

Comparison of the effects of endoscopic intragastric balloons: A single-center study

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ABSTRACT

Introduction: Obesity is a major health care problem and one of the sustained solutions of obesity is bariatric surgery and bariatric endoscopic procedures. An endoscopic intragastric balloon (IGB) is a procedure for achieving weight loss in obese patients. This study evaluated the effects of two types of endoscopic IGBs and compared their outcomes at our center.

Materials and Methods: This retrospective analysis included patients who had endoscopic IGBs between 2021–2024 and recorded their demographic data: age, gender, weight, height, and body mass index (BMI). The patients were divided into two groups according to balloon type—adjustable IGB and non-adjustable IGB—to compare their weight loss, excess weight loss percentage (EWL%), and total weight loss percentage (TWL%). We also analyzed initial balloon volume, increase in balloon volume, balloon intolerance, and balloon complications.

Results: Among the 93 patients included, 50 had non-adjustable IGBs, and 43 had adjustable IGBs. Their mean age was 34.9±8.8 years, 82.8% were women, and the mean BMI was 32.7±4.2 kg/m². Eight patients (8.6%) removed the balloon due to intolerance. The mean weight loss was 9.1±7.6 kg, the mean TWL% was 9.9±7.9, and the mean EWL% was 42.6±66%. IGBs achieved sufficient weight loss ($p<0.00$), with no significant difference in weight loss, EWL%, or TWL% changes found between the adjustable IGB and the non-adjustable IGB groups. Furthermore, no relationship was observed between balloon type or initial balloon volume in patients with early removal. No major complication was observed.

Conclusion: Endoscopic IGBs achieved significant weight loss in patients with obesity, with low complication rates and no significant difference in weight loss between adjustable or non-adjustable IGBs of different volumes.

Keywords: Bariatric Endoscopy, Endoscopic Balloon, Intragastric Balloon, Weight Loss

Introduction

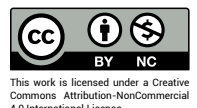
Obesity is a major health care problem affecting more than 600,000 patients worldwide, according to the World Health Organization. The increase in obesity and obesi-

ty-related comorbidities has increased the number of patients presenting at bariatric centers. Bariatric surgeries and bariatric endoscopic interventions are frequently performed to solve these conditions.^[1–6]



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The use of balloons as a bariatric intervention was inspired by the notion of placing objects, such as bezoars, to take up volume in the stomach. The first intragastric balloon (IGB) was produced by Nieben in 1982 after observing the early satiety effect of gastric bezoars in the stomach.^[2,7] An additional mechanism of weight loss is achieved by delaying gastric emptying time through the closing of the stomach antrum.^[8] The balloons are classified in many different ways, including endoscopic balloons or swallowable balloons, air-filled balloons or fluid-filled balloons, adjustable balloons, or non-adjustable balloons. The balloons are made to reach the desired volume by filling with 400–700 ml of air, saline with or without methylene blue, as approved by the Food and Drug Administration.^[7,8]

IGB has gained popularity due to its minimally invasive, reversible, and nonsurgical nature. It is mostly used for weight loss in the patient population with a body mass index (BMI) between 27–35 kg/m². Additionally, fear of bariatric surgery complications, such as bleeding, leakage, and venous thrombosis, may cause patients to prefer balloon application. Furthermore, surgeons refer male patients with a BMI over 50 kg/m², high subcutaneous fat tissue thickness, high volume of left side of liver, and thick mesentery, as well as patients with high comorbid diseases, for balloon applications as a bridging treatment before surgery.^[2,4,5,9]

Many studies have suggested the safety and effectiveness of IGBs. A study from Brazil showed that the mean total weight loss percentage (TWL%) and mean weight loss were 18.4±2.3% (range 0–52%) and 18.3±4.4 kg (range 0–87.5), respectively.^[2,10] Another study suggested that balloons showed the same effectiveness with adolescent populations, with a reduction in BMI of 5.87±3.4.^[11]

However, IGBs may cause complications. Balloon intolerance, described by symptoms such as nausea, vomiting, and abdominal pain, was frequently observed. Spontaneous deflation of the balloon and removal of the balloon before the expected time could be considered minor complications. However, in rare cases, serious complications, such as esophageal or stomach perforation, intestinal obstruction or perforation, and gastric bleeding, may occur, and patients need emergent surgical intervention.^[2,7,12]

The aim of this study was to evaluate the effects of endoscopic IGBs and compare adjustable intragastric balloons (aIGBs) and non-adjustable intragastric balloons (naIGBs) in our center.

