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Destiny of failed adjustable gastric bandings: do all the patients need further bariatric surgery?

Key Words: LAGB; Removal; Revisional surgery; Secondary surgery; Weight regain; Complications.

Abstract

Purpose: The number of Laparoscopic Adjustable Gastric Banding (LAGB) removals has increased throughout the years. The aim of the study was to evaluate the outcomes in patients undergoing LAGB removal with or without further bariatric surgery.

Materials and Methods: Data prospectively collected from consecutive patients undergoing LAGB removal from 2008 to 2016 at our Institution were retrospectively analyzed. Obesity-related comorbidities, complications and body mass index (BMI) before removal and at 1-year follow-up were evaluated.

Results: A total of 156 patients were included in the study. Seventy-six patients had further surgery (SURG group): 55 underwent Laparoscopic Sleeve Gastrectomy (LSG) and 21 Laparoscopic Roux en-Y Gastric Bypass (LRYGB). Eighty patients underwent only LAGB removal (No-SURG group). Mean BMI was lower in the No-SURG group (33.9 vs 36.3 kg/m², p=0.0055). Reasons for removal were different in the two groups: dysphagia, frequent vomiting, and LAGB-related complications requiring urgent treatment occurred more commonly in the No-SURG group (p<0.05): 71.3% vs 51.3%, 67.5% vs. 38.2%, 28.8% vs. 6.6%, respectively. At 1-year follow-up, 96.3% of No-SURG patients regained weight after LAGB removal; 2 (2,5%) patients showed new-onset comorbidities, 4 (5%) needed adjustments in pharmacological therapy and 4 (5%) complained from persistence of GERD

symptoms. Additional surgery provided significant weight loss: mean %TWL was 23.7% after LSGs and 27.2% after LRYGBs.

Conclusions: LAGB is associated with a high rate of reoperation. Further bariatric surgery after LAGB removal should be considered due to weight regain, persistence of GERD symptoms and new-onset comorbidities.

Introduction

Bariatric surgery is the most effective treatment modality in the long term for the management of morbid obesity, with excellent outcomes in weight loss and resolution of obesity-related comorbidities [1]. Multiple surgical techniques have been developed throughout the years. Laparoscopic Adjustable Gastric Banding (LAGB) has been one of the most performed procedures worldwide, peaking at 42.3% of the overall bariatric interventions in 2008 [2]. Its popularity was due to its low operative morbidity and good results in weight loss achievement [3]. In spite of this, long-term studies have demonstrated a high rate of failures and removal [4-5], either due to insufficient weight loss/weight regain or LAGB-related morbidity including banding slippage, pouch dilatation, gastric erosion and port-tube system related complications [7]. There are several options after band failure: revisional banding, conversion to Laparoscopic Sleeve Gastrectomy (LSG), Laparoscopic Roux-en-Y Gastric Bypass (LRYGB), duodenal switch or biliopancreatic diversion. LRYGB and LSG are the most commonly performed revisional procedures, as both are considered safe and effective options [8]. However, some patients only seek band removal and don't consent to conversion to another procedure: these patients seem to be doomed to regain weight [9].

The aim of this study was to analyze the outcomes in weight control one-year after LAGB removal and to assess whether some of the patients who had undergone LAGB removal without additional surgery were able to maintain their weight loss.

Materials and Methods

Data from a prospective bariatric database including patients undergoing LAGB removal from 2008 to 2016 in our Institution were retrospectively analyzed. We included patients with at least 1-year follow-up.

The following data were collected: patient's age, weight, height, comorbidities (hypertension, diabetes, dyslipidemia, obstructive sleep apnea, ischemic heart disease, psychiatric diseases, hypothyroidism, osteoarthritis, cardiovascular events and malignancies), as well as emergency room (ER) visits and emergency operations. Indications for LAGB removal were also assessed.

Outcomes in weight control were evaluated with body mass index (BMI), percentage of excess body weight loss (EWL%) and total weight loss (TWL%). Changes in the use of medications for the treatment of obesity-related comorbidities were also analyzed.

Patients were divided into two groups: patients who underwent LSG or LRYGB (SURG group) and patients without any additional surgery after LAGB removal (No-SURG group).

The data were coded and stored using a Microsoft Office Excel Program. Results were expressed as mean \pm standard deviation (SD). Qualitative data were compared using Fisher's exact test or X^2 test; comparison of quantitative variables was done using parametric (e.g., t-test) and a-parametric tests (e.g., Mann Whitney U test). A p value < 0.05 was considered statistically significant.

