The Safety and Efficacy of Procedureless Gastric Balloon: a Study Examining the Effect of Elipse Intragastric Balloon Safety, Short and Medium Term Effects on Weight Loss with 1-Year Follow-Up Post-removal

Mohammad H. Jamal, Rawan Almutairi, Rawan Elabd, Salman K. AlSabah, Hala Alqattan, et al.

Obesity Surgery
The Journal of Metabolic Surgery and Allied Care

ISSN 0960-8923
Volume 29
Number 4

OBES SURG (2019) 29:1236-1241
DOI 10.1007/s11695-018-03671-w

Springer

Obesity Surgery (2019) 29:1236–1241
https://doi.org/10.1007/s11695-018-03671-w

ORIGINAL CONTRIBUTIONS

The Safety and Efficacy of Procedureless Gastric Balloon: a Study Examining the Effect of Elipse Intragastric Balloon Safety, Short and Medium Term Effects on Weight Loss with 1-Year Follow-Up Post-removal

Mohammad H. Jamal[1] · Rawan Almutairi[1] · Rawan Elabd[1] · Salman K. AlSabah[1] · Hala Alqattan[2] · Talal Altaweel[1]

Published online: 7 January 2019

Abstract

Introduction The Ellipse intragastric balloon (EIGB) is a new swallowable balloon that does not require endoscopy at insertion or removal. The aim of this study is to investigate the safety of EIGB and its efficiency in weight reduction even after 1 year of expulsion.

Method Prospective study on our initial experience with a consecutive group of patients who underwent the insertion of EIGB in the period between September 2016 and February 2017. The patients were followed up to assess pain, nausea, and vomiting after procedure. As well as, the time of balloon extraction, route of extraction, and weight loss.

Results Total of 112 patients underwent EIGB placement. A 1-year follow-up was obtained on 85% of patients. Mean weight and BMI before the procedure 92.2 kg and 34.3 kg/m^2, respectively. One patient had small bowel obstruction. Six patients did not tolerate EIGB and three patients had early deflation. Total weight loss % (TWL%) 10.7, 10.9, and 7.9% at 3, 6, and at date of last follow-up. When data were stratified according to BMI into two groups: group 1 (BMI 27.5–34.9) and group 2 (BMI 35–49), the TWL% for group 1 at 3 months, 6 months, and last day of follow-up are as follows: 10.2%, 10.6%, and 8.8%, while it was 11.5%, 11.2%, and 6.6% for group 2.

Conclusion EIGB are effective, safe, and feasible non-invasive method for weight loss.

Keywords Gastric balloon · Intragastric balloon · Obesity · Weight loss · Swallowable

Background and Introduction

The intragastric balloon (IGB) devices form the bridge between pharmacological therapy for weight loss and surgical interventions. They induce weight loss by increasing satiety, delaying gastric emptying and reducing the amount of food eaten at each meal [1]. Surgical interventions are the most effective for weight loss, but it is generally not offered to those who are overweight or patients with class I obesity not reaching a body mass index (BMI) above 35; therefore, the balloon devices constitute a weight loss intervention available for those who are overweight and those not seeking surgical interventions. Different intragastric balloon devices were made since the introduction of the first intragastric balloon which was the Garren–Edwards Gastric Bubble device in 1985 [2]. The balloons are filled with gas and or with fluid; some can be adjusted at different time intervals to increase the volume inside the balloon and the duration of the balloon in the stomach varies according to different balloon types. They all require endoscopy with some sedation either at insertion or removal. The Elipse balloon is the first intragastric balloon device not requiring endoscopy neither at insertion or removal [3]. The main concern about this balloon is the incidence of bowel obstruction as its self-deflated and not requiring endoscopy for removal. Also, the increased risks of intolerance is there is no endoscopic surveillance of the stomach prior to its

Presented at the annual meeting for the International Federation For The Surgery Of Obesity And Metabolic Disorders, Dubai 2018

✉ Mohammad H. Jamal
Mohammad.jamal@mail.mcgill.ca

[1] Department of Surgery, Kuwait University, Kuwait City, Kuwait

[2] Department of Surgery, McGill University Health Center, McGill University, Montreal, Canada

insertion. It is also of a shorter duration than most balloons as it is excreted at about 4 months from insertion. This theoretically might cause less weight loss than balloons with longer duration. In this study, we aim to investigate our initial cohort of patients who had the Elipse balloon and in particular look at the safety and efficacy of this device not only in the short term but also in the medium term by following them at least for a year after the Elipse excretion.

