



LAPAROSCOPIC ADJUSTABLE SILICONE GASTRIC BANDING FOR MORBID OBESITY

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum 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 June 9, 2004, the Forum concluded that there was insufficient evidence to conclude that the benefits of LAGB outweigh the harms when compared with RYGB. The primary concern focused on uncertainty regarding the intermediate to long-term complication rate following placement of the LAGB. Since the last review, a number of comparative studies have been published, but there have not been any 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/m², class 2 obesity as BMI > 35 , and class 3 (severe, previously termed morbid) obesity as a BMI ≥ 40 kg/m² or > 35 with comorbidities. Patients with a BMI > 50 kg/m² 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



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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/m² 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/m²). 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 These secular trends highlight the need for a high quality evidence base for advising patients and



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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.¹⁸ 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 populations¹⁹:

- Patients with a BMI >40 kg/m²
- Patients with a BMI >35 kg/m² who also have serious medical problems, (diabetes, obstructive sleep apnea) that would improve with weight loss.

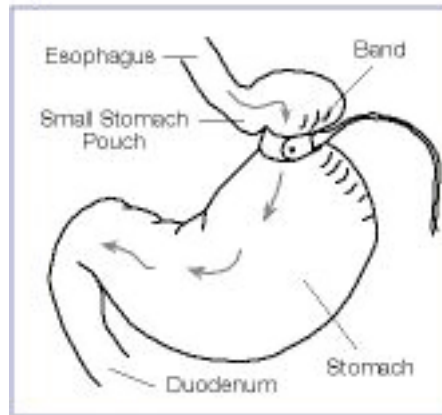
All patients must have failed sustained weight loss programs, have acceptable operative risk, and be committed to life-long follow-up.

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.

Restrictive procedures

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.

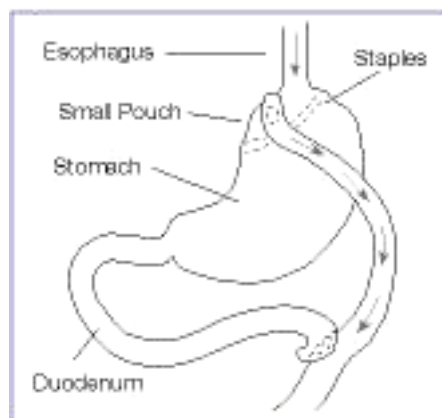
Figure 1: Adjustable gastric banding



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 outlet²⁰. 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).²¹.
²² 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



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and surgical volume.^{23, 24} Clinical trials also suggest that performing RYGB laparoscopically may reduce length of stay and some long-term risks with equivalent outcomes, although this is controversial.²⁵⁻²⁸

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.^{29, 30} 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, and calcium) and the dumping syndrome. Rapid gastric emptying, or dumping syndrome, happens when the jejunum fills quickly with undigested food from the stomach. Symptoms such as nausea, vomiting, bloating, diarrhea, and shortness of breath may occur within minutes of a meal. This happens most commonly when the patient consumes refined carbohydrates and concentrated sweets. Thus, some advocates 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-up¹²⁻¹⁵. 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^{31, 32}. 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 AGB)³³. The investigators have published ten year results with weight loss outcomes significantly greater for gastric bypass compared with banding at all time points.³⁴ 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 concentrations³³. In continued follow-up of these patients, the initial reduction in blood pressure gradually returned to baseline by the third to fourth year post-operatively³⁵.

Adjustable gastric banding

Adjustable gastric banding for treatment of morbid obesity placed by laparotomy was developed by Kuzmak in 1983.³⁶ A device designed to be placed laparoscopically, the LAP-BAND® Adjustable Gastric Banding System (LAGB) (BioEnterics, Carpinteria, CA), was introduced in 1993. Laparoscopic placement is intended to reduce postoperative complications and the length of hospital stay.²⁰

The LAP-BAND® 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 (LAP-BAND® Product Information, 2004). 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^{37, 38} 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



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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.³⁹

Surgeons planning laparoscopic placement of the adjustable gastric banding system are required to have extensive prior experience with laparoscopic surgery and to undergo training by the manufacturer (LAP-BAND[®] Product Information, 2001). Several studies have documented an important learning curve when using the device. Results among patients treated at high-volume centers improve over time: after several hundred implantations the procedures usually have far fewer associated complications than those of the first 50 to 100 cases.

Advantages of a laparoscopic LAGB compared with open LAGB 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.^{20, 40} 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.³⁸ In some instances, the procedure can also be used for revision of failed RYGP or vertical banded gastroplasty.^{41, 42}

Potential disadvantages to laparoscopic LAGB include the occurrence of significant complications and adverse events, sometimes necessitating removal of the device.^{20, 38} 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. An extensive listing of contraindications, warnings, and precautions relating to the Lap Band system are listed on pages three through six of the product information provided by the manufacturer (LAP-BAND[®] Product Information). 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.⁴³ The requirement for active surveillance and adjustment of the band is rarely mentioned in the literature promoting LAGB as a less invasive and completely reversible alternative to RYGB.

TECHNOLOGY ASSESSMENT (TA)

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



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On June 5, 2001, the FDA approved a premarket approval application for the LAP-BAND® Adjustable Gastric Banding (LAGB) System (BioEnterics Corporation, Carpentaria, CA). This device is indicated “for use in weight reduction for severely obese patients with a Body Mass Index (BMI) of at least 40, or a BMI of at least 35, with one or more severe comorbid conditions, or those who are 100 lbs. or more over their estimated ideal weight according to the 1983 Metropolitan Life Insurance Table. It is indicated for use only in severely obese adult patients who have failed more conservative reduction alternatives, such as supervised diet, exercise and behavior modification programs.” As part of its approval, the FDA is requiring annual reports on a post-approval study by the manufacturer to gather long-term safety and effectiveness data on the device, including five year follow-up data on subjects enrolled in a multi-center evaluation of the device.

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 performed for the period from 1966 through January 2007. 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

Ideally, the primary outcomes to be evaluated 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 weight lost; band tolerance; and 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. First the patient’s excess weight at baseline is calculated as the difference between their weight and



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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 surgical result 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/m², "good" between 30 and 35 kg/m², "fair" from 35 to 40 kg/m², and "poor" if >40 kg/m². While resolution of comorbidities associated with severe obesity is probably the most important outcome variable to assess in clinical trials, most investigators (and patients) primarily focus on reductions in excess weight as the key outcome.

