Intragastric Balloon as a Noninvasive Method for Obesity Treatment: A Single-Center Retrospective Study

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Background: The incidence of obesity is increasing globally, with approximately 1 in 3 adults either overweight or obese. Surgery provides the most effective treatment for advanced obesity; however, endoscopic treatment, including intragastric balloon therapy, is commonly used in patients who do not meet the indications for surgery. Our study aimed to evaluate short- and mid-term weight changes of patients who had intragastric balloon therapy.

Material and Methods: In this single-center retrospective study, we enrolled 320 patients with body mass index (BMI) values between 30 and 40 kg/m² and without comorbidities, who underwent intragastric balloon treatment. 284 patients successfully underwent the operation. All patients were followed-up at 6 months after treatment, balloons were removed, and BMIs were recorded. Further follow-up was performed 6 months after balloon removal, and patients' BMI and demographic data were recorded again.

Results: Overall, 320 patients were enrolled in this study. In this cohort, 82 returned to their preprocedural weight at 1 year postprocedure, whereas 260 had BMI lower than the preprocedural values, but higher than the values at 6 months postprocedure. None of the patients had lower BMI compared to their 6-month postprocedural values.

Conclusions: Balloon therapy typically helps patients lose 10% of body weight. Intragastric balloons are effective when used as weight loss tools, but are ineffective at maintaining weight loss. An intragastric device placed for 6 months may also be expected to help the patients develop better eating habits; however, we did not encounter this lifestyle change in our series.

Keywords: intragastric balloon; obesity; endoscopic treatment

Introduction

The incidence of obesity is continuously increasing due to lifestyle changes, and has tripled in the past 35 years, making it one of the most widespread and dangerous epidemic diseases [1,2]. Obesity is evaluated using criteria based almost exclusively on excess weight [3]. It is estimated that one in every three adults can be classified as overweight or obese, meaning that around 1.4 billion people are affected worldwide. Furthermore, it has been well established that obesity is insidious and recurring, and decreases both life quality and expectancy [4,5].

Surgery provides effective treatment for medium and advanced stages of obesity [6,7]; however, there is a huge gap between the number of patients with indications for surgery and the number who receive it [8]. Further, there is a substantial subgroup of patients suffering from excessive weight and associated comorbidities who do not fulfill the official criteria for surgery. For these patients, endoscopic treatments may be an option. Endoscopic options can fill in the gap between medical therapy and surgery. Currently, endoscopic bariatric procedures include restrictive,

bypass, space-occupying, and aspiration therapies. Restrictive techniques include the Primary Obesity Surgery Endoluminal (POSE) (USGI Medical, San Clemente, CA, USA) procedure, sleeve gastroplasty with Apollo OverStitchTM, Transoral Gastroplasty (TOGA), gastric volume reduction using the ACE stapler (Boston Scientific Corporation, Natick, MA, USA), and the Transoral Endoscopic Restrictive Implant System (TERIS) device. Intestinal bypass may be performed using the EndoBarrier^R (GI Dynamics, Boston, MA, USA) duodenal-jejunal bypass liner. A variety of space-filling devices have either been tested or are currently being used, Intragastric balloons (Orbera^R, Reshape DuoTM, Heliosphere^R BAG, ObalonTM), TransPyloric Shuttle^R, and SatiSphereTM. The AspireAssist^R Aspiration Therapy System, which involves removal of food from the stomach after consumption, has also been shown to be effective [9,10,11].

In this field, botox injections have been gaining popularity owing to their ease of application and increased postprocedural comfort. However, intra-gastric balloon (IGB) therapy remains the most accepted endoscopic procedure for obesity, since this procedure physically decreases gastric volume, alters gastrointestinal hormones, and increases the gastric emptying time.

In our study we evaluated short- and mid-term weight changes in patients treated with IGB therapy.

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Materials and Methods

Patient Enrollment

For this single-center retrospective study, we enrolled patients treated in obesity clinic of Kadikoy Sifa Atasehir Hospital between 2017 and 2020. The body mass index (BMI) of all patients was calculated and recorded and all patients were informed about treatment options. First, they were questioned regarding whether they had gone through any weight loss programs with a clinical dietician. Subsequently, they were informed about endoscopic produres, specifically IGB placement. Medical conditions associated with obesity were evaluated. Serum hemograms, biochemistry, and thyroid function tests were performed and recorded in all patients.

Patients with BMI >40 kg/m² were offered surgery. Patients with BMI between 30 and 40 kg/m² and without comorbidities were offered IGB therapy, and this endoscopic procedure was performed in patients who accepted the treatment, after receiving written and verbal information and their informed consent.

Patients with a history of gastric surgery, hiatal hernias, coagulation disorders, psychiatric disorders, alcoholism, drug abuse, or active gastric ulcers and Helicobacter pylori (H.pylori) infections were excluded from the study.

IGB Procedure

The IGB procedure was performed under general anesthesia. All eligible patients received a MedSilTM (JSC, Moscow, Russia) balloon filled with 500 mL saline endoscopically placed in the fundus. All patients were kept under surveillance for 6 hours after the procedure, and those who did not experience nausea or gastric cramps were discharged with prescriptions for antiemetics, antispasmodics, and proton pump inhibitors (PPIs). Patients who experienced severe nausea and cramps despite medical therapy were kept in the hospital for 24 hours.

Patients who experienced intractable vomiting or abdominal pain despite medical treatment 24 hours after balloon placement were rescoped to rule out complications and their balloons were removed if necessary.

