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ORIGINAL ARTICLE

Efficacy of Bioenterics Intragastric Balloon Insertion in Controlling Obesity and Fatty liver in patients

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ABSTRACT
The aim of the current study was to determine efficacy of bioenterics intragastric balloon insertion in controlling obesity and treatment of fatty liver in overweight and obese patients. A total 40 patients, 14 males (35%) and 26 female (65%) with average age of 34.6±4.66 included in this study. The patients were obese with mean weight of 114.53±28.33 kg and mean BMI of 41.75±8.53 kg/m^2. Also, the mean excess weight was 41.2±8.93 kg. Then BIB followed after endoscopic implantation of a gastric balloon associated to restricted diet for 6 months. At the end of the study, anthropometric, Sonographic indexes and aspartate aminotransferase, alanine aminotransferase and alkaline phosphatase (ALP) levels determined. According to the results BIB significantly decreased body weight and increased weight loose after 6 months (P=0.000). Also, serum AST and ALT significantly diminished in patients treated with BIB (P=0.000). Incidence of grade I fatty liver increased after BIB among patients (16 persons). Also, the grade III fatty live was observed in 17 patients before the experiment while detected in 3 patients after 6 months. The reflex was observed in 9 patients. Epigastric pain and reflex + epigastric pain were detected in 5 and 6 patients; respectively. These results suggest application of BIB for 6 months had positive effect on weight loose and fatty liver in obese patients.
***Keywords**: Bioenterics Intragastric balloon, Obesity, Fatty liver*

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INTRODUCTION

Obesity is a serious and chronic disease with genetic and environmental factors. Obesity develops because of excessive fatty tissue in the body and a great number of factors and it also requires medical treatment. The most significant risk factors of obesity constitute reduction in physical activity, feeding habits, age, sex, educational level, marriage, parity and genetic reasons. Obesity that can be transmitted genetically is spreading expeditiously in developed and developing countries in particular. By losing weight, lung function, metabolic parameters, and body fat distribution in patients with overweight/obesity and metabolic syndrome improves [1].

There are around 1.5 billion overweight and obese adults around the world. These adults are in danger of comorbidities such as diabetes, heart disease, stroke and liver disease. But if these people lose just 10% of weight, their risk of comorbidities would significantly decrease. These adults can achieve such weight loss with weight loss therapies. There are numerous weight loss therapies, but each has disadvantages. Bariatric surgery is invasive, expensive and dangerous, while pharmacological methods are relatively ineffective and produce side effects [2]. The silicone intragastric balloon (SIB) was developed in conjunction in 1986 and then renamed the bioenterics intragastric balloon (BIB) [3].

The BIB is intended for temporary use in weight loss therapy for patients who are at least 40% above their ideal weight and who have failed to achieve weight loss with a supervised weight control program [4]. The BIB is designed to be placed in the stomach in a collapsed form, then filled and expanded with saline to act as an artificial bezoar1. As it is filled the BIB expands into an approximately spherical shape. A self-sealing valve permits detachment from external catheters [5]. The BIB is designed to float freely within the stomach. The expandable design of the BIB is to permit adjustment of the fill volume (and thus the size of the balloon) at the time of placement as well as later in the treatment period [6].

Laparoscopic operations in overweight and obese patients are technically challenging and surgical complications increase with higher BMI. It is shown that as little as10% weight loss may have dramatic effects on cardiopulmonary and metabolic function [7]. Currently, intragastric balloons (air- or liquid-filled) are applied in patients with body mass index (BMI)>30 kg/m^2 associated with obesity-related illnesses who failed to respond to conservative management and in subjects whose cardiocirculatory or respiratory conditions preclude any surgical procedure or as a "bridge" toward bariatric surgery, exploiting the improvement of comorbidities expected after Currently, intragastric balloons (air- or liquid-filled) are applied in patients with body mass index (BMI)>30 kg/m^2 associated with obesity-related illnesses who failed to respond to conservative management and in subjects whose cardiocirculatory or respiratory conditions preclude any surgical procedure or as a "bridge" toward bariatric surgery, exploiting the improvement of comorbidities expected after balloon removal and to minimize surgical and anesthetic risks [8]. Tolerance and efficacy in terms of body weight loss have been the most frequently assessed aspects of this procedure to date [9].
The aim of this study was to assess the efficacy of BIB insertion in controlling obesity and fatty liver in overweight and obese patients referred to hospital.

