

THE WEIGHT-REDUCING EFFECT OF ENDOSCOPICALLY – INSERTED INTRAGASTRIC BALLOONS FOR OBESE PATIENTS FAILED WEIGHT CONTROL WITH LIFESTYLE MODIFICATION AND DRUGS



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ABSTRACT

Background

The Food and Drug Administration (FDA) recently approved three intragastric balloons (IGB) devices, ReShape, ORBERA™, and Obalon, for treating obesity. Given the high cost, complication risk, and invasiveness of bariatric surgery, IGB treatment may present a safer and lower-cost option for weight reduction. IGBs are generally placed in the stomach endoscopically for up to 6 months to reduce gastric capacity, enhance feelings of fullness, and induce weight loss. The mechanism of action likely involves stimulation of gastric mechanoreceptors triggering short-acting vagal signals to brain regions implicated in satiety. Balloon efficacy may be influenced by balloon volume, patient gastric capacity, and treatment duration.

Objectives

To evaluate the efficacy, tolerability, and safety of intra-gastric balloons on weight reduction versus obese patients' failed weight controlled by dietary changes and drugs.

Methods

A retrospective study was performed in Sulaimani City from 2017 to Feb./2018. We included 40 obese patients by the World Health Organization (WHO) definition of BMI \geq 30. The subjects aged 18-68 years with intra-gastric balloons were inserted by endoscopy for 4-9 months. Anthropometric measurements were obtained before, during and after the removal of intra-gastric balloons.

Results

In total, 40 cases of obese patients, 21 (52.5%) females and 19 (47.5%) males. The mean age was 37.1 \pm 11.70 years with a range of 18-68 years. BMI and weight significantly reduced early 3-month mean weight 12.78 \pm 2.81 Kg, and late 6-month mean weight 9.05 \pm 1.89 Kg and around 21 Kgs at removal. Only one patient was the IGB removed early by four months and was not included. Late one year after IGB removal, the long-term effect on BMI and weight were recorded and maintained in most persons.

Conclusion

Intragastric balloon (IGB) was effective in our study. The observed weight reduction was maintained through 1 year after removal & IGB appeared safe and tolerable & satisfactory for most obese subjects.

Keywords: *Intragastric balloon, Obesity, Weight reduction, Body mass index.*

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INTRODUCTION

Obesity is a BMI greater than or equal to 30 ^(1,2). Obesity is a global health problem with high morbidity and mortality ^(3,4). The prevalence of overweight and obesity is increasing worldwide. High body mass index is a risk factor for an expanding set of chronic diseases, including cardiovascular disease, diabetes mellitus, chronic kidney disease, many cancers, and various musculoskeletal disorders. ⁽⁵⁾and associated with impaired quality of life, impaired physical functioning, and increased health care costs ^(1,6) High-risk morbid obese patients defined by super obesity (SO), BMI=50kg/m² ⁽⁷⁾.

The Evaluation and assessment of obese patients should include the history of weight gain, the maximum body weight, review of medications that may contribute to weight gain (e.g., corticosteroids, thiazolidinedione's, and antipsychotic agents), previous approaches to weight reduction, patterns of food intake (including binge eating), and physical activity. The patient's readiness for weight reduction should also be addressed, as it is important in weight reduction success rates ⁽⁸⁾. Waist circumference is also useful for intra-abdominal and upper-body subcutaneous adipose tissue. Some guidelines include it as a risk marker in addition to or instead of the BMI ⁽⁹⁾.

Advanced cases of obesity require surgical interventions with drastic lifestyle modifications. Alternatively, mild to moderately obese subjects can achieve 5%-10% weight loss through exercise and dietary changes ⁽¹⁰⁾. However, the weight gain recurs at high rates. Further, pharmacological agents only have more benefits than dietary and exercise programs. The therapeutic or lifestyle management of obesity is a long-term and problematic undertaking. Literature shows that long-term treatments, dietary regimens and weight-loss programs following pharmacotherapy remain largely ineffective ⁽¹¹⁾.

