Effect of intragastric balloon-induced weight loss on body composition, fatty liver, and comorbidities in Egyptian middle-aged obese women: a 6-month follow-up study

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Received 21 February 2015
Accepted 13 August 2015

Egyptian Journal of Obesity, Diabetes and Endocrinology
2015, 1:90–96

Background
Paralleling the increasing prevalence of obesity in the Egyptian population, metabolic syndrome and liver steatosis are also on the rise. Body composition measurement is used to describe the percentages of fat, bone, water, and muscle in human bodies. The available classic weight loss treatments such as low-calorie diet, exercise, behavioral modification, and pharmacotherapy usually achieve only limited weight loss. The BioEnterics Intragastric Balloon (BIB) is an endoscopic liquid-filled device for the treatment of obesity.

Aim
The aim of this study was to examine the safety of BIB insertion in a group of obese middle-aged Egyptian women treated with intragastric balloon to induce weight loss for 6 months and report its effect on their anthropometric measurements, body composition, fatty liver, and comorbidities.

Patients and methods
During the period from February 2012 until August 2013, 47 consecutive middle-aged female patients were enrolled for BIB insertion. Inclusion criteria were mainly based on the BMI ($\geq$30.0 kg/m^2) and on associated comorbidities. Apart from physical and anthropometric evaluation, body composition analysis was performed using a bioelectrical impedance analyzer to estimate fat mass, body fat percentage, and fat-free mass. The Adult Treatment Panel III criteria were used to diagnose metabolic syndrome, and ultrasound evaluation of the liver for the presence and grade of steatosis was performed. BIB placement was carried out after diagnostic endoscopy, under intravenous conscious or unconscious sedation.

Results
The total percentage of complications from BIB insertion was 12.8%, which were mostly mild and reversible. Three (6.4%) patients had their gastric balloon removed early (two voluntarily and one due to de-novo peptic ulcer) and were excluded from the study, whereas the remaining 44 patients continued their 6-month therapy duration. Overall, BIB insertion significantly reduced weight from a mean value of 96.82 ± 14.18 kg at baseline to 83.45 ± 12.03 kg after 6 months ($P < 0.001$). The mean value for the amount of weight lost at endpoint was 13.36 ± 3.29 kg, whereas the mean value for BMI lost at the time of BIB removal was 5.12 ± 1.20 kg/m^2, which was a significant reduction compared with baseline values ($P < 0.001$). No significant change occurred in the liver size over the 6-month study period ($P = 0.12$), whereas a significant decrease in the grade of steatosis was noted. Body fat mass and body fat percentage with bioelectrical impedance analyzer were significantly reduced ($P < 0.001$). However, there was also a significant decline in fat-free mass ($P < 0.001$). Significant favorable changes in the biochemical markers of metabolic syndrome, homeostasis model assessment of insulin resistance index, and liver profile also occurred. An overall 4.6% of patients showed resolution, whereas 31.8% showed improvement in the features of metabolic syndrome.

Conclusion
This study provides anthropometric, biochemical, and body composition evidence on significant improvement in metabolic syndrome, obesity-associated comorbidities, and fatty liver after weight loss induced by the minimally invasive and relatively safe technique. However, it is recommended to continue a weight-reducing diet after BIB removal for achieving long-term effectiveness and to add exercise programs to dietary restriction for promoting more favorable change in body composition.

Keywords:
BIB, body composition, intragastric balloon, obesity, metabolic syndrome, weight

Egyptian Journal of Obesity, Diabetes and Endocrinology 1:90–96

2356-8062

Introduction

The WHO estimated that, by the year 2015, 2.3 billion people will be overweight and 700 million will be obese worldwide [1]. The Middle East, including the

Gulf area and North Africa, is no exception to the worldwide increase in obesity. In 1996, a study [2] showed that the Egyptian population had the highest BMI in the world, averaging 26.3 kg/m^2. In 2002, 45% of urban Egyptian women and 20% of the rural population were proved obese [3].

The rates of obesity grew in Egypt mainly because since the 1990s fats and carbohydrates became more heavily consumed. Furthermore, food is traditionally the center of social events and special occasions in the Egyptian society, whereas the health conscious exercise culture is confined only to the higher socioeconomic class. As parents teach this lifestyle to their children, the prevalence of obesity among children and adolescents increases [4]. In addition, women are more likely to be overweight or obese due to the cultural appreciation of heavier female bodies and the perception of appropriate female behavior and occupations, particularly in rural areas [3,5].

