

US experience with the LAP-BAND system

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Abstract

Laparoscopic adjustable gastric banding is the most commonly performed operation for morbid obesity in Europe and Australia and has been shown to result in significant long-term weight loss. The US Food and Drug Administration (FDA)–monitored clinical trial results with the LAP-BAND system (INAMED Health, Santa Barbara, CA) did not reproduce the results of studies performed elsewhere in the world. This article reviews data from the first and second FDA clinical trials as well as data from continuing US clinical experience. Four American surgeons at 4 centers have performed more than 500 LAP-BAND procedures not included in the first 2 FDA clinical trials. Of these patients, 115 have been followed for at least 9 months, and 43 have been followed for at least 12 months. A retrospective analysis of prospective data gathered from these patients is presented. The percent excess weight loss was 35.6% at 9 months and 41.6% at 12 months. The average body mass index decreased from 47.5 to 38.8 in 9 months and from 47.5 to 37.3 in 12 months. There were no deaths related to the insertion of the device. Of 15 complications requiring operative management (13%) in 12 patients, there were 8 port displacements or tubing breaks (7%), 2 elective explantations (2%), 2 cases of gastric prolapse (2%), 1 gastric pouch dilatation (<1%), 1 port abscess (<1%), and 1 hemorrhage (<1%). Clinical experience with the LAP-BAND system in the United States shows the device to be a safe and effective treatment for morbid obesity, with results comparable to the international data. The combination of proper surgical technique and close patient follow-up with frequent band adjustments, performed in a comprehensive bariatric program setting, may make the LAP-BAND system a powerful surgical tool in the treatment of morbid obesity. © 2002 Excerpta Medica Inc. All rights reserved.

Laparoscopic adjustable gastric banding with the LAP-BAND system (INAMED Health, Santa Barbara, CA) has proved to be safe and effective in Europe and Australia. Experience with the LAP-BAND system since 1993 has demonstrated the safety of the device as reflected by mortality rates of <0.1%, early complication rates of 0.4% to 0.6%, and late complication rates of 2.2% to 13% [1–10]. The complications that occur are rarely life threatening. Long-term results show a 53% to 68% excess weight loss (EWL) maintained up to 3 years after surgery [1–4,6,7,10]. These results have been questioned in the United States, mainly due to less favorable reports based on data gathered during US Food and Drug Administration (FDA)–monitored clinical trials [11,12]. In June 2001, the FDA approved the LAP-BAND system for use in the United States. This article reviews both the short- and long-term American experience with the LAP-BAND system, including 2 FDA-monitored clinical trials (Trials A and B) and a retrospective

analysis of unpublished prospective data from continuing US clinical experience.

FDA Trials A and B

The first FDA-monitored clinical trial to evaluate the LAP-BAND system in morbidly obese patients began in April 1995 [11] and is called Trial A (or LAP-BAND Adjustable Gastric Banding [LAGB] System for Treatment of Clinically Severe Obesity). The last patient in Trial A was implanted in June 1998. Trial A included 8 centers and 299 patients who were followed for 36 months. Of the 299 patients, 292 received the LAP-BAND and 7 received an earlier version of the device, called the adjustable silicone gastric band (ASGB). Patients receiving the ASGB were included only in safety analyses.

A second FDA-monitored clinical trial, called Trial B (or Clinical Evaluation of the LAP-BAND System in Clinically Severe Obese Patients), began in 1999 and also followed patients for up to 36 months. The only published data from Trial B come from Rubenstein [13] and are based on his experience with 63 patients having up to 36 months of

