



# Efficacy and Safety of Intra-gastric Balloon Placements in 1600 Case, an Experience from the Middle East

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## Abstract

**Background and Purpose** Intra-gastric balloons are used as a treatment for obesity. Much of the data collected on balloons had been in the context of clinical trials in academic medical centers or as a bridge to bariatric surgery in obesity centers. The aim of this study was to investigate the efficacy and safety of balloon treatment in private practice.

**Study Design** This is an interventional study.

**Subjects** The study included 1600 patients.

**Place** The study was conducted at the ElKatib Hospital.

**Method** This was a retrospective analysis of 6-month weight loss data and balloon-related complications of patients referred to a private center for obesity treatment.

**Assessment** The assessment was carried out by obtaining full patients' history (personal history, present illness, and previous drug history and operations). Laboratory work was done in the form of CBC, blood sugar, and viral markers. Bioenterics Intra-gastric Balloon (BIB) silicone balloon was used, filled with saline plus methylene blue dye with a volume ranging from 400 to 700 ml. The gained measures were analyzed by using SPSS program, and paired *t* test and chi-square test were used to compare between groups.

**Results** A total of 1600 patients were included (368 male (23%) and 1232 female (77%)) with mean age  $34.1 \pm 10.354$ , mean body weight  $112.45 \pm 26.24$ , and mean body mass index (BMI)  $40.32 \pm 8.17$ . There were 46 patients younger than 18 years and 12 patients older than 60 years. There were 109 patients with a BMI ranging from 25 to < 35 and 737 patients with a BMI  $\geq 40$  kg/m<sup>2</sup>. A total of 1567 patients who attended weight consultation had a mean weight loss  $17.35 \pm 11.07$  from intra-gastric balloon implantation. Thirty-three patients from the total sample were not weighted after the removal of the balloon (dropped out). Percentage excess weight loss (% EWL) =  $100\% \times (\text{baseline absolute weight (AW)} - \text{last weight}) / (\text{baseline AW} - \text{initial body weight (IBW)})$  was found, and weight loss of more than 10% was considered significant. About 49.3% of patients showed significant weight loss > 10%, 24.7% of patients showed weight loss > 20%, while 26% of patients showed no significant weight loss < 10%.

**Conclusion** Intra-gastric balloons on their own, with an intensive lifestyle program and supportive consultations, resulted in safe and short-term substantial weight loss, and may fill the therapeutic gap between pharmacotherapy and surgery.

**Keywords** Intra-gastric balloon · BMI · BIB

## Introduction

Obesity is a worldwide epidemic associated with a number of serious complications. To either prevent or reduce the risk of

developing medical complications, patients have to lose about 5–15% of their weight [1].

Treatment is typically staged with the first step consisting of intensive lifestyle intervention including an energy-restricted diet, physical exercise, and behavior modification. The second step consists of drug treatment, and the final step involves surgery. For motivated patients who have seriously attempted but failed to achieve weight loss by intensive lifestyle modification, pharmacotherapy is recommended [2].

There are many endoscopic interventions for treatment of obesity. These interventions include space-occupying devices like balloons and bezoars or gastric capacity reduction like

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suturing and plication/partition and modifying gastric motor function including injections and implantations [3].

Recent reviews of the most current intragastric balloons concluded that they were effective in promoting short-term weight loss in two-thirds of patients, with significant improvements in co-morbidities [4].

There has been a rapid expansion of intragastric balloons, with different fill volumes and fill media (air, fluid, combination of air and fluid), and balloons that can be adjusted [5].

Most of the studies studied the use of balloon as a bridge to surgery, in order to improve laparoscopic access by reducing the size of the liver, to reduce postoperative complications, and to improve postoperative outcomes and to predict the outcome of restrictive surgery [6].

The aim of this study was to examine the level of efficacy and safety of the balloon in a private practice setting with dietary advice, physical exercise, and behavioral modification.

## Patients and Methods

This was a retrospective analysis of 6-month weight loss data of about 1600 cases from July 2012 to December 2012.

