Banded Versus Non-Banded Sleeve Gastrectomy "Comparative Study"

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ABSTRACT

Background *Laparoscopic sleeve gastrectomy, as a primary operation in the management of morbid obesity, was first reported in 2003, documented as single therapy in the treatment of morbid obesity. With increasing experience, a number of complications have been reported with SG including dilatation of the remaining stomach. Also, doubts still persist regarding long-term weight loss. The placement of a band or gastric ring around the upper sleeve will further limit the volume of food intake and prevent dilatation of the gastric sleeve distal to the band in the long term. The procedure thus combines the potential benefits of SG and gastric banding.* ***Methods:*** *One hundred thirty-nine obese patients were enrolled in this study between (Feb ruary 2014) to (September 2016) in Safwat Elgolf private hospital. They were divided into two groups, group (1) with banded laparoscopic sleeve gastrectomy BLSG (42 patients 30%) and group (2) with non-banded laparoscopic sleeve gastrectomy NLSG (97 patients 70%). We analyzed differences in post-operative excess weight loss, operative time, as well as complication rate between the two groups through 3 years follow up.* ***Results:*** *Early follow-up (first 3 months) showed insignificant excess weight loss difference in both groups. However the difference become significant starting from 6 months postoperatively and continues to the end of 3years follow up. At 6 months the %EWL was 59.2 ± 17.8 for BLSG and 47.2 ± 15 for LSG (P value < 0.001), at 12 months the %EWL 63.8 ± 16 for BLSG and 60.6 ± 21.8 for LSG(P value < 0.001), At 24 months the %EWL was 70.6 ± 17.4 for BLSG and 63.2 ± 23 for NLSG (P value < 0.001) and at 36 months the %EWL was 80.4 ± 13.3for BLSG and 59.3 ± 24.2for NLSG(P value < 0.001). No statistical difference between the two groups as regards operative time.* ***Conclusion:*** *BLSG surgery was found to be safe, feasible and effective; it gives better 1, 2 and 3-year weight loss results than NLG. However. Complication rates are significantly higher in the BLSG than that for NSG, mainly in band related complications, e.g.; stenosis, vomiting and esophageal reflux, but these complications are late and minor. The time required for the device positioning did not influence significantly the surgical time. Further studies will need to be conducted to compare if the weight loss curve converge by 5 years.*
Keywords: *Sleeve gastrectomy, banded sleeve gastrectomy, bariatric surgery, obesity, body mass index*

INTRODUCTION

Bariatric surgery has been recognized as the most effective long-term treatment modality for severe obesity. Among various bariatric procedures, laparoscopic sleeve gastrectomy (LSG) has rapidly gained popularity to become most frequently performed worldwide [(1, 2)].

In the United States alone, 125318 LSGs were performed in 2016, which accounted for 58 percent of all bariatric procedures performed that year. That number increased by 18.8 percent from 2015 and 346 percent from 2011[(3)].

Though bariatric surgery definitely makes good weight loss and resolution of comorbidities, trend of surgical procedures seems to be changing in recent few years. We have seen a gradual fall in popularity of LAGB because of long-term failure of weight loss and complications [(4)] and a rise in the acceptance of LSG as a stand-alone bariatric procedure.

However, sleeve dilatation with subsequent consumption of larger meals is a drawback for this purely restrictive procedure and can be responsible for insufficient weight loss. Furthermore, stomach volume analysis surprisingly revealed that migrated sleeves were smaller than formally correctly positioned sleeves[(5, 6)].

With longer follow-up of the LSG, the failure rate of this procedure is also increasing [(7, 8)]. There is limited data on the mid-term and long-term weight loss (> 5 years and 10 years) after LSG, and thus the

long-term weight loss maintenance is a major concern. Himpens et al. reported an excess weight loss (EWL) of 53% after 6 years [(6)]. While Alverenga et al. reported EWL of 52% at 8 years [8].

To help increase the sustained weight loss of the gastric plication, many surgeons added the adjustable gastric band (11). The laparoscopic adjustable gastric band with plication (LAGBP) procedure promised to increase the weight loss of plication alone and be comparable in results to the laparoscopic sleeve gastrectomy (SG). [(9, 10, 11, 12, 13)].