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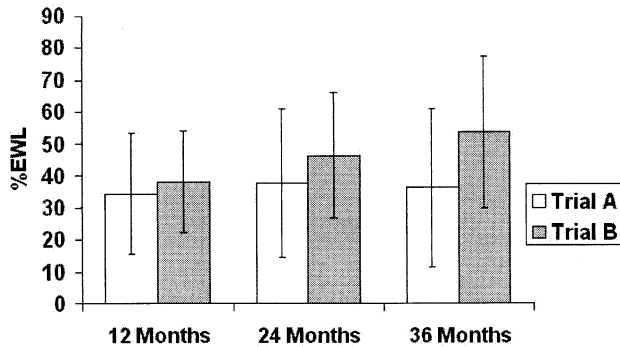


Fig. 1. Mean percent excess weight loss (%EWL) by follow-up visit is shown for Food and Drug Administration (FDA) Trial A [11] and for 63 patients in FDA Trial B [12] of the LAP-BAND device.

follow-up. The 63 patients were implanted with the LAP-BAND between March 1999 and June 2001.

Of the 292 LAP-BAND patients in trial A, 259 (89%) had the band placed by laparoscopy, and 33 (11%) patients had the band implanted via laparotomy (20 were scheduled and 13 were converted during surgery). All 63 trial B patients underwent laparoscopic surgery. The average percent EWL (%EWL) in trial A was 26.5% at 6 months, 34.5% at 12 months, 37.8% at 24 months, and 36.2% at 36 months. The average %EWL in the 63 Trial B patients was 27.2% at 6 months, 38.3% at 12 months, 46.6% at 24 months, and 53.6% at 36 months. The 12-, 24-, and 36-month %EWL results for the 2 series are shown in Fig. 1.

Complications in Trial A appeared to be more frequent than complications among the 63 trial B patients. Nausea or vomiting (or both) occurred in 51% of patients in trial A compared with 23% in trial B (only vomiting, not nausea, was reported in the trial B series), gastroesophageal reflux in 34% versus 2%, gastric prolapse (band slippage)/pouch dilatation in 24% versus 5%, stoma obstruction in 14% versus none reported, esophageal dilatation in 10% versus 6%, port problems in 15% versus 8%, and erosions in 1% versus 1%.

Two deaths occurred during the course of trial A, 1 due to "mixed drug intoxication" 1 week after explantation and the other due to multiple pulmonary emboli 1 day after explantation of the LAP-BAND and conversion to a Roux-en-Y gastric bypass procedure. Neither is believed to have been device related. No deaths were reported among the 63 trial B patients.

Continuing US clinical experience

Study description

A retrospective review was conducted of prospective data collected on patients undergoing LAP-BAND surgery at 4 US medical centers between October 2000 and July 2002 (some patients were implanted before FDA approval

of the LAP-BAND in June 2001). Four surgeons (Jeff W. Allen, M.D., Santiago Horgan, M.D., Jaime Ponce, M.D., and Christine J. Ren, M.D.) performed LAP-BAND surgery on 534 patients, 115 of whom completed at least 9 months of follow-up. Forty-three patients have completed at least 12 months of follow-up.

Indications for surgery were based on the National Institutes of Health recommendations for bariatric surgery [14]. All patients required a body mass index (BMI) ≥ 40 or ≥ 35 in association with comorbidity. Patients were educated and screened with preoperative psychological, nutritional, and medical evaluation. Patients did not undergo formal screening for eating behavior (ie, sweet-eaters vs volume-eaters) but were assessed for motivation and commitment to long-term follow-up.

Three surgeons worked in an academic university setting (JWA, SH, CJR), and 1 surgeon worked in a private-practice setting (JP). All surgeons were experienced in advanced laparoscopy, including other laparoscopic bariatric procedures, and open bariatric procedures and cared for morbidly obese patients within 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 used the pars flaccida technique for LAP-BAND placement.

The surgeons saw their patients every 1 to 2 months after surgery, with postoperative adjustments performed either in the office or under fluoroscopic guidance, determined by symptoms of appetite and progress of weight loss. All patients were encouraged to attend support groups. Diagnostic 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

All 115 patients underwent laparoscopic adjustable gastric banding using the LAP-BAND system and completed a minimum follow-up of 9 months, with the longest follow-up being 18 months. Of 115 patients, 98 were women and 17 were men, with an average age of 42 years (range: 18 to 69) and an average BMI of 47.5 (range: 35.5 to 70). Average body weight was 132 kg (range: 86 to 256 kg).

