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ORIGINAL CONTRIBUTIONS

Five Percent Weight Lost in the First Month of Intragastric Balloon Treatment May Be a Predictor for Long-Term Weight Maintenance

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Abstract
Background Most of the weight loss with the BioEnterics intragastric balloon (BIB) has occurred during the first 3–4 months. This study aimed to evaluate the effect of initial weight loss on long-term weight maintenance.
Methods From 2008 to 2011, 50 patients who had mean body mass index (BMI) of 44.7±12.4 kg/m^2 underwent BIB therapy for 6 months. All patients were given a diet of 1,100 kcal/day. Weight loss parameters [absolute weight loss, BMI loss, percentage of body weight loss (BWL%), and percentage of excess BMI loss] were recorded at the baseline, 1 month, 6 months (time of BIB removal), 12 months, and 18 months from the baseline. Successful weight loss was defined as ≥10 % weight loss after 6, 12, and 18 months.
Results Twenty-seven patients (54 %) achieved a percentage of BWL≥10 at the time of removal. Eighteen (36 %) and 12 (24 %) patients were able to maintain weight loss of 10 % at 12 and 18 months. Percentage of BWL after 1 month was positively correlated with BWL% after 6, 12, and 18 months (r=0.77, 0.65, and 0.62, p<0.001, respectively). Twenty-four patients who lost 5 % of the BWL after 1 month of treatment succeeded in maintaining a lasting percentage of BWL ≥10 after the BIB removal: more precisely, this cutoff point was achieved in 96 % at the time of removal and in 71 %, 50 % at 12 months, and 18 months of follow-up.
Conclusions Five percent BWL after 1 month of treatment may be a predictor for long-term weight maintenance.

Keywords Obesity · Intragastric balloon · Body mass index · Initial weight loss · Follow-up

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Introduction

Obesity is a major cause of morbidity and mortality worldwide [1]. To reduce the incidence of morbidities related to obesity, the World Health Organization recommended that a decrease of 5 to 15 % of body weight should be maintained throughout time [2–4]. In this context, intragastric balloon emerges as an interesting therapeutic tool for this group of patients to manage weight loss above 10 % of initial body weight.

Since the 1980s, the intragastric balloon has been used as an artificial bezoar, to induce satiety by decreasing the capacity of the gastric reservoir, thereby reducing food intake and leading to weight loss in obese subjects [5]. However, some studies state that most of the weight loss with the BioEnterics® Intragastric Balloon (BIB) occurred during the first 3–4 months [6, 7], and that most of patients regained a significant part of the weight lost after BIB removal [8, 9]. The aim of this study was to evaluate the effect of initial weight loss on long-term weight maintenance.

Materials and Methods

Between June 2008 and June 2011, 50 obese patients (five of them were superobese) who selected intragastric balloons

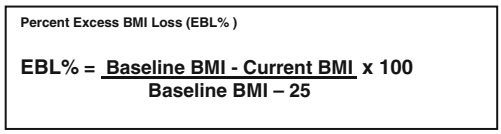

Fig. 1 Formula used for excess body mass index (BMI) calculation. A BMI of 25 kg/m^2 was estimated to be the upper limit of normal

(BIB® system) for weight loss were included in the study. Our patients were 17 men and 33 women, ranging from 16 to 60 years of age (mean age 37.9±10.6 years). Average weight of the group was 127.6±34.6 kg, and average body mass index (BMI) was 44.7±12.4 kg/m^2. Written informed consent was obtained from all subjects.

Criteria for selection were obesity class 2 (BMI≥35 kg/m^2), morbid obesity (BMI≥40 kg/m^2), and failure to achieve weight loss with an adequate weight control program for 6 months. In superobese patients (BMI ≥50 kg/m^2), intragastric balloon was placed as a preparation for bariatric surgery. Additionally, BMI 30–35-kg/m^2 patients with severe obesity-related diseases were included on rare occasions. Contraindications were alcoholism or drug addiction and the presence of gastrointestinal tract lesions such as inflammatory or cancerous diseases, peptic ulcer or esophageal/fundus varices, and a large hiatus hernia (>5 cm in diameter).

