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REVIEW ARTICLE

Primary Banded Sleeve Gastrectomy: a Systematic Review

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Abstract
We aim to investigate any advantages of primary banded sleeve gastrectomy (BSG) over laparoscopic sleeve gastrectomy (LSG). A literature search was performed according to the PRISMA guidelines. There were 236 patients with the mean age of 45.4 years, BMI of 47.9 kg/m^2, operating time of 96.8 min, and LOS of 5.25 days. The median follow-up (F/U) was 1 year with mean F/U of 78% patients. Mean %EWL was 77.4% at 12 months, the complication rate of 11.8%, reoperation rate of 5.5%, and the mortality rate of 0.85%. There are small numbers of published cases with primary BSG in literature. This review is unable to examine the benefits versus risks of BSG in the long term. We need randomized studies with long-term F/U to adequately evaluate this procedure.

Keywords Bariatric surgery · Obesity surgery · Banded sleeve gastrectomy · Sleeve gastrectomy · Weight regain

Introduction

Laparoscopic sleeve gastrectomy (LSG) has been growing in popularity for many years. It is one of the commonly performed bariatric operations [1]. Despite the growing popularity of LSG, Roux-en-Y gastric bypass (RYGB) is considered the gold standard operation for obesity. Long-term data is emerging showing that LSG is compatible with significant long-term excess weight loss (EWL) [2]. While some trials have shown no significant difference in long-term weight loss comparing LSG to RYBG [3], others suggest that RYGB results in a significantly increased EWL compared to LSG [4, 5]. Studies also suggest no significant difference in comorbidity resolution after either LSG or RYGB [4, 5]. Efforts to reduce weight regain via bariatric surgery have led to the evolution of the primary laparoscopic banded RYGB [6]. It has been suggested that this new technique might reduce pouch dilation and therefore prevent weight regain in the long term. It has been hypothesized that the presence of a ring in the proximal portion of the stomach can cause early satiety phenomenon [7]. Weight regain after LSG is a significant concern, but it is not fully understood. Multiple mechanisms have been suggested, the most common being sleeve dilation and loss of some of the restrictive aspect of the sleeve [8]. This has led to primary laparoscopic banded sleeve gastrectomy (BSG) being investigated by a number of centers. There is currently no published systematic review on this topic in scientific literature. This systematic review aims to examine all English language publications on this procedure in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines.

Materials and Methods

This systematic review was carried out according to the PRISMA statement [9]. A comprehensive search was carried out with the Medline (PubMed) database, Google Scholar, and the Cochrane Library in May 2018. The search terms included "banded sleeve gastrectomy," "banded laparoscopic sleeve gastrectomy," and "banded open sleeve gastrectomy." Additional searches were carried out with the term "sleeve gastrectomy" together with additional terms such as "banded," "band," and "primary." No language restriction was placed on the search. The search was independently performed by CP, OE, and KM with results cross-checked to ensure consensus. Case reports, comments and reviews, and abstracts only were excluded from the search.

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The search yielded 130 results for which titles and abstracts were reviewed to determine suitability for inclusion. After review of titles and abstracts, of the 130 articles, 12 were identified for review of the full papers. After further examination of these papers, three were excluded as case reports, one was excluded as an abstract only, and one was excluded for including an ileal interposition graft "neuroendocrine break." One paper [10] selected for inclusion presented an updated and expanded data from a previous case series [11]. This included the earlier results in a new analysis. The earlier paper was therefore excluded from this review, leaving six papers for inclusion [10, 12–16]. All the studies comprised only "primary" BSG, with no revision LSG or secondary banded LSG included within the studies. The PRISMA flowchart for selection is shown in Fig. 1.

Data were extracted from the studies for sample size, age, initial body mass index (BMI), excess weight loss (EWL%) or reduction in BMI, size of gastric sleeve, distance from the pylorus of the staple line, staple line reinforcement, location of band placement, type of band, duration of follow-up, and any complications. Additional data was sought for the length of operation and length of stay was sought; however, limited data available limits the conclusions that can be drawn. Simple statistical tests were used for analysis.

Results

Six studies were included in the analysis: one randomized study by Tognoni et al. [12], one retrospective study with matched controls, one prospective study with comparison to non-banded SG, two prospective case series, and one retrospective study of cases. A summary table of the main results is shown in Table 1, with complications enumerated in Table 2. Weight loss data (%EWL) of individual studies is shown in Fig. 2.

