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Banded versus Non-Banded Sleeve Gastrectomy: A Non-Randomized Clinical Trial

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ABSTRACT

Background: Laparoscopic Sleeve Gastrectomy (LSG) may not have the best weight loss profile at long-term follow-up. Many authors extrapolated the idea of applying bands from Roux-en Y gastric bypass (RYGB) literature to LSG to enhance weight loss. Although the earlier reports seem encouraging, most of these studies were retrospective and underpowered.

Objectives: To compare between body mass indexes (BMI) differences over 3 years between banded LSG (BLSG) and non-Banded LSG (NLSG). We also aimed to compare the emergence/worsening of reflux symptoms.

Patients and methods: This was a prospective, single-center non-randomized clinical trial of 100 patients (N=100) undergoing either BLSG or NLSG. Average age was 36.84 ± 8.91 years, 59 patients (59%) were females. Patients were followed at 3, 6, 12, 24, 36 months to evaluate changes in BMI. Study outcomes included change in BMI between 3rd and 36th months, emergence/worsening of reflux symptoms and remission of comorbidities.

Results: Mean difference in BMI between the first follow-up interval (3 months) and the last interval (36 months) was 13.56±1.93 in BLSG and 10.82±0.39 in NLSG ($p < 0.001$). Weight regain occurred at 36 months in NLSG but not in BLSG. Mean operative time was 45.64±3.41 mins in BLSG and 40.64±4.6 in NLSG ($p < 0.0001$). Remission of morbidities and worsening/emergence of de novo reflux symptoms was similar in both groups ($p > 0.05$).

Conclusions: BLSG may have favorable outcomes than NLSG, this effect persisted without weight regain.

Keywords: Banding, Comorbidities, Metabolic surgery, Reflux, Sleeve gastrectomy.

INTRODUCTION

Laparoscopic sleeve gastrectomy and roux-en-Y gastric bypass (RYGB) are the two most performed bariatric operations, one study based on worldwide pooled data showed that LSG occupied 46% of the total bariatric operations till 2016[1]. LSG was first introduced as a part of the two-stage biliopancreatic diversion duodenal switch (BPD-DS) [2], then it proved its abilities as a stand-alone procedure, which started a new era in bariatric surgery. It provides a favorable profile with its technical simplicity, shorter operating times and better perioperative morbidity, it is also more liable for revision and to be used as staged operation[3]. Although the scope of bariatric surgery has changed from focusing on weight loss to the broader concept of metabolic surgery and treating co-morbidities, weight loss remains a key objective for patients undergoing surgery and should be addressed in the modern bariatric literature[4, 5].

With longer follow-up of the patients with LSG it seemed that failure rates are increasing, one study showed that weight regain and de novo gastroesophageal reflux symptoms started to appear dreadfully[6]. This, in some studies, necessitated conversion to gastric bypass or duodenal switch to maintain significant weight loss and low ghrelin levels[7]. The cause of insufficient weight loss may be multifactorial and attributed to multiple factors, however, increase reservoir size associated with long term gastric pouch dilatation is hypothesized to be one of the main causes[8]. It was theorized that gastric pouch dilatation results from patients' non-compliance with dietary regimens that precipitates pouch dilatation by the mechanical stretching effect of large meals[9]. To address this problem, many authors suggested placing adjustable gastric band below the gastroesophageal junction to restrict pouch expansion and to increase satiety[10].

The usage of bands started in RYGB, bands in RYGB proved to maintain long-term weight loss beyond 5-years, which was better than non-banded group[11]. Banding LSG uses the same concepts to correct for the long-term weight regain, banded laparoscopic sleeve gastrectomy (BLSG) was first implemented in 2009 by applying silicone bands[12]. Many studies have examined the effects of banding on weight loss and regurgitation profiles in LSG, earlier studies showed better weight control over years at the expense of increased gastroesophageal reflux symptoms[13]. However, these studies relied mainly on retrospective cohort patients and many of them were underpowered.