While the cause of insufficient weight loss or weight regain is multifactorial, an increase in the gastric reservoir size due to long-term gastric pouch dilation is frequently suggested to be one of the causes[(14,15)]. In case of weight loss failure, where the inadequate restriction or gastric dilation is a cause of failure, many authors proposed a safe and efficient option to increase restriction by placing an adjustable gastric band below the GE junction [(16,17)].

In our study, we will compare between banded laparoscopic Sleeve gastrectomy (BLSG) and non-banded laparoscopic Sleeve gastrectomy (NLSG) regarding differences in operative time, complication rate, mortality, and excess weight loss between the two groups over the period of the study.

Statistical Analysis

Mean ± standard deviation (SD) was used for normally distributed continuous variables or as percentages for categorical variables. The p value was calculated using paired t test, chi square test, or Fisher's exact test when appropriate. All analyses were performed with SPSS statistical software (version18.0; SPSS Inc., Chicago, IL, USA). A p value of <0.05 was considered statistically significant.

METHODS

A review of prospectively maintained data was done for patients who underwent either BLSG or NLSG between (feb 2014) to (September 2016) in Safwat Elgolf private hospital. The inclusion criteria for both groups were BMI between 30 and 35 with or without comorbidity. Patients were given choice between LAGBP and LSG after detailed discussion with them. The exclusion criterion was lack of at least 3 year follow-up. All patients had failed previous attempts of losing adequate weight by diet, exercise, life style modification, or medicine. The prospectively collected data included patient demographics like age, sex, BMI, and obesity related comorbidities. Operative time, intra- and postoperative complications, as well as the length of stay of hospitalization were also recorded. Postoperative follow-up data was recorded at 1, 3, 6, 9, 12, 18, 24, 36 and months after surgery and analyzed.

One hundred thirty-nine patients (males and females) underwent restrictive procedures for their morbid obesity. They were divided into two groups, group (1) with banded laparoscopic sleeve gastrectomy (42 patients 30%) and group (2) with non-banded laparoscopic sleeve gastrectomy (97 patients 70%).

All the patients met the inclusion/exclusion criteria followed the by NIH Bariatric guidelines. The exclusion criteria included patients above 60 or below 18 years old, history of upper laparotomy, unfit for anesthesia or laparoscopy, major psychological instability and drug abuse.

Informed consent was obtained from all patients to be included in the study, after describing the operative and postoperative details and complications.

Operative Technique

1-NLSG:

All operations were performed in the French position with the surgeon standing between the patient's legs. We used four ports: a 10-mm trocar was placed in the midline above the umbilicus, a 15-mm trocar was placed in the right subcostal area, a 12-mm trocar was placed in the left subcostal area, and a 5-mm trocar was placed in the subxiphoid for the liver retractor. On the left side, lateral to the rectus sheath, an additional 5-mm trocar was placed, thus, to aid in retraction of the omentum when necessary.The stomach was completely mobilized by dividing the greater omentum from the stomach using LigaSure™ (Covidien, USA), starting 1–2 cm from the pylorus and extending up to the angle of His. A 38-Fr calibration bougie was inserted by the anesthesiologist along the lesser curvature of the stomach. The length of the antral remnant was measured from the pylorus (6 cm for group A and 2 cm for group B). From this point, resection began with the use of a 4.8- mm green Endo GIA stapler (Covidien), followed by several firings of a 60-mm blue stapler proximal to the angle of His; an approximately 5–10-mm cuff of stomach was

preserved at the level of the angle of His to avoid including the esophagus in the staple line. The staple line was reinforced using seromuscular invaginating V-Loc™ sutures (Covidien).

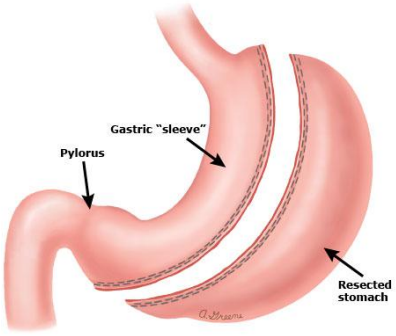

Fig. (1): In a sleeve gastrectomy, the majority of the greater curvature of the stomach is removed and a tubular stomach is created.

