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Laparoscopic Adjustable Gastric Banding: Outcomes

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Introduction

The laparoscopic adjustable gastric banding (LAGB) procedure involves the placement of an adjustable silicone band around the very upper part of the stomach immediately below the gastroesophageal junction. The level of restriction can be adjusted by adding or removing saline from the band via a subcutaneous port fixed to the anterior rectus sheath.

LAGB is the safest of the bariatric procedures [1, 2] with minimal mortality and morbidity. It can be performed as an overnight stay or same-day procedure in even the largest of patients.

The mechanism of action of the LAGB is the induction of early satiation (food satisfaction) with a small meal followed by a longer period of satiety (between-meal lack of hunger). Studies have shown that delay in gastric emptying is not the main mechanism of action and there is a lack of correlation between over-restriction and satiety [3]. Similarly, the band should not physically limit significantly food transit and there should be negligible food found above the band after a meal if the band is correctly adjusted [4]. A range of hormones including insulin, leptin, ghrelin, pancreatic polypeptide, and peptide YY do not play a significant role in LAGB function [5, 6]. It is hypothesized that the mechanical effects of the band and the passage of food bolus through this area of band resistance can generate myoenteric pressure signals [7]. Signals from these receptors may be important in both meal termination and satisfaction, and provide an important sense of well-being, although the functional roles of these receptors remain poorly understood [8].

Ongoing improvements in band placement and postoperative management have reduced morbidity as well as short-term and long-term complications. There have been a number of changes to the procedure of LAGB placement and aftercare since the original description. The surgical technique has been modified, and the majority of LAGB are now placed by the pars flaccida approach rather than the perigastric approach [9]. A randomized controlled trial comparing these techniques demonstrated fewer long-term complications with the pars flaccida approach than the perigastric approach along with a shorter operating time [10].

As the understanding of the mechanism of action of the LAGB has improved, so have aftercare programs. An optimal program will provide regular follow-up focusing on educating patients about correct food choices, small serving sizes, and emphasizing the importance of eating slowly and chewing the food well. Band adjustments should focus on the induction of early and prolonged satiety and when this is achieved, weight loss is optimal. Hunger and food seeking behavior suggests that the band is under-filled. Symptoms of reflux and an inability to eat solid food suggest the band is over-adjusted and that fluid should be removed [3].

Outcomes of LAGB surgery can be measured by change in weight, comorbidity, quality of life, long-term survival, and cost-effectiveness. The need for revisional surgery is another important outcome, and this must be considered in the context of the safety of the revision as well as the effect of the revision on weight, health, and well-being.

Weight Loss Outcomes

Weight loss after gastric banding is typically very steady at 0.5–1 kg/week. This means that weight loss progresses over a 2- to 3-year period and then stabilizes, usually in the range of 40–55 % EWL. Medium- and long-term (4- to 15-year follow-up) outcomes have been reported by individual series showing a great variation in weight loss results from 33 to 70 % EWL [11, 12] (Tables 1 and 2).

The weight loss following LAGB is gradual, 0.5–1 kg per week, and optimal outcomes require lifelong follow-up [13]. Follow-up is more intensive in the first year, with most patients requiring 6–8 visits [14, 15]. After the first year, most patients only require six monthly or annual visits. This model of care fits with the management of obesity as a chronic disease, and has been shown to be cost-effective [16–18].

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There have been two prospective multicenter Food and Drug Administration-monitored clinical trials in the United States. The Lap-Band trial A [19] recruited patients from 1995 to 1998 in eight centers; 259 out of 292 patients had the band implanted laparoscopically by perigastric dissection. The average EWL was 26.5 % at 6 months, 34.5 % at 12 months, 37.8 % at 24 months, and 36.2 % at 36 months. The very high incidence of gastric prolapse and slippages was attributed to the learning curve, as most of the surgeons involved were inexperienced laparoscopic surgeons, as well as the use of the perigastric dissection rather than pars flaccida. There was also a lack of effective follow-up, with an average of only 1.2 adjustments in the first year. The majority of patients were adjusted by radiologist based on a contrast swallow evaluation rather than tailoring the adjustment to the patient's sensation of satiety. There was no good band-specific patient education program.

The Swedish Band clinical study [20] recruited 276 patients in 12 centers in 2003. All patients were implanted laparoscopically by pars flaccida technique. This trial included centers with both large and no experience with gastric banding management. The mean % EWL at 3 years was 41.1 %.