The total number of patients was 236. All the studies comprised only "primary" BSG, with no revision LSG or secondary SG included within the studies. Mean age was 45.4 years, with a mean initial BMI of 47.9 kg/m^2. Within the studies, there were 92 (38.9%) men and 144 (61.1%) females. Median follow-up was 1 year (range 3 to 60 months), with a mean follow-up of 77.9% (range 58.3 to 100%). The mean operative time was 96.8 min (65.1–140.7). The mean complication rate was 11.8% and the reoperation rate was 5.5%. Mortality rate was 0.85%. All papers reported changes in postoperative weight, with the study by Fink et al. [10], Daigle et al. [13], and Lemmens et al. [16] reporting %EWL; Miguel et al. [14] and Alexander et al. [15] reporting % excess BMI loss (EBMIL); and Tognoni et al. [12] reporting reduction in

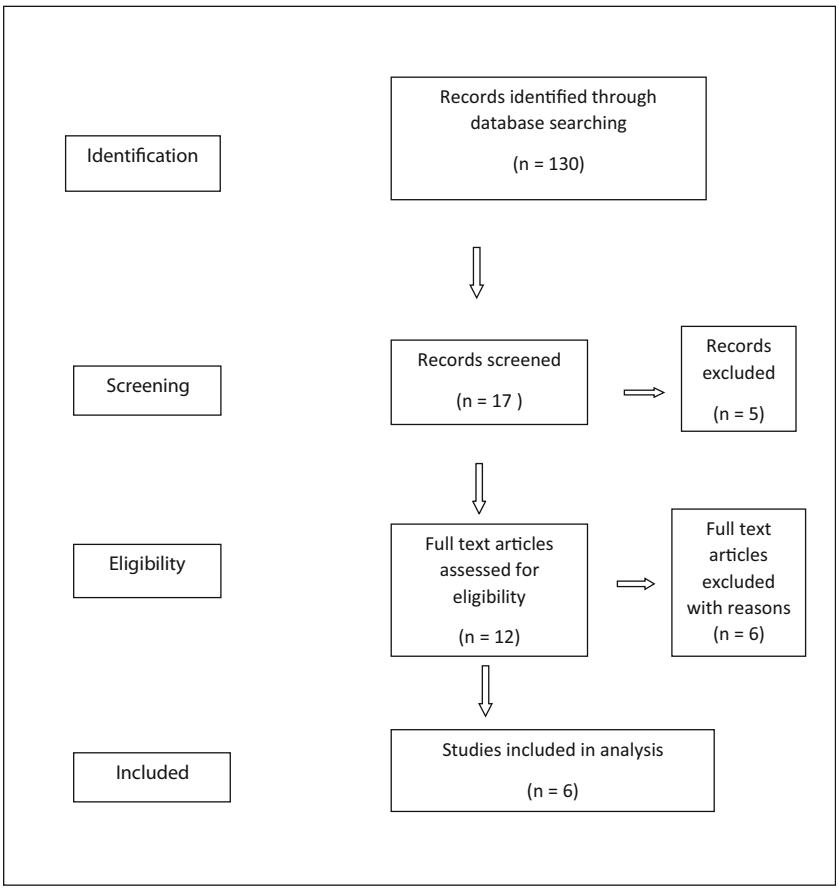

Fig. 1 PRISMA flowchart

Table 1 Summary of basic demographics, operative technique, morbidity, mortality, band type, and location

Studies	Sample size	Men:women	Age (years)	BMI (kg/m^2)	Operation time (min)	Distance from pylorus	Follow-up duration	Morbidity (%)	Mortality (%)	Follow-up (%)	%EWL	Gastric tube	Location of band (from GOJ)	Band type
Alexander et al. 2009 [15]	27	5:22	46	48	–	6 cm	3–24 months	7	0	70	73.1%	50 F	6 cm	Allodern band
Miguel et al. 2009 [14]	33	0:33	36.7	42.33	–	–	1 year	6	3	94	86.5%	32 F	5 cm	Silicone band
Karcz et al. 2014* [11]	25	7:18	42.6	56.1	53.2	5 cm	1 year	12	4	100	58.0%	35 F	4 cm	Minimizer ring
Daigle et al. 2015 [13]	13	6:7	56	53.7	140.7	4 cm	16 months	23	0	58.30	54.8%	34 F	2 cm	Silicone band
Tognoni et al. 2016 [12]	25	9:16	45.7	44.95	84.6	–	1 year	4	0	100	87.9% (17.53 kg)	36 F	4 cm	GaBP ring
Fink et al. 2017 [10]	42	12:30	40.1	54.9	65.1	5 cm	36 months	16.67	0	62	66.7%	35 F	As Karcz paper	Minimizer ring
Lemmens et al. 2018 [16]	96	60:36	47.9	43.7	–	3–4 cm	5 years	14.5	0	83.3	86.7%	40 F	4–5 cm	Minimizer ring

*Updated data of Karcz et al.

