- Have credentials at an accredited facility to perform gastrointestinal and biliary surgery;
- Document that he or she is working within an integrated program for the care of the morbidly obese patient that provides ancillary services such as specialized nursing care, dietary instruction, counseling, support groups, exercise training, and psychological assistance as needed;
- Document that there is a program in place to prevent, monitor and manage short-term and long-term complications; and
- Document that there is a system in place to provide follow-up for all patients, with the expectation that at least 50% of the patients who receive restrictive procedures and 75% of those with malabsorptive operations will be seen, on a regular basis, for at least five years.

Under the ASMBS guidelines, in order to obtain "open" bariatric surgery privileges, the surgeon must meet both the Global Credentialing Requirements and the following requirements:

- Document three proctored cases in which the assistant is a fully trained bariatric surgeon; and
- Document the successful outcomes (with acceptable peri-operative complications rates) for 10 open bariatric surgical cases performed by the applicant.

To obtain laparoscopic bariatric surgery privileges the ASMBS guidelines require the surgeon to satisfy the Global Credentialing Requirements and the following requirements:

- Have privileges to perform "open" bariatric surgery at an approved facility;
- Have privileges at the given facility to perform advanced laparoscopic surgery;
- Document three proctored cases in which the assistant is a fully trained bariatric surgeon; and

- Document the outcomes of 15 laparoscopic bariatric surgical cases performed as primary surgeon, demonstrating an acceptable peri-operative complication rate.

While LAGB is performed in many centers across the US, this technology has not been shown to be as beneficial as established alternatives in the investigational setting. Therefore,

TA Criterion 5 is not met.

CONCLUSION

Since the last review of LAGB by CTAF, the use of the device has increased more than four-fold in the United States. Reflecting that interest, an additional sixteen comparative studies have been published, including two randomized trials. The major addition to the literature has been the publication of data from large administrative databases which confirm the low peri-operative mortality with both LAGB or laparoscopic RYGB (less than 0.1%) and support the observation that significant complications occur about three times more often with RYGB compared to LAGB (7.3% vs. 2.6%). Unfortunately, the two randomized trials are small, single site trials with significant methodologic concerns due to high drop-out rates immediately following randomization.

Compared to laparoscopic RYGB, LAGB is a technically less demanding procedure with shorter operating time, shorter length of hospital stay, and fewer initial complications. Therefore, LAGB has great appeal for surgeons, who could treat more patients with LAGB than RYGB over the same time period. There is a risk that commercial sponsorship of LAGB may promote the use of these devices over RYGB, which has no commercial sponsor. The complex mixture of early and late complications and benefits following both procedures, as well as the impact of patient characteristics on outcomes, requires randomized trials to carefully compare the relative merits of RYGB and LAGB. Given the rapid increase in the number of patients interested in bariatric surgery, such clinical trials are feasible.

Current data clearly demonstrate that weight loss after one to five years is much greater among patients treated with RYGB than among those treated with LAGB. The data regarding measures other than weight loss are less robust, but the findings suggest that significantly more patients would be cured of their diabetes, obstructive sleep apnea, hypertension, and other obesity-associated comorbidities if treated with RYGB rather than LAGB. These effects may in part be mediated by hormonal changes in ghrelin, GLP-1, GIP, and PYY that decrease appetite, increase the sensation of satiety, and increase insulin responsiveness to glycemic loads. When asked, patients who underwent RYGB are more satisfied than comparable who received LAGB. However, early complications (reflected in longer initial hospitalizations and greater early reoperation rates) occurred three times more often in the RYGB groups. Despite the excess of complications, measures of quality of life improve more quickly among patients treated with RYGB. It remains difficult to precisely assess the relative risks and benefits of the two procedures, as the quality of the studies is generally low, and the sample size of the higher-quality studies is small. The major limitation to the current literature is the lack of high quality prospectively collected data on the relative risk for major complications between one and ten years after the two procedures and the lack of large, multicenter randomized trials directly comparing the two procedures.

