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Quality of life of the obese patients after treatment with insertion of intragastric BIB balloon versus Atkins diet in Al Sulaimaneyah province-Iraq

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Abstract

Background ; Health related quality of life (HRQOL) is studied widely, after weight loss by insertion of BioEnterics Intragastric Balloon,but quality of life (QOL) not related to the health of the patients is not studied after body weight loss by any means on wide scale.

Aim: To evaluate extend of body weight loss in general and particularly after BIB insertion or Atkins diet and changes of quality of life in the obese patients after body weight loss.

Patients, materials and 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. Each patient in either group followed up monthly for 18 months ,the patients were interviewed before the star and after completion of the treatments to fill the quality of life questionnaire. The collecting data were analyzed using the IBM SPSS (statistical package for social science) statistics version 21.

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).

Statistically important changes occurred in the quality of life of the patients after either method of treatments to different degrees (p value 0.005917)

Conclusion: BioEnterics Intragastric Balloon reduces more weight and BMI in 6 months in comparison to modified Atkins diet, and results in statistically significant improvement of most aspects of quality of life.

Keywords: obesity, quality of life, loss of weight, BioEnterics Intragastric Balloon, Atkins diet. BioEnterics Intragastric Balloon

1.1.INTRODUCTION;

Obesity is a chronic disease and among the most severe health problems worldwide [(1)] its prevalence is dramatically increasing, and this increase represents a leading public health problem [(2)]

According to the World Health Organization (WHO),one billion adults throughout the world are overweight, with a body mass index (BMI in kg/m2) above 25. Of these, at least 300 million are considered obese (BMI 30 and more). [(3)] Obesity is a worldwide problem, affecting every aspect of the life of the patients .obesity has health related problems ,affecting psychological,spiritual,and physical aspects of the life of the patients.[(4)] Weight loss is a major concern ,surveys consistently show that most adults are trying to lose or maintain weight .[(5)] Low-carbohydrate, high-protein, high fat diets have become increasingly popular, and many best-selling diet books have promoted this approach[(6,7)] The Atkins diet, originally published in 1973 and again in 1992 and 2002, may be the most popular of these diets.[(8)] In the literature the low-carbohydrate diet produced a greater weight loss than did the conventional diet for the first six months.[(9)]

Another option is the implantation of Bioenterics intragastric balloon (BIB) which is a quite popular worldwide, and relatively new method for treating obesity. [(1)] The rationale behind the introduction of a new procedure should rely on the possibility of achieving the weight loss with the consequences of improvement in obesity-related co morbid conditions and quality of life while reducing the complexity of surgery and the inherent immediate and long-term complications. [(10)] Since 1998, the new intragastric balloon (BioEnterics Intragastric Balloon, BIB) was adopted for temporary use for weight loss. The BIB has the characteristics of an “ideal gastric balloon”. [(9)] The BIB can be an important tool for obtaining weight loss in patients whose obesity is not severe enough to warrant surgery. [(11)]

Health related quality of life (HRQOL) is studied widely [(12-18)], after weight loss by insertion of BIB, but quality of life (QOL) not related to the health of the patients is not studied on wide scale. [(1,19,20)] The QOL Scoring is a valid instrument for measuring quality of life across patient groups and cultures and is conceptually distinct from health status or other causal indicators of quality of life.[(4)]

To which extend weight loss in general and particularly after BIB insertion or Atkins diet will improve quality

of life in the obese patients? , we are trying to answer this question. How much obesity will affect different aspects of life, how if they lost weight how much their QOL will changes for better and healthier life?

