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Original article

Laparoscopic adjustable gastric banding versus laparoscopic adjustable gastric banding with gastric plication: midterm outcomes in terms of weight loss and short term complications

Amit Surve, M.D., Hinali Zaveri, M.D., Daniel Cottam, M.D.*, Christina Richards, M.D., F.A.C.S., Samuel Cottam, HS (high school), Austin Cottam, HS

Bariatric Medicine Institute, Salt Lake City, Utah

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Abstract

Background: Laparoscopic adjustable gastric banding (LAGB) is a safe procedure with variable outcomes and large standard deviations. LAGB with gastric plication (LAGBP) is a new restrictive procedure that combines the lap band with gastric plication. This procedure, with its mechanism being below the band anatomically, should augment the weaknesses of the lap band: slips and inadequate weight loss.

Objective: Compare the weight loss results and complication rates between the LAGB and LAGBP.

Setting: Private practice.

Methods: Data was analyzed data from 120 patients retrospectively from 2 surgeons at a single private institution. Seventy-six patients underwent LAGB, and 44 other patients underwent LAGBP between February 2011 and July 2013. All 120 patients are beyond the 1-year postoperative mark and 110 patients are beyond the 2-year postoperative mark. A subset analysis was performed comparing data from both procedures to evaluate weight loss and complications.

Results: There were no significant differences between preoperative age, weight, and body mass index between the patients who underwent either procedure. We had 47.4% and 52.3% follow-up at 1 year for LAGB and LAGBP, respectively, with 91.5% and 92.3% follow-up at 2 year for LAGB and LAGBP, respectively. Complications were low with LAGBP; however, it was not statistically significant ($P = .54$). The LAGBP had a greater percent excess weight loss, percent total weight loss, and percent excess body mass index lost compared with the LAGB at 3, 6, 9, 12, and 24 months, and these differences were statistically significant. Mean percent excess weight loss for LAGB and LAGBP was 28.3% and 34.5% ($P < .05$) at 1 year and 32.1% and 39.2% ($P < .05$) at 2 years, respectively.

Conclusion: LAGBP is a safe, feasible, and reproducible bariatric procedure. The LAGBP performs significantly better than the LAGB for weight loss. The complication and revision rates were slightly higher with LAGB than LAGBP. However, it was not statistically significant. (Surg Obes Relat Dis 2017;13:267–272.)

Keywords: LAGB; LAGBP; Gastric plication; Gastric Band; Weight loss; Band slippage

Laparoscopic adjustable gastric banding (LAGB) is a reversible and adjustable operation with a mean excess weight loss (EWL) of 40% [1]. At the same time, complications such as band slippage, erosion, obstruction

*Correspondence: Daniel Cottam, M.D., Bariatric Medicine Institute, 1046 East 100 South, Salt Lake City, UT 84102.
E-mail: drdanielcottam@yahoo.com

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of the stomach, and esophageal dilation are an all-too-common part of postoperative care [2–5].

Laparoscopic gastric plication (LGP) is a newer minimally invasive weight loss surgery technique that reduces the size of the stomach with simple sutures and does not require resecting the stomach [6]. It is a feasible, safe, and effective surgical method for weight loss and patients lose a mean EWL of 40% to 70% after surgery [7–9]. Talebpour and Amoli introduced plication of greater curvature as an alternative to cutting it and recently published their 12-year results with good outcomes [6]. LGP with LAGB has been reported to decreases band-related complications [10].

Keeping all the advantages and disadvantages in mind, one surgeon in our practice (S2: DC) began combining LAGB with LGP to reduce band-related complications like slippage and poor weight loss that are sometimes seen with LAGB [11–13]. Another surgeon in our practice (S1: CR) performed only LAGB. This retrospective study investigated the weight loss and complication between LAGB with gastric plication (LAGBP) and LAGB.

Methods

This study has been approved by Quorum Review–Independent review board (QR# 31353), before data collection. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

One hundred twenty patients were selected from those who received either the LAGB or the LAGBP between February 2011 and July 2013. Seventy-six patients received the LAGB, and 44 received the LAGBP. All surgeries were performed by one of the 2 surgeons at the same institution. Patients were selected for each surgery based on when they came in and the surgeon they chose. One surgeon in our practice still actively performs LAGB the same way our group has for over 8 years. All patients of this surgeon had LAGB. The other surgeon in our practice stopped performing LAGB in 2012 and began informing patients of the LAGBP option. Patients chose LAGBP based on an extensive preoperative educational experience and signed a specific informed consent detailing the LAGBP procedure that included a diagram of the proposed operation.

