Effectiveness, safety, and tolerability of intragastric balloon in association with low-calorie diet for the treatment of obese patients


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ABSTRACT

Introduction: the endoscopic placement of an intragastric balloon (IGB) in association with a low-calorie diet is an option for the treatment of obesity. The aim of the present study was to evaluate its effectiveness, safety, and tolerance.

Material and methods: thirty-eight patients with no contraindications for IGB were included in this prospective study from March 2004 to January 2007. Balloon removal was performed 6 months later. Weight and body mass index (BMI) were evaluated after IGB removal and at 6 months and 1 year thereafter. Tolerance and complications during treatment were evaluated. Patients filled out a questionnaire to evaluate their subjective perception of treatment.

Results: mean weight loss after 6 months on balloon treatment was 14.10 kg (0-46), and mean BMI reduction was 5.23 kg/m² (0-18). At 12 months after balloon removal 48.4% of patients maintained their weight loss or kept loosing weight. Most common early symptoms included nausea (71.1%) and vomiting (57.9%) with a good response to symptomatic treatment. Complications were seen in 7 patients (18.4%): digestive intolerance in 4 patients, with early removal in 3 of them; moderate esophagitis in 2 patients; and gastric perforation complicated with septic shock and death in 1 patient.

Conclusions:
1. IGB in association with low-calorie diet is an effective, safe, and well tolerated treatment for morbid obese patients.
2. Almost half of patients maintained their weight loss after one year from balloon removal.

Key words: Obesity. Morbid obesity. Intragastric balloon. Endoscopy.

RESUMEN

Introducción: la implantación de un balón intragas trico (BI) por vía endoscópica asociado a una dieta hipocalórica es una alternativa en el tratamiento de la obesidad. El objetivo de nuestro estudio es evaluar su efectividad, seguridad y tolerancia.

Material y métodos: se incluyeron prospectivamente 38 pacientes sin contraindicaciones para la implantación del BI, desde marzo de 2004 hasta enero de 2007. La retirada del balón se realizó 6 meses después de la implantación. Evaluamos el peso e índice de masa corporal (IMC) tras la retirada del balón, a los 6 y 12 meses posretirada, así como la tolerancia y aparición de complicaciones durante el tratamiento. Tras la retirada del balón se realizó un cuestionario a cada paciente evaluando la percepción subjetiva al tratamiento.

Resultados: después de 6 meses de tratamiento la pérdida de peso media fue de 14,10 kg (0-46) y la reducción media del IMC fue de 5,23 kg/m² (0-18). A los 12 meses posretirada del balón el 48,4% de pacientes mantiene o sigue perdiendo peso. Los síntomas precoces más frecuentes fueron náuseas (71,1%) y vómitos (57,9%), con buena respuesta a tratamiento sintomático. Presentaron complicaciones 7 pacientes (18,4%): intolerancia digestiva en 4 pacientes, requiriendo retirada precoz del balón en 3 de ellos; esofagitis moderada en 2 pacientes; y perforación gástrica complicada con shock séptico y exitus en 1 paciente.

Conclusiones:
1. El balón intragástrico asociado a una dieta hipocalórica puede considerarse un tratamiento efectivo, seguro y bien tolerado para el tratamiento de pacientes con obesidad mórbida.
2. La pérdida de peso se mantiene en casi la mitad de los pacientes al año tras la retirada del balón.

INTRODUCTION

Obesity represents one of the most important public health problems due to its prevalence and associated potential complications (1). The first step among the various therapeutic options currently available consists of combining a low-calorie diet with changes in life-style (2,3) and temporary drug therapy. Surgery is only resorted to if medical treatment fails.

Intragastric balloons (IGB) are used not only to obtain weight loss in obese patients but also as a means to reduce risk factors associated with obesity prior to bariatric surgery (4).

IGB have been suggested for the following indications (5,6): a) obese patients with diet therapy refractoryness; b) preoperative temporary use to achieve weight loss and reduce the risks of surgery (7,8); and c) severely obese patients non-candidates for obesity surgery.

The idea of using an IGB for the treatment of obesity –this produces a feeling of satiety– was first put into practice in 1982. The concept was developed by observing patients presenting with gastric bezoars (9). This technique was however abandoned between 1987 and 1989 due to numerous complications and lack of efficacy (10). Defining the features of an ideal IGB was thus required (11).

This study assesses the treatment of obesity with an IGB, i.e., its effectiveness (weight loss following removal in the medium-term), tolerance, complications and patient satisfaction after treatment.