The literature search identified more than 60 case series of LAGB reporting on more than 20,000 patients^{37, 39, 44-9143, 92-121} and 12 comparative trials comparing LAGB to RYGB.^{40, 122-132} One additional comparative trial did not report weight loss outcomes or complications and was not included in this review.¹³³ There are no randomized trials comparing these two procedures although there have been many randomized trials comparing different approaches to RYGB, comparing RYGB to other bariatric procedures, and comparing LAGB to other bariatric procedures. Given the large numbers of trials and concerns about unrepresentative data from centers with limited experience with the procedure, we have limited this review to the 12 comparative studies (Tables 1-5) and to the case series of LAGB describing the outcomes for a minimum of 500 patients (Tables 6-10). For comparison purposes, we also describe the results of case series of laparoscopic RYGB (Tables 11-15) because laparoscopic RYGB arose in popularity about the same time as LAGB. Because there were fewer large case series of laparoscopic RYGB, we included series that described at least 250 patients.

TA criterion 2 is met.

Levels of Evidence: 1, 2, 3



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TABLE 1: Characteristics of the Studies Comparing LAGB to RYGB

Study	Design	Arm	N	Age, years	BMI, kg/m ²	Follow-up, months	Quality	Comments
Hell 2000	Retrospective, no matching.	LAGB	30	36	47	40	Poor	Comparison in different countries
		RYGB	30	41	45	60		
Biertho 2003	Retrospective, no matching	LAGB	805	42	42	NR	Poor	Comparison in different countries
		RYGB	456	40	49			
Weber 2004	Matched on age, sex, BMI	LAGB	103	40	48	42	Fair	
		RYGB	103	40	48	18		
Jan 2005	Retrospective, no matching	LAGB	154	46	51	NR, <24	Poor	
		RYGB	219	42	50			
Parikh 2005	Retrospective, no matching, BMI>50	LAGB	197	43	55	NR, <24	Poor	
		RYGB	97	42	55			
Bowne 2006	Retrospective, no matching, BMI>50	LAGB	60	42	55	18	Poor	
		RYGB	46	43	57	13		
Cottam 2006	Matched on age, sex, BMI, date of surgery	LAGB	181	42	47	NR, 23% at 36+ months	Fair	
		RYGB	181	43	47			
Galvani 2006	Retrospective, no matching	LAGB	470	41	47	NR	Poor	
		RYGB	120	41	46			
Kim 2006	Retrospective, no matching	LAGB	160	42	47	NR	Poor	
		RYGB	232	39	47			
Parikh 2006	Retrospective, no matching	LAGB	480	42.5	46	12	Poor	
		RYGB	235	41	47	12		
Rosenthal 2006	Retrospective, no matching	LAGB	152	54	40	77% with "complete" FU	Poor	
		RYGB	849	47	56			
Jan 2007	Retrospective, no matching	LAGB	406	47	51	~12	Poor	
		RYGB	492	44	49	~16		



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



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

Study	Arm	N	DM	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	-	-	-	-	-	-	-

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



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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	-

* 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.



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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

* 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.



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TABLE 6: Characteristics of the Large Case Series of LAGB (N≥500)

Study	N	Age, years	BMI, kg/m ²	Follow-up, months	Comments
Dargent 1999	500	36	44	28	
Cadiere 2000	652	40	45	"24"	
Angrisani 2001	1265	38	44	"48"	
Szold 2001	715	38	44	17	
Belachew 2002	763	34	42	>48	
Favretti 2002	830	38	46	"84"	
O'Brien 2002	709	41	45	"72"	
Vertruyen 2002	543	41	44	36	
Angrisani 2003	1893	38	44	"around 70% at 5 years"	
Ceelen 2003	625	36	40	20	Swedish band
Steffen 2003	824	43	43	"60"	Swedish band
Weiner 2003	984	38	47	55	
Zinzindohoue 2003	500	40	44	13	
Angrisani 2004	573	38	44	60	
Chevallier 2004	1111	40	44	"84"	Focus on complications
Dargent 2004	1180	40	43	NR approx 24	
Holloway 2004	504	45	49	NR approx 15	
Biertho 2005	824	43	42	40	Swedish band. Likely same as Steffen above.
Keider 2005	2134	38	44	37 60%	Focused on port complications
Ponce 2005	1014	42	48	NR approx 18	Focus on complications



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TABLE 7: Percentage Excess Body Weight Lost in the Large Case Series of LAGB (N≥500)

Study	N	Year 1		Year 2		Year 3		Comments
		EBWL, %	FU, %	EBWL, %	FU, %	EBWL, %	FU, %	
Dargent 1999	500	56	54	65	19	64	4	
Cadiere 2000	652	38	-	62	-	-	-	
Angrisani 2001	1265	-	-	-	-	-	-	
Szold 2001	715	-	-	-	-	-	-	
Belachew 2002	763	40	-	50	-	60	-	66 - 5 years
Favretti 2002	830	-	-	-	-	-	-	
O'Brien 2002	709	47	69	53	47	53	39	54 5 5 years
Vertruyen 2002	543	38	-	61	-	62	-	53 - 5 years
Angrisani 2003	1893	-	-	-	-	-	-	
Ceelen 2003	625	46	-	50	-	47	-	
Steffen 2003	824	30	99	41	90	49	72	57 22 5 years
Weiner 2003	984	54	-	-	-	-	-	54 10 8 years
Zinzindohoue 2003	500	43	69	52	37	55	9	
Angrisani 2004	573	-	-	-	-	-	-	55 67 5 years
Chevallier 2004	1111	-	-	-	-	-	-	
Dargent 2004	1180	49	59	46	49	57	37	54 16 5 years
Holloway 2004	504	50	62	61	24	65	8	
Biertho 2005	824	30	99	42	90	48	72	55 22 5 years
Keider 2005	2134	-	-	-	-	-	-	
Ponce 2005	1014	40	67	53	24	62	7	



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TABLE 8: Resolution of Comorbidities among Patients in the Large Case Series of LAGB (N≥500)*

Study	N	DM	HTN	Dyslipidemia	OSA	GERD	Arthritis	Asthma
Dargent 1999	500	-	-	-	-	-	-	-
Cadiere 2000	652	-	-	-	-	-	-	-
Angrisani 2001	1265	-	-	-	-	-	-	-
Szold 2001	715	-	-	-	-	-	-	-
Belachew 2002	763	-	-	-	-	-	-	-
Favretti 2002	830	-	-	-	-	-	-	-
O'Brien 2002	709	-	-	-	-	-	-	-
Vertruyen 2002	543	-	-	-	-	-	-	-
Angrisani 2003	1893	-	-	-	-	-	-	-
Ceelen 2003	625	55	39	-	-	-	71	-
Steffen 2003	824	-	-	-	-	-	-	-
Weiner 2003	984	92	50	-	85	-	55	64
Zinzindohoue 2003	500	-	-	-	-	-	-	-
Angrisani 2004	573	-	-	-	-	-	-	-
Chevallier 2004	1111	-	-	-	-	-	-	-
Dargent 2004	1180	-	-	-	-	-	-	-
Holloway 2004	504	-	-	-	-	-	-	-
Biertho 2005	824	-	-	-	-	-	-	-
Keider 2005	2134	-	-	-	-	-	-	-
Ponce 2005	1014	-	-	-	-	-	-	-