All patients in our practice signed consent for retrospective blinded data analysis. Patients also underwent a preoperative evaluation including history, physical examination, nutritional, and psychiatric evaluation. Dietary restrictions related to gastric banding were discussed in detail with the patients. Laboratory evaluation included complete blood count and comprehensive metabolic panel, including blood glucose, cholesterol, vitamin B1, B12, D, serum ferritin, and thyroid function tests. The data collected included age, weight, body mass index (BMI), operative time, excess weight loss, and decrease in BMI. Patients have been followed up by their respective surgeon and dietician at frequent postoperative intervals to assess weight loss, percentage of excess weight loss (%EWL), and band tolerance at: 1 week, 1 month, 3 months, 6 months, 9 months, 1 year, and so on. All band adjustments were performed under fluoroscopic guidance to guide fill accuracy.

Descriptive statistics were used to calculate the mean and the standard deviation of the preoperative characteristics such as age, weight, and BMI. Descriptive statistics are presented as means and standard deviations. Comparisons were made between 2 groups using nonlinear regressions. All the data collected was analyzed using Sigma plot statistical software. T tests and chi-squared tests were used for statistical comparison of quantitative data. A P value $<.05$ was considered statistically significant.

Surgical technique

LAGB technique. Our method of band placement has also been described previously in detail (Fig. 1a) [14]. Briefly, after placement of 4 trocars and a liver retractor, a calibration tube was introduced into the stomach to check

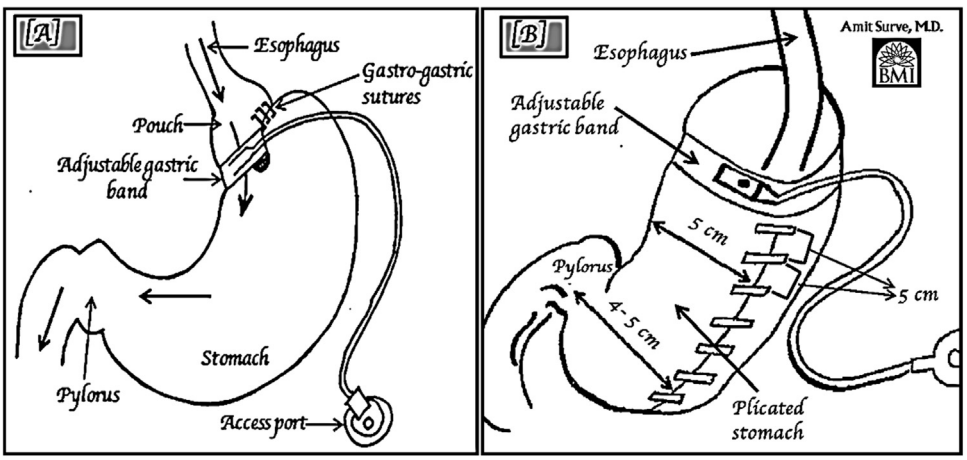

Fig. 1. Hand-drawn sketch of (A) laparoscopic adjustable gastric banding and (B) laparoscopic adjustable gastric banding with gastric plication.

for the presence of a hiatal hernia. Any hernias seen were repaired at that time as per the routine of the operating surgeons.

Once this was accomplished, the angle of His was bluntly dissected, and the Pars flaccida was then entered, and a retro gastric tunnel was dissected. Using the band passer, the band (Allergan, NJ/Inamed, CA) was brought through the dissected tunnel and locked into place. Gastrogastric sutures were used to affix the band to the anterior stomach wall. An additional anterior stitch was also placed to prevent slippage.

LAGBP technique. LAP-BAND AP large was used to perform LAGBP. Our technique of gastric plication has also been described in detail previously [15]: It is similar to Talebpour's plication technique, except that we ensure a minimum of 2 to 3 cm patency within the gastric lumen (Fig. 1b) [6].