In conclusion, current evidence, while predominantly observational, consistently demonstrates greater weight loss and improvements in obesity-related conditions with RYGB compared with LAGB. Both procedures have acceptable morbidity and mortality when performed in appropriate patients at experienced centers. Large, multicenter, randomized trials are needed to determine whether there are subgroups of patients who may benefit from the lower short-term complication rates of LAGB. Until trials demonstrate advantages of LAGB in clearly defined subgroups of patients, RYGB should remain the bariatric procedure of choice.

DRAFT RECOMMENDATION

It is recommended that the use of LAGB for the treatment of obesity does not meet CTAF technology assessment criteria 4 and 5 for safety, effectiveness, and improvement in health outcomes.

October 28, 2009

This is the third assessment of LAGB presented for review by the CTAF panel since 2004

RECOMMENDATIONS OF OTHERS:

Blue Shield Blue Cross Association (BCBSA)

In February 2007 the BCBSA Technology Evaluation Center recommended that 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 a long-term monitoring and follow-up post-surgery.

Centers for Medicare and Medicaid Services (CMS)

Effective for services performed on and after February 21, 2006 CMS has approved the use of laparoscopic adjustable gastric banding for those with a BMI >35 who have at least one co-morbidity related to obesity and who have been unsuccessful with medical treatment for obesity. In February 2009 Type 2 diabetes mellitus was recognized as a co-morbidity.

American Society for Metabolic and Bariatric Surgery (ASMBS)

The ASMBS will be sending a representative to the meeting to provide testimony and participate in discussion regarding this technology with the CTAF panel.

American Gastroenterological Association (AGA)

The AGA has been invited to provide an opinion and to have a representative provide testimony at the meeting.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

SAGES will have a representative at the meeting to provide testimony and participate in discussion regarding this technology with the CTAF panel.

California Chapter of the American Association of Clinical Endocrinologists (CA AACE)

The CA AACE has been invited to provide an opinion and to have a representative provide testimony at the meeting.

ABBREVIATIONS USED IN THIS ASSESSMENT

CTAF	California Technology Assessment Forum
LAGB	Laparoscopic adjustable silicone gastric banding
RYGB	Roux en Y gastric bypass
BMI	Body mass index
NHANES	National Health and Nutrition Examination Survey
SOS	Swedish Obese Subjects
HDL	High density lipoprotein
PYY	Peptide tyrosine tyrosine
GIP	Gastric inhibitory peptide
GLP-1	Glucagon-like-peptide-1
DARE	Database of Abstracts of Reviews of Effects
EBWL	Excess body weight lost
LRYGB	Laparoscopic Roux en Y gastric bypass
VBG	Vertical banded gastroplasty
RCT	Randomized controlled trial
FU	Follow up
N	Number
DM2	Diabetes mellitus, Type 2
OSA	Obstructive sleep apnea
GERD	Gastroesophageal reflux disease
HI	Homeostatic model assessment (HOMA) index=glucose x insulin
VTE	Venous thromboembolic disease
Bleed	Bleeding
Infxn	Infection
Reop	Reoperations
Slip/Dil	Slippage/Dilation
Obst	Obstruction
M. ulcer	Marginal ulcer
IH	Incisional hernia
GB	Gallbladder
NIH	National Institute of Health
ICU	Intensive care unit

SF-36	Short Form-36
ACS	American College of Surgeons
ASMBS	American Society for Metabolic and Bariatric Surgeons

REFERENCES

1. Mokdad AH, Serdula MK, Dietz WH, Bowman BA, Marks JS, Koplan JP. The spread of the obesity epidemic in the United States, 1991-1998. *Jama.* Oct 27 1999;282(16):1519-1522.

2. Flegal KM, Carroll MD, Ogden CL, Johnson CL. Prevalence and trends in obesity among US adults, 1999-2000. *Jama.* Oct 9 2002;288(14):1723-1727.

3. Hedley AA, Ogden CL, Johnson CL, Carroll MD, Curtin LR, Flegal KM. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999-2002. *Jama.* Jun 16 2004;291(23):2847-2850.

