

# Analysis of Safety and Efficacy of Intra-gastric Balloon in Extremely Obese Patients

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## Abstract

**Background** The implantation of an intra-gastric balloon constitutes a short-term effective non-surgical intervention to lose weight. The aim of this study was to evaluate retrospectively the clinical outcome and safety of gastric balloon therapy (GBT) in extremely obese patients.

**Methods** One hundred and nine super- and super-super-obese patients, 64 males and 45 females, mean age  $39.1 \pm 8.4$  years, mean body mass index (BMI)  $68.8 \pm 8.9$  kg/m<sup>2</sup>, who underwent GBT for weight loss, were studied retrospectively. GBT was assessed in massively obese patients concerning tolerance, weight loss, number of comorbidities and complications.

**Results** A significant reduction in patients' weight and BMI was evident after GBT. Regarding safety, no major complications occurred. Minor complications at balloon placement and removal occurred in one (0.9%) and three patients (2.8%) respectively. Mean duration of GBT was  $177.6 \pm 56.8$  days. After GBT, the mean weight loss was  $26.3 \pm 15.2$  kg ( $p < 0.001$ ) and the mean BMI reduction was  $8.7 \pm 5.1$  kg/m<sup>2</sup> ( $p < 0.001$ ) representing a mean percentage of excess BMI lost (%EBL) of  $19.7 \pm 10.2$ . The highest BMI loss was observed in patients with BMI  $> 80$  kg/m<sup>2</sup>. A noteworthy improvement of comorbidities in 56.8% of the

patients was also noted. Of the 109 patients, 69 received subsequent bariatric surgery. All the procedures were performed laparoscopically. Ten patients, with a mean BMI of  $68.6 \pm 10.6$  kg/m<sup>2</sup> after the removal of the first BIB, received a second BIB resulting in a non-significant weight and BMI loss of  $6.3 \pm 9.4$  kg and  $1.8 \pm 2.9$  kg/m<sup>2</sup>, respectively.

**Conclusions** Our study indicates the safety and efficacy of GBT in extremely obese patients particularly as a first step before a definitive anti-obesity operation. GBT appears to be a safe, tolerable, and potentially effective procedure for the initial treatment of morbid obesity.

**Keywords** Intra-gastric balloon · BIB · Super-obesity · Super-super-obesity · Bariatric surgery · Weight loss

## Introduction

As standards of living continue to rise, the global epidemic of overweight and obese patients is rapidly becoming a major public health problem in many parts of the world [1]. Treatment of obesity is a long-lasting and often frustrating procedure. However, even a modest reduction of weight results in significant reduction of comorbidities and related mortality [2, 3]. Treatment of morbidly obese patients is feasible and safe, when carried out in specialized medical institutions properly equipped to care for the obese in a multidisciplinary setting [4].

Among the different treatment options, the placement of an intra-gastric balloon constitutes a short-term, effective, non-surgical intervention to lose weight and is considered to be a restrictive procedure that is completely reversible and repeatable at any time [5]. The BioEnterics® Intra-gastric Balloon (BIB; BioEnterics Corporation, California,

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USA) complies with the requirements for an “ideal gastric balloon” and it is designed to remain in the stomach for a period of 6 months [6]. Balloon placement and removal is performed under endoscopic control. The BIB is designed to mechanically provide a sensation of satiety, resulting in decreased food consumption [7]. It is considered to be a method of facilitating the implementation of new dietary and behavioral habits.

GBT cannot be used as an alternative to surgery for individuals with morbid obesity, since several studies have shown that weight loss diminishes gradually after balloon removal [8–10]. GBT is indicated mainly for obese patients, who do not fulfill the criteria for bariatric surgery and also for super-obese patients (BMI > 50 kg/m<sup>2</sup>), with the aim to achieve a moderate weight loss, preoperatively, and thus to reduce anesthesia risks and surgical complications. BIB may also serve as a smooth introduction to bariatric surgery for morbidly obese patients, who although fit for bariatric surgery, hesitate to proceed to surgical anti-obesity treatment [11]. This retrospective study evaluates safety, tolerance and efficacy of GBT in super-obese (BMI > 50 kg/m<sup>2</sup>) and super-super-obese (BMI > 60 kg/m<sup>2</sup>) patients.