Table 1. Gastric banding short- and medium-term weight loss (1–8 years)

Study	% Excess weight loss					
	1 year	2 years	3 years	4 years	5 years	8 years
FDA trials						
Lap-Band A[a] [19] (1995–2001)			36			
Swedish Band [20] (2003–2006)			41			
Randomized studies						
Angrisani et al. [21]					47	
Nguyen et al. [22]				45		
O'Brien et al.[b] [23]		87				
Dixon et al.[b] [25]		62				
O'Brien et al. [24]		73				
Dixon et al. [26]		40				
Systematic reviews						
Buchwald et al. [27]		47				
O'Brien et al. [13]	43		57		54	59
Cunneen et al. [28]			50–56			

FDA Food and Drug Administration
[a]Perigastric technique
[b]Body mass index between 30 and 40 kg/m^2

There have been two prospective randomized clinical studies comparing gastric banding with the gastric bypass. Angrisani [21] randomized 51 patients and allocated them to undergo either banding ($n=27$) or gastric bypass ($n=24$). At 5 years after the procedure, the band patients had an average % EWL of 47.5 % vs. 66.6 % for the gastric bypass group. In a similar study, Nguyen [22] randomized and followed 86 patients with gastric banding and 111 with gastric bypass. The % EWL at 4 years was 45 % vs. 68 %, respectively.

There have been four randomized controlled trials assessing the effectiveness of LAGB with conservative weight loss programs, with all showing substantially better weight loss and comorbidity resolution in the surgical arm [23–26]. In the initial trial, patients with a body mass index between 30 and 40 kg/m^2 the gastric banding group showed 87 % EWL compared with the conservative arm 22 % EWL at 2 years of follow-up [23].

There have been several meta-analyses and systematic reviews of the literature that included a significant number of gastric band patients. Buchwald et al. [27] published a large bariatric surgery meta-analysis and systematic review that included 136 studies with 3,873 LAGB patients with the majority of the studies having 2 years or less follow-up reported. The mean EWL was 47.5 %. O'Brien et al. [13] extracted reports out of the English literature with more than 100 patients and at least 3-year follow-up. 4,456 band patients were analyzed, and EWL at 1, 3, 5, and 8 years was 42.6 %, 57.5 %, 54 %, and 59.3 %, respectively. Finally, Cunneen et al. [28] published a systematic review comparing data available on the two bands: a total of 129 studies (33 with Swedish band data and 104 with Lap-Band data). The 3-year mean Swedish and Lap-Band EWL was 56.4 % and 50.2 %, respectively, without statistically significant difference.

There have been seven case series reporting long-term (≥10 year) outcomes [29–34]. The weighted mean at maximum follow-up was 51.7 % EWL (Table 2) [12].

Comorbidity and Quality of Life Outcomes

Weight loss following LAGB surgery is accompanied by improvements in, or normalization of, insulin sensitivity and glycemia, obesity-related dyslipidemia, type 2 diabetes, non-

Table 2. Gastric banding long-term outcomes (≥10 years) [12]

Author	Number of patients	Follow-up %	Revisions or reversals (%)	Follow-up (years)	Number of patients at maximum years	Excess weight loss at maximum years (%)
Miller et al. [32]	554	92	8	10	154	59
Favretti et al. [29]	1,791	91	19	11	28	38
Lanthaler et al. [31]	276	80	53	10	Not reported	60
Naef et al. [33]	167	94	20	10	28	49
Himpens et al. [30]	154	54	60	12	36	48
Stroh et al. [34]	200	84	26	12	15	33
O'Brien et al. [12]	3,227	81	43	15	54	47

alcoholic fatty liver disease, sleep disturbance including obstructive sleep apnea and daytime sleepiness, ovulatory function and fertility in women with polycystic ovary syndrome, reflux disease, joint disease, hypertension, and depression among others. The degree of resolution or improvement is variable depending on several factors including percentage of weight loss, severity, and duration of the disease [35, 36].

The improvement in diabetes following weight loss after LAGB is related to the combined effects of improvement in insulin sensitivity and pancreatic beta-cell function associated to weight loss and decreased caloric intake [37]. As beta-cell function deteriorates progressively over time in those with type 2 diabetes, early weight loss intervention should therefore be a central part of initial therapy in severely obese subjects who develop type 2 diabetes [38].

In a randomized controlled trial of LAGB versus optimal conventional therapy in recently diagnosed (<2 years) type 2 diabetes, a clear benefit was shown for the surgical approach [25]. There was remission of diabetes (normal serum glucose, HbA1c < 6.2 % while taking no hypoglycemic therapy) in 73 % of the surgical group and 13 % of the conventional group. There were no serious adverse events in either group.

A large series of 102 type 2 diabetic patients with an average BMI 46.3 kg/m^2 documented 40 % resolution (no medication requirement, with HbA1c <6 and/or glucose <100 mg/dL) at 5 years follow-up after LAGB. The mean duration of the diabetes before surgery was 6.5 years [39].

