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Research Article

Effect of Bioenteric Intragastric Balloon (BIB) insertion on hormones regulating lipid metabolism, a prospective study.

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Abstract

BACKGROUND: The prevalence of obesity is increasing worldwide. Obesity is associated with a number of health-related problems, so treating obesity is an important clinical concern. Bioenteric Intragastric Balloon (BIB) can be an option for treating obesity. Body weight is regulated by a complex system including both peripheral and central factors. Many hormones including Leptin and Ghrelin seem to play an important role in the regulation of food intake and body weight. Few reports are available on the effect of Bioenteric Intragastric Balloon (BIB) on hormonal regulation in patients with obesity. **OBJECTIVES:** The aim of this study was to investigate the effect of Bioenteric Intragastric Balloon (BIB) insertion on hormones regulating lipid metabolism. **METHODS:** The study was conducted on 20 patients with BMI > 30 Kg/m² presented for Bioenteric Intragastric Balloon (BIB) insertion during the period between January 2013 and January 2014. Balloon was removed after 6 months with no complications. Complete lipid profile, serum level of Leptin and Ghrelin were measured before and after removal of the balloon. **RESULTS:** The use of Bioenteric intragastric balloon (BIB) for 6 months caused a significant reduction in body weight and BMI. The mean weight of the participants decreased to 98.75 Kg and mean BMI decreased to 32.45 Kg/ m^2. The mean weight loss was 14.70 Kg. The mean loss in BMI was 5.01 Kg/m2. The excess weight loss (EWL) was 12.95 % and the excess BMI loss (EBL) was 13.34 %. There was a significant reduction in Fasting blood sugar, HbA1c, serum creatinine, serum cholesterol, serum triglycerides, serum LDL and serum Leptin level Meanwhile use of BIB caused a significant increase in serum Ghrelin level.**CONCLUSIONS:** Insertion of Bioenteric intragastric balloon (BIB) for 6 months significantly reduces body weight and BMI. Moreover, Intragastric balloon strongly affects glucose homeostasis, lipid metabolism in addition to hormones involved in energy balance mainly serum leptin and ghrelin.

Keywords: Bioenteric intragastric balloon, Lipid, Metabolism.

Introduction

Obesity represents one of the most important public health problems due to its prevalence and associated potential complications [1]. Numerous diseases are caused or worsened by obesity shortening life expectancy and decreasing quality of life as well [2] [3]. The accepted treatment methods of obesity include the following: diet modification, physical exercise, changing lifestyle

and eating habits, pharmacological treatment, surgery and endoscopic treatment [4].

Bioenteric Intragastric balloons are endoscopic devices filled with liquid or air that are placed into the stomach for a limited period of time. As these devices produce a feeling of early satiety, they are considered to be a temporary and reversible restrictive therapeutic method of facilitating the implementation of adequate dietary and behavioral habits [5,6].

Bioenteric Intragastric Balloon (BIB) has been suggested for the following indication [7,8]: a) obese patients with diet therapy b) preoperative temporary use to achieve weight loss and reduce the risks of surgery and c) severely obese patients non-candidates for obesity surgery [9,10].

Several hormones are involved in the regulation of the energy balance of the body. An excessive accumulation of adipocytes that constitutes a metabolically active tissue, producing biologically active cytokines, plays an important role in lipid and carbohydrate metabolism [11]

There are few available reports on the effect of gastric balloons on hormonal regulation in patients with morbid obesity. This includes effect on body composition, serum levels of ghrelin, leptin, adiponectin, angiopoietin-like protein 3 (ANGPTL-3), angiopoietin-like protein 4 (ANGPTL-4), fibroblast growth factor 19 (FGF19), and fibroblast growth factor 21 (FGF21) as well as the impact on lipid metabolism [12,13].

Body weight is regulated by a complex system, including both peripheral and central factors. Two of the hormones that seem to play an important role in the regulation of food intake and body weight are leptin and ghrelin [14,15].

Ghrelin, a 28-amino acid peptide secreted mainly by the stomach [16]. Ghrelin stimulates both energy gain and the secretion of growth hormone (GH) and insulin leading to weight gain and attainment of a positive energetic balance in the long term [17]. In addition, Ghrelin levels seem to be influenced by age, gender, BMI, growth hormone, glucose, and insulin [18]. Leptin, a 167-amino acid protein produced by adipocytes in the hypothalamus is opposite to that of Ghrelin molecule [19]. Leptin is proportionally released to the amount of fat stored in the white adipose tissue and acts in hypothalamic suppression of food intake and increase in energy expenditure [20].