This prospective non-randomized clinical trial aims to compare between BLSG and NLSG regarding BMI changes over 3 years, we also aim to examine their effects on different obesity subcategories. Traditional operative metrics as mean operative time and post-operative complication as well as the emergence of de novo gastroesophageal reflux w examined.

PATIENTS AND METHODS

This is a prospective non-randomized single-center clinical trial to assess the differences between banded sleeve gastrectomy and non-banded sleeve gastrectomy regarding BMI changes over 3 years of follow-up, traditional operative metrics as mean operative time, mortality risk, remission of comorbidities and the development of reflux

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esophagitis are also evaluated. This study took place between May 2015 and March 2021.

All procedures were performed in El-Demerdash Surgical Hospital. 100 patients were enrolled in this study (59 females and 41 males). All the procedures were performed by experienced surgeon and then the patients were followed-up for three years afterwards.

Inclusion criteria:

- Age > 18 and < 65
- History of failed weight-loss trials with medical treatment
- Body mass index (BMI) > 40 or BMI > 35 with history of obesity-related morbidity.

Exclusion criteria:

- Patients with previous history of extensive abdominal surgery
- History of untreated psychiatric illness and untreated alcohol or drug misuse
- Expected poor post-operative follow-up compliance
- Patients with pregnancy, liver cirrhosis or malignant disease
- Patients who were unfit for general anesthesia

Primary outcome:

Changes in BMI over 5 follow-up intervals: at 3 months, at 6 months, at 12 months, at 24 months and at 36 months.

Secondary outcomes:

1. Resolution of comorbidities, diabetes remission is defined as "normal glycemic measurements of at least 1-year duration without any antidiabetic drugs. Hypertension remission is defined as "normalization of blood pressure maintained after discontinuation of medical therapy for at least one year".
2. Development of reflux symptoms post-operatively. Case definition included de novo appearance "heartburn, feeling of acidic reflux in the mouth and retrosternal chest pain" or worsening of pre-existing symptoms.
3. Traditional operative metrics such as mean operative time and the occurrence of mortality event.

Intervention:

Banded and non-Banded Sleeve Gastrectomy were performed as described **earlier[13]**. We started sleeve formation about 5 cm from the pylorus along 35-F calibration tube, for which we used a violet linear-tri-staplers (GIA- Roticulators, Covidien, Dublin, Ireland), we left a gastric sleeve with capacity of around 100 ml. For silicone ring implantation in BLSG (MiniMizer; Bariatric Solutions) we made a small incision in the peritoneum to cover along the lesser curvature for about 4 cm from the gastroesophageal junction. We then pushed the silicone ring across the incision and directed along the posterior wall of the stomach. We closed the ring at a circumference of 7.5 cm. We secured the ring in place using single Mersilene 3/0 suture. Hiatus hernias were not repaired in this study. Figure (1) shows BLSG.

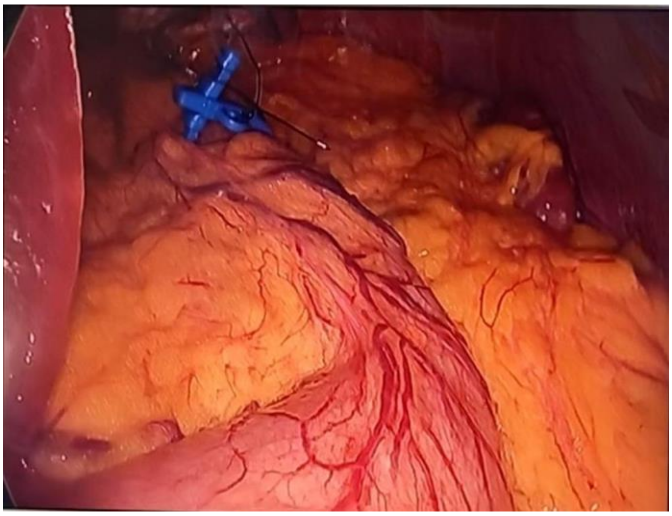

Figure (1): Banded laparoscopic sleeve gastrectomy.