4. Freedman DS, Khan LK, Serdula MK, Galuska DA, Dietz WH. Trends and correlates of class 3 obesity in the United States from 1990 through 2000. *Jama.* Oct 9 2002;288(14):1758-1761.

5. Colditz GA, Willett WC, Rotnitzky A, Manson JE. Weight gain as a risk factor for clinical diabetes mellitus in women. *Ann Intern Med.* Apr 1 1995;122(7):481-486.

6. Williamson DF, Pamuk E, Thun M, Flanders D, Byers T, Heath C. Prospective study of intentional weight loss and mortality in never-smoking overweight US white women aged 40-64 years. *Am J Epidemiol.* Jun 15 1995;141(12):1128-1141.

7. Huang Z, Willett WC, Manson JE, et al. Body weight, weight change, and risk for hypertension in women. *Ann Intern Med.* Jan 15 1998;128(2):81-88.

8. Stevens VJ, Corrigan SA, Obarzanek E, et al. Weight loss intervention in phase 1 of the Trials of Hypertension Prevention. The TOHP Collaborative Research Group. *Arch Intern Med.* Apr 12 1993;153(7):849-858.

9. Felson DT, Zhang Y, Anthony JM, Naimark A, Anderson JJ. Weight loss reduces the risk for symptomatic knee osteoarthritis in women. The Framingham Study. *Ann Intern Med.* Apr 1 1992;116(7):535-539.

10. Fine JT, Colditz GA, Coakley EH, et al. A prospective study of weight change and health-related quality of life in women. *Jama.* Dec 8 1999;282(22):2136-2142.

11. Rand CS, Macgregor AM. Morbidly obese patients' perceptions of social discrimination before and after surgery for obesity. *South Med J.* Dec 1990;83(12):1390-1395.

12. McTigue KM, Harris R, Hemphill B, et al. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med.* Dec 2 2003;139(11):933-949.

13. Arterburn D, Noel PH. Extracts from "Clinical Evidence". Obesity. *Bmj.* Jun 9 2001;322(7299):1406-1409.

14. Douketis JD, Feightner JW, Attia J, Feldman WF. Periodic health examination, 1999 update: 1. Detection, prevention and treatment of obesity. Canadian Task Force on Preventive Health Care. *Cmaj.* Feb 23 1999;160(4):513-525.

15. Glenny AM, O'Meara S, Melville A, Sheldon TA, Wilson C. The treatment and prevention of obesity: a systematic review of the literature. *Int J Obes Relat Metab Disord.* Sep 1997;21(9):715-737.

16. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *Jama.* Oct 13 2004;292(14):1724-1737.

17. Zhao Y, Encinosa W. Bariatric surgery utilization and outcomes in 1998 and 2004. Statistical brief #23. In: Agency for Healthcare Research and Quality R, MD, ed2007.

18. Hinojosa MW, Varela JE, Parikh D, Smith BR, Nguyen XM, Nguyen NT. National trends in use and outcome of laparoscopic adjustable gastric banding. *Surg Obes Relat Dis.* Mar-Apr 2009;5(2):150-155.

19. Maggard MA, Shugarman LR, Suttorp M, et al. Meta-analysis: surgical treatment of obesity. *Ann Intern Med.* Apr 5 2005;142(7):547-559.

20. NIH. NIH conference. Gastrointestinal surgery for severe obesity. Consensus Development Conference Panel. *Ann Intern Med.* Dec 15 1991;115(12):956-961.

21. O'Brien PE, Dixon JB, Laurie C, et al. Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. *Ann Intern Med.* May 2 2006;144(9):625-633.

22. Brethauer SA, Goncalves CG, Cummings DE, Rubino F. Bariatric Surgery as a Treatment for Type 2 Diabetes Mellitus in Obese Patients. *Obesity Management.* June 2009:112-118.

23. Purnell JQ, Flum DR. Bariatric surgery and diabetes: who should be offered the option of remission? *Jama.* Apr 15 2009;301(15):1593-1595.