Materials and Methods

The study was conducted on 20 obese patients who presented for intragastric balloon insertion in the endoscopy unit at Ain Shams University Specialized Hospital during the period between January 2013 and January 2014.

Inclusion criteria included:

1) Obese patients (BMI > 30 Kg/m²)
2) Age over 18 years of age
3) Refraction to low calorie therapy
4) Informed consent for participation in the study
5) No contraindications for BIB placement

Exclusion criteria included:

1) Toxic habits (alcohol or drug abuse)
2) Pregnancy or lactation
3) Psychiatric disorders
4) Anatomical, surgical or pathological alteration of upper gastrointestinal tract
5) Previous gastrointestinal surgery
6) Patients requiring treatment with aspirin, anti-inflammatory drugs, anti-coagulants or corticosteroids
7) Endoscopic findings as Hiatus hernia of 5 cm or greater, gastric or duodenal ulcers
8) Severe gastrointestinal (Ulcerative colitis or Chron's disease) or extra-gastrointestinal diseases (severe liver or renal disease)

All patients participating in the study were subjected to complete medical history (including eating habits and previous treatment), full clinical examination, measurement of body weight (Kg), height (m), BMI (Kg/m²), pelvi-bdominal U/S, complete blood count (CBC), Liver function tests (AST, ALT, total protein, albumin, International

Randomized Ratio, total Bilirubin), Hepatitis markers (HBsAg and HCVAb), Fasting blood sugar (mg/dl), serum glycated Hb (HbA1c%), serum creatinine, serum urea, complete lipid profile (cholesterol (mg/dl), triglycerides (mg/dl) , LDL

(mg/dl), HDL , (mg/dl) VLDL (mg/dl) serum TSH (µIU/ml), serum level of human Ghrelin (GHRL) (pg/ml) and Leptin (ng/ml). All laboratory blood tests were repeated after 6 months interval (at time of removal of the BIB).

Quantitative determination of serum human Ghrelin (GHRL) was performed using Human Ghrelin (GHRL) ELISA kit supplied by KAMIYA BIOMEDICAL COMPANY (Cat. No. KT-15906). It is a competitive inhibition enzyme immunoassay technique for the in vitro quantitative measurement of human GHRL in serum, plasma, tissue homogenates, cell culture supernates and other biological fluids. This assay employs the competitive inhibition enzyme immunoassay technique. A monoclonal antibody specific for human GHRL has been pre-coated onto a micro plate. A competitive inhibition reaction is launched between biotin labeled human GHRL and unlabeled human GHRL (Calibrators or samples) with the pre-coated antibody specific for human GHRL. After incubation the unbound conjugate is washed off. Next, avidin conjugated to Horseradish Peroxidase (HRP) is added to each micro plate well and incubated. The amount of bound HRP conjugate is reverse proportional to the concentration of GHRL in the sample. After addition of the substrate solution, the intensity of color developed is reverse proportional to the concentration of GHRL in the sample. The system reports AFP results in pg/ml. The reference value in normal weight/control subjects is 520 - 700 pg/ml.

Quantitative determination of serum human Leptin was performed using AssayMax Human Leptin ELISA Kit supplied by Assaypro LLC (Catalog No. EL2001-1). The AssayMax Human Leptin ELISA (Enzyme-Linked Immunosorbent Assay) kit is designed for detection of human leptin in plasma, serum, and cell culture samples. This assay employs a quantitative sandwich enzyme immunoassay technique that measures leptin in less than 5 hours. A monoclonal antibody specific for leptin has been pre-coated onto a 96-well micro plate with removable strips. Leptin in standards and samples is sandwiched by the immobilized antibody and a biotinylated polyclonal antibody specific for leptin, which is

recognized by a streptavidin-peroxidase conjugate. All unbound material is then washed away and a peroxidase enzyme substrate is added. The color development is stopped and the intensity of the color is measured. The system reports Leptin results in ng/ml. The reference value in normal weight/control subjects is 0.7 - 5.3 ng/ml in males and 3.3 - 18.3 ng/ml in females.

