JMS 2021;4(3):149-153
UDC:613.25:616.33-072.1-085.477.82

APPLICATION OF INTRAGASTRIC BALLOONS IN OBESITY TREATMENT

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Abstract

Obesity is a complex, chronic, metabolic disease characterized by excessive accumulation of adipose tissue in the body and numerous side effects on health. Endoscopic bariatric therapy (EBT) is just one method of treating obesity. Of the many EBT devices, intragastric balloons (IGBs), which take up some space in the stomach, are the most widely used in clinical practice.

The aim of this study was to demonstrate the effectiveness of the use of IGB in the treatment of obesity and to compare the results of the use of two different IGBs, Spatz and Edd-ball.

The study included 30 overweight patients with BMI (body mass index) between 25 and 40 kg /m^2, treated with IGB application. All patients were monitored for a period of 6 months from IGB placement until its removal.

Number of kilograms lost 6 months after IGB application, BMI change, the presence of comorbidities before and after the intervention, complications durig the intervention and patient satisfaction with the success of the procedure were analyzed. A comparison was also made between the results obtained with the two different types of IGB (Spatz and Edd-ball).

The average weight loss 6 months after IGB application was 15.3 kg. Comparison of BMI values before and 6 months after the intervention showed a statistically significant decrease in BMI after the intervention ($p = 0.00$). The comparison of the lost kilograms in relation to the type of IGB applied did not show a statistically significant difference between the two types of IGB used. Changes in comorbidities after the intervention did not show statistically significant differences.

Despite the limitations of this study, which was performed on a small number of patients, the use of IGB has proven to be an effective method of weight loss. No serious complications or fatalities were reported during the procedure.

Keywords: obesity, intragastric balloon, therapy, endoscopy.

Introduction

Obesity is a complex, chronic, metabolic disease characterized by excessive accumulation of adipose tissue in the body and numerous side effects on health. Until a few decades ago, obesity was not treated as a disease, but in recent years the incidence of obesity has increased dramatically and is becoming a global health problem [1, 2].

Obesity, in itself, is not as big a problem as the complications caused by the diseases that accompany it, such as diabetes, fatty liver change, hypertension, cardiovascular and cerebrovascular diseases, and metabolic syndrome [1, 3].

Therefore, the treatment of obesity is very complex. The basis of this treatment is lifestyle modification, which includes a controlled diet and physical activity. In addition, there is the possibility of using a number of pharmacotherapeutic agents, undergoing weight loss surgery, as well as endoscopic bariatric therapy (EBT). For now, the best starting choice is a lifestyle change with or without pharmacotherapy.

The number of pharmacological drugs recommended for weight loss is on the rise, indicating their poor efficacy, and surgical methods are associated with high risk. However, people with enormous obesity require definitive methods, such as bariatric surgery or EBT [4].

The only methods with long-term effective results in weight loss are bariatric surgery, which, however, is indicated only in patients with severe obesity, including those with a body mass index (BMI) higher than 40 kg / m^2 or at least 35 kg / m^2 with comorbidities present. Surgery is limited by possible complications as well as its own irreversibility [5].

EBT bridges the gap between pharmacotherapy and surgery, and therefore plays an important 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, as well as those with enormous obese who refuse surgery [6].

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 [7].

The basic mechanism by which EBT works is to take up space in the stomach, which reduces its capacity, modifies the motor function of the stomach and causes malabsorption. Of the many EBT devices, intragastric balloons (IGBs), which take up some space in the stomach, are the most widely used in clinical practice [8].

The **aim** of this study is to demonstrate the effectiveness of the use of IGB in the treatment of obesity and to compare the results of the use of two different IGBs, Spatz and Edd-ball.

Material and methods

The study included 30 overweight patients with BMI (body mass index) between 25 and 40 kg / m^2, treated with IGB application, with written consent.

Patients were grouped according to BMI value as follows

- patients with BMI from 25 to 40 kg / m^2 without comorbidities;
- patients with BMI> 35 kg / m^2, or 30 kg / m^2 with comorbidities;
- patients with BMI ≥ 40 kg / m^2, in the process of preparation for surgical bariatric therapy.