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



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TABLE 9: Percentage of Patients with Short-term Complications (30-day) in the Large Case Series of LAGB (N≥500)

Study	N	Death	Perforation	Conversion	VTE	MI/CHF	Bleed	Infxn	Slip	Pulm.
Dargent 1999	500	0	0.2	1.9	-	-	-	-	-	-
Cadiere 2000	652	0.2	0.3	3.8	0	0.2	-	0.6	-	-
Angrisani 2001	1265	0.6	0.4	1.7	0.2	0.2	0.4	0	-	-
Szold 2001	715	0	0.4	0.8	0	0	0.7	0.4	-	-
Belachew 2002	763	0.1	0.6	1.3	-	-	0.1	0.1	-	-
Favretti 2002	830	0	0.1	2.7	-	-	-	-	-	-
O'Brien 2002	709	0	0.3	1.0	0.3	0.7	-	3.4	-	-
Vertruyen 2002	543	0	1.3	1.1	0.2	0.4	0.2	-	-	-
Angrisani 2003	1893	0.4	0.4	3.1	-	-	0.7	-	-	-
Ceelen 2003	625	0	0.2	0.3	-	-	1.1	2.2	-	-
Steffen 2003	824	0	0.1	5.2	0.1	-	1.2	-	-	-
Weiner 2003	984	0	0.1	0	-	-	0.2	0.4	0.1	-
Zinzindohoue 2003	500	0	0.8	2.4	-	1.4	2.6	-	-	-
Angrisani 2004	573	0.6	-	-	-	-	-	-	-	-
Chevallier 2004	1111	0	0.4	1.2	0.2	-	-	-	0.3	1.3
Dargent 2004	1180	0	-	0.4	0.3	-	-	1.1	0.4	0.5
Holloway 2004	504	0	-	0.4	-	-	-	-	-	-
Biertho 2005	824	0	-	8.3	-	-	-	-	-	-
Keider 2005	2134	-	-	-	-	-	-	-	-	-
Ponce 2005	1014	0	0.4	0.1	-	-	-	0.6	-	-



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TABLE 10: Percentage of Patients with Long-term Complications (>30 days post-procedure) in the Large Case Series of LAGB (N≥500)

Study	N	Total	Death	Reoperation	Slip/Dil	Erosion	Obstruction	Port/Tube	IH
Dargent 1999	500	-	-	7.0	1.3	0.6	-	2.5	-
Cadiere 2000	652	-	-	4.4	3.8	0.3	-	2.7	-
Angrisani 2001	1265	-	-	3.2	5.2	1.9	-	4.3	-
Szold 2001	715	-	-	10	9.5	0.4	-	2.5	0.1
Belachew 2002	763	-	-	11	8.0	0.9	-	2.5	0
Favretti 2002	830	-	-	3.9	10	0.5	-	-	-
O'Brien 2002	709	-	-	19	13	2.8	-	3.6	-
Vertruyen 2002	543	-	-	5.9	4.6	0.9	-	2.8	-
Angrisani 2003	1893	-	0.1	4.2	4.9	1.1	-	4.2	-
Ceelen 2003	625	-	-	8.2	5.6	0	1.6	2.6	0.8
Steffen 2003	824	23.2	0.4	2.1	2.7	1.6	-	6.4	-
Weiner 2003	984	-	0	3.7	4.8	-	-	2.6	-
Zinzindohoue 2003	500	-	-	10	8.6	0	-	7.2	0.6
Angrisani 2004	573	-	0.4	5.6	-	-	-	-	-
Chevallier 2004	1111	19	0	11	10	4	5	5.7	0.4
Dargent 2004	1180	-	-	13	9	2	-	-	-
Holloway 2004	504	19	0.2	-	-	-	-	-	-
Biertho 2005	824	-	0.4	15	4.1	2.1	-	-	-
Keider 2005	2134	-	-	-	-	-	-	7.1	-
Ponce 2005	1014	-	-	4.8	2.3	0.2	-	0.5	-



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TABLE 11: Characteristics of the Large Case Series of Laparoscopic RYGB (N≥250)

Study	N	Age, years	BMI, kg/m ²	Follow-up, months	Comments
Schauer 2000	275	42	48	9	
Wittgrove 2000	500	NR	NR	60	
Higa 2001	1500	43	46	36	
Blachar 2002	463	45	NR 130 kg	NR	Focused on complications, overlap with Schauer
Champion 2002	743	~39	~54	~41	Focused on peri-operative complications, not outcomes
DeMaria 2002	281	42	48	<12	
Gould 2002	304	41	49	12	
Smith 2004	328	41	47		
Fernandez 2004	580	42	49	NR	
Hutter 2006	401	41	48	30 days	Focused on 30-day mortality



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TABLE 12: Percentage Excess Body Weight Lost in the Large Case Series of Laparoscopic RYGB (N≥250)

Study	N	Year	1	Year	2	Year	3	Comments
		%EBWL	%FU	%EBWL	%FU	%EBWL	%FU	
Schauer 2000	275	69	37	83	7	-	-	
Wittgrove 2000	500	77	>80%	80	-	75	18	80 NR 5 years
Higa 2001	1500	69	38	69	3	62	1	
Blachar 2002	463	-	-	-	-	-	-	-
Champion 2002	743	-	-	-	-	-	-	
DeMaria 2002	281	70	25	-	-	-	-	
Gould 2002	304	56	7	-	-	-	-	Minimal follow-up
Smith 2004	328	-	35	-	-	-	-	
Fernandez 2004	580	-	-					
Hutter 2006	401	-	-					



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TABLE 13: Resolution of Comorbidities among Patients the Large Case Series of Laparoscopic RYGB (N≥250)*

Study	N	DM	HTN	Dyslipidemia	OSA	GERD	Arthritis	Asthma
Schauer 2000	275	82	70	63	74	72	41	13
Wittgrove 2000	500	98	92	97	98	98	90	-
Higa 2001	1500	-	-	-	-	-	-	-
Blachar 2002	463	-	-	-	-	-	-	-
Champion 2002	743	-	-	-	-	-	-	-
DeMaria 2002	281	88	52	-	-	95	76	-
Gould 2002	304	-	-	-	-	-	-	-
Smith 2004	328	-	-	-	-	-	-	-
Fernandez 2004	580	-	-	-	-	-	-	-
Hutter 2006	401	-	-	-	-	-	-	-

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



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TABLE 14: Percentage of Patients with Short-term Complications (30-day) in the Large Case Series of Laparoscopic RYGB (N≥250)