All candidates were subjected to diagnostic upper GI endoscopy. The insertion procedure was performed in an operating theatre under conscious sedation controlled by the endoscopist using Midazolam 5 mg I.V. Before insertion, the BioEnterics Intragastric Balloon (BIB; BioEnterics Corporation, Allergan USA) is combined with a cylinder and is lubricated with xylocaine gel to facilitate passage through the upper esophageal sphincter. After balloon insertion into the stomach, it is positioned in the fundus under endoscopic control. The chuck is then removed from the catheter and the balloon is filled with 600 ml of a physiological solution of saline mixed with 10 ml of methylene blue dye. After filling the balloon with saline, it is released by a short pull on the catheter. A valve prevents saline from flowing back. During the first 24 hours after placement, all participants received 500mL saline I.V., Pantoprazole 40 mg I.V. and Ondansetron 8mg I.V. All participants were discharged home on oral pantoprazole 40 mg/day on the same day of the procedure. The initial diet was liquid for 2 days with gradual return to solid food. The BIB is left for a period of 6 months.

The BIB was removed after six months. The procedure for balloon removal is also performed under conscious sedation controlled by the

endoscopist using Midazolam 5 mg I.V. The balloon is punctured with a needle, it is then emptied of saline through the catheter and removed using forceps.

Statistical methodology

Data was analyzed using SPSS version 17 (SPSS Inc., Chicago, IL, USA). Data was described as mean ± standard deviation for quantitative variables and as number and percentage for qualitative variables. Student's t-test was used for paired and unpaired observations in the two groups (before and after BIB insertion). A *p* value of < 0.05 was used to express significant statistical difference.

Results

Twenty obese patients were enrolled in this study. Among the patients included there were 11 men (55%) and 9 women (45%). The age of the patients had a mean of 35.1 ± 11.116 years. Mean initial weight was 113.45 ± 11.83 Kg. Mean height was 1.745 ± 0.049 meters. Mean baseline BMI was 37.47 ± 4.045 Kg/ m^2.

Before placement of the Bioenteric intragastric balloon (BIB), the mean value for serum hemoglobin level was 13.63 ± 1.195 gm/dl, serum AST 38.1 ± 18.55 IU/dl, serum ALT 59.6 ± 43.94, serum total protein 7.135 ± 0.529 gm/dl, serum albumin 4.750 ± 0.431 gm/dl, INR 1.175 ± 0.227, serum total bilirubin 0.970 ± 0.138 mg/dl, fasting blood sugar 136.85 ± 41.64 mg/dl, HbA1c 8.015 ± 1.035 %, serum creatinine 0.970 ± 0.260 mg/dl, serum urea 35.30 ± 12.43 mg/dl, serum cholesterol 227.15 ± 73.16 mg/dl, serum triglycerides 233.70 ± 100.79 mg/dl, serum LDL 135.15 ± 40.69 mg/dl, serum HDL 46.60 ± 13.04 mg/dl, serum VLDL 40.65 ± 12.43 mg/dl, serum TSH 3.249 ± 2.247 ug/dl, serum Ghrelin 586.05 ± 199.47pg/ml, serum Leptin 8.815 ± 3.348 ng/ml.

Among the 20 patients, HBsAg was negative in 19 patients (95%) and positive in one patient (5%) while HCVAb was negative in 18 patients (90%) and positive in 2 patients (10%).

The balloon was placed for a period of 6 months. After removal of the balloon, the mean weight of the participants decreased to 98.75 ± 12.87 Kg and mean BMI decreased to 32.455 ± 4.562 Kg/ m^2. The mean weight loss was 14.70 ± 10.047 Kg. The mean loss in BMI was 5.01 ± 0.032 Kg/m2. The excess weight loss (EWL) was 12.95 % and the excess BMI loss (EBL) was 13.34 %. All laboratory blood tests were repeated at time of removal of the BIB. The results showed that the mean value for serum hemoglobin level after removal of the balloon became 13.53 ± 1.14 gm/dl, serum AST 32.00 ± 13.44 IU/dl, serum ALT 45.93 ± 32.11 IU/dl, serum total protein 7.095 ± 0.615 gm/dl, serum albumin 4.790 ± 0.470 gm/dl, INR 1.135 ± 0.175, serum total bilirubin 1.005 ± 0.123 mg/dl, fasting blood sugar 111.95 ± 28.35 mg/dl, HbA1c 6.725 ± 0.881 %, serum creatinine 1.205 ± 0.246 mg/dl, serum urea 33.4 ± 10.49 mg/dl, serum cholesterol 173.40 ± 40.48 mg/dl, serum triglycerides 145.75 ± 42.83 mg/dl, serum LDL 109.25 ± 32.94 mg/dl, serum HDL 51.50 ± 13.27 mg/dl, serum VLDL 38.40 ± 13.67 mg/dl, serum TSH 3.423 ± 1.979 ug/dl, serum Ghrelin 693.15 ± 72.96 pg/ml, serum Leptin 5.520 ± 3.083 ng/ml.

