Turk J Gastroenterol 2010; 21 (4): 333-337

Intragastric balloon treatment of obesity must be combined with bariatric surgery: A pilot study in Turkey

Obesitede intragastrik balon tedavisi bariatrik cerrahiyle birlikte kullanılmalı

Murat SARUÇ[1], Deniz BÖLER[2], Mehmet KARAARSLAN[3], Çağlar BAYSAL[1], Kemal RASA[2], Metin ÇAKMAKÇI[2], Cihan URAS[4], Nurdan TÖZÜN[1]

Departments of, [1]Gastroenterology, [3]Internal Medicine and [4]General Surgery, Acıbadem University, School of Medicine, İstanbul
Division of [2]General Surgery, Acıbadem Hospital, İstanbul

Background/aims: *The treatment of morbid obesity by intragastric balloon (BioEnterics) placement is a safe and effective procedure. Cultural, social and economical factors are known to have an impact on the outcome of therapeutic interventions. This study aimed to evaluate the effect of this method on weight loss and long-term outcome following balloon removal in a cohort of Turkish patients.* ***Methods:*** *Twenty-five patients (11 male, 14 female) who selected BioEnterics intragastric balloon method for weight loss over surgery were included in the study. Their mean age was 35.2±13.4 and mean body mass index was 43.5±8.7 kg/m². Patients who had any contraindication for endoscopic BioEnterics intragastric balloon placement were excluded. BioEnterics intragastric balloon was performed under deep sedation with propofol, and all patients were placed on a 1000 kcal/day diet for six months. Patients were reevaluated six months following balloon removal. Excess weight loss of greater than 25% was considered as end of treatment success. Maintenance of excess weight loss greater than 25% at the end of a six-month follow-up period was considered as long-term success. Results were reported as mean body mass index and mean %excess weight loss±SD. Statistical analysis was done using SPSS computer program.* ***Results:*** *One patient was excluded from the study because of psychological intolerance (1/25) prompting early balloon removal. Twenty-four patients completed both the initial phase and the follow-up period. At the end of the initial six months, the mean body mass index was 35.7±4.6 kg/m² and mean excess weight loss was 46.9±11.3%. Although 22 out of 24 patients (91.6%) had achieved end of treatment success, the mean body mass index was back to 41.9±7.7 kg/m² at the end of the follow-up period. Only two patients were able to maintain excess weight loss of 25% at the completion of the study, resulting in a long-term success rate of 8.3%.* ***Conclusions:*** *BioEnterics intragastric balloon is a safe and effective but temporary therapeutic modality for obesity treatment. After BioEnterics intragastric balloon removal, almost all patients had returned to their initial weights. Therefore, BioEnterics intragastric balloon must only be offered for patients who accept to undergo bariatric surgery after BioEnterics intragastric balloon removal. Losing weight by BioEnterics intragastric balloon before bariatric surgery will improve the morbidity and mortality rates of this modality.*