**Patients and Methods**

We queried our bariatric database from February 2002 to May 2008, capturing all extremely obese patients, who had received GBT. A total of 109 patients were reviewed. The study group consisted of 45 females and 64 males with mean age 39.1±8.4 years (range 17–57). The mean body weight and BMI were 211.0±36.9 kg (range 118.0–310.0) and 68.8±8.9 kg/m<sup>2</sup> (range 50.1–95.7), respectively. Fifteen patients (13.8%) had a BMI (kg/m<sup>2</sup>) of 50–60, 51 patients (46.8%) had a BMI of 60–70, 29 patients (26.6%) had a BMI of 70–80 and 14 patients (12.8%) had a BMI > 80 (Table 1). All patients had been obese for at least 5 years and had failed to achieve weight loss on an adequate weight control program for more than 3 years. All patients were screened for major endocrine disorders.

Patients received GBT either as a preoperative preparation to reduce severe comorbidities and surgical risks (PP subgroup) or as an alternative, upon refusal conventional surgical treatment due to phobia of possible complications and/or mortality (AO subgroup). PP subgroup consisted of 74 patients with mean body weight and BMI of 207.6±33.0 kg (range 118–305) and 68.2±8.1 kg/m<sup>2</sup> (range 53.5–94.1), respectively. The 35 patients of the AO subgroup had a mean body weight and BMI of 216.3±42.9 kg (range 129.9–310.0) and 69.6±10.1 kg/m<sup>2</sup> (range 50.1–95.7), respectively. Between the two subgroups, no significant differences concerning age, sex, and baseline body weight and BMI, were noted. Exclusion criteria for GBT were: (1)

**Table 1** Subgroup analysis of patients’ demographics, weight loss, and BMI change

BMI group	50–60	60–70	70–80	>80
No. of patients	15	51	29	14
Age (years)	41.6±9.6 (22–57)	39.6±8.2 (17–56)	37.7±8.2 (21–54)	37.9±8.6 (25–54)
Female/male	4/11	21/30	15/14	5/9
BIB filling volume (mL)	694±42 (600–750)	686±24 (650–700)	664±63 (500–700)	688±23 (650–700)
GBT duration (days)	180±44.4 (46–223)	184±60.8 (1–270)	188±48.1 (116–366)	179±73.6 (28–333)
Pre-treatment weight (kg)	176.5±32.1 (128.7–221)	200.8±28.7 (118–248.5)	223.6±27.6 (161.2–278)	258.0±29.7 (210–310)
Pre-treatment BMI (kg/m <sup>2</sup> )	56.7±2.5 (50.1–59.9)	65.0±2.9 (60.2–69.7)	73.8±2.7 (70–79.9)	85.9±5.1 (80.4–95.7)
Post-treatment weight (kg)	158.6±32.7 (107–200)	173.3±27.0** (118–226)	197.8±30.4* (130–238)	231.6±36.2 (178–294)
Post-treatment BMI (kg/m <sup>2</sup> )	51.3±3.0** (46.7–57.2)	56.9±5.4** (42.4–67.3)	64.0±6.1** (45.5–75.4)	77.2±8.3* (60.2–87.4)
%EBL	17.1±8.6 (6.4–31.4)	21.2±9.3 (0–52.7)	20.0±12.5 (0–57.7)	15.8±10.1 (0–36.6)

Values expressed as mean±SD (range)

\* p<0.05; \*\* p<0.001

age <16 and >65 years; (2) history of neoplasia; (3) pregnancy; (4) present alcohol or drug abuse; (5) use of anticoagulants or steroids; (6) previous bariatric or gastrointestinal surgery; (7) gastric or esophageal lesions revealed by endoscopy including: esophageal varices, neoplastic lesions, large hiatal hernia (>5 cm), grade III or IV esophagitis, duodenal or gastric ulcer lesions considered to be of high risk for bleeding. All patients had given their written informed consent prior to clinical procedures.

