

## Long-term effectiveness of BioEnterics intragastric balloon in obese patients

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**Background/aims:** The BioEnterics intragastric balloon has been considered an effective and less invasive method for weight loss. This study aimed to evaluate the effect of this method on long-term weight loss. **Material and Methods:** From June 2009 to June 2011, 32 patients (14 male, 18 female) underwent BioEnterics intragastric balloon therapy for 6 months. The mean age of the subjects was 39,7±11,1 years and mean body mass index was 44,4±12 kg/m<sup>2</sup>. All patients were given a diet of 1100 kcal/day. Weight loss parameters [absolute weight loss, body mass index loss, percentage of body weight loss, and percentage of excess body mass index loss (excess body mass index loss%)] were recorded at baseline, after 1 month, after 6 months (time of BioEnterics intragastric balloon removal), and after 12 months from baseline. Successful weight loss was defined as ≥10% weight loss after 6 (end of treatment success) and 12 months (long-term success). Statistical analysis was done using SPSS computer program. **Results:** The mean weight loss and body mass index loss were 12,4 kg (standart deviation, 13,5) and 4,3 kg/m<sup>2</sup> (standart deviation, 4,7), respectively (p<0,001). The mean percentage of body weight loss was 9,5% (standart deviation, 9,8). The percentage of excess body mass index loss reached 25,2% (standart deviation, 25,9). Fifteen patients (46,9%) achieved a percentage of body weight loss >10% at the end of treatment. Eleven of these patients (73%) were able to maintain weight loss of 10% at the completion of the study, resulting in a long-term success rate of 34,4%. Percentage of body weight loss and percentage of excess body mass index loss were inversely related to age (p<0,05). **Conclusion:** BioEnterics intragastric balloon has been effective in long-term loss of body weight.

**Key words:** Obesity, intragastric balloon, body mass index

### Obez hastalarda BioEnterik intragastrik balonların uzun süreli etkinliği

**Giriş ve Amaç:** Bioenterik intragastrik balonun kilo kaybı için etkili ve invazif olmayan bir metod olduğu düşünülmektedir. Bu metodun kilo kaybı üzerindeki uzun süreli etkisini değerlendirmeyi amaçladık. **Gereç ve Yöntem:** 2009 Haziran ayından 2011 Haziran ayına kadar 32 hastaya (14 erkek, 18 kadın) 6 ay süreyle BioEnterik Intragastrik balon tedavisi uygulandı. Hastalarda ortalama yaş 39,7±11,1, ortalama vücut kitle indeksi 44,4±12 kg/m<sup>2</sup> idi. Bütün hastalara 1100 kcal/gün diyet verildi. Kilo kaybı parametreleri (kilo kaybı, vücut kitle indeksi kaybı, vücut kilo kaybı yüzdesi, fazla vücut kitle indeksi kayıp yüzdesi) başlangıçta, 1 ay sonra, 6 ay sonra (Bioenterik intragastrik balon çıkartılma zamanı) ve 12 ay sonra kaydedildi. İstatistiksel analizler SPSS bilgisayar programı kullanılarak yapıldı. **Bulgular:** Ortalama kilo kaybı ve vücut kitle indeksi kaybı sırasıyla 12,4 kg (standart sapma, 13,5) ve 4,3 kg/m<sup>2</sup> (standart sapma, 4,7) idi (p<0,001). Ortalama vücut kilo kaybı yüzdesi %9,5 (standart sapma, 9,8) bulundu. Fazla vücut kitle indeksi kayıp yüzdesi %25,2 (standart sapma, 25,9) ye ulaştı. 15 hastada (%46,9) tedavi sonunda vücut kilo kaybı yüzdesi >%10 oldu. Bu hastaların 11 tanesi (%73) çalışma sonunda %10'luk kilo kaybını koruyabildi. Böylece uzun dönem başarı oranı %34,4 oldu. Vücut kilo kaybı ve fazla vücut kitle indeksi kayıp yüzdesi yaşla ters orantılıydı (p<0,05). **Sonuç:** BioEnterik intragastric balon vücut ağırlığının uzun süreli kaybında etkili olmuştur.

**Anahtar kelimeler:** Obezite, intragastrik balon, vücut kitle indeksi

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**Manuscript received:** 29.10.2012 **Accepted:** 21.01.2013

Turk J Gastroenterol 2013; 24 (5): 387-391  
 doi: 10.4318/tjg.2013.0696

This study has been presented at Asian Pacific Digestive Week, 2012, Bangkok

## INTRODUCTION

The modern lifestyle of increased food consumption and sedentary activities has resulted in a global epidemic of obesity. Recent data has revealed that obesity in Turkey is as high as 29.5% of the population [body mass index, (BMI) >30] (1).

Nonsurgical management of obesity includes dietary changes and exercise, which can facilitate a 5%–10% weight loss (2-4). Unfortunately, once patients stop a weight loss program, weight gain typically occurs (5). Pharmacologic management of obesity is not much better than diet and exercise. In this context, intragastric balloon (IGB) emerges as an interesting therapeutic tool for this group of patients to manage weight loss above 10% of initial body weight.