The average %EWL at 9 and 12 months was $35.6\% \pm$ SD 15.26 (range: 1.5% to 83%, $n = 115$) and $41.6\% \pm$ SD 19.3 (range: 1% to 98.7%, $n = 43$), respectively (Table 1). The average BMI decreased from 47.5 to 38.8 in 9 months ($n = 114$) and from 47.5 to 37.3 in 12 months ($n = 43$). Of patients with 9 months' follow-up, 5 (4%) had %EWL of $<10\%$ and 12 (11%) had %EWL of $<20\%$. Of patients with 12 months' follow-up, 2 (5%) had %EWL of $<10\%$ and 4 (9%) had %EWL of $<20\%$.

Adverse events were seen in 25 patients (22%; Table 2).

Table 1
Percent of excess weight loss in US clinical trials of LAP-BAND: FDA studies versus continuing US clinical experience

Surgeon	n	Average age (yr)	Female/male	Preoperative BMI	n	9-month BMI	9-month %EWL	n	12-month BMI	12-month %EWL
JWA	10	37.7	8/2	44.1	10	33.9	46.8	NA	NA	NA
SH	38	44.9	33/5	45.2	38	38.0	31.8	16	39.3	35.9
JP	44*	39.0	40/4	47.8	43	38.7	36.4	27	36.2	45.0
CJR	23	42.0	17/6	52.0	23	42.3	35.2	NA	NA	NA
All	115	42.2	98/17	47.5	114	38.8	35.6	43	37.3	41.6
FDA trial A	292	38.8	247/45	47.4	185	40.4	30.8	233	39.0	34.5
FDA trial B	63	40.8	56/7	48.8	62	NR	27.2 [†]	59	NR	39.3

FDA = US Food and Drug Administration; BMI = body mass index; %EWL = percent excess weight loss; NA = not applicable; NR = not reported.

* Includes patient who had band explantations 6 months postoperatively.

[†] 6-month data (9-month data not reported).

Table 2
Adverse events in continuing US clinical experience (n = 115)

Adverse event	n (%)
Port displacement/tubing break	8 (7)
Wound infection	5 (4)
Stoma obstruction	2 (2)
Gastric prolapse	2 (2)
Elective explantation	2 (2)
Erosion	1 (<1)
Conversion to open procedure	1 (<1)
Hemorrhage	1 (<1)
Pneumonia	1 (<1)
Gastric pouch dilatation	1 (<1)
Total	25 (22)

There were no deaths related to the insertion of the device. Conversion to an open procedure was necessary in 1 patient (<1%). Acute perioperative complications occurred in 4 patients (3%) and included 2 stoma obstructions, 1 hemorrhage, and 1 case of pneumonia. The patient with the hemorrhage experienced bleeding from a trocar site, which was managed with laparoscopic exploration without need for blood transfusion. The acute stoma obstructions, secondary to edema, were treated conservatively with intravenous hydration and resolved spontaneously. There were no cases of thromboembolism, myocardial infarction, or intestinal sepsis.

Wound infection occurred in 5 patients (4%), who were treated with oral antibiotics. All infections resolved; in 1 of these patients, however, a port abscess developed that required port removal 3 weeks postoperatively, with subsequent port replacement 6 months postoperatively. Wound culture revealed *Pseudomonas*, which was likely a contaminant from a previous laparotomy scar associated with perforated diverticulitis. The patient has had no problems since port replacement, and has maintained good weight loss.