Study	N	Total	Death	Perforation	Conversion	Leak	VTE	Card	Bleed	Infxn	GB	Pulm
Schauer 2000	275	3.3	0.4	0.7	1.1	2.9	0.7	0	3.3	8.7	0	5.8
Wittgrove 2000	500	-	0	-	Excluded	2.2	-	0	0.8	4.8	-	1.4
Higa 2001	1500	-	0.1	0.2	1.3	1.0	0.5	0.4	0.6	0.1	-	-
Blachar 2002	463	5.2	0.2	-	-	5.8	-	-	-	-	1.7	-
Champion 2002	743	-	0	-	0.1	0.4	-	-	0	-	-	-
DeMaria 2002	281	-	0	-	2.8	5.1	1.1	-	-	-	-	-
Gould 2002	304	5.6	0	-	-	1.8	0.7	0.3	0.7	7.6	-	1.0
Smith 2004	328	-	0	1.5	-	-	0.3	0.3	4.9	1.2	-	0.3
Fernandez 2004	580	-	0.7	-	-	4.1	1.0	-	-	-	-	-
Hutter 2006	401	7.0	0	-	-	-	0	0.3	3.5	0.3	-	3.2



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TABLE 15: Percentage of Patients with Long-term Complications (>30 days post-procedure) in the Large Case Series of Laparoscopic RYGB (N≥250)

Study	N	Total	Death	Reoperation	Marg. Ulcer	Stricture	Vitamin Deficiency	Malnutr.	Chole	IH
Schauer 2000	275	-	0	9.8	0.7	4.7	24	0.4	1.5	0.7
Wittgrove 2000	500	-	0	3.0	-	1.6	-	-	-	0
Higa 2001	1500	-	0.4	2.3	1.4	5.6	-	-	1.4	2.5
Blachar 2002	463	6.9	0.2	-	0.4	3.2	-	-	-	-
Champion 2002	743	-	0	-	-	0	-	-	-	-
DeMaria 2002	281	-	0	-	5.1	-	-	-	-	1.8
Gould 2002	304	-	0	-	0.9	5.5	-	-	-	0.9
Smith 2004	328	-	0	-	-	12	-	-	2.4	0
Fernandez 2004	580	-	0	-	-	-	-	-	-	-
Hutter 2006	401	-	0	4.2	-	-	-	-	-	-

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 needing reversal and/or conversion.^{36, 79, 134-136} This led to a series of modifications of the surgical technique.^{38, 57, 71, 137-139}

Case series

Tables 6 through 10 summarize the results from the 20 case series of LAGB that included more than 500 patients. More than 12,000 patients are included in these studies, although there is some overlap between them. For example, the 824 patients in the Steffen and Biertho series^{140, 141} appear to be the same patients, the 500 patients in the original 1999 report of Dargent⁶⁰ are probably included in the 1180 patients in the 2004 report.⁹³ and the Angrisani reports are all from the same registry.^{47, 48, 50, 142} Patients in these trials were about 40 years of age and had a mean BMI of approximately 45 kg/m². The length of follow-up was inconsistently reported across the studies. Often long-term follow-up was claimed, but less than 20% of patients in the case series would actually have data available at long-term follow-up. When available, the percentage of patients contributing data at yearly follow-up intervals is listed in Table 7. Less than half of the studies reported the percentage follow-up at one year. Patients lost to follow-up are particularly concerning after implantation of the LAGB as continued weight loss usually requires regular adjustment of the size of the band. Patients lost to follow-up may represent patients with inadequate weight loss or patients who have suffered significant complications from the band. At later time points, the relatively low follow-up simply reflects the small numbers of patients in the series eligible for follow-up. However, the authors often present their results in terms that suggest nearly complete follow-up. For example, Weiner et al¹⁴³ in their case



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series of 984 patients state “at eight years after starting LAGB, 97% of the 984 patients were able to be examined.” However, they report weight loss outcomes after approximately eight years on only 100 patients. Variable length of follow-up is particularly concerning when trying to evaluate the rate of late complications. The same authors suggest that after their learning curve, the rate of complications decreased markedly. They compare the prevalence of long-term complications (band migration or slippage, port revisions, band removal) in their first 100 patients (26%) to the prevalence in patients 701-800 (9%) and point to the “obvious decrease in complications after the learning curve.” However, the first group had eight years to accumulate complications, while the latter group only had two to three years of follow-up. The incomplete reporting of follow-up and the variable length of follow-up for patients in each series makes it difficult to compare or pool long-term results across the studies.

Excess body weight lost

Table 7 summarizes the weight loss outcomes of the 20 case series. At one year, the percentage of EBWL following LAGB ranged from 30% to 56%. The study with the most complete follow-up (99%)^{140, 141} reported 30% EBWL at one year, while the study reporting the greatest EBWL at one year had only 54% follow-up at that time point.⁶⁰ Longer term weight loss outcomes are less certain. Most studies find that weight loss is slower with LAGB than with RYGB and takes about two years to reach maximal loss. Unfortunately, only two studies reported greater than 50% follow-up for outcomes greater than one year after surgery. In Steffan et al¹⁴¹, the EBWL increases from 30% at one year to 49% at three years. Angrisani et al¹⁴² had 67% follow-up after five years and reported 55% EBWL at that time point. A pattern of increasing weight loss over the first several years after implantation of the LAGB is often reported, but the poor follow-up in most series has led many to question the validity of the results. For instance, a recent systematic review of all of the reports of weight loss following LAGB reported pooled EBWL outcomes at one, three and five years to be 42%, 54.8% and 55.2%, but the percentage of patients with LAGB in the studies who contributed data at each of the time points were 44%, 31%, and 6.4%.¹⁴⁴ Even given the uncertainties about the degree of long-term weight loss, it is clearly much greater than that achieved by diet or any of the weight loss medications¹² and appears to be stable for at least five years.