There is evidence of a reduction in both systolic and diastolic blood pressure (BP) following weight loss in association with LAGB [40]. The outcomes of 147 consecutive hypertensive patients at 12 months after LAGB demonstrated that 80 patients (55 %) had resolution of the problem (i.e., normal BP and taking no antihypertensive therapy), 45 patients (31 %) were improved (less therapy and easier control), and 22 patients (15 %) were unchanged [35]. In a study of 189 hypertensive patients treated by LAGB [41], there was resolution of hypertension (normal pressures, off therapy) in 60 % at 12 months and 74 % at 2 years. The fall in blood pressure is sustained to at least 4 years after surgery [42].

There are major improvements in sleep quality, excessive daytime sleepiness, snoring, nocturnal choking, and observed obstructive sleep apnea with weight loss following LAGB surgery. Obstructive sleep apnea and other sleep disturbances have been studied in 313 patients prior to LAGB and repeated at one year after operation in 123 of the patients [43]. There was a high prevalence of significantly disturbed sleep in both men (59 %) and women (45 %). Observed sleep apnea was decreased from 33 to 2 %, habitual snoring from 82 to 14 %, abnormal daytime sleepiness from 39 to 4 %, and poor sleep quality from 39 to 2 %. However, in a recent randomized controlled trial comparing LAGB to conservative weight loss, despite a marked difference in weight loss, the change in the apnea-hypoxia index (AHI) was not statistically significantly different between groups, reducing by 14 events per hour in the conservative group and 25.5 events per hour in the surgical group [26].

Quality of Life

One large prospective study evaluated QOL after LAGB surgery using the Medical Outcome Study Short Form-36 (SF-36) health survey, which includes both physical and psychosocial dynamics [40]. Among the 459 patients, all of these areas significantly improved after surgery. The patients' QOL within 1 year of LAGB was closer to that of normal community values, and this finding was sustained throughout the 4 years of the study. Similarly in QOL measured as part of an RCT comparing LAGB to conservative weight loss, major benefits were seen across all domains [23].

Long-Term Mortality Outcomes

There are several studies that have examined long-term mortality in patients undergoing bariatric surgery, including LAGB, and comparing this to matched community controls. The range of reduction of medium-term mortality is 64–72 % giving a combined reduction in medium-term mortality of approximately 50 % [44].

An Australian group of 966 patients achieved a mean weight loss of 22.8 % 2 years after LAGB and, when compared with a matched community cohort at a mean of 5 years follow-up, had an adjusted 72 % lower risk of death [45]. Similarly, an evaluation of 821 LAGB patients in Italy documented a 64 % lower risk of death 5 years post-LAGB [46].

Cost-Effectiveness Outcomes

There are a number of studies that have demonstrated that over time LAGB surgery is not only cost-effective, but is delivering direct health cost savings [16, 17, 47]. In a recent study using US health care claims data from over 7,000 LAGB patients compared with a propensity score matched control group with a BMI greater than 35 kg/m^2, there were modest sustained savings in the LAGB group, but continuing cost increases in the control group. The net costs of banding had been reduced to zero in 4 years after band placement. In a subgroup with type 2 diabetes having LAGB surgery, net costs reduced to zero in just over 2 years [48]. Similar analyses in Europe have also demonstrated cost savings following band placement [49].

Revisional Surgery

The long-term need for revisional procedures following LAGB is 8–60 % [12]. In a published series of 3,227 patients who had undergone LAGB from 1994 to 2011 [12], there

was 47.1 % EWL at 15 years ($N=54$; 95 % CI=8.3) and 62 % EWL at 16 years ($N=14$; 95 % CI=13.6). Revisional procedures were performed for proximal enlargement (26 %), erosion (3.4 %), and port and tubing problems (21 %). The band was explanted in 5.6 %. The need for revision decreased as the technique evolved, with 40 % revision rate for proximal gastric enlargements in the first 10 years, reducing to 6.4 % in the past 5 years. The revision group showed a similar weight loss to the overall group beyond 10 years. There was no perioperative mortality for the primary placement or for any revisional procedures.

Impact of Different Methods of Band Placement

Perigastric Dissection

The perigastric pathway was the traditional dissection for placement of the band. One significant problem with this dissection was the band placement through the lesser sac cavity just at the apex. The smooth peritonealized surface of the posterior wall of the stomach could be drawn across the band in response to force (i.e., vomiting) creating a posterior gastric prolapse. The perigastric technique was used in early experience and, along with steep learning curves on the part of the surgeons and early deficiencies in postoperative management protocols, probably contributed to poor results in some centers. In a prospective randomized comparison study [10] between both techniques, the perigastric technique patients had significantly higher incidence of prolapse (mainly posterior) compared with the pars flaccida group (16 % vs. 4 % at 2-year follow-up). Longer follow-up of the perigastric technique, up to 12 years, has demonstrated a high incidence of posterior pouch enlargements and band erosions were encountered [12, 30]. The perigastric approach should be considered a historical technique that has almost disappeared in published clinical practices.

