

The Role of Intra-gastric Balloon on EBL %, Homeostasis of Lipid and Satiety Hormone

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Abstract: *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. Intra-gastric balloon (IGB) represents, in the short-term, an alternative for obese patients non responding to diet and reluctant to surgery. Use of intra-gastric balloon for 6 months significantly reduces body weight and BMI. Moreover, Intra-gastric balloon strongly affects glucose homeostasis, lipid metabolism in addition to hormones involved in energy balance mainly serum leptin and ghrelin.*

Keywords: Obesity, Intra-gastric balloon, Body mass index, weight loss, Ghrelin, Leptin, Follow-up.

1. Introduction

Obesity is a major cause of morbidity and mortality worldwide [1]. Numerous diseases are caused or worsened by obesity shortening life expectancy and decreasing quality of life as well [2],[3]. Treatment of obesity relies mainly on prolonged hypocaloric diet, associated with behavioural changes, drugs or surgery. Hypo-caloric diet is the mainstay of first-line treatment, but longterm response is difficult to achieve. Surgery, mainly represented by laparoscopic adjustable gastric banding (LAGB), sleeve gastrectomy, and Roux-en-Y gastric by-pass (RYGB), markedly reduces body weight and medical complications of obesity [4],[5]. However, serious complications may occur and many morbidly obese patients are reluctant to surgery. Bariatric surgery is an irreversible process [6].

Obese subjects who do not qualify for, or do not give consent to, bariatric surgical procedures constitute a therapeutic problem. An endoscopic method for the treatment of obesity, intra-gastric balloon, can be an option for this group of patients [7].

A number of hormones take part in the regulation of energy balance of the body, including two major ones, ghrelin, synthesized and secreted by A/X cells of the proximal stomach mucosa, and leptin, synthesized mainly by adipose tissue and to a lesser degree in the stomach [8]. The peptides ghrelin and leptin have emerged in the last decade as the most influential contra-regulatory candidates in appetite and energy metabolism regulation [9]-[11].

Ghrelin, a 28-amino acid peptide secreted mainly by the stomach [12]. 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 [13]. In addition, Ghrelin levels seem to be influenced by age, gender, BMI, growth hormone, glucose, and insulin [14]. Leptin, a 167-amino acid protein produced by adipocytes in the hypothalamus is opposite to that of Ghrelin molecule [15]. 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 [16].

Three studies examined ghrelin concentrations during intra-gastric balloon treatment with divergent results [17]–[19]. One study reported decreased fasting ghrelin concentrations after a balloon-induced weight loss of 9.4 % [17]. A second study found similar meal-suppressed ghrelin concentrations in a sham-controlled design [18]. A third study noted increased ghrelin values after 1-month of intra-gastric balloon treatment that normalised to pretreatment levels 3 months after balloon removal [7].

The aim of our study was to prospectively assess the ghrelin- and leptin-induced changes before intra-gastric balloon treatment and at 2, 4 & 6 months of follow-up.

2. Subjects and Methods

The study was conducted on 26 obese patients who presented for intra-gastric balloon insertion in the Ibn Bilal private hospital during the period from June 2015 until the end of February 2016.

Intra-gastric balloon was inserted into the gastric fundus and then filled under endoscopic control with 600 ml of saline stained with methylene blue. 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 intra-gastric balloon was removed endoscopically.

Our patients were 11 men and 15 women, ranging from 18-45 years of age (mean age 32.42± 8.9 years). All patients participating in the study were subjected to complete medical history (including eating habits and previous treatment), measurement of body weight (Kg), height (m), BMI (Kg/m²), fat percent (%), Fasting blood glucose (mg/dl), Glycated Hemoglobin (HbA1c%), complete lipid profile (cholesterol (mg/dl), triglycerides (mg/dl), LDL (mg/dl), HDL, (mg/dl) VLDL (mg/dl), serum level of human Ghrelin (ng/ml) and Leptin (ng/ml) were recorded at baseline, 2, 4 and 6 months from the baseline.

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 leptin throughout 2, 4 and 6 months of follow up –Pearson correlation” was employed. A p value of <0.05 was used to express significant statistical difference. The computer software used for analysis was SPSS 20.0.

