

Obesity treatment by Bioenterics intragastric balloon: Iranian results

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Abstract

We studied the effectiveness, tolerability and safety of Bioenteric Intra gastric Balloon (BIB) for treatment of obesity in Iranian population. 52 patients (46 female (88.5%), mean age: 35.5 ±10, mean body weight: 107.6±25.4 kg) referred to two major training hospitals in Tehran, Iran, after evaluation by a multidisciplinary team, underwent endoscopic BIB placement under unconscious sedation. BIB was removed after 6 months and patients were discharged with drug therapy and 1000 kcal diet. Weight and Body Mass Index (BMI) were assessed at baseline, 6 months and 1 year after BIB insertion. The mean weight and BMI at baseline were 107.6±25.4 kg and 39.4±7.9 kg/m²; 6 months after balloon placement, they were 88.7±21.9 kg and 32.5±7.4 kg and 6 months after balloon removal, they were 93.4±21.9kg and 34.85±8.2 kg/m² respectively. The weight decline was statistically significant throughout the study and follow up with p value <0.001. The most frequent side effects were nausea and vomiting which were resolved in the majority of cases by one week. No major complications, such as death, gastric obstruction, gastric or esophageal perforation, or balloon displacement occurred in our study. BIB is a safe, effective and well-tolerated treatment of obesity, but its effects are temporary, so it should be accompanied and followed by other methods to achieve sustained weight reduction.

Key Words: Obesity, BIB, weight loss, endoscopic procedures.

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Obesity is a complex condition with overwhelming consequences that is becoming a worldwide social and economic problem.^{1,2} Numerous comorbidities are associated with obesity including hypertension, type II diabetes mellitus, coronary artery disease, dyslipidemia, nonalcoholic fatty liver disease, certain cancers and increased mortality.³ The prevalence of obesity in Iran is 10.5% and 22.5% in men and women, respectively, with an increased trend of 5.8% in men and 17.4% in women during a 14-year period.⁴ Calorie-restricted diet, physical exercise and behavior modification are first-line methods to treat obesity, but these along with pharmaceutical therapy have limited efficacy for sustained weight loss in severe obesity.^{5,6} Weight loss surgery has shown to be the most effective method for long-term management of severely obese patients. However it is invasive, expensive and associated with severe complications, (anastomotic leak and ulcer) and with a mortality rate estimated range between 0.1 and 2.0.⁷⁻¹⁰ Intra gastric balloon placement is an alternative for bariatric surgery with a lower risk profile, in particular for subjects who are not surgical candidates. Many recent studies in various countries have shown

that Bioenterics Intra gastric Balloon (BIB) placement is a safe and effective method for short term weight loss.¹¹⁻¹⁶ Although this method is popular and performed frequently in Iran, no reports have been published to date. The objective of this study is to determine effectiveness, safety and tolerability of BIB in Iranians.

Materials and Methods

The study protocol was approved by the local research ethics committee of Beheshti University of Medical Sciences. Before BIB insertion, a written informed consent was provided to all participating patients, that signed the forms before enrollment. From September 2008 to February 2011, 52 obese patients [46 female (88.5%), mean age: 35.5 ±10] referred to gastrointestinal medicine clinic in Taleghani hospital and Imam Hussein hospital, Tehran, Iran. They were included in the study after evaluation by gastroenterologists, nutritionists and endocrinologists, independently. The inclusion criteria were: 1. reduction of operation risk in candidates for bariatric surgery and with BMI > 35; 2. complications of obesity, specifically, type 2 diabetes mellitus, hypertension,

dyslipidemia, etc., and with BMI > 30; 3. recurrent failure of nonsurgical methods of weight loss with BMI > 30. Exclusion criteria were: BMI < 30, esophagitis, active peptic ulcer, varices, or angiodysplasia, large hiatal hernia (>5 cm), chronic therapy with steroids or nonsteroidal anti-inflammatory drugs, alcohol or drug abuse, previous gastric surgery, anticoagulant therapy, pregnancy, psychiatric disorders, low general health status. All patients underwent a diagnostic upper endoscopy to rule out local conditions precluding balloon placement. Those with active peptic ulcer or esophagitis were treated and were included in the study only after a second endoscopy control confirmed the successful treatment. Under unconscious sedation with Propofol and Fentanyl the Bioenterics intragastric balloon (BIB) [INAMED Corporation, Santa Barbara, CA, USA] was implanted in the stomach and inflated with a volume of 500-700ml sterile saline containing 10 ml methylene blue under direct endoscopic vision. The patients were prescribed half saline serum along with antiemetic, anti-acid and analgesic medications and were advised to follow a fully liquid low fat diet for the first three days and then continue with regular meals. All patients were given pantoprazole (40 mg/day) while the balloon was in place. They were also recommended to keep on the low calorie (1,000 kcal) diet and physical exercise. The patients were visited after one week then on a monthly basis for postplacement symptoms and complications evaluation. The BIB was removed 6 months later under endoscopy control and patients were followed up 6 months after balloon removal. Statistical analyses were performed with SPSS 15.0 software (SPSS, Chicago, IL, USA). Paired t, repeated measurement and Wilcoxon tests were used and data were expressed as mean±standard deviation, frequency and percentage. A p value of < 0.05 was considered significant.

