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Research Paper

Comparative Study between Intragastric Balloon and Low-Calorie Diet Regimen for Iraqi Obese Patients

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ABSTRACT:

BACKGROUND:

Obesity is an epidemic health problem and the use of intra gastric balloon emerge as a noninvasive and effective treatment option.

OBJECTIVE:

To compare the effect of intra gastric balloon and low-calorie diet on weight loss.

PATIENTS AND METHODS:

During the period (June 2019 till July 2020) 80 consecutive obese patient divided into 2 groups one treated with low calorie diet and the second with intra gastric balloon and low-calorie diet; their weight loss assessed during 1st,3rd, and 6th months interval and comparison between both group analyzed.

RESULTS:

Mean weight loss in IGB in 1st, 3rd, 6th months were 6.8, 13, 18,2 kg while low calorie diet group weight loss were 5.6, 9.8, 11,6 kg and this is statistically significant. BMI lost in the IGB was 7 kg\m2 which is better than low calorie diet where BMI lost was 4.5 kg\m2.

CONCLUSION:

IGB is more effective weight loss procedure than low calorie diet only.

KEYWORDS: Obesity, Diet, Intra gastric balloon, weight loss.

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INTRODUCTION:

Obesity is a major health problem as it is associated with type 2 diabetes, hypertension, cardiovascular diseases, stroke and increased incidence of certain cancers, notably cancers of rectum, colon, prostate, breast, uterus ,and cervix and now there is a global epidemic of obesity [1,2].

In Iraq about two third of population were obese [3] and there are many treatment options for obesity consists of dieting and physical exercise which is difficult to achieved and maintained while the use of medicine like orlistat, results in not more than 10% excess weight loss (EWL) over placebo [4].

The most effective and long-term treatment for obesity and related disease is bariatric surgery which includes laparoscopic adjustable gastric banding (LAGB), Roux-en-Y gastric bypass, laparoscopic sleeve gastrectomy (LSG), and biliopancreatic diversion (BPD) and these procedures cause more than 50% EWL with decreased overall mortality [4].

Intragastric balloons (IGB) may be an option for obese patients with weight loss failure and it fill the gap between surgery and diet. It acts by enhancing meal suppression of ghrelin hormone secretion by the gastric fundus through balloon contact and balloon-induced delayed gastric emptying; these when combined with healthy diet regiment and behavioral modifications cause weight loss [5].

Low calorie diet includes 800-1500 calories while very low-calorie diet (less than 800 calories) effects balance of food from different food groups [6].

AIM OF STUDY:

To compare the safety and effectiveness between intragastric balloon and low-calorie diet regimen in weight reduction.

PATIENTS AND METHODS:

This is a prospective case series study conducted in Al-Rasool and PAR private hospitals in Erbil during a period between June 2019 till July 2020 with 6 months follow up and involved 80 consequent obese patients divided into 2 groups:

Group (A): 40 patients (26 females and 14 males); their age range between 14-67(average 40); their weight 78-168 (average 102) and their BMI 30-61(average 39 kg /m^2) treated with low calorie diet regimen and physical exercise.

Group (B): 40 patients (28 females and 12 males); their age range between 17-62 (average 39) and their weight 79-174 kg (average 100.7) and their BMI 31.05-60.21(average37.8 kg /m^2) treated with Intra gastric balloon and low-calorie diet regimen and physical exercise.

Intervention: Diagnostic OGD followed by insertion of IGB (a set of silicone devices for gastric filled with 500-650 ml of 0.9 % NaCl solution colored with 2 ml (for 500 ml of NaCl solution) methylene blue (0.1% solution of methylene blue Outcome Measures: The parameters that were used to assess the outcome are body weight and weight loss ,body mass index, percentage excess weight loss (%EWL) which was assessed in 1st ,3rd ,6th months interval and statistical analysis performed by GraphPad software to calculate t-test and P-value.

RESULTS:

Table 1: Demographic characters of patients in both groups.