3. Results

Table 1 demonstrates four measurements for patients (n=26) , the first measurement was before Intra gastric balloon (base line characteristics) ,while second measurement was two months after Intra gastric balloon, the third measurement was four months after Intra gastric balloon and the fourth reading was six months after Intra gastric balloon with the mean ± SD of all studied parameters. It can be noticed from table (3-1) that the mean values of each of body weight (117.192±30.415 kg), body mass index (43.019±11.135 kg/m²) and fat percent (48.818±15.475 %) were significantly declined after two months of gastric balloon (p= <0.001 respectively) compared with that of preoperative means (127.576±33.133 kg, 47.176±12.027 kg/m² and 54.073±16.157 % respectively), and the mean values of body weight (107.923±28.906 kg), BMI (39.392±10.567 kg/m²) and fat percent (44.725±14.835 %) were significantly declined after four months of Intra gastric balloon (p= <0.001) compared with means of pre-operative group, also there are declined in the mean ± SD of these parameters after six months of this procedure (96.923±26.173 kg, 35.465±9.87 kg/m², fat percent 40.02±14.089 % respectively) with a significant difference (p= <0.001). There are increasing in the mean of EBL% during 2, 4 and 6 months post-operative (22.252±13.121, 41.622±23.78 and 63.377±31.276 % respectively) according to continuous dropping in the BMI and weight.

After two months of Intra gastric balloon , mean fasting blood glucose (89.346±9.995 mg/dl) was significantly declined (p= <0.001) compared with pre-operative mean value (99.769±20.424 mg/dl) also there is a significant decreased (p= <0.001) was noticed in mean level of HbA1c % (5.23±0.373) compared with pre-operative mean value (5.67±0.493).

After four months of Intra gastric balloon , the mean values of fasting blood glucose (84.192±6.222) and HbA1c % (5.528±0.511) in patients were significantly decreased (p= <0.001) compared with pre-operative mean values. Six months post-operative showed declining mean in both of fasting blood glucose (82.192±5.122 mg/dl) and HbA1c % (5.157±0.32) with p-value = <0.001.

After two months of Intra gastric balloon, the mean values of serum total cholesterol (166.807±42.035 mg/dl), TG (113.038±30.158 mg/dl), LDL (109.7±40.977 mg/dl) and VLDL (22.607±6.031 mg/dl) were significantly decreased (p= <0.001, 0.001, 0.01 and 0.001 respectively) compared with pre-operative mean values (176.038±48.02,

118.73±33.45, 119.346±49.221 and 23.746±6.69 mg/dl respectively).

Each of total cholesterol, TG, LDL and VLDL were showed a significant decreasing (p= <0.001 for total cholesterol and 0.001 for the others) in their mean value (159.961±34.167, 109.5±27.228, 100.83±32.735 and 21.9±5.445 mg/dl respectively) after four months of Intra gastric balloon compared with pre-operative means, also there are a significant decreasing (p= <0.001, 0.003, <0.001, and 0.003 respectively) in their means (154.807±29.338, 104.384±23.351, 94.43±28.96 and 20.876±4.67 mg/dl respectively) after six months compared with pre-operative means.

The mean value of serum HDL-cholesterol after two months (34.5±7.156 mg/dl) and after four months (37.23±7.262 mg/dl) of Intra gastric balloon was significantly increased (p= 0.04 and <0.001 respectively) compared with pre-operative mean value (33±8.653 mg/dl), also there is a significant increased (p= <0.001) in serum HDL-cholesterol mean (39.5±6.772 mg/dl) after six months of LSG compared with pre-operative mean value.

Mean serum ghrelin hormone two months post Intra gastric balloon procedure (0.488±0.153 ng/ml) was significantly increased (p= <0.001) compared with pre-operative mean value (0.451±0.165 ng/ml), while its level (0.429±0.15 ng/ml) was significantly decreased (p= 0.01) four months post Intra gastric balloon compared with pre-operative mean, but there is a significant increasing (p= <0.001) in its level (0.544±0.183 ng/ml) after six months of Intra gastric balloon, as presented in figure 1.