The attachments and vasculature between the gastric omentum and the greater curve of the stomach were taken down using a harmonic scalpel. We placed interrupted sutures along the greater curve of the stomach invaginating the greater curve using an Endostitch suturing device (Covidian, Mansfield, MA) using a 2–0 Surgidac. These were placed 5 cm apart. A 40 French bougie was placed in the stomach at the time of plication but not sewn tightly, and we tried to maintain a distance of 4 to 5 cm from the lesser curve at all times. A running suture of 2–0 Surgidac was started near the angle of His, and the greater curve was further invaginated until the point 4 cm from the pylorus was reached. We tried to maintain a distance of 5 cm from the lesser curve of the stomach. This gave the appearance of sleeve gastrectomy without resection of any of the greater curve. All sutures were extramucosal. We used the EndoFLIP, Crospon, Ireland device for the first 20 patients but none thereafter.

Once the plication was performed, the lap band was passed as if there was no plication done. The band was placed over nonplicated stomach. This was done to maximize satiety through reduction in stomach size and ability to pass food through the stomach. The only modification of our technique relates to the elimination of the gastrogastric plication sutures to hold the band in place. The tubing was then grasped and brought out through a lateral port site with or without tunneling. The port was tacked to the anterior rectus fascia using tacking sutures.

Table 1
Preoperative characteristic for LAGB and LAGBP (2011–2013)

	LAGB	LAGBP	*P* value
n	76	44	
Male/Female	15/61	6/38	.6
Age (yr)	49.1 ± 1 2.9	50.4 ± 12.4	.5
Weight (lb)	272.4 ± 41.2	260.3 ± 46.1	.1
BMI (kg/m^2)	43.9 ± 5.2	42.4 ± 6	.1

LAGB = laparoscopic adjustable gastric banding; LAGBP = laparoscopic adjustable gastric banding with gastric plication; BMI= body mass index.

Values are expressed at proportions and median ± standard deviation. There is no statistical significant difference in preoperative characteristics between LAGB and LAGBP.

Results

There were no significant differences between the LAGB and LAGBP in gender ratios, preoperative age, weight, and BMI (Table 1).

The LAGB had a mean operative time of 43.9 minutes and the LAGBP had a mean operative time of 72 minutes. The difference between these 2 was statistically significant ($P < .001$).

Weight loss analysis

Subanalyses between both groups were performed. In LAGB group, 76 patients were at the 1-year postoperative mark; data were available for 36 patients (47.4%). Seventy-one patients were at the 2-year postoperative mark; data were available for 65 patients (91.5%).

In LAGBP group, there were 44 patients who were at the 1-year postoperative mark; data were available for 23 patients (52.3%). There were 39 patients who were at the 2-year postoperative mark; data were available for 36 patients (92.3%). Follow-up was greater at 2 years than at

Table 2
%EWL, %TWL, and %EBMIL at 3, 6, 9, 12, and 24 months with LAGB and LAGBP

Month		LAGB	LAGBP	*P*
3	n	71/76 (93.4 %)	44/44 (100%)	
	%EWL	20.8 (19.5–22.1)	25.2 (23.7–26.8)	<.001
	%TWL	10.7 (10.1–11.4)	12.5 (11.9–13.1)	<.001
	% EBMIL	24 (23–26)	29 (27–31)	<.001
6	n	51/76 (67.1%)	31/44 (70.5%)	
	% EWL	24.5 (23.2–25.8)	29.9 (28.3–31.4)	<.001
	%TWL	12.6 (11.9–13.8)	14.7 (14–15.4)	.003
	% EBMIL	29 (27–31)	38 (36–40)	<.001
9	n	34/76 (44.7%)	21/44 (47.7%)	
	% EWL	26.7 (25.3–28.1)	32.5 (30.8–34.2)	<.001
	%TWL	13.7 (13–14.4)	15.9 (15.2–16.7)	<.001
	% EBMIL	32 (30–34)	41 (41–47)	<.001
12	n	36/76 (47.4%)	23/44 (52.3%)	
	% EWL	28.3 (26.7–29.9)	34.5 (32.6–36.5)	<.001
	%TWL	14.5 (13.7–15.3)	16.9 (16.1–17.8)	<.001
	% EBMIL	34 (32–36)	44 (41–47)	<.001
24	n	65/71 (91.5%)	36/39 (92.3%)	
	% EWL	32.1 (29.9–34.2)	39.2 (36.7–41.8)	<.001
	%TWL	16.3 (15.3–17.3)	19.1 (18–20.2)	<.001
	% EBMIL	39 (36–41)	50 (46–54)	<.001

%EWL = percentage excess weight loss; %TWL= percentage total weight loss; %EBMIL = percentage excess body mass index lost; LAGB = laparoscopic adjustable gastric banding; LAGBP = laparoscopic adjustable gastric banding with gastric plication.