Patients	IGB	Diets
Total patient number	40	40
Age	17-62(39)	14-67(40)
Gender	28 females,12 males	26 females,14 males
Weight in Kg	79-174(100.75)	78-168(102)
Height in meter	1.49-1.78(1.63)	1.47-1.8(1.62)
BMI	31.05-60.21(37.8)	30.1-61.7(39.06)
Excess weight	20-104(37.7)	17-103(40)
Comorbidities		
Orthopaedic problems	14	12
D.M.	7	4
Hypertension	13	9
Dyslipidemia	13	11
Respiratory problem	2	1
Hormone disturbance	3	1

The weight loss in patients with IGB was 6.8 ,13,18.2 kg in 1st ,3rd ,6th months interval while in diet 5.6,9.8,11.6 kg as shown in figure (1)

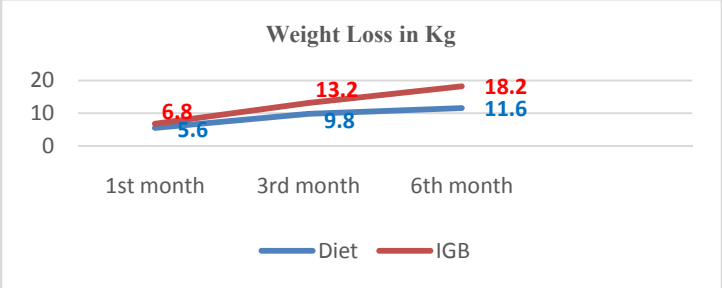

Figure (1)

The BMI reduced from 37.8 to 35.1,32.7,30.8 in 1st ,3rd and 6th months interval respectively in IGB group while in diet only group reduced from 39.06 to 36.86, 35.29, 34.58 in 1st, 3rd and 6th months interval respectively as shown in figure (2).

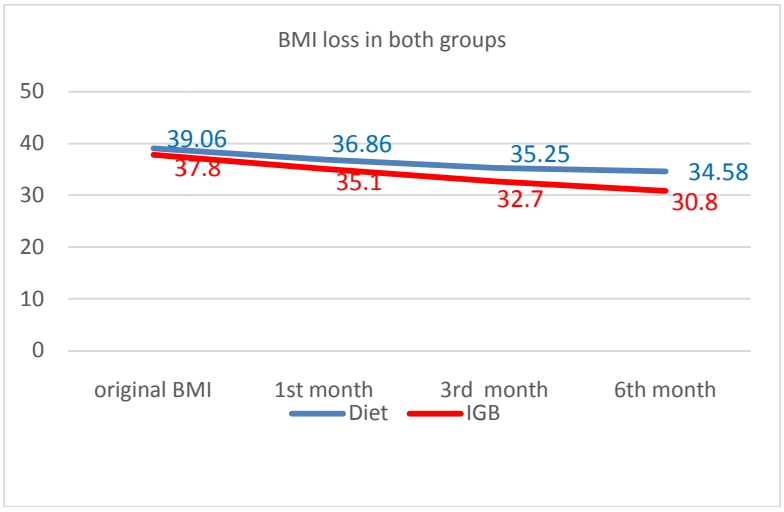

Figure (1)

Table 2: Shows the parameters used to assess weight loss.

Parameters of weight loss	Diet	IGB	T test	P value
Weight loss in Kg				
1 month	2-12(5.6)	4-13(6.8)	3.09	0.0037
3 months	5-17(9.8)	6-22(13.2)	4.74	0.0001
6 months	1-27(11.6)	3-47(18.2)	4.99	0.0001
Percentage of excess weight loss (%EWL)				
1 month	5.7-23.8(14.8)	10.9-27.2(18.8)	4.26	0.0001
3 months	14.2-0.5(26.4)	20.3-58(36.3)	5.04	0.0001
6 months	3.4-58.8(30.7)	10.3-87.1(49.3)	7.11	0.0001
BMI lost after treatment	4.5	7		

The associated co morbidity resolved or improved after weight loss as shown in figure 3.