1.2.PATIENTS, MATERIALS and METHODS;

Prospective study, from a total of 180 patients, 80 of them selected over a period of 4 years from 2008 to 2012 in hatwan ptivate hospital and private clinic, The closing date was 1st January 2013.
The study approved by Ethics Committee of Medical School, University of Sulaimani, all patients signed informed consents on the first interview, for filling the QOL questionnaire .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
These groups are arranged according to following criteria
Inclusion criteria;

1. Unmarried
2. Has no comorbidity
3. Has no psychological problems or on psychotrophic drugs
4. Female
5. No previous IGB insersion or any form of bariatric surgery
6. Has no peptic ulcer diseases
7. Patients not have binge eating
8. Those with BMI 30 to 39.9
9. From age 20-40

Others excluded because of patients with BMI less than 29.9 more than 40,patients on steroid,
Patients on drugs,has previous BIB or bariatric surgery, those have peptic ulcer disease and those not commited to the diet , One lady who 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), was also excluded , those ladies married and got pregnant ,and those with Crohn's disease, patients on anti-inflammatory agents, anticoagulants or steroids, alcoholism or drug addiction. A hiatus hernia of diameter >5 cm was considered a 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**. First upper Gastrointestinal tract checked by oesophagogastroduodenosccopy (OGD) ,then BIB was inserted 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 (Lansoprazole 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
Any patient refused balloon or unable to pay for the balloon insertion and removal (3500 USA$), 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 patients and locality as the following
(not to take the following items ;Sugar, sweet foods and fruits, rice, potato and white bread, 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

1.3. 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 33 kg P value 0.00001) , while in the group B, only 10 patients (25%) lost 17 kg of their body weight as highest loss of weight(P value 0.00010).

From questionnaire filled by interview with each patient before starting the treatment

Most of the patients admitted that they took one outdoor meal per week and minority row meals in a week look to table 2, all are literate from 12th class to whom owing PhD

All the patients admitted the importance to lose weight and have better body shape

, while about two third claimed that it is important to have regular exercise, regular sexual activity, one third to be sexually attractive.

Large number of the patients were embarrassed by prompt discussions in the family because of being obese and jokes and sarcasm and teasing from others they face daily, also embraced by unimportant matters, becoming more apprehensive and three quarter were afraid from what they hear and see from mass media about risks of obesity how their weight and sight became an obstacle for obtaining the job they like and obstacle for success in their jobs, table 3.

All the patients admitted that their obesity narrowed their social circle. Most felt that they have less opportunity to spend time with friends, felt uneasy to show their body in swimming, sports and sex as shown in table 4..

About three quarter were shy ,feeling lonely ,have negative self thoughts, one patient in group A attempt unsuccessful suicide and three patients in group B had suicidal thoughts,

After 6 months from treatment with BIB or treatment with modified Atkins diet, table 6, we interviewed every patient to fill the 2nd questionnaire, about changes in his quality of life after the treatment and losing weight

All patients in group A who treated by BIB and lost greater body weight than patients in group B admitted that they feel happy, sexually attractive, have more regular exercise and sex ,and their self esteem was noticeably improved and their satiety significantly decreased

While all patients in group A and B said that they hear no more jokes, sarcasm on them and not teased by others, table 6.

We compared the most changed aspects of QOL in patients treated with BIB , (group A) with those patients treated with modified Atkins diet (group B), which show statistically important changes in (group A) ,table 7.

1.4. DISCUSION:

The patients in both group A and B, were interviewed for filling QOL questionnaire

Before and after completion of their 6 month treatments ,"studies demonstrated that measurements based on clinical interview have greater diagnostic accuracy than self-administered questionnaires" .[11]

In modifying Atkins diet, to suite our custom of food and available foods in our locality, we abandoned these items beside sugar, for their high calorie and carbohydrate content; rice, white bread and potato, which contains (365,327and 77 kilo calories for each 100gm) respectively. [21]

Sweet foods also abandoned because of their contents of sucrose, glucose or fructose [22,23,24]which all increases energy intake [24] and increases lipid metabolism [25] and finally

increases weight [24,26,27],and reduction in added sugar is one means to achieve reduction in energy density. [26]

Fruit and Fructose cause obesity [23] and significantly alter hepatic insulin sensitivity and lipid metabolism compared with similar amounts of glucose. [22] Fructose as it is not stimulates insulin secretion from beta cells and this lead to increased caloric intake and obesity. [23]

Our allowance for energy from carbohydrate was 100kcal equal to a content of 190gm apple. [27] WHO has suggested that added sugars should provide no more than 10% of dietary energy (28)

and a prudent upper limit of intake is half of the discretionary calorie allowance, which for most American women is no more than 100 calories per day and for most American men is no more than 150 calories per day from added sugars. [26,29]

Mechanism of action of BIB is similar to that of gastric restrictive operations, i.e. a reduction in gastric volume [30,31], which will be available for food intake , Gastric filling is even a required condition for the satiating effect of CCK [32].

