EFFICACY AND SAFETY OF INTRAGASTRIC BALLOON TREATMENT IN OBESITY

Original Article

OBEZİTE TEDAVİSİNDE MİDE İÇİ BALON TEDAVİSİNİN ETKİNLİĞİ VE GÜVENİLİRLİĞİ

Umit Akyuz

Yeditepe University Medical Faculty Department of Gastroenterology.

Cengiz Pata

Yeditepe University Medical Faculty Department of Gastroenterology.

Murat Kalaycı

Yeditepe University Faculty of Medicine, Department of General Surgery.

Fevzi Fırat Yalniz

Yeditepe University Medical Faculty Department of Gastroenterology.

Baki Ekci

Yeditepe University Faculty of Medicine, Department of General Surgery.

Alp Demirag

Yeditepe University Faculty of Medicine, Department of General Surgery

Corresponding Author

Yrd.Doç Dr. Umit Akyuz

Yeditepe University Medical Faculty Department of Gastroenterology.
Tel: 0216 578 41 45
e-mail: akyuzfu@yahoo.com

ABSTRACT

AIM:

Obesity appeared with increasing frequency in recent years. The aim of this study is to evaluate safety and efficacy of intra-gastric balloon therapy in patients with morbid obesity.

MATERIAL AND METHODS

Eighteen patients (11 women and 7 men; Body Mass Index (BMI) > 35 kg/m2) were included into the study, and endocrinological problems are excluded in all of them. Psychiatric examinations were performed in all patients. The mean age of the patients was 40±5 years, and mean BMI was 42±0.96 kg/m^2. Elastic silicon balloon which is filled 500-700 ml saline plus 10 ml methylene blue was used (Bioenterics Intragastric Ballon System INANEMED health Santa Barbara). Patients were discharged with diet (1200-1400 kcal/day). All patients were controlled every week in the first month, every 2 weeks during the follow-up period.

RESULTS

At the end of 3 months, mean weight loss was 12±2.5 kg. BMI was regressed to 35±2 kg/m2 ($p<0.05$). Excep nausea and vomiting during the first month, we did not observe serious complication.

CONCLUSION

Intragastric balloon treatment seems to be safe and effective procedure in obesity treatment.

Key words: *Obesity; intragastric balloon.*

ÖZET

AMAÇ:

Obezite son yıllarda giderek artan bir sıklıkta karşımıza çıkmaktadır. Bu çalışmada amaç morbid obezitesi olan

hastalarda mide içi balon tedavisinin erken dönemde etkinliğini değerlendirmektir.

METOD

Çalışmaya, Vücut Kütle İndeksi (VKİ) >35 kg/m2 olan ve endokrinolojik problemleri dışlanan toplam 18 hasta (11 kadın, 7 erkek) dahil edildi. Hastaların yaş ortalaması 40±5 yıl, VKİ 42±0.96 kg/m2 idi. Her hasta işlem öncesi psikiyatrik olarak da değerlendirildi. Tedavi amacı ile 500-700 ml serum fizyolojik ve 10 ml metilen mavisi ile doldurulan düz elastik silikon balon (Bioenterics Intragastrik Balon Sistemi INANEMED sağlık Santa Barbara) kullanıldı. Olgulara 1200-1400 kalori/gün diyet verildi. Hastalar yan etkiler açısından ilk ay her hafta, daha sonra 15 günde bir kontrol edildi.

SONUÇLAR

Üçüncü ayın sonunda olguların ortalama 12±2.5 kg zayıfladıkları görüldü. VKİ 35±2 kg/m2 'ya gerilediği saptandı ($p<0.05$). Yan etki olarak ilk 1 ay içinde bulantı kusma ve karın ağrısı dışında ek sorun yaşanmadı.

SONUÇ

Mide içi balon yerleştirilmesi morbid obezite tedavisinde etkin ve tolere edilebilir bir yöntem olarak görülmektedir.

