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General Surgery

Which type of obesity benefits most from endoscopic intragastric balloon application?

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ABSTRACT

Objectives: As obesity poses significant health risks, exploring minimally invasive treatments like intragastric balloons becomes crucial for enhanced accessibility and efficacy in managing this pervasive public health challenge. This retrospective study aimed to evaluate the effectiveness of Intragastric Balloon (IGB) application in weight reduction across various degrees of obesity, providing a comprehensive assessment of its efficacy.

Methods: A total of 187 patients with a BMI >30 kg/m^2 underwent IGB application and were categorized into three groups based on the degree of obesity. Statistical analyses were conducted to assess weight loss, excess weight loss, and BMI reduction, focusing on the impact of IGB therapy in different degrees of obesity.

Results: IGB application demonstrated significant efficacy in weight reduction across all degrees of obesity. Notably, the highest rates of excess weight loss were observed in patients with Class 1 obesity. Gender-specific analysis revealed variations in the response to IGB therapy, with females exhibiting higher success rates.

Conclusions: The findings of this study highlight the efficacy of IGB application in achieving weight loss, emphasizing its effectiveness across different degrees of obesity. The notable success in Class 1 obesity underscores the potential of IGB as an effective treatment modality.

Keywords: Gastric balloon, obesity, obesity management, weight loss

In recent years, obesity has become a public health problem with increasing frequency worldwide. The diagnosis of obesity is made using the parameter of the Body Mass Index (BMI), which was defined by Adolphus Quetelet in the mid-19th century and later revised [1]. BMI is calculated by dividing body weight in kilograms by the square of height in meters. For adults, a BMI above 30 kg/m^2 is defined as obesity. Those with a BMI between 30-35 kg/m^2 are classified as Class 1, those with a BMI between 35-40 kg/m^2 as Class 2 and those with a BMI above 40 kg/m^2 as Class 3 obesity [2].

The worldwide prevalence of overweightedness and obesity has doubled within the last 40 years and currently one third of the world population is classified as overweight or people with obesity [3]. According to World Health Organization data, 11% of men and 15% of women worldwide are people with obesity [4]. Although obesity is globally observed more often in women, obesity is seen at a higher rate in men in European countries as Germany, Italy, France and Spain and also in Japan [5].

If left untreated, obesity brings with it many complications including hypertension, diabetes, heart dis-

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eases and major depression and it is associated with a lower rates of life expectancy [5].

Although a conservative treatment strategy including a diet tailored to individual needs, physical activity and behavioral changes, is recommended in the first step to achieve weight loss in the treatment of obesity, if individual treatment goals cannot be achieved with this conservative treatment regimen, pharmacotherapy, surgical treatment or endoscopic treatment modalities such as Intragastric Balloon (IGB) application should be initiated [5, 6]. Surgical methods may be preferred especially in patients with a BMI >35 kg/m^2 who do not benefit from conservative treatment methods and pharmacotherapy [7]. Although bariatric surgery is the most effective treatment method for obesity with everlasting results, since it is associated with difficult accessibility, high cost, and higher rates of morbidity and mortality, there is a need for minimally invasive and effective endoscopic treatment methods for obesity such as IGB application [8].

The effect of IGB which occupies space in the stomach is multifactorial. It provides weight loss by reducing food intake and making physiologic and neurohormonal changes. The IGB is placed endoscopically in the stomach and then filled with liquid or air. The IGB is left in the stomach for 6 months and 1 year depending on the type of intragastric balloon used. In various randomized controlled studies, excess weight loss varying between between 34-50% has been reported with the application of IGB [9-11].

In this study, we have aimed to investigate the effectiveness of IGB application in weight loss according to gender of the patients and different degrees of obesity.

