**HELIOSPHERE Scientific Articles**

**De Castro ML et al.** Obesity Surgery ; 2010 Apr 15  
Efficacy, safety, and tolerance of two types of intragastric balloons placed in obese subjects: a double-blind comparative study

**Sciumè C.** Annali Italiani di Chirurgica, 2009 mar-apr; 80(2):113-7  
Role of intragastric air filled ballon (Héliosphère bag) in severe obesity. Personal experience.

**Trande P et al.** Obesity Surgery, 2008 dec 10  
Efficacy, tolerance and safety of new intragastric air-filled balloon (Héliosphère bag) for obesity: the experience of 17 cases.

**Mion F et al.** Obesity Surgery, 2007; 17: 764-769  
Tolerance and efficacy of an air-filled balloon in non-morbidly obese patients: results of a prospective multicenter study.

**Forestieri P et al.** Obesity Surgery, 2006; 16(5):635-7  
Héliosphère bag in the treatment of severe obesity: preliminary experience.
Efficacy, Safety, and Tolerance of Two Types of Intragastric Balloons Placed in Obese Subjects: A Double-Blind Comparative Study.

De Castro ML, Morales MJ, Del Campo V, Pineda JR, Pena E, Sierra JM, Arbones MJ, Prada IR.

Department of Gastroenterology, Universitary Hospital of Vigo (CHUVI), Vigo, Galicia, Spain, luisadecastroparga@mundo-r.com.

Abstract

The intragastric balloon is a temporary treatment for obese patients. Fluid-filled devices have shown efficacy and safety, and are widely used. Recently, although there are no comparative studies between them, an air-filled balloon, Heliosphere(R) bag, has been proposed. Prospective, double-blind study in 33 patients with morbid and type 2 obesity: 23 female, 43.9 +/- 10 years, 120.3 +/- 17 kg, and body mass index (BMI) of 44.2 +/- 5 kg/m(2), placing 18 gastric balloons filled with 960 cm(3) of air (Heliosphere(R) bag) or 15 balloons filled with 700 ml of saline (Bioenterics-BIB(R)). Both balloons were placed with conscious sedation and removed under general anesthesia 6 months later. Intravenous drugs were given to control symptoms for 48 h. Patients were sent home on a 1000-kcal diet, multivitamin supplements, and oral proton pump inhibitors, and were followed monthly. Complications, symptoms, weight, and quality of life evaluated by the Gastrointestinal Quality of Life Index (GIQLI) scale were recorded. At 6 months, mean weight loss (12.8 +/- 8 vs 14.1 +/- 8 kg), BMI loss (4.6 +/- 3 vs 5.5 +/- 3 kg/m(2)) and percent excess weight loss (27 +/- 16 vs.30.2 +/- 17) showed no significant differences between both groups. At removal, two Heliosphere(R) bags were not found in the stomach, and four patients required extraction of the balloon by rigid esophagoscopy or surgery (p = 0.02). Tolerance was good in both groups, but early removal occurred in three BIB(R) (20%) due to vomits and dehydration. The GIQLI total scores remained unchanged. Both balloons achieve a significant weight loss with good tolerance in obese patients. Nevertheless, Heliosphere(R) bag has severe technical problems that need to be solved before recommending it.
INTRODUCTION: Obesity leads to serious health consequences, therefore many strategies are recommended for preventing or curing this emerging problem. Treatments are various: diet, physical activity, psychotherapy, drugs and bariatric surgery. In order to try to improve the tolerance of intragastric balloons, a new device inflated with air to improve weight loss was developed in 2004 (Heliosphere BAG). We report our personal experience about this tool.

MATERIAL AND METHODS: Between January 2005 and December 2007, in our unit, 50 intragastric air filled insertion were performed under analgosedation and endoscopic control. The balloon was removed (24 hours) in two patients (4%) for acute intolerance. In other 2 patients (4%) the balloon was easily removed after 5 months because of premature desuflation, radiologically confirmed. The remnant 46 balloons were removed after six months. We evaluated efficacy, tolerance and the safety of this procedure.

RESULTS: Forty one women and 9 men, with a mean age of 38.1 years (range 18-62), mean basal BMI of 39.8 (range 28-64) were included, after providing informed consent. Weight and BMI loss were evaluated on all patients. BMI decreased 5.9%, weight loss was 16.8 kg. Tolerance was very good, limited only to some dispeptic symptoms during the first 2 days after insertion. No serious technical problems were noted at balloon insertion. Balloon removal was very simple after correct desuflation after the conclusion of learning curve (10 procedures). DISCUSSION: The aim to treat obesity before bariatric surgery is based on reduction of bariatric surgical risks, general surgical risks and the prevalence of cardiovascular diseases, diabetes, musculoskeletal disorders and some cancers. CONCLUSIONS: The intragastric air filled balloon showed an acceptable profile of efficacy, good tolerance and improvement of comorbidities after 6 months.
Efficacy, Tolerance and Safety of New Intragastric Air-Filled Balloon (Heliosphere BAG) for Obesity: the Experience of 17 Cases

Paolo Trande · Alessandro Mussetto · Vincenzo G. Mirante · Elvira De Martinis · Giampiero Olivetti · Rita L. Conigliaro · Enrico A. De Micheli

Abstract

Background Overweight and obesity lead to serious health consequences, so that many strategies were recommended for preventing or curing this emerging problem. Treatments are various: diet, physical activity, psychotherapy, drugs, and bariatric surgery. Moreover, during these years, the use of intragastric balloon (BIB) to treat obesity increased rapidly, aimed to (1) reduce bariatric surgical risks; (2) reduce general surgical risks; (3) lead to a significant reduction in the prevalence of cardiovascular diseases, diabetes, musculoskeletal disorders and some cancers. Recently, a new device inflated with air to reduce weight has been developed since 2004 (Heliosphere BAG).

Methods Between March 2006 and September 2006, in our unit, intragastric air-filled balloon insertion was performed under general anesthesia and endoscopic control. The balloons were removed after 6 months. We evaluated efficacy, tolerance, and safety of this technique. Seventeen patients (eight men, nine women), with a mean age of 43 ± 10 years (range 18–65), mean basal BMI of 46 ± 8 (range 35–58) were included, after providing informed consent. Weight and BMI loss were evaluated in all patients.

Results BMI decreased 4 ± 3 (range +0.33/−11), weight loss was 11 ± 9 kg (range +1/−29.5; 8.5%). 14/17 patients maintain a BMI > 35 at the time of balloon removal. The difference between initial weight and BMI was statistically significant (p = 0.02 for weight and p < 0.01 for BMI, T Student test). Tolerance was very good, limited only to some dyspeptic symptoms during the first 3 days after insertion. One asymptomatic gastric ulcer was seen at the removal of balloon. Only one severe adverse effect was registered at the time of insertion (acute coronary syndrome in patient with chronic coronary disease). No serious technical problems were noted at balloon insertion. Balloon removal was more difficult and successful in 15/17 cases (one distal migration and one patient led to surgery because of balloon fragmentation).

Conclusion Intragastric air-filled balloon showed a good profile of efficacy and tolerance. Weight loss appeared to be equivalent to other type of balloons. On the other hand, technical problems (especially at the time of removal) probably linked to the device’s material, set a low safety profile.

Keywords Obesity · BMI · Intragastric balloon · Safety · Efficacy

Introduction

Obesity is a common chronic disorder that is affecting a gradually increasing part of the population in western countries. The relationship between severe obesity and serious diseases (hypertension, type 2 diabetes, hyperlipid-
emia, sleep apnea, musculoskeletal disorders, and some cancers) is now demonstrated [1]. To reduce the incidence of morbidities related to obesity, the World Health Organization recommended a decrease of 5% to 15% of body mass index (BMI) [2]. Treatment options to achieve this goal are various: diet, physical activity, psychotherapy, drugs, and bariatric surgery. During these years, the use of intragastric balloon to treat obesity increased rapidly, aimed to obtain weight loss in non-morbid obesity and/or to reduce bariatric surgical risks and general surgical risks [3, 4].

The intragastric balloons induce satiety by decreasing the capacity of the gastric reservoir, thereby reducing food intake and leading to weight loss. The main balloon tested was water-filled (Bioenterics Intragastric Balloon—BIB) [5, 6]. Complications and side effects were reported: low tolerance with nausea and vomiting, damage to gastric mucosa (ulcers), and spontaneous deflation leading to small bowel obstruction.

In order to limit digestive symptoms related to the weight of the balloon, and to improve the tolerance of intragastric balloons, a new device inflated with air has been developed since 2004 (Heliosphere BAG, Fig. 1), made of smooth external pouch of biocompatible silicone with a radio-opaque marker. It weighs 30 g, compared to 600–800 g for a water-filled balloon.

Many studies have been reported, in order to evaluate safety, tolerance, and efficacy of intragastric water- and air-filled balloon [7–9]. Less experience is registered with air-filled balloons. Here, we report a prospective analysis of efficacy, tolerance and safety of intragastric air-filled balloons (Heliosphere BAG) in 17 cases patients with morbid and non-morbid obesity.