Methods

The Elipse™ System

The Elipse balloon (Allurion Technologies, Natick, MA, USA) is a gastric balloon that does not require endoscopy nor sedation for placement and removal. The balloon is enclosed in a small vegetarian capsule attached to a thin catheter. The capsule is easily swollen with water. In case of swallowing difficulty, a stylet is used through the catheter to stiffen it, allowing the physician to help with the insertion during swallowing. The balloon contains a small radiopaque ring that can be used to confirm its correct position inside the stomach at time of fluoroscopy. Once the ring is seen in the stomach at fluoroscopy, the balloon is filled with 550 mL of liquid consisting of distilled water with potassium sorbate preservative. A repeat X-ray at fluoroscopy is then done to ensure the filling of the balloon prior to catheter removal. This device is designed to spontaneously empty through a release valve after around 16 weeks of treatment and be excreted.

Study Design

This is a single-center prospective study of consecutive patients who underwent Elipse™ intragastric balloon (EIGB) insertions with tolerance at Dar Al-Shifa Hospital, Kuwait City, in the first 6-month period of use of the Elipse, September 2016–February 2017. The patients were followed up with their surgeon who inserted the Elipse in the out-patient clinics and through phone interviews at time intervals of 1 month, 3 months, 6 months and last day of follow-up. At the 1-month visit, all patients answered a questionnaire detailing the symptoms that occurred in the immediate period post-insertion. At the 3-month and 6-month visit, the weight was assessed as well as taking details of the method of excretion as well as symptoms experienced. At the date of last follow-up, which was at least 1 year from the time of EIGB excretion, all patients were contacted through phone interviews with a short questionnaire assessing the current weight, post-procedural symptoms such as pain, nausea, and vomiting, as well as, the time of balloon extraction if they noticed and the route of extraction. The weight loss was calculated by applying %TWL and %EWL equation. All patients were followed up by the dietician to administer a high-protein low-calorie diet.

Ethical Considerations

Ethical approval for conducting the study was obtained from Kuwait University Ethical committee and Kuwait Ministry of Health. Personal information or any information that may lead to identification of patients was not collected. Informed consent was obtained from all subjects included in the study.

Anthropometric Measurements

Anthropometric measurements included weight and height of all the subjects. The measurements were obtained on the first out-patient clinic visit and at 3- and 6-month post-insertion in the clinic. At the date of last follow-up, which was at least after 1 year of EIGB removal, patients were contacted by phone interviews and reported their current weight.

Subjects and Inclusion Criteria

Males and females aged 18 years and above, with a minimum BMI of 27.5 kg/m^2, were included. Each patient then was evaluated for eligibility for EIGB implantation. Those with any contraindications for EIGB placement including eating disorders including Bulimia nervosa and anorexia nervosa, previous open abdominal surgery, history of Crohn's disease, severe GERD with hiatal hernia, multiple laparoscopic surgery, bleeding disorders or patients on anticoagulation, history of varices, history of acute pancreatitis, pregnancy, laparoscopic surgery for perforated viscus, and previous gastric surgery were excluded. All patients were seen by the physician and the nutritionist prior to insertion and have undergone blood tests including complete blood count, renal profile, and a thyroid function test. We excluded patients with EIGB intolerance.

Elipse Balloon Deployment

Patients fasted for at least 8 h prior to the procedure and received a single 125 mg per os (PO) dose of the anti-emetic Aprepitant (Emend®) 4 h before the deployment of the balloon.

Post insertion, patients were prescribed ondansetron 8 mg every 8 h, metochlopramide 10 mg every 6 h, and paracetamol 1 g every 6 h for the first 48 h. A phone follow-up was instituted for all patients in the first 3-day post-insertion and if the patient was thought to be dehydrated with repeated nausea and vomiting, then IV hydration and IV antiemetics would be given. Omeprazole 40 mg daily was started 1 week prior to placement and was continued until the end of treatment. Fluid hydration was permitted for the first 24 h. During the first week, a gradual progression to a semi-liquid diet (yogurt, mashed

potatoes, clear soup, puréed vegetables, and eggs) was recommended. At the beginning of the second week, the patient proceeded with caution to a hypocaloric, textured diet plan. Patients were encouraged to regularly exercise.

Statistical Analysis

Statistical analysis was performed using the IBM SPSS Statistics v.25 and the data were checked for out of range codes. Descriptive analysis was conducted and frequencies are reported on Tables 1, 2, and 3. Significance tests were run to detect differences in means or medians between group 1 and group 2. Independent *t* sample test was used for detecting differences in means on the normally distributed variables. On the other hand, variables with skewed distribution were further analyzed using non-parametric *K* independent test for difference in medians. The latter is represented in Table 5.