Contrary to past concepts, obesity is now considered a chronic resistant disease with major morbidity and mortality. Paralleling the increasing prevalence of obesity in the general population the metabolic syndrome is now on the rise. Hypertension, coronary artery disease, diabetes, hypercholesterolemia, osteoarthritis, and nonalcoholic fatty liver disease (NAFLD) have become major issues of concern worldwide [6,7]. The clinical implications of this alarming prevalence of NAFLD are derived from the fact that it may progress to cirrhosis, liver failure, and hepatocellular carcinoma [8].

The most commonly used indicators for obesity are BMI, waist circumference (WC), and waist-to-hip ratio (WHR). Body composition measurement is used to describe the percentages of fat, bone, water, and muscle in human bodies. Body composition [particularly body fat percentage (BF%)] can be measured in several ways, including skinfold thickness, dual energy X-ray absorptiometry, and bioelectrical impedance analyzer (BIA) [9].

According to the current guidelines, weight-reduction programs in overweight and obese individuals should include an initial 6-month period of weight loss, followed by a second phase of weight maintenance over 24 months [10–12]. The goal of the weight loss phase is to achieve a sustained minimum of 10% weight loss to prevent or to reduce the risk for cardiovascular and other obesity-related disorders. The first approach in addressing the multifaceted problem of obesity should consist of a combination of a calorie-restricted diet, physical activity, and behavior modification [13,14]. For motivated patients who seriously attempt but fail to achieve a weight loss of 5–10% in 3–6 months, pharmacotherapy is recommended. According to the American National Institute of Health, bariatric surgery should be offered to patients with BMI higher than 40 kg/m^2, or BMI higher than 35 kg/m^2 with obesity-related medical conditions, such as diabetes, cardiovascular disease, and obstructive sleep apnea [15]. However, there is an intermediate group of patients who do not respond to medical therapy and who are not yet surgical candidates. For this group, another option, the intragastric balloon, has received more attention in the last two decades. Moreover, it has been recommended as an adjuvant for weight reduction before all kinds of planned surgical procedures in the morbidly obese, to reduce surgical risk [16,17].

The BioEnterics Intragastric Balloon (BIB) is an endoscopic device for temporary treatment of obesity. Randomized sham-controlled trials have shown that this liquid-filled intragastric balloon decreases preprandial hunger, increases postprandial satiety, and promotes weight loss in the short term, whereas on the long term it helps individuals modify their eating habits by providing a self-education tool [18,19].

We prospectively followed up a group of obese middle-aged Egyptian women treated with intragastric balloon to induce weight loss for 6 months and reported its effect on their anthropometric measurements, body composition, fatty liver, and comorbidities.

Patients and methods

During the period from February 2012 until August 2013, 47 consecutive middle-aged female patients attending the Hepatology and Gastrointestinal Endoscopy Unit (Medical Research Institute, Alexandria University, Alexandria, Egypt) for BIB placement were enrolled in the study. Inclusion criteria were mainly based on the BMI (≥30.0 kg/m^2) and on associated comorbidities. Written informed consent was obtained from all treated patients. Medical, dieting, and weight histories were taken (plus a bariatric surgeon and a psychiatrist consultation if necessary), followed by physical examination and anthropometry. On the basis of BMI values, obesity was categorized as follows: class IV, BMI of 50 kg/m^2 or greater; class III, BMI of 40–49.9 kg/m^2; class II, BMI of 35–39.9 kg/m^2; and class I, BMI of 30–34.9 kg/m^2. A BIA (Tanita TBF-310; Tanita Corporation, Tokyo, Japan) was used to estimate fat mass (FM), BF%, and fat-free mass (FFM) [20].

Exclusion criteria were as follows: endocrinal or genetic cause for the obese state, malignancy within the previous

5 years, pregnancy, drug abuse, chronic therapy with steroids, NSAIDs, anticoagulants, or antiobesity drugs. Contraindications specifically related to the balloon included gastrointestinal lesions [e.g. a large (>5 cm) hiatal hernia], Los Angeles grade C–D esophagitis, peptic ulceration, varices or gastric antral vascular ectasia, and previous bariatric or abdominal surgery (because of the potential presence of adhesions). Blood samples were obtained for evaluating fasting blood glucose, serum insulin, lipid profile, liver transaminases, and γ-glutamyl transpeptidase at baseline and after therapy completion. The homeostasis model assessment of insulin resistance (HOMA-IR) index was calculated as fasting plasma glucose (mg/dl) multiplied by fasting serum insulin (mU/l) divided by 405 [21].

