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Single-center retrospective evaluation of short and long-term efficacy of intragastric balloon placement in obesity treatment

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Abstract

Obesity is a serious chronic disease caused by genetic and environmental factors. One of the treatment options is intragastric balloon application. This study aimed to evaluate the results of patients who underwent intragastric balloon placement on the short- and long-term treatment of obesity. The data and long-term follow-up results of 34 patients who underwent intragastric balloon placement due to obesity between December 2011 and August 2013 were retrospectively evaluated. Age, sex, body mass index (BMI), presence of additional diseases, duration of intragastric balloon remaining in the stomach, patients' weight, and BMI at intragastric balloon removal, weight measured in December 2019, bariatric surgery performed during the study period if any, and general health status during this period were obtained. The mean weight loss of the patients after intragastric balloon removal was 15.6 ± 9.6 kg (range, 0–45 kg). The mean decrease in BMI after intragastric balloon removal was 11.4 ± 6.4% (range, 0%–26.5%). No patients developed any complications. The procedure was ineffective in the long-term in 76.4% of the patients. The most important disadvantage of intragastric balloon placement application in the treatment of obesity is that the weight lost in the early period is regained in the long-term after balloon removal. In patients scheduled to undergo bariatric surgery, intragastric balloon placement can be applied as a bridge therapy to facilitate preoperative weight loss to reduce complications.

Keywords: Obesity, gastric balloon, weight loss

Introduction

Obesity is a serious chronic disease caused by genetic and environmental factors. More than 1.4 billion adults worldwide are overweight or obese, and an alarming increase in the incidence is observed, especially in developed and developing countries. Obesity causes serious health problems, such as diabetes, hypertension, and heart disease. However, obese patients can prevent the occurrence of these health problems by losing approximately 10% of their weight [1-5].Various endoscopic methods are available in the treatment of obesity, including devices that occupy space in the stomach (either with the device or by causing delayed gastric emptying), those that remove a portion of calories consumed after a meal (aspiration therapy), and those that alter gastric anatomy to reduce gastric volume and accommodation (plication and suturing) [6].

Intragastric balloon (IGB) placement, a common endoscopic method, can be used as a minimally invasive and temporary treatment option between the medical treatment of obesity and bariatric surgery without the need for general anesthesia.

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It causes short term weight loss by decreasing the preprandial feeling of hunger and giving the feeling of postprandial satiety. This method can be applied to those unable to lose weight through diet and exercise or who do not want to undergo an invasive procedure. In addition, IGB placement can be used before bariatric surgery as a bridge therapy to reduce the risk of possible postoperative complications [7-10].

The ReShape integrated dual balloon system, Orbera, Obalon balloon system, Spatz balloon, and Elipse balloon are used in the IGB procedure. These balloons vary in shape (ellipse, spherical), number (single, dual, triple), and adjustability. In addition, the duration of IGB left in the stomach (4, 6, or 12 months) also differs according to the type of balloon used [6]. Serious complications associated with the IGB procedure include esophageal perforation, gastric perforation, intestinal obstruction due to the migration of ruptured balloon, and death [11,12]. Non-serious side effects observed in these procedures include vomiting, nausea, abdominal pain, gastric ulcer, dyspepsia, eructation, abdominal discomfort, abdominal distension, erosive gastritis, gastroesophageal reflux disease, erosive esophagitis, constipation, and diarrhea [13].

Due to the risk of IGB deflation or migration to another location in the body, removal is recommended after 6 months [14]. The present study aimed to determine the effect of IGB procedure on the short- and long-term treatment of obese patients.

Materials and Methods

This retrospective, single-center study evaluated 34 patients who underwent IGB placement for the treatment of obesity in Ege University Faculty of Medicine Department of Gastroenterology between December 2011 and August 2013. Of the 34 patients, two (0.5%) were excluded because their IGBs were removed within 24 h due to epigastric pain. Most of the evaluated data were accessed from the patient files, and the patients were also contacted to inquire about their current weight and long-term results. For all included patients, the protocol number, age, sex, height, weight, body mass index (BMI), presence of other diseases, duration of IGB left in the stomach, development of IGB-related complications, weight, BMI, and percentage of excess weight loss (EWL) at IGB removal, weight measured in December 2019, bariatric surgery performed during the study period, and general health status during this period were obtained and recorded in the case report form. Inclusion criteria were age >18 years, BMI≥35 kg/m^2, no history of bariatric surgery before IGB placement, failing to lose weight through diet and/or exercise therapy for at least 6 months before the procedure, and presence of indications for the IGB procedure according to the decision of an obesity council consisting of doctors specialized in endocrinology and metabolic diseases and psychiatry. Exclusion criteria were BMI < 35 kg/m^2, ≥3 cm hiatal hernia, peptic ulcer or gastric outlet obstruction on endoscopy, history of gastric surgery, psychiatric diseases, alcohol dependence or anticoagulant use, and pregnant or lactating women.