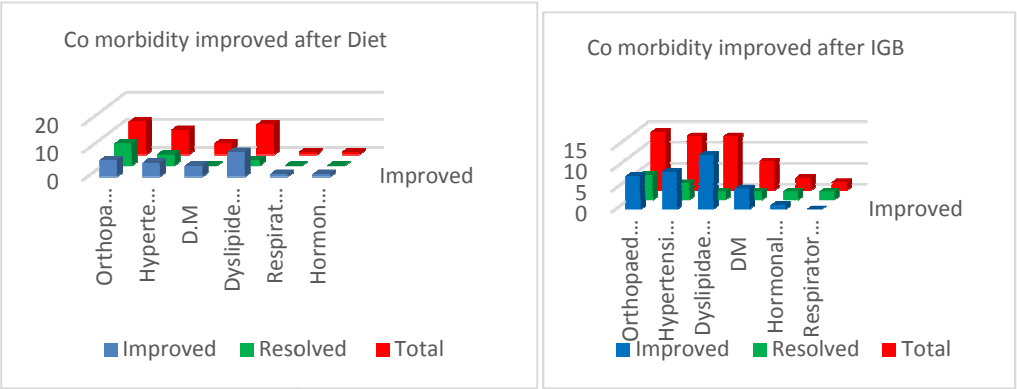

Figure (3)

Morbidity and Mortality

No cases of mortality recorded in both groups nor life threatening complication regarding IGB; while most patients complain from abdominal pain, nausea and vomiting that settled after 4-6 days; 1 patient have vomiting till 9 days.

Mild complain of constipation occurred in both groups and 5 out of 40 in IGB group (12.5%) complain from hair falls.

Six months follow up

On 6 months follow up group (A) shows that 16 patients (40%) regain their weight while group (B)28 patients (70%) regain weight and long term follow up is required to assess the results of both treatment modalities.

DISCUSSION:

Intra gastric balloon is an effective adjuvant device for weight reduction in compare to low calorie diet regimen alone. Mean weight loss in IGB in 1st, 3rd, 6th months were 6.8, 13, 18,2 kg while low calorie diet group weight loss were 5.6, 9.8, 11,6 kg and this is statistically significant with a P-value 0.0001 ; BMI lost in the IGB was 7 kg\m^2 which is better than low calorie diet where BMI lost was 4.5 kg\m^2 so the IGB is more effective than diet.

Although most patients complaining of some sorts of abdominal pain, nausea and vomiting but there was a good improvement in the comorbidities that present prior to the procedures (orthopedics problems, DM, dyslipidemia) and this reflected as improvement in the quality of life.

This study shows that after intragastric balloon implantation in overweight or obese individuals, mean weight loss was 18.2Kg in the 40 individuals in 6 months which is better in compared to those previously reported by sallet JA[7], Herve J[8], Doldi SB[9] and Genco A[10] with the use of BioEnterics intragastric balloon(BIB) who mention a weight loss 12-15.2(average 12.6 kg)also the weight loss is better than Hosam Ghonneim , Al Momen A, El Mogy who shows a mean weight loss of 15.5 kg while [11] .BMI loss in this study are higher than the result of Rajiv Baijal [12]which mention a mean BMI loss of 4.2kg\m^2.

In our study IGB patients lose 49.3% of their excess body weight which is better than that of American society for metabolic and bariatric surgery (ASMBS) where results show 28.5 % lost from excess body weight. [13].

Our result also less than that of Al Momen A, El Mogy [14] which shows mean weight loss of 13 kg. And less than that result of Carbonelli MG, Fusco MA. [15] and Evans JD, Scott MH. [16] which show mean Wt. Loss of 15 kg in 6 months, and less than of Totte E, Hendrickx L. [17] with result of mean Wt. Loss 15,3 kg. And less than Matheus-Vliegen EM, Tytgat GN. [18] where Wt. Loss was 16.7 kg.

Our results were better than that of Hodson RM, Zacharoulis D.[19] Which gave mean Wt. Loss 10.4 kg.

These comparable results in weight reduction and the differences among them could be related to poor compliance of the patients, poor attendance for dietary advice, don't follow the instructions of their diet, the environments and locations that they live in, poor Contact with the Dietitian specialist in addition to patient IQ that differs from one to other and the socio-economic status for patients.

Short-term weight loss might have been higher with more frequent encounters with the dietician (e.g., weekly rather than monthly scheduled visits).

CONCLUSION:

Intragastric balloon therapy was relatively safe procedure and associated with successful weight loss and maintenance at 6 months in compared to low calorie diet regimen, it represents a good option for weight loss.

Ethical consideration

Approvals were obtained from the Arab Board of Health Specialization; also, approval from the local ethical committee obtained and all patients accepted to participate in this study.

Statistical analysis

All the data has been edited, processed and analysed by the use of statistical software package graphpad. A p-value $\leq$ 0.5 was considered statistically significant.

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