The Adult Treatment Panel III criteria were used to diagnose metabolic syndrome. The presence of at least three of the following five conditions was diagnostic of metabolic syndrome: WC greater than 88 cm (for women); serum triglyceride level of at least 150 mg/dl; high-density lipoprotein cholesterol level of less than 50 mg/day (for women); blood pressure of at least 130/85 mmHg; or serum fasting glucose level of at least 110 mg/dl [22].

Ultrasound evaluation of the liver for the presence and grade of steatosis was performed before balloon insertion and after removal using a convex-type real-time electronic transducer (Siemens G50; Siemens, Seoul, South Korea). The severity of liver steatosis was estimated with a comparative assessment of image brightness of the liver relative to the kidneys (mild), blurring of hepatic veins (moderate), or far gain attenuation (severe) [23].

BIB placement was performed (Allergan, Irvine, California, USA) after diagnostic endoscopy, under intravenous conscious or unconscious sedation [24]. The BIB was inflated under direct vision with saline (500–700 ml) mixed with methylene blue (10 ml) solution. The patient was monitored for 3 h to verify tolerance to the balloon. During the following 3 days, patients were contacted daily through telephone. Nausea, vomiting, abdominal cramps, and acid reflux were expected for 72 h and were not considered a complication. They were treated with antiemetic, antispasmodic, and/or acid suppressant medications. Instructions for a 72-h postinsertion liquid diet were provided, followed by a 1000 Kcal diet (carbohydrates 146 g, lipid 68 g, and proteins 1 g/kg ideal weight) under the supervision of professional dietitians (Nutrition Clinic, High Institute of Public Health, Alexandria University, Alexandria, Egypt). After 6 months, endoscopy was performed and balloon removal was carried out. During the 6-month therapy duration patients were followed up monthly for assessment and recording of complications, comorbidities, and weight loss.

Results

Forty-seven middle-aged female patients were enrolled in the study for BIB placement. Their ages ranged from 43 to 59 years with a mean value of 51.4 ± 7.2 years, and only two (4.3%) patients were smokers.

Complications

Table 1 presents the main complications encountered after the first week of BIB insertion and throughout the 6-month therapy duration, including early balloon removal. During the first 72 h after BIB insertion, 33 (70.2%) patients reported nausea, vomiting, acid reflux, and mild abdominal pain, which were successfully managed with medical therapy in the majority of cases. Three (6.4%) patients had their gastric balloon removed early (two voluntarily and one due to de-novo peptic ulcer) and were excluded from the study, whereas the remaining 44 patients continued their 6-month therapy duration. Figure 1 shows the steps for endoscopic insertion of BIB in one of the patients.

Anthropometric measurements

Table 2 and Fig. 2 demonstrate the anthropometric measurements of patients at baseline (before BIB insertion) and endpoint (at the time of BIB removal). The baseline mean BMI value was 37.38 ± 4.65 kg/m^2. None of our patients were of class

Table 1 Reported complications after 1 week from BioEnterics Intragastric Balloon insertion

Complications	*N* (%)[a]
Total complications	6 (12.8)
Nausea and vomiting	5 (10.6)
Gastroesophageal reflux	2 (4.3)
Abdominal pain, dyspepsia	3 (6.4)
Gastritis/peptic ulcer	1 (2.1)
Early balloon removal	3 (6.4)

[a]Total number of patients undergoing BioEnterics Intragastric Balloon insertion: 47.

Table 2 Anthropometric study of patients

Height (cm)	160.73 ± 2.94
Ideal weight (kg)	64.60 ± 2.39
Excess weight (kg)	32.22 ± 12.74
Weight lost (kg)	13.36 ± 3.29
PWL (%)	13.74 ± 2.37
PEWL (%)	45.28 ± 13.42

Data are presented as mean ± SD; PEWL, percentage of excess weight loss at the end of the study; PWL, percentage of weight loss at the end of the study.

