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ORIGINAL CONTRIBUTIONS

Weight Loss Outcomes of Laparoscopic Adjustable Gastric Band with Plication: a Single Center Experience of 66 Patients with 18-Month Follow-Up

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Abstract

Background Laparoscopic adjustable gastric band with plication (LAGBP) is a novel bariatric procedure, which combines the adjustability of the laparoscopic adjustable gastric band (LAGB) with the restrictive nature of the vertical sleeve gastrectomy (VSG). The addition of plication of the stomach to LAGB should provide better appetite control, more effective weight loss, and greater weight loss potential. The purpose of the study was to analyze the outcomes of LAGBP at 18 months.

Methods Data from all patients who underwent a primary LAGBP procedure from December 2011 through June 2016 were retrospectively analyzed. Data collected from each patient included age, gender, weight, body mass index (BMI), and excess weight loss (EWL).

Results Sixty-six patients underwent LAGBP. The mean age and BMI were 44.6 ± 12.7 years and 42.1 ± 5.1 kg/m^2, respectively. The patients lost an average of 49% and 46.8% EWL at 12 months (77.2% follow-up) and 18 months (66.1% follow-up), respectively. The mean band adjustments were 2.1 ± 1.7 (range, 0–7) per patient in 1 year. The mean additional adjustment volume (infusion and withdrawal of saline) was 0.6 ± 1 cc. Dysphagia was the most common long-term complication. The band removal rate was 7.5%. The mortality rate was 0%.

Conclusions LAGBP is a relatively safe and effective bariatric procedure. In light of recent studies demonstrating poor outcomes following LAGB, LAGBP may prove to be the future for patients desiring a bariatric procedure without resection of the stomach.

Keywords LAGBP · LAGB · Laparoscopic adjustable band with plication · Imbrication · Greater curve plication · Bariatric

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Wilkinson first reported the results of gastric greater curvature plication (GCP) in 1981 and called it as gastric (reservoir) reduction [1]. In 2007, Talebpour and Amoli did the first GCP laparoscopically. Their results were published with 800 patients followed up over 12 years [2]. They had an average 70% excess weight loss at 2 years with a standard deviation of 30%. After that, there have been many reports of laparoscopic GCP (LGCP) in the literature [3–5]. However, LGCP has not become a widely practiced procedure here in the USA.

Many surgeons now combine LGCP with the laparoscopic adjustable gastric band (LAGB). This combined procedure has good results with a low morbidity rate [6]. With the LAGB reported as having an excess weight loss range of about 40%, combining the two procedures could potentially have the effect of increasing weight loss while reducing weight recidivism.

There is very limited literature available on the laparoscopic gastric banding with greater curvature plication (LAGBP). Here, we present our experience using LAGBP as a primary

procedure for bariatric surgery and document the safety of the procedure.

Methods

This study has been approved by Quorum Review–Independent review board (QR# 26605/1). Sixty-six patients had LAGBP performed from December 2011 through June 2016. All surgeries were performed by the same surgeon. Patients chose LAGBP based on an extensive preoperative education. Patients were made aware of the LAGBP being a study procedure and informed there was not extensive literature available to review. Patients signed a consent form detailing the LAGBP procedure that included all the potential benefits and risk associated with it.

Data collected from each patient included age, gender, weight, body mass index (BMI), and excess weight loss (EWL). Complication data were also gathered for each patient. This was gathered for short-term complications being defined as less than or equal to 30 days post-operation and long-term being defined as more than 30 days. Patients were told to follow-up with the surgeon for band tolerance at 1 week, 1 month, 3 months, 6 months, 9 months, and 1 year and so on for every 3 months. All the band adjustments were performed under fluoroscopic guidance to guide fill accuracy.

Descriptive statistics were used to calculate the mean and standard deviation of the preoperative characteristics such as age, weight, and BMI. These statistics are presented as means and standard deviations.

Weight loss analysis was done at 3, 6, 9, 12, 15, and 18 months post-op. Non-linear regression was used to identify weights at these time points if patients had not come in near these times but had come in much later. Patients' weight was regressed against time, and then, their weights were interpolated from the regression line. Patient interpolated weights were not used if the goodness of fit of the line was not greater than 90%. This ensured that our interpolations would be as accurate as possible and that weights at 3 months would be exactly at 3 months.

All the data collected were analyzed using SigmaPlot statistical software.

