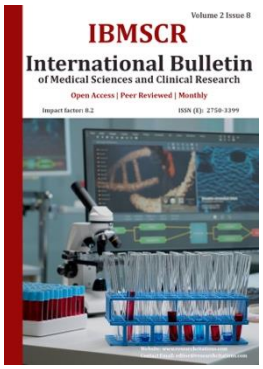

RESULTS OF THE USE OF INTRAGASTRIC BALLOONS IN 486 PATIENTS, A ONE-YEAR PROSPECTIVE ANALYSIS.

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Introduction: To date, the intragastric balloon (IGB) has become a popular alternative for weight loss in Uzbekistan. It can reduce total body weight (TBW) by 6-15%. With the use of a new technique, up to 20%. In our study, we examined the dynamics of weight loss over the course of a year after the implantation of the intragastric balloon.

Methods: A prospective data collection included 486 consecutive patients with overweight or obesity who underwent IGB surgery.

Results: Out of 486 patients, 404 patients (83%) had complete data at the end of 4 and 12 months. Patients included in the study had an initial average body mass index of 35.3 ± 7.2 kg/m^2, which decreased to 31.5 ± 5.7 kg/m^2 ($p < 0.0001$) at the end of 4 months and further decreased to 30.3 ± 5.4 kg/m^2 ($p < 0.0001$) at the end of 12 months. At 4 months, the overall average weight loss was 9.8 kg, while at 12 months, the average weight loss increased to 12.9 kg. At 4 months, the average percentage of weight loss was 10.5%, and by the end of 1 year, the combined % TBW increased to 13.7%.

Conclusion. The main weight loss is usually observed within the first 4 months after the procedure. However, it is important to note that patients can continue to lose weight for up to 1 year. IGB is a safe and effective option for patients seeking weight loss solutions. It has numerous advantages, especially its non-invasiveness, making it even more appealing to those considering this treatment method.

Keywords: Bariatric surgery, gastric balloon, obesity, weight loss.

Introduction

According to the latest report by the World Health Organization (WHO), in 2016, more than 1.9 billion people aged 18 and older were overweight, of which about 650 million were obese [1]. Over the past four decades, the prevalence of obesity worldwide has significantly increased. Among Southeast Asian countries, Malaysia holds the leading position in obesity prevalence: in 2019, the rate was 19.7% compared to 15.1% in 2011 [2, 3]. Uzbekistan is also experiencing a rise in obesity levels, which raises serious concerns due to the increased body fat content among the population across all body mass index (BMI) categories. This leads to an increased risk of developing comorbidities, contributing to both mortality and morbidity rates [2, 4, 5].

Bariatric surgery has proven to be an effective method for achieving significant and sustained weight loss [6, 7]. However, this approach is not suitable for everyone: some patients do not meet the criteria for surgical intervention or are not ready for it. In these cases, non-surgical methods become an alternative, such as the installation of intragastric

balloons (IGB), which are increasingly used to treat overweight and obesity in patients who have not succeeded with other weight loss methods [8].

The effectiveness of intragastric balloons (IGB) in weight control is confirmed by a number of studies. Since their approval and market introduction in 1985, intragastric balloons have undergone numerous improvements aimed at enhancing comfort, safety, and user appeal [9].

Among the existing models on the market, the ORBERA balloon holds a leading position. It is installed under endoscopic control, which ensures high safety and ease of use, especially for patients with obesity. The balloon is designed to be swallowed and to pass through the gastrointestinal tract on its own within 4–6 months. To confirm its correct placement, imaging methods such as ultrasound, fluoroscopy, or abdominal X-ray are used, thanks to the presence of a radiopaque substance.

Method

This study is a retrospective analysis of prospectively collected data from a consecutive cohort of patients who underwent Orbera balloon placement at the RS Laser Clinic, Tashkent Medical Academy, Tashkent, Uzbekistan. The study is prospective and was conducted at a single center from January 2024 to June 2025. Informed consent was obtained from all participants. The aim of our study was to evaluate the impact of the intervention on weight, BMI, and % EWL, which are the key indicators for assessing the effectiveness of bariatric procedures.

