Intragastric Balloon Device: Weight Loss and Satisfaction Degree

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Abstract

Background An intragastric balloon is a non-surgical device enhancing a sensation of early satiety and reducing food intake. The aim of this study is to analyze the results in terms of weight loss and patient satisfaction undergoing intragastric balloon implantation.

Methods Air-filled and water-filled devices were used. All patients were participated in strict follow-up programs. Weight, body mass index (BMI), total body weight loss (TWL), percentage of excess weight loss (EWL), and satisfaction degree were taken into account.

Results Eighty-one patients completed a 6-month period with a device in place; 72 of them were then contacted for a follow-up at 12.3 ± 2.4 months post-removal. During treatment period, in 76 cases (93.8 %), a statistically significant reduction in weight was observed. A statistically meaningful linear correlation between a 3-month EWL (or TWL) and a 6-month EWL (or TWL) was found. At the end of endoscopic treatment, a significant link between baseline BMI and EWL >20 % was found. Sixty-three percent of the patients were not satisfied with the procedure, did not deem useful to change their diet, and refused to perform it again.

Conclusions In our study, at device removal and 1 year thereafter, a statistically significant reduction in weight was observed. Most of the patients were found to have a weight loss more than the cut-off of 20 %. The weight reached at the third month appears to be predictive of the effectiveness of endoscopic treatment. Data showed an overall dissatisfaction with procedure.

Keywords Obesity · Intragastric devices · Satisfaction

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Introduction

Obesity is an alarming health problem worldwide, being a potential cause of chronic degenerative diseases impacting on the duration and quality of life. According to the latest report of the World Health Organization (WHO), in 2014, more than 1.9 billion adults with age ≥18 years (about 18 % of the adult population) had excess weight and, out of these, 600 million were obese. In order to prevent or reduce the incidence of obesity-related complications, the WHO recommends a weight loss of 5–15 % of the initial weight [1–3].

The aim of the treatment of obesity is to reduce excess weight and to maintain the result obtained in time, thus avoiding the recovery of the weight lost. The first approach in the management of obesity is a public health strategy aimed at healthy lifestyles, diet, physical activity, exercise, behavioral therapy, as well as likely psychotherapeutic support. Surgical approach should be considered when medical treatment fails or the degree of obesity and related comorbidities cause a serious impairment of health status [4]. Another treatment for obesity is the endoscopic placement of an intragastric balloon. It is a temporary, less invasive, non-surgical device enhancing a sensation of early satiety and reducing food intake [5].

This study aims at analyzing the results in terms of weight loss and patient satisfaction undergoing intragastric balloon implantation. We analyzed the percentage of patients with significant weight loss after a 6-month period with a balloon and evaluated the effect of the total body weight loss (TWL) and excess weight loss (EWL) during the first 3-month period on the 6-month results. One year after the balloon removal, we assessed the variations in weight and factors influencing intragastric balloon success. At the same time, we noticed the degree of patient satisfaction with the procedure.

Materials and Methods

Consecutive participants who underwent intragastric balloon implantation were included in this prospective longitudinal study. Inclusion criteria for balloon insertion were as follows: body mass index (BMI) ≥30 kg/m^2, well-informed and motivated patients, aged 18 to 65, with acceptable operative risks, who declared compliance with a diet during the first 6 months after insertion of the gastric balloon. Patients with extensive hiatal hernias, gastroduodenal ulcers, erosive gastritis, and with previous history of stomach surgery were excluded.

All patients were selected after preoperative assessment by a team of three bariatric surgeons, two dieticians, two gastroenterologists, a psychologist, and two psychiatrists.

In our experience, two types of device were used: Heliosphere® Newtech (Vienne, France) BAG inflated with an injection of 600–720 ml of air with a total specific weight of 30 g and BIB™ System (Allergan, Irvine, CA, USA) filled with 400–700 ml of water colored with methylene blue dye, with a total specific weight of 720 g.

Placement was carried out under conscious sedation, and the patients were discharged within 24 h of the endoscopic procedure. During hospital stay, the patients were treated with endovenous antispastic (butylscopolamine) or with endovenous prokinetics in case of abdominal pain or vomiting, respectively. All patients took oral proton pump inhibitors (40 mg pantoprazole) on a daily basis while keeping the intragastric device. A liquid diet for 3 days after placement was prescribed to minimize gastric disorders; after a few days, the patients were switched to a soft diet, gradually replaced by a low-calorie diet (800–1000 kcal/day).