BMI. When ideal BMI is taken at 25 kg/m^2 as in these studies, the %EWL and %EBMIL are equivalent, so in this paper, they were taken to be the same. The %EWL for the paper by Tognoni et al. [12] was calculated from data provided within the paper. The mean %EWL was 77.4% (range 54.8 to 87.87%).

In the randomized study [12] comparing LSG with BSG, there was no significant difference in weight loss between the two groups at 3, 6, or 12 months postoperatively (p value = 0.186 at 12 months). There was no difference in the decrease in type 2 diabetes mellitus after 6 months ($p = 0.755$), but there was a significant difference in the decrease in hypertension ($p = 0.022$). The mean operative time was not significantly different between the two groups ($p = 0.144$), and there were no intraoperative complications and no difference in overall complications. In the study by Lemmens [16] comparing banded SG (BSG) to non-banded SG (NBSG), the %EWL at 5-year follow-up was 86.7% ($n = 10/13$) compared to 57.8% ($n = 15/17$) respectively. They also reported that weight regain in BSG was less than in NBSG; however, the complication rate was higher for the BSG group (14.5%) compared to that for NBSG (9.8%).

The studies used a variety of orogastric tubes for sleeve calibration ranging from 32 to 40 F, except Alexander et al. [15] who used a 50-F orogastric tube (Table 1). Distance from the pylorus for the start of the staple line was recorded in four of the papers with a median distance of 4 cm (range 3 to 6 cm). The band was sited with a median distance of 4 cm from the gastroesophageal junction (GOJ) (range 2 to 6 cm). Operative time was reported for three of the papers with a mean duration of 96.8 min (range 65.1 to 140.7 min). Length of stay (LOS) data was only available for two studies [10, 15]. The mean LOS was 5.25 days (range 2.7–7.8).

The mean complication rate of Clavien-Dindo grade II or above was 11.8%, with further reflux, regurgitation, and vomiting noted postoperatively in three of the studies. There were two deaths (0.85%) and 13 patients requiring reoperation (5.5%)—three early (within 30 days of primary operation) due to complications and ten late operations for revision. Four of these needed band removals. There are two deaths that were recorded in the studies: one following staple line leak and one from congestive cardiac failure and underlying arrhythmia. Two patients had a staple line leak or fistula formation, which resulted in one death. Two patients required removal of the band due to band intolerance. Two patients had staple line bleeding, one of which required laparoscopic intervention to control the bleeding. One patient was noted to have a respiratory arrest on recovery from anesthetic that required an intensive care admission. The patient made a full recovery to discharge with no deficit reported. Two pulmonary embolisms were reported with no adverse outcome documented.

Table 2 Complications of cumulative data

Study	Sample Size $n = 236$	Bleeding	Early reop	Late reop	Band removal	PE	Respi arrest	Arrhythmia	Fistula	Abscess	Death
Alexander et al.	27					1				1	
Miguel et al.	33		2						2		1
Daigle et al.	13					1	1	1			
Tognoni et al.	25	1									
Fink et al.	42	1		6	3						1
Lemmens et al.	96	2		4	1					1	

Discussion

Obesity and its related diseases are increasing in prevalence annually [1]. Obesity surgery is currently felt to be the best treatment for suitable patients to achieve long-term sustainable weight loss [5], and the prevalence of surgery is increasing accordingly. Although RYGB is widely thought to be the most effective bariatric operation, LSG continues to increase in popularity. LSG was initially performed as the first step in a biliopancreatic diversion with duodenal switch (BPD-DS) operation [17, 18]; however, patients achieving significant weight loss without conversion to DS led to the development of LSG as a stand-alone operation [19]. Five and 10-year follow-up data for LSG has shown good outcomes but weight regain remains a concern [8]. Weight regain after any bariatric operation has led to ongoing modification of surgical technique to improve postoperative excess body weight loss and weight regain [6]. Laparoscopic banded Roux-en-Y gastric bypasses (LBRYGB) have been performed in numerous trials with encouraging results [6]. LBRYGB was demonstrated to show increased weight loss compared to non-banded RYGB, but widespread use of this technique has not occurred. It was suggested that the band reduced the incidence of pouch dilation and the increase in weight that would be associated with it [6]. Sleeve dilation over time is thought to be a bigger concern and believed to be responsible for weight regain within LSG patients [8]. Proponents of primary banded SG argue that banding would reduce long-term weight regain though the exact mechanisms of it remain incompletely understood. It has been suggested that the consistent, incremental increase of consumed meals is the most likely primary mechanism for sleeve dilatation and hence putting a band around the sleeve prevents dilatation of the sleeve in the long term and may reduce appetite and enhance satiety through perigastric neural pathways [7, 10, 16].

