Obesity Surgery, 12, 385-390

Laparoscopic Banding: Selection and Technique in 830 Patients

F. Favretti, MD; G.B. Cadière, MD[1]; G. Segato, MD; J. Himpens, MD[1]; M. De Luca, MD; L. Busetto, MD; F. De Marchi, MD; M. Foletto, MD; D. Caniato, MD; M. Lise, MD; G. Enzi, MD

From Obesity Center, University of Padova, Padova, Italy and [1]Department of Surgery, Free University, Bruxelles, Belgium

Background: Laparoscopic adjustable gastric banding (LAGB) with the Lap-Band® has been our first choice operation for morbid obesity since September 1993. Results in terms of complications and weight loss are analyzed.

Methods: 830 consecutive patients (F 77.9%) underwent LAGB. Initial body weight was 127.9 ± SD 23.9 kg, and body mass index (BMI) was 46.4 ± 7.2 kg/m². Mean age was 37.9 (15-65). Steps in LAGB were: 1) establishment of reference points for dissection (equator of the balloon inflated with 25 cc air and left crus); 2) creation of a retrogastric tunnel above the bursa omentalis; 3) creation of "virtual" pouch; 4) embedding the band.

Results: Mortality was 0, conversion 2.7%, and follow-up 97%. Major complications requiring reoperation developed in 3.9% (36 patients). *Early* complications were 1 gastric perforation (requiring band removal) and 1 gastric slippage (requiring repositioning). *Late* complications included 17 stomach slippages (treated by band repositioning in 12 and band removal in 5), 9 malpositions (all treated by band repositioning), 4 gastric erosions by the band (all treated by band removal), 3 psychological intolerance (requiring band removal), and 1 HIV positive (band removed). A minor complication requiring reoperation in 91 patients (11%) was reservoir leakage. 20% of patients who had % excess weight loss <30 had lost compliance to dietetic, psychological and surgical advice. BMI declined significantly from the initial 46.4 ± 7.2 to 37.3 ± 6.8 at 1 year, 36.4 ± 6.9 at 2 years, 36.8 ± 7.0 at 3 years, and 36.4 ± 7.8 at 5 years.

Conclusion: LAGB is a relatively safe and effective procedure.

Presented at the 18th Annual Meeting of the American Society for Bariatric Surgery, Washington, DC, USA, June 7, 2001.

Reprint requests to: Franco Favretti, MD, Contrà Chioare, 13, 36100 Vicenza, Italy. E-mail: ffavret@tin.it

Key words: Morbid obesity, bariatric surgery, gastric banding, laparoscopy, weight loss, complications

Introduction

Laparoscopic adjustable gastric banding (LAGB), originated by Kuzmak in 1986,[1] has gained widespread use. It has advantages of an operation that does not open the gastrointestinal tract and can be performed laparoscopically. However, the reported complications (gastric perforation, stomach and/or band slippage, pouch dilatation) are cause for some concern.[2]

LAGB using the Lap-Band™ (BioEnterics, Carpinteria, CA) has been performed in our Institutions since 1993.[3-8] We report the long-term outcome of a large group of morbidly obese patients treated with the Lap-Band® and detail the surgical technique which is of paramount importance to minimize the common complications.

Materials and Methods

From September 1993 to November 2000, 830 consecutive patients, consisting of 647 female (77.9%) and 183 male (22.1%), underwent LAGB at the Institutions of the Obesity Center of Padova Italy. Average age was 37.9 years (range 15-65). Average initial body weight was 127.9 ± SD 23.9 kg, average percent excess weight (%EW) was 208

± 32 and average body mass index (BMI) was 46.4 ± 7.2 kg/m^2. We compared morbidly obese (BMI <50) and super obese (BMI >50). The morbidly obese consisted of 565 patients with BMI 42.7 ± 4.0. The super obese consisted of 235 patients with BMI 55.7 ± 4.9. Abdominal surgery had been performed previously in 207 patients (Table 1).

Twenty-two patients (2.7%) required conversion to an open operation (Table 2). There was no mortality.