Inclusion criteria included patients with a BMI over 27 kg/m^2, suffering from overweight or obesity, but not meeting the specific criteria for bariatric surgery. Age range - from 18 to 65 years. The presence of metabolic syndrome or obesity-related diseases was also taken into account. Additionally, the study included those who declined surgical intervention or used it as a temporary solution before the final operation. The main exclusion criteria were patients with documented history of small bowel obstruction, previous bariatric or metabolic surgery, as well as any signs of esophageal, gastric, or intestinal diseases, such as inflammatory bowel disease or cancer. Additionally, patients with a history of gastrointestinal bleeding, coagulopathy, those taking anticoagulants, patients with eating disorders, severe psychological disorders, swallowing difficulties, or pregnancy were excluded.

The study was conducted according to a standard protocol, which required all eligible patients to observe a 10-hour fasting period before the introduction of the intragastric balloon (IGB). One hour before the procedure, an antiemetic drug (Osetron, intravenously 4 mg/2 ml, once a day) was administered. The medication was continued at a dose of 4-8 mg once or twice a day for another 2 days. All patients were prescribed Spazmalgon 500 mg orally three times a day. For 2 weeks, a proton pump inhibitor, Omeprazole at a dose of 40 mg, was taken. A post-procedure dietary regimen was recommended, consisting of three stages, each lasting 1 week. In the first stage, the patient consumed liquids, in the second, soft foods, and in the third, a regular diet.

The Orbera balloon is swallowed in a deflated state within a capsule connected to a thin catheter, through which the balloon is filled with 550 ml of fluid when it reaches the stomach. In cases where there were difficulties swallowing, a thin guide wire was used as a stylet. The installation procedure was performed on an outpatient basis and took approximately 15-20 minutes. Additionally, for pyloroplasty, the pyloric region was injected with a 10% saline solution. After filling and confirming the correct position of the abdominal cavity balloon, the

catheter is removed using gentle traction. Approximately 4-6 months later, the valve inside the balloon opens endoscopically, followed by its removal from the stomach. All patients had their initial height and weight recorded, and their BMI calculated. The surgeon conducted follow-up examinations of the patients at intervals of 2 weeks, 2 months, and 4 months. Participants' weight was assessed monthly. For 1 year, participants had unlimited access and support from a team of registered dietitians, primarily through text messages and phone calls. During the first month, weekly monitoring was conducted, then bi-weekly for the next 3 months, and monthly for the remaining 8 months.

All data were analyzed using computer software. Values are expressed as mean with standard deviation (SD). Comparison of baseline weight and BMI with weight and BMI differences at each time point (4 or 12 months) was analyzed using a paired two-tailed t-test. Statistical significance was considered at $p < 0.05$.

Results

In this study, intragastric balloons were placed in 486 patients. Complete data with monthly weight recordings over 12 months were available for 404 of them (83%). In 362 cases (90%), a stylet was used for balloon insertion, which helped avoid additional discomfort after an unsuccessful attempt at insertion without auxiliary means. In one patient (0.25%), balloon hyperinflation occurred, making it intolerable; the device was removed endoscopically a few days after placement. Five patients (1.24%) were hospitalized during the first week for rehydration.

Women made up 83% of the study sample, 61% of the participants had a baseline BMI in the range of 30–39 kg/m^2, and 20% had a BMI exceeding 40 kg/m^2. The average total weight loss was 9.6 kg after 4 months and 12.8 kg after 12 months (Fig. 1). Thus, the average body weight decreased from 93.2 kg to 83.6 kg after 4 months and to 80.4 kg after 12 months (Table 1).

