

Bioenterics Intra-gastric Balloon: Safety, Tolerance, and Efficacy of 6 months Balloon Treatment: Egyptian Experience with 50 patients

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Abstract: Background: Intra-gastric balloons have been used since 1985 to treat obesity. Bioenterics Intra-gastric Balloon BIB is an endoscopic device for temporary treatment of obesity. The aim of this study is to evaluate safety, tolerance and efficacy of BIB in obese patients. 61 patients were screened in the study of these 4 were excluded, 57 patients entered, 50 patients completed the study and 7 patients has removed balloon before study period (6 months). As regarding 50 patients who completed study. The mean weight loss was 23.7 Kg, mean BMI loss was 8.6 Kg/m². Balloon positioning and removal was safe and concluded that Bioenteric Intra-gastric balloon is a safe and effective procedure for weight reduction with low morbidity rates.

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Key Words: BIB: Bioenteric Intra-gastric Balloon BMI: Body Mass Index

1. Introduction

Obesity is a 21 century pandemic, the leading cause of morbidity and premature mortality (Busetoo *et al.*, 2011). Medical options for obesity treatment are multiple and invasive therapy may be classified as surgical and non-surgical (Hadson *et al.*, 2001).

Intra-gastric balloon device placement is an invasive non-surgical option that may benefit some obese patients (Niehm and Harboe, 1982). The intra-gastric balloons have been used to treat obesity for the last 25 years, but their clinical utility has not been completely established (Genco *et al.*, 2005). The temporary use of the BIB in obesity is increasing worldwide (Mathus, 2008). BIB positioning is potentially attractive to health-care practitioners who have experienced poor results with dietary programs, medications and behavioral therapy (Bonazzi *et al.*, 2005).

The Bioenteric Intra-gastric Balloon (BIB) is an endoscopic device for temporary treatment of obesity (Allison, 2006).

The Bioenterics intra-gastric Balloon is small and flexible in the collapsed state, expands into a spherical shape 10 cm in diameter when filled with 500-700 ml saline solution, its shell is made of an inert, nontoxic silicone elastomer that is resistant to gastric acid. The balloon has radioopaque self sealing valve that allows adjustment of the volume in a range of 400 to 800 ml (Doldi *et al.*, 2002).

The presence of balloon in the stomach decreases the amount of food consumed in a single meal (Geliebter *et al.*, 1999), however stretching of the stomach wall may change the secretion of the

alimentary tract hormones that affect appetite and energy balance in the body (Imaz *et al.*, 2008).

Aim:

To evaluate safety, tolerance and efficacy of Bioenterics Intra-gastric balloon in obese subjects treated with BIB.

2. Patients and Methods:

The BIB was used in all patients who were selected according to the followings.

Inclusion criteria:-

- 1) Age 18 years or older.
- 2) Failure to achieve weight loss within a supervised weight – control program for at least 6 months.
- 3) A body mass index above 30 kg/m².

Exclusion criteria:

- 1) Patients with a hormonal or genetic cause for the obese state.
- 2) Subjects with BMI lower than 30 Kg/m².
- 3) Previous gastrointestinal surgery.
- 4) Pregnancy or breast feeding.
- 5) Inflammatory diseases of the gastrointestinal tract.
- 6) Potential upper digestive tract bleeding or peptic ulcerations.
- 7) Varices or angiodysplasias in the gastrointestinal tract.
- 8) Large hiatal hernia (>3m).
- 9) Previous fundoplication surgery.
- 10) Psychiatric disorders.
- 11) Alcoholism and drug abuse.
- 12) Grade C-D esophagitis.

3. Results:

Sixty one patients were screened for inclusion in the study, of these 4 were ineligible for the following reasons:-

- ♦ Hypothyroidism, 2 cases.
- ♦ Polycystic ovarian syndrome, 2 cases.

Thus 57 patients entered the study, 50 patients completed the study and 7 patients didn't continue due to early removal of balloon. as regarding 7 patients with early removal and their causes:

1 case removed balloon after 24 hours due to psychological intolerance, 4 cases removed balloon after 1 week due to:

1. Psychological intolerance
2. Abdominal pain
3. Dyspepsia
4. Heartburn
5. Flatulence

1 case removed balloon after 1 month due to persistent nausea and vomiting.

