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Results of Adjustable Intragastric Balloon Use According to Body Mass Index Values

Vücut Kitle İndeksi Değerlerine Göre Ayarlanabilir İntragastrik Balon Kullanım Sonuçları

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Abstract

Aim: In our study, it was aimed to compare the results of the adjustable intragastric balloon (AIGB) in patients according to body mass index (BMI).

Material and Method: We recorded the data of 82 patients that we performed the AIGB procedure in the last four years retrospectively. During the initial implantation of the balloon, inflating was performed with 300-350 cc saline and methylene blue. BMI and excess weight loss ratios (EWL) of the patients and at the time of the balloon removal were noted. Patients' complaints and complications arising after balloon application or additional inflation were reported.

Results: It was determined that there was a statistically significant decrease between weight, BMI, and EWL values measured at the 4th, 8th, and 12th months after the first application was performed (p <0.001). The weight and EWL values were evaluated in two groups as morbidly obese (BMI ≥40) and patients with BMI <40.İt was determined that there was a statistically significant decrease in weight and EWL values in both groups depending on time (p <0.001), in further analysis, the difference between the 8th and 12th months for EWL values was not statistically significant (p>0.05) in morbidly obese patients (BMI≥40), all other differences were statistically significant (p<0.001).

Conclusion: AIGB treatment has satisfactory results in morbidly obese patients. AIGB can be preferred as an alternative method to bariatric surgery in patients where bariatric surgery may be high risk due to comorbidities and in cases where patients do not prefer bariatric surgery.

Keywords: Obesity, intragastric balloon, weight loss

Öz

Amaç: Çalışmamızda hastalarda ayarlanabilir intragastrik balonun sonuçlarının (AIGB) vücut kitle indeksine (VKI) göre karşılaştırılması amaçlandı.

Gereç ve Yöntem: Son dört yılda AIGB uygulaması yaptığımız 82 hastanın verilerini retrospektif olarak incelendi. Balonun ilk implantasyonu sırasında 300-350 cc salin ve metilen mavisi ile şişirme yapıldı. Hastaların ve balonun çıkarıldığı anki VKİ ve kilo verme oranları (EWL) not edildi. Hastaların balon uygulaması veya ek şişirme sonrası oluşan şikayetleri ve komplikasyonları kaydedildi.

Bulgular: VKİ ve EWL değerleri arasında ilk uygulama yapıldıktan sonra 4., 8. ve 12. aylarda ölçülen kilolarla istatistiksel olarak anlamlı azalma olduğu belirlendi (p<0,001). Ağırlık ve EWL değerleri morbid obez (VKİ ≥40) ve VKİ <40 olan hastalar olmak üzere iki grupta değerlendirildi. Her iki grupta da zamana bağlı olarak ağırlık ve EWL değerlerinde istatistiksel olarak anlamlı azalma olduğu belirlendi (p<0,001). İleri analizde, morbid obez hastalarda (BMI≥40) EWL değerleri için 8. ve 12. aylar arasındaki fark istatistiksel olarak anlamlı değildi (p>0.05), diğer tüm farklılıklar istatistiksel olarak anlamlıydı (p<0.001).

Sonuç: AIGB tedavisi morbid obez hastalarda tatmin edici sonuçlara sahiptir. Bariatrik cerrahinin ek hastalıklar nedeniyle yüksek riskli olabileceği hastalarda ve hastaların bariatrik cerrahiyi tercih etmediği durumlarda, AIGB obezite cerrahisine alternatif bir yöntem olarak tercih edilebilir.

Anahtar Kelimeler: Obezite, intragastrik balon, kilo kaybı

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INTRODUCTİON

Despite all the precautions taken, obesity is a rapidly increasing health problem worldwide. Metabolic disorders caused by obesity affect the whole body and lead to many chronic diseases. Current treatments accompanied by diet and sports in the struggle against obesity include medical therapy, endoscopic methods, bariatric surgery, acupuncture, and psychiatric behavior therapy. Bariatric surgery procedures are the treatments that have the fastest effect and in which the maintenance of weight control is possible for a long time.[1,2]

Endoscopic bariatric treatment methods, which may be an alternative to bariatric surgery procedures and have become very popular in recent decades, seem to be preferred more because of their low-risk rates. Endoscopic interventions include intragastric balloons and botulinum toxin applications performed in the last decade.[3-5] There are also opinions that the adjustable intragastric balloons (AIGB) are more useful and efficient than the other types of intragastric balloons.[6]

An important feature of AIGB application is that it can be applied endoscopically under mild sedation. Intragastric balloons allow patients to reduce their food intake by creating a feeling of fullness in their stomachs. It is assumed that intragastric balloons provide peripheral saturation by preventing food intake, reducing intragastric volume, and delaying gastric emptying.[7] In this study, we will present the results of patients who underwent intragastric balloon administration.