In men, the average weight loss was higher: 15.8 kg after 4 months and 20.2 kg after 12 months. However, their initial weight was significantly higher — 116.7 kg compared to 88.2 kg for women. Women lost an average of 8.8 kg and 11.7 kg, respectively, over the same periods. At the same time, a clear dependence was observed between the initial BMI and the amount of weight loss: patients with a BMI ≥ 40 kg/m^2 achieved the greatest results both at 4 and 12 months (Table 1). However, patients with a BMI < 29.9 kg/m^2 also achieved clinically significant weight loss (Table 1). The average BMI of all participants was 35.3 ± 7.2 kg/m^2 and decreased to 31.5 ± 5.7 kg/m^2 by the end of the 4th month, and then to 30.3 ± 5.4 kg/m^2 by the end of the 12-month observation period ($p < 0.0001$, Table 1). The overall average percentage of total body weight loss (%TBWL) was 10.5% after 4 months and 13.7% after 12 months (Fig. 1). In men, this figure reached 15.6%, while in women it was 13.3% by the 12th month. The greater weight loss in men was similarly accompanied by a higher %LMT compared to women at all stages of the study. Additionally, it was found that patients with a higher baseline BMI demonstrated a significantly greater %EWL compared to patients with a BMI < 29.9 kg/m^2 both at 4 and 12 months (Table 1). The mechanism of action of intragastric balloons is based on reducing the volume of the stomach, stretching its walls, and slowing down the evacuation of its contents, which leads to a decrease in hunger and an increase in satiety [11–13]. According to the review by Bazerbarchi et al. (2019), the use of intragastric balloons allows for a reduction in total body weight by 6 to 15%, whereas lifestyle modification alone results in a reduction of 1–5% [13]. The results of the present study are

comparable: the average percentage of total body weight loss was 10.5% at the 4th month and increased to 13.7% by the 12th month. Unlike the study by Perker et al. (2010), where weight loss cessation was observed after 4–6 months, in our patients, weight loss continued up to 12 months. The total loss was 9.8 kg after 4 months and 12.9 kg after one year [14]. Similar results were obtained in the study by Jense et al. (2023) in the Netherlands, where a combined approach—installation of an intragastric balloon along with a 12-month coaching program—resulted in an average weight loss of 11 kg over 12 months. These data confirm the effectiveness of a comprehensive approach to the treatment of overweight and obesity [15].

Table 1

Changes in weight and body mass index (BMI) throughout the study. Before the procedure, patients were divided into groups by sex and BMI. Values are expressed as mean ± standard deviation. * for significant differences.

Parameters	All patients	Men	Women	BMI <29,9	BMI 29,9-39,9	BMI <40
Initial parameters	486	85	401	94	295	97
Final amount after treatment	404	78	326	77	246	81
Initial weight in kg	93.2±20.7	116.7±24.9	88.3±15.7	70.8 ± 6.5	91.2±11.8	121.7±20.8
6 months	83.6±18.2*	100.9±21.3*	79.4±14.6*	64.3 ± 6.5*	81.5±10.1*	108±17.9
12 months	80.4± 17.1*	96.46 ± 20*	76.6±13.75*	62.7±5.8*	78.3±9.7*	103 ± 16.68
P	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
BMI kg.m2	35.3±7.2	39.9±8.3	34.4±6.6	27.6±1.6	34.4±2.7	45.3±5.6
6 months	31.5±5.7*	34.2±6.7*	30.8±5.3*	25.1±2.1*	30.6±2.6*	40.1±4.9
12 months	30.3±5.4*	32.9±6.3*	26.7 ± 5*	24.4±1.8*	29.5±2.6*	38.4±4.6
P	<0.0001	<0.0001	< 0.001	<0.0001	<0.0001	<0.0001

