

# Three Years Experience with the New Intra-gastric Balloon, and A Preoperative Test for Success with Restrictive Surgery

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**Background:** The BioEnterics Intra-gastric Balloon (BIB<sup>®</sup>) is a smooth, spherical, saline-filled, silicone elastomer with a black radiopaque filling valve, intended to induce weight loss by limiting food consumption. This can be considered a "restrictive" procedure, and by using this balloon, we can assess the patient's eligibility for a restrictive surgical procedure (the BIB-Test).

**Methods:** From May 1997 to May 2000, 87 BIB were inserted in 77 moderately to severely obese patients (4 BIB in 1 patient, 2 BIB in 7 patients). 64 patients completed the treatment. Out of these, 18 (16 female, 2 male) underwent laparoscopic gastric banding after BIB removal.

**Results:** After the treatment (3-6 months), weight loss results were as follows: WL 14.3 kg, %EWL 23.5 and loss in BMI 5.3. 12 patients after the preliminary BIB, have been followed  $\geq$  6 months after gastric banding, and have significant further weight loss.

**Conclusions:** BIB appears to have good results. A supervised nutritional and behavioral regimen is mandatory. The balloon may be indicated to: 1) induce weight loss in patients whose obesity is not severe enough to warrant surgery; 2) reduce the surgical risk in those who are massively obese; 3) select patients for gastric restrictive surgery if they lose weight with the balloon. The data showed that patients who had good results with the BIB (positive BIB-Test) are still losing weight after subsequent gastric banding.

*Key words:* Morbid obesity, intra-gastric balloon, endoscopy, laparoscopy, gastric banding

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## Introduction

The idea of using a gastric space-occupying device, giving a sensation of satiety, was first described in 1982 for the treatment of obesity.<sup>1,2</sup> The concept developed from observations in patients with gastric bezoars. The use of free-floating intra-gastric balloons, consisting of different materials, was reported.<sup>3</sup> After an initial enraptured period, a critical period followed, after failure of sustained weight loss after the Garren-Edwards and Ballobes balloons.<sup>4,5</sup>

The BioEnterics Intra-gastric Balloon System (BIB<sup>®</sup>) represents a temporary non-surgical and non-pharmaceutical treatment for obesity in selected patients.<sup>6</sup> It is totally reversible and repeatable. The introduction of a new free-floating balloon has renewed interest.<sup>7</sup> The BIB is a smooth, spherical, saline-filled, silicone elastomer balloon with a black radiopaque filling valve. The mode of action is by partially filling the stomach, to induce satiety or restrict food intake.

The balloon, by limiting food consumption, can be considered to be a "restrictive" procedure. If successful, this may predict the patient's success in a following gastric restrictive surgical procedure (BIB-Test).

## Materials and Methods

From May 1997 to May 2000, 87 balloons were inserted in 77 moderately and severely obese

patients. One patient underwent four balloon insertions and seven patients had two balloons. Of the patients, 54 were female and 23 male, with mean age 38.2 years, weight 128.0 kg (85.0–220.7), BMI 46.6 kg/m<sup>2</sup> (32.1–73.8) and excess weight (EW) 65.0 kg (28.1–155.0). The full course of treatment was completed in 64 patients. After BIB removal, 18 patients (16 female, 2 male) underwent laparoscopic adjustable silicone gastric banding (LASGB) with the Lap-Band® (BioEnterics).<sup>8</sup>

When received, the balloon is deflated and folded back by a gel film on a graduated catheter provided with a mandrine, a Y Luer-lock connector and a reintubation catheter for filling modifications and removal of the balloon. The balloon is filled with saline, and adjustable from 400 to 700 ml. Arrows printed on the surface of the balloon serve as markers to detect the black filling valve, in case of filling modifications or removal.

The inclusion criteria are shown in Table 1. Relative contraindications included esophagitis, gastric or duodenal peptic disease, and *H. pylori* infection. Absolute contraindications are listed in Table 2. A hiatal hernia was considered an absolute contraindication at the beginning of our experience; later, only large hiatal hernias were excluded.

If there were no contraindications, before balloon placement, the patient underwent the following studies: basic clinical chemistries, cardiologic examination, X-rays of chest and digestive tract, gallbladder ultrasound, nutritional evaluation, psychiatric evaluation, and spirometry if indicated.

Before balloon placement, an esophagogastro-duodenoscopy with mucosal biopsy was done to detect any further contraindications.