MATERIAL AND METHOD

The recorded data in the files of 82 patients who underwent AIGB in XXXXXXX General Surgery Clinic between 2016-2020 were collected and analyzed. Ethics committee approval was obtained from Keçiören Training and Research Hospital Clinical Research Ethics Committee (2012-KAEK-15/1596) for our retrospective study. Our study was carried out in accordance with the principles of the Declaration of Helsinki.

82 patients over the age of 18 who applied to the general surgery clinic for gastric balloon treatment for obesity between January 2016 and January 2020 were included in the study. Inclusion criteria were: Morbid obesity (Body mass index (BMI) >40), patients preparing for bariatric surgery to decrease surgical risk, BMI 35-40 and with obesity-related diseases; BMI 35 and who have failed many attempts to lose weight with psychological indications in a multidisciplinary treatment program. The existence of an organic disease of the upper digestive tract, Crohn's disease, anti-inflammatory medicines, anticoagulants, or steroids, drunkenness, or drug addiction were all considered exclusion factors. A hiatus hernia with a diameter of more than 5 cm was recognized as an exclusion criterion.

An adjustable balloon system (Spatz Medical, Great Neck, NY, USA) was administered to the patients. All procedures were performed under sedation by intravenous propofol administration by an anesthesiologist under operating room conditions.

The esophagus and stomach of the patients were examined endoscopically before the implantation of AIGB for the first time. The procedure was terminated in patients with esophagitis, gastritis, or peptic ulcer, and three months after the necessary medical treatments were applied, AIGD was implanted in patients without any pathology. AIGB application was abandoned for two patients who were not included in the study and whose gastritis condition continued after medical treatment.

In patients who underwent AIGB application for the first time, Spatz balloon was first implanted in the stomach fundus with the help of an endoscope. Subsequently, the balloon was inflated with the previously prepared 300-350 cc S.F. + Methylene Blue (MB). The first procedure was completed after no leak or pathology was observed. A second 150 cc or 120 cc SF+MB administration was performed for 19 patients. Thirteen patients were administered 100 cc SF+MB for the third time.

The BMI and excess weight loss ratios (EWL) of the patients during the balloon implantation were recorded. BMI, weight losses, EWL ratios during the second, and if applied, the third procedure and during balloon removal were also recorded. Complaints and complications of patients after balloon implantation or additional inflation were reported. Comorbid disease states, medications used by patients, changes in these conditions were noted. The patients were divided into two groups; morbidly obese group of BMI≥ 40 kg/m^2 and BMI <40 kg/m^2 overweight-obese group which consisted of moderately obese, slightly obese, overweight.

Statistical analysis

Continuous variables, mean±standard deviation, and categorical data were expressed as numbers and percentages. Normality analyses were performed with the Shapiro-Wilk normality test in the intergroup analysis of continuous variables. Repeated Measures ANOVA Test was used to analyze the time-dependent changes of the variables that are suitable for normal distribution. Bonferroni was used as the post-hoc test after the ANOVA test, as the variances were homogeneously distributed. Further analyzes of the dependent groups were performed with the Paired Samples T-test. Based on the difference in the postoperative percent of excess weight loss rates between the groups, a power analysis was performed considering a 5% alpha error, 80% power, and a bilateral hypothesis. Adequate sample size was determined as 27 patients per group. Actual power was 0.812, while effect size d was 1.4372. Analyzes were performed with IBM SPSS Package Program version 24.0 (IBM Corporation, Armonk, NY, USA). P values of <0.05 were considered as statistically significant.

RESULTS

Intragastric balloon implantation was performed in all 82 patients included in the study. The mean age of the patients was 50.86±13.48 years, 68.2% were women, their mean weight was 117.6±27.5 kg, and the mean BMI values were 42.9±10.4 kg/m2. It was determined that there was a statistically significant decrease between weight, BMI, and EWL values measured at the 4th, 8th, and 12th months after the first application was performed (p <0.001). When examining the EWL percentage averages in detail; after the intragastric balloon application, it was found that a decrease of 28±14.2% in EWL percent averages occurred in the first four months, whereas the values between 4 and 8 months had a decrease of 15%±11.8, and between the 8th and 12th months the decrease was only 6%±8.6 (p <0.001). A total change of 51.3%±30.1 in EWL was found between the pre-procedure period and the 12-month post-balloon application. In further analysis, the difference between the 8th and 12th months between weight and BMI values was found to be not statistically significant (p> 0.05), and all other differences were significant (p <0.001) (**Table 1**).

