



## Comparison of the 15-Day, 30-Day and 90-Day Outcomes of 61 Patients who Underwent Intra-gastric Balloon due to Obesity by Gender

Obezite Nedeniyle İntragastrik Balon Uygulanan 61 Hastanın 15 Günlük, 30 Günlük ve 90 Günlük Sonuçlarının Cinsiyete Göre Karşılaştırılması

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### ABSTRACT

**Aim:** To compare the 15-day, 30-day and 90-day outcomes of 61 patients who underwent intra-gastric balloons (IGBs) due to obesity by gender.

**Gereç ve Yöntem:** This retrospective study was conducted on patients who underwent IGB between January 2020 and May 2022. Patients under 18 and patients who were followed up in our clinic after balloon insertion were excluded from the study. The post-procedural outcomes and weight losses were compared with appropriate statistical tests between the gender groups.

**Results:** The mean age of the 61 patients included in the study was  $31.09 \pm 8.38$  years (18-55), and 49 (80.3%) of all patients were women. The patients' mean body mass index (BMI) was  $32.22 \text{ kg/m}^2$ , the highest BMI was  $39.45 \text{ kg/m}^2$ , and the lowest was  $28.23 \text{ kg/m}^2$  before the IGB procedure. The mean per cent weight loss on day 15, day 30, and day 90 was 5.9%, 10.23%, and 14.88%, respectively. Post-procedural complications were seen in 42 (68.9%) patients. The most common complications were nausea (41%) and abdominal pain (32.8%). Only three of 61 patients required hospitalisation after the procedure. In male patients, the rate of comorbid disease before IGB ( $p=0.048$ ), mean height ( $p<0.001$ ), the mean rank of weight ( $p<0.001$ ), the mean rank of BMI ( $p=0.002$ ), and the amount of weight lost (in kilograms) in all three follow-up periods were higher. In the post-procedure follow-ups, the weight-loss rates at the 15<sup>th</sup>, 30<sup>th</sup> and 90<sup>th</sup> days were similar in both genders. In addition, all post-procedure complications were similar in both genders.

**Conclusion:** The amount of weight loss in male patients was higher in male patients, and the rate of weight loss was similar in both genders. Due to identical complication rates, IGB is a method that can be used safely by both genders in the fight against obesity.

**Keywords:** Gastric balloon, gender, weight loss

### ÖZ

**Amaç:** Obezite nedeniyle intragastrik balon (İGB) uygulanan 61 hastanın 15 günlük, 30 günlük ve 90 günlük sonuçlarını cinsiyete göre karşılaştırmak.

**Gereç ve Yöntem:** Bu retrospektif çalışma Ocak 2020-Mayıs 2022 tarihleri arasında İGB yapılan hastalarda yapılmıştır. 18 yaş altı ve balon takıldıktan sonra kliniğimizde takip edilen hastalar çalışma dışı bırakıldı. İşlem sonrası sonuçlar ve kilo kayıpları, cinsiyet grupları arasında uygun istatistiksel testlerle karşılaştırıldı.

**Bulgular:** Çalışmaya alınan 61 hastanın yaş ortalaması  $31.09 \pm 8.38$  (18-55) yıl olup, tüm hastaların 49'u (%80,3) kadındı. Hastaların İGB işlemi öncesi ortalama vücut kitle indeksi (VKİ)  $32,22 \text{ kg/m}^2$ , en yüksek VKİ  $39,45 \text{ kg/m}^2$  ve en düşük  $28,23 \text{ kg/m}^2$  idi. 15. günde, 30. günde ve 90. günde ortalama kilo kaybı yüzdesi sırasıyla %5,9, %10,23 ve %14,88 idi. 42 (%68,9) hastada işlem sonrası komplikasyon görüldü. En sık görülen komplikasyonlar bulantı (%41) ve karın ağrısı (%32,8) idi. İşlem sonrası 61 hastadan sadece üçünün hastaneye yatırılması gerekti. Erkek hastalarda İGB öncesi komorbid hastalık oranı ( $p=0,048$ ), boy ortalaması ( $p<0,001$ ), ortalama ağırlık sırası ( $p<0,001$ ), ortalama VKİ sıralaması ( $p=0,002$ ) ve her üç takip döneminde kaybedilen kilo miktarı (kilogram cinsinden) daha yüksekti. İşlem sonrası takiplerde 15., 30. ve 90. günlerdeki kilo verme oranları her iki cinsiyette de benzerdi. Ek olarak, tüm işlem sonrası komplikasyonlar her iki cinsiyette de benzerdi.