24. de Wit LT, Mathus-Vliegen L, Hey C, Rademaker B, Gouma DJ, Obertop H. Open versus laparoscopic adjustable silicone gastric banding: a prospective randomized trial for treatment of morbid obesity. *Ann Surg.* Dec 1999;230(6):800-805; discussion 805-807.

25. Livingston EH. Procedure incidence and in-hospital complication rates of bariatric surgery in the United States. *Am J Surg.* Aug 2004;188(2):105-110.

26. Santry HP, Gillen DL, Lauderdale DS. Trends in bariatric surgical procedures. *Jama.* Oct 19 2005;294(15):1909-1917.

27. Courcoulas A, Schuchert M, Gatti G, Luketich J. The relationship of surgeon and hospital volume to outcome after gastric bypass surgery in Pennsylvania: a 3-year summary. *Surgery.* Oct 2003;134(4):613-621; discussion 621-613.

28. Flum DR, Dellinger EP. Impact of gastric bypass operation on survival: a population-based analysis. *J Am Coll Surg.* Oct 2004;199(4):543-551.

29. Jones KB, Jr., Afram JD, Benotti PN, et al. Open versus laparoscopic Roux-en-Y gastric bypass: a comparative study of over 25,000 open cases and the major laparoscopic bariatric reported series. *Obes Surg.* Jun 2006;16(6):721-727.

30. Lee WJ, Yu PJ, Wang W, Chen TC, Wei PL, Huang MT. Laparoscopic Roux-en-Y versus mini-gastric bypass for the treatment of morbid obesity: a prospective randomized controlled clinical trial. *Ann Surg.* Jul 2005;242(1):20-28.

31. Lujan JA, Frutos MD, Hernandez Q, et al. Laparoscopic versus open gastric bypass in the treatment of morbid obesity: a randomized prospective study. *Ann Surg.* Apr 2004;239(4):433-437.

32. Puzziferri N, Austrheim-Smith IT, Wolfe BM, Wilson SE, Nguyen NT. Three-year follow-up of a prospective randomized trial comparing laparoscopic versus open gastric bypass. *Ann Surg.* Feb 2006;243(2):181-188.

33. Encinosa WE, Bernard DM, Du D, Steiner CA. Recent improvements in bariatric surgery outcomes. *Med Care.* May 2009;47(5):531-535.

34. Choban PS, Flancbaum L. The effect of Roux limb lengths on outcome after Roux-en-Y gastric bypass: a prospective, randomized clinical trial. *Obes Surg.* Aug 2002;12(4):540-545.

35. Inabnet WB, Quinn T, Gagner M, Urban M, Pomp A. Laparoscopic Roux-en-Y gastric bypass in patients with BMI <50: a prospective randomized trial comparing short and long limb lengths. *Obes Surg.* Jan 2005;15(1):51-57.

36. Sjostrom L, Larsson B, Backman L, et al. Swedish obese subjects (SOS). Recruitment for an intervention study and a selected description of the obese state. *Int J Obes Relat Metab Disord.* Jun 1992;16(6):465-479.

37. Torgerson JS, Sjostrom L. The Swedish Obese Subjects (SOS) study--rationale and results. *Int J Obes Relat Metab Disord.* May 2001;25 Suppl 1:S2-4.

38. Sjostrom CD, Lissner L, Wedel H, Sjostrom L. Reduction in incidence of diabetes, hypertension and lipid disturbances after intentional weight loss induced by bariatric surgery: the SOS Intervention Study. *Obes Res.* Sep 1999;7(5):477-484.

39. Sjostrom L, Lindroos AK, Peltonen M, et al. Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *The New England journal of medicine.* Dec 23 2004;351(26):2683-2693.

40. Adams TD, Gress RE, Smith SC, et al. Long-term mortality after gastric bypass surgery. *The New England journal of medicine.* Aug 23 2007;357(8):753-761.

41. Busetto L, Mirabelli D, Petroni ML, et al. Comparative long-term mortality after laparoscopic adjustable gastric banding versus nonsurgical controls. *Surg Obes Relat Dis.* Sep-Oct 2007;3(5):496-502; discussion 502.