Improvements in co-morbidities

A more important question is whether this weight loss is associated with the prevention or resolution of morbidities associated with obesity. Unfortunately, few of these large case series reported these key outcomes (Table 8). Ceelen et al reported that the co-morbidities resolved in 55% of the patients with diabetes in their series and in 39% of patients with hypertension.⁵⁶ Weiner et al reported even better results with resolution of diabetes in 92%, hypertension in 50% and obstructive sleep apnea in 85%.¹⁴³ These



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outcomes were more fully explored in some of the smaller case series, although the absolute numbers of patients with any of the co-morbidities was relatively small. Frigg et al⁶⁹ presented their results on 295 patients with an average BMI of 45 kg/m² who were treated with LAGB. EBWL was 40% at one year and 46% at two years follow-up. Patients with the following obesity-related co-morbidities had complete resolution of their disease: diabetes 75%, hypertension 58%, sleep apnea 75%, dyspnea 85%, and esophageal reflux 79%. Spivak et al¹¹⁵ had a similar 40% to 43% EBWL in 271 patients, but reported lower rates of disease remission: diabetes 29%, hypertension 40%, sleep apnea 38%, and esophageal reflux 82%. The second US trial approved by the FDA¹¹⁴ also reported on comorbidities. The trial was smaller (n=63) and reported EBWL to be 38% at one year and 47% at two years. Diabetes resolved or improved in 84% of patients, hypertension in 45%, and sleep apnea in 100%. Finally, two very small trials also reported on obesity related diseases. O'Brien et al⁴² reported a series of 28 patients undergoing revision of other obesity surgeries by conversion to open LAGB. Weight loss of 47% of excess weight had occurred at three year follow-up, and a number of comorbidities were markedly improved: five out of 12 patients became normotensive, six out of 11 patients resolved their gastroesophageal reflux symptoms, ten out of 11 patients resolved their sleep apnea, and mean plasma triglyceride and HDL cholesterol levels improved significantly. Abu-Abeid et al⁴⁵ reported on resolution of chronic medical conditions after laparoscopic LAGB performed in 18 patients 60 years or older. The BMI dropped from 44.2 to 30.5 kg/m², and comorbid conditions improved markedly: diabetes mellitus resolved in 71% of the patients, hypertension in 33%, and sleep apnea in 100%.

Patient Risks

The product information (LAP-BAND[®] Product Information, 2004) indicates that in the manufacturer-sponsored trial, the following “all (mild, moderate, severe) adverse events” occurred: nausea and/or vomiting (51%), gastroesophageal reflux (34%), stoma obstruction (14%), dysphagia (9%), abdominal pain (27%), incisional infection (7%), hernia (5%), incisional pain (5%), band slippage and pouch dilatation (24%), port site pain (9%), and port displacement (6%). In addition, the following “serious adverse events” are listed by the manufacturer: band slippage and pouch dilatation (11%), gastroesophageal reflux (3%), nausea and/or vomiting (2%), esophageal dilatation (2%), obstruction of the stoma (8%), infection (2%), deflation of the band due to leakage (2%), band erosion into the stomach (1%), abdominal pain (1%), hernia (1%), dysphagia (1%), and perforation of the stomach (1%). No deaths were reported.

In addition, 27 revision procedures involving 26 subjects (9%) occurred. In nine of the 27 procedures the band was removed and replaced with a new band, and in 16, the procedures were performed to correct band slippage and pouch dilatation (LAP-BAND[®] Product Information, 2004). Of more concern, ultimately 75 (25%) of the 299 subjects in the multicenter trial had their entire LAP-BAND[®] systems removed, 51 as



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countermeasures to adverse events in particular band slippage and pouch dilatation and/or stoma obstruction, gastric erosion, and infection. Insufficient weight loss was also reported as a contributor to the decision to explant 24 of the 75 devices removed (LAP-BAND[®] Product Information, 2004). At one of the multicenter trial sites, investigators following 36 laparoscopic LAGB patients reported removing 42% of the devices that they had implanted because of esophageal dilatation, inadequate weight loss, and other reasons (DeMaria, 2000).

Early complications

The majority of the large case series reported short-term complication rates including peri-operative complications and any significant health outcomes in the first 30 days following the procedure, although these outcomes were not always systematically collected and reported (Table 9). Early mortality was consistently less than one percent and pooling the results gives an overall 30-day mortality rate of 0.1%. The rate of conversion to an open procedure ranged from zero percent to 8.3%. The most common reason for open conversion was an enlarged, fatty liver. Many of the centers report routine supervised fasting of patients for several weeks prior to the procedure in order to decrease the liver size and minimize the need for open conversion. Other perioperative complications, such as gastric perforation, splenic injury, and cardiopulmonary complications also were acceptably low, although not always reported.

Late complications

Uncertainty about the incidence of long-term complications is the primary concern raised by critics of LAGB (Table 10). Several studies have reported summary rates of long-term complications as high as 19% to 23%,^{43, 58, 145} but these often include minor complications. Reported long-term mortality rates are low, but need to be compared to matched controls to evaluate whether these are reasonable. The Scandinavian Obesity Study^{31, 34}, described above, is the only study designed to evaluate whether bariatric surgery has long-term mortality benefits. Those results should be available shortly, but will not have sufficient power to evaluate differences between surgical techniques.

Reoperation rates have been low in some large series, varying between four percent and 11%.^{50, 58, 64, 121, 146} However, other studies have reported much higher rates, varying between 19% and 42%.^{20, 39, 114, 120, 147} Most centers with high reoperation rates reported on very few procedures and were likely in the early, steep part of the learning curve with a new procedure. The largest case series tend to report the lowest rates of both complications and reoperations. Reoperation rates varied from 2.1% to 19% across the largest series (Table 10). Variable length of follow-up and the lack of systematic collection and reporting of outcomes make these numbers difficult to interpret. It is interesting to note that the rate of reoperation in one series



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increased from 2.1% in the initial report of five year outcomes¹⁴¹ to 15% in the most recent report on five year outcomes.¹⁴⁰ Even in the later report only 184 patients (22% of the case series) contributed data in the fifth year of follow-up. In this report, the investigators carefully reported the rates of band complications by year of follow-up and accounted for the number of patients contributing data in each time interval. The number of band complications per year increased from 2.9% in the first year to 6.7% in the second year before decreasing to 3.2% in the fifth year. The rate of major reoperations for band-related complications increased from 2.2% in the first year and peaked at 6.6% in the fourth year. Over the full five years of follow-up the average rate of band complications was 5.0% per year and the rate of reoperations was 4.7% per year. The most common band complications in this study were band intolerance, band leakage, and band slippage. Examples of complications from several other studies are described below.

Chevalier et al⁵⁸ published data on complications in one of the large case series. 896 women and 104 men with a mean age 40.4 years (16.3-66.3) underwent LAGB. Preoperative mean BMI was 44.3 kg/m². There were no deaths. Cumulative rate of complications was 192 (19.2%). 12 were life-threatening (1.2%): gastric perforation (n=4), acute respiratory distress (n=2), pulmonary embolism (n=2), migration (n=3), and gastric necrosis (n=1). 111 patients required an abdominal reoperation (11.1%) for perforation (n=2), slippage (n=78), migration (n=3), necrosis (n=1), esophageal dilatation (n=2), incisional hernias (n=4) and port problems (n=21). The authors note that the complication rate was high during the first four years of use of LAGB, but subsequently decreased with surgical experience and use of the pars flaccida approach.