Key steps in the procedure, standardized by our team and by the Free University of Bruxelles in June 1995, were 1) establishment of reference points for dissection (equator of inflated balloon and left crus), 2) creation of a retrogastric tunnel above the bursa omentalis, 3) creation of the "virtual" pouch, and 4) embedding the band.[9]

Patient Selection

A comprehensive multidisciplinary examination was performed, including an internist with long-standing experience in obesity evaluation and treatment, a psychologist with special training in eating disorders, and a surgeon. Patients with age 18-65 and with BMI >40 were considered for surgery. Less severely obese patients (BMI 35-40) were also considered if they had high-risk comorbid conditions or physical problems interfering with lifestyle.

Appropriate laboratory and instrumental testing was conducted to evaluate the severity of comorbid conditions (diabetes, hypertension, dyslipidemia, hyperuricemia, obstructive sleep apnea, hypoventilation, heart failure, osteoarthritis). Patients with severe psychiatric disease were excluded from surgery, but those with a history of past or current mild depression were allowed. Patients were further screened to identity endocrine causes of obesity, and esophagogastroduodenoscopy was performed to rule out ulcer.

Table 1. Patient features

Period	Sept 1993 – Nov 2000
No. of patients	830 (647 F – 183 M)
Age (yrs)	37.9 (15 – 65)
Weight (kg)	127.9 ± 23.9*
BMI (kg/m^2)	46.7 ± 7.2*
% excess weight	108 ± 16*
Previous abdominal surgery	207 (25%)

*Standard deviation, SD

Table 2. Reasons for conversion to an open operation in 22 patients

Cause	No. of Patients
Risk of perigastric dissection	7 (0.8%)
Left liver lobe hypertrophy	6 (0.7%)
Gastric perforation	4 (0.5%)
Inadequate instruments	2 (0.2%)
Bleeding retrogastric vessels	2 (0.2%)
Band malpositioning	1 (0.1%)
Total	22 (2.7%)

Eating behavior and attitudes were evaluated by the internist and the psychologist. Patients satisfyng the DSM-IV diagnostic criteria for bulimia nervosa were not considered for surgery. Patients without bulimia nervosa were classified according to four eating behavior patterns, not mutually exclusive: a) binge eating disorder (BED), b) sweet eating, c) nibbling, d) gorging. Patients with BED, sweet eating and nibbling, as well as patients with age <20 years and patients with history of depression, were treated preoperatively with a short course of psychological therapy, to improve the patients' ability to cope with the modifications of the eating behavior imposed by LAGB.

Laparoscopic Technique

After initiation of pneumoperitoneum, five 10-mm ports are made. They are located 1) at the junction of the upper third and the second third of the xiphoumbilical line, 2) below the xiphoid, 3) in the left and 4) right hypochondrium, and 5) in the left anterior axillary line below the rib cage. All ports are introduced by an optical port (Visiport™), to reduce the risk of damaging abdominal organs and abdominal wall vessels.

A calibrated balloon-tipped orogastric tube is inserted into the stomach. The balloon is inflated with 25 ml of air and withdrawn to the gastroesophageal junction. This allows clear visibility along the lesser curvature and into the phreno-gastric ligament. These two sites correspond to the most bulging part of the balloon, and are marked with the coagulating hook. The reference point on the lesser curvature is the equator of the balloon,

which, on the phreno-gastric ligament on the greater curvature, corresponds to the left crus. The identification of these two points is essential to ensure correct positioning of the band. The left crus is dissected.

To avoid gastric wall injuries, the calibration tube has to be withdrawn during dissection, which has to be done perpendicularly so as not to enter the inferior mediastinum along the esophagus.

A tunnel is created behind the stomach joining the two dissected reference points. The bursa omentalis (lesser sac) should not be entered, and the dissection should be performed in the phreno-gastric ligament above the peritoneal reflection of the bursa omentalis. An articulating dissector is passed through the tunnel to grasp the tip of the band.

The band is introduced through the path of the left subcostal port. To introduce the band there is no need for ports wider than 10 mm. The port is removed, and its path is utilized.