The endoscopic management of the technique was performed with standard sedation (diazepam 10 mg and joscine-butyl bromide 20 mg IV). The usual balloon filling-volume was 520 ml of saline, which appeared to provide the best compromise between gastric volume occupancy and silicone tissue resistance. Larger volumes were allowed in

**Table 1.** Indications for BIB

BMI > 35
BMI > 30 with correlated pathologies
Reduction of anesthesia risk (bariatric or other surgery)
Reduction of disabling disease
BIB-Test in sweets-eaters or snackers and binge- or compulsive-eaters.

**Table 2.** Contraindications to BIB placement

Active esophagitis
Active gastric or duodenal ulcer
Crohn' disease
Cancers
Potential or active GI bleeding
Alcoholism or drug addiction
Large hiatal hernia (>5 cm)
Prior gastric or intestinal resection
Patients on anticoagulants or gastric irritants
Psychiatric disorders

patients who lacked the sense of satiety or with further balloon substitution.

The BIB®, was inserted through the mouth and down the esophagus. The small caliber of the placement catheter allows easy introduction of a gastroscope beside it, to observe and control the placement and filling steps. Once the balloon is seen below the lower esophageal sphincter and well within the stomach, one can connect a filling-syringe to the Y Luer-lock connector, and fill the balloon with saline containing methylene blue (50:1 ml). If the balloon were to rupture, the patient would observe blue-colored urine and know to contact the physician immediately. After the balloon has been filled, gentle suction is placed on the placement catheter by withdrawing the plunger of the syringe. One cannot withdraw fluid, as the valve will seal with the vacuum created. The balloon is released by pulling the filling-tube gently while the balloon is against the tip of the gastroscope. After release, the balloon is inspected endoscopically. After placement, an x-ray of the abdomen may be performed to check the position of the balloon.

The patient is then given metoclopramide and omeprazole.

Mean duration of the treatment at the beginning was 4 months, but later 6 months. During this period, the patients undergo a supervised nutritional regimen.<sup>7</sup>

At the end of the treatment, the BIB is emptied. A BIB removal kit is now available from Aprine®, to ease withdrawal through the esophagus. Rat-toothed grasping forceps (or a snare) is inserted in the working channel of the gastroscope to grasp the balloon. The endoscope, forceps, and balloon are then gently withdrawn from stomach and the esophagus.

## Results

A total of 64 of the 77 patients completed the entire treatment. After the entire intended term (3-6 months), weight loss results were as follows: mean body weight 113.4 kg, BMI 41.2, percent of excess weight loss (%EWL) 22.1, and WL 14.3 kg (Table 3). Three outcome groups were identified.

The first group consisted of 18 patients (16 female, 2 male) who had good results and wanted to be operated on. The eligibility for LASGB<sup>8</sup> was based on good compliance with the restrictive BIB-induced dietary habit, according to dietitian and psychological follow-up, as well as the good results in weight loss. The weight loss results are shown in Table 4.

The second group consisted of 12 patients (18.7%) who after preliminary weight loss, regained weight because of poor compliance, sweet eating or psychological problems. In this group, a malabsorptive operation was performed (biliopancreatic diversion in 8 patients and double bilio-intestinal bypass in 4 patients).<sup>9</sup>

The third group consisted of 34 patients with mean WL of 16.5 kg. Of these, two patients with the longest follow-up (2 years after BIB removal) are still maintaining EWL of 75%. At 4 months after BIB removal, 28 patients had a mean weight gain of 5.5 kg, but refused surgical treatment. At 1.5 years after BIB removal, 4 patients regained the lost weight and are awaiting operation.

The complications observed were: gastric ulcer (2), transient hypokalemia due to persistent vomiting in the first day after BIB insertion (1), spontaneous deflation (15, 9 with blue urine, 4 balloons expelled in the stools) (Table 5). One patient self-induced vomiting to enable increased food intake. In 4 cases, the balloon was covered with mycelial threads (*Candida albicans*), with no symptoms during treatment.

