The impact of using polytetraflouroethylene (PTFE)-made band in laparoscopic sleeve gastrectomy on the short- and mid-term outcomes of weight loss, a prospective cohort study Sherif Albalkiny, Gamal Fawzy, Ramy Helmy, Mohamed G. Qassem

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Background

Enlarged gastric sleeve size has been closely linked to weight recidivism after laparoscopic sleeve gastrectomy (LSG). Following the same concept of applying a band on the gastric pouch in laparoscopic Roux-en-Y gastric bypass, banded LSG might come out with similar satisfactory mid-term outcomes in maintaining weight loss.

Objective

This study aims to investigate the effect of polytetraflouroethylene (PTFE)-made band on weight loss and maintenance following LSG.

Patients and methods

This prospective study included 99 patients who underwent LSG between January 2015 and January 2018 at Ain Shams University Hospitals. Patients are divided into two groups: group I (N=50) underwent traditional LSG and group II (N=49) underwent laparoscopic banded sleeve gastrectomy (LBSG) using PTFE ring. Follow-up of the percentage of excess weight loss was done, which was our primary outcome. Moreover, assessments of the degree of improvement of preoperative comorbidities, weight regain, as well as detection of postoperative complication whether early or late were done.

Results

Of 99 patients, 80 (81%) patients had completed 1 year, 68 (69%) patients had completed 2 years, and 60 (60%) patients had completed 3 years of follow-up. The percentage of excess weight loss in the LBSG group was higher than in the LSG group and had a statistically significant difference at each given time point after 1 and 3 years. The LBSG group had less weight regain (2%) at the 3-year follow-up visit compared with the LSG group (16%) (P=0.015).

Conclusion

LBSG using PTFE is superior to LSG in promoting and maintaining short-term and mid-term weight loss without adding extra burden in terms of postoperative complications.

Keywords:

banded sleeve gastrectomy, sleeve gastrectomy, weight regain

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Background

Obesity is a common disease affecting more than 300 million adults worldwide [1]. The two-stage procedure, laparoscopic biliopancreatic diversion duodenal switch, was the original precursor for gastrectomy (LSG) laparoscopic sleeve [2]. Consequently, as a stand-alone procedure, sleeve gastrectomy was recognized safe and effective. Nowadays, sleeve gastrectomy has become the most popular bariatric procedure in the world [3] and the most commonly performed bariatric procedure at US academic medical centers [4].

Sleeve gastrectomy procedure is technically easy and safe with relatively short operative time; moreover, its ability to convert, revise, or used as a staged procedure, low perioperative morbidity, and immediate calorie intake restriction are the reasons for its increasing popularity [5,6].

Long-term low satisfactory outcome of the LSG is also increasing [7,8]. In particular, maintenance of longterm weight loss is a major concern. Percentage of excess weight loss (%EWL) of 53% was recorded by Himpens *et al.* [7] after 6 years. Relatively similar % EWL (52%) was reported by Alvarenga *et al.* [9] after 8 years. As a result, further strategies or consensus should be taken by bariatric surgeons around the world to manage the long-term outcome of these patients.

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Etiology for insufficient weight loss or weight regain is multifactorial; an increase in the gastric reservoir size owing to long-term gastric pouch dilation is frequently suggested to be one of the main causes [10,11]. 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 [12,13].

Promising results achieved previously with the use of bands or rings over the gastric tube have been seen in laparoscopic Roux-en-Y gastric bypass [14,15]. Hence, following the same concept, banded LSG might come out with satisfactory long-term outcome [16].

In this study, we evaluate short-term and mid-term outcomes of banded laparoscopic sleeve gastrectomy (BLSG) using polytetraflouroethylene (PTFE) in comparison with the traditional nonbanded sleeve gastrectomy (LSG) in terms of maintenance of the weight loss and incidence of postoperative complications.