All intragastric devices were removed through endoscopy under general anesthesia, and the patients were discharged within the first day.

Endoscopic Technique

Insertion Placement is carried out in the recovery room of the Anesthesiology and Reanimation Department. Patients are positioned in supine decubitus, raising their torsos by 45° before undergoing conscious sedation performed by an anesthetist–reanimator doctor who oversees the entire process. Olympus' dual channel gastroscopes are used in this context. Preliminary endoscopy, which is carried out up to the Treitz ligament to ensure the absence of contraindications, includes drawing bioptic samples from the antrum and at the level of the gastric body for HLO research purposes. The mean length of each session is 13 min, comprising the aforementioned diagnostic gastroscopy and balloon implantation.

A direct radiography of the abdomen is performed immediately after the endoscopic procedure in order to assess the correct positioning of the device.

The Balloon Removal It is carried out in the theater room with patients lying supine and under general anesthesia: orotracheal intubation is considered necessary to minimize risks of inhaling gastric liquid. Removing an intragastric balloon with the aid of the aforementioned endoscopes requires approximately 20 min and is only possible once the balloon content has been sucked out by using a specific set of tools provided by the same producers of the intragastric device.

All patients participated in a strict follow-up program consisting in a monthly consult with physician and dietician until the device was removed. Weight, BMI variations, and dietary compliance were noted. On the intragastric balloon removal day, weight, BMI, TWL, and percentage of EWL were calculated.

One year after the intragastric balloon removal, weight variations and satisfaction degree were assessed through phone interviews. The questionnaire consisted of three questions: (1)

Are you satisfied with treatment?; (2) Has the placement of the intragastric balloon made any changes in your eating habits?; (3) Would you repeat it again? For the first two questions, the patients were given a score from 0 to 3 corresponding to 0—not at all, 1—a little, 2—fairly, and 3—very much; for the last question, the possible answer was YES or NO.

The success of intragastric balloon treatment (end treatment success, ETS) at the device removal was calculated according to two different criteria existing in the literature: EWL ≥20 % or TWL ≥10 % with respect to baseline weight.

Statistical Analysis

Data were analyzed using median (min–max) or mean ± standard deviation for continuous variables or their medians with interquartile range (IQR) in case variables showed to be non-normally distributed. Variations over time of BMI were evaluated by linear mixed-effects model. Association between sex, age, type of balloon, baseline BMI, and 6-month and 1-year results were analyzed with Student *t* test, Wilcoxon and Mann–Whitney test, Spearman test, and one-way ANOVA test.

The relationship between satisfaction and weight loss 1 year after the balloon had been removed was described by the χ^2 test.

p values <0.05 were considered statistically significant.

Results

From November 2006 to November 2014, we prospectively followed a cohort of 93 consenting patients treated with intragastric balloon device. Twelve of them were excluded from the statistical analysis because of treatment interruption (single case of device rupture) or incomplete available data (11 patients). Thus, 81 patients remained. Among the patients who completed the 6-month period with the device in place, 72 out of 81 were then contacted for a follow-up at 12.3 ± 2.4 months post-removal. Nine patients had not completed the year of follow-up.

Treatment Period

We analyzed a population of 81 patients, of whom 58 were females (71.6 %) and 23 were males (28.4 %). Patients had an average age of 46 years, with mean age of 45.1 years (±11.1 years) within a range between 24 and 70 years. Mean baseline weight and BMI were 113 ± 23.5 kg and 39.6 ± 6.9 kg/m^2, respectively. Mean baseline excess weight and excess BMI were 41.8 ± 20.6 kg and 14.6 ± 6.8 kg/m^2, respectively. At the end of the 6-month period, among 81 patients, 2 (2.5 %) subjects increased their weight and 3 (3.7 %) patients kept their weight stable. In 76 cases (93.8 %), a statistically significant reduction in weight was observed ($p < 0.001$). The mean weight was 102.9 ± 23.3 kg with a reduction of 10.1 ± 6.5 kg compared to baseline, and mean BMI was 36.1 ± 6.9 kg/m^2 with a reduction of 3.6 ± 2.3 kg/m^2. The mean %EWL was 28.1 ± 20.1 and the mean TWL was 9.1 ± 5.6 kg. Mean final excess weight and BMI were 31.6 ± 20.8 kg and 11.0 ± 6.9 kg/m^2, respectively.

