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ORIGINAL ARTICLE / ÖZGÜN ARAŞTIRMA

Effects of Intragastric Balloon on Body Mass Index, Lipid Profile and Blood Glucose Regulation: A Prospective Study

İntragastrik Balonun Vücut Kitle İndeksi, Lipit Profili ve Kan Şekeri Regülasyonu Üzerine Etkileri: Prospektif Çalışma

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ABSTRACT

Objective: Obesity remains an increasing public health and socioeconomic problem. Life style changes including healthy diet and physical activity are the first-line therapy for successful weight loss. The intragastric balloon has been considered as an effective and reversible, non-surgical method for weight loss. In this study, we aimed to investigate the effects of Intragastric balloon on weight loss, lipid profiles and blood glucose regulation in obese patients

Methods: 75 consecutive Intragastric balloon patients (55 Female, 20 Male) with a mean age of 35.2±9.6 years were included in this study. The study was conducted prospectively and an air-filled intragastric balloon was introduced in ambulatory settings. In this study, patients' pre-intervention body mass index, peripheral blood parameters such as HbA1c, lipid profiles were recorded and compared with post-intervention values.

Results: The median intervention time for intragastric balloon application was 13 min (8-19). After follow-up period of median 186 days (180-211), BMI was reduced significantly, 41.6±6.7 vs. 34.9±6.4 kg/m^2 ($p<0.001$). The median excess weight loss was found to be 33.2% (14-81.1). There is no statistically significant difference between pre-intervention and post-intervention valuables in terms of low-density lipoprotein, high-density lipoprotein, cholesterol and triglycerides levels ($p>0.05$). On the other hand, only pre and post-intervention HbA1c level was to be statistically significant ($p=0.001$)

Conclusion: There was significant change in BMI and HbA1c level with the intervention of intragastric balloon after follow-up period. For long-term benefit of balloon, further studies are needed.

Key words: Body mass index, HbA1c, Intragastric balloon, obesity

ÖZET

Amaç: Obezite giderek artan bir halk sağlığı ve sosyoekonomik sorun olmaya devam etmektedir. Sağlıklı beslenme ve fiziksel aktivite de dâhil olmak üzere yaşam tarzı değişiklikleri başarılı kilo kaybı için ilk basamak tedavi şekli olarak kabul görülmektedir. Gastrik balon kilo kaybı için etkili, geri dönüşümlü ve cerrahi olmayan bir yöntemdir. Çalışmanın amacı, obez hastalarda intragastrik balonun kilo kaybı, lipit profili ve kan şekeri düzenlenmesine etkilerini araştırmaktır.

Yöntemler: Bu çalışmada hastaların 35,2 ± 9,6 yaş ortalaması ile 75 ardışık mide balonu hastası (55 Bayan, 20 Erkek) çalışmaya dâhil edildi. Çalışma prospektif olarak planlandı ve hava-dolu mide balonu kontrolleri ayaktan poliklinikte yapıldı. Bu çalışmada, hastaların uygulama öncesi vücut kitle indeksi, HbA1c ve lipid profilleri gibi periferik kan parametreleri, kaydedilerek müdahale sonrası değerleri ile karşılaştırıldı.

Bulgular: Mide balonu uygulaması için medyan müdahale süresi 13 dakika (8-19) idi. Medyan 186 gün (180-211) izlem süresinden sonra, BMI, önemli ölçüde 41,6 ± 6,7 'den 34,9 ± 6,4'e azalma tespit edildi ($p <0,001$). Medyan aşırı kilo kaybı (AKK) %33,2 (14-81,1) olarak bulundu. Müdahale öncesi ve sonrası LDL, HDL kolesterol ve TG düzeyleri karşılaştırıldığında, istatistiksel olarak anlamlı farklılık bulunmadı. Öte yandan, sadece müdahale öncesi ve sonrası HbA1c düzeyi istatistiksel olarak anlamlı olduğu saptandı ($p = 0,001$).

Sonuç: İntragastrik balon takılan hastaların takiplerinde BMİ ve HbA1c düzeylerinde anlamlı değişiklikler tespit edildi. Gastrik balonun uzun dönemde yararları için daha ileri çalışmalara ihtiyaç vardır.

Anahtar kelimeler: Vücut kitle indeksi, HbA1c, intragastrik balon, obezite

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INTRODUCTION

Obesity remains an increasing public health and socioeconomic problem. In Turkey, in recent years, the number of people with obesity has increased considerably. According to TURDEP-II study, 36% of adults were obese [1). During last 12-year period, it was figured out that obesity increased 40% in TURDEP-II compared to TURDEP-I [1].