Values are expressed as means (95% confidence interval), n = number of patients / over patients available for follow-up and (% follow-ups). There is a statistical significant difference in weight loss between LAGB and LAGBP. Weight loss is greater with LAGBP than LAGB at 3, 6, 9, 12, and 24 months.

1 year because of the time at which we contacted patients and asked them to visit the clinic to allow us to gather data for this paper.

The data found a statistically significant difference in % EWL with mean of 28.3% (95% CI = 26.7–29.9) and 34.5% (95% CI = 32.6–36.5) ($P < .05$) at 1 year and 32.1% (95% CI = 29.9–34.2) and 39.2% (95% CI = 36.7–41.8) ($P < .05$) at 2 years for LAGB and LAGBP, respectively. Similarly, there was statistically significant difference in percent excess BMI lost with a mean of 34% (95% CI = 32–36) and 44% (95% CI = 41–47) at 1 year and 39% (95% CI = 36–41) and 50% (95% CI = 46–54) at 2 years for LAGB and LAGBP, respectively.

LAGBP had a statistically significantly higher weight loss than LAGB at 3, 6, 9, 12, and 24 months (Table 2, Figure 2).

The LAGBP had lower complication rate compared with LAGB; however, it was not statistically significant (Table 3).

Discussion

In an attempt to avoid the complications of LAGB [2,3], LAGBP was introduced as a novel surgical procedure in 2009 [11,16]. The addition of the plication or imbrication of the stomach to LAGB reduces the volume of the stomach to provide better appetite control, more effective weight loss, and greater weight loss potential [17]. Plication results in initial rapid weight loss and adjustable band ensures long-term maintenance of weight loss by preventing dilation of the stomach over long time.

Our data show the gastric plication adds minimal additional risk to the adjustable gastric band. As a short term, reversible, adaptable procedure, it promises to be a good alternative. Because there is no cutting or stapling of the stomach, the risk of leak is minimal [18]. In addition, unlike the gastric bypass or the duodenal switch the intestinal tract retains its normal continuity so the risk of malnutrition remains low [19–21].

In our study, of all patients who underwent LAGB, 10.5% patients had to undergo revisional surgery, whereas of all the patients who underwent LAGBP as their primary

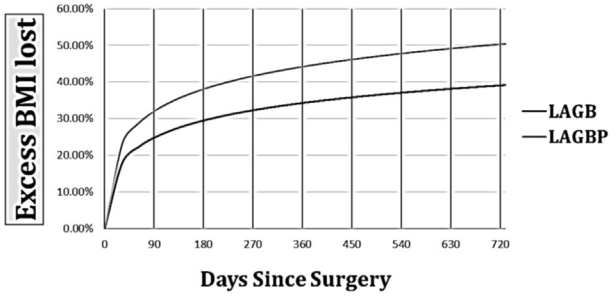

Fig. 2. Days since surgery versus percent excess body mass index lost for laparoscopic adjustable gastric banding (LAGB) and LAGB with gastric plication.

Table 3
Complications with LAGB and LAGBP

	LAGB (n = 76)	LAGBP (n = 44)	*P* value
Band Slippage	5* (6.5%)	1† (2.2%)	
Revision	3/5	-	
Dysphagia	1‡ (1.3%)	1§ (2.2%)	
Band intolerance	6¶ (7.8%)	0	
revision	5/6	-	
Port leakage	4‖ (5.2%)	3# (6.8%)	
revision	-	1/3	
Abscess	0	1** (2.2%)	
Total no. of complications	16 (21%)	6 (13.6%)	.545
Total no. of revisions	8 (10.5%)	1 (2.2%)	.234

LAGB = laparoscopic adjustable gastric banding; LAGBP = laparoscopic adjustable gastric banding with gastric plication; n = total number of patients.

*Of 5 patients with band slippage, 1 patient needed band replacement, 1 patient needed band removal, and 3 patients needed revision.

†This patient had band slippage causing esophageal obstruction, finally leading to band removal.