MATERIALS AND METHODS

From March 2004 to January 2007 38 obese patients showing refractoriness to regular low-calorie treatment and for whom the Endocrinology Department indicated the placement of an IGB were prospectively included. An informed consent was signed by all patients.

The Bioenterics® Intragastric Balloon (BIB) has been available since 1998. It has ideal features (12,13), namely a sphere shape and a smooth surface: it is filled with liquid, has a gastric acid resistant silicone cover, and includes a radioopaque marker which allows for adequate follow-up.

The following procedures were performed prior to BIB placement: complete medical history (clinical recordings, associated conditions, eating habits, previous treatments, psychological and social history), full blood test (hemogram, coagulation, glucose, urea, creatinin, sodium, potassium, albumin, total protein, triglycerides, cholesterol, transaminases, alkaline phosphatase, and thyroid hormones), high digestive endoscopy and a psychiatric evaluation to rule out disorders for which balloon placement is contraindicated.

Among the 38 patients included in the study there were 11 men (28.9%) and 27 women (71.1%). Mean age was 40.47 (23-64). Mean initial weight was 125.32 kg (86.50-210); 117.60 kg in women and 144.25 kg in men. Mean baseline BMI was 47.25 kg/m² (34-80): 47.17 kg/m² in women and 47.42 kg/m² in men (Table I).

<table>
<thead>
<tr>
<th>Table I. Demographic data</th>
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<tr>
<td>Patients: 38</td>
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<tr>
<td>Men: 11/27</td>
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<td>Mean age: 40.47 (23-64)</td>
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<td>Mean initial weight:</td>
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<td>Women: 117.60</td>
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<td>Men: 144.25</td>
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<tr>
<td>Mean initial BMI:</td>
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<tr>
<td>Women: 47.17</td>
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<td>Men: 47.42</td>
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The inclusion criteria were:
— Obese patients (BMI > 30 kg/m²) over 18 years of age.
— Refractoriness to low-calorie therapy.
— Informed consent.
— Positive psychiatric report.
— No contraindications for BIB placement.

Patients showing contraindications for the use of BIB were excluded (14,15):
— Toxic habits (alcohol or drug abuse).
— Pregnancy or lactation.
— Psychiatric disorders.
— Anatomical, surgical or pathological alterations of the upper digestive tract.
— Severe gastrointestinal or extragastrointestinal disease.
— Previous gastrointestinal surgery.
— Patients requiring treatment with aspirin, anti-inflammatory agents, anticoagulants or steroids.

Candidates for BIB placement were admitted to hospital the day before the procedure in accordance with the protocol. A blood test was conducted –complete hemogram, glucose, urea, creatinin, and coagulation. Patients underwent a starvation diet for 8 hours before BIB placement.

The endoscopic placement of BIBs was performed in an operating theatre under general anesthesia with orotracheal intubation (16). The BIB was inflated as standard with 500 cc of saline serum mixed with 10 mL of methylene blue for early detection of leakage through the coloration of patient urine (17). Following BIB placement a protocol for symptomatic treatment of possible early side effects –including nausea, vomiting and epigastric pain– was carried out. Antiemetics and proton pump inhibitors (PPIs) were provided. An initial liquid diet was gradually replaced with a solid diet. All patients remained hospitalized for at least 24 hours following BIB placement to observe and control any side effect.
Patients were discharged according to their clinical evolution and oral tolerance.

Patients were followed up monthly by the Endocrinology Department, including physical examination and complete blood testing. Also, advice on hygiene and diet issues was given: a 1,000-1,500 calorie diet– comprised of the following mean values: 52.3% carbohydrates, 19.5% proteins, 28.2% lipids, 18.12 g of fiber– (18); frequent intakes of small amounts of food – avoiding plentiful meals; caution to avoid lengthy periods in decubitus position shortly after intake, and moderate physical exercise (19).

The length of treatment was 6 months. BIB removal was performed in the operating room with endoscopic control under general anesthesia and with orotracheal intubation. Treatment efficacy was assessed in terms of initial weight loss and BMI decrease following the 6-month treatment. Also, medium-term efficacy was determined as weight loss at 6 and 12 months after BIB removal.

Patients completed a questionnaire following BIB removal to evaluate:

1. **BIB perception:** a) hyporexia; b) early satiety; c) both; d) other.
2. **Discomfort** during treatment, measured on a 1 to 10 scale (1 being minimum and 10 maximum).
3. **Subjective effectiveness** of treatment, also scored on a 1 to 10 scale.
4. **Recommending treatment** to other patients: a) yes; b) no.

