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EFFICACY OF INTRAGASTIC BALLOONS IN WEIGHT REDUCTION

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Abstract

The endoscopic application of intragastric balloons (IGB) is a very effective non-surgical technique in the treatment of excess body weight.

The aim of this study was to analyze the effectiveness of IGB in obesity treatment and to compare the results of using different types of IGB.

Material and methods. The study included 80 overweight patients with a BMI between 25 and 40 kg/m^2, treated with the application of two types of IGB (Spatz and Endd-Ball). Weight control of patients was performed 48 hours, 7 days, 14 days, 30 days, 90 days, and 180 days after the IGB placement, as well as 6 months after the IGB removal. Six months after application, the IGBs were endoscopically removed. The number of kilograms lost, as well as the change in BMI, were analyzed. A comparison between the results obtained with the two different types of IGB (Spatz and Edd-Ball) was made. For statistical processing of the data, a database was created in the statistical program SPSS for Windows, 23.0.

Results. The average weight loss 6 months after the application of IGB was about 15 kg. Comparing BMI values before and 6 months after the intervention showed a statistically significant decrease in BMI after the intervention (p= 0.00) and confirmed the efficacy of IGB. Comparing the lost kilograms in relation to the type of IGB applied did not show statistically significant differences.

Conclusion. The application of IGB has shown to be an effective method for weight loss.

Keywords: obesity, intragastric balloon, therapy, endoscopy.

Introduction

Endoscopic bariatric therapy (EBT) bridges the gap between pharmacotherapy and surgery, so it has a significant role in the treatment of obesity, especially in patients with mild to moderate obesity who fail to lose enough weight through lifestyle changes and pharmacotherapy, and in those with enormous obesity who refuse surgical intervention [1,2,3].

Compared to bariatric surgery, the devices used in EBT are designed to allow weight loss, but are significantly safer, the procedure is reversible, and they are more cost-effective [4].

The basic mechanism by which EBT works is occupying space in the stomach, which reduces its capacity, modifies the motor function of the stomach and causes malabsorption.

Among numerous EBT devices, intragastric balloons (IGB), which occupy a certain space in the stomach, are most commonly used in clinical practice [5].

The application of IGB finds a special place in the treatment of excess body weight, as a very effective non-surgical technique, especially when appropriate patient selection is made, allowing weight loss with minimal side effects compared to bariatric surgery [6].

The effectiveness of IGB is due to creating a feeling of satiety, which is caused by gastric distension and accommodation. The main mechanism for weight loss when using IGB is delayed gastric emptying, which keeps the stomach distended, which in turn, through vagus signals, quickly leads to a feeling of satiety [7,8,9].

The aim of this study was to show the effectiveness of the use of IGB in the treatment of obesity and to compare the results of the use of two different IGB, Spatz and End-Ball.

Material and methods

The material for this clinical, prospective, randomized study consisted of overweight and obese patients treated with IGB application at Sirona Hospital in Pristina, Kosovo.

The study contingent comprised 80 overweight and obese patients who were treated with endoscopic application of IGB. They were randomly divided into 2 groups and a different IGB was applied to each group. Spatz IGB was used in 40 patients, and End-Ball IGB in 40 patients.

Data on age, sex, height and weight were given by all patients.

Body weight was defined through the body mass index (BMI), which was calculated as the quotient of the weight expressed in kilograms and the square of the height expressed in meters (BMI = kg/m^2).

Spatz and Endd-ball IGBs were endoscopically placed in patients, per standard operating protocol, filled with 400 to 1300 ml of fluid, depending on assessment of patients' condition. In several patients with BMI > 35 kg/m^2, depending on the assessment, two IGBs were placed.

Weight control of IGB patients was performed 48 hours, 7 days, 14 days, 30 days, 90 days, and 180 days after IGB placement, as well as 6 months after IGB removal.

In the event of side effects and complications, IGB was removed. Six months after application, IGBs were endoscopically removed and BMI was determined again.

Inclusion criteria

The study analyzed overweight (BMI > 25 kg/m^2) and obese (BMI > 30 kg/m^2) patients who could be followed up after IGB application for at least 6 months after the intervention, with a signed written consent.

Exclusion criteria

Patients who could not be followed for various reasons were not included in the study. As exclusion criteria, all conditions that increase the risk of placement of IGB were considered, such as: large hiatal hernia (> 5 cm), active ulcer in the stomach or duodenum, previous surgical resection of the stomach or duodenum, inflammatory bowel disease, gastrointestinal neoplasms, oropharyngeal abnormalities, active gastrointestinal bleeding, coagulation disorders, varicosities, alcoholism, addiction diseases, pregnancy, psychiatric diseases, use of anti-inflammatory and anticoagulant drugs, presence of cardiovascular, pulmonary and cerebrovascular diseases.