METHODS

In this study, the data of a total of 187 patients aged >18 years, with a BMI of >30 kg/m^2, without any previous application of bariatric surgery, and any intragastric pathology detected during endoscopy, who had undergone IGB application 6 months previously with a diagnosis of obesity in the endoscopy unit of the General Surgery Clinic of Balıkesir University School of Medicine between May 2019 and May 2022 were retrospectively reviewed. Eleven patients whose IGBs were removed because they could not tolerate its application were excluded from the study. The remaining 176 patients were divided into 3 groups according to the degrees of obesity for both genders separately and for the whole patient population and the efficacy of IGB application was evaluated according to the rates of weight loss, excess weight loss and reduction in BMI in these groups. Percentage of excess weight loss is a widely used marker in the literature to determine weight loss in obesity treatment, as recommended by the International Federation for the surgery of Obesity and Metabolic Disorders (IFSO) [12, 13]. In our study, we defined the ideal weight as the weight corresponding to a BMI of 25 kg/m^2 and calculated the percentage of excess weight loss (%EWL) and percentage of total weight loss (%TWL) according to the formulas in Fig. 1. This study was approved by the Clinical Research Ethics Committeeof Balıkesir University School of Medicine (Decision date: 22.11.2023 and no. 2023/179).

Procedural Technique

Informed consent was obtained from all patients

$$\%Total\ weight\ loss = \frac{(Weight\ at\ the\ time\ of\ IGB\ placement) - (\text{Weight at the time of IGB removal})}{\text{Initial weight}} x100$$

$$\%Excess\ weight\ loss = \frac{(Weight\ at\ the\ time\ of\ IGB\ placement) - (\text{Weight at the time of IGB removal})}{(\text{Initial weight}) - (Ideal\ weight)} x100$$

Fig. 1. Formulas for calculating %EWL and %TWL.