Operative Technique

LAGBP technique [7] LAP-BAND AP was used to perform LAGBP. Our technique of gastric plication has also been described in detail previously [8]: it is similar to Talebpour's plication technique, except that we ensure a minimum of 2- to 3-cm patency within the gastric lumen [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 (Covidien, 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 extra mucosal. We used the Endoflip, Crospon, Ireland device for the first 20 patients but none after that. Once the plication was performed, the lap band was passed as if there was no plication done. The band was placed over the nonplicated stomach. This was done to maximize satiety through a reduction in stomach size and ability to pass food through the stomach. The only modification of our technique relates to the elimination of the gastro-gastric 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.

Results

Preoperative characteristics can be seen in Table 1. No intraoperative complication was noted. The blood loss was less than 20 cc for all the patients. The average length of stay was 0.7 ± 0.8 days. The short- and long-term complication following LAGBP can be seen in Table 2. All 66 patients were beyond the 18-month post-operative mark. At the end of 1 year, patients had %EWL of 49 ± 20.3, and at 18 months, %EWL was 46.8 ± 22.5 (Table 3). The total number of adjustments during the study period were 201, and the mean

Table 1 Characteristics of patients undergoing LAGBP

Characteristic	Value
Patient (*N*)	66
Male/female (*N*)	11/55
Age (year)[a]	44.6 ± 12.7
Preoperative weight (lbs.)[a]	255.1 ± 43.2
Preoperative BMI (kg/m^2)[a]	42.1 ± 5.1
Ideal body weight (lbs.)[a]	127.7 ± 18.4
Excess body weight (lbs.)[a]	127.3 ± 33.7
Follow-up (month)[a]	23.1 ± 14.2

[a] Values are expressed as mean ± standard deviation

N number of patients, *LAGBP* laparoscopic adjustable gastric band with plication, *BMI* body mass index

Table 2 Short- and long-term complication with LAGBP

Short-term complication	No.	Long-term complication	No.	LAGB removal (*N*)
DVT	1	Dysphagia	22	3
Cellulitis at the port site	1	GERD	4	
GERD	1	Bloating	2	
Rash from steri-strip	1	Superficial skin infection	1	
Nausea	4	Incisional hernia	1	
		Band slippage	1	1
		Vomiting	1	
		Odynophagia	1	1

No. number of events, *N* number of patients, *MSS* month since surgery, *LAGBP* laparoscopic adjustable gastric band with plication, *DVT* deep venous thrombosis, *GERD* gastroesophageal reflux disease

Short-term complication

One patient developed a DVT and was started on Rivaroxaban. One patient experienced cellulitis at the port site, which was treated with antibiotics. Four patients experienced postoperative nausea and were treated with Ondansetron

Long-term complication

Of the 21 patients who experienced dysphagia, 19 patients underwent band adjustment. Three patients experienced dysphagia because of maladaptive eating. One patient experienced vomiting, and it got resolved after band adjustment. Symptomatic treatment was given for GERD and bloating. The band was removed in five patients 12–54 months after surgery. The most common reason for removal was dysphagia (no. = 3) followed by odynophagia (no. = 1) and band slippage (no. = 1)

additional adjustment volume after LAGBP was 0.6 ± 1 cc (infusion of saline: 0.8 ± 0.5 cc, withdrawal of saline: 1.4 ± 2 cc) (Table 4). The lowest frequency of band adjustments was noted during 16–18 months where patients experienced a slight decrease in EWL (Fig. 1). Five patients (7.5%) needed band removal because of long-term complication. The mortality rate was 0%.

Discussion

The adjustability of the LAGB was key to popularity when it was introduced initially as an effective weight loss procedure in the late 1990s [9]. The ability to adjust the stoma size without re-operation gave the procedure reversibility, unlike any other bariatric procedures. Unfortunately, long-term outcomes after LAGB have not been favorable as demonstrated by poor weight loss and high revision rates [10–13]. That being said, a few studies are showing favorable results as well [14–16]; hence, presently, the long-term efficacy of the procedure is up for debate.

Nonetheless, the LAGBP was invented as a novel new procedure in 2009 combining LAGB and gastric plication [17]. The procedure was invented with the hope of retaining the adjustability of the LAGB and combining it with a reduction in stomach size as seen in other bariatric procedures like vertical sleeve gastrectomy (VSG). We also believed that the band would control the fundic dilation superiorly and the plication would control inferior slips and dilations. Largely, this proved true through the course of the study. Our 7.5% band removal rate over the course of the study is lower than similar papers reporting LAGB alone at 18 months to 4.5 years. We did see an overall reduction in complications with this technique and better weight loss than either alone.