2- BLSG TECHNIQUE:

After completion of standard LSG as mentioned, patients in the BLSG group received a silastic ring (MiniMizer Ring, Bariatric Solutions) that was placed 4–5cm from the gastroesophageal junction. The atraumatic needle of the Minimizer ring is introduced behind the sleeve through the lesser omentum in between the vessels of the lesser curvature. It is closed and fixed with two non-absorbable sutures. Ring circumference of 6.5 or 7cm was used for females and 7 or 7.5cm for males. The placement of the ring added less than 5mins to the operation. The authors caution that in order to avoid the damage to the posterior wall of the stomach: "It is essential that the gastric calibration tube is inside at the moment of the ring closure and that there is 5mm space between the ring and the pouch upon closure.

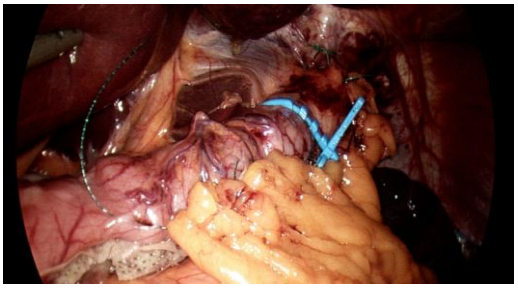

Fig. (2): The laparoscopic banded sleeve gastrectomy (LBSG)

RESULTS

One hundred thirty-nine patients were included in the study out of which 42 underwent BLSG and 97 NLSG. Table 1 summarizes demographic and operative data. The age of BLSG group was significantly less (mean=31.67 years) as compared to LSG group (mean=36.16 years). There were no significant differences in the two groups with respect to preoperative sex, BMI, or co morbidities. The operating time for BLSG was insignificantly longer than that for NLSG: 65.39±32 vs. 59±29.56 min. The postoperative hospital stay was not statistically different between the two procedures.

Table (1): Patient demographics, comorbidities, operation time, postoperative hospital stay, and complications

	BLSG	NLSG	p value
Age (years ± SD)	42	97	0.017
Sex (M: F), n (%)	8:34	20:77	0.832
BMI (mean ± SD)	32.76 ± 1.58	32.64 ± 1.49	0.687
Comorbidities			
Diabetes mellitus (type 2)	3 (7.1%)	8 (8.2%)	1.000
Hypertension	5 (11.9%)	18 (18.6%)	0.332

BLSG Banded laparoscopic sleeve gastrectomy, LSG laparoscopic sleeve gastrectomy, SD standard deviation

Table (2): Percentage excess weight loss (%EWL) between the two groups:

Time (months)	BLSG (n)	%EWL	NLSG (n)	%EWL	p value
3m	42	28.5 ± 9.2	97	26.9 ± 4.8	0.023
6m	41	59.2 ± 17.8	65	47.2 ± 15	< 0.001
9m	39	71.8 ± 18.6	59	56.6 ± 20.3	< 0.001
12	37	63.8 ± 16	56	60.6 ± 21.8	< 0.001
24	31	70.6 ± 17.4	48	63.2 ± 23	< 0.001
36	19	80.4 ± 13.3	37	59.3 ± 24.2	< 0.001

BLSG Banded laparoscopic sleeve gastrectomy, NLSG laparoscopic sleeve gastrectomy, SD standard deviation

Out of the 139 patients, follow-up was possible for 90 patients who had completed 1 year, 77 patients had completed 2 years and 56 patients had completed 3 years.

Weight Loss

The mean preoperative BMI was insignificantly different between the two groups, 32.76 ± 1.58 in the BLSG and 32.64 ± 1.49 in the NLSG group. Early follow-up (first 3 months) showed insignificant excess weight loss difference in both groups, (%EWL for BLSG was 28.5 ± 9.2 after vs. 26.9 ± 4.8 for LSG .However the difference become significant starting from 6 months postoperatively and continue to the end of the study at all recorded follow up times. At 6 months the %EWL was 59.2 ± 17.8 for BLSG and 47.2 ± 15 for LSG (P value < 0.001) , at 12 months the %EWL 63.8 ± 16for BLSG and 60.6 ± 21.8 for LSG(P value < 0.001), At 24 months the %EWL was 70.6 ± 17.4 for BLSG and 63.2 ± 23 for NLSG (P value < 0.001) and at 36 months the %EWL was 80.4 ± 13.3for BLSG and 59.3 ± 24.2for NLSG(P value < 0.001).