When weight and EWL values were evaluated in two groups as morbidly obese (BMI ≥ 40) and overweight-obese patients (BMI <40); although it was determined that there was a statistically significant decrease in weight and EWL values in both groups depending on time (p <0.001), in further analysis, the difference between the 8th and 12th months for EWL values was not statistically significant (p> 0.05) for morbidly obese patients (BMI ≥40), and all other differences were significant (p <0.001). It was observed that EWL percentage means changed by 18.5%±7.2 in the morbidly obese group and 41%±10.6 in the overweight-obese group in the first four months after application and this change was determined to occur in both groups at the eighth month as 7.6%±3.6 vs. 23.5%±12.4 and at 12th months as 1.5%±7 vs. 11.1%±7.6. (**Table 2**).

When evaluated in terms of comorbid diseases, twenty-two patients had Type 2 Diabetes Mellitus (T2DM), eleven patients had hypertension, and three patients had sleep apnea syndrome at the time of treatment onset. After an average of 1-year after AIGB application treatment, we found that four patients with diabetes were discontinued from oral antidiabetic treatment, and two patients switched to oral antidiabetic treatment instead of insulin treatment and two patients under antihypertensive treatment discontinued the treatment due to hypertension. Although a patient with T2DM and sleep apnea syndrome lost 22 kg of weight, we could not find an improvement in both diseases.

Complications

Procedural complications were observed, especially during initial implantation. After balloon implantation, nausea, vomiting, and epigastric pain occurred in four patients, weakness occurred in one patient, only pain occurred in one patient, and melena occurred in one patient. In one patient, the silicone balloon had to be removed 22 days after the procedure due to erythematous urticarial plaques, which appeared on the tenth day after the procedure and did not regress despite medical treatment. The patient recovered from the allergic rash within three days after the balloon was removed. Allergic rashes that occurred in a patient with nausea and vomiting regressed rapidly with antihistaminic treatment.

After the second procedure, in other words, after inflating 120 ccs, nausea and vomiting developed in one patient, and melena developed in another patient. Both patients were discharged after two days of medical follow-up and treatment. In two patients, nausea and vomiting developed after the third inflation, which was 100 cc, and their complaints regressed after three days in one patient and seven days in one patient.

Table 1. Comparison of weight, BMI, EWL and volume changes in patients treated with intragastric balloon according to the months of treatment

	Pre-operative (n=82)	Postoperatif 4th month (n=79)	Postoperatif 8th month (n=80)	Postoperatif 12th month (n=82)	Preop. - Postop. total change between 12 months (n=82)	p
Weight (kg)	117.6±27.5	108.5±25.8	102.8±28.1	98.4±26.6 †	19.2±8.3	<0.001*
BMI (kg/m^2)	42.9±10.4	39.7±9.8	37.9±10.4	35.8±9.7 †	7±3.2	<0.001*
EWL (% average)	-	28%±14.2	15%±11.8	6%±8.6	51.3%±30.1	<0.001*
Balloon volume (cm^3)	-	322.3±25.1	448.9±25.8	538.7±50.4	209.3±41.8	-
Balloon time(month)	-	4.1±0.9	3.9±1.2	4.9±2.7	12.9±3	-

* Repeated Measures ANOVA Test, † Paired Samples T Test, BMI: Body mass index; EWL= Percent of excess weight loss

Table 2. Weight, EWL changes in patients treated with intragastric balloon according to the BMI values

		Pre-operative (n=82)	Post-operative 4th month (n=79)	Post-operative 8th month (n=80)	Post-operative 12th month (n=82)	Preop. - Postop. total change between 12 months (n=82)	p
BMI <40 (n=41)	Weight (kg)	99.7±21.2	88.7±20.1	82.7±20	82.7±17.8	16.8±7.6	<0.001*
	EWL (% average)	-	41%±10.6	23.5%±12.4	11.1%±7.6	68.7±31.4	0.001*
BMI ≥40 (n=41)	Weight (kg)	135.4±20.8	122.9±19.3	120.4±22	114.1±25	16.3±6.5	<0.001*
	EWL (% average)		18.5%±7.2	7.6%±3.6	1.5%±7	33.9±15.8	0.001*

* Repeated Measures ANOVA Test, BMI: Body mass index; EWL= Percent of excess weight loss

The female patient, whose BMI was <30 kg/m^2 and who wanted to continue balloon treatment for 17 months, complained especially of halitosis in the last two months. The most common complication seen in total was nausea in 7 patients, vomiting in 5 patients, pain in 5 patients, weakness in 2 patients, allergic reaction in 2 patients, and melena in 2 patients.

