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Laparoscopic adjustable gastric banding

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Laparoscopic adjustable gastric banding (LAGB) brings several unique aspects to bariatric surgery. It has provided a very safe, effective, reversible, and adjustable system that is widely applicable. The first human LAGB procedure, using the Lap-Band system (INAMED Health, Santa Barbara, CA), was performed on September 1, 1993 [1]. Since then, more than 130,000 Lap-Band devices have been placed, and more than 100 peer-reviewed reports on its use have been published. The extent of the literature on the outcomes of LAGB surgery is comparable (and, in certain aspects, superior) to that on alternative bariatric surgery. Refinements in the placement technique have been widely applied and accepted, making LAGB the most standardized surgical approach to the treatment of obesity described to date.

LAGB surgery is the safest, least invasive operative procedure that can be offered to patients with severe obesity. Because the Lap-Band is the only band approved for use within the United States and the majority of research literature concerns this device, the information presented here refers to Lap-Band use.

Key attributes

Adjustability

One of the most important advantages of LAGB is the capability of adjusting stoma size without reoperation. Adjustment is a simple outpatient procedure involving the injection or withdrawal of saline solution into a subcutaneous access port. This procedure usually takes about 5 minutes. An optimally sized stoma provides for sustained

weight loss and reasonable food tolerance. This gentle approach allows for a more controlled weight-loss rate as compared with nonadjustable stapling techniques (Fig. 1).

Laparoscopic placement

The Lap-Band system can be placed laparoscopically in almost all patients who have not undergone previous gastric surgery, regardless of the degree of obesity (see Video 1). The procedure can be readily performed with an overnight stay, is associated with only modest discomfort, and enables a rapid return to normal activities. Although the procedure requires advanced laparoscopic surgical skills, it is not complex and can be readily performed by appropriately trained surgeons. The procedure has proven remarkably safe, no doubt due in part to the minimal alteration to the gastrointestinal tract and laparoscopic placement.

Reversibility

It should be hoped and expected that the treatments for obesity available today will be superseded by better treatments in the next 20 years. It is an asset of the Lap-Band that it can be removed easily and the stomach allowed to return to its normal configuration. A 20-year-old patient will be only 40 in 20 years' time, and thus retains the option of moving to improved treatments if and when they appear. Removing the band is a minor laparoscopic procedure that can be performed on a 23-hour outpatient basis.

Technique

Whereas the Lap-Band itself has changed little since its introduction in 1993, certain aspects of its surgical placement, postplacement care, and access port design have changed significantly. These changes have been aimed at improving outcome and reducing morbidity, especially the

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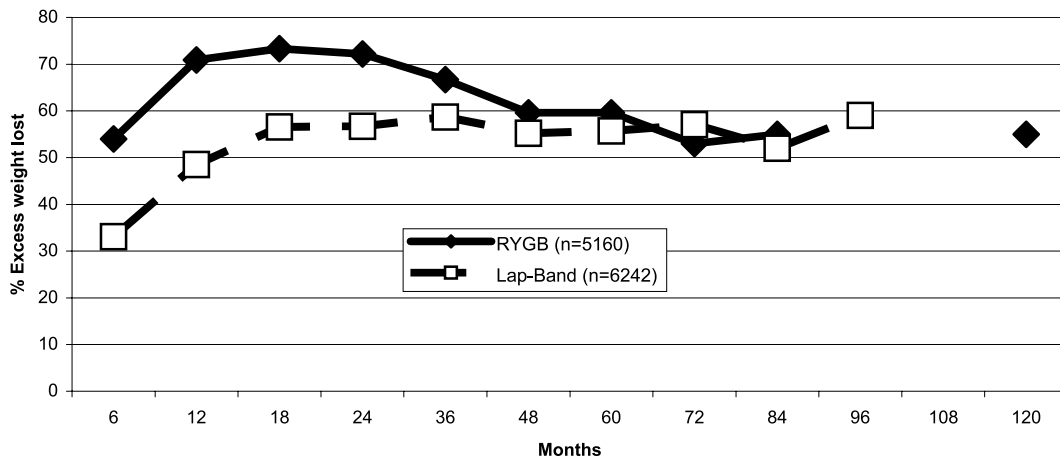


Figure 1. A comparison of %EWL after Lap-Band and RYGB surgery in published series with baseline numbers > 50. (Adapted from Chapman AE, Kirloff G, Game P, et al. Laparoscopic adjustable gastric banding in the treatment of obesity. A systematic literature review. *Surgery* 2004;135:326–51).

significant late complications: band prolapse/slippage/pouch dilatation (several ways of describing an abnormally large segment of stomach above the band), band erosion into the stomach, and system leaks.