Ethical consent:

An approval of the study was obtained from Ain Shams University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of the operation and participation in this study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

Data entry was done through Microsoft EXCEL spreadsheet. All continuous variables were expressed as mean ± standard deviation as measure of variability in the data. Frequency data were summarized as percentages. For continuous variables we used unpaired t-test, ANOVA or repeated-measures ANOVA as appropriate. Generalized linear model using repeated measures ANOVA was created to capture trends over time, within-subject variability between study intervals was assessed for both study groups. Assumptions of normality and equal variances were checked first. Pairwise-comparisons using Post Hoc Tukey HSD correction. Comparison of categorical data was done through chi-squared test for proportions or Fisher-exact test, as appropriate. Tabulation and data analysis was done through IBM SPSS statistics 27. All P-values < 0.05 were considered as statistically significant.

RESULTS

Baseline characteristics

Comorbidity profiles differed significantly between study arms. The difference in mean weight was only marginally significant between both groups (Table 1).

Table (1): Baseline characteristics of the participating patients

		Banded gastrectomy (N=50)	Non-banded gastrectomy (N=50)	Significance
Age		36.72 ± 8.45	36.96 ± 9.43	0.89
Gender	Male	24 (48%)	17 (34%)	0.15
	Female	26 (52%)	33 (66%)	
Comorbidities	DM	25 (50%)	15 (30%)	< 0.001
	HTN	7 (14%)	2 (4%)	
	HTN and DM	0 (0%)	13 (26%)	
	No	18 (36%)	20 (36%)	
Weight (in Kg)		128.20 ± 17.05	121.60 ± 15.99	0.049
BMI		45.14 ± 5.04	44.42 ± 4.87	0.47

Figure (2) gives a visual summary regarding differences in comorbidity profiles between study arms and figure (3) shows the distribution of BMI subscales between study groups.