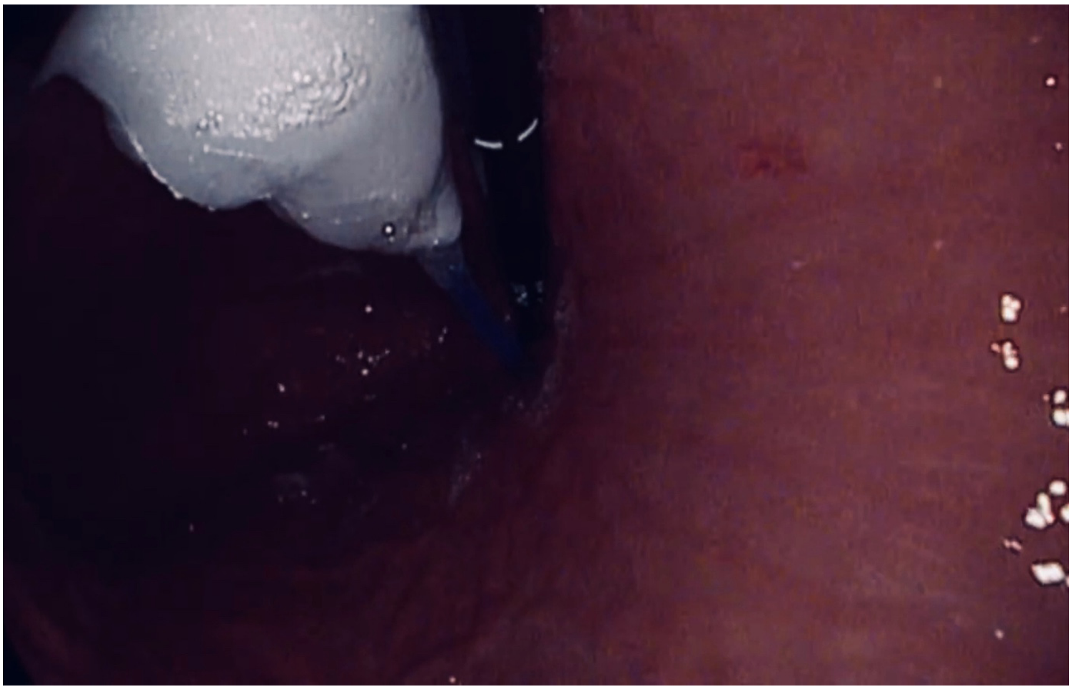

Fig. 2. **Placement of the IGB into the stomach.**

before the application of IGB. After the anesthesiologist administered sedoanalgesia, the esophagus, stomach and duodenum of the patients were carefully evaluated with an endoscope. After endoscopic evaluation, in patients without any detectable pathology such as severe esophagitis, gastritis, peptic ulcer, gastric polyps, Crohn's disease, etc., a non-absorbable silicone-based intragastric baloon was orally advanced into the stomach for 6-month therapy (Fig. 2). After reinsertion of the endoscope into the stomach, the IGB, which was positioned in the corpus-fundus region of the stomach was inflated with approximately 450-600 cc of saline containing methylene blue solution until the endoscope in retrovert position was squeezed between the stomach and the balloon (Fig. 3). Afterwards, the procedure was terminated by pulling the IGB's tube away from its pin. After the procedure, the patients were followed up by the same dietitian team. The patients' balloons were removed after 6 months and their current weights were evaluated.

Statistical Analysis

IBM SPSS Statistics 22 (IBM SPSS, Turkey) program was used for statistical analyses of the results obtained in the study. The conformity of the variables to normal distribution was evaluated by Shapiro-Wilk test, Q-Q graphs and histograms. In addition to descriptive statistical methods (minimum, maximum, mean, standard deviation, frequency, and percentage), Student-t test was used for the comparative evaluation of quantitative data between two groups. One-way Analysis of Variance (ANOVA) was used for the comparative evaluation of quantitative data between more than two groups. Levene's test was used to test the assumption of homogeneity of variances. In the determination of the groups causing differences based on the results of ANOVA test; those with homogeneous variances were evaluated by Tukey HSD and those with non-homogeneous variances by Tamhane T2 post-hoc test. The levels of statistical significance were set at $P<0.05$ and $P<0.01$.

RESULTS

The study was conducted with a total of 176 people with obesity including 135 (76.7%) female and 41 (23.3%) male cases to investigate the efficacy of endoscopic IGB application in different groups of people with obesity with a mean age of 38.36±9.84 years (range: 18-62 years). Based on BMI values, 67.6% (n=119) of the patients were classified as Group 1

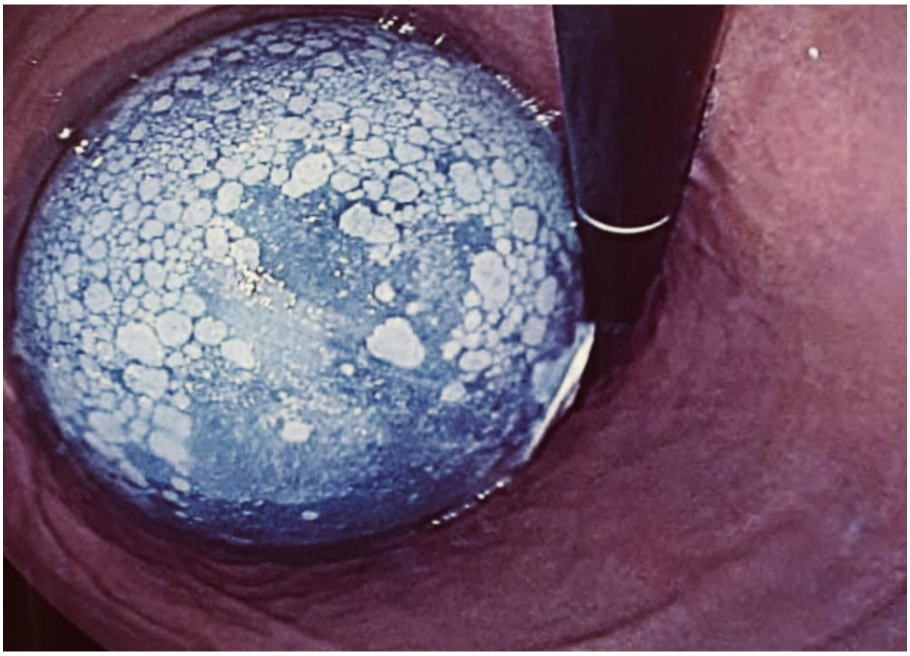

Fig. 3. **Inflating of the IGB in the stomach.**

(Class 1 obesity), 22.2% (n=39) as Group 2 (Class 2 obesity) and 10.2% (n=18) as Group 3 (Class 3 obesity) (Table 1).