IV obesity (BMI≥50 kg/m^2); 12 out of 44 (27.3%) patients were referred for morbid obesity (class III) to reduce body weight before surgery. Class I obesity was documented in 15 (34.1%) patients and class II in 17 (38.6%). Overall, BIB insertion significantly reduced weight from a mean value of 96.82 ± 14.18 kg at baseline to 83.45 ± 12.03 kg after 6 months (P < 0.001). The mean value of the weight lost was 13.36 ± 3.29 kg, whereas the mean value for BMI lost at the time of BIB removal was 5.12 ± 1.20 kg/m^2, which was a significant reduction in endpoint compared with baseline values (P < 0.001). The percentage of weight loss was calculated in reference to initial total body weight, whereas the percentage of excess weight loss was calculated in relation to initial excess weight. The number of participants achieving 10% or greater percentage of weight loss threshold was 42 (95.4%). WC and WHR were also significantly reduced at the endpoint of the study compared with baseline values (P < 0.001).

Ultrasound evaluation of fatty liver

Table 3 summarizes the abdominal ultrasound of fatty liver changes in patients at baseline and endpoint. No significant change occurred in the liver size over the 6-month study period (P = 0.12). However, a significant decrease was noted in the grade of steatosis (P = 0.03), and three (6.8%) patients showed complete resolution of ultrasound features of steatosis.

Laboratory values

Table 4 summarizes the laboratory test results of patients at baseline and endpoint of the study, showing significant changes in the biochemical markers of metabolic syndrome. Following weight loss, fasting blood glucose, serum insulin, HOMA-IR index, cholesterol, and triglyceride concentrations were lowered, whereas high-density lipoprotein was elevated. Liver profile parameters showed significant reduction, particularly serum γ-glutamyl transpeptidase.

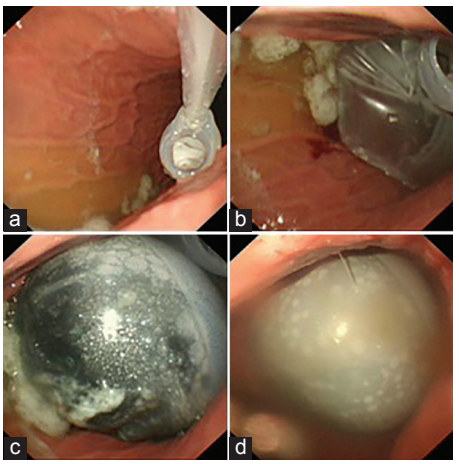
Body composition analysis

Table 5 summarizes the results of body composition analysis of patients using BIA at baseline and endpoint of the study, with significant reduction in the body FM and BF% (P < 0.001). However, there was also a significant decline in FFM (P < 0.001).

Metabolic syndrome and comorbidities

Table 6 and Fig. 3 illustrate the different comorbidities diagnosed in our patients at baseline and their re-evaluation 6 months later at the time of balloon removal. All participants who completed the study (n = 44) had one or more pre-existing comorbidities, which were either recognized through medical history taking from the patient, or incidentally

Figure 1



Steps for endoscopic insertion of BioEnterics Intragastric Balloon (BIB) in one of the patients. (a) Endoscopic picture of the gastric lumen showing BIB Placement Catheter Assembly while the balloon is still uninflated. The balloon must be below the lower esophageal sphincter and well within the stomach cavity. (b) Endoscopic picture of the gastric lumen showing partially inflated BIB *in situ* (300 ml of sterile saline). (c) Endoscopic picture of the gastric lumen showing fully inflated BIB *in situ* (700 ml of sterile saline). (d) Endoscopic picture of the gastric lumen showing fully inflated BIB *in situ* at the end of 6-month therapy duration.

Table 3 Ultrasound study of liver steatosis in patients at baseline and endpoint

Finding	Baseline	Endpoint	*P*
Right lobe dimension (cm)	15.3 ± 3.4	15.1 ± 3.9	0.12
Steatosis grade			
None	5 (11.4)	8 (18.2)	0.03*
Mild	9 (20.5)	8 (18.2)	
Moderate	18 (40.9)	18 (40.9)	
Severe	12 (27.3)	10 (22.7)	

Data are presented as mean ± SD or *n* (%) (n = 44); *Statistically significant at $P \leq 0.05$.