Statistically meaningful variations of BMI over the time were found ($p < 0.001$, linear mixed-effect model). As shown in Fig. 1, most of their weight loss was observed in the first 3–4 months of treatment. Comparing BMI values recorded in each month, there was a noticeable reduction in BMI up to the third month, then the value settled, and lastly it increased slightly (sixth month).

A total of 52 patients, accounting for 64.2 % of the participants, were found to have a weight loss more than the cut-off of 20 % in EWL percentage. Patients who achieved more than 10 % of TWL with respect to baseline were 34 (41.9 %). A strong and statistically significant linear correlation between a 3-month TWL and 6-month TWL was found (Pearson's correlation coefficient $r = 0.81$, $p < 0.0001$) (Fig. 2a). So, it was possible to determine the best equation that approximates data trends (linear regression model, "least square line"):

$$6\,\text{month}-\text{TWL} = 1.1 \times (3\,\text{month}-\text{TWL}) + 0.01$$

This model allows us to predict the value of the 6-month TWL, and so the success or failure of the device, already at the third month of treatment. For example, if a patient has a weight loss of 0.08 kg (8 %) at the third month of treatment, it is expected that at the sixth month, they will have a weight loss equal to $1.1 \times 0.08 + 0.01 = 0.098$ (about 10 %).

The same correlation was found between a 3-month EWL and a 6-month EWL (Pearson's correlation coefficient $r = 0.84$, $p < 0.0001$) (Fig. 2b). In this case, the equation that approximated data trends (linear regression model, least square line) was

$$6\,\text{month}-\text{EWL} = 1.3 \times (3\,\text{month}-\text{EWL}) - 0.01$$

For example, if a patient has a weight loss of 0.25 (25 %) at the third month of treatment, it is expected that at the sixth month, they will have an EWL equal to $1.3 \times 0.25 - 0.01 = 0.31$ (about 31 %).

Follow-Up Period

After 12 months, following a removal follow-up period, a total of 72 patients were assessed. Their mean weight was 110.1 ± 25.2 kg with a reduction of 3.1 ± 7.4 kg with respect to baseline, and their mean BMI was 38.6 ± 7.8 kg/m^2 with a reduction of 1 ± 2.5 kg/m^2. Their mean final excess weight and BMI were 38.8 ± 22.8 kg and 13.6 ± 7.8 kg/m^2, respectively. A statistically significant weight regain compared with

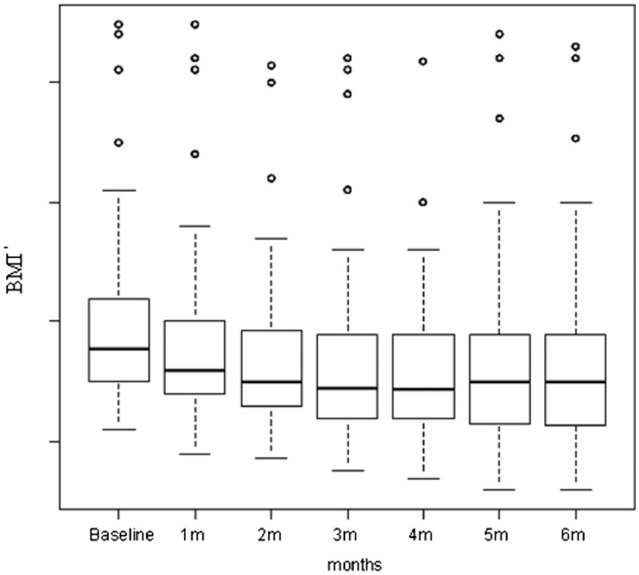

Fig. 1 BMI variations over the time. The weight reduction was observed in the first 3–4 months