Results

A total of 112 patients had the EIGB inserted. Only 106 tolerated the EIGB and were enrolled in the study. Intolerance of the EIGB occurred in six patients and they were excluded. Out of 106 patients who tolerated the EIGB, 90 patients (85%) where successfully followed up for 1-year post-expulsion that is shown in (Fig. 1). Females represented 78 (73.6%) of our sample, while male represented 28 (26.4%). The mean age of patients was 31.3 years (Table 1). The mean weight and BMI of the patients before the EIGB insertion were 92.2 kg and 34.3 kg/m^2, respectively.

Post-procedural symptoms noticed by the patients were abdominal pain 49 (46.2%) and nausea and vomiting 76 (71.7%) (Table 2). Out of 106 subjects, 49 noticed the balloon extraction. Of those, 3 (6.1%) noticed the balloon less than 2 months of the EIGB placement, 5 (4.7%) after 4.5 months, while 11 (22.5%) could not remember the exact time. Majority of patients 30 (61.2%) noticed the EIGB being excreted between 3 and 4.5 months. The extraction route for those who remembered was per rectum in 43 (88%) and 6 (12%) orally (Table 3).

Overall data before stratification are represented in (Table 4). The overall mean TWL% was 7.9% at date of the last follow-up with a mean change of BMI of 2.95. Data were stratified according to BMI into two groups: group 1 and group 2, BMI ranging from 27.5–34.9 to 35–49, respectively. The mean TWL% at date of the last follow-up was 8.8% in group 1 and 6.6% in group 2 $p < .264$ with a mean change of BMI of 3.2 in group 1 and 2.6 in group 2 $p < .826$. The TWL% for group 1 at 3 months, 6 months, and last day of follow-up were as follows: 10.2%, 10.6%, and 8.8%, while it was 11.5%, 11.2%, and 6.6% for group 2, respectively (Table 5) and (Fig. 2). The change in BMI in group one was 3.2, 3.3, and 3.2 at 3 months, 6 months, and last day of follow-up in comparison to 4.5, 4.4, and 2.6 in group 2 (Fig. 3). During Elipse™ excretion, 75 cases (70.7%) were asymptomatic, 13 (9%) had diarrhea, and three (2%) had mild abdominal discomfort.

Table 1 Demographic characteristics of patients

Descriptive data	Mean (Std.)
Age	31.3 (9.1)
Follow-up time (months)	19.6 months (4.7)
Gender	
Females	78 (73.6%)
Males	28 (26.4%)

Table 2 Post-procedural follow-up

	N = 106
Stomach pain	
Yes	49 (46.2%)
No	42 (39.6%)
Unknown	15 (14.2%)
Nausea and vomiting	
Yes	76 (71.7%)
No	16 (15.1%)
Unknown	14 (13.2%)
Requirement of IVF	
Yes	44 (41.5%)
No	49 (46.2%)
Unknown	13 (12.3%)

Discussion

In this single-center study evaluating the experience with the relatively new EIGB, we found an overall mean TWL% of 7.9% at date of the last follow-up with a mean change of BMI

Table 3 Balloon excretion noted, time, and route

Balloon excretion	*N* = 106
Noticed	49 (46.2%)
Unnoticed	48 (45.3%)
Unknown	9 (8.5%)
Time of balloon excretion if noticed	*N* = 49
≦ 2 months	3 (6.1%)
3–4.5 months	30 (61.2%)
> 4.5 months	5 (4.7%)
Cannot remember	11 (22.5%)
Balloon excretion route	*N* = 49
Per rectum	43 (88%)
Orally	6 (12%)

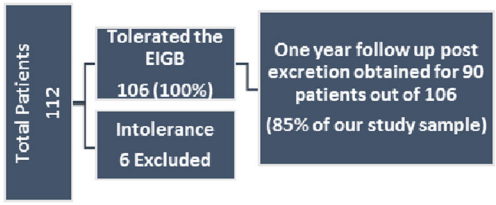

Fig. 1 Flow chart of the study sample

of 2.95. We followed up all our patients at least 1-year post-EIGB insertion with a mean follow-up of 19.6 months, and found maintenance of weight loss, whereby the mean TWL% was 10.9% at 3-month post-EIGB insertion in comparison to 7.9% at date of last follow-up.