After confirmation that the patients have no contraindication for IGB through an esophagogastroduodenoscopy examination, a bioenteric balloon inflated with 550–600 cc SF and methylene blue dye was placed in the stomach by one gastroenterologist (Vardar R.) (Figure 1). IGB was applied to 34 patients, but the balloon was removed within 24 h in two patients who could not tolerate the procedure. Therefore, only the data of 32 patients were evaluated. The patients were observed for 24 hours postoperatively at the hospital and informed that their daily calorie intake should not exceed 1000 kcal. The patients used a 2 × 1 proton pump inhibitor until IGB removal, and they were able to reach the physician anytime. The patients were followed up monthly for dietary compliance and presence of complications and examined by the physician who applied the procedure. Statistical analysis was performed on the data obtained from 32 patients.

Long-term success was defined as weight loss through IGB placement and then underwent bariatric surgery or weight loss through IGB placement and maintainenance of weight.

The mean and median values were obtained for numerical variables, whereas frequency and percentages were used for categorical variables. IBM SPSS 20.0 package program was used for statistical analysis. The chi-squared test (or Fisher exact test) was used to examine the relationship between categorical variables, and the Mann–Whitney U test was used to compare continuous variables. Statistical significance was determined by $p < 0.05$.

Results

The study included 22 (68.8%) and 10 (31.2%) female and male patients, respectively. Their mean age was 40.4 ± 12.1 years (range, 19–62). Their mean initial weight and BMI were 135 ± 25.6 kg (range, 96–192 kg) and 49 ± 10.4 kg/m2 (range, 35.5–79.2 kg/m2), respectively. IGB was left in the stomach for a mean duration of 6.1 ± 0.4 months (range, 6–8 months). After IGB removal, the mean decrease in weight and BMI were 15.6 ± 9.6 kg (range, 0–45 kg) and 43.4 ± 9.9 kg/m2 (range, 27.2–74 kg/m2), respectively. The mean decrease in BMI after IGB removal was 11.4 ± 6.4% (range, 0%–26.5%). The mean EWL percentage at IGB removal was 23 ± 16.2 (range, 0–78.9) (Table 1).