The use of Bioenteric intragastric balloon (BIB) in this study caused a significant reduction in body weight (t = 6.314, $p = 0.0001$), BMI (t = 5.922, $p = 0.0001$), Fasting blood sugar (t = 2.211, $p = 0.0332$), HbA1c (t = 6.314, $p = 0.0001$), serum creatinine (t = 2.902, $p = 0.006$), serum cholesterol (t = 2.875, $p = 0.0066$), serum triglycerides (t = 3.591, $p = 0.0009$), serum LDL (t = 2.213, $p = 0.033$), serum Leptin level (t = 2.249, $p = 0.0305$). Meanwhile use of BIB caused a significant increase in serum Ghrelin level (t = 2.387, $p = 0.0221$).

Discussion

Recently, endoscopic intragastric balloon placement has become more widespread in the multidisciplinary management of obesity treatment [21] since alternative conservative treatments as low-calorie diet, changes in life-

style, pharmacotherapy, etc. have shown unsatisfactory results. Endoscopic placement and removal are not difficult techniques to perform. Also, intragastric balloon tolerance is generally accepted. Specific training is nevertheless recommended [22].

In this study we demonstrated a beneficial effect of Bioenteric Intragastric Balloon (BIB) insertion on body composition. The placement of the intragastric balloon for 6 months resulted in a statistically significant reduction in body weight**.** The mean losses of weight and BMI were 14.7 Kg and 5.01 Kg/m^2 respectively. Our results are comparable to previous reports in which the weight loss was 14.7–17.8 kg and BMI loss was 5.7–6.7 kg/m^2 [23]. Similar results were obtained by others using various types of intragastric balloons.

Table (1): Effect of Bioenteric Intragastric Balloon (BIB) insertion on different body parameters:

	Before BIB	After BIB	Significance
Weight (Kg)	**113.45**	**98.75**	**Highly significant**
BMI (Kg/m^2)	**37.47**	**32.455**	**Highly significant**
Hemoglobin (gm/dl)	**13.63**	**13.53**	**Non Significant**
AST (IU/dl)	**38.1**	**32.00**	**Non Significant**
ALT (IU/dl)	**59.6**	**45.93**	**Non Significant**
Total Proteins (gm/dl)	**7.135**	**7.095**	**Non Significant**
Albumin (gm/dl)	**4.750**	**4.79**	**Non Significant**
INR	**1.175**	**1.135**	**Non Significant**
T. Bilirubin (mg/dl)	**0.970**	**1.005**	**373Non Significant**
Fasting blood sugar (mg/dl)	**136.85**	**111.95**	**Significant**
HbA1c (%)	**8.015**	**6.725**	**Significant**
Creatinine (mg/dl)	**0.970**	**1.205**	**Significant**
Urea (mg/dl)	**35.30**	**33.4**	**Non Significant**
Cholesterol (mg/dl)	**227.15**	**173.4**	**Significant**
Triglycerides (mg/dl)	**233.70**	**145.75**	**Significant**
LDL (mg/dl)	**135.15**	**109.25**	**Significant**
HDL (mg/dl)	**46.60**	**51.50**	**Non Significant**
VLDL (mg/dl)	**40.65**	**38.4**	**Non Significant**
TSH (ug/dl)	**3.250**	**3.424**	**Non Significant**
Serum Ghrelin (pg/ml)	**586.05**	**693.15**	**Significant**
Serum Leptin (ng/ml)	**8.815**	**5.520**	**Significant**

Fig (1):