Intragastric balloon was placed under intravenous propofol sedation in the lateral decubitus position. It was inserted into the gastric fundus and then filled under endoscopic control with 600 ml of saline stained with methylene blue. Patients were then hospitalized for observation. When the patients could take a fluid diet, they were discharged with drug therapy of lansoprazole and butylscopolamine. The patients remained on the fluid diet after the procedure and a 1,100-kcal/day diet was initiated after 1 week. At the end of the 6-month period, the gastric balloon was removed endoscopically. Then, patients were followed up on an outpatient basis by the dietician every 3 months for a period of 12 months.

Weight loss parameters [in kilogram, BMI, percentage of body weight loss (BWL%), and body mass index loss percentage (EBL%)] were recorded at baseline, 1 month, 6 months (time of BIB removal), 12 months, and 18 months from the baseline. Successful weight loss was defined as ≥10 % weight loss after 6 months (end of treatment success), 12 months, and 18 months. Excess EBL% was calculated as shown in Fig. 1 [10].

Descriptive data were expressed as mean±SD. Baseline and outcome variables were compared with paired T test. An independent samples T test was used for different groups. To evaluate the association of percentage of BWL after 1 month (initial BWL%) with the BWL% after 6, 12, and 18 months, "Pearson correlation matrix" was employed. A bilateral α value <0.05 was considered for significance. The computer software used for analysis was SPSS 18.0.

Results

Following insertion of the balloon, almost all patients experienced nausea, cramps, and vomiting lasting 1–5 days. BIB produced no other notable side effects. In all patients, balloon removal was performed without any difficulty. All patients completed the 6-month period with the balloon in place and the additional 12 months after its removal. Also, superobese patients were followed up until the end of the study because they refused bariatric surgery in the first 12 months after BIB removal. There were no complications related to endoscopic balloon placement or removal.

Initial mean BMI was 44.7±12.4 kg/m^2. At the end of 6 months with balloon, the mean BMI was 40.3±10.7 kg/m^2 (p<0.001), mean BWL% was 9.3±8.8, and mean EBL% was 24.0±23.4. End of treatment success (ETS) was reached in 27 out of 50 patients (54 %). The mean BMI was 41.4±10.8 and 42.1±11.1 kg/m^2 at 12 and 18 months, respectively (p<0.001).

Table 1 Weight-linked parameters in all patients

	Baseline	1 month	6 months[a]	12 months	18 months
Weight (kg) (min–max)	127.6±34.6 (88–256)	120.7±30.6 (85–230)	114.9±29.5 (76–216)	118.1±29.5 (72–220)	120±30.2 (75–225)
Weight loss (kg) (min–max)		7±5.7 (0–28)	12.5±13 (−5 to 45)	9.5±13.8 (−6 to 50)	7.6±11.5 (−4 to 40)
BWL% (min–max)		5.2±3.2 (0–12)	9.3±8.8 (−4 to 28)	6.8±9.5 (−4.4 to 31.7)	5.4±8 (−3 to 28)
Number (%) of patients with BWL%≥10		5 (10 %)	27 (54 %)	18 (36 %)	12 (24 %)
BMI (kg/m^2) (min–max)	44.7±12.4 (32.3–97.5)	42.3±10.9 (31.2–86.9)	40.3±10.7 (26.6 to 82.3)	41.4±10.8 (25.2–83.8)	42.1±11.1 (26.3–85.7)
BMI loss (kg/m^2) (min–max)		2.4±2 (0–10.6)	4.4±4.5 (−1.8 to 15.2)	3.3±4.6 (−1.9 to 14.7)	2.6±3.9 (−1.3 to 12.2)
EBL% (min–max)		12.7±7.9 (0–33.3)	24.0±23.4 (−9.5 to 82.8)	16.7±25.1 (−10.9 to 97.8)	13.3±21.5 (−7.5 to 86)