### Statistical analysis

A prospective observational study was carried out in which all outcomes are expressed through mean values (ranges) or percentages with a 95% confidence interval. The statistical analysis was conducted with the SPPS 15.0 software for Windows.

### RESULTS

Mean hospital stay for BIB placement was 2.82 days (2 days in 36.8% of patients [n = 14], 3 days in 47.4% [n = 18], 4 days in 13.2% [n = 5] and 5 days in 2.6% [n = 1]). Lengthy hospital stays resulted from the development of early side effects following BIB placement (1 week), including nausea, vomiting, and epigastralgia, which delayed tolerance to oral intake.

15.8% of patients (n = 6) underwent BIB placement as a bridge treatment to bariatric surgery.

The most frequent associated conditions in our patients were: high blood pressure (HBP) in 23.7% of patients (n = 9), diabetes mellitus (DM) in 21% of patients (n = 8), dyslipemia in 21% of patients (n = 8), and obstructive sleep apnea (OSA) syndrome in 18.2% of patients (n = 7).

In 89.5% of patients the length of treatment with BIB was 6 months. For the remaining patients (10.5%, n = 4) the treatment could not be completed within the time expected due to complications, including severe digestive intolerance non-responsive to phamotherapy in 3 patients who required early BIB removal (during the first, third and fifth month of treatment respectively), and gastric perforation with secondary septic shock leading to death in 1 patient.

During the first few days after BIB placement (1 week), 71.1% of patients had nausea, 57.9% vomiting, and 23.7% epigastralgia. These early side effects decreased throughout treatment, demonstrating good response to symptomatic drug therapy.

Complications were observed in 7 patients (18.4%), most of which were mild-moderate (n = 6) except for 1 severe complication (Table II). The latter included severe digestive intolerance in 4 patients –3 required early BIB removal–, moderate esophagitis (grades II and III) in 2 patients –1 showed self-limited mild upper digestive hemorrhage following BIB removal–, and gastric perforation in 1 patient (during the first month of treatment), which caused a septic shock leading to death.

<table>
<thead>
<tr>
<th>Complications (n = 7 patients, 18.4%)</th>
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<tr>
<td>Digestive intolerance (n = 4 patients)</td>
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<td>Early BIB removal (n = 3 patients)</td>
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<td>First month</td>
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<td>Third month</td>
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<td>Fifth month</td>
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<td>Moderate esophagitis (n = 2 patients)</td>
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<td>Gastric perforation (n = 1 patients)</td>
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<td>Septic shock and death</td>
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After 6 months of BIB treatment associated with a low-calorie diet, mean weight loss was 14.1 kg (0-46): 13.75 kg in women and 14.93 kg in men (Fig. 1). Mean BMI decrease was 5.23 kg/m² (0-18): 5.49 kg/m² in women and 4.63 kg/m² in men (Fig. 2).

The questionnaire submitted to patients assessed the following:

1. **BIB perception:** 47.4% of patients perceived early satiety, 36.8% perceived other sensations (anxiety, hunger, nausea and vomiting), 5.3% hyporexia and 7.9% both hyporexia and early satiety.

2. **Discomfort:** during treatment, the average score on the semi-quantitative discomfort scale was 4; 76.3% of patients graded discomfort with a score equal to or less than 5, while 21.1% of patients gave a score greater than 5.
3. **Subjective effectiveness** (of the treatment): mean value was 5.57. 52.6% of patients graded effectiveness with a score greater than 5, while 44.7% gave a score equal to or less than 5.

4. **Recommending treatment**: almost 2/3 of the patients (65.8%) would recommend treatment with BIB to other patients.

As regards medium-term assessment of treatment effectiveness—6 and 12 months after removal—7 patients could not be followed up: 1 died of septic shock following gastric perforation, and 6 patients failed to undergo endocrine follow-up, hence necessary clinical data could not be obtained.

6 months after BIB removal 19.4% of patients (n = 6) maintained their weight loss, 32.2% (n = 10) continued to lose weight with a weighted mean weight loss of 5.4 kg, and 48.4% (n = 15) gained weight with a weighted mean weight gain of 5.46 kg.

12 months after BIB removal 22.6% of patients (n = 7) maintained weight loss, 25.8% (n = 8) continued to lose weight with a weighted mean weight loss of 9 kg and 51.6% (n = 16) gained weight with a weighted mean weight gain of 9.43 kg.