7th case removed balloon by the end of 3rd month as she was presented with hypokalemia at the emergency department from persistent vomiting that didn't stop during the last 2 weeks.

In the present study BIB positioning was safe after intravenous administration of propofol, we inflated BIB with saline to a volume 700 cc after adding 5 ml methylene blue, the aim of adding methylene blue is to detect rupture of BIB so we tell patient if at any time colour of urine changed to green to tell doctor as this indicate rupture of ballon and must be removed endoscopically within 48 hours to avoid intestinal obstruction. No related hospital morbidity or mortality occurred. During the 3 days following the ballon insertion, most of patients were complaining of nausea, vomiting, abdominal cramps

and acid reflux and these symptoms were treated with antiemetic, antispasmodic, analgesic and acid suppressant medications and all symptoms relieved after 72 hours. Instructions for 1st 72 hours post insertion is liquid diet only then usual food.

After 6 months BIB removal was done using endoscope under anesthesia using propofol 1st by puncture the ballon with needle then as much fluid as possible was removed before grasping the ballon with a snare or a forceps and the endoscope and the grasped ballon was gently removed. In our study ballon removal resulted in one Mallory- weiss laceration and one case with gastric erosions, neither patient was hospitalized and both recovered.

The ballon itself and the technique for positioning and removal is safe, in the current study, the array of complications encountered in previous studies did not occur as spontaneous deflation, complications related to insertion and removal

As regarding 50 patients who completed the study, mean age of patients was 40.1±6.102 (30-47) years and mean height was 1.656±0.052 (1.60-1.750) meter and as regarding sex distribution 15 males and 35 females.

Initial mean body weight was 121 ± 26 (80-157) kg. At month 6 mean body weight was 97±15.6 (70-125) kg (*P* <0.001) high significant decrease. The mean weight loss was 23.7 Kg. Initial mean body mass index was 44±6.2 (31.2-54.3) Kg/m². At month 6 mean body mass index was 35.5±4 (27.3-41.2) Kg/m² (*p*<0.001) high significant decrease. The mean reduction in BMI was 8.6 Kg/m² (Table 2).

The percent of weight loss is 19±5% and the percent of reduction in BMI is 19±5% (Table 3).

Table (1): Demographic data of patients who completed study

Age(y)	
Range	30-47
Mean±SD	40.1±6.102
Height(m)	
Range	1.6-1.750
Mean±SD	1.656±0.052
Sex N(%)	
Male	15(30%)
Female	35(70%)

Table (2): Body weight and BMI before and 6 months after BIB balloon

		Range			Mean ± SD		Paired Differences		Paired t-test	
		Min	Max	Mean	SD	Mean	SD	t	P-value	
Weight (Kg)	Before BIB	80.000	157.000	121.000	20.966	23.700	10.001	16.758	<0.001*	
	After BIB	70.000	125.000	97.300	15.663					
BMI kg/m ²	Before BIB	31.200	54.300	44.188	6.226	8.678	3.601	17.043	<0.001*	
	After BIB	27.300	41.200	35.510	4.023					