Materials and Methods

The study was designed as a retrospective data analysis. Patients who had endoscopic IGBs at our bariatric center between January 2021 and January 2024 were included in the study. Patient demographic data, such as patients' age, gender, pre-balloon weight, height, BMI value, and weight loss, were collected from patient files retrospectively. TWL% and excess weight loss percentage (EWL%) were analyzed statistically. Balloon removal due to patient intolerance, gastric ulcers, or balloon deflations before the expected balloon removal time was recorded. Further, balloon starting volume and increasing balloon volume data were documented and analyzed. Informed consent was not applied due to retrospective study.

Inclusion/Exclusion Criteria

The included patients were those who underwent endoscopic intragastric balloon application with naIGBs and aIGBs. Patients who underwent non-endoscopic intragastric balloon application and those whose data were inaccessible were excluded. A total of 128 patients who underwent intragastric balloon application were accessed from January 2021 to January 2024. Eighteen patients were excluded due to non-endoscopic balloons. Seventeen patients were excluded from the study due to the inaccessibility of their data. Finally, after the exclusion, 93 patients were included in the study: 43 patients who had aIGB for 12 months (Spatz III®), 50 patients who had naIGB for 6 months (MEDSIL®) (Fig. 1).

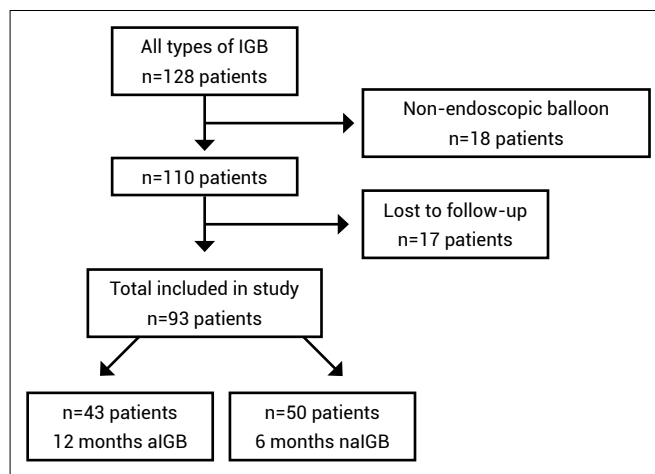


Figure 1. Patient selection data and exclusion process. IGB: Intra-gastric balloon; aIGB: Adjustable IGB; naIGB: Non-adjustable IGB

Balloon Insertion Technique

Intragastric balloon insertion was performed under sedo-analgesia. Routine esophago-gastro-duodenoscopy was performed to control the inside of the upper gastrointestinal tract for esophageal disease, gastric ulcers, gastric malignancy, or giant hiatal hernia. Balloons were then sent into the stomach, and their volume was increased by saline added methylene blue under direct vision. After all the procedures were completed, a third endoscopy was performed to confirm that there were no complications. The aIGBs remained in the stomach for 12 months, while the naIGBs remained in the stomach for 6 months. After the balloon time expired, they were removed endoscopically under sedo-analgesia.

Anti-Emetic Protocol

Aprepitant was routinely administered to each patient two hours before the endoscopic evaluation. After the balloon was placed, proton pump inhibitors, metoclopramide, ondansetron, hyoscine butylbromide, and paracetamol were applied by parenterally. Only liquid diets were allowed for the first three days. Aprepitant (2 more days, once a day), ondansetron (1 week, twice a day), and metoclopramide (1 week, 3 times a day) were administered to all patients.

Calculation of TWL% and EWL%

The total weight loss percentage was obtained by dividing the amount of weight loss by the total body weight. To calculate the excess weight loss percentage (EWL%), the ideal weight was calculated by accepting the BMI as 25 kg/m². The amount of excess weight was determined by subtracting the ideal weight from the starting weight. EWL% was calculated by dividing weight loss by excess weight. The primary outcome of the study was to evaluate the effect of IGB and compare the effects of IGB in our unit.