**Sonuç:** Erkek hastalarda kilo verme miktarı erkek hastalarda daha fazlaydı ve kilo verme oranı her iki cinsiyette de benzerdi. İGB, aynı komplikasyon oranları nedeniyle obezite ile mücadelede her iki cinsiyet tarafından da güvenle kullanılabilir bir yöntemdir.

**Anahtar Kelimeler:** Mide balonu, cinsiyet, kilo kaybı

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## INTRODUCTION

Obesity is a multifactorial and complex disease that occurs due to the interaction of genetic and environmental factors. Although our knowledge about the formation of obesity is not complete yet, it is understood that social, behavioural, cultural, psychological, metabolic and genetic factors play important roles (1,2). The World Health Organization (WHO) closely monitors the changes in the prevalence of overweight and obesity over the years and tries to take measures to protect public health (3). According to the 2015 data by WHO, it is estimated that approximately 39% of the world's population is overweight and obese (4). Obesity is now accepted as a global pandemic, and medical and surgical treatment efforts are being made to reduce its prevalence.

Obesity is a disease that must be treated because of the various health problems it causes (5). The treatment aims to reduce the morbidity and mortality risks by targeting a realistic body weight loss, to make the individual gain adequate and balanced nutrition habits and regular physical activity habits, and to increase the quality of life (6). Nutrition therapy, exercise and behaviour modification therapy are the first steps of the obese individual's treatment program (5). Pharmacological and interventional treatments should be tried in cases that do not benefit first-line treatment. The intragastric balloon (IGB) is one of the interventional treatments used to treat obesity and has become popular. Weight loss results after IGB are promising (7).

This study aimed to compare the 15-day, 30-day and 90-day outcomes of 61 patients who underwent IGBs due to obesity by gender.

## MATERIAL AND METHOD

This retrospective study was conducted after ethical approval (KA EK 2022/07-80). Patients who performed IGBs between January 2020 and May 2022 were included in the study. Patients under 18 and patients who were followed up in our clinic after balloon insertion were excluded from the study.

### The IGB Implantation Process

All patients underwent a routine clinical examination before the IGB procedure. The weight and height of the patients were measured with light clothing and no shoes.

Before obtaining informed written consent, patients have explained the procedures' risks, benefits, and alternatives. During the procedure, the patient was connected to monitoring devices at the left lateral position. The device was implanted under sedation and

analgesia. Intravenous medications were administered through an indwelling cannula. Oxygen was provided continuously through a nasal cannula. Bari Globe® IGB was placed in the stomach through endoscopy. All balloons were filled with methylene blue with a maximal volume of 500 mL.

### Searched Parameters

Demographic data (age, gender), weight and height of the patients were collected. All patients' body mass indexes (BMIs) were calculated before the balloon procedure. BMI was calculated by dividing the patient's weight (kg) by the square of the height in meters. Weight measurement and BMI calculation were repeated on the 15<sup>th</sup>, 30<sup>th</sup> and 90<sup>th</sup> days after the balloon. Changes in weight and BMI between measurement periods were also evaluated. It is aimed to compare the 15-day, 30-day and 90-day outcomes of 61 patients who underwent IGBs due to obesity by gender.

### Statistical Analysis

Statistical analyses were performed using the IBM Statistical Analyses for Social Sciences (SPSS) ver. 23.0 for Windows. Quantitative variables were expressed as mean  $\pm$  standard deviation (SD), median, minimum-maximum, interquartile range and interval. Qualitative variables were reported as numbers and percentages. Kolmogorov Smirnov and Shapiro Wilk tests were used to evaluating the normality distribution. Due to normality test results, the Mann-Whitney U test and independent-sample t-test were used to compare groups. A Fisher's exact test was used to compare qualitative variables. A p-value below 0.05 was considered statistically significant.