Full assessment was carried out before balloon insertion including patients' history (personal history, present illness, drug history, history of previous operations, and any medical

**Table 2** Medical characteristics of the cases

Medical characteristic	Total no = 1600 (100%)	
	No	%
Medical condition		
Cardiac disease	26	(1.6)
Hypertension	241	(15.06)
Diabetes	106	(6.8)
Bronchial asthma	181	(11.3)
Thyroid (hypothyroidism)	36	(2.25)
Osteoarthritis	108	(6.8)
Previous operations		
Yes	1044	(65.3)
No	555	(34.7)

condition). Laboratory work was done in the form of CBC, blood sugar, and HbA1c for diabetic patients and viral markers.

Before starting intragastric balloon therapy, patients were seen in the outpatient clinic to assess their fitness for the procedure. Patients signed an informed consent form, which emphasized the importance of returning after 6 months to have the balloon removed.

Exclusion criteria were pregnancy or breastfeeding, alcoholism or drug abuse, and psychiatric illnesses. Contraindications that were specifically related to balloon

**Table 1** Basic characteristics of the cases

Characteristic	Value	95% CI
	mean ± SD	
	N = 1600	
Age (years)	34.11 ± 10.35	(23.76 → 44.46)
Height (cm) (reviewer #1, comment #2)	166.76 ± 8.65	(158.11 → 175.41)
AW (kg)	112.45 ± 26.24	(86.21 → 138.69)
IBW (kg)	69.80 ± 8.14	(61.66 → 77.94)
EW (kg)	42.65 ± 17.76	(24.89 → 60.41)
BMI (kg/m <sup>2</sup> )	40.32 ± 8.17	(32.15 → 48.49)
BMI class	N (%)	
• Class I (25.0%–< 35%)	109 6.8%	
• Class II (≥ 35.0%–< 40%)	754 47.13%	–
• Class III (≥ 40.0%)	737 46.07%	
Sex	N (%)	
• Male	368 23%	–
• Female	1232 77%	
Smoking	N (%)	
• Yes	375 24.4%	–
• No	1225 76.6%	
Co-morbidities	N (%)	
• Yes	698 43.6%	–
• No	902 56.4%	

**Table 3** Mean weight loss and percent weight loss among patients

Item	Weight (kg)	
	Pre	Post
Mean ± SD	112.45 ± 26.24	95.56 ± 24.41
Range	(86.21–138.69)	(70.21–96.59)
<i>p</i> value	0.000*	
Mean weight loss	17.35 ± 11.07	
Range	(16.21–26.38)	
% of weight loss	No	%
(< 10%)	407	26%
(10–20%)	773	49.3%
(> 20%)	387	24.7%
Total	1567	100%
% excess weight loss (EWL)	50.08 ± 15.23	CI (34.85 → 65.31)
% total weight Loss (TWL)	25.56 ± 10.40	CI (15.16 → 35.96)

\* Significant

placement included gastrointestinal lesions (e. g., hiatal hernia > 5 cm, severe esophagitis, esophageal or gastric varices, and previous bariatric or gastric surgery). The use of anticoagulants, aspirin, and non-steroidal anti-inflammatory drugs was prohibited

Each patient underwent endoscopy under conscious sedation with midazolam to exclude gastrointestinal contraindications and to measure the distance between the incisor teeth and the gastroesophageal junction.

After removal of the endoscope, the balloon placement assembly consisting of a sheath and the type of balloon used (Bioenterics Intra-gastric Balloon (BIB Allergan, USA) silicone filled with (400–700 ml) of saline plus 5% methylene blue as a color indicator).

All cases were instructed to take pantoprazole 40 mg tablet once daily for 6 months. Also, anti-emetics and analgesics were prescribed. Ursodeoxycholic acid 250 mg bid for 1 month was prescribed, as rapid weight loss may lead to gall bladder stones.

The gained measures were analyzed by using SPSS program, and paired *t* test was used to compare between means while chi square test was used to compare qualitative data.