Key words: Intragastric balloon, weight loss, bariatric surgery

Giriş ve Amaç: *Morbid obezitenin Bio-Enterics intra-gastrik balon ile tedavisi güvenli ve etkili bir yöntemdir. Fakat, kültürel, sosyal ve ekonomik faktörlerin tedavi yöntemleri üzerindeki etkileri de bilinmektedir. Bio-Enterics intra-gastrik balon tedavisinin Türk hastalardaki uzun süreli sonuçları bilinmemektedir. Bu çalışmada Bio-Enterics intra-gastrik balon yönteminin kilo vermekteki etkinliği ve balonun çıkartılması sonrası uzun dönem sonuçlarının değerlendirilmesi amaçlanmıştır.* ***Yöntem:*** *Bio-Enterics intra-gastrik balon yöntemiyle zayıflamayı seçen ancak cerrahi bir yöntem istemeyen 25 hasta (11 erkek, 14 kadın) çalışmaya alınmıştır. Ortalama yaş 35.2±13.4 yıl, ortalama vücut kitle indeksi 43.5±8.7 kg/m² bulunmuştur. Endoskopik Bio-Enterics intra-gastrik balon tedavisi için kontraindikasyonu olan hastalar çalışmaya dahil edilmediler. Bio-Enterics intra-gastrik balon derin propofol sedasyonu altında endoskopik olarak yerleştirildi. Tüm hastalara günlük 1000 kcal'lik diyet uygulandı. Balonun yerleştirilmesinden altı ay sonra Bio-Enterics intra-gastrik balon çıkartılarak hastalar balonsuz olarak bir altı ay daha izlendiler. Balon çıkartıldığında, fazla kilonun kaybı eğer %25'den yüksek ise bu tedavi sonu başarı olarak kabul edildi. Eğer balonsuz olarak 6 ay izlendikten sonra halen %25'den fazla fazla kilonun kaybı korunuyor ise, bu da uzun dönem başarı olarak kabul edildi.* ***Bulgular:*** *Sadece bir hasta psikososyal intolerans nedeniyle balonu çıkartılarak çalışmadan çıkartıldı (1/25). 24 hasta ise balonlu 6 ayı ve sonrasında balonsuz izlenen diğer bir altı aylık izlemi tamamladılar. Balonla geçirilen 6 ayın sonunda vücut kitle indeksi 35.7±4.6 kg/m²; ve ortalama fazla kilonun kaybı 46.9±11.3% idi. Tedavi sonu başarı 24 hastanın 22'sinde elde edildi (%91.6). Fakat balonsuz geçirilen 6 aylık izlem sonrası vücut kitle indeksi 41.9±7.7 kg/m² ye yükseldi. Sadece 2 hasta fazla kilonun kaybını %25'in üzerinde tutabildi. Yani uzun dönem başarı %8.3 olarak gerçekleşti.* ***Sonuç:*** *Bio-Enterics intra-gastrik balon obezite tedavisinde güvenli ve etkili bir yöntem olmasına rağmen, sağladığı başarı geçici gibi görünmektedir. Bio-Enterics intra-gastrik balonun çıkartılması sonrası neredeyse tüm hastalar başlangıç vücut ağırlıklarına dönmüşlerdir. Bu yüzden Bio-Enterics intra-gastrik balon tedavisi balonun çıkartılması sonrası bir bariatrik cerrahi yöntemini denemeye istekli kişilere önerilmelidir. Bariatrik cerrahi öncesi Bio-Enterics intra-gastrik balon ile kilo kaybı sağlanması cerrahi yöntemlerin mortalite ve morbidete oranlarında iyileşme sağlayacaktır.*

Anahtar kelimeler: İntragastrik balon, kilo kaybı, bariatrik cerrahi

Address for correspondence: Murat SARUÇ
Acıbadem Hastanesi, Gastroenteroloji Bölümü
Halit Ziya Uşaklıgil Cad No: 1
Bakırköy, İstanbul, Turkey
Phone: +90 212 414 50 48
E-mail: msaruc@hotmail.com

Manuscript received: 29.03.2009 **Accepted:** 01.04.2010

doi: 10.4318/tjg.2010.0117

INTRODUCTION

Obesity is a major cause of morbidity and mortality worldwide (1). It is associated with disorders like hypertension, coronary artery disease, diabetes, hypercholesterolemia, osteoarthritis, and fatty liver disease (2). Obesity is mostly due to excessive caloric intake. Recent data has revealed that obesity in Europe is as high as 26-31% of the population (2).

Healthy nutrition and lifestyle changes remain the main modality for successful weight loss. These approaches may be supplemented by medications. Unfortunately, only 5% of the severely obese patients who have initially lost weight will maintain their body weight over years (3, 4).

Bariatric surgery seems to be the only method for long-term management of severely obese patients (5-9). The most common surgical procedure is laparoscopic adjustable gastric band ligation (9). This procedure creates a lower-volume stomach, resulting in reduced food intake. It is an invasive and expensive method for which long-term follow-up (even lifelong) is required (9).