The efficacy and effectiveness of saline-filled balloons are widely documented in the scientific literature; however, data were scant after balloon removal. This study attempts to evaluate the long-term effectiveness of BioEnterics intragastric balloon (BIB) in obese patients.

## MATERIALS and METHODS

Between June 2009 and June 2011, 32 obese patients who selected intragastric balloons [BioEnterics® Intragastric Balloon (BIB®) system] for weight loss were included in the study. Our patients were 14 men and 18 women with a mean age of 39,7±11,1 years (range: from 19 to 60 years). Their average weight was 126,3±31,6 kg, and average BMI was 44,4±12 kg/m<sup>2</sup>. Written informed consent was obtained from all subjects.

The inclusion criteria were morbid obesity (BMI≥35 kg/m<sup>2</sup>), the presence of obesity-related disorders, and failure with regimens of diet, physical activity, and behavior therapy for at least 6 months. Superobese patients (BMI≥50 kg/m<sup>2</sup>) received BIB® in preparation for bariatric surgery to reduce surgical risk. In addition, BMI 30-35-kg/m<sup>2</sup> patients with severe obesity-related disorders who had failed many attempts at weight loss underwent it on rare occasions. According to the manufacturer's recommendations, contraindications were presence of inflammatory or cancerous diseases of the gastrointestinal tract; potential for upper gastrointestinal bleeding; administration of aspirin, anti-inflammatory agents, anticoagulants, or steroids; alcoholism or drug addiction; and large hernia (>5 cm in diameter), including a hiatus hernia.

BIB® placement was performed under intravenous unconscious sedation (propofol) in the lateral decubitus position. The BIB® system, positioned in the gastric fundus, was inflated under direct vision with an admixture of 600 ml saline and methylene blue. After the procedure, patients were kept in the hospital for observation and for control of symptoms such as abdominal pain and vomiting. Once they could manage a fluid diet, they were discharged with drug therapy of lansoprazole 30 mg/day and butylscopolamine bromide 30 mg/day. The patients remained on the fluid diet until the end of the first week after the balloon placement, and a regular diet was gradually introduced thereafter. A 1100-kcal/day balanced diet was prescribed by dietitians.

Weight loss parameters [kg, BMI, body weight loss (BWL) %, and excess BMI loss (EBL) %] were recorded at baseline, after 1 month, after 6 months (time of BIB removal), and after 12 months from baseline. BWL greater than 10% when the BIB was removed was considered an end of treatment success (ETS). If patients sustained their BWL greater than 10% at the end of six months without balloon, this was considered as long-term success (LTS).

Excess body mass index loss percentage (EBL %) was calculated as shown in Figure 1 (6).

<p><b>Percent Excess BMI Loss (EBL%)</b></p> $\text{EBL\%} = \frac{\text{Baseline BMI} - \text{Current BMI}}{\text{Baseline BMI} - 25} \times 100$
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**Figure 1.** Formula used for excess body mass index (BMI) calculation. A BMI of 25 kg/m<sup>2</sup> was estimated to be the upper limit of normal

Descriptive data are expressed as means (standard deviation, SD). Baseline and outcome variables were compared with paired t-test. To evaluate the association of age and initial BMI with BWL%, and EBL%, Pearson correlation matrix was employed. A bilateral  $\alpha$ -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 for 2-5 days. BIB produced no other notable side effects. In all patients, balloon removal was performed without any difficulty. All patients

completed the six-month period with the balloon in place and the additional six months after its removal. There were no complications related to endoscopic balloon placement or removal.

Initial mean BMI was 44,4±12 kg/m<sup>2</sup>. At the end of six months with balloon, the mean BMI was 40,1±10,9 kg/m<sup>2</sup>, mean BWL% was 9,5±9,8%, and mean EBL% was 25,2±25,9%. ETS was reached in 15 of 32 patients (46,9%). At the end of the six-month follow-up period without balloon, the mean BMI was 41±11 kg/m<sup>2</sup>. Eleven patients could maintain their 10% BWL at the end of follow-up period, thus resulting in a LTS of only 34,4%. Weight-linked parameters in patients are shown in Table 1.

Percentage of BWL (r=-0,379) and percentage of EBL (-0,423) were inversely related to age (p<0,05) at the end of six months with balloon. Also percentage of EBL (-0,355, p<0,05) was inversely related to age although percentage of BWL (-0,346, p=0,052) was not at the end of the six-

month follow-up period without balloon. BWL% and EBL% were not related to initial BMI (Table 2).

**DISCUSSION**

The use of intragastric balloon placement to promote weight loss was first reported by Nieben et al. in 1982 (7). Since then, various balloons have been tested (8). Conflicting results on their efficacy have been reported, and complications have been relatively frequent. In 1999, a new balloon, the BioEnterics® Intragastric Balloon (BIB®) system, which has a spherical shape and higher volume of saline (400–700 ml) was introduced (9, 10). Extensive clinical experiences with the BIB® system have shown a low complication rate, efficacy in weight loss, and improvement of comorbidities (11, 12). However, data were scant after balloon removal.

