



Laparoscopic Sleeve Gastrectomy is Superior to Endoscopic Intra-gastric Balloon as a First Stage Procedure for Super-Obese Patients (BMI ≥ 50)

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Background: The treatment of patients with a BMI ≥ 50 kg/m² is still controversial. Given the many co-morbidities and oftentimes fragile health of super-obese patients, surgeons experienced in bariatrics often advocate a less invasive first stage operation for these patients. This allows them enough weight loss to support a more major second-stage operation such as a gastric bypass or a biliopancreatic diversion / duodenal switch. Thus, the aim of this study was to compare laparoscopic sleeve gastrectomy (LSG) and the BioEnterics intra-gastric balloon (BIB) as a first-stage procedure for effective initial weight loss before more definitive surgery.

Methods: 20 patients (13 males and 7 females) who underwent LSG from May 2001 to December 2002 were compared with 57 patients (33 males and 24 females) obtained as historical controls from two large series who underwent BIB. Patients were evaluated at 6 months in terms of: weight, BMI, percent of excess weight loss (%EWL) and change in BMI.

Results: There were no differences between groups for age, weight and BMI. There were no complications for patients undergoing the LSG. For patients undergoing BIB, 4 patients (7%) had the balloon removed due to intolerance. The mean weight loss for patients undergoing LSG and BIB at 6 months was 45.5 vs 22.3 kg respectively, and the %EWL was 35 for LSG vs 24 for BIB. BMI decreased respectively from 69 to 53 for the LSG group and from 59 to 51 for the BIB group. Weight loss decreased co-morbidities in 90% of patients after both procedures.

Conclusion: Patients undergoing a LSG showed a faster and greater weight loss than those using a BIB at 6 months. Moreover, LSG is a safe procedure, with

reproducible results, in contrast to the BIB which was tolerated by 93% of patients. The results indicate that both mean weight loss and %EWL were better in the LSG group, and that BMI decreased substantially more in the LSG group as well. Although the BIB procedure shows efficacy in reducing weight, the LSG group does so faster and to a greater amount, thus suggesting that this may be a superior procedure as a first stage for super-obesity.

Key words: Morbid obesity, laparoscopy, sleeve gastrectomy, intra-gastric balloon, endoscopy

Introduction

Patients defined as super-obese with a body mass index (BMI) ≥ 50 kg/m² represent approximately 30-50% of all morbidly obese patients. Optimal treatment for these patients is controversial, because even the Roux-en-Y gastric bypass (RYGBP) results in failure of adequate weight loss in 43% of patients with a BMI > 50 .¹ Moreover, co-morbidities often related to super-obesity such as hypertension, diabetes, sleep apnea - hypoventilation, joint disease and hypercholesterolemia make these patients a high-risk for bariatric surgery.

Gagner's group,² in a series of 40 consecutive patients, reported a 38% major complication rate associated with one-stage laparoscopic biliopancreatic diversion with duodenal switch (BPD-DS) in patients with a BMI ≥ 65 , compared with 8% for patients with a BMI 40-60. Based on these results, the concept of a two-stage operative approach has been introduced for super-super-obese patients (BMI

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≥ 60) consisting of an initial sleeve gastrectomy,^{3,4} followed 6-12 months later by a definitive BPD-DS. This approach allows high-risk patients with a BMI ≥ 60 kg/m², to first undergo a simpler and faster operation that affords good initial weight loss, followed by a definitive weight loss operation that is better tolerated after the patient's BMI has dropped.

In 1982, Nieben⁵ proposed the use of an intra-gastric balloon to reduce available stomach volume and consequently, food intake. Numerous air-filled balloons were developed and tested, but they were abandoned due to complications associated with their insertion and presence in the gastric cavity such as: erosion, decubitus and gastric ulcers, balloon rupture with subsequent expulsion and intestinal obstruction requiring surgical intervention. The characteristics of a safe intra-gastric balloon were established in a workshop held in Tarpon Springs, Florida, March 19-21, 1987.⁶

Subsequently, a new smooth spherical saline-filled balloon (BIB, BioEnterics Intra-gastric Balloon, Inamed, Santa Barbara, CA, USA) became accepted as an option for first-stage treatment for weight loss in countries outside the U.S.⁷ The balloon is a silicone, radiopaque, saline-adjustable device that can range in volume from 400 to 700 ml.⁸ It reduces the volume of the stomach, thus mimicking a gastric restrictive surgical procedure, via an endoscopic approach.