**Table 3.** BIB results

Period of treatment:	4.7 months (3-6)
64 Patients completed treatment	
Mean Weight	113.4 kg (70.1-217.0)
Mean BMI	41.2 (32.0-63.8)
Mean WL	14.3 kg (0-82)
Mean BMI Loss	5.3 (0-25.5)
Mean % EWL	23.5 (0-73.3)

**Table 4.** Results of BIB followed by LASGB vs LASGB only, at 12 months

BIB followed by LASGB			LASGB only	
Before Treatment	At BIB Removal	6 mos after LASGB	Before LASGB (no BIB-pre-op)	12 mos after with no BIB
Mean BW 133.5 kg	Mean BW 118.3 kg	Mean BW 91.6 kg	Mean BW 127.5 kg	Mean BW 104.1 kg
Mean BMI 46.1	Mean BMI 41.2	Mean BMI 36.2	Mean BMI 47.8	Mean BMI 39.8
Mean EW 62.3 kg	Mean % EWL 24.4	Mean %EWL 56.1	Mean EW 64.7 kg	Mean %EWL 41.6
	Mean WL 15.2 kg	Mean WL 26.7 kg		Mean WL 23.4 kg

At the end of the treatment, patients filled out a questionnaire to evaluate discomfort, sense of satiety, and patient satisfaction. A sense of satiety during the first half of treatment was present in 50% of patients. A sense of satiety that lasted the entire period of treatment was noted in 36% of patients. Interestingly, 14% of patients had absence of sensation of a foreign body from the beginning. The grade of acceptance was good in more than 80% of patients. Four patients (6.3%) complained of meteorism, 1 patient (1.6%) experienced vomiting and abdominal pain for 2 weeks after placement, and 59 patients (92.2%) experienced no discomfort after the first week of treatment.

## Discussion

Balloon placement was not difficult. The reintubation catheter for BIB removal is no longer available

**Table 5.** Complications of BIB

Vomiting > 2 weeks	4 (6.3%; BIB removal)
Transient hypokalemia	1 (1.4%)
Gastric ulcer	1 (1.4%; peptic ulcer)
	1 (1.4%; decubitus)
Deflations	15 (23.4%)
- urine methylene blue and endoscopic removal (9)	
- BIB deflation at time of removal (2)	
- BIB spontaneous deflation and expulsion with stools (4)	
- 7 out of 42 patients (16.6%) before the 4th month of treatment	
- 8 out of 27 patients (29.6%) after the 4th month of treatment	

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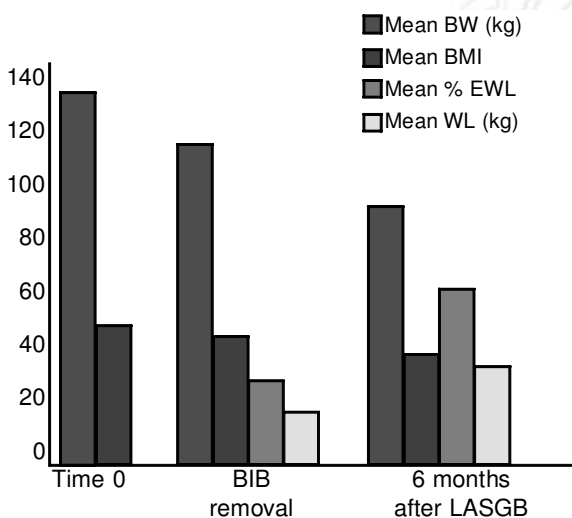
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because of its failure. We developed a modified endoscopic trocar to empty the balloon rapidly. Balloon replacement was done to continue the weight loss or, if weight loss has been inadequate, a second balloon of larger volume was inserted.

Our obese patients are followed closely and assessed by dietitians, with a detailed questionnaire. Patients who had good weight loss with the BIB were offered the LASGB,<sup>8,10</sup> and are maintaining good weight loss following the operation (Figure 1). If we relate this data at 12 months of follow-up, comparing the BIB followed by the LASGB to the LASGB-only patients, there is a sharp difference in the patient outcomes. When the BIB-test is positive (>10 kg weight loss), the patients appear to be very eligible for a restrictive surgical procedure. However, recent reports question the concept that patients with high sweets intake can expect less satisfactory results after gastric restrictive surgery.<sup>12</sup>

When the BIB test is negative, this frequently represents poor compliance with diet and exercise, inadequate balloon inflation, or rupture of the balloon. If the poor results in the BIB can be shown to be due to excess sweets, a malabsorption procedure can be considered. To validate this proposal, a prospective randomized study (BIB + LASGB vs LASGB alone) is underway at our center.



**Figure 1.** Variations of mean BW, mean BMI, mean %EWL and mean WL in 12 patients who underwent LASGB after preliminary BIB treatment.