Long-term complications were experienced in 12 patients (10%) and included 8 port displacements or tubing breaks (7%), 2 cases of gastric prolapse (2%), 1 case of gastric pouch dilatation (<1%), and 1 case of erosion (<1%). The patients with gastric prolapse and pouch dila-

tion were treated electively with laparoscopic repositioning or replacement of the LAP-BAND, which required an overnight hospital admission. They have done well subsequently. The 8 episodes of port displacements and tubing breaks occurred in 7 patients and were corrected surgically in an outpatient surgery setting. One patient experienced 2 consecutive tubing disconnections, likely related to excessive upper extremity and abdominal exertion when pulling herself up into bed while lying on her abdomen. This patient had severe lower extremity arthropathy, which compromised ambulation, and underwent 3 surgical procedures, the last of which was band explantation requested for fear of recurrent tubing problems. The patient with band erosion has been asymptomatic and has been closely monitored; she has refused surgical intervention at this time.

Two patients (2%) requested elective LAP-BAND explantation, 1 who was explanted 6 months postoperatively because of recurrent port displacement, as mentioned earlier, and a second who developed psychologic intolerance after the 9-month follow-up period.

In total, 12 patients (10%) required surgical intervention, in either an outpatient setting or an overnight hospital admission, for complications related to the LAP-BAND. The overall reoperation rate was 13% (15 reoperations in 115 patients).

Conclusion

The bariatric surgeon must incorporate all technical, clinical, and social skills for complete care of the patient. A deficiency in any of these factors may have significant impact on results. LAP-BAND surgery is one of numerous options for weight loss in the morbidly obese. As in any other procedure for this patient population, the 2 tenets of success are technique and follow-up. However, with the LAP-BAND procedure, a third factor is crucial to success: adjustments.

Our experience with the LAP-BAND has been more similar to the international reports than to the results of the FDA clinical trials, confirming the surgery to have a low

morbidity and mortality, with complications being qualitatively minor. Although we found a 22% complication rate with a 13% reoperation rate, all reoperations were performed laparoscopically, with no patient requiring chronic hospitalization or medical support. There were no life-threatening complications.

Although the number of patients with 1-year follow-up in our combined series is small ($n = 43$), the results suggest possible improvements in the incidence of gastroesophageal reflux, gastric prolapse and pouch dilatation, conversion to laparotomy, and stoma obstruction, especially compared with FDA trial A. The results of the FDA trials A and B are very different from those of the European and Australian experience. Not only is there a discrepancy in %EWL (36% in trial A vs 53% to 68% in international studies [1–4,6,7,10]) at 1 to 3 years, but the FDA trials have a higher complication rate. Although the FDA trials documented the incidence of gastric prolapse, no distinction was made between gastric prolapse and gastric pouch dilatation. This is an important omission, because gastric prolapse is a true complication, which requires surgical revision. Gastric pouch dilatation is typically the consequence of an overtightened band, which requires fluid removal. Inexperience in band adjustment may underlie the relatively high rate of gastric prolapse and pouch dilatation seen in the FDA clinical trials.

Inexperience also may have been a factor in the surgical technique used in the FDA clinical trials. All surgeons were open bariatric surgeons who lacked advanced laparoscopic surgery experience. Furthermore, only 3 of 17 surgeons in trial A performed more than 50 procedures over a 3-year period, whereas the other 14 performed an average of 11 procedures. Some failures attributed to the band were actually related to errors in surgical technique (eg, intraoperative needle puncture of the band causing band leakage with failure of restriction and placement of the band too low on the stomach). Use of the perigastric approach, as was performed at that time, may have a higher rate of gastric prolapse [5,15–17]. Rates of these complications were lower in the 63 patients reported in FDA Trial B [12] and in our series of 115 patients. The surgeons involved in these studies possessed laparoscopic bariatric skills. There were no technical mishaps in our series, with only 1 conversion (<1%) to open laparotomy. An important point to address is that the FDA clinical trials used what have come to be considered suboptimal postoperative management practices. Adjustments were made every 3 to 6 months under fluoroscopy according to radiographic band lumen diameter, not according to patient appetite or weight loss. Many patients had their bands overtightened and developed gastric pouch dilatation, which eventually led to esophageal dilatation, a situation that has not been documented in international studies. International surgeons perform adjustments every 1 to 2 months based on patient appetite and weight loss. These frequent follow-up visits allow the surgeon and patient to carefully tailor the band restriction and reinforce behavior

modification. The authors of this article follow these procedures.