42. Christou NV, Sampalis JS, Liberman M, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. *Ann Surg.* Sep 2004;240(3):416-423; discussion 423-414.

43. Peeters A, O'Brien PE, Laurie C, et al. Substantial intentional weight loss and mortality in the severely obese. *Ann Surg.* Dec 2007;246(6):1028-1033.

44. Ashrafian H, le Roux CW. Metabolic surgery and gut hormones - a review of bariatric entero-humoral modulation. *Physiol Behav.* Jul 14 2009;97(5):620-631.

45. Spanakis E, Gragnoli C. Bariatric surgery, safety and type 2 diabetes. *Obes Surg.* Mar 2009;19(3):363-368.

46. Tadross JA, le Roux CW. The mechanisms of weight loss after bariatric surgery. *Int J Obes (Lond).* Apr 2009;33 Suppl 1:S28-32.

47. Vetter ML, Cardillo S, Rickels MR, Iqbal N. Narrative review: effect of bariatric surgery on type 2 diabetes mellitus. *Ann Intern Med.* Jan 20 2009;150(2):94-103.

48. Korner J, Bessler M, Cirilo LJ, et al. Effects of Roux-en-Y gastric bypass surgery on fasting and postprandial concentrations of plasma ghrelin, peptide YY, and insulin. *J Clin Endocrinol Metab.* Jan 2005;90(1):359-365.

49. Korner J, Bessler M, Inabnet W, Taveras C, Holst JJ. Exaggerated glucagon-like peptide-1 and blunted glucose-dependent insulinotropic peptide secretion are associated with Roux-en-Y gastric bypass but not adjustable gastric banding. *Surg Obes Relat Dis.* Nov-Dec 2007;3(6):597-601.

50. Korner J, Inabnet W, Conwell IM, et al. Differential effects of gastric bypass and banding on circulating gut hormone and leptin levels. *Obesity (Silver Spring, Md.* Sep 2006;14(9):1553-1561.

51. Korner J, Inabnet W, Febres G, et al. Prospective study of gut hormone and metabolic changes after adjustable gastric banding and Roux-en-Y gastric bypass. *Int J Obes (Lond).* Jul 2009;33(7):786-795.

52. le Roux CW, Aylwin SJ, Batterham RL, et al. Gut hormone profiles following bariatric surgery favor an anorectic state, facilitate weight loss, and improve metabolic parameters. *Ann Surg.* Jan 2006;243(1):108-114.

53. Rodieux F, Giusti V, D'Alessio DA, Suter M, Tappy L. Effects of gastric bypass and gastric banding on glucose kinetics and gut hormone release. *Obesity (Silver Spring, Md.* Feb 2008;16(2):298-305.

54. Kuzmak L. Gastric Banding. In: Deitel M, ed. *Surgery for the Morbidly Obese Patient*. Philadelphia: Lea & Febider; 1989:225-229.

55. Cadiere GB, Himpens J, Vertruyen M, Germay O, Favretti F, Segato G. Laparoscopic gastroplasty (adjustable silicone gastric banding). *Semin Laparosc Surg.* Mar 2000;7(1):55-65.

56. Cardon A, Berrevoet F, Pattyn P, Hesse U, de Hemptinne B. Alternative technique for creation of a proximal gastric pouch in laparoscopic adjustable silicone gastric banding. *Obes Surg.* Aug 1999;9(4):410-412.

57. DeMaria EJ. Laparoscopic adjustable silicone gastric banding. *Surg Clin North Am.* Oct 2001;81(5):1129-1144, vii.

58. Chevallier JM, Zinzindohoue F, Douard R, et al. Complications after laparoscopic adjustable gastric banding for morbid obesity: experience with 1,000 patients over 7 years. *Obes Surg.* Mar 2004;14(3):407-414.

59. Hell E, Miller KA, Moorehead MK, Norman S. Evaluation of health status and quality of life after bariatric surgery: comparison of standard Roux-en-Y gastric bypass, vertical banded gastroplasty and laparoscopic adjustable silicone gastric banding. *Obes Surg.* Jun 2000;10(3):214-219.