BMI body mass index, *BWL* body weight loss, *EBL* excess BMI loss

[a] BIB removal

Table 2 Pearson correlation coefficients between initial BMI, initial BWL%, and follow-up BWL%

	Follow-up BWL%, *r* (*p*)		
	After 6 months	After 12 months	After 18 months
Initial BMI	0.18 (0.22)	0.21 (0.14)	0.19 (0.19)
Initial BWL% (BWL% after 1 month)	0.77* (0.000)	0.65* (0.000)	0.62* (0.000)

r Pearson correlation coefficient, *BMI* body mass index, *BWL* body weight loss

*$p<0.001$

At 12 and 18 months, 18 (36 %) and 12 (24 %) patients continued to have percent BWL of ≥10, respectively. Although all of five superobese patients had achieved end of treatment success, only two were able to maintain weight loss of 10 % at the end of the follow-up period. Weight-linked parameters in patients were shown in Table 1.

Percentage of initial BWL was positively correlated with the BWL% after 6, 12, and 18 months. Initial BMI was not related to percentage of BWL (Table 2).

The association of percentage of initial BWL with the BWL% at the completion of the study is shown in Fig. 2. The patients with higher initial BWL% had the bigger chance of successful weight loss at the end of the 12-month follow-up period after BIB removal. So, patients who achieved a percentage of BWL≥5 after 1 month with balloon had higher successful weight loss at the end of follow-up period.

Twenty-four patients (48 %) achieved a percentage of BWL≥5 (group A) after 1 month with balloon. ETS was reached in 23 out of 24 patients (95.8 %) and similarly 17 (70.8 %) and 12 (50 %) patients continued to have percent BWL of ≥10 at 12 and 18 months, respectively, in this group. None of the patients with initial BWL% of <5 (group B) were able to maintain weight loss of 10 % at the completion of the study. Patient characteristics and weight-linked parameters of group A losing ≥5 % and group B losing <5 % of initial weight after 1 month of balloon treatment were shown in Table 3.

Discussion

Intragastric balloon treatment for morbid obesity is temporary, so weight maintenance after balloon removal is very important.

The review by Dumonceau et al. (30 studies and 4,877 patients) [11] with the BIB achieved a mean weight loss of 17.8 kg (4–9 kg/m^2). In another meta-analysis from Spain, the authors reviewed the literature systematically and pooled 15 articles and 3,608 patients to estimate the effectiveness and safety of BIBs [12]. They concluded that use of the BIB, within a multidisciplinary weight management program, is a short-term effective treatment for losing weight, but it is not yet possible to verify its capacity to maintain the weight loss over a long period of time [12]. Although there is great variability between subjects and studies, significant factors

