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WIGHT LOSS AND REGAINING WEIGHT, ONE YEAR AFTER INSERTION OF BIOENTERICS INTRAGASTRIC BALLOON VERSUS ATKINS DIET IN AL SULAIMANEYAH PROVINCE-IRAQ

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ABSTRACT: *A variety of effective options exist for the management of overweight and obese patients, including dietary therapy approaches such as low-calorie diets , other options are altering physical activity patterns; behavior therapy techniques, pharmacotherapy , surgery; and combinations of these techniques .Despite these efforts, the prevalence of obesity has doubled in the past 20 years. Any method of weight loss is not optimal and the patients may regain pretreatment weight with time.This work is a trial to compare effects of both Bioenterics intragastric balloon versus Atkins diet on the weight loss and amount of weight may be regained one year after either of these methods. Prospective study, from a total of 180 patients, 80 of them selected over a period of 4 years, included patients divided in to two comparable groups, first treated with insertion of Bioenterics intragastric balloon and the second subjected to modified Atkins diet for 6 months. Body Weight and height were measured with a calibrated scale and a wall-mounted stadiometer while the subjects were wearing light clothing and no shoes at the start and during visit measurements. The collecting data were analyzed using the IBM SPSS (statistical package for social science) statistics version 21. Two comparable groups of obese patients were studied, each group consists of 40 female patients, mean age in group A was 27years (20-39 years) with mean body weight 90 kg (80-100) and mean body mass index 36(31-39.9) who were treated with insertion of Bioenterics intragastric balloon. While mean age in group B was 29 years (20-39 years) with mean body weight 91 kg (80-102) and mean body mass index 36.5 (31-39.9). In group A after completion of the treatment and removal of BIB the at 180 days , mean weight loss was 25 kg (mean BMI 32.3) .At the 360 days in group A, mean BMI was 33.4 and at 540 days was 34 in group. While in group B after completion of the treatment at 180 days , mean weight loss was 13 kg (mean BMI 34.9) ,at the 360 days mean BMI was 36 and mean BMI was 36.5 at 540 days .All patients regained weight and this trend was more evident in group B patients. We conclude that BIB is superior to Atkins diet in early, substantial weight loss and maintaining lost weight after one year from completion of the treatment..*

KEYWORDS: Obesity, Loss of Weight, Bioenterics Intragastric Balloon, Atkins Diet. Bioenterics Intragastric Balloon, Regaining Pretreatment Weight.

INTRODUCTION

WHO defined obesity as a BMI greater than or equal to 30 is, which sub grouped as obesity BMI (= 30-39.9)morbid obesity (= BMI40-50).super morbid obesity when BMI is above 50[1, 2.] Overweight and obesity develops when there is a positive caloric imbalance, and is impacted by genes and the environment [2,3,4].There is more than 1 billion adults throughout the world who are overweight, of these, at least 300 million are considered obese. [5,6,7] Overweight and obesity are associated with social stigmatization and discrimination[5] and numerous comorbidities of great public health concern [5] ,which will increase in all-cause mortality. [8]. A variety of effective options exist for the management of overweight and obese patients, including dietary therapy approaches such as low-calorie diets. [9,10] which produced a great weight loss, [11-13] in a range of 8.3kg and 10.3kg in 2 months and 6 months respectively [7,14,15] .Now more than 10 kg body weight loss considered as responder for any slimming treatment .[16] Other options are altering physical activity patterns; behavior therapy techniques, pharmacotherapy , surgery; and combinations of these techniques .[8] Over the last 30 years the BIB appeared to be safe, provided that it is removed within the period specified by the manufacturer[17].The efficacy of Bioenterics intragastric balloon (BIB) to reduce weight in patients with non-morbid obesity may depend in part on the filling volume.[1,11]. Despite these efforts, the prevalence of obesity has doubled in the past 20 years [6.7] .Any method of weight loss is not optimal and the patients may regain pretreatment weight with time [7, 18, 19]. This work is a trial to compare effects of both BIB and Atkins diet on the weight loss and amount of weight may be regained one year after either of these methods.