Further, conservative treatment is ineffective. In morbid obesity (BMI \geq 40 kg/m²)⁽¹²⁾, while bariatric surgery remains the only option with promising long-term results. However, for subjects unwilling to consent for or do not qualify for bariatric surgery or are contraindicated to surgery, endoscopic bariatric procedures such as intra-gastric balloons are the best possible alternative as a bridge to surgical interventions ⁽¹³⁾. There are three broad categories of bariatric surgical procedures: ⁽¹⁾ pure gastric restriction; ⁽²⁾ gastric restriction with some malabsorption, as represented

by the Roux-en-Y gastric bypass (RYGB) procedure; and ⁽³⁾ gastric restriction with significant intestinal malabsorption ⁽¹⁴⁾. Intra-gastric Balloon (IGB) is one of the currently available strategies for weight loss with significant results in a short period.

The IGB is placed in the stomach using endoscopy and left for six months. Therefore, most of the information on the efficacy and safety of this device is limited to a short period ⁽¹⁵⁾. The intra-gastric balloon is a space-occupying device that takes up gastric volume. There are multiple proposed mechanisms of action, including delayed gastric emptying and hormonal changes. Contraindications to intra-gastric balloon placement include a history of gastrointestinal surgery, clotting or bleeding disorders, pregnancy, and a large hiatus hernia. Once the balloon is removed six months after insertion, the diet and lifestyle program should continue for another 6 months ⁽¹⁶⁾.

Historically, intragastric balloons have required endoscopy and sedation. In addition, the oesophagus and stomach were typically assessed for contraindications with a prior screening endoscopy or concomitant-to-device placement. However, endoscopy still has mild risks in obese patients ⁽¹⁷⁾. The history of intra-gastric balloons (IGBs) began in 1985 with the Garren-Edwards Bubble. It was approved by the US Food and Drug Administration (FDA) for temporary use as a weight loss device ⁽¹⁸⁾. Three IGBs are FDA-approved and commercially available in the USA (Orbera, ReShape Duo, and Obalon) ^(3,19).

PATIENTS AND METHODS

The scientific and ethical committee of the Iraqi Board for Medical Specializations approved the study. Consent was taken verbally from all patients. This retrospective study was conducted from May 2017-Feb to 2018. In forty patients with classes I, II, and III obesity, the intragastric balloon was placed in the stomach by the same endoscopist. Women and men were included, with ages 18-68 years, with a minimum BMI of 31 kg/m². Most of them were free from medical comorbidities such as hypertension, diabetes, hyperlipidemia and the musculoskeletal problem like back pain and osteoarthritis. All had failed trials of lifestyle modifications, including diet & physical activities. The baseline characteristics of the subjects, Table 1.

Inclusion criteria included Obese patients with classes I, II, and III diagnosed as obese by BMI calculation

who had failed dieting, exercise and pharmacotherapy.

Exclusion criteria included pregnant patients, Congestive heart failure, previous gastric operation, Super obese patients whose BMI \geq 50, bleeding disorder, and large hiatus hernia.

Statistical analysis

The data were analysed using the SPSS version 21. Frequency and percentages of the data were calculated, and numerical variables were expressed as mean \pm standard deviation. One sample T-test and T independent student test were used to find the relation between the continuous variables; the significance level was considered if $p \leq 0.05$.

RESULTS

A total of forty patients with three classes of obesity were included in this study, all patients were obese and not overweight, and none of them was super obese with BMI \geq 50. An intragastric balloon was inserted (92.5%) and removed after the completion of the recommended time of 6 months. Only one subject, 50 years female, the balloon was removed earlier at four months because of migration of the balloon and was removed without uneventful complication. Two subjects remained beyond the time of treatment duration of the balloon, Table 2.

Most complications were simple, like epigastric pain, vomiting, and heartburn, and subsided with time. Only one balloon patient migration had occurred, Table 3. The volume of the balloon, mean volume 650.25 \pm 15.44 ml, and the types of balloons, Table 4.

Three subjects (7.5%) were diabetic, and their baseline HbA1c was documented; after the removal of the balloon, there was a significant decline in their results, The changes of Blood pressure and Lipid profile are illustrated in Table 5.

Regarding the weight reduction effect during the early three months of balloon insertion, the weight reduced between 8-20 kg mean body weight loss (12.78 \pm 2.81) kg, then after six months of balloon insertion, minimum weight loss is 4kg while maximum weight loss is 11 kg mean weight loss (9.05 \pm 1.89) kg. Then six months after balloon removal, with follow-up after one year of balloon removal, revealed significant weight reduction among both gender groups, Table 6, Table 7.

The different BMI changes among women and men groups after six months of balloon removal, BMI ranges between 3.29-11.39 kg/m² the changes, Table 8.