Because the intra-gastric balloon can cause patient discomfort, it was our aim to determine whether another approach could provide similar results with decreased morbidity. The aim of this study is to compare laparoscopic sleeve gastrectomy (LSG) and the BIB as first-stage procedures before definitive surgery in the treatment of patients with BMI ≥ 50 kg/m².

Methods

A retrospective chart review was performed for the last 20 consecutive patients (13 males and 7 females) with a BMI ≥ 50 kg/m² at Mount Sinai Hospital, New York, from May 2001 to December 2002, who underwent LSG. These were compared to 57 historical controls (33 males and 24 females) obtained from the literature from two different series^{8,10} that underwent BIB. The studies from the literature were selected as high-quality studies on the topic.

Patient data were evaluated after 6 months for comparisons in weight, BMI, %EWL, and overall weight loss.

Surgical Treatment

1. Laparoscopic Sleeve Gastrectomy

The operation involves laparoscopically removing the greater curvature of the stomach (Figure 1) from the angle of His to the distal antrum, creating a thin gastric tube of 150-200 ml over a 60-Fr bougie. The procedure, which takes an average of 114 minutes, has been performed as described.³

2. Endoscopic BioEnterics Intra-gastric Balloon

The balloon used by both groups was the BIB (Figure 2).^{8,10} Both the placement and the removal of the BIB were performed under monitored sedation or general anesthesia. The deflated balloon was introduced endoscopically through the mouth and positioned in the stomach cavity. The balloon was injected with 500-700 ml of saline and methylene blue (50:1). After inflation, the balloon valve was closed and the balloon position was endoscopically checked again.

Balloon removal occurred 6 months after placement as an outpatient endoscopic procedure by emptying the balloon under endoscopic control with a sclerosis needle and extracting it.^{10,11}

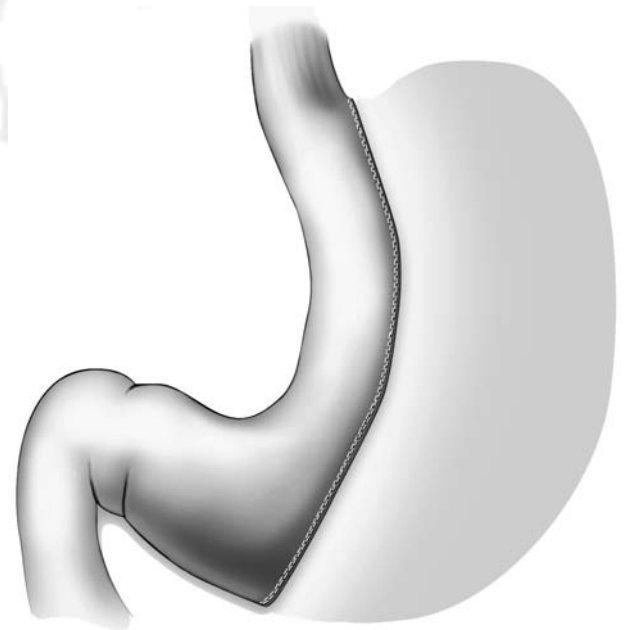


Figure 1. Sleeve gastrectomy: the greater curvature of the stomach is removed from the angle of His to the proximal antrum, creating a 150-200 ml stomach.



Figure 2. Intra-gastric balloon: a spherical smooth radiopaque balloon made from silicone, saline-filled and adjustable in volume from 400-700 ml (from BioEnterics).

Results

Each of the 77 patients was super-obese (BMI ≥ 50 kg/m²), with an average BMI of 68.8 for the LSG (range 60.0-85.1), 60.2 for the BIB by Weiner (range 58.0-72.0)⁸ and 58.4 \pm 6.6 by Busetto.¹⁰ The LSG group had an average age of 43 years (27-63) and weight of 200 kg (157-247). In the BIB group, the Weiner study had an average age of 38 years (20-56) and weight of 195 kg (205-275) and the Busetto study had an average age of 43 years (33-54) and weight of 171 kg (134-305) (Table 1).

The only postoperative complication involved one

Table 1. Co-morbidities in the LSG and BIB groups (These co-morbidities are not described for the Weiner et al⁸ study)

Co-morbidities	LSG	BIB
Hypertension	11 (55%)	30/43 (69.8%)
Sleep apnea	12 (60%)	29/43 (67.4%)
Diabetes	6 (30%)	19/43 (44.2%)
Osteoarthritis	19 (95%)	30/43 (69.8%)
Gastroesophageal reflux	5 (25%)	
Hypercholesterolemia	6 (30%)	12/43 (27.9%)
Depression	14 (70%)	6/43 (14.0%)
Total no. of patients	20	43

trochar-site infection in the LSG.

