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## Body composition modification in obese patients treated with intragastric balloon

**Abstract** At the Centre for the Therapy of Morbid Obesity, a multidisciplinary team attends severely obese patients in a day-care hospital setting. The patients' psychological and nutritional profiles are studied and their body composition investigated with bioelectrical impedance. After the diagnosis, several approaches are proposed; among them, the insertion of a Bioenterics Intragastric Balloon (BIB). For 6 months after insertion, patients were periodically examined and followed a strict personal regimen, behaviour schedule and physical activity programme compatible with the BIB. The results obtained from the first 20 subjects are encouraging. No severe complications have been reported, and after the BIB removal, subjects are maintaining the obtained results with some of them continuing to lose weight.

**Key words** Morbid obesity • Body composition • Bioenterics intragastric balloon (BIB)

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### Introduction

Obesity is one of the most widespread pathologies in western countries [1], causing an increase in general morbidity rates [2]. Obesity is defined as an excess of total body fat (body mass index, BMI $\geq$ 30). Severe obesity relates to a BMI between 30 and 40, and morbid obesity to a BMI of more than 40. The first choice of treatment for patients with severe or morbid obesity is obviously medical – dietary treatment and eventually psychotherapeutic support. However, when conservative methods fail, a different approach is needed. After an attentive clinical and psychological screening, patients can be selected for a more aggressive treatment method (effective and reversible), i.e. the insertion of an intragastric balloon. At present, the Bioenterics Intragastric Balloon (BIB) model is available, which can be placed endoscopically under the cardiac and then filled with 500 cc of saline solution. The BIB is usually left in place for 6 months.

The presence of the balloon provides a permanent sensation of satiety and allows patients to follow a very low-calorie diet. We chose the balloon technique because of the very low risks of the procedure, the simplicity of execution, the benign nature of any complications and the complete reversibility of the treatment when compared with bariatric surgery [3].

### Methods

The Centre for the Therapy of Morbid Obesity accepts severely obese patients, who are attended by a multidisciplinary team in a "day-care hospital" setting. The team comprises a physician specialized in nutrition and dietetics, a dietician, a psychologist, an endoscopist and other specialists as consultants.

The patients are studied carefully from a nutritional and psychological point of view. The following routine tests are performed: blood tests, ECG and cardiologic monitoring, thoracic X-ray, hepatic echography, gastroscopy with biopsy to identify *Helicobacter pylori*, evaluation of nutritional status, and psychological consulting. Spirometry is

performed when necessary. The nutritional examination includes: a preliminary interview to evaluate patient motivation; a careful explanation of the indications and contra-indications of the BIB and the procedure; delivery of informed consent; nutritional evaluation with the analysis of food intake; assessment of body composition by bioelectrical impedance (BIA) and individual dietary indications.

The indications for the insertion of the BIB are: BMI>35, or BMI>30 if an obesity-related disease is found; reduction of the anaesthesiology risk associated with surgical procedures; reduction of medical risk after ruling out chronic pathologies, or BIB testing period in view of gastric banding (Lap Band). The contra-indications are: severe esophagitis; hiatal hernia >5 cm; active peptic and/or duodenal ulcer; Crohn's disease; cancer; bleeding conditions; patients undergoing therapy with gastric-damaging or anti-coagulant drugs; uncooperative and/or psychiatric patients, and patients with alcohol and/or drug dependence.

An intragastric balloon (BIB) (Bioenterics Corporation, CA, USA) was inserted in eligible patients for a 6-month period. Compliance to this non-surgical procedure was evaluated and body composition was investigated with BIA (RJL Systems 101/s, Akern Srl, Florence, Italy). Rapid weight loss in patients on a very low-caloric diet usually represents a major risk of losing fat-free mass (FFM). During the 6 months after BIB insertion, patients were periodically examined by the nutritionist, the dietician and the psychologist. The patients followed a very strict personal diet and a personal behaviour schedule allowing them to achieve good weight loss and to maintain the obtained results over time. Follow-up comprised a weekly medical and dietary check-up for the first month, a monthly abdominal echography to evaluate the BIB position for the first 3 months, an abdominal X-ray after insertion, and monitoring of the faeces and urine, including a blood test, on a bimonthly basis.

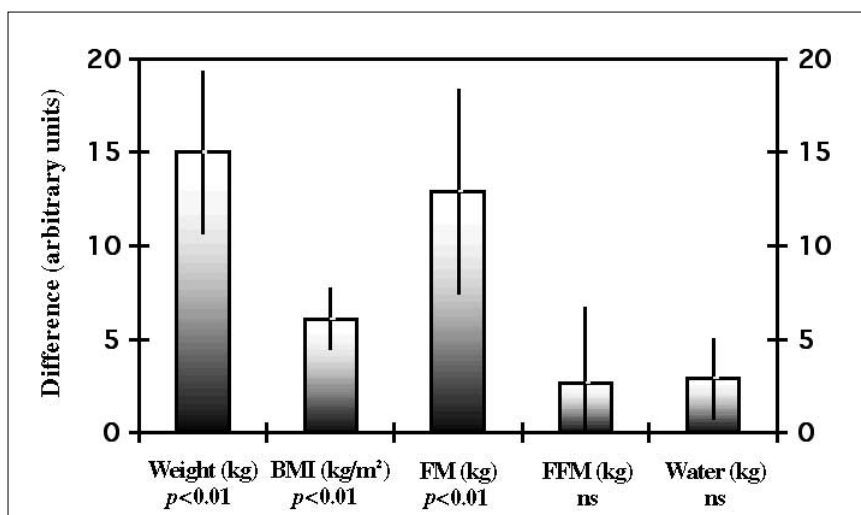
## Results and discussion

The group of 20 patients comprised 12 women [age 18–57 years, initial BMI 26–61.8, initial weight 82–157 kg, initial fat mass (FM) 36–91 kg, initial water 38–52 kg] and 8 men (age 17–54 years, initial BMI 36–47, initial weight 115–135

kg, initial FM 29–59 kg, initial water 50–63 kg). The differences between the initial and the final (after 6 months, at the time of the BIB removal) values of these parameters were calculated for each patient. The differences were then averaged and are shown in Fig. 1 with their relative standard deviations. The statistical significance was analysed using the Student's *t* test (see Fig. 1). The results obtained are encouraging. No severe complications were reported except for some cases of nausea and vomiting during the first week after the BIB insertion. The weight loss was statistically significant and involved mostly fat mass. The patients adopted a good habit of regular physical activity. Since the BIB removal, all subjects are maintaining the obtained results and some of them are continuing to lose weight. The required conditions to maintain the obtained results are continuous nutritional rehabilitation (which must begin before BIB insertion), psychological support, strict periodic follow-up, physical personalized activity planning, and identification of "objectives" to be reached at different times. In conclusion, we intend to use the BIB as a way of continuing a dietary regimen and offering patients the possibility to lose weight more rapidly than with traditional diets, but also in a more natural way compared to bariatric surgery. To obtain good results with this procedure, a strict selection of patients, an intensive periodic follow-up, and a dietary prescription, personalized and integrated with vitamins and fibre if required, are necessary.

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**Fig. 1** Results obtained from a group of 20 patients who were treated with a Bioenterics Intra-gastric Balloon (BIB) for 6 months. The averages of the differences between the initial and the final values are shown. The vertical bars represent standard deviations. The statistical significance was assessed with the Student's *t* test