Results and Discussion

The present research was conducted on 52 patients (Table 1). Ten cases did not completed the 6 months of balloon in place and 6 cases did not completed the following 6 months follow up. The majority of the patients complained of nausea (92.3 %) and vomiting (75%), that were resolved mostly in one week. Other less common side effects are listed in table 2. There was one case of early removal due to intolerance, one case of balloon rupture during placement, 2 cases of gastric bleeding, 2 cases of balloon fluid leakage, 1 case of severe gastritis, 1 case of severe esophagitis and 1 case of pancreatitis. There was no mortality, obstruction or rupture of esophagus or stomach. The mean weight and BMI before balloon placement were 107.6±25.4 kg (range: 75-180) and 39.4±7.9 kg/m² (range: 30.5-71.8). Six months after balloon placement they were 88.7±21.9 kg (range 57-160) and 32.5±7.4 kg (range: 20.6-68.4) respectively. The mean weight and BMI reduction was 18.9±13.9 kg (0-75) and 6.9±4.8 kg/m²

Table 1. Base line subjects characteristics (n=52)

Variable	Mean±SD orN(%)
Age	35.5±10
Sex	F:46(88.5)
Baseline weight	107.62±25.38kg
Baseline BMI	39.4±7.9kg
<i>Associated comorbidities</i>	
Diabetes	4(7.7)
Hypertension	5(9.6)
Dyslipidemia	2(3.8)
Hypothyroidism	10(19.2)
Osteoarthritis	6(11.5)
Gall stone	3(5.8)
Infertility	1(1.9)

BMI: Body Mass Index

(0-25.9) with p value < 0.001. Patients with morbid obesity had the highest total weight loss. For the 36 patient who completed the follow up, 6 months after balloon removal the mean body weight was 93.4±21.9 kg (57-160), which was decreased 8.8 kg compared to the beginning of the study (15 kg decrease in the first 6 months and 6.2 kg increase during follow up). The mean BMI at the end of follow up was 34.8±8.2 kg/m² with a 3.3 kg/m² decrease in comparison to before the balloon placement (5.7 kg/m² decrease during the 6 months of intervention and 2.4 increase in the follow up period). The repeated measurement test and Benferroni multiple comparison test, both showed that there is a significant difference in the mean weight and BMI before compared to 6 month after placement and 6 months after removal with p value <0.001. The Friedman test showed also that distribution of BMI differs significantly before and after balloon placement and even 6 months after balloon removal. The BioEnterics intragastric balloon is a spherical, smooth, silicone elastomer, saline-filled balloon that is resistant to degradation by gastric acid for approximately 6 months. Intra gastric balloon induces satiety by volume displacement and gastric distention and also changes gastric motility and readjust the neurohormonal milieu, eventually resulting in decrease of oral intake.^{17,18} Our results (18.9 kg and 6.9 kg/m², respectively) are comparable to those of a recent spanish meta-analysis of 15 studies, including 3698 patients, that estimated 14.7 kg weight loss and 5.7 kg/m² decline in BMI after 6 months of BIB treatment.¹⁹ On the other hand, a Cochrane database systemic review of nine randomized controlled trials, comprising 395 patients,²⁰ showed no convincing evidence of a greater long term weight loss by intragastric balloon placement compared with conventional management. Our study showed 6.2 kg weight gain during 6 months follow up after balloon

Table 2. Side effects

Variable	<7days	>7days	Total
Nausea	57.7	34.6	92.3
Vomiting	57.7	17.3	75
Fatigue	9.6	13.5	23.1
Bloating	5.8	19.2	25.0
Fullness	1.9	38.5	40.4
Heart burn	9.6	40.4	50.0
Early satiety	5.8	32.7	38.5
Epigastric pain	1.9	21.2	23.1
Diarrhea		3.8	3.8
Hair loss		17.3	17.3
Nail fragility		7.7	7.7
Halitosis		7.7	7.7

Data presented as percentage

removal, but the mean weight reduction compared to the beginning of the study was still significant (8.8 kg). Two recent studies in the region, Al Kahtani K, et al. in Saudi Arabia,¹⁶ and Saruc M, et al. in Turkey,¹⁷ showed mean BMI reduction of 3.6 kg/m² and 7.8 kg/m² compared to 6.9 kg/m² in our study. The procedure was safe and the majority of the side effects were mild, as was reported previously.²⁰ None of our patients experienced major complications, such as death, gastric obstruction, gastric or esophageal perforation, or balloon displacement. The main limitations of our results are the small study sample, the lack of control group and of randomization. However, our study, that is the first report on PIP placement in Iranian population, provides valuable data on efficacy and safety of this method. The study showed, indeed, that BIB is an effective, safe, well-tolerated method for short term weight loss in Iranian population. For long term management of severe obesity, bariatric surgery remains the most effective method, but none of our patients experienced major complications, such as death, gastric obstruction, gastric or esophageal perforation, or balloon displacement. In conclusion, the results of the present study show that BIB is an effective, safe, well-tolerated method for short term weight loss in Iranian population. Though bariatric surgery seems the most effective method for long term management of severe obesity, larger controlled trials, including analyses of metabolic profile are recommended.

List of acronyms

BIB - Bioenterics Intragastric Balloon
 BMI - body mass index

Author's contributions

Each author contributed in equal part to the manuscript.

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Conflict of Interest

The authors declare no conflicts of interests.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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Bioenterics intragastric balloon

Eur J Transl Myol 28 (3): 300-303, 2018

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