All patients were monitored for a period of 6 months from the placement of IGB, until the removal of IGB.

After the removal of the IGB, an analysis of weight loss, the change in BMI, comparison of the presence of comorbidities before and after the intervention and the complications from the intervention were made. A comparison between the results obtained with the two different types of IGB (Spatz and Edd-ball) was also made.

The study did not cover patients who could not be followed from various reasons. Exclusive criteria were all conditions that increase the risk of IGB placement, such as; large hiatal hernia (> 5 cm), active gastric or duodenal ulcer, previous surgical resection of the stomach or duodenum, inflammatory bowel disease, gastrointestinal neoplasms, oropharyngeal abnormalities, dependent gastrointestinal bleeding disorders, gastrointestinal bleeding disorders, pregnancy, psychiatric disorders, use of antiinflammatory and anticoagulant drugs, presence of cardiovascular, pulmonary and cerebrovascular diseases.

For statistical analysis, a database was created in the statistical program SPSS for Windows 23.0. Category variables are represented by absolute and relative numbers, quantitative variables are represented by descriptive parameters (mean, SD, minimum, maximum). Student t-test for dependent samples was used to compare BMI before and after the intervention. Student t-test for independent specimens was used to compare weight lost by balloon type. The value of $p < 0.05$ was taken as the level of significance.

Results

The study was conducted on 30 patients, 22 women and 8 men, who underwent IGB application to induce weight loss. Two different types of IGB were used, Spatz and End-ball. In 5 patients, the former was applied and in the other 25, the latter. The distribution of the descriptive variables in patients undergoing obesity treatment is shown in Table 1.

Table 1. Distribution of descriptive variables in patients undergoing obesity treatment with IGB application

Variable	Mean value	Min	Max	Std.Dev.
Age (years)	34,87	19,00	65,00	11,17
Height (cm)	169,23	154,00	189,00	7,67
Body weight before IGB application (kg)	108,57	75,00	176,00	25,03
Body weight 6 months after IGB application (kg)	94,13	65,00	156,00	23,39
BMI before IGB application (kg/m^2)	38,20	28,00	60,00	7,27
BMI 6 months after IGB application (kg/m^2)	32,20	24,00	57,00	6,52

Weight loss (kg)	15,33	3,00	34,00	7,03

According to the BMI value, the patients were distributed as follows: 16 patients with a BMI of 25 to 40 kg / m2 without comorbidities; 6 patients with BMI> 35 kg / m2, or 30 kg / m2 with comorbidities and 8 patients with BMI ≥ 40 kg / m2.

Prior to the IGB administration, the following comorbidities were registered: hypertension (9 patients), hypothyroidism (1 patient), migraine (1 patient), arthralgia (1 patient), autoimmune disease (1 patient), ulcerative colitis (1 patient) and sterility (1 patient). Four of the patients had controlled diabetes, 11 high fat. There was a family history of obesity in 12 patients. A special diet was administered to 28 patients before the intervention.

In one patient, the procedure was stopped after 14 days, due to constant nausea and urge to vomit. Common complications, such as nausea, vomiting, and discomfort, were noted in 16 patients during the IGB insertion and removal. No serious complications or fatalities were reported.

Changes in comorbidities did not show statistically significant differences before and after the intervention. In 6 patients the hypertension was reduced, in 5 patients the glycemic value was reduced and in 5 patients the fat value was reduced. Most of the patients (26) felt happy and satisfied with the results of the procedure.

Comparison of BMI before and 6 months after the intervention showed a statistically significant decrease in BMI after the intervention ($p = 0.00$).

No statistically significant difference was registered in body weight loss depending on the type of IGB used.

Discussion

The incidence of obesity not only does not decrease, but seems to increase rapidly, so bariatric devices are expected to be further improved. IGB plays an important role in bridging the gap between pharmacotherapy and surgery. In terms of reversibility, safety and cost, IGB has a clear advantage over bariatric interventions, although bariatric surgery has better long-term results. Therefore, when choosing the optimal treatment of obesity, an individual approach is necessary.