Patients and methods

This prospective cohort study included 99 patients who underwent LSG, between January 2015 and January 2018 at Ain Shams University Hospitals, either El-Demerdash or Ain Shams Specialized Hospital.

A written informed consent was obtained from all patients before being assigned to surgery. All patients were counseled and consented about the study, the procedure, and the follow-up before the operation. An approval from the ethical committee (IRB) at the Department of General Surgery, Ain Shams University, was obtained.

Patients were assigned to the selected surgical procedure by senior consultants during the weekly departmental meeting, and each patient had the same opportunity to be assigned to any given group. Selection did not rely on randomization. That is why, our study is designed as a prospective cohort study.

After their approval to participate in the study, patients were divided into two groups: group I (N=50) underwent traditional LSG, and group II (N=49) underwent laparoscopic banded sleeve gastrectomy (LBSG).

We include all patients with age more than 18 years with BMI more than 40 or 35 with one of the known comorbidities, including type II diabetes, hypertension, dyslipidemia, obstructive sleep apnea, gastroesophageal reflux disease (GERD).

Moreover, we excluded patients with endocrinological diseases such as hypothyroidism, Cushing syndrome, patients who had previous bariatric operations, patients with contraindications for insufflation such as cardiovascular or respiratory diseases, or those with psychological disturbances.

Patients were assessed preoperatively in terms of their age, sex, occupation, and history of smoking or alcohol consumption, in addition to their past history of any coexisting medical disease like diabetes mellitus, hypertension, obstructive sleep apnea, dyslipidemia, ISHD, GERD, drug intake, and previous operations.

Moreover, detailed history was taken of their present condition, eating habits, if they were sweet eater or not, previous diet-control trials, and effect of obesity on daily activities and lifestyle.

Complete physical examination with measurement of weight and height was done followed by calculation of BMI (weight kg/height m^2).

All patients were investigated through laboratory workup, which included complete blood picture, coagulation profile (prothrombin time, international normalized ratio, and partial thromboplastin time), renal functions (serum creatinine and blood urea nitrogen), liver functions (alanine aminotransferase, aspartate aminotransferase, total and direct bilirubin, total proteins, and serum albumin), full lipid profile (total cholesterol, high-density lipoprotein, lowdensity lipoprotein, and triacylglycerol), serum electrolytes (sodium, potassium, and calcium), random blood sugar (in diabetics, we add fasting and 2-h postprandial blood sugar and glycated hemoglobin), thyroid profile, and serum cortisol.

Pelvi-abdominal ultrasound for associated gallstones and liver span (hepatomegaly) and upper gastrointestinal endoscopy for detection of associated hiatus hernia, gastritis, peptic and duodenal ulcers, GERD, and any gastric abnormalities were done.

Other preoperative investigations included chest radiograph, ECG, echocardiogram, arterial blood gas, and pulmonary function tests.

ASA score was determined for all patients based on the classification of the American Society of Anaesthesiologists.

Patients were supposed to be followed up in the outpatient clinic at intervals of 3, 6, 12, 24, and 36 months. During each visit, assessment of patient's BMI and calculation of %EWL were done, which were our primary outcomes.

Moreover, assessments of the degree of improvement of preoperative comorbidities, weight gain, as well as detection of postoperative complication whether early or late were done.

A variety of surgical laparoscopic staplers were used manufactured mainly by Ethicon endo-surgery (powered or manual Echelon) and Covidien Auto suture (Medtronic) EndoGIA.

Operative procedure

Patients were positioned with the legs split in the reverse Trendelenburg position with assurance of proper support to the extremities. The surgeon stood between the legs with the assistants on both sides.

Five ports were used to perform this procedure. The first port (10 or 12 mm) was introduced through the middle point of the line between the xiphoid and umbilicus slightly to the left of midline. Two 12-mm ports were on each side of the midline at MCL. There were two 5-mm ports: one at the xiphoid process for liver retractor and the other one at the left subcostal position for the assistant (Fig. 1).

