

Why the LAP-BAND has not hit the

Mainstream

by Joseph E. Chebli, MD



There are currently many options available to patients considering bariatric surgery. The operations can be classified into restrictive operations, malabsorptive operations, and combination restrictive/malabsorptive operations. Restrictive operations are operations that involve creation of a small gastric pouch. This limits the volume of food that can be ingested. There is also a narrow outlet from the pouch, which contributes to a feeling of prolonged fullness. The vertical band gastropasty, or VBG, and the laparoscopic adjustable silicone banding, or LAP-BAND are examples of restrictive procedures. Malabsorptive operations do involve some reduction in the volume of the stomach, but mainly work through a process by which various lengths of small intestine are bypassed. This effectively shortens the gastrointestinal tract and allows food to pass through without being broken down and retained or absorbed by the body. The biliopancreatic diversion or BPD, with or without duodenal switch or DS, is the most common example. The Roux-en-Y Gastric Bypass is an example of a combination restrictive/malabsorptive operation. It involves creation of a small pouch (restriction) and rearrangement of the small intestine (malabsorption).

The Roux-en-Y Gastric Bypass is the most commonly performed bariatric procedure in the United States. The role of the Laparoscopic Adjustable Silicone Gastric Banding using the LAP-BAND is still being determined in North America. This procedure was first introduced by Belachew¹ in 1993. There have been more than 100,000 of these surgeries to date. The majority of the LAP-BAND experience comes from Europe, Australia, and Latin America. Why isn't it the most commonly performed procedure in the United States? There are a multitude of reasons: patient education, insurance obstacles and poor early results in the United States.

The Laparoscopic Adjustable Gastric Banding with the LAP-BAND has proved to be a safe bariatric surgical pro-

cedure. It is minimally invasive, adjustable and easily reversible. It does not involve rerouting or rearranging the intestines. It does not involve dividing the gastrointestinal tract, and therefore it involves no staple lines. It also does not create malabsorption, and there is no need for permanent vitamin and mineral supplementation. The operative time is among the shortest of bariatric procedures and the length of hospital stay is usually one night. This procedure has also proven to be one of the safest operations with a mortality rate of approximately 1 in 2,000. This is about one-tenth the mortality rate of gastric bypass². It works because patients eat less and have a sense of fullness, otherwise known as a sense of satiety.

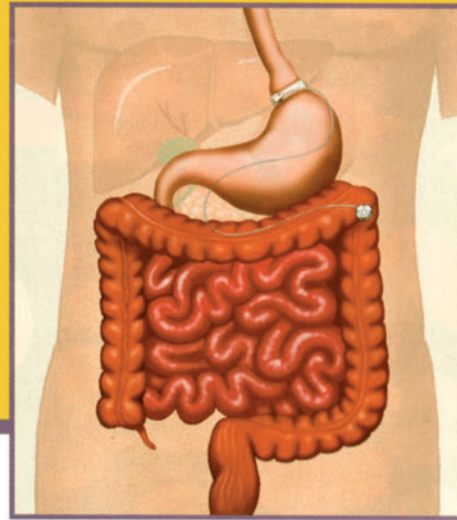
Patient education and understanding are critically important in achieving success with the LAP-BAND. It is important that patients understand the differences between purely restrictive procedures and those that have malabsorptive components. It is imperative that patients understand that a restrictive procedure, like the LAP-BAND, will have a different weight loss profile than a biliopancreatic diversion or gastric bypass. The mean excess weight loss (EWL) from a Gastric Bypass is 70% by 12 months. LAP-BAND patients will lose weight in a slower, more gradual way. People can generally expect to lose 1-2 lbs. a week. A recent publication by Fox³ has shown excellent results in U.S. patients. They have reported a mean excess weight loss of 61% at 12 months, 75% EWL at 24 months, 72% EWL at 36 months, and 60% at 48 months.