MATERIAL AND METHODS

This experiment designed to determine the efficacy of BIB insertion in controlling obesity and fatty liver in overweight and obese patients referred to Sina hospital in 2015. A total 40 patients, 14 males (35%) and 26 female (65%) with average age of 34.6±4.66 were include in this study. The patients were obese with mean weight of 114.53±28.33 kg and mean BMI of 41.75±8.53 kg/m^2. Also, the mean excess weight was 41.2±8.93 kg [10]. The inclusion criteria were being obese with BMI of 30> kg/m^2, without ulcer. The participants completed and signed the informed consent. Then BIB followed after endoscopic implantation of a gastric balloon associated to restricted diet for 6 months. At the end of the study, anthropometric indexes include weight, BMI excess weight were recorded. Sonography before and after 6 months was done to determination and grade fat liver. Side effects of BIB including reflux and epigasteric pain were recorded. All protocols for experiments were approved by the institution of Ethical Committee, Tehran University of Medical Science (TUMS) & Health Services.

Enzyme activity

Prior and at the end of the experiment (after 6 months), aspartate aminotransferase (AST), alanine aminotransferase (ALT) and alkaline phosphatase (ALP) levels determined using commercial detecting kits. The activity of ALT, AST and ALP was determined according to the procedure of Dahlqvist and Thamson [11]. For measuring the activity of ALT, AST and ALP, It was needed to determine total protein in which (calorimetric) method was used [12]. The activity level of ALT, AST and ALP enzyme of each sample is divided into the amount of its total protein. Therefore, the activity level of the enzyme, according to the IU /L is researched.

Statistical analysis

The results are analyzed with SPSS statistical program SPSS 18.0 (SPSS Inc, Chicago IL) and presented as mean ± standard deviation for numerical variables and considering as significant P< 0.05. The comparison between groups compared using pair T-test.

RESULTS

Results of anthropometric index, liver enzyme activity, fatty liver incidence and side effects after BIB in patients are presented in tables and figs 1-2.
According to the table 2, application of BIB for 6 months significantly decreased body weight in patients (P=0.000). Also, BMI significantly diminished in patients treated with BIB (P=0.000). Additionally, administration of BIB significantly improved weight loose after 6 months (P=0.000).

Table 1. Effects of BIB for 6 months on Anthropometric indexes of patients

	Before BIB	**After BIB**	***P value***
Weight (Kg)	114.53±28.33	102.53±28.33	0.000
BMI (Kg/m^2)	41.75±8.53	37.19±8.99	0.000
Excess Weight (Kg)	41.20±8.93	33.39±11.22	0.000

Data are expressed as mean ± SD. Abbreviations: BMI, body mass index. bioenterics intragastric balloon (BIB). * P<0.05 for statistical difference

The results of BIB on liver enzyme activity in presented in table 2. As seen, serum AST and ALT significantly diminished in patients treated with BIB after 6 months (P=0.000). Also, BIB had no effect on serum ALP (P=0.454).

Table 2. Effects of BIB for 6 months on liver enzyme activity in patients

	Before BIB	After BIB	*P value*
AST (IU/L)	66.88±11.35	40.88±11.01	0.000
ALT (IU/L)	76.63±13.06	48.10±11.49	0.000
ALP (IU/L)	173.73±42.83	171.15±38.80	0.454

Data are expressed as mean ± SD. Abbreviations: aminotransferase: AST, alanine aminotransferase: ALT and lucine aminopeptidase: LAP. bioenterics intragastric balloon (BIB). * P<0.05 for statistical difference

According to the results, incidence of grade I fatty liver increased after BIB among patients (16 persons). Also, the incidence of grade II of fatty liver for pre- and post BIB were 23 and 20, respectively. Additionally, the grade III fatty live was observed in 17 patients before the experiment while detected in 3 patients after 6 months.