## RESULTS

The mean age of the 61 patients included in the study was  $31.09 \pm 8.38$  (18-55), and 49 (80.3%) of all patients were women. The mean BMI of the patients was 32.22, the highest BMI was 39.45, and the lowest was 28.23 before the IGB procedure. The mean per cent weight loss on day 15, day 30, and day 90 was 5.9%, 10.23%, and 14.88%, respectively. Clinical parameters and follow-up outcomes of the patients are shown in **Table 1**.

Post-procedural complications were seen in 42 (68.9%) patients. The most common complications were nausea (41%) and abdominal pain (32.8%). Only three of 61 patients required hospitalisation after the procedure. While 2 of 3 hospitalised patients were hospitalised due to acute pancreatitis, the remaining patient was hospitalised due to severe nausea and vomiting. All hospitalised patients were discharged without complications.

**Table 1. Clinical parameters and follow-up outcomes of the patients**

Parameters	N (%) or value
Pre-procedural	
Age	31.09±8.38 (18-55)
Gender	
Female	49 (80.3)
Male	12 (19.7)
Additional disease	
Yes	5 (8.2)
No	56 (91.8)
Weight (kg)	88.88±13.67 (72-134)
Height (meter)	1.65±0.81 (1.50-1.89)
BMI	32.22±2.65 (28.23-39.45)
Post-procedural	
15-day outcomes	
Weight	83.57±12.56 (67-126)
BMI	30.31±2.44 (26.72-36.93)
Weight loss (%)	5.90±1.61 (2.60-8.89)
30-day outcomes	
Weight	79.75±12.25 (60-121)
BMI	28.91±2.35 (25.22-35.35)
Weight loss (%)	10.23±2.18 (5.19-15.28)
90-day outcomes	
Weight	75.47±10.90 (60-113)
BMI	27.38±2.05 (23.88-32.51)
Weight loss (%)	14.88±4.27 (5.13-25.60)
Complications	
Nausea	
Yes	24 (41)
No	36 (59)
Vomiting	
Yes	13 (21.3)
No	48 (78.7)
Abdominal pain	
Yes	20 (32.8)
No	41 (67.2)
Acute pancreatitis	
Yes	2 (3.3)
No	59 (96.7)

### Comparison of Clinical Parameters and Follow-up Outcomes by Gender

Age distribution was similar in both genders. However, in male patients, the rate of another disease before IGB ( $p=0.048$ ), mean height ( $p<0.001$ ), the mean rank of weight ( $p<0.001$ ), the mean rank of BMI ( $p=0.002$ ), and the amount of weight lost (in kilograms) in all three follow-up periods were higher. In the post-procedure follow-ups, the weight-loss rates at the 15<sup>th</sup>, 30<sup>th</sup> and 90<sup>th</sup> days were similar in both genders. In addition, all post-procedure complications were similar in both genders. A comparison of clinical parameters and follow-up outcomes by gender is shown in **Table 2**.

**Table 2. Comparison of clinical parameters and follow-up outcomes by gender.**

Parameters	Female (N=49)	Male (N=12)	P-value
Pre-procedural			
Age (mean rank)	29.45	37.33	0.167*
Additional disease			
Yes	2 (4.1)	3 (25)	
No	47 (95.9)	9 (75)	0.048**
Weight (mean rank)	25.51	53.42	<0.001*
Height (mean±sd)	1.62±0.06	1.77±0.05	<0.001***
BMI (mean rank)	27.47	45.42	0.002*
Post-procedural			
15-day outcomes			
Weight loss (mean rank)	27.73	44.33	0.003*
Weight loss (%) (mean±sd)	5.85±1.69	6.11±1.28	0.629***
30-day outcomes			
Weight loss (mean±sd)	8.67±2.25	11.00±2.44	0.003***
Weight loss (%) (mean±sd)	10.27±2.26	10.09±1.93	0.809***
90-day outcomes			
Weight loss (mean rank)	28.27	42.17	0.015*
Weight loss (%) (mean±sd)	14.73±4.04	15.47±5.28	0.594***
Complications			
Nausea			
Yes	21 (42.9)	4 (33.3)	
No	28 (57.1)	8 (66.7)	0.745**
Vomiting			
Yes	12 (24.5)	1 (8.3)	
No	37 (75.5)	11 (91.7)	0.432**
Abdominal pain			
Yes	19 (38.8)	1 (8.3)	
No	30 (61.2)	11 (91.7)	0.083**
Acute pancreatitis			
Yes	2 (4.1)	0 (0)	
No	47 (95.9)	12 (100)	1.000**