Results

A total of 156 patients were included in the study: 141 females and 15 males (mean age 43.6 ± 10.7 years). Patients were divided into two groups: 80 patients underwent only LAGB removal without any additional surgery (No-SURG group), while 76 patients had further surgery (SURG group). Among the SURG group, 55 patients (72.3%) underwent LSG and 21 (27.6%) had LRYGB. Thirty-seven patients of the SURG group underwent a one-step conversion (11 LRYGB and 26 LSG), whereas 39 had a two-step procedure (10 LRYGB and 29 LSG).

The mean time between LAGB placement and removal was almost the same in the two groups (No-SURG: 6.53 years, $SD=3.94$; SURG: 6.49 years $SD=3.93$; $p=1.000$); the median time with band was 6 years in No-SURG (min 0-max 17 years) and 5 years in SURG group (min 0 – max 25 years). Only 2 patients in the No-SURG group had their LAGB removed less than 1 year after insertion.

Mean follow up was 18.2 months in the SURG group and 15.3 months in the No-SURG group ($p>0.05$). The median length of hospital stay was 2 days (range, 1-21 days) for removals and 5 (range 3-17 days) for secondary interventions. In the SURG-group, mean time between LAGB removal and secondary surgery was 7.3 months for patients undergoing LSG and 6.5 months for those who had LRYGB ($p>0.05$).

Before LAGB placement, mean BMI was 42.7 ± 6.2 kg/m^2 , being higher in the SURG group (44.2 ± 6.7 vs 41.3 ± 5.4 kg/m^2 , $p<0.05$). There were no significant differences in comorbidity rates between the two groups (*Table 1*). We observed that patients who refused secondary intervention attended ER more frequently (28.8% vs 6.6%; $p=0.0003$), because of band-related complications. Furthermore, they had LAGB removal done as an emergency operation more frequently than those who accepted a further bariatric procedure (12.5% vs 2.6%; $p=0.0322$).

At the time of LAGB removal, mean %TWL was 11.3 (\pm 15.9): patients who chose a secondary intervention lost less weight with banding (6.7 ± 13.4 vs 15.9 ± 17.0 ; $p < 0.05$) and had higher BMI (41.2 ± 6.8 vs 34.6 ± 6.8 kg/m²; $p = 0.0001$).

Main indications for LAGB removal were dysphagia, vomiting, GERD symptoms, band slippage and erosion (*Table 2*).

Patients who refused secondary intervention complained of dysphagia and vomiting more frequently ($p < 0.05$). GERD symptoms were present in 56 patients (35.9%), without significant differences between the two groups ($p > 0.05$); failure in weight loss (insufficient weight loss - 29% - and/or weight regain - 67%) was the main reason for LAGB removal in patients who underwent secondary surgery.

In both groups, LAGB removal led to resolution of dysphagia and surgical complication-related symptoms. Four patients in each group (12.1% vs 17.3% $p > 0.05$) experienced postoperative persistence of GERD: two of them, who were initially converted to LSG, eventually underwent a LRYGB with resolution of symptoms.

Comparison of mean BMI and %TWL at 1-year follow-up is reported in *Table 2*. Most patients (96.3%) in the No-SURG group quickly regained weight, and in some cases the weight was greater than before banding. At the time of LAGB removal, 47.5% of the patients in No-SURG group had achieved an acceptable/adequate weight loss (mean %EWL in was 52.3 ± 22.5 and %TWL was 26.4 ± 11.7). However, at 6-month follow-up after LAGB removal both %EWL and %TWL were significantly decreased (10.9 ± 25.5 and 6.9 ± 14.5 , respectively) and only 3 (8.1%) patients out of the 37 who had successful weight loss and refused secondary intervention maintained the weight loss. On the contrary, there was a significant improvement in weight loss in patients who underwent additional bariatric surgery: at 12-month follow-up, %TWL was 23.7 ± 8.6 (%EWL 45.7%) in those who underwent LSG and 27.2 ± 9.1 (%EWL 53.7) in those who underwent LRYGB as a secondary

surgery ($p=0.1220$). The changes in BMI occurred in the two groups of patients are shown in *Figure 1*.

Under the assumption that patients who underwent a 2-step intervention (2-step SURG group) had a similar clinical history to those in the NO-SURG group, these two groups of patients were compared in a further analysis (*Table 3*).

After LASG removal, an increase in weight was observed in the 2-step SURG patients, as well as in the No-SURG patients. During the period of time between LAGB removal and second surgery (7.3 months on average), mean BMI increased from 40.1 ± 7.0 to 43.1 ± 6.5 kg/m^2 . Additional bariatric surgery led to a significant weight loss, with a mean BMI of 30.4 ± 5.2 kg/m^2 and a mean %TWL of 23.0 ± 10.3 one year after surgery.