Results

The study involved 80 overweight and obese subjects, aged 19 to 65 years, with an average age of 35.5 ± 11.9 years, treated with IGB application at Sirona Hospital in Pristina, Kosovo. The gender structure of the respondents consisted of 38.75% (31) male patients and 61.25% (49) female patients.

Six months after the intervention, a significant reduction in BMI was registered compared to the value registered on admission (30.9 ± 4.4 *vs.* 36.5 ± 4.9 kg/m2 (Table 1).

Table 1. Body mass index on admission (BMI 1) and after six months (BMI 6)

Variable	mean ± SD	min – max	**p-level**
Lost kg	15.3 ± 6.8	3 – 34	
BMI 1	36.5 ± 4.9	27.5 – 60.9	t=21.34 ***p=0.00000
BMI 6	30.9 ± 4,4	22 – 53.6	

t (Student t-test); ***p<0.0001

In the period from 48 hours to 6 months after the application of IGB, a significant decrease in body weight was registered (p<0.0001). The average body weight after 48 hours was 106.1 ± 17.8 kg, and after 6 months it was 90.5 ± 14.7 kg. The percentage reduction in body weight at 6 months *versus* 48 hours was 14.7% (Table 2).

Table 2. Change in body weight 48 hours to 6 months after the intervention

Body weight (kg)	mean ± SD	min – max	**p-level**
48 hours	106.1 ± 17.8	76 – 172	Friedman ANOVA Chi Sqr. (N = 76, df = 5) =365.0 ***p=0.00000
7 days	104.7 ± 17.83	75 – 170	
14 days	101.2 ± 16.5	71 – 168	
30 days	98.4 ± 16.0	69 – 160	
90 days	94.4 ± 15.4	67 – 158	
6 months	90.5 ± 14.7	65 – 155	

***p<0.0001

Distribution and change of the variables in relation to the applied IGB are shown in Table 3. The gender structure of the subjects in whom End-Ball IGBs were applied consisted of 30% male and 70% female patients, while Spatz IGBs were applied to 47.5% male and 52.5% female patients. No statistically significant difference was found in the distribution of male and female patients in both groups (p=0.11).

Patients with applied End-Ball IGB were significantly younger compared to patients with Spatz IGB (32.8 ± 9.2 *vs.* 38.1 ± 13.7, p=0.044).

Before the intervention, patients from both groups differed significantly in terms of BMI values, as a result of a significantly higher BMI in the group in which End ball IGB was applied, compared to that with Spatz IGB (37.7 ± 6.2 *vs.* 35.3 ± 2.5 kg/m2, p=0.044). Control BMI values after 6 months of the intervention did not differ significantly between the two groups (31.8 ± 5.8 and 30.1 ± 2.5 kg/m^2, respectively in the End-Ball and Spatz groups, p=0.11).

No statistically significant difference was found in the average kilograms of body weight lost depending on the IGB technique used. Patients of both groups in the period of 6 months reduced the body weight by an average of about 15 kg (p=0.82).

Table 3. Change of variables depending on the applied IGB

Variable	**Type of IGB**			**p-level**
	n	**End ball**	**Spatz**	
Gender				
male n (%)	31	12 (30)	19 (47.5)	X^2=2.6
female n (%)	49	28 (70)	21 (52.5)	p=0.11
Age				
mean ± SD		32.8± 9.2	38.1 ± 13.7	t=2.04 *p=0.044
BMI on admission				
mean ± SD		37.7 ± 6.2	35.3 ± 2.5	t=2,21 *p=0.03
min - max		27.5 – 60.9	33.2 – 44.4	
BMI after 6 months				
mean ± SD		31.8 ± 5.8	30.1 ± 2.5	t=1.62 p=0.11
min - max		22 – 53.6	27.1 – 37.2	
Lost kg				
mean ± SD		15,50 ± 9,0	15.15 ± 3.6	t=0.23 p=0.82
min - max		3 – 34	10 – 22	
Number of applied IGB				
1 n (%)	70	30 (75)	40 (100)	
2 n (%)	10	10 (25)	0	

X^2 (Chi-square test), t (Student t-test); *p<0.05

The comparison of the two IGBs in relation to patients' body weight measured at 6 time points after the intervention presented a significant difference at 48 hours and 7 days postoperatively (p=0.028

and p=0.025, respectively), while the difference at the other time points, 14 days, 30 days, 90 days and 6 months postoperatively was statistically insignificant (p>0.05).