Proper placement technique and postoperative care have proven crucial to achieving optimal outcomes and reducing complications. Any problems with surgical technique, learning curves and postplacement management protocols are likely to have been important factors in the well-reported “disappointing” early results experienced by some U.S. surgeons [3,4].

Avoiding late complications

The most common complication of the Lap-Band system has been enlargement of the gastric pouch, due to either pouch dilatation or slippage of the stomach up through the band. To avoid this complication, some preventive technical modifications to the system have been made:

- Development of the pars flaccida dissection pathway for the placement of the band posterior to the gastroesophageal junction has significantly reduced the incidence of posterior gastric prolapse as compared with the perigastric approach [5]. This technique has been described in greater detail by Fielding and Allen [6].
- A very small (< 15 mL) initial pouch (the “virtual pouch”) is created by proper anterior fixation of the band. This is achieved by embedding the silicone band completely (with the exception of the buckle area) with the application of at least 3 gastro-gastric sutures. It is essential that the band overlies some stomach to achieve satisfactory satiety.

Anterior prolapse is uncommon, but represents technical failure of the anterior fixation and thus is quite avoidable. Erosion of the band into the stomach is a concern, with an incidence of up to 3%. It is noteworthy, however, that the

incidence of band erosion has been markedly reduced by avoiding suturing the gastric wall to the crura of the diaphragm or pushing it onto the buckle area of the band. An Australian series (P. E. O’Brien and J. B. Dixon, personal communication, 2004) with a high early incidence did not find a single case in more than 1000 patients who underwent the modified placement technique. In addition, a series of design changes to the subcutaneous access port has substantially reduced the risk of system leakage.

These modifications have reduced the incidence of all common late complications. Details of the initial surgical approach and the current technique are summarized and compared in Table 1.

Outcomes

Proper placement of the Lap-Band, along with proper follow-up and patient support, have permitted the achievement of critical outcomes in 3 areas that characterize the benefits of the Lap-Band procedure: safety, weight loss, and health and quality of life.

Safety

Lap-Band placement has proven to be a very safe procedure. The Australian Safety and Efficacy Register of New Interventional Procedures-Surgical (ASERNIP-S), in a systematic review of the world literature of LAGB (including all variations), found an early mortality rate of 0.05%, or 1:2000, which is 1/10 the mortality of Roux-en-Y gastric banding (RYGB) and 1/6 the mortality of vertical banded gastroplasty (VBG) [2].

Weight loss

Weight loss progresses over a 2- or even 3-year period and then stabilizes, usually in the range of between 50% and 60% of excess weight (Table 2). The ASERNIP-S review

Table 1
Initial versus current approaches

Initial approach	Current approach
Band placed ~3 cm below the gastroesophageal junction.	Band placed ~1 cm below the gastroesophageal junction.
Greater curve dissection above the first short gastric vessels.	Greater curve dissection at the level of the diaphragm, onto the left crus.
Lesser curve dissection in the perigastric path (next to, or directly on the lesser curve) often via the apex of the lesser sac.	Lesser curve dissection via the pars flaccida path (window in avascular space in lesser omentum, at insertion of right crus) above the lesser sac.
Calibration of balloon volume attempted with transducer (Gastrostometer) with band filled at surgery.	Band left empty at surgery to avoid postoperative obstruction from edema and initial overtightness.
Anterior gastric fixation limited to 1 or 2 central sutures.	Anterior fixation more extensive, extending from extreme lateral greater curve across the body of stomach to near the buckle at the lesser curve.
Gastro-gastric sutures placed to anchor the band below a small gastric pouch, usually 15–30 mL.	Gastro-gastric sutures placed to fix the band below a “virtual pouch” just below the gastroesophageal junction.
Access port placed within the rectus muscle.	Access port placed on the rectus muscle.

reported 56% average excess weight loss (EWL) at 3- and 4-year follow-up, and noted that this level of weight loss was not different from that achieved with RYGB. Data from recently published U.S. studies demonstrate weight outcomes similar to those reported by many international groups (Table 2) [7,8].