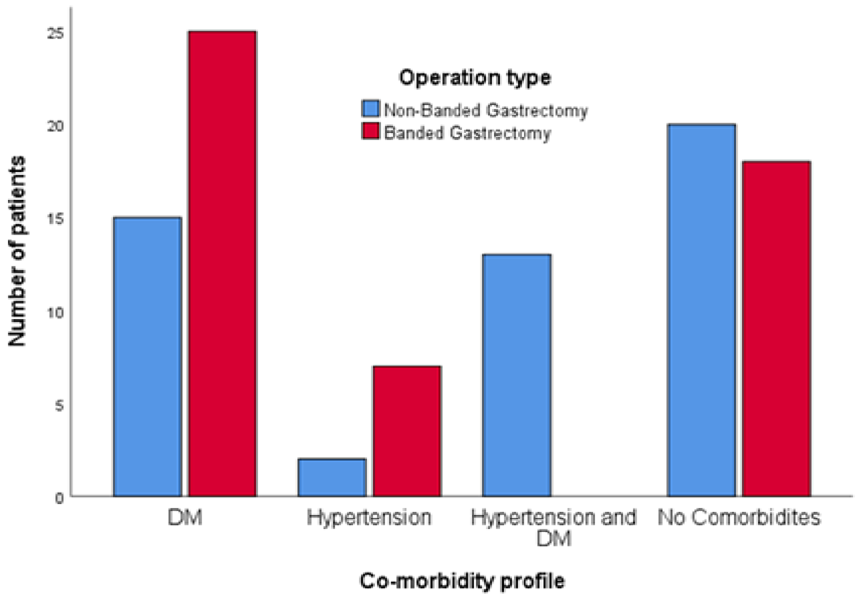

Figure (2): Comorbidity profile

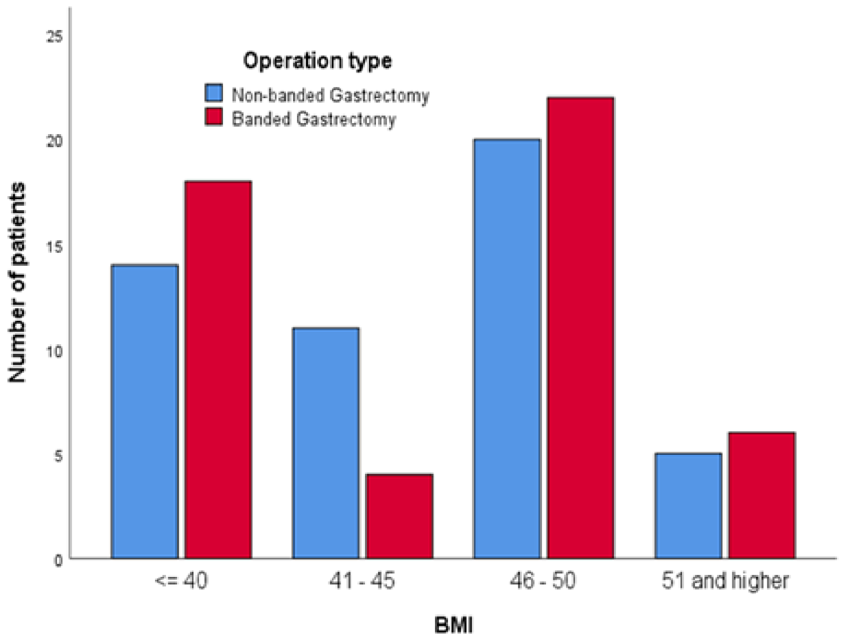

Figure (3): Distribution of BMI strata among study groups

Changes in BMI:

Banded Group:

Mean BMI within the first follow-up interval (at 3 months) was 34.32, this dropped gradually to reach 20.76 at 36 months.

Non-Banded group:

Mean BMI at the start of follow-up at 3 months was 34.44. By the end of follow-up intervals at 36 months, mean BMI was 23.62 (Table 2 and figure 4).
Mean difference between BMI at the first follow-up interval (at 3 months) and the last follow-up interval (at 36 months) was significantly higher in Banded Sleeve group than in non-banded group (P<0.001), which suggests that BLSG is associated with more significant weight loss over study follow-up periods than NLSG.
Wilk's Lambda values was < 0.0001, which gives a significance level of p < 0.001 (F-statistics = 6984.44, p < 0.0001). Revealed that the changes in BMI over every study interval was statistically significant except for the pair between 24 months and 36 months, where BMI scores started to plateau, further analysis for this particular result will follow. This suggests, on the other hand, that both operation types are effective in reducing BMI over study intervals, with BLSG group having better weight loss profile.

We performed between-group variability analysis between study arms and drew line charts (Figure 5) to detect the trends between study arms. The difference at 36 months was statistically significant between study arms (p < 0.001). Taking into consideration that mean BMI for NLSG was 22.62 at 24 months and elevated to 23.62 after 36 months, this may suggest that NLSG may be associated with long term weight regain, however.

Table (2): Changes in mean BMI scores over follow-up intervals

	3 Months	6 Months	12 Months	24 Months	36 Months
Non-banded Sleeve (N=50)	34.44 ± 4.82	29.44 ± 4.820	24.48 ± 4.82	22.62 ± 4.637	23.62 ± 4.637
Banded Sleeve Gastrectomy (N=50)	34.32 ± 4.791	28.32 ± 4.791	22.86 ± 4.121	21.40 ± 3.499	20.76 ± 3.101