Intragastric balloon placement is an alternative gastric restrictive procedure (1) in which a spherical, saline-filled, silicone balloon is endoscopically placed in the stomach and left inflated for six months. Recent studies from many different countries have shown BioEnterics intragastric balloon (BIB) placement in the treatment of morbid obesity to be safe and effective (1, 10, 11). However, cultural, social and economical factors may have some impact on therapeutic interventions. Duration of its effect on weight loss is not well-known in the Turkish population. This study attempts to evaluate the effectiveness of this method on weight loss and long-term outcome following balloon removal.

MATERIALS AND METHODS

Twenty-five severely obese patients (11 male, 14 female) who selected BIB method for weight loss and who did not desire to undergo surgery due to fear of complications or mortality were included in the study. A team consisting of a gastroenterologist, psychiatrist, endocrinologist, general surgeon, and dietitian evaluated the patients and decided together to accept or refuse the indication for the procedure. Patients were included in the study after they singed an informed consent. Their mean age was 35.2±13.4 years and mean body mass index (BMI) was 43.5±8.7 kg/m^2. Patients were excluded from the study if they had any contraindication for endoscopic BIB placement such as peptic ulcer, large hiatal hernia, previous abdominal surgery, pregnancy, or presence of any psychiatric disorder.

The patients were tested for fasting blood glucose, lipid and aminotransferase levels at the beginning, at the time of balloon removal and six months after balloon removal. We also determined the patients' blood pressure and any respiratory problems before, during and after BIB treatment.

We developed a strict protocol to place BIB according to the patient management guidelines provided by the BIB marketing company (10). We placed BIB by endoscopic approach under deep sedation with propofol. After BIB insertion into the gastric fundus, the balloon was inflated under direct vision with methylene blue-added 700 ml saline (Figure 1). The volume of saline was the same regardless of the individual gastric size. Patients were allowed to go home 2 hours after balloon placement and given oral anti-emetics (metoclopramide 10 mg tds), anti-spasmodic (hyoscine-N-butylbromide 10 mg tds) and proton pump inhibitor (lansoprazole 30 mg daily).

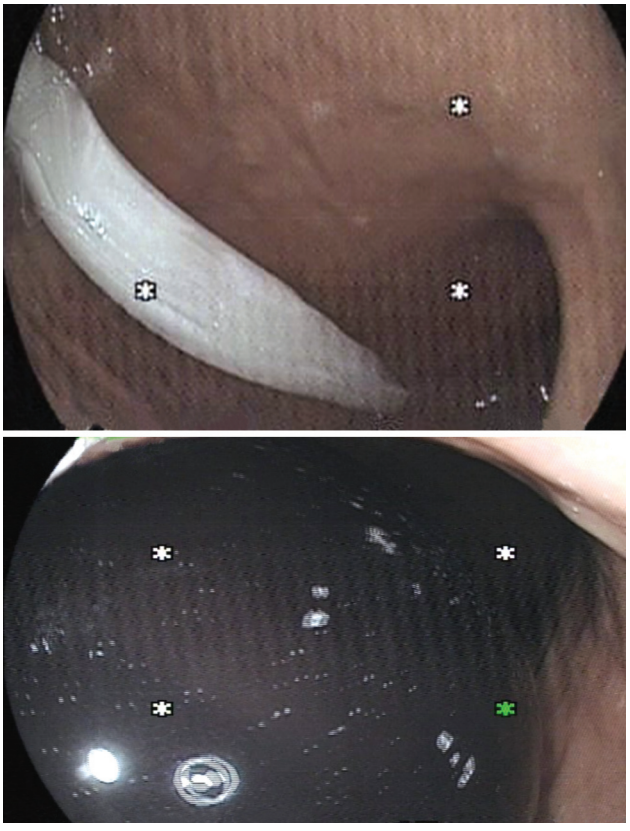

Figure 1. Endoscopic placement and appearance of intragastric balloon.