Our review of the literature shows that there is currently a lack of robust clinical data on primary BSG with only 236 published cases. It included one randomized trial, one comparative study, several case series, and one retrospective study. It is difficult to draw any firm conclusions from such small studies. The one prospective comparative study by Tognoni et al. [12] showed no significant difference in weight loss with LSG compared to BSG in the short term but that is only to be expected as the effect of banding would only become apparent with longer follow-up. The retrospective matched study by Fink et al. [10] also showed no significant difference in weight loss in LBSG compared to LSG at 3-year follow-up. With a cumulative sample size of these two papers [10, 12] of 67 in each arm and no other studies for comparison, it is difficult to draw conclusion with a high degree of certainty from these two papers alone. The comparative study by Lemmens [16] reports results at 5-

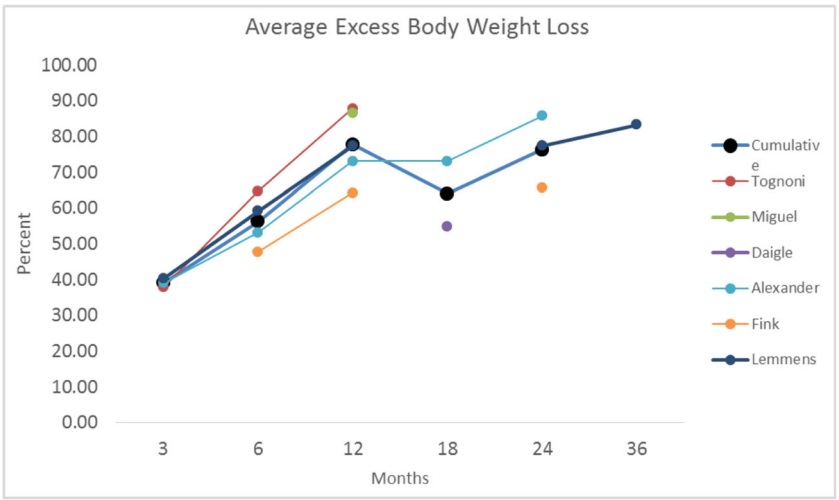

Fig. 2 Mean %EWL of individual studies

year follow-up. However, there are only ten patients in the banded LSG group at 5 years which is a small number to draw up conclusions. We need more studies with longer follow-up data on weight loss and complications to draw conclusions.

The studies showed a degree of variability in operative technique and follow-up protocols. Although all studies used a bougie (32–40) for calibration of the gastric tube, the study by Alexander et al. [15] used a 50-F tube which seems larger than what most sleeve surgeons would recommend. While tube size has not been shown to directly correlate with weight loss, increased gastric volume postoperatively is associated with less initial weight loss [20]. There was a small amount of variability in the distance from the gastroesophageal junction of the placement of the band, varying from 2 to 6 cm. It has been debated in the literature if sleeve dilation and the formation of a neofundus could result in poor weight loss and weight regain following LSG [21]. The small sample size cannot help shed any light on the optimal location of band placement, and there are as yet no comparative studies examining different band locations. Also, different authors have used different prosthetic devices ranging from an alloderm band, silicone band, GaBP ring, and minimizer ring. It is difficult to establish an advantage of one over the other from these studies. The minimizer ring apparently has the advantage over other rings of easy placement, allowing adjustment of the desired diameter and formation of pseudocapsule allowing easy removability.

Median follow-up in studies in this review was 1 year and ranged from 3 to 60 months. While the 3-year data provided by Fink et al. [10] is encouraging, it has not demonstrated a significant difference in weight loss in BSG versus matched LSG. Lemmens reported 86.7% EWL at 5-year follow-up but this is in a small cohort ($n = 10$). This is a small number to draw conclusions. This means published literature cannot really tell us about any potential benefit of the banded sleeve on long-term weight loss outcomes.