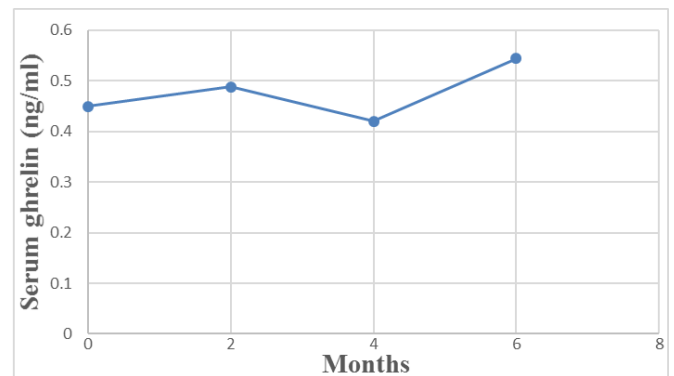


Figure 1: Ghrelin hormone levels in patients underwent Intra gastric balloon pre- and 2, 4 & 6 months post-operative

Finally the mean value of serum leptin after two months (21.275±4.258 ng/ml), four months (17.568±4.021 ng/ml) and six months (18.355±4.034 ng/ml) of Intra gastric balloon was significantly decreased (p= <0.001) compared with the pre-operative mean value (26.222±5.077 ng/ml), as illustrative in figure 2.

Studied parameter	Patients (n = 26)			
	Pre-operative base line Mean ± SD	Two months post-operative Mean ± SD	Four months post-operative Mean ± SD	Six months post-operative Mean ± SD
Body weight (kg)	127.576±33.133	117.192±30.415 p= (<0.001)	107.923±28.906 p= (<0.001)	96.923±26.173 p= (<0.001)
BMI (kg/m ²)	47.176±12.027	43.019±11.135 p= (<0.001)	39.392±10.567 p= (<0.001)	35.465±9.87 p= (<0.001)
Fat percent %	54.073±16.157	48.818±15.475 p= (<0.001)	44.725±14.835 p= (<0.001)	40.02±14.089 p= (<0.001)
EBL %		22.252±13.121	41.622±23.78	63.377±31.276
FBG (mg/dl)	99.769±20.424	89.346±9.995 p= (<0.001)	84.192±6.222 p= (<0.001)	82.192±5.122 p= (<0.001)
HbA1c %	5.67±0.493	5.528±0.511 p= (<0.001)	5.23±0.373 p= (<0.001)	5.157±0.32 p= (<0.001)
Cholesterol (mg/dl)	176.038±48.02	166.807±42.035 p= (<0.001)	159.961±34.167 p= (<0.001)	154.807±29.338 p= (<0.001)
TG (mg/dl)	118.73±33.45	113.038±30.158 p= (0.001)	109.5±27.228 p= (0.001)	104.384±23.351 p= (0.003)
HDL (mg/dl)	33±8.653	34.5±7.156 p= (0.04)	37.23±7.262 p= (<0.001)	39.5±6.772 p= (<0.001)
LDL (mg/dl)	119.346±49.221	109.7±40.977 p= (0.01)	100.83±32.735 p= (0.001)	94.43±28.96 p= (<0.001)
VLDL (mg/dl)	23.746±6.69	22.607±6.031 p= (0.001)	21.9±5.445 p= (0.001)	20.876±4.67 p= (0.003)
Ghrelin (ng/ml)	0.451±0.165	0.488±0.153 p= (<0.001)	0.429±0.15 p= (0.01)	0.544±0.183 p= (<0.001)
Leptin (ng/ml)	26.222±5.077	21.275±4.258 p= (<0.001)	17.568±4.021 p= (<0.001)	18.355±4.034 p= (<0.001)

p: probability level, significant at p < 0.05. BMI Body mass index, EBL% Excess body mass index loss percent, FBG Fasting blood glucose, TG Triglyceride, HDL High density lipoprotein, LDL Low density lipoprotein, VLDL Very low density lipoprotein.

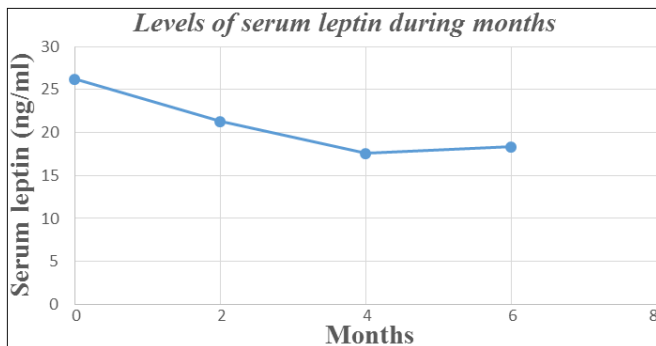


Figure 2: Leptin hormone levels in patients underwent Intra-gastric balloon pre- and 2, 4 & 6 months post-operative.