All patients were given a diet of 1000 kcal/day by a dietician. Six months after BIB placement, we removed the balloon but followed the patient for another six months. Excess weight loss (EWL) greater than 25% when the BIB was removed was considered an end of treatment success (ETS). If patients sustained their EWL greater than 25% at the end of six months without balloon, this was considered as long-term success (LTS). Results were reported as mean BMI and mean %EWL±SD. Statistical analysis was done using the SPSS computer program.

RESULTS

Following insertion of the balloon, almost all patients experienced nausea, cramps and vomiting lasting 3-5 days. After the first week, only two patients complained of abdominal pain. Careful physical examination showed no alarm signs, and repeat endoscopy was not needed. Two months after insertion of the BIB, no patients had any complaints related to the BIB. BIB produced no other notable side effects. In all patients, balloon removal was performed without any difficulty.

Only one patient was excluded from the study because of early balloon removal for psychological intolerance (1/25). Twenty-four patients completed the six-month period with the balloon in place and the additional six months after its removal. There were no complications related to endoscopic balloon placement or removal.

Initial mean BMI was 43.5±8.7 kg/m^2. At the end of six months with balloon, the mean BMI was 35.7±4.6 kg/m^2 and mean EWL was 46.9±11.3%. ETS was reached in 22 of 24 patients (91.6%). Figure 2 shows the changes in BMI during the study period. However, at the end of the six-month follow-up period without balloon, the mean BMI had increased to 41.9±7.7 kg/m^2. Only 2 patients could maintain their 25% EWL at the end of follow-up period, thus resulting in a LTS of only 8.3%.

Improvement in glucose metabolism and liver enzymes was seen in only 16 of 22 patients with ETS. No patients without ETS had any improvement in these parameters. Only the 2 patients with LTS maintained these improvements in liver enzymes and glucose metabolism six months after balloon removal. Figure 3 reveals the changes in metabolic effect of obesity in patients during the study period.

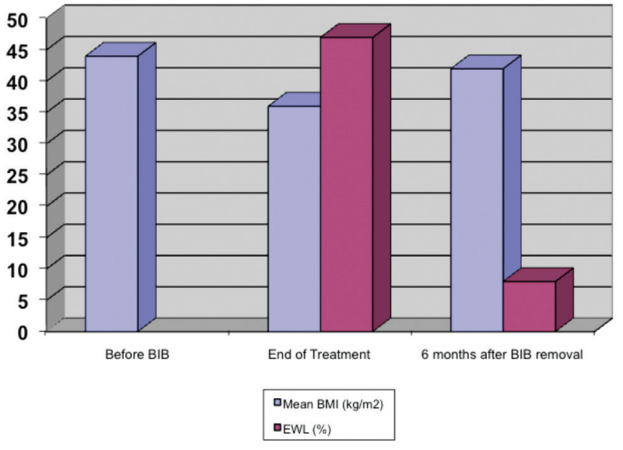

Figure 2. Mean body mass index and percentage of excess weight loss (EWL) during the treatment.

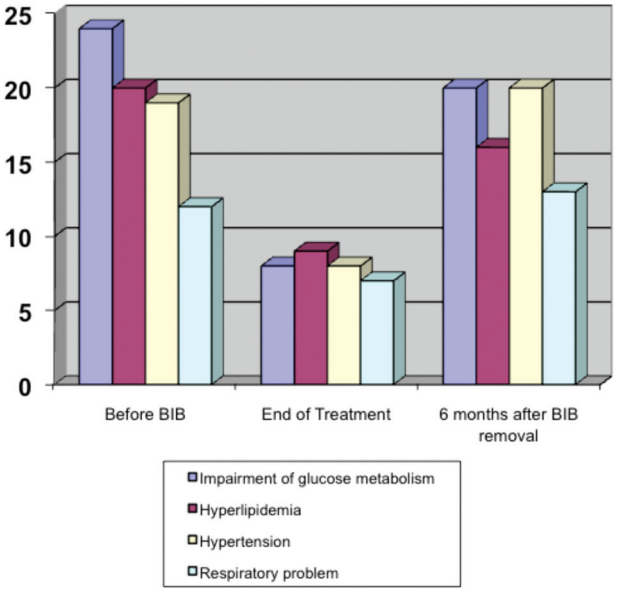

Figure 3. Changes in obesity complications during the treatment.