Statistical Analysis

Mean, standard deviation, median, minimum, maximum, frequency, and ratio values were used in the descriptive statistics of the data. The distribution of variables was measured using the Kolmogorov–Smirnov and Shapiro–Wilk tests. An independent sample t-test was used in the analysis of quantitative independent data with a normal distribution. The Mann–Whitney U test was used in the analysis of quantitative independent data with a non-normal distribution. The Wilcoxon test was used in the analysis of dependent quantitative data,

and the chi-square test was used in the analysis of qualitative independent data. Spearman correlation analysis was used in the correlation analysis. The SPSS 27.0 program was used in all analyses.

Complications

A total of 14 patients (15.1%) had to remove their balloons before the expected expiry date, eight (8.6%) of whom presented with complaints of severe abdominal pain, nausea, and vomiting in the first 10 days; thus, their balloons were removed due to intolerance. In three (3.2%) patients, the balloon had to be removed before its expiry date because of discontinuation of gastric protection medication, which caused gastric ulcers. Spontaneous deflation of the balloon caused early balloon removal in another three (3.2%) patients. Severe complications such as bleeding, gastric, or esophageal perforation, and balloon migration to the intestine were not observed.

Results

The study included 93 patients with a mean age of 34.9±8.8 and a mean BMI value of 32.7±4.2 kg/m² and of whom 82.8% were women. Fourteen patients had their balloons removed before the expected time, and eight patients (8.6%) could not tolerate the balloon procedure (5 cases: 10% naIGB, 3 cases: 6.9% aIGB). Thus, for a subgroup analysis, 50 patients (53.8%) were included in the naIGB group, and 43 patients (46.2%) were included in the aIGB group. The mean weight loss in both balloon groups was 9.1±7.6 kg. The mean TWL% was 9.9±7.9, and the EWL% was 42.6±66%. The mean balloon volume was 449.3±54.1 ml, and 55.8% of the adjustable balloons showed an increased volume. The patients' demographic data are shown in Table 1.

An examination of all patients revealed that they all achieved statistically significant weight loss (p=0.000) (Table 2, Fig. 2).

We divided the patients according to their balloon removal time, yielding two groups: the early balloon removal group and the on-time balloon removal group. A comparison of the groups revealed no significant difference between the two groups in terms of demographic features or BMI values. There was also no relationship between balloon type and balloon volume or balloon removal time (Table 3).

Table 1. Patient demographics

	Min–Max	Median	Mean±SD	
			n	%
Age	17.0–55.0	35.0		34.9±8.8
Gender				
Female			77	82.8
Male			16	17.2
Weight	64.0–140.0	88.0		90.6±15.3
Weight loss	0.0–40.0	9.0		9.1±7.6
Height (m)	1.5–1.9	1.7		1.7±0.1
BMI	23.0–44.1	32.8		32.7±4.2
BMI at the removal time	20.5–44.1	29.5		29.6±4.2
TWL%	0.0–38.1	10.2		9.9±7.9
EWL%	-390.6–242.5	37.3		42.6±66.0
Balloon volume (ml)	350.0–550.0	450.0		449.3±54.1
Last balloon volume (ml)	350.0–720.0	550.0		530.3±82.4
Increase of balloon volume				
(-)			19	44.2
(+)			24	55.8
Early removal of balloon				
(+)			14	15.1
(-)			79	84.9
Balloon type				
naIGB			50	53.8
aIGB			43	46.2

Min–Max: minimum-maximum; SD: standard deviation; BMI: body mass index; TWL%: Total weight loss percentage; EWL%: excess weight loss percentage; naIGB: non-adjustable intragastric balloon; aIGB: adjustable intragastric balloon.

Table 2. Comparison of weight loss

	Pre-balloon weight		Last weight		p
	Mean±SD	Median	Mean±SD	Median	
Weight	90.6±15.3	88.0	81.5±14.8	80.0	0.000 ^w

^wWilcoxon test.

