

# Assessment of the Application of the Intra-gastric Balloon Together with Sibutramine: A Prospective Clinical Study

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## Abstract

**Background** The aim of this study is the prospective evaluation of the results of Bioenterics intra-gastric balloon (BIB) with sibutramine and BIB placement alone in the treatment of obesity.

**Methods** The patients evaluated between March 2006 and January 2007 and enrolled in this study were assessed in two groups as group A (BIB + sibutramine) and group B (BIB). After the follow-up of the patients for 6 months, body mass index (BMI), weight loss, excess weight loss (EWL%), and excess body mass index loss (EBMIL%) values of the patients in both groups were compared.

**Results** According to the comparison of the weights of the patients in groups A and B at 6 months with the beginning weights of the patients in both groups, there was statistically significant weight loss ( $p < 0.01$ ). The total weight loss at 6 months in group A was statistically significantly higher than that in group B ( $p < 0.05$ ). The patients in group A had a mean BMI  $34.53 \pm 6.63$  kg/m<sup>2</sup>, EWL%  $38.77 \pm 11.88\%$ , EBMIL%  $49.93 \pm 21.52\%$  after 6 months; the patients in group B had a mean BMI  $35.29 \pm 6.36$  kg/m<sup>2</sup>, EWL%  $29.06 \pm 17.82\%$ , EBMIL%  $36.51 \pm 23.69\%$  after 6 months. There was no statistically significant difference between group A and group B according to the BMI, EWL%, and EBMIL% values ( $p > 0.05$ ).

**Conclusion** In the management of obesity, using BIB together with sibutramine before the treatment in the patient group who are planned to have surgery, compared with using only BIB, provides more effective weight loss.

**Keywords** Sibutramine · Intra-gastric balloon · Obesity

## Introduction

The prevalence of obesity is dramatically increasing in the world. The high rates of morbidity and mortality appeared to be related with obesity, making the topic more important. There are many methods of treatment; diet, behavior modification, pharmacotherapy, and bariatric surgery [1].

Sibutramine is a pharmacotherapeutic drug that has proved effective in the long-term treatment of obesity, which has been accepted by the US Food and Drug Administration and the European Committee for Proprietary Medicinal Products [2]. On the other hand, Bioenterics intra-gastric balloon (BIB) procedure has recently become a frequently used endoscopic method in the weight loss treatment for obese patients [3]. This procedure has been declared to be a safe and effective method, with low mortality and morbidity rates [4]. In our study, we have aimed to evaluate the results of the combined therapy by comparing weight loss results of the patient group that had BIB procedure together with sibutramine with the patient group that had only the BIB procedure.

## Material and Methods

Between March 2006 and January 2007, in this study we evaluated obese patients who had the Bioenterics intra-

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**Table 1** Sibutramine exclusion criteria

1. Anorexia nervosa
2. Drug hypersensitivity
3. Treatment with monoamine oxidases or other serotonergic drugs
4. Coronary hearth disease
5. Angle closure glaucoma
6. Stroke
7. Congestive hearth disease
8. Arrhythmia
9. Uncontrolled hypertension
10. Severe hepatic and renal disease
11. Pregnancy and lactation
12. Peripheric artery disease

gastric balloon (BIB, Inamed, Santa Barbara, CA, USA) application together with sibutramine (Reductil, Abbott, Turkey) (group A) and those who had the BIB alone (group B). The patient group in Table 1 did not have BIB application. Sibutramine was started at a dose of 15 mg/day to the patients in group A under the control of an endocrinology and metabolism specialist. The patient group in Table 2 was not allowed to use sibutramine.

Bioenterics intragastric balloon application was done under deep sedation, in left lateral decubitus position as Coskun et al. described, and removal procedure was done in the same way [5]. The balloons of the patients who had BIB application was filled with 600 ml of saline mixed with 10 ml of methylene blue. The patients who underwent BIB application were observed for 6 h after the procedure and during this period, we administered 1,000 cc 0.09% NaCl mixed with ondansetron HCl 4 mg/day (Zofran, GlaxoSmithKline, Turkey), hyosine-*N*-butyl bromide 20 mg three times per day (Buscopan, Eczacıbası, Turkey), and omeprazole 20 mg/day (Losec, AstraZeneca, Turkey) to the patients who were discharged after this period with advices. In our BIB applications, a diet program of 1,200 Kcal/day was prepared by a dietician routinely. Six months after the BIB application was determined as the removal time and

**Table 2** Balloon exclusion criteria

1. Esophagitis (>grade 2)
2. Hiatal hernia (>5 cm)
3. Active peptic ulcer
4. Chrohn's disease
5. Major psychiatric disease
6. Pregnancy
7. Previous gastrointestinal surgery
8. Chronic use of steroids, NSAIDs, or anticoagulants
9. Alcohol or narcotics addiction
10. Structural anomalies in the GI tract
11. Lesions with high risk of bleeding
12. Severe hepatic disease

**Table 3** Changes in the BMI and weight values according to the groups

		Group A (Mean ± SD)	Group B (Mean ± SD)	<i>p</i>
Weight (kg)	Initial	121.42±29.45	111.50±18.30	0.333
	6 month	101.00±27.68	97.41±12.83	0.714
	Initial–6 month <i>p</i> <sup>+</sup>	0.001**	0.001**	
BMI (kg/m <sup>2</sup> )	Initial	41.66±7.66	40.62±7.62	0.740
	6 month	34.53±6.63	35.29±6.36	0.779
	Initial–6 month <i>p</i> <sup>+</sup>	0.001**	0.001**	

\*\**p*<0.01

the balloons of all the patients were removed successfully and the patients were discharged after a 2-h observation period. Before the application, the beginning weights and body mass index (BMI) of the patients were recorded. After the 6-month follow-up, the new BMI, weight loss values, excess weight loss (EWL%) and excess body mass index loss (EBMIL%) values of the patients in group A and group B were calculated and compared.