### Patients and Methods

Obese patients were evaluated by a multidisciplinary team (surgeon, gastroenterologist, dietician, and a psychologist). Weight and BMI loss were evaluated on all patients. Inclusion criteria were failure to achieve weight loss within a diet-control program and a BMI of at least 35 kg/m² (grade II obesity). General exclusions criteria were: malignancy within the previous 5 years, pregnancy, alcoholism and drug abuse, and psychosis. Specific contraindications were gastrointestinal lesions like neoplasias, ulcers, angiodyplasias, varices, grade C/D esophagitis, large hiatal hernia (more than 3 cm) and previous bariatric surgery. Specifically informed consent was obtained by all patients. Heliosphere was performed under general anesthesia and endoscopic control. If previous endoscopy ruled out abnormalities, then the balloon was inserted under general anesthesia and endoscopic control. After standard endoscopy and lubrication of its sheath with lidocaine gel, the balloon was passed through esophagus down to the stomach, positioned in the gastric fundus. The end of the connection catheter was positioned 1–2 cm below the cardia, according to the manufacturer’s instructions. After this positioning, the balloon was released from its silicone envelope then inflated with 960 cc of air. Once released, the balloons’ correct location beneath the cardia was checked endoscopically.

During the first day after insertion, intravenous saline plus omeprazole (40 mg) and N-butilbromuro hyoscine (10 mg) was given to all patients. Ondasetron was administered only on demand, if nausea or vomiting occurred. In the first and second day, post-insertion patients began liquid diet and were discharged from hospital on day 3, with a protocol diet consisting of semi-liquid foods for the first week (800 kcal) then semi-solid until the removal (1,000 kcal). A specific and multidisciplinary follow-up was put into effect for all patients. The balloons were removed after 6 months, after complete air deflation. Endoscopic control was performed.

Between March 2006 and September 2006, in our unit, intragastric air-filled balloon was implanted in 17 patients (nine women). The mean age was 43±10 years (range 18–65), mean basal BMI 46±8 (range 35–58). We implanted the balloon in nine patients with a BMI>45, that were successively related to bariatric surgery, and in eight patients with a BMI between 35 and 45 (four patients presented poorly controlled hypertension and four failed to lose weight with diet and medical therapies).

### Results

Balloon insertion was successful in all cases, with a mean duration of 17 min (range 9–31); mean time of hospitalization
was 3.24 days (range 2–7). No technical problems were noted at balloon insertion. Only one clinical, severe adverse effect was registered at the time of insertion (acute coronary syndrome). Balloon removal was more difficult and successful in 15/17 cases. One patient showed distal migration of the balloon, and one underwent surgery because of balloon fragmentation. No one of these two patients had other side effects.

Weight loss was evaluated on all patients. BMI decreased 4±3 (range +0.33−11), weight loss was 11±9 kg (range +1−29.5; 8.5%). Fourteen of 17 patients maintained a BMI≥35 at the time of balloon removal (Table 1). The difference between initial weight and BMI was statistically significant (p=0.02 for weight and p<0.01 for BMI, T Student test). Only three of nine patients with morbid obesity underwent successively bariatric surgery.

Tolerance was very good, limited only to some dyspeptic symptoms during the first 3 days after insertion. Early nausea was in fact reported in 17/17 patients, vomiting in 12/17. These symptoms disappeared with “on demand” therapy and not registered after the first 3 days. An “endoscopic” side effect was registered at the removal of balloon: one asymptomatic gastric ulcer was noted (Fig. 2). Early satiety sensation was experienced in all patients after eating.

Discussion

The investigation about obesity and its relationship with serious diseases led, during the past years, to reconsider the use of intragastric balloon. This procedure was in fact abandoned about 20 years ago because of serious and frequent adverse side effects [10–12]. To reduce this collateral effect, new criteria for an “ideal” balloon were proposed [13]: roundness, smoothness, and with a radio-opaque marker. The air-filled intragastric balloon (Heliosphere BAG) respects those criteria. Moreover, its weight is 30 g, compared to 600–800 g of liquid-filled balloons, and about risk of spontaneous deflation, is made of an internal polyurethane envelope and an external silicone, to ensure air-tightness.

Transient collateral effect like nausea and vomiting are common, particularly in the first days after balloon implantation: in our series nausea was reported in 17/17 patients and vomiting in 12/17. After 6 months, mild/
moderate weight loss was obtained in 15 of 17 patients. No technical problems were noted at balloon insertion, while balloon removal was more difficult. One patient showed desufflation and distal migration of the balloon, while in one patient (5.8%), a surgical removal was necessary for balloon fragmentation.

This new device can be considered a good help for the temporary treatment of morbid and non-morbid obesity. In our experience, the Heliosphere BAG showed only some technical problems during its removal even if they can be considered serious side effects. The results in terms of weight loss and BMI loss were satisfactory and were similar to other balloons [5, 7, 8].

In conclusion, intragastric air-filled balloon showed a good profile of efficacy and tolerance. On the other hand, technical problems (especially at the time of removal) probably linked to the device’s material, set a low safety profile.

However, more controlled and larger studies are necessary to confirm the efficacy and the safety of this device.

References

Tolerance and Efficacy of an Air-filled Balloon in Non-morbidly Obese Patients: Results of a Prospective Multicenter Study

François Mion¹,²; Rodica Gincul; Sabine Roman¹,²; Sylvain Beorchia³; Frank Hedelius⁴; Nicolas Claudel⁵; Roger-Michel Bory⁶; Etienne Malvoisin⁷; Frédérique Trepo¹; Bertrand Napoleon⁶

¹Hospices Civils de Lyon, Fédération des Spécialités Digestives, Hôpital E. Herriot, Lyon; ²Université Claude Bernard Lyon 1, France; ³Clinique Sauvegarde, Lyon; ⁴Clinique Pasteur, St Priest; ⁵Polyclinique du Beaujolais, Arnas; ⁶Clinique Ste Anne-Lumière, Lyon; ⁷Fédération de Biochimie, Hôpital E. Herriot, Lyon, France

Background: Intragastric balloons have been proposed to induce body weight loss in obese subjects. Most studies were performed using liquid-filled balloons. Air-filled balloons may increase digestive tolerance. Our goal was to study the tolerance and efficacy of a new air-filled intragastric balloon in non-morbidly obese patients.

Methods: 32 patients were included, with a mean BMI of 35.0 (range 30.1-40.0). The balloon was inserted under general anaesthesia, inflated with 800 ml of air, and removed 4 months later. Tolerance and body weight were monitored until 12 months after removal. Ghrelin levels were measured before balloon insertion, 1 and 4 weeks after, and before removal.

Results: Weight loss was significant at 1, 2 and 4 months after balloon insertion (6, 7 and 10 kg, respectively, \(P<0.001\)). Early removal of the balloon occurred in 3 cases. 28 patients were contacted 12 months after balloon removal: 2 had undergone gastric banding; among the 26 remaining, the mean weight loss was 7 kg. 9 patients (30%) remained with a weight loss >10%, and satisfaction with the method was 87% for these 9 patients, and 22% for the other patients who had weight loss <10% (\(P<0.04\)). Fasting plasma ghrelin levels increased at week 1 and 4 after balloon insertion, and decreased at week 16 (\(P<0.001\)).

Conclusions. The air-filled intragastric balloon was safe. Its effect on weight loss appeared equivalent to other balloons. 12 months after balloon removal, 30% of the patients maintained a weight loss >10%.

Key words: Obesity, ghrelin, human, intra-gastric balloon

Introduction

Overweight and obesity are increasing worldwide. To reduce the incidence of morbidities related to obesity, the World Health Organization recommended a decrease of 5 to 15% of body weight, maintained throughout time.¹ Currently, the therapeutic options to achieve this goal are dietary restriction, physical activity, pharmacological drugs, and bariatric surgery for morbid obesity. The use of intragastric balloons has been advocated,²⁴ both as a way to obtain weight loss in non-morbid obesity,³ or before bariatric surgery in super-obese patients⁶-⁸ in order to decrease the mortality and morbidities related to these operations. In the 1980s, the first intragastric balloons available were air-filled polyurethane pouches with filling volumes from 200-500 ml. However, the high number of complications resulted in abandonment of these devices, and led experts to define the characteristics of an ideal intragastric balloon.⁹ Smoothness, durability and radio-opacity were the main criteria; unsolved design variables were shape, filling medium and volume.

Most recent results reported silicone intragastric balloons inflated with liquid. However, these liquid-filled balloons are frequently associated during the
first weeks after intragastric insertion with nausea and vomiting.\textsuperscript{10-12} These symptoms of digestive intolerance may be related to the weight of the balloon rather than to its size. In order to try to improve the tolerance of intragastric balloons, a new device inflated with air to reduce its weight has been developed (Heliosphere BAG\textsuperscript{®}, Helioscopie, Vienne, France). Its design follows the Tarpon Spring criteria.\textsuperscript{9} For smoothness and radio-opacity, the external pouch is made of biocompatible silicone with a radio-opaque marker. Its durability has been improved by the use of multiple pouches with a combination of materials with different properties. It weighs 30 g, instead of 600-800 g for a liquid-filled balloon. A preliminary report\textsuperscript{13} of this device in 10 morbidly obese patients, found it difficult to insert, and spontaneous deflation occurred in 4 out of 5 patients. Since then, the design of the Heliosphere BAG\textsuperscript{®} has been modified, especially by decreasing the size of the inflation valve, in order to improve its insertion and removal. We report here the tolerance and efficacy results of a prospective multicenter study with the modified Heliosphere BAG\textsuperscript{®}, in 32 patients with non-morbid obesity.