PATIENTS, METHODS AND MATERIALS

Prospective cohort study, from a total of 180 patients .80 patients selected over a period of 4 years from 2008 to 2012 in hatwan private hospital and private clinic, the closing date was 1st January 2013. The study approved by Ethics Committee of Medical School, University of Al Sulaimaneyah, all patients signed informed consents on the first interview, before starting the treatment. Included patients divided in to two comparable groups. Group A; 40 obese female patients with mean body weight 90 kg (80-100) and mean Body mass index (BMI) 36 (31-39.9) treated with insertion of Bioenterics intragastric balloon (BIB). Group B; 40 obese female patients with mean body weight 91 kg (80-102) and mean BMI 36.5 (31-39.9), subjected to modified Atkins diet for 6 months, each patient in either group followed up monthly for 18 months. All the patients in both groups were unmarried females with comparable age (20-39 years of age), have BMI 30 to 39.9 .Have neither comorbidity, psychological problems nor previous BIB insertion or any form of bariatric surgery, peptic ulcer diseases and not have binge eating. Others excluded because of their BMI (less than 29.9 or more than 40),patients on

psychological drugs, anti-inflammatory agents, anticoagulants or steroids, alcoholism or drug addiction, and those not committed to the diet were excluded .One patient forced us to remove the BIB on 21st day postinsertion ,because of intractable epigastric pain and vomiting not responding to intravenous (IV) ondansetron 8mg 8 hourly, pantoprazol -40mg , single oral dose_ as proton pump inhibitor (PPI), also excluded , Crohn's disease, hiatus hernia of diameter >5 cm was considered as contraindication. The baseline assessment included medical history, physical examination, anthropometric status (body weight/ height, BMI), blood pressure, electrocardiogram, laboratory diagnostics (complete blood count, coagulation, hepatic profile, renal profile, lipid profile, fasting blood glucose levels, glycosilated hemoglobine—HbA1c, and CRP) and transabdominal ultrasound, upper gastrointestinal endoscopy .While patients in group A subjected also to spirometry, chest radiography.

Body Weight and height were measured with a calibrated scale and a wall-mounted stadiometer while the subjects were wearing light clothing and no shoes at the start and during visits measurements.The BioEnterics Intragastric Balloon (BIB) (Allergan Inc, Irvine, Calif), **CA, USA**.BIB was inserted after checking of upper Gastrointestinal tract by oesophagogastroduodenosccopy (OGD), next the BIB inserted then under sedation (intravenous Medazolm 1mg) with the assistance of an anesthesiology team. The BIB was filled with a volume of 600-ml sterile saline containing 10 ml methylene blue (10%). The position and size of the inserted intragastric balloon was verified by abdominal radiography and ultrasound. All patients were put on intravenous (IV) ondansetron 8mg 8 hourly for first three days and a proton pump inhibitor (Pantoprazole 40 mg, single oral daily dose for first three weeks) for the first four weeks.

Each patient asked to visit as outpatient; the first in 7 days then 14 days, followed later by monthly controls. The balloon was removed after 6 months as recommended by the manufacturer Patients who refused balloon or unable to pay for the balloon insertion and removal (3500 USA$), were told the details about the Atkins Diet. Because of shortage of most of the Atkins foods and formulas here so Atkins meals modified to suit our custom of foods and locality as the following (not to take the following items ;Sugar, sweet foods and fruits, rice, potato and white bread which contains (365,327and 77 kilo calories for each 100gm) respectively [20], allowing just 100 k calorie in the form of one green apple weighing 190 gm). The collecting data were analyzed using the IBM SPSS (statistical package for social science) statistics version 21.
A T- test analysis was made, P values less than 0.05 were considered positive and statistically important