Table1. The baseline characteristics of the subjects (n=40) included intragastric balloon therapy.

Characteristics	Average (mean \pm SD)	Range
Age (yrs.)	37.1 \pm 11.7	18-64
Female (%)	52.5	
Male (%)	47.5	
Body weight (Kg)	99.5 \pm 5.22	89-112
Mean Height (cm)	1.67 \pm 0.07	1.5-1.82
Mean BMI (kg/m ²)	35.67 \pm 2.70	31-44
Residency		
Inside Sulaimani	70 %	
Outside Sulaimani	30%	

Table 2. Duration of balloon remaining in place.

Number	Time (months)	Percent
1	4	2.5
8	6	20.0
19	7	47.5
10	8	25.0
2	9	5.0
Total 40		100.0

Table 3. The list of complications.

Complication	Number	Percent
Pain, vomiting	2	5.0
Pain, vomiting, peptic ulcer	1	2.5
Pain, vomiting, heartburn	26	65.0
Pain, vomiting, heartburn, hematemesis	3	7.5
Pain, vomiting, heartburn, peptic ulcer	7	17.5
Pain, vomiting, migration, peptic ulcer, deflation	1	2.5
Total	40	100.0

Table 4. The Types of balloons.

Types	Frequency	Percent
Orbera	25	62.5
Heliosphere	15	37.5

Table 5. shows the results of BP, HbA1c, TG, Cholesterol changes.

Characteristics	Mean \pm SD before	Mean \pm SD after IGB	P. value
Mean Blood Pressure			
Systolic (mm Hg)	164.00 \pm 5.47	138.0 \pm 4.47	<.001
Diastolic (mm Hg)	94.0 \pm 5.47	82.0 \pm 4.47	<.001
Mean HbA1c %	9.67 \pm 0.57	6.67 \pm 0.33	<0.002
Mean TG mg/ dL	525.56 \pm 101.25	241.11 \pm 60.3	<.001
Mean Cholesterol mg/ dL	330.0 \pm 24.49	212.50 \pm 29.86	<0.001

Table 6. weight changes before balloon and after removal.

Weight	Mean \pm SD	P-value
Mean weight (kg)	99.50 \pm 5.22	
Mean Weight 6 Months after removal	77.68 \pm 7.01	< 0.001
Mean Weight one year after removal	80.05 \pm 7.25	< 0.001

Table 7. Comparison between male and female groups reveals changes in weight reduction.

Sex	N	Mean	SD	P. value
Mean Weight				
Male	19	100.89	5.70	< 0.066
Female	21	98.24	4.51	
Weight six months After removal				
Male	19	79.11	8.31	< 0.078
Female	21	76.38	5.47	
Weight one year After removal				
Male	19	82.32	8.62	< 0.023
Female	21	77.90	4.97	

Table 8. BMI Difference between males and females after six months.

	sex	N	Mean kg/m ²	SD	P. value
BMI	Male	19	33.77	1.25	< 0.010
	Female	21	37.38	2.52	
BMI six Month after removal	Male	19	26.57	1.85	< 0.082
	Female	21	29.32	3.06	

DISCUSSION

The data of 40 obese patients were analysed for whom intragastric balloons were endoscopically inserted to assess weight changes and decreasing BMI, safety, tolerability, efficacy and complications of IGB. Historically, the initial indication for the IGB placement was to reduce preoperative weight to decrease surgical morbidity and mortality in super-obese patients with BMI $\geq 50\text{kg/m}^2$.⁽²⁰⁾ IGB application is a repeatable and reversible restrictive method compared to other surgical bariatric interventions^(21, 22). Therefore, IGB application has an important role in reducing mortality and morbidity of morbidly obese patients when applied before bariatric or other surgical procedures⁽²²⁾.

The majority of complications were mild to moderate in our study; pain and vomiting with heartburn are 65% which was higher than those recorded by Issam Merdan et al. study in Mosul, Iraq⁽²³⁾ (29.2%), the early removal of balloon only in one patient (2.5%) due to migration of balloon while in Issam Merdan et al. was occurred in 6 patients (2.4%), (0.8%) in Genco et al.⁽²⁴⁾ peptic ulcer related to balloon in our study was 20%, but in Issam Merdan et al. was 0.8%. The mortality rate was 0.0%, 0.4% in Issam Merdan et al., 0.08% in Genco et al. in Italy⁽²⁴⁾, and 0.07% recorded in Dumonceau et al. study in Geneva, Switzerland⁽²⁵⁾.