We found a trend towards statistical significance in BMI change and TWL% with more follow-up when we stratify patients according to their BMI, whereby patients with a BMI higher than 34.9 have more weight regain post-balloon expulsion when compared to those with a BMI lower than 34.9.

This may suggest the possibility that patients with a higher BMI have more metabolic disturbances that might better be suited for more aggressive interventions; however, more studies are needed to clarify that and the metabolic changes if any associated with balloon devices. The interest in the use of intragastric balloon devices is increasing, mainly due to patient choice. The majority of the obese population is not seeking bariatric surgery despite its safety and effectiveness for fear of complications along with other factors [4, 5]. In the 1980s, the use of these devices declined due to the high rate of early deflation with associated migration leading to small bowel obstruction. In 1991 and based on the Tarpon Spring Criteria for the ideal gastric balloon, the BioEnterics intragastric balloon was developed which requires insertion and extraction after 6 months by using endoscopy under sedation [6].

The majority of the intragastric balloon literature is on the endoscopic fluid-filled balloons including the BioEnterics® Intragastric Balloon (BIB®). The Elipse device is a fluid filled balloon that does not require endoscopy neither at the time of insertion nor removal with an ease of insertion with short procedure duration. Its capsule thickness is thinner and with a duration that is shorter than most other balloons, which might cause less weight loss theoretically when compared with balloons that stay longer, have a thicker capsule, and can be filled with more fluid than the Elipse balloon which can only accommodate 550 ml. However, in this study, we showed results comparable to the most widely used intragastric balloons [7–9].

In terms of safety, we observed one small bowel obstruction early in this series due to early incomplete deflation 2-month post-insertion (Fig. 4). We inserted 140 balloons after the incidence of small bowel obstruction with no further episodes. These cases were not included in this study as this study specifically examines our initial 6-month experience with more than a year of follow-up post-expulsion. We managed the small bowel obstruction laparoscopically with three ports insertion, the balloon was found in the distal jejunum and small enterotomy made over it prior to fluid aspiration by a laparoscopic needle followed by the balloon removal and the closure of enterotomy with 3.0 vicryl suture. The patient made an uneventful recovery and was discharged 2 days later. Examination of the deflated balloon showed a fault in the valve that was corrected in the most updated version of the Elipse device. Endoscopic surveillance is thought to be beneficial prior to balloon device insertion; however, the Elipse is a swallowable balloon not requiring endoscopy which may raise the concern of adverse events or intolerance of the balloon due to the lack of prior endoscopy. We take detailed history prior to insertion in order to identify patients with symptoms requiring endoscopy prior to insertion. In a study, comparing two groups of patients, one having the balloon inserted with endoscopy to another group having the balloon inserted without endoscopy, no difference was found between the groups in terms of intolerance or adverse outcomes (Table 6) [10]. A potential disadvantage of the Elipse is that it must be filled with a certain volume (550 cc) without adjustment based on the size of the fundus endoscopically causing potentially more balloon intolerance. In this study, six patients (5%) could not tolerate the Elipse balloon due to

Table 4 Overall data

	Before Mean (Std.)	At 3 months Mean (Std.)	*P* value	At 6 months Mean (Std.)	*P* value	At LDF Mean (Std.)	*P* value
Average weight (kg) Range	92.2 (20.7) 53–149	82.8 (17.3) 55–139	0.001	83.5 (20.0) 53–141	0.003	85.2 (19.2) 54–145	0.014
Average BMI (kg/m^2) Range	34.3 (5.1) 27.5–49	30.9 (4.6) 22.8–46	< .000	30.9 (5.2) 22.3–45.6	< .000	31.7 (5.1) 22.7–44.8	0.001
Change in BMI		3.7 (2.2)		3.7 (2.6)		2.95 (4.0)	
Average weight loss (kg)		10.1 (6.8)		10.1 (7.1)		7.2 (6.7)	
Average TWL%		10.7 (5.5)		10.9 (6.9)		7.9 (6.7)	

Table 5 Data stratified according to BMI

	$N = 103^{\&}$	Initial BMI	Initial weight	Change in BMI At 3 months	% TWL	% EWL	Change in BMI At 6 months	% TWL	% EWL	Change in BMI At LDF	% TWL	% EWL
Group 1*	64	31.2 (2.6)	81.4 (12.2)	3.2 (1.4)	10.2 (4.1)	55.4 (35.7)	3.3 (1.7)	10.6 (5.2)	71.9 (98.1)	3.2 (4.5)	8.8 (5.6)	48.6 (45.9)
Group 2*	39	39.6 (3.9)	109.8 (20.2)	4.5 (2.9)	11.5 (7.1)	32.7 (19.8)	4.4 (3.5)	11.2 (8.9)	31.8 (26.7)	2.6 (3.1)	6.6 (8.0)	18.7 (24.7)
P value		< .000^	< .000^	.283^^	< .895^^	< .000^^	.467^^	.520^^	.002^^	.826^^	< .264^^	< .000^^