**Table 4** BMI mean before and after insertion of balloon

	BMI (kg/m <sup>2</sup> )	
	Pre	Post
Mean ± SD	40.32 ± 8.17	34.26 ± 7.71
Range	32.15–48.49	18.57–35.04
<i>p</i> value	0.000*	

\* Significant

**Table 5** Mean of weight loss among patients with co-morbidities and those without

Co-morbidities	Mean ± SD	<i>t</i> test	<i>p</i> value
Diabetes			
Diabetic (106)	16.55 ± 9.05	0.777	0.437
Non-diabetic (1416)	17.41 ± 11.20		
Hypertension			
Hypertensive (241)	16.98 ± 11.009	3.148	0.002*
Non-hypertensive (1326)	19.41 ± 11.22		
Bronchial asthma			
Asthmatic (181)	16.12 ± 10.006	1.565	0.118
Non-asthmatic (1386)	17.51 ± 11.19		
Cardiac lesion			
Cardiac (26)	16.84 ± 9.80	0.240	0.810
Non-cardiac (1541)	17.36 ± 11.09		
Thyroid			
Yes (36)	17.84 ± 9.90	0.263	0.850
No (1531)	15.46 ± 12.09		
Osteoarthritis			
Yes (108)	16.19 ± 10.20	1.67	0.29
No (1459)	17.81 ± 10.19		

**Results**

A total of 1600 patients were included (368 male (23%) and 1232 female (77%)) with mean age 34.1 ± 10.354, mean body weight 112.45 ± 26.24, and mean BMI 40.32 ± 8.17. There were 46 patients younger than 18 years and 12 patients older than 60 years. There were 109 patients with a BMI ranging from 25 to < 35 and 737 patients with a BMI ≥ 40 kg/m<sup>2</sup> as shown in Table 1.

The presence of co-morbidities as hypertension, diabetes mellitus, bronchial asthma, thyroid disease, and cardiac disease were found in 37.3% of patients. Blood pressure and laboratory test were known for some patients and full history was taken from patients including history of previous operations; we found that about more than 60% of them had a previous history of operations and about 400 female patients had previous history of cesarean section as shown in Table 2.

**Table 6** Mean of HbA1c in diabetic patients before and after intervention

	HbA1c % <i>N</i> = 106	
	Pre	Post
Mean ± SD	9 ± 2.1	7.4 ± 1.7
Range	7–12	
<i>p</i> value	0.0001*	

\* Significant

**Table 7** Mean of systolic and diastolic blood-pressure in hypertensive patients before and after intervention

	Systolic blood pressure (mmHg) <i>N</i> = 241		Diastolic blood pressure (mmHg) <i>N</i> = 241	
	Pre	Post	Pre	Post
Mean ± SD	150 ± 22.2	130 ± 15.3	95 ± 10.1	85 ± 5.2
Range	125–180		80–105	
<i>p</i> value	0.0001*		0.0001*	

\* Significant

A total of 1567 patients who attended weight consultation had mean weight loss  $17.35 \pm 11.07$  from intragastric balloon implantation. Thirty-three patients from the total sample were not weighted after the removal of the balloon (dropped out). Percentage excess weight loss (% EWL) =  $100\% \times (\text{baseline AW} - \text{weight}) / (\text{baseline AW} - \text{IBW})$  was found and weight loss of more than 10% was considered significant. About 49.3% of patients showed significant weight loss > 10%, 24.7% of patients showed weight loss > 20%, while 26% of patients showed no significant weight loss < 10% as shown in Table 3.

Table 4 shows the significant difference in the BMI before and after insertion of balloon with *p* value = 0.000.

A total of 698 patients from 1600 patients had medical disorders like diabetes mellitus, hypertension, bronchial asthma, and cardiac lesion. There was no significant difference between diabetic, cardiac, and bronchial asthma patients and those without these diseases. But there was a statistically significant difference between hypertensive and non-hypertensive patients regarding weight loss with *p* value = 0.002 as shown in Table 5.