Insurance obstacles have contributed mightily to the inability of patients to undergo laparoscopic adjustable banding in the United States. Insurance carriers that cover gastric bypass do not necessarily offer the LAP-BAND as a covered benefit. Many patients do not want to undertake the financial burden of an out-of-pocket operation. Ironically, many of the same insurance carriers do endorse and cover other gastric restrictive procedures such as the

$$\% \text{ EWL} = \frac{\text{Current Amount of Weight Lost}}{\text{Pre-op Weight} - \text{Ideal Body Weight}}$$

example: If you weighed 200 lbs. pre-op and had an IBW of 100 lbs., and lost 70 lbs. at 12 months, you would have a % EWL of 70lbs / (200-100) or 70%

$$\% \text{ EWL} = \frac{70}{200 - 100} = \frac{70}{100} = 70\%$$



A small pouch is created by encircling the upper stomach with the LAP-BAND

Illustration courtesy of INAMED Health

Vertical Band Gastroplasty or VBG. The VBG does not offer the advantage of adjustability, is not easily reversible and involves staple lines that may break down. A common reason for denial of the LAP-BAND by insurance companies is that the procedure is considered "investigational" or "experimental." The LAP-BAND has been FDA approved since June 2001. Based on this approval, by definition, the procedure cannot be termed experimental.

Acceptance of the LAP-BAND has also been difficult given some early negative results in the United States. The first FDA monitored clinical trial, which has been coined Trial A, did not produce overwhelming results.⁴ The mean excess weight loss was 34.5% at 12 months, 37.8% at 24 months and 36.2% at 36 months. The most disappointing results that were published independently of the other Trial A surgeons were from DeMaria⁵. Most significantly, they reported a 71% incidence of dilatation of the esophagus at 21 months. An important point to consider when evaluating the data from Trial A is that the majority of the surgeons were bariatric surgeons who performed mostly open procedures. Only two surgeons performed more than fifty cases over the three-year period, and the other fifteen surgeons averaged only eleven surgeries. Many of the problems were likely due to over inflation of the band and improper follow-up. Rubenstein⁶ is responsible for the only data from Trial B. He reported an EWL of 38.3% at 1 year, 46.6% EWL at 2 years and an EWL of 53.6% at 3 years.

Much has been made of one of the complications of the LAP-BAND procedure termed gastric prolapse or gastric slippage. This is a process by which stomach below the band comes through the band and gets caught above the band. Early slip rates were 15%, and were a reflection of the perigastric technique in which the band was deployed flush with the stomach. More recently, the most commonly employed technique is the pars flaccida approach. This involves placing the band around the stomach as well as

tissue surrounding the stomach, which reduces the likelihood of the band migrating. This newer approach has dropped the slip rate to 3%.^{2,3} Other complications from this surgery include band erosion, tubing breaks, access port problems and early obstruction problems. The majority of complications can be handled laparoscopically and are not considered life-threatening.

Results from Europe and Australia have been impressive. O'Brien² has demonstrated excess weight loss of 57% at 6 years. Dargent⁷ has reported 64% EWL at 3 years. Vertruyen⁸ has 7 year data showing 52% EWL, Belachew⁹ 50-60% EWL at 5 years, and Cadiere⁹ 62% EWL at 2 years. As insurance obstacles continue to be overcome, better U.S. data becomes available, and patient education improves, the LAP-BAND will become more popular. Then it will become more mainstream in the United States. ■

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5. Demaria EJ, Sugeran HJ, Meador JG, et al, "High failure rate after laparoscopic adjustable silicone gastric banding for the treatment of morbid obesity," *Ann Surg* 2001; 233:809-818.
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9. Cadiere GB, Himpens J, Vertruyen M, et al, "Laparoscopic gastroplasty (adjustable silicone gastric banding)," *Semin Laparosc Surg* 2000; 7:55-65.

Dr. Chebli offers patients the Laparoscopic Roux-en-Y Gastric Bypass, the Open Roux-en-Y Gastric Bypass, and the LAP-BAND. For more information, visit www.metrobariatrics.com or call 703.620.3211.