Once the band has been closed, the stoma is calibrated accurately with the Gastrostenometer™ II Electronic Sensor (BioEnterics, Carpinteria, CA). Saline solution was injected into the band until the fourth light of the Gastrostenometer is illuminated (corresponding to a stoma diameter of 12.5 mm), as originally described by Kuzmak. However, with this band calibration a minority of patients (about 15%) complained of frequent vomiting in the first months after surgery. Therefore, we use a wider band stoma calibration intraoperatively, and adjust the stoma diameter postoperatively according to the patient's needs.[11] Thus, at the end of the calibration procedure, the saline used is half of the volume needed to reach the 12.5 mm stoma diameter or the saline is totally removed. The stoma diameter obtained after the band deflation is not measured; however, the volume of saline that was needed to achieve the correct stoma size is recorded and is used as a guideline for postoperative band adjustments.

Next, retention sutures are applied to prevent band and/or stomach slippage, and are placed in the seromuscular layer of the stomach from proximal to distal to the band. These anti-slippage sutures should start as close as possible to the greater curvature, embedding the band. If there is a gap on the lesser curvature, it should be closed by applying one or two stitches distal to the band from the lesser curvature to the hepato-gastric ligament, taking care not to damage the vagus nerve. Thus, a "virtual" pouch based on the 25 ml measurement, is made.

The reservoir is implanted on the left anterior rectus sheath just distal to the costal margin.

The morning after surgery a Gastrografin® upper GI series is done to exclude the possibility of gastric perforation and to assess band position and competence.

Results

At 7-year follow-up, 97% of the 830 patients were able to be examined. Major complications requiring reoperations developed in 3.9% (36 patients). *Early* complications were 1 gastric perforation (requiring band removal) and 1 stomach slippage (treated by band repositioning).

Late complications are shown in Table 3. In analyzing the major complications requiring reoperation, the patients were divided into 8 groups of 100, according to the date of the initial operation. The first 100 patients had 20 major complications, the second 100 had 6, the third 100 had 4, the fourth 100 had 5, the fifth 100 had 1, and the sixth, seventh and eighth 100 patients have had no major complication (Figure 1).

Reservoir leakage was regarded as a minor complication requiring reoperation, and has occurred in 11% (91 patients).

Stomach slippage occurred in 83 patients (10%).

Table 3. Major complications requiring reoperation

Complication	No., Band Treatment	
Early:		
Gastric perforation	1 removal	(0.1%)
Stomach slippage	1 repositioning	(0.1%)
Late:		
Stomach slippage	17, 12 repositioning, 5 removal	(1.8%)
Malpositioning	9 repositioning	(0.9%)
Erosions	4 removal	(0.5%)
Psychological intolerance	3 removal	(0.4%)
HIV +	1 removal	(0.1%)
Total	36	(3.9%)

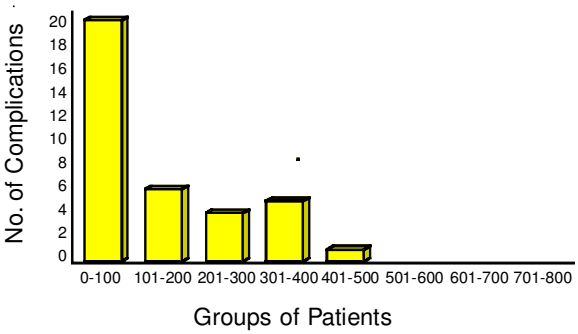

Figure 1. Distribution of major complications.

The band was immediately completely deflated, and a course of antacid therapy with a proton-pump inhibitor and a modified liquid diet were prescribed for 1 month. The patient was then advanced to a solid diet, and, if the symptoms of stomach slippage did not reappear, the band was inflated step-by-step (no more than 1.5 cc per inflation). In our series, 65 patients (8.1%) did not require reoperation. If stomach slippage reappeared, band repositioning or removal was performed, according to clinical judgement. In 18 patients (1.9%), reoperation was required (band repositioning in 13, band removal in 5).

