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CLINICAL RESEARCH

Short- and Long-Term Efficacy of Intragastric Air-Filled Balloon (Heliosphere® BAG) Among Obese Patients

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Abstract
Background Obesity is an increasing health problem worldwide. The intragastric balloon as a temporary endoscopic treatment of obesity can play an important role among the aforementioned group of obese individuals. It can also be used as a preoperative test before subjecting patients to restrictive bariatric surgery. Furthermore, the intragastric device may be applied to patients affected by severe obesity as a "bridge treatment" before they undergo major surgery in order to reduce chances of operation-related risks. To date, there are insufficient data in the literature on the long-term results of the intragastric balloon.

Methods Our study includes an analysis of our experience with Heliosphere® BAG from 2006 through to 2010, concerning early weight loss and weight loss maintenance over at least 18 months since the device's removal. The 32 patients who completed the 6-month treatment had recorded a mean weight loss of 12.66 kg and a mean overweight loss of 24.37 % (SD, 12.74).
Results A total of 16 patients are subjected to an 18-month follow-up. Their pretreatment and long-term body mass index (BMI) were calculated: 6 months later, when devices were removed, they showed a mean weight of 99.75 kg (SD, 17.90; $p<0.001$) and a mean weight loss of 13.62 kg and 26.14 % (SD, 12.79). 18 months after removing Heliosphere® BAG, the 16 patients' mean BMI was 37.28 kg/m² (SD, 5.41; $p=0.004$), with a mean weight of 103.56 kg (SD 17.25; $p=0.0125$), and a mean weight loss of 9.8 kg or 18.2 % (SD, 12.07).
Conclusions Heliosphere® BAG enables modest short-term weight loss with little side effects, although mid/long-term follow-up may entail partial weight gain. We believe it can be considered a useful bridge treatment in bariatric surgery in order to reduce chances of preoperative risks.

Keywords Intragastric air-filled baloon · Obesity · Endoscopy

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Introduction

Obesity is an increasing health problem in Italy and the world, leading to further comorbidities. The WHO recommends a 5–15 % decrease in body mass index (BMI) in order to lower chance of such comorbidities [1, 13]. Mere dietary and behavioral measures proved ineffective in most instances concerning long-term control of overweight.

In the long term, bariatric surgery proved to be the most effective measure in the treatment of obesity, both in terms of

lasting loss of overweight and of a decrease in comorbidities related to elevated BMI, leading to a decrease in mortality rates linked to pathological obesity [2–5]. However, the obese population includes a large group of individuals who do not follow a proper hypocaloric diet and, therefore, are not eligible for bariatric surgery for BMI-related reasons or because of their refusal to undergo surgery.

Having recorded significant weight loss among patients with gastric bezoars, several devices aimed at reproducing such conditions have been created since 1982 [15, 16]. The intragastric balloon as a temporary endoscopic treatment of obesity [6, 7] can play an important role among the aforementioned group of obese individuals [12]. It can also be used as a preoperative test before subjecting patients to restrictive bariatric surgery [14]. Furthermore, the intragastric device may be applied to patients affected by severe obesity as a "bridge treatment" before they undergo major surgery in order to reduce chances of operation-related risks.

Heliosphere® BAG, which is air inflatable [8], has been used alongside the water-inflatable device since 2004. Our own experience in treating pathological obesity began in 2004. The intragastric balloon was added to our range of treatments in 2006.

This work includes an analysis of our experience with Heliosphere® BAG from 2006 through to 2010, concerning early weight loss and weight loss maintenance over at least 18 months since the device's removal.

Patients and Methods

Of the patients, 45 underwent endoscopic treatment by intragastric balloon at the Department of General Surgery of Trieste's University Hospital between November 2006 and November 2010. The patients' mean age was 45 (range, 25–70); the group comprised 15 male and 30 female subjects.

Our data concerning the positioning includes patients affected by moderate obesity (BMI>30 kg/m²) with comorbidities or by severe obesity (BMI>35 kg/m²) even without comorbidities. Heliosphere® BAG was applied to patients affected by severe obesity as a preoperative device in order to facilitate initial weight loss and thus reduce operation-related risks [17, 18]. All patients were selected by a multidisciplinary team comprising of gastroenterologist, dietitian, and psychiatrist. Patients with extensive hiatal herniae, gastroduodenal ulcers, erosive gastritis, and with previous history of stomach surgery were excluded.

Positioning was carried out under conscious sedation. Patients were discharged within 24 h of the endoscopic procedure. All intragastric devices were removed through endoscopy under general anesthesia, discharging the patient within the first day. While hospitalized, patients were treated with endovenous antispastic (butylscopolamine) in case of abdominal pain or with endovenous prokinetics in case of vomiting. All patients took oral proton pump inhibitors (40 mg Pantoprazole) on a daily basis while keeping the intragastric device.

Patients were strictly overseen by the Bariatric and Dietary Departments, whose follow-up program included a first visit within 1 week of the discharge and further monthly check-ups until the device's removal. Overweight and its percentage loss were calculated according to the ideal weight obtained using Lorentz's formula [19]. Weight variations were assessed through phone interviews taking place after at least 18 months since removing the device.

