



Effectiveness of Intra-gastric Balloon Treatment for Obese Patients: Retrospective Clinical Trial

Obez Hastaların Tedavisinde İntra-gastrik Balonun Etkinliği: Retrospektif Klinik Çalışma

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ABSTRACT

Objective: Obesity is a serious and chronic disease with genetic and environmental interference. Several treatment modalities exist such as medical treatment, surgical treatment, endoscopic interventions.

Methods: Thirteen patients' data were evaluated retrospectively at the Erzincan University Medical Faculty Hospital Endoscopy Unit. Intra-gastric balloons were performed between 2012 January-2013 December. When patients gain the desired weight, approximately 8 to 12 months later; the balloons were removed.

Results: The mean duration of gastric balloons in patients was 10.0±1.22 months. It was determined that the mean weight loss within the prescribed time was 25.1±5.5 kg. There is a statistically significant difference among the values when comparing the values before and after gastric balloon ($p=0.001$)

Conclusion: Intra-gastric balloon replacement is a safe and effective procedure for weight reduction. The intra-gastric balloon can play a role for the temporary weight reduction of morbidly obese patients in diet supporting, as well as in the preoperative treatment of patient candidates for bariatric surgery or other surgical procedures in order to decrease morbidity and mortality. (*JAREM 2013; 3: 97-9*)

Key Words: Obesity, gastric balloon, endoscopy

ÖZET

Amaç: Obezite çevresel ve genetik faktörlerle iştirakli ciddi ve kronik bir hastalıktır. Medikal, cerrahi ve endoskopik girişimler olarak birkaç tedavi şekli mevcuttur.

Yöntemler: Erzincan Tıp Fakültesi Endoskopi Ünitesindeki 13 hastanın verileri retrospektif olarak değerlendirildi. İntra-gastrik balonlar 2012 Ocak-2013 Aralık tarihleri arasında uygulandı. Ortalama 8-12 ay sonra, hastalar istenilen kiloya gerileyince, balonlar çıkarıldı.

Bulgular: Gastrik balonların ortalama kalma süresi 10,0±1,22 ay olarak bulundu. Belirtilen sürede ortalama kilo kaybı 25,1±5,5 kg. saptandı. Değerleri gastrik balon öncesi ve sonrası olarak kıyasladığımızda istatistiksel olarak belirgin fark bulundu ($p=0,001$).

Sonuç: Kilo vermek için intra-gastrik balon yerleştirilmesi güvenli ve efektif prosedürdür. İntra-gastrik balon uygulaması diyet desteğinde ki morbid obez hastalarda geçici kilo azaltımı; bariatrik tedaviye gönüllü hastaların preoperatif tedavileri için ve diğer cerrahi girişimlerde morbiditeyi-mortaliteyi azaltmak için idealdir. (*JAREM 2013; 3: 97-9*)

Anahtar Sözcükler: Obezite, gastrik balon, endoskopi

INTRODUCTION

Obesity is a serious and chronic disease with genetic and environmental factors. Obesity develops because of excessive fatty tissue in the body and a great number of factors and it also requires medical treatment. The most significant risk factors of obesity constitute reduction in physical activity, feeding habits, age, sex, educational level, marriage, parity and genetic reasons. Obesity that can be transmitted genetically is spreading expeditiously in developed and developing countries in particular. By losing weight, lung function, metabolic parameters, and body fat distribution in patients with overweight/obesity and metabolic syndrome (MS) improves (1).

Currently, research is focused on the development of alternative methods of obesity treatment that are not associated with a high

operative risk; therefore, the endoscopic treatment of obesity is of great interest. Endoscopy has an unquestionable role in the pre-operative evaluation of patients undergoing bariatric surgery, and also in the assessment and treatment of its complications (2, 3). The purpose of our study is to share early term results of the patients with obesity whom we treated by gastric balloon.

METHODS

Thirteen patients' (12 females, 1 male) data were evaluated retrospectively at the Erzincan Medical Faculty Hospital Endoscopy Unit. The procedure was done between 2012 January-2013 December. All subjects underwent upper endoscopy after an overnight fast with an Olympus Evis Exera II CRV-180 (Olympus Corp. Tokyo, Japan) endoscope. Subjects were kept in the left lateral decubitus position during the procedure. Benzocaine spray was

used to anesthetize the posterior pharyngeal wall since the endoscopy was performed without sedation.

Exclusion criteria for the subjects with normal gastroesophageal function included any abdominal symptoms or any medication that could affect the gastroesophageal segment high-pressure zone, including antacids, H2 blockers, proton pump inhibitors, prokinetic agents, antibiotics and anticholinergics, GERD, hiatal hernia, conditions and disorders including a history of abdominal pain, heartburn, difficulty in swallowing, pain on swallowing, dysphagia, abdominal surgery involving the stomach or esophagus, nausea or vomiting, diabetes, scleroderma, esophageal motility disorders, noncardiac chest pain, achalasia, and existing pregnancy.

Under dietitian control patients started a diet and exercise program. The Spatz gastric balloon (Figure 1, 2) was implanted to all patients endoscopically. At first, the balloons were inflated by 350 cc methylene blue liquid. According to patients' weight loss, balloons were inflated up to the maximum of 700 cc liquid within two or three months periodically with 100 cc methylene blue mixed physiologic saline. When patients gain the desired weight, approximately 8 to 12 months later; the balloons were removed. Oral intake was stopped two days before the deflation day. The balloons were deflated by endoscopically. Oral intake restarted two hours later after the deflation time. All the inflation and deflation procedures completed as ambulatory care. Written informed consent of all patients were obtained before the procedure.