* <0.001 = highly significant

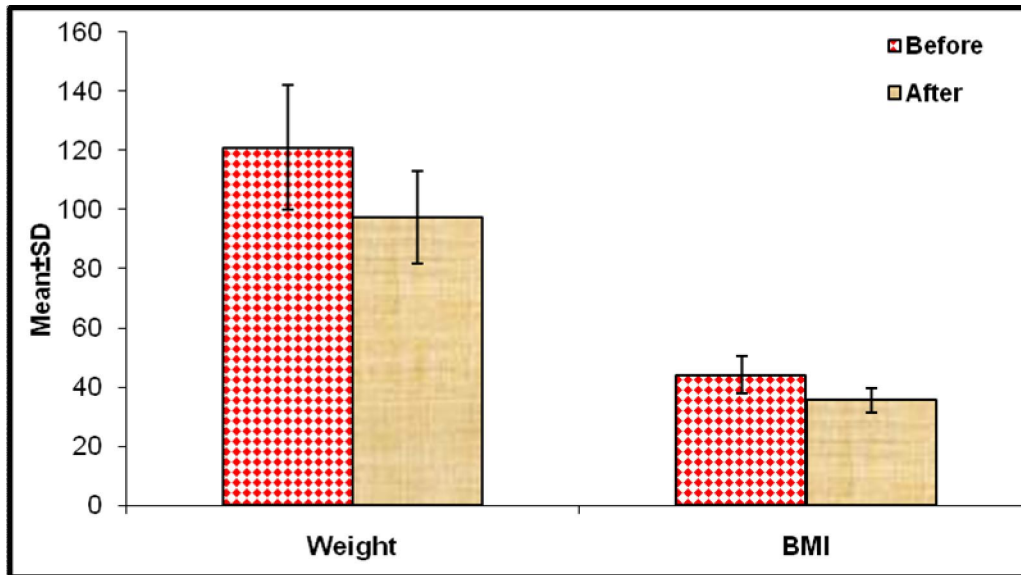


Figure (1): Body weight and BMI before and 6 months after BIB

Table (3): Weight loss and BMI reduction after BIB

% of change	Range	Mean±SD
Weight	11.972-29.936	19.154±5.803
BMI	11.879-30.018	19.116±5.842

Paired t-test to compare between before and after and student t-test Analysis of data was done by IBM computer using SPSS (Statistical Program for Social Science version (12)).

4. Discussion:

Several researchers over the years have tried different balloon devices as they were thought to be promising and less invasive than surgery for the treatment of morbid obesity (De waele *et al.*, 2000). By the end of the '80s, several prospective, controlled studies reported that devices, such as Ballobes and Garren-Edwards gastric bubbles had no significant effects for weight reduction, the reasons for this were considered to be the small volume of the balloon (220 ml for Garren - Edwards and 400 ml for Ballobes) and the air filling of these balloons having no weight effect on the stomach walls, and also their cylinder shape in addition made them less effective for weight reduction, in addition, these devices had high rates of complications (gastric erosion 26%, gastric ulcer 14%; Mallory- Weiss tears 11%) (Al momen and Elmogy, 2005).

The introduced BIB has a spherical shape, high volume capacity (500-700 ml) and uses saline for filling not air as other previous balloons (Galloro *et al.*, 1999). Studies have found that complication rates are very low (Geliebter *et al.*, 2010).

In the present study BIB positioning was safe, no related hospital morbidity or mortality. In our

study the mean weight loss is 23.7 kg and the mean BMI loss 8.6kg/m². On contrary Imaz *et al.*, 2008 reported results of BIB done to be the following, mean weight loss is 14.7 kg and the BMI loss is 5.7 kg/m². Other researchers as Genco *et al.*, 2005 reported results of BIB done on Italian patients to be the following, mean weight loss is 12.6 kg and the BMI loss is 4.9 kg/m². This high discrepancy in our results of BIB other than these 2 studies may be attributed to the fact that in our study we did high proper selection of patients entering study as all our patients evaluated by the inclusion and exclusion criteria before entering the study to reach to these high results. As Weight loss has traditionally been the main outcome measure in bariatric procedures which is done on a large scale these days (Kotzampassi and Hrewsbury, 2008). In our study the mean weight loss is 23.7 kg and the mean BMI loss is 8.6 kg/m². Obviously this high outcome in our study although it is not comparable to results obtained from bariatric surgery (Sallet *et al.*, 2006), but at least with BIB no related morbidity or mortality reported in comparison to morbidities and mortalities that occur with Bariatric surgery, also results have been confirmed in studies that the benefit of 10 kg weight loss in terms

of Co-morbidities (diabetes, blood pressure, lipids, etc) and related mortality is highly significant (Del pozo *et al.*,2009), In this study, BIB was a safe and effective procedure for weight reduction, with low morbidity and no mortality rates. The balloon can play a role in the treatment of obese patients. Whether BIB is of benefit in the long –term treatment of obese patients remains to be determined by more extended studies for long term follow up

Conclusion:

Bioenterics Intra gastric Balloon is a safe and effective procedure for weight reduction

Statistical analysis:

Paired t-test to compare between patients before and 6 months after balloon.

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