## Patients and Methods

Thirty-two patients (27 women), with a mean age of 35 years (range 18-57), mean BMI of 35 (range 31-40, <35 13 patients, \(\leq 40\) 19 patients) were included, after providing informed consent. The study had been approved by the CCPPRB Lyon B (local independent ethics committee). All subjects had failed previous attempts to lose weight by dietary restrictions. Patients were excluded from the study if they had previous digestive surgery (except for gallbladder removal and appendectomy), past history of gastric ulcer, or presence of a large hiatal hernia, severe esophagitis (\(\geq\)class B of Los Angeles classification) or severe gastritis at the time endoscopy. Before balloon insertion, subjects were measured and weighed, and blood samples were obtained for standard biochemistry, fasting glucose, cholesterol, triglycerides, TSH, total ghrelin, aspartate and alanine transaminases and gamma-glutamyl transferases levels. A standardized dietary questionnaire and a specific quality-of-life questionnaire (IWQOL-Lite)\textsuperscript{14} were administered.

Intragastric balloon insertion was performed under general anesthesia and endoscopic control: the Heliosphere BAG\textsuperscript{®} was inflated with 800 ml of air. All operators were expert endoscopists with previous animal and clinical experience with insertion and removal of the Heliosphere BAG\textsuperscript{®}. The total time for balloon insertion and early complications were recorded. A systematic follow-up including dietary counseling (to obtain a daily food intake of around 1300 kcal), a systematic interview about signs of digestive intolerance, physical examination, weight measurement, abdominal X-ray to detect balloon deflation, and quality-of-life questionnaire, was performed at week 1 and 4 after balloon insertion. Blood samples for fasting total ghrelin levels were obtained at week 1 and 4 after balloon insertion, and on the morning before balloon removal (week 16). Endoscopic balloon removal under general anesthesia and tracheal intubation (to avoid tracheal inhalation) was planned 4 months after balloon insertion. The total time for balloon removal and early complications were recorded. A final visit was planned 1 year after balloon removal for physical examination and body weight measurement. The patients’ satisfaction with the procedure was evaluated at that time.

## Statistical Analyses

All results are expressed as mean (range), unless otherwise indicated. Temporal evolution of weight, quality of life and ghrelin results were analyzed using ANOVA for repeated measurements. The PLSD Fischer’s test was used for post-hoc comparisons. Analyses were performed using Statview\textsuperscript{®} for Windows software (SAS Institute Inc, v5.0, Cary, NC, USA).

## Results

### Technical Considerations

Balloon insertion was successful in all cases, with a mean duration of the procedure of 12 minutes (range 8-30). Difficulties were encountered in two cases in opening the sheath, in three cases due to the impression of an incomplete unfolding of the balloon, and in one case for the separation of the balloon from its insertion catheter. The mean diameter of the balloon on X-ray at day 1 was 130 mm (range 113-142 mm).
Balloon removal was successful in all cases, but frequently more difficult than insertion, with a mean duration of the procedure of 21 minutes (range 5-80) \((P<0.0001\) vs time for insertion). Two successive procedures were needed in one case (the balloon was removed with a larger endoscope with two operating channels). The balloon was estimated to be deflated by >50% in two patients. The upper GI endoscopy revealed no lesion except for one gastric ulceration. The endoscopists reported difficulties: to introduce the needle of the catheter into the balloon in 1 case; to grasp the balloon with the removal catheter in 6 cases (use of a rescue polypectomy snare in 3 cases); and to remove the balloon in 11 cases (10 cases at the esophagogastric junction and 3 cases at the upper esophageal sphincter). These difficulties were found to be related to the size of the inflation valve, which has been further modified since that time.

**Balloon Tolerance**

In three cases, patients requested balloon removal between 3 and 52 days after balloon implantation because of severe left upper quadrant abdominal pain (2 cases) and psychological intolerance (1 case). Abdominal pain was reported as moderate to severe in 11 patients at week 1. Early nausea and vomiting were reported by 27 patients (84%): the mean duration was 3.1 days (range 1-8). Only 4 patients (13%) reported mild and intermittent episodes of vomiting at week 4.

**Weight Loss**

Weight loss was evaluated on 28 of the 32 patients: one patient did not return for balloon removal despite several phone calls and letters with acknowledgment of reception, and the 3 patients in whom balloon removal was performed earlier than planned were excluded from the analysis (per protocol). Body weight significantly decreased at week 4, 8 and 16 after balloon insertion (Figure 1). The mean percentage of body weight (BW) loss at week 16 was 9.3\% (range 3-20). Nine patients lost >10\% of BW with the balloon. Twelve months after balloon removal, 2 patients had undergone gastric banding in the interval: among the 26 patients remaining, the mean percentage of BW loss was 8.6\% (range -5 to 24). Eight patients (30\%) maintained weight 10\% lower than their initial BW. In terms of BMI, 5 patients were <30 kg/m\(^2\) and 16 were 30.1-35 kg/m\(^2\). Only 7 patients remained had a BMI >35 kg/m\(^2\). No significant changes in blood pressure and blood biochemistry were noted before insertion and before removal (week 16) of the balloon (data not shown).

**Quality of Life**

The IWQOL-Lite score was significantly improved at week 16 after balloon insertion compared to pre-insertion values (Figure 2, \(P=0.0032\)). A significant improvement of the score was observed for the mobility \((P=0.0027)\) and work \((P=0.0234)\) dimensions, but not for the self-respect \((P=0.074)\), sex \((P=0.111)\) and social life \((P=0.183)\) dimensions.
Of the patients, 60% were satisfied with the balloon method for weight loss, at 1 year after balloon removal. Among the 8 patients with weight loss >10%, 7 (88%) were satisfied with the method, while only 4 of 18 patients (22%) with a weight loss ≤10% were satisfied (P=0.0358).

Ghrelin Results

Fasting total ghrelin plasma levels significantly increased at week 1 and 4, and returned to pre-balloon insertion values at week 16, before balloon removal (Figure 3). No correlation was found between the variations of ghrelin levels and body weight loss (data not shown).

Discussion

Intragastric balloons have regained popularity for the treatment of obesity. After an initial period of interest in the early 1980s, the procedure was abandoned quickly because of the frequency of severe adverse events, mainly intestinal obstruction due to balloon migration beyond the stomach. The criteria for an “ideal” balloon were proposed in 1987. The new Heliosphere BAG® respects those criteria: it is round, smooth and contains a radio-opaque marker. With regard to the filling of the balloon with air rather than with liquid, the idea was to reduce digestive intolerance of the balloon by decreasing its weight: the inflated Heliosphere® balloon weighs 30 instead of the 600-800 g of liquid-filled balloons. One sham-controlled study using the air-filled 500-ml Ballobes® balloon showed that this kind of balloon was safe, but did not result in additional benefit in terms of weight loss compared to a very low-caloric diet. By increasing the size of the balloon (800 ml instead of 500), the objective was to improve efficacy. With regard to the risk of spontaneous deflation, this new air-filled balloon is made of an internal polyurethane envelope and an external silicone, to ensure both air-tightness and smoothness.

In terms of efficacy on weight loss, our results are comparable to those reported in the literature with liquid-filled balloons. This weight loss was accompanied by a significant improvement in quality of life. This well-being related to weight loss may encourage patients to go on with their modified lifestyle and food habits acquired while the balloon was in place in the stomach. Although the majority of patients regained some weight 1 year after balloon removal, 30% of our patients retained a 10% body weight loss at the end of follow-up.

With regard to BMI, it must be stressed that 12 months after balloon removal, 5 patients were below the obesity cut-off (BMI < 30), while only 7 still had a BMI ≥35. Intragastric balloons may thus be useful in the long term in selected patients, as shown by other studies. In terms of digestive tolerance, our results in the first week appear to be similar to those reported in the literature with the liquid-filled balloon, ranging from 40 to 90% but without the dehydration or other electrolytic problems usually described. Abdominal pain was the cause of early removal of the balloon in 2 cases: this observation has also been made with liquid-filled balloons. We did not find any endoscopic lesions at the time of balloon removal, except for one asymptomatic gastric ulcer. Small bowel obstructions, hemorrhagic ulcers and gastric perforations have been reported with liquid-filled balloons, albeit in much larger series than ours. Contrary to the study reported by Forestieri et al, we found this air-filled balloon safe, with only 2 cases of spontaneous deflation of >50% at the time of balloon removal.

The endoscopic insertion and removal techniques are not difficult, but specific training is recommended, to decrease the duration of the learning curve. Some difficulties have been reported by the endoscopists in our study, especially for balloon removal. Most problems were related to the size of the inflat-
ing valve, resulting in difficult passage of the balloon through the cardia and the upper esophageal sphincter. Since then, the valve design has been modified.

Weight loss in obese patients is associated with changes in levels of hormones involved in the regulation of satiety and energy metabolism. Blood levels of leptin are increased in obese subjects in relation to the adipose tissue mass, and decreased with weight loss. Adiponectin levels are decreased in obese subjects, and this decrease parallels the development of insulin resistance. Ghrelin, a hormone with orexigenic and adipogenic properties, primarily secreted by the fundic glands of the stomach, is usually decreased in states of excessive caloric intake. Its secretion increases with diet-induced weight loss, as one of the compensatory responses of the body to an energy deficit. Our results showed a significant increase of plasma ghrelin levels during balloon treatment, probably related to the negative caloric balance during the first 4 weeks after balloon insertion. Ghrelin levels before balloon removal returned to the values before balloon insertion.