BIB insertion was performed, after diagnostic endoscopy, including a test for *Helicobacter pylori*, under conscious sedation (midazolam), with the patient in lateral decubitus position. The balloon was placed in the stomach and inflated under direct vision with normal saline stained with methylene blue. The filling volume was adjusted in accordance with the size of the accommodating stomach, which was estimated during endoscopy, aiming at achieving maximum restriction. In 77 patients (70.6%), a filling volume of 700 ml was utilized. Once able to tolerate oral fluids, patients were discharged from the hospital with a regular proton pump inhibitor and, if required, spasmolytic and anti-emetic medication. The patients were advised to observe a fully liquid diet for the first 3 weeks, progress to half-solid food during the fourth week and then continue with regular meals under specific dietary instructions. Balloon extraction was routinely planned after 6 months. However, removal could be performed before the theoretical date in case of intolerance or complications. Endoscopy was performed under intravenous conscious sedation and the BIB was removed. Follow-up regarding tolerance and efficacy evaluation as well as patient's eating protocol and quality of life questionnaire assessment were performed at 1, 3, and 6 months after balloon insertion. The questionnaire of the bariatric quality of life index, previously developed by our institution, as well as, the BAROS questionnaire was used [12]. Patients were evaluated by a multidisciplinary team consisting of a bariatric surgeon, an internist, a dietitian, and a physiotherapist. At every visit, the position of the balloon was assessed with ultrasonography.

The results are presented as mean±standard deviation for numerical variables and absolute numbers (percentage) for categorical variables. Paired Student's *t* test was used for comparisons between super-obese patients, before and after GBT. Mann–Whitney *U* test was used for comparisons between groups. Pearson's analysis and multivariate regression analysis were performed to determine any correlation between weight loss, BMI changes, balloon volume, duration of treatment, number of complications and the other continuous variables. In all statistical analyses, a *p* value<0.05 was considered to be significant. The percentage of excess BMI lost (%EBL) was calculated using the formula  $\%EBL = [(preoperative\ BMI - current\ BMI) / (preoperative\ BMI - 25)] \times 100$  [13].

## Results

GBT was assessed in massively obese patients concerning tolerance, weight loss, number of comorbidities, and complications.

### Balloon Placement and Removal

Structural abnormalities of the upper gastrointestinal tract, previous to BIB positioning, were observed in 32 patients (29.4%): 13 cases of grade I esophagitis, three cases of grade II esophagitis, 20 cases of small hiatal hernia of ≤3 cm, three cases of hiatal hernia of ≤5 cm, two cases of gaping cardia, and 20 cases of antrum gastritis. *H. pylori* infection was detected in two cases. The presence of *H. pylori* infection was not considered as a contraindication for GBT. Both patients, a week after BIB insertion, received anti-*H. pylori* eradication therapy for 7 days. There were no complications during BIB placement except in one case, where the patient became agitated during the procedure and pulled at the endoscope, resulting in leakage of the balloon. Therefore, the balloon had to be changed and a new one was placed in a second attempt. During the first week after BIB insertion, almost 90% of the patients reported nausea, abdominal discomfort, and/or episodes of vomiting. The symptoms disappeared or lessened remarkably after the first week in all but ten cases (9.2%). Six patients required prolonged use of anti-emetic or spasmolytic medication for up to 3 weeks but without necessitating the early removal of the balloon.

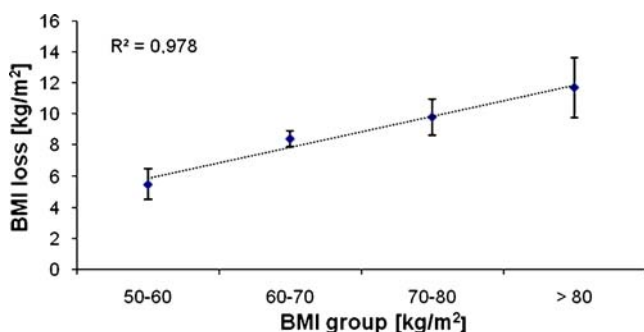
The mean period of BIB treatment was 177.6±56.8 days (range 1–366). In 25 patients (22.9%), GBT lasted for more than 200 days (mean duration 232.8±40 days) due to patients' unwillingness to keep to the scheduled removal of the balloon. Two patients, for fear of regaining weight, denied balloon extraction repeatedly. Eventually, the balloon was removed after 333 and 366 days, respectively. Early balloon removal was performed in five cases (4.6%), because of balloon intolerance; within the first week in two patients and in the rest of them between the second week and the second month. All adverse effects resolved after balloon removal. The endoscopic deflation and removal of the balloon was uneventful in most of the patients. Problems were encountered in three cases (2.8%): in one patient, removal could not be performed due to a filled stomach despite a mandatory 12-h starvation prior to balloon extraction. Another patient exhibited signs of respiratory depression and was managed with benzodiazepine antagonist and oxygen administration. In both cases, the extraction was performed in a second session on the next day without complications. The third patient did not tolerate the removal procedure even with high doses of sedation. Thus, the balloon was removed in unconscious