Brethauer et al. [8] showed that the addition of plication to the LAGB not only led to the reduction of stomach size, but

Table 3 Weight loss analysis for patients who underwent LAGBP

Month	3	6	9	12	15	18
Patient (*N* [%])	65/66 (98.4%)	64/66 (96.9%)	57/66 (86.3%)	51/66 (77.2%)	45/66 (68.1%)	41/66 (62.1%)
BMI (kg/m^2)[a]	37.2 ± 5.2	35.5 ± 5.2	34.6 ± 5	33.8 ± 5	34.3 ± 4.9	34.4 ± 5.5
% EWL[a]	30.3 ± 14.6	40.6 ± 17.2	45.4 ± 19.2	49 ± 20.3	46.8 ± 18.2	46.8 ± 22.5
% TWL[a]	11.6 ± 5.3	15.6 ± 6	17.5 ± 6.8	18.6 ± 7	18.3 ± 7	18.2 ± 8.6
Change in BMI (kg/m^2)[a]	4.6 ± 2.4	6.5 ± 2.6	7.3 ± 3.1	7.7 ± 3	7.7 ± 3.1	7.6 ± 3.6

[a] Values are expressed as mean ± standard deviation

BMI body mass index, *N* number of patients, *EWL* excess weight loss, *TWL* total weight loss

Table 4 The details of band adjustment following LAGBP

Month	1–3		4–6		7–9		10–12		13–15		16–18		Total	
No.	34		49		38		35		27		18		201	
Band adjustment	I	W	I	W	I	W	I	W	I	W	I	W	I	W
No.°	34	0	46	3	34	4	31	4	22	5	16	2	183	18
Volume (cc)[a]	1.2 ± 0.5	0	0.7 ± 0.2	0.8 ± 0.8	0.6 ± 0.2	0.6 ± 0.2	0.6 ± 0.3	1.5 ± 1.6	1 ± 1	2.7 ± 3.3	0.6 ± 0.6	0.6 ± 0.5	0.8 ± 0.5	1.4 ± 2

[a] Value expressed as mean ± standard deviation

LAGBP laparoscopic adjustable gastric band with plication, *No.* total number of times the patients required band fill, *I* infusion of saline, *W* withdrawal of saline, *no.*° number of times the patients required infusion or withdrawal of saline

The mean band adjustments were 2.1 ± 1.7 (range, 0–7) per patient in 1 year. The total number of adjustments during the study period was 201, and the mean additional adjustment volume was 0.6 ± 1 cc (I: 0.8 ± 0.5 cc, W: 1.4 ± 2 cc). The most adjustments were required during 4–6 months; however, the frequency of adjustment declined after 6 months

also provided better appetite control, more effective weight loss, and a greater weight loss potential.

Our results demonstrated that the weight loss progressively increased from the day of surgery to about 12 months (49% EWL), post-operatively. After that, the patient's weight seemed to stabilize 18 months after surgery (46.8% EWL). Interestingly, this is considerably lower when compared to international studies of both Ahluwalia et al. [18] and Wei Ji Lee et al. [19]. But if compared to studies within the USA, the results are comparable to the study conducted by Chaudhary et al. [20] and Cottam et al. [7]. We believe that this difference is not due to technique or equipment but may be due to lower dietary fat intake in other countries, more smoking or easier access to medical care.

Many authors have tried to compare LAGBP with LAGB and VSG procedures in the hope to discover which is the preferred procedure [7, 19, 21]. When the efficacy of the LAGBP in terms of weight loss is compared with these surgeries, we see that it lies somewhere in between the two. All studies demonstrate a significantly higher %EWL with the LAGBP when compared to the LAGB [7, 18–20]. This is due to the restrictive nature of LAGBP when compared with the LAGB. One of the drawbacks of the LAGBP is the higher complication rate when compared to the LAGB [19]. However, the rate of revision surgery is lower with LAGBP than the LAGB [7].

When LAGBP is compared to VSG, the VSG seems to be the more effective bariatric procedure [19, 21]. Interestingly,