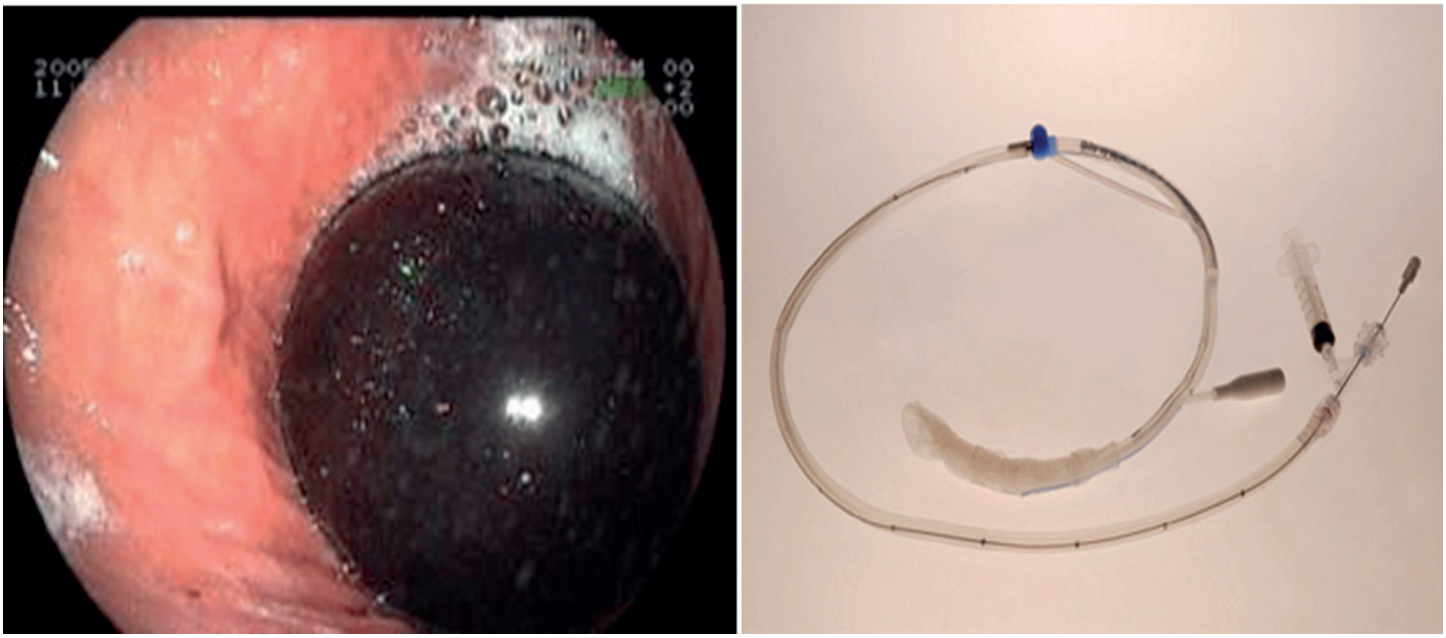

Figure 1. Intragastric balloon used in the procedure.

Table 1. Short term results of the intragastric balloon procedure.

	Mean ± SD (min–max)
Age	42 (19–62)
Initial weight (kg)	135 ± 25.6 (96–192)
Initial BMI (kg/m2)	49 ± 10.4 (35.5–79.2)
After balloon procedure BMI (kg/m2)	43.4 ± 9.9 (27.2–74)
After balloon procedure wieght loss (kg)	15.6 ± 9.6 (0–45)
After balloon procedure BMI decrease (%)	11.4 ± 6.4 (0–26.5)
Percent excess weight loss (%)	23 ± 16.2 (0–78.9)
Duration of balloon procedure (months)	6.1 ± 0.4 (6–8)

SD: standard deviation, BMI: body mass index.

Of the 32 patients, 20 (62.5%) did not have any comorbidities. Among the remaining patients, comorbidities include hypertension (HT) in six patients (18.8%), diabetes mellitus (DM) in three patients (9.4%), DM + HT in two patients (6.2%), and DM + chronic kidney disease in one patient (3.1%). None of the 32 patients developed any complications related to the IGB procedure.

Seventeen (53.1%) patients were successfully contacted by phone after a mean of 81 months (range, 76–96 months). The long-term results showed that seven (41.1%) patients who returned to their initial weight underwent bariatric surgery. Furthermore, six patients (35.3%) who returned to their initial weight did not undergo bariatric surgery. Of these six patients, two died; one because of Burkitt lymphoma and the other because of chronic renal failure. One (5.9%) patient lost 13 kg and reduced her BMI by 9.2%, benefiting from IGB as a bridge therapy before bariatric surgery. Three (17.7%) patients who lost 21, 15, and 14 kg following IGB placement reduced their BMI by 8%, 13.7%, 7.4% kg/m2, respectively and maintained their weight after balloon removal (Figure 2). Comparison of demographic and clinical characteristics of successful and not successful patients is shown in Table 2. No statistical significance was observed between the two groups.

Table 2. Comparison of demographic and clinical characteristics of successful and not successful patients.

	Group of patients		P
	Successful (n = 4) (Mean ± SD)	Not successful (n = 13) (Mean ± SD)	
Age	48.25 ± 6.29	40.70 ± 14.53	0.350
Sex[n(%)]			
Female	2(50)	8(61.5)	1.000
Male	2(50)	5(38.5)	
Beginning weight (kg)	145 ± 34.54	141.30 ± 28.29	0.956
Beginning BMI (kg/m2)	56.71 ± 18.42	49.96 ± 8.34	0.624
After balloon procedure BMI (kg/m2)	51.5 ± 17.75	44.7 ± 8.22	0.477
After balloon procedure wieght loss (kg)	15.75 ± 3.6	15.15 ± 10.95	0.350
After balloon procedure BMI decrease (%)	9.55 ± 2.88	10.5 ± 6.7	0.956
Classification of BMI [n(%)]			
35–39.9	2(15.4)	0(0)	0.696
40–49.9	5(38.5)	2(50)	
≥50	6(46.2)	2(50)	
Percent excess weight loss (%)	21.7 ± 12.03	19.11 ± 12.7	0.871
Duration of balloon procedure (months)	6.0 ± 0	6.15 ± 0.55	0.871

SD: standard deviation, BMI: body mass index.