Table 4 Laboratory values of patients at baseline and endpoint

Laboratory tests	Baseline	Endpoint	*P*
Fasting blood glucose (mg/dl)	116 ± 45	93 ± 43	<0.001*
Serum insulin (mU/l)	12.4 ± 7.2	8.0 ± 4.5	<0.001*
HOMA-IR	3.2 ± 1.7	2.2 ± 1.3	<0.001*
Total cholesterol (mg/dl)	201 ± 43	182 ± 67	<0.001*
LDL (mg/dl)	112 ± 75	102 ± 69	0.006*
HDL (mg/dl)	44 ± 14	46 ± 13	0.04*
Triglycerides (mg/dl)	184 ± 78	115 ± 41	<0.001*
ALT (IU/l)	38 ± 22	34 ± 24	0.02*
AST (IU/l)	29 ± 19	25 ± 17	0.03*
GGT (IU/l)	31 ± 21	23 ± 15	0.009*

Data are presented as mean ± SD; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, γ-glutamyl transpeptidase; HDL, high-density lipoprotein; HOMA-IR, homeostasis model assessment of insulin resistance; LDL, low-density lipoprotein; *Statistically significant at $P \leq 0.05$.

diagnosed *de novo* during patient screening before balloon placement. Metabolic syndrome-associated, as well as other frequently reported, comorbidities such as respiratory symptoms (obstructive sleep apnea and/or exertional dyspnea) and joint pains were included. The resolution of comorbidities was defined as normalization of laboratory values or disappearance of physical symptoms and signs resulting in complete cessation of pharmacological therapy. Improvement in comorbidities was defined as requiring lower drug dosage, or shifting to milder therapy. All types of comorbidities showed statistically significant resolution/improvement at the time of BIB removal. Patients who showed resolution/improvement in comorbidities demonstrated significantly higher body weight loss ($P = 0.02$) and BF% loss ($P < 0.001$) compared with those who showed no change in comorbidities. No correlation was found between the presence of comorbidities at baseline and the occurrence of complications from BIB insertion ($P = 0.17$).

Table 5 Body composition study of patients with bioelectrical impedance analyzer at baseline and endpoint

Parameter	Baseline	Endpoint	*P*
Body fat (kg)			
Range	28.50–72.20	21.20–54.10	<0.001*
Mean ± SD	44.08 ± 12.13	32.72 ± 8.81	
BF%			
Range	36.0–57.70	31.20–48.10	<0.001*
Mean ± SD	44.76 ± 5.58	38.58 ± 4.66	
FFM (kg)			
Range	48.30–58.60	44.80–58.90	<0.001*
Mean ± SD	52.74 ± 2.57	50.73 ± 3.42	

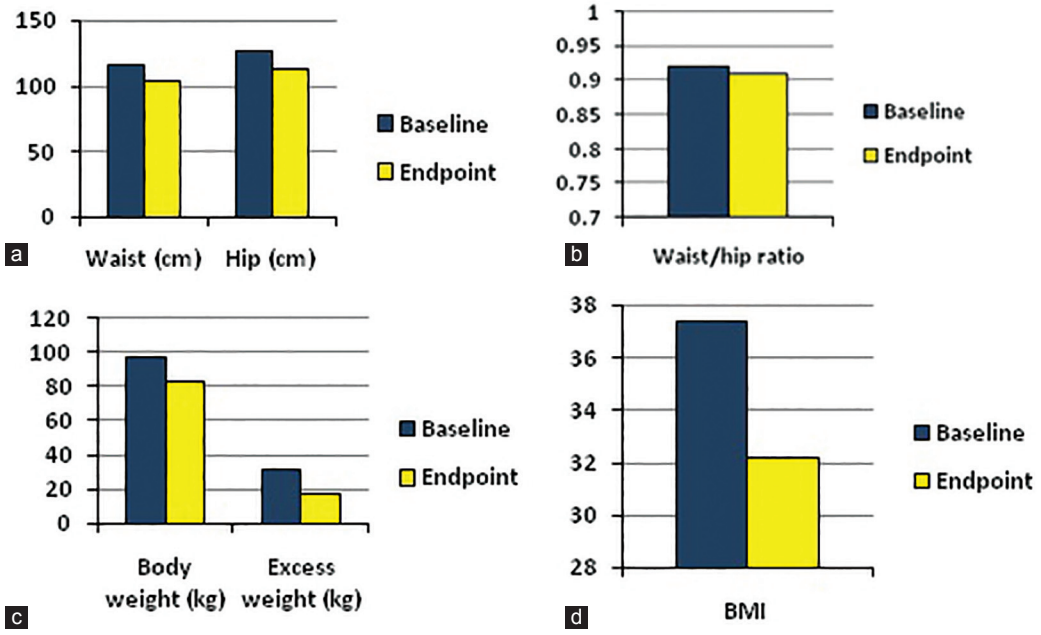
Data are presented as mean ± SD ($n = 44$); BF%, body fat percentage of total body weight; FFM, fat-free mass; *Statistically significant at $P \leq 0.05$.