Overall, the comparison between No-SURG and 2-step SURG groups did not show significant differences in outcomes, with the exception of GERD symptoms, which were reported more frequently in the No-SURG group.

The rate of postoperative complications in the SURG-group was low; main complications, graded according to the Clavien–Dindo classification, are reported in *Table 4*. In LSG group, one patient suffered from acute respiratory failure which required ICU management and one patient had a staple line leak which required reoperation. No major complications occurred in the LRYGB group.

Obese-related comorbidities were positively influenced by the weight loss: 8 patients stopped antihypertensive drugs, 2 patients stopped the anti-diabetic treatment and one who suffered from OSAS no longer required CPAP ventilation. In the other group, 2 patients showed new-onset comorbidities and 4 patients needed adjustments in pharmacological therapy.

Discussion

Disappointing long-term results of LAGB have been reported in the Literature: for instance, we observed a high rate of band slippage with pouch dilatation and severe esophagitis in a group of patients submitted to LAGB at one year after the intervention, leading to either removal or reoperation [4].

Although some patients have good weight loss and comorbidity improvement with LAGB, LAGB placement has significantly decreased during the last ten years because of a high rate of failure and complications, requiring revisional surgery in up to 60% of patients [10].

Failure in weight loss – namely, insufficient weight loss or weight regain - is the most common reason for revisional surgery; we defined weight loss failure as $EWL < 25\%$, as many Authors do, even though agreement on a standard definition of failure still needs to be found [11]. Band-related complications are another frequent reason for band removal and they occur with a mean annual rate of 5.0%. Annual reoperation rate is estimated to be as high as 4.7% [12].

In our study, the time between LAGB placement and its removal ranges between three and nine years; patients underwent removal mainly because of dysphagia and weight regain, whereas band slippage was the most common surgical complication. Patients who experienced complications related to the LAGB or had LAGB removed in an emergent setting tended to refuse a secondary intervention, even when they failed to lose weight. Patients with dysphagia and frequent vomiting also tended to refuse revision: this was partly due to their unpleasant experience with the previous bariatric surgery and partly due to the associated weight loss, at such a point that some of them felt they didn't need further treatments. Unfortunately, in our series only three patients maintained their weight loss after LAGB removal.

There are only a few studies reporting on patients' course after LAGB removal without additional surgery, since most of these patients are lost to follow-up. The majority of these

studies report poor outcomes in weight control. For instance, Lanthaler et al. [13] studied 41 patients with banding failure: 26 patients had their band removed/deflated without further surgical intervention, whereas 15 patients underwent a second bariatric operation. In this study, weight regain was analyzed after band removal/deflation or during the period between removal and secondary surgery. The Authors observed a change in BMI from 29.3 to 37.9 kg/m² in the removal group and from 29.6 to 38.2 kg/m² in patients waiting for reintervention: only five patients in this series maintained their weight loss and all other subjects regained weight. Aarts et al. [9] evaluated 21 patients without additional surgery, finding that all of them regained weight: median % EWL decreased from 41% at band removal to 9%, 0% and -11% after 1, 2, and 5 years, respectively. Kirshtein et al. [14] compared patients undergoing different surgical options as revisional surgery to patients who had band removal only, reporting lower EWL% and impaired quality of life in patients who had no further surgery.

In our study, %TWL was -9.1 ± 8.7 , BMI increased significantly after LAGB removal and reached the mean value of 41.9 kg/m² after two years. Weight regain seemed to peak one year after LAGB removal. The weight appeared to slightly decrease in most of patients at 2-year follow up, probably because of substantial changes in eating habits and dietetic support.

Several procedures have been proposed as revisional interventions after LAGB removal. Re-LAGB has been considered as an effective option for patients who had adequate weight loss but experienced band related complications. For instance, Riele et al. [15] observed good long-term outcomes in patients successfully treated with LAGB, whilst patients with band failure had poor long-term in terms of weight loss. Some surgeons reported a high incidence of morbidity, with recurrent or additional band-related complications [16]. LRYGB is one of the most performed conversion procedures: long-term studies have shown its efficacy in obtaining durable weight loss and diabetes remission, with low surgical complications [17]

[18], even though nutritional deficiencies and hypoglycemia symptoms can occur [19]. LSG provides adequate weight loss with low morbidity rates, so that its use has significantly increased in the last years [20] [21]. However, it has been noticed that heartburn worsens in some patients and de novo GERD might develop postoperatively, that is responsive to proton pump inhibitors (PPI) in the majority of cases [22]. In our series, both conversion to LSG and LRYGB were feasible and effective, with no significant differences in weight outcomes and surgical complications. These findings are consistent with those reported in a recent systematic review [8], which compared the clinical outcomes of the two surgical procedures. LSG and LRYGB were associated with similar complication and conversion rates, mean length of hospital stay, and entity of weight loss at 6 and 12 months; nevertheless, increased %EWL and BMI reduction were reported at 24 months after LRYGB.