RESULTS

Two comparable groups of obese patients were studied, each group consists of 40 female patients, mean age in group A was 27years (20-39 years) with mean body weight 90 kg (80-100) and

mean BMI 36(31-39.9) who were treated with insertion of BIB. While mean age in group B was 29 years (20-39 years) with mean body weight 91 kg (80-102) and mean BMI 36.5 (31-39.9). They have lost weight in the first 6 month of treatment as shown in table 1 ,with the highest loss of body weight in group A, as 19 (47.5%) of them lost (31-33) kg , while in the group B, only 10 patients (25%) lost 17 kg of their body weight as highest loss of weight. On the first post-treatment measuring (day 180),we found half of the patients in group A, to have substantial weight loss (31-35kg), while three quarter of the patients in group B lost (10-15 kg), and maximal loss of body weight was 17 kg in 3 patients .

Table I; **Extend and number of body weight loss in the patients of both groups A and B after completion of the treatments of 6 months period**

Groups	**Weight loss (10-15 kg)**	**Weight loss (16-20 kg)**	**Weight loss (21-25 kg)**	**Weight loss (26-30 kg)**	**Weight loss (31-35 kg)**
A	4	6	7	4	**19**
B	**30**	10	0	0	0
P value	0.00010 **Significant**		0.00001 **Significant**		

While in day 360 (6 months after completion of the treatments),17(42.50%) of the patients of group A, sustained their weight loss (31-33 kg).But 5 patients in group B, sustained their range of body weight loss, and one patient loss three more kilos of his body weight ,in same time four patients in group B gained 3-5kg . At day 540 (one year after completion of treatments, 4 patients from group A, who lost (31-33kg) of their body weight, have gained (1-4 kg) of weight, at same time 6 patents in group B gained (1-10 kg) body weight.

Table II; Extend and number of body weight loss in the patients of both groups A and B after six months and one year after completion of the treatments

Groups and subgroups		**Weight at 180 days** At the end of the treatment	**Weight at 360days** 6 months after completion of the treatments	**Weight at 540 days** 12 months after completion of the treatments	**P value**
A	**Weight loss (10-15 kg)**	4 (10.00%)	3 (7.50%)	5 (12.50%)	0.00438 **Significant**
	Weight loss (16-20 kg)	6 (15.00%)	8 (20.00%)	7 (17.07%)	
	Weight loss (21-25 kg)	7 (17.07%)	7 (17.07%)	8 (20.00%)	
	Weight loss (26-30 kg)	4 (10.00%)	5 (12.50%)	6 (15.00%)	
	Weight loss (31-35 kg)	**19 (47.50%)**	**17 (42.50%)**	**14 (34,14%)**	
B	**Weight loss (10-15 kg)**	**30 (75.00%)**	**34 (85.00%)**	**40 (100%)**	0.00012 **Significant**
	Weight loss (16-20 kg)	10 (25.00%)	5 (12.50%)	0 (0.00%)	
	Weight loss (21-25 kg)	0 (0.00%)	1 (2.50%)	0 (0.00%)	
	Weight loss (26-30 kg)	0 (0.00%)	0 (0.00%)	0 (0.00%)	
	Weight loss (31-35 kg)	0 (0.00%)	0 (0.00%)	0 (0.00%)	

Maximal weight loss in patients of group A, at 540^{th,} day was 31kg in 13 patients and 32kg in one patients, which means 14 patients sustained their lost weight in a range of (31-32 kg). But maximal loss of weight in group B was (16-20 kg) ,all of them regained weight (7-10 kg), and all descended to group of (10-15 kg loss of body weight),while one patient in group A descended to group of minimal loss of weight.