In conclusion, this preliminary study shows that the Heliosphere BAG is safe, and efficient in terms of initial weight loss. In some patients, this initial weight loss is maintained 12 months after balloon removal. Specific training may be required for the endoscopic insertion and removal of the balloon. Its tolerance appears acceptable: this balloon may represent another therapeutic option for the multidisciplinary management of obesity. A registry has been implemented in France to monitor balloon safety and assess weight loss 1 year after balloon removal, in the setting of morbid obesity. Controlled trials and studies looking at the mechanisms of action of the gastric balloon are still needed.

This study was undertaken by the Société Française d’Endoscopie Digestive (SFED). The design of the study and data analyses were performed by the authors, independently from the maker of the balloon (Helioscopie, Vienne, France). Helioscopie provided the balloons for the study.

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Heliosphere® Bag in the Treatment of Severe Obesity: Preliminary Experience

P. Forestieri; G.D. De Palma; A. Formato; M. E. Giuliano; A. Monda; V. Pilone; A. Romano; S. Tramontano

Università degli Studi di Napoli Federico II, Dipartimento Universitario di Chirurgia Generale, Geriatrica, Oncologica e Tecnologie Avanzate, Cattedra di Chirurgia Generale, Naples, Italy

Background: Various intragastric balloons have been used in obese patients for temporary weight loss. Recently, a new balloon, the Heliosphere® Bag, was proposed. In a preliminary study, we evaluated the safety and efficacy of this device.

Methods: The Heliosphere® Bag was used in 10 patients, selected according to the guidelines for obesity surgery. The manufacturer's instructions were followed in positioning the device. Heliosphere® Bag positioning was performed, after diagnostic endoscopy, under unconscious sedation. After placement, the balloon was slowly inflated with 840-960 cc of air, which gives the inflated final volume of 650-700 cc of air, as the air is compressed. On the first and second post-treatment day, intravenous saline (30-35 ml/kg/d) with omeprazole (20 mg/d), ondansetron (8 mg/d) and butylscopolamine bromide (20 mg t.i.d.) were given to all patients. All patients from day 3 after placement began liquid diet and were discharged home on day 4 on a 1000 kcal diet (carbohydrate 146 g, lipid 68 g, protein 1 g/kg ideal weight). After 6 months, the Heliosphere® Bag was removed. The patients were followed monthly, and complications and their treatment, post-placement symptoms, BMI and %EWL were recorded. Data were expressed as mean ± SD.

Results: From Sept-Dec 2004, 10 patients (5M/5F) underwent Heliosphere® Bag placement, with age 35.2 ± 15.7 years (17-49), BMI 43.3 ± 8.1 kg/m² (35-51.2), and weight 126.8 ± 23.7 kg (98.4-148). Heliosphere® Bag positioning was quite difficult in all patients due to low pliancy and large size of the bag, causing patient discomfort. System failure at time of Heliosphere® Bag positioning was observed in 5/10 patients (50%). At time of removal, the Heliosphere® Bag was not found in the stomach in one patient. In 3 other patients, the balloon was found partially deflated. At the time of balloon removal after 6 months, BMI was 37.4 ± 13.4 (28.9-42.1) and %EWL was 29.1 ± 20.1 (9.0-57.4). BMI loss was 5.2 ± 13.1 (1.9-11.2) and mean weight loss was 17.5 ± 16.2 kg (5-33).

Conclusions: Although weight loss was satisfactory, this device cannot be considered an advance for the temporary treatment of morbid obesity. This balloon still has some instrumental and technical problems that need to be solved: high rate of system failure at positioning, high rate of spontaneous deflation, absence of a marker such as methylene blue, and large size with low pliability that cause significant patient discomfort.

Key words: Morbid obesity, intragastric balloon, Heliosphere® Bag, weight reduction program

Introduction

The idea of using a gastric space-occupying device, giving satiety sensation, for the treatment of obesity, was first described by Nieben in 1982. This concept arose from observations in patients with gastric bezoars. During the years, several intragastric air-filled free-floating balloons were proposed. After an initial enraptured period, a critical phase followed because of the failure and/or high complication-rate of the Garren-Edwards, Ballobes, Taylor, and Wilson-Cook balloons. In the last few years, the BioEnterics Intragastric Balloon (BIB®) was introduced, with a very low complication rate and satisfactory reported weight loss. More recently, a new intragastric balloon, the Heliosphere® Bag, was proposed for obesity treatment. We evaluated the safety and efficacy of this new device, preliminarily.
Patients and Methods

The Heliosphere® Bag was implanted in 10 patients, who were selected according to the guidelines for bariatric surgery. These patients were evaluated independently by internists, dieticians and psychologists for preoperative selection. Specifically written informed consent was signed by all the treated patients.

The Heliosphere® Bag consists of a double bag polymer balloon covered with a silicone envelope, an introduction kit pre-connected to the intragastric balloon for air-filling, and the extraction kit consisting of an emptying catheter and extraction forceps provided in separate packaging. Heliosphere® Bag positioning was performed, after diagnostic endoscopy, under unconscious sedation. The first two balloons were placed under conscious sedation, but because of patient discomfort and difficulties to insert the device, all others underwent unconscious sedation.

After lubrication of its protective sheath, the balloon was passed and positioned in the gastric fundus beneath the inferior esophageal sphincter. The end of the connection catheter was positioned 1-2 cm below the cardia, according to the manufacturer’s instructions. After this positioning, the balloon was released from its silicone envelope by cutting its safety loop and pulling on the end thread of a small chain. The injection catheter was connected to a 60 cc syringe, and the balloon was slowly inflated with 960 cc of air, which gives the final inflation volume of 700 cc of air, as the air is compressed (The balloon cannot be repositioned during the filling process without risking premature disconnection of the filling catheter). Once filled, the stainless steel cannula was unscrewed and the needle within the catheter was removed, and then the balloon was released by pulling gently on the filling-catheter while the balloon lay against the tip of the endoscope or the inferior esophageal sphincter. Once released, the balloons’ correct location beneath the cardia was checked endoscopically. The balloon is not radiopaque but the tip is radiopaque.

On the first and second day after insertion, intravenous saline (30-35 ml/kg/d) with omeprazole (20 mg/d), ondansetron (8 mg/d) and butylscopolamine bromide (20 mg t.i.d.) were given to all patients. All patients from day 3 post-placement began liquid diet and were discharged from hospital on day 4, a roughly 1000 kcal diet (carbohydrate 146 g, lipid 68 g, and protein 1 g/kg ideal weight).

Six months after placement, the Heliosphere® Bag was removed, after complete air-deflation by a dedicated instrument inserted through the operating channel of the gastroscope. Then, the balloon was grasped and gently withdrawn.

Patients were followed monthly, and complications and their treatment, symptoms, BMI and percent excess weight loss (%EWL) were recorded. Data were expressed as mean ± standard deviation.

Results

From Sept-Dec 2004, 10 patients (5M/5F) underwent Heliosphere® Bag placement. Age was 35.2 ± 15.7 years (17-49), BMI 43.3 ± 8.1 kg/m² (35-51.2), and weight 126.8 ± 23.7 kg (98.4-148). The bag positioning was slightly difficult in all cases due to rigidity and large size of the device causing patient discomfort.

System failure at time of Heliosphere® Bag positioning was observed in 5/10 patients (50%). In 2 patients, it was impossible to unscrew the steel cannula after air-inflation of the balloon, and the connection tube was extracted with its mandril. In the other 3 patients, rupture of the pulling thread that opens the balloon from its wrapper into the stomach was observed; in these 3 patients, the connection tube was opened longitudinally to expose the remnant of the thread. A new balloon was inserted in the patients who had system failure at time of positioning.

At the time of removal, the Heliosphere® Bag was not found in the stomach of one patient. Abdominal X-rays were negative. After 20 days, the patient had repeat abdominal x-rays and underwent CT-scan. Because the Heliosphere® Bag was not found, we conclude that it passed in the stool. In 3 other patients, the balloon was found partially deflated.

At time of Heliosphere® Bag removal after 6 months, BMI was 37.4 ± 13.4 (28.9-42.1), %EWL was 29.1 ± 20.1 (9.0-57.4), BMI loss was 5.2 ± 13.1 kg/m² (1.9-11.2), and weight loss was 17.5 ± 16.2 kg (5-33).

All the patients completed 6 months of treatment without serious complications except nausea and vomiting in the first days after placement. Early satiety sensation was experienced in all patients after eating.
Discussion

In 1987, 75 international gastroenterology experts at a Tarpon Springs meeting conceived the attributes considered fundamental for a good intragastric balloon. These attributes are a smooth surface with no external seams or protuberances which could cause gastric mucosal ulcerations, a small and flexible deflated balloon that can be inserted and removed under direct endoscopic vision, filled with fluid for weight, and made of a soft and highly elastic material. The Heliosphere® Bag in this study is of large size and not resilient enough, causing some difficulties and resistance during pharyngeal and esophageal passage, with patient discomfort. Moreover, the Heliosphere® Bag is air-filled (floating), one of the considered causes of low success and complications of previous intragastric devices. Methylene blue instilled into saline-filled balloons allows detection of balloon rupture, and its absence leads to exposing patients to several disturbing diagnostic procedures. One patient in this study was exposed to repeated X-ray radiation due to the absence of any signal of balloon deflation and its passage in the stool.