Health and quality of life

Dramatic improvement in or resolution of serious medical comorbidities accompanies the weight loss after LAGB with the Lap-Band system. Table 3 summarizes published comorbidity changes associated with the procedure. There are major improvements in the conditions of the metabolic syndrome, which is characterized by impaired glucose tolerance, dyslipidemia, and hypertension. Improvement in insulin sensitivity and pancreatic beta-cell function associated with weight loss induces remission in most of those with type 2 diabetes mellitus and reduces the risk of developing type 2 diabetes mellitus in others [30–32]. It is important that type 2 diabetes be treated early, to prevent irreversible beta-cell damage and maintain the ability to reverse the pathological process. Improvement in dyslipidemia is characterized by increased levels of high-density lipoprotein cholesterol and decreased levels of triglycerides.

Table 2
Percent excess weight loss

Study	n	Months after surgery							
		12	18	24	36	48	60	72	84
International									
Weiner 2003 [9]	984								59.3*
Zinzindohoue 2003 [10]	500	42.8		52	54.8				
Rubin 2003 [11]	250	42.1		51.4	55.5				
Fielding (2003) [12]	76	46.7			59.1		61		
Belachew 2002 [13]	763						50–60†		
O'Brien 2002 [14]	706	47	51	52	53	52	54	57	
Cadiere 2002 [15]	652	38		62					
Vertruyen et al. 2002 [16]	543	38		61	62	58	53		52‡
Dargent 1999 [17]	500	56		65	64				
Toppino et al. 1999 [18]	361	42							
Fielding et al. 1999 [19]	335	52	62						
Paganelli et al. 2000 [20]	156	43							
Niville and Dams 1999 [21]	126	48	58						
Berrevoet et al. 1999 [22]	120	46	53						
U.S.									
Hewitt 2004 [23]	500	36		47§					
Ren and Allen 2003 [24]	445	44.3							
Spivak 2003 [25]	271	40		43					
Fox 2003 [7]	105	61		75	72				
Rubenstein 2002 [8]	63	38.3		46.6	56.3				
Ren, Horgan and Ponce 2002 [26]	43	41.6							

* Percentage at 96 months.

† Percentage reduction of excess weight for patients with >5-year follow-up.

‡ Percentage at 86 months.

§ Percentage at 30 months.

Table 3
Effect of LAP-BAND® system on comorbidities of obesity (2001–2004 articles)

	Resolved	Improved*	Resolved or improved†	No change	Worse
Type 2 diabetes mellitus			92%		
Abu-Abeid (Israel) (2001) [27]	71%	29%	100%	NR	NR
Bacci (Italy) (2002) [28]	NR	100%	100%	0%	0%
Fielding (Australia) (2003) [12]	100%	0%	100%	0%	NR
Frigg (Switzerland) (2004)‡ [29]	75%	8%	83%	NR	NR
O'Brien (Australia) (2002) [14]	54%	43%	97%	3%	0%
Rubenstein (U.S.) (2002) [8]	NR	84%	84%	NR	NR
Zinzindohoue (France) (2003) [10]	45%	35%	80%	17%	3%
Hypertension			78%		
Abu-Abeid (Israel) (2001) [27]	33%	66%	99%	NR	NR
Bacci (Italy) (2002) [28]	33%	45%	78%	22%	0%
Fielding (Australia) (2003) [12]	56%	13%	69%	31%	NR
Frigg (Switzerland) (2004)‡ [29]	58%	42%	100%	NR	NR
O'Brien (Australia) (2002) [14]	55%	31%	86%	14%	0.7%
Rubenstein (U.S.) (2002) [8]	NR	45%	45%	NR	NR
Zinzindohoue (France) (2003) [10]	28%	43%	71%	27%	2%
Sleep Apnea			95%		
Abu-Abeid (Israel) (2001) [27]	100%	0%	100%	0%	0%
Fielding (Australia) (2003) [12]	67%	33%	100%	0%	NR
O'Brien (Australia) (2002) [14]	4%	NR	94%	NR	NR
Rubenstein (U.S.) (2002) [8]	100%	0%	100%	0%	0%
Zinzindohoue (France) (2003) [10]	80%	0%	80%	20%	0%
Osteoarthritis, Degenerative Joint Disease, Arthralgia			83%		
Abu-Abeid (Israel) (2001) [27]	0%	100%	100%	0%	0%
Frigg (Switzerland) (2004)‡ [29]	52%	24%	76%	NR	NR

NR—not reported specifically.

* Includes those noted as “improved or resolved” where percent resolved is not specified.

† Combines resolved and improved as not all studies reported these separately. The combined averages (means) of studies for comorbidities are not controlled or adjusted for length of follow-up, study size, method of measurement, or criteria for assessment.