Endoscopy

Positioning is carried out in the recovery room of the Anaesthesiology 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's 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 Heliosphere® BAG implantation, the latter being inflated with an injection 600 ml of air. Direct radiography of the abdomen is subsequently performed in order to assess its correct positioning.

Removal is carried out in the operating room with patients lying supine and under general anesthesia, as orotracheal intubation is deemed necessary to minimize risks of inhaling gastric liquid. Removing Heliosphere® BAG with the aid of the aforementioned endoscopes requires approximately 20 min and is only possible once the air has been sucked out using a specific set of tools provided by the same producers of the aforementioned intragastric device.

Results

Of the patients, 32 out of 45 have concluded the 6-month period, while the remaining 13 patients are still carrying the intragastric device. Three patients underwent laparoscopic gastric bypass surgery after having the device removed. Sixteen patients among all those who have completed the 6-month balloon treatment were contacted on the phone. By then, having their devices removed for at least 18 months was a precondition for assessing the efficacy of Heliosphere® BAG in terms of weight variations. No patients

Table 1 Results among all patients who completed the 6-month treatment

Thirty-two patients who completed the 6-month period				
Initial BMI	Post-removal BMI	Percentage of initial overweight	Percentage of overweight loss	Weight loss (kg)
40.22 kg/m² (SD, 5.74)	35.90 kg/m² (SD, 5.79)	83.83 % (SD, 20.24)	24.37 % (SD, 12.74)	12.66 kg

were subjected to early removal of the intragastric device, whereas only one case of spontaneous balloon exsufflation was recorded, with a displacement to the level of the ileocecal valve, leading to intestinal obstruction and requiring urgent surgery. After extraction, we verified the device surface and any injuries were observed.

All patients were discharged within 24 h of placing the device. Of the patients, 11 out of 45 repeatedly regurgitated during the first 10 h after said procedure: on average, the patients vomited 4.3 times after placement of the device intragastric. Post-insertion physical pain was always estimated according to the Visual Analog Scale and never exceeded level 4. The 32 patients who completed the 6-month treatment had recorded an initial mean BMI of 40.22 kg/m² (SD, 5.74), with a mean weight of 114.65 kg (SD, 21.37) and a mean overweight of 83.83 % (SD, 20.24).

Six months later, at the end of the treatment, their mean BMI was 35.90 kg/m² (SD, 5.79; $p<0.001$) with a mean weight of 102 kg ($p<0.001$), determining a mean weight loss of 12.66 kg and a mean overweight loss of 24.37 % (SD, 12.74; see Table 1).

A total of 16 patients are subjected to an 18-month follow-up. Their pretreatment and long-term BMI were calculated: their initial mean BMI was 40.62 kg/m² (SD, 5.32); their initial mean weight was 113.37 (SD, 19.82), while their mean overweight was 85.00 % (SD, 21.44). Six months later, when devices were removed, their mean BMI was 35.75 kg/m² (SD, 5.59; $p<0.001$), with a mean weight of 99.75 kg (SD, 17.90; $p<0.001$) and a mean weight loss of 13.62 kg and 26.14 % (SD, 12.79).

Eighteen months after removing Heliosphere® BAG, the 16 patients' mean BMI was 37.28 kg/m² (SD, 5.41; $p=0.004$), with a mean weight of 103.56 kg (SD, 17.25; $p=0.0125$), and a mean weight loss of 9.8 kg or 18.2 % (SD, 12.07; see Table 2).

Discussion

All publications consulted contain no assessments of the mid- and long-term efficacy of the air-inflated intragastric device. In about 56 % of the cases analyzed by a number of experts [10], patients successfully manage to maintain the weight lost throughout at least 12 months after removing the water-inflated balloon (BIB®, Bioenteric Intragastric Baloon), which they carried for 9 months on average as against the usual 6 months, with better results recorded among overweight patients during positioning (BMI <30). Further documents consulted highlight the positive results obtained using the same device (maintaining at least 10 % of overweight lost compared to initial weight) in 24 % of the instances, 2.5 years after removal [11].

We decided to use the air-filled device to reduce postoperative discomfort, such as epigastric pain, severe vomiting, that water filled balloons may cause.

Our data shows that air-inflated intragastric balloon Heliosphere® BAG leads to modest weight loss in the short term both in terms of BMI and percentage of excess weight loss. In particular, all our patients recorded an average 12.66 kg weight loss by the time they had their devices removed, with a BMI reduction of 4.32 points, enabling them to decrease their level of obesity from classes III to II. Such results are statistically significant and in line with the data found in other works [8, 9]. They are, however, secondary to an adequate multidisciplinary selection of patients before the procedure.