Our study has some limitations related to the retrospective nature of the data analysis. Furthermore, the vast majority of included patients underwent LAGB insertion in several Italian medical centers and were then referred to our Institution for LAGB removal and secondary surgery, as a result, we had limited information about the primary LAGB procedure and their clinical history. Nevertheless, the existing literature concerning the outcomes in obese patients undergoing LAGB removal without further surgery is limited and the available studies include a small number of patients.

Conclusions

Patients who require band removal after gastric banding for complications or weight loss issues seem to rapidly regain their weight if no further bariatric surgery is performed. We suggest that these patients should be informed about this eventuality and that a further counselling for a secondary intervention should be offered. After conversion to LRYGB or

LSG, short-term weight loss and improvement of comorbidities are acceptable. Both LRYGBP and LSG seem to be appropriate options in this setting.

Conflict of Interest

The authors declare they have no conflict of interest.

Ethical Approval

For this type of study formal consent is not required.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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Figure legend

Figure 1. Mean BMI over time

Tables

Table 1. Patient data prior LAGB removal

	Total, N=156	No-SURG group, N=80	SURG group, N=76	P value
Age, years	43.6 (± 10.7)	44.3 (± 11.1)	42.8 (± 10.2)	0.3816
Female, N (%)	141 (89.1%)	71 (88.8%)	70 (89.7%)	1.0000
BMI before LAGB	42.7 (± 6.2)	41.3 (± 5.4)	44.2 (± 6.7)	0.0033
Comorbidities				
<i>Hypertension</i>	49 (31.4%)	20 (25%)	29 (38.2%)	0.0865
<i>Diabetes mellitus</i>	12 (7.7%)	5 (6.3%)	7 (9.2%)	0.5574
<i>Obstructive sleep apnea</i>	10 (6.4%)	3 (3.8%)	7 (9.2%)	0.2017
<i>Dyslipidemia</i>	4 (2.6%)	3 (3.8%)	1 (1.3%)	0.6206
<i>Osteoarthritis</i>	33 (21.2%)	13 (16.3%)	20 (26.3%)	0.1694
<i>Hypothyroidism</i>	18 (11.5%)	9 (11.3%)	9 (11.8%)	1.0000
<i>Cardiovascular events</i>	2 (3.2%)	2 (2.5%)	0	0.4971
<i>Neoplasia</i>	6 (3.8%)	1 (1.3%)	5 (6.6%)	0.1100
<i>Psychiatric disorder</i>	19 (12.2%)	5 (6.3%)	14 (18.4%)	0.0267
Band related ER visits, N (%)	28 (18.0%)	23 (28.8%)	5 (6.6%)	0.0003
Emergency operations, N (%)	12 (7.7%)	10 (12.5%)	2 (2.6%)	0.0322
TWL% at the band removal	11.3 (±15.9)	15.9 (±17.0)	6.7(±13.4)	0.0003
EWL% at the band removal	19.4 (± 43.2)	28.3 (± 54.1)	10.0 (± 24.7)	0.0078
BMI at the band removal	37.9 (± 7.5)	34.6 (± 6.8)	41.2 (± 6.8)	0.0001
Mean time with band, years	6.5 (± 3.9)	6.5 (± 3.9)	6.5 (±3.9)	1.0000