Another large case series reported safety data on 1893 patients who underwent LAGB at 27 Italian centers.⁵⁰ There were 1534 women and 359 men with a mean BMI of 44 (range 30.4-83.6) and a mean age of 37.8 +/- 10.9 years (range; 17-74). The mortality rate was 0.53% (n = 10), mainly due to cardiovascular complications (myocardial infarction, pulmonary embolism). The conversion rate to open laparotomy was 3.1% (59/1893) and was higher in super obese patients (BMI>50) than in morbidly obese patients (BMI <50) (p <0.05). Postoperative complications occurred in 193 patients (10.2%), including tube port failure (n = 79; 40.9%), gastric pouch dilation (n = 93; 48.9%), and band erosion (n = 21, 10.8%). Most PD (65.5%) occurred during the first 50 patients treated at each center.

In summary, LAGB clearly leads to significant weight loss in the morbidly obese. 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, hypertension, and sleep apnea with the procedure, although long-term follow-up data are lacking. Early studies reported high rates of complications, but these have come down markedly with increased surgical experience and improvements in the fixation technique (pars flaccida). Peri-



operative mortality rates are remarkably low in centers performing large numbers of the procedure. Concerns remain 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 the 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. Additionally, bariatric surgical mortality has consistently been shown to be related to the age, sex, pre-operative BMI, and co-morbidities of the patient ^{148, 149}.

Alternatives to LAGB surgery include low-calorie (800-1200) and very-low (400-800) calorie diets, behavioral modification, exercise and pharmacologic agents; and vertical banded gastroplasty or RYGB surgeries. The National Institute of Health (NIH) Consensus Conference¹⁹ 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.¹⁵⁰ 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.¹⁵¹ The failure of conservative and dietary treatment to control morbid obesity has led to the development of surgical methods of control.¹⁵²

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. Given the promising data for LAGB discussed above, it would be reasonable to perform a randomized clinical trial 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. Unfortunately, no randomized trials have been published.

Uncontrolled case-series of laparoscopic RYGB

For comparison purposes, Tables 11 to 15 summarize the same outcomes as Tables 6-10, but for laparoscopic RYGB. The age and BMI distribution in these trials was similar to those reported in the case series of LAGB. In general, reported follow-up was shorter than that reported for LAGB. Weight loss at one year in the RYGB case series was substantially greater than that reported for LAGB (median EBWL 69% RYGB vs. 43% LAGB), although only one of the case series reported adequate follow-up (EBWL 77% with >80% follow-up).¹⁵³ Weight loss in that trial was stable out to five years (EBWL 80%), but follow-up was quite low at three years and greater. Resolution of comorbidities in trials reporting these data was quite good (Table 13), but the data are too sparse for adequate comparison to LAGB. Short-term mortality was reported in all trials and was < one percent in each study. The pooled mortality was 0.1%. The conversion rate to open procedures was low (0.1 to 2.8%) although reporting was incomplete in some case series and one of the studies excluded patients converted to open procedures. Anastomotic leaks at suture lines are a grave concern, particularly in laparoscopic RYGB. In these case series this complication was reported for 0.4 to 5.8% of the patients with the two largest series reporting the fewest leaks. Overall short-term complication rates were not consistently reported, but ranged from 3.3% to 7.0% in four of the smaller studies. Long-term complication rates were low (6.9% in the one study reporting total events), but follow-up was very short for many of the studies and systematic collection of significant long-term complications was not routinely reported. Only one study reported on vitamin deficiency: a worrisome 24% - predominantly iron deficiency anemia.¹⁵⁴ The rates of marginal ulcer formation ranged from 0.4 to 5.1% and strictures were reported for zero to 5.6% of patients. A combination of the variable length of follow-up, the lack of standard definitions for many of the outcomes and the lack of systematic collection of these complications likely explains the greater than ten-fold difference in complication rates between these case series. Thus, it is impossible to make any meaningful comparisons between the rate of long-term complications observed after LAGB and those observed after RYGB based on the case-series data.

Comparative trials of laparoscopic adjustable silicone gastric banding to vertical banded gastroplasty

There have been three randomized studies comparing LAGB to VBG and one non-randomized comparative study. These are discussed here in part to demonstrate the feasibility of randomization in studies of surgical treatments of morbid obesity and in part because RYGB has clearly been shown to be superior to VBG in randomized clinical trials.

Morino et al¹⁵⁵ performed the largest and longest RCT comparing LAGB to VBG. 100 morbidly obese patients, with body mass index (BMI) 40 to 50 kg/m², without compulsive eating, were randomized to either LAGB (n = 49) or LVBG (n = 51). Minimum follow-up was two years (mean 33.1 months). There were no



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deaths or conversions in either group. Mean operative time was 94.2 minutes in LVBG and 65.4 in LAGB ($P < 0.05$). Early morbidity rate was non-significantly lower in LAGB (6.1%) versus LVBG (9.8%) ($P = 0.754$). Mean hospital stay was shorter in LAGB versus LVBGs: 3.7 days versus 6.6 ($P < 0.05$). Late complications rate in LVBG was 14% (7 of 50) and in LAGB 32.7% (16 of 49) ($P < 0.05$). The most frequent complication was the slippage of the band (18%). Late reoperation rate in LVBG was 0% (0 of 50) versus 24.5% (12 of 49) in LAGB ($P < 0.001$). Excess weight loss in LVBG was, at two years, 63.5% and, at three years, 58.9%; in LAGB, excess weight loss, respectively, was 41.4% and 39%. The authors concluded that for patients with BMI 40 to 50 kg/m², LAGB requires shorter operative time and hospital stay but LVBG is more effective in terms of late complications, reoperation rate, and weight loss.

A second RCT by Nilsell et al¹⁵⁶ compared the clinical results of LAGB to VBG in Sweden. Fifty-nine morbidly obese patients were randomized to adjustable gastric banding ($n = 29$) or vertical banded gastroplasty ($n = 30$). Outcomes included weight loss, complications, the need for surgical revision, reflux symptoms and the patient's own evaluation. Five years after surgery the mean (SEM) weight reduction for adjustable gastric banding was 43 (3.0) kg and was 35 (4.8) kg for VBG. One patient in each group died of unrelated causes during follow-up. One patient in the vertical banded group required reoperation for an anastomotic leak on the third postoperative day. A total of three patients in the adjustable group required reoperation and eleven in the vertical banded group required reoperation. In contrast to Morino, they conclude that adjustable gastric banding carries a smaller risk of reoperation than vertical banded gastroplasty and the weight reduction is in the same order of magnitude. The major difference between the two studies is that VBG was performed laparoscopically in the study of Morino et al, but was performed by laparotomy in the study by Nilsell. Currently, the majority of bariatric surgeries in the United States and in Europe are performed laparoscopically.