The World Health Organization recommended a decrease of 5%-15% of body weight to reduce the incidence of morbidities related to obesity [2]. Therefore, there has been a search for effective therapeutic methods that would cause weight loss. Life style changes including healthy diet and physical activity are the first-line therapy for successful weight loss [3]. Medication therapy for obesity remains as second-line therapy [4]. Some studies indicate that such therapies have limited efficacy for ongoing effect. Majority of patients turn back to their previous weights after a while. In the case of failure of conservative methods, surgery could be an option which is a more aggressive approach [5,6].

The intragastric balloon has been considered as an effective and reversible, non-surgical method and minimal invasive approach for weight loss. It helps the ingestion of smaller portions of meals by providing feeling of satiety. It has been recommended both for non-morbid obese patients and for morbid obese patients prior to bariatric surgery to decrease operation related morbidity and mortality [6,7].

In this study, we use to behalf of the examined the effects of intragastric balloon on weight reduction, lipid profile and HbA1c level.

METHODS

Ethics and patient selection

After the local ethics committee approval (ANEAH.EK.2013/83), from April 2012 to April 2014, 75 consecutive intragastric balloon patients were included in this study. The patients who were admitted to our clinic for weight reduction with >35 kg/m^2 BMI and who were not accepted for bariatric surgery were included. All patients were evaluated by multidisciplinary team including endocrinology, pulmonary diseases, psychiatry, general surgery, anesthesia and reanimation for bariatric intervention and informed consent was taken. All intragastric balloon applications were performed by two surgeons. Patients' demographic characteristics, pre-intervention body mass index (BMI), peripheral blood parameters such as HbA1c, lipid profile were recorded and compared with post-intervention values.

Inclusion and exclusion criteria

Only patients who were 18-60 years old were included and international normalizing ratio (INR) less than 1.5 IU, a prothrombin time (PT) of less than 15 second, a normal or near normal partial thromboplastin time (PTT), a platelet count greater than 50,000 per mm3 to limit the risk of bleeding, and the absence of any infection at the time of balloon insertion. The exclusion criteria were; active H.pylori infection according to result of pathology, active gastric ulcer, previous gastric resection or fundoplication, alcohol or drug abuse, psychiatric disorders, sweet eaters and patients who were not allowed to undergone an intervention. Also, patients who had renal failure or immunosuppression were excluded.

Intragastric balloon application technique

An air-filled intragastric balloon (Heliosphere BAG®; Heliscopie, Vienne, France; IHB) was introduced in ambulatory settings. Under intravenous sedo-analgesia with 2 mg dormicum, 25 mg dolantin and 2 mg/kg propofol, all patients were prepared in left lateral decubitus position just like upper gastrointestinal (GI) endoscopy. After the formal evaluation of upper GI tract, the endoscope was removed. Sheath covered intragastric balloon was curved by hand to easy fit the orogastric tracts. The balloon was introduced 50-55 cm from the incisors. With the help of endoscope, appropriate localization of the intragastric balloon in gastric fundus was confirmed, the sheath was removed and the balloon was filled with 660 cc air. After the confirmation of safe and correct application of the intragastric balloon with endoscope, the intervention was ended.

Follow up after intragastric balloon application

After the balloon application all patients were observed 4 to 6 hours. Proton pump inhibitors (PPI) and antiemetic drugs were prescribed and high-pro-

tein liquid regimen was suggested strongly in first two days. After this period, 800-1200 kcal diet was applied to patients and as long as, the intragastric balloon was effective. All patients were invited to the outpatient clinic visit monthly and the balloon localization was controlled with ultrasonography in all visits in radiology department.

Statistical Analysis

Continuous data were presented as median and range or mean ± standard deviation (SD). Dichotomous (two categories) and categorical data were presented as numbers with percentages. The differences between the pre and post-interventions were assessed with T-Test and Wilcoxon Signed Rank test. A two-tailed p value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS, version 16.00 (Chicago, IL, USA).

