



Intragastric balloon therapy for obesity: Is it safe and effective?

Obezite tedavisinde intragastrik balon yöntemi güvenli ve etkili mi?

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Abstract

Aim: Bariatric surgery is a costly and invasive method with permanent effects and medications for treatment of obesity is less costly but may cause systemic side effects. Intragastric balloon (IGB) therapy is a minimal invasive and temporary option between medical therapy and bariatric surgery. The aim of this study is to evaluate the safety and efficiency of intragastric balloon application and present our results.

Methods: 39 patients who underwent IGB therapy between 2015 and 2017 were included in the study. IGB was advanced into the stomach, and then the balloon was filled with saline and methylene blue solution. The patients were assessed by a nutritionist during the follow-up period and after balloon removal they were evaluated for results.

Results: Of 39 patients, 33 were female and the median body mass index (BMI) was 33.2 kg/m² before the procedure. Three patients (7.6%) could not tolerate the balloon; therefore balloon extraction was performed on the day 1, 5 and 25. Median duration of therapy was 8 months (1 day-17 months). While excessive weight loss (EWL) ratio was 22.8% in patients whose balloon was removed in 6 months, EWL ratio was 41.6% in patients whose balloon remained more than 6 months. The median BMI after balloon removal was 28.3 kg/m². The only complication was spontaneous IGB deflation and excretion transanally.

Conclusion: Intragastric balloon therapy may be recommended as a safe and effective option for the patients who have had failed attempts of diet and exercise and will not undergo bariatric surgery.

Key words: obesity, gastric, balloon, colonization, bariatric

Öz

Amaç: Obezite tedavi yöntemlerinden bariatrik cerrahi, invazif ve maliyetli bir yaklaşım olup kalıcı yan etkilere sahipken, göreceli daha az maliyetli medikal tedavinin sistemik yan etkileri söz konusu olabilir. İntragastrik balon (IGB) uygulaması ise medikal tedavi ve bariatrik cerrahi arasında minimal invazif ve geçici bir yöntemdir. Bu çalışmanın amacı, IGB uygulamasının etkinliğini ve güvenliğini değerlendirmektir.

Yöntemler: Çalışmaya 2015 – 2017 yılları arasında IGB tedavisi uygulanan 39 hasta dahil edildi. İşlem öncesi ve sonrası vücut kitle indeksi (VKİ), fazla kilonun kayıp oranı, balonun hastalar tarafından tolere edilebilmesi ve gelişen komplikasyonlar değerlendirildi.

Bulgular: İşlem öncesi ortalama vücut kitle indeksi (VKİ) değeri 33.2 kg/m² olan 39 hastanın 33'ü (%84,6) kadındı. İşlemi tolere edemeyen 3 hastanın (%7,6) balonu 1., 5. ve 25. günlerde çıkarıldı. Tedavinin ortalama süresi 8 aydı (1 gün-17 ay). Balonları ilk 6 ayda çıkarılan hastalarda fazla kilonun kayıp oranı %22,8 iken, 6 aydan uzun kalanlarda bu oran %41,6 idi. Balon çıkarılması sonrası VKİ ortalama değeri 28.3 kg/m² olarak bulundu. Sadece bir hastada (%2,5) spontan IGB rüptürü ve balonun defekasyonla atılması görüldü.

Sonuç: IGB uygulaması başarısız diyet ve egzersiz denemeleri olan ve bariatrik cerrahi yapılmayacak hastalara güvenli ve etkili bir yöntem olarak önerilebilir.

Anahtar Kelimeler: obezite, mide, balon, üreme, bariatrik

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Introduction

Over 1.4 billion adults worldwide are overweight or obese [1]. Obesity may cause some health problems such as diabetes, hypertension, and heart disease. It has been shown that losing weight of about 10% may be adequate to postpone or prevent the onset of diabetes and other obesity-related illnesses [2-5].

While bariatric surgery has established effectiveness in treating morbidly obese patients, it is not generally used in patients whose BMI is between 30 to 34.9 kg/m², due to its costs, invasiveness and possibly permanent side effects [6]. Medications for treatment of obesity are non-invasive and less costly, but they result in restricted loss of weight and may have major side effects [7].

Intragastric balloon (IGB) therapy is a minimal invasive and temporary option between medical treatment of obesity and bariatric surgery. IGB works by decreasing preprandial hunger, maintaining postprandial satiety, and promoting weight loss in the short term [8]. This method may be feasible in patients who are not yet candidates for surgery, who have failed previous attempts at weight loss with diet and exercise, those who refuse or who are unable to access to surgery, and hoping to lose a significant amount of weight without the invasiveness of surgery or the systemic side effects of drugs. Besides, severely obese patients (BMI > 50 kg/m²) are at risk of having operative technical difficulties due to massive amounts of intra-abdominal fat and hepatomegaly or anesthesia-related complications. Preoperative weight loss may decrease the complexity and risks following bariatric procedure [9-11]. IGB therapy may be used as a bridge to bariatric surgery of these patients.