COMPLICATION

The complication rate was higher for the BLSG group (20.9%) compared to the NLSG group (6%) (Table 3).However, most of the complications seen within the

BLSG group were late and minor. There was only one early complications seen with BLSG group and was post-operative bleeding at stable line which was controlled laparoscopically.there were significant increased in vomiting and band related complications, e.g;stenosis and esophageal reflux in group A (BLSG)(15%) and (4%) than that for B group NLSG (15%) and (4%) respectively. Ring related problems seen within the BLSG group were the following: 1 patient with a functional stenosis at the level of the ring, he needed ring enlargement to 7.5 cm after 30 months. Two patients had reflux symptoms that were not present at the first year post operative. There was no difference in the episodes of dysphagia between the BLSG group and the NLSG group in the first post-operative year. However, there was more difference in the dysphagia in the following years between the 2 groups, with the BLSG group having more episodes. The exact level of dysphagia is hard to quantify since these patients adapt their eating pattern to their specific level of gastric restriction. Most of the patients do not complain about this

because of the fear of weight regain in case of loss of restriction.

DISCUSSION

The aim of this study was to investigate and evaluate rate of weight loss and amelioration of obesity co-morbidities for two bariatric procedures (banded sleeve gastrectomy and non-banded sleeve gastrectomy) and both techniques were done laparoscopically.

Despite the fact that the LSG has gained tremendous popularity worldwide, the durability remains a major concern. Insufficient weight loss and weight regain in the mid-term follow-up as well as in some long-term follow-up has been described [(18)]. One of the major reasons for this failure is pouch dilation. There are many reasons for the gastric pouch dilatation, including technical error during the operation. The superior pouch dilation may occur because of an incomplete release of the posterior gastric fundus or preservation of a part of the fundus to avoid injury of the esophagogastric junction or when the last stapler is fired > 1 cm away from the gastroesophageal (GE) junction. On the other hand, an inferior pouch dilatation may rise due to antral preservation, which may occur due to the misplacement of the boogie or misidentification of the pylorus [(19)].

Table 3: Complication rate in the 2 groups:

	BLSG(NO:42)	**NLSG(NO:97)**
Early minor	-	-
Early major	-	Post-op bleeding-1 (1 %)
Total early complications	0	1%
Late minor	Vomiting-6 (15%) Ring-related problems-4 (4%)	Vomiting-5 (5%) -
Late major	Omega bypass-1 (1.9%) –	-
Total late complications	20.9%	5%
Total overall complications	20.9%	6%

Abbreviations: n, number of patients; NLSG, non-banded laparoscopic sleeve gastrectomy; BLSG, banded laparoscopic sleeve gastrectomy

Literature has shown that there has been an improved weight loss in vertical gastroplasty and RYGB with an additional circular reinforcement of a gastric pouch [20, 21]. So, why would an additional circular reinforcement improve weight loss in LSG? To answer this question, one has to observe the mechanism of laparoscopic adjustable gastric banding (LAGB) and LSG separately and with its combined effect. It has been found that weight loss after LAGB is mainly due to satiety and not restriction [22]. While LSG does not have much effect on satiety compared to other bariatric procedures, thus implanting an additional circular reinforcement in LSG would improve this effect. Additionally, satiety is also increased due to slow food transportation in the longitudinal part of the sleeve due to continued restriction [23]. At the same time, the ileal break mechanism will be triggered due to the fast transit of food bolus into the small intestine. All these effects combined improve the weight loss in BLSG. Several prosthetic devices and materials have been used for weight loss surgery, including linea alba, fascia lata, meshes,porcine, and bovine grafts; however, the most commonly used

ring is a silastic ring (e.g., Minimizer® or GaBP ring™). The

minimizer ring has an advantage over other rings because of the easy placement and closure and the intraoperative flexibility allowing adjustment to the desired diameter. Ease of placing the ring is assisted by a blunt, silicone covered introduction

needle that simplifies retro gastric placement [(16)]. Additionally, it forms a pseudo-capsule which does not easily incorporate in scar tissue and is easily removable [20]. In this current study, overall weight loss after NLSG is within the range mentioned in the literature. The position statement issued by the ASMBS on LSG has shown an EWL after LSG ranges between 53 and 69% with a tendency