Pneumoperitoneum is established to 15 mmHg and a 30° angled scope is used. The short gastric vessels of the greater curvature and retrogastric attachments are divided with the Harmonic Scalpel (Ethicon Endosurgery) or a sealer/divider instrument (Ligasure, Valley Lab). The dissection extends proximally to the esophagogastric junction and distally toward the pylorus. Dissection is continued until the left crus of the diaphragm is well visualized (Fig. 2).

The antrum is preserved and the greater curvature of the stomach is divided 4–6 cm from the pylorus. This procedure is performed using two firings of 60-mm green cartridge (4.8-mm staple height) after insertion of the calibration tube (Boogie) laparoscopic linear stapler (Fig. 3).

A 40-F gastric calibration tube is then inserted transorally and aligned along the lesser curvature. A vertical subtotal, sleeve gastrectomy is then fashioned along the lesser curvature 1 cm away from the calibration tube toward the esophagogastric junction. This procedure is performed with multiple firings of a 60-mm blue cartridge (3–5-mm staple height) laparoscopic linear stapler (Fig. 4).

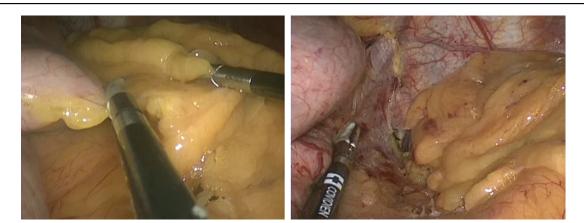
A band is tailored from a vascular graft, which is made from PTFE. This band is 12-cm long and 1-cm wide. It is placed 4–5 cm from the gastroesophageal junction in the LBSG group, where the ring is introduced behind the gastric pouch through a small aperture in the lesser omentum in between the vessels of the lesser

Figure 1



Ports' position.

Figure 2



Dissection of the greater omentum and short gastric till exposure of left crus of diaphragm.

curvature. It is then closed loosely around the gastric sleeve using small metal clips. It is important to leave a 5-mm space between the ring and the pouch upon closure (Fig. 5). This band is preferred over the manufactured rings, like silicon minimizer, owing to its financial affordability.

The resected stomach is retrieved by way of the right paramedian trocar site with a large plastic impermeable homemade endobag.

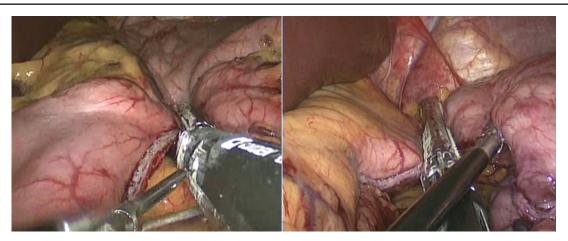
The gastric calibration tube (Boogie) is used for injection of the methylene blue dye for performing a

Figure 3



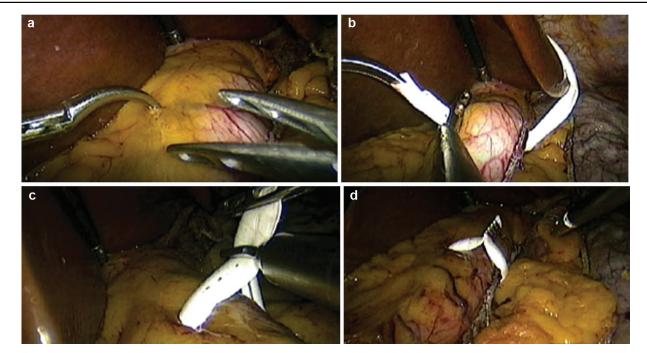
Start of stomach division 4-6 cm from the pylorus.

Figure 4



Fashioning of the gastric tube towards the OG junction.

Figure 5



(a) Steps of band placement. Creating a hole in lesser curvature 4 cm caudal to GOJ. (b) Steps of band placement. Passing the band around the gastric sleeve. (c) Steps of band placement. Securing the band with metal clips. (d) Steps of band placement. The final view of banded sleeve.