All patients underwent follow-up at 6 months posttreatment for balloon removal nd measurement of BMI, and their balloons were removed and BMI data were recorded. A further follow-up was performed 6 months after balloon removal and their BMI and demographic data were were recorded again.

Results

Between 2017 and 2020, 320 patients were seen for obesity in the general surgery outpatient clinic of our institute. 6 patients who had not undergone a formal diet program were referred for a clinical dietician consultation. Surgical treatment was offered to 30 patients with BMI above 40 kg/m². Of these, 12 patients underwent surgery; the 18 patients who declined to undergo surgery were included in the study. No significant abnormalities were observed on the serum hemograms, biochemistry, or thyroid function tests of the patients included in this study.

During the preprocedural gastroscopy, severe Helicobacter pylori gastritis was observed in five patients, duodenal ulcers were seen in four patients, and six patients were observed to have hiatal hernias and erosive esophagitis. These 15 patients were therefore excluded from the study and administered relevant medical treatment.

Postoperatively, three patients experienced severe nausea and vomiting despite medical intervention and their IGBs were subsequently removed.

The procedure was successfully performed in the remaining 284 patients who were included in the study.

Regarding patient demographics, 180 patients were female and 108 were males. The mean age was 42 years. The average BMI of the patients at presentation was 34 (30–44) kg/m², and the average BMI after 6 months was 30 kg/m². The average BMI of patients 1 year postoperatively was 32 kg/m². The extra weight loss was 43% (17–100 kg) at 6 months and 23% (–4 to –67) at 1 year. Total body weight loss was 11% (6–22) at 6 months and 6 % (–2 to –14) at 1 year. For patients whose BMI were > 40 kg/m², the extra weight loss at 6 months was 23% (17–33) and 8% (–4 to –14) at 1 year. For the same group total body weight loss was 9% (7–12) at 6 months and 3% (–2 to –5) at 1 year.

Of the patients who successfully underwent IGBs, 82 had returned to their preprocedural weight at 1 year. BMIs of 260 patients' were lower compared to their preprocedure values, but were higher than their 6-month values when the balloons were removed. None of the patients had lower BMI at 1 year compared to their 6-month values.

Discussion

The rapid and continuous incidence of obesity has promoted the emergence of new treatment alternatives. Personalized diets have been selected by obese patients. This approach involves following a calorically restricted diet to achieve long-term weight loss in overweight or obese individuals. The aim of these plans is to reduce the caloric intake while preserving the balance among nutrients and providing required nutrition [12]. Pharmacotherapy and lifestyle changes tend to lead to a weight loss of 2-9% of total body weight [13]. Conversely, depending on the type and volume of the balloon used, IGB therapy can achieve a 8-15% short-term loss of total body weight [11].

Obesity surgery can result in a loss of 13–30 % of total body weight depending on the type of procedure performed [13], with gastric banding at the lower end of the spectrum and sleeve gastrectomy at the higher end. Numerous studies have shown that IGBs facilitate more effective weight loss than lifestyle changes alone, and this fact formed the basis for the FDA approval of this procedure.

However, it is clear that the contemporary literature on this subject is limited by the significant heterogeneity among

studies. Most studies are observational and were performed retrospectively, which makes them susceptible to bias.

Long-term efficiency in terms of weight loss has not been established for existing balloon techniques. The study on this topic suggests that long-term significant weight loss is limited compared to surgery and this fact should be communicated to patients [14]. Additionally, it can be difficult to evaluate the effect of varying diets and lifestyles in patients with IGBs on the ultimate weight loss outcome. Long-term studies evaluating weight loss, metabolic parameters, and hormonal changes are therefore needed. Furthermore, cost efficiency should be thoroughly examined in order to enhance the governance of health care providers. Lastly, although intragastric devices are generally considered very safe, attention should be drawn to the rare, but possibly life threatening, complications associated with these devices. A prior meta-analysis investigating the complications associated with IGBs determined that prevalences of gastric perforation, balloon migration, and mortality were 0.1%, 1.4%, and 0.08%, respectively [15]. These complications may be caused by a multitude of factors, including malpractice, patient noncompliance, or lack of proper follow up.

Both patients and clinicians continuously opt for lessinvasive procedures since they carry less risk. New innovative devices such as the swallowable balloon are gaining popularity due to their convenience and ease of administration; however, the long term results are unknown. While still in the development phase, the magnetically assisted gastric capsule may be the best choice for future noninvasive obesity treatment. Long-term comprehensive research and follow-up to evaluate efficiency and safety are paramount.

Conclusions

IGB therapy typically helps the patient lose 10 % of body weight. Furthermore, although IGBs are effective when used as weight loss tools, they are ineffective for weight maintenance. However, 6 months of intragastric device implantation could be expected to help patients develop better eating habits. Nevertheless, our study showed no such improvements in eating habits in our patient group, with most regaining weight after balloon removal. This finding supports the notion that behavioral problems and bad eating habits are the root cause of obesity.

Availability of Data and Materials

Data can be accessed from the corresponding author upon request.

Author Contributions

LE designed and performed the research. LE analyzed the data, drafted the manuscript and approved the final manuscript. LE agrees to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Ethical approval was obtained from Kanuni Sultan Süleyman Teaching and Research Hospital ethical committee (Approval no 2023-02-46). A written consent was taken from all patients. The study is in accordance with the Declaration of Helsinki.

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Conflict of Interest

The author declares no conflict of interest.

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