\*Mann Whitney U test, \*\*Fisher's exact test, \*\*\*Independent samples t-test.

## DISCUSSION

World Health Organization defines obesity as an "abnormal or excessive fat accumulation in adipose tissue to the extent that health may be impaired". The global prevalence of obesity is higher in women than men on all continents, in both developed and developing countries (9). This study compared the weight loss process by gender. Before the procedure, in men, the presence of any comorbid diseases, mean height, the mean rank of weight, and the mean rank of BMI were higher. In addition, the amount of weight lost (in kilograms) in all three follow-up periods was higher in males. In the post-procedure follow-ups, only the 30<sup>th</sup>-day weight loss rate was higher in females, while the weight-loss rates at the 15<sup>th</sup> and 90<sup>th</sup> days were similar in both genders. In addition, all post-procedure complications were similar in both genders. This study is the first to compare the early period weight loss process according to gender.



The IGB has been used as an artificial object to induce satiety by decreasing the capacity of the gastric reservoir; the main part of weight loss with the IGB occurs in the first few months. Machytka et al. showed that after six weeks of IGB, the mean weight loss was 2.4 kg, and the mean per cent excess weight loss (%) was 12.4 % (10). The study by Dogan et al. showed that weight loss after balloon procedure in the first month was between 0 and 28 kg with a mean of  $7\pm 5.7$  kilograms and a mean of body weight loss (%) of  $5.2\pm 3.2$  (0–12). The same study also found that five per cent of body weight loss after one month of treatment may predict long-term weight maintenance (11). In our study, weight loss (%) in the first month was  $12.63\pm 1.72$  (8.21 to 15.28). In addition, weight loss in kilograms was higher in men. However, mean weight losses (%) were similar between the gender groups.

According to data obtained from previous studies, the mean % excess weight loss was around 40% (12). In a study with ten patients, the pre-procedural BMI of the patients was  $40.2\text{kg/m}^2$  (36.5–48.7), and the mean third-month BMI was  $37.4\text{kg/m}^2$  (33–45) (13). In another study with 112 patients, the weight loss in the third month after the IGB was  $10.1\pm 6.8$  kilograms, and the mean total weight loss (%) was 10.7%. In the same study, total body weight loss in women was higher than in men ( $14.4\pm 5.0$  vs  $13.8\pm 5.2$ ) (14). In the study of Mion et al., median weight loss in kilogram on the third-month insertion of an IGB was 5.0 (0–12), and median excess weight loss (%) was 36.2 (range 0 to 118) (15). In this study, weight loss (%) in the third month was  $14.88\pm 4.27$  (range from 5.13 to 25.60); in men, weight loss in kilograms was higher. However, there was no difference in the percentage of both sexes.

The most common complications following IGB administration are nausea, vomiting and abdominal pain. Vomiting can be controlled with discontinuation of oral intake, intravenous fluid administration, methochlorpropamide or ondansetron treatments and usually disappears within a few days (16). However, there may be vomiting unresponsive to treatment and may require removal of the balloon. It can lead to dehydration and electrolyte imbalance. Other reported complications include esophagitis, GER, peptic ulcer, gastrointestinal bleeding, acute pancreatitis, oesophageal perforation, acute gastric dilatation, gastric perforation, and death due to aspiration (17). The most common complications of the present study were nausea and abdominal pain. Only three patients required hospitalisation, 2 of them due to acute pancreatitis and the remaining due to severe nausea and vomiting.