Band Placement Without Gastro-Gastric Plication

Few authors have suggested the placement of a gastric band without gastro-gastric plication. In this technique the band is being placed in a similar fashion as described in the pars flaccida dissection. Care is taken to make very minimal dissection at the angle of His creating a small opening just big enough for the dissector. Also during the retrogastric dissection, meticulous attention is given to the creation of a very narrow retrogastric tunnel before the introduction of the laparoscopic adjustable gastric band. It has been suggested that the narrow and tight posterior tunnel will hold the band in the appropriate position avoiding slippage. No gastro-gastric imbrication sutures are placed. Slow and very gradual adjustments with careful monitoring to avoid vomiting may help to prevent band displacement.

Two randomized control studies comparing this technique with the traditional placement with imbrication plication sutures have been published with opposite results. In the first one, Fried et al. [50] compared 50 patients in each group showing no difference in band slippages or erosions at 3-year follow-up. In the second one, Lazzati et al. [51] studies 81 patients divided into two groups and early termination of the study was documented secondary to three early slippages in the non-plication group. This technique needs to be studied further and it is not well accepted within the bariatric surgery community.

Summary

The LAGB helps to develop early satiation following a small meal followed by a prolonged period of satiety. Weight loss is variable ranging from 36 to 56 % of the excess body weight at 3–5 years and an average of 48 % at long-term follow-up (≥10 years) with a need for both of revision and removals.

Type 2 diabetes resolution can be achieved in 40–56 % at 2–5 years follow-up and it is dependent on weight loss, and severity and duration of diabetes before surgery. Other comorbidities and quality of life also improve.

There is a 64–72 % lower risk of death at 5 years after the LAGB and the cost-effectiveness is significant, with net costs of banding reduced to zero in 4 years after band placement.

Review Questions and Answers

1. The LAGB helps to develop early satiation by:
   a. Limiting significantly the food transit
   b. Decreasing the ghrelin levels
   c. Altering the levels of several gastrointestinal hormones
   d. Generating myoenteric pressure signals

ANSWER: d

Studies have shown that delay in gastric emptying is not the main mechanism of action and there is a lack of correlation between over-restriction and satiety. The band should not physically limit significantly food transit. There is negligible food found above the band after a meal with the band correctly adjusted to induce satiety. A range of hormones including insulin, leptin, ghrelin, pancreatic polypeptide, and peptide YY do not play a significant role in LAGB function. It is hypothesized that the mechanical effects of the band and the passage of food bolus through

this area of band resistance can generate myoenteric pressure signals. Signals from these receptors may be important in both meal termination and satisfaction, although the functional roles of these receptors remain poorly understood.

2. Weight loss after LAGB:
   a. Is achieved completely during the first year after surgery
   b. Has not been documented beyond 5 years
   c. Dependent in great part to an effective follow-up program
   d. Is similar to nonsurgical medical weight loss therapy

ANSWER: c

Weight loss after gastric banding progresses over a 2- or even 3-year period and then stabilizes, usually in the range of between 40 and 55 % of excess weight. Several studies have documented outcomes beyond 5 years. Weight loss outcomes are correlated with a need for lifelong follow-up with regular band adjustments. There have been randomized controlled trials assessing the superior effectiveness of LAGB vs. conservative weight loss programs.

3. The comorbidities of obesity following LAGB:
   a. Do not change
   b. Improve substantially
   c. Do not translate to an improved mortality risk
   d. Are not associated with a cost-benefit

ANSWER: b

There is an improvement in all comorbidities of obesity following LAGB and this translates to an improved risk ratio for mortality as well as a cost-benefit to the community.

4. Revisional surgery after LAGB:
   a. Is required by an average of 28 % of patients 10 years after the primary procedure
   b. Has a higher mortality than the primary procedure
   c. Leads to poor weight loss compared with prior to the procedure
   d. Conversion to an alternative bariatric procedure should be preferred

ANSWER: a

While there is an 8–60 % need for revision at 10 years post LAGB, this is consistent with the reoperation rate for any bariatric procedure as well as the revision rate for other procedures performed for benign disease (reflux, joint prosthesis). Revisions can be performed safely, and the weight loss following a revision usually resumes the pre-revision trajectory. Conversion to an alternative procedure should be considered if the lower esophageal sphincter complex is ineffective [52].

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