The follow-up in our series is relatively short, but the weight-loss results—41.6% EWL and decrease in BMI from 47.5 to 37.3 1 year after LAP-BAND placement—are encouraging and consistent with the international experience. DeMaria and colleagues reported the most disappointing results of the LAP-BAND system [12]. The investigators, who were participants in FDA trial A, published their experience independently of other trial A centers. With 37 patients followed up to 4 years, they reported %EWL of 34.5% at 12 months ($n = 28$), 36% at 24 months ($n = 24$), 38% at 36 months ($n = 15$), and 44% at 48 months ($n = 4$). African American patients ($n = 5$) had the poorest results, with 11.5% EWL at 36 months, which may have affected the overall weight loss results. Excluding African Americans, EWL was 44% ($n = 12$) at 36 months. This may be an important difference between US and non-US studies, because the vast majority of patients in international studies to date are white. Because of the small sample size in our study, we are unable to comment on this possible disparity.

Of particular concern in the report by DeMaria and colleagues was the finding of increased esophageal dilatation in 18 of 25 patients (71%) after 21 months. The likely cause of worsening esophageal and gastric pouch dilatation in these patients was the further tightening of their bands. Six of these patients required band removal. None of these patients underwent esophageal manometry to quantify dysmotility, and so the question of long-term achalasia remains unanswered. In the subset of 63 patients in trial B who had at least 3 years of follow-up after LAP-BAND placement, 4 (6%) had developed mild esophageal dilatation, all of whom were asymptomatic [13]. As mentioned previously, this complication has not been reported in international studies, nor has any other FDA trial participant reported it in a published study. Although we have not seen esophageal dilatation in our series, it is possible that the problem will arise with longer term follow-up. To date, however, esophageal dilatation has not been observed on postoperative esophagrams, despite significant weight loss.

DeMaria and colleagues [12] reported 15 patients (41%) who required band removal (10 days to 42 months after surgery), most due to inadequate weight loss. In contrast, we have had to remove only 2 bands of 115 patients (2%) with up to 18 months of follow-up. This disparity may be due to expectations on the part of both surgeon and patient regarding the rate of weight loss. The rate of weight loss after gastric bypass is usually rapid in the first 6 months and then slows until a plateau is reached 18 months after surgery. The rate of weight loss after gastric banding is slow and steady, averaging about 1 to 2 lb per week, or 4 to 8 lb per month. The plateau can be reached 2 to 3 years after surgery. The 63 patients from trial B demonstrated this trend: %EWL averaged 27.2% at 6 months, 38.3% at 12 months, 46.6% at 24 months, and 53.6% at 36 months [13].

Our continuing experience with LAP-BAND procedures

in the United States reflects the application of advanced laparoscopic techniques, attention to the lessons learned from the international experience and the FDA clinical trials, and the availability of a comprehensive bariatric program. In all 4 medical centers, the authors were already performing laparoscopic bariatric surgery in the setting of a bariatric program when the LAP-BAND studies began. The LAP-BAND system is seen as an effective surgical option for bariatric surgeons and their patients. The perioperative results show that use of the LAP-BAND in qualified hands is safe, with low mortality and morbidity rates. Short-term weight loss cumulatively and separately follows the trend observed in the international data, increasing gradually and consistently at 9 months, 12 months, and 15 months after surgery. Because adjustments are performed similarly to the way they are performed in Europe and Australia, it can be postulated that long-term weight loss in our patients will mirror the international experience as well.

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