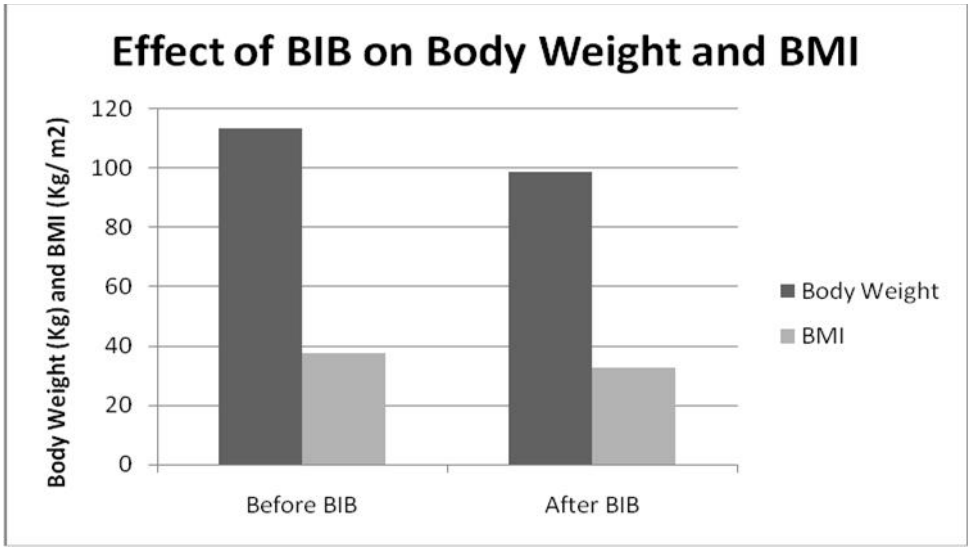

Fig (2):

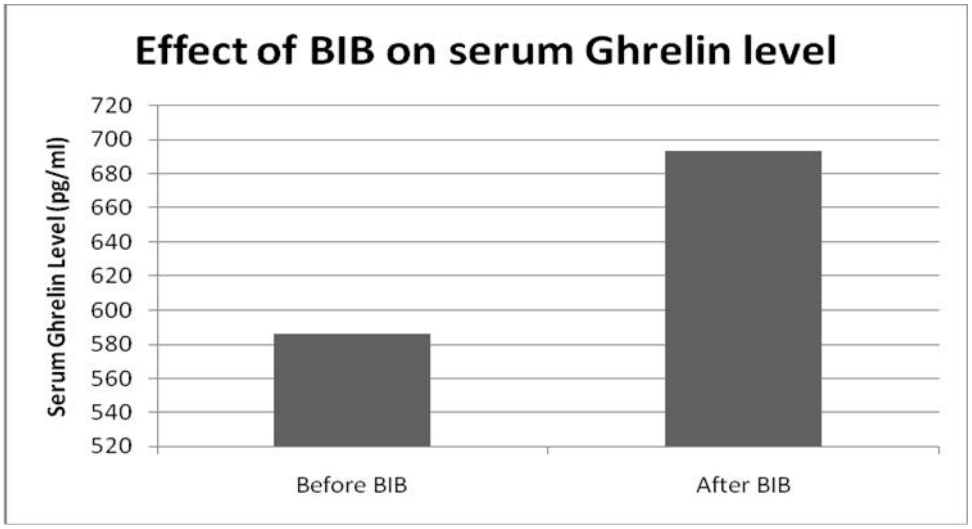

Fig (3):

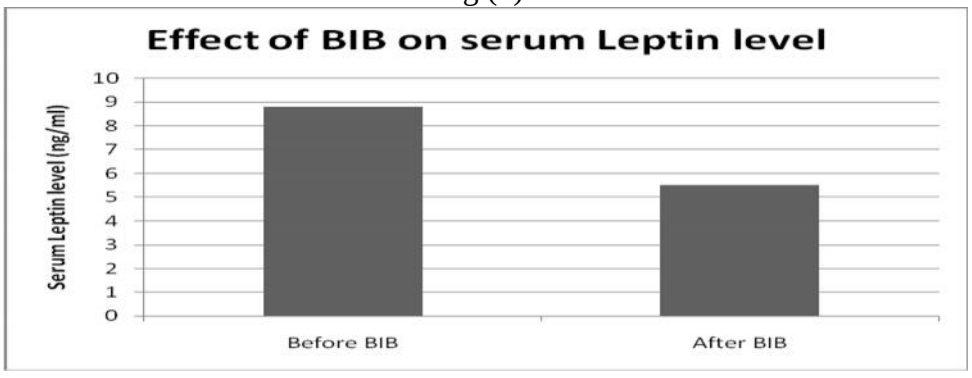

Fig (4): An intragastric balloon was placed (BIB®, Inamed, Health-Allergan Medical, Santa Barbara, CA, USA) under endoscopic guidance.

Fig (5): Abdominal X-ray revealed an intragastric balloon in the upper abdomen (white arrows

Fig (6): Computed tomography revealed a balloon in the stomach.