Table 6 Comorbidities at baseline and endpoint of the study

Comorbidities	At baseline	Resolution	Improvement	No change	*P*
Metabolic syndrome[a]	16 (36.4)	2 (4.6)	14 (31.8)	0 (0)	<0.001*
Hyperglycemia[b]	18 (40.9)	4 (9.1)	10 (22.7)	4 (9.1)	0.006*
High serum TG[c]	13 (29.5)	3 (6.8)	6 (13.6)	4 (9.1)	0.03*
Low serum HDL[d]	12 (27.3)	4 (9.1)	5 (11.4)	3 (6.8)	0.02*
Hypertension[e]	21 (47.7)	8 (18.2)	10 (22.7)	3 (6.8)	<0.001*
Respiratory symptoms[f]	8 (18.2)	6 (13.6)	1 (2.3)	1 (2.3)	<0.001*
Joint pains	24 (54.5)	10 (22.7)	13 (29.5)	1 (2.3)	<0.001*

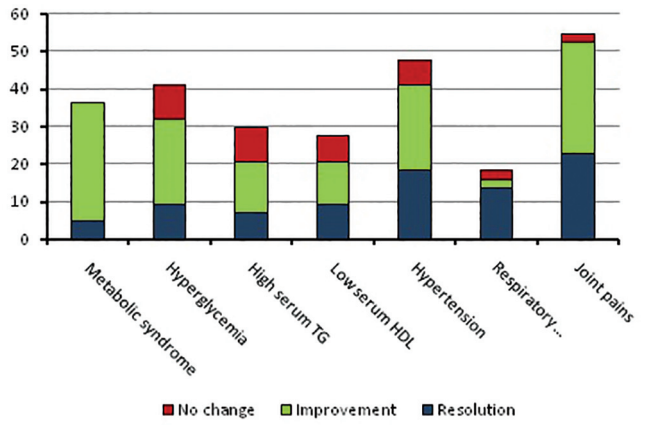
Data are presented as *n* (%) ($n = 44$); HDL, high-density lipoprotein; TG; triglycerides; [a]Diagnosed according to the Adult Treatment Panel III criteria; [b]Fasting hyperglycemia (≥110 mg/dl); [c]TG ≥ 150 mg/dl; [d]HDL<50 mg/dl; [e]Blood pressure ≥ 130/85 mmHg; [f]Obstructive sleep apnea and/or exertional dyspnea on minimal effort; *Statistically significant at $P \leq 0.05$.

Figure 2



Anthropometric study of patients at baseline and endpoint. (a) Waist and hip measurements at baseline and endpoint ($P < 0.001$). (b) Waist-to-hip ratio at baseline and endpoint ($P < 0.001$). (c) Body weight measurements at baseline and endpoint ($P < 0.001$). (d) BMI at baseline and endpoint ($P < 0.001$).

Figure 3



Comorbidities at baseline and endpoint (%). HDL, high-density lipoprotein; TG, triglycerides.

Discussion

The classic weight loss treatment lines include low-calorie diet, exercise, behavioral modification, and pharmacotherapy. Because these modalities achieve modest and usually transient weight loss, bariatric surgery and other interventional modalities (such as the intragastric balloon) have emerged in the last two decades as an adjuvant line of therapy for patients with high BMI, particularly those with obesity-related medical conditions, such as diabetes, cardiovascular disease, and obstructive sleep apnea [15].