DISCUSSION

Due to excessive calorie intake as a result of more accessible nutrients and a sedentary lifestyle, the prevalence of obesity increases rapidly. Current treatment approaches to fight obesity are lifestyle changes, medical treatment, endoscopic methods, and bariatric surgery. Together with lifestyle changes and medical treatment, 3-9% weight loss in 1 year can be achieved.[8] The disadvantages of pharmacological treatment are the incidence of side effects and cost. Also, many studies proved that weight loss was put back after the drug use is discontinued. Although the most effective method is surgery, many patients do not accept it because of its risks and high cost.

Adjustable intragastric balloon application, which is one of the most popular endoscopic methods in recent years, is superior to other balloon applications and surgical procedures regarding both cost and complications. Early and late complications are reported between 11% to 23% after surgical operations.[9] Nausea constitutes the majority of the complication rates that appear to be high in the intragastric balloon and adjustable intragastric balloon application, and this complaint can be resolved by medical treatment or spontaneously resolve within the first 3-7 days.[10] In our study, similar to the literature, the most frequently encountered problem in terms of complications was nausea, which occurred in 7 patients. However, nausea and vomiting rates were lower compared to other studies. The most undesirable complication was an allergic reaction, which resulted in the removal of the balloon on the 20th day. No complication in the form of balloon collapse or perforation developed in any of our patients.

In obese patients (BMI ≥ 30 kg/m^2) and especially in patients with a high cardiovascular risk profile and high overall mortality risk due to comorbid diseases, intragastric balloon application is recommended in preventive treatment.[11] Also, it has been stated that intragastric balloon implantation can be indicated in selected patients who have a BMI <30 kg/m^2 and who cannot achieve weight loss with a controlled diet program or pharmacotherapy.[12] In our study, BMI of two patients was <30 kg/m^2, BMI of nine patients was between 30 and 40 kg/m^2, and in total, 50% of our patients were below the morbid obesity limit. It was observed that the AIGB application was statistically significantly efficient in weight loss and EWL levels in both morbid obese patients and patients with a BMI <40 kg/m^2. It was found that the effect was better in patients who are under morbid obesity levels (BMI <40 kg/m^2) than patients with morbid obesity levels.

One of the critical features of intragastric balloons is their duration of use. While AIGB can be used for almost a year, other disposable balloons have a usage period of 3 to 6 months. The literature also reveals the importance of the duration of the intragastric balloon in the body in terms of lost weight. In the study of Mion et al.[13] performed with swallowable Obalon®, patients lost an average of 5 kg in 12 weeks period. Weight loss between 8.7 and 17.4 kg were reported in different studies performed with Orbera balloon, while the average weight loss was 16.9 kg.[14-16] The average weights of our patients to whom we applied AIGB were 117.6±27.5, according to the values recorded in Table 1. In the 4th month, an average weight loss of approximately 9.1 kg was found, while the amount of weight loss was 14.8 kg in the 8th month. The average weight loss of the patients at the end of the 12th month was recorded as 19.2 kg. This result shows that the amount of weight loss increases with increasing time. However, it was observed that patients lost weight at a much faster rate in the first four months, the weight loss acceleration slowed down between 4 and 8 months and decreased to lower rates between 8 and 12 months. Although the balloon was inflated in the fourth and eighth months, it could be mentioned that patients developed tolerance to the balloon over time. From this point of view, it can be estimated that shortening the balloon inflation time intervals, shortening the balloon's remaining duration in the body in parallel with this finding will yield better results.

In the data published by Usuy et al.[10] regarding Spatz AIGB, it was observed that the weight loss rate obtained in patients with a BMI rate > 40 kg/m^2 was higher than patients with a BMI < 40 kg/m^2. However, according to our data, although both patient groups benefited statistically significantly, it stands out that patients with BMI <40 kg/m^2 benefit more from AIGB when these two patient groups are compared. This result may be since the stomachs of morbidly obese patients develop a tolerance to the balloon more quickly.