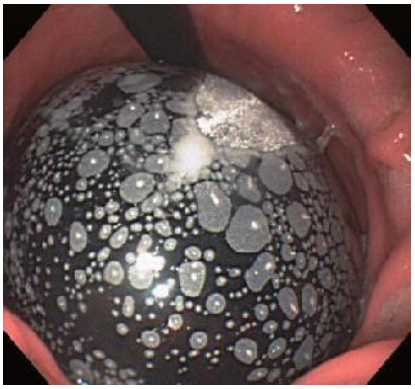

Fig (4)

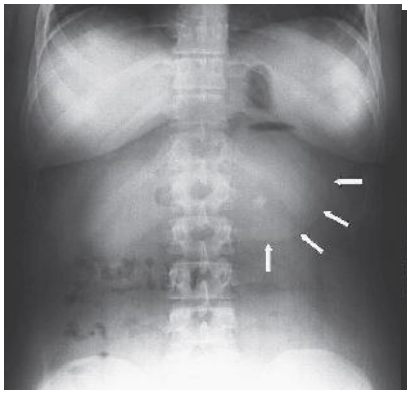

Fig (5)

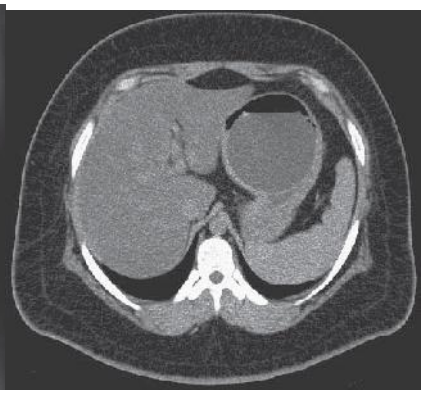

Fig (6)

The mean weight loss fluctuated from 9.7 to17.8 kg in these studies 6 months following balloon insertion [24].

In this study we found a positive effect of the BIB insertion on glucose tolerance. The observed improvement of glycated hemoglobin levels was statistically significant. Moreover, there is significant reduction in fasting glucose levels. Decreases in glycated hemoglobin in patients with BIB were reported in several studies. Sekino describes a decrease in glycated hemoglobin; however, this decrease was not statistically significant [25]. In a 6-month study with BIB, Konopko-Zubrycka documented a significant decrease in fasting glucose and insulin response [26]. Similar results were seen by Mathus-Vliegen in their randomized study [27].

In this study we noticed that insertion of Bioenteric Intragastric Balloon (BIB) for 6 months caused a significant reduction in serum cholesterol, triglycerides and LDL. But no significant increase in serum HDL was found. These results are in agreement with those of Konopko-Zubrzycka et al who stated that in patients with morbid obesity treated with BIB, weight loss was accompanied by a decrease in total cholesterol by 17.6% ($p < 0.001$), triglycerides by 25.5% ($p < 0.01$) and LDL by 27.5% ($p < 0.001$) and increase in plasma HDL [34].

The recently discovered hormone, ghrelin, has been recognized as an important regulator of energy homeostasis. Ghrelin, a GH-releasing peptide isolated from the stomach, induces weight gain by stimulating food intake [28]. Furthermore, ghrelin seems to decrease the metabolic rate and the catabolism of fat [29]. Therefore, biological effects of ghrelin appear to be the opposite of those of leptin, which has been suggested to be the key signal reflecting adipose stores [30].

We demonstrated in this study a significant increase in serum Ghrelin 6 months after insertion of BIB. These findings are in concordance with the data obtained by Marek Bužga et al who stated that the levels of ghrelin increased significantly 3 months following the insertion of the intragastric balloon. Subsequently, the levels of

ghrelin decreased but were still above the values measured at baseline [31]. Also Konopko-Zubrycka et al found increases in plasma ghrelin 1 and 6 months after the insertion of an intragastric balloon [26]. Moreover, Mion et al. reported similar effects on the levels of ghrelin in air-filled intragastric balloons in non-morbidly obese patients [32].

In the present study, serum Leptin was found to increase significantly 6 months after insertion of BIB. These results are in agreement with those of Marek Bužga et al in which serum Leptin showed a significant decrease 6 months after the insertion of the balloon which is probably related to the decrease in the amount of adipose tissue after MedSil® balloon application [31]. The decline in plasma leptin levels was similarly reported in three studies with the introduction of the BIB in morbidly obese patients [33].

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