Even if BIB filled with a volume of (400 mL) it will reduce food intake [33] ,but we filled the balloon with 600cc, [9,30] saline containing 10cc of 10% methyline blue .To obtain maximal weight loss without complications like epigatric pain and severe nausea and vomiting , as rationale in treating obesity must be "the achieving the

weight loss while reducing the complexity of surgery and the inherent immediate and long-term complications" . [10] This volume of the balloon will cause more stomach distension, wich will increase release of Leptin [33] , CCk [32] , and reduces the secretion of Ghrelin, [33] which are associated with subjective hunger ratingsand with lower food intake. [32]

Although QOL improved in both groups A & B, the results reinforce the benefit of BIB over Atkins in improving the different aspects of QOL. Finding showed that in all patients(100%)of group A admitted happiness and satisfaction with the results, their self esteem improved noticeably, felt their self sexually attractive ,have more regular sex(P value 0.0113772) and exercises(P value 0.0113772), and their satiety well diminished(P value 0.0143772) . While (62.5-92.5%) from group B felt this way.

Only in two aspects all the patients from group B like group A , improved significantly ,these are feeling of sexually attractive and no more hearing of jokes and sarcasm and teasing from others .

We could explain these differences, patients in group A lost substantial weight(P value0.00001) , as" patients with minor weight loss are less positive" [34] for improvement in QOL. Weight loss appears to profoundly enhance health related QOL ([35], long lasting weight loss improves health related QOL in majority of the patients subjected to weight loss treatments,[36,37]this result is in parallel with other study [38],the author found the primary outcome as changes in overall QOL, the peak improvement in weight and QOL were noted after 6 months and one year from the starting of the treatments. [39]This may declare that the 6 to 12 months may be enough for any sliming treatments before evaluation the extend of weight loss and its effect on QOL, as we scheduled our groups of patients.

Pretreatment psychological aspects, may not related to BMI of the patients [40-42]

Our results correlated lowering of BMI after the treatment, with improvements in QOL, which is in line with other studies. [38, 39, 43]

One of these changes in both groups but for different levels is satiety, which was measured by " two ways ,asking the patient to answer subjectively and amount of food taken in each meal" , which is in line of a study[33],we noticed the different level of satiety between patients of group A (100% so much decrease)versus patients of group(62.5% so much decrease) (p value 0.0000).we could explain this ,because of stomach distension and presence of BIB in the stomach ,all the patients in group A have decrease the appetite (so much). There is no thesis in the litreture as long as we searched for, comparing satiety between similar groups to our groups , but there is a study comparing BIB + diet to Diet alone regarding amount of weight loss ,but not QOL [9],while the changes in QOL in psychological ,sexual and self esteem, in group A is much higher than group B and a study by Y. Mart . [38]

BIB reduces more weight and BMI in 6 months in comparison to modified Atkins diet, and results in statistically significant improvement of most aspects of QOL.

CONCLUSION:

BIB reduces more weight and BMI in 6 months in comparison to modified Atkins diet, and results in statistically significant improvement of most aspects of QOL.