At the moment, this new device cannot be considered an advancement for the temporary treatment of morbid obesity. The Heliosphere® Bag has some instrumentation and technical problems that need to be solved: a high rate of system failure on positioning, high rate of spontaneous deflation, absence of an indicator such as methylene blue, and large bag size with low pliancy that cause high patient discomfort. The results of this experience with the Heliosphere® Bag in terms of mean %EWL (29.1), weight loss (17.5 kg) and BMI loss (5.2 kg/m²) were satisfactory. However, its efficacy in weight loss should be proved by larger series. At the moment, we suggest that the use of the Heliosphere® Bag be limited to controlled clinical trials and only in referral centers for obesity treatment. These studies should be conducted only after basic structural design modifications are completed and have been shown to be effective.

None of the authors has any commercial involvement with any intragastric balloon.

References


(Received December 13, 2005; accepted January 10, 2006)
## Syntheses of HELIOSPHERE articles

<table>
<thead>
<tr>
<th>Patients</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>33</td>
<td>50</td>
<td>17</td>
<td>32</td>
<td>10</td>
</tr>
<tr>
<td>18 Héliosphère®</td>
<td>15 Bioenteric®</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Extraction</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
<td>4 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Mean Age (years)</td>
<td>-</td>
<td>38.1 (18-62)</td>
<td>43 (18-65)</td>
<td>47 (24-60)</td>
<td>35.2 (17-49)</td>
</tr>
</tbody>
</table>

### EFFICACITE

<table>
<thead>
<tr>
<th>Initial BMI(kg/m²)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
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<tbody>
<tr>
<td>44.2</td>
<td>39.8</td>
<td>46</td>
<td>36.8</td>
<td>43.3</td>
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<table>
<thead>
<tr>
<th>BMI Loss (kg/m²)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
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</thead>
<tbody>
<tr>
<td>H : 4.6</td>
<td>5.9%*</td>
<td>4</td>
<td>5</td>
<td>5.2</td>
<td></td>
</tr>
<tr>
<td>B : 5.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>final BMI (kg/m²)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
</tr>
</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>34.6</td>
<td>37.4</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight Loss (kg)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
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<tbody>
<tr>
<td>H : 12.8</td>
<td>16.8</td>
<td>11</td>
<td>13.1</td>
<td>17.5</td>
<td></td>
</tr>
<tr>
<td>B : 14.1</td>
<td></td>
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<table>
<thead>
<tr>
<th>Excess Weight Loss (%)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
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</thead>
<tbody>
<tr>
<td>H : 27%</td>
<td>31%</td>
<td>-</td>
<td>31%</td>
<td>29.1%</td>
<td></td>
</tr>
<tr>
<td>B : 30.2%</td>
<td></td>
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<td></td>
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### TOLERANCE

<table>
<thead>
<tr>
<th>Vomitting &amp; nausea (%)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Late : 20%</td>
<td>0%</td>
<td>-</td>
<td>-</td>
<td>Early : 84% Mean time : 3.1 days</td>
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<table>
<thead>
<tr>
<th>Epigastric Pain (%)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
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<tbody>
<tr>
<td>-</td>
<td>0</td>
<td>-</td>
<td>Early : 31%</td>
<td>-</td>
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<table>
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<tr>
<th>Early Extraction (%)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H : 0%</td>
<td>4% (intolerance)</td>
<td>0%</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>B : 20%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deflated (%) / Migration (%)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H : - / 11%</td>
<td>4% (à 5 months) / 0%</td>
<td>- / 6%</td>
<td>0%</td>
<td>30% / 10% (n=1)</td>
<td></td>
</tr>
<tr>
<td>B : - / 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Occlusion</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
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</thead>
<tbody>
<tr>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Gastric Perforation (%) Mortality (%)</th>
<th>De Castro ML.</th>
<th>Sciumè C.</th>
<th>Trande P.</th>
<th>Mion F.</th>
<th>Forestieri P.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>
International Federation for the Surgery of Obesity and metabolic disorders XIV World Congress
Paris, France
2009

- O-099 From Overweight to Super-Obesity: The Efficacy of Air Filled Balloon.
  A. Giovanelli

- O-102 Gastric Balloon Efficiency on Weight Loss (WL) with a Multidisciplinary Medical Follows Up.
  V. Costil

- P-158 Caribbean Prospective Multidisciplinary Study of Management of Obesity with the Air-Filled Intragastric Balloon.
  R. Romney

- P-259 Air Filled Balloon - Brazilian Multicentric Study.
  M. Falcao

- V-053 Video Demonstration of Safe and Quick Extraction of Héliosphère Intragastric Balloon.
  B. Napoléon
O-099 From Overweight to Super-Obesity: The Efficacy of Air Filled Balloon

Presenter: A. Giovanelli
Cliniche Humanitas Gavazzeni, Bergamo, Italy

Background: Intragastric balloon may be used in overweight, morbid obesity and even in super-obesity as a pre-surgical weight-loss procedure. An interdisciplinary approach is related with the best results and weight loss maintenance.

Methods: More than 800 air-filled balloon implantations have been studied till now. 602 treated patients data are available from multiple case series in Europe. Our aim is to assess the efficacy of the Heliosphere balloon in the three main indications: BMI below 35, BMI between 35 and 50 and BMI above 50. All cases were recorded in the same database.

Results: Balloon insertion and removal were successful in all the procedures. Tolerance was excellent with less than 3% of early removal for abdominal pain or psychological intolerance. At removal, the 167 patients with BMI below 35 have lost an average of 12.2 kg±1.14 (62% of excess weight loss). The 353 patients with BMI between 35 and 50 have lost an average of 19.8 kg±1.2 (51.3% of EWL). The 63 patients with BMI above 50 have lost an average of 15.9 kg±2.6 (BMI reduction of 5.88 kg/m).

Conclusion: Air-filled intragastric balloon may be used in weight loss control in each level of overweight or obesity. The procedure is efficient and safe. The new generation of Heliosphere intragastric balloon makes the procedure even safer. To obtain the best results in a long term, a multidisciplinary nutritional and psychological follow-up is required.
O-102 Gastric Balloon Efficiency on Weight Loss (WL) with a Multidisciplinary Medical Follows Up

Presenter: V. Costil
Centre des médecins spécialistes de la Défense, Paris la Défense, France

Methods: Since 30 months, 137 patients are included in a prospective, comparative and non-randomized study. The average of initial BMI was 33.9 kg/m with the mean excess weight of 25.1 kg. Both types of gastric balloons were implanted for 6 months then removed. Throughout their use and after extraction, medical follow-up by a gastroenterologist, nutritionist and psychiatrist were done to help modify alimentary habits and behavior.

Results: From the 108 extractions done, EWL was 54.7±1.0 %, WL was 10.5± 1.5 kg and BMI decrease was 4.1 kg/m. For the patients who are compliant with the multidisciplinary follow-up, their weight still decreases (WL 16 kg after 12 months). Between both HELIOSPHERE® and BIB® gastric balloons, the weight loss was similar (9.6 kg vs 11.4 kg N.S.) but adverse events, such as nausea and vomiting (p<0.05) and retrosternal burning (15.6% vs 31.4% N.S.), were less with the HELIOSPHERE®. For overweight and obese people which are not indicated for bariatric surgery (BMI too low), gastric Balloon is a good way to lose weight significantly. Results show that the compliance during 12 months to a regular multidisciplinary following-up is essential to avoid weight regain or to continue losing weight. However, if the longterm follow-up is neglected, weight regain can be significant.

Conclusion: Gastric balloon can help overweight and obese patients, for whom bariatric surgery may be contraindicated, to reduce weight. Behavior change is essential to avoid weight regain.
P-158 Caribbean Prospective Multidisciplinary Study of Management of Obesity with the Air-Filled Intragastric Balloon

Presenter: R. Romney
Hepatology-Gastroenterology, Baie-Mahault, Guadeloupe

Co-authors: M. Durand 1, D. Siarras 2, S. Beauvarlet 3, S. Dagnaux 1, P. Bourgeois 1, R. Riahi 4, S. Clairville-Etzol 5, Y. Partouche 6
1Cabinet médical des Galeries de Houelbourg BAIE-MAHAULT Guadeloupe;
2Cabinet de nutrition BAIE-MAHAULT Guadeloupe;
3Cabinet de diététique BAIE-MAHAULT Guadeloupe;
4Chirurgie Plastique Reconstructrice et Esthétique BAIE-MAHAULT Guadeloupe;
5Cabinet de chirurgie digestive et générale Pointe-à-Pitre Guadeloupe;
6Service de médecine de la Clinique les Eaux Claires BAIE-MAHAULT Guadeloupe

Background: In the French Caribbean, obesity has recently become a plague due to diminution of exercise, stressful life and occidental diet. 40% of the adult population is considered overweight and children’s obesity has reached 10% at the age of; 6The aim of the study was to assess the benefit of a multidisciplinary program to cure obesity in our population including the Héliosphere air balloon.

Methods: From February 2007 to March 2009, 75 patients were followed by a multidisciplinary group and treated with Héliosphère. The group was composed of two gastroenterologists, a psychologist, a nutritionist and a physical coach. Every patient signed up to see regularly each member of the group. The results are given in mean ± standards deviations.

Results: 75 patients (6 M/69F, age: 36.6 years ± 2.06) have an average initial BMI of 39.43 kg/m² ± 1.48. After 6 months follow-up, subject showed significant reduction in weight (15.18 kg ± 1.88), percent excess of mass loss (42.49 % ± 5.44) and BMI loss (5.44 kg/m² ± 0.68). There were few sideeffects: epigastric pain (7%), no early removal. Minor complications were oesophagitis reflux (4%) and constipation (16%). 5 patients experienced spontaneous deflations after more than 6 months, only one led to a small bowel obstruction solved by a surgical approach. We observed 65% of improvement or resolution of comorbidities.