Statistical analysis

Statistical analysis were done by SPSS 17.0 (SPSS Inc., Chicago, IL) software. All *p* values were two-sided in tests, and *p* values less than 0.05 were considered to be statistically significant.

RESULTS

Mean hospitalization time was 1.2 days. The mean duration of gastric balloons in patients was 10.0 ± 1.22 months. It was deter-



Figure 1. The gastric balloon is applied in the previous view

mined that the mean weight loss within the prescribed time was 25.1 ± 5.5 kg. It was also found that the mean body mass index (BMI) of patients was 40.44 ± 4.88 kg/m before applying the gastric balloon, while the mean BMI was 31.08 ± 3.70 kg/m² after the treatment process. There is a statistically significant difference among the values when comparing the values before and after the gastric balloon (*p*: 0.001) (Table 1). The demographics and results summary is shown in Table 2.

DISCUSSION

The management and treatment of obesity is complex. A large number of specialists are needed to support health care in obese patients, especially endocrinologists, dieticians, gastroenterologists, surgeons, psychologists and psychiatrists. The accepted treatment methods of obesity include the following: diet modification, physical exercise, changing lifestyle and eating habits, pharmacological treatment, surgery and endoscopic treatment. The most physiological method of treatment is diet modification; however, the beneficial effect is difficult to obtain. Behavioral therapy, which includes changing lifestyle and eating habits, plays a role in supporting long-term results in all obese patients, independent of the treatment method used. Pharmacological treatment options (eg, sibutramine and orlistat) are limited and, unfortunately, are associated with complications and contraindications. The National Institute of Health has recommended weight loss surgery as an appropriate alternative in carefully selected individuals with severe obesity BMI of 40 kg/m² or greater, or a BMI of 35 kg/m² or greater



Figure 2. Stomach balloon applied view

Table 1. Statistical analysis of weight and BMI differences

	Mean	Std. Deviation	95% Confidence Interval of the Difference		P
			Lower	Upper	
Weight differences	25.07	5.37	21.82	28.32	.000
BMI differences	9.35	2.76	7.68	11.03	.000

Mean value of weight differences before and after the procedure was 25.1 kg (sd: 5.4; CI: 21.8-28.3) *p*: 0.000. Mean value of BMI differences before and after the procedure was 9.3 kg/m² (sd: 2.8; CI: 7.7-11) *p*: 0.000

Table 2. Patient Demographics and results summary

	Mean	Std. Deviation
Age	42.00	9.05
Height	164.92	9.42
Weight BP	109.53	11.63
Weight AP	84.46	11.78
Balloon Affixed Time	10.00	1.22
Bmi BP	40.44	4.88
Bmi AP	31.08	3.70
Weight Loose	25.07	5.37
Weight Loose in a Month	2.52	0.48

BP: before procedure; AP: after procedure; BMI: body mass index

with serious comorbid conditions when diet, behavioral and pharmacotherapy interventions fail (2-4).

The use of intra-gastric devices to promote weight reduction is not a novel method (5, 6). Several researchers, over the years, have used different types of balloons as they were thought to be promising as less invasive than surgery for the treatment of morbid obesity. At the end of the 1990s, several prospective and controlled studies have reported that Ballobes or Garren-Edwards gastric bubbles had no significant effects as adjuvant device for weight reduction in morbidly obese patients. Reasons for this were considered to be the small volume of the balloon (220 mL for Garren-Edwards and 400 mL for Ballobes), the air filling with no weight effect on the stomach wall, and the cylinder-like shape of these devices. In addition, these devices had a high rate of complications (gastric erosion: 26%; gastric ulcer: 14%; Mallory-Weiss tears: 11%) (7-10). Gastric hemorrhagia may mimic a dieulafoy lesion (11).

The patients with spatz gastric balloon are able to lose weight on a desired scale by performing a suitable diet. There are some advantages, such as starting spatz type gastric balloons with low volume and adjusting this volume endoscopically in accordance with weight loss. Moreover, starting with a low volume is able to reduce gastric irritation findings within the first 7-10 days, which is also an advantage.

This retrospective study shows that intra-gastric balloon treatment is a safe and effective procedure for weight reduction. The intra-gastric balloon can play a role for the temporary weight reduction of morbidly obese patients in diet support, as well as in the preoperative treatment of patient candidates for bariatric surgery or other surgical procedures (i.e. orthopaedic prosthesis) in order to decrease morbidity and mortality. In order to show a higher impact on the treatment of obesity, we are preparing a new prospective study about the intra-gastric balloon. Long lasting prospective studies must done to see late complications of the intra-gastric balloon.

CONCLUSION

The intra-gastric balloon is safe and effective in overweight patients, helping to reduce progression to obesity and decreasing the prevalence of a number of important.

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Etik Komite Onayı: Çalışmanın retrospektif tasarımından dolayı etik kurul onayı alınmamıştır.

Hasta Onamı: Çalışmanın retrospektif tasarımından dolayı hasta onamı alınmamıştır.

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