Among patients with an 18-month follow up, a slight weight recovery (3.82 kg on average) compared to post-removal levels has been recorded, with a subsequent BMI increase of 1.53 compared to data obtained after 6 months. Nevertheless, average body weight and BMI levels remain lower than pretreatment levels. Patients' level of obesity remains as class II. An 18.2 % overweight loss has been recorded after at least

Table 2 Results among 16 patients contacted at least 18 months after BIB removal

Sixteen patients contacted subsequently							
Initial BMI	Percentage of initial overweight	Post-removal BMI	Weight loss (kg)	Percentage of overweight loss	BMI after 18 months	Weight loss (kg) after 18 months	Percentage of overweight loss after 18 months
40.62 kg/m² (SD, 5.32)	85.00 % (SD, 21.44)	35.75 kg/m² (SD, 5.59)	13.62 kg	26.14 % (SD, 12.79)	37.28 kg/m² (SD, 5.41)	9.8 kg	18.2 % (SD, 12.07)

18 months since removing the device, with no additional bariatric interventions. It is a positive achievement for a non-surgery solution, although patients remain obese and continue to be exposed to its risks and comorbidities.

Considering a modest, midterm weight loss and, on the other hand, a slight weight increase in the mid and long term, the device can provide modest results in terms of weight loss, usually helping to maintain lower weight than before treatment. Furthermore, it may bring significant advantages as a bridge treatment to bariatric surgery to be carried out within few months after removing the balloon, according to data found in publications [17, 18]. Sequential treatment could be conceived for carefully selected patients with BMI <40 and no comorbidities. Following positive results obtained with the first treatment and, in case patients lack necessary prerequisites or refuse to undergo bariatric surgery, the second treatment would include positioning a second balloon after carrying out esophagogastroduodenoscopy in order to avoid gastric damage.

Conclusion

Air-inflated intragastric device (Heliosphere® BAG) enables modest short-term weight loss with little side effects, although mid/long-term follow-up may entail partial weight gain. We believe it can be considered a useful bridge treatment in bariatric surgery in order to reduce chances of preoperative risks. However, successful implementation is strictly related to pretreatment assessments and subsequent regular check-ups carried out by a multidisciplinary team of experts.

Conflicts of interest None.

References

1. WHO. Obesity: preventing and managing the global epidemic. Report of a WHO consultation on obesity. Geneva: WHO; 1998.
2. Buchwald H, et al. Bariatric surgery: a systematic review and methanalysis. JAMA. 2004;292:1724–37.
3. Maggard MA, Shugarman LR, et al. Meta-analysis:surgical treatmente of obesity. Ann Intern Med. 2005;142:547–59.
4. Sjostrom L, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med. 2007;357:741–52.
5. Christou NV, et al. Surgery decreases long-term mortality, morbidity, and health care use in morbidly obese patients. Ann Surg. 2004;240:416–24.
6. Galloro G, De Palma GD, Catanzano C, et al. Preliminary endoscopic tecnica report of a new silicone intragastric baloon in the treatment of morbid obesity. Obes Surg. 1999;9:68–71.
7. Weiner A, Gutberlet H, Bockhorn H. Preparation of extremely obese patients for laparoscopic gastric banding by gastric baloonm therapy. Obes Surg. 1999;9:261–4.
8. Trande P, Musetto A, Mirante VG, et al. Efficacy, tolerance and safety of new gastric air-filled balloon (Heliosphere BAG) for obesity: the experience of 17 cases. Obes Surg. 2010;20 (9):1227–30.
9. Forestieri P, De Palma GD, Formato A, et al. Heliosphere® BAG in the treatment of severe obesity: preliminary experience. Obes Surg. 2006;16:635–7.
10. Herve J, Wahlen CH, Schaeken A, Dallemagne B, Dewandre JM, Markiewicz S, Monami B, Weerts J, Jehaes C. What becomes of patients one year after the intragastric balloon has been removed? Obes Surg. 2005;15(6):864–70.
11. Dastis NS, François E, Deviere J, et al. Intragastric balloon for weight loss: results in 100 individuals followed for at least 2.5 years. Endoscopy. 2009;41(7):575–80.
12. Imaz I, Martínez-Cervell C, García-Alvarez EE, et al. Safety and effectiveness of the intragastric balloon for obesity. A meta-analysis. Obes Surg. 2008;18(7):841–6.
13. Goldstein DJ. Beneficial health effects of modest weight loss. Int J Obes Relat Metab Disord. 1992;16:397–415.
14. Loffredo A, Cappuccio M, De Luca M, et al. Three years experience with the new intragastric balloon, and a preoperative test for success with restrictive surgery. Obes Surg. 2001;11:330–3.
15. Nieben OG, Harboe H. Intragastric balloon as an artificial bezoar for treatment of obesity. Lancet. 1982;1:198–9.
16. Sallet JA, Marchesini JB, Paiva DS, et al. Brazilian multicenter study of the intragastric balloon. Obes Surg. 2004;14:991–8.
17. De Waele B, Reynaert H, Urbain D, et al. Intragastric balloons for preoperative weight reduction. Obes Surg. 2000;10:58–60.
18. Busetto L, Segato G, De Luca M, et al. Preoperative weight loss by intragastric balloon in super-obese patients treated with laparoscopic gastric banding: a case–control study. Obes Surg. 2004;14:671–6.
19. Lorentz FH. Der konstitutionsindex der Frau. Klin Wochenshr. 1929;16:734–6.