Conclusions: With a multidisciplinary approach, Heliosphere intragastric balloon has been effective to control obesity inducing an excess weight loss of almost 43%. It was not associated with mortality nor major complication during the 6 month period.
CARIBBEAN PROSPECTIVE MULTIDISCIPLINARY STUDY OF MANAGEMENT OF OBESITY WITH THE AIR-FILLED INTRAGASTRIC BALLOON

Rémy ROMNEY M.D., Cabinet Médical des Galeries de houelbourg — GUADELOUPE

BACKGROUND:
In the French Caribbean, obesity has recently become a plague due to diminution of exercise, stressful life and occidental diet. 40% of the adult population is considered overweight and children’s obesity has reached 10% at the age of 6. The aim of the study was to assess the benefit of a multidisciplinary program to cure obesity in our population including the HELIOSPHERE air balloon.

METHODS:
From February 2007 to March 2009, 75 patients have been treated with HELIOSPHERE®:

69 women & 6 men
Mean age: 36.6 ± 2.06
Average Initial BMI: 39.43 ± 1.48 Kg/m²

and followed-up by Multidisciplinary group:
2 gastroenterologists,
1 psychologist,
1 nutritionist,
1 physical coach.

6 MONTHS RESULTS

EFFICIENCY

Weight loss (kg) 15.18 ± 1.88
Excess Weight loss (%) 42.49 ± 5.44
BMI loss (Kg/m²) 5.44 ± 0.68

65 % of improvement or resolution of comorbidities.

TOLERANCE
No Early removal.

7 % epigastric pain, 4 % Oesophagitis reflux, and 16 % constipation.

5 spontaneous deflations (6.7%) after more than 6 months of portage and 1 lead to a small-bowel obstruction solved by surgery.

WITH A MULTIDISCIPLINARY APPROACH, HELIOSPHERE® INTRAGASTRIC BALLOON HAS BEEN EFFECTIVE TO CONTROL OBESITY INDUCING AN EXCESS WEIGHT LOSS OF ALMOST 43%.
IT WAS NOT ASSOCIATED WITH MORTALITY NOR MAJOR COMPLICATION DURING THE 6 MONTH PERIOD.

14TH WORLD CONGRESS OF THE INTERNATIONAL FEDERATION FOR THE SURGERY OF OBESITY - PARIS, FRANCE 2009
P-259 Air Filled Balloon - Brazilian Multicentric Study

Presenter: M. Falcao
Obesity Treatment and Surgery Nucleus - NTCO, Sao Paulo, Brazil

Co-authors: M. Galvao Neto 2, E. Alves 1, A. Ramos 2, C. Martins 3, J. Campos 4, E. Ferraz 4
1Obesity Treatment and Surgery Nucleus - NTCO Salvador Brazil;
2Gastro Obeso Center Sao Paulo Brazil;
3San Rafael Hospital Salvador Brazil;
4Federal University of Pernambuco Recife Brazil

Background : The intragastric balloon stills the main option as endoscopic treatment of obesity, besides its temporary manner. The air filled balloon (Helioscopie®, France) is a recent technical improvement that had been proven its efficacy but more data still necessary to address it. A Brazilian multicentric study was conducted among 4 bariatric surgery centers in order to prospectively access data on safety and efficacy

Methods : 236 patients (173 female), with weight from 72-156Kg (m=109,2Kg), BMI 34-52 (m=34,8) from January of 2005 to December of 2008 were implanted. Balloon implant and explants runs under with anesthetic assistance and lasts 6 m in a specific multidisciplinary program.

Result : There was significant weight loss (> 30%EWL) in all but 2 patients, meaning 15-72%EWL (42%EWL). Implant time varies from 15-60 min (min= 26 min), explants time from 18-123 min (m=42 min). The explants times reduced significantly to a mean of 28 min (p<0,005) after the 10 first cases of each center. Adverse Events (AE) occurred on 35,1% of vomiting, 25% abdominal pain and 4,6% of Dehydration. Complications happened on 0,85% of balloon deflation. 0,42% of early removals, 0,42% of gastric ulcers, 3,81% of re-admitted patients and 2,97% of fungus balloon contamination. No implant or explants complication, no severe AE and no deaths were observed.

Conclusion : Air filled intragastic balloon shows to be is a safe and effective method of endoscopic bariatric treatment on a prospective multicentric trial
V-053 Video Demonstration of Safe and Quick Extraction of Heliosphere Intragastric Balloon

Presenter: B. Napoléon
Hôpital Edouard Herriot, Lyon, France

Intragastric balloons are efficient to obtain a significant weight loss in obese. Last generation of Heliosphere, intragastric balloons, filled with air, have major advances allowing an easiest retrieval. Nevertheless a systematic step by step procedure is needed to facilitate the extraction. This video demonstrates the most useful procedure to extract the balloon rapidly and safely.
Gastric Balloon Efficiency On Weight Loss WITH A MULTIDISCIPLINARY MEDICAL FOLLOW-UP

Vianna Costil, Pôle Santé, Centre des médecins spécialistes, Paris la Défense, France

Introduction
Gastric balloon is a help to lose weight by giving a sensation of satiety in a multidisciplinary approach. There are two types of balloon: The Bioenterics Balloon (BB), a saline-filled balloon (550cc-700cc) and the Heliosphere Balloon, an air filled balloon (60cc).

Aims
To study the efficacy of the gastric balloons to lose weight and to maintain the weight loss 6 months after removing the balloon. To compare the two types of balloon (saline and air filled balloons).

Methods
154 patients are included in a prospective, comparative and non-randomized study. Both types of gastric balloons were implanted for 6 months then removed.

Results

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Min-Max</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>34.7 years (± 1.6)</td>
</tr>
<tr>
<td>Weight</td>
<td>93.1 kg (± 2.6)</td>
</tr>
<tr>
<td>BMI</td>
<td>33.70 kg/m² (± 1.2)</td>
</tr>
<tr>
<td>Sex</td>
<td>141 female - 13 male</td>
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<tr>
<td>Balloon</td>
<td>72 water-filled - 79 air-filled</td>
</tr>
</tbody>
</table>

**Efficacy**

<table>
<thead>
<tr>
<th></th>
<th>At removal</th>
<th>6 months after removal</th>
<th>12 months after removal</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>%</td>
<td>Mean ± SD</td>
<td>%</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>123</td>
<td>83.16 ± 1.89</td>
<td>47</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>123</td>
<td>30.00 ± 0.90</td>
<td>47</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>123</td>
<td>10.5 ± 1.42</td>
<td>47</td>
</tr>
</tbody>
</table>

**Tolerance; Vomiting**

- No
- Yes

**Similar Efficacy for Both Balloons**

Gastric balloon can help overweight and obese patients, for whom bariatric surgery may be contraindicated, reduce weight. Behavior change is essential to avoid weight regain.
International Federation for the Surgery of Obesity and metabolic disorders
XIII World Congress

Buenos Aires, Argentina

2008

- **P155. AIR-FILLED INTRAGASTRIC BALOON: A PRE-SURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS.**
  A GIOVANELLI
P155. AIR-FILLED INTRAGASTRIC BALOON: A PRE-SURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS.

A Giovanelli

**Background:** literature data shows gastric bypass mortality rate is > 2% for > 50 BMI but less than 1% for < 50 BMI. Air-filled intragastric balloon have been proposed to induce body weight loss in obese subjects with a > 50 BMI.

**Methods:** we report about a selected group of 882 patients from Italy, Spain, France and Dominican Republic till February 2007. F:M 4,2:1. mean age 37,7 (range 15-67). Two indications: unique treatment in BMI<35 (50,3%) and preoperative placement in morbid obesity with BMI>35 (33,2%) and superobesity BMI>50 (16,5%). In particular 20 patients with BMI > 50 underwent a gastric bypass after BAG procedure. The other ones treated with adjustable gastric band without mortality or postoperative problems or are waiting for other bariatric steps. Balloon insertion was successful in all cases and placed in 87% in sedation. 97,2% removed six months later in sedation or general anaesthesia without evidence of problems.

**Results:** Good weight loss: mean BMI reduced from 55,4 (range 50-76) to 49,7 (range 45,7-49,9) in 56% of the superobese with a mean BMI loss of 4,26 kg/m2. Good tolerance of the device with a lower early-removal. In particular, no death after laparoscopic gastric bypass are reported in our experience.

**Conclusions:** Intragastric balloon is safe and an effective first-step in super-obesity treatment. Risk of failure of laparoscopic approach, peroperative complications and mortality are reduced in the second step surgical procedures.
Air-filled intragastric balloon: a presurgical device to reduce BMI and mortality before gastric bypass

Multicentric European experience: France – Italy – Spain
A. Giovanelli – Humanitas Gavazzeni Bergamo Italy - www. gavazzeni.it – obesità@gavazzeni.it

Literature data shows gastric bypass mortality rate is > 2% for > 50 BMI but less than 1% for < 50 BMI.

Air-filled intragastric balloon have been proposed to induce body weight loss in obese subjects with a > 50 BMI.

782 patients till February 2007 are analyzed in a similar clinical and demographic features group from France, Italy and Spain. Among these, 602 were removed and the analysis concern the data on extraction.

Good weight loss in most of the patients with mean BMI loss of 3.12 kg/m² after BAG procedure.