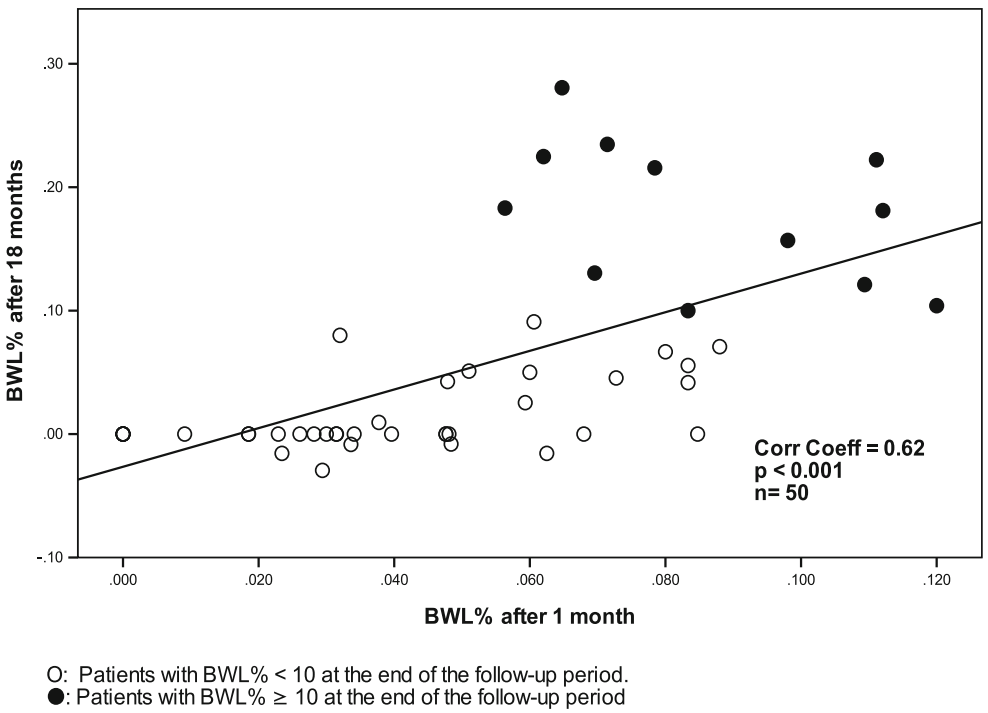

Fig. 2 The association of percentage of initial BWL with the BWL% after 18 months (*BWL* body weight loss)

Table 3 Patient characteristics and weight-linked parameters of all patients, group A losing ≥5 %, and group B losing <5 % of initial weight after 1 month of balloon treatment

	Group A	Group B	*p* value[a]
No. of patients	24 (8 M/16 F) (4 of them are superobese)	26 (9 M/17 F) (1 of them was superobese)	
Age (years) (min–max)	35.5±11 (16–60)	40.1±9.9 (19–58)	0.126
Initial weight (BWL, kg) (min–max)	136.2±44 (98–256)	119.7±20.8 (88–188)	0.094
Initial BMI (kg/m^2) (min–max)	48±15.3 (34.3–97.5)	41.7±8 (32.3–74.4)	0.069
EBL% after 6 months (min–max)	41±17.8 (13–82.8)	8.2±15.6 (−9.5 to 48)	<0.001
EBL**%** after 12 months (min–max)	33.6±26.6 (−9.6 to 97.8)	1.1±7.5 (−10.9 to 29.3)	<0.001
EBL**%** after 18 months (min–max)	26.8±24.1 (−4.4 to 86)	0.7±5.3 (−7.5 to 24.4)	<0.001
%BWL after 6 months (min–max)	16.7±5.5 (5–28)	2.5±4.9 (−4 to 16)	<0.001
%BWL after 12 months (min–max)	13.9±9.2 (−3.1 to 31.7)	0.3±2.9 (−4.4 to 9.6)	<0.001
%BWL after 18 months (min–max)	11±8.5 (−2 to 28)	0.3±1.9 (−3 to 8)	<0.001
Number (%) of patients with ETS	23 (95.8 %)	4 (15.4 %)	<0.001
Number (%) of patients with BWL%≥10 at 12 months	17 (70.8 %)	1 (3.8 %)	<0.001
Number (%) of patients with BWL%≥10 at 18 months	12 (50 %) (2 of them are superobese)	0 (0 %)	<0.001

M male, *F* female, *BMI* body mass index, *BWL* body weight loss, *EBL* excess BMI loss, *ETS* end of treatment success

[a] Independent samples *T* test was used for groups A and B

related to greater weight loss include initial BMI, patient's degree of motivation, and adherence to the dietitian's program control [13, 14].