In women, there was no statistically significant difference between BMI classes in terms of the average rate of achieved weight loss and the amount of decrease in BMI (P>0.05), however, a statistically significant difference was detected between BMI

Table 1. **Demographic characteristics of the patients before IGB application**

		Female (n=135)	Male (n=41)	Total (n=176)
Age (year)		38.99±10.27 (18-62)	36.29±7.99 (18-50)	38.36±9.84 (18-62)
Age groups	**18-35 years**	46 (34.1)	18 (43.9)	64 (36.4)
	36-45 years	49 (36.3)	15 (36.6)	64 (36.4)
	> 45 years	40 (29.6)	8 (19.5)	48 (27.3)
Body weight (kg)		89.53±10.29 (69-139)	104.83±14.12 (78-144)	93.10±12.99 (69-144)
Excess weight (kg)		23.06±8.77 (13-54)	27.80±10.76 (16-58)	24.16±9.45 (13-58)
BMI (kg/m^2)		33.71±3.33 (30.04-42.68)	34.06±3.41 (30.00-42.72)	33.79±3.34 (30.00-42.72)
BMI groups	**Group 1**	91 (67.4)	28 (68.3)	119 (67.6)
	Group 2	31 (23)	8 (19.5)	39 (22.2)
	Group 3	13 (9.6)	5 (12.2)	18 (10.2)

Data are shown as mean±standard deviation (minimum-maximum) or n (%) where appropriate. BMI=Body Mass Index, IGB=Intragastric Balloon.

classes in terms of the average rate of excess weight loss (P<0.001) (Table 2). As a result of the statistical evaluations performed to determine the BMI class from which the intergroup differences originated, we found that the average rate of excess weight loss in Group 1 was significantly higher when compared to Groups 2 (P<0.001) and 3 (P<0.001), while a significant difference was not detected between Groups 2 and 3 in this respect (P>0.05).

In men, there was no statistically significant difference between BMI classes in terms of the average rate of achieved weight loss (P>0.05), whereas a statistically significant difference was revealed in terms of the average rate of excess weight loss (P<0.001) (Table 2). As a result of statistical evaluations performed to determine the BMI class from which the intergroup differences originated, it was found that the average rate of excess weight loss in Group 1 was significantly higher those in Groups 2 (P=0.002) and 3 (P<0.001), whereas there was no difference between Groups 2 and 3 in this respect (P>0.05). In men, there was a statistically significant difference between BMI classes in terms of the average amount of decrease in BMI (P=0.006) (Table 2). As a result of the statistical evaluations performed to determine from which BMI class the difference originated, we disclosed that the average amount of decrease in BMI of Group 3 was significantly higher than those of Groups 1 (P=0.022) and 2 (P=0.047) (P<0.05), while there was no significant difference between Groups 1 and 2 in this respect (P>0.05).

Although a statistically significant difference was not found between BMI classes in terms of average rate of achieved weight loss (P>0.05), a statistically significant difference was found in terms of the average rate of achieved excess weight loss (P<0.001) (Table 2). As a result of the statistical evaluations performed to determine from which BMI class the difference originated, it was found that the rate of excess weight loss in Group 1 was significantly higher those estimated for Groups 2 (P<0.001) and 3 (P<0.001), while any statistically significant difference could not be detected between Groups 2 and 3 in this regard (P>0.05). A statistically significant difference was re-

Table 2. Comparison of rates of weight loss, excess weight loss and reduction in BMI according to classes of BMI in patients treated with IGB at the end of six-month follow-up

Classes of BMI	n (%)	Weight Loss (%)	Excess Weight Loss (%)	Decrease in BMI (kg/m^2)
Women	135 (76.7)	15.8±5.82	77.28±38.70	5.32±1.99
Group 1	91 (67.4)	16.03±5.98	91.98±36.77	5.10±1.95
Group 2	31 (23)	15.31±6.20	51.29±22.91	5.56±2.19
Group 3	13 (9.6)	15.33±3.69	36.38±8.53	6.31±1.54
P value		0.801	**<0.001****	0.091
Men	41 (23.3)	14.94±4.10	59.27±23.77	5.12±1.55
Group 1	28 (68.3)	14.34±4.38	67.43±23.62	4.61±1.43
Group 2	8 (19.5)	16.82±2.91	47.50±8.52	6.16±1.08
Group 3	5 (12.2)	15.32±3.74	32.40±10.43	6.27±1.55
P value		0.332	**<0.001****	**0.006***
Total	176 (100)	15.60±5.47	73.09±36.52	5.27±1.90
Group 1	119 (67.6)	15.63±5.67	86.20±35.61	4.98±1.84
Group 2	39 (22.2)	15.62±5.68	50.51±20.74	5.68±2.02
Group 3	18 (10.2)	15.33±3.59	35.28±8.96	6.30±1.50
P value		0.976	**<0.001****	**0.007****