The most recent trial randomized 100 patients (50 per group) to either LAGB or open VBG.¹⁵⁷ The hospital length of stay was significantly shorter in the LAGB group. Three LAGB procedures were converted to open (6%). Immediately after VBG, three patients needed reexploration due to a leak, including one who died (2%). Follow-up was 100% at two years. The EBWL was significantly greater in the VBG group compared to the LAGB group (70% vs. 55%, $p < 0.001$). Co-morbidities decreased similarly in both groups. Two years after LAGB, 20 patients (40%) needed reoperation for pouch dilation/slippage ($n=12$), band leakage ($n=2$), band erosion ($n=2$) and access-port problems ($n=4$). In the VBG group, 18 patients (36%) needed repeat surgery due to staple-line disruption ($n=15$), stenosis ($n=2$) or insufficient weight loss ($n=1$). Eight additional VBG patients developed incisional hernias. Overall weight loss outcomes favored the VBG group, though both groups required a large number of repeat procedures due to long-term complications.

In the one trial comparing LAGB to RYGB and VBG,⁴⁰ the percentage excess weight loss was >75% (“excellent”) in 73% of patients following RYGB vs. seven percent following VBG and three percent following LAGB. More detailed comparisons between LAGB and RYGB in this study will be described below.

Comparative trials of laparoscopic adjustable silicone gastric banding to Roux-en-Y gastric bypass

Tables 1 to 5 summarize the 12 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. None of the trials randomized patients and the two groups in most of the studies are far from comparable. For example, in two of the studies the patients treated with LAGB had surgery performed in Europe and those receiving RYGB had their surgeries performed in the United States.^{40, 122} Similarly two of the studies had age differences at the time of surgery of four to five years^{40, 126} and two other studies had differences in baseline BMI that ranged from seven to 15 kg/m².^{122, 131} Only two studies matched patients by age, sex, and BMI,^{124, 132} and only one study matched additionally by date of surgery.¹²⁴

Weight loss outcomes consistently favored RYGB by large amounts (Table 2). The median absolute difference in EBWL between the two groups across the ten studies reporting weight loss outcomes at one year was 27%, a large and clinically significant difference. In several of the studies, these differences tended to narrow over time, though in others the differences remain stable after about two years. These results were mirrored in the data on resolution of comorbidities (Table 3). The results for the two studies that matched patients^{124, 132} 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/m².¹²³ 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 recent 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.^{125, 128}

Short-term complication rates generally favored LAGB. Operative times were shorter and hospitalization length of stay was consistently shorter. There were fewer deaths in the LAGB group (0.06% vs. 0.17%), though mortality was low in both groups. Rates of conversion to open procedures, perforation, bleeding, and anastomotic leaks were very low in both groups. Overall, the absolute difference in major early complications was between 1.1% and 6.3% in favor of LAGB. However, long-term complications were more common in the LAGB group and several studies reported large differences in the rates of long-term



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complications. For instance, in the first trial with matching,¹²⁴ 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. Longer follow-up in the LAGB group may explain this difference, although reoperation rates were 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).¹²⁴ Long-term reoperation rates were also much higher in the LAGB group than the RYGB group in three of the six other comparative trials reporting reoperations.^{123, 126, 131} 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.

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.

Only one of the studies directly comparing LAGB to RYGB reported data on patient satisfaction.¹²³ 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. 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).

Comparison of techniques in laparoscopic adjustable silicone gastric banding

Several studies compared different types of adjustable bands, and different approaches to fix the band in place. The most important innovation is the pars flaccida method of band fixation compared with the traditional perigastric approach.

Greenslade et al (2004) evaluated the Swedish Adjustable Gastric Band prospectively in a consecutive series of 273 patients. The first 58 patients had their band sited by the 'peri-gastric' technique, with the



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subsequent 215 using the 'pars flaccida' technique, which provides better posterior fixation of the band. Results from these two groups were considered separately. Prolapse of the stomach through the band was the major complication occurring in 13 of the 58 peri-gastric patients (22.4%). Median preoperative BMI was 42.1, falling below 30 by two years. In the pars flaccida group there were no instances of prolapse, but the major complication was three cases of band erosion (1.4%). Median preoperative BMI was 42.9 for this group, falling to 32 by three years. There was one death in the series due to myocardial infarction. The authors concluded that weight loss with the SB appears durable overall with an acceptable complication rate once the pars flaccida technique was employed.

The benefit of the pars flaccida technique was also noted in the large case series of Chevalier et al⁵⁸ using LAGB. 896 women and 104 men with mean age 40.4 years (16.3-66.3) underwent LAGB. The cumulative rate of complications was 192 (19.2%). Before October 2000, they used the perigastric technique, and the slippage rate was 24% (91 / 378). Then, they changed to the pars flaccida approach and the slippage rate fell to 2% (13 / 622). The pars flaccida approach demonstrated improved safety in risk of perforation and slippage.

The Swedish Adjustable Gastric Band (Obtech) 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.¹⁵⁸ 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/m² (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.¹⁵⁹ From January to May 2001, 60 patients were randomized to LAGB (n=30) or the Heliogast band (Helioscopic). 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.

Summary

LAGB techniques have evolved over time with a concomitant decrease in early and late complications. However, the same argument can be made for RYGB, particularly when performed laparoscopically. 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 appear to be more common in the LAGB group. 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. Furthermore, when asked, patients receiving RYGB appear to be more satisfied than patients receiving LAGB.

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.⁶⁵ 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



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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 morbidly obese patients 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 Bariatric Surgeons (“ASBS”) and American College of Surgeons (ACS) are currently preparing guidelines to define criteria for Centers of Excellence in Bariatric Surgery.

Physician Qualifications

The “ASBS” 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



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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 ASBS 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 ASBS 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.

TA Criterion 5 is met.

CONCLUSION

The prevalence of morbid obesity is increasing at alarming rates in the United States. The only long-term treatment that has been shown to be effective at achieving and maintaining weight loss for these patients is bariatric surgery. Indeed, the number of bariatric procedures performed has increased by a factor of nine over the six-year period from 1998 to 2004. It is essential that the highest level of evidence be available to



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guide this exponential growth in the use of bariatric surgeries. The current surgical standard in the United States is RYGB (88% of bariatric procedures performed in 2002) with many studies reporting excellent weight loss, reversal of obesity related morbidities, and low morbidity and mortality. Randomized, controlled studies have demonstrated that RYGB is superior to VBG, a less complicated restrictive procedure that was proposed in the past as a safer alternative to RYGB. Other randomized trials have demonstrated similar efficacy, with less surgical morbidity, when RYGB is performed laparoscopically rather than as an open procedure.

