



# Favorable early results of gastric banding for morbid obesity

## The American experience

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### Abstract

**Background:** In 2001 a new device for surgical weight loss was approved by the Food and Drug Administration (Lap-Band, Inamed Health). We describe initial results of laparoscopic gastric banding for morbid obesity in two American academic centers.

**Methods:** Prospective data was collected on consecutive morbidly obese patients undergoing laparoscopic adjustable gastric banding, and evaluated retrospectively.

**Results:** Four hundred forty-five consecutive patients underwent Lap-Band from May 2001 through December 2002. The 103 men and 341 women had an average age of 42.1 years (range 17–72 years) and an average body mass index (BMI) of 49.6 kg/m<sup>2</sup> (range 35.2–92.2 kg/m<sup>2</sup>). One operation required conversion to laparotomy due to bleeding; the rest were completed laparoscopically. Mean length of stay was 1.1 days (range 1–10 days). There was one death. Additional complications included band slippage in 14 patients (3.1%), gastric obstruction without slip in 12 (2.7%), port migration in 2 (0.4%), tubing disconnections in 3 (0.7%), and port infection in 5 (1.1%). Two bands (0.4%) were removed due to intra-abdominal abscess 2 months after placement. There was one band erosion (0.2%) and no clinically significant esophageal dilation. Ninety-nine patients have 1-year follow-up and have lost an average of 44.3% excess body weight.

**Conclusion:** Laparoscopic gastric banding has much to offer the morbidly obese. We present data showing weight loss rivaling gastric bypass and acceptably low complications. These results parallel success with this device outside America.

**Key words:** Gastric banding — Morbid obesity — Lap-Band — Surgical weight loss

The first silicone-based adjustable gastric band (Lap-Band System, Inamed Health; Santa Barbara, CA) was approved by the Federal Drug Administration (FDA) in the summer of 2001 for general use in the United States. This novel device for the surgical treatment of morbid obesity has sustained excellent results outside of the United States [1, 2, 5–7, 12, 13, 16, 20]. However, the initial American experience, including the clinical trial leading to FDA approval, has been suboptimal—with lower than expected weight loss and higher than expected rates of complications [8]. We report on our initial experience with this device in two academic surgical practices.

### Methods

Data were prospectively collected on 445 consecutive patients who underwent laparoscopic adjustable gastric banding (LAGB) using the Lap-Band System between May 2001 and December 2002.

Indications for surgery were based on the National Institutes of Health recommendations for bariatric surgery [15]. All patients had a body mass index (BMI)  $\geq 40$  kg/m<sup>2</sup>, or  $> 35$  kg/m<sup>2</sup> in association with a recognized comorbidity. Patients were educated and screened with preoperative psychological, nutritional, and medical evaluation. Patients did not undergo formal screening for eating behavior (i.e., sweet eaters vs volume eaters), but were assessed for motivation and commitment to long-term follow-up.

All operations were performed by one of two fellowship-trained laparoscopic bariatric surgeons (C.J.R., J.W.A.) at university centers in a setting of a comprehensive bariatric program. After completion of mandatory training in an INAMED Health (formerly BioEnterics Corporation) Lap-Band System workshop and on-site proctoring with an expert surgeon, each surgeon utilized the pars flaccida technique for Lap-Band placement as described previously [12]. Briefly, the pars flaccida technique is a method to gain access to the posterior aspect of the gastroesophageal junction in order to encircle the upper stomach circumferentially. This technique requires minimal gastric dissection, maintains normal gastric anatomy, and avoids disruption of the lesser sac. The last point is important in the prevention of gastric prolapse, also known as a “slipped band.” The band is not filled initially with saline and is secured in place with anterior gastro-gastric fundoplication. The tubing leading to the band is connected to a reservoir port that is secured to the anterior rectus sheath in a midabdominal location.

Routine contrast esophagrams were performed postoperatively to evaluate for perforation or obstruction, as well as document band

**Table 1.** Adverse events following laparoscopic adjustable gastric banding ( $n = 445$ )

Adverse event	<i>n</i> (%)
Perioperative	
Death	1 (0.2%)
Malignant hyperthermia	1 (0.2%)
Splenectomy	1 (0.2%)
Stoma obstruction	12 (2.7%)
Device-related	
Tubing disconnection/leak	4 (0.9%)
Port infection	5 (1%)
Port migration	4 (0.9%)
Delayed	
Gastric prolapse	14 (3%)
Erosion	1 (0.2%)
Explantation	4 (0.8%)
Total	47 (10.5%)

position and pouch size. Patients were then discharged on a liquid diet for 2 weeks, which progressed to puree and then solid food over the course of 6 weeks.