Forty-eight hours and 7 days after the intervention, patients in whom the End ball IGB was applied had a significantly higher average body weight than patients in whom the Spatz IGB was used (110.6 ± 22.2 *vs*. 101.8 ± 10.6 kg, and 109.2 ± 22.1 *vs*. 100.3 ± 10.9 kg, respectively).

At the other time points, patients in whom the End ball IGB was applied also had a higher average body weight compared to patients in whom the Spatz IGB was used, but without a statistically confirmed significant difference. At the end of the follow-up, 6 months after the intervention, the average body weight was 93.4 ± 18.9 kg in the End ball IGB group, and 87.6 ± 8.3 kg in the Spatz IGB group (Table 4).

Table 4. Weight change depending on the applied IGB

Weight (kg)	**Type of IGB**		**p-level**
	End ball	**Spatz**	
48 hours			
mean ± SD	110.6 ± 22.2	101.8 ± 10.6	t=2.2 *p=0.028
min - max	76 – 172	87 – 133	
7 days			
mean ± SD	109.2 ± 22.1	100.3 ± 10.9	t=2.3 *p=0.025
min - max	75 – 170	86 - 134	
14 days			
mean ± SD	104.6 ± 20.8	97.9 ± 10.3	t=1.8 p=0.074
min - max	71 – 168	84 – 130	
30 days			
mean ± SD	101.6 ± 20.9	95.6 ± 9.1	t=1.7 p=0.097
min - max	69 – 160	83 – 122	
90 days			
mean ± SD	96.5 ± 19.9	92.3 ± 9.2	t=1.2 p=0.24
min - max	67 – 158	81 – 119	
6 months			
mean ± SD	93.4 ± 18.9	87.6 ± 8.3	t=1.8 p=0.08
min - max	65 – 155	78 – 114	

t (Student t-test); *p<0,05

Discussion

IGBs probably represent the starting point of endoscopic bariatric therapy. Depending on the system used, with the help of gastroscopy or just by swallowing a capsule, an empty balloon is inserted into the stomach. The balloon is then inflated with air or physiological solution in a volume of 400-700 ml. This reduces the volume of the stomach, which results in a feeling of satiety, which then leads to a decrease in appetite and thus to weight loss [1,4,5].

For most systems, treatment is limited to 6 months. In this study, Spatz and Endd-ball IGBs were endoscopically placed in patients, per standard operating protocol, filled with 400 to 1300 ml of fluid, depending on the patients' condition assessment. Ideally, this procedure should represent only one component of a continuous weight loss program, and the patient should be supported by an interdisciplinary team of health professionals [10,11].

The side effects of the treatment are minimal compared to those of bariatric surgery [12].

It can be said that the first idea for today's IGB systems dates back to 1939, when Michael DeBakey analyzed cases of gastric bezoars and concretions and found that 38% of these patients experienced weight loss. However, the vast majority of patients suffered from nausea and vomiting, without necessarily losing weight [13].

The first IGB, the Garren-Edwards Gastric Bubble, was introduced in 1985 and caused similar side effects in patients. The FDA approved the system, but it was withdrawn after seven years due to numerous side effects, including gastric erosion, gastric ulcers, small bowel obstruction, and Mallory-Weiss fissures, as well as insufficient efficacy in weight loss [13].

Despite these first disappointing experiences, other IGB systems were developed and successfully introduced to the European and American markets: the Orbera® Intragastric Balloon System (Apollo Endosurgery Inc, Austin, TX, United States, formerly BIB) was approved for use in Europe in 1997, and from FDU in 2015. For this IGB system, there are abundant scientific data available, which refer to its efficiency and safety, so it can be assumed that it represents the most widely applied IGB system in the world. As of 2015, two more balloon systems have been approved by the FDA: ReShape® Integrated Dual BalloonSystem (ReShape Medical, Inc., San Clemente, CA, United States) and Obalon® (Obalon Therapeutics, Inc.). It is the first IGB system that can be swallowed, allowing up to three balloons to be placed without endoscopy. However, removal of the Obalon® IGB System requires endoscopy. In addition to these IGB systems, there are a number of other IGBs that are only approved in some countries or are still part of clinical trials. Within these systems, the Spatz3® intragastric balloon (Spatz FGIA Inc.) differs from other balloons because it is adjustable and can remain in place for 12 months. The Elipse® balloon (Allurion Technologies) is the only swallowable system that is removed by natural excretion and therefore ideally does not require any endoscopic procedure [13,14].

Today, a large number of IGBs supplied with modern technology are in use, which work on the same principle, but cause much fewer side effects. In the last 20 years, IGBs have been constantly developing.

The Spatz adjustable balloon is an IGB volume adjustable saline-filled balloon approved for 1-year use [14,15].