Based on the type of balloon, patients in the aIGB group had significantly higher BMI and weight than the naIGB group ($p < 0.05$). There was no statistically significant difference between the two groups in the analysis of weight loss, EWL%, and TWL%, as shown in Table 4.

Further comparison of two aIGB patient subgroups—those who had and those who did not have increased balloon—revealed no significant difference in terms of weight loss, EWL%, TWL% or balloon removal time (Table 5).

Discussion

Obesity has become an epidemic disease, and the number of obese or overweight individuals is increasing daily, with concurrent increases in patients treated at bariatric centers for bariatric surgical operations or bariatric endoscopic procedures. Endoscopic methods for weight loss are frequently preferred by patients because they are reversible and have low complication rates. IGBs are being used in in-

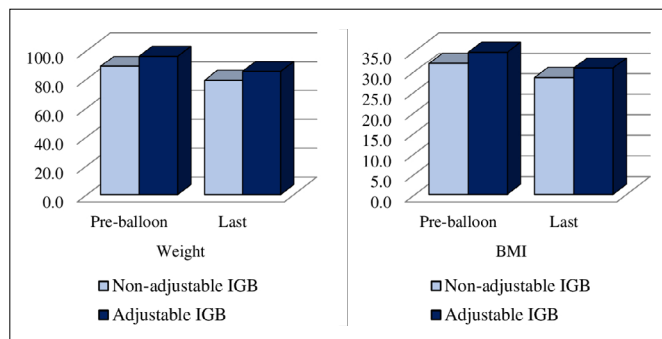


Figure 2. Weight and BMI loss.

creasing numbers due to weight loss, bridging treatments, or fear of complications from bariatric surgeries.^[2,13–17]

Many studies have suggested that IGBs provide statistically significant weight loss. A systematic review of 26 studies and over than 6000 patients demonstrated a mean weight loss of 15.7±5.3 kg and a mean BMI change of 5.9±1.0 kg/m² with naIGB. The findings also showed that the EWL% changed by 36.2±6.3%.^[7] Another study from Brazil consisting of 41863 patients suggested a mean weight loss

of 18.3±4.4 kg and a mean total weight loss percentage of 18.4±2.9%.^[2] A randomized controlled study related to aIGB indicated that median weight loss was 15 kg (0–34 kg) in 1 year.^[3] A meta-analysis and review showed that IGBs decrease total body weight loss percentage by 7.6–14.1% at 6 months and 7.5–14% at 12 months.^[1] Our results are compatible with the literature, as we recorded a mean weight loss of 9.1±7.6 kg, a mean TWL% of 9.9±7.9%, and a mean EWL% of 42.6±66.0% (Table 1). When the weight loss was compared according to balloon types, no significant difference was observed in terms of TWL%, EWL% or weight loss in both balloon types. Although the BMI and excess weight of patients who underwent aIGB were statistically significantly higher and aIGB was used for longer period of time, our study showed that there was no significant difference in terms of weight loss between aIGB and naIGB. It could be said that naIGB provides same efficiency (in term of weight loss) in a shorter time than aIGB (Table 4).

A systematic review and meta-analysis consisting of 5549 patients suggested that there was no relationship between

Table 3. Comparison of groups according to balloon removal time

	Early balloon removal		On-time balloon removal		p		
	Mean±SD		Median				
	n	%	n	%			
Age	36.4±9.2		38.5		0.500 ^t		
Gender							
Female	12	85.7	65	82.3	0.754 ^{x2}		
Male	2	14.3	14	17.7			
Weight	83.8±9.70		83.5		0.095 ^m		
Height	166.2±6.6		165.2		0.109 ^m		
BMI	31.7±4.0		32.6		0.327 ^t		
TWL%	4.8±6.1		0.0		10.8±7.9	10.9	0.011 ^m
EWL%	17.9±22.6		0.0		47.0±70.1	41.7	0.006 ^m
Balloon volume (ml)	426.8±47.5		400.0		453.3±54.5	475.0	0.084 ^m
Last balloon volume (ml)	550.0±0.0		550.0		528.5±85.9	550.0	0.734 ^m
Increase in balloon volume							
(-)	6	66.7	13	38.2	0.127 ^{x2}		
(+)	3	33.3	21	61.8			
Balloon type							
NaIGB	5	35.7	45	57.0	0.142 ^{x2}		
aIGB	9	64.3	34	43.0			

^tindependent sample t-test; ^mMann–Whitney U test; ^{x2}chi-square test; TWL%: total weight loss percentage; EWL%: excess weight loss percentage; BMI: body mass index.