Figure 6



Leak test done with methylene blue.

leak test. The proximal duodenum is compressed with atraumatic instruments to allow stomach distension with dye, which suggests the pouch size to be in the range of 100–150 ml (Fig. 6).

Data management and analysis

The collected data were revised, coded, tabulated, and introduced to a PC using the Statistical Package for the Social Sciences (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0.; IBM Corp., Armonk, New York, USA).

Data were presented, and suitable analysis was done according to the type of data obtained for each parameter, where the descriptive statistics, such as mean and SD were used for parametric numerical data, whereas frequency and percentage for nonnumerical data.

On the contrary, analytical statistics included Student t test, which was used to assess the statistical significance of difference between two study group means; χ^2 test, which was used to examine the relationship between two qualitative variables; and Fisher's exact test, which was used to examine the relationship between two qualitative variables when the expected count is less than 5 in more than 20% of cells. *P* value less than 0.05 was considered significant.

Results

Of the 99 patients included in the study, 42 (42.5%) were males and 57 (57.5%) were females who underwent LSG between January 2015 and January 2018 at Ain Shams University Hospitals either El-Demerdash or Ain Shams Specialized Hospital and then were followed up for 3 years. Of 99 patients, 50 underwent conventional LSG (group I) and 49 underwent LBSG (group II).

Table 1 Demographic data of study population

	Group I (LSG) (<i>N</i> =50) (mean±SD)	Group II (LBSG) (<i>N</i> =49) (mean±SD)	P value
Age	43±10	42.5±9.8	0.8
BMI	41±4.6	41±4.5	0.87
Sex	n (%)	n (%)	0.62
Male	20 (40)	22 (45)	
Female	30 (60)	27 (55)	
Preoperative comorbidities	n (%)	n (%)	
DM	20 (40)	23 (47)	0.48
HTN	33 (66)	30 (61)	0.62
Obstructive sleep	18 (36)	20 (40)	0.62
apnea			
Dyslipidemia	35 (70)	32 (65)	0.61
GERD	23 (46)	21 (42.8)	0.75

DM, diabetes mellitus; GERD, gastroesophageal reflux disease; HTN, hypertension; LBSG, laparoscopic banded sleeve gastrectomy; LSG, laparoscopic sleeve gastrectomy.

Table 2 Percentage of excess weight loss between the two groups

Percentage of excess weight loss	Group I (LSG) (mean±SD)	Group II (LBSG) (mean±SD)	P value
After 3 months	32±5.7	35±4	0.0037
After 6 months	44.5±8.7	48±5.3	0.0136
After 12 months	57±8.3	61±3.2	0.0061
After 24 months	66±12.6)	71±3.3	0.034
After 36 months	64±16)	70.5±5	0.04

LBSG, laparoscopic banded sleeve gastrectomy; LSG, laparoscopic sleeve gastrectomy.

Demographic characteristics and rates of preoperative comorbidities are seen in Table 1. Of 99 patients, 80 (81%) patients had completed 1 year, 68 (69%) patients had completed 2 years, and 60 (60%) patients had completed 3 years of follow-up.

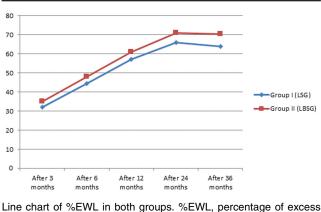
Weight loss analysis

The weight loss data of both groups are demonstrated in Table 2 as %EWL. In the LBSG group, the percentage was higher than in the LSG group, with a statistically significant difference at each given time point.

At 1 year, the patients had a mean±SD %EWL of 57 ± 8.3 and 61 ± 3.2 in LSG and LBSG, respectively (*P*=0.0061).