In Europe and elsewhere in the world, LAGB is the bariatric procedure of choice. Its supporters argue that LAGB is a safer, less invasive surgical treatment for morbid obesity than RYGB and that it is completely reversible. The need for frequent and relatively invasive adjustment of the band is usually downplayed. In uncontrolled studies, LAGB has good results in terms of weight loss, although less than that typically achieved with RYGB. However, most of these studies suffer from limited follow-up and a lack of systematic and consistent collection of outcomes. The operative mortality is low and studies have demonstrated complete resolution of diabetes, hypertension, and sleep apnea in over 50% of treated patients suffering from these obesity-related diseases. However, postoperative morbidity is considerable. Serious and potentially lethal complications, such as late gastric erosions of the band into the stomach, can occur. Patients receiving the LAGB also are at risk for late complications such as port dislodgement, tubing leaks, band slippage, pouch dilatation, and band erosion through the gastric wall. In one study, these complications were most common during the third and fourth post-operative year with complications occurring in five percent of patients each year over five years of follow-up. Thus, studies with relatively short and incomplete follow-up may greatly underestimate the risks for these complications. Reoperation rates have varied between four percent and 12%, but appear to be roughly equivalent to other bariatric surgeries. However, in two studies, the Lap Band device had to be removed entirely in 31% to 41% of patients. Recent studies demonstrated that LAGB using the pars flaccida techniques significantly decreases band slippage rates and may decrease long-term complications. Bariatric surgeries performed laparoscopically are technically demanding and should only be performed in high-volume centers by experienced surgeons in the context of a multidisciplinary weight management program.

The uncontrolled results for LAGB are roughly equivalent to those achieved by RYGB and VBG. However, in the twelve nonrandomized comparative trials directly comparing LAGB to RYGB, the weight loss and comorbidity resolution after LAGB were significantly less than after RYGB. The length of surgery, length of the hospital stay, and the perioperative morbidity rates were consistently lower with LAGB. However, long-term complications appear to be more common after LAGB. In one study, patients were more satisfied with the results after RYGB than after LAGB. Mortality in the 30 days following the operation was approximately



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0.1% for both procedures. Unfortunately, there are no randomized trials directly comparing LAGB TO RYGB. One of the randomized trials comparing LAGB to VBG demonstrated greater weight loss with VBG, fewer reoperations, and comparable morbidity and mortality. Given that VBG has fallen out of favor partly due to better results with RYGB in comparative trials, these data raise the concern that despite the popularity of LAGB, RYGB may be a more effective procedure.

There is a risk that commercial sponsorship of the LAGB may promote the use of these devices over RYGB, which has no commercial sponsor. LAGB is a technically less demanding procedure with shorter operating time, shorter length of hospital stay, and fewer initial complications. Thus, the procedure has great appeal for individual surgeons who will be able to treat more patients with LAGB than RYGB over the same period of time. However, the complex mix of early and late complications and benefits following both procedures and the impact of patient characteristics on outcomes require randomized clinical trials to carefully compare the relative merits of RYGB and LAGB. Given the rapid increase in the numbers of patients interested in bariatric surgery, clinical trials are feasible. In the ideal randomized trial, both procedures would be performed laparoscopically by surgeons who have performed at least 100 of the procedures. Key outcomes that should be collected prospectively according to standard protocols applied at each site should include peri-operative morbidity, total mortality, excess body weight loss, reversal of morbidities (DM, HTN, dyslipidemia, OSA) at one and three years, quality of life, reoperation rates, procedure reversal rates, and long-term complications such as nutritional deficiencies, marginal ulcers, bowel obstruction, band complications, and port complications. Complete follow-up for a minimum of three years for all participants is necessary to minimally assess these outcomes. As Chapman et al concluded in their recent systematic review “the long -term efficacy of LAGB remains unproved, and evaluation by randomized controlled trials is recommended to define its merits relative to the comparator procedures.” Only after publication of such studies will patients and surgeons be able to assess whether the possible lower rates of early complications with LAGB outweigh the benefits of greater weight loss and fewer long-term complications with RYGB.

RECOMMENDATION

It is recommended that the use of laparoscopic adjustable silicone gastric banding for the treatment of morbid obesity does not meet CTAF technology assessment criteria 4 for safety, effectiveness, and improvement in health outcomes.

The CTAF panel voted to accept the recommendation as written.

February 28, 2007



RECOMM ENDATIONS OF OTHERS

Blue Cross Blue Shield Association (BCBSA)

The BCBSA Technology Evaluation Center Medical Advisory Panel met on November 2, 2006 and determined 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)

On February 21, 2006 the CMS determined that the evidence is adequate to conclude that open and laparoscopic Roux-en-Y gastric bypass, laparoscopic adjustable gastric banding, and open and laparoscopic biliopancreatic diversion with duodenal switch are reasonable and necessary for Medicare beneficiaries who have a body-mass index ≥ 35 , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

American Society for Bariatric Surgery (ASBS)

An ASBS representative provided testimony at the meeting. The ASBS web site provides information regarding their guidelines: <http://www.asbs.org/html/about/asbsguidelines.html>.

American Gastroenterological Association (AGA)

The AGA does not have a formal opinion regarding the use of this technology. A representative provided testimony at the meeting.

Society for American Gastrointestinal and Endoscopic Surgeons (SAGES)

A SAGES representative provided testimony at the meeting.



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ABBREVIATIONS USED IN THIS ASSESSMENT

LAGB	Lap Band Adjustable Gastric Banding System	MI	Myocardial Infarction
BMI	Body Mass Index	Rem	Band Removal
AGB	Adjustable Gastric Banding	Infxn	Infection
VBG	Vertical Banded Gastroplasty	PNA	Pneumonia
BPD	Biliopancreatic Diversion	Leak	Anastomotic Leakage
SOS	Swedish Obese Subjects Study	RYGB	Roux En Y Gastric Bypass
LAGB	Adjustable Silicone Gastric Banding		
GP	Gastric Perforation	SB	Swedish Band
VTE	Venous Thromboembolic Disease	S/D	Slippage/Dilation
SB-EP	Swedish Band – Esophagogastric Placement		
Port	Port Problems (Leaks)	SB-GP	Swedish Band – Gastric Placement
IH	Incisional Hernia	EGP	Esophagogastric Placement
BE	Band Erosion	RGP	Retrogastric Placement
Mort	Mortality	EBWL	Excess Body Weight Loss
Bleed	Bleeding	PD	Pouch Dilatation
Pneu	Pneumonia	SEM	Standard Error Of The Mean
Obst	Obstruction		
DM	Diabetes Mellitus		
HTN	Hypertension		
OSA	Obstructive Sleep Apnea		
GERD	Gastroesophageal Reflux Disease		
LRYGB	Laparoscopic Roux En Y Gastric Bypass		
LVBG	Laparoscopic Vertical Banded Gastroplasty		

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