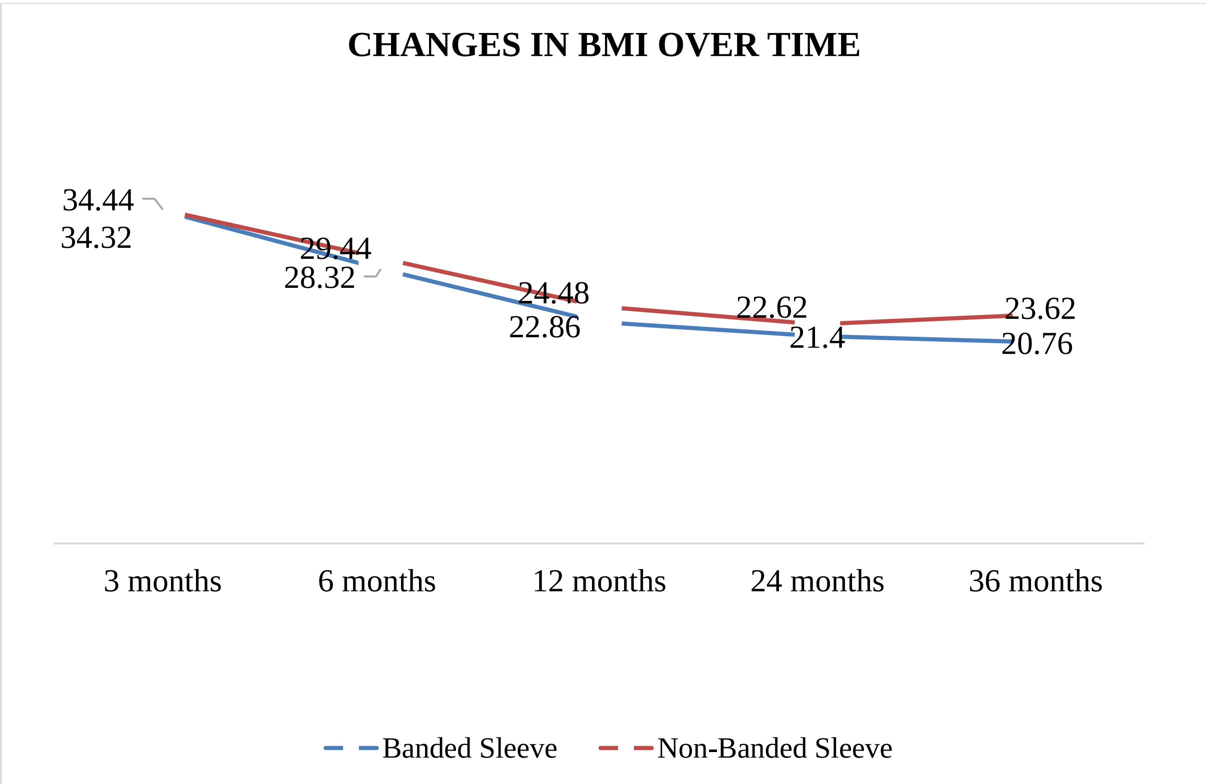

Figure (4): Changes in BMI over time **(N=50 for each group)**.