LDF last date of follow-up
*Group 1: BMI 27.5 to 34.9
*Group 2: BMI 35 to 49
& Three patients had missing height and thus were excluded from this analysis
^*P* values were generated using independent *t* sample test for difference in means
^^*P* values were generated using *K* independent sample test for difference in medians

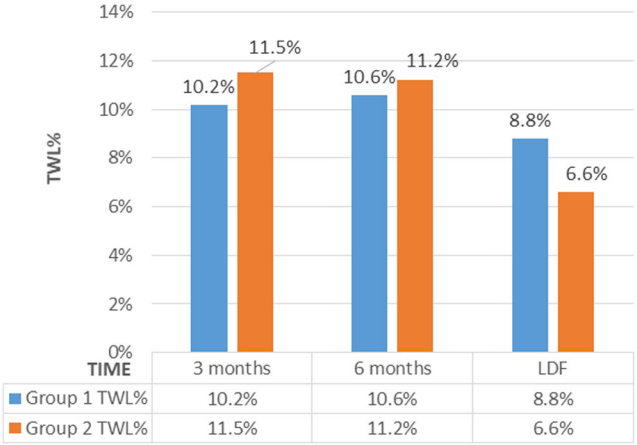

Fig. 2 Percentage of total weight loss [%TWL] of each group of patients at different time intervals. [LDF, last day of follow-up which was at least 1 year after excretion] (group 1: BMI 27.5 to 34.9; group 2: BMI 35 to 49)

repeated nausea and vomiting associated with epigastric pain. All had the device removed endoscopically in the exact manner of removal as other intragastric fluid-filled balloons. None of them had findings at endoscopy that would explain the intolerance such as ulcers or gastritis. This is slightly a higher percentage of intolerance than other studies examining the EIGB [11] and other intragastric balloons [12]. This could be explained by the fixed amount of fluid that fills the EIGB without the ability to adjust the filled fluid according to the fundic size.

The balloon was excreted by mouth in 6 patients (12%) out of 49 patients who noticed the EIGB excretion. This did not result in any adverse event but caused psychological distress to those patients and would be an important counseling point pre-insertion.

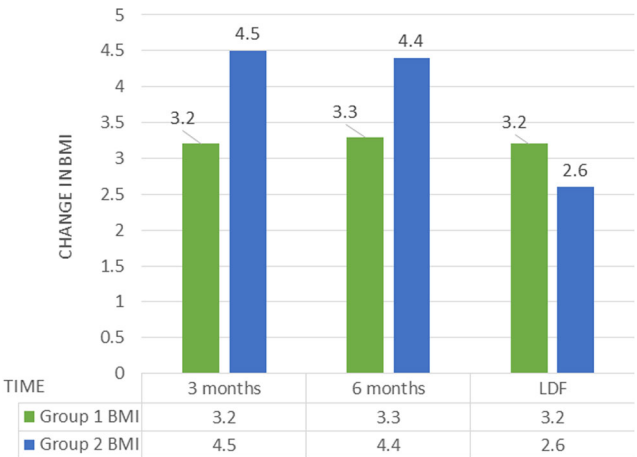

Fig. 3 Each group of patients at different time intervals, showing the different changes in BMI. [LDF, last day of follow-up which was at least 1 year after excretion] (group 1: BMI 27.5 to 34.9; group 2: BMI 35 to 49)