## Statistics

The SPSS (Statistical Package for Social Sciences) for Windows 10.0 program was used for the statistical analysis to evaluate the results of the study. Besides descriptive statistical methods (mean, standard deviation), for comparison of quantitative data and comparison of the parameters between groups, Student's *t* test was used to evaluate the study data. For the comparison of the parameters in the group, paired sample *t* test was used. Results were evaluated in 95% confidence interval and *p*<0.05 significance level.

## Results

In our study, a total of 24 patients (nine male, 15 female) whose mean age was 35.75 years were assessed prospec-

**Table 4** Assessment of the changes in the weight loss, BMI% loss, and EWL% according to groups

	Group A (Mean±SD)	Group B (Mean±SD)	<i>p</i>
Total Weight Loss	20.41±5.68	14.08±8.62	0.047*
EWL%	38.77±11.88	29.06±17.82	0.131
BMIL%	49.93±21.52	36.51±23.69	0.160

\**p*<0.05

tively. In group A, six patients were female (50%) and six were male (50%), and mean age was  $34.67 \pm 10.75$  (22–62) years. In group B, nine patients were female (75%) and three were male (25%), and mean age was  $36.83 \pm 8.60$  (23–56) years. In group A, before the application, the mean initial weight of the patients was  $121.42 \pm 29.45$  kg, mean weight of the patients at 6 months was  $101.00 \pm 27.68$  kg ( $p < 0.01$ ), mean beginning BMI of the patients was  $41.66 \pm 7.66$  kg/m<sup>2</sup>, and mean BMI of the patients at 6 months was  $34.53 \pm 6.63$  kg/m<sup>2</sup> ( $p < 0.01$ ). The EWL% value of the patients after 6 months in group A was calculated as  $38.77 \pm 11.88\%$ , and the EBML% value after 6 months was calculated as  $49.93 \pm 21.52\%$ . In group B, before the application, the mean initial weight of the patients was  $111.50 \pm 18.30$  kg, mean weight of the patients at 6 months was  $97.41 \pm 12.83$  kg ( $p < 0.01$ ), mean beginning BMI of the patients was  $40.62 \pm 7.62$  kg/m<sup>2</sup>, and mean BMI of the patients at 6 months was  $35.29 \pm 6.36$  kg/m<sup>2</sup> ( $p < 0.01$ ). The EWL% value of the patients after 6 months in group B was calculated as  $29.06 \pm 17.82\%$ , and the EBML% value after 6 months was calculated as  $36.51 \pm 23.59\%$  (Tables 3 and 4). The total weight loss at 6 months in group A was statistically significantly higher than that in group B ( $p < 0.05$ ). There was no statistically significant difference in terms of EWL%, EBML%, and BMI values between groups A and B ( $p > 0.05$ ).

## Discussion

Calorie restricting diet, exercise, behavior therapy, and pharmacotherapy are the first line of treatment in obesity. In the morbid obese patients, as these first-line treatment modalities frequently fail to have meaningful results, bariatric surgery becomes the treatment of choice. Recently, intragastric balloon application has been used as a temporary endoscopic treatment modality for obesity [6]. Intragastric balloon application has been used in the patient group that are planning to have bariatric surgery to decrease life-threatening comorbidities and surgical risks [7–9]. There are significant weight losses after intragastric balloon application as reported in other studies. Genco et al. retrospectively analyzed 2,515 patients (mean BMI:  $44.4$  kg/m<sup>2</sup>) who underwent BIB procedure; after 6 months of treatment the mean BMI was  $35.4$  kg/m<sup>2</sup>, mean EWL% value was  $33.9\%$  [4]. Doldi et al. was reported  $14$  kg of weight loss in 281 treated patients (initial BMI  $41.8$  kg/m<sup>2</sup>) after 6 months of follow-up [10]. In our study, mean weight loss after 6 months in the patient group that had undergone only BIB procedure was calculated as  $14.08 \pm 8.62$  kg. Sibutramine as a pharmacologic agent is a selective reuptake blocker of serotonin and norepinephrine [11]. In many multicentric studies, sibutramine has been

frequently used as a single treatment agent in large patient series for 6–24 months. Bray et al. had made a study of 1,047 patients for a 6-month period where they found 5% reduction of weight in 67% of the patients, and 10% reduction in 35% of the patients [12]. In a metaanalysis of 12 studies where sibutramine was used, authors reported that there was 3.4- to 6.0-kg weight loss in 16–24 weeks [13]. Other than these, there have been studies that showed encouraging results about the combined use of sibutramine. Wadden et al demonstrated that the use of sibutramine combined with behavioral therapy resulted more weight loss [14].

In our study, there was statistically significantly higher total weight loss in group A at 6 months compared with the beginning than that in the group B ( $p < 0.05$ ). On the other hand, the reduction of BMI of the patients at 6 months in group A was higher than that in group B, and similarly the EWL% and EBML% values were higher in group A than that of group B. But there was no significant statistical difference between the two groups in terms of those variants ( $p > 0.05$ ). In this study, we have thought that if we had had more number of patients, there might have been statistically significant differences in terms of the BMI, EWL%, and EBML% values. So, more studies involving larger series are needed.

In conclusion, preoperative combined use of BIB together with 6 months of treatment with sibutramine results in effective weight loss. This can result in preoperative improvement in comorbidities and reduction in the risk of planned bariatric surgery.

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