RESULTS

The mean age was 35.2±9.6 years and 55 female (73.3%) and 20 male (26.7%) were in the study. The median time of follow-up was 186 days (180-211). The median intervention time for intragastric balloon application was 13 min (8-19). After follow-up period BMI was reduced significantly, 41.6±6.7 vs. 34.9±6.4 kg/m^2 (p<0.001). The median excess weight loss (EWL) was found to be 33.2% (14-81.1) (Table 1). The hemorrhage was occurred in one patient (1.3%). The patient was hospitalized and monitored; complete blood count was followed by frequent intervals. After then, esophagogram and abdominal ultrasonography were taken and minor mucosal hemorrhage was detected. The hemorrhage was stopped spontaneously and she was discharged with healing. The balloon desufflation was occurred in four patient last month of their follow up and the balloons were seen their stool. A nonspecific abdominal pain was presented 2 of patients (2.6%) and 3 of patients (4%) had nausea and vomiting. The medical treatment was given them with proton pomp inhibitor and they were followed as outpatients. The intragastric balloon was removed in three patients (4%) because of they could not tolerate. In our study, major complication was not observed. We have found no statistically significant differences in the comparison of pre and post-intervention LDL, HDL, cholesterol and TG levels (p=0.159, p=0.830, p=0.408 and p=0.051 respectively). On the other hand, only pre and post-intervention HbA1c level was found to be statistically significant (p=0.001). Pre and post-intervention features of the patients were presented in Table 2.

Table 1. Patient characteristics and complications

Mean Age	35.2±9.6
Sex (F/M)	55/20
Median follow-up (day)	186 (180-211)
Balloon application time (Min)	13 (8-19)
EWL (%)	33.2 (14-81.1)
Complications	**n (%)**
Hemorrhage	1 (1.3)
Desufflation	4 (5.3)
Abdominal pain	2 (2.6)
Nausea and vomiting	3 (4)
Removal of balloon	3

F/M: Female/Male, Min: Minute, EWL: Excess weight loss

Table 2. Pre and post-intervention features of the patients

	Pre-intervention	Post-intervention	p value
BMI	41.6 ± 6.7	34.9 ± 6.4	<0.001
LDL	134.8 ± 30.5	131.2 ± 30.7	0.159
HDL	46.3 ± 10.9	46 ± 10.6	0.830
Cholesterol	200.8 ± 38	197.1 ± 53	0.408
TG	138 (44.5-452.1)	115,6 (14.9-448)	0.051
HbA1c	5.6 ± 0.9	5.5 ± 0.7	0.001

BMI: Body mass index, LDL: Low density lipoprotein, LDL: High density lipoprotein, TG: Triglyceride

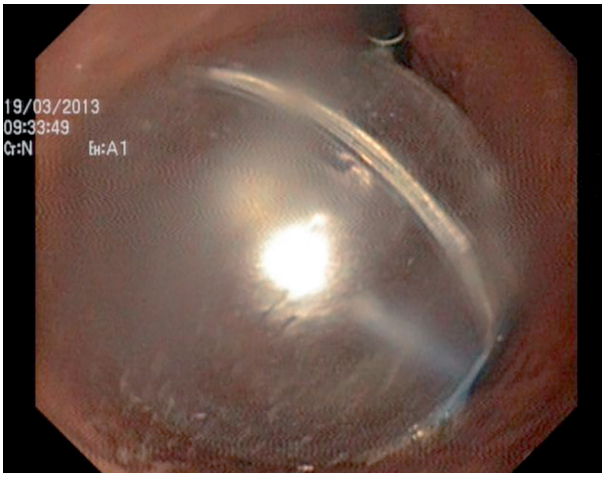

Figure 1. Insertion of intragastric balloon

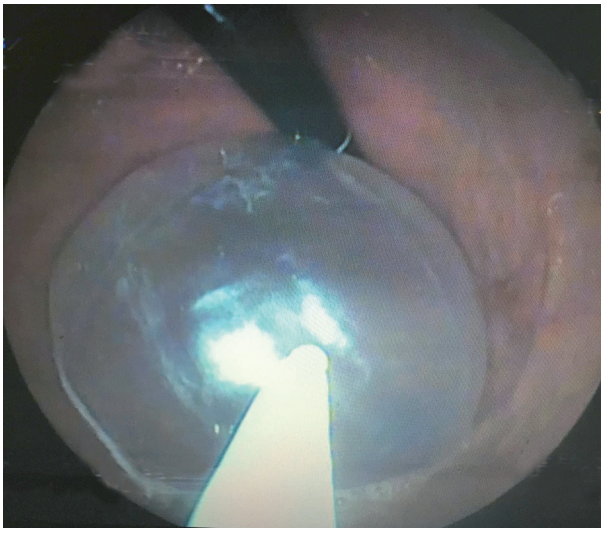

Figure 2. Removal of intragastric balloon

DISCUSSION

In our study, we showed that significant weight loss occurred after intragastric balloon procedure. Metabolic parameters had improved with this treatment modality.