Table III; Extend and number of maximal body weight loss in the patients of both groups A and B after one year after completion of the treatments

Groups and subgroups		**Maximal Weight at 180 days** 12 months after completion of the treatments	**P value**
A	**Weight loss (31 kg)**	**13 (32.50%)**	0.01754 **significant**
	Weight loss (32 kg)	1 (2.50%)	
	Weight loss (33 kg)	0 (0.00%)	
	Weight loss (34 kg)	0 (0.00%)	
	Weight loss (35 kg)	0 (0.00%)	
B	**Weight loss (10 kg)**	**33 (82.50%)**	0.00097 **significant**
	Weight loss (11 kg)	2 (5.00%)	
	Weight loss (12 kg)	1 (2.50%)	
	Weight loss (13 kg)	1 (2.50%)	
	Weight loss (14 kg)	3 (7.50%)	

Table IV; Extend and number of minimal body weight loss in the patients of both groups A and B after one year after completion of the treatments

Minimal weight loss	**Group A**	**Group B**	**P value**
Weight loss (10 kg)	**0(0.00%)**	**20(50.00%)**	0.02301**significant**
Weight loss (11 kg)	0 (0.00%)	7 (17.07%)	
Weight loss (12 kg)	0 (0.00%)	2 (5.00%)	
Weight loss (13 kg)	1 (2.50%)	11 (27.50%)	
Weight loss (14 kg)	**4 (10.00%)**	**0 (0.00%)**	0.00449 **significant**
Total	**5 (12.50%)**	**40 (100%)**	

In group A after completion of the treatment and removal of BIB the at 180 days , mean weight loss was 25 kg (mean BMI 32.3) .At the 360 days in group A, mean BMI was 33.4 and at 540 days was 34 in group. While in group B after completion of the treatment at 180 days , mean weight loss was 13 kg (mean BMI 34.9) ,at the 360 days mean BMI was 36 and mean BMI was 36.5 at 540 days .All patients regained weight and this trend was more evident in group B patients.

DISCUSION

Initially both groups lost weight as shown in table 1, although the substantial loss was in group of BIB, which was effective in (100%) of the patients ,which is more than Croatian study which revealed effectiveness in 76%, the mean weight loss in our patients was 25 kg (10-33 kg)) also higher than Croatian and Coskun et al. , who show an average weight reduction of 14 kg (range 2–37) .[21] . In group B, the maximal loss of weight 14kg with mean 12 kg which is comparable to a study conclude that weight losses at the end of treatment were 13.1kg.[18].We could explain these differences by the facts that: Distension of "gastric balloons with a volume of_400 ml of fluid reduced food intake" [22] and effective in weight loss, as in a series of studies of Geliebter et al. and Geliebter. [21]. We filled the balloon with 600 ml of the solution, which will cause more gastric distension, more satiety and more weight loss in our patients, who have lost weight substantially [23] and earlier than diet, and those have substantial and early loss [10] on any slimming method will sustain weight for longer period. [4, 10, 22, 24]. Diet group were also responder as they lost more than 10 kg [16] ,but patients in group B ,subjected to diet failed to maintain their lost weight [8] ,may be because of poor adherence and high attrition .[10] . Experience reveals that lost weight usually will be regained, unless a weight maintenance program consisting of dietary therapy was followed [5, 23, 24] but maintenance dietary programs are difficult to sustain over the long term. [4, 7, 25] .A it is not clear that the diet is safe for long period, we advised patients in group B to follow the diet just for 6 months, its effect was temporary and after completion of the period, they started to regain weight. **[7,26]** Our results showed in diet group weight loss (10-14kg) after one year ,and 15% maintained their full end-of-treatment weight losses which was more than a study showed 4.7kg wt loss after 1 year and only 5% maintained their full end-of-treatment weight losses[18]. After BIB there was also regaining of weight, in group A two patients at 360 days regained (1-4 kg) & 5 patients at (540) days regained (3-9 kg), while in group B six patients at 360 days regained (1-10 kg) & 6 patients at (540) days regained (4-12 kg). Subjects treated with BIB lost more weight during the six-month of the study than did those were on modified Atkins diet and most of them maintained their full end of treatment weight loss. We conclude that BIB is superior to Atkins diet in early, substantial weight loss and maintaining lost weight after one year from completion of the treatment.

CONCLUSION

We conclude that BIB is superior to Atkins diet in early, substantial weight loss and maintaining lost weight after one year from completion of the treatment.

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