At follow-up, 20% of the 830 patients lost compliance with the dietary, psychological and surgical advice. The operation in these patients is considered a failure (%EWL <30).

The change in BMI is shown in Figure 2 (Table 4). The percent excess weight loss (%EWL) was reviewed in the 479 patients at 3 years follow-up (Figure 3). We considered the first, second the third groups in Figure 3 (142 patients, 29.6%) with a %EWL 0-30 as a "failure"; the fourth, fifth and sixth groups (235 patients, 49.1%) with %EWL

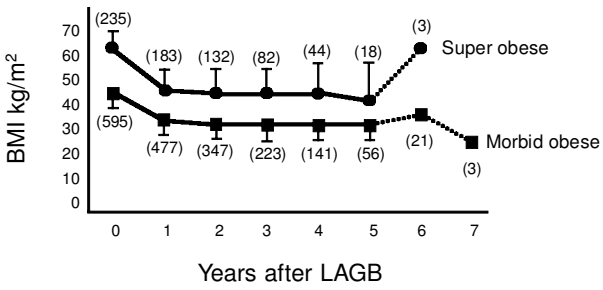

Figure 2. Changes in BMI following LAGB (830 patients). SD and no. of patients at each time interval.

Table 4. Weight loss (course of BMI) in entire series, morbidly and super obese

Years	0	1	2	3	4	5	6	7
BMI (series)	46.4	37.3	36.4	36.8	36.6	36.4	39.9	29.4
BMI (morbidly obese)	42.7	34.7	34.0	34.3	34.6	34.8	37.6	29.7
BMI (super obese)	55.7	44.1	42.7	43.3	43.0	41.6	56.0	–

31-60 as a good result; the seventh, eighth, ninth and tenth groups (102 patients, 21.3%) with%EWL 61-100 an excellent result.

Discussion

LAGB is the most common bariatric operation performed in Italy.[9] It has been our operation of choice since September 1993.[3,6,7] Suitability must be determined with the psychologist, and the results can be optimized by adequate psychological support postoperatively.

The surgical technique has been modified and standardized, and operating time has decreased. The morbidity rate had been 3.9% and mortality rate 0. There is a striking difference between our results and the results reported by Oria (who has not performed this procedure) in his literature review.[2] Key steps in the LAGB, standardized by our team and the Free University of Bruxelles, were: reference points for dissection (inflated balloon equator and left crus); retrogastric tunnel above lesser sac; imbrication over band.[4]

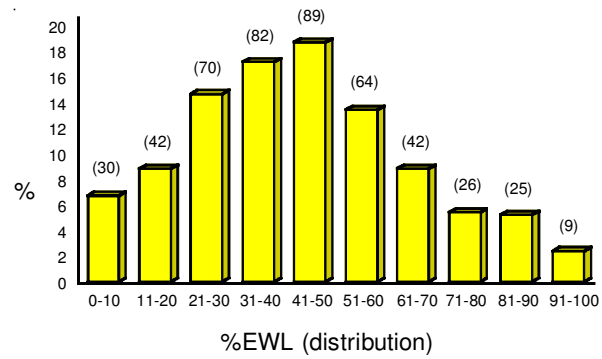

Figure 3. Distribution of the %EWL in the patients at 3 years following the LAGB.

LAGB has less weight loss than gastric bypass. However, with 97% follow-up and 479 patients in at 3 years, %EWL was good (31-60) and excellent (61-100) in almost 70% of patients.

The LAGB has complications,[8] but less than and with a lower risk than other bariatric operations. The complications can usually be corrected by laparoscopy.

Current Approach to Complications

1) *Erosion*. The band is removed by laparoscopy. To reach the site of the band, which is usually covered by adhesions, it is advisable to follow the connecting tube and to pull it. The buckle of the band is easily identified, and a cut on its weak part permits removal of the band. A few stitches are applied to the damaged gastric wall. We usually perform gastroscopy and a methylene blue test, to confirm that there is no leak; we then insert a nasogastric tube to ensure decompression and a perigastric drain.