It is placed in the gastric cavity, thereby reducing the rest of the stomach lumen and delaying its emptying. The application of the Spatz balloon allows overcoming the known limitations of previous balloons, such as short-term implantation, difficulty in adjusting the balloon volume, and migration of the balloon into the intestine. A specific feature of the Spatz balloon is a thin, retractable filling catheter, which allows intragastric volume adjustment *in situ*. Because the balloon volume is externally adjustable, it can be adjusted according to patient tolerance and desired weight loss.

The End-Ball IGB is a spherical, elastic, saline/air filled polyurethane IGB. Conventional End-Ball IGBs are filled with either saline or air, both filling materials having their own advantages and disadvantages. Air-filled IGBTs are well tolerated but less effective in terms of weight loss. Saline-filled IGBs are better in reducing body weight, but are associated with more complications. A specific feature of the End-Ball IGB is that the endoscopist can select any ratio of air and saline for infusion, and the balloon is inserted and removed endoscopically [14,15].

In addition to gastric distension and humoral factors, gastric emptying is another important mechanism that causes weight loss after IGB6 administration. Studies show that three months after IGB placement, solid and liquid gastric emptying time obtained by scintigraphy slows down significantly, which positively correlates with weight loss [16].

However, despite these findings, the question arises as to whether the initial effects of IGB placement persist throughout treatment. While subjective hunger and food cravings decrease shortly after IGB placement, these changes disappear in the same subjects two months after IGB administration [6,16].

Both types of IGB were used in this study. Six months after the intervention, a significant decrease in BMI was registered compared to the value registered on admission. The use of the two different types of IGB in the study showed no statistically significant difference in terms of body weight reduction and BMI between patients of the two groups six months after the intervention (BMI was 31.8 ± 5.8 and 30.1 ± 2.5 kg/m^2, respectively in the End ball and Spatz groups, p=0.11). Comparison of the two IGBs with respect to patients' body weight measured at 6 time points post-intervention showed a significant difference at 48 hours and 7 days postoperatively (p=0.028 and p=0.025, respectively). Patients from both groups in the period of 6 months reduced their body weight by an average of about 15 kg (p=0.82).

Adverse effects after IGB placement are common and similar in all systems currently in use. The rate of adverse events reported in individual studies varies greatly depending on the focus of the study. However, it is clear that most patients with IBD suffer from nausea and vomiting. Meta-analyses report that 23% to 72% of patients experience nausea and 20% to 50% of patients carrying IGBT report abdominal pain [17,18].

It is particularly significant that serious side effects are often registered. According to an FDA trial of the most commonly used gastric balloon, Orbera®, gastric ulcers were reported in 10% of participants. Gastric ulcer was registered in 35% of patients who wore ReShape® IGB, which is

probably due to the high filling volume of up to 900 ml[19]. However, according to a large systematic review that included 26 studies, mostly case series, gastric ulcer was recorded in only 0.3% of patients. Other rare but serious complications after IGB balloon placement include intestinal obstruction (0.8%), gastric perforation (0.1%) and death (0.05%) [20].

Many patients tend to tolerate gastrointestinal side effects in favor of weight loss. Early IGB removal has been observed in 3.5% to 7% of patients [20,21].

Interestingly, the tolerability but also the effectiveness of IGB depends on the localization, with more side effects and more weight loss with antral position [22].

The adjustable Spatz3® IGB was developed to overcome tolerability issues, allowing the balloon to be adjusted according to side effects and weight loss goals. However, a case-control study comparing side effects of Spatz3® and Orbera® found no significant differences in side effects and weight loss outcomes between the two IGB [23], and another study showed concerns regarding long-term safety [24]. Some single studies suggest that air-filled balloons such as Heliosphere® BAG (Heliscopie, Vienna, France) or Obalon® prevent nausea and vomiting and are also effective in weight loss[13].

This is very significant because early air-filled balloons were taken off the market due to inefficiency and safety issues. Whether newer generations of these IGBs have overcome these problems remains to be investigated by studies directly comparing air- and fluid-filled IGBs. In order to prevent or overcome nausea and vomiting, after placement of IGB, patients regularly receive antiemetic therapy. Prospective studies have shown that serotonin receptor antagonists are effective, and even more so if they are combined with midazolam [24,25]. In our study, the procedure was discontinued in one patient seven days after IGB application due to nausea, vomiting and persistent pain.

Conclusion

The idea of IGB remains attractive because, unlike bariatric surgery, it is a therapy that is minimally or non-invasive, reversible and time-limited. However, the effect on weight loss is far from what can be expected from surgical procedures. As with any medical therapy decision, the advantages and disadvantages of the methods must be considered to ensure the best solution for the patient.

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