Spanish serie followed a drastic diet (from 900 to 2,000 kcal/day- Median: 1,000kcal/day), with a very good efficiency: more than 26kg lost in 6 months.

RESULTS

Good weight loss in particular in super obesity

Mean BMI reduced from 55.4 to 49.7 in 56% of the super obese with a mean BMI loss of 4.26 kg/m². Good tolerance of the device with a low early-removal and low occurrence of complications.

13.3% of super obese treated with BAG before surgery underwent a VLS gastric bypass without mortality.

86.7% underwent a VLS adjustable gastric band or other gastrorestrictive procedures without surgical problems or mortality.

CONCLUSIONS

Air-filled intragastric balloon is safe and an effective first-step in super obesity treatment. Risk of failure of laparoscopic approach, preoperative complications and mortality are reduced in the second step surgical procedures.
International Federation for the Surgery of Obesity and metabolic disorders
XII World Congress

Porto, Portugal

2007

- **P114. AIR FILLED INTRAGASTRIC BALLON (BAG) : ITALIAN MULTICENTRIC RESULTS.**
  A. GIOVANELLI

- **V10. AIR-FILLED INTRAGASTRIC BALLOON FOR OBESITY TREATMENT.**
  M. P. GALVAO NETO
Italian multicentric experience with air filled intragastric balloon (Eliosphere BAG) in 350 patients since 2005 is reported in a similar clinical and demographic features group even before bariatric surgery (IB test) than as unique bariatric option.

**Results**

- **BMI**: 39.6 (range 25-72)
- **PEWL**: 33% (range 2.2-96%) after 6 months.

**Complications**

- 1.2% early removal for psychological or physical intolerance
- 23% nausea
- 4.3% severe vomiting
- 4.3% epigastric pain
- 6.4% gastric failures
- 0.6% intestinal migration and spontaneous evacuation

**Conclusions**

- **BAG** may be a choice in body-weight control.

In **morbid obesity** the indication are: no-operable patients, gastrorestrictive-test, pre-surgery (especially in superobese).

In **severe overweight** may be used as a unique treatment. Selection criteria tend to a study a good compliance to a new dietetic life-style.

Results show the same effectiveness on weight loss with a better psychological and physical tolerance of air filled BAG confronted with other balloons.

Low incidence of gastric and systemic problems is performed in all our series.

Follow-up role is remarked: carefully monitored by a multidisciplinary team of endoscopists, surgeons, dieticians and psychologists.

Intragastric balloon (air or liquid filled) may not be considered a resolution for morbid obesity in long term but a possible step. In severe overweight bag is a good therapeutic option.
- **O31. Intragastric Balloon for Obesity: Comparative Study with 420 Patients: New Generation Airfilled vs Liquid-filled.**
  C Hermida

- **P14. Heliosphere Intragastric Air Balloon: Our Initial Experience in the Dominican Republic.**
  DK Ramirez

- **P76. Heliosphere Intragastric Air Balloon: Our Initial Experience in the Dominican Republic.**
  DK Ramirez

- **P106. Air-filled Intragastric Balloon (Bag): Multicentric Preliminary Results.**
  A Giovanelli

- **P132. Tolerance and Efficacy Evaluation of an Air-filled Intragastric Balloon in Non-morbid Obesity: 16 Months Follow-up.**
  F Mion
O31. INTRAGASTRIC BALLOON FOR OBESITY: COMPARATIVE STUDY WITH 420 PATIENTS: NEW GENERATION AIRFILLED VS LIQUID-FILLED.

C Hermida, I Cortijo, A Diaz, C Gonzalez-Perrino, C Arribas.
Instituto Medico Europeo De La Obesidad, Madrid, Spain.

Background: Intragastric balloons (IB) have been proposed as an aid to lose weight for obese patients. A study has been conducted to compare the effectiveness of a new generation of airfilled balloon (Helioscopie, Vienne, France) to the previously available liquid-filled balloon (Inamed).

Methods: From August 2004 to June 2005, 420 patients were included in a randomized prospective monocentric study. – Group A: Air-filled balloon – 900 cc – Group B: Liquid-filled balloon – 400-700 cc All patients had multidisciplinary assistance. Balloon placement and removal were done under general anesthesia and endotracheal intubation. Removal was planned after 6 months.

Results: 420 patients (132 M/288 F, 192 A/228 B:) were included: Average age 36.8 ± 10.2 Range (18-56), Average BMI 37.7 ±4.5 kg/m2 – Range (27.0-52.1). The two groups had similar demographic and clinical characteristics. After 6 months of treatment: Mean weight loss: Group A: 24.73 ± 10.85, Group B: 24.33 ± 9.94. Complications were: – Nausea and vomiting: 12% group A vs 40% group B – Epigastric pain: 8% group A vs 46% group B – Early removals: 0.7% group A vs 8.1% group B – 8 slight esophageal erosions and one esophageal perforation during air-filled balloon removal learning curve.

Conclusions: Our study shows: 1) Equal effectiveness on weight loss; 2) Better immediate tolerance with air-filled balloons; 3) Necessity of training for air-filled balloon removal.
P14. HELIOSPHERE INTRAGASTRIC AIR BALLOON: OUR INITIAL EXPERIENCE IN THE DOMINICAN REPUBLIC.


Background: In Latin America, the obesity rate has tripled in the last decade alone; in the Dominican Republic, the rate of obesity is at 30% in males, 34% in females and 49% in adolescents. We have added the Intragastric Air Balloon as an option to achieve weight loss in our Bariatric Unit program.

Methods: In the last 15 months, 64 patients were included in our clinic to receive an intragastric balloon for the treatment of their obesity (37 female, 27 males), their average BMI was 38.9 kg/m² and their average age was 36.2 yrs. The balloon was placed with the help of general anesthesia (average time of placement 22 min). The follow-up until removal was at least 6 months. For the removal, we used general anesthesia (average time 25 min).

Results: The balloon was removed after a mean time of 8 months. We did not encounter gastric perforation, dilation, bleeding nor reflux problems. The most common side effects were nausea/vomiting and abdominal pain (average duration 2.7 days). 1 balloon was removed the third week for psychological intolerance. At the time of removal, average BMI, weight loss and excess weight loss were respectively 32.4 kg/m², 17.2 kg and 51%.

Conclusion: Heliosphere intragastric balloon is an effective and safe option to achieve weight loss. Besides, as 31% of the balloons were removed after 8 months without any problem or side-effect, a longer period of treatment should be discussed.
P76. HELIOSPHERE INTRAGASTRIC AIR BALLOON: OUR INITIAL EXPERIENCE IN THE DOMINICAN REPUBLIC.


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Conclusion: Heliosphere intragastric balloon is an effective and safe option to achieve weight loss. Because 31% of the balloons were removed after 8 months without any problem nor sideeffect, a longer period of treatment should be discussed.
P106. AIR-FILLED INTRAGASTRIC BALLON (BAG): MULTICENTRIC PRELIMINARY RESULTS.

Cliniche Humanitas Gavazzeni, Italy.

**Background:** Multicentric experience with air-filled intragastric balloon (Heliosphere BAG) in 195 patients is reported since 2005.

**Methods:** Report is about a similar clinical and demographic characteristics group even before major surgical procedures (IB test) than as a unique bariatric option. Average BMI: 41.1±4.0 (29- 72), 73%F 27%M. Average age 37.9±10. 35% balloons placement without anesthesia, all patients with a multidisciplinary approach, removal always with endotraqueal intubation after 6 months.

**Results:** Average BMI 36.6±3.8 after 6 months. Very good compliance (no psychological intolerance). Complications: no death, 16% nausea, 4.3% severe vomiting, 4.3% epigastric pain, 6.4% gastric failures, no intestinal dislocation, no early removal.

**Conclusion:** Intragastric balloon may be an aid to lose weight occupying a definite option in morbid obesity treatment: nonoperable patients, presurgery in super-obese, gastrorestrictive test. In severe obesity the balloon may be used as unique treatment. Selection criteria tend to the psychological compliance to a new dietetic life-style. Preliminary results show the same effectiveness on weight loss with a better tolerance of air filled BAG confronted with liquid filled balloon BIB. Technical problems especially in the removal necessitate a training (in resolution with the new BAG generation with a more fable valve). Follow-up role is remarked: carefully monitored by a team of expert endoscopists, surgeons, dieticians and psychologists. Intragastric balloon (airor liquid-filled) may not be considered a resolution for morbid obesity in the long-term but a possible step.
P132. TOLERANCE AND EFFICACY EVALUATION OF AN AIR-FILLED INTRAGASTRIC BALLOON IN NON-MORBID OBESITY: 16 MONTHS FOLLOW-UP.

F Mion, B Napoleon, S Roman, S Beorchia, F Hedelius, N Claudel, RM Bory.
Hôpital E. Herriot, Rhône-Alpes, France.

Background: The goal of this study was to evaluate the tolerance and the efficacy of a new air-filled balloon, in non morbid obese patients.

Methods: 32 patients (27 females, mean age 35 years), with a nonmorbid obesity for 8 ± 6 years (mean BMI: 35 ± 3), were included. A balloon (Heliosphere® BAG, Helioscopie, France) was inserted under endoscopy, inflated with 800 ml of air, and removed 4 months later. A specific nutritive program limited the daily caloric intake to 1300 Kcal. Weight loss and complications were evaluated.