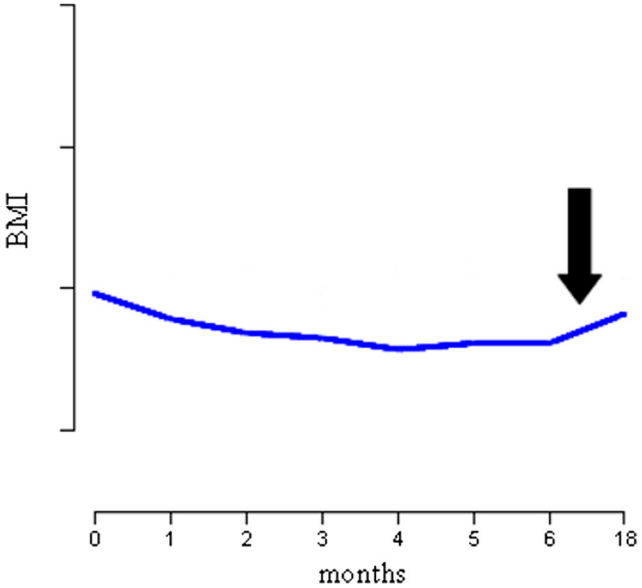

Fig. 3 BMI values during follow-up period. The *arrow* shows the weight regain after the balloon removal

6-month-period values was observed ($p < 0.001$), but the final weight was lower than the baseline (Fig. 3). Mean %EWL was 8.9 ± 20.6 and mean TWL was 2.7 ± 6.3 kg. In particular, 10 patients (13.9 %) continued losing weight, 14 subjects (19.4 %) kept their weight stable, whereas 31 cases (43.1 %) gained weight, although lower than the baseline observed, and finally, 17 (23.6 %) patients reached more weight from baseline.

We subsequently analyzed the relation between baseline BMI, age, gender, type of device (air-filled versus water-filled balloon) and EWL >20 % after a 6-month period and 18 months thereafter.

No statistically significant correlation between gender and EWL >20 % (*t* test and Mann–Whitney test) was found after a 6-month period or after 18 months. The same results were observed about age, but, in order to have homogeneous groups, the parameter age was divided in quartiles in this case.

By applying the one-way ANOVA test, we did not notice any statistical correlation between age and EWL >20 %, either after a 6-month period or during follow-up.

At the end of endoscopic treatment, we found a significant correlation between baseline BMI and EWL >20 % ($p = 0.0004$, $r = -0.41$) and TWL >10 % ($p = 0.003$, $r = -0.35$). Also now, the choice of cut-off was made according to the quartiles of the distribution of baseline BMI, so as to have homogeneous comparison groups. By comparing groups, it was observed that significant differences between baseline BMI and EWL occurred between ≤35 vs ≥42 kg/m^2 ($p = 0.003$) and ≤35 vs 38–42 kg/m^2 ($p = 0.04$) (one-way ANOVA test) (Fig. 4). However, no correlation was noticed after 18 months of follow-up.

At Student *t* test and Mann–Whitney test, a significant correlation between EWL/TWL and type of device was not found, either at a 6-month period or after 18 months thereafter.

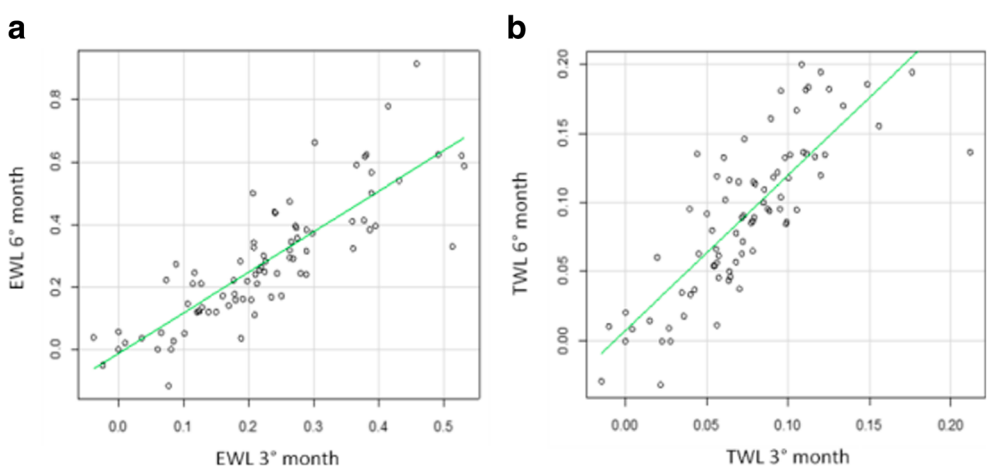

Fig. 2 **a** Correlation between 3-month TWL and 6-month TWL; **b** correlation between 3-month EWL and 6-month EWL. The linear correlation showed that the weight reached at the third month appeared to be predictive of the effectiveness of endoscopic treatment