Most of the weight loss occurred in the first two months (70% of total lost weight). In the third and fourth months, the patients succeeded in losing only 25% of total lost weight. In the last two months (5th and 6th months), almost all patients ceased to lose weight, and some patients regained some of the weight initially lost.

We found no correlation between the amount of weight lost and the patient's age. There was also no statistical correlation between the age and gender of the patients and LTS.

DISCUSSION

The use of intragastric balloons to promote weight loss was first reported in the 1980s (11-13). Seve-

ral balloon types were tried but early and late results were poor (1, 14, 15). In the early years, balloon treatment often produced complications (16, 17). The most recently introduced BIB uses saline for inflation. BIB has a spherical shape and high volume (400-700 ml) (17, 18). BIB has been shown to have very low complication rates, despite its extensive clinical use (19-21). The experiences did not reveal very good long-term results; in fact, there are only a few studies that have investigated the long-term success rates (22).

In a metaanalysis from Spain, the authors reviewed the literature systematically and pooled 15 articles and 3,608 patients to estimate the effectiveness and safety of BIBs (22). They concluded that use of the BIB, within a multidisciplinary weight management program, is a short-term effective treatment for losing weight, but it is not yet possible to verify its capacity to maintain the weight loss over a long period of time (22).

The goal of our pilot study was to determine the long-term effectiveness and safety of BIB in obese Turkish patients. Our data showed that the short-term effect is quite good but the long- term results were unacceptable and disappointing. Although intestinal obstruction, balloon migration, balloon rupture, peptic ulceration, aspiration, gastric rupture, and esophagitis were all reported in the literature as complications of BIB (1, 22-24), we did not experience any complication in our series.

Nevertheless, our results revealed that the outcome of BIB was not very effective. BIB was shown to be a safe but not very effective modality in our small-sized, single-center pilot study. Following our evaluation of the results of this study, our center no longer advocates the use of BIB as a long-term weight loss tool in the treatment of morbid obesity. If severely obese patients meet the criteria for bariatric surgery, we advise them to undergo surgery rather than BIB. The results of our study completely changed our institution's approach to endoscopic treatment of obesity. If a patient insists on the BIB option, then our obesity team moderates the patient's expectations and emphasizes that use of BIB will also require a great motivation and lifestyle change to achieve long-term weight loss. We only insert a BIB if the patient understands and accepts the data of this study. Another indication for BIB is to obtain initial weight reduction in the super-obese patient just before bariatric surgery, which was reported by several authors previously (1,25). This weight loss will be adequate to shrink the fatty liver and reduce intraperitoneal fat to facilitate surgery and decrease the morbidity and mortality.

BioEnterics intragastric balloon (BIB) is a safe and effective but temporary therapeutic modality for the treatment of obesity. After BIB removal, almost all patients returned to their initial weights. Therefore, BIB must be offered for patients who accept to undergo bariatric surgery after BIB removal. Losing weight by BIB before bariatric surgery will improve the morbidity and mortality rates of surgery.