Table 4. Comparison of balloon types

	NaIGB		aIGB		p		
	Mean±SD		Median	Mean±SD			
	n	%		n		%	
Age	36.3±8.6		37.0	33.3±8.9		32.0	0.105 ^t
Gender							
Female	42	84.0		35	81.4		0.740 ^{x2}
Male	8	16.0		8	18.6		
Weight	87.5±14.0		84.0	94.2±16.0		90.0	0.035 ^m
Weight loss	8.5±7.3		9.0	9.9±8.0		9.0	0.501 ^m
Change in groups p	0.000 ^w			0.000 ^w			
Height	169.4±7.6		67.7	168.4±7.2		168.1	0.784 ^m
BMI	31.4±4.0		31.1	34.3±3.8		34.6	0.000 ^m
TWL%	9.2±7.6		10.0	10.7±8.3		10.7	0.463 ^m
EWL%	49.6±50.5		39.1	34.4±80.2		37.3	0.652 ^m
Balloon volume (ml)	487.1±23.4		500.0	405.3±45.8		400.0	0.000 ^m
Excess Weight	19.7±10.2		19.7	25.8±11.7		25.6	0.011 ^t
Early removal of balloon							
(+)	5	10.0		9	20.9		0.142 ^{x2}
(-)	45	90.0		34	79.1		

^tindependent sample t-test; ^mMann–Whitney U test; ^{x2}chi-square test; NaIGB: non-adjustable intragastric balloon; aIGB: adjustable intragastric balloon; TWL%: total weight loss percentage; EWL%: excess weight loss percentage; BMI: body mass index.

balloon volume and weight loss and that an increased volume of up to 700 ml did not cause early removal. The analysis also found that decreased volume could cause distal esophagitis.^[18] In our study, the mean balloon volume was 449.3±54.1 ml. Change in balloon volume or increased balloon volume did not result in a statistically significant difference in weight loss, EWL%, or TWL%, as in the literature (Table 5).

Although IGBs take up space in the stomach and provide early satiety, it was observed that four patients in the naIGB group gained weight with the balloon in their stomachs. Furthermore, we had five patients who, although lost weight with the balloon, could not lose any weight as soon as the balloon was removed. Thus, 18% of the patients with naIGB did not benefit from the balloon. We also observed that six patients in the aIGB group lost weight but remained at the same weight after the balloon was removed. These findings show that 16.1% of all patients in our study did not achieve weight loss with balloons, which indicates that the balloon should be supported with a strict diet program and exercise and that it does not produce the same results for every patient.

One of the most undesirable aspects of balloon application is early balloon removal due to intolerance, which manifests as severe abdominal pain, nausea, and vomiting following insertion. In the literature, balloon removal rates due to intolerance vary widely. A study related to aIGB showed that balloon removal due to intolerance was 17%.^[3] A systemic review showed that the rate of early balloon removal was 3.5%.^[7] Another study suggested an early removal rate of 2.2% that consisted of 2.5% with aIGBs, 2.4% with naIGBs, and 0.8% with air-filled IGBs.^[2] A study that consisted of 1770 elipse gastric balloons suggested that the early removal rate was 2.9%. In our study, the early removal of IGBs due to intolerance was 8.6%, which is compatible with the literature. All patients who could not tolerate the balloon were female, and the intolerant patients in the balloon group had a statistically lower BMI. Additionally, neither balloon type nor initial balloon volume resulted in a change in balloon tolerance (Table 4).

A Brazilian study showed 141 gastric ulcers with IGBs and the need for removal in 28 cases. The authors suggested that the percentage of gastric ulcers with aIGB was 5.7%.