‡ At 4-year follow-up.

Together with reduced blood pressure, these changes provide a substantial reduction in cardiovascular risk. Other medical conditions caused or aggravated by obesity, including sleep apnea, daytime sleepiness, asthma, and gastroesophageal reflux, are also significantly improved by LAGB [27,29,33]. Weight loss is also associated with improved fertility and more favorable pregnancy outcomes [34].

All aspects of quality of life improve substantially, especially physical ability, and post-weight loss quality of life measures approximate those of the general population [35]. Major improvements in body image and a reduction in depressive symptoms have also been reported [36,37]. These changes provide perhaps the most compelling data demonstrating the value of Lap-Band surgery and underlie the great satisfaction reported by those who have undergone the procedure.

Complications

Although the Lap-Band system is remarkably safe in the perioperative phase, the possible need for reoperation some years after placement because something moved or broke is an ongoing concern. The ASERNIP-S review reported a sum of perioperative and late complications of any kind of 11.3% for LAGB, which compares favorably with the sums

of 23.6% for VBG and 27.4% for RYGB [2]. As the problems leading to the need for reoperation have been addressed with modifications in the LAGB technique, the incidence of all common late complications has decreased [38]. Current techniques, if applied carefully, reduce the incidence of pouch enlargement to < 5%, and erosions and leaks in the system should now be rare events. The broad acceptance of standard techniques developed in a response to early problems has allowed the Lap-Band system to become the first truly standardized, widely used surgical therapy for severe obesity. No doubt further refinements will allow even better results.

Long-term patient care

Severe obesity is a chronic condition requiring indefinite therapy and follow-up. Surgery is an effective therapy but is not a cure, and patients and bariatric surgical teams must recognize the responsibilities of long-term care. This feature of postsurgical care is quite unlike that of usual surgical practice. The care of the Lap-Band patient needs to be comprehensive, skilled, and indefinite. Training and commitment is required to achieve optimal outcomes. The treating practitioner needs to know when and how to adjust the

band; how to suspect, appropriately investigate, and manage complications; how to treat obesity-related comorbidities; and how to apply the art of general bariatrics, which includes nutritional, movement and exercise and behavioral therapies.

It is quite unrealistic to place this burden on the surgeon alone, because the level of care requires a multidisciplinary team if significant numbers of patients are to be treated. As with all bariatric surgical patients, long-term care and follow-up should be considered mandatory for patients undergoing LAGB.

Indications for therapy

The National Institutes of Health (NIH) criteria were devised before any laparoscopic procedure of the LAGB type was developed, and risk-to-benefit ratios for then-current bariatric surgeries were significantly higher. The safety, efficacy, and broad applicability of Lap-Band surgery present us with some new issues that need to be resolved:

1. Are the current NIH criteria still appropriate, or should a broader group of patients be considered for Lap-Band surgery? The application to subjects with BMI 30 to 35 kg/m² with significant obesity-related comorbidity (eg, type 2 diabetes mellitus) requires consideration. It is also a logical choice in adolescents.
2. There is clear evidence to support the safety and efficacy of LAGB in becoming the primary intervention for bariatric patients in appropriate centers with comprehensive, long-term follow-up.
3. There is sufficient documentation in the literature to support using the Lap-Band system in specific subgroups of morbidly obese patients, including the superobese [12], diabetics [8,10,14,30–32,34], sweets eaters [39], adolescents [40–42], the elderly [27], high-risk patients, and those planning pregnancy [43–45]. At this time, there is little good evidence that any specific group of patients will respond better to other types of obesity surgery.
4. If Lap-Band surgery is to become more common for treating severe obesity and related diseases, then strategies need to address ongoing care of the large number of patients needing indefinite follow-up. In fact, all bariatric patients, regardless of the type of surgery, need long-term care for their chronic disease. Comprehensive training is required for surgeons, physicians, and other members of a multidisciplinary team.

U.S. data

Experience with the Lap-Band system began in 1995 with the initiation of a prospective clinical trial monitored

by the U.S. Food and Drug Administration (FDA). This first trial, known as the “A” trial, involved Lap-Band system implantations in 292 patients at 8 centers over a 3-year period, with a 3-year follow-up after implantation. All procedures in this trial were completed using the perigastric dissection pathway, and for most of the participating surgeons this was their first laparoscopic bariatric experience. Follow-up nuances specifically related to band adjustment frequency and volumes were not fully appreciated in this initial experience. This, combined with the early surgical technique, resulted in a mean %EWL of 36.2% at 3 years.