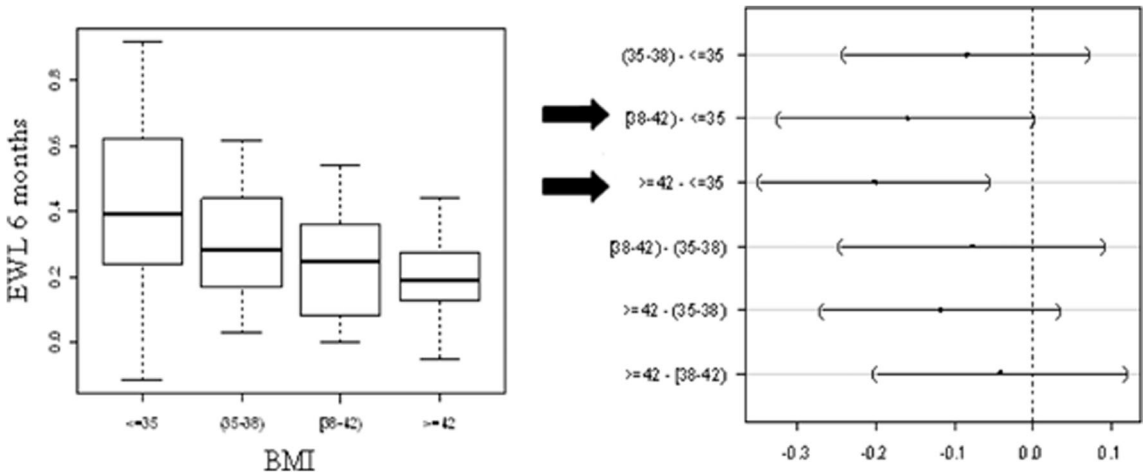

Fig. 4 Correlation between baseline BMI and EWL (one-way ANOVA test): the *arrows* show the groups of baseline BMIs of patients in whom the most EWL at 6 months was recorded

At removal, data showed a greater efficacy of the water-filled device compared to the air-filled balloon (mean weight loss 11 versus 8 %, respectively), without reaching statistical relevance.

Satisfaction

After 18 months since balloon placement, a questionnaire was administered to 72 patients. The survey was made up of three items. As shown in Table 1, 63 % of patients were not satisfied with the procedure and did not think it is useful to change their diet. In addition, most of them refused to undergo it again. Subsequently, a correlation between the failure declared by the patients and weight loss failure seen in the data analysis showed that the degree of satisfaction was independent of weight loss (χ^2 test, $p = 0.79$). Among the patients who had successful weight, 59.1 % were not satisfied with the procedure, and among patients who did not have any success weight, 65.3 % were unhappy with the procedure.

Conclusion

Obesity is a common, serious, and costly health problem that affects an increasing number of people. Obesity is often related to medical conditions including heart disease, stroke, type 2 diabetes, and certain types of cancer, some of the main preventable causes of death. The estimated annual medical cost of obesity in the USA was $147 billion in 2008; the medical costs for people who were obese were $1429 higher than those of normal weight.

There is no single or simple solution to obesity: increasing physical exercise and applying changes to diet and behavior are the first steps to lose weight. Many people fail to reach these goals; therefore, they resort to bariatric procedures.

The placement of an intragastric balloon device is a minimally invasive treatment associated to a minimal operational risk procedure. The use of an intragastric space-occupying device for treating obesity has been supported in the past by experiments on rats. Geliebter et al. proved that rats with ingested inflated balloon lost statistically more weight than rats with deflated balloons or no balloons [6]. Intragastric balloons were shown to slow gastric emptying besides reducing food intake.

We observed a statistically relevant decrease in weight and BMI after 6 months of treatment compared to baseline values. Most of the weight loss was observed in the first 3–4 months of treatment; the same has been shown by other studies [7, 8].

Although our data show an average weight loss inferior to the data of literature [8–14], in our study, a statistically significant reduction in weight was observed in 93.7 % of cases. In

Table 1 Questionnaire

	0 not at all	1 a little	2 fairly	3 very much
Are you satisfied with treatment?	35 %	28 %	16 %	21 %
Has the placement of the intragastric balloon made changes in your eating habits?	35 %	28 %	23 %	14 %
			Yes	No
Would you repeat it?			30 %	70 %

particular, most of the patients registered were found to have a weight loss superior to the cut-off of 20 %.