Table 5. Comparison of groups due to increase of balloon volume

	Increase of balloon volume (-)			Increase of balloon volume (+)		p	
	Mean±SD		Median	Mean±SD			Median
	n	%		n	%		
Age	34.3±8.7		37.0	32.5±9.2		31.0	0.527 ^t
Gender							
Female	16	84.2		19	79.2		0.673 ^{x²}
Male	3	15.8		5	20.8		
Weight	89.9±14.8		86.0	97.6±16.4		95.5	0.056 ^m
Height	166.0±7.1		64.0	170.3±6.8		70.6	0.047 ^t
BMI	33.9±3.0		34.4	34.6±4.3		34.8	0.553 ^t
TWL %	9.3±6.8		10.0	11.8±9.3		13.1	0.335 ^t
EWL %	36.6±28.5		34.4	32.8±105.4		40.7	0.749 ^m
Balloon volume (ml)	428.9±45.1		400.0	386.7±37.5		377.5	0.001 ^m
Early balloon removal							
(+)	6	31.6		3	12.5		0.127 ^{x²}
(-)	13	68.4		21	87.5		

^tindependent sample t-test; ^mMann–Whitney U test; ^{x²}chi-square test.

^[2] Although we recommended the use of proton pump inhibitors for all patients, we had to remove the balloon before its expiry date due to gastric ulcers in three patients (3.2%). Gastric ulcers were seen in patients with aIGB insertion, one of whom was removed in the fourth month and the other two in the third month. This can be related to the balloon or balloon volume increasing to erode the stomach wall and causing ulcers.

IGBs are preferred as an option for patients who want to lose weight but are afraid of the complications of bariatric surgeries. However, although very rare, IGBs can lead to mortal complications and the need for urgent surgery. In the literature, there are case reports of cases that caused intestinal obstruction due to intestinal migration with balloon deflation, cases that required urgent laparoscopic exploration due to gastric perforation, and cases that underwent emergency surgery due to esophageal rupture.^[19–22] A review suggested that 22 gastric perforations, 2 esophageal perforations, and 12 bowel obstructions have been reported in the literature.^[23] No such major complications were observed in our study. According to our experience, inflating the balloon under direct endoscopic vision protects patients from incidental iatrogenic esophageal injuries. This is one aspect that makes endoscopic balloons more applicable than non-endoscopic balloons.

Furthermore, the fact that intestinal obstruction cases are rarely seen in non-endoscopic balloons^[24] is provoking investigations into the reliability of leaving balloons to be excreted through the gastro-intestinal tract rather than removing balloons endoscopically. We noted the benefit of inflating the balloon with methylene blue in three of our patients (3.2%). We prevented the migration of balloons and intestinal obstructions by removing the balloon endoscopically due to the presence of methylene blue in the urine before the expected balloon expiry date.

Limitations

This study was a single-center retrospective study. A multi-center and prospective study might have achieved more statistically significant results in both types of IGBs. Loss of follow-up rates in the obese population and single-day discharge conditions of endoscopic balloon procedures caused the loss of many patient data, thereby reducing the number of patients in the study. Gastric ulcers that occurred due to discontinuing their stomach-protecting agent medications caused early balloon removal, further reducing the number of patients who reached the balloon expiration date. Establishing a more stringent follow-up program can help reduce the loss of patients to follow-up and patients' data.

Conclusion

Endoscopic IGBs achieved sufficient weight loss in both groups without major complications. Balloon type, increase in balloon volume, and initial balloon volume did not cause statistically significant differences in weight loss or TWL%. Further multi-center prospective studies are needed on the sustainability of this weight loss and weight regain rate.

Disclosures

Ethics Committee Approval: This study was approved by the İzmir Bakırçay University Non-Interventional Clinical Trials Ethics Committee on 10.07.2024 with the 1693 decision no 1693.

Peer-review: Externally peer-reviewed.

Conflict of Interest: None declared.

Authorship Contributions: Concept – B.K., Y.O.; Design – B.K., S.Ç.E.; Supervision – S.Y., Y.O.; Materials – B.K.; Data Collection – S.Y., Y.O.; Analysis and/ or interpretation – B.K., S.Y.; Literature Search – B.K., S.Ç.E.; Writing – B.K., S.Ç.; Critical Review – S.Y.

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