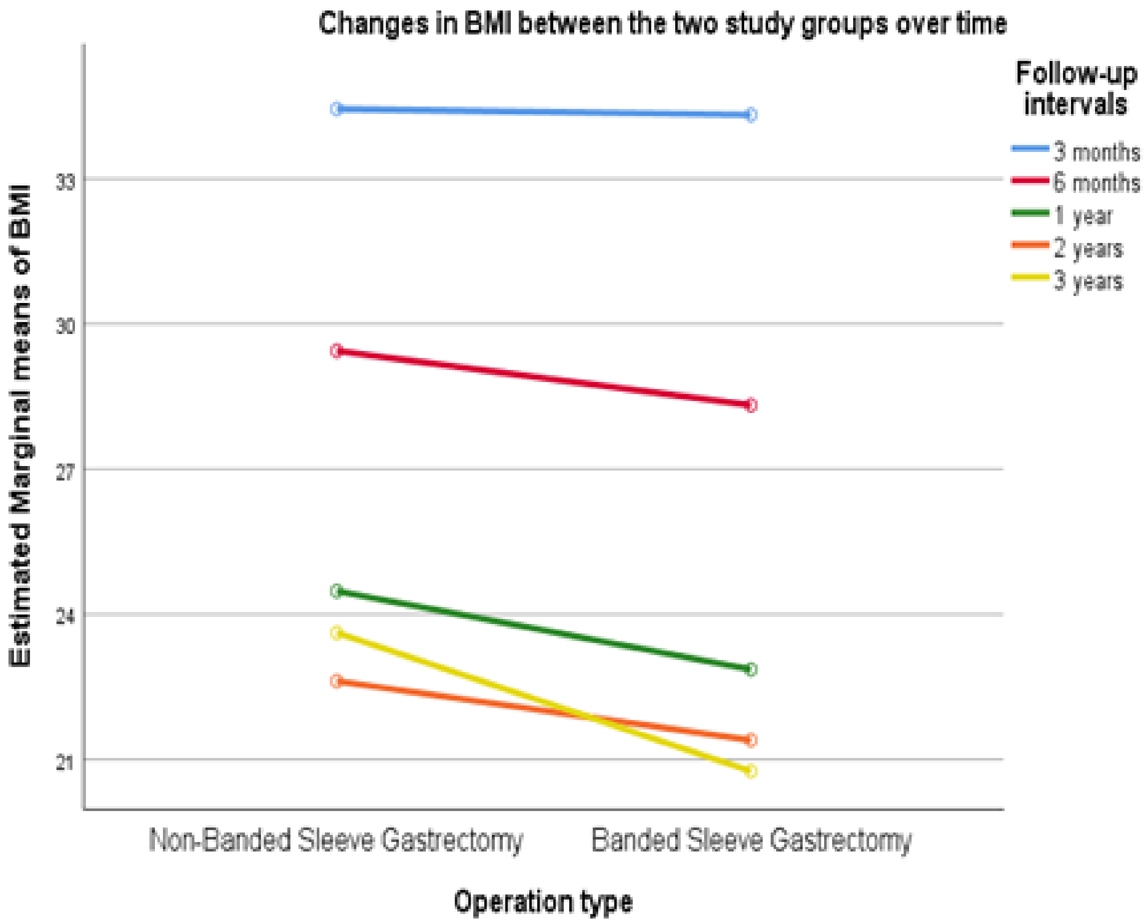

Figure (5): Line chart for BMI changes in study groups **(N=50 for each group)**.

Baseline BMI as predictor variable:

We took into consideration the non-randomized study design and the statistically significant difference regarding BMI at baseline. We performed linear regression model with the difference in BMI between BMI at 3 months and BMI at 36 months as the dependent variable and baseline BMI with operation type as independent variables. We checked for collinearity and normality assumptions. Adjusted R-squared of the model was 0.75, which shows nearly perfect fit and underlies the importance of incorporating BMI differences among study arms in analysis. Standardized coefficients beta was 0.512 for BMI variable and 0.666 for operation type, both were highly statistically significant ($p < 0.001$).

We classified BMI at baseline in 4 strata (<40, 41-45, 46-50 and above 50). In BLSG Group mean BMI difference between 3 months and 36 months among < 40 stratum was 11, all higher strata had a mean difference of 15.

In NLSG group mean difference between 3 months and 36 months was 10.50 ± 0.52 in < 40 stratum and above 50 it was also 11. ANOVA analysis for NLSG group was significant ($p < 0.001$) suggesting difference among strata. We couldn't perform ANOVA analysis for the BLSG group as one of the strata had N < 5 which violates ANOVA assumptions. Table (3) summarizes these data.

Table (3): Differences on BMI changes between 3 months and 36 months among different baseline BMI strata

BMI	< 40	41-45	46-50	Above 50	Total
Banded (N=50)	11± 2.41	15± 3.71	15± 3.62	15± 3.72	13.56± 1.94
Non-Banded (N=50)	10.5 ± 0.52	10.82± 0.41	11± 1.81	11± 2.12	10.82 ± 0.39

Operative and post-operative metrics:

Mean operative time was significantly higher in Banded Gastrectomy group. No mortality occurred in any arm. Regarding the incidence of post-operative reflux esophagitis or comorbidity resolution, the difference wasn't significant. Table (4) summarizes these findings.