REFERENCES

1. Ganesh R, Rao AD, Baladas HG, Leese T. The Bioenteric Intragastric Balloon (BIB) as a treatment for obesity: poor results in Asian patients. Singapore Med J 2007; 48: 227-31.
2. Wilborn C, Beckham J, Campbell B, et al. Obesity: prevalence, theories, medical consequences, management, and research directions. J Int Soc Sports Nutr 2005; 2: 4-31.
3. Deurenberg P, Yap M. The assessment of obesity: methods for measuring body fat and global prevalence of obesity. Baillieres Best Pract Res Clin Endocrinol Metab 1999; 13: 1-11.
4. Weisell RC. Body mass index as an indicator of obesity. Asia Pac J Clin Nutr 2002; 11 (Suppl 8): 681-4.
5. O'Brien PE, Brown W, Smith A, McMurrick PJ, Stephens M. Prospective study of a laparoscopically placed, adjustable gastric band in the treatment of morbid obesity. Br J Surg 2007; 86: 113-8.
6. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta analysis. JAMA 2004; 292: 1724-37.
7. Biertho L, Steffen R, Ricklin T, et al. Laparoscopic gastric bypass versus laparoscopic adjustable gastric banding: a comparative study of 1,200 cases. J Am Coll Surg 2003; 197: 536-46.
8. Clegg AJ, Colquitt J, Sidu MK, et al. The clinical effectiveness and cost-effectiveness of surgery for people with morbid obesity: a systematic review and economic evaluation. Health Technol Assess 2002; 6: 1-153.
9. Chapman A. Systematic review of laparoscopic gastric banding for the treatment of severe obesity: update and reappraisal. ASERNIP-S report 31. 2nd ed. Adelaide: A SERNIP-S, 2002.
10. Patient Management BIB Program. Practice Builder Program supplied by Inamed Health, Santa Barbara, California.
11. Nieben OG, Harboe H. Intragastric balloon as an artificial bezoar for treatment of obesity. Lancet 1982; 1: 198-9.
12. McFarland RJ, Grundy A, Gazet JC, Pilkington TRE. The intragastric balloon: a novel idea proved ineffective. Br J Surg 1987; 74: 137-9.

13. Schapiro M, Benjamin S, Blackburn G, et al. Obesity and the gastric balloon: a comprehensive workshop. Tarpon Springs, Florida, March 19-21, 1987. Gastrointest Endoscop 1987; 33: 323-7.
14. Benjamin SB, Maher KA, Cattau EL Jr, et al. Double-blind controlled trial of the Garren-Edwards gastric bubble: an adjunctive treatment for exogenous obesity. Gastroenterology 1988; 95: 581-8.
15. Mathus-Vliegen EMH, Tytgat GNJ. Intragastric balloons for morbid obesity: results, patient tolerance and balloon life span. Br J Surg 1990; 77: 76-9.
16. Hogan RB, Johnston JH, Long BW, et al. A double-blind, randomized, sham-controlled trial of the gastric bubble for obesity. Gastrointest Endosc 1989; 35: 381-5.
17. Meshkinpour H, Hsu D, Farivar S. Effect of gastric bubble as a weight reduction device: a controlled crossover study. Gastroenterology 1988; 95: 589-92.
18. De Waele B, Reynaert H, Urbain D, Willems G. Intragastric balloons for preoperative weight reduction. Obes Surg 2000; 10: 58-60.
19. Totte E, Henrickx L, Pauwels M, Van Hee R. Weight reduction by means of intragastric device: experience with the bioenterics intragastric balloon. Obes Surg 2001; 11: 519-23.
20. Al-Momen A, El-Mogy I. Intragastric balloon for obesity: a retrospective evaluation of tolerance and efficacy. Obes Surg 2005; 15: 101-5.
21. Sallet JA, Marchesini JB, Pavia DS, et al. Brazilian multicenter study of the intragastric balloon. Obes Surg 2004; 14: 991-8.
22. Imaz I, Martinez-Cervell C, Garcia-Alvarez EE, et al. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg 2008; 18: 841-6.
23. Sallet JF. The intragastric balloon. Endoscopic gastroplasty for the treatment of obesity. Americana, SP; Caminho Editorial, 2002.
24. Doldi SB, Micheletto G, Perrini MN, et al. Treatment of morbid obesity with intragastric balloon in association with diet. Obes Surg 2002; 12: 583-7.
25. Genco A, Cipriano M, Bacci V, et al. Bioenterics intragastric balloon (BIB): a short-term double-blind, randomized, controlled, crossover study on weight reduction in morbidity obese patients. Int J Obes (Lond) 2006; 30: 129-33.