A second trial, also FDA-monitored and known as the “B” trial, included a mix of perigastric and pars flaccida procedures as the technique was evolving worldwide during 1997 to 1999. One center in the “B” trial reported results more in line with the growing body of international data, with mean %EWLs of 38.3% at 12 months, 46.6% at 24 months, and 53.6% at 36 months. Overall, significantly fewer complications were also seen in “B” trial [8].

A third, “expanded access,” FDA-monitored “C” trial was also conducted with 1-year follow-up just before FDA approval was granted in June 2001. All procedures in the “C” trial were completed using the pars flaccida technique by surgeons who had gained proficiency with advanced laparoscopic surgical procedures, such as laparoscopic gastric bypass, before enrolling Lap-Band patients in the study. These surgeons also benefited from a more complete understanding of the essential role of band adjustments in concert with frequent follow-up. The results of this trial were reported by 4 centers with data on 534 patients, 115 of whom had 9 months of follow-up and 43 of whom had 12 months of follow-up. The average %EWL was 35.6% ± standard deviation (SD) 15.26 at 9 months and 41.6% ± SD 19.3 at 12 months [26].

Recently, several publications reported U.S. results. Ren et al. [24] presented data on 445 patients, 99 of whom had 12 months follow-up with 44.3% EWL. Spivak et al. [25] reported his results on 271 patients with 1- and 2-year follow-up; he achieved 40% EWL at 12 months (n = 72) and 43% EWL at 24 months (n = 21). In a report primarily on early complications in 120 patients, Sarker et al. [46] reported a %EWL of 31.4% at a mean follow-up of 6.4 months.

Dalton Surgical Group experience

From October 2000 through April 2004, 831 Lap-Band procedures were performed in our program based in Dalton, Georgia. The perigastric technique was performed in 44 patients, and the pars flaccida technique was performed in 787 patients. Early data from this cohort were presented in an earlier report [1]. In our study cohort, the mean age was 41.6 years (range, 18–69 years), the mean BMI was 47.5 kg/m² (range, 34.9–81 kg/m²), and 82% were women. The mean operative time was less than 1 hour, and the average

length of hospital stay was 0.4 day. No deaths occurred. One conversion to laparotomy was required secondary to hepatomegaly with difficult mobilization. The rate of postoperative obstruction was 1.6% ($n = 14$), with all obstructions occurring in the first 150 pars flaccida cases.

After we adopted the principles of perigastric fat excision and the 2-step technique to avoid encircling the lesser curvature fat inside of the band, no cases of postoperative obstruction occurred. Delayed complications included 9 cases (20%) of gastric prolapse (mainly posterior) in the first 44 perigastric cases, and 11 cases (1.4%) of anterior prolapse (including 2 concomitant hiatal hernias) in the 787 pars flaccida cases, along with 3 tubing breaks (0.3%), 6 port abscesses (0.7%), 2 band erosions (0.2%), and no cases of persistent esophageal dilatation. One case of erosion presented 4 months after surgery with a delayed port infection, and the other presented with a lack of restriction 1 year postoperatively.

Weight loss was 41.8% EWL at 1 year ($n = 450$), 52.6% EWL at 18 months ($n = 233$), 59.1% EWL at 2 years ($n=96$), and 61.3% EWL at 3 years ($n = 25$), with 88% follow-up. Our diabetic patients lost an average of 38% EWL at 1 year ($n = 67$) and 52% EWL at 2 years ($n = 18$), with a 77% resolution rate and a significant decrease in HbA_{1C}, from 7.6% before surgery to 5.4% 2 years after surgery.

Most complications were minor and easily managed on an outpatient basis. Patient satisfaction was very high, even in those experiencing complications. These results follow the trends established in the worldwide literature (Table 2).

Summary

Bariatric surgery offers a long-term solution for the problem of severe obesity. The major benefits of sustained weight loss include the reversal of numerous obesity-related illnesses, making bariatric surgery one of the most powerful therapies in current clinical practice. LAGB is proving to be an acceptable form of bariatric surgery because of its safety, effectiveness, long-term weight-loss maintenance, and reversibility. Its appropriate expanded application in our communities requires broader training options and a major commitment by surgeons and associates to comprehensive, optimal, long-term care of bariatric patients. Our severely obese patients have a serious, but treatable, condition.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version, at [10.1016/j.soard.2005.02.018](http://dx.doi.org/10.1016/j.soard.2005.02.018).

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