Results: Weight loss was significant at 1, 2 and 4 months after balloon implantation (6 [range: 2-10], 7 [1-13] and 10 [3-20] kg, respectively, p<0.001). Severe left upper quadrant abdominal pain lead to an early removal of the balloon in 3 cases. No other complication occurred except for nausea and vomiting during the first week. 28 patients were contacted 12 months after balloon removal: 2 had undergone gastric banding; among the 26 remaining, the mean weight loss was 7 [-6 to 23] kg. 8 patients (30%) remained with a weight loss > 10%. The patients’ satisfaction with the method was 87% for those 8, and only 22% for the others with a weight loss <10% (P<0.04).

Conclusions: This newly designed air-filled balloon is safe, with no spontaneous deflation observed. Its efficacy seems equivalent to other balloons in terms of weight loss (10 kg at 4 months). One year after balloon removal, 30% of the patients maintained a weight loss greater than 10%.
TOLERANCE AND EFFICACY EVALUATION OF A NEW AIR-FILLED INTRAGASTRIC BALLOON IN NON MORBID OBESITY: 16 MONTHS FOLLOW-UP

F. MION, R. GINCUL, B. NAPOLEON, S. ROMAN, S. BEORCHIA, F. HEDELIUS, N. CLAUDEL, R. BORY. Armas, Lyon, St Priest, FRANCE

INTRODUCTION
Intra-gastric balloons (IGB) have been used for the treatment of morbid and non-morbid obesity. Liquid-filled IGB may lead to vomiting, dehydration and ulcers due to their weight. A new air-filled IGB has been devised to overcome these problems (Heliosphere® BAG, Helioscopie, France).

GOALS OF THE STUDY
- Evaluate the tolerance and efficacy of a new air-filled IGB, associated with standardized nutritional support, in non morbid obese patients

METHODS
Heliosphere® BAG was placed under endoscopic guidance, inflated with 800 ml of air, and removed 4 months later. A specific nutritive program limited the caloric intake to 1300 Kcal/day during 8 weeks.

RESULTS

INSERTION / REMOVAL
- IBG insertion was simple in all cases
  Mean duration of procedure: 12.5 min
- Removal more difficult
  Mean duration: 21 ± 17 min
  (p= 0.0072 vs insertion)
  Difficulties in 47% of cases, to:
  - grasp the balloon: 3 cases
  - pass the cardia: 11 cases
  - pass the UES: 3 cases

Safety
All balloons were in the stomach at removal
1 balloon deflated at D8, removed at M2 (still in the stomach)

Variations of IGB volume

<table>
<thead>
<tr>
<th>Tolerance</th>
<th>Abdominal pain</th>
<th>Nausea</th>
<th>Vomiting</th>
<th>Number of days with vomiting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 8</td>
<td>10 (31%)</td>
<td>8 (25%)</td>
<td>27 (84%)</td>
<td>2.5 (0 – 8)</td>
</tr>
<tr>
<td>Month 1</td>
<td>6 (19%)</td>
<td>1 (3%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Month 3</td>
<td>0</td>
<td>1 (3%)</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

2 early IGB removals (Day 3 & Day 5): severe pain and vomiting

Follow-up 1 year after balloon removal
28/32 patients contacted
2 underwent gastric banding
26 remaining:
  mean weight loss: 7 kg (-6 to 23)
  8 patients with weight loss > 10%

patients' satisfaction:
  87% for those with WL>10%
  22% for those with WL ≤ 10%
  (p<0.04)

CONCLUSIONS
- Heliosphere® BAG is safe
- Induces less vomiting than liquid-filled IGBs
- Specific left upper quadrant abdominal pain, probably related to the air inflation
- Efficacy similar to liquid-filled IGBs on weight loss and QOL
- One year after balloon removal, 30% of patients retained a weight loss > 10%

IFS 2006
### FROM OVERWEIGHT TO OBESITY: THE EFFICACY OF AIR FILLED BALLOON

**A Giovanelli (2009)**

14TH WORLD CONGRESS OF IFSO, Paris, France

**GASTRIC BALLOON EFFICIENCY ON WEIGHT LOSS (WL) WITH A MULTIDISCIPLINARY MEDICAL FOLLOW-UP**

**V Costil (2009)**

14TH WORLD CONGRESS OF IFSO, Paris, France

**CARIBBEAN PROSPECTIVE MULTIDISCIPLINARY STUDY OF MANAGEMENT OF OBESITY WITH THE AIR FILLED INTRAGASTRIC BALLOON**

**R Romney (2009)**

14TH WORLD CONGRESS OF IFSO, Paris, France

**AIR FILLED INTRAGASTRIC BALLOON - BRAZILIAN MULTICENTRIC STUDY**

**M Falcao (2009)**

14TH WORLD CONGRESS OF IFSO, Paris, France

**AIR-FILLED INTRAGASTRIC BALLOON: A PRE-SURGICAL DEVICE TO REDUCE BMI AND MORTALITY BEFORE GASTRIC BYPASS**

**A. Giovanelli (2008)**

13TH WORLD CONGRESS OF IFSO, Buenos Aires, Argentina

**AIR FILLED INTRAGASTRIC BALLOON (BAG) ITALIAN MULTICENTRIC RESULTS**

**A. Giovanelli (2007)**

12TH WORLD CONGRESS OF IFSO, PORTO, Portugal

**AIR FILLED INTRAGASTRIC BALLOON (BAG) ITALIAN MULTICENTRIC RESULTS**

**A. Giovanelli (2006)**

11TH WORLD CONGRESS OF IFSO, SYDNEY, AUSTRALIA

**HELIOSPHERE INTRAGASTRIC AIR BALLOON: OUR INITIAL EXPERIENCE IN THE DOMINICAN REPUBLIC**

**DK Ramirez (2006)**

11TH WORLD CONGRESS OF IFSO, SYDNEY, AUSTRALIA

**INTRAGASTRIC BALLOON FOR OBESITY: COMPARATIVE STUDY WITH 420 PATIENTS**

**C Hermida (2006)**

11TH WORLD CONGRESS OF IFSO, SYDNEY, AUSTRALIA

**TOLERANCE AND EFFICACY OF AN AIR-FILLED BALLOON IN NON-MORBIDLY OBESE PATIENTS: RESULTS OF A PROSPECTIVE MULTICENTER STUDY**

**H. Claudez (2005)**

13TH UNITED EUROPEAN GASTROENTEROLOGY WEEK, COPENHAGEN, DENMARK

<table>
<thead>
<tr>
<th>Patients</th>
<th>583</th>
<th>167 with BMI &lt; 35</th>
<th>353 with 35 ≤ BMI &gt; 49</th>
<th>64 with BMI ≥ 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follow-up</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Removal</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Average age</td>
<td>ND</td>
<td>ND</td>
<td>37 ± 2</td>
<td>36 (15-67)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial BMI (kg/m²)</th>
<th>ND</th>
<th>33.9</th>
<th>39.4 ± 1.48</th>
<th>34.8 (34-52)</th>
<th>ND</th>
<th>43.5 (29 - 76)</th>
<th>41.1 (29 - 72)</th>
<th>38.9</th>
<th>37.7 +/- 4.5</th>
<th>36.8 (30 - 44)</th>
<th>35 (30.1 - 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI Loss (kg/m²)</td>
<td>ND</td>
<td>ND</td>
<td>5.88</td>
<td>4.1</td>
<td>5.4 ± 0.7</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Final BMI (kg/m²)</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>39.6 (25 - 72)</td>
<td>36.6 ± 3.8</td>
<td>32.4</td>
<td>ND</td>
<td>34.6 (25.9 - 50.8)</td>
<td>31.8 (24.6 - 38.1)</td>
</tr>
<tr>
<td>Weight Loss (kg)</td>
<td>12.2 ± 1.1</td>
<td>19.8 ± 1.2</td>
<td>15.9 ± 2.6</td>
<td>10.5 ± 1.5</td>
<td>15.18 ± 1.9</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
<td>17.2</td>
</tr>
<tr>
<td>EWL (%)</td>
<td>62</td>
<td>51.3</td>
<td>54.7 ± 1.0</td>
<td>42.5 ± 5.4</td>
<td>42 (15-72)</td>
<td>ND</td>
<td>ND</td>
<td>33 (3.2 - 96)</td>
<td>ND</td>
<td>51</td>
<td>ND</td>
</tr>
</tbody>
</table>

**Vomiting & Nausea (%)**

| ND | > with BIB than with Heliosphere (p<0.05) | ND | 35.1 | ND | Vomiting : 4.3 | Nausea : 4.3 | Most related Adverse events : nausea, vomiting and abdominal pains | Mean time : 2.7 days | H: 12 | B: 49 | Mean time : 3.1 days (1 to 8) | 10 |

**Epigastric Pains (%)**

| ND | > with BIB than with Heliosphere (NS) | 7 | 25 | ND | 4.3 | 4.3 | 84 | H: 8 | B: 46 | 31 | 80 Epigastric pains (1st week) |

**Early removal (%)**

| <3 | ND | 0 | 0.42 | ND | ND | ND | ND | ND | ND | ND | ND | ND | ND |

**Migration (%)**

| ND | ND | 1 removal > 6 months | ND | 0.6 | 0 | 0 | 0 | ND | 0 | No migration | No gastrique perforation |

**Deflation (%)**

| ND | ND | 6.7 removal > 6 months | ND | ND | ND | ND | ND | ND | ND | 1 spontaneous deflation (4th month) without migration |

**HELIOSPHERE**

July 2010