The effectiveness and safety of intragastric balloon have been a matter of debate for quite some time. In our work, the total percentage of complications from BIB insertion was 12.8%, which were mostly mild and reversible. This was not different from the results of Imaz *et al.* [25], who extracted data from 3442 patients treated with BIB and found that the majority of complications were mild. Although they admitted that the early removal rate was significant (4.2%), half of these removals, however, were voluntary. As regards the effectiveness of BIB in reducing weight, a review article in 2007 of nine randomized, controlled trials on 395 obese patients found little benefit of intragastric balloon placement for weight loss [26]. However, another extensive meta-analysis [25] in 2008 collected data from 15 studies that used BIB on 3608 patients and estimated a pooled weight loss of 14.7 kg and a pooled BMI loss of 5.7 kg/m^2. Our results showed similar numbers; the average weight lost at the time of BIB removal was 13.36 ± 3.29 kg, whereas the average BMI lost was 5.12 ± 1.20 kg/m^2, demonstrating a significant reduction from baseline values for both parameters. It remains to be established, however, whether the beneficial effect of BIB-induced weight loss also translates into reduced rates of different obesity-related morbidities. Our participants who had the BIB placed and were kept on a 1000 Kcal diet throughout the follow-up period mostly showed a positive outcome as regards insulin sensitivity, hepatic steatosis, and features of the metabolic syndrome. Compared with baseline, 9.1% of our patients became normoglycemic, 18.2% became normotensive, 6.8% attained normal serum level of triglycerides, and 9.1% achieved normal high-density lipoprotein. Significant favorable changes in insulin sensitivity (in terms of HOMA-IR index) and liver steatosis (in terms of ultrasound image and liver enzymes) also occurred. In addition, 13.6% were totally cured from their respiratory symptoms and 22.7% were completely relieved from joint pains. Keeping in mind that the main contributory factor in the development of the metabolic syndrome is the accumulation of fat around the abdominal viscera and inside the intra-abdominal solid organs, this beneficial effect of BIB on comorbidities, fatty liver, and liver enzymes is likely attributed to loss of visceral fat. By reducing the size of the gastric reservoir, the intragastric device might induce a negative energy balance between dietary energy intake and energy expenditure [27].

In our study we did not include controls for comparison, but our primary aim was to examine the safety of BIB insertion, as well as its effect on liver steatosis and some components of the metabolic syndrome. In addition, we acknowledge that our assessment of liver steatosis with ultrasound and not using histology might have been suboptimal for the evaluation of the actual impact on liver tissue steatosis, which was mainly attributed to the refusal of most patients to undergo the invasive procedure of liver biopsy for no significant reason. This frequently encountered obstacle was in fact also reported in a study by Mattar *et al.* [28], in which 70 patients underwent liver biopsy after dramatic surgically induced weight loss. Although their results proved significant and widespread improvement or resolution of NAFLD and NASH, the authors admitted to their compulsion to obtain liver biopsies intraoperatively despite the possible technical and operator bias.

Another objective of our study was to measure the effect of BIB-induced weight loss for 6 months on body composition. A significant decline in body FM and BF% was recorded in our patients. However, there was also a significant reduction in FFM. Although the commonly used indicators for obesity are BMI, WC, and WHR, these indicators are limited by their inability to distinguish fat from muscle. BIA is a method used to determine the body composition, particularly body fat, FFM, and BF%. These measurements are equally important for any given weight-loss trial, not only because the reduction in body fat ultimately leads to a decrease in risk factors for metabolic syndrome but

also because a concomitant decline in lean tissue can frequently be observed during a weight-reduction program – as was encountered in our study. Given that the FFM represents a key determinant of resting metabolic rate (RMR), thus a decrease in lean tissue could hinder the progress of weight loss by reducing the RMR. Losing FM when maintaining a constant FFM and RMR should be, therefore, a desirable goal for weight-reduction programs to achieve long-term effectiveness. Studies have proved that exercise training has great implications on decreasing the percentage of body fat while sustaining FFM. Hence, the addition of exercise programs to dietary restriction would act synergistically to encourage more favorable changes in body composition than separate diet or physical activity [29].

In conclusion, this study provides anthropometric, biochemical, and body composition evidence on significant improvement in metabolic syndrome, obesity-associated comorbidities, and fatty liver after weight loss induced by a minimally invasive and relatively safe technique. However, BIB insertion alone (similar to any other short-term weight loss modality) could be limited by high rates of relapse and weight regain after removal. Therefore, it is recommended to continue a weight-reducing diet after BIB removal for achieving long-term effectiveness, and to add exercise programs to dietary restriction for promoting more favorable change in body composition.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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