sedation with endotracheal intubation. Endoscopy at BIB extraction revealed new or worsened gastrointestinal lesions in 11 patients (10.1%) including one case of progression of esophagitis (I → II), one case of progression of gastritis, two cases of enlarged axial hernia, three new cases of antrum gastritis, three new cases of small axial hernia, and two new cases of gaping cardia. No correlation between balloon volume or duration of treatment and the number of gastric side effects was noted.

No mortality occurred in our cohort. Furthermore, no major complication such as balloon deflation, intestinal obstruction, or gastric perforation occurred in our patients.

### Weight Loss

A significant loss of  $26.3 \pm 15.2$  kg (range 0–80.0) in mean body weight of the patients at the time of balloon removal was noted ( $p < 0.001$ ). The overall mean BMI reduction of  $8.7 \pm 5.1$  kg/m<sup>2</sup> (range 0–28) was also significant ( $p < 0.001$ ). This represents a mean %EBL of  $19.7 \pm 10.2$  (range 0–57.7). However, 16 patients (14.7%) lost less than 10% of their excess BMI, while four of these patients did not lose weight at all. Subgroup analysis of weight loss and BMI change is shown in Table 1. The most substantial BMI loss was observed in the most massive obese patients (Fig. 1). There was no correlation between balloon volume and body weight or BMI loss as well as between pre-treatment BMI or body weight and %EBL. %EBL was proven independent of patients' age, sex, and obesity-related comorbidities (diabetes mellitus, arterial hypertension, sleep apnea, and mobility disorders) in a multivariate analysis. Furthermore, there was no significant difference in the efficacy of GBT comparing the patients, who had the balloon in place for less than 200 days with those who had a prolonged GBT (>200 days). Additionally, no significant difference concerning weight loss, BMI change, and %EBL was noted between the PP and AO subgroups (Table 2). From the PP subgroup, 69 patients received subsequent surgery:



**Fig. 1** Mean BMI loss after GBT: the trend line, the correlation coefficient and the standard error of the mean (SEM) for each group are shown

Roux-en-Y gastric bypass ( $n=30$ ), sleeve gastrectomy ( $n=20$ ), biliopancreatic diversion ( $n=16$ ) and adjustable gastric band ( $n=3$ ) whereas five did not. Of these five patients, three ( $\text{BMI} > 70$  kg/m<sup>2</sup>) did not lose any weight after 6 months and in combination with their comorbidities, they were considered surgically untreatable. The other two surprisingly refused surgical treatment. Interestingly only 35% (5/14) of the patients with initial BMI  $> 80$  kg/m<sup>2</sup> received definitive surgical treatment, whereas more than 60% of the remainder patients were operated after BIB removal (Fig. 2). All the procedures were performed laparoscopically.

Ten patients with a mean BMI of  $68.6 \pm 10.6$  kg/m<sup>2</sup> after the removal of the first BIB received a second BIB due to insufficient weight loss or long waiting list until definitive surgical treatment. The mean time interval between the first balloon removal and the second balloon implantation was  $40.9 \pm 62.1$  days. During this period one patient lost additional weight, three patients kept their weight, and six patients regained weight. In the patients, who regained weight, the balloon-free period was always longer than 20 days. The overall mean body weight and mean BMI loss, without reaching a statistically significant level, after the second GBT, were  $6.3 \pm 9.4$  kg and  $1.8 \pm 2.9$  kg/m<sup>2</sup> respectively. The mean %EBL was  $5.5 \pm 6.9$ . One patient had an EBL of more than 20%, four patients had an EBL of 5–10% and three patients did not lose weight at all. Of the patients treated with a second BIB four patients received subsequent surgery: Roux-en-Y gastric bypass, biliopancreatic diversion (one patient each), and sleeve gastrectomy (two patients).