Four BIB patients (7%) had the BIB removed: one for balloon dysfunction, one for abdominal pain, and two for noncompliance. One patient had spontaneous elimination of the balloon in the stool. Two patients (3%) had other complications that did not require removal of the balloon: one severe vomiting with mild dehydration and the other a skin reaction of unknown origin.

Table 2 shows weight-related parameters of the LSG versus BIB groups. Although preoperative BMI was higher in the LSG group, the change in BMI and weight loss was markedly greater in the LSG group (fall in BMI of 9.4 and 6.4 units in the BIB groups versus 15.9 in the LSG group, and weight loss of 26 and 18 kg in the BIB versus 45.5 kg in the LSG group). Figures 3 and 4 respectively show the relational trend between BMI and %EWL and the follow-up at 6 months. BMI decreased for the LSG from 69 to 53 and for the BIB from 59 to 51 (Figure 5).

Each patient from LSG and BIB groups had an improvement in co-morbidities such as hypertension, osteoarthritis and sleep apnea. The improvement was accompanied by a decrease in the use of associated medications.

Discussion

Scopinaro et al¹² first introduced the BPD in 1976. Later, Hess¹³ and Marceau¹⁴ introduced the duodenal switch (DS) modification. With excellent early results these patients demonstrated a very low-incidence of long-term metabolic complications such as bone disease, protein malnutrition, fat-soluble vitamin deficiency and iron deficiency anemia.^{14,15} DS has been found by many surgeons to give optimal sustained weight loss results, particularly in the super-obese.¹⁵⁻¹⁷

Although EWL $>50\%$ is considered successful for many patients with RYGBP, super-super-obese patients often remain morbidly obese, even with a substantial weight loss, with a BMI >35 kg/m² when they reach their final weight.¹⁸ Therefore, BPD-DS with the greater degree of malabsorption and subsequent weight loss afforded, is a viable option that must be considered for these patients, but the serious co-morbidities of super-obese patients often limit their options.



Table 2. Comparison of the literature review regarding LSG and BIB^{8,10} in super-obese patients (BMI ≥ 50 kg/m²)

Author	n	Preop BMI (kg/m ²)	Follow-up (Months)	Mean Weight (kg)	% EWL	BMI Loss (kg/m ²)	Final BMI (kg/m ²)	Mean Weight Loss (kg)
Busetto ¹⁰	BIB	43	5.4	171	26.1	9.4	49	26
Weiner ⁸	BIB	17	4	195	21	6.4	53.8	18
Gagner	LSG	20	6	200	34.9	15.9	53.0	46

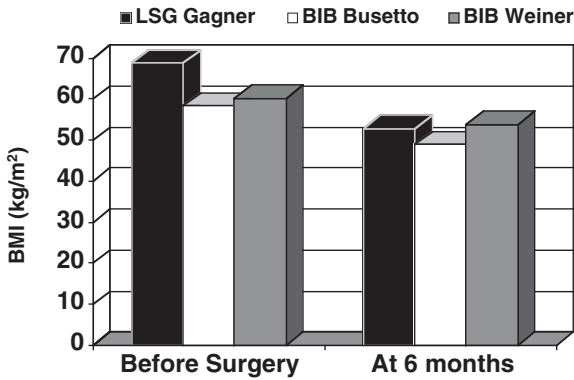


Figure 3. Relation between BMI and follow-up in months.

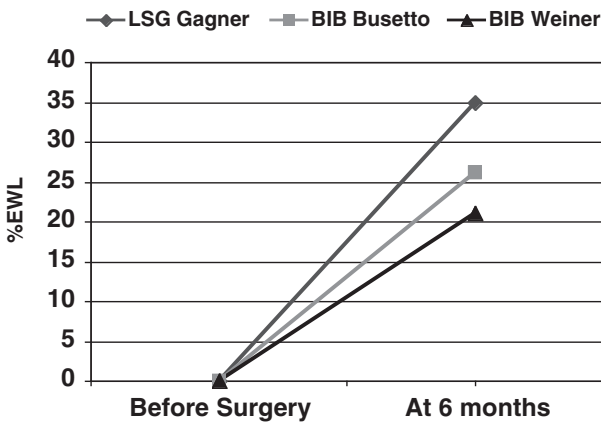


Figure 4. Relation between %EWL and follow-up in months.