The review by Dumonceau et al. (30 studies and 4,877 patients) (13) reported a mean weight loss of

**Table 1.** Weight-linked parameters in patients.

	Baseline	1 month	6 months <sup>a</sup>	12 months
Weight (kg) (min-max)	126,3±31,6 (88-256)	119,6±28 (85-228)	113,9±28,7 (76-216)	116,7±29,5 (72-220)
Weight loss (kg) (min-max)		6,7±5,1 (0-28)	12,4±13,5 (-5-40)	9,7±14,8 (-6-44)
BWL% (min-max)		5,1±2,8 (0-11)	9,5±9,8 (-4-28)	7,3±11,1 (-4-32)
Number (%) of patients with BWL%>10%		3 (9,4%)	15 (46,9%)	11 (34,4%)
BMI (kg/m <sup>2</sup> ) (min-max)	44,4±12 (32,3-97,5)	42±10,5 (31,2-86,9)	40,1±10,9 (26,6-82,3)	41±11 (25,2-83,8)
BMI loss (kg/m <sup>2</sup> ) (min-max)		2,4±1,9 (0-10,6)	4,3±4,7 (-1,8-15,2)	3,4±5,1 (-1,9-13,8)
EBL% (min-max)		12,7±7 (0-33,3)	25,2±25,9 (-9,5-82,8)	18,6±30 (-10,9-97,8)

<sup>a</sup> BIB removal. BMI: body mass index; BWL: body weight loss; EBL: excess BMI loss.

**Table 2.** Correlation of age and initial BMI with weight-linked parameters (Pearson)

	Age	Initial BMI	BWL% after 6 months	EBL% after 6 months	BWL% after 12 months	EBL% after 12 months
Age	Correlation	1	.156	-.379*	-.423*	-.346
	Sig. (2-tailed)		.393	.032	.016	.052
	N	32	32	32	32	32
Initial BMI	Correlation	.156	1	.056	-.194	.109
	Sig. (2-tailed)	.393		.760	.288	.552
	N	32	32	32	32	32

BMI: body mass index; BWL: body weight loss; EBL: excess BMI loss.

**Table 3.** 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) <sup>a</sup>	(19)	21,3 kg	12,6 kg
Herve (2005)	(20)	12,0 kg	8,6 kg
Doldi (2004)	(22)	15,5 kg (female)	-1,3 kg (14 months)
Melissas (2006) <sup>b</sup>	(23)	41,6% EWL <sup>c</sup>	23,9% EWL (6-30 months)
Angrisani (2006)	(24)	32,9% EWL	27,1% EWL
Ganesh (2007)	(25)	4,4 kg	1,5 kg (6-12 months)
Ohta (2009)	(26)	12 kg	6,4 kg
Present study		12,4 kg	9,7 kg (6 months)

<sup>a</sup> One-year balloon treatment. <sup>b</sup> Data in the successful group were used. <sup>c</sup> Percent excess weight loss. EWL: Excessive weight loss.

17.8 kg (4-9 kg/m<sup>2</sup>) achieved after the balloon removal. In another metaanalysis from Spain, the authors reviewed the literature systematically and pooled 15 articles and 3.608 patients to estimate the effectiveness and safety of BIBs (14). They concluded that the use of 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 (14). Although there is great variability between subjects and studies, significant factors related to greater weight loss include initial BMI, patient's degree of motivation, and adherence to the dietitian's program control (15, 16).

Although there are no evolutionary studies that assess the long-term effectiveness, there is experience that a non-insignificant percentage of these patients can recover partial or total weight loss after the balloon is removed (13). However, in other patients, these results are encouraging. Thus, Carbonelli *et al.* (17) described that after extraction of the balloon, the majority of patients had lost weight and some continued to lose it. In their studies performed one year post-removal, Escudero-Sanch's *et al.* (18) noted that 48% of patients maintained or continued losing weight, Mathus-Vliegen and Tytgat (19) reported that 55% of patients had a sustained weight loss greater than 10%, and

Herve *et al.* (20) found a excessive weight loss (EWL) of 26.8%. Published outcomes of weight loss 1 year after the balloon removal are summarized in Table 3. About a third to half of weight lost with the balloon is regained after the balloon is removed. Our data seem to show moderate results. 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 (21).

There is only one study that have investigated the long-term success rate in Turkish population (27). Saruç *et al.* demonstrated that after BIB removal, 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 EWL of 25% at the end of the six-month follow-up period, resulting in a long-term success rate of 8,3% (21). Unlike this study, we found that the short-term success rate (ETS) is lower (46.9%), but the long-term success rate (LTS) is higher (34.4%).

In conclusion, intragastric balloon placement is a safe and effective procedure in obese Turkish patients, and about a third of the treated patients could be expected to maintain their lower weight after the balloon is removed.

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