### Comorbidities

In more than 95% of the patients, one or more obesity-related comorbidities were present: 74 patients (67.8%) with arterial hypertension (elevated blood pressure with systolic blood pressure of 140 mmHg or higher or diastolic blood pressure of 90 mmHg or higher or usage of antihypertensive medication), 61 patients (55.9%) with musculoskeletal system disorders (degenerative joint disease of the spine or lower extremities related to obesity), 53 patients (48.6%) with type 2 diabetes mellitus (previously diagnosed and treated with insulin or hypoglycemic agents or combination of both) and 39 patients (35.7%) with sleep apnea (previously diagnosed based on polysomnography or because of reported frequent loud intermittent snoring, periods of apnea during sleep, and excessive daytime drowsiness). Additionally, many patients suffered from obesity-related skin lesions (21.1%), depression (16.5%) or COPD (16.5%). Other comorbidities in smaller numbers were heart failure, coronary heart disease and stress urinary incontinence. Obesity-related comorbidities after GBT remained unchanged in 47 patients (43.1%),

**Table 2** Comparison of post-treatment values between PP & AO subgroups

	Preoperative preparation subgroup (PP) (n=74)	Anti-obesity subgroup (AO) (n=35)	p value
Post-treatment weight (kg)	182.0±31.6 (107–271)	180.4±40.7 (109–294)	0.934
Post-treatment BMI (kg/m <sup>2</sup> )	59.4±8.1 (42.4–87.1)	59.7±10.0 (46.7–87.4)	0.862
%EBL	20.4±9.6 (0–57.7)	20.9±9.1 (0–45.3)	0.798

Values expressed as mean±SD (range)

whereas in 62 patients (56.8%) at least one related disorder was improved. Improvement with hypertension was determined by a decrease in the baseline value (the mean blood pressure reading was calculated from three measurements using an electronic sphygmomanometer over a period of 30 min of rest) or in the number and dosage of medications. Musculoskeletal system disorders amelioration was concluded by the improvement in the patient's mobility or the decreased need of pain-relief medications. Diabetes improvement was evaluated in terms of better glucose control and a decrease in the number and the dosage of medications (as reported by the attending or the primary care physician). Sleep apnea improvement was based on the decreased need for continuous positive airway pressure or the reported reduced daytime sleepiness and better quality of sleep. The majority of the patients (78%) described an overall improvement in the quality of life.

## Discussion

This is one of the largest reported cohorts of extremely obese patients, who underwent BIB insertion for the treatment of obesity. The results of this retrospective study, despite its limitations, confirm that BIB insertion appears to be a safe, tolerable, and potentially effective procedure for the initial treatment of morbid obesity.

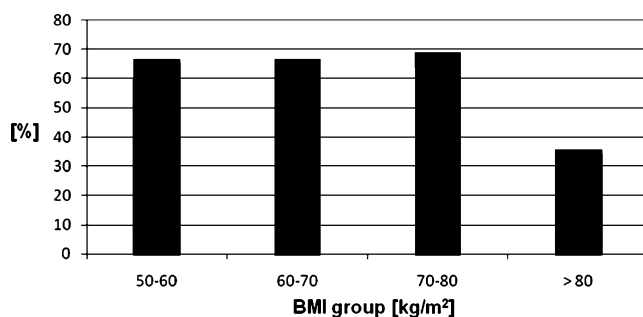
GBT before a surgical procedure, in such a group of patients, may reduce operative risks, regardless of whether the surgery is bariatric or not. It has been shown that a

modest preoperative weight loss of 10% to 20% can reduce the complications of surgery [14]. Preoperative weight loss is probably the most important method for reducing surgical risk in extremely obese patients [15, 16]. Conversions to open surgery, in super-obese patients, are more frequently related to technical difficulties, due to bad exposure and undersized operating field, caused by the excessive intra-abdominal fat deposition and ponderous fatty livers [8, 17]. The BIB-induced weight loss is associated with a significant reduction in liver volume [18]. Our results support previous studies, which have demonstrated that even a partial weight loss improves the surgical risk and lessens the technical difficulties of a laparoscopic approach to massively obese patients [17, 18]. After GBT, 69 patients received laparoscopic bariatric surgery successfully; no conversion to open surgery was necessary.