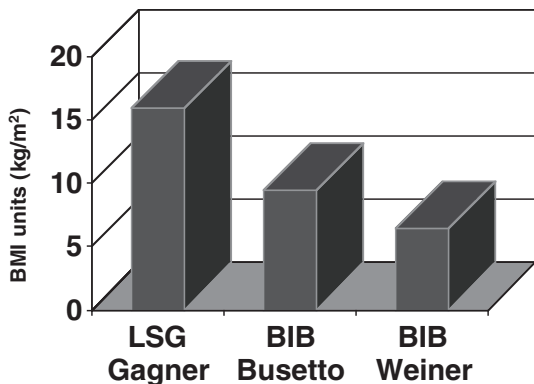


Figure 5. Comparison of the loss of BMI units between the series.

For this reason, our group has proposed the utility of two-stage laparoscopic BPD-DS. Patients with BMI ≥ 60 kg/m² undergo sleeve gastrectomy as a first-stage restrictive operation, and after 6-12 months the second-stage BPD-DS is performed when weight loss plateaus. Our group previously reported similar good results with the sleeve gastrectomy as a first-stage procedure for RYGBP.³ In that series, 7 patients with a mean initial weight of 181 kg and a mean BMI of 63 (58-71 kg/m²) underwent sleeve gastrectomy; 11 months after this procedure, they had a mean weight of 145 kg with a mean BMI of 50 and a mean weight loss of 37 kg (33% EWL), supporting the safety and reproducibility.

Moreover, if the patient experiences adequate weight loss, the second procedure (BPD-DS or RYGBP) may not be necessary, and the patient can be followed longer after the sleeve gastrectomy. If the weight loss is not satisfactory at the time of the definitive surgery, another option is placement of a gastric band to further decrease the gastric volume and improve the weight loss.

On the other hand, the literature indicates that BIB is a beneficial procedure when used in preparation for the future surgical procedures. Several studies have described the best timing and the class of patients that could benefit from the BIB.^{8,10,19,20} Doldi et al²¹ reported a retrospective analysis of 303 patients treated with the BIB. The mean initial BMI was 42 (29-81 kg/m²), and the BIB was left in place for 5 months (4-6 months). The mean %EWL obtained was 35 (5-100). Positive results were obtained in patients with BMI >40 (16.8 and 13.2 kg respectively at 4 and 6 months), while patients with BMI <40 lost 11.6 and 9.1 kg. With such a large BMI range, the benefits and contraindications of the balloon in different classes of obese patients were examined, and the balloon was most effective in morbidly obese patients (BMI >40) and super-obese patients (BMI ≥ 50) in preparation for bariatric surgery (Table 3).

Good results are reported with the short-term (up

**Table 3.** Literature series about BIB

Authors	Patients	Mean Months	Mean Wt (kg)	Mean BMI (kg/m ²)	Mean Wt loss	Mean BMI loss	Mean %EWL
Loffredo ²⁰ 2001	64	4.7	113.4	41.2	14.3	5.3	23.5
Totte ¹⁹ 2001	126	4.7	35.3*	37.7	15.4		3 m: 48.6 6 m: 50.8
Doldi ⁷ 2000	281	5	117.4	41.8	4 m: 13.9 6 m: 12	4 m: 4.8 6 m: 4.1	35
Doldi ²¹ 2004	303	5	118.8	42	4 m: 13.9 6 m: 12	4.9	35

* Mean initial excess weight. m = months.

to 6 months) use of BIB. It is important that the time interval between removal of the BIB and the subsequent bariatric operation be maintained as short as possible in order to avoid the regain of weight.

Important issues to consider are the complications that can occur with both procedures. LSG is an operation with the attendant risks of any surgical treatment.

In Doldi's series²¹ the complications were intolerance (7.2%) and BIB rupture (3.7%). Minor complications for the BIB include gastroesophageal reflux, balloon deflation, gastroduodenal ulcer formation with pain, and bleeding. Most authors described balloon intolerance in 2-7% of BIB placements, which usually results in extraction of the balloon.^{7,22} More serious although infrequent complications have been bowel obstruction²³ and gastric perforation.^{24,25} Because of these complications, some patients may need to have the BIB removed before reaching the sixth month.

Conclusion

LSG provided a safe first-stage operation that allows more rapid and greater weight loss compared with the BIB at 6 months. Although the LSG requires general anesthesia and a hospital stay of 2-3 days compared to the outpatient BIB, the LSG was safely performed in all patients in this study with 1 minor complication. BIB carries with it problems of intolerance in 7% of patients and a greater degree of minor and major complications. Both techniques result in major improvement in co-morbidities during the 6-month follow-up in 90% of the patients, most notably in

hypertension, sleep apnea and osteoarthritis. Both procedures are effective as a first stage for patients with BMI ≥ 50 kg/m², although the LSG was better tolerated and showed superior results in this limited series. Future studies should be prospective randomized for final confirmation.

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