60. Kyzer S, Raziel A, Landau O, Matz A, Charuzi I. Use of adjustable silicone gastric banding for revision of failed gastric bariatric operations. *Obes Surg.* Feb 2001;11(1):66-69.

61. O'Brien P, Brown W, Dixon J. Revisional surgery for morbid obesity--conversion to the Lap-Band system. *Obes Surg.* Dec 2000;10(6):557-563.

62. Holloway JA, Forney GA, Gould DE. The Lap-Band is an effective tool for weight loss even in the United States. *Am J Surg.* Dec 2004;188(6):659-662.

63. Angrisani L, Lorenzo M, Borrelli V. Laparoscopic adjustable gastric banding versus Roux-en-Y gastric bypass: 5-year results of a prospective randomized trial. *Surg Obes Relat Dis.* Mar-Apr 2007;3(2):127-132; discussion 132-123.

64. Nguyen NT, Slone JA, Nguyen XM, Hartman JS, Hoyt DB. A Prospective Randomized Trial of Laparoscopic Gastric Bypass Versus Laparoscopic Adjustable Gastric Banding for the Treatment of Morbid Obesity: Outcomes, Quality of Life, and Costs. *Ann Surg.* Aug 27 2009.

65. Biertho L, Steffen R, Ricklin T, et al. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding: a comparative study of 1,200 cases. *J Am Coll Surg.* Oct 2003;197(4):536-544; discussion 544-535.

66. Bowne WB, Julliard K, Castro AE, Shah P, Morgenthal CB, Ferzli GS. Laparoscopic gastric bypass is superior to adjustable gastric band in super morbidly obese patients: A prospective, comparative analysis. *Arch Surg.* Jul 2006;141(7):683-689.

67. Cottam DR, Atkinson J, Anderson A, Grace B, Fisher B. A case-controlled matched-pair cohort study of laparoscopic Roux-en-Y gastric bypass and Lap-Band patients in a single US center with three-year follow-up. *Obes Surg.* May 2006;16(5):534-540.

68. Galvani C, Gorodner M, Moser F, et al. Laparoscopic adjustable gastric band versus laparoscopic Roux-en-Y gastric bypass: ends justify the means? *Surg Endosc.* Jun 2006;20(6):934-941.

69. Jan JC, Hong D, Bardaro SJ, July LV, Patterson EJ. Comparative study between laparoscopic adjustable gastric banding and laparoscopic gastric bypass: single-institution, 5-year experience in bariatric surgery. *Surg Obes Relat Dis.* Jan-Feb 2007;3(1):42-50; discussion 50-41.

70. Jan JC, Hong D, Pereira N, Patterson EJ. Laparoscopic adjustable gastric banding versus laparoscopic gastric bypass for morbid obesity: a single-institution comparison study of early results. *J Gastrointest Surg.* Jan 2005;9(1):30-39; discussion 40-31.

71. Kim TH, Daud A, Ude AO, et al. Early U.S. outcomes of laparoscopic gastric bypass versus laparoscopic adjustable silicone gastric banding for morbid obesity. *Surg Endosc.* Feb 2006;20(2):202-209.

72. Parikh MS, Laker S, Weiner M, Hajiseyedjavadi O, Ren CJ. Objective comparison of complications resulting from laparoscopic bariatric procedures. *J Am Coll Surg.* Feb 2006;202(2):252-261.

73. Parikh MS, Shen R, Weiner M, Siegel N, Ren CJ. Laparoscopic bariatric surgery in super-obese patients (BMI>50) is safe and effective: a review of 332 patients. *Obes Surg.* Jun-Jul 2005;15(6):858-863.

74. Rosenthal RJ, Szomstein S, Kennedy CI, Soto FC, Zundel N. Laparoscopic surgery for morbid obesity: 1,001 consecutive bariatric operations performed at The Bariatric Institute, Cleveland Clinic Florida. *Obes Surg.* Feb 2006;16(2):119-124.