The aim of this study was to evaluate the safety and efficiency of IGB application.

Material and methods

Patients

After the ethics committee approval (Bezmi Alem Vakif University-54022451-050.05.04-17/12/2018-7410), a total of 39 patients who have undergone IGB therapy due to obesity in our endoscopy unit between April 2015 and June 2017 were retrospectively evaluated. The investigation conformed to the principles outlined in the Declaration of Helsinki. The patients comprised of 33 female (84.6%) and 6 male (15.3%), with a median age of 37 years (range, 20-62 years). Before the procedure, informed consent was obtained from all patients and median BMI was calculated as 33.2 kg/m² (range, 28-63 kg/m²).

Procedure

Under endoscopic view and propofol sedation, an upper gastrointestinal endoscopy was performed before the procedure to exclude other pathologies. The balloon (MedSil® Intragastric Balloon, Russia) was advanced blindly into the stomach, then the endoscope was reinserted and the balloon was positioned in the stomach and filled with saline (600 mL) and methylene blue solution (10 mL). After 2 hours of observation, the patients were given a liquid diet and were discharged when they tolerated the diet. Proton pump inhibitors (during treatment) and antiemetics (1-2 weeks) were prescribed. They were recommended to have a liquid diet for 4 weeks and thereafter a soft diet with calorie restriction. Follow-up controls were performed weekly in the first month, then on the third and sixth months. All patients were informed that the duration of IGB therapy was 6 months. During

the follow-up controls with a nutritionist, the nutrition plan and weight control were assessed, and nutritional education was reinforced. IGBs were extracted endoscopically using the IGB removal kit and microbiological examination was performed on all the balloons. Patients were evaluated in terms of weight loss (WL) (kg), excessive weight loss (EWL) (%), body mass index (BMI) (kg/m²) changes, time of balloon removal, microbiological examination of the removed balloons, procedure-related side effects, symptoms and complications.

Statistical Analysis

Data were evaluated using SPSS for windows 21.0 software (SPSS Inc., Chicago, IL). Descriptive statistics were calculated as frequency and percentage for categorical variables and as mean, standard deviation and median for numerical variables.

Table 1. Characteristics of the patients.

Feature	n (%)
Sex	
Female	33 (84.6%)
Male	6 (15.3%)
Age (years)	37 (20-62)
BMI (before treatment, kg/m ²)	33.2 (28-63)
Median excessive weight (kg)	34 (17-105)

Table 2. Outcomes of IGB application.

Feature	n
Duration (months) (n(range))	8 (1-17)
BMI (After balloon removal, kg/m ²)(n(range))	28.3 (19.7-61.9)
Median weight loss (kg)(n(range))	10 (0-42)
Median EWL (%) (n(range))	33.3 (0-110)
IGB therapy duration <6 months, median EWL (%)	22.8 (0-67.6)
IGB therapy duration >6 months, median EWL (%)	41.6 (0-110.5)
Median balloon extraction time (months)	8
Early balloon removal (n (%))	3 (7.6)
Patients with positive balloon culture (n (%))	9 (23)

Results

IGB was placed successfully in all patients with a success rate of 100%. Characteristics of the patients are presented in Table 1. The median BMI before treatment was 33.2 kg/m² (range 28-63) and median duration of the therapy was 8 months. While the median weight loss was 10 kg, EWL ratio was 33% and median BMI was 28.3 kg/m² (range 19.7-61.9) after the treatment (Table 2).

More than 60% of the patients have continued to experience mild and intermittent gastrointestinal symptoms after the second week of therapy, but the symptoms were severe enough to necessitate balloon removal only in 3 patients (7.6%). The symptoms that caused early removal were significant nausea and vomiting (n= 1), abdominal pain (n=1), and reflux and burping (n=1) on the 1st, 5th and 25th day of the balloon application, respectively. In the other patients, the IGB's remained between 2 and 17 months (Table 3).

There was spontaneous IGB deflation and excretion of the balloon transanally in one patient (2.5%). In 9 patients (23%), microbiologic examination of the removed balloon revealed positive culture results (Table 4).

While the median duration of IGB therapy was 8 months in all patients, this period was 5 months in the patients with fungal or bacterial contamination of the balloon. In addition, the median rate of patients complaining of at least one symptom was 66%, while this rate was 23% in patients with positive culture results.

Table 3. Side effects of IGB therapy.