Statistically, a strong and linear correlation between a 3-month %EWL (and TWL) and 6-month results was noticed and the weight reached at the third month appeared to be predictive of the effectiveness of endoscopic treatment. Thus, we suppose that the third month could be the right time to make decisions. Considering that the main part of weight loss occurs in the first few months, if the weight lost by the patient is unsatisfactory at the end of the third month, the frequency of visits to the dietitian may be increased and physical activity encouraged. On the contrary, for not sufficiently motivated patients, removal of the balloon could be justified.

One year after the device removal, a weight regain was recorded but the mean final weight was lower than the baseline and 24 patients (33.3 %) maintained or continued losing weight.

Considering the relation between baseline BMI, age, gender, type of device (air-filled versus water-filled balloon), and EWL >20 % after a 6-month period and 18 months thereafter, we were aware of a clear correlation between baseline BMI and a 6-month weight only.

Our study results show that %EWL at the time of balloon removal was significantly higher in patients with lower compared to higher BMI categories. In particular, %EWL was higher in patients with BMI $\leq$35 kg/m^2 than those with $\geq$35 kg/m^2. This result is similar to other studies in the literature [7, 15]. This is an important tool because for patients with BMI $\leq$35, intragastric balloon placement is one of the few available procedures. According to the literature [16–18], our data showed weight gain, although lower than baseline, in 43.1 % of cases, whereas 23.6 % of patients [18] reached more weight from baseline.

In our study, two types of device were placed in order to compare their effectiveness: in 58 patients, the air-filled balloon was used, whereas the water-filled device was planted in 29 subjects. No link between the type of balloon and EWL at the time of removal or 1 year thereafter was found. Better preliminary results were achieved with water-filled balloon [19], but the difference was not significant, which might have resulted from the fact that a small sample size had been used.

The last endpoint of the study was the evaluation of patient satisfaction with the procedure. Several studies have investigated the quality of life obtained by weight loss using different questionnaires, such as Medical Outcomes Study (MOS) Short Form (SF-36) standard version, Health-Related Quality of Life (HRQL), and Bariatric Analysis and Reporting Outcome System (BAROS) [9, 20–22]. All these surveys are internationally approved and validated but are generic about intragastric balloon procedure. BAROS questionnaire is a specific survey for bariatric surgery involving %EWL, clinical improvement, procedure complications, and quality of life, but not satisfaction with the procedure. Only few studies involving patients treated with intragastric balloons are actually available for assessing the degree of satisfaction with the procedures adopted.

Our questionnaire was created as an internal quality control procedure in order to detect the subjective impressions of the effectiveness of intragastric procedure leaving out the quality of life of patients before and after the treatment. The survey was administered to all patients with an 18-month follow-up. Data showed a global dissatisfaction with the procedure. Another aim of this study was to verify the hypothesis that dissatisfaction with the procedure was related to weight loss failure. This could be not demonstrated although their BMI kept on declining significantly over the time.

The limitations of our study should be acknowledged for some reasons. Firstly, after intragastric balloon removal, no dietary counseling was conducted and patient eating behaviors and physical activity were not recorded. From the questionnaire, we know that eating habits were not modified. Secondly, weight variations and satisfaction degree were assessed through phone interviews. This modality of data collection is not objective and verifiable. On the other hand, we recorded data from all patients at the end of each follow-up, and not only by those with good results and motivated, which would have invalidated the statistical analysis.

In conclusion, intragastric device is a minimal operational risk procedure that achieves significant results within 6 months of treatment. Our data show a significant decrease in BMI during the balloon in place with a spike between the third and the fourth month of treatment. In addition, a water-filled balloon is more effective than an air-filled device, although this result did not reach statistical significance. Their weight decreased linearly; thus halfway through the procedure, a prediction of the final result can be made. If at the third month, weight loss is not the expected one, corrective strategies can be put in place or even consider removing the device. In our opinion, despite the encouraging results achieved in large population studies, the intragastric balloon success rate as a treatment option is still questionable [10, 12, 23]. During the follow-up period, patients regained gradually their weight; only subjects with lower BMI reached better results. Moreover, patients described an overall dissatisfaction with treatment. The device had not given them the tools to change their eating habits, and therefore, they would not repeat the same procedure.

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Compliance with Ethical Standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent was obtained from all individual participants included in the study.

Conflict of Interest The authors declare that they have no competing interests.

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