At 3 years, the patients had a mean±SD %EWL of 64 ± 16 and 70.5 ± 5 in LSG and LBSG, respectively (*P*=0.04). These results clearly show that %EWL increase over time in the LSG group, while continue to be steadier over time in the LBSG group, with a statistically significant difference between the two groups.

Figure 7



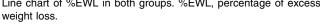


Table 2 shows the distribution of %EWL for both groups at the 3-year follow-up visit. These results show that in the LSG group, 38% of the patients had less than 50%EWL at the 3-year follow-up, whereas none of the LBSG-treated patients had less than 50%EWL (Fig. 7).

Weight regain

The LBSG group had less weight regain (2%) at the 3-year follow-up visit compared with the LSG group (16%) (*P*=0.015). After 3 years in the LSG group, 84% had no increase in BMI points compared with 98% in the LBSG group. In the LSG group, 10% of the patients had an increase of less than 5 BMI points compared with 2% in the LBSG group, whereas 6% of the LSG group had an increase of more than 5 BMI points compared with zero patients in the LBSG group (Table 3). Subsequently, LBSG has better maintained steady weight loss based on the long-term outcome.

The overall complication rate was higher for the LBSG group (32.5%) compared with the LSG group (24%) (Table 4). However, most of the complications seen within the LBSG group were late and minor. The total number of patients with early complications within the LBSG group was four: two patients with postoperative bleeding and two patients with intraabdominal collection secondary to postoperative leakage.

Relaparoscopy was performed in five cases from both groups, where reinforcement sutures applied to the stapler line was done to control bleeding in one case and washout of intraperitoneal collection after endoscopic stenting was done in the other four cases complicated with leakage from both groups. Band is removed from the LBSG group during relaparoscopy.

Table	3 Wei	ight r	egain
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Weight regain after 36 months	Group I (LSG) [<i>n</i> (%)]	Group II (LBSG) [n (%)]	P value
Total	8 (16)	1 (2)	0.015
<5 points BMI	5 (10)	1 (2)	
>5 points BMI	3 (6)	0	

LBSG, laparoscopic banded sleeve gastrectomy; LSG, laparoscopic sleeve gastrectomy.

Vomiting is the principal late complication that occurred in both groups with higher frequency within LBSG with seven (14%) patients in comparison with four (8%) patients within LSG, but this was not statistically significant (P=0.31).

In our study, 61 patients experienced different postoperative reflux symptoms such as heart burn, belching, and regurgitation in both groups of sleeve gastrectomy, where 27 (44%) patients still having reflux symptoms were reported (13 and 14 patients after LSG and LBSG, respectively). Improvement of symptoms was reported in 13 (21%) patients. New-onset reflux symptoms (de novo GERD) developed in 21 (34.5%) patients (nine and 12 patients in LSG and LBSG, respectively). On the contrary, reflux symptoms completely resolved in two patients from each group (Table 5).

In view of the operative time, intraoperative complications, duration of hospital stay, and use of analgesics, there was no significant difference between the two groups.

Discussion

Despite the utmost popularity and the wide-scale acceptance of LSG as a gold standard bariatric procedure, weight recidivism after LSG has become a major concern for both surgeons and patients. Gastric pouch dilatation is believed to be the main precursor of weight regain in LSG patients [17]. As a result, new strategies and innovations are being developed attempting to promote weight loss steadiness after LSG. In this context, encircling the gastric sleeve with a band has been introduced as a potential solution, as it is claimed to reduce appetite and enhance satiety [18].

Weight regain

Demographic characteristics like age, sex, BMI, and preoperative comorbidities did not show statistical significance among the two groups. In our series, % EWL in group II (LBSG) significantly exceeded than that in group I (LSG) at each individual follow-up

Complications	Group I (LSG) [n (%)]	Group II (LBSG) [n (%)]	P value	
Early postoperative				
Postoperative Bleeding	1 (2)	2 (4)	0.54	
Postoperative Leakage	3 (6)	2 (4)	0.66	
Intraabdominal collection/abscess	2 (4)	2 (4)	0.98	
Relaparoscopy and washout	2 (4)	3 (6)		
Total early complication	8 9			
Late complication				
Vomiting/regurgitation	4 (8) 7 (14)		0.31	
Band migration/slippage	0 0		-	
Overall total complication	12 (24) 16 (32.5)			

Table 4 Postoperative complications

LBSG, laparoscopic banded sleeve gastrectomy; LSG, laparoscopic sleeve gastrectomy.