2) *Slippage*. Options available are:

a) *Deflation of the band.* In most of the cases, the pouch returns to normal size and motility. After 1 month, the band is gradually inflated with no more than 1.5 cc at a time. If after deflation an upper GI series still shows slippage and the contrast passes with difficulty through the band, band removal or repositioning must be performed.

b) *Pull-through technique.* In the case of anterior gastric wall slippage, the band must be deflated and exposed; then it is feasible to reduce the slippage by carefully pulling the band proximally on the gastric wall, and applying imbricating retention sutures. The position of the band on the lesser curve and the location of the retrogastric tunnel have to be checked, and if they are not correct, repositioning has to be done.

c) *Repositioning*. In the case of posterior gastric wall slippage (the most common form of slippage), it is advisable to remove the band and to reposition it higher up. The reference points for dissection have to be identified again to be sure that the retrogastric tunnel will be well above the lesser sac.

If the usual perigastric technique for dissection and creation of the retrogastric tunnel is not possible due to local adhesions, the pars flaccida technique can be readily utilized. In this case, dissection begins directly lateral to the equator of the calibration balloon in the avascular space of the pars flaccida. After viewing the caudate lobe of the liver, blunt dissection is continued with direct visualization until the right and then the left crus is seen, followed to the angle of His.

d) *Removal.* See above.

3) *Malposition/Pouch Enlargement.* A malfunctioning Lap-Band® due to malpositioning, leads to enlargement of the pouch. If this occurs, we deflate the band (as above). If after deflation an upper GI series still shows pouch enlargement and the contrast passes with difficulty through the band, repositioning must be performed. The perigastric or pars flaccida technique can be used.

4) *Esophageal Enlargement.* In the instance of enlargement of the esophagus, the band has to be deflated (as above). If after deflation an upper GI series still shows enlargement of the esophagus and contrast passes with difficulty through the band, it means that the band is malpositioned and that too much gastric tissue is encompased by the band. Removal or repositioning of the band must be performed.

References

1. Kuzmak L. A review of 7-years experience with silicone gastric banding. Obes Surg 1991; 1:403-8.
2. Oria HE. Silicone adjustable gastric banding for morbid obesity. Systematic review update, Jan. 1999 - May 2000. Obes Surg 2000; 10:322-3.
3. Cadiere GB, Bruyns J, Himpens J et al. Laparoscopic gastroplasty for morbid obesity. Br J Surg 1994; 81:1524.
4. Cadiere GB, Himpens J, Favretti F et al. Laparoscopic gastroplasty (adjustable silicone gastric banding). Semin Laparosc Surg 2000; 7:55-65.
5. Chelala E, Cadiere GB, Favretti F et al. Conversions and complications in 185 laparoscopic adjustable silicone gastric banding cases. Surg Endosc 1997; 11: 268-71.
6. Favretti F, Cadiere GB, Segato G et al. Laparoscopic placement of adjustable silicone gastric banding: early experience. Obes Surg 1995; 5:71-3.
7. Favretti F, Cadiere GB, Segato G et al. Laparoscopic adjustable silicone gastric banding: technique and

results. Obes Surg 1995; 5:364-71.

8. Favretti F, Cadiere GB, Segato G et al. Bariatric analysis and reporting outcome system (BAROS) applied to laparoscopic gastric banding patients. Obes Surg 1998; 5:500-4.
9. Favretti F, Cadiere GB, Segato G et al. Laparoscopic adjustable silicone gastric banding (Lap-Band™): how to avoid complications. Obes Surg 1997; 7:352-8.
10. Angrisani L, Alkilani M, Basso N et al. Lap-Band adjustable gastric banding system (LAGB): a 4-year multicenter Italian experience. Obes Surg 2000; 10:323 (abstr 47).
11. Busetto L, Pisent C, Segato G. The influence of a new timing strategy of band adjustment on the vomiting frequency and the food consumption of obese women operated with laparoscopic adjustable silicone gastric banding (LAP-BAND™). Obes Surg 1997; 7:505-12.

(Received August 16, 2001; accepted January 29, 2002)