‡This patient had worsening gastroesophageal reflux disease and was unable to eat and finally had band removal.

§This patient had severe dysphagia and wished to get the band removed.

¶Of 6 patients with band intolerance, 5 needed revision and 1 needed band removal.

‖Of 4 patients with disconnected port leak, 1 had port displacement, 1 had a flipped port, and 2 needed reoperation and replacement.

#Three of our patients (6.8%) complained of lack of satiety and on fluoroscopy had a leak at the port site. Port leaks required an operation to replace the port or the tubing. We had to replace ports in 2 patients (4.5%). Conversion to an alternate bariatric procedure (duodenal switch) was required for 1 patient (2.2%).

**A computed tomography scan revealed a splenic abscess in 1 patient (2.2%) who complained of abdominal pain and underwent a laparoscopic splenectomy with drainage of the splenic abscess.

procedure only 2.2% underwent revisional surgery. It also seemed to reduce the risk of prolapse or slippage, one of the major complications associated with gastric band surgery. However, this difference did not rise to statistical significance due to the small sample size.

This paper has attempted to give an account of the positive and negative outcomes that are seen with LAGB and LAGBP. Our port disconnect leak rate was higher than others reported in the literature [10,22]. This is directly related to our tunneling technique and has now been changed. The most significant aspect of our study was the weight loss between the 2 groups. Our study clearly supported the data of others that the LAGBP offers superior weight loss compared with LAGB alone [16,23,24]. However, the readers of this paper will have to judge if 22% EWL increase at 2 years is worth the additional trouble and expense of performing a plication.

One of the negative aspects of LAGBP was longer operative time compared with LAGB. Although the operative time was longer, the only major complication that occurred after LAGBP was a splenic abscess caused by methicillin-resistant *Staphylococcus aureus*. We performed a splenectomy

in this case as the abscess was not responsive to antibiotics. However, with only 1 patient experiencing this problem, we cannot be sure this was due to the plication.

Another interesting, but perhaps nonsignificant limitation is the fact 2 surgeons performed the procedures in the study. Although LAGBP may be classified as a different procedure, it should be compared with LAGB, since they are so similar. In our case, we came as close as possible to matching the patients, because each patient had exactly the same follow-up plan with exactly the same follow-up providers performing dietary and exercise and band fills. Additionally, this paper is not meant to be the last word in comparing the LAGB to LAGBP: Many more papers and long-term results will be needed to reaffirm the findings of this study. When we designed this paper we believed that using a single practice to compare 2 different techniques would allow a more compelling comparison than would using the historical data from the literature. However, the fact still remains that 2 separate surgeons performed these surgeries.

Another limitation of our study is low follow-up rate at 9 and 12 months. We cannot hide this fact. However, we dealt with this issue by performing nonlinear regression analysis rather than simple *t* test or analysis of variance test for our data. The use of nonlinear regression allowed our line of best fit to have a higher correlation coefficient compared with a linear regression. Regression analysis allowed us to include all patients' data. This type of analysis is very accurate and statistically overcomes linear data problems with low follow-up at certain time points.

The other shortcoming is our complication sample size. It would be intriguing to declare that slips are reduced with this technique but this was impossible with our limited numbers. The only complication that rose to significance was revisions and since detailed breakdown reveals many different causes for revisions, all we can truly say is reoperation rates are higher.

Some have suggested that plication of the stomach below the band will lead to higher erosion rates. Although this has not been proven, our study with its 2-year follow-up is too short to assess this outcome. In light of the already low rate of erosions and adequately powered study to assess this would require several hundred matched patients with 3-year follow-up. The focus of this study was solely on weight loss and short-term complications.

Another extremely important question when looking at this study relates to the EWL at 2 years. Some may question whether a full plication is warranted for a 22% increase in EWL for the LAGBP. This is impossible to answer in such a paper and really must be decided on the basis of training of the surgeon and the risk profile of the patient. This paper with its statistical significance suggests, but does not prove, that greater weight loss is found by extending the gastric plication when placing a lap band. It also suggests that large numbers of patients would be needed to prove a difference in complications rates between the 2 groups.

Conclusion

LAGBP technique is a safe, feasible, and reproducible bariatric procedure. Our study found that LAGBP performed significantly better than LAGB for weight loss. Complication and revision rates were slightly higher with LAGB than LAGBP. However, it was not statistically significant.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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