Although there are no evolutionary studies that assess long-term effectiveness, there is experience that a nonsignificant percentage of these patients can recover partial or total weight loss after the balloon is removed [11]. However, in other patients, these results are encouraging. Thus, Carbonelli et al. [15] describe that after extraction of the balloon, the majority of patients have achieved weight loss and some continue to lose weight. Studies realized 1 year post-removal are as follows: Escudero-Sanchís et al. [16] noted that 48 % of patients maintained or continued losing weight, Mathus-Vliegen and Tytgart [17] noted that 55 % of patients had a sustained weight loss greater than 10 %, and Herve et al. [18] maintained the EWL% of 26.8 %. Recently, Kotzampassi et al. demonstrated that percentage of patients having EWL% of >20 % were 83 % at time of balloon removal, 53 and 27 % at 12 and 24 months, respectively, and 23 % at the 60-month follow-up period of 195 obese patients [7]. Published outcomes of weight loss 1 year after the balloon removal are shown in Table 4. The weight regained after BIB® removal varies between one third and a half of the weight lost with the BIB®. Our results are similar.

After a 12-month follow-up, our patients showed a BWL of 7.6 kg and BMI reduced by 2.6 kg/m^2, similar to other studies with the BIB (Table 4). There was only one study that has investigated the long-term success rate in Turkish population [8]. Saruç et al. demonstrated that after the removal of BioEnterics intragastric balloon, almost all patients had returned to their initial weights in Turkey. They found that although 22 out of 24 patients (91.6 %) had achieved end of treatment success (EWL% of >25 %), only two patients were able to maintain excess weight loss of 25 % at the end of

Table 4 Published outcomes of weight loss 1 year after the balloon removal

Author (year)	Reference	Weight loss	
		At time of balloon removal	After 1-year follow-up
Mathus-Vliegen (2005)[a]	[17]	21.3 kg	12.6 kg
Herve (2005)	[18]	12.0 kg	8.6 kg
Doldi (2004)	[19]	15.5 kg (female)	−1.3 kg (14 months)
Melissas (2006)[b]	[20]	41.6 % EWL[c]	23.9 % EWL (6–30 months)
Angrisani (2006)	[21]	32.9 % EWL	27.1 % EWL
Ganesh (2007)	[1]	4.4 kg	1.5 kg (6–12 months)
Ohta (2009)	[22]	12 kg	6.4 kg
Present study		12.5 kg	7.6 kg (12 months)

[a] One-year balloon treatment

[b] Data in the successful group were used

[c] Percent excess weight loss

the 6-month follow-up period, resulting in a long-term success rate of 8.3 % [8].

Although intragastric balloon has been used as an artificial bezoar, to induce satiety by decreasing the capacity of the gastric reservoir, the main part of weight loss with the BIB has occurred in the first few months. So, Al-Momen et al. [6] denote that patients with the intragastric balloon achieved most of the weight loss in the first few months. Totte et al. [23] also suppose that this effect is associated with the gastric adaptation to the balloon. Their patients demonstrated 50.8 % EWL after 6 months, of which 48.6 % EWL occurred in the first 3 months. And finally, Kotzampassi et al. [7] demonstrated that those who lost 80 % of the total weight lost during the first 3 months of treatment succeeded in maintaining a lasting percentage of EWL of >20 after the BIB removal. But there are no studies demonstrating the relationship between initial percentage of BWL and maintaining weight loss.

In our study, none of the patients with initial BWL% of <5 were able to maintain weight loss of 10 % at the end of the 12-month follow-up period after BIB removal. But successful weight loss was obtained in 96, 71, and 50 % at 6, 12, and 18 month, respectively, in patients losing ≥5 % of their initial weight after 1 month of balloon treatment. Thus, we are suggesting that the patients who lost at least 5 % of the BWL after 1 month of treatment can achieve a significant weight loss and maintain it 1 year after BIB removal. Otherwise, BIB treatment might be used as a bridge to an immediate definitive bariatric operation or whenever a patient regains weight.

Conclusion

In conclusion, 5 % weight loss after 1 month of balloon treatment may be a predictor for long-term weight maintenance. So, maintaining weight loss is not expected in the patients who lose <5 % of their initial weight after 1 month of balloon treatment.

Conflict of interest Dr. Umit Bilge Dogan, Dr. Yuksel Gumurdulu, Dr. Mustafa Salih Akin, and Dr. Serkan Yalaki have no conflicts of interest.

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