The idea for IGB comes from the use of gastric bezoars for weight loss. IGB was first used in 1982, and in 1985. The Garen-Edwards gas bubble has been approved for use in the treatment of obesity by the United States Food and Drug Administration (US FDA) [9,10].

The effectiveness of IGB is due to their ability to create 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, through vagus signals, quickly results in a feeling of satiety [11, 12].

Vagus stimulation is induced by mechanoreceptors in the gastric wall, which are stimulated by gastric distension [13].

Garen-Edwards's IGB was withdrawn from the market due to frequent complications associated with its use, such as gastric erosions and ulcers. Many IGBs obtained with modern technology are in use today, which work on the same principle, but cause much fewer side effects.

Spatz adjustable balloon (Figure 1) is an IGB volume adjustable balloon filled with saline approved for 1-year use [14].

It is placed in the gastric cavity, which reduces the rest of the lumen of the stomach and delays its emptying. The application of the Spatz balloon allows the known limitations of previous balloons to be overcome, such as short-term implantation, difficulty adjusting the balloon volume, and migration of the balloon into the intestine. A special feature of the Spatz balloon is a thin, removable charge catheter, which allows intragastric volume adjustment in situ. Because the volume of the balloon is externally adjustable, it can be adjusted according to the patient's tolerance and the desired weight loss.

End-Ball IGB (Figure 2) is a spherical, elastic, polyurethane IGB filled with saline / air. Conventional IGBs are filled with either saline or air, and both fillers have their advantages and disadvantages. Air-filled IGBs are well tolerated, but are less effective in terms of weight loss. Saline-filled IGBs are better at losing weight, but are associated with more complications. A specific feature of 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 [1].

Macitka et al. implanted Spatz IGB in 18 patients at 12 months, and the average weight loss at 24 and 52 weeks was 15.6 kg (with 26.4% excess weight loss, EWL) and 24.4 kg (with 48 , 8% EWL), respectively [14].

Brooks et al. reported the results of a 1-year implantation of a Spatz adjustable balloon in 73 patients [15]. According to them, patients lost an average of 21.6 kg (19% of body weight) with 45.7% EWL. Catheter impact was reported as a major complication in 3 patients (4.1%), requiring extraction surgery. No lethal outcome was reported [15].

Russo et al. compared the Spatz adjustable balloon to the IGB BioEnterics (BIB), also known as the OrberaTM. In their case-control study, they compared patients' weight loss, weight maintenance after balloon removal, and short- and medium-term complications, and found no statistically significant differences in these parameters between the two balloons [16]. However, long-term severe complications as well as high mortality have been reported [17].

In our study, the procedure was discontinued in only one patient, 14 days after application, due to persistent nausea and vomiting. During the procedure, nausea, vomiting, and discomfort were reported in 16 patients during IGB insertion and removal, but no serious complications or fatalities were reported.

The average weight loss 6 months after IGB application in our study was 15.3 kg, which is consistent with data from published studies [1,14, 18].

Buzga et al. reported an average weight loss of 14.7 kg with 32.1% EWL in 20 patients within 6 months of end-ball IGB administration [18]. The results are similar to those of conventional balloons with a low complication rate [18]. Keren and Rainis reported an average weight loss of 23.5 kg, an average BMI reduction of 6.4 kg / m2 and an EWL of 39.2% in 114 patients treated with End-Ball IGB. Significant weight loss was also observed in the period of one year after the removal of the balloon [19].

In our study, the comparison of lost weight with the type of IGB used did not show a statistically significant difference.

Conclusion

Despite the limitations of this study, which was performed on a small number of patients, the use of IGB has proven to be an effective method of weight loss. No serious complications or fatalities were reported during the procedure. A statistically significant decrease in BMI was recorded 6 months after the intervention. Patients were satisfied with the results achieved. However, the long-term benefits of losing weight remain to be seen.

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