Patients were seen every 1 to 2 months during the first year after surgery to monitor weight loss, appetite, food restriction, and comorbidities. Follow-up was then decreased to every 3 months. Band adjustments were performed in the office based on progression of weight loss, food restriction, and hunger. Band adjustments involved percutaneously accessing the midabdominal port with a Huber needle and injection or removal of sterile saline solution. Failure to access the ports percutaneously occasionally required radiographic localization techniques, including ultrasound and fluoroscopy. Symptoms of increased appetite, less than anticipated weight loss, and minimal intake restriction were cues to inflate the band. Symptoms of dysphagia or food intolerance resulted in band deflation. Esophagrams were not routinely utilized to calibrate band adjustments, only for diagnostic purposes.

All patients were encouraged to attend support groups. Radiographic and endoscopic studies were performed for symptoms of dysphagia, reflux, or suspected device failure. All data were collected prospectively in an electronic database and collated, ensuring anonymity of all patients.

## Results

A total of 445 patients underwent LAGB using the Lap-Band system from May 2001 to January 2003. There were 341 female and 103 male individuals with an average age of 42.1 years (17–72 years) and an average BMI of 49.6 kg/m<sup>2</sup> (35.2–92.2 kg/m<sup>2</sup>). Average body weight was 299.4 lb (160–565 lb).

Conversion to laparotomy was necessary in one patient (0.2%) because of bleeding and required splenectomy, while one patient underwent planned laparotomy for LAGB due to previous hepatic surgery. One operation was aborted due to extreme hepatomegaly in a male patient with BMI = 43, which resulted in bleeding and nonvisualization of the gastroesophageal junction. Mean length of hospital stay was 1.1 days (0–10 days). Adverse events occurred in 10.5% of patients (Table 1).

There was one death after surgery (0.2%). This patient experienced sudden arrest the afternoon after surgery from presumed cardiac arrhythmia. A postoperative gastrografin swallow was normal and the post-mortem examination on the 51-year-old female revealed no iatrogenic injury or cause of death. One male patient

with BMI = 53 and extreme android obesity developed malignant hyperthermia requiring 5 days intensive care on respiratory support. Although he recovered fully, the patient developed bilateral buttock myonecrosis requiring wide debridement and 6 months rehabilitation. The patient is presently ambulating with a walker.

Acute postoperative stoma obstructions secondary to peri-band edema occurred in 12 patients (27%). Seven patients (1.2%) were treated conservatively with intravenous hydration and resolved spontaneously; four patients (1.1%) required laparoscopic revision to remove perigastric fat incorporated within the band; and one patient required laparoscopic band explantation. The band explantation was performed in a patient suffering from acromegaly and a significantly thick gastric wall. Laparoscopic band revisions were typically necessary in patients who had complete gastroesophageal obstruction on postoperative esophagram. All postoperative stoma obstructions occurred in the first 125 operations performed by one surgeon (C.J.R.), with none occurring subsequent to change in surgical technique. This modification involved removal of perigastric fat, especially in viscerally obese individuals such as males and diabetics, to minimize the amount of fat incorporated within the band, which caused external gastric compression and subsequently obstruction. Common locations of large perigastric fat pads are the anterolateral aspect, retroesophageal, and the lesser curve.

There were no known cases of thromboembolism, myocardial infarction, or intestinal sepsis.

There were 13 (3%) reservoir port-related complications. Port infection occurred in five patients (1.1%), who, despite antibiotic therapy, failed to resolve and required their ports to be removed. All ports were removed under local anesthesia to allow for resolution of infection with oral antibiotics and open wound care. All ports were subsequently replaced 3–6 months after removal. Port disconnection occurred in three patients. Disconnection typically occurred as a break in the silicone tubing at its connection to the access port. One port required replacement because of a leak from a needlestick. Although completely asymptomatic, port disconnections and leaks must be corrected in order to maintain the Lap-Band's function as a restrictive device. Surgical correction has required a minor ambulatory procedure to replace the access port and reattach the tubing. There were four port migrations (0.9%) secondary to suture disruption, requiring resecuring of the access port to the underlying fascia.

Gastric prolapse, or band slippage, occurs as a consequence of the inferior portion of the stomach sliding up through the band resulting in displacement of the band. This causes asymmetric gastric pouch enlargement and gastroesophageal obstruction. Fourteen cases of gastric prolapse (3.1%) were seen and were treated electively with laparoscopic repositioning or replacement of the Lap-Band, which required an overnight hospital admission. One patient chose to have her band removed because of slippage. One patient had a second prolapse after having it repaired, and she, too, had it repositioned laparoscopically.