There was a significant weight loss > 10% in 72 out of 106 diabetic patients and 31 of them showed improvement of their HbA1c while 11 of them stopped their oral hypoglycemic medications. In hypertensive patients, 180 patients out of 241 showed significant weight loss > 10% with good control of blood pressure, and there was a statistically significant difference in HbA1c and blood pressure before and after intervention with *p* value = 0.0001, 0.0001 as shown in Tables 6 and 7. Also, as shown in Table 8 there was a statistically significant reduction in the number of anti-hypertensive drugs used by hypertensive patients on pre- and postintervention comparison.

**Table 8** Antihypertensive drugs in hypertensive patients before and after intervention

	Hypertensive patients <i>N</i> = 241				MN	<i>p</i> value
	Pre		Post			
	No	%	No	%		
1 drug	71	29.5%	150	62.2%	39.85	0.0001*
2 drugs	170	70.5	91	37.8%		

According to the Clavien-Dindo classification which is based on the type of therapy used to correct a specific complication after balloon insertion, the majority of patients (89.3%) belonged to grade I, 10% belonged to grade II whom were divided into 6.4% with gastritis and 3.6% with reflux esophagitis and were controlled by giving PPIs for 6 months but six patients did not respond to PPI with food intolerance and had their balloon removed, and 0.7% of patients belonged to grade III with only one case diagnosed with pancreatitis but we do not know if it was a complication of the balloon or not; ten patients were diagnosed with gall bladder stones and this may be attributed to rapid weight loss (Table 9).

Regarding the spontaneous intragastric balloon deflation, there were 20 patients with spontaneous deflations and subsequent change in the color of urine. All of them had their balloon endoscopically removed, and all of them were included in the study.

## Discussion

This study is one of the few studies that were done to examine the efficacy and safety of intragastric balloon treatment in a private center. A total of 1600 patients were included (368 male (23%) and 1232 female (77%)) with mean age  $34.1 \pm 10.354$ , mean body weight  $112.45 \pm 26.24$ , and mean BMI  $40.32 \pm 8.17$ .

A total of 1567 patients who attended weight consultation had mean weight loss  $17.35 \pm 11.07$  from intragastric balloon implantation. Thirty-three patients from the total sample were not weighted after the removal of the balloon (dropped out) with a significant difference (*p* value = 0.000) in the BMI before and after insertion of balloon.

**Table 9** Clavien-Dindo classification for postoperative complications

Clavien-Dindo classification	Total no = 1567 (100%)	
	No	%
Grade I	1400	(89.3%)
Grade II	156	(10%)
Grade III	11	(0.7%)

This was agreed with the study done by Mathus et al. [7] which reported that patients lost a mean of 15.8 kg and 20.9 kg after 3 and 6 months of balloon therapy while patients who were not seen between the time of balloon placement and removal, lost 19.4 kg of weight. Both major (0.5%) and minor (5.4%) complications were surprisingly infrequent given that these balloons were administered in private practice with less frequent follow-up.

In the study done by Paula et al. [8], the patients mean age was 38 (18–68) year and 61 was female (75.3%). The initial mean weight and mean BMI were 100 Kg (range 69–171) and 36 Kg/m<sup>2</sup> (range 27.6–65.6), respectively. The final mean weight and BMI were 90.6 Kg (range 58–151) and 32.6 Kg/m<sup>2</sup> (range 22.8–52.2), respectively. There was a significant weight loss at the end of the treatment, mean absolute weight loss was 9.37 Kg (9.18% of initial weight) ( $p = 0.0001$ ).