In addition to the limitations mentioned above, there is an issue regarding the outcome measures used in these studies. There is considerable debate within the bariatric community with regard to the most appropriate method(s) of expressing weight loss post bariatric surgery [22]. Within the studies in this review, three different outcome measures were used: excess body weight loss, excess BMI loss, and BMI reduction. This makes any comparison of weight loss outcomes difficult. If ideal body weight is calculated using a BMI of 25 kg/m^2, then EBWL% and EBMIL% should be the same, and with sufficient data, they can be calculated from the BMI reduction. Such calculations were applied in this paper to enable the comparison and cumulation of the results for analysis. None of the studies report the comorbidity resolution or metabolic results. The other weakness of this review is that most are retrospective studies with variable follow-up. Variations in the surgical technique and prosthesis further compromise the quality of the data. We have simply pooled the results and hence the statistical validity of such heterogeneous data is limited. Despite these shortcomings, the importance of this review article is that it gives the surgeons an idea of what to expect from this procedure.

A morbidity rate of 11.8% with a reoperation rate of 5.5% and mortality of 0.85% is in line with results from other large studies into LSG [23]. However, complications of BSG such as band slippage, erosion, or intolerance would likely manifest at long-term follow-up. Long-term exposure to high pressures within the gastric sleeve coupled with a band could lead to higher rates of sleeve dilation proximal to the ring, and band erosion when compared to LBRYGB. Foo et al. [24] reported a case series of six leaks post BSG at their institution over an 18-month period, compared with six leaks in LSG patients. The median time to leak after BSG was 58 days (range 34–230 days). All six patients with leak post BSG required surgical intervention for band removal and washout of the abscess cavity. This compares with only one operative intervention required in the leak post LSG for washout of abscess cavity. The other leaks post LSG were managed with endoscopic stenting and percutaneous drainage of an abscess. This highlights the potential need for mandatory operative intervention for complications of BSG compared to LSG. Fink et al. reported six late reoperations during their 3-year follow-up and Lemmens reported four reoperations during their 5-year follow-up. More studies with longer-term follow-up are required before definitive conclusions can be drawn.

Obesity is a recognized risk factor for gastroesophageal reflux disease (GORD), and LSG as a treatment for obesity has been shown to improve reflux symptoms [25]. However, LSG has been described in some patients to worsen preexisting GORD [26, 27]. Given conflicting reports in the literature, we might expect to see either worsening or improving reflux symptoms in patients with BSG. In patients with preexisting reflux, Fink et al. [10] reported an improvement in reflux in patients with BSG compared to LSG with an odds ratio of 1.61. New-onset reflux was present in 45% of BSG group compared to 50% LSG group. The relative risk of dysphagia was 1.4 when a ring was placed. Their study also showed that patients with frequent regurgitation undergoing BSG were likely to suffer from postoperative reflux. They hypothesize that ring placement may aggravate reflux in patients with frequent regurgitation. They reported that a high rate (44%) of patients had relevant regurgitation in BSG compared to only 4% of patients in LSG. Regurgitation post BSG leads to three band removals within their series (7.1%) at mean postoperative time of 14 months. This represents additional reoperation load and morbidity associated with the BSG. Daigle et al. [13] reported that of two patients with preoperative acid reflux, one experienced improvement in symptoms and one showed no change in symptoms. Two patients experienced de novo postoperative reflux. No patients in their

series required reoperation for band removal due to reflux or regurgitation. Alexander et al. [15] showed a significant reduction in reflux symptoms post BSG ($p = 0.04$), with complete resolution of reflux in eight out of 15 patients with preoperative reflux, and symptomatic improvement in the rest. Three patients developed de novo mild reflux post BSG. No patients required reoperation for band removal due to reflux in their study. Lemmens et al. [16] reported 7.2% (seven patients) patients with vomiting in their study. They did not have exact numbers of patients describing reflux problem. While all articles have reported a high rate of vomiting and dysphagia, none of them have evaluated the quality of life (QoL) index or GERD questionnaire in these patients. We would encourage the authors to report this in future studies.

Conclusion

This systematic review identifies 236 cases in six published studies in the entire scientific literature with a median follow-up of 12 months and the longest follow-up in one study of 60 months ($n = 10$ patients). This review is unable to examine the benefits versus risks of primary banded SG in the long term because of the lack of data on these aspects. We need randomized studies with long-term follow-up to adequately evaluate the pros and cons of this procedure.

Authors' Contribution CP, OE, and KM participated in the literature search. KM conceived the idea for the topic. CP collected most of the data and OE analyzed it. CP, OE, and KM contributed to manuscript writing. All authors contributed to the manuscript. All authors have seen the final version and approve it.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval For this type of study, ethical approval is not required.

Abbreviations *SG*, sleeve gastrectomy; *BSG*, primary banded sleeve gastrectomy; *PRISMA*, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; *EWL*, excess weight loss; *BMI*, body mass index; *RCT*, randomized controlled trial; *RYGB*, Roux-en-Y gastric bypass; *GORD*, gastroesophageal reflux disease

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