75. Weber M, Muller MK, Bucher T, et al. Laparoscopic gastric bypass is superior to laparoscopic gastric banding for treatment of morbid obesity. *Ann Surg.* Dec 2004;240(6):975-982; discussion 982-973.

76. Desaive C. Surgery for morbid obesity. *Acta Chir Belg.* Sep-Oct 1996;96(5):192-196.

77. Kuzmak LI. A Review of Seven Years' Experience with Silicone Gastric Banding. *Obes Surg.* Dec 1991;1(4):403-408.

78. Morino M, Toppino M, Garrone C. Disappointing long-term results of laparoscopic adjustable silicone gastric banding. *Br J Surg.* Jun 1997;84(6):868-869.

79. Niville E, Dams A. Late pouch dilation after laparoscopic adjustable gastric and esophagogastric banding: incidence, treatment, and outcome. *Obes Surg.* Aug 1999;9(4):381-384.

80. Anderson PG, Watson DI. A new surgical technique for the silicone gastric band in the presence of a large hiatus hernia. *Obes Surg.* Apr 1999;9(2):202-204; discussion 204-205.

81. Chelala E, Cadiere GB, Favretti F, et al. Conversions and complications in 185 laparoscopic adjustable silicone gastric banding cases. *Surg Endosc.* Mar 1997;11(3):268-271.

82. Favretti F, Cadiere GB, Segato G, et al. Laparoscopic adjustable silicone gastric banding (Lap-Band): how to avoid complications. *Obes Surg.* Aug 1997;7(4):352-358.

83. Furbetta F, Gambinotti G, Robortella EM. 28-month experience with the lap-band technique: results and critical points of the method. *Obes Surg.* Feb 1999;9(1):56-58.

84. Lesti G, Graziani S, Lanci C, Cericola S, Sardellone A. Adjustable silicone gastric banding: use of the ultrasound technology in laparoscopic approach. *Obes Surg.* Feb 1999;9(1):65-67.

85. Anthone GJ, Lord RV, DeMeester TR, Crookes PF. The duodenal switch operation for the treatment of morbid obesity. *Ann Surg.* Oct 2003;238(4):618-627; discussion 627-618.

86. Livingston EH, Huerta S, Arthur D, Lee S, De Shields S, Heber D. Male gender is a predictor of morbidity and age a predictor of mortality for patients undergoing gastric bypass surgery. *Ann Surg.* Nov 2002;236(5):576-582.

87. Bennett W. Dietary treatments of obesity. *Ann N Y Acad Sci.* 1987;499:250-263.

88. Reinhold RB. Late results of gastric bypass surgery for morbid obesity. *J Am Coll Nutr.* Aug 1994;13(4):326-331.

89. Ramsey-Stewart G. Vertical banded gastroplasty for morbid obesity: weight loss at short and long-term follow up. *Aust N Z J Surg.* Jan 1995;65(1):4-7.

90. Nguyen NT, Goldman C, Rosenquist CJ, et al. Laparoscopic versus open gastric bypass: a randomized study of outcomes, quality of life, and costs. *Ann Surg.* Sep 2001;234(3):279-289; discussion 289-291.

91. Muller MK, Wenger C, Schiesser M, Clavien PA, Weber M. Quality of life after bariatric surgery--a comparative study of laparoscopic banding vs. bypass. *Obes Surg.* Dec 2008;18(12):1551-1557.

92. te Riele WW, Vogten JM, Boerma D, Wiezer MJ, van Ramshorst B. Comparison of weight loss and morbidity after gastric bypass and gastric banding. A single center European experience. *Obes Surg.* Jan 2008;18(1):11-16.

93. Lancaster RT, Hutter MM. Bands and bypasses: 30-day morbidity and mortality of bariatric surgical procedures as assessed by prospective, multi-center, risk-adjusted ACS-NSQIP data. *Surg Endosc.* Dec 2008;22(12):2554-2563.

94. Lindsey ML, Patterson WL, Gesten FC, Roohan PJ. Bariatric surgery for obesity: surgical approach and variation in in-hospital complications in New York State. *Obes Surg.* Jun 2009;19(6):688-700.