Because of our belief that surgical approaches generally give better results in morbidly obese patients, we generally recommend surgical treatment to morbidly obese patients in our clinic. The patients included in this study consisted of either surgically high-risk patients due to their comorbidities, or patients who did not want surgical treatment because of their fear of surgery. We have seen that AIGB treatment is a statistically significant method for weight loss in morbidly obese patients. However, this effect was higher in the non-morbid obese patient group.

Despite the low rates of the regression of comorbid diseases, the AIGB application had satisfactory results, compared to surgical treatment.

The most significant limitation of this study was the low number of patients. The main reason was that our hospital was located in an economically lower area of our city, and patients did not have the financial power to supply AIGB.

CONCLUSIONS

Endoscopic treatment methods applied for obesity yield results just as successful as surgical techniques. It is observed that it is effective, especially in increasing the quality of life of patients who are not suitable for surgery and suffering from comorbid diseases.

Quite satisfying results are obtained in obese patients with AIGB treatment. In the morbidly obese patient group, AIGB is an advantageous method for weight loss when surgery may be risky due to comorbid diseases or surgery is not preferred by patients. In our opinion, the point to be considered in AIGB is that by keeping the balloon inflation frequencies shorter, without allowing the patients to develop tolerance to the balloon and adjusting the duration of the balloon in the body of patient not to exceed one year, we believe that it will provide optimum benefit for the patients. We think that we will be more enlightened about this subject with further studies that will be conducted with a randomized, prospective design and include a higher number of patients under these conditions.

ETHICAL DECLARATIONS

Ethics Committee Approval: Ethics committee approval was obtained from Keçiören Training and Research Hospital Clinical Research Ethics Committee (Date: 28.02.2018, Decision No: 2012-KAEK-15/1596).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

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. Buchwald H, Avidor Y, Buchwald H, et al. Bariatric surgery:a systematic review and meta-analysis. JAMA 2004;292:1724-1737.
2. Salcan S, Ezmeci T. Obesity prevalence and effective factors in high school students in Erzincan city center. J Contemp Med 2021;11(3):330-4.
3. Mathus-Vliegen EMH. Intragastric balloon treatment for obesity:what does it really offer? Dig Dis. 2008;26(1):40–4.
4. Brooks J, Srivastava ED, Mathus-Vliegen EMH. One-year adjustable intragastric balloons:results in 73 consecutive patients in the U.K. Obes Surg 2014;24(5):813-9.
5. Bustamante F, Brunaldi VO, Bernardo WM, et al. Obesity treatment with botulinum toxin-a ıs not effective:a systematic review and meta-analysis. Obes Surg 2017;27(10):2716–23.
6. Machytka E, Klvana P, Kornbluth A, et al. Adjustable intragastric balloons:a 12-month pilot trial in endoscopic weight loss management. Obes Surg 2011;21:1499-507.
7. Mathus-Vliegen EMH. Endoscopic treatment:the past, the present and the future. Best Pract Res Clin Gastroenterol 2014;28:685-702.
8. Yanovski SZ, Yanovski JA. Long-term drug treatment for obesity: a systematic and clinical review. JAMA 2014;311:74-86.
9. Chang SH, Stoll CR, Song J, et al. The effectiveness and risks of bariatric surgery:an updated systematic review and meta-analysis, 2003-2012. JAMA Surg 2014;149:275-87.
10. Usuy E, Brooks J. Response rates with the Spatz3 adjustable balloon. Obes Surg 2018;28(5):1271-6.
11. Calle EE, Thun MJ, Petrelli JM, Rodriguez C, Heath Jr CW. Bodymass index and mortality in a prospective cohort of U.S. adults. N Engl J Med 1999;341:1097-105.
12. Mitura K, Garnysz K. In search of the ideal patient for the intragastric balloon short and long-term results in 70 obese patients. Wideochir Inne Tech Maloinwazyjne 2016;10:541-7.
13. 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;23:730-3.
14. Kim SH, Chun HJ, Choi HS, Kim ES, Keum B, Jeen YT. Current status of intragastric balloon for obesity treatment. World J Gastroenterol 2016;5495-504.
15. Bayraktar O , Özçelik AA , Öktemgil AR, Bayraktar B. Intragastric balloon therapy for obesity:Is it safe and effective? ACEM 2019;4(1):25-8.
16. Gaur S, Levy S, Mathus-Vliegen L, Chuttani R. Balancing risk and reward:a critical review of the intragastric balloon for weight loss. Gastrointest Endosc 2015; 81:1330-6.