for weight regain [24]. In this currents study, NLSG patients quickly lost 60.6% EWL at year 1; however, further weight loss after year 1 was not significant and had some weight regain in the following years (%EWL dropped from 63.2% at 2 years to 59.3% at 3 years). However, the BLSG group had increased %EWL at each follow-up visit. %EWL at 1 year after BLSG was 63.8% which was again increased to 70.6% at 2 years which was again increased to 80.4% at 3 years. These results indicate that additional banding does not only increase %EWL in early postoperative years but continues to do so in late post-operative years as well. (Table 2). At 3-year follow-up, only 2% of the BLSG patients had weight regain when compared to 19.6%of NLSG patients (19.6%) ($P < 0.001$). Some may argue that the impressive difference in the weight regain might be a result of frequent dysphagia in this group. However, as we discussed earlier, the exact level of dysphagia is hard to objectify, and

thus it is difficult to conclude if this is one of the reasons for higher weight loss or less weight regain with the BLSG group. Beside insufficient weight loss, band-related complications are the major throw backs for the fading popularity of LAGB. On the other hand, we cannot compare the ring with the adjustable

band. The adjustable band causes restriction by compressing the stomach wall, while the ring for the sleeve only prevents dilatation. In this study, 4 patients in the BLSG group had ring-related complications. two patients had functional stenosis at the level of the ring, which was corrected at 30 months by ring enlargement to 7.5 cm. These 2 patients then had full resolution of their symptoms. The other two patients suffered from 2ry esophageal reflux which markedly improved by proton pump inhibitors. An advantage of the MiniMizer Ring® over other rings is that one can enlarge it, or make it smaller. In this study, we did not see any ring erosions, slippage or migrations. This is explained by the fact that the ring does not compress the stomach wall. Only when the food bolus is passing there is a temporary compression. This inhibits the patients of eating too fast. The same results were shown by Alexander et al., who did not note a high migration incidence either [25].

Alexander et al. used AlloDerm® rings, which have the tendency to stretch over time and allow a relatively quick passage of higher volumes of food. [25]. Karcz et al. [16] observed two Minimizer® ring-related vomiting and needed ring removal (8%). Symptoms resolved immediately after ring removal.

Mason et al. [21] have performed many vertical banded gastroplasties (VBG) using a Marlex ring. Although Marlex rings have a higher incidence of strictures, he did experience few ring-erosions requiring ring removal. Fink et al. [26] experienced 3 ring removals (7.1%) due to severe regurgitation. The most important thing to note in his study is that he did not see an increased ring removal rate in the longer follow-up period. Stubbs et al. found that most of the ring removal after banded LRYGB (BLRYGB) is associated with the ring size and he recommended increasing the ring size from 5.5 to 6.5 cm, to avoid these complications [27]. In our study, we have used 6.5 to 7 cm for all the females and 7 to 7.5 cm for all the males.With larger ring sizes, we expect lower incidence rate of ring related Problems. All the studies suggest that, although the ring related problems can be challenging to patients as well as to surgeons, the reported incidence after BLSG is 4% in our study and can be resolved without sequels. Mason et al. [26] have performed many vertical banded gastroplasties (VBG) using a Marlex ring. Although Marlex rings have a higher incidence of strictures, he did experience few ring-erosions requiring ring removal. For every advantage, there is a cost. In this study, the BLSG group had higher complication rates compared to NLSG group. Complication rates are significantly higher in the BLSG than that for NSG, mainly in band related complications, e.g; stenosis, vomiting and esophageal reflux,(19% and 5% for BLSG and LSG respectively. but these complications are late and minor.

CONCLUSION

Our study clearly shows that BLSG gives better 1, 2 and 3-year weight loss results than NLG. However, LSG patients begin to gain weight from 2 to 3 years while the BLSG remains weight stable till the end of the study. Complication rates are significantly higher in the BLSG than that for NSG, mainly in band related complications, e.g.; stenosis, vomiting and esophageal reflux. but these complications are late and minor. Both procedures appear safe at 3 years. Further studies will need to be conducted to

compare if the weight loss curve converge by 5 years.

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