**DISCUSSION**

Recently, endoscopic IGB placement has become more widespread in the multidisciplinary management of obesity treatment (20) since alternative conservative treatments—low-calorie diet, changes in life-style, pharmatherapy, etc.—have shown unsatisfactory results. Endoscopic placement and removal are not difficult techniques to perform. Also, IGB tolerance is generally accepted. Specific training is nevertheless recommended (21).

A significant incidence of early side effects (1 week) was seen in this study: 71.1% of patients suffered from nausea, 57.9% from vomiting, and 23.7% from epigastralgia. These results are similar to those reported in other series (14,22,23). Said symptoms improved with drug therapy in most patients in the course of treatment. Nevertheless, 18.4% (n = 7) of patients had complications, most of which were mild-moderate (n = 6): 4 patients showed digestive intolerance—early BIB removal was required in 3 cases; 2 patients developed moderate esophagitis following BIB removal. Other larger series indicate further complications including intestinal occlusion, gastric ulcers, and balloon deflation with spontaneous migration (8,17). One severe complication should be highlighted, i.e., gastric perforation, also reported in other published studies (14,24). In most cases, the latter showed a positive clinical outcome following surgery, but in the present study said perforation was followed by septic shock leading to death. This event took place during the first month of treatment with BIB. No complications due to early drug treatment-resistant side effects were observed either during endoscopic BIB placement or throughout prolonged hospital stay (2 days). The one decease involved a high-risk patient with significant associated conditions (HBP, DM and OSA syndrome) who did not comply with the low-calorie diet or advice regarding hygiene and diet. In the course of surgery large amounts of food were observed in the gastric cavity. The cause of gastric perforation could not be determined.

Deaths in obesity treatment with BIB have been reported in other studies (25,26). Mortality in the research at hand is not negligible (2.6%, n = 1 patient) but it should be noted that the sample is small. Similar mortali-
ty rates have been reported in other small series (27). On the contrary, larger studies such as Genco et al. (2,515 patients) show a lower mortality rate (17).

Results drawn from the present study stress the need for a low-calorie diet and changes in life-style associated with BIB treatment to achieve effectiveness in terms of weight loss, tolerance improvement, and fewer complications (28). Patient selection criteria should be strict. Also, suitable patient follow-up during treatment is necessary.

Most patients display a high degree of acceptance towards treatment with BIB. In this series, 76.3% of patients graded discomfort with a score equal to or less than 5. Perceived sensation in 47.4% of patients included satiety. These results are similar to those seen in previous studies (18).

WHO recommends a drop of approximately 10% in body weight, since initial weight loss may significantly reduce the severity of risk factors associated with obesity (29).

Results attained in the present series show a positive BMI evolution from 47.25 to 42.06 (kg/m²). Both mean initial weight loss 6 months after the treatment and mean BMI decrease as reported in this study are similar to those described by Loffredo et al. and Mathus-Vliegen et al. (10,18). Individual weight loss proved highly variable, ranging from none to a maximum weight loss of 46 kg, thus resulting in a mean weight loss of 14.10 kg.

The success of the technique at hand is directly related to patient motivation and compliance with a low-calorie diet and changes in life-style (28,30,31).

Weight loss maintenance in the medium and long-term is controversial, and only a few studies have assessed the issue. Present research proves that half of obese patients (51.6%) gained weight 12 months following BIB removal, and 48.4% maintained their weight loss or continued losing weight (22.6 and 25.8% respectively). Outcomes as regards maintaining weight loss 1 year after BIB removal show a resemblance to data obtained in previous studies (10,32).

The treatment of obesity with BIB therefore responds to the objectives established by WHO with regard to initial weight loss (approximately 10% of body weight) and to efficacy– partially at least– for mid-term treatment (22).

In conclusion, the use of BIB associated both with a low-calorie diet and a program seeking behavioral changes can be considered a valid therapy option in the multidisciplinary treatment of obesity (33). The latter has proven to be safe and effective in attaining motivating initial weight loss. It shows good overall tolerance and few complications. Some risks and severe complications, however, cannot be ruled out. Benefits following BIB placement seem to be maintained in the medium-term (12 months after device removal) although further, lengthier follow-up is required to assess long-term effectiveness.

Appropriate patient selection and patient compliance both with diet and lifestyle changes are the key pillars to obtain optimal results.

REFERENCES

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