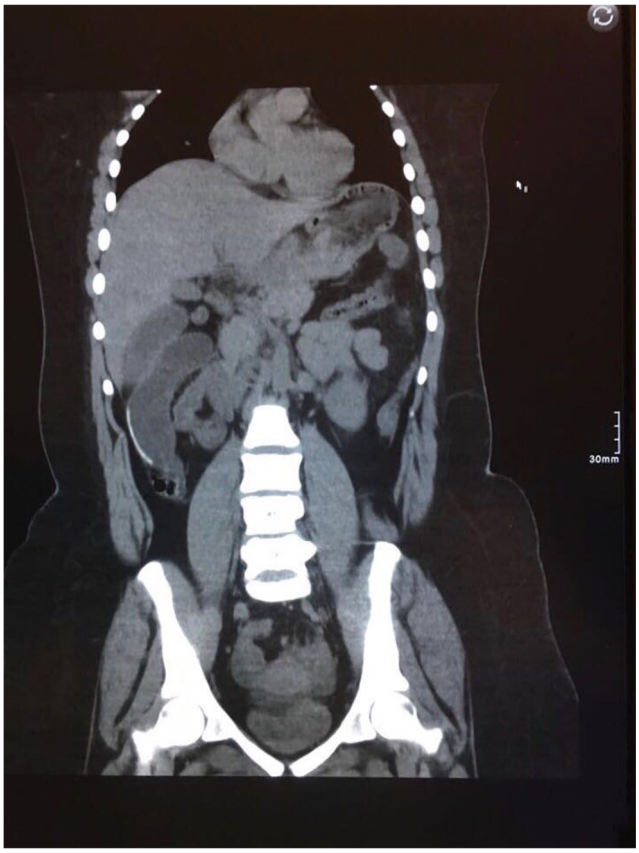

Fig. 4 CT scan for patient with small bowel obstruction due to EIGB

The advantages of the self-deflation include the avoidance of endoscopy and the avoidance of the increased risks of adverse events in those patients with balloon devices requiring endoscopic removal that are lost to follow-up. Of note is that one patient got pregnant 3-month post-insertion despite clearly counseling her pre-insertion to avoid pregnancy; the balloon was self-deflated on time without any adverse events. In communities with high birth rate, this might constitute an advantage for the self-deflated balloons avoiding anesthesia and endoscopy in an unintended pregnancy. Our study contains many limitations including that it is a single-center, single-surgeon study. Also, the follow-up is only 1-year post-excretion without longer term follow-up. We did not study the impact of the Elipse device in terms of medical comorbidities nor the quality of life and did not compare it head to head with diet only or other non-invasive techniques for weight loss.

Table 6 Adverse outcome of EIGB

Adverse outcomes	
Small bowel obstruction	1
Early balloon deflation	3
Balloon intolerance	6

Conclusion

In conclusion, the Elipse device is a safe and effective treatment for excess body weight especially in those with a BMI below 34.9. More studies are needed to determine its safety and in particular to investigate about the rate of small bowel obstruction.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval Ethical approval for conducting the study was obtained from Kuwait University Ethical committee and Kuwait Ministry of Health.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

References

1. Nunes GC, Pajecki D, de Melo ME, et al. Assessment of weight loss with the intragastric balloon in patients with different degrees of obesity. Surg Laparosc Endosc Percutan Tech. 2017;27(4):e83–e6.
2. Meshkinpour H, Hsu D, Farivar S. Effect of gastric bubble as a weight reduction device: a controlled, crossover study. Gastroenterology. 1988;95(3):589–92.
3. 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.
4. Jung F, Dietrich A, Stroh C, et al. Changes in attitudes towards bariatric surgery after 5 years in the German general public. Obes Surg. 2017;27(10):2754–8.
5. Stanford FC, Kyle TK, Claridy MD, et al. The influence of an individual's weight perception on the acceptance of bariatric surgery. Obesity (Silver Spring). 2015;23(2):277–81.
6. Genco A, Dellepiane D, Baglio G, et al. Adjustable intragastric balloon vs non-adjustable intragastric balloon: case-control study on complications, tolerance, and efficacy. Obes Surg. 2013;23(7):953–8.
7. Genco A, Cipriano M, Materia A, et al. Laparoscopic sleeve gastrectomy versus intragastric balloon: a case-control study. Surg Endosc. 2009;23(8):1849–53.
8. Force ABET, Committee AT, Abu Dayyeh BK, et al. Endoscopic bariatric therapies. Gastrointest Endosc. 2015;81(5):1073–86.
9. Force ABET, Committee AT, Abu Dayyeh BK, et al. ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies. Gastrointest Endosc. 2015;82(3):425–38. e5
10. Mathus-Vliegen EMH. Is endoscopy really necessary for placing intragastric balloons? Obes Surg. 2018;28(1):169–75.
11. Alsabah S, Al Haddad E, Ekrouf S, et al. The safety and efficacy of the procedureless intragastric balloon. Surg Obes Relat Dis. 2018;14(3):311–7.
12. Imaz I, Martínez-Cervell C, García-Álvarez EE, et al. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg. 2008;18:841–6.