Data are shown as mean±standard deviation or n (%) where appropriate. BMI=Body Mass Index.
One-Way Analysis of Variance (ANOVA), *P<0.05, **P<0.01

vealed between BMI classes in terms of the average amount of decrease in BMI in all patients (P=0.007) (Table 2). As a result of the statistical evaluations performed to determine from which BMI class the difference originated, average amount of decrease in BMI of Group 3 was significantly higher than those of Groups 1 (P=0.015) and 2 (P=0.046), while there was no significant difference between Groups 1 and 2 in this respect (P>0.05).

When male, and female patients treated with IGB were compared in terms of rates of weight loss, excess weight loss and the amount of decrease in BMI, the average rate of excess weight loss was found to be statistically significantly higher in women than in men in Group 1 (P<0.001) (Table 3).

DISCUSSION

Obesity is a chronic disease associated with different morbidity and mortality rates and its prevalence has been increasing in recent years. Current approaches to the treatment of obesity include lifestyle modifications, pharmacologic treatment and bariatric surgery. Although bariatric surgery is the most effective treatment method with long-lasting favorable results, because of its disadvantages such as difficult accessibility, higher cost, morbidity and mortality rates, there is a need for minimally invasive and effective bariatric treatment methods such as IGB application [8].

A total of 135 female patients included in our study were compared according to the degrees of their obesity. Statistically significantly higher rates of excess weight loss was detected only in Group 1 (P<0.001), while no difference was found between three groups in terms of other parameters (Table 3). In the comparison of the three groups in which 41 male patients were divided according to their degrees of obesity, the rate of excess weight loss was statistically significantly higher in Group 1 (P<0.001) and the decrease in BMI was statistically significantly higher in Group 3 (P=0.006) (Table 2). We divided the entire patient population into three groups according to the degree of obesity, and observed that the decrease in BMI (P=0.007) was higher in Group 3, and the rates of excess weight loss were significantly higher in Group 1 (P<0.001) compared to the other groups (Table 2). The reason why the effect of IGB application on excess weight loss was seen especially in class 1 obesity group may be that the initial body weights are comparatively lower in this patient group and therefore the percentage of decrease achieved is proportionally much greater (Fig. 1).

In our study, we observed that the IGB procedure provided an average success rate of 77% in women and 59% in men in achieving the ideal weight. In our opinion, the difference between the rates of achieving the ideal weights between men and women may be that women aim to achieve their ideal weights more strongly as a result of social pressure on them in the context of gender.

Fittipaldi-Fernandez *et al*. [14] reported a weight loss of 19.13±8.86 kg and a significant decrease in

Table 3. Comparison of rates of weight loss, excess weight loss and BMI reduction in male, and female patients treated with IGB application at the end of six-month follow-up period

Classes of BMI	Gender		Weight Loss (%)	Excess Weight Loss (%)	Decrease in BMI (kg/m^2)
Group 1	**Female**		16.03±5.98	91.98±36.77	5.10±1.95
	Male		14.34±4.38	67.43±23.62	4.61±1.43
		P value	0.167	**<0.001****	0.155
Group II	**Female**		15.31±6.20	51.29±22.91	5.56±2.19
	Male		16.82±2.91	47.50±8.52	6.16±1.08
		P value	0.511	0.651	0.461
Group III	**Female**		15.33±3.69	36.38±8.53	6.31±1.54
	Male		15.32±3.74	32.40±10.43	6.27±1.55
		P value	0.994	0.415	0.965