There were minimal complications associated with balloon placement and removal (0.9% and 2.8% respectively). In agreement with our results, the latest Cochrane systematic review over intragastric balloon for obesity confirmed the safety of the GBT [19]. However, after BIB extraction, we noticed a moderate increase in endoscopic lesions probably due to prolonged mechanical effect of the balloon on the gastric mucosa and the gastroesophageal junction. This finding is concordant with the recent report of Rossi et al., who found an increased incidence of erosive esophagitis after BIB insertion [20].

The prolonged GBT (>200 days) did not cause an increased number of gastrointestinal side effects but also did not lead to significant different BMI change or %EBL comparing to GBT lasting less than 200 days. Previous report, of a series of 69 obese patients who underwent GBT, has demonstrated that the main weight reduction is accomplished in the first 3 months [21]. Additionally, in a recent randomized trial of BIB placement versus sham in a population of 22 morbidly obese patients, BIB-induced satiety was completely lost after 4 months of treatment [7].

All patients had been clearly instructed, regarding the necessity of a subsequent bariatric operation, to increase the eventually obtained weight loss. Nevertheless, 40 of them, after BIB removal, did not receive surgery. Of these 40 patients, 35 did not proceed to a permanent surgical solution due to perseverance of possible surgical complications (AO



**Fig. 2** Percentage of patients receiving subsequent surgery

subgroup) and two due to a compromise with their short-term improvement of comorbidities.

Compared with surgical treatment, GBT can be attractive to patients as it is less invasive than surgery. On the other hand, BIB is a temporary anti-obesity treatment, which induces only a short-term weight loss [22, 23]. The mean % EBL in our series was  $19.7 \pm 10.2$ . Obviously, this outcome is not comparable to results obtained from bariatric surgery, but noteworthy improvement of comorbidities occurred. Spyropoulos et al. recently reported also a significant improvement in super-obese patient comorbidity status, after a prospective evaluation of 26 patients treated with BIB [24].

After balloon removal, surgery has to follow immediately. The repeated insertion in the 10 patients of our series did not produce a significant result. Despite this small number of patients, we noted that body weight increases markedly after the removal of the BIB. Thus, at least from our study, GBT with a second BIB seems to be ineffective. The eating disorders are still present, the capacity of the stomach is again increased, and the patients are able to continue their food intake without limitation. Angrisani et al. observed the almost total regain of excess weight, 1 year after BIB removal, in 82 patients, who had refused any other kind of treatment [25].

The optimal surgical treatment for super-obese patients has been a challenge, and is often debated among bariatric surgeons. Furthermore, there is no consensus, with regards to specific criteria allowing to select patients either for restrictive or malabsorptive procedures, in order to improve the final outcome. BIB may be used as an indirect “preoperative test” to detect compliant patients, who may be suitable for a restrictive surgical procedure. If patients are unable to reduce their body weight a procedure such as a gastric bypass or biliopancreatic diversion may be more appropriate [8, 23, 26, 27]. The selection of the bariatric procedure in our cohort was based on patient’s BMI, gender, obesity-related comorbidities, eating habits, and GBT efficacy. Compliant patients to GBT were defined those with loss of  $\geq 10\%$  of pre-treatment body weight. In patients with failure of GBT and post-treatment BMI  $> 60 \text{ kg/m}^2$ , laparoscopic sleeve gastrectomy was offered as a first-step procedure. A thorough discussion over possible surgical options in conjunction with the individual characteristics of every patient, the postoperative quality of life, the expected weight loss, and the possible complications was carried out in every case.

In conclusion, GBT represents a useful but temporary way of achieving a vital BMI improvement in extremely obese patients, particularly as a first step before a definitive anti-obesity operation. BIB, when applied in specialized institutions with long-standing experience in the treatment of obesity, can be safely placed even in these high-risk obese patients.

**Conflict of interest** The authors disclose no commercial interest in the subject of study.

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