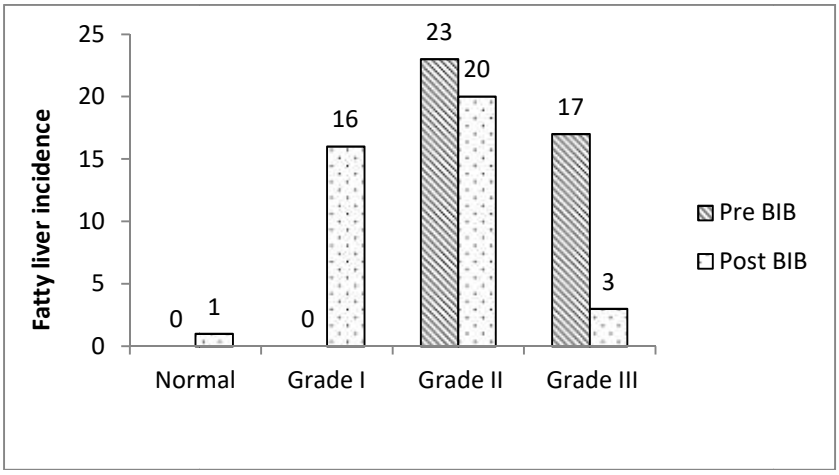

Figure 1. Fatty liver incidence based on the grade (none, I, II and III) in patients before and after bioenterics intragastric balloon (BIB). There are significant differences between groups with different superscripts in a column (a b and c; P<0.05).

Incidence of side effects after BIB is presented in fig. 2. As seen, the reflex was observed in 9 patients. Also, in 5 patents epigastric pain detected. Additionally, 6 patients had reflex + epigastric pain.

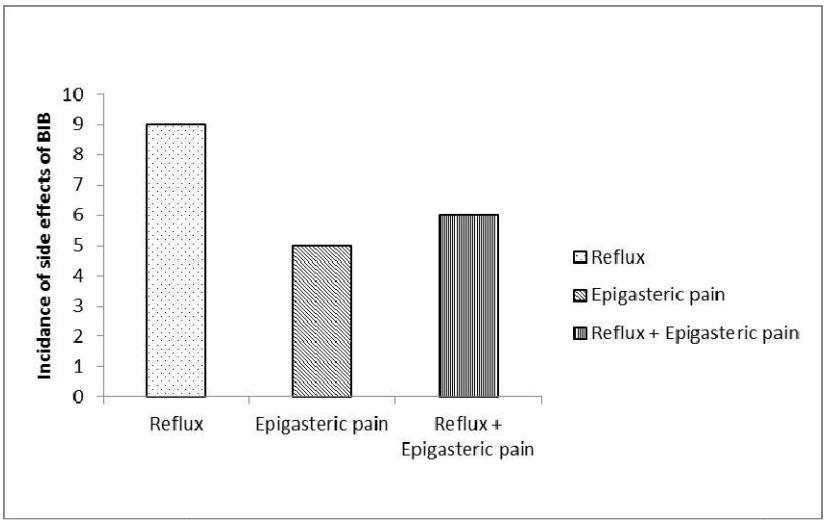

Figure 2. Incidence of side effects after bioenterics intragastric balloon (BIB).

DISCUSSION

Preoperative weight loss is probably the most important method for reducing surgical risks in extremely obese patients. As observed in this study, BIB decreased body weight and increased weight loose after 6 months. Broadly, management of obesity comprises primary management of obesity, management of obesity-related diseases and management of complications of bariatric surgery like bleeding, anastomotic

strictures and fistulae. The spectrum for endoscopic management of obesity is wide. It comprises gastric volume reduction procedures by balloon insertion, stapling or plication devices as well as small bowel approach procedures like the duodenal- jejunum bypass sleeve.