One patient, subsequently diagnosed with systemic lupus erythematosus, developed a band erosion (0.2%), but has refused surgical intervention at this time because of its asymptomatic nature and her weight loss of 90% excess weight. She has been closely monitored. Two bands (0.4%) were removed because of intraabdominal abscess 2 and 3 months after placement. One abscess was a localized intrahepatic collection in the left lobe from a presumed infected liver hematoma. The second was a left subphrenic abscess. A total of 4 bands were explanted as described above. There has been no evidence of esophageal dilatation.

Four patients were lost to follow-up, and 99 of the 445 were available for 1-year review. The average % excess weight loss (EWL) at 12 months after LAP-BAND surgery was  $44.3\% \pm 17$  (6.5–92%). The average BMI decreased from  $52.7 \text{ kg/m}^2$  to  $39.3 \text{ kg/m}^2$  (22–72  $\text{kg/m}^2$ ).

## Discussion

Laparoscopic adjustable gastric banding has become a powerful tool in the treatment of morbid obesity. Its use in the United States is growing, but few U.S. data exist given the short time since FDA approval. Our initial experience demonstrates outcomes comparable to many published series [1, 2, 5–7, 13, 16, 20]. We have demonstrated the safety and efficacy of LAGB in a group of American patients, who have a relatively high BMI ( $52.7 \text{ kg/m}^2$ ), as compared to international data, where average BMI is typically  $45 \text{ kg/m}^2$ . Given that the weight loss after LAGB is gradual, usually over 3 years, our EWL of 45% at 1 year is encouraging. Rubinstein showed 38% EWL at 1 year after LAGB, yet achieved 54% EWL by 3 years [8]. We have closely followed the techniques of band implantation and adjustment described by Fielding [12, 13] and by O'Brien [16]. Our 1-year data match theirs and attest to the importance of both surgical technique and patient follow-up with band adjustments in achieving successful weight loss with LAGB. Weight loss at 1 year in this series, as in other published series, is slightly less than that commonly reported for RYGB [19]. However, over time, weight loss appears to continue in patients who have undergone a gastric band, such that 3- and 5-year data result in 55–65% EWL [1, 2, 5], similar to Roux-en Y gastric bypass (RYGB).

The Lap-Band is presently the safest available surgical tool for morbid obesity, as reflected in our mortality of 0.2%. This is, along with adjustability, the major appeal of this procedure to the bariatric patient, particularly when compared to the 1–3% mortality in recent RYGB and biliopancreatic diversion (BPD) series [10, 14, 17].

The major perioperative complication was acute obstruction immediately after surgery. This was due to inadequate removal of perigastric fat in our early experience. After changing our technique, there have been no obstructions in the last 320 cases. This is an essential part of the pars flaccida technique in Lap-Band placement [12].

Gastric prolapse was the most common complication in this series, occurring in 3% of patients. However, we were able to manage this problem laparoscopically in all cases and there was no associated peritonitis or additional adverse sequelae. This contrasts sharply with RYGB where an anastomotic leakage, for example, can present a life-threatening situation. A recent review of a very large experience with RYGB from one institution, with overall 2.4% mortality, showed a 4.5% leak rate, with 16% mortality in patients who leaked [10]. Furthermore, in our series, in all but one instance the band was able to be replaced or repositioned laparoscopically. Use of the pars flaccida technique has greatly reduced the incidence of slip/prolapse compared to experience from the mid to late 1990s, when the FDA A trial occurred [3, 4, 8, 9].

One patient, found postoperatively to have SLE, developed an erosion of the device into the lumen of the stomach. Erosion, occurring in 0.6% to 3% of most large series, typically presents with weight regain, or less frequently with port infection. They are characterized by their benign course. Treatment options include observation, as in this case, band replacement after suture of the defect, and band removal followed by biliopancreatic diversion [2, 3, 9, 11, 16].

Esophageal dilatation can follow any gastric restrictive procedure. The most common cause of esophageal dilatation after LAGB is overtightening at adjustment. We have not specifically studied this entity in our initial assessment of these patients at 1 year. Several patients, particularly those with dysphagia or possible gastric prolapse, had esophagrams months after placement, and no cases of dilatation have been seen. However, as suggested by DeMaria and Sugerma, this may be a late finding, and routine esophagrams at 3 years may elucidate this further [8].

Apart from its great safety, the main benefit of LAGB is its adjustability. No rigid protocols were used by the investigators to determine when the bands needed to be tightened or loosened. Instead it was a clinical decision based on appetite, degree of food restriction, and weight loss. A band that is too tight, and thus too restrictive, can lead to protracted vomiting and may predispose to gastric prolapse or esophageal dilatation.

## Conclusion

The Lap-Band System is a safe, effective, adjustable device for the treatment of morbid obesity. The weight loss in this series compares well with results at the same time period from international studies and is an improvement over that seen in the FDA trial. The real test of this operation will be its ability to provide long-term weight loss.

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