Table (4): Differences in operative and post-operative metrics

		Banded gastrectomy (N=50)	Non-banded gastrectomy (N=50)	Significance
Operative time (in minutes)		45.64 ± 3.41	40.64 ± 4.6	< 0.0001
Mortality		0 (0%)	0 (0%)	1
Reflux esophagitis	Yes	16 (27%)	11 (22%)	0.26
	No	34 (73%)	39 (78%)	
Resolution of Comorbidity (N=32 in banded, N=30 in non-banded)	Yes	17 (53.1%)	17 (56.7%)	0.78
	No	15 (46.9%)	13 (43.3%)	

DISCUSSION

This prospective non-randomized clinical trial aimed to compare between LSG and BLSG. We calculated the mean difference in BMI between the first follow-up interval, which was at 3 months and last follow-up visit at 36 months, it was better and more significant in BLSG compared to non-banded LSG. Repeated measures ANOVA for trends revealed weight regain at 3 years in LSG compared to BLSG, which had more stable weight loss profile, however longer follow-up periods are still needed to confirm these findings. Baseline BMI predicted the degree of change in BMI over study period, which was greater in higher BMI strata.

Operative and post-operative metrics analysis showed that BLSG had significantly higher operative time compared to NLSG. No mortality occurred in both study arms. Regarding the emergence of de novo reflux esophagitis, it occurred more in BLSG however the difference wasn't statistically significant. Resolution of primary comorbidity was similar and non-significant among study groups.

So why the modern medical literature thought about banding? To illustrate we need to remember the original difference between LSG and laparoscopic adjustable gastric banding (LABG). Research found that LABG exerts its effects through satiety and not restriction, that it activates peripheral satiety mechanisms without any physical hindrance related to meal size[14]. LSG, on the other hand, has minimal effect on satiety compared to traditional bariatric operations, thus combining two mechanisms for weight loss magnifies the effect[15]. It is also to be mentioned that satiety may be augmented by the slow food transmission within the longitudinal part of the sleeve.

At the last follow-up interval (at 36 months) it was noted that NLSG group showed weight regain compared to BLSG that remained stable during this interval. These results line with those derived from **Lemmens**[11] work, which showed that at 5-years follow-up only 2% of BLSG had weight regain compared to 19.6% in NLSG group (p < 000.1). These findings are supported by the fact that removal of the band caused an increase in weight afterwards[16].

Literature review regarding excess weight loss in BLSG group shows divergent results, **Tognoni *et al.*** [17] failed to show statistically significant results between NLSG and BLSG over 12 months of follow-up, however BLSG had slightly lower BMI means compared to NLSG. Similarly, **Karcz *et al.*** [10] performed a matched-cohort analysis of 50 patients divided equally between both study arms, they couldn't find statistically significant difference in percentage of estimated weight loss at 12 months.

Contrary to the results derived from the literature, which shows poor outcomes in patients over 50 BMI[18]. Ours showed their effectiveness in achieving weight loss over study intervals, however these results need to be interpreted cautiously as the total number of patients who had over 50 BMI was small.

Reflux remains a corner stone factor when evaluating the successes and drawbacks of LSG. In our study the difference between NLSG and BLSG wasn't significant. However, it occurred more in BLSG (27% vs 22%). It was proposed that LSG may worsen or result in new-onset reflux symptoms[19, 20]. However, it should be taken into consideration that obesity itself is a risk factor for reflux and NLSG or BLSG may achieve weight loss, and this improves reflux symptoms.

Study limitations include the non-randomized nature which may not allocate co-morbidities evenly between study arms. The study may not be powered enough to detect the resolution of comorbidities and the emergence of reflux esophagitis symptoms.

CONCLUSIONS

Over 3 years of follow-up, weight loss was significantly higher in BLSG group compared to NLSG. Weight regain occurred at 36 months in NLSG while weight loss persisted in BLSG during the same interval. Although the literature gives disappointing results for those who are over 50 on BMI scale, our results show that BLSG may be a safe and feasible option in this group.

Remission of comorbidity, emergence of de novo or worsening of pre-existing reflux symptoms was similar between both arms. Mean operative time was statistically higher in BLSG group.

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