Data are shown as mean±standard deviation. BMI=Body Mass Index, IGB=Intragastric Balloon.
Student t-Test *P<0.05, **P<0.01

BMI from 36.94±5.67 kg/m2 to 30.08±5.06 kg/m2 in 5444 patients who had undergone IGB application and reported the average rates of total weight loss (18.42±7.25) and excess weight loss (65.66±36.24) as indicated. Similar to our study, the average rate of excess weight loss was highest in class 1 and lowest in class 3 obesity groups (class 1: 76.67%; class 2: 56.01% and class 3: 45.45%) and the rate of excess weight loss was higher in women (69.71%) than in men (53.39%) [14].

In a meta-analysis where fifteen studies were evaluated, the decrease in BMI was reported as 5.7 kg/m2, simillar to our study; however, the rate of excess weight loss achieved was reported as 32% at a rate much lower than we detected in our study [15].

In a study on 34 patients investigating the efficacy and safety of IGB application in different obesity groups, an average decrease of 6.8% ±7.3 % or 7.3 kg in the weight, and an average reduction of 7.0 % or 2.7 kg/m^2 in BMI of the whole patient group were observed at the end of 6-month follow-up period. Similar results were observed in the subgroup analysis of patients with BMI >40 kg/m^2, accordingly, the average percentage decreases in mean total body weight (7.2% or 8.9±8.4 kg), and in BMI (6.9% or 3.0±3.3 kg/m^2) were achieved [16]. In the aforementioned publication, lower rates of weight loss and BMI reduction were reported compared to our study, which may be due to the smaller number of patients included in the cited study.

In another study in which weight loss achieved with IGB application was evaluated in patients with different degrees of obesity, average rates of weight loss (18.9%), excess weight loss (60.1%), and a decrease of 6.76 kg/m^2 in BMI were reported as indicated. In the same study, patients were divided into five groups according to the degrees of obesity and each group was compared in terms of their weight before IGB application (T0), at the first (T1), sixth (T2) and sixth (T3) months after removal of IGB. As a result, statistically significant differences were found between T0 and T1 and also between T1 and T2 time points in all groups in terms of all weight loss assessment methods used; however, no significant difference was observed between T2 and T3 time points [17].

Although the retrospective nature of the study, the short-term follow-up of patients after the removal of IGB, the lack of standardization in diet and exercise, the absence of an assessment of the metabolic and hormonal effects of IGB, the lack of monitoring of patient compliance and lifestyle changes, and the absence of a comparison between different types of IGB are limitations of this study, the high patient volume relative to similar studies in the literature and the comparison of patients based on gender and degrees of obesity constitute its strengths.

Limitations

The limitations of our study include the lack of evaluation of patients' psychosocial factors, the lack of a comprehensive assessment of side effects and tolerability, and the absence of a comparison with bariatric surgery.

CONCLUSION

Our study has shown that the effect of IGB application on excess weight loss is especially seen in patients with class 1 obesity. In addition, our average success rates of 68% in females, 50% in males, and 64% in all patients in achieving ideal weight were higher than many other success rates reported in the literature for accomplishing ideal body weights. This shows that IGB application is a good and effective treatment option especially for class 1 obesity. We also observed that it could be a method to help lose weight in type 2 and 3 obese patients who have conditions preventing them from undergoing surgery. However, we believe that prospective randomized controlled studies with a higher number of patients are needed to determine the efficacy of IGB application in the treatment of obesity.

Ethical Statement

This study was approved by the Clinical Research Ethics Committeeof Balıkesir University School of Medicine (Decision date: 22.11.2023 and no. 2023/179).

Authors' Contribution

Study Conception: AGŞ, EA; Study Design: AGŞ, EA; Supervision: AGŞ, EA; Funding: AGŞ, EA; Materials: AGŞ, EA; Data Collection and/or Processing: AGŞ, EA; Statistical Analysis and/or Data Interpretation: AGŞ, EA; Literature Review: AGŞ, EA; Manuscript Preparation: AGŞ, EA; and Critical Review: AGŞ, EA.

Conflict of interest

The authors disclosed no conflict of interest during the preparation or publication of this manuscript.

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