Anahtar kelimeler: *Obezite; intragastrik balon.*

INTRODUCTION

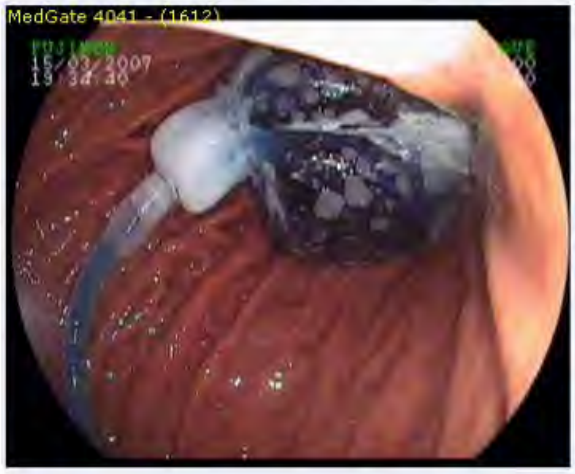
Authorities view obesity as one of the most serious public health problems of the 21st century. It causes significant health issues and is associated with metabolic syndrome, nonalcoholic fatty liver disease and diverse complications related to them. Obesity also increases all-cause mortality, as well as death from any cancer, and cardiovascular and respiratory diseases. (1).

Dieting and physical exercise are the mainstays of treatment for obesity. In morbid obesity, pharmacologic (should be carefully used because of their severe side effects) and surgical treatment modalities preferred. The surgical procedures could be classified as the stomach volume reducing techniques such as intra-gastric balloon replacement, gastric bypass bracelet, and gastroplasty; and reducing ability to absorb nutrients from food by gastric by-pass procedures. Intragastric balloon replacement is one of the most preferred procedure because it is minimally invasive and does not disturb anatomy (2). Balloon intolerance, balloon perforation, esophagitis and peptic ulcer development are the complications of this procedure (3).

The aim of this study is to evaluate safety and efficacy of intra-gastric balloon therapy in patients with morbid obesity.

MATERIAL AND METHODS

Eighteen patients whose Body Mass Index (BMI) > 35 kg/m2 (11 women and 7 men) were included in this study. The patients with primary metabolic problems were excluded after a careful endocrinologic examination. Psychiatric examinations were performed in all patients. Informed patient consents were taken from all patients. Elastic silicon balloon which is filled 500-700 ml saline plus 10 ml methylene blue was used (Bioenterics Intragastric Ballon System INANEMED health Santa Barbara). Gastric balloons were placed endoscopically **(Figure 1).**



Patients were discharged with 1200-1400 kcal/day diet. All patients were controlled every week in the first month, every 2 weeks during the follow-up period. SPSS 13 version (Chicago, USA) used in statistical analysis. We used nonparametric tests since our patient population was small.

RESULTS

Mean age of patients was 40±5 years, and mean BMI was 42±0.96 kg/m^2. The clinical and demographic distribution of patients summarized in **Table 1.**

Sex (M/F)	11/7
Age(years)	40±5
BMI	42±0.96
Glucose (mg/dl)	105±13
Total Cholesterol (mg/dl)	245±26.2
Trigliserid (mg/dl)	190±34

Table 1: *Clinical and demographical distribution of patients.*

At the end of 3 months period, patients lost 12±2.5 kg weight and their BMI regressed to 35±2 kg/m^2 ($p<0.05$). Except nausea, vomiting and stomach pain during the first month, we did not observe any serious complication. In %40 of patients (n=7) esophagitis detected. (3 cases Grade A, 4 cases Grade B) We did not have any problem related with gastric balloon tolerance.

DISCUSSION

Current guidelines recommend a multidisciplinary approach in order to solve this problem. No matter what the treatment option, weight reduction increases the success of the treatment (4, 5). In our study; intra-gastric balloon

followed by diet; we found statistically significant weight reduction after 3 months. Genco et al(4) evaluated 2515 patients and the overall complication ratio was found %2.8. They report 5 perforations while 2 of them died because of perforation. Other reported complications in the literature are; gastric ulcer development, obstruction, esophagitis and balloon perforation. In our study, although we did not observe any severe complication, our esophagitis prevalence found to be higher than the literature. (%40 vs %1.2) (4). This could be explained as the routine usage of proton pump inhibitors after the procedure in other clinical trials (5).

As conclusion; intra-gastric balloon replacement could be an option in obesity treatment in selected cases.

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