Symptoms	n (%)
Abdominal pain	25 (64)
Lasting longer than 2 weeks, mild and intermittent	7(17.9)
Nausea and vomiting	25 (64)
Dyspepsia and burping	27 (69)
Reflux and burning	18 (48)

the removed balloons.	n
Microbial Growth	
Fungi	6
Candida Albicans	3
Cryptococcus Laurentii	1
Stephanoascus Ciferrii	1
Candida SPP	1
Bacteria	3
Burkholderia Cepacia	1
Enterobacter Cloacae	1
Serratia Marcescens	1

Table 3. Side effects of IGB therapy.

Discussion

The main reason of struggle for weight loss in obese patients is that obesity is associated with a noteworthy raise in mortality and comorbidities such as type 2 diabetes mellitus, coronary heart disease, hypertension, dyslipidemia [12, 13].

The efficiency of IGBs on weight loss has been reported in many randomized studies [14]. Losing weight induces a reduction in energy consumption which makes it challenging to succeed and preserve weight loss. Regaining of lost weight is a common problem in treating obesity [1]. The amount of weight loss may vary depending on the type of balloon used, and is about 30% of excessive body weight [14]. Similar to the literature, the median excess weight loss rate was determined as 33% in this study.

Approximately 50% of the weight loss which succeed during IGB therapy can be maintained for one year after balloon removal with diet and exercise [1, 15]. In a study consisting of approximately 400 patients who lost ≥20% of EWL with IGB therapy, it has been declared that the same amount of EWL could be preserved in 23% of the patients at five-year follow up [15].

Therefore behavior modification strategies are advised to minimize subsequent weight gain [16-18]. The duration of IGB therapy can be modified according to endoscopist's preference, type of the balloon and the patient's need. Repeated therapies are shown to be as effective as the initial treatment. IGBs may be re-applied in patients who request further weight loss after a compulsory one-month interval [19, 20]. Remaining the balloons in the stomach longer than the planned period may cause risk of rupturing and migrating into the intestine. While usually migrated balloons are excreted uneventfully, some may cause intestinal obstruction [1, 21, 22]. The patients were informed about the balloon removal time and the possible complications of therapy. But some of the patients have disrupted the follow-up procedure and delayed the balloon removal time. The reasons were declared as satisfaction of losing

weight and avoiding to increase the cost by repeating process. The median EWL of the patients whose balloons were removed within 6 months after the procedure was 22.8%, and this rate was 41.6% in patients whose balloons were removed after the 6th month. No complications were observed in these patients except one who excreted the balloon transanally uneventfully.

In the early days of the IGB therapy, most of the patients have some gastrointestinal symptoms due to gastric accommodation of the balloon. These symptoms include abdominal pain, nausea, vomiting, burping, dyspepsia, acid reflux and constipation [23, 24] and usually resolved with proton pump inhibitors, antiemetics and anticholinergics. However, early balloon removal may be necessary if severe symptoms persist [25, 26]. And three patients (7.6%) of this study had persisting symptoms which caused early removal.

The stomach is usually sterile or colonized by small amounts of bacteria or yeasts. But overgrowth may not occur in the existence of a normal healthy microbiota [27, 28]. Delayed gastric emptying and gastric stasis which are the effects of IGB's may be initiative factors causing opportunistic organisms to colonize readily [29]. Hypochlorhydric gastric medium formed by proton pump inhibitors is considered to be an other predisposing factor for opportunistic infections [30, 31]. Microorganisms that colonize the stomach consist of streptococci and lactobacilli as well as Veillonella and Clostridium subspecies, and Candida albicans as a common cause of colonization of medical devices [32].

Microbiological examination was performed to determine if the symptoms of the patients were related to the colonization of the balloons. Microbial growth was detected in the balloon of 23.7% (n=9) of patients. All were opportunistic microorganisms and the majority (n= 5) was Candida albicans. No antimicrobial treatment was given to the patients with positive culture results. Because the infection defined on the balloon was just local colonization, there were no signs of systemic infection. But, the presence of microbial contamination did not influence the duration of the balloon therapy and the frequency of symptoms and side effects.

Like other therapeutic endoscopic procedures, balloon removal can also be associated with gastrointestinal bleeding, esophageal tear or perforation and the other complications. No serious complication was observed in our analysis.

Mortality rates were reported as 0 – 0,005% in a systematic review published in 2016 [33]. And the only study that presented its results on IGBs remained in the stomach over six months declared greater results than that up to 6 months without complications [34].

This retrospective study has some limitations. Low number of patients, lack of long-term results and evaluating the effectiveness of the procedure only with weight loss and BMI were the major limitations.

In conclusion, IGB therapy is a minimal invasive and temporary option between medical treatment and bariatric surgery and may be recommended as a safe and effective option as an interval approach.

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