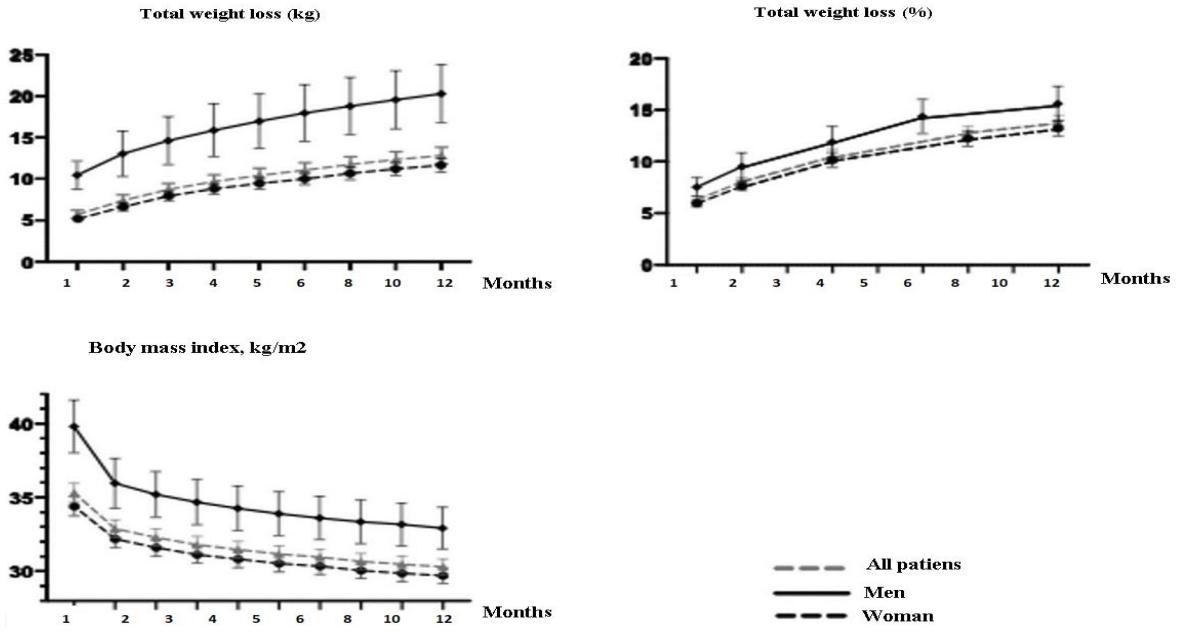

Fig. 1 Total weight loss, percentage of total weight loss, and BMI from baseline to 12 months after the introduction of the swallowed intragastric balloon. Men (solid black line), women (dashed black line) and all individuals (dashed gray line). Error bars represent the 95% confidence interval of the mean.

A month after the balloon was installed, it was noted that all patients either maintained their achieved body weight or continued to lose weight throughout the year of observation. As mentioned earlier, the Orbera company provides continuous support to patients, and typically, follow-up observation concludes after the intragastric balloon (IGB) is removed, approximately 4 months later. However, in this study, patients were monitored for the entire year, primarily through text messages and phone calls. Such prolonged and structured support, combined with lifestyle counseling and modification, may play a key role in ensuring sustainable weight loss. After the balloon is removed after 4 months, its physical impact ceases, which theoretically could lead to weight regain. Nevertheless, the implementation of a comprehensive year-long program allowed for the maintenance or even enhancement of the positive effect of IGB therapy, as confirmed by the results of this study. Meanwhile, determining the optimal duration of the balloon's therapeutic effect remains a challenging task and requires further research.

Conclusion

The present study is the largest prospective study conducted in Uzbekistan since the introduction of intragastric balloons in the region. The participation of representatives from various ethnic groups broadens the demographic representation of the population and enhances the generalizability of the obtained results. The data obtained serve as empirical confirmation of the method's effectiveness in achieving weight loss and a reduction in body mass index (BMI).

The application of a comprehensive approach, combining balloon therapy and long-term follow-up over one year, had a significant impact on the positive outcomes achieved by the patients. Continuous monitoring and evaluation of effectiveness over an extended period provide valuable data on the potential for long-term weight maintenance.

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