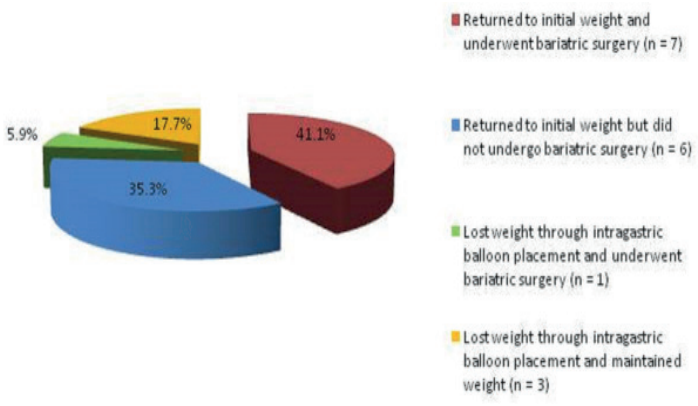

Figure 2. Long-term results of patietns who underwent intragastric balloon placement.

Discussion

Obesity is an important health problem because of comorbidities, mortal complications, and increased prevalence. Therefore, there is an ongoing search for the development of new treatment strategies. Today, bariatric surgery is the most efficient, sustainable, and long-term treatment option for obesity in selected cases. However, new, safe, and effective methods, such as endoscopic approaches, including IGB, are still being investigated, and tested for weight loss as an alternative to the surgical option. In our study, the efficacy of the IGB procedure applied to obese patients was evaluated in terms of the short- and long-term results.

The literature contains several studies investigating the results of IGB in different countries. For example, mean weight loss

after 6 months of IGB placement was reported as 16.6 ± 9.33 kg in a study conducted in Spain [15], 22.14% ± 7.39% in another Spanish study [16], 22.3 kg in a study conducted in the USA [17], 18 kg in a study conducted in Turkey [18], median of 10 kg (range, 0–42) in another Turkish study [19], and 11.5 kg in a meta-analysis covering various countries [20]. In the present study, the mean weight loss after 6 months was 15.6 ± 9.6 kg (range, 0–45 kg). During sixth month follow-up, the mean decrease in BMI and EWL% were 11.4% ± 6.4% (range, 0%–26.5%) and 23% ± 16.2% (range, 0%–78.9%), which is consistent with the literature.

Other studies were also conducted with different endoscopic methods. One study using the TransPyloric shuttle, the EWL% was 31.3% ± 15.7% at 6 months [21]. Furthermore, the EWL% was 49.9% ± 7.7% after aspiration therapy [22] and 42.16% ± 21.8% at 6 months after performing primary bariatric surgery using the endoluminal method [23]. In another study using the endoscopic sleeve gastroplasty method, the EWL% was 47.8% ± 29.4% after 6 months [24]. These results indicate that weight loss in IGB placement is not as high compared with the other endoscopic methods.

In the long-term results of the treatment, we did not expect a statistically significant difference between patients who were successful and those who were not in terms of demographic and clinical features because the etiology of obesity is multifactorial, and many variables affect the treatment response [25]. In the literature, phenotypes of obesity were also reported [26]. Therefore treatment planning will be a more appropriate approach after the determination of phenotypes.

In the current literature, serious complications due to IGB placement are rare. Among these complications, mortality is reported at a rate of 0.05%, gastric ulcer at 0.3%, gastric perforation at 0.1%, and balloon migration at 0.09% [18]. None of our patients had any serious complications related to the IGB procedure. Frequent follow-up of cases and ensuring their easy access to the physician would be an appropriate approach to minimize the risk of complications. Genco et al. removed the IGB within 24 h of placement in 11 of 2515 cases (0.44%) due to treatment intolerance [13]. In our study, the rate of balloon removal within 24 h due to intolerance was 0.58% (2/34).

The most important disadvantage of the IGB procedure used in the treatment of obesity is that the weight lost in the early period is regained in the long-term after balloon removal. We consider that in patients scheduled for bariatric surgery, IGB placement used as bridge therapy can provide benefits in facilitating preoperative weight loss to reduce the risk of postoperative complications. Further studies are required to better determine the long-term effects of the IGB procedure.

Conflict of interests
The authors declare that they have no competing interest

Financial Disclosure
All authors declare no financial support.

Ethical approval
Local ethics committee approval was obtained (20-3T/34).

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