## CONCLUSION

Obesity is a multifactorial and complex disease, and IGB is one of the treatment methods in treating this disease. While the amount of weight loss in male patients was higher in male patients, the rate of weight loss was similar in both genders. Due to identical complication rates, IGB is a method that can be used safely by both genders in the fight against obesity.

## ETHICAL DECLARATIONS

**Ethics Committee Approval:** The study was carried out with the permission of Çanakkale Onsekiz Mart University Ethics Committee (Decision No: KA EK 2022/07-80).

**Informed Consent:** All patients signed the free and informed consent form.

**Referee Evaluation Process:** Externally peer-reviewed.

**Conflict of Interest Statement:** The authors have no conflicts of interest to declare.

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## REFERENCES

1. Tunçbilek E. Obesite genetik bir hastalık mıdır. Çocuk Sağlığı ve Hastalıkları Derg 2005;48(1):101-8.
2. Çolak B. Morbid obesity surgery and complications. Selcuk Med J 2015;32(1):19-22.
3. Nittari G, Scuri S, Petrelli F, Pirillo I, Di Luca N, Grappasonni I. Fighting obesity in children from European world health organization member states. Epidemiological data, medical social aspects, and prevention programs. La Clinica Terapeutica 2019;170(3):e223-e30.
4. Chooi YC, Ding C, Magkos F. The epidemiology of obesity. Metabolism 2019;92:6-10.
5. Güler Y, Gönener HD, Altay B, Gönener A. Adölesanlarda obezite ve hemşirelik bakımı. Fırat Sağlık Hizmetleri Derg 2009;4(10):165-81.
6. Kumsar U, Yılmaz U, Olgun N. Obezitede Güncel Yaklaşımlar. Diyabet, Obezite ve Hipertansiyonda Hemfiliyetlik Forumu Derg 2011;3(1):21-9.
7. Sullivan S, Swain J, Woodman G, et al. Randomized sham-controlled trial of the 6-month swallowable gas-filled intra-gastric balloon system for weight loss. Surg Obes Related Dis 2018;14(12):1876-89.
8. Collaborators GO. Health effects of overweight and obesity in 195 countries over 25 years. N Engl J Med 2017;377(1):13-27.
9. Mauvais-Jarvis F. Sex differences in metabolic homeostasis, diabetes, and obesity. Biol Sex Differ 2015;6(1):1-9.
10. Machytka E, Chuttani R, Bojkova M, et al. Elipse™, a procedureless gastric balloon for weight loss: a proof-of-concept pilot study. Obes Surg 2016;26(3):512-6.
11. Dogan UB, Gumurdulu Y, Akin MS, Yalaki S. Five percent weight lost in the first month of intra-gastric balloon treatment may be a predictor for long-term weight maintenance. Obes Surg 2013;23(7):892-6.

12. Mion F, Gincul R, Roman S, et al. Tolerance and efficacy of an air-filled balloon in non-morbidly obese patients: results of a prospective multicenter study. *Obes Surg* 2007;17(6):764-9.
13. Erken U. Obezite Tedavisinde Bionterics Intragastrik Balon. *End Lap ve Minimal Invaziv Cerrahi* 2003;10(3):139-45.
14. Jamal MH, Almutairi R, Elabd R, AlSabah SK, Alqattan H, Altaweel T. The safety and efficacy of procedureless gastric balloon: a study examining the effect of ellipse intragastric balloon safety, short and medium term effects on weight loss with 1-year follow-up post-removal. *Obes Surg* 2019;29(4):1236-41.
15. Mion F, Ibrahim M, Marjoux S, et al. Swallowable Obalon® gastric balloons as an aid for weight loss: a pilot feasibility study. *Obes Surg* 2013;23(5):730-3.
16. Serhat B, Turan İ, Özütemiz Ö. Morbid obezite tedavisinde intragastrik balon uygulaması sırasında meydana gelen balon rüptürü vakası. *Akademik Gastroenteroloji Derg* 2007;6(2):94-6.
17. Nijhof H, Steenvoorde P, Tollenaar R. Perforation of the esophagus caused by the insertion of an intragastric balloon for the treatment of obesity. *Obes Surg* 2006;16(5):667-70.