Patients under treatment for obesity have variable individual response rates, depending on compliance, motivation, feeding habits, etiology of obesity (familial, genetic), physical activity and drug therapy. To standardize the circumstances under which BIB was placed, we strictly selected an obese cohort with BMI more than or equal to 30 kg/m^2 and excluded those with genetic cause of obesity. We also included patients who were previously maintained on a full diet control program, without adequate weight reduction, as declared by their referring dietician. Although the balloon inflation volume ranges between 400-650 ml, we standardized the fill volume to 500 ml [13]. In a study Peker [14], relied on the presence of highly significant difference between the mean BMI before and after 6 months of balloon implantation. The authors didn't individualize the BMI loss for each patient. Similarly, they calculated an overall mean excess weight loss % (29.16% ± 15.99%) without description of how many patients achieved an actual target of excess weight loss %.

In previous studies effectiveness of gastric balloons, at 6 months the mean weight loss achieved was 13.4 (8.8) kg, the decrease of BMI and waist circumference were 5 (3.4) kg/m2 and 8.1 (6.4) cm and the ratios % LTW and % excess weight loss situated on 11 (7) and 27.3 (19.9) respectively, showing a gradual increase along the implantation time of these devices. The BIB slows gastric emptying and reduces ghrelin, an orexigenic hormone originating from the stomach, but the BIB does not increase cholecystokinin, which is expected due to gastric distention caused by the balloon. The BIB has a place in the treatment of obesity when used for weight loss prior to obesity surgery. A case control study demonstrated that 6 months of preoperative weight loss using the BIB reduced the length of the hospital stay, operative time, intraoperative complications (0% vs 7%) and the conversion of laparoscopic to open procedures (0% vs 16.3%) [15]. Perhaps changes in other hormones induced by the balloon presence inhibited adiponectin synthesis by the fatty tissue, the process usually described in literature as a response to body mass reduction. On the other hand, it can be assumed that body mass decrease does not cause immediate changes in adiponectin level [16].

Also, serum AST and ALT diminished in patients treated with BIB. In this study, incidence of grade I fatty liver increased while grade III decreased after BIB among patients. The reflex was observed in 9 patients. Epigastric pain and reflex + epigastric pain were detected in 5 and 6 patients, respectively. As regards to endoscopic procedures of placement and withdrawal of these devices, we found a great variability in the literature, performing both by general anesthesia, with conscious sedation controlled by the endoscopist or performing one procedure, usually the retrieval, under anesthesia. We choose the latter option as consider withdrawal to be a more complex procedure than placement, although the gain in safety that occurs by incorporating an anesthesiologist should be contrasted with the greatest economic cost that it represents. Regarding the implantation procedure, in this study there were neither adverse cardio-vascular nor respiratory events justifying the administration of antiarrhythmic, inotrope or vasopressor drugs or performing resuscitation, although obese patients required high doses of benzodiazepines to obtain adequate sedation as these drugs are administered in body weight basis [17].

Despite the success of the BIB for inducing preoperative weight loss in preparation for obesity surgery, several disadvantages remain. First, the placement requires insertion and removal endoscopically, which necessitates at least conscious sedation. Second, the stomach gradually adapts to the balloon, necessitating removal after 3–6 months, and, following removal, weight is regained. Development of a gastric balloon that does not require endoscopic placement and that has the potential to be used chronically might effective for long-term treatment of obesity [18].

Doldi *et al.* [19] demonstrated that up to 45% of patients regain weight 6 months after balloon removal. Only 5% of severely obese patients are able to obtain long term weight loss. Although the majority of patients regain some weight 6 months after balloon removal, there are some studies reporting a lengthy maintenance of weight loss after balloon removal. For instance, it reported that 90% of patients maintain their reduced bodyweight at the end of the first year [20]. So, we think further studies need to determine effect of long-term application of BIB on weight loose in overweight and obese patients. Beside the weight loss, only a few studies have been performed so far to assess the effect of the BIB positioning on obesity related comorbidities. A large retrospective study by the Italian group for Lap-Band has shown that the weight loss induced by the BIB, though modest, caused most comorbidities associated with obesity to be either resolved or improved, in particular respiratory disorders, hypertension, type II diabetes and osteoarthropathy [10].

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