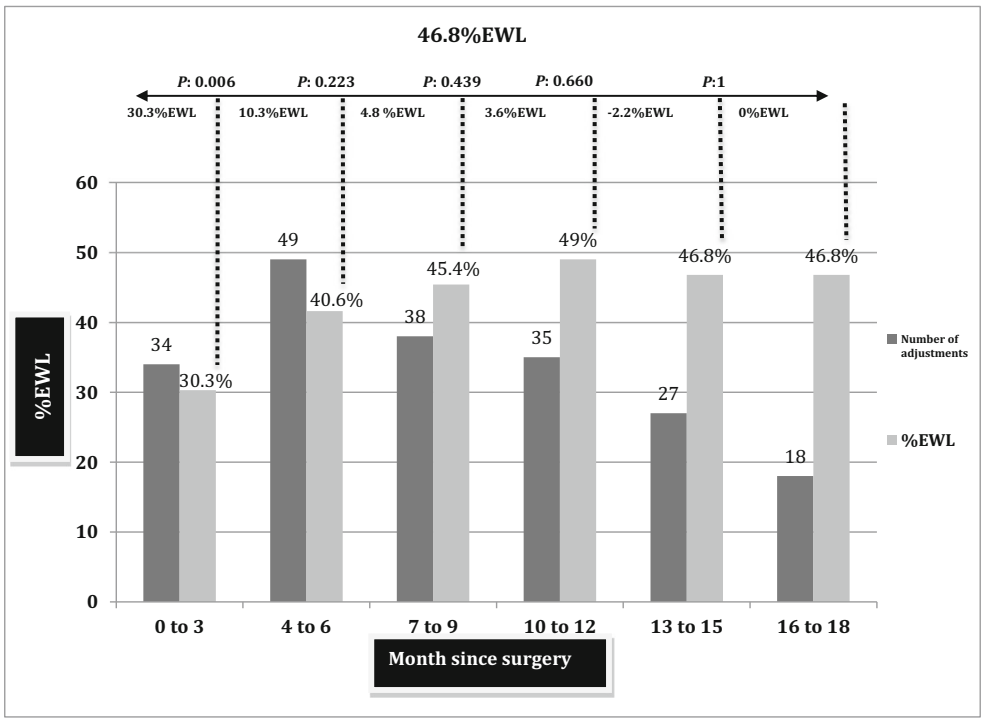

Fig. 1 The relationship between the frequency of band adjustment and weight loss. Abbreviation: %EWL-percent excess weight loss. The maximal weight loss was in the immediate postoperative period (1–3 months). Although the frequency of adjustments declined after 6 months, patients still experienced an increase in EWL but it was not statistically significant. The lowest frequency of band adjustments was noted during 16–18 months where patients experienced a slight decrease in EWL

though the mean %EWL in these studies [19, 21] favors VSG, we see significant overlap in the standard deviations %EWL of the two procedures. This equates to relatively similar weight loss seen after both procedures [22]. Regarding safety profile, LAGBP has an added advantage of a low risk of the post-operative leak [23]. This is most likely attributed to the lack of cutting or stapling of the stomach. In a study published on post-operative leaks after VSG, Gagner et al. found an overall incidence of 2.14% [24]. When you compare these results with studies of LAGBP [5, 7, 18–20, 23], only the study by Andraos et al. reports one leak in 120 patients (0.8%) [23] and Narwaria et al. [5] report one leak in 30 patients. Andraos et al. report that the leak may have been due to post-operative vomiting leading to stretching of sutures and Narwaria et al. attributed to lack of experience with the procedure. This tentatively points towards the relative safety of LAGBP as compared to VSG during the discussion of post-operative leaks. Larger studies analyzing the complication profile of LAGBP are needed to confirm its safety.

As with any retrospective studies, limitations do exist. Our study was limited by many factors, specifically by small sample size. This is one of the largest case series in the USA using LAGBP as a primary weight loss procedure, but larger sample size is required to truly explore the advantages and disadvantages of LAGBP as a weight loss procedure. Also, since this is not a long-term study, it is impossible to say that the long-term issues that have caused concern with band and gastric plication in terms of revisions due to severe scar tissue on the plication or around the band are not valid. A definitive risk benefit analysis of the benefits of the combined approach has yet to be published.

We did not evaluate the quality of life in these patients, and this is the limitation of the study. The other major limitation of this study is the rate of patient attrition. The inclusion of all patients at 12 and 18 months would have strengthened our study and may have influenced the outcome. Also, our follow-up time is relatively short, and although this procedure does show favorable outcomes, long-term studies are needed to define the efficacy and safety profile of the procedure.

Finally, as our study is a stand-alone study showing the outcomes of LAGBP, it lacks a comparison group of gastric plication alone to determine whether it improves the procedure. Our study also needs to be compared to a case-matched series of LAGB and VSG to determine its relative benefits over the other surgeries.

Conclusions

LAGBP has proven in multiple studies to be relatively safe and result in effective weight loss at 1-year post-surgery. Our study favorably adds to the ever-growing literature regarding this new procedure. In light of recent studies demonstrating poor outcomes following LAGB, LAGBP may prove to be the future for patients desiring a bariatric procedure without resection of the stomach.

Additional studies with larger numbers and longer follow-up are needed to determine whether LAGBP provides enduring weight loss and to establish a safety profile for the procedure.

Compliance with Ethical Standards

Conflict of Interest Daniel Cottam, the corresponding author reports personal fees and other from Medtronic, outside the submitted work.

All other authors have no conflicts of interest to declare.

Statement of Human and Animal Rights 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.

Since this is a retrospective study: formal consent is not required for this type of study.

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