Table 5 Effects of laparoscopic sleeve gastrectomy and laparoscopic banded sleeve gastrectomy on gastroesophageal reflux disease

GERD	Persistent reflux symptoms	Improvement of symptoms	De novo GERD	Disappearance of reflux symptoms
Group I (LSG) (N=50)	13	8	9	2
Group II (LBSG) (N=49)	14	5	12	2
	27	13	21	4
Total		61		

GERD, gastroesophageal reflux disease; LBSG, laparoscopic banded sleeve gastrectomy; LSG, laparoscopic sleeve gastrectomy.

interval: 3, 6, 12, 24, and 36 months. In the last year of follow-up, weight relapse was almost negligible in LBSG in comparison with LSG, where EWL decreased from 66 ± 16 to 64 ± 12.6 . These results clearly reflect the crucial role of band utilization in promoting and maintaining satisfactorily steady weight loss. A plausible explanation is that band is thought to minimize sleeve dilatation, which is predicted to occur with the passage of time. The retrospective matched study by Fink *et al.* [18] showed no significant difference in weight loss in LBSG compared with LSG at 3-year follow-up.

Fink *et al.* [19] did a randomized controlled trial that involved 94 patients with 3-year follow-up. It concluded that LBSG provided better weight loss and increased quality of life than LSG 3 years after surgery. Although regurgitation was the main adverse effect of LBSG, incidence of de novo reflux esophagitis was not increased after LBSG.

Based on the long-term follow-up of 5 years, two recent publications agreed that LBSG achieves greater weight loss with the minimal drawbacks including band-associated complications [20,21]. After 3 years of follow-up of our study, only one patient of the LBSG showed weight regain by less than 5 points of BMI, and none showed weight regain in more than 5 points of BMI. This was statistically significant in comparison with the LSG group, which demonstrated eight cases with weight regain.

Postoperative complications

Although the overall complication rate was relatively higher in LBSG arm, it did not record statistical significance with the other comparative arm. The incidence of early postoperative complications was roughly identical among two groups. Interestingly, band-related complications like band erosion, tightness, and migration were never recorded during our study's duration. Foo *et al.* [22] reported a case series of six leaks after BSG at their institution over an 18-month period, compared with six leaks in LSG patients. In our series, leaks occurred in two patients and three patients in LBSG and LSG, respectively.

Parmar *et al.* [23] conducted a systematic review in 2018, which enrolled only 236 patients with LBSG in six published studies. The median follow-up was 1 year, with mean follow-up of 78% of patients. Mean % EWL was 77.4% at 12 months, the complication rate of 11.8%, the reoperation rate of 5.5%, and the mortality rate of 0.85%. They could not reach a sharp conclusion about the merits and drawbacks of LBSG owing to the shortage of data on the long-term outcome, encouraging performing further randomized long-term research studies [23]. A comparative study by Lemmens *et al.* [21] reported 86.7% EWL at 5-year

follow-up. However, there were only 10 patients in the banded LSG group at 5 years, which is a small number to draw up robust conclusions.

Gentileschi et al. [24] conducted a randomized clinical trial on a pool of 50 patients who were subdivided equally into two groups: banded and nonbanded LSG. The follow-up period was 4 years. They concluded that banded LSG can achieve greater weight loss, with no added risk of complications, recommending placing a perigastric band during the primary LSG. Interestingly, this study was nearly similar to ours in terms of conclusion and follow-up period; however, our study included a double sample size but without randomization.