The efficacy of IGB is assessed depending on weight loss in kg in the early three months of balloon insertion, then after six months, also six months after removal and one year, with BMI lost after six months and one year after removal. The study shows that the patients lost weight between (8-12) kg mean weight lost (12.7 \pm 2.8) kg in the early three months (short-term effect); some of the studies showed the main weight loss obtained in the first 3-4 months during IGB deployment and the efficacy depended upon the volume of the balloon^(21,19) in Gaur et al.⁽¹⁹⁾ study was 12.9 \pm 0.8kg, while in Dumonceau et al.⁽²⁵⁾, Geneva, Switzerland study was 12.9 kg similar effects as our study. Then after six

months of insertion, the mean weight loss (9 \pm 1.9) kg the total weight loss at removal equal to 21.35 \pm 6.63 kg was higher than Issam Merdan et al.⁽²³⁾, which was 14.7 kg, Abdelsalam et al.⁽²⁶⁾, Egypt study was 17.17 – 8% at the removal of the balloon, nearly equal to Coskun et al.⁽²⁷⁾ study, in Turkey was 28.63 \pm 19.29 kg, and 24kg in Issam Merdan et al.⁽²³⁾ study. IGB has significant efficacy on weight reduction in the short term by giving good instruction to patients to continue regular exercise and dietary regimens. P. value 0.001.

Regarding BMI lost after six months of IGB removal in our study from baseline mean BMI 35.67 \pm 2.7kg/m² to 28.01 \pm 2.88kg/m² (p-0.001), similar ranges were shown in other studies, while in Issam Merdan et al.⁽²³⁾ was (9.1) kg/m², the mean BMI reduction from 39.28 \pm 6.98 kg/m² to 34.70 \pm 7.11 kg/m² in Coskun et al.⁽²⁷⁾, BMI changes from 45.33 \pm 11.18 kg/m² to 39.14 \pm 10.73kg/m² in Abdel Salam et al. study⁽²⁶⁾. Also, Gaur et al. showed that BMI reduced from 54.4 kg/m² to 48.1kg/m², similar to our study. Regarding following up the patients six months after IGB removal, the mean weight reduced to 77.68 \pm 7.01 kg {mean body weight before balloon insertion was 99.5 \pm 5.22kg}. (p-0.001), it seems that the efficacy of the balloon remained till that time. While in Gaur et al.⁽¹⁹⁾, the mean weight at base 116.2 kg reduced to 113.1 (average weight loss 15.9kg), also in Almaghaiseeb et al., Saudi⁽¹³⁾ baseline mean body weight was 94.73 \pm 16.38kg was reduced to 81.06 \pm 14.84kg in both studies the efficacy was lower than our study following six months after removal. Moreover, we also compared both gender groups for six months following; the efficacy of the balloon showed that is not a big difference. In the male group, the mean weight was 100.89 \pm 5.7 to 79.11 \pm 8.31 kg, and in the female group, the mean weight was 98.24 \pm 4.51 to 76.38 \pm 5.47 kg (p-0.078), it was not a significant change.

The long-term effects of IGB on weight were obtained after one year of follow for the obese patients, but they regained some weight compared with short-term benefits during IGB insertion and at removal, which

was shown in the results. Still, nearly 19.45 kg were lost one year after IGB removal {21.35 kg lost during IGB removal}. In Herve et al. study ⁽²⁸⁾, the mean weight loss in Belgium was 8.6kg (12.03 kg lost during balloon removal).in Mathus-Vliegen-Tytgat et al. study in the Netherlands ⁽²⁹⁾, the mean body weight lost was 12.6kg after one year of IGB,(21.3kg lost at the time of removal of IGB) but in this study, the duration of balloon insertion was 1year. And BMI reduction in both groups of males and females in our study from 33.77kg/m², 37.38kg/m² to 27.82kg/m², 27.27kg/m², respectively, one year after IGB removal.

In conclusion, the use of IGB and dietary and regular exercise in obese patients have excellent results in losing weight with relatively few complications. It shows good tolerance and safety. Although a few risks and severe complications cannot be ruled out, it showed excellent short-term and long-term efficacy and significantly enhances weight loss. However, in the long term, some weight may be regained and this should encourage close follow-up of patients after removal.

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