In our study the median excess weight loss (EWL) was found to be 33.2% (14-81.1) and BMI loss was 6.7 kg/m^2. In the study of Buzga, mean EWL was 19.3% and mean BMI loss was 5.5 kg/m^2 [8]. In a large study with 2515 cases by Genco et al, EWL was 33.9% as mean value [9]. Buzga et al, showed that intragastric balloon resulted in significant reduction in body weight. Mean loss of weight was 18.4 kg in their study [8]. During 6 month period fat mass decreased on average by 11.7 kg. Loss of fat-free mas was about 5.3 kg. In the literature, the mean weight loss changed from 9.7 to 17.8 kg during 6 months following balloon application [9]. Weight loss can change according to balloon type. As far as the long-term effect of intragastric balloon on weight loss is concerned, there are different results in the literature. It was observed that 6 month follow-up period after balloon removal; almost all patients had returned to their beginning weights in the study of Saruç and his collegaues [10]. On the other hand, Kotzampassi et al indicates that intragstaric balloon seems to be effective for weight loss and maintenance for five year period [11].

In the study of Buzga, positive effect of intragastric balloon on glucose tolerance was observed [8]. HbA1c decreased significantly with the application of intragastric balloon. But, no significant change was seen in fasting glucose level [8]. Sekino et al also described a decrease in glycated hemoglobin with balloon procedure; however, this decrease was not statistically significant [12]. Konopko-Zubrycka documented a significant decrease in fasting glucose and insulin [13]. In our study, HbA1c levels decreased significantly also.

Beside weight loss, there are some studies in the literature assessing the effect of weight loss on metabolic parameters. A retrospective study by Italian group shown that weight loss induced by gastric balloon caused the comorbidities to be improved especially hypertension, type 2 diabetes [9]. They reported resolution of comorbidities in 44.3% of subjects at the end of treatment. In the study by Crea et al it was observed that average body weight loss was 14.1 kg at the time of removal of intragastric baloon [14]. HDL cholesterol and uric acid levels did not change, while the incidence of metabolic syndrome, hypertension, hypertriglyceridemia, type 2 diabetes mellitus and hypercholesterolemia diminished at 6months and 1 year following intragastric balloon removal [14]. Crea and colleagues declared that incidence of metabolic syndrome decreased from 34.8% to 14.5 % after removal of balloon.

We showed that after application of 6-month period of intragastric balloon the level of HDL was increased. Meanwhile, there was a decrease in LDL level but these changes were not significant. In the study of Buzga, HDL level did not change and LDL level decreased insignificantly. In another study by Forlano, severe liver steatosis decreased from 52% to 4% after removal of balloon [15].

In a randomized controlled study by Fuller, 31 subjects were randomized to intragastric balloon procedure with 12 month behavioral modification. Rest 35 subjects were performed only 12 month behavioral modification as control group. At 6 month, weight loss was as mean 14.2 kg and 4.8 kg in intragastric balon and control group, respectively ($p<0.0001$). There was a significantly greater reduction in waist circumference in balloon group and metabolic syndrome remission was greater in

balloon group as percentage when compared to only behavioral modification group [16].

In a large series of 2515 cases by Genco et al, mean BMI loss was 4,9 kg/m^2. This result was smaller compared to bariatric surgery outcomes but remarkable regression of co-morbidities occurred [9]. In that study preoperative co-morbidity had decreased by 89.1%.It was found that intragastric balloon was safe and effective. Rate of morbidity and mortality was low in that large series of cases [9]. In a study with 100 cases, conducted by Yasawy et al [17] on the obesity and gastric balloon, it was found that intragastric balloon effective achieved weight loss and resolved obesity related morbidities such as diabetes mellitus, hypertension, dyslipidemia, and fatty liver. Therefore, balloon procedure may be a good treatment modality for patients who will have bariatric surgery by improving metabolic parameters [7].

Our studies include some limitations. First, our sample size was lower than literature and secondly, our follow-up period was not enough to clearly evaluate metabolic parameters.

In conclusion, in the present study, we detected less BMI, level of LDL, TG, cholesterol and HbA1c after application of intragastric balloon follow-up period. Intragastric balloon can a role in the preoperative treatment of morbidly obese patients to be prepared for bariatric or other elective surgeries by decreasing morbidity and mortality risk. For long-term benefit of balloon, further studies are needed.

Declaration of Conflicting Interests: The authors declare that they have no conflict of interest.

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