Leptin was positively correlated with LDL at 2 months of follow up and with Fat percent at 6 months, while negatively correlation was shown with HDL after 4 months of follow up (Table 2).

Table 2: Pearson correlation between leptin and LDL, HDL & Fat % during follow up

		2 Months	4 Months	6 Months
		LDL	HDL	Fat %
LEPTIN	r	0.409	-0.39	0.421
	p	0.038	0.04	0.03

r Pearson correlation coefficient, correlation is significant at the 0.05 level (2-tailed), LDL Low density lipoprotein, HDL High density lipoprotein.

The 6-month treatment with Intra-gastric balloon caused a significant reduction in serum leptin concentration. A decrease in the amount of adipose tissue after balloon application resulted in a diminution of serum leptin level. In clinical studies, a decrease in leptin level was observed after body mass reduction due to diet or bariatric surgery [38], [39].

4. Discussion

The intra-gastric balloon has been shown to be a safe and effective procedure for temporary weight reduction, with low mortality and morbidity [19]. Intra-gastric balloons have played an essential role in the preoperative treatment of morbidly obese patients who are scheduled to undergo bariatric or other elective surgery by minimizing mortality and morbidity risks [20].

The placement of the intra-gastric balloon for 6 months resulted in a statistically significant reduction in body weight. The declining in our weight 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/m² [21]-[23]. Similar results were obtained by others [24]-[26].

The fat percent % decreased on average by 14 during the 6-month period. The loss of body fat is the most important objective of obesity treatment. However, the current decline of fat is often observed. Maintenance of fat-free mass is of particular importance in obesity treatment to minimize the reduction in energy expenditure seen after weight loss. This may be a result of the negative energy balance, lower body weight, and less stimulation for muscle growth in the lower limbs [27]-[29].

In this study we found a positive effect of the Intra-gastric balloon insertion on serum glucose. 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 Intra-gastric balloon were reported in several studies. Sekino describes a decrease in glycated hemoglobin; however, this decrease was not statistically significant [30]. In a 6-month study with Intra-gastric balloon, Konopko-Zubrycka documented a significant decrease in fasting glucose and insulin response [7]. Similar results were seen by Mathus-Vliegen in their randomized study [31]-[33].

In this study we noticed that insertion of Balloon for 6 months caused a significant reduction in serum cholesterol, triglycerides and LDL and there is a significant increase in serum HDL was found. These results are in agreement with those of Konopko-Zubrycka 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 [7].

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 [34].

In our study, plasma leptin significantly decreased, probably reflecting the drop in body fat, whereas plasma ghrelin increased. In a previous study of non-morbidly obese patients treated with intra-gastric balloon, plasma levels of leptin and ghrelin significantly decreased 6 months after balloon insertion [35]. In another study of obese Caucasians receiving balloon, plasma leptin decreased during the first 3 months after balloon placement, then remained stable during 3 months [36]. Yet another study compared subjects with an Intra-gastric balloon placed for 6 months to 15 morbidly obese controls treated with a low-calorie diet. Plasma leptin decreased and plasma ghrelin increased by a third one month after balloon placement, then decreased reaching the starting level 3 months after removal [7]. Overall, during the 6 months with balloon, plasma leptin always decrease, whereas plasma ghrelin peaks during the first 3 months after placement then decreases.

Mion et al. reported the effect of air-filled balloon on weight reduction and ghrelin concentration in nonmorbidly obese patients. The insertion of the balloon resulted in a marked reduction of body weight and increase in plasma ghrelin concentration. The plasma ghrelin rose significantly 1 month after the balloon placement and returned to the initial level 4 months after the placement of the air balloon [35].

In the present study, we observed a similar increase in plasma ghrelin 2 months after the balloon insertion; however the marked decrease of the ghrelin level was observed 4 months after the balloon removal. However, it should be noted that, in experimental studies, the extension of the stomach wall by direct delivery of water to the stomach did not affect ghrelin concentration [36].

The decline in plasma leptin levels was similarly reported in

three studies with the introduction of the intra-gastric balloon in morbidly obese patients [14]. The concentration continued to fall at lesser marginal levels until the end of the study. Furthermore, the decrease in leptin concentrations showed a correlation to the fat percent %. This effect might be ameliorative on obesity-related comorbidities [37].

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