95. Ballantyne GH, Wasielewski A, Saunders JK. The Surgical Treatment of Type II Diabetes Mellitus: Changes in HOMA Insulin Resistance in the First Year Following Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) and Laparoscopic Adjustable Gastric Banding (LAGB). *Obes Surg.* Sep 2009;19(9):1297-1303.

96. Lee H, Kim D, Lee S, Nam K, Kim E. Initial Evaluation of Laparoscopic Roux-en-Y Gastric Bypass and Adjustable Gastric Banding in Korea: A Single Institution Study. *Obes Surg.* Apr 29 2008.

97. Lee WJ, Chong K, Lee YC, et al. Effects of obesity surgery on type 2 diabetes mellitus Asian patients. *World J Surg.* Sep 2009;33(9):1895-1903.

98. Lee WJ, Lee YC, Ser KH, Chen JC, Chen SC. Improvement of insulin resistance after obesity surgery: a comparison of gastric banding and bypass procedures. *Obes Surg.* Sep 2008;18(9):1119-1125.

99. Longitudinal Assessment of Bariatric Surgery C, Flum DR, Belle SH, et al. Perioperative safety in the longitudinal assessment of bariatric surgery. *The New England journal of medicine.* Jul 30 2009;361(5):445-454.

100. Mognol P, Chosidow D, Marmuse JP. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding in the super-obese: a comparative study of 290 patients. *Obes Surg.* Jan 2005;15(1):76-81.

101. Bende J, Ursu M, Csiszar M. Initial experience with laparoscopic adjustable gastric banding in Hungary. *Obes Surg.* Feb 2004;14(2):236-238.

102. Blanco-Engert R, Weiner S, Pomhoff I, Matkowitz R, Weiner RA. Outcome after laparoscopic adjustable gastric banding, using the Lap-Band and the Heliogast band: a prospective randomized study. *Obes Surg.* Oct 2003;13(5):776-779.

103. Colquitt JL, Picot J, Loveman E, Clegg AJ. Surgery for obesity. *Cochrane Database Syst Rev.* 2009(2):CD003641.

104. Cunneen SA. Review of meta-analytic comparisons of bariatric surgery with a focus on laparoscopic adjustable gastric banding. *Surg Obes Relat Dis.* May-Jun 2008;4(3 Suppl):S47-55.

105. Cunneen SA, Phillips E, Fielding G, et al. Studies of Swedish adjustable gastric band and Lap-Band: systematic review and meta-analysis. *Surg Obes Relat Dis.* Mar-Apr 2008;4(2):174-185.

106. Farrell TM, Haggerty SP, Overby DW, Kohn GP, Richardson WS, Fanelli RD. Clinical application of laparoscopic bariatric surgery: an evidence-based review. *Surg Endosc.* May 2009;23(5):930-949.

107. Picot J, Jones J, Colquitt JL, et al. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. *Health Technol Assess.* Sep 2009;13(41):1-190, 215-357, iii-iv.

108. Tice JA, Karliner L, Walsh J, Petersen AJ, Feldman MD. Gastric banding or bypass? A systematic review comparing the two most popular bariatric procedures. *Am J Med.* Oct 2008;121(10):885-893.

109. Treadwell JR, Sun F, Schoelles K. Systematic review and meta-analysis of bariatric surgery for pediatric obesity. *Ann Surg.* Nov 2008;248(5):763-776.

110. Garb J, Welch G, Zagarins S, Kuhn J, Romanelli J. Bariatric Surgery for the Treatment of Morbid Obesity: A Meta-analysis of Weight Loss Outcomes for Laparoscopic Adjustable Gastric Banding and Laparoscopic Gastric Bypass. *Obes Surg.* Aug 5 2009.

111. Buchwald H, Estok R, Fahrbach K, et al. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. *Am J Med.* Mar 2009;122(3):248-256 e245.

112. Fielding GA, Rhodes M, Nathanson LK. Laparoscopic gastric banding for morbid obesity. Surgical outcome in 335 cases. *Surg Endosc.* Jun 1999;13(6):550-554.