In our study about 49.3% of patients showed significant weight loss >10%, 24.7% of patients showed >20%, while 26% of patients showed no significant weight loss <10%. And this was consistent with the study done by Negrin et al. [9] which included 100 consecutive overweight/obese individuals (mean body mass index (BMI) 35.0 ± 5.6 kg/m<sup>2</sup>) were prospectively followed after endoscopic implantation of a saline-filled intragastric balloon at 6 months, mean weight loss was 12.6 ± 8.3 kg, 63 individuals had ≥10% baseline weight loss with no severe morbidity detected. Leonardo [10] showed from the results obtained from records of 700 cases of patients treated with intragastric balloon that a total of 500 patients had a ratio of weight loss relative to the initial total weight of the patient (3.74% of the patient from 0 to 5%, 13.79% of patients in 5 to 10%, 31.57% of patients of 10 to 15%, 26.8% of patients 15 to 20%, and 24.1% of patients above 20%).

In a study done by Deniz [11] on 101 obese patients with a BMI of 27 for 6-month duration, 54 were women and 47 men. The average age was 39 (18–66 years old). At the start, the BMI of the 101 patients was, on average, 41 (27.0–81) and weight varied between 73 and 283 kg. The average weight loss in 6 months was 18 kg (6–43 kg), the average reduction of the BMI amounted to 6.0 (0–13). Six patients with BMI of 40 showed no weight loss. There were no serious complications or deaths.

In conclusion, intragastric balloon therapy may fill the gap between weight loss drugs and surgery. Even in private practice, patients were able to lose weight safely without or with minimal complications. As balloon use in private practice grows, it will be critical to ensure that patients return for follow-up to avoid complications. Future studies may be needed to assess the benefits of

intragastric balloon therapies compared with intensive lifestyle intervention with or without pharmacotherapy. Limitation of the study includes no follow-up for patients after six months.

## Compliance with Ethical Standards

**Conflict of Interest** The authors declare that they have no conflict of interest.

**A Statement of Informed Consent** Informed consent was obtained from all individual participants included in the study.

**A Statement of Human Rights** The study has been approved by the ministry of health and the hospital ethics committee and has been performed in accordance with the ethical standards.

## References

1. World Health Organization. Obesity: preventing and managing the global epidemic. Report of a WHO consultation on obesity, Geneva, Report no.: WHO/NUT/NCD/98.1 Geneva: WHO; 1998.
2. Isidro L, Cordido F. Approved and off-label use of obesity medications, and potential new pharmacologic treatment options. *Pharmaceuticals*. 2010;3:125–45.
3. Swidnicka-Siergiejko A, Wróblewski E, Dabrowski A. Endoscopic treatment of obesity. *Can J Gastroenterol*. 2011;25(11):627–33.
4. Imaz I, Martinez-Cervell C, Garcia-Alvarez EE, et al. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. *Obes Surg*. 2008;18:841–6.
5. de Moura EG, Orso IR, Martins BC, et al. Improvement of insulin resistance and reduction of cardiovascular risk among obese patients with type 2 diabetes with the duodenojejunal bypass liner. *Obes Surg*. 2011;21:941–7.
6. Melissas J, Mouzas J, Filis D, et al. The intragastric balloon – smoothing the path to bariatric surgery. *Obes Surg*. 2006;16: 897–902.
7. Mathus-Vliegen Elisabeth MH, Alders PRH, Chuttani R, et al. Intragastric balloons in a private practice setting. *Gastrointest Endosc*. 2015;47:302–7.
8. Elia PP, Freire A, Silva GC, Teixeira N, Teixeira JM, Feldman G, Moraes CE, Wrobel D and Carvalho G. Efficacy and safety of intragastric balloon for obesity and pre-obese patients: a Brazilian experience gastrointestinal endoscopy. 2010;71(5).
9. Negrin Dastis S, François E, Deviere J, et al. Intragastric balloon for weight loss: results in 100 individuals followed for at least 2.5 years. *Gastrointest Endosc*. 2009;41:575–80.
10. Almeida LS. Results of 700 cases of intragastric balloon. *Gastrointest Endosc*. 2015;81(5S):AB459.
11. Uyak D, Galle V. Endoscopic treatment of obesity using a gastric balloon (B.I.B) study data of 101 patients with a BMI of 27 or more with gastric balloon implantations. *Gastrointest Endosc*. 2010;71(5)

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