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

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		

Table II ; general aspects of QOL of the obese patients in both groups A and B before starting the treatments

General aspects of QOL	Scoring							
	Not at all		Just a little		Not so much		much	
Groups	A	B	A	B	A	B	A	B
importance of regular exercise	8	9	15	13	1	3	26	25
importance of regular sexual activity	0	0	5	4	4	4	31	32
importance to be sexually attractive	2	2	18	10	3	12	17	16
sleepiness	6	6	0	3	7	6	37	27
shortness of breath on minimal exertion	5	6	0	5	7	5	28	24
excessive sweating	2	5	8	5	1	0	29	30
important to lose weight	0	0	0	0	0	0	40	40
importance to have better body shape	0	0	0	0	0	0	40	40

Table III ; Psychological aspects of QOL of the obese patients in both groups A and B before starting the treatments

Self esteem aspects of QOL	Scoring							
	Not at all		Just a little		Not so much		much	
Groups	A	B	A	B	A	B	A	B
shyness	0	0	2	1	8	8	30	31
Introversion (Lonliness)	2	3	4	5	4	5	27	30
Negative self opinion	1	2	2	2	2	1	35	35
Self trust in achieving things	25	27	10	9	4	4	1	0
Suicidal thinking	35	37	4	2	1	1	0	0
Suicidal attempts	39	40	0	0	0	0	1	0

Table IV ; Social and spiritual aspects of QOL of the obese patients in both groups A and B before starting the treatments

General aspects of QOL	Scoring							
	Not at all		Just a little		Not so much		much	
Groups	A	B	A	B	A	B	A	B
Embarrassed by prompt discussions in the family	0	1	0	0	7	6	33	33
Embarrassed by jokes and sarcasm and teasing from others	1	1	0	1	0	0	39	38
Afraid from what they hear and see from mass media	2	4	3	3	7	3	28	30
Weight and sight became an obstacle for obtaining the job they like	3	3	5	4	6	4	26	29
weight and sight became an obstacle for success in their jobs	1	2	0	7	9	0	30	31
Embraced by unimportant matters	0	0	0	0	0	0	40	40
Becoming more apprehensive	0	4	10	3	0	5	30	28

Table V ; Self esteem aspects of QOL of the obese patients in both groups A and B before starting the treatments

Social and spiritual aspects of QOL	Scoring							
	Not at all		Just a little		Not so much		much	
Groups	A	B	A	B	A	B	A	B
Feeling sad	0	1	0	1	1	1	39	37
Feeling uneasy in showing their bodies	1	1	3	2	1	2	35	35
Body weight narrowed their social circle	0	0	0	0	0	0	40	40
Decreased opportunity for spending time with friends.	0	0	0	0	0	0	38	38

Table VI ; Aspects of QOL of the obese patients in both groups A and B after completion of the treatments

Aspects of QOL	Scoring							
	Not at all		Just a little		Not so much		much	
Groups	A	B	A	B	A	B	A	B
Feeling happy	0	0	0	0	0	7	40	33
Satisfaction with the new body image	0	3	0	6	1	1	39	30
Improved Self esteem	0	1	0	0	0	2	40	37
Feeling of Sexually attractive	0	0	0	0	0	0	40	40
Have better or more regular sex	0	0	0	3	0	3	40	34
Have better or more regular exercise	0	0	0	2	0	4	40	34
Spending more time with friends	0	0	0	2	2	3	38	35
Nervousness, embracing by unimportant matters	38	33	1	2	1	2	0	3
Hearing sarcasm or teasing by others	40	36	0	1	0	3	0	0
Negative thoughts	39	34	1	1	0	1	0	4
Satiety decreased	0	0	0	13	0	2	40	25

Table VII; Comparison the highest respond reflecting changes QOL of the obese patients in both groups A and B after completion of the treatments

Aspects of QOL	Comparison by highest respond		P value	
	Group A Who answered by much	**Group B** Who answered by much		
Feeling happy	40	33	**0.005917**	significant
Satisfaction with the new body image	39	30	**0.0036889**	significant
Improved Self esteem	40	37	**0.079362**	
Feeling of Sexually attractive	40	40	**0.4936709**	
Have better or more regular sex	40	34	**0.0113772**	significant
Have better or more regular exercise	40	34	**0.0113772**	significant
Spending more time with friends	38	35	**0.0217377**	significant
Nervousness, embracing by unimportant matters	0	3	**0.079362**	
Hearing sarcasm or teasing by others	0	0	**0.4936709**	
Negative thoughts	0	4	**0.0414411**	
Satiety decreased	40	25	**0.0143772**	significant