Table 2. Causes for band removal and results

	Total, N=156	No-SURG group, N=80	SURG group, N=76	P value
Causes of band removal:				
Dysphagia, N (%)	96 (61.5%)	57 (71.3%)	39 (51.3%)	0.0135
Vomiting, N (%)	83 (53.2%)	54 (67.5%)	29 (38.2%)	0.0004
GERD, N (%)	56 (35.9%)	33 (41.3%)	23 (30.3%)	0.1826
Insufficient weight loss, N (%)	28 (18.0%)	6 (7.5%)	22 (29.0%)	0.0007
Weight regain, N (%)	80 (51.3%)	29 (36.3%)	51 (67.1%)	0.0001
Surgical causes, N (%)	51 (32.7%)	30 (37.5%)	21 (27.6%)	0.2325
<i>Band slippage, N (%)</i>	15 (9.6%)	9 (11.3%)	6 (7.9%)	0.5986
<i>Erosion, N (%)</i>	10 (6.5%)	8 (10.0%)	2 (2.6%)	0.0992
<i>Port complications, N (%)</i>	7 (4.5%)	4 (5.0%)	3 (4.0%)	1.0000
<i>Esophageal dilatation, N (%)</i>	7 (4.5%)	2 (2.5%)	5 (6.6%)	0.2674
<i>Reflux esophagitis, N (%)</i>	6 (3.9%)	4 (5.0%)	2 (2.6%)	0.6820
<i>Stenosis, N (%)</i>	4 (2.6%)	3 (3.8%)	1 (1.3%)	0.6206
<i>Gastric pouch dilatation, N (%)</i>	2 (1.3%)	0	2 (2.7%)	0.2357
Weight at 1-year follow up				
BMI	39.3 (±6.3)	45.5 (±5.3)	32.8 (±9.1)	0.0001
TWL%	12.9 (± 18.9)	-9.1 (±8.7)	25.5 (±9.5)	0.0001

Table 3. Causes for band removal and results in 2-steps conversion patients

	Total, N=119	No-SURG group, N=80	2-step SURG group, N=39	P value
Causes of band removal:				
Dysphagia, N (%)	75 (63.0%)	57 (71.3%)	18 (46.2%)	0.0093
Vomiting, N (%)	66 (55.5%)	54 (67.5%)	12 (30.8%)	0.0002
GERD, N (%)	41 (34.5%)	33 (41.3%)	8 (20.5%)	0.0390
Insufficient weight loss, N (%)	20 (16.8%)	6 (7.5%)	14 (35.9%)	0.0004
Weight regain, N (%)	52 (43.7%)	29 (36.3%)	23 (59.0%)	0.0297
Surgical causes, N (%)	39 (32.8%)	30 (37.5%)	9 (23.1%)	0.1466
<i>Band slippage, N (%)</i>	12 (10.1%)	9 (11.3%)	3 (7.7%)	0.7487
<i>Erosion, N (%)</i>	10 (8.4%)	8 (10.0%)	2 (5.1%)	0.4948
<i>Port complications, N (%)</i>	7 (5.9%)	4 (5.0%)	3 (7.7%)	0.6820
<i>Esophageal dilatation, N (%)</i>	4 (3.4%)	2 (2.5%)	2 (5.1%)	0.5965
<i>Reflux esophagitis, N (%)</i>	4 (3.4%)	4 (5.0%)	0	0.3016
<i>Stenosis, N (%)</i>	4 (3.4%)	3 (3.8%)	1 (2.6%)	1.0000
<i>Gastric pouch dilatation, N (%)</i>	0	0	0	1.0000
Band related ER visits, N (%)	25 (21.0%)	23 (28.8%)	2 (5.1%)	0.0033
Emergency operations, N (%)	10 (8.4%)	10 (12.5%)	0	0.0293
Mean time with band	6.2 (±3.7)	6.5 (± 3.9)	5.5 (±2.9)	0.1582
Weight data:				
BMI before LAGB	42.4 (±6.1)	41.3 (± 5.4)	44.1 (±5.9)	0.0113
TWL% at the band removal	13.2 (±16.8)	15.9 (±17.0)	8.2 (±14.9)	0.0174
BMI at the band removal	36.5 (±7.1)	34.6 (± 6.8)	40.1 (±7.02)	0.0001
TWL% at 1-year follow up	14.1(±21.3)	-9.1 (±8.7)	23.0 (±10.3)	0.0000
BMI at 1-year follow up	37.5 (±5.3)	45.5 (±5.3)	30.4 (±5.2)	0.0000

Table 4. Postoperative complications after secondary surgery

	Total, N=76	LSG, N=55	LRYGB, N=21	P value
Early complications (<30 days)				
<i>Grade ≤II</i>	2 Pneumonia	2	0	1.0000
	1 Bleeding	0	1	
	1 Hematoma	1	0	
	1 Obstruction	1	0	
<i>Grade ≥III</i>	1 Leak (IIIb)	1	0	1.0000
	1 Respiratory failure (IVa)	1	0	
<i>Total (%)</i>	7 (9.2%)	6 (10.9%)	1 (4.8%)	0.6658
Long term failure	2 Further bariatric surgery	2	0	1.0000