There have been several concerns about the banding device owing to the risk of displacement, erosion, or slippage. Those concerns were raised based on the previous data reported with the use of adjustable gastric banding, when many patients required a revision surgery to sort out the complication [25]. In contrast to the adjustable gastric banding, the band in LBSG is relatively thin ring, left loose exerting no pressure on the sleeve, and more importantly, carries minimal dissection on the lesser omentum [24]. Currently, the number of LBSG is too small, and the follow-up is not long enough to make any definitive conclusions. However, based on a metaanalysis including more than 8000 patients after banded RYGB and with 10-year follow-up, the rate of those complications is very low (2.3% of erosion and 1.5% of slippage) [26]. Therefore, a meta-analysis on a large number of LBSG cases is warranted to study band complications precisely.

Gastroesophageal reflux disease as a specific complication

LSG has been repeatedly linked to worsening of preexisting GERD in the literature [27]. Our study recorded seven (14%) and four (8%) patients with regurgitation in LBSG and LSG, respectively. In spite of statistical insignificance, we hypothesize that ring placement may aggravate reflux and regurgitation, so we recommend appropriate patient selection and counseling before LBSG. In contrast, Fink et al. [18] reported an improvement in reflux in patients with BSG compared with LSG with an odds ratio of 1.61. New-onset reflux was present in 45% of BSG group compared with 50% of LSG group. The relative risk of dysphagia was 1.4 when a ring was placed. Their study also showed that patients with frequent regurgitation experience undergoing BSG were likely to postoperative reflux. Regurgitation post BSG leads

to three band removals within their series (7.1%) at mean postoperative time of 14 months. Alexander et al. [28] showed a significant reduction in reflux symptoms after BSG (P=0.04), with complete resolution of reflux in eight of 15 patients with preoperative reflux, and symptomatic improvement in the rest. Three patients developed de novo mild reflux after BSG. No patients required reoperation for band removal owing to reflux in their study [28]. Lemmens et al. [21] reported 7.2% (seven patients) of patients with vomiting in their study. They did not have exact numbers of patients describing reflux problem. In a recent systematic review by Grehrer et al. [29], the authors found the data to be inconclusive in terms of the effect of LSG on GERD. Of the included studies, four showed an increased incidence of GERD postoperatively, whereas seven showed a decrease in the incidence of GERD.

Band material

PTFE, also known as Teflon, is a synthetic material, readily available. In this work, this material is preferred over the other known materials in the literature owing to the following reasons:

- (1) It is markedly cheaper than other band materials, especially silicon ones.
- (2) It is believed that PTFE is easier to manipulate and softer on surrounding tissues; hence, band-related complications are expected to be less.
- (3) It carries a relatively low rate of infection.

In this regard, we encourage researchers to study differences between PTFE and other materials that are utilized to band gastric sleeve.

During the literature review, studies showed a degree of variability in the following:

- (1) Calibration tube (Boogie) size ranged between 32 and 40 F.
- (2) The location of band was 2-6 cm from cardia.
- (3) Band material was alloderm band, silicone band, GaBP ring, or minimizer ring [23].
- (4) Methods of expressing weight loss after bariatric surgery were excess body weight loss, excess BMI loss, or BMI reduction [30].

Such differences render any comparison of weight loss outcomes difficult; hence, they should be well considered during comparison of various studies.

Study limitations

Although our study had a relatively large sample size with follow-up for 3 years, yet randomized studies with

long-term follow-up for 5–10 years are warranted to investigate and evaluate the actual pros and cons of this procedure. Metabolic results and remission of comorbidities were not reported in this study. To confirm the role of band in preventing sleeve dilatation, computed tomography volumetry may be needed in the follow-up.

Conclusion

LBSG using PTFE is superior to LSG in promoting and maintaining short-term and mid-term weight loss without adding extra burden in terms of postoperative complications. Long-term studies are further warranted.

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Conflicts of interest

There are no conflicts of interest.

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